ANNEX XV INVESTIGATION REPORT

A review of the available information on lead in shot used in terrestrial environments, in ammunition and in fishing tackle

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1.1	13 September 2018	
1.2	17 September 2018	Corrected references on pages 38-39 and updated references list pages 84-85. Included findings on new study on page 39. Included Advice on game meat from ANSES in table 6 on page 43.
1.3	12 November 2018	Corrected tons of lead for bullets in executive summary (page 4)
1.4	27 November 2018	Corrected missing references

Report

Introduction

On 12 March 2015, the European Commission requested ECHA to prepare an Annex XV restriction dossier on lead in shot used in wetlands[1].

ECHA submitted the proposal on 12 April 2016 proposing a restriction on *the use of lead and its compounds in shot (containing lead in concentrations greater than 1 % by weight) for shooting with a shot gun within a wetland or where spent gunshot would land within a wetland, including at shooting ranges or shooting grounds in wetlands*[2].

ECHA's scientific committees evaluated the proposed restriction (https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/17005/term) and concluded the following:

- RAC concluded that the restriction proposed on lead in gunshot is an appropriate Union-wide measure to address the identified risk in terms of its effectiveness in reducing the risk, practicality and monitorability.
- SEAC concluded that the proposed restriction is the most appropriate EU-wide measure within the targeted scope of the mandate given to the Dossier Submitter.
- RAC concluded that the large-scale contamination of wetlands with thousands of tonnes of lead disposed annually from the use of lead gunshot for is clear.
- RAC concluded that lead poisoning of waterbirds through the ingestion of spent lead pellets results in the mortality of approximately one million waterbirds per year in the EU. Additional sub-lethal effects in waterbirds and the secondary poisoning of predatory or scavenging birds (documented e.g. for marsh harrier), as well as of humans consuming wetland game (e.g. ducks), is very likely. This is despite 24 Member States having legislation on this issue (albeit with varying scopes and effectiveness).
- SEAC concluded that the Dossier Submitter demonstrated that the benefits of the restriction to society will outweigh its costs without yet taking into account further on non-quantified benefits including impacts to human health. In addition, SEAC concluded that the assessment by the Dossier Submitter indicates that the cost to hunters seem to be reasonable, in particular when compared to the average budget of a hunter.
- ECHA's scientific committees concluded that the enforceability of the proposal would have been improved by a wider restriction covering all uses of lead shot. In particular, RAC and SEAC concluded: "Considering practicality and enforcement possibilities (see below), a restriction covering all use of lead gunshot (i.e. a total ban) would be the most appropriate measure."

[1] https://echa.europa.eu/documents/10162/13641/echa_annex_xv_restriction_proposals_en.pdf/ed07424a-328d-88e0-b7c6-412251426582. This included all forms of shooting (i.e. hunting and sport shooting) where spent shot would fall into a wetland.

[2] https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/17005/term

The opinion of ECHA's scientific committees was sent to the Commission on 17 August 2018; the Commission has three months to prepare their draft decision.

In addition to preparing the Annex XV restriction proposal for the use of 'lead in shot in or over wetlands', the Commission asked ECHA to start collecting information on the potential risks to human health and/or the environment posed by several other uses of lead.

This would include relevant information on socio-economic considerations (e.g. on the suitability of alternatives) required to prepare an Annex XV restriction report for these uses should they be considered to potentially pose an EU-wide risk. The specific uses considered were:

1. the use of lead in ammunition (shot and bullets) for hunting in terrains outside of wetlands (i.e. in terrestrial environments) and for target shooting[3] outside of wetlands;

2. the use of lead sinkers and jigs for fishing.

Information was obtained through a call for evidence conducted for the preparation of the lead in shot over wetlands dossier, literature reviews and discussions with relevant experts, including the European Food Safety Authority (EFSA), the United Nations Secretariat of the Convention on the Conservation of Migratory Species of Wild Animals (UN CMS)[4] , members of the European Federation for Hunting and Conservation (FACE)[5] and of the Lead Ammunition Group (LAG)[6].

This report summarises the information that has been collected until now and their key findings (individual reports on the three topics are provided as annexes). It provides a preliminary appraisal of the availability, reliability and significance of the information collated in relation to the requirements of an Annex XV restriction report, prior to the preparation of an Annex XV report.

Key uncertainties, assumptions and information gaps, in relation to the required elements of an Annex XV restriction report, are identified.

The report concludes that there is sufficient evidence to justify further measures the use of lead in fishing weights and in ammunition (shot and bullets).

[3] This has been separated in this report into two categories: lead shot used in terrestrial environments and lead bullets used in terrestrial environments.

[4] https://www.unbonn.org/index.php/CMS

[5] https://www.face.eu/

[6] http://www.leadammunitiongroup.org.uk/

Summary

Use of lead gunshot in the terrestrial areas

The available information suggests that the use of lead gunshot in terrestrial areas[7] poses a risk to both human health and the environment. This builds on the evidence presented in the proposal to restrict the use of lead in shot in wetlands. In general:

- The use of lead gunshot in terrestrial areas can lead to the lead poisoning of various species in terrestrial areas, including predators and scavengers affected through secondary poisoning. Some species of waterbirds (e.g. geese and swans) forage for food and grit in terrestrial areas and can ingest lead while doing so (resulting in lead poisoning), as discussed in the proposed restriction on the use of lead gunshot in or over wetlands[8]. To protect these species entirely and fully implement the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA)[9], further regulatory action on the use of lead gunshot in terrestrial areas would be necessary.
- Of the EU member States currently only the Netherlands, Denmark and the Flemish Part of Belgium have restricted the use of lead outside of wetlands.
- Humans are exposed to lead through the consumption of lead contaminated game meat (hunted with both lead shot and lead ammunition).
- Alternatives to lead gunshot ammunition are available (mainly steel, bismuth and tungsten as with lead in shot in wetlands). A detailed analysis of the economic impacts of substitution in terrestrial areast has not been carried out for the purposes of this report. However, it is likely that the underlying assumptions on the requirement to replace shotguns or the relative price differential between lead and lead-free shotgun ammunition are the same from those used in the assessment of the impacts of a restriction on lead gunshot used in wetlands. Indeed, some of the costs to hunters who hunt in both wetland and terrestrial environments have already been taken into account in the lead in shot in wetlands impact assessment. The previous work on the use of lead shot in wetlands demonstrates that the adaptation cost for an individual hunter is limited and it is unlikely that this conclusion would be different for uses of lead shotgun ammunition in terrestrial areas.
- It is estimated that in the EU around 14 000 tons of lead shot per years is dispersed into the terrestrial areas. This could lead, as a very preliminary assessment, extrapolated from the mortality in wetlands to 1 to 2 million birds dying each year.
- Shooting ranges using lead shot represent a significant risk of soil contamination in terrestrial areas, and risk contaminating nearby (ground) water sources in the EU.

[7] With Terrestrial areas, we mean : outside of wetlands.

[8] The assessment submitted by the AEWA Secretariat in the Public Consultation on the use of lead shot in or over wetlands, confirmed that the majority of waterbirds species vulnerable to lead poisoning (85 out of 100 AEWA-listed species) feed primarily in wetlands.

[9] http://www.unep-aewa.org/

- It is estimated that sports shooters in the EU consume around 10 000 to 20 00 tonnes of lead per year.
- A comprehensive, Union wide measure, such as a restriction on the use of lead across all habitats would simplify any enforcement activities by Member States (see introduction).

Use of lead in other types of civilian ammunition

- Similar to shotgun pellets, other types of lead ammunition[10] (e.g. rifle bullets) 'fragment' upon impact resulting in a dispersion of lead in the tissues of the target. This dispersed lead is often believed to be removable by cutting away and discarding tissue from around the wound channel. However, recent research suggests that lead fragments disperse widely as microscopic particles (potentially as nanoparticles) in tissues and that cutting away tissues from around the wound channel is not sufficient to remove all lead that would be available for human consumption. Therefore, the consumption of game shot with lead-based ammunition can result in exposure to consumers. As lead is considered a non-threshold toxicant, the consumption results in risks to humans, particularly in large consumers of game, related to various endpoints, notably neurodevelopment in children.
- Hunters traditionally remove the entrails of quarry killed in the field and either leave this on the ground or bury it. Hunters do this for food hygiene reasons. The entrails (which contain fragments of lead ammunition) are consumed by animals (including birds and mammals), irrespective of whether they are buried or not, resulting in exposure to lead and lead poisoning[11].
- Within the EU there is no Member State that has regulated the use of lead in civilian ammunition, there are however regional and local bans in place in the German lander, some regions in Italy and some national parks among which Parco Nazionale Stelvio, Italy.
- In 2004 more than 150 tonnes of lead was dispersed into the environment by hunting with lead bullets.
- Dealing with the exposure of humans by regulating the maximum level (ML) of allowable lead in food, under Regulation EC1881 (2006) for example, would not suffice. As this measure would target game meat only and does not address lead ingestion by raptors and scavengers.
- It is concluded that elimination of lead at the source (i.e. restricting the use of lead ammunition) is the most appropriate solution as:
  1. Lead concentrations in shot animals remain (lead fragments can be distant from the wound channel)
  2. Game meat is often consumed by hunters outside of food control mechanisms.
  3. The measure would protect scavengers and predators (birds and mammals) from

[10] This report only covers civilian use of ammunition, military uses and uses for police purposes are not covered in this report.

[11] Part of the tradition actually comes from intentionally leaving this meat for other animals.

secondary lead poisoning.

4. Suitable alternatives are available and thus there is no need to replace existing guns.

- Should further regulatory action be required then there is a need to explore how differentiations can be made between shooting for spots and hunting purposes.

Use of lead in fishing tackle e.g. weights, sinkers and lures

- Lead-based fishing tackle is frequently lost during use. In fact, some contemporary fishing practices encourage the deliberate release of lead weights to the aquatic environment in some circumstances (termed as 'dropping the lead'; to ensure fish welfare in the event that rigs are lost or snagged).
- Several EU Member States (DK, SE, UK) have existing legislation or voluntary agreements prohibiting the use of lead in fishing tackle. In some cases, only certain sizes of weights/sinkers have been prohibited as these are thought to pose the greatest risk to birds. Restrictions are also in place in North America. The European Fishing Tackle Trade Association (EFTTA) published a position paper in June 2015 calling on the European fishing tackle trade to phase out lead fishing weights (sinkers) heavier than 0.06 grams.
- It is estimated that in the EU as much as 2000-6000 tonnes of lead is dispersed into the environment by fishing with lead sinkers per year.
- Risks (in terms of mortality) of waterbirds has been linked to the use of lead fishing weights. There is extensive information available on the decline (and subsequent recovery after risk management) of the mute swan *Cygnus olor* in the UK (Kirby et al., 1994) and Ireland (O'Halloran et al., 1998) as a result of ingestion of lead fishing weights. These risks are unlikely to be limited to these two Member States as these species and the use of lead fishing weights are ubiquitous throughout the EU.
- The majority of other data on ingestion in other species (e.g. divers/loons) is from observations reported from studies in North America (Scheuhammer et al., 2003; Sidor et al., 2003). However, the feeding behaviour and ecology of affected species of waterbirds (can be expected to be similar in European populations; resulting in similar risks. To protect these European populations further regulatory action adressing the use of lead in fishing sinkers may be necessary.
- Risks are predominantly associated with ingestion of lead weights of a certain size range. These types of weight tend not to be used in commercial fishing. However, long-term dissolution of all lost/discarded lead-based fishing tackle in the aquatic environment will contribute to overall exposures of lead to the environment.
- The advantages and drawbacks of restricting the marketing and use of fishing sinkers were investigated in detail in a study contracted by the European Commission to COWI (European Commission, 2004). The study investigated releases to the environment and the social costs of phasing out the use of lead in recreational and commercial fishing in the EU and included an analysis of the suitability, availability and relative cost of alternatives. The total estimated cost in the EU-25 for various phase-out options ranged from € 0.6 million to € 207 million per year, depending on the scope of phase out. Corresponding cost-effectiveness estimates for the different phase-out options

ranged from € 300 to € 39 000 per tonne of emission avoided. Although now relatively old, this study incorporates most of the necessary information for preparing an Annex XV restriction on the use of lead in commercial and/or recreational fishing.

- In addition, the practice of home 'casting' of various types of lead-based fishing tackle for recreational anglers appears, based on the predominance of online retailers, to be widespread. The risks of consumer exposure to lead containing dusts or vapours during these activities appears to be likely and appropriate and effective risk management measures are not always consistently used to minimise the associated risks. The risks from this practice could also be addressed by further regulatory action.
- It is therefore concluded that the risk from lead in fishing tackle could be significantly reduced through a restriction on their marketing and use.

Use of lead ammunition at shooting ranges

- Further work is need to establish to what extent bullet type and calibres differ between sport shooting and hunting based on i.e. bullet type..
- There are growing concerns in the scientific community on the exposure of target shooters to lead dust used in lead ammunition, primers and propellants.
- There could be an added value in setting minimum risk management measures (RMMs) for lead exposure and emission control at shooting ranges.

Part I: Use of lead gunshot in the terrestrial areas

1. Introduction

This part provides an initial qualitative analysis of the risks and impact of the use of lead gunshot in the terrestrial areas i.e. the use of lead gunshot outside of wetlands[12]. The report builds on the restriction proposal on the use of lead in gunshot in or over wetlands[13], prepared by ECHA at the request of the Commission.

Lead gunshot is used in the terrestrial environment both for hunting and sports shooting. Hunted game are usually small animals like pheasant, rabbit, hare and fox. However, larger game like wildboar are also hunted using lead gunshot.

1.1. Hazard, exposure, emissions and risk

1.1.1. Hazard

Lead is a toxic heavy metal and is non-essential (i.e. having no biological function). It is a non-specific poison affecting most body systems, having negative effects on general health, reproduction and behaviour.

Absorbed lead affects all animals, from migratory birds to humans (Green and Pain, 2015). Lead presents risks to wildlife, especially wild birds (Watson et al., 2009; Pain et al., 2015), as well as domestic stock (Payne et al., 2013).

Lead-based ammunition is considered to be the most significant unregulated source of lead deliberately emitted into the environment in the EU (Group of Scientists 2014)[14].

Lead differs from many contaminants in that there is no evidence for a threshold for a number of critical endpoints including developmental neurotoxicity and nephrotoxicity, i.e. there is no level below which observable effects in humans cannot be seen (EFSA 2013).

Birds

The proposed restriction on the use of lead in shot in or over wetlands, contains a comprehensive review of the hazard information for wetland birds. It should be noted that some wetland species (such as geese and swans) also feed in terrestrial environments.

This chapter provides a non-exhaustive overview related to the terrestrial environment. Terrestrial birds are exposed to lead ammunition through ingestion of pellets as wetland birds.

The two principal routes by which birds can be exposed to spent lead gunshot are:

- **Primary ingestion**. This is defined for the purposes of this report as the ingestion of lead gunshot by birds through normal feeding or foraging activity whereby birds

[12] Wetlands defined according to the Ramsar Convention.

[13] https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/17005/term

[14] https://www.zoo.cam.ac.uk/research/groups/conservation-science/European-Statement

mistake lead gunshot for food or 'grit' normally ingested to facilitate the grinding of food within the gizzard.

- **Secondary ingestion.** This is defined for the purposes of this report as the ingestion of lead gunshot or fragments of lead gunshot through the consumption of prey or a scavenged carcass (including unretrieved quarry). Secondary poisoning can also occur through the consumption of tissues that have accumulated lead as a result of the dissolution of ingested or embedded gunshot.

Some typical terrestrial species, such as members of the order of galliforms (e.g. grouse, pheasant, quail and partridge) and doves, can ingest spent shot as grit while raptors are usually poisoned through ingesting lead shot or bullet fragments in dead or injured prey or gut piles (Friend, 1987; Kendall et al., 1996).

In general, the likelihood of a bird becoming poisoned is related to the retention time of lead shot within the gut, frequency and history of exposure to lead, and factors such as nutritional status and environmental stress (Pattee and Pain, 2003). A proportion of exposed birds will die and mortality can occur following the ingestion of just one lead gunshot (Pain and Rattner, 1988).

Raptors and scavenger birds are especially affected by lead poisoning (Miller et al., 2002; Golden et al., 2016). Lead is rapidly dissolved in raptor stomachs, and subsequently absorbed. When large amounts of lead are rapidly absorbed, illness and death can be sudden, in apparently good physical condition, and birds may die. All raptor species that feed on game could potentially be exposed (via ingestion) to lead, the likelihood varying according to the proportion of game in the diet, the size of game taken, the season, and the local hunting intensity (Pain et al., 1993).

Ingested lead fragments may be rapidly regurgitated, for example, in the pellets of raptors, or may be retained in the gut for longer periods resulting in complete dissolution of lead and absorption into the bloodstream. Ingestion of lead fragments usually results in at least some absorption of lead. Where sufficient lead is absorbed, poisoning ensues.

Lead concentrations are generally highest in the blood directly after absorption, and in liver and kidneys for days to months after absorption. Lead deposited in bone can remain for years, and reflects lifetime exposure (Pain, 1996).

Various authors have attempted to define tissue concentrations in birds indicative of excessive exposure, sub-lethal poisoning and acute poisoning (Franson et al., 1996; Pain, 1996). These concentrations vary somewhat between taxa, and the diagnosis of poisoning is usually based on signs of poisoning in combination with blood lead levels in live birds, and on tissue concentrations, sometimes, but not necessarily, in combination with evidence of exposure to lead in dead birds. Other than in cases of point source contamination, high concentrations in the tissues of birds result primarily from the ingestion of ammunition or anglers' weights (Fisher et al., 2006).

The effects of acute lead toxicity in birds commonly include distension of the proventriculus, green watery faeces, weight loss, anaemia and drooping posture (Redig et al., 1980; Reiser and Temple, 1981; Franson et al., 1983; Custer et al., 1984; Sanderson and Bellrose, 1986; Mateo, 1998b). Sub-lethal toxic effects are exerted on the nervous system, kidneys and circulatory system, resulting in physiological, biochemical and behavioural changes (Scheuhammer, 1987). Vitamin metabolism can be affected (Baksi and Kenny, 1978), and birds can go blind (Pattee et al., 1981). Lead toxicosis depresses the activity of certain blood enzymes, such as delta aminolevulinic acid dehydratase (ALAD), essential for haemoglobin production, and may impair immune function (Grasman and Scanlon, 1995; Redig et al., 1991). Over longer periods, haematocrit and haemoglobin levels are often reduced. As a result of physiological and behavioural changes, birds may become increasingly susceptible to predation, starvation and infection by disease, increasing the probability of death from other causes (Scheuhammer and Norris, 1996).

Lead can affect reproductive success. Grandjean (1976) showed a correlation between thin eggshells and high concentrations of lead in European kestrels (*Falco tinnunculus*), and poisoning significantly decreased egg production in captive Japanese quail (*Coturnix japonica*) (Edens and Garlich, 1983). However, in the Spanish imperial eagle (*Aquila adalberti*) only low lead levels were found in eggs, despite adult contamination (Gonza´ lez and Hiraldo, 1988). In ringed turtle doves (*Streptopelia risoria*), significant testicular degeneration has been reported in adults following shot ingestion (Kendall and Scanlon, 1981; Veit et al., 1982) and seminiferous tubules may be devoid of sperm (Kendall et al., 1981). Locke and Friend (1992) concluded from their wide-ranging study that all bird species would be susceptible to lead poisoning after ingesting and retaining shot.

More recently, Vallverdú-Coll et al. (2015b) studied the developmental effect of lead in mallard ducklings hatched from field collected eggs in the Ebro delta (Spain). The prevalence of lead shot ingestion in this wetland was around 30 %, so mallard hens could frequently be exposed to lead shot before and during the laying season. Ducklings with blood lead levels above 180 ng/mL showed reduced body mass and died during the first week post hatching. Although mallards are waterbirds, it is likely that also terrestrial species might be similarly affected.

Other recent studies (Vallverdú-Coll et al., 2016b) indicate that the adverse effects of lead can be also observed in the reproductive function of males, as it has been found in bird species (other than mallards), in particular on the integrity of the acrosome and the motility of the spermatozoa, which can have consequences on the oocyte fecundation.

In general, while acute exposure results in death of the animal, chronic sublethal exposure may have severe consequences on reproduction, antioxidant defense and on the immunity system. Additional information would need to be gathered to evaluate these aspects.

Animals other than birds

Lead poisoning from shot ingestion has also been reported in mammals, such as cattle. Scheuhammer and Norris (1996) reported that some studies indicated that dairy cattle fed grass or corn silage contaminated by lead shot can suffer from lead poisoning (Howard and Braum, 1980; Frape and Pringle, 1984; Rice et al., 1987).

Rice et al. (1987) reported that in 14 steers fed chopped silage prepared from a field that had been used for clay target shooting, one animal died, a second demonstrated clinical signs of lead poisoning, and all animals had substantially inhibited ALAD enzyme activity (a sensitive biomarker of elevated lead exposure)[15].

In addition, several shooting ranges have been found to give rise to a significant run-off of heavy metals (as referred to by Mariussen et al., 2012). Domestic animals or wildlife may drink from contaminated streams or they may graze on contaminated pasture in the shooting range area (Mariussen et al., 2012).

In general, the deposition of ammunition residues in shooting ranges may pose a threat to the surrounding environment and fauna.

Human health

Lead affects humans in a similar way to other animals, the highest impacts are on the nervous system, especially on the developing brain in babies and young children. Hazard information is extensively discussed in the "Annex XV Restriction Report on Lead in Shot", published by ECHA in 2017[16]. Here some key elements and only a few studies (as examples) are reported.

