

Draft of a wording aid for the application for an amendment

No	Article	Act	Keywords	Description
X	X	(NpSG)	<ul style="list-style-type: none"> • Further development of the New Psychoactive Substances Act (NpSG) • Restriction on the release of nitrous oxide (N₂O), gamma-butyrolactone (GBL) and 1,4-butanediol (BDO) (also known as 'knock-out drops') to prevent their misuse. 	<ul style="list-style-type: none"> • Inclusion of nitrous oxide, GBL and BDO in a new Annex to the NpSG for the protection of public health against misuse of nitrous oxide for the purposes of recreational abuse, as well as of GBL and BDO for the purposes of recreational abuse or in committing criminal offences (in particular sexual offences, in which they are also known as 'knock-out drops' or 'date rape drugs') • Handling ban for nitrous oxide in relation to nitrous oxide containers with more than 8 g content and handling ban for GBL/BDO in relation to the pure substance or preparations with a content of 20 percent or more. This applies only to the extent that it does not involve handling for recognised commercial, industrial and economic purposes, taking into account their industrial use as bulk chemicals. • For the protection of children and young people in particular: For nitrous oxide, for <u>all</u> packaging sizes and, for GBL/BDO in relation to the pure substance or preparations with a content of 20 percent or more: <ul style="list-style-type: none"> • Ban on sale to, purchase by and possession by minors • Introduction of a general ban on sale to end users by means of vending machines and mail order. • Exemption: If the substances are contained in a preparation or container from which it would be technically impossible to remove the substance without disproportionate effort (e.g. pre-filled spray cream)

Draft - point X

(Subordination of three psychoactive substances (laughing gas, GBL and BDO) under the NpSG)

The following Article Xa is inserted after Article X:

**“Article Xa
Amendment of the New Psychoactive Substances Act¹**

The New Psychoactive Substances Act of 21 November 2016 (Federal Law Gazette I p. 2615), as last amended by Article 1 of the Ordinance of 21 June 2024 (Federal Law Gazette 2024 I No 210), is amended as follows:

1. § 2 Point 1 shall be worded as follows:

‘1. New psychoactive substance

- a) a substance or preparation of a substance belonging to one of the groups of substances listed in Annex I; or
- b) a substance listed in Annex II, or a preparation of such a substance, if that substance or preparation has the properties listed in column 2 of Annex II;’

2. § 3 shall be amended as follows:

a) Paragraph 1 is worded as follows:

‘(1) It is prohibited

- 1. to trade, place on the market, manufacture, transfer, acquire, possess or administer to another person a new psychoactive substance referred to in § 2(1)(a) or a new psychoactive substance referred to in § 2(1)(b), which has the characteristics set out in column 3 of Annex II,

¹*Notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).*

2. to trade in a new psychoactive substance referred to in § 2(1)(b) by mail order or self-service at vending machines, to place it on the market, to bring it into the scope of the Act or to acquire it,
3. to supply a new psychoactive substance referred to in § 2(1)(b) to persons under the age of 18 or to make it available to persons under the age of 18 for direct consumption,
4. to acquire or possess, as a person under the age of 18, a new psychoactive substance referred to in § 2(1)(b).'

b) Paragraph 2 is amended as follows:

aa) In subparagraph 1, the word 'and' at the end is replaced by a comma.

bb) In subparagraph 2, the full stop at the end is replaced by the word 'and'.

cc) The following subparagraph 3 is added:

'3. the acts referred to in points 2 to 4 of paragraph 1, if they take place in forms of administration for which it would be technically impossible to remove the respective new psychoactive substance without disproportionate effort.'

3. In the first sentence of § 6, the words '§ 7(11)' are replaced by the words '§ 20, sentence 1'.

4. In § 7, the comma and the words 'for construction and' are replaced by the words 'and for', the words 'and for consumer protection' are deleted and the words 'list of substance groups in the Annex' are replaced by the words 'list of substance groups in Annex I and the list of substances in Annex II'.

