

Regulation Impact Statement: Banning the importation of substances which mimic the effects of illicit drugs

Attorney-General's Department

May 2014

Timeframe for public comment

The Attorney-General's Department seeks public comment on this Regulation Impact Statement (RIS). Submissions on the RIS will be open until **5pm on Friday, 16 May 2014**. Submissions should be sent to criminal.law@ag.gov.au and addressed to Anthony Coles, Assistant Secretary, Criminal Law and Law Enforcement Branch.

Problem

Substances which mimic the effects of, or that are marketed as legal alternatives to, illicit drugs but whose chemical structures fall outside existing controls (also known as new psychoactive substances or 'NPS') have been a growing problem for Australian governments in recent years. NPS are frequently marketed as 'legal highs' and are purchased in Australia either over the internet or from retailers such as sex shops, head shops and tobacconists. There have been a number of reports both in Australia and overseas directly linking the consumption of these substances to deaths and serious injury.

NPS have received significant media attention in Australia in recent years following a number of tragic deaths of people who had recently consumed these substances. For example, in October 2012, a NSW man died and his girlfriend was hospitalised after they consumed 'bath salts'. In December 2012 and July 2013, two NSW teenagers died following their consumption of NBOMe, a substance with hallucinogenic effects similar to LSD.

These substances are potentially very dangerous. They are unknown chemical compounds which masquerade as illicit drugs (such as cannabinoids, ecstasy or LSD), but that are presented as being legal analogues of those drugs.

This marketing of NPS as 'legal highs' is particularly concerning. When manufacturers and retailers assert that they are 'legal' it may suggest to potential users that the substances have been tested and authorised for sale. It can create the impression that NPS are safe or somehow less harmful than the illicit drugs whose effects they are supposed to replicate.

This is not the case. These substances are typically untested, there is often great variation in the concentration of active ingredients between different products and their short and long term health effects are often unresearched and unknown.¹ Further, labelling NPS as 'legal' is not always correct, as the substances may be listed specifically as illicit drugs, or caught as analogues of listed illicit

¹ Australian Crime Commission, *Illicit Drug Data Report 2012-13* p 154.

drugs. For example, the product involved in one high profile case had been presented by the product's retailer, its distributor and the legal advisor to the distributor as being 'legal', when it in fact contained Alpha-PVP, an illegal analogue of methcathinone, a listed illicit drug.²

The market for NPS

Current indications are that the market for NPS in Australia does not compare with the scale of established illicit drug markets. However, based on international data, this market has a clear potential for growth if left unchecked. Findings from the 2013 Report of the Ecstasy and Related Drugs Reporting System (a national monitoring system for ecstasy and related drugs in regular drug users) note that NPS continues to grow as a class of drug, with 44% of the sample reporting using at least one NPS, compared to 40% in 2012.

There is significant global concern about the health risks of NPS use. The United Nations Office on Drugs and Crime (UNODC) 2013 World Drug Report notes that, worldwide, the number of NPS reported by Member States rose from 166 at the end of 2009 to 251 by mid-2012. This exceeds the total number of 234 illicit drugs currently controlled by the international drug conventions.

A 2013 UK Parliamentary report noted that between 2005 and 2012, some 236 new psychoactive substances were formally identified and logged on the European Monitoring Centre for Drugs and Drug Addiction's (EMCDDA) early warning system. In 2012, for the fourth consecutive year, a record number of new substances (73) were detected in Europe, up from 49 substances in 2011, 41 substances in 2010 and 24 in 2009. In terms of popularity, the EMCDDA's 2012 annual report highlighted that in 2011, a European survey of more than 12,000 young people (aged 15-24), estimated that 5% of young Europeans had used 'legal highs' at some time, with about half of the countries falling in the range 3-5%.

The supply of NPS is big business. The Australian Crime Commission (ACC) has noted that NPS:

*are sold in Australia at low prices per dose, [and] have the potential to generate criminal profits in excess of those obtained from trafficking more established illicit drugs, such as heroin and cocaine, although at present the [NPS] market does not compare in size with more traditional illicit drug markets.*³

Similarly, there have been reports that retailers have known about possible dangers involved with specific NPS, but continued to sell those substances because 'the profit margins were too high'.⁴

The active ingredients in NPS are exclusively imported into Australia from overseas manufacturers, though they may be packaged or prepared for sale within Australia. Though the precise number and

² NSW State Coroner, *Finding after an inquest into the death of Glenn Punch*, 29 October 2013, <<http://www.coroners.lawlink.nsw.gov.au/agdbasev7wr/assets/coroners/m401601I7/glenn%20punch%20finding%2029%20oct%202013.pdf>>. Alpha-PVP has also been specifically listed as an illicit drug under the Commonwealth *Criminal Code*.

³ Australian Crime Commission, *Illicit Drug Data Report 2012-13*, p 158.

⁴ R Olding, 'Lawyer kept 'bath salts' ingredient secret as Glenn Punch was dying', *Sydney Morning Herald*, 10 October 2013, viewed 5 May 2014, <<http://www.smh.com.au/nsw/lawyer-kept-bath-salts-ingredient-secret-as-glenn-punch-was-dying-20131010-2vam0.html>>.

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weight of NPS detections and seizures varies from year to year, the Australian Customs and Border Protection Service (ACBPS), the Australian Federal Police and ACC have all reported an increased number of detections and seizures of NPS at the border since 2006. This trend mirrors the experience in other countries.⁵ However, statistics for NPS likely underrepresent the scale of the problem as the forensic testing of these substances is more limited than for mainstream illicit drugs and because law enforcement agencies collect only limited data on substances (or their analogues) that are not listed as illicit.

Current illicit drug regulation

Current Commonwealth criminal laws, set out in part 9.1 of the *Criminal Code* and the *Customs (Prohibited Imports) Regulations 1956* (Prohibited Imports Regulations), ban substances by chemical structure, with analogue clauses to capture structurally similar substances. Newly identified NPS are progressively added to these lists as evidence about their harms becomes available. In considering whether to list a substance by regulation under the Criminal Code, the Minister for Justice must be satisfied that the substance is likely to be taken without appropriate medical supervision, and:

- taking the substance would create a risk of death or serious harm
- taking the substance would have a physical or mental effect substantially similar to that caused by taking a listed illicit drug
- the substance has the capacity to cause physiological dependence
- the substance is banned as an illicit drug in an Australian State or Territory, or in a foreign country, or
- the substance poses a substantial risk to the health or safety of the public.

The Government may also list previously undetected and harmful NPS (including their precursors) by chemical structure in the Criminal Code for up to 18 months under an emergency determination, to allow time to assess whether they should be listed indefinitely. In considering whether to make an emergency determination about a substance, the Minister for Justice must be satisfied that there is an imminent and substantial risk that the substance will be taken without appropriate medical supervision, and:

- taking the substance may create a risk of death or serious harm
- taking the substance may have a physical or mental effect substantially similar to that caused by taking a listed illicit drug
- a public official has found the substance in the course of his or her duties, and there is limited or no known lawful use for the substance in Australia, or
- the substance may pose a substantial risk to the health or safety of the public.

Criminal laws based on the chemical structure of a substance are important in controlling illicit drugs whose harms are known. This approach is ill-suited to dealing with the increasing rate of introduction of new, untested and potentially harmful substances, each with a different chemical structure. There is evidence that, as one substance is banned, suppliers will quickly import new

⁵ Australian Crime Commission, *Illicit Drug Data Report 2012-13*, p 157.

substances with slightly different chemical structures that have been designed to evade criminal controls.⁶ In circumstances where there are an almost limitless number of potential NPS,⁷ controls based solely on the structure of illicit drugs will permanently lag behind the market. Potentially dangerous substances will continue to be imported and sold while authorities undertake lengthy processes to identify them, assess their harms and list them by their structure.

ACBPS officers currently detain unregulated NPS on the basis that they suspect those substances are illicit drugs. If the detained substances are not illicit drugs, officers cannot formally seize them and must allow their importation, even if the ACBPS suspects the substance is being imported solely for recreational human consumption.

Objectives

The broad objective of the policy is to reduce the impact of NPS on public health and make existing criminal laws more effective in responding to this emerging issue. Governments need time to assess the health effects, harms and risks of NPS detected in Australia before they can implement specific criminal offences or other controls on individual substances. The health risk that NPS pose can be significant. As NPS are often unregulated and unassessed, there is little knowledge and information about their effects, which can pose problems for assessment and successful treatment of harms resulting from their use.

There is also limited data available about the scale of their importation, manufacture, supply and use. In these circumstances, it is not possible to set out more definite and measureable outcomes for the policy. However, a number of the policy options explored below will assist in developing an evidence base about the problem posed by NPS. This data will be used to guide further policy development in the future.

Options

AGD has identified four key options for tackling the public health and criminal law issues that NPS pose.

AGD notes that Commonwealth action is only one aspect of the national response to NPS. The policy must complement the work of the Intergovernmental Committee on Drugs (IGCD) to develop a coordinated national response to NPS, which includes law enforcement, health and education initiatives. Further, Commonwealth action should complement State and Territory efforts to control the manufacture, supply and advertisement of NPS. New South Wales, Queensland and South Australia have already implemented laws that ban substances based on their psychoactive effect, rather than their chemical structure.

⁶ United Nations Office of Drugs and Crime, *World Drug Report 2013*, p 59.

⁷ United Nations Office of Drugs and Crime Global SMART Programme, *The challenge of new psychoactive substances*, 2013, pp 1-2.

1. Implement a ban on the importation of substances which mimic the effects of illicit drugs that are otherwise unregulated

Stopping NPS at the border is fundamental to halting their supply in Australia. There is no domestic production of the active ingredients in NPS; they are imported into Australia from overseas.

Banning the importation of otherwise unregulated psychoactive substances will assist in preventing manufacturers from evading existing border controls by tweaking the chemical structure of illicit drugs. The measure will operate as a safety net to ensure that potentially harmful substances which mimic the effects of, or are intended as an alternative to, illicit drugs—but are otherwise unregulated—can be seized.

