ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME: LEAD

IUPAC NAME: LEAD

EC NUMBER(S): 231-100-4

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CONTACT DETAILS OF THE DOSSIER SUBMITTER:

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Note on terminology

Various English language terms are commonly used in relation to hunting, shooting and fishing (as well as to birds and their habitats). As these terms sometimes have different meanings for different stakeholders this could potentially result in misunderstanding. Therefore, for the purposes of this Annex XV report, the usage of certain key terms is outlined below.

Whilst every effort has been made to ensure the consistent use of terminology in this report, source material may not always have used these terms consistently.

Waterfowl	The term waterfowl is typically used in Europe to refer to species from the avian family Anatidae, i.e. ducks, geese and swans. These birds are adapted for surface water swimming (i.e. having webbed feet and oily feathers). However, a broader interpretation to include other waterbirds (e.g. common snipe) that are hunted is not uncommon. Hunted waterfowl and waterbirds can be referred to as game waterfowl.
Wildfowl	The term wildfowl can refer to Anatidae but may also be used to refer to any hunted (game) bird, including upland and lowland 'fowl' game birds such as grouse, pheasants or partridges. However, the term is principally associated with the hunting of game *waterfowl*.
Waterbird	The term waterbird is used in the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA) to refer to birds that are ecologically dependent on wetlands for at least part of the annual cycle. This definition includes many European species of divers, grebes, pelicans, cormorants, herons, storks, rails, ibises, spoonbills, flamingos, ducks, swans, geese, cranes, waders, gulls, terns and auks.
Raptors (predatory or scavenging)	Predatory birds (birds of prey) that have keen vision, powerful talons with claws and strong curved beaks, including owls. These birds can also scavenge carrion, either occasionally or as their main food source. Generally considered to exclude storks, gulls, skuas and penguins, even though these birds are also predators.
Scavenging birds (non-raptor)	Other bird species that typically scavenge carrion e.g. vultures, corvids, gulls
Projectile(s)	Object(s) expelled from the barrel of a gun. Examples of relevant types of projectiles are bullets, gunshot, shotgun 'slugs', air gun pellets and BBs.
Primer	A chemical compound that ignites the propellant (e.g. gunpowder) when struck by a firing pin. Primer may be placed either in the rim of the case (rimfire) or in the centre of the base of the case (centrefire).
[gun] barrel	A barrel is the metal tube that the projectile travels through as a result of pressure from burning gunpowder, compressed air, or other like means. The barrel also guides the projectile in the intended direction.
Hunting	Pursuing and killing live quarry using a gun.

Sports shooting	Shooting at any inanimate (non-living) target with a gun. Includes practice, or other shooting, performed in preparation for 'hunting'. Examples of relevant types of targets are 'clay pigeons', paper targets, biathlon targets, silhouettes etc.
Wildfowling	The hunting of wildfowl, particularly ducks, geese and waders.
Small game	For example, waterfowl, pheasants, partridges, hares, squirrels, musk rats, beavers, rabbits, foxes, racoon dogs, wild cats, martens, badgers, polecats etc.
Large game	For example, roe deer, chamois, mouflon sheep, fallow deer, sika deer, ibex, moose, brown bear, wild boar, red deer, seals, wolf, jackal etc.

Change version history

Version	Change history	Date	Prepared by
1.0	Pre-publication of the Annex XV restriction report and its annexes. Version 1.0 was submitted on 15.01.2021, and published on the ECHA website on 3 February 2021 (this version is not meant for consultation).	15.01.2021	Dossier submitter
2.0	Revised version of the Annex XV restriction report and its annexes to take into account some of the recommendations of the RAC and SEAC rapporteurs made during the conformity check. This version is intended to be used for the 6-month consultation. The main changes in the Annex XV restriction report and its annex are listed below. The following sections in the Annex XV restriction proposal were updated: - Executive summary: updated to reflect the changes in the main body of the report - Section 1.4 - Information on good hygiene practice to reduce lead exposure of shooters (added) - Section 1.4 - information on lead gunshot, and bullets recovery RMMs incidence (added) - Section 1.4 - information on ferrous chemical amendments (added) - Section 1.4 - information remediation (updated) - Section 1.5 – estimation of lead released from hunting and sports shooting (updated) - Section 1.5 – primary and secondary exposure to birds, including likelihood of ingestion (updated) - Section 1.5 – risk characterisation for the environment (updated) - Section 1.5 - Additional risks related to sports shooting – clarification on the contamination of recreational areas (added) - Section 1.6 – HH hazard assessment (updated) - Section 1.6 – exposure assessment for lead in game meat (updated) - Section 1.6 – risk characterisation for the HH (updated) - Section 1.8 – baseline for hunting and sports shooting (updated) - Section 1.8 – impact on birds (updated) - Section 2.1 – impact assessment and RO comparison approach (clarified) - Section 2.2 – outcome of the RO analysis for hunting and sports shooting (clarified)	24.03.2021	Dossier submitter

Version	Change history	Date	Prepared by
	- Section 2.3 – justification of the restriction option (clarified) - Section 2.5 - impact of the restriction on lead in hunting (updated) - Section 2.6 - impact of the restriction on lead in sports shooting (updated) - Section 2.7 - impact of the restriction on other shooting (updated) - Section 3.1 – uncertainties on human health risks, and SEA sensitivity analysis for hunting (added) - Section 3.2 - uncertainties on human health risks, estimated releases, and number of shooting ranges for sports shooting (added) - Section 4.2 – conclusion for sports shooting (updated) The following sections in the Annexes were updated: - Annex A.1 - Legislation in the EU related to lead bullets (updated) - Annex A.2.- Manufacturing process description (split shots) (added) - Annex B.4 - Field evidence of lead and steel shot behaviour in soils (added) - Annex B.7 - Toxicity to birds (duplicate information removed) - Annex B.9 – Sports shooting (updated) - Annex B.10 – Human health (updated) - Annex D.1 – Baseline for lead in hunting (updated) - Annex D.1 – Alternative for lead in gunshot and bullets (updated) - Annex D.1 – Assumptions for the impact assessment (updated) - Annex D.4 – Existing EU legislation and other Union-wide risk management options on fishing tackle (clarified) - Annex D.4 – Alternatives for fishing tackle (iron added) - Annex E.4 (updated) In addition, various spelling mistakes and formatting issues were corrected throughout. Complementary reference information was added and the wording was reviewed for consistency.		

Preface

The preparation of this Annex XV restriction report on lead in shooting, hunting and fishing was initiated based on Article 69(1) of the REACH Regulation at the request of the European Commission[1].

The proposal has been prepared using version two of the Annex XV restriction report format and consists of a summary of the proposal, a report setting out the main evidence justifying the proposed restriction and Appendices with more detailed information and supporting analysis.

ECHA (hereafter referred to as the Dossier Submitter) would like to thank the many stakeholders that made contributions to the call for evidence (3/10/2019 until 16/12/2019), the stakeholder workshop on lead in shooting and hunting held in February 2020 and the fishing round table held on 18 November 2020.

This version of the report has been reviewed for confidential information and any such information has been redacted.

[1] https://echa.europa.eu/documents/10162/13641/rest_lead_ammunition_COM_request_en.pdf

Executive 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 Commission (EU Commission, 2019)[2]. The restriction proposal is complementary to the existing restriction on the use of lead gunshot in wetlands.

Since 'ammunition' is a generic term describing one or more components (e.g. primer, propellant, projectiles and casing), the Dossier Submitter clarified with the Commission that the scope of the request 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 this Annex XV 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 the police, security services and customs forces, 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.

Indoor uses of lead projectiles are also excluded from the scope. The exhaustive list of uses excluded from the scope of the restriction proposal is available in Table 1.

Regarding the use of lead in fishing tackle, the scope includes tackle used 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 Annex XV report and proposed restriction.

Following these clarifications, the Dossier Submitter identified relevant lead projectiles and fishing tackle, and the articles were split into a series of different uses after considering the technical function of lead, the operational conditions and the potential for substitution with alternatives. The Dossier Submitter further subdivided the uses in different supply chains, type of lead article and operating conditions.

An example of this approach is the differentiation between the use of lead gunshot at shooting ranges (e.g. for shooting at clay pigeons) versus the use of lead gunshot for hunting. These uses have similar technical requirements and substitution profiles but involve different operational conditions (e.g. number of shots fired, possibility to implement risk management measures), and affect different actors.

The uses assessed by the Dossier Submitter as well as the uses excluded from the scope are listed in Table 1.

[2] https://www.echa.europa.eu/documents/10162/13641/rest_lead_ammunition_COM_request_en.pdf/f607c957-807a-3b7c-07ae-01151001d939

Table 1 Overview of the uses assessed, and uses out of scope

Sector of use	Use #	Use in scope of the Annex XV restriction investigation
Hunting	1	Hunting with shot shell ammunition
	2a	Hunting with bullets – small calibre[1]
	2b	Hunting with bullets – large calibre
Sports shooting	3	Outdoor sports shooting with shot shell ammunition
	4	Outdoor sports shooting with bullets
	5	Other outdoor shooting using air rifle/gun/pistol
Shooting with historical weapons	6	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments
Fishing	7	Lead in fishing sinkers and lures
	8	Lead in fishing nets, ropes and lines (where lead in embedded/enclosed in the fishing nets, ropes and lines)
The following uses are 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 analysis, 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 (EU Commission, 2019)[3]*, and subsequent clarifications; [3] should be understood as inside a building*

Irrespective of the source of lead release to the environment, its hazard (particularly its hazard via ingestion) is similar. Therefore, a single generic environmental risk assessment was conducted for all uses that could result in primary and secondary poisoning of wildlife (with a focus on birds). This was done on the basis that it was not practicable or meaningful to disaggregate the risks to birds resulting from the different uses. Other risks relevant for the sports shooting sector only, as for example risks to livestock (ruminants) and the soil compartment in general, were also assessed at a qualitative level.

The hazards of lead, as well as its toxicokinetics (i.e. bioavailability and absorption) are in general well understood and documented for the environment. Ingestion of lead objects by birds (including lead projectiles and fishing sinkers and lures) results in a range of acute and chronic toxicological effects (including death) dependent on the quantity of lead ingested

[3] https://www.echa.europa.eu/documents/10162/13641/rest_lead_ammunition_COM_request_en.pdf/f607c957-807a-3b7c-07ae-01151001d939

and the body weight of the animal. Numerous studies have reported incidences of the ingestion of lead projectiles and fishing tackle.

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 this report 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 this report as the indirect ingestion of lead via the consumption of food (e.g. embedded fragments/particles in prey or carrion, contaminated silage or grass, lead contaminated tissues).

The primary ingestion route is relevant for bird species that feed in nearshore soils and sediments or that rely on the ingestion of grit or stones to grind their food. For example, lead gunshot and split shot sinkers[4] may appear similar to grit or food items such as seeds (cf. Figure 1-1). 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 results in elevated tissue concentrations through dissolution). It is not only small sized lead object that can be ingested. Various lead objects 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.

Figure 1-1: Why lead can be mistaken for grit or 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

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[4] 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'.

'dropping the lead') to ensure a better catch rate.

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 1.94 million tonnes of lead would be released to the environment over the next 20 years.

Table 2 gives a summary of the identified risks and estimated lead releases to the environment for all the uses.

Environmental risk characterisation is based on a weight of evidence approach underpinned by key case studies on (i) poisoning or mortality of birds after lead projectile or sinker/lure ingestion, (ii) lead concentration in bird tissues after ingestion of lead objects (including comparison with threshold value for specific adverse effects), (iii) lead concentrations in the soils of shooting ranges, iv) poisoning of livestock. Risks to surface water and groundwater were assessed under the humans via the environment route.

The Dossier Submitter estimates that, in the EU, at least 135 million birds are at risk of primary poisoning from lead gunshot, 14 million are at risk of secondary poisoning and seven million birds are at risk because of the 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.

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 cessation.

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 via the environment may occur via the intake of food and drinking water contaminated from shooting activities and 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[5].

In terms of human risk characterisation, the Dossier Submitter is reflecting the human health risk associated to the game meat consumption by calculating the effect of the blood lead level increment with respect to:

[5] 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.

- Loss of IQ points in young children,
- % increase in the prevalence of chronic kidney disease (CKD) in adults, and
- increase in systolic blood pressure in adults.

The Dossier Submitter estimates that in any given year about 1 million children are vulnerable to lead exposure.

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 gunshots, projectiles and fishing tackle are essentially described and assessed 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, the Dossier Submitter considered data generated outside Europe.

The Dossier Submitter 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 use 8.

Nevertheless for all the other uses assessed, the Dossier Submitter concludes that (consistent with the final RAC opinion of the use of lead gunshot in wetlands and other restrictions on lead), 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.

The four main justifications for an EU-wide restriction measure are:

1. To ensure a harmonised high level of protection of the environment and human health to address the risks identified.
2. To address the lack of EU wide commitment to fulfil the EU Birds Directive, the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA), the (CMS) Convention[6] and the CMS Memorandum of Understanding on the Conservation of Migratory Birds of Prey in Africa and Eurasia (Raptors MOU)[7] to protect birds and their habitats.
3. To ensure the free movement of goods within the Union.
4. To ensure a level playing field for all engaged in sports shooting within the EU.

To address the risks, the Dossier Submitter conducted an analysis of risk management options (RMOs) identifying for each use the most effective (i.e. in terms of targeting the identifed risk, risk reduction and proportionality to the risk), practical and monitorable measure(s). The RMOs assessed included regulatory measures under REACH and other existing EU legislation as well as other possible Union-wide RMOs such as voluntary measures, training to obtain hunting/fishing licences, etc.

The Dossier Submitter assessed the overall risk reduction potential and the socio-economic impacts of the proposed restriction options for each sector (hunting, sports shooting, fishing and other outdoor-uses), and took into account the potential interlinkages between those

[6] Convention on Migratory Species: https://www.cms.int/en/legalinstrument/cms
[7] https://www.cms.int/raptors/en/legalinstrument/birds-prey-raptors

sectors (for example, when lead projectiles are used both for hunting and sports shooting).

As a result, the Dossier Submitter is proposing a restriction comprising three main types of measures:

1. A ban on placing on the market combined with a ban on using lead articles 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, 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 comply with the restriction. **This includes a ban on the placing on the market and use of lead gunshot for <u>any purpose</u>.**
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, for example for the bullets (i.e. projectiles not defined as gunshot).
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 sinkers as well as 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, projectile). 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 RMMs, the Dossier Submitter proposes conditional derogations, with an obligation to comply with strict operational conditions at the point of sale or at the point of use, respectively. The derogation would be accompanied by a reporting requirement to monitor the effectiveness of the operational conditions and improve the quality of information available to assess the risks from uses of lead in the future. The granting of derogations as well as the reporting requirement will be done at the level of EU Member States.

Specifically, the largest volumes 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 RMMs (i.e. shooting in designated sports shooting range 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.

The derogation for continued use of lead gunshot for sports shooting (identified as 'OPTIONAL CONDITIONAL DEROGATION' in Table 2 below) is presented as an option in case policy makers would not wish to impose a ban on lead gunshot for sports shooting (either on the placing on the market or on the use). The intention of this option is to retain a degree of control (and harmonisation) over the conditions of continued use. The derogation outlined as 'OPTIONAL CONDITIONAL DEROGATION' would set a minimum standard of RMMs at sites using lead gunshot and would introduce obligations for Member States to properly identify and 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 requirement for the Member States which would grant such a derogation. 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 the restriction including the optional conditional derogation for gunshot is not as effective in controlling the identified risks as a ban on use (identified as 'PREFERRED OPTION' in the summary table below), but may be considered more proportionate by decision makers, should the rules of these competitions continue to require the use of lead gunshot

Table 2 presents for each use, the main risks identified, the estimated releases to the environment and the proposed restriction option.

Table 2 Use overview including annual releases to the environment, main risks identified and proposed restriction

Sector of use	Use #	Use title	Main risk(s) identified	Estimated releases to the environment [tpa, in 2020]	Restriction option(s) proposed
Hunting	1	Hunting with shot shell ammunition	- Primary and secondary poisoning of wildlife (birds) - Humans via consumption of game meat	14 000 (13 000 – 15 000)	Ban on placing on the market and using – associated with a transition period (5 years to be confirmed) + Information obligation at the point of sale (retailer duty).
	2a	Hunting with bullets – small calibre	- Secondary poisoning of wildlife (birds)	24 (16 – 26)	Ban on using – associated with a transition period (5 years to be confirmed) + Information obligation at the point of sale (retailer duty). + Labelling obligation (supplier duty)
	2b	Hunting with bullets – large calibre	- Secondary poisoning of wildlife (birds) - Humans via consumption of game meat - Humans in case of home-casting	122 (110 – 142)	Ban on using – associated with a transition period (18 months to be confirmed) + Information obligation at the point of sale (retailer duty). + Labelling obligation (supplier duty)
Sports shooting	3	Outdoor sports shooting with gunshot	- Primary poisoning of wildlife (birds) - Secondary poisoning of livestock (ruminants) via silage grown on shooting ranges/ areas used as agricultural land - Humans - exposure from shooting (lead dust) - Humans (via environment) from drinking water and food	35 000 (26 000 – 45 000)[8]	**PREFERRED OPTION - same as use 1, i.e.**: Ban on placing on the market and using – associated with a transition period (5 years to be confirmed) + Information obligation at the point of sale (retailer duty). *[OPTIONAL CONDITIONAL DEROGATION under strict conditions (with permitting granted by Member States)* *+ Labelling obligation (supplier duty)* *+ Reporting]*

[8] A detailed description of all assumptions and uncertainties is provided in Annex B 9.1.3 (Sports shooting (all uses))

Sector of use	Use #	Use title	Main risk(s) identified	Estimated releases to the environment [tpa, in 2020]	Restriction option(s) proposed
	4	Outdoor sports shooting with bullets	- Ingestion of contaminated soil in the backstop berm area by livestock (ruminants) on shooting ranges/ areas used as agricultural land - Humans - exposure from shooting (lead dust) - Humans in case of home-casting (use 6) - Humans (via environment) from drinking water and food	42 000[9] (4 000 – 80 000)[10]	Conditional derogation under strict conditions (at the point of sale and point of use), otherwise: ban on using (unless bullet traps are used at the point of use) – associated with a transition period depending on the calibre: - Small calibre: 5-year transition period - Large calibre: 18-month transition period + Information obligation at the point of sale (retailer duty). + Labelling obligation (supplier duty)
	5	Other outdoor shooting using air rifle/gun/pistol			
Shooting with historical weapons	6	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments			
Fishing	7	Lead in fishing sinkers and lures	- Primary and secondary poisoning of wildlife (birds) (sinkers and lures ≤ 50 g) - Humans in case of home-casting (all weights of sinkers and lures)	3 000 (2 000 – 7 000)	Ban on placing on the market and using – associated with a transition period depending on the type and weight of the sinkers and lures: - Sinkers and lures ≤ 50 g: 3-year transition period - Sinkers and lures > 50 g: 5-year transition period - Wire: no transition period + Ban on the use with drop off techniques (no transition period) + Information obligation at the point of sale (retailer duty).

[9] For specific uses as shooting using air rifle/gun/pistol and shooting activities incl. muzzle-loaders, historical re-enactments, it was not possible to estimate the specific single release

[10] A detailed description of all assumptions and uncertainties is provided in the Annex B 9.1.3 (Sports shooting (all uses))

Sector of use	Use #	Use title	Main risk(s) identified	Estimated releases to the environment [tpa, in 2020]	Restriction option(s) proposed
	8	Lead in fishing nets, ropes and lines (where lead in embedded/enclosed in the fishing nets, ropes and lines)	- No risk to birds or other taxa identified. - No risk to human health identified	3 000 (2 000 – 4 000)	No restriction proposed.

Note: as a visual aid for the reader, the proposed restrictions including a comprehensive ban on placing on the market and using are identified with a red background in the last column of the table. Restriction proposal without a ban on placing on the market are in yellow and blue. The blue background indicates that conditional derogations are proposed.

Regarding the timeline for the impact assessment, 2022 was assumed to be the first full year of entry into force of the proposed restriction, and a 20-year period was assumed as horizon of the impact assessment.

The Dossier Submitter assessed the overall risk reduction potential and the socio-economic impacts of the proposed restriction for each individual sector and use affected and concluded 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 €70 million. A less robust estimate was made for the reduced risk of CKD in about 1 150 individuals. A tentative valuation value of €7.5 million to €75 million.

In addition, the alternatives identified have in general a better environmental footprint[11] than lead.

The cost-effectiveness of avoided emissions (where possible and meaningful to quantify) was estimated to range between 0.5 and 1 513 € per kg of lead release avoided depending on the affected sector (Table 3). 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.

Table 3 Effectiveness of the proposed restriction

Sector	Emission reduction over 20 year	Total costs [NPV 20-year]	Cost effectiveness [€/kg avoided releases]	Reference in the report
Hunting with gunshot	210 000 tonnes	€956 million	4.63 €/kg	Section 2.5
Hunting with small calibres bullets	360 tonnes	€544 million	1 513 €/kg	Section 2.5
Hunting with bullets for large calibres	2 257 tonnes	€227 million	101 €/kg	Section 2.5

[11] 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

Sector	Emission reduction over 20 year	Total costs [NPV 20-year]	Cost effectiveness [€/kg avoided releases]	Reference in the report
Sports shooting with gunshot - ban on marketing and use[1]	525 000 tonnes	€249 million	0.48 €/kg	Section 2.6.2
[Sports shooting with gunshot – optional derogation under strict conditions][2]	*[498 750 tonnes]*	*[€8 527 million upper bound]*[3]	*[17 €/kg]*	Section 2.6.2
Sports shooting with small calibre bullets – derogation under strict conditions	283 500 tonnes	€280 million	0.50 - 0.99 €/kg	Section 2.6.2
Sports shooting with large calibre bullets – derogation under strict conditions	349 650 tonnes	€319 million	0.46 - 0.91 €/kg	Section 2.6.2
Fishing	48 300 tonnes	€9 300 million	193 €/kg	Section 2.8
Total for the preferred option	**~ 1 500 000 tonnes**	**~€12 000 million**	**8 €/kg**	**-**

Note: ; [1] preferred option of the Dossier Submitter; [2] not the preferred option of the Dossier Submitter; [3] Total costs are calculated based on the assumption that all ranges will choose to update risk management measures to achieve > 90 % recovery to allow the continued use of lead gunshot

In addition, Table 4 presents a summary of the main costs and benefits of the proposed restriction for the different uses.

Table 4 Costs and benefits of the proposed restrictions for the different uses

Sector of use	Use #	Use title	Main costs identified (i.e. negative impacts)	Main benefits identified (i.e. positive impact)
Hunting	1	Hunting with shot shell ammunition	Total cost of the proposed restriction: €956 million over a 20-year period	~ 213 000 tonnes of lead releases avoided over a 20-year period. Reduce and prevent lead accumulation/availability in the habitats for species at risk of lead poisoning via primary and secondary routes. Avoid the mortality of about 1.2 million birds annually, valued at €114 million, due to direct ingestion of lead shot (this includes a limited number of species only for which mortality rates could be estimated and monetisation done and does not include monetisation of sub lethal effects). Avoid exposure to lead for humans (via diet), quantified impact €70 million per year for IQ loss and €7.5-75 million per year in chronic kidney diseases (shared benefit across use 1 and 2b). Overall positive impact expected on the environmental footprint of the alternatives. Positive impact on wildlife, ecosystem, and associated leisure activities. EU Birds Directive, AEWA, CMS and CMS Raptors MOU[12] commitment fulfilled. Total societal benefit: €191 -260 million (annualised).
	2a	Hunting with bullets – small calibre	Total cost of the proposed restriction: €544 million over a 20-year period	
	2b	Hunting with bullets – large calibre	Total cost of the proposed restriction: €227 million over a 20-year period	
Sport s shooti	3	Outdoor sports shooting with shot shell ammunition	Total cost[13] of the proposed restriction (preferred option) for sports shooting: €848 million over a 20-year period	~ 1 160 000 tonnes of lead releases avoided over a 20-year period with the preferred option for sports shooting. *[If the optional derogation under strict conditions for lead*

[12] https://www.cms.int/raptors/en/legalinstrument/birds-prey-raptors
[13] Total costs= €249 million + €280 million + €319 million (from previous table)

Sector of use	Use #	Use title	Main costs identified (i.e. negative impacts)	Main benefits identified (i.e. positive impact)
	4	Outdoor sports shooting with bullets	*[If the optional derogation under strict conditions for lead gunshots would be implemented instead of a ban, then the total cost of the restriction for sports shooting would be: €8 527 million; this is an upper bound assuming all ranges will implement risk management measures to achieve > 90 % recovery]*	*gunshots would be implemented instead of a ban, then the total amount of lead releases avoided over the 20-year period would be: 1 135 000 tonnes].* Reduce and prevent lead accumulation/availability in the habitats for species at risk of lead poisoning via primary and secondary routes. Avoid mortality due to sub lethal effects of birds and other taxa. Avoid exposure to lead for ruminants (via soil). Avoid exposure to lead for humans (via environment) from drinking water and food. EU Birds Directive, AEWA, CMS, CMS Raptors MOU commitment fulfilled. Total societal benefit: unquantified.
	5	Other outdoor shooting using air rifle/gun/pistol		
Shooting with historical weapons	6	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments		

Sector of use	Use #	Use title	Main costs identified (i.e. negative impacts)	Main benefits identified (i.e. positive impact)
Fishing	7	Lead in fishing sinkers and lures	Total cost of the proposed restriction: €9 300 million over a 20-year period, including €680 million for the EU industry compliance cost (which corresponds to an annualised[14] cost of €364 million including €11 million for the EU industry compliance cost). It represents €30 additional expense per fisher per year (i.e. 3% of the average yearly fishing budget of a fisher) Potentially up to 100 workers in SMEs at risk of losing their job.	Reduce and prevent lead accumulation/availability in the habitats for species at risk of lead poisoning via primary and secondary routes. 48 300 tonnes of lead releases avoided during a 20- year period. Avoid mortality due to sub lethal effects of birds and other taxa. Positive impact expected on children health if the lead home-casting activity decreases as expected (not quantified). Overall positive impact expected on the environmental footprint of sinkers and lures, despite the risk to potentially create another littering issue in the environment (inherent to the fishing practice), depending on the type of alternative used. Positive impact on wildlife, ecosystem, and associated leisure activities. EU Birds Directive and AEWA commitment fulfilled. Total societal benefit: unquantified.

[14] Annualised cost considering 20-year period for the impact assessment, and 4% discount rate

In conclusion, the Dossier Submitter finds that the proposed restriction is practical, enforceable and monitorable for each individual sector and use affected.

The proposed restriction is practical and implementable because where a ban on placing on the market and/or use is proposed, alternatives already exist, and are for most uses already broadly available, technically and economically feasible.

The transition periods and derogations for certain uses are proposed with the aim to minimise costs to society, without unnecessary delay of the emission reduction. The transition periods proposed will ensure that producers, retailers and consumers will have sufficient time to transition to suitable alternatives including the time needed to scale up production capacity.

Information at the point of sale and/or labelling are proposed for uses where there is a transition period before further action enters into force (e.g. a ban on use). This requirement should be seen as a 'change-management' element, which aims at (i) increasing consumer awareness of the hazard and risk of lead, and (ii) preparing end-users to change their purchasing behaviour. A labelling requirement is only proposed where a ban is proposed solely on the use.

The proposed conditions for sports shooting are also practical, as demonstrated by the existing examples in Norway, Denmark, Sweden and the Netherlands were limitations on the use of lead shot for clay target shooting have been implemented successfully. Bullet traps have been found to capture lead effectively and have been signalled at many ranges throughout the EU.

For the above reasons, the proposed restriction is therefore considered implementable and manageable.

The main components of the proposed restriction are also enforceable, and the scope of the proposed restriction is clear and unambiguous. Experience with enforcing restrictions on non-lead rifle ammunition already exists in various areas in the EU, and existing methods to enforce existing ban on gunshot and projectiles could also be used for the inspection of restriction on lead fishing tackle (e.g. ICP-MS[15] testing to check the presence of lead).

The ban on placing on the market proposed for uses #1, #3 and #7, in addition to a ban on use will facilitate the enforceability of the restriction. Indeed, spot checks of imported goods (at customs), but also manufacturer and retailer site inspections are simpler than an enforcement at the point of use. Nevertheless, enforcement at the site of use could be performed by the relevant national enforcement authorities for fishing, hunting or sports shooting matters. These inspectors, usually fisher/shooters themselves or used to perform such inspections (licence, equipment, etc.), are assumed to be knowledgeable and skilled to recognise lead articles, drop-off techniques or equipment in the case of fishing for example.

With regard to lead in fishing tackle, a ban on using lead fishing tackle cannot be dissociated from a ban on placing on the market. From a practical point of view, it is easier to check compliance with a ban on placing on the market rather than a prohibition of use. However, a ban on using lead fishing sinkers and lures is considered necessary to discourage the use of home-casted lead fishing tackle. If the use of lead in fishing tackle continues to be permitted, it could indeed provide a greater incentive for casting at home, which could also create a bigger issue in terms of human health than the current situation. Home-casting of lead fishing sinkers and lures may indeed become particularly attractive for

[15] ICP-MS stands for 'Inductively Coupled Plasma Mass Spectrometry'

fishers if the price of non-lead fishing tackle in shops and internet webstores rises.

The role of enforcement at all levels of the supply chain (including at the sites of use) is crucial to ensure a level playing field and a fair competition for EU manufacturers, whilst achieving the release reduction expected from the proposed restriction, and ensuring that the overall expected net risk reduction (both for the environment and human health) can be achieved.

Finally, monitoring of the effectiveness of the proposed restriction (including compliance) could be achieved through various methods. The most conclusive method is to measure the prevalence of ingested or embedded lead gunshot, projectiles or fishing tackle in bird species at risk over time. Many of the current studies highlighting the problem of lead poisoning in various bird species use this method and it can readily be adapted to monitor the effectiveness of the proposed restriction.

The presence of alternatives to lead on the market could also be monitored using market surveys or mystery shopping.

Finally, in case the derogation for continued use of lead gunshot for sports shooting ('OPTIONAL CONDITIONAL DEROGATION') is preferred to an outright ban, the reporting requirement will allow the Commission to monitor the continued used of lead gunshot in different EU Member States. This requirement will also facilitate the enforcement of the sports shooting uses by identifying the designated locations where lead gunshot can be used under strict conditions.

The proposed restriction entry is the following:

<u>Short title:</u>

Restriction on the placing on the market and use of lead in outdoor shooting and fishing.

<u>Scope description:</u>

The text of the proposed entry in Annex XVII (proposed restriction – Table 5) has been carefully drafted to describe the intention of the Dossier Submitter. The final legal wording (i.e. to update Annex XVII of REACH) would be decided by the European Commission and would need to take into account the restriction on the use of lead in gunshot in wetlands.

Some elements of the proposal are presented in square brackets [….]. This is intended to indicate that either this element of the conditions of the restriction is (i) included on the basis of a preliminary conclusion that is subject to a review by the Dossier Submitter during the opinion-making phase (i.e. after the consultation) or (ii) that the element is not preferred by the Dossier Submitter, but may be favoured by the decision maker.

The elements in green font present an optional derogation: the four elements are proposed in conjunction with each other (i.e. as a set of measures) in order to achieve an optimum risk reduction potential of this option

For the purposes of the Committees' opinion development, the restriction entry could be split in separate entries for fishing, gunshot and other types of projectiles.

Table 5 Proposed restriction entry

Designation of the substance	Conditions of the restriction
Lead and its compounds	1. Shall not be placed on the market in a concentration equal or greater than 1 % w/w: a. in fishing sinkers and lures b. in fishing wires c. in gunshot 2. Shall not be used, in a concentration equal or greater than 1 % w/w: a. in fishing sinkers and lures b. in fishing wires c. in gunshot d. in any other projectiles not defined as a gunshot 3. Shall not be used, in a concentration equal or greater than 1 % w/w, in fishing sinkers where the combination with any fishing equipment, rig or technique release the sinker during use. 4. By way of derogation: *a. [OPTIONAL CONDITIONAL DEROGATION (part 1/4): Paragraph 1c shall not apply to the placing on the market of lead gunshot for sports shooting if:* *- the retailer has a permit, granted by the Member State [where the article is placed on the market], to place lead gunshot for sports shooting on the market]* *b. [OPTIONAL CONDITIONAL DEROGATION (part 2/4): Paragraph 2c shall not apply to the use of lead gunshot if:* *- the individual has a permit, granted by the Member State, to use lead gunshot for sports shooting; AND* *- the use takes place at a designated location that has a permit, granted by the Member State, to use lead gunshot for sports shooting; AND* *- the following measures are in place at the designated location:* *▪ Regular [at least once a year] lead shot recovery with [>90%] effectiveness (calculated based on mass balance of lead used vs lead recovered in previous years) to be achieved by appropriate means (such as walls and/or nets , and/or surface coverage); AND* *▪ Containment, monitoring and, where necessary, treatment of surface (run-off) water to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive; AND*

  - *[Ban of any agricultural use within site boundary]"]*

c. Paragraph 2d shall not apply to the use of 'lead projectiles not defined as a gunshot' for sports shooting, if the following measures are in place:
   - the use takes place at a designated location for sports shooting with 'lead projectiles not defined as a gunshot'; AND
   - the following measures are in place at the designated location:
     - Regular lead recovery with [>90%] effectiveness (calculated based on mass balance of lead used vs lead recovered) achieved by the means of bullet containment (i.e. bullet traps) AND
     - [Ban of any agricultural use within site boundary]

5. Without prejudice to the application of other community provisions on the classification, packaging and labelling of substances, mixtures, and articles:

   a. Retailers of gunshot, 'projectiles not defined as a gunshot', fishing sinkers and lures of any dimension or weight, and containing lead in concentrations equal to or greater than 0.3 % w/w, shall ensure that, at the point of sale, in close proximity, the following information is clearly and visibly provided to consumers and professionals:
      - 'Contains lead'
      - 'Lead is very toxic to the environment and birds'
      - 'Lead may damage fertility or the unborn child'
      - 'The use of lead in [gunshot outside of wetlands / projectiles / fishing sinker / lures to be selected as appropriate] will be banned in the EU from [EiF+TP as specified in paragraph 7]'.
      - Lead-free alternatives are available.'

      The information listed above shall be in the official language(s) of the Member State(s) where the articles are placed on the market, unless the Member State(s) concerned provide(s) otherwise.

   b. Suppliers of 'projectiles not defined as a gunshot' containing lead in concentrations equal to or greater than 0.3 % w/w, shall ensure, before the placing on the market, that product packaging is clearly, visibly, and indelibly labelled with the information listed in paragraph 5a.
      The labelling shall be in the official language(s) of the Member State(s) where the articles, are placed on the market, unless the Member State(s) concerned provide(s) otherwise. If the packaging is too small, and the information listed in paragraph 5a cannot be provided on the packaging, this information can be provided in fold-out labels (leaflet); or on tie-on tags.

   c. [OPTIONAL DEROGATION (part 3/4): Suppliers of 'gunshot' containing lead in concentrations equal to or greater than 0.3 % w/w, shall ensure, before the placing on the market, that product packaging is clearly, visibly, and indelibly labelled with the information listed in paragraph 5a. In addition, individual cartridges shall be labelled:

- *'Contains lead'*
- *'Not permitted for hunting'.*

The labelling shall be in the official language(s) of the Member State(s) where the articles, are placed on the market, unless the Member State(s) concerned provide(s) otherwise. If the packaging is too small, and the information listed in paragraph 5a cannot be provided on the packaging, this information can be provided in fold-out labels (leaflet); or on tie-on tags.]

6. [OPTIONAL DEROGATION (part 4/4): Member States shall report on an annual basis to the Commission:
   - *the number of permits granted to designated locations in the Member State under paragraph 4b and their location.*
   - *the number of permits granted to individuals in the Member State under paragraph 4b.*
   - *the quantity of lead gunshot used in the Member State under paragraph 4b.]*
7. Entry into force of the restriction:
   a. *paragraph 1a and 2a shall apply 3 years from entry into force of the restriction for sinkers and lures which have a weight equal or less than 50 g*
   b. *paragraph 1a and 2a shall apply 5 years from entry into force of the restriction for all sinkers and lures which have a weight greater than 50 g*
   c. *paragraph 1b, 2b and 3 shall apply as soon as possible from entry into force of the restriction*
   d. *paragraph 1c, and 2c, shall apply [5 years] from entry into force of the restriction*
   e. *paragraph 2d shall apply [18 months] from entry into force of the restriction for centrefire ammunition with a calibre greater than or equal to 5.6 mm*
   f. *paragraph 2d shall apply [5 years] from entry into force of the restriction for centrefire ammunition with a calibre less than 5.6 mm and 'any projectiles not defined as a gunshot' of any calibre*
   g. *paragraph 5a shall apply 6 months from entry into force of the restriction.*
   h. *paragraph 5b shall apply [18 months] from entry into force of the restriction.*
   i. [paragraph 5c shall apply [5 years] from entry into force of the restriction.]
8. This restriction on lead in outdoor shooting and fishing shall not apply to the following applications: indoor shooting inside a building, police, law enforcement, military applications, [voluntary military training], protection of critical infrastructure, commercial shipping or high-value convoys, soft-target and public space protection, [self-defence], security purposes, technical testing and/or proofing, testing and development of materials and products for ballistic protection, forensic analysis, historical and other technical research or investigation. (i.e. these applications are outside of

the scope).

9. For the purposes of this regulation:
   - 'centrefire ammunition' means ammunition where the primer is located in the centre of the case head or base;
   - 'fishing wire' means metal in the form of thin thread often cut in smaller pieces and used as a sinker in certain types of 'lures';
   - 'gunshot' means pellets used [or intended for use in quantity] in a single charge or cartridge for shooting with a shotgun;
   - 'hunting' means pursuing and killing live quarry using a gun;
   - 'lure' means an object that is used to attract fish or animals, so that they can be caught. Lures might also have the same technical function as 'sinkers';
   - 'projectile': means an object intended to be expelled from a gun, irrespective of the means of propulsion;
   - 'shotgun' means a smooth-bore gun;
   - 'sinker' means a weight that is attached to a fishing line or a net to keep it under the water, or to keep the fishing line, or net, in a certain position;
   - 'sports shooting' means shooting at any inanimate (non-living) target with a gun. It includes practice, or other shooting, performed in preparation for 'hunting'.

10. Member States may maintain national provisions for protection of the environment or human health in force on [Publications office - please fill in the date of entry into force of this amending Regulation] and restricting lead in gunshot, or any other projectiles more severely than provided for in paragraph 1 to 8).

    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.

In addition, some other union-wide measures, other than REACH restriction (cf. Annex D), are listed by the Dossier Submitter, and could be implemented by national associations, whenever applicable, to support the proposed REACH restriction, for example:

- The possibility to incorporate into the national hunting exam (to obtain a hunting licence) a mandatory module on the hazards of lead and the risks of using lead ammunition. This could be done at the Member State level whenever such hunting exam takes place.
- A collection of a small fee from the fishing licences (whenever existing) in order to support the change and transition to non-lead alternative of both the consumers and the EU manufacturers. A fee of 10 cents collected on each licence in Europe would represent a minor increase of the licence fee, and could potentially generate an annual revenue of €1.2 million that could be used to support the R&D effort of European industry to, and help European manufacturers to transition to non-lead

alternative solutions. This fee could also support an education campaign for consumers (see next bullet point).

- A voluntary education and action campaign from the sector associations (fishing and trade) targeted to consumers to promote the use of non-lead fishing tackle, and the recovery and recycling of lead fishing tackle.

1. Problem analysis

1.1. Background

At the request of the Commission[16], ECHA proposed a restriction on the use of lead in gunshot in wetlands in April 2017. ECHA's scientific committees for risk (RAC) and socioeconomic analysis (SEAC) completed their opinions on the proposal in August 2018[17].

In September 2018, as part of the original request of the European Commission to propose a restriction on the use of lead gunshot in wetlands, ECHA published a report on the risks from the use of lead in gunshot in terrestrial environments, in other types of ammunition in any terrain and in fishing tackle (ECHA, 2018b). The report concluded that there is sufficient evidence that risks from these uses are not adequately controlled to justify additional risk management.

On 16 July 2019, the European Commission requested ECHA to prepare a follow-up restriction proposal on 'the placing on the market and use of lead in ammunition, i.e. gunshot used in terrains other than wetlands, and bullets used both in wetlands and in terrains other than wetlands, as well as of lead in fishing tackle, to address the concerns posed by these articles' (EU Commission, 2019)[18].

The request from the Commission noted that the proposed restriction options should be targeted at addressing the risks identified for each of the articles concerned.

In January 2021, the REACH Regulation was amended to include the restriction of lead gunshot in wetlands[19]. This assessment, and proposed restriction for lead gunshot in terrestrial areas, is complementary to the existing restriction on the use of lead in gunshot in wetlands.

1.2. Scope

<u>Concerns to be addressed:</u>

ECHA (ECHA, 2018b) identified concerns for both the environment and human health from the use of lead in ammunition and fishing tackle. Therefore, the scope of this Annex XV report addresses both risks.

<u>Lead in ammunition:</u>

As far as the definition of lead in ammunition is concerned, it is important to note that ammunition can be used both in firearms or airguns[20]. Firearms shoot projectiles by means of pressured gases resulting from a chemical reaction (combustion) whilst airguns shoot projectiles by means of compressed air or other gases that are mechanically pressurised without involving any chemical reaction.

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16 https://www.echa.europa.eu/documents/10162/13641/rest_lead_shot_pvc_tattoo_formaldehyde_request_redacted_en.pdf/f8fb716f-6174-4329-623c-69d8805a2b0d

17 Details of the restriction on the use of lead on gunshot, including assessment reports, committee opinions and consultation comments are available on the ECHA website: https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e180c0ac38

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

19 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2021.024.01.0019.01.ENG&toc=OJ%3AL%3A2021%3A024%3ATOC

20 Firearms and airguns can also be called using various words such as weapon, gun, handgun, long gun, pistol, revolver, rifle, etc. which are sub-categories of firearms and airguns. These terms might be used specifically in this report to refer to a specific type of ammunition or shooting tool.

Ammunition is a generic term which comprises a wide variety of complex (and less complex) articles[21]. Ammunition may be composed of one or several of the following components depending on the type of ammunition and the type of firearms or airguns used to shoot:

- Primer;
- Explosive materials and propellants;
- Projectile(s);
- Cartridge casing.

Some of the above-mentioned ammunition components can contain lead or lead substances (e.g. lead styphnate is used as a primer whilst lead in a component of brass alloy which is frequently used in cartridge casing). Nevertheless ECHA (2018b), and the Commission's request[22] both focussed on lead projectiles (referred to as specific example such as 'lead gunshot, bullet, or pellet'), and upon clarification with the Commission, it was indeed confirmed that the scope of the Annex XV restriction report should only cover projectiles rather than other potentially lead containing components of ammunition.

However, during the investigation, data indicating that the use of lead or lead substances as primers and propellants in ammunition result in risks that are not adequately controlled became apparent. Whilst remaining outside of the scope of this restriction proposal, these conclusions have been documented in this Annex XV report for information.

Lead projectiles are used in many different applications. The focus of the Annex XV report is on civilian use of ammunition only. Police and military use of ammunition is explicitly excluded from the scope of the Annex XV report. Nevertheless, the Dossier Submitter is aware of the strong interaction between civilian and military use of ammunition in terms of systems design and development, but also in terms of production and production capacity.

Regarding the civilian uses of lead in projectiles, lead projectiles are not only used for hunting but also for indoor and outdoor sports shooting and other outdoor applications. The term 'target shooting' was used in the investigation report but on further consideration was deemed to be too broad. Upon stakeholder advice, the term 'sports shooting' will be used instead as this is better understood by stakeholders and covers more precisely the activities in the scope of the assessment. Only outdoor uses of projectiles are within the scope of the Annex XV restriction report as per the Commission description in its request (i.e. 'wetlands and in terrains other than wetlands'). This means that indoor sports shooting is not within the scope.

The projectiles in the scope of the Annex XV restriction report can be grouped under the following two main categories:

- Gunshot to be shot with a shotgun (also referred as 'gunshot' or 'shot' for simplicity); where multiple shot/pellets are contained in a shotshell
- Other types of projectile (single): bullet is the most common example, but it includes also full metal jacket (if allowed by the local hunting legislation), slug (single shot/pellet in a shotshell), as well as BB (small metallic ball), air gun pellet, etc.

An example of gunshot and other type of projectiles is presented in Figure 1-1.

[21] Cf. Appendix A for examples of ammunitions

[22] https://echa.europa.eu/documents/10162/13641/echa_annex_xv_restriction_proposals_en.pdf/ed07424a-328d-88e0-b7c6-412251426582

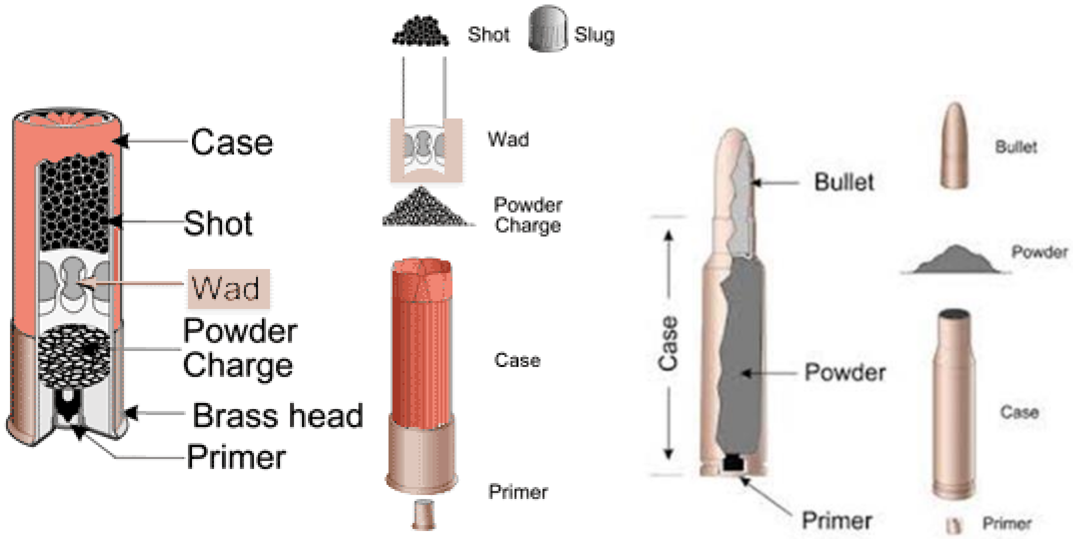

Figure 1-1: Examples of gunshot (left hand-side) and other types of projectiles (e.g. bullet on the right hand-side) within the scope of the proposed restriction

While gunshot can only be shot using firearms, the other type of projectile can be shot using firearms and airguns.

To summarise, with regard to ammunition, the scope of the proposed restriction is the **placing on the market and the use of lead projectiles used in firearms and airguns, for (civilian) outdoor activities.**

Lead in fishing tackle:

In addition, as per the Commission request[23], the Annex XV report also investigates the placing on the market and use of lead in fishing tackle in recreational, commercial and subsistence fishing (cf. Annex A).

Even if the term 'fishing gear' is more common in the context of commercial fishing, the Dossier Submitter decided to use the term 'fishing tackle' within this report to designate 'the equipment used when fishing for recreational, subsistence or commercial purposes'. In addition, while the demarcation between recreational and commercial fisheries is reasonably clear in Europe, the demarcation between subsistence and recreational fishing is absent (Hyder and J, 2017). Under EU legislation on fisheries, any fishing where catches are sold is considered commercial. Conversely, where catches are not sold, this activity and its impact are generally monitored as recreational fishing. Hence in this report the Dossier Submitter will only talk about recreational and commercial fishing (cf. Annex A).

There is a large and diverse range of sizes, colours and shapes of fishing tackle made of lead (cf. Annex A). The lead fishing tackle of interest in this Annex XV report can be categorised into three main types, that are further defined in section 2.3.2.3:

- Fishing sinkers and wires (also known as 'fishing weights')
- Fishing lures (including jigs)

23 https://echa.europa.eu/documents/10162/13641/echa_annex_xv_restriction_proposals_en.pdf/ed07424a-328d-88e0-b7c6-412251426582

- Fishing nets, ropes and lines where lead in embedded/enclosed in the fishing nets, ropes and lines

The scope of the Annex XV report will cover the placing on the market and the use of these three types of tackle for recreational and commercial activities. Both fishing in freshwater (i.e. in rivers, lakes and ponds) and in marine water (i.e. in the sea) are within the scope of this work.

Finally, the understanding of the Dossier Submitter is that the Commission's request does not cover the manufacture/production of 'fishing tackle and ammunition' (at industrial sites). These 'industrial' uses have therefore not been considered as candidates for restriction and are not assessed in this Annex XV report.

Nevertheless, the preparation/manufacturing/processing of fishing tackle or lead bullets at home, or in 'non-industrial' settings (called 'home-casting' in this report) was further investigated as the ECHA investigation report (ECHA, 2018b) concluded that risks from this activity may not be adequately controlled.

The Dossier Submitter identified that the casting of lead bullets and lead fishing tackle activity in 'non-industrial' settings presents a concern both for human health and the environment. These activities, either performed by the general public in a private setting (at home), or at larger scale in 'garage' type settings or in the backrooms of fishing shops, are carried out without the supervision of the usual national OSH, and industrial emission supervisions and regulations. In addition, the fishing tackle and ammunition produced via 'home-casting' contributes also to the overall quantity of lead fishing tackle released to the environment while hunting, or fishing. In addition, the effects of different risk management options on the prevalence of home-casting is relevant to consider as part of their effectiveness (in reducing identified risks). Therefore, for all these reasons, the assessment of the risks associated with 'home-casted' lead fishing tackle and lead ammunition is within the scope of the Annex XV report.

Finally, from a geographical point of view the scope of the Annex XV report is limited to the European Union composed of 27 Member States as of 2020. It is also referred as 'EU27-2020' in this document.

1.3. Identity of the substances, physical and chemical properties

1.3.1. Substance identification

This Annex XV report concerns the use of zero-valent lead massive (particle diameter ≥ 1 mm) or lead alloys used in gunshot, bullets and fishing tackle, and addresses risks to both human health and the environment.

Lead massive is currently the only lead substance (lead compound) associated with use as gunshot, bullets or fishing tackle, including its use as a constituent in lead-containing alloys (which are 'special mixtures' under REACH). However, as the adverse effects resulting from lead exposure are ultimately mediated by dissociated / dissolved lead ions, which could be from any lead compound, the proposed restriction also extends to the use of other lead-containing substances, irrespective of whether they are known to be used in ammunition or fishing tackle or not. As a necessary consequence, the identity of these 'hypothetical' lead-containing substances are not elaborated in this Annex XV report.

Whilst it is considered to be unlikely that other lead-containing substances would be used as a substitute for lead massive (or lead alloys) in ammunition or fishing sinkers, this approach is analogous to the previous Annex XV reports for lead in gunshot in wetlands, lead in jewellery and lead in consumer articles and is intended to prevent 'regrettable substitution' of lead with other lead substances to circumvent the objectives of this proposed restriction.

Table 1-1: Identification of lead

Identifier	
EC Number	231-100-4
EC name	Lead
CAS number	7439-92-1
Molecular formula	Pb
Molecular weight range	207.1978

1.3.2. Physical chemical properties

The main physical chemical properties of lead are summarised below, in Table 1-2 based on information from REACH registration dossiers.

Table 1-2: Relevant physical chemical properties of lead

Property	Results	Value used for CSA / Discussion
Physical state at 20°C and 1013 hPa	Lead is available on the market in both powder and massive forms. In both forms it is a solid, grey-blue element.	Value used for CSA: solid
Melting / freezing point	The melting point has been determined with a representative sample to be 326 °C (study result, EU A.1 method).	Value used for CSA: 326 °C at 1013 hPa
Boiling point	The test item has no boiling point at atmospheric pressure up to the final temperature of 600 °C (study result, EU A.2 method).	
Relative density	The relative density (compared to water at 4 °C) is D4R = 11.45 (study result, EU A.3 method).	
Water solubility	The water solubility has been determined with a representative sample to be 185 mg/L at 20°C (study result, EU A.6 method).	Value used for CSA: 185 mg/L at 20 °C
Flammability	Test result available for flammability (EU A.10 method).	Value used for CSA: non flammable
Explosive properties	Waiving (study scientifically unjustified).	Value used for CSA: non-explosive
Oxidising properties	Waving (other justification).	Value used for CSA: Oxidising: no

1.3.3. Justification for grouping

The various uses of lead in fishing tackle, gunshot and projectiles (e.g. bullets) are grouped because of the following reasons:

- Similarity in substance identity, all three sectors of use utilise lead in the massive form or lead alloys.
- Similar sizes of some lead fishing tackle (e.g. some sinkers and lures) and lead shot ammunition result in similar pathways of exposure and risk.
- The hazards and potential risks posed by lead projectiles, gunshot and some fishing tackle are similar; they ultimately result in lead poisoning of environmental receptors (principally birds).

1.3.4. Classification and labelling

Lead powder (particle diameter <1 mm) or lead massive (particle diameter ≥ 1 mm) are classified for reproductive toxicity, Repr. 1A (H360FD) and lactation, Lact. (H362). In addition, a specific concentration limit for lead powder of 0.03 % applies; for lead massive a generic concentration limit of ≥ 0.3 % applies.[24]

A proposal for a harmonised classification for lead powder and lead massive was adopted by ECHA's Risk Assessment Committee on 30 November 2018. The proposal includes to retain the classifications for Repr. 1A (H360FD) and Lact. (H362) and to add Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).[25] The updated harmonised C&L has been adopted for lead powder in the Commission Delegated Regulation (EU) 2020/1182 and applies from 1 March 2022 (ATP15[26]) (see also Table). With regard to lead massive it is stated in this amendment to the Regulation that "*in view of the lower dissolution rate of the massive form, the malleable structure of lead, the specific intentional production of the powder and the different environmental classification between massive and powder forms for existing entries in Annex VI for other metals, further assessment needs to be done by RAC on whether to apply the same environmental classification to the massive as to the powder form of lead. In addition, new scientific data has been made available suggesting that the environmental classification for the massive form as recommended in the RAC opinion might not be appropriate. Therefore, the environmental classification for the massive form will not be included in Annex VI to Regulation (EC) No 1272/2008 until RAC has had the opportunity to deliver a revised opinion.*"

On 24 June 2020, RAC[27] received a request from ECHA in accordance with Article 77 (3) (c) of the REACH Regulation to (i) reassess the ERV values for lead using existing data set from the original CLH dossier taking into account the new chronic toxicity study for lead in *Lymnea stagnalis* following OECD TG 243, and (ii) re-examine of whether the powder and massive forms of lead warrant the same classification for hazards to the aquatic environment.

[24] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1179
[25] https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e180db34ea
[26] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=uriserv:OJ.L_.2020.261.01.0002.01.ENG
[27] https://www.echa.europa.eu/documents/10162/13579/rac_mandate_art77_3c_lead_en.pdf/da03fe7b-19a1-5dfa-3086-6e0c2973dc65

Table 1-3: Harmonised classification and labelling according to Regulation 1272/2008 and its amendments

Index No	International Chemical Identification	EC / CAS No	Hazard class category	Hazard statement code(s)	Spec. Conc. Limits, M-factors, ATEs
082-013-00-1	Lead powder [particle diameter <1 mm]	231-100-4 7439-92-1	Repr. 1A Lact. Aquatic Acute 1[1] Aquatic Chronic 1[1]	H360FD H362 H400 H410	Repr. 1A; H360D: C ≥ 0.03 % M = 1 M = 10
082-014-00-7	Lead massive [particle diameter ≥ 1 mm]	231-100-4 7439-92-1	Repr. 1A Lact.	H360FD H362	GCL ≥ 0.3 % applies

Note: [1] shall apply from 1 March 2022 onward

1.4. Manufacture and use

This section summaries the following uses in the EU27-2020 that have been considered in this Annex XV Restriction Report:

- lead in gunshot in terrestrial environments;
- lead in other types of ammunition;
- lead in fishing tackle.

Detailed information on each use is included in Annex A. Some indicative information on the manufacture processes is also provided in Annex A.

1.4.1. Uses overview

The Dossier Submitter identified various uses of lead in projectiles and in fishing tackle, either from the call for evidence (CfE), literature searches or stakeholder consultation. These uses are identified in Table 1-4 below.

The uses in Table 1-4 are assessed to determine if they pose a risk for human health or the environment that is not adequately controlled. Each of the uses have a different 'substitution profile' and there would be different consequences for society for a restriction on placing on the market or use. These are described in the 'Impact Assessment' outlined in Section 2 of the report with supporting information and analysis presented in Annex D.

Table 1-4: Overview of uses and technical functions

Sector of use	Use #	Use title	Use overview - Brief description of the use of lead and its technical function
Hunting	1	Hunting with shot shell ammunition	Used as a projectile, either by itself or in quantity (i.e. gunshot) where the technical function is to provide mass for energy transfer to a target Projectiles can be of various sizes and shapes depending on the desired ballistic properties. They can be used by consumers or professionals The ballistic properties vary depending on whether ammunition is for hunting or sports shooting as well as the size and type quarry and the type of gun used. Projectiles can sometimes be coated with another metal (termed 'jacketed').
	2a	Hunting with bullets - small calibre[1]	
	2b	Hunting with bullets - large calibre	
Sports Shooting	3	Outdoor sports shooting with shot shell ammunition	
	4	Outdoor sports shooting with bullets	
	5	Outdoor shooting with air rifle/pistol	
Shooting with historical weapons	6	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments	

Sector of use	Use #	Use title	Use overview - Brief description of the use of lead and its technical function
Fishing	7 and 8	Lead in fishing tackle	Uses of lead in fishing tackle means: - Recreational fishing with lead fishing tackle (Consumer use) - Commercial fishing with lead fishing tackle (Professional use) - Home-casting of lead fishing tackle (Consumer use) The main function of lead in fishing tackle is to provide additional weight in order to (i) cast and set the bait or lure at a certain location and distance (up to 200 m), and/or to (ii) sink the fishing tackle e.g. the line and fishing hook, or the net, while allowing fishing (CfE #1034 - Vlaams Instituut voor de Zee). The following types of fishing tackle can usually be made of lead: - Sinkers (or weight) including wires (sometimes also referred to as lead core) - Lures including jigs - Nets, ropes or lines in commercial fishing essentially Use 7 covers all the lead uses related to sinkers and lures and use 8 covers the uses where lead is embedded in the fishing tackle (i.e. nets with lead embedded in the nets, ropes or lines).

Notes: [1] includes hunting with airgun

1.4.2. Manufacture of lead gunshot and bullets

The production of lead gunshot and lead bullets is described in Annex A. For gunshot there are two main production processes: tower and Bleimeister. Bullets are made either via cutting or casting.

Lead gunshot is made in various sizes and placed on the market in cartridges of various load weights and gauges (cartridge diameter). Hunters and sports shooters select cartridges that fit in their guns and are suited to the type of shooting undertaken. On average a lead sports shooting cartridge contains about 24 g of lead gunshot (fixed by International Sports Shooting Federation (ISSF) rules) and a hunting cartridge contains between 30 and 34 g depending on the number of individual gunshot pellets (load) and their size. The latter two (load and size) specifications allow hunters to select a cartridge that is suitable for the intended quarry. For further information see Annex D.

Lead bullets are supplied to the market in various forms: either in ready-to-use cartridges or as separate components for ‘reloading’ by hunters. Hunters and shooters can choose between various calibres and bullet weights. Calibre size is positively related to the size of game being hunted or is (in sports shooting) set out by International Sports Shooting Federation such as the International Sports Shooting Federation of the International Biathlon Union. Hunters can furthermore choose the weights of the bullets, again bullet weight is positively related to game size.

Lead bullets are not only used for (recreational) hunting but also in different forms of pest control or wildlife population management. This is done by both volunteers and by professionals in the service of wildlife agencies.

Despite the availability of lead-free alternatives, lead bullets and lead gunshot remain the most popular material for both sports shooting and hunting in jurisdictions where lead has not been regulated.

Where restrictions on lead gunshot and lead bullets are in place, alternatives are more widely available and more competitively priced. Such restrictions are in place (full bans for lead shot) in the Netherlands and in Denmark. The implementation of the REACH restriction on the use of lead gunshot in wetlands across the EU should increase availability. Restrictions for bullets are in place in various Laender in Germany, national parks in Austria and in Italy and France and on a wider scale in Denmark with an upcoming nationwide ban in 2023.

The ammunition value chain can be complex with various interactions by manufacturers, ammunition loaders and cartridge suppliers. Some manufacturers are global players and some other manufacturers supply only on a local scale, parts and components can be sold together by dedicated assemblers or be put on the market as such for reloading purposes.

1.4.3. Use of lead in hunting

Hunting is performed in various forms: driven, stalking, from the high seat, in groups.

Lead is traditionally used to produce projectiles; it is used as mass to transfer energy. Within hunting such an energy transfer is intended to transfer sufficient energy to a target to result in a rapid kill (where unnecessary suffering is minimised). Hunting regulations often require a minimum calibre or a bullet weight in order to ensure that hunting is performed within what is perceived as ethical limits.

As such, materials other than lead can provide the same energy provided the basic parameters of energy transfer are met: sufficient weight combined with sufficient speed to provide at a given distance a sufficient energy transfer.

1.4.4. Use of lead in sports shooting

Sports shooting is usually performed at dedicated locations (temporary or permanent) where individuals practice or compete. Sports shooting is a test of accuracy (target shooting) combined in some disciplines with swiftness of reaction (clay target type sports) or physical endurance (biathlon).

Various types of ammunition are used, ranging from air pellets to small calibres, shot cartridges and larger calibres over longer distances. Rules for the various types of shooting are set by international shooting organisations such as the International Biathlon Union (IBU), the International Sports Shooting Federation (ISSF) or by the Federation International des armes de Chasse (FITASC). Concerning the Olympic sports shooting events, the organisation of the sport is delegated to the IBU and to the ISSF.

Training and competitions can take place at sites with varying degrees of risk management measures (e.g. using berms and/or nets, and/or surface coverage).

1.4.4.1. Good hygiene practice to reduce lead exposure of shooters

Lead in the primer and the outer surface of the projectile is vaporized and released into the air after a firearm is discharged. Lead dust and fragments are also released when the projectile impacts solid surfaces. For these reasons, surfaces in shooting ranges may be contaminated with fine lead dust. This dust can also be breathed in and swallowed. Lead dust may be suspended in the air or stick to people's hands, hair, face, clothing, and footwear. This dust may be transported on skin, hair, clothing and equipment from a shooting range into a car and into homes[28].

Good hygiene practice is therefore recommended such as:

- No eating, drinking or smoking while shooting as this makes swallowing of lead more likely;
- Washing hands, neck and face with soapy cold water before taking breaks and when finished shooting for the day;
- Showering after shooting;
- Change of clothes and shoes before leaving the shooting range if possible.

Wearing personal protective equipment is also recommended:

- Using clothing and shoes dedicated to shooting activities or wearing disposable coveralls. Clothes used for shooting should always be washed separately from general laundry.
- Wearing gloves when shooting, handling ammunition, casings or when cleaning handguns.

Furthermore, use of suitable face masks (such as FFP2) has been demonstrated to reduce exposure to lead during indoor shooting (Mühle, 2010).

In the CSR (2020) it is stated that basic hygiene practice to minimise lead exposure should be taught, including prohibitions on smoking and eating in areas where firearms are discharged. Respiratory protection should be available if the type and calibre of the firearm to be used exceeds the capacity of the ventilation systems in place. Precautions regarding "carry home" of lead contaminated dust should also be provided.

Such good hygiene practice should also be followed while recovering lead gunshot or lead bullets.

1.4.4.2. Risk management measures for the environment at shooting ranges

RMM in the Chemical Safety Report (CSR)

The REACH registration Chemical Safety Report (CSR) for lead provided in 2020 by the Lead Registrant, describes various professional and consumer uses of lead in ammunition.

Exposure Scenarios (ES) for these various uses of lead in ammunition are described, including an ES for the professional and consumer (non-military) use of lead ammunition, (service life). In this ES, the use of lead ammunition in sports shooting is covered, in relation to outdoor pistol/rifle shooting and clay target shooting (incl. sporting clays or simulated game hunting). The RMM identified in the CSR as "required" to prevent releases during service life at different types of shooting ranges are the following:

[28] https://www.vssclub.org/shooting-hygiene.html

- Measures to prevent rivers from crossing the lead deposition area
- Bullet containment in the shooting range: at least one or a combination of bullet traps, sand traps or steel traps
- Overhanging roof over the lead impact zone to prevent runoff
- Control of water runoff
- Lead shot deposition must be within the boundaries of the shooting range
- Remediation plan upon closure

Specifically, the identified RMM are supposed to be applied according to the following Table 1-5. No information is provided in the CSR in relation to the expected specific effectiveness of each of the measures.

Table 1-5: RMM to prevent releases during service life in a typical outdoor pistol/rifle range and (sporting) clay target range, as indicated in the REACH registration Chemical Safety Report (CSR), 2020

RMM to prevent releases during service life	Outdoor pistol/ rifle range	Clay target range	Sporting clay target range (simulated game hunting)
Measures to prevent rivers from crossing the lead deposition area	required	required	required
Bullet containment in the shooting range: at least one or a combination of bullet traps, sand traps or steel trap	required		
Overhanging roof over the lead impact zone to prevent runoff	required		
Control of water runoff		required	required
Lead shot deposition must be within the boundaries of the shooting range	required	required	required
Remediation plan upon closure	required	required	required

However, the Dossier Submitter has noted that available evidence does not suggest that these recommended RMM are always in place.

For example (as indicated in the Stakeholders Questionnaire, 2020):

- Danish Sports Shooting Association (Skydebaneforeningen), when indicating the measures in place in their rifle/pistol ranges, they only indicated that lead is removed from the ranges to guarantee a safe operation with no mention to the presence of overhanging roof over the impact zone. They clarified that "shooting ranges in Denmark are "very old" and were not built having the protection of the environment as main objective.
- Swedish Shooting Sport Federation (Svenka Skyttesportforbundet) confirmed that permits granted to operate a pistol /rifle range prescribe the characteristics of

berms/backstop (consisting of sand or fine gravel) from a safe operation point of view, with no mention of the presence of overhanging roof over the impact zone in outdoor pistol/rifle ranges.

- Cyprus Shooting Sport Federation, in relation to the control of run off in clay (sporting) target shooting ranges, only stated: "sewage control systems exist in all ranges", not indicating whether installation of controlled surface water intakes with drainage pipes and infiltration systems, possibly with control devices for the analysis of the discharged water, are in place,.
- German Shooting Sport and Archery Federation in relation to the control of run off in clay (sporting) target shooting ranges, stated that: "Typical measures are the installation of a controlled surface water intake with drainage pipes and infiltration systems, in which also control devices for the analysis of the discharged water can be installed. These measures are only required in particularly sensitive locations and their percentage is approx. 25 % of all ranges".
- France: in relation to bullet containment for biathlon: *"But the ranges not equipped with bullet's collectors don't have any wall and the bullets go directly in the berm. Until now the permits granted to operate a range advise to have a wall and bullet collectors, but this is at the moment not yet something mandatory."*

Guidance for RMMs to be applied at shooting ranges

US EPA published a guidance for best management practices for lead at outdoor shooting ranges (US EPA, 2005).

In the German shooting range guidelines (German BMI, 2012) and its update (German BMI, 2013), which is legally binding, detailed technical guidance are provided on establishment, approval and operation of shooting ranges (in German language).

The Finnish Ministry of the Environment published a document on best available techniques (BAT) for the management of the environmental impact of shooting ranges (Kajander and Parri, 2014).

The Environmental Protection Authority Victoria, Australia, published a guidance for managing contamination at shooting ranges (Victorian EPA, 2019) as well.

This list is not intended to be exhaustive.

RMMs to recover lead gunshot

Lead shot recovery from natural soil and agricultural land requires removal of the impacted soil horizon and is not feasible in forests. Therefore, specific means are required to be able to recover lead shot effective and periodically.

Measures may include vertical barriers such as walls and/or nets and horizontal barriers such as coverage of the natural soil.

Vertical barriers

Most frequently used vertical barriers are walls. Figure 1-2 presents a scheme for walls at trap and skeet ranges.

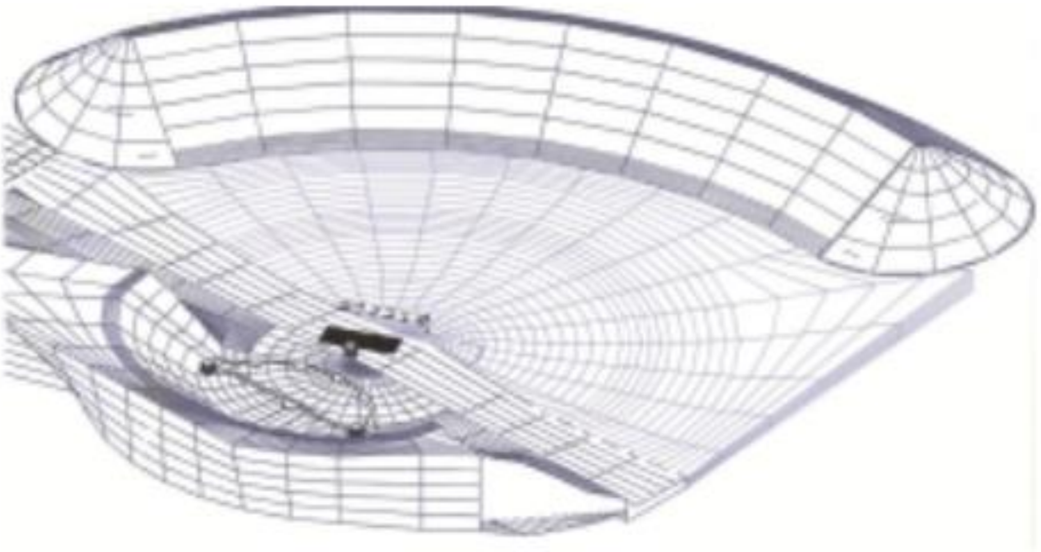

Figure 1-2: Scheme for walls for trap and skeet ranges (Bavarian StMLU, 2003)

Nets are also used as a vertical barrier. An example is presented in Figure 1-3. Net systems are available to effectively capture and collect lead shot (Bavarian LFU, 2014).

Vertical barriers have the benefit to reduce the shot fall zone (Figure 1-4) and to concentrate the lead shot to assist lead recovery (Victorian EPA, 2019).

Figure 1-3: Example for a vertical barrier in a clay shooting range (Herrmann, 2013)

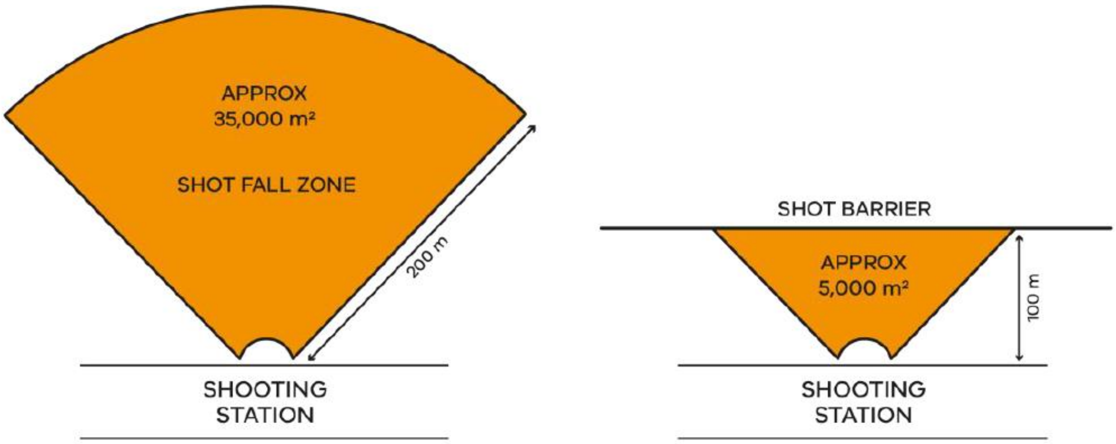

Figure 1-4: Reduction in the shot fall zone by using a barrier at a trap station (Victorian EPA, 2019)

Horizontal barriers

To properly recover lead shot, horizontal barriers might also be required. Figure 1-5 presents an example of a horizontal barrier. Drawback of a horizontal barrier without a vertical barrier is the vast surface of land that is required and the spreading of lead shot. Furthermore, it would need to be ensured that no lead shot would land outside the range boundaries.

Figure 1-5: Example of a horizontal barrier (Bavarian LFU, 2014)

In Figure 1-6 a combination of a vertical and horizontal barrier is presented.

Figure 1-6: Example of a range with a horizontal and a vertical barrier (Bavarian StMLU, 2003)

Horizontal barriers could consist of materials such as membranes, plastic, specific geotextiles or asphalt (Bavarian LFU, 2014, Kajander and Parri, 2014).

For ranges with lead contaminated soil, an impermeable barrier to cover the soil is likely to be ineffective, as percolation can still occur, and the soil chemistry may be adversely affected by the development of anaerobic soil conditions. Therefore, for existing ranges, before the installation of an impermeable barrier is carried out, removal of the contaminated soil is likely to be needed.

Range layout to optimize lead recovery

Overlapping shot fall areas may improve the efficiency of lead recovery (Victorian EPA, 2019).

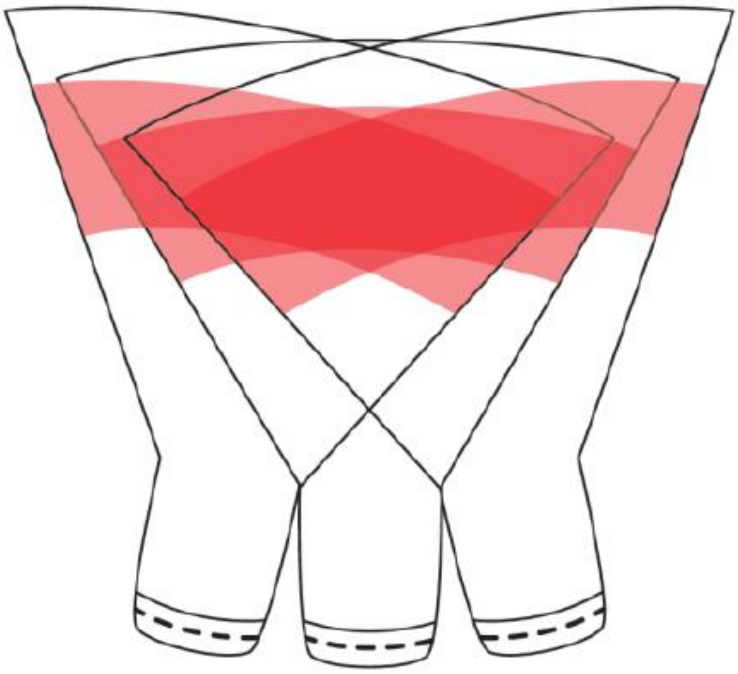

Figure 1-7: Using overlap to reduce shot fall area at trap field (Victorian EPA, 2019)

Such measures can be applied to trap and skeet ranges but may not be suitable for all shooting range layouts such as in “sporting” shotgun disciplines.

With regards to lead shot recovery, the following specific information was submitted by several stakeholders:

- For shotgun ranges that do not have structures for the collection of lead shot in place, recovering and recycling is more difficult; if it would be done in a shooting range that is in operation, the investments needed in the required infrastructure would be significant. Therefore, the recovering is done at the shooting range only when the operation ceases or in the case the pollutant risk level is assessed to be too high (Finnish Shooting Sport Federation).
- 40 % of recovery rate was achieved by manually collecting lead shot by individuals who have contracts with shooting ranges for recycling (Cyprus Shooting Sport Federation).
- Almost 100 % recovery is achieved for trap/skeet shotgun ranges, in case shot net systems and appropriately prepared deposition areas on earth walls and in the flat are used (German Shooting Sport and Archery Federation).
- FITASC suggested that lead recovery may be mandatory at the time of closure for shooting ranges that are shutting down and recommended the use of techniques to stabilise lead to reduce its potential to migrate.

Considering state of art RMMs, the Dossier Submitter considers that a regular lead recovery rate of ≥ 90 % for lead shot may be achievable in many instances.

With regards to the interval between lead recovery, the German Shooting Sport and Archery Federation has provided the following information: “*On shotgun ranges with shot trap systems made of vertical nets or walls, the lead shot is collected and reclaimed one to three times a year, depending on the intensity of use. At shot trap systems with nets, the lead shot is recovered by hand using simple devices (broom and shovel) or smaller machines (wheel loader with trailer). This work is usually carried out by shooting range staff or club* *members in compliance with the relevant occupational health and safety regulations and lasts about one to two days."*

Data on the incidence of ranges in the EU that recover > 90 % lead gunshot is not available. For shotgun ranges, regular lead recovery is expected to be infrequent. The Dossier Submitter assumes that ranges having state of art environmental risk management measures in place to recover > 90 % of lead shot (annually) are less than 200 (< 5 %) in the EU, based on the limited examples identified, for example in the Finnish (Kajander and Parri, 2014) guidance on Management of the Environmental Impact of Shooting Ranges[29] or as reported by some stakeholders like the German Shooting Sport & Archery Federation.

Since lead shot will remain on top of the soil between removal intervals with the risk of mobilisation of lead to run-off water, the design of the ranges require measures to immobilize lead and to construct a drainage and collection system for the management of lead-contaminated drainage water (see following sections).

Recovery reduces lead burden on the soil. However, it is to be assumed that a certain fraction of the lead shot and fragments may remain in the soil even following regular lead recovery. A remediation plan is required in the CSR (2020) for the end of service life.

RMMs to recover lead bullets

Bullets are either trapped in a bullet trap or a berm.

Bullet traps

Bullet traps are a very effective means to allow controlled containment, easy and frequent collection and recycling of the lead bullets (see Figure 1-8) and therefore minimising the releases to the environment.

[29] https://www.enviro.wiki/images/e/ef/2014-Mgmt_of_the_Environmental_Impact_of_Shooting_Ranges_The_Finished_Env..pdf

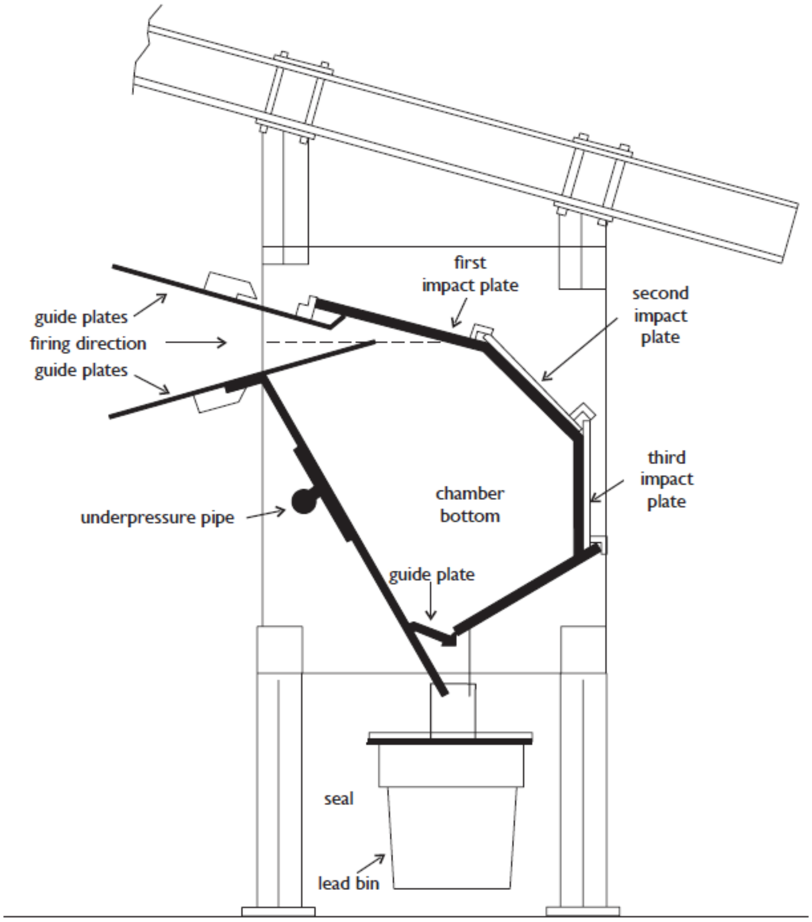

Figure 1-8: Example of a total containment bullet trap (Kajander and Parri, 2014)

In the CSR (2020) bullet containment in the shooting range is required: at least one or a combination of bullet traps, sand traps or steel trap.

According to the German shooting range guidelines (German BMI, 2012) and its update (German BMI, 2013), the following definition of bullet trap systems are provided (translated to English):

Bullet trap systems are self-contained assemblies which, as technical equipment or installations in shooting ranges, safely dissipate the bullet energy of impacting bullets. They must be designed and constructed in such a way that:

- *the absorption or rejection or conduction of impacting projectiles, of whatever type, takes place reliably and safely*
- *enable the projectile material to be disposed of and separated from the catch material as far as possible*
- *safe firing (no dangerous rebound of projectiles and fragments) is ensured for the shooters when shooting at close range*
- *the removal of bullet trapping material is as simple and safe as possible.*

The design and materials used in bullet trap systems must be adapted to the intended use of the respective type of ammunition and weapon and to the shooting technique.

In terms of safety, the bullet trap systems must be coordinated as a self-contained unit with the other structures of the internal safety of a firing range, and in the case of open firing ranges, also with external safety.

The bullet trap systems are classified according to their shooting sport or other intended purpose and the respective energy (E0) of the projectiles.

Examples for the construction of different bullet traps are provided in the German shooting range guidelines (German BMI, 2012), the Finnish BAT (Kajander and Parri, 2014) and in the thesis from Kärki (2016).

Figure 1-9: Example of a prototype of biathlon target equipment and bullet traps installed in a shipping container (Kajander and Parri, 2014)

Figure 1-10: Example for field-target trap (German BMI, 2012)

Kärki (2016) found bullet recovery relative to the amount shot of 91.0 to 91.7 % for shooting to cardboard flats and 87.1 to 87.8 % for biathlon.

With regards to lead bullet recovery, the following information has been submitted to ECHA:

- 100% recovery and recycling: in bullet trap systems (for rifles, pistols and airgun weapons) which are emptied regularly in compliance with the relevant occupational health and safety regulations (German Shooting Sport and Archery Federation);
- 95 to 100% lead recovered (Royal Netherlands Shooting Sport Association);
- Average of 65% lead recovery and recycling is achieved, depending on the type of range including impact berms/backstop (Swedish shooting sport federation).

In a survey among Member States and stakeholders, lead recovery rates for biathlon close to 100% were reported in case bullet traps were used. The use of berms resulted in much lower recovery rates. Therefore, the Dossier Submitter considers that by using bullet traps a lead recovery rate of >90% is achievable.

Data on the incidence of ranges in the EU that recover > 90 % lead bullet is not available.

For rifle and pistol ranges lead recovery by using bullet traps is one of the options among the required risk management measures described in the CSR but there is no evidence that this is a frequently used risk management measure in all EU countries. Soil berms seem to be a commonly used containment (safety) measure based on the available evidence[30]. Based on information available to the Dossier Submitter it is assumed that at about 70 % of rimfire, centerfire and pistol/revolver ranges lead bullets and fragments are removed from backstop berms. This might suggest that in about 30 % of ranges bullet traps are used to recover lead bullets. Based on the Dossier Submitter's understanding of the German shooting range guidelines[31] (requiring the use of bullet trap[32]), it is expected that the majority of ranges in Germany have bullet traps already in place. In addition, Germany is

[30] See for example section 1.4.4.1. Risk management measures for the environment at shooting ranges.
[31] https://www.bundesanzeiger.de/pub/de/amtliche-veroeffentlichung?1
[32] The DS has requested confirmation to the German Competent Authorities, in relation to the current legislation in place in Germany.

likely to host half of the rifle and pistol ranges in the EU[33]. If those assumption would be correct, ca. 50 % of the bullets in the EU would already been recovered. Based on this information the Dossier Submitter assumes that bullet traps are used in 30 to 50 % of the rifle/pistol ranges in the EU.

Recovery reduces lead burden on the soil. However, depending on the discipline and method of recovery, fragments may remain in the soil even after recovery. Therefore, at the end of service life of a permanent range, a remediation plan is required as indicated in the CSR (2020).

Berm with roof

Berms are frequently used as a safety related RMM and to trap bullets. However, according to the CSR (2020) bullet containment (see above) is compulsory.

In backstop berms the bullets are trapped in soil. Contamination hotspots are the target area and the berm (see Figure 1-11).

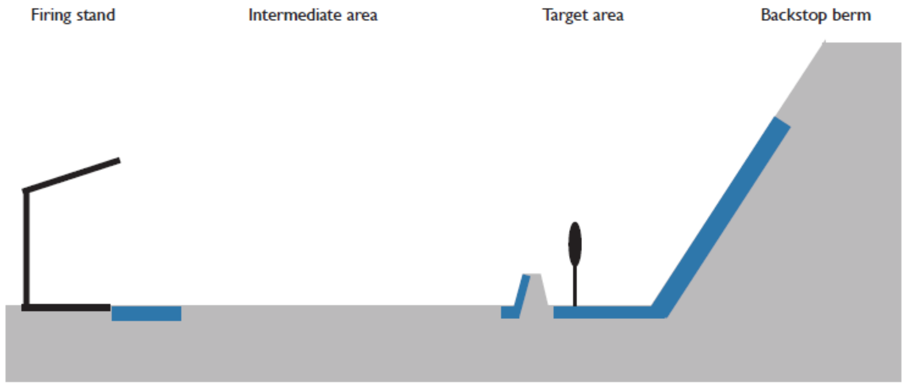

Figure 1-11: Contamination hotspot areas at a rifle or pistol range (Kajander and Parri, 2014)

For outdoor rifle and pistol ranges, impact backstops and target areas may be covered with a roof or other permanent cover to prevent rainwater from contacting berms. However, the roof must be carefully designed to avoid safety issues with ricochets, etc (US EPA, 2005). Furthermore, if a roof keeps a berm too dry, it could crack and erode. This can increase the risk of contamination spreading through wind as dust.

Using a berm made with sand (instead of earthen ones) could slow down lead weathering, but it may increase lead leachability in the long term (Victorian EPA, 2019).

Removal of lead from earthen backstops usually requires soil removal. Continued use of the backstop without removing the lead may result in increased ricochet of bullets and fragments. In addition, the backstop may lose its slope integrity because of "impact pockets" that develop (US EPA, 2005).

In the Finnish report on Best Available Techniques (BAT) for the management of environmental impact of shooting ranges (Kajander and Parri, 2014) three techniques are described for backstop berm renovation:

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[33] This assumption is currently based on data discussed in the Annex (section B.9.1.3) and further clarification was requested for the Competent Authority; it would also need to be verified in the consultation on the Annex XV report in 2021.

- Regular removal of the soil in the impact areas containing the most bullet scrap. The removal interval depends on the number of shots and is recommended every three to five years. It is particularly effective at new ranges when used regularly, allowing the removal of the most significant part of the bullets. At old ranges, some of the load is often deeper in the backstop berm and not affected by the technique. This technique is considered suitable for pistol and rifle ranges where the bullets accumulate in the impact areas. However, it is often expensive on the long term.
- Screening of the impact areas. The soil in the impact areas containing the most bullet scrap is removed regularly. The screening interval depends on the number of shots, recommended 3 to 5 years. The bullets are screened out of the soil that can then be returned to the structure or disposed of as waste. The bullets can be recycled. Fine-grained metal remains in the berm and disturbing the soil may increase the solubility of the metals. The spread of dust with metal content must be controlled. This technique is considered of limited suitability for pistol and rifle ranges where the bullets accumulate in the impact areas. At old ranges, there is the risk of the metal particles attached to the soil become mobile. Most usable at new ranges at sites where the reduction of load is considered to be a sufficient measure.
- Removal of bullet scrap and soil in their entirety. The contaminated soil containing bullet scrap is removed and transported away from the area. Removal in this manner, requires quite extensive earthmoving work. The soil and bullet scrap can be separated by screening. The mass replacement work causes some dust generation and the contamination of clean soil brought to the site. This risk management method is considered effective in principle, but an expensive solution that has poor eco-efficiency.

According to the German shooting range guidelines (German BMI, 2012) and its update (German BMI, 2013), natural hills or walls shall not be used as bullet trap. A berm covered with appropriate material or a wall may be required in addition to the bullet trap for safety reasons as for example for biathlon or for silhouette shooting.

Considering the negative aspects of berms to trap bullets and the availability of highly efficient bullet traps to prevent environmental exposure, the Dossier Submitter concludes that a berm is less effective compared to bullet traps.

Reduction of mobilisation of lead

Spent lead bullets and shot are most often deposited directly on and into soil during shooting. When lead is exposed to air and water, it may oxidize and form one of several compounds. The specific compounds created, and their rate of migration, are greatly influenced by soil characteristics, such as pH and soil types. Knowing the soil characteristics of an existing range site is a key component to developing an effective lead management plan (US EPA, 2005).

Lead shot will remain on the surface between removal intervals with the risk of corrosion and mobilisation of lead to run-off water. There are several measures to reduce mobilisation of lead described in the literature.

Lime amendment

The main purpose of liming spreading is to adjust soil pH. Lime spreading should occur around earthen backstops, sand traps, trap and skeet shortfall zones, sporting clays courses and any other areas where the bullets/shots or lead fragments/dust accumulate. Spreading lime over the shot fall zone should raise the pH of the very topsoil layer to a pH closer to ideal levels and reduce the migration potential of lead, pH should be checked annually and multiple samples around the site should be taken.

Phosphate amendment

The main purpose of phosphate spreading is to bind the lead particles to form pyromorphite[34]. Phosphate spreading should be repeated frequently during the range's lifetime (even on a year basis). Based on information from Scheckel et al. (2013) and US EPA (2015) the following has to be noted:

- not suitable for all concentration ranges of Pb;
- long-term stability of pyromorphite and environmental conditions that could cause it to break down and release soluble Pb into soil not fully clear;
- pH level of soil may influence the chemical form of Pb in soil, with certain forms of Pb not easily reacting with phosphate to form pyromorphite.
- if applied in excess amendments may run off the application area and contaminate ground or surface water;
- uncertainties on the effects on the mobility of important Pb co-contaminants (e.g., As): possible enhanced mobility.
- unclear long term effects on soil quality for agricultural purposes.

Ferrous chemical amendments

The use of ferrous chemical amendments is also reported in the literature, in the form of industrial by-products, as potential stabilisers of metal contaminants (Berti and Cunningham, 1997; Aboulroos et al, 2006; Bertocchi et al, 2006; Kumpiene et al, 2007; Spuller et al, 2007). Such by-products include fly ash, beringite, bauxite and birnessite, which contain not only iron, but also aluminium and manganese oxides, have been shown to be effective in stabilising lead and other metals through different mechanisms to varying degrees, depending on their chemical composition (Sanderson et al, 2012).

Okkenhaug (2013) reports that metallic iron adsorbs heavy metals when oxidised and creates binding sites in the form of iron oxyhydroxides. The process is known to be pH dependent (e.g. iron oxyhydroxides adsorbed lead only when lime was added) and pH did not decrease. In the soil many reactions are occurring simultaneously, with other metals and organic matter in competition for binding sites available with organic matter.

Ultimately the effectiveness of each of these amendments is modified by soil properties, such as pH, texture, clay content, organic matter, as well as naturally occurring iron and manganese oxides (Dayton et al, 2006).

The use of ferrous chemical amendment is further discussed in Annex B (B.4.2.1).

Vegetation

Vegetative ground covers can impact the mobility of lead and lead compounds. Vegetation absorbs rainwater, thereby reducing the time that the lead is in contact with water. Vegetation also slows down surface water runoff, preventing the lead from migrating off-site. However, recovery activities usually require vegetation to be removed before or during

[34] Pyromorphite is several orders of magnitude less soluble than most common Pb minerals in soils, suggesting that transformation of soil Pb to pyromorphite would reduce the bioavailability and therefore toxicity of Pb. Soluble Pb can be immobilized in pure systems as pyromorphite by adding sources of P, still doubts remain about the effectiveness of this approach in natural soil systems. Possibilities of inadequate immobilization, or dissolution of pyromorphite after P-amendments have been reported. (Karna et al, 2018)

recovery. Furthermore, vegetation that attracts birds and other wildlife should be avoided to prevent potential ingestion of lead by wildlife (US EPA, 2005).

Excessively wooded areas (such as those often used for sporting clay ranges) inhibit lead recovery by making the soils inaccessible to some large, lead-removal machinery (US EPA, 2005).

New shooting ranges should be designed with few plants as possible to improve lead recovery and to reduce the attractivity for birds and other wildlife (US EPA, 2005).

Surface cover

Removable surface covers may be used at outdoor trap and skeet ranges. In this case, impermeable materials (e.g., plastic liners) are placed over the shot fall zone during non-use periods. This provides the range with two benefits during periods of rainfall: (1) the shotfall zone is protected from erosion; and (2) the spent lead shot is contained in the shotfall zone and does not come in contact with rainwater (US EPA, 2005).

Surface water (runoff) control

There are two factors that influence the amount of lead transported offsite by surface water runoff: the amount of lead fragments left on the range and the velocity of the runoff.

Runoff control may be of greatest concern when a range is located in an area of heavy annual rainfall because of an increased risk of lead migration due to heavy rainfall events.

Examples of runoff controls include (US EPA, 2005):

- filter beds to collect and filter surface water
- containment traps and detention ponds to settle out lead particles during heavy rainfall
- dams and dikes to reduce the velocity of surface water runoff
- ground contouring to prevent lead from being transported off site.

For shotgun and other ranges, synthetic liners (e.g., asphalt, Astroturf™, rubber, other synthetic liners) can also be used beneath the shotfall zone to effectively prevent rainwater or runoff from filtering through lead and lead contaminated soil. Synthetic liners will generate increased runoff, which must be managed (US EPA, 2005).

These runoff controls are especially important at ranges at which the lead accumulation areas are located up-gradient of a surface water body or an adjacent property. Since lead particles are heavier than most other suspended particles, slowing the velocity of surface water runoff can reduce the amount of lead transported in runoff.

Use of a roof to cover the back-stop berm is an option at rifle and pistol ranges to reduce runoff (CSR, 2020).

After the end of life of a range without remediation, it is unlikely that maintenance will be made to control run off, with increased risks for nearby surface water and other receptors.

Groundwater control

Measurement of ground or leaching water is specifically relevant for older shooting ranges with heavy soil contamination that are located in water sensitive areas or with specific soil conditions; if leaching water or groundwater measurements show levels above the national threshold, remediation of the soil is required. Figure 1-12 provides an example of a system to measure leaching water at a shooting range.

Figure 1-12: Example for measurement of seepage water in a shooting range (Schleswig-Holstein LANU, 2005)

Remediation

Remediation of contaminated soil may be required at the end of life of a sport shooting range using lead ammunition, for example in case a risk to groundwater (which it is likely to materialise during the end of life phase rather than during the service life phase) is identified. Remediation is expected to be needed in case the site is intended to be used after the end of life for agricultural uses or other recreational uses. Remediation is the most expensive RMM measure and may cost up to several millions of euros depending on the site.

Remediation is expected to be needed in ranges located in a water sensitive area and operating for several years or even decades with accumulation of lead shot or lead bullets in the soil. However, in sensitive areas, such as wetlands, remediation may not be technically feasible.

The implementation of this measure is depending on different legislation in place in the EU at national level to identify contaminated sites and on funding availability. Therefore, there is no certainty about the actual implementation of this measure. A remediation plan is anyway indicated in the REACH registration Chemical Safety Report (CSR), 2020 as a RMM to prevent lead releases during the end of life of a sport shooting range.

Based on the information gathered by the Member States survey (2020), in some Member States operators/owners of shooting ranges are responsible for remediation expenses when sites are decommissioned (see Table 1-6). Additional information on legislation in European countries related to remediation is expected to be shared in the consultation 2021. This is also expected to clarify whether in some countries the financial burden to remediate contaminated sites lays on national (public) bodies. Currently available information (from some countries only) is reported in Table 1-6.

Table 1-6 Information on remediation practices in several European countries in relation to the specific responsibility of operators/owners of shooting ranges.

	Are operators/owners of shooting ranges in your country responsible for remediation expenses when sites are decommissioned?
Belgium	**Walloon region:** In Wallonia, according to the Permis Environnement decree, permits must

	impose "the measures (...) for rehabilitation", defined as follows: "set of operations, with a view to the reintegration of the establishment into the environment in view of its reassignment to a functional use and/or with a view to the elimination of the risks of pollution from it; rehabilitation is, for the soil, that which results from the obligations referred to in Article 19 of the Decree of 1 March 2018 on soil management and soil remediation". **Flemish region:** Yes: according to the Flemish Soil Decree, users/operators/owners have the obligation to carry out an exploratory soil investigation on land where certain risk activities are taking or have taken place. This needs to be done upon transfer of land, periodically, and at closure of the activities. Shooting ranges are on the list of activities for which this needs to be done. If soil or groundwater contamination is detected, the user/operator/owner of the land is responsible for further investigation and remediation of the contamination (including the contamination that might have spread to neighboring land). He has also the liability according to the 'polluter pays'-principle
Bulgaria	Yes
Cyprus	No. Only for temporary shooting ranges.
Estonia	No
Finland	Yes
Germany	Yes
Iceland	No
Italy	The decontamination is carried out by specialized companies.
Latvia	No
Lithuania	No
Luxembourg	Yes
Netherlands	Yes
Norway	Yes. According to the Pollution Control Act Section 7
Poland	Yes. The manner of liquidating shooting range is specified in administrative decision approving for use.
Slovakia	Yes. They bear costs on lead waste removal and processing under Act on waste
Slovenia	No
Spain	No, it is not establish in the Arms Regulation
Sweden	No. Not regulated in the planning and building legislation. General environmental legislation shall always apply, but there are no specific provisions addressing shooting ranges.

In the case of a regular recovery of lead shot or bullets in place, the remediation at the end of service life in ranges using lead ammunition is expected to be less expensive compared to ranges without any recovery of lead shot or bullets.

End of service life

For all shooting ranges, even for rifle or pistol ranges with almost 100% lead recovery, contamination of the soil of a shooting range above background level is to be assumed. A remediation plan, for the end of service life, is requested in the CSR (2020) suggesting that further actions are required in addition to applying RMM during service life.

It has to be noted that the RMM applied during service life such as measures to reduce mobilisation of lead, surface water (runoff) and/or groundwater control would need to be continued at the end of service life unless remediation is performed.

Summary of effectiveness of environmental RMMs

Considering the available literature (including guidance) on shooting ranges, the identified RMM are summarised in terms of environmental effectiveness (at qualitative level) in the following Table 1-7. Appropriate RMMs should be implemented based on expert advice, considering the location of the range and the site specific characteristics.

It must be noted that in many instances, RMM (as surface water runoff control) applied during service life may need to be continued at the end of service life unless remediation is performed.

Table 1-7: Environmental effectiveness of different types of RMM applied in shooting ranges

	Measure	effectiveness	Comment
Lead recovery	Wall and/or nets and/or soil coverage to recover shot	Effective	To achieve a high percentage of recovery, several measures might need to be in place
	Bullet trap	Very effective	Regular lead recovery: easy, cheap
	Backstop berm (with or without a cover) to trap bullets	Not effective	Often considered as a "safety" measure, specifically when no cover is present. No regular lead recovery possible; mechanical disturbance of the berm may increase soil contamination
Reduction of lead mobilisation	Lime amendment	Measures may contribute in some sites to reduce lead mobilisation but are not proved to be effective in natural soil systems in the long term to prevent lead migration	Adjustment of pH to reduce migration potential of lead
	Phosphate amendment[35]		Immobilisation of lead in natural soil systems may not be successful; it may have a negative impact on the environment (eutrophication). Expert advice is required
	Vegetation		Vegetation reduces mobilisation of lead but needs to be removed before or during lead recovery
Surface water (runoff) control	Such as: - Filter beds - Containment traps and detention ponds - Dams and dikes - Ground contouring	Effective	Especially in clay target ranges where lead recovery is performed once a year or less, expert advice is required on the most appropriate measure(s) required to control and clean surface (runoff) water

[35] See Appendix B for more details and references.

	Measure	effectiveness	Comment
Groundwater control	Measurements of leaching water or groundwater	Effective	Especially relevant for older shooting ranges with heavy soil contamination and located in water sensitive areas or with specific soil conditions (easily leaching to groundwater); if leaching water or groundwater measurements show levels above the national threshold, remediation of the soil is required
Remediation	remediation	Effective	Remediation is very expensive.

It should be noted that shooting ranges (at which lead shot or bullets are used), even if all required environmental RMMs are implemented, should not be located in sensitive areas[36].

1.4.5. Manufacture and use of fishing tackle

Lead is used to manufacture various kinds of fishing tackle, such as fishing sinkers and lures, but also fishing nets, ropes and lines.

1.4.5.1. Sinkers and lures

Fishing sinkers and lures are attached in some manner to the fishing line where the lead provides weight to assist in casting, and to carry the fishing line with attached lures or bait and hooks to a certain depth in the water. Annex A presents various examples of fishing sinkers and lures. Sinkers can also be attached to a fishing net (cf. further details below).

Some fishing tackle consists solely of lead, for example sinkers, while in lures, lead has been added to obtain additional functions to the main function of lures which is to attract the fish: lead might indeed be added to give sufficient weight to the lure in the water.

There is no universal shape or size of lead fishing tackle due to differences in the type of fish being sought, the equipment being used, and the environmental / fishing conditions. For example, lead fishing sinkers may have various shapes: split shot (i.e. shots with a notch where the line is attached), triangular, egg, cone, teardrop, elongated oval shapes etc. Lead fishing lures might also encompass various shapes such as jig-head, hard lure, trolling spoon or flies. Lead fishing sinkers and lures which may be lost or discarded in aquatic (freshwater and marine) or terrestrial environments range in weight from 0.01 g (dust split shot size n°13[37], or styl weight n°11) to several kilograms (e.g. downrigger marine weight to catch sharks for example).

The production of lead fishing tackle is relatively simple and may take place in small workshops. There are for example, two main techniques to produce lead fishing sinkers and lures:

[36] Water sensitive areas are for example wetlands, areas adjacent to surface waters, biosphere reserves, landscape, nature conservation, medicinal spring and drinking water protection areas, areas with rare or valuable soils and areas whose soils have pH values less than 4 or greater than 9. The use of lead gunshot in or around wetlands will be restricted based on Commission Regulation (EU) 2021/57 of 25 January 2021.
[37] Split shot size No13 weights 0.01 g. Split shots range in weight from 0.01 g to 4.8g. The smallest split shots (≤0.06 g) are often referred as 'dust split shot'.

1. Melting of lead and casting by gravity (also known as 'à la louche' technique) using iron moulds
2. Melting of lead and casting by injection using silicone moulds

In addition, to these techniques, split shots[38] with a size below 4 mm, are produced using 'hunting' gunshot as a raw material.

Detailed descriptions of the various manufacturing processes are available in Annex A.

In addition to the 'industrial' production, described above, lead fishing sinkers and lures can also be produced by individuals at home, or in the back rooms of fishing shops for retail and/or personal use. Production volumes by individuals (aka 'home-casting') is estimated to be substantial in some European countries based on interviews with stakeholders, and information received via the call for evidence. A local survey of fishers in the Netherlands (n=164) reported that approximately 52% of the respondents casted or are still casting their own lead fishing tackle (CfE #1153 - Modified Materials BV). In some areas, home-casting might account for up to 30% of the lead fishing tackle (ECHA Market Survey, 2020). Stakeholders indicated that home-casting was still promoted by some fishing associations (CfE #1153 - Modified Materials BV, and ECHA Market Survey, 2020). There is unfortunately no consolidated data to estimate the scale of home-casting across the EU. In 1994, the US EPA estimated that 0.8 – 1.6 million anglers in the U.S. produced their own lead sinkers, representing ca. 5% of US fishers at that time, and about 30% of the quantity of lead fishing tackle placed annually on the US market (US EPA, 1994).

Home-casting is very easy to perform. The raw material for home-casting can be lead ingots, lead pieces (including 'old' lead fishing tackle) which are available at home, or from fishing tackle shops, small metal recycling workshops, scrap sellers or directly from the internet. The lead is melted and then poured into moulds to manufacture lead sinkers or lures of any size. Moulds and melting equipment can be readily purchased on the internet or day-to-day kitchenware and home equipment (such as a cooking pot, or silicone baking moulds) may also be used. In addition, individuals may also purchase lead shot (ammunition), and cut a groove in the shot with a special tool sold in fishing tackle shops or on internet creating a split shot fishing sinker. Finally, plenty of instructions (videos, pictures) are freely available on the internet to perform home-casting. Details on home-casting is available in Annex A.

'Home-casters' either use the manufactured lead fishing tackle for their personal use or sell it within the local area to other individuals, angling clubs or small retailers, such as fishing tackle stores (ECHA Market Survey, 2020). Most home manufacturers seem to produce non-split shot fishing sinkers.

The lead fishing tackle value chain is relatively short. Lead fishing sinkers and lures are directly distributed from manufacturing companies to large retail companies or are purchased by a distributor who then supplies smaller retailers. Distributors range in scale from individuals to national or even European-wide companies. A significant amount of lead fishing sinkers and lures are also supplied directly from manufacturers located outside Europe, or 'home-manufacturers' to consumers or small retailers by post in case of purchase via social media or via the internet (e.g. Facebook, Alibaba, ebay, Amazon, Wish, made-in-china.com, etc.).

