EUROPEAN
COMMISSION

Brussels, XXX
[…](2025) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards carcinogens, germ cell mutagens or reproductive toxicants subject to restrictions

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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(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 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[1], and in particular Article 68(2) thereof,

Whereas:

(1) Entries 28, 29 and 30, set out in the Table of Annex XVII to Regulation (EC) No 1907/2006, prohibit the placing on the market and use, for supply to the general public, of substances that are classified as carcinogen, germ cell mutagen or reproductive toxicant (CMR) category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[2], and that are listed in Appendices 1 to 6 of Annex XVII to Regulation (EC) No 1907/2006, and of mixtures containing such substances in specified concentrations.

(2) Regulation (EC) No 1272/2008 as amended by Commission Delegated Regulations (EU) 2024/2564[3] and (EU) 2025/1222[4] included new harmonised classifications of substances as CMR categories 1A and 1B. Furthermore, Delegated Regulation (EU) 2024/2564 replaced certain entries for reproductive toxicant category 1B with new ones. It is therefore appropriate to update Appendices 1, 2, 4 and 6 of Annex XVII to Regulation (EC) No 1907/2006 to include the newly classified substances and to replace existing entries.

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1 OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj.

2 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 (OJ L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

3 Commission Delegated Regulation (EU) 2024/2564 of 19 June 2024 amending Regulation (EC) No 1272/2008 as regards the harmonised classification and labelling of certain substances (OJ L, 2024/2564, 30.9.2024, ELI: https://eur-lex.europa.eu/eli/reg_del/2024/2564/oj).

4 Commission Delegated Regulation (EU) 2025/1222 of 2 April 2025 amending Regulation (EC) No 1272/2008 as regards the harmonised classification and labelling of certain substances (OJ L, 2025/1222, 20.6.2025, ELI: http://data.europa.eu/eli/reg_del/2025/1222/oj).

(3) The amendments to Regulation (EC) No 1272/2008 by Delegated Regulation (EU) 2024/2564 will apply from 1 May 2026. The amendments to Regulation (EC) No 1272/2008 by Delegated Regulation (EU) 2025/1222 will apply from 1 February 2027. Since this Regulation will enter into force after 1 May 2026, the restriction introduced by this Regulation as regards the substances classified by Delegated Regulation (EU) 2024/2564 as CMR categories 1A and 1B should apply from the date of entry into force of this Regulation. In contrast, the restriction as regards the substances classified by Delegated Regulation (EU) 2025/1222 as CMR categories 1A and 1B should apply from 1 February 2027. The date of application of this Regulation does not prevent operators from applying earlier the restrictions related to CMR categories 1A and 1B listed in the Annexes to Delegated Regulations (EU) 2024/2564 and (EU) 2025/1222.

(4) The CAS numbers listed for three substances referred to in Appendices 1 and 2 of Annex XVII to Regulation (EC) No 1907/2006 should be updated to reflect the up-to-date identification of those three substances and ensure clarity and accuracy in the application of the restriction.

(5) Appendix 6 of this Regulation includes dinitrogen oxide (EC No 233-032-0; CAS No 10024-97-2) because of its classification as reproductive toxicant category 1B. However, the substance is authorised as food additive nitrous oxide (E 942) in accordance with Regulation (EC) No 1333/2008[5]. In particular, in accordance with Annexes II and III to that Regulation that substance may be placed on the market and used in all categories of foods and in food additives, in food enzymes and in food flavourings at *quantum satis*. Its use as a food additive is subject to safety re-evaluation by the European Food Safety Authority (EFSA) as part of the re-evaluation programme provided for in Commission Regulation (EU) No 257/2010[6]. A derogation from the restriction is appropriate to allow the use of dinitrogen oxide by the general public as a food additive as well as the presence of the substance in food. If necessary, the Commission should be able to propose a revision of the derogation in a future update of the restriction based on the outcome of the EFSA assessment.

(6) As highlighted by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), dinitrogen oxide is also known to be abused as a drug, leading to poisonings and concerns, including regarding neurotoxicity, from frequent or heavy inhalation of the substance. However, this Regulation is not specifically targeted at preventing the abuse of dinitrogen oxide as a drug or at addressing the abovementioned hazardous property of dinitrogen oxide. Nevertheless, when granting a derogation to allow the use of dinitrogen oxide as a food additive, the possibility that the derogation could be exploited for the sale of the substance as a drug should be taken into account. On the one hand, cartridges containing dinitrogen oxide could be misused. On the other hand, aerosol dispensers with dinitrogen oxide do not provide ready access to the substance and are therefore unlikely to be misused. Therefore, to minimise the possibility of misuse, the derogation should include specific conditions for the sale of cartridges containing this substance, such as restrictions on the

[5] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p.16, ELI: http://data.europa.eu/eli/reg/2008/1333/oj).

[6] Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 80, 26.3.2010, p. 19, ELI: http://data.europa.eu/eli/reg/2010/257/oj).

maximum volume of the substance that can be sold to members of the general public, as well as age restrictions on the sale of the cartridges containing the substance.

(7) This Regulation is without prejudice to other regulatory frameworks, including national legislation of Member States, that may set stricter measures to address the abuse of dinitrogen oxide as a drug.

(8) The derogation from the provisions set out in entry 30, set out in Table 1 of Annex XVII to Regulation (EC) No 1907/2006, granted by entry 1 of Appendix 11 of Annex XVII to that Regulation, has ended on 1 June 2013, and should therefore be deleted.

(9) Regulation (EC) No 1272/2008 requires that, for the purposes of classification, the concentration of a classified substance in a mixture should be considered, and where applicable, the sum of the concentrations of individual classified substances should also be taken into account, in accordance with the additivity rules set out in Annex I, and Part 1 of Annex VI, to that Regulation. Entries 28, 29 and 30, set out in Table 1 of Annex XVII to Regulation (EC) No 1907/2006, should therefore be amended to ensure that the restriction follows the additivity rules set out in Regulation (EC) No 1272/2008, thereby maintaining consistency and coherence with Regulation (EC) No 1272/2008.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Points (2)(b), 3(g), (h) and(i), (4)(b), (5)(h) to (m) and (6)(b) of the Annex shall apply from 1 February 2027.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen