Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Appendix to the

Opinion

on an Annex XV dossier proposing restrictions on

Lead and its compounds

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Note: Work package WP B.1 has not been developed

Committee for Risk Assessment (RAC)

Ad-hoc RAC Supporting Group

Evaluation of an

Annex XV dossier proposing a restriction on

Lead and its compounds

in outdoor shooting and fishing

Work Package report WP A.1

Environmental risks to wildlife (birds) and livestock – weight of evidence across all uses

3 June 2022

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1. Description of the Work Package

1.1. Background

This work package report describes and evaluates the environmental risks to wildlife (birds) and livestock (ruminants) resulting from the use of lead ammunition in hunting and sports shooting and lead fishing tackle in fishing activities.

Irrespective of the source of lead release to the environment, its hazard (particularly its hazard via ingestion) is similar. Therefore, the Dossier Submitter performed a single generic semi-quantitative environmental risk assessment for all uses that could result in primary and secondary poisoning of 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 the risks to livestock (ruminants) and the soil and aquatic compartment in general, were assessed at a qualitative level.

The risks related to the soil and aquatic compartment and the risks to humans via the environment are not part of this work package report. They are discussed in WP A.2 and WP A.5 respectively.

1.2. Objectives

The following topics are covered in the present work package:

1. Weight of evidence for risks to birds posed by all uses within scope
2. Adverse effects on bird species reported in the literature
3. Bird species with predicted risks based on ecology
4. Quantitative estimates of bird mortality (for impact assessment)
5. Risks to livestock

2. Summary of the Dossier Submitter proposal

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

Lead gunshot, and other lead projectiles (e.g., bullet fragments in prey or carrion), that remain in the environment after use are available to be ingested. Lead fishing tackle is also frequently lost during use and affects birds in the same way as lead gunshot and projectiles if ingested. In addition, some contemporary fishing practices, and some fishing tackle suppliers, encourage the deliberate release of lead sinkers to the aquatic environment in some circumstances (termed as 'dropping the lead') to ensure a better catch rate. It is not only small sized lead object that can be ingested. Various lead objects including bullets and other projectiles and 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.

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

- primary ingestion defined as the ingestion of any lead object directly from the environment, e.g., after mistaken it for food or grit (which is deliberately ingested to aid the processing of food);
- secondary ingestion defined as the indirect ingestion of lead that occurs after the consumption of lead-containing food, e.g.
    - ingestion of embedded fragments/particles of lead that are present in the tissues of prey or carrion,
    - ingestion of lead fragments/particles that are present in discarded viscera (gut piles) from the field dressing of large game,
    - ingestion of lead fragments/particles present in contaminated silage.

The primary ingestion route is most relevant for seed eating (granivorous) bird species or those that rely on the ingestion of grit or stones to process their food in the gizzard. For example, lead gunshot and split shot sinkers may appear similar to grit or food items such as seeds. Further to primary (direct) ingestion, predatory or scavenging birds (as well as other wildlife) are at risk of secondary ingestion of lead gunshot, bullet fragments or fishing tackle by eating food that contains these objects.

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 44 000 tonnes of lead are dispersed in the environment every year: 57% from sports shooting, 32% from hunting and the rest from fishing activities. Assuming current releases and if no further regulatory action was taken, approximately 876 000 tonnes of lead would be released to the environment over the next 20 years.

The Dossier Submitter estimates that, in the EU, at least 135 million birds are at risk of primary poisoning of lead gunshot, 14 million because of secondary poisoning arising from the ingestion of lead gunshot or other lead projectiles, and seven million because of ingestion of fishing sinkers and lures, representing in total 92 species including 54 red-listed ‘threatened’ species.

3. Relevant information from the consultation of the Annex XV restriction report

The comments received related to the environmental risk assessment to wildlife either focused on not paying sufficient interest in sub-lethal effects of lead in birds or highlighted that the assessment should focus on population effects rather than on effects in individual birds.

RAC acknowledges that it is likely that lead sub-lethal effects in birds are even more common than lethal effects and that sub-lethal effects could also be the cause for accidents resulting in lethality (Monclus et al. 2020) but still these effects would not be classified as lead-related mortality. However, as the sub-lethal effects can be expressed in many ways, and there is no way of quantifying them, RAC supports that they cannot be assessed quantitatively. RAC considers that by focusing on the number of species at risk (92) rather than on bird mortality, sub-lethal effects and welfare issues are also covered. The fact that 54 of these 92 sensitive species are red-listed (and some threatened) further emphasises the degree of concern.

RAC confirms the view that effects in individual birds are of concern, and for the 54 red-listed species effects in individual birds may also have population effects (risk for extinction), reinforcing the concern.

Other comments noted that other wild and domestic animals, such as hunting dogs, can also be exposed and poisoned by lead from ammunition, and that there is evidence of predatory wild mammals (bear) being poisoned. RAC acknowledges this risk but is still of the view that no quantitative assessment of this risk can be performed.

4. Evaluation

The approach proposed by the Dossier Submitter for the hazard and exposure assessment and the risk characterisation is detailed in the following Table 1.

Table 1: Dossier Submitter's approach to the 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 and the resulting environmental concentrations after considering relevant environmental fate, behaviour and transport processes. Information on prevalence/probability (likelihood and frequency) 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 or adjacent to shooting ranges. Qualitative assessment of risks to the soil and aquatic compartments and groundwater (for uses at shooting ranges only).

The environmental assessment presented here relates exclusively to wildlife (birds) and livestock. The assessment of the hazards and risks of lead to the aquatic and terrestrial compartments resulting from the use of lead ammunition in sports shooting are discussed in the work package report WP A.2. Humans via the environment hazards and risks are evaluated in WP A.5.

4.1 Environmental hazard assessment

Extensive data on the effects of short and long-term lead exposure on a wide variety of aquatic and terrestrial organisms have been collated in REACH registration dossiers as well as previously in the EU voluntary risk assessment for lead and its compounds (LDAI, 2008). Compelling evidence is presented by the Dossier Submitter related to the non-compartment specific effects of lead which include data on the acute and chronic toxicity of lead in animals (with a focus on birds) caused by primary or secondary ingestion, as well as relevant thresholds for adverse effects in biota (i.e., blood lead thresholds).

Wildlife (birds)

The Dossier Submitter reports a comprehensive number of studies related to the ecotoxicological effects of lead in terrestrial birds with predatory or scavenging behaviour that were not assessed in the previous wetland restriction. Lead and its compounds pose a hazard to a variety of aquatic and terrestrial organisms with short-term and long-term effects. The toxicity of lead largely depends on its bioavailability, which is higher for the ionic forms dissolved in water while other speciation forms, including the metallic (massive) lead, are less bioavailable but represent potential sources that under specific environmental conditions can release soluble species having greater mobility and bioavailability. Non-compartment-specific effects in living organisms are attributed to primary and secondary lead ingestion, resulting in both acute and chronic toxicity. The Dossier Submitter provides a detailed assessment of lead toxicity in different bird species taking into account the most recent bird population size data reported to the European Commission (i.e. EEA species list and Euroredlist datasets). In this respect, primary poisoning derives from the ingestion of lead particles (shot, bullets and fishing tackle), which are mistakenly ingested during feeding or foraging activities. On the other hand, secondary poisoning can also occur upon consumption of lead-embedded preys, carrion (Golden et al. 2016, Plaza and Lambertucci 2019, Grade et al. 2019), contaminated soil, plants or invertebrate preys (Pain et al., 2014). The toxicokinetics of lead are closely related to the processes that regulate calcium uptake in the organism and at cellular level (Simons, 1993). The absorption of lead occurs in the intestine but is largely influenced by stomach characteristics, retention time of lead in the gastrointestinal tract (Schulz et al., 2006), diet and gender. Of note, biochemical changes in female birds associated with active laying can enhance the intestinal absorption of lead and accumulation of lead in bones as reported by Taylor and Moore (1954 cited by USFWS, 1986). Once absorbed, lead enters into the bloodstream and is rapidly deposited in the liver, kidney, bone and in the growing feathers. The greatest lead concentrations are generally found in the bone, followed by kidney and liver. Lead is not metabolized in the organisms. The non-absorbed lead can be excreted by both bird genders or eliminated in the eggs by female birds, with potentially harmful effects in the developing embryos. It is however recognized that the continuous exposure to lead will promote its retention into the organism (Pain and Green, 2015). Several studies have been conducted on the bioaccumulation potential of lead in aquatic and terrestrial organisms. Based on an extensive overview of the literature, typical bioconcentration/bioaccumulation factors of 1 553 L/kg (wet weight) and 0.39 kg/kg (dry weight) have been estimated for the aquatic and soil compartments, respectively. Apart from this, adverse effects on living organisms from acute or chronic lead exposure can induce both lethal and sub-lethal effects. Ingestion of lead objects may be sufficient to induce adverse effects and even to cause mortality in small-sized ducks (Guillemain et al., 2007), doves (Schulz et al. 2006), waterfowls and vultures (Barrett and Karstad, 1971; Pattee et al., 1981; Franson et al., 1986; Beyer et al., 1998). On the other hand, typical sub-lethal effects include impaired immune function, reduced mobility, reduced migratory and reproductive capacity, altered behavior, increased predation risk and enhanced susceptibility to other life-threatening conditions (i.e hunting, trauma-flying accidents). RAC recognizes that the ecotoxicological effects associated to lead exposure and described by the Dossier Submitter can have profound impact on the bird population (Demendi and Petrie, 2006, Meyer et al. 2016, Newton et al., 2016, Ecke et al., 2017, Pain et al.,2019, Monclus et al., 2020), representing also a relevant hazard to other living organisms.

The blood levels of lead are a good indicator of recent exposure and usually remain elevated for several weeks to several months after ingestion. A study from Buekers et al (2008) has analyzed the relationship between the plasmatic levels of lead and its toxicity in mammals and birds, extrapolating an HC5 value of 18 µg/dL and 71 µg/dL, respectively. Other studies indicate that the lead concentration in the blood and other organs of waterbirds can be used as indicators of environmental exposure and relates to the occurrence of clinical signs and the extent of lead poisoning. For instance, the background blood concentration in wild birds is <20 ug lead/dL, sub-clinical effects appear at concentrations in the range of 20-50, clinical poisoning at 50-100, and severe clinical poisoning (e.g., mortality) when the concentration exceeds 100 ug lead/dL blood wet weight. In most of the cases, with the exception of the bone tissue, severe clinical poisoning was associated with lead concentrations around 5 times greater than those observed in the unexposed birds, but there are differences in sensitivity between bird species. However, it is important to note that these threshold levels cannot be considered as equivalent to the PNEC values derived according to the regulatory hazard assessment.

Other taxa

According to the Dossier Submitter, there is limited information on lead poisoning upon primary or secondary ingestion of lead ammunition and fishing tackle in mammalian species. It has been proposed that predatory and scavenging mammals such as bears, foxes, raccoon dogs, mustelids and wild boar can potentially ingest meat, gut piles and game contaminated with lead (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.

The Dossier Submitter presented an analysis of the limited information available on ruminants. Some reports indicate that lead poisoning can have detrimental effects in cattle (Wijbenga et al.,1992; Scheuhammer and Norris, 1995). A recent review on lead poisoning in cattle from different sources suggests that animals dying of acute poisoning exhibit severe alterations in the liver, kidney, gastrointestinal tract and central nervous system, while subacute poisoning is rather characterized by nephrosis and laminar cortical necrosis of the cerebellum. By contrast, chronic lead poisoning mainly results in emaciation, muscle waste and serious abnormalities in foetus development (Payne et al., 2013). Other studies have investigated the effects of lead poisoning in livestock such as cows and calves. Grazing in areas with deposition of lead from shot or bullets or being fed with contaminated silage produced from fields located on shooting ranges are primary sources of hazard, while the direct ingestion of lead particulate as shot pellets might have a minor impact (Brown et al., 2005, Rice et al., 1987, Scheuhammer and Norris, 1995, Vermunt et al., 2002). Symptoms reported in calves consisted in a number of neurological disorders culminating in rapid death of the animals (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), presumably reflecting a difference in lead oral absorption, which is very low for sheep (around 1%) but highly efficient (around 50%) for calves (Wilkinson et al., 2003). In this respect, as reported by the Dossier Submitter, absorbed lead concentrations in ruminants are typically elevated in the liver and kidney but long-term exposure can promote lead storage in the bone (Rumbeiha et al., 2001). In terms of adsorption, the main toxicological hazard from lead poisoning due to ammunition residue derives from feeding and ingestion of contaminated feed such as corn stock. Lead shot can also contaminate broad-leafed vegetation, which is subsequently harvested and processed for silage, an event that promotes the conversion of metallic lead into more soluble and bioavailable lead salts (St. Clair and Zaslow, 1996, Swain, 2002). Also, while lead shots tend to deposit in the reticulum (forestomach) in an inert form without becoming bioavailable (Bischoff, 2021), the lead shot embedded in feed such as maize can bypass the rumen reticulum reaching the gastrointestinal tract. Here, the acidic conditions produced during the fermentation process can favour the production of lead salts, which are more readily absorbed and can induce toxicity. Since lead is able to cross the blood brain barrier, it is believed that the cerebellar haemorrhage and oedema associated with capillary damage play a key role in the pathogenesis of lead neurotoxicity (Bradbury and Deane, 1993). Taking into account additional toxicokinetic processes, the inorganic lead is not metabolised in ruminants and its elimination is very slow and quite inefficient, mainly through the faeces and secondarily through the urinary excretion (Fick et al., 1976, Pearl et al., 1983).

Some authors have provided a quantitative analysis of lead toxicity, reporting NOEC values for different mammalian species and extrapolating a HC_5 of 18 μg/dl based on the blood lead concentrations. However, these estimates have not been corroborated by subsequent studies, and thus caution should be taken in their interpretation. On the other hand, the REACH Registration Dossier estimates the No Effect Concentration for secondary poisoning in mammals at 10.9 mg/Kg food ($PNEC_{oral}$). In conclusion, RAC supports the view that lead poses a serious hazard to mammals, taking also into account that the lead-induced toxic effects in humans (neurotoxicity, hematologic disorders, etc.) most likely will also affect mammalian species exposed to environmentally relevant lead concentrations.

4.2 Environmental exposure

4.2.1 Releases to the environment

The Dosser Submitter analysed the releases of lead to the environment for different sectors (i.e., about 14 000 tonnes in hunting, about 6 000 tonnes in fishing and about 25 000 tonnes in sports shooting).

Each lead shotgun cartridge may contain several hundred pellets (depending on shot size) that are dispersed into the environment during hunting or sports shooting. Only a small proportion of the pellets (e.g., in the order of 1 % or fewer) are likely to hit the intended target (Cromie et al., 2010). The remainder is dispersed in the environment. Environmental persistence of shot (and bullet fragments) can be quite protracted, ranging from decades to hundreds of years (Jørgensen and Willems, 1987). Lead ammunition can contaminate the range soil as the result of projectiles fragmentation and leaching due to process weathering (as rainfall, freezing, wind, etc.).

Concerning the fishing sector, the main sources of lead release is unintentional loss of lead fishing tackle, sinkers and lures, spillage of small lead sinkers on the bank or shore, and lack of appropriate waste management.

Lead from ammunition (hunting)

The Dossier Submitter estimates that total amount of lead gunshot used by hunters in the EU-27 per year after the implementation of the wetland restriction is in the order of 14 000 tonnes per year. The estimate for lead bullets is 134 tonnes per year.

Lead from ammunition (sports shooting)

The Dosser Submitter estimates that 24 500 tonnes of lead gunshot and about 420 tonnes of lead bullets[1] are released annually based on the information of total number and type of shooting ranges gathered from national authorities within the European Economic Area and information provided in the consultation by relevant stakeholders (Member State (MS) Survey, 2020; FITASC and other sources). There are thousands of active outdoor shooting ranges in the EU/ European Economic Area (EEA) that can vary in size and type, some may also be intended to host international sports competitions, others are used for recreational activities by members of private clubs (with basic or no environmental risk management measures in place). Shooting ranges may be temporary or permanent areas and in some Member States may be located in areas used for agricultural purposes (MS Survey, 2020).

It is estimated that around 20 000 shooting ranges exist in the EU. However, this number should be considered with caution, since, some EU countries did not provide the information required and, according to the MS survey, some private clubs for recreational activities are not registered and several data relating to shooting ranges are available at the municipal level only. The Dossier Submitter used a cautious approach to avoid overestimating the number of existing ranges and has generally selected the lower bound of the number of ranges (between different sources).

Lead from fishing tackle

The Dossier Submitter estimates that the total quantity of lead released from fishing tackle is 6 000 tonnes/year: 3 000 tonnes/year from fishing sinkers and lures plus 3 000 tonnes/year from nets, ropes and lines. Except in some specific fishing practices, the lead fishing tackle is not intentionally released to the environment during use. The main sources of release identified for fishing sinkers and lures are unintentional loss of lead fishing tackle, spillage of small lead sinkers on the bank or shore, and lack of appropriate waste management.

With regard to nets, ropes and lines, a study commissioned by the EU Commission (Deloitte, 2018) identified the following main sources of release to the environment: accidental loss, intentional dumping, no appropriate formal waste management (e.g., landfilling, difficult to recycle or separate from the plastic).

Release estimates are based on literature data. For fishing sinkers and lures, the estimates are based on estimated numbers of fishers and estimated annual loss per fisher. The loss estimates for lead in nets, ropes and line were made by combining information from the

[1] For sports shooting with bullets, the calculations for the releases to the environment reported by the Dossier Submitter take into account the existing risk management measures.

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).

4.2.2 Primary and secondary poisoning of wildlife (birds)

Direct exposure (primary ingestion)

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 which are ingested to aid digestion. Evidence of exposure is often reported in terms of 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 and the frequency of ingestion, 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). Lead exposure has also been shown to be higher during the hunting season than during the non-hunting season (Monclus et al., 2020), and dependent on hunting pressure (Helander et al., 2021).

While many species of waterbirds (as ducks and geese) 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, they may still be exposed to non-regulated uses of lead, such as lead shot in terrestrial habitats and lead fishing tackle in wetlands. Species such as geese and swans are at greater risk of exposure to lead because they frequently feed in both wet and dry (terrestrial) fields. Many species of piscivorous birds, as well as species that feed in soils and sediments near the coast, are at risk of lead poisoning due to the consumption of lost or discarded lead sinkers (Scheuhammer et al 2003).

In commercial fishing, lead is encased / embedded / threaded into nets, ropes and lines (Danish EPA, CfE # 1220) and lead from this type of fishing tackle is typically not ingested by birds (UK EPA, CfE # 936). RAC supports that ingestion of this type of fishing tackle is not likely, and there is no data to indicate the opposite.

Indirect exposure (secondary ingestion)

In general, the predatory and scavenging 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). Studies on a variety of species/populations of live wildfowl have shown that >20 % of individuals (across 22 species) carry gunshot in their flesh (Pain et al., 2015). The percentage of waterfowl with embedded shot differ between species, areas with different hunting pressures and the age of birds (Mateo, 2009). It is expected that the percentages will decrease with the introduction of the new restriction on hunting in wetlands.

Isotope ratio analysis can identify ammunition as the source of lead but cannot differentiate between shot and bullets. Monclus et al., 2020 acknowledge other sources of exposure, such as lead-based gasoline, mining activities and industry but note the importance on leaded ammunition as a main source affecting birds.

Monclús et al. (2020) reviewed the impact of lead on raptors and the likely main source of exposure in 114 studies. The meta-analysis determined if there was evidence for differences in exposure across feeding traits, geographical regions, between hunting and non-hunting periods, and changes over time. The study concluded that obligate scavengers (vultures) and 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.

The ad hoc expert group (UNEP/CMS) provided specific information on the likelihood of ingestion by European bird species of lead ammunition in terrestrial environments and lead fishing weights. They identified 29 species of scavengers and raptors in the highest risk level of secondary lead poisoning by showing high concentration of lead in their tissues. They also provided classifications for birds at low/high risk of secondary poisoning.

4.2.3 Primary and secondary poisoning of other taxa

Livestock (ruminants)

Several studies 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).

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 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).

Rice et al. (1987) reported that in 14 steers fed with 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. A mean blood lead concentration of 2300 µg/L was reported. 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.

Bischoff et al. (2012) reported median blood lead concentrations in cattle of 290 µg/L and Payne et al. (2013) reported mean concentrations of 1620 µg/L, in both cases caused by lead gun shot.

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).

Vermunt et al. (2002) reported lead poisoning in some dairy cows having consumed lead shot contaminated maize silage. Large numbers of shot gun pellets were found mixed in with the silage.

The study by Bischoff et al., 2014, highlights a clear Pb concentration in the milk (range 0.06-0.47 mg/L) produced by dairy cows having consumed lead shot contaminated maize silage (mean lead exposure 649 mg/kg bw/day). The blood lead levels in the cows ranged between 882-1220 μg/L. Based on this study, the Dossier Submitter considers that there is a potential exposure of humans through the consumption of milk.

Other species at risk for lead exposure include poultry (Payne et al., 2013) and hunting dogs (Knutsen et al., 2019).

4.3 Characterisation of risks

The (main) risks identified by the Dossier Submitter with regards to uses are summarised in the Table 2 and discussed in the following sections.

Table 2: Identified environmental risks with regards to uses (BD Table 1-26)

Use #	Use name	Identified risk
1	Hunting with gunshot	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 gunshot	Primary poisoning of wildlife (birds) 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 Primary poisoning (ingestion of lead gunshot) by poultry when feeding on land previously/also used for shooting or nearby a shooting range where lead may fall outside the range perimeter. Soil, groundwater and surface water contamination
4	Outdoor sports shooting with bullets	Ingestion of contaminated soil (mainly in backstop berm area) and vegetation by livestock (ruminants) on shooting ranges/ areas used as agricultural land Soil, groundwater and surface water contamination
5	Outdoor shooting using airguns	Same as use 4 with additional potential for primary poisoning of wildlife (birds) if pellets are not contained
6	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments	Same as use 4
7	Lead in fishing 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 nets, ropes and lines	No risk to birds or other taxa identified.

The environmental risk characterisation proposed by the Dossier Submitter is based on a weight of evidence approach underpinned by a number of key case studies focused on:

- primary and secondary poisoning or mortality of birds after lead projectile or sinker/lure ingestion for the relevant uses (uses 1,2,3,7)

- lead concentration in bird tissues after ingestion of lead objects (including comparison with threshold value for specific adverse effects)
- lead concentrations in the soils of shooting ranges
- poisoning of domestic animals (livestock) grazing on shooting ranges.

Risks to soil, surface water and groundwater are assessed in the work package report WP A.2. The risks to humans via the environment (game) are assessed in work package WP A.5.

4.3.1 Primary and secondary poisoning of wildlife (birds)

The Dossier Submitter estimates that, in the EU, at least 135 million birds are at risk of primary poisoning of lead gunshot, 14 million because of secondary poisoning arising from the ingestion of lead gunshot or other lead projectiles, and seven million because of ingestion of fishing sinkers and lures, representing 92 species in total including 54 red-listed 'threatened' species. RAC supports these estimates and recognizes that limited information exists for wildlife mammals.

Both primary and secondary poisonings of birds from lead are well documented. Therefore, RAC supports that there is robust evidence that the use of lead ammunition and fishing tackle remains widespread in Europe and the exposure of different bird species can induce adverse effects as well as mortality and potentially affect the survival of endangered species.

For the risk characterisation, the Dossier Submitter assumes that a quantitative comparison of PEC/PNEC values is unnecessary since the adverse effects from the ingestion of lead ammunition and fishing tackle have been widely documented. Based on this consideration, which is also supported by agreements (Raptor MoU74), wildlife conservation projects and recommendations under UNEP AEWA auspices (UNEP-AEWA 2011) worldwide, the risk characterisation for birds (primary and secondary poisoning) takes into account the following information:

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

Regarding primary poisoning, the Dossier Submitter describes a number of studies mainly related to the ingestion of lead shots by grey partridges (*Perdix perdix*) and fishing tackles by mute swans (*Cygnus olor*). In the first case, the mortality ranged between 4.5% (Potts, 2005) and 10% in grey partridges (Meyer et al., 2016) while the estimates for mute swans between 1971 and 1981 indicated a mortality of about 34%, which declined to 6% between 1987 and 2014 after legislation in England and Wales banned the sale and use of lead fishing weights (Grade et al., 2019).

The Dossier Submitter also describes the impact of secondary poisoning derived from the ingestion of lead shot in predatory or scavengers birds species such as griffon vultures (*Gyps fulvus*) or Eurasian buzzards (*Buteo buteo*). In the former case, a detailed report confirmed lead poisoning in 3 female griffon vultures due to very high lead content in the blood, liver and kidney, ultimately causing mortality (Carneiro et al.,2016). Also, lead levels related to acute exposure were found in the liver of 2.7% of Eurasian buzzards and concentrations in the femur consistent with exposure to lethal doses, were seen in 4.0% of buzzards (Taggart et al., 2020). Another evidence of secondary poisoning from the ingestion of lead ammunition was reported by a recent study that analyzed the cause of death of 170 scavenger birds, including different vulture species (i.e. bearded vultures, griffon vultures, Egyptian vultures) and red kite (*Milvus milvus*). The results showed that lead poisoning was the primary cause of death in 4.1% of all the cases but the study revealed also a significant association between lead concentration and the occurrence of traumatic events (i.e. collisions or falls) as well as electrocution, indicating that lead can also contribute to a variety of death causes (Berny et al.,2015).

The recent study by Burns et al (2021) tries to estimate how the bird population in the EU has changed over the last 40 years, and found a 17-19% decline. The decline was biggest for species associated with agricultural land, but there were no efforts to specifically study the effects of lead.

Comparison of lead concentration in tissues with indicative thresholds

A study conducted on red-legged partridges (*Alectoris rufa*) with ingested shots revealed that the mean lead levels in the liver (21.51 µg/g d.w.) were greater than those regarded as a threshold for subclinical poisoning (Ferrandis et al. 2008). Similarly, Butler et al. (2005) found that the median concentration in the bone (48.8 ppm d.w.) of ring-necked pheasants (*Phasianus colchicus*) exposed to lead on shooting estates in Great Britain due to the ingestion of shot and other sources, was greater than the indicative threshold for severe clinical poisoning. Accordingly, concentrations of lead in the blood and liver corresponding to the threshold of severe clinical poisoning have been reported in griffon vultures (*Gyps fulvus*) after secondary poisoning caused by lead shot ingestion (Carneiro et al., 2016). Lastly, Franson et al. (2003) examined a vast number of waterbirds from different species with ingested fishing tackle to reveal that in 64% and 71% of the cases, respectively, the liver and blood concentrations of lead were greater than the indicative threshold for background level, with maximum levels indicating severe clinical poisoning.

Based on these data, RAC supports the conclusion that lead from ammunition and fishing tackle poses a significant risk to a number of bird species.

Mortality in the EU

The ingestion of lead objects (lead shot, ammunition fragments and fishing tackles) can cause mortality in birds and in this regard some data indicate that even the ingestion of a single lead gunshot may be lethal to a small-sized duck (Guillemain et al., 2007), or a dove (Schulz et al. 2006). Evidence from mallard ducks (*Anas platyrhynchos*) showed that mortality dose-dependently increased in ducks ingesting commercial lead shot, ranging from 35% (single shot ingestion) to 80-100% with higher amounts (Finley and Dieter, 1978). Consistently, Brewer et al., (2003) reported a mortality of 90% for birds dosed with 0.2 g of lead shot. Similar conclusions apply to the effects of lead fishing tackle ingestion as well, as evidenced by Twiss and Thomas (1998). However, RAC notes that the available datasets do not allow to make robust conclusions on mortality of terrestrial birds in the EU from the ingestion of lead shots and bullets. Despite this limitation, some authors have tried to estimate the mortality of selected bird species. For instance, a recent study applied the Bellrose methodology to identify the percentage of pheasant and red-legged partridge dying from lead ingestion in UK, revealing values of 0.56% and 0.32%, respectively (Pain et al., 2019). RAC, however, notes that these numbers and the overall impact on birds ecology might be underestimated since neither juveniles nor long term effects of lead poisoning were taken into account. Additional studies investigating the mortality caused by primary ingestion of lead shot in grey partridges (*Perdix perdix*) suggest values ranging from 0.3% to 4%. RAC supports the Dossier Submitter's estimates that the mortality for terrestrial birds ranges between 0.5% and 2%, taking also into account a number of uncertainties related to different species. RAC also deems reasonable the Dossier Submitter's assumption to use the central value of this range (1%) for the impact assessment of lead shot ingestion (primary poisoning) in bird species. As already mentioned, compelling evidence indicate that secondary poisoning can affect predators and scavenger birds that consume contaminated preys or carcasses (Pain et al., 2019). However, a number of limitations and uncertainties currently preclude the possibility of making robust estimates of bird mortality in the EU due to secondary ingestion of lead ammunition. Nevertheless, it is agreed that this mechanism represents a relevant cause of death in predatory and scavenging birds (Monclus et al., 2020) and might have a significant impact in predators or scavenging species with a critical conservation status. Similar considerations and uncertainties also apply to the estimate of bird mortality due to secondary poisoning caused by the ingestion of lead fishing tackle given the absence of adequate data sets in the EU. RAC however agrees with the Dossier Submitter that the extent of mortality in waterbirds and terrestrial birds is expected to be quite high in areas with intensive fishing activity (UNEP-AEWA, 2011) and have an additive effect when summed to the mortality caused by the ingestion of lead shot.

***Taken together, RAC supports that there is evidence that primary and secondary poisoning caused by lead ingestion represents an important source of risk for waterbirds and terrestrial birds leading to enhanced mortality and potentially affecting the survival of endangered species*.**

Information on lead as a co-factor in other causes of mortality

The Dossier Submitter concludes the risk characterisation by providing information on lead ingestion (from ammunition and fishing tackle) as an indirect cause of bird mortality. In this regard, sublethal amounts of lead have been shown to increase the likelihood of mortality from hunting (Pain et al. 2015) and natural predators (Meyer et al., 2016,) as well as the susceptibility to various diseases or flying accidents (Newton et al., 2016, Pain et al., 2019).

RAC supports this analyses and notes that the list of bird species at most risk is quite comprehensive, representing 92 species including 54 red-listed 'threatened' species, but does not exclude that other species currently considered at low risk of lead poisoning might also be adversely affected (the species are listed in tables B.9-24 to-B.9-26 of the Annex to the background document).

4.4 Risks related to sports shooting

Regarding the risks to livestock (grazing ruminants), the Dossier Submitter reports a number of studies demonstrating the occurrence of lead poisoning in cattle either via ingestion of contaminated soil and grass due to grazing on shooting ranges or being fed with silage contaminated with lead gunshot from shooting ranges (Braun et al., 1997, Macnicol, 2014, Muntwyler, 2010, Rice et al., 1987, Scheuhammer and Norris, 1995, Vermunt et al., 2002).

As specified by the European Commission Directive 2002/32/EC[2], 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.

On the other hand, Regulation 1275/2013[3], 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 for forage (maximum relative to a feed with a moisture content of 12 %). Taking into account that the lead concentrations reported in material harvested on shooting ranges can exceed these values by two orders of magnitude, RAC agrees that the use of this material as forage represents a relevant source of risk for the livestock.

In addition, according to the Swiss expert system for risk assessment of contaminated soils (Swiss BUWAL, 2005), cows could be endangered when grazing on contaminated soil that exceeds 1000 mg lead/kg (dry matter). Based on this, grazing on shooting ranges may constitute a relevant risk, considering the average lead concentration in soil at shooting ranges.

Overall RAC concludes that grazing on shooting ranges, or use of material harvested on shooting ranges for silage, may cause significant exposure to livestock, and notes in particular the limit of 30 mg lead/kg for lead in forage, and that any forage produced from material harvested on a shooting range is likely to breach the limit regularly and constitute a risk for the livestock.

5. Uncertainties

There are many uncertainties in the estimate of the number of shooting ranges and in the amount of lead released every year. There are various, not always consistent, estimates of the amount of lead used in sports shooting.

Risk of lead fishing tackle for the wildlife is not underpinned by extensive exposure data. The scientific documentation on the extent of lead fishing tackle ingestion by birds is in general very poor. It is difficult to identify small lead objects ingested by birds, and to distinguish a lead shot from a lead sinker after it has been eroded in the gizzard of birds.

There are uncertainties in the estimates of bird mortality in the EU due to secondary ingestion of lead ammunition. Uncertainties also concern the estimate of bird mortality due to secondary poisoning caused by the ingestion of lead fishing tackle given the absence of adequate data sets in the EU. Another uncertainty concerns the occurrence of sub-lethal effects of lead in birds, which are likely to be rather common but cannot be quantified.

Hunting statistics are incomplete and very uneven in EU Member States. It is likely that scavenging mammals are exposed to lead through offal or discarded meat left in the

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

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

environment. However, there is only a few such documented cases and RAC agrees with the Dossier Submitter that this cannot be elaborated any further.

6. Conclusions

- The hazardous properties of lead are well-known and have been assessed in many previous opinions from the RAC, the latest being the opinion on an Annex XV dossier proposing restrictions on lead in gunshot in wetlands (ECHA, 2018).
- There is robust evidence for lead toxicity to birds through direct and indirect exposure/mechanisms.
- The toxicity of lead to predatory or scavenging wildlife mammalian species has not been studied, but the toxicity to other mammalian species is well-known. EFSA (2013) concluded that there is no threshold for the neurodevelopmental toxicity in humans, and many toxicological effects appear in other mammalian species.
- There is robust evidence for lead being very toxic to domestic animals (livestock).
- The Dossier Submitter estimates of lead releases to the environment from hunting, fishing and sporting activities are plausible and in the order of 44 000 tonnes per year to in EU. The possibilities for wildlife to be exposed to lead therefore is widespread.
- Direct exposure of birds is well documented both in aquatic and terrestrial environments.
- Indirect exposure of predatory or scavenging birds from ammunition and increased mortality in these species is well documented. Sub-lethal effects may also affect the predatory birds. There is a correlation between lead blood levels and behaviour (e.g., flight height and movement rate).
- Poisoning of waterbirds from lead used in fishing can occur but it is not well studied so the magnitude of this problem is difficult to assess.
- It is likely that scavenging mammals are exposed to lead through offal or discarded meat left in the environment. However, there is only a few such documented cases and the Dossier Submitter does not provide any further elaborations.
- Grazing on shooting ranges, or use of silage produced at shooting ranges, may cause significant exposure to livestock, and RAC notes in particular the limit of 30 mg lead/kg in forage that is likely to be breached regularly. Grazing/forage constitutes a risk for livestock if shooting ranges are used for agricultural purposes.
- RAC concludes that indirect exposure to lead of predatory or scavenging bird species is a major concern, especially as it affects many bird species that are being threatened.
- The Dossier Submitter provided a list of 92 birds species that might be considered to be at most risk of lead poisoning from shooting and fishing, e.g., based on typical feeding patterns, and it cannot be excluded that other species currently considered at low risk of lead poisoning might also be adversely affected if exposed.

7. References

Additional references not included in the Background Document to the opinion on the Annex XV dossier proposing restrictions on lead in outdoor shooting and fishing:

Burns F. et al. 2021. Abundance decline in the avifauna of the European Union reveals cross-continental similarities in biodiversity change. *Ecology and Evolution*. 2021;11:16647–16660.

Committee for Risk Assessment (RAC)

Ad-hoc RAC Supporting Group

Evaluation of an

Annex XV dossier proposing a restriction on

Lead and its compounds

in outdoor shooting and fishing

Work Package report WP A.2

Additional environmental risks related to sports shooting ranges (soil/surface and groundwater)

3 June 2022

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1. Description of the Work Package

1.1. Background

This Work Package WP A.2 is tasked to evaluate the Dossier Submitter's assessment that the use of lead in gunshot, bullets, and other projectiles poses a risk to the environment and human health via the intake of food and drinking water contaminated from shooting activities. In the absence of adequate data, the Dossier Submitter describes the risks to human health and the environment in a qualitative manner.

The key topics set for this work package evaluation are:

- Risks to soil
- Risks to surface and groundwater (including drinking water sources)

This WP A.2 evaluation relates to the use of lead ammunition in sports shooting.

The use of lead ammunition remains widespread in Europe despite its well documented hazard properties and adverse effects on both wildlife and human health. Approximately 39 000 tonnes of lead from projectiles (gunshot and bullets) are dispersed in the environment every year, 64% from sports shooting.

The Dossier Submitter has identified risks to the environmental compartments and indirectly the human health receptor from exposure to lead gunshot and lead contamination at shooting ranges. These risks arise predominantly from lead contamination of the soils of shooting ranges and associated risks to surface water and groundwater. Additionally, livestock and humans may be at risk from ingestion of lead via intake of contaminated food and drinking water.

In this work package WP A.2, RAC is evaluating the risks to the soil, surface and groundwater compartments resulting from the use of lead ammunition. The risks related to ingestion of lead by livestock and to humans via intake of food and drinking water contaminated with lead are described in the work package reports WP A.1 and WP A.5 respectively.

1.2. Objectives

The following topics are covered in the present work package:

1. Are the Dossier Submitter's identified risks to the environmental compartments of such significance at shooting ranges that they require Union-wide measures to curb lead emissions?
2. Is lead contamination of groundwater a significant issue at/under/adjacent to any shooting ranges/areas in the EU, and is there evidence to support the Dossier Submitter's conclusion that lead from ammunition is mobile in soils and drives lead contamination into groundwater and hence pollutes drinking water aquifers?

2. Summary of the Dossier Submitter proposal

The Annex XV restriction report states that metallic lead is released into the environment at shooting ranges via the following exposure pathways:

- 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 groundwater (vertical migration).

However, the Dossier Submitter considers lead mobility may significantly differ among sites, based on site-specific conditions (pH, clay content, cation exchange). Lead contamination from shooting can occur during both service life and at the end of life (i.e., older/closed shooting ranges), and is expected to occur both on site and off site.

At a conceptual level, the Dossier Submitter [Background document, section 1.5.3.7.] considers environmental risks both during and after the service life of a shooting range/lands are:

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

Additionally, the Dossier Submitter rates (Background document, section 1.5.4.4) the potential impact of various shooting activities on soils and surface/groundwater by scale and intensity of shooting (deposition rates of lead onto surface), where shooting occurs under different scenarios, without RMMs (a and b) and with RMMs (c and d):

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

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);

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, 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.

d) Permanent outdoor shooting ranges with the following RMMs implemented (in addition to the RMMs listed in the above scenario [c]):

- 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, and/or soil coverage);

- Monitoring and treatment of surface (runoff) water;

- Ban of any agricultural use within site boundaries.

Ultimately, the Dossier Submitter combines conceptualisation of the risks from shooting and the different types/intensity of shooting ranges to enable a qualitative risk assessment for soil, groundwater, and surface water (Background document, Table 1-31).

According to the WCA report (2021)[4] (Appendix 1 to the Background Document), the contamination of groundwater from lead shot beneath shooting ranges is site specific and can occur where overlying soils are shallow (less than 3m), and where soil pH is less than pH 6 (high risk scenario). The WCA report (2021) proposes to quantify the number of sites classifying as high risk by setting out the four hydrogeological scenarios (see below) where this is a likelihood, and specifying the areas using GIS (Geographical Information System). The four scenarios where lead can be a high risk to groundwater are:

1. Acidic soil (pH <6) with relatively high organic matter content and low iron, manganese and phosphate content;

2. Coarse (usually sandy) soils that allow vertical migration of dissolved or fine particulate lead;

3. Preferential flow pathways, including macropore flow down soil cracks, plant root channels and animal burrows; and,

4. Shallow depth to groundwater (< 3m).

Hence, according to WCA's findings, hydrogeological conditions control the potential for transport of lead through the vadose zone and into groundwaters.

A new WCA report (2022)[5] (Appendix 4 to the Background Document) concludes that the presence of iron will not increase, but perhaps rather decrease, the mobility of lead in soil.

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[4] WCA (2021). Contract/Project Number P0979 to ECHA. WCA Environment Ltd UK. *Assessment of the potential for the use of lead ammunition at shooting ranges to contaminate groundwater and drinking water.* Final Report to ECHA from WCA UK. August 2021 (Appendix 1 to the Background Document).

[5] WCA (2022). Contract/Project Number P0979 to ECHA. WCA Environment Ltd UK. *REACH restriction support – Lead in fishing tackle and ammunition (part 7).* March 2022. (Appendix 4 to the Background Document).

3. Relevant information from the consultation of the Annex XV restriction report

The comments received under the scope of this work package relate to the environmental risks resulting from the deposition of lead on sports shooting areas and the measures in place to avoid/ minimise lead mobility and migration.

Comment #3192, specifies that in Poland all outdoor shooting ranges where projectiles containing lead can be used, must have at least 80 % of lead periodically removed from the soil and soil acidity must be monitored and kept within pH range 6.5-8.5. This good practice agrees with the WCA report (2021) conclusion that specific groundwater vulnerability for lead arising from shooting activities will be high where there is a combination of high lead emission rate, driven by usage on acidic soils with moderately high organic carbon, in zones with high intrinsic groundwater vulnerability (*i.e.* shallow soils).

Comment #3240, specifies that in Finland the goal at the range area is to determine how the operations cause an environmental load (e.g., have pollutants migrated into surface waters, or on what timescale is it possible for the pollutants to migrate into the groundwater), and what impact this will have on the environment (e.g. impact on the aquatic ecosystem or changes to groundwater quality).

Comment #3483, also from Finland considers Finland is a wet country with acidic soils which increases mobility of lead in soils and via surface water.

The WCA report (2021) is in agreement with these two comments (#3240, #3483) and indicates the science behind lead migration in wet climates. Lead pollutants migrating into surface waters are facilitated by elevated rainfall (where precipitation is much greater than evapotranspiration), and hydrogeological conditions will control the potential for transport of lead through the vadose zone (soils above the water table) and into groundwaters in the following way:

- The key soil properties that may prompt lead movement from the soil surface to underlying layers are low pH (<6), coarse textured and freely draining soils with relatively high levels of dissolved organic carbon and low iron and manganese content.
- Transport directly to the groundwater body (aquifer) where there is a presence of shallow groundwater (< 3m).

Several stakeholder comments relate to the contention that the use of steel gunshot on shooting ranges, as an alternative to lead, will mobilise lead and other metals in soils at shooting ranges, and refer to recent open-source evidence produced by Lisin et al. (2022).

The WCA report (2022) counters this view showing that field-based evidence does not support the claims in Lisin et al. regarding acceleration of lead migration or iron, impacts upon surface and ground waters. The weathering of soils and the binding of lead species to arising organic matter or iron hydroxide precipitates (from steel shot) reduces the potential for lead to be mobilised or cause toxicity. In fact where iron hydroxide precipitates are present, they are a more important binding phase for lead species than organic matter. This is further discussed in the work package report WP B.2.

Further comments from the public consultation which are relevant for this work-package WP A.2 are listed under Attachment A.

4. Evaluation

Risks to soil

The Dossier Submitter determines that a typical shooting range can be divided into different segments based on the pollutant load, with a maximum distance of 300m affected, from the point of gun discharge. Terrain contours and trees have a significant effect on the spread of the shot, as do wind conditions.

The Dossier Submitter describes 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. 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. Lack of wind breaks (such as trees, which can reduce windy conditions), lack of ground cover such as grasses and other vegetation will influence the likelihood that dust could become airborne and travel at distance.

The Dossier Submitter cites Lepke et al. (2006) who proposed a simplified segmentation for a typical (300 m) shooting range, to determine expected soil lead concentrations:

- 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 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.

Lead contamination of shooting ranges at 200 – 300 g of lead per square meter has been found at a site which had been in operation for 14 years (Adsersen et al., 1983).

EU Directive 2002/32/EC100, sets lead concentrations in harvested material (forage) should be below 30 mg/kg. As per the literature described by the Dossier Submitter, lead concentrations in material harvested on shooting ranges can have lead concentrations far in excess of 30 mg/kg, constituting therefore a risk and should not be used as animal forage.

Overall RAC concludes lead contamination of shooting ranges at 200 – 300 g of lead per square meter can be found, and constitutes a risk to on and off-site terrestrial receptors as applicable.

Risks to surface water

The Dossier Submitter states that surface water contamination is assumed for lead, from lead ammunition (gunshot and bullets) being deposited on or in the soil and subsequent corrosion and dissolution of the lead. The Dossier Submitter states risk level is assumed to increase with increasing amount of deposition. The more rainfall, the more likely it is that surface water will spread contaminants.

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, but these criteria are specific to only some geographic areas. Vegetation slows down surface water runoff, preventing the lead from migrating off-site. 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. For surface water with lower water velocities (e.g. lakes), lead particles and artefacts will become buried in bottom sediments, where they would move into the anoxic sediment layer and may be strongly adsorbed onto sediment and soil particles, and show reduced mobility, without mechanical disturbance.

Studies at shooting ranges cited by the Dossier Submitter illustrate the range of concentrations occurring downgradient. In the surface water of two shooting ranges in Florida (Ma et al., 2002), 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. According to investigations in Finnish shooting ranges (Kajander and Parri, 2014), the Dossier Submitter shows lead and 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%).

After the end of life of a range without remediation, it is unlikely that maintenance will be made to control runoff, with increased risks for nearby surface water and other receptors. The Dosser Submitter determines RMMs applied during service life may need to be continued at the end of service life unless remediation is performed.

Overall RAC concludes surface water migrating from shooting ranges without RMMs, may constitute a risk of contamination at all receiving surface waters, and their off-site animal/bird/fish/drinking water receptors, as applicable. Monitoring and treatment of surface water will be important to control this risk.

Risks posed to groundwater

RAC has reviewed and evaluated the WCA reports (2021, 2022) and agreed with the WCA analysis of the risks posed by lead ammunition to an EU wide soil, surface water, and groundwater receptor (environment), and indirectly to human health receptors (use of groundwater as drinking water).

RAC supports that hydrogeological conditions typically control the potential for transport of lead through the vadose zone and into groundwaters. RAC noted that detailed GIS analysis would be required to estimate the number and location of the high risk areas characterised by the report, highlighting that this would be a complex task.

RAC agreed that the risk of groundwater contamination may vary from very low to high depending on the specific characteristics of the site. The combination of acidic soils, coarse soils, preferential flow pathways or macropores and shallow depths to groundwater (<3m) lead to high vulnerability to lead contamination. However, RAC noted it is difficult to estimate the prevalence and extent of groundwater vulnerability to lead contamination at shooting ranges at European, national or even regional scale. Local factors will always influence potential risks more than generic considerations, but some areas with high intrinsic vulnerability are likely to occur in all EU Member States, although to differing extents.

Overall, RAC concludes the risk of groundwater contamination may vary from very low to high depending on the soil characteristics.

RAC Qualitative Risk Assessment

RAC considers the conceptualisation of risks determined by the Dossier Submitter to the environmental compartments (and drinking water) from the use of lead in gunshot, bullets, and other projectiles should follow the approach specified in EC (2010) - Guidance Document No. 26. A conceptual model implemented with this guidance enables the risks of lead from gunshot hazards to be assessed, caused by diffuse (lead powder/dust dispersion/dilution/infiltration) and point source pollution (lead fragments/shot/dust as deposition/inhalation/ingestion), and at different scales, ranging from site scale (local) up to the scale of a groundwater body (regional or national scale).

RAC used the EC (2010) conceptual model approach to scrutinise the Dossier Submitter's qualitative evaluation of risks and applied the model to all environmental and human health risks resulting from the use of lead in ammunition and fishing tackle. This RAC full written analysis is detailed under Annex 1: RAC Qualitative Risk Assessment Approach, and is not repeated here.

5. Uncertainties

The number and the location of shooting ranges where there is a high risk for ground water contamination are not known and thus constitutes an uncertainty.

6. Conclusions

RAC agrees with the Dossier Submitter that it is not possible or feasible to perform a quantitative risk assessment for all risks identified. RAC has applied a conceptual model to scrutinise the Dossier Submitter's qualitative evaluation of risks to soil and groundwater related to the use of lead ammunition at sports shooting. Based on this, the following conclusions are made.

The risk of groundwater contamination at sports shooting ranges may vary from **very low** to **high** depending on the soil characteristics and hydrogeological conditions which typically control the potential for transport of lead through the vadose zone and into groundwaters. Four key factors can lead to **high** risks to groundwater, which influence the risk of mobilisation of lead and its migration through the vadose zone, and to groundwater as:

1. Acidic soil (pH <6) with relatively high organic matter content and low iron, manganese and phosphate content;

2. Coarse (usually sandy) soils that allow vertical migration of dissolved or fine

particulate lead;

3. Preferential flow pathways, including macropore flow down soil cracks, plant root channels and animal burrows; and,

4. Shallow depth to groundwater (< 3m).

Although the number of shooting ranges where these four conditions occur are probably limited to a small fraction of total sites in Europe, this fraction may not be insignificant. Detailed GIS analysis would be required to estimate the number of these sites and hence determine the proportion of sites forming a high risk to groundwater.

Any surface water migrating from shooting ranges without RMMs, may constitute a risk of contamination at all receiving surface waters, and their off-site animal/bird/fish/drinking water receptors, as applicable. Monitoring and treatment of surface water will be important to control this risk.

Lead concentrations in soil and material harvested on shooting ranges can be high and constitute a risk to on and off-site terrestrial receptors.

7. References

Additional references not included in the Background Document to the opinion on the Annex XV dossier proposing restrictions on lead in outdoor shooting and fishing:

CIRIA C553 (2001). Contaminated land risk assessment. A guide to good practice. ISBN: 978-0-86017-552-0

Clausen JL, Bostick B, Korte N (2011). Migration of lead in surface water, pore water, and groundwater with a focus on firing ranges. Critical Reviews in Environmental Science and Technology. 41 (15), 1397-1448.

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ATTACHMENT A

Comments from the consultation on the Annex XV report relevant to Work Package WP A.2

Comment #3187 (Finland): Information on this topic is widely available and it is known that lead does not end up in groundwater supply from normal shooting range conditions (sand based backstops for projectiles). After reading into these, this whole endeavour seems completely political.

Comment #3192 (Poland): All outdoor shooting ranges where projectiles containing lead can be used, must have at least 80 % of lead periodically removed from the soil (frequency depends on the depth of the groundwater table) and soil acidity must be monitored and kept within pH range 6.5-8.5.

Comment #3198 (Germany): If no renovation takes place after a shutdown, the abandoned sites are monitored by means of a monitoring system. At regular intervals (3 to 8 years), soil and groundwater investigations and a risk assessment are carried out in accordance with the laws / ordinances applicable in Germany (Federal Soil and Contaminated Sites Act).

Comment #3228 (Belgium): "Agricultural activities' are a dominating main source of lead discharges to water in 1999/2000 for several countries of the OSPAR. This is due to the reported amounts of lead discharges from groundwater.

Comment #3240 (Finland): Sufficient protection level of the soil and groundwater, any structural protective solutions, and water management solutions for the range area must also be examined site-specifically. The goal is to determine how the operations cause an environmental load (e.g., have pollutants migrated into surface waters, or on what timescale is it possible for the pollutants to migrate into the groundwater), and what impact this will have on the environment (e.g. impact on the aquatic ecosystem or changes to groundwater quality). If there is reason to suspect that the soil or groundwater has been contaminated, the party responsible for the treatment shall establish the level of contamination of the area and the need for treatment. If the party responsible for the treatment fails to fulfill the obligation to establish the state of contamination, the state supervisory authority may order the party in question to fulfil this obligation. An assessment of the need for the treatment of contaminated soil and groundwater shall take into account the present and future use of the contaminated site, its surroundings and the groundwater, and any hazard or harm to the environment and health that would be caused by the contamination. The state supervisory authority shall order that treatment of contaminated soil or groundwater be undertaken if the party responsible for treatment does not take action. Any party whose operations have caused the contamination of soil or groundwater is required to treat the soil or groundwater (contaminated site) to a state where it does not pose a risk or cause harm to health or the environment.

Comment #3251 (Denmark): Activities at shooting ranges will often or always involve a risk of soil polution but rarely or never constitute a risk for polution of the groundwater.

Comment #3379 (Germany): If no remediation takes place, the abandoned locations are monitored by monitoring systems. At regular intervals (3 to 8 years), soil and groundwater investigations and a risk assessment are carried out in accordance with the applicable laws in Germany (Federal Soil and Contaminated Sites Act).

Comment #3426 (Finland): If there is reason to suspect that the soil or groundwater has been contaminated, the party responsible for the treatment shall establish the level of contamination of the area and the need for treatment. If the party responsible for the treatment fails to fulfill the obligation to establish the state of contamination, the state supervisory authority may order the party in question to fulfil this obligation. An assessment of the need for the treatment of contaminated soil and groundwater shall take into account the present and future use of the contaminated site, its surroundings and the groundwater, and any hazard or harm to the environment and health that would be caused by the contamination.

Comment #3483 (Finland): According to our study based on questionnaires and previous regional surveys, the total number of Finnish outdoor shooting ranges is between 2000 and 2500. Most of the ranges are small and only ca. 5% exceed 20 ha. Almost a third of the ranges can cause a groundwater pollution risk, while only few cause an immediate health risk. In the first instance, 50-60 shooting ranges identified as being high-risk areas should be investigated in detail. At present, the risk management options at Finnish shooting ranges are very limited. Hence, soil excavation combined with disposal is the most common remediation technique. Finland is a wet country with acidic soils which increases mobility of lead in soils and via surface water.

Committee for Risk Assessment (RAC)

Ad-hoc RAC Supporting Group

Evaluation of an

Annex XV dossier proposing a restriction on

Lead and its compounds

in outdoor shooting and fishing

Work Package report WP A.3

Human health risks due to shooting

3 June 2022

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1. Description of the Work Package

1.1. Background

Hunting or sports shooting with lead-containing ammunition may lead to the uptake of lead fumes and dust from the ammunition while shooting. The type of firearm, calibre and the facility where it is used influence the potential magnitude of exposure. In addition to the lead projectiles, lead in primers also have an impact on the total exposure to lead from lead ammunition. Exposure to lead during the shooting may result in the accumulation of lead in the body of sports shooters and hunters and in adverse health effects associated to the body lead burden.

This work package report presents the risks to human health resulting from the act of shooting. Other human health risks associated with hunting and sports shooting such as the risks resulting from the melting of lead by hunters to prepare ammunition (termed 'home-casting') as well as from the consumption of game meat containing fragments of lead gunshots or other lead projectiles or other food or drinking water containing lead are not part of this work package report.

1.2. Objectives

The main objective of this work package report is to describe and assess the lead exposure and risks of sport shooters and hunters due to inhalation and dermal contact when practising shooting.