[38] Split shots are a specific types of fishing sinkers. Fishing line is placed into this sliced area and then the sinker is 'pinched' onto the line.

The general picture emerging from the ECHA market survey (2020) is that the market has evolved from a local market to a more global market since the last report from the European Commission on "Advantages and drawbacks of restricting the marketing and use of lead in ammunition, fishing sinkers and candle wicks" (COWI, 2004). Indeed, on one hand, for logistical reasons (rapid response to market demand), fishing tackle remains supplied by European (global or local) manufacturers[39] of which many are SME foundries, or SMEs specialised in the fishing sector. While for the foundries, the lead fishing tackle manufacturing might represent up to 50% of their foundry activity, the other SMEs producing lead fishing tackle might be either very specialised, or might have fishing tackle manufacturing as a small part of their activity in the fishing sector. This picture of the EU manufacturing of lead fishing tackle should be nuanced with the fact that European manufacturing seems to have been condensed during the past 20 years and that for example it is estimated that about 20 companies remains today as European manufacturers of lead fishing sinkers and lures (with only approximately five major EU manufacturing companies with a global market), while COWI was reporting 159 manufacturing companies in 2004.

On the other hand, the import of fishing tackle from outside Europe seems to have increased. This view is based on information provided by EU manufacturers who have seen their production and sales reduce over the past 20 years. There is some confirmation of this when extrapolating the data from the Prodcom and Comext databases for the past 20 years (see Annex A).[40] The main actors in the supply chain also indicate that 'price competition' and 'fewer environmental constraints' are the main reasons for the significant changes in the market during the past 20 years, and the shift from a European supply of lead fishing tackle to an international one (cf. Annex A).

The Dossier Submitter estimates that (based on 2020 data) approximately 1 300 tonnes of lead sinkers and lures were manufactured each year in the EU for the European market (cf. Annex D). Between 5 to 10 % of European manufacturer production is sent for export. In addition to EU manufacturing, it is estimated that ca. 4 100 tonnes of lead fishing tackle are imported each year to Europe (cf. Annex D). The main importing countries for lead fishing tackle are China, US, Canada, UK and Japan.[41]

To summarise, it is therefore estimated that 5 400 tonnes of lead fishing sinkers and lures are annually placed on the EU market, and that 75 % of this quantity is imported (cf. Annex D).

Following the market survey undertaken by the Dossier Submitter and discussions with various supply chain actors, it is estimated that about half (55 %) of the sinkers and jigs placed on the EU market have a weight below 50 g.

1.4.5.2. Fishing nets, ropes and lines

Lead is used for similar purposes in fishing nets, ropes and lines (CfE #1034 - Vlaams

[39] Including home-manufacturers
[40] Prodcom provides statistics on the production of manufactured goods. The term comes from the French "PRODuction COMmunautaire" (Community Production) for mining, quarrying and manufacturing: sections B and C of the Statistical Classification of Economy Activity in the European Union (NACE 2). Comext is a statistical database on trade of goods managed by Eurostat, the Statistical Office of the European Commission. It is an important indicator of the performance of the European Union (EU) economy, because it focuses on the size and the evolution of imports and exports.
[41] Source: KOMPASS (2020), information available from www.kompass.com.

Instituut voor de Zee). It adds weight so the fishing nets, ropes and lines can sink at the desired depth. It is sometimes referred to as 'ballast'. There are two types of ballasts used in fishing nets, ropes and lines: lead sinkers (often barrel shaped ones), and lead cores (often three) braided together and covered with another material (often plastic). The description of the production of fishing nets, ropes and lines is provided in Annex A.

While sinkers and lures may be used for recreational and commercial fishing, the market survey undertaken by ECHA has revealed that fishing nets, ropes or lines containing lead are essentially used for commercial purposes only. This information was also confirmed by the European Fishing Tackle Trade Association (EFTTA).

A few EU companies still manufacture lead fishing nets, ropes or lines in the EU, mostly Southern (Spain, Portugal and Italy) and Northern (Finland, Sweden) Europe. It seems that contrary to the manufacturing of lead sinkers and lures, the manufacturing activities have remained in Europe. This may be because both the manufacturing and the maintenance of the fishing nets, ropes and lines is done in the same factories.

1.5. Environmental risk assessment

1.5.1. Approach to environmental risk assessment

A single, generic, environmental risk assessment was performed for the uses of lead in lead shot, lead bullets and lead fishing tackle. This was on the basis that the source of lead exposure does not affect the resulting effects on the environment and it was not practicable or meaningful in most instances to disaggregate the exposure resulting from the different uses as they comprise a combined source of exposure to the environment. Nevertheless, where relevant, and where data allowed, a more detailed assessment of the risks from specific uses was undertaken e.g. for sports shooting. The approach for the hazard, exposure and risk characterisation is detailed in Table 1-8.

Table 1-8: Approach to environmental risk assessment

Hazard assessment	Information on the hazard of lead for the aquatic and terrestrial compartments. Information on the acute (short-term) and chronic (long-term) toxicity of lead in animals (with a focus on birds) occurring after primary or secondary ingestion from laboratory or field studies; including any relevant thresholds for adverse effects in biota (i.e. blood lead thresholds).
Exposure assessment	Information on the releases of lead to the environment[42] and the resulting environmental concentrations after considering relevant environmental fate, behaviour and transport processes. Information on prevalence/likelihood of exposure in wildlife (with a focus on birds) and domestic animals (livestock). Information on biota concentrations i.e. tissue lead concentrations.
Risk characterisation	Incidence of adverse effects in wildlife (with a focus on birds) arising from ingestion of lead, including comparison of biota concentrations with relevant thresholds. Incidence of adverse effects in domestic animals (livestock) grazing on shooting ranges.

[42] Releases of lead gunshot to wetlands, as defined by the Ramsar Convention, are not included in the assessment as they are already restricted.

1.5.2. Environmental hazard assessment

Information on the hazard of lead for the aquatic and terrestrial compartments are discussed in Annex B.

Non-compartment specific effects are discussed both in Annex B and in the following sections. This include information on the acute (short-term) and chronic (long-term) toxicity of lead in animals (with a focus on birds) occurring after primary or secondary ingestion including any relevant thresholds for adverse effects in biota (i.e. blood lead thresholds).

1.5.2.1. Wildlife (birds)

Massive forms of lead (as used in lead ammunition and fishing tackle) pose a significant hazard to any bird that ingests it. Lead poisoning is a general term for acute or chronic toxicity resulting from the ingestion of lead. The likelihood of a bird species ingesting lead is closely associated with is ecology (ecological niche and habitat that it occupies) and physiology.

The principal routes [43]by which animals are exposed to lead from ammunition or fishing tackle are:

- **primary ingestion (primary poisoning)** defined for the purpose of this report 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 this report as the indirect ingestion of lead via the consumption of food (e.g. embedded fragments/particles in prey or carrion, contaminated silage or grass, lead contaminated tissues).

Primary and secondary ingestion of lead objects (including fragments/particles derived from objects) will be the principal focus of this assessment. However, other routes of exposure are also possible although they have been studied less intensively (Pain et al., 2014). For example, ingestion via soil, plants or invertebrate prey containing lead derived from lead ammunition is also possible[44]. This may be especially relevant in shooting ranges (e.g. rifle and pistol ranges) as briefly presented in Section 1.5.4 (case studies). Similarly, consumption of tissues containing lead as a result of the absorption of previously 'shot in' pellets or fragments in wounded (but survived) wildlife is also possible (Pain et al., 2014).

Primary ingestion is particularly relevant for bird species with muscular gizzards that 'grind down' any ingested metallic lead object (which enhances dissolution and subsequent uptake in the intestine) as well as for bird species susceptible of ingesting lead pieces via the consumption of prey or carrion/viscera left in the environment (secondary ingestion).

The literature describing the causes and consequences of lead poisoning in birds (either through primary or secondary ingestion) is vast. The first extensive analysis of lead poisoning caused by lead ammunition was initiated as early as the 1930s by the US Fish and Wildlife Service (USFWS). Modern scientific reviews evaluating lead-containing ammunition as a cause of lead poisoning include: Rattner et al. (2008), Franson and Pain (2011), Delahay and Spray (2015), Golden et al. (2016), Plaza and Lambertucci (2019), Grade et

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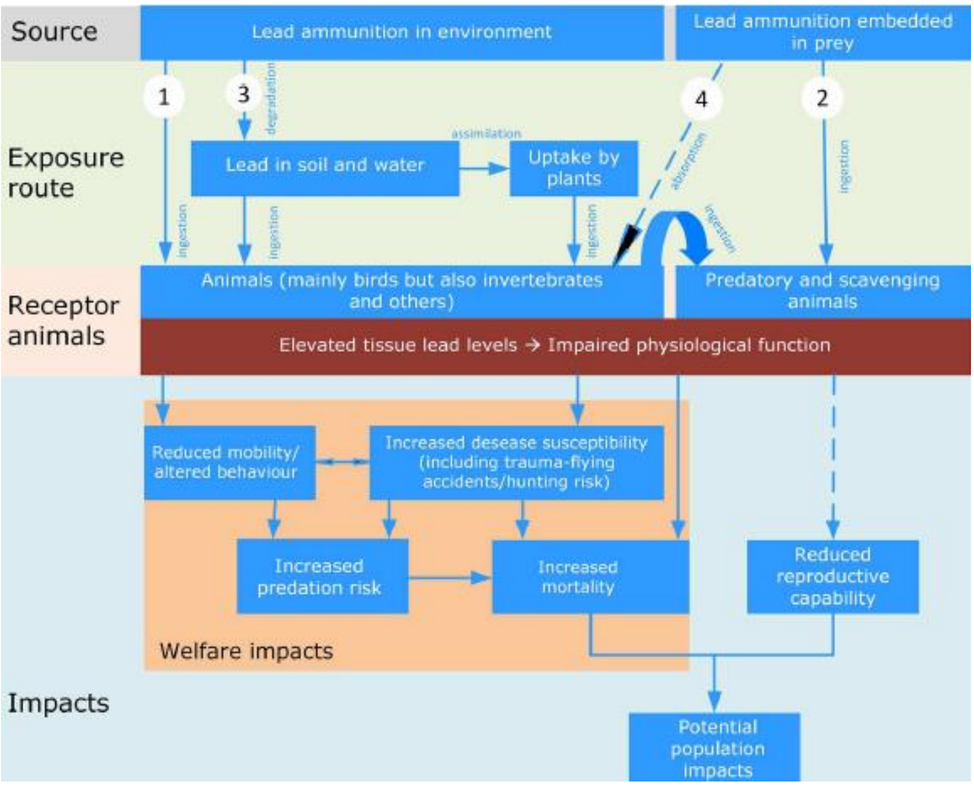
[43] Lead availability for primary and secondary ingestion (uses 1,2,3,7 is discussed in Annex B.9.1.1.).
[44] These routes are acknowledged to be relevant but have not been the primary focus of the assessment. Additional relevant information may become available via the consultation on the Annex XV report in 2021.

al. (2019), LAG (2015). The relationship between lead poisoning and the use of lead-containing fishing tackle has been more recently reviewed in Franson et al. (2003), Scheuhammer (2003), Haig et al. (2014), Grade et al. (2019).



Notes: Ingestion Route 1 corresponds to primary ingestion. Route 2 corresponds to secondary ingestion. *Ingestion routes 1 and 2 are also relevant for fishing tackle.*

Figure 1-13: Lead ingestion routes and receptors related to lead ammunition sources (adapted from Pain et al. (2014))

Toxicokinetics (birds)

In general, the toxicokinetics of lead in birds are closely associated with the biochemical mechanisms and processes that regulate the absorption, distribution and metabolism of calcium. This is a result of the similarity of lead, in terms of atomic structure and mass, to calcium which leads to affinity to calcium uptake channels, enzymes and other biochemical processes that normally involve calcium (Simons, 1993) The lead ion is not metabolised or bio-transformed in birds, though it does form complexes with a variety of proteins and non-protein ligands. It is primarily absorbed, distributed and then the non-accumulated lead is excreted (WHO, 2003).

Absorption

Factors that influence the absorption of lead have been extensively investigated since the 1950s and reviewed by many authors including Pain and Green (2015). The uptake of lead pieces (shot, bullets, fishing tackle) by birds after ingestion is known to vary depending on several factors, including the individual digestive physiology of different bird species.

The main factors affecting the absorption of lead include: stomach characteristics, retention time of lead in the gastrointestinal tract (Schulz et al., 2006), diet and gender. These are outlined below. However, the absorption of lead occurs in the intestine. Any lead ingested becomes more soluble in the stomach and after passing into the intestines, is absorbed as lead salts into the body of the bird (USFWS, 1986).

Stomach characteristics

Following ingestion, lead particles pass down the oesophagus, through the proventriculus (stomach), the primary function of which is gastric secretion, and enters the ventriculus, which is modified into a gizzard in birds. The gizzard is a muscular organ that often contains stones or 'grit' that is used, in the absence of teeth, to grind up food during digestion.

The characteristics of gizzards differ between species, e.g. the well-muscled gizzard of geese can develop pressures of up to 275 mm Hg, which is significantly greater than the pressures of 180 and 125 mm Hg observed for ducks and hens, respectively (FAO, 1996).

According to Golden et al. (2016) citing Farner (1960), species that feed on coarse objects like grain or plant material have muscular gizzards for grinding that are larger than birds whose diet is largely meat.

Grinding of ingested food material in the gizzard, whilst necessary for normal digestion, facilitates the erosion of any ingested lead particles, leading to greater absorption in the gastrointestinal tract than would occur if the lead remained as ingested (Golden et al. 2016). Thus, the particularity of avian digestive physiology is key factor in the lead poisoning observed in birds after the consumption of lead objects.

Different species of birds have different stomach pH. For example, the pH of a duck stomach ranges from 2.0 - 2.5, whilst that of an eagle is closer to 1.0 (USFWS, 1986). In scavengers acidic gastric juices can promote rapid lead dissolution (Fisher et al., 2006; Berny et al., 2015).

Retention time in the gastrointestinal tract

The anatomical characteristics of bird species differ and can influence the retention time and thus the absorption of ingested lead pieces (Franson and Pain, 2011). Individual pieces of lead may either be rapidly regurgitated or, alternatively, passed rapidly through the gut; both resulting in limited absorption of lead. Other pieces may be retained within the gastrointestinal tract until completely dissolved and absorbed. Intermediate retention and absorption, between these two states, is also possible (Franson and Pain, 2011).

In general terms, most lead ingested will either pass through the gastrointestinal tract or be completely eroded within 20 days of initial ingestion (Franson, 1986, Sanderson et al., 1986) cited by Pain and Green, 2015; LAG Annex 4). However, if not ejected from the body within the first 24 hours, lead objects become subjected to grinding within the gizzard and dissolution within the stomach (USFWS, 1986).

Birds of prey typically regurgitate 'pellets' comprising the indigestible portions of their food (e.g. bones, hair and feathers). Lead pieces present in prey can be regurgitated in these pellets.

Falconiformes, with an average gastric pH of 1.6, regurgitate pellets with no bones. Owls, in comparison, with a gastric pH of 2.35 regurgitate pellets with nearly all the bones of their prey (Duke et al., 1975).

In addition, according to Duke (1997) cited by Golden et al. (2016) periodic reverse peristalsis moves the contents of the upper ileum and duodenum back into the stomach, an adaptation hypothesized to allow for greater digestion of nutrients without lengthening the gastrointestinal tract, which would be disadvantageous to flying due to added weight.

Diet

The diet of birds is one of the most important factors in determining the extent of lead absorption after ingestion. In general, because of the grinding that occurs in the gizzard, bird species that prefer whole or part-grain diets are more susceptible to lead poisoning than bird species that prefer 'grainless' diets (USFWS, 1986). Rattner et al. (1989), considered diet to be the most important factor affecting lead-shot toxicity in waterfowl.

More recently, Ferrandis et al (2008) reported that supplying red-legged partridge (*Alectoris rufa*) with large seeds (i.e., corn) may increase the risk of lead shot ingestion.

The nutritional, chemical and physical characteristics of diet are known to affect lead absorption and subsequent deposition in tissues (Jordan and Bellrose, 1951; Longcore et al., 1974a; Sanderson and Irwin, 1976; Koranda et al., 1979, Sanderson and Bellrose, 1986; Scheuhammer, 1996 all cited by Franson and Pain 2011). Differences in the toxicity observed in similarly conducted experimental studies are thought to be related to differences in the diets used in the experiments (Rodrıguez et al. 2010).

Diets high in protein and calcium are known to mitigate the effects of lead exposure (Koranda et al., 1979; Sanderson, 1992; Scheuhammer, 1996 all cited by Franson and Pain 2011). For example, calcareous grit consumption can reduce the rate of dissolution of ingested lead gunshot by reducing acidity within the gizzard (Martinez-Haro et al. 2009).

Other physiological factors

Taylor and Moore (1954 cited by USFWS, 1986), reported that the biochemical changes in female birds associated with active laying enhance the accumulation of lead in bones as does a calcium deficient diet. The medullary bones of birds (i.e. tibia, femur, sternum, ilium, ischium and pubis) supply up to 50 percent of the calcium used in egg production and this rapid turnover of calcium in the laying bird leads to an increased deposition of lead in these bones (USFWS, 1986). Finley and Dieter (1978 cited by Golden et al., 2016), reported that lead concentrations in femurs of laying mallards (*Anas platyrhynchos*) were four times higher than in non-laying females.

When calcium is mobilised for eggshell formation, intestinal absorption of calcium, and concurrently lead, can increase, resulting in greater bone lead concentrations in similarly exposed females than in male birds (Scheuhammer, 1996 cited in Golden et al., 2016). A diet deficient in calcium increases lead absorption in female birds (Scheuhammer and Norris, 1996).

Distribution

Absorbed lead is transported around the body in the bloodstream and deposited rapidly into soft tissues, primarily the liver, kidney, bone and in growing feathers. The greatest lead concentrations are generally found in bone, followed by kidney and liver.

Intermediate concentrations are found in brain and blood whilst the lowest concentrations are found in muscle tissues (Longcore et al., 1974; Custer et al., 1984; Garcia Fernandez et al., 1995; cited by Pain and Green, 2015; LAG Annex 4).

The concentration of lead in blood is a good indicator of recent exposure to lead and usually remains elevated for several weeks to several months following ingestion. Lead in bone is relatively immobile accumulating over an animal's lifetime, although it can be mobilised, particularly in birds, and especially in female birds (Pain and Green, 2015, LAG Annex 4).

Metabolism

Lead competes with calcium ions, resulting in substitution for calcium in bone. It also mimics or inhibits many cellular actions of calcium and alters calcium flux across membranes (Simons, 1993; Flora et al., 2006).

Calcium plays two important physiological roles in birds. It provides the structural strength of the avian skeleton and plays a vital role in many of the biochemical reactions within the body via its concentration in the extracellular fluid (Dacke, 2000; Harrison and Lightfoot, 2006).

The control of calcium metabolism in birds has developed into a highly efficient homeostatic system, able to quickly respond to increased demands for calcium during egg production and during rapid growth rate when young (Bentley, 1998).

There are distinct differences between mammalian and avian systemic regulation of calcium. The most dramatic difference is in the rate of skeletal metabolism at times of demand. This is best demonstrated by an egg-laying bird where 10 % of the total body calcium reserves can be required for egg production within a 24-hour period (Klasing, 1998). The calcium required for eggshell production is mainly obtained from increased intestinal absorption and a highly labile reservoir found in the medullary bone. The homeostatic control of the medullary bone involves oestrogen activity (Bentley, 1998).

Lead also binds to sulfhydryl groups in proteins and breaks disulphide bonds that are important for maintaining proper conformation for biological activity. In addition, it can alter many enzymes via its competing effects with other cations, such as ferrous iron and zinc (Speer, 2015). Effects on specific targets are described in the section describing sub-lethal effects.

Elimination

In general, some of the lead absorbed will be eliminated from the body in waste, but with continuous or repeated exposure some absorbed lead will continue to be retained and bone lead concentrations will increase (Pain and Green, 2015; LAG Annex 4).

Lethal and sub-lethal effects from ingestion of lead ammunition and fishing tackle

The toxic effects of lead are broadly similar in all vertebrates. These effects are well known from many experimental and field studies and have been the subject of many reviews (e.g. Eisler, 1988; Pattee and Pain, 2003; Franson and Pain, 2011; Ma, 2011; cited in Pain et al., 2015).

Many toxicological studies with lead shot have been conducted using captive birds. These studies have involved species from various taxa, particularly wildfowl species but some studies have investigated effects on predatory and scavenging species. These studies typically involve dosing of birds with lead gunshot and subsequent monitoring of blood lead concentrations and physiological and other clinical signs, such as altered behaviour (e.g. Hoffman et al., 1981, 1985, reviewed in Eisler, 1988, Pattee and Pain, 2003, Franson and Pain, 2011 cited in Pain et al., 2015; Golden et al., 2016). Many authors have reported the signs of lead poisoning in birds and the dose of lead gunshot necessary to result in either lethal or sub-lethal effects (Locke and Thomas, 1996; Rattner et al., 2008; Franson and Pain, 2011; Franson and Russell, 2014, all cited in Golden et al., 2016; Rodrıguez et al., 2010).

The conclusions of studies using lead gunshot can be considered to also be relevant for lead fishing tackle. As noted by Twiss and Thomas (1998) commonly used lead sinkers and jigs weigh between 0.5 and 15 g. Experiments with mallard ducks (*Anas platyrhynchos*) demonstrated that mortality was dose related in ducks given commercial lead shot; one #8 shot (0.073 g of lead) caused 35 percent mortality with higher amounts of lead causing 80 to 100 percent mortality (Finley and Dieter, 1978). More recently Brewer et al. (2003)

reported a mortality of 90 percent for birds dosed with 0.2 g of lead shot. This suggests that even one lead sinker or jig of the minimum weight, can be lethal. Twiss and Thomas (1998) also noted that birds that died following the ingestion of a lead sinker are usually in good body condition (Pokras and Chafel, 1992), which implies acute toxicity rather than a chronic condition.

The sub-lethal effects associated with ingestion of lead objects can arise after both acute (short-term) and chronic (long-term) exposure. These are elaborated further in Annex B, and include:

- **Haematology**
- **Cardiovascular system**
- **Kidney histopathology**
- **Growth and body condition**
- **Behaviour and learning**
- **Immune function**
- **Susceptibility to hunting**
- **Reproduction and development**

A number of studies have developed tissue thresholds or reviewed existing thresholds for blood, liver, kidney and bone tissue in birds (Friend 1985; 1999; Franson, 1996; Pain, 1996; and Pattee and Pain, 2003, cited by Rattner et al., 2008; Buekers et al., 2008, Pain et al., 2009; Franson and Pain, 2011; Newth et al., 2016).

Table 1-9 shows the most common thresholds used as indicators of lead exposure (acute or chronic) that can result in adverse effects in birds and other wildlife. The thresholds can also be used for interpreting tissue concentrations for managing wildlife on contaminated areas. These indicative thresholds should only be interpreted as representative of the likelihood that certain clinical and sub-clinical effects in birds will occur and should not be considered to be equivalent to PNECs. Importantly, Pain et al. (2019) reported that sub-lethal effects have been found at lower blood lead concentrations than previously reported (i.e. those reported in Table 1-9), suggesting that previous effect-level 'thresholds' should be abandoned or revised. For example, Espın et al. (2014), cited by Pain et al. (2019), investigated blood lead concentrations that cause effects on oxidative stress biomarkers using blood taken from 66 griffon vultures *(Gyps fulvus)* in Spain, and found that levels >15 µg/dl can result in oxidative stress, risking damage to cell components.

Additional information is provided in Annex B (section B.7.2.1. Toxicity to birds).

Table 1-9: Summary of indicative thresholds for interpreting lead concentrations in various tissues types in birds and other wildlife

Endpoint	**Lead concentration**			**Reference**
Wildlife monitoring	HC5 = 18 (95% CI 12 – 25) µg/dL blood (mammals) HC5 = 71 (95% CI 26 – 116) µg/dL blood (birds)			Buekers et al. (2008)
	Blood	Liver	Bone	

Endpoint	Lead concentration					Reference
General criteria for lead poisoning in wild birds	Wet weight µg/dL	Wet weight µg/g or ppm	Wet weight µg/g or ppm	Dry weight µg/g or ppm	Dry weight µg/g or ppm	Rattner et al. (2008); Derived from: Friend (1985, 1999), Franson (1996), Pain (1996) and Pattee and Pain (2003).
Background	<20	<0.2	<2	<8	<10	
Subclinical poisoning	20 to <50	0.2 to <0.5	2 to <6	>20	10 to 20	
Clinical poisoning	50 to 100	0.5 to 1	6 to 15	-	-	
Severe clinical poisoning	>100	>1	>15	>50	>20	
Winter body condition in whooper swans	>44 µg/dL blood					Newth et al. (2016)

*Notes: **Subclinical concentrations**: tissue concentrations reported to cause physiological effects only (e.g., inhibition of ALAD activity). **Toxic concentrations**: tissue concentrations associated with the clinical signs of lead shot poisoning such as microscopic lesions in tissue, weight loss, anorexia, green diarrhoea, anaemia, and muscular incoordination. **Mortality concentrations**: tissue concentrations associated with death in field, captive or experimental cases of lead poisoning (Franson, 1996).*

1.5.2.2. Other taxa

Lead poisoning from ingestion of lead ammunition and fishing tackle has not been extensively studied in mammalian species.

Predatory and scavenging mammal species such as bears, foxes, raccoon dogs, mustelids and wild boar might be exposed to lead through the consumption of contaminated gut piles, discarded meat or unretrieved game left in the environment (Boesen et al., 2019, Kalisinska et al., 2016, Legagneux et al., 2014, McTee et al., 2017). However, information for these wild species is not sufficient to be further elaborated.

Limited information is available on ruminants which is addressed below.

Toxicokinetics (ruminants)

The physiology of the ruminant digestive system, retention time of lead in the gastrointestinal tract, diet and gender all affect the toxicokinetics of lead.

Absorption

Lead absorption after oral ingestion ranges from 1 to 80 %, and varies considerably depending on the animal species, dose, form of lead (e.g. solid vs dissolved, organic vs inorganic), food/feed composition, nutritional status (e.g. any mineral deficiencies including calcium, iron and zinc or high dietary fat; (Smith and George, 2009)) and age.

Lead shot tends to remain lodged in the reticulum (forestomach) of a cow and is not passed on through to the remaining chambers of the rumen, omasum and abomasum. The reticulum is an alkaline environment in which lead shot can remain in an inert way for a long time without becoming bioavailable and causing any toxicological issues or visible clinical symptoms (personal communication Bischoff, 2021).

However, lead shot as a source of lead poisoning in cattle has been reported (Frape and Pringle, 1984, Rice et al., 1987). Metallic lead in gunshot is unlikely to dissolve in the relatively mildly alkaline environment of the reticulum. However, it is soluble in the more acidic environment of the gastric stomach (abomasum) where lead can become more bioavailable and absorbed.

Lead has a higher bioavailability when exposed as lead acetate rather than as metallic lead materials as demonstrated in ruminants (Mehennaoui et al., 1997). Oral absorption of lead acetate varied between 6 and 14 % of the administered dose (Fick et al., 1976, Pearl et al., 1983), whereas for lead chloride, this value was approximately 2 % (Mehennaoui et al., 1997). Similar values were reported in calves (Pinault and Klammerer, 1990).

The greater toxicological hazard from lead poisoning due to ammunition residue would be from feeding and ingestion of contaminated feed such as corn stock. Lead shot from rough shooting or organised shooting events can become lodged in broad-leafed vegetation subsequently harvested and processed for silage. The lead shot embedded in feed such as maize can then bypass the rumen reticulum directly to the acidic parts of the gastrointestinal tract. Additionally, the acid conditions produced during the fermentation process of the vegetation provides suitable conditions for the production of lead salts which are more readily absorbed by the ruminant.

Distribution

Although lead is generally poorly absorbed in adult ruminants, blood levels may rise to 200 - 400 µg/dL within 12 hours after ingestion of toxic doses (100 mg/kg body weight) and decline to 0.1 µg/dL within 72h. However, the blood lead levels remain above controls for a period of two months (Allcroft and Laxter, 1950, Allcroft, 1951), due to the slow rate of elimination of lead. In the lactating ewe, the half-life of distribution is short (2 - 3 days, (Mehennaoui et al., 1997)) and these values are lower than those observed in cattle (5 - 9 days, (Oskarsson et al., 1992)). Concentrations of absorbed lead are generally high in the liver and kidney but following long-term exposure, inorganic lead is predominantly stored in bone. There is some excretion of Pb into milk, which is another possible mode of entrance into the human food chain (Rumbeiha et al., 2001).

The relationship between lead concentration in blood of exposed cows and lead concentrations in milk was found to be exponential and relatively constant up to a blood lead level of 0.2-0.3 mg/kg (20-30 µg/dL) and increased significantly at higher blood levels (Oskarsson et al., 1992).

Since lead is able to cross the blood brain barrier, cerebellar haemorrhage and oedema associated with capillary damage can occur resulting in the observed neurotoxic effects (Bradbury and Deane, 1993).

Metabolism

Inorganic (metallic) lead is not metabolised but is either passed through the gastrointestinal tract or retained in the reticulum and rumen. Blood Pb concentrations at any given time depend on the absorption of lead remaining in the gastro-intestinal tract and mobilisation from bone.

Elimination

Elimination of lead from the body is incomplete and very slow, which explains the potential for accumulation in some tissues. The major route of elimination of ingested lead is via faeces. Faecal excretion represents unabsorbed lead with a variable proportion of lead excreted with bile. Urinary excretion is usually <2 % of the ingested dose in ruminant species (Fick et al., 1976, Pearl et al., 1983). The elimination half-life of lead is approximately 250 days in lactating ewes (Mehennaoui et al., 1997) and between 95 and 760 days in cattle (Mehennaoui et al., 1988, Rumbeiha et al., 2001).

Lethal and sub-lethal effects from ingestion of particulate lead

A review on lead poisoning in cattle and sheep from different sources such as lead batteries or lead paints has been published by (Payne et al., 2013). The authors reported that in animals dying of acute poisoning, gross lesions of lead poisoning will be minimal with typically congestion of the liver and the kidneys appear pale. There may be gastrointestinal haemorrhage and possibly grossly visible oedema of the central nervous system. In cases of subacute poisoning, there may be laminar cortical necrosis within the cerebrum, which can sometimes be observed grossly and is similar to changes seen in animals with cerebrocortical necrosis and sulphate poisoning. There may be nephrosis. In cases of chronic poisoning, there may be illthrift, emaciation, muscle wastage and developmental abnormalities in foetuses. In lambs, chronic lead poisoning is typically associated with nephrosis and there may also be osteoporosis and fractures, which can affect the vertebral column.

As mentioned above, lead poisoning of livestock such as cows, especially calves, grazing in areas with deposition of lead from shot or bullets or being fed with silage produced from fields located on shooting ranges has been reported (Brown et al., 2005, Rice et al., 1987, Scheuhammer and Norris, 1995, Vermunt et al., 2002b)[45]. Symptoms reported in calves (seven to nine months of age) that were put on pasture in the target area of a shooting range consisted of neurological disturbances and included maniacal movements, opisthotonos, drooling, rolling of the eyes, convulsions, licking, champing of the jaws, bruxism, bellowing and breaking through fences (Braun et al., 1997).

In contrast, for sheep grazing on shooting ranges, no mortality has been reported (Johnsen and Aaneby, 2019, Johnsen et al., 2019). This difference in mortality is assumed to be due to differences in oral absorption which is as little as 1% for sheep but as high as 50% for calves (Wilkinson et al., 2003). In the CSR (2020) the $NOAEC_{oral}$ for Holstein calves is reported to be 500 mg lead/kg food[46].

[45] Regulation (EU) 1275/2013 (animal feed) sets a limit of 10 mg lead/kg (12 % moisture) for animal feed. Regulation (EC) 1881/2006 sets a limit of 0.1-0.3 mg lead/kg food for vegetables and fruits intended for human consumption.
In general, lead concentrations in the harvested material (used as forage) should be below 30 mg/kg (maximum relative to a feed with a moisture content of 12 %) as specified in European Commission DIRECTIVE 2002/32/EC on undesirable substances in animal feed, for this material to be fed to livestock.

[46] For hens, the respective $NOAEC_{oral}$ are reported with 201 to 751 mg/kg food.

1.5.3. Environmental exposure

Information on the releases of lead to the environment and the resulting environmental concentrations (taking into account relevant environmental fate, behaviour and transport processes) from lead uses related to sectors of uses (i.e. hunting, fishing and sports shooting) are discussed in the following section and in Annex B.

Information on prevalence/likelihood of exposure in wildlife (with a focus on birds) and domestic animals (livestock) are presented in the following sections in relation to sectors of uses (i.e. hunting, fishing and sports shooting). However, it has to be noted that in most instances disaggregating the exposure resulting from the different uses (as they comprise a combined source of exposure to the environment) is not practicable or meaningful, as for example in the case of secondary poisoning of wild birds.

Information on biota concentrations i.e. tissue lead concentrations are discussed in Annex B.

1.5.3.1. Releases to the environment

In this section the releases of lead to the environment in the EU27-2020 from uses of lead related to different sectors (i.e. hunting, fishing and sports shooting) are reported. Information on environmental concentrations are discussed in Annex B.

Lead from ammunition (hunting)

The Dossier Submitter has estimated the releases to the environment from different uses related to the hunting sector. Estimates are presented in Table 1-10.

Table 1-10: Estimated amount of lead ammunition released (tonnes) in the EU for hunting per year

Use #	Ammunition type	Estimated releases in EU 27-2020 [tpa in 2020]
1	Lead shot for hunting	1 000 (13 000 to 15 000)[1]
2a	Lead bullets for hunting - small calibre	24 (16 – 26)
2b	Lead bullets for hunting - large calibre	122 (110 to 142)
5, 6	Air rifle, muzzle loading	Not estimated (data not available)

Notes: [1] AMEC (2012) estimated that releases of lead shot from hunting on non-wetland areas accounted for about 20 859 tonnes of lead per year. The sum of other estimates for Spain, Italy and the UK only (EU-28) ranged from 15 600 to 29 000 per year with IT: 6 000 tonnes (Guitart and Mateo, 2006); ES: 1 600 to 10 000 tonnes (Andreotti and Borghesi, 2012); UK:8 000 to 13 000 tonnes (Pain et al. (2014), based on numbers of birds killed and likely numbers of cartridges used 'per bird', including misses).

Given that the proposed restriction on the use of lead in wetlands addressed a volume of 5 000 to 7 000 tonnes of lead per year, the Dossier Submitter estimates that total amount of lead gunshot used and released by hunters in the EU-27 per year after the implementation of the wetland restriction is in the order of 13 000 to 15 000 tonnes per year.

Concerning lead bullets, the estimated baseline tonnage of lead use per year is based on hunting statistics (i.e. the number of animals hunted per year in the EU-27) combined with assumptions on the weight and use of lead bullets (Annex D). The Dossier Submitter estimates that the total quantity of lead released from bullets used for hunting is 130 - 160 tonnes per year.

Lead from ammunition (sports shooting)

A detailed description on the number of ranges, type of ranges included in the estimates and amount of lead used in the EU in sports shooting (including assumptions and uncertainties) is provided in Annex B (section B 9.1.3.) Based on this, the Dossier Submitter has estimated the releases to the environment from different uses related to the sports shooting sector. Estimates are presented in Table 1-11.

Table 1-11: Estimated amount of lead ammunition released (tonnes) in the EU in sports shooting per year

Use #	Ammunition type	Number of shooting ranges in EU 27-2020	Estimated releases in EU 27-2020 [tpa in 2020]
3	Lead shot for sports shooting	About 4 000	35 000 (26 000 – 45 000)
4, 5, 6	Lead bullets for sports shooting	About 16 000	42 000 (4 000 - 80 000)

Due the many uncertainties described in Annex B (section B 9.1.3.) (related to the estimate of the number of shooting ranges and to the amount of lead used every year), the amount of lead released every year has been assumed to be in the range of the estimated amount of lead ammunition used, with the aim to refine data on uses and releases during the forthcoming consultation (2021).

Specifically it is noted that:

- The estimates on the numbers of shooting ranges provided by national sports shooting association do not necessarily overlap with the estimates provided by national authorities. The reasons for this type of divergence are not fully clear and may be related to the fact that the Dossier Submitter requested MS information on registered ranges mainly, whist some ranges may not need to be registered being private clubs. The Dossier Submitter has favoured a cautious approach to avoid overestimating the number of existing ranges and has generally selected the lower bound of the estimated number of ranges (among different sources and values), as in the case of Germany for rifle and pistol ranges.
- Based on the information provided in the REACH registration Chemical Safety Report (CSR) for lead (2020) it can be assumed that on a typical outdoor pistol/rifle range and clay target range 5 000 kg/year and 10 000 kg/year of lead are used, respectively. However, the Dossier Submitter has taken into account different scenarios (considering information gathered by stakeholders) and has used in some scenarios values significantly lower than the ones indicated in the CSR (2020), to avoid overestimating the amount of lead actually being used (See Section B.9.1.3 of the Annex).
- There is no complete information at the EU level (in many Member States) related to a potential annual recovery of lead in many shooting ranges. No RMM is currently

considered mandatory at the EU level (Member States survey, 2020), including measures described in the CSR for lead (2020). Available information on lead recovery does not indicate that annual recovery is currently a typical practice in the EU (Member States survey, 2020).

- For shotgun ranges, regular lead recovery is expected to be infrequent and could be assumed to be in place in less than 5 % of EU ranges (see section 0). Taking into account the low number of such ranges in the EU and the overall uncertainties in the calculation of the quantities of lead shot used (see for details Annex (section B.9.1.3)), the amount of lead released every year has been assumed to be within the estimated amount of lead ammunition used and consequently no further adjustments are made.
- For rifle and pistol ranges lead recovery by using bullet traps is one of the options among the required risk management measures described in the CSR but there is no evidence that this is a frequently used RMM in all EU countries. Overall, no data is available on the total recovery rate of lead bullets in the EU. Soil berms seem to be a commonly used containment (safety) measure based on the available evidence[47]. Based on the Dossier Submitter's understanding bullet traps are used in 30 to 50 % of the rifle/pistol ranges in the EU (0). Taking into account the overall uncertainties in the calculation of ammunition used annually in the EU ranging from 4 000 to 80 000, (see for details Annex (section B.9.1.3)), the central value of the amount of lead used every year has been assumed to be the most likely estimate to reflect the actual amount of lead ammunition released.
- The amount of lead released into (temporary) shooting areas at the EU level has not been estimated due to the lack of specific information, but it is considered to be likely to be additive to the amount of lead releases estimated.

Lead from fishing tackle

Except in some specific fishing practices, essentially those reported for carp fishing (cf. Annex D), lead fishing tackle is not intentionally released to the environment during use. However, releases do occur under reasonably foreseeable conditions of use. The main sources of release identified for fishing sinkers and lures are:

- Unintentional loss of lead fishing tackle, for example when a line breaks, when the tackle is pulled out of the tackle clip/swivel, or when the tackle gets stuck in a natural obstacle (e.g. stones, branches, trees, foliage etc.)
- Unintentional spillage of small lead sinkers on the bank or shore (e.g. split shots)
- Deliberate dropping of 'backlead' or main lead sinker during carp fishing. This practice is recommended by some fishing tackle suppliers in order to improve the catch rate (fish21, 2017).
- Lack of appropriate waste management (i.e. lead fishing tackle ends up in household waste)

With regard to nets, ropes and lines, Deloitte, in a study commissioned by the EU Commission, identified the following three main sources of release to the environment (Deloitte, 2018):

- Accidental loss
- Intentional dumping
- No appropriate formal waste management (e.g. landfilling, difficult to recycle or separate from the plastic)

[47] See for example section 1.4.4.1. Risk management measures for the environment at shooting ranges.

The estimated releases to the environment are summarised in Table 1-12.

It is important to note that there is no one-to-one relationship between the quantity of lead fishing tackle placed on the market annually, and the quantity lost. The release estimates for fishing sinkers and lures were established using the estimated number of fishers and the estimated annual loss per fisher reported in literature. The loss estimates for lead in nets, ropes and line was made by combining information from the Deloitte study, and the impact assessment for the Single Use Plastic (SUP) Directive (EU Commission, 2018) on estimated incidence of net, rope and line losses, as well as information on the content of lead in nets reported in the literature (Tateda et al., 2014). More details on the calculation can be found in Annex D.

Table 1-12: Estimated amount of lead from fishing tackle released to the environment in 2020 per year

Use #		Estimated releases in EU27-2020 [tpa in 2020]
7	Lead from fishing sinkers and lures	3 000 (2 000 – 7 000)
8	Lead from nets, ropes and lines	3 000 (2 000 – 4 000)
	Total lead from fishing tackle	6 000 (4 000 – 11 000)

1.5.3.2. Lead availability for primary and secondary ingestion (use 1,2,3,7[48])

Lead availability for primary and secondary ingestion is discussed in Annex B (section B 9.1.1).

1.5.3.3. Primary and secondary poisoning of wildlife (birds)

The likelihood that lead objects, such as lead ammunition and fishing tackle, are ingested is dependent on: 1) the availability of lead objects in the environment, 2) the specific feeding behaviour of birds, which depends on their ecology, and 3) other environmental and anthropogenic factors (e.g. habitat type).

The environmental and anthropogenic factors that influence the distribution of lead shot in the environment and thus exposure can be summarised as follows (UNEP/CMS/COP11/Inf.34, 2014):

- proximity to hunting or other shooting activities;
- shooting intensity (which may change in different areas);
- compliance with bans (where already in place);
- time in relation to hunting seasons (exposure towards the end of a hunting season is greater);
- habitat over which lead is used and its attractiveness to birds;
- local conditions (affecting sinking/movement of shot over time);

[48] In commercial fishing (use 8) lead is enclosed/embedded/threaded in nets, ropes and lines (CfE #1220 from Danish EPA), and lead from this type of fishing tackle is not considered to be available to enter the food chain.

- land management and land disruption;
- chemical and physical processes in the environment.

An assessment of which EU bird species would be at greatest risk of ingesting lead objects from ammunition or fishing tackle was performed. A list of 533 wild bird species occurring naturally and regularly in Europe (Birdlife, 2015)[49,50] was taken as the starting point for the analysis, to which other criteria were applied to determine individual species risk in a weight of evidence approach:

1. **Direct evidence of lead object ingestion and/or poisoning in the scientific literature**; reporting research done in the EU-27 (preferred) or outside the EU-27 (taking into account that risks to birds and other taxa within the EU can be expected to be similar to those elsewhere, due to conserved feeding ecology/habitat etc).
2. **Indirect evidence of likelihood of exposure based on feeding ecology;** Assuming that the same taxonomic family of birds have similar feeding behaviour. When assessing primary ingestion, evidence was also considered concerning the ingestion of grit and stones by bird species, within the same bird family.
3. **UNEP/CMS ad hoc Expert Group's assessment**[51] of the likelihood of ingesting (i) lead ammunition in terrestrial environments and (ii) lead fishing weights; especially in relation to EU species for which published literature was not available. The approach of UNEP/CMS ad hoc Expert Group is described in Annex B.

The approach to conclude on the likelihood of exposure was the following:

- EU species for which multiple lines of evidence indicated that ingestion had either occurred, or could be reasonably expected to occur, based on the three elements above, were considered **'potentially at risk'** and are further discussed in the following sections and in section 1.8.5.
- All other EU species were considered **'at low risk'** of ingestion. Specifically, based on the assessment made by the UNEP/CMS ad hoc Expert Group (which is also expected to be submitted in the consultation 2021 with additional information), many other species (in the order of some hundreds) may also be at some (low) risk of lead poisoning. For these species, based on the assessment made by the UNEP/CMS ad hoc Expert Group, a preliminary impact assessment (in term of number of birds) has been done (in relation to lead poisoning from ammunition) by the Dossier Submitter and it is summarised in section 1.8.5.

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[49] European Red List (2015) http://datazone.birdlife.org/info/euroredlist. This dataset was then compared with EU (2020) list of bird species released by the European Environment Agency (EEA). Member states as per the Birds Directive Article 12 reporting requirements (Council directive 2009/147/EC) (once available), in order to confirm which species occur in the EU.

[50] Additional information on species range is available from: Clements, J. F., T. S. Schulenberg, M. J. Iliff, S. M. Billerman, T. A. Fredericks, B. L. Sullivan, and C. L. Wood. 2019. The eBird/Clements Checklist of Birds of the World: v2019. https://www.birds.cornell.edu/clementschecklist/download/

[51] At the request of the Dossier Submitter, an *ad hoc* expert group (UNEP/CMS ad hoc Expert Group) of the UNEP-CMS provided specific information on the likelihood of ingestion by European bird species of lead ammunition in terrestrial environments and lead fishing weights, including species for which literature information of ingestion is limited. The mandate for the CMS Secretariat to support the request from the Dossier Submitter is provided from UNEP-CMS Resolution 11.15(Rev COP13): *"6. Urges the Secretariat to consult regularly with relevant stakeholders, including government agencies, scientific bodies, non-governmental organizations and the agricultural, pharmaceutical, hunting and fishing sectors, in order to monitor the impacts of poisoning on migratory birds and to support the elaboration of national strategies and sector implementation plans as necessary to minimize detrimental impacts;".* The Dossier Submitter understands that further information will be submitted by the UNEP/CMS ad hoc Expert Group in the consultation on this Annex XV report in 2021.

1.5.3.4. Likelihood of primary ingestion of gunshot and fishing tackle by birds (uses 1,3,7[52])

Many species (belonging to different taxonomic families of birds)[53] are likely to ingest lead shot and lead fishing tackle[54] in different types of habitats. Lead shot ingestion may also occur in the terrestrial environment from shot ingested in areas/ranges where sports shooting is practiced[55]. However, shooting ranges may have different level of attractiveness to birds depending on their specific location.

Exposure has been documented in more than 120 species worldwide (reviewed by Scheuhammer and Norris 1995, Fisher et al. 2006, Mateo (2009), Pain et al. 2009, Tranel and Kimmel 2009; Haig et al. 2014, Pain et al. 2019, Grade et al.2019).

In the following paragraphs likelihood of exposure is discussed separately for "waterbirds" and "terrestrial species". The objective of such grouping is to highlight that exposure is often the result of a combined source of exposure and therefore a single species may be exposed to multiple sources of lead during its lifetime.

Waterbirds

While many species of waterbirds are expected to be protected from exposure to lead gunshot in EU wetlands as a consequence of the restriction on the use of lead gunshot in wetlands[56], some waterbirds are additionally exposed to lead shot in terrestrial habitats, for example when feeding in agricultural areas, and may be exposed to lead fishing tackle in wetlands, specifically, rivers, lakes and marine habitats.

According to the 2017 assessment by UNEP/AEWA Secretariat of the 150 migratory waterbird species (AEWA-listed species) which occur regularly within the EU, 100 species are vulnerable to lead poisoning from spent lead gunshot. Of these, 85 species were assessed as feeding *primarily* in wetlands. Overall, the species that could be expected to be at most risk of exposure to lead gunshot in **terrestrial environments** are listed in Table 1-13. Geese , swans and cranes are at greatest risk of exposure because they frequently feed in both wet or dry fields. The other species listed may feed in fields which have been flooded.

Table 1-13: AEWA-listed migratory waterbird species being at most risk to be exposed to lead gunshot in terrestrial habitats as assessed by UNEP/AEWA Secretariat in 2017 and by UNEP-CMS ad hoc Expert Group (2020).

[52] In commercial fishing (use 8) lead is enclosed/embedded/threaded in nets, ropes and lines (Danish EPA, CfE #1220 from Danish EPA), and lead from this type of fishing tackle is not considered to be available to enter the food chain.
[53] In general, birds with a muscular gizzard may directly ingest spent lead gunshot in the environment (UNEP 2014) such as Anseriformes, Galliformes and granivorous Columbiformes (including many of the most hunted EU species). Other potentially affected orders of birds include e.g.: Gruiformes, Charadriiformes, Pterocliformes, Passeriformes.
[54] Lead fishing tackle come in a variety of different shapes and sizes. They range from the very small (0.01 g) to the very large (>25 g). Widely used types include split shot, worm, egg and pyramid weights. Split shot ranges in size from 0.01 g to about 4.8 g, with the very small ones resembling the shape of lead shot ammunition. In addition, fishers often use jigs. These are fishing lures which consist of a (lead) weight body which is attached to a hook. More information on all types of fishing tackle is provided in Appendix D.
[55] Ingestion of lead shot in wetlands was assessed in the restriction proposal on the use of lead shot in wetlands. Available data does not allow to assess the specific exposure arising from this "point source" in the terrestrial environment.
[56] 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.

Taxonomy	Common name	"IUCN Red List Category (EU)"
Anas acuta	Northern Pintail	VU
Anas crecca	Common Teal	LC
Anas platyrhynchos	Mallard	LC
Anser albifrons	Greater White-fronted Goose	LC
Anser anser	Greylag Goose	LC
Anser brachyrhynchus	Pink-footed Goose	LC
Anser caerulescens	Snow Goose	NE
Anser erythropus	Lesser White-fronted Goose	CR
Anser fabalis	Bean Goose	LC
Branta bernicla	Brent Goose	LC
Branta leucopsis	Barnacle Goose	LC
Branta ruficollis	Red-breasted Goose	NT
Cygnus columbianus	Tundra Swan	EN
Cygnus cygnus	Whooper Swan	LC
Cygnus olor	Mute Swan	LC
Anthropoides virgo	Demoiselle Crane	NE
Grus grus	Common Crane	LC

Notes: The overview was provided for the purpose of informing the opinion making by RAC and SEAC on the proposed restriction of lead in gunshot in wetlands and was done by the UNEP/AEWA Secretariat in cooperation with the Wildfowl & Wetlands Trust (WWT). The assessment was submitted in the consultation on the Annex XV report for the wetlands restriction proposal (2017), comment #1873. This information has been confirmed in the recent assessment of the UNEP-CMS ad hoc Expert Group (2020).

Waterbird species have been documented to be affected by the ingestion of lead fishing tackle although the available evidence is generally limited as only a few species have been studied (Grade et al., 2019)[57]. However, worldwide, 33 species of birds have been documented to have ingested lead fishing tackle (Grade et al., 2019)[58]. US EPA (1994) estimated that 75 North American bird species can be at risk of lead tackle ingestion due to their feeding behavior. Scheuhammer et al. (2003) stated that all species of piscivorous birds, as well as species that feed in nearshore soils and sediments, are at risk of lead poisoning from consumption of lost or discarded lead sinkers.

In addition, it is also be possible that in some cases it might become difficult to distinguish (when documenting ingestion) between the different lead sources (for example shot ammunition and small split shot used for fishing), for example if a split shot has become ground down in the birds gizzard. This possibility seems to be confirmed by Mudge (1983) when assessing the incidence and significance of ingested lead pellet poisoning in British wildfowl: *"the majority of pellets found in gizzards were spent shot from shotgun cartridges. Anglers' split shot were only identified with certainty in one pochard and four mute swans. However, in a further three mute swans, and in many cases with other species, the pellets were too heavily eroded for their origin to be reliably judged."*

The feeding behaviour of species (including the tendency to ingest grit and stones) affects the likelihood to ingest different types and sizes of fishing tackle. UNEP-AEWA (2011) stated that waterbirds usually ingest fishing tackle mistaking them for food or grit.

AEWA listed species of ducks (Anatidae) will be susceptible to ingesting split shot in the same way that they are susceptible to ingesting spent gunshot. Angler's lead weights have been reported in Greater Scaup (*Aythya marila*) by Grade et al. (2019) and in common pochard (*Aythia ferina*) by Mudge (1983). Species like the mallard and pintail that mostly feed in shallow water and sift through bottom sediments to find food may be especially vulnerable (Eisler, 1988). Twiss and Thomas (1998) reported the deaths of at least six species of waterbirds in Canada after ingesting one or more lead fishing weights, with the common loon being the species most often affected. Loons are well known to ingest lead sinkers when they sift through sediment in the water, looking for invertebrates or possibly pebbles that aid in digestion in the gizzard (Michael, 2006). Grade et al. (2019) reported that the majority of fishing tackle objects ingested by loons (in US) that died from lead poisoning, were jigs and sinkers.

Franson (2003) reported findings for 28 species of waterbirds examined for ingested lead fishing weights. Of 2 240 individuals, 23 had ingested tackle, including common loons

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[57] Grade et al. (2019) also report ingestion of fishing tackle by non-avian species, including 3 mammal and 2 reptile species; Humans, *Homo sapiens* (Mowad et al. 1998, St. Clair and Benjamin 2008), Dog, *Canis lupus familiaris* (Bengfort and Carithers 1976) Harbor seal, *Phoca vitulina* (Zabka et al. 2006), Snapping turtle, *Chelydra serpentina* (Borkowski 1997) Painted turtle, *Chrysemys picta* (Scheuhammer et al. 2003).

[58] Trumpeter swan (*Cygnus buccinators*), Mute swan (*Cygnus olor*), Tundra swan (*Cygnus columbianus*), Whooper swan (*Cygnus cygnus*), Canada goose (*Branta Canadensis*), Wood duck (*Aix sponsa*), Mallard (*Anas platyrhynchos*), American black duck (*Anas rubripes*), Redhead (*Aythya americana*), Greater scaup (*Aythya marila*), White-winged scoter (*Melanitta deglandi*), Long-tailed duck (*Clangula hyemalis*), Red-breasted merganser (*Mergus serrator*), Common merganser (*Mergus merganser*), Great blue heron (*Ardea Herodias*), Great egret (*Ardea alba*), Snowy egret (*Egretta thula*), Green heron (*Butorides virescens*), Black-crowned night-heron (*Nycticorax nycticorax*), White ibis (*Eudocimus albus*), Double-crested cormorant (*Phalacrocorax auritus*), Sandhill crane (*Antigone canadensis*), Brown pelican (*Pelecanus occidentalis*), American white pelican (*Pelecanus erythrorhynchos*), Northern gannet (*Morus bassanus*), Laughing gull (*Leucophaeus atricilla*), Herring gull (*Larus argentatus*), Royal tern (*Thalasseus maximus*), Common loon (*Gavia immer*), Red-throated loon (*Gavia stellate*), Little penguin (*Eudyptula minor*), Bald eagle (*Haliaeetus leucocephalus*), Great horned owl (*Bubo virginianus*).

(*Gavia immer*), brown pelicans (*Pelecanus occidentalis*) and one double-crested cormorant (*Phalacrocorax auritus*) and one black-crowned night heron (*Nycticorax nycticorax*).

More in general, the ingestion of anthropogenic debris in the oceans by birds was studied by Roman et al. (2016). They found that debris ingestion occurred in Procellariiformes, Suliformes, Charadriiformes and Pelecaniformes, across all surveyed habitats, and among birds that foraged by surface feeding, pursuit diving and search-by-sight. Fishing debris (66.7 ± 16.7%) was the most abundant item ingested by coastal marine birds. Fishing debris, including fishing line, lures, hooks and sinkers (83.3 ± 16.7%), was also the most common item ingested by diving birds. Fishing debris was found in the digestive contents of all seabird orders, but constituted the most abundant ingested debris type only in Suliformes (83.3 ± 16.7%).

UNEP-AEWA (2011) concluded that whilst fishing tackle comes in a variety of different shapes, waterbirds usually ingest smaller weights, weighing less than 50 g and being smaller than 2 cm in any dimension. However, larger waterbirds can ingest larger-sized, heavier weights. Available evidence supports this conclusion. For example, (Franson, 2003) reported the size of ingested lead weights ranging from split shot of 7 mm in the longest dimension to a 22 × 39 mm pyramid sinker, weighing around 2 and 79 g, respectively. Furthermore, Franson (2003) reported that six of the ingested lead weights were more over 25.4 mm in the longest dimension. In loons even jigs exceeding 100 g have been radiographically detected (Grade, 2019). Grade et al. (2019) list the typical weights of tackle found in loons ranging from 0.3 to 30.4 g for sinkers and 0.3 to 20.9 g for eroded jigs. Pokras (2009) concluded based on 522 carcasses of common loons that they mostly ingest objects less than 2.5 cm long and weighing less than 25 g.

According to Franson et al. (2001) the size range of stones ingested as grit in common loons suggests that birds do not ingest lead fishing weights greater than 25.4 mm in any dimension if ingested as grit. It is therefore likely that larger tackle is ingested while consuming fish with attached tackle (i.e. via the secondary ingestion route).

Figure 1-14: Fishing weights found in the stomachs and gizzards of birds that died from lead poisoning (after Field Manual of Wildlife Diseases, General Field Procedures and Diseases of Birds, USGS, 1999)

UNEP-AEWA (2011) concluded that the weights that tend to be ingested are exclusively used for sport angling (i.e. recreational fishing, use 7). In commercial fishing (use 8) lead is enclosed/embedded/threaded in nets, ropes and lines (CfE #1220 - Danish EPA), and lead from this type of fishing tackle is not typically ingested by birds (CfE #936- UK EPA).

Table 1-14 lists the species occurring in the EU27-2020 that are most likely to ingest lead fishing tackle, with a focus on lead fishing sinkers (especially in relation to the Anatidae family). However, the list is not intended to be exhaustive. Additional information may become available in the consultation on the Annex XV report, in relation to other species at potential risk (especially in relation to coastal marine birds). UNEP/CMS ad hoc Expert Group assessment (2020) focused on lead fishing sinkers.

When direct evidence of ingestion was not available for a specific species, feeding ecology, taxonomy and UNEP/CMS ad hoc Expert Group opinion were used to conclude on the likelihood of exposure, following the approach indicated in Section 1.5.3.2.

Table 1-14: AEWA-listed migratory EU species (belonging to different families) being most likely to ingest lead fishing tackle

Family	*Taxonomy*[1]	Common name	IUCN Red List Category	Main reason for concluding on the likelihood of exposure[2]
Anatidae	*Anas Acuta*	Northen Pintail	VU	Feeding ecology as confirmed by UNEP/CMS Expert Group opinion. Evidence for birds within the same family
Anatidae	*Anas crecca*	Common Teal	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group opinion. Evidence for birds within the same family
Anatidae	*Anas platyrhynchos*	Mallard	LC	Listed by Grade et al. (2019)
Anatidae	*Aythya ferina*	Common Pochard	VU	Listed by Mudge (1983)
Anatidae	*Aythya fuligula*	Tufted Duck	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group opinion Evidence for birds within the same family
Anatidae	*Aythya marila*	Greater Scaup	VU	Listed by Grade et al. (2019)
Anatidae	*Aythya nyroca*	Ferruginous Duck	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group. Evidence for birds within the same family
Anatidae	*Cygnus columbianus*	Tundra Swan	EN	Listed by Grade et al. (2019)
Anatidae	*Cygnus cygnus*	Whooper Swan	LC	Listed by Grade et al. (2019)
Anatidae	*Cygnus olor*	Mute Swan	LC	Listed by Grade et al. (2019) See also case study under section “Risk Characterisation”(1.5.4)

Family	*Taxonomy*[1]	Common name	IUCN Red List Category	Main reason for concluding on the likelihood of exposure[2]
Anatidae	*Marmaronetta angustirostris*	Marbled Teal	CR	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group. Evidence for birds within the same family
Anatidae	*Netta rufina*	Red-crested Pochard	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group. Evidence for birds within the same family
Anatidae	*Oxyura leucocephala*	White-headed Duck	VU	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group. Evidence for birds within the same family
Anatidae	*Spatula clypeata*	Northern Shoveler	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group. Evidence for birds within the same family
Anatidae	*Spatula querquedula*	Garganey	VU	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group. Evidence for birds within the same family
Gaviidae	*Gavia adamsii*	Yellow-billed Loon	NE	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group. Evidence for birds within the same family (common loon (*Gavia immer*) and red-throated loon (*Gavia Stellata*) listed by Grade et al. (2019))
Gaviidae	*Gavia arctica*	Arctic Loon	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group. Evidence for birds within the same family (common loon (*Gavia immer*) and red-throated loon (*Gavia Stellata*) listed by Grade et al. (2019))
Gaviidae	*Gavia immer*	Common Loon	VU	listed by Grade et al (2019)
Gaviidae	*Gavia stellata*	Red-throated Loon	LC	listed by Grade et al. (2019)
Pelecanidae	*Pelecanus crispus*	Dalmatian Pelican	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group. Evidence for birds within the same family (brown pelican (*Pelecanus occidentalis*) and American white pelican (*Pelecanus erythrorhynchos*) listed by Grade et al., 2019)

Family	Taxonomy[1]	Common name	IUCN Red List Category	Main reason for concluding on the likelihood of exposure[2]
Pelecanidae	*Pelecanus onocrotalus*	Great White Pelican	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group. Evidence for birds within the same family (brown pelican (*Pelecanus occidentalis*) and American white pelican (*Pelecanus erythrorhynchos*) listed by Grade et al., 2019)
Threskiornithidae	*Platalea leucorodia*	Eurasian Spoonbill	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group

Notes: [1] Among these species some may be at higher risk than others, based on specific habitat preferences; [2] When direct evidence of ingestion was not available for a specific species, feeding ecology, evidence for birds within the same family and UNEP/CMS ad hoc Expert Group opinion were used to conclude on the likelihood of exposure. UNEP/CMS ad hoc Expert Group assessment focused on lead fishing weights.

Terrestrial birds

Several groups of terrestrial bird species ingest spent lead shot deposited in the environment, either accidentally when feeding or intentionally when pellets are mistaken for grit[59] which are ingested to aid digestion. Evidence of exposure is often reported in terms of prevalence of lead shot ingestion, which typically refers to the presence or absence of lead gunshot in the gizzard of a bird. However, of equal interest is the number of lead gunshot that have been ingested, i.e. the magnitude of the exposure. In addition, lead in various tissues can provide evidence of occurring lead exposure in wild species.

The prevalence of lead gunshot ingestion has been reported to vary between species and populations, most likely as a function of diet and grit preference (Mateo et al., 2014 citing Pain, 1990; Mateo et al., 2000; Figuerola et al., 2005). Most birds that eat plant material (as seeds) and some that eat invertebrates ingest grit (Best and Gionfriddo, 1994, Gionfriddo and Best, 1999). Best and Gionfriddo (1994) found that of 90 bird species from 10 orders, 69% ingested grit. Grit ingestion tends to be highest in granivores and lowest in insectivores, and grit size ingested varies among species and genera. In general, ingested grit size varies with the body weight of birds (larger birds generally eat larger grit) and diet. However, most grit-eating birds will eat quite a wide range of grit sizes.[60]

Butler et al. (2005) studied the ingestion of pellets in common pheasants (N = 437) killed

[59] More precisely gastroliths (grit and stones).
[60] Frequently used shot for shooting birds include: size 9 shot which is about 2 mm diameter, a number 6 which is 2.6 mm and number 4 which is 3.1 mm. While the smallest lead shot commonly used (no 9) is about 2 mm diameter, eroding shot in the top few cm of the soil can be smaller than this (e.g. Vyas et al 2000). Deposited shot can be of similar size to ingested seeds and grit found in the intestines of several songbird species (<0.2-3.4 mm, cited in Vyas et al 2000). GIONFRIDDO, J. P. & BEST, L. B. 1995. Grit use by house sparrows: effects of diet and grit size. *The Condor,* 97**,** 57-67. found that in 60 House Sparrow gizzards, individual grit particle sizes ranged from 0.1 mm to 2.4 mm. Even some smaller and largely insectivorous birds have been reported to ingest larger gastroliths, e.g. up to 6mm diameter in barn swallows (BWP, Volume V, page 267). Grit size up to 14.9 mm in white-naped cranes from Japan and 14.0 mm in hooded cranes were reported by UEGOMORI, M., HARAGUCHI, Y., OBI, T. & TAKASE, K. 2018. Characterization of gizzards and grits of wild cranes found dead at Izumi Plain in Japan. *Journal of Veterinary Medical Science***,** 17-0407. The body weights of these crane species overlap with the common crane found in Europe.

on 32 game farms in the United Kingdom from 1996 to 2002, and as a global prevalence, 3 percent had ingested pellets. Of these, 77 percent had ingested a single pellet, 15 percent two pellets and 8 percent three pellets. The prevalence of pellets ingested in the common pheasant was studied in 14 game farms in Hungary, with rates from 0 to 23.1 percent (N = 947) (all areas: 4.75 %), and the number of pellets ingested varied between one and eight (Imre, 1997).

As reported by Potts (2005), a pheasant on the Sussex Downs in 1970, had ingested 87 lead shot (Beer 1988), and a grey partridge (*Perdix perdix*) in Denmark in 1976 had ingested 34 (Clausen and Wolstrup, 1979). Butler et al. (2005) reported that one red partridge (*Alectoris rufa*) (0.16 %) of the 637 collected between 1955 and 1992 in the United Kingdom contained lead shot in its gizzard, as well as two other partridges (1.4 %) of 144 fired in the 2001-02 hunting season. Soler-Rodríguez et al. (2004) also examined seven red partridges in Spain and found 14 shot in one of the gizzards.

Romero et al. (2020), in their analysis based on 530 samples of different species[61], studied the presence of lead pellets in the crop, gizzard and intestine of the birds. They included in their study birds killed by hunters with firearms and other means, in different types of territories (and different provinces in Spain) with different hunting intensity (game farm, hunting estates, airport, etc.) and during different moments of hunting seasons. The number of specimens suspected to have ingested lead shot (including red-legged partridges, common woodpigeons, rock doves and stock doves) was 28 (5.6%), and the geometric mean concentration of hepatic Pb was 0.054 $\mu g\ g^{-1}$ (wet weight, ww). A low percentage of samples (4.8%) were above the abnormal exposure threshold (0.65 $\mu g\ g^{-1}$ ww).

Figure 1-15: Red partridge (*Alectoris rufa*) and red partridge gizzard with ingested lead shot. Photo author (left): Rafael Mateo. Photo author (right): E. Pérez-Ramírez. Both figures after Descalzo and Mateo, 2018.

Thomas et al. (2009) when studying red grouse (*Lagopus lagopus scoticus*[62]) analysed leg and foot bones from adults and juveniles collected from hunter-shot birds on different estates in UK in 2003. The lead content of bones was measured by atomic absorption spectrophotometry, and corresponding stable lead isotopes by inductively coupled plasma mass spectrometry. At the Glendye (N=111) and Invermark (N=85) estates, 5.4% and 3.5%, respectively of birds had highly elevated bone lead concentrations (>20 microg/g dry

[61] Seven species were studied: 107 common woodpigeons (*Columba palumbus*), 99 rock doves (*Columba livia*), 30 stock doves (*Columba oenas*), 31 European turtle doves (*Streptopelia turtur*), 219 red-legged partridges (*Alectoris rufa*), 13 Barbary partridges (*Alectoris barbara*), 31 common quails (*Coturnix coturnix*).

[62] Red grouse (*Lagopus lagopus scoticus*) is a subspecies of *Lagopus lagopus*. *Lagopus lagopus* is commonly known as willow ptarmigan or willow grouse.

weight). In bones of these highly exposed birds, a combination of Pb(206):Pb(207) and Pb(208):Pb(207) ratios was consistent with ingestion of lead gunshot available in Europe. By contrast, Yorkshire grouse experienced a high incidence (65.8%) of bone lead >20 microg/g. The Pb(206):Pb(207) and Pb(208):Pb(207) ratios in bones of these highly exposed birds were consistent with a combined exposure to ingested lead gunshot and lead from galena mining in the region.

Stamberov et al. (2018) reported that in quail (*Coturnix coturnix*) gathered during the 2016/2017 hunting season in Bulgaria, after the sectioning and revision of the gizzard and its contents, they found a graphite-coloured lead fragment (defined by XRF) of oval shape and diameter of approximately 1.3 mm and weighing 0.018 g. The study suggests that the pellet was ingested.

Mourning Doves (*Zenaida macroura*) are also very likely to ingest spent lead shot (Kendall et al., 1996). As reviewed by Franson et al. (2009), in several studies, ingested lead shot were found in 0.3 % to 6.4 % of mourning Doves (Castrale, 1991, Kendall et al., 1996, Schulz et al., 2002).

Walter and Reese (2003) found ingested lead pellets in 5.7 % of 123 gizzards from chukars (*Alectoris chukar*) in Oregon, the first known discovery of ingested lead pellets in this species. Larsen et al. (2007) also reported the ingestion of lead pellets in chukars (*Alectoris chukar*) to be 10.7 %, with ingested lead pellets found from birds harvested in four different counties on several different mountain ranges in the US. Larsen et al (2007) noted that the ingestion of lead pellets by chukars was not reported in early (pre-1980) research in North America despite several studies (Zembal, 1977, Knight et al., 1979, and others), which evaluated dietary preferences. This suggests that a general accumulation of lead shot in the environment over the years might enhance the likelihood of ingestion for some species and that an absence of wildlife surveillance programmes may explain the apparent lack of evidence of ingestion (Kuiken et al., 2011, Ryser-Degiorgis, 2013).

Table 1-15: Examples of ingestion of lead shot in commonly hunted EU terrestrial birds

Species	N	% overall ingestion (average)	Country	References
Grey partridge (*Perdix perdix*)	1318 (collected between 1947 and 1992)	1.4	UK	Pott (2005)
Red-legged partridge (*Alectoris rufa*)	637 (collected between 1955 and 1992)	0.16	UK	Butler et al. (2005)
	144 (2001/02 hunting season)	1.4	UK	Butler et al. (2005)
	76 (collected during 2004 and 2006)	3.9	ES	Ferrandis et al. (2008)
	530	5.6%	ES	Romero et al. (2020)

Species	N	% overall ingestion (average)	Country	References
Common pheasant (*Phasianus colchicus*)	437 (collected between 1996 and 2002)	3	UK	Butler et al. (2005)
	947	4.75	HU	Imre (1997)

Examples of lead residues in tissues have been reported by several authors.

As reviewed by Franson and Pain, (2011), a wild ring-necked pheasant (*Phasianus colchicus*) found dead with 29 lead shot in its gizzard had 168 mg/kg (wet weight presumed but not stated) of lead in the liver (Hunter and Rosen 1965). Two female ring-necked pheasants from shooting estates with ingested lead shot had lead concentrations of 378 and 220 mg/kg dry weight in wing bones (Butler et al. 2005). Keymer and Stebbings (1987) reported lead poisoning as the cause of death in a grey partridge (*Perdix perdix*) with 40 mg/kg wet weight of lead in the liver and 100 mg/kg wet weight in the kidney. A grey partridge had lead residues of 130 mg/kg in the liver and 440 in the kidney (wet weight presumed but not stated) with 34 lead pellets in the gizzard (Clausen and Wolstrup 1979).

Clausen and Wolstrup (1979) reported liver and kidney lead residues of 48 and 200 mg/kg (wet weight presumed but not stated), respectively, in a wood pigeon (*Columba palumbus*) that died of lead poisoning.

To take into account that many species have not been specifically and extensively studied in relation to the ingestion of lead shot the likelihood of exposure for these species can be evaluated by extrapolation from other species in the same bird group based on similarity of feeding ecology. In addition, data on grit/small stone ingestion can also be used as a proxy for the likelihood that a species will ingest lead shot. References about the ingestion of gastroliths for many species have been taken from Wings (2004) and Gionfriddo and Best (1999).

Considering the EU Phasianidae family (order of Galliformes) and their feeding ecology, the species listed in Table 1-16 have the greatest likelihood to ingest lead shot.

Table 1-16: EU species belonging to the Phasianidae family that are likely to ingest lead shot

Taxonomy	Common name	"IUCN Red List Category (EU 27)"	Main reason for concluding on the likelihood of exposure in the species belonging to the Phasianidae family
Alectoris barbara	Barbary partridge	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group Evidence for birds within the same family

Taxonomy	Common name	"IUCN Red List Category (EU 27)"	Main reason for concluding on the likelihood of exposure in the species belonging to the Phasianidae family
Alectoris chukar	Chukar	LC	Evidence of lead shot ingestion Larsen et al. (2007)
Alectoris graeca	Rock partridge	VU	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group Evidence for birds within the same family
Alectoris rufa	Red-legged partridge	LC	Evidence of lead shot ingestion Butler et al. (2005)
Bonasa bonasia	Hazel grouse	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group[63] Evidence for birds within the same family
Coturnix coturnix	Common quail	LC	Evidence of lead shot ingestion/ poisoning[64] Stamberov et al. (2018)
Lagopus lagopus	Willow grouse	*VU*	Evidence of lead poisoning Thomas et al. (2009)
Lagopus muta	Rock ptarmigan	*VU*	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group Evidence for birds within the same family
Lyrurus tetrix	Black grouse	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group Evidence for birds within the same family
Perdix perdix	Grey partridge	LC	Evidence of lead shot ingestion Pott (2005)
Phasianus colchicus	Common pheasant	LC	Evidence of lead shot ingestion Butler et al. (2005)

[63] Other evidence available for Non-EU species of grouse include: Ruffed Grouse (*Bonasa umbellus*) as reviewed by Tranel and Kimmel (2009).
[64] Other evidence available for Non-EU species of quail include: Scaled Quail (*Callipepla squamata*); Northern Bobwhite Quail (*Colinus virginianus*) as reviewed by Tranel and Kimmel (2009).

Taxonomy	Common name	"IUCN Red List Category (EU 27)"	Main reason for concluding on the likelihood of exposure in the species belonging to the Phasianidae family
Tetrao urogallus	Western capercaillie	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group opinion Evidence for birds within the same family

Note: Only selected references are listed in the table as example, including references from non-EU countries.

Considering the EU Columbidae (order of Columbiformes) group and their feeding ecology, the species listed in Table 1-17 have the greatest likelihood to ingest lead shot.

Table 1-17: EU species belonging to the Columbidae family being likely to ingest lead shot

Taxonomy	Common name	"IUCN Red List Category (EU 27)"	Main reason for concluding on the likelihood of exposure in the species belonging to the Columbidae family
Columba livia	Rock dove	LC	Evidence of lead shot ingestion Romero et al. (2020)[65]
Columba oenas	Stock dove	LC	Evidence of lead shot ingestion Romero et al. (2020)
Columba palumbus	Common woodpigeon	LC	Evidence of lead shot ingestion Romero et al. (2020)[66]
Streptopelia decaocto	Eurasian collared-dove	LC	Feeding ecology as confirmed UNEP/CMS ad hoc Expert Group Evidence for birds within the same family
Streptopelia turtur	European turtle-dove	*NT*	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group Evidence for birds within the same family
Columba bollii	Dark-tailed laurel-pigeon	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group Evidence for birds within the same family
Columba junoniae	White-tailed laurel-pigeon	*NT*	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group Evidence for birds within the same family

[65] Other evidence available from different countries for this species includes Dement et al. 1987, Tavernier et al. 2004, as reviewed by Pain et al (2009).
[66] Other evidence available for this species includes Clausen & Wolstrop (1979) as reviewed by Tranel and Kimmel (2009).

Taxonomy	Common name	"IUCN Red List Category (EU 27)"	Main reason for concluding on the likelihood of exposure in the species belonging to the Columbidae family
Columba trocaz	Madeira laurel-pigeon	LC	Feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group Evidence for birds within the same family

Note: Only selected references (for some species) are listed in the table as example.

In addition, based on the feeding ecology as confirmed by UNEP/CMS ad hoc Expert Group, the following species are also considered to be likely to ingest lead shot:

- Eurasian woodcock (*Scolopax rusticola*), belonging to the Scolopacidae (Sandpipers and Allies) family;
- Pin-tailed sandgrouse (*Pterocles alchata*), Black-bellied sandgrouse (*Pterocles orientalis*) belonging to the Pteroclidae (Sandgrouse) family.

1.5.3.5. Likelihood of secondary ingestion of shot, bullets and fishing tackle by birds: overview (uses 1,2,3,7[67])

In general, bird species may ingest when feeding, lead contaminated tissues (of preys and carrion), lead ammunition and fishing tackle present within the alimentary tract and/or embedded in either live prey or carrion that they feed on (UNEP, 2014). This may occur for example, when:

- Scavenging birds consume offal or discarded meat (containing either lead shot or bullet fragments) left on the ground by hunters.
- Predatory birds feed on debilitated/wounded prey (e.g. by non-lethal shot) or animals with embedded lead shot (previously wounded but recovered) or birds having ingested lead shot mistaken by grit (Pain et al. (2009)).
- Piscivorous (fish eating) species ingest fishing tackle attached/ingested to/by fish.
- Predators and scavengers feed on waterbirds poisoned by fishing weights (Goddard et al. (2008), Rattner et al. (2008); UNEP-AEWA, 2011).

An example of lead fragments which may become available to birds, from the copper jacket fragmented lead core of a lead-based bullet is provided in Figure 1-16. Copper (non-lead) expanding bullets, compared to lead-based bullet are designed to expand into 4–6 frontal petals (or "mushroom"), exhibit less frangibility and tend to remain intact.

[67] In commercial fishing (use 8) lead is enclosed/embedded/threaded in nets, ropes and lines (Danish EPA, CfE #1220), and lead from this type of fishing tackle is not considered to be available to enter the food chain.

Figure 1-16: Lead fragments from the copper jacket fragmented lead core of a lead-based bullet (left) compared with a copper (non-lead) expanding bullet. (after Golden et al. (2016); Photo courtesy of Institute for Wildlife Studies, P.O. Box 1137 Tres Pinos, California 95075).

The likelihood of secondary ingestion of ammunition or fishing related lead is a combination of the feeding behaviour and anthropogenic factors that influence the distribution of lead. In general, all species that are (at least opportunistic) carnivores, i.e. consume the flesh of other animals at some rate, may be exposed to lead from ammunition and fishing tackle via secondary ingestion. When assessing lead exposure in wildlife a separation between exposure to lead shot, bullets or fishing tackle is often not possible, as many species may ingest different sources of lead when feeding.

For this assessment avian species susceptible to secondary poisoning due to their feeding ecology, via ingestion of ammunition or fishing tackle[68], are categorised according to Table 1-18. Feeding behaviour determines how the species will consume food resources available to them. Specialist species utilise specific resources and have relatively little variation in their diet in comparison to generalist species.

Table 1-18: Avian species categorised by their susceptibility to secondary lead ingestion

Avian species categorised by their susceptibility to secondary lead ingestion	Description	Diet
Vultures (obligate scavengers)	Old and New World species (families Accipitridae and Cathartidae, respectively)	Carrion only

[68] Alternative sources (paint, contaminated water or soils) have also been described in the literature as possible causes of intoxication in wildlife (KATZNER, T. E., STUBER, M. J., SLABE, V. A., ANDERSON, J. T., COOPER, J. L., RHEA, L. L. & MILLSAP, B. A. 2018. Origins of lead in populations of raptors. *Animal Conservation,* 21**,** 232-240.). Confirmation of the source of lead in wildlife can be done with isotope ratio analysis (SCHEUHAMMER, A. M. & TEMPLETON, D. M. 1998. Use of stable isotope ratios to distinguish sources of lead exposure in wild birds. *Ecotoxicology,* 7**,** 37-42.However, the growing use of recycled lead may interfere with distinctive isotopic ratios (SANGSTER, D., OUTRIDGE, P. & DAVIS, W. 2000. Stable lead isotope characteristics of lead ore deposits of environmental significance. *Environmental Reviews,* 8**,** 115-147.).

Avian species categorised by their susceptibility to secondary lead ingestion	Description	Diet
Facultative scavengers, raptor species[69]	Species belonging to families Falconidae and Accipitridae	Live prey and carrion
Facultative scavengers, omnivores	Predominantly species that belong to families Laridae and Corvidae	Plant material, carrion
Opportunistic scavengers, other species	Non-scavenging nocturnal raptor species such as owls. Other species with evidence of secondary poisoning due to hunting or fishing related lead	Live prey, possible scavenging accounts less than 10 % of the diet

This assessment considers scavenging as the common denominator among the identified groups. Obligate scavengers are the most specialised species eating carrion only. However, the group "opportunistic scavengers, other species" consists of all species below a 10 % scavenging threshold[70] - but with evidence of scavenging leading to secondary poisoning. Within this group are species, such as common loons, that ingest fishing gear with their catch, as well as nocturnal birds of prey – a subgroup that rarely scavenges.

The specific groups and example species susceptible to exposure to lead by secondary ingestion are listed in Table 1-19. Species with non-European distribution are mainly discussed in the Annex B.

The information was gathered by identifying the most comprehensive review articles on the matter of ammunition and/or fishing tackle related lead poisoning in birds, assessing the original papers and complementing this with additional relevant information. For European raptor species, one of the most recent and comprehensive reviews and meta-analysis was done by Monclús et al. (2020). For this assessment, we extracted the studies reviewed and grouped by Monclús et al. (2020) with either confirmed or suggested (i.e. expert opinion) ammunition related source, consisting of 14 facultative and 4 obligate scavengers as well as one nocturnal bird of prey. However, for many of the remaining species with undetermined source of lead exposure, either lacking expert judgement of the likely source or isotope assessment, the review found a correlation between higher lead levels and hunting season (cf Annex B.).

Lead tissue concentrations in these species are presented in Annex B. Furthermore, a global review of lead contamination in vultures (Plaza and Lambertucci, 2019) was used in

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[69] Avian species predominantly consuming vertebrates by hunting or scavenging or both, are classified as birds of prey, or raptors. In *Commentary: Defining Raptors and Birds of Prey (MCCLURE, C. J. W., SCHULWITZ, S. E., ANDERSON, D. L., ROBINSON, B. W., MOJICA, E. K., THERRIEN, J. F., OLEYAR, M. D. & JOHNSON, J. 2019. Commentary: Defining Raptors and Birds of Prey. Journal of Raptor Research, 53***,*** 419-430.)* it is stated that no standard definition for raptors and birds of prey exists. However, it is suggested to consider Accipitriformes, Cathartiformes, Falconiformes, Strigiformes and Cariamiformes as birds of prey. For this assessment, only the first four are discussed as there is no known cases of exposure in the last one.

[70] As per defined by BUECHLEY, E. R. & SEKERCIOGLU, C. H. 2016. The avian scavenger crisis: Looming extinctions, trophic cascades, and loss of critical ecosystem functions. *Biological Conservation,* 198**,** 220-228.

screening info for vultures in Europe and elsewhere. Other sources such as conference proceedings was also used when relevant and also information from the Call for evidence (2019).

The group consisting of facultative scavengers that are omnivores, e.g. corvids, is discussed together with the final group, opportunistic scavengers and others. Despite corvids being considered as the most common and frequent scavengers, studies on the issue of ammunition related lead contamination are relatively scarce. We listed 11 species with reported cases of ammunition and/or fishing tackle related lead exposure.

The UNEP/CMS ad hoc Expert Group also shared information relevant for secondary poisoning. This is discussed at the end of this section.

Table 1-19: Species (groups) susceptible to lead exposure via secondary ingestion

Family	Group	Category	Diet Description	Potential source of exposure[1]
Birds of prey				
Accipitridae	hawks	Facultative scavenger	Live prey and carrion	Shot, bullets, fishing tackle
	eagles	Facultative scavenger	Live prey and carrion	
	buzzards	Facultative scavenger	Live prey and carrion	
	harriers	Facultative scavenger	Live prey and carrion	
	kites	Facultative scavenger	Live prey and carrion	
	Old World vultures	Vultures (obligate scavengers)	Carrion only	Shot, bullets
Pandionidae	osprey	Piscivorius	Fish only	Fishing tackle
Falconidae	falcons	Facultative scavenger	Live prey and carrion	Shot, bullets
Cathartiformes	New World vultures	Vultures (obligate scavengers)	Carrion only	Shot, bullets
Strigiformes	Owls	Non-scavenging birds of prey	Live prey	Shot, bullets
Other				
Laridae	gulls	Facultative scavenger	Live prey, carrion, fish, other	Shot, bullets, fishing tackle

Family	Group	Category	Diet Description	Potential source of exposure[1]
	terns	Piscivorius	Predominantly fish	Fishing tackle
	skimmers	Piscivorius	Predominantly fish	Fishing tackle
Corvidae	crows	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	ravens	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	rooks	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	jackdaws	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	jays	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	magpies	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	treepies	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	choughs	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	nutcrackers	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
Other	loons	Piscivorius	Fish	Fishing tackle
	albatross	Piscivorius	Fish	Fishing tackle
	storks and herons	Facultative	Live prey, plant material, carrion	Shots, bullets

Family	Group	Category	Diet Description	Potential source of exposure[1]
	skuas and jaegers	Facultative	Live prey and carrion	Shots, bullets

Notes: [1] ingestion of different type of lead (ammunition versus fishing tackle) has different levels of likelihood depending on the specific species feeding ecology.

Vultures

Globally there are 23 vulture and condor species (hereafter "vultures") occurring in the New World (America, Cathartidae family) and the Old World (Europe, Asia and Africa, Accipitridae) (Plaza and Lambertucci, 2019). In this section exposure data related to vultures are discussed, with a focus on species with European distribution. Additional information is discussed in Annex B.

Vultures as obligate scavengers are highly specialised to consume carrion only, therefore being almost entirely dependent on this food source. Due to their social behaviour and also co-evolutionary history with tracking down hunters and other species in search of carrion, the likelihood to consume contaminated carrion, if available in the population's range, can be high for all individuals in the given vulture population (Ogada et al., 2012). Lead exposure of vultures is most connected to big game hunting where predominantly bullets are used (Hunt et al., 2006). Exposure occurs when hunters leave gut piles and discarded meat containing ammunition or ammunition fragments from their quarry in the environment (Mateo-Tomas et al., 2015). However, lethal exposure to shot via secondary ingestion is also possible and seems to be spatio-temporally connected in higher density of hunting activities of smaller game (Donázar et al., 2002).

Lead exposure in vultures has been reported and reviewed in many recent scientific papers (Gangoso et al., 2009, Carneiro et al., 2014b, Carneiro et al., 2016, Behmke et al., 2015, Bounas et al., 2016, Garbett et al., 2018, Naidoo et al., 2017, Krüger and Amar, 2018, Ganz et al., 2018, Plaza and Lambertucci, 2019, van den Heever et al., 2019, Roach and Patel, 2019, Miglioranza Rizzi Possignolo, 2019). Vultures are considered the most threatened bird guild in the world due to anthropogenic factors (Botha et al., 2017). Due to their threated status, vultures are now being targeted for conservation action in the Convention on Migratory Species Multi-species Action Plan to Conserve African-Eurasian Vultures (CMS-MsAP), and reducing the threat of lead toxicity has been identified as a priority across the range states (CfE #1151, Vulture conservation foundation).

Plaza and Lambertucci (2019) reported that 13/23 vulture species had been studied globally for lead exposure and 88 % of the articles discovered lead concentrations above the threshold in some tissues in these species. The most common reported lead source was ammunition, although not always confirmed through isotope studies.[71] The source of lead was confirmed through isotope ratios in 13 % (8/62) of the studies (Plaza and Lambertucci, 2019). Out of 62 reviewed articles of lead poisoning and exposure in vultures by Plaza and Lambertucci (2019), 72 % (45/62) came from North America and 30 % (19/62) from Europe. 15 of the European studies came from Spain, likely reflecting that most vultures in Europe live in Spain and furthermore, that hunting is a significant activity in the country (Plaza and Lambertucci, 2019).

A comprehensive recent review of the effects of lead from ammunition on birds and other wildlife by Pain et al. (2019) list exposure and poisoning incidents in two different vulture species in Europe; bearded vulture (*Gypaetus barbatus)* and Griffon vulture (*Gyps fulvus*) and in four species outside Europe (Table 1-12). Other cases of lead exposure in Egyptian vulture (*Neophron percnopterus*) and cinereous vulture (*Aegypius monachus*) in Europe were listed in Pain et al. (2009).

Overall, all four European vulture species have been found to suffer the effects of

[71] Some articles reported other sources of lead such as mining and pollution or then the source was not investigated.

ammunition related lead (Table 1-20)[72]. Recorded cases for the four species include uses of lead ammunition in big game hunting, small game hunting and in pest control. Spatio-temporal connection of lead exposure with hunting season and hunting activity has been confirmed in multiple studies in Europe and globally (Plaza and Lambertucci, 2019).

Table 1-20: Vulture species with European distribution and their association to ammunition related lead exposure

Species And Conservation Status (IUCN Red List EU 27)	Details of EU population*	Reported lead poisoning via secondary ingestion[1]
Egyptian vulture (*Neophron percnopterus*) VU	Only European vulture that migrates to Africa in winter. Sedentary population in Canary Islands. Majority of European population in Iberian peninsula, 1 300-1 500 pairs. France (80 pairs) and Italy (10 pairs)	Donázar et al. (2002), Gangoso et al. (2009)
Bearded vulture (*Gypaetus barbatus*) VU	Rarest vultures in Europe, total population in the area estimated to range from 600 to 1000 pairs. Pyrenees 100 pairs, Corsica 8 pairs, Crete 9/10 pairs and reintroduced population in the alps, 20 breeding pairs.	Ganz et al. (2018); Hernández and Margalida (2009)
Griffon vulture (*Gyps fulvus*) LC	Breeding population in Europe between 19 000 - 21 000 pairs, distributed mostly in Portugal, Spain and French Pyrenees	Berny et al. (2015) Carneiro et al. (2014b)
Cinereous vulture (*Aegypius monachus*) LC	Total European breeding population approximately 1800 pairs, mainly in Spain. Greece has the only remaining colony in the Balkans with 25+ pairs and France has reintroduced population of about 25 pairs.	Cardiel et al. (2011)

**Source: Vulture conservation foundation https://www.4vultures.org/vultures/ (reviewed 01.09.2020)*

Notes: [1] Either acute poisoning or chronic accumulation

A small, sedentary population of re-introduced bearded vultures in the Alpine region has been connected to lead poisoning and exposure due active ungulate hunting in the area. The IUCN Red List conservation category for the species on European level is considered vulnerable. Ganz et al. (2018) discovered high lead concentration in liver and bone in bearded vultures of the Swiss Alps, higher than those found for the same species elsewhere in Europe or North America, reaching the levels compatible with acute poisoning. Two of five bearded vultures had very high bone lead concentrations (58.90 µg/g and 100.04 µg/g). Madry et al. (2015) showed isotope-proven connection to ammunition derived lead burden

[72] All four European vulture species are exposed to lead ammunition via secondary ingestion. Pain et al. (2009), suggests that feeding ecology can provide a useful proxy for susceptibility to ammunition derived lead exposure in all vulture species. In Appendix B tissue concentrations of lead in European vulture species (reviewed by Monclus et al., 2020 are reported.

in golden eagles in the same area, species also known to scavenge. Golden eagles are non-migrant in the area as bearded vultures are, so it is plausible to assume the species scavenge and consume the same resources and furthermore, that the lead burden in bearded vulture originates from active ungulate hunting in the area[73].

Elevated, above threshold blood lead levels in 14 (24%) Egyptian Vultures from the Canary Islands (n=137 nestlings and adults) have been found by Gangoso et al. (2009). One of the studied birds showed a blood lead concentration of 178 µg/dL. Bounas et al. (2016) reported the first confirmed case of Egyptian vulture lead poisoning in the Balkans where the vulture BLL was recorded at 3210 µg/L. Dissolved ammunition related lead was suspected as the cause (Bounas et al., 2016) .

In the French Pyrenees, embedded lead shot was found in 8 out of 120 studied griffon vulture (*G. fulvus*) and Pb poisoning was recorded as cause of death for three of the birds (Berny et al., 2015). Derived isotope signature was considered consistent with an ammunition source. During a five-year study from Aragon, Spain, 691 blood samples were collected from griffon vultures to assess blood lead levels and the source of the lead. The study found spatiotemporal association with high blood lead levels and point sources, such as ammunition and ingestion of ammunition supported by the isotope-ratio analysis was concluded as source (Mateo-Tomás et al., 2016). Nine Egyptian vultures were included in the study and detected during the hunting season in fall and winter, where the density of hunting e.g. pigeons is high, some 170 000 pigeons killed annually (Jean, 1996, Berny et al., 2015).

The cinereous vulture (*Aegypius monachus*)[74] has two known lead poisoning cases in Europe (Hernández and Margalida, 2009, Cardiel et al., 2011). Cardiel et al. (2011) found 2/3 tested birds exceeding lead bone concentration threshold exceeding subclinical threshold (Franson and Pain, 2011). Outside Europe, In Korea and Mongolia the species have been reported with high concentrations of lead in blood and liver, being higher in individuals trapped in Korea than Mongolia, very likely due to the high levels of hunting activity in the former (Kenny et al., 2015);(Kim and Oh, 2016).

Overall, different species may exhibit different response to lead exposure. For example, in obligate scavenging birds some variability of symptoms across species has been found. Turkey vultures (*Cathartes aura*) seem to be relatively tolerant of repetitive lead exposure, whereas the mortality of critically endangered California condors from lead poisoning is considered very high and ammunition-related lead being the reason for the near extinction event of the species (Carpenter et al., 2003, Finkelstein et al., 2010).

Facultative scavengers, raptor species

In this section exposure data related to facultative scavengers, raptor species, are discussed, with a focus on species with European distribution. Non-European cases and additional information is discussed in the Annex B, including recorded tissue concentrations of the studied birds when available.

The diet of a facultative scavenging raptor consists of live prey in addition to carrion. Predation risks are higher for injured (potentially shot with lead) and intoxicated (potentially

[73] The review by Mónclus et al. (2020) considers the study by Ganz et al. (2018, also reviewed by Pain et al. 2019) as having unknown lead source for studied bearded vultures. However, the authors draw attention very clearly to ammunition related lead (Ganz et al., 2018). Therefore, the study should be considered suggesting ammunition related contamination with consideration of isotope evidence from other species in the area with similar diet (see Appendix).

[74] Sometimes referred to as black vulture

lead poisoned and still carrying metallic lead) individuals, therefore debilitated prey may form a large part of the diet of predators. The presence of embedded lead shot in waterfowl is the main cause of lead poisoning for raptors in wetlands (Pattee and Hennes, 1983). The percentage of birds with embedded shot differs between species, areas with different hunting pressures and the age of birds (Mateo, 2009). Pain et al. (2014) report a wide range of European and North American studies in which the prevalence of embedded shot in live waterfowl is frequently > 20 %. The risk for facultative scavenging raptor species therefore results from the combination of the anthropogenic factors that influence the distribution of lead, preferred prey species and sometimes also even age and gender.[75]

On the basis of the current assessment, 13 species in this group have been found to have been exposed to ammunition related lead due secondary ingestion of contaminated carrion and/or prey in Europe (Table 1-21). Elsewhere the current number is 13 of which two species are also included in the European number as their distribution reaches other parts of the world [76].

Table 1-21: Ammunition related lead exposed facultative scavengers and raptors with European distribution

Species	Details of confirmed source of exposure	Other e.g. spatiotemporal connection suggesting ingestion
European Honey-buzzard (*Pernis apivorus*) LC	Lead shot in the gizzard (Lumeij et al., 1985)	Not available
Common buzzard (*Buteo buteo*)	Suggested ingestion of ammunition supported by isotope-ratio analysis (Taggart et al., 2020) Shotgun pellets in stomach (MacDonald et al., 1983)	Suggested ingestion of ammunition (Komosa and Kitowski, 2008, Mateo et al., 2003)
Rough-legged buzzard (*Buteo lagopus*)	Not available	Suggested ingestion of ammunition (Komosa and Kitowski, 2008)
Spanish Imperial Eagle (*Aquila adalberti*) VU	Two birds with embedded shot(Pain et al., 2005)	Suggested ingestion of ammunition (Pain et al., 2005)
Greater spotted eagle (*Aquila clanga*) VU	Not available	Suggested ingestion of ammunition (Komosa and Kitowski, 2008)

[75] In birds of prey it is common for the females being of larger size, e.g. in Eurasian sparrowhawks female can be up to 25 % larger and therefore prey on different species than the male. Furthermore, juvenile birds of prey are suspected occasionally to hunt more prey with embedded shot due to inexperience in hunting in comparison to adults PAIN, D. & AMIARDTRIQUET, C. 1993. Lead poisoning of raptors in France and elsewhere. *Ecotoxicology and Environmental Safety,* 25**,** 183-192, KITOWSKI, I., JAKUBAS, D., WIĄCEK, D., SUJAK, A. & PITUCHA, G. 2017. Trace element concentrations in livers of Common Buzzards Buteo buteo from eastern Poland. *Environmental Monitoring and Assessment,* 189**,** 421..PAIN, D. & AMIARDTRIQUET, C. 1993. Lead poisoning of raptors in France and elsewhere. *Ecotoxicology and Environmental Safety,* 25**,** 183-192, KITOWSKI, I., JAKUBAS, D., WIĄCEK, D., SUJAK, A. & PITUCHA, G. 2017. Trace element concentrations in livers of Common Buzzards Buteo buteo from eastern Poland. *Environmental Monitoring and Assessment,* 189**,** 421..

[76] Therefore, 21 facultative avian scavenger species globally have been strongly associated with exposure to ammunition related lead. Nocturnal non-scavenging species have been studied for lead exposure, and both European and American cases have been found. For these species, secondary ingestion of embedded lead via prey animal only, rather than carcass, is the assumed exposure route.

Species	**Details of confirmed source of exposure**	**Other e.g. spatiotemporal connection suggesting ingestion**
Golden Eagle (*Aquila chrysaetos*) LC	Ingestion of ammunition supported by the isotope ratio analysis (Jenni et al., 2015, Madry et al., 2015)	Suggested ingestion of ammunition (Kenntner et al., 2007)
Bonneli's eagle (*Aquila fasciata*) LC	Isotope ratio indicating non-mining source (Badry et al., 2019); regurgitated pellets containing lead, prevalence in pellets related to small game hunting (partridge and rabbits) (Gil-Sanchez et al., 2018)	Not available
Western Marsh-harrier (*Circus aeruginosus*)	Regurgitated pellets containing lead, source overlaps with wetland species and injured mammals (Pain et al., 1993) Lead shot in regurgitated pellets (Mateo et al., 1999)	Suggested ingestion of ammunition (Komosa and Kitowski, 2008)
White-tailed eagle (*Haliaeetus albicilla) LC*	Lead shot and/or ammunition in the gizzard/oesophagus/digestive tract or stomach (Isomursu et al., 2018, Helander et al., 2009, Krone et al., 2009b, Krone et al., 2004, Müller et al., 2007, Kenntner et al., 2001) Also, concern of fishing tackle ingestion (based on feeding ecology[77] and information reported in CfE #1083 from MME Birdlife Hungary, which includes a picture taken in 2019, in the Danube Ipoly National, where the female white-tailed eagle brought a large fish with a torn lead sinker hanging which was nearly swallowed by one of the chicks).	Suggested ingestion of ammunition (Komosa and Kitowski, 2008, Kitowski et al., 2017)
Red Kite (*Milvus milvus*) NT	One individual with lead shot in the GI-tract (Molenaar et al., 2017) Regurgitated pellets containing shot (Pain et al., 2007)	(Berny et al., 2015)
Peregrine Falcon *(Falco peregrinus*) LC	Shot in GI-tract (Andreotti et al., 2018)	Suggested ingestion of ammunition (Mateo et al., 2003, Pain et al., 1995)
Eurasian sparrowhawk (*Accipiter nisus*)	Not available	Suggested ingestion of ammunition (Pain et al., 1995)
Northern goshawk (*Accipiter gentilis*) LC	Not available	Suggested ingestion of ammunition (Komosa and Kitowski, 2008)

Notes: Confirmed source of exposure: either presence of lead (embedded and or ingested) and or isotope-ratio

[77] Mlíkovský (2009) reported that the food of the White-tailed Sea Eagle (Haliaeetus albicilla) at Lake Baikal (Russia), in a long-term study (1991-2001) revealed that these eagles feed predominantly on water birds, mainly ducks.

analysis confirming source of leaf. Other evidence of exposure may include e.g. expert opinion on the source.

Common buzzard (*Buteo buteo*), has been found with elevated levels of lead in number of individuals in several locations in Europe, such as in the Netherlands (Jager et al., 1996), UK (Pain et al., 1995, Pain and Amiardtriquet, 1993), Italy (Battaglia et al., 2005), Spain (Pérez-López et al., 2008) and Portugal (Carneiro et al., 2014a). Taggart et al. (2020) confirmed the suggested ingestion of ammunition by isotope-ratio analysis. In UK, MacDonald et al. (1983) discovered lead pellets from the stomach of lead-poisoned bird.

Spanish Imperial Eagle (*Aquila adalberti*) an Iberian endemic with a small population, has been reported to have suffered lead exposure in several occasions (Fernandez et al., 2011). Fernandez et al. (2011) found a spatial association with lead tissue concentrations in eagles and intensively hunted areas. However, populations of the Spanish imperial eagle in the vicinity of wintering waterfowl have higher exposure (Mateo et al., 2001, Pain et al., 2005). Spanish imperial eagle is a typical big raptor, being a long-lived species with individuals breeding relatively late and with one or two chicks only, and therefore the population cannot sustain high mortality, especially in adults (Ferrer et al., 2003, Pain et al., 2005). Pain et al. (2005) discovered two individuals with embedded shot.

Bonneli's eagle (*Aquila fasciata*), an endangered species studied recently by Gil-Sánchez et al. (2018) in south-eastern Spain, was found to have been exposed to lead shots likely related to red-legged partridge (*A. rufa*) and European rabbit (*Oryctolagus cuniculus*) hunting in the studied areas. A negative effect in breeding success was documented, and the authors warn it may have an effect in other European populations of the species, as the juveniles dispersing from the study populations are known to act as a source sustaining other populations (Gil-Sanchez et al., 2018). In Portugal, isotope ratio analysis of lead in 80 Bonnelli's eagle feathers (Mean 0.17, range 0.02 - 0.87, n = 80) indicated a non-mining source of lead (Badry et al., 2019).

In Germany, lead intoxication has been identified as the major cause of death in white-tailed eagles (*Haliaeetus albicilla*), with 25 % of carcasses examined having died because of lead toxicosis; lead from both shot and bullet fragments was implicated (Krone et al., 2003). Lead poisoning from ammunition is considered to be the single most important cause of mortality in this population (Krone et al., 2009a). White-tailed eagles from both Austria and Germany have been found lethally poisoned by lead by Kenntner et al. (2001), the number of poisoned determined by liver lead concentration was 30% of studied 57 individuals. Lead fragments were detected in the gizzards of two dead individuals (Kenntner et al., 2007). In Sweden, 22 % of 116 white-tailed eagles collected and examined between 1981 and 2004 had elevated (>6 microg/g d.w.) lead concentrations, indicating exposure to leaded ammunition, and 14 % of the individuals had either liver or kidney lead concentrations diagnostic of lethal lead poisoning (Helander et al., 2009). The lead isotope ratios suggested that the source of lead in specimens with lethal concentrations differed from that of ones exhibiting background concentrations of lead (< 6 microg/gd.w.). Furthermore, lead shots and fragments were found in the digestive tract of some birds (Helander et al., 2009). In Poland, Kitowski et al. (2017) found 36 % of 22 studied white-tailed eagles had acute lead poisoning according to their liver lead values. Studied individuals were collected during winter from the northern and southern parts of eastern Poland, and in southern areas where waterbodies freeze and the eagles consume more carrion and prey than northern population by water, the levels of lead were higher. When fish availability sharply declines, white-tailed eagles are known to switch to waterfowl and carrion (Nadjafzadeh et al., 2013). As white-tailed eagles are also fish consuming, there is also a plausible concern of fishing gear ingestion.

Raptor species that feed on waterbirds are also at risk due to secondary ingestion of lead fishing tackle (Rattner et al., 2008, Ishii et al., 2017, cited by Garvin et al., 2020).

In the Swiss Alps, Madry et al. (2015) showed isotope-proven connection to ammunition derived lead burden in golden eagles, species also known to scavenge. Jenni et al. (2015) discovered lead tissue concentration and pattern suggesting episodic and repeated lead intake in golden eagles, likely resulting from ammunition in carcasses foraged by the studied eagles, also in the Swiss Alps. In golden eagles an increased mortality in immatures and subadults exceeding a certain bone lead concentration threshold has been detected, resulting in lower bone lead concentration in the population in younger age groups - falsely suggestive of low exposure or higher tolerance (Madry et al. 2015).

Northern goshawk (*Accipiter gentilis*) preys on live birds such as partridges and pigeons, which may have lead shots embedded in their flesh. Goshawks studied in Spain had geometric mean lead concentration in bones equal to 1.57 mg/kg (Mateo et al. 2003) and in France one specimen have been found with a liver lead concentration of 711mg/kg (Pain & Amiard-Triquet 1993). Komosa and Kitowski (2008) reported median bone concentrations of 7 µg g-1 d.w. for six studied birds and ingestion of ammunition was suspected as the cause for accumulation.

For red kites (*Milvus milvus*) there are two references in the literature recoding direct evidence of lead shot ingestion, other reporting lead shot in regurgitated pellets and other in a GI-tract of a studied bird (Pain et al., 2007; Molenaar et al., 2017). Molenaar et al. (2017) reported bone lead mean values exceeding severe clinical poisoning in 11 birds (30.3-187.5). A peregrine falcon (*Falco peregrinus*) was found to have ingested shot by Andreotti et al. (2017) and there are at least two suggested cases of ingestion in the literature for the species (Mateo et al., 2003; Pain et al., 1995). Pain et al. (1993) suggested the source of lead shots to be either small mammals or birds with embedded and/or ingested lead. A comprehensive review and meta-analysis of lead contamination in raptors in Europe by Monclús et al. (2020) concluded that among obligate vultures, three species of facultative scavengers (golden eagle, common buzzard and white-tailed sea eagle) accumulated the highest lead concentrations in tissues and generally were the species most at risk of lead poisoning.

Facultative and opportunistic scavengers (other species)

In this section examples of exposure data related to facultative scavengers, omnivores, are discussed. Due to limited information for this group, the review is global and includes all known cases of lead exposure for the species. Facultative omnivorous scavengers with recorded cases of ammunition related lead exposure are mostly species of corvids and gulls. Corvid species are among the most common vertebrates recorded scavenging large game remains globally and common raven (*Corvux corax*) being the most common vertebrate scavenger (Mateo-Tomas et al. 2015). Also, species considered as opportunistically scavenging omnivores and other, mainly owls and piscivorous species are discussed.

Table 1-22: Ammunition related lead exposed facultative scavengers and raptors with non-European (or overlapping) distribution

Species	Country	Details of exposure	Reference
Common Raven (*Corvus corax)*	USA	Increase in BLL along the moose hunting season, isotope ratio analysis indicate ammunition source (Legagneux et al., 2014) Sixfold higher lead median levels in blood during a hunting season (West et al., 2017)	Legagneux et al. (2014) ; West et al. (2017)
Rook (*Corvus frugilegus*)	Europe	A bird delivered in a rehabilitation centres that subsequently died with a high liver lead content (6.33 ppm dw, N = 1 of 24). Suggested secondary exposure due to species' propensity to scavenge or eat grit/small stones and mistakenly ingest spent ammunition	Kitowski et al. (2017)
Hooded Crow (*Corvus Cornixa*)	Europe	A bird delivered in a rehabilitation centres that subsequently died with a high liver lead content (21.77 ppm dw, N = 1 of 6) Suggested secondary exposure due to species' propensity to scavenge or eat grit/small stones and mistakenly ingest spent ammunition	Kitowski et al. (2017)
Magpie (*Pica pica*)	Europe	A bird delivered in a rehabilitation centres that subsequently died with a high liver lead content and magpie (8.62 ppm dw, N = 1 of 2.) Suggested secondary exposure due to species' propensity to scavenge or eat grit/small stones and mistakenly ingest spent ammunition	Kitowski et al. (2017)
California Gull (*Larus californicus*)	USA	Ingested shot found in autopsy, unclear if due scavenging or/and primary ingestion	Quortrup and Shillinger (1941)
Glaucous-winged Gull (*L. glaucescens*)	USA	Ingested shot found in autopsy, unclear if due scavenging or/and primary ingestion	NWHL (1985)
Herring Gull (*L. argentatus*)	USA	Ingested shot found in autopsy, unclear if due scavenging or/and primary ingestion	NWHL (1985)
Eurasian Eagle Owl (*Bubo bubo)*	Europe	Suggested ingestion of ammunition	Mateo et al. (2003)
Common loon (*Gavia immer*)	USA, Europe	Fishing tackle (jig head and sinkers) retrieved from loon carcasses. Timing of the study suggest secondary route instead of grit ingestion. Tackle was the cause of death for 123 birds (n=253, 48.6%)	Grade et al. (2018)

Species	Country	Details of exposure	Reference
Wandering albatross (*Diomedea exulans*)	South Georgia Islands	Ingestion of fishing tackle as a bycatch, estimated 1300–2048 items of gear are consumed per annum by the wandering albatross population	Phillips et al. (2010)
Woodpeckers (Denrocopus/Dyocopus etc sp.)	Europe	No direct evidence of scavenging, however unknown lead exposure reported by Mörner & Pettersson (1999) and records of woodpecker scavenging by Mateo-Tomas et al. (2015) could indicate a plausible risk.	Mörner and Petersson (1999);Mateo-Tomas et al. (2015)

Notes: Confirmed source of exposure: either presence of lead (embedded and or ingested) and or isotope-ratio analysis confirming source of leaf. Other evidence of exposure may include e.g. expert opinion on the source.

Ravens and corvids in general are also known to be the first species to arrive to gut piles of moose (Gomo et al., 2017), including species such as magpie (*Pica pica*), Eurasian jay (*Garrulus glandarius*), hooded crow (*Corvus corax)*, Siberian jay (*Perisoreus infaustus*) in addition to ravens. It is therefore possible that also other corvid species than those with records of exposure are at risk of ingesting lead fragments while scavenging.

Craighead and Bedrosian (2008) examined 302 blood samples from common ravens (*Corvus corax*) scavenging on hunter-killed large ungulates and their offal piles to determine if lead rifle-bullet residuum was a point source for lead ingestion in ravens. They took blood samples during a 15-month period during two hunting seasons. Of the ravens tested during the hunting season, 47 % exhibited elevated blood lead levels (≥10 µg/dL) whereas 2 % tested during the nonhunting season exhibited elevated levels. Females had significantly higher blood lead levels than did males. Results were considered representative of the ingestion of lead during the hunting season and suggesting exposure to lead from rifle-shot big-game offal piles (Craighead and Bedrosian, 2008).

Many species of gulls (family laridae) are considered as scavengers but can have highly adjustable diet but due their habitat requirements can also be exposed to primary ingestion of lead shot and fishing tackle. Quortrup and Shillinger (1941) found one species of gulls with ingested shot from USA western lake areas, whereas in 1985 two more were reported by National Wildlife Health Laboratory (NWHL, 1985).

Mateo-Tomas et al. (2015) reported scavenging behaviour for two woodpecker species (*Dendrocopos major* and *Dryocopus martius*) in Scandinavian boreal forests indicating a possibility for a scavenging behaviour to result in lead exposure. Therefore, the source of exposure may well be either primary or secondary in this case.

An example of "other species" that may ingest fishing tackle by secondary ingestion are loons. As reported by Phillips et al. (2010), loons probably ingest lead sinkers in several ways. Sinkers found in dead loons are sometimes associated with hooks and lines. In such cases, loons may have keyed in on live fish used for bait and ingested the fishing gear directly from anglers. Loons are primarily piscivorous, and can ingest fish or baitfish that have broken free from anglers, but still contain fishing tackle. Grade et al. (2018) recorded fishing tackle as the cause of death for 123 common loons (n=253, 48.6%) in the US. The birds had ingested jigs and sinkers. The timing of the study suggests secondary route instead of grit ingestion and some of the tackle was also outside of the size range of grit. As loons are relatively long lived (some sources estimate a lifespan of up to 30 years) and slow to mature, not breeding until they at least 4 years old. Females lay only one clutch a year of

1-3 (usually 2) eggs. Both parents incubate the eggs, feed the young, and protect them from predators for the first 3-4 months of life, so the loss of a breeding adult is likely to cause the loss of the offspring (of the year) (Phillips et al., 2010).

UNEP/CMS ad hoc Expert Group assessment of secondary lead poisoning in EU27 bird species

The UNEP/CMS ad hoc Expert Group assessment categorised species at risk of secondary poisoning according to feeding ecology and direct evidence of lead ingestion and/or poisoning in peer-reviewed literature and, in addition, extrapolation to other species in a bird group based on similarity in habitat use and feeding ecology of species in which lead exposure/poisoning has not been investigated.

On the species level, UNEP/CMS ad hoc Expert Group reports 29 species of scavengers and birds of prey in the higher levels of risk of exposure in EU27. The assessment of secondary poisoning by the Dossier Submitter identified 21 of these species based on literature of exposure and lead tissue concentration evidence. The information is discussed in previous sections. The Dossier Submitter notes that the difference of eight species is mainly related to a read-across within the same taxonomic groups.

Due to UNEP/CMS ad hoc Expert Group input, skuas and jaegers as well as storks and herons are also considered at risk due to their feeding ecology.

UNEP/CMS ad hoc Expert Group also provided classifications for birds at low risk of secondary poisoning, being in line with this assessments' approach to look into feeding ecology of certain species as an indication of exposure risk, such as many species of gulls.

1.5.3.6. Primary and secondary poisoning of wildlife (taxa other than birds)

Predatory and scavenging mammal species may be exposed to lead through the predation and consumption of contaminated game and through contaminated gut piles, discarded meat or unrecovered game left in the environment by the hunters (Pain et al., 2019).

All carnivorous scavenging mammals consume both prey and scavenge i.e. there is no obligate scavengers in class Mammalia. As hunting is energetically costly and risky, favouring scavenging when the opportunity arises is common for many predatory mammal (Carbone et al., 2007). Due to demanding nature of hunting, predators favour debilitated or otherwise weak prey: old, new-borns, pregnant or wounded individuals (Mattisson et al., 2016).

Overall, there are limited data for mammals compared to bird species. However, ammunition related lead is often suspected as source of lead poisoning (Rogers 2012, Lazarus, 2020). One case of acute lead toxicosis in a cougar (*Puma concolor*) was recorded in Oregon, US in 2010 due to ingestion of ammunition related lead (Burco et al., 2012). Retrieved stomach contents contained mostly of 2-3 mm shot and occasional metal bullet jacket and brown glass.

As described in the report made by the California Research Bureau (2019) only a small subset of the literature concerning lead toxicosis in marine and land mammals focuses on lead fishing sinkers and tackle (Eisler, 1988; Pokras and Kneeland, 2008). An example of lead toxicosis was reported referring to a seal. In June 2004, in California researchers examined a harbour seal at a rehabilitation centre. The seal was underweight for its age, dehydrated, and having seizures. After the seal died, a necropsy revealed a lead fishing sinker in the animal's stomach. It was determined the animal died of acute, high-dose lead toxicosis consequent to the ingestion of the sinker. The researchers found it likely that the seal, while foraging for food, ingested a fish attached to fishing tackle used by either recreational or commercial anglers (Zabka et al., 2006).

Bear exposure to fishing tackle has also been speculated, in cases where they would be feeding on fish with embedded tackle (e.g. Rogers et al., 2012).

Due to the lack of data related to taxa other than birds, this risk is not elaborated in the assessment other than at qualitative generic level.

1.5.3.7. Additional risks related to sports shooting (uses 3,4,5,6)

Metallic lead is released into the environment at shooting ranges during their service life[78]. Each pathway is site-specific and may or may not occur at any individual range (US EPA, 2005):

- Lead oxidizes and dissolves when exposed to acidic water or soil.
- Lead particles or dissolved lead can be moved by storm water runoff (horizontal migration.
- Dissolved lead can migrate through soils to ground water (vertical migration).

Lead transported by surface water runoff can represent a risk for off-site receptors (Duggan and Dhawan, 2007). Lead mobility may significantly differ among sites, based on site-specific conditions, as further discussed in Annex B.

The Dossier Submitter has identified both risks to the environment and to humans (via the environment) as conceptually described in Annex B. However, risks to human health (humans via the environment) are not discussed in this section.

Risks can occur during both service life and at the end of life of shooting ranges and are expected to occur both on site and off site (via different pathways), although with site-specific differences.

At a conceptual level, for both shotgun ranges and rifle and pistol ranges, additional environmental risks during service life and at the end of life are:

- Risks to soil
- Risks to surface water and groundwater
- Risks to livestock in shooting ranges/areas used as agricultural land.

Although in general risks (and receptors) for shotgun ranges using lead shot and rifle and pistol ranges using lead bullets appear to be similar, specific differences in terms of risk profiles have to be expected for shooting disciplines using lead shot versus shooting disciplines using lead bullets. For example, the migration of lead into surface water is more likely at shotgun ranges than at pistol and rifle ranges because the pollutant load caused by shotgun shooting is wider and the erosion of shot is more rapid than that of bullets because

[78] Lead exposure to the aquatic and terrestrial compartments may also occur in areas with intensive hunting with lead shot (use 1). However, no information is available to further elaborate this. Lead exposure to the aquatic compartment due to the use of fishing tackle (uses 7) may also occur. Specific exposure information related to EU waterbodies are not readily available based on the Dossier Submitter's knowledge. However, Jacks et al. (2001), estimated that dissolution of elemental lead in Swedish rivers amounted to approximately 1% of the deposited lead is dissolved yearly provided is not buried. The loss being larger in fast running waters. More recently, the California Research Bureau (2019) stated that the rate at which lead from fishing tackle dissolves in water depends on several factors, including the alkalinity of the water and the dissolved salt content.

of their smaller size (Kajander and Parri, 2014)[79]. In addition, in shooting ranges, spent shot and bullets usually fall within an area of deposition which is substantially larger for shot compared to bullets. Figure 1-17 and Figure 1-18 provide examples of possible lead deposition areas in a shotgun and rifle/pistol range, respectively.

Figure 1-17: Example of lead shot deposition from a shotgun range on lands with different zoning (Victorian EPA, 2019)

Figure 1-18: Example of lead deposition on agricultural land from a rifle/ pistol range (Victorian EPA, 2019)

In general, spent lead projectiles used in sports shooting (all uses) can contaminate (depending on the use of the soil during the service life or the end of life of a range):

- Agricultural soils (with projectiles landing on grazing, cropping or horticultural areas)
- Rivers, lakes and other wetlands (directly or for example via rainfall run-off)
- Recreational areas (for adults and children)[80] (see also Annex B 9.1.3.)

[79] Migration is particularly affected by the amount of surface runoff formed in the range area and coming from outside the area (determined by the inclination of the top soil, amount of rainfall, soil types, and vegetation).

[80] Urrutia-Goyes et al. (2017) measured lead concentrations in the topsoil of a former range in Greece. The area was then rehabilitated into a public park. However, lead concentrations measured with different methods were reported with 5 560, 2 043, and 7 160 mg/kg, demonstrating heavy contamination. The authors performed a human health risk assessment and concluded that that the main exposure pathway of concern, especially for children, is ingestion, followed by dermal contact and inhalation.

- Residential areas

A simplified model of indirect pathways from a shooting range is shown in Figure 1-19.

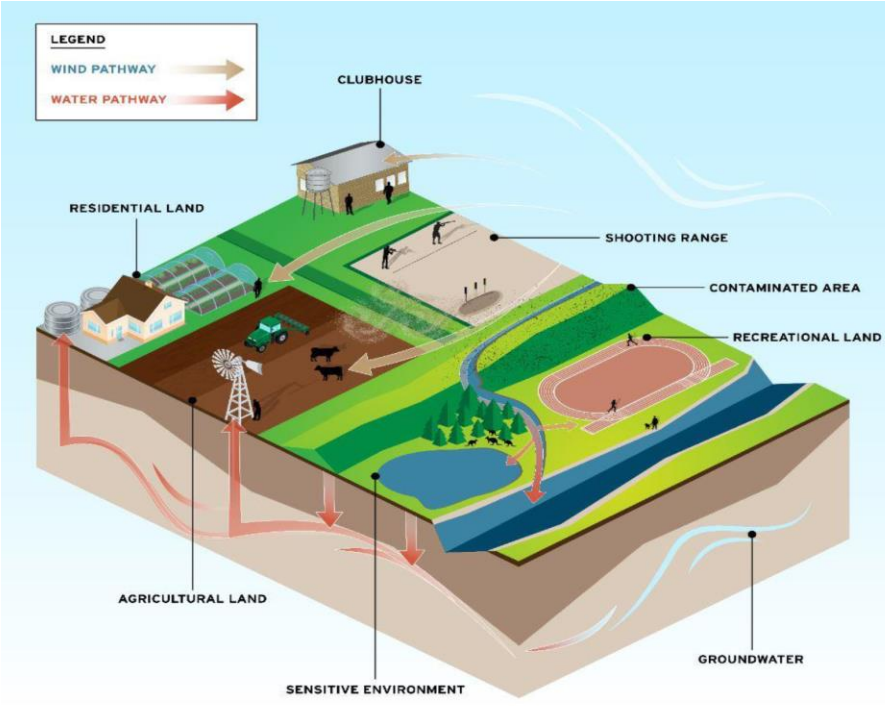

Figure 1-19: Simplified model of water and wind pathways that can spread lead off site from a shooting range (Victorian EPA, 2019). Note: indicative only and not to scale.

Victorian EPA (2019), when reviewing water and wind pathways, noted that water can move dissolved lead or fine lead in particles which has bonded to soil or organic matter. When lead is in its solid metallic form it is least likely to spread, but after it is weathered and exposed to air, soil and water it can be more mobile. Dissolved lead can be washed away by rainwater and flushed into rivers, lakes, dams and groundwater. Rivers and streams can spread contamination downstream into wetlands, farms, etc. It is important to note that groundwater is both a pathway and a potential receptor. When impacted water reaches groundwater, the contamination can continue to travel underground.

The more rainfall, the more likely it is that surface water will spread contaminants. It is also important to consider how long water remains on the surface of the range. In boggy and wet conditions lead can weather more easily and become more mobile. The slope of the land gives a good indication of how water can spread contamination. It is important to consider both the surface runoff that may flow onto a range as well as runoff leaving a range (Victorian EPA, 2019).

Wind can blow dust particles to other areas. There are two kinds of dust which are relevant to shooting ranges, soil dust and lead dust (Victorian EPA, 2019). When conditions are suitable, fine particles of contaminated soil may be blown from a shooting range as dust. There are many conditions[81] which influence the likelihood that dust could become airborne and the distance it could travel, including windy conditions, dry soil conditions, such as during summer and drought, fine soil particles, lack of wind breaks (such as trees, which

[81] A combination of these conditions can be a strong indicator that wind could carry dust to a receptor. Similarly, if they are not present then it is less likely that wind poses risks.

can reduce windy conditions), lack of ground cover such as grasses and other vegetation. Small amounts of lead dust can also be released after firing.

Surface and ground water

Lead exposure in **surface (run-off) water** of shooting ranges results from corroding lead shot or bullets lying on the surfaces of the range and from lead dust produced during shooting and deposited on the ground. The mobility of lead in surface water depends on the soil conditions and measures applied to limit lead mobility. Even if it can be assumed that in many shooting ranges surface water is collected and lead concentrations are measured, only very few data are published. For example, in the surface water of two shooting ranges in Florida, lead concentrations in retention ponds were measured with 289 µg/L and 694 µg/L. In another range, lead concentrations in a retention pond and a lake close to the range were low with 8 µg/L (Ma et al., 2002). According to investigations in Finnish shooting ranges (Kajander and Parri, 2014), lead and the other metals were found to migrate from the shooting range via surface water. Total lead concentration was >50 µg/L for 7/18 samples (39%) and 10-50 µg/L for 4/18 samples (22%). Soluble lead concentration was >50 µg/L for 3/8 samples (38%) and 10-50 µg/L for other 3/8 samples (38%).

Lead from shot, bullet and lead dust from shooting deposited on the ground accumulates in the soil and migrates towards the **ground water**. The time point when the contamination reaches the ground water depends on the soil conditions and the distance to the ground water. For sites for which a potential risk to ground water has been identified, usually lead concentrations in ground water are monitored to decide on risk reduction measures which is usually remediation. However, published data are scarce.

For example, in an US trap-shooting range running for more than 37 years, water samples from wells located along the bank of the slough contained dissolved lead concentrations higher than 400 µg/L, and as high as 1 000 µg/L. In contrast, a natural background concentration of lead from ground water in a well upgradient from the site is about 1 µg/L (Soeder and Miller, 2003). In a shooting range in Germany (Mainbullau) with use of lead gunshot for more than 40 years, lead concentrations in leaching water were determined in five different locations with 44.5, 1 460, 198, 64.4, and 12.9 µg/L. The action levels for phase 1 (25 µg/L) requiring supervision was exceeded by 4/5 measurements and action levels for phase 2 (100 µg/L) requiring remediation, was exceeded by 2/5 measurements (Bavarian WWA Aschaffenburg, 2019).

According to investigations in Finnish shooting ranges, lead concentrations that are clearly elevated from the background level are uncommon. In 5 of 24 samples the total lead concentrations in groundwater was > 10 µg/L, whereas the concentration of soluble lead was below 10 µg/L in 13 samples analysed (Kajander and Parri, 2014).

Soil

The lead total metal content in unpolluted soils is below 20 mg/kg for lead in remote or recently settled areas (Alloway, 1995). This content is greatly increased in soils polluted by human activities, even reaching values which multiply by more than 100 times those present commonly in uncontaminated or low-contaminated soils[82].

[82] Lead content in shooting ranges soils may even reach values comparable to those found in lead mining areas. At the EU level no common limits for soil quality or soil pollutants as lead is currently established, apart from one exception: the Sewage Sludge Directive in its annexes defines limits for heavy metals (including lead) in agricultural soils on which sewage sludge is applied.

A typical structure of pistol and rifle range can be divided into different segments based on the pollutant load. Different guidance or publications related to shooting ranges suggest slightly different segmentation of a typical (300 m) range. One of this, Lepke et al. (2006)[83] proposed a simplified segmentation, also indicating generally expected soil concentrations for different soil sectors:

- Sector including backstop berm, target stand and a band of land about 5 to 10 meters wide around the berm: pollution from lead normally exceeds 1 000 mg Pb/kg. More than 20 000 mg of bullets or their fragments per kg of earthy material can be found in this area. The lead content is in the same order of magnitude as that existing in exploitable deposits of the same metal (i.e. lead mining areas).
- The immediate surroundings of the backstop berm: here lead pollution often fluctuates between 200 and 1 000 mg Pb/kg.
- The areas farthest from the backstop normally show only concentrations of lead less than 200 mg Pb/kg.

Bullets primarily accumulate in the impact area in the backstop berm behind the targets, bullet traps, or other bullet collection structures. A small number of bullets end up in the intermediate area, other parts of the backstop berm, or even outside the range area, if the backstop berm is not sufficiently high or wide, as a result of missed shots or ricochets. At ranges with moving targets and modifiable ranges, the impact areas are not as clearly defined as at traditional rifle ranges; therefore, the metal distribution in the backstop berm is more even.

In sports where metal targets are shot, such as in biathlon and silhouette shooting, the bullet fragments against the target, and fine metal fragments spread to the surface layer of the range in the area surrounding the targets. Metal dust is also generated and accumulates in the surface layer of the target area when certain metal bullet traps are used. At silhouette ranges, the soil contamination spreads more evenly throughout the entire shooting range area, as there are several targets and low intermediate berms in the intermediate area.

At shotgun ranges, gunshot is dispersed across almost the entire surface layer of the range area due to the nature of the shooting activity. The flight distance of shot is directly proportional to their size[84]. Thus, at skeet ranges, shot spread over the firing sector to distance of around 200 m from the firing stand, and around 250 m at trap ranges. If larger shot are used at the ranges during practice, the shot may spread as far as over 300 m from the firing stand (Kajander and Parri, 2014). Terrain contours and trees have a significant effect on the spread of the shot, as do wind conditions.

Dinake et al. (2019) reviewed literature from 1983 to 2018 to provide an overview on the pollution status of shooting range soils from lead. Lead concentration as high as 97.6 g/kg has been measured in a shooting range soil in the United States of America (Clausen and Korte, 2009), 67.0 g/kg in Canada (Laporte-Saumure et al., 2012), 29.2 g/kg in Japan (Hashimoto et al., 2009), 384 g/kg in Botswana, Africa (Sehube et al., 2017), 300 g/kg in the Netherlands and 206.6 g/kg in New Zealand. One of the first studies with assessment of lead pollution of shooting ranges was carried out by Adsersen et al. (1983) some 35 years

[83] 3rd edition. The report was made by the Swiss Federal Office for the Environment (FOEN), Division Soil and biotechnology, Section Contaminated sites. The purpose of the report was to explain the procedure to receive Federal funding for measurements like investigation and remediation of municipal shooting ranges. Lead levels reported are based on the results of fields investigations performed in Switzerland (more than 1 000 fields).

[84] At a rough estimate, gunshot fly many hundreds of metres (Finnish BAT)

ago who found 200 – 300 g of lead per square meter of the studied site which had been in operation for 14 years. The accumulation of lead into shooting range soils and nearby environment has seen drastic surge in recent years reaching highs of 200 g/kg (Rooney and McLaren, 2001) and 300 g/kg in berm soils of a shooting range (Van Bon and Boersema, 1988).

In agricultural soils close (10 m) to a shooting range, lead was concentrated in the arable layer at total concentrations ranging from 573 to 694 mg/kg (Chrastný et al., 2010)[85].

Dinake et al. (2019) also reported on the synthetic precipitation leaching procedure (SPLP), which is a technique used to simulate possible underground water pollution in areas highly contaminated with lead e.g., Sehube et al. (2017). It simulates acid rain at pH 4.0 that can mobilise high concentrations of Pb and leach to underground water sources. By extension, the SPLP helps assess the mobility, bioavailability and toxicity of lead in shooting range soils. The United States Environmental Protection Agency (US EPA) has set 15 µg/l as the critical level for lead mobility in soils. SPLP lead concentration that exceeds this limit poses a pollution risk to underground water. The SPLP lead concentrations were 6 850 and 19 910 µg/l at two shooting ranges (TRR and MPR) respectively (Cao et al., 2003). The SPLP lead concentrations were more than 400 and 1 000 times the US EPA critical limit for shooting ranges . Dinake et al. (2019) also observed that underground water at three shooting ranges was at risk of being polluted as the determined SPLP lead concentrations at Range-G, Range-O and Range-L were 1.19 × 103 µg/l, 3.62 × 103 µg/l and 3.80 × 103 µg/l respectively and exceeding the set US EPA critical limit by a factor of up to 200.

Other studies have been carried out that revealed that acidic precipitation has the ability to leach sufficient amounts of lead from shooting range soils and thus pose a significant risk to both surface and underground water sources (Cao and Dermatas, 2008, Hardison Jr et al., 2004, Isaacs, 2007, Lafond et al., 2013, Laporte-Saumure et al., 2011, Laporte-Saumure et al., 2012). The high SPLP Pb concentration found in shooting range soils suggest that the lead chemical species that form thin layers on the surface of lead shots and bullets are instantly bioavailable and are susceptible to leaching (Dinake et al., 2019).

Plants

Lead concentrations in some shooting ranges have been reported to reduce plant dry weight, photosynthesis, water absorption and root growth (Koeppe, 1977).

A linear correlation between lead in soil and bioaccessible lead concentrations in vegetation has been demonstrated (see Figure 1-20) at rifle and pistol firing ranges (Bennett et al., 2007).

[85] SPLP lead concentration of up to 24.0 µg/l

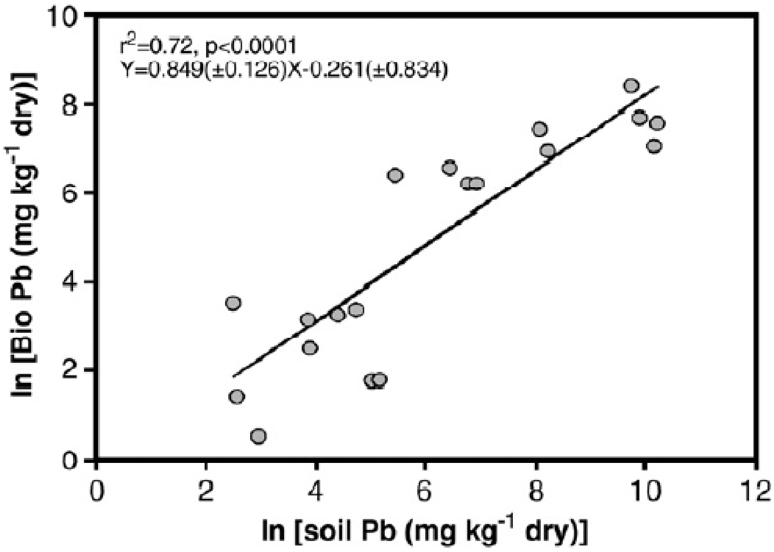

Figure 1-20: Correlation between ln-transformed bioaccessible lead concentrations in vegetation and soil lead concentrations (Bennett et al., 2007)

Concentrations of lead in the oilseed rape plants (*Brassica napus* L.) were largest in the shooting range area of most intense lead shot deposition (>5 000 mg/kg); in root samples the lead concentration exceeded 400 mg/kg. The authors also reported reduced crop density of plants grown within a shot-fall zone at soil lead concentrations 1 500 to 10 500 mg/kg (Mellor and McCartney, 1994).

Turpeinen et al. (2000) examined the effects of pine (*Pinus sylvestris*) and liming (pH-change with $CaCO_3$) on the mobility and bioavailability of lead in boreal forest soil, previously used as a shooting range area, under laboratory conditions. Solubility and mobility of lead were measured, and bioavailability of lead was assessed directly using a luminescent bacterial sensor for lead. Lead concentration in the soil (shot removed) was 9 804±1 599 mg/kg for topsoil (0 - 5 cm) and 325±96.5 mg/kg in mineral soil (5 - 20 cm). Control values were 32.7 ± 5.7 and 17.6 ± 6.3 mg/kg, respectively. Lead concentration in pine seedlings (n = 3) were 2 720.9 ± 471.9 mg/kg in roots, 76.6 ± 62.6 mg/kg in stem, and 5.5 ± 3.1 mg/kg in needles. The pine seedlings reduced lead concentrations of drainage water from 198 ± 13 µg/L without pine seedlings to 101 ± 10 µg/L with pine seedlings.

In agricultural soils very close (10 m) to a shooting range, Chrastný et al. (2010) measured increased lead concentrations in the biomass of spring barley (*Hordeum vulgare* L.) mainly in roots (138 versus 11 mg/mg) and leaves (16 versus 1 mg/kg) but also in stems (4.2 versus 1.6 mg/kg) and spikes (2.4 versus 1.2 mg/kg). The authors identified two possible pathways of lead: (1) through passive diffusion-driven uptake by roots and (2) especially through atmospheric deposition.

Ma et al. (2002) and Cao et al. (2003) performed a study focussing on weathering of lead bullets and its effect on the environment at five outdoor shooting ranges in Florida, USA. The lead concentrations in bermudagrass along the central transect of Ranges 3 and 5 are shown in Table 1-23. Generally, lead concentrations in grasses grown close to berms contained more lead, which is attributable to the fact that soils close to the berms contained more total lead and plant-available lead. Compared with the lead concentrations in the roots (up to 1 342 mg/kg), lead concentrations in grass shoots were lower (<806 mg/kg). However, there is still a considerable amount of lead being transported into the aboveground biomass.

Table 1-23: Lead concentration in soil and bermudagrass growing on shooting ranges (Cao et al., 2003)

Range	Distance (m)	Lead concentration (mg/kg dry weight)			
		Soil total	Plant-available	roots	shoots
3 (CWR)	1.5	354	12.1	512	324
	31.5	148	5.61	115	86.7
	61.5	464	73.2	1 166	511
	91.5	6 800	136	1 342	806
5 (MHR)	1.5	1 066	6.75	438	134
	31.5	562	46.3	769	500
	61.5	1 018	28.2	698	518
	91.5	2 715	68.2	952	500

Dallinger (2007) reported the lead concentrations in samples from plants growing in front of berms with 19-34, 1.5-13, and 9.6-17 mg/kg and for plants growing on berms with 175-4 700, 37-835, and 580-715 mg/kg. The type of plants sampled is not mentioned.

Poisoning of livestock (ruminants)

Limited literature is available related to poisoning of livestock in relation to lead ammunition released into the environment.

Braun et al. (1997) reported that five calves were put on pasture in the target area of a shooting range. Acute lead poisoning occurred in one of the calves after five days of grazing, the remainder became ill one to three days later. The concentration of lead in the dry matter of a grass and a soil sample from the target zone of the shooting range were 29 550 mg/kg and 3 900 mg/kg, respectively.

Muntwyler (2010) reported acute intoxication and mortality of two cows that were grazing behind the berm of a shooting range in Aargau (Switzerland). An investigation of the area revealed that the fences were located closer to the berm (2 and 5 m) than allowed (10 m fenced area and an additional 20 m surrounding the fence for which grazing is banned).

In general, the available evidence does not suggest that risks from the direct ingestion of lead gunshot are very likely to occur (Allcroft (1951) cited by Scheuhammer and Norris (1995)). Bjørn et al. (1982) noted no elevation in blood lead concentrations of heifers grazing in pastures where upland bird hunting was common, and Clausen et al. (1981) reported that cattle retaining up to 100 lead pellets in the reticulum nevertheless had normal lead concentrations in liver and kidney tissue.

However, other studies indicate that dairy cattle fed grass or corn silage contaminated with lead gunshot can suffer from lead poisoning (Howard and Braum, 1980, Frape and Pringle, 1984, Rice et al., 1987).

Rice et al. (1987) reported that in 14 steers fed chopped silage prepared from a field that had been used for clay target shooting, one animal died, a second demonstrated clinical signs of lead poisoning, and all animals had substantially inhibited ALAD enzyme activity. It was further noted that even when lead pellets were removed, samples of silage still contained an average of 0.23 % lead, which would have resulted in the ingestion of about 18 g of lead per steer per day, based on the consumption of about 8 kg of silage per animal. Rice et al. (1987) suggested that this concentration of lead would have been sufficient to cause toxicity, independent of ingestion of any lead gunshot pellets. The mechanical/chemical processes of producing silage from material containing lead pellets and/or uptake of lead by plants growing in soils contaminated with metallic lead may be more important risk factors than ingestion of lead shot pellets per se (Scheuhammer and Norris, 1995).

Properly made silage is very acidic (pH< 4.8), and in such an acid environment a proportion of the metallic lead is converted into a more soluble lead salt (St. Clair and Zaslow, 1996, Swain, 2002).

Some case studies are presented in the risk characterisation section. The following table summarises examples of levels of lead in different tissues following ingestion of lead shot.

Table 1-24: Tissue levels of lead in ruminants following ingestion of lead gunshot

Pb source (country)	N	Pb exposure	Tissue Pb levels					Reference
			Blood	Liver	Kidney	Muscle	Milk	
Cattle								
Lead shot (USA)	22	NR	290 µg/L (median)	-	-	-	-	(Bischoff et al., 2012)
Silage contaminated by lead shot (USA)	6	649 mg/kg bw/d	882 – 1220 µg/L (range)	-	-	-	0.0619 – 0.4657 mg/L (range)	(Bischoff et al., 2014)
Lead shot (UK)	22	NR	1620 µg/L (mean)	-	-	-	-	(Payne et al., 2013)
Lead shot contaminated grass silage (USA)	12	NR	2300 µg/L (mean)	-	-	-	-	(Rice et al., 1987)

Pb source (country)	N	Pb exposure	Tissue Pb levels					Reference
			Blood	Liver	Kidney	Muscle	Milk	
Local bird shooting field (Denmark)	24	NR	28 µg/L (max)	-	-	-	-	(Bjørn et al., 1982)
Sheep								
Grass contaminated by shooting range (Norway)	23	0.33 mg/kg bw[86]	-	0.3 mg/kg (mean)	-	-	-	(Johnsen and Aaneby, 2019)

Notes: N: Number of animals; NR: Not reported; - : Not measured

1.5.4. Risk characterisation

The identified (main) risks with regards to uses are summarised in the following table and are discussed in the following sections.

Table 1-25: Identified environmental risks with regards to uses[87]

Use #	Use name	Identified risk
1	Hunting with shot shell ammunition	Primary and secondary poisoning of wildlife (birds)
2a	Hunting with bullets - small calibre	Secondary poisoning of wildlife (birds)
2b	Hunting with bullets - large calibre	Secondary poisoning of wildlife (birds)
3	Outdoor sports shooting with shot shell ammunition	Primary poisoning of wildlife (birds[88]) Ingestion of contaminated soil and vegetation by livestock and secondary poisoning of livestock (ruminants) via silage grown on shooting ranges/ areas used as agricultural land Soil, groundwater and surface water contamination

[86] Worst case scenario based on a calculated intake from ingestion of soil whilst grazing on the contaminated land. The estimated intake attributed to grass ingestion alone was 0.0074 mg/kg bw

[87] Risks to humans via the environment are discussed within the human health risk assessment.

[88] Information on risks to poultry in agricultural areas used for shooting may become available in the consultation on the Annex XV report.

Use #	Use name	Identified risk
4	Outdoor sports shooting with bullets	Ingestion of contaminated soil[89] and vegetation by livestock (ruminants) and wildlife on shooting ranges/ areas used as agricultural land Soil, groundwater and surface water contamination
5	Outdoor shooting with air rifle	Same as 4
6	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments	Same as 4
7	Lead in fishing tackle: sinkers and lures	Primary and secondary poisoning of wildlife (birds) – when the weight of the sinker or lure is ≤ 50 g
8	Lead in fishing tackle: nets, ropes or lines	No risk to birds or other taxa identified[90].

1.5.4.1. Primary and secondary poisoning of wildlife (birds)

In this section a single environmental risk characterisation in relation to the primary and secondary poisoning of wildlife (birds) for the relevant uses (1,2,3,7) is presented. This is on the basis that it was not practicable or meaningful to disaggregate the risks to birds resulting from the different uses as they are often the result of a combined source of exposure. Nevertheless, where relevant a more detailed discussion of the risks from specific uses is undertaken.

When considering risks to birds related to the ingestion of lead ammunition and fishing tackle, adverse impacts have been documented worldwide, as discussed in the previous sections. Therefore, there is no advantage to undertake a risk characterisation based on comparing PEC/PNEC ratios.

This assumption is also supported by agreements (AEWA, CMS, CMS Raptor MoU[91]), bans[92]

[89] Mainly soil in the backstop berm area.
[90] In Use 8, lead is enclosed/embedded/threaded in nets, ropes and lines (CfE #1220 from Danish EPA), and lead from this type of fishing tackle is not typically ingested by birds (CfE #936 from UK EPA).
[91] The Memorandum of Understanding on the Conservation of Migratory Birds of Prey in Africa and Eurasia (Raptors MoU). The European Union is a Signatory Party of this not-legally binding agreement since 2011. https://www.cms.int/raptors/en/signatories-range-states
[92] In Europe bans on the use of lead gun shot in the terrestrial environment are in place in Denmark and the Netherlands. In Denmark there is also a ban on the import and placing on the market of fishing tackle.

wildlife conservation projects[93], recommendations under UNEP AEWA auspices (UNEP-AEWA, 2011)[94] throughout the world, aiming to limit the use of lead ammunition and fishing tackle in response to these risks or have recommended the phase out of lead ammunition and fishing tackle.

Therefore, the risk characterisation related to birds (primary and secondary poisoning) summarises information on the following:

1. Selected case studies on the impacts on birds;
2. Examples of comparison of the lead concentration in various tissues of birds, with indicative thresholds of adverse effect in birds;
3. Mortality in the EU;
4. Information on lead as a co-factor in other causes of mortality.

Selected case studies on the impacts on birds

- Primary poisoning from ingestion of lead shot and fishing tackle: Grey partridges (lead shot), mute swans (fishing tackle)
- Secondary poisoning from ingestion of lead ammunition: Eurasian buzzards (lead shot), different species (lead ammunition).

Potts (2005) reported the results of an assessment of the extent of lead poisoning in wild **grey partridges** (*Perdix perdix*) in the UK, based on post mortem analysis of 1 318 dead birds collected between 1947 to 1992. Grey partridges are granivorous birds, typically ingesting lead shot while foraging for seeds or grit.

Over the period between 1947 and 1992, post-mortems exams were carried out by three successive pathologists, with the only main difference (as regard the applied methodology) that in the period 1947–1958 sublethal ingestion was not recorded. The results of the post-mortems from each period are given in Table 1-26.

Table 1-26: Results of post-mortem per period (Pott, 2005)

Period	Total post-mortems	Ingested lead cited as cause of death
1947-1958	872	3 (0.3%)

[93] For example, across Europe there have been several initiatives to reduce the use of lead ammunition and promote non-lead hunting practices. In the Italian Alps the use of lead ammunition has been banned in the Stelvio National Park and Sondrio Province. At Hohe Tauern National Park in Austria, in the Pyrenees, and as part of GypConnect and GypHelp LIFE conservation projects, at the Cévennes National Park in the French Massif Central, and in Haute-Savoie, pilot project where hunters try non-lead ammunition are being carried out. More recently in the Lombardia region (Italy) a regional Decree (n. 13690 dated 11/11/2020) foresees a transition towards non-lead ammunition for hunting ungulates and subsequently birds species in the terrestrial habitats. The Generalitat Valenciana have banned the use of lead ammunition in two areas in Maestrazgo, to protect vultures there including birds released as part of the new bearded vulture reintroduction project. (https://www.4vultures.org/research-into-the-lead-contamination-of-wild-vultures/)

[94] Under the African-Eurasian Migratory Waterbird Agreement (AEWA) auspices, based on existing data and literature, in 2012 the Technical Committee recommended to the 5th Meeting of the Parties to AEWA (MOP5), to decide to amend the AEWA Action Plan as follows: " Parties shall endeavour to phase out the use of lead shot for hunting in wetlands and the use of lead fishing weights as soon as possible in accordance with self-imposed and published timetables".

Period	Total post-mortems	Ingested lead cited as cause of death
1963-1969	224	9 (4.0%)
1970-1992	222	6 (2.7%)
Total	1 318	18 (1.4%)

The number of shot found in the gizzards varied between 1 and 34. It was estimated that all of the birds that contained three or more ingested lead shot had died as a result of lead poisoning.

Based on the available data, Potts (2005) compared the incidence of ingested lead shot in grey partridge with the situation in waterfowl in the UK where extensive surveys during 1979 – 1981 showed that 8.6 ± 2 % of waterfowl found dead had ingested lead gunshot [Mudge, 1983; Anatidae, excluding mute swan (*Cygnus olor*) that had ingested angler's split shot]. The overall incidence in all the grey partridges found dead by Potts (2005) study during 1963 – 1992 was 4.5 ± 1 %, equivalent to 52 % that of waterfowl.

Potts (2005) also reported the results of a study on chick food from 1968 to 1978 on the Sussex Downs, where the gizzards of 29 wild chicks aged up to 6 weeks were examined, highlighting the incidence of lead gunshot ingestion in the two groups of birds. The results of the study on chick, from the examination of gizzard contents, indicated that that two (6.9 ± 4.7 %) of 29 chicks contained lead shot, 13 in 1 and 14 in the other.

Meyer et al. (2016) estimated the effects of ingestion of lead shot in terrestrial habitats (on small-game hunting areas) for grey partridges at population level. The grey partridge population that the authors chose to model was the continental European population of grey partridges, which was stable in the early 20th century but has declined since the 1970s. Lead shot ingestion reduced population size of partridges by 10 %, and when combined with bait and pesticide poisons, by 18 %.

As recently reviewed by Grade et al. (2019), the problem of mortality in wildlife from lead fishing tackle ingestion was first documented in **mute swans** (*Cygnus olor*) in the United Kingdom (UK). Lead fishing tackle accounted for 50 % of documented swan mortalities throughout England in 1980–1981, and estimated that approximately 3 000–3 500 swans in the UK died annually as a result of lead poisoning. Researchers also documented declines in local populations amid high rates of mortality from lead tackle ingestion . The majority (>70 %) of documented lead poisoned swans had ingested split shots (Birkhead, 1982, Sears, 1988) and about 7 % had ingested larger weights (Sears and Hunt 1991). In comparison, less than 2 % of cases of lead poisoning among mute swans in the UK were attributable to ingested lead shot ammunition (Sears and Hunt 1991). Lead tackle ingestion impacted both adult swans and cygnets (Birkhead, 1982, Wood et al., 2019, Sears, 1988, Kirby et al., 1994). After legislation took effect in 1987 in England and Wales to ban the sale and use of lead fishing weights, mute swan deaths from lead poisoning declined from 34 % of documented mortalities between 1971 and 1986 to 6 % between 1987 and 2014 (Wood et al., 2019)

Carneiro et al. (2016) reported about 3 cases of lead poisoning, associated with the ingestion of lead shot, in adult female **griffon vultures** (*Gyps fulvus*) found in the Iberian Peninsula, where their conservation status is considered to be near-threatened. The birds were found prostrate and immediately transferred to a wildlife rehabilitation centre, where they died within 24 hours after supportive treatment. Necropsy and histopathologic examinations were done in two birds and metal analyses were done in all birds to determine their cause of death. In one vulture, nine uneroded lead pellets were recovered from the stomach, and moderate to severe hemosiderosis was seen histologically in the liver, lungs, and kidneys. Diagnosis of lead poisoning was confirmed by results of metal analyses, which revealed extremely high lead concentrations in blood (969-1384 µg/dL), liver (309-1 077 µg/g dry weight), and kidneys (36-100 µg/g dry weight) for all three vultures.

Taggart et al. (2020) have recently published a comprehensive analysis regarding tissue concentrations and origins of lead in **Eurasian buzzards** (*Buteo buteo*). The study suggested that most of the lead acquired by Eurasian buzzards is probably obtained when they prey upon or scavenge gamebirds and mammals shot using lead shotgun pellets. Eurasian buzzards found dead in the United Kingdom during an 11-year period were collected and the concentrations of lead in the liver and femur were measured. Concentrations consistent with acute exposure to lead were found in 2.7% of liver and concentration consistent with exposure to lethal levels were found in the femur of 4.0% of individuals. Lead concentration in the femur showed no variation among or within years, but was greater for old than for young birds. The lead concentration in the liver was not influenced by age, but varied among years and showed a tendency to increase substantially within years throughout the hunting season for gamebirds. The resemblance of the stable isotope composition of lead from buzzard livers to that of lead from the types of shotgun ammunition increased significantly with increasing lead concentration in the liver. Stable isotope results were consistent with 57 % of the mass of lead in livers of all of the buzzards sampled being derived from shotgun pellets, with this proportion being 89% for the birds with concentrations indicating acute exposure to lead.

Berny et al. (2015) analysed the cause of death of 170 scavenger birds found dead in the French Pyrenees over a seven-year period (2005-2012). All birds found dead were submitted to full necropsy, X-Ray, parasitological and toxicology screenings (including heavy metals). In total 8 **Bearded Vultures**, 120 **Griffon Vultures**, 8 **Egyptian Vultures** and 34 **Red Kites** were collected and analysed. Results indicated that poisoning was by far the most common cause of death (24.1 %), followed by trauma/fall (12 %), bacterial diseases and starvation (8 %) and electrocution (6 %). Illegal use of banned pesticides was responsible for most of the cases of poisoning (53 % of all poisoning cases) but lead poisoning was also important (17 % of all poisoning cases). Lead isotopic signature could be associated primarily with hunting ammunition. Lead poisoning was also associated with trauma, indicating that lead could be a significant contributor to different causes of death. Lead poisoning cases (all 7 cases) were identified in the fall and winter.

Comparison of the lead concentration in various tissues of wild birds with indicative thresholds of adverse effect (examples for primary and secondary poisoning)

Table 1-27: Indicative thresholds of adverse effect

Details of study (geographical, temporal and species scope), Reference	Tissue type and concentration	Interpretation relative to indicative thresholds of adverse effects
Ferrandis et al. (2008) 2004; n = 2 partridges with ingested shot, Spain (birds shot at the beginning of the hunting season in a driven shooting estate, private upland small-game hunting estate, where frequency of partridge hunting events per year ranges 0 - 2). Total sample n = 10 (n = 8 being partridges without lead shot ingested)	liver Pb (µg/g)d.w. 2004, mean 21.51 (range 0.19 - 42.83)	Mean concentration observed in liver greater than indicative threshold for subclinical poisoning.
Butler et al. (2005) (1997), n = 95 female pheasants, UK (overall lead shot ingestion rate 3 %)	Bone : (7 - 445) ppm d.w. median : 48.8 ppm d.w.	Median concentration observed in bone greater than indicative threshold for severe clinical poisoning
Carneiro et al. (2016) N = 3 Griffon vultures, ingestion of lead shot, Iberian Peninsula.	Blood: (969 - 1384 µg/dL) liver (309 - 1077 µg/g d.w.),	Blood and liver: severe clinical poisoning
Franson et al. (2003) 1995 - 1999, n = 2 240 individuals of 28 species, ingestion of lead fishing tackle (US). (Ingested lead fishing tackle was found in eleven Common Loons, ten Brown Pelicans, one Double-crested Cormorant and one Blackcrowned Night Heron)	Of waterbirds with ingested lead sinkers: 64 % and 71 %, respectively, had lead concentrations of ≥ 2 ppm wet weight in their livers or 0.2 ≥ ppm wet weight in blood. Maximum lead concentrations in liver and blood were 26.0 ppm and 13.9 ppm wet weight, respectively. *(In birds without ingested lead liver lead concentrations were ≥ 2 ppm wet weight in 0.7 % of those tested (N = 866) and blood lead concentrations were 0.2 ≥ ppm in 2.2% (N = 742)*	Liver and blood levels (of waterbirds with ingested lead sinkers, 64 % and 71 %, respectively) greater than indicative threshold for background level, with maximum levels indicating severe clinical poisoning

Details of study (geographical, temporal and species scope), Reference	Tissue type and concentration	Interpretation relative to indicative thresholds of adverse effects
Monclus et al. (2020) review[95]	See Annex B (section B 9.1) Studies with evidence of ammunition related lead exposure recording lead tissue concentrations	See Annex B (section B 9.1) Studies with evidence of ammunition related lead exposure recording lead tissue concentrations

Data on mortality in the EU

Mortality of wildlife from lead poisoning from ammunition source is often a neglected issue as many (e.g. hunters) state they have never found a lead poisoned animal (Pain et al., 1998). However, it is widely recognised that carcass survival from scavenging and searcher efficiency are two key factors known to bias the mortality estimates of any wild species (Prosser et al., 2008, Etterson, 2013, Teixeira et al., 2013).

Prosser et al. (2008) lists 19 carcass removal studies where the mean observed carcass survival time ranges from 0.65 to 10.4 days. Carcass persistence seems to be shorter for smaller animals such as small birds (Santos et al., 2011, Ponce et al., 2010). It is likely that the mortality from lead poisoning may often result in frequent and mainly invisible losses of birds, in small numbers, that remain undetected (Stutzenbaker et al., 1986, Scheuhammer, 1987, Newth et al., 2013). Poisoned birds often become reclusive and carcasses may be scavenged before being detected (Sanderson et al., 1986, Stutzenbaker et al., 1986, Newth et al., 2013, Pain, 1991).

Humburg and Babcock (1982) display the difficulty of finding intact waterfowl carcasses in search of documenting non-hunting waterfowl losses; only 22.4% (934 of 4165) of waterfowl carcasses were found intact in the study and the rest was described as piles of feathers, wings and bones and partially scavenged carcasses Humburg and Babcock (1982).

It is recognised that the available datasets for many hundreds of terrestrial species do not allow for a mortality estimate at the EU level from the ingestion of lead shot or bullets, as done for waterbirds species ingesting lead shot in wetlands by ECHA (2017). However, some studies, applying different methodologies at specific local datasets, tried to estimate mortality for some game species. For example: Pain et al. (2019a), based on Bellrose methodology[96], estimated for Pheasant and Red-legged partridge the percentage of population in UK as dying from lead ingestion to be 0.56 % and 0.32 % respectively. This being an underestimation, considering that juveniles were not included and that it does not account for sub-lethal poisoning, possibly leading to additional mortality (see point 4). Meyer et al. (2016) indicated that "percentage of deaths from lead shot ingestion for grey partridge were modelled as 4%, for direct proximal cause of death" based on several studies screened by the authors. Potts (2005) based on post-mortem analysis made by three successive pathologists, of 1 318 dead wild grey partridges collected between 1947 to

[95] The review of Monclus et al. (2020) lists 114 studies of lead contamination in Europe with information of exposure source and tissue concentrations. 54 studies with ammunition related exposure are presented in Appendix B. Monclus et al. (2020) concluded that vultures and facultative scavengers (especially golden eagle, common buzzard and white-tailed sea eagle) accumulate the highest lead concentrations in tissues and are at highest risk of lead poisoning.
[96] Green and Pain, (2020). In this paper, the authors reported a re-analysis of the Bellrose method.

1992, found that mortality over different periods ranged from 0.3 % to 4 %. Therefore, mortality (via primary ingestion) within many game bird species might be expected to vary within this range. The Dossier Submitter has assumed the range 0.5 - 2.0% to be the most likely mortality range for terrestrial game bird species, recognising the uncertainty of this assumption in relation to different species. The central value of this range (1 %) has been used for the impact assessment of the species affected by the ingestion of lead shot (primary poisoning). See section "Impacts on birds".

As reviewed by Pain et al. (2019), lead from ammunition is available to predators and scavengers in the flesh of their prey either as whole gunshot/bullets or ammunition fragments. There is extensive literature linking the lead poisoning of predators and scavengers to ammunition sources (via secondary poisoning). This includes significant evidence: for example, temporal and spatial correlations between elevated tissue lead levels in birds and hunting activities and lead isotopic studies to match tissue lead concentrations with sources.

However, in relation to mortality from ingestion of lead ammunition via secondary poisoning, no EU estimate appears to be currently feasible based on the available data. In addition, it would not be possible to determine the percentage of birds dying due to the secondary ingestion of lead shot versus secondary ingestion of bullets fragments because birds may feed on different types of prey. Monclus et al. (2020) noted that: *"overall, lead continues to cause mortality in many raptor species, as determined by diagnosed clinical cases and from the exceedance of lethal threshold levels".*

Lead poisoning (and consequent mortality) is likely to have a significant impact on predatory and scavenger species that naturally have a low reproductive rates, such as vultures. For predators and scavenging species with a critical conservation status, such as the Bearded vulture (*Gypaetus barbatus*), the rarest vulture in Europe, mortality of even a single individual caused by either the ingestion of lead shot or lead bullets (fragments) via secondary poisoning may be of concern for the survival of the species[97].

Sources of lead poisoning are not limited to lead ammunition. For example, raptor species that feed on waterbirds are also at risk due to secondary ingestion of lead fishing tackle (Rattner et al., 2008, cited by Garvin et al., 2020).

In relation to bird mortality (AEWA-listed species) from ingestion of fishing tackle, no estimate on mortality of EU birds from the ingestion is currently available or possible due to the lack of adequate datasets. Although the extent of waterbirds mortality related to lead fishing tackle ingestion cannot be currently estimated, it can be expected to be high for a number of waterbird species (especially in relation to lead fishing sinkers) in areas with high fishing activity (UNEP-AEWA, 2011) and can be regarded as additional to the mortality occurring following the ingestion of lead shot. It is noteworthy that ingestion of even one lead sinker or jig of the minimum weight, can be lethal, as in the case of the ingestion of a single lead shot.

The Dossier Submitter also notes that lead poisoning from multiple sources (as lead shot and fishing tackle) concerns several European bird species that are considered to have vulnerable or endangered conservation status in the EU, notably the white-headed duck

[97] In modern ecosystems, hunters are to be considered the top predator and the remnants of hunting are a more important wildlife food source now than at any other time in history (Haig et al., 2014) for many species, especially obligate scavengers. Therefore burying remnants of hunting containing lead particles, may not be a viable solution to reduce mortality, because it would critically reduce food availability for many species, including rare species.

(Oxyura leucocephala) and marbled teal *(Marmaronetta angustirostris)*, especially in relation to lead fishing sinkers. For already threatened species, any additional mortality caused by lead fishing tackle ingestion may be of concern also for the survival of that species.

In addition, it is essential to consider that some waterbirds may also feed in terrestrial environments and therefore become exposed to spent lead gunshot outside of wetlands and die, as previously noted in the risk assessment of the use of lead gunshot in wetlands (ECHA, 2017). However, it is not possible to determine the percentage of birds dying due to the ingestion of lead shot in terrestrial environment because it is not possible to distinguish between shot ingested in wetlands and shot ingested outside of wetlands.

Information on lead (in ammunition and fishing tackle) as a co-factor in other causes of mortality

In general, lead ingestion can increase susceptibility of birds to other causes of death and may be the ultimate, underlying cause of some deaths. Sublethal lead poisoning may not be fatal but could impair the immune system, increasing susceptibility to disease or increasing inattentiveness, which in turn increases susceptibility to accidents and predation that are reported as proximal causes of death (Meyer et al., 2016).

Sublethal lead poisoning can for example increase the likelihood of mortality from hunting (Bellrose, 1959; Demendi and Petrie, 2006; Heitmeyer et al., 1993, cited by Pain et al. 2015). As reviewed by Newth et al. (2016), birds with reduced body condition may be more susceptible to disease and other mortality factors such as flying accidents and weaker birds may be at increased risk of predation (Kelly and Kelly, 2005; Newth et al., 2012; Scheuhammer and Norris, 1996).

In a study by Ecke et al. (2017) on Golden Eagles (*Aquila chrysaetos*), lead levels in blood were correlated with progress of the moose hunting season. Based on analyses of tracking data, the authors found that even sublethal lead concentrations in blood (25 ppb, ww), could likely negatively affect movement behaviour (flight height and movement rate) of this scavenging species.

1.5.4.2. Species at risk of lead poisoning in the EU (use 1,2,3,7)

Based on the analysis provided in the previous sections, the following species are considered to be at most risk of lead poisoning from shooting and fishing (Table 1-28 and Table 1-29). It is noteworthy that other species, not in this list, might also be at some (low) risk of lead poisoning, as indicated by the UNEP/CMS ad hoc Expert Group (2020). Specifically, based on the assessment made by the UNEP/CMS ad hoc Expert Group (which is expected to be submitted in the consultation on the Annex XV report with additional information), many species (in the order of some hundreds) are at low risk of lead poisoning. The impact assessment (in term of number of birds at risk) done by the Dossier Submitter is available in section 1.8.5.

Table 1-28: Species at most risk of lead poisoning from lead ammunition (lead gunshot) in the terrestrial environment and from lead fishing tackle in the EU, generally referred to as "waterbird" species

Taxonomy	Common name	EU IUCN Red List Category / primary poisoning source relevant for the current restriction proposal[1]
Anas acuta	Northern Pintail	VU / lead shot in the terrestrial environment and lead fishing tackle
Anas crecca	Common Teal	LC /lead shot in the terrestrial environment and lead fishing tackle
Anas platyrhynchos	Mallard	LC /lead shot in the terrestrial environment and lead fishing tackle
Anser albifrons	Greater White-fronted Goose	LC/ lead shot in the terrestrial environment
Anser anser	Greylag Goose	LC/ lead shot in the terrestrial environment
Anser brachyrhynchus	Pink-footed Goose	LC/ lead shot in the terrestrial environment
Anser caerulescens	Snow Goose	NE/ lead shot in the terrestrial environment
Anser erythropus	Lesser White-fronted Goose	CR/ lead shot in the terrestrial environment
Anser fabalis	Bean Goose	LC/ lead shot in the terrestrial environment
Branta bernicla	Brent Goose	LC /lead shot in the terrestrial environment
Branta leucopsis	Barnacle Goose	LC /lead shot in the terrestrial environment
Branta ruficollis	Red-breasted Goose	NT/ lead shot in the terrestrial environment
Cygnus columbianus	Tundra Swan	EN / lead shot in the terrestrial environment and lead fishing tackle
Cygnus cygnus	Whooper Swan	LC / lead shot in the terrestrial environment and lead fishing tackle

Taxonomy	Common name	EU IUCN Red List Category / primary poisoning source relevant for the current restriction proposal[1]
Cygnus olor	Mute Swan	LC/ lead shot in the terrestrial environment and lead fishing tackle
Aythya ferina	Common Pochard	VU/ lead fishing tackle
Aythya fuligula	Tufted Duck	LC/ lead fishing tackle
Aythya marila	Greater Scaup	VU/ lead fishing tackle
Aythya nyroca	Ferruginous Duck	LC/ lead fishing tackle
Marmaronetta angustirostris	Marbled Teal	CR/ lead fishing tackle
Netta rufina	Red-crested Pochard	LC/ lead fishing tackle
Oxyura leucocephala	White-headed Duck	VU/ lead fishing tackle
Spatula clypeata	Northern Shoveler	LC/ lead fishing tackle
Spatula querquedula	Garganey	VU/ lead fishing tackle
Gavia adamsii	Yellow-billed Loon	NE/ lead fishing tackle
Gavia arctica	Arctic Loon	LC/ lead fishing tackle
Gavia immer	Common Loon	VU/ lead fishing tackle
Gavia stellata	Red-throated Loon	LC/ lead fishing tackle
Pelecanus crispus	Dalmatian Pelican	LC/ lead fishing tackle
Pelecanus onocrotalus	Great White Pelican	LC/ lead fishing tackle
Platalea leucorodia	Eurasian Spoonbill	LC/ lead fishing tackle
Anthropoides virgo	Demoiselle Crane	NE/ lead shot in the terrestrial environment
Grus grus	Common Crane	LC/ lead shot in the terrestrial environment

Notes:[1] risks of lead gunshot ingestion in wetlands were analysed in a previous assessment on the use of lead gunshot in wetlands; some species (for example species in the family of loons) may also *ingest fishing tackle via secondary ingestion.*

Table 1-29: Raptors, scavengers and other species, generally referred to as "terrestrial" species, at most risk of lead poisoning from lead ammunition in the EU

Taxonomy	Common name	EU IUCN Red List Category / type of lead poisoning[1]
Aquila adalberti	Spanish Imperial Eagle	VU/secondary poisoning
Aquila chrysaetos	Golden Eagle	LC/secondary poisoning
Aquila fasciata	Bonelli's Eagle	NT/secondary poisoning
Aquila heliaca	Eastern Imperial Eagle	NT/secondary poisoning
Aquila nipalensis	Steppe Eagle	NE/secondary poisoning
Accipiter gentilis	Northern Goshawk	LC/secondary poisoning
Aegypius monachus	Cinereous Vulture	LC/secondary poisoning
Neophron percnopterus	Egyptian Vulture	VU/secondary poisoning
Gypaetus barbatus	Bearded Vulture	VU/secondary poisoning
Gyps fulvus	Griffon Vulture	LC/secondary poisoning
Buteo buteo	Eurasian Buzzard	LC/secondary poisoning
Buteo lagopus	Rough-legged Buzzard	EN/secondary poisoning
Buteo rufinus	Long-legged Buzzard	LC/secondary poisoning
Circus aeruginosus	Western Marsh-harrier	LC/secondary poisoning
Clanga clanga	Greater Spotted Eagle	CR/secondary poisoning
Haliaeetus albicilla	White-tailed Sea-eagle	LC/secondary poisoning
Milvus migrans	Black Kite	LC/secondary poisoning
Milvus milvus	Red Kite	NT/secondary poisoning
Circus cyaneus	Hen Harrier	LC/secondary poisoning

Taxonomy	**Common name**	**EU IUCN Red List Category / type of lead poisoning[1]**
Circus macrourus	Pallid Harrier	EN/secondary poisoning
Circus pygargus	Montagu's Harrier	LC/secondary poisoning
Clanga pomarina	Lesser Spotted Eagle	LC/secondary poisoning
Hieraaetus pennatus	Booted Eagle	LC/secondary poisoning
Falco biarmicus	Lanner Falcon	VU/secondary poisoning
Falco cherrug	Saker Falcon	VU/secondary poisoning
Falco peregrinus	Peregrine Falcon	LC/secondary poisoning
Falco rusticolus	Gyrfalcon	VU/secondary poisoning
Corvus corax	Common Raven	LC/secondary poisoning
Corvus corone	Carrion Crow	LC/secondary poisoning
Columba livia	Rock Dove	LC/primary poisoning
Columba oenas	Stock Dove	LC/primary poisoning
Columba palumbus	Common Woodpigeon	LC/primary poisoning
Streptopelia decaocto	Eurasian Collared-dove	LC/primary poisoning
Streptopelia turtur	European Turtle-dove	NT/primary poisoning
Columba bollii	Dark-tailed Laurel-pigeon	LC/primary poisoning
Columba junoniae	White-tailed Laurel-pigeon	NT/primary poisoning
Columba trocaz	Madeira Laurel-pigeon	LC/primary poisoning
Pterocles alchata	Pin-tailed Sandgrouse	LC/primary poisoning
Pterocles orientalis	Black-bellied Sandgrouse	EN/primary poisoning
Scolopax rusticola	Eurasian Woodcock	LC/primary poisoning

Taxonomy	Common name	EU IUCN Red List Category / type of lead poisoning[1]
Alectoris barbara	Barbary Partridge	LC/primary poisoning
Alectoris chukar	Chukar	LC/primary poisoning
Alectoris graeca	Rock Partridge	VU/primary poisoning
Alectoris rufa	Red-legged Partridge	LC/primary poisoning
Bonasa bonasia	Hazel Grouse	LC/primary poisoning
Coturnix coturnix	Common Quail	LC/primary poisoning
Lagopus lagopus	Willow Grouse	VU/primary poisoning
Lagopus muta	Rock Ptarmigan	VU/primary poisoning
Lyrurus tetrix	Black Grouse	LC/primary poisoning
Perdix perdix	Grey Partridge	LC/primary poisoning
Phasianus colchicus	Common Pheasant	LC/primary poisoning
Tetrao urogallus	Western Capercaillie	LC/primary poisoning

Notes: [1] some species at risk of secondary poisoning may also ingest fishing tackle via secondary ingestion (for example species feeding on waterbirds)

1.5.4.3. Additional risks related to sports shooting

In addition to the risks identified and discussed in the previous section, additional specific risks have been identified for the uses related to sports shooting.

Specifically, the Dossier Submitter has identified risks to the environment and to humans (via the environment) as conceptually described in Annex B, section B.9 (see "Exposure pathways, on site and off site, in a range with no environmental RMM in place **during service life**" and "Exposure pathways, on site and off site, in a range with no environmental RMM in place **during end of life**").

Risks can occur during both service life and at the end of life and are expected to occur both on site and off site (via different pathways), although with site-specific differences. Risks to human health (humans via the environment) are discussed in subsequent sections of this report.

Although in general risks (and receptors) for shotgun ranges using lead shot and rifle and pistol ranges using lead bullets appear to be similar, specific differences in terms of risk profiles have to be expected for shooting disciplines using lead shot versus shooting disciplines using lead bullets.

At a conceptual level, for both shotgun ranges and rifle and pistol ranges, additional environmental risks during service life and/or at the end of life are the following ones:

- Contamination of soil
- Contamination of surface water and groundwater
- Lead poisoning of livestock in shooting ranges/areas used as agricultural lands.

Risks to surface water and groundwater

The risk to surface and groundwater from lead exposure in shooting ranges is addressed in section Risk from consumption of contaminated drinking water (uses # 3, 4) related to indirect exposure to human via the environment. It has to be noted that risk to groundwater is likely to materialise during the end of life phase rather than during the service life phase of a shooting range.

Risks related to soil

The concentration of lead in soil at shooting ranges is discussed in Annex B, section B9. Specifically, a review of research studies (over 35 years) on contamination of shooting range soils from lead ammunition by Dinake et al. (2019) is provided. Data from gunshot and rifle/pistol shooting ranges demonstrate contamination of the soil up to 300 000 mg/kg (Dinake et al., 2019).

Background value of lead in soil is 40 mg/kg (dry matter) (Carlon, 2007).

While the areas closest to (< 100 m), and furthest from (> 180 m), the firing position are comparatively less contaminated in shotgun ranges, they are still likely to have high levels of lead contamination compared to normal background levels in agricultural environments. For this reason, shooting ranges should not neglect these areas and actively manage the entire shot fall zone (Victorian EPA, 2019).

Within an EU project, metals in topsoil were analysed according to the standards as defined in the Finnish legislation for contaminated soil. For lead, the threshold value that indicates the need for further assessment of the area was set at 60 mg/kg. The lower guidance value indicating a risk for human health has been set at 200 mg/kg and the higher guidance value indicating an ecotoxicological risk at 750 mg/kg (Tóth et al., 2016).

Based on those threshold values, lead soil contamination in shooting ranges represents a risk to many taxa and to humans via the environment.[98]

Risk to livestock (grazing ruminants)

Several studies (Braun et al., 1997, Macnicol, 2014, Muntwyler, 2010, Rice et al., 1987, Scheuhammer and Norris, 1995, Vermunt et al., 2002a) have discussed lead poisoning in cattle either via ingestion of contaminated soil and grass when grazing on shooting ranges or when being fed with (lead gunshot) contaminated silage (secondary poisoning). A few

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[98] Currently, at the EU level no common limits for soil quality or soil pollutants as lead is established, apart from one exception: the Sewage Sludge Directive in its annexes defines limits for heavy metals (including lead) in agricultural soils on which sewage sludge is applied. A new publication by the European Environment Agency and the European Topic Centre on urban, land and soil systems on functional soil quality indicators, may become available during 2021.

case studies are discussed more in detail in this section.

- **Cattle grazing on shooting ranges (Switzerland)**
  Mortality was reported in calves put on pasture on an area containing an old shooting range in Switzerland, for which the concentration of lead in the dry matter of a grass and a soil[99] sample from the target zone of the shooting range were 29 550 mg/kg and 3 900 mg/kg (Braun et al., 1997). As reported by Braun et al. (1997), acute lead poisoning occurred in one of the calves after five days of grazing, the remainder became ill one to three days later. The most important symptoms consisted of neurological disturbances and included maniacal movements, opisthotonos, drooling, rolling of the eyes, convulsions, licking, champing of the jaws, bruxism, bellowing and breaking through fences. All but one calf, which was euthanatized, died within several hours of the occurrence of the first symptoms. Post-mortem examination of this calf revealed acute cardiac, renal and pulmonary haemorrhage, acute tubulonephrosis and acute severe pulmonary emphysema.

- **Cattle fed pasture supplemented with maize silage (New Zealand)**
  As reported by Vermunt et al. (2002a), the herd consisted of 140 spring-calving, Friesian dairy cows fed high-quality pasture, which had been supplemented with maize silage for the previous 4 weeks, at a rate of 4 kg per cow per day.
  In 2001, four pregnant cows showed severe nervous signs. The animals had charged through fences and were agitated. On closer examination three of them appeared to be blind, had muscle tremors and abdominal contractions, and were head pressing when forced into a corner of the cattle yards. The cardinal signs (rectal temperature, heart and respiratory rates) were all within their respective normal ranges. At that stage, differential diagnoses included hypomagnesaemia, nervous ketosis, and polio-encephalomalacia due to thiamine (vitamin B1) deficiency or lead poisoning.
  Blood samples were collected in order to rule in / out hypomagnesaemia and nervous ketosis, respectively. Each animal was treated with thiamine hydrochloride and also a 20% magnesium sulphate solution. Sufficient thiamine for additional treatments was left with the owner.
  The day following the symptoms outbreak, the three clinically affected cows were revisited by veterinary staff. One cow was euthanised because they were moribund. A field necropsy was carried out, but no gross lesions or abnormalities were detected. A kidney sample was taken for further toxicology analysis. The next day another cow was euthanised and a kidney sample was collected for lead analysis. Then also the third cow became extremely ill. This cow was also euthanised and a post-mortem examination carried out. A large amount of lead shot was found in the reticulum and a presumptive diagnosis of lead poisoning was made. Again, a kidney sample was taken for lead analysis. A cursory examination of the fore stomach

[99] In bermudagrass growing on a shooting range, lead concentrations as high as 800 mg/kg (dry matter) were also measured CAO, X., MA, L. Q., CHEN, M., HARDISON JR, D. W. & HARRIS, W. G. 2003. Weathering of lead bullets and their environmental effects at outdoor shooting ranges. *Journal of Environmental Quality,* 32**,** 526-534.. In plants growing on the berm, concentration in plant was as high as 4 700 mg/kg DALLINGER, R. 2007. Umwelttoxikologisches Gutachten zum Risikopotential der Schwermetallbelastung in einem Schießstand-Areal auf dem Grund des Natur-und Tierparks Goldau verfasst im Auftrag des Direktors des Natur- und Toerparks Goldau. Available at: https://www.researchgate.net/publication/337812044_Umwelttoxikologisches_Gutachten_zum_Risikopotential_der_Schwermetallbelastung_in_einem_Schiessstand-Areal_auf_dem_Grund_des_Natur-und_Tierparks_Goldau_verfasst_im_Auftrag_des_Direktors_des_Natur-und_T..

> contents of the carcasses of the other cows also revealed numerous gunshot pellets amongst the digesta.
> An on-farm investigation identified the maize silage as the source of the lead poisoning. Large numbers of shotgun pellets were found mixed in with the silage. The silage being fed had been purchased from a nearby gun club, which grew the crop beneath the target firing range. A sample of the silage was taken for lead analysis and the farmer was advised to immediately stop feeding this supplement. The lead concentration in the silage, following removal of any lead gunshot, was 32 mg/kg (on a dry matter basis). The sample of maize silage was thoroughly washed at the laboratory, so no lead pellets were present when tested. However, the maize silage fed to the cows was found to be heavily contaminated with lead from the shooting range.
> The lead shot was harvested and ensiled along with the maize, and became incorporated in the feed. Properly made silage is very acidic (pH < 4.8), and in such an acid environment a proportion of the metallic lead is converted into a more soluble lead salt, which then leaches into the silage, making it toxic.

Macnicol (2014) also reported that about 100 Southland dairy cows "had died or been destroyed after contracting lead poisoning" which was later confirmed as the result of lead become embedded in the fodder beet (silage).

Conclusion

As specified by the European Commission Directive 2002/32/EC[100], lead concentrations in the harvested material (forage) should be below 30 mg/kg (maximum relative to a feed with a moisture content of 12 %) for this material to be fed to livestock. Regulation 1275/2013[101], amending the Annex I to Directive 2002/32/EC, indicates a limit of 10 mg lead/kg (12 % moisture) for lead in animal feed materials with several exceptions, including of 30 mg/kg (maximum relative to a feed with a moisture content of 12 %) for forage. The lead concentrations in material harvested on shooting ranges can have lead concentrations hundred times greater than 30 mg/kg (12% moisture), constituting therefore a risk and should not be used as animal forage.

In addition, according to the Swiss expert system for risk assessment of contaminated soils (Swiss BUWAL, 2005), it must be assumed that cows could be endangered when grazing on contaminated soil that exceeds 1 000 mg lead/kg (dry matter). Based on this, grazing on shooting ranges may constitute a risk, considering the average soil concentration in a shooting range.

1.5.4.4. Level of risks related to all uses

The Dossier Submitter has endorsed a semi-quantitative approach to describe the identified risks for soil, groundwater, surface water, livestock (ruminants[102]), birds, in terms of expected risk level for hunting, sports shooting, and fishing.

For sports shooting, the Dossier Submitter has considered the following generic scenarios:

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[100] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02002L0032-20131227&from=EN#E0021

[101] https://eur-lex.europa.eu/eli/reg/2013/1275/oj

[102] Additional information on livestock poisoning (ruminants and poultry) in relation to land used for sport shooting where agricultural activities may be carried out during service life and/or end of life is expected to become available during the consultation on the Annex XV report.

Use of lead shot (use #3) for sports shooting under different scenarios

a) Temporary shooting areas (shooting intensity about 5 000 - 10 000 rounds per year) with no environmental RMMs in place

Following the definition of the CSR (2020), shooting areas are "*areas not specifically designed and operated for shooting but where shooting activities can take place*". These areas do in most cases not comply with best practice guidelines and may not be subject to, or comply with, relevant environmental regulations. The definition of a shooting area differs distinctively among EU Member States. For example, in the Flemish environmental legislation (Belgium), shooting *areas* are defined as "shooting contests organised maximum twice per year on the same piece of land with a maximum duration of 4 consecutive days". Shooting areas are exempted from the Flemish soil pollution regulation and can therefore not be considered as technical areas.

No data are available on the impact of temporary shooting areas on soil, surface or groundwater contamination. Assuming limited intensity of shooting, the risk to soil and surface water might be low, but might build up over time under certain circumstances such as annual shooting at the same spot over several years. Lead shot deposited on the soil may be ingested by birds with consequent poisoning but the likelihood of such poisoning depends on site specific conditions.

Due to the limited shooting activity in a temporary area, the risk may be low but under certain circumstances (higher deposition at certain spots) cannot be excluded.

b) Permanent outdoor shooting areas (shooting intensity about 10 000 rounds per year with a service life of 30 - 40 years) with no environmental RMMs in place (any type);

For this scenario b) the same applies as for scenario a) with the difference of higher contamination due to regular shooting over many years. Therefore, there is a higher likelihood of harm to humans or the environment occurring. An example for a permanent shooting area would be a clay target area which is not specifically designed and operated for shooting. Such areas do typically not comply with best practice guidelines as indicated in the CSR (2020) and are not subject to, or comply with, relevant environmental regulations.

The Dossier Submitter considers that due to the high annual shooting intensity (10 000 rounds) of a sporting clay parcours, that has no environmental RMMs in place and which is usually located in natural surroundings with trees and bushes, there is a relevant risk for soil and surface water contamination as well as for poisoning of birds and possibly of ruminants (if the shooting ground is also used for agricultural purposes).

c) Permanent outdoor shooting ranges (shooting intensity about 10 000 - 100 000 rounds per year with a service life of 30 - 40 years) with environmental RMMs in place such as:
    - Measures to prevent rivers from crossing the lead deposition area
    - Control of water runoff
    - Lead shot deposition within the boundaries of the shooting range
    - Remediation plan upon closure

Compared to a temporary clay target area, the CSR (2020) defines a shooting range as an area designed and operated specifically for recreational shooting. The owner/operator of the site complies with environmental regulations. There is a remediation plan upon closure in place. The range has clearly defined boundaries and it is assumed that lead ammunition is not allowed to be deposited outside the boundaries of the range.

This scenario reflects the conditions described in the CSR (2020) for outdoor shooting ranges. Because of accumulation of lead shot in and on soil, the Dossier Submitter considers that the environmental RMMs described in the CSR (2020) for permanent shooting ranges are not enough to protect soil and potentially groundwater from contamination and poisoning of birds. The risk of surface water contamination can be considered low because of the required control of runoff water. In case agricultural use (e.g. grassing by ruminants) of the land is allowed there can be a relevant risk.

d) Permanent outdoor shooting ranges with the following OCs and RMMs implemented (in addition to the RMMs listed in the above scenario):
   - Regular (at least one a year) lead shot recovery with ≥ 90 % effectiveness calculated based on mass balance of lead used vs lead recovered to be achieved by appropriate means (such as walls and/or nets, and/or soil coverage);
   - Monitoring and treatment of surface (run-off) water;
   - Ban of any agricultural use within site boundaries.

The Dossier Submitter considers that to minimise the risks from outdoor shooting ranges, further measures than those specified in the CSR (2020) are required. The Dossier Submitter considers that the risks to soil and groundwater can be minimised by regular (at least one a year) recovery of lead shot that is not in contact with the natural soil. Monitoring and treatment of surface water is important to control this risk. Regular lead shot collection might reduce but not eliminate the risk to birds. Any agricultural use within the site boundaries should be banned to control the risk for humans (via food) and for ruminants. Even if risks are minimised at such ranges, remediation (e.g., final lead shot recovery with topsoil removal) at the cessation of use may still be required, depending on the land future zoning[103].

Use of lead bullets (use # 4, 5 and 6) for sports shooting under different scenarios

The environmental risks from lead bullets can be minimised by using appropriate bullet traps. Risks usually arise from trapping the bullets in soil berms.

a) Temporary shooting areas[104], limited shooting

Due to the limited shooting, the environmental risks to soil, surface water and agricultural use are likely to be low but might rise to a relevant level in case of accumulation of lead bullets in small areas. In case appropriate bullet traps are used to trap the bullets, the risks are minimised.

b) Permanent outdoor rifle and pistol ranges, intensive shooting, use of berm to trap bullets

Permanent outdoor rifle and pistol ranges that use berms to trap bullets are often old ranges operating since a long time. Especially the contamination of the berm area presents a high environmental risk to soil, surface water and potentially ground water. Coverages of such berm with a roof reduces the risk from mobilisation of lead by rain but does not eliminate the risk of contamination of soil, groundwater, or surface water. The Dossier Submitter notes that this scenario is not in accordance with the requirements of the CSR (2020).

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[103] Land for example can be used for agricultural uses or even residential or recreational purposes.
[104] Temporary rifle/pistol area might for example apply to biathlon events or for a muzzle loading event, firing with historical weapons.

c) Permanent outdoor rifle and pistol ranges with the following OCs and RMMs implemented:
   - bullet trap with regular recovery (> 90 % effectiveness)
   - ban of any agricultural use within site boundary

This scenario basically reflects the requirements specified in the CSR (2020) with appropriate bullet containment as the main means to control the risk from lead bullets. Appropriate bullet traps allow recovery of up to 100 % of spent lead ammunition.

The Dossier Submitter considers that in addition to the requirements specified in the CSR (2020) any agricultural use at a permanent range should be banned due to the residual risks.

A remediation of the site/facility at the cessation of the use would ensure removal of remaining contaminations.

A semi-qualitative analysis of the level of risks identified during service life for the use of lead shot and bullets in the above listed scenarios is presented in Table 1-30.

Soil contamination (uses 1, 2, 3, 4, 5, 6): The contamination of soil from shooting activities depends on the deposition of lead ammunition on the soil and its corrosion and solubility on and in the soil (see section B.4.2.1 in the Annex). For hunting with bullets (uses 2a, 2b) the risk level for soil contamination is considered low (+) due to the low intensity of shooting during hunting and because bullets often remain in the carcass. The risk level for soil contamination is also considered low in case of lead gunshot recovery higher than 90 % (uses 3d) or lead bullet recover > 90 % by installing suitable bullet traps (uses 4a, 4c, 5, 6). The risk level for soil contamination is considered low to medium (+ to ++) for infrequent shooting and/or limited shooting frequency with low to moderate amount of ammunition deposited on soil. This is assumed for hunting with shot (use 1) and for sports shooting on temporary shotgun areas (use 3a) and temporary rifle/pistol ranges that retain bullets in soil berm (use 4a, 5, 6). High risk level for soil contamination (+++) is assumed for permanent shotgun and rifle/pistol areas or ranges with intensive shooting and deposition of the ammunition in soil (uses 3b, 3c, 4b).

Groundwater contamination (uses 1, 2, 3, 4, 5, 6): In general, the risk to groundwater might be negligible or low in the terrestrial environment if shooting occurs far from sensitive areas[105]. Specifically, the risk level for ground water contamination is assumed to be negligible to low for hunting (uses 1, 2a, 2b) and low at shooting areas with limited shooting intensity (uses 3a, 4a, 5, 6) and for shooting ranges with lead shot and lead bullet recovery > 90 % (uses 3d, 4c, 5, 6). Ground water contamination can be relevant in case of deposition of usually larger amounts of lead accumulating in soil and migrating towards the ground water. The time point when the contamination reaches the ground water depends on the soil conditions and the distance to the ground water (see section B.4.2.1 in the Annex). Consequently, the risk level can range from low risk level (e.g., high deposition but ground water very deep and soil conditions are not promoting migration), to high risk level (e.g., medium or high deposition with ground water level close to the contamination horizon and/or soil conditions promoting the leaching of lead). This may apply to uses 3b, 3c, 4b.

Surface water contamination (uses 1, 2, 3, 4, 5, 6): Surface water contamination can be assumed for lead ammunition (gunshot and bullets) being deposited on or in the soil and

[105] The use of lead shot (in any type of shooting) will not be allowed in wetlands (as defined by the Ramsar Convention) as a consequence of the forthcoming restriction on the use of lead shot in wetlands.

subsequent corrosion and dissolution of the lead (see section B.4.2.2 in the Annex). The risk level is assumed to increase with increasing amount of deposition. The risk level is assumed to be low (+) for hunting with bullets (use 2a, 2b) and for sports shooting when bullets are trapped in suitable bullet traps (uses 4a, 4c, 5, 6). For shotgun ranges a risk for surface water contamination is always present due to the deposition of the gunshot on the soil and its corrosion. In case of limited shooting intensity such as hunting with gunshot (use 1) and on temporary shotgun ranges (use 3a) the level of risk is assumed to vary between low and moderate (+ to ++), depending on the amount of deposition at specific areas. To control the risk of water-runoff (+), the use of specific measures is required to collect, contain, and treat the surface water (uses 3c, 3d).

For fishing (use 7 and 8) the risk for water contamination is considered negligible to low. A risk from fishing (use 7 and 8) can be expected when a high lead dissolution rate occurs (due to the waterflow velocity, pH, etc), and is combined with a high rate of lead fishing tackle exposure (i.e. intense fishing practice, and therefore higher loss of fishing tackle).

The dissolution rate of lead in aquatic environments is relatively slow but increases with acidity, low water hardness (< 25 mg/L $CaCO_3$), and greater water velocity (see section B.4.2.2 in the Annex). Aquatic environments fulfilling these criteria are specific to some areas. A typical example of such conditions, where lead would dissolve more quickly and would become more bioavailable, is high-flow rivers/rapids populated with salmon. This is why, local bans are for example in place in specific salmon-populated rapids in Sweden where the salmon fishing is a popular activity.

As indicated in Annex B, in aquatic environments with lower water velocities (e.g. lakes), lead particles and artefacts would also be buried in bottom sediments, where they would move into the anoxic sediment layer and may be strongly adsorbed onto sediment and soil particles, and where the dissolution of elemental lead will be reduced, without mechanical disturbance.

For these reasons, the risk for water contamination from use 7 and 8 is considered negligible to low.

Birds (uses 1, 2, 3, 5, 7): The risks of lead poisoning depends on the availability of lead for birds (see section B.9.1.1. in the Annex). Birds can ingest (primary poisoning) lead gunshot (mistaken for grit) used for hunting (use 1) or sports shooting (3a, 3b, 3c, 3d), or lead air pellets (use 5). Risks can also arise from the consumption of meat containing lead fragments (secondary poisoning) such as viscera and carcasses from large game hunting left in the field (use 2b) or animals wounded or shot with lead ammunition (uses 1, 2a, 2b), animals shot for pest control with lead ammunition (uses 1, 2a, 2b) but not recovered and animal carrying ingested lead shot (uses 1). Direct intake of lead shot may also depend on the attractiveness of the area to birds e.g. presence of bushes, trees and forests (US EPA, 2005).

With regards to fishing (use 7) the risk is related to both primary and secondary poisoning (by consumption of prey having ingested split anglers' shot or other types of tackle or while consuming fish with attached fishing tackle). The risk levels for bird poisoning are considered high (+++) for all conditions under which lead (to be considered as lead sinkers and lures ≤50 g, fragments or lead available in tissues) is available to birds[106] for ingestion.

Livestock grazing and agricultural use (uses 1, 2, 3, 4, 5, 6): Lead dust from shooting and corroded lead shot are one source of increased lead concentrations in the biomass of

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[106] Even a single pellet can be lethal to different species of birds.

grass or crops used for agricultural purposes (Chrastný et al., 2010) or for elevated exposure of ruminants grazing on such lands or being fed with silage from shooting ranges (see section 1.5.3.7.4). The level of risk is considered to depend on the amount of gunshot deposition on terrestrial areas that might also be used for agricultural purposes. Low risk level (+) is assumed for hunting with bullets (uses 2a, 2b) and for sports shooting when more than 90 % of lead bullets are contained in bullet traps (uses 4a, 4c, 5, 6) and in case agricultural use is banned on the range (uses 3d, 4c). Low to moderate risk levels are assumed for areas with frequent hunting with shotguns (use 1), temporary shotgun areas (use 3a), and for temporary or permanent pistol/rifle ranges with low shooting intensity and deposition of the bullets in soil without a ban of agricultural use of the contaminated area (uses 4a, 5, 6). High risk level is assumed for permanent pistol/rifle ranges with high shooting intensity and deposition of the bullets in soil without a ban of agricultural use of the contaminated area (use 4b).

To describe the level of risks occurring, the following qualitative ranking is used: +: negligible to low risk or risk controlled; ++: moderate risk; +++: high (main) risk; N/A: not applicable.

Table 1-30: Semi-quantitative judgement on the level of risks related to the use of lead for hunting, outdoor sports shooting and fishing

Use	Scenario	Soil	Ground water	Surface water	Birds	Livestock (ruminants) in shooting ranges/ areas used as agricultural land[1]
1	Hunting with gunshot	+ to ++	+	+ to ++	+++	+ to ++
2a	Hunting with bullets - small calibre	+	+	+	+++	+
2b	Hunting with bullets - large calibre	+	+	+	+++	+
3	Outdoor sports shooting - gunshot					
3a	Temporary shotgun areas, no ENV RMM, limited shooting intensity	+ to ++	+	+ to ++	+++	+ to ++
3b	Permanent shotgun areas, no ENV RMM, intensive shooting	+++	+ to +++	+++	+++	+++

Use	Scenario	Soil	Ground water	Surface water	Birds	Livestock (ruminants) in shooting ranges/ areas used as agricultural land[1]
3c	Permanent shotgun range, ENV RMMs in place: - prevent rivers from crossing - control water runoff - lead deposition within range - remediation plan upon closure	+++	+ to +++	+	+++	+++
3d	Permanent shotgun range, ENV RMMs in place (in addition to 3c): - regular (annual) collection of lead shot (>90% effectiveness) - monitoring and treatment of surface (runoff) water - ban of agricultural use within site boundary	+	+	+	+++	+
4	Outdoor sports shooting - bullets					
4a	Temporary rifle/pistol areas, limited shooting intensity:					
	- use of soil berm to trap bullets	++	+	+ to ++	[2]	+ to ++
	- use of bullet traps	+	+	+	N/A	+
4b	Permanent rifle/pistol ranges, intensive shooting: - use of soil berm to trap bullets	+++	+ to +++	+++	[2]	+++

Use	Scenario	Soil	Ground water	Surface water	Birds	Livestock (ruminants) in shooting ranges/ areas used as agricultural land[1]
4c	Permanent rifle/pistol ranges: - use of bullet traps - ban of any agricultural use within site boundary	+	+	+	N/A	+
5	Outdoor shooting air rifle/pistol (assuming low shooting intensity)					
	- use of air pellet traps	+	+	+	N/A	+
	- air pellets deposited on soil	++		++	+++	+ to ++
6	Other outdoor shooting activities (assuming low shooting intensity)					
	- use of bullet traps	+	+	+	N/A	+
	- use of soil berm to trap bullets	++		++	[2]	+ to ++
7	Fishing sinkers and lures	N/A	N/A	+	+++ (sinkers and lures ≤ 50 g)	N/A
8	Fishing nets, lines and ropes	N/A	N/A	+	N/A	N/A

Notes: [1] the risk relates to grazing of ruminants on ranges with ingestion of contaminated soil and vegetation and (secondary) poisoning via silage grown on shotgun ranges/areas. [2] Some birds may also ingest contaminated soil while feeding. This route has not been assessed due to the lack of specific data. Additional information may become available in the consultation on the Annex XV report.

1.6. Human health risk assessment

1.6.1. Approach to human health risk assessment

In this human health risk assessment, the hazards related to lead exposure via hunting, outdoor sports shooting and fishing are described and, since there is no evidence for thresholds for critical lead-induced effects, toxicological reference (BMDL) values for these activities are applied. Indirect exposure via the environment from these uses is also assessed, primarily through the consumption of game meat obtained using lead ammunition, but also via the consumption of milk and meat from cattle suffering from sub-clinical poisoning. Risks to human health via drinking water and the consumption of crops grown on agricultural soils adjacent to or within shooting areas are discussed qualitatively.

Occupational lead exposures arising from the manufacture of ammunition or fishing sinkers, professional shooting or commercial fishing are not explicitly assessed as these risks are considered, for the purposes of this assessment, to be addressed by existing binding occupational limit values for lead.

The exposure pathways of key concern are inhalation and oral intake.

Inhalation exposure results from fumes, aerosols or dusts arising from firing lead-containing gunshot or other projectiles (e.g. bullets) as well as from the melting of lead by consumers to prepare ammunition or fishing tackle (termed 'home-casting').

Oral intake of lead (as lead dust) occurs after handling lead gunshot, other projectiles or fishing tackle (an example of hand-to-mouth exposure) or by the mouthing or unintended ingestion of lead-containing objects, usually by children. Another important source of oral lead intake from the uses assessed occurs indirectly via the environment and occurs either via the consumption of game meat containing fragments of lead gunshots or other lead projectiles or via the consumption of other food or drinking water containing lead.

Only the key studies used as the basis for the assessment are cited in the Annex XV report. Additional studies that were assessed to be less relevant are summarised in Annex B.

Table 1-31: Approach to human health risk assessment

Hazard assessment	Information on toxicokinetics, acute (short-term) and chronic (long-term) toxicity of lead in humans from epidemiological studies; including any relevant thresholds for adverse effects in biota (i.e. blood lead thresholds).
Exposure assessment	Information on lead concentration in human blood following direct exposure to lead by inhalation (shooting) or oral intake (outdoor shooting, fishing) or indirect exposure via the environment from the consumption of game meat (hunting) or milk/meat from cattle suffering from sub-clinical poisoning.
Risk characterisation	Incidence of adverse effects in shooters (from hunting and outdoor shooting activities), fishers (home-casting), hunter family members (consumption of game meat), children (oral ingestion of lead particles), general population (drinking water, food).

1.6.1.1. Integrated assessment model for lead exposure and health outcomes

The analysis presented hereafter is based on an integrated assessment model that converts oral or inhalation lead exposure to blood lead levels and then to expected health outcomes. The modelling combines various data sources and relies on numerous model parameters, most of which were provided by EFSA for the purpose of this restriction proposal. In particular, EFSA provided data on game meat consumption rates, which was further differentiated into (i) game meat from ungulates and other large game that are typically hunted with bullets and (ii) game meat from birds and small mammals, such as rabbits, that are typically hunted with gunshot. The same differentiation was applied to lead concentration data in samples of game meat collected by EFSA. These then served as input data into a traditional integrated assessment model (IAM) that combines intake, resulting exposure, and expected health impacts (Rheinberger and Hammitt, 2012).

Premises of the modelling

Excess lead exposure may lead to a variety of detrimental health effects in children and adults (EFSA, 2010). The most sensitive and best researched endpoint related to lead exposure of children aged 7 or younger is impairment of neurocognitive development, which is typically measured in IQ loss. Such impairments have also been observed in children that were exposed *in utero* via umbilical cord blood. For adolescents and adults, the most sensitive endpoint is impairment of renal function leading to chronic kidney disease (CKD).

Various models have been developed to determine benchmark doses (BMDs) and benchmark dose lower bounds (BMDLs) for the aforementioned endpoints. The models which will be used in this assessment all relate blood lead (PbB) concentrations to health impacts. Therefore, the first task of an integrated assessment is to model lead exposure via ingestion or inhalation. The following generic model is devised to estimate daily exposure:

$$D\left[\frac{\mathrm{\mu g}}{\mathrm{kg_{BW}\ day}}\right] = I\left[\frac{\mathrm{g}}{\mathrm{kg_{BW}\ day}}\right] * C\left[\frac{\mathrm{\mu g}}{\mathrm{kg}}\right],$$

where D denotes the daily lead dose either ingested or inhaled via pathway I with lead concentration C. In a next step, the daily dose needs to be converted into an incremental PbB concentration:

$$\mathrm{PbB}\left[\frac{\mathrm{\mu g}}{\mathrm{L}}\right] = D\left[\frac{\mathrm{\mu g}}{\mathrm{kg_{BW}\ day}}\right] * \gamma\left[\frac{\mathrm{\mu g}}{\mathrm{L}} \Big/ \frac{\mathrm{\mu g}}{\mathrm{kg_{BW}\ day}}\right],$$

with γ being a conversion parameter that translates daily lead dose into incremental PbB concentration accounting for the bioavailability of metallic lead. Importantly, γ will differ between different age groups. Once PbB levels are estimated, these can be used to predict health outcomes in the affected population. For this, the following relationships can be derived from EFSA's benchmark doses:

$$\Delta\mathrm{IQ} = \beta_{\mathrm{IQ}}\left[-1\ \mathrm{IQ\ point}/\frac{\mathrm{\mu g}}{\mathrm{L}}\right] * \mathrm{PbB}\left[\frac{\mathrm{\mu g}}{\mathrm{L}}\right],$$

$$\Delta\mathrm{CKD} = \beta_{CKD}\left[-10\ \%\ \mathrm{CKD\ risk}/\frac{\mathrm{\mu g}}{\mathrm{L}}\right] * \mathrm{PbB}\left[\frac{\mathrm{\mu g}}{\mathrm{L}}\right],$$

$$\Delta\mathrm{CVD} = \beta_{CVD}\left[-10\ \%\ \mathrm{CVD\ risk}/\frac{\mathrm{\mu g}}{\mathrm{L}}\right] * \mathrm{PbB}\left[\frac{\mathrm{\mu g}}{\mathrm{L}}\right],$$

where the β's are slope parameters that can be derived from the BMD(L)s for the endpoints IQ, CKD and CVD (▪) in the following generic way:

$$BMD(L)_{\blacksquare} = \mathrm{b}_{\blacksquare}\left[\frac{\mathrm{\mu g}}{\mathrm{L}}\right] \leftrightarrow \beta_{\blacksquare}\left[-risk/\frac{\mathrm{\mu g}}{\mathrm{L}}\right] = \mathrm{b}_{\blacksquare}{}^{-1}.$$

Calibration of the model

In order to calibrate these models, the parameters $\langle \beta_{IQ}, \beta_{CKD}, \beta_{CVD}, \gamma \rangle$ must be set as well as the typical habits of hunters and their families. For that purpose, ECHA cooperated with EFSA and obtained information about the concentration of lead in different types of game meat and information about consumption rates of game meat in high frequency consumers (summarised below). Moreover, the EFSA opinion on lead (EFSA, 2010) may be used as a starting point to specify $\langle \beta_{IQ}, \beta_{CKD}, \beta_{CVD}, \gamma \rangle$. All of these elements are subsequently brought together in the impact assessment part (Section 2.5.2.1) of this report.

1.6.2. Hazard assessment

1.6.2.1. Toxicokinetics

Absorption

Oral ingestion and inhalation are the most significant routes of lead exposure, whereas dermal absorption is considered as minimal (LDAI, 2008). However, even though absorption directly through the skin is considered negligible, lead can become systemically available through hand-to-mouth behaviour. This route of exposure is possible for both children and adults that come in contact with lead containing articles, both at home and occupationally (Klein and Weilandics, 1996).

Representative uptake rates for lead in adults and children via different exposure routes are presented in Table 1-32. According to the information in the Chemical Safety Report of the REACH Registration (CSR, 2020), inhalation absorption is 100 %, whereas oral absorption from food is 10 % in adults and 50 % in children. ATSDR (2019) reported similar rates for inhalation absorption with 95 % and for gastrointestinal absorption with 3 to 10 % for adults and 40 to 50 % for children. It is noted that the uptake estimates are only applicable to relatively low exposure levels yielding PbB levels up to 150 µg/L.

Table 1-32: Representative lead uptake rates (CSR, 2020)

Route of intake	Adults	Children
Oral (food)	10 %	50 %
Oral (soil)	6 %	30 %
Dermal	< 0.01 %	< 0.01 %
Air (deep lung deposition)	100 %	100 %
Air (upper airway deposition)[1]	variable	NA

Notes: [1] upper airway deposition is expected for many occupational aerosols and uptake will thus vary as a function of pulmonary deposition patterns and the extent of translocation to the gastrointestinal tract where GI uptake kinetics will predominate. Non-linearity as a function of exposure level imparts additional variability into upper airway uptake estimates. Given that upper airway deposition is expected primarily in the occupational setting, upper airway deposition is Not Applicable (NA) to children

The efficiency of oral lead uptake varies depending on e.g. particle size and shape (surface area), amount of time particles spent in the gastrointestinal tract, concurrent food intake and the iron- and calcium status of the individual. Small lead-containing particles have a higher surface-to-volume ratio and will undergo more rapid dissolution upon ingestion.

Whereas 200 µm particles exhibit gastrointestinal uptake efficiency approximately one order of magnitude lower than for soluble compounds, a decrease in particle size to 6 µm (equivalent to the size of a particle that might be inhaled and subsequently translocated to the gastrointestinal tract) will increase uptake five-fold and largely mitigate potential impacts of speciation upon relative bioavailability (Barltrop and Meek, 1979). Case reports (mainly for children) prove that even one larger piece of lead ingested orally can create sufficient systemic exposure to produce clinical lead intoxication or even death. Precise prediction of the bioavailability that will result from ingestion of an individual lead fragments is thus a complex function of particle size, dissolution rates and residence time in the gastrointestinal tract. As a worst-case assumption, it can be assumed that the bioavailability of metallic lead is equivalent to that of soluble lead compounds such as e.g. lead acetate (LDAI, 2008).

Sahmel et al. (2015) quantified the hand-to-mouth transfer efficiency of lead dust. The saliva of six adult volunteers was collected and poured onto a sheet of wax paper placed on a balance scale. The volunteers handled lead fishing weights with both hands for approximately 15 seconds and then pressed three fingers from the right hand (test hand) into their saliva 10 times, with ~0.45 kg of pressure. The left hand (control hand) was used as a comparison for dermal loading of lead and had no contact with saliva. SKC Full Disclosure® wipes were used to collect lead from the saliva and skin surfaces. Samples were analysed using the NIOSH 7300 method, which was modified for wipes. The mean lead skin-to-saliva transfer efficiency was 24 % (range: 12 – 34 %).

In a recent Swedish study (Swedish NFA, 2014b), the percentage of lead released in stomach-like environment (0.1 M hydrochloric acid) was measured in relation to exposure duration and rocking of the sample. At the start, 8 mg of metallic lead in the form of metal shavings was placed in 40 ml of hydrochloric acid for up to 120 hours either stationary without rocking (Stillastående), slight rocking (Vaggning) or heavy rocking (Ökad vaggning). The results are presented in Figure 1-21.

Panel A **Panel B**

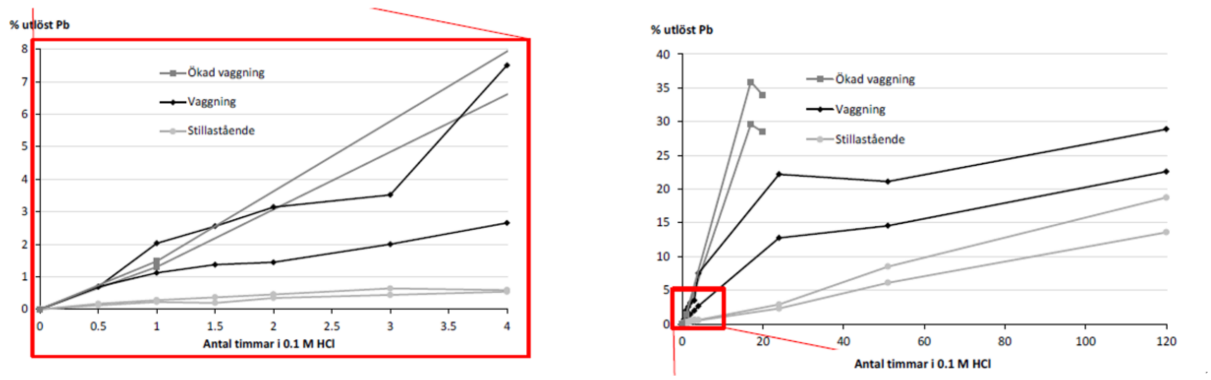

Figure 1-21: Percentage of lead released in stomach-like environment (0.1 M hydrochloric acid) after a certain time with heavy rocking (Ökad vaggning), rocking (Vaggning) or without rocking (Stillastående) (Swedish NFA, 2014b)

As Figure 1-21 shows already after half an hour samples with a rocking motion have a higher percentage of lead than stagnant samples. After 1 hour, 1-2 percent of lead was released in the rocked samples while less than 0.5 % of lead dissolved from stationary samples. The difference between stationary samples and rocked samples increased over time. The figure also shows that if the speed in the rocking movement is increased, lead is released faster. After two days, the rocking movement stopped, and all samples were left stationary during the rest of the trial. Consequently, starting from 51 hours all four samples show the same release rate (same slope).

In the "increased rocking" experiment, no sub-samples were taken after 20 hours. The solutions were provided instead, standing still and after three months no visible traces of lead particles could be found in any of the test tubes. This experiment demonstrates that in a stomach-like environment relevant amounts of lead (up to 35 %) can be dissolved. For the *in-vivo* situation, it should be noted though that not all lead in solution may be absorbed due to the usual presence of food in the stomach that might reduce the absorption.

Metabolism

The lead ion is not metabolised or bio-transformed in the body, though it does form complexes with a variety of proteins and non-protein ligands. It is primarily absorbed, distributed and then the non-accumulated lead is excreted (WHO, 2003).

Distribution

Once it is absorbed, inorganic lead appears to be distributed to both soft tissues (blood, liver, kidney, etc.) and mineralising systems (bones, teeth) in a similar manner regardless of the route of absorption. The distribution of lead seems to be similar in children and adults, but in adults a larger fraction of lead is stored in skeletal tissue. More than 90 % of the total amount of accumulated lead in adults ends up in bone and tooth, while in children, 75 % is accumulated in bones. The distribution of lead in the body is initially dependent on the rate of delivery by the bloodstream to the various organs and tissues. A subsequent redistribution may occur based on the relative affinity of particular tissues for the element and its toxicodynamics (ATSDR, 2007).

Lead concentration is also related to calcium status; stored lead can therefore be released from bone tissue into the blood stream in situations where a person suffers from calcium deficiency or osteoporosis (LDAI, 2008).

It should be noted that lead is easily transferred to the foetus via the placenta during pregnancy. The foetal/maternal blood lead concentration ratio is approximately 0.9 (Carbone et al., 1998). As explained by Bradbury and Deane (1993) the blood-cerebral barrier is permeable to lead ions and the most sensitive end-point is connected to neurotoxicity and developmental effects.

Elimination

Elimination takes place mostly via urine (>75 %), and 15 to 20 % is excreted via bile and faeces (TNO, 2005). The half-life of lead in the human body differs across tissues. Blood lead and lead in soft tissue is considered the most labile with a half-life of approximately 40 days, while bone lead is very stable with a half-life of several decades (ATSDR, 2007). In chronically exposed infants and children, lead is progressively accumulated in the body and is mainly stored in skeletal tissue. Lead is eliminated from bone very slowly; the half-life can be 10 to 20 years or more. In this way, lead can lead to an internal exposure long after the external exposure has ended, by redistribution between different tissue pools (LDAI, 2008).

1.6.2.2. Acute toxicity

Very limited data are available on the acute toxicity of lead and its compounds for humans and it is difficult to accurately establish the dosimetry for physiological effects caused by the inhalation or ingestion of lead and its inorganic compounds after the administration of a single dose. Most data for acute toxicity actually describes the effects of ingestion or inhalation of lead compounds over a period of weeks or years – exposure time-frames that are more accurately regarded as being sub-acute to chronic in duration. Confusion is also caused by traditional definitions in the medical literature which refer to acute and chronic lead intoxication (poisoning) syndromes, both of which are actually the result of sub-chronic or chronic exposure events over extended time frames (CSR, 2020).

Symptoms of lead intoxication may include abdominal pain, constipation, headaches, irritability, memory problems, infertility and tingling in the hands and feet. It causes almost 10 % of intellectual disability of otherwise unknown cause and can result in behavioural problems. Some of the effects are permanent. In severe cases anaemia, seizure, coma or death may occur (CDC, 2018, WHO, 2019).

Acute inhalation of metal fumes including lead (Graeme and Pollack Jr, 1998), copper (Nemery, 1990) and especially zinc oxide (Cooper, 2008) may cause so-called metal fume fever. Metal fume fever is a poorly understood influenza-like or malaria-like reaction. Reported symptoms are the abrupt onset of fever, shaking chills, malaise, excessive salivation, thirst, nausea, myalgia, headache, cough and respiratory distress. The pathogenesis is poorly understood; allergic and immunologic mechanisms are most often postulated. Tolerance to metal fumes develops and symptoms appear only after exposure to metal fumes following a period of abstinence. Metal fume fever will not occur on subsequent successive days of fume exposure.

1.6.2.3. Repeated dose toxicity

Signs of chronic lead poisoning include among others: sleepiness, irritation, headache, pains and others (LDAI, 2008). Blood lead level (PbB) is often the best reflection of the prevailing lead exposure status of the individual (Danish EPA, 2014). EFSA (2010) concluded, based on available human data, that the most critical effects in relation to small increases in PbB levels were developmental neurotoxicity in children aged 7 and younger and effects on blood pressure and chronic kidney disease in adults. The specific effects of lead (haematological effects, effects on blood pressure and cardiovascular effects, kidney effects, neurotoxicity and developmental effects, hyperactivity or attention deficit disorder, and neurological effects of post-natal exposure in children) are summarised in Annex B to the Background Document to the Opinion on the Annex XV dossier proposing restrictions on lead in shot (ECHA, 2018c).

In a recent toxicological profile lor lead, ATSDR (2020) summarised the available information on health effects of lead and concluded that for the most studied endpoints (neurological, renal, cardiovascular, hematological, immunological, reproductive, and developmental), effects occur at the lowest PbB levels studied, which are ≤ 50 µg/L.

Haematological effects

Effects of lead on blood can be detected at low levels of exposure but are not considered to be adverse (ECHA, 2018d). As exposure rises, greater impact on haematological parameters can be expected. At PbB levels < 100 µg/L an inhibition of enzymes such as ALAD is observed; ALAD is involved in the synthesis of haeme (LDAI, 2008). These enzymatic effects are not considered adverse but are sometimes used as biomarkers of lead exposure. At higher levels of lead exposure, the cumulative impacts of lead upon multiple enzymes in the haeme biosynthetic pathway begin to impact the rate of haeme and haemoglobin production (EFSA, 2010). As PbB levels increases, further decreases in blood haemoglobin and loss of erythrocytes due to a lead-induced increased membrane fragility results in the development of anaemia (NAS 2013 as cited in (ATSDR, 2020)). Decreased haemoglobin production can be observed at PbB levels ≥ 400 µg/L in children. Impacts on haemoglobin production are sufficient to cause anaemia are associated with PbB levels ≥ 700 µg/L.

Effect on blood pressure and cardiovascular effects

Exposure to lead has been associated with a variety of adverse effects on the cardiovascular system in animals and humans. The most studied dose-response relationship is on the effect of lead exposure on blood pressure; more frequently reported for systolic than for diastolic blood pressure. Based on detailed analyses of five human studies, EFSA (2010) concluded that a PbB level of 36 µg Pb/L was associated with a 1 % increase in systolic blood pressure. Based on modelling this PbB level was converted to a daily lead exposure of 1.50 µg Pb/kg bw per day.

In a recent study Barry et al. (2019) investigated 211 adult men occupationally exposed to lead with the median age of 61.9 years (range 36.9-85.3 years). Median (IQR) bone, maximum past blood and current blood leads were 13.8 (9.4 – 19.5) µg lead per bone mineral gram, 290 (140 – 380) µg/L and 25 (15 – 44) µg/L, respectively. Bone lead was associated with increased continuous systolic blood pressure, driven by the top two bone lead quartiles.

According to industry data in the REACH registration dossier, reviews and meta-analyses of the current literature on the blood lead/blood pressure relationship indicate that there is at best a weak positive association between blood lead and blood pressure in the general population and occupational studies with average PbB levels below 450 µg/L. However, it can be hypothesised that a modest increase in blood pressure would increase the overall incidence of cardiovascular disease in a large population of individuals. This consideration of "societal risk" as opposed to "individual risk" merits careful examination. As indicated in the REACH Registration, given that recent studies find a lack of impact of environmental exposures upon blood pressure, a dose-response function that would serve as the basis for any health-based limit linked to blood pressure cannot be derived. The lack of dose dependent impacts indicates that lead impacts upon blood pressure are not a health endpoint suitable for quantitative risk assessment.

However, in a recent population-based cohort study including 14 289 adults, Lanphear et al. (2018) reported that low-level environmental lead exposure is a risk factor for cardiovascular disease mortality in the USA. The geometric mean concentration of lead in blood was 27.1 µg/L (geometric SE 13.1). 3 632 (20 %) participants had a concentration of lead in blood of at least 50 µg/L. During median follow-up of 19.3 years (IQR 17.6 – 21.0), 4 422 people died, 1 801 (38 %) from cardiovascular disease and 988 (22 %) from ischaemic heart disease. An increase in the concentration of lead in blood from 10 µg/L to 67 µg/L, which represents the tenth to 90^{th} percentiles, was associated with all-cause mortality (hazard ratio 1.37, 95 % CI 1.17 – 1.60), cardiovascular disease mortality (1.70, 1.30 – 2.22), and ischaemic heart disease mortality (2.08, 1.52 – 2.85). The population attributable fraction of the concentration of lead in blood for all-cause mortality was 18.0 % (95 % CI 10.9 – 26.1), which is equivalent to 412 000 deaths annually. Respective fractions were 28.7 % (15.5 – 39.5) for cardiovascular disease mortality and 37.4 % (23.4 – 48.6) for ischaemic heart disease mortality, which correspond to 256 000 deaths a year from cardiovascular disease and 185 000 deaths a year from ischaemic heart disease. Landrigan (2018) drew the conclusion from this analysis that lead has a much greater effect on cardiovascular mortality than previously recognised. Lanphear and colleagues' calculation that lead accounts for more than 400 000 deaths annually in the USA represents a tenfold increase over the number of deaths currently ascribed to lead. The authors argue that previous estimates have produced lower numbers because those analyses assumed that lead has no effect on mortality at amounts of lead in blood below 50 µg/L and, thus, did not consider the effects of lower exposures. Landrigan (2018) also concluded that these findings have substantial implications for global assessments of cardiovascular disease mortality.

Kidney effects

Exposure to lead has been associated with functional renal deficits including changes in proteinuria, glomerular filtration rates or creatinine levels and clearance. EFSA (2010) concluded a PbB level of 15 µg Pb/L to be associated with a 10 % increase of chronic kidney disease (CKD) in the population measured as reduction in the glomerular filtration rate (GFR) to values below 60 mL/min. Based on modelling this PbB level was converted to a daily lead exposure of 0.63 µg Pb/kg bw/d.

In the REACH Registration dossier of lead compounds (CSR, 2020), relevant studies (e.g. (Roels et al., 1994, Weaver et al., 2003)) were reviewed. The registrant concluded that blood lead levels at or below 600 µg/L appear to guard against the onset of lead nephropathy. A NOAEL of 600 µg/L was therefore adopted for renal effects and provided the basis for the DNEL proposed in the registration dossier. However, EFSA's CONTAM Panel concluded that there is no evidence for a threshold for renal effects in adults.

In ATSDR (2020), the most recent studies on effects of lead on kidney are summarised. Several large cross-sectional studies have examined associations between PbB and GFR in adults. Three large studies relied on data collected as part of the US NHANES survey. The Muntner et al. (2003) study, which included 4 813 hypertensive subjects and 10 938 normotensive subjects, found an association between increasing PbB levels and decreasing GFR in the hypertensive group. Navas-Acien et al. (2009) included 14 788 adult subjects and reported decreased GFR (< 60 mL/minute/1.73 m^2) among participants in the highest PbB quartile (mean > 24 µg/L). Spector et al. (2011) included 3 941 adults. In the age group ≥ 60 years, the estimate for the decline in GFR was 4.5 mL/minute/1.73 m^2 per doubling of PbB. The mean PbB level in this group was 22 µg/L.

In a recent study Barry et al. (2019) investigated 211 adult men occupationally exposed to lead with the median age of 61.9 years (range 36.9-85.3 years). Median (IQR) bone, maximum past blood and current blood leads were 13.8 (9.4 – 19.5) µg lead per bone mineral gram, 290 (140 – 380) µg/L and 25 (15 – 44) µg/L, respectively. Bone lead was not associated with a reduction in GFR.

Harari et al. (2018) performed a prospective population-based cohort study with 4 341 individuals enrolled into the Malmö Diet and Cancer Study - Cardiovascular Cohort between 1991 and 1994 and for which blood lead level measurement were performed at that time (referred to as 'baseline'). 2 567 individuals were followed up (2007 – 2012) for changes in GFR. Blood lead levels were presented in quartiles. Proportion of men, proportion of individuals with low education, alcohol consumption, waist circumference, hypertension and proportion of current smokers were all higher in the highest quartile (Q4; median 46 µg/L; range 33 – 258 µg/L) compared to the three lower quartiles (Q1 - Q3). Mean GFR at baseline and follow-up were 76 and 70 mL/min/1.73 m^2, respectively. At both time points GFR was slightly lower in the group with the highest blood lead level. At baseline, linear regression analyses adjusted for age, sex, smoking, alcohol intake, diabetes mellitus, waist circumference, eGFR at baseline, and education level showed a statistically significant inverse association between lead levels (in quartiles) and eGFRs.

Barry and Steenland (2019) investigated the mortality in a cohort of 58 368 male lead-exposed workers that was followed for a median of 19 years and experienced 6 527 deaths. Average maximum blood lead was 259 µg/L and mean year of first blood lead test was 1997. Findings suggested associations with chronic renal disease, although the trend was not statistically significant.

Several smaller cross-sectional studies have also found associations between increasing PbB level and decreasing GFR in adult populations in which mean or median PbB levels were <100 µg/L (see references in ATSDR (2020)).

Collectively, these studies indicate that lead exposure is associated with decreasing GFR, and effects on GFR are evident in populations with PbB levels <100 µg/L. People with on-going renal disease or hypertension may be more vulnerable to the effects of lead. Estimates of the decline in GFR associated with increasing PbB levels vary across studies, with some studies indicating declines of 3 to 6 mL/minute/1.73 m^2 at PbB levels <100 µg/L (Pollack et al., 2015, Spector et al., 2011, Yu et al., 2004). However, the estimates may be inflated by reverse causality for associations between deceasing GFR and increasing lead body burden.

Neurotoxicity and developmental effects

According to the CLH report submitted by KEMI (2012), the nervous system is the main target organ for lead toxicity. The developing foetus and young children are most vulnerable to lead induced neurotoxicity as the nervous system is still under development. The immaturity of the blood-brain barrier may also contribute to the vulnerability, as well as the lack of high-affinity lead binding proteins in the brain that trap lead ions in adults (Lindahl et al., 1999). Young children often exhibit hand-to-mouth behaviour and also absorb a larger percentage of orally ingested lead than adults, thus leading to a greater systemic exposure (EFSA, 2010).

Several epidemiological studies have been conducted examining the impacts of prenatal lead exposure on birth outcome and neurobehavioral development in children. Negative effects of perinatal lead exposure on neurobehavioral performance have been demonstrated both in experimental animals as well as in human prospective studies. Similarly, studies have demonstrated that postnatal exposure to lead may severely impact scholarly achievements.

JECFA (2010) and Lanphear et al. (2005) concluded that negative impact on IQ is the most sensitive endpoint for lead exposure and that no safe blood lead level has yet been established. Lanphear et al. (2005) examined data from 1 333 children who participated in seven international population-based longitudinal cohort studies. EFSA (2010) concluded a PbB level of 12 µg Pb/L to be associated with a 1 % reduction on the IQ scale in children. Based on modelling this blood lead level was converted to a daily lead exposure of 0.5 µg Pb/kg bw/d.

Budtz-Jørgensen et al. (2013) published benchmark dose (BMD) calculations underlying the EFSA opinion. BMD results were quite robust to modelling assumptions with the best fitting models yielding lower confidence limits (BMDLs) of about 1.0 to 10 µg/L PbB for the dose leading to a loss of one IQ point. This range is confirmed by Rocha and Trujillo (2019) whose review of effects of low-level lead exposure on behaviour and cognition suggests that PbB levels below 30 µg/L may produce diminished cognitive function and maladaptive behaviour in humans and animal models.

1.6.2.4. DNEL/BMDL derivation

Workers

Chronic DN(M)ELs for workers are presented in the following Table 1-33.

Table 1-33: DNELs for the workers as reported in the CSR for lead (CSR, 2020)

Exposure pattern	Route	Descriptors	DNEL/DMEL	Most sensitive endpoint
Acute – systemic effects	Dermal (mg/kg bw/d)	NA	NA	NA
	Inhalation (mg/m^3)	NA	NA	NA
	Oral (mg/kg bw/d)	NA	NA	NA
Acute – local effects	Dermal (mg/cm^2)	NA	NA	NA
	Inhalation (mg/m^3)	NA	NA	NA
Long-term - systemic effects	Systemic (µg Pb/L blood)	NOAEL = 400 µg/L	400 µg/L	Adult neurological function
		NOAEL = 100 µg/L	100 µg/L	Developmental effects of pregnant women
Long-term - local effects	Dermal (mg/cm^2)	NA	NA	NA
	Inhalation (mg/m^3)	NA	NA	NA

In the CSR, a DNEL of 400 µg lead /L blood for adults is proposed to protect workers from neurological effects in the workplace. This workplace DNEL is lowered to 100 µg lead/L blood for pregnant women (and those that are breastfeeding) which, from a practical standpoint, may apply to all women of reproductive capacity.

The Commission asked the advice of RAC to assess the scientific relevance of occupational exposure limits from some chemicals including lead and its compounds. On 17 October 2019 ECHA provided a draft scientific report for evaluation of limit values for lead and its compounds at the workplace with the proposal of a biological limit value (BLV) of 150 µg Pb/L blood[107]. The consultation on this draft opinion ended on 16/12/2019 and RAC provided an opinion by 26/09/2020[108].

General population

DN(M)ELs according to the CSR

In the REACH Registration CSR (2020), a DNEL of 200 µg Pb/L blood is derived for adults in the general population based on a NOAEL of 400 µg/L for effects on adult neurological function and using an assessment factor of 2. For children, tenfold lower DNELs have been derived. Table 1-34 summarises the DNELs for the general population outlined in the REACH

[107] https://echa.europa.eu/documents/10162/4ce397fa-433f-fa30-af4d-bb2c2f72549b
[108] https://echa.europa.eu/oels-activity-list/-/substance-rev/22917/term

registration.

Table 1-34: DNELs for the general population[1] as reported in the CSR for lead (CSR, 2020)

Exposure pattern	Route	Descriptors	DNEL/DMEL	Most sensitive endpoint
Acute – systemic effects	Dermal (mg/kg bw/d)	NA	NA	NA
	Inhalation (mg/m^3)	NA	NA	NA
	Oral (mg/kg bw/d)	NA	NA	NA
Acute – local effects	Dermal (mg/cm^2)	NA	NA	NA
	Inhalation (mg/m^3)	NA	NA	NA
Long-term - systemic effects Neurological function	Systemic (µg Pb/L blood)	NOAEL = 400 µg/L	200 µg/L	Adult neurological function
		NOAEL = 100 µg/L	50 µg/L	Foetal development for a pregnant woman
		NOAEL = 50 µg/L	50 µg/L	IQ development in individual child
		NOAEL = 20 µg/L	20 µg/L	IQ development large population of children
Long-term - local effects	Dermal (mg/cm^2)	NA	NA	NA
	Inhalation (mg/m^3)	NA		NA

Notes: [1] general population includes consumers and humans via the environment. In rare cases it may also be relevant to derive a DNEL for specific subpopulations, such as children.

REACH Annex I, 0.5 requires that "*The chemical safety assessment shall be based on the information on the substance contained in the technical dossier and on other available and relevant information. […] Available information from assessments carried out under other international and national programmes shall be included. [] Deviations from such assessments shall be justified.*"

ECHA notes that the registrant has not taken into account the assessment and conclusion performed by the EFSA CONTAM Panel (EFSA, 2010) and did not justify the deviation from the BMDL values identified for the general population (adults and children) as presented in the following section.

Benchmark doses calculated by EFSA

The EFSA CONTAM Panel (EFSA, 2010) concluded that there is no evidence for a threshold for critical lead-induced effects and used the BMD approach to derive reference points for risk characterisation, where the BMD is defined as that PbB level or tibia bone lead concentration, respectively, which is associated with a pre-specified change in the outcome (i.e. loss in IQ, increase in blood pressure, or increase in the incidence of CKD), denoted the benchmark response (BMR). The lower one-sided 95 % confidence bound of the BMD, denoted BMDL, was taken as the reference point.

IQ loss in children

The EFSA CONTAM Panel (EFSA, 2010) used the complete individual data from the seven studies analysed by Lanphear et al. (2005) to determine the 95th percentile lower confidence limit on the benchmark dose (BMD) of 1 % extra risk (corresponding to 1 IQ point) as a reference point for the risk characterisation of lead when assessing the risk of intellectual deficits in children measured by the Full Scale IQ score. The CONTAM Panel considered several model equations to model this relationship. The logarithmic and piecewise linear models resulted in acceptable and similar fits. The mathematical properties of the logarithmic model and the marked uncertainty associated with the relationship at PbB levels <100 µg/L were such that the CONTAM Panel concluded that the piecewise linear model, using the segment fit to the lower PbB levels, provided a reliable estimate of the **$BMDL_{01}$ of 12 µg Pb/L**.

Chronic kidney disease in adults

The EFSA CONTAM Panel (EFSA, 2010) selected as benchmark response (BMR) for chronic kidney disease (CKD) a 10 % change in the prevalence of chronic kidney disease (CKD), defined as a GFR below 60 mL/1.73 m^2 body surface/min. A 10 % response was selected for the BMR as such a change was within the range of observable values and could have significant consequences for human health on a population basis.

The populations in whom the $BMDL_{10}$ values were derived, consisted of a large number of individuals from NHANES (n=15 000), which are representative of the US general population that accounted for a substantial proportion of inter-individual variation in toxicokinetics. The prevalence of kidney disease was compared with concurrent PbB levels. The EFSA CONTAM Panel noted that this effect would depend on lead exposure over a prolonged interval of time, during which such exposure was declining appreciably. Hence, the $BMDL_{10}$ intake value for this endpoint is likely to be numerically lower than necessary to protect against lead-induced CKD.

The EFSA CONTAM Panel fitted the quantal dose-response models recommended by EFSA to the incidence data as shown in columns 1-3 of

Table 1-35. When fitting these data, separately from cadmium, using a BMR of 10 % as recommended by the Scientific Committee of EFSA (2009) and an acceptability criterion of $p > 0.01$ for the model fit, a $BMDL_{10}$ of 15 µg/L was obtained. The highest PbB quartile of > 24 µg/L (median PbB level of 32 µg/L) was associated with an Odds Ratio (95 % CI) of 1.56 (1.17 - 2.08) adjusted *inter alia* for cadmium.

Table 1-35: Dose-response relationship between PbB levels and CKD prevalence as reported by Navas-Acien et al. (2009)

PbB quartiles (µg/L)[1]	Median µg/L (n)	CKD prevalence number of cases (%)	Odds Ratio (95% CI)	
			Non-adjusted for cadmium[2]	Adjusted for cadmium[3]
≤11	8 (3 242)	147 (4.5)	1 (reference)	1 (reference)
11-16	13 (3 167)	274 (8.7)	1.08 (0.79-1.47)	1.10 (0.80-1.51)
16-24	19 (3 734)	468 (12.5)	1.25 (0.92-1.69)	1.36 (0.99-1.85)
>24	32 (4 635)	779 (16.8)	1.41 (1.07-1.86)	1.56 (1.17-2.08)

Notes: [1] quartiles of concurrent PbB levels; [2] adjusted for survey year, age, sex, race/ethnicity and BMI; [3] adjusted for survey year, age, sex, race/ethnicity, BMI, education, smoking, alcohol intake, hypertension, diabetes mellitus, menopausal status and blood cadmium level (log-10 µg/L)

Cardiovascular effects in adults

The EFSA CONTAM Panel (EFSA, 2010) considered a 1 % increase of systemic blood pressure (SBP) annually or on average in the whole population a public health issue, since this would result in an increased risk of cardiovascular morbidity and coronary heart disease (CHD) mortality in a population. Assuming an average SBP of 120 mmHg and a benchmark response level of 1 %, the dose associated with an increase of SBP by 1.2 mmHg corresponds to a BMD_{01}. BMD_{01} and $BMDL_{01}$ values were derived based on the slope estimates from five selected studies on blood and tibia bone lead concentration. Longitudinal data allowed the calculation of a BMD_{01} for the mean annual increase of SBP by 1% in an individual, whereas cross-sectional data allowed only the calculation of the BMD_{01} on a population-based increase of the means. The CONTAM Panel determined four $BMDL_{01}$ values for SBP ranging from 15 to 71 µg/L (longitudinal 27 and 71 µg/L, cross-sectional studies 15 and 21 µg/L). Given the strong overlap of the study results and the absence of any obvious design deficiencies in the studies, the CONTAM Panel proposed a mean **$BMDL_{01}$ for SBP of 36 µg/L** from the four studies and a $BMDL_{01}$ = 8 µg/g for tibia bone lead concentrations. A summary of the BMDL values defined by EFSA is given in Table 1-36.

Table 1-36: Toxicological reference values for lead toxicity by (EFSA, 2010)

Endpoint	Population	BMDL (µg/L)	Slope factor ($\beta_{\blacksquare}$)	Definition
Developmental neurotoxicity	children	**12**	8.33E-2	$BMDL_{01}$: 1 % change in full scale IQ score, i.e. a decrease in IQ by 1 point on the full scale IQ score
Kidney toxicity/ nephrotoxicity	adults	**15**	6.66E-2	$BMDL_{10}$: 10 % change in the prevalence of chronic kidney disease (CKD), defined as a GFR below 60 mL/1.73 m^2 body surface

Endpoint	Population	BMDL (µg/L)	Slope factor ($\beta_{\blacksquare}$)	Definition
Cardiovascular effects	adults	**36**	2.77E-2	$BMDL_{01}$: 1 % change in systolic blood pressure (SBP), corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult

Since of the EFSA CONTAM Panel (EFSA, 2010) concluded that there is no evidence for a threshold for critical lead-induced effects, the following BMDL values are considered as toxicological reference values for long-term oral exposure of the general population:

- $BMDL_{01}$ of 12 µg/L for developmental neurotoxicity in children (decrease in IQ by 1 point on the full scale IQ);
- $BMDL_{10}$ of 15 µg/L for 10 % increase in the prevalence of chronic kidney disease (CKD) in adults ;
- Toxicological reference values for lead toxicity by EFSA (2010) $BMDL_{01}$ of 36 µg/L for 1 % increase in systolic blood pressure (SBP) in adults, corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult

Benchmark doses for IQ loss in children calculated by Budtz-Jørgensen et al. (2013)

The study team that had prepared the calculations for the benchmark analysis of the EFSA CONTAM Panel (EFSA, 2010) subsequently published an international pooled analysis for obtaining a benchmark dose for environmental lead exposure in children (Budtz-Jørgensen et al., 2013). In this study, the authors used a BMR of 1 IQ point corresponding to 1 % of the population average IQ of about 100 (as recommended by EFSA). For continuous data, the metric of the BMR is often defined as a percent change in the mean response as compared to the background response (EFSA Scientific Committee, 2017). While the EFSA Guidance on the BMD approach generally recommends a BMR of 5 % for continuous data as a default, EFSA notes that this be modified based on toxicological or statistical considerations. As for IQ loss, a vast literature is available that suggests it is inappropriate to base an exposure limit on a loss of 5 IQ points as this is too serious an effect. Considering that economists are calculating the loss of expected lifetime income per IQ point, the authors considered EFSA's BMR selection defensible, also in light of the public health consequences of population-wide IQ loss.

The authors estimated various models, considering all studies pooled, as fixed or as random effects, with different mathematical expressions to study the dose/response relationship. These resulted in different BMD estimates that are summarised in Table 1-37. The logarithmic model yielded the lowest BMDs and BMDLs, while the linear model gave the highest. The linear model also showed the poorest fit to the data. The weaker fit of the linear model is most clearly seen for concurrent and peak lead. The superiority of the piecewise linear model compared to the linear was confirmed by likelihood ratio testing. The two piecewise linear models produced almost identical BMD results. Both for concurrent and peak lead the 100 µg/L-curve fitted slightly better, and yielded BMDLs that were slightly higher. The logarithmic model generally had a better fit than the piecewise linear model.

A thorough sensitivity analysis showed that the benchmark results were fairly robust and depended only slightly on the specific modelling assumptions. The two best fitting dose-response functions - the Hill model and a logarithmic model - both yielded BMDLs of 1.0 to

2.6 µg/L, while piecewise linear models produced somewhat higher BMDLs of approximately 10 µg/L.

Table 1-37: Benchmark modelling results using standard dose-response models (Budtz-Jørgensen et al., 2013)

Model	Parameter	Breakpoint	No. below break point	PbB (µg/L)	
				BMD	BMDL
Concurrent lead	logarithmic			3.54	2.60
	Linear			55.81	40.54
	piecewise linear	breakpoint 75 µg/L	499	16.47	9.80
	piecewise linear	breakpoint 100 µg/L	688	17.97	**11.99**
Peak lead	logarithmic			3.93	2.73
	Linear			96.70	65.67
	piecewise linear	breakpoint 75 µg/L	103	7.12	4.34
	piecewise linear	breakpoint 100 µg/L	244	10.34	6.89
Life time lead	logarithmic			3.55	2.50
	Linear			64.46	44.98
	piecewise linear	breakpoint 75 µg/L	302	9.54	6.09
	piecewise linear	breakpoint 100 µg/L	482	14.84	9.69
Early childhood lead	logarithmic			5.58	3.43
	Linear			80.61	52.43
	piecewise linear	breakpoint 75 µg/L	305	15.02	8.09
	piecewise linear	breakpoint 100 µg/L	488	37.69	16.10

For the piecewise linear dose-response function, which was selected by EFSA (2010) as basis for its recommended $BMDL_{01}$ of 12 µg/L for loss of one IQ point in children, the authors found that the slope can depend on whether the dose is below or above the breakpoint.[109]

Benchmark calculations performed by ECHA

IQ loss in children

In addition to the current opinion of the EFSA CONTAM Panel on lead (EFSA, 2010) ECHA has used BMD and BMDL estimates from a set of more complex models estimated in Budtz-Jørgensen et al. (2013) for the purpose of benchmark modelling.[110] Table 1-38 reports the

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[109] Mathematically the dose-response function takes the following form: $f(d) = \beta_1(d1_{d<d_0} + d_0 1_{d>d_0}) + \beta_2(d - d_0)1_{d>d_0})$, where d_0 is the breakpoint and β_1 and β_2 are the slope parameters below and above the breakpoint, respectively. Although slightly more complex than for logarithmic and linear models, benchmark analysis is still straightforward especially if the exposure-induced loss in outcome reaches the BMR before the breakpoint.

[110] It should be noted that these models are compatible with EFSA's most recent guidance on the benchmark dose approach (EFSA 2017).

corresponding BMD_{01} and $BMDL_{01}$ values which are on average four times lower than the $BMDL_{01}$ recommended by the EFSA CONTAM Panel (EFSA, 2010). A **$BMDL_{01,IQ}$ of 4 µg/L** will be used for sensitivity analysis.

Table 1-38: Benchmark modelling for concurrent child lead concentration using sophisticated dose-response models (Budtz-Jørgensen et al., 2013)

Model	Parameter	BMR	PbB (µg/L)	
			BMD	BMDL
Hill model	h = 1		6.77	1.81
	h >1		9.06	1.82
Hybrid approach	P_0 = 5 %	BMR = 1 %	3.54	2.60
	P_0 = 5 %	BMR = 2.5 %	11.35 *(4.54)*[1]	7.81 *(3.12)* [1]
	P_0 = 5 %	BMR = 5 %	35.58 *(7.12)* [1]	21.70 *(4.34)* [1]

Notes: [1] values in italics denote average effect per IQ point and have been converted by dividing the original BMD(L) estimate by the corresponding BMR in order to make them comparable with $BMD(L)_{01}$. They should however not be interpreted as actual $BMD(L)_{01}$ values.

CKD in adults

In addition to the current opinion of the EFSA CONTAM Panel on lead (EFSA, 2010) ECHA has estimated additional BMD and BMDL estimates applying the open source tool PROAST (v. 67.0, accessible under https://proastweb.rivm.nl/). As reported in Table 1-39, most of the obtained $BMDL_{10}$ values are somewhat lower than the $BMDL_{10}$ value for CKD recommended by the EFSA CONTAM Panel (EFSA, 2010). A **$BMDL_{10,\ CKD}$ of 12.7 µg/L** will be used for sensitivity analysis.

Table 1-39: Benchmark modelling results for CKD obtained with PROAST v. 67.0

Model	No. par	loglik	AIC	Accepted	BMDL	BMDU	BMD	conv
two.stage	3	-4786.12	9578.24	yes	13.8	15.0	14.4	yes
log.logist	3	-4785.22	9576.44	yes	13.7	15.1	14.4	yes
Weibull	3	-4786.07	9578.14	yes	13.7	16.0	14.5	yes
log.prob	3	-4783.37	9572.74	yes	13.5	Inf	14.2	yes
gamma	3	-4786.04	9578.08	yes	13.8	16.1	14.5	yes
logistic	2	-4803.74	9611.48	yes	22.0	23.7	22.7	yes
probit	2	-4800.76	9605.52	yes	21.0	22.7	21.8	yes
LVM: Expon. m5-	4	-4780.08	9568.16	yes	12.8	17.3	13.7	yes
LVM: Hill m5-	4	-4780.08	9568.16	yes	**12.7**	18.1	14.5	yes

Cardiovascular effects in adults

No additional modelling was undertaken. EFSA (2010) defined a corresponding $BMDL_{01}$ of

36 µg/L for 1 % increase in systolic blood pressure (SBP) in adults, corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult.

Summary

As noted above, EFSA's guidance on the benchmark dose approach (EFSA Scientific Committee, 2017) has significantly changed since the EFSA CONTAM Panel recommended its BMD(L) values for developmental neurotoxicity, kidney toxicity, and cardiovascular effects of lead exposure (EFSA, 2010). Without implying that the established benchmark values are no longer valid, ECHA has gathered additional modelling data to derive its own set of BMDL values for the purpose of sensitivity analysis. These are summarised in Table 1-40.

Table 1-40: Toxicological reference values for lead toxicity used by ECHA for sensitivity analysis

Endpoint	Population	ECHA 2020		
		BMDL (µg/L)	Slope factor ($\beta_{\blacksquare}$)	Definition
Developmental neurotoxicity	children	**4**	2.5E-1	$BMDL_{01}$: 1 % change in full scale IQ score, i.e. a decrease in IQ by 1 point on the full scale IQ score
Kidney toxicity/ nephrotoxicity	adults	**12.7**	7.87E-2	$BMDL_{10}$: 10 % change in the prevalence of chronic kidney disease (CKD), defined as a GFR below 60 mL/1.73 m^2 body surface
Cardiovascular effects	adults	**36**	2.77E-2	$BMDL_{01}$: 1 % change in systolic blood pressure (SBP), corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult; Not updated

1.6.3. Exposure assessment

There are several pathways through which consumers can be exposed to lead used in hunting, sports shooting, and fishing activities. Most relevant are inhalation exposure and oral intake, with higher absorption following inhalation. Indeed, inhaled lead lodging deep in the respiratory tract seems to be absorbed equally and totally (95 %), regardless of chemical form, whereas the oral absorption of metallic lead is assumed to be up to 10 % in adults and up to 50 % in children (ATSDR, 2019).

Inhalation exposure can result from lead fumes, aerosols and/or dusts from shooting during sports shooting or hunting, and from melting lead to cast ammunition or fishing sinkers and lures. Oral exposure can result from intake of lead dust (hand-to-mouth) while shooting or handling lead gunshot, bullets or fishing sinkers and lures, when eating, drinking or smoking in an environment containing lead dust, from chewing or swallowing lead fragments. Oral exposure can also occur indirectly via the environment, such as from the consumption of game meat containing fragments of lead gunshot or bullets, or the consumption of milk, meat or drinking water. High lead exposure may also result from swallowed lead particles retained in the Annex or from incorporated lead fragments following a gunshot wound.

Analysis of lead in whole blood (PbB) is the most common and accurate method of assessing lead exposure. PbB reflects recent exposure whereas bone lead measurements are an indicator of cumulative exposure as lead remains in bones for decades (ATSDR, 2019). When evaluating PbB levels the following has to be noted:

- PbB levels provide information on recent exposure; to assess cumulative exposure from previous years or decades, lead levels in bone would need to be measured.
- PbB levels in the EU general population have been decreasing over the last 40 years.
- PbB levels in males are generally higher than in females.
- Based on data from Germany, recent statistically derived reference values (95^{th} percentile) for the general population are 4 µg/L for adult men, 3 µg/L for adult women and 3.5 µg/L for children (HBM4EU, 2019).
- To analyse the risk of a specific exposure scenario, the increase in the PbB level resulting from this exposure source was compared to the reported control/ background level.

1.6.3.1. Inhalation of lead fumes or dusts from outdoor shooting (uses # 1, 2, 3, 4, 5, 6)

The review by Laidlaw et al. (2017) provides information on the sources of potential lead exposure from shooting guns and firing ranges, mostly indoor shooting ranges. The authors note that most projectiles are made from lead, and a large amount of lead may also be present in the primer, composed of approximately 35 % lead styphnate and lead peroxide (and also contains barium and antimony compounds), that ignites in a firearm barrel to provide the propulsion for the projectile (Tripathi and Llewellyn, 1990, Hawa et el., 2010, Basu, 1982, meng and Caddy, 1997, Romolo and Margot, 2001; references as cited by Laidlaw et al., 2017). A portion of the lead projectile disintegrates into fine fragments while passing through the gun due to misalignments of the gun barrel (Tripathi and Llewellyn, 1990, as cited by Laidlaw et al., 2017).

Lead particles, along with dust and fumes originating from the lead primer and the projectile fragments are ejected at high pressures (18 000 – 20 000 psi; 124 – 128 mpa) from the gun barrel, a large proportion of which occurs at right angles to the direction of fire in close proximity to the shooter (Tripathi and Llewellyn, 1990, as cited by Laidlaw et al., 2017).

Figure 1-22 shows a schematic outline of an outdoor and an indoor shooting range. In this case, the outdoor shooting range has a "roofed area" covering the shooter. Major differences are the larger dimension of an outdoor range compared to an indoor range and usually natural ventilation in the outdoor range and artificial ventilation in the indoor range.

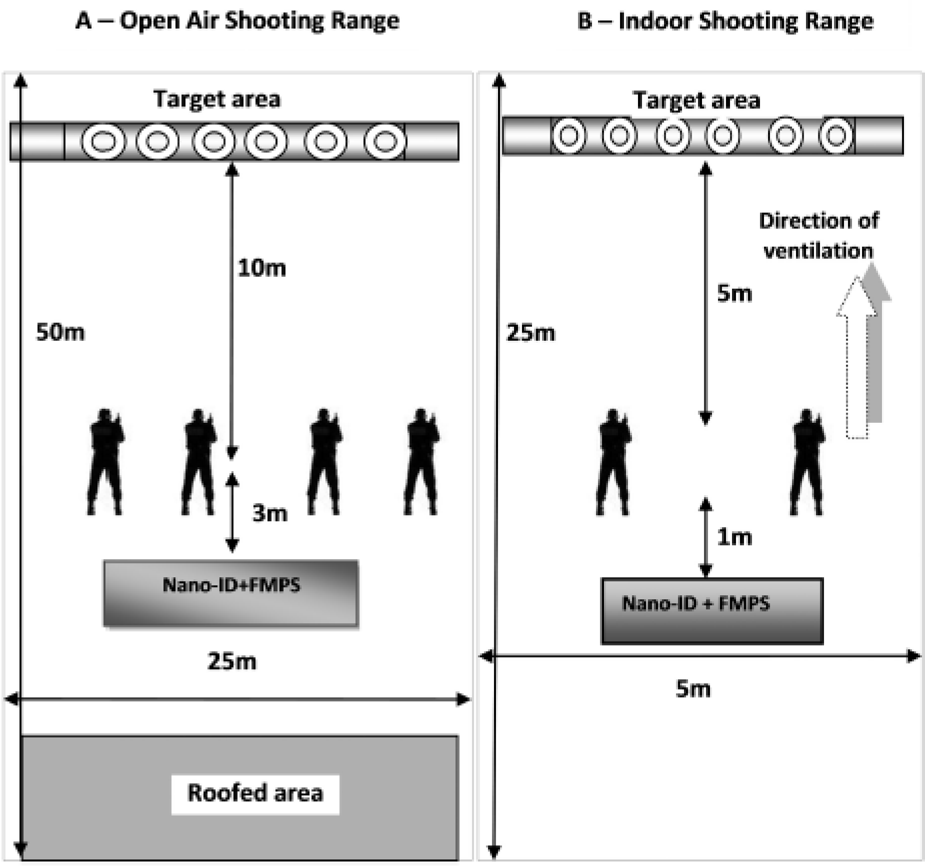

Figure 1-22: Schematic outline of the situation on outdoor [panel A] and indoor [panel B] shooting ranges (Source: Lach et al., 2015)

The shooter can inhale fine lead particulates (mainly from the primer) which constitutes the primary exposure pathway. Fine and coarse particulates from both the primer and projectile fragments also attach to the shooter's hands, clothing, and other surfaces, and can be inadvertently ingested, providing a secondary lead exposure pathway (Dalby et al., 2010, Mathee et al., 2017). Deposition of lead-containing gunshot residues on hands, followed by hand-to-mouth activity, could contribute to elevated PbB levels (Bonanno et al., 2002). Finally, shooters may be exposed to lead that has accumulated in soil dust when changing targets at outdoor firing ranges.

Instructors are generally exposed to the highest concentrations of airborne lead and tend to have the highest PbB levels due to their regular duties, which include supervising the range, cleaning, and test-firing weapons, and preparing training ammunition from commercially purchased components. A positive correlation was reported between exposure of firearm instructors to elemental lead at covered outdoor firing ranges and increased PbB concentrations (Tripathi et al., 1991).

The current Annex XV report and restriction proposal addresses risks from outdoor shooting. Indoor shooting ranges are not intended to be within the scope of this restriction because the request from the Commission refers to "terrains", which is interpreted as referring to 'outdoor' environments. However, specific information collected from indoor shooting ranges provide useful information on the hazard of shooting that need to be adapted to the conditions of outdoor shooting ranges for risk assessment.

Lead concentration in air

Lead concentrations were measured in breathing air near the chest and face of two instructors in a covered outdoor shooting range while cadets were firing non-jacketed and jacketed lead ammunition with police revolvers. For the non-jacketed bullets mean lead concentrations were 67.1 µg/m^3 (range 36.7 - 95.6 µg/m^3) and 211.1 µg/m^3 (range 49.1 - 431.5 µg/m^3) for the two instructors, respectively. Using copper-jacketed bullets, lead concentrations in the air were reduced by more than 90 % to 5.4 and 8.7 µg/m^3 (Tripathi et al., 1991).

Bonanno et al. (2002) performed an initial investigation into lead exposure to target shooters using an outdoor covered pistol range. Lead concentration in air was measure in the breathing zone (collar) of the shooters. Airborne lead and lead dust levels were also examined on horizontal surfaces and on the hands of the shooters. The effects of ammunition calibre, ammunition type and shooting season on airborne lead levels were investigated. During summer, the front wall of firing lanes was removed in order to improve ventilation. In two competitions (one in summer, 29 August and one in winter season, 7 November), each participant fired 120 rounds, 60 rounds with 22 calibre and 60 rounds with centre-fire (45 calibre) total firing time was about 1 hour. Lead concentrations in the air were 286 and 235 µg/m^3 for the 22 calibre and 579 and 1 558 µg/m^3 for the 45 calibre weapons. The use of larger calibre also resulted in higher concentrations of lead dust on the hand of the shooter (324 and 353 µg) compared to 233 and 50 µg for the lower calibre. In the third competition (during winter-time 20 November), 60 rounds with centre-fire using a specific low lead 45 calibre ammunition (WinClean™) resulted in a 99 % reduction of lead in the breathing air (ca. 15 µg/m^3).

Lach et al. (2015) studied aerosols formed during shooting events in indoor and outdoor shooting ranges. Conventional (TOX) and so called 'green' ammunition (NON-TOX) was used, where lead is replaced by other metals and substances. Lead concentrations were measured by stationary devices placed one and three meters behind the shooter for the indoor and the outdoor range, respectively. The total measured lead mass aerosol concentration ranged from 2.2 µg/m^3 for indoor shooting with NON-TOX ammunition to 10 µg/m^3 for outdoor shooting with TOX ammunition and to 72 µg/m^3 for indoor shooting with TOX ammunition. The proportion of the total mass of airborne particles deposited in the respiratory tract varied from 34-70 %, with a median of 55.9 % as calculated using the ICRP lung deposition model.

Wang et al. (2017) measured the task-based personal exposure of one shooter to total fume, lead and acidic gasses during two-hour shooting sessions at indoor and outdoor shooting ranges. Pistols with a short barrel (Sig Sauer P226, Newington, NH) and rifles with a long barrel (Rock River Arms AR15, Colona, IL) were used. The pistol used 9 x 19 mm Parabellum (also known as Luger) ammunition (Winchester, Alton, IL), while the rifle used .223 Remington ammunition (Remington, Madison, NC). Both types of ammunition had full-metal-jacketed bullets with brass casings. The respirable airborne lead concentration during two-hour shooting sessions was between 200 and 1 700 µg/m^3, although not directly comparable were exceeding the Occupational Safety and Health Administration 8-h time-weighted-average permissible exposure limit (PEL) of 50 µg/m^3. Indoor ventilation effectively removed gaseous pollutants but was unable to reduce the particulate fume and lead exposure to acceptable levels. Outdoor ventilation relied more upon natural weather and had a larger deviation. The authors discuss the high fume and lead concentrations for outdoor rife shooting with the calm weather condition resulting in little natural dilution.

In a covered outdoor shooting range for clay shooting athletes, Chun et al. (2018) measured lead exposure of 292 µg Pb/m^3 air with personal air samplers and 18.7 µg Pb/m^3 with group samplers. PbB levels measured in the shooters are reported below in the respective section.

PbB levels in shooters

Most information on PbB levels in shooters is available from training scenarios in indoor shooting ranges.

Demmeler et al. (2009) observed that the larger the calibre of the weapon, the higher the PbB levels of indoor shooters. The following median PbB levels were reported in 131 sports shooters (9 females, 182 males) from 11 clubs with indoor shooting ranges in relation to the weapon used:

- airguns (n = 20): 33 µg/L (range 18 – 127 µg/L);
- airguns and 0.22 calibre weapons (n = 15): 87 µg/L (range 14 – 172 µg/L);
- 0.22 calibre and large calibre handguns (9 mm or larger) (n = 51): 107 µg/L (range 27 – 375 µg/L)
- large calibre handguns (n = 32): 100 µg/L (range 28 – 326 µg/L)
- only use of large calibre handguns (n = 11; International Practical Shooting Confederation shooters): 192 µg/L (range 32 - 521 µg/L).

The authors did not measure PbB levels in non-shooting persons but discussed that PbB levels for the German population were 33 µg/L in 1998 and further decreased since that time. They reported a clear difference between the uptake of lead from shooters using lead-containing cartridges and airgun users. The former group (n = 110) had a median of 105 µg/L (range 14 – 521 µg/L) whereas the latter (n = 20) had median PbB levels of 33 µg/L. PbB levels of the first group also depended on the training time or rather on the time of exposure within the period of 1 month. The Spearman's rank correlation coefficient of 0.395 (P <0.001) showed an upward trend of PbB levels with the time spent on the range per month. PbB levels did not only depend on the factors mentioned above, but also on the rounds shot each month which were examined by analyses of quartiles. 27 marksmen shooting fewer than 200 rounds per month (1st quartile) had a median of 87 µg/L (range 28 – 314 µg/L). 28 marksmen shooting between 200 and 399 rounds per month (2nd quartile) had a median of 90 µg/L (range 27 – 315 µg/l). Shooters (n = 29) of the 3rd quartile group which included 400–680 rounds per month had 118 µg/l (range 29 – 375 µg/L) whereas shooters (n = 23) of the 4th quartile group (more than 680 rounds per month) had indeed 138 µg/l (range 37 – 521 µg/L).

Mühle (2010) reported in his thesis a high correlation between number of shots per month and increased PbB levels (Figure 1-23), even though the sample was fairly small.

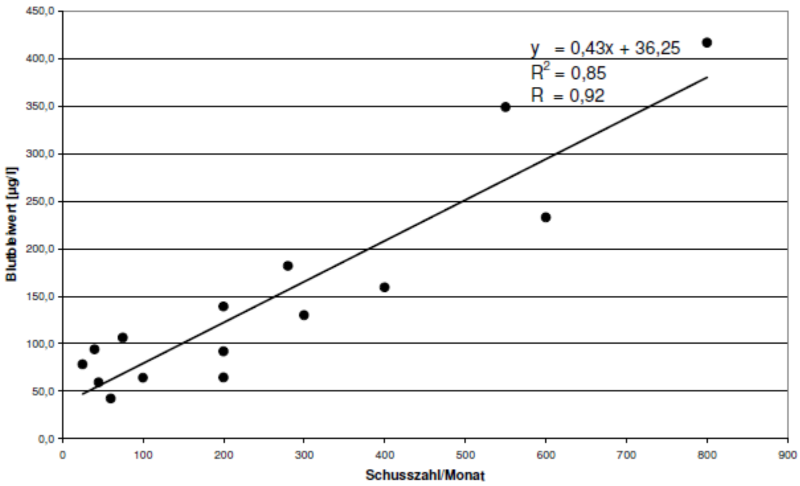

Figure 1-23: Correlation of number of shots per month (Schusszahl/Monat) with PbB levels (Blutbleiwert) in indoor sports shooters (Mühle, 2010)

Laidlaw et al. (2017) reviewed 36 articles that reported blood lead levels from shooters using lead bullets at mainly indoor shooting ranges. In 31 studies, PbB levels > 100 µg/L were reported in some shooters, 18 studies reported PbB levels > 200 µg/L, 17 studies > 300 µg/L, and 15 studies PbB levels > 400 µg/L. For indoor shooting ranges, the quality of the ventilation system has been identified as important measure to limit exposure. Laidlaw et al. (2017) noted that there is a "lack of evidence" gap in the literature demonstrating that ventilation systems can maintain air lead levels at indoor ranges below the US OSHA (50 µg/m^3) or California (0.5 – 2.2 µg/m^3) guideline.

Only very limited relevant information is available on PbB levels measure in sports shooters training in outdoor ranges.

Gunshot

Chun et al. (2018) investigated the exposure to lead and other metals in 9 male and 5 female Korean clay shooting athletes in an outdoor shooting range. Exposure was 292 µg Pb/m^3 air measured with personal air samplers and 18.7 µg Pb/m^3 with group samplers as reported above. Mean PbB level and standard deviation was 45.2 ± 16.0 µg/L for both sexes combined. The differences in PbB levels were significant between the sexes with 36 ± 7.7 µg/L for females and 51 ± 16.4 µg/L for males. According to the authors, the PbB levels were higher than the upper limit of normal (data not provided). Mean PbB levels in the general population of Korea (2010 to 2011) were reported with 18.3 ± 7.9 µg/L for females and 22.2 ± 10.4 µg/L for males (Eom et al., 2017). Chun et al. (2018) reported that PbB levels increased with increasing training frequency: 29 µg/L; 4 times/week (n = 1); 36.4±5.5; 5 times/week (n = 7); 58.2±15.5; 6 times/week (n = 6). However, due to the marked sex-related differences in PbB levels, such a separation according to training frequency would have to be performed according to sex. Without such a separation the presented data might be interpreted in a way that females trained less frequently compared to males. The differences in PbB levels between the general population of Korea and the clay shooters were 18 and 29 µg/L for females and males, respectively.

Bullets

In a pilot project, which is published only as an abstract, Turmel et al. (2010) measured blood lead levels and pulmonary function in 12 biathletes using a gun powder cartridge containing a lead bullet of 2.6 grams. 12 cross-country skiers of similar for age, sex, anthropometric status, number of training hours per week and prevalence of atopy were used as controls. Lung function did not differ between the groups but mean PbB levels in biathletes (0.087 ± 0.015 µmol/L; 18 ± 3.1 µg/L) was slight but significantly higher compared to the cross-country skiers (< 0.04 ± 0.0 µmol/L; < 8.3 µg/L). The type of ammunition used was not specified. The difference in PbB levels between biathletes and cross-country skiers was ≥ 10 µg/L.

Mathee et al. (2017) investigated in South Africa 87 shooters (80 males, 7 females) from one outdoor and three indoor shooting ranges and as controls 31 archers (23 males, 8 females) from three archery ranges. The mean experience in shooting was 22 years. 92 % of the shooters used non-jacketed lead bullets and 54 % of the shooters were also hunters. Shooters had significantly higher PbB levels compared to archers. The twelve shooters from the outdoor shooting range had on average a 43 µg/L higher PbB level (70 ± 42 µg/L) compared to 20 archers (27 ± 14 µg/L) (of which 19 did not perform gun shooting). Mean PbB levels for shooters training in three indoor shooting ranges were 78, 134 and 165 µg/L higher (105 ± 70 µg/L, 161 ± 98 µg/L, 192 ± 163 µg/L) compared to the 20 archers (27 ± 14 µg/L). Considering all gun shooters, irrespective of indoor or outdoor training, PbB levels were 42 µg/L lower for females compared to males. Shooters with higher shooting frequency (more than monthly) showed higher PbB levels compared to shooters shooting less frequently (less than monthly). Casting of own bullets increased PbB concentrations by 22 µg/L, hunting by 34 µg/L and placing bullets in the mouth by 82 µg/L.

Vandebroek et al. (2019) investigated, among others, 10 police officers (8 males, 2 females) having shooting training only a few times a year (mean 10±5.2 hours per year). The officers used 9 mm ammunition with a lead bullet totally covered by copper and a NON-TOX primer (not containing antimony, barium, or lead) while shooting for "a few hours". It is not specified if shooting was performed in an indoor or outdoor shooting range. Mean PbB levels were 14.1 µg/L before and slightly elevated with 14.7 µg/L after shooting. P50 and P95 reference values for lead were 1.8 µg/L and 4.9 µg/L, respectively.

1.6.3.2. Exposure of hunters (uses # 1, 2)

Since it is not possible to separate between lead exposure from shooting trainings, hunting, handling of ammunition and consumption of game meat, lead exposure of hunters is considered on its own. However, it should be noted that the database on PbB levels in hunters is very limited and all published studies have certain limitations and uncertainties.

Gunshot and bullets

Iqbal et al. (2009) investigated PbB levels from 736 males and females from six cities in North Dakota, aged 2 to 92 years, 80.8 % of whom reported a history of wild game consumption (venison, other game such as moose, birds; waterfowl excluded) and 55.5 % lead-related hobbies car/boat repair, lead casting, target shooting. PbB levels for males (14.9 µg/L) were 6 µg/L higher compared to females (8.9 µg/L). For lead-related hobbies such as casting bullets, hunting or target shooting the PbB level increment was 5 µg/L compared to persons with no lead-related hobbies. It has to be noted that blood samples were taken 4 to 5 months after the hunting season and that hunting activity as such was not analysed.

In one Italian study (Fustinoni et al., 2017), PbB levels were measured in hunters hunting birds and mammals and consuming game meat. The information on hunters with > 10 hunts per year indicates that hunting (which may include assembling of the ammunition) has a higher impact on PbB levels than the consumption of game meat. In hunters undertaking > 10 hunts per year and consuming game meat (n = 61) the median PbB level was 37 µg/L, **23 µg/L higher compared to the controls** with a median PbB level of 14 µg/L. It has to be noted that in this study individuals who had consumed game meat the week before were excluded and that the PbB measurements were performed outside the regular hunting season. Therefore, the measured PbB levels are expected to underestimate the actual exposure from game meat consumption and hunting.

In a study in two groups of native people in Canada with subsistence hunting of migratory birds using gunshot and bullets (Tsuji et al., 2008), mean PbB levels for males (which can be assumed to be the hunters) were 47 and 53 µg/L higher compared to the levels of inhabitants of a highly industrialised city.

Bullets

For 25 male hunters in Switzerland the increase in PbB level compared to the controls was reported to be 2 µg/L (Haldimann et al., 2002). However, since the control group was not characterised with regards to their hunting activities and the consumption of game meat, the result cannot be used for the assessment of hunting activities and game meat consumption.

For gun shooters using non-jacketed bullets training in indoor or outdoor shooting ranges in South Africa, the PbB levels of shooters that are also hunting were on average 34 µg/L higher than those of shooters not hunting (Mathee et al., 2017).

1.6.3.3. Inhalation exposure from melting lead ('home-casting') of ammunition or fishing tackle (mainly uses # 2, 4, and 7)

To home-cast lead bullets or sinkers and lures for fishing, lead is melted down and poured into moulds. Lead melts at the relatively low temperature of 327°C and lead fumes are released at 482°C, which can be inhaled and absorbed. Lead fumes mixed with air forms a fine yellowish/brown dust (lead oxide) which can be inhaled and which also settles on surfaces. The main hazard activities involve hot lead smelting, casting and handling dross (the contaminate residue that is skimmed off in the melting process[111]). Good hygiene and ventilation are mentioned as the best way to reduce lead exposure.

Fishing sinkers and lures (use 7) are often produced by home-casting and small-scale casting by individuals or in the 'back rooms' of fishing tackle shops. This may result in relatively high exposure to lead as the lead is likely to be cast with no or insufficient exposure abatements technology (risk management measures). In addition, the casting may have significant health impact of the persons involved.

Many suppliers sell moulds for casting lead bullets, fishing sinkers and lures. However, some suppliers warn that lead dust and fumes can be extremely toxic and recommend that even if melting and casting lead is performed outdoors, protection with a respirator is required.

Several reports or studies have been published describing toxicity symptoms in persons melting lead or in children living in the vicinity of lead melting activities (Bressler et al., 2019, Brown et al., 2005, Mathee et al., 2017, Olivero-Verbel et al., 2007, Yimthiang et al., 2019). As a worst-case example, an Alaskan adult male patient suffered from lead poisoning as a result of inhaling lead dust and fumes from melting and casting lead for several years. This patient was anaemic and showed a high level of neutrophils. The PbB level was 1 330 µg/L, the highest PbB level ever recorded in Alaska (State of Alaska Epidemiology, 2001).

[111] https://oem.msu.edu/images/annual_reports/lead%20hazards%20casting%20and%20reloading-sept.pdf

1.6.3.4. Oral exposure to lead dust (hand-to-mouth) from shooting or handling lead ammunition or fishing tackle (uses 1, 2, 3, 4, 5, 6 and 7)

From occupational settings, the oral uptake of lead dust by the hand-to-mouth route under insufficient hygiene measures and its contribution to the blood lead burden is well known. However, the database is very limited and does not permit to quantify the risk from oral exposure to lead dust (hand-to-mouth) from shooting or handling lead ammunition.

Lead dust associated with shooting may be deposited on all surfaces of a shooting range, with specifically high concentrations in the impact area (Mirkin and Williams, 1998). Lead dust can adhere to shooter's clothes and potentially contaminate vehicles and homes. The CDC (1996) measured carpet dust lead concentrations in FBI student dormitory rooms and in 14 non–student dormitory rooms at a firing range and training facility. They observed that student dormitory rooms had significantly higher lead levels than non–student dormitory rooms, suggesting that the FBI students were contaminating their living quarters with lead. 'Take home lead' has been described mostly for occupational settings but given the fine particle nature and lead concentrations of dust associated with shooting, the 'take home lead' pathway of exposure from shooting must be recognised and curtailed (Laidlaw et al., 2017).

In the CSR (2020), the amount of lead ingested from reloading activities (home-casting) was calculated with 14 µg for cleaning spent cartridges and with 4.7 µg for reloading lead bullet or shot. The Norwegian Scientific Committee for Food Safety (VKM) (Knutsen et al., 2013) reported that PbB levels were significantly higher in participants who reported self-assembling of lead-containing bullets (median PbB 31 µg/L compared to 16 µg/L in the control group).

The practice to keep lead bullets in the mouth for shooting was reported for 17 % of the shooters investigated with an average PbB level increment of 82 µg/L (Mathee et al., 2017). Reports of lead poisoning among adults retaining two or more ingested lead shot pellets in the Annex have been published for example by Hillman (1967) or Madsen et al. (1988).

Sahmel et al. (2015) quantified the mean lead skin-to-saliva transfer efficiency with 24 % (range: 12–34 %). Based on this study the hand-to-mouth exposure from lead dust on the skin from fishing sinkers and lures (and lead bullets or shots) is highly plausible.

Therefore, shooters and personnel cleaning shooting ranges or recovering lead shots or bullets can be expected to have high potential for lead exposure in case strict hygiene measures to prevent exposure are not applied.

1.6.3.5. Swallowing of lead fragments (uses # 1, 3, 5, and 7)

Grade et al. (2019) reported that poison control centres (outside the EU) are commonly consulted on cases of ingestion of lead and previous studies had noted that some of these are fishing weights (Cole et al., 2010). In the absence of data from the EU, the reported data from outside the EU are used as a surrogate. In 2016, 2 412 of the poisoning cases reported to poison control centres in the US were due to single exposures to lead, typically due to the ingestion of small lead items (Gummin et al., 2017). In many cases the lead item ingested was not defined. However, in 38 cases reported to US poison control centres in 2016 the item ingested was specifically recorded as lead fishing tackle and most of these (28 cases) were due to ingestion by children under 6 years of age (Gummin et al., 2017).

Grade et al. (2019) noted that not all ingestions of lead sinkers will result in reports to poison control centres and the toxic impacts of the exposure may not be immediately evident. It is likely that the poison control centre numbers underestimate the total number of children exposed to lead via this route.

Retention of lead fishing sinkers in the stomach and intestines of children following ingestion has been demonstrated and can result in long-term elevation of lead levels (Mowad et al., 1998).

Significantly elevated blood lead levels from 450 to 690 µg/L have been documented in children ingesting fishing sinkers (Cole et al., 2010, McCloskey et al., 2014, Mowad et al., 1998, St. Clair and Benjamin, 2008). The ingestion of lead pellets by children resulted in PbB levels of 530 to 650 µg/L (Rozier and Liebelt, 2019, Treble and Thompson, 2002).

The practice to bite lead split shot to secure onto the fishing line has frequently been reported (Grade et al., 2019). Carrier et al. (2012) report a 21-year-old man with signs of lead intoxication and PbB levels of 1 410 µg/L. The patient reported that he commonly chewed fishing lead sinker and may sometimes swallow them during the preparation of the fishing rod.

1.6.3.6. Indirect exposure of humans via the environment

Consumption of game meat bagged with lead ammunition (uses # 1 and 2)

Consumption of meat from game hunted with lead ammunition is likely to be a relevant source of lead exposure. However, only limited information has been found in the scientific literature. For this reason, ECHA collaborated as part of the preparation of this dossier with EFSA in order to estimate the possible impact of (fragments of) lead shots and bullets on high-end consumers of game meat.

Impact of lead shots and bullets on lead concentration in game meat

Lead shot used for hunting can 'fragment' after hitting quarry animals resulting in small particles of lead being distributed within the tissues of an animal. Some of these fragments may reside in edible tissues away from the primary wound and remain there after butchery and food preparation (Green and Pain, 2014). According to the available evidence, it is not possible to successfully remove all embedded fragments of lead from the wound channels of shotgun shot game as tiny lead particles would go unnoticed.

Felsmann et al. (2016) investigated the effect of lead bullets on game meat. The projectile that penetrates the animal body generates a temporary cavity and this phenomenon is accompanied by a change in the pressure within the funnel of a wound and in the adjacent tissues. A cavity is formed behind the projectile and may persist even after the projectile has left the target. Its size is difficult to predict and the momentary shape of the frontal part of a projectile seems to have a major impact on its formation and size (Felsmann et al., 2012). Due to the temporary cavity phenomenon, especially pressure fluctuations in adjacent tissues, it may be assumed that this phenomenon is responsible for lead transfer deep into the tissues that surround the path of a wound.

The highly variable results of studies on the content of lead at the same distance from the path of a wound in individual animals are unsurprising due to this physical phenomena (Dobrowolska and Melosik, 2008). The increased lead levels in animals where projectiles were hitting bones, as reported by other authors, seem to confirm the hypothesised lead transfer from projectiles to animal tissues. After hitting the bone, a projectile may be fragmented, the core may be exposed, and secondary projectiles may be generated. Detached fragments most often move at a different velocity than the projectile core, contaminating a larger area of tissues (Knott et al., 2010). These fragments increase the surface of lead elements that come in contact with the surrounding tissues. Detached projectile fragments and comminute bone become secondary projectiles that generate a temporary cavity and, although an individual "secondary" temporary cavity may coalesce, it always expands the area of contaminated tissues (Felsmann et al., 2016).

The Norwegian Scientific Committee on Food Safety (Norwegian VKM, 2013) reviewed the data on the impact of different ammunition types on the lead concentration in game meat and found that expanding lead-containing bullets produce a cloud of lead particles in the meat around the wound channel. Fragment sizes varied between < 1mm and up to 10 mm. Disruptively-expanding bullets may retain down to 10 % (fragmenting type) or 20-80 % (semi-fragmenting type) of their original weight. Expanding bullets may retain 60-100 % of their original weight, and some bonded types appear to be considerably more stable than unbonded types although great variations exist. Disruptively-expanding, expanding unbonded and some expanding bonded lead-containing bullets produced on average 200 radiographically visible fragments per bullet (range of averages 90 - 370), and up to 800 fragments per bullet were detected for individual bullet types. Very small fragments presumably remain undetected. Other types of bonded expanding lead-containing bullets produced fewer than 10 fragments per bullet. Non-lead disruptively-expanding bullets produced on average 6 to 23 fragments, while non-lead expanding-nose bullets produced 0 to 2 fragments. Lead fragments from disruptively-expanding, unbonded and some bonded expanding lead-containing bullets were found by radiography in various species (roe deer, red deer, wild board, sheep, chamois) with an average radius of 15 cm around the wound channel. The maximal penetration length of visible fragments was on average 29 cm. In a study on sheep, fragments from more stable types of expanding lead-containing bonded bullets were found at distances less than 5 cm. This is comparable to fragments from non-lead disruptively expanding bullets and non-lead expanding-nose bullets measured in the same study. Corresponding studies on moose have not been found. An available study indicates that lead concentrations above 0.1 mg/kg can be found at 25 cm distance from the wound channel in red deer and wild boar shot with various unknown types of lead ammunition (Norwegian VKM, 2013).

Broadway et al. (2020) investigated fragmentation in deer shot with three different types of low velocity lead ammunition (rifled slugs, sabot slugs and modern muzzle-loading bullets). All radiographed deer had evidence of fragmentation, with a geometric mean of 13.1 (95 % CI = 10.3, 16.8) fragments per deer. Most fragments (89 %) were <5 mm from wound channels, and no fragment travelled beyond 205 mm from a wound channel. Fragments were often retained within the muscle tissue of deer with a geometric mean rate of 0.55 (95 % CI = 0.48, 0.65). Muzzleloader bullet fragments were larger than those generated by rifled and sabot slugs, and sabot slug fragments had the shortest dispersal from wound channels. Shoulder-shot placement and bone contact for all ammunition resulted in a significantly larger number of fragments. Shoulder-shots also generated more small fragments and higher fragment retention in muscle tissue. The author concluded that, compared to high-velocity rifle bullets, significantly fewer lead fragments are made available to humans and wildlife that consume game shot with low-velocity ammunition types.

Best practices to handle game meat

European hunters generally follow "best practice" as advised by several wildlife authorities. This basic game meat handling advice is often part of the hunting education prior to any compulsory hunting exam. For example, it is recommended to remove the meat around the gunshot wound defined as any meat that is visibly affected by the bullet and an additional 10 cm of meat visibly unaffected by the bullet (e.g., (Swedish NFA, 2014d).

The FACE Guidance on managing risks from lead[112] mentions the following:

"All expanding lead core bullets fragment on impact and shed lead particles through the meat as the bullet penetrates. This is also true for lead shot. This gives rise to microscopic *particles of lead widely distributed throughout the carcase. Expanding lead core bullets typically release thousands of fragments of varying size (including millions of nanoparticles) and the larger ones can be visualized using X-rays (Arnemo et al., 2016) (Knott et al., 2010).*

The lead levels are greatest immediately surrounding the wound channel, but may remain detectable up to 30 cm away depending on bullet type, bullet resistance during penetration and bullet velocity upon impact.

Attempts to remove lead ammunition from game meat can be successful at significantly reducing the levels of lead contamination. Research in Sweden has shown that proper handling of game shot with lead ammunition can effectively eliminate the risk (Swedish NFA, 2014a). The Federal Institute for Risk Assessment, Germany (BfR, 2011) states that cutting out large sections of meat around the bullet hole is not always enough to guarantee removal of lead.

Risk management options can include the application of appropriate game meat handling techniques, eating game shot with non-lead ammunition, or reducing their intake of game shot with lead ammunition."

Discard of lead contaminated meat

Lead concentration in the wound channel can be very high. Dobrowolska and Melosik (2008) reported for 16/20 meat samples from the wound channel of wild boar and red deer lead concentrations > 100 mg/kg wet weight, 1/20 even exceeding 1 000 mg/kg wet weight. Swedish Swedish NFA (2014a) reported median and maximum lead concentrations from the wound channel of 146 and 1 829 mg/kg wet weight.

Several investigations studied lead concentration in game meat in relation to the distance to the wound channel. In tissues from wild boar and red deer hunted with unspecified different brands of expanding lead-based ammunition routinely used in Poland (Dobrowolska and Melosik, 2008) maximum concentrations measured at the entry wounds were ca. 1 100 mg/kg wet tissue (wild boar) and 480 mg/kg (red deer) and at exit wounds 740 mg/kg (wild boar) and 120 mg/kg (red deer). In all samples taken at 5 cm and 15 cm distance from the wound channel, the tissue concentrations exceeded 0.1 mg/kg. At 25 cm distance, nine of the 10 red deer and eight of the 10 wild boar samples were still greater than 0.1 mg lead/kg, and at 30 cm five (red deer) and eight (wild boar) of the 10 samples in each species were greater than 0.1 mg lead/kg (see Table 1-41).

Table 1-41: Lead concentration in wild boar and red deer at different distance from the bullet pathway (Dobrowolska and Melosik, 2008)

Indiv. No.	Carcass weight	Lead concentration (mg/kg wet weight)[1]						
		Wound		Distance from bullet pathway (cm)				
		entrance	exit	5	15	25	30	control

[112] https://www.leadammunitionguidance.com/lead-ammunition-in-game-meat/

Indiv. No.	Carcass weight	Lead concentration (mg/kg wet weight)[1]						
		Wound		Distance from bullet pathway (cm)				
		entrance	exit	5	15	25	30	control
Wild boar								
1	86	**1 095.9**	**736.0**	**32.2**	**11.2**	**4.2**	**3.3**	0.3
2	82	**189.2**	**67.4**	**18.9**	**6.2**	0.2	0.2	0.2
3	78	**125.2**	**59.8**	**14.2**	**0.8**	0.2	0.2	0.1
4	76	**131.4**	**77.7**	**11.9**	**3.8**	0.2	0.2	0.2
5	43	**361.4**	**633.1**	**47.5**	**6.8**	**3.8**	**3.1**	0.3
6	34	**179.2**	**395.4**	**26.2**	**5.2**	**2.6**	**0.9**	0.1
7	32	**74.0**	**95.0**	**5.1**	**0.9**	0.1	0.1	0.1
8	32	**65.5**	**158.3**	**8.2**	**0.8**	0.2	0.2	0.2
9	29	**76.5**	**212.3**	**10.3**	**0.8**	0.2	0.2	0.2
10	26	**69.7**	**176.3**	**10.2**	**2.3**	0.1	0.1	0.1
Red deer								
1	116	**234.6**	**76.5**	**43.8**	**8.6**	**0.3**	0.1	0.1
2	113	**364.8**	**102.6**	**53.7**	**5.7**	**1.1**	**0.8**	0.2
3	110	**185.8**	**67.3**	**31.9**	**7.9**	**0.2**	0.1	0.1
4	102	**476.9**	**92.7**	**87.5**	**16.9**	**4.8**	**1.1**	0.3
5	98	**156.6**	**60.4**	**16.9**	**5.1**	0.2	0.2	0.2
6	97	**243.8**	**97.2**	**42.7**	**13.7**	**0.3**	**0.2**	0.1
7	96	**176.8**	**67.9**	**38.7**	**9.6**	**0.2**	0.1	0.1
8	93	**346.5**	**123.7**	**64.2**	**12.5**	**5.8**	**0.9**	0.3
9	89	**198.5**	**64.9**	**32.1**	**2.6**	**0.2**	0.1	0.1
10	88	**135.7**	**59.9**	**23.2**	**4.3**	0.1	0.1	0.1

Notes: [1] lead concentrations exceeding the individual control value are marked in bold

Investigations from Sweden on moose meat samples found lead concentrations ranging from levels below detection limit 0.02 mg/kg up to 31 mg/kg. 54 Percent of the samples (29/54) showed lead concentrations above the detection limit and 33 % of the samples (18/54) exceeded the lead concentration of 0.1 mg/kg. Samples from wild boar showed that up to 10 cm around the wound channel 50 % of the samples exceeded 0.1 mg/kg and 15 cm from the wound channel 27 % of the meat samples exceeded this level (Swedish NFA, 2014b, Swedish NFA, 2014c). More detailed data are provided in Table 1-42.

Table 1-42: Lead content (mg/kg) in the meat of wild boar in relation to the distance to the wound channel (Swedish NFA, 2014c, Forsell et al., 2014, Swedish NFA, 2014b)

	Sample in relation to wound channel	N	Lead concentration (mg/kg)			Samples >0.1 mg/kg
			Min	Median	Max	
Wild boar	Wound channel	18	0.011	**146**	**1 829**	94 %
	0 to 5 cm	18	0.007	**9**	**1 466**	89 %
	5 to 10 cm	18	0.004	**0.11**	**18**	50 %
	10 to 15 cm	15	0.004	0.04	**29**	27 %

Removal of lead shots and lead bullet fragments results in discarding a considerable quantity of meat, especially in large game animals. In Norway, discarding meat close to wound channels results in approximately 200 tonnes of contaminated meat being discarded annually, representing an economic loss of around €3m (Kanstrup et al., 2018).

Lead in game meat

Animals shot with lead ammunition frequently contain lead fragments in the carcass which contaminate meals made from game meat with concentrations of lead substantially above the maximum levels set by the food contamination Regulation (EC) No 1881/2006. The maximum permissible levels for bovine animals, sheep, pig and poultry are 0.1 and 0.5 mg Pb/kg wet weight for meat and offal, respectively. No maximum levels for lead in wild game have been set. The Swedish National Food Administration (Swedish NFA, 2020) considers that meat of game with lead contents exceeding this limit value should not be considered as safe food according to Article 14 of EU Regulation No. 178/2002. Röschel et al. (2020) propose that (EC) No 1881/2006 is amended to incorporate a maximum level for game meats as a supplementary measure to the replacement of lead ammunition. This would harmonise food safety standards for lead in meat traded across and imported into the EU.

Game meat bagged with lead shots

Pain et al. (2010) found that a high proportion of meat samples from game bagged with shot had lead concentrations exceeding 100 ppb w/w (0.1 mg/kg w/w). For example, 56 % and 47 % of fresh meat samples from partridge and pheasant, respectively, exceeded 0.1 mg Pb/kg, 21 % and 18 % exceeded 1.0 mg Pb/kg, and 5.7 % and 2.4 % exceeded 10 mg Pb/kg.

For the purpose of this restriction proposal, EFSA provided data on the lead concentration in game meat in the EU (EFSA, 2020). Based on common hunting practices it was assumed that duck, game birds, hare, partridge, pheasant, quail and rabbit were bagged with lead shot. About 50 % of the samples (1 313/2 574) are from "duck" and might originate from wetland hunting. About 2 % of the samples (48/2 574) are undefined "game birds". EFSA used lower bound and upper bound concentrations derived from the practice of handling non-quantified or non-detected food chemical concentration results by assigning a value of zero to lower-bound estimate and a value equal to the LOQ for the upper-bound estimate. As reported in Table 1-43 , the lead mean lower bound concentration in the samples analysed was 0.352 mg Pb/kg. Highest mean lower bound lead concentrations were found in hares (0.9 mg/kg) and pheasants (0.7 mg/kg). Highest reported maximum values were 104 and 113 mg/kg for hares and pheasants, respectively. The percentage of samples > 0.1 mg lead per kg game meat is 13 %.

Table 1-43: Concentration of lead in meat intended for consumption from game hunted with lead shots in the EU (EFSA, 2020)

Species	N	Samples below detection limit (%)	Lead concentration in game meat (mg/kg)			Samples > 0.1 mg/kg (%)
			Mean lower bound	Mean upper bound	Max	
Duck	1 313	73	0.081	0.096	17.900	89 (7 %)
Game birds	48	24	0.207	0.214	1.797	14 (29 %)
Hare	341	60	0.889	0.903	104.000	50 (15 %)
Partridge	17	82	0.054	0.081	0.840	1 (6 %)
Pheasant	713	48	0.676	0.683	113.000	160 (22 %)
Quail	129	74	0.024	0.044	0.400	12 (9%)
Rabbit	11	64	0.341	0.347	1.000	4 (36%)
All[1]	**2 574**	**63**	**0.352**	**0.366**	113.000	**330/2574 (13 %)**

Notes: [1] this row also includes one result from pigeon and one from snipe not displayed in the table

Cooking methods may affect the bioavailability of lead in game meat. Lead particles in game meat can dissolve while cooking, producing soluble lead salts that then contaminate parts of the meat. These salts have greater bioavailability and may pose an increased risk compared to metallic lead particles (Mateo et al., 2007).

Cooking small game meat (red-legged partridge breast) under acidic conditions (i.e. using vinegar) has been found to increase the final lead concentration in the meat as well as its bioavailability (Pain et al., 2010). Hence the percentages of samples exceeding certain benchmarks may further increase after cooking and especially after cooking under acidic conditions.

Game meat bagged with lead bullets

The Swedish National Food Administration (Swedish NFA, 2020) carried out a survey of the lead content in minced meat of game that has been handled in game handling facilities in Sweden. A total of 50 samples of minced meat of moose and 50 samples of minced meat of wild boar were analysed. The samples were taken at 47 different game handling facilities, from Norrbotten to Skåne. The total proportion of samples with levels of lead that were likely to come from lead ammunition was 36 percent (36 samples out of 100). For wild boar, levels of lead with probable origin from lead ammunition were present in 42 percent of the samples (21 of 50 samples) and for moose in 30 percent of the samples (15 of 50 samples). The remaining 64 percent (64 out of 100 samples) were below the detection limit for the analysis (45 samples) or had a content that was within the measurement uncertainty (19 samples). The results show that 15 percent of the 100 samples have lead levels that were above the limit found in current EU legislation for, among other things, meat from domestic animals and poultry (0.10 mg / kg wet weight). For wild boar this limit is exceeded in 16 per cent of the samples (8 of 50 samples) and for moose in 14 per cent of the samples (7 of 50 samples). A further 21 percent of the samples (21 samples out of 100) had lead contents that are unlikely to originate in a background exposure (26 percent of the wild boar samples and 16 percent of the moose samples).

EFSA also provided data on lead concentration in game meat in the EU (EFSA, 2020). Based on common hunting practices it was assumed that chamois, deer, moose, roe deer and wild boar were bagged with lead bullets. As reported in Table 1-44, the lead mean lower bound concentration in the samples analysed was 2.5 mg Pb/kg. Highest mean lower bound lead concentrations were found in roe deer (mean 10.9 mg/kg), wild boar (2.8 mg/kg) and deer (1.9 mg/kg). Meat from moose showed low mean concentrations of about 0.03 mg/kg. Highest reported maximum values are 588, 3 650, and 5 309 mg/kg for roe deer, wild boar, and deer, respectively. The percentage of samples > 0.1 mg per kg game meat is 13 %.

Table 1-44: Concentration of lead in meat intended for consumption from game hunted with lead bullets in the EU (EFSA, 2020)

Species	N	Samples below detection limit (%)	Lead concentration in game meat (mg/kg)			Samples >0.1 mg/kg (%)
			Mean lower bound	Mean upper bound	Max	
Chamois	15	87	0.002	0.010	0.021	0
Deer	5 034	55	1.992	2.006	5 309.000	514 (10 %)
Moose	330	48	0.026	0.035	2.720	9 (3 %)
Roe deer	314	48	10.893	10.903	588.620	*Included under "deer*
Wild boar	4 040	47	2.810	2.827	3 650.000	818 (20 %)
All[1]	**10 334**	**52**	**2.501**	**2.515**	5 309.000	**1 341 (13%)**

Notes: [1] this row also includes results from the generic category "game mammals" not displayed in the table

The low concentration of lead in moose meat reported by EFSA is in contrast to data by Lindboe et al. (2012) who reported mean lead concentrations of 5.6 mg/kg ranging up to 110 mg/kg for 52 samples of ground meat from moose shot in Norway.

The data reported by EFSA for wild boar and wild deer are in a similar range as reported for France (ANSES, 2018) with 3.4 mg Pb/kg meat (mainly wild boar and wild deer).

Studies from Germany investigated lead concentrations in game meat shot under controlled conditions, prepared by trained personal and inspected for marketability. Three samples of 100 g per animal were taken of marketable meat from around the area close to the wound channel, the saddle and the haunch. Compared to game shot with non-lead ammunition, the use of lead ammunition significantly increased lead concentrations in game meat of red deer (Table 1-45), roe deer and wild boar (Table 1-46). Mean lead values were lowest for samples taken from the haunch and highest for samples taken close to the wound channel. Mean lead concentrations for marketable meat taken from around the wound channel were 5.4 mg/kg for wild boar, 14.0 mg/kg for roe deer (Gerofke et al., 2018) and 58.2 mg/kg for red deer (Martin et al., 2019). Individual maximum values reported were very high exceeding even 1 000 mg/kg (Gerofke et al., 2018, Martin et al., 2019).

Table 1-45: Lead concentration (mg/kg) in marketable meat of red deer in Germany (Martin et al., 2019)

Sample origin	N	Mean (95 % confidence interval)	Lead concentration (mg/kg)				
			Median	P75	P90	P95	Max
Haunch	64	**0.015** (0.012; 0.019)	0.010	0.020	0.030	0.034	0.09
Saddle	64	**0.054** (0.019; 0.101)	0.014	0.023	0.040	0.220	1.14
Close to wound	64	**58.2** (0.970; 168.6)	0.016	0.024	0.820	48.04	3442.00

Table 1-46: Lead concentration (mg/kg) in marketable meat of roe deer and wild boar in Germany (Gerofke et al., 2018)

Sample origin	N	Quantifiable (%)	Lead concentration (mg/kg)					
			Mean	Geometric mean (95 % CI)	Median	P95	P97	Max.
Roe deer								
Haunch	745	296 (39.8)	**0.169**	0.003 (0.002;0.005)	0.006	0.064	0.132	73
Saddle	745	336 (45.1)	**0.968**	0.0043 (0.002;0.008)	0.009	0.164	0.643	189
Close to wound	745	456 (61.2)	**13.958**	0.014(0.007;0.027)	0.025	2.237	9.676	4 728
Wild boar								
Haunch	514	205 (39.9)	**0.086**	0.004 (0.002; 0.008)	0.014	0.067	0.132	14
Saddle	514	259 (50.4)	**1.716**	0.007 (0.003; 0.016)	0.021	0.691	1.729	650
Close to wound	514	783 (50.8)	**5.367**	0.011 (0.005; 0.075)	0.025	1.446	5.809	1 582

Wilson et al. (2020) analysed ground venison packets from shotgun and archery-harvested white-tailed deer in Illinois in 2013 and 2014. The shotgun venison packets were either processed by three different commercial meat-processing plants ('commercial') or from a custom processor specialised in processing venison only ('custom'). Radiographs indicated that 48 % of 27 ground venison packets from 10 shotgun-harvested deer contained metal fragments, while none of the 15 packets from three archery-harvested deer contained fragments. ICP-MS analysis verified that all metal fragments from seven of the venison samples from shotgun-harvested deer were composed of lead, with average concentrations from 1.04 to 8.42 mg/kg dry weight. Shotgun-harvested venison packets from a commercial processor were more likely ($z = 3.59$; $p < 0.001$) to have fragments and had significantly more ($W = 298.5$; $p = 0.004$) fragments than archery-harvested packets from a commercial processor (see Table 1-47). The author calculated that a single serving of ground venison containing one of these metal fragments embedded in it would be predicted to have a lead concentration ranging from 6.4 to 51.8 mg/kg.

Table 1-47: Data from ground venison packets from white-tailed deer (Wilson et al., 2020)

Type of harvest	processor	Number of packets	% with fragments	Number of fragments per packet
Archery	Commercial	15	0.0±0.0	0.0±0.0
Shotgun	Commercial	21	57.1±10.8	0.86±0.19
Shotgun	Custom	6	16.7±29.8	0.16±0.15

Summary

Lead concentrations in game meat vary significantly, depending on the cut of meat. However, even if prepared under best practices a relevant proportion of game meat has substantially higher lead concentrations than the regulatory maximum level for lead in meat (0.1 mg Pb/kg meat). Of specific concern are individual samples showing very high lead concentrations even above 1 000 mg/kg.

A high proportion of meat samples from game bagged with shot had lead concentrations exceeding 0.1 mg/kg w/w. For example, 56 % and 47 % of fresh meat samples from partridge and pheasant, respectively, exceeded 0.1 mg Pb/kg, 21 % and 18 % exceeded 1.0 mg Pb/kg, and 5.7 % and 2.4 % exceeded 10 mg Pb/kg (Pain et al., 2010). The mean lead concentration in game meat bagged with lead shots was 0.366 mg/kg with 13% of the samples exceeding 0.1 mg/kg (EFSA data 20.06.2020).

The mean lead concentration in game meat bagged with lead bullets was 2.515 mg/kg with 13 % of the samples exceeding 0.1 mg/kg (EFSA data 20.06.2020). In marketable meat of red deer, mean lead concentrations in meat close to the wound channel was 58 mg/kg, in meat from the saddle and haunch < 0.1 mg/kg (Martin et al., 2019). In marketable meat from roe deer the mean lead values for close to the wound channel (13.96 mg/kg), saddle (0.97 mg/kg) and haunch (0.17 mg/kg) all exceeded 0.1 mg/kg. For wild boar meat, the mean concentrations of the samples close to wound channel (5.37 mg/kg) and saddle (1.72 mg/kg) exceeded 0.1 mg/kg (Gerofke et al., 2018).

Game meat consumption

Green and Pain (2019) reviewed the published information on game meat consumption in the EU. The authors conclude that the main consumers of game are hunters and their families and associates, and that a few percent of the general population in most EU Member States may be frequent (a few times per month) or high-level (once per week or more) consumers of game meat. Gerofke et al. (2018) concluded that for the average consumer of game meat in Germany the additional uptake of lead only makes a minor contribution to the average alimentary lead exposure. However, for high-frequency consumers (mainly members of hunter households) the uptake of lead from ammunition fragments may be several times higher than the average alimentary lead exposure.

While other parts of the general population do consume game meat, the focus of this restriction proposal is on game meat consumption of hunters and their families. Game meat consumption of hunter families has been estimated to be 50 g meat/day (Haldimann et al., 2002), up to 91 meals/year or 50 g/day (Gerofke et al., 2018), more than one game meat meal per week, resulting in 50 g/day for adults and 25 g/day for children (ANSES, 2018) and 23 g/day on average with P95 of 97 g/day (AESAN, 2012).

For the purpose of this restriction proposal, EFSA provided recent data on the consumption of game meat in the EU. The Dossier Submitter considers that the 95th percentile of chronic consumption of game meat is a good proxy of high frequency consumers such as hunter households. The P95 chronic daily consumption of game meat for different age groups as provided by EFSA is reported in Table 1-48. Of specific importance for this assessment are data on infants and toddlers that are specifically sensitive to lead-related IQ loss. Data from pregnant and lactating women were not considered due to the low number of data.

Table 1-48: Minimum, maximum and median across surveys of the 95th percentile of the chronic daily consumption of meat from game hunted with lead shots and bullets in the EU (EFSA data 20.06.2020)

Population	Ammun.	N (S)[1]	Daily consumption of game meat (g/kg bw and day)[2]		
			Min P95	Med P95	Max P95
Infants	Shot	1-15 (5)	0.450	0.658	4.261
	Bullet	1-8 (3)	0.891	1.667	2.147
Toddlers	Shot	1-25 (10)	0.153	1.131	4.922
	Bullet	1-30 (7)	0.114	2.219	5.245
Other children	Shot	1-56 (13)	1.181	2.632	6.154
	Bullet	1-27 (11)	0.710	2.630	11.920
Adolescents	Shot	1-84 (14)	0.474	1.646	3.902
	Bullet	1-6 (12)	0.334	1.149	2.454
Adults	Shot	1-218 (20)	0.172	1.606	3.664
	Bullet	1-68 (16)	0.252	1.560	6.597
Elderly	Shot	1-74 (16)	0.090	1.112	2.851
	Bullet	1-27 (11)	0.444	1.244	2.946
Pregnant women	Shot	1-3 (5)	0.127	0.887	2.241
	Bullet	6 (1)	1.566	1.566	1.566
Lactating women	Shot	4 (1)	1.228	1.228	1.228
	Bullet	4 (1)	4.635	4.635	4.635

Notes: [1] range of number of subjects N in (S) surveys; [2] Some of the 95th percentiles presented in this table were calculated based on information from less than 60 subjects and might hence not be statistically robust.

Summary

Game meat consumption of hunter families has been estimated to be 50 g meat/day for adults (ANSES, 2018, Gerofke et al., 2018, Haldimann et al., 2002) and 25 g/day for children (ANSES, 2018). AESAN (2012) estimated 23 g/day on average and 97 g/day as 95th percentile. Based on data from EFSA for chronic consumption of game meat, the median daily game meat consumption of high frequency consumers (95th percentile as proxy for hunter family members) was 1.61 and 1.56 g/kg bw/day for adults consuming game harvested with shots and bullets, respectively, which would be 113 and 109 g/day for an adult of 70 kg body weight.

For children, only limited data is available from the EFSA database. For infants (0 to 12 months of age) the median of the 95th percentile was 0.66 and 1.67 g/kg bw and day. Assuming a body weight of 5 kg, a daily lead intake of 3.30 and 8.35 g/day result. For toddlers (1 to 3 years), the median of the 95th percentile was 1.13 and 2.22 g/kg bw/day. Assuming a body weight of 12 kg, a daily lead intake of 13.56 and 26.64 g/day result.

Measured PbB levels related to consumption of game meat

Very limited data is available on how frequent game meat consumption affects PbB levels in hunter families. When reviewing the published studies that measured PbB levels in game meat consumers, the following has to be considered:

- Men usually have higher PbB levels compared to females;
- Shooting /hunting has a significant contribution to the PbB level;
- Professional or leisure activities may contribute to PbB levels.
- The available studies investigating PbB levels in hunter and/or members of hunter families usually do not separate the data with respect to sex or shooting/hunting activities. Therefore, it is difficult to draw conclusions on PbB levels.

All reviewed data can be found in Annex B.

Hunt et al. (2009) fed lead fragment-containing venison to four pigs to test bioavailability; four controls received venison without fragments from the same deer. The total amount of lead fed to each pig was unknown, but quantitative analysis of similar packages from other deer in the study showed 0.2 to 168 mg (median 4.2 mg) of lead. Mean blood lead concentrations in pigs peaked at 22.9 µg/L (maximum 38 µg/L) two days following ingestion of fragment-containing venison, significantly higher than the 6.3 µg/L averaged by the controls. The results indicate that after a single feeding of median 4.2 mg lead per pig, the PbB level increase was 17 µg/L. After 7 days the PbB levels returned to the baseline values.

The available data indicate that subsistence hunters living in the circumpolar region show the highest increases in PbB levels. For example, Bjerregaard et al. (2004) reported that sea bird consumption of one to three times per week resulted in an increase of the mean PbB level of more than 30 µg/L, for daily consumption even more than 90 µg/L. However, the data for males and females were not separated and the lead contribution from hunting was not considered. In males with even higher sea bird consumption, PbB level increases were 59 µg/L (5 - 15 bird equivalents per month), 67 µg/L (15 - 30 bird equivalents per week) and >113 µg/L (> 30 bird equivalents per week) (Johansen et al., 2006). Again, the lead contribution from the hunters in this group was not considered separately. Tsuji et al. (2008) separated the data for male and females and reported a clear different in the PbB levels of males and females. Compared to females in an urban area, PbB levels were 6 and 15 µg/L higher in native females. For males, PbB levels were 47 and 53 µg/L higher compared to the controls. Most probably a relevant fraction of the PbB level increase might be due to hunting activities. However, it was not reported how many of the circumpolar residents were hunters.

Males and females from hunter families (n = 115) consuming game meat, mainly moose meat, hunted with lead bullets in Sweden (Swedish NFA, 2014a, Swedish NFA, 2014c) had 5.3 µg/L higher PbB levels compared to the control group. For non-hunting women (n = 35) of hunter families the consumption of game meat resulted in PbB levels about 30 % higher (ca. 3.5 µg/L).

In a more recent publication on hunter families in Sweden, PbB level increase was 3.3 µg/L and 5.6 µg/L for females (n = 16) and males (n = 14), respectively, for moose meat consumption two to three times per week (Wennberg et al., 2017, Swedish NFA, 2014a). Hunting activities were not reported.

No increase in the PbB level was observed in non-hunting family members (possibly 10 females) that consumed game meat hunted with shots or bullets (Fustinoni et al., 2017). However, persons consuming game meat prior to testing were excluded.

Summary

The data on PbB level increments from game meat consumption only (excluding hunting and shooting activities) are very limited. The available data indicate a small increase in PbB level of 3 to 5 µg/L in adults with consumption of moose meat two to three times a week . For groups relying on subsistence hunting, the PbB contribution from game meat consumption seems to be higher; in one study the increment for females (assumed to be non-hunters) was 6 and 15 µg/L (Tsuji et al., 2008). No reliable PbB level measurements in children from hunter families are available.

Additional sources of indirect exposure to humans via the environment

In addition to the consumption of game meat, it is also relevant to consider the potential for indirect exposure to humans via the environment via other pathways. These pathways are primarily relevant to hunting with lead gunshot (use #1) as well as uses of lead for sports shooting (uses #3 and 4).

Meat and dairy products

The risk of grazing ruminants being exposed to lead shot could be more prevalent than anticipated since clay pigeon shooting and the shooting of game birds is an increasingly popular rural business and can result in the contamination of land used for pasture, fodder or silage (Payne et al., 2013).

Lead poisoning of cattle is regularly reported in the US and the UK, arising from various sources: lead-containing paint, batteries as well as spent ammunition. Several studies report exposure of ruminant animals to ammunition derived lead, principally via the consumption of silage (Bjørn et al., 1982, Frape and Pringle, 1984, Howard and Braum, 1980, Payne et al., 2013, Rice et al., 1987).

Payne et al. (2013) present two cases of lead-shot ingestion and subsequent lead poisoning reported in cattle in which quantities of lead shot were retrieved from the reticulum or abomasum. The author postulates that lead shot deposited beyond the perimeter of the shooting zone falls on to grassland or arable fields. In these environments the lead shot becomes trapped in vegetation where it can be consumed by grazing ruminants. In addition, trapped lead shot can be incorporated in silage where the acidic environment of the silage making process can result in the formation of lead compounds that are more readily absorbed then metallic lead.

In contrast, Johnsen and Aaneby (2019) reported that sheep grazing at a shooting range used by the Norwegian Armed Forces were at little or no risk of acute or chronic lead poisoning. These data would suggest that sheep have lower sensitivity to lead poisoning than cattle, although the authors noted that the sheep had reduced soil ingestion rates compared to background information.

Root and leaf crops

Concentrations of lead in the soil of a shooting range can be very high. In the sector including backstop berm, target stand and a band of land about 5 to 10 meters wide around the berm, lead concentrations normally exceed 1 000 mg lead/kg. More than 20 000 mg/kg soil of bullets or their fragments can be found in this area. In the immediate surroundings of the backstop berm lead concentrations often fluctuates between 200 and 1 000 mg lead/kg (Dinake et al., 2019). In agricultural soils close (10 m) to a trap shooting range, total lead concentrations were reported to range from 573 to 694 mg/kg (Chrastný et al., 2010).

A direct correlation between lead in soil and lead in plants has been reported (Bennett et al., 2007). In the biomass of spring barley (*Hordeum vulgare* L.) grown on shooting ranges, lead concentrations were 138 mg/mg in roots, 16 mg/kg in leaves, 4.2 mg/kg in stems and 2.4 mg/kg in spikes (Chrastný et al., 2010). Regulation 1881/2006 limits lead in cereals to 0.2 mg lead/kg food for human consumption.

Drinking water (via surface water or groundwater)

The concentration of lead in **surface (run-off) water** at US shooting ranges has been reported from 8 µg/L to 694 µg/L (Ma et al., 2002). In Finnish shooting ranges (Kajander and Parri, 2014), total lead concentration was > 50 µg/L in more than 60 % of the samples.

Lead concentrations greater than 1 000 µg/L have been reported in **groundwater** affected by US shooting ranges (typically old shooting ranges located in sensitive areas), exceeding the threshold for lead in drinking water by more than 100-times (Soeder and Miller, 2003). In a shooting range in Germany (Mainbullau) with use of lead shots for more than 40 years, lead concentrations for leaching water was determined in five different locations with 44.5, 1 460, 198, 64.4, and 12.9 µg/L. The action levels for phase 1 (25 µg/L) requiring supervision was exceeded by 4/5 measurements and action levels for phase 2 (100 µg/L) requiring remediation, was exceeded by 2/5 measurements (Bavarian WWA Aschaffenburg, 2019). According to investigations in Finnish shooting ranges, lead concentrations clearly elevated from the background level are uncommon. In 5 of 24 samples the total lead concentrations in groundwater was > 10 µg/L, whereas the concentration of soluble lead was below 10 µg/L in 13 samples analysed (Kajander and Parri, 2014).

1.6.4. Risk characterisation

Lead affects virtually every system in the body, including the blood, the cardiovascular, renal, endocrine, gastrointestinal, immune and reproductive systems. Nevertheless, the most critical target for lead appears to be the central nervous system (CNS), particularly the developing brain, where it has the potential to cause impaired cognitive development and intellectual performance in children even at low exposure levels (EFSA, 2010).

Lead can accumulate in the body, primarily in the skeleton. From the skeleton, it is released gradually back into the blood stream, particularly during physiological or pathological periods of bone demineralisation such as pregnancy, lactation and osteoporosis, even if lead exposure has already ceased. Lead can be transferred from the mother to the foetus/infant in utero and through breast milk (EFSA, 2010).

Human exposure to lead from shots, bullets or fishing sinkers and lures mainly occurs via inhalation (shooting or home-casting) or oral intake of lead dust (hand-to-mouth) or from the consumption of meat bagged with lead shots or bullets. Secondary exposure to lead from such sources via the environment (such as water, soil, plants animals) is possible but not further investigated within this restriction.

For risk characterisation, the EFSA CONTAM Panel (EFSA, 2010) used the BMD approach to derive references points:

- $BMDL_{01}$ of 12 µg/L for developmental neurotoxicity in children (decrease in IQ by 1 point on the full scale IQ);
- $BMDL_{10}$ of 15 µg/L for 10 % increase in the prevalence of chronic kidney disease (CKD) in adults ;
- $BMDL_{01}$ of 36 µg/L for 1 % increase in systolic blood pressure (SBP) in adults, corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult

The CONTAM Panel noted that there are many caveats regarding their interpretation and the uncertainty associated with the derivation of the BMDL values. For example, the prevalence of kidney disease was compared with concurrent PbB levels. The EFSA CONTAM Panel noted that this effect would depend on lead exposure over a prolonged interval of time, during which such exposure was declining appreciably. Hence, the $BMDL_{10}$ intake value for this endpoint is likely to be numerically lower than necessary to protect against lead-induced CKD.

In the absence of a threshold for the critical effects, ECHA is reflecting the health impact by calculating the effect of the PbB level increment with respect to:

- IQ decrease in IQ points for children,
- % increase in the prevalence of chronic kidney disease (CKD) in adults, and
- increase in systolic blood pressure (in mmHg) in adults.

In the following sections the risks related to the individual exposure scenarios are summarised.

Table 1-49: Identified human health risks with regards to uses

Use number	Use name	Identified risk
1	Hunting with shot shell ammunition	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from oral exposure to lead dust (hand-to mouth) Risk from oral exposure and/or swallowing of lead fragments Risk from consumption of meat from game
2a	Hunting with bullets - small calibre	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from oral exposure to lead dust (hand-to mouth) Risk from consumption of meat from game

Use number	Use name	Identified risk
2b	Hunting with bullets - large calibre	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from inhalation exposure from melting lead ('home-casting') Risk from oral exposure to lead dust (hand-to mouth) Risk from consumption of meat from game
3	Outdoor sports shooting with shot shell ammunition	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from oral exposure to lead dust (hand-to mouth) Risk from oral exposure and/or swallowing of lead fragments
4	Outdoor sports shooting with bullets	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from inhalation exposure from melting lead ('home-casting') Risk from oral exposure to lead dust (hand-to mouth)
5	Outdoor shooting with air rifle	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from oral exposure to lead dust (hand-to mouth) Risk from oral exposure and/or swallowing of lead fragments
6	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from oral exposure to lead dust (hand-to mouth)
7	Lead in fishing tackle: sinkers and lures	Risk from inhalation exposure from melting lead ('home-casting') Risk from oral exposure to lead dust (hand-to mouth) Risk from oral exposure and/or swallowing of lead fragments
8	Lead in fishing tackle: nets, ropes or lines	No exposure scenario, and risk identified in the literature.

1.6.4.1. Risk from inhalation exposure to lead fumes or dusts from shooting (uses # 1, 2, 3, 4, 5, 6)

With regards to shooting the risks for elevated PbB levels depends very much on the frequency and the conditions of shooting and can range from low risks (low increases in PbB levels) to very high increases reaching even toxic PbB levels. Based on the information from Demmeler et al. (2009), Laidlaw et al. (2017), Mathee et al. (2017), and Mühle (2010) the factors contributing to exposure to lead and elevated PbB levels are:

- use of fire weapons (with lead-containing primer) compared to use of air weapons;
- increasing calibre of the weapon;
- increasing shooting frequency;
- reduced ventilation.

The use of lead-containing primer increases lead exposure significantly (Lach et al., 2015). However, primers are outside the scope because lead styphnate has already been identified as a substance of very high concern (SVHC) and is on the candidate list for authorisation (Annex XIV of REACH).

High exposure and risks have been reported for shooters training indoor and, depending on the shooting intensity, ventilation might not (always) be sufficient to reduce exposure to required levels. However, indoor shooting is out of scope because the request from the Commission to ECHA to develop this restriction speaks about 'terrains', which is interpreted as referring to 'outdoor'. For shooters training outdoor the database is insufficient to draw a firm conclusion. Due to natural ventilation in outdoor shooting ranges, exposure could be expected to be lower than reported for indoor shooting. However, in one study the measured lead concentrations outdoors were even higher than indoors with ventilation and was considered to be due to missing natural ventilation (wind) (Wang et al., 2017).

Insufficient information is available or has been provided on the association between the use of different specified types of shots or bullets under standardised conditions and resulting lead levels in air and/or resulting PbB levels in shooters.

Indoor shooting

High exposure has been demonstrated for indoor sports shooters with PbB levels often >200 µg/L or even >400 µg/L (Laidlaw et al., 2017). PbB levels of 200 and 400 µg/L are associated with an increase in the prevalence of chronic kidney disease of 133 % and 267 %, respectively, and with an increase in systolic blood pressure of 6.7 and 13 mmHg. At such PbB levels, further effects (e.g., clastogenic effects or effects on sperm quality) may occur (ECHA, 2019).

Laidlaw et al. (2017) concluded that shooting lead bullets at firing ranges results in elevated PbB levels at concentrations that are associated with a variety of adverse health outcomes and the topic of health risk is an ongoing topic of study. Of major concern is the number of women and children among recreational shooters, who are not afforded similar health protections as occupational users of firing ranges. Nearly all PbB level measurements compiled in the reviewed studies exceed the level of 50 µg/L recommended by the U.S. CDC/NIOSH, and thus firing ranges, regardless of type and user classification, constitute a significant and currently largely unmanaged public health concern. Primary prevention of this risk requires development of lead-free primers and projectiles. Prevention includes better oversight of ventilation systems in indoor ranges and development of airflow systems at outdoor ranges, protective clothing that is changed after shooting, and cessation of smoking and eating at firing ranges. The mismatch between what is recommended for individuals by the U.S. CDC is in stark contrast to the allowable levels for occupational exposure, and there are no real systematic biomonitoring programmes for firing range users to measure cumulative health effects caused by persistent low and even high-level lead exposure. Recreational shooters and the general public are provided no legal protections from lead exposures at firing ranges.

Also Wang et al. (2017) found that ventilation systems are effective but unable to reduce lead exposure to acceptable exposure levels.

It was demonstrated that by using jacketed lead bullets with lead-free primer (Tripathi et al., 1991), lead-free primer (Lach et al., 2015) or "low-lead" bullets (Bonanno et al., 2002) lead exposure can be reduced by over 90 %.

Outdoor shooting

For outdoor shooting only limited information is available. Lead exposure in outdoor shooting ranges is more heterogeneous compared to indoor shooting because exposure depends more on the natural ventilation (wind) (Bonanno et al., 2002). Usually, lead exposure is considered to be lower in outdoor shooting ranges compared to indoor ranges but under condition of low natural ventilation (low wind), the lead concentration could even be higher (Wang et al., 2017).

For 12 biathletes in Canada using a gun powder cartridge containing a lead bullet of 2.6 g, PbB levels were measured with 18 ± 3.1 µg/L. They were ≥ 10 µg/L higher compared to the PbB level of 12 matched cross-country skiers with <8.3 µg/L (Turmel et al., 2010). A PbB level increase of 10 µg/L is associated with an increase in the prevalence of chronic kidney disease of 7 %, and with an increase in systolic blood pressure of 0.3 mmHg.

For clay shooting athletes in Korea (Chun et al., 2018) the PbB levels were 36±7.7 µg/L for 5 females and 51±16.4 µg/L for 9 males. Mean PbB levels in the general population of Korea (2010 to 2011) were reported with 18.3±7.9 µg/L for females and 22.2±10.4 µg/L for males (Eom et al., 2017). The lead level increment of 17.7 µg for females is associated with an increase in the prevalence of chronic kidney disease of 11.8 %, and with an increase in systolic blood pressure of 0.6 mmHg. The increment of 28.8 µg/L for males with an increase in the prevalence of chronic kidney disease of 19 %, and with an increase in systolic blood pressure of 1.0 mmHg.

Twelve shooters training in an outdoor shooting range in South Africa with non-jacketed lead bullets had in mean PbB levels of 70 ± 42 µg/L, which were 43 µg/L higher compared to the PbB levels of 20 archers (27 ± 14 µg/L) of which 19 did not perform gun shooting (Mathee et al., 2017). A PbB level increment of 43 µg/L is associated with an increase in the prevalence of chronic kidney disease of 29 %, and with an increase in systolic blood pressure of 1.4 mmHg.

1.6.4.2. Risk for hunters (uses # 1, 2)

Since it is not possible for hunters to separate between the risk attributed to shooting trainings, hunting and consumption of game meat, it is considered together.

For 61 Italian hunters with >10 hunts/year and consuming game meat the PbB level was in median 37 µg/L, which was 23 µg/L higher compared to the controls with 14 µg/L (Fustinoni et al., 2017). However, the PbB levels can be assumed not to be representative because persons with recent game meat consumption were excluded and the PbB levels were determined outside the hunting season. A PbB level increment of 23 µg/L is associated with an increase in the prevalence of chronic kidney disease of 15 %, and with an increase in systolic blood pressure of 0.8 mmHg.

