Government of **Western Australia**
Department of **Health**

Supply of nitrous oxide

Consultation Regulatory Impact Statement

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Contents

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1 Introduction

Nitrous oxide is a gas, which is usually supplied as compressed liquified gas in either cylinders or small bulbs (also known as cream chargers).

This gas is used medically for the purposes of anaesthesia, sedation and pain management. Products for therapeutic use are classified as prescription only medicines, also known as Schedule 4 medicines.

Nitrous oxide is also used as a food additive, as a propellant for whipped cream, to infuse flavours into alcoholic drinks and to create mousses and foams.

In the automotive industry, this gas is used to enhance engine performance. Nitrous oxide for automotive use has a small amount of sulfur dioxide added to discourage inhalation.

Recreational use of nitrous oxide has occurred for centuries, with 'laughing gas' parties documented in Britain in the early 1800s.[1] The small bulbs, that are routinely used recreationally, are colloquially referred to as nangs, whippets, hippy crack, NOS and nitro[2].

Although recreational use of any drug always carries some risk, people who use nitrous oxide infrequently and in low doses do not usually experience significant harm. Deaths from nitrous oxide use are rare, and those that do occur are mainly due to hypoxia (lack of oxygen), accidents or injuries.

Increasing use of nitrous oxide as a recreational drug is a worldwide phenomenon.

Australian data shows a significant increase in the use of nitrous oxide as a recreational drug, particularly over the last five years. Over this period, the number of people reporting use has increased and the use pattern has changed. The amount of nitrous oxide used per session has increased and people are using this drug more often. These changing use patterns have been accompanied by increasing reports of serious and prolonged adverse effects.

In Western Australia (WA), the changes in the pattern of recreational use of nitrous oxide, and the subsequent health harms, are similar to other parts of Australia[3].

There has been a concurrent increase in the number of businesses offering online ordering of nitrous oxide bulbs or cylinders with fast delivery (sometimes within 15 minutes) at any time of the day or night.

In late 2020, the WA Minister for Health tasked the Mental Health Commission with responding to the increasing harm associated with use of nitrous oxide for intoxication[4]. The Minister noted

[1] Zuck, D. Nitrous oxide: are you having a laugh? Royal Society of Chemistry, Education in Chemistry, 1 March 2012, accessed 5 April 2022 <https://edu.rsc.org/feature/nitrous-oxide-are-you-having-a-laugh/2020202.article>
[2] Alcohol and Drug Foundation. Drug Facts: Nitrous oxide, accessed 8 April 2022 <https://adf.org.au/drug-facts/nitrous-oxide/>
[3] Grigg J, Lenton S (2020). Increasing trends in self-reported use of nitrous oxide among WA EDRS samples. National Drug and Alcohol Research Centre, University of New South Wales, NSW.
[4] Western Australia, Legislative Assembly 2020, *Debates*, 19 November, pp 8082n-8084a. Available at <A40+S1+20201119+p8082b-8084a.pdf (parliament.wa.gov.au)>

a range of responses were under consideration including targeted education, industry codes and regulatory changes. The Minister also acknowledged it was important that any responses avoided unnecessary impacts on the sale and supply of nitrous oxide for legitimate uses.

2 What are the public health risks of concern?

2.1 Damage to the nervous system

There have been multiple reports of people experiencing damage to their nervous system, in association with recreational use of nitrous oxide, in countries across the world[5,6,7], including in Australia.[8,9,10,11,12]

Patients have been diagnosed with a range of neurological complaints including: myeloneuropathy, peripheral neuropathy, polyneuropathy, myelopathy and subacute degeneration of the spinal cord.

The syndrome known as 'subacute degeneration of the spinal cord' occurs due to irreversible inactivation of vitamin B12 by nitrous oxide. The effect of nitrous oxide on vitamin B12 is described as a 'functional deficiency' because sometimes vitamin B12 blood levels will be normal but metabolism of this vitamin will still be impaired. This has effects on a number of biochemical pathways, including decreasing the body's ability to make the proteins necessary to form the myelin sheath (fatty sheath) that surrounds some nerve cells. This fatty sheath speeds transmission of nerve signals and is essential for normal spinal nerve function.

Nerve fibres that control both movement and sensation are damaged. A general feeling of weakness is often the first sign of this damage. Tingling, a pins-and-needles sensation and numbness can be felt in both hands and feet. People may lose the sense of where their limbs are (position sense) and may not be able to feel vibrations. The limbs feel stiff, movements become clumsy and walking may become more difficult.

A recent warning issued by the French Association of Addictovigilance Centres suggests neurological damage associated with recreational nitrous oxide inhalation may also be the result

[5] Keddie S, Adams A, Kelso A et al. No laughing matter: subacute degeneration of the spinal cord due to nitrous oxide inhalation. J Neurol 2018;265:1089-1095.
[6] Garakani A, Jaffe R, Savla D et al. Neurologic, psychiatric and other medical manifestations of nitrous oxide abuse: a systematic review of the case literature. Am J Addict 2016;25:358-369.
[7] Yu, M, Qiao, Y, Li, W, Fang, X et al. Analysis of clinical characteristics and prognostic factors in 110 patients with nitrous oxide abuse. Brain and Behavior 2022;12:e2533.
[8] Redmond J, Cruse B, Kiers L. Nitrous oxide-induced neurological disorders – an increasing public health concern. Intern Med J 2021 Sep 27. doi: 10.1111/imj.15544. Epub ahead of print. PMID: 34569693.
[9] Lightfoot E, Brownlie D, Lightfoot J. Nitrous oxide toxicity: When laughing gas is no laughing matter – a discussion of two cases. Emerg Med Australas 2020;32:710-711.
[10] Chiew A, Raubenheimer J, Berling I et al. Just "nanging" around - harmful nitrous oxide use. A retrospective case series and review of internet searches, social media posts and the coroner's database. Intern Med J 2021 May 24. doi: 10.1111/imj.15391. Epub ahead of print. PMID: 34029427.
[11] Evan E, Evans M. Nangs, balloons and crackers. Recreational nitrous oxide neurotoxicity. Aust J Gen Pract 2021;50:834-838.
[12] Mosalski S, Tanner A, Shiner C. Recreational nitrous oxide misuse is resulting in serious neurological impairment and persistent disability among users. Med J Aust 2021;215:237.

of direct toxicity to nerve axons (the fibre inside the myelin sheath that transmits messages along the nerves).[13] A case series from Victoria has reported clinical findings consistent with this warning: some patients presented with predominantly motor neuropathy with little sensory involvement and some patients deteriorated even after normalisation of measures of functional vitamin B12 deficiency.[8]

Treatment of the neurological effects involves ceasing use of nitrous oxide, administering vitamin B12 injection, providing standard treatments for neurological pain and, if needed, a rehabilitation program and psychological support.

