Australian Government
Attorney-General's Department

Deputy Secretary
National Security and Criminal Justice

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Your reference: 15249

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Dear Mr McNamara

Regulation Impact Statement – final assessment second pass

Thank you for providing the Office of Best Practice Regulation's (OBPR) first pass final assessment comments on the Regulation Impact Statement (RIS) prepared for the measure to ban the importation of new psychoactive substances (NPS).

I write now to provide you with the attached RIS for second pass final assessment. The RIS identifies the regulatory burden to business, community organisations and individuals. As agreed with your office, there is no additional cost to these regulatory impacts.

I am satisfied that the RIS addresses the concerns raised in your letter of 5 June 2014. The RIS now more clearly articulates the uncertainties and limitations of the evidence available about the NPS market in Australia.

The changes to the RIS are explained in greater detail below.

Question 1: What is the policy problem you are trying to solve?

1. Evidence of problem

OBPR raised concerns that the RIS did not contain sufficient information about the health, behavioural and social problems associated with NPS. It sought quantification of the health costs and long-term side effects of NPS, and an assessment of those in relation to legal substances, such as alcohol. OBPR also sought information about uncertainties over the size and scope of the risks involved in NPS consumption and the factors driving demand for and use of NPS.

The Attorney-General's Department (AGD) has amended the RIS to more explicitly acknowledge the limitations of the evidence in relation to the use of NPS. The RIS acknowledges that, while there have been greater efforts to collect and analyse data on NPS in recent years, it is difficult to assess the full extent of the problem. The nature of these substances means there is limited information available about them, their prevalence, use and health effects. The term 'NPS' covers a broad range of new and emerging synthetic drugs, the structure, effects and health consequences of which are constantly evolving.

Further, the RIS states that data collection and analysis has historically focused on more established drugs, both licit and illicit. Because NPS are a relatively recent phenomenon, and because they exist on the fringes of legality, there is no quantitative data on their precise health costs and long-term side effects.

However, the RIS notes that the evidence that is available, particularly from the Australian Crime Commission, suggests that the distribution and use of NPS is likely to become a much bigger problem if nothing is done. This echoes the experiences of other countries, particularly Ireland and New Zealand, which have seen a rapid rise in the public availability and use of NPS.

2. Description of fast-track listing processes

OBPR stated that the RIS would benefit from a description of the existing fast-track listing process for NPS.

AGD has expanded upon its description of the emergency determination provisions in the Criminal Code. These provisions were amended in 2012 to expand the period for which a substance could be listed as a serious drug, and to refine the criteria that must be satisfied before a determination can be made. These amendments were intended to assist in the timely listing of newly detected and emerging NPS. However, AGD's experience has been that, even with this fast-track emergency determination process available, illicit drug laws are unable to keep pace with the rate of introduction of previously unknown NPS.

3 & 4. Size of the problem

OBPR noted that the RIS should more consistently describe the scale of the problem, particularly in light of the analysis in the section on regulatory impacts which suggests that an import ban would likely only affect 1,000 imports per year. These statistics about imports that may be affected by the import ban were based on preliminary analysis by the Australian Customs and Border Protection Service (ACBPS).

AGD has amended the RIS to more clearly and consistently articulate the scale of the problem posed by NPS. Consistent with the issues identified above about the limited amount of information available about NPS, the RIS highlights the difficulties involved in assessing the size of the problem, using drug seizure statistics as an example. According to the *Illicit Drug Data Report 2012-13* (IDDR), there were about 60 seizures of novel psychoactive substances and drug analogues in 2012-13. These seizures primarily related to listed illicit drugs (such as novel cathinone-type substances, synthetic cannabinoids and novel piperazine-type substances) and their analogues, rather than to NPS that are uncontrolled. However,

preliminary data from the ACBPS suggests that, in a similar period, it would have stopped for further analysis about 1,000 imports on suspicion that they involved the importation of an NPS. The ACBPS could not ultimately seize these substances because subsequent testing showed they were not a listed illicit drug. While some of these substances may not have been NPS, the RIS notes that the discrepancy between this figure and the figure in the IDDR illustrates the difficulty involved in gathering reliable data on substances that are largely unregulated.

As noted above, the limited data available about the NPS market suggests that it is growing, that there is potential for further growth, and that this is consistent with international trends.

Question 2: Why is government action needed?