For 25 male hunters in Switzerland the increase in PbB level compared to the controls was reported with 2 µg/L (Haldimann et al., 2002). However, since the control group was not characterised with regards to hunting activities and the consumption of game meat, the result cannot be used for the assessment of hunting activities and game meat consumption.

For gun shooters using non-jacketed bullets training in indoor or outdoor shooting ranges in South Africa, the PbB levels of shooters that were also hunting were in mean 34 µg/L higher compared to shooters not hunting (Mathee et al., 2017). A PbB level increment of 34 µg/L is associated with an increase in the prevalence of chronic kidney disease of 23 %, and with an increase in systolic blood pressure of 1.1 mmHg.

In a study in two groups of native people in Canada undertaking subsistence hunting of migratory birds using gunshot and bullets (Tsuji et al., 2008), mean PbB levels for males (which can be assumed to be the hunters) were 47 and 53 µg/L higher compared to the levels of inhabitants of a highly industrialised city. PbB level increments of 47 and 53 µg/L are associated with an increase in the prevalence of chronic kidney disease of 31 and 35 %, and with increase in systolic blood pressure of 1.6 and 1.8 mmHg.

For groups relying on subsidiary hunting in Canada, any type of lead bullets had an increased Relative Risk (RR) of 1.406 for PbB level exceeding 50 µg/L (C.I. 1.044 – 1.894, p = 0.019). The RR of elevated PbB level (> 50 µg/L) for lead shot shell users was reported with 1.510 (C.I. 1.100 – 2.075, p = 0.007). Users of non-lead shot had no significant risk of having elevated PbB levels greater than 50 µg/L (RR = 1.048, C.I. 0.824–1.333, p = 0.702), and no significant differences in PbB levels between users and non-users of non-lead shot shell were found (p = 0.353) (Liberda et al., 2018).

1.6.4.3. Risk from inhalation exposure from melting lead (‘home-casting’) of ammunition or fishing tackle (mainly uses # 2, 4, and 7)

Lead intoxication with a PbB level of 1 330 µg/L was reported for one man melting and casting lead for several years (State of Alaska Epidemiology, 2001).

For shooters casting their own bullets the PbB increment was reported with 22 µg/L (Mathee et al., 2017), which is associated with a 15 % increase in the prevalence of chronic kidney disease and with an increase in systolic blood pressure of 0.7 mmHg.

For children living in the vicinity of persons melting lead to cast fishing sinkers, lures or bullets, increases of PbB levels ranged from 36 µg/L to ≥ 100 µg/L (Brown et al., 2005, Mathee et al., 2017, Yimthiang et al., 2019). Such PbB levels are associated with decreases in IQ points from 3 to > 8.

1.6.4.4. Risk from oral exposure to lead dust (hand-to-mouth) from shooting or handling lead ammunition or fishing tackle (use 7 only)

No data is available to quantitatively characterise the risk.

From occupational settings the oral uptake of lead dust by the hand-to mouth route and its contribution to the lead burden is well known.

Risk can be assumed to be highest from oral uptake of lead dust from shooting in shooting ranges and hygiene measures are an important tool to limit exposure.

The mean lead skin-to-saliva transfer efficiency was 24 % (range: 12–34 %) (Sahmel et al., 2015). Based on this study the hand-to-mouth exposure from lead dust on the skin from fishing tackle (and lead bullets or shots) is highly plausible.

1.6.4.5. Risk from oral exposure and/or swallowing of lead fragments (uses # 1, 3, 5, and 7)

High PbB levels of 530 and 650 µg/L have been documented for children following ingestion of small lead fragments intended to be used for hunting, sports shooting or fishing (Mowad et al., 1998, Rozier and Liebelt, 2019). Those incidences are acute intoxications that require medical treatment. No information is available on the impact of acute lead intoxication on the chronic lead burden in children and the resulting risk.

The habit to chew lead to attach it to the fishing line has been reported by many recreational fisher (Grade et al., 2019). The case of one recreational fisher who used to chew leaded fishing tackle and unintendedly swallowed tackle was reported with an acutely toxic PbB level of 1410 µg/L (Carrier et al., 2012).

For gun shooters using non-jacketed bullets training in indoor or outdoor shooting ranges, the PbB levels of shooters keeping lead bullets in their mouth were in mean 82 µg/l higher compared to shooters not keeping lead bullets in their mouth (Mathee et al., 2017).

1.6.4.6. Indirect exposure to humans via the environment

Risk from consumption of meat from game hunted with lead ammunition (uses # 1, 2)

In Table 1-50:, ECHA calculated the daily intake of lead from the consumption of game meat, the resulting incremental PbB levels, and the corresponding health impacts based on the following considerations:

- To calculate the daily intake of lead from game meat, ECHA has used the information from EFSA on the minimum, median and maximum (across surveys) 95th percentile of the chronic daily consumption of game meat in young children (infants and toddlers) and adults as a proxy for the consumption of hunter families that are high-frequency consumers of game meat as presented in Table 1-48.
- For the lead concentration in game meat, ECHA has used data from EFSA on the mean lower bound concentration of lead in game meat hunted with lead shots (0.366 µg Pb/kg meat; see also Table 1-43) and lead bullets (2.516 µg Pb/kg meat; see also Table 1-44: Concentration of lead in meat intended for consumption from game hunted with lead bullets in the EU (EFSA, 2020)), respectively. ECHA considers that the EFSA data on median lead concentration in game meat is not representative for the population at risk because this value does not reflect the consumption of game meat samples with high lead concentration. This is because when considering game meat consumption **over the whole year** hunter families will consume different parts of the game which may have very different lead concentrations ranging from no increased lead concentration to very high levels for meat produced from the area around the wound channel. Such a scenario is best reflected by using the mean value.
- ECHA notes that the mean value may be considered as a conservative approach. This is because the lead concentration in the EFSA data is highly skewed with a median lead concentration that is orders of magnitude lower than the mean value.
- For the calculation of PbB levels resulting from daily lead intake via game meat, ECHA has adapted the dietary intake values in µg/kg bw that correspond to the BMDLs reported in EFSA (2010) to the bioavailability of metallic lead. The following assumptions were made.

For **developmental neurotoxicity in children** aged ≤ 7 (reduction on IQ scale), EFSA (2010) concluded on a $BMDL_{01}$ (decrease in IQ by 1 point on the full scale IQ) of 12 µg Pb/L blood (1 µg/L = 0.083 IQ points). According to EFSA, 12 µg/L corresponds to a lead intake from diet containing soluble lead of 0.5 µg Pb/kg bw/day. Assuming 50 % bioavailability of metallic lead compared to lead ions for children results in the following relationship:

12 µg Pb/L blood ≙ 1 µg/kg bw/day.

For the increase of prevalence of **CKD in adults**, EFSA (2010) concluded on a $BMDL_{10}$ (10 % increase in the prevalence of CKD) of 15 µg Pb/L blood (1 µg/L = 0.667 % increase in the prevalence of CKD). According to EFSA, 15 µg/L corresponds to a lead intake from diet containing soluble lead of 0.63 µg Pb/kg bw/day. Assuming 10 % bioavailability of metallic lead compared to lead ions for adults:

15 µg Pb/L blood ≙ 6.3 µg Pb/kg bw/day ↔
2.4 µg Pb/L blood ≙ 1 µg/kg bw/day.

For the increase in **systolic blood pressure in adults**, EFSA (2010) concluded on a $BMDL_{01}$ (1 % change in SBP corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult) of 36 µg Pb/L blood (1 µg/L = 0.033 mmHg). According to EFSA, 36 µg/L corresponds to an intake of diet containing soluble lead of 1.5 µg/kg bw/day. Assuming 10 % bioavailability of metallic lead compared to lead ions for adults:

36 µg Pb/L blood ≙ 15 µg Pb/kg bw/day ↔
2.4 µg Pb/L blood ≙ 1 µg/kg bw/day.

In Table 1-50 the calculated mean values for daily intake of game meat for the 95 percentile population (used as proxy for hunter families), incremental PbB levels and resulting health impacts are summarised for children (infants and toddlers) and adults. The results indicate that the mean consumption of game hunted with lead shot results in a low impact with medium IQ losses of 0.24 and 0.41 IQ points for infants and toddler, respectively, whereas the mean consumption of game meat hunted with bullets has a much higher impact with mean IQ loss of 4.1 and 5.9 IQ points for infants and toddler, respectively. For adults, the mean increase in the prevalence of CKD is 0.9 and 6.3% for game hunted with shot and bullets, and the mean increase in systolic blood pressure would be 0.05 and 0.31 mmHg for game hunted with shot and bullets.

To take into account the strongly skewed underlying distribution, the full distribution of predicted PbB levels was taken forward to quantify the baseline risks and to monetise such risks (see section 2.5.2.1).

Table 1-50: Calculated mean values for daily intake, incremental PbB levels and health impacts from the consumption of meat from game hunted with lead bullets or shots in the EU based on data from EFSA (20.06.2020)

Popu-lation	Type of ammu - nition	Game meat consumption (g/kg bw and day; P95)[113]		Lead conc. in game meat (µg/g meat; mean Ub)[114]	Daily intake of lead (µg/kg bw/d; mean)	PbB level increment (µg/L: mean)	IQ point loss in children	Incr. preval. of CKD (%) in adults	Incr. in SBP (mmHg) in adults
Infants	Shots	Min	0.450	0.366	0.165	1.974	0.16	—	—
		Med	0.658	0.366	**0.241**	**2.887**	**0.24**	—	—
		Max	4.261	0.366	1.558	18.693	1.56	—	—
	Bullet	Min	0.891	2.516	2.242	26.898	2.24	—	—
		Med	1.667	2.516	**4.194**	**50.325**	**4.19**	—	—
		Max	2.147	2.516	5.401	64.816	5.40	—	—
Toddlers	Shots	Min	0.153	0.366	0.056	0.671	0.06	—	—
		Med	1.131	0.366	**0.413**	**4.962**	**0.41**	—	—
		Max	4.922	0.366	1.799	21.593	1.80	—	—
	Bullet	Min	0.114	2.516	0.287	3.442	0.29	—	—
		Med	2.219	2.516	**5.582**	**66.989**	**5.58**	—	—
		Max	5.245	2.516	13.195	158.341	13.20	—	—
Adults	Shots	Min	0.172	0.366	0.063	0.151	—	0.1	< 0.01
		Med	1.606	0.366	**0.587**	**1.409**	—	**0.9**	**0.05**
		Max	3.664	0.366	1.339	3.215	—	2.1	0.11
	Bullet	Min	0.252	2.516	0.634	1.522	—	1.0	0.05
		Med	1.560	2.516	**3.925**	**9.419**	—	**6.3**	**0.31**
		Max	6.597	2.516	16.596	39.831	—	26.6	1.32

A robustness check of the lead intake values obtained in the above calculations can be made by comparison to a study by Lindboe et al. (2012) that investigated the lead content of ground meat from moose (*Alces alces*) from 52 samples intended for human consumption in Norway and predicted human exposure through this source. In 81 % of the batches, lead levels were above the limit of quantification of 0.03 mg/kg, ranging up to 110 mg/kg. The mean lead concentration was 5.6 mg/kg, i.e. 56 times the EU limit for lead in meat. The lead intake from exposure to moose meat over time, depending on the frequency of intake and portion size, was predicted using Monte Carlo simulation. For consumers eating a moderate meat serving (2 g/kg bw), a single serving would give a lead intake of 11 µg/kg bw on average, with maximum of 220 µg/kg bw. Using Monte Carlo simulation, the median

[113] See Table 1-48.
[114] See Table 1-43 and Table 1-44: Concentration of lead in meat intended for consumption from game hunted with lead bullets in the EU (EFSA, 2020).

(97.5th percentile) predicted weekly intake of lead from moose meat was 12 µg/kg bw (27 µg/kg bw) for one serving per week and 25 µg/kg bw (45 µg/kg bw) for two servings per week. A weekly intake of 27 µg Pb/kg bw would result in a daily intake of 3.86 µg Pb/kg bw/day. This value corresponds well with the EFSA data for median game meat consumption by adult members of hunting households (3.9 µg Pb/kg bw/day).

Another sensitivity check was made by applying the All Ages Lead Model (AALM, v. 2.0), which is a simulation model developed by U.S. EPA that predicts lead concentration in body tissues and organs of hypothetical individuals based on simulated intake and lifetime of lead exposure.[115] According to U.S. EPA, "the purpose of the model is to provide risk assessors and researchers with a tool for rapidly evaluating the impact of possible sources of lead in a specific human setting where there is a concern for potential or real human exposure to lead". When applying the AALM model to simulate steady state PbB levels in high-frequency game meat consumers, the Dossier Submitter found a close agreement with the values predicted for infants and toddlers based on the EFSA (2010) relationship between chronic dietary intake and PbB level (12 µg Pb/L blood ≙ 1 µg/kg bw/day). For adults, PbB levels simulated with the AALM model were roughly a factor of two larger than those obtained with the EFSA relationship (2.4 µg Pb/L blood ≙ 1 µg/kg bw/day).

The data indicate that game meat consumption by hunter families can have a relevant impact on the neurodevelopment of young children. The performed calculations may be underestimated because they do not include lead exposure *in utero*. Furthermore, even if the estimate includes infants (under the age of 12 months), the mobilisation of the lead accumulated in the body of the lactating female hunter family member and its elimination with the milk might be underrepresented.

The data also indicate that game meat consumption by hunter families can have an impact on the incidence of chronic kidney disease in adults (males and females). The effects on the cardiovascular system might to be lower.

The impact of game meat consumption and the accumulation of lead in the body of female hunter family members at reproductive age on the offspring during pregnancy and the mobilisation of lead with elimination via the milk during lactation as addressed above is of concern. Consequently, advice is provided from national authorities such as French ANSES[116] or German BfR[117] that children and women at childbearing age should not consume game meat (see also sections B.10.2.2 and B.10.2.3).

Number of high-frequency consumers of game meat

Based on national statistics of the number of hunters, ECHA calculated that there are 6.0 million hunters in the EU-27 (Röschel et al., 2020). According to Eurostat data, the average household size in the EU-27 is 2.3. Thus, hunter families comprise about 13.8 million individuals (3.1 % of the EU-27 population). The number of female hunter family members at reproductive age is expected to be between 6.0 and 18.8 million.

As the share of the EU-27 population aged 7 or younger is approximately 8 % of the total population of and assuming an equal age distribution in hunter families as in the general EU population suggests that about 1.1 million children aged 7 or younger are particularly vulnerable to lead exposure.

[115] The software is downloadable under: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=343670
[116] https://www.anses.fr/en/content/consumption-wild-game-action-needed-reduce-exposure-chemical-contaminants-and-lead
[117] http://www.bfr.bund.de/cm/349/research-project-safety-of-game-meat-obtained-through-hunting-lemisi.pdf

Risk from consumption of contaminated drinking water (uses # 3, 4)

Risks for the consumption of lead contaminated drinking water may originate from the deposition of lead on and in soil of shooting ranges using lead gunshot or lead bullets with corrosion of lead and its mobilisation to surface water and groundwater.

For several shooting ranges a risk for human via the environment has been demonstrated. For example, in surface (run-off) water of US shooting ranges measured at retention ponds, measured lead concentrations were 8 µg/L, 289 µg/L and 694 µg/L (Ma et al., 2002), in Finnish shooting ranges total lead concentration was >50 µg/L in more than 60% of the samples (Kajander and Parri, 2014). Compared to the threshold of 10 µg/L for lead in drinking water (Directive 98/83/EC), such measured lead concentrations demonstrate a risk that requires appropriate RMM to avoid contaminated run-off water to be released to the environment.

In ground water from old shooting ranges in the US and Europe, lead concentrations above 1 000 µg/L have been reported (Soeder and Miller, 2003, Bavarian WWA Aschaffenburg, 2019), exceeding more than 100-times the background level in drinking water (Carlon, 2007). Such contaminations of the ground water usually require remediation of the soil to eliminate the risk to human health via drinking water.

Risk from consumption of contaminated food (uses # 1, 3, 4)

Risks for the consumption of lead contaminated food may also originate from the deposition of lead on and in soil of shooting ranges or from lead shot deposited on agricultural land with consequent uptake of lead by plants used for human consumption as well as the uptake of lead from soil or gras by grazing ruminants delivering milk and meat for human consumption.

A direct correlation between lead in soil and lead in plants has been reported (Bennett et al., 2007). In the biomass of spring barley (*Hordeum vulgare* L.) grown on shooting ranges, lead concentrations were 138 mg/mg in roots, 16 mg/kg in leaves, 4.2 mg/kg in stems and 2.4 mg/kg in spikes (Chrastný et al., 2010). Regulation 1881/2006 limits lead in cereals to 0.2 mg lead/kg food for human consumption, demonstrating that there is a risk for human health to consume food crown on shooting ranges.

In terms of potential for indirect exposure it is reasonable to assume that there is potential for cattle, and their products, containing elevated lead concentrations to enter the food chain, but only if they do not display overt clinical symptoms of lead poisoning that would otherwise result in their removal from the herd and disposal.

The potential exposure of humans to lead via the diet would be greatest for subsistence farmers (and their families) eating meat and dairy products derived entirely from a cattle herd with sub-clinical lead poisoning following exposure to lead ammunition via grazing on land used for shooting or the consumption of silage contaminated with lead shot. To assess the significance of exposure via this route a 'worst-case local scale'[118] exposure assessment was performed considering the scenario of an adult farmer and a young child consuming all their meat and dairy products from sub-clinically poisoned cattle.

Dietary exposure is typically calculated based on representative consumption rates for a variety of foodstuffs. Meat and dairy products are of most relevance in this scenario and

[118] Local scale is a typical worst case since all food products are derived from the vicinity of a point source (EUSES guidance)

consumption rates are taken from the EUSES model, which uses the highest country-average consumption rate from the EU Member States for each food as input to the assessment of exposure to chemicals from the diet.

- Adult daily intake of meat is 0.301 kg/d ww in EUSES; and
- Adult daily intake of dairy products is 0.561 kg/d ww.

Children are commonly the most sensitive receptors in the assessment of dietary exposure as they consume more in relation to their bodyweight and they may also be more sensitive to the toxic effects of the substance under assessment. This is a particular issue with lead as neurobehavioural effects in children (as measured by IQ score) are the most critical health effect (Lanphear et al., 2005). EFSA Scientific Committee (2012) guidance on parameter values for dietary exposure assessment indicates that a young child consumes 52.3% of an adult diet[119], which can be applied to modify the adult consumption values for meat and dairy products given in EUSES, i.e.:

- Child's daily intake of meat is 0.157 kg/d ww; and
- Child's daily intake of dairy products is 0.293 kg/d ww.

Cattle are only likely to show clinical signs of lead poisoning at PbB levels higher than 250 to 400 µg/L; a PbB level of 300 µg/L in cattle exposed to lead from ammunition is therefore unlikely to alert a farmer to the possibility of poisoning and result in its removal from the food chain. Blood lead level is the most common metric to represent lead poisoning but equivalent concentrations in meat and milk are required for dietary exposure assessment. Bischoff et al. (2014) presents a correlation between milk and blood lead concentrations[120] that suggests a cow with a blood lead level of 300 µg/L would produce milk containing 0.3 mg/L lead. Data from APHA indicates that the lead content of animal tissue from cattle with a similar blood lead level would be 10 - 20 mg/kg lead dw (for a mid-range value of 15 mg/kg dw this would equate to approximately 5 mg/kg ww based on water content of roughly 70 %). These calculated concentrations in meat and milk (including milk used for the manufacture of dairy products) are an order of magnitude higher than the maximum levels permitted for lead, which are 0.10 mg/kg ww in meat (0.50 mg/kg ww in offal) and 0.020 mg/kg ww in milk[121].

Table 1-51: and Table 1-52: detail the dietary exposure assessment for a subsistence farmer and a young child consuming meat and milk/dairy produce from cattle with a blood lead level of 300 µg/L. It should be noted that this assessment may underestimate the potential exposure from dairy produce as the concentration of lead in products such as cheese will be higher than that in milk.

Table 1-51: Dietary exposure assessment for subsistence adult (farmer)

[119] An average European toddler (1-3 years) weighs 12 kg and has a total mean food consumption rate of 114.4 g/kg bw/day; an average adult weights 70 kg and consumes 37.5 g/kg bw/day EFSA SCIENTIFIC COMMITTEE 2012. Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. *EFSA journal,* 10**,** 2579..

[121] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1881-20150521&from=EN

Foodstuff	Lead conc. (mg/kg ww)	Consumption rate (kg/d ww)	Lead intake (mg/d)	Bodyweight (kg)	Dietary lead exposure (mg/kg bw/d)
Meat	5	0.301	1.5	70	0.021
Milk/dairy	0.3	0.561	0.17	70	0.002
Total					0.023

The predicted dietary exposure to lead for an adult subsistence farmer under this scenario is 23 µg/kg bw/d, which is 15 times higher than the $BMDL_{01}$ established by (EFSA, 2012) for cardiovascular effects in adults (1.5 µg/kg bw/d) and 37 times higher than the $BMDL_{10}$ for nephrotoxicity effects (0.63 µg/kg bw/d).

Table 1-52: Dietary exposure assessment for the child of a subsistence farmer

Foodstuff	Lead conc. (mg/kg ww)	Consumption rate (kg/d ww)	Lead intake (mg/d)	Bodyweight (kg)	Dietary lead exposure (mg/kg bw/d)
Meat	5	0.157	0.785	12	0.065
Milk/dairy	0.3	0.293	0.088	12	0.007
Total					0.072

Under this scenario predicted dietary exposure to lead for a toddler is 72 µg/kg bw/d, which is more than 140 times higher than the $BMDL_{01}$ of 0.5 µg/kg bw/d established by (EFSA, 2012) for developmental neurotoxicity in young children.

This scenario illustrates that worst-case exposure estimates do not correspond with negligible potential exposure.

However, in the absence of evidence that this scenario could reasonably occur in practice in the EU, the Dossier Submitter considers this to be a hypothetical, illustrative, scenario, and which is not part of the main analysis.

1.6.4.7. Level of risk with regards to all uses

Except for game meat consumption, the available information is not sufficient to properly quantify the risks from the assessed uses. In the absence of additional data, the risks for human health associated with the use of lead gunshot or bullets for hunting, sports shooting and with the use of fishing tackle are therefore described and assessed in a semi quantitative manner by combining the potential for exposure with the frequency of exposure. The outcome of this analysis is reported in Table 1-53.

Inhalation of lead from shooting (uses # 1, 2, 3, 4, 5, 6): There is a risk from shooting of increased uptake of lead and consequent health effects. The risk is higher for the use of firearms (with lead-containing primer) compared to use of air weapons and is increasing with (i) the increasing calibre of the weapon, (ii) increasing shooting frequency and (iii) limited ventilation (see section 1.6.4.1). Considering that this restriction is focussing on outdoor shooting with natural ventilation and does not address the risks from primers, no high risk level is expected. It is assumed that the risk level increases with increasing shooting frequency. Consequently, it is considered that the risk level from inhalation of lead from hunting (uses 1, 2a, 2b) and shooting at temporary areas (uses 3a, 4a, 5, 6) with low shooting intensity is low (+) and moderate (++) for more frequent shooting at permanent outdoor sports shooting ranges (uses 3b, 3c, 3d, 4b, 4c) .

Inhalation of lead from home-casting (mainly uses #2, 4, and 7): In the absence of information on the incidence of home-casting of lead fishing tackle and lead bullets for hunting or sports shooting and the unknown concentration of lead in air from home-casting, only the semi-quantitative analysis was performed. Even though not all hunters/shooters/fishers are home-casting, there is a high exposure/risk from home-casting activities for the person performing the home-casting and for vulnerable population such as children who live with hunters/shooters/fishers. Information and case studies are mostly available for home-casting fishing tackle (see section B.9.2.6) which was promoted a few years ago (see section D.4.5.7 in the Annex). However, the same high lead exposure and risks can be assumed for home-casting of lead fishing tackle and lead bullets resulting in a high risk level (+++).

With regard to the home-casting of lead ammunition, the Dossier Submitter assumes that home-casting is mainly performed for large calibre bullets that do not require high accuracy such as for hunting (use 2b). For sports shooting where high precision is required and often small calibre bullets are used, home-casing is not likely to take place. However, for sports shooting with older or historical weapons (use 6) home-casting of bullets individually fit to the weapon can still be reasonably assumed to take place.

Lead enclosed in fishing nets, ropes and lines (use 8) is not home casted.

Hand-to-mouth intake (all uses): For most activities handling lead, there is a general risk for hand-to-mouth intake of lead dust. This risk is specifically high for lead dust formation while shooting with lead gunshot or bullets. Usually, good hygiene measures such as washing of hands, changing clothes, and avoiding smoking, drinking or eating are recommended for shooting activities to limit the risk. It can be reasonably assumed that with increasing shooting intensity the risk will increase. Therefore, the risk level is considered as low to moderate (+ to ++) in case of limited shooting intensity while hunting (uses 1, 2a, 2b) or sports shooting (uses 3a, 4a, 5, 6), and high (+++) in case of intensive shooting at permanent shooting ranges with high shooting intensity and high dust deposition at the range (uses 3b, 3c, 3d, 4b, 4c). For fishing (use 7) no shooting is involved. However, intensive handling of lead fishing tackle can be assumed, for which a skin-to-saliva transfer efficiency of 24 % was reported (Sahmel et al., 2015). Therefore, a moderate risk level (++) is assumed. Good hygiene practice such as hand washing, no smoking, drinking or eating during fishing could be expected to reduce the intake of lead. Nevertheless, these good hygiene practices are not communicated to consumers when they purchase lead sinkers and lures (ECHA market survey), and the guidance on safe use submitted in the REACH registration dossier, and published on ECHA dissemination website does not indicate neither any hygiene measures for consumers[122].

[122] Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/16063/9

For use 8, lead is enclosed in nets, ropes, and lines and therefore no direct contact between lead and the hand of the fishers occur.

Intoxication from ingestion (uses # 1, 3, 5, and 7): Incidental case reports for acute intoxication have been published (e.g., small lead shots, fragments) indicating a risk. Due to the low incidence of reported cases, the overall risk level is not considered as high, even if the reported effects (intoxication) are of high concern. A relevant criterion is availability of lead fragments of ingestable size for children; of concern for potential ingestion are lead gunshot (uses 1, 3), lead air pellets (use 5), and small lead fishing tackle (use 7). It is noted that the safe storage of lead gunshot and lead fishing tackle at home is crucial to prevent inadvertent ingestion by children. However, the reported cases of children with intoxication from small lead items (Gummin et al., 2017, Rozier and Liebelt, 2019, Treble and Thompson, 2002) (see section 1.6.3.5) clearly demonstrate that this might not necessarily be the case. Therefore, a moderate risk level (++) is assumed. This relates also to the habit of many fishers to bite lead sinkers (use 7) to attach them to the fishing line (Grade et al., 2019, Carrier et al., 2012) and the possibility to swallow such fragments.

Indirect exposure via the environment:

Game meat consumption (uses # 1 and 2): European hunters generally follow "best practice", as advised by several wildlife authorities, when handling game meat. Depending on the cut, lead concentrations in game meat intended for consumption can be very different. The available data indicate that even if prepared under best practices a relevant proportion of game meat (Pain et al., 2010)has substantially higher lead concentrations than the regulatory maximum level for lead in meat (0.1 mg Pb/kg meat). Around 13 % of the game meat in the EFSA database showed lead concentrations above this maximum level (see sections B.9.2.1 and B.9.2.2 in the Annex). Of specific concern are individual samples with lead concentrations above 1 000 mg/kg, specifically from deer and wild boar (see section B.9.2.2). Based on data from the EFSA database on lead concentration in game meat, on the intake of game meat (95th percentile used as a proxy for persons of a hunter household), and assuming lead metal bioavailability of 10 % for adults and 50 % for children, ECHA calculated for children a blood lead level increase which has a relevant impact (+++) on IQ with a loss of more than 2 to more than 4 IQ points for consumption of game meat bagged with bullets (use 2b). For game bagged with gunshot (use 1), the data indicate a lower risk with IQ loss of 0.2 to 0.4 IQ points (see section 1.6.4.6.1). However, since there is no evidence for a threshold of lead for developmental neurotoxicity in children, the risk arising from the consumption of game meat bagged with gunshot is also considered to have a relevant impact (+++).

There could also be risks to humans via the environment via the intake of **food** grown on soil contaminated from shooting activities and from **drinking** water contaminated from lead from shooting ranges. The risks are assumed to increase with increasing deposition and in case of contaminated food, the use of contaminated areas for agriculture. The risks are assumed to be low (+) in case of hunting with bullets because the bullets (uses 2a and 2b) typically remain in the carcass of the game. For hunting with shot (use 1) and for temporary shotgun areas (use 3a), the risk might be low to moderate (+ to ++) depending on the amount of gunshot deposition on terrestrial areas that might also be used for agricultural purposes and the corroding gunshot might lead to contamination of surface water. In the case of permanent shotgun ranges with high shooting intensity but without any environmental risk management measures (use 3b), there is a high risk (+++) of contamination of surface water and potentially groundwater under certain circumstances and in case of agricultural use also a risk for contamination of food. At permanent shotgun ranges (use 3c) the risk is considered moderate (++) due to risk management measures in place to prevent run-off of contaminated surface water; however, accumulation of gunshot in soil (with potential groundwater contamination) and effects on food in case of agricultural use of the range might still occur that might potentially lead to a higher risk (+++). For permanent shotgun ranges (use 3d) the risk is considered low (+) because risk management measures are in place to prevent surface water and ground water contamination and the agricultural use of the range area is banned. For rifle and pistol ranges, the risk is depending on the type of bullet containment. In case appropriate bullet traps are used, the risk can be considered as controlled (+), whereas in the case of soil berms used to trap bullets, moderate to high risks (based on shooting intensity) can be assumed due to mobilisation of lead to surface water and to soil. Consequently, for a temporary rifle/pistol range (use 4a) trapping bullets in a soil berm the risk is considered to be between low (+) and moderate (++) and for a permanent rifle/pistol range with intensive shooting (use 4b) high (+++). Depending on the type of bullet trap the risks for outdoor shooting with air rifle (use 5) and for other outdoor shooting activities (use 6), the risks vary from low to medium (+ to ++), assuming limited shooting intensity.

To describe the level of risks occurring, the following qualitative ranking is used: +: negligible to low risk or risk controlled; ++: moderate risk; +++: high (main) risk; N/A: not applicable.

Table 1-53: Semi-quantitative judgment on the level of risks related to the use of lead for hunting, outdoor sports shooting and fishing

Use #	Use description	Inhalation		Oral intake		Exposure via environment	
		Outdoor shooting	Home-casting	Hand-to mouth (dust)	Ingestion (frag-ments)	Game meat cons.	Drinking water, food
1	Hunting with shot	+	N/A	+ to ++	++	+++	+ to ++
2a	Hunting with bullets - small calibre	+	N/A	+ to ++	N/A	N/A	+
2b	Hunting with bullets - large calibre	+	+++	+ to ++	N/A	+++	+
3	Outdoor sports shooting - gunshot						
3a	Temporary shotgun areas, no RMM, limited shooting intensity	+	N/A	+ to ++	++	N/A	+ to ++
3b	Permanent shotgun areas, no ENV RMM, intensive shooting	++	N/A	+++	++	N/A	+++

Use #	Use description	Inhalation		Oral intake		Exposure via environment	
		Outdoor shooting	Home-casting	Hand-to mouth (dust)	Ingestion (frag-ments)	Game meat cons.	Drinking water, food
3c	Permanent shotgun range, ENV RMMs in place: - prevent rivers from crossing - control water runoff - lead deposition within range - remediation plan upon closure	++	N/A	+++	++	N/A	++ to +++
3d	Permanent shotgun range, ENV RMMs in place (in addition to 3c): - regular (annual) collection of lead shot (>90% effectiveness) - monitoring and treatment of surface (runoff) water - ban of agricultural use within site boundary	++	N/A	+++	++	N/A	+
4	Outdoor sports shooting - bullets						
4a	Temporary rifle/pistol areas, limited shooting intensity:						
	- use of soil berm to trap bullets	+	N/A	+ to ++	N/A	N/A	+ to ++
	- use of bullet traps	+	N/A	+ to ++	N/A	N/A	+
4b	Permanent rifle/pistol ranges, intensive shooting: - use of soil berm to trap bullets	++	N/A	+++	N/A	N/A	+++

Use #	Use description	Inhalation		Oral intake		Exposure via environment	
		Outdoor shooting	Home-casting	Hand-to mouth (dust)	Ingestion (frag-ments)	Game meat cons.	Drinking water, food
4c	Permanent rifle/pistol ranges: - use of bullet traps - ban of any agricultural use within site boundary	++	N/A	+++	N/A	N/A	+
5	Outdoor shooting air rifle/pistol (assuming low shooting intensity)	+	N/A	+	++	N/A	+ to ++
6	Other outdoor shooting activities (assuming low shooting intensity)	++	++	+	N/A	N/A	+ to ++
7	Fishing sinkers and lures	N/A	+++	++	++	N/A	+
8	Fishing nets, lines and ropes	N/A	N/A	N/A	N/A	N/A	N/A

1.7. Justification for an EU wide restriction measure

The four main justifications for an EU wide restriction measure are:

1. To ensure a harmonised high level of protection of the environment and human health to address the identified risks
2. To address the lack of EU wide commitment to fulfil the Birds Directive commitment towards the protection of birds and their habitats
3. To ensure the free movement of goods within the Union
4. To ensure a level playing field for all engaged in sports shooting

As demonstrated in the previous sections, lead in ammunition and lead in some uses of fishing tackle (such as sinkers and lures) present risks to the environment and human health, in particular to vulnerable populations such as children, which are not adequately controlled.

With regard to the risk for the environment, some species, such as waterfowl, game birds and pigeons, ingest spent gunshot, or fishing tackle incidentally along with the grit needed to digest food and may die from lead poisoning. Poisoned birds are also an easier prey for predators and scavenger birds which then might be affected by lead toxicity as well.

A Union-wide action to address the environmental risk associated with lead gunshot spent outside of EU wetlands is needed to ensure a harmonised level of protection. In a recent restriction proposal (use of lead shot in wetlands) it was concluded that even with a broad definition of wetlands, the risk to water birds and various AEWA species is not completely addressed as many species forage outside of wetlands and would therefore still be at risk of ingesting lead. Since the flyways of these migratory birds and many other species cross several Member States, regulating the risk to them at Union level is likely to ensure the needed protection all over the EU.

A Union-wide action will also support implementation of the European Birds Directive[123] which states in article 4.4 that ' (…) Member States shall take appropriate steps to avoid pollution or deterioration of habitats or any disturbances affecting the birds (…) Member States shall also strive to avoid pollution or deterioration of habitats.'

The EU is a signatory party to the AEWA, CMS[124], and CMS Raptor[125] MOU (since 2005, 1983 and 2011, respectively) Union-wide action would guarantee the effective implementation of these agreements/memoranda. Managing risks on a Member State level would typically result in national regulations that differ with regards to their effectiveness. A harmonised

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[123] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:020:0007:0025:EN:PDF

[124] The Convention on Migratory Species (CMS/Bonn Convention) is an Intergovernmental treaty which aims to conserve terrestrial, marine and avian migratory species throughout their range, on a global scale. Appendix I of CMS lists migratory species threatened with extinction: Parties strive towards strict protection of the species, their habitats and conservation/restoration/mitigation actions. Appendix II lists migratory species that need or would significantly benefit from international co-operation. CMS acts as a framework Convention. The agreements may range from legally binding treaties (called Agreements) to less formal instruments, such as Memoranda of Understanding.

[125] Signatories to the Raptors MOU (Memorandum of Understanding on the Conservation of Migratory Birds of Prey in Africa and Eurasia) commit to adopting and implementing measures to conserve migratory birds of prey and their habitats, including for example, providing a legal framework to protect migratory species, and, developing cooperative international projects and initiatives to promote effective conservation efforts. In December 2019, there were 60 Signatories to the Raptors MoU, including the European Union (since 2011), and 17 individual EU Member States. Of the 93 species covered by the Raptors MOU, 44 occur in Europe.

restriction proposal will ensure a consistent and effective approach.

A further reason to act on a Union-wide basis is related to the health risk posed by lead in particular to children, where there is no safe level of ingestion for neurodevelopmental effects. Adult and child exposure to lead might happen via (i) the exposure to lead fumes during lead fishing tackle home-casting activity, and (ii) the consumption of game meat contaminated with lead from bullets or shot. Regarding this latter risk associated with game consumption, it pertains particularly to hunter families, especially to their children. This is especially the case for those engaged in subsistence hunting.

This issue cannot be dealt with by regulating the maximum level (ML) of allowable lead in food, under Regulation EC1881 (2006). Although MLs have been set for foodstuffs derived from wild game, wild game itself is not in the list (Thomas, 2013). It has been shown that lead concentrations in game meat frequently exceed the relevant ML of 0.1 mg/kg, set for lead in other meat from domestically raised animals (Pain et al., 2010, EFSA, 2020). For example, EFSA (2020) reported mean upper bound lead concentrations in game meat of 0.366 mg/kg for 2 574 meat samples from small game usually hunted with shot and concentrations of 2.515 mg/kg for 10 334 meat samples from large game hunted with bullets. In Gerofke et al. (2018) the highest concentrations measured were 113 mg/kg for pheasant and 5 309 mg/kg for deer.

Although the issues surrounding the use of lead for hunting are known and, in some cases, lead to voluntary actions, such as in the UK. The understanding of the Dossier Submitter is that the market on itself will not self-regulate and regulatory action is required. Given these arguments, there seems to be a justified reason to address the issue at the source: lead bullets and lead shot (Giuggioli et al., 2017).

With regards to sports shooting, action at EU level is warranted to ensure a consistent high level of protection across the EU. The risks posed by the use of lead in shooting ranges affect the same receptors (i.e. surface and groundwater) that are typically regulated under EU wide legislation.

With regard to lead in fishing tackle, in EU27-2020, the voluntary commitment from the sector[126] to phase-out lead from fishing tackle by 2020 did not lead to any action nor reduction of the risk, and there is currently no EU wide measure in place to address the risks of lead in fishing tackle. The only current legally binding ban on lead in fishing tackle is in Denmark where all type of fishing tackle used in both commercial and recreational fishing are banned from import and placing on the market (cf. Annex D). In addition to the Danish Regulation, some local ban also exists in specific rivers or lakes in Sweden, for example.

Some voluntary national initiatives and agreements also emerge, for example in Benelux countries (CfE #1034 - Vlaams Instituut voor de Zee), which encourage the use of alternatives to lead fishing tackle. Nevertheless, none of these initiatives set a concrete total phase-out of lead in fishing tackle, and they are currently not legally binding, which means that the compliance with these national agreements and initiatives are not legally enforceable.

Last but not least despite the fact that a number of fishers are willing to pay more to replace their current lead fishing tackle by more environmentally friendly ones (cf.

[126] In June 2015, EFTTA called on the fishing trade and the angling community to voluntarily stop manufacturing, importing, retailing and using angling weights (sinkers) made of lead above the size of 0.06 grams and replace them with suitable lead free alternatives by 2020 at the latest. https://www.eftta.co.uk/media-centre/news/eftta-position-statement-on-angling-lead-weights-sinkers

Annex D), stakeholders indicate that there is no incentive to switch to non-lead fishing tackle as long as the use of lead is not banned by a Regulation (e.g. CfE #909 - Sportvisserij Nederland, #1247 - Wildfowl & Wetlands Trust, ECHA market survey). For the manufacturers, further market incentives to develop and place on the market non-lead fishing tackle can be encouraged by announcing a phase-out of lead, with a concrete end date (Grade et al., 2019).

Another important underlying principle to consider is that measures that are introduced at EU level are more effective than a ban in few European countries, as it becomes also better known to non-EU countries importing into the EU, rather than a specific national ban. Compliance is consequently improved. The EU internal market is also promoted by harmonising European Community rules, rather than national specific rules.

Therefore, for all these reasons, an EU wide action is justified.

1.8. Baseline

1.8.1. Baseline for lead in hunting

In the call for evidence, little information was submitted on the actual volume of lead used in the said activities itself, which would be the best possible estimation of emission of lead. The Dossier Submitter therefore estimated the amount of lead released based on the previous assessment (for the wetlands dossier) and based on hunting statistics.

The baseline scenario describes how the use of lead would evolve in the absence of any regulatory action.

1.8.1.1. Gunshot

The use of lead in shot for hunting is still widespread: its perceived ballistics performance in combination with the lower price of lead has a consequence that many hunters prefer to shoot with lead and are not inclined to start using steel on their own initiative.

An observation in a paper from Thomas (2013) states that the use of non-toxic ammunition usually advances only when the use of lead is regulated. In that respect there are some current actions that could have an impact on the trends in the use of alternatives to lead shot:

1. The use of lead shot is impacted by an upcoming restriction on the use of lead over wetlands[127]. This will have an impact on the extent to which hunters will be able to use lead shot and may encourage them to use alternatives to lead shot also outside of wetlands as alternatives become more attractive, both in terms of availability as well as in price.
2. In the UK a voluntary initiative has been proposed by several of the larger hunting associations to phase out the use of lead within five years (by 2025), inspired by an increasing concern on the effects of lead on wildlife and human health. Also in more practical terms, pressure has increased from supermarkets to supply game meat that is free from lead. Although the UK is outside of the EU as of the first of January 2021, this UK initiative is still of importance for the EU market as their initiative will create

[127] Currently the 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, has been published. In Annex XVII to Regulation (EC) No 1907/2006, in entry 63, the conditions of the restriction are available.

an increased demand for non-lead shot and hence increase the availability of alternatives to lead shot and lower their prices. Next to this the organisations leading this voluntary move have asked the CIP[128] to approve additional shot size and gauges.

In the dossier concerning the use of lead in wetlands, the Dossier Submitter based on information from industry, estimated that around 21 000 tonnes of lead were released per year in lead shot cartridges for hunting. A share of that volume is addressed under the proposal on lead over wetlands, the remaining share of that volume is addressed in the current dossier.

Given that the proposed restriction on the use of lead in wetlands addressed a volume of 5 000 to 7 000 tonnes of lead per year, the Dossier Submitter estimates that the total amount of lead that is released by hunters in the EU-27 after the implementation of the wetland restriction is in the order of 14 000 tonnes per year with low and high estimates ranging from about 13 000 to about 15 000 tonnes per year.

Assuming a release over 20 years would result in about 280 000 tonnes (260 000 - 300 000 tonnes). Detailed information on the baseline is available in Annex D.

1.8.1.2. Bullets

Even though most hunters are still considered to be using lead bullets (copper jacketed) there is a moderate growing trend in the use of copper bullets. This trend is inspired by a desire of hunters to have better performance bullets. Copper bullets are considered to perform better as their mass retention is higher. Besides this, there is a growing concern about the consumption of game meat that contains lead. Advice from hunting associations and food safety agencies have led some hunters to use non-lead bullets.

Despite this decrease in the use of lead bullets, the global trend in using non-lead ammunition is in the order of 10 % of bullets used, i.e. an estimated 10 % of all hunters in the EU-27 use non-lead bullets. In some areas, where there are local or regional regulations on the use of lead ammunition this percentage can be higher; in Finland this percentage can be as high as 20 % (whilst in neighbouring Sweden the global use is about 2 %). Information received in the call for evidence would suggest that the overall global use in Europe is about 10 %.

Like for lead shot, a few developments are expected to have a positive influence on the availability non-lead rifle ammunition.

1. The Danish hunting association together with ministry of the environment recently announced an initiative to phase out the use of lead in bullets for hunting from 2023.
2. The German Bundesrat has expressed that the use of lead in hunting ammunition should be reduced and that this can be achieved at reasonable cost within foreseeable time as there is sufficient non-lead hunting ammunition on the market.

The estimate baseline tonnage of lead use per year is based on hunting statistics (i.e. the number of animals hunted per year in the EU-27) combined with assumptions on the weight and use of lead bullets. A similar approach for estimating the volume of uses was applied by

[128] The Commission internationale permanente pour l'épreuve des armes à feu portatives ("Permanent International Commission for the Proof of Small Arms" – commonly abbreviated as C.I.P.) is an international organisation which sets standards for safety testing of firearms. (The word portatives ("portable") in the name refers to the fact the C.I.P. tests small arms almost exclusively; it is ordinarily omitted from the English translation of the name.) As of 2015, its members are the national governments of 14 countries, of which 11 are European Union Member States. The C.I.P. safeguards that all firearms and ammunition sold to civilian purchasers in Member States are safe for the users.

Environment Canada[129] and an estimate of this kind has also been submitted in the call for evidence by the Finnish hunting association. Based on these sources as well as on the earlier work done in the framework of ECHA's screening report, the Dossier Submitter estimated the amount of lead release to the environment for hunting with **small calibre bullets** to be around 24 tonnes per year with low and high estimates ranging from 16 to 26 tonnes per year. Assuming a release over 20 years would result in 480 tonnes (320 – 520 tonnes).

For hunting with **large calibre bullets** the annual release to the environment is around 122 tonnes per year with low and high estimates ranging from 110 to 142 tonnes per year. Assuming a release over 20 years would result in 2 440 tonnes (2 200 – 2 840 tonnes).

1.8.2. Baseline for lead in sports shooting

Legislations in place to regulate the specific use of lead shot in sports shooting can be summarised as following:

- In Sweden, Norway and Denmark the use of lead shot in shooting ranges is banned in the entire territory (with some derogations in place; see below);
- In the Netherlands the use of lead shot is banned for clay pigeon shooting.
- In Belgium, in the Flemish region, there is a regional ban for the entire territory.

According to the responses of Member State Competent authorities provided in the MS survey 2020 (Annex E.5), the following derogations have been granted:

- in Denmark derogations have been given to the Danish Shooting Union (DSU), for use of lead shot on their shooting ranges, as the International Shooting Sport Federation (ISSF) does not allow the use of alternative shot in such international competitions including the Olympic games. DSU applied a derogation for hosting a Compak sporting competition[130]; the international shooting organizations (FITASC) rules for such competitions require to use lead shot. However, no derogation was granted for training; the Danish athletes in this discipline are training with steel shot.
- In Sweden the following exemptions apply: exemptions in Regulation SFS 1998:944 related to shooting tests, hunting trail shooting, hunter's examination with approved test leaders; and exemptions in Regulation NFS 2002:18 related to licensed shooters representing Sweden at international competitions in skeet, trap and double trap. This derogation applies to both training and competition.
- In Norway derogations have been granted to organisations for training to and participation in international competitions for which lead shot is the only allowed ammunition.
- In the Netherlands derogations are granted for professional athletes.
- In Belgium, in the Flemish region, derogations are granted only if the environmental permit allows this use, and this is only possible if extra measures are in place to collect fired shots.

Other more generic legislation (not specific to address lead contamination related issues) identified by ECHA are the following ones:

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[129] https://www.canada.ca/en/environment-climate-change/services/management-toxic-substances/list-canadian-environmental-protection-act/lead/using-more-lead-free-ammunition/lead-ammunition-executive-summary.html

[130] According to Wikipedia Compak Sporting is a "compacted" form of sporting clays, which is a shotgun sport usually spread over 12 to 36 stations (shooting areas) occupying around 200 acres (0.81 km^2), presenting 2 or 3 different clay targets at each.

- In Cyprus, a national ban on the use of lead bullets at shooting ranges is in place for the entire territory.

In other Member States, the use of lead in sports shooting is not regulated under a specific nationwide legislation. However, some environmental legislations may apply to control or minimize some risks (mainly to groundwater) during the service life and/or end of life of a shooting range. In Finland for example, an environmental permitting system has been set up in which larger ranges are evaluated on the use of lead ammunition. A review of some of the old permits is foreseen (Finnish sports shooting Association, 2020). In Germany a system has been put in place with guidelines (to some extent binding such as German BMI (2012)) that set the conditions under which lead can be used by prescribing the design of shooting ranges.[131]

1.8.2.1. Gunshot

It is estimated that there are about 4 000 clay target shooting ranges in the EU. See Annex B (section B.9.1.3) for details.

The estimated annual amount of lead shot released to the environment at shotgun ranges is about 35 000 tonnes (26 000 – 45 000 tonnes). See section 0 for details.

Assuming a release over 20 years would result in 700 000 tonnes (520 000 – 900 000 tonnes) of lead released to the environment.

In the absence of a restriction it is not expected that more risk management measures would be implemented to collect lead gunshot because the measures are costly and would therefore not be implemented without a legal requirement.

1.8.2.2. Bullets

It is estimated that about 16 000 pistol/rifle shooting ranges exist in the EU. This is the best estimate the Dossier Submitter could obtain based on various stakeholders surveys (MS survey 2020 and stakeholders questionnaire 2020 as described in Annex B (section B.9.1.3).

The estimated annual amount of lead bullets released is about 42 000 tonnes (4 000 – 80 000 tonnes). See section 0 for details.

Assuming a release over 20 years would result in 840 000 tonnes (80 000 – 1 600 000 tonnes) of lead deposited in the environment.

In the absence of a restriction it is not expected that more risk management measures would be implemented to collect lead bullets in bullet traps. In the CSR (2020) bullet traps are mentioned as a compulsory measure; however, it is assumed that bullet traps are only implemented in 30 to 50 % of the ranges in the EU (section 0). Since bullet traps are costly, it is not expected that - without a legal requirement - more bullet traps would be installed.

1.8.3. Baseline for lead in fishing tackle

The baseline scenario below describes the situation in the absence of restriction for the different uses identified for lead in fishing activities, i.e fishing with sinkers and lures, fishing with nets, ropes and lines, and finally home-casting of lead fishing tackle. Detailed information to support the baseline is available in Annex D.

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131 Various guidance have been identified by the Dossier Submitter and are listed in the section on Risk Management Measures.

1.8.3.1. Fishing with lead sinkers and lures (recreational and commercial fishing)

Sinkers and lures are used both for recreational and commercial fishing. The market for such fishing tackle has remained stable for the past two decades. Overall, in Europe, the number of fishers remains also stable despite some significant decrease reported in some countries. It is estimated that there are currently between 12 and 23 million recreational fishers in Europe: 6 - 17 million in freshwater and 6 million in marine water (see Annex A). In addition to the recreational fishing, it is estimated that about 14 000 vessels are fishing using lead fishing sinkers and jigs for commercial fishing activities (see Annex A).

It should be noted that even if the number of recreational fishers remains stable, the makeup of the population of fishers changes also over time, with people leaving or entering recreational fishing[132], this phenomena is also known as the 'Leaky Bucket'. The 'Leaky Bucket' illustrates the annual turn-over of fishing participants, or in other words the fact that some fishers are joining/re-joining the fishing activity and others are quitting every year. For example, in the US (phenomena reported in Europe but no consolidated data available), new participants represents 6 % of the fishers every year, and returning ones about 10 % (after one or several years without any fishing activity) (US, 2018).

During the ECHA market survey, some stakeholders described the market as 'steady' or 'stagnant' with an increased proportion of lead fishing tackle imported from outside Europe. The increase proportion of import could be confirmed when looking at the same Eurostat data between 2004 and 2020 (cf. Annex A and D).

The ECHA market survey, and the call for evidence, confirmed that the market for fishing tackle is still dominated by lead tackle in most of the EU countries, except where a national ban is currently in place (e.g. Denmark, and UK outside EU27-2020). Lead remains indeed very popular with fishers because it is cheap, it performs well, it is versatile and none of the non-lead alternatives currently offer the overall performance of lead tackle in terms of mass density, malleability, ease of production and cost.

There are also examples where companies developed, and placed on the market alternatives, but did not achieve a breakthrough in the market despite a functional material and a competitive price. Retailers have indeed no incentive to remove totally lead fishing tackle from their shops as this would imply, in the current situation (i.e. in the absence of regulatory action), a loss of both customers and sales due to the alternative being more expensive and having lower density (experience from a Swedish retailer Fladen Fishing AB in 2007 reported in (KEMI, 2007)).

The market for fishing tackle is changing, even if this change is extremely slow. While lead fishing tackle may still constitute the largest percentage of the fishing tackle market, over the last decade the availability of sinkers and lures made from other materials has expanded, and new non-lead products have entered the market. Nevertheless, despite the production of lead alternatives by several suppliers (cf. Annex D on alternative availability), most retailing shops and websites are not stocking these products and/or carry only a very limited selection (if any). Information submitted during the call for evidence indicates that the use of lead in fishing tackle remains widespread in Europe. For example, a recent survey carried out in Belgium by VLIZ (Flanders Marine Institute) indicates that 6 % of anglers only currently use alternatives (CfE #1034 - Vlaams Instituut voor de Zee).

[132] https://library.wur.nl/WebQuery/wurpubs/fulltext/466439

Considering the Danish or UK situation as an example, one may expect that lead fishing tackle will probably keep on dominating the European market as long as lead is legal because it is widely available, it works well for fishing, it is cheap, there is currently no market incentive at the EU level to switch to alternatives. There is also here a lack of public awareness on lead hazard for the environment and human health.

The underlying drivers of the lead fishing tackle baseline are complex, with several factors leading to one or another direction. The baseline scenario adopted for the analysis is therefore that, in the absence of an EU-wide restriction, lead will continue to be used and placed on the market as fishing sinkers and lures in the same order of magnitude as today. Since the releases in the environment are essentially due to unintentional loss by the fisher (inherent to the fishing practice itself), the Dossier Submitter assumes that the loss of lead fishing tackle in the environment will therefore remain stable during the 20-year analyticalperiod used for the impact assessment.

It is estimated that 3 000 tonnes (2 000 – 7 000 tonnes) of lead sinkers and lures would be lost annually to the environment, which corresponds to a total of 60 000 tonnes (40 000 – 140 000 tonnes) during a 20-year analytical period in EU27-2020 (cf. Annex D).

1.8.3.2. Fishing with lead nets, ropes and lines

Lead nets, ropes and lines are essentially used for commercial fishing, and in marine water.

Lead is encapsulated in fishing nets in long ropes, head ropes, so that the net is vertical in the water. Sinker lines containing lead are also available. In some trawling, lead is used to weigh the trawl down on the bottom. Purse seine is a long net with floats at the top and lead sinkers at the bottom (cf. Annex A).

The current European use of lead for nets, ropes and lines is estimated between 9 000 and 18 000 tpa and has decreased in the past decade. This quantity is based on assumptions on the fishing fleet of the Member States (Eurostat data) and how much lead is contained in the different commercial lead nets, ropes and lines (Tateda et al., 2014). This figure is probably an overestimate as not all nets, ropes and lines on commercial vessels are made out of lead. The Annex D details the assumptions and calculations performed by the Dossier Submitter.

Lead fishing nets, ropes and lines might be lost in the environment (aka 'ghost nets') but no major wear and tear occurs during the use of these fishing tackle (CfE #1220 - Danish EPA). It is estimated that currently around a fifth of lead fishing nets, ropes and lines are lost yearly by commercial fishers (EU Commission, 2018).

The newly adopted EU 'Single Use Plastic and Fishing Gear' Directive (EU) 2019/904 (aka SUP directive) is also addressing the issue of fishing gear[133] that are lost or disposed in the sea. The SUP Directive sets an extended producer responsibility (EPR) schemes which aims for the fishing gears at setting a minimum collection rate of 50 % and a recycling target of 15 %, both to be met by 2025[134]. This goal is supported by the Directive (EU) 2019/883[135]

[133] 'fishing gear' is defined in (EU) 2019/904 as 'any item or piece of equipment that is used in fishing or aquaculture to target, capture or rear marine biological resources or that is floating on the sea surface, and is deployed with the objective of attracting and capturing or of rearing such marine biological resources'

[134] https://www.europarl.europa.eu/legislative-train/theme-new-boost-for-jobs-growth-and-investment/file-single-use-plastics-and-fishing-gear-reducing-marine-litter-from-plastics

[135] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L0883&from=EN

which aims at protecting the marine environment against the negative effects from discharges of waste from ships, by improving the availability and use of adequate port reception facilities and the delivery of waste to those facilities.

The SUP Directive is also requesting the development of a standard on the circular design of fishing gear, and the duty for Member States to organise and put in place Awareness Raising activities.

Even if the directive is initially intended to reduce plastic waste and is targeting fishing gear containing plastic/polymer (cf. Article 2 of SUP Directive), the scope and intention of the SUP Directive is broad enough to impact in a positive manner the nets, ropes and lines made of both plastic and lead.

The baseline scenario adopted for the analysis is therefore that, in the absence of an EU-wide restriction, and thanks to the implementation of the SUP Directive that could indirectly benefit to this restriction proposal, lead use in fishing nets, ropes and lines will decrease over time. For the same reason, the releases in the environment due to unintentional loss by the fishers is assumed to decrease steadily over a 20-year period from 3 000 tonnes in 2022 to 1 500 tonnes in 2041 (assuming a 50 % drop in loss by 2025), which corresponds to a total release of **34 500 tonnes (23 000 – 46 000 tonnes) during the 20-year analytical period in EU27-2020** (cf. Annex D).

1.8.3.3. Home-casting of lead fishing tackle (consumer use)

As long as home-casting, and the sale of home-casting equipment and lead ingot and scrap is legal, home-casting will remain a popular Do It Yourself activity for fishers. The main reason is that home-casting is easy and cheap to do, and there is currently a lack of public awareness on lead hazard for human health from home-casting activity.

There is no indication on the scale of the home-casting practice in Europe (cf. Annex A).

For the baseline, it is assumed that this activity will remain stable during a 20-year period. Due to lack of data, no quantification is made, only a trend is given.

1.8.4. Baseline release estimates for all uses

Based on the previous details, the estimated releases and exposures in case of absence of a restriction are summarised in the tables and figures below. The numbers indicated in brackets correspond to the lower and upper boundary of the baseline estimates.

Table 1-54: Baseline release estimate to the environment over the 20-year period

Type of use	Quantity released to the environment over 20 years(tonnes)
Lead in hunting (gunshot)	280 000 (260 000 - 300 000)
Lead in hunting (bullets – small calibre)	480 (320 – 520)
Lead in hunting (bullets – large calibre)	2 440 (2 200 – 2 840)
Lead in sports shooting (gunshot)	700 000 (520 000 – 900 000)
Lead in sports shooting (bullets)	840 000 (80 000 – 1 600 000)

Type of use	Quantity released to the environment over 20 years(tonnes)
Lead in fishing	94 500 (63 000 – 186 000)
Total	**1 937 400**

1.8.5. Impacts on birds

Member States are required to report to the European Commission on the population sizes of all wild bird species that are naturally present in the EU Member States (Council Directive 2009/147/EC of April 1979, amended in 2009, on the conservation of wild birds "Birds Directive") every six years. For the latest cycle, Member States submitted their information from 2013 to 2018 in mid-2019 by application of the format established in 2011 and updated in 2016. The results have been published in 2020[136].

According to a guideline document by the Directorate-General for Environment (*Reporting under Article 17 of the Habitats Directive: Explanatory notes and guidelines for the period 2013-2018*) the assessment of the bird species population status on EU level is based primarily on species breeding-season data (DG Environment, 2017). Winter population data is only reported for a subset of taxa, called the key wintering species[137] (DG Environment, 2017). Most of the key wintering species are migratory species that either do not breed in the EU or are significantly more abundant here during winter, and species gathering in large flocks on a limited number of specific areas and are therefore easier to monitor (Röschel et al., 2020). In general, birds can be much more mobile during the winter season due to weather and food availability, which could potentially complicate the aggregation of the Member States' data (Röschel et al., 2020).

Number of bird individuals at risk of poisoning across EU 27-2020 from lead ammunition and fishing tackle can be found in the following table. The assessment considered different relevant exposure sources.

Table 1-55: Number of individual birds at most risk of lead related ammunition or fishing tackle poisoning via primary or secondary routes across EU27[138]

[136] See https://www.eea.europa.eu/themes/biodiversity/state-of-nature-in-the-eu/explore-nature-reporting-data and EEA technical report *State of nature in the EU. Results from reporting under the nature directives 2013–2018, Technical report No 10/2020, European Environment Agency, Copenhagen.* (EEA 2020)
[137] There are 86 species in the key wintering species list DG ENVIRONMENT 2017. Reporting under Article 17 of the Habitats Directive: Explanatory notes and guidelines for the period 2013-2018.. According to RÖSCHEL, L., NOEBEL, R., STEIN, U., NAUMANN, S., ROMÃO, C., TRYFON, E., GAUDILLAT, Z., ROSCHER, S., MOSER, D. & ELLMAUER, T. 2020. State of Nature in the EU-Methodological paper Methodologies under the Nature Directives reporting 2013-2018 and analysis for the State of Nature 2000., the majority of the species for which winter data were requested, i.e. the key wintering species, are covered by coordinated international schemes, such as the African-Eurasian Waterbird Census (coordinated by Wetlands International).
[138] According to population numbers of EU27 bird species 2013-2018 reported to EEA according to Birds Directive article 12 requirements. Species at low risk are not included in this estimate.

Type of risk	**Applied population estimate**[1]	**Number of individuals at risk across EU 27-2020**[2]	**Estimated mortality from direct ingestion only (not including mortality from sublethal poisoning)**
Primary poisoning lead shot			
Primary poisoning (lead shot only) breeding population[3]	Breeding	127 559 526	***0.5 - 2.0 %*** ***(central value 1 %)***
Primary poisoning (lead shot only) wintering population for key wintering* species only	Wintering	7 869 678	***0.5 - 2.0 %*** ***(central value 1 %)***
Total for primary poisoning from lead shot		***135 429 204*** ***i.e. about*** ***135 000 000***	***1 354 292***
Secondary poisoning (ammunition)			
Secondary poisoning breeding population	Breeding	14 391 990	Not defined *(dataset not sufficient and not possible to distinguish mortality due to different sources. For vulnerable species mortality of even a single individual is concerning in terms of conservation)*
Secondary poisoning wintering population for key wintering species only (n = 1)	Wintering	227	Not defined *(dataset not sufficient and not possible to distinguish mortality due to different sources)*
Total for secondary poisoning		***14 392 217*** ***i.e. about*** ***14 000 000***	***Not defined***
Primary poisoning fishing tackle[4]			
Primary poisoning (fishing tackle) breeding population	Breeding	38 590	Not defined *(dataset not sufficient to define specific mortality due to ingestion of this source for AEWA listed species) For vulnerable species mortality of even a single individual is concerning in terms of conservation)*

Type of risk	Applied population estimate[1]	Number of individuals at risk across EU 27-2020[2]	Estimated mortality from direct ingestion only (not including mortality from sublethal poisoning)
Primary poisoning (fishing tackle) wintering population for key wintering species only	Wintering	7 375 347	Not defined *(dataset not sufficient to define specific mortality due to ingestion of this source for AEWA listed species. For vulnerable species mortality of even a single individual is concerning in terms of conservation)*
Total for primary poisoning from fishing tackle		***7 413 937*** ***i.e. about*** ***7 000 000***	***Not defined***

Notes: [1] as per EEA reporting requirements, population estimates are established according to breeding population sizes. For certain species, i.e. key wintering -species, the winter estimate is considered to be relevant; [2] as 2020 data for Romania was unavailable, it was amended with data from the 10th Birds Directive Article 12 report (2008–2012); [3] Netherlands and Denmark population info excluded due to lead shot ban. Belgium 50% of the population across the species included due to partial lead shot ban; [4] in Denmark there is a ban on the import and placing on the market of fishing tackle. However, since there is no ban on the use, data from Denmark was not excluded.

In the following table, the number of species at risk are correlated to IUCN classification.

Table 1-56: Number of species at most risk of lead exposure in the EU 27-2020 from different ingestion routes with respective IUCN Red List categories

Exposure route	Number of species at risk in the European Union	Breakdown of IUCN categories within the species (CR/EN/VU/NT/LC/NE)[1]
Primary poisoning from ammunition	41	1/2/4/3/28/3
Secondary poisoning from ammunition	29	1/2/6/3/16/1
Primary poisoning from fishing tackle	23	1/2/6/1/13/0

Notes: [1] CR = critically endangered, EN = endangered, VU = vulnerable, NT = near threatened, LC = least concern, NE = not evaluated

Further details of this assessment can be found in Annex B.

In addition to the species at most risk of lead poisoning, other species (in the order of hundreds) can still be at some (low) risk as assessed by the UNEP/CMS ad hoc Expert Group (2020). Specifically, based on this, the Dossier Submitter has calculated (using population numbers of bird species 2013-2018 reported to EEA according to Birds Directive article 12 requirements) that additionally about 650 million birds (at least) would be at some low risk of lead poisoning from the primary ingestion of lead shot and about 50 million (at least) birds would be at some risk of secondary poisoning from lead ammunition. Additional information is expected to become available in the consultation 2021 to refine this estimate.

2. Impact assessment

2.1. Overview of the restriction options analysis

2.1.1. Identification of the restriction options

In its request to ECHA to prepare an Annex XV restriction dossier on lead in ammunition and in fishing tackle, the European Commission (Commission, 2019) asked the Dossier Submitter (ECHA) to 'provide a thorough assessment of the option(s) that appear more viable, so that RAC and SEAC have all relevant information and analysis at hand in order to be able to define the most appropriate restriction option when elaborating their opinions, so as to inform and support the Commission's risk management decision.'

To address this request, the Dossier Submitter conducted a detailed analysis of a series of diverse restriction options for each sector of use identified in this Annex XV restriction report (i.e. hunting, sports shooting and fishing). These assessments are underpinned by information on uses, releases, availability of alternatives and socio-economic impacts. Each restriction option is also analysed against the criteria outlined in the Annex XV to REACH for assessing the appropriateness of a REACH restriction: effectiveness (i.e. targeting, risk reduction and proportionality to the risk), practicality (e.g. implementability, availability of alternatives, cost, affordability), enforceability and monitorability.

The detailed analysis of each restriction option per sector of use is available in Annex D.

The restriction options for each sector are listed by the Dossier Submitter according to the principle of the hierarchy of control[139]:

- Elimination, i.e. remove the source of hazard
- Substitution, i.e. replace the source of hazard
- Engineering control, i.e. isolate the source of hazard
- Administrative control, training, procedure, or policy, that lessen risks, i.e. information or advice (compulsory or voluntary)

Whenever relevant, the impact of a transition period on sub-category of projectile type (e.g. gunshot vs bullet) or fishing tackle type (e.g. sinkers, lures, of different weight, and nets, ropes and lines) are also part of the restriction option analysis.

Where good quality and detailed information on cost elements was available (albeit with some uncertainties), the Dossier Submitter has undertaken a quantitative impact assessment of the restriction options proposed. Sensitivity analysis has been undertaken on key uncertainties. In most cases, it was not possible to quantify the benefits of a restriction option (e.g. valuation of specific environmental impacts). Instead, a qualitative assessment of the benefits was made and supported with quantitative information where available. For some restriction options information on potential impacts are presented and summarised, but no quantitative estimates of the cost and/or benefit of a potential restriction are provided because: (i) the available information suggested that the potential costs were low in comparison to those of other restriction options (e.g. information to consumers), or (ii) because of the lack of information available to the Dossier Submitter, specifically on sports shooting. It is expected that the consultation on the Annex XV restriction report will give

[139] https://echa.europa.eu/documents/10162/13655/pg_15_qualitative-human_health_assessment_documenting_en.pdf

more information or validate some of the hypotheses that were used.

Therefore, the impact assessment of each restriction option per sector of use is comprised of a mix of the available cost information together with a qualitative assessment of other impacts, particularly to identify where a restriction option would have a disproportionate impact from a societal perspective.

2.1.2. Ranking of the restriction options

Once a set of plausible restriction options were identified for a use; i.e. fulfilling all the REACH restriction criteria (effective, practical, enforceable and monitorable), the Dossier Submitter scored them to identify the most appropriate one, or a combination of the most appropriate ones, to address the identified risks.[140]

There are many possible ways of scoring the restriction options analysed for each use. The Dossier Submitter selected a **simple Decision Matrix Analysis approach**.

First, the Dossier Submitter selected key dimensions. The key dimensions selected allowed to compare each restriction option against the others. In addition, the key dimensions selected represents key elements of an effective option in term of overall risk reduction, and proportionality to the risk. No scoring on practicality, enforceability or monitorability were proposed as only restriction options fulfilling these REACH criteria were compared between each other.

The key dimensions selected by the Dossier Submitter for the scoring are:

- **Lead emission reduction**: i.e. ranking according to how much lead releases into the environment will be avoided during the 20-year period of the impact analysis (best score assigned to the largest releases avoided). While this approach cannot describe absolute risk reduction, it is an effective means of comparing the restriction options, as this information provides an indication of the potential for a restriction option to reduce exposure and risk to birds (mainly related to primary and/or secondary poisoning of wildlife). This dimension would also allow to compare the effect of each restriction option with regards to the European commitment towards AEWA to improve the protection of birds (including IUCN) species at the EU level.
- **Other environmental risk reduction (for fishing only)**: this dimension is looking at potential net risk reduction for the environment other than from lead emission reduction. This dimension looks, for example, at the sustainability of the alternatives and/or potential additional/different burden on the environment associated with a restriction option (e.g. environmental footprint, aquatic toxicity, etc.).
- **Human health risk reduction (for fishing only)**: this dimension is looking at what are the potential net risk reduction (or increase) for human health.
- **Overall risk reduction (for outdoor shooting)**: addressing human health and other environmental risk reduction together as described above for the fishing sector.
- **Costs:** this dimension looks more specifically at the costs expected to accrue in the EU for a specific set of stakeholders (depending on the available information). For fishing, it is the cost for the European manufacturers that will be looked at for

[140] If only one plausible restriction option is identified, then no scoring will be performed.

example. This dimension also looks at the affordability of the proposal for the European industry.

- **End user acceptance (for fishing only):** end user should be understood here as the end user of the object targeted by the proposed restriction, for example the fisher for the fishing sector. This dimension looks at the assumed end user acceptance of different restriction options and reflects on the discussions held with stakeholders during the preparation of the restriction dossier. The end user acceptance is an important element in the adherence to the restriction option proposed, as the (non)acceptance by the end user could compromise the effectiveness, and in particular the net risk reduction capability, of the restriction option, for example as a consequence of deliberate non-compliance (e.g. increase of home-casting activity as a response to a ban on placing on the market only). Where the acceptance does not affect the effectiveness of the proposed reduction this dimension is ignored, hence this dimension is only applied to the fishing sector.

Once the dimensions were selected, the Dossier Submitter scored each restriction options for each dimension by ranking them. For each dimension, the restriction options were ranked from highest score for best (e.g. 4 points if 4 ROs are compared) to lowest score for poorest (1 point). The ranking of the options is based on the detailed impact assessment of each restriction option presented in the Annex D. Whenever possible the ranking is based on numerical values (e.g. for the releases avoided).

Finally, each score per key dimension is added up for each of the restriction options. The option that scores the highest is presented as the preferred option.

The Dossier Submitter presents its analysis and ranking of the plausible restriction options for hunting with gunshot (Table 2-1) and bullets (Table 2-2), sports shooting with gunshot (Table 2-3) and bullets (Table 2-6), and for the fishing sectors (Table 2-9).

2.2. Outcome of the restriction option analysed per sector

2.2.1. Hunting

The Dossier Submitter wishes to emphasise that none of the proposed restriction options (ROs) amount to a ban of hunting. In fact, this dossier highlights that hunting provides significant social, cultural, economic, and environmental benefits in different regions throughout the European Union. The general framework of hunting as well as the recognition of the role of hunting in nature conservation are both well established[141]. Instead, the ROs that are proposed target the identified problem of lead contamination, consider various possibilities to substitute lead ammunition, ensure that lead remains contained in bullets or is removed from game meat.

The restriction options also include considerations with regards to effectiveness, practicability and monitorability:

- Effectiveness: The restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk (also with regards to the costs)
- Practicality: the restriction must be implementable, enforceable and manageable; it also includes considerations on the transition time required to implement the proposed restriction option

[141] https://ec.europa.eu/environment/nature/info/pubs/docs/factsheets/hunting.pdf

- Monitorability: it must be possible to monitor the result of the implementation of the proposed restriction.

With regards to effectiveness, lead emission reduction, overall reduction of risks and costs are the criteria addressed:

- Emission reduction is considered as the reduction of the annual amount of lead released to the environment.
- Overall reduction of risks related to the release of lead shot or bullets for hunting, including the reduction of risks for human health (consumption of game meat), the reduction of risks for the environment (birds) and the risks for human health and environment for alternatives(s), where relevant.
- Costs are considered with regards to substitution and possible gun replacement.

For a better overview, the restriction option analysis for sports shooting with lead shot and bullets are addressed separately.

2.2.1.1. Restriction options for hunting with gunshot

List of restriction options considered

Concerning the environmental and human health risk associated with the use of lead gunshot in hunting (covered by use 1), the Dossier Submitter identified and analysed the following restriction options (cf. Annex D):

- RO1: Ban on the placing on the market and use of lead gunshot for hunting
- RO2: Require specific design/construction of lead gunshot
- RO3: Ban on the placing on the market of game meat collected with lead gunshot or maximum levels of lead in game meat
- RO4: Advices to cut away more meat when handling game and meat bagged with lead gunshot
- RO5: Compulsory information on the hazards of lead and the risks of using lead ammunition to be incorporated in national hunting exams and labelling of risks of lead on the package at the points of sale

The proposed restriction options are listed according to the principle of the hierarchy of control:

- Elimination i.e. remove the hazard (i.e. RO1) by means of substitution to a substance that has a more benign toxic profile.
- Engineering control, i.e. isolate the hazard (i.e. RO2, RO3, RO4)
- Administrative control (RO4, RO5) putting in place policies, training or advice to ensure target groups' attitude.

Outcome of the restriction option analysis

Table 2-1 gives an overview of the qualitative restriction option analysis made by the Dossier Submitter. According to the basic principle described in section 2.1., and the analysis of the restriction options presented in Annex D, the Dossier Submitter identified only one plausible restriction option (RO1) i.e. fulfilling all the REACH restriction criteria (effective, practical, enforceable and monitorable). Regarding the effectiveness of the restriction options, indeed only RO1 is showing significant emission reduction, and a high overall risk reduction (cf. Annex D).

For this reason, no scoring, and no further ranking of the restriction options is presented in this section. Although, each restriction option was assessed individually in Annex D, the Dossier Submitter considers that, even if not effective to address the risks, the restriction options assessed within this Annex XV Dossier are not mutually exclusive and could be proposed in conjunction with one another, this is why RO1 to RO5 are presented in Table 2-1 without any scoring.

Table 2-1: Restriction option analysis for hunting with gunshot

Dimension		RO1	RO2	RO3	RO4	RO5
Effectiveness	Overall	Yes (very high)	No	No	No	Yes (low)
	Emission reduction (20 years)	High (210 000tonnes)	No	Medium (reduction in use of lead shot for game marketed)	No	Low (only voluntary)
	Costs per year	Relatively low (steel shot almost same price as lead shot: €3m - €132m	Higher (costs for different design expected to be higher than use of lead shot)	Relatively low (steel shot almost same price as lead shot)	Relatively low (cost for advice to remove lead shot)	Relatively low (cost for information sheet on risk; cost to advise during hunting exams)
	Overall reductions of risks (HH and ENV) incl. risks related to alternative(s)	High (i.e., prevents intoxication of wildlife and HH effects)	Low (does not prevent intox. of wildlife)	Low (hunter families and birds still at risk)	Low (does not prevent intox. of wildlife)	Low (only voluntary)
Practicality		Yes (alternative available)	Not analysed	Yes	No (not practical to remove all shot**)**	Yes
Monitorability/ Enforceability		Yes	Not analysed	Yes	Low	Yes

After consideration of the various options, the available information, the reasonable assumptions, and the qualitative considerations of the options, the Dossier Submitter concludes that the most effective, practical and monitorable way (i) to address the risk posed by lead gunshot to wildlife, (ii) to address the risk for human health posed by consumption of game meat, (iii) to minimise those risks, (iv) and to prepare the hunters to the change, is a combination of the following restriction options:

- **A ban on the placing on the market and use of shot for hunting**
- **Compulsory information on the hazards/risks of lead within national hunting exams**
- **Labelling of risks of lead on the package at the points of sale.**

2.2.1.2. Restriction options for hunting with bullets

List of restriction options considered

Concerning the environmental and human health risk associated with the use of lead bullets in hunting (covered by use 2), the Dossier Submitter identified and analysed the following restriction options (cf. Annex D):

- RO1a: Ban on the use of small calibre (<5.6 mm centrefire and rimfire in general) lead bullets for hunting
- RO1b: Ban on the use of large calibre (≥5.6 mm centrefire) lead bullets for hunting
- RO2: Require specific bullet design/construction when lead is used (to minimise lead fragmentation)
- RO3: Ban on placing on the market of game meat collected with lead bullets or maximum levels of lead in game meat
- RO4: Advices to cut away more meat when handling game and meat bagged with lead bullets or shot
- RO5: Compulsory information on the hazards of lead and the risks of using lead ammunition to be incorporated in national hunting exams and labelling of risks of lead on the package at the points of sale.

The proposed restriction options are listed according to the principle of the Hierarchy of control:

- Elimination, i.e. remove the hazard (i.e. RO1a, RO1b) by means of substitution to a substance with a less toxic profile
- Engineering control, i.e. isolate the hazard (i.e. RO2)
- Administrative control (RO3, RO4, RO5) by putting in place policies, training or advice to ensure target groups' attitude.

Outcome of the restriction option analysis

Table 2-2 gives an overview of the qualitative restriction option analysis made by the Dossier Submitter. According to the basic principle described in section 2.1., and the analysis of the restriction options presented in Annex D, the Dossier Submitter identified only two plausible restriction options which are addressing a different but complementary scope (RO1a and RO1b) i.e. fulfilling all the REACH restriction criteria (effective, practical, enforceable and monitorable). Regarding the effectiveness of the restriction options, indeed only RO1a and RO1b are showing significant emission reduction, and overall risk reduction (cf. Annex D).

For this reason, no scoring, and no further ranking of the restriction options is presented in this section. Although, each restriction option was assessed individually in Annex D, the Dossier Submitter considers that, even if not effective to address the risks, the restriction options assessed within this Annex XV Dossier are not mutually exclusive and could be proposed in conjunction with one another, this is why RO1 to RO5 are presented in Table 2-2 without any scoring.

Table 2-2: Restriction option analysis for hunting with bullets

Dimension		RO1a	RO1b	RO2	RO3	RO4	RO5
Effectiveness	Overall	Yes (high)	Yes (high)	No	No	No	Yes (low)
	Emission reduction (20 years)	High (360 tonnes)	High (2 257 tonnes)	No reduction	Partial reduction	No reduction	Low (only voluntary)
	Cost per year	High (€21m - €70m)	Medium (€9m - €28m)	Not analysed	Low (< €9m - €28m)	Costs to remove more meat higher than costs for use of alternative	Low
	Overall reductions of risks incl. risks related to alternative	Medium (i.e., prevents intoxication of wildlife)	Medium (i.e., prevents intoxication of wildlife and HH effects)	Low (does not prevent intox. of wildlife)	Low (hunter families and birds still at risk)	Low (does not prevent intox. of wildlife)	Low (only voluntary)
Practicality		Limited (currently only a few alternatives available on the market that are not approved)	Yes (sufficient number of alternatives available)	Not analysed	Yes	No (impractical to remove all impacted meat)	Yes
Monitorability/ Enforceability		Yes	Yes	Not analysed	Yes	Low	Yes

After consideration of the various options, the available information, the reasonable assumptions, and the qualitative considerations of the options, the Dossier Submitter concludes that the most effective way (i) to address the risk posed by lead bullets to wildlife, (ii) to address the risk for human health posed by consumption of game meat, (iii) to minimise those risks, (iv) and to prepare the hunters to the change, is a combination of the following restriction options:

- **A ban on the use of lead bullets for hunting with large calibres (≥5.6 mm centrefire)**

- **A ban on the use of lead bullets for hunting with small calibres (< 5.6 mm) centrefire and rimfire**
- **Compulsory information on the hazards/risks of lead within national hunting exams**

2.2.2. Sports shooting

Concerning the environmental and human health risk associated with the use of lead in sports shooting, the Dossier Submitter identified and analysed different restriction options for the use of lead shot and lead bullets. (cf. Annex D):

In addition, other Union-wide risk management options other than REACH Restriction were also investigated by the Dossier Submitter such as voluntary measures i.e. ISSF code of practice (cf Annex D).

The Dossier Submitter wishes to emphasise that none of the proposed restriction options amounts to a ban of sports shooting. In fact, this dossier highlights that sports shooting provides significant social, cultural, and economic benefits throughout the European Union. Instead, the restriction options that are proposed target the identified problem of lead contamination, consider various possibilities to substitute lead ammunition, ensure that lead is contained at sports shooting facilities or is minimised otherwise.

The restriction options include also considerations with regards to effectiveness, practicability and monitorability:

- Effectiveness: The restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk (also with regards to the costs)
- Practicality: the restriction must be implementable, enforceable and manageable; it also includes considerations on the transition time required to implement the proposed restriction option
- Monitorability: it must be possible to monitor the result of the implementation of the proposed restriction.

With regards to effectiveness, lead emission reduction, overall reduction of risks and costs are the criteria addressed.

- Emission reduction is considered as the annual amount of lead released to the environment that would need to be recovered from soil. This criterion was used because the Dossier Submitter considers that lead that is frequently collected from a surface without direct contact to soil would minimise the risk to human health and the environment, whereas lead that would need to be recovered from the soil poses a risk to human health and the environment.
- Overall reduction of risks related to the release of lead shot and bullets for sports shooting, including the reduction of risks for human health via environment (drinking water, food), the reduction of risks for the environment (soil, birds wildlife and livestock) and the risks for human health and environment for alternatives(s), where relevant.
- Costs are considered with regards to environmental risk management measured that need to be installed to meet the requirements.

For a better overview, the restriction option analysis for sports shooting with lead shot and bullets are addressed separately.

2.2.2.1. Restriction options for sports shooting with gunshot

List of restriction options considered

Concerning the environmental and human health risk associated with the use of lead in sports shooting (covered by use 3), the Dossier Submitter identified and analysed the following restriction options for shorts shooting with shot (cf. Annex D):

- RO1: Ban on the **placing on the market** and **use** of **lead shot** for sports shooting
- RO2: Ban on the **placing on the market** and **use** of **lead shot** for sports shooting with a derogation for **permitted retailers** to sell and **permitted individuals** to use (e.g. Olympic/ISSF elite level only; training and events) with permitting done by Member States with annual reporting[142] to the Commission.
- RO3: Ban on the **placing on the market** and **use** of **lead shot** for sports shooting with a derogation conditional that the use takes place at a designated location that has a permit, granted by the Member State, to use lead gunshot for sports shooting and the following measures are in place at the designated location :
    - Regular [at least once a year] lead shot recovery with [> 90 %] effectiveness (calculated based on mass balance of lead used vs lead recovered) to be achieved by appropriate means (such as walls and/or nets[143], and/or surface coverage); AND
    - Containment, monitoring and, where necessary, treatment of surface (run-off) water to ensure compliance with the Environmental Quality Standards (EQS) for lead specified under the Water Framework Directive; AND
    - [Ban of any agricultural use within site boundary]

- RO4: Ban on the **placing on the market** and **use** of **lead shot** for sports shooting with a derogation for **permitted retailers** to selling and **permitted individuals** to use (such as Olympic/ISSF; training and events) at permitted sites/facilities with permitting done by Member State with annual reporting[144] to the Commission where *[the risks to the environment (including wildlife and livestock) and humans (via the environment) are minimised and]* the following OCs and RMMs are implemented:
    - Regular [at least once a year] lead shot recovery with [>90%] effectiveness (calculated based on mass balance of lead used vs lead recovered) to be achieved by appropriate means (such as walls and/or nets[145], and/or surface coverage); AND
    - Monitoring and, where necessary, treatment of surface (run-off) water to ensure compliance with the Environmental Quality Standards of the Water Framework Directive; AND
    - [Ban of any agricultural use within site boundary].

[142] Reporting should cover the number of retailers permitted to sell lead ammunition as well as the number of permitted individuals
[143] in some sources referred to as 'shot curtains'
[144] Reporting should cover the number of sites and volume of lead ammunition used at each site
[145] in some sources referred to as 'shot curtains'

- RO5: Compulsory information on the hazard/risk of lead, transition periods and availability of alternatives at point of sale and on product packaging. Individual cartridges should be indelibly labelled (contains lead (Pb) shot, for sports shooting only [at permitted sites]).

The proposed restriction options are listed according to the principle of the hierarchy of control:

- Elimination, i.e. remove the hazard (i.e. RO1, partly RO2) by means of substitution to a substance with a more benign toxic profile.
- Engineering control, i.e. isolate the hazard (i.e. RO3) ensure that the hazard is contained
- Administrative control (i.e. RO4, RO5) by means of training and or policies.

Outcome of the restriction option analysis

The Dossier Submitter did the scoring according to the basic principle described in section 2.1.

Table 2-3 gives an overview of the ranking made by the Dossier Submitter, and Table 2-4 and Table 2-5 explain how the ranking was made for each dimension.

Table 2-3: Restriction option analysis for sports shooting with gunshot

Dimension		RO1	RO2	RO3	RO4	RO5
Practicality		**Currently limited**	Yes	Yes	Yes	Yes
Monitorability/ Enforceability		Yes	Yes	Yes	Yes	Yes
Effectiveness	Emission reduction (high reduction high score, low reduction low score)	5	2	3	4	1
	Overall reductions of risks incl. risks related to alternative(s) (high reduction high score, low reduction low score)	5	2	3	4	1
	Costs (low cost high score, high cost low score)	4	3	1	2	5
	Overall score	**14**	**7**	**7**	**10**	**7**

Notes: ranking 5 is best and 1 is worst

In Table 2-4 a summary of the restriction option analysis for sports shooting with lead gunshot is presented.

Table 2-4: Restriction option analysis for sports shooting - gunshot

RO Nr	Short description of RO	Effectiveness	Practicality	Monitorability/ enforceability
RO1	Ban on the **placing on the market** and **use** of **lead gunshot** for sports shooting	Lead release avoided in 20 years: 525 000 tonnes (score: 5/5) Overall risk reduction: high (score 5/5) Total costs (20 years) to switch to alternative: €249 million (NPV, 4 %) (score 4/5)	currently limited due to social reasons (participation at Olympic games)	yes
RO2	As RO1, but derogation for **permitted retailers** to sell and **permitted individuals** to use; permitting by Member State; reporting to the Commission	Lead release avoided in 20 years:262 500 tonnes (score: 2/5) ENV and HH risks reduced but still possible (score 2/5) Total costs (20 years) for shooters without a permitted to switch to alternative: €193 million plus costs to establish a permitting system (3/5)	yes	Yes
RO3	Ban on the use of lead shot for sports shooting with a derogation at **permitted sites** with **lead shot recovery [≥90%],** monitoring and treatment of surface (run-off) water; ban of any agricultural use within site boundary	Lead release avoided over 20 years: 472 500 tonnes (score: 3/5) ENV and HH risks minimised (score 3/5) Total costs (20 years): €8 527 million (score 1/5)	yes	yes

RO4	As **RO3** but only for **permitted athletes**	Lead release avoided over 20 years: 498 750 tonnes(score: 4/5) ENV and HH risks minimised (4/5) Total costs (20 years): lower than €8 527 million because not all existing sites are expected to be equipped with RMM to recover > 90 % lead shot (score 2/5)	yes	yes
RO5	Compulsory information on the hazard/risk of lead, transition periods and availability of alternatives at point of sale and on product packaging. Individual cartridges should be indelibly labelled (contains lead (Pb) shot, for sports shooting only [at permitted sites]).	Lead release avoided over 20 years: no change (Score: 1/5) ENV and HH risks: awareness raising (score 1/5) Costs: costs for information and labelling (score 5/5)	yes	yes supports other RO in enforcement

The Dossier Submitter has performed a scoring of the restriction option. The dimensions “Emission reduction”, “Overall reduction of risks”, and “Costs” were used for scoring as described at the beginning of this section. The rationale for the scoring is provided in Table 2-5.

Table 2-5: Justification for scoring of restriction options

Dimension	Ranking rationale
Emission reduction	Then looking at the potential releases avoided, a ban on placing on the market and use of lead shot (RO1) would be the most efficient way of reducing the releases of lead to the environment because it would target the emission at its source (i.e. ammunition), and it would target shot that can be purchased at stores. For the restriction options RO2, RO3, and RO4, emission reduction is considered as the reduction of lead that is deposited in or on soil and that requires removal of the soil to recover lead. Lead shot that is recovered regularly from surface coverage without direct contact to soil is not considered as a release, noting that there remains a residual risk for birds. Restriction option RO5 does not have an effect on the reduction of releases. Therefore, in term of releases to soil avoided, the Dossier Submitter ranks the restriction options as follows (best: highest emission reduction): RO1 (5 scores) > RO4 (4 scores) > RO3 (3 scores) > RO2 (2 scores) > RO5 (1 score)
Overall reduction of risks	This dimension addresses the overall reduction of risks related to the release of lead shot, including the reduction of risks for human health via environment (drinking water, food), the reduction of risks for the environment (soil, birds wildlife and livestock) and the lower risks for human health and environment for alternatives(s) compared to lead. The reduction of risks related to lead is directly related to the emission reduction (see above). The risks from the alternatives replacing lead might also affect humans and the environment in a negative manner. Indeed, some of the current alternatives have a higher environmental footprint (more energy needed for example to produce lead free bullets and shot), some alternatives are not recyclable (while lead is), in addition not all alternatives are completely harmless to the environment themselves, and for some alternatives no sufficient studies exist to clear completely any potential hazard for the environment (cf. Annex C on analysis of alternatives). However, it should be stressed that it is the Dossier Submitter's conclusion that for the main alternatives to lead (copper for bullets and steel for shot) they are safe to use. Therefore, the Dossier Submitter ranks the restriction options as follows (best to worse): RO1 (5 scores) > RO4 (4 scores) > RO3 (3 scores) > RO2 (2 scores) > RO5 (1 score)
Costs	The ranking is mainly based on the cost estimates, reflecting the relative costs of additional risk management measure that are required to reduce the release of lead to the environment. The less costly the restriction scenario, the best the ranking. RO1, rank highest because no further action is required. RO2 and RO5 rank next, for which some actions are required but no expensive costs for risk management measures. RO3 and RO4 are ranking low due to the need for expensive risk management measures. The Dossier Submitter ranks the restriction options as follows (cheapest to most expensive): RO5 (5 scores) > RO1 (4 scores) > RO2 (3 scores) > RO4 (2 scores) > RO3 (1 score)

The Dossier Submitter considers that **RO1** is scientifically the preferred restriction option, which would be a ban on the placing on the market and use of lead shot for sports shooting because suitable alternative shot material is available. This restriction option also ranked highest with score 15. As mentioned above, this restriction option would be effective, introduces the least compliance burden, and has the highest cost benefit with lowest overall costs. However, this restriction option lacks practicality since Olympic and ISSF rules currently require the use of lead shot for skeet and trap disciplines. Assuming that there will be no rule changes in the short term that would allow the use of alternative shot materials, and acknowledging the importance of participation in international sports shooting competitions to society, a complete ban on placing on the market and use of lead shot, including all sports shooting, may be considered, by decision makers, to have an unacceptable socioeconomic impact for athletes and interested public following such sports events.

The restriction option with the next highest score is **RO4** with score 10. Within this restriction options the use of lead shot is only allowed for permitted athletes at permitted sites at which the risks from lead shot for human health and environment are minimised . Therefore, this restriction option would minimise the risks but still allow Member States to host international events and EU athletes to participate and train for them.

The restriction options RO2 and RO3 rank next with score 7 each.

Within **RO2** Member States are permitting individual athletes the use of lead shot; however, no further risk management measures are required to reduce lead release. By limiting the use of lead shot in the EU to permitted athletes would reduce lead release by roughly 50%; consequently, relevant risks would remain.

Within **RO3** the use of lead shot is allowed for recreational sports shooters and athletes at permitted sites at which the risks from lead shot for human health and environment are minimised as far as possibly by > 90 %.

RO5 scores lowest but is useful information for the user about the hazard and risks of lead and supporting enforcement by an indelibly labelling of the cartridges e.g., with "contains lead (Pb) shot, not permitted for hunting".

The Dossier Submitter considers that the restriction options RO2, RO3 and RO4 would be most effective and monitorable when **combined with RO5**.

The Dossier Submitter acknowledges that the costs of the described risk management measure to minimise the risks for humans and environment are not insignificant. Taking into account the availability of suitable alternatives, the Dossier Submitter considers that the socio-economic impact of the use of lead shot in international competitions such as Olympic games does not outweigh the costs required to minimise the risk for humans and the environment.

Although, each restriction option was assessed individually, the Dossier Submitter considers that the restriction options assessed within this Annex XV Dossier are not mutually exclusive and could be proposed in conjunction with one another. After consideration of the various options, the available information, the reasonable assumptions, and the above ranking of the options, the Dossier Submitter concludes that the most effective way to minimise the risks for (i) human health via environment (soil, drinking water), (ii) wildlife, and (iii) ruminants, would be

- **A ban on the marketing and use of lead gunshot for sports shooting**

Considering that participation in international competitions requires the use of lead shot, the following option could be practical means to minimise the identified risks, if a ban is not considered to be appropriate by decision makers:

- **A ban on the marketing and use of lead gunshot for sports shooting with derogation for**
    - **permitted retailers to sell; AND**
    - **permitted athletes to use; AND**
    - **at permitted sites; AND**
    - **risk management measures are in place (e.g., regular recovery >90%, surface water control) to minimise the risks.**

The following restriction option should be combined with the above restriction option:

- **Compulsory information on the hazard/risk of lead, transition periods and availability of alternatives, and the indelibly labelling of individual cartridges (contains lead (Pb) shot, not permitted for hunting .**

2.2.2.2. Restriction options for sports shooting with bullets

List of restriction options considered

Concerning the environmental and human health risk associated with the use of lead in sports shooting (covered by uses 4, 5 and 6), the Dossier Submitter identified and analysed the following restriction options for shorts shooting with bullets (cf. Annex D):

- RO1: Ban on the **use** of **lead bullets** for sports shooting
- RO2: Ban on the **use** of **lead bullets** for sports shooting with a derogation conditional that the use takes place at a designated location for sports shooting with bullets and the following measures are in place at the designated location:
    - Regular lead recovery with [≥ 90 %] effectiveness (calculated based on mass balance of lead used vs lead recovered) achieved by the means of bullet containment (i.e. bullet traps); and.
    - [Ban of any agricultural use within site boundary]
- RO3: Compulsory information on the hazard/risk of lead, transition periods and availability of alternatives at point of sale and on product packaging. Individual cartridges should be indelibly labelled (contains lead (Pb), for sports shooting only at permitted sites]).

The proposed restriction options are listed according to the principle of the Hierarchy of control:

- Elimination, i.e. remove the hazard (i.e. RO1) by means of substitution to a substance with a more benign toxic profile.
- Engineering control, i.e. isolate the hazard (i.e. RO2)
- Administrative control (RO3)

Outcome of the restriction option analysis

The Dossier Submitter did the scoring according to the basic principle described in section 2.1.

Table 2-6 gives an overview of the ranking made by the Dossier Submitter, and Table 2-7 and Table 2-8 explain how the ranking was made for each dimension.

Table 2-6: Restriction option analysis for sports shooting with bullets

Dimension		RO1	RO2	RO3
Practicality		currently limited	yes	yes
Monitorability/ Enforceability		yes	yes	yes
Effectiveness	Emission reduction (high reduction high score, low reduction low score)	*not calculated*	2	1
	Overall reductions of risks incl. risks related to alternative(s) (high reduction high score, low reduction low score)	*not calculated*	2	1
	Costs (low cost high score, high cost low score)	*not calculated*	1	2
	Overall score	***not calculated***	**5**	**4**

Notes: ranking 5 is best and 1 is worst

Table 2-7: Restriction option analysis for sports shooting - bullets

RO Nr	Short description of RO	Effectiveness	Practicality	Monitorability/ enforceability
RO1	Ban on the **use** of **lead bullets** for sports shooting	Lead release avoided over 20 year:not calculated due to missing alternative Overall risk reduction: not calculated due to missing alternative Costs: not calculated due to missing alternative	Currently limited due to missing approved alternatives	yes

RO Nr	Short description of RO	Effectiveness	Practicality	Monitorability/ enforceability
RO2	Ban on the use of lead **bullets** for sports shooting with a derogation at **permitted sites** with **lead recovery [>90%],** monitoring and treatment of surface (run-off) water; ban of any agricultural use within site boundary	Lead release avoided over 20 years: 283 500 tonnes for small calibre bullets and 349 650 tonnes for large calibre bullets(score: 2/2) Overall risk reduction: risks minimised (score 2/2) Costs: investment costs (1/2)	yes	yes
RO3	Compulsory information on the hazard/risk of lead, transition periods and availability of alternatives at point of sale and on product packaging. Individual cartridges should be indelibly labelled (contains lead (Pb) shot, for sports shooting only [at permitted sites]).	Lead release: no change (Score: 1/2) Overall risk reduction: awareness raising (score 1/) Costs: low (score 2/2)	yes	yes

The Dossier Submitter has performed a scoring of the restriction option to allow an independent analysis. The dimensions "Emission reduction", "Overall reduction of risks", and "Costs" were used for scoring as described at the beginning of this section. The rational for the scoring is provided in Table 2-8.

Table 2-8: Justification for scoring of restriction options

Dimension	Ranking rationale
Emission reduction	Looking at the potential releases avoided, a ban on placing on the market and use of lead bullets (RO1) would be the most effective way of reducing the releases of lead to the environment because it would target the emission at its source (i.e. ammunition), and it would target bullets that can be purchased at stores. However, in the absence of suitable alternative(s), RO1 is currently not an option. RO2 would minimise the release > 90 %. RO3 does not have an effect on the reduction of releases. Therefore, in term of releases to soil avoided, the Dossier Submitter ranks the restriction options as follows (best: highest emission reduction): RO2 (2 scores) >> RO1 (1 score)

Dimension	Ranking rationale
Overall reduction of risks	This dimension addresses the overall reduction of risks related to the release of lead bullets, including the reduction of risks for human health via environment (drinking water, food), the reduction of risks for the environment (soil, birds wildlife and livestock) and the lower risks for human health and environment for alternatives(s) compared to lead. The reduction of risks related to lead is directly related to the emission reduction (see above). However, in the absence of suitable alternative(s), RO1 is currently not an option Therefore, the Dossier Submitter ranks the restriction options as follows (best to worse): RO2 (2 scores) >> RO3 (1 score)
Costs	The ranking is mainly based on the cost for the risk management measure to contain bullets. The less costly the restriction scenario, the better the ranking. In the absence of suitable alternative(s), RO1 is currently not an option RO3 ranks best, for which some actions are required but no expensive costs for risk management measures. RO2 is ranking low due to the need for risk management measures. The Dossier Submitter ranks the restriction options as follows (cheapest to most expensive): RO3 (2 scores) > RO2 (1 score)

The Dossier Submitter considers that **RO1**, is currently not an option because only few alternative bullets are available which are not (yet) approved by CIP, the Olympic rules require the use of lead bullets, and the risks from lead bullets in sports shooting can be minimised by using bullet containment, i.e. bullet traps.

RO2 is the preferred restriction option because appropriate risk management measures (bullet traps) are available that minimise the risk, are required in the CSR (2020) and implemented within the EU at many but not at all facilities.

RO3 in combination with RO2 would in addition to inform the user about the hazard and risks of lead and supporting enforcement by an indelibly labelling of the cartridges e.g., with "contains lead (Pb) shot, for sports shooting only".

Therefore, the Dossier Submitter concludes that the most effective way to minimise the risks for (i) human health via environment (soil, drinking water) and (iii) ruminants, would be:

- **A ban on the use of lead bullets for sports shooting with derogation at designated locations for sports shooting with lead recovery > 90 %.**
- **[Ban of any agricultural use within site boundary]**

The following restriction option should be combined with the above restriction option:

- **Compulsory information on the hazard/risk of lead, transition periods and availability of alternatives, and the indelibly labelling of individual cartridges (contains lead (Pb), for sports shooting only [at permitted sites]).**

2.2.3. Fishing

List of restriction options considered:

For the lead in fishing tackle covered by use 7 and 8, based on the identified risks both for the environment and the human health, the following restriction options were analysed by the Dossier Submitter (cf. Annex D):

- RO1: Ban on placing on the market material and equipment for home-casting activities
- RO2: Ban on using fishing tackle rig or equipment intended to drop off lead sinkers
- RO3a: Ban on placing on the market and using lead fishing sinkers and lures
- RO3b: Ban on placing on the market and using fishing nets, ropes and lines containing lead
- RO4: Ban on placing on the market lead fishing sinkers and lures
- RO5: Ban on using lead fishing sinkers and lures
- RO6: RO3a with a derogation for lead split shots conditional to the placing on the market in spill proof and child resistant packaging
- RO7: Compulsory information to consumers at the point of sale (presence, toxicity and risk of lead, as well as availability of alternatives…)

The proposed restriction options are listed according to the principle of the hierarchy of control:

- Elimination, i.e. remove the hazard (i.e. a RO1 and RO2)
- Substitution, i.e. replace the hazard (i.e. R03 to RO5)
- Engineering control, i.e. isolate the hazard (i.e. RO6)
- Administrative control (RO7)

While RO1, RO3a, RO3b, RO4, and RO6 target the companies placing on the market material and equipment for home-casting (RO1), or different type of lead fishing tackle (RO3a, RO3b, RO4 and RO6); RO2, RO5 and RO7 are targeting only the fishers (consumers or professional fishers).

RO2 is focussing specifically on the emerging practice in EU of the intentional drop off of sinkers ('backlead' or main sinker) for carp fishing for example. Even though a ban on placing on the market and use would have been more efficient than a ban on use only, a ban on placing on the market cannot be proposed as a REACH restriction option because this is beyond the scope of REACH which can restrict a substance or a use, but not a technique or an object to use the substance.

RO6 is trying to address with a 'containment measure' the issue of the split shots which are very small sinkers[146] and can be easily spilled inadvertently by the fisher on the water shore (CfE #936 – UK EPA). This restriction option was investigated as alternatives for the smallest dust split shots (≤ 0.05 g) were not specifically identified during the ECHA market survey, even if other technical solutions (e.g. tungsten putty) could be applied on fishing line instead of dust split shots (cf. Annex D).

[146] Split shots range from 0.01 g to 4.8g. The smallest split shots (≤0.06 g) are often referred as 'dust split shots'.

With RO7, retailers will be requested to inform at the point of sale the consumers about the presence, toxicity and risk of lead to human health and the environment. They will also be asked to inform that alternatives to lead fishing tackle are available. RO7 is built on the recent work from Schulz et al., which highlight that the initial step to change fishers (and hunters) behaviour toward lead fishing tackle and ammunition is to have stakeholders recognising the importance of the lead issue both for the human health and the environment, and "use that concern as a catalyst for a positive change in their consumer purchasing behaviour"(Schulz et al., 2019).

RO3a which has been assessed with two different boundaries (LOW and HIGH) and RO3b are very similar. The aim of these restriction options is to ban the placing on the market and the use of different types/dimensions of lead fishing tackle. Nevertheless, RO3a and RO3b differ in term of scope and scale of the ban of lead fishing tackle. RO3b is about lead embedded in nets, ropes and lines, while RO3a is about lead in fishing sinkers and lures. The LOW boundary of RO3a focuses on lead fishing sinkers and lures ≤ 50 g, and the HIGH boundary of RO3a has no size limitation for sinkers and lures. The cut-off value of 50 g was set, because lead fishing tackle that tends to be ingested by birds have a maximum weight of 50 g. Fishing tackle weighing less than 50 g and having a size of less than 2 cm in any dimension are indeed often mistaken for food or grit ((Franson et al., 2001, Grade et al., 2019, Grade et al., 2018, Scheuhammer and Norris, 1995, Pokras et al., 2009) and (CfE #1247- Wildfowl & Wetlands Trust)). Other cut-off values were also investigated (e.g. ban on split shots only, and ban on sinkers and lures ranging from 0.06 g to 28.35 g similar to the UK ban) but dismissed for various reasons that are further explained in Annex D.

The combination of RO3a (HIGH boundary) and RO3b could be seen as a comprehensive ban of all lead fishing tackle used for recreational and commercial fishing as it would include lead sinkers, and lures but also nets, ropes, and lines made of lead. In practice it means that all types of lead fishing tackle and all sizes of fishing tackle would be banned from being placed on the market, and used, if those two restriction options were combined. While RO3a would affect both recreational and commercial fishers using angling as the main fishing technique, i.e. ca. 14 000 commercial vessels; RO3b would essentially affect commercial fishers., as fishing with nets, ropes and lines is essentially performed by commercial fishers.

Figure 2-1 depicts the difference and interconnection between RO3a and RO3b.

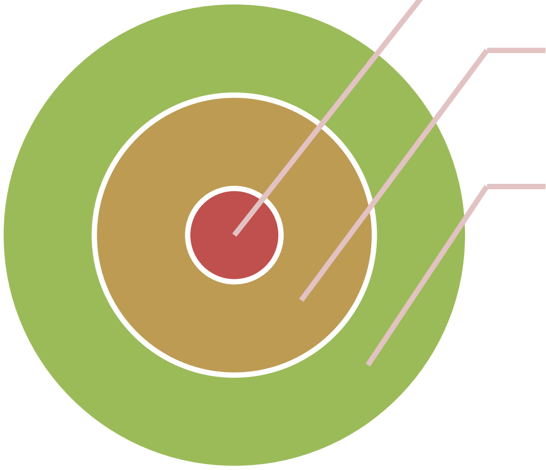

Figure 2-1: Lead fishing tackle – RO3a and RO3b scope

RO4 and RO5 together would be equivalent to RO3a (HIGH): RO4 is indeed a ban on placing on the market only, and RO5 a ban on use only of lead fishing sinkers and lures.

It is important to note that the restriction options including a ban on using lead fishing tackle (i.e. RO3a (LOW and HIGH), and RO5) intend to ban the use of any lead fishing tackle whatever its source of supply: i.e. from retailers or home-casted, while one the other hand a ban on placing on the market only (e.g. RO4) could only target the sold fishing tackle (and not the home-casted ones for personal use).

The Dossier Submitter evaluated each individual restriction option's ability to reduce the number of lead fishing tackle available for exposure to birds, as well as the ability to reduce the human health exposure to lead (essentially during home-casting activity, and ingestion of lead fishing tackle by children).

For some of the restriction options (e.g. RO3a), the need and impact of a transition period was also analysed as part of a sensitivity analysis in section 3.3.2.

In addition, other Union-wide risk management options other than REACH Restriction were also investigated by the Dossier Submitter such as (i) voluntary educational programmes, (ii) voluntary industry agreement to reduce the use of lead in fishing tackle, (iii) information campaign to promote the use of alternatives, (iv) mandatory training on the risk of lead to obtain a fishing licence, (v) retailer voluntary scheme to sell only fishing tackle from authorised sources (vi) taxation on lead fishing tackle and (vii) fee collected from the licences purchase in order to support the European transition to non-lead alternatives (cf. Annex D).

Outcome of the restriction option analysis

Some options were dismissed at an early stage during the restriction option analysis (cf. Annex D for further details), for the following reasons:

- A 'total ban on fishing activities', even if addressing the risk identified both for human health and wildlife is dismissed as disproportionate and not within the mandate given by the European Commission (EU Commission, 2019). The request from the Commission indeed clearly stated that the proposed restriction proposal should "*identify viable restriction options <u>targeted</u> at addressing the identified risks*".

- A 'ban on home-casting activities' is also dismissed as the home-casting activities which is performed in the private sphere cannot be enforced.[147]
- RO1, on the placing on the market of material and equipment for home-casting activities, is not targeted enough, does not address all the risks identified (in particular the risks for wildlife) and is not enforceable.
- RO3b, targeted to the fishing nets, ropes and lines, would be disproportionate with regard to the current knowledge of lead exposure risk (both to human and wildlife) from these types of fishing tackle.
- RO5 is not implementable and enforceable in a harmonised way.

All the above-mentioned options were therefore not considered by the Dossier Submitter for the ranking exercise. Only the following restriction options were considered further: RO2, RO3a (LOW and HIGH), RO4, RO6 and RO7.

A ban on all lead fishing sinkers and lures (i.e. RO3a with HIGH boundary) would have probably been unwarranted if the protection of birds would be the only goal of the proposed restriction. Lead fishing tackle heavier than 50 g, are indeed not typically ingested by birds.

However, as the goal of the restriction is to reduce all risks associated to lead, including also to reduce the exposure and risk to lead during home-casting and fishing activities, and more especially the risk for children for whom lead is a non-threshold substance for neurodevelopmental effects, the Dossier Submitter considered both the LOW and HIGH boundary for the ranking exercise. Indeed, RO3a (LOW and HIGH) would ban the use of any lead fishing tackle whatever its source of supply: i.e. from retailers or home-casted ones. A ban on using lead fishing tackle for fishing, would therefore indirectly reduce the incentive for home-casting activity (because a fisher could not use anymore what he would have manufactured), and the associated risk.

The Dossier Submitter considered that the restriction options RO2, RO3a (LOW and HIGH boundary), RO4, RO6 and RO7 are implementable, enforceable, and manageable and the result of the implementation of the proposed restriction can be duly monitored. Therefore, only these options have been ranked according to the key dimensions discussed earlier in this section.

Table 2-9 gives an overview of the scoring made by the Dossier Submitter, and Table 2-10 explains how the ranking and scoring was made for each dimension. The Dossier Submitter did the scoring according to the basic principle described in section 2.1.

[147] Note that other restriction options can address indirectly the issue of home-casting. For example: a ban on using lead fishing tackle would capture the use of home-made fishing tackle for fishing. 'If you can't use, don't make it!' principle.

Table 2-9: Restriction option analysis for fishing

	RO2	RO3a LOW	RO3a HIGH	RO4	RO6	RO7
Emission reduction	2	3	6	4	5	1
Other environmental risk reduction	1	4	4	4	1	1
Other human health risk reduction	1	5	6	1	4	1
Costs (for EU industry)	6	2	1	1	1	5
End user acceptance	5	2	1	4	3	6
Unweighted score count	**15**	**16**	**18**	**14**	**14**	**14**
Weighted score count	**17**	**19**	**24**	**18**	**19**	**15**

Table 2-10: Ranking rationale for fishing ROs

Dimension	Ranking rationale
Emission reduction	As indicated in Annex D, it is difficult to evaluate the effect of communication and awareness raising on consumers behaviour, and in particular how much such action, on its own, would impact the releases of lead to the environment. Therefore, taking a conservative approach, RO7 is ranked as the worst option in term of emission reduction efficiency. Using a similar reasoning, RO2 which targets a very specific type of fishing practice (carp fishing with intentional drop of lead) will not reduce drastically releases of lead to the environment on its own. On the contrary, a ban on the placing on the market and on use is the most effective way for reducing the releases of lead fishing tackle to the environment, because it would target the emission at its source (i.e. the fishers). It would target both the lead fishing tackle that could be purchased from a shop or internet, and the home-casted ones. A comprehensive ban both on placing on the market and on use is therefore more effective in term of releases reduction than a ban on placing on the market only, as a ban on placing on the market only (RO4) would not address the release to the environment of home-casted sinkers and lures. Considering also that the larger the scope of the ban, the more releases are avoided, and based on the releases estimates calculated in Annex D for RO3a LOW, RO3a HIGH, RO4 and RO6[148], the Dossier Submitter ranks the

[148] Releases reduction over a 20-year analytical period as reported in Appendix D:

Dimension	Ranking rationale
	restriction options as follows: (Best option) RO3a HIGH > RO6 > RO4 > RO3a LOW > RO2 > RO7 (Worst option).
Other environmental risk reduction	This dimension is looking at what are the other potential positive and negative net risk reduction for the environment **other than lead emission reduction**. While the options RO3a to RO6 would reduce the amount of lead released to the environment, the alternatives, even if much better than lead in term of effects on birds, might also have some negative impact on the environment, and on other environmental compartments in particular. Indeed, some of the currently identified alternatives have a high environmental footprint (more energy needed for example to produce fishing sinkers), some are not recyclable (while lead is), in addition not all alternatives are completely harmless to the environment (e.g. zinc for the aquatic environment), and for some of them no sufficient studies exist to clear completely any potential hazard for the environment (cf. Annex C on analysis of alternative substances). Considering these potential side-effects, and not being able to predict which alternatives will replace lead in the future, RO3a, RO4 and RO6 which all involve lead replacement by alternatives, will be ranked better than the other options, but cannot be ranked with the highest score (i.e. 6 points). RO6 entails the replacement of most of the lead by alternatives, nevertheless lead would still be permitted for the smallest dust split shots (≤ 0.06 g), and despite the spill proof design proposed for the packaging, such split shots could still be lost inadvertently during the fishing practice (e.g. if the fishing line breaks). Considering that the smallest lead tackle sizes have the greatest surface area and bioavailability potential, this option is proposed to be ranked worse than RO3a and RO4. RO2 would still allow the use of lead, while prohibiting the intentional drop off which is today a marginal practice. The risk for the environment remains the same as today, therefore RO2 is ranked, together with RO6, as the worst case for the environment compared to any other alternative. RO7 would also be ranked among the worst option: even if the Dossier Submitter believes that an awareness of the risk of lead might trigger the curiosity and the demand of consumers for safer alternatives, the effect of such a measure cannot be quantified. Therefore, taking a conservative approach, RO7 is ranked as the worst option in terms of other environmental impact. Based on all these arguments, and the detailed assessment provided in Annex D for each RO, the following ranking is proposed for this dimension: (Best options) RO3a HIGH / RO3a LOW / RO4 > RO2 / RO6 / RO7 (Worst options).
Human health risk reduction	RO3a is the only option to address the home-casting issue, and the associated risk of lead fumes and lead particles inhalation, this is why RO3a HIGH and RO3a LOW are ranked respectively first and second. Indeed, RO3a prohibit the use of lead sinkers whatever its source of supply (retailer or home-casted ones).

- RO3a HIGH: 48 300 tonnes
- RO6: same order of magnitude of RO3a HIGH but a bit lower than RO3a HIGH (reasoning in Appendix D)
- RO4: 43 470 tonnes
- RO3a LOW: 28 050 tonnes

Dimension	Ranking rationale
	RO6 with its spill and child proof packaging is also protecting the children from accessing and ingesting split shot, so this option is ranked third in term of human health benefit. RO4 and RO2 would still allow the use of lead sinkers and lures by fishers, therefore a risk for human health remains. It is assumed also that RO2 might trigger an increase in home-casting lead fishing tackle from fishers who cannot find anymore their usual fishing tackle from retailers. Neither RO2, nor RO4 address the home-casting problem, and an increase of human-health exposure from increased home-casting activity could be expected. These two options would therefore be ranked as the worst ones. In a similar manner as for the awareness raising on the environmental issue, taking a conservative approach, RO7 is ranked among the worst option in terms of human health impact, even if the Dossier Submitter believes that RO7 could have a positive impact in reducing the home-casting habit, and in improving the hygiene habits when manipulating lead fishing tackle. Based on all these arguments, and the detailed assessment provided in Annex D for each RO, the following ranking is proposed for this dimension: (Best option) RO3a HIGH > RO3a LOW > RO6 > RO2 / RO4 / RO7 (Worst option).
Costs	This dimension is looking more specifically at the costs of the restriction options for the European manufacturing activity of fishing tackle. It gives an indication of the affordability potential of the European Industry to roll-out the different restriction options. The less costly the restriction scenario, the better the ranking. Based on the cost estimates for the European Industry, and considering that some options, even if not quantified, would have a low investment costs, the Dossier Submitter concluded on the following ranking based on the assessment provided in Annex D for each RO: (Best option) RO2 >RO7 >>>>RO3a LOW >RO6/RO4/RO3a HIGH (Worst option).
End user acceptance	End user should be understood here as the fisher. This dimension looks at the assumed end user acceptance of different restriction options. For the fishing sector, it is indeed an important element for the adherence of the restriction option proposed, as the (non)acceptance by the end user could compromise the effectiveness, and in particular the net risk reduction capability of the restriction option. Not accepting the proposed restriction, and in particular if the enforcement is not effective, could trigger a different response from the end user: increase the home-casting activity and increase the human health risk, rather than purchasing alternatives. The Dossier Submitter has ranked end user acceptance assuming that end user acceptance usually decreases with perceived constraints to individual freedom. The better the end user acceptance, the best the ranking: RO7 >RO2 >RO4 >RO6 >RO3a LOW >RO3a HIGH

The unweighted score count favours RO3a HIGH over the other five options.

One may object that the key dimension of a restriction on lead in fishing tackle should be emission avoidance. Correspondingly, one may wish to give more weight to this dimension. A weighted score count giving twice as much weight to emission avoidance would then still favours RO3a HIGH (a ban on placing on the market and using fishing sinkers and lures) over the other options. RO3a LOW (a ban on placing on the market lead fishing sinkers and lures below 50 g) and RO6 (i.e. RO3a HIGH with a derogation for split shots) come second and third.

Although, each restriction option was assessed individually, the Dossier Submitter considers that the restriction options assessed within this Annex XV Dossier are not mutually exclusive and could be proposed in conjunction with one another. After consideration of the various options, the available information, the reasonable assumptions, and the above ranking of the options, the Dossier Submitter concludes that the most **effective way** (i) to address and reduce the risks posed by fishing tackle to wildlife, (ii) to address and reduce the risks to human health posed by home-casting and potential exposure and ingestion of lead by children, but also (iii) to support the EU commitment toward the preservation of bird species (AEWA MoU), (iv) and to prepare the fishers to the change, would be a combination of the following restriction options:

- **A ban on placing on the market and using lead fishing sinkers and lures (RO3a HIGH)**. This ban would be accompanied with different transition periods to allow the lead fishing tackle manufacturers, suppliers and retailers to develop and switch to alternatives, i.e. (i) no transition period for lead wire, (ii) a transition period of three years is proposed for lead fishing sinkers and lures with a weight ≤ 50 g, and (iii) a transition period of five years for the sinkers and lures with a weigh > 50 g.
- **A ban on using fishing tackle rig or equipment intended to drop off lead sinkers** (RO2). No transition period granted.
- **The obligation to inform at the point of sale the consumers about the presence, the toxicity and the risk of lead for human health and the environment** (RO7). The information at the point of sale would also include information on the upcoming ban and the availability of alternatives. This obligation would apply to all lead fishing tackle placed on the market (no size restriction), and would be accompanied with a transition period of six months to allow the lead fishing tackle retailers (shops and websites) to put in place the necessary information campaign towards their customers.

In addition, some other Union-wide measures beyond REACH, assessed by the Dossier Submitter (cf. Annex D), could be recommended as complementary measures to support the proposed REACH restriction on lead in fishing tackle, and could be implemented by national associations in order to accompany the European industry and the consumers in this change of fishing practices. These other measures are complementary to each other, as one would allow to finance the other one:

- A collection of a small fee from the fishing licences (where existing) in order to support the change and transition to non-lead alternative of both the consumers and the EU manufacturers. A fee of 10 cents collected on each licence in the EU would represent a marginal increase in the licence fee for an individual, but would generate an annual contribution of €1.2 million, which could be used to support European R&D to develop and place on the market suitable alternatives and/or help the European manufacturers to transition to non-lead alternatives. Alternatively, the income could also be used to support an education campaign towards the consumers (see next bullet point).

- A voluntary education programme and action campaign to promote the use of non-lead fishing tackle, organised and lead by the sector associations (fishing and trade) targeted to the consumers to promote the use of non-lead fishing tackle, and the recovery and recycling of lead fishing tackle. Efforts encouraging fishers to use non-lead alternatives could benefit from a European-wide coordination by fishing associations for example.

2.3. Proposed restriction

2.3.1. Title and scope of the proposed restriction

Short title:

Restriction on the placing on the market and use of lead in outdoor shooting and fishing.

Scope description:

The text of the proposed entry in Annex XVII (proposed restriction) has been carefully drafted to describe the intention of the Dossier Submitter. The final legal wording (i.e. to update Annex XVII of REACH) would be decided by the European Commission, and would need to take into account the existence of an already binding restriction on the use of lead in gunshot in wetlands.

The text *in blue italic font* in the right-hand column is intended to help the reader to understand the purpose of each of the conditions of the proposed restriction. This information is not intended to be part of the final restriction proposal. Note that further detailed explanation of the intention of the Dossier Submitter is also provided in section 2.3.2.

Some elements of the proposal are presented in square brackets […]. This is intended to indicate that either this element of the conditions of the restriction is (i) included on the basis of a preliminary conclusion that is subject to a review by the Dossier Submitter during the opinion-making phase (i.e. after the consultation) or (ii) that the element is not preferred by the Dossier Submitter, but may be favoured by the decision maker. The elements in green font present an optional derogation, the four elements work only in conjunction with each other.

For the purposes of the Committees' opinion development, the restriction entry could be split in separate entries for fishing, gunshot and other types of projectiles.

Table 2-11: Proposed restriction entry (annotated)

Designation of the substance	Conditions of the restriction	*Rationale*
Lead and its compounds	1. Shall not be placed on the market in a concentration equal or greater than 1 % w/w:	*A ban on placing on the market is proposed for some articles when suitable alternatives are available, and their ban is not considered to result in disproportionate impacts to society.* *A ban on placing on the market, in addition to a ban on use, is considered to offer advantages for enforceability and effectiveness (i.e. combining paragraph 1 and 2).* *The ban on placing on the market is combined with specific transition periods to avoid disproportionate impacts from an immediate ban on placing on the market.*
	a. in fishing sinkers and lures	*Use of lead fishing sinkers, wires and lures is associated with uncontrolled risks and can be substituted with already available, technically and economically feasible alternatives.*
	b. in fishing wires	
	c. in gunshot	*All uses of lead gunshot are associated with uncontrolled risks and can be substituted with technically and economically feasible alternatives. [Nevertheless, the Dossier Submitter describes **as an option** a derogation from this condition for certain disciplines of sports shooting at international and Olympic level (currently requiring the use of lead gunshot) under strict conditions of use to minimise risks. By proposing this option, the Dossier Submitter recognises that this may be the preference of the decision maker – see*

Designation of the substance	Conditions of the restriction	***Rationale***
		paragraph 4]. *Note: no ban is proposed for the placing on the market of projectiles other than gunshot as uses other than hunting and sports shooting could be inadvertently affected.*
	2. Shall not be used, in a concentration equal or greater than 1 % w/w:	
	a. in fishing sinkers and lures	*In addition to being purchased from the market, lead fishing sinkers and lures may be 'home-casted'. A ban on placing on the market would not control the risks for the environment and human health associated with 'home-casted' fishing sinkers and lures (and may in fact inadvertently encourage the practice of 'home-casting'). To achieve an effective control of risks the ban on placing on the market of fishing sinkers and lures is therefore complemented with a ban on use.*
	b. in fishing wires	*Lead fishing wire can be cut into small pieces and added to lures (including home-made lures). No transition period for this use is proposed as suitable alternatives are already available.*
	c. in gunshot	*A comprehensive ban (paragraph 1+2) on the use of lead in gunshot is proposed as suitable alternatives are available. It implicitly includes **both hunting and sports shooting uses**.* *The ban on use is associated with a transition*

Designation of the substance	Conditions of the restriction	*Rationale*
		*period to allow society to adapt. [Nevertheless, the Dossier Submitter describes **as an option** a derogation from this condition for certain disciplines of sports shooting at international and Olympic level (currently requiring the use of lead gunshot) recognising that this may be the preference of the decision maker – see paragraph 4].*
	d. in any other projectiles not defined as a gunshot	*The ban on the use of other projectiles implicitly includes projectiles used for both hunting and sports shooting, incl. muzzle loading ammunition and air rifle/pistol pellets, [full metal jacket bullets if allowed for hunting], and slugs.* *Different transition periods are proposed depending on the availability of alternatives for different calibres (< or ≥ 5.6 mm, rimfire vs centrefire). Where risks can be minimised (i.e. under controlled conditions for sports shooting) specific derogations from this ban are proposed in paragraph 4.*
	3. Shall not be used, in a concentration equal or greater than 1 % w/w, in fishing sinkers where the combination with any fishing equipment, rig or technique release the sinker during use.	*Relates to the use of lead sinkers in combination with fishing tackle (e.g. swivel) or techniques (rigs) which are intended to intentionally release sinkers into the environment. The use of lead sinkers is associated with uncontrolled risks. No transition period is proposed for this condition as it aims at immediately prohibiting an emerging practice that deliberately disperses lead sinkers. Only a ban on the use of sinkers*

Designation of the substance	Conditions of the restriction	*Rationale*
		(rather than the type of tackle/rig) is under the remit of the REACH regulation.
	4. By way of derogation:	*Derogations in paragraph 4 for sports shooting. The square brackets apply to the sub-paragraphs related to sports shooting with lead gunshot.*
	a. ***[OPTIONAL CONDITIONAL DEROGATION (part 1/4):*** *Paragraph 1c shall not apply to the placing on the market of lead gunshot for sports shooting if:*	***Optional derogation*** *to allow some sports shooters and their staff or clubs to purchase lead gunshot for sports shooting. This derogation works only in conjunction with the derogation 4b, which allows only permitted individuals to use lead gunshot for sports shooting under strict conditions to minimise the release of lead to the environment, and the requirements set in 5c and 6.*
	- *the retailer has a permit, granted by the Member State [where the article is placed on the market], to place lead gunshot for sports shooting on the market]*	*To be discussed – which/how MS grants the permit in case of internet retailer (one MS only, or permit per MS).*
	b. ***[OPTIONAL CONDITIONAL DEROGATION (part 2/4):*** *Paragraph 2c shall not apply to the use of lead gunshot if:* - *the individual has a permit, granted by the Member State, to use lead gunshot for sports shooting; AND* - *the use takes place at a designated location that has a permit, granted by the Member State, to use lead gunshot for sports shooting; AND* - *the following measures are in place at the designated location:* ▪ *Regular [at least once a year] lead shot recovery with [> 90 %] effectiveness (calculated based on mass*	*This derogation works only in conjunction with the derogation 4a, and the conditions set in paragraph 5c and 6.*

Designation of the substance	Conditions of the restriction	*Rationale*
	balance of lead used vs lead recovered in previous years) to be achieved by appropriate means (such as walls and/or nets , and/or surface coverage); AND ▪ *Containment, monitoring and, where necessary, treatment of surface (run-off) water to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive; AND* ▪ *[Ban of any agricultural use within site boundary]"]*	
	c. Paragraph 2d shall not apply to the use of 'lead projectiles not defined as a gunshot' for sports shooting, if the following measures are in place: - the use takes place at a designated location for sports shooting with 'lead projectiles not defined as a gunshot'; AND - the following measures are in place at the designated location: ▪ Regular lead recovery with [> 90 %] effectiveness (calculated based on mass balance of lead used vs lead recovered) achieved by the means of bullet containment (i.e. bullet traps) AND ▪ [Ban of any agricultural use within site boundary]	*Derogation to allow some sports shooters to use for example lead bullets and practice their sport under strict conditions to minimise the release of lead to the environment.*
	5. Without prejudice to the application of other community provisions on the classification, packaging and labelling of substances, mixtures, and articles:	
	a. Retailers of gunshot, 'projectiles not defined as a gunshot', fishing sinkers and lures of any dimension or weight, and containing lead in concentrations equal to or greater than 0.3 % by weight, shall ensure that, at the point of sale, in close proximity, the following information is clearly and visibly provided to consumers and professionals:	*'Change-management' condition, which aims at (i) increasing consumer awareness of the hazard and risk of lead, and (ii) preparing them to change their purchasing behaviour. This condition is NOT a labelling requirement, but is consistent with the principles of the CLP*

Designation of the substance	Conditions of the restriction	*Rationale*
	- 'Contains lead' - 'Lead is very toxic to the environment and birds' - 'Lead may damage fertility or the unborn child' - The use of lead in [gunshot outside of wetlands / projectiles / fishing sinker / lures to be selected as appropriate] will be banned in the EU from [EiF+TP as specified in paragraph 7]'. Lead-free alternatives are available.' The information listed above shall be in the official language(s) of the Member State(s) where the articles are placed on the market, unless the Member State(s) concerned provide(s) otherwise.	*regulation. This condition is targeted to the retailers only, and should apply until the relevant ban on placing on the market enters into effect.* *The last statement (The use of lead in [article] will be banned in the EU from [date]) is proposed to boost the uptake of alternatives by the end-users (fishers, hunters, sport-shooters).*
	b. Suppliers of 'projectiles not defined as a gunshot' containing lead in concentrations equal to or greater than 0.3 % by weight, shall ensure, before the placing on the market, that product packaging is clearly, visibly, and indelibly labelled with the information listed in paragraph 5a. The labelling shall be in the official language(s) of the Member State(s) where the articles, are placed on the market, unless the Member State(s) concerned provide(s) otherwise. If the packaging is too small, and the information listed in paragraph 5a cannot be provided on the packaging, this information can be provided in fold-out labels (leaflet); or on tie-on tags.	*Only a labelling proposed for 'bullets or projectiles', as they will continue to be placed on the market with restricted use. The proposed wording is inspired from the CLP Regulation.*
	c. ***[OPTIONAL DEROGATION (part 3/4):*** *Suppliers of 'gunshot' containing lead in concentrations equal to or greater than 0.3 % by weight, shall ensure, before the placing on the market, that product packaging is clearly, visibly, and indelibly labelled with the information listed in paragraph 5a. In addition, individual cartridges shall be labelled:* - *'Contains lead'* - *'Not permitted for hunting'.* *The labelling shall be in the official language(s) of the Member*	*This derogation works only in conjunction with the optional derogation 4a and 4b, and the conditions set in paragraph 6.* ***Optional*** *additional labelling requirement for shotgun cartridges in event that the derogation for use of lead gunshot for sports shooting is preferred to a ban. Labelling was recommended by RAC in their opinion on the proposed restriction of lead in gunshot in wetlands and would aid the enforcement of the restriction for*

Designation of the substance	Conditions of the restriction	*Rationale*
	State(s) where the articles, are placed on the market, unless the Member State(s) concerned provide(s) otherwise. If the packaging is too small, and the information listed in paragraph 5a cannot be provided on the packaging, this information can be provided in fold-out labels (leaflet); or on tie-on tags.]	*hunting in the event that lead gunshot was still permitted to be placed on the market for sports shooting.*
	*6. **[OPTIONAL DEROGATION (part 4/4):** Member states shall report on an annual basis to the Commission:* *- the number of permits granted to designated locations in the Member State under paragraph 4b and their location.* *- the number of permits granted to individuals in the Member State under paragraph 4b.* *- - the quantity of lead gunshot used in the Member State under paragraph 4b.]*	*This derogation works only in conjunction with the derogation 4a, 4b and the conditions set in paragraph 5c.* *In case the derogation for continued use of lead gunshot for sports shooting, set out in paragraph 4b, is preferred to an outright ban the reporting requirement will allow the Commission to monitor the continued used of lead gunshot in different Member States.* *This requirement will also facilitate the enforcement of paragraph 2c and 4 by identifying the designated locations where lead gunshot can be used under strict conditions.*
	7. Entry into force of the restriction: a. *paragraph 1a and 2a shall apply 3 years from entry into force of the restriction for sinkers and lures which have a weight equal or less than 50 g* b. *paragraph 1a and 2a shall apply 5 years from entry into force of the restriction for all sinkers and lures which have a weight greater than 50 g*	*Transition periods proposed based on SEA. Transition periods allow the supply chain to put in place the requirements set in the proposal (transition to non-lead alternatives or implementation of RMMs).*

Designation of the substance	Conditions of the restriction	***Rationale***
	c. *paragraph 1b, 2b and 3 shall apply as soon as possible from entry into force of the restriction*	*i.e. no transition period for fishing wires, and the use of lead sinkers with tackle or rigs for intentional drop-off, for which many alternatives already exists.*
	d. *paragraph 1c, and 2c, shall apply [5 years] from entry into force of the restriction*	
	e. *paragraph 2d shall apply [18 months] from entry into force of the restriction for centrefire ammunition with a calibre greater than or equal to 5.6 mm*	
	f. *paragraph 2d shall apply [5 years] from entry into force of the restriction for centrefire ammunition with a calibre less than 5.6 mm and 'any projectiles not defined as a gunshot' of any calibre*	*Alternatives for smaller 'bullets or projectiles other than gunshot (e.g. air rifle/pistol pellets, BBs and 'muzzle loading') would need a longer transition period.*
	g. *paragraph 5a shall apply 6 months from entry into force of the restriction.*	
	h. *paragraph 5b shall apply [18 months] from entry into force of the restriction.*	*Consistent with transition period for restriction of centrefire cartridges with a calibre greater than or equal to 5.6 mm for hunting.*
	i. [paragraph 5c shall apply [5 years] from entry into force of the restriction.]	*Consistent with transition period for restriction of lead gunshot for hunting and sports shooting.*
	8. This restriction on lead in outdoor shooting and fishing shall not apply to the following applications: indoor shooting inside a building, police, law enforcement, military applications, [voluntary military training], protection of critical infrastructure, commercial shipping or high-value convoys, soft-target and public space protection, [self-defence], security purposes, technical testing and/or proofing, testing and development of materials and products for ballistic protection, forensic analysis, historical and other technical research or investigation. (i.e. these applications are outside of the scope).	*To clearly states that these uses are out of scope.*

Designation of the substance	Conditions of the restriction	*Rationale*
	9. For the purposes of this regulation: - 'centrefire ammunition' means ammunition where the primer is located in the centre of the case head or base; - 'fishing wire' means metal in the form of thin thread often cut in smaller pieces and used as a sinker in certain types of 'lures'; - 'gunshot' means pellets used [or intended for use in quantity] in a single charge or cartridge for shooting with a shotgun; - 'hunting' means pursuing and killing live quarry using a gun; - 'lure' means an object that is used to attract fish or animals, so that they can be caught. Lures might also have the same technical function as 'sinkers'; - 'projectile': means an object intended to be expelled from a gun, irrespective of the means of propulsion; - 'shotgun' means a smooth-bore gun; - 'sinker' means a weight that is attached to a fishing line or a net to keep it under the water, or to keep the fishing line, or net, in a certain position; - 'sports shooting' means shooting at any inanimate (non-living) target with a gun. It includes practice, or other shooting, performed in preparation for 'hunting'.	*The definitions of 'gunshot' and 'shotgun are taken from the restriction on lead gunshot in wetlands.* *Definition of gunshot: the elements in [] are not in the wetland restriction regulation proposed by the Commission. It aims at clarify the definition.*
	10. Member States may maintain national provisions for protection of the environment or human health in force on [Publications office - please fill in the date of entry into force of this amending Regulation] and restricting lead in gunshot, or any other projectiles more severely than provided for in paragraph 1 to 8). The Member State shall communicate the text of those national provisions	*Same paragraph proposed by the Commission in the final legal text of the lead in wetland restriction*

Designation of the substance	Conditions of the restriction	*Rationale*
	to the Commission without delay. The Commission shall make publicly available without delay any such texts of national provisions received.	

In addition, some other measures, other than REACH restriction (cf. Annex D), are listed by the Dossier Submitter, and could be implemented by national associations, whenever applicable, to support the proposed REACH restriction, for example:

- The possibility to incorporate into the national hunting exam (to obtain a hunting licence) a mandatory module on the hazards of lead and the risks of using lead ammunition. This could be done at the Member State level whenever such hunting exam takes place.
- A collection of a small fee from the fishing licences (whenever existing) in order to support the change and transition to non-lead alternative of both the consumers and the EU manufacturers. A fee of 10 cents collected on each licence in Europe would represent a minor increase of the licence fee, and could potentially generate a annual revenue of €1.2 million that could be used to support the R&D effort of European industry to, and help European manufacturers to transition to non-lead alternative solutions. This fee could also support an education campaign for consumers (see next bullet point).
- A voluntary education and action campaign from the sector associations (fishing and trade) targeted to consumers to promote the use of non-lead fishing tackle, and the recovery and recycling of lead fishing tackle.

2.3.2. Justification of the proposed wording for the restriction entry

2.3.2.1. Identification of the substance (designation)

Substance identity

The substance identity 'lead and its compounds' is consistent with the one in the restriction on the 'use of lead gunshot in or over wetlands'. It covers both lead and lead compounds such as lead alloys.

The proposed wording, associated to the proposed concentration limit (cf. below) would avoid the risk of regrettable substitution of lead by another substance containing lead either as a constituent of another substance, or an alloy.

Concentration limit

The concentration limit in paragraph 1 sets the maximum allowed concentration of lead permitted in the various articles that are within the scope of the restriction.

The proposed concentration limit of 1 % w/w is the same as currently adopted for the restriction on the 'use of lead gunshot in wetlands'. This limit was selected based on the US 'non-toxic' gunshot approval (cf. Annex C) process that limits the maximum concentration of lead in any 'non-toxic' gunshot to 1 % (w/w) in order to avoid a significant toxicity danger to migratory birds and other wildlife, or their habitats. As such, the proposed concentration limit is considered to sufficiently address the risk for the birds whilst being readily achievable by producers of alternatives.

The consistency of the enforcement of the proposed restriction for the three sectors (hunting, sports shooting and fishing), and the restriction on 'use of lead gunshot in wetlands' will also be insured, and the proposed concentration limit can be verified using the standardised analytical methods developed for the restriction on the 'use of lead gunshot in wetlands'.

It should nevertheless be noted that, according to the Dossier Submitter's understanding, the maximum content of lead in bullets made of alternative varies between 1 to 3 % depending on the alternative material that is used. For example, the lead content of copper bullets is usually ~ 1% whereas the lead contents of brass bullets is usually ~ 3 %. In setting a concentration limit there are several key points to consider:

- Through stakeholder discussion the Dossier Submitter was informed that around 20 % of today's used of non-lead ammunition in Germany concerns brass based bullets.
- The upcoming Danish legislation on lead in ammunition, covering bullets, will set to the best of the Dossier Submitters knowledge, the limit at 3 – 4 %, through discussion with Danish experts the Dossier submitter has learned that there's a reasonable level of confidence that the maximum concentration of lead can be lowered should a European legislation prescribe this.
- The California legislation sets the maximum lead content in bullets at 1 % maximum, so compliant ammunition must be available given the size of this market.

Similar to the considerations during the development of the restriction on the use of lead gunshot in wetlands, a lower concentration limit (e.g. 0.3 % w/w which corresponds to the generic concentration limit for reprotoxic constituents) might be too stringent to achieve in practice for the manufacturers.

2.3.2.2. Restriction on 'placing on the market' and/or 'use' (paragraphs 1 and 2)

'Placing on the market' should be understood as 'placing on the EEA market (i.e. EU + Iceland, Norway and Liechtenstein)' as set under REACH Article 3(12), i.e. 'supplying or making available, whether in return for payment or free of charge, to a third party. Import is deemed to be placing on the market'.

'Use' should be understood as 'use' under REACH Article 3(24). The use definition under REACH is broad and includes 'keeping' and 'any other utilisation' such as hunting, shooting, or fishing.

2.3.2.3. Fishing tackle (paragraphs 1, 2, and 3)

The proposed restriction targets fishing tackle that is known to be made from or to contain lead, and for which a risk for human health and the environment needs to be addressed:

- 'Sinker': a weight that is attached to a fishing line or net to keep it under the water, or to keep the fishing line in a certain position. Fishing sinkers can be attached to the fishing line, or net, using a variety of techniques, for example: crimping on the line, tying to a loop on the sinker, or, threading the line through the hole in the centre of the sinker, etc..
- 'Lure': an object that is used to attract fish or animals, so that they can be caught. Lures might in addition perform the same technical function as sinkers.
- 'Wire': metal in the form of thin thread often cut in smaller pieces and used as a sinker in certain types of lures.

The restriction wording does not make any difference regarding how and by whom the lead fishing tackle has been manufactured. For example, sold home-casted fishing tackle would be captured by the ban on placing on the market, and home-casted fishing tackle for personal use would be captured by the ban on using lead fishing tackle.

The proposal excludes lead fishing nets, ropes and lines from the scope of the proposal where lead is embedded, because no risk for birds, nor the human health has been identified for these types of fishing tackle. Lead is indeed threaded or enclosed and lead does not wear out, and lead from this fishing tackle is not typically ingested by birds.

It is important to note that the sinkers that would be added on fishing nets, e.g. barrel-shaped sinkers added on purse seine nets (cf. Annex A), would fall under the definition of fishing sinkers and would therefore be subject to a ban with a transition period as described in paragraph 4.

As the sinkers, lures and wires, subject to the proposed restriction, might have different shapes, names or terminology (e.g. 'sinker' can also be called 'weight' or 'ballast' etc), the Dossier Submitter is proposing a broad definition of 'sinker', 'lure', and 'wire' in paragraph 7. Coated lead sinkers, lures and wires would also be captured by this definition if the content of lead is > 1 % w/w.

In addition to lead fishing tackle, the restriction is also targeting the use of 'Fishing tackle and fishing rigs for intentional drop off sinkers' (paragraph 3). This provision should be understood as equipment or technique used to intentionally drop-off lead sinkers to the environment. Examples of such equipment or rig are provided in Annex D. The condition set in paragraph 7 can only be enforced at the point of use, i.e. during fishing (for both the equipment and the technique). Even though a ban on placing on the market and use would have been more efficient than a ban on use only, a ban on placing on the market cannot be proposed as a REACH restriction option because this is beyond the scope of REACH which can restrict a substance or a use, but not a technique or an object to use the substance.

2.3.2.4. Ammunitions (paragraph 1, 2 and 4)

As described in section 1.2, the term ammunition is not appropriate to designate the lead objects in scope of restriction proposal. The term 'projectile' is more appropriate and more specific.

The projectiles in the scope of the Annex XV restriction report can be grouped under the following two main categories:

- **Gunshot to be shot with a shotgun** (also referred as 'gunshot' 'shot' for simplicity in the restriction entry wording); where multiple shots/pellets are contained in a shotshell
- **Other types of projectile** (single): bullet is the most common example, but it includes also full metal jacket (if allowed by the local hunting legislation), slug (single shot/pellet in a shotshell), as well as BB (small metallic ball), air gun pellet, etc.

2.3.2.5. Information at the point of sale (paragraph 5a)

This requirement is complementary to the proposed ban on placing on the market and use of fishing tackle, and to the ban on use of lead ammunition.

It corresponds typically to the first measure in 'change-management' which aim at (i) creating consumers awareness of the hazard and risk of lead, and (ii) preparing the consumers for changing their purchasing behaviour.

The condition on 'information at the point of sale' is NOT a labelling requirement under the CLP requirement, but it is in analogy to the CLP regulation (e.g. the 0.3% concentration limit is from the GCL set in the CLP for Repro 1A substances without SCL, and the proposed wording to be applied at the point of sale is in analogy to the CLP hazard and precautionary statements). This condition is targeted to the retailers only, and should apply until the relevant ban on placing on the market kicks-in.

'Point of sale' should be understood as a place where a customer executes the payment for goods or services (and where sales taxes may become payable). The transaction may occur in person or online.

2.3.2.6. Labelling requirement (paragraph 5b and 5c)

Lead massive, as well as lead in articles are exempted from the labelling obligations under the CLP.

The labelling requirement, and proposed wording in paragraph 5b is in analogy to the CLP requirement, and would apply only to projectiles other than gunshot, as these projectiles will continue to be placed on the market with restricted use.

For example, the 0.3% threshold is in analogy to the GCL set in the CLP for Repro 1A substance without SCL, and the proposed wording is in analogy to the CLP Regulation as well.

The labelling requirement in paragraph 5c works only in conjunction with the optional derogation 4a and 4b, and the conditions set in paragraph 6. This additional labelling requirement would apply to shotgun cartridges in the event that the derogation for use of lead gunshot for sports shooting is preferred to a ban.

Labelling was recommended by RAC in their opinion on the proposed restriction of lead in gunshot in wetlands and would aid the enforcement of the restriction for hunting in the event that lead gunshot was still permitted to be placed on the market for sports shooting.

2.3.2.7. Transition periods (paragraph 7)

Transition periods for fishing sinkers, lures and wires (paragraphs 7a, 7b)

The main drivers to define the length of the transition period are the availability of alternatives, and the capacity for the European industry to switch to the production of alternatives. A ban without any transition period would most probably mean an immediate closure of the remaining European lead fishing tackle producers, and a loss of activities for the retailers as there is currently in Europe not enough capacity in the production of alternatives to absorb the existing market. In addition, enough time is needed for the sector to research and develop new alternatives.

The two-step approach transition period proposed for the sinkers and lures would provide enough time for industry to develop and place on the market alternatives and then to adapt its existing manufacturing equipment. A shorter transition period (3 years) is proposed for lead sinkers and lures ≤ 50 g because this size of fishing tackle can be both ingested by birds, and home-casted, while the lead sinkers and lures > 50 g present essentially a risk for the human health associated to the home-casting practice.

Finally, as alternatives to lead wires are already widely available in retailers' shops, no transition period is proposed for this type of fishing tackle.

Transition period for fishing tackle and fishing rigs for intentional drop off sinkers (paragraph 7c)

Considering that these novel fishing tackle and fishing rigs induce an intentional release of lead to the environment, and considering that techniques, and fishing tackle exist where the sinkers are not drop off. No transition period is granted.

Transition period for gunshot (paragraph 7a and 7b)

Five years, however, some indications exist that (given the scale of lead use), even longer transition period may be required.

Transition period for bullets (paragraph 7e and 7f)

Large calibres (5.6 mm centrefire and larger)

Alternatives are already widely used throughout Europe and obligatory in several jurisdictions. Most manufacturers have set up production lines that make CIP compliant non-lead bullets. For non-CIP countries, USA produced SAAMI approved bullets can be used. The assessment of the Dossier Submitter is that 18 months would be enough time as a transition period.

Small calibres (smaller than 5.6 mm centrefire, and rimfire cartridges)

For small calibres, the situation is different as much R&D is still needed. However, it should be noted that some US companies have reacted to California regulation and have designed lead free ammunition of smaller calibres. The recent introduction of the same size calibres by RWS, Norma and CIC on the European market could result in the rapid adaptation of this calibre group in the EU as well. The Dossier Submitter identified three options to deal with this group of calibres:

a) Exempt altogether the calibres for small game and accept a left-over emission of around 30 - 40 tonnes per year

b) Grant a long transition period (5 years)

c) Or recommend in the restriction a review clause.

The initiative in Denmark (expected entry into force 2023) will provide more clarity on this. The Dossier Submitter judges that by the present state of the market (some alternatives available) and the possibility of increased import of US- made calibres would warrant a longer transition period than for larger calibres. This transition period should be five years long.

Transition period for information to consumers at the point of sale (paragraph 7g)

A short transition period of 6 months is proposed in order to quickly raise the consumers awareness regarding the hazard and risk of lead for the environment and the human health. The proposed restriction condition would need to be implemented at the point of sale, i.e. either on the retailing website or at the retailer shop and would not require major revamping or adaptation at the point of sale. Therefore, a short transition period is proposed.

2.4. Approach to impact assessment

There are various uses of lead in ammunition and fishing tackle which involve different sectors and different stakeholders in the value chain. Exposure and releases to the environment vary also depending on the type of use. Because of different technical functions needed for each use, the readiness, availability and costs of suitable alternatives vary also among the uses. For the purpose of this impact assessment, the uses are therefore grouped into three overarching sectors: hunting, sports shooting and fishing.

Because of the differences in the identified uses of lead, different restriction conditions are proposed, and use-specific impacts are expected from the restriction. This is particularly true for the risk reduction capability, the costs, benefits and other socio-economic impacts of the proposed restriction. In order to recognise these specificities, separate impact assessments (incl. risk reduction capability (effectiveness), costs, socio-economic aspects and proportionality) are carried out for the different sectors of use concerned by the proposed restriction, i.e. for the use of lead in hunting, sports shooting and fishing. Details are provided in Annex D.

The practicability of the proposed restriction including its implementation, manageability, enforceability and monitorability is also discussed for each individual sector.

The geographical scope of the impact assessment is the European Union as of 2020 (i.e. excluding the UK); at times the abbreviation EU27-2020 is used in the Annex XV report. The Dossier Submitter recognises and acknowledges that once adopted the proposed restriction will also apply to EEA States, but because of a lack of data for Iceland, Liechtenstein and Norway, impacts in these countries were not assessed specifically.

Regarding the timeline for the impact assessment, 2022 was assumed to be the first full year of entry into force of the proposed restriction, and a 20-year period was assumed as horizon of the impact assessment. Unless otherwise noted, all costs are expressed in 2020 € (i.e. costs are discounted at 4 % discount rate to the study reference year of 2020, and expressed either in Net Present Value (NPV) or in annualised costs over the 20-year period).

For most of the sectors, a conclusive quantification of the benefits expected from the restriction is not possible due to a lack of data and the non-threshold character of lead with regard to children's exposure (neurotoxicity). This specificity makes it challenging to quantitatively demonstrate that the benefits of the proposed restriction outweigh its costs. Instead, the Dossier Submitter has adopted a cost-effectiveness approach considering releases of lead as a proxy for risk, and complemented this analysis wherever possible with a quantitative cost-benefit approach.

2.5. Impacts of a restriction on lead in hunting

The preferred restriction conditions for lead in hunting is a combination of the following elements

- A ban on placing on the market, and on the use of lead shot for hunting
- A ban on the use of lead bullets to be introduced in a two-step approach with
    - a transition period of 18 months for centrefire rifle ammunition in calibre larger than 5.6 mm
    - a longer transition period of five years for smaller centrefire calibres and rimfire calibres.
- The obligation to inform hunters on the risk of using lead on the package of the bullets and shot (labelling requirement) as well as an introduction of a module on lead poisoning in hunter education programs (education).

The understanding of the Dossier Submitter is that, based on existing hunting legislation, advice from manufacturers etc. three groups of animal species can be distinguished: small game birds, small game mammals and large game (see Table 2-12). The precise analysis is described in Annex D. The Dossier Submitter's analysis infers that a general ban on lead in hunting (shot and bullets) would lead to different impacts for hunting the different species groups in the table below.

Table 2-12: Species per game type

Species group	Species or groups of species	Use	Volume of lead releases [tonnes per year]
Small game birds	Waterfowl, pheasants, partridges	Use 1[149]	13 000 to 15 000
Small game mammals	Hare, squirrel, musk rat, beaver, rabbit, fox, racoon dog, wild cat, martens, badger, polecat (non-exhaustive list)	Use 1, Use 2a	16 to 26
Large game	Roe deer[150], chamois, mouflon, fallow deer, sika deer, ibex, moose, brown bear, wild boar, red deer, seals, wolf, jackal (non-exhaustive list)	Use 2b	110 to 142

The choice of the limit of 5.6 (5.56) mm centrefire is chosen because:

- 5.6 (5.56) mm centrefire is in many hunting legislations regarded as the minimum calibre for hunting or for hunting roe deer.

[149] In some MS game bird species are also shot with bullets.
[150] Roe deer can in certain MS also be hunted with shotguns.

- The smallest calibre size that was successfully tested in comparison of lead and non-lead ammunition is 5.56 mm centrefire (.22 and .223 calibre).

These arguments are developed further in appendix D.1.1.

2.5.1. Conclusions on alternatives and technical solutions

Hunters affected by the proposed restriction would have to switch to alternative ammunition. The most used alternatives for lead gunshot are steel gunshot and bismuth gunshot (although tungsten-based cartridges are also available) and copper and brass for bullets. These alternatives are already widely used in the EU and internationally. Annex D demonstrates that they are technically feasible, comparable in price, and have a more benign human health and environmental hazard and risk profile than lead based ammunition.

Annex C also shows that the material that used for the alternatives (steel, bismuth and copper, brass) are safer alternatives and as such pose less risk for human health and the environment.

2.5.1.1. Availability

Gunshot

Since the concern of dispersal of lead shot in wetlands and the fatal poisoning of water birds was raised in the 1970s, several non-lead and non-toxic shot types were developed and put into commercial production. Steel shot cartridges are produced by most European manufacturers (in the study of Thomas (2014) by all companies). Whilst steel shot is the most common alternative, particularly in the context of fowl hunting (Thomas, 2014), many European manufacturers have production lines of other non-lead products, including bismuth and tungsten based gunshot. In addition, North American manufacturers sell a variety of non-lead ammunition types in Europe.

Thomas (2014) report on a survey of typical online retailers that confirms that non-lead gunshot cartridges are widely available to consumers in most European countries, but stocks of non-lead ammunition held in local retail shops may be limited in quantity, specification, and brand. Hence, a local consumer may not currently be able to purchase the most suitable alternative for their specific needs. This should be alleviated already to large degree by the upcoming restriction on the use of lead in wetlands.

The costs of producing steel shot are comparable to those of producing lead shot even though the raw material is somewhat cheaper. This is because the filling of a cartridge with steel pellets requires more loading time per cartridge than the filling with lead pellets. However, in the consultation on the wetland proposal, one producer of both lead and steel shot commented in the consultation that technological improvements have been made. For this reason, the Dossier Submitter expects that in the long run the retail prices of steel shot will fall further, provided supply and demand of the raw material remain in balance.

The Dossier Submitter carried out an investigation into the commercial availability of three of the common medium gauges – 12, 16, and 20 – used in Europe to hunt small-sized game. Of the three gauges 12 is the most popular, whereas 16 and 20 are less popular among European hunters. The most popular medium gauge – 12 – is available under a wide range of brand names drawing upon a host of alternative materials ranging from steel to tungsten. The least widely-used gauge of the three – 16 – is offered by a very limited number of providers of alternatives and ostensibly only in steel and bismuth. The gauge 20 cartridges are available in steel, copper, tungsten, and bismuth versions, much akin to the gauge 12, albeit under fewer brands. Given that the most common cartridges are 70 mm in length, the Dossier Submitter has collected data for the cartridges of that length for all the three gauges.

Given the popularity of the gauge 12 it is only natural that there were far more lead and non-lead alternatives identified for it than for the other two gauges. More specifically, there were 13 lead-based brands identified for gauge 12, vis-à-vis 5 and 6 brands for gauges 16 and 20, respectively. For steel-based alternatives, the differences were even starker, characterised by the presence of up to seventeen different brands for gauge 12, and 2 brands for each of the remaining two gauges. The gauge 16 was not found in copper version, while the gauges 12 and 20 claimed two brands and one brand respectively. For bismuth, the equal number of brands (2) were identified for both the gauge 12 and the gauge 16, whereas the gauge 20 was found to be available in at least 3 different brands. Lastly, for tungsten, the number of identified brands totalled 10 in case of the gauge 12, whilst no brand was available for the gauge 16, and only two brands for the gauge 20.

It is expected, based on observations with the introduction of past restrictions, that the supply will follow demand and that an introduction of a regulation will stimulate the development and market introduction of alternatives. It must be noted that this analysis was carried out whilst the wetlands dossier was still under discussion, therefore availability of alternatives is likely to increase with the implementation of the dossier covering the use of lead shot in wetlands.

Bullets

The analysis of Thomas (2013) suggests that alternatives for the most popular cartridges are available on both the EU and US market. The 37 leading ammunition manufacturers produce a wide range of 35 non-lead bullet calibres that in theory cover a wide variety of hunting types. An analysis for the European market is made by Thomas et al. (2016) in which the authors conclude that product availability (i.e. that which is made) of non-lead rifle ammunition in a wide range of calibres[151] is large in Europe and is suited for all European hunting situations. At least 13 major European companies make non-lead bullets for traditional, rare, and novel rifle calibres. Local retail availability is now a function of consumer demand, which relates, directly, to legal requirements for use.

The call for evidence comments brought forward that there are no, or limited alternatives to lead for several hunting situations. The present state of the art in industry capabilities would suggest that the following types of hunting would be mostly impacted in case of a restriction on the use of all lead bullets:

- Rimfire hunting (22 LR, etc.), used for hunting the smallest game species and when shooting small predators caught in cage traps. Comments from the call for evidence suggested that no equal performing alternatives are sufficiently available.
- Full Metal Jacket (FMJ) bullets in small game hunting, e.g. Nordic bird hunting. This type of bullet is used in long distances and high accuracy is demanded.
- For calibre 5.6 mm (centerfire) and larger, it is generally accepted that the modern, well-maintained, rifles can be used to fire accurately non-lead as well as lead bullets within most hunting situations.

[151] The term calibre may apply to the diameter of the gun but can also apply to a set of dimensions (including weigh and length) set by the proofing authority (CIP).

- Furthermore the Dossier Submitter had received information that for seal hunting (where this is allowed for population management) lead bullets are required, this is further explained in Annex D1.2.2.

The Dossier Submitter notes that, small lead-containing calibres are scheduled to be phased out with a longer transition period under the Californian regulation limiting the use of lead ammunition for hunting (Duncan, 2014). Since the introduction of the Californian regulation, alternatives in that same calibre have been developed (Winchester .22/ RW .22 CCI .22). Given that many of the manufacturers in the US also have agencies for distribution in Europe, it can be expected that in the case of a restriction for these small calibres further developments of alternatives will take place. Currently two European manufacturers (Norma and RWS) offer lead free bullets (based on food safe zinc) in this calibre, one US brand (CCI) offers a non-lead version for this calibre as well. According to the website of CCI, the company has a distribution network encompassing Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Luxembourg, the Netherlands, Malta, Poland, Portugal, Slovakia, Sweden, covering 21 out of the 27 Member States.

The Dossier Submitter performed an investigation into the availability of non-lead alternatives for some of the common calibre types used in the European Union. Of all the examined calibres only two calibres of rifle ammunition- .222 REM and 17 HMR – were found to have fewer than five non-lead alternative brands available, whereas the remaining calibres had non-lead alternatives available in excess of at least five, or sometimes even ten, different brands. Some of the non-lead brands were available for most of the calibre types. Of these KJG-SR (Sax Munitions GmbH), Evolution Green (RWS), ZERO (GECO), TUG Nature+ (Brenneke), Naturalis (Lapua), Ecostrike (Norma), HIT (RWS), and GMX (Hornady) were some of the most encountered brands. Much akin to their lead-based counterparts, non-lead alternatives are available in a multitude of grains for hunters to choose from, depending on their specific hunting needs and preferences.

Air pellets

Hunting with air rifle ammunition is legally allowed only in some Member States (Sweden, Denmark, Hungary, Denmark) and in the United Kingdom. When used for hunting, lead pellets are used for pest control. As vermin are not considered "game", there is no risk to humans from ingesting lead fragments in game meat.

Unlike for hunting bullets, there are no known studies or peer reviewed tests comparing the performance of lead and non-lead (often tin) based air rifle pellet for hunting.

Product reviews on hunting and online purchasing fora would suggest that the accuracy of air rifles for hobby shooting (which would cover a fair share of their use) is adequate. However, these tests or reviews are not conclusive enough to come to a firm decision on product suitability. Some manufacturers market[152] their lead-free air rifle ammunition as suitable for hunting, examples of these are the RWS Hypermatch lines and or the H&N Barracude green line.

[152] https://www.hn-sport.de/en/air-gun-hunting/baracuda-green-177 & https://rws-ammunition.com/en/products/air-gun-pellets

2.5.1.2. Technical feasibility

Gunshot

A hunter has several substitution choices when faced with a restriction on lead gunshot. These choices are, to a certain extent, informed by the proof marks on their gun. Unfortunately, prior to the development of standardised CIP proof marks, other proofs were commonly used, adding to the uncertainty hunters may find themselves confronted with in relation to substitution.

Some guidance can be found on the BASC website[153]:

For steel/steel-like shot, a different process is involved. A standard or superior/magnum-proofed gun can fire standard steel shot cartridges, subject to conditions. To fire high performance steel, it must pass a steel shot proof, a more rigorous test of the gun's ability to handle the different pressures (same as high performance lead) and shot hardness of steel/steel-like shot cartridges. A gun successfully passing Steel Shot proof has to be stamped with a Fleur de Lys on its barrel.

Further guidance on when steel shot can be used is given on the website of the Beschussamt Ulm[154], the Ulm proofing house in Germany.

Table 2-13: Overview of possibilities to use steel shot[155]

Calibre	proof		Max operating pressure (bar)	Max allowable shot diameter	Max allowable speed V2.5 (m/s)
	before 2014	since 2014			
2070	N	CIP N	830	2.6	390
20/70	V	CIP S	1050	3.25	410
20/76	V	CIP S	1050	3.25	430
16	N	CIP N	780	3.00	390
16	V	CIP S	1050	3.5	420
20/76	V	CIP S	1050	3.25	430
12/70	N	CIP N	740	3.25	425
12/70	V	CIP S	1050	4.00	430

[153] https://basc.org.uk/technical/
[154] https://www.beschussamt-ulm.de/beschussamt/Interne_Dokumente/Dokumente/VF_504_M_Info-Verwendung-Bleifreie-Schrote.pdf
[155] Source: https://www.beschussamt-ulm.de/beschussamt/Interne_Dokumente/Dokumente/VF_504_M_Info-Verwendung-Bleifreie-Schrote.pdf

Calibre	proof		Max operating pressure (bar)	Max allowable shot diameter	Max allowable speed V2.5 (m/s)
	before 2014	since 2014			
12/76	V	CIP S	1050	4.00	430
12/89	V	CIP S	1050	4.00	430
CIP		All approved non-lead shot can be shot from firearms with this proof mark It is generally recommended to shoot lead-free shot in larger shot sizes or higher gas pressures; this can only be carried out on weapons with a choke of ≤ 0.5 mm or in connection with the corresponding exchange choke.			

Table 2-13 gives an overview on when steel shot can still be used, highlighting that a number of possibilities exist to use lead free ammunition with standard (normal) proofed guns. In line with the findings of (Putz, 2012), steel (standard) can still be used in most shotguns (older, pre-1961 and more modern, post-1961) models.

According to the rules of proof, some old (not standard proofed) shotguns should not be used with steel gunshot of any kind[156]. Nor can any shotgun be proofed to High Performance Steel level with a chamber length less than 70mm (because there is a CIP chamber-length criterion).

In Europe, the regulatory body (CIP) has developed two standards for steel shot shells, called **standard steel** and **high-performance steel**. Like the US, these standards include limits for chamber pressure, but also include velocity, momentum and shot size. CIP believes these regulatory standards are necessary to ensure the steel shot marketed in CIP countries is matched to the range of firearms that are manufactured and used in Europe.

SAAMI suggest the last three of these CIP standards appear to be controls to limit the chance of choke swelling in thin wall barrelled and tightly choked guns. The American manufacturers believe these additional controls may not eliminate the possibility of choke swelling – in their opinion, it is the design of the wad that is the most significant controlling parameter.

European gun manufacturers and retailers are often including "proofed for steel" in their advertising for new guns. This means that the barrels and choke tubes have been constructed to ensure choke swelling does not occur, and that higher chamber pressures can be safely used from the CIP's High-Performance group. It does not mean that an existing gun, without this proof stamp, is inherently unsafe to use steel loads that generate lower chamber pressures, comparable to existing lead shot loads.

Given there are always new hunters taking up this activity and hence having to use non-lead gunshot, hunters will have a choice (ascending order of cost) to:

1. Use a standard proofed shotgun (which the majority of already hunters will have) to fire standard steel cartridges (little or no extra cost or even saving);

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156 Personal communication, John Swift and Niels Kanstrup.

2. Use a standard proofed shotgun to fire standard bismuth or tungsten-based cartridges (approximately four to five times the cost of existing lead cartridges);
3. Where the hunter only owned a non-proofed shotgun, they would have the option to buy a new shotgun (either standard or high-performance steel proofed); or start to use bismuth (or tungsten shot);
4. Where a hunter owns a standard proofed shotgun and wants to fire high performance steel ammunition, it can possibly be re-proofed to high-performance steel or a replacement gun can be purchased.

Most hunters will possess at least one shotgun that is standard proofed since most, if not all shotguns sold after 1970 are standard proofed. Hence, most hunters will have to choose whether to use standard bismuth or steel cartridges. Only relatively few (assumed to be up to 10 – 15 %) are likely to see any merit in sending their gun for re-proofing against the high-performance steel specification. Some hunters with magnum proofed guns *may* get them re-proofed for high-performance steel. It is expected that most hunters will opt for the least cost option and aim to use bismuth rather than replacing old guns.

Hunters shooting goose or coastal wildfowling and who are not prepared to pay for more expensive bismuth or tungsten-based cartridges are more likely to require a gun proofed for high performance steel.

The exact number of old guns that would need to be replaced is not precisely known. Many Member States do not keep a register of shotguns or do not require any registration of the number of shotguns owned per hunter.

Lead-like shot types like tungsten matrix shot or bismuth-tin shot can be used in any European gun with any type of choke constriction. Also, standard loaded steel shot cartridges can be used in any modern gun suited to fire lead shot. The only possible concern about the use of steel and other hard shot in standard guns pertains to the choke region of the barrel, where large shot (larger 3.5 mm diameter) passing through an abruptly developed, tightly-choked barrel could cause a small ring bulge to appear around the choke cones. However, this is widely considered not to be a safety issue, but rather a cosmetic concern (Coburn, 1992).

Practical guidance on the compatibility of steel shot is available for hunters in Germany[157,158,159], France[160,161] (see also (BARON, 2001), and Austria (Putz, 2012), and is all of a similar nature, explaining to hunters which sort of cartridges can be used in guns with different proof marks (Table 2-13).

This advice is in line with the CIP specification on the use of steel shot. It must be noted that if any of the limits for the standard proof are exceeded, then the cartridges must be treated as high performance cartridges and can only be used from a steel proofed gun (with 'fleur de lys' marking).

Using steel gunshot cartridges therefore becomes a matter of carefully selecting cartridges based on the specification of the shotgun that a hunter owns. The CIP specification for standard and high-performance steel cartridges, and the BASC's explanation of these

157 http://www.flintenschuetze.de/cms/front_content.php?idcat=119
158 http://www.jagd-bayern.de/fileadmin/_BJV/Jagd_In_Bayern/jib_2006_07/JiB_7_06_Alternativ_Schrote.pdf
159 https://www.beschussamt-ulm.de/beschussamt/Interne_Dokumente/Dokumente/VF_504_M_Info-Verwendung-Bleifreie-Schrote.pdf

specifications, clearly outline the types of steel gunshot cartridges that can be used in different shotguns[162]. Not complying with these rules can result in 'ring bulging', overload and increased wear and tear in guns.

Hunting success with lead free alternatives is widely discussed in a number of studies, a detailed assessment of which can be found in Annex D. Comments from the call for evidence (Gun Trade Association, British Sports shooting Council) highlighted that non-lead shotgun ammunition has been found to perform effectively in the field.

As to the use of robust guns, be that side by sides, over and under, semi-automatics or pump-action guns, designed and proofed for high performance cartridges with lead or non-lead shot, there seems to be no limitations in the use of non-lead shot, and steel shot cartridges of either standard or high performance quality is regarded to be the most suited for bird hunting depending on quarry size, hunting conditions, shooting distances.

Some hunters may, for different reasons, need to have their gun(s) proofed, modified or, eventually replaced. Based on the Dossier Submitter's analysis the cost of such actions is rather limited compared to the general budget of average European hunters.

Bullets

From the available studies, it appears that two main factors determine the technical feasibility of alternatives; bullets are compared usually in calibre size (i.e. does the bullet fit in the gun), and on hunting efficiency (will the bullet not cause unnecessary harm to the animal).

The evidence suggests that most hunters of large game can use lead free bullets without the need to adapt guns. Comments from the call for evidence however underline that in certain hunting situations alternatives would require further development.

Non-lead hunting bullets are typically composed of copper or brass (an alloy of copper and zinc) instead of lead. Due to the lower density these bullets are often longer or lighter, and in the latter case need to be faster to transport the same amount of kinetic energy. Non-lead bullets retain most of the mass and produce no or few fragments which pose a health risk to humans.

The suitability of non-lead bullets in hunting is discussed by (Kanstrup et al., 2016) who concludes that for hunting purposes there is no consistent and significant difference between lead containing and non-lead bullet for hunting roe and red deer under normal circumstances. These results are similar to those in other studies (Knott et al., 2009)(Gremse and Rieger, 2012). Further studies by Martin et al. (2017) indicate that abandoning of lead as a bullet material for hunting bullets is possible.

In the Italian Alps the use of lead ammunition has been banned in the Stelvio National Park and Sondrio Province. At Hohe Tauern National Park in Austria, in the Pyrenees, and as part of GypConnect and GypHelp LIFE conservation projects, at the Cévennes National Park in the French Massif Central, and in Haute-Savoie, pilot project where hunters try non-lead ammunition are being carried out.

These findings on the suitability of lead are echoed in the latest advice of the German Bundesrat concluding that (German Federal Council, 2020):

'Some of the more than 15 years of use of lead-free rifle ammunition in large parts of

[162] http://www.chircuprodimpex.ro/produse/alice-non-toxice-de-vanatoare/cip-regulations-on-steel-shot-ammunition.pdf

Germany have shown that there are no deficits in terms of killing effect compared to lead-containing rifle ammunition.'

The German Bundesrat furthermore concludes that the current minimum legal energy requirements for bullets (1000 J for Roe Deer[163] and 2000 J, with 6.5 mm for large ungulates) can be met by non-lead ammunition. More recently the Danish authorities announced[164] the phase out of lead-based rifle ammunition for hunting, effective from 2023, and then become the first country in the world with a total ban on lead ammunition for hunting (similar to California). This will apply to all calibres and applications but, to the understanding of the Dossier Submitter, not to training and competition shooting (i.e. sports shooting).

The situation is less clear for calibres smaller than 5.6 mm. The recently introduced lead free ammunition for these calibres has not been extensively tested. Some field tests exist with European hare which have not been satisfactory (Hampton et al., 2020), whereas on the other hand tests exist in the US with hunting of prairie dogs (McTee et al., 2017, Hampton et al., 2020) which showed that hunting with this type of ammunition can be done without an impediment on hunting success. Some test in the grey literature[165] have indicated that the performance of such non-lead bullets (test performed with Norma .22 Eco strike) has in the meantime improved.

2.5.1.3. Economic feasibility

Gunshot

In the call for evidence commenters had indicated that the prices of steel and lead cartridges are comparable, a similar conclusion had been arrived at in the dossier on wetlands. ECHA verified whether this still holds by performing a market analysis.

ECHA has collected information on prices across a multitude of retail stores located in the EU. For the gauge 12/70 mm, 28 online stores in 8 EU countries were examined, compared for 16/70 mm: 30 online stores in 14 (countries), where examined and for gauge 20/70 mm 34 (online stores) and 11 (countries), where examined. Perhaps the most striking and interesting finding is that for the gauges 12/70mm and 20/70mm, the average price of steel-based alternative is cheaper than that of lead-based shot.

For the gauge 12/70 mm, steel cartridges were found to be the most price competitive. On average, steel cartridges were 29 % cheaper than lead-based ones. Cartridges with copper shot on average cost 176 % more than lead cartridges, whereas the differences between bismuth and tungsten, on the one hand, and lead, on the other, were even more accentuated. The average prices of bismuth and tungsten cartridges exceeded that of lead cartridge by 306 % and 647 % respectively.

As regards the gauge 16/70 mm, popularity of which has been on the decline around the globe, lead cartridges were found to be the cheapest, followed by steel and bismuth respectively. Steel cartridges cost on average 17 % more than their lead-based counterparts, whereas those made of bismuth cost 375 % more.

For the gauge 20/70mm, much akin to the gauge 12/70mm, steel cartridges were found to be on average 30 % cheaper than lead-based ones. However, the price differences between

[163] This is understood to be achieved in practice by 5.6 mm centrefire.
[164] https://www.dr.dk/nyheder/regionale/oestjylland/danmark-vil-helt-droppe-blypatroner-i-jagt-som-det-foerste-land-i
[165] https://midwestoutdoors.com/greatoutdoors/norma-ammunition-22-long-rifle-performance-review/

other alternatives and lead were less accentuated in this gauge than in the 12/70mm. In particular, the average price of copper cartridges was found to be 91 % more expensive than that of lead cartridges, whereas the figure stood at 126 % and 357 % for bismuth and tungsten, respectively.

Comments from the call for evidence indicated that it might be difficult to source non-lead cartridges for calibre .410[166] (the smallest shot gun size) although other commenters suggested that alternatives for this gauge are available.

Bullets

A comparison of prices for lead-core and non-lead rifle ammunition was presented by Thomas (2013). That study compared the retail prices of nine commonly used calibres (from .223 to .416) of assembled rifle ammunition in different weights, types, and brands available across the USA. It found that prices for the two types of ammunition were generally comparable, and where the non-lead products cost more, the relatively small increase was not enough to deny purchase and use. The same result applies to bulk lead and lead compounds purchase of bullets for ammunition hand-loaders: lead-core and non-lead bullets cost about the same at the retail level.

A regulated use of non-lead rifle ammunition in hunting would increase an economy of scale effect across the most widely used bullet calibres and lower their prices. Kanstrup (2015) concluded that non-lead rifle ammunition is largely available in all normal calibres (particularly 6.5×55, 308 Win. and 30–06) in Danish hunting stores at prices comparable to equivalent lead products. The lowest range of availability was found in the small calibres (<6 mm). In Germany, Gremse and Rieger (2015) found non-lead rifle ammunition in adequate supply across the range of hunting calibres typically used, with ammunition for small calibres (≤6 mm) being offered mostly by specialty manufacturers. Pricing comparisons in Germany mirror the conclusions of Thomas (2013) and Kanstrup and Thomas (2019).

ECHA undertook a market analysis of its own to validate some of the comments submitted in the call for evidence as well as to validate arguments brought forward to support and or object to substitution.

The independent market analysis centred on assessing the market availability and pricing of non-lead alternatives for some of the most popular calibre sizes in the European Union.

ECHA surveyed more than 120 online retail stores located in the EU. While performing online searches, ECHA collected information on prices for both lead-based ammunition and non-lead alternatives. The result of this analysis underlines the findings of Thomas. Very concretely, this analysis has shown that on average the prices of lead bullets and non-lead bullets are comparable, especially for large calibres, whereas for small calibres the prices for non-lead bullets are higher.

In Table 2-14 the price difference between lead bullets and non-lead bullets is outlined for different calibres and the respective game type.

Table 2-14: Price difference per cartridge for different calibres found in market analysis between non-lead and lead equivalent (excluding VAT)

[166] The terms calibre .410 and gauge 36 are interchangeable, due to tradition gauge 36 is often referred to as .410.

Calibre	Prices lead-containing	Prices non-lead	Price difference with lead equivalent (2020 prices, in euro)	Game type
17 HMR	€1.35	€4.3	€2.68	small
.222 REM	€1.65	€2.5	€0.85	large
.243 Win	€2.25	€2.85	€0.5	large
6.5x55	€2.55	€4.3	€1.75	large
7x64	€3.15	€3.55	€0.4	large
.30-06 Spr.	€3	3.25	€0.25	large
.308 Win.	€2.85	€3.6	€0.75	large
.300 Win.Mag	€3.7	44.3	€0.6	large
8x57	€3.2	€3.9	€0.7	large
9.3 x 62	€3.65	€4.6	€0.95	large

The price differences per calibre type were used further in the impact assessment. Given the cut off between small and large calibre at 5.55 mm (See section D.1.1.2 of the appendix) the price difference for small calibre was based on calibre 17 HMR and relevant comparison of minimum and maximum prices, whereas the price difference for large calibre were based on the average (and minimum and maximum comparison) of all price difference for large calibres. The results of this are presented in Table 2-15.

Table 2-15: Price differences between lead and non-lead (price difference expressed in Euro, excluding VAT)

Game type	Price difference with lead equivalent (2020 prices, in euro) (average of all relevant calibres		
	low	medium	high
Small game	€2.36	€2.52	€2.68

Game type	Price difference with lead equivalent (2020 prices, in euro) (average of all relevant calibres		
	low	medium	high
Large game	€0.66	€1.2	€1.7

2.5.1.4. Conclusion on alternatives

Table 2-16: Availability, technical and economic feasibility of alternatives

Risk Option	Availability	Technical feasibility	Economic feasibility
Ban on marketing and use of lead shot for hunting	Good	Good	Good
Ban on use of bullets - small calibre - for hunting	Poor	Poor	Poor
Ban on use of bullets - large calibre - for hunting	Good	Good	Good

2.5.2. Effectiveness and risk reduction

2.5.2.1. Human health impact

The following main human health risks have been identified within this restriction:

- Game meat consumption (quantitative assessment)
- Home-casting of lead bullets (qualitative assessment)

Home casting of lead bullets (use 2b)

For home-casting a quantitative assessment was not performed due to missing information on the incidence of home-casting lead bullets and the concentration of lead in the air from home-casting.

Due to the proposed ban on using lead bullets for hunting, fewer hunters will have an incentive to home-cast their bullets, and fewer people would therefore be exposed to lead fumes and dust, and in particular the children living in the same household as the hunters who are casting lead.

Game meat consumption (uses 1 and 2b)

The most relevant health endpoints associated with exposure to lead are neurotoxic effects in children aged 7 and younger, as well as increases in the incidence of chronic kidney disease (CKD) and in cardiovascular effects (increase in systolic blood pressure) in adults (EFSA, 2010).

Human exposure to lead can occur following inhalation of lead fumes and dusts from shooting with lead-containing ammunition, from home-casting of lead bullets and fishing tackle, from handling lead-containing shots, bullets, from oral intake (hand-to mouth) of lead dust on the weapon and clothes of the hunter or on the fishing tackle, oral intake of lead shots by children, and from the consumption of game meat hunted with leaded ammunition. Lead exposure can either be measured as lead concentrations in the air following shooting or home-casting or, most frequently, as blood lead (PbB) level in humans.

Different types of game meat can be discerned. The meat of large ungulates (incl. species like deer, moose and boars) are typically shot with bullets; the meat of smaller mammals such as hare and rabbit are shot with either small calibre bullets or gunshot; birds (in particular waterfowl) are typically bagged using gunshot. For larger calibres ≥ 5.6, non-lead bullets are readily available and widely used in practice. Similarly, a wide range of non-lead alternatives for gunshot in standard proofed shotguns are readily available and widely used in practice. A substitution to non-lead ammunition for calibres ≥ 5.6 and for gunshot would thus have an almost immediate effect on the exposure to lead via most types of game meat, the exception being smaller mammals hunted with small calibre bullets. However, a look at the average EU hunting bag (Thomas et al., 2020) suggests that this prey makes up less than 10 % of the weight of mammal kills in the EU. Given that smaller animals such as hare and rabbit have less meat compared to their total body weight than larger animals, it may thus be inferred that the proposed restriction option would eliminate the concern of lead contamination in more than 90 % of mammalian game meat, and in 100 % of bird meat consumed in the EU.

The objective of this section is to i) quantify the baseline risk of neurotoxic effects in children of hunter families and are assumed to be high-frequency consumers of game meat, and ii) monetise the risk reduction that could be achieved by banning lead ammunition (shot and bullets equal to or larger than calibre 5.5). Moreover, an attempt is made to quantify the baseline chronic kidney disease (CKD) risk in adults that belong to hunter families and are assumed to be high-frequency consumers of game meat. For the cardiovascular risk, another endpoint associated with chronic lead exposure, the available evidence suggests that exposure via game meat consumption is trivial and hence no quantifiable effects are assumed to result from a ban on lead ammunition.

The impact assessment follows the integrated assessment model outlined in section 1.6.3.6 of this report and relies on dose-response functions that are derived from the $BMDL_{01}$ of 12 µg Pb/L for neurotoxic effects and the $BMDL_{10}$ for CKD of 15 µg/L as proposed by EFSA (2010). For the purpose of sensitivity analysis, the dose-response functions are derived from the ECHA BMDLs as presented in Table 1-40.

Impact on IQ

The assessment of neurotoxic impacts in children exposed excessively to lead via game meat consumption follows the well-established link between concurrent blood lead (PbB) levels and full-scale IQ (Budtz-Jørgensen et al., 2013, Crump et al., 2013, Lanphear et al., 2005).

To start with, the vulnerable population was characterised as children aged ≤ 7 that belong to a hunter household. According to figures reported by Thomas et al. (2020), it can be assumed that there are about 6.0 million hunters in the EU-27. The average household size across the EU-27 in 2019 was 2.3 (Eurostat 2020). There is no reason to assume that the household sizes of hunter families would be systematically different from those of the general population. This suggests that hunter families comprise roughly 13.8 million individuals in the EU-27. Since 15.2 % of the total EU-27 population is aged 14 or younger

(Eurostat 2020), one can extrapolate that each birth cohort corresponds to about 1 % of the population. One thus finds that ~ 8 % of hunting family members are children aged 7 or younger. In absolute terms, **about 1.1 million children belong to the high-exposure group**. Each year, 140 000 individuals are newly born into this group and another 140 000 grow out of it.

Information about lead intake and resulting PbB levels in this group is scarce and some assumptions are necessary to approximate them. A key assumption made in the following analysis is that the 95th percentile of chronic game meat consumption (measured in µg Pb/kg bw/day) frequency for children observed in food recall surveys is an appropriate proxy for the frequency of game meat consumption by children of hunter families. This does not preclude that other individuals belong to the group of high-frequency game meat consumers, but the focus here is on hunter families.

EFSA data on lead contamination (measured in µg/kg) in two bundles of game meat—one consisting of meat from species typically hunted with bullets and the other one typically hunted with gunshot—were used to model lead ingestion by children. Importantly, one may expect the lead intake over time to be correlated. E.g., if a hunter has minced the meat from the shoulder of an elk including meat around the wound channel, it is reasonable to assume that the entire batch has elevated lead levels. The implication of consuming this batch over time is that the lead intake by an individual child is unlikely to be independent and identically distributed. In order to account for such correlations, it is advisable to not focus on a central measure of lead contamination but to work with the empirical cumulative distribution function (ECDF) of the EFSA contamination data instead.

Using the conversion steps outlined in the sections on human health risk assessment, one can combine lead contamination and daily lead intake to derive the predicted PbB levels in children from chronic game meat consumption. When doing so for different moments of the aforementioned ECDF one obtains a long-tailed distribution with a median incremental PbB level of 0.6 µg/L in infants and 0.8 µg/L in toddlers, respectively. The corresponding mean incremental PbB levels are 100-fold larger (Table 2-17), reflecting the skewed nature of the ECDF.[167]

Table 2-17: IQ loss modelling following the methodology described in the risk assessment part

	Mean	Min	P25	P50	P75	P95	P99
Lead contamination in game meat (µg/kg)							
shot	366	0	10	20	50	500	4 440
bullet	2516	0	10	20	54	420	19 000
Daily intake of lead (µg/kg bw/day)							
Infants							
shot	0.241	0.000	0.007	0.013	0.033	0.329	2.922

167 The predictions were triangulated using the AALM modelling tool. As discussed in a separate Annex, the results were closely aligned.

	Mean	Min	P25	P50	P75	P95	P99
bullet	4.194	0.000	0.017	0.033	0.090	0.700	31.673
Toddlers							
shot	0.413	0.000	0.011	0.023	0.057	0.566	5.022
bullet	5.582	0.000	0.022	0.044	0.120	0.932	42.161
Incremental PbB level (µg/L)							
Infants							
shot	2.9	0.0	0.1	0.2	0.4	3.9	35.1
bullet	50.3	0.0	0.2	0.4	1.1	8.4	380.1
total	53.2	0.0	0.3	0.6	1.5	12.3	415.2
Toddlers							
shot	5.0	0.0	0.1	0.3	0.7	6.8	60.3
bullet	67.0	0.0	0.3	0.5	1.4	11.2	505.9
total	72.0	0.0	0.4	0.8	2.1	18.0	566.2
Predicted IQ loss per child (points) based on the EFSA $BMDL_{01}$							
Infants							
shot	0.24	0.00	0.01	0.01	0.03	0.33	2.92
bullet	4.19	0.00	0.02	0.03	0.09	0.70	31.67
Toddlers							
shot	0.41	0.00	0.01	0.02	0.06	0.57	5.02
bullet	5.58	0.00	0.02	0.04	0.12	0.93	42.16

It is well known that the mean value is not a robust measure of centrality for strongly skewed distributions. For this reason, the full distribution of predicted PbB levels was taken forward for modelling IQ loss in exposed children. More specifically, an age-weighted average for infants and toddlers was used to estimate neurotoxic effects. As PbB levels have to be elevated over a longer period in order to result in detrimental impacts on the developing brain (see also the discussion in Lanphear et al. 2005), it was assumed that for each infant there would be 3 toddlers exposed. Applying the EFSA $BMDL_{01}$ for IQ loss (EFSA 2010), the predicted IQ loss for various moments of the ECDF were thus obtained by the following formulas:

IQ loss (shot) = ¼ * IQ loss (shot; infants) + ¾ * IQ loss (shot; toddlers);

IQ loss (bullets) = ¼ * IQ loss (bullets; infants) + ¾ * IQ loss (bullets; toddlers); and

IQ loss (ammunition) = IQ loss (shots) + IQ loss (bullets).

Figure 2-2 depicts the resulting ECDF for IQ loss from lead in shot (orange), bullets (light blue) and ammunition (dark blue). Focusing on the aggregate IQ loss (i.e. from both types of ammunition), a closer inspection of the distribution function suggests 50 % of the population at risk lose > 0.06 IQ points and 6% lose > 1 IQ point.

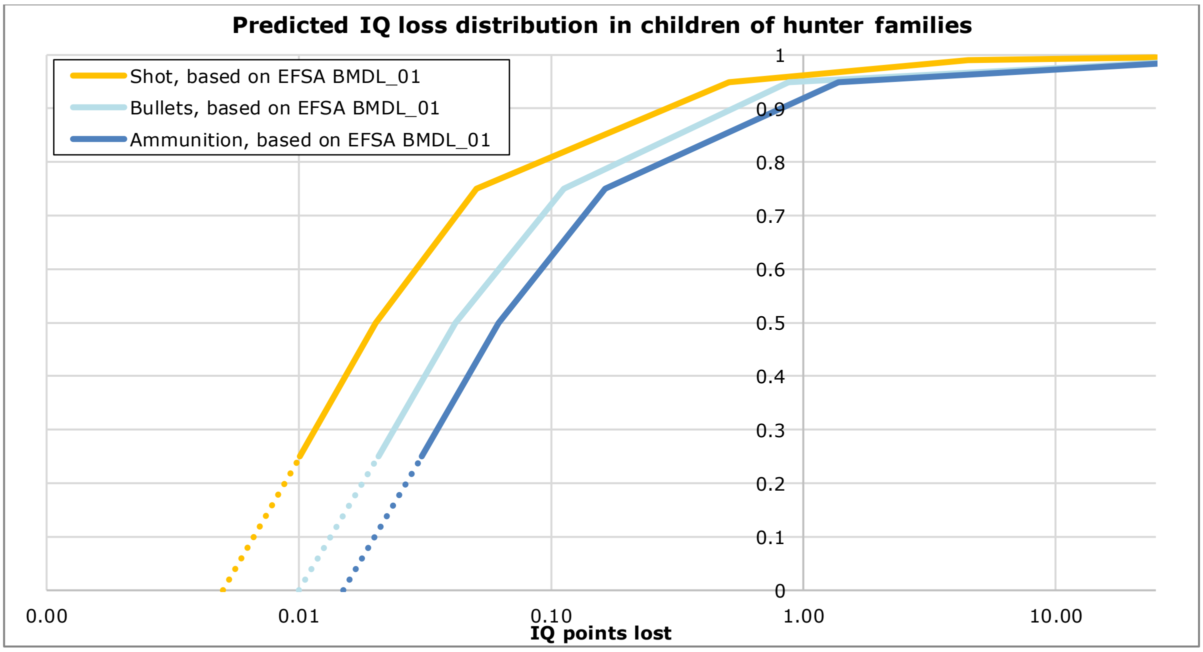

Figure 2-2: Empirical cumulative distribution functions (ECDFs) of IQ loss in high-frequency game meat consumers

These estimates of IQ point loss may be monetised based on the most comprehensive analysis of the IQ-lifetime earnings relationship to date (Lin et al., 2018), which found expected lifetime earning losses between $10 337 and $14 764 per IQ point (in 2014$). When inflation adjusted (https://www.bls.gov/data/inflation_calculator.htm), these values corresponds $11 242 to $16 056 in 2020$, or €9 500 to €13 600 in 2020€. Based on that, a value of €10 000 per IQ point lost may be assumed. Applied to the above aggregate ECDF, one may then infer that the value of IQ loss associated with the median lead intake by any birth cohort is larger than €40m (50 % * 140k * 0.06ΔIQ * €10 000 per ΔIQ).

Dating back to the work of Grosse et al. (2002), the methodology for monetising IQ loss is well established in the environmental health literature. Nevertheless, there has been an ongoing debate in SEAC about the valuation of marginal IQ point loss. It is therefore important to stress that the ECDF in Figure 2-2 allows for a more robust monetisation of predicted IQ loss by focusing only on the most exposed individuals. Indeed, if one considers only those children prone to lose 1 or more IQ points, one obtains a corresponding welfare loss of that is larger than €80m (6 % * 140k * 1ΔIQ * €10 000 per ΔIQ).

This value ignores that a proportion of bullets used for hunting ungulates are already lead-free and hence the welfare loss needs to be scaled down by the proportion of lead-free bullets in the market. As per section 2.5.1.1 (Availability) of this restriction report, the proportion of lead-free ammunition corresponds to 10 %. Therefore, a baseline welfare gain of €70m (€80m * 10%) is assumed by the Dossier Submitter to result from the restriction option proposed.

Risk of CKD

The association between PbB levels and increased CKD risk in adults is less established than the one between PbB levels and neurotoxic effects in children. However, they are still relevant at the population level since the group of highly exposed individuals is larger in the adult population than in the child population. In order to gauge the size of that population the same sources were used as before. Starting from the assumption that hunter families comprise roughly 13.8m individuals in the EU-27, and excluding those 20 % of family members aged ≤ 20 (Eurostat 2020) as well as deducting 10 % of hunters who already use lead-free gunshot and bullets, **there are about 10 million individuals at increased risk of developing CKD**.

As for children, it is assumed that the 95th percentile of chronic game meat consumption (measured in µg Pb/kg BW/day) frequency observed in food recall surveys is an appropriate proxy for the frequency of game meat consumption by adult members of hunter families. This does not preclude that other individuals belong to the group of high-frequency game meat consumers, but the focus here is on hunter families.

Following the analysis for children, EFSA data on lead contamination (measured in µg/kg) in two bundles of game meat—one consisting of meat from species typically hunted with bullets and the other one typically hunted with gunshot—were used to model lead ingestion by adults. One may again expect the lead intake to be correlated over time. Consequently, the analysis below rests on the empirical cumulative distribution function (ECDF) of the EFSA contamination data for adults.

In order to monetise the impacts associated with excess CKD risk, one has to first determine the prevalence of CKD in the EU population (assuming that members of hunter families have the same background CKD risk than the general population). A recent study by Brück et al. (2016) finds substantial differences in CKD prevalence across the EU. These differences may be driven by the prevalence of various CKD risk factors such as diet, lifestyle, differences in general population age distributions, etc. Focusing on CKD stages 3-5 (defined as estimated glomerular filtration rates (eGFR) < 60 mL/min/1.73 m^2), the age- and sex-adjusted prevalence of CKD varied between 1.0 % (95 %-CI: 0.7 % - 1.3 %) in central Italy and 5.9 % (95 %-CI: 5.2 % - 6.6 %) in northeast Germany. Based on this, it stands to reason that any CKD prevalence rate conjectured for the EU-27 general population is subject to uncertainties. Notwithstanding these uncertainties, a general population prevalence rate of 3.5 % (i.e. the mid-point of the CKD prevalence rates found in Brück et al. (2016) will be assumed hereafter.

This estimate should be interpreted with caution, however, as it is based on EFSA's $BMDL_{10}$ which has been recognised as a worst-case value due to some methodological choices in its derivation (see EFSA (2010)). Moreover, people need to be permanently exposed over at least 5 years to build up PbB levels that could lead to them developing CKD, which implies that the population at risk may be overestimated.

Using the conversion steps outlined in the sections on human health risk assessment, one can combine lead contamination and daily lead intake to derive the predicted PbB levels in adults from chronic game meat consumption. When doing so for different percentiles of the aforementioned ECDF, one obtains a long-tailed distribution with a median incremental PbB level of 0.2 µg/L in adults. The corresponding mean incremental PbB levels are 50-fold larger (see Table 2-18), reflecting the skewed nature of the ECDF.[168]

Table 2-18: CKD excess risk modelling following the methodology described in the risk assessment part

	Mean	Min	P25	P50	P75	P95	P99
shot	366	0	10	20	50	500	4 440
bullet	2516	0	10	20	54	420	19 000
Daily intake of lead via game meat (µg/kg bw/day)							
Adults							
shot	0.587	0.000	0.016	0.032	0.080	0.803	7.131
bullet	3.925	0.000	0.015	0.031	0.085	0.655	29.640
Predicted Incremental PbB level (µg/L)							
Adults							
shot	1.4	0.0	0.0	0.1	0.2	1.9	17.1
bullet	9.4	0.0	0.0	0.1	0.2	1.6	71.1
total	10.8	0.0	0.1	0.2	0.4	3.5	88.2
Predicted excess CKD risk (percentage points) per adult based on the EFSA $BMDL_{10}$							
Adults							
shot	0.94	0.00	0.03	0.05	0.13	1.28	11.41
bullet	6.28	0.00	0.02	0.05	0.14	1.05	47.42
total	7.22	0.00	0.05	0.10	0.26	2.33	58.83

Figure 2-3 plots the resulting ECDFs for excess CKD risk from lead in shot (orange), bullets (light blue) and ammunition (dark blue). Focusing on the aggregate excess CKD risk (i.e. from both types of ammunition as reported in the last row of Table 2-18), a closer

[168] The predictions were triangulated using the AALM modeling tool. As discussed in a separate Annex, the results were qualitatively similar.

inspection of the distribution function suggests 50 % of the population at risk face an excess risk larger than 0.1 percent points and 3.3 % of the population bear an excess CKD risk of ≥ 10 %.

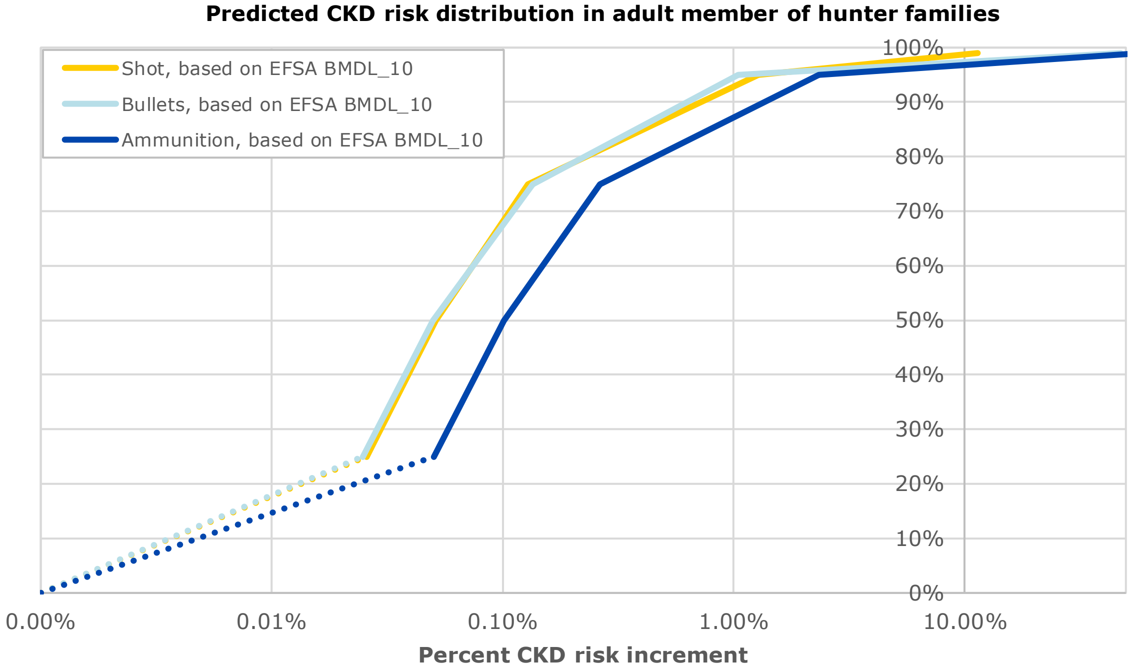

Figure 2-3: Empirical cumulative distribution functions (ECDFs) of excess CKD risk in adult high-frequency game meat consumers

In order to monetise the impacts associated with excess CKD risk, one has to first determine the prevalence of CKD in the EU population (assuming that members of hunter families have the same background CKD risk than the general population). A recent study by Brück et al. (2016) finds substantial differences in CKD prevalence across the EU. These differences may be driven by the prevalence of various CKD risk factors such as diet, lifestyle, differences in general population age distributions, etc. Focusing on CKD stages 3-5 (defined as estimated glomerular filtration rates (eGFR) < 60 mL/min/1.73 m^2), the age- and sex-adjusted prevalence of CKD varied between 1.0 % (95 %-CI: 0.7 % - 1.3 %) in central Italy and 5.9 % (95 %-CI: 5.2 % - 6.6 %) in northeast Germany. Based on this, it stands to reason that any CKD prevalence rate conjectured for the EU-27 general population is subject to uncertainties. Notwithstanding these uncertainties, a general population prevalence rate of 3.5 % (i.e. the mid-point of the CKD prevalence rates found in Brück et al. (2016) will be assumed hereafter.

As shown in Figure 2-3, 3.3 % of the 10 million individuals at risk, or 330 000 individuals, face an excess CKD risk of ≥ 10 %. Without the ingestion of lead via game meat one would expect a general population prevalence of 3.5 % among these individuals. However, one expects a higher prevalence in high-frequency game meat consumers based on the excess risk these individuals bear from lead ingestion. Combining the baseline prevalence rate of 3.5 % with the insights from the ECDF depicted in Figure 2-3, one may expect 1 155 additional cases of CKD (stages 3-5) in this group of extremely exposed individuals.[169]

This estimate should be interpreted with caution, however, as it is based on EFSA's $BMDL_{10}$ which has been recognised as a worst-case value due to some methodological choices in its

[169] 330k*3.5%*110% – 330k*3.5%*100% = 1 155.

derivation (see EFSA 2010). Moreover, people need to be permanently exposed over at least 5 years in order to build up PbB levels that could lead to them developing CKD, which implies that the population at risk may be overestimated.

For the purpose of an *indicative* valuation, one may instead assume that the etiologic fraction of CKD cases might be as much as an order of magnitude lower. Accordingly, it will here be assumed that the number of attributable cases of CKD across the EU is between 100 and 1 000. These are cases based on prevalence (i.e. the number of current cases of CKD over a specified period of time) and should not be confused with new cases which would have to be calculated based on incidence (i.e. the number of new cases of CKD during a specified period of time). Hence, instead of valuing new cases, one may turn to disability-adjusted life years (DALYs) and value those.

Both the European Burden of Disease study as well as the Global Burden of Disease study provide collated disability weights for kidney disease (see ECHA 2015). For primary/disseminated/terminate CKD, the EBD study finds average disability weights of 0.27/0.36/0.52. As CKD stage 3 will be more prevalent than CKD stages 4 or 5, an aggregate disability weight of 0.3 will here be assumed. Based on this disability weight, the attributable cases are associated with roughly 30 - 300 DALYs. As an approximation, these may be monetised by multiplication with the value of a statistical life year (VSLY).[170] Following ECHA 2016, the current VSL (€3.5 million – 5 million) endorsed by SEAC corresponds to a VSLY of €200 000 to €290 000. Applying a central value of €250k per VSLY, the DALYs associated with lead intake via game meat correspond to an *indicative* value of €7.5 million to €75 million. Importantly, it should be stressed that many assumptions have been made to arrive at this estimate and the scientific evidence on which those assumptions were based is less robust than the scientific evidence underpinning the neurotoxicity assessment.

2.5.2.2. Environmental risk reduction and releases avoided to the environment

The avoided emission change per restriction option is also subject to change of the underlying assumptions of the assessment.

For **gunshot** the baseline is a release of 14 000 tonnes per year and 280 000 tonnes in 20 years (see section 1.8.1.1). A full ban on marketing and use of lead gunshot would result in releases only during the transition period of 5 years of 70 000 tonnes (5 * 14 000 tonnes). This would be 210 000 tonnes avoided lead in 20 years.

For **small calibre bullets** the baseline is a release of 24 tonnes per year, which results in an average release of about 480 tonnes in 20 years. A full ban the use of small calibre lead bullets would result in releases only during the transition period of 5 years of 120 tonnes (5 * 24 tonnes). The avoided release would be 360 tonnes in 20 years.

For **large calibre bullets** the baseline is a release of 122 tonnes per year, which results in an average release of about 2 440 tonnes in 20 years. A full ban the use of large calibre lead bullets would result in releases only during the transition period of 18 months (1.5 years) of 183 tonnes (1.5 * 122 tonnes). The avoided release would be 2 257 tonnes in 20

170 Herrera et al. (2020) explain why this will typically result in a lower bound estimate of the value of disease.

years.

Table 2-19 gives and overview of releases avoided in 20 years.

Table 2-19: Releases to the environment under different scenarios per RO (tonnes per year)

Restriction option	Avoided release in 20 years (t)
Ban on marketing and use of lead shot for hunting	210 000
Ban on use of bullets for hunting - small calibre -	360
Ban on use of bullets for hunting - large calibre	2 257

In terms of risk to wildlife, especially birds, as indicated in section 1.5, lead ammunition and/or lead contaminated tissues (in prey), when ingested by a bird, trigger severe adverse effects and could lead to mortality. Studies on sub-lethal effects of lead intake are ongoing, but the ones available suggest that lead can also affect reproductive success in various bird species. Recent studies (Vallverdú-Coll et al., 2016a) indicate that the adverse effects of lead can be observed in the reproductive function of males, in particular on the integrity of the acrosome and the motility of the spermatozoa, which can have consequences on the oocyte fecundation. Although not all species may be equally sensitive to lead this aspect is considered critical for long-term effects, potentially in many species.

Without a ban on marketing and use of lead shot for hunting (if taking into account species considered to be at most risk of lead poisoning only) at least 135 million birds would be at risk of primary poisoning from lead gunshot. Of the 135 million birds being at most risk of primary poisoning, at least 1.2 million game birds would die annually due the direct ingestion of lead shot. Other birds (not quantified) would die as a consequence of sublethal effects. The expected risk reduction for many terrestrial (migratory) species from the proposed restriction would also fulfil the EU obligations under the Birds Directive and the CMS convention.

Without a ban on marketing and use of lead shot for hunting and on the use of bullets (small and large calibre) for hunting, 14 million birds (including raptors and scavengers species considered to be at most risk of lead poisoning only) would be at risk of secondary poisoning arising from the combined ingestion of lead gunshot, other lead projectiles and lead contaminated tissues in prey. Lead poisoning (and consequent mortality) is likely to have a significant impact on predatory and scavenger species that naturally have a low reproductive rate. The number of birds dying from secondary poisoning from both lethal and sublethal effects could not be quantified due to the lack of specific data. However, for already threatened species, any additional mortality caused by the ingestion of lead ammunition or lead contaminated prey may be of concern for the survival of that species. Therefore, for raptors and scavengers species which usually feed on prey and carcasses (including animals killed being considered as pest and abandoned on the ground) shot with both lead pellets and lead bullets, only a comprehensive restriction on both shot and bullets (small and large calibre) would guarantee a comprehensive protection, in line with the obligations under the Birds Directive and the CMS convention (including the CMS Raptors MOU). It has to be noted that in modern ecosystems, hunters can be considered the top predator and the remnants of hunting (i.e. discarded viscera of large game after 'field dressing') are a more important wildlife food source now than at any other time in history

(Haig et al., 2014) for many species, especially obligate scavengers. Burying remnants of hunting if containing lead particles would critically reduce food availability for many species, including rare species and cannot be considered as an option to reduce risks.

In addition to the species at most risk of lead poisoning assessed by the Dossier Submitter, other species may still be at some risk as assessed by the UNEP/CMS ad hoc Expert Group (2020), without a restriction. Specifically, based on this assessment, the Dossier Submitter has calculated (see section 1.8.5) that additionally about 650 million birds (at least) would be at some risk of lead poisoning from the primary ingestion of lead shot and about 50 million birds (at least) would be at some risk of secondary poisoning from lead ammunition. Additional information is expected to be available in the consultation 2021 to refine this estimate.

In addition, with a ban on marketing and use of lead shot for hunting, a more comprehensive protection of waterbirds (consistent with existing EU obligations under the Birds Directive and AEWA), also taking into account species feeding on terrestrial habitats, would be achieved.

2.5.3. Costs and other economic impacts

2.5.3.1. Costs within EU27-2020

The following categories of costs, related to the ban on marketing and use of lead shot for hunting and ban on the use of lead bullets – small and large calibres - for hunting have been taken into account within the EU27-2020.

- Research and Development (R&D) costs
- Industry compliance costs, i.e. raw material costs, energy costs, loss of recycling benefits and manufacturing equipment costs (aka capital costs)
- Retailers compliance costs
- Enforcement costs
- Consumers costs (costs to hunters)

R&D costs

European companies that are manufacturing lead shot and lead bullets will incur R&D costs from developing new alternatives. Within this context however it has to be noted that many of the European manufacturers already have set up lines for the production of lead free shot and lead free bullets, therefore the assumption is that most of the R&D cost have already been incurred before this restriction. On the other hand, retailers and ‘brands’, to stay innovative and gain market shares, design and develop regularly new products to be placed on the market.

Industry compliance costs

The target shooting market (60 – 80 %) will not be impacted by the proposed regulations if conditions for highly effective annual lead recovery rate > 90 %of lead are met; neither will the ammunition sectors’ growing exports. Steady growth in the target shooting market is expected to mitigate any shifts in hunting equipment sales. Lead ammunition supplies are expected to continue to be in strong demand by target shooters, personal protection consumers, and hunters outside the EU. With the phase-in of the proposed regulations, hunters may be expected to purchase more nonlead ammunition at higher per unit costs, which should yield higher per unit margins until manufacturer competition and higher production runs reduce costs.

Retailer compliance costs

Retailers are known to keep stocks of ammunition (bullets and shot) to satisfy local customer demand. In the call for evidence many retailers (mostly SMEs) stepped forward to highlight the potential negative consequences a ban on the use of lead in hunting would have for their business.

Ammunition has a limited shelf life and cannot be stored or kept forever. Several manufacturers give advice on the maximum shelf life their ammunition may have:

Lapua for example advises that Lapua products have been designed to be usable for several years. The condition of cartridges strongly depends on the storage conditions. In good conditions, about 10 - 15 degrees Celsius, and in normal humidity the cartridge can be used for at least 5 years[171].

Furthermore, in most Member States regulations are in force concerning the safe storage of ammunition that limit the amount of ammunition a store can keep. Especially for SME's this amount be limited and therefore with a long enough transition period this impact may be limited. In all cases, given the scope of the restriction, lead ammunition can still be used in shooting ranges that can comply with the conditions.

Enforcements costs

In terms of enforcement costs, it is assumed that REACH enforcement authorities would conduct spot checks of imported hunting ammunition (customs), manufacturers site inspection, retailers site inspections, and retailers website inspection once the restriction option would enter into force (i.e. after the transition period).

In addition, it is assumed that the preferred restriction option would allow inspections at the site of use (e.g. on hunting spots) to be performed as well by the national relevant enforcement authorities (either hunting associations or local area authorities or ministries depending on the EU country).

It is assumed that the enforcement costs (administrative, testing, and on the field) for enforcement authorities and industry will effectively be zero, existing inspections covered under the wetlands proposal will be used for this proposal as well and no additional cost will arise.

Cost for hunters

Once the restriction enters into force, it is assumed that hunters will continue to consume the same quantity of bullets and shot to continue their activity.

The main elements included in the substitution cost assessment are (details are presented in Annex D):

- **'one-off' costs** for the adaptation and/or replacement of the current stock of guns unsuitable
- incremental **'operational' costs** incurred as a continuous consequence of switching to alternative ammunition,

The cost for hunters consists of increased prices for alternatives as well as the cost associated with having to buy a new gun earlier than anticipated because of this restriction.

One-off cost

A fraction of the hunters will have to change their shotguns. Even though standard proofed guns can fire standard steel there may still be a fraction of hunters that have shotguns that

[171] https://www.lapua.com/ammunition/faq/

are not suitable for steel, although these hunters may use bismuth as an alternative. To make a conservative assessment the Dossier Submitter uses assumptions similar to the ones used in the wetlands dossier.

One-of costs consist of any modification that a hunter must make to their shotgun in order to fire steel shot: these include any cost incurred by a hunter to ensure their shotgun can use steel gunshot (e.g. for a choke modification) as well as the cost for prematurely replacing a shotgun that is unsuitable for use with standard steel gunshot. It also includes the costs some hunters may incur for testing (re-proofing) to ensure that their shotgun is suitable for use with standard or high-performance steel gunshot. Importantly, not all hunters will need to replace, re-proof or modify a shotgun that is not suitable for use with steel gunshot as they may switch over to bismuth shot or other alternative ammunition that can be used in any existing shotgun that is currently used with lead gunshot.

For large calibre rifles, existing non-lead bullets can be used without adaptation. A decision to ban the use of lead bullets would imply that the need would arise to replace certain rifles for small calibre bullets. Copper bullets with small calibres may not stabilize when fired from the same rifle barrel, which relates to the function of the twist rate of the barrel's rifling. However, for those small calibre rifles that may not fire copper bullets as accurately, the rifle should be either substituted, or the barrel be changed to one having the appropriate rifling (Caudell et al., 2012). Depending on the restriction option that is preferred, hunters may be confronted with the need to purchase a new gun.

Operational costs

Those hunters that hunt with lead ammunition will face an increased cost for using lead free alternatives, the cost of such alternatives vary as per the intended game. These differences are described in the section of economic feasibility of alternatives.

Gunshot

The information that was submitted in the call for evidence as well as the market analysis performed by the Dossier Submitter, highlights that the costs for steel shot are comparable to the costs of lead shot, although there may exist some regional differences.

To study the costs of a regulatory action, the Dossier Submitter developed best-, central-, and worst-case scenarios. The scenarios vary according to the extent of any regulation on the use of lead shot that already exists, the average prices of steel compared to lead shot and the need for testing and need to purchase new guns. The outcome of this assessment is shown in Table 2-20: Substitution scenarios for hunting with gunshot .

The main assumptions concerning the need for gun replacement, cost associated with using alternatives and adaptation that hunters already may have made as a consequence of the restriction of lead shot in wetlands are described in Annex D.

