

**EXPLANATORY MEMORANDUM TO**  
**THE MISUSE OF DRUGS (ENGLAND AND WALES AND SCOTLAND)**  
**(AMENDMENT) REGULATIONS 2023**

**2023 No. 1099**

**1. Introduction**

- 1.1 This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by Command of His Majesty.

**2. Purpose of the instrument**

- 2.1 These regulations amend the Misuse of Drugs Regulations 2001 (S.I. 2001/3998) (“the 2001 Regulations”) to place nitrous oxide, and preparations or products containing nitrous oxide (collectively, “nitrous oxide”), in Schedule 5 to the 2001 Regulations and to make provision for lawful access to the substance for legitimate purposes, including medical use. They exclude nitrous oxide from the general wholesale permissions to import, export and possess Schedule 5 controlled drugs and instead create a tailored solution by which only certain activities are exempted.

**3. Matters of special interest to Parliament**

*Matters of special interest to the Joint Committee on Statutory Instruments*

- 3.1 None.

**4. Extent and Territorial Application**

- 4.1 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law is) is England, Wales, and Scotland.
- 4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England, Wales, and Scotland.

**5. European Convention on Human Rights**

- 5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

**6. Legislative Context**

- 6.1 The Misuse of Drugs Act 1971 (Amendment) Order 2023 (“the 2023 Order”) controls nitrous oxide as a Class C drug under the Misuse of Drugs Act 1971 (“the 1971 Act”) and comes into force on 8 November. Prior to that, nitrous oxide was a “psychoactive substance” under the Psychoactive Substances Act 2016 (“the 2016 Act”). It ceases to be in scope of the 2016 Act when it becomes a controlled drug, as controlled drugs are exempted substances under section 3(1) and paragraph 1 of Schedule 1 of that Act. Instead, the offences and enforcement powers available under the 1971 Act apply.
- 6.2 The 2001 Regulations regulate legitimate access to drugs considered “dangerous or otherwise harmful” and which are therefore controlled under the 1971 Act. Drugs so controlled are scheduled in one of five schedules under the 2001 Regulations, and the schedule in which a drug is placed is based on an assessment of its medicinal and

therapeutic usefulness, the need for legitimate access and the potential harm when misused. The Schedule into which a drug is placed dictates the circumstances in which it may be lawful to import, export, produce, supply, administer and possess that drug, and may also impose requirements about prescription writing, record keeping, labelling and destruction.

- 6.3 Drugs placed in Schedule 5 to the 2001 Regulations are, ordinarily, wholly excepted from the prohibitions on the import, export and possession of controlled drugs (by regulation 4 of the 2001 Regulations). Similarly, the 2001 Regulations ordinarily permit any person to administer to another person any Schedule 5 controlled drug (by regulation 7 of the 2001 Regulations).
- 6.4 This instrument places nitrous oxide in Schedule 5 to the 2001 Regulations but excludes the substance from these general permissions for importation, exportation, possession and administration to another. Instead, new regulation 4C creates a bespoke exemption from the prohibition on importation and exportation, production, supply and possession of nitrous oxide where a person does not intend to wrongfully inhale the substance and/or, in the cases of importation, exportation, production and supply, does not know or is not reckless as to whether it is likely that another person will wrongfully inhale it.
- 6.5 "Wrongful inhalation" means any inhalation by a person which is not for a medical or dental purpose (for example, the recreational inhalation of nitrous oxide for its psychoactive effect) or is not of nitrous oxide which has been released into the atmosphere (for example, directly from a canister or a balloon) (new Regulation 4C (5)). Medical purposes are defined as the purposes of preventative medicine, medical diagnosis or the provision of medical care and treatment.
- 6.6 The specific permissions for persons to possess, supply, produce and administer Schedule 5 drugs (excluding the permissions outlined in paragraph 6.3 above), will also apply to nitrous oxide. For example, the permissions in regulation 6 of the 2001 Regulations which enable constables or couriers, or any person holding a drug supplied by or on the prescription of a medical practitioner, to lawfully supply and possess the drug in the circumstances specified will apply. Similarly, the permissions in regulation 8 of the 2001 Regulations, such as for pharmacists to manufacture or compound any Schedule 5 drug, will apply. This enables recognised legitimate uses, such as for enforcement or medicinal or analytical uses, to continue in the same way as they can for other Schedule 5 drugs.
- 6.7 In addition, these regulations amend regulation 10 of the 2001 Regulations to make provision for possession, supply and production of nitrous oxide by certain scientific education and research laboratories (to enable legitimate scientific research). The amendments also create the potential for the Secretary of State to issue group authorities and/or written authorities to authorise other activities (not permitted by the 2001 Regulations) relating to nitrous oxide. This will enable exceptional cases to be dealt with, should novel or new uses of nitrous oxide not in scope of the exemption, materialise. As with all controlled drugs, other activities may also be rendered lawful if they occur under a Home Office licence issued in accordance with regulation 5 of the 2001 Regulations.
- 6.8 Nitrous oxide will be subject to regulations 24 and 26 of the 2001 Regulations, which relate to the preservation of records relating to, and the furnishing of information with respect to, Schedule 5 drugs.