It is also of note that oral vitamin B12 supplementation is not effective in preventing the neurological effects of nitrous oxide use. There are reports of severe ataxia (impaired ability to control body movement, often resulting in difficulty with walking and balance) in people who regularly use nitrous oxide and who have also taken oral vitamin B12 regularly in an attempt to reduce their risk of adverse outcomes.[14]

Even with active treatment, recovery from the neurological effects of nitrous oxide use may be prolonged and some people are left with long-term disability.

Information about 22 people who presented to public hospitals in New South Wales indicates thirteen required inpatient physical rehabilitation due to poor mobility. One of these 13 cases returned to their home country for rehabilitation and of the remaining 12, nine required walking aids at discharge. Median length of hospital admission was 31 days.

Case series from the United States[15] and the United Kingdom[16] have similarly found very few patients fully recovered before hospital discharge.

The risk of nerve damage has been shown to increase as the amount of nitrous oxide used per session increases.[17] For people who reported using 1 to 2 bulbs per session, the probability of reporting paraesthesias (abnormal nerve sensation, such as tingling or pricking, often described as ‘pins and needles’) was 1.86%. By contrast, for those reporting using 100 bulbs per session, the probability of reporting paraesthesia was 8.48%.

2.2 Behavioural changes

Changes in behaviour can occur at the same time as nervous system effects when nitrous oxide is used. These include becoming irritable, agitated, confused and drowsy. Some people develop psychiatric symptoms such as delusions (sometimes with paranoia) and delirium.

[13] French Association of Addictovigilance Centres, Micallef J, Mallaret M et al. Warning on increased serious health complications related to non-medical use of nitrous oxide. Therapie 2021;76:478-479.
[14] Blair C, Tremonti C, Edwards L, Haber P, Halmagyi G. Vitamin B12 supplementation futile for preventing demyelination in ongoing nitrous oxide misuse. Med J Aust 2019;211:428-429.
[15] Garakani A, Jaffe R, Savla D et al. Neurologic, psychiatric and other medical manifestations of nitrous oxide abuse: a systematic review of the case literature. Am J Addict 2016;25:358-369
[16] Keddie S, Adams A, Kelso A et al. No laughing matter: subacute degeneration of the spinal cord due to nitrous oxide inhalation. J Neurol 2018;265:1089-1095.
[17] Winstock AR, Ferris JA. Nitrous oxide causes peripheral neuropathy in a dose dependent manner among recreational users. J Psychopharmacol 2020;34:229-236.

2.3 Other adverse effects

When nitrous oxide gas is discharged from a bulb or cylinder, it is intensely cold and under pressure. There have been reports of severe frostbite to the nose, lips and throat (including the vocal chords) and ruptures in lung tissue where people who recreationally use have inhaled nitrous oxide directly from a bulb or cylinder.

2.4 Effects on driving

A small study of ten subjects who inhaled medical nitrous oxide and were then tested on a driving simulator showed negative effects on driving ability for up to 30 minutes after the short exposure to nitrous oxide.[18] A more recent study of the use of a 50:50 mix of nitrous oxide and oxygen for analgesia and sedation in patients undergoing colonoscopies similarly showed it took 30 minutes for psychomotor test results to return to baseline, even though patients were assessed as having clinically recovered within 3 to 25 minutes (median 8 minutes).[19]

There are emerging reports of traffic crashes, where the driver has been inhaling nitrous oxide whilst driving. Media reports in the Netherlands document the Dutch police reporting 960 traffic accidents where the driver was under the influence of nitrous oxide in 2019 compared to only 60 such accidents in 2016. In 2019, Veilig Verkeer, a Dutch road safety organisation, led a social media campaign to draw attention to the number of traffic accidents in the Netherlands that are thought to be connected to the use of ‘laughing gas’ behind the wheel.[20]

There is no roadside test for the presence of nitrous oxide. However, it is not surprising driver impairment can occur following inhalation of a substance known to cause euphoria, sedation, reduced coordination of movements, blurred vision, confusion and disorientation, impaired memory and cognition, dissociation and dizziness and/or light-headedness.

3 Cases presenting to Western Australian emergency departments

During 2020 there were 22 nitrous oxide related presentations to emergency departments at WA public hospitals, including 8 patients with severe subacute degeneration of the spinal cord.

Six of the eight patients with severe neurological symptoms were male and the mean age was 27 years (range 19 to 36 years). These patients reported heavy and chronic nitrous oxide exposure, with a mean number of bulbs used per day of 150 (range 50 to 300 per day) and a duration of use between 3 months and “many years”.

These patients required lengthy hospital admissions. The mean length of stay was 12 days (range 3 to 32 days) in an acute care hospital, followed by a mean of 40 days (range 32 to 45 days) at a rehabilitation centre. Some patients reported ongoing functional disability at follow-up, including difficulty walking, poor balance and nerve pain.

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[18] Moyes D, Cleaton-Jones P, Lelliot J. Evaluation of driving skills after brief exposure to nitrous oxide. South Afr Med J 1979;56:1000-1002.

[19] Trojan J, Saunders BP, Woloshynowych M, Debinsky H, Williams C. Immediate recovery of psychomotor function after patient-administered nitrous oxide/oxygen inhalation for colonoscopy. Endoscopy 1997;29:17-22.

[20] Available at < Campagne tegen lachgas achter het stuur: 'Onbegrijpelijk dat mensen dat doen' | Veilig Verkeer Nederland (vvn.nl)>

4 Who is at most risk of harm from recreational nitrous oxide use?

4.1 Harmful use patterns

Greater harm is associated with:

- Using a large amount of nitrous oxide in a single session
- Using nitrous oxide more often and
- Using nitrous oxide for a long period of time.

Importantly, in recent years, new patterns of supply have emerged which facilitate harmful use patterns. Businesses/suppliers appear to be targeting recreational users by providing large quantities of nitrous oxide along with associated paraphernalia, offering 24 hr delivery services and often promoting their activities through social media.

4.2 Characteristics of people using nitrous oxide

Nitrous oxide is known as a 'party drug' and is commonly used at night venues, clubs, pubs, events like music festivals and other parties attended by young adults.

Data from the United States showed nitrous oxide use was most common in the 13 to 39 year age group, with a mean age of 26.4 years for one data system (NEISS[21]) and 27.6 years for another data system (FAERS[22]).[23] In the Netherlands, young adults up to 35 years are most likely to use this recreational drug and cases reported to poisons centres in the United Kingdom had a median age of 23 years (range 6 to 34 years).[18] In all these data sets, use by males was more common than use by females.

In Australia, information about recreational drug use is collected through the Australian Institute of Health and Welfare's National Drug Strategy Household Survey (NDSHS)[24] and through the Ecstasy and Related Drugs Reporting System (EDRS).[25]

The NDSHS collects information from teenagers and adults residing in private dwellings across Australia and there were 22,272 completed responses in 2019.

Data collection for the EDRS is via interviews conducted annually with a selected group of people who regularly use ecstasy/MDMA and other stimulants, recruited from all capital cities of Australia (n=774 in 2021). The EDRS sample is not intended to be representative of all consumers or of drug use in the general population but is used to monitor for emerging drug trends. The EDRS interviews capture information about drugs that are routinely used in the context of entertainment venues and other recreational locations such as nightclubs, dance parties, pubs and music festivals.

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[21] NEISS = National Electronic Injury Surveillance System

[22] FAERS = FDA Adverse Event Reporting System

[23] Forrester M. Nitrous oxide misuse reported to two United States data systems during 2000 to 2019. J Addict Dis 2020;39:46-53.

[24] Available at <https://www.aihw.gov.au/about-our-data/our-data-collections/national-drug-strategy-household-survey>

[25] Available at <https://ndarc.med.unsw.edu.au/project/ecstasy-and-related-drugs-reporting-system-edrs>.

In the most recent NDSHS (2019), the per cent of people (aged 14 years and over) reporting use of inhalants in the previous 12 months had risen from 0.4% in 2011 to 1.0% in 2016 and 1.4% in 2019. Nitrous oxide and 'poppers' (amyl nitrate and other nitrates) were the most common forms of inhalants (reported by 6 out of 10 people who used inhalants).

In the 2021 national EDRS report, 49 per cent of the sample reported recent use (past 6 months) of nitrous oxide. Recent use of nitrous oxide was stable from 2003 (26%) to 2014 (23%), and since then has more than doubled (54% in 2020; 53% in 2019). There is significant variation between the states and territories ranging from 33% in the South Australian sample to 69% in the New South Wales sample in 2021. In WA, 45% of people in the sample reported recent use of nitrous oxide in 2021, which was significantly less than the 62% reporting recent use in 2020.

During both 2020 and 2021, there was a decrease in frequency of use of nitrous oxide by the EDRS sample in WA, with recent nitrous oxide consumers reporting use on a median of 4 days in the preceding six months in both years. By contrast, in 2019, nitrous oxide was reportedly used by recent consumers on a median of 10 days in the preceding 6 months, with 26 per cent reporting weekly or more frequent use.[26] However, in 2020, over half (52%) the WA survey participants who reported recent use also reported they reduced or completely ceased using nitrous oxide when the COVID-19 associated restrictions came into effect, so trends from 2020 and 2021 may not be indicative of future trends.

The 2019 national EDRS data showed nitrous oxide was more commonly used by younger adults, with those in the 18 to 19 year age group five times as likely to report recent use than those over 25 years of age and those in the 20 to 24 year age group nearly three times as likely to report recent use than older adults. There was also a greater proportion of males who reported recent use (57.1% compared to 46.4% of females).

In 2019, a more detailed analysis of the WA EDRS data on nitrous oxide use was also undertaken.[27] Key findings from this analysis of WA EDRS participants included:

- A steady increase in recent (past six month) nitrous oxide use over the last decade.
- Use on a median of 10 occasions (in the 6 months preceding the interview) by recent users in 2019 compared to only three occasions in 2018. This represented the highest past 6 month use frequency since the WA EDRS survey commenced in 2003.
- Weekly use reported by a quarter of recent users in 2019, up from 10 per cent in 2018.
- Use of a median quantity of 10 bulbs during a 'typical' session, with a range of 1 to 100 bulbs reported.
- Use of a median 'maximum' per session of 25 bulbs. The maximum amount used in WA has been higher than the national median for the past seven years.

[26] Grigg, J. & Lenton. S. (2021). Increasing trends in recent use of coke, ket, nangs and poppers among Perth EDRS samples. Drug Trends Bulletin Series. Sydney: National Drug and Alcohol Research Centre, UNSW Sydney. Available at <https://ndarc.med.unsw.edu.au/sites/default/files/ndarc/resources/EDRS_WA%202020_23092021.pdf

[27] Grigg, J. & Lenton, S. (2020). Increasing trends in self-reported use of nitrous oxide among WA EDRS samples. Drug Trends Bulletin Series. Sydney: National Drug and Alcohol Research Centre, University of New South Wales. http:// doi.org/10.26190/5f20ea395c544.

4.3 Characteristics of people harmed by nitrous oxide

In Australia, two case series[28,29] of patients presenting to hospitals with neurological disorders found these patients were of a similar age to the broader group of people who use nitrous oxide recreationally (median age 22 years and 23.8 years respectively). However, a greater proportion of the patients were female (50% or more). There was a predominance of international students, particularly of Asian ethnicity.

People with an already low level of vitamin B12 are at risk of developing neurological dysfunction at lower usage levels. Spinal cord degeneration has been reported following a single short exposure to nitrous oxide, in association with pre-existing vitamin B12 deficiency.[30]

There is evidence nerve damage occurs more commonly in females, possibly due to the higher incidence of vitamin B12 deficiency in women of reproductive age and may be related to diet (higher rates of vegetarian and vegan diets).[31]

5 Cost of public health harm

The modified Rankin scale (mRS) is commonly used to measure the degree of disability of people following a stroke. This scale has also been used for assessing disability associated with other neurological conditions. The mRS runs from zero to 6 with zero meaning ‘no symptoms’ and 6 meaning the patient has died.

Published cases from New South Wales[32] and Victoria[33] reported a mRS score of 3 or 4 at discharge for many patients. A mRS score of 3 is described as ‘moderate disability, requires some help, but able to walk unaided’ whilst a mRS score of 4 means ‘moderately severe disability, unable to attend to own bodily needs without assistance and unable to walk unassisted’.

Given that neurological dysfunction related to nitrous oxide use can result in ongoing disability and the age group most commonly affected is people aged under 25 years, the financial cost to the health system, the person with the disability and society more generally is likely to be significant.

Financial impacts include:

- Costs associated with inpatient admission, including both acute care and rehabilitation.

[28] Redmond J, Cruse B, Kiers L. Nitrous oxide-induced neurological disorders – an increasing public health concern. Intern Med J 2021 Sep 27. doi: 10.1111/imj.15544. Epub ahead of print. PMID: 34569693.
[29] Chiew A, Raubenheimer J, Berling I et al. Just "nanging" around - harmful nitrous oxide use. A retrospective case series and review of internet searches, social media posts and the coroner's database. Intern Med J 2021 May 24. doi: 10.1111/imj.15391. Epub ahead of print. PMID: 34029427.
[30] Cartner M, Sinnott M, Silburn P. Paralysis caused by “nagging”. Med J Aust 2007;187:366-367.
[31] Winstock AR, Ferris JA. Nitrous oxide causes peripheral neuropathy in a dose dependent manner among recreational users. J Psychopharmacol 2020;34:229-236.
[32] Blair C, Tremonti C, Edwards L, Haber P, Halmagyi G. Vitamin B12 supplementation futile for preventing demyelination in ongoing nitrous oxide misuse. Med J Aust 2019;211:428-429.
[33] Redmond J, Cruse B, Kiers L. Nitrous oxide-induced neurological disorders – an increasing public health concern. Intern Med J 2021 Sep 27. doi: 10.1111/imj.15544. Epub ahead of print. PMID: 34569693.

- Costs associated with community-based rehabilitation after discharge from hospital.
- Costs associated with ongoing disability such as loss of earnings, equipment needs and care needs, including medical and psychosocial aspects.

As described in Section 3, during 2020, eight people were admitted to WA public hospitals with severe neurological issues related to nitrous oxide use. The total cost to WA Health associated with seven of these admissions[34], including both inpatient and outpatient follow-up, was $598,928 and, on a per patient basis, ranged from $7425 to $289,686.

These eight patients ranged in age from 19 to 36 years. If any of these patients were employed, they could also have lost earnings during, at the very least, their period of inpatient admission. Based on average weekly earnings (full-time total hours[35]), an average inpatient admission of 12 days would amount to an earning loss of $3107 per patient. However, given that all these patients had periods of rehabilitation after their inpatient admission (average 40 days) and had ongoing functional disability, their loss of earnings is likely to be considerably higher.

These figures indicate significant cost to both the WA Health system and those directly affected by the adverse outcomes of use of larger quantities of nitrous oxide for the purpose of intoxication.

6 Current and emerging supply patterns

Nitrous oxide bulbs are not generally sold in major supermarkets but are available in convenience stores, from catering and hospitality suppliers (both online and from 'bricks and mortar' stores, including via 'click and collect' transactions) and home kitchenware suppliers.

More recently, online only businesses dedicated to express delivery of nitrous oxide bulbs and cylinders have emerged. Businesses dedicated to express delivery of nitrous oxide bulbs and cylinders also sell other paraphernalia such as balloons, whipped cream dispensers and 'cream crackers'. Cream crackers are devices used to access the gas in nitrous oxide bulbs without needing a whipped cream dispenser.

These online only businesses generally use the term 'nangs' to describe the nitrous oxide bulbs they offer for sale. This term is associated with the use of nitrous oxide as an intoxicant.

Online businesses claiming to be able to deliver 'nangs' within 15 to 60 minutes of an order being placed and which deliver 'nangs' overnight, particularly on Friday and Saturday evenings, can be easily found by searching online. There have been a number of reports in the media

[34] Costs were not available for one patient, their length of stay (LOS) was 3 days which was the shortest LOS for all patients in the case series.
[35] November 2021 average weekly total earnings for full-time adults (seasonally adjusted), available at: Average Weekly Earnings, Australia, November 2021 | Australian Bureau of Statistics (abs.gov.au).

over recent years describing how these businesses operate and these media reports indicate nitrous oxide supplied by 'nang' sellers is inhaled recreationally.[36,37,38]

7 Current regulation of nitrous oxide

Apart from nitrous oxide for therapeutic use, which is classified as a Schedule 4 substance (prescription only medicine), other nitrous oxide products are not currently regulated by the Medicines and Poisons legislation.[39] However, as detailed in Section 10, nitrous oxide (when not for therapeutic use) will be classified as a Schedule 6 substance (poison) from 1 October 2022.

Section 206 of the Criminal Code makes it an offence for a person to sell or supply an intoxicant to another person in circumstances where it is reasonable to suspect, that the person, or another person, will use the substance to become intoxicated. An intoxicant is defined as a drug, or a volatile or other substance, capable of intoxicating a person. The maximum penalty for this supply offence is a fine of $12,000 or imprisonment for 12 months.