Lead shot can 'fragment' after hitting quarry animals resulting in smaller particles of lead being distributed within the tissues of an animal. Some of these fragments may reside in tissues a considerable distance from the primary wound and remain there after butchery and food preparation (Green and Pain, 2015). According to the available evidence, it is not possible for consumers to successfully remove all embedded fragments of lead from the wound channels of shotgun shot game. Tiny lead particles would go unnoticed by consumers. In addition, removing lead pellets may not be a practical option for game meat retailers either. In the UK, the Food Standards Agency, referring to the sale of small game, in a risk assessment (FSA 2012), stated that:

"Regarding sale of small game, colleagues from the FSA Operations Group have indicated that the lead pellets are very small and it would be impractical to ensure they are removed during the dressing procedure: trying to remove them would be very time consuming and would cause damage to the birds which would likely make them unsellable."

Pain et al. (2010) examined wild shot in gamebirds[17] (mainly terrestrial birds) obtained in the UK to determine the potential hazard to human health from exposure to fragments of

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[15] It was further noted that, even when lead pellets were removed, samples of silage still contained an average of 0.23 % of lead, which would have resulted in the ingestion of about 18 grams 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 shot pellets. The mechanical/chemical process of producing silage from material containing lead pellets may be a more important risk factor than ingestion of lead shot pellets per se.

[16] In addition, in the Response to Comments (RCOM) document replying to comments received in the public consultation on the lead in shot in wetlands dossier, the Dossier Submitter (ECHA) assesses additional evidence submitted on the non-threshold nature of certain effects of lead and concludes this new information does not change its original assessment that lead is non-threshold.

[17] Wild-shot pheasant (*Phasianus colchicus*), red-legged partridge (*Alectoris rufa*), woodpigeon (*Columba palumbus*), red grouse (*Lagopus lagopus*), woodcock (*Scolopax rusticola*) and mallard (*Anas platyrhynchos*).

shot in the tissues. During X-ray analysis, the study found small fragments in 76 % of the 121 gamebirds examined. Most fragments were less than about a tenth of a shot in size. The fragments were sometimes clustered around bone, but sometimes appeared to be scattered throughout the bird.

The authors noted that small fragments cannot be effectively removed because they are both too small to be detected by the human eye, and because their removal would require discarding a large proportion of the gamebird carcass. Usually when a gamebird is killed, several shot have penetrated it and the lead fragments and high tissue lead concentrations remain even when those shot pass through the bird, as sometimes happens.

Proportions of samples exceeding 100, 1 000 and 10 000 ppb[18] by wet weight (chosen as thresholds), were calculated. The thresholds 100, 1 000 and 10 000 ppb by wet weight (w/w), are equivalent to 0.1, 1.0 and 10 mg/kg or ppm[19]. 100 ppb wet weight is the EU (1881/2006) ML (maximum level) permitted in bovine animals, sheep, pigs and poultry (excluding offal). No ML has been set for game.

Pain et al. (2010) found that a high proportion of samples had lead concentrations exceeding 100 ppb w/w (0.1 mg/kg w/w).

Another important parameter when considering the bioavailability of lead present in game meat for consumers is cooking. Cooking methods may affect the bioavailability of lead in game meat. Mateo et al. (2007) reported that cooking small game meat under acidic conditions (i.e. using vinegar) increases the final lead concentration in the meat as well as its bioavailability. 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).

Green and Pain (2015) reported that, in general, the bioavailability of dietary lead derived from ammunition (the proportion of the ingested amount which is absorbed and enters the blood) can be expected to be lower than that of other lead compounds in food. This is thought to be because some of the ingested ammunition lead may remain as metallic fragments after cooking and digestion. However, while the absolute bioavailability of ammunition-derived lead may be lower than that of lead in the general diet, the minimum plausible value of absolute bioavailability is nonetheless substantial and capable of causing elevation of blood lead concentrations.

1.1.2. Exposure/emissions

Environmental emissions

The total emissions of lead from hunting (cartridges only) estimated by the consultancy firm AMEC (2012), was about 21 000 tonnes for the EU 27. However, other estimates of

[18] Parts per billion.

[19] Parts per million

annual releases of lead gunshot, indicate the tonnage is probably significantly higher: (using average values of lead shot) 6 000 tonnes in Spain[20]; 4 600-10 000 tonnes in Italy[21]; 8 000-13 000 tonnes in the UK[22] .

Hirschfeld and Heyd (2005) estimated that the total amount of birds shot annually in Europe is about 101 million. Taking a hit rate of between 0.2 and 0.06 shots per bird, an average lead content of 30 g per cartridge and some 100 million birds shot annually, a potential yearly consumption of between 15 000 and 50 000 tonnes of lead was calculated.

Based on the information on cartridge consumptions that was reported in the AMEC report (AMEC, 2012), an estimation was in made the 'Annex XV report on lead in shots over wetlands' that the proposed measure would reduce the amount of lead emissions from 21 000 tonnes to around 7 000 tonnes which would imply that around **14 000 tonnes of lead would be dispersed into terrestrial areas**.

In Norway, the use of lead shot at shooting ranges has been prohibited since 2002. Specifically, in Norway there is a total ban on the use of lead shot at shooting ranges, without any differentiation between shooting ranges within and outside of wetlands. Training of hunters is therefore carried out in Norway using alternative materials – mostly steel.

In Sweden, sport shooting with lead shot is also totally banned. There is a derogation for shooters who compete on the Olympic level in the games trap and skeet, but these few shooters represent only a tiny fraction of the whole.

In Germany, 39 out of 662 shooting ranges (5.8 %) have only been mandated to use non-lead shot since 2004[23]. However, no information is currently available on the emissions.

In Finland, according to the available information there is no specific ban on the use of lead shot in shooting ranges. According to Sorvari et al. (2006), there are between 2 000 and 2 500 outdoor shooting ranges (using both shot and bullets) in Finland. A survey on both military and civilian ranges, estimated in this country an annual deposit of approximately 500 kg lead per range (cited by Strømseng et al., 2009).

Further data would need to be gathered from other Member States.

Lead shot densities in hunting estates and shooting ranges

According to Mateo (2009), lead shot densities in upland habitats have not been well studied compared to wetlands. Imre (1997) found 0-1.09 shot/m^2 in four common pheasant hunting estates in Hungary (mean 0.46 shot/m^2). Ferrandis et al. (2008) studied shot densities on a driven shooting estate in Central Spain used for hunting of red-legged partridge (Alectoris rufa). The reported density was 7.4 shot/m^2 in 1 cm of soil depth. This is possibly a low density compared with other estates because the frequency of driven

[20] Guitart and Mateo (2006).

[21] Andreotti and Borghesi (2012).

[22] Based on numbers of birds killed and likely numbers of cartridges used 'per bird', including misses (Pain et al., 2015).

[23] Based on information available at: https://www.beuth.de/de/publikation/umwelt-und-schiessen/66549358.

shootings per season in the study area only ranged from zero to two and the number of hunters spaced around 40 m apart was from six to 16 per shooting line. The densities might be higher in other more intensively driven shooting estates, where farm-reared partridges are released in large numbers just before the hunting day and driven shootings are conducted during all of the hunting season.

In the Brescia district (northern Italy), an area with more than 5 100 hunting posts, Andreotti and Borghesi (2012) estimated a conservative mean of 5-6 kg of lead pellets dispersed in the surroundings of each post annually.

For hunting, the method and scale of the activity will determine the density of shot deposited in the local environment. Very high densities of lead shot are usually found next to shooting ranges and clay pigeon shoots.

More information would be needed about lead shot densities in upland habitats in Europe, especially in intensive hunting/shooting areas.

AMEC (AMEC, 2012) reports a total supply of lead shot to the European markets of around 30 000 to 40 000 tonnes for 2013. Deducting from the amount the total amount of leads shot used for hunting (see previous section) would imply that **10 000 to 20 000 tonnes of lead that is consumed by sports shooters.**

Soil and groundwater contamination from shooting ranges

According to ILA-E (2010), a shooting area is an "area not specifically designed and operated for shooting but where shooting activities can take place". These areas do not necessarily comply with best practice guidelines and may not be subject to, or comply with, relevant environmental regulations. ILA-E (2010) notes that the definition of a shooting area differs among the EU Member States. For example, under Flemish (Belgium) environmental legislation, shooting areas are defined as "shooting contests organised up to a maximum of twice per year on the same piece of land with a maximum duration of four consecutive days". Shooting areas are exempted from the Flemish soil pollution regulation and can therefore not be considered as technical areas.

In addition, at the European level there is no common definition of contaminated sites (CSs) agreed. However, the term 'contaminated site' refers to a well-defined area where the presence of soil contamination has been confirmed and this presents a potential risk to humans, water, ecosystems or other receptors (EEA, 2014).

Remediation may be needed depending on the severity of the risk of adverse impacts to receptors (under the current or planned use of the site). Shooting ranges would need to be cleaned up under most national legislations, when risk of adverse impacts to receptors are identified. Most European countries have national legislation (or in some cases regional legislation) to deal with local soil contamination, but no legal framework has yet been established at EU level (EEA, 2014).

In Finland, shooting ranges represent one third of the local sources of soil contamination (EEA, 2014). No additional details are currently available. This specific condition in Finland might be due to the especially acidic conditions of the topsoil layer (below PH 5), as reported by Salminen et al. (2005), which may facilitate the dissolution of elemental lead.[24]

Several recent studies in Norway (Mariussen et al., 2012 and Mariussen et al., 2018) have confirmed the long-term effects of lead contamination (and other metals) in shooting ranges on the surrounding areas/receptors.

In relation to groundwater, lead is listed in the minimum list of substances for which Member States have to consider establishing threshold values, under Article 4.2 of the Water Framework Directive (Directive 2000/60/EC). In relation to surface water, lead and its compounds are listed as priority substances in the WFD.

According to Sorvari et al. (2006), a third of all shooting ranges in Finland may result in a risk to groundwater as they were located less than 100 m from the nearest aquifer. However, very few sites were located adjacent to a domestic water intake. The authors identified three cases of groundwater pollution. In these cases, the maximum lead concentration was about tenfold greater than the guideline value for domestic water (10 µg/l). Two of the aquifers had been used (previously) for supplying tap water to nearby residential areas.

The number of shooting ranges that may represent a serious source of soil and groundwater/water contamination in the EU is not known.

Further data would need to be gathered for other Member States.

Exposure of terrestrial birds to lead shot

Fisher et al. (2006) published a comprehensive review of the available data of lead poisoning from ammunition in terrestrial birds, including from lead shot. They found that 59 terrestrial bird species had been documented to have ingested lead or suffered lead poisoning, including nine globally threatened or near threatened species. Table 1 summarises the species affected by lead shot ingestion based on the review of Fisher et al. (2006).

Table 1: Lead shot ingestion and poisoning

Species	**Evidence**	**Countries**	**References**
Chukar (*Alectoris chukar*)	Ingestion	USA	Walter and Reese (2003)
Grey partridge (*Perdix perdix*)	Ingestion and poisoning	Denmark, UK	Clausen and Wolstrup (1979); Keymer and Stebbings (1987); Potts (2005)

[24] Site-specific physico-chemistry should be considered when assessing lead dissolution, speciation and mobility. In general, site-specific hydrologic and geologic conditions can greatly influence lead mobility and also atmospheric conditions can weather metallic lead into more soluble and mobile forms (SAAMI, 1996).

Common pheasant (*Phasianus colchicus*)	Poisoning	Denmark, UK, USA	Calvert (1876); Elder (1955); Clausen and Wolstrup (1979); National Wildlife Health Laboratory (1985); Dutton and Bolen (2000)
Wild turkey (*Meleagris gallopavo*)	Ingestion	USA	Stone and Butkas (1978)
Scaled quail (*Callipepla squamata*)	Ingestion	USA	Campbell (1950)
Northern bobwhite quail (*Colinus virginianus*)	Ingestion	USA	Stoddard (1931); Keel et al. (2002)
Great horned owl (*Bubo virginianus*)	Poisoning	Canada	Clark and Scheuhammer (2003)
Eurasian eagle owl (*B. bubo*)	Poisoning	Spain	Mateo et al. (2003)
Snowy owl (*Nyctea scandiaca*)	Poisoning	Captive	MacDonald et al. (1983)
Long-eared owl (*Asio otus*)	Poisoning	Spain	Brinzal (1996)
Rock pigeon (*Columba livia*)	Ingestion	USA	Dement et al. (1987)
Common wood-pigeon (*C. palumbus*)	Poisoning	Denmark	Clausen and Wolstrup (1979)
Mourning dove (*Zenaida macroura*)	Ingestion	USA	Locke and Bagley (1967); Lewis and Legler (1968); Best et al. (1992)
Sandhill crane (*Grus canadensis*)	Ingestion	USA	Windingstad et al. (1984); National Wildlife Health Laboratory (1985)
Whooping crane (*G. americana*)	Poisoning	USA	Hall and Fisher (1985)

Clapper rail (*Rallus longirostris*)	Ingestion	USA	Jones (1939)
King rail (*R. elegans*)	Ingestion	USA	Jones (1939)
Virginia rail (*R. limicola*)	Ingestion	USA	Jones (1939)
Sora (*Porzana carolina*)	Poisoning	USA	Jones (1939); Artmann and Martin (1975); Stendell et al. (1980)
Common moorhen (*Gallinula chloropus*)	Ingestion	Europe, USA	Jones (1939); Locke and Friend (1992)
Common coot (*Fulica atra*)	Ingestion	France	Pain (1990a)
American coot (*F. americana*)	Ingestion	USA	Jones (1939)
American woodcock (*Scolopax minor*)	Ingestion	Canada	Scheuhammer et al. (1999, 2003)
Ruffed grouse (*Bonasa umbellus*)	Ingestion	Canada	Rodrigue et al. (2005)
California gull (*Larus californicus*)	Ingestion	USA	Quortrup and Shillinger (1941)
Glaucous-winged gull (*L. glaucescens*)	Ingestion	USA	National Wildlife Health Laboratory (1985)
Herring gull (*L. argentatus*)	Ingestion	USA	National Wildlife Health Laboratory (1985)
European honey-buzzard (*Pernis apivorus*)	Unknown (ingestion or shot)	Netherlands	Lumeiji et al. (1985)
Red kite (*Milvus milvus*)	Ingestion or poisoning	Germany, Spain, UK	Mateo (1998a); Mateo et al. (2001, 2003); Kenntner et al. (2005)
Bald eagle (*Haliaeetus leucocephalus*)	Poisoning	Canada, USA	Platt (1976); Jacobson et al. (1977); Kaiser et al. (1980b); Pattee and Hennes (1983); Reichel et al. (1984); Frenzel and Anthony (1989); Craig et al. (1990);

			Langelier et al. (1991); Elliott et al. (1992); Scheuhammer and Norris (1996); Wayland and Bollinger (1999); Miller et al. (2000, 2001); Clark and Scheuhammer (2003); Wayland et al. (2003)
White-rumped vulture (*Gyps bengalensis*)	Poisoning (origin unknown)	India	Oaks et al. (2004)
Eurasian griffon (*G. fulvus*)	Poisoning	Spain	Mateo et al. (1997); Guitart (1998); Mateo et al. (2003)
Western marsh-harrier (*Circus aeruginosus*)	Poisoning	France, Germany, Spain	Pain et al. (1993, 1997); Mateo et al. (1999); Kenntner et al. (2005)
Northern harrier (*C. cyaneus*)	Ingestion	Canada, USA	Martin and Barrett (2001); Martin et al. (2003)
Eurasian sparrowhawk (*Accipiter nisus*)	Ingestion	France, Captive	MacDonald et al. (1983); Pain and Amiard-Triquet (1993)
Sharp-shinned hawk (*A. striatus*)	Ingestion	Canada, USA	Martin and Barrett (2001)
Cooper’s hawk (*A. cooperii*)	Ingestion	Canada, USA	Snyder et al. (1973); Martin and Barrett (2001)
Northern goshawk (*A. gentilis*)	Poisoning	Canada, France, Germany, USA, Captive	Stehle (1980); Pain and Amiard-Triquet (1993); Martin and Barrett (2001); Kenntner et al. (2003, 2005)
Red-tailed hawk (*Buteo jamaicensis*)	Poisoning	Canada, USA	Franson et al. (1996); Martin and Barrett (2001); Clark and Scheuhammer (2003)
Common buzzard (*B.*	Poisoning	France, Germany;	Stehle (1980); MacDonald et al.

buteo)		UK, Captive	(1983); Pain and Amiard-Triquet (1993); Pain et al. (1995); Kenntner et al. (2005)
Rough-legged buzzard (*B. lagopus*)	Poisoning	USA	Locke and Friend (1992)
Spanish imperial eagle (*Aquila adalberti*)	Poisoning	Spain	Gonzalez and Hiraldo (1988); Mateo (1998a); Mateo et al. (2001); Pain et al. (2004)
Golden eagle (*A. chrysaetos*)	Poisoning	Canada, Spain, USA	Bloom et al. (1989); Craig et al. (1990); Cerradelo et al. (1992); Scheuhammer and Norris (1996); Wayland and Bollinger (1999); Clark and Scheuhammer (2003); Wayland et al. (2003)
White-tailed eagle (*Haliaeetus albicilla*)	Poisoning	Greenland	Krone et al. (2004)
American kestrel (*Falco sparverius*)	Ingestion	Canada, USA	Martin and Barrett (2001)
Laggar falcon (*F. jugger*)	Poisoning	Captive	MacDonald et al. (1983)
Prairie falcon (*F. mexicanus*)	Poisoning	Captive	Benson et al. (1974); Stehle (1980)
Peregrine falcon (*F. peregrinus*)	Poisoning	UK, Captive	MacDonald et al. (1983); Pain et al. (1995)
Turkey vulture (*Cathartes aura*)	Ingestion	Canada, USA	Wiemeyer et al. (1986); Martin et al. (2003)
Andean condor (*Vultur gryphus*)	Poisoning	Captive	Locke et al. (1969)
King vulture (*Sarcorhampus papa*)	Poisoning	Captive	Decker et al. (1979)

White-throated sparrow (*Zonotrichia albicollis*)	Ingestion	USA	Vyas et al. (2000)
Dark-eyed junco (*Junco hyemalis*)	Ingestion	USA	Vyas et al. (2000)
Brown-headed cowbird (*Molothrus atar*)	Ingestion	USA	Vyas et al. (2000)
Yellow-rumped warbler (*Dendroica coronata*)	Poisoning	USA	Lewis et al. (2001)
Brown thrasher (*Toxostoma rufum*)	Poisoning	USA	Lewis et al. (2001)
Blue-headed vireo (*Vireo solitarius*)	Poisoning	USA	Lewis et al. (2001)

Countries are given for wild birds; captive birds are simply listed as captive and were poisoned through shot present in their feed. Conservation status is from BirdLife International (2004) and is coded as: CR, critically endangered; EN, endangered; NT, near threatened; and LC, least concern. Evidence of 'Poisoning' indicates tissue lead concentrations indicative of poisoning (e.g. Franson et al. (1996)) with the source of poisoning most likely to be lead gunshot and/or diagnosis of lead poisoning in one or more individuals; 'Ingestion' indicates evidence of ingestion of shot usually in the absence of tissue analysis. Species are ordered using Sibley and Monroe (1990).

Raptors and scavengers (birds)

Lead poisoning is a significant cause of mortality or morbidity in many avian raptor and scavenger species in the EU and globally. In addition, lead poisoning can significantly undermine conservation efforts.

Statistics released by "The Raptor Center, College of Veterinary medicine, University of Minnesota"[25] on bald eagles (*Haliaeetus leucocephalus*), a highly protected species in the US, showed that:

- 90 % of the bald eagles received each year (120-130) in the center for all types of problems have elevated lead residues in their blood.
- 20–25 % percent of these eagles have sufficiently high levels to cause clinical lead poisoning. Most of these birds die or are euthanised.
- Data on location of origin and seasonal timing of lead poisoning events in eagles indicate that spent lead ammunition from both shotguns and rifles is the source of lead exposure.
- Banning of lead ammunition for waterfowl hunting only was not sufficient to reduce

[25] See: https://www.raptor.umn.edu/our-research/lead-poisoning.

the occurrence of lead poisoning in bald eagles.

This confirms the complexity of protecting species feeding/scavenging on different types of environment (using different feeding strategies). There is no reason to expect this would be different in the EU, for example, lead poisoning is responsible for >20 % of reported causes of mortality of white-tailed eagles (*Haliaeetus albicilla*) in some parts of Europe (Kenntner et al. 2001, Krone et al. 2006).

Other species in Europe particularly vulnerable to the ingestion of lead in their prey include: Golden Eagle (*Aquila chrysaetos*) (Kenntner et al. 2007); Eurasian Griffon Vulture (*Gyps fulvus*) (Berny et al. 2015); Bearded Vulture (*Gypaetus barbatus*) and Egyptian Vulture (*Neophron percnopterus*) (Donazar et al. 2002). All of these birds are listed as species in Annex I to the EU's Birds Directive with the latter two also being globally threatened. In addition, the White-tailed Eagle (Krone et al. 2006, Helander et al. 2009) and the Marsh Harrier (*Circus aeruginosus*) (Pain et al. 1997) are also vulnerable to the ingestion of lead, but preferably feed in wetland habitats.

Several other raptor species are exposed to lead through shot, as reported by Fisher et al. (2006): American kestrel, sharp-shinned hawk (*Accipiter striatus*), Cooper's hawk, northern goshawk (*Accipiter gentilis*), northern harrier (*Circus cyaneus*) and red-tailed hawk (*Buteo jamaicensis*). Rough-legged buzzards (*Buteo lagopus*) have been reported to be poisoned following shot ingestion by Locke and Friend (1992).