2. Summary of the Dossier Submitter proposal

Inhalation exposure can result from lead fumes, aerosols and/or dusts from shooting during sports shooting or hunting. Oral exposure can result from intake of lead dust (hand-to-mouth) while shooting or handling lead gunshot or bullets when eating, drinking or smoking in an environment containing lead dust, or from chewing or swallowing lead fragments.

Analysis of lead in whole blood (PbB) is the most common and accurate method of assessing lead exposure. When evaluating PbB levels the following has to be noted:

- PbB levels provide information mostly on recent exposure; to assess cumulative exposure from previous years or decades, lead levels in bone would need to be measured. However, gradual release of accumulated lead from bone stores results in endogenous exposure and may keep PbB levels elevated for long periods after the cessation of the exposure.
- 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 lead background values (95th 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.

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. According to the Dossier Submitter, 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 in shooting and elevated PbB levels are:

- use of firearms (with lead-containing primer) compared to use of air guns;
- increasing calibre of the gun;
- 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 of the restriction proposal 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 proposal speaks about 'terrains', which is interpreted as referring to 'outdoor'. For shooters training outdoors 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 to the Dossier Submitter on the association between the use of different specified types of shot or bullets under standardised conditions and resulting lead levels in air and/or resulting PbB levels in shooters.

In the case of hunters, since it is not possible to separate between the risk attributed to training, hunting and consumption of game meat, it is considered together.

Different studies show significant increase in PbB level among hunters (up to 53 µg/L) compared to the levels of inhabitants of a highly industrialised city. PbB level increments of 53 µg/L are associated with an increase in the prevalence of chronic kidney disease of 35%, and with increase in systolic blood pressure of 1.8 mmHg.

3. Relevant information from the consultation of the Annex XV restriction report

Several comments were submitted by sector associations and individuals on lead exposure of outdoor sports shooters. In contrast to known lead exposure from indoor sports shooting, several comments considered that lead exposure from outdoor sports shooting is negligible. However, new data provided on exposure of shooters was very limited although some comments indicated that regular PbB monitoring of sports shooters is performed. The Muzzle Loaders Associations International Federation (comment #3277) provided information on the blood lead level of one shooter in Austria (concurrent PbB of 72 µg/L) who does intensive shooting (muzzle, black powder, big and small-bore pistol and rifle, military rifle, air pistol) and related activities (home casting, re-loading).

Another comment (comment #3237) reports the results of a small-scale survey of middle-aged men eating a significant amount of game meat and engaged in sports shooting, and half of them also engaged in cartridge recharging. Their blood lead levels ranged from 0.09 to 0.19 µmol/L [4 to 39 µg/L], averaging 0.13 µmol/L [27 µg/L]. One person, who also carried out casting work, had a blood lead content of 0.7 µmol/L [145 µg/L]. FITASC/ISSF (comment #3221) commented that there is no possible emission of lead dust in clay target sports shooting using lead shot cartridges. This is because in modern cartridges that use plastic wads there is no contact between the barrel's bore and the lead load. Furthermore, when a lead pellet hits the ground, it has close to zero speed and zero energy. To support this statement, reference was made to a professional Olympic skeet shooter with 'perfectly normal' blood lead levels.

Several reasons were brought forward contributing to the low exposure such as:

- Open air environment with natural ventilation
- Technical measures to limit exposure of outdoor shooters meaning that:
    - lead is contained in the cartridge (comment #3194)
    - shooting positions are minimum 2 to 2.5 metres apart
    - minimum firing distance to the target to prevent exposure from the projectile splashing on the target or berm.

A single blood lead level measurement of one Olympic medallist in shotgun shooting was also provided in the consultation (comment #3518). The result was below the LOQ (32µg/L).

4. Evaluation

Sports shooters

There is clear evidence from the literature showing that the practice of shooting results in an increase of the lead body burden. This is caused not only by lead shots/bullets but also lead primers used in guns. How much lead-containing primers vs gunshot/bullets contribute to the total lead emissions/exposure is not clear, but according to some papers a significant proportion of lead may come from primers (Laidlaw et al., 2018).

The literature data show that lead exposure is generally higher at indoor shooting. In indoor shooters, blood lead levels may easily exceed 150 µg/L, which is the limit proposed by RAC[6] for occupational exposure to lead and which is linked to the increased risk of neurological effects in adults. Even levels higher than 400 µg/L have been reported in several instances.

[6] RAC Opinion on scientific evaluation of occupational exposure limits for Lead and its compounds: https://echa.europa.eu/documents/10162/ed7a37e4-1641-b147-aaac-fce4c3014037

The EU Chemical Agents Directive[7] defines 400 µg/L as the blood lead level limit above which medical surveillance of workers is needed. Additionally, the Directive sets a binding biological limit value for lead in blood of 700 µg/L. If workers exceed this level, they should be immediately removed from the tasks involving exposure to lead. As discussed in the RAC opinion on Occupational Exposure Limit Values for Lead (2020), the present limit values defined by the EU Chemical Agents Directive are far too high in light of the current understanding of the health risks of lead. Therefore, RAC has proposed to decrease the present binding biological limit value for lead in blood to 150 µg/L. However, this limit value will apply only to adults and does not protect from the developmental neurotoxicity of lead. In addition, it should be noted that the limits and requirements for health surveillance in the EU Chemical Agents Directive apply only to workers employed in shooting ranges or practising shooting as part of their job (like police). There are no legal requirements for health surveillance or blood lead measurements of “leisure” shooters or athletes practising shooting regularly even though their exposure can be as high as those professionals mentioned earlier, especially if they train indoors (Laidlaw et al., 2018). The registry data collected by Gelberg and DePersis (2008) from the New York State Heavy Metals Registry indicates that hobbyists involved in target shooting have higher lead levels in blood than range employees (208/348 had PbB 250-390 µg/L, 108/348 had PbB 400-590 µg/L and 26/348 had PbB>600 µg/L). However, these data also included lead measurements in blood of indoor shooters.

Overall, in a significant number of cases it is difficult to differentiate the contribution of outdoor and indoor shooting to the total lead exposure of sports shooters since a large number of them may practise both indoor and outdoor depending on the season. Based on the available information, exposure to lead in outdoor shooting can be estimated to be generally lower than in indoor shooting (Lach et al., 2015, Mathee et al. 2017). However, depending on the shooting place and e.g., weather conditions, high exposure levels have also been measured in outdoor shooting.

The main studies providing information on lead air emissions during outdoor shooting include Lach et al., 2015, Bonanno et al., 2002; Tripathi et al., 1989, Chun et al., 2018 and Wang et al., 2017.

Lach et al., 2015 made industrial hygiene measurements in both indoor and outdoor gun shooting ranges. In indoor shooting ranges using lead ammunition (lead both in primers and bullets), air levels of 70 µg/m^3 of lead were measured immediately behind the shooter, whereas in outdoor shooting ranges, levels of 10 µg/m^3 on average were measured about 3 m behind the shooter. Higher levels have been, however, measured in personal air sampling. Bonanno et al. (2002) measured lead concentrations of 286 and 235 µg/m^3 in the breathing zone of shooters using a 22 calibre weapon, and 579 and 1 558 µg/m^3 for shooters using 45 calibre weapons in an outdoor covered pistol range. The use of larger calibres also resulted in higher concentrations of lead dust on the hand of the shooters (324 and 353 µg) compared to 233 and 50 µg for the smaller calibre. In an older study by Tripathi et al. (1989) average air levels of 128 µg/m^3 were reported in the personal air samples of shooters in a covered outdoor shooting range. Wang et al. (2017) measured respirable airborne lead concentrations of 200 and 1 700 µg/m^3 during two-hour shooting sessions in an outdoor

[7] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC): https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0024:EN:HTML

shooting range, higher levels were detected during rifle shooting than during pistol shooting. In this study, the levels during outdoor rifle shooting range were even higher when compared to the levels they measured in one indoor shooting range during rifle shooting. This suggests that, under condition of low natural ventilation (low wind), outdoor shooting is not safer than indoor shooting.

Chun et al. (2018) measured lead exposure levels up to 292 µg /m^3 in personal air samplers and 18.7 µg /m^3 in stationary samplers in a covered outdoor shooting range for clay shooters using gunshot ammunition.

The RAC opinion on Occupational Exposure Limit Values for Lead (2020) concluded that occupational lead exposure as 8 h TWA should be reduced below 4 µg/m^3 in order to prevent an increase of PbB levels >150 µg/L in long-term occupational exposure occurring 5 d/week. Compared to this, if a typical shooting session lasts 1 h/day, inhalation exposure should remain below 32 µg/m^3 if shooting is regularly occurring 5 d/week in order to prevent an increase of PbB above 150 µg/L. Naturally, if the shooting is less regular/more occasional, the risk for lead accumulation is lower. In addition, the type of gun may have a significant impact on the lead emissions; high calibre guns seem to result in higher lead emissions than smaller calibre guns and rifle shooting results in higher emissions than pistol shooting (Bonanno et al., 2002, Wang et al, 2017).

Overall, based on the available air measurement data it can be concluded that shooting outdoors may result in significant lead emissions in the breathing zone of the shooter, although the exposure is lower than in indoor shooting and depends e.g., on ventilation and the number and proximity of shooters. In addition, according to information submitted in the consultation of the Annex XV report, the plastic cartridge may reduce the lead emissions in gunshot shooting but RAC notes that there is no measured data provided on this.

The fumes formed when shooting may be inhaled, and they may contaminate hands and clothes resulting in hand-to-mouth exposure. The relative importance of primer vs bullet/shot on the total lead emissions caused by shooting is not clear from the available data. According to Bonanno et al. (2002), the use of specific low lead ammunition with brass bullet and lead-free primer resulted in up to 99 % reduction of lead in the breathing zone air. Tripathi et al. (1990) evaluated the impact of jacketing of bullets and concluded that copper-jacketed bullets significantly reduced airborne lead levels by a factor of 21 in the personal breathing zone samples (lead levels of 5.88 µg/m^3 were measured in personal breathing zone samples). In a study by Lach et al. (2015), the use of lead-free primer resulted in lead levels of 2.2 µg/m^3 in an indoor shooting range whereas the use of lead ammunition resulted in lead levels of 72 µg/m^3.

Specific biomonitoring data in outdoor shooting has been summarised by Ladlaw et al. (2018). Overall, data concerning specifically outdoor shooting is very limited; most of the data is from shooters performing indoor shooting or both indoor and outdoor shooting. In a study by Mathee et al. (2017), twelve shooters at an outdoor shooting range had on average 43 µg/L higher PbB level (70 ± 42 µg/L, range 20-172 µg/l) when compared to 20 archers (27 ± 14 µg/L). PbB levels of shooters training in three indoor shooting ranges were 105 ± 70 µg/L, 161 ± 98 µg/L, 192 ± 163 µg/L, respectively. Shooters with higher shooting frequency (more than monthly) showed higher PbB levels compared to shooters shooting less frequently; higher PbB levels were also associated with casting of own bullets, hunting and placing bullets in the mouth.

Tripathi et al. (1989) measured PbB levels in six cadets after shooting exercises using non-jacketed lead bullets at a covered outdoor shooting range. An increase in lead levels in blood from 50-80 µg/L (at day 0) to 90-260 µg/L (at day 5) was seen. At day 69 after the shooting, the levels had decreased to 60-140 µg/L. Gulson et al. (2002) measured the variation of PbB levels with time after shooting in one subject. After four months without shooting, one week after an outdoor shooting session, the PbB level of the subject was 32 µg/L and increased to 67 µg/L following four visits to an outdoor shooting range during four months. Indoor shooting with copper jacketed bullets (Cu coating up to 1 mm thick electroplated onto a Pb core) did not seem to increase the PbB levels. The PbB levels dropped to 38 µg/L after two months without shooting.

Löfstedt et al. (1999) reported a positive correlation between PbB levels and consumed bullets in police officers practising shooting. PbB levels of 50 µg/L (10–182 µg/L) were measured in male officers (n=575), which were higher than in female officers (37 µg/L, n=53).

Turmel et al. (2010) noted that mean PbB levels in biathletes (18 ± 3.1 µg/L; 0.087 ± 0.015 µmol/L), were slightly but significantly higher compared to the cross-country skiers (< 8.3 µg/L;< 0.04 ± 0.0 µmol/L).

Regarding the use of gunshot in sports shooting, Chun et al. (2018) measured mean PbB levels (±SD) of 45.2 ± 16.0 µg/L in Korean clay shooters (n=14). Mean PbB levels in the general population of Korea (2010 to 2011) were reported to be 18.3 ± 7.9 µg/L for females and 22.2 ± 10.4 µg/L for males (Eom et al., 2017). PbB levels increased with increasing training frequency. It should be, however, noted that the numbers of clay shooters studied were low.

A few measurements of lead in blood for shooters were provided in the consultation on the Annex XV report. However, the data submitted was very limited and therefore did not provide much additional information; a PbB measurement in one shooter using muzzle-loading guns supported the increase in PbB levels when practising shooting.

Shooting with air rifle seems to result in lower lead emissions and no clear increases in PbB levels have been observed in the available studies (Svensson et al., 1992; Demmeler et al., 2009) but the data is very scarce.

The overall conclusion is that outdoor shooting using firearms (both gunshot and single projectile shooting) results in exposure to lead and elevation of blood lead levels in shooters. Increases in PbB levels up to 30 µg/L seem likely. In very frequent shooters using high calibre/rifle guns, PbB levels may even increase higher than this. In some cases, levels close to (or even above) 150 µg/L have been suggested but in these cases contribution of indoor shooting cannot be excluded. It should be, however, noted that background PbB levels in the population vary between regions/countries due to other environmental sources of lead and it is the total cumulative body burden which affects the risk. Therefore, it is often difficult to assess the contribution of shooting based on single PbB measurements.

Developmental neurotoxicity is an effect of lead causing concerns at very low PbB levels and it is not possible to identify a threshold for this effect. Therefore, it is important to recognise young females who may become pregnant as a special sensitive subgroup of sports shooters whose exposure is of special concern.

Lead emissions caused by shooting are not derived from gunshot/bullets only, but a significant proportion of lead may come from lead primers. It is not possible to estimate for certain how much the primer vs the gunshot/bullet contributes to final lead exposure. RAC notes that primers are out of scope of this restriction proposal, which may have an impact on the effectiveness of the restriction to reduce shooters' exposure to lead.

Hunters

Hunters are exposed to lead not only during hunting, but also during practising and via the consumption of game meet and casting of ammunition. Contribution of these different sources is difficult to separate. The highest increases in PbB related to hunting have been seen in studies with native Canadian, Alaskan and Greenland populations, who also consume high amounts of game meat and may also practise home-casting. In these populations, elevated blood lead levels have been seen also in samples taken from cord blood and lead isotope studies have shown a strong indication that the source of lead is lead ammunition. Most of the studies have evaluated the contribution of game meat consumption on PbB levels in these populations. Only one of these studies provides some information on the potential contribution from hunting itself. This is the study by Liberda et al. (2018), who studied Canadian native populations and found significantly increased relative risk for elevated PbB lead levels among those who performed hunting (n=689) when compared to those not performing hunting (n=723). The Relative Risk (RR) of PbB exceeding 0.24 µmol/L (50 µg/L) in hunters was 1.75 (95% C.I. 1.444–2.122) when compared to non-hunters. However, it is not stated whether the game meat consumption patterns of hunters vs non-hunters were similar. Similarly, subjects who used a firearm compared to non-firearm users had a RR of 2.073 (C.I. 0.983–4.373; p = 0.031) of having PbB that exceeded 0.24 µmol/L (50 µg/L).

In Europe, Fustinoni et al. (2017) measured lead levels in blood in 74 males and 21 females in Italy, of which 69 were hunters (hunting mammals and birds) and 26 non-hunters. For non-hunting subjects, the median PbB levels were 14 µg/L in subjects with (n=8) and 15 ug/L in subjects without (n=18) game meat consumption. For hunters, the median PbB levels were 36 µg/L with game meat consumption (n=62) and 40 µg/L without (n=7) game meat consumption. PbB levels were correlating with hunting and wine consumption but not e.g. with game meat consumption. Since the sampling was made outside the hunting season, the PbB levels represent the long-term body burden of lead rather than recent (peak) exposures.

In the correlation analyses performed by Mathee et al. (2017, see above) hunting was associated with higher B-Pb levels among the shooters.

One comment from the consultation of the Annex XV report provided the results of a small-scale survey of middle-aged men eating substantial amounts of game meat and engaged in sports shooting, and half of them also engaged in cartridge recharging. Their blood lead levels ranged from 4 to 39 µg/L, averaging 27 µg/L. One person, who also carried out casting work, had a blood lead content of 145 µg/L.

Overall, the data on the lead exposure due to hunting *per se* is very limited but it suggests that also hunting may result in some increase in blood lead levels, if done frequently. Hunters' exposure is affected not only by hunting, but also by possible home-casting and game meat consumption. Based on available data it is not possible to establish a difference between hunting with gunshot or with bullets.

5. Uncertainties

The following uncertainties have been identified within the scope of the present report:

- There are several variables which have an impact on the exposure to lead due to outdoor sports shooting, including jacketing of the bullets, closed plastic cartridges, shooting frequency, type of the arm used, facilities and ventilation/wind in shooting facilities.

- It is not clear the impact of lead-containing primer vs shot/bullet on the total lead emissions and exposure.

- In the case of hunting, the specific data is very limited. Hunters' exposure is affected not only by hunting, but also by possible home-casting and game meat consumption.

6. Conclusions

1. Outdoor sports shooting using firearms (both gunshot and single projectile shooting) may result in exposure to lead and elevation of blood lead levels in shooters. Increases in PbB levels up to 30 μg/L seem likely and even above 30 μg/L is possible in frequent shooters. This results in a medium to low risk in the RAC qualitative risk assessment for non-pregnant adults.

2. RAC notes that even small increases of lead in blood may cause a risk for the foetus of the pregnant shooter since no threshold has been identified for the neurodevelopmental effects of lead.

3. Jacketing of lead bullets reduces lead emissions but does not prevent those totally. An undefined proportion of lead emissions is caused by lead primers. Although plastic cartridges used nowadays in shotguns may limit lead emissions, there is no measured data available on this.

4. Shooting with airguns seems to result in clearly lower lead emissions and no clear increases in PbB levels have been observed in the available studies.

The data on lead exposure due to hunting *per se* is very limited but it suggests that also hunting may result in a relative increase in blood lead levels if performed regularly.

7. References

All references cited are included in the Background Document to the Opinion on the Annex XV dossier proposing restrictions on lead in outdoor shooting and fishing.

Committee for Risk Assessment (RAC)

Ad-hoc RAC Supporting Group

Evaluation of an

Annex XV dossier proposing a restriction on

Lead and its compounds

in outdoor shooting and fishing

Work Package WP A.4

Human health risk assessment home-casting, hand-to-mouth and oral exposure

3 June 2022

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1. Description of the Work Package

1.1. Background

When assessing the risk for lead exposure related to hunting, sports shooting and fishing, all steps in these processes need to be considered. Sometimes the first step of potential exposure is the 'home-casting' of ammunition and fishing sinkers. The Dossier Submitter has evaluated the exposure from these processes as part of the overall assessment of human exposure and risk from lead in ammunition and fishing sinkers. In this work package, RAC evaluates the data used by the Dossier Submitter and their conclusions as presented in the Background Document to the opinion on the Annex XV dossier proposing restrictions on lead in outdoor shooting and fishing.

1.2. Objectives

The following topics are covered in the present work package:

3. Does home-casting of ammunition and fishing sinkers occur in the EU?

4. Are there data showing exposure that could be related quantitatively or qualitatively to home-casting?

5. Is home-casting as such of concern when it comes to lead exposure?

6. How much does home-casting contribute to human exposure to lead in relation to overall exposure to lead from ammunition and fishing?

2. Summary of the Dossier Submitter proposal

According to the Dossier Submitter, home-casting of fishing sinkers is common in parts of the EU, and home-casting of lead bullets may occur. Many studies have shown increased blood lead levels in populations involved with home-casting sinkers, and the chemical safety report of the registration for lead (CSR, 2020) provides an exposure estimate for home-casting of bullets. There is also evidence of people swallowing fishing sinkers, and of keeping bullets in the mouth during hunting, making oral exposure to lead highly likely. Based on this information, a risk from home-casting is concluded.

3. Relevant information from the consultation of the Annex XV restriction report

Numerous comments were submitted in the consultation on the Annex XV report, some confirming that home-casting does occur, especially in western Europe and perhaps mainly by sea anglers. However, no information that could allow for a quantitative risk assessment was provided.

Most comments concerned the proposed transition period for the entering into force of a ban of lead fishing sinkers and lures and the availability of alternatives to lead, indicating that many alternative materials exist but that more time (i.e., a longer transition period) is needed to ensure a wide availability. Iron putty (iron and a polymer such as PHA - Polyhydroxyalkanoate) was proposed as alternative for small lead split shot, while recognising that also tin is available on the market for this purpose. The comments also indicated that zinc and copper are not, or seldomly, used as alternatives. The need for a transition period was recognised in many comments. However, RAC supports the Dossier Submitter in that no robust justification was provided to support a longer transition period from that originally proposed, i.e., 3 and 5 years for lead fishing sinkers and lures weighing ≤ 50 g and > 50 g, respectively.

Although the comments in general were positive towards restricting the release of lead to the environment, many requests for derogations were submitted.

One request for a derogation concerns the use of lead in the smallest split shot (<0.06 g). However, RAC notes that split shots are easily dropped, and as they are generally applied to the fishing line at the shore, there is a risk that birds will ingest these shot which, because of their small size, are likely to be highly bioavailable. Thus, from a risk perspective, a derogation is not supported. Furthermore, alternatives to lead split shot are available (e.g., iron putty and tin), and although the alternatives are claimed to damage the line, it is possible that also lead split shot may damage the line if too much pressure is applied when attaching the shot. Reference is made to some fishing competition rules requiring the use of lead split shot, but RAC does not find that a sufficient reason for a derogation.

A derogation is requested for those sinkers whose size will prevent ingestion by birds, e.g., > 50 g. However, lead sinkers >50 g are not proposed to be banned based on their risks to birds, but to limit the risks to humans while home-casting. Therefore, RAC supports the ban of lead sinkers >50 g and a transition period of 5 years considering the currently more limited availability of alternatives. The 50 g threshold was also contested in the consultation (referring to a lower threshold in corresponding UK legislation), but RAC supports this limit based on observed cases of ingestion of such weights (<50 g) in birds and that there is no need to harmonise with the thresholds used in the UK legislation.

A derogation is also requested for lures having a hard plastic cover (i.e., plugs, wobblers). However, it seems that lead has been already substituted with tungsten in such sinking lures. RAC does not support this derogation request.

Other topics raised concerns, e.g., the concentration limit of lead (1%), tax on lead, labelling and communication, but RAC supports that they do not warrant revising the restriction proposal.

4. Evaluation

Fishing sinkers

Lead has a low melting point (325°C), which enables 'home-casting' of fishing sinkers and ammunition. According to the ECHA Market Survey (2020), 'home-casting' of fishing tackle seems rather common in many countries (concerning up to 30% of the fishers in some regions). There are also surveys conducted in Member States (NL and DK) supporting that home-casting does occur. Lead fumes and (subsequently) lead dust may be formed when the temperature exceeds 482ºC, potentially resulting in inhalation exposure and dermal contamination that through hand-to-mouth exposure can result in ingestion and thus oral exposure. Direct dermal exposure of hands from the solid lead may also contribute to exposure (through hand-to-mouth exposure).

Artisanal melting of scrap lead is a relatively simple process, e.g., on a gas stove, using a small cooking pot, pan or crucible. Scrap lead produces dross on the surface as it becomes fully molten; this is usually removed with an implement by hand. The molten lead is then poured into moulds and left to harden. Remaining lead in the pot can be left to cool for the next time and the dross is discarded. In terms of exposure, the fisher or shooter is working with molten metal at arms-length, quite possibly with their head occasionally over the vessel in a position to inhale any fume. While lead melts at 325°C, it is easy to overheat the vessel to the point of fuming (above 482°C). Risk management measures such as extraction or personal protective equipment are likely to be absent, with the possible exception of gloves to prevent burns.

There is no information on how likely fume formation is during home-casting considering that fumes, according to the Dossier Submitter, are formed when the melting temperature exceeds the melting point by approximately 150ºC. However, several studies indicate that home-casting may lead to lead exposure. As a worst case, an Alaskan adult male patient suffered from lead poisoning, (blood lead level 1 330 µg/L) as a result of inhaling lead dust and fumes from melting and casting lead for several years (State of Alaska Epidemiology, 2001). Other studies described in the Background Document include an epidemiological study showing that lead melting practices were strongly associated with elevated blood lead levels in South African remote subsistence fishing communities (Mathee et al., 2013), and an epidemiological study indicating that the main sources of lead exposure in children in Cartagena, Colombia (Olivero-Verbel et al., 2007) were from their parents working in a metal melting factory or with producing fishing equipment (fishing net sinkers).

The Background Documents also refers to a few other studies (melting batteries to produce fishing sinkers and handling lead sinkers) but their relevance to home-casting is unclear to RAC. Reasons are, e.g., that melting a (car?) battery seems much more difficult than starting from small scrap lead pieces, and that it is not clear how much dermal exposure during the attachment of the sinkers to the fishing nets contribute to the total exposure.

Overall, RAC concludes that these studies show that lead exposure during home-casting is possible. The exposure routes could be both inhalation of fumes and oral exposure to dust through hand-to-mouth movement. However, it is not clear to RAC if the conditions in subsistence fishing communities in South Africa and Colombia are relevant for the EU (considering i.e., magnitude of expected exposure to lead and confounding from industrial activities), whereas the single case in Alaska (with very high blood lead levels) perhaps is relevant. RAC concludes that exposure to lead during home-casting is possible, but quantification of exposure and risk is not possible.

Handling of lead fishing weights was shown by Sahmel et al. (2015) to result in lead contamination of hands, and subsequent transfer from skin to saliva of 24% of the skin content. That handling of lead fishing sinkers can result in lead exposure is also supported by an epidemiological study from Thailand, showing that parental occupation in producing fishing nets with lead weights in their homes in coastal fishing communities was associated with a marked increase in the prevalence of high blood lead levels in the (parent) workers as well as in their children (Yimthiang et al., 2019). However, it is not clear how extensive their contact with lead sinkers were and other working conditions. RAC concludes that exposure to lead from direct contact with lead fishing sinkers is possible, but quantification of exposure and risk is not possible.

Direct oral exposure to lead from fishing weights is also likely when closing lead split shot by biting while applying the fishing weight on the fishing line. This habit may be rather common among fishers applying small weights, but the weights might also accidentally be swallowed as reported by US poison control centres (Gummin et al 2017). RAC concludes that direct oral exposure to lead from fishing sinkers is possible and likely to occur, but quantification of exposure and risk is not possible.

Ammunition

There are no studies in the Background Document reporting lead exposure when 'home-casting' ammunition. However, such data may be available as the CSR (2020) report exposure up to 20 µg lead/event in reloading activities (involving home-casting), and a Norwegian study has reported statistically significantly higher blood lead levels (31.4 vs 15.6 µg/L) in 13 hunters reporting self-assembling of lead-containing bullets than in 134 hunters not doing that (Meltzer et al., 2013). In a South African study (Mathee et al., 2017), home-casting (in 22% of participants) did not affect blood lead concentrations, whereas 17% of shooters (i.e., 14 shooters) at shooting ranges reported that they keep bullets in the mouth, making direct oral exposure possible. The blood lead measurement indicated higher levels in shooters keeping bullets in the mouth, but the difference was not statistically significant. RAC concludes that exposure to lead from home-casting ammunition and from keeping lead ammunition in the mouth is possible, but quantification of exposure and risk is not possible.

Overall conclusion

Overall, RAC concludes that 'home-casting' fishing weights and ammunition is likely to result in lead exposure via fumes, dust and direct contamination of skin from lead. The magnitude is likely to depend on many factors, such as local practices and conditions, source of lead, and type of product home-casted. The Dossier Submitter estimates that 1 ton of lead per year is used per Member State for home-casting, but it is not known to RAC how plausible this figure is. Although 'home-casting' may be common in some European regions, there is no European data to support a quantitative risk characterisation. However, if 'home-casting' is performed under inadequate conditions (e.g., temperatures >482^{o}C and with poor ventilation), exposure of the person conducting the 'home-casting' as well as of family members is possible and potentially of concern, as shown by data from other parts of the world.

5. Uncertainties

The main uncertainty concerns the lack of European data to support that 'home-casting' fishing weights and ammunition results in exposure to lead. There is however data clearly showing that home-casting occurs in Europe, although the extent of the practice is uncertain. Data from other parts of the world show that lead exposure from home-casting is likely, but it is questionable if the conditions and magnitude of work in, e.g., subsistence fishing communities in South Africa or Colombia are relevant for Europe.

6. Conclusions

5. Home-casting of ammunition and fishing sinkers occurs in the EU, as shown by the selling of moulding forms and various surveys. Home-casting fishing sinkers may be common in some regions, but an overall estimate of how common these practices are is not available.

6. Data from other parts of the world indicate that home-casting can result in substantial exposure to lead, but it is not clear to RAC how relevant these data are for European conditions. Thus, RAC concludes that exposure is possible, but a quantitative assessment is not possible.

7. It is not possible to conduct a risk assessment specifically for home-casting, but when it occurs, RAC concludes that this practice can contribute to exposure and in worst-case conditions the exposure can be substantial.

8. Home-casting of fishing sinkers and ammunition can contribute to human exposure to lead, but the quantitative contribution is probably highly case-specific, and no quantitative assessment is currently possible in relation to overall exposure to lead.

9. Lead exposure through direct contact with lead fishing sinkers and ammunition is likely, resulting in oral exposure via hand-to-mouth transfer, but quantification of exposure and risk is not possible.

7. References

All references cited are included in the Background Document to the Opinion on the Annex XV dossier proposing restrictions on lead in outdoor shooting and fishing.

Committee for Risk Assessment (RAC)

Ad-hoc RAC Supporting Group

Evaluation of an

Annex XV dossier proposing a restriction on

Lead and its compounds

in outdoor shooting and fishing

Work Package WP A.5

Human health risks related to the consumption of game meat and other meat and dairy products

3 June 2022

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1. Description of the Work Package

1.1. Background

Food and especially game meat consumption is one potential source of lead exposure. The highest amounts of game meat are consumed in hunters' families, which are considered to be at the highest risk. Especially vulnerable are small children whose neurological development may be impaired due to lead exposure. Lead deposited next to shooting ranges may contaminate the soil and result in lead exposure of cattle grazing on land contaminated with lead ammunition. Subsistence farmers (and their families) eating meat and dairy products derived from cattle exposed to lead are at highest risk in this case.

1.2. Objectives

The following topics are covered in the present work package:

6. What is the level of exposure to lead due to game meat consumption in hunters' families?

7. What kind of risk will game meat consumption cause?

8. What is the contribution to the overall level of concern?

9. What is the prevalence and level of exposure caused by other meat or dairy products?

2. Summary of the Dossier Submitter proposal

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 other type of lead projectiles, as the existing best practices to handle hunted game meat do not eliminate the lead in the game meat.

The risks to human health via drinking water and consumption of crops and/or meat from cattle grown on agricultural soils adjacent to or within shooting areas are discussed qualitatively. The risks to human health from consumption of contaminated game meat are assessed quantitatively by the Dossier Submitter.

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

- 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 resulting from the consumption of game meat.

3. Relevant information from the consultation of the Annex XV restriction report

Extensive comments were submitted on human health risks associated with game meat consumption. These are summarised below.

Comments related to the lead levels in game meat and to the consumption of game meat

During the consultation, stakeholders provided information on the use of non-expanding full metal jacket (FMJ) or other non-expanding bullets such as open tip match bullets (OTM) and small calibre weapons for the hunting of special species and possible lead contamination related to these uses. The Finnish Hunting association (comment #3255) performed a field test which suggests that FMJ, OTM and .22 LR bullets do not cause lead contamination in game meat. These field tests showed that the difference of weight of FMJ, OMT and .22LR bullets before and after impact was negligible (some bullets were even reported with higher weight after impact due to meat remnants that got stuck in the bullet). This suggests that these bullets do not cause any contamination of game meat with lead and/or any secondary poisoning. Small calibres and FMJ or OTM bullets are allowed only for use in the hunting of small game or seals in some countries (Scandinavia, Baltic countries) (comments #3255, 3262).

The European Federation for Hunting and Conservation ('FACE') provided comments regarding the human health risk assessment and the EFSA (2020) input data for consumption and lead content of game meat used by the Dossier Submitter in the assessment (comment #3467).

Regarding the lead content in game meat, FACE questioned the relevance, reliability and scientific validity of the data. According to FACE, the high average value provided for game hunted with bullets (2.516 mg/kg) in contrast with the low value provided for shots (0.366 mg/kg) is not supported by the scientific literature, where it is generally observed that average lead concentrations are higher in birds than in large game species (see AESAN 2012, Food Standards Agency in Scotland 2012). Further, values provided by EFSA (2020) for deer and wild boar do not stand a comparison with other publications. For instance, the German Federal Institute for Risk Assessment found that lead content (P95) in roe deer was 0.582 mg/kg (n=2 235) and in wild boar 1.446 mg/kg (n=1 542) (Gerofke et al 2018). EFSA reported that the mean lead content in roe deer was 0.048 mg/kg (P95 0.124 mg/kg, n=733), and in wild boar 1.143 mg/kg (P95 0.67 mg/kg, n=966) (EFSA 2012a).

FACE also questioned the use of the the maximum allowable level (ML) of 0.1 mg Pb/kg set by Commission Regulation (EC) No 1881/2006[8] for meat from domesticated animals (bovine animals, sheep, pigs, and poultry) as a threshold for a "dangerous concentration" in game meat, since there is no ML established for game. Additionally, FACE expressed their disagreement with the approach followed by the Dossier Submitter for the risk assessment, where the samples with a lead concentration above 0.1mg/kg (i.e., worst case) were used as a surrogate for all game meat. In another comment (#3363), it was noted that the recommendation for setting up the same maximum lead concentration limit in game meat (mammals) as for beef, sheep, pork and poultry is impractical, because so called lead-free alternatives also contain lead which makes it impossible to ensure compliance with this value.

In relation to game consumption, FACE considered the values used by the Dossier Submitter based on the 95th percentile as an overestimation, not representing the whole hunting community of the EU 27. In their opinion, these high values are not likely to occur even amongst indigenous hunters using game as their main nutrition (Chan et al., 2017). FACE consider that as the input values used in the dietary exposure assessment are incorrect, the Dossier Submitter 's human health risk assessment fails to reliably estimate the risks resulting from game meat consumption.

Other commenters agreed with the Dossier Submitter's assessment and brought some further issues to the attention of RAC and the Dossier Submitter (comments #3209, 3494, 3485).

The German competent authority raised the issue of lead nanoparticles found in game meat and provided a publication where the topic is highlighted as an *"unattended source of lead with a largely unknown toxicological impact to humans" (Kollander et al., 2017)*. It also highlighted the fact that lead bioavailability and adsorption increases when cooking meat in acidic conditions (Schulz et al., 2021) (comment #3209).

The European Environmental Bureau (EEB, comment #3494) commented on the content of lead in game and indicated that lead levels used in the restriction proposal for some types of game animals (small game) are notably below previously reported levels. This is further supported by the recent publication by Pain et al., (2022) suggesting even 14-times higher mean game meat lead levels in small pray hunted with shotgun than the lead levels presented in the Annex XV report. EEB further questioned the Dossier Submitter's statement that 'European hunters generally follow "best practice", as advised by several wildlife authorities, when handling game meat" since there is no proof provided for such a statement.

Comment #3485 highlighted that in Italy the consumption of game meat has steadily increased over the last decades, leading to a situation in which frequent game meat consumption is no longer limited to hunter families, but has become "frequent among people living in the countryside, mainly in mountainous areas where wild ungulates are very abundant. In a large part of Alps and Apennines, the number of servings per month consumed by non-hunters can be relevant, especially during the hunting season".

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[8] Commision Regulation 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32006R1881

The Wildfowl & Wetland Trust (#3303) as well as an individual commenter (#3460) pointed out that they believed that lead concentrations, particular in birds, could be higher than in the EFSA dataset (EFSA, 2020) and provided additional data on lead concentrations found in game meat.

Finally, WWF (comment #3446), raised the issue of the presence of lead residues and their quantification in big game meat and sausages. In this sense, Garcia Fernandez et al. (2018) evaluated the presence of lead in 86 pieces of sausages bougth across different Spanish regions and concluded that the probability of a person consuming a piece of sausage with lead levels above the legally established levels is close to 50% (one in every two pieces). In addition, the average lead concentration of the contaminated samples reached almost 0.4 mg/kg, which is four times the maximum concentration limit set up in Commission Regulation (EC) No 1881/2006 for meat from livestock.

Comments related to the qualitative risk assessment

The International Lead Association (ILA) & Pb REACH Consortium (PbRC) provided comments criticising the qualitative health risk assessment performed by the Dossier Submitter (comment #3223). In their opinion, the benchmark dose (BMD) modelling is too conservative/uncertain and does not take into account recent publications on the association between low-dose blood lead and neurological functioning (IQ) in children, as well as studies on low-dose blood lead on adult neurological function, cardiovascular disease, and kidney disease.

ILA further noted that a predicted IQ loss of 1 point associated with 12 µg/L lead blood levels may be no more than statistical “noise” and calls into question whether a change in IQ of 1 point can be considered “adverse”, given that IQ tests possess an approximate error rate of ±3 IQ points, and questioned the effectiveness of the restriction.

4. Evaluation

4.1 Indirect exposure of humans via environment: Game meat consumption

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 all lead in game meat. In particular, consumption of meat from game hunted with lead ammunition is likely to be a relevant source of lead exposure since lead particles and fragments may reside in edible tissues despite best practises in handling game meat.

After hitting quarry animals, lead shot used for hunting can ‘fragment’ with 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 hunted game as tiny lead particles would go unnoticed.

Hunting with bullets also results in lead transfer deep into the tissues that surround the wound. Felsmann et al. (2016) investigated the effect of lead bullets on game meat and indicated that the projectile penetrates the animal body generating a temporary cavity which is accompanied by a change in the pressure within the funnel of a wound and in the adjacent tissues. Due to this phenomenon, lead transfers deep into the tissues that surround the path of a wound. Contamination can be worsened if the bullet hits a bone and further disintegrates, contaminating a larger area of tissues with fragments of increased surface area.

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. Further, 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. In general, 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.

European hunters are thought to generally follow "best practice" to handle meat as lead concentration in the wound channel can be very high. The FACE Guidance on managing risks from lead mentions the following on managing risk from ammunition:

"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."

Lead in game meat

Animals hunted 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 Commission 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. However, the Swedish National Food Administration (Swedish NFA, 2020) considers that game meat with lead contents exceeding this limit value should not be considered as safe according to Article 14 of Regulation (EC) No 178/2002[9]. Röschel

[9] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying

et al. (2020) proposed that Commission Regulation (EC) No 1881/2006 should be amended to incorporate a maximum lead concentration level for game meat 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.

The concentration of lead in game meat will vary in relation to the distance to the wound channel. 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 NFA (2014a) reported median and maximum lead concentrations from the wound channel of 146 and 1 829 mg/kg wet weight. RAC notes that the measured lead concentrations are highly scattered, especially for wild boar and is probably also dependent of different parameters linked to how the bullet reaches the meat, i.e., the part of the body hit by the bullet and the distance and angle of entrance for the bullet. Table 1 (Table 1-42 of the Background Document) and Table 2 (Table 1-43 of the Background Document) presents lead concentrations at different distances from the wound channel for wild boar and red deer according to Dobrowolska and Melosik (2008) and the Swedish NFA(2014) and Forsell et al. (2014), respectively.

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down procedures in matters of food safety: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32002R0178

Table 1: 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
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 (last column) are marked in bold

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Table 2: 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 [1]
			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 %

Notes: [1] Threshold set by Commission Regulation (EC) No 1881/2006 for lead in meat

RAC agrees that the removal of meat at a distance of 10 to 15 cm from the wound channel significantly reduces the probability to ingest meat with a high lead concentration. However, this practice does not allow to totally exclude the ingestion of meat containing lead above the limit set by Commission Regulation EC No 1881/2006, as 27 % of the wild boar samples presented a lead concentration higher than 0.1 mg/kg at a distance of 10 to 15 cm from the wound channel.

The concentration of lead will also vary depending on the type of game hunted. For animals hunted with lead shot (duck, game birds, hare, partridge, pheasant, quail and rabbit), EFSA derived lower bound and higher bound values for the lead concentration in meat intended for consumption (see Table 3 below, Table 1-45 of the Background Document).

Table 3: Concentration of lead in meat intended for consumption from game hunted with lead shot 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 %)

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	
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

In other studies, i.e.: Pain et al. (2010), it was found that a high proportion of meat samples from game hunted with gunshot 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. The Food Standards Agency in Scotland estimated that the mean lead concentration in pheasants equals to 1.87 mg/kg (median 0.078 mg/kg, n=58) and partridges 1.33 mg/kg (median 0.169 mg/kg, n=53). These values are above the reported values by EFSA. Further Mateo et al 2011, found that 54.7% of hunted red partridge had lead levels equal to 2.55 mg/kg, which is above the maximum residue level of 0.1 mg/kg w/w and above the value provided by the Dossier Submitter. Additionally, a recent review, submitted to RAC during opinion development (Pain et al., 2022) suggests up to 14-times higher mean lead levels in small prey hunted with shotgun than the estimates based on EFSA data (2020) used by the Dossier Submitter. Thus, there are some uncertainties related to the lead concentration in game meat for small game.

The probability to ingest lead shot pieces is higher when consuming small birds like quail for example since this bird is eaten in one piece. This means that if the breast for example was hit by shot, the probability to ingest a piece of lead is very high. The bioavailability of lead in game meat is also affected by cooking (under acidic conditions, with vinegar (Pain et al., 2010; Shulz et al 2021)) and might be affected by the time period before consumption but no data were presented on this by the Dossier Submitter. 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).

EFSA also provided data on lead concentration in game meat hunted with bullets in the EU (EFSA, 2020, Table 1-46 in the Background Document reproduced as Table 4 below). Based on common hunting practices it was assumed that chamois, deer, moose, roe deer and wild boar were hunted with lead bullets.

Table 4: 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%)**

The data reported by EFSA for wild boar and wild deer are in a similar range as reported by ANSES (2018) for France (3.4 mg Pb/kg). However, Gerofke et al (2018), reports lower values for roe deer (0.582 mg/kg) and wild boar (1.446 mg/kg). The mean lead concentrations of the samples close to the wound channel (5.37 mg/kg) and saddle (1.72 mg/kg) exceeded 0.1 mg/kg (Gerofke et al., 2018). Lindboe et al. (2012), on the other hand, 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 Swedish National Food Agency found a median lead level in minced moose meat of 0.03 mg/kg. As regards roe deer and fallow deer, the mean lead level in the samples was 0.25 mg/kg. In marketable meat of red deer hunted under controlled conditions and prepared by trained professionals, the mean lead concentration in meat close to the wound channel was 58 mg/kg, and in meat from the saddle and haunch < 0.1 mg/kg (Martin et al., 2019). In marketable meat from roe deer, they reported mean lead values close to the wound channel (13.96 mg/kg), saddle (0.97 mg/kg) and haunch (0.17 mg/kg), all exceeding 0.1 mg/kg.

In the consultation of the Annex XV restriction report, the analysis presented by the Dossier Submitter was challenged in terms of the representativeness of the data and its scientific validity. The use of the maximum allowable level (ML) of 0.1 mg Pb/kg set by Commission Regulation (EC) No 1881/2006 for meat from domesticated animals (bovine animals, sheep, pigs, and poultry) as the threshold for a "dangerous concentration" of lead in game meat was also put into question. It should be noted that in the restriction proposal the Dossier Submitter has not used this ML for risk assessment or proposed this to be used as a dangerous level that should be applied also for game meat, but it is rather used only as reference point. Thus, this is a misinterpretation.

RAC notes that the EFSA data presented by the Dossier Submitter includes more than 12 000 entries from 26 Member States plus United Kingdom and Macedonia. Germany, Slovakia, Check Republic, Austria and France with 3 193, 1 926, 1 637, 1 340 and 1 335 are the most represented countries. Yet other countries such as Hungary (>500 data points), Portugal (>500), Denmark (>450), Latvia (>400), Poland (>300), etc., are well represented. Other countries such as Spain, Sweden, Belgium, Lithuania, Norway account for more than 100 data points. Considering the high number of samples and recognising that the level of reporting across Member States is never equally exhaustive, RAC concludes that the EFSA data is suitable for risk assessment.

RAC further notes that data on lead concentrations in game meat vary significantly, depending on the cut of meat. Variability is also found across studies and can be explained by the degree of fragmentation of the ammunition, the path the ammunition takes, and the level of care applied to remove the flesh surrounding the wounds, among others. In this sense, non-expanding full metal jacket bullets may result in lower lead contamination of game meat as non-jacketed or partially (or semi-) jacketed expanding bullets.

However, in spite of the variability in lead concentration in meat across studies and depending on the cut of the meat, RAC considers the data provided by EFSA as the most comprehensive and exhaustive dataset available for lead concentration in game meat and supports their use for further calculations.

The data shows that, 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 and the fact that a non-negligible fraction of hunter families might be exposed to high concentrations over a long period of time. In this sense, RAC recognises that using mean concentration values for the risk assessment is a conservative approach, yet it better reflects the above scenarios and therefore is deemed suitable for risk assessment. As shown in Tables 3 and 4 above, the mean lead concentration in game meat bagged with lead shot was 0.351-0.366 mg/kg, while the mean lead concentration in game meat bagged with lead bullets was 2.501-2.515 mg/kg. In both cases, 13 % of the samples presented a lead concentration above 0.1 mg/kg (EFSA, 2020).

Consumption of game meat

While other parts of the general population do consume game meat, the focus of the assessment presented in the Background Document is on game meat consumption by hunters and their families. Indeed, Green and Pain (2019) reviewed the published information on game meat consumption in the EU and concluded that the main consumers of game are hunters and their families and associates, and that a low percentage 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.

For the purpose of this restriction proposal, EFSA provided recent data on the consumption of game meat in the EU via food recall surveys (EFSA, 2020). In the restriction proposal, the Dossier Submitter initially considered that the 95th percentile of chronic consumption of game meat were a good proxy of high frequency consumers such as hunter households. However, after taking into account the comments received in the consultation of the Annex XV restriction report, the Dossier Submitter updated their approach and used the median value of chronic consumption of game meat instead as a better proxy of high frequency consumers such as hunter households. The median (P50) chronic daily consumption of game meat for different age groups, as provided by EFSA, is reported in Table 5 below (reproduced from Table 1-50 from the Background

Document). Of specific importance for this assessment are the data on infants and toddlers, who are specifically sensitive to lead-related IQ loss. Data from pregnant and lactating women were not considered due to their low number.

Table 5: Minimum, maximum and median across surveys of the median (P50) of the chronic daily consumption of meat from game hunted with lead gunshot and bullets in the EU (EFSA, 2020)

Population	Ammun.	N (S)[1]	Daily consumption of game meat (g/kg bw and day)[2]		
			Min P50	Med P50	Max P50
Infants	Shot	1-15 (5)	0.89	1.00	1.67
	Bullet	1-8 (3)	0.14	0.43	4.26
Toddlers	Shot	1-25 (10)	0.11	1.46	4.82
	Bullet	1-30 (7)	0.15	1.01	2.82
Other children	Shot	1-56 (13)	0.44	0.79	4.45
	Bullet	1-27 (11)	0.26	1.18	2.82
Adolescents	Shot	1-84 (14)	0.13	0.89	2.45
	Bullet	1-6 (12)	0.11	0.57	2.83
Adults	Shot	1-218 (20)	0.21	0.58	1.37
	Bullet	1-68 (16)	0.10	0.65	1.76
Elderly	Shot	1-74 (16)	0.42	0.63	1.36
	Bullet	1-27 (11)	0.09	0.58	1.53
Pregnant women	Shot	1-3 (5)	0.40	0.49	0.73
	Bullet	6 (1)	0.22	0.63	0.95
Lactating women	Shot	4 (1)	0.76	0.76	0.76
	Bullet	4 (1)	0.13	0.84	1.56

Notes: [1] range of number of subjects N in (S) surveys; [2] Some of the medians presented in this table were calculated based on information from fewer than 60 subjects and might hence not be statistically robust.

Game meat consumption of hunter families has been estimated to be 50 g/day for adults (ANSES, 2018, Gerofke et al., 2018, Haldimann et al., 2002) and 25 g/day for children (ANSES, 2018). Sevillano Morales et al. (2011) estimated only for wild boar and red deer an average consumption of 23 g/day and 96.7 g/day as 95th percentile. Assuming a similar amount of small game hunted with shot is consumed, a value of 193 g/day would represent the 95th percentile.

Based on EFSA data on chronic consumption of game meat, the median daily game meat consumption of high frequency consumers was set at 0.65 and 0.58 g/kg bw/day for adults consuming game hunted with gunshot and bullets, respectively. This corresponds to a daily intake of 45.6 g and 40.9 g 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 value indicated was 0.43 and 1.0 g/kg bw/day. Assuming a body weight of 5 kg, this corresponds to a daily intake of 2.1 and 5.0 g, respectively. For toddlers (1 to 3 years), the median value indicated was 1.01 and 1.46 g/kg bw/day. Assuming a body weight of 12 kg, this corresponds to a daily intake of 12.2 g and 17.5 g, respectively.

RAC notes that these data take into account only direct consumption of meat and not meat by-products (like sausages, paté, etc.) made with game meat and sold to the general public, which could increase the daily intake of game meat in the general population. Nevertheless, RAC agrees with the Dossier Submitter that the most important consumers of game meat are hunters and their families.

Measured blood lead (B-Pb) levels related to consumption of game meat

The Dossier Submitter notes that very limited data are available on how frequent game meat consumption affects B-Pb levels in hunter families. When reviewing the published studies that report measured B-Pb levels in game meat consumers, the following is considered:

- Men usually have higher B-Pb levels compared to females;
- Shooting /hunting has a significant contribution to the B-Pb level;
- Professional or leisure activities may contribute to B-Pb levels.
- The available studies investigating B-Pb 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 their influence on B-Pb levels.

The available data indicate a small increase in B-Pb level of 3 to 5 µg/L in adults that consume moose meat two to three times a week (see Swedish NFA, 2014a, Swedish NFA, 2014c, Wennberg et al., 2017, Swedish NFA, 2014a). Further, the available data suggest that subsistence hunters in the circumpolar regions have the highest levels of lead; in one study the increment for females (assumed to be non-hunters) was 6 and 15 µg/L (Tsuji et al., 2008). No reliable B-Pb level measurements in children from hunter families are available.

RAC notes that no biomonitoring data for hunter families are available.

4.2 Additional sources of indirect exposure of humans via the environment

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). In fact, 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). The risks to cattle resulting from the consumption of lead has been further assessed in the work package report WP A.1.

Root and leaf crops can be another source of exposure to lead. 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 Pb/kg. In the immediate surroundings of the backstop berm lead concentrations often fluctuates between 200 and 1 000 mg Pb/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). Commission Regulation (EC) No 1881/2006 limits lead concentration in cereals to 0.2 mg/kg food for human consumption.

Drinking water (via surface water or groundwater): The potential lead contamination of surface and groundwater resulting from the use of lead ammunition at sports shooting ranges has been assessed under the work package report WP A.2. Although a risk for human health can be anticipated if contaminated ground or surface water is used as drinking water, there is insuffcent information available to make any reliable human health risk assessment related to the consumption of drinking water contaminated via the environment by lead deposition on shooting ranges.

4.3 Risk Characterisation

Risks from game meat consumption

For risk characterisation, the Dossier Submitter used EFSA CONTAM Panel (EFSA, 2010) BMDL calculations 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.

It is recognised that 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 B-Pb 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 other words, the BMDL10 value may depend on earlier higher exposure levels, and if a BMDL10 value could be calculated based on those exposure levels, it might be higher.

In the absence of a threshold for the critical effects, the Dossier Submitter is reflecting the health impact by calculating the effect of the increase of B-Pb 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 (this endpoint was however not used in the human health impact assessment).

RAC recognises the conservative nature and uncertainties related to EFSA BMDLs especially for CKD and SBP and especially at low B-Pb levels. Regardless of these uncertainties, RAC considers that the EFSA BMDLs are, however, acceptable estimates for use in risk characterisation.

The Dossier Submitter used the following approach to calculate the risk to humans via the environment as a result of consumption of meat from game hunted with lead ammunition:

- To calculate the daily intake of lead from game meat, the Dossier Submitter used the EFSA data on the minimum, median and maximum (across surveys) 50^{th} percentile (P50) 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 (see Table 5 above).

- For the lead concentration in game meat, the Dossier Submitter used the EFSA data on the mean upper bound concentration of lead in game meat hunted with lead shot and lead bullets (see Table 6 below). According to the Dossier Submitter, 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 of lead for those cut of meat from the area around the wound channel. Such a scenario is best reflected by using the mean value.

- The Dossier Submitter points out that the use of the mean value to characterise the concentration of lead in game meat may be considered as a conservative approach. This is because, according to the EFSA dataset, the lead concentration in game meat is highly skewed with a median value that is orders of magnitude lower than the mean value. RAC notes that the mean value for game meat lead levels used for risk characterisation is significantly higher than the P95 level and this has an important impact on the B-Pb levels modelled for infants and toddlers.

- For the calculation of B-Pb levels resulting from daily lead intake via game meat, the Dossier Submitter 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, 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 corresponds to 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 corresponds to 6.3 µg Pb/kg bw/day ↔
2.4 µg Pb/L blood corresponds to 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 corresponds to 15 µg Pb/kg bw/day ↔
2.4 µg Pb/L blood corresponds to 1 µg/kg bw/day.

In Table 6 (reproduced from Table 1-54 from the Background Document) the calculated mean values for daily intake of game meat for the 95 percentile population (used as proxy for hunter families), incremental B-Pb levels and the resulting health impacts are summarised for children (infants and toddlers) and adults. The results indicate that the median consumption of game hunted with lead shot results in a low impact with IQ losses of well below 1 for infants and toddlers, respectively, whereas the median consumption of game meat hunted with bullets has a much higher impact with IQ loss of 2.51 and 3.66 IQ points for infants and toddler, respectively. For adults, the mean increase in the prevalence of CKD is 0.38 and 2.35% for game hunted with shot and bullets, and the mean increase in systolic blood pressure would be 0.02 and 0.12 mmHg for game hunted with shot and bullets.