5. The Annex shall become Annex I.

6. The following Appendix II is added:

Annex II:

International Nonproprietary Names (INN) of the World	Proper- ties of the sub- stance	Charac- teristics of the new	other non-pro- prietary or common names	chemical names according to the	European Commu- nity (EC) number
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Health Organi- zation	or prepara- tion	psy- choac- tive sub- stance		nomencla- ture of the Internat- ional Union of Pure and Applied Chemistry (IUPAC)	
1,4-butanediol	Sub- stance: Pure ma- terial Prepara- tions: Any prepara- tion con- taining more than 20 per- cent	Each sub- stance	BDO, tetram- ethylene glycol, 1,4-butylene gly- col, 1,4-dihy- droxybutane, B1D, Sucol B, diol 14B, 1,4-BD	Butane-1,4- diol	203-786-5
γ-Butyrolactone	Sub- stance: Pure ma- terial Prepara- tion: Any prepara- tion con- taining more than 20 per- cent	Each sub- stance	Gamma-butyro- lactone, GBL, butyro-1,4-lac- tone, dihydrofu- ran-2-one, 1- oxa-cyclopentan- 2-one, 4-butano- lide	oxolan-2- one	202-509-5
Nitrous oxide	Sub-	Packing	Nitrous oxide,	Nitrous ox-	233-032-0,

stance:	in a con-	dinitrogen	ide
Pure ma-	tainer	monoxide, azo-	
terial	with a	oxide, E 942	
	capacity		
Prepara-	of more		
tions:	than 8 g		
Each			
prepara-			
tion			

Justification

In relation to number 1

The legal definition of a new psychoactive substance (NPS) in § 2(1) is recast.

By recasting § 2(1), this legal definition will in future include both substances and their preparations that can be assigned to one of the groups of substances listed in Annex I (point (a)) and substances and their preparations listed in Annex II (point (b)).

§ 2 Point 1(a) corresponds to the previous definition. This legal definition also includes the most synthetically produced substances, which are sometimes referred to as 'designer drugs', 'research chemicals' or 'legal highs'. Some of them are new substances that are specifically produced by drug market players to circumvent substances already covered and prohibited by law, and some are substances that have been developed by the pharmaceutical industry but which have not been further developed into active pharmaceutical ingredients due to their psychotropic side effects. They are characterised by the fact that they can be assigned to one of the groups of substances listed in Annex I.

In addition to the NPS already subject to the New Psychoactive Substances Act (NpSG), the misuse of psychoactive industrial chemicals poses an increasing risk to public health. Their misuse is associated with serious health risks that can be difficult to assess. Explosions and deflagration of containers that are not completely emptied, for example of nitrous oxide containers, also cause health risks for the employees of waste management companies. In addition, the packaging waste generated by the use of these substances can cause damage to the sorting and recycling plants used during disposal.

Due to the wide legal use, these substances, some of which are traded in large quantities, are not suitable for inclusion under the German Narcotic Drugs Act (BtMG). Such classifica-

tion would have a significant impact on traffic, in particular due to the resulting authorisation requirements and the very small-scale reporting requirements. As a result, there is a regulatory and criminal liability loophole in relation to these psychoactive industrial chemicals, which is to be closed by their inclusion in the NpSG. As the existing Annex to the NpSG does not contain any groups of substances to which the psychoactive industrial chemicals can be assigned, a second Annex (Annex II) that lists individual substances is to be added to the NpSG. In contrast to the previous Annex of the NpSG, which defines substance groups, Annex II records individual substances as a positive list in accordance with the classification of the BtMG. In view of the wide range of legal uses these psychoactive substances have, where they are traded as everyday products, use as an ingredient at certain concentrations defined in column 2 of Annex II should be excluded from the legal definition. The use of these products, such as nail polish removers containing GBL, should not be prevented or made more difficult by including the substances. The sole aim of the law is to prevent their misuse for the purposes of recreational abuse, and not to restrict their widely recognised use for other purposes. For example, products containing GBL and BDO are not covered by the legal definition of § 2(1)(b) if the concentration of the substance in the product is so low that misuse for the purposes of recreational abuse is unlikely, since the concentration of the substance in such a preparation is too low for the psychoactive effect.