In Europe, species found to have elevated levels of lead in their liver, indicative of shot ingestion, include: Eurasian eagle owl (*Bubo bubo*), long-eared owl (*Asio otus*), red kite (*Milvus milvus*), western marsh-harrier, Eurasian sparrowhawk (*Accipiter nisus*), northern goshawk, common buzzard (*Buteo buteo*), and peregrine falcon (*Falco peregrinus*) (Pain and Amiard-Triquet, 1993; Pain et al., 1993, 1995, 2007; Mateo, 1998a; Mateo et al., 2001, 2003).

Further data on other species (e.g. Corvids) will need to be gathered.

Golden et al., (2016) in their recent review on scavengers (in the US) conclude that although there are multiple sources of lead in the environment, scientific evidence points to spent lead ammunition (including lead shot) as the most frequent cause of lead exposure and poisoning in scavenging birds. Details on exposure data are provided in the authors' study.

Finally, it is important to note that scavengers like vultures have a very critical role in the ecosystems, as consumers of dead animals, they can prevent the spreading of diseases such as anthrax and rabies[26]. Therefore, any improvements in their conservation status can be significant in terms of guaranteeing the conservation of the entire ecosystems.

[26] See: https://www.4vultures.org/vultures/.

Prevalence of lead shot ingestion

As reported by Mateo (2009), Butler et al. (2005), in a study of lead shot ingestion in 437 common pheasants shot in 32 estates in the UK from 1996 to 2002, an overall prevalence of 3 % was found; the number of ingested shot were 1 (77 %), 2 (15 %), or 3 (8 %). In another study made by Imre (1997), the prevalence of lead shot ingestion in common pheasants (n=947) from 14 hunting estates in Hungary ranged from 0 to 23.1 % (all areas = 4.75 %), and the number of ingested shot ranged from one to eight.

More recently, Ferrandis et al. (2008) examined 76 red-legged partridges shot in the same estate where lead shot density was studied (7.4 shot/m^2), and the prevalence of lead shot ingestion was 3.9 %, with important variations between years (20 % in 2004, 1.5 % in 2006), with corresponding lead values in liver and bone tissues. This difference may be explained by variations in diet and grit selection between years, according to Mateo (2009).

Presence of embedded lead shot in preys

According to Mateo (2009), upland gamebirds are intensively hunted in some estates by means of driven shooting techniques, especially in places where farm-reared partridges and pheasants are released in large numbers. An undetermined number of birds, depending on the habitat, may not be retrieved by hunters, as occurs in waterfowl. The presence of lead shot embedded in the bodies of shot red-legged partridges in a driven shooting estate in Spain was 87.5 %, with the number of embedded shot ranging from one to 22 and a mean ± SD of 4.19 ± 3.48 shot/partridge (R. Mateo unpublished data).

Embedded lead represents a major risk for raptors and scavengers feeding on birds of prey and/or their carcasses.

However, as reported by Scheuhammer and Norris (1996), the phenomenon of embedded shot is not restricted to birds. Platt (1976) reported that a population of eagles wintering in a Utah desert ingested shot by feeding heavily on hunter-killed jackrabbits (*Lepus californicus*). Jackrabbits were identified as a potential major source of lead for bald eagles in the US Great Plains, Black Hills, and the High Plains of Texas (USFWS[27], 1986). Embedded shot in small game mammals is thus an additional source of lead ingestion in raptors and scavengers. This is also expected to be the case in the EU.

Additionally, wild mammals feeding on preys/carcasses, which may be shot with lead pellets, may also be at risk. Additional data would need to be gathered to evaluate this aspect.

Human exposure

Several national food safety and risk assessment agencies of five European (four EU) countries have evaluated risks and advised that pregnant women, babies and young

[27] U.S. Fish and Wildlife Service.

children avoid eating game meat shot with lead ammunition or reduce the amounts consumed (summarised in Knutsen 2015), see also Table 6.

In Denmark and Netherlands, there are already total bans on lead gunshot in place that effectively protect consumers as well. Therefore, it is assumed to be feasible that a similar ban is implemented in other EU countries.

The route of exposure of humans to lead from ammunition is similar to that of raptors, i.e. the consumption of lead fragments from ammunition in the flesh of game animals (e.g. Pain et al. 2010).

Some data related to exposure of humans have already been discussed in the "Annex XV Restriction Report on Lead in Shot in wetlands", published by ECHA in 2017, which suggested that exposure to lead (from lead shot) for regular consumers of game meat may be not negligible. A comprehensive statistical analysis of wild game consumption habits among EU hunters/citizens was not found.

A recent assessment made in Italy by Ferri et al. (2017) indicated that Italian hunters ate game, on average, four times per month with an average of 100–200g of game meat per serving and maximum highest intakes of 3 kg per month. Meat, liver, and heart were the preferred food items. Ferri (Ferri et al, 2007) analysed the consumption habits of 766 Italian shooters[28] (96 % males, 4 % females), on average 52 years old, through the distribution of questionnaires delivered during the shooters' attendance to training and teaching courses[29].

Specifically, the assessment made in Italy by Ferri et al. (2017) investigates the relevance for intakes of cadmium, perfluorooctane sulphonic acid, and caesium (137) as priority contaminants in game meat, and indicates that an average of 100–200g game per serving, four servings per month, was consumed by Italian hunters, with highest intakes of 3 000g per month. Meat, liver, and heart were the preferred food items. Mammalian and bird game was regularly consumed with friends and relatives in 83 % and in 60 % of cases, respectively.

(Ferri et al, 2007) concluded that Mammalian and feathered game was regularly consumed with friends and relatives in 83 % and in 60 % of cases, respectively. In Italy, it was estimated that there was a **regular consumption** of wild game by about 3 % of the Italian population (Ferri et al., 2017).

The most consumed wild species recorded were pheasant > woodcock > choke among birds, and wild boar > hare > roe deer among mammals. Accounting for a consumer population of 751 876 shooters in Italy, it was estimated that there was a regular consumption of wild game in around **the 3 % of the Italian population** (Ferri et al., 2017).

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[28] Of 834 questionnaires, 766 were fully accepted for the further statistical evaluation.

[29] These courses were given in the context of Regulation 853/2004/EC provisions on food hygiene.

Green and Pain (2015) used data from the UK National Diet and Nutrition Survey (NDNS) programme to estimate the quantity of gamebird meat eaten per year by people in the UK. They found that the total mass of gamebird meat eaten per year by the whole UK population was about 11 232 tonnes (95 % C.L. 9 162 – 16 251). No estimates were done for the consumptions of other species (e.g. hare) which may be hunted with lead shot, see also section 3.2.3 on page 58.

In addition, currently in the EU, there does not seem to exist a well-regulated "placing on the market" for small game (like birds and hare) and harmonised recommendations for domestic game consumption, to reduce the exposure to lead.

This seems confirmed by the existence of contradicting regulations, within Member States, which do not appear to be beneficial to protect consumers' health in a consistent manner. For example, in Italy, a regional regulation made in 2017 by Emilia-Romagna region, establishes that[30]:

- It is necessary to use lead free ammunition to shoot wild game, when the game meat is intended for being placed on the market.
- It is not necessary to use lead free ammunition to shoot wild game, when the game meat is not intended for being placed on the market but is only harvested by the hunters for domestic consumption.

In another region, Tuscany, the regional regulation[31] made in 2014, makes no recommendations at all about the use of lead ammunition (including lead shot), both for the commercialisation of game meat shot with lead ammunition and for domestic consumption.

Recent national or regional surveys on wild game consumption habits among hunters may be available at national or regional levels and could be further gathered through a specific call for evidence.

In any case, a harmonised risk management measure in place at the EU level, would also protect regular consumers of game meat hunted with lead shot, especially for domestic consumption.

In addition to animals directly hunted with lead shot, Sorvari (2011) reported, that consumption of food items produced within the impact area of a shooting range pose a risk of exposure to lead to humans. Heier et al. (2009), cited in LAG[32] 2015, showed that trout in cages in a stream in Scandinavia subject to run-off from a shooting range showed elevated lead levels within three weeks[33]. However, no specific data for this type of exposure is currently available.

[30] Regione Emilia-Romagna, Determinazione Num. 1807, 13/02/2017.

[31] "Bollettino Ufficiale della Regione Toscana, 31 dicembre 2014".

[32] http://www.leadammunitiongroup.org.uk/

[33] The lead was isotopically traced to the lead pellets used on the range.

1.1.3. Risks

No risk characterisation has been carried out at this stage for human health as lead is a non-threshold substance.

However, it is noted that national food safety and risk assessment agencies in several European countries have evaluated the risks and advised that pregnant women, babies and young children should avoid eating game meat shot with lead ammunition or reduce the amounts consumed (summarised in Knutsen 2015)[34].

Similarly, for the purposes of this preliminary investigation, no quantitative risk characterisation has been undertaken for the environmental compartment and it has to be evaluated whether it is necessary to undertake a quantitative risk characterisation for environmental receptors.

In addition, it should be noted that for some species like raptors and scavenging birds (living in terrestrial habitats), an estimate of the number of individuals dying annually in the EU, due to lead shot only, would be particularly challenging. This is because of the specific ecology and opportunistic behaviour of these species, feeding on a range of food types which may contain either lead shot or fragments of lead bullets.

Of interest here is a recent analysis by Meyer et al. (2016) which used population models to evaluate how lead shot ingestion might affect population size or growth rate in three European bird species, the grey partridge (*Perdix perdix*), common buzzard (*Buteo buteo*), and red kite (*Milvus milvus*).

These species are all known to ingest lead shot directly or through secondary mechanisms. Observed population trends were a decreasing population for partridge (in continental Europe), a stable population for buzzards (in Germany), and an increasing population for red kite (in Wales). Although lead shot ingestion did not change the modelled trend direction for the three species, it reduced population size and slowed population growth. Lead shot ingestion at the modelled rates reduced the size of a declining partridge population by 10 % and reduced the annual growth rate of a recovering red kite population from 6.5 % to 4 %.

These results have uncertainties but suggest that declining or recovering populations are sensitive to lead shot. However, REACH does not require evidence of 'population level' impacts to demonstrate that there is an unacceptable risk to either the environment or human health on an EU-wide basis, particularly for non-threshold substances.

Further studies, focusing also on risk-related aspects, are expected to be published following the ongoing updates of the LAG report[35].

[34] Lead shot can 'fragment' after hitting quarry animals as lead bullets. See section on "Hazard".

[35] See: http://www.leadammunitiongroup.org.uk/wp-content/uploads/2015/06/Executive-Summary-to-LAG-Update-Report.pdf.

2. Justification for further EU wide action

The main reasons to act on a Union-wide basis are related to the health risks posed by lead – a known non-threshold substance – to humans through the consumption of game meat. This risk pertains particularly to people who have regular consumption of such meat, such as hunters and their close network (families, friends, including children). The number of regular consumers can be significant in many Member States.

In the EU, Commission Regulation 1881/2006 sets maximum levels (MLs) for certain contaminants in food; for lead, the ML is 0.1 ppm in bovine animals, sheep, pigs and poultry (excluding offal). However, no ML has been set for game meat, in which average levels in the UK (gamebirds) and EU (all game) can exceed the EU ML for domestic animal meat by 12-31 times (Pain et al. 2010, EFSA 2013). Therefore, further EU wide action is warranted to guarantee a harmonised protection for the consumers of game meat (containing lead shot) in the EU.

In addition, further EU measures (such as a restriction under REACH) could harmonise risk management legislation related to the use of lead gunshot for hunting and in shooting ranges across EU Member States. This could address the risks to the entire terrestrial ecosystems (including soil and groundwater contamination) and to vulnerable receptors, such as raptors and scavengers birds, which are the object of many conservation programmes at EU level.

The enforceability of such a restriction is also expected to be easier at Member State level, compared to the restriction covering wetlands only.

3. Impact assessment

There are no previous and comprehensive impact assessments that specifically investigate the impacts and benefits of abatement of lead in the terrestrial areas at EU level. Some cost estimates are available as per the AMEC study (Amec, 2012).

3.1. Alternatives

The alternatives that can be used for hunting outside wetlands do not differ from the alternatives used for wetland hunting. For the latter, the ECHA dossier on lead in shot over wetlands found that the effectiveness of the alternatives[36] is comparable to lead-containing shot.

The limiting factor preventing the extensive use of alternatives in all Member States seems to be the lack of specific national restrictions.

Data available for the Netherlands, Denmark, Norway and Italy, seem to suggest that the ammunition market is driven by regulation, meaning that the availability of the alternatives on the market depends on the regulatory measures implemented:

- In the Netherlands and in Denmark, the transition to the use of alternatives to lead shot has been successfully completed following national restrictions and hunters

[36] See: https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/17005/term

have adapted to the new ammunition, as discussed in the Annex XV dossier on the use of lead in shot over wetlands.

- In Norway, there has been a regulation of the use of lead shot for hunting in wetlands since 1991. The regulation was amended several times, and in the period 2005 to 2015 there was a total ban on production, import, export, sale and use of lead shot[37].

  In this period, shots of alternative materials to lead were used in Norway, mostly steel, but also some heavier metals like bismuth and tungsten. Availability of shotgun ammunition was not a problem in this period and hunters could find most types of ammunition in relevant stores[38].

  In 2015, the use of lead shot for hunting (non-wetlands species) was reintroduced apparently because of national political preferences at that time[39]. However, the total ban on the use of lead shot in shooting ranges is still in place.

  After the total ban for hunting was repealed and a partial restriction was introduced that allowed the use of lead shot for hunting of non-wetland species, the availability of alternatives in the market changed significantly. Most stores have only a limited supply of alternative shots, and it is reported that, in many cases, the stores recommend to use lead shot for all purposes, including hunting of wetland species. Norway concluded (in the comment sent for the public consultation) that when a partial restriction of lead shot is adopted, information on the benefits of alternative materials for health and the environment should be carefully distributed to hunters and stores, and inspections in the field should be frequently performed. In addition, manufacture of lead shot in Norway was resumed because of the repeal of the total ban.

- In Italy, the use of alternatives is limited to a very small market segment: hunting of waterfowl. Non-confidential data gathered in Italy by the Italian National Association of Manufacturers of Arms and Ammunition (ANPAM (2015)[40]), indicates a correlation between national restrictions and the use of lead-free ammunition by Italian hunters. Specifically, the current legislation in Italy prohibits the use of lead shot in about 50 % of Italian wetlands and the estimated use of lead-free shot for hunting ducks (in wetlands) was about 50 %. Alternatives to lead shot for hunting other game (than waterfowl) e.g. pheasant, rabbit and hare, have no market, since there is no restriction in place on the use of lead shot. The estimated consumption of alternatives to hunt rabbit, pheasant and hare was below 1 % of the overall shot consumption in 2015.

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[37] An impact assessment had been prepared by Norwegian authorities for the general ban of lead shot in Norway (2005) with the aim of minimising lead use and exposure and to comply with obligations under global conventions (Norwegian Environment Agency, *Konsekvensvurdering av forslag til forskrift om blyhagl, 2005*).

[38] Information provided in the public consultation on lead in shot over wetlands by Norway.

[39] In 2014, members of the Norwegian Parliament proposed to repeal the general ban on lead shot and reintroduce a regulation that facilitated the use of lead shot for hunting outside of wetlands. In 2015, the proposal was adopted after a vote in the Parliament.

[40] The Italian National Association of Manufacturers of Arms and Ammunition: https://www.anpam.it/home-english.

Table 2: Ammunition types in Italy (non-migratory game species and waterbirds).

Target species	Number/ year (estimated)	Lead ammunition			Alternative ammunition				
		Calibre	**Shot/ bullet weight**	**Shot size**	**Material**	**Calibre**	**Shot/ bullet weight**	**Shot size**	**% (estimated)**
Wildboar (shotgun)	500 000	12	32	-	steel, zinc-tin alloy	12	22-30	-	5%
Ducks	3 000 000	12-20	> 35 g (> 30 g cal 20)	> 2.9 mm	steel - tungsten	12	> 32 g	> 3.1 mm	50%
Grey-red legged partridge	3 000 000	12-20	32-34 g (> 30 g cal 20)	2.3 - 2.5 mm	steel	12-20	32 g (24 g cal 20)	2.7-2.9 mm	< 1%
Pheasant	10 000 000	12-20	32-34 g (> 30 g cal 20)	2.5 - 2.9 mm	steel	12-20	32 g (24 g cal 20)	2.7-3.3 mm	< 1%
Corvids	2 000 000	12	34-40 g	2.5 - 2.9 mm	steel	12-20	34	2.9-3.3 mm	< 1%
Rabbit	1 000 000	12-20	32 g (> 28 g cal 20)	2.3-2.5 mm	steel	12-20	32 g (26 cal 20)	2.5-2.7 mm	< 1%
Hare	500 000	12	35-42 g	3.3 mm	steel - tungsten	12	35 g	3.5 mm (3.1 tungsten)	< 1%
Fox (shotgun)	50 000	12	40-50 g	3.5 - 4.1 mm	steel - tungsten	12	35 g	3.7 mm (3.5 tungsten)	< 1%

Source ANPAM (2015).

Based on the information received by Norway in the public consultation on lead in shot over wetlands, it appears that:

- When using steel shots, too long firing distances must be avoided. However, shotgun is a short-range weapon and if a shotgun is fired at a maximum distance of 35 metres, the shot material will have a limited influence on the ammunition performance.
- Using shots of the same material for training as is intended for hunting would reduce the need for adaptation for hunters.
- Other evidence already gathered in the dossier on the use of lead in shot over wetlands, confirms that hunters' skills are much more relevant than the ammunition types to determine the hunting success. The fact that several countries in the EU have already implemented a full ban, is the main evidence that the alternatives can work well for all hunting activities and also for sports shooting.
- The ammunition market is regulatory driven, meaning that the availability of the

alternatives on the market depends on the regulatory measures implemented. Without a regulatory measure at the EU level, it seems reasonable to assume that the demand for lead-free ammunition will not grow spontaneously.

3.2. Socio-economic impacts

The socio-economic impacts of a possible regulatory action proposal on lead gunshot used in terrestrial habitats would focus on the benefits in terms of risk reductions to humans (through food consumption) and animals (through primary and secondary lead poisoning), and the associated costs to hunters and gun and shot manufacturers in the EU. In the following sections, both benefits and costs of a restriction will be briefly discussed in a qualitative manner.

3.2.1. Costs

The assessment of the substitution costs implied by possible further regulatory action addressing the use of lead in terrestrial habitats, would require a further analysis. However, unless there is a switch to high performance steel, no reproofing or new guns are required.

According to the evidence gathered for the restriction proposal on the use of lead in shot over wetlands, some old shotguns (manufactured before 1970) may have lower tolerance for the pressure that builds up when using normal steel shot. For these shotguns, steel shot can be unsuitable.

A specific quantitative data gathering relevant for the use of lead gunshot in terrestrial environments was beyond the scope of this report. In an Annex XV report, specific information would have to be gathered from industry to quantify the expected costs for gun and shot manufacturers at the EU level.

During the opinion development of the lead gunshot over wetlands dossier , new information became available which led SEAC rapporteurs to conclude that the differential in the market price between lead gunshot and steel gunshot was marginal (less than two euro cents per cartridge). Moreover, information by major shotgun manufacturers suggests that modern shotguns (manufactured after 1970) can use normal steel shot without any re-proofing. These two factors suggest the costs to hunters of further action would be limited.

3.2.2. Benefits

One of the expected direct benefits of further action on the use of lead shot in terrestrial areas is a reduction in bird mortality due to lead poisoning.

Unlike for the wildfowl and waterfowl that inhabit wetlands, the number of studies that examine mortality of birds due to lead poisoning outside of wetlands are less numerous. Some data on the proportion of birds with ingested gunshot are available for some species in the UK (see Table 3)

Table 3: proportion of terrestrial birds with ingested gunshot

Species	Proportion of birds with ingested gunshot	Study
Hunter shot red-legged partridge	1.4%	Butler, 2005
Hunter shot pheasant	3%	Butler et al, 2005
Grey partridge	4.5% for adults and juveniles	Potss, 2005

Based on these figures (Paine et al, 2015 conclude that about 600 000 terrestrial gamebirds are likely to have ingested gunshot at any tie an many times more throughout the shooting season. All birds that ingested lead shot suffer from sub lethal effects of lead poisoning and a good portion of these birds perhaps of the order of hundreds of thousands are likely to die from lead poisoning each year in the UK alone.

Upscaling the known effects from lead poisoning, as documented in the Annex XV Repot on lead in shots over wetlands, to terrestrial areas could imply that an additional **1 to 2 million terrestrial birds would die each year due to lead poisoning**

Studies on sub-lethal effects of lead intake are ongoing, but the ones available suggest that lead can affect reproductive success in various bird species. Recent studies (Vallverdú-Coll et al., 2016b) indicate that the adverse effects of lead can be observed in the reproductive function of males, in particular on the integrity of the acrosome and the motility of the spermatozoa, which can have consequences on the oocyte fecundation. Although not all species may be equally sensitive to lead this aspect is considered critical for long-term population effects, potentially in many species.

Other expected benefits of a possible regulatory action are:

- The reduction of human exposure to lead, through the consumption of lead shot contaminated game meat (e.g. pheasant, rabbit, wildboar) can be expected to be particularly relevant in specific populations such as children and adults (including hunters) frequently consuming game meat. This item is briefly introduced in Part II in the section on Benefits where the study of (green and Pain, 2015) is discussed which has shown Further work should focus on the distinction between the effects of lead shot and lead in ammunition for civilian use.

- In general, as lead is a non-threshold substance (as confirmed by ECHA’s Committee for Risk Assessment (RAC) in the assessment of the “Annex XV Restriction Report on Lead in Shot”) any reduction of dietary lead exposure (because of a possible regulatory action) will contribute to further reducing the human health risks posed by lead. An EU wide measure could harmonise the currently highly variable risk management approaches on this matter (at national and regional level) throughout the EU and provide a harmonised protection for consumers of game meat (containing lead shot) in the EU.

