

[REDACTED]

**CONSULTATION: PROPOSED AMENDMENTS TO THE POISONS
STANDARD,
JULY 2016 (MEDICINES)**

**SUBMISSIONS SUPPORTING THE PROPOSED AMENDMENTS
TO THE POISONS STANDARD (MEDICINES)**

Proposed amendment

Proposal to amend the entry for N,N-dimethyltryptamine (DMT) in schedule 9 to allow exemptions for naturally occurring DMT in very low concentrations and liquid form for religious purposes. The quantity of DMT found per serving of the tea is approximately 0.25 mg/mL.

Responses to section 52E(1)

52E(1)(b) - the risks and benefits associated with the use of a substance

Based on [REDACTED] research conducted, it appears that the proper use of the substance is for religious / spiritual/ healing purposes within a safe controlled environment with the religious / spiritual leader owning the responsibility and care of the process. It is classed as a plant based natural medicine.

Numerous scientific research studies performed (for example McKenna, 2004; Gable, 2007; Bouso & Riba, 2011; Barbosa et al., 2012; dos Santos, 2013 (a and b), show us that the use of the substance is safe while also states how it should not be used, used with care or the risk from ingesting the substance with certain foods. Other research has shown that the use of the substance can bring about many health benefits ranging from mental, emotional, physical and spiritual.

As the substance is currently illegal in Australia, many people venture to countries where the substance is legal in order to receive the health benefits or in search of spiritual enlightenment.

There have been reported overseas cases of fake religious / spiritual leaders who mislead people into believing they are solely ingesting the substance in question, when in fact it has been mixed with other substances for the purposes of rape, sexual assault and robberies. For this reason, it needs a federal regulation that allows authentic religious / spiritual leaders to offer the substance in a controlled safe environment, while under their care.

The risks associated with the use of the substance is based upon how the substance is consumed, in what type of environment and if it is not used in its traditional form and used for recreational purposes.

If the person administering the substance does not have the appropriate training or the authorisation from the indigenous community to perform such healing, this then would pose risks. This is also evident of any pharmaceutical drug that is not regulated and administered by a doctor.

52E(1)(c) - the potential hazards associated with the use of a substance

If the substance is not regulated with conditions to only allow religious / spiritual leaders to be in possession of the substance, then it may be used for other purposes which may not be favourable.

52E(1)(g)- the potential for abuse of a substance

The potential risks of the abuse of the substance may occur if it is not used in its traditional form for religious / spiritual purposes and used for recreational purposes. The effects will be different and may cause harm and injury when used for anything other than healing purposes.

A greater concern is the abuse of pharmaceutical drugs, alcohol and other illegal substances. The use of n n-dimethyltryptamine will be in a controlled environment, only to be served by a religious / spiritual leader for religious and healing purposes.

Pharmaceutical drugs, alcohol and other illegal substances are much more readily available and are being significantly abused in many ways. For example, alcoholic beverages that are spiked with date rape drugs, dependence and addiction on pharmaceutical drugs and alcohol.

Alcohol is the most widely used drug in Australia which deteriorates health, a high risk of death, violence, serious injury and illness.

52E(1)(h)- the purposes for which a substance is to be used

Religious / spiritual / healing purposes including mental, physical, emotional and spiritual. For example, a wide range of health benefits for the body and its organs.

52E(1)(i)- any other matters that the Committee considers necessary to protect public health, including the risks (whether imminent or long-term) of death, illness or injury resulting from its use

A clear regulation and licence for only religious / spiritual leaders to carry and supply the substance.

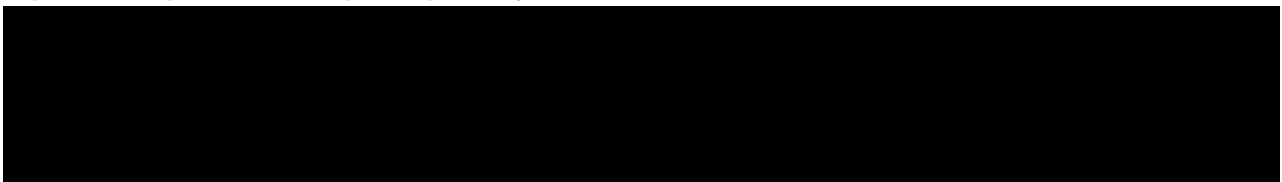
Additional submissions

Whether you support the amendments, if so, why?

I support the proposed amendment as I believe it to be a basic Human Right for an indigenous person or community to be able to practice and fulfil their religious / spiritual belief.

This will also allow for people who are unwell (ranging from minor to severe cases) to have access to a natural medicine, as treatment, as well having the ability to provide a means for spiritual development.

An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.





The Human Rights Act 2004 states...

Section 14(1)(b)

'the freedom to demonstrate his or her religion or belief in worship, observance, practice and teaching, either individually or as part of a community and whether in public or private.'

Section 14(2)

'No-one may be coerced in a way that would limit his or her freedom to have or adopt a religion or belief in worship, observance, practice or teaching.'

Section 27(1)

'Anyone who belongs to an ethnic, religious or linguistic minority must not be denied the right, with other members of the minority, to enjoy his or her culture, to declare and practise his or her religion, or to use his or her language.'

This submission has been prepared with a specific consideration of s 52E(1)(b): the purposes for which the substance is to be used and the extent of use of the substance, in this case DMT containing tea. From the outset, whilst the proposed amendments are a step in the right direction, as loosening the regulatory regime around the consumption of DMT-containing teas reflects the burgeoning global recognition of the value such substances play in the spiritual life of many people, the author holds grave concerns over the practical and/or useful impact the proposed changes to the Poisons Schedule will have on the legal framework that applies to DMT containing tea. However, there are several important points that ought to be on record and this submission is made with the intention to raise those points.

It must be stated that the consumption of teas containing DMT has a long history of being used in a shamanic context. Winkelman (2010) defined shamanism as an intrinsic aspect of human nature that addresses spirituality. Eliade (1964) posited that shamanism is ‘...at once mysticism, magic and “religion” in the broadest sense of the world’.ⁱ Dhall (2015) observed that the essence of shamanism consists of the shamanic practitioner employing altered states of consciousness to commune with an interconnected and sentient universe for the wellbeing of the shaman and the wider Earth community.ⁱⁱ

Archaeological and ethnological research indicates that shamanic methods are at least 20,000-30,000-years old.ⁱⁱⁱ The perennial dimensions of shamanism are evident as there are numerous similarities in both the ontology and loci of commitment amongst geographically dislocated indigenous groups separated by vast timescales (from a human perspective): from the jungles of South America to the steppes of Siberia and even the deserts of Australia. Winkelman (2013) identified a biological basis to the perennial nature of core shamanism in the stimulation of ancient brain structures and linkages across the evolutionary strata of the brain that function in theta state.^{iv} These brain states correlate with the phenomenology of shamanic altered states of consciousness.

Such altered states can be brought about through many practices, including fasting, dancing, cleansing and purification rituals (commonly referred to as 'sweat lodges'), and via the ingestion of sacramental plants (i.e. DMT containing teas). It is this last avenue to non-ordinary states of shamanic consciousness to which this submission speaks. That is to say, any changes to the scheduling of DMT containing tea should recognise the longstanding practice of administering such teas in a shamanic context for tens of thousands of years, a practice that is thought to extend millennia beyond the existence of any other spiritual practice in human history.

From the outset of this submission, I feel compelled to establish a preliminary albeit significant matter of terminology; namely the distinction between 'drugs' and 'entheogens'. In the simplest terms, Dhall (2015) noted that there is a category of substances that have been ingested for millennia to voluntarily enter into a non-ordinary state of consciousness for the purpose of enhancing the wellbeing of both the shaman and the wider Earth community. The etymology of the term 'entheogen', has been explicated by the Counsel of Spiritual Practices as producing a phenomenological experience of '[god within; god- or spirit-facilitating] a psychoactive sacramental; plant or chemical substance taken to occasion primary religious experience.'^v Tupper (2002) succinctly defines as entheogens as '...psychoactive plants used as spiritual sacraments'.^{vi} It is noted and emphasised that this position is in contradistinction to the dominant (and coarse-grained) paradigm which adopts the assumption that '...a priori regards hallucinogenic drugs use as maleficent and devoid of merit'.^{vii}

The distinction between 'drugs' on the one hand, and 'entheogens' on the other is important because to appreciate the texture of this submission, and presumably many other submissions on the consumption of DMT containing teas, the aforementioned distinction sits at the heart of the perspective offered. The contemporary understanding of 'drugs' is, as is often the case, the result of the excessive simplification of nuanced and complex issues and the vagaries of socio-historical political discourse. In this instance, the dialogue surrounding the *Convention on Psychotropic Substances*, ratified by the United Nations in 1971. In essence, an international concern to regulate the importation and exportation of opium in 1912 evolved into a comprehensive regulatory framework to strictly control

myriad substances with psychoactive effects. Unfortunately, the process of scheduling was undertaken in the shadow of post colonialism, a shadow that still lingers today. In framing the postcolonial paradigm, Dhall (2015) observed that along the road to modernity shamanic practitioners were subject to grave persecution in ages past as colonisation, missionaries, commercial interests and governments all overwhelmed tribal peoples and ancient cultures,^{viii} as Jilek (2005) stated:

Before the Age of Enlightenment, the shaman was condemned as daemoniac charlatan. From the 19th until the mid-20th century, the shaman was generally considered as afflicted with a psychiatric or epileptic condition, a notion based on the misinterpretation of altered states of consciousness in shamanic ritual as psychopathological. [This pathologisation]...of shamanic healers and their rituals constitutes a Eurocentric and positivistic fallacy... until the late 19th-century, this often also meant persecution by government authorities who were using the church to facilitate colonisation, subordination and acculturation of aboriginal peoples who recognised in shamanism an important factor for the survival of indigenous cultures.^{ix}

Thus, when considering the list of plants and substances to be scheduled in the 1971 UN convention, the miscognition of shamanism stripped the ritualised ingestion of DMT containing teas (and indeed the wider category of plants and substances called ‘entheogens’), of their biosocial context. In so doing, many psychoactive plants used for millennia in the discharge of important social, cultural and religious functions, were lumped together under the umbrella of ‘drugs’ and simply seen as ‘...malevolent agents’ in popular discourse,^x the ingestion of which was forbidden. This simplistic mindset is on display in Australia today, as evinced the ‘key overall messages’ of the National Drugs Campaign in Australia which include identifying ‘...real risks and harms associated with using illicit drugs [and the]...real benefits of not using...illicit drugs.’ There is no attention paid in Governmental discourse to the nuanced distinctions raised in this submission, notwithstanding the observation that the perspective offered in this submission does not rest upon ‘soft’ research.

It is reflecting upon, and striving to remedy the miscognition around plants and extracts used for millennia in shamanic contexts for the specific purpose of enhancing the wellbeing

of both the shaman and wider Earth community that one of the key proposals contained in this submission is that the notion of 'religious use' be refined to recognise the category of psychoactive substances that ought to be categorised as 'entheogens', of which DMT-containing teas are one.

It is important to acknowledge the robust research that indicates that there is *no difference* between the mystical experience derived from the ingestion of entheogens and the mystical experience brought about through other technologies of consciousness which include fasting, prayer, ordeal, and meditation. On this point, Winkelman (2010) cited Griffiths et al (2006) when he observed that 'the differences between drug and nondrug alterations of consciousness are presumed to be so obvious that their common substrate is not considered', however he went on to highlight that the phenomenological similarities of drug-induced and natural mystical experiences has been demonstrated in double-blind clinical trials.^{xi}

The Shamanic use of DMT-containing teas.

The proposed changes to the scheduling of DMT-containing teas refer primarily to scheduling of DMT itself. DMT is the simplest of the tryptamine psychedelics, with a weight of 188 molecular units. Strassman (2001) noted that DMT molecule is not significantly larger than glucose, the simplest sugar in our bodies, which weighs 180, and only ten times heavier than water, which weighs 18.^{xii}

The shamanic use of DMT-containing teas is thought to go back tens of thousands of years. There are numerous mythologies surrounding the genesis of DMT containing teas which will not be mentioned here. The two most common names such teas are known by are 'ayahuasca' and 'yage'. Ayahuasca is generally made from two ingredients, the ayahuasca vine (*Banisteriopsis caapi*) and the leaf of the chacruna plant (*Psychotria viridis*), however, there are analogues, substitutes and variants, many of which have entheogenic use. The etymology of the term 'ayahuasca' is from two Quechua words: *aya* meaning 'spirit', 'ancestor' or 'dead person' and *huasca*, which means 'vine' or 'rope'. Thus, ayahuasca is

taken to mean ‘the vine of souls’ which, Heaven and Charing (2006) argue implies that it is a means of communication with the spirit of universe herself.