- 6.9 The effect of these amendments, together with the 2023 Order, is to prohibit the import, export, possession, production or supply of nitrous oxide for wrongful inhalation, while also permitting those activities for legitimate uses such as for medical, dental or veterinary use or as part of industrial or manufacturing processes.

## 7. Policy background

### *What is being done and why?*

- 7.1 On the 27 March 2023, the Government published its Anti-social Behaviour Action Plan (available here: - [Anti-Social Behaviour Action Plan - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/115442/anti-social-behaviour-action-plan.pdf)), which set out the Government's approach to ensuring that people can live without the fear of anti-social behaviour. As part of that plan, the Government committed to ban nitrous oxide. The 2023 Order gives effect to that commitment by controlling nitrous oxide as a Class C drug under the 1971 Act. Amendments to the 2001 Regulations are necessary to ensure its continued availability for legitimate use, including medical use.

### *Explanations*

- 7.2 Nitrous oxide is used for pain relief in medical settings, including dentistry. It also has a wide variety of legitimate uses in industry, manufacturing and technical processes, such as food packaging, but also in catering, as a whipped cream propellant. Hobbyists also use it in activities such as drag racing and model rocketry. The Government recognises that those users are not misusing nitrous oxide for its psychoactive effect. For this reason, the exemption focuses on whether people intend to wrongfully inhale it or know, or are reckless as to whether, others will wrongfully inhale it. In practical terms, that means those who are importing or possessing nitrous oxide because they plan to inhale it themselves for its psychoactive effect, or to provide it to others for them to do so, or the producers or suppliers who are turning a blind eye to whether the people who buy their products are using it for proper purposes or simply for its psychoactive effect, will be committing offences. Legitimate businesses, individual users and organisations will not. The Government believes this to be a proportionate and targeted response which will reduce abuse and harms, while not unduly inhibiting legitimate businesses and users.
- 7.3 The Government recognises that nitrous oxide has legitimate uses and does not wish to unduly burden those seeking to use it for those purposes. To inform that decision the Government ran a public consultation from 2 March date to 27 May 2023 *Nitrous oxide: legitimate uses and appropriate controls*. The consultation and response can be found here: [Nitrous oxide: legitimate uses and appropriate controls - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/consultations/nitrous-oxide-legitimate-uses-and-appropriate-controls). Further detail about the response to the consultation is outlined in paragraph 10.1.
- 7.4 In line with our statutory duty, the Government also consulted the ACMD on 1) the appropriate scheduling of nitrous oxide under the 2001 Regulations; and 2) how to enable non-medical, lawful uses, including industrial uses. Further detail is provided in paragraph 10.2.
- 7.5 The Government's approach will exclude nitrous oxide from the provisions which ordinarily make the import, export, production, supply, possession with intent to supply and possession of controlled drugs unlawful, where the conditions of the exemption are met. This will ensure that persons conducting activities which do not relate to the wrongful inhalation of nitrous oxide are not criminalised.

- 7.6 Wrongful inhalation means inhalation other than for medical or dental purposes, and which is not accidental inhalation of nitrous oxide which has been released into the atmosphere (such as in industrial processes). Medical, dental and veterinary administration of nitrous oxide (which may involve inhalation) will therefore continue to be lawful, as will other activities such as use in industry or model rocketry. There is a requirement on importers, exporters, producers and suppliers to take appropriate steps (i.e., to not be reckless) to ensure that subsequent users will not inhale the substance recreationally.
- 7.7 This approach will not require a controlled drug licence to be held for the legitimate use of nitrous oxide. It will not impose safe storage requirements. Producers and wholesale dealers will be required to keep invoices (or like records) of each quantity of nitrous oxide they obtain and supply, and retail dealers to keep records of each quantity of nitrous oxide they obtain (by regulation 24 of the 2001 Regulations). Additionally, producers, dealers, medical practitioners and other specified persons may be required, where requested, to provide information in relation to nitrous oxide to the Secretary of State (by regulation 26 of the 2001 Regulations). All legitimate users will be encouraged to take measures to ensure that they are not reckless as to whether the substances will be used for wrongful inhalation.

## **8. European Union Withdrawal and Future Relationship**

- 8.1 This instrument does not relate to withdrawal from the European Union/ trigger the statement requirements under the European Union (Withdrawal) Act 2018 / implement any future relationship agreement with the European Union within the meaning provided by section 37 of the European Union (Future Relationship) Act 2020.

