

# Impact assessment

## Background

In December 2022, the EMCDDA (to be known as EUDA from July 2024) published the report: “Recreational use of nitrous oxide: a growing concern for Europe.” The report showed that there had been an increase in recreational use of nitrous oxide in European countries since 2010, with a particular rise from around 2017. This increase was linked to greater availability and sales of large nitrous oxide containers. Nitrous oxide is relatively inexpensive, easy to purchase, and easy to use. According to the report, users who consume nitrous oxide for intoxication purposes may also perceive it as a safe drug. Several specialized, often online-based, outlets for nitrous oxide have emerged, and social media plays a major role in advertising and as a sales channel. As the number of users has increased, so has the number of intoxications. Around the same time the EMCDDA published its report, several Norwegian media outlets reported on increased use of nitrous oxide as an intoxicant among young people, particularly in the Oslo area.

To gain an overview of the extent of use and potential harmful effects, the Ministry of Health and Care Services assigned the following task to the Norwegian Institute of Public Health (NIPH):

NIPH is to describe the available information on the extent of nitrous oxide use in Norway today. If sufficient information is not available, NIPH is to propose a plan for mapping and summarizing the extent of nitrous oxide use in Norway. NIPH is to summarize the knowledge on potential health harms (both psychological and physical) that use may cause and estimate the actual extent of health damage resulting from use in Norway as of today. NIPH is also to summarize, with particular attention to the Nordic and European countries, the knowledge on the extent of use and harm in other countries, regulations that have been implemented, and any effects of these regulations or other measures in other countries, if such evaluations exist. The deadline for the assignment was April 1, 2023.

According to the Norwegian Institute of Public Health (NIPH), there is currently little systematic information available on the extent of nitrous oxide use in Norway. The Norwegian Customs Service reports a sharp increase in nitrous oxide imports over the past two years, linking this to growing recreational use among young people. The National Criminal Investigation Service (Kripos) reports a similar trend, particularly associated with the Oslo area.

The drug information service Rusinfo reports very few inquiries about nitrous oxide. Between 2017 and 2021, fewer than 10 inquiries were registered annually, while in 2022, there were 13 inquiries (0.2% of all inquiries). Figures from the Norwegian Poison Information Centre are also low. From 2014 to 2021, there were 1–7 inquiries per year related to self-inflicted nitrous oxide exposure, but in 2022, this number rose to 39. Overall, few acute injuries related to nitrous oxide use are reported in Norway however, there seems to be an increase in injuries related to the use of nitrous oxide.

The EMCDDA notes that social media is used to promote and sell nitrous oxide. In some cases, vendors have shifted from physical stores to social media platforms due to the introduction of sales restrictions. Sharing within peer groups has also been highlighted as an important method of distribution.

There are several websites targeting Norwegian customers, with content in Norwegian, offering delivery to Norway and providing information about the legal framework for purchasing and

possessing nitrous oxide in the country. Some vendors warn against using nitrous oxide for recreational purposes and provide information about potential health risks associated with such use. Norwegian waste management agencies report an increased number of empty nitrous oxide canisters being discarded.

## **Potential psychological and physical health harms from recreational use of Nitrous Oxide**

### *Acute Physical Health Injuries*

Nitrous oxide becomes extremely cold when transitioning from liquid to gas form (around -40 to -50°C). If the gas is inhaled directly from the container, it can cause frostbite to the face and airways. Within seconds, users can suffer frostbite to the nose, lips, vocal cords, and the mucous membranes of the mouth and lungs—without necessarily feeling pain. The gas pressure can also cause acute lung injury, a condition that requires emergency medical treatment.

### *Effects and Side Effects of Recreational Nitrous Oxide Use*

The intoxicating effects of nitrous oxide occur quickly after inhalation and last for about 1–5 minutes. Users may experience elevated mood, uncontrollable laughter, numbness, sensory distortions, a dreamlike state, and impaired judgment (altered consciousness and dissociation) (EMCDDA, 2022). When combined with other substances, the high may be intensified, judgment further impaired, and the risk of injury increased.