Both the *caapi* and *viridis* (or analogue/s) are required to make an orally active DMT-containing tea such as ayahuasca, because monoamine oxidases (MAO), which are naturally occurring enzymes that occur in high concentrations in the blood, liver, stomach and brain and intestines, will simply break DMT down within seconds. It is for this reason that any legislative or schedule change that fails to include a sacramental monoamine oxidase inhibitor is of little to no value.

Whilst a description of the phenomenological effects of DMT-containing teas is not relevant to this submission, I will simply note the observation of Heaven and Charing (2006), who state ‘...one of the most potent and best-known of the sacred hallucinogens is ayahuasca, the use of which underlines the sanctity of nature for the shamans who prepare and imbibe it’.^{xiii}

Global trend toward liberalisation.

There has been growing body of literature identifying the therapeutic and spiritual benefits that can follow the consumption of DMT-containing teas, such as Brierly and Donaldson (2012) and Loizaga-Velder & Verres (2014),^{xiv} to name but two. This submission is not speaking specifically the modern usage of DMT-containing teas beyond noting that there is increasing weight of evidence identifying measurable therapeutic outcomes for a number of ailments and maladies. Such studies reflect the belated modern movement toward the liberalization of regulation of DMT-containing teas. To wit, a brief case note on a relevant case is provided below.

In November 2000 the Uniao Do Vegetal (UDV), a Christian Spiritist religion originating in Brazil filed a lawsuit against the US Drug Enforcement Agency (DEA) and other federal government agencies for violations of the First Amendment to the US Constitution and the Religious Freedom Restoration Act (RFRA). The RFRA requires the government not to interfere with religious conduct unless it can demonstrate a “compelling interest” in doing

so. The UDV claimed that the DEA's interference with their importation, distribution, possession and use of "Daime Tea", a DMT containing brew similar to Ayahuasca, amounted to an unlawful interference with their religious freedoms. On February 21, 2006 Roberts CJ delivered the unanimous decision of the US Supreme Court which ruled in favour of the UDV. In making this ruling the Court made numerous observations about the current legal status of DMT containing plant brews, both within the USA and internationally, and concluded that notwithstanding the concerns for public health and safety argued by the government, that it was clear that when Congress moved to schedule DMT, little consideration was given to the potential, or lack thereof, of harm posed by the particular use at issue in this case. Accordingly, the Court considered that any perceived concerns regarding the potential for abuse and damage to public safety arising out of the use of DMT, were largely attached to the use of DMT as an isolated substance rather than to the circumscribed, sacramental use of DMT containing brews as envisioned by the UDV.

In reference to the current submission, it is important to recognise that there is established jurisprudence from US in favour of allowing the sacramental consumption of DMT-containing teas. Such developments speak directly to the softening global position on these teas, and also allow Australian policy to be formed in a manner consonant with the wider global community.

Suggested modifications to the proposed changes to the Poisons Act.

The avalanche of scholarly material supporting the view that entheogens (of which DMT-containing teas are but one example) show a vast and well-documented history of being used in a shamanic context for the wellbeing of the shaman and wider Earth-community. This submission does not intend to cover this vast field, rather the purpose of this submission is to make the delegate aware that this literature exists, and to provide the delegate with material that speaks directly and succinctly to subject matter of this consultation. The anthropological evidence that supports this submission establishes the purposes and extent of use for entheogens in general, and also cover DMT-containing teas in particular. For this reason, the author of this submission notionally supports the re-

scheduling of DMT-containing teas. However, pragmatism demands several further and necessary amendments to the scheduling of DMT-containing teas:

1. Tramachi (2006) discerns a number of pieces of evidence that allude to the use of DMT by the First Australians, and he also highlighted strong evidence to show the consumption of DMT in other shamanic cultures.^{xv} For this reason, changes to the scheduling of DMT should reflect other traditional modes of ingestion in a shamanic context, which include smoking, salves and insufflation.
 - a. At the very least, changes to scheduling should reflect a different unit of measurement. Measuring the dosage to individuals in terms of milligrams/ millilitre of tea is of very limited value as the dosage in mg/ kg of body weight supervenes upon the qualitative experience. It is for this reason that that Strassman's (2001) clinical trials of intravenously administered DMT used the second and more meaningful measurement. Whilst the author recognises the usefulness of the mg/ ml standard for establishing importation controls, the author suggests that there is little practical benefit to this standard. Furthermore, the specified concentration is very, very low.
2. Other ingredients in DMT containing teas remain scheduled in Australia; such as the harmine component. Such an omission is perplexing and renders the proposed changes *prima facie* meaningless in an Australian context.
3. As noted above, the phrase 'religious use' ought to be replaced or supplemented with a wider term; such as 'sacramental use' or, better yet, a class of 'entheogens' ought to be contemplated and slotted into the policy discussion.
 - a. For this reason, more apt legislation would consider and adopt standards that reflect the processes around the traditional modes for preparing DMT-containing teas. A detailed consideration of this area is beyond the scope of this submission.

4. The proposed changes to the *Poisons Standard* appear to be quite misguided. The legal morass in which the sacramental use of entheogens is currently mired are far wider than the scope of changes currently up for comment.
 - a. The suite of legislative and policy changes required to make a useful contribution to the sacramental use of entheogens in general and DMT-containing teas in particular must necessarily include changes to, *inter alia*, the *Misuse of Drugs Act*, *Crimes Act*, *Criminal Code* and *Therapeutic Goods Act*.

In conclusion, whilst changing the scheduling of DMT-containing teas is step in the right direction and hence worthy of support, the proposed changes fall well short of achieving any meaningful or practical reform that the author is able to discern.

ⁱ Eliade, M. (1964) *Shamanism: Archaic Techniques of Ecstasy*, Bollingen Series 76, Pantheon, New York, xxv.

ⁱⁱ Dhall, A. (2015) 'Shamanism, Wellbeing and Law: a lawyer's contemplation on an ancient technology of consciousness for the wellbeing of both the individual and wider Earth community', Invited submission to 10th *National Conference on Clinical and Experimental Hypnosis, Mind, Body Practices and Health and Happiness*, Bangalore, India, 20-22 November 2015.

ⁱⁱⁱ Above n 1, 40.

^{iv} Winkelman, M. (2013) 'Shamanic Cosmology as an Evolutionary Neurocognitive Epistemology', 32, 1, *International Journal of Transpersonal Studies*, 77-99.

^v Counsel of Spiritual Practices, Entheogen Project, available at <<http://www.csp.org/practices/entheogens/entheogens.html#1>>, last viewed May 5, 2016.

^{vi} Tupper, K. (2002) 'Entheogens and Existential Intelligence: The Use of Plant Teachers as Cognitive Tools', 27, 4, *Canadian Journal of Education*, 499-516.

^{vii} Ibid.

^{viii} Above n 2.

^{ix} Jilek, W.G. (2005) 'Transforming the Shaman: Changing Western Views of Shamanism and Altered States of Consciousness', 7, 1, *Investigacion en Salud*, 8-15.

^x Tupper K. (2008), 'Drugs, discourse and education: A critical discourse analysis of a high-school drug education text', 29, 2, *Discourse: Studies in the Cultural and Politics of Education*, 223-238.

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- ^{xi} Winkelman, M. (2010) *Shamanism: A Biopsychosocial Paradigm of Consciousness and Healing 2nd Ed*, Praeger, Oxford, 26.
- ^{xii} Strassman, R. (2001) *DMT: The Spirit Molecule A Doctor's Revolutionary Research into the Biology of the Near-Death and Mystical Experiences*, Park Street Press, 52.
- ^{xiii} Heaven, R. and Charing, H.G. (2006) *Plant Spirit Shamanism: Traditional Techniques for Healing the Soul*, Destiny Books, Rochester, 82.
- ^{xiv} Brierly, D. & Davidson, C. (2012) 'Developments in harmine pharmacology – Implications for ayahuasca use and drug-dependence treatment, 39, *Progress in Neuro-Psychopharmacology & Biological Psychiatry*, 263-272; Loizaga-Velder & Veres, R. (2014) 'Therapeutic Effects of Ritual Ayahuasca Use in the Treatment of Substance Dependence – Qualitative Results', 46, 1, *Journal of Psychoactive Drugs*, 63-72.
- ^{xv} Tremacchi, D (2006), *Vapours and Visions: Religious Dimensions of DMT use*, PhD Thesis, submitted to the University of Queensland in June 2006.



Submission:

Proposed amendments to the Poisons Standard, July 2016 (Medicines)

1. Proposed amendment:

PIPER METHYSTICUM (KAVA)	<p>Proposal to amend part a) of the existing Schedule 4 entry to include the following:</p> <ul style="list-style-type: none">• iii) the amount of dried whole or peeled rhizome in the unit dose of powder does not exceed 3 g; and, where containing more than 25 mg of kavalactones per dose, compliant with the requirements of the Required Advisory Statements for Medicine Labels; and is packaged with a dose controlled measuring device (Scoop); and is limited to a maximum quantity of 200g of powder per package;• or• iv) the liquid form contains 125 mg or less of kavalactones per unit dose of liquid. and, where containing more than 25 mg of kavalactones per dose, compliant with the requirements of the Required Advisory Statements for Medicine Labels; and is packaged in a single serve packaging. <p>It is also proposed that there is the addition of the mandatory warning statement "Do not exceed recommended daily dose" to be added to all Kava packaging.</p>
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Background:

Kava causes muscle relaxation, pleasant mood and social behaviour. It is used medicinally for anxiety, insomnia, urinary tract infections and pain, including arthritic pain. Current research shows promise for its use for the prevention of cancers, attention deficit-hyperactivity disorder (ADHD), epilepsy, psychosis, depression, migraines and other headaches, chronic fatigue syndrome (CFS), common cold and other respiratory tract infections, tuberculosis, muscle pain, and cancer prevention.

Kava was originally banned due to perceived dangers of hepatotoxicity and "negative health and social outcomes in some indigenous communities" - however these have been linked to solvent extracts using aerial parts of the plants rather than traditionally prepared aqueous extracts of the root. The pyridone alkaloid pipermethystine is thought to be the cause of liver toxicity, it is present in the leaves but not the root/rhizome of the plant. Bans on the use of kava in its traditional form (ie: aqueous extract of root powder) have been linked to increased use of other more harmful substances including alcohol.

The EU lifted its ban on Kava in 2014 saying it could not have substantial health concerns. In 2015 a report from the University of Hawai'i noted that "[I]n the history of Western kava use, toxicity is still considered relatively rare. Only a fraction of the handful of cases reviewed for liver toxicity could be, with any certainty, linked to kava consumption and most of those involved the coingestion of other medications/supplements. That means that the incident rate of liver toxicity due to kava is one in 60-125 million patients." (*PubMed — Contemporary Pacific and Western perspectives on `awa (Piper methysticum) toxicology. Showman AF, Baker JD, Linares C, Naeole CK, Borris R, Johnston E, Konanui J, Turner H.*)

Support for amendment:

supports this amendment on the basis that Kava is a plant with a very long established precedent of use, well-researched toxicity, low relative potential for abuse, and very significant positive benefits, both demonstrated and potential.

2. Proposed amendment:

N,N-DIMETHYLTRYPTAMINE	Proposal to amend the entry for N,N-dimethyltryptamine (DMT) in schedule 9 to allow exemptions for naturally occurring DMT in very low concentrations and liquid form for religious purposes. The quantity of DMT found per serving of the tea is approximately 0.25 mg/mL.
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Background:

DMT is a tryptamine that is produced endogenously in the brains of humans and other mammals and is also present in a wide variety of plant species. It is the primary psychoactive component of *ayahuasca*, a plant-based brew that - in keeping with global historical context - has been used in ceremonial settings for thousands of years by a wide range of independent Amazonian cultures. The typical intention of such usage is the healing of physical, mental, emotional and spiritual ailments. In recent decades use of the tea has begun to spread outside South America. It is widely purported to be effective in the treatment of addiction, severe emotional distress, depression, and a number of other conditions. There are legal precedents from court rulings in the USA and EU upholding citizens' rights to the sacramental use of DMT decoctions.

