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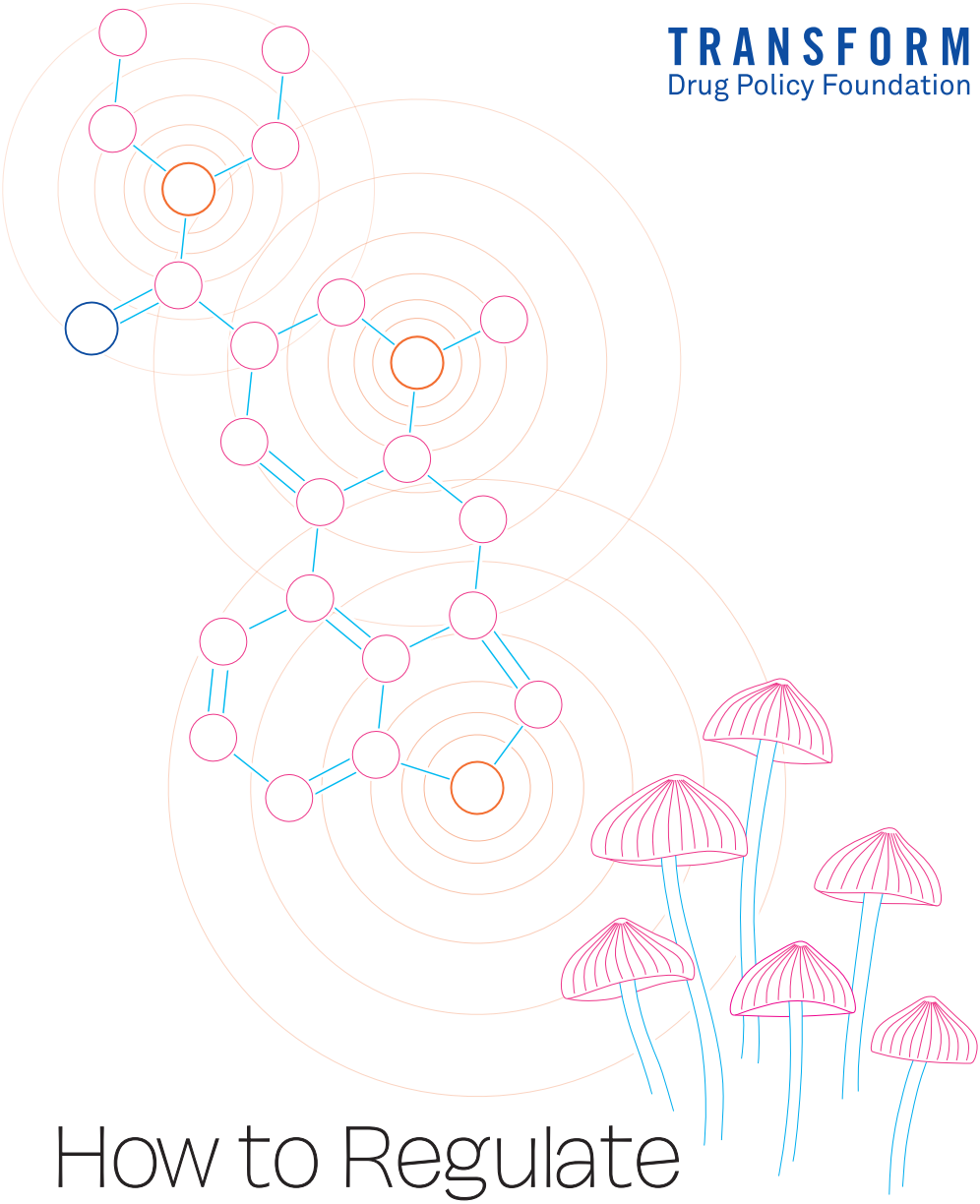

How to Regulate Psychedelics

A Practical Guide

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We are an independent, UK-based charity working nationally and internationally towards a just and effective system of legal regulation for all drugs.

At Transform, we educate the public and policymakers on effective drug policy; we develop and promote viable options for legal regulation; and we support governments, policymakers and practitioners in achieving positive change that contributes to safer and healthier societies. Through our Anyone's Child campaign we amplify the voices of those who have been directly affected by drug policy failures and want reform.

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Glossary

Decriminalisation

The removal of criminal penalties for certain activities related to drug use — usually possession of small amounts for personal use, but sometimes minor supply or cultivation offences. In some legal systems criminal penalties are replaced by civil sanctions (such as small fines), while in other systems no penalties are applied. It is sometimes confused with *legalisation*, which is a distinct concept allowing for legal supply of formerly prohibited drugs.

Legalisation

The process of ending or repealing the *prohibition* of a drug. The term refers to the process of legal reform, rather than the specific policies that may come after. Legalisation, therefore, means the step between prohibition and legal regulation.

Legal regulation

Establishes formal controls over their production, availability, and use. This includes controls on price, taxation, marketing, quality, and implementing age restrictions. Each drug will be regulated based on an assessment of the risks it presents.[1]

1 Transform Drug Policy Foundation, What is legal drug regulation?, https://transformdrugs.org/drug-policy/models-of-regulation

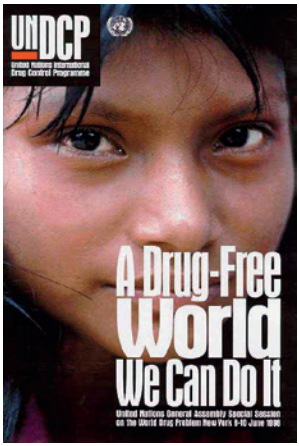
It is a positive sign that the drug policy debate has increasingly moved from *Should we legally regulate drugs?* to *How do we regulate responsibly and effectively?*

Introduction

Psychedelic drugs are a source of fascination and wonder for many. Humans' relationship with these drugs dates back as much as 8,000 years, from the use of plants containing DMT among ancient Mesoamerican civilisations and ceremonial use of *Psilocybe* mushrooms among communities in the Americas and Europe, to the use of the peyote cactus as a religious sacrament among Indigenous communities in North and Central America.[2] Despite this relationship reaching back into antiquity, more recent history has seen production, possession and supply of this group of drugs (both plant-based and synthetic) prohibited across most of the world as part of the wider punitive drug policy model, or the *war on drugs* as it has been popularly known since the 1970s.

More recently still, explorations into the science of psychedelics, including their mode of action and medical/therapeutic potential, have fuelled a rapidly expanding debate on their role in society — frequently referred to as the *psychedelic renaissance*. Research into the medical use of psychedelics, and its attendant public discourse, are both relatively well-advanced. Yet non-medical use has remained marginalised in much of the public and debate. This guide, therefore, focuses on the policy questions

2 Guerra-Doce, E. (2015), Psychoactive Substances in Prehistoric Times: Examining the Archaeological Evidence, *Time and Mind*. 8(1) https://doi.org/10.1080/1751696X.2014.993244; Jay, M. (2019), *Mescaline: A global history of the first psychedelic* (New Haven and London: Yale University Press), p.15.; Santiago, F.H., Moreno, J.P., Cázares, B.X. et. al. (2016), Traditional knowledge and use of wild mushrooms by Mixtecs or *Ñuu savi*, the people of the rain, from Southeastern Mexico. *Journal of Ethnobiology and Ethnomedicine*. 12(35), p.3. https://doi.org/10.1186/s13002-016-0108-9; Jones P.N. (2007), The Native American Church, peyote, and health: Expanding consciousness for healing purposes, *Contemporary Justice Review*. 10(4) https://doi.org/10.1080/10282580701677477.



UN International Drug Control Programme, *A drug-free world: we can do it*, 1998

raised by the reality of extensive non-medical use of psychedelic drugs.

There is now a growing consensus that the so-called war on drugs has not only failed on its own terms, with the promised drug free world more distant than ever, but has been a vast drain on public resources and often actively counterproductive. It has made drugs riskier, incentivised higher-risk behaviours, created obstacles to effective health interventions, generated stigma and criminalisation of already oppressed and exploited communities, and fuelled organised crime and associated violence and corruption, contributing to insecurity across the world.[3]

There is, however, less consensus on what to do *after the war on drugs*. Despite there being plentiful, eloquent critiques of the failure of prohibition, these have not necessarily produced credible visions for an alternative approach which public, professional and policy-maker audiences can buy into — how a future legally regulated drug market might function. It is, however, a positive sign that the drug policy debate has increasingly moved from *Should we legally regulate drugs?* to *How do we regulate responsibly and effectively?* Here, we will focus on the latter question.

Transform's proposals focus on regulatory models for the non-medical use of four of the most commonly used psychedelics, sometimes referred to as the *classic* psychedelics: LSD, psilocybin, DMT and mescaline. Transform proposes a flexible four-tiered model that seeks to manage both the variety of preparations of these psychedelics (both plant-based and synthetic), as well as the various ways in which they are used.[4]

This guide reflects the social and political environment of Transform and its authors in the Global North, and while we hope its analysis and recommendations can be useful more broadly, they need to be seen in this context. This guide addresses

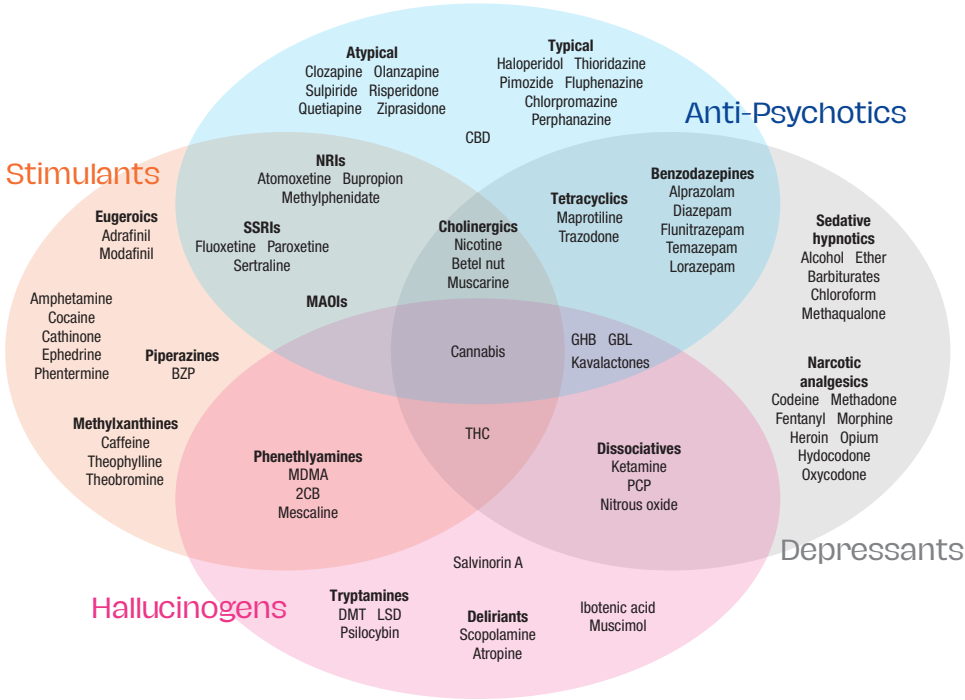
3 Rolles, S., Murkin, G., Powell, M. et. al. (2016), *Alternative World Drug Report 2nd edition* (Transform Drug Policy Foundation) https://transformdrugs.org/publications/the-alternative-world-drug-report-2nd-edition

4 For simplicity — and excusing taxonomic imprecision — plants and fungi containing the chemical compounds psilocybin/DMT/mescaline are from here on collectively referred to as "plant-based psychedelics". Here this term also refers to all psychoactive preparations derived from them. Where LSD/psilocybin/DMT/mescaline are synthesised, these will be referred to as synthetic psychedelics.

some of the discussion points at the interface of Western and Indigenous use of psychedelics but does not include specific proposals for regulation of existing religious use and traditional Indigenous use. This is rightly the policy domain of the relevant impacted communities (which the authors are not a part of). In addition, in some cases religious and traditional Indigenous use is already covered by existing local legal and regulatory frameworks (*See:* Protection for religious and Indigenous uses, p.56).

Proposed models for psychedelic regulation

Psychoactive drugs: a basic taxonomy



Adapted from McCandless, D. (2010). *Drugs World*. informationisbeautiful.net/visualizations/drugs-world/

1 What are psychedelics?

Psychedelics are a group of psychoactive drugs which are able to alter mood, cognition, and perception, sometimes including visual and sensory distortion, hallucinations, and cross-sensory perception.[5] These drugs belong to the broader category of hallucinogens, which also includes deliriants (e.g. scopolamine, diphenhydramine and myristicin — found in nutmeg) and dissociatives (e.g. ketamine, nitrous oxide, PCP and Salvia divinorum).[6] The precise definition of psychedelics is subject to some debate because, within the hallucinogen group (and other drug groupings), effects often overlap and the drugs are all, to some extent, able to alter consciousness and perception.

The *classic* psychedelics are generally distinguished by their basic mode of action on the brain (binding to and activating the serotonin receptor 5-HT2A). These substances can be naturally occurring and/or synthetic. They include LSD (lysergic acid diethylamide, a synthetic or semi-synthetic drug), psilocybin and psilocin (naturally occurring in *Psilocybe* or so-called *magic* mushrooms), DMT (dimethyltryptamine, naturally occurring in a number of plants such as *Mimosa hostilis* and *Psychotria viridis*) and mescaline (naturally occurring in the San Pedro and peyote cacti, among others).[7]

5 Definition taken from: Nichols, D.E. (2016), Psychedelics. *Pharmacological Review*. 68(2) https://doi.org/10.1124/pr.115.011478

6 *Deliriants* include the mandrake, henbane and datura plants (and some pharmaceuticals at high doses including Benadryl). These have a specific mode of action in the brain and create profound hallucinations. They are also more toxic than other hallucinogens, often associated with unpleasant physical side effects and are correspondingly not widely used recreationally. Dissociatives, including ketamine, PCP and nitrous oxide, tend to induce a sensory deprivation or out of body, lucid dream-like experience by blocking the conscious mind from other parts of the mind (ketamine and nitrous oxide are used as anaesthetics because of these effects). *Entactogens*, including MDMA (ecstasy) and other phenethylamines, are used recreationally to elevate mood and produce strong feelings of empathy and well-being.

7 Psilocybin is the (non-psychoactive) *pro-drug* of psilocin, the psychoactive compound. Unlike psilocybin, psilocin is unstable in the presence of oxygen so is only found in trace amounts in *Psilocybe* mushrooms. When consumed, psilocybin is rapidly broken down into psilocin, enabling the psychoactive effects. Ibogaine, extracted from the Tabernanthe plant family native to West Africa, is commonly classified within the grouping of classic psychedelics. Due to its currently very low prevalence of use, beyond a narrow set of comparatively under-researched therapeutic environments, it is not discussed in this guide.

Ketamine, nitrous oxide and MDMA are sometimes also referred to as psychedelics due to their ability to produce some of the same, or similar, altered states of consciousness as classic psychedelics. However, these are not their only or even dominant effects. While these drugs are often a part of psychedelic discourse, they are not included in this guide due to their considerably different effect/risk profiles and patterns of use compared to the classic grouping.[8] Other psychedelics, including ibogaine, 5-MeO-DMT and 2C-B, as well as the ever-expanding list of new synthetic psychedelics (often coming under the somewhat ill-defined umbrella term *novel psychoactive substances* or NPS), are also not specifically discussed here. However, the principles we set out here could prove useful when exploring the regulation of these drugs with similar or overlapping effects, risk profiles, and patterns of use.

While plant-based psychedelics have been used for millennia, the term *psychedelic* is relatively recent, originally coined by psychiatrist Humphry Osmond in 1956. The word combines the Greek words *psyche* (the mind) and *delos* (manifesting) to mean *mind manifesting*. Osmond felt this was a preferable description to the term *psychotomimetic* which was in common use among the medical community at the time due, in particular, to LSD's perceived ability to induce or replicate psychotic symptoms.[9] Osmond argued that the effects of psychedelics did not present a model, or analogy, of psychosis, and that the term psychedelic has "no particular connotation of madness, craziness or ecstasy, but suggested an enlargement and expansion of the mind."[10]

The name was taken up by people using psychedelics within the growing counterculture movement in the 1960s, eventually becoming a more generally accepted term in policy making and academia. Psychedelics are also sometimes described as *entheogens*, meaning *the divine within*.[11] This term is usually used to emphasise the spiritual elements that some associate with psychedelic experiences and has been used on the US policy stage among groups attempting to decriminalise plant-based psychedelics. The use of the term *psychedelic* within Western discourse sometimes comes into tension with uses within Indigenous and other religious contexts where these substances are referred to as *sacraments* or, in more traditional contexts, *medicine*.

8 A regulatory model for MDMA has been proposed by Transform. See: Rolles, S., Slade, H., Nicholls, J. (2020), *How to Regulate Stimulants: A practical guide* (Transform Drug Policy Foundation) https://transformdrugs.org/publications/how-to-regulate-stimulants-a-practical-guide

9 Osmond, H. (1957), A review of the clinical effects of psychotomimetic agents. *Annals of the New York Academy of Sciences*. 66(3) https://doi.org/10.1111/j.1749-6632.1957.tb40738.x

10 Pollan, M. (2018), *How to Change Your Mind: What the New Science of Psychedelics Teaches Us About Consciousness, Dying, Addiction, Depression, and Transcendence*, p.163.

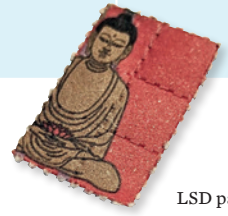
11 Pollan, M. (2018), *How to Change Your Mind*, p.26.

Table 1

Overview of the four classic psychedelics

LSD

Overview	Preparation	Dosage[12]	Effects and duration of effects[13]
Synthesised in 1938, lysergic acid diethylamide is a semi-synthetic psychoactive compound derived from lysergic acid, a natural substance occurring in the rye ergot fungus. LSD can also be prepared entirely synthetically.	LSD is a white powder in pure form. Due to its extremely high potency, it is commonly diluted to a manageable dosage and ingested as drops or paper blotters on which a solution is dried.	**Low**: 10–30µg **Moderate**: 30–100µg **High**: >100µg[14]	Effects can take place within 30–60 minutes of ingestion and can last 8–14 hours.[15]



LSD paper blotter

12 Dosages in Table 1 are approximate. While dosage is the most important predictor for the effects of each psychedelic e.g., a high dosage will elicit a more intense experience, or "trip", effects can further vary between individuals depending on various factors including weight, genetics, psychological state, method of consumption, previous experience of use, the consumption environment (*See:* Set and Setting, p.43).

13 Duration and intensity of effects are dosage dependent. See: Holze, F., Vizeli, P., Ley, L. *et. al.* Acute dosage-dependent effects of lysergic acid diethylamide in a double-blind placebo-controlled study in healthy subjects. *Neuropsychopharmacology*. 46 (2021) https://doi.org/10.1038/s41386-020-00883-6; There is some suggestion that a subjective distinction in experience between plant and synthetic drugs (beyond cultural context), or between different plant/fungi species (containing the same primary active drug) may exist due to an "entourage effect" of other active compounds found in the plants. While plausible, research evidence for such effects remains inconclusive, and differences are likely to be marginal.

14 Holze, F., Vizeli, P., Ley, L. et. al. (2021), Acute dosage-dependent effects of lysergic acid diethylamide in a double-blind placebo-controlled study in healthy subjects https://www.nature.com/articles/s41386-020-00883-6; Erowid, LSD Dosage, Accessed: 1st June 2023 https://erowid.org/chemicals/lsd/lsd_dose.shtml

15 Holze, F., Ley, L., Müller, F. *et. al.* (2022), Direct comparison of the acute effects of lysergic acid diethylamide and psilocybin in a double-blind placebo-controlled study in healthy subjects. *Neuropsychopharmacology*. 47 https://doi.org/10.1038/s41386-022-01297-2

Psilocybin/psilocin

Overview	Preparation	Dosage	Effects and duration of effects
Psilocybin and psilocin (a psychoactive phosphate ester of psilocybin) together naturally occur in more than 180 species of mushroom.[16] The psilocybin content in a mushroom can vary significantly depending on the variety, ranging from 0.2% to 3% per gram of dried weight.[17] Psilocybin can also be prepared synthetically.	Either fresh or dried mushrooms are ingested, sometimes in foods/ beverages. Extractions into tinctures are also common. The sclerotia (a sub-soil mass of mycelium of which mushrooms are the fruiting body) can also be ingested — sometimes known as truffles or philosopher's stone.[18] When synthesised, psilocybin is a white powder in pure form.	**Low**: 10mg of psilocybin/ 1g dried mushrooms[19] **Moderate**: 15–30mg of psilocybin/ 1.5–3g dried mushrooms **High**: >30mg psilocybin/ >3g dried mushrooms[20]	Effects can take place within 30 minutes of ingestion, with peak effects around 60–90 minutes, and last 3–6 hours.

Psilocybe semilanceata
(Liberty cap mushrooms)

16 ICEERS, Psilocybin Mushrooms: Basic Info, Accessed: 1st February 2023 https://www.iceers.org/psilocybin-mushrooms-basic-info/. There are other species of hallucinogenic mushrooms which contain different psychoactive drugs, notably the Fly Agaric (*Amanita muscaria*). Mushrooms such as this are toxic and far less widely consumed so are not discussed in this guide.

17 Stamets, P.(1995), *Psilocybin Mushrooms of the World: An Identification Guide*, (USA: Random House), p.36.

18 Since 2008 the possession and supply of *Psilocybe* mushrooms has been illegal in the Netherlands however, *Psilocybe sclerotia* are not specifically included. Due to this legal loophole these so-called "truffles" are available for sale as part of the Dutch coffee shop model and through *smart* shop and online sales.

19 This suggested weight is for a species with 1% psilocybin content per gram of dried weight, such as the *Psilocybe semilanceata* (known as liberty cap).

20 The potency of *Psilocybe* mushrooms varies depending on the species, the state of preservation, if they are consumed fresh or dried, and other factors.

DMT

Overview	Preparation	Dosage	Effects and duration of effects
DMT is a naturally occurring psychedelic compound found in many plant and animal species, with a similar structure and action to LSD and psilocybin. DMT can be synthesised or extracted from plant sources.[21]	DMT is a white powder in pure form. It is vaped or smoked, sometimes as a herb mixture known as Changa.[22] This is the most common preparation for non-medical/recreational use.[23] DMT can be ingested orally only when combined with an MAO inhibitor which prevents DMT from being broken down in the body. DMT is used in the traditional Amazonian preparation ayahuasca, in which a DMT-containing plant such as *Psychotria viridis* (but can vary depending on the region) is brewed with the *Banisteriopsis caapi* vine (an MAO inhibitor).	**Low**: 5–10mg **Moderate**: 20–30mg **High**: >30mg These dosages are for vaporised or inhaled DMT.[24] When ingested in the form of ayahuasca, DMT content can vary depending on the preparation.[25]	Different methods of consumption alter the duration of the experience. **DMT inhaled**: effects are rapid and last 10–45 minutes. **Ingested** (e.g., as ayahuasca): effects can occur within 60 minutes and last 2–6 hours (longer with repeat dosing common in ceremonial use).

DMT crystals

21 DMT should not be confused with 5-MeO-DMT which is similar in chemical structure but different in its effects. 5-MeO-DMT is not addressed in this guide.