This section of the Criminal Code does not consider how much of the intoxicant is supplied, when the intoxicant is supplied, whether the supply is from an online supplier or from a 'bricks and mortar' store or the age of the person to whom the intoxicant is supplied.

The *Misuse of Drugs Act 1981* has clauses that make it an offence to sell or supply a psychoactive substance. However, these clauses are not intended to capture psychoactive substances with legitimate uses, such as nitrous oxide.

8 Reform objectives

- Introduce additional supply controls to reduce serious public health harm, by limiting purchasing behaviour associated with higher risk recreational use.
- As far as possible, minimise the regulatory impact of any supply controls on businesses that are genuinely supplying nitrous oxide for use as a food additive.
- Ensure continued access to nitrous oxide for legitimate use as a food additive, including allowing home cooks to continue to purchase small quantities.
- Provide targeted education resources for suppliers/retailers, consumers and health professionals.
- Liaise with those supplying and using nitrous oxide as a food additive to encourage responsible supply and use.

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[36] Hickey, P 2018, 'Troubling phenomenon: potentially deadly nitrous oxide being delivered to people's front doors', *WA Today*, 6 February, accessed 12 April 2022, <https://www.watoday.com.au/national/western-australia/troubling-phenomenon-potentially-deadly-nitrous-oxide-being-delivered-to-peoples-front-doors-20180206-h0uig9.html>

[37] Flint J, 2018, 'Nitrous oxide: dangerous drug delivery as easy as pizza in Perth', Perth Now, 9 December, accessed 12 April 2022, <https://www.perthnow.com.au/news/health/nitrous-oxide-dangerous-drug-delivery-as-easy-as-pizza-in-perth-ng-b881043293z>

[38] Baker, E 2019, 'Doctors call for legally available nangs, or nitrous oxide bulbs, to be banned', *Perth Now*, 24 June, accessed 12 April 2022, <https://www.perthnow.com.au/news/7-news-perth/doctors-call-for-legally-available-nangs-or-nitrous-oxide-bulbs-to-be-banned-ng-b881240551z>

[39] Current as at September 2022

- Maintain *status quo* for nitrous oxide products intended for automotive use, provided the product has sulfur dioxide added to deter use via inhalation.

In 2020, the Mental Health Commission convened a working group with representatives from the Department of Health, emergency department physicians, WA Police, Department of Mines, Industry Regulation and Safety, relevant clinicians and academic experts from the National Drug Research Institute. The working group has collaborated to develop responses to reduce harms associated with the sale, supply and consumption of nitrous oxide for the purpose of recreational use.

9 Education and liaison

The Mental Health Commission is convening an industry reference group and will be developing education resources for the following target groups:

- Industry/retailers: potential harms of nitrous oxide use and information about national and state-based regulatory controls.
- Consumers: information about harm reduction strategies and referral pathways.
- Health professionals: harms related to higher-risk use, encourage prevention, early intervention, diagnosis and treatment.

10 National regulatory action to reduce harm

During 2021, the inclusion of nitrous oxide (for non-therapeutic use) into the schedules of the national Poisons Standard[40] was considered. The schedules of the Poisons Standard are adopted by reference into the WA Medicines and Poisons legislation. Other states and territories similarly adopt the schedules, and the packaging and labelling controls applicable to those schedules, into their equivalent legislation.

The final decision was issued by the Delegate of the Secretary of the Commonwealth Department of Health on 8 October 2021. Details of the decision are available on the Therapeutic Goods Administration website at: Notice of final decisions to amend (or not amend) the current Poisons Standard in relation to nitrous oxide | Therapeutic Goods Administration (TGA).[41]

The decision is to include nitrous oxide in Schedule 6, except when the substance is included in Schedule 4. The Schedule 4 entry for nitrous oxide is limited to therapeutic use and remains unchanged.

Proposals to include nitrous oxide in Schedule 10 or Schedule 7 were rejected, at least in part because these more restrictive schedules would place a significant regulatory burden on the legitimate use of nitrous oxide as a food additive and as an engine performance enhancer.

[40] Available at: https://www.tga.gov.au/publication/poisons-standard-susmp
[41] Available at: https://www.tga.gov.au/scheduling-decision-final/notice-final-decisions-amend-or-not-amend-current-poisons-standard-relation-nitrous-oxide

Schedule 6 substances must be labelled with the word ‘Poison’ and are defined as “substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warning and safety directions on the label”.

In addition to the standard wording used on all Schedule 6 poisons, nitrous oxide products will need to be labelled with the following additional statements:

- Do not intentionally inhale contents.
- WARNING – May cause irreversible nerve damage if inhaled.

Regulatory controls over all Schedule 6 poisons include:

- Can only be supplied to people apparently aged 16 years and older (Penalty $30,000 fine)
- An offence to supply in circumstances where the supplier could reasonably suspect the use of the poison will be in a way that could be expected to pose a serious threat to the health, safety and welfare of an individual or the public more broadly (Penalty $30,000 fine)
- Provision for the issuing of a ‘compliance notice’ to impose restrictions on a supplier where a restriction is considered necessary to protect the health, safety and welfare of an individual or the public more broadly (Penalty for breaching a compliance notice is a fine of $30,000).
- Must be stored out of reach of children in the retail setting (Penalty $45,000)
- Must not be disposed of in a manner that constitutes, or is likely to constitute, a risk of public health or safety (Penalty $45,000).
- Free samples can only be supplied in circumstances where the recipient has the opportunity to refuse the free sample at the time of supply (Penalty $30,000).

The penalties would be applicable where a person was found guilty, through court prosecution, of an offence in relation to the storage, supply or disposal of nitrous oxide in Schedule 6.

The Schedule 6 decision will come into effect on 1 October 2022. The delayed implementation date is intended to provide sufficient time for manufacturers to ensure packaging and labelling of their products is compliant with the mandatory requirements for Schedule 6 poisons.

