Committee for Risk Assessment (RAC)
Committee for Socio-economic Analysis (SEAC)

Background document

to the Opinion on the Annex XV dossier proposing restrictions on
Lead in shot

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Note on terminology

Various English language terms are commonly used in relation to birds and their habitats. Some of these terms are based on ecology or scientific taxonomy, whilst others are rooted in traditional hunting practice. Some of these terms are used interchangeably, but may have different meanings for particular stakeholders. As this could lead to misunderstanding, the usage of certain key terms are outlined below. Whilst every effort has been made to ensure the consistent use of terminology in this report, source material may not always used these terms consistently.

Wetland	The most widely accepted definition of a wetland is the one set out in the text [Article 1(1)] of the Convention on Wetlands, signed in Ramsar, Iran, in 1971 as: *"areas of marsh, fen, peatland or water, whether natural or artificial, permanent or temporary, with water that is static or flowing, fresh, brackish or salt, including areas of marine water the depth of which at low tide does not exceed six metres".* Wetland habitats have also been defined under other EU legislation such as the Habitats Directive and referred to in the Birds Directive (Art 4(2)).
Waterbird	The term waterbird is used in the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA) to refer to birds that are ecologically dependent on wetlands for at least part of the annual cycle. This definition includes many European species of divers, grebes, pelicans, cormorants, herons, storks, rails, ibises, spoonbills, flamingos, ducks, swans, geese, cranes, waders, gulls, terns and auks. The Ramsar Convention defines 'waterfowl' as birds that are 'ecologically dependent on wetlands' and this definition is therefore consistent with the use of the term waterbird within AEWA.
Waterfowl	Without prejudice to the use of the term waterfowl within the context of the Ramsar convention (outlined above), the term waterfowl is typically used in Europe to refer to species from the avian family Anatidae i.e. ducks, geese and swans. These birds are adapted for surface water swimming (i.e. having webbed feet and oily feathers). However, a broader interpretation to include other waterbirds (e.g. common snipe) that are hunted is not uncommon. Hunted waterfowl and waterbirds can be referred to as game waterfowl.
Wildfowl	The term wildfowl can also refer to Anatidae, but may also be used to refer to any hunted (game) bird, including upland and lowland 'fowl' game birds such as grouse, pheasants or partridges. However, in these instances, the term is principally associated with the hunting of game *waterfowl*.
Raptors (predatory or scavenging)	Predatory birds (birds of prey) that have keen vision, powerful talons with claws and strong curved beaks, including owls. These birds can also scavenge carrion, either occasionally or as their main food source. Generally considered to exclude storks, gulls, skuas and penguins, even though these birds are also predators.
Scavenging birds (non-raptor)	Other bird species that typically scavenge carrion e.g. corvids
Hunting	The practice of pursuing and killing wild animals for sport of food.
Wildfowling	The hunting of wildfowl, particularly ducks, geese and waders.

Preface

The preparation of this restriction dossier on lead in shot used in wetland was initiated on the basis of Article 69(1) of the REACH Regulation. The scope of this proposal is limited to lead in shot used in wetlands as that was the scope set out in the request from the Commission.

The proposal has been prepared using version 2 of the Annex XV restriction report format and consists of a summary of the proposal, a report setting out the main evidence justifying the proposed restriction and a number of Annexes with more detailed information, analysis and detailed references that underpin the report.

The Dossier Submitter would like to thank the many stakeholders that made contributions to the call for evidence and during subsequent discussions during the development of this report, but particularly:

Alessandro Andreotti (ISPRA)
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This version of the report has been reviewed for confidential information and any such information has been redacted.

Summary

The use of lead gunshot in wetlands leads to a risk to waterbirds that ingest spent lead shot dispersed into the environment. The use of lead gunshot in wetlands also leads to a risk via secondary poisoning to species that either predate or scavenge birds contaminated with lead gunshot (either as embedded or ingested gunshot, or accumulated lead in tissues from the dissolution of gunshot). In response to these risks, restrictions on the use of lead gunshot have been enacted in many countries e.g. US, Canada and the majority of EU Member States.

The conclusion of the Dossier Submitter's risk assessment is that, despite many Member States implementing legislation to prevent or reduce the use of lead gunshot in wetlands, the use of lead in gunshot in or over wetlands is not adequately controlled on a Union-wide basis. Therefore, an analysis of risk management options (RMOs) was conducted to identify the most appropriate measure to address these risks, including regulatory measures under REACH, existing EU legislation and other possible Union-wide RMOs.

On the basis of an analysis of the effectiveness, practicality and monitorability of these RMOs, the following restriction is proposed:

Proposed restriction

Brief title: restriction on the use of lead gunshot in or over wetlands.

Lead and lead compounds	1. Shall not be used in gunshot for shooting with a shot gun within a wetland or where spent gunshot would land within a wetland. 2. Lead gunshot shall not be in the possession of persons in wetlands; 3. For the purposes of paragraphs 1 and 2: • "shot gun" means a smooth-bore gun, • "gunshot" means pellets used in quantity in a single charge or cartridge in a shotgun; • "lead gunshot" means any gunshot made of lead, or any alloy or compound of lead with lead comprising more than 1% of that alloy or compound; • "wetlands" are defined according to Article 1(1) of the Convention on Wetlands of International Importance especially as Waterfowl Habitat (Ramsar Convention). 4. Paragraphs 1 and 2 shall apply 36 months from entry into force of the restriction; 5. Member States may, on grounds of human health protection and environmental protection, impose more stringent measures than those set out in paragraphs 1 and 2. Member States shall inform the Commission of such measures.

The proposal restricts the use of lead gunshot, containing > 1% lead, for shooting with a shotgun over or within wetlands, including shooting ranges or shooting grounds in wetlands.

Risk to birds is the primary concern addressed by this restriction proposal but there are also concerns related to indirect exposure to humans from consuming waterbirds that have been shot with lead gunshot and the general condition of wetland environments. These latter concerns can be considered to be co-benefits.

