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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Subject:	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

Delegations will find attached document D(2026) 112095.

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EUROPEAN
COMMISSION

Brussels, XXX
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[...] (2026) 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)

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)

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/EC¹, 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 Council², 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) 2024/2564³ and (EU) 2025/1222⁴ 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.

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 made by Delegated Regulation (EU) 2024/2564 are to apply from 1 May 2026. The amendments to Regulation (EC) No 1272/2008 made by Delegated Regulation (EU) 2025/1222 are to 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) Following the classifications of lead, in both powder and massive form, and most lead compounds as reproductive toxicant category 1A, Appendix 5 of Annex XVII to Regulation (EC) No 1907/2006 was amended by Commission Regulation (EU) 2017/1510⁵ to include lead (EC No 231-100-4; CAS No 7439-92-1) in both powder [particle diameter < 1 mm]⁶ and massive form [particle diameter ≥ 1 mm]⁷. That Appendix was also amended by Commission Regulation (EU) 2023/1132⁸ to include most lead compounds⁹. Consequently, lead, in both powder and massive form, and most lead compounds fall within the scope of entry 30 of Annex XVII to Regulation (EC) No 1907/2006 and their placing on the market and use for supply to the general public as substances on their own, in mixtures or as constituent of other substances is banned.
- (6) According to Article 3(3) of Regulation (EC) No 1907/2006, an article is an object which during production is given a special shape, surface or design, which determines its function to a greater degree than does its chemical composition. As regards fishing sinkers, their function is to provide weight to fishing devices, such as lines or lures. Most fishing sinkers need to be heavy, dense and chemically stable in order to perform their function. Those characteristics are directly related to the chemical composition of the fishing sinkers. For most fishing sinkers, the shape, surface and design of the sinker could be considered less relevant for the function of the sinker than the chemical composition. Against that background, it could be considered that most fishing sinkers are not articles pursuant to Regulation (EC) No 1907/2006, but rather substances or mixtures. As a result, fishing sinkers containing lead or lead compounds

⁵ Commission Regulation (EU) 2017/1510 of 30 August 2017 amending the Appendices to Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards CMR substances (OJ L 224, 31.8.2017, p. 110, ELI: <http://data.europa.eu/eli/reg/2017/1510/oj>).

⁶ Index No 082-013-00-1.

⁷ Index No 082-014-00-7.

⁸ Commission Regulation (EU) 2023/1132 of 8 June 2023 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards carcinogenic, mutagenic or reproductive toxicant substances subject to restrictions (OJ L 149, 9.6.2023, p. 49, ELI: <http://data.europa.eu/eli/reg/2023/1132/oj>).

⁹ Except those specified elsewhere in Annex VI to Regulation (EC) No 1272/2008. See Index No. 082-001-00-6.

(‘lead fishing sinkers’) that are classified as reproductive toxicant category 1A and listed in Appendix 5 of Annex XVII to Regulation (EC) No 1907/2006, could be subject to the provisions set out in entry 30 of that Annex.