RAC notes that to take into account the strongly skewed underlying distribution, the Dossier Submitter took forward the full distribution of predicted B-Pb levels to quantify the baseline risks and to monetise such risks.

Table 6: Calculated mean values for daily intake, incremental B-Pb levels and health impacts from the consumption of meat from game hunted with lead bullets and shot in the EU based on data from EFSA (2020)

Popu-lation	Type of ammu-nition	Game meat consumption (g/kg bw and day; P50[1]		Lead conc. in game meat (µg/g meat; mean upper bound)[2]	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	Shot	Min	0.14	0.366	0.051	0.615	0.05	—	—
		Med	**0.43**	**0.366**	**0.155**	**1.864**	**0.16**	**—**	—
		Max	4.26	0.366	1.558	18.694	1.56	—	—
	Bullet	Min	0.89	2.516	2.241	26.891	2.24	—	—
		Med	**1.00**	**2.516**	**2.508**	**30.095**	**2.51**	—	—
		Max	1.67	2.516	4.193	50.315	4.19	—	—
Toddlers	Shot	Min	0.15	0.366	0.056	0.670	0.06	—	—
		Med	**1.01**	**0.366**	**0.371**	**4.450**	**0.37**	—	—
		Max	4.82	0.366	1.031	12.369	1.03	—	—
	Bullet	Min	0.11	2.516	0.286	3.432	0.29	—	—
		Med	**1.46**	**2.516**	3.663	**43.953**	**3.66**	—	—
		Max	4.82	2.516	12.130	145.562	12.13	—	—

Popu-lation	Type of ammu-nition	Game meat consumption (g/kg bw and day; P50[1]		Lead conc. in game meat (µg/g meat; mean upper bound)[2]	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
Adults	Shot	Min	0.10	0.366	0.035	0.084	—	0.06	< 0.01
		Med	**0.65**	**0.366**	**0.238**	**0.571**	—	**0.38**	**0.02**
		Max	1.76	0.366	0.645	1.548	—	1.03	0.05
	Bullet	Min	0.21	2.516	0.520	1.247	—	0.38	0.04
		Med	**0.58**	**2.516**	**1.469**	**3.525**	—	**2.35**	**0.12**
		Max	1.37	2.516	3.437	8.250	—	5.50	0.27

Notes: 1 – See Table 5; 2 – See Table 3 and Table 4**: Concentration of lead in meat intended for consumption from game hunted with lead bullets in the EU (EFSA, 2020)**

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 (minced) 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 concentrations 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 (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). RAC notes that the best data for robustness check would be biomonitoring data on B-Pb levels of these hunter families, but this is not available for infants and toddlers.

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 lead exposure[10]. 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 B-Pb 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 B-Pb level (12 µg Pb/L blood ↔ 1 µg/kg bw/day). For adults, B-Pb 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).

These 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 underestimates 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 milk might be underrepresented.

The available 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 impact of game meat consumption and the accumulation of lead in the body of female hunter family members at reproductive age and on offspring during pregnancy and the mobilisation of lead with elimination via the milk during lactation is of concern. Consequently, advice is provided from national authorities such as French ANSES[11] or German BfR[12] that children and women at childbearing age should not consume game meat.

Based on national statistics of the number of hunters, the Dossier Submitter calculated that there are 6 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 were estimated to be 2.1 million.

As the share of the EU-27 population aged 7 or younger is approximately 8 % of the total population and assuming an equal age distribution in hunter families as in the general EU population, the Dossier Submitter estimates that about 1.1 million children aged 7 or younger are particularly vulnerable to lead exposure.

RAC considers that the Dossier Submitter's approach to use mean game meat lead values may result in a conservative estimate of the risks because of the highly skewed distribution of the lead levels in game meat (leading to a very high mean value). Uncertainties are also due to the limited biomonitoring data available from hunters'

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[10] The software is downloadable under: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=343670

[11] https://www.anses.fr/en/content/consumption-wild-game-action-needed-reduce-exposure-chemical-contaminants-and-lead

[12] http://www.bfr.bund.de/cm/349/research-project-safety-of-game-meat-obtained-through-hunting-lemisi.pdf

families to support these high lead exposures in children. On the other hand, the use of e.g., median level may underestimate the risk. It should be noted that some game meat samples present lead concentrations which are 10-fold higher than the average levels. If this game meat is consumed by young children, it will result in significant increases in B-Pb levels. For example, if a toddler consumes highly contaminated game meat with a lead content of 19 mg/kg (representing 99th percentile of large game meat lead levels) in 12 meals per year (i.e. once per month, 100 g meat/meal) and otherwise lead levels in the consumed meat remain at median level or below (having only minor impact on total exposure), the average lead intake of the toddler would result about the same (close to 5 µg/kg/day) as in the Dossier Submitter's scenario.

These scenarios with infrequent intake of highly contaminated meat instead of constant consumption of game meat with arithmetic mean levels of lead are perhaps more likely. In these scenarios, accumulation of lead into the body after infrequent peak exposures differs from the accumulation of constant exposure, with high peak levels resulting in rapid increase in B-Pb levels followed by decrease close to background levels within two weeks. ATSDR (2020) modelled B-Pb levels after ingestion of a 0.9 mg dose of soluble lead (with assumed 100% absorption) after single or repeated peak exposures in a 30 month old child (Figure C-1 in ATSDR 2020, https://www.atsdr.cdc.gov/toxprofiles/tp13.pdf). After a single peak exposure, the levels declined rapidly within the first month returning to approximately 120% of the baseline in approximately 35 days following the dose. After the six repeated exposures, B-Pb returned to approximately 120% of baseline in approximately 570 days after the last exposure event reflecting the accumulation of lead in bone and the slow transfer of lead from bone to blood after exposure ceases. It should be noted that this modelling was made for soluble lead assuming 100% bioavailability and, therefore, the absolute values do not correctly reflect game meat scenarios. However, the intention of this example is only to show the kinetics of B-Pb after peak exposures. The role of single peak exposures in the long-term neurological effects of lead in children is unknown. However, if these peak exposures are repeated, they will result in gradual long-term increase in B-Pb levels.

Available data show that hunter families frequently eat game meat (up to 1-2/week), but there is no data on how lead levels vary between these meals. The Dossier Submitter has assumed similar levels in all meals but a higher variation between the meals is likely. The example above assuming consumption of high lead levels via game meat once per month, and otherwise lower levels in the meat, also supports a concern for children in hunter families.

Regarding adults, RAC notes the Dossier Submitter has not quantitatively characterised the risks related to the increment of prevalence of chronic kidney disease (CKD) and the increase of systolic blood pressure (SBP) as done for IQ loss in children. Yet, Table 6 reports small increases of CKD and SBP for adults based on the consumption of game meat bagged with shot and bullets, respectively. However, the clinical relevance of especially those small increases in SBP is unclear.

Nevertheless, some biomonitoring data for adults presented in the Background Document suggests that B-Pb levels in adults might not be affected by the consumption of game meat (except in some native populations practising subsistence hunting). This is in line with the modelled B-Pb levels showing only small increases in B-Pb levels with median consumption of game meat even when using the conservative mean values for the game meat lead levels. Even though it is possible to speculate that there might be cases where hunters that need to maximise their income from selling game meat are consuming the most contaminated parts, and will be exposed to even higher levels, it is not possible to verify this.

In addition to the quantitative assessment of the risks, the Dossier Submitter further assessed the risks in a qualitative manner by combining the potential for exposure with the frequency of exposure*.*

Based on data from the EFSA database on lead concentration in game meat and on the intake of game meat (50th percentile used as a proxy for persons of a hunter household), assuming lead metal bioavailability of 10 % for adults and 50 % for children and considering that there is no evidence for a threshold of lead for developmental neurotoxicity in children, the Dossier Submitter estimated that for children a blood lead level increase will result in a high risk. For adults, low risk was concluded based on the assessment described above.

Overall, considering 1) the sensitivity of small children to the effects of lead and 2) the possibility of high levels of lead in some pieces of game meat, RAC agrees that there is a risk for children resulting from the consumption of game meat. Yet the Dossier Submitter's scenario based on the constant daily consumption of game meat with lead levels corresponding to the arithmetic mean of all measurements may overestimate the risk. Further, how probability of exposure vs severity of effects are weighted in the Dossier Submitter's qualitative approach is not clear. For this reason, RAC applied a best practice approach to qualitative risk assessment, based on a conceptual model, considering the potential sources of exposure, the receptor, the pathway and their probability and severity of effects (EC 2010, ISO 21365:2019) (see Annex 1).

For children, exposure modelling suggests that up to medium increases in B-Pb levels are highly likely in high game meat consumption scenarios (representative of hunter families). In some cases, even severe increases (>30 µg/l) are possible if highly contaminated meat is consumed. Overall, based on RAC's assessment, this scenario results in moderate to high risk for children. Developmental neurotoxic effects are relevant also in the case of offspring of pregnant females.

In the case of adults, modelling shows only minor increases in B-Pb levels even in high consumption scenarios. This is in accordance with the limited biomonitoring data showing no clear association between game meat consumption and B-Pb levels. Therefore, using qualitative risk assessment, RAC concluded for adults the risk from game meat consumption is considered low. However, RAC would like to highlight the risks of game meat consumption for females at fertile age, and especially pregnant females. Although in adults increases in B-Pb levels due to game meat consumption are lower than those expected in small children, there is no threshold for the developmental neurotoxicity of lead, and therefore for pregnant females the risk is considered at least moderate since at least mild increases in B-Pb levels are expected in case of frequent game meat consumption.

For the purpose of **impact assessment and to evaluate the effectiveness and risk reduction of the restriction,** rather than mean values, the Dossier Submitter used the empirical cumulative distribution function of the EFSA data on the lead concentrations in game meat and estimated the blood lead levels and the corresponding IQ loss and increase of CKD values for the whole distribution (see Figures 1 and 2 below). This approach was followed since the mean value is not a robust measure of centrality for strongly skewed distributions.

For the impact of lead in game meat on **IQ loss**, the Dossier Submitter estimated that about 1.1 million children were at risk of high exposure and built the cumulative empirical distribution function showed in the figure below. The results suggest that 50 % of the population is at risk to lose > 0.05 IQ points and 6% to lose > 1 IQ point.

For monetising the health impact in children, the Dossier Submitter used either the median lead intake by any birth cohort, or only children prone to lose ≥1 IQ points. It should be noted that both these approaches ignore the upper end of the curve, which may include some exceptionally high (and therefore rather unlikely) lead exposures.

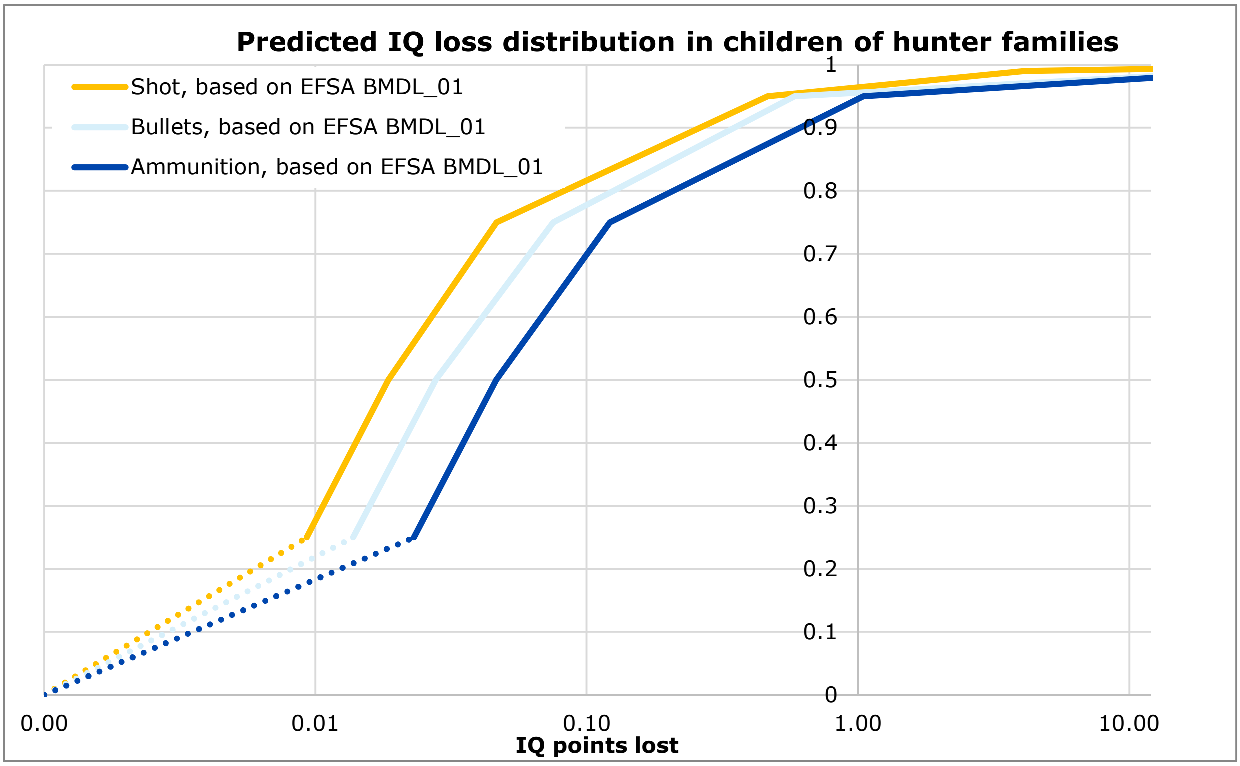

Figure 1: Empirical cumulative distribution functions (ECDFs) of IQ loss in high-frequency game meat consumers (Figure 2-4 in the Background Document)

Although the association between B-Pb levels and **increased CKD risk** in adults is less established than the one between B-Pb levels and neurotoxic effects in children, the Dossier Submitter considers that it might still be relevant at the population level since the group of exposed individuals is larger in the adult population than in the child population. The Dossier Submitter estimated that the size of the exposed adult population is about 10 million individuals.

Figure 2 below shows the resulting empirical cumulative distribution functions for excess CKD risk. The distribution function suggests 50 % of the population at risk faces an excess risk larger than 0.04% and 3.1 % of the population bears an excess CKD risk of ≥ 10 %.

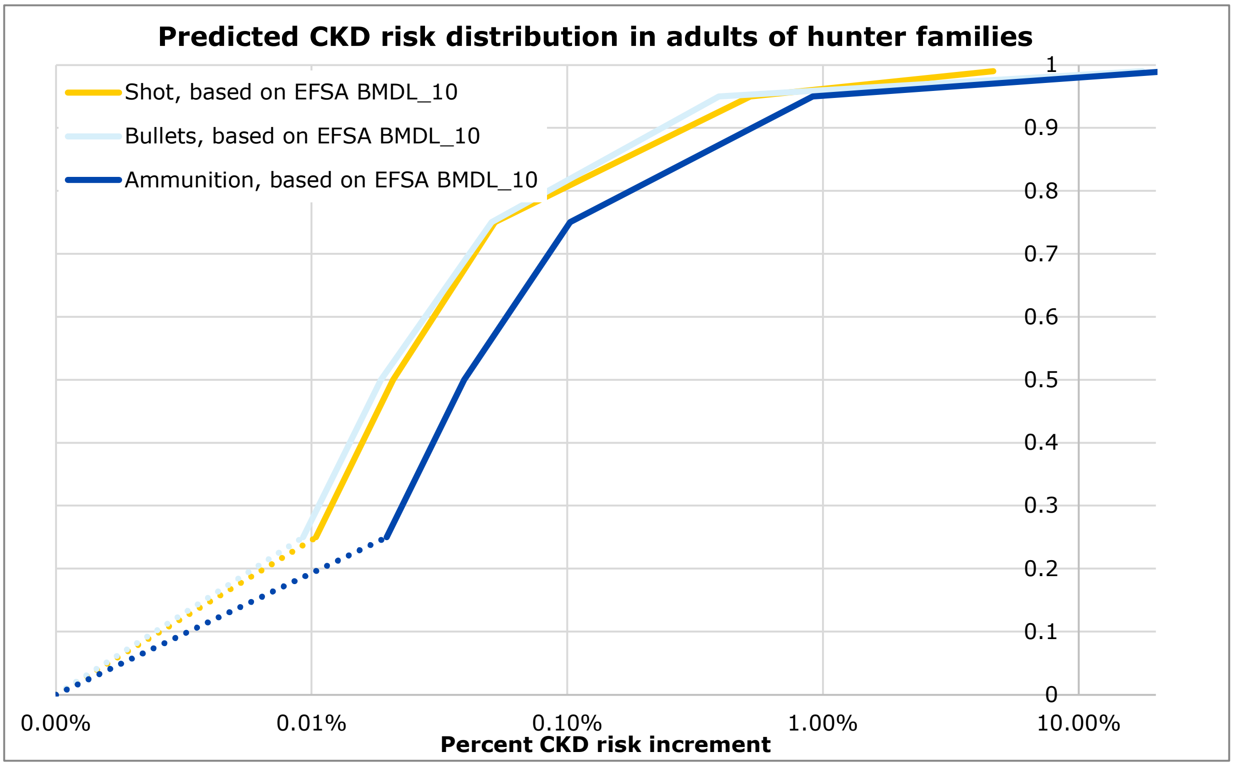

Figure 2 : Empirical cumulative distribution functions (ECDFs) of excess CKD risk in adult high-frequency game meat consumers

According to the Dossier Submitter, one may expect 1 085 additional cases of CKD (stages 3-5) in this group of extremely exposed individuals. This value might however be overestimated, as it is based on EFSA's BMDL10 which has been recognised as a worst-case value. In addition, long term repeated exposure to highly contaminated game meat (with lead levels >5 000 mg/kg) is needed to result in an excess CKD risk of >10%. Considering the distribution of lead in game meat, this might occur only in rather rare cases. Accordingly, for monetisation, the Dossier Submitter assumed that the number of attributable cases of CKD across the EU is between 100 and 1 000.

RAC agrees with the Dossier Submitter's approach to take the whole distribution of blood lead levels forward for the human health impact assessment. This approach is likely to give a more realistic overview of the variability of lead exposure from game meat consumption than a single point estimate. RAC notes that, for IQ loss, the Dossier Submitter used either the median lead intake by any birth cohort, or only children prone to lose ≥1 IQ points for monetising the risks. Both these approaches ignore the upper end of the curve including some exceptionally high (and therefore rather unlikely) lead exposures. RAC agrees with this approach but notes significant uncertainties caused by large variability in game meat lead levels and lack of data on the B-Pb levels among high game meat consumers.

Regarding CKD risk for adults, RAC noted that the results of Dossier Submitter analysis should be interpreted with caution because of the conservative nature of EFSA BMDL, and because of the need for long term (>5 years) constant exposure via highly contaminated game meat. Therefore, RAC agrees with Dossier Submitter that the real numbers of CKD cases are likely to be significantly lower than predicted by the model.

Risk from consumption of contaminated food and drinking water

In the work package report WP A.1 the risks to the environment are assessed for livestock (ruminants) grazing in shooting ranges and areas used as agricultural land. Risks to humans from the consumption of lead contaminated food may also originate from the deposition of lead on and in soil of shooting ranges used as agricultural land with consequent uptake of lead by plants used for human consumption as well as 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). Commission Regulation (EC) No 1881/2006 limits lead in cereals to 0.2 mg/kg food for human consumption, demonstrating that there is a risk for human health resulting from the consumption of food grown on shooting ranges.

It is also 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 higher 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'[13] 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 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.

[13] Local scale is a typical worst case since all food products are derived from the vicinity of a point source (EUSES guidance)

Children are commonly the most sensitive receptors in the assessment of dietary exposure as they consume more in relation to their body weight 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[14], 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 B-Pb levels higher than 250 to 400 µg/L; a B-Pb 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 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 (UK Animal & Plant Health Agency) 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, according to Commission Regulation (EC) No 1881/2006.

Tables 7 and 8 (Tables 1-55 and 1-56 of the Background Document) 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 7: Dietary exposure assessment for subsistence adult (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)

[14] 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.

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 8: 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 and illustrative scenario, which is not part of the main analysis.

Risks for the consumption of lead contaminated drinking water may originate from the deposition of lead on and in the soils of shooting ranges using lead gunshot or lead bullets, with corrosion of lead and its mobilisation to surface water and groundwater as drivers. The potential lead contamination of ground and surface waters resulting from the use of lead ammunition at sports shooting ranges has been assessed under the work package report WP A.2. As in the case of food, no further information is available to assess potential health risks from the consumption of drinking water contaminated via the environment by lead deposition on shooting ranges. Based on the available information, the Dossier Submitter has estimated the risk for humans due to indirect exposure via food and drinking water to vary between low (+) to high (+++) depending on the shooting frequency and risk management measures at the shooting range.

RAC notes that there is no data on the human exposure via food or drinking water and agrees with the Dossier Submitter that the situation may vary depending on the shooting frequency and the risk management measures in place at the shooting range. When there is no agricultural land adjacent to the shooting range and groundwater contamination is unlikely (soil not favorable for the transfer of lead to groundwater) the probability of exposure can be considered unlikely. Higher probability (high concern) for environmental contamination is related to shooting ranges with high intensity of shooting, adjacent to agricultural land, and with soil favorable for lead movement to surface water and groundwater. Considering the apparent lack of evidence supporting this exposure route, this is not considered a frequent case and is therefore judged to be a low probability resulting in low-moderate risk, the highest risks being related to the exposure of children and pregnant females.

5. Uncertainties

There are several uncertainties associated with the derivation of the BMDL values.

There are uncertainties in relation to the estimation of lead concentrations in hunted animals. Sampling from larger animals may be misleading because it is possible to obtain both highly contaminated and completely uncontaminated samples from the same animal. The analysis of a sample that is close enough to the wound channel may lead to very high maximum lead concentrations.

In addition, according to the EFSA dataset, the amount of lead in game meat hunted with bullets is much higher than the amount of lead in game hunted with gunshot. A possible reason might be related to the temporary cavity phenomenon of bullets, especially pressure fluctuations in adjacent tissues. This phenomenon may be responsible for lead transfer deep into the tissues that surround the path of a wound. On the other hand, a recent study (Pain et al., 2022) suggests up to 14-times higher mean lead levels in small prey hunted with shotgun than the estimates based on EFSA data (2020) used by the Dossier Submitter.

There are uncertainties in relation to the daily consumption of meat from game hunted with lead gunshot and bullets in the EU for sensitive groups such as pregnant and lactating women, since very few data are available. The Dossier Submitter considered as most relevant for risk assessment the data on infants and toddlers as the most sensitive group for developmental neurotoxicity and the data on adults in general in regard to the risks for chronic kidney disease and increase in blood pressure without sex division. No relevant measured data on B-Pb levels are available from infants and toddlers in high game meat consuming families either.

Very limited data are available on how frequent game meat consumption affects B-Pb levels in hunter families. The data presented in the report is modelled and cannot be compared with real measured values.

There is very limited data available to assess exposure and potential health risks from the consumption of food or drinking water contaminated via the environment by lead deposition on shooting ranges.

6. Conclusions

- Data related to the amount of lead in game meat is available from various studies where the concentration of lead in meat intended for consumption was measured. It is, however, noted that there is a large variability in the game meat lead levels. However, the available data indicate that 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 /kg meat).

- Information received in the consultation of the Annex XV restriction report indicates that non-expanding bullets (FMJ) and small calibre pistols used for the hunting of small game or seals may not result in similar lead contamination of the game meat as observed with expanding ammunition.

- The data on the concentration of lead in game meat and game meat consumption allows for an estimation of the risk of lead for sensitive population groups such as toddlers and infants, as well as for getting general conclusions for adults.

- The risks for neurodevelopmental effects in children and for CKD in adults associated with incremental B-Pb levels from the consumption of meat from game hunted with lead bullets or gunshot are quantitatively estimated. B-Pb values are, however, based on modelling and only limited crosschecking (for adults) can be done with real data adding uncertainty to the results.

- RAC considers that the Dossier Submitter's approach to use the mean values for game meat lead levels in the risk characterisation (in contrast to the impact assessment; see point 9 below) may result in a conservative estimate of risks due to the highly skewed distribution of the lead levels in game meat. On the other hand, higher lead levels in small game meat reported in some studies compared with the data used by the Dossier Submitter reduce the possible overestimation caused by this. In addition, since some pieces of game meat may contain more than one order of magnitude higher amounts of lead when compared to the mean levels used by the Dossier Submitter, similar total intakes of lead may follow even after few meals/year of this highly contaminated meat. This may result in significant increases in B-Pb levels in children.

- RAC concludes that there is a moderate to high risk for neurodevelopmental effects in children.

- In adults, the effect on B-Pb levels are smaller, and there is no biomonitoring data available from European hunters consuming game meat to contradict this smaller effect. However, some effects on CKD and some cardiovascular effects are possible, but the level of adversity of these effects is not clear, so a low risk is concluded.

- It should be noted that developmental neurotoxic effects are relevant also in the case of pregnant females. Although in adults increases in B-Pb levels due to game meat consumption are lower than those expected in small children, since there is no threshold for the developmental neurotoxicity of lead, also for pregnant females the risk for developmental neurotoxicity is considered relevant.

- Instead of single point estimate of game meat lead levels and B-Pb levels in hunters and their families, the Dossier Submitter took the whole distribution of blood lead levels forward for the human health impact assessment. RAC agrees with this approach, which gives a more realistic overview of the variability of lead exposure from game meat consumption.

- Limited evidence is provided to substantiate the risk of lead from contaminated food or drinking water. Yet, the evidence provided indicate potential risks which can be a concern in permanent shotgun areas with no environmental risk management measures or in intensive shooting areas.

- RAC therefore concludes that human exposure to lead via the environment is an important concern for game meat consumption in hunting with lead gunshot and bullets, and for lead contaminated food in case of sports shooting ranges with no environmental risk management measures or in intensive shooting areas.

7. References

Additional references not included in the Background Document to the opinion on the Annex XV dossier proposing restrictions on lead in outdoor shooting and fishing:

García-Fernández Antonio J., Isabel Navas Ruíz, Pedro María-Mojica, Irene Valverde Domínguez, Eduardo A. Hernández Hernández. 2018. Plomo en productos cárnicos de caza mayor: estimación de riesgos por su consumo.

Chan L, Receveur O, Batal M, Sadik T, Schwartz H, Ing A, Fediuk K, Tikhonov C. 2017. First Nations Food, Nutrition and Environment Study (FNFNES): Results from Saskatchewan. Ottawa: University of Ottawa.

Pain et al. (2022). How contaminated with ammunition-derived lead is meat from European small game animals? Assessing and reducing risks to human health. Ambio https://doi.org/10.17863/CAM.83511

Food Standards Scotland, 2012, 'Risk to human health from exposure to lead from lead bullets and shot used to shoot wild game animals'.

Committee for Risk Assessment (RAC)

Ad-hoc RAC Supporting Group

Evaluation of an

Annex XV dossier proposing a restriction on

Lead and its compounds

in outdoor shooting and fishing

Work Package WP B.2

Risk of alternatives to lead in ammunition and fishing tackle

3 June 2022

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1. Description of the Work Package

1.1. Background

As a consequence of the proposed restriction, hunters and fishers affected will have to switch to alternative ammunition and fishing tackle. According to the Dossier Submitter, there are various alternatives to lead in ammunition and fishing sinkers e.g. steel, copper, bismuth, tungsten.

This work package report describes the alternatives to lead ammunition and fishing tackle available and their risks to human health and the environment.

1.2. Objectives

The following topics are covered in the present work package:

- Relative risk reduction from use of alternatives:
  - Human health
  - Environment: birds, aquatic / terrestrial compartment
- Does the use of alternatives affect (increase) the mobility of lead in soils at existing shooting ranges?
- Ricochet
- Noise
- Other externalities (GHG potential, circularity)

2. Summary of the Dossier Submitter proposal

Based on the analysis performed of the available information, the Dossier Submitter concludes that alternatives to lead gunshot, in particular **steel gunshot**, can be used effectively in hunting and sports shooting. Other alternatives, such **as bismuth or tungsten-based gunshot**, can also be used to replace lead gunshot. Among the alternatives for lead gunshot, the Dossier Submitter includes in its assessment coated lead which has been placed on the market on various forms, i.e., **coated with nickel or copper.**

Lead bullets are usually semi-jacketed which consist of a hard lead alloy core and a jacket partly surrounding this core. The semi-jacket of most bullets consists of tombac, a copper-zinc alloy with a copper content of >80 %. In addition, there are semi-jacketed lead-containing bullets with a semi-jacket consisting of steel for hunting (Gerofke et al., 2018). The Dossier Submitter states that most of the non-lead bullets developed to replace lead are made from **pure copper or copper-zinc** alloy (brass), with or without other metal jacket coatings. Polymers are also used in the manufacture of bullets, for example, as a polymer shell to encase the lead projectile or as a major component of the bullet. According to the Dossier Submitter, a wide variety of non-lead bullets already exist for most larger game; the challenges in substitution are within the smaller calibres that are used for hunting smaller game and pests and the calibres used at sports shooting.

Additionally, alternatives to lead fishing sinkers and lures are widely available on the EU market including, 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 their assessment of the risks of the alternatives to lead ammunition and fishing tackle, the Dossier Submitter has identified potential human health risks related to inhalation exposure to particles or fumes from alternative substances while shooting or home-casting. Potential health effects of alternative metals include respiratory tract irritation (e.g., copper), metal fume fever (mainly zinc) and risk for carcinogenic effects in the respiratory tract (e.g., nickel). With regards to dermal exposure, the handling of ammunition and fishing tackle is not expected to pose a human health risk for the majority of alternative substances, except in the case of nickel, which has skin sensitising properties. Furthermore, the consumption of meat from game hunted with non-lead ammunition is not likely to result in a health risk for consumers if game meat hygiene measures have been properly applied.

The major environmental risks identified by the Dossier Submitter for alternative materials are related to the aquatic environment and to wildlife feeding on wounded or dead birds or on the viscera of game left in the field.

The Dossier Submitter notes that zinc and copper are classified for aquatic toxicity in powder form. Additionally, nickel, zinc and lead-coated ammunition and fishing tackle may result in a risk to wildlife if ingested. Birds may pick up the shot/weights from the ground or from the bodies of wounded or dead birds. Spent alternative bullets and their fragments may also be ingested by scavengers from discarded gut piles, non-retrieved killed or wounded animals. The lead coating will be abraded by the gizzard action once ingested by the bird and the lead core will be dissolved in the highly acidic environment of the avian stomach, as tested by Irby et al. (1967).

3. Relevant information from the consultation of the Annex XV restriction report

Numerous comments were submitted regarding the availability and suitability of alternative materials. The main comments related to the risks from the alternatives to lead are discussed in section 4 below.

4. Evaluation

4.1. Background information on alternatives

Gunshot in hunting

In the case of gunshot, lead has historically been used as gunshot in cartridges (TemaNord, 1995) because of its:

- softness and lubricating features (resulting in low abrasion of the shotgun barrel);
- low melting point (making it easily transformed into shot);
- high density (yielding high momentum after firing);
- relatively low price and high abundance (resulting in low cost of cartridges)

Based on these properties, lead is often considered to be an ideal material for use in ammunition. Other materials often have somewhat different ballistic behaviour to lead but this does not necessarily result in a conclusion that they are technically inferior to lead gunshot. Among the alternatives for gunshot, the Dossier Submitter includes in its assessment coated lead which has been put on the market on various forms, i.e., coated with nickel or copper.

Non lead options were widely assessed in the restriction proposal for lead in shot over wetlands. The main alternatives for lead in shot are based on the use of different metals with steel and bismuth as the most commonly used materials, although tungsten-based cartridges are also available.

The European markets are dominated by **steel** shot because of price, availability (Thomas, 2019) and also performance, which is seen comparable to lead (Scheuhammer, 1995; Pierce, 2014)[15].

Bismuth is recognised to have good performance provided the shot size is increased to allow for density lower than lead. Originally used in its pure form, nowadays it is generally alloyed with 3–6 % tin to reduce its frangibility. This material has been considered suitable and fully approved in USA and Canada (Thomas 2019). According to the Dossier Submitter, bismuth can be used as alternative to lead without concerns over compatibility with guns. The Dossier Submitter considers that 100 % of new guns currently on the market are compatible with steel gunshot and that a maximum of 15 % of existing (old) guns (pre 1961) may not be compatible with steel gunshot. In this case, bismuth can be a solution. It is available in most gauges and with a wide variety of loadings. Main issue with bismuth is that it is a scarce metal, which is produced as a by-product of lead production as pointed out in several comments in the consultation on the Annex XV report.

Tungsten has a density which makes it favourable for good ballistics and performance, so the percentage of tungsten in shot material is important for alloys. This alternative is suitable for use in appropriately proved guns and widely available, and in the US for example, it has been approved as nontoxic alternative by the US Fish and Wildlife Service. As for bismuth, the availability of tungsten is limited globally and its price is higher than steel.

Other alternatives are proposed by the Dossier Submitter, including copper and its alloys, zinc and its alloys or tin. As described later on, some of these alternatives are not recommended because of their (eco)toxicity (i.e., zinc).

In terms of the suitability or performance of alternative shot in killing game, this has already

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[15] Steel is one hundred times harder than lead, with only two-thirds its density, resulting rather different ballistic properties when compared to lead. Therefore, rather than steel, “soft iron” is used for shots, which is manufactured by annealing iron containing approximately 1 % or less carbon (Thomas, 2019)

been evaluated in the Annex XV restriction report on the use of lead in shot over wetlands (ECHA, 2018b), and by ECHA's Committees for Risk assessment (RAC) and Socio-Economic Analysis (SEAC). The conclusion of SEAC on alternative ammunition was that steel gunshot has a comparable performance once shooters have adjusted to its ballistic properties, e.g., in terms of patterning.

Gunshots in sports shooting

According to the Dossier Submitter, although the evidence concerning the use of alternative shot in competitive clay target shooting is less clear than for hunting, Thomas and Guitart (2013) report that **steel** shot meet all the ISSF technical requirements. 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). For all disciplines, lead or other soft material must be used as the projectile but an approval of the material by the ISSF is required.

In non-Olympic events, governing rules are set out by the FITASC, who in their rules state that the use of lead is mandatory. This means that ISSF and FITASC rules encourage the use of lead both in official and non-official events.

Nevertheless, there are possibilities to substitute lead by steel, provided the ISSF and other federations (IOC) would allow it, as shot made from steel is currently not approved by the ISSF.

Bullets in hunting

The Dossier Submitter summarises the alternatives to lead bullets which include coated lead bullets and non-lead alternatives. **Coated lead bullets** are usually semi-jacketed bullets which consist of a hard lead alloy core and a jacket partly surrounding this core. The percentage of other metals (mainly antimony, arsenic and zinc) determines the degree of hardness of the alloy. The semi-jacket of most bullets consists of tombac, a copper-zinc alloy with a copper content >80 %. Additionally, Tombac always contains arsenic, which determines the hardness of the material. Furthermore, there are semi-jacketed lead-containing bullets with a semi-jacket consisting of steel for hunting. Semi-jacketed bullets are expanding bullets. However, there are also full metal jacket bullets (FMJ), which have lead core surrounded by an outer shell ("jacket") of harder metal (gilding metal, cupronickel, or, less commonly, a steel alloy). These are not expanding bullets and are allowed for hunting of specific game in Nordic and Baltic countries only. FMJ bullets are also commonly used by the military (military uses are outside the scope of this proposal).

The main non-lead alternatives on the market developed to replace lead are made from **pure copper** or **copper-zinc alloy**, with or without other metal jacket coatings (Paulsen et al. 2015; Thomas et al. 2016). Non-lead monolithic bullets consist of almost pure copper (density 8.96 g/cm^3) or 100 %-electrolyte copper. Copper can also be alloyed with approximately 5 % (up to 40 %) zinc brass to make similar non-lead bullets (Thomas, 2019). **Bronze**, which is made out of 90 % copper and 10 % tin is potentially suitable for bullets, although metal hardness can be problematic. **Tombac** is another material used which consist of copper mixed with a higher zinc content (5 to 20 %). In tombac there is additionally always arsenic present which determines the hardness of the material. The semi-jacket of most bullets consists of tombac (Gerofke et al., 2018).

Other materials include **polymers** which can be used differently. Polymers can be used as a shell to encase the lead projectile, as nose of the bullet or as a major component of the bullet. **Tungsten** can be used at any concentration as a densifier with other approved material (Thomas, 2019).

Although viable alternatives exist for most cases, the present state of industry capabilities suggests that the following types of hunting would be mostly impacted in case of a ban on the use of lead bullets:

- Rimfire hunting (22 LR, etc.), used for hunting the smallest game species and when shooting small predators caught in cage traps.
- Full Metal Jacket (FMJ) bullets in small game hunting, e.g., Nordic bird hunting. This type of bullet is used for long distance shooting and high accuracy is demanded.
- For seal hunting (where this is allowed for population management purposes), lead bullets are stated to be required for the high precision needed.

For calibre 5.6 mm (centrefire) and larger, it is generally accepted that modern, well-maintained, rifles can be used to fire accurately non-lead as well as lead bullets within most hunting situations.

The use of air rifles for hunting is practically zero, although some use is authorised for pest control. Unlike for lead bullets, there are no known studies or peer reviewed tests that would compare the performance of lead and non-lead (often tin) based airgun pellets for hunting.

Hunting with muzzle loading, historic arms can be grouped under the 'black powder hunting 'category. This modality of hunting is only authorised in Finland, UK, France, Spain, Italy, Hungary and Denmark. Muzzle-loading shotguns are used for hunting live quarry and for clay pigeon shooting. The number of these types of guns in Europe is unknown.

Bullets in sports shooting

The Dossier Submitter indicates that for the rifle and pistol projectiles, the ISSF rules state that the projectiles made of "lead or other (similar) soft material" are permitted. However, the viable alternatives for the bullet calibres used in sports shooting providing the level of accuracy needed are limited.

Fishing sinkers and lures

Lead has remained very popular with fishers because it is cheap, performs well, is versatile and none of the non-lead alternatives currently offer the overall performance of lead sinkers and lures in terms of mass density, malleability, ease of production and cost. Nevertheless, there are functional alternative with a competitive price on the market. These alternatives include bismuth, brass, bronze, ceramic/glass, copper, concrete, high density polymer, stainless steel / rebar, stones or pebbles, tin, tungsten, zamac, and zinc. Lead coated with plastic is also used.

Among the alternatives, **bismuth** has successfully been used for some fishing sinker applications (e.g. nail sinker type), and seems suitable as sinkers and lures according to Thomas (2019). Yet, the use of bismuth as an alternative is rare.

Ceramic sinkers are also reported to be an adequate alternative in fisher blogs, despite their larger size, which could be a disadvantage.

Stones seem to be a popular alternative among the carp fishers especially in soft or muddy bottoms. They offer good camouflage for the fish and can be made by the fishers themselves or purchased from retailers that are specialised in this type of alternatives. Similar to stones, concrete is also used.

Another alternative is **steel** which has also successfully been used as a replacement for lead for some fishing sinker applications. In order to prevent corrosion, the steel weights must be coated or be made from stainless steel.

Tin is also widely used as an alternative for lead split shot fishing sinkers because its softness and ductility/malleability meet the requirements of this application (i.e., it can be pinched repeatedly on and off fishing lines).

Also **tungsten** has successfully been used as a replacement for lead for some fishing tackle applications. This material has the advantage of being smaller and harder than lead and therefore less likely to get stuck on rocks. Its price is, however, higher. Powdered tungsten can be mixed with a soft polymer putty that can be squeezed around fishing lines, and then be removed and re-used later. Such putty could be used to replace lead split shot for example. Tungsten powder can also be mixed with hard plastic polymers and shaped into many forms designed for use as fishing sinkers using thermoforming technology.

Other reported alternatives include **brass, bronze, iron, high density polymer, glass, zinc** or other approved material.

4.2 Risk of alternatives

For the analysis on the risks of alternatives to human health and the environment, the Dossier Submitter combines the hazard and exposure data of alternatives and compares them with the main risks identified for lead both for human health and for the environment. The analysis is supported by data on the alternatives assessed and listed as non-toxic for wildlife by the US Fish and Wildlife Service (US FWS, 1997).

Table 1 below (Table C.3-9 from Annex 3 of the Background Document) summarises the risk reduction potential of the alternatives described by the Dossier Submitter.

Table 1: Toxicity of the alternative substances compared to lead

Alternative material	**Human health inhalation** **(mg/m^3; inhalable)**	**Human health** **Game meat** **(game meat)**	**Aquatic toxicity**	**Wildlife toxicity (ingestion)**
Lead	**Yes**, risk increases with calibre, frequency, low ventilation	**Yes**	Depending on Pb release from shot: Pb metal not classified; Pb powder Aquatic Acute/Chronic 1	**Yes**
Alternative shot for hunting				
Lead, coated	Risk seems low	**Yes**	Depending on release of and risk of coating material and release of Pb over time	**Yes**
Bismuth-tin (3-6 %) alloy	>13 (Bi)	No	No: Bi not classified	No
Brass (copper-zinc alloy)	>1 (Cu) >2 (Zn)	No	Depending on Cu, Zn (and Pb) release from shot	
Bronze (copper-tin alloy)	>1 (Cu) >2 (Sn)	No		

Alternative material	**Human health inhalation** **(mg/m^3; inhalable)**	**Human health** **Game meat** **(game meat)**	**Aquatic toxicity**	**Wildlife toxicity (ingestion)**
Copper (Cu)	>1 (Cu)	No (based on data generated with Cu bullets)	Depending on Cu release from shot: Cu metal not classified; Cu granulated Aqua Chronic 2; Cu powder self-class. Aqua Acute/Chronic 1	No
Nickel (Ni) (alloying metal)	**>0.03; carc (Ni)**	**>4 µg/kg**	Depending on Ni release from shot: Ni metal not classified; Ni powder Aquatic Chronic 3; Ni release from shots	**Yes**
Steel (soft iron >99 % Fe)	>3 (Fe)	No oral	No: Fe not classified	No
Tin (Sn)	>2 (Sn)	No hazard identified	No: Sn not classified, Sn release from W shot under anaerobic conditions	
Tungsten (W)	>5 (W)		No: W not classified; no W release from shots	No

Alternative material	Human health inhalation (mg/m³; inhalable)	Human health Game meat (game meat)	Aquatic toxicity	Wildlife toxicity (ingestion)
Tungsten - bronze	>5 (W) >1 (Cu)		No: Cu release 30-50-times lower than from Cu shot	
Zinc (Zn)	>2 (Zn); zinc fever		Depending on Zn release from shots: Zn metal not classified Zn powder Aquatic Acute/Chronic 1	**Yes**
Alternative bullets for hunting				
Lead, coated	Low	**Yes (based on Pb data)**	n/a	**YES**
Copper, pure	>1 (Cu)	No (based on data)	n/a	No
Brass (copper-zinc <40 %)	>1 (Cu) >2 (Zn)	No (assumed based on Cu and Zn data)	n/a	
Bronze (copper-tin 10 %)	>1 (Cu) >2 (Sn)		n/a	
Tombac (copper-zinc up to 20 %)	>1 (Cu) >2 (Zn)	No	n/a	
Tungsten (often used as alloying metal)	>5 (W)	>0.48 mg/kg bw (DNEL oral)	n/a	

Alternative material	**Human health inhalation** **(mg/m³; inhalable)**	**Human health** **Game meat** **(game meat)**	**Aquatic toxicity**	**Wildlife toxicity (ingestion)**
Zinc	>2 (Zn); zinc fever	No (based on data)	n/a	**YES**
Alternative fishing tackle				
Lead, coated		n/a	Depending on releases of coating material and Pb over time + Might fall under the microplastics definition	**YES** **+** Might fall under the microplastics definition
Bismuth	>13 (Bi)	n/a	Bi not classified	
Brass	Home-casting less likely	n/a	Cu, Zn (and Pb) release under certain conditions	
Ceramic/Glass		n/a		
Copper	Home-casting less likely	n/a	Cu metal not classified; Cu granulated Aqua Chronic 2; Cu powder self-class. Aqua Acute/Chronic 1; Cu release from shot under certain conditions	No
Concrete		n/a		

Alternative material	**Human health inhalation** **(mg/m^3; inhalable)**	**Human health** **Game meat** **(game meat)**	**Aquatic toxicity**	**Wildlife toxicity (ingestion)**
High density polymer	Home-casting not likely	n/a	Might fall under the microplastics definition	Might fall under the microplastics definition
Iron	Home-casting less likely	n/a	Fe release but Fe not classified	
Rebar (for reinforcing bar)	Home-casting not likely	n/a		
Stainless Steel (e.g., 11 % Cr, 8 % Ni)	Home-casting not likely	n/a	Corrosion resistant: no releases of Fe, Cr or Ni	
Steel (Fe, <2 % carbon; 1 % Mn)	Home-casting not likely	n/a	Not corrosion resistant: releases of Fe (not classified) and Mn (Mn self-classified Aquatic Chronic 2 or 3)	
Stones and pebbles				
Tin	>2 (Sn)	n/a	Sn not classified, Sn release from W shots under anaerobic condition	
Tungsten	Home-casting not likely	n/a	W not classified; no W release from shot	No
Zamac or Zamak™	>2 (Zn);	n/a		

Alternative material	**Human health inhalation (mg/m³; inhalable)**	**Human health Game meat (game meat)**	**Aquatic toxicity**	**Wildlife toxicity (ingestion)**
Zinc	>2 (Zn) zinc fever;	n/a		**YES**

Human health risks of alternatives

The Dossier Submitter considers that potential human health risks related with the use of alternative substances could result from inhalation of fumes/dusts from shooting and home-casting and from the consumption of game bagged with such alternative substances.

As discussed in the work package report WP A.3, airborne lead exposure and related risks can be significantly reduced by using a non-lead primer and jacketed or non-lead bullets. On the basis of the available data, it is however not fully clear how much primer vs shot/bullet impacts on the total emissions caused by shooting.

For the case of non-lead alternatives only limited information is available on the metal emissions following controlled shooting with defined alternative shot and/or bullets compared to lead shot or bullets.

One series of publications suggested a health risk from exposure to copper and possibly zinc in volunteers from controlled shooting with alternative bullets (Voie et al., 2014). However, the exposure scenario of this study reflects a military use, and therefore the results are most probably less relevant for hunting or outdoor sports shooting activities especially when considering that the shooting was performed in semi-air-tight tent made of plastic and wood. Yet, in the absence of reliable data on exposure following hunting and outdoor shooting activities, the Dossier Submitter considers that it provides information that may be considered as “worst case” for the general population (hunter or sports shooter). In the study, 54 to 55 healthy men per study were shooting in a semi-airtight tent for 60 min with either leaded (SS109, RUAG), non-leaded (NM229, NAMMO), or modified non-leaded ammunition (n= 19; NM255, NAMMO). Especially the copper levels in air exceeded the DNEL derived by industry (1 mg/m^3, fraction not specified) in the case of both leaded and non-leaded ammunition, being two times higher in the case of non-leaded ammunition. It should be noted that SCOEL has given an IOELV recommendation of 0.01 mg/m^3 for respirable fraction of copper. Also, the zinc concentration exceeded the German MAK value for respirable (0.1 mg/m3) but not for inhalable fraction (2 mg/m^3), the levels in the case of non-leaded ammunition being higher.

In 42 of the 54 volunteers, general symptoms such as chills, headache and/or malaise appeared 3–12 h after shooting. More symptoms were reported when non-leaded ammunition was used compared with leaded and modified non-leaded ammunition (Voie et al., 2014). Copper and zinc fumes are known to cause so-called metal fume fever when exposed at high level especially after a break in exposure (e.g., in occupational settings typically after holidays). A follow-up study evaluated the effects of shooting with leaded and non-leaded ammunition on the respiratory function and did not detect any difference between the type of bullets (Borander et al., 2017 [16]). RAC concludes that also when using non-leaded bullets, it is important to ensure good ventilation and follow-up the levels of air impurities, including copper and zinc fumes. However, the risk for elevated levels is higher in indoor shooting which is outside the scope of this restriction. In outdoor shooting the levels are expected to be significantly lower when compared to the levels measured in confined spaces with poor

[16] https://pubmed.ncbi.nlm.nih.gov/28408655/

ventilation. In addition, the hazards related to zinc and copper fumes are mainly limited to non-cancer lung effects (including inflammation, and metal fume fever after high exposures). Neither of them is accumulating in the human body.

No information could be retrieved on the metal concentration in the air while home-casting bullets or fishing sinkers and lures. Based on their melting points, bismuth (271°C), tin (232°C), zinc (420°C), and zamac (380-390°C) could be considered to be potentially used for home-casting of bullets and/or fishing sinkers and lures. Antimony (630°C), aluminium (660°C), copper (1085°C) and its alloys such as brass (900-940°C) or bronze (950°C) would require specific equipment for home-casting. Fumes formed in home-casting from metals like zinc cannot to be excluded. However, since there is no data on exposure levels, no conclusion whether this poses a risk to human health can be reached. As mentioned above, hazards related to zinc fumes are mainly inflammatory lung effects and metal fume fever (at levels above 2 mg/m^3).

Further to the inhalation assessment, the Dossier Submitter evaluates the risk of handling alternative ammunition and fishing sinkers and lures and concludes that the handling of ammunition containing nickel is of potential risk with regards to skin sensitisation. RAC wants to emphasise that this applies only to alloys likely to release relevant amounts of nickel. Alloys containing nickel are classified for skin sensitisation when the release rate of 0.5 µg $Ni/cm^2/week$, as measured by the European Standard reference test method EN 1811, is exceeded. The handling of alternative ammunition or fishing sinkers and lures containing iron (steel), copper, bismuth, tin, tungsten is considered to be of no relevant risk.

In the case of the risks from meat consumption from game hunted with alternative ammunition, the use of semi-jacketed expandable bullets may not have risk-reduction benefits since this coating allows expansion of the lead bullet and thereby does not prevent contamination of the game meat with lead. Most of the coated bullets used for hunting are semi-jacketed bullets. Full metal jacket (FMJ) bullets can be used for the hunting of specific game in Nordic countries. The Finnish Hunting association (comments #3255) performed a field test suggesting that FMJ, open tip match bullets (OTM) and .22 LR bullets do not cause lead contamination in game meat. In field tests the weight difference of FMJ, OMT and .22LR before and after impact was negligible (some bullets were even reported with higher weight after impact due to meat remnants that got stuck in the bullet). This suggests that these bullets do not cause significant contamination of game meat with lead. Small calibres and FMJ or OTM bullets are allowed only for use in the hunting of small game or seals in some countries (Scandinavia, Baltic countries).

For non-lead alternatives, data available on the contamination of meat is limited. No data on bismuth levels in game meat hunted with bismuth ammunition are available. However, bismuth has shown a low toxicity in sub-chronic toxicity study in rats even when a water-soluble salt has been administered. It is therefore considered to cause a low concern for human health due to the consumption of meat from game hunted with bismuth.

Reliable data on the metal concentration in game meat following the use of alternative shot or bullets are only available for game hunted with copper and zinc bullets. The most comprehensive study, by Schlichting et al. (2017), examined the contamination of copper and zinc in game meat from roe deer, wild boar and red deer hunted either with lead bullets (surrounded by a tombac jacket with a high copper and zinc content) or non-lead ammunition (solid bullets made of copper or alloys of copper and zinc). The outcome of this study shows that the use of both lead-based ammunition and alternative non-lead ammunition results in the contamination of edible parts of the game with copper and zinc at levels similar to those reported in other studies and comparable to the levels regularly detected in meat and its products from livestock (pig, cattle, sheep). If the mean or median values are considered, then the intake of copper is between 0.2 and 0.5 mg and the intake of zinc is between 5.2 and 7.5 mg per day for average consumption. The authors of the study conclude that a health risk for the consumer due to an average consumption of game meat with the reported content of copper or zinc is unlikely. The authors further highlight that the intake of copper through the consumption of farm animals is much higher than it is through the consumption of hunted game meat. This only applies, of course, if game meat hygiene measures have been properly applied, i.e., the meat close to the wound channel has been widely cut out and areas with hematomas have also been widely removed.

RAC agrees with the Dossier Submitter that copper and zinc levels in game meat do not cause health concern for humans. This is further supported by the maximum residue level (MRL) for copper permitted in food of animal origin from pigs, cattle, sheep, goats, horses, poultry and other farm animals which is 5 mg/kg (fresh weight) according to regulation (EC) No 149/2008 and the amending regulation (EC) No 149/2008. Mean, median and 95th values of copper amounts in game meat from the studies available are far from these values. Further, EFSA found that the contribution of the proposed MRL to total consumer exposure to copper was negligible. It amounts up to 0.7 % of the Acceptable Daily Intake (ADI) of an adult (Schlichting et al., 2017).

During the consultation of the Annex XV restriction report, it was noted that the maximum concentration of lead in ammunition specified in the restriction conditions should be increased from 1% to 3%, since up to 3% of lead in brass is common. There is no quantitative data to estimate the impact of this difference (1% vs 3%) to human exposure to lead via game meat or to risks to wildlife. The impact is estimated to be low especially when considering that in alloys, other alloying metals may limit the release of individual metal components. Considering that copper-based bullets are the main alternative for lead bullets, RAC supports this request.

Other alternatives assessed by the Dossier Submitter include steel and tungsten. Iron has a lower oral toxicity compared to lead, copper or zinc. Like zinc and copper, iron is an essential element in humans with regulated gastrointestinal absorption. The potential health risk from the consumption of meat from game hunted with steel ammunition is not expected to be higher than that for zinc or copper bullets in case appropriate meat hygiene is applied.

Tungsten showed adverse effects on kidneys in a sub-chronic toxicity study in rats when a water-soluble salt was administered. However, like in the case of bismuth due to missing information on tungsten concentrations in game meat, no conclusion on human health risk can be drawn.

Environmental risks of alternatives

Aquatic toxicity

For aquatic toxicity, the Dossier Submitter presented information on the toxicity of shot alternatives to lead. In two studies, the leaching behaviour of various metals (lead, bismuth, copper, steel, zinc and tungsten) and their toxicity to *Daphnia magna* (EC50 value for 48 h immobilisation) of commonly available gunshot pellets was investigated under standardised medium for daphnids (Fäth et al., 2018) and under different water conditions (geology/redox conditions) (Fäth and Göttlein, 2019).

These studies used a high pellet/water ratio and concluded on the inadvisability for copper- and zinc-based as well as zinc-coated gunshot based on the high risks they pose to the aquatic environment.