This restriction would also consistently implement the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA)[1] across the EU Member States. The EU, as well as the majority of Member States (except for Malta, Poland and Austria), are Parties. Two hundred and fifty four species of migratory waterbirds are included in the AEWA. These species all cross international boundaries during their migrations and require good quality habitat for breeding and to support their annual migration. There are close links between the AEWA, the Ramsar Convention on Wetlands of International Importance and the European Nature Directives (Birds and Habitats Directives). One of the obligations of the AEWA Parties is to phase out the use of lead shot for hunting in wetlands as soon as possible[2].

The proposed restriction is acknowledged to only address part of the risks to waterbirds from the use of lead gunshot as certain species of waterbirds (~15% of AWEA species occurring regularly in the EU) typically feed outside of wetlands where they may ingest spent lead gunshot e.g. in agricultural areas. As such, a restriction focussed on wetland habitats, even where wetlands are defined broadly, may not fully meet existing obligations under AWEA.

Summary of the justifications

Identified hazard and risk

Hundreds of species of birds are dependent on wetlands for at least part of their annual cycle. Waterbirds, including waterfowl (ducks, geese and swans), are known to ingest the 'spent' lead gunshot that is dispersed into the environment by hunting and sports (i.e. target and clay-pigeon) shooting. Further to direct ingestion, predatory or scavenging birds (as well as other wildlife) are at risk of secondary poisoning through eating contaminated waterbirds that have lead gunshot embedded in their tissues ('shot-in') or digestive tract (or where embedded or ingested gunshot results in elevated tissue concentrations through dissolution).

Ingestion of lead gunshot leads to a range of acute and chronic toxicological effects, including death, dependent on the quantity of lead gunshot ingested and the size of the bird. Ingestion of a single lead gunshot may be sufficient to cause the mortality of a small-sized duck. The time to death after ingestion of lead gunshot in experimental studies varies between species and dose. Waterfowl generally die within 2–4 weeks of exposure, whilst some raptors are reported to survive for up to 15 weeks after exposure before death.

Ingestion of lead gunshot also results in sub-lethal effects (such as on body condition or immune system function). Sub-lethal exposure has been linked to other mortality factors

[1] The AEWA, developed under the auspices of the United Nations Environment Programme, is an intergovernmental treaty dedicated to the conservation of migratory waterbirds and their habitats across Africa, Europe, the Middle East, Central Asia, Greenland and the Canadian Archipelago. http://www.unep-aewa.org/.

[2] This aim is codified in Paragraph 4.1.4 of the Action Plan to AEWA, which is legally binding on all Parties.

such as flying accidents, increased risk of predation and an increased likelihood of mortality from hunting.

It is estimated that, based on an assessment of 22 species of waterfowl and 11 species of waders and rails, between 400 000 and 1 500 000 waterbirds currently die every year from ingesting lead shot. These estimates should be considered as minimum impacts as they do not account for sub-lethal poisoning within these species, or for lethal effects on other waterbird species that could also ingest spent lead gunshot. These estimates also do not take into account lethal or sub-lethal effects on predatory or scavenging birds via secondary poisoning.

The annual consumption of shot cartridges in Europe is estimated to be between 600 and 700 million units. This corresponds to a total of 18 000-21 000 tonnes of lead that is annually dispersed into environment from hunting[3]. This includes releases to both wetlands and non-wetland environments. The available evidence from Europe suggests that lead shot is not evenly distributed across wetlands and that there are areas with a high density of gunshot in soils and sediments, influenced predominantly by the hunting technique practiced. For example, hunting from fixed blinds or shooting posts tends to result in a greater density of shot within a given area than mobile forms of hunting.

In addition to environmental risks, there may also be risks to human health from the consumption of wildfowl shot with lead shot. These risks are also considered in this restriction proposal, although qualitatively. Exposure to lead in humans is associated with a wide range of adverse effects, including various neurodevelopmental effects, mortality (mainly due to cardiovascular diseases), impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes.

For children, the weight of evidence for adverse effects is greatest for an association between blood lead concentration and impaired neurodevelopment, specifically reduction of intelligence quotient (IQ). Use of lead gunshot may also endanger water resources at a local level.

On the basis of a qualitative assessment of the risks to humans from the consumption of wildfowl shot with lead gunshot, the risks to consumers cannot be ruled out.

Justification that action is required on a Union-wide basis

Whilst legislation of one kind or another to prevent or reduce the use of lead gunshot in wetlands is common in EU Member States, the scope of the enacted measures are not harmonised e.g. there are difference in the definition of a wetland used or the proportion of wetland habitats within a Member State that are subject to the conditions of the legislation.

These disparities result in different levels of risk reduction in different Member States. These inconsistencies are sufficiently significant that it can be concluded that the risks posed by the use of lead gunshot in wetlands are not adequately controlled on an EU-wide basis. This is particularly true considering some Member States have no legislation to prevent or reduce

[3] The quantity of lead dispersed into wetlands from sports (target) shooting remains unquantified, but recognising that the majority of lead gunshot is currently used for sports shooting rather than hunting this could be significant.

the use of lead gunshot in wetlands. The proposed restriction would also ensure the consistent implementation of the AEWA.

Non-compliance with existing legislation is also often noted as an issue by Member States and stakeholders and will affect the realised risk reduction of any legislation. However, the proposed restriction under REACH is first and foremost intended to harmonise risk management legislation related to the use of lead gunshot in wetlands across EU Member States at a sufficient high-level to address the identified risks to waterbirds and predatory and scavenging birds that occur in wetlands. Whilst 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.

A Union-wide action is also needed to address the environmental risk associated with the use of lead gunshot in EU wetlands since the flyways[4] of migratory birds typically cross several Member States. Regulating the risk to them at Union level is likely to ensure an appropriate level of protection throughout the EU.

Effectiveness

It is concluded that the proposed restriction is capable of significantly reducing the risks to waterbirds in wetlands. However, based on the experiences of some Member States when implementing their own legislation, complementary enforcement and awareness-raising programmes are likely to be necessary to realise this potential risk reduction. In addition, the restriction will not totally eliminate the risks to waterbirds and other species of birds as ingestion of spent lead shot occurs outside of wetlands.