- (7) At the same time, lead fishing sinkers fall within the scope of a specific restriction process under Article 69(1) of Regulation (EC) No 1907/2006, which was initiated by the Commission on 16 July 2019¹⁰. During that process, the European Chemicals Agency (‘the Agency’) concluded¹¹ that lead or its compounds in certain fishing tackle, including fishing sinkers, poses a risk to the environment and human health that is not adequately controlled and that needs to be addressed on a Union-wide basis. The Agency proposed specific restriction conditions to address the identified risks from lead fishing tackle. They identified in which fishing tackle lead poses a significant risk and should therefore be restricted, and in which fishing tackle lead could be permitted because of lower risks or lack of suitable alternatives. The Agency also proposed transitional periods of different durations for the application of the restriction to different types of lead fishing tackle, depending on the risks they pose and the availability of alternatives. Based on the Agency’s recommendations, entry 63 of Annex XVII to Regulation (EC) No 1907/2006 should be amended to introduce specific restrictions on the placing on the market and use of lead or its compounds in fishing tackle, including lead fishing sinkers.
- (8) The provisions set out in entry 30 of Annex XVII to Regulation (EC) No 1907/2006 generically address the risks posed by any substance included in Appendix 5 or 6 due to its harmonised classification as reprotoxic category 1A or 1B, when the substance on its own, in a mixture or as constituent of other substances is supplied to the general public. Since any amendment to entry 63 of Annex XVII to Regulation (EC) No 1907/2006 would be based on recommendations that specifically address the risks posed by lead fishing sinkers, including risks for fishing-sinker users, it is therefore more appropriate to only regulate the placing on the market and use of lead fishing sinkers in the context of a separate amendment of entry 63 of Annex XVII to Regulation (EC) No 1907/2006. The placing on the market and the use for supply to the general public of lead and its compounds, on their own, in mixtures or as constituents of other substances in any fishing sinkers should therefore be granted a derogation from entry 30 of Annex XVII to Regulation (EC) No 1907/2006.
- (9) Appendix 6 to Regulation (EC) No 1907/2006 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 a food additive (nitrous oxide (E 942)) in accordance with Regulation (EC) No 1333/2008¹². 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 food 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 257/2010¹³.

¹⁰ https://echa.europa.eu/documents/10162/17233/rest_lead_ammunition_COM_request_en.pdf.

¹¹ European Chemicals Agency, *Annex XV Restriction Report – Lead in outdoor shooting and fishing*, 24 March 2021, <https://echa.europa.eu/documents/10162/da9bf395-e6c3-b48e-396f-afc8dcef0b21>.

¹² 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>).

¹³ 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>).

A derogation from the restriction under Regulation (EC) No 1907/2006 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 or in food packaging. It is furthermore appropriate to include a review clause for the derogation that allows the use of dinitrogen oxide by the general public as a food additive, to ensure revision of that derogation should the outcome of the EFSA re-evaluation warrant a change under Regulation (EC) No 1333/2008.

- (10) 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 poisoning and other concerns, including regarding neurotoxicity, from frequent or heavy inhalation of the substance. While not specifically targeting the prevention of abuse of dinitrogen oxide as a drug or at addressing the hazardous properties of dinitrogen oxide, 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 dinitrogen oxide, such as restrictions on the maximum content of the substance that can be supplied to members of the general public, as well as age restrictions on the sale of cartridges containing the substance.
- (11) Pressurised containers of dinitrogen oxide could cause significant risks of explosion at the waste stage. However, the derogation for small cartridges and aerosol dispensers with dinitrogen oxide is not expected to lead to concerns during the handling of waste.
- (12) In some Member States, dinitrogen oxide is also allowed to be used in motorsports to increase motor performance. That use occurs in particular hobby motorsports where cars are equipped with a closed system enabling the use of dinitrogen oxide filled in special large containers. Banning the use of dinitrogen oxide would require hobby motorsport competitors to stop the sport completely or to use alternative substances, which may for some of those competitors be prohibitively costly due to refitting or replacing the vehicle. It could also lead to a shift from organised, safety-regulated and certified events to unofficial, uncontrolled events, thereby increasing the risk of uncontrolled access to the substance facilitating drug abuse and also be detrimental to road safety and potentially lead to severe consequences for motorsport competitors and other road users. Therefore, a derogation for the use of dinitrogen oxide in motorsports should be allowed under certain conditions.
- (13) As the derogation for motorsports could be abused by consuming dinitrogen oxide as a drug, the supply and use of the substance should only be allowed for motorsport competitors in those Member States where personal licences for such supply and use are issued or recognised.
- (14) The containers of dinitrogen oxide used in motorsports are refillable. When they enter the waste stage after many years of use, they are depressurised as part of standard practice. Therefore, the derogation for motorsports is not expected to lead to concerns during the handling of waste.
- (15) In order to address the public health issue, which affects mainly young people, of abusive use of dinitrogen oxide as a recreational drug when used in food, food

additives and certain motorsports containers, Member States should be allowed to maintain stricter measures in this regard.

- (16) The derogation from the provisions of 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, ended on 1 June 2013, and should therefore be deleted.
- (17) 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.
- (18) 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)(c) 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