Brief summary of research relating to the risks/benefits, toxicity, and potential for abuse of brews containing DMT:

- A 1996 paper in the Journal of Nervous & Mental Disease surveyed a group of 15 regular ayahuasca users in Brazil and found that 11 out of the 15 participants had a history of moderate to severe alcohol use; 5 reported episodes of associated violent behaviour and a diagnosis of alcohol abuse disorder prior to their use of ayahuasca; 4 subjects also reported previous use of other drugs of abuse including cocaine and amphetamines; 2 subjects had past major depressive disorders; and 3 had past phobic anxiety disorders. The authors found that at the time of the assessment none of the subjects had a current psychiatric diagnosis using the CIDI. **According to the authors, the subjects' problems were resolved as a consequence of their regular ritual use of ayahuasca.**
Grob CS, McKenna DJ, Callaway JC, Brito GS, Neves ES et al. Human psychopharmacology of hoasca, a plant hallucinogen used in ritual context in Brazil. J Nerv Ment Dis. 1996; 184(2):86-94.
- An entry in the 2005 Journal of Psychoactive Drugs found that first time ayahuasca users exhibited a **“remarkable reduction of minor psychiatric symptoms”** and **“calmer, more assertive and vivacious behaviours”**.
Riba, J. y Barbanoj, M.J. “Bringing ayahuasca to the clinical research laboratory”, Journal of Psychoactive Drugs. 2005; 37(2): 219-30.

- A 2007 study noted that “Separate animal studies of the median lethal dose of DMT and of several harmala alkaloids indicated that a lethal dose of these substances in humans is probably greater than 20 times the typical ceremonial dose.” and concluded that **“a decoction of DMT and harmala alkaloids used in religious ceremonies has a safety margin comparable to codeine, mescaline or methadone. The dependence potential of oral DMT and the risk of sustained psychological disturbance are minimal.”**
Gable RS. Risk assessment of ritual use of oral dimethyltryptamine (DMT) and harmala alkaloids. Addiction. 2007;102(1):24-34.
- The Journal of Ethnopharmacology published a paper in 2007 which found that ayahuasca had a **significant effect in relieving feelings of anxiety, hopelessness and panic** in a group of study participants.
Santos RG, Landeira-Fernandez J, Strassman RJ, Motta V, Cruz AP. Effects of ayahuasca on psychometric measures of anxiety, panic-like and hopelessness in Santo Daime members. J Ethnopharmacol. 2007. 112(3):507-13
- The Medical Science Monitor in 2008 studied the long-term health and safety of 32 regular ayahuasca users in Oregon (USA). The study found that while most of them had shown some past psychiatric disorder or some drug or alcohol abuse disorder, at the time of the assessment all had low anxiety and no reactivation of addictions, only two of them reported an active psychiatric disorder. Again, the participation in the ayahuasca rituals is thought to be responsible of the reported benefits. **The study states that “There simply is no evidence from within the data collected to assert that there are concerning harms.”**
Halpern JH, Sherwood AR, Passie T, Blackwell KC, Rutenber AJ. Evidence of health and safety in American members of a religion who use a hallucinogenic sacrament. Med Sci Monit. 2008; 14(8):SR15-22.
- A study from the Journal of Psychoactive Drugs in 2009 looked at the effects of ayahuasca over six months on people who hadn’t previously drank the tea. The results found **no adverse impact on quality of life or psychiatric symptoms. Regular users did score higher, however, on tests of emotional and social functioning.**
Barbosa PC, Cazorla IM, Giglio JS, Strassman R. A six-month prospective evaluation of personality traits, psychiatric symptoms and quality of life in ayahuasca-naïve subjects. J Psychoactive Drugs. 2009. 41(3):205-12.
- In a 2010 study designed specifically to assess clinical efficacy of ayahuasca involving 3 female participants with a clinical diagnosis of recurring depressive disorder and current mild/severe depressive episode without psychotic symptoms, subjects received an oral dose of 3ml/kg of ayahuasca. **After a single ayahuasca dose, depressive symptoms were significantly decreased from 40 minutes after intake until day 14, when symptoms began to reach baseline levels.**
Lima F, Ribero L, Machado JP, Porfirio J, Quevedo J, et al. The therapeutic potential of harmine and ayahuasca in depression: Evidence from exploratory animal and human studies. In: R. dos Santos (Ed.): The Ethnopharmacology of Ayahuasca. 2010. Kerala, India, Research Network. Pp: 75-85.
- An article in Drug and Alcohol Dependence in 2010 assessed the addiction potential of ayahuasca. **The results did not suggest any addictive properties of the brew, but rather that it helped people conquer other addictions.**
Fábregas JM, González D, Fondevila S, Cutchet M, Fernández X, et al. Assessment of addiction severity among ritual users of ayahuasca. Drug Alcohol Depend. 2010. 111(3):257-61.

Suggested improvements to the amendment:

Although changes to the SUSMP will be insufficient to effectively alter legislation pertaining to the use of ayahuasca/DMT in Australia, any small move in this direction is welcome. In terms of scheduling, to begin to approach a basic level of efficacy it would be preferable if this amendment was expanded to:

- *alter the scheduling of harmala alkaloids (currently S9) which are an absolutely vital component of the ayahuasca brew;*
- *provide for the cultivation/possession/distribution of plants containing DMT and harmala alkaloids;*
- *make any provisions possible for the legal importation of these substances/plants;*
- *define, replace, or supplement the term 'religious use'.*

Support for the amendment:

██████████ broadly supports this amendment on the basis that this is a substance with low toxicity, low potential for abuse, and significant demonstrated positive benefits. All of this is in addition to the pertinent issue of human rights/religious freedoms. In short, ██████ believe that people's right to access this extremely useful sacrament should be upheld.

- ENDS -

[REDACTED]

April 12, 2016

To: Australian Government
Department of Health
Therapeutic Goods Administration

Ladies/Gentlemen,

[REDACTED]

I support the proposal to amend the entry for N,N-dimethyltryptamine (DMT) in schedule 9 to allow exemptions for naturally occurring DMT in very low concentrations and liquid form for religious purposes. My arguments are the followings:

Naturally occurring DMT from sources of *Psychotria viridis* or *Diplopterys cabrerana* combined with naturally occurring harmine from source of *Banisteriopsis caapi* (*ayahuasca* or *yajé*, respectively) is safe up to a 50 mg dose (even a range exceeding small doses) in a right set and setting, which is granted within the religious services organized by the União do Vegetal . The typical ceremonial dose of DMT in the ayahuasca tea is around or below 25 mg. Important to note (I experience a lot of confusion on this issue) that the ingredients of ayahuasca are not addictive! On the contrary, these substances have anti-addictive potentials. That therapeutic benefit is a result of a very complex action among which the facilitation of spiritual experiences seems to be very important. Another usual misconception, that DMT has no medical use, is not supported by evidence – [REDACTED]
(<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0106533>).

In my opinion, it is very important for decision makers to be aware that ayahuasca should not have to be placed under the same consideration like the recreational drugs. Classical hallucinogens (where DMT belongs to) – while they were extensively studied in the fifties for their possible psychiatric use – got marginalized and stigmatized after in the sixties for sociopolitical reasons, and not due to controlled studies pointing against them. As a result, all research activity got halted and nowadays almost every professional in psychiatry (and related fields), who are not investigating them, have limited knowledge of these compounds.

Sincerely yours,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[illegible]

comment on the Australian Government Department of Health's consideration of rescheduling very low concentrations of naturally occurring dimethyltryptamine (DMT) when used for religious purposes.

identified that UDV member

subjects appeared to have benefited a great deal from their religious use of ayahuasca, with beneficial effects observed over time in their medical and psychological health, personal integrity and responsible function within their families, work settings and in the community. [REDACTED] many UDV members who prior to their entry into the UDV had had serious problems with alcohol and drug abuse as well as other psychological disturbances, all of which had evidently resolved following their entry into the UDV and participation in periodic religious ceremonies utilizing an ayahuasca sacrament.

[REDACTED] [REDACTED] was highly impressed to learn of the system of monitoring the UDV has employed to oversee medical and psychological safety during and following ayahuasca ceremonies. [REDACTED] consider this medical and psychological monitoring program to be indicative of the high level of responsibility the UDV leadership has taken to ensure that their members suffer no ill-effects from their participation in religious ayahuasca ceremonies.

Ayahuasca is a decoction of two plants native to the Amazon, *Banisteriopsis caapi* and *Psychotria viridis*. The *Psychotria* plant contains very small quantities of DMT (approximately 0.25 mg/mL per serving). Drawing from findings in [REDACTED] ayahuasca research studies as well as those of [REDACTED] investigations, it is my opinion that the periodic ingestion of such a modest dose of DMT, within the context of UDV religious ceremonies, is not only safe and well-tolerated by church members, but also often facilitates evident improvement in psychological health and ethical conduct. Consequently, [REDACTED] strongly support government sanction of the religious use of ayahuasca by the UDV, as is the case in Brazil and the United States.

Sincerely,

[REDACTED]



Technical Report about Ayahuasca

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Ayahuasca is a liquid produced by the slow decoction of the *Banisteriopsis caapi* vine, which contains harmine, harmaline and tetrahydroharmine, and the leaves of the *Psychotria viridis* shrub, which contains DMT (Schultes & Hofmann, 1992). Ayahuasca is considered a sacred drink by an uncountable number of indigenous Amazonian groups and a medicine by mestizo healers in much of South America. The traditional and modern use of ayahuasca extends from Panama to Bolivia, including Peru, Ecuador, Colombia, and Brazil, countries in which its medicinal use is intensely present in urban centers (Luna, 1986, 2011). Ayahuasca is presently used as a medicine in ceremonies officiated by Indians, mestizos, and diverse professionals who have learned to use it in its places of traditional origin (Labate et al., 2009; Labate & Jungaberle, 2011; Luna, 2011; Labate & Bouso, 2013). The therapeutic properties of ayahuasca are due to its action on the brain: it activates the cerebral areas related to episodic memory and awareness of emotions and internal sensations (Riba et al., 2006; de Araujo et al., 2011).

The antiquity of ayahuasca use is unknown. The oldest traces of possible use of ayahuasca have been found in the Azapa desert in the north of Chile, where residues of harmine have been found in hair analyzed from mummies from the Tiwanaku period between 500 and 1000 C.E. In the Azapa valley *Banisteriopsis caapi* does not grow, nor does any other harmine-containing plant, which suggests an intense commerce between the ancient populations of Chile and the Amazonian peoples; probably the former provided the latter with salt and the latter provided the former with medicines, among them ayahuasca. It is also known that the ancient inhabitants of the north of Chile (Azapa and Atacama deserts) were inveterate consumers of DMT-type hallucinogens: the most ancient remains of paraphernalia for consuming hallucinogens have been found precisely in excavations carried out in the Atacama desert and dated at 480 C.E +/- 60 years. (Llagostera et al., 1988) and today many of these artifacts can be contemplated, among other places, in the Chilean Museum of Precolumbian Art in the city of Santiago. The use of hallucinogens like DMT was considered a sacred practice among the ancient Chilean citizens.

DMT is on the list of substances subject to international control by the United Nations, but neither ayahuasca nor any plant that contains DMT, nor any plant preparation made with plants that contain DMT is subject to control. (JIFE, 2010, 2013). The alkaloids present in the *Banisteriopsis caapi* vine are also not subject to international control. In 2008 Ayahuasca was declared Cultural Patrimony of Peru, due to its ancestral use as a traditional medicine (Instituto Nacional de Cultura, 2008) and its use for religious purposes is firmly established and legalized in Brazil (Labate et al., 2009). The religious use of ayahuasca on the part of certain churches is also legally protected and regulated in Holland, Canada, and the United States and the churches in which ayahuasca is considered a sacrament and is consumed for that purpose have expanded internationally into numerous European, American and Asian countries (Labate et al., 2009; Labate & Jungaberle, 2011).