22 Drug Science, DMT (N,N-dimethyltryptamine), Accessed 1st February 2023) https://www.drugscience.org.uk/drug-information/dmt/#1612864609475-a2d06688-73a1

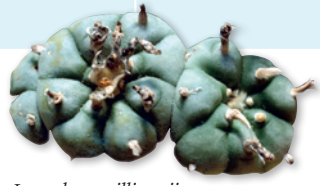
23 Winstock, A., (2014) Dimethyltryptamine (DMT): Prevalence, user characteristics and abuse liability in a large global sample, *Journal of Psychopharmacology*. 28(1) https://pubmed.ncbi.nlm.nih.gov/24284475/

24 See Timmermann, C., Roseman, L., Haridas, S., Carhart-Harris, R.L. (2023), Human brain effects of DMT assessed via EEG-fMRI, *Proceedings of the National Academy of Sciences*. 120(13) https://www.pnas.org/doi/full/10.1073/pnas.2218949120; Barker, S.A. (2022), Administration of N,N-dimethyltryptamine (DMT) in psychedelic therapeutics and research and the study of endogenous DMT, *Psychopharmacology*. 239(6) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8782705/; Erowid, DMT Dosage, Accessed 5th July 2023 https://erowid.org/chemicals/dmt/dmt_dose.shtml

25 ICEERS, Ayahuasca: Basic Info, Accessed: 15th August 2023 https://www.iceers.org/psilocybin-mushrooms-basic-info/

Mescaline

Overview	Preparation	Dosage	Effects and duration of effects
Mescaline is a psychoactive compound found in several cacti species including San Pedro (*Trichocereus pachanoi* and *Trichocereus peruvianus*), peyote (*Lophophora williamsii*), and the lesser known Peruvian Torch (*Trichocereus peruvianis*), and Bolivian Torch (*Echinopsis lageniformis*). Mescaline can also be synthesised. There can be considerable variation in mescaline content between species, and between plants of the same species. The content of peyote is approximately 0.4% per gram of fresh weight and 3–6% per gram of dried.[26] The content of San Pedro can be variable, with reports of up 0.25–1.2% per gram of fresh weight.[27]	Raw plant material is usually prepared as a drink. Mescaline can also be extracted from the plant. Synthesised, mescaline is a white powder in pure form.	**Low**: 100–200mg **Moderate**: 200–300mg **High**: >300mg[28]	Effects can take place within 30 minutes of ingestion, with peak effects within 2 hours and last 10–12 hours.[29]



Lopophora williamsii
(Peyote)

26 Dinis-Oliveira R.J., Pereira C.L., da Silva D.D. (2019), Pharmacokinetic and pharmacodynamic aspects of peyote and mescaline: clinical and forensic repercussions, *Current Molecular Pharmacology*. 12(3) https://www.eurekaselect.com/article/93599

27 Keeper Trout (2014), *Cactus chemistry by species* https://troutsnotes.com/pdf/CactusChemistry_2013_Light.pdf

28 Erowid, Mescaline Dosage, Accessed 5th July 2023 https://erowid.org/chemicals/mescaline/mescaline_dose.shtml; Vedøy Uthaug, M., Davis, A., Forrest Haas, T., Davis, D. et. al. (2022), The epidemiology of mescaline use: Pattern of use, motivations for consumption, and perceived consequences, benefits, and acute and enduring subjective effects. *Journal of Psychopharmacology*. 36(3) https://journals.sagepub.com/doi/epub/10.1177/02698811211013583

29 Dinis-Oliveira R.J., Pereira C.L., da Silva D.D. (2019), Pharmacokinetic and pharmacodynamic aspects of peyote and mescaline: Clinical and forensic repercussions. *Current Molecular Pharmacology*. 12(3) https://www.eurekaselect.com/article/93599

The psychedelic *gold rush* raises a range of challenging questions around the commercialisation and availability of psychedelics and the risk of corporate capture

2 Why regulate psychedelics and why now?

The psychedelic "renaissance" and the cultural framing of psychedelics

With psychedelics, as has happened with cannabis, exploration into how to facilitate medical applications has generally preceded, and is now overlapping with, the wider contemporary debates on how to regulate non-medical use. Much of the recent reform has occurred in the United States, although there are examples across the world. At the time of writing, some form of decriminalisation of certain plant-based psychedelics has been introduced in nearly 20 US cities.[30] The states of Oregon and Colorado have gone a step further by opting, in 2020 and 2022 respectively, to legalise and regulate the production and provision of certain plant-based psychedelics. These initiatives were initially framed primarily as medical/therapeutic although the new legal frameworks can facilitate adult access without

30 Psychedelic Alpha, Mapping Psychedelic Drug Policy Reform in the United States, Accessed: March 2023 https://psychedelicalpha.com/data/psychedelic-laws

Michael Pollan at the MAPS Psychedelic Science Conference, 2023 PHOTO: Steve Rolles

needing a prescription, therefore allowing for a broader spectrum of motivations (*See:* Psychedelic Regulation in the United States, p.117). Some other local US initiatives are more specifically limited to therapeutic access for people with a certain diagnosis, such as PTSD. This is also the case in Australia where, in 2023, the Government rescheduled psilocybin, as well as MDMA, making both available by prescription for the treatment of certain mental health conditions.[31] Jamaica offers an example of a jurisdiction where fresh/unprepared *Psilocybe* mushrooms have never been prohibited and are legal to use, cultivate and share. Since 2021, the Jamaican Government has been actively encouraging the development of psilocybin-related research and business opportunities.[32]

The resurgence of research into the medical and therapeutic potential of psychedelics, suppressed for decades since a previous blossoming of research in the 1960s, has been a key factor in these reforms. It is clear psychedelics have significant potential to treat a range of psychiatric disorders.[33] Marlan (2019) believes this is

31 Department of Health and Aged Care — Australian Government (2023), Change to classification of psilocybin and MDMA to enable prescribing by authorised psychiatrists, https://www.tga.gov.au/news/media-releases/change-classification-psilocybin-and-mdma-enable-prescribing-authorised-psychiatrists

32 Jamaica Information Service, Protocols in Place for 'Magic Mushrooms', 18th July 2021 https://jis.gov.jm/protocols-in-place-for-magic-mushrooms/; Bricken, H., Jamaica: Psilocybin Leader, *Psychedelics Law Blog*, 19th August 2022 https://www.lexology.com/library/detail.aspx?g=5b70de70-2f0f-4e28-a492-f55384f07faa; Jampro encourages local investment in psilocybin, *Jamaica Observer*, 2nd February 2022. https://www.jamaicaobserver.com/business/jampro-encourages-local-investment-in-psilocybin/

33 For a comprehensive overview of medical research into psychedelics see Nutt. D., (2023) *Psychedelics*, Hodder & Stoughton

because "psychedelics operate differently from modern medicine in that they provide users with powerful mystical or psychological experiences which can act as catalysts for changes in thought patterns and behaviour."[34] This, in turn, has led to dramatically increased funding for research, including from commercial actors who see considerable financial rewards to be gained in the lucrative field of psychiatric medicine.[35] In some countries, such as the United States, public funds from state or federal governments are beginning to trickle through for psychedelic research and treatment.[36] The psychedelic *gold rush*, however, raises a range of challenging questions around the commercialisation and availability of psychedelic compounds, and the risk of corporate capture of both future regulatory systems and wider policy development (*See:* Preventing the emergence of monopolies, and mitigating risks of corporate capture, p.52).[37]

While medical and therapeutic research into psychedelics is undoubtedly driving public debate and policy reform forward, it risks establishing a reform narrative which places legitimate access to psychedelics entirely within the context of medical therapeutic use. This narrative therefore has potential to delegitimise or stigmatise other user motivations, such as recreational and spiritual/ceremonial use, portraying them as less valid or deserving of attention, and perpetuating their criminalisation.

Psychedelics are used by a wide range of people for varying reasons and in different contexts. Use may be spontaneous, semi-planned, or deeply embedded in religious or therapeutic practice. Currently, the availability of psychedelic substances varies enormously, both between and within different jurisdictions; some (e.g. *Psilocybe* mushrooms) are accessible for free to those with some specialist knowledge of foraging or cultivation, others can be purchased by those familiar with navigating the illegal market, and yet others often require travel or access to constrained circles of supply (e.g., DMT when consumed as ayahuasca).[38]

Within the wider public debate, there have been some notable shifts towards engaging

34 Marlan, D. (2019), Beyond Cannabis: Psychedelic Decriminalization and Social Justice. *Lewis & Clark Law Review*. 23(3) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3438542

35 Psychedelic Alpha, Psychedelic Funding in 2022, Accessed: 18th May 2023 https://psychedelicalpha.com/news/psychedelic-funding-in-2022

36 Johns Hopkins, Johns Hopkins Medicine Receives First Federal Grant for Psychedelic Treatment Research in 50 years. 18th October 2021 https://www.hopkinsmedicine.org/news/newsroom/news-releases/johns-hopkins-medicine-receives-first-federal-grant-for-psychedelic-treatment-research-in-50-years

37 Tvorun-Dunn, M. (2022), Acid liberalism: Silicon Valley's enlightened technocrats, and the legalization of psychedelics, *International Journal of Drug Policy*. 110 https://pubmed.ncbi.nlm.nih.gov/36279734/

38 Ayahuasca is primarily consumed in the Amazon rainforest where it is cultivated or harvested and produced, although its use is increasingly being observed in other countries as use spreads.

with other motivations of use beyond therapeutic application. Interest has also been renewed around psychedelic consumption motivated by spiritual experiences, exploration of consciousness, or the pursuit of wider personal, emotional wellbeing (*See:* Motivations for psychedelic use, p.37). The *psychedelic renaissance* has also included the increasing popularity of psychedelics for functional and cognitive performance enhancement, most prominently in the form of *microdosing* (where low, sub-perceptual dosages are consumed over an extended period). Evidence demonstrating efficacy of microdosing with robust trial data (beyond a placebo effect) remains mostly elusive.[39]

While patterns of, and motivations for, psychedelic use vary widely, the cultural framing of psychedelic experiences and political advocacy on their behalf has been dominated by a relatively narrow range of perspectives. This has usually been that of more affluent, white consumers in the Global North who speak with a degree of established economic and cultural capital, in many cases imbuing the experience with spiritual or political significance. This includes an ever-increasing list of high-profile public intellectuals, opinion formers and celebrity advocates, bolstered by a seemingly endless stream of media features and documentaries. We must therefore be conscious of the degree to which this can skew both how the discourse is framed as well as the kind of policy proposals that emerge. User groups are more diverse than the dominant narrative in the mainstream, and particular attention must be given to those who lack these levels of power and privilege — groups historically more marginalised in policy debate and design. This is most obviously relevant to Indigenous communities coming up against the pressures of Western culture (*See:* Protection for religious and Indigenous use, p.56). However, it is also pertinent for larger but less-visible groups including young people using psychedelics in recreational settings.

39 Cavanna, F., Muller, S., et.al. (2022), Microdosing with psilocybin mushrooms: a double-blind placebo-controlled study, *Translational Psychiatry*. 12(1) https://www.nature.com/articles/s41398-022-02039-0

Psychedelic exceptionalism

Certain types of drugs, or groups of people who use drugs, have frequently been privileged or prioritised by policy and law reforms, while leaving others subject to sanctions. This phenomenon has already been witnessed with cannabis reforms, and now with some emerging psychedelic reforms in the United States.[40] Such *drug exceptionalism* is intrinsically arbitrary. Even if it may help progress the reform debate for a particular drug, it will do so by benefiting some members of society over others. This narrative, even if unintended, risks increasing stigma and punishments imposed on people who use other drugs. The arguments for decriminalisation and regulation apply universally across all drugs (*See:* Decriminalisation, p.66).

Psychedelic drugs, as a group, should not be treated as exceptional and more viable for decriminalisation or legal regulation simply because they are perceived to present lower risks than other drugs, be therapeutically more useful, or be somehow more spiritually significant. Indeed, a strong argument can be made that the opposite is true; the riskier the drug, and the greater its associated social and health harms, the more urgent it becomes to place the drug (or group of drugs) within an appropriate legal and regulatory framework which prioritises and promotes public health goals.

It is also important to not view individual drugs as isolated regulatory challenges. In the context of normalised polydrug use and intersecting drug markets and cultures, it is clear that the legal policy response to one drug (or drug group) can impact on the markets, using behaviours and associated social and health challenges of other drugs as well — this can have both positive and negative outcomes. Evolving drug regulation policy should ideally be sophisticated enough to monitor and manage this complex interplay of different drug markets and using behaviours, and the legal policy environments that shape them (*See:* A case for lower-threshold *Psilocybe* mushroom access, p.99).

Regardless, it seems likely that drugs generally perceived as lower risk, such as cannabis and psychedelics, will often be legalised and regulated first for reasons of public acceptability and political expediency. The emerging realities of incremental reform, however, do not mean that it is desirable from an ethical or practical policy perspective. While psychedelic reforms, like cannabis reforms, offer opportunities

40 For example, the US city Detroit approved Proposal E in 2021 which specifically decriminalised the "possession and therapeutic use of entheogenic plants, including psilocybin mushrooms, peyote, and iboga" and did not include other illegal drugs.

to demonstrate that formerly prohibited drugs can be moved into a new safer system and be responsibly regulated, incremental reforms also risk granting selected drugs, their users and associated markets special status while stigmatising people who use other drugs. Reform advocates should be mindful of the fact that this incremental process, and its accompanying challenges, are somewhat inevitable and in some places already underway. Where it does occur, we must be attentive in informing public discourse of the wider debate. Drugs need regulating because of their risk and criminalisation/prohibition increases those risks, while responsible regulation can reduce them.

Further, while psychedelics present different challenges for regulation because of their risk profiles and particular cultures of use, this does not mean they fall entirely beyond the ambit of legitimate interventions. They do pose risks and those risks can be significant. The goal of regulation, from a public health perspective at least, must be to identify vulnerabilities and target the risks that do exist while not unjustifiably restricting freedoms of use in relation to those risks. This rationale applies across the board, not just to the drugs we read about in glossy feature articles or hear promoted on celebrity podcasts.

Psychedelics and prohibition

For many reasons, the negative social and economic costs of prohibition, at least viewed globally, are smaller for psychedelics than for most other illegal drugs or drug groups. While more precise estimates of the size and value of the illegal psychedelics market are unavailable due to the absence of the systematic data collection seen with many other drugs, the limited available prevalence data suggests that the market is considerably smaller in value terms than other more widely used drugs such as opioids, cannabis, cocaine or MDMA. Correspondingly, the associated problems of organised crime, violence, street dealing, or negative international development and security impacts are assumed to be comparatively small. In general, the little data available points to psychedelic drug use and related criminal behaviour being small contributors to increasing law enforcement budgets, and targeted arrest or incarceration.

Yet, even if the unregulated psychedelics market is smaller in scale, people have been, and continue to be, criminalised and sometimes imprisoned for production,

Lower risk does not mean zero risk, and unregulated production and supply can increase the risk profile of psychedelics

trafficking, supply and possession/use. This can cause life-long, or even intergenerational, harm. Historically, criminalisation of certain psychoactive plants has had a significant negative impact on Indigenous communities due to punitive enforcement and related stigmatisation. These communities have been oppressed via the prohibition of their traditional use of psychedelics, intentionally disconnecting them from their religious traditions and ceremonial practices.[41] There are multiple cases of individuals being arrested and prosecuted for possession or import of psychedelics for use in their religious practices.[42] Furthermore, the stigma precipitated by prohibition has created barriers to education, community building and accountability within the psychedelic using landscape. This is particularly the case for communities of colour who have been disproportionately impacted by wider prohibition.[43] For these communities, the increased threat of criminalisation means they more generally lack a physical safe space to use psychedelics, but also a political safe space to publicly advocate for their inclusion in the psychedelic debate (*See:* Embedding social justice, equity and human rights into policy design, p.51).[44]

Nonetheless, the perceived concentration of use among more privileged demographics, the relatively low health harms associated with illegal psychedelic use, and the relatively low social harms associated with illegal psychedelic markets goes some way to explaining why psychedelic use is a low enforcement priority relative to other commonly used illegal drugs.[45] Notably, this relatively low level of enforcement is despite psychedelics being categorised in the *most harmful* classification in international, and most national drug scheduling frameworks. Those

41 Jay, M., *Mescaline*, p.40.; George, J. R., Michaels, T. I., Sevelius, J., & Williams, M. T. (2020), The psychedelic renaissance and the limitations of a White-dominant medical framework: A call for Indigenous and ethnic minority inclusion, *Journal of Psychedelic Studies*. 4(1), pp.4-15. https://doi.org/10.1556/2054.2019.015

42 Chacruna, Community Alert! Arrests and Encounters with Law Enforcement are Increasing. 29th September 2021 https://chacruna.net/sacred-plant-law-enforcement-arrests-increasing/; ICEERS, Ayahuasca Country-by-Country Legal information, Accessed: 27th July 2023 https://www.iceers.org/adf/

43 Harvey, I., Why the Psychedelic Community is so White. *Psymposia*, 29th November 2016 https://www.psymposia.com/magazine/why-the-psychedelic-community-is-so-white/

44 George, J. R., Michaels, T. I., Sevelius, J., & Williams, M. T. (2020), The psychedelic renaissance and the limitations of a White-dominant medical framework: A call for Indigenous and ethnic minority inclusion, *Journal of Psychedelic Studies*, 4(1), pp.4-15 https://doi.org/10.1556/2054.2019.015

45 Despite the comparatively low enforcement profile of psychedelics there are examples, historical and current, of harsh sentencing for production, supply and trafficking offences. See, for example, the 2004 Casey William Hardison case.

high-harm classifications, in turn, lack any evidence-based risk assessment to justify them, even within their own conceptually narrow terms of reference.[46]

Despite some examples of harsh sentencing and occasional spikes in enforcement around particular drug markets, the low enforcement priority regarding psychedelics can be quite striking. For example, looking at England and Wales in 2019, only 18 people were sentenced for LSD possession or supply (amounting to 0.05% of all drug offences recorded that year).[47] Compare these numbers to the enforcement of heroin (both LSD and heroin are Class A, annual prevalence of heroin is twice that of LSD) for which 4,420 people were sentenced, or of amphetamines (a Class B drug, with an annual prevalence of use equivalent to LSD) for which 1,039 people were sentenced.[48]

Lower risk does not, however, mean zero risk, and it is certainly the case that unregulated production and supply can increase the risk profile of psychedelics. Adulteration, mis selling of more risky drugs, unknown potency, an absence of information on dosage, encouragement of use in unsupervised environments without health or safety services, and bringing users into contact with markets for other drugs, are all risks exacerbated by prohibition. The market penetration of NBOMes, a potent and highly toxic group of synthetic drugs commonly mis-sold as LSD, provides an instructive example.[49] Further, prohibition stymies access to good harm reduction information and support which increases the risk to individual users. Prohibition makes all drugs less safe regardless of the starting point (*See:* Psychedelics risks and policy implications, p.41).

46 LSD, DMT and Psilocybin are all Schedule 1 under the UN convention, Class A in the UK and Schedule 1 in the US

47 Ministry of Justice (2022), *Criminal Justice System Statistics quarterly*: December 2021 https://www.gov.uk/government/statistics/criminal-justice-system-statistics-quarterly-december-2021 represents the most recent criminal justice statistics for a year without COVID lockdown restrictions which may have skewed enforcement outputs.

48 Ministry of Justice (2022), *Criminal Justice System Statistics quarterly*: December 2021. https://www.gov.uk/government/statistics/criminal-justice-system-statistics-quarterly-december-2021

49 Zawilska, J., Kacela, M., Adamowicz P.(2020), NBOMes–Highly Potent and Toxic Alternatives of LSD. *Frontiers in Neuroscience*. 14(78) https://doi.org/10.3389/fnins.2020.00078; Suzuki, J., Poklis, J., Poklis, A. (2014), "My friend said it was good LSD": A suicide attempt following analytically confirmed 25I-NBOMe ingestion, *Journal of Psychoactive Drugs*. 46(5) pp.379-382. https://doi.org/10.1080/02791072.2014.960111; United Office on Drugs and Crime (2019), *World Drug Report 2019: Book 5, Cannabis and Hallucinogens* wdr.unodc.org/wdr2019/prelaunch/WDR19_Booklet_5_CANNABIS_HALLUCINOGENS.pdf

Who is using psychedelics?

Global prevalence data on psychedelics, as reported by the United Nations Office on Drugs and Crime (UNODC), is based on self-reporting from member states and is weak compared to reporting for most other drugs. Many states either do not provide any data, or report on the wider group of hallucinogens (which generally includes ketamine, PCP and other drugs, alongside the classic psychedelics) and offer no breakdown by drug. Most drug-specific prevalence of use data for psychedelics relates to the two most prevalent psychedelics — LSD and *Psilocybe* mushrooms — with detailed data mostly coming from the United States and the European Union. Because of their historically low prevalence of use, there is especially limited survey data on DMT (not specifying ayahuasca), and mescaline.[50]

Wastewater analysis has only occasionally included LSD but no other psychedelics, and in any case none was detected.[51] There is some seizure data, mainly for LSD and DMT, although this is a poor indicator of consumption patterns at the best of times; according to the UNODC World Drug Report, global police and customs seizures of psychedelics are relatively low but DMT seizures have been increasing, especially since 2016.[52] Furthermore, the variation in strength of LSD on the illegal market (between 10,000 and 40,000 doses in a gram) tends to provide erratic annual data that does not reveal much about market trends. In 2020, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) noted that LSD, "a drug that has been uncommon in Europe for the last two decades appears to be becoming more available" and though the "overall number of LSD seizures has more than doubled since 2010 ... the quantity seized has fluctuated."[53]

Going forward, policy making could be significantly informed by national governments, regional bodies (notably the EMCDDA), and relevant UN agencies (UNODC, International Narcotics Control Board, World Health Organization) systematically gathering more sophisticated and coordinated prevalence and health surveillance data for a range of psychedelics. The available data does, however, indicate some key trends.

50 United Office on Drugs and Crime (2019), *World Drug Report 2019: Book 5, Cannabis and Hallucinogens* https://wdr.unodc.org/wdr2019/en/cannabis-and-hallucinogens.html

51 Mastroianni, N., López-García, E., *et.al.* (2017), Five-year monitoring of 19 illicit and legal substances of abuse at the inlet of a wastewater treatment plant in Barcelona (NE Spain) and estimation of drug consumption patterns and trends, *Science of the Total Environment* 609 https://doi.org/10.1016/j.scitotenv.2017.07.126

52 United Office on Drugs and Crime (UNODC) (2019), *World Drug Report 2019: Book 5, Cannabis and Hallucinogens* https://wdr.unodc.org/wdr2019/en/cannabis-and-hallucinogens.html

53 European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) (2020), *European Drug Report: Trends and Developments* https://www.emcdda.europa.eu/publications/edr/trends-developments/2020_en

The proportion of people using psychedelics is low compared to other drugs

According to the EMCDDA, "The overall prevalence levels of LSD and [*Psilocybe*] mushroom use in Europe have been generally low and stable for a number of years."[54] The most recent available national surveys for most EU countries show last-year prevalence among young adults (15-34) is equal to or less than 1% for both LSD and *Psilocybe* mushrooms; there are some exceptions for *Psilocybe* mushroom use including Czechia (2.7% in 2021) and Finland (2% in 2021), and LSD use including Ireland (2.4% in 2019).[55] This is in contrast to EU-wide figures of 15.1% for cannabis, 2.3% for cocaine, and 2.0% for MDMA.[56]

While annual prevalence of use is relatively low, lifetime prevalence is higher than many might expect. 2021 National Drug Use and Health survey data suggests 11.5% of the US population (18 years or older) reported taking LSD at some point in their lives (around 30 million people).[57] The most recent data for other psychedelic use in the US is from 2016, when lifetime use for: *Psilocybe* mushrooms was 9.3%; mescaline was 3.3%, and DMT was 0.9%.[58]

Data for Latin America is scarce, however, some of the available studies indicate that the prevalence of psychedelic use in the region is relatively high. According to a UNODC study of university students in Colombia, Bolivia, Peru and Ecuador, psychedelics (collectively) were the second most prevalent drug among students after cannabis.[59] According to this study, life-time LSD use in particular has increased, from 0.5% in 2009 to 3.8% in 2016.

54 EMCDDA (2020), *European Drug Report: Trends and Developments* https://www.emcdda.europa.eu/publications/edr/trends-developments/2020_en

55 EMCDDA (2023), *Other drugs — the current situation in Europe (European Drug Report 2023)*, https://www.emcdda.europa.eu/publications/european-drug-report/2023/other-drugs_en

56 EMCDDA (2023), *Cannabis — the current situation in Europe (European Drug Report 2023)*, https://www.emcdda.europa.eu/publications/european-drug-report/2023/cannabis_en; EMCDDA (2023), *Cocaine — the current situation in Europe (European Drug Report 2023)*, https://www.emcdda.europa.eu/publications/european-drug-report/2023/cocaine_en; EMCDDA (2023), *MDMA — the current situation in Europe (European Drug Report 2023)*, https://www.emcdda.europa.eu/publications/european-drug-report/2023/mdma_en

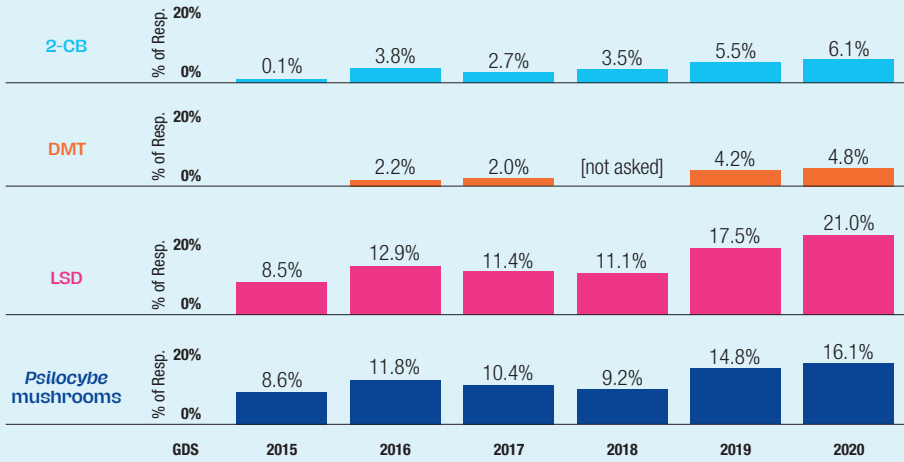
57 Substance Abuse and Mental Health Service Administration (SAMHSA) (2023), National Survey on Drug Use and Health: 2021 https://www.samhsa.gov/data/report/2021-nsduh-detailed-tables

58 SAMHSA (2016), Results from the 2016 National Survey on Drug and Health: Detailed tables https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.pdf

59 UNODC (2017), III Estudio epidemiológico andino sobre consumo de drogas en la población universitaria, Informe Regional 2016 https://www.unodc.org/documents/peruandecuador/Informes/Otros/Informe_Universitario_Regional.pdf

Table 2

Last 12-month use of psychedelics and selected other drugs (global)



Taken and adapted from the Global Drug Survey (2020), Psychedelics Key Findings Report[60]

The frequency with which people use psychedelics is generally lower than for other drugs

According to available data, reported frequency of use for LSD and *Psilocybe* mushrooms is lower than, for example, cocaine, alcohol or cannabis. Of people who reported using LSD or *Psilocybe* mushrooms in the 2020 Global Drug Survey, 83.5% and 89.6% respectively used 10 or less times a year, 22.3 and 34.1% respectively used only once, and less than 2% used more than 50 times.[61]

Use of psychedelics seems to have been rising in recent years

While in the EU, last-year prevalence of all psychedelics which are recorded has remained relatively stable, last-year use of LSD in the United States appears to have been rising, from 0.5% in 2015 to 0.9% in 2018. However, since 2018 it has remained stable at just under 1%.[62]

60 Global Drug Survey (2020), *GDS 2020 Psychedelics Key Findings Report* https://www.globaldrugsurvey.com/wp-content/uploads/2021/03/GDS2020-Psychedelics-report.pdf

61 Winstock, A., et al (2021), *GDS 2020— Psychedelics key findings report* (Global Drug Survey) https://www.globaldrugsurvey.com/wp-content/uploads/2021/03/GDS2020-Psychedelics-report.pdf

62 SAMHSA (2019), National Survey on Drug Use and Health: 2018 https://www.samhsa.gov/data/report/2018-nsduh-detailed-tables; SAMHSA (2023), National Survey on Drug Use and Health: 2021 https://www.samhsa.gov/data/report/2021-nsduh-detailed-tables

The Global Drug Survey (GDS) provides a useful insight into psychedelic use among a self-selecting online sample of a mostly younger population (average age 27) who use drugs. Over half of the participants reported illegal drug use in the last year. The GDS results seen in table 2 echo data from the United States, observing a general rise in psychedelic drug use over the five years from 2015 to 2020.