- A more comprehensive protection of waterbirds (consistent with existing EU obligations under the Birds Directive and AEWA), taking into account species also feeding on terrestrial habitats, would be achieved.
- The protection of terrestrial species vulnerable to lead poisoning would be achieved or at least partially achieved (raptors and scavengers may feed on prey and carcasses shot with both lead pellets and lead bullets).
- An EU wide measure would avoid the emission of lead shot from both hunting and shooting activities, significantly reducing the amount of lead accumulating in the environment. This would also help to reduce the potential for future lead contamination of water sources and drinking water catchments, especially from target shooting activities.
- The avoided or reduced remediation costs at shooting ranges (for new shooting ranges and existing ones, respectively), e.g. upon decommissioning. Remediation may be needed depending on the severity of the risk of adverse impacts to receptors under the current or planned use of the site. Shooting ranges need to be cleaned up under most pieces of national legislation, with potentially high costs, when risk of adverse impacts to receptors are identified. Most European countries have national legislation (or in some cases regional legislation) to deal with local soil contamination, but no legal framework has been established at the EU level (EEA, 2014). Thus, an EU wide measure could harmonise the risk management approaches throughout the EU.
- Positive impacts on wild mammals (e.g. wild boars) feeding/scavenging on preys/carcasses which may be shot with lead pellets would need further data gathering.
- Positive impacts on water sources, e.g. groundwater sources located in proximity of shooting ranges

A detailed data gathering on the overall benefits was beyond the scope of this report. It is acknowledged that some aspects of the benefit assessment may be challenging.

This includes the monetisation of the benefits from the avoided consumption of lead-contaminated game meat, which would be particularly challenging because quantitative information on the consumption of game meat by consumers often integrates the exposure from the use of both lead gunshot and lead bullets.

3.3. Derogations

A possible derogation might be necessary for professional sport shooters who train for international (Olympic) competitions[41] and for the shooting facilities where this training takes place. Other derogations, would need to be identified and assessed, case by case,

[41] International/Olympic disciplines requiring the use of lead ammunition (FITASC/ISSF).

and based on additional information provided by relevant stakeholders.

3.4. Enforcement

Compared to the proposed restriction on the use of lead shot over wetlands, it is anticipated that further action on lead gunshot in the entire EU territory would improve the practicability and monitorability of the existing measures. This is because it would allow for a compliance check by REACH enforcement authorities at the point of sale, i.e. by monitoring the placing on the market of the gunshot. An example of the success of such a measure is provided by Denmark and the Netherlands where total bans on lead gunshot are already in place.

In addition, it is expected that a ban on placing on the market of lead gunshot would remove the need for a possession ban in wetlands.

3.5. Transition period

No specific information was gathered as part of this report.

4. Conclusions

Impacts on human health from the consumption of lead contaminated game meat are not negligible and may negatively affect vulnerable populations including children and regular game meat consumers (including hunters and their networks). For example, national food safety and risk assessment agencies in several Member States have evaluated risks and advised that pregnant women, babies and young children avoid eating game meat shot with lead ammunition or reduce the amounts consumed (summarised in Knutsen 2015).

Based on recent data on wild game consumption habits among Italian hunters[42], it appears that a fraction of the EU adult population is exposed to lead through the consumption of game meat. A quantitative risk assessment might be performed to gauge the effects of lead exposure in this population, although lead is a non-threshold substance for humans and therefore a qualitative assessment may be sufficient to describe the risks to the EU consumers of game meat containing lead. In general, reducing one of the sources of lead intake, e.g. from ingestion of game meat, can successfully reduce the overall exposure to lead of humans.

In the EU, Commission Regulation 1881/2006 sets maximum levels (MLs) for certain contaminants in food; for lead the ML is 0.1 ppm in bovine animals, sheep, pigs and poultry (excluding offal). No ML has been set for game meat, in which average levels in the UK (gamebirds) and EU (all game) can exceed the EU ML for domestic animal meat by a factor of 12-31 (Pain et al. 2010, EFSA 2013). It can be expected that an EU wide measure could guarantee a harmonised protection of the consumers of game meat (containing lead shot) and specifically address the risks to frequent consumers, which are currently not addressed by any other EU legislation.

Lead emissions from ammunition sources (such as lead shot) are a relevant source of lead directly released into the environment without any implementable risk management

[42] In Italy, it was estimated that there was a regular consumption of wild game in around the 3 % of the Italian population (Ferri et al., 2017).

measures to reduce and avoid the consequent contamination of the terrestrial ecosystems in the EU. For example, only a small proportion of the pellets (≤1 %) are likely to hit and be retained in a killed bird (Cromie et al., 2010), while ≥99 % of the pellets per shot are spread in the environment.

Impacts on the terrestrial ecosystems would need to be further assessed before concluding on their magnitude. However, at least for shooting ranges where lead is released in high concentrations, the contamination of the soil might represent a serious concern. For example, the European Environmental Agency (EEA) (2014) found that shooting ranges represent one third of the local sources of soil contamination in Finland. Similar results are likely in other Member States, too.

Additional information is needed about lead shot densities in upland habitats in Europe, especially in intensive hunting/shooting areas. For example, fixed hunting posts exist in many countries and once information on their location is gathered, it could be possible to estimate the lead shot densities expected around these sites, based on the available reference data for specific countries.

Even many years after the actual deposition of lead, remediation of contaminated sites may be warranted. It seems reasonable to assume that further contamination of many EU sites could be avoided in the future, if alternative gunshot would be used on shooting grounds/ranges as is the case in several EU Member States including Sweden, Norway, Denmark, and the Netherlands.

Raptors are especially vulnerable to lead poisoning since they may be exposed to both lead shot and lead bullets (either as entire pellets or fragments of pellets and bullets). Raptors and humans share similar exposure routes to lead from ammunition and their biological systems are affected in broadly similar ways.

Although there is no extensive dataset (comparable to the one for waterbirds) on the mortality of terrestrial species due to lead shot, data available on flagship species like raptors suggest that risks to wildlife from the exposure to lead shot exist and are not negligible.

Reducing one of the sources of lead intake to raptors, e.g. lead shot from terrestrial shooting, reduces their overall exposure to lead and improves the conservation status of the most vulnerable raptors species, which are subject to extensive conservation programmes at the EU level.

Sub-lethal effects are potentially of high concern for many terrestrial species. Studies are on-going, but the available data suggest a possible correlation of lead poisoning with reproductive impairments. A recent analysis by Meyer et al. (2016) on three European terrestrial bird species indicated that although lead ingestion did not change the modelled population trend direction for the three species, it reduced population size and slowed population growth.

The extension of the restriction to the terrestrial habitats would eliminate the residual risk to those waterbirds, which partially feed outside of wetlands, as confirmed by UNEP-AEWA's Secretariat in the context of the work done to support the restriction on the use of lead shot in and over wetlands in the EU.

In addition, a total ban on lead shot would mean there is no need to restrict the possession[43] of lead shot in wetlands. There would be no need to check hunters in the field because controls could be done at the retail level and thus facilitate enforcement.

[43] See "Compiled RAC and SEAC opinion": https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/17005/term

Part II: Lead bullets for civilian use

1. Introduction

Lead ammunition (excluding ammunition used in military and police activities) is still widely used in hunting. COWI (Cowi, 2004) estimated the total emission of lead in 2005 for the EU15, Hungary, Lithuania and Poland together to be 150 tonnes per year for hunting using centre firing ammunition.

Hunting bullets are typical used for hunting big game such as deer, elk and other larger mammals. Some calibres are also used for smaller game and pest control.

As a consequence of a growing awareness of the issue of lead in game meat and the introduction of bans on using lead ammunition[44], the development of lead free alternatives has accelerated and hunters nowadays have access to a wide variety of alternatives that perform equally well (and sometimes better[45]) than traditional lead ammunition.

There appears to be an on-going trend among hunters to use more lead-free ammunition initiated either by the introduction of several bans in German federal states or by an increased awareness of the effects of lead in game meat. There is no documentation of this trend but several sources indicate this[46].

Lead ammunition fragments upon impact, causing a dispersion of lead in the target body. This dispersed lead has been considered to be removable by cutting away enough meat around the wound. However, recent research suggests that the lead is dispersed much more deeply in the tissue than previously thought and in very small particles, down to the nano-levels. Therefore, cutting away meat around the wound is not a sufficient guarantee that all the lead is effectively removed.

In addition, hunters traditionally remove the intestines of the shot animal and leave (or bury) this on (in) the ground. Hunters do this for food hygiene reasons, to conserve the quality of the meat. However, the intestines are available to other animals; partly motivated by a tradition of actually intentionally leaving this meat for other animals to consume. If there is lead contamination of the intestines then this will expose the scavenging animal. The use of lead ammunition (bullets) for hunting mammals results in lead-uptake in the food chain where scavengers and raptors are exposed to lead resulting in sub-lethal and lethal effects.

Consequently, lead is available to both humans by consumption of lead in game meat and to other animals through the consumption of the intestines that are left.

Furthermore, at shooting ranges the use of lead ammunition (and lead based primers)

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[44] See Section 1.4: local bans in Germany and a state wide ban in California.

[45] The National Rifle Association NRA awarded Barnes best hunter ammunition product of the year in 2012 for its copper bullets, see: https://www.ammoland.com/2012/01/barnes-vor-tx-ammunition-awarded-the-2012-american-hunter-ammunition-product-of-the-year/#axzz5OtWILZ6w

[46] Personal communication Niels Kanstrup and with Nammo Lapua Oy

results in lead dust and fumes that results in human exposure to lead.

1.1. Key previous assessments

The European Commission (2004)[47] investigated the advantages and drawbacks of restricting the marketing and use of lead ammunition. Although relatively old (and perhaps in need of some updating), this investigation, in essence, contains **all the necessary information for the preparation of an Annex XV restriction on the use of lead in ammunition**.

For example, information on risks, volumes and alternatives (including price differences to lead-based ammunition). These data would be relatively straightforward to update using the same methodology as originally used.

Furthermore, the standardised regulatory impact assessment (Duncan, 2014) supporting the Californian ban on the use of lead in hunting ammunition provides a good update on the current state of play vis-à-vis further impacts and effectiveness and availability of alternatives.

Concerning risks and mitigation measures, the work of the lead ammunition group (LAG, 2015). offers a good starting point

1.2. Manufacture

Recent market research (Environment Canada, 2018) on the ammunition manufacturing industry state that 'bullets are usually made from lead or lead alloy' and are produced by pouring molten lead into a mould. Cases for rifle/handgun ammunition are usually made of brass, steel or aluminium, with brass being the most common. Primers are made from two pieces of metal that encase a small amount of impact-sensitive explosive material. Gunpowder can be made by the ammunition manufacturers or purchased from suppliers. (See Figure 1-1)

There are two main categories of ammunition:

Rimfire	Rimfire is a method of ignition for metallic firearm cartridges as well as the cartridges themselves. It is called rimfire because the firing pin of a gun strikes and crushes the base's rim to ignite the primer.
Centerfire	A centerfire cartridge is a cartridge with a primer located in the centre of the cartridge case head. Unlike rimfire cartridges, the primer is a separate and replaceable component. Centerfire cartridges have supplanted the rimfire variety in all but the smallest cartridge sizes.

[47] Available at: https://ec.europa.eu/growth/sectors/chemicals/reach/studies_en

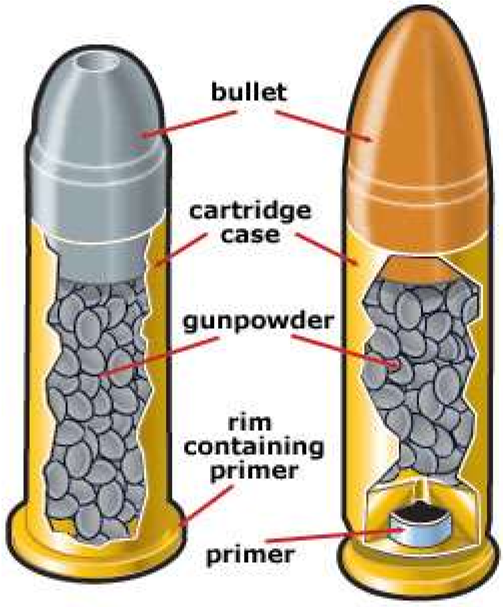


Figure 1-1: anatomy of bullets (Left: centrefire, Right: rimfire)

Ammunition assembly is highly automated. In brief, primers are inserted into the cases, the cases are then charged or filled with the correct amount of gunpowder, and the projectiles then inserted into the cases. Ammunition is manufactured in runs, which are assigned lot codes that are printed on the ammunition's box and allow it to be inventoried and traced. Manufacturers routinely test fire ammunition to ensure safety and quality. If a performance issue is found, ammunition from that lot can be recalled.

Ammunition manufacturers sell to wholesale distributors, who in turn sell to retailers.

Remanufacturing/reloading cartridges involves the reuse of previously fired cases and reloading these with the other components including primer and propellant. The projectile reloaded can be previously used/recycled or can be newly produced. Reloading is usually carried out by hunters.

The main European manufacturers that are part of the Association of European Manufacturers of Sporting Ammunition (AFEMS) are the following:

Table 4: Ammunition manufacturers in the EU

AREX D.o.o. Sentjernej	NOBELSPORT MARTIGNONI S.p.A.
BELOM	NORMA Precision AB
BROWNING INTERNATIONAL S.A.	POBJEDA TECHNOLOGY GORAŽDE D.D
CHEDDITE France S.A.	PPU PRVI PARTIZAN A.D.
ELEY Ltd	RUAG Ammotec GmbH

ELEY Hawk Ltd	RUAG Ammotec
FIOCCHI Munizioni S.p.A.	RUAG Hungarian Ammotec Inc.
FN HERSTAL S.A.	Saltech AG
GGG	Sako Ltd
IDEAL	SELLIER & BELLOT a.s.
MAXAM Outdoors S.A.	SPF TAKHO
MEN METALLWERK ELISENHUETTE GMBH	Sarsilmaz Patlayici Sanayi A.S.
NAMMO LAPUA OY	

source: AFEMS website[48]

There may be more ammunition manufacturers that are not part of AFEMS that supply the EU market, such as Blaser, Brenneke, Geco, Hornady International, Sauvestre, Sax and Schnetz.

Furthermore, the European market is supplied with ammunition that is produced outside of the EU by (among others) the following main producers: Kent ammunition, Remington and Winchester.

Information on the producers of alternatives can be found under the Section 3.1.3. on alternatives.

1.3. Hazard, exposure/emissions and risk

1.3.1. Hazards

Birds (scavengers and predators)

Scavenging and predatory birds are highly susceptible to lead poisoning. They consume embedded lead shot or fragmented lead bullets in unretrieved hunter-killed carcasses, discarded intestines, or hunter-crippled animals, as has been observed with bald eagles preying upon shot and injured waterfowl.

Upon impact, lead-based projectiles can produce hundreds of small fragments resulting in contaminated animal carcasses and gut-piles that serve as carrion for birds of prey and scavengers. Arnemo (Arnemo et al., 2016) found that globally, 33 raptor species and 30

[48] www.afemns.org

other terrestrial bird species are reported to have ingested and/or been poisoned by lead fragments from hunters' ammunition (Pain et al. 2009).

The species include Gruiformes[49], Galliformes[50] and various other avian taxa, including 10 globally threatened or near threatened species. Lead poisoning is of particular conservation concern in long-lived slow breeding species, especially those with initially small populations such as the five globally threatened[51] and raptor species reported as poisoned by lead ammunition in the wild.

In areas where lead ammunition is used, all raptors that feed on game or other hunted species are potentially at risk from lead poisoning. Species that scavenge, or both hunt and scavenge, are likely to be at particular risk from lead ingestion through feeding on injured or hunter-killed but unretrieved prey. Season and local hunting intensity play an important part in determining the level of dietary lead exposure (Pain et al. 1993, Mateo 1998a). For example, bald eagles (*Haliaeetus leucocephalus*) found sick, injured or dead with significantly elevated lead exposure in British Columbia, the greatest number were found between January and March when they were feeding heavily on wintering waterfowl (Elliott et al. 1992).

The prevalence of bald eagles with elevated lead exposure was found to be higher in areas of high waterfowl hunting intensity than in areas with low hunting intensity (Wayland and Bollinger 1999). Similarly, Pain et al. (1997) found a significantly higher prevalence of elevated blood lead concentrations in marsh harriers (*Circus aeruginosus*) in France during, compared to outside, the hunting season.

Raptors are at risk both from prey killed with shotguns, such as wildfowl, rabbits and rodents, and from prey killed with rifles, such as deer and other large game. The prevalence of exposure to lead from bullets is likely to be higher in larger raptors, and poisoning from bullet fragments has been reported in wild bald eagles, golden eagles (*Aquila chrysaetos*), Steller's sea eagles (*Haliaeetus pelagicus*), white-tailed eagles (*H. albicilla*), and California condors (*Gymnogyps californianus*).

In addition, Johnson et al. (2013) reported that lead contamination of carcasses remains a serious threat to the health and sustainability of scavenging birds.

The main anthropogenic source of lead found in the blood of wildlife is lead-based ammunition. Lead from ammunition is the primary source for sub-lethal lead poisoning such as that seen affecting golden eagles in Sweden (Ecke et al., 2017). This hypothesis is supported by (a) the observed impaired flight performance in terms of decreased flight height and movement rate with increasing concentrations of lead in the blood and (b) the strong positive correlation between progress of the moose hunting season on the observed effects.

Ecke et al. (2017) report that annually about 150 000 to 200 000 moose are shot in Finland and Scandinavia[52]. The hunting period is fixed throughout the region and annual quotas are designated. Golden eagles exhibit a foraging response to the availability of moose gut-

[49] Crane–like.

[50] Usually referred to as 'gamebirds'.

[51] Bald eagles, golden eagles, steller's sea eagles. white-tailed eagles and California condors.

[52] Sweden, Finland and Norway among others.

piles and cutoffs during the hunting season. During the 2013−2014 hunting season, a total of 166 000 moose were harvested in Sweden (57 %), Finland (23 %), and Norway (20 %). During this period, an estimated 215 kg of lead from spent ammunition was deposited in gut piles, offal, and carcasses left for scavenging. This corresponded to more than 100 000 lethal doses for eagles.

Fraucke et al., (2017) also demonstrate that lead poisoning from ammunition is a significant mortality factor for white-tailed sea eagle (*Haliaeetus albicilla*) in Sweden. The authors conclude that a total of 22 % of all eagles examined (118) had elevated (>6 µg/g d.w.) lead concentrations, indicating exposure to leaded ammunition, 14 % of the individuals had either liver or kidney lead concentrations diagnostic of lethal lead poisoning (>20 µg/g d.w.). Lead concentrations in liver and kidney were significantly correlated.

In individuals with lead levels <6 µg/g, concentrations were significantly higher in the kidneys than in liver; in individuals with lead levels >20 µg/g, concentrations were significantly higher in liver. The lead isotope ratios indicate that the source of lead in individuals with lethal concentrations is different from that of individuals exhibiting background concentrations of lead (<6 µg/g d.w.) The proportion of lead poisoned white-tailed sea eagles remained unchanged over the study period, including two years after a partial ban of lead shot was enforced in 2002 for shallow wetlands.

Fraucke et al (2017) concluded that the use of lead in ammunition poses a threat to all raptors potentially feeding on shot game or offal. Kanstrup et al., (2017) argue that it is common practice to gralloch (i.e. remove internal organs from) killed deer (especially roe deer) where the hunting takes place and further argue that the number of gut piles left in nature is directly related to the number of killed animals.

More recently (Isomorsu et al, 2018) found that throughout the period 2000-2014 secondary poisoning of lead was the cause of death in 31% (of 123 carcasses) of the cases. Lead shot has been banned in waterfowl hunting in continental Finland for two decades, they are legal in terrestrial hunting exposing the eagles to lead embedded in mammal carcasses and offal. Åland allows lead ammunition in all hunting, including spring hunt of eiders, important prey of the White Tailed Eagle. General wildlife health surveillance in Finland reveals annually lead poisonings, particularly in White Tailed Eagles and whooper swans,

Lead can cause mortality, or can indirectly affect populations through effects on the food base, avian behaviour, reproductive success, and recruitment. Lead can (1) decrease the abundance and availability of prey, (2) bioaccumulate in prey causing increased lead poisoning in predators, or (3) increase prey availability by interfering with its hiding or escape behaviour. Moreover, lower abundance of prey can lead to starvation or nutrient deficiencies, which amplify the absorption and retention of lead. Lead also causes decreases in clutch and egg size, mortality of embryos and nestlings, depression of growth, and deficits in behaviour that affect survival. Lead decreases migratory behaviour, and increases vulnerability to cold stress, hunters, and other predators.

Humans

Much of what is known about the effects of lead is based on the relationship between exposure and blood-lead levels as sampling from the tissues where lead accumulates over time is impracticable and seldom possible.

Data from Norway, Poland, Sweden, the UK, and Canada reveal that meat from hunter-killed deer species and wild boar (*Sus scrofa*) may contain metallic lead levels far exceeding the European Commission's 0.1 mg lead/kg criterion for domestically reared meats, especially in minced meat (Knott et al. 2010; Fachehoun et al. 2015: Knutsen et al. 2015).

Body systems that are particularly sensitive to low levels of blood lead are the haematopoietic, nervous, cardiovascular and renal systems (EFSA 2013).