The mechanism of action by which ayahuasca produces its effects is highly sophisticated. The harmala alkaloids (harmine, harmaline and tetrahydroharmine) have the property of acting as inhibitors of monoamineoxidase (MAO), an enzyme present in the gastrointestinal tract which serves to degrade monoamines. As DMT is a monoamine, if it is ingested orally, the endogenous MAO deactivates it, keeping it



from reaching the brain. At some moment in the remote past, the indigenous people of the Amazon Basin discovered that adding leaves of *Psychotria viridis*, which, as already mentioned, contain DMT, to a decoction of *Banisteriopsis caapi* (which contains harmala alkaloids), turns the DMT bioactive. This is due to the harmala alkaloids, which, acting as MAOIs, block the MAO present in the gastrointestinal tract and in this way the DMT present in the leaves of *Psychotria viridis* can reach the brain (Mckenna et al., 1984; Riba et al., 2003). This sophisticated indigenous discovery has been uncovered by science only recently, in the decade of the 1980s of the last century. DMT is found in its natural form in many animal species (Shulgin & Shulgin, 1997) and in human urine, blood, and cerebrospinal fluid. (Barker et al., 2012). Its physiological role is still unknown today, although there are those who speculate that it may be at the base of dreams and other spontaneous altered states of consciousness (Callaway, 1988; Strassman, 2001).

During the last decades, clinical trials have been carried out on humans in which both DMT in purified form (administered intravenously) and ayahuasca (administered orally) have been administered in a laboratory context, and its acute effects have been characterized both at a psychological and a somatic level. In these studies it has been demonstrated that DMT and ayahuasca have very different pharmacodynamics. The acute effects of DMT appear in an intense and almost immediate way after its intravenous administration (Strassman & Qualls, 1994; Strassman et al., 1994), while ayahuasca exercises its effects in a slower and more progressive way, beginning at 45 to 60 minutes after administration, reaching its maximum effects after 2 hours and disappearing after 4 to 6 hours (Riba, 2003; dos Santos, 2011). The maximum intensity of the effects of DMT is approximately double the maximum effect of ayahuasca at equivalent doses (Grob et al., 1996), which makes the global effects of ayahuasca much more controllable than pure DMT.

Ayahuasca, whether administered in a laboratory context or ingested in a traditional context, produced, as evaluated with questionnaires to measure its subjective effects, transitory modifications in emotion, thought content, perception and somatic sensations (Grob et al. 1996; Riba et al, 2001, 2003; Dos Santos et al, 2011, 2012) even to the point of being able to carry out complex tests of cognitive performance (Bouso et al., 2013). The volunteers in these studies also describe the effects of ayahuasca as "I like the medicine" and "good effects" (Riba et al., 2001, 2003; dos Santos et al., 2011, 2012). The curve of effects that ayahuasca produces corresponds with the curve of the presence of DMT in the plasma, disappearing from the organism after 8 hours (Riba et al., 2003).

Studies have been published in which neuroimaging techniques have been used in order to determine the cerebral areas that activate after the ingestion of ayahuasca. Both studies show that ayahuasca activates the cortical and paralimbic areas. Specifically, in the first of these studies (Riba et al., 2006), bilateral increments in cerebral perfusion were found in the inferior frontal gyrus and the anterior insula, the activity being most intense in the right hemisphere. Activations in the anterior cingulate and medial frontal cortex in the right hemisphere, areas involved in awareness of interoceptive and emotional processes, as well as emotional arousal, were also found. Increased cerebral blood flow in the ventral anterior cingulate gyrus and the subcallosal was also recorded, structures related to decision making and emotions. The left amygdala, a structure involved in the processing of potentially threatening stimuli, and the parahippocampal convolution,

a structure associated with the hippocampus and intimately involved in the processing of the memory, also showed higher blood perfusion compared to placebo. No differences were found compared to placebo in any other brain area.

In the second neuroimaging study (de Araujo et al., 2011), performed with Functional MRI (fMRI) activation in primary visual areas were also found, its magnitude when a photograph was being remembered by subjects under the influence of ayahuasca being comparable to baseline activation levels recorded with the presentation of a natural image with eyes open. According to the authors, this effect causes the brains of volunteers to interpret the ayahuasca experience as if it were "real," not in the sense of a hallucinatory experience, but with the experiential endowment of sense experience. This overall pattern of activation may be at the base of the introspective processes, memories of past experiences charged with emotional connotations, and complex cognitive processes, which are such prototypical experiences with ayahuasca (Shanon, 2002). These brain and cognitive phenomena may explain why ayahuasca is considered a potential psychotherapeutic ethnobotanical tool (Cavnan & Labate, 2013). Indeed, one study found that, under the effects, ayahuasca reduced the scores of panic and hopelessness in ritual users (Santos et al., 2007). Another study found antidepressant effects of ayahuasca in patients with major depression (Osório et al., 2011).

Some side effects after the administration of ayahuasca in the laboratory have been described, but they are localized and isolated (Riba et al., 2001; Riba & Barbanoj, 2005, 2006; dos Santos et al., 2011, 2012). Cases in which psychiatric effects have appeared in the context of ayahuasca ritual use have also been documented, although their occurrence is rare (Lima & Tofoli, 2011). This suggests that ayahuasca, in principle, is contraindicated for people with serious psychiatric disorders.

As far as the effects of ayahuasca on the organism, clinical trials carried out with volunteers, both in laboratory conditions and natural contexts, suggest that ayahuasca is physiologically very safe (Riba, 2003; dos Santos, 2011). The impact of ayahuasca on the cardiovascular system is minimal, producing light increases in blood pressure and cardiac rate. (Riba et al., 2001, 2003; dos Santos et al., 2011, 2012). It has also been shown to transiently increase concentrations of the hormones prolactin, cortisol and growth hormone (dos Santos et al., 2011, 2012) and in regard to the immune system, it decreases in a time-dependent manner the subpopulations of CD4 and CD3 lymphocyte cells and increases the "*natural killers*" (NK) (dos Santos et al., 2011, 2012). These transitory physiological changes do not seem to have negative effects: in the general blood analyses carried out before and after on volunteers in clinical trials, no changes in hematological and biochemical functions were observed (Riba et al., 2001; Riba & Barbanoj, 2005).

The principal side effect that ayahuasca induces is nausea and vomiting (Callaway, et al., 1999; Riba et al., 2001; Riba, 2003; Riba & Barbanoj, 2005; dos Santos, 2011; dos Santos et al., 2012). The action of ayahuasca on vomiting is due, first, to the specific organoleptic properties of the decoction, and secondly, to its serotonergic action (Callaway et al., 1999). In any case, this is not an adverse reaction considered



important by the participants in the sessions but rather as something understood as a potential therapeutic effect called "the purge" in traditional Amazonian medicine (Luna, 1986, 2011). "The purge," in the contexts of traditional use, is understood as a physical and psychological cleansing of internal conflicts that can afflict the participant, and is considered an essential part of the therapeutic benefits (Luna, 1986, 2011).

It has also been shown in clinical trials that ayahuasca does not produce tolerance (dos Santos et al., 2012). As far as its potential for abuse, in the neuroimaging studies cited earlier, no active areas have been found in the reward centers. Rather, in this sense, the existing evidence indicates that ayahuasca can be a useful tool in the treatment of addictions (Bouso & Riba, 2013). In fact, there are various clinics in South America that specialize in the treatment of drug addiction, the most important of these being Takiwasi, in Peru (Mabit, 2007).

One of the first studies carried out in humans showed how many participants in ritual ayahuasca sessions had abandoned the consumption of alcohol and other drugs, such as cocaine, as a consequence of their participation in the rituals (Grob et al., 1996). This finding has been found again in later studies (Halpern et al., 2008). A recent study, in which 127 users of ayahuasca in traditional contexts were evaluated and compared with 115 controls, no evidence was found of criteria of addiction according to the biopsychosocial indicators evaluated with the ASI (Addiction Severity Index) nor was it found that the continued use of ayahuasca was associated with the noxious biopsychosocial effects occasioned by drugs of abuse. Rather, the groups of ayahuasca users consumed less alcohol and other drugs than the control subjects and these high scores on the biopsychosocial indicators of addiction were replicated a year later, confirming the consistency of the results (Fábregas et al., 2010). One study, carried out with adolescents belonging to a Brazilian ayahuasca church, found that they consumed significantly less alcohol than the controls, concluding that ayahuasca, far from producing abuse or dependency, for these adolescents was a protecting factor against the consumption of alcohol (Doering-Silveira et al., 2005a).

Medium-term and long-term studies have also been carried out in which there has been no evidence of neuropsychological or psychopathological alterations derived from the continued consumption of ayahuasca. A prospective study carried out with people who drank ayahuasca for the first time has found improvements in measures of mental health and reductions in physical pain six months after initiating the ritual consumption of ayahuasca (Barbosa et al., 2005, 2009). Other studies have found lower indices of psychopathology and greater psychosocial integration in habitual users of ayahuasca (Bouso et al., 2012; Halpern et al., 2008) and two other studies have found no neuropsychological alterations, evaluated through tests of neuropsychological performance, in habitual users of ayahuasca after 10 to 15 years of continuous consumption (Grob et al., 1996; Bouso et al., 2012). One of these studies evaluated 127 users of ayahuasca with a history of a minimum of 15 years of consumption, and compared them with 115 controls, finding better scores in psychopathological tests and in some of the neuropsychological tests, results that showed themselves to be consistent in each of the evaluations separated by a year that was carried out on the subjects (Bouso et al., 2012). Studies with adolescent members of ayahuasca churches have also not found

neuropsychological or psychiatric alterations associated with the ritual consumption of ayahuasca (da Silveira et al., 2005; Doering-Silveira et al., 2005b).

In conclusion, in the literature on the short-term, medium-term, and long-term effects, it is shown that ayahuasca is a substance that is physiologically and psychologically acceptably safe (McKenna, 2004; Gable, 2007; Bouso & Riba, 2011; Barbosa et al., 2012; dos Santos, 2013).

Signed by:

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[REDACTED]

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May 4th 2016

Submission regarding the proposed amendments to the Poisons Standard (Medicines) referred by the delegate for scheduling advice to the Advisory Committee on Medicines Scheduling (ACMS)

[REDACTED]
[REDACTED]
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[REDACTED]

[REDACTED]

The international perspective of [REDACTED] about this subject matter and [REDACTED] considerable expertise in the area of ayahuasca and other ethnobotanicals stimulated us to do an in-depth reading of the proposed amendments to the Poisons Standard referred by the delegate for scheduling advice to the Advisory Committee on Medicines Scheduling (ACMS) with [REDACTED] and associated experts in Australia and around the world.

Considering that the proposed amendments to the Poisons Standard (Medicines), particularly the one referring to N,N-DIMETHYLTRYPTAMINE, has a direct implication on the phenomenon of the use of plant materials that fall within the area of expertise of [REDACTED], and since [REDACTED] share the goal of the Australian Government to work towards the protection of public health and safety in a world where the use of ayahuasca has become widespread, in this letter [REDACTED] present some initial considerations [REDACTED] hope the Advisory Committee on Medicines Scheduling (ACMS) will take into account.

[REDACTED] submission specifically address the proposal to amend

“The entry for N,N-dimethyltryptamine (DMT) in schedule 9 to allow exemptions for naturally occurring DMT in very low concentrations and liquid form for religious purposes. The quantity of DMT found per serving of the tea is approximately 0.25 mg/mL”,

as it specifically affects the legal status of ayahuasca utilization in Australia, for religious purposes, and will cover the following issues:

1. Our reasons to support this particular amendment.
2. Suggested improvements to this particular amendment.

As summarized in the accompanying letter, [REDACTED] welcome and support this proposal to amend the entry for N,N-dimethyltryptamine (DMT) in schedule 9 to allow exemptions for naturally occurring DMT in very low concentrations and liquid form for religious purposes.

However, [REDACTED] believe that introducing the proposed threshold (approximately 0.25 mg/mL) of the DMT contained in the ‘naturally occurring liquid form’ (this is, the Amazonian brew ayahuasca) is problematic and possibly counterproductive for the achievement of the amendment’s goals: balancing the protection of public health versus the right for people to drink ayahuasca as part of their religious practice.

This subject matter and its dimensions of science, policy, health, human rights, culture, religion, and traditional medicine are very complex, and decisions regarding an amendment of this scope and importance are equal complexity. Therefore [REDACTED] would be more than willing to offer your committee an in-depth oral presentation by world-leading researchers and experts in this field, to assure the Committee obtains a comprehensive view on this matter.

Meanwhile, [REDACTED] remain at your disposal for any additional information you may request.

Yours Truly,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1. Our reasons to support this particular amendment.

The [REDACTED] welcomes and supports the Australian government's proposal to amend the entry for N,N-dimethyltryptamine (DMT) in schedule 9 to allow exemptions for naturally occurring DMT in very low concentrations and liquid form for religious purposes.

