Consultation on a proposed restriction on lead and its compounds in ammunition for outdoor shooting and in fishing tackle[1]

SUMMARY

The proposed restriction aims at *'addressing the risks for human health and the environment posed by the use of lead in ammunition, i.e. gunshot used in terrains other than wetlands, bullets and pellets used both in wetlands and in terrains other than wetlands, as well as of lead in fishing tackle'* as per the request of the European Commission[2]. The restriction proposal refers exclusively to outdoor civilian uses and is complementary to the existing restriction on the use of lead gunshot in wetlands.

Ingestion of lead objects by birds (including lead projectiles, fishing sinkers and lures) results in a range of acute and chronic toxicological effects including death. The effects are dependent on the quantity of lead ingested and the body weight of the animal. Numerous studies have reported incidences of the ingestion of lead projectiles and fishing tackle. According to the restriction report, at least 135 million birds are at risk of primary poisoning from lead gunshot, 14 million birds are at risk of secondary poisoning arising from the ingestion of lead gunshot or other lead projectiles, and seven million birds are at risk because of ingestion (primary poisoning) of fishing sinkers and lures.

Lead is not only hazardous for the environment, it is also toxic to humans of all ages and affects various organs. The detrimental health effects of lead are well documented. The range of reported adverse effects includes neurodevelopmental effects, cardiovascular diseases, impaired renal function (including chronic kidney disease – CKD), hypertension, impaired fertility, and adverse pregnancy outcomes. However, the greatest public health concern is the neurodevelopmental toxicity of lead in children aged seven and younger. It is estimated that in any given year about 1 million children are vulnerable to lead exposure resulting from the use of lead in ammunition for outdoor shooting and in fishing tackle.

The restriction proposes to ban the use of lead where technically and economically feasible alternatives exist. This includes the sale and use of lead gunshot for hunting and sports shooting. For other uses, where alternatives show lower performance, such as for bullets and airgun pellets in outdoor sports shooting, the proposal intends to restrict the use to those sports shooting ranges where measures are in place to effectively collect the spent lead ammunition before it can result in risks.

RESTRICTION REPORT CONSULTATION

The consultation on this proposed restriction will start on 24 March 2021 and end on 24 September 2021. ECHA's Committees welcome early comments **by 5 May 2021** to help them in the first discussion of the proposal in June 2021.

[1] The information note has been prepared based on the restriction report prepared by ECHA.
[2] European Commission (2019): https://www.echa.europa.eu/documents/10162/13641/rest_lead_ammunition_COM_request_en.pdf/f607c957-807a-3b7c-07ae-01151001d939

RESTRICTION REPORT CONSULTATION

Interested parties can comment on the restriction report using the relevant web form on the ECHA website. When submitting information, please keep in mind:

- It is necessary to provide **supporting evidence** to justify the information submitted in the consultation, otherwise ECHA's Committees may not be able to independently evaluate the information submitted.
- Information should be submitted as early as possible in the process (see the plenary plan below).
- Information arriving after the closing date or via other channels than the web form **will not** be taken into account by ECHA's Committees.
- It is your responsibility to remove confidential information from the comments and attachments submitted with non-confidential status. If you need more time to collect information on certain aspects while other information is readily available, we advise you to file separate submissions so that information can be used optimally during the opinion development process.

Further information can be found in the consultation guidance available at: https://echa.europa.eu/documents/10162/13641/restriction_consultation_guidance_en.pdf

Respondents are also encouraged to take into account when certain aspects of the proposal are planned to be discussed in the Committees' plenary meetings (see table below) and time their submissions accordingly (multiple submissions are possible throughout the consultation).

	Committee	
Plenary meeting of the Committee (timing)	**Committee for Risk Assessment (RAC)**	**Committee for Socio-Economic Analysis (SEAC)**
1 (2.5 months after consultation starts)	Verify the proposed scope. Conclude on hazard and hold preliminary discussion on exposure/risk.	Verify the proposed scope. Conclude on costs of the proposed restriction and hold preliminary discussions on its benefits.
2 (5.5 months after consultation starts)	Conclude on exposure/risk and hold preliminary discussion derogations.	Conclude on benefits and hold preliminary discussions on proportionality and derogations.
3 (8.5 months after consultation starts)	Finalise the derogations. Finalise the opinion plus justification text and adopt the final opinion.	Conclude on proportionality and derogations. Finalise the opinion plus justification text and agree the draft opinion.
4	Not relevant.	Conclude on issues raised during the SEAC draft opinion consultation. Adopt the final opinion.

Information on the hazards of the substance(s) and the costs of the proposal would make the most impact if submitted by month two and exposure/risk, benefits and derogations by month four of the consultation. This early submission would also allow the information to be considered at the appropriate time. This timing takes into account that stakeholders have access to the dossier much earlier than in the past, as it is pre-published approximately two weeks after submission or more than six weeks in advance of the start of the consultation.

It is possible to submit more than one consultation response during the six-month period. Please take this into account when deciding when to submit information.

The final opinions of both of ECHA's Committees are scheduled to be available by March 2022. ECHA will send these opinions to the European Commission, which will take the decision whether to include the proposed restriction in the Annex XVII of the REACH Regulation.

PROPOSED RESTRICTION

Scope

The scope of the restriction proposal is on the placing on the market and the use of lead in projectiles used in firearms and airguns for civilian outdoor activities. Therefore, the use of lead in other ammunition components such as primers, propellants or casings are outside the scope of the restriction report and the restriction proposal.

In addition, military uses of lead projectiles, along with other similar non-civilian uses of lead projectiles, such as by law enforcement and customs authorities, are also outside the scope of the restriction proposal. It should nevertheless be noted that the use of lead in full metal jacket ammunition (a type of bullet used by the military, police and security services), which can sometimes be used for hunting, is within the scope of the restriction proposal in case of civilian use.

The restriction proposal also includes the placing on the market and the use of lead in fishing tackle for both recreational and commercial fishing irrespective of whether these take place in freshwater (i.e. in rivers, lakes and ponds), estuarine or marine environments. In addition, as fishing sinkers can be either purchased from a retailer or manufactured directly by consumers (also known as 'home-casting'), the use of both purchased and home-casted fishing tackle containing lead is in the scope of the proposed restriction.

The list of uses assessed in the restriction proposal are detailed in the table below.

Sector of use	Use in scope of the restriction investigation
Hunting	Hunting with shot shell ammunition Hunting with bullets – small calibre[1] Hunting with bullets – large calibre

Sector of use	Use in scope of the restriction investigation
Sports shooting	Outdoor sports shooting with shot shell ammunition Outdoor sports shooting with bullets Other outdoor shooting using air rifle/gun/pistol
Shooting with historical weapons	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments
Fishing	Lead in fishing sinkers and lures Lead in fishing nets, ropes and lines (where lead in embedded/enclosed in the fishing nets, ropes and lines)
Uses out of scope[2]	Indoor shooting[3], police, law enforcement, military applications, protection of critical infrastructure, commercial shipping or high-value convoys, soft-target and public space protection, security purposes, technical testing and/or proofing, testing and development of materials and products for ballistic protection, forensic, medical, historical and other technical research or investigation.

Notes: [1] this use includes hunting with airgun; [2] uses out of the scope as per the Commission request and subsequent clarifications; [3] should be understood as inside a building.

Reasons for action

The principal routes by which animals are exposed to lead from ammunition or fishing tackle are:

- primary ingestion (primary poisoning) defined for the purpose of the restriction as the ingestion of any lead object directly from the environment through normal feeding or foraging activity (e.g. mistaking for grit),
- secondary ingestion (secondary poisoning) defined for the purpose of the restriction as the indirect ingestion of any lead object via the consumption of food (e.g. embedded fragments in prey or carrion).

The primary ingestion route is relevant for bird species that rely on the ingestion of grit or stones to grind their food. For example, lead gunshot and split shot sinkers[3] may appear similar to grit or food items such as seeds, as shown in the figure below. Further to direct ingestion, predatory or scavenging birds (as well as other wildlife) are at risk of secondary poisoning through eating contaminated animals (e.g. a dead animal or a fish) that have lead gunshot, bullet, or fishing tackle embedded in their tissues or digestive tract (or where embedded or ingested lead objects result in elevated tissue concentrations through dissolution). It is not only small sized lead object that can be ingested. Various lead objects

[3] Split shot sinkers are round sinkers with a small slot through a portion of it. Split shot sinkers range from 0.01 g to 4.8 g in weight. The smallest split shots (≤0.06 g) are often referred as 'dust split shots'.

including bullets and other projectiles, but also sinkers and lures up to 50 g (and even more for some types of birds), have been found in the gizzards, or digestive tracts of birds.