In humans, lead has effects on the following body systems:

Nervous system	EFSA 2010
Urinary system	EFSA 2010
Cardiovascular system	EFSA 2010
Immune system	EFSA 2010
Reproductive system	EFSA 2010
A range of organ among which the brain	EFSA 2010

NEUROTOXICITY

A large number of studies have examined the relationship between blood lead levels (B-Pb) and measures of nervous system function in children and adults. Toxic effects of lead upon the nervous system in adults include impairment of central information processing, especially for visuospatial organisation and short-term verbal memory, psychiatric symptoms and impaired manual dexterity. There is also evidence that the developing brains of children are especially susceptible to the effects of lead exposure, even at low concentrations of lead. A meta-analysis of the results of seven studies published between 1989 and 2003 of the IQ of 1 333 children in relation to B-Pb (Lanphear et al*.* 2005), and a refinement/reanalysis of the same data (Budtz-Jorgensen 2010) found marked decreases in IQ with increasing B-Pb, even at low B-Pb values. The effects of lead on the developing nervous system appear to persist, at least until late teenage years.

CARDIOVASCULAR EFFECTS

Long-term low-level exposure to lead is associated with increased blood pressure in humans. Meta-analyses support a relatively weak, but statistically significant, association between B-Pb levels and systolic blood pressure, amounting to an increase in systolic blood pressure of approximately 1 mm Hg with each doubling of B-Pb (Nawrot et al*.* 2002, Staessen et al*.* 1994), without any clearly identifiable B-Pb threshold for this effect.

NEPHROTOXICITY

A range of cross-sectional and prospective longitudinal studies have been conducted to examine the relationship between serum creatinine levels, which rise when kidney filtration is deficient, and B-Pb. Studies suggest an increased likelihood of chronic kidney disease as B-Pb levels rise, and the EFSA CONTAM[53] Panel concluded that nephrotoxic effects are real, that they may be greater in men than women, and that they are exacerbated by concurrent diabetes or hypertension.

Table 5: Benchmark Dose Modelling (BMDLs) for relevant endpoints

Benchmark responses (BMRs)	**BMDL (95th percentile lower confidence limit of the benchmark dose – BMD of extra risk) derived from blood lead levels (µg/L)**	**Corresponding dietary lead intake value (µ/kg bw per day)**	**Population level effects of MR**
1 % (1 point) reduction in IQ in young children	$BMDL_{01}$ = 12	0.50	The BMR for IQ could impact the socio-economic status of a population and its productivity. Studies in the USA have related a 1 point reduction in IQ to a 4.5 % increased risk of failure to graduate from high school and a 2 % decrease in productivity in later life (Schwartz 1994, Grosse et al. 2002)
1 % increase in systolic blood pressure (SBP) in adults (equivalent to 1.2 mm Hg change)	$BMDL_{01}$ = 36	1.50	A 1 % increase in SBP has been related to an increase in the percentage of the population treated for hypertension by 3.1 % and a 2.6 % or 3.4 % increase in expected annual mortality from cerebral stroleor myocardical infarction respectively (Selmer et al. 2000)
10 % increase in expected incidence of chronic kidney disease in adults	$BMDL_{01}$ = 15	0.63	

Source: EFSA, 2010

In addition, Hunt et al. (2009) and Fachehoun et al. (2015) show that people risk exposure to bioavailable lead when they eat venison from deer killed with standard lead-based rifle bullets and processed under normal commercial procedures. Hunt et al. (2013) conclude that, in a majority of cases, one or more consumers of a hunter-killed, commercially processed deer will consume lead from bullets. Similar conclusions for European game meat have been reached by Pain et al. (2010).

Exposure to lead from spent bullets is easily preventable if hunters use lead-free copper bullets that are now widely available and generally regarded as fully comparable to lead-based bullets for use in hunting. The potential for toxic exposure to copper from these

[53] EFSA COMTAM: European food safety Agency 's Panel on Contaminants in the Food Chain

bullets is presumably insignificant because little or no fragmentation occurs and there is no meat wastage from having to discard tissue suspected of contamination.

1.3.2. Exposure/emission

The estimates of emissions in this report are directly linked to the amount of ammunition and type of ammunition used and based on data/data interpretations from COWI (2004), AFEMS, AMEC (2012)[54] and ECHA (2017).

Rimfire cartridges are, according to (COWI, 2004), only used for sporting purposes[55] and mainly cover ammunition for calibre .22 (5.6 mm) guns. According to International Sports Shooting Federation ((SSF) rules, rimfire calibre .22 ammunition is used within the disciplines of rapid fire pistol, 25 m pistol and standard pistol, 50 m pistol and 50 m rifle (including running target).

A survey of European manufacturers indicates that the weight of the bullet of a calibre .22 cartridge generally ranges between 30 and 40 grains. AFEMS estimates [AFEMS 2004a] the lead content of an average rimfire cartridge to be 2.4 grams.

Centre fire rifle cartridges for sports shooting are used in the ISSF-discipline of 300 m rifle (calibres of up to 8 mm).

AFEMS estimates [AFEMS 2004a] the average lead content of a cartridge in this category to be 7 grams (125-185 grains) and this is based on weight distributions of 6.5 mm, 7.65 mm and WIN 308 rifle cartridges. A similar estimate is made for centre fire cartridges used for hunting.

There is no updated information on the production of lead ammunition or consumption by hunters in the EU. COWI (COWI, 2004) estimated the combined total emission of lead in 2005 for the EU15, Hungary, Lithuania and Poland to be 150 tonnes per year for hunting using centre firing ammunition. Further work would warrant updated figures on the types and tonnages of lead ammunition used.

Humans

Humans can be exposed to ammunition (both shot and rifle) derived lead as a consequence of consuming game meat that has been shot with lead containing ammunition as well as during target practice at shooting ranges.

<u>Consumption of game meat</u>

For decades, the principal approach of public health authorities to assessing health impacts of lead in the diet has been to identify a tolerable rate of dietary intake.

This sought to maintain exposure below a no-observed-adverse effect-level (NOAEL) that was assumed to exist. In 1982, the Joint Food and Agriculture Organisation/World Health Organisation Expert Committee on Food Additives (JECFA) set a Provisional Tolerable Weekly Intake (PTWI) of dietary lead of 25 µg/kg bw for infants and children. This was

[54] Available here: https://echa.europa.eu/documents/10162/13580/abatement+costs_report_2013_en.pdf/6e85760e-ec6d-4c8a-8fcf-e86a7ffd037d.

[55] All tough they are actually also used for some small game hunting (source:personal communication with David Scallan (FACE)_

extended to all age groups in 1993 and confirmed by JECFA in 1999. The PTWI was endorsed in 1992 by the European Commission's Scientific Committee for Food (SCF 1994). The European Commission carried out an updated lead exposure assessment in 2004 (SCOOP 2004) and, together with the SCF opinion, this formed the basis of setting maximum levels of lead in foodstuffs in the EU (Regulation (EC) No 1881/2006).

However, today it is considered that there is no blood lead concentration below which negative physiological effects of lead are known to be absent (EFSA 2010, ACCLPP 2012). Hence, the concept of a tolerable intake level has been called into question. In 2007, the European Commission requested the European Food Safety Authority (EFSA) to produce a scientific opinion on the risks to human health related to the presence of lead in foodstuffs. In particular, EFSA was asked to consider new developments regarding the toxicity of lead, and to consider whether the PTWI of 25 µg/kg bw was still appropriate.

Following a detailed analysis of the toxicological information, the EFSA CONTAM Panel based their dose-response modelling on chronic effects in humans, and identified developmental neurotoxicity in young children and cardiovascular effects and nephrotoxicity in adults as the critical effects for the risk assessment.

Several authorities in the EU have issued warnings on the consumption of game meat pointing out the possible contamination of it with lead as a source of concern:

Table 6: Advise given on game meat by several food safety agencies

Authority	Date	Scope of advice
UK Food Safety Agency, https://www.food.gov.uk/science/advice-to-frequent-eaters-of-game-shot-with-lead	October 2016	To minimise the risk of lead intake, people who frequently eat lead-shot game, particularly small game, should cut down their consumption. This is especially important for vulnerable groups such as toddlers and children, pregnant women and women trying for a baby, as exposure to lead can harm the developing brain and nervous system.
Germany http://www.bfr.bund.de/cm/349/research-project-safety-of-game-meat-obtained-through-hunting-lemisi.pdf	December 2014	In an exposure estimate, the BfR concluded that, with consumption of two meals of game meat per year (normal consumers) and also of five meals a year (high consumers) with the eating habits that are customary in Germany, the additional lead uptake from the game meat is of no toxicological significance for adults. This statement does not apply to children and pregnant women. As the developing nervous system of foetuses and children shows a particularly sensitive reaction to lead, every additional uptake of lead should be avoided by these population groups.
Spain	February 2012	Although the information available in Spain regarding

Authority	Date	Scope of advice
http://www.aecosan.msssi.gob.es/AECOSAN/docs/documentos/seguridad_alimentaria/evaluacion_riesgos/informes_cc_ingles/LEAD_GAME.pdf		the lead content in wild game meat and its consumption is incomplete, following the analysis of data available in Spain, it has been shown that the average lead content in pieces of large and small game exceeds the European Union general limits for meat and offal (there are no specific limits for this food) and these contents are similar to those found throughout Europe and other countries. It has been proved that wild game meat is consumed in Spain, although it is more common for hunters and their families. It is not restricted to the hunting season, and its consumption of products that come from it, such as cured sausage or pâté, by the general public in restaurants is not negligible.
Norway http://www.vkm.no/dav/cbfe3b0544.pdf	June 2013	At the individual level, the risk for adverse effect is likely to be small. At present lead levels, adults with normal blood pressure will most likely not experience any clinical symptoms by a small increase, although it may add to the burden of those individuals who are at risk of experiencing cardiovascular disease. A small reduction in the intelligence of children will not be notable at the individual level, but at the population level it can, for instance, increase the proportion not able to graduate from school. Lead exposure was declining in the population on which the reference value for increased prevalence of chronic kidney disease was based. EFSA noted that this reference value (15 µg/L) is likely to be numerically lower than necessary. The implications of having a concurrent blood lead concentration above the reference value cannot fully be interpreted, since it is not known when and at which level of lead exposure the kidney disease was initiated. However, an eventual increased risk of chronic kidney disease would be higher among those who consume cervid meat regularly or more often than those who rarely consume such meat. For these reasons, continued effort is needed to reduce lead exposure in the population.
Sweden https://www.livsmedelsverket.se/globalassets/rapporter/2014/bly-i-viltkott---del-4-riskhantering.pdf	October 2014	Need not be discarded from a risk perspective, but consumption should be limited up to once per month. Pregnant women planning pregnancy and children under seven years, however, should continue to avoid consumption.
France	March 2018	Because the expert appraisal highlighted a health

Authority	Date	Scope of advice
https://www.anses.fr/en/content/consumption-wild-game-action-needed-reduce-exposure-chemical-contaminants-and-lead		concern related to lead, the Agency is proposing various levers for action to reduce consumer exposure (substitution of lead ammunition, trimming of meat, frequency of consumption). Pending additional data and given the level of lead contamination in large wild game (deer and wild boar), the Agency recommends that women of childbearing age and children avoid all consumption of large wild game, while other consumers should limit themselves to occasional consumption, around three times a year.

Exposure to lead at shooting ranges.

In addition to the exposure of humans to meat containing lead, significant exposure can occur at shooting ranges.

Several sources of airborne lead have been identified: fragmentation of bullets during firing; the explosive vaporisation of the primer, which can contain both lead styphnate and lead peroxide; and inadequate ventilation of the range (Landrigan et al., 1975b; Fischbein et al., 1979; Muskett and Caswell, 1980; Dams et al., 1988).

Instructors are generally exposed to the highest concentrations of airborne lead and tend to have the highest blood lead concentrations due to their regular duties, which include supervising the range, cleaning and test-firing weapons, and preparing training ammunition from commercially purchased components. A positive correlation was reported between exposure of firearms instructors to elemental lead at covered outdoor firing ranges and increased blood lead concentrations (Tripathi et al., 1991). Concentrations of airborne lead can be significantly reduced (97–99 %) by using a lead-free primer and bullets jacketed with nylon, brass or copper (Valway et al., 1989; Robbins et al., 1990; Tripathi et al., 1990, 1991; Goldberg et al., 1991; Löfstedt et al., 1999; Bonanno et al., 2002).

A recent study by Laidlaw (Laidlaw et al., 2017), provides a review of the existing literature compiling data from a broad range of recent studies of firing range users, employees, and their families, including indoor and outdoor ranges, in an attempt to document and clarify risks by firing range use, setting, and shooting behaviour. The study focuses on the use of lead primers and lead bullets. The study does not cover shooting ranges where lead shot is used although the concerns might be similar. The authors reviewed 36 articles that included blood lead levels (BLLs) from shooters at firing ranges. In 31 studies, BLLs > 10 µg/dL were reported in some shooters, 18 studies reported BLLs > 20 µg/dL, 17 studies > 30 µg/d, and 15 studies BLLs > 40 µg/dL.

Shooting at firing ranges results in the discharge of lead dust, elevated BLLs, and exposures that are associated with a variety of adverse health outcomes. Women and children are among recreational shooters at special risk and they do not receive the same health protections as occupational users of firing ranges. Nearly all BLL measurements compiled in the reviewed studies exceed the current reference level of 5 µg/dL recommended by the U.S. Centers for Disease Control and Prevention/National Institute of Occupational Safety and Health (CDC/NIOSH). Therefore firing ranges, regardless of type and user classification, currently constitute a significant and unmanaged public health problem.

1.4. Existing risk management measures

In recent years, there have been several regulatory initiatives that address human and wildlife exposure to lead originating from ammunition:

California

Effective 1 July 2008, the California Fish and Game Commission modified the methods of take to prohibit the use of projectiles containing lead when hunting big game and non-game species in an area designated as the California condor range.

In October 2013, Assembly Bill 711 was signed into law requiring the use of non-lead ammunition when taking any wildlife with a firearm in California. This law requires the Commission to adopt by 1 July 2015, regulations that phase-in the statute's requirements, but it must be fully implemented by 1 July 2019.

The California Department of Fish and Wildlife CDFW conducted extensive public outreach during 2014 and proposed regulations that phase-in the non-lead requirement. This outreach effort included question and answer sessions at sportsmen's shows, meetings with hunting organisations and a series of eight public workshops throughout the state. CDFW then presented draft regulations, as modified by public input from these workshops, to the Fish and Game Commission.

In April 2015, the Fish and Game Commission adopted CDFW's proposed regulations, which will implement the non-lead requirement in the following three phases:

Phase 1 – Effective 1 July 2015, non-lead ammunition will be required when taking Nelson bighorn sheep and all wildlife on CDFW wildlife areas and ecological reserves.

Phase 2 – Effective 1 July 2016, non-lead shot will be required when taking upland game birds with a shotgun, except for dove, quail, snipe, and any game birds taken on licensed game bird clubs. In addition, non-lead shot will be required when using a shotgun to take resident small game mammals, furbearing mammals, non-game mammals, non-game birds, and any wildlife for depredation purposes.

Phase 3 – Effective 1 July 2019, non-lead ammunition will be required when taking any wildlife with a firearm anywhere in California.

Existing restrictions on the use of lead ammunition in the California condor range remain in effect while implementation proceeds.

Europe

There are currently no national bans in force in the UE Member States in force that limits that address the use of lead in civilian ammunition. There are regional bans in Germany (See section below) and in Italy (See section 1.1.2 on page 11) and some local initiatives such in Parco Nazionale Stelvio[56]

Germany

Three of 16 German Federal States (Schleswig Holstein (LTSH 2014), Baden-

[56] Personal communication Enrico Bassi

Wuerttemberg (MLRV 2014) and Saarland (CdS Saarland 2014)) have regulated the use of lead bullets for hunting.

In Schleswig Holstein, the use of lead bullets and shotgun slugs for hunting has been banned since 1 April 2015. This action was based on the results of Gremse and Rieger (2012, 2014) (LTSH 2014).

In Baden-Württemberg, the use of lead bullets has been banned for hunting cloven-hoofed game since 2016.

At Saarland, state-wide restrictions of bullets containing lead have been in place, since 1 April 2014, with a grace period granted to phase out their use by 2017.

The Federal State of North Rhine Westphalia is in the process of passing hunting legislation, which will restrict the use of lead bullets and shotgun slugs in hunting (MKULNV 2014).

Land in Germany is mostly owned by private, municipal, conventual, state and federal entities. 10 of the 16 forestry services of the Federal States, the Federal Forest Service and the 14 National Park Offices have rulings in place banning the use of lead rifle bullets on their land (DJV 2014).

The City of Rostock municipal forest (City of Rostock 2011), the German Federal Environmental Foundation (DBU 2011), the City of Greifswald (Greifswald 2011) and the City of Fuerstenwalde (City of Fuerstenwalde 2014), restricted the use of lead bullets in 2008, 2012 (both DBU and Greifswald) and 2013 respectively.

The Lead Ammunition Group reports that as well as policy developments, there have been changes in practice. Beginning in 2016, being mindful of lead-contaminated game potentially going into the human food chain, Forest Enterprise England (FE) required their staff to use non-lead ammunition for deer and boar culling. The decision was made following successful trials of selected non-lead bullets and was based on the evidence that lead from lead ammunition can contaminate carcasses and that FE’s marketing position could be seriously damaged if they continued to put lead-contaminated meat into the human food chain when there are proven alternatives available.

2. Justification for EU action

2.1. Lead for hunting purposes

Action on an EU-wide level is warranted as:

1. this provides better protection of raptors and scavengers who could (e.g. in the Alps) cross borders easily.
2. Game meat is traded on the free market.

This issue cannot be dealt with by regulating the maximum level (ML) of allowable lead in food, under Regulation EC1881 (2006). Although MLs have been set up for foodstuffs derived from wild game, wild game itself is not in the list (Thomas, 2013), whereas lead concentrations in game shot with bullets frequently exceed MLs set for other domestically raised meats (Pain et al., 2010). As argued further by Thomas (Thomas, 2013), inspection and quality control mechanisms exist and could be used. However, several arguments would lead to a conclusion that elimination of lead at the source (i.e. restricting the use of lead ammunition) is a better solution:

1. Lead concentrations in shot animals remain (lead fragments can be distant from the wound channel) and could result in frequent false positives and negatives in controls.
2. Game meat is often directly consumed by hunters.
3. The measure is not sufficient to protect scavengers and raptors (birds and mammals) from lead.

2.2. Lead for shooting purposes

Lead may constitute a health risk at firing ranges. However, this as such may not necessarily warrant action in terms of a restriction on the use of lead bullets. Other sorts of action under e.g. the Chemical Agents Directive may achieve the same goal and should be considered under a risk management options analysis.

Prevention includes changing clothing after shooting, behavioural modifications such as banning of smoking and eating at firing ranges, improved ventilation systems and oversight of indoor ranges, and development of airflow systems at outdoor ranges.

Emissions to the environment can be adequately dealt with by range-design and ensuring entrapment of bullets and spent shot. Eliminating lead dust risk at firing ranges requires primary prevention and using lead-free primers and lead-free bullets.

2.3. Differentiate between shooting and hunting

If a differentiation needs to be made between hunting and sports shooting then any further regulatory action could explore whether difference exist between sports and hunting bullets. The same calibres are often used both in sports and hunting[57] .So one cannot differentiate sport and hunting based on calibre. However, bullet types may be an option. It appears that bullets for target shooting are full-jacket bullets that are not allowed for hunting (due to low hitting expansion). So, a way to differential could be allowing lead full-jacket bullets under a certain weight threshold as they would not be suitable for hunting. This option should be further analysed and assessed with the ISSF rules and existing rules for hitting power for hunt ammunition in force.

3. Impact assessment

Impact assessments of a restriction on the use of lead ammunition (and lead shot) have been carried out by COWI (COWI, 2004), Amec (2012) (cost assessment) and by (Duncan, 2014) for the Californian lead ammunition ban.

3.1. Alternatives

3.1.1. Introduction

The main category of alternatives (copper based) kill the animal by a different type of impact as discussed by Caudell (Caudell et al., 2012) (See Figure 3-1):

[57] Personal communication Niels Kanstrup

- Lead bullets have long been the most common type of ammunition as lead is soft, easily moulded and heavy. With early firearms such as muzzleloaders, lead bullets retained their shape, but modern, higher-velocity centerfire rifles often cause lead bullets (even those sheathed in copper) to fragment upon impact.
- Copper and other copper alloy bullets and slugs are harder than lead and typically remain intact on impact, transferring more energy to the target by folding downward into "petals" (see Figure 3-1: Difference in bullet fragmentation between copper and lead bullets
- (Source: http://www.dec.ny.gov/docs/wildlife_pdf/htbullslug.pdf) that greatly expand the surface area. The result is a very effective, quick, humane kill and more edible, uncontaminated meat.

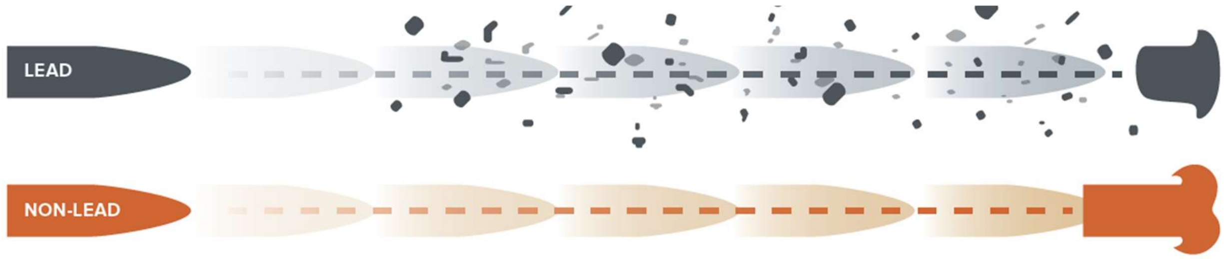


Figure 3-1: Difference in bullet fragmentation between copper and lead bullets

(Source: http://www.dec.ny.gov/docs/wildlife_pdf/htbullslug.pdf)

Bullet fragmentation is considered to be one of the main methods of increasing the permanent damage to the wound cavity and increases the chance of near-instantaneous incapacitation when the central nervous system is not hit. As copper bullets are not designed to fragment, shot placement becomes more critical if instant or near instant incapacitation is desired.

3.1.2. Suitability of alternatives

From the available studies, it appears that two main factors determine the technical feasibility of alternatives; bullets are compared usually in calibre size (i.e. does the bullet fit in the gun), and on hunting efficiency (will the bullet not cause unnecessary harm to the animal).

The suitability of lead-free bullets in hunting is discussed by Kanstrup (Kanstrup et al., 2016), who concludes that for hunting purposes there is no consistent and significant difference between lead containing and lead-free bullet for hunting roe and red deer under normal circumstances. These results are similar to other studies mentioned by Kanstrup (Spicher, 2008; Knutt et al., 2012; Gremse and Rieger, 2012). Further studies by Gremse (Gremse, 2014a) and (Gremse, 2014b) indicate that abandoning of lead as a bullet material for hunting bullets is possible. Quick and ethical kills of animals in hunting activities can be ensured regardless of bullet material.

A more recent study (Martin et al., 2017) is more definitive. It sets the length of the escape distance[58] as an indicator for adequate bullet effectiveness for human killings of game animals in hunting. Based on 2 059 shooting records (Martin et al., 2017) concluded that there is no indication that non-lead ammunition results in longer escape distances of dear or wild boar. The length of the escape factor depends more on other factors such as shot placement, shooting distance, hunting method or the age of the animals.

Caudell (Caudell et al., 2012) conclude that for most typical hunting equipment, the level of performance is good enough with standard alternative ammunition but there might be certain scenarios (outside of typical hunting) where higher performance lead-free bullets are desired. These scenarios include most notably professional wildlife management where the penetration and consecutive continued flight of the bullet after hitting the animal may pose additional risks (e.g. wildlife management at airports).

3.1.3. Availability of alternatives

The analysis of Thomas (Thomas, 2012) suggests that alternatives for the most popular cartridges are available on both the EU and US market. The 37 leading ammunition manufacturers produce a wide range of 35 lead-free bullet calibres that in theory cover a wide variety of hunting types. An analysis for the European market is made by Thomas (Thomas et al., 2016) in which the authors conclude that product availability (i.e. that which is made) of non-lead rifle ammunition in a wide range of calibres is large in Europe and is suited for all European hunting situations. At least 13 major European companies make non-lead bullets for traditional, rare, and novel rifle calibres. Local retail availability is now a function of consumer demand, which relates, directly, to legal requirements for use.

Information from FACE[59] would suggest that for certain calibres there is a problem securing non-lead ammunition for .22LR (a very popular round for pest control) and the .243 WIN (a popular multipurpose deer/fox). A non-lead .243 round that was heavy enough to be legal for large deer would have to be longer than current barrels are able to stabilise, so there would need to be a shift to larger calibres or many hunters would need new barrels. There are several other calibres below .6mm where alternatives are poorly available including air rifles and pistols used for target shooting. Indeed, these calibres in lead containing form (or similar calibres) are scheduled to be phased out with a longer transition period under the Californian regulation regarding the use of lead ammunition for hunting (Duncan, 2014). Since the introduction of the Californian regulation, alternatives in that same calibre have been developed (Winchester .22).

Kanstrup (Kanstrup et al 2016) present a list of lead free ammunition that is available in Europe (See Table 7) wherein data is presented on lead free bullet availability from the principal 13 European rifle ammunition makers that have already developed their own brands. Kanstrup argues that is this is in response to the ongoing demand for and evaluation of non-lead rifle ammunition in Germany (Gremse and Rieger 2015), and possibly, for export into the growing North American market.

Kanstrup (2016) concludes that the major companies, Blaser, Brenneke, Fiocchi, Geco, Lapua, Norma, Rottweil, RWS, Sako, Sellier & Bellot, Sax, Sauvestre, Schnetz, and

[58] The distance an animal may run after being shot, essentially the shot should ensure the distance is short to ensure unnecessary suffering.

[59] Personal communication from David Scallan, FACE.

Hornady International, list calibres suitable for hunting every European game species and for every commonly used rifle and concludec from this that the product availability (i.e. that which is manufactured, as opposed to what is commonly available at the retail level) of non-lead rifle ammunition is not a limiting factor in Europe in the further growth in the use of non-lead bullets.

(Kanstrup et al, 2016) point out that regulation will be the most important factor determining both the product availability and, especially, the local retail availability of non-lead ammunition, besides influencing competitive prices (Thomas 2015). Kanstrup continues with pointing out that this was the case when the US federal government banned nationally the use of lead shotgun ammunition for waterfowl hunting in 1991 and ushered in the rapid transition to the mandatory use of lead-free shot.

Data or arguments are missing to see how the market will react to an increase in demand. This is highlighted by Southwick associates (Southwick associates, 2014[60]) who point out that as a consequence of the California lead ban, most lead-free ammunition manufacturers are SMEs and are not able to ramp up production levels to the levels required to satisfy the expected increased demand for lead-free alternatives. The level required is determined by the amount of hunters and under the assumption that hunting activity remains at current levels. **Further work could include an analysis of the current market situation in California to see if the increased demand was met by industry**

[60] See: http://nssf.org/share/PDF/CA-Alternative-Ammo-Impacts_9-15-2014.pdf

Table 7: Comparison of listed retail prices for different brands of commonly used lead-free and lead-core rifle hunting ammunition in

Brenneke Non-lead TUG Nature+	**Brenneke Non-lead TAG**	**RWS Evolution Green**	**RWS HIT**	**RWS Bionic Yellow**	**Blaser CDC Bullet**	**Norma Barnes TSX**	**Norma Kalahari**	**Hornady International**	**Hornady Super-performance**	**Sako Powerhead Barnes TSX**
7 × 57	.308 Win	.270 Win	.308 Win	.308 Win	7 × 64	7 mm Rem Mag	.270 Win	6.5 × 55	.223 Rem	270 Win
7 × 57R	.30–06	.308 Win	.30–06	.30–06	7 × 65R	.300 Win Mag	.270WSM	7 × 64	.243 Win	.308 Win
7 × 64	.300 Win Mag	.30–06	.300 Win Mag		7 mm Rem Mag	.375 H&H	.280 Rem	7 × 57	.25–06 Rem	.30–06
7 × 65R	8 × 57JS	.300 Win Mag	7 mm Rem Mag		.308 Win		7 × 64	7 × 65R	.270 Win	9.3 × 62
.308 Win	8 × 57JRS	.30R Blaser	7 × 64		.30–06		7 mm Rem Mag	8 × 57JS	7 mm Rem Mag	9.3 × 66 Sako
.30–06	9.3 × 62	7 × 57R	7 × 65		.300 Win Mag		.308 Win	8 × 57JRS	7 mm–08	9.3 × 74R
.30R Blaser	9.3 × 74R	7 × 64			.30R Blaser		.30–06	9.3 × 62	.308 Win	.375 H&H
.300 Win Mag		7 × 65R			8 × 57JS		.300Win Mag	9.3 × 74R	.30–06	
8 × 57JS		7 mm Rem Mag			8 × 57JRS		.300 WSM		.300 Win Mag	

8 × 57JRS		8 × 57JS			8 × 68S				.338 Win Mag	
8 × 68S		8 × 57JRS			9.3 × 62				.375 H&H	
9.3 × 62		9.3 × 62			9.3 × 74R					
9.3 × 74R		9.3 × 74R								
Nickel-plated	Copper	Tin core	Copper	Brass	Copper	Copper	Gilding metal nickel-plated	Copper	Copper	Copper
steel jacket,		nickel-plated	nickel-plated							
tin core										
Fragmenting	Partially fragmenting	Partially fragmenting	Non-fragmenting	Partially fragmenting	Non-fragmenting	Non-fragmenting	Partially fragmenting	Non-fragmenting	Non-fragmenting	Non-fragmenting
Sako Powerhead II Barnes TTSX	**Sako DGS Solid**	**Fiocchi Freccia Nera**	**Sellier & Bellot eXergy**	**Geco Zero**	**Sauvestre**		**Sax KGJ**		**Schnetz KG**	**Lapua Naturalis**
.222 Rem	9.3 × 62	308 Win	6.5 × 55SE	.300 Win Mag	.243 Win	….cont.	.223 Rem	….cont.	22 Hornet	.243Win

.243 Win	9.3 × 74R	.30–06	.270 Win	.30–06	6.5 × 57	.30 R Blaser	.22–250	.300 Win Mag	5.6 × 50R	6.5 × 55SE
6.5 × 55SE	.375 H&H		7 × 57	.308 Win	.270 Win	8 × 57JRS	.243 Win	.300 WSM	.222 Rem	.308 Win
.30–06	.416 Rigby		7 × 57R	7 mm Rem Mag	.270 WSM	8 × 68S	6.5 × 55	8 × 57JS	5.6 × 52R	.30–06
.308 Win	.450 Rigby		7 × 64	7 × 57	.280 Rem	35 Whelen	6.5–284	8 × 57JRS	6 × 62	8 × 57JS
.300 Win Mag	.500 Jeffery		7 × 65R	7 × 57R	7 mm ’08 Rem	9.3 × 62	6.5 × 57R	8 × 68S	6 × 62R	.338 Lapua
7 × 64			7 mm REM Mag	7 × 64	7 × 57R	9.3 × 74R	6.5 × 68	.338 Lap Mag	6.5 × 57	9.3 × 62
7 mm Rem Mag			.308 Win	7 × 65R	7 × 64	.338 Win Mag	.270 Win	8.5 × 63	6.5 × 63 mm	
8 × 57JS			.30–06	8 × 57JRS	7 × 65R	.375 H&H	.270 WSM	8.5 × 65R	6.5 × 65	
			.300 Win Mag	8 × 57JS	7 mm Rem Mag	.404NE	7 × 57	9.3 × 62	6.5 × 65R	
			8 × 57JS	9.3 × 62	.30–06	.458 Win Mag	7 × 57R	9.3 × 72R	7 × 66	
			8 × 57JRS	9.3 × 74R	.308 Win	.458 Lott	7 × 64	9.3 × 74R	7 × 75R	
			9.3 × 62		.300 Win Mag		7 × 65R	.375 H&H	.30R Blaser	

			9.3 × 74R		.300 WSM		7 mm Rem Mag	10.3 × 60R	.300 Wby Mag	
					.300 Wby Mag		7 mm WSM	.416 Rem Mag	.300 RUM	
							7.5 × 55 Swiss		8 × 75RS	
							.308 Win		.338 Win Mag	
							.30–06			
Copper, plastic tip	Brass	Copper	Copper	Copper, tin core	Copper, plastic tip		Copper, plastic tip		Copper, plastic tip	Copper
Non-fragmenting	Non-expanding, Non-fragmenting	Non-expanding	Non-expanding	Fragmenting	Non-fragmenting		Fragmenting		Fragmenting	Non-fragmenting
URLs: www.brenneke-ammunition.de, https://rws-munition.de, www.blaser.de, www.norma.cc, www.hornady.com, www.sako.fi, www.fiocchigfl.it, www.sellier-bellot.cz, www.geco-munition.de, www.sauvestre.com, www.sax-munition.de, www.schnetz.at, www.lapua.com										

(Source: Kanstrup et al 2016)

3.2. Socio-economic impacts

3.2.1. Cost of alternatives

The data presented by Thomas (2012) suggests that for most of the calibres produced, alternatives are made at a higher cost. Market forces, manufacturers' cost and volatile global metal prices drive the difference in price (especially for copper). The conclusion from Thomas (Thomas, 2013) can however not be considered as representative per se, as Thomas only consulted one web page.

Furthermore Thomas (2012) concluded that the amount of bullets used per year combined with the increased costs of using alternatives vis-à-vis the total budget of the hunter (hunting done with rifles) would mean there would be a drastic increase in costs for this type of hunting. Often the prices paid for licenses (per cull) are such that the increased cost for non-lead ammunition is only marginal. Research from the USA would also suggest that hunting activity is price-inelastic, implying that changes in the prices of ammunition do not lead to changes in hunting in the short and in the long term (Duncan, 2014)

Tomas (2012) presents a table of USA prices from which he concludes that the most realistic comparison is between the prices for Federal Premium TSX and Federal Premium lead-core ammunition, because the same company is using the same components, technology, and marketing to establish the price of the two product lines.

The prices of cartridges of a given calibre and bullet mass vary among manufacturers, both for lead-core and lead-free offerings. However, for calibres 7 mm Remington, .30-06, .300 Winchester, .375 H & H, and .416 Rigby, the prices for lead-free and lead-core ammunition made by Federal were identical.

These are among the most commonly used cartridges for hunting deer, elk, moose, and bears in North America and Europe, and African plains game. For calibers .223 Remington, and .243 Winchester, the price differences were inconsistent across all brands of ammunition. In some cases the lead-core products were more expensive: for others, lead-free products were cheaper.

For the popular calibre .270 Winchester, lead-free cartridges were slightly more expensive, 1–2$ per box over lead-core cartridges at 37.99$ per box of 20.

The largest price difference in this comparison was for the calibre .300 H & H. The price of Federal TSX was 8$ higher than the lead-core equivalent at 55$ per box of 20. This is now a comparatively rare hunting cartridge in the USA, but not for plains game in Africa.

An important observation is that lead-core cartridges made by Remington, in calibres .270 Winchester, 7 mm Remington, .30-06, .300 Winchester, and .375 H & H were listed at much lower prices than other makers' lead-core and lead-free bullets, and provide products for cost-conscious hunters.

A comparison of prices for lead-core and non-lead rifle ammunition was presented in Thomas (2013). That study compared the retail prices of nine commonly used calibres (from .223 to .416) of assembled rifle ammunition in different weights, types, and brands available across the USA. It found that prices for the two types of ammunition were generally comparable, and where the non-lead products cost more, the relatively small increase was not enough to deny purchase and use. The same result applies to bulk purchase of bullets for ammunition hand-loaders: lead-core and non-lead bullets cost about the same at the retail level. An economy of scale effect is likely to lower the price of non-lead ammunition further, as more hunters adopt this ammunition. A regulated use of non-lead rifle ammunition in hunting would increase an economy of scale effect across the most widely used bullet calibres. Kanstrup (2015) concluded that non-lead rifle ammunition is largely available in all normal calibres (particularly 6.5 × 55, 308 Win. and 30–06) in Danish hunting stores at prices comparable to equivalent lead products. The lowest range of availability was found in the small calibres (<6 mm). In Germany, Gremse and Rieger (2012) found non-lead rifle ammunition in adequate supply across the range of hunting calibres typically used, with ammunition for small calibres (≤6 mm) being offered mostly by specialty manufacturers. Pricing comparisons in Germany mirror the conclusions of Thomas (2013).

The above consideration applies only to ammunition used in hunting. Rifle target shooters may fire many more rounds during training and practice, and should the price of their selected non-lead ammunition exceed that of the lead equivalent, an extra cost is realized, unless economy of scale effects eventually render differences slight or non-existent.

Further work on the price differences and understanding these price differences needs to be done.

An understanding needs to be created on how further regulatory action affect hunting and various options for measures can or should be considered. For example, in California, the legislator chooses different transition periods for different calibres depending on the current availability of lead-free alternatives for those calibres.

3.2.2. Need to replace guns

There is little clarity on the need to replace guns. Most of the literature does not take this into account and speaks of re-calibration of existing guns and or more frequently cleaning of the gun. As such, the construction of lead-containing bullets (copper jacketed) would suggest that a real need to replace does not exist. There are, however, adjustments needed to the rifling (vis-à-vis the lighter bullet head) that need to be further explored to better understand the need to replace guns.

The California impact assessment assumes that 10 % of the guns (or gun-owners) need to replace guns due to the gun’s age, and their dependency on rare calibres for which it is likely that alternatives will not be developed. Discussions with industry[61] on this subject indeed suggest that there is little need to replace guns but that for some calibres, alternatives are not yet readily available (or never will be) and hunters may need to purchase new guns.

COWI (2004) estimated the costs per hunter assuming a retail price of a rifle cartridge of € 0.04 - 0.35€ and a cost of non-lead rifle cartridges of 120 % compared to lead cartridges. A ban on lead in rifle cartridges would imply annual, incremental costs to the average European hunter in the range of € 0.03 to € 0.3. Duncan et al. (2014) estimate the total compliance cost per hunter to be in the order of $ 180 (covering ammunition, recalibration

[61] Personal communication with Nammo Lapua Oy.

and firearms costs, which on an average budget of around $ 2500 implies a 7 % increase.

3.2.3. Benefits

Wildlife

Predatory and scavenging birds may be exposed to high levels of lead when they ingest shot or bullet fragments embedded in the tissues of animals injured or killed with lead ammunition. Lead poisoning was a contributing factor in the decline of the endangered California condor population in the 1980s, and remains one of the primary factors threatening species recovery.

In response, a ban on the use of lead ammunition for most hunting activities in the range of the condor in California was implemented in 2008. Monitoring of lead exposure in predatory and scavenging birds is essential for assessing the effectiveness of the lead ammunition ban in reducing lead exposure in these species.

In this study, the authors (Kelly et al., 2011) assessed the effectiveness of the regulation in decreasing blood lead concentrations in two avian sentinels, golden eagles and turkey vultures, within the condor range in California. The authors compared blood lead concentrations in golden eagles and turkey vultures before the lead ammunition ban and one year following implementation of the ban. Lead exposure in both golden eagles and turkey vultures declined significantly post-ban. Their findings provide evidence that hunter compliance with lead ammunition regulations was sufficient to reduce lead exposure in predatory and scavenging birds at study sites.

Additionally, the Arizona Game and Fish Department has promoted the voluntary use of non-lead ammunition for hunting within the condor range in Arizona since 2003. These efforts led to a decrease in condor lead exposure and a reported 80 % hunter compliance during the 2007 hunting season.

These findings provide direct evidence that regulating the use of lead ammunition for hunting can reduce lead exposure in predatory and scavenging birds. Since the initiation of the ban in 2008, ammunition manufacturers have increased their production of non-lead ammunition in response to demand, and numerous non-lead ammunition alternatives are now available for hunting both small and large game and non-game species.

Replacement of lead ammunition with non-lead alternatives will greatly reduce the risk of lead poisoning and associated mortality in predatory and scavenging birds, and may benefit the conservation of these species.

Monetisation

Monetising the positive impacts of a ban would require valuing the loss of birds in terms of social costs. Methods similar to those used in the shots over wetlands report can be used. Two studies have been identified that analyses cost and increased efforts in conservation required to overcome losses in bird populations.

Hunt et al. (2017) studied the number of golden eagle pairs required to support windfarm mortality. They estimated that the entire annual reproductive output of 216–255 breeding pairs would have been necessary to support published estimates of 55–65 turbine blade-strike fatalities per year. Although the vital rates forming the basis for these calculations may have changed since the data were collected, their approach should be useful for gaining a clearer understanding of how anthropogenic mortality affects the health of raptor populations, particularly those species with delayed maturity and naturally low reproductive rates.

Ferri ear et al. (2017) concludes that the actual capacity of production in captivity of young per year greatly affects the duration and hence the cost of any reintroduction program (Morandini and Ferrer, 2017). Again, using the information provided by the Gypaetus foundation, during the 10 years of releases, 37 individuals have been set free (3.7 per year). According to simulations, with this number of young per year, releases need to continue for more than 23 years to achieve a viable population (see Ferrer et al., 2014; Morandini and Ferrer, 2017).

Consequently, the real total cost of this approach based in captive breeding would be € 14 680 500 (33 years of operating cost: € 12 886 500 plus 23 years of release: € 1 794 000), against € 1 068 830 using another suggested approach (extracting wild young from food-supplemented nests).

In other words, in an standard reintroduction program releasing 10 young per year during 10 years, each one of the released young bred in captivity costs around € 146 805 and each young coming from a food-supplemented wild population that were released costs € 10 680.

Captive breeding programs may be the only option when the remaining wild populations are so small that extractions would not be possible or if no wild populations remain. In addition, there are sometimes captive animals that could not themselves be released but could be useful for producing young for release. Nevertheless, when a reintroduction program is planned, differences in the total cost of the two alternative strategies (breeding in captivity versus the harvesting of wild nestlings) can be so great as to settle any argument over methodology.

Humans

Restricting lead ammunition and lead shot will lead to a reduction in dietary exposure to lead. The impacts of this reduction can be calculated as the BMDLs are associated with specific effects in populations (EFSA CONTAM Panel). Assuming the relationship between lead intake and the response (lead is a non-threshold substance) it is possible to combine this with lead exposure to calculate impacts. The main parameters in exposure to lead through food, are:

- frequency of consumption of lead containing game meat;
- quantity of consumption; and
- amount of lead contained in food.

In their study, Green and Pain (Green and Pain, 2015) estimate that the consumption of game meat is per capita 8.6 kg of game meat per year if a game meal contains 100 grams of meat (FSA, 2002) for the UK. (Green and Pain, 2015) recalculate the BMDL to the average consumption of game meat that would lead to that effect and conclude that in the UK estimated that thousands of children in the UK (calculated to be in the range 4,000-48,000) could be at potential risk of incurring a one point or more reduction in IQ as a result of current levels of exposure to ammunition derived dietary lead.