Nitrous oxide is commonly used as a food additive (food additive code number 942). Once a food additive has been added to a food, it is no longer classified as a scheduled substance. This means aerosol cans of cream, which contain nitrous oxide pre-mixed with liquid cream, emulsifiers and stabilisers, are exempted from the Poisons Schedules and are therefore not regulated through the Medicines and Poisons Act. As with all foods, these products will be regulated through the *Food Act 2008*, which applies the national Food Standards Code to all foods offered for sale in WA.

11 Food businesses and nitrous oxide regulation

The significant risk of long-term neurological effects from use of larger amounts of nitrous oxide as an intoxicant remain a concern, despite the nationally agreed changes to the scheduling of nitrous oxide. The public records of the scheduling decision note that “the regulation of nitrous

oxide is not solely a scheduling issue"[42]. The scheduling Delegate was of the view that creating a Schedule 6 entry supported other strategies and restrictions implemented by the states and territories, to mitigate the risk from the inappropriate use of nitrous oxide.

In WA, all food businesses must be either registered or notified under the *Food Act 2008* which means there is a mechanism by which a supplier of nitrous oxide food additive products can readily differentiate between legitimate food businesses and other businesses or individuals.

Food businesses include, but are not limited to, distributors and importers, retailers, food transport businesses, hospitality venues including cafes, restaurants and bars, mobile food operators, hospitals, residential care facilities and childcare facilities, accommodation facilities such as hotels and motels, market stalls and home delivery of food, including by charitable and community organisations.

The registration process means businesses, including those operated by sole traders and those operated from a residential location, that are likely to be using nitrous oxide to prepare whipped cream, cocktail drinks or other food products should be able to provide their supplier with evidence of their registration as a food business.

Notification rather than registration is only applicable in limited circumstances, such as where the business only serves complementary drinks in conjunction with another business conducted on the premises (for example, a hairdresser providing tea and coffee to their clients) or only sells shelf stable products that are entirely contained in a closed package (for example, a liquor store with no tastings).

Training organisations that require nitrous oxide for legitimate educational purposes, such as for courses teaching commercial cookery, should also be readily identifiable and in many cases will operate as a food business.

In order to reduce the likelihood of the supply of nitrous oxide occurring in a manner that is associated with use in a harmful way, the following suite of restrictions on supply to individuals or end-user businesses (or other entities) that are not food businesses are proposed:

- Limit the **amount** of nitrous oxide that can be purchased per transaction or delivery
- Limit the hours **when** nitrous oxide can be sold
- Limit **how soon** orders for nitrous oxide can be delivered
  and
- Limit the **type of product** that can be supplied to different kinds of users.

These proposed supply controls do not affect Section 206 of the Criminal Code. A supplier could still be prosecuted under Section 206 if there was evidence that the supplier could have reasonably known that the purchaser was intending to use the nitrous oxide for the purpose of intoxication.

[42] Australian Department of Health. Notice of interim decisions on proposed amendments to the Poisons Standard (nitrous oxide) – March 2021. Published 30 July 2021. Available at: https://www.tga.gov.au/scheduling-decision-interim/notice-interim-decisions-proposed-amendments-poisons-standard-nitrous-oxide-march-2021

The onus would be on the seller to ensure they were supplying in accordance with any regulated restrictions. Section 15(1) of the Medicines and Poisons Act already includes a requirement that the supply of a Schedule 6 poison must be in accordance with the regulations. The penalty for an offence under this clause is $30,000.

Further information on each of these proposals is provided in Section 12.

12 Options for reform

12.1 Limit the amount of nitrous oxide per transaction or delivery

Each small bulb of nitrous oxide contains 8g of compressed liquified gas, which is sufficient to whip 500 mL of cream via a whipped cream dispenser. The smallest commercial pack of bulbs is a box of 10 bulbs, which means one box of bulbs could be used to whip 5 litres of liquid cream, to produce around 15 litres of whipped cream.

It is considered unlikely that a home cook would need to use more than, at most, a few bulbs during one food preparation session.

In other words, one box of 10 bulbs per transaction should be sufficient for a home cook.

On the other hand, businesses that prepare food, including drinks, may need to buy multiple packs or larger packs of bulbs or even use nitrous oxide in cylinders.

It is therefore proposed that individuals and end-user businesses or other entities that are not registered as food businesses are limited to purchasing one box of 10 nitrous oxide bulbs per transaction. These limits would be applicable to both 'in person' purchasing and online sales.

12.2 Limit when nitrous oxide can be sold

In 2019, South Australia amended their *Controlled Substances (Poisons) Regulations 2011*[43] to impose penalties on both 'bricks and mortar' stores and online businesses selling nitrous oxide by making it an offence to sell between the hours of 10 pm and 5 am.

It is proposed that the same restrictions on hours of supply be applied in WA, including both sales at 'bricks and mortar' stores and delivery following an online order.

However, if consultation determines there is a need, delivery outside the hours of 10 pm and 5 am could be allowed where the recipient of the order is a food business.

12.3 Limit how soon orders for nitrous oxide can be delivered

Online businesses selling nitrous oxide, that is reported to be used recreationally, routinely advertise they are able to deliver within fifteen minutes to an hour of an order being placed.

It is proposed, as a disincentive to this type of marketing, that there be a 24 hour delay from when an order is received until the order is dispatched for delivery. However, this restriction would only be applicable where an order is made by an individual or an end-user businesses

[43] Available at:https://www.legislation.sa.gov.au/lz?path=/c/r/controlled%20substances%20(poisons)%20regulations%202011

that is *not* registered as a food business. This restriction would only be applicable to orders rather than direct 'in person' sales within a 'bricks and mortar' store.

12.4 Limit the type of product that can be supplied

It is proposed that supply of cylinders of food grade nitrous oxide be limited to registered food businesses only. These cylinders generally contain 580 g nitrous oxide, which is the equivalent of 72.5 x 8 g bulbs.

This would mean an individual or an entity that is not a food business could only purchase food additive nitrous oxide in small bulbs.