AGD acknowledges that there are many substances that would be psychoactive when ingested by humans, but which have a legitimate use, such as medicines or foods. Therefore the import ban will specifically exclude substances that have a legitimate use, such as food, tobacco, alcohol, therapeutic goods, industrial chemicals, agricultural chemicals and veterinary chemicals. These will continue to be dealt with under existing regimes, such as the *Therapeutic Goods Act 1989* (TG Act) and the *Industrial Chemicals (Notification and Assessment) Act 1989* (ICNA Act). The measure will include a power to exclude other legitimate uses by regulation, and to issue permits to allow imports for limited purposes (such as for law enforcement to develop appropriate forensic reference standards).

If an importer seeks to import a psychoactive substance with a legitimate use, then he or she will continue to be required to seek the relevant authorisations and comply with the relevant standards under the appropriate regulatory scheme. This proposal will not affect the existing requirements to which importers are subject under the TG Act, ICNA Act, *Food Standards Australia New Zealand Act 1991* (FSANZ Act), *Imported Food Control Act 1992* (Imported Food Act) and the *Agricultural and Veterinary Chemicals Code 1994* (AgVet Code), which may include assessment, registration or listing of the substance.

AGD does not propose to create a new mechanism to regulate psychoactive substances. If a substance has a legitimate use, then the person seeking to import it will continue to be responsible for ensuring that the importation complies with the appropriate regulatory scheme, including ensuring it has been assessed, registered and approved by the relevant body.

The ban will also not cover illicit drugs. These will continue to be dealt with under the serious drug offences in the Criminal Code or the Prohibited Imports Regulations. In effect, this option will control the importation of substances that will, in AGD's experience, eventually be banned under the existing illicit drugs control schemes.

To be effective at the border, the ban will be supported by changes to allow ACBPS officers to use their existing search and seizure powers in relation to psychoactive substances. The measure is designed to fit within the existing framework for searching for and seizing suspicious substances. An officer will only use these new powers once he or she has determined that the substance is not listed as an illicit drug and does not have a legitimate use.

This will be a small but important change. ACBPS officers already stop many NPS at the border on suspicion that they are illicit drugs. This option will give those officers the certainty to stop and seize psychoactive substances destined for use as alternatives to illicit drugs, without affecting legitimate importations.

There will also be appropriate review mechanisms to ensure that substances with a legitimate use are not incorrectly seized under the measure. This mechanism will allow an importer who believes his or her goods have been incorrectly seized to make representations and provide evidence to the ACBPS about either the fact that the substance does not have a psychoactive effect, or that it has a legitimate use.

As outlined above, this option would complement State and Territory efforts to control the manufacture, supply and advertisement of NPS, and other elements of a national response developed by the IGCD. A national response aimed at reducing the supply of NPS is crucial in reducing the impact of these substances on public health.

2. Explore a pre-market assessment scheme for psychoactive substances

New Zealand has established a pre-market assessment scheme for psychoactive substances under the *Psychoactive Substances Act 2013*. This scheme allows psychoactive substances that have been assessed as 'low risk' to be legally sold in New Zealand.

A pre-market assessment scheme would ban the importation, manufacture, supply and advertisement of all substances with a psychoactive effect and that were otherwise unregulated, unless authorised by a Government regulatory agency. Such an authorisation would only be granted if the agency had assessed the substance to be a low-risk to human health, including examining its specific pharmacological, psychoactive and toxicological effects, its potential to cause death, serious injury or dependence, and the likelihood of its misuse. The onus would be on the person applying for the licence to demonstrate to the agency that the substance was not harmful.

AGD does not consider further exploration of a pre-market assessment scheme to be a viable way of dealing with NPS, even though it may assist in reducing some of the harm associated with NPS use.

Exploration of these issues, obtaining national agreement on them, and setting up and implementing a new regulatory regime for psychoactive substances would be an extremely lengthy process. During this time, the status quo would continue. Untested and unsafe products will continue to be presented as legal alternatives to illicit drugs and they will continue to cause harm to individuals and the community.

The New Zealand Government recently announced the withdrawal of all interim approvals for psychoactive products following consistent reports of 'severe adverse reactions' to those products.⁸

Further exploration of such a regime would also be contrary to the Government's approach to NPS, which is to list substances as border controlled drugs in the Criminal Code as evidence about their

⁸ P Dunne (NZ Associate Health Minister), *All remaining legal highs to be withdrawn from sale*, media release, Wellington, 27 April 2014, viewed 5 May 2014, <<http://www.beehive.govt.nz/release/all-remaining-legal-highs-be-withdrawn-sale>>.

use and harms has become available. It would also be contrary to recent moves in a number of jurisdictions, such as New South Wales, Queensland and South Australia, to comprehensively ban substances that seek to mimic the effects of illicit drugs.

In these circumstances, AGD considers that the overall net benefit of exploring a pre-market assessment scheme is low.

3. Education campaign

An education campaign about the health risks involved in consuming NPS may assist in reducing demand for them. Although there is limited research and evidence on the short- and long-term health effects of NPS consumption, reports of both fatal events and non-fatal overdoses from NPS are increasing. This option would not have any regulatory impact.

