II

(Non-legislative acts)

REGULATIONS

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

(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 (EC) 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(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.
- (2) The Union and 23 Member States are Contracting Parties to the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (²) (AEWA). Contracting Parties are required under paragraph 4.1.4 of the Action Plan annexed to AEWA to endeavour to phase out the use of lead shot for hunting in wetlands as soon as possible in accordance with self-imposed and published timetables.
- (3) Article 4(2) of Directive 2009/147/EC of the European Parliament and of the Council (³) requires Member States to pay particular attention to the protection of wetlands, and particularly to wetlands of international importance, in the taking of conservation measures with regard to regularly occurring migratory species.
- (4) On 3 December 2015, the Commission asked the European Chemicals Agency ('the Agency') pursuant to Article 69(1) of Regulation (EC) No 1907/2006 to prepare a dossier with a view to extending the restriction on lead and lead compounds in Annex XVII to that Regulation in order to control the risk to the environment and human health posed by the use of lead or lead compounds in gunshot used for shooting in wetlands ('the Annex XV dossier'). At the same time, the Commission also asked the Agency to start collecting information on other uses of lead ammunition, including hunting in terrains other than wetlands and target shooting, and on the use of lead weights for fishing.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ https://www.unep-aewa.org/sites/default/files/basic_page_documents/agreement_text_english_final.pdf

⁽²⁾ Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7).

- (5) On 21 June 2017, the Agency published the Annex XV dossier (4) proposing the introduction of a restriction on the use of lead and lead compounds in gunshot for shooting with a shotgun within a wetland or where spent gunshot would land within a wetland. The Agency also proposed introduction of a restriction on the possession of gunshot containing a concentration of lead equal to or greater than 1 % ('lead gunshot') in wetlands in order to enhance enforceability of the proposed restriction on the use of lead in gunshot for shooting. The Agency concluded that the use of lead in gunshot in wetlands leads to a risk to waterbirds that ingest spent lead gunshot, leading to toxicological effects, including death.
- (6) The number of waterbirds estimated to die in the Union from lead poisoning is in the order of one million every year. The use of lead in gunshot also leads to a risk to species that feed on birds contaminated with lead gunshot, and a risk to humans from consuming waterbirds shot with lead gunshot, although the latter risk was assessed by the Agency only qualitatively. Exposure to lead by humans is associated with neurodevelopmental effects, impaired renal function and fertility, hypertension, adverse pregnancy outcomes and death.
- (7) The Agency concluded that lead-free gunshot alternatives, such as steel and bismuth gunshot, are widely available, technically feasible and have better human health and environmental hazard and risk profiles than lead gunshot. Moreover, steel gunshot, the most likely alternative to be used, is available at a comparable price to that of lead gunshot.
- (8) Provisions prohibiting or restricting the use of lead in gunshot in wetlands exist in the majority of Member States, but the disparities between them result in different levels of risk reduction. Furthermore, the migration routes of migratory birds typically cross several Member States and therefore birds could ingest spent lead gunshot in Member States where no or more limited measures are in place. The Annex XV dossier demonstrated that Union-wide action is necessary to address the risks arising from the use of lead in gunshot in wetlands in a harmonised manner. Harmonisation legislation should however be based on a high level of protection. The outcome of harmonisation should therefore not be to oblige the Member States that have stricter national provisions on lead in gunshot to abandon those provisions, as this would imply a reduction in the level of protection of environment and health in those Member States.
- (9) The Agency suggested a period of three years for introduction of the restriction.
- (10) On 9 March 2018, 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 that opinion, RAC concurred with the Agency's conclusion that ingestion of spent lead gunshot by waterbirds causes toxicological effects, including death. As to human health, RAC concluded that lead is highly toxic and that no threshold has been established either for neurodevelopmental effects in children or for blood pressure or renal effects in adults, so any exposure to lead therefore constitutes a risk. RAC concluded that the proposed restriction is an appropriate Union-wide measure to address the identified risks.
- (11) RAC strongly supported a shorter period than the three years proposed by the Agency. The reason given was that each year of delay would result in approximately 4 000 additional tonnes of lead being released into wetland areas, resulting in the death of somewhere in the order of 1 million birds.
- (12) On 14 June 2018, the Agency's Committee for Socioeconomic Analysis (SEAC) adopted an opinion pursuant to Article 71(1) of Regulation (EC) No 1907/2006, concluding that the proposed restriction is an appropriate Union-wide measure to address the identified risks, taking into account the fact that the socioeconomic benefits of the measure would be proportionate to the socioeconomic costs. In addition, SEAC concluded that the cost of the proposed restriction would be borne mainly by hunters, and that the cost increase to hunters was reasonable.

⁽⁴⁾ https://echa.europa.eu/documents/10162/6ef877d5-94b7-a8f8-1c49-8c07c894fff7

- (13) SEAC considered that a shorter period than the three years suggested in the Annex XV dossier could pose a challenge in terms of implementation for those Member States that currently have only a limited or no ban on the use of lead gunshot in wetlands, although SEAC did also acknowledge that a shorter transitional period might be feasible, having regard to the fact that lead-free gunshot is already available on the market and that, in terms of increased costs for early replacement of guns, a shorter period would have only a minor impact.
- (14) The Forum for Exchange of Information on Enforcement was consulted during the restrictions process in accordance with Article 77(4)(h) of Regulation (EC) No 1907/2006 and its recommendations were taken into account.
- (15) On 17 August 2018, the Agency submitted the opinions of RAC and SEAC (5) to the Commission.
- (16) Taking into account the Annex XV dossier, the opinions of RAC and SEAC, the socioeconomic impact and the availability of alternatives, the Commission considers that there is an unacceptable risk to the environment and a potential risk to human health stemming from the discharge of lead gunshot in or around wetlands, which needs to be addressed on a Union-wide basis. It is therefore appropriate to introduce a restriction on the act of discharging lead gunshot in or around wetlands.
- (17) Given the difficulty for enforcement authorities in catching hunters in the act of actually discharging gunshot, the restriction should also include the carrying of lead gunshot whilst shooting. This will make it possible to enforce the restriction on discharging gunshot far more effectively and will therefore ensure the effectiveness of the restriction in addressing the risks identified to the environment and human health. The restriction should not be linked to ownership rights. The term 'carrying' should therefore be used instead of 'possession' which was the term suggested by the Agency.
- (18) A restriction on carrying lead gunshot should, however, apply specifically to carrying whilst shooting, as opposed to carrying in some other context, for example when transporting gunshot across wetlands for delivery elsewhere. The Commission considers, moreover, that the restriction on carrying should be directly linked to the particular type of shooting within the scope of the restriction (shooting in or around wetlands). This is in view of the fact that comments submitted during the public consultation on the Annex XV dossier indicated that, in some Member States, hunters involved in other types of shooting are quite likely to walk through different types of terrain, wetlands as well as other terrains, on a typical day's shooting. The Commission also considers that, in order to aid enforcement, the restriction on carrying should cover not only carrying while out wetland shooting, but also carrying as part of going wetland shooting, in other words where there is a close connection with the actual shooting. This would cover, for example, carrying while heading out on, or returning home from, a day's wetland shooting or carrying by someone helping hunters on a shooting expedition.
- (19) Given the practical difficulties in proving the particular type of shooting that a person found carrying lead gunshot is intending to do, it is appropriate to establish a legal presumption that anyone found in or around wetlands carrying lead gunshot while out shooting, or as part of going shooting, is presumed to be carrying that gunshot while out wetland shooting, or as part of going wetland shooting. In other words, it would be for that person to show that he or she was actually intending to go shooting elsewhere and was merely passing through the wetland area in order to go shooting elsewhere.
- (20) As regards geographical scope, the Agency proposed that the restriction on discharging lead gunshot should apply not only in wetlands but also in areas where 'spent gunshot would land within a wetland'. The Commission notes that there was some support in RAC for quantitatively defining a fixed buffer zone around wetlands rather than relying on a test based on where spent gunshot would land. The Commission agrees that a fixed buffer zone is likely to make it easier to comply with the restriction and to enforce it. The restriction should therefore apply to discharging lead gunshot not only in wetlands but also in a fixed buffer zone around wetlands, defined quantitatively. Taking into account the need to ensure proportionality, the size of the fixed buffer zone should be set at 100 metres around wetlands.

⁽⁵⁾ https://echa.europa.eu/documents/10162/b092e670-3266-fb5d-6296-544eaccb5d4a

- (21) In view of the enforcement advantages and effectiveness of the restriction as a result of not having to catch hunters in the actual act of discharging lead gunshot, the Commission considers it appropriate to apply the restriction on carrying lead gunshot not only to carrying in wetlands but also to carrying in the fixed buffer zone around wetlands.
- (22) As gunshot is generally not designed or placed on the market specifically or exclusively for use in or around wetlands, a restriction on the placing on the market of lead in gunshot would affect shooting in all terrains. Therefore, the restriction should be limited to the discharge of and carrying lead gunshot.
- (23) The restriction should apply to gunshot containing a concentration of lead equal to or greater than 1 %. 1 % is the concentration limit applied for the purposes of the 'non-toxic' gunshot approval process in the United States of America in order to avoid a significant toxicity danger to migratory birds and other wildlife, or their habitats. Moreover, a 1 % concentration threshold for the restriction is considered to be sufficient to address the risks posed by lead-containing gunshot material whilst also being readily achievable by producers of alternative gunshot, given that some of those alternatives are likely to contain lead as an impurity.
- (24) It is appropriate to mirror the definition of 'wetlands' used in the Convention on Wetlands of International Importance (Ramsar Convention) signed in Ramsar on 2 February 1971 for the purposes of the restriction, as was proposed by the Agency and confirmed in the opinions of RAC and SEAC, since that definition is comprehensive, covering all types of wetlands (including peatlands, where many waterbirds are also found), and since the Ramsar Convention has also developed a classification system for wetland types to help in the identification of wetlands.
- (25) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the restriction and Member States should be allowed sufficient time to prepare for its enforcement. Taking into account the views expressed by RAC and SEAC regarding the feasibility and appropriateness of a shorter period than the three years proposed by the Agency, and taking account particularly of the estimated impact each year of introducing more lead into wetlands through the use of lead gunshot, application of the restriction should be deferred for 24 months.
- (26) In September 2018, the Agency published the results of an investigation report (6) reviewing the available information on various uses of lead including, among other things, in gunshot used in terrains outside of wetlands, namely terrestrial environments. Since the investigation report found, inter alia, that the available information suggested that the use of lead gunshot in terrestrial environments posed a risk to both human health and the environment, the Commission requested the Agency in 2019 to prepare an Annex XV dossier with a view to a possible restriction on the placing on the market and use of lead in ammunition and in fishing tackle (7).
- (27) Moreover, in their opinions on the Annex XV dossier on the use of lead in gunshot for shooting in wetlands, RAC and SEAC indicated their agreement with the Agency's view that a ban on the placing on the market and use of lead gunshot in all terrains would result in a higher level of environmental protection and would be more effective from the point of view of practicality and enforceability.
- (28) In some Member States, the restriction introduced by this Regulation may give rise to particular difficulties due to the specific geographical conditions in those Member States. For Member States with a significant proportion of wetlands in their territory, a ban on discharging and carrying of lead gunshot in and around wetlands could in practice have a similar effect to a total ban on all shooting across the whole territory since hunters of all kinds would almost inevitably find themselves frequently in or near wetlands. Moreover, the resources that would have to be devoted to the enforcement of a restriction targeted only at areas in and around wetlands may not be much smaller, and may indeed be greater, than the resources needed to enforce a restriction covering their territory as a whole.

⁽⁶⁾ https://echa.europa.eu/documents/10162/13641/lead_ammunition_investigation_report_en.pdf/efdc0ae4-c7be-ee71-48a3-bb8abe20374a

⁽⁷⁾ https://echa.europa.eu/documents/10162/13641/rest_lead_ammunition_COM_request_en.pdf/f607c957-807a-3b7c-07ae-01151001d939