5. Including outcomes in the RIS

OBPR has noted that it would be best practice for the RIS to identify measurable outcomes for objectives, as this would assist in comparing options, as well as reviewing the success of measures.

AGD has included two broad outcomes in the RIS, noting that our ability to measure success will be hampered by the uncertainties in the scope of the problem, identified above. Despite the limitations on available data, AGD has identified that a successful policy to reduce the impact of NPS on public health should involve the following outcomes:

- a reduction in the number of reports of persons presenting to emergency departments following the consumption of unknown or unidentified drugs, and
- a reduction in the number of premises selling NPS, whether as 'legal highs' or otherwise.

The RIS notes that there will be further limitations on the Commonwealth's ability to affect the success or otherwise of these outcomes. The Commonwealth's primary legislative responsibility with respect to NPS is at the border, and laws relating to the manufacture, supply and advertisement of NPS are primarily the responsibility of States and Territories. Accordingly, and without greater information about NPS generally, it is not possible to set out more definite and measureable outcomes for the policy.

In addition, the RIS notes that Commonwealth action is only one aspect of the national response to NPS. The Commonwealth's policy must complement the work of the Intergovernmental Committee on Drugs 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.

Question 4: What is the likely net benefit of each option?

6. Additional information on impacts

OBPR requested that the RIS provide greater information on a range of matters relating to the impacts of the measure, including the size of health benefits, impacts on importers, distributers, wholesalers and users of NPS, costs associated with law enforcement and prosecution, and costs to legitimate importers.

As noted above, this information is not available. The nature of NPS and the NPS market makes its collection extremely difficult. Without reliable and comprehensive data on the NPS market, it is not possible for AGD to quantify the health benefits, impacts on importers, distributers, wholesalers and users or the costs associated with law enforcement and prosecution. Similarly, without greater knowledge about the number of NPS imported into Australia, it is not possible to assess how many of the 1,000 suspicious imports identified by the ACBPS would be likely to be NPS and seized under the import ban.

This change has affected the manner in which the RIS deals with each option. As AGD does not have information sufficient to quantify the problem or the impacts of each option, it cannot assess whether any option is likely to have a net benefit or net detriment. While AGD can make assessments about the likely or potential impacts of each option, without more reliable data on the NPS market, it is not possible to assess with certainty whether an import ban, a pre-market assessment, an education campaign or continuing with the status quo will have the greatest net benefit, or even a net benefit.

However, this conclusion must be considered in light of:

- recent reports—from users, clinical observations and the media—about deaths and serious harm following NPS consumption
- evidence from New Zealand about ongoing harm from the consumption of psychoactive products
- the potential for unknown, untested but toxic substances to be supplied for human consumption
- AGD's experience that NPS are typically listed as illicit drugs once information about their harms and effects becomes available, and
- the Australian Crime Commission's assessment of the NPS market as having the potential for growth.

The RIS notes that these factors tend to suggest that a precautionary import ban on NPS may have some benefits, particularly in inhibiting the future growth of the market. However, the RIS also notes that it is not possible to quantify these benefits, or to properly weigh them against the likely costs of the ban. In these circumstances, AGD considers that an import ban is likely have an overall benefit, but concludes that it is not possible to quantify this.

7. Ability to circumvent the ban

OBPR noted that the RIS needed to explore the effectiveness of an import ban, and to identify the potential for people to circumvent it, such as by incorrectly labelling a product to suggest it was legitimate or hiding it in a product that was lawfully able to be imported.

AGD has amended the RIS to include discussion of the possible impacts of attempts to circumvent an import ban. The RIS notes that successfully circumventing the ban would reduce its practical effect.

The RIS also notes that, in the absence of comprehensive and reliable data about demand for, and use of, NPS, it is not possible to make an assessment of the number of people who may continue to desire NPS even after they have been banned. It is, therefore, not possible to estimate the number of people who will attempt to import NPS by hiding these substances in legitimate goods. However, based on experience with respect to other illicit drugs, AGD has assumed that at least some people will attempt to circumvent the ban.

For a number of reasons, the impact of attempts to circumvent the ban are likely to be very low. First, the ACBPS and the Australian Federal Police have significant experience in finding goods that hide illicit commodities, including illicit drugs. These officers will use similar skills, expertise and information to stop and seize suspicious substances, even where they may appear to be a legitimate good. Secondly, as outlined previously, AGD expects that clarifying that NPS are illegal is likely to reduce demand for them. Reduced demand will similarly reduce the number of people who will attempt to circumvent the ban.