Why lead can be mistaken for food by birds

Figure legend: These photos are identical except that the eight lead split shot sinkers are circled in the second photo. They are nearly indistinguishable from the surrounding gravel. Photo courtesy of New York State Department of Environmental Conservation (Schroeder, 2010)

Lead gunshot, and other lead projectiles (e.g. bullets), that remain in the environment after use are available to be ingested. Lead fishing tackle is also frequently lost during use and affects birds in the same way as lead gunshot and projectiles if ingested. In addition, some contemporary fishing practices, and some fishing tackle suppliers, encourage the deliberate release of lead sinkers to the aquatic environment in some circumstances (termed as 'dropping the lead').

The use of lead ammunition and fishing tackle remains widespread in Europe despite its well documented hazard properties and adverse effects on both wildlife and human health. Approximately 97 000 tonnes of lead are dispersed every year in the environment: 79% from sports shooting, 14% from hunting and the rest from fishing activities. Assuming current releases, and if no further regulatory action was taken, approximately two million tonnes of lead would be released to the environment over the next 20 years.

It is estimated that, in the EU, at least 135 million birds are at risk of primary poisoning of lead gunshot, 14 million are at risk because of secondary poisoning arising from the ingestion of lead gunshot or other lead projectiles, and seven million birds are at risk because of ingestion (primary poisoning) of fishing sinkers and lures.

Lead is not only hazardous for the environment; it is also toxic to humans of all ages and affects various organs. Lead can accumulate in the body, primarily in the skeleton, and is then released gradually back into the blood stream, even if lead exposure has already ceased. This legacy effect may last for months to years after exposure.

Human exposure to lead occurs via two main routes: inhalation and ingestion. Inhalation exposure may occur during (i) the shooting of gunshot and projectiles, and (ii) the melting of lead for the home-casting of gunshot, projectiles and fishing tackle (via lead fumes and dust). Ingestion of lead (as small objects or dust) may happen via (i) direct ingestion, mouthing or chewing, or (ii) via hand to mouth exposure when manipulating lead gunshot, projectiles or fishing sinkers and lures.

Human ingestion of lead may also occur via the consumption of game meat hunted with lead gunshot or projectiles, as the existing best practices to handle hunted game meat do not eliminate lead in game meat[4].

Except for game meat consumption, the available information is not sufficient to properly quantify the risks to human health from the assessed uses. In the absence of adequate data, the risks to human health associated with the use of lead gunshot, projectiles and fishing tackle have been described and assessed in the restriction report in a semi-quantitative manner. The risk assessment is underpinned by various studies reporting potential and actual incidence of lead exposure, as well as elevated blood lead levels observed after shooting, ingestion of lead fishing tackle, or home-casting activities. Where European studies were not available, data generated outside Europe have been taken into consideration.

The assessment performed does not identify any risk to human health or the environment associated with the use of lead in fishing nets, ropes and lines where lead is embedded/enclosed. Therefore, no restriction is proposed for this specific use.

Nevertheless for all the other uses assessed, the restriction report concludes that the use of lead in gunshot, bullets, projectiles, fishing lures and sinkers poses a risk to wildlife, livestock, environment and human health that is **not adequately controlled**, and needs to be addressed at the EU level.

Some Member States, or regions, have enacted legally binding national measures prohibiting the use of lead in hunting, outdoor shooting or fishing to reduce lead emissions and exposure. Notwithstanding these efforts, only Union-wide measures will effectively curb lead emissions, and exposure and address the identified risks.

Consequences of the action

The restriction proposal comprises three main types of measures:

1. A ban on placing on the market combined with a ban on using lead ammunition or fishing tackle where their use will inevitably result in releases to the environment, irrespective of the conditions of use, and where suitable alternatives are available (i.e. technically and economically feasible and resulting in an overall reduction of the risk for human health and the environment). For some of these uses, a transition period is proposed to allow sufficient time for stakeholders to adapt to the restriction. This includes a ban on the placing on the market and use of lead gunshot for any purpose.
2. Where a ban on placing on the market would disproportionately affect uses outside of the scope of the proposed restriction a ban on the use only is proposed.
3. An obligation for the retailers to inform consumers at the point of sale about the phase out timelines for uses of lead in ammunition and fishing tackle as well as

[4] Current EU food regulations do not set a maximum permissible level of lead in wild game intended for consumption. However, should such a level be set, this would not be fully protective as it would not affect exposure of lead via game meat that is consumed outside of the market (i.e. own use, use by friends or family). This measure is also not fully protective for wildlife as the entrails left after the hunt could still contain lead and would contribute to the exposure to lead for raptors and scavengers.

information on the presence, toxicity and risk of lead to human health and the environment. Retailers will also be obliged to inform customers about alternatives to lead-containing articles (fishing tackle, gunshot, projectiles). This requirement is built on recent studies that highlight the importance of hunters' and fishers' awareness for changing purchasing behaviour.