The proposed restriction is considered to be a proportionate measure as the expected benefits arising from the measure are anticipated to outweigh the socioeconomic costs. In addition, the restriction is also considered to be cost effective and affordable for the affected actors (including hunters):

- The proposed restriction is estimated to result in an overall annual societal cost of €21-36m. The incremental cost to an EU wetland hunter (including costs for necessary testing, technical adaptations to shotguns, premature replacement of shotguns and the incremental cost of more expensive alternative ammunition) is in the order of €20 to 30 per year. The extent to which an individual hunter has to bear this cost depends on the scope of the current legislation in their Member States preventing or reducing the use of lead in shot cartridges.
- Based on the expected impact of the restriction on lead dispersal in EU wetlands, the corresponding annual benefits of the restriction that can currently be quantified are estimated to be substantially larger than €105m. Several of the benefits, for example on reduced secondary poisoning of predatory and scavenging birds and on reduced risks to human health, are only described qualitatively.
- The estimated cost-effectiveness of the restriction (€0.3-25 per kg of lead emission avoided, with a central value of €9/kg lead) is in the same order of magnitude as, or lower than, the cost-effectiveness of reducing emissions of other substances restricted under REACH.

[4] Migration routes

- The annual cost for a hunter is likely to be marginal compared to their overall hunting budget and therefore the proposed restriction is considered to be affordable. In addition, the restriction could be beneficial to European gun manufacturers and retailers.
- Although affordability considerations do not imply that a regulatory measure entails a net welfare gain, the analysis suggests that the proposed restriction would be unlikely to exert disproportionate costs to society as a whole.

It is concluded that the proposed restriction is effective because it is capable of significantly reducing the identified risks within a reasonable timescale and the benefits of the risk reduction exceed the costs.

Practicality

The proposed restriction is practical because it is implementable, enforceable and manageable:

Implementability

- There is already a high level of familiarity related to the issues of using lead gunshot in wetlands.
- The restriction proposal is implementable. This is demonstrated by the fact that many EU Member States have already implemented national legislation to prevent or reduce the use of lead gunshot in wetlands without a significant impact on the number wetland hunters or on the size of the average bag (quantity of birds killed). Several Member States have 'wide' scope area-based bans, underpinned by the Ramsar definition of a wetland (upon which this restriction proposal is also based), although efforts and resources to educate and inform hunters with regards to where they can and cannot use lead gunshot, including mapping or guidelines, are likely to be necessary to facilitate implementation.
- Alternatives to lead gunshot cartridges exist, and are technically and economically feasible. The prices of lead and steel gunshot cartridges are currently comparable, while bismuth and tungsten-based gunshot cartridges, which are currently produced, sold and used in far lower volumes, are likely to remain more expensive than lead (and steel) gunshot cartridges. Modern shotguns and the majority of existing shotguns can be used with a 'standard' steel shot cartridge (sometimes after some adaptation to 'choke'). However, the use of 'high performance' steel shot (typically required for hunting large waterfowl e.g. geese) requires a shotgun that has passed a specific 'steel shot' proof.

Enforceability

- Member States who have implemented legislation to prevent or reduce the use of lead gunshot in wetlands are already enforcing similar provisions to this restriction, particularly those Member States that have enacted complete bans or bans with a 'wide' geographic scope. As such, it is considered that other Member States can equally set up supervision mechanisms to monitor compliance with the proposed restriction. Where it is necessary to test for the presence of lead in ammunition, or in hunted species, test methods exist for lead in articles and enforcement authorities have experience in applying them.
- Widespread non-compliance with existing restrictions on the use of lead gunshot in wetlands is not uncommon. A restriction on possession was proposed by

stakeholders to enhance enforceability options for Member States. It is the Dossier Submitter's understanding that the definition of use under REACH extends to the possession of a substance, mixture or article[5]. However, a specific paragraph has been added to the restriction proposal to explicitly outline that possession within a wetland is within the scope of the proposal to ensure that the intention is clear during opinion and decision making (and public consultation).

- Based on experience in the United States and elsewhere, it may be beneficial (in terms of realised risk reduction) to introduce mandatory or voluntary training schemes for hunters in Member States on the risks of lead poisoning in wildlife and how these can be avoided by adopting alternatives. However, whilst this may be true, these measures are not included in the proposed restriction.

Manageability

- Given the information regarding the risks of lead shot in wetlands and the availability of alternatives, the manageability of the restriction is anticipated to be high.

Monitorability

- Monitoring of the effectiveness of the proposed restriction (including compliance) could be achieved through various methods. The most conclusive being to measure the prevalence of ingested or embedded lead gunshot in waterbirds over time. Many of the current studies highlighting the current problem of lead poisoning in waterfowl use this method. These methods can readily be adapted to monitor the effectiveness of the proposed restriction.

[5] see Annex E: Section 1.1

Report

1. The identified problem

1.1 Background

Waterfowl such as ducks, geese and swans that typically inhabit wetlands, frequently ingest 'spent' lead gunshot that is dispersed into the environment by hunting and target shooting with shotguns. Ingestion of lead gunshot leads to a range of acute or chronic toxicological effects (often termed as lead poisoning[6]), including death; dependent on the quantity of lead ingested and the size of the species. Ingestion of a single lead gunshot can be sufficient to cause the death of a small waterfowl. Other species of waterbirds, such as waders, rails and flamingos, also ingest lead shot. Further to direct ingestion, predatory or scavenging birds (as well as other wildlife) can be exposed to lead gunshot through the waterbirds that they predate or scavenge, which can lead to secondary poisoning. In addition to effects on birds, the use of lead gunshot in wetlands could result in adverse effects on general environmental quality.

Hundreds of species of birds are dependent on wetlands for at least part of their annual cycle. To protect them, two hundred and fifty four species of migratory waterbirds are included in the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA)[7]. The AEWA, developed under the auspices of the United Nations Environment Programme, is an intergovernmental treaty dedicated to the conservation of migratory waterbirds and their habitats across Africa, Europe, the Middle East, Central Asia, Greenland and the Canadian Archipelago. The EU, as well as the majority of Member States (except for Malta, Poland and Austria), are Parties. The EU is also a party of the Convention on the Conservation of Migratory Species of Wild Animals (CMS)[8].

