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COMMISSION REGULATION (EU) .../...

of XXX

**amending 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 lead in fishing tackle**

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

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amending 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 lead in fishing tackle

(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(1) thereof,

Whereas:

- (1) Annex XVII to Regulation (EC) No 1907/2006 lays down restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles. Entry 63 of that Annex contains restrictions with respect to lead (CAS No 7439-92-1, EC No 231-100-4) and lead compounds ('lead'), including a restriction on lead in gunshot in or around wetlands that was introduced by Commission Regulation (EU) 2021/57².
- (2) Lead is classified under Regulation (EC) No 1272/2008³ as very toxic to aquatic life, and toxic for reproduction, due to its adverse effects on fertility and the development of the nervous system of the foetus and the child, leading to permanent damage and intelligence quotient (IQ) loss. No safe lead-concentration threshold has been identified under which lead has no ill effects on human health. Lead is also associated with an increased risk of cardiovascular, kidney and central-nervous-system diseases

¹ OJ L 396, 30.12.2006, p. 1.

² Commission Regulation (EU) 2021/57 of 25 January 2021 amending 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 lead in gunshot in or around wetlands (OJ L 24, 26.1.2021, p. 19 ELI: <http://data.europa.eu/eli/reg/2021/57/oj>).

³ 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>

in adults. Moreover, exposure to lead can have a range of acute and chronic toxicological effects, including death, in animals, particularly in birds ⁴.

- (3) The Union and its Member States are Contracting Parties to the Convention on the Conservation of Migratory Species of Wild Animals ⁵ (CMS). The Preventing Poisoning Working Group (PPWG) developed Guidelines to Prevent the Risk of Poisoning to Migratory Birds, which were adopted in 2014 by CMS Resolution 11.15. The Guidelines recommend both the phasing-out of the use of lead ammunition across all habitats and the phasing-out of the use of lead fishing weights in areas where migratory birds have been shown to be particularly at risk of lead poisoning.
- (4) On 16 July 2019, the Commission asked ⁶ the European Chemicals Agency (the Agency), pursuant to Article 69(1) of Regulation (EC) No 1907/2006, to prepare a dossier (Annex XV dossier) to address the concerns regarding human health and the environment posed by lead in: (i) ammunition, including gunshot used in terrains other than wetlands and bullets used both in wetlands and in terrains other than wetlands; and (ii) fishing tackle. The mandate did not extend to uses of ammunition for indoor shooting, or to uses by the police, the military and other security forces.
- (5) On 24 March 2021, the Agency published the Annex XV dossier ⁷ in which it concluded that lead in ammunition and fishing tackle poses a risk to the environment and human health, in particular to vulnerable populations such as children that is not adequately controlled and that needs to be addressed on a Union-wide basis. With regard to the risk for the environment, the ingestion by birds and other animals of unrecovered lead-based ammunition, lead-based sinkers ('lead sinkers') and lead-based lures ('lead lures') from hunting, sports shooting and fishing activities results in the poisoning and frequent death of animals. Furthermore, lead accumulation at sports-shooting ranges can result in the leaching of lead-polluted surface water into local watercourses and may affect groundwater, potentially poisoning people, livestock and wildlife. The Agency also concluded that there are human health risks associated with consuming the meat of animals killed with lead ammunition, particularly for children aged 7 and younger, or when making lead ammunition or sinkers or lures at home.
- (6) The Agency estimated that, if the current releases of lead from shooting and fishing in the Union continue, approximately 876 000 tonnes of lead will be released into the environment over the next 20 years. This will place at least: (i) 7 million birds at risk of poisoning because of the ingestion of sinkers and lures (ii) 135 million birds at risk of poisoning through ingestion of lead gunshot; and (iii) 14 million birds at risk of poisoning through ingestion of lead via the consumption of food; . In addition, the Agency estimated that, each year, about 13.8 million individuals from hunters' families, including 1.1 million children aged 7 or younger, are vulnerable to lead exposure from game meat.
- (7) Against this background, the Agency proposed a restriction of lead in ammunition and fishing tackle which included, inter alia, a restriction on the placing on the market and use of lead in a concentration of equal to or greater than 1% in sinkers, lures, fishing

⁴ The Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC), *Background document to the Opinion on the Annex XV dossier proposing restrictions on Lead in shot*, p. 3. <https://echa.europa.eu/documents/10162/28acf817-61a6-3ca6-4e85-a71ef0e07740>.

