

Message 001

Communication from the Commission - TRIS/(2026) 1323

Directive (EU) 2015/1535

Notification: 2026/0241/MT

Notification of a draft text from a Member State

Notification – Notification – 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 - Nezahajuje prodlení - Fristerne indledes ikke - Καμμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késésekét - Non fa decorrere la mora - Atidėjimai 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: 20261323.EN

1. MSG 001 IND 2026 0241 MT EN 13-05-2026 MT NOTIF

2. Malta

3A. Department for Health Regulation

3B. Department for Health Regulation

4. 2026/0241/MT - S70E - Hazardous substances and preparations

5. Restriction on the Recreational Use of Dinitrogen Oxide Regulations, 2026

6. The regulations aim to protect public health by restricting access to dinitrogen oxide for non-legitimate purposes, while safeguarding its continued availability for legitimate industrial, medical, pharmaceutical, catering and other lawful uses.

7.

8. The regulations establish a comprehensive legal framework under the Public Health Act to prohibit the

recreational use of nitrous oxide in response to growing public health concerns, while safeguarding its legitimate use in sectors such as healthcare, industry, and catering. They introduce controls across the entire supply chain—including importation, sale, possession, and advertising—by banning recreational use outright, restricting consumer access to products not intended for inhalation, and limiting advertising accordingly. Enforcement is strengthened through delegated powers to the Executive Police and a reversal of the burden of proof in legal proceedings, ensuring accountability. Overall, the framework balances strict public health protection with the continued availability of nitrous oxide for legitimate purposes.

9. The misuse of dinitrogen oxide (commonly known as 'nitrous oxide' or 'laughing gas') for recreational inhalation has emerged as a growing public health concern both internationally and locally. Recreational use is associated with acute and chronic health risks, including neurological damage, hypoxia, accidents and fatalities. The products are often marketed in ways that disguise their intended recreational use, particularly through the sale of canisters and associated paraphernalia.

The regulations aim to protect public health by restricting access to dinitrogen oxide for non-legitimate purposes, while safeguarding its continued availability for legitimate industrial, medical, pharmaceutical, catering and other lawful uses.

In preparing the regulations, consideration was given to enforcement practicability, proportionality, consumer protection, and the avoidance of unnecessary regulatory burdens on compliant businesses, particularly SMEs operating lawfully.

9a. Risk for the legitimate public interest objective

Malta is addressing a serious and immediate public health risk arising from the widespread recreational use of dinitrogen oxide (nitrous oxide), particularly among young persons. Evidence at national level shows increasing misuse, facilitated by its perceived low risk and the absence of effective regulatory controls. Recreational inhalation is associated with significant health harms, including neurological damage and loss of consciousness.

The risk is heightened in Malta due to:

- Early tourism season, attracting large numbers of youths;
- Multiple mass gatherings, parties and concerts;
- Observed widespread presence of cylinders in public spaces.

Given the rapid escalation and high exposure environment, there is a high probability of harm materialising in the immediate term, requiring urgent intervention.

Contribution of the measure to achieving the objective

The measure directly addresses the identified risk by:

- Prohibiting recreational inhalation of dinitrogen oxide;
- Restricting supply, sale, possession and advertising linked to recreational use;
- Imposing obligations on suppliers to ensure distribution only for legitimate purposes;
- Enabling enforcement by competent authorities.

Importantly, the measure preserves legitimate uses (medical, industrial, catering), ensuring proportionality. It is therefore direct, targeted and effective in reducing misuse while maintaining lawful activities.

Consistency and systematic nature of the objective

The measure forms part of a coherent and systematic public health approach:

- It is grounded in Malta's obligations under the Public Health Act;
 - It aligns with EU-level recognition of increasing nitrous oxide misuse;
 - It applies a risk-based regulatory model, restricting harmful use while permitting legitimate activities.
- The objective is therefore pursued in a consistent, proportionate and evidence-based manner.

9b. Less restrictive alternatives considered

Malta considered:

- Awareness and prevention campaigns;
- Monitoring without immediate regulation.

Existence of less restrictive measures achieving the objective

No less restrictive measure was identified that could effectively and immediately mitigate the identified risk.

Reasons for rejecting alternatives

No alternatives were available :

- There was immediacy and addressing rapidly escalating misuse, particularly during high-risk periods (tourism, mass events);
- Malta needed enforceable measures for effective control over supply and use;
- Evidence shows continued widespread availability and misuse (including visible cylinder proliferation);
- The regulatory gap enables unrestricted access, reinforcing misuse.

Given the high likelihood of imminent harm, with also cases referred to hospital, only binding legislative measures with immediate effect were considered sufficient.

9c. Proportionality of restrictions

The measure is proportionate because:

- It does not impose a total ban; legitimate uses remain permitted;
- Restrictions are limited to recreational use and associated supply chains;
- Obligations on operators are reasonable and targeted.

It therefore represents a balanced intervention.

Assessment against internal market impact

The impact on the internal market is limited because:

- Trade for legitimate uses (medical, industrial, catering) remains unaffected;
- Restrictions target misuse-related transactions only;
- The measure respects the principle of proportionality.

Balancing public interest vs internal market impact

Malta concluded that public health protection clearly outweighs any limited impact on the internal market because:

- The health risks are serious and well-documented;
- Trends were seen for usage also by adolescents and children;
- Complaints on discarded waste and environment impact, and danger from pressurised containers;
- Call by parents for regulation;

- The probability of harm is high due to current patterns of misuse and seasonal risk factors also evidenced by hospital referrals of persons who used products;
 - Failure to act would result in significant health, environment and societal consequences;
 - The measure is targeted and minimises disruption to legitimate economic activity.
- The restriction is therefore justified, necessary, and proportionate.

10. References of the Basic Texts: No Basic Text exists

11. Yes

12. Malta is facing an urgent and escalating public health threat arising from the widespread recreational misuse of dinitrogen oxide (nitrous oxide), particularly among young persons. National observations indicate a rapid increase in use, driven by its perceived low risk and the absence, until now, of robust regulatory controls. Recreational inhalation poses serious and immediate health risks, including neurological damage, loss of consciousness, and potential long-term impairment. The urgency of intervention is further amplified by the current high-risk context, including the early onset of the tourism season, a surge in large-scale gatherings such as parties and concerts, and the evident proliferation of nitrous oxide cylinders in public spaces. In view of this rapidly evolving situation and the high likelihood of imminent harm, immediate regulatory action is essential to prevent further escalation and protect public health.

13. No

14. No

15. No

16.

TBT aspects: No

SPS aspects: No

European Commission

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