



2024/2797

4.11.2024

COMMISSION IMPLEMENTING DECISION (EU) 2024/2797

of 31 October 2024

on authorising temporarily the measure taken by the French Republic on the labelling of products containing dinitrogen oxide only

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ⁽¹⁾ and in particular Article 52 thereof,

Whereas:

- (1) On 16 January 2024, the French Republic ('France') informed the Commission in accordance with Article 52(1) of Regulation (EC) No 1272/2008 that it has justifiable grounds for believing that dinitrogen oxide, although satisfying the requirements of that Regulation, constitutes a serious risk to human health due to reasons of classification and labelling of containers containing that chemical substance.
- (2) On 20 December 2023, France adopted a national measure regarding the labelling of packaging units of products containing only dinitrogen oxide ⁽²⁾. That measure ('the Decree') was published in the Official Journal of the French Republic on 21 December 2023 and is to become applicable 7 months after its publication.
- (3) The Decree provides that the statement '*causes damage to the nervous system through repeated or prolonged inhalation exposure*', in accordance with the model and characteristics set out in the Annex to that Decree ⁽³⁾, is to be placed on the packaging of products containing only dinitrogen oxide or, where those products are sold per unit, on their immediate container. That statement and the pictogram provided in the Annex to the Decree mirror the hazard statement H372 and hazard pictogram used in case of classification as Specific Target Organ Toxicity – Repeated Exposure Category 1 (STOT RE 1) in accordance with Table 3.9.5 of Annex I to Regulation (EC) No 1272/2008.
- (4) Dinitrogen oxide is not currently subject to harmonised classification and labelling requirements. By subjecting it to the mandatory labelling requirements corresponding to classification as STOT RE 1 irrespective of the self-classification performed in accordance with the requirements of Regulation (EC) No 1272/2008, the Decree imposes additional requirements which go beyond the provisions of that Regulation. For those reasons, the labelling requirements in the Decree and in Annex I to that Decree have the potential to hinder the placing of products on the French market, which comply with the applicable rules pursuant to Regulation (EC) No 1272/2008.
- (5) France has provided justifiable grounds in accordance with Article 52 for believing that dinitrogen oxide presents a serious risk to human health (adverse effects on the nervous system when inhaled). The number of intoxication cases notified to the National Agency for the Safety of Pharmaceutical and Health Products in France has doubled in one year from 254 in 2020 to 472 in 2021. There has been a threefold increase in the number of serious cases between 2020 (82 cases) and 2021 (265 cases). Moreover, 303 cases were reported to French poison centres in 2021 compared to 134 in 2020. The intoxications were mainly caused by the recreational misuse of dinitrogen oxide, usually involving young adults and in certain cases adolescents. Among the reported effects, neurological effects were most commonly reported as well as cardio-vascular and developmental effects. France also informed the Commission on 16 January 2024 that the substance was increasingly sold in higher quantities and bigger packages.

⁽¹⁾ OJ L 353, 31.12.2008, p. 1.

⁽²⁾ Décret No 2023-1224 du 20 décembre 2023 relatif à l'apposition d'une mention sur chaque unité de conditionnement des produits contenant uniquement du protoxyde d'azote.

⁽³⁾ The Annex provides for the full labelling elements, i.e. the hazard statement and pictogram corresponding to labelling for STOT RE 1 in a red frame.

