THE HAPPY HERB COMPANY

Committee Secretary
Senate Legal and Constitutional Affairs Committee
PO Box 6100
Parliament House
Canberra ACT 2600
legcon.sen@aph.gov.au

Submission from the Happy Herb Company regarding the Crimes Legislation Amendment (Psychoactive Substances and Other Measures) Bill 2014.

Summary

- *The new legislation is intended to pre-emptively ban emerging synthetic psychoactive substances, many of which are deemed dangerous to human health.*
- *Dangerous and/or illicit plants are already covered by existing import laws. These cannot have their molecular structures tweaked to exploit loopholes in the law, as is the case with novel chemical drugs.*
- *A large number of harmless herbs that are beneficial to health while also producing mild psychoactive effects are not covered by existing Therapeutic Goods Administration (TGA) or Food Standards Australia New Zealand Act (FSANZ Act) regulations; thus they would be illegal to import under the new law. Undertaking the studies necessary to add to the list of TGA regulated botanicals is prohibitively expensive for virtually anyone outside of large pharmaceutical corporations.*
- *Thus **plants and botanical extracts should be exempted from the proposed law**, in a manner similar to that employed by the anti-synthetic laws which were enacted last year in New South Wales.*
- *TGA regulations and the FSANZ food laws do not account for ethnic diversity and the traditional use of herbs, thus the new importation laws are discriminatory.*

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1. ***General outline***

1.1. The Happy Herb Company (*HHC*) commends the Parliament for seeking to reduce harms caused by new psychoactive substances (*NPS*.) As noted in the explanatory memorandum for the Federal Crimes Legislation Amendment (*Psychoactive Substances and Other Measures*) Bill 2014, our initial submission broadly supported the intention of the legislature to regulate untested emerging chemicals.

1.2. Schedule 1 of the bill will ban the importation of all "psychoactive" substances whose chemical structures fall outside existing controls, with the stated aim of "protecting public health from the effects of untested and unknown chemical compounds." [1]

1.3. However, if this schedule fails to provide a clear exemption for plants and botanical extracts (*as was provided in the NSW Drugs and Poisons Legislation Amendment (New Psychoactive and Other Substances) Bill 2013*) the bill in its current form will create an instance of gross legislative overreach.

1.4. Of the estimated 4 million species of plants on Earth,[2] there exist countless non-addictive herbs that are considered beneficial to human health. Of these, vast numbers exhibit mild psychoactivity along with negligible or non-existent adverse health effects. However a great deal of these substances have not yet been listed by the TGA or the FSANZ Act.

1.5. The process of adding a herb or botanic extract to the TGA's Australian Register of Therapeutic Goods (*ARTG*) is a lengthy and prohibitively expensive process that involves using clinical trials to confirm any of the claims about or recommended uses for a product. For this reason, to designate all plants that exhibit an arbitrary (*and vaguely defined*) level of psychoactivity as "guilty until proven medicinal" is to place an inordinate burden on importers who must prove that a substance does not have a psychoactive effect, or that it has a "legitimate" use under the terms of the new law.

1.6. Dangerous plants can be, and already are, easily prohibited through existing legislation without importers being able to circumvent that legislation through making minor modifications to the molecular structure of a substance; this is the crucial difference between a naturally occurring plant and a compound created in a laboratory. Existing import laws effectively deal with illicit herbal drugs which by their nature cannot be chemically altered to take advantage of loopholes. Essentially plants should never have been targeted by the proposed legislation, and their inclusion would be significantly problematic.

1.7. Though the goal of this law should be to support better health and well-being outcomes for all Australians, if plants and botanical extracts are not excluded from the jurisdiction of this bill then Australian citizens and businesses will be deprived of their legitimate right to import, study and use numerous harmless and benign herbs.

1.8. In addition, TGA regulations and the FSANZ food laws do not embrace ethnic diversity, thus the new importation laws are discriminatory. Multitudes of herbs have long histories of traditional use in other countries, and many cannot be grown in

1 Crimes Legislation Amendment (Psychoactive Substances and Other Measures) Bill 2014 - Explanatory Memorandum
2 Botanic Gardens Conservation International http://www.bgci.org/ourwork/1521/

Australia due to climactic conditions so must be imported.

1.9. At this point it is unclear as to whether the proposed importation law captures processed herbal extracts if the plant from which they are derived is already covered by the TGA/FSANZ Act lists.

1.10. Despite mounting scientific evidence that complementary health and well-being products can provide safe, efficacious and cost-effective[3] support to conventional medical practices, we live in an age of 'pharmacological hegemony' where the wealth and lobbying influence of large pharmaceutical corporations ensures that the decks are increasingly stacked against natural alternatives. Consider the following as a case in point which illustrates the extent to which pharmaceutical drugs are the mainstay of modern medical practice:

> "*Prescriptions of antipsychotic drugs given to children have doubled in only five years [in Australia], data obtained under freedom of information laws shows. Antidepressant prescriptions have also risen, bucking international trends to reduce the use of the drugs after they were linked to children developing suicidal thoughts.*" [4]

1.11. A blanket ban on all plants and botanical extracts that are not covered by existing TGA regulations and the FSANZ Act and could be deemed psychoactive is likely to have a negative economic impact on a number of small Australian businesses who trade in these plants.

2. ***Recommendations***

There exists legal precedent under which plants and plant extracts can be exempted from the new law: Section 36ZE 1(h) of the NSW Drugs and Poisons Legislation Amendment (New Psychoactive and Other Substances) Bill 2013, which states that:

"(1) This Part does not apply to the following substances: (h) any plant or fungus, or extract from a plant or fungus, that is not, or does not contain, a substance specified in Schedule 1"

It is recommended that the law be thus amended in order to exclude plants and botanical extracts.

3 NICM - Cost effectiveness of complementary medicines
"Complementary medicine is a significant and mostly privately funded component of the healthcare landscape. Preliminary studies and usage patterns indicate that complementary medicine may represent substantial potential in disease prevention, in addressing the burden of chronic disease and achieving greater health and wellbeing at reduced cost."
http://www.nicm.edu.au/health_information/health_economics/cost_effectiveness_of_complementary_medicines_report

4 Sydney Morning Herald - Concern at psychiatric drugs used on children
http://www.smh.com.au/national/health/concern-at-psychiatric-drugs-used-on-children-20120514-1yn4e.html

3. ***Remarks on the effects of prohibition***

3.1. As stated in HHC's initial submission, rather than blanket prohibition we as an organisation advocate for an evidence-based regulatory approach to the issue of drugs in society, recommending that this be treated as a public health matter rather than a criminal one. Prohibition simply enlarges the black market, as the public demand for psychoactive substances does not diminish in accordance with supply.[5]

3.2. It is ironic and unfortunate to note that a large portion of the current proliferation of emerging synthetic psychoactive substances have come about largely due to the criminalisation of a naturally occurring plant (*cannabis*) the adverse health effects of which are well understood and lesser (*both quantitatively and qualitatively*) than other socially sanctioned drugs such as alcohol and tobacco.

4. ***About the Happy Herb Company***

"Promoting the appreciation, information, benefits, culture, use, and availability of all natural plants and herbs."

Happy Herb Shops can be found all around the country, with almost 50 locations across Australia and the USA. We stock a wide range of exclusive herbs, herbal extracts and other natural products.

Many of our shops also offer consultations with qualified herbalists and naturopaths. As a not-only-for-profit business, the company is proud to donate 10% of all its profits towards social enterprise ventures to further support local and international communities.

5 World Health Organization Calls for Drug Decriminalization and Broad Drug Policy Reforms
http://www.drugpolicy.org/news/2014/07/world-health-organization-calls-drug-decriminalization-and-broad-drug-policy-reforms

International Drug Policy Consortium - Drug Policy Guide - 2nd Edition
http://idpc.net/publications/2012/03/idpc-drug-policy-guide-2nd-edition

Transform Drug Policy - The Benefits of Legal Regulation
http://www.tdpf.org.uk/resources/benefits-legal-regulation

5. ***APPENDIX I: Short list of examples of potentially affected herbs/substances***

The following are examples of useful plants and natural substances which are not listed under TGA or FSANZ regulations and thus would be illegal to import under the proposed legislation:

5.1. Ilex guayusa

Guayusa is an Amazonian plant, the leaves of which containing caffeine and polyphenol antioxidants. It is consumed as a healthier alternative to coffee, as it contains roughly twice the antioxidants of green tea plus chlorogenic acids which have been reported to contribute to cardiovascular health, help reduce high blood pressure, and regulate body weight. In addition, guayusa contains 15 essential amino acids and has ferulic acid, which can help improve blood circulation.
There are no tannins in guayusa, so it lacks the astringent, bitter taste sometimes associated with green and black teas. Has been traditionally used for thousands of years in Ecuador to heighten awareness and focus. Reportedly used by women to relieve symptoms of menopause, and to support the liver and stomach.
There have been no known reports of this plant causing any adverse health effects. [6]

5.2. Calea zacatechichi

A herb which has been known to affect people's ability to recall dreams. The Chontal Indians of the Oaxaca region in Mexico have used this plant for centuries as a medicine that clarifies the senses. C. zacatechichi is used in a great number of Chontal folk remedies as an appetite stimulant, cleansing agent for deep wounds and minor burns, to treat diarrhoea, reduce fevers, as a application to heal skin rashes and swollen scalps, and most notably to relieve headache pains.
The plant is still used in Mexican folk medicine as a laxative and treatment for fever. A tea made from the leaves is said to be particularly good for the stomach and disorders of the digestive system. It is also used for menstrual complaints.
There have been no known reports of this plant causing any adverse health effects. [7]

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6 *Loizeau P.-A. and G. Barriera (1 March 2007). "Aquifoliaceae of Neotropics Ilex guayusa Loes.". Monographia Aquifoliacearum. Retrieved 2 August 2011*
Shemluck, Melvin (1979). The flowers of Ilex guayusa (Report).
To assess antioxidant capacity of Guayusa (Report). Center of Studies of Biological Research and Evaluation (CEIEB in Spanish) Pharmacy and Food Institute Universidad de la Habana. 2010.

7 *Bork, P. M., Schmitz, M. L., Kuhnt, M., Escher, C., and Heinrich, M. Sesquiterpene lactone containing Mexican Indian medicinal plants and pure sesquiterpene lactones as potent inhibitors of transcription factor NF-kappaB. FEBS Lett. 1-27-1997;402:85-90.*
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Roman, Ramos R., Alarcon-Aguilar, F., Lara-Lemus, A., and Flores-Saenz, J. L. Hypoglycemic effect of plants used in Mexico as antidiabetics. Arch.Med.Res 1992;23:59-64.
Simonienko, K., Waszkiewicz, N., Szulc, A. [Psychoactive plant species--actual list of plants prohibited in Poland]. Psychiatr.Pol. 2013;47:499-510.
U.S. Food and Drug Administration. (Updated: May 2008). FDA Poisonous Plant Database.
Venegas-Flores, H., Segura-Cobos, D., Vazquez-Cruz, B. Antiinflammatory activity of the aqueous extract of Calea zacatechichi. Proc.West Pharmacol.Soc. 2002;45:110-111.
Wu, H., Fronczek, F. R., Burandt, C. L., Jr., Zjawiony, J. K. Antileishmanial Germacranolides from Calea zacatechichi. Planta Med. 2011;77:749-53.

5.3. Heimia salicifolia

Has a long history of use for a variety of ailments by native peoples in Central America and Mexico. Said to induce a sense of calmness with improved memory function. This plant is antisyphilitic, diuretic, laxative, sweat promoting and useful in afterbirth baths and in enhancing wound healing. H. salicifolia contains:

- *Vertine, the clinically demonstrated effects of which include anticholinergic, anti-inflammatory, antispasmodic, hyperglycemic, hypotensive, sedative, tranquilizer, and vasodilator activity.*
- *Lythrine, which has been found to have diuretic activity.*
- *Heimidine, which has been found to have anti-inflammatory activity.*

There have been no known reports of this plant causing any adverse health effects.[8]

5.4. Voacanga africana

Western African tree, thousands of years of traditional use to increase endurance and stamina. The total alkaloids of V. africana are reported to be very slightly toxic. They act as CNS depressants and hypotensives. Dregamine is reported to have local anaesthetic activity, has convulsant and respiratory stimulant properties and is said to inhibit fatigue. Tabernaemontanine is claimed to be of use when given orally in certain geriatric conditions, (arteriosclerosis, cerebral trauma, headache, vertigo, memory difficulties etc, peripheral circulatory irregularities). A mixture of the HCl salts of this with Vobasine and Ochropamine is stated to have an anti-inflammatory, antipyretic and analgesic effect comparable with acetylsalicyclic acid (aspirin).
There have been no known reports of this plant causing any adverse health effects.[9]

5.5. Botanic extracts, eg: theobromine

Theobromine is usually extracted from the cacao plant and is also found in common tea. It has a similar, but lesser, effect to caffeine in the human nervous system (in fact, theobromine may naturally occur in the body as it is a product of the liver's metabolism of caffeine.) In modern medicine, theobromine is used as a vasodilator, a diuretic, and cardiac stimulant.
There have been no known reports of this substance causing any significant adverse health effects.[10]

At this point it is unclear as to whether the proposed importation law excludes processed herbal extracts under the plant from which they are derived in the TGA/FSANZ Act lists.

8 *"Heimia salicifolia Link". Germplasm Resources Information Network. United States Department of Agriculture. 2002-09-17. Retrieved 2010-03-20.*

9 *Bisset, N.G. "Phytochemistry and Pharmacology of Voacanga Species." Agricultural University Wageningen Papers 85, no. 3 (1985): 81–114.*
http://database.prota.org/PROTAhtml/Voacanga%20africana_En.htm

10 *Theobromine in the ChemIDplus database*
http://www.rsc.org/chemistryworld/podcast/CIIEcompounds/transcripts/theobromine.asp
http://blogs.plos.org/speakeasyscience/2012/02/14/the-curious-toxic-chemistry-of-chocolate/

5.6. Naturally occurring amino acids and neurotransmitters

Useful substances such as Tyrosine, GABA, and 5HTP could be considered "psychoactive". Though these are naturally occurring in the human brain it is unclear as to whether their import will be affected by the new law.