According to the NIPH report, nitrous oxide displaces oxygen from the blood, brain, and body. Air typically contains about 21% oxygen. After inhaling pure nitrous oxide, the lungs are left without oxygen. As a result, the blood pumped to the brain lacks oxygen. Oxygen is then "drawn" from brain cells into the blood, rather than being delivered from the blood to the brain. This causes the brain to be slightly "suffocated" with each inhalation of pure nitrous oxide. Large, repeated, or frequent use increases the risk, as the brain, nervous system, and heart are highly vulnerable to oxygen deprivation. The danger is also greater when inhaling directly from a gas cylinder, using a mask or a plastic bag over the head, or in a small, enclosed space (e.g., a car).

Common side effects after small doses of nitrous oxide include hallucinations, dizziness, confusion, headache, tingling sensations, and nausea/vomiting. Some of these effects are due to oxygen deprivation. These symptoms usually subside shortly after use ends, but dizziness and impaired coordination may persist for up to 30 minutes. Fatigue and restlessness may last up to an hour after use. Nitrous oxide use is associated with an increased risk of falls and accidents. It also intensifies flames and combustion processes, so users should not smoke while using it. Due to general impairment and disorientation, individuals should not drive, cycle, operate machinery, or engage in other demanding activities until the effects have completely worn off. In recent years, there has been a significant increase in nitrous oxide involvement among apprehended drivers in the Netherlands (EMCDDA, 2022).

### *Long term use*

Frequent and repeated use of nitrous oxide causes many small episodes of oxygen deprivation, which can cumulatively lead to brain and heart damage. This may manifest as problems with concentration, memory, learning, indecisiveness, as well as blood clots and heart disease (EMCDDA, 2022). With prolonged and excessive use over several months, serious and long-lasting organ damage may occur,

such as bone marrow damage with reduced blood cell production, and nerve damage (neuropathy). A deficiency in vitamin B12 is considered the main cause of such injuries. Symptoms of nerve damage may include muscle weakness and numbness or tingling in the legs. It is not known exactly how long it takes for neurological damage from nitrous oxide to develop. Some individuals appear to be more vulnerable than others. Prompt treatment is important to avoid long-term and, in the worst case, permanent damage.

There is very limited knowledge about the psychological, psychiatric, and cognitive long-term effects of nitrous oxide use. The most commonly reported symptoms are psychotic symptoms such as delusions, hallucinations, bizarre behavior, and mania. There have also been reports of anxiety attacks, depression, and personality changes. The same applies to impaired cognitive function. It remains unclear whether nitrous oxide can cause addiction in the traditional sense.

## **Content of the draft regulation**

### *Regulation of Nitrous Oxide*

The Ministry has assessed whether the challenges related to increased use of nitrous oxide for recreational purposes should be addressed through regulation or whether other preventive measures should be used instead. In this assessment, the Ministry has considered that the evaluation of the UK ban showed that the prohibition did not appear to have had any impact on the prevalence of the substance, and that introducing a ban may lead to unintended market changes, including increased involvement of organized criminal groups, theft from legal supply chains, and homemade or unregulated production. Furthermore, the Ministry refers to concerns expressed by the EMCDDA (EUDA) regarding substitution with more harmful substances found in products such as deodorants, spray paint, or other legal intoxicating substances.

