

EN
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Answer given by Mr Brunner
on behalf of the European Commission
(11.8.2025)

Nitrous oxide can lawfully be placed on the market as a food additive¹ and is an industrial chemical². Recently, the Commission adopted a delegated act³ under the Regulation on Classification, Labelling and Packaging (CLP)⁴ subjecting by 1 February 2027 nitrous oxide to a harmonised classification and labelling as toxic for human reproduction and the nervous system.

Following this classification, it is planned to update an existing restriction prohibiting the placing on the market and use for the general public under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation⁵ to include nitrous oxide within its scope. This is not targeted at the use of the substance as a drug.

When nitrous oxide is classified as a medicinal product, any issue related to its inappropriate or off-label use shall be reported as misuse through the national pharmacovigilance system⁶.

As regards the illicit drugs framework, the EU Drugs Agency (EUDA) follows the developments and provides guidance related to nitrous oxide in the European drug market⁷. However, nitrous oxide does not fall under the definition of ‘drug’ within Council Framework Decision 2004/757/JHA⁸ on combating drug trafficking.

¹ According to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, <http://data.europa.eu/eli/reg/2008/1333/2025-04-23>.

² Subject to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (REACH Regulation), <http://data.europa.eu/eli/reg/2006/1907/2025-04-22>, and Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (CLP Regulation), <http://data.europa.eu/eli/reg/2008/1272/2025-02-01>.

³ Commission Delegated Regulation (EU) 2025/1222 of 2 April 2025 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council as regards the harmonised classification and labelling of certain substances, https://eur-lex.europa.eu/eli/reg_del/2025/1222.

⁴ https://publications.europa.eu/resource/cellar/e2325a32-040a-11f0-9503-01aa75ed71a1.0021.02/DOC_2.

⁵ Entry 30 of Annex XVII of REACH, <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02006R1907-20250422>.

⁶ This obligation is in accordance with the Article 102 of Directive 2001/83/EC, <https://eur-lex.europa.eu/eli/dir/2001/83/oj/eng>, and the Good Pharmacovigilance Practices (GVP) guidelines VI, which rule that Member States take all appropriate measures to encourage the reporting of suspected adverse reactions, including those arising from misuse, ensuring the continued safety monitoring of medicinal products.

⁷ See EU Drugs Agency’s 2025 European Drug Report, https://www.euda.europa.eu/publications/european-drug-report/2025_en and Report on the Recreational use of nitrous oxide – a growing concern for Europe (2022), https://www.euda.europa.eu/publications/rapid-communication/recreational-use-nitrous-oxide-growing-concern-europe_en.

⁸ Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, https://eur-lex.europa.eu/eli/dec_framw/2004/757/oj/eng.

Nitrous oxide is not monitored by the EU Early Warning System (EWS) on new psychoactive substances. For the substance to be monitored, Member States must notify it to EUDA with analytical data⁹. EUDA then conducts a review to see if it meets the conditions for formal notification. The legitimate uses of nitrous oxide make its monitoring in the EWS more difficult¹⁰.

Where the CLP Regulation applies, nitrous oxide should be labelled with the required pictograms, warning words, hazard and precautionary statements, e.g. 'Danger' and 'Causes damage to the nervous system after prolonged or repeated exposure'.

⁹ Regulation (EU) 2023/1322 of the European Parliament and of the Council of 27 June 2023 on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023R1322&qid=1754040141958>.

¹⁰ EUDA, Report on the Recreational use of nitrous oxide – a growing concern for Europe (2022), https://www.euda.europa.eu/publications/rapid-communication/recreational-use-nitrous-oxide-growing-concern-europe_en.