The most common 'naturally occurring DMT in liquid form' is the Amazonian brew known as 'Ayahuasca', used for sacramental purposes in the context of Brazilian-origin churches and indigenous cultural and folk healing practices around the Amazon basin, which have expanded worldwide and considerably increased the number of people involved in these practices.

The main reasons why we consider this amendment is positive and necessary are the following:

1. **It would particularly affect the utilization of the Amazonian brew 'Ayahuasca'.** Ayahuasca is the name given to the decoction of the Amazonian medicine plant *Banisteriopsis caapi*, that contain alkaloids belonging to the chemical family of betacarbolines, harmines, harmalines and tetrahydroharmine (known generically as harmala alkaloids). Betacarbolines act in the human body as inhibitors of the enzyme monoamine oxidase (MAO). Ayahuasca has been used for centuries throughout the upper Amazon rain forest. In the process of preparation of ayahuasca, different ethnic groups and shamans add other plant species. There is a very wide scope of ayahuasca recipes and preparation methods. The most popular plant species used currently is the *Psychotria viridis*, which naturally contains DMT (N,N-dimethyltryptamine), a tryptamine alkaloid found in many plant species and even endogenously in animals and the human body. Although DMT is not psychoactive when taken orally because the endogenous MAO enzymes would destroy it before reaching the brain, a complex pharmacological process occurs with the consumption of the ayahuasca brew, allowing the DMT to be orally active. However, the brew 'ayahuasca' is named after the vine *Banisteriopsis caapi*, also called ayahuasca, which is considered the central ingredient of the brew. Therefore understanding the ayahuasca as just a mechanism to activate the effects of the DMT would be highly reductionistic and distorted. As mentioned before, the ceremonial use of ayahuasca is a complex whole composed of many elements, which all together define its effects, safety and benefits for the user (for more information, see Sánchez & Bouso, 2015).

2. **During the last decades practices involving the use of ayahuasca have spread beyond their traditional contexts**, through the interconnection of societies in our globalized world. The religions incorporating their use as a sacrament (groups like Santo Daime or União do Vegetal) have settled in an increasing number of countries, along with indigenous healers as well as occidental practitioners who often are direct disciples schooled in the indigenous spiritual traditions.

This expansion of ayahuasca drinking practices deserves a response from local and national governments to guarantee the protection of these practices as a manifestation of **the fundamental and universal rights to freedom of religion and thought**. This right is recognized in broadly ratified international instruments, such as the 1948 UNGA Universal Declaration of Human Rights (Art. 18), the 1950 European Convention on Human Rights (Art. 9) and the 1969 American Convention on Human Rights (Art. 12).

3. **The practices of ayahuasca drinking defy traditional conceptualizations and categorizations of illegal drug "abuse"** as defined by the dominant international drug control regime. Equating the ritualistic, religious and therapeutic/personal development use of these traditional plants to the problematic use of controlled drugs like opiates, cocaine or

methamphetamine—or treating the traditional shamans, their disciples and the church leaders necessarily as “drug traffickers” profiteering in illegal markets—is misinformed, not based on evidence, and contributes to confusion about the human-rights based legitimacy of these practices.

4. Ayahuasca has no reported recreational use and is typically consumed in careful ceremonial settings in certain indigenous spiritual traditions, or in religious ceremonies. For a significant population in Europe and other parts of the world, ayahuasca drinking in ceremonial contexts has become a means to promote their spiritual and personal development, overcome suffering and deepen their relationship with themselves, their families, their communities and their environment. Practices involving the use of these materials are for most part taking place in ceremonial group settings rather than the isolated purchase and intake of psychotropic substances as happens with other controlled substances. [REDACTED] research and that of other scientific studies shows that people engaging in ceremonial ayahuasca practices do not seek novel experiences (as with early drug experimentation), but rather to improve aspects of their lives, overcome obstacles in their personal or interpersonal space or connect with their spirituality, god or life purpose. Further, the average age of ayahuasca drinkers identified through our research is high (around 35 years old) and their level of education also generally high. This all indicates that ayahuasca drinking is a unique type of contemporary psychoactive substance use that requires a specific political treatment.

5. Ayahuasca has an extensive history of human cultural use. The oldest traces of possible use of ayahuasca have been found in the Azapa desert in the north of Chile, where residues of harmine have been found in hair analyzed from mummies from the Tiwanaku period between 500 and 1000 C.E. In the Azapa valley *Banisteriopsis caapi* does not grow, nor does any other harmine-containing plant, which suggests an intense commerce between the ancient populations of Chile and the Amazonian peoples; probably the former provided the latter with salt and the latter provided the former with medicines, among them Ayahuasca (Ogaide et al, 2009).

6. Ayahuasca is not under international control according to the International Narcotics Control Board, even though ayahuasca naturally contain small amounts of DMT, the alkaloid included in the 1971 Convention on Psychotropic Substances (and under the Australia’s Poisons Standard March 2016). In a letter to [REDACTED] in response to an inquiry for a court case in Chile in 2010, the INCB confirmed that ‘No plant or concoction of plants that contain DMT are under international control’, meaning ayahuasca is clearly distinguished from pure, chemically extracted DMT (see letter annexed; see also Tupper & Labate, 2012).

7. The legal situation of Ayahuasca is far more complex than a simple reduction to a DMT extraction. It is a fact that ayahuasca and pure, extracted DMT are two different things from juridical, cultural and pharmacological/psychological point of view. Pure, extracted DMT is only active if smoked or injected and is linked to very different patterns and contexts of use. However, the fact that DMT is illegal under the 1971 Convention, and ayahuasca naturally contains DMT makes its legal status unclear and can result in legal prosecution when law enforcement construes ayahuasca as illegal because it is a DMT preparation. Again, understanding ayahuasca as a mechanism to activate the effects of DMT would neglect the whole cultural dimension of ceremonial drinking practices and would not reflect a comprehensive understanding of this phenomenon (see ADF website).

8. Some ayahuasca practices are protected as religious manifestations or cultural patrimony. For example in 2008 Ayahuasca was declared Cultural Patrimony of Peru, due to its ancestral use as a traditional medicine (Instituto Nacional de Cultura, 2008) and its use for religious purposes is firmly established and legalized in Brazil (Labate et al., 2009), and also legally protected under specific circumstances in the United States and the Netherlands. Churches that utilize ayahuasca as a sacrament have expanded internationally into numerous European, American and Asian countries (Labate et al., 2009; Labate & Jungaberle, 2011).

9. We firmly believe, based on our expertise, that the highest level of protection of public health and safety in relation to these practices can only be achieved with strategies of legally protecting specific responsible ceremonial ayahuasca practices that have integrated consumption of the brew into a time-honored tradition. The large body of scientific research accumulated over the last two decades offers a thorough understanding that ayahuasca can be consumed safely within controlled environments.

9.1

As an example, [REDACTED] [REDACTED] a technical report on ayahuasca, written by the world's most renowned bio-medical scientists who have researched this traditional plant-based brew for the last fifteen years in clinical and observational research. The original report is attached in pdf to this letter (annex1). An excerpt from the report says:

Ayahuasca, whether administered in a laboratory context or ingested in a traditional context, produced, as evaluated with questionnaires to measure its subjective effects, transitory modifications in emotion, thought content, perception and somatic sensations (Grob et al. 1996; Riba et al, 2001 , 2003; Dos Santos et al, 2011, 2012) even to the point of being able to carry out complex tests of cognitive performance (Bouso et al., 2013).

Studies have been published in which neuroimaging techniques have been used in order to determine the cerebral areas that activate after the ingestion of ayahuasca (Riba et al., 2006; de Araujo et al., 2011). Both studies show that ayahuasca activates the cortical and paralimbic areas. This overall pattern of activation may be at the base of the introspective processes, memories of past experiences charged with emotional connotations, and complex cognitive processes, which are such prototypical experiences with ayahuasca (Shanon, 2002). These brain and cognitive phenomena may explain why ayahuasca is considered a potential psychotherapeutic ethnobotanical tool (Cavnar & Labate, 2013). Indeed, one study found that, under the effects, ayahuasca reduced the scores of panic and hopelessness in ritual users (Santos et al. , 2007). A recent study found antidepressant effects of ayahuasca in patients with major depression (Osório et al., 2015).

Some side effects after the administration of ayahuasca in the laboratory have been described, but they are localised and isolated (Riba et al., 2001; Riba & Barbanoj, 2005, 2006; dos Santos et al., 2011, 2012). In the general blood analyses carried out before and after on volunteers in clinical trials, no changes in hematological and biochemical functions were observed (Riba et al., 2001; Riba & Barbanoj, 2005). Cases in which psychiatric effects have appeared in the context of ayahuasca ritual use have also been documented, although their occurrence is rare (Lima & Tofoli, 2011). This suggests that ayahuasca, in principle, is contraindicated for people with serious psychiatric disorders.

The report concludes:

In conclusion, in the literature on the short-term, medium-term, and long-term effects it is shown that ayahuasca is a substance that is physiologically and psychologically acceptably safe (McKenna, 2004; Gable, 2007; Bouso & Riba, 2011; Barbosa et al., 2012; dos Santos, 2013).

9.2

Far from generating tolerance and having potential for dependence, ayahuasca is used as a tool in the treatment of chemical dependency; By way of example, scientific evidence demonstrates the following:

As far as its potential for abuse, in the neuroimaging studies cited earlier, no active areas have been found in the reward centres. Rather, in this sense, the existing evidence indicates that

ayahuasca can be a useful tool in the treatment of addictions (Bouso & Riba, 2013). In fact, there are various clinics in South America that specialise in the treatment of drug addiction, the most important of these being Takiwasi, in Peru (Mabit, 2007). The first study carried out in humans showed how many participants in ritual ayahuasca sessions had abandoned the consumption of alcohol and other drugs, such as cocaine, as a consequence of their participation in the rituals (Grob et al., 1996). This finding has been found again in later studies (Halpern et al., 2008). A recent study, in which 127 users of ayahuasca in traditional contexts were evaluated and compared with 115 controls, no evidence was found of criteria of addiction according to the biopsychosocial indicators evaluated with the ASI (Addiction Severity Index) nor was it found that the continued use of ayahuasca was associated with the noxious biopsychosocial effects occasioned by drugs of abuse. Rather, the groups of ayahuasca users consumed less alcohol and other drugs than the control subjects and these high scores on the biopsychosocial indicators of addiction were replicated a year later, confirming the consistency of the results (Fàbregas et al., 2010). One study, carried out with adolescents belonging to a Brazilian ayahuasca church, found that they consumed significantly less alcohol than the controls, concluding that ayahuasca, far from producing abuse or dependency, for these adolescents was a protecting factor against the consumption of alcohol (Doering-Silveira et al., 2005a).

Other studies have found lower indices of psychopathology and greater psychosocial integration in habitual users of ayahuasca (Bouso et al., 2012; Halpern et al., 2008) and two other studies have found no neuropsychological alterations, evaluated through tests of neuropsychological performance, in habitual users of ayahuasca after 10 to 15 years of continuous consumption (Grob et al., 1996; Bouso et al., 2012; Thomas et al., 2013). Ayahuasca-assisted therapy for addiction: Results from a preliminary observational study in Canada. *Current Drug Abuse Reviews*, 6(1), 30-42.).

10. Taken into consideration all the reasons and evidences explained above, we consider that **public policies regarding ayahuasca, or ‘DMT in its naturally occurring liquid form,’ aspire to best protect both public health and the human rights of people for whom ayahuasca is an important sacrament in their religious practice should take into account:**

- a) The important cultural and religious value of their use within ceremonial contexts (Cavnar & Labate, 2014), whose benefits for individuals and communities have been historically documented;
- b) The scientific evidence regarding their acceptable safety profile when utilized in responsible and controlled environments (Cavnar & Labate, 2014), and the evidence regarding their potential to improve health, quality of life and well-being;
- c) The political precedents in other countries regarding regulatory approaches towards the use of these ethnobotanicals in religious practices or cultural heritage.

Therefore, we firmly believe this amendment is a step in the right direction to advance the recognition of ayahuasca utilization for religious purposes, and it will have a positive impact on public health and safety.

