Regulatory Impact Statement

Amendment to the Misuse of Drugs Act 1975

Agency Disclosure Statement

This Regulatory Impact Statement has been prepared by the Ministry of Health.

This statement analyses the options available for regulating the NBOMe family of hallucinogens. Options considered in this Regulatory Impact Statement include legislative and non-legislative measures.

Section 4B(2) describes the matters that the Minister must have regard to and on which the Expert Advisory Committee on Drugs must give advice. Of these matters, the Committee was unable to provide advice on the neurotoxicity, reproductive toxicity, genotoxicity, carcinogenicity, potential appeal to vulnerable populations or the ability of the drug to create physical or psychological dependence. This is because this information does not exist or was not available. Despite these gaps in the information, the Committee was of the opinion that sufficient information existed to allow a recommendation to be made.

The estimated reductions in harm to the public and enforcement and treatment costs are based on the assumption that higher penalties and tighter controls will cause a decrease in demand, which is expected to result in a decrease in supply that may reduce impacts over time. Due to the similar effects and dosage forms of Lysergic Acid Diethylamide (LSD) and various members of the NBOMe family, seizure information is reported as a combined total of LSD and NBOMe. It has been assumed that the increase in seizures of LSD and NBOMe in New Zealand is mostly due to an increase in NBOMe seizures, rather than LSD seizures. This is because the drastic increases in New Zealand seizure information coincide with reports of drastic increases in international NBOMe use, whereas international LSD use is declining. It has also been assumed that the increase in LSD and NBOMes seizures reflects an increase in the illicit use of LSD and NBOMes, rather than an improved rate of seizures.

No further work is required before the proposal can be implemented.

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Executive summary

1. The NBOMes are a family of hallucinogenic compounds that are currently regulated in New Zealand under the Psychoactive Substances Act 2013. The United Nations Commission on Narcotic Drugs recently recommended that 25B-NBOMe, 25C-NBOMe and 25I-NBOMe be included in Schedule I of the Convention on Psychotropic Substances 1971. Many other countries already regulate these substances under controlled drugs or medicines legislation.

2. The Expert Advisory Committee on Drugs recently performed a comprehensive and evidence-based review of the information available on the NBOMe family. The committee recommended that 25B-NBOMe, 25C-NBOMe and 25I-NBOMe be included in Part 1 of Schedule 2 of the Misuse of Drugs Act 1975 as class B1 controlled drugs.

3. The proposal will:
   - ensure that New Zealand, as a State Party, meets its obligations under Article 7 of the Convention on Psychotropic Substances
   - regulate access to the NBOMe family in line with the risk of harm posed to individuals by their misuse
   - send a message that these substances are harmful and should not be used as recreational drugs.

4. The proposal is expected to reduce use of these substances through increased prison sentences and controls in comparison to the status quo. Enforcement and treatment services costs are expected to increase in the short term, but decrease in the long term as a result of the proposal.

5. Minimal impact on the public, the psychoactive substances industry or the scientific research community is expected as a result of this proposal because access to all members of the NBOMe family with psychoactive properties is already regulated.

Status quo and problem definition

Current regulatory environment

6. NBOMes are a group of more than 30 structurally related, hallucinogenic compounds currently regulated by a default position under the Psychoactive Substances Act 2013. That is, they are not able to be sold as they are unapproved psychoactive substances. Of the NBOMe family, 25B-NBOMe, 25C-NBOMe and 25I-NBOMe are the most commonly seen on the illicit market.

7. There is no established therapeutic or diagnostic use for, and no known research being conducted on, any member of the NBOMe family in New Zealand. The NBOMe family mostly appears to have been developed for use as recreational drugs.

8. NBOMes produce similar effects to lysergic acid diethylamide (LSD). They are usually sold in the same dosage form and often sold as each other or mistaken for each other. As a result, NBOMe and LSD seizures are reported as a combined total.

9. The United Nations Commission on Narcotic Drugs recently recommended that 25B-NBOMe, 25C-NBOMe and 25I-NBOMe be included in Schedule I of the Convention on

Psychotropic Substances 1971, but this has not yet been implemented. New Zealand is a signatory to the Convention.