Use is highest among young adults

In 2021, last-year use of LSD among 18–25-year-olds in the US was 3% — three times higher than the national average. In comparison, in the same year, last-year prevalence for people aged 26 or over was 0.6%.[63] Use among 18–25-year-olds has increased since 2002 where it stood at 1.8%.[64] However, this remains lower than the 1990s when LSD use among 17–18-year-olds was 5-9% before falling rapidly to 2% in 2003.[65]

Psychedelics are more commonly used among people who use other drugs (often in combination with psychedelics), and people who regularly go to nightclubs

According to the EMCDDA, "substantially higher drug prevalence estimates [for *Psilocybe* mushrooms] are found in [clubbing] surveys than those found in general or school population surveys.[66] Furthermore, the use of psychedelics among nightclub goers is higher among those who also use other drugs. An English survey from 2000 found that 24% of nightclub goers had used *Psilocybe* mushrooms at some point (compared to 11% of the general population); this rose to 44% among those who had also used other drugs.[67] A more recent 2022 Global Drug Survey observed a similar link between frequency of nightclub visits and reported prevalence of psychedelic use.[68]

63 SAMHSA (2023), National Survey on Drug Use and Health: 2021
https://www.samhsa.gov/data/report/2021-nsduh-detailed-tables

64 SAMHSA (2020), National Survey on Drug Use and Health: 2019 — Detailed Tables
https://www.samhsa.gov/data/report/2019-nsduh-detailed-tables

65 UNODC (2019), *World Drugs report, Book 5: Cannabis and hallucinogens*
wdr.unodc.org/wdr2019/prelaunch/WDR19_Booklet_5_CANNABIS_HALLUCINOGENS.pdf

66 EMCDDA (2006), *Hallucinogenic Mushrooms: an emerging trend case study*
https://www.emcdda.europa.eu/system/files/publications/406/TP_Hallucinogenic_mushrooms_107298.pdf

67 EMCDDA (2006), *Hallucinogenic Mushrooms: an emerging trend case study*
https://www.emcdda.europa.eu/system/files/publications/406/TP_Hallucinogenic_mushrooms_107298.pdf

68 Winstock, A., et al (2022) 2022 *Drug Trend Report: Time, Music, Clubbing, Age, and Diet*
https://www.globaldrugsurvey.com/wp-content/uploads/2022/02/2022WowReport_Final.pdf

Questions remain around what level of risk justifies some form of regulatory intervention from the state and what the practicalities are of such interventions across a broad range of using behaviours

3 How to think about psychedelics regulation

Psychedelic reform challenging public health thinking?

Evidence-based and ethical drug policy should minimise risk, both to individuals who use drugs and to wider society. For psychedelics, as with all drugs, this means identifying their associated risks, whether intrinsic to their pharmacology or related to specific using behaviours and environmental variables (including illegal supply), and exploring options to reduce or eliminate them.

Yet, psychedelics challenge some key assumptions of conventional public health thinking about drug policy. Even among advocates of regulation, the *benefits* of drugs are rarely given equal consideration to the risks. This is partly because of an entrenched tendency within drug (including alcohol) research to put questions of pleasure to one side, but it also reflects a view that the role of the state is primarily to prevent known harms, rather than engaging in the promotion of benefits or

pleasures. In the case of well-evidenced therapeutic benefits, the argument for facilitating access is strong and also fits within well-established medical institutional structures. However, in the case of less tangible, and far more subjective, spiritual or wellness benefits, let alone the potential benefits of simple enjoyment, the case is much harder to define.

This is a problem for drug policy generally but raises particularly interesting questions in relation to psychedelics. The risks of psychedelic use (particularly when some basic precautions are taken) are relatively modest (*See:* Overview of key risks of psychedelic use and their policy implications, p.44), and the benefits are potentially significant. In the context of psychedelics, the risk/benefit balance is unusually positive overall, perhaps to the extent that it could upend conventional public health thinking around drugs which has commonly put most emphasis on moderation, prevention, and abstinence. In other words, if psychedelics can improve the health and well-being of individuals, and even communities, could it be rational to want more people to have regulated legal access to them, not fewer?

Such an arguably heretical proposition comes with a number of caveats. Despite the possible benefits gained from an increase in prevalence of use, this does not mean that immoderate or high-risk use by individuals should be encouraged (however that may be defined). Acknowledging that an increase in certain psychedelic using behaviours is not necessarily harmful (as would be the assumption, for example, with alcohol or smoking) is not the same as actively advocating for it. This simple acknowledgement may, in itself, be enough to re-centre thinking; even where benefit maximisation is not a stated goal, policy should focus on reducing higher-risk use and encouraging safer, responsible use, rather than the historic preoccupation of drug policy to drastically reduce population prevalence. The benefit maximisation side of the equation is arguably a social or community responsibility rather than the job of regulators.

Questions remain around what level of risk justifies some form of regulatory intervention from the state and, in turn, what the practicalities are of such interventions across a broad range of using behaviours.

Motivations for psychedelic use

Motivations for use need to be considered when developing policy and regulation, given their role in shaping consumption behaviours, and associated risks and harms.

Because motivations overlap — one can, for example, seek spiritual insights and hope to enjoy the experience at the same time, or derive therapeutic or spiritual benefits from use in recreational settings — it is impossible to develop a neat typology for why people may use psychedelics. Systematic research on the subject is limited, with survey results inevitably shaped by the question methodology, while conjecture is widespread. However, recent analyses of motivations across a range of drug types suggest a clear skew towards particular motivations over others among study participants who have taken psychedelics. Formal medical or therapeutic use in clinical settings, about which we can speak with more certainty, only constitutes a tiny fraction of the total consumption, with the overwhelming majority using psychedelics informally either for sensory enhancement and pleasure seeking in recreational settings (more commonly at low-medium doses), or for personal, spiritual, religious or therapeutic reasons.

A small UK survey (n=174) among people using *Psilocybe* mushrooms (conducted during the brief period in which they were legally available for sale (*See: Psilocybe mushrooms: A UK case study*, p.113) found that "for a laugh", "like hallucinations" and "to alter perspective" ranked highest among motivations for use.[69] However, regulation should also respond to the less-recorded motivations. For example, Kettner *et. al.* (n=1,967) found that reasons for use of psychedelics tend more towards the desire to "broaden consciousness", "spiritual experience" and "experience nature" than for cannabis use.[70]

Kazmarek identified motivations for DMT use changing over time, notably including "convenience" (due to its short acting effects), with initial use often being prompted by curiosity.[71] Indeed, in the 2019 Global Drug Survey (n>5,000), "curiosity" ranked as the highest motivation, with 91% of participants saying it was important, while

69 Riley, S., Blackman, G. (2008), Between Prohibitions: Patterns and Meanings of Magic Mushroom Use in the UK, *Substance Use and Misuse*, 43(1) https://www.tandfonline.com/doi/abs/10.1080/10826080701772363

70 Kettner, H., Mason, N. L., Kuypers, K.P.C. (2019), Motives for Classical and Novel Psychoactive Substances Use in Psychedelic Polydrug Users. *Contemporary Drug Problems*, 46(3) pp.304-20. https://doi.org/10.1177/0091450919863899

71 Kazmarek, T. (2020), Intrinsic Motivations and perceived benefits of US males for taking dimethyltryptamine. (PhD dissertation, Walden University) https://scholarworks.waldenu.edu/dissertations/8550/#:~:text=Study%20results%20indicated%20that%20

"mind expansion", "learning more about self", "deeper understanding of the world", and "increased spiritual understanding" were cited more often than simply-defined "recreation/fun".[72] These findings were echoed in a 2013 survey of US college students, where 92% cited "curiosity", followed by "achieve a mystical experience", "introspection" and "enhance creativity".[73] Notably, potentially more concerning motivations such as "dealing with stress" and "escape from life" which, with other drugs, has usually been associated with increased risk of problematic or dependent use, scored much lower.[74]

Below are three broad overlapping categories of motivations for psychedelic use and examples of how these should be reflected in regulation (For more detail, *see:* Proposals for regulation p.65).

Recreational

The relatively limited survey data available indicates that a significant majority of psychedelic use takes place in recreational/community settings, motivated by curiosity, sensory enhancement and pleasure seeking, (alongside potential personal improvement/wellness/spiritual benefits). Here regulation of the retail of psychedelics or supervised experiences serves to reduce risk by licensing vendors and venues; ensuring safety and quality control over any drug preparations being sold; enforcing availability controls (age access, safer using environments); and providing access to relevant, targeted information to enable responsible using decisions (from civil society and community groups, and at point of sale on packaging and from trained vendors).

Medical/therapeutic

The binary distinction between medical and non-medical use is problematic when considering the many ways in which most people who use psychedelics report mixed motivations for use. Particularly when we consider the cluster of motivations (below) that could be considered to be for the enhancement of overall personal wellbeing (which here is referred to as *wellness*), the questions around how to

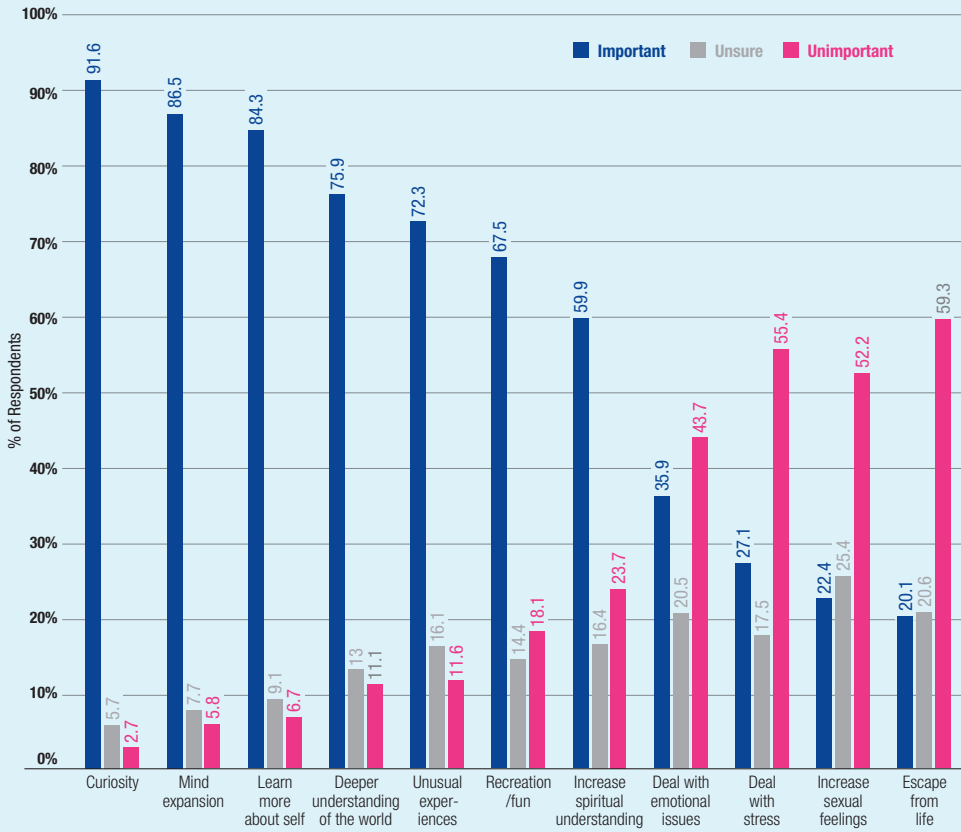
72 Global Drug Survey (2019), *GDS key findings report 2019* https://www.globaldrugsurvey.com/gds-2019/

73 Hallock, R., Dean, A., Knecht, Z. et. al. (2013), A survey of hallucinogenic mushroom use, factors related to usage, and perceptions of use among college students, *Drug and Alcohol Dependence*. 130 https://pubmed.ncbi.nlm.nih.gov/23265089/

74 Global Drug Survey (2019), *GDS key findings report 2019* https://www.globaldrugsurvey.com/gds-2019/; Winstock, A. cited in Daly, M. Psychedelic use on the rise and Gen Z seeks to "enhance connectedness", *Vice* 15th September, 2021 https://www.vice.com/en/article/epn35p/psychedelic-use-on-the-rise-as-gen-z-tries-to-enhance-connectedness

Table 3

Importance of different motivations for psychedelic use over a lifetime [Using global sample of *n*>5,000]



Taken from Global Drug Survey (2017), GDS Key Findings Report[75]

navigate consumer expectations, claims about the drug, promotions and marketing, etc., begin to get complicated.

Formal medical treatment is the easiest motivation to delineate, as it takes place within the defined parameters of existing (and already highly regulated) clinical

75 Global Drug Survey (2017), *GDS Key findings report 2017* https://www.globaldrugsurvey.com/wp-content/themes/globaldrugsurvey/results/GDS2017_key-findings-report_final.pdf

settings, using prescribed drugs for a stated diagnosis or indication. This nearly always includes board-certified, licensed healthcare professionals.

Informal medical treatment, including self-medication, is much harder to define, not least given the blurred boundaries and overlaps with spiritual/wellness motivations (*See:* below). Nevertheless, certain regulatory needs are clear and focus on consumer protection mechanisms particularly regarding transactional/commercial activities. Where medical claims are made about retail products or services, these should be subject to the same requirements of evidence, evaluation and regulation as other medicines and treatments. This similarly applies to service providers and guided use practitioners. The desire to use psychedelics as a form of therapy to address emotional, psychological or mental health conditions is understandable, but in order to prevent suppliers from making false or unproven claims, exploiting vulnerable individuals, or offering services which engage in risky practices without adequate training or safeguards, a regulatory scheme must consider what policies would ensure responsible conduct. Where therapeutic claims are being made, particularly in regard to specific conditions, they should also be subject to regulation to prevent exploitation or misleading of consumers which could cause direct or indirect harm. (*See:* Psychedelics regulation in the United States, p.117).

Spiritual/wellness

This third grouping, sometimes overlapping with medical and recreational use, includes a wider set of motivations that incorporates personal exploration and growth, the pursuit of wellness, and (even harder to define) spiritual motivations that can include ritual or ceremonial practices.

Where such motivations lead to seeking out formally guided or supervised psychedelic use — as opposed to individual use or use in a peer-support context — either one-on-one or in group sessions offered on a commercial or transactional basis (even when not-for-profit), regulation of the people providing the guided session may be necessary to ensure basic duties of care, ethical conduct, and safeguarding are provided. Even with exemptions for existing religious and Indigenous use in place in many jurisdictions, regulation should be framed to avoid a religious loophole that could be (and already is) exploited by unscrupulous actors (*See:* Protection for religious and Indigenous use, p.56).

Psychedelic risks and policy implications

A starting principle for this discussion is that any risks associated with drug use and drug markets are increased under prohibition and can be substantially mitigated by targeted regulatory interventions combined with a policy focus on public health and harm reduction. Historically, drug risks have been narrowly and over-simplistically defined into alphabetical (A, B, C) or single-digit (1–4) rankings. These rankings have then commonly been translated into tiered hierarchies of legal sanctions, with more severe punishments for the drugs considered more harmful or with a higher dependency potential. There is, however, no consistent evidence that the harsher sanctions are associated with lower levels of use.

The risks of psychedelics are, like all drugs, significantly shaped by the dosage, the ingestion method, parallel risk behaviours such as polydrug use, and other factors relating to physical and mental health (including some genetic factors) (*See:* Table 4, p.44). In the literature on psychedelics, particular attention has been drawn to the roles of the emotional and psychological state of the consumer — *the set* — and the context in which the drug is being taken — *the setting* (*See:* p.43). Given this complexity, simplistic numeric or alphabetical drug-harm rankings become effectively useless when looking at separate drug-using events, or different people using different psychedelics in different ways.

Recently, researchers have produced more sophisticated attempts to rank drug harms across a range of criteria, which place psychedelics (LSD and psilocybin specifically) at or near the bottom of the scale of drugs and their associated harms.[76] The Global Drug Survey provides some context for psychedelic risks. When comparing the percentage of people who use different drugs having to seek emergency medical treatment, *Psilocybe* mushrooms consistently ranked lowest on this measure among all the drugs listed (with 0.6% of respondents), and LSD, while higher, still placed

76 Nutt D.K., King L.A., Phillips L.D. (2010), Drug harms in the UK: A multicriteria decision analysis, *Lancet*. 376(9752) pp.1558–65 https://doi.org/10.1016/S0140-6736(10)61462-6; van Amsterdam, J., Opperhuizen, A., Koeter, M., et. al. (2010), Ranking the harm of alcohol, tobacco and illicit drugs for the individual and the population. *European Addiction Research*. 16(4) pp.202–7. https://karger.com/ear/article-abstract/16/4/202/119853/Ranking-the-Harm-of-Alcohol-Tobacco-and-Illicit?redirectedFrom=fulltext; van Amsterdam J, Nutt, D., Phillips, L., van den Brink W. (2015), European rating of drug harms. *Journal of Psychopharmacology*. 29(6) pp.655–60 https://journals.sagepub.com/doi/10.1177/0269881115581980; Taylor M, Mackay K, Murphy J. et. al. (2012), Quantifying the RR of harm to self and others from substance misuse: results from a survey of clinical experts across Scotland, *BMJ Open*. 2(4) http://dx.doi.org/10.1136/bmjopen-2011-000774; Bonomo, Y., Norman, A., Biondo, S. *et. al.* (2019), The Australian drug harms ranking study, *Journal of Psychopharmacology*. 33(7) pp.759–68. https://journals.sagepub.com/doi/10.1177/0269881119841569; Bonnet, U. *et. al.* (2020), Ranking the harm of psychoactive drugs including prescription analgesics to users and others — A perspective of German addiction medicine experts, *Frontiers in Psychiatry*, 26 https://journals.sagepub.com/doi/10.1177/0269881119841569

at the lower end of the scale (1% of respondents).[77] Nonetheless, legal classification systems have generally placed psychedelics in the highest, strictest categories associated with most harmful or risky use which, somewhat ironically, has restricted research that could shed further light on both benefits and harms.

Of course, the use of psychedelic drugs is not risk free, as the referenced harm ranking studies make clear. Yet, psychedelics stand in almost unique contradistinction to stimulant and depressant drug groups, and indeed most other hallucinogens, in that their association with dependence and overdose deaths is essentially absent.[78] This is not to say people are never harmed by or during psychedelic use, but rather that specifically these two health threats, that have historically dominated public discourse on drug harms, have little to no association with psychedelics. A third risk commonly associated with drug use, the danger posed to overall mental health, does exist regarding psychedelics. The historical tendency to see psychedelic effects as analogous to psychosis has been widely challenged, but the risk of acute psychological shock, ranging from a transient *bad trip* to longer-lasting psychological trauma such as Hallucinogenic Persisting Perception Disorder (HPPD), is real, even if comparatively rare.[79]

While it is easy to observe that the risks for psychedelics are lower than most other drugs, or drug groupings, it is also important to be wary of overgeneralisation of risks in more granular policy making. There are a range of psychedelic drugs and preparations, a range of motivations for people using them, variations in individual vulnerabilities, and a range of cultural contexts and environments in which they are used. These are associated with a range of risks and policy responses must be pragmatic and flexible to accommodate this variety.

In the context of this guide, it is important to note that the literature on psychedelic-associated risk has been historically skewed heavily towards LSD, with DMT, mescaline, and psilocybin receiving comparatively less research attention (emerging

77 The low ranking of *Psilocybe* mushrooms is partly due to the generally lower frequency of use compared to other drugs. Some caution is also needed in interpreting this data since psychedelics are commonly used in combination with other drugs. See: Winstock, A., *et.al.*(2022), *GDS 2021 Key Findings Report (Global Drug Survey)* https://www.globaldrugsurvey.com/wp-content/uploads/2021/12/Report2021_global.pdf

78 Nichols, D.E. (2016), Psychedelics, *Pharmacological Review*. 68(2) pp.264-355. https://doi.org/ 10.1124/pr.115.011478; Winstock, A., Karr, S., Borschmann, R. (2014), Dimethyltryptamine (DMT): prevalence, user characteristics and abuse liability in a large global sample, *Journal of Psychopharmacology*. 28(1) https://pubmed.ncbi.nlm.nih.gov/24284475/

79 Prideaux, E. (2023), HPPD, 'Flashbacks', and the Problem of Psychedelic Anxiety https://psychedelic.support/resources/hppd-flashbacks-and-the-problem-of-psychedelic-anxiety/

research on psilocybin and ayahuasca has significantly addressed some of the gaps in understandings).

Set and setting

A characteristic of psychedelics which differentiates them from other drugs is that their potential effects are more highly dependent on the *set and setting*. The psychologist Timothy Leary, who coined the term, considered them to be the most important determinant to influence the direction of a psychedelic experience.[80]

Set refers to the psychological state of the individual, including their expectation, intention, mood and personality, as well as pre-existing psychological factors. Setting is the environmental context in which the person uses psychedelics.[81] For example, being in a good mood and a positive environment increases the likelihood of a positive and enjoyable experience, and conversely, feeling anxious or using in a threatening or unsafe environment, increases the likelihood of a negative or challenging experience. It is therefore essential that information on the importance of set and setting is incorporated into all harm reduction information for people using psychedelics. This allows consumers to make more informed choices on whether having a psychedelic experience is right for them in the moment.

Set and setting is now also a fundamental consideration in psychedelic medical research.[82]

Indigenous communities in their traditional use of psychoactive plants and fungi have long engaged with this principle in their psychedelic use and, as part of their ritual practice, have involved preparation such as fasting, prayer, or singing before or during ceremonies among many other elements.[83] The increasing use of psychedelics in related settings means that more people are using certain psychedelics in contexts with some kind of tradition attached to it, likely increasing the overall safety profile in those settings.

80 Leary T, Litwin G, Metzner R. (1963), Reactions to psilocybin administered in a supportive environment, The Journal of Nervous and Mental Disease. 137, pp.561–573 https://pubmed.ncbi.nlm.nih.gov/14087676/

81 Hartogsohn, I. (2017), Constructing drug effects: A history of set and setting, Drug Science, Policy and Law. 3 https://journals.sagepub.com/doi/10.1177/2050324516683325; Carhart-Harris, R.L., Roseman, L. et.al. (2018), Psychedelics and the essential importance of context, Journal of Psychopharmacology. 32(7) pp.725-731 https://journals.sagepub.com/doi/abs/10.1177/0269881118754710?journalCode=jopa

82 Devenot, N., et.al. (2022), Psychedelic identity shift: A critical approach to set and setting, Kennedy Institute of Ethics Journal. 32(4). pp.359-399 https://doi.org/10.1353/ken.2022.0022

83 Beyer S.V. (2010), Singing to the Plants: A Guide to Mestizo Shamanism in the Upper Amazon. (Albuquerque: University of New Mexico Press) in Hartogsohn, I. (2017), Constructing drug effects, Drug Science, Policy and Law. 3 https://journals.sagepub.com/doi/10.1177/2050324516683325

Table 4

Overview of key risks of psychedelic use and their policy implications

Dependence risks	Policy implications
Psychedelics are not associated with dependence/substance use disorder or withdrawal symptoms, and propensity for patterns of compulsive/frequent use is low.[84] The US-based National Institute on Drug Abuse acknowledges that "the use of psychedelic drugs, such as psilocybin and LSD, does not typically lead to addiction".[85] For LSD, psilocybin and mescaline tolerance develops rapidly, including cross-tolerance between them; this means the same dosage will have a diminishing effect if used frequently, acting as a natural check on more intensive use.[86] In the short-term, tolerance can lead to increasing the dosage to experience the desired effects. Tolerance does not develop for DMT, and evidence suggests a low risk of dependency.[87] The often-intense effects of psychedelic use do not generally lend themselves to more frequent use seen more commonly with other drugs such as stimulants or depressants. Psychedelics do not function as a form of longer-term self-medication or escape associated with frequent use of many other drugs.	Communicate harm reduction information to consumers via packaging, vendors at point of sale (retail and supervised) and public education campaigns, including on: • Effects at different dosages • Potential development of tolerance to and cross-tolerance between psychedelics • Note distinction of DMT not developing tolerance/ cross-tolerance

84 See: Schlag, A. K., Aday, J., Sala, I. (2022), Adverse effects of psychedelics: From anecdotes and misinformation to systematic science, *Journal of Psychopharmacology* 36(3), pp.260-61 https://journals.sagepub.com/doi/pdf/10.1177/02698811211069100; Nichols, D.E. (2016), Psychedelics, *Pharmacological Review*. 68(2), pp.264-355 https://doi.org/10.1124/pr.115.011478; This is not the case with all drugs from the wider hallucinogen grouping such as Ketamine or PCP.