The National Drugs Campaign (NDC) is the Commonwealth Government's primary education campaign on drugs. It adopts a primary prevention approach to dealing with the use of drugs in the Australian community. The objective of the NDC is to reduce the uptake of drugs by raising awareness of the harms associated with drug use and encouraging and supporting decisions not to use. The next phase of the NDC will feature messaging that stresses the unknown content, unpredictability and harmful effects of a range of illicit drugs, including NPS.

However, public education messaging, such as the messaging delivered by the NDC, will need to ensure that it does not inadvertently promote interest in the use of NPS as an alternative to established illicit drugs. This is especially the case in relation to emerging NPS because there continues to be a misconception that NPS are safe because they are presented as being legal. Indeed, there is evidence that, once the harms of a previously used NPS have been established, users will seek an alternative NPS.⁹

Education is of crucial importance in tackling the public health challenges posed by NPS. It will assist in reducing demand for NPS.

However, on its own, an education campaign would neither be effective to control the use of NPS, nor to effectively reduce the associated risks to public health in Australia. Alone, an education campaign would allow people to continue to legally import and promote as legal substances that could lead to serious injury or death. An effective response to NPS requires measures that both decrease demand and limit supply.

Accordingly, AGD considers that the overall net benefit of an education campaign is low, unless it is also accompanied by effective mechanisms to limit the supply of NPS.

⁹ Research conducted for the development of the NDC has consistently highlighted that a lack of knowledge about the content and source of illicit drugs is a key concern amongst young people. Further, research conducted among people who take illicit drugs has shown that they are concerned about the range of substances found in drugs, and can influence their decisions about consumption.

4. Continue to progressively ban dangerous substances based on their chemical structure

This is the status quo. Under this option, people will be able to continue importing untested and potentially harmful substances into Australia for use as alternatives to illicit drugs.

As set out above, structure-based controls are insufficient to tackle the challenges posed by NPS. While the emergency determination mechanism under the Criminal Code enables the Minister to ban substances for up to 18 months on the basis of their chemical structure, this approach is ill-suited to dealing with both the increasing number of NPS (each with a different chemical structure) and the rate at which they are being imported into Australia. Under this approach, Government controls will always be behind the market, allowing potentially dangerous substances to be legally imported and sold while authorities identify them, assess their harms and list them by their chemical structure.

AGD considers that this option is not feasible. It does not address a significant and known vulnerability at the border and allows people to legally import substances that could lead to serious injury or death. AGD considers that there is an overall net detriment in continuing with the status quo.

Impacts of an import ban

The proposal to ban the importation of NPS is expected to have a substantial positive impact on public health, but a minor regulatory impact. It would apply criminal penalties to the importation of substances intended to be used in the same manner as illicit drugs. Some States, such as New South Wales, Queensland and South Australia, have already moved to control and criminalise these substances by introducing bans that are not based on chemical structure.

The measure will fix a loophole that allows importers to import NPS with a chemical structure intended to evade existing illicit drug import offences. It will supplement the existing import bans on some NPS in the Criminal Code and Prohibited Imports Regulations by preventing the importation of psychoactive substances which have no legitimate use or which are otherwise unregulated.

The measure will not affect the importation of substances with a legitimate use but which may also have a psychoactive effect. This includes therapeutic goods, food, alcohol, tobacco and industrial, agricultural and veterinary chemicals. Existing border controls and regulatory processes will continue to govern the importation of these substances. For example, if a person wishes to import a therapeutic good that also has a psychoactive effect, he or she will need to obtain the relevant authorisations and approvals to import the substance from the Therapeutic Goods Administration.

Based on experience, many of the substances that will be captured by the new import offence will eventually be banned under the Criminal Code and Prohibited Imports Regulations. In this sense, the proposal brings forward the time at which these substances are prevented from entering the country. This will prevent their large-scale public distribution and potentially dangerous effects on individuals' health while the Government assesses whether or not importing them should be subject to more significant penalties.

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The primary impact of the measure will be to prevent businesses and individuals from obtaining NPS for retail sale as 'legal highs' or for personal use. This will result in a range of public health benefits flowing from reduced consumption of untested and unknown NPS.

The measure may also result in increased costs for legitimate importers in that it may prompt importers to comply with the requirements of existing regimes regulating the importation of goods and substances. However, as importers should have been complying with those regimes in the first place, any additional costs will only arise out of improved compliance with existing regulation.

These issues are explored in more detail below.

Health benefits

Implementing the proposed import ban on NPS will have clear public health and safety benefits. As there is no evidence to suggest that the active ingredients in NPS are manufactured in Australia, the ban will significantly curtail their supply within Australia.

Health risks of NPS

There is limited evidence about the health risks associated with the use of NPS in Australia due to their relatively recent introduction into the Australian market and ever changing content and composition. Despite this, there is evidence to suggest that users of NPS risk being exposed to significant physical, mental and social harms. This data comes from a range of sources, including user reports and clinical observations.

While the health-related problems associated with the use of NPS vary, commonly documented effects include:

- cardiovascular problems
- severe psychological disorders
- increased risk of cancer
- agitation
- severe psychosis
- rapid heart rate (tachycardia), and
- hypertension.

Some of these health issues associated with NPS are similar to those associated with the drugs they are intended to mimic. In other cases, they are different.

There is also evidence that the toxicity of many NPS may be greater than illicit substances. Users of NPS may reach toxicity levels very quickly, and these substances may pose a higher risk of overdose than the illicit drugs whose effects they are intended to mimic. Further, while the side effects of established illicit drugs are well documented, data on human toxicity related to the use of NPS remains limited. The significant variation in chemical content and concentration in NPS products can make determining toxicity levels and understanding side effects difficult. This variation can pose enormous challenges for health professionals, particularly in emergency departments, who must diagnose and treat the often severe side effects associated with overdoses and the use of NPS.

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Preventing individuals and businesses from obtaining NPS for retail sale or personal consumption

NPS are currently being openly sold and marketed as 'legal highs' by, for example, internet retailers, tobacconists and adult shops. As noted above, the sale of NPS can generate significant profits for retailers and wholesalers. The body representing a number of NPS retailers has estimated that, nationally, the NPS market is worth \$600 million.¹⁰ As there are no known domestic manufacturers of the active ingredients for NPS, the import ban will prevent these businesses from legally acquiring these products for sale, and prevent them from profiting from their sale. It will also prevent businesses which import, distribute or wholesale NPS from accessing those substances and profiting from them.

Similarly, the import ban will prevent individuals from legally purchasing NPS over the internet from overseas and importing them into Australia for personal consumption or resale.

Legality of NPS

The legality of products containing NPS is often questionable. Accurate information about their ingredients is often difficult to obtain, and those ingredients may already be controlled or banned under existing Commonwealth, State and Territory legislation.

Further, the legality of sale of NPS varies across jurisdictions. New South Wales, Queensland and South Australia have criminalised the manufacture, supply and advertisement of substances that have been designed, or are intended, to mimic illicit drugs.

Therefore, introducing an import ban on NPS will ensure that those substances are illegal. As noted above, in addition to the comprehensive bans on NPS in New South Wales, Queensland and South Australia, various NPS are already listed as illicit drugs (or captured by analogue clauses) in all jurisdictions and, based on experience, many will be listed by chemical structure in the future as information about the risks they pose and their health effects becomes available. This further limits the actual regulatory impact of the measure: NPS are either already banned or likely to be banned in the near future.

Possible displacement effects

By improving ACBPS officers' powers to seize NPS at the border, the import ban will reduce the availability of these substances for human consumption.

The absence of data around NPS use and the drug habits of users makes it difficult to predict how reduced availability of NPS may affect current users. It may cause current users to shift their NPS consumption to other, more established illicit drugs.¹¹ Other users may shift their consumption to licit drugs, such as alcohol, or cease consuming drugs for non-therapeutic purposes altogether.

¹⁰ Eros Association Inc, *Response to Questions on Notice from the Legal Affairs Committee of the Legislative Assembly of New South Wales*, 22 November 2012, p 1.

¹¹ Recent studies have shown connections the use of more established illicit drugs and the use of NPS. For example, the Ecstasy and Related Drugs Reporting System found that, in 2013, 37% of participating users had used an NPS in the last six months: National Drug and Alcohol Research Centre, *Australian Drug Trends 2013*:

If 100% of NPS users were displaced into using other, more established illicit drugs, there would be no net positive benefit from the ban on NPS. Established illicit drugs have been banned because they have been assessed as carrying the potential for serious harm to the user and to society.

However, health workers, particularly in emergency departments, have significant experience in dealing with these better researched drugs, their hallmarks and side effects. Reducing the range of substances that confront front-line health workers would assist in avoiding circumstances, like those involved in reported cases, where hospital staff are hampered in their ability to treat adverse reactions to NPS by a lack of publicly available knowledge about the active ingredients of particular illicit drugs.¹²

Further, as set out above, increased seizures of NPS at the border will improve law enforcement knowledge of the substances available on the NPS and illicit drug market. This additional knowledge will assist in improving health outcomes for persons who suffer adverse effects as a result of taking NPS. It will likely reduce the number of NPS that law enforcement and health officials first encounter as a result of overdoses and other adverse health effects.

Compliance costs

AGD expects that this measure will have a minimal impact on compliance costs.

At the outset, AGD notes that regulating the importation of chemical substances is quite complex. There are few, if any, substances the importation of which is not governed by a series of standards, such as those under the FSANZ Act, or subject to authorisation or listing, such as under the TG Act. This proposal will not change the requirements of those regulatory regimes, or make the process of importing chemicals more complex for legitimate businesses.

Currently, the ACBPS detains at the border substances it suspects may be illicit drugs while it assesses whether or not they should be seized. In making this assessment, the ACBPS will test the substance and correspond with both the importer and relevant regulatory authorities. Goods may be detained for a period of time while the ACBPS makes this assessment.