2. Suggested Improvements

As stated above, [REDACTED] welcome and support the proposed amendment to re-schedule DMT to allow exemptions for naturally occurring DMT in very low concentrations and liquid form for religious purposes. However, **we believe that introducing a threshold of DMT naturally contained in liquid form as being problematic** and even counterproductive, for the achievement of the amendment's goals. **Public policy considerations should not be arbitrary** but have a scientific basis on one hand, and should give proper considerations to cultural contexts (where there is a recognized history of ritual use over time) and human rights. The establishment of a specific threshold of DMT to determine whether an ayahuasca brew is violating the "poisons" standard doesn't seem to have a sound basis, rather seems arbitrary, doesn't add to the protection of physical health (as explained below), and goes against the logic of the traditions that understand Ayahuasca as a sacred brew and not a chemically standardized product.

The alleged **reasons not to establish the concentration of DMT as an indicator to determine the legality of ayahuasca** drinking for religious purposes are the following:

1. Most of the ayahuasca drunk outside the Amazon is likewise prepared there, **so it is very difficult, if not impossible, to know the exact content of the brew in beforehand**. This includes the difficulty of estimating the precise concentration of DMT, as it comes from the plant *Psychotria viridis*, and its presence in the brew is a natural phenomenon, and not the result of a chemical process or an artificial addition. The concentration of DMT varies from plant to plant and depends on several factors -such as the moment of harvest, the altitude where the plant grows or the season when it is collected.
2. In the potential case that ayahuasca is brewed in Australia, using either Amazonian or non-Amazonian plants, it would be likewise **impossible to estimate in advance the concentration of DMT** contained in each batch for the same reasons explained above. And it is eventually very unlikely that each time someone brewed or received a batch of ayahuasca this can be analyzed to determine the exact proportion of DMT.
3. **The physiological and psychological effects of ayahuasca are dependent on multiple factors**, including the complex pharmacological processes of the combination of all alkaloids present in the brew and the body, the set (mental and physical state of the person drinking the ayahuasca) and setting (cultural context).
4. The preparation of the ayahuasca, a process of boiling plants together in water, **results in relatively low concentrations** of the alkaloids as observed by science in analyzed samples (contrary to chemical extraction processes). **Their physical toxicity is negligible** in the amounts typically utilized in ceremonial ayahuasca practices.
5. **It is virtually impossible to suffer an overdose of ayahuasca** for two reasons: 1) because of its lack of physical toxicity as has been already mentioned; 2) because ayahuasca has an emetic effect, so in the very unlikely event that someone were to drink a very large and/or continuous amount in one sitting the probability of vomiting increases, thus reducing the amount of alkaloids absorbed and thereby some of the consequent effects.
6. Finally, and derived from the reasons explained in the previous points, **what is most relevant in terms of the safety of ayahuasca drinking is that it takes place in a controlled, safe environment, the preparation and pre-screening of the individual and post-ceremonial integration**, all of which are key aspects that should be considered

in protecting the health and safety of individuals. Religions such as Santo Daime and União do Vegetal, as well as facilitators who have been trained and initiated in indigenous spiritual traditions, are invariably taught to conduct their sacred ceremonies in a safe and responsible manner, for the benefit of the individual and community they serve. Thus, regulated frameworks for ceremonial ayahuasca drinking—developed in cooperation with communities of drinkers and ceremonial leaders—are the most appropriate way to distinguish between safe and unsafe practices.

In conclusion, ■■■ suggest the following as the complete amendment:

“The entry for N,N-dimethyltryptamine (DMT) in schedule 9 to allow exemptions for naturally occurring DMT in very low concentrations and liquid form for religious purposes.”

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[REDACTED]

[REDACTED]

Why not Drug War Victories?

Governments have been losing this war for more than forty years but at last a step towards success has now been identified by the TGA



Response to this mooted TGA Amendment:

“Proposal to amend the entry for N, N-dimethyltryptamine (DMT) in schedule 9 to allow exemptions for naturally occurring DMT in very low concentrations and liquid form for religious purposes. The quantity of DMT found per serving of the tea is approximately 0.25 mg/ml.”

The Sacred Journey - Restoring the Earth Hallow Sacraments
Addiction & Earth Reunion - Solutions from the Amazonian Rainforest
“Daime is a gateway to the Divine – it cannot be used recreationally”

The entheogenic churches have demonstrated that religioning [1] IS measurable! Psychiatrist Professor Charles Grob of the UCLA School of Medicine, found communicants of Ayahuasca Church *União do Vegetal* to be psychologically and physically healthier than average, and he has recommended ayahuasca as a treatment for depression. [1] Reconnection.

Taking the clients from the dealers

What we can do is to take the clients from the dealers."

President Reagan's re-election campaign speeches prior to his Second Term.

Inspired by the above statement

Entheogenic religion takes the clients from the dealers, it emulates the largely drug abuse free First Nations by creating the social and cultural capital they have long possessed. Looked at this way drug abuse and addictions are a form of cultural poverty. There are no instant solutions but as witnessed by the reduction in smoking, culture-change is a real answer.

Initiating Culture Change – Drug Harm Minimisation with Entheogens

Response to the:

“Proposal to amend the entry for N, N-dimethyltryptamine (DMT) in schedule 9 to allow exemptions for naturally occurring DMT in very low concentrations and liquid form for religious purposes. The quantity of DMT found per serving of the tea is approximately 0.25 mg/ml.”

Particularly because it has a direct bearing on the real cause of drug abuse, (a matter with which the [REDACTED] is socially [REDACTED] proffer some informative comments and a deeper analysis below.

[REDACTED]

[REDACTED]

Rectifying the anomalies

There are two immediate issues we will first address followed by a comprehensive deeper analysis.

There are potential religious freedom/human rights, cultural and geo-political issues, and unintended ramifications of the present law regarding DMT for at it present it fails to discriminate between extracted crystal and liquid traditional form. This leaves a number of religions in legal no man's land. The [REDACTED] advice is that Ayahuasca is not a preparation of DMT and the proposed amendment is in line with that advice. Without this 'prophylactic' change however there remains a risk of prosecution and such a prosecution would:

- 1) Violate the UN Convention of the Rights of Indigenous People ratified by Australia in 2009. It would do so by abrogating both its intention, spirit, and in particular Article 12. (As this Convention is based on the UN Declaration of Human Rights. The law without this clarification has the potential to abrogate the freedom of religion provision enshrined in this Charter.

Religious freedom is one of the human rights under the International Covenant of Civil and Political Rights that cannot be abrogated even in times of public emergency. It may be unthinkable that this right could be at risk but as things stand an overzealous drug squad could arrest congregants and ministers and impound the Eucharist.

- 2) [REDACTED] know for that the Wattle Song Lines are being maintained to this day, including [REDACTED]. This ceremony employs Aboriginal ancient wattle songs and a wattle entheogen that might be illegal - not conducive to Reconciliation.

The separation of church and state is a pillar of the Australian Constitution

The Wattle is our National Floral Emblem; it is an entheogenic Earth Sacrament. A prosecution would breach the Separation of Church and State. [REDACTED]

[REDACTED] Not an intended consequence of course, an obvious anomaly that had not been thought through, but nevertheless at present a fact.

On the other hand countries such as Brazil, Peru, and Uruguay have honoured their entheogenic plants by declaring them part of their National Patrimony. Australia as the home of the Acacia, it has the widest range of entheogenic (DMT spirit molecule) flora on the planet. Is it not time we too honoured this precious blessing?

The state has not yet crossed that Rubicon but without the amendment the risk remains. In the United States mainstream religion was unnerved by the prosecution of the UDV concluding that if one holy sacrament can be criminalised could any be considered safe, and swung their support behind the UDV. The proposed amendment would clear up all such matters.

A Brief Overview of Historic Contemporary Acacia Religions

There are a number of Acacia/Ayahuasca religions in Australia including the Islamic Sufi Fatima School; another is the Centro Espírita Beneficente União do Vegetal (UDV) [1]

As stated above, [REDACTED] still maintaining at least some of the Wattle Songlines. The Ark of the Covenant was built from acacia wood, and from the Egyptian Book of the Dead. 'I betook myself to the Acacia Tree of the [divine] Children.'

Acacia is the key heritage entheogen in Africa, Iran/Arabia, and the Americas. In March 1914 Grand Ayatollah Rohani of Iran issued a formal legal ruling (that is, a *fatwa*) determining the use of entheogens to be licit and thus permissible (*ḥalāl*) for Shi'i Muslims provided it be under the direction and supervision of qualified experts (*ahl al-ikhtisāṣ*), and that, moreover, such plant substances as a rule do not impair the mind he noted.

Professor Benny Shanon of the Hebrew University of Jerusalem author of: 'The Antipodes of the Mind: Charting the Phenomenology of the Ayahuasca Experience,' has written on Biblical entheogens and Ayahuasca and creativity.

The Egyptian Gods were said to have been born from the Acacia Goddess Saosis beneath an acacia, says Pyramid Text 436. The Egyptian coffin texts also refer to the Acacia tree; they state that parts of the Sacred Acacia tree of Saosis are '**squashed and bruised**' by the deceased.

These parts were then said to have a magical healing effect. (Interestingly a literal pounding is a continuing tradition, thousands of years later. It is part of the process of brewing this sacrament; the fechio ritual, as you will see in the documentary, 'Santo Daime no Fantastico.' [REDACTED])

Entheogen or 'Earth Sacrament'

These are naturally occurring entheogenic substances, also referred to as 'sacred medicines' and 'power plants' which have been used by ancient and contemporary shamans and modern churches and which have been revered by the ancestors of those of European, African, Middle Eastern and from the Americas for thousands of years. These are traditionally employed for shamanic healing, to deepen intra human connection, address tribal problems, commune with Nature, the spirit world and the transcendent. It is further being demonstrated that entheogens, for example, our national floral emblem the Wattle, along with Ayahuasca/Yagé (Daime/Hoasca tea) and African Iboga, can be useful in the treatment of addictions. Iboga excepted: this group all contain small amounts of DMT.

First Nations Apprenticeship

The growing scientific literature supporting the effectiveness of psychoactive plants for the treatment of addictions points to the need to more seriously consider their use with people with substance use disorders. In this regard ancient wisdom regarding the safe and effective use of the plants in religious contexts can be highly informative.

As was voiced from many nations and civil society groups at the recently concluded UN General Assembly Special Session (UNGASS) on the world drug problem, the current focus on criminalisation and harsh repression is resulting in enormous social costs. The UNGASS draft outcome document reaffirms the need for all human rights to be fully respected.

Power plant employing First Nations developed forms of social & cultural capital that militates against drug abuse. It is their level of social maturity in this arena that we need, with their cooperation, to emulate. It is this form of mentorship and related social capital that we must-needs develop.

Drug use Policies

Any illicit drug policy that fails to remove or render drugs profitless is doomed to failure. Proscription increases the profits and has failed to even keep drugs out of prisons. Therefore, weaning the public from profane, secular-recreational misuse of the holy plant sacraments by restoring their traditional religious status is a long-term solution to drug abuses. This is achieved by fostering cultural maturity and building the required social capital, in short by emulating the First Nations.

Social dividend

"Daime is the Gateway to the Divine – it cannot be used recreationally."

The Brazilian Government Commission Report into entheogenic religions that resulted in their recognition and legal protection 1986 [2].

"The lack of positive ritualised entheogen use in our society linked to the search for deeper meaning is part of the cause for their destructive use. "

Professor Charles Grob & Dr Bravo, UCLA School of Medicine.

Professor Grob was one of the scientists involved in Hoasca Project, the scientific evaluation of União do Vegetal, (Union with the plants) Brazilian entheogenic religion.

Legal, Earth Sacrament Holy Communion – The Required Transitional Circuit Breaker

A thousand mile journey begins with the first step. Without doubt this Amendment is the necessary first step in initiating the necessary societal shift and so begin to weaken the hold drug abuse and organised crime has upon our nation. That would be quite a dividend. Let's have some drug war victories.

[REDACTED]

[REDACTED]

[REDACTED]

[*1] The U.S. Supreme Court in 2006 voted unanimously that UDV is a bonafide religion. The Catholic Bishops Association, Presbyterians, Episcopalians, Evangelicals the Jewish Congress and Christian Science this battle on the side of UD. Concerned that if the Secular State can proscribe on sacrament NO sacrament is safe.

[*2] **Ayahuasca in Brazil:** "In Brazil, CONFEN (the Federal Drug Council) has consistently upheld the right of the Daime Church to practice its religion and healing practices using the Daime. A study was made of the Daime by the CONFEN in 1987^{[10][11]}, which included visits to the various churches and observation of the making of the Daime. It also included study of another group of Ayahuasca users, who call the drink *vegetal* (União do Vegetal - UDV). The work group^[12], which made the study, included representatives not only of the CONFEN but also of several other government agencies. The conclusion^[13] of the study was that the Daime was a very positive influence in the community, encouraging social harmony and personal integration." **Note:** Ayahuasca use comes under the jurisdiction of Brazil's Conservation Department. Santo Daime's Sierra Irenu Amazonia Conserve Reserve is I think, 250,000 hectares. Wikipedia.

Resources:

Santo Daimé No Fantástico:



The Hoasca Project

<http://www.maps.org/research-archive/ayahuasca/hoasca.html>

<http://www.ayahuasca.com/tag/history/>

Relatedly, kindly also Google Dr Richard Halpern of Harvard and the Native American Church Peyote Sacrament: <http://www.maps.org/news-letters/v11n2/11210moj.html>

To whom it may concern,

regards to the Consultation: Proposed amendments to the Poisons Standard, July 2016 (Medicines) with consideration to N,N-DIMETHYLTRYPTAMINE: Proposal to amend the entry for N,N-dimethyltryptamine (DMT) in schedule 9 to allow exemptions for naturally occurring DMT in very low concentrations and liquid form for religious purposes. The quantity of DMT found per serving of the tea is approximately 0.25 mg/mL.

This author is in support of this motion and wish to highlight various benefits of this practice as well as show its uses throughout history as a pathway for religion and spiritual growth, religion as per the text book definition, 'The belief in and worship of a superhuman controlling power, especially a personal God or Gods.'

The word Ayahuasca, a brew which combines various plant medicines and whose active compound is DMT (N,N-DIMETHYLTRYPTAMINE), literally translates from Quechua to 'The vine of the soul' and is administered by a Shaman in ceremony to participants who have come to progress their spiritual path or for healing of various ailments.

The below details refer to US Supreme court hearings, but the law and legal precedents are valid here in this country also I believe.

'On November 22, 2000, the UDV filed a lawsuit against certain agencies of the federal government for violations of the First Amendment to the US Constitution and the Religious Freedom Restoration Act (RFRA).

RFRA requires that the government not interfere with religious conduct unless it can demonstrate to a court that it has a "compelling interest" in doing so. If it is unable to do so, RFRA requires the government to allow people to practice their religion.

On February 21, 2006 the United States Supreme Court issued a unanimous decision affirming Religious Liberty in the case of [*Gonzales vs. O Centro Espirita Beneficente União do Vegetal*](#).'

In recent years DMT (N,N-DIMETHYLTRYPTAMINE) was reject from being approved for removal from the schedule 9 list for religious purposes stating that the application did not provide any details of data or studies to support the claim that these substances were less hazardous.

As shown below.

REASONS FOR FINAL DECISIONS BY DELEGATES OF THE SECRETARY TO THE DEPARTMENT OF HEALTH AND AGEING
FOR AMENDMENTS TO THE POISONS STANDARD

- MARCH 2011

(f) Other matters

- Claimed that substances with less hazardous profiles (cannabis sativa, dimethyltryptamine [DMT]) were listed in Schedule 9. [The application did not provide any details of data or studies to support the claim that these substances were less hazardous.]
- Reiterated that the risks associated with ethyl alcohol were greater than those associated with cannabis and/or DMT. The applicant provided a one page graphical comparison of the addictive properties of six different substances (sourced from the Henningfield PhD, for the National Institute on Drug Abuse, reported in the 2 August 1994 edition of the New York Times). Specifically, the graph:
 - Compared the dependence, withdrawal, tolerance, reinforcement and intoxication characteristics of nicotine, heroin, cocaine, alcohol, caffeine and marijuana. [It was noted that the graph did not provide any information on the properties of DMT].
 - Presented these properties on a scale ranging from 0 (less serious) to 6 (more serious).
 - Rated the withdrawal and intoxication effects of alcohol as "more serious". [It was noted that the graph did not contain any information on the methodology or analysis used to reach its conclusions.]

Below are extracts from various studies noting the lack of addictive properties of DMT tea, long term benefits from use of Ayahuasca and its use in assisting with addiction, depression and other ailments.

Assessment of addiction severity among ritual users of ayahuasca

Drugs of abuse typically show dopaminergic effects, activating the striatum and the ventral-tegmental area, within the so-called "neural reward circuit" (Camí and Farré, 2003).

DMT, on the other hand, interacts with serotonergic neurotransmission, binding to 5-hydroxytryptamine 2A receptors (for a review see Riba, 2003).

Though there is evidence that some hallucinogens may act also on the dopaminergic system (Nichols, 2004; Passie et al., 2008; Vollenweider et al., 1999), a recent study using the neuroimaging technique SPECT (Single Photon Emission Computerized Tomography) did not find any changes in reward-related regions such as the striatum or the ventral-tegmental area.

Results showed that both ayahuasca-using groups scored significantly lower than their respective controls on the ASI Alcohol Use and Psychiatric Status subscales. At the 1 year follow-up these differences were still significant in the jungle-based group but not in the urban group.

Two other studies carried out in adolescents also failed to find psychiatric disorders (Da Silveira et al., 2005) and neuropsychological deficits (Doering-Silveira et al., 2005). A recent study of a US group of ritual ayahuasca users did not find evidence of psychopathology when scores were checked against normative data (Halpern et al., 2008). The above results are in line with the data obtained in our present study for the Medical Status and Psychiatric Status subscales.

ayahuasca has a low abuse potential, as previously concluded by others (Gable, 2007).

In conclusion, the ritual use of ayahuasca, as assessed with the ASI in currently active users, does not seem to be associated with the psychosocial problems that other drugs of abuse typically cause.

<https://www.ucm.es/data/cont/docs/114-2015-01-22-Assessment%20of%20addiction%20severity%20among%20ritual%20users%20of%20ayahuasca.pdf>

Risk assessment of ritual use of oral dimethyltryptamine (DMT) and harmala alkaloids.

However, ayahuasca is far from being a substance that generates addiction: not a single case of anyone getting 'hooked' on it in scientific literature. "It's not addictive. We carried out a study in Brazil and found no evidence of dependence or abstinence syndrome among regular consumers," Bouso. On the contrary, ayahuasca has been successfully used for detoxification from other drugs, such as the ones mentioned above, tobacco or alcohol.

Gable, R. S. (2007). "Risk assessment of ritual use of oral dimethyltryptamine (DMT) and harmala alkaloids." *Addiction* **102**(1): 24-34.

conclusion:

A decoction of DMT and harmala alkaloids used in religious ceremonies has a safety margin comparable to codeine, mescaline or methadone. The dependence potential of oral DMT and the risk of sustained psychological disturbance are minimal.

<http://www.ncbi.nlm.nih.gov/pubmed/17207120>

PLoS One. 2012; 7(8): e42421.

Personality, Psychopathology, Life Attitudes and Neuropsychological Performance among Ritual Users of Ayahuasca: A Longitudinal Study

The increasing number of individuals using ayahuasca on a regular basis has raised public health concerns [2]. Drugs of abuse such as heroin, cocaine, alcohol or amphetamines share a common neurobiological mechanism which involves the so-called “neural reward system”, inducing functional changes in brain structures related to pleasure such as the striatum and the dopaminergic ventral-tegmental area [15]. The activation of this neural circuit is considered to play a crucial role in modulating the consequences of drug abuse, which may include psychological, medical, legal, employment and family problems [16]. DMT, on the other hand is a serotonergic drug, binding to postsynaptic 5-HT_{2A} receptors [17], [18]. Although some studies have found that hallucinogenic drugs like psilocybin or LSD (lysergic acid diethylamide) may also modulate dopaminergic neurotransmission [19]–[21], a neuroimaging study using SPECT (Single Photon Emission Computerized Tomography) found that ayahuasca increases regional brain blood flow in frontal and paralimbic areas [22], but did not find any changes in reward-related regions such as the striatum or the midbrain.

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3414465/>

Evidence of health and safety in American members of a religion who use a hallucinogenic sacrament

There simply is no evidence from within the data collected to assert that there are concerning harms from the full practice of Santo Daime. Most side-effects, as detailed, from ayahuasca were temporal to ingestion, manageable, and rarely persisted beyond a day or two.

http://www.maps.org/research-archive/w3pb/2008/2008_Halpern_23045_1.pdf

Potential anti-depressant treatment

Antidepressant effects of a single dose of ayahuasca in patients with recurrent depression: a preliminary report.

RESULTS:

Statistically significant reductions of up to 82% in depressive scores were observed between baseline and 1, 7, and 21 days after AYA administration, as measured on the Hamilton Rating Scale for Depression (HAM-D), the Montgomery-Åsberg Depression Rating Scale (MADRS), and the Anxious-Depression subscale of the Brief Psychiatric Rating Scale (BPRS). AYA administration resulted in nonsignificant changes in Young Mania Rating Scale (YMRS) scores and in the thinking disorder subscale of the BPRS, suggesting that AYA does not induce episodes of mania and/or hypomania in patients with mood disorders and that modifications in thought content, which could indicate psychedelic effects, are not essential for mood improvement.

CONCLUSIONS:

These results suggest that AYA has fast-acting anxiolytic and antidepressant effects in patients with a depressive disorder.

<http://www.ncbi.nlm.nih.gov/pubmed/25806551>

Exploring the therapeutic potential of Ayahuasca: acute intake increases mindfulness-related capacities.

Furthermore, recent open-label studies in patients with treatment-resistant depression found that a single ayahuasca dose induced a rapid antidepressant effect that was maintained weeks after administration

CONCLUSIONS:

The present findings support the claim that ayahuasca has therapeutic potential and suggest that this potential is due to an increase in mindfulness capacities.

<http://www.ncbi.nlm.nih.gov/pubmed/26612618>

Studies above have clearly shown that DMT tea, when is used correctly as part of a ceremony has shown neither health concerns, issues with addiction or any negative repercussions. DMT tea could thus be considered safe when proper protocols are followed, especially if compared to other substances presently not holding any or lesser legal scheduling; for example alcohol, tobacco, nutmeg.

Furthermore studies above have shown to have positive aspects to them and in fact assist with several ailments such as addiction, depression, and neurogenesis.

This is money that could be better used within this country.

Considering all the evidence above, I trust this delegation will take careful consideration of all facts and scientific evidence presented above and rule in favour of removing restrictions of DMT tea from schedule 9 listing for religious reasons.

The science is in, DMT Tea, is not addictive
DMT tea is not addictive.

Please find attached an email copy of several of the scientific papers sited.

Please do not hesitate to contact [REDACTED] should further information be required on any of the above.

Kindest Regards

[REDACTED]

[REDACTED]

N,N- DIMETHYLTRYPTAMINE

Proposal to amend the entry for N,N-dimethyltryptamine (DMT) in schedule 9 to allow exemptions for naturally occurring DMT in very low concentrations and liquid form for religious purposes. The quantity of DMT found per serving of the tea is approximately 0.25 mg/mL.

Comments on Proposed Amendment on N,N-dimethyltryptamine (DMT)

Regarding the legal issue with Ayahuasca in Australia, to my knowledge [REDACTED] has ever been arrested with Ayahuasca in Australia some years ago. [REDACTED] contained a small amount of DMT, and no conviction was recorded. This being the case, and the DMT being in a tea form and not in an extracted form, people like myself who work with Ayahuasca in Australia, perhaps perceive it more of something like a grey area, which law enforcement has not pursued as an problematic issue in Australian society. The opposite is clearly true, as people are gaining much benefit and healing from Ayahuasca, it is not a drug of addiction or dependence and right throughout Amazonia has a long history of significant use, and is rapidly increasing in popularity around the world in the context of healing and shamanism.

[REDACTED] like to point out that the reason DMT is a prohibited compound is because the United States ban of LSD in 1966 catalysed a blanket ban of all psychotropic compounds in the 1971 UN Convention on Psychotropic Substances, not from any significant research or inquiry into the nature and effects of DMT.

As this fax from the Secretary of the Narcotics Board makes clear, none of the plants involved in the making of Ayahuasca tea are presently specifically controlled:

“No plants (natural materials) containing DMT are at present controlled under the 1971 Convention on Psychotropic Substances. Consequently, preparations (e.g. decoctions) made of these plants, including ayahuasca are not under international control and, therefore, not subject to any of the articles of the 1971 Convention.”

https://www.erowid.org/chemicals/ayahuasca/ayahuasca_law10.shtml

Presumably, this also includes the Australian Acacia, of which many species contain DMT.