When estimates for waterfowl are combined with those for waders, rails and flamingos, between approximately 400 000 and 1 500 000 birds are estimated to die annually throughout the EU from lead poisoning. Of these, between 65 000 and 200 000 are estimated to occur in Member States without legislation preventing or reducing the use of lead gunshot in wetlands. Therefore, only imposing measures on the four Member States (Romania, Poland, Ireland and Slovenia) without existing legislation on the use of lead gunshot in wetlands would not greatly affect the number of birds dying annually.

These estimates of annual mortality should be considered as minimum impacts as they do not account for sub-lethal poisoning within these species, or for lethal effects on other waterbird species that could also ingest spent lead gunshot. These estimates also do not take into account lethal or sub-lethal effects on predatory or scavenging birds via secondary poisoning.

Wetlands are a characteristic feature of many landscapes, either as a major landform or as small and scattered areas. They are typical habitats across marine, coastal and freshwater

[6] 'Lead poisoning' is widely used to describe a range of toxicological effects in birds, including death, resulting from the accumulation of lead in body tissues.

[7] See http://www.unep-aewa.org/.

[8] http://www.cms.int/en/legalinstrument/cms

areas (e.g. lakes, rivers, bogs and marshes). Wetlands encompass a wide range of hydrological and ecological types and each type has particular characteristics.

AEWA species cross international boundaries during their migrations and require good quality habitat for breeding and wintering as well as suitable sites throughout their annual migration. There are close links between the AEWA, CMS, the Ramsar Convention and the European Nature Directives (Birds and Habitats Directives).

The framework of legal measures and international agreements as described above, together require subscribed parties to:

a) Protect habitats, including wetlands;

b) Maintain favourable populations of certain listed species.

One of the obligations of AEWA Parties (from 2000) was to phase out the use of lead shot for hunting in wetlands as soon as possible[9].

Restrictions on the use of lead gunshot have been enacted across the globe (e.g. US, Canada). Within the EU, most Member States have implemented legislative measures to control the use of lead gunshot in wetlands, but it is notable that these are not consistent in terms of their scope.

In addition to environmental risks, there may also be risks to human health from the consumption of waterfowl shot with lead gunshot. These risks are also considered in this restriction proposal.

In December 2015, based on a concern that the risks of lead in gunshot may not be adequately controlled by existing national measures already in place, the European Commission requested ECHA to prepare an Annex XV restriction proposal for the use of lead in shot in wetlands[10],[11]. The Commission's request highlighted that *'the need for harmonisation of the use of lead in shot in wetlands is a priority as national legislation has already been enacted by some Member States (or regions in some Member States)'.* The analysis subsequently undertaken by ECHA and presented in this Annex XV report reflects this mandate. The risks from the use of lead gunshot outside of wetlands or from other uses of lead ammunition have not yet been assessed. ECHA may undertake additional work on these uses at the request of the Commission.

1.2 Manufacture and use

Lead is used by consumers and professionals in gunshot and other ammunition across a range of sporting, military and law enforcement uses. These uses are registered under REACH. The life-cycle of lead in ammunition is shown in Figure 1.1.

[9] This aim is codified in Paragraph 4.1.4 of the Action Plan to AEWA, which is legally binding on Parties.

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

[11] At the same time, with the view to a further restriction proposal in the future, the European Commission requested ECHA to collect relevant information on the risks to human health and the environment from: (a) the use of lead gunshot outside of wetlands, (b) the use of other types of lead ammunition, and (c) the use of lead weights for fishing.

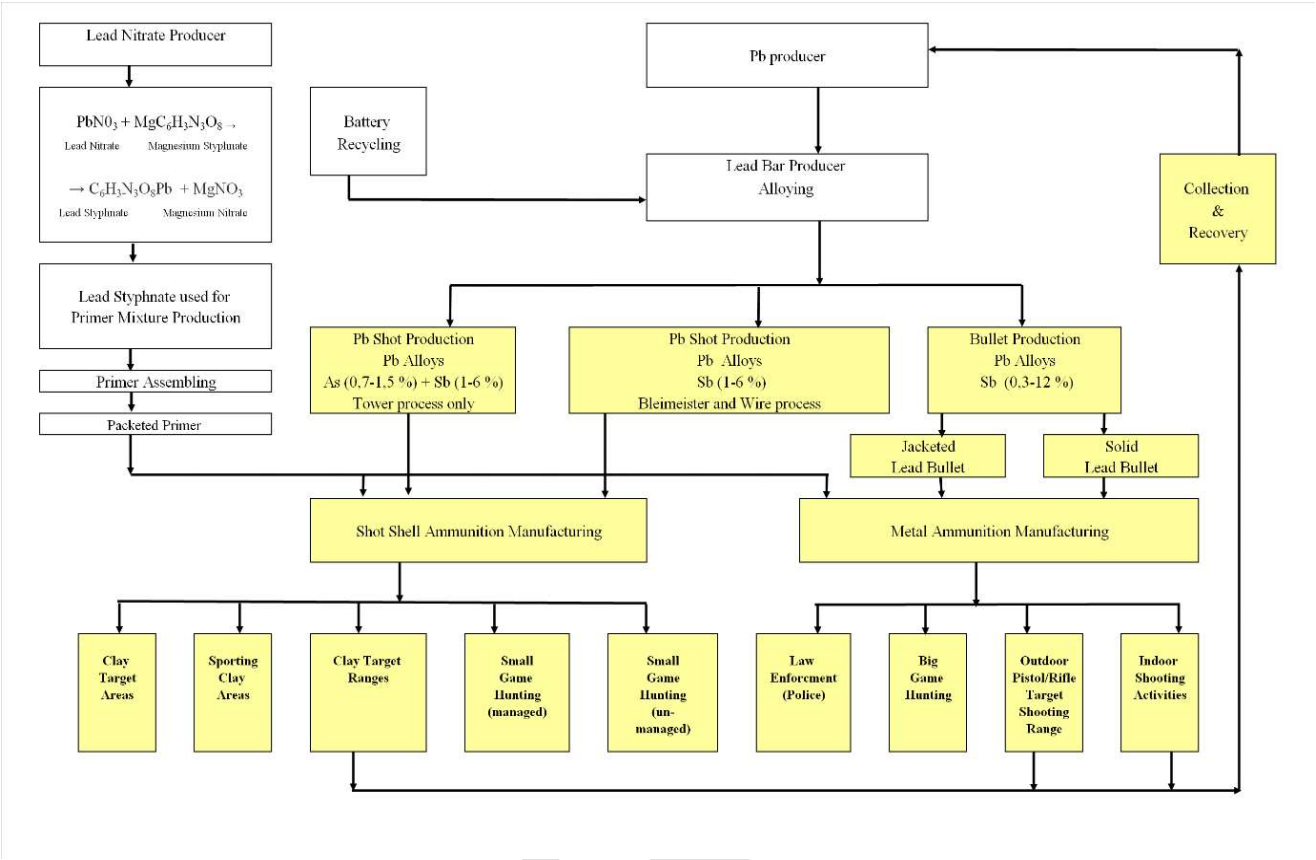

Figure 1.1. Summary of the life cycle of lead in ammunition, including lead gunshot (reproduced from ILA-E, 2010)