In the Ministry's view, harm reduction and other preventive measures, such as targeted information campaigns, can also be important and effective tools to reduce the harmful effects and use of nitrous oxide as an intoxicant. Nevertheless, the Ministry believes that the sale of nitrous oxide should be regulated, as this could reduce both the availability and demand for nitrous oxide used for recreational purposes and thereby reduce associated harms and problems. There is a need to clarify that nitrous oxide should not be sold for recreational use through a ban on such sales. According to the Ministry, a clear age limit and restrictions on the quantity that can be sold to and imported by private individuals are also measures that can make the products less accessible, which may help limit the harmful effects of nitrous oxide. Regulation also sends an important signal that nitrous oxide is not a harmless product and that its consumption can cause health damage. In the Ministry's assessment, there is a high risk that nitrous oxide products sold to consumers will be used for recreational purposes, and that it is therefore "necessary," pursuant to Section 4 of the Product Control Act, to establish requirements in regulations that, among other things, limit the sale of nitrous oxide to consumers.

However, the Ministry does not believe that private individuals' use and possession of nitrous oxide should be regulated at this time. Based on current knowledge about the health and social harms associated with nitrous oxide use, the Ministry considers that it would not be proportionate to introduce a ban on use and possession for private individuals.

The Ministry has also considered whether a licensing scheme for the sale of nitrous oxide should be introduced. This is not proposed at this time, but the Ministry will consider whether such a scheme should be introduced in the future.

The Ministry believes that the introduction of regulation on the sale of nitrous oxide must be evaluated to determine its impact on various types of sales, usage, associated health harms, and any need for adjustments to the regulatory framework.

#### *Prohibition on the Sale of Nitrous Oxide for Recreational Use*

Section 3 of the Product Control Act establishes a duty of care, requiring that anyone who sells a product that may pose a health risk must exercise caution and take reasonable measures to prevent and limit such harm. Because inhalation of nitrous oxide can cause serious health effects such as frostbite, and damage to the lungs, brain, and heart, selling nitrous oxide for recreational use would be in violation of this duty of care.

The duty of care is a general standard, and in this case, there is a need for a clear legal norm that defines lawful behavior and enables the imposition of sanctions in the event of violations. The Ministry therefore believes that a clear prohibition on the sale of nitrous oxide for recreational use should be included in the regulation specifically governing nitrous oxide (see proposed Section 4). Such a prohibition would serve as a clear foundation for the more detailed provisions and make it explicit that nitrous oxide may only be sold for legitimate purposes such as food production and medical use.

#### *Prohibition on the Sale of Nitrous Oxide to Persons below a specified age limit*

It is further proposed to introduce a ban on the sale of nitrous oxide to persons under the age of 18, regardless of intended use (see draft Regulations Section 5). The Ministry sees no reason why children should be able to purchase nitrous oxide cartridges. It is noted that the use of nitrous oxide in cooking primarily occurs in industrial settings, and there is therefore generally little need for children and adolescents to purchase the substance. In cases where nitrous oxide is used for cooking in private homes, the potential health risks mean that, in the Ministry's view, it is not disproportionate to require that the purchaser has reached the minimum age.

The Ministry considers that the age limit should be at least 18 years (see draft Regulations Section 5). An age limit of 20 years could potentially be more effective in preventing the use of nitrous oxide for recreational purposes, for example during graduation celebrations or university orientation weeks. However, since there are legitimate areas of use for nitrous oxide, such as cooking, it would be unnecessarily intrusive to prohibit sales to individuals between the ages of 18 and 20.

#### *Quantity limitation for the sale of nitrous oxide products to consumers*

The Ministry further proposes to introduce a quantity limitation on the sale of nitrous oxide to consumers over the age of 18, see draft Regulations Section 6. The purpose of this limitation is to prevent private individuals from gaining access to large amounts of nitrous oxide that could be used for intoxication.

The proposal entails a ban on selling more than 17 grams of nitrous oxide to each individual consumer per day. A limitation of 17 grams corresponds to the quantity restriction under Danish legislation. The Ministry considers it appropriate to introduce a quantity limitation at the same level as in Denmark.

The limitation is justified by the fact that nitrous oxide cartridges of various sizes are available on the market, and the amount of nitrous oxide per container varies between manufacturers. For example, small cartridges may contain between 8 and 8.5 grams of nitrous oxide. A 17-gram limit would therefore correspond to two such cartridges. The Ministry considers it irrelevant whether the permitted amount of 17 grams is sold in one or several containers.