85 National Institute on Drug Abuse, Psychedelic and Dissociative Drugs [Accessed: 18th October 2023) https://nida.nih.gov/research-topics/psychedelic-dissociative-drugs#experience-withdrawal

86 Tolerance and cross-tolerance also apply to the consumption of 2C-B. See: Ruckerh, J., Iliff, J., Nutt, D.J. (2018), Psychiatry & the psychedelic drugs. Past, present & future, *Neuropharmacology*. 142, pp.200-18. https://www.sciencedirect.com/science/article/pii/S002839081730638X

87 Carbonaro, T., Gatch, M. (2016), Neuropharmacology of N,N-dimethyltryptamine, *Brain Research Bulletin*. 126(Pt. 1) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5048497/; Winstock, A., Karr, S., Borschmann, R. (2014), Dimethyltryptamine (DMT): prevalence, user characteristics and abuse liability in a large global sample, *Journal of Psychopharmacology*. 28(1) https://pubmed.ncbi.nlm.nih.gov/24284475/

Physiological risks	Policy implications
Psychedelics are considered to be physiologically very safe and non-toxic up to relatively high doses.[88] They have been linked to cause of death in only a handful of reported cases.[89] They can have some symptoms including nausea, fatigue, increased heart rate and heightened blood pressure.[90] This may present risks to some individuals with health vulnerabilities, especially when used with other drugs. Serious or life-threatening effects (such as seizures) appear to be very rare.[91] Toxicity is more associated with mis selling of other more toxic and riskier drugs marketed as particular psychedelic drugs, such as NBOMes sold as LSD.[92] This risk largely disappears in the context of regulated legal products. In the case of *Psilocybe* mushrooms, the "biggest danger to your health... is eating a poisonous mushroom by mistake."[93]	Regulating products for sale to ensure standardised product contents and dosage — (largely removing risk from mis-selling or adulteration). Communicate harm reduction information to consumers via packaging, vendors at point of sale, and/or public education campaigns, including: • Contents and dosage • Potential physical symptoms and list of health vulnerabilities • Risk for consumers regarding contraindications with prescribed drugs, including SSRIs[94] • Harm reduction advice for different consumption methods • Safe foraging practices and species identification of *Psilocybe* mushrooms

88 Schlag, A. K., Aday, J., Sala, I. (2022), Adverse effects of psychedelics: From anecdotes and misinformation to systematic science, *Journal of Psychopharmacology*. 36(3) p.260-61 https://journals.sagepub.com/doi/pdf/10.1177/02698811211069100; Nichols, D.E. (2204), Hallucinogens, *Pharmacology & Therapeutics*, 101(2) https://doi.org/10.1016/j.pharmthera.2003.11.002;

89 Nichols, D.E. (2204), Hallucinogens, *Pharmacology & Therapeutics*. 101(2) https://doi.org/10.1016/j.pharmthera.2003.11.002

90 Holze, F., Vizeli, P., Ley, L. *et al.* (2020), Acute dose-dependent effects of lysergic acid diethylamide in a double-blind placebo-controlled study in healthy subjects, Neuropsychopharmacology, 46 https://doi.org/https://doi.org/10.1038/s41386-020-00883-6

91 Simonsson, O., *et. al.* (2022) Prevalence and associations of classic psychedelic-related seizures in a population-based sample, *Drug and Alcohol Dependence* 239

92 Zawilska, J., Kacela, M., Adamowicz P. (2020), NBOMes–Highly Potent and Toxic Alternatives of LSD. *Frontiers in Neuroscience*. 14 https://doi.org/10.3389/fnins.2020.00078; Suzuki, J., Poklis, J., Poklis, A. (2014), "My friend said it was good LSD": A suicide attempt following analytically confirmed 25I-NBOMe ingestion. *Journal of Psychoactive Drugs* 46(5) pp.379-382 https://www.tandfonline.com/doi/full/10.1080/02791072.2014.960111; UNODC (2019), *World Drug Report 2019: Book 5, Cannabis and Hallucinogens*

93 Frank, Magic Mushrooms, Accessed 19th June 2023 https://www.talktofrank.com/drug/magic-mushrooms

94 Limited research suggests SSRIs may also negatively interact with phenethylamines such as mescaline and 2C-B; more research is needed to understand the specific risk, see: Funda, I., Brunt, T., Contrucci, R. (2020), Novel Phenethylamines and Their Potential Interactions With Prescription Drugs: A Systematic Critical Review, Therapeutic Drug Monitoring 42(2) https://journals.lww.com/drug-monitoring/abstract/2020/04000/novel_phenethylamines_and_their_potential.13.aspx

Physiological risks (continued)	Policy implications
Physiological effects specific to the preparation or mode of consumption: • Smoking DMT poses risk of respiratory irritation and burns[95] • Ingesting ayahuasca can cause nausea and vomiting, although in traditional contexts this is anticipated and encouraged as a purgative element of ceremonial practice. Cacti consumed for mescaline are also associated with nausea and vomiting.[96] • SSRIs combined with the MAO inhibitors in ayahuasca can lead to serotonin syndrome.[97]	Regulating guided/supervised experiences in safer environments with trained/licensed guides who should: • Request information from participants regarding prescription drug use, including SSRIs. • Be trained to respond appropriately to adverse reactions should they occur. (*See:* Regulation of commercial guided or supervised psychedelic use p.101).

95 Global Drug Survey (2022), GDS2022: Spikey, succulent psychedelics; San Pedro and peyote, the mescaline cacti, Accessed: 25th July 2023 https://www.globaldrugsurvey.com/gds-2022/gds2022-spikey-succulent-psychedelics-san-pedro-and-peyote-the-mescaline-cacti/

96 Global Drug Survey (2022), GDS2022: Spikey, succulent psychedelics; San Pedro and peyote, the mescaline cacti, Accessed: 25th July 2023 https://www.globaldrugsurvey.com/gds-2022/gds2022-spikey-succulent-psychedelics-san-pedro-and-peyote-the-mescaline-cacti/

97 Long-term ritual consumption of ayahuasca has not been found to be toxic or harmful to adults, see: dos Santos, R.G., (2013), Safety and side effects of ayahuasca in humans — an overview focusing on developmental toxicology, Journal of Psychoactive Drugs 45(1) https://doi.org/10.1080/02791072.2013.763564; For serotonin syndrome, see: Gillan, K. (2010), Triptans, serotonin agonists, and serotonin syndrome (serotonin toxicity): a review, American Headache Society 50(2) https://pubmed.ncbi.nlm.nih.gov/19925619/

Risk of negative experiences

Psychedelic experiences can be subjectively frightening, anxiety inducing or distressing in the short term without necessarily leading to longer-term psychological damage or trauma.[98] Many assumptions about such risks are based on methodologically weak studies from the 1950s and 1960s, and case reports of mental distress need to be treated cautiously for this and other reasons.[99]

"Challenging psychedelic experiences are not uncommon. The very nature of the psychedelic state, with its limitless sensations, expressions, and dynamics, can be disorienting, confusing, and at times frightening. The same elements that can influence someone's decision to explore psychedelics — change in perception, expanded awareness, and altered consciousness — can be the very things that can contribute to a difficult experience, challenging our beliefs and assumptions about ourselves and the universe." Sara Gael, Harm Reduction Officer, MAPS[100]

Different dosages alter the intensity of the psychedelic experience.[101] Dosage control can be a challenge with psychedelics, particularly when only very small quantities of the drug are required to elicit powerful effects. When taken orally, the time between consumption and effect can sometimes be over an hour (*See:* Table 1, p.16) leading to over-hasty redosing. When psychedelics are smoked or vaped (common with DMT) the onset is almost immediate, adding to the intensity.

Policy implications

Regulating products for sale to ensure standardised product contents and dosage which reduces risk of consuming an unintended amount makes overdose less likely. This does not eliminate the risk of taking too much but at least reduces the risk of unknown or unpredictable dosage, making overdose less likely.[102]

Communicate harm reduction information to consumers via packaging, vendors at point of sale, and/or public education campaigns, including:

- Contents and dosage
- Effects at different dosages of each drug incl. risks around higher dosages, frequency of use, and development of tolerance/cross-tolerance
- Effects elicited through different methods of consumption
- Key risks for young people, novice users and people with psychological or mental health vulnerabilities
- The importance of set and setting

Provision of psychedelic welfare services with relevant training for welfare providers in social environments such as festivals and the night-time economy.

Provision of free, confidential phone or online support services for people experiencing distress during or after psychedelic use for when access to in-person welfare services is not available (*See:* Psychedelic welfare services, p.96).

Regulating guided/supervised experiences in safer environments with trained/licensed guides, where:

- Psychological distress can be appropriately supported should it occur
- Offer appropriate post-experience aftercare/ integration

98 Dyck, E. Elcock, C. (2020), Re-framing bummer trips: scientific and cultural explanations to adverse reactions to psychedelic drug use. *The Social History of Alcohol and Drugs*. 34(2) https://doi.org/10.1086/707512

99 Huber, B (Date Unknown)., What do we know about the risks of psychedelics? https://michaelpollan.com/psychedelics-risk-today/; Krebs, T. Johansen, P. (2013), Psychedelics and Mental Health: A Population Study. *PLoS One*. 8(8) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3747247/

100 Gael, S. (2017), Understanding and Working with Difficult Psychedelic Experiences, *MAPS Bulletin*. 27(1) https://maps.org/news/bulletin/understanding-and-working-with-difficult-psychedelic-experiences/

101 Liechti, M.E., Holze, F. (2022), Dosing Psychedelics and MDMA, *Current Topics in Behavioural Neurosciences*. 56(3) https://link.springer.com/chapter/10.1007/7854_2021_270

102 Overdose is defined here as taking more than intended, potentially leading to undesired or negative effects; this can be quite common.

Mental health risks	Policy implications
The focus on potential mental health benefits of psychedelics within specific supervised settings should not obscure possible mental health risks. Larger-scale population studies have not found use of psychedelics to be an independent risk factor for mental health problems (and suggest some benefits) although case studies suggest psychedelics can potentially precipitate, exacerbate or reveal certain mental health problems — particularly for people with certain pre-existing vulnerabilities (such as family histories of psychotic disorders or schizophrenia) using outside of controlled environments.[103] Psychedelics can cause so-called *flashbacks* in some users — recurring transient psychedelic experiences after acute effects have passed. Whilst such experiences are quite common (and not exclusive to psychedelic drugs) such effects are usually mild and reduce in intensity and frequency over time. When more persistent or distressing, the syndrome is called HPPD. This is rare, but identifiable at a population level (for example in reddit discussion forums) even if hard to identify in clinical contexts with small sample sizes and more effective screening, so more precise conclusions on prevalence are hard to establish.[104]	Communicate harm reduction information to consumers via packaging, vendors at point of sale, and/or public education campaigns, including: • Highlighting increased risks and dosage-related risks for people with specific mental health vulnerabilities • Vendor training should include requirements to offer relevant mental health risk advice Regulating guided/supervised experiences in safer environments with trained/licensed guides who should: • Screen for certain mental health vulnerabilities (incl. family history) and offer appropriate advice and care as part of a responsible risk-management approach • Be trained to respond appropriately to adverse reactions should they occur • Offer appropriate post-experience aftercare/ integration

103 Krebs, T,. Johansen P (2013), *Psychedelics and Mental Health: A Population Study*. PLoS One. 8(8) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3747247/; van Amsterdam, J. (2011), Harm potential of magic mushroom use: A review, *Regulatory toxicology and pharmacology*. 59 https://doi.org/10.1016/j.yrtph.2011.01.006

104 Schlag, A. K., Aday, J., Sala, I. (2022), Adverse effects of psychedelics: From anecdotes and misinformation to systematic science, *Journal of Psychopharmacology* 36(3) pp.260-61 https://journals.sagepub.com/doi/pdf/10.1177/02698811211069100

Risk of injury while impaired	Policy implications
When using psychedelics, judgement can be impaired and in rare cases can lead to an individual doing something that may cause harm to themselves or others. This risk is increased when using psychedelics in unsupervised or dangerous settings.[105] Incidences of self-harm under the influence of psychedelics, including fatalities or suicides, have occurred, but are very rare — although high-profile media reporting (and use of anecdote in anti-drug messaging) contributes considerably to public perception (or misperception) of such risks.[106] Psychedelic use impairs psychomotor skills and reaction times during the experience, as well as causing sensory and perceptual distortions — on a dosage dependent basis — creating risks of personal injury, as well harm to others e.g., driving or operating machinery while impaired.	Communicate harm reduction information to consumers via packaging, vendors at point of sale, and/or public education campaigns, including: • Risks of injury while impaired, particularly in regard to high-risk environments and risks associated with impaired driving (driving under the influence will remain illegal, albeit an enforcement challenge) • The legal risks of being under the influence Provision of safer environments such as psychedelic welfare services in social environments such as festivals and the night-time economy. Regulating guided/supervised experiences to lower risk of injury, where: • Environments are inspected/approved for safety • Emergency incidents can be appropriately managed should they occur.

Polydrug use risk	Policy implications
Unlike polydrug use with stimulants or depressant drugs, polydrug use with psychedelics is not a significant contributor to mortality risks.[107] However, polydrug use increases risk for all drug use. Risks of acute adverse events — distress, anxiety, negative thought loops etc. — are increased when psychedelics are used in combination with other drugs. Use of high-dose psychedelics with alcohol can present a particular risk of vomiting and choking when incapacitated.	Communicate harm reduction information to consumers via packaging, vendors at point of sale, and/or public education campaigns, including: • Risks of polydrug use, particularly with alcohol Establish psychedelic-only retail outlets that do not sell other drugs as well

105 Nichols, D.E. (2004), Hallucinogens, *Pharmacology & Therapeutics*. 101(2) https://linkinghub.elsevier.com/retrieve/pii/S0163725803001657

106 Schlag, A. K., Aday, J., Sala, I. (2022), Adverse effects of psychedelics: From anecdotes and misinformation to systematic science, *Journal of Psychopharmacology* 36(3) pp.260-61 https://journals.sagepub.com/doi/pdf/10.1177/02698811211069100

107 van Amsterdam, J. (2011), Harm potential of magic mushroom use: A review, *Regulatory toxicology and pharmacology* 59 https://doi.org/10.1016/j.yrtph.2011.01.006

The process of legalisation and regulatory design offers a chance to be innovative and ambitious, to do things differently and better, not only to create a more equitable and just policy and market landscape, but also to help repair the harms of past policy failings

4

Embedding social justice, equity and human rights into policy design

The decriminalisation and legal regulation of currently prohibited drugs creates unique opportunities to remake policy, designing new markets and regulatory frameworks in ways that can embed and prioritise principles of social justice, equity and human rights — too often absent or actively undermined in both unregulated illegal markets, as well as inadequately regulated legal markets.

Without a strong commitment to these principles, there is a risk that inequities and injustices of the *drug war* era will be significantly replicated post-legalisation. People from socially and economically marginalised communities risk being excluded from policy making decisions, facing disproportionate obstacles to the enjoyment of benefits from emerging markets, and greater barriers to accessing legally regulated psychedelics and related services. The process of legalisation and regulatory design offers a chance to be innovative and ambitious, to do things differently and better, not only in creating a more equitable and just policy and market landscape, but also to help repair the harms of past policy failings.

Key elements in achieving this ambition, explored below, include:

- Firstly, preventing the emergence of monopolies/oligopolies to mitigate the risks of corporate or regulatory capture and ensure a diverse market;
- secondly, implementing *equity programmes* that facilitate and empower historically marginalised and impacted communities to meaningfully participate in, and shape, policy and regulatory frameworks;
- thirdly, through a parallel reparative process of reinvestment of market surplus into marginalised communities and those disproportionately impacted by the *war on drugs*;
- and finally, ensuring reparatory justice for Indigenous communities.

This must all be established alongside a comprehensive decriminalisation process that includes resentencing and expungement (deletion/removal) of past criminal records (*See:* Decriminalisation, p.66).

Preventing the emergence of monopolies and mitigating risks of corporate capture

Based on current consumption patterns, a legal non-medical psychedelics market is likely to be significantly smaller than equivalent legal markets for recreational cannabis, alcohol and tobacco products. Nevertheless, it is a potentially lucrative global industry, particularly regarding supervised/guided use. The parallel medical psychedelics industry is also growing rapidly, with further exponential expansion likely leading to encroachment into non-medical markets and policy making.

Other industries, notably new legal cannabis markets in North America, demonstrate the risks of rapid expansion of newly legalised industries, followed by market consolidation, and the emergence of powerful corporate monopolies or oligopolies — particularly where medical and non-medical industries merge. Without adequate protection, this can lead to corporate/regulatory capture, the process by which corporate resources (legal, financial, advocacy and PR) are deployed to shape market architecture and policy and law-making processes in favour of corporate profits, over

the interests of the wider public.[108] There is already a vast amount of speculative investor capital flowing into the emerging medical/therapeutic psychedelics market.[109]

It is therefore imperative that any regulatory framework for psychedelics is designed to prevent the emergence of monopolies and mitigate the attendant risks of corporate/regulatory capture. Crucially, such efforts must be hardwired into the regulatory framework from the outset. As global alcohol and tobacco markets have shown, allowing problematic market dynamics dominated by powerful transnational corporations to become established and embedded makes regulatory reforms in the future much more difficult, although not impossible.

Such risk mitigation can be achieved in a number of ways. It will be important to build in road-tested anti-monopoly measures that help ensure a more diverse equitable market landscape populated by small and medium sized businesses. This can most obviously be achieved by limiting the number of production or retail licences available to any one commercial entity, and ensuring any such ownership limits are enforced. Preventing licences for existing medical psychedelic industry actors, major pharmaceutical companies, or companies involved in other non-medical drug production such as alcohol, tobacco, and cannabis will add an additional tier of protection.

Exploring options for non-commercial market models can also be an important component of this strategy. This should certainly include allowing home cultivation, foraging and not-for-profit sharing of plant-based psychedelics, and membership-based not-for-profit associations — which can go some way to limiting the scale of commercial markets by providing alternative forms of access (See: Proposals for regulation, p.65). Offering preferential licensing terms to, or prioritising licence applications from, non-for-profit organisations, for-benefit corporations, or social enterprises is another way in which these aims could be furthered, and where well-developed and financed equity programmes will be key (*See:* below).

Existing commercial interests in the medical psychedelics sphere may

108 See section: Corporate capture in Rolles, S., Slade, H. (2021), *How to regulate cannabis: A practical guide* (Transform Drug Policy Foundation) https://transformdrugs.org/publications/how-to-regulate-cannabis-3rd-ed; Title, S. (2022), Bigger is not better: Preventing monopolies in the national cannabis market, *Drug Enforcement and Policy Center* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4018493

109 Schuster-Bruce, C., Lee, Y.J., Meet the top 14 VCs who've bet the most cash on turning psychedelics into medical treatments, *Business Insider*, Date Unknown https://www.businessinsider.com/list-top-venture-capital-investors-psychedelics-industry-2023?r=US&IR=T

unfortunately be ambivalent about, or even actively obstruct wider reform efforts where they perceive it as undermining progress towards medical or therapeutic commercialisation. Naturally occurring psychedelic compounds and established therapeutic modalities are already becoming embroiled in disputes around patents and other forms of Intellectual Property (IP) protection. It has been argued that these patents are necessary to ensure continued research, which comes at a significant cost and therefore requires that investments are protected.[110] How to ensure support for research while protecting against corporate attempts to control and limit availability and access for medical use is a question that is yet to be resolved.

However, the sudden influx of psychedelic patents has garnered criticism from key stakeholders including "patient advocates, scientists, journalists, lawyers, and members of Indigenous communities."[111] Patents risk allowing a small number of companies to capture the emerging markets and further risk restricting access *beyond* medical use as well. With patents attempting to create legally protected monopolies on natural compounds, existing production processes and preparations, and generic concepts (such as the nature of an indoor environment during supervised use), many actors hoping to enter the market or provide commercial supervised or therapeutic services are at risk of exclusion. In particular, it is essential that, in the market and its design, provisions are made for the effective participation of communities that have already been historically excluded from this currently overwhelmingly Western, white and male space (*See also:* Protection for religious and Indigenous use, p.56).

These issues are already being played out within the formal medical psychedelic space where the underrepresentation of people of colour and women has frequently been highlighted.[112] As the NGO Chacruna has stated, "There are very few people of color, let alone women of color, leading psychedelic science, especially in the United States. The boards of the primary funding organizations, as well as the scientific teams, are comprised primarily of white men."[113] This is despite these people often playing an important role in informal and unregulated therapeutic psychedelic spaces.[114]

110 Marks, M., Cohen, I.G (2021), Patents on psychedelics: the next legal battlefront, *Harvard Law Review*, https://harvardlawreview.org/forum/no-volume/patents-on-psychedelics-the-next-legal-battlefront-of-drug-development/

111 *Ibid.*

112 Proto.life, Inside the movement to decriminalize psychedelic pharma, 29th October 2020 https://proto.life/2020/10/inside-the-movement-to-decolonize-psychedelic-pharma/

113 Sevelius, J., How Psychedelic Science Privileges Some, Neglects Others, and Limits Us All, *Chacruna*, 25th July 2017, https://chacruna.net/how-psychedelic-science-privileges-some-neglects-others/

114 George, J. R., Michaels, T. I., Sevelius, J., & Williams, M. T. (2020), The psychedelic renaissance and the limitations of a White-dominant medical framework: A call for Indigenous and ethnic minority inclusion, *Journal of Psychedelic Studies*. 4(1), pp.4-15 https://doi.org/https://doi.org/10.1556/2054.2019.015

There is also a parallel issue of market access — particularly regarding supervised use services with a therapeutic/wellness focus. The historical, systemic disparities in access to healthcare are compounded by the prohibitively costly nature of most existing supervised/guided experiences in the Global North. It is grimly ironic that an emerging market — making claims to heal trauma, and now able to open up as the end of the *war on drugs* edges closer — is excluding populations who have been most traumatised by the brutalities of the *war on drugs*. It is important to ensure access to market participation — including supporting diversity among licensed supervisors/guides, as well as affordable access to therapeutic/wellness services — whether operating within formal clinical settings or not.

Equity programmes

Psychedelic reforms can be informed by pioneering community-led work in emerging legal cannabis markets in some US states that has helped establish the working principles and viability of *equity programmes* that proactively support participation of marginalised and disproportionately impacted communities in emerging markets.[115] Key policy design elements to incorporate into regulatory and licensing frameworks for psychedelic cultivation/production, retail and supervised/guided use to prioritise social justice and equity goals should include:

- Proactive engagement with underrepresented groups on their potential participation in the psychedelic space.
- Reducing financial barriers for equity applicants: waivers and discounts should be available on application fees, licensing and other fees, as well as access to capital in the form of grants or loan schemes, and funding for a range of training programmes. Given that equity applicants are frequently small businesses, fee discounts can range from smaller discounts to full waivers depending on the size of the business and the type of licence being sought.
- Advantages/prioritisation in the licensing process for equity applicants (including applicants from not-for-profit associations and social enterprises), for example, exclusivity for equity applicants for a period before opening up applications to the wider market.

115 Title, S. (2021), Fair and Square: How to Effectively Incorporate Social Equity Into Cannabis Laws and Regulations, *Drug Enforcement and Policy Center* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3978766

- Technical assistance and wraparound benefits to help 'level the playing field' for equity candidates, including legal and account services and other forms of workforce development and training.
- Formally reviewing equity programmes to ensure that they are achieving their stated outcomes, and updating them based on evidence of effectiveness, for example, adjusting processes, financing and eligibility criteria.

Cannabis equity programmes are generally funded by tax revenues and licence fees, but also commonly include mechanisms for the redirection of a proportion of tax revenues back into impacted communities, supporting drug service provision and wider social programmes. In New York State, 40% of tax revenue is redirected in this way, and in New Jersey the figure is 70%. Even if revenues from psychedelics are somewhat smaller, the opportunity to replicate this unique and positive policy model should be embraced. In the case of commercialised products and psychedelic services that directly or indirectly draw on traditional Indigenous knowledge, such as ayahuasca ceremonies, efforts should be made to support benefit sharing with the relevant Indigenous communities (*See:* below).

Protection for religious and Indigenous uses

Psychoactive plants, including those containing the psychedelics psilocybin, mescaline and DMT, have been used across the globe by different Indigenous communities for thousands of years, often in ritual and ceremonial settings as forms of traditional sacrament or medicine within their distinct cultural contexts. Psychedelics also play an important role as sacraments in several religious organisations. The religious or ceremonial functions of psychedelics can provide valuable lessons to inform policy design, however, they also raise difficult questions about whether state regulation of such practices is appropriate or justifiable. Ultimately, the rights of religious and Indigenous communities to freedom of belief and practice using psychedelics must be secured (this principle extends to all psychoactive plants) and not be encroached upon by regulatory frameworks for other forms of access to psychedelic drugs (including retail and supervised/guided use models). As outlined below, some protections formally exist at UN-level, however, they are inadequate. This means state-level exemptions and protections

are necessary, while managing the risk that they could be exploited by unscrupulous actors as cover to avoid regulatory oversight.

The nominal protections, under various UN mechanisms, of the rights of religious and Indigenous communities to practise their cultural, spiritual, and religious traditions that involve psychoactive plants are partial and often contradictory. Further, such practices have frequently been undermined, stigmatised and, in many cases, criminalised.

The most obvious problems involve the glaring contradictions and incompatibility between two key UN treaty mechanisms: the outdated UN drug treaties which can criminalise such practices, and the more recent and progressive United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) which seeks to secure them (*See:* Psychedelics and the UN drug treaties, p.107).

The UNDRIP recognises the cultural identity of Indigenous peoples and their right to self-determination, including a right to enjoy their culture, and a right to their traditional medicines.[116] Furthermore, under the 1971 UN Convention on Psychotropic Substances (one of the three treaties that constitute the basis of the UN global drug control regime), the traditional/religious use of psychoactive plants is specifically included, within certain parameters, as an optional exemption from wider drug prohibition.[117] Article 32.4 states that:

> *A State on whose territory there are plants growing wild which contain psychotropic substances from among those in Schedule 1 and which are traditionally used by certain small, clearly determined groups in magical or religious rites, may, at the time of signature, ratification or accession, make reservations concerning these plants, in respect of the provisions of article 7, except for the provisions relating to international trade.*[118]

This is a potentially important provision that, in one sense, can be seen as being endorsed and enhanced by the UNDRIP. However, the rights that Article 32 confers

116 United Nations Human Rights Office of the High Commissioner, United Nations (2007), UN Declaration on the Rights of Indigenous Peoples https://www.ohchr.org/en/Indigenous-peoples/un-declaration-rights-Indigenous-peoples#:~:text=The%20Declaration%20addresses%20both%20individual,all%20matters%20that%20concern%20them

117 The three key treaties shaping international law on drugs are: the 1961 UN Single Convention on Narcotic Drugs; the 1971 UN Convention on Psychotropic Substances; and the 1988 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. See: Transform Drug Policy Foundation, Global Drug Policy, Accessed: 24th August 2023 https://transformdrugs.org/drug-policy/global-drug-policy

118 Article 32.4, 1971 UN Convention on Psychotropic Substances https://www.unodc.org/pdf/convention_1971_en.pdf

Many religious and Indigenous communities who were not involved in treaty negotiations at domestic or international levels, are potentially criminalised by default

are not automatic or universal; it places the burden on member state governments to implement reservations, usually at the point of signing the treaties. This leaves many religious and Indigenous communities who were not involved in treaty negotiations at domestic or international levels, unable to enjoy such rights and potentially criminalised under domestic and/or international law by default.

The various issues are confused further by the fact that, unlike psychoactive plants generally, cannabis, opium and coca are specifically prohibited in plant form by the 1961 Single Convention. The option for reservations on traditional/religious use of any psychoactive plants, combined with the fact that there are specific wider exemptions for plants containing psychedelics under the treaties (*See:* Psychedelics and the UN drug treaties, p.107) does, however, appear to make international law less of an issue for the traditional/religious use of psychedelic plants than it has been for the traditional/religious use of coca, cannabis or opium.

A number of exemptions related to psychedelics have been implemented in domestic law. This includes the permitted use of peyote cactus by members of the Native American Church in the United States, who also do not need to declare its use upon joining the US military (as would be the case with non-exempted mescaline or other illegal drug use). Further, a limited set of licensed individuals are permitted to supply peyote to the Native American Church under a restrictive supply scheme.

> *The listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration. Any person who manufactures peyote for or distributes peyote to the Native American Church, however, is required to obtain registration annually and to comply with all other requirements of law.*[119]

In 2006, religious protection was also granted in the United States to the União do Vegetal, a church combining Indigenous Brazilian beliefs with contemporary Christian teachings. A unanimous Supreme Court ruling permitted the church to

119 U.S. Food and Drug Administration, CFR— Code of Federal Regulations Title 21, Accessed 16th August 2023 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1307.31#:~:text=Sec.,peyote%20are%20exempt%20from%20registration

import and use *Hoasca* (ayahuasca).[120] This ruling relied on the Religious Freedom Act which prohibits Federal Government from substantially burdening a person's exercise of religion (*See:* Ayahuasca, p.86). The Canadian Government has provided similar religious exemptions, allowing for the import and use of ayahuasca for churches which use it in their religious. These exemptions are provided alongside strict controls on import and storage to avoid diversion, with a focus on the health and safety of members and visitors to the church.[121] As of 2022, only the constitutions of Bolivia (Art. 42) and Ecuador (Art. 57) include regulation specific to Indigenous traditional medicine.[122] (*See:* Psychedelics and the UN drug treaties, p.107).

The International Guidelines on Human Rights and Drug Policy

These guidelines, compiled by the UN Development Programme, WHO, UNAIDS, Office of the United Nations High Commissioner for Human Rights, and the Center for Human Rights and Drug Policy, serve as expert guidance — rather than representing a formal legal mechanism. Described as a "reference tool to ensure human rights compliance", they apply existing international human rights law to drug policy and provide "support for legal reforms and policy change" including in relation to protection of religious and Indigenous rights and traditional use of drugs:[123]

> *Everyone has the right to freedom of thought, conscience, and religion, which includes the freedom to manifest one's religion or belief, either individually or in community with others, in public or private. This right applies to those for whom such manifestations may involve the use of drugs for religious or spiritual purposes.*
>
> *Indigenous peoples have the right to maintain, control, cultivate, use, and protect and conserve medicinal and other plants and seeds that form a part of their cultural or ethnic identity or part of their spiritual or religious traditions, customs, and ceremonies. This includes plants that have psychoactive effects.*

120 US Supreme Court, Gonzales v. O Centro Espírita Beneficente União do Vegetal, 546 U.S. 418 (2006) https://supreme.justia.com/cases/federal/us/546/418/

121 Rochester, J. Rev. Dr., How our Santo Daime Church received religious exemption use ayahuasca in Canada. *Chacruna* 2017 https://chacruna.net/how-ayahuasca-church-received-religious-exemption-canada/

122 Celidwen, Y., Redvers, N., Githaiga, C. *et al.*, (2022), Ethical principles of traditional Indigenous medicine to guide Western psychedelic research and practice, *The Lancet Regional Health — The Americas*. 18 https://www.thelancet.com/journals/lanam/article/PIIS2667-193X(22)00227-7/fulltext

123 International Guidelines on Human Rights and Drug Policy, About, Accessed: 22nd August 2023 https://www.humanrights-drugpolicy.org/about/; Section 10 and Section 4.3 in International Guidelines on Human Rights and Drug Policy (2019) https://www.humanrights-drugpolicy.org/site/assets/files/1640/hrdp_guidelines_2020_english.pdf

In terms of specific recommendations flowing from these rights, the guidelines are clear that states should:

i Refrain from interfering with Indigenous peoples' exercise of their cultural, spiritual, and religious practices, including those involving plants that have psychoactive effects.

ii Adopt appropriate legislative, administrative, and other measures to ensure that drug control efforts do not interfere with Indigenous peoples' rights to enjoy their culture and to practise their religion, including with members separated by international borders.

iii Take measures to protect Indigenous communities from actions by private companies and third parties that deny Indigenous people their traditional sources of nutrition, medicines, livelihoods, and ceremonies, including those involving plants that have psychoactive effects.

iv Consider exemptions within drug legislation allowing Indigenous peoples to use controlled psychoactive substances for traditional, cultural, and religious purposes.

Exemptions and protections as outlined in the *International Guidelines on Human Rights and Drug Policy* (*See:* box, above) must be more widely reflected in the development of policy reforms to prevent the creation of regulatory burdens which could unduly encroach on religious freedoms and the rights of Indigenous peoples. However, policymakers must move with caution to ensure that this principle does not become a loophole to be exploited by commercial interests or illegitimate actors attempting to avoid regulatory oversight. This is particularly the case for commercial actors who are seeking to market guided or supervised use. Appropriation of traditional Indigenous culture, and incorporation of ceremonial elements is a common feature of many guided psychedelic enterprises, often offering exclusive boutique experiences at an extremely high cost.[124] This is already an expanding, and largely unregulated, commercial market. Reforms should ensure that secular community or group-use contexts are caught by regulatory frameworks where necessary (i.e., when commercial) and prevent religious exemptions from opening a door to profit-driven exploitation and unregulated services. Further, exemptions should be permitted with careful consideration to ensure this principle is not abused.

124 Celidwen, Y., Redvers, N., Githaiga, C. *et al.* (2023), Ethical principles of traditional Indigenous medicine to guide Western psychedelic research and practice, *The Lancet Regional Health – Americas* 18 https://doi.org/10.1016/j.lana.2022.100410; Leonhardt, M., Here's how much 'magic mushroom retreats' like Goop Lab's actually cost, *CNBC*, 24 January 2020 https://www.cnbc.com/2020/01/24/heres-how-much-magic-mushroom-retreats-like-goop-labs-actually-cost.html

Of course, defining what is and is not a legitimate religion or traditional use poses its own challenges, and exemptions for emerging religions/churches may need to be granted at a national, regional or local level on a case-by-case basis.

Recognition of Indigenous relationships with plant-based psychedelics

As medical and non-medical for-profit industries in the Global North ready themselves to profit from the potentially lucrative regulated psychedelic market, Indigenous communities that have traditionally used plant-based psychedelics risk further marginalisation, exploitation and harm. Not only are they at risk of being economically excluded from these benefits that psychedelic reforms offer, but the rapidly expanding market also threatens the ecological sustainability of these plants and Indigenous peoples' continued relationship with them. Colonisation has already disconnected and disturbed Indigenous communities' traditional psychedelic practices, their communities and their land narratives. The emerging commercial market risks further endangering these ties. Industry actors, sometimes unapologetically (*See:* Ayahuasca, p.86), are already seeking to gain financially from the knowledge and established ritual psychedelic practices of these communities.

The appropriation by white, Western communities of traditions conducted by often marginalised groups can lead to members of these groups becoming detached from their own traditions.[125] It is therefore key to embed cultural sensitivity and reparatory justice for Indigenous communities into drug policy, specifically here regarding exploitation/appropriation of traditional psychedelic practices. The road to achieving this is inevitably complex, not least because Indigenous Peoples are not a singular group. Each community will have different experiences and ways of thinking. Policy relating to these communities will therefore need to be nuanced and Indigenous led. The current low engagement and lack of representation within scientific research emphasises the need for this.[126] There are, however, already several considered recommendations for how policymakers can approach this issue.

125 George, J.R., *et al.* (2020), The Psychedelic Renaissance and the Limitations of a White-Dominant Medical Framework: A Call for Indigenous and Ethnic Minority Inclusion, *Journal of Psychedelic Studies*. 4(5) https://doi.org/10.1556/2054.2019.015

126 *Ibid.*

Industry actors are already seeking to gain financially from the knowledge and established ritual practices of Indigenous communities

In 2021, an Indigenous-led group with members from different communities across the world, gathered to formulate ethical standards on how Western psychedelic research and practice should engage with Indigenous communities and their traditional use of plant-based psychedelics via a global Indigenous consensus process.[127] The group believes the eight interconnected ethical principles of Reverence, Respect, Responsibility, Relevance, Regulation, Reparation, Restoration, and Reconciliation capture "important elements that may be relevant to many Indigenous Nations" while acknowledging that some Indigenous communities may not want to engage in this dialogue.[128] These principles offer guidelines that could inform the foundation of psychedelic policy development where relevant communities are impacted. Regulators must not rely on the voluntary activities of individual industry actors, who may promise forms of engagement with these ethical principles, but which are potentially based in an inequitable relationship, often guided by self-interest, and are not binding or subject to formal scrutiny.

Work is already being done to ensure the rights and agency of Indigenous communities is promoted within the psychedelic landscape, led by the communities themselves. Organisations such as the Indigenous-led Indigenous Medicine Conservation Fund (IMC Fund) promote benefit sharing. Benefit sharing is defined as "the action of giving a portion of advantages or profits derived from the use of genetic resources or traditional knowledge to Indigenous communities in order to achieve justice in exchange."[129] The IMC fund aims to facilitate the flow of these advantages from psychedelics companies and other people to Indigenous communities while allowing communities to have a way of guiding the process. As well as benefit-sharing, the IMC seeks to protect and strengthen Indigenous communities' cultures and conserve their land.

127 "The panel composition included ... community members with extensive experience and knowledge in traditional Indigenous medicines. This included representatives from Canada (Denésuliné [N.R.]), Colombia (Inga [M.E.], Misak [J.C.]), El Salvador (Nahua Pipil Kakawira [J.N.R.]), Guatemala (Maya Kakchiquel [A.S.T.]), Kenya (Kikuyu [C.G.]), Mexico (Maya Tseltal [Y.C.], Nahua [Y.C.], and Wixárika [Y.V.R.]), Peru ([K.A.]), and the United States (Chickasaw [D.M.])." See: Celidwen, Y., Redvers, N., Githaiga, C. et al., (2022), Ethical principles of traditional Indigenous medicine to guide western psychedelic research and practice, *The Lancet Regional Health — The Americas* 18 https://www.thelancet.com/journals/lanam/article/PIIS2667-193X(22)00227-7/fulltext

128 *Ibid.*

129 Grow Medicine, Growing Awareness, Accessed: 30th July 2023 https://growmedicine.com/growing-awareness/

World Ayahuasca Conference, 2019 PHOTO: ICEERS

There are already international legal instruments which could be applied to relevant psychedelic markets as they expand. Notably, the Nagoya Protocol, adopted in 2010, was established to ensure legal certainty and transparency in relation to access to genetic resources, by embedding dialogue, consent and benefit sharing into policy development (some countries such as the United States, have not yet adopted this protocol).[130]

The Free, Prior and Informed Consent (FPIC) right, recognised in UNDRIP "allows Indigenous Peoples to provide or withhold/withdraw consent, at any point, regarding projects impacting their territories."[131] However, to be successful it must be honoured; FPIC has, so far, often failed to be acknowledged within the context of traditional medicines.[132]

130 Convention on Biological Diversity, The Nagoya Protocol on Access and Benefit-sharing, Accessed 1st July 2023 https://www.cbd.int/abs/

131 Food and Agriculture Organisation, Indigenous Peoples: Free, Prior and Informed Consent, Accessed: 1st July 2023 https://www.fao.org/indigenous-peoples/our-pillars/fpic/en

132 George, J.R., et al. (2020), The Psychedelic Renaissance and the Limitations of a White-Dominant Medical Framework: A Call for Indigenous and Ethnic Minority Inclusion, *Journal of Psychedelic Studies*. 4(5) https://doi.org/10.1556/2054.2019.015

Ending the criminalisation of people who use drugs is a vital pre-condition for a meaningful public health and rights-based response to drugs

5 Proposals for regulation

Below we propose a four-tiered model that attempts to manage the variety of psychedelic preparations and the different ways in which they are used:

Prescribed medical provision of psychedelic drugs within a clinical context is not a focus of this guide as it is/will be already captured in existing regulatory frameworks. This discussion is premised on the basic principle that the adult use and possession for personal use of any drugs should not be subject to any form of criminal or

administrative sanction. There are important questions around the process of decriminalisation and sequencing of such reforms as a possible transitional step toward a comprehensive model of regulated supply.

Decriminalisation: a foundational principle for all drug reform

Ending the criminalisation of people who use drugs (a more useful description than "decriminalising drugs" which is often confused with legalisation) is both important in its own right — addressing an unjust, harmful, stigmatising and discriminatory law — as well as being a vital pre-condition for a meaningful public health and rights-based response to drugs.

The 2019 Common Position Statement from the United Nations Chief Executives Board (CEB), chaired by the UN Secretary General and representing all 31 UN agencies, including the World Health Organization (WHO) and UN Office on Drugs and Crime (UNODC), has expressed strong and unanimous support for the decriminalisation of possession and use of drugs. The statement calls on member states to "promote alternatives to conviction and punishment in appropriate cases, including the decriminalisation of drug possession for personal use".[133]

Decriminalisation, though not a formally defined term, here refers to the removal of criminal penalties for certain activities related to drug use. This is usually possession of small amounts of a drug for personal use, but sometimes also includes minor supply or cultivation offences.

While multiple jurisdictions around the world have adopted some form of decriminalisation for some or all drugs, there is considerable variation in the scope and implementation of the policies.[134] How possession for personal use and supply is distinguished varies widely between jurisdictions.[135] In some legal systems criminal

133 UN Nations system Chief Executives Board for Coordination, Summary of Deliberations, 7 and 8 November 2018 https://unsceb.org/sites/default/files/imported_files/CEB-2018-2-SoD.pdf

134 Talking Drugs, Drug Decriminalisation Across the World, Accessed: 20 June 2023 https://www.talkingdrugs.org/drug-decriminalisation

135 Transform Drug Policy Foundation, México Unido Contra la Delincuencia (2018), Quantity thresholds for drug possession https://transformdrugs.org/publications/thresholds-briefing-2018-mucd-transform

penalties are replaced by civil sanctions (such as fines or mandatory treatment assessments), while in other systems no penalties are applied, although, with few exceptions, drugs are routinely confiscated. There is also an important distinction between *de facto* decriminalisation, where drug-related activity remains a criminal offence but the law is not enforced in practice, and *de jure* decriminalisation, where decriminalisation is formally established in a legal framework through statute or constitutional court decisions.

Recommended decriminalisation model

- Should be *de jure* — possession for personal use should no longer be an offence of *any* kind or be subject to any sanctions, this includes no fines or fees, no finding of child neglect or denial of custody or loss of parenting time; no revocation of probation, parole, or other supervised release; no denial of medical care, public benefits, housing, employment, education, or access to personal finance/credit.[136]
- Drugs for personal use should not be confiscated.
- Should avoid fixed or binding thresholds (to distinguish between possession for personal use and supply) that trigger automatic penalties or assumption of guilt. A system of guideline thresholds with additional guidance on aggravation/mitigation that includes a presumption of innocence (regarding possession with intent to supply) below a certain quantity, but allows a degree of flexibility for police/prosecutors/courts above it, is a better approach. Any thresholds, even guidelines, should be set high enough to minimise risks of people in possession for personal use being found guilty of intent to supply. Threshold systems or related guidelines should be easy to understand for both individual users and enforcement authorities (see above).[137]
- Should include decriminalisation of cultivation of small amounts of plant-based drugs, for example *Psilocybe* mushrooms or San Pedro cactus, for personal use within the definition of possession for personal use in relation to any guideline thresholds (similar provisions have already been made for cannabis in multiple jurisdictions).

136 Removing an offence altogether rather than removing only the criminal sanctions is more accurately described as legalisation, but we do not use the term here to avoid confusion with legalisation in the context of supply — as it is more commonly used.

137 For more discussion on possession / supply thresholds see: Transform Drug Policy Foundation, México Unido Contra la Delincuencia (2018), Quantity thresholds for drug possession and supply offences https://transformdrugs.org/publications/thresholds-briefing-2018-mucd-transform

- Should include decriminalisation of small scale, non-transactional or not-for-profit supply among friends or peers.[138]
- Should include automatic and permanent deletion of all criminal records or convictions (also known as expungement) relating to historic offences no longer deemed to be offences, and automatic resentencing provisions for those who remain imprisoned under the former offences.[139]

Implementation and political strategy

There is an open question around the sequencing of decriminalisation of possession/cultivation/use, and legalisation and regulation of drug production and supply — which will be resolved only at a local level depending on the political environment.

If decriminalisation is not already in place, there is no practical reason why decriminalisation and legalisation cannot happen at the same time, as happened with cannabis in Canada, for example. If the political commitment to both reforms has been secured, this is certainly preferable. However, while decriminalisation is a prerequisite for legal regulation, the reverse is not the case, and it seems likely in many contexts that a staged process will occur, even if sub optimal, with decriminalisation happening first. The process of decriminalisation itself may also be incremental.

Such change may be shaped by the domestic political environment, but decriminalisation has generally commanded wider public and institutional support than legalisation and regulation. If decriminalisation becomes politically viable while legalisation and regulation is not, then the pragmatic position should be to make the move. Any reduction in the harmful criminalisation of people who use drugs is welcome, and can help create space for a more sensible discussion on legal regulation, preparing the ground — both politically and institutionally — for further reforms (*See:* Psychedelic exceptionalism, p.24)

138 To note, some supply offences would still exist in this context but would be covered by other existing laws, for example, supply to a minor, poisoning, etc.

139 See section 3.a. in Rolles, S., Slade, H. (2022), *How to regulate cannabis: A practical guide* (Transform Drug Policy Foundation) https://transformdrugs.org/assets/files/PDFs/How-to-Regulate-Cannabis_3rd_ed.pdf

Model 1: Private use, including home cultivation, foraging and not-for-profit sharing

The consumption of psychedelics, as well as the personal cultivation and foraging of plant-based psychedelics, are all behaviours that take place almost exclusively in the private sphere, and exist largely outside of the realm of formal regulation. While the state has a responsibility to provide health and risk information and encourage responsible choices and safer use, there is little more it can, or arguably should, do in this context.

A comprehensive decriminalised model would specifically include removing criminal sanctions for:

- Foraging (excluding peyote, and other endangered or protected species in particular regions, *see:* Peyote and conservation protections, p.72)
- Small-scale cultivation of plant-based psychedelics for personal use
- Small-scale, not-for-profit sharing

In the absence of regulated supply, such an approach — sometimes prosaically referred to as a *Grow, Gather, Gift* model — would not only remove the threat of criminalisation from people who use psychedelics, but would additionally provide a legal avenue, albeit quite limited, for access to plant-based psychedelics through private, non-commercial community or person-to-person networks.

A precedent for such a model is provided by some cannabis decriminalisation approaches which allow for, or at least nominally tolerate, small-scale cultivation within the decriminalised personal possession threshold. *Psilocybe* mushrooms are likely to make up the majority of cultivation and foraging activity for plant-based psychedelics.

Decriminalising personal possession, cultivation and foraging inevitably raises a series of questions around the parameters that define personal use and not-for-profit sharing, and how activities beyond these parameters would be addressed. The key aim of any personal use and possession thresholds would be to limit the potential for unlicensed secondary commercial sales. We would suggest that any enforcement

Psilocybe mushroom growing kit PHOTO: Steve Rolles

(and related sanctions) should focus on such commercial activity itself, rather than establishing arbitrary and historically problematic possession thresholds.[140] If thresholds are adopted they should default towards higher values, acknowledging the nature of foraging seasons and cultivation/harvest cycles, the significant variation in consumption behaviours, any allowance for not-for-profit sharing, and the difficulties in assessing quantities of psychoactive drugs in plants and their various preparations. Broadly defined guideline thresholds for law enforcement are preferable to fixed or binding thresholds.

Where psychedelics are supplied by one individual to another in the form of a transactional exchange, either in the context of retail sales or administration in some form of guided or supervised setting, then such a transaction and/or supervised administration should be subject to a level of regulation to minimise risks and harm (*See:* Membership-based not-for-profit associations, p.73, Flexible licensed psychedelic production and retail adaptable to different products and environments, p.77, and Regulation of commercial guided or supervised psychedelic use, p.101).

As previously mentioned, while it is likely that the majority of home cultivation will be for *Psilocybe* mushrooms (due to the higher prevalence of use, and ease of cultivation), individuals will also seek to cultivate cacti for mescaline use, as well as DMT-containing plants.

140 For more discussion on quantity threshold issues see: Transform Drug Policy Foundation, México Unido Contra la Delincuencia (2018), Quantity thresholds for drug possession and supply offences https://transformdrugs.org/assets/files/PDFs/quantity-thresholds-for-possession-briefing-2018.pdf

Grow kits for non-psychoactive mushrooms, and mushroom-growing media are already widely available and unlicensed. Sales of *Psilocybe* mushroom spores (used to cultivate the fungi when added to an appropriate growing medium) should be permitted and unlicensed for retail for private cultivation but would reasonably require adult-only age restrictions. However, growing kits already inoculated with *Psilocybe* spores should not be available for sale without licence — given the challenges of determining when psychoactive content would be meaningfully present. As with cannabis growing equipment, even if controls exist over sale or distribution of the cultivated plant, in this case fungi, controls over growing kits that have legitimate other uses are not practical, even if they were justified. Further, regulatory controls on spores/seeds, such as age access limits, may require a bespoke legal mechanism, since they do not contain any active drug content that would engage wider drug-specific regulations.

The San Pedro and peyote cacti are both already available for sale for ornamental garden use in many parts of the world and are not generally subject to domestic legal enforcement on sales, even where nominally prohibited. They are also not controlled under the UN drug conventions, despite the extractable psychoactive components they contain being subject to Schedule I prohibitions (*See:* Psychedelics and the UN drug treaties, p.107). San Pedro grows relatively quickly and is an easy cacti species to care for, which makes it a more popular candidate for home cultivation and use. Peyote, on the other hand, is relatively expensive although, in contrast to growing in the wild, cultivated plants can grow and mature considerably faster.[141] Nevertheless, for both cacti it still takes at least three years before they mature, which is a significant time commitment for a harvest.

Given the small market and psychedelic consumption niche these cacti occupy in their natural plant form, there seems little compelling reason to bring them under additional controls, unless they begin to be grown for production and sale at a much larger scale for drug products, whether for extraction of mescaline, or semi-prepared plant-based mescaline products. If this happens, production and products would need to be appropriately licensed in a similar way to *Psilocybe* mushrooms. Other, currently more niche plant-based psychedelics may present different challenges, such as plants containing DMT (*See:* Ayahuasca, p.86).

141 Stork, C.M (2023), Peyote — Reference Module in Biomedical Sciences, *Elsevier* https://doi.org/10.1016/B978-0-12-824315-2.00865-4

Peyote and conservation protections

The peyote cactus, a small button-like cactus containing mescaline, which grows in parts of Texas in the United States and in Mexico, has been a focus of discussions in psychedelic reform movements, especially in the United States. It is the sacramental plant of several Indigenous communities of Mexico (including the Wixárika, Nayeeris and Chichimecas among others) and of North America (such as the Sioux or Lakota, Cherokee and Apaches).142 It is also a religious sacrament for members of the Native American Church (NAC) which exists in the United States, Canada and Mexico; in the United States, members of the NAC are permitted through religious exemption to use peyote in their ritual practice.[143]

However, a recent wave of reform focusing on the decriminalisation of plant-based psychedelics has, in some cases, included peyote.[144] This has led some Indigenous American communities, who have been excluded from discussions on reform, to sound the alarm, concerned for the environmental vulnerability of peyote and the threat to its future use as a sacrament in the Church's ritual practice. Under both US federal law and Texas state law, only members of the NAC are currently permitted to legally acquire, possess, use and transport peyote.[145] Licensed peyoteros harvest peyote and sell it to members of the NAC who travel from all over North America to Texas to purchase.

The cactus was placed on the red list of threatened species by the International Union for Conservation and categorised as vulnerable in 2013 with drastic population reduction reported in the Mexican state of Coahuila and southern Texas.[146] There are fears that reform movements to decriminalise possession of plant-based psychedelics including peyote will lead to increased harvesting of peyote by individuals outside of the Native American Church, putting further strain on its population. Even with use limited to NAC members, peyote is suffering from depletion in the wild due to a combination of habitat loss, poor harvesting practices and illegal harvesting.[147]

It takes up to 15 years for peyote to mature in the wild, and best practice suggests waiting at least eight years between harvests to allow proper regeneration. Legal access to

142 ICEERS, Peyote: Basic Info, Accessed: 20th June 2023 https://www.iceers.org/peyote-basic-info/

143 Exempted by US Federal Government, Title 21 CFR 1307.31 https://www.ecfr.gov/current/title-21/chapter-II/part-1307/subject-group-ECFR68c82f2ca866120/section-1307.31

144 Labate, B., Feeney, K., Decriminalize Nature Targets peyote: Drug Reform or Settler Colonialism?, *Chacruna*, 1st July 2022 https://chacruna.net/decriminalize_nature_drug_reform_settler_colonialism/

145 Hausfeld, R., Native American Churches request that peyote not be included in decriminalisation initiatives, *Psymposia*, 16th March 2020 https://www.psymposia.com/magazine/nac-peyote-decriminalization/

146 Schwertner-Charão L., Delgado-Martínez, R., Treviño Carreón, J. *et al*. (2022), Interactions between facilitator species and Lophophora williamsii (Lem. ex Salm-Dyck) J.M.Coult (Cactaceae) in a rosetophyllus desert scrub in México *Journal of Arid Environments* 205 https://doi.org/10.1016/j.jaridenv.2022.104824

147 Hausfeld, R., Native American Churches request that peyote not be included in decriminalisation initiatives, *Psymposia*, 16th March 2020 https://www.psymposia.com/magazine/nac-peyote-decriminalization/

foraging wild peyote should not be expanded beyond current allowances for the Native American Church on the basis of its ecological vulnerability and the spiritual significance of peyote growing in ancestral gardens.

Lophophora williamsii (peyote)
PHOTO: Peter A. Mansfield

However, peyote should be protected under conservation laws rather than via punitive drug laws (*See:* Decriminalisation, p.66). Protections are already in place: in Mexico peyote is classified as a species for special protection through the Official Mexican Standard; and is listed by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). [148] The pressure on the peyote population could further be alleviated by supporting habitat preservation to both protect and help regenerate numbers. Groups have already been working on regeneration, setting up nurseries to cultivate peyote which they can then replant in the wild. The Cactus Conservation Institute is one such initiative which is working to repopulate ancestral peyote gardens in Texas without interfering with use by the Native American Church. [149] Commercial cultivation of peyote may also reduce the pressure on the wild peyote population in the future by providing a sustainable point of access to people not using peyote within these ritual settings.

Model 2: Membership-based not-for-profit associations for plant-based psychedelics

The not-for-profit association model (also known as collectives, or co-operatives when operating under group ownership) for cannabis emerged in Spain around 2001, where the decriminalised status of small-scale cannabis cultivation for personal use was stretched to incorporate collective growing and sharing of cannabis within not-for-profit membership-based Cannabis Social Clubs (CSCs).[150] These operate as private, non-profit organisations in which cannabis is collectively grown and

148 Secretaría de Gobernación, Anexo Normativo III — Lista de especies en riesgo (NOM-059-SEMARNAT-2010), 14th November 2019 https://www.dof.gob.mx/nota_detalle.php?codigo=5578808&fecha=14/11/2019#gsc.tab=0; CITES, CITES and Cactis: An introduction to cacti covered by the Convention on International Trade in Endangered Species https://www.kew.org/sites/default/files/2019-09/CITESandCacti_full.pdf

149 Cactus Conservation Institute, Conservation Accessed: 1st July 2023 https://cactusconservation.org/conservation/

150 See Parés Franquero, Ò., Saiz, J. (2015), *Innovation Born of Necessity: Pioneering Drug Policy in Catalonia* (Open Society Foundations) https://www.opensocietyfoundations.org/publications/innovation-born-necessity-pioneering-drug-policy-catalonia

The cannabis social club model could be readily adapted or expanded to include plant-based psychedelics

distributed to registered members. With no profit motive to increase cannabis consumption or initiate new users, the clubs can offer a more public-health centred alternative to large-scale retail drug markets. Variations on the Spanish model have since been developed and adapted into legal frameworks in Uruguay and Malta, with similar proposals in development for reforms in Germany, Czechia, and Colombia.[151]

Although a relatively new and still-evolving model, cannabis social clubs represent a small-scale, *de facto* (Spain) or *de jure* (Uruguay, Malta) legal model of production and supply that has been demonstrated to work. Where problems have emerged, such as in Spain, these mostly relate to the entry of profit-seeking actors exploiting the lack of formal regulation.[152]

The CSC model brings specific benefits to association members, who have access to a legal supply within a safe and supportive community-based environment, allowing greater access to harm reduction education. Wider society benefits by the illegal market (and its associated problems) being undermined, while avoiding the risks of an over-commercialised retail market. It provides lessons that can inform the development of future regulatory models for other drugs, as well as offering a useful transitional model that policymakers can potentially implement within a decriminalisation framework before more formal legal production and retail systems are allowed.

The unusual evolution of the CSC model in Spain, an activist-led process of repeated strategic litigation, has meant that the Spanish CSCs remain unlicensed, operating only within an informal set of community guidelines and parameters established by case law. This is despite efforts by activists and some regional governments to establish a formal regulatory framework for the CSCs.[153] Uruguay, by contrast, has established a formally licensed and regulated not-for-profit association model, alongside a licensed pharmacy retail cannabis model, licensed home growing, and prescription medical provision, usefully demonstrating how multiple drug

151 At the time of publication

152 Parés Franquero, Ò., Saiz, J. (2015), *Innovation Born of Necessity: Pioneering Drug Policy in Catalonia* (Open Society Foundations) https://www.opensocietyfoundations.org/publications/innovation-born-necessity-pioneering-drug-policy-catalonia

153 *Ibid.*

supply options can exist in parallel.[154] In Malta's cannabis model, by contrast, the membership-based not-for-profit associations are the only formal source of cannabis for non-medical use, alongside decriminalised small-scale home growing provisions.[155]

Changa containing DMT, for smoking
PHOTO: Dominic Milton Trott

Some form of this model may be useful if international legal obstacles preclude establishment of a formally regulated retail market, something that will be required in the long term in most countries to ensure fair access. This constraint, for example, is currently shaping how legal non-medical cannabis access in the EU may look, moving towards a membership-based not-for-profit association model (*See:* Psychedelics and the UN drug treaties, p.107).

The cannabis social club model could be readily adapted or expanded to include plant-based psychedelics. Under a not-for-profit association model:

- The products supplied would be limited to plant-based psychedelics.[156] Associations would likely focus on fresh, dried, or modestly processed *Psilocybe* mushrooms, but the cultivation of other plant-based psychedelics such as the San Pedro or peyote cactus for mescaline, or plants containing DMT, would also work within this model — even if these are likely to be more niche.
- Associations would be licensed by a centralised drug regulatory authority (*See:* below) and operate on a not-for-profit basis.
- Individual local home-growing allowances are pooled to one or more growers who would then cultivate this allowance on behalf of association members and supply them from what is harvested.
- Supply is only available to association members; no commercial sales are permitted. These members would have access to a maximum amount over a given period (determined by the drug regulatory authority licensing arrangements) to reduce perceived or actual risk of secondary sales.

154 Transform Drug Policy Foundation (2018), Cannabis legalisation in Uruguay: Public health and safety over private profit https://transformdrugs.org/blog/cannabis-legalisation-in-uruguay-public-health-and-safety-over-private-profit

155 *See:* Maltese Authority for the Responsible Use of Cannabis https://aruc.mt/

156 In the first instance, no synthetic preparations, such as LSD, would be available, although this could be considered at a future point when the model is better established.

Strict rationing may not be as necessary for psychedelics as it is for cannabis due to their comparatively lower frequency of use and lower association with dependency.

- The vendors dispensing the products in the associations should be subject to the same administrative and training requirements as retail vendors (*See:* Training requirements and responsibilities of vendors, p.97).
- The association could potentially provide supervised or guided psychedelic experiences for members, or preparation or integration sessions. In this scenario they would be subject to the same controls as other commercial service providers (*See:* Regulation of commercial guided or supervised psychedelic use, p.101).
- Import permits could be granted for social clubs providing supervised or guided psychedelic experiences, such as the import of ayahuasca components. These could be done in partnership with Indigenous communities or associations cultivating the plants (*See:* Ayahuasca, p.86).
- Membership numbers should be limited. In Uruguay the cannabis clubs are limited to 100 members, in Malta they are limited to 500. The frequency of consumption, amount consumed and, therefore, accessing of clubs is likely to be much lower for psychedelics than cannabis, so membership numbers could potentially be higher. Limits on membership should be balanced against the need to ensure equitable access.
- Care should be taken to ensure fair access for all groups in society, with rules preventing discriminatory membership criteria.
- Provision of specific support to set up associations should be ensured for groups who have been historically more marginalised (*See:* Embedding social justice, equity and human rights into policy design, p.51).

Model 3: Flexible licensed psychedelic production and retail adaptable to different products and environments

As a baseline, some degree of regulation is needed over any products for human consumption. For drugs with potentially profound effects and non-trivial risks, which certainly describes the psychedelic drugs under discussion here, any form of retailing will require a bespoke regulatory response. This will be over and above standard forms of consumer protections and trading standards, familiar for more conventional consumer goods. This must naturally include established trade description protections and producer/vendor liability so consumers can be confident they know what they are buying, with access to accurate information on content, dosage, effects and risks to facilitate informed decision making.

Transform has considered models for regulated retailing for cannabis, MDMA, cocaine and amphetamines in some detail in recent publications.[157] These recommendations erred towards stricter forms of regulation as a starting point, while maintaining flexibility to relax some controls going forward, based on careful outcome monitoring. This is partly a precautionary principle, noting that even the most thoughtful scenario-modelling may not capture every eventuality, and a more cautious starting point will also help assuage political and public concerns and wariness. It is also partly an acknowledgement that it is easier to relax too-strict regulations, than to impose new ones on an entrenched but inadequately regulated market.

The levels of risk associated with psychedelics justifies a licensing system for all retail vendors. The general principle that higher-risk products justify a higher level of intervention applies to psychedelics as much as to any drug, i.e., certain types of preparations or higher dosage preparations should be subject to stricter controls and, over a certain risk threshold, retail prohibitions may be justified.

The comparatively low levels of risk associated with most psychedelic use (*See:* Overview of key risks of psychedelic use and their policy implications, p.44) places them nearer to cannabis in terms of regulatory thinking about

157 Rolles, S., Slade, H. (2022), *How to regulate cannabis: A practical guide* (Transform Drug Policy Foundation) https://transformdrugs.org/publications/how-to-regulate-cannabis-3rd-ed;
Rolles, S., Slade, H., Nichols, J. (2020), *How to regulate stimulants: A practical guide* (Transform Drug Policy Foundation), https://transformdrugs.org/publications/how-to-regulate-stimulants-a-practical-guide

For drugs with potentially profound effects and non-trivial risks, which certainly describes the psychedelic drugs under discussion here, any form of retailing will require a bespoke regulatory response

possible retail models. For example, Transform's "standard model" proposed for stimulants makes a strong case for state monopoly retailing to mitigate specific concerns around corporate profiteering and marketing of those drugs, such as cocaine, with a greater risk of potentially harmful high frequency or dependent patterns of use. For psychedelics, the possibility of state monopoly retailing remains an attractive option, particularly at the early stages of legal market access, but not essential.

One can see how higher potency cannabis concentrates may justify a higher degree of regulation than lower potency herbal cannabis, just as distinctions need to be made between coca leaf, cocaine powder, and crack cocaine, or between beverages with different levels of alcohol content. For psychedelics too, certain riskier preparations justify stricter regulation, or even retail prohibitions (for example, intravenous preparations), while lower-risk psychedelic preparations, such as dried *Psilocybe* mushrooms, could be available at a lower regulatory threshold (*See:* A case for lower threshold access to *Psilocybe* mushrooms, p.99).

In line with these general regulatory principles, Transform proposes a licensed retail model overseen by a dedicated regulatory authority, with licensed production supplying licensed outlets, both physical and online, which can sell a range of preparations of psilocybin, LSD, DMT and mescaline to adults only. At the outset of a new retail market, the regulatory authority may licence a range of plant-based and synthetic products. A review process will examine proposals from producers or consumers for new product licences (such as different product preparations) reflecting market evolution, product innovation, or a shift in consumer demand or consumption behaviours.

Below is a general proposed framework for the licensed production and retail of psychedelics that includes a degree of flexibility to accommodate different products, retail environments and risk behaviours.

Overarching regulatory system

In most respects the challenges of licensing the production and retail of psychedelics are similar to those for other recreational or medical drugs. However, while the broad principles and institutional systems are similar, the details will often differ. A dedicated psychedelics regulatory authority should be established. Given the overlap of markets for different drugs, potential for overlapping ownership of production, distribution and retail of different drugs, and shared issues around regulating newly legalised drugs in particular, a regulatory authority should sensibly be a division within a wider drug regulatory authority perhaps operating within the health department. Managing interdepartmental work with other agencies as appropriate — such as enforcement and tax — the authority would be responsible for regulating psychedelics, as well as other drugs which are used non-medically including alcohol, tobacco and cannabis. This creates certain efficiencies in the use of existing expertise and the deployment of shared resources to help avoid unreasonably high application and licensing fees.

Care, however, must be taken to ensure that this leads to a race to the top, not the bottom, in drug regulation. In many countries (including the UK) tobacco and alcohol are, or have been, very poorly regulated, with responsibilities divided between multiple agencies. Historic and current corporate capture by the alcohol industry, in particular, is still leading to public health issues being marginalised.

Tasks of a new psychedelics regulatory authority would include:

- Establishing the parameters of the new regulatory framework, including specifying what products could be produced and sold, setting and enforcing rules/standards for not-for-profit membership associations, and setting training standards and licensing/enforcement of service providers in supervised settings.
- Issuing licences for production and sale of psychedelic drug products (some responsibilities could be devolved to local/regional authorities depending on the size of the jurisdiction).
- Inspection and enforcement of licence conditions (potentially working with other agencies where relevant, such as trading standards, health and safety inspectorates, customs, police, etc).
- Monitoring, evaluation and review of the regulatory framework (adapting and updating regulations in response to emerging evidence).

Production controls

Retailed psychedelic products would be cultivated (plant-based) or manufactured (synthetic), processed, packaged and supplied by companies, or other legal entities, in accordance with their licence conditions for production standards, quality control, dosage, packaging and labelling requirements.

For production of synthetic and extracted psychedelic products, such as LSD, DMT and mescaline, quality control standards could be determined by the regulatory authority and should operate under best practice frameworks to include (among others): quality checks, sanitation and hygiene, inspection of raw materials and registration of active substances, cross-contamination mitigation, accurate labelling, and regular manufacture inspections and audits. These standards could be modelled on Good Manufacturing Practice (GMP) guidelines without necessarily having to meet the exacting standards of pharmaceutical medicine production which would potentially be prohibitively expensive.[158] Existing regulatory frameworks such as those used for herbal medicines, supplements or foods could be used or adapted for plant-based psychedelic products. Ultimately, regulation standards must control restrictions on claims being made on the product, safe manufacturing practices, e.g. no toxic contaminants being used in production, adequate packaging and labelling, etc.[159]

Production of fresh and dried (prepared) *Psilocybe* mushrooms does not differ significantly from production of other mushrooms used for food, herbal medicines or supplements — so there are no particular novel challenges here. These controls could be extended and adapted in response to an ongoing review process.

Product controls

Risk to the user can be profoundly shaped not just by the type of drug taken but also by the drug preparation, personal variables of the consumer (including age, weight, and pre-existing health issues) and consumption behaviours (frequency of use, dosage, mode of use, polydrug use, using environment, etc.). Regulated, clearly labelled products, sold by licensed and trained vendors, will reduce these risks by

158 See, for example, the European Medicines Agency good manufacturing practice guidelines https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice

159 See for example, the European Medicines Agency guidelines for herbal medicinal products, https://www.ema.europa.eu/en/human-regulatory/herbal-medicinal-products

ensuring consumers have accurate information on what they are consuming and the associated risks and harm reduction.

Preparation

Psychedelic drugs come in a range of preparations that require different degrees and types of control. For synthetic or extracted LSD, mescaline, DMT and psilocybin, the primary preparation would be a pill form for oral use. DMT in pill form would need to be combined or taken in combination with an MAO inhibitor to become active for oral use.[160]

The regulatory authority may additionally consider other product preparations, and means of delivery, on a case-by-case basis. As synthesised DMT has most commonly been smoked rather than taken orally, there may be an imperative to develop safer products based on vaping technology which enable inhaled use while avoiding the respiratory risks of heat and combusted material. DMT vape products have already been informally developed for the illegal market. Any licensed vape products would require bespoke regulatory controls to address the specific challenges of such technologies.[161]

Psychedelics in liquid-dropper form, most notably with LSD, have proven a popular preparation in some illegal markets. Concerns around such products have focused on the problems in delivering uniform units, which makes dosage inconsistent.[162] Regulators may reasonably lean towards limiting oral synthetic preparations to pill form, at least in the early stages of a market roll out. If, however, liquid forms are adopted, care should be taken to ensure bottle/pipette designs allow precise calibration. Similarly, where market demand already exists for extracted tinctures of *Psilocybe* mushrooms, there may be a case for licensing an appropriately dose-calibrated tincture product.

Plant-based products would be sold in standardised units by weight (this would be dependent on the species and its percentage of psychoactive drug per

160 Although strictly not to be marketed as an ayahuasca pill, see discussion on pp.86-88.

161 For some relevant discussions see 'How to regulate electronic cannabis delivery systems', p.166 in Rolles, S., Slade, H. (2022), *How to regulate cannabis; A practical guide*, (Transform Drug Policy Foundation) https://transformdrugs.org/publications/how-to-regulate-cannabis-3rd-ed

162 Jackson, R. L. (2021), "The Uncertain Method of Drops": How a Non-Uniform Unit Survived the Century of Standardization, *Perspectives on Science*. 29(6) https://direct.mit.edu/posc/article/29/6/802/107113/The-Uncertain-Method-of-Drops-How-a-Non-Uniform

gram) — packaging and vendor-supplied information on dosage and effects, and risk management would then relate to these units. For plant-based psychedelics, it is likely that most of the market will focus on *Psilocybe* mushrooms as they are appealing to a wider range of consumers, comparatively inexpensive and easy to grow, can be consumed unprocessed, and the margin of error for mis-dosing is lower than, for example, LSD when given basic product information (*See:* A case for lower-threshold access to *Psilocybe* mushrooms, p.99).

Fresh mushrooms are generally more potent than the dried equivalent (as the active psilocybin content breaks down), but the variable water content of fresh mushrooms also results in broader dosage ranges than the dried equivalent, increasing risks of misdoing based on weight. Labelling on potency would need to be calibrated accordingly, for which dried mushrooms present a lower regulatory burden. Dried mushrooms also reduce other risks associated with fresh plant products, such as mould or spoiling. Regulators might, therefore, wish to opt for the retail of dried products only. The same will be the case for San Pedro and peyote cactus although these are not as practical or as common to consume unprepared as mushrooms. It is likely consumers purchasing from a regulated market will prefer extracted or synthesised mescaline in pill form to avoid the unpleasant experience of consumption — particularly if their motivations are not connected to ritual practice.

People will naturally seek ways to consume *Psilocybe* mushrooms in more palatable forms than unprocessed fresh or dried plant matter. Indeed, mushroom edibles, such as infused chocolates or honey, or in beverages such as mushroom tea, are already popular in different informal markets. The reality of current preferences for mushroom-based edibles in the illegal market raises a series of regulatory and policy challenges in the context of any legal retail markets. It is important to look at the lessons from emerging markets for cannabis-infused edibles in North America, where regulation has often had to play catch up with rapidly expanding demand and commercial market product innovations.

A serious concern exists around accidental poisonings, where people mistake drug-infused edibles for conventional food products. This has been a particular issue regarding cannabis-infused confectionaries (e.g., brownies or gummies) that are naturally attractive to children. In jurisdictions where such products have become more available in the regulated market, there has been a fairly consistent rise in reports of accidental paediatric ingestions (even if numbers remain small compared

to other forms of accidental poisonings, and rarely lead to serious complications).[163] Reports suggest a similar, albeit smaller scale, rise in accidental paediatric ingestions from mushroom infused edibles has occurred where such products have become more available on informal markets.

A strong case can be made for avoiding retail availability of psychedelic-infused edibles, particularly those in the form of confectionery

A strong case can therefore be made for avoiding retail availability of psychedelic-infused edibles altogether, particularly those in the form of confectionery. Such restrictions have been put in place regarding cannabis-infused edibles in some legal cannabis jurisdictions.[164] As a minimum standard child resistant packaging and prohibiting any marketing, packaging or branding attractive to children or resembling confectionery products should be a requirement (*See:* Packaging, p.91). If fresh or dried mushrooms (and other plant-based psychedelics) are available, people can, of course, prepare them for consumption however they wish.

Preventing sales of infused edibles or beverages may seem overly restrictive but given the practical challenges evident with regulating cannabis edibles and the political vulnerabilities associated with a likely increase in accidental poisonings, it is not a disproportionate precaution. This is especially the case when the contours of a legal access model are still being established and given the fact that edibles/beverages are still easily prepared for private use.

The availability of dried *Psilocybe* mushrooms in powder form (in carefully dosed pills, for example), or extracted into a tincture with a clearly dose-calibrated pipette dropper, are other options for licensed products that would offer a more easily palatable product, while avoiding the pitfalls of infused edibles that are attractive to either small children or adolescents. Provision of psychedelics in a prepared edible form for consumption within a guided/supervised experience (*See:* below) may also not be problematic if certain precautions are taken on dosage, preparation, storage, etc.

163 Manthey, J. et. al. (2023) Technical report: Effects of legalizing cannabis, *Institut für interdisziplinäre Sucht- und Drogenforschung* https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Drogen_und_Sucht/Abschlussbericht/ECaLe_Technical_Report.pdf

164 See: Gouvernement du Québec, The Cannabis Regulation Act, Accessed: 16th August 2023 https://encadrementcannabis.gouv.qc.ca/en/loi/loi-encadrant-le-cannabis/

Flexible licensed production and retail model for psychedelics: Summary table

For more detail *see*: Model 3: Flexible licensed psychedelic production and retail, p.77

Overarching model

- Licensed companies would produce psychedelic products in accordance with parameters established by a dedicated drug regulatory authority.
- Retailers licensed by the regulatory authority would purchase psychedelic products from licensed producers and sell in specialised outlets.

Note: Parallel regulatory systems would be in place for the decriminalisation of private use, including home cultivation, foraging and not-for-profit sharing; membership-based not-for-profit associations for plant-based drugs; and commercial guided or supervised use (see relevant chapters)

	LSD 	DMT 	Mescaline 	Psilocybin 
Production	LSD produced under licence	Synthetic/extracted DMT products produced under licence	Synthetic/extracted and plant-based mescaline products produced under licence	Synthetic/extracted and plant-based psilocybin products produced under licence
Quality controls	• Controls of synthetic/extracted products would be adapted from best practice Good Manufacturing Practice (GMP) frameworks in pharmaceutical production • Controls of plant-based products would be modelled on equivalent frameworks for herbal medicines or food supplements e.g. no toxic contaminants in production, packaging and labelling requirements, etc.			
Preparation	• Pill form	• DMT preparation for vaporisation/ inhaled use • DMT in pill form with a Monoamine oxidase inhibitor (MAOI)	• Pill form (synthetic extracted) • Live plant or dried plant material	• Pill form (synthetic/ extracted/pressed dried mushroom) • Dried mushrooms
Dose (excluding microdose preparations)	• Threshold dose per pill (multiple, splittable pills for lower/higher dose calibration)	• Threshold dose per pill (multiple splittable pills for lower/higher dose calibration) • Dose-calibrated vape/inhalation products	• Threshold dose per pill (multiple splittable pills for lower/higher dose calibration) • Plant-based products dose-calibrated by weight	

	LSD	DMT	Mescaline	Psilocybin
Packaging	• Unbranded packaging with mandated/prominent content, strength, risk and harm reduction information • Tamper and child resistant packaging design • Environmentally sustainable materials			
Price	• Minimum Unit Pricing at the outset of a new market • No promotional pricing deals, e.g. buy one, get one free			
Outlet type	• Single function physical or online outlet for selling licensed psychedelic products • Options for a temporary/mobile licence for Psilocybe mushrooms sales at one-off events e.g. festivals • Options available for parallel sale of other consumer goods e.g. Psilocybe mushroom cultivation kits but excluding other drug sales, including alcohol			
Outlet location and density	• Locations of physical outlets would be determined by local or municipal authorities, operating within parameters established by the drug regulator (regarding maximum or minimum outlet density), or other restrictions (such as proximity to schools)			
Outlet appearance and signage	• Functional rather than promotional, with restrictions on external appearance and signage			
Respons-ibilities for vendors	• Enforcement of regulatory controls including age access, no sales to intoxicated persons, and purchase quantity limits • Provision of printed, in-person, or live online health and harm reduction information to purchasers at point of sale			
Vendor training requirements	• Accredited training to implement screening for risk vulnerabilities and offer tailored health and harm reduction information and advice to consumers, including referral to relevant drug/support services			
Age of purchaser	• Minimum age determined by jurisdiction, but no younger than 18			
Quantity sales restrictions	• Sales would be restricted to quantities for personal use, but with a high threshold to account for variation in consumption needs/behaviours			
Premitted locations for use	• Issues relating to consumption/use in public spaces should be addressed using existing (or appropriately amended) legislation covering public intoxication, or antisocial behaviour • Consumption could be formally tolerated in certain commercial social spaces (for example in clubs or at festivals/events) even if psychedelics were not available for sale — with accompanying specialised staff training and welfare services			
Advertising	• No marketing, branding or promotional activity for retail or online outlets beyond functional availability and price information for adult customers. Strictly no medical claims			

Ayahuasca

Ayahuasca brew PHOTO: ICEERS

Ayahuasca is the name of a traditional brewed preparation (technically a *decoction*) of two or more plants, which has been used for millennia as part of traditional ceremonial and spiritual rituals by Indigenous communities in the Amazon basin. It can include the DMT containing plants *Psychotria viridis* or *Diplopterys cabrerana* (among others), brewed in combination with other plants such as the *Banisteriopsis caapi* vine which contains MAO inhibiting harmala alkaloids which prevents DMT from being broken down in the body and so facilitates its psychoactive effects when consumed orally. [165] There are a range of preparations with different names and ingredients used by different groups in the region (including Caapi, Dápa, Mihi, Kahí, Natem, Pindé, Yajé, Daime, and Vegetal).

In the 20th century, a number of ayahuasca churches emerged in Brazil including the Santo Daime, the União do Vegetal (UDV), and Barquinha. ICEERS describes the churches as "syncretic religious sects that combine shamanic, esoteric, spiritualist and Christian elements, among others, around the ritual use of ayahuasca, daime or hoasca, as the drink is called in these settings." [166] They have an estimated 30,000 members and have expanded branches across the Americas and in Europe (*See:* Protection for religious and Indigenous use, p.56).