- (29) Given the difficulties described, the need for the measure to be not only effective, but also simple and fair on the hunting community as a whole, and also the results of the Agency's investigation report and the views of RAC and SEAC, the Commission considers that those Member States where such difficulties are likely to arise should be given the option to impose a different restriction in their territory which would prohibit both the placing on the market of lead gunshot, and also the discharging of and carrying lead gunshot throughout their territory, whether in wetlands or elsewhere, in connection with any type of shooting.
- (30) In the interests of legal certainty, it is important to identify clearly the Member States who are to be eligible to make use of that option. The option should be available to those Member States where at least 20 % of their territory is made up of wetland areas. A 20 % threshold should cover those Member States who are likely to experience the difficulties due to the specific geographical conditions.
- (31) Since the restriction that could be imposed by those Member States would be more stringent than the one limited to areas in and around wetlands, it is appropriate to set a longer period for the introduction of that restriction. That period should be set at 36 months, which corresponds to the period originally suggested by the Agency in the Annex XV dossier.
- (32) For reasons of transparency and legal certainty, the Member States making use of the option should be required to notify the Commission of their intention and to communicate the measures adopted by them to give effect to it within certain deadlines, and the Commission should make the notices of intention as well as texts of the adopted national measures publicly available without delay.
- (33) A number of Member States have in place national provisions prohibiting or restricting lead in gunshot for the protection of the environment or human health in a more severe manner than laid down in this Regulation. Forcing those Member States to reduce the existing level of protection in order to comply with this Regulation might lead to the increase of use of lead in gunshot 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 such stricter provisions.
- (34) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (35) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by 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, 25 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, in entry 63, the following paragraphs are added in the second column:

- '11. Doing either of the following acts after 15 February 2023 in or within 100 metres of wetlands is prohibited:
- (a) discharging gunshot containing a concentration of lead (expressed as metal) equal to or greater than 1 % by weight;
- (b) carrying any such gunshot where this occurs while out wetland shooting or as part of going wetland shooting.

For the purposes of the first subparagraph:

- (a) "within 100 metres of wetlands" means within 100 metres outward from any outer boundary point of a wetland;
- (b) "wetland shooting" means shooting in or within 100 metres of wetlands;
- (c) if a person is found carrying gunshot in or within 100 metres of wetlands while out shooting or as part of going shooting, the shooting concerned shall be presumed to be wetland shooting unless that person can demonstrate that it was some other type of shooting.

The restriction laid down in the first subparagraph shall not apply in a Member State if that Member State notifies the Commission in accordance with paragraph 12 that it intends to make use of the option granted by that paragraph.

- 12. If at least 20 % in total of the territory, excluding the territorial waters, of a Member State are wetlands, that Member State may, in place of the restriction laid down in the first subparagraph of paragraph 11, prohibit the following acts throughout the whole of its territory from 15 February 2024:
- (a) the placing on the market of gunshot containing a concentration of lead (expressed as metal) equal to or greater than 1 % by weight;
- (b) the discharging of any such gunshot;
- (c) carrying any such gunshot while out shooting or as part of going shooting. Any Member State intending to make use of the option granted by the first subparagraph shall notify the Commission of this intention by 15 August 2021. The Member State shall communicate the text of the national measures adopted by it to the Commission without delay and in any event by 15 August 2023. The Commission shall make publicly available without delay any such notices of intention and texts of national measures received by it.
- 13. For the purposes of paragraphs 11 and 12:
- (a) "wetlands" means areas of marsh, fen, peatland or water, whether natural or artificial, permanent or temporary, with water that is static or flowing, fresh, brackish or salt, including areas of marine water the depth of which at low tide does not exceed 6 metres;
- (b) "gunshot" means pellets used or intended for use in a single charge or cartridge in a shotgun;
- (c) "shotgun" means a smooth-bore gun, excluding airguns;
- (d) "shooting" means any shooting with a shotgun;
- (e) "carrying" means any carrying on the person or carrying or transporting by any other means;
- (f) in determining whether a person found with gunshot is carrying gunshot "as part of going shooting":
 - (i) regard shall be had to all the circumstances of the case;
 - (ii) the person found with the gunshot need not necessarily be the same person as the person shooting.

14. Member States may maintain national provisions for protection of the environment or human health in force on 15 February 2021 and restricting lead in gunshot more severely than provided for in paragraph 11.

The Member State shall communicate the text of those national provisions to the

The Member State shall communicate the text of those national provisions to the Commission without delay. The Commission shall make publicly available without delay any such texts of national provisions received by it.'