12.5 No additional supply controls proposed for automotive grade nitrous oxide

Nitrous oxide intended for enhancing engine performance usually has a small amount (100 ppm) of sulfur dioxide added, to deter inhalation. Sulfur dioxide has a strong, pungent odour and is very irritating to the respiratory tract, eyes, mucous membranes and skin.

Nitrous oxide products which include sulfur dioxide as a denaturant are very unlikely to be inhaled recreationally. It is proposed that these type of nitrous oxide products are not made subject to any additional supply restrictions. Automotive grade nitrous oxide products will be regulated as Schedule 6 poisons from 1 October 2022

12.6 Option for approval of purchase by a non-food business, organisation or individual

It is also proposed that a clause be added to allow the Chief Executive Officer of the Department of Health to authorise a person (who is not operating a registered food business), a non-food business or organisation to purchase nitrous oxide in Schedule 6 in a manner outside the proposed supply controls.

For example, a person could be authorised to purchase a larger quantity of nitrous oxide per transaction or could be authorised to have their orders dispatched in less than 24 hours.

Any such authorisation would need to be in writing and specify the quantity, type of product and could be for a defined period. This type of authorisation would provide an option for an individual or an entity that is not a food business, to be exempted from one or more of the restrictions on sale that would normally apply.

It is not anticipated this clause would be used extensively but it would provide an avenue for purchase of nitrous oxide where it was required for *bona fide* industrial, research or educational purposes.

13 Consultation

Consultation will be managed by the Department of Health, in liaison with the Mental Health Commission. A focus of the consultation will be to gain an understanding of how supply and use is managed by the food industry, including restaurants, catering businesses and bars, with the aim of ensuring an appropriate level of access to nitrous oxide for use as a food additive is

maintained. Whilst some regulatory impact on legitimate food businesses is necessary to protect public health, the intention is to minimise this as much as possible.

It is intended targeted consultation will be undertaken with:

- Industry peak bodies representing wholesalers, retailers and the restaurant, catering and hotels industry.
- Possibly individual businesses servicing the restaurant, catering and hotels industry.
- Peak bodies representing relevant health practitioner groups and other healthcare providers, including those working in the alcohol and other drugs area (limited to notification of the availability of the online consultation).
- WA Police in relation to their role in the investigation and prosecution of breaches of the proposed supply controls over nitrous oxide.

A public consultation survey will be published on the Department of Health's online consultation hub at: https://consultation.health.wa.gov.au/. During the consultation period, anyone will be able to complete the online survey which will include questions about each of the proposed supply controls as well as questions about financial and other impacts on food businesses, wholesalers, retailers, organisations and individuals.

A copy of the proposed questions for the public consultation survey is included in Appendix 1.

To participate in the public consultation: go to the Western Australian Department of Health's online consultation page at https://consultation.health.wa.gov.au/ and search for "nitrous oxide".

14 Proposed monitoring of supply control impacts

The aim of the proposed supply controls is to change purchasing patterns in a manner that reduces the incidence of the serious adverse health outcomes being experienced by recreational users of nitrous oxide.

Although likely influenced by multiple factors, review of the number of people presenting to WA public hospital emergency departments with nitrous oxide associated neurological conditions can be used as an indicator of the effectiveness of the proposed supply controls.

Changes to the availability of nitrous oxide 'nangs' from online businesses, especially those located in WA or claiming to supply to WA, could also be used to assess the impact of any regulatory changes. Review of information provided to potential clients by these businesses, via their websites, would be an indicator of their awareness of the changes. Test purchases could be made to check whether these businesses are adhering to the regulatory requirements.

Audits of computerised 'point of sale' or other records of supply by wholesalers and retailers can also be used to provide evidence of adherence to limits on quantity and product type supplied as well as the time (hour) of supply.

Other information which could indicate an effect of the proposed supply controls would be changes in reports from local government authorities of discarded/used cream chargers. These

are currently found in large numbers in car parks, public gardens and other public spaces maintained by local government.

There may also be an opportunity to include pertinent questions in future EDRS surveys to assess whether participants have noticed changes in availability or whether they have changed their purchasing behaviour.

Appendix 1 Questions for online consultation survey

Please provide your opinion for each of the options for controlling supply of nitrous oxide to individuals and end-user businesses that are not food businesses.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Maximum of 10 bulbs (1 box) per transaction	☐	☐	☐	☐	☐
No sales or deliveries between 10 pm and 5 am.	☐	☐	☐	☐	☐
24 hour delay between order placement and dispatch.	☐	☐	☐	☐	☐
Only bulbs can be purchased, not cylinders.	☐	☐	☐	☐	☐

About you

To help us understand your responses better, please answer the following questions.

How would you like your submission to be treated?

(Required)

Please select only one item

☐Publish my submission with my name and/or organisation.

☐Publish my submission anonymously.

☐Do not publish my submission (confidential submission).

What is your name?

Name_____

You name will not be published, unless you have chosen to have your submission published with your name and/or organisation details. The Department will not provide your name to third parties.

What is your email address?

Email_____

If you provide an email address, you will be sent a link to a .pdf of your survey responses.

In this survey, are you providing your own individual views or the official views of an organisation or business?

(Required)

Please select only one item

☐My own views.

☐The views of an organisation or business.

If you are responding on behalf of an organisation or business, please provide the name and contact details:

Name of organisation or business

Address and other contact details

Which ONE of the following options BEST describes you?

(Required)

☐Food business operator or employee that uses nitrous oxide.

☐Someone who uses nitrous oxide in home cooking, but does NOT operate a food business.

☐Business, organisation or individual that uses nitrous oxide (with added sulfur dioxide) for automotive purposes.

☐Someone who uses nitrous oxide recreationally.

☐Business, organisation or individual that uses nitrous oxide for another purpose, not otherwise listed.

☐Retail business operator or employee that sells nitrous oxide to end users.

☐Wholesale business operator or employee that sells nitrous oxide (includes a wholesale business with a retail arm).

☐Health professional.

☐Health-related business or organisation, including patient support organisations.

☐Member of the public.

☐Consumer organisation.

☐Business or industry organisation.

☐Government Department.

☐Academic or researcher at a tertiary institution or other research facility.