## **9. Consolidation**

- 9.1 The Government intends to consolidate the 2001 Regulations in due course.

## **10. Consultation outcome**

- 10.1 The Government ran a consultation from 2 May to 27 June 2023 which was primarily targeted at businesses which use nitrous oxide, but also members of the public who use nitrous oxide for purposes other than its psychoactive effect, for example, in catering to whip cream. This sought to understand the full range and scale of legitimate uses of nitrous oxide (to enable the design of a legal framework to permit its use for legitimate purposes once controlled under the 1971 Act). The Government received 105 responses to the consultation: 84 were responses to the online survey and 21 were received by email. The majority of respondents to the section in the online survey about the impact of the three proposals (48 out of 77 responses, 62%) felt that Proposal 2 – which would not require licensing for legitimate purposes - would have either a low or no impact on their organisation or business in terms of loss of revenue or administrative burden. This compared with 22% (17) of respondents to the online survey reporting low or no impact for Proposal 1, licensing for all legitimate purposes (outside healthcare) and 35% (27) of respondents to the online survey for Proposal 3, the licensing for import, export, production, supply, and an exemption for possession for legitimate purposes. The responses to the consultation have helped the Government to design the legal framework to permit the use of nitrous oxide for legitimate purposes while it is controlled as a Class C drug under the 1971 Act. The

Government's full response to the consultation can be found here: [Nitrous oxide: legitimate uses and appropriate controls - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/consultations/nitrous-oxide-legitimate-uses-and-appropriate-controls).

- 10.2 As outlined at paragraph 7.4, the Government has consulted the ACMD. The consultation with the ACMD fulfils the Government's duty under section 31(3) of the 1971 Act. The Government accepted the ACMD's recommendation that nitrous oxide be scheduled under Schedule 5 to the 2001 Regulations, with modifications, on the basis that it would offer the most suitable controls while enabling medical-related and non-medical-related uses with the fewest burdens. The ACMD advice of 11 August is available at the following link: [Advice on scheduling and lawful access to nitrous oxide - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/consultations/advice-on-scheduling-and-lawful-access-to-nitrous-oxide). The Government response of 5 September can be found here: [Government letter to the ACMD: scheduling of nitrous oxide \(publishing.service.gov.uk\)](https://publishing.service.gov.uk/government/consultations/government-letter-to-the-acmd-scheduling-of-nitrous-oxide)

## **11. Guidance**

- 11.1 The decision to control nitrous oxide as a Class C drug under the 1971 Act and the provisions to enable its legitimate use will be communicated to key stakeholders and the wider public. The Home Office will issue a circular with legislative guidance for the police and the courts, as well as a factsheet clarifying the law for members of the public, including businesses. The Government will continue to update its messaging on the harms of this substance, including through its FRANK information and advisory service online, which is aimed at young people and adults to inform them of drug related risks and harms.

## **12. Impact**

- 12.1 There is no anticipated impact on business, charities, or voluntary bodies from these Regulations. This is due to the design of exemptions to ensure that legitimate use and supply of nitrous oxide is maintained without disruption.
- 12.2 For an assessment of all potential impacts, including public sector impacts, a full Impact Assessment was submitted with the explanatory memorandum for the 2023 Order and published on legislation.gov.uk. It is accessible here: [Impact Assessment \(legislation.gov.uk\)](https://legislation.gov.uk/ukSI20230001/ia)

## **13. Regulating small business**

- 13.1 The Regulations apply to activities that are undertaken by small businesses.
- 13.2 The Government intends to minimise the burdens on legitimate users of nitrous oxide, while mitigating risks of harm, misuse and diversion, through amendments to the 2001 Regulations introduced by these Regulations.

## **14. Monitoring & review**

- 14.1 The Government will monitor the efficacy of the control and scheduling measures, prevalence and harms of nitrous oxide using a range of sources including the Crime Survey for England and Wales, the Smoking, Drinking and Drug Use Among Young People in England survey and the Scottish Health Survey as well as registered deaths. It will also maintain oversight through the healthcare regulatory bodies in England and through engagement with the Devolved Administrations.

**15. Contact**

- 15.1 Sam Hardy at the Home Office, Telephone: 020 7035 1784 or email: Sam.Hardy@homeoffice.co.uk can be contacted with any queries regarding the instrument.
- 15.2 Marcus Starling, Deputy Director for the Drug Misuse Unit at the Home Office can confirm that this explanatory memorandum meets the required standard.
- 15.3 The Minister for Crime, Policing and Fire, the Rt. Hon. Chris Philp MP, can confirm that this explanatory memorandum meets the required standard.