In addition, where a ban on placing on the market or on use would be disproportionate, or where releases to the environment could be minimised using appropriate risk management measures, derogations are proposed. These derogations include obligations to comply with strict operational conditions at the point of sale or at the point of use.

The largest volume of bullets placed on the market are for sports shooting, where the Dossier Submitter has concluded that the risks can be managed via the use of adequate measures (i.e. shooting in designated sports shooting ranges with appropriate containment measures in place). Therefore, a ban on placing on the market of projectiles other than gunshot is not proposed if the risk is controlled at the point of use.

Although not the preferred option to address the identified risks, the restriction proposal includes details of an optional derogation for the continued use of lead gunshot for sports shooting in case policy makers would not wish to impose a ban on lead gunshot for sports shooting. This derogation would set minimum standards for risk management measures, as well as licensing obligations, at sites using lead gunshot and would introduce obligations for Member States to license only those athletes that have a legitimate need to use lead gunshot (for example to train for or participate in international competitions). In addition, this derogation would be accompanied by a labelling requirement for the supplier and a reporting obligation for the Member States. This will allow the Commission to monitor the continued use of lead gunshot in different EU Member States and facilitate the enforcement of the derogation.

It is important to note that this optional derogation is not as effective in controlling the identified risks as a ban on use but may be considered more proportionate with regard to its socio-economic impacts on internationally competing athletes, should the rules of these competitions continue to require the use of lead gunshot.

The overall risk reduction potential and the socio-economic impacts of the proposed restriction for each individual sector and use affected have been assessed and the conclusion is that the proposed restriction is effective in terms of net risk reduction, and proportionate in terms of costs.

The proposed restriction is indeed estimated to result in a cumulative emission reduction of approximately 1.5 million tonnes of lead over the 20-year period following its entry into force. This represents a reduction of 78% of the quantified emissions of lead that would have occurred in the absence of the proposed restriction.

As regards human health, the most important and most robustly quantified impacts relate to the protection of children of households that frequently consume game meat. Under plausible assumptions, it is estimated that the ban of large-calibre lead bullets and lead gunshot could avoid IQ loss in about 7 000 children per year, corresponding to a welfare loss of roughly €70m. A less robust estimate was made for the reduced risk of CKD in about 1 150 individuals. A tentative valuation value of €7.5m to €75m.

In addition, the alternatives identified have in general a better environmental footprint[5] than lead.

The cost-effectiveness of avoided emissions (where possible and meaningful to quantify) was estimated to range between 0.5 €/kg and 1 513 €/kg per kg of lead release avoided depending on the affected sector. Overall, the restriction appears to be more cost-effective than previous REACH restrictions which were addressing similar human health concerns, but less cost-effective than the restriction on the use of lead in wetlands, which had a central cost-effectiveness estimate of 9.8 €/kg of lead emission avoided.

The costs of the labelling requirement could not be quantified but are minor in comparison to other costs estimated.

HOW TO SUBMIT A COMMENT IN THE CONSULTATION OF THE PROPOSED RESTRICTION

When you are ready to make your comments, click on the appropriate link on the ECHA website. Please be aware that it is not possible to save your submission and come back to it, so you should already have your comments prepared in an attachment or saved in some other format in advance. The web form contains five main parts:

- Introduction: Containing some general information on the restriction and a link to this note and the guidance.
- Section 1: Personal information.
- Section 2: Organisational information.
- Section 3: Non-confidential comments on the proposal – both general comments and information on specific information requests (see below). Your responses can be entered directly into the form or through section 4 as an attachment. However, please do not submit the same comments via both means. General comments can be on any aspect of the restriction report, including on issues related to socio-economic analysis.
- Section 4: Non-confidential attachments can be added here.

SPECIFIC INFORMATION REQUESTS

In addition to comments on the overall dossier, interested parties will be invited to submit responses to specific information requests.

The specific topics on which information is requested will be published on the consultation page on ECHA's website at: https://echa.europa.eu/restrictions-under-consideration

[5] Considering the following elements: toxicity and risk for the human health, toxicity and risk for the environment (both aquatic toxicity and wildlife ingestion), sourcing of the raw material (extraction vs recycling), resource depletion (water, energy, chemical) and emission of Greenhouse gases