1.3 Use of lead gunshot in or over wetlands

This Annex XV restriction report considers the use of lead gunshot in or over wetland environments. Other uses of lead-based ammunition (e.g. rifle ammunition) have not be assessed. However, uses of lead gunshot also occur outside of wetland areas and it is therefore acknowledged that this assessment only partially assesses the risks from lead gunshot to the environment. Equally, it is acknowledged that the scope of assessment may introduce additional issues that need to be considered e.g. compliance, enforcement.

Use of lead shot in wetlands can be broadly categorised into two sub-uses: hunting and sports (target) shooting.

Hunting in wetlands using lead gunshot is primarily for wildfowl, such as ducks, geese and some waders. However, hunting of small mammals and smaller species of deer (i.e. roe deer) could also occur within a wetland. Hunting is also practiced as part of agricultural and wildlife management (pest and predator control). It may also be undertaken for other specific reasons, such as the protection of public health or to ensure air safety.

The REACH registration Chemical Safety Report (CSR) for lead does not include the use of lead gunshot for hunting in or over wetlands as an 'identified use' and was therefore not subject to an assessment of safe use.

Detailed Exposure Scenarios for various uses of lead in ammunition are described in a supplementary risk assessment[12] for the use of lead in ammunition (available on request from the Lead Registrant or the International Lead Association)[13]. This supplementary assessment identified the use of lead gunshot in or over wetlands as a *'use advised against'*. This conclusion made by the Registrants was based on an acknowledgement of the widespread restrictions already in place across the EU in relation to the risks from lead gunshot in wetlands, rather than the outcome of a risk assessment.

Section 2.4 of the REACH Registration CSR for lead, does not identify the use of lead shot in or over wetlands as a 'use advised against[14]'. Instead, this section reports that there are no uses advised against 'other than legal restrictions on the use of lead'. Whilst legal restrictions could be interpreted to include those that have been enacted in some Member States to prohibit or reduce the use of lead gunshot in or over certain wetlands the uses advised against in the CSR are not wholly comparable to the conclusion of the supplementary assessment. Therefore it is concluded by the Dossier Submitter that the current operational conditions and risk management measures in the CSR are not sufficient to manage the risk from lead shot in wetlands.

Sports shooting with lead gunshot within or in the proximity of a wetland may result in risks to waterbirds and are therefore considered within this restriction proposal. Sports shooting, most typically comprising either a trap or skeet formats, can take place at either shooting 'ranges' or shooting 'areas'. Further details are provided in Annex A.

1.4 Wetlands

Wetlands encompass a wide range of hydrological and ecological types and each type of wetland has particular characteristics. Wetlands are a characteristic feature of many landscapes, either as a major landform or as small and scattered areas. They are typical habitats across marine, coastal and freshwater areas (e.g. lakes, rivers, bogs and marshes).

Wetlands in the EU can be broadly categorised into seven general types (EC, 1995; Table 1.1):

- Marine and coastal wetlands;
- Estuaries and deltas;
- Rivers and floodplains;
- Lakes;
- Freshwater marshes;
- Peatlands;
- Man-made wetlands.

[12] This is outlined in "Exposure and risk assessment on use of lead in ammunition", draft version, prepared by the Lead REACH Consortium (2010), to be annexed to the main lead Chemical Safety Report.

[13] The supplementary risk assessment is not included in the submitted registration documentation.

[14] The lead registrant commented in the public consultation that they would update section 2.4 of the lead metal registration dossier as soon as possible to correct the error in the CSR of not identifying the use of lead shot in or over wetlands as a "use advised against".

Wetlands depend completely on the hydrological cycle (both natural and regulated) of the surrounding water catchment area. Because they receive and retain water from their surroundings, wetlands accumulate chemicals and sediments from these areas and are also subject to eutrophication (EEA, 2000).

Wetlands provide a range of ecosystem services, including as carbon sinks. They supply drinking and process water, provide fisheries and irrigation, act as a buffer against flooding, receive sewage water, support transport conduits, act as a source of hydroelectricity, and provide resources such as peat, game and berries. They also have significant recreational value (EEA, 2000). For example, peatlands, particularly blanket bogs, are a significant water supply source in the UK, notably in northern England (Bonn et al., 2009).

The most widely accepted definition for a wetland is that set out in the text of the Convention on Wetlands, signed in Ramsar, Iran, In 1971 and which came into force in 1975 (EC, 2007). Since then, almost 90% of UN Member States and all EU Member States have become "Contracting Parties".

Wetlands are defined by the Ramsar convention [Article 1(1)] as:

> ***"areas of marsh, fen, peatland or water, whether natural or artificial, permanent or temporary, with water that is static or flowing, fresh, brackish or salt, including areas of marine water the depth of which at low tide does not exceed six metres".***

The Ramsar Convention has also developed a Classification System for Wetland Types (Ramsar, 2013), designed to aid rapid identification of the main wetland habitats represented at sites (Table 1.2).

The Ramsar definition of a wetland is acknowledged to be comprehensive and inclusive, comprising marine, coastal, inland and human-made wetlands (including rice fields) as well as many upland habitats, such as 'peatlands' and alpine wetlands (created from snowmelt). Of particular interest in relation to this restriction proposal are peatlands[15] because of their suitability for many wetland birds (particularly waders) and the fact that they are also frequently associated with 'terrestrial' hunting/shooting, rather than waterbird hunting. It is important to distinguish between the Ramsar definition, which is a generic description of wetland habitats, and Ramsar 'sites', which are specific sites (geographical areas) designated by Member States under the Ramsar Convention. Ramsar 'sites' typically only comprise a small proportion of total wetland habitats within a Member State[16].

