



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Message 201

Communication from the Commission - TRIS/(2024) 2858

Directive (EU) 2015/1535

Notification: 2024/0552/DE

Forwarding of the response of the Member State notifying a draft (Germany) to request for supplementary information (INFOSUP) of European Commission.

MSG: 20242858.EN

1. MSG 201 IND 2024 0552 DE EN 18-10-2024 DE ANSWER

2. Germany

3A. Bundesministerium für Wirtschaft und Klimaschutz, Referat EB3

3B. Bundesministerium für Gesundheit, Referat 122

4. 2024/0552/DE - C00C - CHEMICALS

5.

6. Dear colleagues of the European Commission,

We are pleased to comply with your request for additional information on the German regulatory project. We are happy to answer your questions as follows:

The urgency of the procedure:

The misuse of nitrous oxide (laughing gas) for intoxication purposes has increased significantly in Germany in recent months. In the view of the Federal Government, rapid legislative action is required to limit the risk of escalating abuse and further deaths. The German federal states also share the assessment of a high urgency and, by resolution of the Federal Council of 14 June 2024 called on the Federal Government to establish a suitable legal framework as soon as possible to restrict the sale of nitrous oxide, particularly to children and young people, to such an extent that abuse is prevented.

Nitrous oxide consumption-associated health disorders and damage have increased significantly. The health consequences are also much more severe than originally assumed. In addition to serious and sometimes irreversible damage to health in case of long-term use (blood count and nerve damage), acutely significant, life-threatening, or fatal consequences of nitrous oxide abuse are increasingly being reported.

In detail:

Consumption results in significant health effects, including death. As regards nitrous oxide, a total of 26 deaths were reported in Germany up to July 2024. In the absence of suitable nitrous oxide detection methods, the exact number of nitrous oxide-induced or nitrous oxide-associated accidents is not known, but a significantly higher number of unreported accidents and a further increase can be assumed.

According to the Federal Criminal Police Office (BKA), 11 deaths related to nitrous oxide were registered in 2023, with the BKA assuming an increasing trend and a high number of unreported cases. Overall, police-recorded nitrous oxide incidents in Germany increased from over 70 in 2021 to over 200 in 2022 and to more than 300 in 2023. It should be noted that due to the lack of regulation of nitrous oxide, there is no legal reporting obligation and it can be legally traded. In North Rhine-Westphalia, the number of abuse cases known to the State Criminal Police Office more than tripled between 2022 and 2023.

The BKA has also been notified of cases of serious crime involving nitrous oxide. This includes, for example, dangerous bodily injury offences and rapes, in which the perpetrator was under the influence of nitrous oxide during the commission



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

of the offence or used it as a knockout agent, as well as robberies, in which (legally available) nitrous oxide bottles were the stolen goods.

https://www.bka.de/EN/CurrentInformation/StatisticsSituationReports/SituationReports/NarcoticsCrime/2023/BLB_RG_2023_node.html, last

retrieved on 14 October 2024.

BKA Narcotics Crime, Federal Situation Report 2023, p. 21.

LKA NRW – Narcotics Crime – Situation Report NRW 2022, p. 33.

Overall, the consumption prevalence of nitrous oxide has risen sharply since 2022 and, according to a representative survey in Frankfurt am Main, is currently the substance with the highest prevalence values among pupils aged 15 to 18 after alcohol, tobacco, e-cigarettes/tobacco heaters, and cannabis (lifetime: 17 %, 12 months: 12 %, 30 days: 6 %) (Source: Werse et al. (2023): MoSyD Annual Report 2022). As part of the NEWS project, an increase in nitrous oxide consumption was identified in the survey of consumers. While the 30-day prevalence of nitrous oxide was 2.3 % in 2022 (Bergmann et al., 2023), it was 4.0 % in 2023 (Special evaluation; source: Bergmann et al. (2024): NEWS Trendspotter Report (April 2024): nitrous oxide). The 12-month prevalence increased from 5.0 % in 2022 to 8.9 % in 2023. A large number of reports of nitrous oxide-associated accidents from across Germany indicate a marked increase in the consumption prevalence of nitrous oxide in 2024. For example, we refer to press reports from Munich, Dortmund and Duisburg. The increase in the number of nitrous oxide cylinders disposed of in household waste is also an indication of the widespread use of consumption for intoxication purposes, especially in urban areas. There, the discarded cartridges lead to explosions in waste incineration plants and sometimes cause considerable property damage. Personal injuries have also already been caused. In Berlin, approximately 250 nitrous oxide cartridges per day are reported in one waste incineration plant alone.

Nitrous oxide for intoxication purposes is rapidly distributed through established sales channels (e.g. new websites are constantly being added to the internet). There are now also German online shops that deal exclusively with the distribution of nitrous oxide for intoxication purposes. Meanwhile, nitrous oxide is offered on the internet or in kiosk shops in different flavours such as mango, strawberry, coconut, and various bottle sizes, usually 640 g. In online shops, there are sets combined with balloons or neoprene bags, which are intended to protect against the cold generated by an open gas bottle.

