



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Enforcement

Notification of Regulatory Barriers

Notification Number : 2024/0552/DE (Germany)

## Drafting aid for an extension of the New Psychoactive Substances Act

Date received : 01/10/2024

End of Standstill : Not applicable

### Message

Message 001

Communication from the Commission - TRIS/(2024) 2672

Directive (EU) 2015/1535

Notification: 2024/0552/DE

Notification of a draft text from a Member State

Notification – Notificación – Notifizierung – Нотификация – Oznámení – Notifikation – Γνωστοποίηση – Notificación – Teavitamine – Ilmoitus – Obavijest – Bejelentés – Notifica – Pranešimas – Paziņojums – Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Ne zahajuje prodlení - Fristerne indledes ikke - Καμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késések - Non fa decorrere la mora - Atidējimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħ il-perijodi ta' dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20242672.EN

1. MSG 001 IND 2024 0552 DE EN 01-10-2024 DE NOTIF

2. Germany

3A. Bundesministerium für Wirtschaft und Klimaschutz, Referat EB3

3B. Bundesministerium für Gesundheit, Referat 122

4. 2024/0552/DE - C00C - CHEMICALS

5. Drafting aid for an extension of the New Psychoactive Substances Act

6. The New Psychoactive Substances Act is being updated to reflect the latest findings by amending the Act to include the psychoactive substances nitrous oxide, GBL and BDO. The law is being redrafted.

7.

8. The drafting aid contains a legislative amendment to the New Psychoactive Substances Act (NpSG). The amendment is



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intended to expand the existing NpSG. The current aim is to place the psychoactive substances nitrous oxide, 1,4-butanediol (BDO) and gamma-butyrolactone (GBL), pursuant to the NpSG, in a new Annex for the protection of public health. In order to curb the spread and risk of abuse, it is necessary to further develop the NpSG's existing Annex structure for other psychoactive substances because of the way they work, the extent of their abuse and the associated health risks. A second Annex is necessary to separate the previous psychoactive substance groups from the three mass chemicals in which these substances are transferred. The existing Annex, which lists substance groups of psychoactive substances, remains unchanged in terms of content and will be renamed Annex I.

9. This amendment adds nitrous oxide, GBL and BDO to Annex II of the NpSG for the protection of public and individual health and to combat their distribution for the purposes of recreational abuse. The aim of the ban is to reduce the wide availability and use of the psychoactive substances nitrous oxide, GBL and BDO for intoxication purposes, while ensuring their availability for industrial, commercial and scientific purposes.

The most common effects of using nitrous oxide for intoxication that occur during or shortly after recreational abuse are dizziness, confusion, and headache. With intensive use (even once), a vitamin B12 deficiency can develop, which can cause neurological damage and blood conditions such as megaloblastic anaemia. Excessive use can lead to paralysis symptoms. In people who suffer from a functional vitamin B12 deficiency, severe, sometimes irreversible, neurological damage can occur after single use. In recent years, the consumption of nitrous oxide for the purposes of recreational abuse has increased very strongly among adolescents, including vulnerable groups, such as young and inexperienced users. According to non-representative studies, nitrous oxide is already the substance with the highest prevalence levels among adolescents after alcohol, tobacco, e-cigarettes/tobacco heaters and cannabis.

GBL and BDO are used in a wide range of commercial and industrial applications. At the same time, however, they are also misused for the purposes of recreational abuse or to commit crimes (e.g. robbery, rape). Directly taken, GBL and BDO metabolise in the body into the substance gamma hydroxybutyrate (GHB), which is registered as a narcotic drug in Germany. Poisoning can lead to coma, bradycardia and hypothermia. With long-term use of GBL or BDO, there is a risk of addiction. As the psychoactive GHB is water and alcohol soluble and potentially leads to a lack of willpower with subsequent memory loss, GBL and BDO are also misused as knock-out drops in sexual offences (so-called 'date rape drugs') and property offences. Due to the fact that the body breaks down GHB quickly, it is difficult to prove that it has been taken or administered, particularly in a criminal context, which represents an additional risk. There are therefore hardly any reliable figures on the misuse of GBL as a recreational substance in Europe. Based on consumer reports on the internet, as well as numerous seizures and reports from addiction counselling, a large number of unreported cases can be assumed.

With their inclusion in a new Annex of the NpSG, the necessary legal bases are created in order to be able to take effective action, in particular against the manufacture and trade of nitrous oxide, GBL and BDO for abusive purposes. In principle, it is prohibited to place on the market, trade, manufacture, bring into the scope of the Act, acquire and possess nitrous oxide in larger cartridges (containing more than 8 g) and GBL and BDO in preparations with a content of more than 20 percent and as a pure substance. Due to their properties as technically non-replaceable industrial chemicals used in large quantities, recognised uses for commercial, industrial and scientific purposes are exempted from the ban. In order to protect children and adolescents, the NpSG provides for a complete ban on the supply of these psychoactive substances to minors in the case of nitrous oxide for all packaging sizes and in the case of GBL/BDO with regard to the pure substance or preparations containing 20 percent or more of the psychoactive substance, as well as a ban on their possession by minors. An exception is only provided for forms of administration in which it would be technically impossible to remove the psychoactive substances without disproportionate effort. This applies, for example, to pre-filled spray cream containers with permanently installed nitrous oxide cartridges.

10. Reference to the basic texts: The basic texts were submitted as part of an earlier notification:  
2023/0091/D

11. Yes

12. The use of nitrous oxide, GBL and BDO as recreational drugs poses an extreme threat to youth, health and society



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and therefore forms the basis for their inclusion in Annex II. Severe, irreversible damage to health cannot be ruled out. The further development of the NpSG is urgently needed due to the extent of misuse and the immediate risks to human health posed by nitrous oxide, GBL and BDO. It is aimed at protecting public and individual health, in particular the health of adolescents and combating the further distribution of the psychoactive substances nitrous oxide, GBL and BDO. Seizures by German law enforcement authorities and the increase in treatment needs due to health problems by users indicate a high market presence of these three substances. The substances are currently freely available in online shops and vending machines. There are currently no age restrictions on the purchase of these substances. The risk assessment confirms that the three psychoactive substances nitrous oxide, GBL and BDO pose a significant risk to human health and society. Recent reports show that neurologists and addiction specialists find, among others, that the risks and harms of recreational nitrous oxide abuse appear more significant than originally assumed.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

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European Commission

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