There are four possible outcomes from this process:

1. The ACBPS establishes that the substance is an illicit drug (whether under the Criminal Code or Prohibited Imports Regulations) based on its chemical structure. The ACBPS refers the substance to the AFP for further investigation and, potentially, prosecution.
2. The ACBPS establishes that the substance has a legitimate use because it falls within the regulatory scope of an existing regime (such as under the TG Act, FSANZ Act, ICNA Act or the AgVet Code). The ACBPS refers the substance to the relevant regulatory body to establish whether the importer has the appropriate authorisations or permissions to import it. If the

Findings from the ecstasy and related drugs reporting system, 2013, accessed 5 May 2014, <<http://ndarc.med.unsw.edu.au/resource/key-findings-2013-edrs-drug-trends-conference-handout>>.

¹² R Olding, 'Lawyer kept 'bath salts' ingredient secret as Glenn Punch was dying', *Sydney Morning Herald*, 10 October 2013, viewed 5 May 2014, <<http://www.smh.com.au/nsw/lawyer-kept-bath-salts-ingredient-secret-as-glenn-punch-was-dying-20131010-2vam0.html>>.

importer has the appropriate authorisations or permissions to import the substance (or if authorisation or permission is not necessary), the ACBPS will allow its importation.

3. The ACBPS establishes that the substance has a legitimate use because it falls within the regulatory scope of an existing regime. If the relevant regulatory body confirms that the importer does not have the appropriate authorisations or permissions to import the substance, the regulatory body may direct the ACBPS to seize the goods on its behalf.
4. The ACBPS cannot establish that the substance is an illicit drug or that it is subject to an existing regulatory scheme. In this case, the ACBPS must release the substance.

The proposed measure would only affect the fourth category of goods. Under the proposed measure, if the ACBPS cannot establish that the substance is an illicit drug or is subject to an existing regulatory scheme, it will be able to seize the substance if it reasonably believes the substance is psychoactive. Once the ACBPS has seized the goods, the importer will have an opportunity to dispute the seizure.

The ACBPS will not detain additional substances for further investigation under the proposed measure. Rather, officers will only be able to use the new powers to formally seize substances they already detain on suspicion that they are illicit drugs.

Preliminary data from the ACBPS indicates that the measure is likely to affect about 1,000 importations each year, whether in cargo, in the post or on a person. This is an extremely small number in the context of the tens of millions of inspections that the ACBPS undertakes each year. For example, in 2012/13, the ACBPS inspected over 100,000 units of sea cargo, 1.5 million units of air cargo, 15.5 million letters, 30 million parcels, 31.5 million air passengers, 715,000 cruise ship passengers and 550,000 crew members of commercial ships.

Enforcement costs to business and individuals

The measure will involve some enforcement costs to business and individuals. These will arise once the ACBPS seizes the substance on suspicion that it is psychoactive.

However, the measure will not itself directly impose additional regulatory costs on importers. Rather, it will require importers who dispute the seizure of their goods to provide evidence about those goods (such as their intended purpose). Where that evidence shows a legitimate purpose, the substance will be dealt with in accordance with the applicable regime.

As noted above, the ACBPS will not detain additional shipments under the measure. Therefore the measure will not impose additional costs on importers whose goods the ACBPS has detained on suspicion of being an illicit drug, at least until the ACBPS makes the decision to formally seize the substance.

There is only a small possibility that ACBPS officers will seize substances with a legitimate use, if at all, as the ACBPS will liaise with importers to determine the intended use of a substance following its detention. In the event that the ACBPS does seize such a substance, the measure will include appropriate oversight mechanisms to allow an importer to dispute the seizure of goods. Importers

engaging with these mechanisms will incur some regulatory costs. However, these costs will be attributable to existing regulatory schemes, as explained in more detail below.

The costs involved will include:

- the time a business takes to write letters or fill out forms disputing the seizure
- gathering evidence and preparing reasons to establish that a substance has a legitimate use and should be dealt with under the appropriate scheme
- the time a business takes to gather that evidence and prepare those reasons for submission to the ACBPS, and
- the delay flowing from the ACBPS's seizure of the goods.

Disputes over the seizure of a substance will generally only involve questions of whether or not the substance had a legitimate use. That is, importers will use the review process to provide evidence to demonstrate that the substance should have been dealt with under some other regulatory scheme (which may or may not allow it to be imported). Any importer who demonstrates this may be in breach of the regulatory requirements of that other scheme (which may, for example, impose a requirement to label the goods in a particular way, or to have them registered).

The relevant information and evidence to be provided to the ACBPS to dispute the seizure would be routinely held by businesses, not-for-profit entities and individuals. Evidence of business operations, sale or end use could be used to satisfy the ACBPS that the substance was being imported for a legitimate purpose (that is, under an existing regulatory scheme).

The measure will therefore improve compliance with existing regulatory regimes. It will prompt importers to comply with schemes with which they should already have been complying. This may require some importers to incur costs in registering to import their goods under those regimes, and in having their goods tested and assessed to ensure that they comply with relevant standards. However, the measure will not require importers to incur costs additional to those they should have incurred in complying with those existing schemes. The costs involved in improved compliance are therefore business-as-usual costs.