⁵ <https://www.cms.int/en/convention-text>.

⁶ https://echa.europa.eu/documents/10162/17233/rest_lead_ammunition_COM_request_en.pdf.

⁷ 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>.

wires and drop-in sinkers. Moreover, the Agency proposed imposing information obligations on retailers of those products and labelling obligations on ammunition suppliers. The proposed restriction is intended to reduce lead emissions by approximately 630 000 tonnes, of which 48 300 tons from avoided use of lead in fishing tackle, over the 20 years following its introduction. This would be a reduction of 72% compared with a situation without the proposed restriction. The restriction would also avoid IQ loss in about 7 000 children per year, preventing a welfare loss of roughly EUR 70 million.

- (8) On the availability of alternatives, the Agency identified many alternatives to lead in fishing tackle (such as brass, concrete, pebbles, steel, tin, zinc and tungsten) but acknowledged that some of these alternatives, especially brass and zinc, also harm the environment. The Agency noted that alternatives to lead fishing wires are widely available in retail shops and that drop-in sinkers can be replaced with: (i) different techniques; and (ii) alternative sinkers that are not intended to be dropped off during use and therefore do not cause a direct and intentional release of lead to the environment.
- (9) The Agency recommended that the restrictions on fishing wires and drop-in sinkers should enter into application as soon as possible, given the availability of alternatives and the need to prevent the direct and intentional release of lead into the environment. By contrast, it recommended a range of periods in order to defer the entry into application of: (i) the restrictions on other articles within the scope of the Annex XV dossier; and (ii) the information and labelling obligations. This would allow operators to adapt to the new rules and put in place the necessary risk management measures.
- (10) The Agency considered a derogation for split shot that weighs 0.06 g or less and is placed on the market in spill-proof and child-resistant packaging, but eventually decided not to recommend it because of the residual risk to birds.
- (11) Only a limited number of Member States have national provisions in place that prohibit the use of lead in fishing to reduce lead emissions and exposure. The Annex XV dossier demonstrated that Union-wide action to address the risk associated with lead in fishing tackle is necessary in order to ensure a harmonised level of protection across the Union.
- (12) On 2 June 2022, the Agency's Committee for Risk Assessment (RAC) adopted an opinion pursuant to Article 70 of Regulation (EC) No 1907/2006 with respect to the Annex XV dossier. In its opinion, RAC concurred with the Agency's conclusion that the use of lead in fishing poses a wide range of risks to both human health and the environment. RAC concluded that the restriction proposed by the Agency would be the most appropriate Union-wide measure to address the identified risks.
- (13) RAC did not support a derogation for split shot weighing 0.06 g or less, even if placed on the market in spill-proof and child-resistant packaging, because this would decrease the level of environmental protection provided by the restriction.
- (14) RAC supported the labelling and information requirements proposed by the Agency for lead in fishing tackle. However, RAC recommended avoiding confusion by increasing the lead concentration limit that would trigger the requirements from 0.3% to 1% by weight, so as to align it with the concentration limit that triggers the ban on placing on the market and use.
- (15) On 2 December 2022, SEAC adopted an opinion pursuant to Article 71(1) of Regulation (EC) No 1907/2006. It concluded that the proposed restriction would be

the most appropriate Union-wide measure to address the identified risks as concluded by RAC, provided that the conditions are modified as proposed by SEAC. This takes into account the proportionality of the socio-economic benefits of the measure to its socio-economic costs.