As well as the Ramsar Convention, wetland habitats are conceptually or operationally defined under various existing EU-relevant legislation, such as the Birds and Habitats Directives, or EU environmental monitoring schemes, such as the Corine Land Use programme.

[15] 'peatlands' can occur in several categories in the Ramsar Classification System for Wetland Types, i.e. I, E, K, U, Xp (Ramsar, 2002).

[16] The list of Ramsar sites designated in each Member State, is publicly available: http://www.ramsar.org/country-profiles

Further details of the various definitions of wetlands and wetland habitats applied in the EU and relevant aspects of wetland hydrology are given in section B.4.3.3.1 and B.4.3.3.2, respectively, of Annex B.

Table 1.1. Seven general types of wetlands in the European Union (from EU, 1997)

Wetland category	Description
Marine and coastal wetlands	A variety of wet habitats occur along flat coasts. Coastal currents form sand and shingle spits that may isolate brackish lagoons and temporary ponds. Vast mudflats, isolated dune slacks, salt marshes and meadows are typical wetlands of the Atlantic and North Sea coasts. The Danish-German-Dutch Wadden Sea is the largest wetland (10 000 km^2) within the European Union. Since ancient times, large brackish to saline lagoons have provided necessary shelter for the installation of harbours and the development of important trade cities in the Mediterranean and Baltic, such as Venice or Gdansk.
Estuaries and deltas	Estuaries are situated where a river mouth widens into the sea, with intermediate salinity, and where tidal action is an important regulator. Estuaries are normally very productive due to their nutrient-rich waters and are often used by young fish as nursery areas. In the European Union they occur mainly along the coasts of the Atlantic, the Irish and the North Sea. Large centres of human trade and culture developed in connection with estuaries, for example London on the Thames, or Rotterdam, Antwerp and Gent on the Rhine, Maas and Schelde estuary complex. Intertidal mud and sand flats, salt marshes and rocky outcrops complement the range of wetland habitats. The Mediterranean Sea is notable for its river deltas which have developed in the absence of tidal water movements at the mouth of sediment-rich rivers. They consist normally of complexes of lagoons, marshes, lakes, temporary pools, river channels, irrigated agriculture and shallow coastal zones. In the European Union, the Camargue (Rhone) as well as the deltas of Ebro, Po, and Evros are among the best known.
Rivers and floodplains	The periodic flooding of the area between the river bed and the raised land on the edge of a valley used to be a common feature of many European rivers and streams. Very few rivers are still allowed to spread out periodically over floodplains that include temporary sand and gravel banks, wet meadows, grassy marshes, flooded forest, and oxbow lakes. Where flooding has been regulated, only small areas of riverine forests and floodplain wetlands remain. The French Loire is probably one of the last remaining larger rivers with substantial parts of its floodplains remaining.
Lakes	Lakes and ponds are characterised by their open water surface. They are formed in basins with badly drained soils or by geological faults, landslides or glacial action. Most European lakes are permanent with freshwater but, especially in the Mediterranean climate of southern Europe, temporary lakes with brackish water are more widespread. Along shallow lakeshores, light that penetrates to the bottom allows the development of rooted vegetation creating biologically rich transition zones between open water and dry land.

Wetland category	Description
Freshwater marshes	Freshwater marshes are common wherever groundwater, surface springs, streams or runoff causes frequent flooding or more or less permanent shallow water. Their widespread distribution and variety is a reason for the range of terms used to describe freshwater marshes. Some of the larger ones have standing water throughout most of the year and often develop uniform beds of cattail and reed.
Peatlands	Under conditions of low temperature, waterlogging and oxygen deficiency, dead plant matter accumulates as peat. Where water drainage is impeded and peat deposits accumulate; distinctive fens and bogs are created. For climatic reasons, peatbogs mainly occur in the more humid Atlantic and boreal, but also in the alpine and continental parts of Europe. Many peatlands are so delicately balanced that even very slight changes in environmental conditions may cause substantial alteration or degradation. Peat soils often still occur on the drained agricultural land of former wetland sites.
Man-made wetlands	Past and current human activities have created different types of wetlands that have a certain interest for specific plants and animals. Undisturbed, abandoned, and restored parts of gravel pits and other excavations provide a variety of habitats. Large parts of traditional and industrial salines at the Mediterranean and Atlantic coasts are important refuelling sites for migratory birds and vital breeding grounds for colonially nesting birds. The biological value of reservoirs depends much on the slope of their shores and the fluctuations of their water levels. Rice paddies can provide interesting habitats as long as they are not polluted by agrochemicals.

Figure 1.2. Corine land cover classes relevant to the Ramsar definition of a wetland

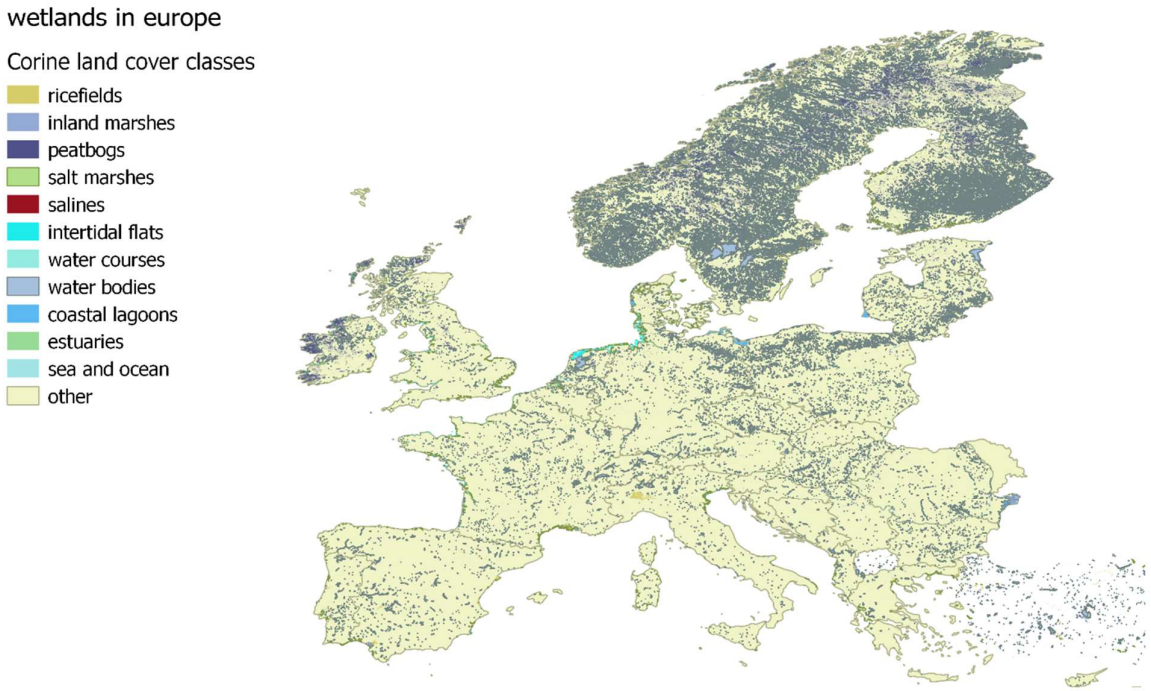

Table 1.2. Ramsar Classification System for Wetland Type.

Marine/Coastal Wetlands	
A	**Permanent shallow marine waters** in most cases less than six metres deep at low tide; includes sea bays and straits.
B	**Marine subtidal aquatic beds**; includes kelp beds, sea-grass beds, and tropical marine meadows.
C	**Coral reefs.**
D	**Rocky marine shores**; includes rocky offshore islands, sea cliffs.
E	**Sand, shingle or pebble shores**; includes sand bars, spits and sandy islets; includes dune systems and humid dune slacks.
F	**Estuarine waters**; permanent water of estuaries and estuarine systems of deltas.
G	**Intertidal mud, sand or salt flats.**
H	**Intertidal marshes**; includes salt marshes, salt meadows, saltings, raised salt marshes; includes tidal brackish and freshwater marshes.
I	**Intertidal forested wetlands**; includes mangrove swamps, nipah swamps and tidal freshwater swamp forests.
J	**Coastal brackish/saline lagoons**; brackish to saline lagoons with at least one relatively narrow connection to the sea.
K	**Coastal freshwater lagoons**; includes freshwater delta lagoons.
Zk(a)	**Karst and other subterranean hydrological systems**; marine/coastal
Inland Wetlands	
L	**Permanent inland deltas**.
M	**Permanent rivers/streams/creeks**; includes waterfalls
N	**Seasonal/intermittent/irregular rivers/streams/creeks.**
O	**Permanent freshwater lakes** (over 8 ha); includes large oxbow lakes.
P	**Seasonal/intermittent freshwater lakes** (over 8 ha); includes floodplain lakes.
Q	**Permanent saline/brackish/alkaline lakes**.
R	**Seasonal/intermittent saline/brackish/alkaline lakes and flats**.
Sp	**Permanent saline/brackish/alkaline marshes/pools**.
Ss	**Seasonal/intermittent saline/brackish/alkaline marshes/pools**.
Tp	**Permanent freshwater marshes/pools**; ponds (below 8 ha), marshes and

	swamps on inorganic soils; with emergent vegetation water-logged for at least most of the growing season.
Ts	**Seasonal/intermittent freshwater marshes/pools on inorganic soils**; includes sloughs, potholes, seasonally flooded meadows, sedge marshes.
U	**Non-forested peatlands**; includes shrub or open bogs, swamps, fens.
Va	**Alpine wetlands**; includes alpine meadows, temporary waters from snowmelt.
Vt	**Tundra wetlands**; includes tundra pools, temporary waters from snowmelt.
W	**Shrub-dominated wetlands**; shrub swamps, shrub-dominated freshwater marshes, shrub carr, alder thicket on inorganic soils.
Xf	**Freshwater, tree-dominated wetlands**; includes freshwater swamp forests, seasonally flooded forests, wooded swamps on inorganic soils.
Xp	**Forested peatlands**; peatswamp forests.
Y	**Freshwater springs**; oases
Zg	Geothermal wetlands
Zk(b)	**Karst and other subterranean hydrological systems**; inland
Human-made wetlands	
1	**Aquaculture** (e.g. fish/shrimp) **pond**.
2	**Ponds**; includes farm ponds, stock ponds, small tanks; (generally below 8 ha).
3	**Irrigated land**; includes irrigation channels and rice fields.
4	**Seasonally flooded agricultural land** (including intensively managed or grazed wet meadow or pasture).
5	**Salt exploitation sites**; salt pans, salines, etc.
6	**Water storage areas**; reservoirs/barrages/dams/impoundments (generally over 8 ha).
7	**Excavations**; gravel/brick/clay pits; borrow pits, mining pools.
8	**Wastewater treatment areas**; sewage farms, settling ponds, oxidation basins, etc.
9	**Canals and drainage channels, ditches.**
Zk(c)	**Karst and other subterranean hydrological systems**, human-made

2. Hazard, exposure and risk

2.1 Identity of the substance and physical and chemical properties

This Annex XV report concerns the use of zero-valent 'elemental' lead massive (particle diameter ≥ 1 mm) used as gunshot in or over 'wetlands'.

Although often present as a constituent in an alloy, which are considered to be 'special mixtures' under REACH, elemental lead is currently the only lead-containing substance (lead compound) that is known to be used in gunshot. Lead-based alloys used in gunshot (lead >90%) typically contain variable proportions of antimony (up to 6 %) and arsenic (up to 1.5 %) to produce specific properties in the lead shot, such as hardness and roundness. Further details of the production of lead shot and the composition of lead massive that has been registered are provided in Annex A.

Table 2.1. Identifiers for elemental lead

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

The key physicochemical properties of lead are summarised below, based on information extracted from REACH registration dossiers.