If an importer successfully disputes the seizure of the substance, then the substance will be referred to the appropriate regulatory body for consideration. It may or may not be able to be imported, depending on whether it has actually been imported in accordance with the relevant scheme. For example, it may be that the importer demonstrates the substance is an industrial chemical as a result of the review, based on evidence not available at the time of the seizure. The importer would then have to comply with the relevant requirements under the ICNA Act in order to be able to import the substance. This includes registration as an introducer with the National Industrial Chemicals Notification and Assessment Scheme and listing of the substance on the Australian Industrial Chemical Scheme.

If the importer unsuccessfully disputes the seizure, then it will incur no further regulatory costs. The importation is deemed to be unlawful and the substance will be destroyed.

Similarly, there will be no regulatory cost for the importer if the ACBPS seizes a substance and the importer does not dispute the seizure. The importation is unlawful and the substance will be destroyed.

The proposed measure will include the ability to exclude additional substances with a legitimate use by regulation. AGD does not anticipate that the process for creating such regulations will have regulatory impacts upon businesses or individuals. This is because of the breadth of coverage of the TG Act, FSANZ Act, Imported Food Act, ICNA Act, *Agricultural and Veterinary Chemicals (Administration) Act 1992* and AgVet Code, and the provisions under those Acts that allow for the importation of substances for medical, research and other purposes. Taken together, AGD does not anticipate that there will be circumstances where legitimate industry will require access to substances that are not initially covered under one of those Acts and which would otherwise fall within the terms of the proposed measure. The regulation making power is intended to more simply accommodate unanticipated changes to the regulation of the importation of chemical substances (for example, if Government decides to impose a specific regulatory scheme on a subset of foods or therapeutic goods, or if it changes the regulatory scope of the National Industrial Chemicals Notification and Assessment Scheme).

Criminal justice impacts

Under the ban, it would be a criminal offence for a person to import a psychoactive substance that was otherwise unregulated. As with all criminal offences, the ban would have criminal justice impacts on individuals and businesses, border protection and law enforcement agencies and prosecution services and corrective services operators.

If a person or business does attempt to contravene the law, the ban may have significant impacts upon them. The person or business would be charged with an offence and may incur legal fees in defending those charges. If they were found guilty of having committed the offence, the person or business may be given a fine, or the person sent to prison for a period of time.

Prosecution of a person will result in an increased workload for border protection and law enforcement agencies, who will investigate the alleged offence, and prosecutions services. Similarly, if a person is convicted of an offence and sent to prison, this will result in increased costs for corrective services operators.

However, these impacts should not be overstated. Its primary purpose is precautionary, to stop as many NPS from entering the country as possible. Criminal offences are necessary to give effect to the ban, but they are not its focus.

Further, a number of factors will reduce the criminal justice impacts of the ban. First, as noted above, AGD does not expect that the ban will affect a large number of substances or importations. Further, AGD expects that the number of attempted imports of these substances will reduce. The ban will be a definitive statement that NPS are not legal. Importers will no longer be able to attempt to avoid illicit drug controls by tweaking the structure of NPS and there may be a reduction in the number of attempts to import these substances. Reduced importations of NPS will correspondingly

reduce the number of potential investigations, charges, prosecutions and convictions for contraventions of the offence.

AGD also anticipates that the ban will have only a limited impact on the workload of border protection agencies. The ACBPS already detains NPS at the border on suspicion of being illicit drugs. The ban will simply clarify its power to seize these substances.

In these circumstances, the criminal justice impacts of the ban on individuals, businesses and governments will be minor.

Effect of the ban

While it is difficult to estimate the precise impact that an import ban will have on the NPS market, curtailing the supply of NPS is a crucial step in reducing the number of people who die or are seriously injured as a result of consuming them. It will also deliver demand-side benefits by clearly reinforcing public awareness of the potential health risks associated with NPS.

Overall, AGD considers that an import ban will have a medium net benefit. The health benefits clearly and significantly outweigh the impact of the ban on:

- individuals who use or supply NPS
- businesses which profit from the distribution, wholesale or retail sale of NPS
- individuals and businesses which may now need to demonstrate the legitimate purpose of a substance they wish to import, and
- border protection and law enforcement agencies, prosecution services and corrective services operators which may have small increases in workloads.

Regulatory Burden and Cost Offset (RBCO) Estimate

Any regulatory costs that the ban on the importation of NPS will impose on businesses, not-for-profit entities or individuals are excluded from the RBCO calculation.

As noted above, the measure will not increase the number of goods or substances that the ACBPS detains at the border on suspicion of being an illicit drug. It will only allow the ACBPS to seize those substances that it reasonably suspects are psychoactive. The measure will not, therefore, increase the regulatory burden on businesses, not-for-profit entities or individuals who import goods in compliance with existing regulatory regimes.

The regulatory costs involved in disputing a seizure will fall outside the RBCO. To be successful in disputing the seizure, the importer will have to show that the substance in fact had a legitimate use and was regulated under another scheme. In this case, the regulatory costs involved will be the business-as-usual costs involved in complying with that scheme. These are excluded from calculation.