Under the conditions set out in § 7, the possibility to extend Annex II by means of an ordinance to include further psychoactive substances should exist if, according to scientific knowledge, this is necessary because of how they are used as psychoactive substances, because of the extent of their incorrect use and because of the direct or indirect danger to public health. The power to issue ordinances under § 7 also includes amendments to columns 2 and 3 of Annex II.

Re subparagraph 2

By including the substances listed in Annex II, and their preparations, in the definition of NPS within the context of § 2(1) if the properties listed in Annex II, column 2, are fulfilled, the administrative ban on handling NPS, § 3(1), is extended to them. The ban opens up the possibility to seize and destroy these products, thus taking into account the special requirement to protect public health without criminalising consumers. The administrative ban is intended to limit the distribution of these substances for the purposes of recreational abuse and to limit their consumption and use for the purposes of recreational abuse as far as possible.

In accordance with the intention of the NpSG, it remains the case that the administrative ban on possession and acquisition extends beyond the criminal provisions stated in § 4. However, the broad application of the psychoactive industrial chemicals covered by Annex II makes it necessary to limit the scope of the administrative ban. To this end, the second sen-

tence orders that the administrative ban described in the first sentence only applies to the substances and their preparations listed in Annex II if one of the variants listed in the second sentence is fulfilled, i.e., if they fulfil the properties listed in column 3 of Annex II (subparagraph 1). In the case of nitrous oxide, for example, this excludes packaging sizes that are also regularly used in the private sector for purposes other than for recreational abuse purposes. For example, filling quantities with up to 8 g of content are regularly used for foaming whipped cream.

Only nitrous oxide capsules with a content of more than 8 g grams are subject to the administrative ban as it cannot be assumed that a lower quantity can be used for the purposes of recreational abuse.

In order to combat consumption for the purposes of recreational abuse, even at smaller quantities, and in particular to better protect young people from quick and anonymous access to NPS, in the interests of health and the protection of children and young people, it is planned that even NPS that do not meet the characteristics set out in column 3 of Annex II may not be traded, placed on the market or brought within the scope of the Act by mail order or for self-service at vending machines (subparagraph 2). In addition, a strict ban on sale to, purchase by and possession by, to or for persons under the age of 18 shall apply, regardless of the distribution channel (subparagraph 3).

The term 'mail order' shall also be understood so as to include online retail. In practice, this is intended to exclude widespread distribution channels, as a significant part of the trade in psychoactive substances currently takes place over the internet. In some cases, the substances are also available at self-service vending machines. Only by explicitly applying the ban described in the first sentence of paragraph 1 to these forms of distribution can the availability of these substances be restricted.

The ban on mail order and vending machines intertwines with the ban on dispensing to young people in order to reduce omnipresent availability in the interests of the protection of public health, children and young people. Young people in particular could take advantage of these distribution channels to circumvent the age restriction. The age restriction itself is particularly intended to protect this vulnerable group from the health consequences of consuming such substances. Imposing a general ban on their sale to this group is, therefore, justified.

An exception to the fundamental ban of mail order and vending machines and the ban on sale to, possession by and purchase by, to or for persons under 18 years of age shall exist for cases in which the substance is in a form of administration (container, preparation and so on) in which it would be technically impossible to remove the respective substance without

disproportionate effort. For example, nitrous oxide is used as a propellant for foaming. The nitrous oxide capsules are firmly installed in the containers and contain only a small amount of nitrous oxide. The effort required here to access the nitrous oxide (for example, by cutting the can and then removing the small amount within the capsule) would be disproportionate to the amount of the psychoactive substance obtained from it. Considering the frequent use of these products in everyday life, it would be particularly disproportionate to exclude them from mail order, for example in the context of food retail delivery services, or from use by young people. For cream spray cans, on the other hand, in which the capsules are screwed on, something different applies. Here, it is possible to remove the nitrous oxide with very little effort.

In addition, the exemptions from the ban according to paragraph 1 pursuant to § 3(2) shall remain unaffected.

Re subparagraph 3

The Federal Criminal Police Office Act (Bundeskriminalamtgesetz, BKAG) was recast by the Act to Reorganise the Federal Criminal Police Office Act of 1 June 2017 (BGBl. I p. 1354). As a result, the reference to the BKAG should be corrected.

Re subparagraph 4

The power to issue ordinances under § 7 continues the legal situation with regard to the NPS and extends it to include the possibility of amending the list of substances listed in Annex II by means of a statutory ordinance of the Federal Ministry of Health, which requires the consent of the Bundesrat, in agreement with the Federal Ministry of the Interior and Home Affairs, with the Federal Ministry of Justice and with the Federal Ministry of Finance, and after consulting experts, if this is scientifically necessary because of how they are used as psychoactive substances, because of the extent of their incorrect use and because of the direct or indirect danger to public health. At the same time, the designations of the German federal ministries are to be updated, see § 1(2) of the Responsibilities Adjustment Act.

Re subparagraph 5

The previous Annex becomes Annex I.

Re subparagraph 6

The new Annex II shall include individual substances that, due to their chemical structure, cannot be assigned to one of the substance groups in Annex I. With the current draft law, nitrous oxide (N_2O / nitrous oxide), 1,4-butanediol (BDO) and γ -butyrolactone (GBL) shall be included in the new Annex II and thus subject to the regulations of the NpSG.

The recreational consumption of nitrous oxide is increasing. The possible public health risks are many and should be taken seriously, especially for the vulnerable members of the community.

The European Drugs Agency reports in its publication 'Recreational nitrous oxide use in Europe: situation, risks, responses', available at https://www.euda.europa.eu/sites/default/files/pdf/14854_en.pdf, about an increase in recreational consumption of nitrous oxide.

If nitrous oxide is inhaled, the user experiences a short high after a few seconds, which includes mild hallucinations and feelings of warmth and happiness. In the case of intensive acute consumption, there is a risk of unconsciousness. This becomes particularly risky if users want to increase the intensity of the effect by, for example, pulling a plastic bag filled with nitrous oxide over their heads. In these cases, if the user loses consciousness, the danger of suffocation is high. With direct consumption from a gas cartridge, there is a risk of frostbite occurring where the skin comes into contact with the cartridge as it cools rapidly to -55° C, as well as of injuries to the lung tissue due to gas pressure. Long-term exposure to nitrous oxide was also found to be associated with depletion of vitamin B12 reserves, resulting in megaloblastic anaemia and spinal cord damage. The damage can also affect nerves that are responsible for controlling the muscles. Mixed use with other drugs (such as opiates or benzodiazepines) carries further risks. This means that there is a need for legal action to protect the health of the population, particularly children and young people, from incorrect consumption for the purposes of recreational abuse.

In the case of nitrous oxide, consumption for the purposes of recreational abuse usually occurs via gas-filled balloons, which are usually filled using nitrous oxide cylinders ranging from 640 g to 2 kg in capacity. These are often supplied alongside consumer accessories such as, for example, balloons and rubber hoses. Sometimes, the containers are colourfully designed and the nitrous oxide is flavoured by means of nozzles.

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 the chemical industry, nitrous oxide has no major material use. However, nitrous oxide is produced here as a by-product that is directly emitted or, for the most part, now destroyed as a greenhouse gas in exhaust gas cleaning systems. In addition, nitrous oxide for inhalation is a prescription drug and is processed accordingly by the pharmaceutical industry. As a medicinal product within the context of § 2(1), (2), (3a) and (4), first sentence, of the Medicinal Products Act, it can only be acquired on prescription and is excluded from the scope of the NpSG pursuant to § 1(2)(2).

The properties regulated in column 3 of Annex II exempt individual cartridges of no more than 8 g from the administrative ban laid down in the first sentence of § 3(1). In this respect, in particular, their supply, for example by supermarkets, remains permissible. However, the

regulation of § 3(1) sentence 2 excludes, among other things, mail order and the supply to vending machines as well as the supply to, possession by and purchase by or for persons under the age of 18, unless this is done in such a way that does not allow the respective substance to be removed without disproportionate effort. The use of larger containers by industry for recognised uses remains exempt from the ban under § 3(2)(1). With regard to public health protection, on the one hand, and the widespread use of cartridges filled with 7-8 g of nitrous oxide for whipped cream among consumers on the other, the introduction of this limit is appropriate. If bottle sizes commonly used for recreational consumption are banned, average prices per unit of consumption will rise significantly as a result, owing to the higher purchase costs of cartridges available in retail outlets. This will cause consumption to appear less attractive and reduce demand.

