



Australian Government
Department of Health
Therapeutic Goods Administration

Notice of final decisions to amend (or not amend) the current Poisons Standard in relation to nitrous oxide

8 October 2021

Note

New text is shown as green, larger font, with a horizontal line above it.

1 Notice of final decisions to amend (or not amend) the current Poisons Standard

This web publication constitutes a notice for the purposes of regulation 42ZCZS and regulation 42ZCZX of the *Therapeutic Goods Regulations 1990* (the **Regulations**). In accordance with regulations 42ZCZS and 42ZCZX, this notice publishes:

- the decisions made by a delegate of the Secretary pursuant to regulations 42ZCZR and 42ZCZU;
- the reasons for the final decision; and
- the date of effect of the decision.

2 Final decisions on proposed amendments referred to the Advisory Committee on Medicines Scheduling (ACMS #33, March 2021)

2.1 Final decision in relation to nitrous oxide

Proposal

The applicant proposed to create a new Schedule 10 entry for nitrous oxide when supplied in small bulbs, and when not included in Schedule 4 for therapeutic use, to mitigate harms associated with recreational use of the substance.

Final decision

Pursuant to regulation 42ZCZN of the Regulations, a Delegate of the Secretary has, in relation to the proposed amendment, made a final decision to amend the scheduling of nitrous oxide in the current Poisons Standard as follows:

Schedule 6 - New Entry

NITROUS OXIDE **except** when included in Schedule 4.

Schedule 4

NITROUS OXIDE for therapeutic use.

Appendix E, Part 2 - New Entry

Poison	Standard statements
NITROUS OXIDE when included in Schedule 6.	A [For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor.]

Appendix F, Part 1 - New Entry

112. WARNING - May cause irreversible nerve damage if inhaled.

Appendix F, Part 2 - New Entry

38. Do not intentionally inhale contents.

Appendix F, Part 3 - New Entry

Poison	Warning statements	Safety direction
NITROUS OXIDE when included in Schedule 6.	112 (WARNING - May cause irreversible nerve damage if inhaled.)	38 (Do not intentionally inhale contents.)

Index - Amend Entry

NITROUS OXIDE

Schedule 6

Schedule 4

Appendix E, Part 2

Appendix F, Part 3

Materials considered

In making this final decision, the Delegate considered the following material:

- The [application \(//www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-acms-accs-and-joint-acmsaccs-meetings-march-2021\)](http://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-acms-accs-and-joint-acmsaccs-meetings-march-2021) to amend the current Poisons Standard with respect to nitrous oxide;
- The 78 [public submissions \(https://consultations.health.gov.au/tga/march_2021/\)](https://consultations.health.gov.au/tga/march_2021/), including 15 written submissions, received in response to the [pre-meeting consultation \(//www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-acms-accs-and-joint-acmsaccs-meetings-march-2021\)](http://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-acms-accs-and-joint-acmsaccs-meetings-march-2021) under regulation 42ZCZK of the Regulations;
- The advice received from the meeting of the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #27);
- The seven [public submissions \(https://consultations.health.gov.au/tga/march_2021_interim_nitrous_oxide/\)](https://consultations.health.gov.au/tga/march_2021_interim_nitrous_oxide/), including six

written submissions, received in response to the interim decision consultation under regulation 42ZCZP of the Regulations;

- Subsection 52E(1) of the *Therapeutic Goods Act 1989*, in particular (a) risks and benefits of the use of a substance; (b) the purpose for which a substance is to be used and the and extent of use; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health;
- The Australian Health Ministers' Advisory Council's [Scheduling Policy Framework](http://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals) (<http://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals>) (SPF 2018);
- The [Scheduling handbook: Guidance for amending the Poisons Standard](http://www.tga.gov.au/publication/scheduling-handbook-guidance-amending-poisons-standard) (<http://www.tga.gov.au/publication/scheduling-handbook-guidance-amending-poisons-standard>);
- A review by Garakani et al., [Neurologic, psychiatric, and other medical manifestations of nitrous oxide abuse: A systematic review of the case literature](https://doi.org/10.1111/ajad.12372) (<https://doi.org/10.1111/ajad.12372>);
- A case report and review by Hathout and El-Saden, [Nitrous oxide-induced B12 deficiency myelopathy: Perspectives on the clinical biochemistry of vitamin B12](https://doi.org/10.1016/j.jns.2010.10.033) (<https://doi.org/10.1016/j.jns.2010.10.033>);
- A letter by Blair et al., [Vitamin B12 supplementation futile for preventing demyelination in ongoing nitrous oxide misuse](https://doi.org/10.5694/mja2.50371) (<https://doi.org/10.5694/mja2.50371>);
- A dataset collected by the UK Office for National Statistics; [Deaths related to volatile substance abuse and helium, Great Britain](https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths) ([https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/](https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths) and
- A [safety data sheet](https://www.boc-gas.com.au/en/images/Nitrous%20Oxide%20SDS_tcm351-496573.pdf) (https://www.boc-gas.com.au/en/images/Nitrous%20Oxide%20SDS_tcm351-496573.pdf), for compressed nitrous oxide.

Reasons for the final decision (including findings on material questions of fact)

I have made a final decision to confirm my [interim decision \(pdf,225kb\)](#)

(<http://www.tga.gov.au/sites/default/files/notice-interim-decisions-proposed-amendments-poisons-standard-nitrous-oxide-march-2021.pdf>), to amend the current Poisons Standard with respect to nitrous oxide.

My reasons for making the final decision are those set out in the interim decision. In making my final decision, I have taken into account the material detailed in the interim decision and the responses received after the second call for public submissions, published on 30 July 2021 under regulation 42ZCZP of the Regulations. I note that four out of six public submissions were fully supportive of the interim decision and two were partially supportive.

I note that most submissions supported the interim decision, including submissions from the Alcohol and Drug Foundation and the National Drug Research Institute who consider the interim decision to be a proportionate and balanced approach. However, several specific concerns were raised by the NSW Poisons Information Centre (NSW PIC). Their submission outlined growing hospitalisation numbers due to nitrous oxide misuse, and requested that large quantities of the gas be included in Schedule 7, 9 or 10. The NSW PIC also suggested that the Schedule 6 label be

expanded to mention loss of sensation and balance, though they were concerned that labelling alone may not be sufficient to mitigate harm. I also note NSW PIC calls for a full evaluation of the available harms data.

I have carefully considered each of these suggestions and concerns, though I am not of the view that nitrous oxide meets the Schedule 7 (or above) scheduling factors or requires an expanded label. It is unclear whether reducing the permitted quantity for sale would significantly impact supply for illicit use; however, supply to legitimate users would be detrimentally affected. As such, I consider that the changes set out in the interim decision are appropriate at this time. I reiterate my view that reducing harms from the misuse of nitrous oxide requires a range of strategies beyond scheduling. Should it be necessary, consideration of further conditions may be considered in the future, including restrictions on sales quantities.

Proposed implementation date
1 October 2022

Category: Scheduling

Tags: ACMS

URL: <https://www.tga.gov.au/node/940680> (<https://www.tga.gov.au/node/940680>)