Regulation Impact Statement: Banning the importation of substances which mimic the effects of illicit drugs

If the importer is unsuccessful in disputing the seizure, the regulatory costs involved will be costs of non-compliance with the ban on the importation of psychoactive substances. These are also excluded from calculation.

Importers will not be required to fill out any documentation in order to comply with the import ban. However, they may be required to fill out forms in order to comply with existing regulatory regimes. Again, these costs are excluded from calculation.

Regulatory Burden and Cost Offset (RBCO) Estimate Table

Average Annual Compliance Costs (from Business as usual)				
Costs (\$m)	Business	Community Organisations	Individuals	Total Cost
Total by Sector	\$0	\$0	\$0	\$0
Cost offset (\$m)	Business	Community Organisations	Individuals	Total by Source
Agency	\$0	\$0	\$0	\$0
Within portfolio	\$0	\$0	\$0	\$0
Outside portfolio	\$0	\$0	\$0	\$0
Total by Sector	\$0	\$0	\$0	\$0
Proposal is cost neutral? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no				
Proposal is deregulatory <input type="checkbox"/> yes <input checked="" type="checkbox"/> no				
Balance of cost offsets \$0				

Consultation

AGD has consulted extensively throughout government in developing the measure, including with the Health and the ACBPS. It has also consulted with regulatory agencies whose regimes may be affected by the proposed import ban.

AGD will issue this RIS for public consultation. In addition to placing it on its own website and that of the Office of Best Practice Regulation, AGD will specifically send the RIS to stakeholder groups, including the Plastics and Chemical Industries Association, members of the Precursor Industry Reference Group and the Eros Association, to obtain their views on the potential impact of the measure.

Conclusion

AGD's preferred approach is to implement the option with the highest net benefit, by introducing legislation banning the importation of otherwise unregulated psychoactive substances. This will have a direct impact on the ability of retailers to source and supply NPS. AGD notes that this import ban is not intended to replace existing mechanisms to progressively ban dangerous substances under the Criminal Code. It will supplement those mechanisms by allowing authorities time to assess the risk posed by new substances as they appear, without those substances being readily available for purchase and consumption.

An import ban will have the highest net benefit of the options canvassed in this RIS. As noted above, options of an education campaign about the dangers of NPS or continuing the current practice of banning substances based on their chemical structure will, on their own, be insufficiently effective in reducing the health impacts of NPS.

An import ban on psychoactive substances without a legitimate use is a small but important step in reducing the number of people who are harmed, directly or indirectly, from using unsafe, untested and dangerous substances which masquerade as legal or legitimate alternatives to listed illicit drugs. As the active ingredients for the substances are imported into Australia from manufacturers overseas, an import ban is a vital part of preventing their sale and distribution, and in allowing ACBPS officers to seize them at the border.

Banning the importation of psychoactive substances without a legitimate use will also send a message about the dangers associated with their use. That these compounds are currently being sold, over the internet and from domestic businesses, as 'legal' alternatives to listed illicit drugs suggests that they are somehow safe, even where their potential harms are completely unknown, or where the media has reported the death or serious injury associated with taking them. This representation has the potential to cause, and has in fact caused, great harm to members of the public who purchase NPS in the belief that 'legality' implies the substance has been tested and assessed as safe and appropriate for sale.

While there is limited data to quantify the precise health benefits that would flow from an import ban, AGD considers that the benefits flowing from reduced consumption of NPS outweigh the commercial interests of businesses which sell these substances. As noted above, NPS currently exist at the fringes of legality. Their consumption has been linked to deaths and serious injury. They mimic the effects of illicit drugs but have been designed to get around existing controls on those drugs. Several NPS, such as 4-methylmethcathinone, benzylpiperazine and a range of synthetic cannabinoids, have been prohibited under the Criminal Code and SUSMP as evidence about the harms and dangers associated with their use became available.

The ban will also enhance the Commonwealth's ability to list new, harmful substances as they emerge. It will clarify ACBPS officers' ability to seize substances they suspect are illicit drugs, improving law enforcement and health agencies' understanding of the NPS market, their ability to assess the harms associated with the use of specific substances and the Commonwealth's ability to institute appropriate controls on those substances.

Regulation Impact Statement: Banning the importation of substances which mimic the effects of illicit drugs

While banning the importation of NPS into Australia is a key part of reducing the health effects associated with their use, it is not a complete answer to the challenges posed by NPS. A ban will not be fully effective in reducing supply unless it is accompanied by complementary measures from States and Territories to ban the manufacture, supply and advertisement of NPS. New South Wales, Queensland and South Australia have all recently implemented such bans. It will also require concerted and coordinated effort from health and law enforcement agencies across the Commonwealth and States and Territories to implement effective measures to reduce both supply and demand for these substances.

Implementation and review

Implementation of the measure to ban the importation of NPS will require legislative change.

If the ban is implemented, AGD and ACBPS would review its operation after two years of operation. This review would consider the effectiveness of the ban and its impact on the importation of substances for legitimate purposes, including whether the ban is appropriately targeted and the adequacy of the exemption categories and review mechanisms.