Although inhaling the contents of a single 8-gram nitrous oxide cartridge may cause health damage, the Ministry still believes that consumers must be able to purchase nitrous oxide for legitimate purposes such as cooking. This also relates to the assessment of whether the limitation can be considered a necessary and proportionate intervention in the freedom to offer goods under the EEA Agreement.

The Ministry recognizes that the use of nitrous oxide in motorsports is a legitimate purpose for purchasing nitrous oxide. Therefore, the Ministry believes that an exception to the quantity limitation should be included in the regulation for cases where licensed motorsport participants are purchasing nitrous oxide for use in motorsport. An exception to the age requirement of 18 years is not considered necessary, but it must be documented that the nitrous oxide is intended for licensed motorsport use. The proposal includes only an exception to the quantity limitation for sales. No exception is proposed for the regulation of importation.

The Ministry has assessed how a quantity limitation on the sale of nitrous oxide can be complied with by businesses. Among other things, it has considered whether it would be appropriate to introduce a registry system to monitor consumers' purchases of nitrous oxide. The Ministry has concluded that it is neither necessary nor appropriate to introduce such a registry.

The proposed regulation assumes that businesses maintain control over their own sales outlets. This means that if a business is aware that a consumer has purchased nitrous oxide from others on the same day, this information must be taken into account when considering whether to sell nitrous oxide to the same consumer. However, the proposal does not impose a duty to investigate on the business, and a registry system would therefore go beyond what is necessary.

#### *Requirement for the supplier to ensure compliance with the sales restrictions*

To ensure that the proposed restrictions on the sale of nitrous oxide are effective, it is proposed to establish specific requirements for suppliers to monitor compliance, see draft Regulations Section 7.

Firstly, it is proposed that suppliers of nitrous oxide should be required to verify that individuals attempting to purchase the substance meet the age requirement, see draft Regulations Section 7, first paragraph. For in-person sales, age verification can be done by requiring approved identification, such as a driver's license or passport. For online sales, age must be verified by other means, such as Bank ID or similar. The Ministry considers that the business itself is best positioned to determine the method of age verification, as long as it effectively ensures that the customer meets the age

requirement. A self-declaration solution, where the consumer confirms their age by ticking a box in a pop-up window or similar, will not be considered sufficient, as such a solution can easily be bypassed.

Regarding compliance with the quantity limitation, it is proposed that suppliers selling nitrous oxide above the permitted limit must verify that the buyer is a business entity registered with a valid organization number in the Central Coordinating Register for Legal Entities, see draft Regulations Section 7, second paragraph. This register contains basic information about businesses, including a nine-digit organization number for each registered entity. The organization number can be used by a business to document that it is a commercial entity and not a consumer. The information in the register (except for personal ID numbers) is publicly available to anyone seeking information about a business, pursuant to Section 22, second paragraph of the Register Act. The register provides data in various formats, including real-time open data.

To verify that the buyer is a registered business, the supplier must conduct the verification in a way that confirms the person wishing to purchase nitrous oxide is the same as the entity associated with the provided organization number. This means that the organization number must be checked against the buyer's identity. The purpose of this verification is to prevent the use of fictitious or incorrect organization numbers. The required documentation may vary depending on the circumstances, and it is up to the supplier to determine the appropriate method.

However, the obligation to verify that the buyer matches a registered organization number does not guarantee that nitrous oxide will not be sold for recreational use, in violation of the draft Regulation Section 4. Therefore, the supplier must also verify that the purpose of the purchase is not for intoxication or resale for such use, see draft Regulations Section 7, second paragraph. For example, if the organization number belongs to a company whose registered activity has no connection to legitimate nitrous oxide use (such as food production or kitchen equipment sales), the supplier cannot confirm that the purchase is legitimate. In such cases, the registered information about the company's activity and stated purpose in the register will be helpful. If this information does not indicate that the company uses or sells nitrous oxide for legitimate purposes (e.g., if the registered activity is "furniture delivery and installation" or "agriculture"), it is unlikely that the purchase is legitimate. The buyer must then provide other documentation to prove that the purchase has a legitimate purpose.