Bismuth is considered a safer alternative than lead. No detectable leaching rate of bismuth or other metals (tin, nickel, iron, lead) was identified and therefore no immobilisation effects over Daphnia.

Stainless steel can be used to manufacture fishing sinkers and lures. It has been noted that stainless steel sinkers can leach cadmium and other elements under acidic conditions. However, the pH required is unlikely to be encountered during most fishing uses (Katz and Jelinski, 1999).

In the case of steel, when testing the leaching rate of two commercial steel shot, the leaching of iron itself was not reported (Fäth and Göttlein, 2019).

The same occurs with tungsten. When testing the leaching rate of a commercial tungsten shot (Ultimate) no leaching was observed. However, leaching of tin occurred under anaerobic conditions (Fäth and Göttlein, 2019). In its analysis the Dossier Submitter concludes that based on the available data there are no indications for aquatic toxicity, or other environmental hazard of tungsten used in shot and fishing tackle. The reported risk for aquatic toxicity of tin under anaerobic condition (Fäth and Göttlein, 2019) would require further investigations.

Results are summarised in Table 2 (Table C.3-8 from Annex C from the Background Document) with grey values representing those that exceeded the EC50 for *Daphnia magna* according to Khangarot and Ray (1989).

Table 2: Metal concentrations (in µmol/L) for different shot types during short- and long-term exposure leaching tests[1]

Shot type (main component)	Leached element	Metal concentration (µmol/L), mean ± standard error				
		ADaM	Siliceous (pH 6.5) aerobic	Calcareous (pH 7.6) aerobic	Siliceous (pH 6.5) anaerobic	Calcareous (pH 7.6) anaerobic
Short term period (1 day; 8 days)						
PL (Pb)	Pb	**1.81±0.26**	**1.77±0.36**	0.32±0.15	<LOQ	<LOQ[a]
	Sn	<LOD[b]	<LOQ	**0.39±0.06**	<LOQ	**0.31±0.08**

Shot type (main component)	**Leached element**	**Metal concentration (μmol/L), mean ± standard error**				
		ADaM	**Siliceous (pH 6.5) aerobic**	**Calcareous (pH 7.6) aerobic**	**Siliceous (pH 6.5) anaerobic**	**Calcareous (pH 7.6) anaerobic**
Blind Side (Fe)	Zn	**13.39±3.35**	**11.82±3.91**	2.47±0.26	0.21±0.01	<LOD
Hubertus (Zn)	Zn	**33.79±4.56**	**29.99±9.02**	3.96±0.81	1.33±0.19	<LOQ
Silver (Pb)	Ni	0.59±0.08	**0.68±0.09**	0.55±0.06	**1.56±0.47**	**0.65±0.10**
Sweet Copper (Cu)	Cu	**1.91±0.51**	**3.53±1.06**	**2.63±1.12**	0.14±0.01	<LOQ
Ultimate (W)	Sn	<LOD	<LOD	<LOD	0.89±0.29	0.89±0.44
Long-term period (15 days; 22 days)						
PL (Pb)	Pb	0.60±0.25	**4.30±1.12**	0.20±0.09	<LOQ	<LOQa
	Sb	<LOQ	<LOQ	**0.75±0.05**	<LOQ	0.59±0.05
Blind Side (Fe)	Cr	<LOQ	<LOQ	<LOQ	0.10±0.01	<LOQ
	Zn	**34.70±0.92**	24.82±1.29	3.78±0.16	0.49±0.11	<LOD[b]
Hubertus (Zn)	Zn	30.48±1.79	**55.71±3.75**	4.83±0.15	0.69±0.10	<LOQ
Silver (Pb)	Ni	**1.34±0.19**	0.52±0.02	0.31±0.04	**1.20±0.23**	<LOQ
Sweet Copper (Cu)	Cu	4.11±0.37	**5.92±0.27**	**6.35±0.10**	<LOQ	<LOQ
Ultimate (W)	Sn	<LOQ	<LOD	<LOD	**1.23±0.07**	0.65±0.08

Notes: [1] information as provided by (Fäth and Göttlein, 2019) including data from (Fäth et al., 2018);

Abbreviations: ADaM: standardized medium termed "Aachener Daphnien Medium; LOQ: Limit of quantification; LOD: limit of detection; bold values indicate homogeneous subsets with the significant highest concentrations among the tested environments determined by ANOVA. Grey shading represents those values that exceeded the EC50 for Daphnia magna according to (Khangarot and Ray, 1989)

Overall, RAC notes the aquatic toxicity of gunshot metal alternatives such as copper, zinc, nickel or brass will depend on the metal release and the characteristics of the environment to which these particles are released. These alternatives are not recommended for gunshot due to their risk to the aquatic compartment. Other alternatives such as steel, tungsten, tungsten-bronze or bismuth are considered of low risk for the aquatic environment. Data available show that these alternatives do not classify for the aquatic compartment and have low leaching rates (Fäth and Göttlein, 2019).

The Dossier Submitter considers that – in contrast to gunshot – aquatic toxicity of alternative bullets is less relevant because bullets might either remain in the carcass of the bagged animal or in the soil. In addition to exposure considerations, RAC also notes that copper and zinc massive are not classified for the aquatic compartment. When zinc is alloyed with copper to produce brass, its mobility in solution is lowered. Also, copper and brass bullets fragment less.

For fishing tackle, the Dossier Submitter considers that the available alternatives present less risk than lead from a human health and environmental standpoint, though there are some data gaps for zamac, zinc, ceramic, tin and bismuth, which makes a full comparison difficult. Further, many of the alternatives reported, such as tungsten, bismuth or tin were assessed as non-toxic for the wildlife in the US (US FWS, 1997) as alternatives to lead gunshot. The same conclusion can be reached for fishing sinker and lures. Also, none of the alternatives for sinkers and lures are classified for the aquatic environment in their massive form. Yet, this does not mean they are harmless, since metals such as zinc and brass, although less than lead, are toxic to wildlife.

In the case of fishing sinkers made of polymer, the Dossier Submitter mentions that they could fall under the definition of the restriction proposal on microplastics and could therefore not be placed on the market once the microplastic restriction is adopted and published in the official journal.

RAC agrees with the above reasoning and considers the alternatives available for fishing tackle present a risk reduction both for human health and the environment compared to lead. RAC also notes that losses of fishing tackle, no matter the material used, will continue, since the loss of fishing material in inherent to the fishing activity.

Potential of lead mobilising other metals in soil

The FITASC report (FITASC, 2020) states that shooting steel shot in areas where lead shot has previously been fired can be harmful for the environment. The literature review of field evidence from two lead-contaminated soil types with different soil chemistries (peatland with low pH and high organic matter; sandy moraine with neutral pH low organic matter) presented in the Ramboll report commissioned by the Dossier Submitter (Appendix 3 to the Background Document) shows the addition of steel shot has no significant effect on lead mobilisation, compared to steel-free samples. According to this study, there is no significant theoretical evidence of soil acidification related to the chemical reactions of iron in steel shots, due to both the fundamental chemistry of iron oxidation, the buffering capacity of soils and the greater contribution of other natural processes to soil acidification (e.g., microbes and acid rain). Ultimately there is little evidence that steel-induced acidity in soils would promote the mobility of lead.

Several stakeholder comments on this issue refer also the recent open-source evidence produced by Lisin et al. (2022), which they consider supporting the claim that the use of steel gunshot on shooting ranges will mobilise lead and other metals in soils at shooting ranges. This study was carefully evaluated by WCA (2022, Appendix 4 of the Background Document). The WCA (2022) analysis counters this view showing that field-based evidence does not support the claims in Lisin et al. regarding acceleration of lead migration or iron, impacts upon surface and ground waters. The weathering of soils and the binding of lead species to arising organic matter or iron hydroxide precipitates (from steel shot) reduces the potential for lead to be mobilised or cause toxicity. In fact, where iron hydroxide precipitates are present, they are a more important binding phase for lead species than organic matter.

RAC agrees with the Dossier Submitter and the recent analysis by WCA (2022) that there is no evidence that steel-induced acidity in soils would promote the mobility of lead.

Toxicity to wildlife

The toxicity to wildlife of alternatives was also assessed by the Dossier Submitter. For the case of coated lead alternatives, it is reported that attempts to coat lead shot to prevent the degradation and uptake of lead while in the gizzard/stomach of birds have all failed (USFWS, 1986), (Scheuhammer and Norris,1995), (Friend et al., 2009), Thomas (2019). The coating (if used for shot or fishing tackle) will wear off or will be dissolved in the highly acidic environment of the avian gizzard and stomach, exposing the lead core to the digestive actions of the gut. Some coatings of fluoropolymers, such as Teflon, have been assessed as non-toxic for wildlife and are approved by the US Fish and Wildlife Service but only on non-toxic cores made of material approved by the US Fish and Wildlife Service.

For non-lead alternatives, information is already available on eleven accepted (non-toxic) alternatives for hunting fowl (US FWS, 1997). These alternatives, used for hunting with shot, should also be safe for hunting with bullets. In addition, the Dossier Submitter presented data on the toxicity of various alternatives to birds which were fed with copper, iron/steel shot, tin, tungsten, etc (see Thomas, 2019; Franson et al. 2012; Krone et al., 2009b, Brewer et al., 2003, Thomas, 2016, Grandy IV et al., 1968, Pamphlett et al. 2000; Stoltenberg et al. 2003). RAC notes that the studies presented mainly involve dosing of birds with non-lead gunshot and the subsequent monitoring of acute endpoints, including mortality or body weight loss over periods of 30 days. From the alternatives assessed (copper, tungsten, tin, brass, zinc, bismuth and its alloys) only zinc showed toxicity to birds. Feeding of six zinc shots to 10 ducks did not results in mortality but in 80 % body weight loss during a four-week retention period. Presumably, discarded small fishing weights made of zinc would be also toxic to waterbirds that might ingest them. Further, tungsten alloys showed also carcinogenicity which derives from their nickel and cobalt content, and not the tungsten.

Chronic data was also presented. Chronic studies in which pure tungsten-based shot are placed, continuously, in the foregut of ducks over 150 days indicate that there are no adverse physiological effects, nor disruption of ducks' reproduction and development of their progeny (Thomas, 2016). When shot made of bismuth-tin alloy was implanted into mice intra-peritoneally for extended periods of time no toxic effects were reported (Pamphlett et al., 2000; Stoltenberg et al., 2003). Although mobilisation of bismuth from the shot occurred over months, no detrimental effects on weight gain, movements, and appetite were observed.

Substitutes for lead sinkers are made from e.g., pure tin, stainless steel, tungsten-plastics, and bismuth-tin alloys, all of which are non-toxic to wildlife

Nevertheless, RAC highlights uncertainties related to the chronic exposure of birds to the alternatives and to the toxicity of alternatives to raptors and scavengers which may consume spent bullets or their fragment and who usually have a lower stomach pH than the birds tested, increasing the probability of bullets being dissolved in their stomachs.

Other risks related to the alternatives

Concerns with steel relate to its potential to cause some choke expansion ("bulging"), particularly with heavy loads in very old traditional lightweight guns. Nevertheless, bulging was found not to be a significant issue over the twenty or so years since steel shot was introduced (Coburn, 1991). In comments received in the consultation of the Annex XV restriction report, it was highlighted that care is needed when shooting steel shot as it could ricochet more than lead (see e.g., comments by the Finnish Hunting Association, comments #3240, #3226). Ricochet was for instance a central part of the Danish debate during the transition from lead to non-lead gunshot in the 1990s since many actors were concerned that steel shot, would create an increase in ricochet accidents. Today, there is no evidence that the change from lead to non-lead shot has caused any change in risk of injury. Research from DEVA (DEVA, 2013) concluded that ricochet from lead and steel is comparable.

RAC notes that when hunting, in theory the risk of ricochet depends on the physical environment, i.e., the risk of hitting rocky surfaces and obstructions like bushes and trees. RAC is of the opinion that ricochet of steel does not represent a higher risk than if using lead. A further issue related to the substitution of lead with steel is the increase in generation of noise because of the increased pressure generated in the gun when using steel. RAC notes this can be an issue in particular if people are living in close proximity to shooting ranges.

Finally, the Dossier Submitter remarks that some of the comments received in the consultation of the Annex XV restriction report (comments by AFEMS, #3246) highlighted alternatives to lead could play a role in the ignition of forest fires by means of their ricochets causing sparks. The Dossier Submitter investigated these claims and found that (Finney et al., 2013):

"As with all fire behaviour and ignition research, moisture content of the organic material will be an important factor in ignition. Peat moisture contents of 3-5 %, air temperatures of 34-49 °C (98-120 °F), and relative humidity of 7 to 16 % were necessary to reliably observe ignitions in the experiments. Peat moisture contents above this (perhaps 8 %) did not produce ignitions. Field conditions matching the experimental range would imply summer-time temperatures, as well as solar heating of the ground surface and organic matter to produce a drier and warmer microclimate where bullet fragments are deposited."

RAC notes and agrees with the Dossier Submitter that is highly unlikely that when the European hunting season opens (legal hunting periods) these conditions will be met regularly. However, if hunting occurs outside the official season and alternatives indeed cause relatively greater sparks, this might result in an increased risk for forest fires.

4.3. Environmental Footprint of alternatives

In addition to the above assessment, the Dossier Submitter presented an analysis of the environmental footprint of the alternatives against the following criteria (see Wood E & IS GmbH, 2020):

- Toxicity and risk for human health

- Toxicity and risk for the environment (both aquatic and wildlife ingestion)

- Sourcing of the raw material to manufacture fishing tackle and ammunitions (extraction vs recycling)

- Resource depletion associated to the sourcing/production of the raw material and the manufacturing of fishing tackle and ammunition (at the end of the supply chain)

- Impact on climate change and in particular emission of greenhouse gases from the sourcing/production of the raw material, and the manufacturing process of fishing tackle and ammunition.

The analysis is not exhaustive and does not include a full Life Cycle Assessment but provides an indicative impact assessment of alternatives compared to lead using a qualitative approach. Although outside the remit of the restriction, it is considered relevant within the context of the future EU Chemicals strategy, and the EU Green Deal policy developed at the European level.

The outcome of this qualitative assessment presented by the Dossier Submitter is summarised in Table 3 below (Table C.4-7 from Annex C from the Background Document).

Table 3: Summary of the global environmental footprint of lead and its alternatives

Material	HH toxicity	Env toxicity (aqu.+wildlife)	Sourcing	Resources depletion	CO_{2e} emissions
Lead	High (1)	High (1)	Low (3)	Moderate (2)	Moderate (2)
Alternative metals					
Bismuth	-	-	High (1)	High (1)	High (1)
Copper	Moderate (2)	Moderate (2)	Moderate (2)	Moderate (2)	High (1)
Iron	-	-	Moderate (2)	Moderate (2)	Moderate (2)
Nickel	High (1)	Moderate (2)	Low (3)	High (1)	Moderate (2)
Tin	-	-	Low (3)	Moderate (2)	High (1)
Tungsten	-	-	Moderate (2)	Moderate (2)	High (1)

Zinc	Moderate (2)	High (1)	High (1)	Moderate (2)	Moderate (2)
Alternative alloys					
Brass (copper-zinc alloy)	-	-	Low (3)	Moderate (2)	Moderate (2)
Bronze (copper-tin alloy)	-	-	Low (3)	Moderate (2)	High (1)
Zamac (zinc-aluminium alloy)	-	-	Low (3)	Moderate (2)	Moderate (2)
Alternative steels					
Rebar	-	-	Low (3)	Moderate (2)	Moderate (2)
Stainless Steel (e.g., 11 % Cr, 8 % Ni)	-	-	Low (3)	Moderate (2)	Moderate (2)
Steel (Fe, <2 % carbon; 1 % Mn)	-	-	Low (3)	Moderate (2)	Moderate (2)
Other Inorganic					
Ceramic / glass	-	-	High (1)	Moderate (2)	Moderate (2)
Concrete	-	-	High (1)	High (1)	Low (3)
Stones / pebbles	-	-	Low (3)	Low (3)	Low (3)
Other Organic					
High density polymer	-	High (1)	Moderate (2)	Moderate (2)	High (1)

Source: based on Annex C, section C.4.5. from the Background Document, (Wood E & IS GmbH, 2020),and (Ichlokmanian; Bert, 2017)

RAC has no possibility to perform any detailed life-cycle analysis of these alternatives but in general supports the Dossier Submitter's view that there are alternatives (e.g., steel for gunshot, brass for bullets and several alternatives for fishing tackle) which are likely to result in clearly lower environmental footprint when compared to lead. However, the environmental footprint of bismuth and tungsten is, in combination with limited availability such, that the use of these metals should be limited to 'antique' shotguns that are not fit for steel gunshot.

5. Uncertainties

RAC acknowledges that information on alternatives have uncertainties associated with:

- Lack of reliable information on the concentration of metals in the air following controlled shooting with defined alternative shot and/or bullets compared to lead shot or bullets in outdoor shooting.
- Limited data on the metal concentration in game meat following the use of alternative shot or bullets other than copper and zinc bullets.
- Lack of sufficient studies on the potential hazard for the environment of some of the alternatives.
- Lack of data on the effects of chronic exposure of birds to alternatives and on the toxicity of alternatives to raptors and scavengers which may consume spent bullets or their fragments and who usually have a lower stomach pH than the birds tested increasing the probability of bullets being dissolved in their stomachs.

6. Conclusions

RAC concludes that in general the potential human health and environmental risks related to the use of alternative substances to lead are low. Many of the alternatives proposed present a lower risk to human health and the environment than lead. This is the case of the most common used alternatives for gunshot, i.e., bismuth, tungsten and steel as well as for copper and zinc and their alloys, which are used as an alternative for bullets. The same materials can be used also for fishing sinkers and lures and other types of ammunition.

The main human health concerns are related to the fumes/dusts from shooting, but these concerns are mainly related to indoor shooting or shooting in other poorly ventilated spaces which fall outside the scope of the present restriction proposal. Although home-casting of e.g., zinc materials may in principle result in the formation of zinc fumes, it is not even known if home- casting of zinc occurs. The main health concerns associated with zinc fumes are however related to inflammatory lung effects or metal fume fever caused by acute high-level exposures. Additionally, the risks presented by alternative non-lead -containing shot/bullets resulting from the consumption of contaminated game meat are estimated to be low compared to lead.

RAC concludes that for the environment, potential risks of alternatives are related to the aquatic toxicity and toxicity to wildlife. Especially discarded small fishing weights made of zinc may cause toxicity to waterbirds if ingested. Toxicity of both zinc and copper to the aquatic organisms depends on the rate of metal release and the characteristics of the environment to which these particles are released. Release is reduced with increasing particle size (from fine powder to massive particles like shot) and also with alloying. When zinc is alloyed with copper or tin to make brass or bronze, respectively, its mobility in solution is lowered. Therefore, brass and bronze, whether used in bullets or fishing weights, exhibit less potential toxicity to aquatic environment than fine zinc powder. RAC also concludes that there is no evidence to support the claim that steel-induced acidity in soils would promote the mobility of lead and therefore increase lead-caused risks to the environment.

RAC notes that the evaluation of the Dossier Submitter is also supported by the North America list of approved substances where alternatives were evaluated for non-toxicity.

7. References

Additional references not included in the Background Document to the opinion on the Annex XV dossier proposing restrictions on lead in outdoor shooting and fishing:

Fetter CW, Boving TB, Kreamer DK (2018). Contaminant Hydrogeology, 3rd edn. Waveland, Long Grove. ISBN-10: 1478632798

Committee for Risk Assessment (RAC)

Ad-hoc RAC Supporting Group

Evaluation of an

Annex XV dossier proposing a restriction on

Lead and its compounds

in outdoor shooting and fishing

Work Package B.3

Effectiveness of Risk Management Measures at shooting ranges

3 June 2022

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1. Description of the Work Package

1.1. Background

This work package report assesses the effectiveness and practicability of the risk management measures at shooting ranges for sports shooting. For the purpose of this assessment, a shooting range is considered as a designated temporary or permanent area where the use of ammunition, gunshot or projectiles made out of lead takes place. In Europe shooting ranges vary in size and type, ranging from large complexes which may be intended to host sports competitions (with state of art environmental risk management measures in place) to small areas used for recreational activities only (with only basic or no environmental risk management measures in place). Consequently, the design of a shooting range differs a lot among EU Member States.

The Dossier Submitter has used a qualitative approach to describe the risks resulting from sports shooting, considering different scenarios for use of lead gunshot and use of lead projectiles not defined as gunshot (i.e. bullets and airgun pellets). The Dossier Submitter considers that, in addition to the requirements specified in the CSR (2020) of the REACH registration dossiers, any agricultural use at a permanent range should be banned due to the residual risks to the environment. A remediation of the area at the end of life cycle would ensure removal of remaining contamination.

According to the Dossier Submitter, the environmental risks during service life and at the end of life for all types of shooting ranges are represented by risks to soil, surface (run-off) water, groundwater and to birds and livestock in shooting ranges and areas used as agricultural land. These risks have been evaluated by RAC under work packages WP A.1 and WP A.2. From there, the mortality in terrestrial birds is expected to be quite high in areas with intensive shooting activity. Grazing on or foraging from active or abandoned shooting ranges constitutes a risk for livestock (poultry, ruminants). Additionally, under the work package WP A.2, RAC concluded that risks to the environment during the service life and at the end of life of a shooting range/lands included significant risks to top soil, and the receiving surface (run-off) water but generally not to groundwater (or its derived drinking water)(but can be high locally depending on the soil characteristics and hydrogeological conditions). Monitoring and treatment of surface (run-off) water will be important to control this risk, as would the installation of risk management measures (RMMs) to control lead contaminated run-off water and prevent the pollution of any rivers and lakes/lagoons, and surface water in general.

The human health risks during shooting activities have been evaluated by RAC under work package WP A.3. RAC concluded that outdoor shooting using firearms (lead gunshot and other projectiles) results in exposure to lead and elevation of blood lead levels in shooters resulting in low to moderate risks. Shooting with airguns seems to result in lower risks to shooters.

The risks to environment and indirect human health receptors from uses of lead at shooting ranges have been evaluated by RAC under WP A.5. Evidence indicates potential moderate risks in permanent shooting areas where lead gunshot is used with no RMMs, or in intensive shooting areas.

Shooting ranges for lead gunshot are divided in temporary or permanent outdoor shooting areas with no RMMs in place, and permanent outdoor shooting areas with different levels of RMMs in place.

Shooting ranges for lead projectiles (e.g. bullets and airgun pellets) are divided in shooting ranges for rifle and pistols with different levels of RMMs (e.g., different types of berms, roof, remediation plan). The shooting can be further divided in static shooting (on targets) and dynamic shooting (on a moving target).

1.2 Objectives

The following topics are covered in the present work package:

- How effective the RMMs at shooting ranges are – the level of reduction or elimination of risks of exposure.
- The practicality of the RMMs at shooting ranges – the achievability of the suitability to implement containment and recovery measures.

2. Summary of the proposal by the Dossier Submitter

The restriction proposed by the Dossier Submitter includes a non-preferred derogation for the use of lead gunshot for sports shooting at designated shooting ranges. The proposal introduces a derogation for licenced individual athletes to use lead gunshot at a designated location that has a permit granted by the Member State for use of lead gunshot for sports shooting where the following measures are implemented: regular (at least once a year) lead gunshot recovery with >90 % effectiveness (calculated based on mass balance of lead used vs lead recovered in the previous year) to be achieved by appropriate means (such as wall and/or nets and/or surface coverage) and containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off control) to ensure compliance with the environmental quality standards (EQS) for lead specified under the Water Framework Directive to minimise the risks. In addition, the proposal contains a ban of any agricultural use within site boundary together with annual reporting to the Commission of permits, licences and quantity of used lead gunshot.

For the derogation of the use of other lead projectiles (e.g. bullets and airgun pellets) at shooting ranges, lead projectile containment and recovery is necessary via trap chamber or a ‘best practice’ sand trap comprising of a sand trap with a water impermeable barrier between the base of the sand trap and the underlying soil and an overhanging roof or a permanent cover. In addition, containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off) need to be in place to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive.

The Dossier Submitter considers that the risk management measures (RMMs) identified in the derogations for the use of lead gunshot and other projectiles in sports shooting are required to ensure an effective minimisation of risks resulting from the use of lead ammunition in shooting ranges. The recommended RMMs in the CSR of the registration dossier (CSR, 2020) are not appropriate in reducing the risks.

The CSR of the REACH registration (CSR, 2020), covers the use of lead ammunition in three different types of shooting ranges (outdoor pistol /rifle, clay target and sporting clay target range). The RMMs identified in the CSR to prevent releases during service life at the different types of shooting ranges are the following:

- Measures to prevent rivers from crossing the lead deposition area
- Bullet containment and recovery in the shooting range: at least one or a combination of bullet traps, trap chambers, sand/soil traps or steel traps or berms
- Overhanging roof over the lead impact zone to prevent surface water run-off
- Control of water run-off – immobilisation plan and drainage/collection system
- Lead shot deposition must be within the boundaries of the shooting range
- Remediation plan upon closure

The measures to prevent rivers crossing the deposition area, the collection of lead and the remediation plan upon closure are recommended for the three types of shooting ranges. Bullet containment and overhanging roof in the impact area are only recommended at outdoor pistol/rifle ranges while a water run-off control system is only defined for clay target ranges.

A remediation plan for the end of service life is recommended in the CSR of the REACH registration (CSR, 2020), suggesting that further actions are required in addition to applying RMMs during service life. This is because 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.

Training and competitions can take place at shooting ranges with varying degrees of operational conditions and risk management measures (e.g. using berms and/or nets, and/or surface coverage). However, the Dossier Submitter has noted that the recommended RMMs are not always in place. Additionally, different conditions and measures are specified by various international sport shooting organisations.

The Dossier Submitter has evaluated the effectiveness of the RMMs at shooting ranges at a qualitative level (see Table 1 below, Table 1-7 from the Background Document).

Table 1. Effectiveness of different RMMs applied in shooting ranges according to the Dossier Submitter

	Measure	effectiveness	Comment
Lead recovery	Wall and/or nets and/or soil coverage	Effective: effectiveness depending on the specific type of shooting practised and corresponding type of shooting ground	To achieve a high percentage of recovery, several measures might need to be in place. It may not be applicable in all types of shooting grounds (e.g. wooded areas for 'sporting' clays). Unrecovered lead gunshot may be ingested by birds.
	Bullet) traps such as trap chambers or sand traps with containment of the lead	Very effective	Regular lead recovery: is possible. Depending on the type of trap, measures may be needed to control surface and groundwater contamination
	Backstop berm (with or without a cover) and without an impermeable layer to soil)	Not effective	Often considered as a "safety" measure, specifically when no cover is present. Mechanical disturbance of the berm during lead recovery may increase soil and surface water contamination

	Measure	effectiveness	Comment
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 , especially at the end of service life when such measures would be discontinued. Amendment practices are not expected to be applicable in temporary shooting grounds	Adjustment of pH to reduce migration potential of lead expected to be discontinued at the end of service life
	Phosphate amendment		Immobilisation of lead in natural soil systems may not be successful; it may have a negative impact on the environment (eutrophication).
	Vegetation		Vegetation reduces mobilisation of lead but needs to be removed before or during lead recovery
Surface water (run-off) control	Such as: - Filter beds - Containment traps and detention ponds - Dams and dikes - Ground contouring	Effective	Especially in clay target ranges or rifle/pistol ranges with sand traps or sand/soil berms
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 that promote leaching of lead to groundwater; if leachate or groundwater measurements show elevated concentrations, remediation of the soil or installation of bullet trap is required
Remediation	remediation	Effective	Remediation is very expensive.