More recently, ayahuasca ceremonies have attracted rapidly growing interest in the Global North, with increasing numbers participating over the past decade, either by travelling to traditional communities — a form of "shamanic tourism" — or participating in ceremonies run by travelling traditional Amazonian shamans, or others who have adopted versions of these traditional ritual practices.[167] Based on extrapolation from various fragmented data sources from the Americas, Europe, Australia and New Zealand, ICEERS have estimated lifetime prevalence of ayahuasca use at over four million, with over 800,000 people using in 2019. Only 10% of the figure of four million are estimated to belong to Indigenous groups where ayahuasca is traditionally used. [168]

165 See: Mechanism of action in Laban, T., Saadabadi, A. (2022), Monoamine oxidase inhibitors (MAOI), *Stat Pearls Publishing* https://www.ncbi.nlm.nih.gov/books/NBK539848/

166 *Ibid.*

167 ICEERS (2020), *Ayahuasca in Spain: An evaluation of ayahuasca participants using public health indicators — Executive Summary* https://www.iceers.org/wp-content/uploads/2020/05/ICEERS_Ayahuasca_report_en-1.pdf; ICEERS, Health and Status of Ayahuasca — Ceremony Participants in the Netherlands Accessed: 1st June 2023 https://www.iceers.org/health-status-of-ayahuasca-ceremony-participants-in-the-netherlands/

168 ICEERS (2020), *Ayahuasca in Spain* https://www.iceers.org/wp-content/uploads/2020/05/ICEERS_Ayahuasca_report_en-1.pdf

This proliferation of ayahuasca ceremonies raises profound and difficult questions around potential appropriation of traditional Indigenous cultures. There are, however, also opportunities here for cultural exchange where non-Indigenous people who conduct ceremonies can learn from traditional shamans on the Indigenous people's terms. It is also notable that the expansion of ayahuasca into the Global North has occurred almost entirely within ceremonial contexts, with the benefit maximising/harm reduction nature of traditional knowledge and practices significantly preserved in ways not seen with, for example, the historic export of other psychoactive substances such as coca, cacao, tobacco, or *Psilocybe* mushrooms. A more detailed exploration of these issues is beyond the scope of this discussion, although related issues around development and equity, and religious and Indigenous rights are explored elsewhere (*See:* Embedding social justice, equity and human rights into policy design, p.51).

The reality of significant existing use, and growing demand for participation in ayahuasca ceremonies does, however, require a policy response. Viewed through a regulatory lens, ayahuasca is particularly challenging. Its precise composition and ingredients vary between Indigenous cultures, and individual shamanic preparations, making it intrinsically difficult, if not impossible, to standardise in the way that for example *Psilocybe* mushrooms can be. Indeed, Western concepts of standardised products and regulatory institutions are fundamentally at odds with the deeply embedded traditional cultural context of ayahuasca ceremonies which is indivisible from the brew itself for the Indigenous communities who practise with it.

The ayahuasca experience is also more associated with physical effects than other psychedelic preparations (although these effects, commonly involving vomiting, are understood as an intrinsic part of the experience) and one that responsible users and guides understand to require minimum standards of preparation, guidance, and supervision.[169] The ICEERS publication *Towards Better Ayahuasca Practices: A guide for Organizers and Participants* offers a useful example of such guidance, providing "a series of minimum safety standards to support ayahuasca sessions in non-Amazonian contexts, as well as to inform prospective participants of ayahuasca sessions so that they can better assess the safety and responsibility of the sessions in which they are going to participate, and thus make an informed choice." [170]

169 ICEERS (2019), *Towards better ayahuasca practices: A guide for organisers and participants* https://www.iceers.org/wp-content/uploads/2020/05/Guia-ayahuasca_eng_30.09.19.pdf

170 ICEERS (2019), *Towards better ayahuasca practices: A guide for organisers and participants* https://www.iceers.org/wp-content/uploads/2020/05/Guia-ayahuasca_eng_30.09.19.pdf

Despite the physical effects, research shows the risks of ayahuasca use are relatively low and suggests there's no reason not to include it in a regulated guided experience model as proposed below.[171] Organisers should reasonably be expected to have specific training to supervise ayahuasca experiences (group or individual) and screen for vulnerabilities such as physical or mental health issues, pregnancy, and contraindications with certain medications, notably SSRIs (*See:* Overview of key risks of psychedelic use and their policy implications, p.44). As discussed in the commercial guided or supervised use model, traditional shamans could potentially practise ayahuasca ceremonies without having to complete supervised use training. However, in the absence of a relevant practitioner licence, a shaman or other traditional guide should practise in the presence of a licensed practitioner/supervisor. This is not to question the traditional knowledge of Indigenous practitioners but rather is a reasonable form of regulatory oversight to protect against the risk of inadequate safety standards or bad actors. The idea of shamanic "accreditation" is another Western construct that cannot easily be imposed on diffuse Indigenous cultural knowledge.

It does, however, seem hard to envisage the regulated supply of ayahuasca outside of some form of appropriately supervised ceremonial context. In a Western commercial environment, the suggestion of a pre-prepared retail ayahuasca product for general sale would represent a profound misunderstanding of, and affront to, its Indigenous cultural meaning. The absence of IP protection on the traditional preparations (and language) may make attempts at marketing of such products inevitable in more commercially oriented emerging psychedelics markets and should be strongly resisted.

A synthetic DMT preparation for oral use in pill form (with an MAO inhibitor, taken either in combination or separately) seems an inevitable innovation, but such a pharmaceutical product should not be associated with, or sold as ayahuasca (or related terms) in any way. As an indicator of looming problems, a Canadian company has, controversially, already produced what it has described as an "ayahuasca pill", reported to be based on a full-plant extraction of alkaloids from the *Psychotria viridis* and *Banisteriopsis caapi* vine.[172]

Dosage

Poor understanding of dosage and its related drug effects is a risk factor in itself, as is the unknown and unpredictable potency of some drugs and preparations. A harm

171 See, for example, Bouso, J.C., Andión, Ó., Sarris, J. et. al. (2022), Adverse effects of ayahuasca: Results from the Global Ayahuasca Survey, *PLOS Global Public Health* https://journals.plos.org/globalpublichealth/article?id=10.1371/journal.pgph.0000438

172 Leite, M., Canadian Company Announces Ayahuasca Pills, *Chacruna*, 22nd December 2022 https://chacruna.net/canadian-company-announces-ayahuasca-pills/

reduction approach should ensure that people who use psychedelic drugs have accurate knowledge of the dosage being consumed, and the nature of the effects they are likely to experience, including how rapidly it will be felt, how long it will last, and its intensity.

All psychedelic products available for sale should therefore be sold in standardised dosage units, with a single unit set at the threshold perceptual dosage, allowing multiples or increments in dosing to be achieved.[173] Dosage and content information should be clearly set out on the packaging, alongside health, safety and harm reduction information (*See:* below). There would be a requirement for trained vendors to also supply this information and related guidance (*See:* below).

Price

We know from alcohol and tobacco research that pricing is an important lever when it comes to shaping drug consumption behaviours. Price regulation, however, is a lower concern for psychedelics given their lower frequency of use and assumed lower price elasticity.[174]

Nevertheless, establishing some form of Minimum Unit Pricing (MUP) can serve as a sensible precaution to prevent psychedelic drugs being sold, for example, as a loss leader to get people into the shop or online store to buy other products (e.g. merchandise or drug paraphernalia), or as a way to put less well-resourced smaller competitors out of business (*See:* Preventing the emergence of monopolies, and mitigating risks of corporate capture, p.52).

Differential pricing could also be used to a limited extent to steer people towards less risky products or preparations, although given the bulk of the market will already be *Psilocybe* mushrooms this may be unnecessary. However, any MUPs must not be so high that they drive people back to cheaper, illegal supplies (or other more risky drugs) because the price premium ends up outweighing the benefits of regulated legal supply. Pricing structures should generally not be used to promote use; promotional deals and buy one, get one free type offers should not be allowed.

173 Microdosing products — not explored here — would need a different unit/dosage schedule.

174 Price elasticity of demand (PED) measures the responsiveness of demand after a change in price. e.g., if price increases by 10% and demand fell by 20%, then PED = -20/10 = -2.0. Some products show a steeper decline in demand for a given price rise than others. Psychedelics are thought to have a low PED i.e., price has to rise a lot to cause a significant reduction in demand. That is to say, reducing or raising prices will do relatively little to affect demand.

Packaging design proposal

Other elements (not visible) include: • braille content labelling • use-by dates • folded paper insert with detailed health information and harm rereduction advice

CREDIT: Nick Ellis, Halo, halostudio.love

Packaging

Packaging shapes our drug usage and purchasing decisions, from encouraging use (and brand switching or loyalty) to carrying health information and warnings for safer or reduced use. Potential models range from attractively branded labels without health warnings that appear on many alcohol products, to the functional designs of pharmaceutical products, or plain tobacco packs covered in graphic health warnings.[175]

Packaging for psychedelic drug products should involve plain packaging, devoid of promotional branding or other marketing, particularly anything that may appeal to children. Options could exist to have certification marks similar to Fairtrade accreditation in order to benefit social equity producers and retailers or sustainable cultivation practices. Design should be restricted to clear product and safety information in accessible language and simple graphics. Some may argue that plain packaging with prominent health warnings could negatively influence the expectations and mindset of the user, but this is ultimately a necessary requirement for a product that carries potential risks, and the alternative would be some form of design/branding that could influence them in other ways. Therefore, plain packaging with an emphasis on functionality is a reasonable default and does not preclude the consumer being able to transfer the product into their own preferred form of storage post-purchase.

Child-resistant, tamper-evident, sustainable packaging should be used with a requirement for secure storage in locked containers when in the retail store. Tamper-evident packaging contains a seal that makes it obvious if the container has been opened or otherwise tampered with (e.g., blister packs and other forms of sealed containers).

Where there is insufficient space for more than the key information on the packaging, inserts can be included (with online information also accessible via QR code), as well as information leaflets provided by vendors. Information should include:

Drug-specific information:

- Contents: Using both technical names and popular terms
- Dosage: Total active contents, and contents per unit (e.g., pill)

175 See UK example of regulations on tobacco packaging: Department of Health and Social Care((2016), Packaging of tobacco products https://www.gov.uk/government/publications/packaging-of-tobacco-products

- Use-by/best before dates, storage instructions and information on potency loss over time e.g., plant-based products such as mushrooms risk developing mould and losing potency more rapidly if not stored properly
- Safer methods of consumption, including information on set and setting (*See:* Set and setting, p.43)
- Key effects, including how long they will last, how quickly they are likely to begin, and what they will feel like
- Potential side effects, both physiological and psychological
- Likely different effects on different people by dosage (particularly according to body mass and levels of experience i.e., novice users)
- What to do in the event of an adverse experience, including when/who to call for advice
- A web link/QR code sign posting to online resources and harm reduction support

General risks:

- Risks of consumption when in combination with other non-medical or medical drugs
- Acute and chronic health risks, existing medical conditions, including mental health and pregnancy
- Impaired competence for driving, operating machinery etc.
- Accidental ingestion by children

Vendor and outlet controls

The licensing of retail outlets, and the requirements for people working in them, can play a fundamental role in influencing how people consume products. Licensing by outlet is the standard process in most countries for regulating alcohol and tobacco, usually administered at a local level to be responsive to local needs. Licensing authorities determine the number, location, shape and layout of outlets, the kind of promotions allowed in them, the staff training requirements and so forth.

Cannabis store front in British Columbia, Canada PHOTO: Northwest

Outlet type and licensing

A single-function physical or online outlet retailing non-medical drugs only is desirable to discourage potentially risky polydrug use (notably use with alcohol) and related impulse purchasing. However, for physical psychedelic sales this may not always be commercially viable except in larger towns and cities due to the small scale of the psychedelics market. Some people, for health, disability, geographical or other reasons, may not be able to easily access physical retail outlets. If such outlets were the only option, it could potentially exclude people from accessing the legal market, and possibly incentivise purchase from the illegal market or the diversion of legally obtained drugs into a parallel informal market. This is particularly the case if per-customer purchase quantities are restricted. In this context it seems inevitable that some form of online market with home deliveries will need to be permitted to ensure demand can be met in an equitable fashion.

A single-drug function psychedelic retail outlet should be a cautious default starting point for any new regulated market.[176]

- Physical outlets should be adult-only entry (similar to, for example, cannabis stores in Canada and the USA), with an age ID verification needed for those who look under 25. Drug products would be sold, or viewed on request, over the counter.
- There is no obvious need to restrict sales of other non-drug products such as books, art, clothes etc, or (non-drug) food and non-alcoholic drinks.
- Local regulatory authorities would determine if and how physical outlets could be licensed to provide online sales/delivery as well (this might, for example, be restricted to delivery within a certain catchment or local jurisdiction or be related to an equity programme or anti-monopoly measures).

Online outlets present a separate set of regulatory challenges. Online sales already make up a significant proportion of illegal psychedelics bought via darknet crypto markets that are, at best, subject to minimal informal self-regulation. Far better controls would be needed.

- Online outlets would be licensed with requirements similar to regulated online pharmacies. Evidence of licensing must be prominently displayed on the website.[177]
- Online outlets would be restricted to selling only psychedelics.
- Online outlets would be required to provide prominent and accessible information on drug risks, harm reduction guidance, and links to other relevant drug services.
- Risk information would be linked to an online pre-purchase screening process — (e.g., questionnaires that would ask about, for example, previous experience with psychedelics and specific individual vulnerabilities) — much as many online pharmacies already operate.

176 Guided by local considerations, regulatory agencies could explore future options for integration of licensed psychedelics sales with cannabis or other non-medical drugs, for example MDMA (see Transform's guide to stimulant regulation), on a case-by-case basis. However, policy experts consulted for this guide expressed reservations around multiple drug-type retail licences — particularly regarding risks around allowing existing legal cannabis retailers dominating any future psychedelics market, as well as encouraging polydrug use. Any such licensing decisions would need to be approached with caution and avoided in the in the initial instance of establishing a psychedelics market.

177 General Pharmaceutical Council (2022), Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet https://www.pharmacyregulation.org/sites/default/files/document/guidance-for-registered-pharmacies-providing-pharmacy-services-at-a-distance-including-on-the-internet-march-2022.pdf

The aim of drug regulation is not to increase use, or profits, but to manage markets in order to minimise harm

- As far as possible, regulated online retailing should seek to maintain the benefits of face-to-face interactions with a licensed and trained vendor/practitioner, including an option to have an audio or video-link conversation with a trained individual. This could be required for first-time buyers via a membership programme.
- Sales would require identification and purchaser age verification. Delivery would be to the named individual purchaser, with age identification and signature required.

Advertising and promotion

The aim of drug regulation is not to increase use, or profits, but to manage markets in order to minimise harm. Such regulation would involve ensuring no marketing or promotional activity would be allowed for retail in physical or online outlets beyond functional availability and basic price information for adult customers. This would include, as discussed (below), controls on a physical outlet's signage, web design, the packaging of the product and other information, and (above) price promotions. Particular attention will be needed for the evolving challenges of restricting online and social media marketing, including prohibiting targeted pop-up and banner ads.

Outlet appearance and signage

Outlet appearances should be in line with wider restrictions on promoting use, particularly to young people (regulation on cannabis retailers in some Canadian provinces provides a useful precedent).[178] The external appearance and signage of psychedelic outlets should be simple and functional, rather than promotional, and should not appeal to children. Similar restrictions should be applied to website designs. The display of psychedelic drugs, images of psychedelic drugs, packaging, labels or other displays should not be visible to people when walking by a store, whether through a window, door or other means.

178 See: Appearance and signage in Rolles, S., Slade, H. (2022), *How to regulate cannabis: A practical guide* (Transform Drug Policy Foundation) https://transformdrugs.org/assets/files/PDFs/How-to-Regulate-Cannabis_3rd_ed.pdf or Slade, H. (2020), *Capturing the market: Cannabis regulation in Canada*, (Transform Drug Policy Foundation) https://transformdrugs.org/publications/capturing-the-market

Psychedelic welfare services

PsyCare welfare tent at an event PHOTO: PsyCare UK

Though the physiological risks of psychedelics are relatively low, their ability to create alterations in perception, mood and cognition means psychedelic experiences can be challenging. This can lead to distress and potential negative and traumatic feelings during and following use. Offering real-time services, including spaces in which challenging experiences can be supported and difficulties alleviated is fundamental to ensuring the wellbeing of individuals who use psychedelics. In social environments where psychedelic use is likely to take place, such as festivals and clubs, it is strongly recommended that welfare services specialising in psychedelic welfare and harm reduction are made available. Services such as PsyCare in the UK, the Zendo Project in the United States or Échela Cambeza in Colombia have considerable experience in providing dedicated support.[179]

The MAPS' Zendo Project sets out four principles, which are generally accepted within psychedelic welfare, to inform supporting a person who is having a challenging psychedelic experience:

- Safe space — Moving the individual to a comfortable and calm environment, and if possible, avoiding noisy or crowded spaces which may exacerbate the challenging effects.
- Sitting, not guiding — Being a calm presence and promoting feelings of trust and security without getting ahead of the process.
- Talk through, not down — Helping the person to connect to what they are feeling and not resisting it. It is widely acknowledged that a challenging trip can be made more difficult if the individual resists the emotional/psychological effects they are experiencing.
- Difficult is not necessarily bad — Encouraging the individual to not view the challenging experience as negative but rather as something to learn from.[180]

Of course, not all psychedelic use will be happening in festival or club spaces. It is therefore important to guarantee free access to welfare services to anyone who may be struggling

179 PsyCareUK, Using psychedelics at festivals & events. Accessed 1st May 2023 https://www.psycareuk.org/usingpsychedelics/; Zendo Project https://zendoproject.org/; Échela Cambeza, Serivicios, Accessed 30th July 2023 https://www.echelecabeza.com/servicios/

180 Zendo Project, About, Accessed: 1st June 2023 https://zendoproject.org/about/

with their psychedelic use, both during and after, including the significant proportion who will be using in private spaces. A wide roll out of a hotline or online service that anyone can access should be encouraged. Examples of this are already running such as the Fireside Project's Psychedelic Peer Support Line available via phone, text or a downloadable app.[181] These services can also help individuals with post-experience integration, a form of support to process potentially profound or traumatic experiences. ICEERS offers a free dedicated integration service — this is a "complement to — but not a replacement for — medical, psychological or psychiatric attention."[182]

Outlet location

While a high density of alcohol outlets has been associated with increased consumption and related risks, this is less likely to be a risk with psychedelic drugs which are used far less frequently and not associated with patterns of dependent use. The psychedelics market is much smaller than for alcohol, tobacco or cannabis, in terms of numbers of consumers, and frequency of use, so the number of outlets needed or commercially viable is likely to be much smaller. Issues around impulse purchase are also likely to be fewer, and online sales, as discussed above, would significantly address concerns about localised under-availability. For these reasons, controls on outlet location and density are a lower concern. However, too low a level of availability may incentivise illegal markets to meet demand. For example, in municipalities in the Netherlands that have zero or a low density of cannabis *coffee shops*, individuals are more likely to buy from the illegal market.[183] The location of physical outlets would be determined by local or municipal authorities, operating within parameters established by the drug regulatory authority (regarding maximum or minimum outlet density), or other restrictions (such as proximity to schools).

Training requirements and responsibilities of vendors

All retail staff interacting with customers (in physical stores and online) would be required to undertake accredited training in upholding their statutory duties around licensing conditions including age restrictions, sales to intoxicated customers, and any quantity purchase limits.

181 Fireside Project https://firesideproject.org/

182 ICEERS, Support Center https://www.iceers.org/support-center-2/; For more information on integration see PsyCare Aftercare and Integration https://www.psycareuk.org/aftercareintegration

183 EMCDDA (2008), A cannabis reader: Global issues and local experiences: Volume 1. p.150. www.emcdda.europa.eu/publications/monographs/cannabis-volume1_en

Training should also include: how to carry out basic assessments of a customer's key risk vulnerabilities (first time use, histories of mental health problems, use of SSRIs, etc.) in order to provide tailored advice; provision of general and product-specific information on issues relating to risks; safer consumption/harm reduction education (including describing dosage-specific effects and issues around set and setting); and signposting to further support and advice. It would be mandatory for vendors to offer this to each customer at point of purchase. Vendor training requirements and accredited courses would be developed by the regulatory authority and provided by accredited trainers. Responsibility for ensuring implementation should also be laid out in licence operating conditions and would be monitored and enforced by the regulatory authority.

Purchaser controls

Age of purchaser

Age restrictions at point of purchase must be required to restrict youth access.

- Minimum age should be determined nationally but should be no younger than 18 due to the increased risks of usefor younger people. Every purchaser is required to provide a valid ID.
- It should be a specific offence to purchase for, or provide psychedelics to, people under the minimum age.[184]
- Age controls would be in place for entry into physical stores (although ID should only be necessary for those who look under 25). A digital age verification process would be required for online purchase.

Purchase quantity restrictions

Per purchase amount can be limited to a reasonable quantity for personal use, the primary aim being to prevent larger-scale bulk buying and unlicensed resale. Determining what these purchase limits should be is difficult given the wide range of dosages consumed, the variable frequency of use, and the inevitability of sharing. It would also be difficult to prevent stockpiling through repeat purchases, or purchase

184 There may be some exceptional circumstances where such sanctions would not be applied (for example, use in certain religious/ceremonial contexts). It is essential that any sanctions are proportionate and avoid criminalisation as far as possible.

from different outlets. The modest risks such controls would be seeking to mitigate suggest that any purchase quantity limits should not be unreasonably restrictive.

Permitted locations for use

Issues relating to consumption/use in public spaces should be addressed using existing (or appropriately amended) legislation covering public intoxication, or antisocial behaviour. Consumption could be formally tolerated in certain commercial social spaces (for example in clubs or at festivals or events) even if drugs were not available for sale — with accompanying specialised staff training and welfare services.

A case for lower-threshold access to *Psilocybe* mushrooms

Using regulatory frameworks to make more risky drugs or preparations relatively less available and less risky drugs or preparations relatively more available can encourage lower risk drug consumption behaviours. In the context of the wider psychedelics market this principle could be applied to *Psilocybe* mushrooms and be achieved through differential application of controls on licensing of production and retailers, availability, and price controls.

Secret Garden Party Festival, UK PHOTO: Steve Rolles

- The Global Drug Survey's data suggests *Psilocybe* mushrooms have the lowest acute risk among all commonly used drugs, as measured by rates of seeking emergency medical treatment, at a rate of 0.6% among consumers surveyed. This rate compares to 1% for LSD.[185]
- In a self-selecting survey, frequency of use among people who use *Psilocybe* mushrooms was relatively low, with almost 90% using 10 or fewer times a year.[186]
- Dried *Psilocybe* mushrooms are relatively easy to dose by weight, sight, or number when in possession of some basic potency information via packaging or vendor. This reduces

185 Winstock, A., *et al.*(2022), *GDS 2021 Key Findings Report* (Global Drug Survey) https://www.globaldrugsurvey.com/wp-content/uploads/2021/12/Report2021_global.pdf

186 Winstock, A., *et al.* (2021), *GDS 2020 Psychedelics Key Findings Report*, (Global Drug Survey) https://www.globaldrugsurvey.com/wp-content/uploads/2021/03/GDS2020-Psychedelics-report.pdf

the risk of taking more than desired or intended, compared to highly potent extracted or synthetic psychedelic preparations such as LSD.

- They are relatively short acting (3–6 hours) compared to LSD or mescaline (6–12+ hours), offering a more manageable experience.
- They are cheaper, quicker and easier to cultivate than other plant-based psychedelics.

It should be emphasised that *Psilocybe* mushroom use is not without risks, particularly at high dosages. That said, given relative risks, *Psilocybe* mushrooms can act as a form of harm reduction particularly in moderate dosages where they offer a degree of sensory stimulation and heightened awareness without a potentially intense or overwhelming experience. This can serve as a lower risk alternative to some other recreational drugs widely used in social environments — including psychedelics such as LSD, as well as ketamine, alcohol, MDMA, cocaine, amphetamines, and various NPS. Experiences with legal retail availability of Psilocybe mushrooms in the UK and Netherlands suggests that even poorly regulated sales can be relatively non problematic (*See:* *Psilocybe* mushrooms: A UK case study, p.113).

In practical terms, this would involve lower threshold access to a retail licence for sales of certain *Psilocybe* mushroom products in specific situations. These could include licensed over-the-counter sales from less-specialised retail outlets or providing temporary mobile licences to sell single, moderate dosages of dried mushrooms at festivals and events — these sales would also be age restricted. Environmental risk assessments for these venues may be required and psychedelic welfare services would be necessitated on site — with information on their availability made available at point of purchase. Since regulations for low-threshold licences would still require fully trained vendors, provision of appropriate health education information, sale of products produced by licensed producers which meet the same quality controls including packaging, means it is likely that existing fixed-site licence holders would be more readily able to obtain these temporary mobile licences. Marketing and promotions would remain prohibited.

Model 4: Regulation of commercial guided or supervised psychedelic use

Where psychedelics are administered by one individual to another, or to a group, for use in some form of supervised or guided experience within a commercial context, some regulatory oversight will be appropriate. The supplier and/or the facilitator must reasonably carry a degree of responsibility, and related liability, for those in their care. The precise nature of this will be drug and context specific and could range from informal, self-regulated guidelines on best practice at private not-for-profit events through to more formal licensing of commercial suppliers, guides and venues.

For such regulatory models, there are lessons to be learnt from traditional ritual or ceremonial use. Such use operates within well-established social and cultural controls, ensuring that use is only very occasional, and that set and setting (*See:* p.43) are clearly delineated through careful ritualised preparation. As Haden *et al.* note: "Many Indigenous societies have traditionally integrated the use of psychedelic preparations using time-tested ceremonial safeguards to minimise adverse effects."[187] In such contexts people who use are generally well-informed, prepared and organised. The experience is supported by mentoring and peer guidance, with a corresponding respect for the potentially profound and intense nature of the drug experience.

Viewed thus, the guided or supervised experience provides a model for effective self-regulation. However, potential risks exist in these environments too. The provision of psychedelics in a supervised setting places consumers in a highly vulnerable position and creates the potential for abuses of power. Sufficient ethical training, facilitator accountability and supervision, and other formalised safeguards are necessary in this context to mitigate such risks.

Safe provision of supervised services requires adequate screening of participants to identify and act on potential vulnerabilities, provision of care in the event of an adverse reaction, ensuring safe consumption environments, the avoidance of false or misleading medical claims, and the protection of participants from any form of exploitation or abuse. Lessons may be taken from other existing practices, such as

187 Haden, M., Emerson, B., Tupper, K., (2016) A Public-Health-Based Vision for the Management and Regulation of Psychedelics, *Journal of Psychoactive Drugs*. 48(4) pp.1–10 https://doi.org/10.1080/02791072.2016.1202459

hypnotherapy, with similar challenges around abuse of power over suggestible and vulnerable individuals; here solutions have included licensed bodies of practitioners with codes of practice.[188]

Haden, Emerson, and Tupper (2016) make an elegant suggestion for how such regulation might work. They propose that a government authority would oversee a "College of Psychedelic Supervisors" on the basis that "supportive oversight and compassionate guidance of the psychedelic experience are key to a beneficial outcome and prevention of harms, there is a need for trained, competent, experienced supervisors."