### *Import restrictions*

In order to effectively prevent private persons from buying nitrous oxide for intoxication purposes the Ministry proposes a ban on private importation of nitrous oxide. A ban on private individuals importing nitrous oxide is considered a prerequisite for achieving the regulation's objective. The 2024 ESPAD survey shows that young people largely gain access to nitrous oxide through foreign online stores. The Norwegian Customs Authority has clearly stated that it would be extremely challenging to monitor shipments of up to 17 grams of nitrous oxide per day to private individuals. If private individuals are able to circumvent the ban, it could undermine the purpose of the regulation – to reduce health damage resulting from the use of nitrous oxide for intoxication. Therefore, banning this type of import is considered a necessary measure. Importation for commercial purposes is not intended to be covered by the ban. Foreign actors will still be able to supply nitrous oxide to businesses with legitimate purposes for use. They will also be able to supply retailers in Norway. Thus, foreign actors retain access to the Norwegian market for selling their products.

### *Supervision and control*

The Ministry of Health and Care Services proposes granting the Norwegian Directorate of Health the authority to supervise compliance with the provisions of the regulation.

Although the proposed regulation will govern consumer purchases of nitrous oxide, the primary purpose of the regulation is not consumer protection. Nor is it primarily concerned with environmental or climate impacts, such as waste or emissions of nitrogen dioxide. While these are important issues to address, the main justification for the proposal is the health risks associated with nitrous oxide use.

This objective aligns with the Directorate of Health's mission to improve the health of the entire population through comprehensive and targeted efforts across services, sectors, and levels of government. The Directorate already has supervisory responsibilities related to other potentially harmful substances, including in the areas of alcohol and tobacco. For example, it is responsible for ensuring compliance with rules on private importation of alcohol and the regulations on the content, labeling, and design of tobacco products. In the Ministry's view, there is a thematic connection between the sale of nitrous oxide for intoxication purposes and the regulation of alcohol and tobacco, making the Directorate of Health a suitable supervisory authority for nitrous oxide as well.

### *Supervisory Authorities' Control*

According to Section 8, second paragraph of the Product Control Act, the supervisory authority shall have free access to buildings, vehicles, warehouses, facilities, areas, etc., where products that may have effects as mentioned in Section 1 are located, or where consumer services that may cause health damage are offered.

The Ministry refers to the comments on the individual provisions in Ot.prp. No. 51 (1974–1975), where it is stated in relation to Section 8 that: "Implementation of the law necessitates effective control and therefore also free access for the supervisory authorities to the products."

In other words, supervisory authorities must have unrestricted access to areas where the relevant products are located. For retailers of nitrous oxide, this means that the supervisory authority must have access to the premises where the nitrous oxide is stored.

Online sales are not directly regulated by the law, but the wording in Section 8, second paragraph, regarding free access to areas where the product is offered, is interpreted by the Ministry to also include the ability of the supervisory authority to inspect online stores.

The Norwegian Directorate of Health shall supervise compliance with the requirements set out in the draft Regulations. This includes verifying whether nitrous oxide is being sold for intoxication purposes, whether adequate age verification is being conducted, whether quantities sold exceed the permitted limit, and whether sellers verify that business buyers are registered in the Central Coordinating Register and operate in a field related to legitimate use of nitrous oxide.

