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

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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 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).

[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.

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 $\leq$ 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.

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

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

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

6. Conclusions

1. 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).

2. There is robust evidence for lead toxicity to birds through direct and indirect exposure/mechanisms.

3. 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.

4. There is robust evidence for lead being very toxic to domestic animals (livestock).

5. 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.

6. Direct exposure of birds is well documented both in aquatic and terrestrial environments.

7. 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).

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.