- (16) SEAC could not reach a conclusion as to whether a derogation for the use of lead in split shot weighing 0.06 g or less would be justified on socio-economic grounds. This was due to a lack of evidence on: (i) the availability and technical performance of alternatives; and (ii) the socio-economic impacts of a restriction on this use.
- (17) SEAC did not have sufficient information to reach a conclusion as to whether the cost of providing information at the point of sale (as proposed by the Agency and supported by RAC) would be fully justified, or whether other educational measures could more effectively influence purchasing behaviour. SEAC agreed with RAC that the same concentration limit of 1% by weight that was being proposed for restricting the placing on the market and use of lead in fishing tackle should also apply to labelling and information requirements in order to avoid confusion and assist enforcement. SEAC also supported RAC's proposal to apply the labelling and information requirements to alternatives containing copper and copper alloys only when the lead content is equal to or greater than 3% by weight.
- (18) The Forum for Exchange of Information on Enforcement was consulted in accordance with Article 77(4), point (h), of Regulation (EC) No 1907/2006. Its recommendations were taken into account.
- (19) On 27 February 2023, the Agency submitted the opinions of RAC and SEAC⁸ to the Commission.
- (20) Taking into account the Annex XV dossier, the opinions of RAC and SEAC, the socio-economic impact and the availability of alternatives, the Commission considers that there is an unacceptable risk to the environment and human health stemming from the use of lead in ammunition and fishing tackle, and that that risk needs to be addressed on a Union-wide basis. It is therefore appropriate to restrict the placing on the market and use of such ammunition and fishing tackle.
- (21) To reduce complexity and increase legal clarity, the Commission considers that the restriction of lead in ammunition and fishing tackle, as proposed in the Annex XV dossier, covered by the opinions of RAC and SEAC, and assessed in the Forum advice, should be adopted by means of two separate Commission Regulations.
- (22) The restriction of lead in fishing tackle should apply to fishing tackle with a lead concentration equal to or greater than 1% by weight. It is considered that the 1% concentration limit is sufficient to address the identified risk and can be readily achieved by producers of alternatives, given that some of those alternatives are likely to contain lead as an impurity.
- (23) The Commission considers that sinkers weighing more than 1 Kg are not at risk of being ingested by birds and should therefore not be restricted. The Commission also considers that the restriction on the placing on the market and use of fishing wires and drop-in sinkers should apply after a period of only six months, in order to rapidly prevent the direct and deliberate release of lead into the environment while still

⁸ The Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC), *Opinion on an Annex XV dossier proposing restrictions on lead and its compounds*, 2 December 2022, <https://echa.europa.eu/documents/10162/2c82ef18-ce5d-4b4f-8ff0-002932154acc>.

granting sufficient time to operators to adapt to the restriction. Moreover, the Commission concurs with the Agency, RAC and SEAC that a weight that is enclosed, embedded or threaded in a fishing net, a lure or a line does not contribute to the identified risk to birds. Therefore, the Commission considers that it should not be covered by the restriction.

- (24) For fishing lures containing copper alloys, a concentration of lead less than 3% by weight should be allowed in order to avoid changes in machinery leading to large increases in production costs. That derogation is necessary in order to ensure the continuing production of brass lures, which are the most common alternatives to lead lures.
- (25) The Commission acknowledges the technical difficulties involved in finding alternatives to lead that are both sufficiently malleable and heavy enough to be used in split shot. It therefore considers that a derogation for the use of lead in split shot weighing 0.06 g or less is justified if the split shot is placed on the market in spill-proof and child-resistant packaging in order to minimise accidental releases into the environment.
- (26) The Commission concurs with RAC and the Agency that a requirement for retailers to display information at physical and online points of sale, as well as on packaging, is justified in order to warn users of the risks of using lead sinkers and lures.
- (27) To avoid unnecessary waste and facilitate enforcement, the restriction should not apply to the use of certain fishing sinkers and lures that were placed on the market in the Union before the entry into application of the respective provisions in this restriction.
- (28) Some Member States have national provisions in place for the protection of the environment or human health that prohibit or restrict the use of lead in lures, sinkers or fishing wires that are stricter than those laid down in this Regulation. Requiring those Member States to reduce their existing level of protection in order to comply with this Regulation might lead to a greater use of lead in those Member States. Such a result would not be compatible with the high level of protection required by Article 114(3) of the Treaty. Member States should therefore be allowed to maintain stricter provisions.
- (29) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (30) The measures provided for in this Regulation are in accordance with the opinion of the Committee set up under Article 133 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*.

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