### *Reactions to Violations of the Provisions*

#### *Orders for Correction or Closure*

It is proposed in Section 10 of the draft Regulations that the Norwegian Directorate of Health may issue decisions requiring the correction of unlawful conditions or the closure of illegal operations in the event of violations of the draft Regulations Sections 4 to 7 (the prohibition against offering nitrous oxide for intoxication purposes, the prohibition against offering nitrous oxide to persons under 18, the

prohibition against offering nitrous oxide in violation of the quantity limitation, or breaches of the requirement to ensure compliance with these provisions).

Orders for correction or cessation are administrative measures imposed by public authorities in response to legal violations. These measures are not considered administrative sanctions or penalties under the European Convention on Human Rights (ECHR). The order is directed at the person or entity most responsible for the operation, which may be a private individual or a business.

Determining who is responsible must be assessed on a case-by-case basis.

Failure to comply with the Directorate's order for correction or cessation may, in certain cases, trigger other administrative reactions, such as coercive fines.

### *Coercive Fine*

According to Section 13 of the Product Control Act, the King may impose a coercive fine in the event of a violation of conditions, orders, or prohibitions issued under the authority of the Act. This also includes violations of regulations issued pursuant to Section 4.

Since coercive fines can already be imposed for breaches of the draft Regulations, there is, in principle, no need for a separate provision on coercive fines in this proposal. However, the Ministry finds it appropriate that the authority to impose such fines be assigned to the Norwegian Directorate of Health, which is the supervisory authority under the regulation, rather than to the King, who currently holds this authority under the Product Control Act.

On this basis, it is proposed that the Directorate of Health should be authorized to impose coercive fines in accordance with the rules in Section 13 of the Product Control Act to ensure compliance with the provisions of this regulation, see draft Regulations Section 11.

For example, it may be relevant to issue a decision on a coercive fine to ensure compliance with an order under draft Regulations Section 10 (order to correct unlawful conditions or cease illegal operations).

### *Administrative Fines*

The Ministry considers that administrative fines should also be applicable for violations of the proposed provisions. It is noted that an administrative fine is a response to a legal violation that has already occurred. The obligation to pay does not lapse even if the violation is corrected or ceased. An administrative fine is considered a sanction under the European Convention on Human Rights (ECHR). Therefore, the specific procedural rules and legal safeguards established by the ECHR must be respected when issuing such fines.

Section 12a of the Product Control Act states that the King may issue regulations on the imposition of administrative fines for violations of regulations under Section 4. Based on this, it is proposed that administrative fines may be imposed on anyone who intentionally or negligently violates the proposed provisions in the draft Regulations, including:

- The prohibition against selling nitrous oxide for intoxication purposes (Section 4)
- The prohibition against selling nitrous oxide to persons under 18 (Section 5)
- Quantity restrictions for sale and import (Sections 6 and 8)
- The requirement to ensure compliance with sales restrictions (Section 7)

Section 44 of the Public Administration Act provides that administrative fines may be imposed either as fixed rates or assessed individually within an upper limit set by law or regulation. The Ministry proposes the following maximum limits:

- For businesses: up to 15 times the National Insurance base amount (folketrygdens grunnbeløp)
- For individuals: not to exceed 2 times the base amount



These amounts represent the maximum ceiling for fines. The actual fine within this ceiling must be determined based on specific factors. The Ministry refers to Section 6b-2 of the Product Regulation and Sections 44(3) and 46 of the Public Administration Act. Based on this, the Directorate of Health may consider the following factors when determining the fine amount:

- The preventive effect of the fine
- The severity and duration of the violation
- The degree of fault of the violator
- The violator's financial capacity
- Benefits gained or potentially gained from the violation
- Any previous violations of the regulation

### **The Proposal's Compatibility with EEA Law**

Nitrous oxide containers, like most other products, are subject to the fundamental rules of the EEA Agreement on the free movement of goods, cf. Article 11 of the EEA Agreement. However, restrictions on these rights may be imposed based on specific legal and court-developed principles. First, it must be demonstrated that the trade restrictions being introduced pursue legitimate objectives. Furthermore, the restrictions must be suitable and necessary to achieve the goals of the regulation.