- (6) On 25 April 2022, France submitted to the European Chemicals Agency (the Agency) a proposal for the harmonised classification and labelling of dinitrogen oxide. On 16 March 2023, in accordance with Article 37(4) of Regulation (EC) No 1272/2008, the Committee for Risk Assessment (RAC) of the Agency adopted an opinion proposing harmonised classification and labelling at Union level for dinitrogen oxide ⁽⁴⁾ ('the RAC Opinion') and transmitted that RAC Opinion together with the comments to the Commission on 15 June 2023. The RAC Opinion proposes, amongst others, that dinitrogen oxide be classified as STOT RE 1, specifying the nervous system as the organ affected but without specifying a route of exposure.
- (7) Including the harmonised classification and labelling of dinitrogen oxide as STOT RE 1 in Annex VI to Regulation (EC) No 1272/2008 in accordance with Article 37(5) of that Regulation would trigger the obligation to classify and label dinitrogen oxide in accordance with the requirements set out in that Regulation. The mandatory labelling with the hazard statement H372 and the relevant hazard pictogram as provided for in Table 3.9.5. of Annex I to Regulation (EC) No 1272/2008 are also provided for in the Decree. However, Article 4(1) of Regulation (EC) No 1272/2008 requires manufacturers, importers and downstream users to classify substances or mixtures in accordance with Title II of that Regulation before placing them on the market in the absence of harmonised classification, and Article 15 of that Regulation lays down the requirements to review and adapt the classification in light of new scientific or technical information.
- (8) Should manufacturers, importers and downstream users decide to classify and label products containing dinitrogen oxide as STOT RE 1, in accordance with the RAC Opinion, they should not be required to duplicate the related hazard communication elements outlined in the Decree.
- (9) The Decree provides that the statement which is to be placed on the packaging of products containing only dinitrogen oxide does not constitute an obstacle to commercialising products containing only dinitrogen oxide produced and commercialised in another Member State or in Türkiye, or legally produced in a state which is a member of the European Economic Area, which state ensures an equivalent level of safety to that required by the Decree. However, the Decree does not set out the conditions for such equivalence to be acceptable. Therefore, the Decree should not hinder the placing on the market of products containing only dinitrogen oxide, produced and commercialised in another Member State or in Türkiye, or legally produced in the European Economic Area, which are self-classified and labelled as STOT RE 1 in accordance with the requirements of Regulation (EC) No 1272/2008.
- (10) The Decree should therefore be authorised as a temporary measure, in accordance with Article 52(2) of Regulation (EC) No 1272/2008, applicable for a duration of 36 months or until the date when a harmonised classification of dinitrogen oxide as STOT RE 1 becomes applicable following adoption of a Commission Regulation in accordance with Article 37(5) of Regulation (EC) No 1272/2008, whichever date is earlier. However, France should accept the placing on the market in France of dinitrogen oxide which is classified and labelled as STOT RE 1 in accordance with the requirements of Titles II and III of Regulation (EC) No 1272/2008 and, where harmonised classification and labelling is established by a Commission Regulation in accordance with Title V of Regulation (EC) No 1272/2008 through an entry in Part 3 of Annex VI, in accordance with that entry, to avoid a duplication of the related hazard communication elements.
- (11) The Decision is limited in scope to the substances and mixtures subject to Regulation (EC) No 1272/2008.
- (12) Since the measure is likely to have consequences on the internal market of dinitrogen oxide, it should enter into force as soon as possible after its adoption, in other words on the day of its publication.

⁽⁴⁾ European Chemicals Agency, Committee for Risk Assessment, Opinion proposing harmonised classification and labelling at EU level of dinitrogen oxide, 16 March 2023, EC Number: 233-032-0, CAS Number: 10024-97-2, CLH-O-0000007281-79-01/E.

- (13) The measures provided for in this Implementing Decision are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽⁵⁾,

HAS ADOPTED THIS DECISION:

Article 1

The measure provided for in Decree No 2023-1224 regarding labelling of packaging units of products containing only dinitrogen oxide ⁽⁶⁾ notified to the Commission by France on 16 January 2024 is authorised for 36 months from the date of entry into force of this Decision or until the date a Commission Delegated Regulation providing for the harmonised classification and labelling of dinitrogen oxide in accordance with Article 37(5) of Regulation (EC) No 1272/2008 as STOT RE 1 becomes applicable, whichever is the earliest.

France shall allow the placing on the market, in France, of dinitrogen oxide classified and labelled as STOT RE 1 in accordance with Regulation (EC) No 1272/2008.

Article 2

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 31 October 2024.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁵⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>).

⁽⁶⁾ Décret No 2023-1224 du 20 décembre 2023 relatif à l'apposition d'une mention sur chaque unité de conditionnement des produits contenant uniquement du protoxyde d'azote.