

Decision

§ 43 1 Annex

2025-02-20 S2025/00326 (in part)

Ministry of Health and Social Affairs

Kommerskollegium (National Board of Trade) PO Box 6803 113 86 Stockholm

## Impact assessment

Several of the provisions on nitrous oxide may constitute measures having an effect equivalent to a quantitative restriction on imports. They may therefore constitute barriers to trade within the meaning of Article 34 of the Treaty on the Functioning of the European Union (TFEU) and obstacles to the freedom to provide services within the meaning of Article 56 TFEU, respectively. These include the proposals on notification requirements for retail sales, age requirements, quantity limits for sales to private individuals, the ban on the sale of nitrous oxide as an intoxicant, and the possibility of charging fees for notification and supervision.

Nitrous oxide is a substance that can cause serious health risks and death. The use of nitrous oxide as an intoxicant has increased significantly in recent years. The measures proposed can therefore be justified on grounds of the protection of human health or life.

The measures proposed for nitrous oxide will apply to both Swedish and foreign operators, regardless of whether sales are conducted in a physical store or on the internet. Although the measures target activities on Swedish territory – points of sale in Sweden and imports into Sweden – they apply equally regardless of who carries out the activities. The measures are therefore not discriminatory.

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The notification obligation is necessary in order to be able to exercise supervision over the sale of nitrous oxide. A notification requirement is less restrictive than other options, such as a permit requirement. The age requirement is necessary to prevent children and young people from using nitrous oxide as an intoxicant. The ban on the sale of nitrous oxide as an intoxicant and the quantity restriction are necessary to protect public health, in particular the health of children and young people.

The regulation is designed to achieve the purpose of the law. The measures are less restrictive than other alternatives, such as a total ban on the sale of nitrous oxide. Nitrous oxide for e.g. cooking will continue to be allowed to be sold in retail to private individuals, with certain quantity limits. Sales of nitrous oxide to traders are not subject to the quantity restriction. The quantity limit and age requirement also apply to imports. The rules on imports coordinate the requirements for sales and imports, which is necessary in order to achieve the purpose of the restrictions. The proposal on supervisory fees is needed to ensure effective supervision and compliance. Since the starting point is that the fees should reflect the authority's actual costs of supervision, they do not go beyond what is necessary.

In summary, the measures are not deemed to go beyond what is necessary to achieve the objective of protecting public health. The regulation aims to protect consumers, especially children and young people, from the health risks of nitrous oxide, without imposing unnecessarily extensive bans or restrictions. The objective cannot be achieved by any other less intrusive means, by less extensive restrictions or by restrictions which have a lesser impact on intra-EU trade. The provisions must therefore be deemed as proportionate. The consequences that the regulation may have for those who sell or use nitrous oxide as an intoxicant must therefore be accepted. For those who sell or use nitrous oxide for other purposes, the law is not expected to have any major consequences, and this market is relatively small.

In view of the above, the measures are acceptable in accordance with Articles 34, 36 and 56 TFEU.