The Ministry considers it clear that the proposed measures pursue a legitimate objective. In this case, the objective is the protection of human life and health. This is a legally recognized justification for trade restrictions under Article 13 of the EEA Agreement. The main part of the above-mentioned proposals will hereinafter be assessed in accordance with this regulatory framework.

The proposal to prohibit the sale of products containing nitrous oxide to persons under the age of 18, however, should in the Ministry's view be assessed under a different set of rules established in case-law. The Ministry will first assess this proposal and then assess the remaining proposals in accordance with Article 11 of the EEA Agreement, cf. Article 13.

#### ***Prohibition on the sale of nitrous oxide to persons under 18***

Article 11 of the EEA Agreement prohibits quantitative import restrictions and measures having equivalent effect, unless these are justified by legitimate considerations in accordance with Article 13 – including the protection of public health. In the Ministry's view, the proposal to introduce a prohibition on the sale of products containing nitrous oxide to persons under the age of 18 does not, however, constitute a barrier to trade under Article 11 of the EEA Agreement. An age limit for the sale of products containing nitrous oxide, as is the case for *inter alia* alcoholic beverages and energy drinks, constitutes a so-called selling arrangement, in line with the EFTA Court's judgment in Case E-9/00 (*EFTA Surveillance Authority v Norway* – the “*Rusbrus*” case). Measures constituting selling arrangements are not regarded as measures having equivalent effect to quantitative import restrictions where they apply to all traders operating within the national territory and affect the marketing of domestic and imported products in the same manner, in law and in fact, cf. the so-called *Keck* doctrine.<sup>1</sup>

The Ministry's proposal is consistent with this doctrine, as the proposed 18-year age limit for the sale of products containing nitrous oxide will cover all products containing nitrous oxide available on the

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<sup>1</sup> Joined Cases C-267/91 and C-268/91, Criminal proceedings against Bernard Keck and Daniel Mithouard

market, will apply to all traders, and will affect the marketing of domestic and imported products in the same manner.

#### *Assessment under Article 11 in conjunction with Article 13 of the EEA Agreement*

The Ministry considers that the proposal to prohibit the sale of products containing nitrous oxide for the purpose of intoxication, the proposal containing quantity restrictions on sales of nitrous oxide to consumers and the proposal to prohibit consumers from importing products containing nitrous oxide into Norway, all constitute restrictions under Article 11 of the EEA Agreement. The question is whether the restrictions may nevertheless be justified under Article 13.

Norway has chosen a particularly high level of protection for public health. According to established case-law, it is for the Member States to determine the level of protection for public health and the means by which that protection is to be achieved. This implies that the Member States enjoy a certain margin of discretion. However, this margin must be exercised within the limits of the principle of proportionality. The assessment of proportionality consists of two main elements: suitability and necessity.

The requirement of *suitability* implies that it must be “reasonable to assume that the measure would be able to contribute to the protection of human health”, cf. Case E-16/10 *Philip Morris*, para. 83. This applies even in the presence of some scientific uncertainty regarding the suitability and necessity of the measure. Furthermore, the measure must in fact pursue the objective of protecting public health in a consistent and systematic manner. This means that “...the national legislation as a whole and the various relevant rules are appropriate for ensuring attainment of the objective relied upon only if they genuinely reflect a concern to attain that objective in a consistent and systematic manner...”, as required under the case-law of the Court of Justice, cf. Case C-539/11 *Ottica New Line*, para. 47.

The Ministry considers the proposed measures suitable for protecting human life and health corresponding to the level of health protection chosen by Norway. By prohibiting the sale of products containing nitrous oxide for the purpose of intoxication, introducing quantity restrictions on sales of nitrous oxide to consumers and by prohibiting consumers from importing products containing nitrous oxide into Norway, the availability of products with nitrous oxide to consumers will be reduced, thereby reducing the potential for harmful use, intoxication and the risk of health damage. The proposed measures also send a strong signal that inhaling nitrous oxide is highly dangerous, which in itself may have a preventive effect and reduce harmful use. Therefore, the Ministry considers that the measures are suitable for achieving the objective of protecting public health.