Firstly, [REDACTED] point out based upon [REDACTED] research, proposing a limit to the amount of DMT per millilitre does not appear to represent clear and useful policy. 250 micrograms per ml, is a very small amount of DMT and is effectively useless in an Ayahuasca preparation to my mind. 100ml would then contain 25mg of DMT which basically does pretty much nothing to most people most of the time.

500 micrograms (or 0.5g) per ml is a more reasonable ratio of DMT in Ayahuasca tea. Even then 100ml (a big cup in the ayahuasca world, where 30-50ml is often a typical dose) will need to be

drunk in order for there to be beginning psychoactive effect, of 50mg of DMT. And 200ml (100mg) will be required to obtain significant effects, with 300ml being required for many people equalling 150mg of DMT.

simply not viable due to the large amount of liquid the individual would need to drink.

Also this statement, "DMT in very low concentrations" is surely an implication that higher doses of DMT are undesirable? People such as [REDACTED] who have much experience with DMT, would say under dosing is not taking full advantage of the states that DMT can take people: the true "work" as it were. Although higher doses can catalyse deeper states in an appropriate setting, even with the higher doses, if a good facilitator is present, there is no necessary danger to increasing the DMT dosage. [REDACTED] complaint with the Ayahuasca scene in Australia and the world, is that many facilitators are not dosing their DMT high enough, with large numbers of people 50-100 people, and people are not experiencing the fullest benefit of the medicine. This is a global problem [REDACTED].

Many [REDACTED] do not believe that [REDACTED] Brazilian churches (who are the extent religious practitioners of ayahuasca) have an exclusive right to drink ayahuasca, because their practice is religious and [REDACTED] is not, as if religion is "higher" and more valid reason for being able to access such plant medicines? [REDACTED] do not believe are relevant for the greater majority of Australian people, and are primarily cultural relevant for Brazilian people with a [REDACTED] orientation.

[REDACTED] working to create a tradition or way that works in Australia. The way [REDACTED]. In this place the people can surrender very deeply to the interactive work of the medicine.

People who take ayahuasca in Australia, do not expect to be arrested or taken to jail for experiencing plant medicines which have serious and conscientious usage all over the world. Therefore, decriminalisation, whereupon we are not liable to be criminals is very obviously the only sane way forward, and this proposal to the TGA at least marks a potential change in the legislation.

[REDACTED] believe there is a large potential industry here, and potential tourism potentials. DMT and Ayahuasca are in a sense, like Bungee jumping or parachuting, and many are attracted to experiencing the unusual and potentially extreme inner states they can catalyse. Ayahuasca is largely safe when drunk correctly and with a careful and considered intention, but every now and then accidents happen. For a safe culture to proceed, decriminalisation would allow a safer culture to proceed, because as Ayahuasca becomes more and more popular, there are liable to be more and more accidents.

In the event of decriminalisation, then there can be a chance at openly educating practitioners, the carrying out of the necessary research and give Australia a huge potential foothold in an industry that could potentially be worth tens of millions of dollars per year. This could be an enormous boon for Australia, with another primary industry emerging in the coming decades, the growing of acacia trees for their DMT. [REDACTED] point out Australian acacia trees contain the highest DMT content in any known plant, from which the most plant matter can be sustainably harvested. The only competition that Australian acacias have is Mimosa Hostilis which grows in Brazil and requires the DMT is harvested from the root bark, when the phyllodes or leaves from Australian Acacia can be sustainably harvested in large quantities over a long period of time.

the use of DMT and ayahuasca is rapidly increasing all over the world, and more and more people are finding great human benefit from drinking Ayahuasca. Psychotherapeutic use of DMT, which allows surrender, deep internal psychological processing, is very commonly said to be 10 years of psycho-therapy. Limiting the usage of DMT to a religious organisations, undermines the extent and breadth of this profound work.

At this time in Australia, and the world, Ayahuasca is increasingly gaining traction in society, and yet nowhere in the world that are governments sending SWAT teams into ayahuasca ceremonies, arresting and jailing ayahuasca facilitators and users, as this is not a sustainable governmental policy. In the Netherlands for example the use of ayahuasca is tolerated and practitioners openly advertise, and nowhere in the world is ayahuasca use considered a problematic issue in any society.

What must proceed at some point is a sensible government policy, which does not criminalise people who are seeking healing and increased awareness through the use of such plant medicines as Ayahuasca. As Australia has the highest number of DMT containing plants in the world with many dozens of acacias containing DMT according to underground researchers, with the acacia being the national floral emblem, and one of the most vital and informed cultures of people using psychedelics on the planet, perhaps Australia does have an obligation to be at the forefront of this movement.

It would behoove the Australian government in its different sectors to actually truly **innovate** a sensible policy on such matters, not unending red tape and regulation, or permits and permission slips, but plain decriminalisation and plan for a sustainable future, believe must include people sensibly and the consciously utilisation of plant medicines such as Ayahuasca.

What'smore, need to think about protecting sensitive acacia populations, and decriminalising DMT in general, would push this agenda forward and open a large potential export market in the coming decades as nowhere in the world are acacia phyllodes specifically scheduled.

DMT especially in Ayahuasca tea, does bring people to be inspired to live their lives. What is being addressed are core issues, like feeling unmotivated in life, not having direction, feeling there is no colour or meaning in life. issues with domestic violence, and this issue was solved from one weekend of Ayahuasca. therapy or medication is effective in treating this issue.

Ayahuasca is not a mere hallucinogen, the effect is one of clarity of mind and described it as an initiation into being itself.

contains a preparation of Acacia which lasts three days, AS an initiation. Perhaps, Australian culture needs to look at initiating our youth into the nature of being and beingness, which is not occurring in our society and seriously think about the possible role that DMT could have in Australian and global society, and create legalisation that seriously reflects the possible and immense value that DMT could have in society.

Ayahuasca - Sacred Drink with Pharmacological Potential

Ayahuasca, also known as hoasca, santo daime or vegetal, is obtained from tea decoction of two plants, the *Psychotria viridis* (chacrona, rainha), bush similar to coffee and belongs to rubiaceae family, and the *Banisteriopsis caapi* (mariri, jagube, caapi, yagé), a Malpighiaceae family member, native liana of the Amazon rainforest. The mariri has a peculiar characteristic of accumulating water and is useful as an alternative source for survival in the jungle.

The active principle N, N-dimethyltryptamine (DMT), found in the leaves of chacrona, is a non-selective agonist of serotonin receptors, whose action on the 5-HT_{2A} receptor promotes cognitive and sensory effects of beverage as reported by users as *miração* (visions with reality perception and expanding human senses; to differentiate hallucination). The mariri liana contains β -carbolines harmine, harmaline and tetrahydroharmine, which are alkaloids inhibitors of monoamine oxidase-A (MAO), enzyme responsible for the degradation of serotonin. Ayahuasca is a perfect combination of these two plants that act synergistically. DMT would be rapidly inactivated by MAO present in the liver and intestine without the presence of β -carbolines.

The use of ayahuasca is part of an ancient culture of various tribes of the Amazon region of Brazil, Peru and Bolivia including the Ashaninka, Kaxinawás, Ticunas and Tucanos. From the 1930 it was introduced in the rituals of Christian religions in Brazil, as the União do Vegetal, Santo Daime, Barquinha and Alto Santo, in sessions that generally occur every 14 days. This religious use has legal protection in the country since 1986, through Resolution No. 6 of the Federal Narcotics Council, and subsequently confirmed by Resolution No. 1 CONAD of 25 January 2010, which also prohibited the marketing of tea and reaffirmed need for scientific studies to

ensure a possible therapeutic use. The religious use of ayahuasca also has legal support in other countries, including the United States and the Netherlands, recently ayahuasca was recognized as intangible heritage of the Brazilian culture.

The acute lethal dose of ayahuasca in rats corresponds to more than 50 times the human dose ritual, confirming the safety of the use of this drink in the religious context. But the recreational use of this drink can constitute a risk to the user, and should be curbed by the authorities.

Ayahuasca users within religions report many benefits to your mental, spiritual and physical health. Additionally, studies show the therapeutic potential of this drink in the treatment of various diseases, including drug addiction and depression. The harmine, β -carboline highest concentration present in mariri, has antipyretic action, antibiotic, antifungal, antimalarial, antileishmaniose and chemotherapy. The potential therapeutic use of ayahuasca is a promising line of research. Therefore, the use of ayahuasca with responsibility in a religious context like União do Vegetal is safe and can contribute to improve health.

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[REDACTED]

My submission relates to DMT and is in my capacity as a private citizen.

[REDACTED] it is absurd that a substance which occurs naturally in every human being and in so many plants around the world should be a controlled substance, particularly given the fact that the role it plays in humans is not well understood (for example, why it is released close to death).

However, this is not the matter at hand.

I support the proposed amendments to DMT. [REDACTED] interest in DMT and the potential it provides to explore spirituality beyond the confines of the material world view. [REDACTED] read extensively on the use of DMT in various forms around the world, and the transformative and enriching experiences that result, to the betterment of those who consume it. It is also well documented that DMT has been used safely for thousands of years, particularly in the form of ayahuasca, by shamen in the jungles of South America. This use has extended to the US where ayahuasca can be legally used as part of religious ceremonies by the likes of Uniao de Vegetal. More recently, Rick Strassman conducted research on DMT via intravenous use. These show that when administered by appropriately trained people, DMT is completely safe, as would be expected of a naturally occurring substance.

Much has been written about DMT and the spiritual awakening and subsequent journeys of personal growth that can occur from its use. [REDACTED] read extensively on the subject, [REDACTED].

Unfortunately this is very difficult to do in Australia without breaking the law, as most – if not all – of the substances (the majority naturally occurring, just like DMT) are classified the same as cocaine, a proven addictive and dangerous substance.

[REDACTED] attain spiritual experiences through the use of DMT. Extracting DMT is relatively easy, although does come with the risk of being caught with a class A drug. Consuming DMT is very difficult. It cannot be consumed orally without the use of MAO inhibitors. MAO inhibitors themselves carry certain risks if not used correctly (avoiding certain foods), or are themselves banned/controlled substances. Smoking DMT is very difficult as the smoke is very harsh. However, through perseverance it is obviously possible as there are many reports online of people having had 'breakthrough' experiences by smoking DMT. For me, the key barrier to consuming DMT is the concern stemming from having to try to achieve a breakthrough experience without assistance from an experienced person. While extracting DMT is relatively simple, finding someone to assist with the experience, and in particular provide a safe and supportive environment is very difficult, given DMT is illegal. As a result, [REDACTED] attempts to date have been frustratingly unfulfilling, and in the current environment, I don't see a simple way to move past this.

I support the proposed amendment because it would bring the consumption of DMT into the light, although not the mainstream. If it was not legally fraught to consume DMT, it would be easier to find experienced people to guide and assist the process. This would make the spiritual experiences more attainable to people like [REDACTED] are interested in exploring these, with the hope of achieving the insight that has been possible over thousands of years. This would be of great benefit to me as I do not subscribe to the materialist view of the world and am seeking to explore other dimensions and states of consciousness, but without success to date. [REDACTED] achieve personal growth [REDACTED]. Were DMT consumption to be more widespread, the community at large would benefit from a louder and better-articulated point of view different to the narrow corporatized material narrative that

dominates the contemporary cultural discourse. A broader perspective, particularly one forcing the consideration of the impacts of a material view of the world which leads inevitably to consumption of the world's resources and the unavoidable destruction of the natural environment on which we depend would benefit the world's population. While this may seem a stretch – and while a small minority of the world's scientists disagree with the risk from climate change – the survival of mankind in the long run depends on a more balanced view of our place in the world and realisation that we cannot go on consuming its resources in an unlimited fashion.

The submission guidelines suggest articulating the benefits. I can't see a greater benefit that reversing the destruction of the natural environment we depend on. Again, while this may seem a long bow to draw, one need only look at the way so-called primitive cultures who had access to substances like DMT in their natural forms have always existed in harmony with the environment. The use of substances like DMT to achieve altered states of consciousness extends back around 40,000 years. The use of the substances were suppressed through the 'civilising' activities of the spread of empires (e.g. the Spanish invasion of central and south America), and more recently through the war on drugs, which for the last 50 or so years have severely restricted access to these substances.

support the proposed amendment. would also note that is no risk of DMT being abused as a recreational drug. It is difficult to consume and according to descriptions of its use, not at all suitable for recreational use.