It is further noted that the appropriate RMMs should be implemented based on expert advice taking into account the location of the range and the site-specific characteristics. Also in many instances, RMMs (as surface water run-off control) applied during service life may need to be continued after the end of service life unless remediation is performed.

Human health risks from lead exposure to shooters are according to different contributions to the consultation (i.e., sport shooting federations and shooting associations) mitigated by:

- Providing training to shooters handling lead ammunition on the potential health risks and special training (e.g. risks in using black powder and shooting with muzzle loaders);
- Having good hygiene practice in place at the shooting ranges (guidance for washing hands, no food consumption when handling lead ammunition, use of gloves and keeping shooting clothes separate);
- An open air environment providing natural ventilation conditions;
- Lead containment in the cartridges: it has been stated that lead exposure to shooters can be reduced when using large calibre ammunition jacketed with copper and zinc;

- Shooting positions 2 to 2.5 metres apart;
- The firing distance to the target or berm preventing exposure from the projectile splashing;
- Roof-covered (outdoor) shooting ranges have ventilation conveying fresh air in the direction of the shooting openings and it has been also stated that the roof over the shooters may not extend more than 3m in front of the shooter.

3. Relevant information from the consultation of the Annex XV restriction report

During the consultation on the Annex XV dossier, around 100 comments from different stakeholders with relevance to this work package were submitted.

47 comments were received on measures to limit the release of lead gunshot to the environment from sport shooting. Some comments requested a ban on the use of lead gun shot in sport shooting. Other comments concerned the use of lead gunshot under strict environmental conditions, thus allowing a high recovery rate. These comments were taken into account by the Dossier Submitter in their refined assessment of several restriction options, including options for continuing the use of lead gunshot under strict environmental conditions (see Background Document section 2.3 and 1.4.4.2.2.1). For sports shooting with gunshot, the Dossier Submitter considers it necessary to specify both the regular recovery frequency (at least once a year) and the effectiveness of recovery (> 90 %) to minimise all identified risks.

83 comments were received on measures to limit the release of lead bullets to the environment. Also after the consultation the Dossier Submitter still proposes to only allow the use of lead bullets under strict environmental conditions at locations designated for sports shooting. The received comments demonstrate that the term "bullet trap" is used and understood in multiple ways. Consequently, the Dossier Submitter updated the Background Document to clarify the terminology used, e.g. by using the term 'trap chamber'.

In chapter 4.1.7.3. of the Background Document "Type of bullet containments", the Dossier Submitter in detail reflects on the received comments and amended the Background Document with the information received on the types of bullet containments (section 1.4.4.2) and assessed the impacts (section 2.6) on the identified risks via soil, surface water and groundwater caused by other bullet containment systems than bullet trap chambers such as i) sand traps (with an impermeable layer to soil), ii) sand/soil berms (without an impermeably layer to soil) and iii) soil berms. Based on this assessment, the Dossier Submitter now proposes to add as alternative to a bullet trap chamber a 'best practice sand trap', consisting of a sand trap with an impermeable layer to the soil, an overhanging roof or a coverage, and a water management system to contain, monitor and treat surface water.

In the original Annex XV report, the Dossier Submitter proposed '*Regular lead recovery with [>90 %] effectiveness (calculated based on mass balance of lead used vs lead recovered)*' as a condition under which the use of lead bullets on designated shooting areas could be derogated from the restriction. With the addition of a 'best practice' sand trap as an alternative bullet containment option, the Dossier Submitter considers that this specification of effectiveness is no longer applicable because lead bullet recovery might take place only every 3 to 5 years for a typical 'best practice sand trap'.

53 comments were received on the topic of "remediation". The comments confirmed that different legislations with regards to remediation of shooting ranges are in place across the EU and that not all shooting ranges may be remediated at the end of life. Therefore, the Dossier Submitter considers that the current restriction proposal with the implementation of strict RMMs at shooting ranges *during* service life would help to minimise lead mobilisation to the environment and would facilitate an effective "clean-up" of lead at the end of service life (see Background Document section 1.4.4). and that remediation is not required in the proposal.

RAC has assessed the comments and the responses from the Dossier Submitter and supports the Dossier Submitter.

4. Evaluation

The Dossier Submitter presents a number of risk management measures (RMMs) to control the identified risks which are described below. RAC supports the conclusion of the Dossier Submitter on the efficiency and practicality of the measures for risk reduction.

Measures to reduce the mobilisation of lead

The Dossier Submitter introduces several measures to reduce the **mobilisation** of lead described in the literature:

Lime amendment raises the pH of the topsoil and reduce the migration potential of lead. However, increase of the water-soluble lead in the berm have been shown which increases lead leaching from the berm. The effect of the treatment should be checked annually with multiple samples. Lime could be applied 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.

Phosphate amendment may theoretically bind the lead particles to form pyromorphite, but only if spreading is repeated frequently. However, because of high uncertainty about the effectivity, the phosphate amendment is not suitable equally for all different concentrations of lead contaminations.

Vegetative ground covers can mechanically impact the mobility of lead and lead compounds by the vegetation absorbing the rainwater, thereby reducing the time that lead is in contact with water. Also by slowing down surface water run-off, preventing the lead from migrating off-site. But this would require removal of the vegetation cover during recovery and could attract birds and wildlife which should be avoided to not facilitate lead ingestion. 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. New shooting ranges should be designed with as few plants as possible to improve lead recovery. RAC notes that recovery requires removal of the vegetation before or during this activity and that vegetation which attracts birds and other wildlife should be avoided to prevent potential ingestion of lead.

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.

Measures for surface (run-off) water and groundwater control

Surface (run-off) water control may influence the amount of lead transported offsite by surface water run-off depending on two factors: the amount of lead fragments left on the range and the velocity of the run-off. Run-off 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 run-off controls include:

- 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 run-off
- using vegetation and trees to prevent lead from being transported off site.

Synthetic liners (e.g. asphalt, Astroturf ™, rubber, other synthetic liners) are used to prevent leaching through lead contaminated soil, however creating increased run-off from new lead shot, which must be managed.

These run-off 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 run-off can reduce the amount of lead transported. The use of a roof to cover the berm may be an option at rifle and pistol ranges to reduce water run-off. 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.

Measurement of ground or leaching water is specifically relevant for older or shutdown 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. Monitoring of lead concentrations in surface (run-off) water from shooting ranges appears not to be very common. It is argued that when appropriate measures are applied (e.g. impermeable layer, frequent projectile removal, pH balancing), risks would be minimised and monitoring of groundwater would not be warranted.

An immobilisation plan and construction of a drainage and collection system for the management of lead-contaminated drainage water is often required, as lead shot is expected to remain on top of the soil between removal intervals with the risk of mobilisation to run-off water.

It is unclear whether appropriate monitoring of soil contamination is carried out in all EU countries.

Remediation of contaminated soil is the RMM often applied in case a risk to groundwater is to be assumed or has been demonstrated. It is the most expensive measure. Remediation is often performed in ranges located in a water sensitive area and being operated for several years or even decades with accumulation of lead shot or lead bullets in the soil. The level of implementation of this measure depends on the national legislation requirements to identify contaminated sites and on funding availability. Therefore, there is no certainty about the actual implementation of this measure, despite the recommendation for a remediation plan indicated in the CSR of the REACH registration (CSR, 2020) as a RMM to prevent lead releases. For those ranges with a regular recovery of lead shot and bullets, the need for remediation at the end of service life is expected to be limited compared to ranges where recovery of lead ammunition is not implemented. Recovery reduces the lead burden at shooting ranges. However, depending on the discipline and method of recovery, fragments may remain in the soil even after recovery. Therefore, remediation of a permanent range may be necessary at the end of service life, for example in case of risk to groundwater.

The Dossier Submitter concludes that lead shot and bullets are often deposited directly on and into soil during shooting and remain in the soil between removal and even after recovery measures have been applied with the risk of corrosion and mobilisation of lead to run-off water. The Dossier Submitter also adds that 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 is a key component to developing an effective lead management plan.

Lead gunshot recovery

There are different RMMs that can be implemented to improve the recovery of lead gunshot at shooting ranges. The range layout may be designed to optimize lead recovery with overlapping shot fall areas which may improve the efficiency of lead recovery. However, this measure can be applied effectively at trap/skeet ranges but may not be suitable for all shooting range layouts in the “sporting” shotgun disciplines.

An impermeable barrier could be applied at existing ranges. However, removal of the contaminated soil is needed before installation as noted by the Dossier Submitter. It would be ineffective to cover already contaminated soil with an impermeable barrier due to percolation and anaerobic soil conditions affecting the soil chemistry.

Vertical barriers are most frequently used e.g. walls and nets. Vertical barriers have the benefit to reduce the shot fall zone and to concentrate the lead shot to assist recovery.

Horizontal barriers may be additionally required for proper recovery of lead shot at shooting ranges and to ensure that no lead shot would land outside the range boundaries.

Mechanical intervention is done by extracting gunshot deposited on the surface and concealed in the ground with screening and purification equipment. Filtering and replacing the soil and cleaning of recovered gunshot allows to perform lead melting. No information was provided on the effectiveness of lead recovery using this method.

Manual interventions can be used to recover lead gunshot from difficult terrains. Lead collection from podzolic soils is claimed to be possible however, according to the information provided in the Background Document, it would require significant infrastructure when the shooting range is in operation. The recovery of lead from shooting ranges located in difficult terrain would usually only be possible after the final shut down of the shooting range.

Manually collecting lead shot by individuals have been shown to achieve up to 40% recovery rate. It has been mentioned by a shooting federation that at ranges with vertical barriers lead shot is collected and reclaimed one to three times a year, depending on the intensity of use either by hand using simple devices (broom and shovel) or smaller machines (wheel loader with trailer) during a period of one to two days.

Mechanical sieving can break down weathered metallic lead-bullets into small pieces, increasing total lead concentration in the soil.

Lead bullet containment and recovery

Different RMMs for the collection of bullets at shooting ranges are described in the Background Document.

Berms with or without an impermeable layer to soil catch ammunition usually into an earth/soil, gravel and/or sand layer so that the contamination hotspots are the target area and the berm.

The backstops and target area surfaces can be covered with a layer of wood chips, sawdust or similar to protect surrounding areas from secondary ricochets. This thick layer (approx. 50 cm) is reported to effectively prevent wildlife from ingesting bullets or shot in the backstop. A 'self-healing' surface coverage (e.g. cloth) or a rubber granulate layer containing a waterproof membrane on top of the soil embankment and a drain pipe could also be applied. The backstops and target areas may be covered with a roof or other permanent cover to prevent rainwater from contacting berms (e.g. for outdoor rifle and pistol ranges). The roof must be carefully designed to avoid safety issues as well as to avoid that the berm gets too dry so that it could crack and erode which would also increase the risk of contamination through wind as dust. A roof or a permanent cover could reduce the weathering of lead projectiles.

Sand berms (with low soil moisture, low organic matter and high pH) could slow down lead weathering, but may increase lead leachability in the long term. Weathering consists of both chemical (transformation of metallic to ionic lead) and physical reactions (transfer of lead-bullets to soil fraction). The use of 'bullet traps with sand' can be developed further (runoff control, the use of membranes, filters etc.) to minimise the possibility of leaching. Lead bullet weathering of 5 % in sand traps and 34 % in soil berms is reported.

Soil replacement is required for lead recovery from the backstops and the target area. Removal of contaminated soil and addition of new layer of soil and/or sand/soil is also relevant for minimising ricochet risk and to remedy slope integrity due to "impact pockets" development. Replacement of a soil berm with sand/soil berm has been shown to reduce lead bullet weathering as total leachable lead concentrations in sand is shown to be lower than in soil. Regular removal of the soil in the impact areas is particularly effective at new ranges when used regularly, allowing the removal of the most significant part of the ammunition. 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. Berm renovation can include regular removal or screening of the soil in the impact areas with an interval depending on the number of shots but recommended every three to five years. After screening the soil, soil can either be returned or disposed of as waste, whereas the lead can be recycled. Removal or screening of soil is considered suitable for new constructions and at a limited type of ranges (e.g. pistol and rifle) where the bullets accumulate in the impact areas. A more expensive but effective method is to remove the soil, separating any ammunition scrap and install a layer of new soil.

Sand traps comprise sand mass or a similar material contained within a concrete or other structure which is open towards the firing point. Sand absorbs the energy of the bullets and helps the separation of spent bullets and fragments during recovery and disposal operations. The base of the sand should be isolated from the underlying soil to prevent any lead contamination, infiltration water must be collected from the top of the lining via underground drains and treated if necessary. An overhanging baffle/roof should be fitted to prevent leaching and dissolving of lead bullet fragments. Ricochets risk should be mitigated by regular removal of accumulated bullets.

A 'best practice' sand trap is considered to consist of a sand trap with an impermeable layer to the underlying soil, covered either with an overhanging roof/baffle or other permanent cover combined with a water management system for containment, monitoring and treatment (where necessary) of surface (run-off) water and sub-surface drainage to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive. The 'best practice' sand traps could be an alternative to bullet trap chambers, especially for dynamic disciplines with a moving target where a trap chamber doesn't work. Recovery is typically done only every 3 to 5 years for 'best practice' sand traps, and can be rather high, without environmental releases, if done correctly.

Trap chambers are self-contained fully enclosed assemblies with an opening towards the shooting point adapted to the intended use and type of ammunition and typically made of metal. They allow for effectively controlled containment, easy and frequent collection and also recycling of lead projectiles.

According to the CSR of the registration dossier (CSR,2020), at least one or a combination of bullet trap chambers, sand traps or steel trap is required for bullet containment at shooting ranges. A berm covered with appropriate material or a wall may be required in addition to the bullet trap chamber (e.g. for biathlon or for silhouette shooting).

Recovery of bullets/lead from bullet trap chambers, sand berms, sand/soil berms or soil berms could create metal containing dust which need to be controlled with additional measures.

RAC evaluation of the effectiveness of the risk management measures

RAC agrees with the Dossier Submitter that different national regulations (implying the use of different types of risk management measures during the life cycle and at the end of life stage) may exist for the operation of shooting ranges, but that no EU harmonised measure is in place to manage risks resulting from the use of lead ammunition in sports shooting at shooting ranges. The Dossier Submitter notes that effective risk management measures at shooting ranges need to be site-specific taking into account various "factors" such as the type of shooting, ammunition used, slope of the site, type of soil, vegetation, climate, potential for run-off to surface water and potential for leaching to groundwater. Lack of a harmonised EU-wide framework for monitoring and removal of contamination of the surface or run-off water, groundwater and soil of the shooting ranges are supporting that lead contamination is likely and the need for EU measures.

RAC notes the need for application of a combination of appropriate RRMs for effective mitigation of risks from using lead ammunition at shooting ranges.

RAC agrees with the Dossier Submitter that the described measures available for theoretically reducing the mobilisation of lead (e.g., addition of phosphate or lime) are likely not effective enough in natural soil systems to hinder environmental contamination in the long term. This is due to the uncertainties in effectiveness of the applied measures such as mechanical sieving that can increase total lead concentration in soil. Another factor is the variability in practical applications at different shooting ranges throughout different practiced disciplines especially at the end of service life when such measures would be discontinued.

In contrast, almost 100% recovery has been achieved for trap chamber systems (for rifles, pistols and airgun weapons) and trap/skeet shotgun ranges with net systems and appropriately prepared deposition areas on earth walls and in the flat.

RAC also agrees with the Dossier Submitter that the described measures for surface (run-off) water and groundwater control are effective to reduce the risk of environmental contamination. As lead gunshot will remain on top of the soil for quite some time between removals, and projectiles in sand traps, with risk of mobilisation to surface (run-off) water, the design of the ranges require measures to manage lead-contaminated run-off water.

RAC notes that monitoring and treatment of surface (run-off) water will be important to control lead (residual) risks due to its mobility. In addition, monitoring of lead in the surface (run-off) and groundwater is key to detect and control lead contamination during and at the end of service life at shooting ranges.

RAC notes that lead ammunition accumulated in shooting ranges may represent a hot-spot of pollution which may result in leakage of lead polluted water into streams and lakes. The relevance and significance of different pathways is often site-specific and may or may not occur at any individual range. In areas of lead ammunition deposition in soil, lead concentrations can be extremely elevated and shotgun ranges are likely to have high levels of lead contamination compared to normal background levels in agricultural environments. RAC agrees with the Dossier Submitter that any agricultural use at shooting ranges should be banned due to evidence of lead contamination above the background level of the shooting range areas and the consequent residual risks for humans (via food) and for livestock.

RAC notes the need to mitigate (residual) risks from the use of lead ammunition at shooting ranges as lead related contamination may occur both on-site and away from the point of use (off-site), for example in: agricultural and/or residential, recreational soils as well as surface (run-off) water and/or groundwater and concomitant risks to birds and livestock (poultry, ruminants).

Adequate risk management measures implemented during the service life of a range are likely to reduce (to some extent) the need for subsequent remediation at the end of service life. Even if risks are minimised during the service life of the shooting range, remediation (e.g., final lead gunshot recovery with topsoil removal) at the cessation of use may still be required, depending on how the land will be used in the future.

RAC agrees with the Dossier Submitter that a remediation plan is a useful measure to ensure the removal of remaining contamination at the end of service life of a shooting range. RAC also supports the need to establish an immobilisation plan and construction of a drainage and collection system for the management of lead-contaminated drainage water.

Use of gunshot in shooting areas

For the use of gunshot in permanent shooting areas, RAC agrees with the Dossier Submitter that where RMMs are implemented such as regular at least once a year lead gunshot recovery and containment, soil protection, monitoring and treatment of surface (run-off) water, the level of risks are reduced. Consequently, RAC concludes that the environmental risks from lead gunshot can be minimised by using appropriate environmental RRMs.

Temporary outdoor shooting areas are considered to have limited shooting and thus likely lower environmental risks to soil, surface water and agricultural use but risks might rise to a relevant level in case lead gunshot accumulate in small areas. Also, even if there is fewer gunshot, there is still a risk for birds ingesting gunshot and for gunshot ending in harvested materials if agricultural use is allowed. Thus, there is still a risk to mitigate at temporary outdoor shooting areas.

Use of projectiles in shooting areas

Permanent outdoor rifle and pistol ranges with intensive shooting activity may today use sand/soil berms or soil berms to trap projectiles. Sand/soil berms are used frequently in Nordic countries. Soil berms are often used in old ranges that have been in operation for a long time. The Dossier Submitter considers the contamination of the berm area presents a high environmental risk to soil, surface water and potentially groundwater. Covering berms with a roof reduces the risk from the mobilisation of lead by rain/snow but does not minimise the risk of contamination of soil, groundwater or surface water. The Dossier Submitter notes that the effectiveness of recovery of lead bullets from sand/soil berms were reported to be 65 %. RAC agrees that the available data indicate that sand/soil berms are not sufficiently efficient in trapping lead. Trap chambers or 'best practice' sand traps applied on permanent outdoor rifle and pistol ranges are considered by the Dossier submitter to reflect the requirements specified in the CSR of the registration (CSR,2020) with appropriate containment as the main means to control the risk from lead projectiles. The Dossier Submitter considers that appropriate trap chambers allow recovery of up to 100 % of spent lead ammunition and notes that the data on recovery from 'best practice' sand traps are not available but are likely to be rather high. The Dossier Submitter considers that in case appropriate trap chambers or 'best practice' sand traps are used to contain the projectiles, the risks are minimised. RAC supports this assessment and requiring the use of appropriate trap chambers or 'best practice' sand traps at permanent shooting ranges for projectiles.

The Dossier Submitter considers that in addition to the requirements specified in the CSR (2020) for sand traps (containment with an overhanging roof and a sealing to soil), a water management system to contain, monitor and treat surface water would minimise lead contamination of water runoff. In addition, the required measure such as trap chamber or sand trap with an overhanging roof might not be suitable for dynamic shooting disciplines, for which a permanent cover would be required to reduce rainwater from entering the trap. In addition, any agricultural use should be banned due to the residual risks.

RAC agrees with the Dossier Submitter and considers bullet trap chambers and 'best practise' sand traps designed to minimise the risk to soil by an impermeable layer and to surface water by a water management system more effective measures than different type of berms for lead bullet containment.

Measures for the containment of lead bullets via trap chambers or sand traps (with a roof or cover and an impermeable barrier to the underlying soil) are already in place at many ranges in the EU, contributing to reduce the identified risk to the environment. However, the effectiveness of existing soil berms or sand/soil berms used frequently does not appear to be sufficient to control the identified risks. Renovation of existing sand traps, sand/soil berms or soil berms to 'best practice' sand traps would effectively contribute to control risks, especially risks related to the soil and surface water compartment.

The recovery rates for biathlon may be close to 100% if bullet trap chambers are used. RAC agrees with the Dossier Submitter that trap chambers can be considered effective measures to contain and recover both large and small calibre projectiles. Sand traps and soil berms are more frequently used, but depending on their design are likely to be (significantly) less effective in preventing release of lead to the environment. For dynamic disciplines sand traps or berms may be a more practical measure to contain projectiles, but could be significantly less effective in preventing subsequent release of lead to the environment.

RAC considers that a regular lead shot recovery rate of ≥90% may be achievable when using a combination of adequate RMMs at shooting ranges. However, in practice, these RMMs, as well as regular lead recovery, are today seldom implemented. It is further explained that >90% of effectiveness of recovery based on a mass balance is proposed as an operational threshold with an objective to achieve minimisation of releases of lead to balance high levels of recovery with practicality. The measures to regularly recover lead shot may in practice not reach 100% effectiveness, and a final clean-up of the site at the end of service life might be desirable. RAC concurs with these considerations.

RAC also notes the need to control also the generation of metal containing dust during screening of soil during bullet recovery from backstops.

5. Uncertainties

- There is an uncertainty as to the effectiveness of RMMs at gunshot shooting ranges.
- There is an uncertainty as to the effectiveness of RMMs at shooting ranges for projectiles (e.g., bullets).
- There are uncertainties as to the current implementation of water management systems and remediation plans.
- There is an uncertainty as to how collaborative sport shooting organisations will be, as their rules will affect the effectiveness of the proposed measures.
- The effectiveness of some currently used RMMs at shooting ranges are unclear.

Shooting ranges vary greatly in size and type, varying from state of art sites to shooting ranges with only basic or no RMMs in place during the life cycle and at the end of the life stage of the shooting range. Different shooting ranges have different capacity to achieve the minimum set measures of recovery or containment required. This is not discussed in the restriction dossier and RAC also lacks a discussion on whether the type of shooting activities, the different disciplines practiced, layout and size of the shooting ranges also influence the effectiveness of each RMMs. It is however mentioned that RMMs should be implemented taking into account the location of the range and the site-specific characteristics. Very effective recovery techniques for lead shot may be applicable only at specific type of ranges (trap and skeet) or applicable at new shooting ranges rather than at temporary ranges or at ‘sporting clay’ ranges. Specifying the precise means, such as walls and/or nets and/or surface coverage, to achieve >90% recovery as part of the derogation for using lead gunshot at shooting ranges cannot be done as the choices will depend on site-specific factors.

Concerning shooting ranges for projectiles, application of a combination of RRMs for effective mitigation of risks from using lead projectiles at shooting ranges is needed, but as shooting ranges differs in many aspects, it is unclear how effective different RMMs will be. Even though applying several measures at once may not be applicable for all types of ranges and/or disciplines for the purpose of reaching a high level of protection from lead contamination, a set of measures is needed depending on the type of ammunition used and the type of sport shooting. Trap chambers are likely to be very effective, but it is unclear precisely how effective best practice sand traps will be. Lead bullet recovery techniques such as removal and screening of soil is only suitable for specific types of ranges (pistol/rifle) and when a specific type of trap (chamber) is used. Berm soil management techniques have several limitations such as metal dust generation and the need to control for it as well as the costs associated with the transport of soil to be treated outside the area. Also the fine-grained metal remaining in the soil during screening activities may become mobile and the increased solubility of lead can thus contribute to soil and/or surface water contamination.

It is unclear to what extent effective water management systems are in place today. Surface (run-off) water control measures are considered especially relevant in clay target or rifle/pistol ranges with sand traps, sand/soil berms or soil berms. Groundwater monitoring is considered especially relevant for older shooting ranges located in water sensitive areas or with specific soil conditions that promote easy leaching of lead to groundwater. If leachate or groundwater measurements show elevated concentrations, remediation of the soil or installation of a bullet trap is required.

It is unclear to what extent remediation plans are in place, even though they are required in the CSR. RAC notes that the use of effective RMMs and water management systems may limit contamination of the environment, but when a shooting range is closed there is need for a remediation plan to limit future contamination of the environment.

As indicated by the potential need for the optional derogation, an uncertainty concerns to what extent the sport shooting organisations will collaborate with the intention of the restriction. It is such rules that require use of lead gunshot in some shooting disciplines. Thus, rules for the various types of shooting activities are set by various sport shooting organisations.

Several environmental RRMs used today at permanent shooting ranges have major limitations and uncertainties with regards to their effectiveness and practicality, e.g., phosphate amendment of soil. There may be also negative effects or additional risks involved with the application of the techniques. Phosphate application may cause increased run-off and contamination of surface water with phosphate and/or lead, possibly enhance the mobility and effects of other contaminants such as arsenic, or increase the growth of vegetation. Vegetation could attract birds and wildlife which should be avoided to not facilitate lead ingestion especially when designing new shooting ranges. Removal of impacted soil is hampered with increased vegetation where manual intervention to recover lead gunshot is required and a grass layer would need to be removed to recover the lead gunshot. There are unclear long-term effects on soil quality for agricultural purposes for some measures especially at the end of service life when such measures would be discontinued.

5. Conclusions

RAC concludes in line with the Dossier Submitter that in case of use of lead gunshot a regular lead recovery rate of > 90% must be achieved.

RAC supports having the effectiveness calculated based on mass balance of lead used vs lead recovered in the previous year. RAC acknowledges that a recovery rate expressed in percentage presents significant challenges for enforcement. The >90% of effectiveness is most probably only achievable with a combination of appropriate risk management measures that will vary depending on the type of shooting range and the type of shooting discipline.

In the case of the use of lead projectiles other than gunshot (bullets and airgun pellets), RAC concludes in line with the Dossier Submitter that at specific types of shooting ranges (e.g., target ranges) and specific types of shooting disciplines (e.g., Olympic sports shooting or biathlon) containment with bullet trap chambers may achieve very effective recovery (>90%). There is still some uncertainty remaining concerning the effectiveness of “best practise sand traps”, but RAC support their use as an alternative solution, especially needed for some specific shooting disciplines.

RAC notes and supports that the derogation for projectiles containment and recovery via trap chamber or a ‘best practice sand trap’ which should consist of a sand trap with a water impermeable barrier between the base of the sand trap and the underlying soil and an overhanging roof or a permanent cover.

RAC recommends remediation at the end of service life of shooting ranges.

RAC concludes that appropriate measures for soil, surface (run-off) water and groundwater control (including monitoring), containment and treatment would lead to mitigation of (residual) risks to birds, livestock and humans.

RAC supports the ban of any agricultural use within the shooting range boundary.

7. References

All references cited are included in the Background Document to the Opinion on the Annex XV dossier proposing restrictions on lead in outdoor shooting and fishing.