Whereas Pain and Green treat the BMDL's as a substitute for thresholds, we propose to use the view taken by RAC in the lead in jewellery and lead in articles opinions where the non-threshold effect is much more emphasised and a quasi linear relationship between blood lead level and effect is assumed.Monetisation

The endpoints of most interest are those that involved the functioning of the nervous, cardiovascular and renal body system for which ECHA (ECHA 2016) and previous opinions of ECHA (ECHA lead in jewellery, lead in articles) find the following valuation factors:

Table 8: WTP values of helth endpoints relevant for lead

Endpoint	Vehicle	Valuation factor =	Remark
Nervous system	Loss of value of IQ points	reductions in lifetime earning per IQ point of € 8 000, with a lower and upper bound of respectively € 2 400 - € 25 000	
Renal system	WTP	Acute: 532 per case Chronic 2 761 per case	Lead: long term, chronic
Cardiovascular	To be identified	To be identified	

The study by Pain and Green shows that the number of cases of effects of lead containing consumption in the population can be large. On the other hand, there are arguments stating that the number of cases might be lower as especially hunting families consume high amounts of lead containing meat (and fowl) with more intense effects. Pain and Green perform this sensitivity analysis. The approach followed by Pain and Green can be applied to the European dataset using the EFSA data of the CONTAM panel and WTP values for the relevant endpoint exist

3.3. Potential derogations

3.3.1. Vintage guns

During the public consultation on lead in shots over wetland, comments were submitted by the Vintage Arms Association (UK) concerning the limited possibilities to use non-lead alternatives with vintage and antique guns.

Vintage and antique guns are defined (by rules of the association) as guns pre-dating 1939. These types of guns can only support lead, as there was no other type of ammunition available when they were designed. Many muzzle loading and black powder rifles depend on the expansion of soft lead ammunition during shooting for accuracy.

More abrasive metals would cause excessive wear to the barrels and a dangerous loss of accuracy, which could result in bullets flying wide of the bullet catcher. The approved type of arms, used for deer hunting in the UK, are required to exceed 2 450 fps muzzle velocity. Vintage and black powder rifles produce around 1 400 fps, so they cannot be legally used for hunting deer. Because of the ranges involved and the accuracy required, hunters use modern rifles with telescopic sights.

The information that was submitted highlights that there is indeed a potential for a derogation for vintage guns, but there is not (yet) sufficient data that would warrant such a derogation on a European level.

3.3.2. Shooting ranges

For shooting ranges, besides a restriction on the marketing and use of lead bullets, other options exist to manage risks for both human health and the environment.

There might, for example, be range constructions that would ensures that bullets are captured in a specifically designed bullet catcher. This enables the lead to be recovered for recycling and contaminated waste to be properly disposed. Where necessary, appropriate physical and chemical precautions are taken to avoid environmental damage. Further measures to limit human exposure can be in occupational risk management measures (RMMs) (such as ventilation) that could limit exposure to lead dust.

On the other hand, complete phasing out of lead ammunition would eliminate the problem at the source and could prevent lead ammunition being used for hunting. Examples are known of shooting ranges that do no longer allow lead-based ammunition except for calibre types for which a suitable alternative is not yet available.

The advantages and disadvantages of a wider restriction that includes shooting should be compared to other measures.

3.4. Enforcement

The framework for enforcement is extensively discussed in the lead in shot over wetland proposal. The enforcement for ammunition will need to follow the same framework should the restriction focus on use. If there is a focus on sales and placing on the market then enforcement is expected to be more straightforward.

3.5. Transition period

The transition period for the proposal on lead shot over/in wetlands was recommended to be three years. RAC arguments were presented to shorten this, as any additional years would imply an excess mortality for waterbirds, SEAC balanced these arguments to shorten the transition period with arguments in terms of shotgun proofing and the availability of infrastructure to do so in a limited number of countries that have not yet implemented the AEWA agreement.

Thomas (2015a) identified eight European and European–US companies that make lead-free rifle bullets in 27 different calibres, all available to hunters. The results of the field testing of copper bullets for hunting roe and red deer indicate that bullets of calibre >6 mm could be authorised for immediate use throughout Denmark (Kanstrup et al. 2016). Copper bullets of calibre <6 mm may not stabilise as well when fired from the same rifle barrel. This is a function of the twist rate of the barrel's rifling (Caudell et al. 2012).

A transition to the regulated use of these smaller calibre bullets could take longer to allow hunters to change gun barrels to a more appropriate twist rate, and/or to await the development of denser lead-free bullets. It is worthwhile to note that the State of California has set out the following path to phasing out lead:

> Phase 1 – Effective 1 July 2015, non-lead ammunition will be required when taking Nelson bighorn sheep and all wildlife on CDFW wildlife areas and ecological reserves.
>
> Phase 2 – Effective 1 July 2016, non-lead shot will be required when taking upland game birds with a shotgun, except for dove, quail, snipe, and any game birds taken on licensed game bird clubs. In addition, non-lead shot will be required when using a shotgun to take resident small game mammals, furbearing mammals, non-game mammals, non-game birds, and any wildlife for depredation purposes.
>
> Phase 3 – Effective 1 July 2019, non-lead ammunition will be required when taking any wildlife with a firearm anywhere in California.

The bill in California entered into force in 2015 and is effectively granting a 4 year period to phase out lead completely, even for smaller bullets.

4. Conclusions

- The use of lead ammunition poses a risk to scavengers and raptors. Humans are exposed from consuming game meat and from lead dust at shooting ranges.
- The most effective manner to deal with lead is at the source i.e. through a regulatory action on the use of lead ammunition. Other measures (setting maximum lead levels in game meat) are protective for human health, but would not be protective enough for scavengers and raptors. Additionally, such a limit value would not protect hunters that consume their own meat.
- Measures on the use of lead ammunition in hunting have, at least in California, proven to be effective in reducing the exposure in raptors and scavengers to lead.
- Alternatives for lead ammunition exist. Many manufacturers have responded to existing legislation by producing lead-free ammunition.

- Action on an EU level is warranted to provide a harmonised level of protection to raptors and scavengers who are known to cross borders and game meat that can be traded freely within the single market.

Part III – lead in fishing weights / sinkers

1 Introduction

This annex describes the information that has be collected on the use of lead and its compounds in fishing weights. Critically, this annex provides a preliminary appraisal of the availability, reliability and significance of the information collated in relation to the requirements of an Annex XV restriction report, prior to the preparation of an Annex XV report. Key uncertainties, assumptions and information gaps, in relation to the required elements of an Annex XV restriction report, are identified.

Lead fishing sinkers are traditionally used in commercial and recreational fishing. When lead fishing sinkers are lost through broken line or other means, birds can inadvertently eat them. Water birds like loons and swans often swallow lead when they scoop up pebbles from the bottom of a lake or river to help grind their food. Eagles ingest lead by eating fish which have themselves swallowed sinkers. The amount of lead use din fishing is estimated to be between 4000 and 15 0000 tonnes per year. Growing concerns on the amount of lead dispersed in the environment and its effects this have led, in Canada, Denmark but also more recently in the Netherlands to a growth in the amount of alternatives that are available at prices comparable to the traditional lead sinkers

1.1 Key previous assessments

The advantages and drawbacks of restricting the marketing and use of fishing sinkers were investigated in detail in a study contracted by the European Commission (European Commission, 2004). Although relatively old (and perhaps in need of some updating), this study, in essence, contains **all the necessary information for the preparation of an Annex XV restriction on the use of lead in commercial and recreational fishing**.

For example, information on risks, volumes, alternatives (including price differences to lead-based tackle) are included and these data would be relatively straightforward to update using the same methodology as originally used.

1.2 Manufacture, use and existing risk management

Manufacture and use

The report to the European Commission (2004) provides extensive and detailed information on the manufacture and use of lead in fishing weights. The key information is summarised below:

Lead fishing weights (also termed 'sinkers') are used in both angling (also termed as 'recreational fishing') and commercial fishing. In angling, lead weights are a component of various types of 'lures' used to attract fish as well as other elements of equipment ('tackle'), including the following (see

Figure 4-1):

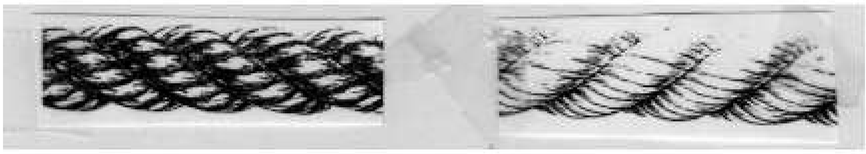
- sinkers/weights (trolling, egg, bank, pyramid, cannonball, disc);
- Jigs;

- wobblers (minor use);
- downrigger weights;
- split shot and styles;
- Floats (minor use); and
- pirks.

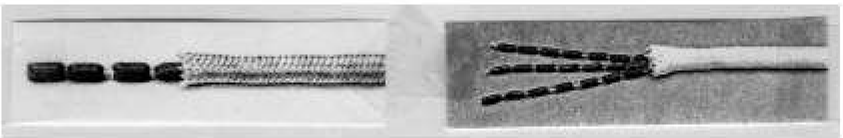
Figure 4-1: Types of lead weights used for angling

Commercial fishing typically involves sinkers/weights, lead lines and seine ropes (COWI, 2004):

Seine ropes are used for large seines (nets), mainly used for fishing benthic fish on relatively shallow water as in the North Sea. The seine rope is typically designed as a woven rope with a thin lead wire woven into the filaments of polypropylene or polyester, which is sewn to the net. Benthic seine nets are mainly used in Denmark, Scotland, Norway and Iceland. Seine ropes are produced in different diameters and the weight of the ropes range from about 23 to 85 kg per 100 m.



Lead lines are used all over Europe for pound nets (or set nets). A line is made of small pieces of lead beads threaded on a plastic rope. The string of lead beads is covered by a woven plastic stocking of polypropylene, polyester or other plastics and the stocking is sewn or woven on the net. Lead lines are produced in different diameters and the weight range from about 2 to 20 kg per 100 m.



Sinkers/weights are used all over Europe for large ring nets or seines for pelagic fish, some type of trawls, fykes, hoop nets and other types of net fishing. The size and design of the weights may differ considerably and the weights shown below represent a few examples only. Lead weight for fishing nets ranges from about 50 g to several kg per weight.

The weight of split shot ranges from fractions of a gram to about 50 grams. The weight of sinkers, which consists of a lead body with one or more eyelets to fasten the fishing line with a knot, range from a couple of grams to several hundred grams. Downriggers may weight up to 5 kg whereas the weight of pirks typically ranges from 100-600 grams. Wobblers and floats are mainly made of wood or plastics, but often contain a small part of lead.

Split shot, small sinkers/weights, and wobblers are mainly used in freshwater, whereas larger sinkers/weights, downrigger weights and pirks are used for sea fishing.

Based on the data available, the total consumption of lead for angling equipment in EU15 and EU25 is estimated at 1 900 – 5 600 and 2 000 - 6 000 tonnes/year respectively, of which about 50 % is used for freshwater fishing. The consumption of lead for commercial fishing in EU15 and EU25 is similarly estimated at 1 900 – 8 700 and 2 000 - 9 000 tonnes/year (COWI, 2004).

As the data available on national consumption of lead for angling is highly variable, COWI (2004) did not consider it to be reasonable to estimate consumption figures for countries for which no data is available. As manufacturing of lead sinkers is relatively simple and may take place in small workshops, no major manufacturers in Europe seem to exist, and the general picture emerging is that with respect to ordinary sinkers most countries are supplied by their own manufacturers of which many are small or have sinker manufacturing as a minor activity besides manufacturing of other lead based products.

Concerning commercial equipment, national data are even scarcer than for angling. The estimates presented are based on data regarding the size and composition of the fishing fleet combined with estimates for the size and quantity of typical fishing equipment for different vessels. It has not been possible to estimate figures for consumption for manufacturing in the different countries.

COWI (2004) also reported production data for fishing tackle from PRODCOM[62] and import/export data from the EU COMEXT[63] database. **An up-to-date search on relevant codes could be usefully undertaken.**

1.3 Hazard, exposure, emissions and risk

1.3.1 Hazard

Lead is a highly toxic heavy metal and is non-essential, having no biological function. It is a non-specific poison affecting most body systems, having negative effects on general health, reproduction, behaviour and potentially resulting in death.

Absorbed lead affects all animals in which it has been studied, from migratory birds to humans. Lead presents risks to wildlife, especially wild birds (Watson et al., 2009; Pain et al., 2015), to domestic stock (Payne et al., 2013) and to humans (Green and Pain, 2015).

Lead differs from many contaminants in that there is no evidence for a threshold for a number of critical endpoints including developmental neurotoxicity and nephrotoxicity, i.e. it has not proven possible to determine a level below which observable effects in humans cannot be seen (EFSA, 2013).

Birds

Tufts (2004) indicates that, besides lead shot, waterfowl also ingest small sinkers. Because sinkers are generally much larger than shot pellets, a single lead sinker may induce acute

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[62] Prodcom provides statistics on the production of manufactured goods. The term comes from the French "PRODuction COMmunautaire" (Community Production) for mining, quarrying and manufacturing: sections B and C of the Statistical Classification of Economy Activity in the European Union (NACE 2).

[63] Comext is a statistical database on trade of goods managed by Eurostat, the Statistical Office of the European Commission. It is an important indicator of the performance of the European Union (EU) economy, because it focuses on the size and the evolution of imports and exports

poisoning. An American study on the causes of mortality of 600 loons showed that fishing lures were responsible for about 10 % of the deaths. The loons most often ingested weights of 1/4 - 1 ounce (28.35 g). The types of lures recovered from the loons could be split into sinkers (40 %), split shot (16 %), jigs (16 %), pellets (2 %), shot (2 %) and miscellaneous (6 %) [Tufts, 2004 / COWI, 2004].

Scheuhammer and Norris (1995) describe the ingestion and toxicity of lead sinkers to waterbirds, with particular reference to the situation in Canada and the USA.

Ingestion of fishing weights in swans in Great Britain and in common loons and other waterbirds in the United States have been extensively documented and reviewed (Nature Conservancy Council, 1981; Birkhead, 1982; O'Halloran et al., 1988; US EPA, 1994).

In Great Britain, the mute swan (*Cygnus olor*) population had declined since the 1960s, a trend that has dramatically reversed since 1986–87, when the sale of small lead fishing weights was banned (Kirby et al., 1994). Unpublished research results from Canada have also documented significant mortality of common loons and other birds from sinker ingestion. For example, data are available from Ontario, Quebec, and the Maritimes that demonstrate that lead sinker or jig ingestion accounts for roughly 30 % (38 of 127 birds examined) of adult loons found dead in locations where loon habitats and sport angling overlap. These data are consistent with US research.

A large, ongoing study has demonstrated that over 50 % of recorded adult common loon mortalities in the New England states during the breeding season is attributable to lead sinker or jig ingestion and that this source of mortality is of greater importance than any other single mortality factor, including tumours, trauma, fractures, gunshot wounds, and infections.

The importance of sinker ingestion as a mortality factor is less important, but still significant, in some other locations in the United States — for example, 17 % of the recorded mortalities in Minnesota (Ensor et al., 1992). Analyses at Canadian Wildlife Service (CWS)'s National Wildlife Research Centre confirmed a direct link between sinker ingestion and loon mortality from lead poisoning. Of 28 individual common loons with lead analysis data, only those loons with confirmed evidence of lead sinker or jig ingestion (six) have elevated tissue lead concentrations (e.g., 17–95 μg/g dw in liver) (Scheuhammer, unpublished data).

Evidence gathered to date indicates that sinker/jig ingestion is the only significant source of elevated lead exposure and of lead toxicity for common loons. In Ontario, about four-fifths of the lead poisoning deaths in loons are from ingestion of lead sinkers, and one-fifth is from ingestion of lead-headed jigs. Lead poisoning from sinker ingestion has also been documented in numerous other species of waterbirds in the United States, including trumpeter, tundra, and mute swans, various duck species, and sandhill cranes (US EPA, 1994a). In principle, any species of bird that has feeding habits similar to those of loons or of other species confirmed to have ingested sinkers or jigs are also at risk for lead poisoning from this source. Table 9 summarises data on mortality in waterbirds from the ingestion of lead sinkers in Canada.

Table 9: Confirmed and suspected cases of avian mortality from ingestion of fishing sinkers in Canada

Species	Number diagnosed as lead poisoned	Number with sinker/jig	province
Bald Eagle	29	1	British Columbia
Common Loon	21	30	Ontario
	3	3	Quebec
	4	4	New Brunswick, Nova Scotia, Prince Edward Island
Common merganser	?	2	Ontario
Canada Goose	?	2	Ontario
	?	1	New Brunswick
Trumpeter Swan	?	1	British Columbia
Mallard	?	1	Ontario
Greater Scaup	?	1	Ontario
White-winged Scoter	?	1	Ontario

Source:

Mammals

This is currently an information gap.

Human health

While the hazards of lead to humans are well known, and will not be reported further in this report, no information on specific hazards to human health from the use of lead fishing sinkers has been identified, apart from as a result of accidental ingestion.

However, the hazards of lead are potentially relevant to consumers that undertake 'casting' activities (as reported to occur in Denmark). Home moulding kits for weights, jigs and pirks are widely available for sale online.

1.3.2 Releases and exposure

Releases

COWI (2004) provides a cautious estimate on the total annual consumption of lead 'sinkers', covering all lures and fishing equipment (excluding commercial fishing) for the (then) EU25.

COWI estimated that the annual consumption in the (then) EU25 was 2 000 – 6 000 tonnes of lead. It is not known how much of this is used in inland waters (freshwater). Data from the UK and Denmark indicate that it is a minor part, whereas it seems to be a major part in Poland and 100 % in countries like the Czech Republic. It will here be assumed that half of the sinkers are used in freshwater; the remaining part used in the sea. It gives an estimated consumption for fishing in inland waters in EU25 of 1 000 – 3 000 tonnes. The loss of lead with fishing sinkers to inland waters in EU15 have previously based on the Dutch and Danish data been estimated at 1 000 – 3 000 tonnes (TNO, 2001).

Based on the experiences from the UK and Denmark, it is roughly estimated that split shot (used in inland waters) accounts for about 10 % of the total consumption corresponding to 200 - 600 tonnes/year and it is consequently estimated that 800 – 2 400 tonnes is the uses for other lures (small sinkers, jigs, etc.) used in inland waters in (the then) EU25.

Table 10: Annual consumption of lead for fishing sinkers for angling in 2004

Member state	Consumption t Pb/year	Total Population Million	Number of active anglers Million 1)	Consumption g Pb/capita/year	Consumption kg Pb/angler/year
Czech republic	40-100	10.3	0.23	4-10	0.2-0.4
Denmark	97-170	5.3	0.45	18-32	0.2-0.4
France	-	59.2	4		
Hungary	80-100	10.2	0.325	8-10	0.2-0.3
Netherlands	28	15.9	1.5	2	0.02
Poland	1,020-1,530	38.6	0.6	26-40	1.7-2.6
Sweden	200	9.0	2.02	22	0.1
Sweden	3.5	9.0	2.02	0.4	0.002
UK	500-1,000	59.6	4	8-17	0.1-0.3
Canada	388-559	32.5	0	12-17	-

Source: COWI,2004

The UK total figure for lead sinkers was tentatively estimated between 500 to 1 000 tonnes per year, or between 225 to 450 tonnes per year for inland waters (with split shot removed). These figures must be heavily caveated and therefore treated as indicative only.

Information on the quantity of lead released to the environment is likely to require further refinement, particularly in response to the contemporary angling practice lead dropping[64] has become a widespread UK angling phenomenon since then (and possible also in other EU Member States).

Exposure

Human exposure could occur during 'casting' weights, jigs or pirks (exposure to dusts and/or fumes from melted lead); this may be a particular concern where this takes place by consumers at high temperatures without appropriate risk management measures.

Accidental ingestion of fishing weights, resulting in lead poisoning, can also occur (Mowad et al. 1998; Gorospe and Gerstenberger, 2008).

Risk

Risks (in terms of mortality) of waterbirds have been linked to the use of lead fishing weights in the past. There is extensive information available on the decline (and subsequent recovery after risk management) of the mute swan (*Cygnus olor*) in the UK (Kirby et al., 1994) and Ireland (O'Halloran et al., 1998) as a result of ingestion of lead fishing weights. More recent research (Grade et al., 2018) indicates that population level effects can be observed and that replacing fishing sinkers and jigs can have immediate benefits.

The majority of other data on ingestion in other species (e.g. divers) is from observations reported from studies in North America (Scheuhammer et al., 2003; Sidor et al., 2003). However, the feeding behaviour and ecology of affected species of waterbirds (divers/loons) can be expected to be similar in European populations; resulting in similar risks.

Quantitative risk characterisation, on an EU level, for the risks to waterbirds may not be possible for ingestion (or secondary poisoning).

Risks to human health from casting activities could be assessed using exposure modelling methods.

[64] Lead dropping (conservative example): an angler dropping a lead weight (average 3.5 oz) on each 'take' would add 1 kg of lead to the lake bed per 10 takes. It is assumed there are c. 300 000 UK carp anglers and one in nine of them drops the lead on every take, or when a fish is hooked. Each angler fishes for six months each year and drops five 3.5 oz (average weight) leads per month. This equates to c. 100 tonnes of lead per year, or 1 million weights. Yet, each angler would be discarding in a season considerably less lead than the two examples quoted above, although these might represent more 'exceptional' cases.

1.4 Existing risk management

REACH restriction on lead in consumer articles

Fishing sinkers and weights are derogated from the restriction of the use of lead in consumer articles on the basis that they are stored for safety reasons and thereby not accessible by children in normal or reasonably foreseeable conditions of use.

Denmark

The sale of lead-containing fishing sinkers in Denmark has been banned since 1 December 2002. For commercial fishing equipment, an exemption until December 1 2004 was granted. However, it should be noted that neither the 'home casting' of lead weights or the use of lead weights are prohibited by the Danish regulation on products containing lead.

According to the Danish Angler's Association (Danmarks Sportsfiskerforbund), home casting of pirks was widespread whereas home casting of sinkers was less common because of the low price of the sinkers. The exact lead consumption for the activities is not known but could be in the order of one kg or more per year per angler. According to a substance flow analysis of lead, 14-40 tonnes of lead was used for home casting in Denmark in 2000 (Lassen et al. 2003, cited in COWI 2004). In recent years, the Danish Angler's Association has stopped courses in home casting on the basis of environmental controls.