10. To comply with their obligations under Article 7 of the Convention on Psychotropic Substances, New Zealand must:

- prohibit use of the substances except for scientific and very limited medical purposes by duly authorised persons
- require that manufacture, trade, distribution and possession be under a special licence or prior authorisation
- closely supervise the activities and acts mentioned in a and b
- restrict the amount supplied to a duly authorised person to the quantity required for the authorised purpose
- require records to be kept concerning the acquisition of the substances and the details of their use
- prohibit export and import except by the competent authorities or authorised persons
- require a separate import or export authorisation for each import or export of a controlled substance.

11. Many other countries, including the United Kingdom, the United States of America and some states of Australia, already regulate NBOMes under controlled drugs or medicines legislation.

12. The Misuse of Drugs Act 1975 was established to restrict access to substances that pose at least a moderate risk of harm to the user. The Psychoactive Substances Act was established to allow controlled access to substances that pose no more than a low risk of harm. The penalties applied under each regime are related to the level of harm posed by the substances that each regime is designed to control.

- The penalty for possession of an unapproved psychoactive substance is a fine ($500), but the penalties for dealing in psychoactive substances without the appropriate licences are large fines ($40,000 to $500,000) or short terms of imprisonment (up to two years).
- The penalty for possession of a controlled drug is a fine ($500 to $1,000) and/or a short term of imprisonment (up to six months), but the penalties for dealing in, or conspiring to deal in controlled drugs are long terms of imprisonment (up to life).

13. Substances are controlled under the Misuse of Drugs Act only after it has been demonstrated that they pose at least a moderate risk of harm. In contrast, it must only be demonstrated that a substance is capable of producing a psychoactive effect in order to be controlled under the Psychoactive Substances Act.

Risk of harm

14. Adverse effects resulting from clinical NBOMe intoxication include increased heart rate and blood pressure, seizures and fever. Internationally, 25B-NBOMe, 25C-NBOMe and 25I-NBOMe have been implicated in 24 deaths. Little is known about the risk of harm posed by other members of the NBOMe family.

15. The New Zealand Expert Advisory Committee on Drugs recently reviewed the information available on the NBOMe family against the criteria for scheduling substances under the Misuse of Drugs Act.

16. The Expert Advisory Committee on Controlled Drugs concluded that 25B-NBOMe, 25C-NBOMe and 25I-NBOMe pose a high risk of harm that is in line with drugs that are scheduled as class B1 controlled drugs under the Misuse of Drugs Act. The committee further concluded that there was insufficient evidence to justify specifically scheduling any other member of the NBOMe family under the Misuse of Drugs Act. On this basis, it is unlikely that 25B-NBOMe, 25C-NBOMe and 25I-NBOMe could ever be approved as psychoactive products.

Trends and costs

17. The number of LSD/NBOMe seizures reported by New Zealand Police and the New Zealand Customs Service has increased from 63 in 2010 to 223 in 2014, and the amount seized has increased from 836 doses to 26,965 doses for the same period. The growing trend in the misuse of NBOMes in New Zealand is likely attributable to:
    - higher gains for the dealer or manufacturer; NBOMes are ten times cheaper and easier to manufacture than LSD
    - the low number of prosecutions for NBOMe possession or supply under the Psychoactive Substances Act due to the fact it is new and unfamiliar legislation
    - public confusion over whether they are legal because there is no list of substances regulated under the Psychoactive Substances Act and internationally, the NBOMe family is not regulated consistently.

18. Retaining the status quo is likely to mean an increase in the availability of NBOMes in New Zealand, resulting in increased:
    - costs to enforcement agencies and advice and treatment services
    - numbers of individuals potentially harmed by using unsafe substances
    - harm to society from individuals exhibiting drug seeking, anti-social and dangerous behaviour.

Objectives

19. The objectives of this proposed amendment are to:
    a) ensure compliance with New Zealand's obligations under Article 7 of the Convention on Psychotropic Substances
    b) regulate access to the NBOMe family in line with the risk of harm posed to individuals by their misuse
    c) send a strong message that these substances are harmful and it is not in the public interest for them to be used as recreational drugs.

20. The objectives are weighted in the order they are presented.

Options and Impact analysis

21. Three options were identified and considered against the objectives of the proposal. These options are to:
    - retain the status quo (all NBOMes with psychoactive properties to continue to be regulated under the Psychoactive Substances Act)

- reduce the demand for NBOMes by providing education on their harms
- place 25B-NBOMe, 25C-NBOMe and 25I-NBOMe in Part 1 of Schedule 2 of the Misuse of Drugs Act as class B1 controlled drugs.