> *The function of the College would be to establish, monitor, and enforce standards of practice amongst its registrants. The College would be administered by individuals who had training and experience in psychedelic supervision, including Indigenous, spiritual, and medical practitioners. It would be tasked with granting licences for new supervisors, dealing with complaints (e.g., psychological or sexual abuse) and developing and implementing best practices. This College would be responsible for licensing facilities or environments where psychedelics are administered, including inspection and certification to ensure that best-practice requirements have been met. They would develop regulations, performance standards, procedures, guidelines, and accreditation criteria which would be used to structure appropriate environments, and to ensure the delivery of high-quality, safe psychedelic administration and supervision.*[189]

Haden *et al*. go on to propose a two-tier system, with a lower-tier psychedelic supervisor certification process to establish basic training and instruction (in set, setting, safety, and dosage management) for personal and private group use, and a higher threshold psychedelic supervisor licensing process involving more advanced training (and specialisation) for supervision of commercial or larger organised group activities. The issue of incorporating existing traditional practices into the system could be tackled by proposing that traditional guides would have a key role in developing best practice and training programmes, and could practice alongside, or with the oversight of a licensed supervisor (if they had not themselves obtained a licence). Lessons on how this might work in a formal context could be taken from,

188 See, for example, details on regulation by the UK National Hypnotherapy Society https://nationalhypnotherapysociety.org/about-us/regulation

189 Haden, M., Emerson, B., Tupper, K., (2016) A Public-Health-Based Vision for the Management and Regulation of Psychedelics, *Journal of Psychoactive Drugs*. 48(4) pp.1–10 https://doi.org/10.1080/02791072.2016.1202459

for example, training programmes developed by ICEERS.[190] Haden et. al. note "The advantages of licensure of these supervisors to participants seeking experiences within an existing spiritual community are that there would be quality oversight and a complaint registration and resolution process which may not exist in the current tradition."

Haden *et al.* outline the role and responsibilities of psychedelic supervisors in creating and maintaining safe environments, these include:

- Screening individuals, for example, regarding age restrictions, physical and mental health diagnoses, or pharmaceutical medication regimes which may exclude some participants.
- Obtaining informed consent from participants for all elements of the experience, for example, around consensual touch during guided use such as holding hands. Issues around consent and withdrawal of consent need to be discussed and formally agreed in advance.[191]
- Involving participants in the choice of dosage, with guidance from the supervisor and clear information about different dosage effects and duration.
- Understanding and communicating the different pharmacological profiles of the psychedelics.
- Managing interactions between participants in group settings, recognizing that this is dosage dependent. High dosages need more controls, as everyone has different experiences and all participants have a right to not be intruded upon, for example, by an extrovert individual, or someone who is having a difficult emotional experience.
- Ensuring the continuous presence of responsible individuals who can intervene if a participant experiences a difficult physical or emotional state.
- Preventing the operation of a motor vehicle or machinery while under the influence of the psychedelic, as impairment from any substance can involve risk to self or others.

190 ICEERS, Increasing the Safety of Ayahuasca Sessions: A harm reduction course for facilitators in non-traditional contexts Accessed: 8th August 2023 https://iceersacademy.mykajabi.com/ayasafety-en

191 This is a complicated aspect specific to the nature of a psychedelic guided experience, and care must be taken in how consent of a participant is assured at all times.

- Providing participants with integration following the session, supporting the processing of the experience.

This general model for licensed supervisors offers a useful foundation for regulating commercial provision of supervised psychedelic experiences. The proposed regulatory authority would:

- Oversee the training and accreditation process.
- Licence venues/consumption spaces (with considerations of health and safety considerations regarding using environments).
- Establish best practice guidelines, and rules for screening, safeguarding, emergency care, and restrictions on marketing and promotion (enforced with sanctions including loss of licence, and fines).[192]

Licensing provisions would also be necessary to obtain, store and supply specific psychedelic products within parameters established by the regulatory authority. Not-for-profit associations (*See:* above) could be able to offer supervised psychedelic experiences if operating within this system.

192 More serious issues around exploitation, abuse, or other criminal conduct should be dealt with by relevant law and authorities.

A legal market for *plant-based* psychedelics, including international trade, could potentially avoid issues of non-compliance with international legal obligations under the UN drug treaty framework

6 Psychedelics and the UN drug treaties

The current legal status of psychedelic drugs in international law is somewhat ambiguous. While the 1971 UN Convention on Psychotropic Drugs includes the control of LSD, mescaline, DMT, and psilocybin/psilocin in Schedule I, the commentary to the convention (the official guide to its implementation and use) makes it clear that the plants containing mescaline, DMT, and psilocybin/psilocin are not controlled:[193]

> *The cultivation of plants from which psychotropic substances are obtained is not controlled by the Vienna Convention. ... Neither the crown (fruit, mescal button) of the peyote cactus nor the roots of the plant ... nor* Psilocybe *mushrooms themselves are included in Schedule 1, but only their respective principles, mescaline, DMT and psilocybin/psilocin.*[194]

193 For a detailed explanation of the scheduling system, see: Jelsma, M. (2019) Classification of Psychoactive Substances: when science was left behind (The Global Commission on Drugs) p.9 http://www.globalcommissionondrugs.org/reports/classification-psychoactive-substances

194 Commentary on the Convention on Psychotropic Substances, New York 1976 p.385, p.387 https://www.incb.org/documents/Psychotropics/conventions/Commentary_on_the_Convention_1971.pdf

More recently, the UNODC World Drugs Report in 2019 clarified that:

> *For the hallucinogens that are under international control, the 1971 Convention does not cover the plants or plant material from which these substances can be extracted. As an example, psilocybin is under international control but the mushroom* Psilocybe mexicana*, from which it is extracted, is not. Nevertheless, under the national legislation of many countries, both the psychoactive substance and the plant material from which the substances are extracted are controlled.*[195]

A legal market, including international trade between member states, in plant-based psychedelics (*Psilocybe* mushrooms, mescaline-containing cacti, and plants containing DMT) would likely avoid potential issues of non-compliance with international legal obligations under the UN drug treaty framework. Unlike coca leaf, opium poppies and cannabis, three key drug plants that are specifically named and prohibited under the treaties, these plants containing psychedelics are in fact specifically exempted.

Where, however, there is a lack of clarity and, correspondingly, considerable room for interpretation by member states, is around determining at what point a psychedelic plant — when growing, freshly harvested, or in some way prepared — becomes a product that engages the treaty prohibitions. Would, for example, *Psilocybe* mushrooms that were dried, powdered and put into standardised-dosage pills count as a non-prohibited *plant material*? On the face of it, the answer appears to be yes — this would be plant material rather than an extracted or synthesised pharmaceutical product.

It is important to be clear that any legal ambiguities or exemptions relating to psychedelic plants or plant materials do not extend to LSD, or any pharmaceutical preparations of mescaline, DMT or psilocybin/psilocin (either extracted or synthetic).

Any legal market for non-medical use of plant-based psychedelics might potentially attract criticism from the treaty watchdog, the International Narcotics Control Board (INCB), for going against the (essentially prohibitionist) spirit of the treaties. The flexibility in interpretation of the treaty wording, particularly given the guidance in the commentary, means that it would not, however, appear to represent a specific

195 United Office on Drugs and Crime (2019), World Drug Report 2019: Book 5, Cannabis and Hallucinogens https://wdr.unodc.org/wdr2019/prelaunch/WDR19_Booklet_5_CANNABIS_HALLUCINOGENS.pdf

breach of formal treaty obligations in the same way as the legal cannabis markets in Uruguay, Canada and the USA have done. Notably, the small-scale legal and quasi-legal markets that have emerged for some plant-based psychedelics around the world have not yet attracted formal condemnation from the INCB.

Plants containing psychedelics are specifically exempted in the UN drug treaty frameworks

Recently there has been growing interest in seeking to revisit the scheduling of psychedelics under the drug conventions.[196] This has focused on the possibility of rescheduling key psychedelics that are currently being explored for medical use from Schedule I, to a lower and less restrictive schedule. Such a move to reduce some of the legal barriers to accessing these drugs for scientific and medical purposes, particularly if it led to similar rescheduling at a domestic level, would further facilitate research.

The possibility of rescheduling psychedelics has had an increased profile since the recent rescheduling of cannabis (its removal from the most restrictive Schedule IV). This has been widely viewed as the UN system belatedly signalling the potential utility of cannabis-based medicines.

This discussion raises a number of issues. It is important to note that even if rescheduled, unless the specific substances were removed from international controls altogether (i.e., de-scheduled) they would still be prohibited for non-medical and scientific purposes, i.e., any forms of non-medical or recreational use (unless they come under the plant form exemptions detailed above). It is also the case that medical and scientific uses are already permitted for drugs controlled under the conventions, indeed such provision is nominally one of the treaty's core functions. This places psychedelics in Schedule I of the 1971 UN Convention, the highest schedule for those drugs considered most dangerous; notably they are also not included in Schedule IV, indicating a high risk of misuse and no medical utility, as cannabis previously was. Moving to a lower schedule would have some practical implications in terms of issues such as monitoring and reporting obligations under the treaties but would arguably be more important as a political signal, acknowledging that the risks of psychedelics, relative to other drugs, had been overstated and classification in Schedule I was a historic error.

196 See, for example, Psychedelic Access and Research European Alliance **https://parea.eu**

United Nations Office on Drugs and Crime, Vienna PHOTO: Steve Rolles

For a rescheduling to happen, the WHO's Expert Committee on Drug Dependence (ECDD) would be required to undertake a review for each drug under consideration, to make a recommendation for rescheduling, and for that recommendation to then be passed by a vote in the Commission on Narcotic Drugs. At each stage in this process there are potential obstacles. Firstly, the ECDD will generally only undertake a review if requested (and possibly funded) by one or more member states, limiting the ability of civil society to advocate directly. Secondly, despite the very obvious mis-scheduling of psychedelics in Schedule I, an ECDD review may not come to the conclusions reform advocates seek, particularly in the increasingly polarised and politicised UN drug control space. This possibility was demonstrated by the ECDD's extraordinary decision, following the recent cannabis review, to not recommend moving cannabis from Schedule I, where it sits alongside drugs such as heroin and cocaine, despite the review analysis clearly acknowledging cannabis was lower risk than these other drugs. Thirdly, and perhaps most significantly, even if a rescheduling is recommended by the ECDD, the political dynamics of the CND mean that overcoming the prohibitionist bloc of member states to win a vote to reschedule any drug downwards could be very unlikely. Even the modest reform of cannabis scheduling (removal from Schedule IV) was only passed by a narrow vote margin, with a number of other ECDD recommendations voted down.

The pursuit of psychedelic rescheduling is a worthwhile undertaking and one that will have some political and practical benefits for medical research if successful. Even if ultimately unsuccessful, it could still stimulate useful public and high-level policy debate. However, the limitations of such an effort also need to be acknowledged: the time it would take (the cannabis review process took over four years, even after it was agreed to proceed), the political pitfalls implicit in the somewhat tortured rescheduling process, and the limited impact of rescheduling for reform around

non-medical psychedelic use. A failed rescheduling attempt could serve to entrench the status quo for the foreseeable future.

The problems of the UN scheduling system run far deeper than misclassification of certain drugs; the entire malfunctioning and outdated international drug control framework is in urgent need of modernisation and a more fundamental realignment away from the failed punitive prohibitionist thinking that underpins it.[197] Efforts to reform psychedelics policy at the national level should run in parallel with any efforts in multilateral forums, acknowledging the reality that most drug policy reforms in recent decades have been bottom-up processes. Those seeking to reform psychedelics policy who expect leadership from the UN drug control institutions are likely to be disappointed.

197 Jelsma, M. (2019) Classification of Psychoactive Substances: when science was left behind (The Global Commission on Drugs) p.9 http://www.globalcommissionondrugs.org/reports/classification-psychoactive-substances

Appendix 1

Psilocybe mushrooms: A UK case study

Psilocybe mushroom sales from a head shop in Camden, London, UK, 2005
PHOTO: Alex Segre

In 2003, a legal loophole was identified that allowed fresh *Psilocybe* mushrooms to be sold legally for a brief period in the UK. In response to an inquiry from a head shop owner seeking clarification on the law under the Misuse of Drugs Act 1971, a letter from the Home Office stated that, while psilocybin and psilocin were Class A drugs.[198]

> *The growing of* Psilocybe *mushrooms and the gathering and possession of them do not contravene the Misuse of Drugs Act 1971. It is, however, an offence under the 1971 Act to possess a "preparation" or "product" of the controlled drugs psilocin or psilocybin. The courts have held that where the mushrooms have been prepared (e.g., by drying or by making into a powder) so that "they have ceased to be in their natural state and have been in some way altered by the hand of man" they constitute a "preparation" or "product" of the Class A controlled drug psilocin.*[199]

198 A head shop is a retail outlet specialising in the sale of drug-related paraphernalia.

199 Breadmore, I. (2003), Hallucinogenic Mushrooms (Letter) Accessed 8th August 2023 https://magicmushroomsuk.wordpress.com/2003/02/17/breadmore-i-2003-hallucinogenic-mushrooms-letter/

This definition of a *preparation* or *product* remained somewhat ambiguous, later leading to a number of court cases focusing on whether dried mushrooms, mushrooms in fridges, or mushrooms in packages constituted a preparation or not. However, the letter unambiguously declared that:

- It is not illegal to grow and pick *Psilocybe* mushrooms and eat them fresh.
- It is not illegal to sell or give away a growing kit as the mushrooms themselves are not controlled.
- It is not illegal to sell or give away a freshly picked mushroom provided that it has not been prepared in any way.

This allowed entrepreneurs to import fresh *Psilocybe* mushrooms from the Netherlands (where they were also legal at that time) and sell them in the UK (often with a printed, laminated copy of the Home Office letter affixed to the wall, by way of perceived official permission). This period of legal *Psilocybe* mushroom sales lasted just over two years, until section 21 of the Drugs Act 2005 designated fresh *Psilocybe* mushrooms as a Class A drug, alongside any counterparts "altered by the hand of man".[200]

The period offers a unique insight into the impact of a legal market (albeit not formally regulated), and its subsequent prohibition. While most vendors only sold the mushrooms to adults, there was no regulatory framework of the type set out in this publication. Indeed, concerns around irresponsible retailing were a significant factor leading to the ban, with media and politicians drawing attention to the high visibility of unregulated sales to young people from high street shops and market stalls.

The UK Government's Regulatory Impact Assessment for the Drugs Act 2005 estimated that the market was turning over around £1 million a year (earning the treasury £175,000 in VAT) with imports of 1000 kg of fresh *Psilocybe* mushrooms being sold from over 300 outlets. Even if this estimate was a conservative one, it represents only a tiny fraction of the estimated turnover of the UK's illegal drugs market (around £9 billion), or alcohol market (around £16 billion).

British Crime Survey data suggests that use of *Psilocybe* mushrooms increased from 2003-5, during the time the legal loophole was effective, a pattern mirrored by a fall

200 UK Legislation, Drugs Act, 2005. Accessed: 1st February 2023 https://www.legislation.gov.uk/ukpga/2005/17/contents

and then rise in LSD over the same period — possibly suggesting some displacement from LSD to *Psilocybe* mushrooms although caution is needed interpreting significance of the data given the small numbers.[201] Psilocybin mushroom use had been rising, and LSD use falling, for the five years before the legal psilocybin mushroom market opened in 2003, and use of both has fluctuated up and down by greater amounts post-2005.[202] The increase in use of *Psilocybe* mushrooms in the late 1990s and early 2000s also appears to have been a broader pan-European trend.[203] It is reasonable, however, to assume the sudden and widespread legal (and unregulated) availability of *Psilocybe* mushrooms — the novelty of which under an avowedly prohibitionist government should not be underestimated — did contribute to some increase in prevalence.

Trying to discern any health impacts of the legal market is difficult. The absence of overdose deaths means *Psilocybe* mushrooms do not feature in drug-related death data, and no data is available from this period A&E admissions or hospital admission with *Psilocybe* mushrooms as the primary cause. As is the case today in the UK, the only distinction made in data is between LSD and other hallucinogens.

There is some suggestion of a small increase in clinicians accessing the National Poisons Information Service with inquiries about *Psilocybe* mushrooms, but these represent less than 0.2% of online inquiries, and less than 0.1% of phone inquiries (for both *Psilocybe* mushrooms and LSD), a rate of less than one call a week. So again, it is hard to draw any conclusions.

So, the UK's brief era of unregulated legal *Psilocybe* mushroom sales may have marginally increased general population use, with greater increases among young people and drug using populations, but with no clear evidence of an increase in health harms. Even allowing for the limitations in evidence-gathering (with established surveillance systems generally poor at monitoring emerging or low-level drug consumption behaviours), if the legal market had led to a surge in mushroom-related health harms it would have left some footprint in the data; there is none evident.

201 Home Office (2012), Tables for 'Drug misuse declared: findings from the 2011 to 2012 Crime Survey for England and Wales' https://www.gov.uk/government/statistics/drug-misuse-declared-findings-from-the-2011-12-crime-survey-for-england-and-wales--2

202 McCambridge, J., Winstock, A., Hunt, N., & Mitcheson, L. (2006). 5-Year Trends in Use of Hallucinogens and Other Adjunct Drugs among UK Dance Drug Users, European Addiction Research. 13(1), pp.57–64 https://karger.com/ear/article-abstract/13/1/57/119252/5-Year-Trends-in-Use-of-Hallucinogens-and-Other?redirectedFrom=fulltext

203 European Monitoring Centre for Drugs and Drug Addiction (2006), Hallucinogenic Mushrooms: An Emerging Trend Case Study https://www.emcdda.europa.eu/publications/thematic-papers/mushrooms_en

In late 2004 the UK Government produced a Regulatory Impact Assessment (RIA) for the proposed *Psilocybe* mushroom ban under the then Drugs Bill (enacted the following year). Following standard procedures, this considered the economic and social impacts of three options; leaving the law as it was (with unregulated legal sales); banning fresh *Psilocybe* mushroom sales (making them Class A under the Misuse of Drugs act alongside psilocybin, LSD etc); or formally regulating legal sales. In laying out the Government's desire "to clarify the law to prevent the open sale of a dangerous hallucinogenic drug" the RIA noted the "growing concern over the impact they have on public health."[204] The absence of any data to back up the prominent health concerns, particularly regarding the impact of unregulated legal sales was notable. Indeed, the only engagement with health impacts of the legal market was to note and then summarily dismiss a potentially positive displacement effect of legal availability: "It is claimed that the increase in use has contributed to the decline in the prevalence of ecstasy. Nevertheless, both are controlled drugs and are harmful."

204 Home Office (2004) Drugs Bill — Final Regulatory Impact Assessment (currently not available online; available from Transform on request)

Appendix 2

Psychedelic regulation in the United States

In 2023, the United States is spearheading the psychedelic drug reforms in the Global North, largely through ballot initiatives to allow access to psychedelics for medical/therapeutic use, decriminalise personal possession, and to allow home cultivation for personal use.

In 2019, Denver (Colorado) became the first US city to implement de facto decriminalisation by making the personal possession of psilocybin the lowest enforcement priority.[205] Since then, more than 15 cities and counties have passed similar initiatives, decriminalising psilocybin as well as other psychedelics and their preparations (including mescaline, DMT, ibogaine and ayahuasca).[206]

In 2020, Oregon voters initiated the first state-level reform to regulate the production and supply of psilocybin, passing Ballot Measure 109, which allows supervised adult use access. Then in 2022 Colorado passed a similar ballot, Proposition 122, which initially will regulate psilocybin but has potential to further expand this to DMT, ibogaine and mescaline (excluding peyote).[207] Colorado's bill also decriminalised personal use of the aforementioned drugs. Oregon has since opened up licence applications, with Colorado aiming to do the same in 2024.

Colorado and Oregon both positioned the need to regulate psychedelics as a response to an increasing mental health crisis, with access to psilocybin only available as part of a supervised/guided use experience. In both states, psilocybin will be produced by regulated private companies and made available through licensed psilocybin facilities under supervision, with no provision to purchase for take home use. Colorado has termed these facilities healing centres, exemplifying the focus on health and mental wellbeing over other motivations for use.

However, both Oregon and Colorado have stated no professional medical diagnosis

205 Denver, Colorado, Initiated Ordinance 301, Psilocybin Mushroom Initiative (Ma 2019), Accessed: 1st August 2023 https://ballotpedia.org/Denver,_Colorado,_Initiated_Ordinance_301,_Psilocybin_Mushroom_Initiative_(May_2019)

206 Psychedelic Alpha, Psychedelic Legalization & Decriminalization Tracker, Accessed: 1st May 2023 https://psychedelicalpha.com/data/psychedelic-laws

207 Colorado General Assembly (2022), Proposition 122: Access to Natural Psychedelic Substances, https://leg.colorado.gov/sites/default/files/initiative%2520referendum_proposition%20122%20final%20lc%20packet.pdf

will be required to access the psilocybin facilities and that individuals will be able to access use for any reason, demonstrating that the therapeutic/adult-use framing is distinct from more formal medical practice using licensed and prescribed medicines.

To prevent market consolidation, Colorado has also stated that individuals will not be allowed to have a financial interest in more than five healing centres. This is particularly important in Colorado, where the psilocybin facilities will be able to obtain both a cultivation and supervised therapy licence (also known as vertical integration).

In regard to mescaline, both states have excluded the possession and sharing of peyote from the list of decriminalised plant-based psychedelics which will allow some protection for Indigenous traditional uses of the cactus (*See:* Peyote and conservation protections, p.72). Even though, compared to other drugs, psychedelics have played a smaller part in enforcement statistics, it is fundamental that deletion of criminal records and resentencing for any psychedelics-related convictions are included in the reforms. Further, in an attempt to learn lessons from their regulated cannabis markets, both states have identified measures to ensure social equity in the market, and to mitigate risks of corporate capture or market monopolies.[208] Both states will offer reduced licensing fees for social equity applicants and licenses will not require a previous professional licence or degree.

State-level reforms are now also in the legislature in California, New York, Massachusetts and several other jurisdictions in the United States. Despite various city-, county- and state-level reforms of psychedelics, all psychedelics remain controlled at the federal level. This disparity in state and federal law is likely to see a range of reform approaches to psychedelics emerge across the US states, comparable to cannabis reforms over the last decade. For the most part these law reforms have focused on natural plant materials, while chemically synthesised psychedelics such as LSD or related substances such as MDMA and ketamine have been largely excluded from the reform discussions.[209]

If the psychedelics market proves to be as lucrative as some investors expect, there will be a need for proactive measures to ensure benefits are shared more

208 Transform Drug Policy Foundation, Designing more equitable cannabis markets, 4th May 2021 https://transformdrugs.org/blog/designing-more-equitable-legal-cannabis-markets

209 Oregon's Measure 110 included the decriminalisation of the personal possession of LSD. California's bill SB58 to decriminalise psychedelics initially included LSD but was removed in later amendments.

widely. Early models are providing some pointers to how the market may emerge, but the landscape could evolve rapidly, with more overtly non-medical use being acknowledged and catered for as time goes by.

Table 5

Overview of Colorado and Oregon regulation models for supervised use of psychedelics

	Oregon	Colorado
Overall model	Supervised adult-use model in licensed facilities	Supervised adult-use model in licensed facilities or approved spaces
Substances	Psilocybin and psilocin Cultivation of *Psilocybe cubensis* only Chemical synthesis prohibited	Psilocybin and psilocin Option to expand to ibogaine and, from 2026, DMT and mescaline
Regulating authority	Oregon Psilocybin Service	Natural Medicine Advisory Board
Production	Licensed private companies	Licensed private companies Facilities can also be licensed to cultivate
Age access threshold	21+	21+
Outlets	Licensed private facilityes, with supervision on site and no take-home option	Licensed private facilities, with supervision on site and no take-home option Regulators can also approve facilitated use at a private residence or in other spaces such as healt care facilities or hospices
Marketing	Advertising allowed but must not: • Appeal to or target people under 21 • Contain false or misleading information • Make health claims that are not supported by scientific evidence	TBC
Home grow	Not permitted	Permitted in grounds of private home, ensuring crop is securetly inaccessible to people under 21
Expungement	Not specified	Application for record sealing for any convictions related to personal use or possession of named plants and substances

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How to Regulate Psychedelics: A Practical Guide

Recent explorations into the science of psychedelics and their therapeutic potential have fuelled a rapidly expanding discussion on their role in society. Yet, while attention has been focused on their medical use, non-medical use — particularly in recreational settings — has been marginalised in the public debate.

This guide from Transform Drug Policy Foundation aims to address this gap and help inform emerging developments at this critical moment in psychedelic policy evolution. It maps out how the classic psychedelics can be responsibly legally regulated in a post-prohibition world, making concrete proposals for a four-tiered regulatory framework:

- Private use, including home cultivation, foraging and not-for-profit sharing
- Membership-based not-for-profit associations
- Flexible licensing models for production and retail sale
- Regulation of commercial guided or supervised use

Drawing on Transform's more than two decades of experience in global drug policy analysis and advocacy, this guide sets out recommendations for establishing a just and effective system of legal regulation, addressing challenging questions in the debate including corporate capture mitigation, equity, Indigenous rights, psychedelic exceptionalism, and international treaty law.

"Once again Transform have come up with a well thought out and practical plan for the regulation of another group of currently illegal drugs — in this case psychedelics. Their ideas would be both easy to implement and to engage with and will, if adopted, radically enhance the safe use of these remarkable agents"

Professor David Nutt, Scientific Chair of Drug Science

"This is a timely and needed contribution to the growing debate on the future of psychedelic regulation. The number of jurisdictions making the move towards psychedelic reform will continue to grow and this guide provides answers to some of the key questions on how to achieve it successfully. As a regulator, I value the resources and expertise Transform brings to these critical issues in drug policy"

Dominique Mendiola, Senior Director,
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