Finally, the RIS notes that complementary State and Territory measures will be important in ensuring that, even if a person does successfully import an NPS, it cannot legally be sold, supplied or advertised. This will improve the effectiveness of the ban: NPS that are hidden in a product with a legitimate use cannot later be legally converted and sold as an alternative to an illicit drug.

Question 5: Who will you consult and how will you consult them?

8. Length of consultation period

OBPR raised concerns that AGD did not consult on the RIS for 30 days, in accordance with best practice requirements.

AGD provided the RIS to external stakeholders on 6 May 2014 and received comments on it up until 22 May 2014. The consultation version of the RIS remains on AGD's website and we continue to welcome comments on the options proposed in the RIS, notwithstanding that this is the final version.

Question 6: What is the best option from those you have considered?

9 & 10. Recommending the option with the greatest net benefit

OBPR stated that the analysis of the problem and impacts of options in the RIS did not support the conclusion that the ban on the importation of NPS would deliver an overall net benefit. OBPR also noted that the RIS must recommend the option with the greatest net benefit.

Based on the changes explained above, particularly those resulting from the limited information available in relation to the NPS market, AGD has modified its conclusions in the RIS.

AGD considers that the problems posed by the importation, sale and distribution of unknown chemical compounds which masquerade as illicit drugs are not insignificant, but accepts that NPS are not currently as great a societal or public health problem as other illicit drugs. However, there is clear potential for the NPS market to grow, which would only exacerbate existing public health issues.

AGD also remains of the view that there are good reasons for the Government to take precautionary action to tackle NPS and prevent the market from growing, as governments have done in a number of other countries. While AGD acknowledges the lack of comprehensive data about the potential effects and benefits of an import ban on psychoactive substances without a legitimate use, it considers that such a ban is likely to be effective in reducing the public health impacts of NPS.

However, in the absence of comprehensive data about the likely health benefits, potential displacement effects and impacts on businesses, community organisations and users, AGD accepts that it is unable to demonstrate, to the level required by the *Australian Government's Guide to Regulation* (Guide) that an import ban would have a net benefit.

For similar reasons, AGD cannot demonstrate the overall benefit of exploring a pre-market assessment scheme. However, AGD considers that such a scheme would be contrary to Government policy to list NPS as illicit drugs as evidence about their use and harms becomes available. It would also be contrary to recent developments in New Zealand, which has a pre-market assessment scheme, and which has now withdrawn all interim approvals for the supply of NPS following continued reports of harm to users.

AGD has not changed its conclusions in relation to an education campaign or the status quo. While these options may complement others, on their own they are unlikely to be sufficiently effective to reduce the health impacts of NPS.

AGD accepts that that it is unable to demonstrate, to the standard required by the Guide, that any of the options explored above has the greatest net benefit. In such a situation, the Guide requires that no recommendation be made for regulatory change.

Notwithstanding that no recommendation for regulatory change can be made in accordance with the Guide, AGD still considers that there is evidence to merit Government considering intervention to reduce NPS use by imposing a ban on their importation. While NPS are not currently as great a societal or public health problem as other illicit drugs, the problems posed by the importation, sale and distribution of unknown chemical compounds which masquerade as illicit drugs are not insignificant. There is clear potential for the NPS market to grow, which would only exacerbate existing public health issues.

Accordingly, the RIS sets out AGD's belief that there are good reasons for the Government to take precautionary action to tackle NPS and prevent the market from growing, as governments have done in a number of other countries. While AGD acknowledges the lack of comprehensive data about the potential effects and benefits of an import ban on psychoactive substances without a legitimate use, it considers that such a ban is likely to be effective in reducing the public health impacts of NPS.

Further, AGD notes that an import ban may assist in obtaining evidence about NPS. While this information will assist in determining the controls to be placed on NPS as they are detected, it will also assist in developing a more reliable evidence base about the Australian NPS market. Greater information about the NPS market would be useful in guiding the review of any ban, and in considering whether it is the most appropriate measure to tackle NPS.

Accordingly, I am satisfied that the RIS is consistent with the Guide.

I submit the RIS to the Office of Best Practice Regulation for formal final assessment.

Yours sincerely

Katherine Jones
Deputy Secretary
Attorney-General's Department
30 June 2014