The next question is whether the proposed prohibition is *necessary* in order to achieve the objective of protecting public health at the particularly high level of protection chosen by Norway. More specifically, whether the measure is necessary to counteract the use of nitrous oxide as intoxicant and thereby reduce the health risks and protect public health particularly among children and adolescents. The necessity test requires an assessment of whether the measure goes beyond what is necessary to attain the legitimate objectives pursued, or if it could be attained by an alternative measure that is equally useful but less restrictive to the fundamental freedoms guaranteed by the EEA Agreement, cf. case E-2/24 *Bygg og Industri AS*, para. 132.

The EFTA Court has ruled that the requirement of necessity entails an assessment of whether the chosen measure is "... functionally needed in order to achieve the legitimate objectives of the legislation at the level of protection chosen by the Contracting Party ...".<sup>2</sup> Thus, there cannot exist other, less trade restrictive measures having the effect of fully achieving the objectives at the level of protection chosen.

Nitrous oxide is not inherently a dangerous product when used as intended, whether for cooking or medical purposes. A total ban on the sale of nitrous oxide would therefore constitute an unnecessary and disproportionate trade restriction not covered by the exceptions in Article 13 of the EEA Agreement. However, the use of nitrous oxide can lead to serious health damage, cf. above. To prevent such harm, the Ministry considers it necessary to restrict its sale. The proposed restrictions are specifically aimed at preventing harmful use and do not prevent nitrous oxide from being sold to commercial actors or to consumers over 18 within a defined quantity limit.

With regard to the proposal to prohibit consumers from importing products containing nitrous oxide into Norway, a ban on private individuals importing these products is considered a prerequisite for achieving the regulation's objective. The 2024 ESPAD survey shows that young people largely gain access to nitrous oxide through foreign online stores. The Norwegian Customs Authority has clearly stated that it would be extremely challenging to monitor shipments of up to 17 grams of nitrous oxide per day to private individuals. If private individuals are able to circumvent the ban, it could undermine the purpose of the regulation – to reduce health damage resulting from the use of nitrous oxide for intoxication. Therefore, banning this type of import is considered a necessary measure. With a total ban on importation by private individuals, the Customs Authority would be able to carry out more effective controls and contribute to a real reduction in illegal imports of nitrous oxide.

The Ministry cannot see that there are any alternative, less restrictive measures that would contribute as effectively to the objective of protecting children and young people at the particularly high level of protection that Norway has chosen as the above-mentioned measures. Thus, the Ministry considers that prohibiting the sale of products containing nitrous oxide for the purpose of intoxication, introducing quantity restrictions on sales of nitrous oxide to consumers and prohibiting consumers from importing products containing nitrous oxide into Norway all constitute necessary measures in order to achieve the objective of protecting public health. More specifically, the Ministry assesses that these measures are necessary to counteract the use of nitrous oxide as intoxicant and thereby reduce the health risks and protect public health particularly among children and adolescents.

According to the Ministry's assessment, the ban should not be considered arbitrary discrimination or a disguised restriction on trade. Importation for commercial purposes is not covered by the ban. Foreign actors will still be able to supply nitrous oxide to businesses with legitimate purposes for use. They will also be able to supply retailers in Norway. Thus, foreign actors retain access to the Norwegian market for selling their products.

In summary, the Ministry finds that the proposals are based on legitimate objectives and meet the requirements of suitability and necessity. Thus, the Ministry concludes that the measures are compatible with the rules on the free movement of goods, cf. Article 11, cf. Article 13 of the EEA Agreement.

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<sup>2</sup> Case E-3/06 *Ladbroke's*, para. 58.