In addition, there are new offers via vending machines, previously unknown in Germany, which enable omnipresent availability without any age and quantity controls and create additional consumer incentives.

The health consequences of the use of nitrous oxide for intoxication purposes include hazards arising directly or indirectly from the typical effects of nitrous oxide (including accidents and injuries under the influence of nitrous oxide), as well as health risks associated with long-term or frequent use. Since the beginning of this year, police authorities have been reporting on the consumption of nitrous oxide in connection with the driving of motor vehicles as a new phenomenon.

Adolescent consumes nitrous oxide and falls in front of train. Süddeutsche Zeitung 29 November 2023; Weltmann S (2024) Party Drug: The first city up the fight against nitrous oxide. WAZ 3 May 2024; Anonymous (2024) Driving under the influence of drugs. Süddeutsche Zeitung 10 May 2024.

Nitrous oxide cylinders damage waste incineration plants, Süddeutsche Zeitung 1 August 2024, Nitrous oxide containers endanger waste incineration plants, EUWID Recycling and Disposal, 25 July 2024, Orange does not find it funny, taz 15 August 2024; Berlin: 250 Nitrous oxide cartridges per day in waste disposal, Journal for Municipal Economy, August 9, 2024.

Berlin: 250 Nitrous oxide cartridges per day in waste disposal, Journal for Municipal Economy, August 9, 2024.

Nitrous oxide at the snack vending machine: point of sale causes trouble, NDR 7 May 2024; Gifhorn: At least 11 machines are continuing to supply nitrous oxide, Gifhorner Rundschau 11 July 2024; Laughing gas alongside chocolate and jelly babies – discussion on vending machines in Selm, Ruhr Nachrichten 23 July 2024; Obtain nitrous oxide simply from the machine – parents are outraged, SWR3 22 May 2024.

This is a very dangerous phenomenon and a completely underestimated danger. For the years 2021 to 2023, 136 cases were reported to the BKA in which the driver participated in road traffic under the influence of nitrous oxide or consumed



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

nitrous oxide while driving. The reported traffic accidents resulted in minor to moderate injuries, occasionally also life-threatening or, in one case, fatal injuries.

There is an urgent concern that, due to the increase in consumption, a similar development of road traffic hazards as in the Netherlands could be imminent. Prior to the implementation of the ban there, 63 road accident fatalities and 370 serious injuries related to nitrous oxide-associated accidents were reported within 1.5 years (2019-2021).

Health hazards associated with long-term or frequent use include vascular and organ-damaging effects. In particular, significant recurrent haematological secondary diseases and paralysis symptoms, including brain damage, are observed. To ensure that nitrous oxide can continue to be sold when lawfully placed on the EU market as an EU-approved food additive, in particular with regard to the 'intended general ban' on online trade:

According to the current state of science and technology, nitrous oxide has a widely recognised use for commercial, industrial and scientific purposes. For example, nitrous oxide is used as a food additive in food technology as a propellant for foaming dairy products (e.g. whipped cream). In view of the wide range of legal uses of nitrous oxide, such as a food additive, recognised uses for commercial, industrial or scientific purposes according to the current state of science and technology are excluded from the prohibitions. The mail order ban does not apply in this respect. At the same time, it is ensured that cartridges with a typical filling quantity of up to eight grams of nitrous oxide for intended private use remain available on the market for the adult end consumer. The draft also provides for an exception to the mail order ban in cases where the substance is in a form (container, preparation, etc.) that allows extraction of the substance concerned only with disproportionate effort.

The legal restrictions provided for, including prohibitions on the supply of goods to children and adolescents, are necessary measures to counter the omnipresence and availability of nitrous oxide.

dortmund.polizei.nrw/presse/unterschaetzte-gefahr-polizei-dortmund-warnt-eindringlich-vor-lachgas-konsum-am-steuer-es-herrscht-lebensgefahr, last accessed on 14 October 2024.

<https://teamalert.nl/media/hb4dliqr/factsheet-jongeren-en-lachgas-in-het-verkeer-infographic.pdf>, last accessed 14 October 2024; Ntv.de: Nitrous oxide-driven to death, 2 December 2021

Ziegenfuß T., Zander R. Nitrous oxide as a party drug. *Anaesthesiology*. 2024 July;73(7):482-487; Paralysis and irreversible nerve damage – The underestimated nitrous oxide risk, *Die Welt*, 26 February 2024; Physicians warn of nerve damage caused by nitrous oxide, *Deutsches Aerzteblatt*, 25 March 2024.

To counteract nitrous oxide for the end consumer and the resulting risk of further abusive consumption.

Finally, the New Psychoactive Substances Act, to which nitrous oxide is to be subject, does not apply to medicinal products within the meaning of Section 2(1), (2), (3a), and (4), first sentence, of the Medicinal Products Act.

European Commission

Contact point Directive (EU) 2015/1535

email: grow-dir2015-1535-central@ec.europa.eu