Table 2-20: Substitution scenarios for hunting with gunshot

Scenario	Best-case	Central-case	Worst-case
Number of hunters impacted in terrestrial hunting	3.6 m (60% of all hunters)	3.8 m (65% of all hunters)	4.1 m (70% of all hunters)

Scenario	Best-case	Central-case	Worst-case
Number of shotguns to be replaced in terrestrial hunting	0	190 073	413 252
One-off cost for premature replacement of shotguns	€0m	€125m	€ 135m
Annual operational cost (i.e. annual incremental cost to be spent on shot)	€0m	€75m	€109m
Annualised one-off cost for testing	€2m	€2m	€2m
Annualised one-off cost for new guns	€0m	€9 m	€21m
Total annualised cost to hunters	€3m	€86 m	€132 m
Annual emission reduction from replacement	12 976 tonnes	13 757 tonnes	14 955 tonnes
Additional cost per hunter (p.a.)	--	€20	€26
Average hunter's budget (p.a.)	€ 3 000	€ 3 000	€ 3 000
Fraction of average hunter's budget	**--**	**0.7 %**	**0.9 %**

Bullets

To study the costs of the proposed restriction, three scenarios ('best case', 'central case' and 'worst case') were developed. These scenarios are based on different assumptions on the following elements determining the overall cost of the restriction:

Under the best-case scenario, the assumption is made that the fraction of hunters already using non-lead bullets is as high as 15 %, which may be an overestimate. Comments in the call for evidence estimated this fraction to be only 10 %, but it is known that many hunters, due to the German legislations, and local restriction in parks in Austria and Italy have come in contact with lead free bullets and start to use them. The fraction of hunters using non-lead bullets further decreases in the central (10 %) and worst-case scenario 5 %.

Concerning small calibres , it is assumed that hunters will have to buy new guns or change barrels for calibre size lower than 5.6 mm. Hunters will at most change barrels and not the stock of the guns, because the stock of a gun is often chosen to fit the anatomy of a hunter and will not easily be changed. The Dossier submitter has considered this in the cost assessment with the low impact scenario assuming a change of barrels and in the middle and higher impacts scenario assuming change of guns

The price difference in the low-medium and high scenarios for substitution and associated costs are summarised in Table 2-21.[172]

Table 2-21: Substitution scenarios and associated cost for bullets (bullets in small and large calibres, prices per bullet in €)[173]

Scenario	Best case	Central case	Worst case
5 % of all hunters use lead free (emission in tonnes per year)	137	153	168
10 % of all hunters use lead free (emission in tonnes per year)	132	146	161
15 % of all hunters use lead free (emission in tonnes per year)	126	140	154
small calibre (up to 5.5 mm) prices per bullet	€ 2.36	€ 2.52	€ 2.68
large calibre (5.5 mm and larger) prices per bullet	€ 0.66	€ 1.2	€ 1.75
Small calibre			
Number of guns to be replaced	403 628	605 442	1 210 884
One-off cost for premature replacement of guns with small calibre (annualised)	€ 49 m	€ 334 m	€ 1 242 m
Annualised one-off cost for new guns	€ 10 m	€ 22 m	€ 36 m
running cost (ammunition)	€ 12 m	€ 27 m	€ 34 m
total	€ 21 m	€ 49 m	€ 70 m
Emission avoided (tonnes per year)	16	24	26
Large calibre			
Running cost (ammunition)	€ 9 m	€ 18 m	€ 28 m

172 Technical details on how the replacement cost for the respective stock of shotguns is calculated and how this estimate is annuitized are described in AppendixD

173 Prices are reported without VAT.

Scenario	Best case	Central case	Worst case
Emission avoided (tonnes per year)	110	122	142

It should be noted that all the prices for alternative bullets are based on retail prices and therefore include the Member State specific value-added tax (VAT). The reason for ignoring the VAT in the cost calculation is twofold. First, that way one can estimate the additional cost an individual hunter must bear if the restriction is implemented; second, the relevant VAT varies from Member State to Member State, making any aggregate calculation cumbersome. It is acknowledged, however, that the current approach overestimates the societal cost of the proposed restriction as the VAT is a distributional cost only.

2.5.3.2. Other impacts for society

While non-civilian uses are not within the scope of the proposed restriction, the restriction may have unforeseen consequences on its supply. This is relevant for defence uses where **security of supply** considerations mean that contingency planning must be in place in the event of a sudden increase in demand (e.g. a conflict situation). Previous experience in the US and the UK from the Iraq conflict showed that the supply was an issue due to increased demand (AFEMS Submission).

AFEMS in their submission to the call for evidence stated that concerning bullets, that the widely cited 2019 California ban on the use of lead ammunition for hunting (Assembly Bill 7111) solely covers hunting. Sports shooting with bullets is not within scope and the impact assessment conducted. AFEMS concluded the following relating to the impact on ammunition manufacturers:

"*Steady growth in the target shooting market is expected to mitigate any shifts in hunting equipment sales. Lead ammunition supplies are expected to continue to be in strong demand by target shooters*"

This means that the increasing demand from sports shooting was considered to offset the impact on increased costs associated with non-lead products for hunting.

In the call for evidence, AFEMS reported that many of the manufacturers offer alternatives at below cost, at cost, or for a lower profit margin. They do so to be able to offer a full range of products to customers who want to or are required to use non-lead ammunition.

2.5.3.3. Cost-effectiveness, affordability, and proportionality to risk

Affordability considerations

Examples from Denmark and the Netherlands for lead shot and in Germany where similar restrictions of lead in bullets (albeit with different scope) are already in place, indicate that switching to alternative materials is possible and affordable for hunters whether it be on the basis of a regulatory requirement (as in Germany and the Netherlands and Denmark) or on the basis of a desire for bullets whether or not combined with a desire for improved quality of meat (Finland).

Even if the restriction costs would be fully passed through to hunters (via price increments for ammunition), these costs are low compared to the average hunting budget spent yearly by hunters.

Based on the compliance cost estimates reported and the average yearly expenses per hunter presented in Annex D, the purchase of non-lead alternatives both shot and bullets would induce an additional expense (operational cost only) as per the overview in Table 2-22.

Table 2-22: Yearly cost per hunter per restriction option

Restriction Option	Cost of restriction per hunter (€/a)		
	Best case	Most likely	Worst case
Ban on marketing and use of lead shot for hunting	€0.0	€19	€26
Ban on use of bullets - small calibre - for hunting	€12	€27	€40
Ban on use of bullets - large calibre - for hunting	€ 2.6	€7	€7

Moreover, the proposed measures are estimated to only impose a limited cost on the individual hunter. Based on the cost estimates presented in Table 2-22 of this restriction report, it can be expected that the additional cost to an average hunter for purchasing non-lead shot ammunition rather than lead shot ammunition will range from €0 (best case) to €40 (worst case) per year (Table 2-22). The worst case corresponds to 1.3% of the average annual hunting budget of a European hunter (see Table 2-23), which is in the order of €3 000 (Pinet, 1995).

Table 2-23: Burden relative to the average hunter's annual budget

Restriction option	Low	Central	High
Ban on marketing and use of lead shot for hunting	0.0%	0.77%	0.86%
Ban on use of bullets - small calibre - for hunting	0.4%	0.9%	1.3%
Ban on use of bullets - large calibre - for hunting	0.07%	0.23%	0.23%

This additional cost seems economically reasonable even for subsistence hunters with a significantly lower hunting budget.

The Dossier submitter recognises that the budget of a hunter may differ per hunting culture and could vary from as low as € 500 per year to € €2 000 per year, A hunter typically spends money on several items in the pursuits of their activity. These expenditures can be broken down in the following cost items. Pinet (Pinet, 1995) examines and described the following elements: Legal expenditure, Expenditure on yearly hunting rights, Expenditure on equipment, Expenditure on transport, Dog-related expenditure,

Legal expenditure

In most European countries, access to hunting is controlled by the authorities which may impose an exam, a hunting licence (national or not, annual or not), a weapons permit, insurance cover etc. A special licence may sometimes be required to hunt certain game species. Depending on the country, this expenditure accounts for 6 to 10% of the total. Although relatively low, when repeated every year, it becomes psychologically sensitive and looms disproportionately large in the hunter's mind. Moreover, certain studies have shown that younger hunters, often with more limited financial resources, feel this even more acutely.

Expenditure on yearly hunting rights

Most hunters hunt on territories they do not own, be they private or public areas (state forests or properties). Access to these areas means paying fees or rents. This expenditure is higher in more densely populated countries where free circulation in open spaces is limited. This money goes to the landowners, as well as to the gamekeepers and rangers who contribute to the overall hunting quality of the territory. Game breeders also benefit indirectly from hunting rents, as very few hunters buy game themselves. That said, there are hardly any game breeders in Scandinavia. The share of hunting fees in total spending varies from country to country and place to place from 0 to 25%, with an average between 15 and 18%.

Expenditure on equipment

The most specific item of hunting expenditure. Firearms (shotguns or rifles) and ammunition (cartridges for small game or bullets for large game) are definitely not the only item of equipment. Whether an economy or luxury model, the firearm is always a long-lasting item written down over a long period of time. In this sense, the impact of this one-off purchase is relatively low compared to overall expenditure on equipment. Specialised equipment (scopes, binoculars, knives), cartridge belts, game bags, gun sleeves and yearly maintenance are included in equipment expenditure, along with smaller items (whistles, decoys, etc.). This expenditure also includes a third line: general clothing (water and windproof clothes, shoes or boots) and special items (headgear, special clothes, shooting sticks, nets, etc.)

This heading covers a large range of equipment, but it is usually inexpensive and long lasting, and therefore written down over a number of years. The overall share of equipment in total spending is around 15%.

Expenditure on transport

Two major categories of hunters can be identified in this respect:

- "regional" hunters, who do not drive far but hunt often (in some cases over 100 outings a year);

- "national" hunters, who hunt less frequently but further away.

In both cases, this means high overall mileage, and travel costs thus account for around 25% of total yearly spending.

Dog-related expenditure

Less than 12% of European hunters do not have a dog and, conversely, at least 5% have four or more. Unlike guns, dogs need daily feeding, increasingly on purchased pet food. Specialised breeds (hounds, pointers, bloodhounds or retrievers) are often bought from professionals. They need veterinary care, sometimes following injury. Leashes and other equipment must be bought. The dog therefore represents the biggest expenditure heading in the hunter's budget - around 30% on average.

Miscellaneous expenditure

Although it breaks down into various lines, this heading accounts for no more than 5% of the average hunter's budget. It includes membership fees of specialised associations, expenditure on hunting trips outside the home area or abroad (less than 10% of the hunter population), information (books and magazines), gifts (exceptional purchases of luxury clothing), souvenirs (paintings, prints, sculptures).This miscellaneous spending represents no more than 5% of the average budget. These budget headings may vary from country to country.

On this basis, and using existing regional studies, it is possible to calculate the average annual European hunter's budget.

The most recent studies give the following information:

- Belgium €5 800 (1992);
- Spain €2 450 (overestimated, 1993);
- Scotland €1 720 (1990);
- France €1 200 (1993);
- Ireland €350 (underestimated, 1992).

After weighting the figures according to numbers of hunters in each country, the average expenditure comes out at €1 680. Bearing in mind the methodological differences in terms of coverage and representativeness of the sample, an average of € 1 500 per European hunter could be a reliable estimate. Correcting for inflation, in 2020 terms, this is equivalent to about € 3 000 euro.

Pinet (1995) assumes that half of the budget on arms is spent on the annual cost of new guns and the other half on ammunition, implying that on average a European hunter spends per year 5% of his budget on ammunition, i.e. an annual cost of about €75. This is not very different from the spending known in the US where on an average about 6% if the budget of a hunter is spent on ammunition. Assuming a worst-case scenario where indeed non-toxic shot is more expensive. The average spending of €75 would increase to about €100. In the total budget this would imply that the budget needs to increase with 1.5%.

It is worth noting that this is an average budget and heterogeneity exists among hunters (REGHAB Study, April 2002). For Finland, there are significant differences between the various profiles of hunters with some spending less than €500 and others spending more than €2 000 (in 2001 price levels) per year. Despite the fact that the average spending per bird is about equal, the annual hunting bag in Finland was assessed to be 10 birds per hunter, whereas in the UK the annual hunting bag was assessed to be almost 35 bird per hunter (no distinction was made between waterfowl and other types of fowl). In a country where waterfowling is less intensive (such as Finland), the acquisition of a new gun may not be the first choice to adapt to the proposed restriction. Instead, hunters who do not own a standard-proofed shotgun may turn to bismuth or tungsten shot.

Although affordability considerations do not imply that a regulatory measure entails a net welfare gain, the analysis suggests that the preferred restriction would be unlikely to exert disproportionate costs to society overall, but hunters may be impacted differently across the EU.

Cost-effectiveness considerations

The proposed restriction is anticipated to reduce lead emissions to the environment according to the estimates in Table 2-24. Over the 20-year study period, the expected impact is a reduced emission of lead of about 210 000 tonnes.

Considering the aggregated costs imposed on hunters (in terms of more expensive ammunition and the premature replacement of shotguns that cannot fire non-lead shot ammunition), these abatement figures suggest that the total cost per tonne of lead emission avoided is in the range of €4.6/kg to €1 513/kg.

Table 2-24: Overview of cost and cost effectiveness.

Risk Option	Yearly cost	Cost over 20-year period (NPV,4%)	Emission avoided over 20-year period (tonnes), based on central case	Cost-effectiveness[174] (€/ kg avoided release)
Ban on marketing and use of lead shot for hunting	€86 m	€956 m	210 000 tonnes	4.63 €/kg
Ban on use of bullets for hunting - small calibre -	€49 m	€544 m	360 tonnes	1 513 €/kg
Ban on use of bullets for hunting - large calibre -	€18 m	€227 m	2 257 tonnes	101 €/kg

Notes: For shot and small calibre bullets cost and emission reduction over 20-year period are assumed to occur after the first 5 years. In the first five years no cost and emission reduction are assumed.

If one compares the cost-effectiveness of the current restriction proposal to the one for decaBDE, for example, where one major environmental impact was accumulation of the substance in birds of prey, it is obvious that the current proposal is an order of magnitude more cost-effective. Considering the known hazard properties of lead, it can thus be concluded that the proposed restriction is a cost-effective measure of addressing lead emissions to the environment.

Overall, the preferred restriction for lead in shot and in bullets appears to be as cost effective as previous REACH restrictions, including the restriction on lead in PVC which was addressing similar human health concerns (Figure 2-4). This clearly shows that the proposed measures under this restriction are in the same order of magnitude of other restrictions that were deemed to be proportionate.

It is noted that

[174] Small differences can occur due to rounding and annualisation of impacts over the study period

1. the cost-effectiveness of the restriction of shot outside of wetlands is almost of equal magnitude as the cost-effectiveness of lead in wetlands.
2. cost-effectiveness for small calibres is lower than the cost effectives for large calibres, as it is more expensive to restrict the use of small bullets than the use of large bullets.

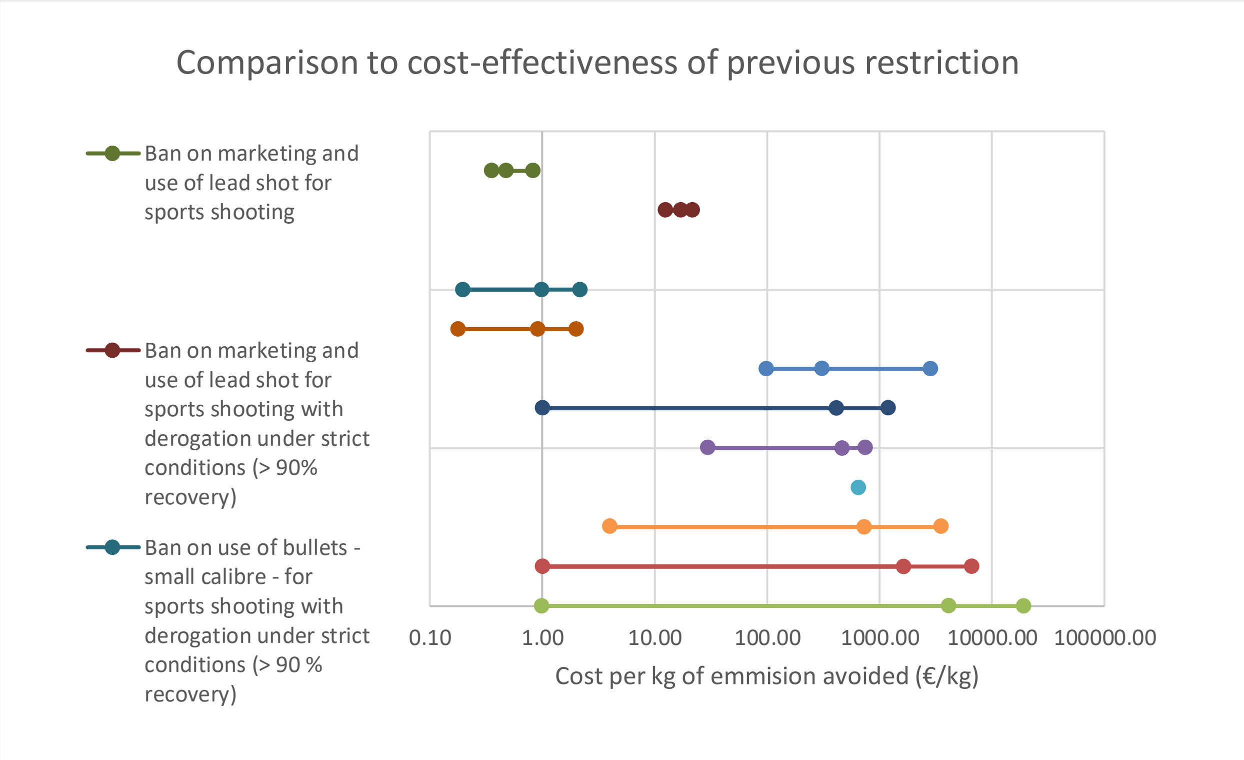

Figure 2-4: Cost-effectiveness comparison with other REACH restriction

Cost-benefit considerations

Whilst it is difficult to accurately predict all the welfare impacts induced by the current restriction proposal, some elements on both the benefit and the cost side have been quantified. In particular, the estimated cost to wetland hunters from prematurely replacing shotguns when these are not suitable to fire any form of steel gunshot ranges from €0 (best case assuming that shotguns currently used by wetland hunters in the EU are already suitable to using steel shot) to €465m and € 1 241m for small rifle guns (worst case, assuming that 413 252 shotguns and 1 210 884 small rifle guns would have to be replaced which would otherwise not have been replaced over the 50 years following the entering into force of the proposed restriction.

Both scenarios are based on extreme assumptions and should not be misinterpreted as representing expected regulatory impacts. The central case is that the restriction proposal will require the premature replacement of about 190 073 shotguns and 605 442 small rifle guns, which would have either been replaced over the 20 years following the entering into force of the restriction proposal (95% of these shotguns), or would not have been replaced over the 50 years following the entering into force.

This central case entails the aforementioned replacement cost of around €88m for shot guns cartridges, about €27 m for small rifle calibres and about and about € 18m for large calibre rifles, which can be made commensurable with the annual cost increment associated with the switching to non-lead (steel and bismuth) shot by standard annuitisation.

At a discount rate of 4%, the annuitised replacement cost in the central scenario is close to €9m for shot guns and close to €22 m for small rifle guns. This annuity needs to be added to the incremental cost of switching to alternative ammunition, which is estimated at 75.8 m per year under the central scenario (assuming that current cartridge prices for lead, steel, and bismuth gunshot remain stable) for gunshot cartridges and €27 and €18 respectively for small and large calibre rifles. Adding to this figure the annuitised cost of testing old shotguns for their suitability to using steel shot (€1.9m) results in a central annual cost estimate of €86.9 accruing to terrestrial hunters in the EU and €49 and €18 for small and large calibres, respectively. This cost estimate ignores the residual value of replaced guns. Any such residual value would have to be annuitised and deducted from the above figure to obtain the net cost to hunters.

To approximate the profit made by producers and retailers, and then multiply the cost estimate by an average 40% to arrive at an estimate of the total mark-up of approximately €75.2. An unknown fraction of this mark-up will be the actual producer surplus gain and should thus be deducted from the consumer surplus cost to arrive at the net social cost of the restriction.

Information from an application for authorisation made by one EU gun manufacturer suggests that only around 15% of shotguns sold in the European market are EU-manufactured. Likewise, the raw material for steel shot is mostly imported from Asia. Hence, a substantial share of the regulation-induced mark-ups might accrue to non-EU actors in the supply chain. Taking all this together suggests that the total producer surplus gain to EU manufacturers and retailers is an order of magnitude smaller than the regulation-induced consumer welfare loss.

A key objective of the restriction proposal is the reduction of lead poisoning in both terrestrial birds (including predatory/scavenging birds) and waterbirds in the EU because of the ingestion of lead ammunition and lead fishing tackle.

Partwise monetisation of this externality of the use of lead shot is possible at least for terrestrial birds ingesting lead shot under the following assumption. It is possible to value the premature death of an individual game bird by the opportunity cost of not being able to shoot it. This opportunity cost can be approximated by the stocking cost incurred to raise one bird of the same species. Stocking costs for 17 game bird species for which lead gunshot ingestion represents a risk have been gathered by the Dossier Submitter through a market survey made in the EU 27-2020[175]. However, these 17 species do not represent the total number of species at risk of lead poisoning in the EU identified by the Dossier Submitter.

The Dossier Submitter assumes that the aggregate opportunity cost for restocking approximately 1 200 000 terrestrial birds (related to EU 26) from these 17 species that are currently lost per year due to lead poisoning is amounts to approximately €114 million per year. This captures only part of the bird species that are vulnerable to lead poisoning from different sources of lead (in ammunition and fishing tackle) in the EU. It should be noted

[175] The Dossier Submitter carried out an extensive market research to identify market prices of the many hunted bird species in the European Union. The Dossier Submitter identified more than 120 breeders/sellers across 17 countries, from which the pricing information was gathered either by email or by means of online searches. When the prices were available in currency other than EURO, they were converted to EURO using the exchange rate of the day. After the data collection was completed, the Dossier Submitter proceeded to examine the pricing information and to determine the lowest, the highest and the average prices for each of the bird species.

that this figure does not include benefits to birds beyond the 17 species assessed (refer to Annex D), including some iconic species such as the Eurasian griffon (*Gyps fulvus*), nor does it include other indirect benefits discussed in the restriction report.

Whereas the human health impacts have been quantified in section 2.5.2.1, there are a number of other values to consider.

In its opinion on lead in shot over wetlands, SEAC considered as well that a restriction will also reduce lethal and sub-lethal effects of lead on predatory and scavenging birds, which are exposed through eating birds, and which have ingested lead gunshot or have embedded lead gunshot in their tissue. The Dossier Submitter was not able to quantify these impacts.

Other non-quantified impacts of the proposed restriction include potential impacts on other wildlife than birds (exposed through the food chain) as well as on wetland ecosystems at large. Also, lead gunshot as a potential source of lead contamination of (drinking) water resources was not assessed by the Dossier Submitter.

In terms of social welfare, the reduction of the adverse effects from the use of lead gunshot in wetlands has multiple consequences, which are summarised below:

- increased (long-term) opportunities for hunting
- increased (long-term) opportunities for leisure activities, e.g. bird watching
- reduced amount of lead released in the environment and related contamination of water resources (avoided remediation costs)
- better protection of bird populations and wetlands in general (non-use value).

Table 2-25 provides an overview of all cost and benefits considered by the Dossier Submitter.

Table 2-25: Costs and benefits comparison of the preferred restriction

Costs			Benefits	
Annual costs to hunters (shot) – use 1	€86m		Use value	
Distributional cost in term of generated tax revenue with an average VAT rate of 20%		Avoided opportunity cost associated with the annual mortality of terrestrial species	Avoided opportunity cost associated with the annual mortality of terrestrial species	€114
Annual cost to hunters for hunting with small calibres	€49m	Beneficial impacts on leisure activities including bird watching	Beneficial impacts on leisure activities including bird watching	Non-quantified
Annual cost to hunters for hunting with large calibres	€18m		Human health benefit of avoided IQ loss (shot and bullet)	€70m

Costs		Benefits	
		Human health benefit of CDK	€7.5m – €75m
		Human health benefits of reduction to lead dust during shooting	Non-quantified
		Non-use value	
		Protection of wildlife and ecosystem services	Non-quantified
		Protection of rare bird species	Non-quantified
Total societal cost	€153m	total societal benefit	€191.5m - €259m

However, this restriction should also be looked at in conjunction with the restriction on lead in and over wetlands. The two measures are complementary and indeed the benefits of the two proposals should be looked at together. Such a more holistic view is provided in Table 2-26.

Table 2-26: Overview of costs and benefits of the wetland restriction and this restriction proposal together

	Costs	Benefits	
		Use value	
Wetlands	€35m (societal cost)	Avoided opportunity cost associated with the annual mortality of approximately 700 000 waterfowl from 16 wetland bird species known to ingest lead shot.	€105m
		Avoided opportunity cost associated with the annual mortality of terrestrial species	€114m

	Costs	Benefits	
Terrains outside of wetlands	€86m	Avoided opportunity cost associated with the annual mortality of other waterbirds, predators and scavengers.	Non-quantified
		Beneficial impacts on leisure activities including bird watching	Non-quantified
Bullets for small calibre	€49m	Human health benefit of avoided IQ loss (Shot and bullet)	€70m
		Human health benefit of CDK	€7.5m -€75m
Bullets for large calibre	€18m	**Non-use value**	
		Protection of wildlife and ecosystem services	Non-quantified
		Protection of rare bird species	Non-quantified
Sum	€188m (societal cost)		€296m - €364m

2.5.3.4. Proportionality of the proposed restriction

Taking all the non-quantified benefits into consideration (Table 2-26) it seems plausible to conclude that the societal benefits of the proposed restriction will outweigh its costs even under worst case assumption.

In the worst-case assumption, the total cost of substitution closes in on € 230m, which is in the range of the expected benefits of € 190m -260m. The quantified expected benefits are an underestimate: for only 17 out of 533 species a monetisation has been made whereas a number of the types of benefits were not quantified and /or monetised. This cost-benefit ratio makes it plausible that this restriction is proportionate.

2.5.4. Information on the length of the transition period

European ammunition industry is very dependent on the EEA market as 69 % of the AFEMS members turnover is made in the EEA market (AFEMS submission). Those manufacturers who mainly produce for the European market face the severest difficulties. They will stop producing ammunition for these 8 uses completely, at least temporarily. The duration is dependent on their ability to substitute to another raw material and end-users' willingness to substitute. Only a few companies said they can substitute in the short term (0 - 3 years). Most manufacturers outlined that they can substitute in the longer term (5 - 10 years).

These arguments seem to be echoed by recent discussion the UK where in reaction to a recent call for a voluntary phase out of the use of lead shot, three (Eley Hawk, Gameborne, Lyalvale Express) companies reacted[176] by stating that:

We cannot make a complete switch over to these products within a five year period without substantial investment into the industry. BASC and its fellow organisations do not have an understanding of the manufacturing processes involved and are therefore in no position to determine the length of time required to evolve.

Tungsten and Bismuth materials are very limited in their availability and significantly more costly to produce than steel. This will result in huge increases in costs, based on raw material prices, for smaller gauge shooters who cannot use steel. This may price many shooters out of the sport.

Other sources indicated that security of supply of steel shot would be in threat if sports shooting would be in scope of a ban on placing on the market as well.

The length of the transition period is of importance when large scope and large investment costs arise. Of the restriction options analysed this would mean that the length of the transition period has a significant influence on the costs of substituting lead shot and on the cost of substituting lead bullets for small and rim fire calibres.

Table 2-27: Length of transition periods for the ROs

Restriction Option	Short transition period (0-3 years)	Medium transition period (3-5 years)	Long transition period (5-10 years)
Ban on marketing and use of lead shot for hunting	Sudden increase in demand for steel may influence price for steel	Demand effect is lower	As per medium, but impact is lower
Ban on use of bullets - small calibre - for hunting	Few alternatives available. Few companies can substitute, extra costs incurred due to increased need for R&D (above normal budget for innovation)	Provide more time to develop further alternatives, more time for gun replacement results lower compliance cost	As per medium, but impact is lower
Ban on use of bullets - large calibre - for hunting	Market already supplies a variety of alternatives, recommendation initiatives in DK and DE propose a short transition period	N/A	N/A

[176] https://www.gunsonpegs.com/articles/cartridges/cartridge-companies-respond-to-the-proposed-phase-out-of-lead-shot

2.5.5. Other practicability and monitorability considerations

2.5.5.1. Implementability and manageability

The restriction is implementable; many examples exist of situations where hunters have already switched to lead free ammunition (bullets or shot) which demonstrates that a restriction on the use of shot and bullets is possible and implementable.

2.5.5.2. Enforceability

The wetlands restriction poses challenges to enforcement authorities in terms of enforceability. With a partial restriction pertaining to wetlands only, lead shot will still be distributed throughout the EU and will remain purchasable. Field inspections by national authorities to enforce compliance with the restriction appear rather impractical and expensive. SEAC concluded that for hunters, a total ban would be easier to comply with because enforcers will not have to identify the wetland area covered by the restriction.

Presumably, if this is accompanied with any labelling activity (steel shot is now, on the cartridge, already identified as such) enforcement would be made easier.

The addition of 'placing on the market' will facilitate enforcement, a conclusion already reached by Forum in their advice on the enforceability of the proposal on lead in shot over wetlands.

Enforcing a ban on lead containing bullets may be more difficult in practice, for sure the package of ammunition carried by hunters may give some indication as to whether hunters use lead bullets or not. On a bullet level, the differences between lead bullets and copper bullets can be seen, except when fully jacketed lead bullets are used.

Should game meat be made commercially available then certificates of testing obtained already with current testing methods would create an incentive for users to comply with the legislation and at the same time allow enforcers to verify to what extent compliance with the legislation is achieved.

With a restriction entry focused on 5.6 mm centrefire, enforcers will have several options to verify whether hunter complies with the regulation:

1. Calibre, indicated on the back of the cartridge itself, manufacturers place a mark (engraving) on the back of the cartridge to indicate the calibre of the cartridge.
2. Rimfire vs centrefire, identified as the difference in the back of the cartridge.

Figure 2-5: Calibre markings on the bottom side of a cartridge case and the bottom side of a rimfire cartridge (left) and a centrefire cartridge (right) show in for centrefire the place of

the detonator in the centre of the bottom side of a cartridge

Figure 2-6: Difference between 5.6 mm and .22 lr

3. Lead content, lead swipe tests are available[177] that will detect any lead on a projectile other more modern tests are using solid phase microextraction[178].
4. In the FAQ on the California legislation, the question on enforcement answers that "*All ammunition in a hunter's possession may be inspected by wildlife officers. In some cases, if a wildlife officer suspects a hunter is in possession of lead ammunition and cannot prove otherwise in the field, he or she may seize a cartridge or bullet for further analysis. Hunters are encouraged to assist in confirming compliance by retaining and carrying in the field ammunition boxes or other packaging.*"

2.5.5.3. Monitorability

The same tools, methods and equipment that are now used to establish the risk of lead in venison can be used to monitor any progress on the phasing out of lead.

[177] https://dps.mn.gov/divisions/bca/bca-divisions/forensic-science/Pages/forensic-programs-crime-scene-rhodizonate.aspx
[178] https://www.newscientist.com/article/dn13622-gunshot-residue-test-fingers-lead-free-bullets/

2.6. Impacts of a restriction on lead in sports shooting

The restriction proposal will focus on a balance between substitution of lead shot and bullets and identifying suitable OC and RMMs that can be put in place to avoid emissions of lead into the environment.

2.6.1. Conclusion on alternatives

2.6.1.1. Gunshot

The rules on firearms and the corresponding ammunition that can be used in Olympic events is given in the "official statutes rules and regulations" developed by the International Sports Shooting Federation (ISSF). These rules have been accepted for Tokyo Olympics in 2020. For all disciplines, lead or other soft material must be used as the projectile.

The exact rules[179] of the ISSF on shot in skeet and trap (rule 9.4.3.1, c) require that pellets must be made of lead, lead alloy or of any other ISSF approved material. As such, there is no material barrier for competitive shooting using alternative gunshot materials, but an approval of the material by the ISSF is required.

In non-Olympic events, governing rules are set out by the FITASC[180], whom in their rules state that the use of lead is obligatory: chapter 7.8 weapon and ammunition states "the cartridge load must not exceed to 28 grams of lead".

The current situation is that ISSF and FITASC rules encourage the use of lead[181] ammunition at national and local level, even in non-official disciplines/events.

For example, the French association for clay target shooting requires[182] the use of lead. In reaction to this, Thomas (2013) argues that steel would be a suitable alternative because of:

1. the volume of cartridges fired by competitors,
2. the parity with prices for lead cartridges,
3. the suitability of steel shot to be used in trap and skeet events,
4. and the ease of substitution for lead shot in conventional 12 and 20 gauge shotgun cartridges.

According to Thomas and Guitart (2013), Olympic skeet and trap shooting regulations do not stipulate which gauge of shotgun can be used, only the shot load. Consequently, 12-gauge guns dominate the events because of the higher number of shot that can be fired at each target compared to those fired from 20-gauge guns. This facilitates the use of 12-gauge cartridges for Olympic shooting events.

Thomas (2013) presents a number of factory loads of steel shotgun cartridges (see Table 2-28) that are widely available and that could be considered as alternative for lead shot in shooting.

Table 2-28: Characteristics of steel shotgun cartridges for clay target shooting made by major international cartridge companies in 12 and 20 gauge (ga)

179 https://www.issf-sports.org/getfile.aspx?mod=docf&pane=1&inst=462&file=1.ISSF-Shotgun-Rules_2020.pdf
180 https://www.fitasc.com/upload/images/Rglts_PCH_01012017_ENG.pdf
181 http://www.ffbt.asso.fr/assets/filemanager/consignes%20dorganisation%202020.pdf
182 http://www.ffbt.asso.fr/pages/faire-du-ball-trap/ball-trap-temporaire.html

Company and cartridge gauge	Shot mass (oz and g)	Shot size (English) and diameter (mm)	Muzzle velocity (fps and mps)
Kent Gamebore			
12 ga	1 oz 28.4 g	#7 (2.4 mm)	1290 fps: 393 mps
12 ga	7/8 oz 24.8 g	#7 (2.4 mm)	1350 fps: 451 mps
20 ga	7/8 oz 24.8 g	#7 (2.4 mm)	1215 fps: 370 mps
Federal			
12 ga	1 oz 28.4 g	#6, 7 (2.6, 2.4 mm)	1375 fps: 419 mps
12 ga	11/8 oz 31.9 g	#7 (2.4 mm)	1145 fps: 349 mps
20 ga	¾ oz 21.5 g	#7 (2.4 mm)	1210 fps: 369 mps
Winchester			
12 ga	1 oz 28.4 g	#7 (2.4 mm)	1325 fps: 404 mps
20 ga	¾ oz 21.5 g	#7 (2.4 mm)	1325 fps: 404 mps
Remington			
12 ga	1 oz 28.4 g	#7 (2.4 mm)	1325 fps: 404 mps
20 ga	¾ oz 21.5 g	#7 (2.4 mm)	1325 fps: 404 mps
Rio Cartridges			
12 ga	1 oz 28.4 g	#7 (2.4 mm)	1325 fps: 404 mps
20 ga	7/8 oz 24.8 g	#7 (2.4 mm)	1325 fps: 404 mps

Notes: Velocity of shot is given as feet per second (fps), and meters per second (mps). All cartridges are 70 mm.

According to Thomas and Guitart (2013) the loads presented in the table closely fit the ISSF requirements:

1. Given the lower density of steel shot versus lead shot, it is necessary to use steel shot of a larger diameter than the lead equivalent, coupled with an increase in shot velocity, to achieve the same ballistic efficiency and effective range. Thus, a shot diameter of 2.6 mm might be advisable for Olympic trap shooting, in which targets may be broken at a longer distance than in skeet shooting. The ISSF regulations

would, already, allow pellets of this diameter to be used ((ISSF, 2012).

2. The maximum allowable velocity of steel shot cartridges, as set by the International Proof Commission is 425 m/s (Government of Victoria, 2011). A velocity of 390 m/s, for example, would equate with the same velocity of many lead shot cartridges, and still enable steel shot cartridges to perform well at the distances that trap, and skeet targets are usually hit.

It therefore appears that the possibilities to substitute lead exist but using alternatives would require approval of the ISSF and other federations. The Dossier Submitter concludes that the use of lead shot in sports shooting is not limited by technical barriers but rather by organisational barriers.

2.6.1.2. Bullets

For the rifle and pistol projectiles, the ISSF rules state that the projectiles made of "lead or other (similar) soft material" are permitted.

The information received in the call for evidence and various other sources point to the fact that sports shooting (apart from some specific long ranges shooting events) is mainly done using small calibres.

Very limited quantities of 0.22LR ammunition loaded with copper projectiles are available. Independent testing with this copper ammunition shows the enclosing circle diameters for only 5 shots at 45.7m (50 yards) to on average 35.6mm. This would not be considered acceptable for even entry level target shooting.

The bullet calibres used (air and firearms) are .22LR, .30-.38 and 0.177 Air. These are the basic calibres used in many of the ISSF and IBU events, which are *de facto* standard as well for all sports shooting activities leading to these events, see Table 2-29.

Table 2-29: Popular examples of calibres used in sports shooting

Air	Small bore	Full bore
4.49mm AIR	0.22LR Precision Rifle	7.62 / 308
4.50mm AIR	0.22LR Precision Pistol	6mm BR
4.51mm AIR	0.22LR Rifle	6mm XC
0.22 AIR	0.22LR Pistol	6.5 x 55
0.177 AIR	0.22LR Biathlon	7.5 x 55
	0.22LR High Velocity	6mm x 47
	0.22LR Heavy Weight	9mm
		38 Super

Air	Small bore	Full bore
		45 ACP
		10 mm
		40 CAL
		223 Rifle

Source: eley Ltd, presentation at ECHA workshop 1/11 February 2020[183].

Only international standard .22 in. (5.6 mm)-long rifle rim-fire ammunition may be used, and it is forbidden to bring ammunition not conforming to these rules to the venue. The bullets must be made of a uniform substance, lead or a similar soft material such as a lead alloy. The weight of the bullet must not exceed 2.75 grams and not be less than 2.55 grams.

The muzzle velocity must not exceed 360 m/s, measured 1 m after leaving the muzzle.

The impact momentum of bullets fired from a distance of 50 m must not exceed 0.9 Ns (= 0.09 kg m s^{-1}) with a maximum tolerance of 11 %, i.e. 0.099 Ns. This means that the maximum permitted impulse is 1.0 Ns (= 0.1 kg m s^{-1}).

Stakeholders at the ECHA workshop and in the call for evidence highlighted that the test with lead fee bullets have shown that these type of bullets have an accuracy that is sufficient for hunting but that the accuracy achieved with lead free bullets is not sufficient for sports shooting purposes.

In the winter Olympics, the biathlon is the event that combines excellence in the disciplines in cross-country and shooting. There are also other international events. The rules in terms of the firearm and ammunition are given in the IBU event and competition rules. The biathlete carries a small-bore rifle, which must weigh at least 3.5 kg, excluding ammunition and magazines. The rifles use .22 LR ammunition and are bolt action or "Fortner" ("straight-pull bolt") action. The target range shooting distance is 50 m. There are five circular shooting targets to be hit in each shooting round. When shooting in the prone position, the target diameter is 45 mm; when shooting in the standing position, the target diameter is 115 mm. Manufacturers have engineered .22 LR ammunition to give the shooter the best possibly of using skill to hit the target. All projectiles in competitions are lead based as it has the best ballistic performance. Using a different material would mean poorer ballistic performance and non-competitive shooting. Athletes would also need to learn to shoot with the new ammunition.

The main drawback that lead-free bullets exhibit in sports shooting conditions is that the systematic grouping is larger than the size of the target. In shooting sports, a shot grouping, or simply group, is the pattern of projectile impacts on a target from multiple shots taken in one shooting session. The tightness of the grouping (the proximity of all the shots to each other) is a measure of the precision of a weapon, and a measure of the shooter's consistency and skill. On the other hand, the grouping displacement (the distance between the calculated group centre and the intended point of aim) is a measure of

[183] https://echa.europa.eu/fi/-/lead-in-hunting-and-sports-shooting-workshop

accuracy.

In order to support the claim of lack of accuracy some commenters submitted test results (Gunlex) which are also available on-line[184]

Rimfire

Gunlex reported on a test with COPPER-22 ammunition with bullets weighing 1.05 g, made from compressed polymer/copper dust material by US company CCI (the only nonlead .22 ammunition on market – manufacturer already stopped production, but some is still available). The test results demonstrated the inaccuracy of the ammunition for target shooting, the grouping (i.e. the systematic spread of the gun without human intervention) was considerably more spread then with lead bullets (see Table 2-30).

Table 2-30: Results of testing a copper-22 ammunition

Ammunition	Group 1	Group 2	Group 3	Group 4	Group 5	Average dispersion
Copper/ polymer	13 mm	29 mm	39 mm	34 mm	40 mm	31 mm
Solid lead	6 mm	7 mm	5 mm	7 mm	10 mm	7 mm

Distance was measured between centres of the two most distant hits. According to the test shooter, this dispersion is insufficient not only for target shooting, but (considering additional disperse caused by average shooter and firearm) even for recreational shooting or small game hunting.

Centerfire

In the same test, Gunlex tested four commonly available nonlead ammunition with lead sporting ammunition as control group. Gunlex chose 308 Win. calibre, as (according to Gunlex) this represents the most common calibre for hunting and target shooting. The tested ammunition were:

- Hornady Superformance International (monolithic copper alloy bullet with plastic tip)
- Hornady Custom International (monolithic copper alloy bullet with uncovered expansion tip)
- Sellier&Bellot XRG (monolithic copper alloy bullet with aluminium tip)
- Sellier&Bellot TXRG (monolithic copper alloy bullet with plastic tip)
- Sako Racehead HPBT (lead core / full metal jacketed bullet) (control group)

The test concluded that the values of dispersion are sufficient for hunting purposes and for short-to-medium distance sports shooting where precision is not critical (for example, disciplines like dynamic rifle or shooting metal silhouettes). Curretn accuracy of lead free bulelts is regarded to be insufficient for any precision-based shooting discipline

2.6.1.3. Air pellets

Pellets are used extensively in sports shooting where the accuracy and precision of the shot is dependent on the interplay between the pistol/rifle used in terms of rifling and the pellet shape, size, weight, and plasticity. Pellets are available in different calibres each with a

[184] https://gunlex.cz/en/3595-comparative-test-of-lead-and-nonlead-ammunition

variety of configurations (e.g. flat-nose, round-nose, pointed, hollow-point). Each calibre may also be available in different weights. Pellets provide the highest accuracy in the rifled barrels of adult precision air rifles and air pistols. Each configuration may be available in different calibres and for each calibre in different weights.

Lead is used as the pellet material, due to its combination of properties (density, plasticity, low melting temperature) meaning that it grips the rifling and deforms into the barrel dimensions and has enough weight for continued momentum. There is no other material that has the same range of properties, plasticity and low melting temperature. Non-lead pellets are commercially available in low quantities and are generally made of tin-zinc alloys.

As one of the most accurate calibres for long distance shooting, the .177 calibre pellet is by far the most popular on the market today. As the smallest pellet of the available calibres, the .177 can be fired at the highest velocities means greater accuracy for longer distances. The .22 calibre pellet is larger in weight and size compared to .177 calibre pellets. The .25 calibre is the largest of the common calibres.

The air pellet 0.17 requires extreme precision at 10 m. Similarly, the 0.22LR requires extreme precision at 50 m. To land a 10.9 (bullseye), the centre of the shot needs to be within a circle diameter of 0.5 mm at 10 m for 0.17 and within 1.6 mm at 50 m for 0.22. As lead is the only allowed material in the Olympic shooting events for air pistol and air rifle, competitors at local, national and international events aimed at qualifying for the Olympics will need to practice with lead pellets. The rifles and pistols used are engineered for lead pellets where the accuracy and precision of the shot is tailored to the projectile, its intended range and the spot size.

Stakeholders furthermore argued that here is currently no alternative to lead for pellets that gives required precision needed for target shooting. In addition, pellets can be collected and recycled in shooting ranges.

This was confirmed in a test performed by Gunlex[185] who tested EXACT tin pellets of 4.5 mm calibre, weighing 0.440 g, from Czech manufacturer JSB Match Diabolo, using EXACT lead pellets weighing 0.547 g, from the same manufacturer, as control. The distance was set at 25 meters in indoor range. For each ammunition, four groups of five pellets were shot, see Table 2-31.

Table 2-31: Results of testing air gun pellets (comparison of tin with lead)

Ammunition	Group 1	Group 2	Group 3	Group 3	Average disperse
Tin	< 1 mm	5 mm	4 mm	8 mm	4.35 mm
Lead	< 1 mm	< 1 mm	< 1 mm	< 1 mm	1 mm

The distance was measured between centres of two most distant hits. According to the test shooter, this dispersion is sufficient for recreational shooting but insufficient for sports target shooting.

185 https://gunlex.cz/en/3595-comparative-test-of-lead-and-nonlead-ammunition

➔ The test for shooting with air pellets showed that for target shooting alternatives to lead are not suitable. The Dossier Submitter could not confirm whether the required accuracy with lead free air rifle pellets can be achieved with other brands.

2.6.2. Effectiveness and risk reduction

2.6.2.1. Human health impact

The following main human health risks have been identified within this restriction:

- Exposure from sports shooting
- Home-casting of lead bullets
- Human exposure via environment from drinking water and food

Exposure from sports shooting

Information on exposure levels in indoor shooting ranges and from blood lead levels in indoor shooters demonstrates that lead exposure increases with shooting frequency, calibre of the weapon, and insufficient ventilation (Demmeler et al., 2009). The frequent use of lead ammunition in large calibre weapons under insufficient ventilation can result in blood lead concentrations in a toxic range (Laidlaw et al., 2017). Only very limited information is available on blood lead levels in shooters performing at outdoor shooting ranges.

Due to limited availability of information and due to relevant limitations in the available studies, no meaningful quantification of inhalation exposure is possible, however. Similarly, there is not enough information available to quantify the oral intake of lead dust deposited on the weapon and the clothes of the shooter or hunters. The proposal to ban the marketing and use of lead gunshot and to use alternative shot material(s), which is the Dossier Submitter's preferred option, would prevent such risks to sports shooters.

In case of derogations for lead gunshot and/or lead bullets - even under strict environmental conditions - the risks for sports shooters from lead exposure would remain the same as they are currently.

Recommendations on good hygiene practice (see for example section 1.4.4.1) to limit lead exposure of the sports shooter and family members are important and are expected to be best practice at all shooting ranges in the EU. However, specific information on best practice recommendations at shooting ranges in the EU was usually not available to the Dossier Submitter. An EU-wide harmonisation of a complete list of recommendations for sports shooters might be beneficial.

Furthermore, recommendation could be provided to sports shooters to use non-lead primers and jacketed bullets (where possible), which can reduce lead exposure by about 90 %, (Bonanno et al., 2002, Tripathi et al., 1991).

Home casting of lead bullets

For home-casting a quantitative assessment was not performed due to missing information on the incidence of home-casting lead bullets for sports shooting and the concentration of lead in the air from home-casting. As already mentioned (see section 1.6.4.7) the Dossier Submitter assumes that home casting is mainly expected for older or historic weapons (use 6). Due to the proposed derogation for the use of lead bullets for sports shooting under strict environmental conditions, it can be assumed that home-casting of lead bullets for sports shooting will continue; however, as mentioned above, the Dossier Submitter expects that the risk will be limited to shooters with home-casting bullets for specific uses such as old and historic weapons.

Human via the environment from drinking water and food

The risk for human exposure to lead via the environment from food and drinking water is mainly related to soil with lead contamination from shooting activities. Contaminated food may include cereals, fruits or vegetables grown on contaminated soil, dairy products and meat from cows fed e.g. with silage from areas contaminated by shooting.

Directive 98/83/EC sets a threshold of 10 µg/L for lead in drinking water and Regulation 1881/2006 limits lead for example in cereals to 0.2 mg lead/kg food for human consumption. The predicted dietary exposure to lead for an adult subsistence farmer (see section 1.6.4.6) was calculated with 23 µg/kg bw/d, which is 15 times higher than the $BMDL_{01}$ established by (EFSA, 2012) for cardiovascular effects in adults (1.5 µg/kg bw/d) and 37 times higher than the $BMDL_{10}$ for nephrotoxicity effects (0.63 µg/kg bw/d).

The proposal to ban the marketing and use of lead gunshot and a ban on the use of lead bullet for sports shooting would prevent such risks. In case of derogations for gunshot and bullets under strict conditions, the Dossier Submitter considers that an addition ban of any agricultural use within the site boundaries would reduce such risks.

2.6.2.2. Environmental risk reduction and releases avoided to the environment

Gunshot

For sports shooting with gunshot, the Dossier submitter identified five restriction options (see section 2.2.2.1). The amount of lead avoided for such restriction options is summarised in Table 2-32.

The baseline is a release of 35 000 tonnes per year and 700 000 tonnes in 20 years (see section 1.8.2.1).

A full ban on marketing and use of lead gunshot (RO1) would result in releases only during the transition period of 5 years (5 * 35 000) of 175 000 tonnes. This would result in 525 000 tonnes avoided lead.

RO2 is an option that would allow only permitted athletes to use lead shot. This would concern about 12 000 athletes in EU-27 shooting about 50 % of the released gunshot. Assuming a transition period of 5 years with a release of 175 000 tonnes (5 * 35 000) and 50 % release during 15 years with 262 500 tonnes (15 * 35 000 * 0.5), it would result in a total release of 437 500 tonnes in 20 years which would be an avoided release of 262 500 tonnes.

RO3 concerns the ban on marketing and use of lead gunshot with derogation that stringent risk management measures would need to be in place to recover more than 90 % lead shot. The emission during the transition period of 5 years results in a release of 175 000 tonnes (5 * 35 000). During the following 15 years the release would be limited to 10 % due to risk management measures resulting in a release of 52 500 tonnes (15 * 35 000 * 0.1). The total release would be 227 500 which would be an avoided release of 472 500 tonnes in 20 years.

RO4 combines the restriction options RO2 and RO3. The emission during the transition period results in a release of 175 000 tonnes (5 * 35 000). During the following 15 years the release would be limited to 10 % due to risk management measures and limited to permitted athletes that consume about 50% of the released amount of lead shot. This would result in a release of 26 250 tonnes (15 * 35 000 * 0.1 * 0.5). The total release would be 201 250 which would be an avoided release of 498 750 tonnes in 20 years.

RO5, which are compulsory information, is not expected to result in large reduction of lead releases.

Table 2-32: Avoided releases of lead gunshot for sports shooting for the different restriction options

RO	Short description of RO	Avoided release in 20 years (t)
RO1	Ban on the **placing on the market** and **use** of **lead shot** for sports shooting	525 000
RO2	As RO1, but derogation for **permitted retailers** to sell and **permitted individuals** to use; permitting by Member State; reporting to the Commission 1)	262 500
RO3	Ban on the use of lead shot for sports shooting with a derogation at **permitted sites** with **lead shot recovery [≥ 90 %],** monitoring and treatment of surface (run-off) water; ban of any agricultural use within site boundary	472 500
RO4	As **RO3** but only for **permitted athletes[1]**	498 750

Notes: [1] it is assumed that permitted athletes in the EU (ca. 12 000) would release ca. 50 % of the total amount of shot used by all sports shooter in the EU

In terms of risk reduction to birds, only a ban on the placing on the market and use of lead shot for sports shooting would achieve a full protection of all species susceptible to ingest lead shot. All other restriction options would still make lead shot available for ingestion to birds, especially in areas which may be attractive to them (including agricultural fields). "Lead contaminated birds" may represent a risk to predators as well.

In terms of risk reduction to livestock (as ruminants) which may graze on contaminated land and/or which may be fed with lead shot contaminated silage, there are uncertainties related to the actual extent of these practices. However, a ban of any agricultural use within site boundary would be the minimum RMM to reduce risks to livestock. About risks to poultry[186] there was no data available on the extent of such farming activities in the EU on soils used for sport shooting. However, a ban of any agricultural use within site boundary would be the minimum RMM to reduce risks to this type of livestock as well.

The Dossier Submitter could not assess (due to lack of data) the risks related to the ingestion of lead contaminated soil by wildlife.

[186] Poultry may ingest shot as all other birds species but this risk was not assessed by the Dossier Submitter specifically due to the lack of specific data.

Risks (reduction) to humans via the environment are discussed under the human health section.

Bullets

For sports shooting with gunshot, the Dossier submitter identified three restriction options (see section 2.2.2.2).

The baseline is 42 000 tonnes per year and 840 000 tonnes in 20 years released for small and large calibre. In the absence of reliable data on the proportion of small calibre bullets and large calibre bullets, it is assumed to be 50 % each, which would be a baseline release of 21 000 tonnes per year and 420 000 tonnes in 20 years, each.

RO1 is a ban on the use of lead bullets for sports shooting. However, in the absence of suitable alternatives for sports shooting, such a restriction option is currently not implementable.

RO2 concerns a ban on the use of lead bullets at a designated location for sports shooting and measures are in place to recover lead with > 90 % effectiveness. Different transition periods for small calibre bullets (5 years) and large calibre bullets (18 months) are proposed.

For small calibre bullets the emission during the transition period of 5 years results in a release of 105 000 tonnes (5 * 21 000). During the following 15 years the release would be limited to 10 % due to risk management measures resulting in a release of 31 500 tonnes (15 * 21 000 * 0.1). The total release in 20 years would be 136 500 which would be an avoided release of 283 500 tonnes.

For large calibre bullets the emission during the transition period of 18 months (1.5 years) results in a release of 31 500 tonnes (1.5 * 21 000). During the following 18.5 years the release would be limited to 10 % due to risk management measures resulting in a release of 38 850 tonnes (18.5 * 21 000 * 0.1). The total release in 20 years would be 70 350 which would be an avoided release of 349 650 tonnes.

For small and large calibre bullets combined the release in 20 years would be 206 850 tonnes resulting in an avoided release of 633 150 tonnes.

Table 2-33: Releases of lead bullets used for sports shooting and avoided releases in case of a ban under strict conditions (> 90 % lead recovery)

RO	Short description of RO	Avoided release in 20 years (t)
RO1	Ban on the **use** of **lead bullets** for sports shooting	*Currently not implementable*
RO2	Ban on the use of lead **bullets** for sports shooting with a derogation at designated locations with **lead recovery [> 90 %]**; ban of any agricultural use within site boundary	

RO	Short description of RO	Avoided release in 20 years (t)
	- small calibre bullets (transition period 5 years)	283 500
	- large calibre bullets (transition period 18 months)	349 650
	- total	633 150

In terms of risk reduction to livestock (as ruminants) which may graze on contaminated land, there are uncertainties related to the actual extent of these practices. However, a ban of any agricultural use within site boundary would be the minimum RMM to reduce risks to livestock. The Dossier Submitter could not assess (due to lack of data) the risks related to the ingestion of lead contaminated soil by wildlife.

Risks (reduction) to humans via the environment are discussed under the human health section.

2.6.3. Cost and other economic impact

2.6.3.1. Gunshot

As result of the restriction option analysis, the Dossier Submitter has identified the following two restriction options to be taken forward with the following as the preferred option:

- **A ban on the marketing and use of lead gunshot for sports shooting**

Considering that participation in international competition require the use of lead shot, the following (non-preferred) option was identified:

- **A ban on the marketing and use of lead gunshot for sports shooting with derogation for**
  - **permitted retailers to sell; AND**
  - **permitted athletes to use; AND**
  - **at designated locations permitted by Member State; AND**
  - **risk management measures are in place (e.g., regular recovery > 90 %, surface water control) to minimise the risks.**

The cost and other economic impact is addressed for such restriction options.

Ban on marketing and use of gunshot

The calculations for the cost involved with a ban on the use of gunshot is presented in Table 2-34. The following considerations were made:

- Bismuth and tungsten are, for their high price, not considered as viable alternatives for lead in sports shooting
- Although in principle no gun replacement appears to be needed (see section on alternatives) a conservative replacement rate of 10 % was used.

- Cost and emission reduction over 20-year period are assumed to occur after the first 5 years. In the first five years no cost and emission reduction are assumed.

Similar assumptions have been used to estimate the impacts of a ban on lead gunshot for spots shooting but with exception for sport shooters that compete at international level (See Table 2-35)

Table 2-34: Calculation of cost associated with ban on shot for sports shooting

Parameter	Data		
Volume of lead used per year	35 000 tons		
Weight per cartridge	Based on FITASC contribution: 60 % of shooters use 28 gram cartridge, 40% of shooters use 24 gram cartridge. 60 % 28 gram and 40% 40 gram = 26.4 gram per cartridge on average		
Number of cartridges	35 000 tonnes / 26.4 gram per cartridge = 1 326 million cartridges		
Price per cartridge	€0.42		
Price difference	Min	Middle	Max
	1 % higher price for steel	2 % higher price for steel	5 % higher price for steel
	€0.0042	€0.0084	€0.021
Compliance costs	Nr of cartridges * price difference		
	€5.6 m	€11.1 m	€27.8 m
Number of sports shooters in the EU	2.5 million (based on FITASC information)		
Costs for premature replacement	10 % replaces gun prematurely = € 11.3 m for forwarding cost of gun replacement		
Cost per year after the transition period	€16.9 m	€22.4 m	€39 m
Cost over 20-year period (NPV, 4%)	€187 m	€249 m	€435 m

Parameter	Data		
Cost effectiveness per year after the transition period	0.48 €/kg	0.64 €/kg	1.12 €/kg
Cost effectiveness over 20 years	€249 m (central case), (NPV, 4%, 20 years) / 15 * 35 000 tonnes = 0.48 €/kg		

Table 2-35: Calculation of cost associated with ban on shot for sports shooting with a derogation for international athletes

Parameter	Data		
	min	mid	max
Volume of lead used per year	14 840	19 160	23 480
Weight per cartridge	Based on FITASC contribution: 60 % of shooters use 28 gram cartridge, 40% of shooters use 24 gram cartridge. 60 % 28 gram and 40% 40 gram = 26.4 gram per cartridge on average		
Number of cartridges	562 m	725 m	889 m
Price per cartridge	€0.42		
Price difference	Min	Middle	Max
	1 % higher price for steel	2 % higher price for steel	5 % higher price for steel
	€0.0042	€0.0084	€0.021
Compliance costs	Nr of cartridges * price difference		
	€2.36 m	€6.09 m	€18.67 m
Number of sports shooters in the EU	2.5 million (based on FITASC information)		
Costs for premature replacement	10 % replaces gun prematurely = € 11.3 m for forwarding cost of gun replacement		

Parameter	Data		
Cost per year after the transition period	€13.7 m	€17.4 m	€30m
Cost over 20-year period (NPV, 4%)	€151 m	€193 m	€333 m
Cost effectiveness per year after the transition period	0.92 €/kg	0.91 €/kg	1.27 €/kg
Cost effectiveness over 20 years	€249 m (central case), (NPV, 4%, 20 years) / 262 500 tonnes = 0.74 €/kg		

Derogation of the ban under strict conditions

As shooting ranges are a major source of lead emissions to the environment, the restriction proposal with regards to the derogation from the ban on placing on the market and use under strict conditions (such as regular lead shot recovery > 90 %) looks at various measures for lead abatement. A site-specific impact assessment for all shooting ranges in the EU/EEA is beyond the scope of this restriction proposal since there is no suitable EU/EEA dataset that identifies all shooting ranges with corresponding information on their operational conditions and risk management measures in place. Instead, the Dossier Submitter, based on the CSR for lead (CSR, 2020), has analysed four representative scenarios to model the likely impacts that the proposed restriction would have on shooting ranges for skeet, trap and sporting/COMPAK throughout the EU.

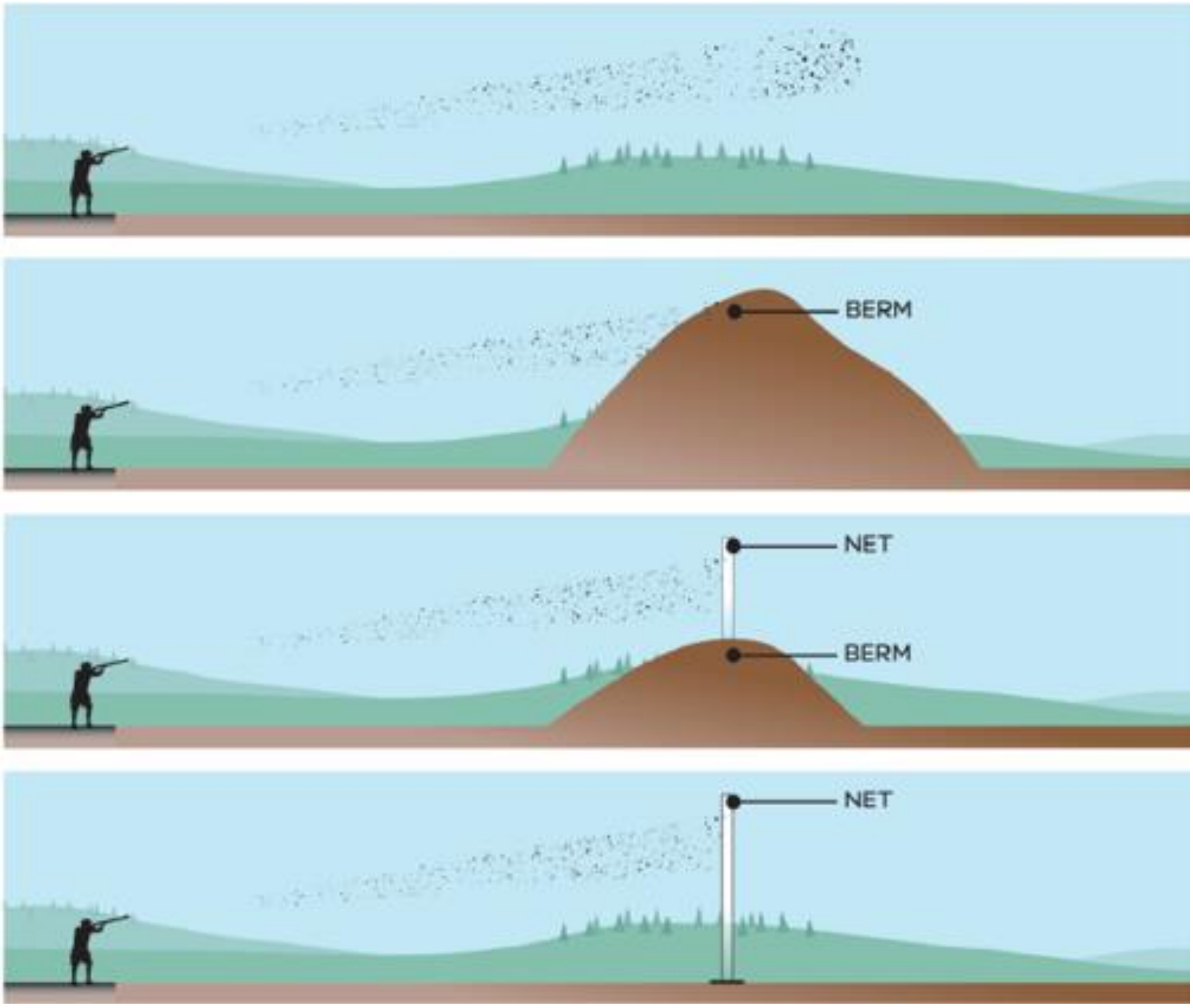

Figure 2-7: How berms and nets limit the spread of shot.

The main principle of containing lead at shooting ranges is to design the range in such a way that lead will not escape, be kept within the boundaries of the range and lead shot recovery is facilitated. In practice this is achieved by installing berms (with or without nets) of sufficient height, which will stop lead in flight. This is illustrated in Figure 2-7Figure 2-7: How berms and nets limit the spread of shot.

According to Figure 5.20 of the Finnish BAT (Kajander and Parri, 2014), the area for one trap range is ca. 50 000 m^2 and for one skeet range ca. 60 000 m^2. The value of 60 000 m^2 is taken forward for further analysis.

The Dossier Submitter assumes that a berm reduces the shotfall zone by 30 % to 70 % of the original area and a berm and/or a net to 50%. This is a simplified approach, because the reduction in the shotfall zone is dependent on the distance from the shooting stand to the barrier and the type of discipline. For a trap range with a shot net the reduction can be up to 85 % (15 % of the original area), whereas for a skeet range the reduction can be only up to 30 % (70 % of the original area) as indicated by Victorian EPA (2019) on page 55.

By designing ranges in such a way that several stands are next to each other with overlapping shotfall zone, the deposition area can be reduced further. Based on Figures 2., 12. and 13. of Australian EPA (2019) and Figures 4.3 and 4.4 of AFEMS (2002) the Dossier Submitter assumes that for three adjacent ranges the deposition area is about 1.5-times the deposition area of a single range. This has a relevant impact on the cost effectiveness of risk management measures and recovery of lead.

Costs of risk management measures

To achieve a lead shot recovery rate of > 90 % measures such as berm and/or shot nets and/or surface coverage are required to reduce the shot fall zone and to enhance regular recovery of lead shot. Information on the costs of such measure are very limited.

The following assumed costs have to be considered as rough estimates providing hints on the magnitude of costs rather than exact costs.

The Finnish BAT (Kajander and Parri, 2014) reports that the cost for installation of a berm may vary between €300 000 and €600 000 for a given range for the installation of a berm alone. Since for ranges in this scenario no RMMs are currently in place, the higher value of €600 000 is taken forward for the impact assessment. The Finnish BAT assessed these costs at a rate of €3.5 per m^3. The Dossier Submitter correcting this upwards to €20[187] per m^3 to account for an increased price for groundworks which would yield a cost of **€3.5 million per berm**. However, it should be noted that this would cover the costs of a berm alone and does not include any additional costs arising from the installation of shot nets.

Another solution which is sometimes opted for is to place a net at a suitable distance combined with suitable surface coverage of the impact zone. The Finnish BAT does not give the costs of such a net. Other sources (KNSA[188]) have made estimations of the costs of such nets based on a unit price of €250 per m^2 (2014 prices). Assuming this to be installed with a height of 5 meters high over ¼ of a circle at 150-metre distance and correcting for inflation would give investment costs of **€300 000 - €400 000** for shot nets.

Further costs for surface coverages might arise, for which no cost estimates are available for most materials except asphalt as specified in the Finnish BAT.

In addition, there will be costs for containment, monitoring and, where necessary, treatment of surface (run-off) water to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive. The Finnish BAT (Kajander and Parri, 2014) provides a value of €9 000 for installation of a water treatment system for an area covering around 2 000 m^2.

The Finnish BAT provides the total costs for design and implementation of **measures for pollutant management with €1 500 000**, and the costs for **maintenance with €50 000** (for a 10-year period). The Dossier Submitter takes forward those costs and assumes that such measures would be suitable to achieve a recovery rate of > 90 %.

Furthermore, the costs for a final clean up of the range need to be considered. Two case studies have been found that describe the cost of remediation to remove lead contamination at end of service life from old:

- Germany, Remscheid shooting range (shot and bullets) in use 1926 - 1996 remediation of 11 150 m^2 area with costs of €750 000 (Richter and Hohmann, 2019).

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[187] https://www.livios.be/nl/bouwinformatie/ruwbouw/voorbereidende-werken/grondwerken/wat-kosten-grondwerken/

[188] https://www.knsa.nl/media/1332/122-voorstel-bodembescherming-tegen-loodhagel-kleiduivenschietbaan-emmer-compascuum-knsa-en-milieuadviesbureau-van-den-bos-15-04-2014.pdf

- Germany, Lemgo-Lüerdissen, trap and skeet range in use for more than 50 years, ca. 50 000 mg Pb/kg, 37 000 m^2 area to be remediated, 7 500 m^3 contaminated soil, ca. 148 t lead resulted in costs of €950 000 Euro (Lampe, 2012).

Based on those examples, the total costs of soil removal to recover lead the main impact areas of one range at the end of service life are assumed to be €750 000 - 950 000. For remediation of the whole area of a shooting range (of about 60 000 m^2) more than €1 million has to be assumed.

To calculate the costs for regular soil removal each 5 to 15 years, the second example provides information implying that the cleaning of contaminated soil would cost at the minimum **€126 per m^3**.

Costs for the impact on the environment

Contaminating soil with lead has a negative impact on the environment because it can be assumed that a fraction of the lead deposited will be mobilized over the time leading to increased lead concentrations in water, soil, plants and consequently entering the food chain. No monetisation of this negative impact was performed yet.

Scenarios

The Dossier Submitter identified (based on the Chemical Safety Report attached to the registration file) a number of scenarios for different types of ranges, which are described in Table 2-36.

Table 2-36: Scenarios and range types used for impact assessment

Scenario	Operation conditions	Represents
A: Shooting areas or ranges where steel is used	-	-
B: Temporary areas without relevant RMM (no lead recovery)	Shooting intensity (rounds per year): 5 000 – 10 000	Temporary ranges such as annual clay target competition on local level
C: Permanent ranges without relevant ENV RMM (lead recovery < 50 %)	Shooting intensity (rounds per year): 5 000 – 10 000	Ranges organised in open areas
D: Permanent ranges with some ENV RMM (berm reducing the shotfall zone to 70 %; lead recovery 50 - <90%)	Shooting intensity (rounds per year): 10 000 -100 000	Ranges that are constructed with some RMM possibly used by regional clubs.
E: Permanent ranges with different ENV RMM (reducing the shotfall zone to 50% (30 – 70 %); lead recovery >90%)	Shooting intensity (rounds per year): 100 000 – 350 000	Rather large ranges, with well develop RMM where large competitions (even international) could be organised

To investigate the impacts of a restriction (ban on the marketing and use of lead shot with derogation to regularly recover > 90 % lead shot) within these types of ranges the Dossier Submitter compared the comparative advantage between the options to continue the use of lead gunshot by installing additional RMM and avoiding the need to install RMM by shifting to use non-lead shot.

On many ranges, additional environmental RMMs would need to be installed to ensure lead recovery is sufficiently effective to allow continuation of using lead shot. Following several best practice documents, these RMMs would at least include the construction of a berm, (height and distance to be determined) not only for lead abatement but also for safety and noise abatement, as well as additional measures such as a net on top of the berm (in case the berm does not have a sufficient height) and surface coverage to be able to collect more than 90% lead shot spent.

The cost of collecting lead varies but it can be assumed that members of shooting clubs help in collecting lead, by organising regular clean-up, such as every six months. Evidence is given, for example, through the explanation on lead collection in France[189] but also by site visits that the Dossier Submitter undertook. In some cases, such as in Finland the additional cost of clean-up that may be incurred, are covered by the members in the form of an eco-contribution.

The Dossier Submitter further assumes that the incremental cost involved in using alternatives at shooting ranges is driven by the (small) price differences between lead and alternatives (steel) and by any cost coming from the use of alternatives.

The most likely alternative to lead gunshot is steel shot (see section on alternatives), which can be purchased by sports shooters at comparable prices (see section on suitability of alternatives). The Dossier Submitter assumes that steel shot is at a maximum 4 % more expensive than lead gunshot. This means that while the average market price per lead shot cartridges is €0.45, the average price per steel shot cartridge corresponds to €0.46.

Although the European sports shooting confederation reports wooden structures to prevent ricochets, which have been installed in the Netherlands (personal communication), the German shooting range guidelines (German Bundesministerium der Justiz, 2012) prescribes only the use of safety glasses when using alternative gunshot at shooting ranges. Based on this, the Dossier Submitter concludes that the use of alternative shot does not require additional RMMs compared to the use of lead shot. From an internet search it was learned that the prices of such glasses vary between €5 - 50 depending on brand, make, etc. The Dossier Submitter assumes a price between €5 - 50 per shooter.

To evaluate the different scenarios, costs are calculated for a shooting range with one stand only. In reality, FITASC and ISSF rules prescribe several shooting stands.

A trap range uses 5 shooting positions to fire at clay targets launched from a centre trap house. The targets are thrown at different angles away from the trap house. A skeet uses 8 shooting positions to fire at clay targets launched from both high and low houses. The targets are thrown at the same pattern, but the angle of shot varies because the shooter moves to the different positions. These shooting angles tend to create a semi-circular pattern of lead shot as it falls to the ground." (US EPA, 2005).

A: Shooting areas or ranges where steel shot is used

[189] https://questions.assemblee-nationale.fr/q15/15-3842QE.htm

Baseline

A few Member States have implemented legislation that restricts the use of lead at shooting ranges. In Sweden, Norway and Denmark the use of lead shot in shooting ranges is banned in the entire territory (with some derogations in place; see below); in the Netherlands the use of lead shot is banned for clay pigeon shooting. In Belgium, in the Flemish region, there is a regional ban for the entire territory.

Impact

No impacts are expected to arise as consequence of this restriction.

B: Temporary areas where lead is used (without any ENV RMMs)

Baseline

Temporary shooting range can be organised at virtually any suitable area of land, typically they are organised for yearly events that last 2 - 3 days at maximum. For temporary areas, it is assumed that no RMMs are in place to limit lead emissions and/or recover lead shot. Use of RMMs at temporary areas are reported sporadically, as for example reported by the French ball trap organisation. Incidental use of agricultural foil has been reported[190], but there is insufficient information to model this as part of this scenario.

Lead shot recovery or remediation is usually not performed for temporary ranges and therefore, no running costs emerge. However, the contamination of such temporary shooting areas has an impact on the quality of soil, the quality of agricultural products grown on such areas and for wildlife and livestock. This impact has not been monetised yet.

Impact

The Dossier Submitter calculates that the annual amount of lead dispersed in a typical temporary shooting area is in the order of 120 - 240 kg corresponding to 5 000 – 10 000 shots per year (or 2 - 3 days of shooting per year).

Based on the assumed price difference of €0.2 per cartridge between lead and steel shot, the incremental cost from switching to steel shot is in the order of €100 - 200 per year, depending on the intensity of shooting. Importantly, this annual cost will be shared by all shooters participating in the use of the area. Using the estimates from Thomas and Guitart (2013) of around 100 shots per person, this would amount to 50 - 100 participants per event, resulting in an increased cost per person of €2 - 4 per shooting participant.

If agricultural foil is used to recover lead shot (assumed price of the foil about €0.2 per m^2[191]), then this would imply costs of up to (50 000 m^2) * €0.2 per m^2 = €10 000 per use. The actual price may vary on the required quality of the foil. Higher quality foil is less likely to break would be more expensive.

The lead that could potentially be recovered would be between (5 000 - 10 000 * 0.024 - 0.028 kg), i.e. 120 – 280 kg, against a price for recovered lead of about €1 per kg the value of this recovered lead would be in the order of €120 - 280.

This example is hypothetical, in reality shot will also fall outside the temporary ranges. The practicality of such measures can also be questioned, as the required quantity of foil would be vast and the foil would need to be of sufficient quality to be able to prevent spillages. Furthermore, the temporary character and the envisaged use for other purposes after the

190 https://questions.assemblee-nationale.fr/q15/15-3842QE.htm
191 https://www.btndehaas.nl/afdekmateriaal/plastic-folie/landbouwplastic

event (often for agricultural uses) would result that the foil solution would need to be handled for every, separate event. No re-use of the foil is foreseen.

This leads the Dossier Submitter to assume that the measure is not practical and that the required recovery rate (in case of a condition) would not be met in practice, so not only is the measure not efficient nor practical but will also not lead to the required level of control.

Consequently, for temporary shooting ranges the cost to recover lead shot would be €9 000 – 10 000 whereas the incremental cost from using steel shot instead of lead shot would be maximum €200.

Table 2-37: Baseline and impact costs for temporary areas (B)

Baseline costs	Costs for RMMs required to achieve recovery > 90 %	Costs for use of alternative(s)
Lead recovery or remediation is usually not performed leading to persistent contamination of the area (not monetised yet)	Recover > 90 % not feasible; Cost of foil: €10 000 (minimum)	Use of steel shot: At shooting intensity of 5 000 to 10 000 rounds of shot/year: €2 000 - 4 000 over the lifetime of a shooting range (40 years). (€20 - 40 per shooter)

➔ As a full ban of lead shot is less costly and more effective than any conceivable set of RMMs, it is the most proportionate matter for temporary ranges.

C: Permanent ranges without relevant ENV RMMs (low lead recovery)

Baseline

For some permanent ranges no RMMs will be in place. This would, for example, apply to trap and skeet disciplines but also to ranges used for shooting disciplines that are usually located in natural environments with adjunct trees and bushes. The effectiveness of lead recovery under these conditions is assumed to be not higher than 40 % (less than 50 %). It is assumed that for such ranges lead contamination may be removed only at the end of service life with possible infrequent lead collection from the surface or removal of the topsoil during service life. The total costs of soil removal to recover lead at the end of service life are assumed to be far higher than €1 million.

In the case of areas with trees and bushes, the collection of lead from the surface or the removal of topsoil is likely to be more expensive, more difficult and/or even not possible.

Example case

Blackburg shooting range, US; source Craig et al. (2002):

The shotgun range occupies a cleared 60 m long by 60 m wide slightly sloping surface now covered with grass. The shooting ranges are completely surrounded by second growth forest, last cut over in the 1930s, dominated by red and white oaks that are up to 31 cm in diameter and contain as many as 60 growth rings. Some pines are up to 33 cm in diameter and contain up to 90 growth rings. The shooting range was established in 1993, has been in continuous use since that time, and appears to be increasingly used.

From the description of the case the Dossier Submitter assumes no RMM are in place. Reference is made to occasional clean-up of the range by means of replacing the topsoil. The claimed disposition rate (assumed to be equal to the possible recovery rate) is in the order of 15 % of the lead, assuming this all falls within the hot zone of 60 m.

The case is exemplary for this class of shooting ranges where no RMM are put in place.

Impact

To achieve a recovery rate of > 90 % for such a range, the construction of a berm and/or possible installation of shot curtain, shot nets, on the top of the berm (or replacing a berm), together with a surface cover at the impact zone or, alternatively, the installation of nets and surface coverage would be required which are costly.

Costs of €1 500 000 for the implementation of environmental risk management measures and €50 000 for maintenance (for every 10 years) are assumed (Kajander and Parri, 2014).

Based on height and position of the berm in relation to the shooting stand, additional shot nets might be required on top of the berm as well as surface coverage of the impact zone. Assuming this to be installed with a height of 5 meters high over ¼ of a circle at 150-meter distance and correcting for inflation would give investment costs of €300 000 for shot nets.

To calculate the costs for soil removal at the end of service life, it is assumed that an area of max 30 000 m^2 (50 % reduction in shotfall zone by RMMs) would need to be removed at a soil depth of 5 cm resulting in a soil volume of 1 500 m^3. Assuming €126 perm^3 would result in costs of €189 000.

On the other hand, the use of alternatives to lead shot (such as steel) would, over the lifetime of such a range, lead to an incremental cost of €2 000 – 4 000 (NPV, 4 %, over 40 years, yearly costs of €128). Using the estimates from Thomas and Guitart (2013) of around 100 shots per person, this would amount to 50 - 100 participants per event, resulting in an increased cost per person of €20 - 40.

Table 2-38: Baseline and impact costs for permanent ranges without ENV RMM (C)

Baseline costs[1]	Costs for RMMs required to achieve lead recovery > 90 %	Costs for use of alternative(s)[2]
Remediation costs (end of service life) >> €1 million	Installation of berm and/or shot nets and/or surface coverage for lead recovery and water containment and treatment: €3 800 000 Maintenance of RMMs: €50 000 (for every 10 years); Regular lead recovery: no costs Cost of clean up (end of service life): €189 000 (€126/$m^{3;}$ for 30 000 m^2, soil layer of 5 cm) **Total cost over 40 years, ca 4 million, assign equal payments over the entire 40-year period** **Total costs over 20 years: ca. €2 million, assign equal payments over the entire 20-year period**	Use of steel shot; At shooting intensity of 5 000 to 10 000 rounds of shot/year: €2 000 - 4 000 over the lifetime of a shooting range (40 years). (€20 - 40 per shooter)

Notes: [1] costs for the environmental impact not quantified; [2] in case of substituting lead gunshot with steel gunshot, additional clean up costs might arise, this is considered as advancing the cost of existing end-of life clean- up.

- ➔ Comparison of the cost of installing environmental RMMs that would result in a lead recovery rate of > 90 % to the incremental costs of switching from lead to steel shot suggests that a ban can be considered to be the most proportionate matter for this type of shooting range.

D: Permanent ranges with some ENV RMM (lead recovery ~ 50 %)

Baseline

These ranges are assumed to have at least a berm in place that may or may not be covered. The effectiveness of lead recovery is assumed to be around 50 %, i.e. 50 % of all lead used at the site is thought to be recovered. An example of such a range would be the Nokia range in Finland as described in (Kajander and Parri, 2014)[192].

In case of berms already installed, the dispersion zone of lead is reduced by −30 % to an area of 70% of the original surface (i.e. the original surface of ~60 000 m^2) is reduced to about 42 000 m^2). These facilitates the concentration and subsequent recovery of lead shot from soil.

One cost that would need to be incurred is for periodical soil layer service operations. In feedback from the German Shooting Sport and Archery Federation, the Dossier Submitter learned that: *'In case of shot trap walls made of sand / earth and free deposition areas, the upper soil layer with the lead shot is removed every 5 to 15 years depending on the intensity of use (alternatively: after abandonment of the use of the range) and the lead shot is mechanically separated either on site or using a treatment device and recycled. This work is carried out by specialized companies.'*

With regards to lead recovery, it is assumed that during service life soil from the *main* shotfall zone will be removed, whereas at end of life the soil of the whole range will be removed. Assuming 10 000 m^2 main shot fall zone removal of the upper 10 cm soil layer (at higher intensity the cleaning of the soil is thought to be needed at greater depth) results in a volume of 1 000 m^3 soil to be removed. Assuming €126 per m^3 costs of €126 000 result, required about every 10 years. For 40 years this would be three time the costs. In addition to the removal of the upper soil from the whole range (60 000 m^2 * 0.7 = 42 000 m^2) at the end of life of (42 000 m^2 * 0.1 m * 126 €/m^3 = €529 200). For this scenario it is assumed that 10 cm of the upper soil would need to be removed due to accumulation of lead on the soil.

The amount of lead that can be recovered every ten years would amount to 100 000 shot/year * 10 years * 0.5 (50% recovery rate) * 0.024 kg lead/shot = 12 000 kg lead which, against a purchasing price (i.e. the price offered to clients who bring in lead) of 0.5 €/kg lead[193] can deliver a value of €6 000 (max).

Example case

Nokia range, Finland; Source: Finnish BAT (Kajander and Parri, 2014).

The earthen berm at the Nokia shooting range was constructed in 2005, and it is covered with the decommissioned wire of a paper machine for shot collection. The backstop berm is located at around 150 metres from the firing stand, and its height is 4.5 metres measured from the shooting height (Väyrynen 2011 as cited in Finnish BAT). The range is considered

[192] NB: this follows a description of the site as in 2014 or earlier. In the meantime operational conditions of the site may have changed. The example is quoted here for analytical purposes.

to be typical for this class, as some risk management measures are in place to recover lead. A lead shot recovery rate of 55 % is reported.

Impact

To continue operating with lead, further environmental risk management measures would need to be installed to ensure lead recovery > 90 %. Based on height and position of the berm in relation to the shooting stand, addition of shot nets might be required on top of the berm, surface coverage of the impact zone and a system to contain, monitor and treat surface water. Deducing from to costs of €1 500 000 the costs for installing a berm (€600 000), results in installation costs of €900 000 and maintenance costs of €50 000 for every 10 years.

To calculate the costs for soil removal at the end of service life, it is assumed that a soil volume of 30 000 m^2 (50 % reduction in shotfall zone by RMMs) would need to be removed at a 5 cm resulting in a soil volume of 1 500 m^3. Assuming €126 per m^3 would result in costs of €189 000.

The cost of using alternatives at the given shooting intensity, resulting in €1 280 per year, resulting in €26 000 extra for use over the lifetime of a range (NPV, 4%).

The total costs over 20 years for one stand are summed up to ca. €0.7 million.

Those costs are calculated for one trap or skeet stand. However, for larger ranges where competitions are hosted multiple stands are usually next to each other. As already indicated, this design combines the shotfall zones of multiple stands. As indicated above for 3 stands next to each other the shotfall zone is assumed to be 1.5-times the shotfall zone for one stand. Consequently, risk management measure can be combined reducing the cost. As presented in Table 2-39, total costs over 20 years for three stands are summed up to ca. €0.9 million which is only slightly higher than for one stand (€0.7 million).

Table 2-39: Impact on permanent range with some RMM (D)

Baseline costs[1]	Costs for RMMs required to achieve lead recovery > 90 %	Costs for use of alternative(s)[2]
One stand Costs for lead recovery from soil every 10 years (for 40 years lifetime of the range): €907 000	**One stand** Berm available; costs for installing further RMMs €293 000 Maintenance of RMMs: €50 000 (for 10 years) Regular lead recovery: no net costs Cost of clean up (end of service life, 5 cm of soil): €189 000 (60 000 m^2 * 0.5 * 0.05 m = 1 500 m^3 * €126/m^3) **Total cost over 40 years ca. €0.6 million, assign equal payments over the entire 40-year period** **Total cost over 20 years ca. €0.4 million, assign equal payments over the entire 20-year period**	Use of steel shot: At shooting intensity of 10 000 to 100 000 shots/year: €25 000 over the lifetime of a range (40 years)

Baseline costs[1]	Costs for RMMs required to achieve lead recovery > 90 %	Costs for use of alternative(s)[2]
	Three adjacent stands Berm available; costs for installing further RMMs € 293 000 * 1.5 = € 440 000 Maintenance of RMMs: €50 000 * 1.5 = €75 000 (for 10 years); €200 000 * 1.5 = €300 000 (for 40 years) Regular lead recovery: no net costs Cost of clean up (end of service life): €283 500 (60 000 m^2 * 1.5 * 0.5 * 0.05 m = 2 250 m^3 * €126/m^3) **Total costs over 40 years €0.64 m for three stands, €214 000 per year and per stand** **Total costs over 20 years €0.4 m for three stands, € 132 000 per year and per stand**	

Notes: [1] costs for the environmental impact not quantified; [2] in case of substituting lead gunshot with steel gunshot, additional clean up costs might arise, this is considered as advancing the cost of existing end-of life clean- up.

➔ Comparison of the cost of installing environmental risk management measures that would result in a lead recovery rate of > 90 % to the incremental costs of switching from lead to steel shot suggests that a ban can be considered to be the most proportionate matter for this type of shooting range.

E: Permanent ranges with ENV RMM (lead recovery > 90 %)

Baseline

On these sites where an appropriate boundary exist (berms or next or any combination) that would allow 90 % recovery of lead and where regular collection of lead takes place including larger soil cleaning operations, the Dossier Submitter does not expect that additional cost (investment or operation) will be incurred. Maintenance costs of €50 000 recurring at a ten-year interval are assumed.

The amount of lead that can be recovered annually would amount to 350 000 shot/year * 0.9 (90 % recovery) * 0.024 kg lead/shot = 7 560 kg lead. Against a purchasing price (i.e. the price offered to clients who bring in lead) of 0.5 €/kg can deliver a value of €3 780 (max).

It can be assumed that members of shooting clubs help in collecting lead by organising regular clean-up (such as every six months). Evidence is given, for example, through the explanation on lead collection in France[194] but also by site visits that the Dossier Submitter undertook. In some cases, such as in Finland, the additional cost of clean-up that may be incurred are covered by the members in the form of an eco-contribution. Assuming that shooting ranges seek to minimise their cost, the cost of the voluntary clean-up is considered to be effectively zero. Some members will need to take time off from work or spend their free time to do this work, which has a cost as well. But the Dossier Submitter considers that

[194] https://questions.assemblee-nationale.fr/q15/15-3842QE.htm

these members express a preference to do this work to keep their hobby or ability to compete in international competitions.

To calculate the costs for soil removal at the end of service life, it is assumed that the soil of the shotfall zone (60 000 m^2 reduced by 50 % due to RMMs) would need to be removed at a depth of 5 cm (1 500 m^3). Assuming €126 per m^3 would result in costs of €189 000.

Example case

Lonata range, Italy; Source: Finnish BAT (Kajander and Parri, 2014).

Mesh-covered earthen berms have been constructed at the Lonato shooting range in Italy to stop the shot. In Lonato, the bottom edge of the berm is at around 90 metres from the firing stands. The height of the berm is around 23 metres. There is a net in the front edge of the berm with PVC plastic underneath to ensure that the shot is stopped and recovered. There is also PVC plastic at the bottom edge of the berm, preventing vegetation from growing and allowing the collection of the shot. The shot is collected from the bottom of the edges of the berms at regular intervals of every six months. There is a low berm in front of the bottom edge, but it is mainly for landscaping purposes (Aarrekivi, 2011; Bufi et al., 2007 as cited in (Kajander and Parri, 2014)).

Impact

For this scenario where risk management measures are already in place to frequently recover lead gunshot > 90 %, maintenance costs of €50 000 for every 10 years arise as well as the costs for the final clean-up at the end of service life (40 years). To calculate the costs for soil removal at the end of service life, it is assumed that a soil volume of 30 000 m^2 (50 % reduction in shotfall zone by RMMs) would need to be removed at a 5 cm resulting in a soil volume of 1 500 m^3. Assuming €126 per m^3 would result in costs of €189 000. Total cost for maintenance and cleaning at the end of service life would therefore sum up to €389 000.

The cost of using alternatives at the given shooting intensity results in € 62 000 and €90 400 for use over 20 and 40-years, respectively (NPV, 4%). The Dossier Submitter considers that in case of substituting lead gunshot with steel gunshot, additional clean up costs might arise; this is considered as advancing the cost of existing end-of life clean up.

On such sites the use of alternatives would result in (albeit small) higher cost to shooters.

- ➔ No additional costs for risk management measures would be incurred to meet a lead recovery rate of > 90 %, compared to the incremental costs of switching from lead to steel shot suggests that continuing to use lead would be the most efficient matter.

Synopsis

Table 2-40 gives an overview on the information that was gathered and combined to obtain an order of magnitude estimate regarding the baseline costs and the investment costs needed per site to achieve a minimum recovery rate of > 90 % in comparison to the costs of using steel. In addition, costs for maintenance and final clean up at the end of service life are provided.

It is to be noted that the environmental risk management measures required in scenario C (permanent ranges, no ENV RMMs) would also apply to new ranges.

Table 2-40: Overview of investment costs for different site to achieve a recovery rate of > 90 %

Scenario	Baseline costs[1]	Costs for RMMs required o achieve recovery > 90%	Costs for the use of alternative(s)[2]
A: Any area or range using steel shot	No lead used; no costs in relation to lead	Not applicable	Only steel used
B: Temporary areas; no ENV RMMs; 5 000 – 10 000 rounds per year	No lead recovery assumed; Areas often not remediated	Not achievable in practice for a temporary range	€2 000 – 4 000 per range (40 years)
C: Permanent ranges; no ENV RMM; 5 000 – 10 000 rounds per years	< 50 % lead recovery; Costs to recover lead from soil (40 years): >> €1 million	Costs for RMMs, maintenance and end-of life cleaning: €2 million (20 years) €4 million (40 years)	€2 000 – 4 000 per range (40 years)
D: Permanent ranges; some ENV RMM available (e.g., berm) 10 000 -100 000 rounds per years	>50 - < 90% lead recovery; Costs to recover leadfrom soil (40 year): ca. €0.9 million	Costs for RMMs, maintenance and end-of life cleaning: €0.4 million (20 years); €0.6 million (40 years)	€26 000 per range (40 years)
E: Permanent range; ENV RMMs available to recover > 90 % lead 100 000 – 350 000 rounds per year	> 90 % lead recovery Costs for maintenance and end-of life cleaning: €389 000	No additional costs	€90 400 per range (40 years)

Notes: [1] costs for the environmental impact not quantified; [2] in case of substituting lead gunshot with steel gunshot, additional clean up costs might arise, this is considered as advancing the cost of existing end-of life clean-up

In order to provide more insight into those costs involved at being able to recover lead (at different lead recovery rates), the cost per type of range can be combined with information on the rate of recovery of lead that is theoretically possible into a Marginal Abatement Cost (MAC) curve. Policy-makers use MAC-curves in order to demonstrate how much abatement an economy can afford and the area of focus, with respect to policies, to achieve the emission reductions.

Combining the various cost information with key information on example case with claimed recovery rates gives some insight in what lead recovery can be achieved at which costs.

However, only few shooting ranges have reported the amount of lead shot that is kept at the shooting range in combination with the RMM that are installed in order to achieve that.

The marginal abatement cost curve is displayed in

Figure 2-8, where (A)-(D) denote the risk management measures described in Table 2-40.

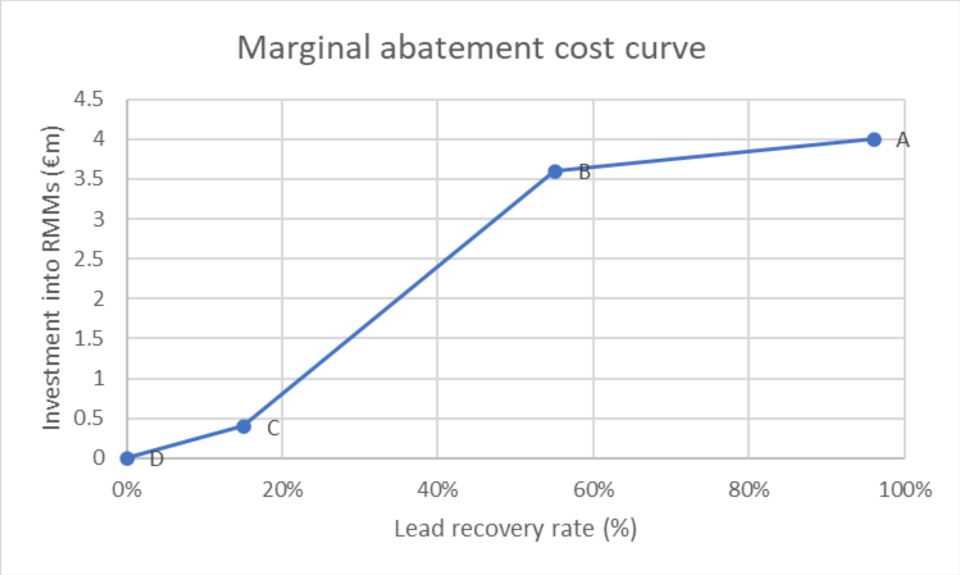


Figure 2-8: Marginal abatement cost curve for shooting ranges

Extrapolating the cost to an EU wide scale can be achieved by multiplying the costs in Table 2-40 with the number of ranges per category in Europe. The precise number of ranges in the EU that fall into which category is unknown but is assumed to be 4 000 to 5 000. The Dossier Submitter has suggested a random distribution of these ranges to define an order of magnitude estimation. This can only give an order of magnitude estimate as the specific requirement per range can vary as per the environment of the range and its specific surroundings and thus investment need in infrastructure to meet a 90 % shot capture rate (ad theoretical recovery rate) may be bespoke for each and every site.

Table 2-41: Estimation of number of ranges in the EU

Scenario	Number of sites impacted by the need to install further RMMs		
	low	middle	High
Temporary area	5 %; 200 - 250	5 %; 200 - 250	5 %; 200 - 250
Permanent range, no RMM	30 %; 1 200 – 1 500	45 %; 1 800 – 2 250	60 %; 2 400 – 3 000
Permanent range some RMM (<90% recovery)	60 %; 2 400 – 3 000	40 %; 1 600 - 2 000	20 %; 800 - 1 000

Scenario	Number of sites impacted by the need to install further RMMs		
	low	middle	High
Permanent range RMM (>90% recovery)	5 %; 200 – 250	10 %; 400 – 500	15 %; 600 – 750
Total	4 000 – 5 000	4 000 - 5 000	4 000 - 5 000

Costs to implement risk management measures at all sites

Combining the information from Table 2-40 and Table 2-41, the estimated cost of implementing RMMs across all affected sites in the EU27-2020 can be obtained; which is estimated at €6.2bn - 11bn. The purpose of this estimate is not to give an exact estimation of all cost but rather to obtain an order of magnitude estimation that can be refined further with information coming from the consultation.

The value that was deducted would amount to an annualised vale of €456 million to €798 million (over a 20-year period, discounted at 4 %) resulting in a cost-effectiveness value of 17.1 €/kg compared to a cost-effectiveness value for lead shot in hunting of 6 €/kg, demonstrating that substitution might be less costly to comply with.

Assuming:

- a transition period of 5 years after which cost will be incurred, the cost (NP,4%, 20 years) will be €8 527 m (range: €6 210- €10 845 m),
- an emission reduction of 498 750 tonnes (RO4, see section 2.6.1.2)

gives a cost effectiveness estimate of 17.9 €/kg.

Those costs are calculated for the assumption that all sited will be equipped with RMMs to achieve lead recovery of high effectiveness (> 90%).

Costs to implement risk management measures at a fraction of existing sites

To be developed further, based on input from the consultation on the Annex XV report.

2.6.3.2. Bullets

As result of the restriction option analysis, the Dossier submitter has identified the following restriction options:

- **A ban on the use of lead bullets for sports shooting with derogation at designated locations with regular lead recovery > 90 %.**
- **Compulsory information on the hazard/risk of lead, transition periods and availability of alternatives, and the indelibly labelling of individual cartridges (contains lead (Pb), for sports shooting only [at permitted sites]).**

The Dossier Submitter has examined the cost and other economic impact for the measures for lead abatement with regards to the derogation from the ban on the use of lead bullets under strict conditions (such as regular bullet recovery of > 90 % by means of bullet trap).

The calculations for the costs involved with such a strict derogation are presented in Table 2-42 for small calibre bullets and in Table 2-43 for large calibre bullets.

The following considerations were taken into account:

- The cost over the twenty-year period are assumed to occur after the transition period which is five years for small calibre bullets and 18 months for large calibre bullets
- An emission reduction is assumed to occur after the respective transition period.

Table 2-42: Calculation of costs associated with different bullet traps for small calibre bullets

Parameter	Data		
Volume of lead	21 000 ton		
Type of RMM	Steel container, 2000 euro basic cost, adaption needed	Stapp bullet trap[1]	Sacon bullet trap[2]
20 year cost (per stand)	€4 000	€20 000	€44 000
Yearly cost	€200	€1 000	€2 200
Number of ranges in Europe			
Low	5 000	5 000	5 000
High	10 000	10 000	10 000
% already installed with suitable bullet trap	50 %	50 %	50 %
Number of stands per range	5	5	5
Cost 20 year period (NPV, 4%), low	€28 m	€140 m	€308 m
Cost 20 year period (NPV, 4%), high	€56 m	€280 m	€617 m
Total avoided emission over 20 year period			

Parameter	Data		
Cost effectiveness	0.06 -0.12 €/kg	0.30 -0.6 €/kg	0.66 - 1.32 €/kg
Emission reduction over 20 years	283 5000 tonnes, no emission during transition period, 90% reduction expected after 5 years		
Cost effectiveness over 20-year period	0.10 - 0.20 €/kg	0.50 - 0.99 €/kg	1.09 - 2.18 €/kg

Notes: [1] Stapp bullet trap, see www.stapp.se; [2] Sacon bullet trap, terrancorp.com

Table 2-43: Calculation of costs associated with different bullet traps for large calibre bullets

Parameter	Data		
Volume of lead	21 000 ton		
Type of RMM	Steel container, 2000 euro basic cost, adaption needed	Stapp bullet trap[1]	Sacon bullet trap[2]
20 year cost (per stand)	€4000	€20 000	€44 000
Yearly cost	€202	€1 010	€2 222
Number of ranges in Europe			
Low	5 000	5 000	5 000
High	10 000	10 000	10 000
% already installed with suitable bullet trap	50 %	50 %	50 %
Number of stands per range	5	5	5
Cost 20 year period (NPV, 4%), low	€31 m	€159 m	€351 m

Cost 20 year period (NPV, 4%), high	€63 m	€319 m	€703 m
Total avoided emission over 20 year period	349 650 tonnes, no emission during transition period, 90% reduction expected after 18 months		
Cost effectiveness	0.06 -0.12 €/kg	0.30 - 0.6 €/kg	0.66 -1.32 €/kg
Cost effectiveness over 20-year period	0.09 - 0.18 €/kg	0.46 - 0.91 €/kg	1.01 – €2.01 €/kg

Notes: [1] Stapp bullet trap, see www.stapp.se; [2] Sacon bullet trap, terrancorp.com

2.6.4. Cost-effectiveness, and cost-benefit considerations

2.6.4.1. Cost-effectiveness considerations

Table 2-44 summarises the cost-effectiveness for the restriction options for sports shooting.

Table 2-44: Cost-effectiveness of restriction options for shorts shooting

Risk Option	Emission avoided over 20-year period (t)	Cost (€) over 20 year period (NPV, 4%)	Cost-effectiveness (€/ kg avoided release)
Ban on marketing and use of **lead shot** for sports shooting	525 000 tonnes	€249 million	0.48 €/kg
Ban on marketing and use of **lead shot** for sports shooting with derogation under strict conditions (> 90% recovery)	498 750 tonnes	€8 257 million	17.1 €/kg
Ban on use of **bullets - small calibre** - for sports shooting with derogation under strict conditions (> 90 % recovery)	283 500 tonnes	€280 million	0.50 - 0.99 €/kg
Ban on use of **bullets - large calibre** - for sports shooting with derogation under strict conditions (> 90 % recovery)	349 650 tonnes	€319 million	0.46 - 0.91 €/kg

If one compares the cost-effectiveness of the current restriction proposal to the one for decaBDE, for example, where one major environmental impact was accumulation of the substance in birds of prey, it is obvious that the current proposal is an order of magnitude more cost-effective. Considering the known hazard properties of lead, it can thus be concluded that the proposed restriction is a cost-effective measure of addressing lead emissions to the environment.

Overall, the preferred restriction for lead in shot and in bullets appears to be as cost effective as previous REACH restrictions, including the restriction on lead in PVC which was addressing similar human health concerns (cf.Figure 2-9). This clearly shows that the proposed measures under this restriction are in the same order of magnitude of other restrictions that were deemed to be proportionate.

Figure 2-9: Comparing cost-effectiveness of proposed options for sport shooting with other REACH restrictions.

2.6.4.2. Cost-benefit considerations

The annual net cost for sports shooter from the restrictions on sports shooting is expected to be in the order of 22.4 million euro per year based on the substitution cost for shot and costs risk management measures for the restriction option with derogation under strict condition.

For sports shooting a number of non-quantified benefits were identified:

- Reduce and prevent lead accumulation/availability in the habitats for species at risk of lead poisoning via primary and secondary routes.
- Avoid mortality due to sub lethal effects of birds and other taxa.
- Avoid exposure to lead for ruminants (via soil).
- Avoid exposure to lead for humans (via environment) from drinking water and food.
- EU Birds Directive and AEWA MOU commitment fulfilled.

Comparing the costs to sport shooters within the overall benefits of this proposal, make it plausible that this restriction is proportionate.

2.7. Impacts of a restriction on others uses of lead ammunition

Besides the uses of lead in sports shooting and hunting, there are the following other uses of lead:

2.7.1. Lead used in muzzle loading and historic arms

- During the dossier development the Dossier Submitter has discussed the issue with:The vintage arms association (during opinion making on wetland proposal)
- The *Muzzle* Loaders Association of Great Britain
- The Muzzle Loaders Association international confederation.

Alternatives

It is generally understood that there are limited alternatives available for shooting with muzzle loading. Interviewed stakeholders highlighted the impossibility to use material other than lead, out of concerns of prematurely wearing out the rifles these groups of shooters own. Some manufacturers (Barnes, Hornady) have developed lead free muzzle loading ammunition, but no detailed technical test shave been found that confirm whether these alternatives can be used in antique muzzle loaders or whether their use is only suitable for replica muzzle loaders. The Firearms Directive states that '*.. However, reproductions of antique weapons do not have the same historical importance or interest attached to them and may be constructed using modern techniques which can improve their durability and accuracy..'* (DIRECTIVE (EU) 2017/853 , art 27).

Hunting

Although in theory muzzle loading bullets can meet some of the energy requirements set in hunting legislations (as in the UK, Finland, France, Spain, Italy, Denmark and Hungary) their use is generally considered a niche use.

Authentic historic arms are rarely used for hunting, out of concern for damage. Their design allows the use of lead only and no alternatives are considered suitable.

In some Member States, hunting with muzzle loaders (also known as black powder hunting) is allowed, however this use is generally considered to be a niche activity. One author (Sanchez et al., 2016) argues there is less concern of contamination of game meat compared with modern lead ammunition. The authors conclude that:

"*Under regulations banning use of all lead bullets, users of traditional muzzle loading and black powder cartridge rifles could be excluded from hunting because of current limitations in effective non-lead options for those types of firearms (Epps, 2014), and some individuals would be blocked from important cultural and subsistence foraging activities. Similarly, regulations that restrict non-lead bullets prevent muzzle-loading hunters from voluntarily avoiding lead and could discourage hunters from buying fast-twist rifles designed to shoot long lead-free bullets with sufficient accuracy. Instead, regulations that allow lead-free bullets of any type (including those which require use of sabots), in addition to traditional non-expanding lead bullet designs could simultaneously reduce lead ingestion risks to humans and wildlife, while also allowing and encouraging primitive weapons hunters to continue participation in hunting*."

➔ However, there is uncertainty as to whether lead fragmenting is absent with these replicas as well. Both the volume of use and the efficacy of alternatives have not been confirmed. More information would be needed (in the consultation) to confirm further conclusions.

Sports shooting

The stakeholders indicted that most of their use takes place within the confinements of a shooting ranges where lead can be recovered.

Proposed restriction and impact

As result of the restriction option analysis for the use of bullets in sports shooting, the Dossier Submitter has examined the cost and other economic impact for the measures for lead abatement with regards to the derogation from the ban on the use of lead bullets under strict conditions (such as regular bullet recovery of > 90 % by means of bullet trap) (see section 2.6.3.2).