According to a leading Danish wholesaler of fishing tackle, cross-frontier trade of lead-containing lures is not considered to take place to any appreciable extent, whereas home casting of sinkers has increased significantly after the regulation went into force. As home casting of sinkers is relatively simple, it must be expected that the activities increase if the price of sinkers increase.

Netherlands

Since 22 May 2018, a Green Deal came into force between several ministries, water boards, environmental NGOs, sectoral branch organisations and the sports fishing organisation to eliminate the use of lead for sports fishing. The elimination of lead goes alongside the promotion of lead-free alternatives. Recent tests have shown that lead-free alternatives can compete with lead-based fishing sinkers and jigs in term of both price and performance.

United Kingdom

The use of lead split shot and sinkers above 0.06 grams and below 1 ounce (28.35 grams) has been prohibited in the UK since January 1987. According to a leading UK manufacturer of split-shot and small sinkers, home casting and cross-frontier trade does not take place in any significant quantities.

Sweden

COWI (2004) report that there are voluntary restrictions on lead fishing sinkers in some rivers in Sweden.

North America

The status of the use of lead in fishing weights in North America is described in detail by Thomas and Guitart (2010) and summarised below. They note that given the success of the USA and Canada in banning the use of lead shot, a parallel action to prohibit the use of lead sinkers in the USA and Canada could have been expected, but that this has not happened, despite evidence of the need to act within both the USA and Canada (Twiss and Thomas, 1998; Scheuhammer et al., 2003; Sidor et al., 2003).

Thomas and Guitart (2010) offer several explanations for this lack of regulatory action. For example, the Migratory Birds Treaty Act does not apply to angling, or the equipment used in this sport. The hunting and angling constituencies are also very different, as in Europe, with the same political consequences (Thomas, 1997).

Thomas (2003) also identified two competing federal agencies attempting to regulate lead in the environment, the US Fish and Wildlife Service (USFWS) and the US Environmental Protection Agency (USEPA), despite the fact that the principal victims of lead poisoning were migratory birds under the jurisdiction of the USFWS (Perry, 1994; Sidor et al., 2003).

The US EPA intended using the Toxic Substances Control Act in 1994 to regulate a ban on lead sinkers, but that law did not contain regulative provisions for determining what was an acceptable non-toxic substitute (Thomas, 2003). Moreover, pro-lead factions indicated that it was inappropriate to apply regulations to areas of the nation where the species most afflicted by sinker ingestion did not occur naturally, or where the incidence of lead poisoning from sinkers was slight or non-existent. The US EPA has ceased action on this issue. Lead-free sinkers are required when angling in several small areas of the USA, but each directed under separate pieces of legislation, and none under a nation-wide regulation (Thomas, 2003; Rattner et al., 2008).

In contrast to the USA, Canada banned the use of lead sinkers in every national park and national wildlife area in 1996 through a simple amendment of their National Parks Act and the National Wildlife Act (Thomas, 2003). The criterion used to revise the National Parks Act was that lead sinker use (with the inevitable loss of sinkers) was inconsistent with ecological integrity – a concept embedded within the act.

While this is an important legal precedent, the majority of recreational angling occurs outside these federal areas that comprise, geographically, less than 15 % of Canada. A similar ban on the use of lead sinkers has not been enacted in any province. A proposal to use the federal Canada Environmental Protection Act to ban the manufacture, importation and sale of lead sinkers across Canada was proposed to Parliament (Caccia, 1995), but not adopted by successive Liberal and Conservative governments.

The EU and North American approaches differ in the criteria used to regulate lead sinkers. Where lead sinkers have been banned from use in Canada and the USA, mortality of birds due to lead weight ingestion has been the single criterion (Twiss and Thomas, 1998; Thomas, 2003), as also in the UK when enacting its lead sinker ban in 1987. In Canada's national park legislation, this known mortality and potential for further mortality from lost sinkers was translated into a negative impact on the ecological integrity of national park communities.

Other European legislation

The European Parliament did not support a previous proposal for a ban on the use of lead sinkers, as proposed under the 2008 'Laperrouzze Report' (CEPHFS, 2008). This proposal was based on water quality considerations and not on the mortality of birds that might ingest lost fishing weights.

Table 11: overview of lead legislation in the EU

	Legal or voluntary use restrictions (Year of entry into force)	Instrument
Austria	no	
Belgium		
- Federal	no info * (sea water)	
- Flanders	no info (fresh water and commercial)	
- Brussels	no (all applications)	
- Walloon		
Bulgaria		
Cyprus	no	
Czech Rep.	no	
Denmark	yes (2002) derogation for commercial fishing until Dec 1 2004	The sale on lead sinkers is prohibited by Statutory Order no 1012 on prohibition of import and marketing of products containing lead
Estonia	no	
Finland	no	
France	no	
Germany	no **	
Greece	no	
Hungary	no	
Ireland	no	
Italy		
Latvia	no	
Lithuania	no	
Luxembourg	no	
Malta	no	
Netherlands	no	
Poland	no	Restrictions may according to questionnaire response be applied by means of voluntary code of good conduct for sport fishing and professional fishing
Portugal	no	
Romania	no	
Slovenia	no	
Spain		

Sweden	partly (year not informed)	Voluntary restriction on the use of lead sinkers in some river systems
UK	partly (1987)	The use of lead split shot and sinkers above 0.06 grams and below 1 ounce (28.35 grams) in fresh water is prohibited by the Control of Pollution (Anglers' Lead Weights) Regulation 1986 as amended

Source: Thomas & Guitart, 2009 and COWI, 2004

2 Justification for an EU-wide action

The proposed restriction on the use of lead in gunshot used in or over wetlands is underpinned, predominantly, by the risks this use poses to waterbirds, as recognised by the Birds Directive and AEWA.

As the use of lead in certain fishing equipment are known to be ingested by certain species of waterbirds (i.e. notably swans and divers) they contribute to the lead poisoning risk posed to waterbirds. In addition, metallic lead in fishing equipment lost in aquatic systems will degrade over time contributing to overall releases of lead to the aquatic environment (lead is a priority substance under the Water Framework Directive (WFD)).

It is acknowledged that the proposed restriction on the use of lead gunshot in or over wetlands will not address all of the risks to waterbirds from lead poisoning. Therefore, further regulatory action on the use of lead fishing weights will complete the protection of waterbirds from ingesting metallic lead in wetlands. Remaining risks to waterbirds from the ingestion of lead gunshot outside of wetland areas would still be present.

Fishing (and the manufacture and sale of fishing equipment) is practised across the Union, equally waterbirds at risk of ingestion of lead shots are migratory across the Union.

A restriction under REACH could harmonise risk management legislation related to the use of lead containing fishing tackle across EU Member States at a sufficiently high-level to address risks to waterbirds and other vulnerable receptors e.g. raptors and scavenging birds. It would also contribute to limiting the risks posed by lead to the aquatic ecosystem in general.

While the enforceability of the proposed restriction has been considered as part of the restriction proposal, the enforcement of any subsequent restriction, particularly the enforcement strategy adopted, is primarily the responsibility of the Member States.

3 Impact assessment

3.1 Analysis of alternatives

Scheuhammer and Norris (1995) report various alternatives to the use of lead fishing sinkers and jigs, including tin, bismuth, antimony, steel, brass, tungsten, terpene resin putty, and polypropylene. All of the alternative products are more expensive than lead, and each differs slightly with respect to the types of uses for which it is appropriate.

Fishing sinkers are diverse in shape and weight, reflecting the different fishing methods for which they are used. The alternative products, either alone or in combination, appear to have effectively provided substitutes for all of the current lead sinkers and jigs on the market. However, the European Fishing Tackle Trade Association (EFTTA) (EFTTA, 2015) consider that there are no suitable alternatives to very small fishing weights (split shot ≤0.06 g and style ≤0.048g).

Table 12 Subsitutes for lead in anglers's equipment alterntaive metlas and price indication of products marketed in 2004

Type of equipment	Alternative material	Price indication (retail level in Denmark) 2)
Split shot	Tin, tungsten composite/alloy	+ 200-300% 3)
Sinkers/weights	Zinc, iron/steel, Bismuth, tungsten composite/alloy	+10-100% 3) + 400-1000%
Jigs	Zinc alloy, steel	-0%
Pirks	Zinc alloy, iron/steel	+ 10%-?
Downriggers	Zinc alloy, iron,	+ 10%-?
Woblers	Tungsten - zinc or tin alloys may likely be used	+ 10%-?
Floats	No alternative - zinc, tin or tungsten alloys may likely be used	+?

Source: COWI, 2004

Scheuhammer and Norris (1995) reported that the majority of non-toxic sinker manufacturers are located in the United States; however, bismuth sinkers and jigs are manufactured in Canada.

Tin sinkers are perhaps the most common and popular alternatives to lead and are available in most styles and sizes. Owing to its brittleness, bismuth cannot be crimped and therefore is not available as split shot, but it may be purchased in other forms (egg, worm, swivels, bullet slips, jig heads, etc.). Low melting point metals, including bismuth and tin, may be poured into the same or similar moulds currently used to manufacture lead sinkers; however, bismuth expands as it cools, in contrast to lead, and therefore must be poured only into high-quality milled moulds (BiLogic Tackle, personal communication).

Steel, zinc, and brass sinkers are currently available in various forms and sizes; however, metallic zinc is known to be toxic to waterfowl and other birds, although it is less toxic than lead (Grandy et al., 1968; Zdziarski et al., 1994).

Tungsten/polymer putty compounds are relatively expensive and are not now widely available in North America.

A limited selection of non-toxic alternatives to lead fishing sinkers, including steel, bismuth, and tin, is currently available from large retail chain stores and from tackle and sporting goods stores in Canada. Bismuth sinkers and jigs are also available directly from the manufacturer in Canada. Most large companies that provide alternative sinker products in the United States and Great Britain already have distributors in Canada.

The US EPA (1994a) has estimated that the average US sport angler would incur an additional expense of about $ 4.00 or less per year on non-toxic sinkers, should lead sinkers be banned.

Appendix 8 estimates the costs Canadian anglers would face if lead sinkers were to become unavailable and non-toxic alternatives were substituted.

3.2 Economic impacts of further regulatory action

COWI (2004) estimated that, on average, anglers annual expenses may increase by € 1.50-10.40/year considering raw materials as well as other elements included in the retail price. Other consequences are assessed to be small and without significance regarding the use of lead-free equipment.

Regarding the consequences for commercial fishing, test fishing with lead-free equipment was scheduled to take place in 2004 and no precise experience with lead-free sinkers and equipment is yet available. Concern is raised related to the extra volume of substitute metals and the extra noise coming from handling steel or zinc equipment compared to lead equipment. Also, the impacts on substitutes on net materials need to be clarified.

The technical suitability of alternatives to lead weights for commercial fishing was considered to be uncertain when the COWI (2004) study was published – stating that sea tests were scheduled. The outcome of these sea trials is not known.

The restriction options available differ from restricting lead sinkers for angling in inland waters to a total ban on the use of large lead sinkers for angling and a ban on the use of lead for commercial fishing. The costs of these measures are in Table 13

Table 13 Costs to fishers under different restriction options

	Phase-out of lead sinkers for angling in inland waters	Total phase-out of lead sinkers for angling	Phase-out of lead sinkers for commercial fishing
Total costs to anglers/the fisheries per tonne lead substituted (€/t) 1)	19,000-39,000	12,000-34,500	300-1,330
Total costs to anglers/the fisheries in the EU25 (million €/year) 1)	19-117	24-207	0.6-12
Reduced lead load to the environment in the EU25 (t lead/year)	900-2,700	1,800-5,400	100-1,800
Total costs to anglers/the fisheries in the EU15 (million €/year) 1)	18-110	23-198	0.57-11.6
Reduced lead load to the environment in the EU15 (t lead/year)	850-2,520	1,700-5,040	95-1,740

Source: COWI, 2004

Scheuhammer and Norris (1995) report that in 1991, 5.5 million Canadians aged 15 years or older (26.4 % of the total Canadian population) took part in recreational fishing (Filion et al., 1993), an average of 14 days per participant.

The average cost per angler was estimated to be $ (Canadian Dollars) 502.00 per season (approx. $ 35.00 per day), although provincial variation was observed (Filion et al., 1993). Fishing equipment, including boats, motors, fishing rods, and reels, accounted for approximately 45 % of the total angling budget, or $ 224.00 per year. The other major constituent of the angler budget was transportation, which accounted for an estimated $ 112.00 per year.

The US EPA (1994a) estimated that the average angler purchased $ 1.50 – $ 3.50 (U.S.) worth of lead fishing sinkers per year. The average price per sinker was estimated to be $ 0.14 from a survey of retail stores. Therefore, in the United States the average angler may purchase 820 sinkers per year, approximating one sinker per angling day. Based on the similarity of participation in the United States and Canada (i.e., an average of 14 days), it is assumed that Canadian use of sinkers would also be similar to that in the United States.

Table 14 average annual angling budget and cost associated with the use of lead and alternative fishing sinker products.

Canadian angler: total annual budget = $ 502,00					
	price range sinkers ($)[a]	mid-range sinker ($)[a]	average expenditure[a]	Average increase/angler/year ($)[a,b]	increase in budget(%)[c]
material					
lead	0.003-0.25	0.14	1.96	0	0
tin	0.004-0.33	0.18	2.52	0.56	0.1
bismuth	0.14-1.59	0.86	12.04	10.08	2

[a] All prices in Canadian Dollars

[b] Based on the estimate of 14 sinkers purchased per year

[c] Percent increase in total angling budget of $502 per year.

Source: Scheuhammer and Norris, 1995)

Lead fishing sinkers account for less than 1 % of the total angling budget. The average angler may spend up to an additional $ 10.00 for the use of alternative sinker products. Prices for other alternative sinker products made from steel, glass, or plastic are not available; however, they are believed to fall within this range. Grahame Maisey, President of Belvoirdale (US distributor for Dinsmores tin sinkers), and the US EPA (1994a) have stated that deposition of lead sinkers into the environment is often accidental through spillage. A survey conducted in 1986 in the United States estimated that for every one split shot sinker used, four to six sinkers were spilled and lost (Lichvar, 1994). Split shot sinkers are estimated to account for almost half of the total lead sinker market in terms of the number of sinkers sold (US EPA, 1994a).

Relatively little of a typical angler's budget goes towards sinkers. Lead fishing sinkers generally account for less than one percent of the total angling budget (Scheuhammer and Norris 1995). Far more of an angler's expenses are for items such as boats and boat trailers; motors and associated fuel and maintenance costs; equipment such as depth finders and auto pilots; rods and reels; transportation to and from the fishing area; guided fishing trips; and attire such as vests, jackets, waterproof clothing, and boots. The United States Fish and Wildlife Service reported that in 2006, the average fisher spent $1,407 per year for costs related to fishing (U.S. Fish and Wildlife Service 2006). One percent of this, using Scheuhammer and Norris's estimates, would amount to only $14 for sinkers yearly.

A 1995 study estimated that the average angler would spend up to an additional $10.00 per year for the use of non-toxic sinkers, and that switching to lead-free alternatives would, in most cases, cause an increase of less than one percent in the average recreational angler's annual expenses (Scheuhammer and Norris 1995). The 79
EPA, in 1994, estimated that anglers spent about $1.50–$3.50 per year on sinkers and that the average increase in annual costs to individual anglers in switching to alternative sinkers and jigs would be less than $4.00 (U.S. Environmental Protection Agency 1994).

In a Canadian study, Scheuhammer (2009) also acknowledged that many of the non-lead tackle products are more expensive than lead, but that switching to non-lead products was estimated to increase the average Canadian angler's total yearly expenses by only about $2.00. The Washington Departments of Ecology and Health expect that replacing lead fishing weights with non-toxic alternatives will increase the cost of fishing weights by a factor of up to 4.5, depending on the type of alternative tackle used (Washington State Department of Ecology and Washington State Department of Health 2009).

Industry has been concerned that, due to the higher price tags associated with non-lead tackle, sales would decrease as anglers purchased less tackle. However, this has not proven to be the case in Great Britain, where the sale of alternative sinkers boomed within the first three years following the 1987 ban, because anglers had to replace their lead sinkers with the non-toxic substitutes. After three years, the volume of sinker sales returned to the same level as before the ban, indicating that overall demand was unaffected by increases prices (COWI. 2004).

Data reported in COWI (2004), particularly in relation to the costs difference between lead fishing weights/sinkers and alternative materials is likely to require revision, specifically now that other initiatives (such as the Green Deal in the Netherlands) have increased demand and availability of alternatives.

3.3 Benefits

Benefits are associated with fewer cases of lead poisoning in waterbirds and, potentially, reduced risks to humans undertaking casting activities at home.

The proportion of overall waterfowl that are lead poisoned as a result of ingestion of fishing equipment versus lead gunshot is difficult to estimate, although for some species – certain swans and divers (loons) the risks from fishing tackle appear to be greater than other species of waterbirds (e.g. ducks, waders and rails).

The US EPA (Federal register, volume 59 (issue 46 09/03/1994)) made an assessment in which several risk management options were compared to the overall estimated cost per angler (of $ 4.00) with the number of sinkers that would not be lost in the environment under the various risk management options. The EPA assessed that the number of sinkers lost over a period of 10 years would range from near zero to about 4.8 billion. A ban on the manufacture, processing and distribution in commerce would result in 470 million to 4.2 billion fishing sinkers per year.

Based on economic valuation literature, the US EPA made an estimation of the number of non-endangered birds for which the regulatory costs would equal the value of birds. The valuation studies focused primarily on use value and do not account for values that society places on endangered species. The estimation also did not take into account the value of risk reduction to humans, which will occur. The result of the US EPA's analysis indicates that a likely break-even range is equal to 367 000 to 3.4 million non-threatened or non-endangered species.

The example of this estimation shows that the potential benefits on the environment are potentially large, especially considering that the upper bound estimate of 3.4 million birds represents only 5 % of the total autumn population of birds, a fraction of the population at risk. Even if only 1 % of the sinkers would be removed, approximately 4.7 million birds could potentially be saved, well in excess of the high end of the break-even analysis.

A future Annex XV report would need to analysis further the approach set out above and see to what extent it can be applied to the European context.

3.4 Enforcement

Lead fishing weights have been banned for many years in the UK – fishing bailiffs are familiar with enforcing such restrictions. There are also reports of trading standards officers in the UK enforcing this restriction at point of sale.

3.5 Potential derogations

- Certain, larger fishing weights and weights for commercial fishing may justify derogations from any restriction (but not if they are cast by consumers).
- The technically feasibility of alternatives for very small lead split shot and styles are questioned by the European Fishing Tackle Trade Association (EFTTA). However, they do not suggest an upper size limit for which lead can be safely used.

4 Conclusions

- Lead-based fishing tackle is frequently lost during use. In fact, some contemporary fishing practices encourage the deliberate release of lead weights to the aquatic environment in some circumstances (termed as 'dropping the lead'; to ensure fish welfare in the event that rigs are lost or snagged).
- Several EU Member States have existing legislation or voluntary agreements prohibiting the use of lead in fishing tackle (Denmark and Sweden and the UK). In some cases, only certain sizes of weights/sinkers have been prohibited as these are thought to pose the greatest risk to birds. Restrictions are also in place in North America. The European Fishing Tackle Trade Association (EFTTA) published a position paper in June 2015 calling on the European fishing tackle trade to phase out lead fishing weights (sinkers) heavier than 0.06 grams – in response to the risk of poisoning of migratory birds.
- Risks (in terms of mortality) of waterbirds has been linked to the use of lead fishing weights. There is extensive information available on the decline (and subsequent recovery after risk management) of the mute swan (*Cygnus olor*) in the UK (Kirby et al., 1994) and Ireland (O'Halloran et al., 1998) as a result of ingestion of lead fishing weights. These risks are unlikely to be limited to these two Member States as these species are ubiquitous throughout the EU.
- The majority of other data on ingestion in other species (e.g. divers) is from observations reported from studies in North America (Scheuhammer et al., 2003; Sidor et al., 2003). However, the feeding behaviour and ecology of affected species of waterbirds (divers/loons) can be expected to be similar in European populations; resulting in similar risks.
- Risks are predominantly associated with ingestion of weights of a certain size range. Commercial uses of lead tend not to use these types of weights. However, long-term dissolution of all lost/discarded lead-based fishing tackle in the aquatic environment will contribute to overall exposures of lead to the environment.
- The 'protection' of waterbirds (consistent with existing EU obligations) is not completely achieved by the proposed restriction on the use of lead gunshot in or over wetlands. Therefore, further regulatory action on the use of lead gunshot to fully implement AEWA would appear necessary.
- The advantages and drawbacks of restricting the marketing and use of fishing sinkers was investigated in detail in a study contracted by the European Commission to COWI (European Commission, 2004). The study investigated releases to the environment and the social costs of phasing out the use of lead in recreational and commercial fishing in the EU and included an analysis of the suitability, availability and relative cost of alternatives. The total costs for various phase-out options ranged from € 0.6 to

207 million per year, depending on scope. Corresponding cost-effectiveness estimates for the different phase-out options ranged from € 300 to 39 000 per tonne of lead. Although now relatively old (and potentially in need of some updating), this study incorporates all the necessary information for preparing an Annex XV restriction on the use of lead in commercial and/or recreational fishing.

- In addition, the practice of home 'casting' of various types of lead-based fishing tackle for recreational anglers appears, based on the predominance of online retailers, to be widespread. The risks of consumer exposure to lead containing dusts or vapours during these activities appear to be reasonably foreseeable and it is unlikely that appropriate and effective risk management measures are consistently used to minimise risks. The risks from this practice could also be addressed with a restriction.

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