22. Table One contains an analysis of these options against the objectives of the proposal. A more detailed analysis, along with the impacts is outlined below Table One.

Table One: Assessment of options against the objectives

Objectives	Options		
	1. Status quo	2. Reduce the demand for NBOMes by providing education on their harms	3. Schedule 25B-NBOMe, 25C-NBOMe and 25I-NBOMe as class B1 controlled drugs
1. Comply with the Convention on Psychotropic Substances	Partially	Partially	Yes
2. Regulate in line with the risk of harm	Partially	Partially	Yes
3. Messaging on drug harm	No	Partially	Yes

Option one: Retain the status quo

Compliance with objectives

23. This option does not fully comply with New Zealand's obligations under Article 7 of the Convention on Psychotropic Substances because the psychoactive substances regulatory regime does not provide for the:
    - prohibition of substances except for scientific and very limited medical purposes by duly authorised persons
    - issuance of separate import or export authorisations for each import or export of a controlled substance.

24. The Psychoactive Substances Act is designed to regulate substances that pose no more than a low risk of harm. Since NBOMes pose a high risk of harm, this option does not regulate these substances in line with the risk of harm posed by these substances.

25. The status quo does not send a message that NBOMes are harmful due to the confusion over whether a psychoactive substance is unapproved because it poses more than a low risk of harm or because an application for approval has not been submitted.

Impact analysis

26. Retaining the status quo will have no immediate impact on the industry or the public.

27. As discussed in point 19, the growing trend in the misuse of NBOMes in New Zealand indicates that this option is likely to result in increases in:
    - costs to enforcement agencies, and advice and treatment services
    - harm to individuals and society over time.

28. There are no expected benefits from retaining the status quo.

Option two: Reduce the demand for NBOMes by providing education on their harms

Compliance with objectives

29. For the same reasons as discussed in points 24 and 25, this option does not fully meet the first two objectives.

30. This option sends a message that NBOMes are harmful but this option does not go far enough towards addressing the harms that have been reported.

Impact analysis

31. This option involves seeking to reduce demand for NBOMes through community education programmes. This option is not expected to reduce harm immediately, therefore the growing trend in the misuse of NBOMes in New Zealand indicates that this option is likely to result in **short term** increases in:
    - costs to enforcement agencies, and advice and treatment services
    - harm to individuals and society.

32. There would be funding requirements for providers of these education programmes that would not necessarily be directly offset by the reduction in costs to enforcement agencies.

33. A reduction in demand is expected to result in reduced supply, which may reduce enforcement agency costs over time. This option would not be expected to impact on the psychoactive substances industry or research community.

34. While this option has been considered as a standalone option, it is most likely to be implemented in addition to either of the other options to maximise their impact.

Option three: Regulate NBOMes under the Misuse of Drugs Act

Compliance with objectives

35. This option fully complies with the first objective with respect to NBOMes. This is because the requirements for meeting New Zealand's obligations under Article 7 of the Convention on Psychotropic Substances are already in place for substances scheduled under the Misuse of Drugs Act.

36. This option regulates access to the NBOMe family in line with the risk of harm posed by these substances because:
    - only the risk profiles of 25B-NBOMe, 25C-NBOMe and 25I-NBOMe are consistent with a class B1 controlled drug
    - members of the NBOMe family that are structurally similar to the three common NBOMe substances will be regulated as Class C controlled drugs under the analogue provisions of the Misuse of Drugs Act
    - members of the NBOMe family that are **not** structurally similar to the three common NBOMe substances, but are capable of producing a psychoactive effect will continue to be regulated under the Psychoactive Substances Act

- any remaining members of the NBOMe family will continue to not be regulated, but are unlikely to be targets of abuse due to their inability to produce a psychoactive effect, and the risk of harm is thereby limited.