A sperate analysis for muzzle loaders in hunting is not performed due to a lack of information. More information would be needed in volume of use in hunting to complete a quantitative impact assessment.

2.7.2. Lead ammunition used in air rifles for outdoor shooting

Hunting

Hunting with air rifle ammunition is legally allowed only in some Member States (Sweden, Denmark, Hungary, Denmark) and in the United Kingdom. When used for hunting, lead pellets are used for pest control. As vermin are not considered "game", there is no risk to humans from ingesting lead fragments in game meat.

Sports shooting

Airguns are also used for informal target shooting and for competition shooting. Airguns fire a small pellet, usually in calibres .22 (5.7 mm) or .177 (4.5 mm).

Alternatives

Lead-free airgun pellets are usually made from zinc alloy. Though harder than lead, this material is still malleable and should not cause damage to the barrel of an air rifle.

In the call for evidence it was highlighted that there are practically no non-lead air rifle pellets on the Finnish market (or are yet to come on the market). Non-lead pellets can be up to four times more expensive than lead ones and are less accurate.

One commenter reported that the 15 largest UK online ammunition retailers offered 146 airgun pellets for sale. Of these 76 % were lead, at an average price of £0.030/ pellet. The remaining 24 % of non-lead pellets were on average £0.044/ pellet which could be indicative that a switch to lead free air gun ammunition for hunting would not be disproportionally burdensome.

Assuming that as per (Kanstrup and Haugaard, 2020) the use is limited to species like pigeons, crows, waders, starlings. Combining this with the reported bag data would suggest a total cost in the order of several tens to hundreds of thousands of euros, whereas its use would contribute to the overall reduction of lead, albeit by a margin of several 1 000s of kilos at max.

Airgun competition shooting requires high precision equipment and ammunition and current non-lead options are not of sufficient quality. Thus, there is still a significant amount of development required to produce airgun pellets that behave comparably in the field and at the same ranges as existing lead pellets.

Unlike for hunting bullets, there are no known studies or peer reviewed tests comparing the performance of lead and non-lead (often tin) based air rifle pellet for hunting.

Product reviews on hunting for a and online purchasing fora would suggest that the accuracy of air rifles for hobby shooting (which would cover a fair share of their use) is adequate. However, these tests or reviews are not conclusive enough to come to a firm decision on product suitability. Some manufacturers market[195] their lead-free air rifle ammunition as suitable for hunting, examples of these are the RWS Hypermatch lines and or the H&N Barracude green line.

In the call for evidence one test was submitted by Gunlex, (see section 2.6.1.1.) which is also available online[196]. The authors of the test conclude that lead free air rifle pellets would not be suitable for precisions sports shooting due to their lack of accuracy. The authors concluded that lead fee pellets would be suitable for recreational shooting but not for precisions sports.

- ➔ Both the volume of use and the efficacy of alternatives for hunting have not been confirmed. More information would be needed (in the consultation) to confirm further conclusion.

Proposed restriction and impact

As result of the restriction option analysis for the use of bullets in sports shooting, the Dossier Submitter has examined the cost and other economic impact for the measures for lead abatement with regards to the derogation from the ban on the use of lead bullets under strict conditions (such as regular bullet recovery of > 90 % by means of bullet trap) (see section 2.6.3.2).

A separate analysis of air rifle ammunition is not done for hunting, more information would be needed to confirm further conclusions. Although lead free air pellets seems to be available no further test have confirmed their efficacy for hunting.

2.7.3. Lead ammunition used for other purposes

The following uses have been brought forward by stakeholders as uses where lead is still used or is needed and that are out of scope of the assessment by the Dossier Submitter.

Table 2-45: Use of lead ammunition for other purposes

Type of shooting	Description
Technical testing and/or proofing	Testing of firearms or ammunition and proofing is aimed at the establishment of technical properties of firearms or ammunition. Institutes of technical expertise, manufacturers, or proof houses (which can be public authorities as well as authorised private entities) practice testing and proofing. Lead ammunition can be required for testing or proofing purposes e.g. when technical characteristics of firearms designed for the use of lead projectiles are to be established.

[195] https://www.hn-sport.de/en/air-gun-hunting/baracuda-green-177 & https://rws-ammunition.com/en/products/air-gun-pellets
[196] https://gunlex.cz/en/3595-comparative-test-of-lead-and-nonlead-ammunition

Type of shooting	Description
Manufacture	Manufacturers of firearms or ammunition are almost exclusively private enterprises even when firearms and ammunition for military or security purposes are concerned.
Testing and development of materials and products for ballistic protection	Means of ballistic protection such as bulletproof vests must be always tested with a relevant array of ammunition including common lead projectiles so that the real-world results are yielded. Manufacturers of means of ballistic protection are almost exclusively private entities.
Forensic analysis, historical and other technical research or investigation	The purpose of these kinds of research or investigation is usually aimed at the establishment of effects of firearms and ammunition on analysed objects or in examined (criminal, historical etc.) contexts. The objectives of the examination determine the means of any professional research or investigation. Most cases of e.g. forensic analysis are concerned with the use of lead ammunition. Private technical and forensic experts are frequently contracted by police investigators (as well as by the other participants to the criminal proceeding including courts and attorneys). Research as well as expert investigation are usually undertaken by entities other than military forces or police (such as by universities, research institutes or individual researchers/authorised collectors).
Voluntary military training	Voluntary military (or auxiliary police) training include different types of participation of the public on the training for national defence purposes. The persons included in the voluntary training programmes are either reservists (in systems with general military drafting schemes) or volunteers (in systems consisting of professional armed forces and complementary voluntary reserves). This type of training is characterised by the use of firearms and ammunition which are identical or comparable to those used by the armed forces (or security forces) of the state. On the other hand, the training exercises are usually organised by reservist or volunteer associations which are not (in peace) part of the military or other armed forces. These trainings take place either in shooting ranges run by an official agency or (predominately) in private shooting ranges run by local shooting clubs.
Protection of critical infrastructure, commercial shipping, or high-value convoys	These are uses of ammunition mainly by professional entities such as commercial security agencies. They usually work in close cooperation with official law-enforcing authorities. The choice of ammunition is based on required efficiency and on limitations given by the environment in which the ammunition is used (non-lead projectiles might not be an option e.g. due to higher penetration and thus higher risk of damage to the protected infrastructure).

Type of shooting	Description
Soft-target and public space protection	These types of use of ammunition are very close to the previous two examples. However, the risk of hitting a third person is critical in these cases. Thus, the risk of either ricochet or shoot-through must be minimalised. It must be noted that the risk of a ricochet in these model situations are significantly higher than in the context of hunting or sports shooting. This is due to the environment in which the soft-target protection takes place (buildings, streets or indoor spaces where the risk of hitting a hard surface is high; dangerous ricochets occur especially at curved hard surfaces such as cobblestones, car wheels or street lampposts). In many instances, there is no non-lead alternative to ammunition for those purposes.
Self-Defence	The meaning of "self-defence" is the use of a firearm for the protection of life, personal integrity or property; the person entitled to the use of a firearm for the legal self-protection usually has to receive an official authorisation to carry a firearm for this purpose. In the EU-context such authorisations are generally granted only in exceptional cases. The use of a firearm for self-defence is limited to the very resisting the imminent threat (attack) as defined by the national law. From the tactical perspective, the use of a firearm in self-defence is relatively close to the use of a firearm by the police. Thus, the technical requirements for firearms and ammunition are similar (including the need for lead projectiles in most cases). It has to be emphasized that a typical self-defence situation encompasses circa 1 to 3 shots and those situations as such are extremely rare. It is obvious, that from the perspective of lead emission into the environment the cases of self-defence are negligible.

Type of shooting	Description
Non-lead ammunition for security purposes	There are non-lead projectiles for security purposes; however, these projectiles are typically loaded in specialized ammunition. They cannot be regarded a general substitute to lead containing ammunition. Examples of non-lead ammunition for security purposes: - "Frangible" projectiles – this type of bullet is intended to prevent the risk of ricochets and shoot-through especially in highly sensitive places such as power plants; the bullet is usually manufactured from moulded metallic powder; the range and precision are significantly lower than in the case of classic ammunition; the use for self-defence is problematic – when soft tissues are hit, the projectile does not have enough "stopping-power", on the contrary, when bones are hit, the projectile fragments substantially more than a lead projectile and causes enormous devastation of tissues. - Solid expanding bullets – these are projectiles manufactured from solid piece of non-lead metal (zinc, brass, bronze, sintered steel). A typical projectile of this type has an opened (hollowed) tip point, which enables the bullet to expand after the hit of a specified target. These projectiles can be used only under certain conditions; e.g. (i) the use for military or quasi-military purposes, incl. training; (ii) the use is forbidden by international treaties on the law of war; (iii) the use for purposes other than hunting or target-shooting is prohibited by the EU Firearms Directive.. On general, these projectiles cause significantly higher destruction of bodily tissues compared to non-expanding lead projectiles.

2.7.4. Costs and economic impacts

For the uses reported in section 2.7.1 and 2.7.2 there is not enough information with the same level of details as for the other uses documented in this report.

Concerning air guns, the information suggests that the alternatives may be feasible for uses other then sports shooting and abatement would not be disproportionally expensive. On the other hand, the contribution to the overall risk reduction would be marginal. There where the use takes place on sporting grounds, i.e. as in 'sports shooting', emission of lead are deemed to be controlled by the proposed measures for lead in sports shooting.

Concerning muzzle loaders, stakeholders' feedback would suggest that a restriction on lead in hunting would technically not be feasible and would be disproportionate. More information is needed in the public consultation to support such a derogation for antique muzzle loaders and other antique firearms and confirm the suitability of lead free ammunition for replica's. There where the use takes place on sporting grounds, i.e. as in 'sports shooting', emissions of lead are deemed to be controlled by the proposed measures for lead in sports shooting.

2.7.5. Cost-effectiveness and cost-benefit considerations

Air guns

Assuming a similar performance level in recreational shooting and in some forms of pest control (there where air rifles can be used). The suggested price difference per pellets of about 1 ct would suggest that the impact could be proportionate in comparison with the overall benefits of this restriction proposal.

Assuming that as per (Kanstrup and Haugaard, 2020) the use is limited to species like pigeons, crows, waders, etc. and combining this with the reported bag data would suggest a total cost in the order of several tens to hundreds of thousands of euro's, whereas its use would contribute to the overall reduction of lead, albeit by a margin of several 1 000s of kilos at max.

Muzzle loaders

Given the high value of use and the possible destructive effects of non-lead ammunition on the weapon, it is not likely that muzzle loaders are used frequently for hunting and/or contribute highly to the overall burden of lead. A ban on using lead in hunting for muzzle loaders would impact owners of muzzle loaders significantly and the achieved reduction of lead emission are expected to be low.

2.7.6. Other practicability and monitorability considerations

2.7.6.1. Implementability

Air guns & Muzzle loader

In principle a restriction on the use of air rifle pellets can be enforceable, it is no different to other restrictions either at national or EU level that have been imposed.

2.7.6.2. Enforceability

A restriction on the use of lead air pellets will be difficult to enforce. Air guns can in various jurisdictions be obtained without a hunting license and the same counts for air pellets which can sometimes be bought without any restriction such as the need to have and demonstrate a hunting license.

Where air rifles are used for hunting or pest control the same means of enforcement are at the enforcer's disposal as for the other uses. Air rifles for these purposes must be of a certain power (measured by either muzzle velocity and energy requirement at a certain distance) and are often registered on a person's hunting license. However, the pellets that are required can still be purchased without any restriction.

A restriction on the use of lead containing muzzle loading ammunition might be difficult to enforce as in private gun owners could be enticed to homecasting, a practice assumed to be already widely used by owners of this kind of guns. There were the use of lead takes place at events or shooting ranges, spot check could be enforced, although the use of these guns would in this situation fall under the proposed measure for shooting ranges.

2.7.6.3. Monitorability

The proposed restriction on lead for these uses (air rifle and muzzle loaders) can be monitored.

The presence of lead and non-lead ammunition on the market could be monitored using the same methodologies as the one used by the Dossier Submitter to perform the market survey: contact manufacturers, importers, retailers, consult website and social media pages. Mystery shopping campaigns on websites and in retailers' shops could also be conducted for the same purposes.

2.8. Impacts of a restriction on lead in fishing tackle

The proposed restriction option for lead used in fishing tackle is a combination of the following elements:

- **A ban on placing on the market and using lead fishing sinkers and lures.** This action would foresee a ban of lead headed by fishing tackle-specific transition periods to allow manufacturers as well as the suppliers and retailers of fishing tackle to develop and switch to alternatives: (i) no transition period is proposed for lead wire, (ii) a transition period of three years is proposed for lead fishing sinkers and lures with a weigh ≤ 50 g, and (iii) a transition period of five years is proposed for the sinkers and lures with a weight > 50 g.
- **A ban on using fishing tackle rig or equipment intended to drop off lead sinkers**. No transition period proposed.
- **The obligation to inform buyers at the point of sale about the presence, toxicity and risk of lead to human health and the environment, as well as the upcoming ban and the availability of alternatives.** This obligation would apply to all lead-containing fishing tackle placed on the market (no size restriction), and would be headed by a transition period of six months to allow retailers to put in place the necessary information towards their customers.

The following sections summarise the impact assessment of the proposed restriction option. Supporting information, such as detailed calculations, are provided in Annex D. Brief assessments of alternative restriction options are also presented in Annex D.

As the restriction conditions foresee different transition periods to facilitate the adoption of non-lead alternatives, uptake of these alternatives is the assumed response of the supply chain. However, it is noted that a ban on using fishing sinkers and lures is difficult to enforce.

2.8.1. Effectiveness and risk reduction capacity

2.8.1.1. Human health impact

Due to the lack and scarce statistics on exposure (in particular on home-casting), only a qualitative assessment can be made on the human health impact of the proposed restriction option.

The impact on human health of the proposed restriction option is mainly twofold.

First, there will be a reduction of exposure to lead via ingestion, mouthing, chewing and manipulation of lead fishing tackle as lead in fishing tackle will be banned both for sale and use. This will in particular benefit children who may represent in some EU countries up to 20 % of the fishers. On average, the Dossier Submitter estimates that ca. 10 % of the fishers in Europe are below 12. This number should be taken with caution as it is derived from statistics from a few countries only (cf. Annex A).

Second, thanks to the ban on using lead fishing tackle, the use of lead sinkers and lures will be prohibited step-wise (≤ 50 g, and then > 50 g), there will therefore be less opportunity for the fishers to use their home made sinkers and lures (i.e. melted and home-casted). As a consequence of the ban on use, less and less people will have an incentive to home-cast their lead sinkers and lures, and fewer people would therefore be exposed to lead fumes and dust, and in particular the children living in the same household as the fishers who are casting lead.

Overall, the exposure to lead, especially for children, is expected to be reduced. However, as it is difficult to supervise individuals in this area, both in their private home, but also when they fish, the effectiveness of the restriction to guarantee the reduction of the risk for human health cannot therefore be 100% guarantee.

In order to be successful, it is therefore important to inform and explain to the fishers the risks of lead, and home-casting for their health, and the health of their family, and contextualise the proposed ban. During the transition period preceding the ban on sales and use, an awareness and information campaign, as well as information in retailer's shops and websites on the presence, and toxicity of lead fishing tackle, would probably alter the views of the fishers on lead fishing tackle and consequently the way they act (cf. Annex D).

Last but not least, banning the use of fishing tackle containing lead is required for the prohibition on placing on the market lead fishing tackle to be effective. If the use of lead in fishing tackle continues to be permitted, it could indeed provide a greater incentive for casting at home, which would create a bigger issue in terms of human health than the current situation. Home-casting of lead fishing sinkers and lures may indeed become particularly attractive for fishers if the price of non-lead fishing tackle in shops and internet webstores rises.

2.8.1.2. Environmental risk reduction and releases avoided to the environment

As indicated in section 1.5, one single lead fishing tackle, when ingested by a bird, triggers severe adverse effects and could generally lead to mortality. Nevertheless, conducting an environmental risk reduction analysis is complicated by a number of factors that have been highlighted in section 1 of the Annex XV report. For example, (i) the large number of bird species potentially at risk, (ii) the scarcity of available data and studies on birds and lead fishing tackle ingestion, (iii) the deaths from all causes vs the deaths from lead fishing tackle ingestion specifically, (iv) the difficulty to retrieve bird carcasses, make it difficult to estimate current exposures and effects (Grade et al., 2019). It is also difficult to estimate the probability that a lost lead fishing tackle will be picked up and ingested by a bird. Lastly, the accumulation of lead in the environment based on historical fishing, together with uncertainties about its continued availability to birds, are some of the factors that make it difficult to estimate the potential effectiveness of the restriction in reducing exposure and observed effects. Because of these difficulties, the approach taken in the environmental impact assessment is to illustrate the potential sources of exposure (unintentional loss or spillage, deliberate dropping or dumping, and inappropriate waste management) and describe the circumstances that suggest that a number of birds are potentially at risk (i.e. birds at risk because of their feeding ecology), including birds listed as vulnerable, endangered or critically endangered on the IUCN lists.

Even though there has been positive impact on bird mortality in Great Britain after the entry into force of the 1987 law (Kirby et al., 1994), it is difficult for the reasons indicated above to extrapolate such a result to the European scale. The benefits for the environment of the proposed restriction option are therefore essentially presented in terms of quantity of lead fishing tackle releases avoided as a result of the implementation of the proposed restriction option. The proposed restriction would address both the unintentional and the intentional (e.g. drop off sinkers) release of lead fishing tackle, and would also address the releases of purchased and home-casted sinkers thanks to the ban on use contained in the proposed restriction.

The proposed restriction option is anticipated to reduce lead emissions from fishing in the EU27-2020 by ca. 48 300 tonnes (32 200 – 112 700 tonnes) over the 20-year analytical period. This corresponds to a reduction of releases by approximately 51 % compared to the baseline (Annex D). The remaining releases would come from the lost fishing nets, ropes and line containing enclosed lead.

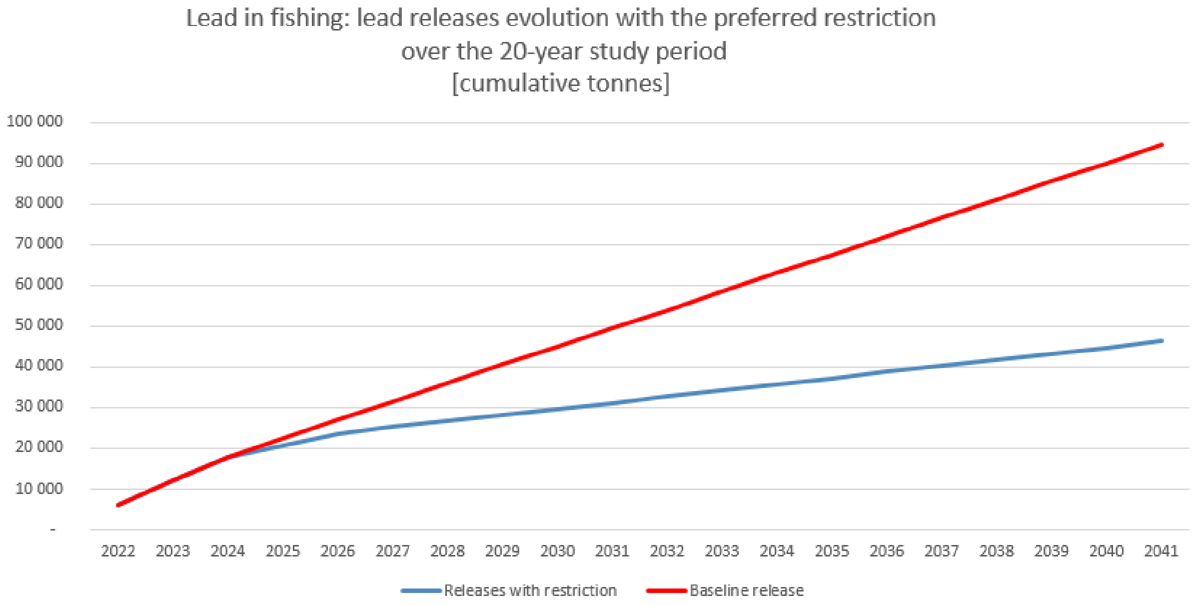


Figure 2-10: Remaining releases of lead in fishing with the proposed restriction in place

2.8.1.3. Conclusions on risk reduction from alternatives and technical solutions

Multiple alternatives[197] to lead in fishing tackle were identified via literature review of recently published articles (Canada, 2018, Thomas, 2019), the ECHA market survey (cf Annex D and E), and information provided via the ECHA call for evidence (CfE #909 from Sportvisserij Nederland, CfE #1034 from VLIZ, CfE #1078 from Belgium - The marine environment department, CfE #1153 from Modified Materials BV, CfE #1170 from an individual, and CfE #1190 from Pallatrax Angling International Ltd). For example: bismuth, ceramic/glass, copper and its alloys such as brass and bronze, concrete, high density polymers, iron, reinforced bars (Rebar), (stainless) steel, stones or pebbles, tin, tungsten, zamac (zinc-aluminium alloy), and zinc.

In general, the alternatives currently available for fishing tackle are better than lead from a human health and environmental standpoint, though there are some data gaps for the zamac, zinc, ceramic, tin and bismuth, which makes a full comparison difficult (cf. Annex C).

Potential health effects of alternative metals include respiratory tract irritation (e.g., copper and its alloys), and metal fume fever (mainly zinc) in case of home-casting. To evaluate the risk for hunters, sports shooters and fishers following inhalation, occupational exposure limits (OELs) might be the best proxy for the assessment. However, relevant exposure data measuring, for example zinc and copper in the air, are not available.

[197] An alternative is a possible replacement for a substance. The alternative should be able to replace the function that the substance performs. An alternative could be another substance or could be a technology, or a combination of both. The word 'alternative' does not imply or mean that the alternative is suitable (i.e. technically, economically feasible and resulting in an overall reduction of the risk for the human health, and the environment).

No risk is identified via skin contact from the handling of fishing tackle made of alternatives.

With regard to the potential effects on the environment, tungsten, which is a common alternative to lead thanks to its high density[198], as well as bismuth and tin were assessed as non-toxic for the wildlife in the US, and are already approved in various formulations by the US Fish and Wildlife services (US FWS, 1997) as alternatives to lead gunshots. Although these substances have been assessed as non-toxic alternatives to lead gunshots only, the same conclusion could apply to fishing tackle.

While none of the alternatives for sinkers and lures are classified for aquatic toxicity (in their massive form), some of them are however not completely harmless to the environment. For example, 'heavy metals' such as zinc and brass (even if less toxic than zinc and lead), currently used as an alternative to lead fishing sinkers and lures, are toxic for the wildlife and birds in particular (cf. Annex C).

In addition, some independent analysis revealed the presence of lead in sinkers and lures marketed as 'lead-free', 'non-lead' or 'non toxic' in proportion that can vary between 2 and 100% (CfE #909 - independent Kiwa inspection report (confidential), and retailer informal communication during the ECHA market survey).

Because fishing lines can break, fishing tackle can be pulled out from the tackle clip/swivel, or might get stuck in a natural obstacle (e.g. stones, branches, trees, foliage etc.), some loss of fishing tackle in the environment during fishing is inevitable and inherent to the fishing activity itself. **This means that accumulation and littering of fishing tackle in the environment is inevitable whatever the alternative used**. The alternative to lead should therefore be considered carefully and with caution.

According to VLIZ (CfE #1034) and the Swedish Chemicals Agency (KEMI, 2007), the ideal lead alternative (aka suitable alternative) should (i) not contain heavy metals such as lead, or zinc, that are toxic to the wildlife, (ii) match ideally the mass density of lead (11.34 g/cm^3) which contributes to the optimal casting (fishing) properties, (iii) should be biodegradable and (iv) the production process also ideally needed to offer perspective on the (future) elaboration of a do-it-yourself (DIY) / home-casting method.

The assessment of the global environmental footprint of the alternatives is outside of the remit of the restriction process. Nevertheless, having in mind the implementation of the future EU Chemicals Strategy, this aspect should not be neglected when looking at the alternatives, and in particular at the overall environmental risk reduction of the alternatives. Using a simplistic approach, the Dossier Submitter described and compared lead and its alternatives against the following criteria that could be used to understand the possible global environmental footprint of the alternatives (cf. Annex C):

- Toxicity and risk for 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)
- Emission of greenhouse gases

The outcome of this simplistic, relative comparison is summarised in the Table 2-46 for the alternatives that can be used in fishing sinkers and lures.

[198] Tungsten has a density of 19.25 g/cm^3 that far exceeds that of lead (11.34 g/cm^3).

Table 2-46: Environmental footprint of lead and its alternatives (impact)

Material	HH toxicity	Env toxicity (aquatic + wildlife)	Impact on sourcing	Impact on resources depletion	Impact on CO_{2e} emissions
Lead (including coated lead)	High	High	Low	Moderate	Moderate
Alternative metals					
Bismuth	-	-	High	High	High
Copper	Moderate	Moderate	Moderate	Moderate	High
Iron	-	-	Moderate	Moderate	Moderate
Tin	-	-	Low	Moderate	High
Tungsten	-	-	Moderate	Moderate	High
Zinc	Moderate	High	High	Moderate	Moderate
Alternative alloys					
Brass	-	-	Low	Moderate	Moderate
Bronze	-	-	Low	Moderate	High
Zamac	-	-	Low	Moderate	Moderate
Alternative steels					
Rebar, stainless steel, steel	-	-	Low	Moderate	Moderate
Other Inorganic					
Ceramic / glass	-	-	High	Moderate	Moderate
Concrete	-	-	High	High	Low
Stones / pebbles	-	-	Low	Low	Low
Other Organic					
High density polymer	-	High	Moderate	Moderate	High

Source: Annex C

2.8.2. Costs and other economic impacts

Only the costs and impacts within the EU27-2020 area are considered.

The information available, and the assumptions made, does not allow the Dossier Submitter to estimate accurately the total cost of the proposed restriction. In addition, not all costs have been monetised, therefore the overall cost of the proposed restriction conditions might be higher than the one mentioned. Nevertheless, the estimates could be considered in terms of order of magnitude. Detailed information is available in Annex D.

2.8.2.1. Costs within EU27-2020

The total cost of the proposed restriction option is estimated to be €9.3bn (€NPV – 20 year-analyticalperiod).

The following broad categories of costs were taken into account to estimate the costs of the restriction within EU27-2020:

- R&D costs
- Industry compliance costs, i.e. raw material costs, energy costs, loss of recycling benefits and manufacturing equipment costs (aka capital costs)
- Retailers' compliance costs (i.e. costs to implement the restriction condition related to consumers information at point of sale)
- Enforcement costs
- Consumers and commercial fishers' costs (cf. section 2.5.3.2)

Table 2-47 below provides a summary of the cost estimates of the proposed restriction within EU27-2020. The assumptions used to estimate the costs are summarised below and further detailed in Annex D. Note that, where available, assumptions indicated in brackets present lower and upper bounds that could be used for the purpose of a sensitivity analysis.

R&D costs

European companies that are currently manufacturing lead fishing tackle will incur R&D costs from developing new alternative technologies. There was no information provided on this topic by stakeholders via the Call for Evidence, nevertheless, during the ECHA market survey, information was provided by some stakeholders (essentially retailers and manufacturers) on the costs of previous attempts to develop alternatives to lead fishing tackle, and estimated costs of future R&D. The effort and capacity in R&D might vary also depending on the size and market (global vs local) of the EU manufacturers as well as their turn-over and financial capacity to invest in R&D. For the purpose of the analysis, a cost of €75 000 (€50 000 as the lower bound, €100 000 as the upper bound) for European manufacturers with a global market (EU market at least), and a cost of €5 000 for manufacturers with a local market (their own country, or region only) is assumed and will be spread out evenly over the period when the sector is assumed to be developing and implementing alternatives, i.e. before the first transition period ends.

It is important to note that the manufacturers of lead fishing tackle, are usually lead foundries, or SMEs producing lead fishing tackle as a side activity, or as their main activity (ECHA market survey); these types of industry might not have the capacity, in terms of human and financial resources, to engage in a proper R&D programme. On the other hand, retailers and 'brands', in order to stay innovative and gain market shares, design and develop regularly new products to be placed on the market. So, the R&D effort, in case of a restriction on lead in fishing, could also become a joint effort, or could be taken over by other supply chain actors.

Industry compliance costs

Additional costs would be incurred for manufacturers of fishing tackle because of higher raw material prices, changes to the manufacturing process (e.g. new moulds) and higher energy costs.

The call for evidence and the ECHA market survey did not bring much information on how the different actors in the supply chain would react, and to which alternative they would move, therefore the Dossier Submitter has made a series of realistic assumptions which represents a plausible scenario. These assumptions are described and summarised in Annex D.

The industry compliance cost corresponds to the 'reformulation' costs and are strongly linked to the selected alternative(s) to replace lead in fishing tackle. Indeed, as mentioned in Annex D, alternatives to lead have different physical and processing properties which imply that existing tools (e.g. moulds) will have to be replaced, and additional raw material and energy costs will be required.

If the EU manufacturers could move to a better alternative than lead. Several scenarios are possible depending on the alternative selected. In some cases, capital investment costs might be needed in order to buy new tools, such as moulds and machinery. In addition, additional operational costs will be induced, such as higher energy cost due to the higher melting point of the existing alternatives to replace lead.

The current manufacturing of lead fishing tackle and lures is a semi-manual, basic process (cf. Annex A) which consists in the melting and then casting of lead in moulds either via gravity or injection.

With the proposed restriction option, and in particular the transition period proposed for the different weights of fishing sinkers and lures, the Dossier Submitter is assuming that the same machinery will be used for the manufacturing of lead and non-lead fishing tackle, and that only different moulds and melting temperature will be used.

It should be noted that with this assumption, there might be a risk of cross contamination between lead and non-lead alternative during the manufacturing process. This could for example explain why the testing of some already available non-lead alternatives do contain traces of lead (CfE #909 - Sportvisserij Nederland and ECHA market survey).

The Dossier Submitter assumes that existing manufacturers will not switch to a totally different technology (e.g. from lead moulding to plastic injection, or tungsten technology for example), and in case the investment in machinery would be too significant, other industrial actors already equipped with such machinery would take over the market. Therefore, the capital costs considered are essentially linked to the purchase of new moulds. Reusing existing moulds might not be possible as the alternative substance have different density, which implies different size of fishing tackle.

In addition, as indicated in Annex C, some of the alternative substances have a low or non-existing recyclability. Meaning that some residues from the manufacturing process (e.g. manufacturing waste), cannot be sold to fabricators (who manufacture metal from the beginning to the end) or smelters (who recover metals) or are sold at a lower price than lead. This loss of benefits, even if acknowledge by the Dossier Submitter, has not been monetised and accounted for.

Retailer compliance costs

Retailers compliance costs are estimated to be null, because they are considered as part of the normal business and maintenance of the shops or websites.

The transition to non-lead fishing tackle is assumed to have no additional cost for the retailers in term of stock, or loss of profit since fishing tackle is not expected to remain on shop shelves for a long time. The proposed transition period would give also enough time for the retailers to prepare to the transition to non-lead alternatives and sell their stocks of lead fishing tackle.

With the proposed restriction option, retailers will also be requested to inform at the point of sale the consumers about the presence, toxicity and risk of lead to human health and the environment. This is very similar to a price tagging or advertisement campaign that is performed on regular basis by a shop or website owner.

The restriction obligation would apply to all lead fishing tackle placed on the market (no size restriction), and would be accompanied with a transition period of six months to allow the lead fishing tackle retailers to put in place the necessary information for their customers in the shop shelves or on their website.

It should be clear that the retailers will not be asked to label or re-label individually all the fishing tackle they sell, nor request from their suppliers that they would label or re-label individually the fishing tackle supplied. An information 'corner', or a poster sufficiently visible, understandable and in the national language of the customer is expected to raise awareness and consciousness of the customer, which will induce a change of behaviour (cf. Annex D).

Enforcement costs

In terms of enforcement costs, it is assumed that REACH enforcement authorities would conduct spot checks of imported fishing tackle (customs), manufacturers' site inspections, retailers' site inspections, and retailers' website inspections once the restriction option would enter into force (i.e. after the transition period). The estimate includes staff time, laboratory testing, overheads and other inspection-related expenses.

In addition, it is assumed that the proposed restriction option would allow inspections at the site of use (e.g. on fishing spots) to be performed as well by the national relevant enforcement authorities (either fishing associations or local area authorities or ministries, depending on the EU country).

It is assumed that the enforcement costs (administrative, testing, and on the field) for enforcement authorities and industry will be ca. €55 000 per year for the duration of the analytical period (20 years), after the entry-into-effect of the restriction (i.e. after the transition period has elapsed). However, it should be highlighted that this is likely an overestimate, as the enforcement costs of a new restriction would likely be incurred in the years immediately following the entry-into-effect and approach zero by the end of the analytical period as compliance increases.

Costs for the fishers

Once the restriction would have entered into force, it is assumed that the fishers will continue to purchase the same quantity (in term of weight) of fishing tackle as today.

This assumption is based on the UK and Danish experience when they put in place their respective bans on fishing tackle, and might be underestimated for the first years after the entry into force of the proposed ban. For example, in Great Britain, the sales of alternative sinkers increased within the first three years after the entry into force of the ban and returned to the same level as before the ban after that, indicating that the overall demand for alternative sinkers was not affected by increased prices (COWI, 2004).

In practice this would mean that ca. 5 400 tpa (4 000 – 10 000) of fishing sinkers and lures would still be purchased yearly in Europe after the full entry into force of the restriction.

The costs for the fishers during the analytical period (20 year) is calculated considering (i) the transition period proposed for the different sizes of fishing sinkers and lures, (ii) the current distribution of sinkers' sizes, and (iii) the current average price of the alternatives (ECHA market survey, 2020).

With regard to the price of the alternative, the current expensive prices cannot be solely explained by the cost of the raw material or manufacturing process. There seems to be an important mark-up within the supply chain for some of these marketed 'user friendly products' (cf. Annex D). In addition, scale economy would be expected in the future with an increase in European demand, and a decrease of selling price is therefore expected once more alternatives become available on the market.

The restriction costs for the fishers is estimated to be €9 300 million (NPV – 20 year-period). The detailed assumptions and calculations are available in Annex D.

Total costs of the restriction proposal in EU27-2020

When the UK ban came into force in 1987, and the Danish ban came into force, the costs incurred by the manufacturers of alternatives were passed to the consumers. The Dossier Submitter is therefore assuming that such a scenario remains plausible with the proposed restriction, and that all the costs incurred by the manufacturers of fishing tackle (in Europe or elsewhere) will be passed on to the consumers through increased product prices, therefore the R&D/industry compliance/retailers costs, and the consumer cost should not be double-counted.

If the additional manufacturing costs are fully transferred to the prices, as it is currently with the available alternatives on the market, the overall industry compliance costs (EU + outside EU) and the costs to fishers should be equivalent.

The costs for the European Industry (industry compliance costs for the European manufacturers) are also indicated in Table 2-47 as it gives a flavour of the effort and capability of the European Manufacturers to switch to alternatives (cf. section 2.8.2.2 for further discussion on affordability).

Table 2-47: Summary of costs estimates in EU27-2020

	Total costs [€NPV-20 years]	Annualised costs [€]
Costs for the fishers, including:	€9 300 million	€680 million
EU industry compliance costs	€146 million	€11 million
EU retailer compliance costs	0	0
Enforcement costs	€0.5 million	€0.04 million
Total costs of the restriction	**€9 300 million**	**€680 million**

2.8.2.2. Affordability considerations

With regard to the affordability, it might be difficult to conclude firmly on this aspect, and to predict for all supply chain actors if the proposed restriction will be affordable or not. The answer is therefore a bit more nuanced: while the Dossier Submitter concludes that the proposed restriction option for lead in fishing tackle is affordable for the fishers and retailers, it might not be the case for the European manufacturers.

Impact and affordability for the European manufacturers

The affordability for the European manufacturers is strongly dependent on three main elements: the proper enforcement of the proposed restriction option, the length of the transition period which should give enough time for the European industry to switch to alternatives, but also the financial capacity of the European Industry to invest in new moulds, and/or technologies. It is therefore difficult to predict and be conclusive on this specific point.

Examples from the UK and Denmark where similar restrictions of lead in fishing tackle (albeit with different scope) are already in place, indicate that switching to alternative materials is possible for both the European fishing tackle industry and fishers.

Indeed, as laid out in section 2.8.2.1 and in Annex D (for the details), the main drivers for costs to be incurred by the European fishing tackle industry are the raw material prices and the associated energy costs to manufacture fishing tackle (as melting of the raw material is essential in the production process). The changes to the manufacturing process (capital investment) represent a small proportion of the total costs incurred by the European industry. Nevertheless, these costs to replace prematurely (iron) moulds will have to be supported by the companies within a very short period of time before the entry into force of the proposed ban. This premature replacement of moulds will have to be done by the EU manufacturers without having the certitude that their market shares would remain. If enough time is given to industry to transition to alternatives to lead and a market for non-lead alternatives is established through the restriction, the proposed restriction should be affordable for industry as long as they have enough cash flow to engage in this change of tools. Such an assumption would need to be verified during the consultation of the Annex XV proposal. Industry and fishing associations' initiatives could also help the European industry to comply with the proposed restriction by sponsoring or supporting the transition to new tools and equipment. Some financial support to help the European industry to transition to alternatives could also be granted through the financial support mechanisms established through the European Green Deal policy.

Impact and affordability for the recreational fishers

Depending on the type of alternative, non-lead fishing tackle might be more expensive than the lead version. During the ECHA market survey, the Dossier Submitter also noted that alternative fishing tackle ≤ 50 g were in general more expensive than the alternatives for fishing tackle > 50 g (cf. Annex D).

Even if the restriction costs would be fully passed through to the fishers (via price increments for fishing tackle), these costs are low compared to the average fishing budget spent yearly by fishers (e.g. fishing rods, reels and other tackle, licenses, fishing trips, and boats).

Based on the restriction cost estimates reported in section 2.8.2.1, and the average yearly expenses per fisher presented in Annex A, the purchase of non-lead alternatives would induce an additional expense of €30 per fisher per year, which represents 3% of the average fishing budget of a fisher (30% of the average expenses for fishing tackle), and an additional expense of ~ €2 per fisher per fishing day[199] (cf. Annex D).

It should also be noticed that, in contrast to some hunters or sports shooters, fishers do not have to replace their main equipment (i.e. boat, or fishing rod) to be able to use the non-lead fishing tackle.

Affordability for the recreational fishing sector

Some stakeholders have reported a possible performance loss for the fishers in case of inferior fishing tackle quality, or fishing performance, e.g. casting shorter distance, shorter depth (CfE #909 from Sportvisserij Nederland, #1034 from VLIZ and #1078 from Belgium - The marine environment department). The alternatives to lead may indeed behave differently during the casting, or in water as fishing tackle made of alternatives are usually

[199] These additional expenses are in the same order of magnitude as in the US and Canada (CANADA 2018. Environment and Climate Change Canada, Study to gather use pattern information on lead-sinkers and jigs and their non-lead alternatives in Canada. ToxEcology Environmental Consulting Ltd. ISBN: 978-0-660-24578-2.).

larger than the one made of lead. The Dossier Submitter acknowledges these differences but considers that, with an appropriate design and conception, these differences do not affect the main technical function, and the usability of the fishing tackle. Similar conclusions were reached by the Environmental Ministry of North Rhine-Westphaliain Germany after a study (Olaf Niepagenkemper, 2015) they commissioned in 2015 on the impact of the fishing tackle material on fishing performance and usability (cf. Annex D).

In addition, from the existing bans on lead in fishing tackle, there is no evidence that the additional cost for the fishers associated with the purchase of alternatives, or a possible loss of performance, would have a negative impact on the fishing participation. For a majority of fishers, according to a recent American survey, the top five main motivations to fish are not to catch a fish but rather to (1) get exercise, (2) be with family and friends, (3) be close to nature, (4) enjoy the sounds and smells of nature and (4) observe scenic beauty (US, 2018). EFTTA, the European Fishing Tackle Trade Association, reported also in 2017 to the European Parliament that the fishers' motivations for fishing is not "catching a fish" but rather "relaxing outdoor, creating social links, experiencing natural settings, enjoying clear water and environment" (EFTTA, 2017). Therefore, no impact from the proposed restriction option is expected on the fishing sector itself, and on the tackle trade sector alone which generates about €2 to 3 billion yearly turnover alone (EFTTA, 2017).

Impact and affordability for commercial fishers

In economic terms, recreational fishing is often discussed in terms of expenditures or total economic value experienced by fishers, in total or per trip. The commercial fishing is, by contrast, often described in terms of the value of fish landed or fleet operating profits.

The commercial fishers' net profit is what remains after other expenses such as the maintenance of physical capital (e.g. fishing gear/tackle and boat). Again, it could reasonably be assumed that commercial fishers net profit would not be too much hampered by a slight increase of consumable such as fishing tackle.

With regard to the value of the fish landed, no performance loss for the commercial fishers has been reported from Denmark on the use of non-lead alternatives for commercial line fishing.

Impact and affordability on the supply chain

In addition to the impact for the manufacturers who would have to reorganise their production to phase out lead from the fishing tackle intended for the internal market, the proposed restriction would also require the importers, only-representatives, retailers and the web retailers of fishing tackle (including the non-specialised websites such as Amazon, eBay, Wish, or Alibaba) to (i) inform their customers (till the transition period enters into force), but also (ii) ensure and check that lead is not present in the fishing tackle placed on the market. As discussed in section 2.8.2.1, this is assumed to be affordable by those actors.

2.8.2.3. Other impacts for the society

Impact on EU employment and SMEs

The ECHA market study, and the analysis of the KOMPASS database indicate that the manufacturers of lead fishing tackle could fall essentially under the European SME definition[200]. In addition, the analysis of this information shows that the European

[200] https://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en

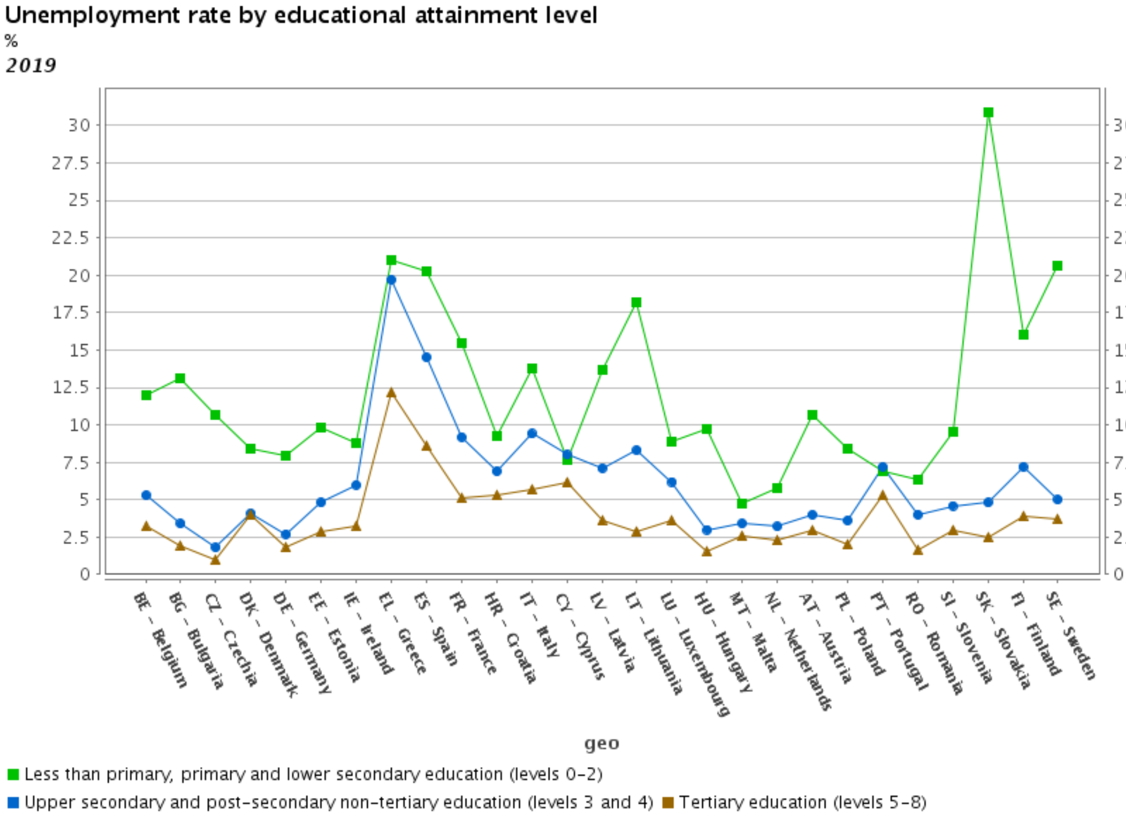
manufacturers are separated into three different subgroups: (i) the 'global' manufacturers with significant capital and huge portfolio of lead fishing tackle and other lead products. These manufacturers, usually foundries, have a 'global business' meaning that they supply most of the EU countries (and even export outside Europe), (ii) the 'local' manufacturers which have a smaller portfolio and usually supply lead fishing tackle within their country of origin (local business), these companies are either specialised in the fishing business or manufacture lead fishing tackle among many other fishing equipment or products, and finally (iii) the home manufacturers who might be fishers, fishing associations or fishing shops producing lead fishing tackle for their own use or for selling in small fishing tackle shops.

The impacts on these three sub-groups were examined separately.

Global and local manufacturers could be able to respond and adapt to the restriction proposal if they can switch to alternative processes and/or materials which have similar physical properties as lead (e.g. melting point), if they are given enough time to adapt. In addition they could remain viable if they can use the existing machinery and equipment.

In case of a sudden restriction, i.e. without or with a too short transition period, global manufacturers have indicated that they would lose half of their revenue and would have to lay off up to half of their staff. For local businesses, it is expected that most of them would shut down their business, especially if they are too specialised to be able to afford a restriction without or with a too short transition period.

At the European scale, and assuming three European manufacturers with a 'global market' (i.e. market in multiple EU countries and outside the EU), and 10 European manufacturers with a 'local' market (i.e. market limited to the country where they manufacture), it represents up to 100 employees that could lose their jobs in SMEs. Employees working as smelters have usually a low educational background and might have difficulties in finding another job (see Figure 2-11).



Source of Data Eurostat
Last update: 01.09.2020
Date of extraction: 06 Oct 2020 08:49:28 CEST
Hyperlink to the graph: https://ec.europa.eu/eurostat/eurostat/tgm./drawGraph.do&init=1&plugin=1&language=en&pcode=tepsr_wc140&toolbox=legend
Disclaimer: This graph has been created automatically by Eurostat software according to external user specifications for which Eurostat is not responsible. Graphic included
General Disclaimer of the EC website: https://ec.europa.eu/info/legal-notice_en
Short Description: The indicator presents unemployment rates of those aged 15-74, broken down by educational attainment level. The educational attainment level is coded according to the International Standard Classification of Education (ISCED). Data until 2013 are classified according to ISCED 1997 and data as from 2014 according to ISCED 2011.
• Less than primary, primary and lower secondary education (ISCED levels 0-2)
• Upper secondary and post-secondary non-tertiary education (ISCED levels 3 and 4)
• Tertiary education (ISCED levels 5-8) (ISCED 1997: levels 5 and 6)
The indicator is based on the EU Labour Force Survey.
Code: tepsr_wc140

Figure 2-11: Unemployment rate by educational attainment level

Finally, if home manufacturers are unable to easily switch to alternatives, they could also be financially impacted as retail sale of sinkers and lures is usually a second source of income for them. Assuming that this additional source of income might not always be declared by the home-caster to the tax authorities, this potential impact is not considered further.

Impact on trade and competition

The effects of the proposed restriction are expected to have a neutral net effect on trade and competition for the following reasons:

(1) There is a steady and ineluctable erosion of the EU production of lead fishing tackle, while the imports keep on increasing (cf. Annex D).
(2) There is a lack of production capacity of non-lead fishing tackle to answer to the growing demand.
(3) There is a potential for new exports and new markets outside the EU for non-lead alternatives.

No information became available during the call for evidence and the ECHA market survey, that would point towards noticeable impacts on trade or competition which would not occur in absence of the restriction.

Indeed, as explained in Annex A, it is suspected that the volumes of imports of lead fishing tackle from outside Europe would have been multiplied by four during the past 20 years. In addition, to confirm this assumption, some important EU manufacturers of lead fishing tackle indicated that their production has been reduced by a factor or two compared to 10 years ago, and for others, by a factor of three to four compared to 20 years ago (ECHA market survey, 2020).

The proposed restriction can be seen as a threat for the European industry, but also as an opportunity as it will create a new market and a new demand for non-lead fishing tackle inside Europe. This opportunity can be supported by the proposed transition period, which should give the European industry sufficient time to adapt. The local production of non-lead fishing tackle can also be seen as a strength as EU manufacturers will be more responsive to the customers' demand than the imports.

Finally, on the export side, the demand for non-lead fishing tackle might also arise outside Europe in the future due to changes of regulations in non-EU countries.

The effect on trade and competition could therefore turn from neutral to positive with an early, strong and systematic enforcement including at the fishing spots (cf. section on enforcement below).

Impact on innovation

In the long term the restriction proposal can promote the innovation and competitiveness of the European fishing tackle manufacturers as it will force and support, via the additional non-REACH measures, the research and the development of sustainable non-lead alternatives. European manufacturers could become the front runners on non-EU markets if similar lead fishing tackle ban are implemented, for example, in Canada, US, UK.

2.8.3. Cost-effectiveness, and cost-benefit considerations

2.8.3.1. Cost-effectiveness considerations

The proposed restriction is anticipated to reduce lead releases to the environment by about 48 300 tonnes over a 20-year analytical period (cf. section 2.8.1.2 and Annex D). Considering the total costs of the proposed restriction option, the cost-effectiveness of the proposed restriction is estimated to be €193 per kg of lead release avoided (with a lower bound close to €0 per kg of lead release avoided in case cheaper alternatives are used, and an upper bound of €996 per kg of lead release avoided if considering that all lead fishing tackle would be replaced by the most expensive alternative for the consumer).

Overall, the proposed restriction for lead in fishing tackle appears to be more cost-effective than previous REACH restrictions (Figure 2-12). However, the proposed restriction option for lead in fishing tackle is less cost-effective than the restriction on lead in gunshot in wetlands, which ranged between €0.3/kg to €25/kg and was addressing the same type of environmental impact (ingestion of lead fragments by birds).

Overall, the Dossier Submitter concludes that the proposed restriction is a cost-effective measure for addressing lead releases to the environment from fishing activities.

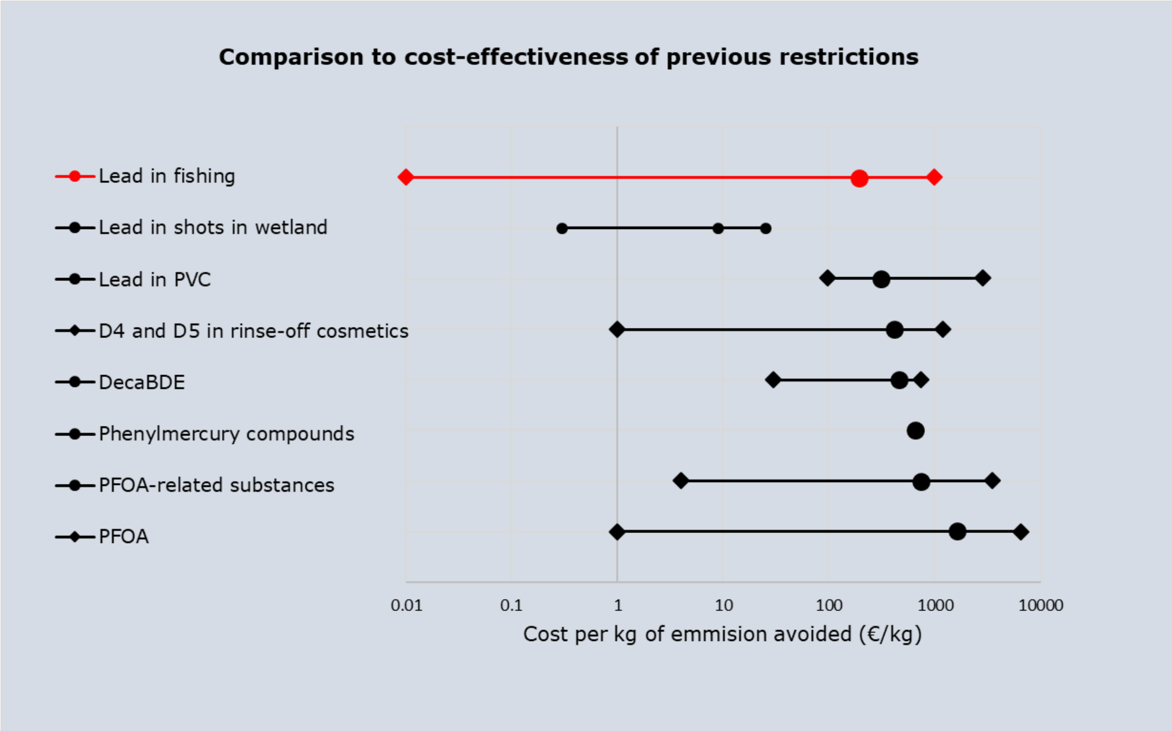


Figure 2-12: Cost-effectiveness comparison with other REACH restrictions

2.8.3.2. Cost-benefit considerations

Table 2-47 summarises the main costs and benefits of the proposed restriction option for lead in fishing tackle that were identified in the previous sections. The analysis also considers additional elements such as welfare impact for the EU producers, and valuation considerations of human health and environmental effects.

Welfare and distributional impact for the EU producers

As a distributional impact, the restriction would result in increased tax generation, and increased profits for importers, retailers and EU manufacturers of alternative fishing tackle: this is based on the assumption that the retailing prices of alternative fishing sinkers and lures are more expensive than the lead ones.

On the European producer side, the quantification of welfare impacts is measured using the manufacturer and retailer surplus. A part of the replacement cost accruing to fishers (i.e. consumer surplus loss) will result in a windfall surplus[201] to fishing tackle manufacturers and retailers. Since the restriction will likely affect current market prices for fishing tackle, it is difficult to estimate the size of this surplus gain. Yet, an attempt can be made based on the assumption that retail price (incl. VAT) of fishing tackle is roughly three times the ex-factory price of fishing tackle (ECHA market survey, 2020). Importantly, this mark-up is thought to capture both the income earned as well as the expenses made by manufacturers, wholesalers, and retailers to sell the product (i.e. costs that are not genuinely related to the production, but to the transportation, stocking and selling of fishing tackle).

[201] (Producer) surplus is defined as the difference between the amount for which the manufacturer/retailer is willing to supply goods and the actual market price. As such it is a measure of company welfare.

To approximate the profit made by producers and retailers, one could thus subtract an average of 20% VAT from the annualised net cost accruing to fishers (estimated at €680 million) to arrive at €544 million, and then divide this amount by three to arrive at an estimate of the total mark-up of approximately €180 million. An unknown fraction of this mark-up will be the actual producer surplus gain and should thus be deducted from the consumer surplus cost to arrive at the net social cost of the restriction.

However, one can assume based on COMEXT data that only ~25% of fishing tackle placed on the common market are produced inside the EU, and most of the metals to produce non-lead fishing tackle are imported from Asia (cf. Annex A and Annex C). Hence, a substantial share of the regulation-induced mark-ups might accrue to non-EU actors in the supply chain. Taking all of this together suggests that the total producer surplus gain to EU manufacturers and retailers is smaller than the regulation-induced consumer welfare loss.

Valuation of human health effects

Given the non-threshold nature of lead for neurotoxic effects in children, and considering that children might be exposed to lead fumes during home-casting activities and possibly via accidental mouthing, detrimental health impacts on them cannot be excluded. However, it is currently not possible to quantify this risk as information that would be needed to underpin a quantitative health impact assessment is not available (cf. section 1.6).

One would expect that the proposed restriction, and in particular the information towards home casters of fishing sinkers on the hazard and risk of lead, would have a deterring/discouraging effect on home-casting thereby reducing health risks to children. Indeed, one could assume that if fishers better understand why they should not use lead fishing tackle, then they will refrain from manufacturing them at home. However, because a home-casting ban could hardly ever be enforced, and as the restriction proposal's success is bound to a strong enforcement at the point of use (i.e. at the fishing spots), there is a risk that the proposed restriction on placing on the market of lead fishing tackle would inadvertently increase home-casting and thus increase children's exposure to lead fumes at home. This is a risk that cannot be ignored, especially if alternative sinkers and lures available on the market are substantially more expensive than lead sinkers and lures.

Valuation of environmental effects

As environmental amenities are usually not traded in markets, estimating values for them is inherently difficult. However, some methods to value specific amenities, and empirical estimates are reported in the environmental economics literature[202]. Therefore, a relevant economic value associated with the prevented loss of birds can be considered here.

Birds may be valued for various reasons. These include:

- birdwatching;
- aesthetic value for hikers, campers, anglers, and nature walkers in national and state parks and other natural environments;
- biodiversity value as part of and essential to the health of ecosystems;
- potential future genetic or medical value;
- pest control (e.g. insects, mice) and 'carcass-removal services' (e.g. scavengers); and
- game for hunting.

[202] Environment and Climate Change Canada maintains the Environmental Valuation Reference Inventory (EVRI), which is a searchable online compendium of summaries of environmental and health valuation studies.

Activities related or associated to birds such as birdwatching appear on the rise in Europe[203]. Nevertheless, information on birdwatching activities in Europe is scarce compared to other regions in the world. By way of comparison, a US National yearly Survey[204] reports that in 2016 approximately 45.1 million persons (i.e. ca. 14% of the US population) engaged in the US in wildlife-watching recreation (incl. watching birds). The recreational benefits measured as expenditure associated with wildlife watching including birdwatching, bird photography, and bird feeding was found to be approximately $1 100 per person[205] (ca. €950). The same study reports that 37 million people engage in bird feeding for an average expenditure of $107 per person (ca. €90).

A concrete example of birds' ecosystem value is as a 'carcase-removal service'. Whelan et al. (2015) suggests that 'carcass-removal services' of vultures in Spain led to minimum annual savings of about €1 million, because without vultures the carcasses of free-ranging livestock would have to be disposed of professionally.

On the assumption that society values both the existence of birds (non-use value) and the services or pleasures they provide (use value), one could attempt to estimate the number of birds which when protected from primary or secondary lead poisoning would correspond to the estimated costs of the restriction proposal. Such a comparison provides a kind of break-even estimate of the number of birds that would need to be protected from ingesting lead so that the restriction proposal would result in a net benefit to society. As discussed above, it seems impossible at this time to obtain a point estimate of either the break-even number of birds to be protected or the value per individual bird protected. However, a ballpark estimate may still be attainable. Here, the Dossier Submitter proposes to calculate a range of the number of birds to be protected on the basis of risk reductions to non-threatened / non-endangered birds. It should be kept in mind that this range estimate, even if it offers useful information, does not measure the absolute benefits of the restriction proposal.

Looking solely at the birdwatching value to society, and assuming that the same proportion of people in Europe and the US are engaged in birdwatching, and that Europeans spend as much as Americans for birdwatching activity (€90 to €950/year), the Dossier Submitter divided the costs of the proposed restriction option by estimates of the economic value of birdwatching. The results of the analysis suggest a break-even range of 0.7 - 7.5 million birds[206] (whether threatened/endangered or not). While not trivial, the upper bound of this estimate, 7.5 million birds represents the estimated number of birds at risk of ingesting lead fishing tackle as depicted in Table 1-55.

Conclusion

While reductions in risk to endangered species and human health have not been monetised, they cannot be ignored.

Regarding the benefit for the wildlife, several endangered species are indeed potentially at risk from the ingestion of the smaller lead fishing sinkers and lures (i.e. ≤ 50 g) as described in section 0. In addition, even if the existence value for the endangered birds have not been accounted for, evidence suggests that part of the society does place a 'high' value on endangered species. For instance, in 2019, a European LIFE project was initiated

[203] https://www.responsibletravel.org/docs/Market/Analysis//Bird-Based/Tourism.pdf
[204] https://www.fws.gov/wsfrprograms/Subpages/NationalSurvey/nat_survey2016.pdf
[205] While this average expense is for all wildlife watching, the U.S. Fish & Wildlife Service study indicates that in the US, 45m people (70%) engage in birdwatching.
[206] Total cost of the proposed restriction / Economic of value of birdwatching = €680 million / (90€ to 950 €/year) = 0.7 – 7.5 million

to restore the habitat in Sicilia of a bird that among other threats is at risk of ingesting lead fishing tackle (cf. 1.5.4.1): €3.4 million will be spent on preservation efforts for the Marble Duck alone[207]. While not a measure of the social value of birds, European LIFE type projects demonstrate that the health and safety of birds is a concern for part of our society.

Regarding the benefits for human health, the proposed restriction option encompasses indirectly the home-casting of lead fishing sinkers and lures. Human health benefits and risk reduction are therefore 'in theory' expected because exposure to lead fumes and dust during home manufacturing would be expected to be reduced. Nevertheless, as explained before, it is important to acknowledge the risks associated with the proposed restriction, and in particular the fact that instead of reducing the exposure to lead fumes and dust, the proposed restriction might inadvertently increase this issue especially if alternative sinkers and lures available on the market are substantially more expensive than lead sinkers and lures.

Even if benefits exist, the proposed restriction has also a cost both for the fishers and the EU producers that need to be acknowledged.

Table 2-48 summarises the main costs and benefits of the proposed restriction option for lead in fishing tackle that were identified in this document.

Table 2-48: Costs and benefits comparison of the proposed restriction

Costs of the proposed restriction (i.e. negative impacts)		**Benefits of the proposed restriction (i.e positive impacts)**	
Monetised (Annualised)			
Annual costs of the proposed restriction	€680 million	Distributional impact in term of generated tax revenue (with an average VAT rate of 20 %)	€136 million
Including annualised EU industry compliance costs	*€11 million*	Distributional impact in term of supply chain surplus gain (EU and non-EU)	€180 million
Additional yearly expense for a fisher	*€30 per fisher per year (i.e. 3% of the average yearly fishing budget of a fisher)*		
Quantified			
Workers in lead	Up to 100 workers	Quantity of lead	On average 2 400 tpa

[207] IFE Marbled duck PSSO - Habitat recovery and management actions to increase Marbled duck breeding population in "Pantani della Sicilia SO" area - LIFE18 NAT/DE/000797: https://ec.europa.eu/environment/life/project/Projects/index.cfm?fuseaction=search.dspPage&n_proj_id=7241

<table>
<tr><th colspan="2">Costs of the proposed restriction
(i.e. negative impacts)</th><th colspan="2">Benefits of the proposed restriction
(i.e positive impacts)</th></tr>
<tr><td>foundry that are at risk of losing their job</td><td>with low educational background</td><td>releases avoided to the environment</td><td></td></tr>
<tr><td></td><td></td><td>Protection of birds at risk of ingesting lead fishing tackle</td><td>7.5 million birds including 9 critically, endangered or vulnerable bird species</td></tr>
<tr><td colspan="4">Qualitative</td></tr>
<tr><td colspan="2">Risk to inadvertently increase the incidence and frequency of home-casting of lead fishing tackle, and the associated children exposure, if the price of non-lead fishing tackle in shops and internet webstores rises, and if the enforcement at the point of use is not done effectively.</td><td colspan="2">Expected to impact positively some children's health due to reduced lead home-casting activities.</td></tr>
<tr><td colspan="2">Risk to potentially create another littering issue in the environment (inherent to the fishing practice), depending on the type of alternative used.</td><td colspan="2">Overall positive impact expected on the environmental foot-print of sinkers and lures.</td></tr>
<tr><td colspan="2"></td><td colspan="2">Protection of wildlife and ecosystem services.</td></tr>
<tr><td colspan="2"></td><td colspan="2">Positive impact on leisure activities including bird watching</td></tr>
<tr><td colspan="2"></td><td colspan="2">Fulfilment of European commitment toward the AEWA with regard to protection of endangered bird species.</td></tr>
<tr><td>Summary of the societal costs and benefits:</td><td colspan="3">Monetised costs: at least €364 million (annualised) including €11 million for the EU industry compliance cost.
It represents €30 additional expense per fisher per year (i.e. 3% of the average yearly fishing budget of a fisher)
On average: 2 400 tpa of lead releases avoided.
Potentially up to 100 workers in SMEs at risk of losing their job.
Positive impact expected on children health if the lead home-casting activity decreases as expected.
Overall positive impact expected on the environmental foot-print of sinkers and lures, despite the risk to potentially create another littering issue in the environment (inherent to the fishing practice), depending on the type of alternative used.</td></tr>
</table>

Costs of the proposed restriction (i.e. negative impacts)	Benefits of the proposed restriction (i.e positive impacts)
	Positive impact on wildlife, ecosystem and associated leisure activities. EU Birds Directive and AEWA MOU commitment fulfilled.

2.8.4. Other practicability and monitorability considerations

2.8.4.1. Implementability and manageability

The proposed restriction is considered implementable and manageable.

The proposed restriction includes a ban on using fishing tackle rig or equipment intended to drop off lead sinkers. Such rig techniques and equipment are recent and are promoted by some fishing tackle providers only. As described in Annex D, alternative techniques or equipment are available and economically feasible.

Alternatives[208] are also already available, technically and economically feasible (cf. Annex D) for the fishing sinkers, lures and wire. Multiple alternative substances to lead in fishing tackle were identified via literature review of recently published articles (Environment and Climat Change Canada, 2018, Thomas, 2019), the ECHA market survey (cf Annex D and E), and information provided via the ECHA call for evidence (CfE #909 from Sportvisserij Nederland, CfE #1034 from VLIZ and CfE #1078 from Belgium - The marine environment department). For example: bismuth, ceramic/glass, copper and its alloys such as brass, concrete, high density polymers, reinforced bars (Rebar), (stainless) steel, stones or pebbles, tin, tungsten, zamac (zinc-aluminium alloy), and zinc.

In general, the alternatives currently available for fishing tackle are better than lead from a human health and environmental standpoint, though there are some data gaps for some alternatives which makes a full comparison difficult.

Among the alternatives, none of them meets the technical performance requirements for every type of fishing tackle, applications or fishing techniques but each alternative could successfully be used for one or more types of sinkers or lures (cf. Annex D). Some alternatives made of steel, stone or pebble, are competitive in price with lead, while others are several times the price of equivalent lead fishing tackle. For example, a sinker or lure in tungsten costs over ten times more than the lead version (cf. Annex D).

In addition, new and more sustainable alternatives could be developed in the future.

Finally, the transition to suitable alternatives could be feasible if a sufficiently long transition period is given to the European industry to adapt their manufacturing equipment and to gear up in terms of capacity of production.

For all these reasons, the proposed restriction is considered implementable and manageable.

[208] An alternative is a possible replacement for a substance. The alternative should be able to replace the function that the substance performs. An alternative could be another substance or could be a technology, or a combination of both. The word 'alternative' does not imply or mean that the alternative is suitable (i.e. technically, economically feasible and resulting in an overall reduction of the risk for the human health, and the environment).

2.8.4.2. Enforceability

The three components of the proposed restriction are enforceable, and the scope of the proposed restriction is clear and unambiguous.

Firstly, the enforcement of the ban on placing on the market could be done using one of the following methods:

- Spot checks of imported fishing tackle (customs).
- Manufacturer site inspections.
- Retailers site inspections.
- Retailers/social media website inspections.

Such an enforcement could include one or more of the following checks:

- Laboratory testing to check the presence of lead in selected fishing tackle. ICP-MS[209] is a common method to detect lead.
- Paper inspection: verification of paper records such as inventory records (purchased goods, sold goods, source of supply, material composition).

The paper inspection could play a key role in order to identify and track non-legal supply chain patterns such as the selling and distribution of 'home-made' lead fishing tackle.

Secondly, the enforcement of the obligation to inform at the point of sale the consumers, could be done together with the retailer inspections via a visual inspection. It can be easily visually verified that information on lead hazard and risk are available, and visible at the points of sale, in the shops and on websites selling lead fishing tackle.

Finally, with regard to the enforcement of the ban on use (use of lead fishing tackle, and use of techniques or equipment to intentionally drop off sinkers), it will have to be carried out on the sites of use, i.e. on fishing spots. REACH inspectors might not be the most appropriate inspectors to ensure the respect of the restriction provision. Nevertheless, the enforcement on the site of uses could be performed by the existing national relevant enforcement authorities for the fishing matters, i.e. either fishing associations or local area authorities or ministries depending on the EU country. These inspectors, usually fishers themselves or used to perform fishing inspections (licence, equipment, fish), are assumed to be knowledgeable, and skilled to recognise lead fishing tackle and drop off techniques or equipment.

With regard to lead in fishing tackle, a ban on using lead fishing tackle cannot be dissociated from a ban on placing on the market. From a practical point of view, it is easier to check compliance with a ban on placing on the market rather than a prohibition of use. However, a ban on using lead fishing tackle is considered necessary to stop the use, exposure and releases of home-casted lead fishing tackle (cf. Annex D).

Despite the proposed restriction, there is a risk of fishers making their own lead fishing tackle (via home-casting), or buying lead fishing tackle from the Internet or abroad (i.e. outside EU). Indeed, while the market among professionals might self-regulate once a restriction is in place, recreational fishers might still be able to purchase lead-fishing tackle directly from other individuals via friends, relatives, but also Facebook, social medial, or shops and websites located outside Europe (cf. examples in Annex D).

For example, Perrins et al. examined lead poisoning of swans in the United Kingdom following the 1987 ban on placing on the market (Perrins et al., 2002). In this study, 13.7%

[209] ICP-MS stands for 'Inductively Coupled Plasma Mass Spectrometry'. It is a type of mass spectrometry.

of fishing tackle with weights that were removed from rescued swans (34/249 swans) included illegal lead weights, suggesting that some anglers may be violating the ban, unless the swans had ingested lead weights that were lost prior to the ban. In addition, an unpublished study using surveys to assess compliance of anglers to the 1987 UK ban found that 7% of anglers were using banned lead fishing weighs (Rattner et al., 2008).

Even if under the proposed restriction the use of lead fishing tackle will be prohibited, the role of enforcement at all levels of the supply chain (including at the fishing spots) is crucial to ensure a level playing field and a fair competition for the EU manufacturers, but also to achieve the foreseen releases reduction from the proposed restriction. During the call for evidence, the UK competent authorities reported some issues enforcing the current UK ban on internet sales, stock of existing lead tackle, and illegal sale of lead weight in some outlet (CfE #936 – UK EA). In Denmark, an enforcement campaign revealed in 2010 that almost 10 years after the entry into force of the ban on importing and placing on the market lead fishing tackle, such fishing tackle were still available in stores: the Danish EPA, carried out spot checks, and analysed 266 randomly selected fishing tackle from 20 stores across the country and found there were excessive amounts of lead in 100 cases. In only one store was all the tackle lead-free[210].

2.8.4.3. Monitorability

The proposed restriction on lead in fishing tackle is monitorable.

The presence of lead and non-lead fishing tackle on the market could be monitored using the same methodologies as the one used by the Dossier Submitter to perform the market survey: contact fishing tackle manufacturers, importers, retailers, consult website and social media pages. Mystery shopping campaigns on websites and in retailers' shops could also be conducted for the same purposes.

In addition, the Member States could take advantage of the existing provisions set in the SUP Directive (EU) 2019/904. Indeed, under the SUP Directive, Member States would be required to monitor fishing tackle containing plastic placed on the market, as well as waste fishing tackle collected, with a view to the establishment of binding quantitative EU-wide collection targets[211].

Expanding these monitoring and data requirements to reporting data on lead presence in fishing tackle would be useful for the monitoring of the proposed restriction. This might not be a big additional effort as there is an overlap between the actors in the supply chain placing on the market lead fishing tackle and fishing tackle containing plastic.

[210] https://eng.mst.dk/chemicals/chemicals-in-products/the-chemical-inspection-service/control-of-lead-in-fishing-tackle/

[211] Article 13 (1 and 2): '(1) Member States shall, for each calendar year, report to the Commission (…) data on fishing gear containing plastic placed on the market and on waste fishing gear collected in the Member State each year. The first reporting period shall be the calendar year 2022. (2) The data and information reported by Member States (…) shall be accompanied by a quality check report. The data and information shall be reported in the format established by the Commission'

3. Assumptions, uncertainties and sensitivities

3.1. Lead in hunting ammunition

3.1.1. Main assumptions

Wetland dossier and hunters and Member States' reaction

The Wetlands dossier was adopted and published in the official journal on 25 January 2021. The final wording of the legal text defines wetlands according to the Ramsar definition, included a buffer zone of 100m and offers the possibility to Member States with more than 20% land cover of wetlands to put in place more stringent measures (i.e. a full ban on the use of lead shot).

As the publication of this restriction was very recent, the Dossier Submitter has no knowledge on whether a) Member States will make use of the possibility to put in place more stringent measure or b) to what extent hunters will react to the new legislation above the required change to use lead in wetlands. The Dossier Submitter has tried to capture this uncertainty by assuming low-middle-high scenarios of adaptation. These assumptions have an influence on the share of alternatives that are assumed to be used for the terrains outside of wetlands (terrestrial compartment) as well as on the estimation of compliance cost of hunting outside wetlands.

Reaction to on-going legislation

During the development of the dossier two initiatives were launched that may have an impact or even a spill-over effect. Firstly, Denmark announced a full ban on the use of lead bullets in hunting. Secondly: the German Bundesrat issued a statement that within a short period of time lead bullets in hunting could be abandoned for hunting ungulates at least.

These two initiatives may have a spill over effect, outside of their jurisdictions, on the level of use of alternatives to lead and therefore on the overall emission reduction of this proposal. Furthermore, they may have a spill over effect on other markets as well as on the availability of alternatives as

Need to buy new guns

The Dossier Submitter has analysed the overall need for gun replacement already in the wetland restriction proposal. This information as well new information submitted in the call for evidence and further investigations of the Dossier Submitter lead the Dossier Submitter to understand that here is little need for gun replacement as it is more likely that hunters will choose the less costly option (less costly than buying a new gun) of switching to bismuth. This has led to estimates of the cost of compliance that are relatively lower than the cost of compliance estimated in the wetlands dossier. This is expressed by a lower cost-effectiveness, i.e. less expenses per tonne of lead abatement.

A further explanation of the main assumptions that are made can be found in Annex D.

3.1.2. Uncertainties

Human health risks

Insufficient information is available to conclude on potentials health risks of hunters in the EU from the use of lead ammunition. Information on blood lead levels in hunters in relation to frequency of hunting (including hunting training) and the type of ammunition used would help to clarify the health risk for hunters.

No information is available on the incidence of hunters in the EU that are home-casting lead bullets for hunting.

No information is available on the incidence of small children in the EU ingesting lead gunshot used for hunting.

The risk assessment for the consumption of game meat in the EU is based on data from EFSA on the concentration of lead in game meat and the consumption of game meat with the 95th percentile of the consumption as a proxy for game meat consumption in hunter families. Appropriate measured data on blood lead levels in hunter family members frequently consuming game meat would help to verify the calculated blood lead levels and the resulting risks. Specifically, exposure of female members of hunter families and small children (under the age of 7) would be of interest due to the specific concern of developmental neurotoxicity of lead for small children. Of importance would be the following information to be considered when performing new studies such as:

- sufficient number of hunter family members and controls
- identification of the gender
- identification of the age (children under the age of 7, children older than 7 years, adults, elderly)
- clarification of the hunting status (hunter or non-hunter)
- type of game meat consumed
- amount and frequency of consumption of game meat
- identification of other sources of lead intake
- appropriate control groups of as same gender, same age group, non-hunting status.

Hunting statistics

It was not possible to find hunting statistics for all EU Member States with a similar level of detail, the Dossier Submitter encountered differences in detail varying from very detailed (Finland) to more rudimentary (e.g. Belgium). Interpolation had to be used to compile an EU wide game bag. This, per nature of the exercise, introduces uncertainty. This uncertainty has been boxed off with higher and lower end estimations which have an influence on the amount of lead that is assumed to be used and hence on the estimation of cost-effectiveness.

Transition period

A sufficiently long transition period may allow more time for hunters and industry to adjust to the increased need to use non-lead ammunition. A longer transition period is expected to have a positive impact on compliance but would (during the transition period) inevitably lead to an increase in release of lead to the environment.

Price of steel shot

Some stakeholders submitted information on the expected demand and supply for steel to produce steel shot. In a UK voluntary agreement to phase out the use of lead in hunting, the UK manufacturers pointed out a similar risk of shortage of supply. Such a shortage of supply would have an influence on the manufacturers abilities to provide ample supply of non-lead shot. This could have an influence in the short to medium term on the prices of steel shot and hence on the cost to comply with this regulation.

Enforcement cost

The Dossier Submitter is assuming that the enforcement is feasible, practical and can be done in a harmonised and thorough manner both at the point of sale, and at the point of use of the fishing tackle. These assumptions on the enforcement most probably overestimate the benefits, and the risk reduction of the proposed restriction.

3.1.3. Sensitivity

This section explores in a simple manner the sensitivity of key outcomes of the socio-economic analysis (such as the remaining releases, the average annualised costs of the restriction and its cost-effectiveness) associated with potential variations in a few key input variables.

The sensitivity analyses are summarised in the Table 3-1 where the arrows indicate the impact of the uncertainty of some key parameters on the key outcomes of the socio-economic analysis (such as the average annualised costs of a restriction and its cost-effectiveness).

↑ means that the assumption increases the estimates / ↓ means that the assumption lowers the estimates.

Table 3-1: Summary of SEA sensitivity analysis (lead in hunting)

Parameter tested	Impact on releases reduction	Impact on annualised costs	Impact on cost-effectiveness
Adaptation to wetlands restriction is lower than the Dossier Submitter assumes	↑	↑	↑
Less hunters will opt for switching to bismuth instead of buying new gun	None	↑	↓
Longer transition period	↑	↓	↓
Price of steel shot	none	↑	↑

3.2. Lead in sports shooting

3.2.1. Main assumptions

Despite several survey's (including Member States survey (2020))[212] and extensive search from the Dossier Submitter, little confirmation could be found on the amount of risk management measures (RMM) already in place at shooting ranges. No RMM was reported to be "**mandatory**" at national level, from the Member States survey (2020). Of course, example cases have been found and good practices have been identified. But given the overall wide geographic and high number of shooting ranges throughout the EU, little information was found on concrete measures in place. A database of this level of detail and geographic coverage does not exist on European wide level and often not even on a national level.

This has an influence on any conclusion the Dossier Submitter can reach on the degree and extent of the capabilities of shooting range owners and operators to guarantee a certain amount of lead recovery. To overcome this, the Dossier Submitter has tried to box off this

[212] See Annex E.5

uncertainty with various scenarios covering the different types of shooting ranges known to the Dossier Submitter which inevitably introduces an uncertainty. In the absence of precise information, the Dossier Submitter reverted to scenario building, comparing various degrees of lead containment with the level of RMM (physical infrastructure required).

3.2.2. Uncertainties

Human health risks

Insufficient information is available to conclude on potential health risks in the EU from the use of lead ammunition for outdoor sports shooters. Information on blood lead levels in sports shooters (practicing outdoor) in relation to the type and frequency of ammunition used (including information if a lead-containing primer is used), the discipline and the conditions of shooting (such as covered or open stand) would help to clarify the health risk for outdoor shooting.

Recovery of lead gunshot and lead bullets from bullets traps is expected to result in relevant exposure in case strict personal hygiene measures are not applied. There might be specific concern when lead recovery is performed by recreational shooters and not by professionals. No information is available how lead recovery would add to the body burden of recreational shooters.

No information is available on the incidence of sports shooters in the EU that are home-casting lead bullets for sports shooting.

No information is available on the incidence of small children in the EU ingesting lead gunshot or air pellets used for sports shooting.

There is also no information to judge on the human health risks in the EU from the consumption of drinking water or food contaminated via the environment by lead deposition on shooting ranges throughout the EU.

Amount of lead used in sports shooting

An estimate on the number of ranges in Europe, based on the results of the Member States survey (2020), was made as described in Annex B 9.1.3. An estimate on the amount of lead used in Europe was also made as described in Annex B 9.1.3, based on information available in the CSR (2020) and on stakeholders' information (sport shooting associations). However, the overall number is uncertain. Comparison with the overall mass balance of ammunition import/export and production in the EU (see Annex A.2), highlights this uncertainty. The amount of lead releases (and related uncertainties) is discussed in detail in section 1.5.3 under 1.5.3.1.2. Lead from ammunition (sports shooting).

Number of ranges in Europe

An estimate was made on the number of ranges in Europe, based on the results of the Member States survey (2020) as described in Annex B 9.1.3. However, the overall number is uncertain. The number of temporary ranges/areas in Europe could not be established by the Dossier Submitter, even though they appear to be commonly used in some countries, e.g. in France.

Transition period

A sufficiently long transition period may allow more time for sports shooters and industry to adjust to the increased need to use non-lead ammunition. A longer transition period is expected to have a positive impact on compliance but would (during the transition period) inevitably lead to an increase in release of lead to the environment. A longer transition period may as well increase the incentive to improve RMM, typically this would be an infrastructure cost and more time in a transition period would allow more time for range operators to secure funding to improve RMM.

Price of steel shot

Some stakeholders submitted information on the expected demand and supply for steel to produce steel shot. In a UK voluntary agreement to phase out the use of lead in hunting, the UK manufacturers pointed out a similar risk of shortage of supply. Such a shortage of supply would have an influence on the manufacturers' abilities to provide ample supply of non-lead shot. This could have an influence in the short to medium term on the prices of steel shot and hence on the cost to comply with this regulation.

3.2.3. Sensitivity

This section explores in a simple manner the sensitivity of key outcomes of the socio-economic analysis (such as the remaining releases, the average annualised costs of the restriction and its cost-effectiveness) associated with potential variations in a few key input variables.

The sensitivity analyses are summarised in the Table 3-3 where the arrows indicate the impact of the uncertainty of some key parameters on the key outcomes of the socio-economic analysis (such as the average annualised costs of a restriction and its cost-effectiveness).

🡩 means that the assumption increases the estimates / 🡫 means that the assumption lowers the estimates / negligible.

Table 3-2: Summary of SEA sensitivity analysis (lead in sports shooting)

Parameter tested	Impact on releases reduction	Impact on annualised costs	Impact on cost-effectiveness
Amount of RMM already in place at shooting ranges	🡫	🡫	🡫
Higher Amount of lead used in sports shooting	🡩	🡩	Negligible
Higher amount of lead ranges in Europe	?	🡩	?
Longer transition period	🡩	🡫	?
Higher price of steel shot	None	🡩	🡩

3.3. Lead in fishing tackle

3.3.1. Main assumptions and uncertainties

Uncertainties

On one hand, the lethal and sub-lethal effects of lead on wildlife and humans are known and scientifically documented for decades, and cannot be argued against; but on the other hand, the risk of lead fishing tackle for the wildlife and fishers is not underpinned by extensive exposure data. Indeed, the scientific documentation on the extent of both the lead fishing tackle ingestion by birds and the exposure to lead fumes and vapour during home-casting is in general very poor. According to Grade et al., this can be explained by three main reasons: (1) the lack of funding and research on this topic, (2) the difficulty to retrieve bird carcasses that would have died from lead fishing tackle poisoning, and (3) the inaccurate classification of small lead object ingested by birds due to the difficulty to distinguish a lead ammunition from a lead sinkers after it had been eroded in the gizzard of the birds (Grade et al., 2019).

In order to circumvent this lack of scientific data, and in order to be able to conclude on the risk both for the wildlife and the human health, the Dossier Submitter has taken the approach to look at specific case studies performed on well documented birds to confirm the environmental risk, and on specific populations to confirm the human health risk when home-casting.

In addition, as discussed in the previous sections, the three main uncertainties with regard to the impact assessment are:

1. EU manufacturers' and consumers' reaction to the ban

The Dossier Submitter assumes that the expected reaction from EU manufacturers to the proposed restriction would be 'reformulation', i.e. the EU manufacturers would switch their manufacturing from lead fishing tackle to non-lead ones.

Nevertheless, the continuity of the manufacturing activity of the EU manufacturers are bound essentially to consumer responses to the ban (will they continue buying European products, or will they purchase cheaper products sold on the Internet without guarantee that they do not contain lead, will they do more home-casting?), and the effectiveness of the enforcement. The expected EU manufacturers' reaction to the ban and the impact on the employment in these SMEs is therefore highlighted as an important uncertainty.

The assumption on the expected EU manufacturers' and consumers' reaction to the proposed restriction may therefore overestimate the affordability of the EU manufacturers.

2. Home-casting

Uncertainties exist both on the extent of the current practice, which are estimated by some stakeholders as representing up to 30% of the lead fishing tackle placed on the market, but also on the potential response from the fishers to the restriction proposal.

It is indeed assumed and expected that the restriction proposed for lead in fishing tackle would stop 'indirectly' the practice of home-casting. This assumption is plausible considering that the proposed restriction includes a ban on the use of lead fishing tackle (purchased and home-casted ones) at the fishing spots, as well as information to the consumers on the hazard and risk of lead at the point of sale.

Nevertheless, as the home-casting is performed in the private sphere (and not within the scope of the proposed restriction), and as the enforcement at the point of use is uncertain, it is also possible that the quantity of home-casted lead fishing tackle would not decrease. In fact, the home-casting of lead fishing tackle may even increase as fishers would be tempted to avoid purchasing more expensive lead-free sinkers and lure. This could possibly undermine the intended health benefits expected from the proposed restriction.

This uncertainty is also discussed in section 2.8.3.2.

3. Enforcement of the proposed restriction:

The Dossier Submitter is assuming that the enforcement is feasible, practical and can be done in a harmonised and thorough manner both at the point of sale and at the point of use of the fishing tackle. These assumptions on the enforcement most probably overestimate the benefits, and the risk reduction of the proposed restriction. The uncertainties related to the enforcement are also discussed in section 2.8.4.2.

Assumptions

In addition, to these three major uncertainties, a number of assumptions were made due to the limited information provided in the responses to the call for evidence and the ECHA market survey. For some of the assumptions, a sensitivity analysis is performed:

- Recreational fishing statistics (number of fishers, licences, average fisher expenses):

There are no consolidated statistics at the European level on recreational fishing (cf. Annex A). The general lack of socio-economic data on recreational fishing is also recognised both by EFTTA (European Fishing Tackle Trade association), and EAA (European Angling Association) and was presented and discussed with some members of the EU parliament in 2017[213].

The Dossier Submitter contacted various Fishers Associations, such as the European Angling Association (EAA), the International Sport Fishing Confederation (CIPS), the International Sea Fishing Federation (FIPS-M), the International Game Fish Association (IGFA), the European Federation of Sea Anglers (EFSA) and the European Anglers Federation (EAF), in order to obtain information and statistics on number of fishers, fishing licences and fishing expenses. Via EAA, only the Finnish, Dutch, Slovenian and Spanish national fishing associations responded to the Dossier Submitter questionnaire. Information and country specific statistics were also gathered from literature and internet search, and compared with US and Canadian data for which national statistics are available.

The assumptions on number of fishers, fishing licences and fishing expenses per fisher, even if uncertain and not underpinned by an EU wide survey or statistics are considered plausible when comparing all the available data available for specific countries (European or not). The estimated number of fishers was discussed with stakeholders during the Fishing round table (cf Annex E), and was considered plausible by the participants.

The detailed assumptions on fishing-related statistics are described in Annex A.

- Estimations of lead fishing tackle manufactured and placed on the market in Europe:

There are currently no statistics, nor consolidated information on the use, and sales of lead in fishing tackle in Europe: customs and Member States do not have any statistics on this topic, the European and national trade and fishing associations do not monitor the use and sales of lead either.

[213] https://www.eaa-europe.org/european-parliament-forum/ep-recfishing-forum-2014-2019/08-march-2017-socio-economic-data.html

In addition to the traditional supply chain (industrial manufacturer->distributor/wholesaler->retailer->fishers), fishers, angling clubs, or retailers, may also cast their own fishing tackle (aka home-casting) either for their own use or for direct retail to other fishers. EU-wide statistics or precise information of lead in home-casting activity is missing as well. Some plausible and justified estimates and assumptions have therefore been made based on data gathered during the ECHA market survey. All assumptions are described in detail in Annex D.

- Baseline - lead fishing sinkers and lures lost/released to the environment:

Information on lead fishing sinkers and lures released to the environment is available in the ECHA investigation report (ECHA, 2018a). This information is, primarily, reproduced from an earlier 2004 European Commission study on 'Advantages and drawbacks of restricting the marketing and use of lead in ammunition, fishing sinkers, and candle wicks' (COWI, 2004). The information is therefore rather old (data from 2004), scarce (limited to some Member States), and all assumptions that were used to estimate the used and released tonnage (from recreational and commercial fishing) not always explicit or fully traceable.

Limited information has been submitted during the call for evidence on lead tonnage lost/released in the environment (CfE#1153 - Modified Materials BV).

There is no European level study to estimate the amount of lead fishing tackle lost yearly in the environment. This might be explained by the fact that the loss of lead tackle is influenced by the intensity of fishing effort, the type of fishing, the fisher skills and experience but also the characteristics of the water body (vegetation, bottom structure, rocky areas), and varies spatially and seasonally.

In order to estimate the losses of lead fishing tackle in the environment, the Dossier Submitter has therefore conducted a literature review, and explored different methodologies in order to estimate the quantity of lead fishing tackle releases yearly in the environment.

Based on this research, which is further detailed in Annex D, the Dossier Submitter presented **plausible** assumptions. Nevertheless, due to the level of uncertainties, the Dossier Submitter undertook a sensitivity analysis on one of the key input parameters to estimate the quantity of lead released in the environment: the average amount of lead fishing sinkers and lures lost per year/per fisher.

- Costs of the restriction proposal:

The cost of the restriction proposal is essentially driven by the retailing cost of non-lead fishing tackle.

Uncertainty remains regarding which substances/raw materials will be used to replace lead in non-lead fishing tackle, many options are plausible.

In order to estimate the cost of the restriction proposal, the Dossier Submitter considered the current average retailing price of the non-lead fishing tackle (ECHA market survey). Nevertheless, due to the lack of consumers' demand, competition on the market for that type of product, and the potential lack of economy of scale at the manufacturing level, the current retailing prices might be overestimated compared to the future. The outcome of the ECHA market survey reported in Annex D indicates also that the retailing price of non-lead fishing tackle varies depending on its size (≤ or > 50 g). In addition, the retailing prices of some alternatives do not match, and exceed by far, the usual profit margin in the sector. Therefore, the Dossier Submitter undertook a sensitivity analysis on the following parameters: retailing price of non-lead fishing tackle and proportion of lead fishing-tackle ≤ 50 g.

3.3.2. Sensitivity analysis

This section explores in a simple manner the sensitivity of key outcomes of the socio-economic analysis (such as the remaining releases, the average annualised costs of the restriction and its cost-effectiveness) associated with potential variations in a few key input variables.

The sensitivity analyses are summarised in the Table 3-3 where the arrows indicate the impact of the uncertainty of some key parameters on the key outcomes of the socio-economic analysis (such as the average annualised costs of a restriction and its cost-effectiveness).

↑ means that the assumption increases the estimates / ↓ means that the assumption lowers the estimates / negligible).

Table 3-3: Summary of SEA sensitivity analysis (lead in fishing tackle)

Parameter tested	Impact on releases reduction	Impact on annualised costs	Impact on cost-effectiveness
Average quantity of lead lost per year per fisher (sinkers and lures) is **lower** than the default value	↓	None	↑
Retailing price of non-lead fishing tackle is **lower** than the default value	None	↓	↓
Proportion of fishing tackle ≤ 50 g is **higher** than the default value (55%)	Negligible	↑	↑
Longer transition periods	↓	↓	Negligible
Reversed transition period (i.e. 5 years for sinkers and lures > 50 g, and 3 years ≤ 50 g)	Negligible	↓	Negligible

4. Conclusions

The conclusions of the report are summarised below per sector:

4.1. Hunting

Identified risk

For all uses of lead that are identified in this dossier, the Dossier Submitter concludes that (consistent with the final RAC opinion of the use of lead gunshot in wetlands and other restrictions on lead), the use of lead in gunshot, bullets, and projectiles poses a risk to wildlife such as birds and to human health that is not adequately controlled, and needs to be addressed at the EU level.

Availability and suitability of alternatives

Alternatives to lead gunshot exist and are technically and economically feasible. The prices of lead and steel shot are currently comparable, while bismuth and tungsten, which are produced, sold and used in far lower volumes, are likely to remain more expensive than lead.

Where field trials comparing lead and steel shot have been conducted, no differences were found in a number of measures, including the number of birds killed per shot or wounded per shot (e.g. see Pierce et al., 2014). Further, hunters in Denmark, the Netherlands and the Flemish region of Belgium where the use of lead shot is illegal do not report problems with the effectiveness of non-lead shot.

Alternatives to lead bullets for large game are used, are as effective as their lead-based counterparts and are economically feasible. Alternatives for small game, although available (albeit not widely), do not yet meet all technical requirements.

Various field studies including Gremse and Rieger (2012), Kanstrup et al. (2016), Knott et al. (2009) and Martin et al. (2017), have found no difference in the escape distances between lead and non-lead bullet and conclude that non-lead ammunition is as effectives as lead ammunition.

For small calibre bullets (less than 5.6 mm , rimfire) the Dossier submitter has identified that currently only a few alternatives are available on the EU market and that little evaluation has been done yet of their technical suitability. Furthermore some uses of lead bullets (FMJ) for Nordic bird hunting and the suitability of non-lead ammunition for seal hunting must be verified during the suitability and availability of alternatives for this group of bullets must be confirmed during the consultation of the Annex XV proposal.

Economic feasibility

The price difference between lead and non-lead ammunition has gradually declined over the years, to such an extent that the prices for lead and non-lead are comparable. That said, there remain differences either due to local demand (in the absence of regulations), local variations and various calibre or shot sizes for which a suitable alternative does not yet exist.

Effectiveness & risk reduction

Using non-lead shot and bullets would reduce the lead intake from game meat consumption for adults and children from hunter families, reduce lead exposure whilst shooting and/or whilst reloading, reduce the risks from home-casting lead bullets and from the oral intake of lead dust from handling shots and bullets (hand-to-mouth).

Using non-lead shot and bullets would reduce risks to wildlife especially birds. Hundreds of species of terrestrial birds, including game birds, raptors and scavengers would be protected from both lethal and sub lethal effects (see also section 2.5.2.2), in line with the EU obligations under the Birds Directive and the CMS convention.

In addition, a more comprehensive protection of waterbirds (consistent with existing EU obligations under the Birds Directive and AEWA), also taking into account species feeding on terrestrial habitats, would be achieved.

Practicality

The proposal is deemed to be practical, as demonstrated by the existing limitation on the use of lead shot in the Netherlands and in Denmark as well as by existing legislation concerning bullets at Laender level in Germany and various other legislations that are in place in national parks, state forests and other jurisdictions at national levels.

Enforceability

The measure is considered to be enforceable. Methods exist to inspect hunters for lead and with the addition of 'placing on the market' in the scope of the proposed restriction, the measure is assumed to facilitate enforceability as inspections can be done at point of sale.

Monitorability

The restriction is monitorable. The existing methods that were used to verify the extent of lead posing can also be used to verify and monitor progress of the phase-out of lead. At slaughterhouses, existing methods can be used to detect any lead in game meat.

4.2. Sports shooting

Identified risks

For all uses of lead that are identified in this dossier, the Dossier Submitter concludes that the use of lead in gunshot and bullets in outdoor sports shooting poses a risk to the environment (soil, surface water and under certain circumstances also ground water), wildlife such as birds, livestock, and human health that is not adequately controlled, and needs to be addressed at the EU level.

It has to be noted that only a complete ban on the (marketing and) use of lead in ammunition for sports shooting would eliminate the risk to the environment and human health. In case of derogations under strict environmental conditions, the risks to the environment will be reduced; however, the risks to birds from gunshot will still remain. Furthermore, such derogations will not have an impact on the risks for shooters; such risks are usually reduced by recommendations of good hygiene practices.

Indoor shooting is not in the scope of this restriction because it was considered that occupational health and safety measures would be sufficient to also protect recreational shooters. However, the Dossier Submitter has identified potential risks for occupational and recreational shooters from inhaling lead while indoor shooting. Blood lead levels in indoor shooters have been demonstrated to increase with increasing calibre of the weapon used (Demmeler et al., 2009) and with increasing shooting frequency (Mühle, 2010). In a more recent review (Laidlaw et al., 2017) 36 studies were compiled reporting blood lead levels mainly from indoor shooters (both occupational and non-occupational) with > 100 µg/L (31 studies), > 200 µg/L (18 studies), > 300 µg/L (17 studies), and > 400 µg/L (15 studies). Such elevated blood lead levels are associated with a variety of adverse health outcomes. The authors noted that there is a "lack of evidence" gap in the literature demonstrating that ventilation systems can maintain air lead levels at indoor ranges below the required values which is for example 50 µg/m^3 (US OSHA)[214] or 0.5 – 2.2 µg/m^3 (California guideline). The authors consider that of major concern is the number of women and children among recreational shooters, who are not afforded similar health protections as occupational users of firing ranges; regardless of type and user classification, shooting ranges constitute a significant and currently largely unmanaged public health concern. The author also noted that primary prevention of this risk requires development of lead-free primers and projectiles. Prevention includes better oversight of ventilation systems in indoor ranges and development of airflow systems at outdoor ranges, protective clothing that is changed after shooting, and cessation of smoking and eating at shooting ranges. There are no real systematic biomonitoring programmes for recreational shooting range users to measure cumulative health effects caused by persistent low and even high-level lead exposure. Recreational shooters and the general public are provided no legal protections from lead exposures at firing ranges.

The Dossier Submitter notes that the available information on lead exposure in shooting ranges and consequent blood lead levels in shooters are not suitable to separate the increment from lead-containing primers (such as lead styphnate) from the increment coming from lead bullets or from brass alloy which is frequently used in cartridge casing. Lead styphnate (EC number 239-290-0) is already identified as a substance of very high concern[215].

The Dossier Submitter also notes that alternative bullet materials for sports shooting with sufficient precision and accuracy are currently not available (see following paragraph). Furthermore, jacketing of lead bullet which can be performed for large calibre bullets does not seem to be a possible alternative (by design) for small calibre bullets that are frequently used for sports shooting.

Availability and suitability of alternatives

For sports shooting, the dossier concluded differently per type of ammunition:

1. Gunshot can be used effectively in sports shooting. Alternative shot material has been found to be effective in sports shooting as well, the barriers for further advancing with alternatives are not technical but are rather imposed by the rules of the ISSF, FITASC and other organisations that require lead shot to be used and/or have not approved other shot material.
2. Alternative shot material for bullets (and air pellets) exhibit sub-optimal performance in terms of required accuracy.

Economic feasibility

The Dossier Submitter performed an evaluation of the impact of a ban on the use of lead shot and compared as well various scenarios under which the transition to alternatives would be less costly than the requirement to install RMMs. From this analysis the Dossier Submitter concluded that in most cases switching to alternatives is more efficient except for when the RMM in place are already sufficiently effective.

Effectiveness

Using non-lead shot and prescribing the containment of bullets via bullet traps,

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[214] https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1025
[215] https://echa.europa.eu/de/proposals-to-identify-substances-of-very-high-concern-previous-consultations/-/substance-rev/3457/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=239-290-0&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true

accompanied with regular clean recovery of lead would reduce the spread of lead into the environment and relieve the ecosystem from the burden of lead. Other measures could achieve a high level of containment of lead but would achieve this at a higher cost, impacting the cost-effectiveness rate.

It is important to note that the complementary option concerning elite athletes is not as effective in controlling the identified risks as a ban on use but may be deemed more proportionate regarding its socio-economic impacts on internationally competing athletes, due to the rules established by the ISSF.

Practicality

The proposal is deemed to be practical, as demonstrated by the existing examples in Norway, Denmark, Sweden and the Netherlands were limitations on the use of lead shot for clay target shooting have been implemented successfully.

Similarly, bullet traps have been found to capture lead effectively and are expected to be already available in many ranges throughout the EU.

Enforceability

The measure is considered to be enforceable. Methods exist to inspect shooters for use of lead shot and with the addition of in the scope of the proposed restriction, 'placing on the market' in the scope of the proposed restriction, the measure is assumed to facilitate enforceability as inspections can be done at point of sale.

Should derogations be put in place that rely on RMM (physical infrastructure) then the presence of this infrastructure can be inspected, and the recovery rate of lead can be determined using the required bookkeeping. Environmental monitoring of lead could give conclusion on compliance as well.

Monitorability

The method is considered to be monitorable. In cases with nearby pollution the monitoring requirement can lead to conclusion on the success of either the RMM or the switch to non-lead ammunition.

4.3. Fishing

The proposed restriction for the lead in fishing tackle is three-fold: (1) a ban on placing on the market and using of lead fishing sinkers and lures with different transition periods depending on the weight of the lead fishing sinkers and lures, (2) a ban on using fishing tackle rig or equipment intended to drop off intentionally sinkers, and (3) the obligation to inform the buyers at the point of sale about the presence, toxicity and risk of lead to human health and the environment.

The proposed restriction, and in particular the phase out of the placing on the market and the use of lead fishing sinkers and lures is the most effective way to reduce at EU level the lead poisoning of birds and exposure of adults and children to home-casting fumes and vapours. It would also support the implementation of the EU Birds Directive, and AEWA agreement, as the main benefit of the proposed restriction for lead fishing tackle is essentially measured in terms of number of lead fishing tackle removed from the market or reduced for exposure to birds. Each lead fishing tackle which does not enter the environment reduces the number of lead fishing tackle available for ingestion and potential bird mortality.

Nevertheless, this ban, to be successful, should be accompanied by an obligation for the retailers to inform at the point of sale the consumers about the presence, the toxicity and the risk of lead for human health and the environment during the proposed transition periods. This third restriction condition is indeed a crucial element to trigger a change of perception and behaviour regarding lead within the fishing community. It aims at engaging stakeholders about the importance of the lead issue and leverage that concern as a trigger for positive change in their purchasing or DIY behaviour.

A voluntary support from the European and national fishing associations in explaining and educating the fishing community on the hazard and risks of lead would also be an asset for the successful roll-out of the proposed restriction. Such an approach, which would combine both regulatory actions (i.e. the proposed restriction) and voluntary/education programmes is recommended in recent studies (Grade et al., 2019).

The proposed restriction, via the proposed bans and information at the point of sale, would stimulate the availability, sale, and use of non-lead alternatives. Even though it would provide a warranted market incentive to the European industry to invest in non-lead alternatives, European manufacturers of lead sinkers and lures would also require time and financial support to update their production processes and equipment, as they are typically SMEs and might not have sufficient liquidity to switch to the manufacturing of alternatives. The assumptions regarding the length of the transition period and the affordability of the European manufacturers to switch to alternatives would need to be verified during the consultation on the Annex XV report.

For other producers, such as the manufacturers of alternatives, the proposed restriction could be seen as an opportunity for new markets rather than a burden. They would also need time and financial support to build up their capacity to respond to the demand.

In any case, enough time should be allowed for European manufacturers, retailers, and users to adapt to the changes resulting from any restriction on lead in fishing tackle. Industry and fishing association initiatives could also help the European industry in this transition by sponsoring or supporting the European manufacturers transition via the levy of a small fee from the fishing licences for example. Some additional financial support to help the European industry to transition to alternatives could also be granted through the financial aid mechanisms established by the European Green Deal policy, and the newly adopted Chemicals Strategy.

The enforcement of the proposed restriction at every level of the supply chain including on social media, where home-made fishing sinkers and lures can be purchased, and at the fishing points, where home-casted fishing tackle can also be used, is also critical to ensure the success of the proposed restriction. Experiences from Denmark and the UK, which have had a ban on the import and sales of fishing tackle in place for many years, prove that an active enforcement at every level of the supply chain is the only way to ensure that the ban is applied in practice (CfE #936- UK EA, and Danish enforcement experience[216]).

If the restriction options are prioritised based on **economic efficiency and affordability** rather than being based on their effectiveness in eliminating or minimising the identified risks (cf. section 2.8 and 3.2) then RO7 (Compulsory information to consumers at the point of sale about the presence and toxicity and risk of lead), together with complementary measures undertaken by EU fishers and trade associations, could be the most cost-effective option. However, this would not, in all likelihood, prevent the continued use of lead in

[216] https://eng.mst.dk/chemicals/chemicals-in-products/the-chemical-inspection-service/control-of-lead-in-fishing-tackle/

fishing tackle or the continued lead poisoning of birds.

Last but not least, two important issues could not be addressed by the proposed restriction either because they were beyond the boundary of the REACH Regulation, or because they were out of the scope of the Commission request. These two issues that would need to be addressed separately by the legislator are:

1. A ban on placing on the market fishing tackle rig or equipment intended to drop off intentionally sinkers. Such a ban is beyond the REACH mandate which can restrict a substance or its use, but not ancillary equipment or techniques.
2. Because the loss of fishing tackle in the environment during fishing is inevitable and inherent to the fishing activity itself, the accumulation and littering of fishing tackle in the environment is inevitable whatever the alternative used. The alternative to lead should be therefore be considered carefully and with caution. Some identified alternatives, e.g. zinc, are toxic for the wildlife but are not addressed by the current restriction proposal. A restriction on zinc fishing tackle is indeed beyond the scope of the Commission request which was specifically on 'lead' fishing tackle. Only a generic approach banning all substances toxic for the environment would have allowed to tackle the issue of 'toxic' alternatives.

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