☐None of the options describe me.

☐Prefer not to say.

If you don't think any options describe you, please describe yourself below:

(Required)

_____

Questions for food businesses

These questions are to help us better understand the impact of the proposed supply controls on food businesses.

Please choose ONE option that best describes the type of food business you operate or work in:

☐Hotel, cafe or restaurant that uses nitrous oxide in food preparation.

☐Catering business (NOT home-based) that uses nitrous oxide in food preparation.

☐Home-based food business that uses nitrous oxide in food preparation.

☐Food manufacturing business that uses nitrous oxide as a food additive.

☐Other type of food business, not described in the previous options, that uses nitrous oxide.

☐Prefer not to say

Do you think the additional supply controls will make it easier or harder for your food business to access nitrous oxide?

Please select only one item

☐Much harder ☐Harder ☐No change expected ☐Easier ☐Much easier

Does your business currently purchase ‘in store’ or have nitrous oxide delivered, between 10 pm and 5 am?

☐Very often ☐Often ☐Sometimes ☐Rarely ☐Never

Please describe any effects you think the proposed supply controls will have on your business, in the box below:

Questions for wholesalers

These questions are to help us better understand the impact of the proposed supply controls on wholesalers who supply nitrous oxide products.

Choose which of the following types of customer your business supplies: Please select all that apply

☐Other wholesalers and/or manufacturers.

☐Retail businesses that on-sell nitrous oxide products to end users.

☐Food businesses, such as hotels, cafes, restaurants and caterers.

☐Other types of end-user business (that are not food businesses).

☐Members of the public.

☐None of the options describe my customers.

☐Prefer not to say.

Which of the following checks would be feasible for your business, to ensure you only sell larger quantities of nitrous oxide to food businesses? Please select all that apply

☐Check your customer has a current Certificate of Registration as a food business when they first set up their account.

☐Check your customer has a current Certificate of Registration as a food business annually.

☐Check your customer has a Certificate of Registration as a food business each time they make a purchase, even when they have an account.

☐Require a new customer to make a signed declaration that they are a food business but do not require them to show their Certificate of Registration as a food business.

☐My business only sells food products that already have nitrous oxide added to them, such as cans of aerosol whipped cream.

☐My business should not have to do any checks - the onus should be on the purchaser to only order cylinders or larger quantities of bulbs if they are a registered food business.

☐None of the above options are feasible for my business.

How much do you think the proposed supply restrictions on nitrous oxide will financially impact your business?

When determining the financial impact on your business, please consider compliance costs (such as checking whether a purchaser is a food business) and costs associated with potential changes in inventory and sales volumes.

☐No impact

☐Very small impact

☐Small impact

☐Medium impact

☐Large impact

☐Very large impact

☐Extreme impact

Questions for retailers

These questions are to help us better understand the impact of the proposed supply controls on retailers, who supply nitrous oxide products to end users.

Please choose ONE option that best describes your retail business:

☐Convenience store

☐Supermarket

☐Petrol station store

☐Online only supplier

☐Other retail supplier without an online store

☐Other retail supplier with both 'bricks and mortar' store and online store.

☐None of the options describes the retail business

☐Prefer not to say

Which of the following checks would be feasible for your business to ensure you only supply larger quantities of nitrous oxide to food businesses?

Please select all that apply

☐Check your customer has a current Certificate of Registration as a food business each time they make a purchase.

☐Require your customer to set up an account if they wish to purchase a larger quantity of nitrous oxide and check their Certificate of Registration as a food business as part of the account set up process.

☐Require your customer to register with your website before they can make a larger purchase of nitrous oxide and require them to upload a scan or photo of their Certificate of Registration as a food business at that time.

☐Require your customer to upload a scan or photo of their Certificate of Registration as a food business each time they make an online purchase of a larger quantity of nitrous oxide.

☐When a purchaser tries to make a purchase of a larger quantity of nitrous oxide, ask them to make a signed declaration that they are a food business but do not require them to show their Certificate of Registration as a food business.

☐ Restrict all customers to only purchasing 10 bulbs of nitrous oxide per transaction.

☐No checks will be necessary as the business only sells food with nitrous oxide already added, such as cans of aerosol whipped cream.

☐My business should not have to do any checks - the onus should be on the purchaser to only order cylinders or larger quantities of bulbs if they are a registered food business.

☐None of the above options are feasible for my business.

How much do you think the proposed supply restrictions on nitrous oxide will financially impact your business?

When determining the financial impact on your business, please consider compliance costs (such as checking whether a purchaser is a food business) and costs associated with potential changes in inventory and sales volumes.

☐No impact

☐Very small impact

☐Small impact

☐Medium impact

☐Large impact

☐Very large impact

☐Extreme impact

Questions for health professionals and health related businesses/organisations

Please choose ONE option that best describes your health profession or health organisation/business type:

☐Registered health practitioner

☐Registered health practitioner who primarily works in the Alcohol and Other Drugs (AOD) sector

☐Health professional who is not AHPRA registered and who works in the AOD sector

☐Health professional who is not AHPRA registered and who does not work in the AOD sector

☐AOD sector healthcare provider/business, that provides care to individual patients/clients

☐Healthcare provider/business that provides care for individual patients/clients, but not primarily in the AOD sector.

☐Other type of health-related business

☐Health profession member organisation

☐Patient support organisation

☐Other type of health organisation, not otherwise listed

Final questions (all respondents)

Please choose how much OVERALL impact the proposed supply controls will have for you (or your business or organisation if you are answering on their behalf): Please select only one item

☐No impact

☐Very small impact

☐Small impact

☐Medium impact

☐Large impact

☐Very large impact

☐Extreme impact

How much do you think the proposed supply controls will reduce health harm related to recreational use of nitrous oxide? Please select only one item

☐No reduction

☐Very small reduction

☐Small reduction

☐Large reduction

☐Very large reduction

If you have other ideas about how to reduce the health harms associated with recreational use of nitrous oxide, please provide details in the box below:

If you have any other comments, please provide details in the box below:

This document can be made available in alternative formats on request for a person with disability.