E.g.: People take the amino acid tyrosine for depression, attention deficit disorder (ADD), attention deficit-hyperactivity disorder (ADHD), the inability to stay awake (narcolepsy), and improving alertness following sleep deprivation. It is also used for stress, premenstrual syndrome (PMS), Parkinson's disease, Alzheimer's disease, chronic fatigue syndrome (CFS), alcohol and cocaine withdrawal, heart disease and stroke, ED (erectile dysfunction), loss of interest in sex, schizophrenia, and as an appetite suppressant.[11]

6. ***APPENDIX II: Existing Legislation***

6.1. There are three levels of laws that affect our use of plants:

- *State legislation:*
  - Each state and Territory has its own statutes pertaining to drugs, poisons, smoking products, and medicines. These are named and divided differently in each state.

- *Federal legislation:*
  - The Criminal Code Act covers a core range of inebriating plants that are considered illegal in most of the Western world.
  - The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) is the most comprehensive list of medicinal, poisonous and psychoactive substances in Australia. It is created and updated by the Therapeutic Goods Administration.
  - The Customs Act controls what can be imported to and exported from Australia. Some things that are legal to possess or consume inside the country cannot be imported.

- *International Treaties:*
  - International Narcotics Convention
  - International Declaration of Human Rights
  - Codex Alimentarius

6.2. The TGA

Any product for which therapeutic claims are made must be listed, registered or included in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia. The TGA has the power to cancel a product from the ARTG if their stipulated regulations are not complied with.
Getting goods listed on the ARTG is a lengthy and costly process that involves using clinical trials to confirm any of the claims about or recommended uses for a product.
The Therapeutic Goods Advertising Code Committee monitors and enforces the advertising of therapeutic goods. This includes general information about therapeutic goods, whether

11 http://www.webmd.com/vitamins-supplements/ingredientmono-1037-tyrosine.aspx?activeingredientid=1037&activeingredientname=tyrosine

you sell them or not. Their definition of 'therapeutic good' is actually quite broad and many people in Australia sell products that would come under this definition without realising it. The TGA Executive has overall responsibility for the management of the TGA's regulatory functions and activities and works closely with the pharmaceutical industry. Some interest groups in Australia claim that the TGA actively makes laws that repress herbal medicinal products to protect the pharmaceutical industry, but this is unproven.

6.3. SUSMP

The Therapeutic Goods Act 1989 (Cth), and the accompanying schedule, The Standard for the Uniform Scheduling of Medicines and Poisons or the Poisons Standard 2010 (Cth) or the SUSMP (they are all different names for the same thing) categorise different plants and chemicals as 'therapeutic goods', 'dangerous drugs', 'poisons' etc.
The SUSMP is the most comprehensive list of plants, medicines, drugs and poisons in the country and is what most legislation, both national and state, look to for guidance when making laws about these things (except for what is considered internationally recognised illicit drugs such as cocaine and marijuana), which are covered by the Drug acts of the various states.

6.4. NATIONAL CUSTOMS ACT

There are restrictions placed on the importation of herbal products into Australia that in some ways differ from the restrictions placed on use or sale within the country. For example, Kava is a restricted import, and its sale is regulated strictly, but its use is not restricted.
Since Customs falls under s52 of the Constitution, it is a federal area of law. This means that the penalties for customs breaches are dealt with by the federal police and courts and are generally more severe than state law penalties.
The list of prohibited imports is contained in the Customs (Prohibited Imports) Regulation (1956).

Some of the plants or plant constituents contained in this list are:

- Cannabis,
- Coca leaves,
- Cannabis resin,
- Cathinone (unclear as to whether this includes the plant Khat, which contains cathinones, or just the isolated substance itself),
- Ibogaine,
- Isosafrole,
- Ephedrine,
- Heroin,
- Kava,
- Mescaline,
- Muscimol (amanitas),
- Morphine,
- Poppy straw,
- Psilocine (including all fungi that contain psilocine),
- Psilocybin (including all fungi that contain psilocybin), seeds of the plant Papaver somniferum.
- Yohimbine
- Anything containing calamus or oil of calamus
- Preparations that purport to be a remedy for drunkenness, alcoholic habit or drug habit.
- Plants and parts of plants of the following genus or species: Argyreia nervosa; Ephedra sinica; Ipomoea hederacea; Ipomoea tricolor; Ipomoea violacea; Lophophora; Mitragyna speciosa; Papaver bracteatum; Piptadenia peregrina (Anadenanthera peregrina); Rivea corymbosa; Salvia divinorum
- Abortifacients, that is, substances that purport to produce abortion.