GBL and BDO are psychoactive industrial chemicals with broad legal uses. They are used, among other things, in industrial and manufacturing processes, as well as in many consumer products as solvents for shellac and resins, additives to drilling oils, stripping agents and textile additives, and as ingredients for acetone-free nail polish removers.

Like nitrous oxide, GBL and BDO are misused for the purposes of recreational abuse. This use for the purposes of recreational abuse includes both deliberate self-intoxication and the administration to third parties in order to take advantage of the substances' intoxicating effects (knock-out drops). The two prodrugs GBL and BDO, which themselves have little or no psychoactive effect, are converted into the psychoactive substance gamma-hydroxybutyric acid (GHB) within the human body. The substance GHB is approved in Germany for the treatment of narcolepsy. It is a dose-dependent neuromodulator with an intoxicant effect. GHB is listed in Annex III of the BtMG and can be prescribed and marketed as a medicinal product in compliance with the provisions of narcotics law. There are significant public health risks associated with the precursors BDO and GBL as a result of the risk of GHB poisoning caused by excessive consumption, which can lead to coma, bradycardia and hypothermia. Both GHB and its precursors GBL and BDO are becoming increasingly significant drugs in Germany. Their effect can be compared to that of alcohol or benzodiazepines. Chronic use of GBL or BDO also poses 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 not only for the purposes of recreational abuse, but also as knock-out drops in sexual offences (so-called 'date rape drugs') and property offences. Due to the fact that the body breaks GHB down quickly, it is difficult to prove that it has been taken or administered, particularly in a criminal context, which poses 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. In its 2024 European Drugs Report, available at <https://www.euda.europa.eu/sites/default/files/pdf/>

[31875_en.pdf?602898](#), the European Drugs Agency indicates that there were 16 emergencies related to GBL and BDO in 11 EU Member States and Norway in 2022. However, it can be assumed that this figure is not representative, as a significant number of unreported cases is to be expected, especially where sexual offences are concerned, as these are either not reported or a (forensic) connection with GBL/BDO/GHB is not established.

The inclusion of GBL and BDO in Annex II makes it possible, among other things, to prohibit placing these substances on the market, as well as their trade, manufacture and introduction into the scope of the Act, and to ensure that these substances are safe, thereby preventing their misuse for the purposes of recreational abuse or for use as knock-out drops. Both GBL and BDO are subject to the voluntary European monitoring system within the framework of commodity monitoring (voluntary cooperation between industry and trade with the competent authorities, in particular the Joint Commodity Monitoring Centre of the Customs Investigation Bureau and the Federal Criminal Police Office at the Federal Criminal Police Office). This monitoring system shows good results with regard to the control of the production and traffic of such substances in Germany, due to the regular and reliable cooperation with the companies involved in the chemical industry and trade in chemicals in Germany. In this respect, there are measures to counteract misuse for the purposes of recreational abuse, which are also used. Nevertheless, when it comes to GBL or BDO misuse where the intention is for the purposes of recreational abuse from the outset, the limits of this cooperative European monitoring system are reached.

The ban in § 3(1) sentence 1 includes the pure substance and preparations with a content of BDO or GBL of more than 20 percent. As a result of the introduction of this limit, the various recognised uses according to the current state of science and technology, for example in nail polish removers and façade cleaners, as products that can be passed on to consumers remain excluded from the scope of the NpSG. On the other hand, the levy as an alleged cleaning agent with BDO or GBL with a high percentage of the respective substance is subject to the administrative ban in the future and is punishable under the conditions of § 4.

Financial impact

No significant impact on the German federal budget is expected. As the three chemicals are highly available domestically, there is no risk of increased customs seizures of illegal imports. The necessary customs control measures are also required without the legal change, as otherwise incoming persons would also have to be inspected for other prohibited substances or objects.

Criminal proceedings, the number of which may increase, are the individual responsibility of each German federal state.