Impact analysis for Option 3

37. The immediate effect of this option would be to increase the controls on NBOMes and their structural analogues and the prison sentences imposed for breaches of these controls in comparison to the status quo. In comparison to the controls imposed under the Psychoactive Substances regime, the controls imposed under the Misuse of Drugs regime include:
    - tighter scrutiny of compliance with license conditions,
    - tighter record keeping and storage requirements,
    - restrictions on the amounts able to be imported,
    - restrictions on what types of research can be conducted and by whom,
    - a requirement for import and export permits for each individual import or export
    - a prohibition on import and export except where both the importer and exporter are authorised by the competent authorities of their country or region.

38. This option is not expected to reduce harm immediately, however and the growing trend in the misuse of NBOMes in New Zealand indicates that this option is likely to result in **short term** increases in:
    - costs to enforcement agencies, and advice and treatment services
    - harm to individuals and society.

39. As the consequences of the proposed classification begin to impact on the illicit market, demand and supply are expected to decrease as a result, along with the harms posed by these substances to individuals and society. The potential harm to vulnerable populations posed by these substances will also be reduced by the harm minimisation strategies outlined in the National Drug Policy. A reduction in costs to treatment services as fewer individuals use these substances is also expected.

40. Researchers intending to study 25B-NBOMe, 25C-NBOMe and 25I-NBOMe and their structural analogues will need to hold licences to deal in controlled drugs. The cost of an application for a licence to deal in controlled drugs is $1000. In addition, there is a $200 fee for each importation of a controlled drug. The impact of the proposed amendment on researchers is expected to be minimal because all current holders of licences to research psychoactive substances also hold licences to deal in controlled drugs or are associated with companies who hold them.

41. This option means that the penalties faced for possession of, or dealing in, any member of the NBOMe family will be in line with their respective risk profiles. This option is in line with the requirements of the Misuse of Drugs Act and with the government's harm minimisation strategy on regulating illicit drugs.

Consultation

42. New Zealand Police, the New Zealand Customs Service, the Ministry of Justice, the Corrections Department New Zealand, the National Drug Intelligence Bureau, Te Puni Kōkiri, the New Zealand Treasury, the New Zealand Ministry of Foreign Affairs and Trade, and the Ministry of Social Development were all consulted on this proposal. No significant objections or concerns were raised.

43. The Ministry of Health has not engaged industry or the consumers of psychoactive products in considering the options and objectives contained in this Regulatory Impact

Statement. This is because there is a risk of stockpiling during the classification process. The Act does require the Minister to consider the advice of the Expert Advisory Committee and the committee includes a consumer representative.

Conclusions and recommendations

44. The increased enforcement and treatment costs, and harms over time, combined with a failure to fully meet any of the objectives make the status quo (option one) unsuitable.

45. Option two is expected to reduce harm to individuals and society, and result in an overall reduction in enforcement and treatment costs over time. This is not the preferred option, however, because the results will be slow to be realised and this option does not adequately address the harms posed by these substances.

46. Option three is the preferred option because it is the only option that fully meets all of the objectives. This option is also expected to reduce harm to individuals, vulnerable populations and society. In addition, option three is expected to result in an overall reduction in enforcement and treatment costs over time with minimal negative impacts on the psychoactive substances industry, the research community and enforcement agencies. This approach is also consistent with the requirements of the Misuse of Drugs Act and the government's harm minimisation approach to the regulation of harmful substances in New Zealand.

Implementation plan

47. The Ministry of Health will notify the New Zealand Customs Service, New Zealand Police, the Corrections Department of New Zealand, the Institute of Environmental Science and Research and all holders of licences to research psychoactive substances of the change to the legislation.

48. A media statement has been prepared to advise the public of the classification, the rationale behind it and the new penalties for offences.

49. The Ministry of Health will continue to work closely with the New Zealand Customs Service and New Zealand Police to ensure that the change in legislation is enforced appropriately.

Monitoring, evaluation and review

50. The impact of the law change will be monitored through existing reporting mechanisms, such as regular drug surveys and police and hospital reports. A joint agency committee, consisting of representatives of the National Drug Intelligence Bureau, the New Zealand Customs Service, New Zealand Police and the Ministry of Health will monitor the effects of the change and agree a response to any issues arising.

51. No formal review is planned because the recommendation brings New Zealand into line with the United Nations Convention on Psychotropic Substances. The Expert Advisory Committee on Drugs will also continue to monitor the available information on, and the international regulatory status of, all members of the NBOMe family to ensure that New Zealand continues to comply with their obligations as a State Party to the Convention.