Table 2.2. Relevant physicochemical properties of lead

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

2.2 Justification for grouping

As the adverse effects resulting from lead exposure are ultimately mediated by dissociated / dissolved lead ions, which could be formed from any lead compound, the proposed restriction also extends to the use of other lead-containing substances in gunshot. This is irrespective of whether they are known to be used as gunshot[17]. However, the identity of these lead-containing substances are not elaborated in this Annex XV report.

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

[17] At least one MS with national legislation covers lead and its compounds.

2.3 Classification and labelling

2.3.1 Regulation (EC) No 1272/2008 (CLP Regulation)

There are harmonised classifications for lead massive (particle diameter ≥ 1 mm) and lead compounds according to Annex VI of the CLP Regulation (9th ATP).

Table 2.3. Harmonised classification for lead massive (particle size ≥ 1 mm) and lead compounds

Index No	International Chemical Identification	EC/ CAS No	Hazard Class and Category Code(s)	Hazard statement code(s)	Spec. Conc. Limits	M-Factors
082-014-00-7	Lead massive: [particle diameter ≥ 1 mm]	EC: 231-100-4; CAS: 7439-92-1	Lact. Repr. 1A	H362 H360FD		

2.3.2 Industry self-classification and labelling

In addition to the harmonised classification, industry has also self-classified massive lead.

Table 2.4. Industry self-classification for lead massive (particle size ≥ 1 mm)

Hazard class and category code	Hazard Statement
STOT RE 1	H372: Causes damage to organs; causes damage to central nervous system, blood and kidneys through prolonged or repeated exposure by inhalation or ingestion
Aquatic Chronic 2	H411: Toxic to aquatic life with long-lasting effects – *applicable to lead massive with arsenic grade only*

2.4 Environmental assessment (risks to birds).

2.4.1 Hazard

Lead and its compounds are hazardous for the environment. Extensive data on the effects of short and long-term lead exposure on a wide variety of aquatic and terrestrial organisms have been collated in REACH registration dossiers as well as covered in the EU voluntary risk assessment for lead and its compounds (LDAI, 2008). As this restriction proposal is primarily focussed on the specific risks to birds posed by the ingestion of spent lead gunshot, general 'compartment specific' ecotoxicity data are of limited relevance and are were not assessed in detail. Instead, only effects data that are directly relevant to the ingestion of lead shot by birds (either directly or through secondary poisoning) are presented.

Metallic lead (sometimes termed 'massive' lead) transforms/dissociates to liberate soluble/bioavailable species of lead relatively slowly in the environment. However, massive forms of lead (as used in lead gunshot) that are available for birds to ingest (spent gunshot)

are known to pose a significant hazard. This is particularly true for bird species with muscular gizzards (such as many waterfowl) that act to 'grind down' any ingested metallic lead particles, which enhances dissolution and subsequent uptake in the intestine. The hazard posed by lead gunshot is closely associated with the physiology of particular species of birds and the ecological niches (habitats) that they occupy.

The literature describing the causes and consequences of lead poisoning in birds is extensive and comprehensive. Therefore it would be disproportionate to summarise all the available studies in detail. Instead, the assessment in this restriction report is comprised of a summary of key data on lethal and sub-lethal avian toxicity that has been primarily identified from the large number of relevant expert scientific reviews and assessments that are available[18].

The first extensive assessment of the relationship between lead poisoning and the use of lead shot for hunting, was initiated as early as the 1930s[19] by the US Fish and Wildlife Service (USFWS). Other relevant scientific reviews include Bellrose (1959), Sanderson and Bellrose (1986), Rattner et al. (2008), Franson and Pain (2011), UNEP (2014c), Delahay and Spray (2015), LAG (2015) and Golden et al. (2016).

2.4.1.1 Routes of exposure

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 dossier as the ingestion of lead gunshot by birds through normal feeding or foraging activity whereby birds mistake lead gunshot for food or 'grits' normally ingested to facilitate the grinding of food items within the gizzard. The primary ingestion exposure pathway has been extensively documented and reviewed (e.g. by Bellrose, 1959; Franson and Pain, 2011).

- **Secondary ingestion.** This is defined for the purposes of this dossier as the ingestion of lead gunshot or fragments of lead gunshot via the consumption of prey or a scavenged carcass. 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.

Birds exposed through primary ingestion are those that feed in areas that are 'shot-over' using lead gunshot. The scope of this assessment is focussed on birds that are exposed to spent lead gunshot in wetlands (including shooting ranges located within wetland areas). However, terrestrial areas are also 'shot over' with lead gunshot and any birds feeding in these areas (particularly geese) may be exposed to spent lead gunshot.

Waterbirds, defined as species that are dependent on wetlands for some or all of their lives, are particularly prone to ingesting shot as they mistake them for food or the grit that is intentionally ingested to aid their digestion (UNEP, 2014c).

[18] Where the scope of review articles includes both lead gunshot and lead bullets, only data referring to lead gunshot has been reported here

[19] http://www.nwhc.usgs.gov/disease_information/lead_poisoning/

Bird species susceptible to secondary ingestion (affected via secondary poisoning) include predatory and scavenging raptors (e.g. falcons, hawks, eagles, vultures and owls) and possibly other scavenging birds (e.g. gulls, corvids). The presence of embedded lead gunshot in waterfowl is the main cause of lead poisoning for raptors in wetlands (Patte and Hennes, 1983, cited by Mateo 2007a). The percentage of waterfowl with embedded shot in their bodies (i.e. individuals that have previously been wounded and survive) is known to be variable, according to species, hunting pressure and age (Mateo, 2009). Details of the prevalence of lead gunshot are discussed further in subsequent sections of this report and in Annex B.

2.4.1.2 Absorption and toxicokinetics

The absorption of lead by birds after they ingest lead gunshot depends on several factors, including digestive physiology, retention time of lead in the gastrointestinal tract, diet and gender.

Following ingestion, lead shot passes down the oesophagus, through the proventriculus (stomach), the primary function of which is gastric secretion, and enters the ventriculus, which is modified into a gizzard in birds. The gizzard is a muscular organ that often contains stones or 'grit' that is used, in the absence of teeth, to grind up food during digestion. The absorption of dissolved lead occurs in the intestine. A diagram of the digestive tract of a goose is shown in Figure 2.1.

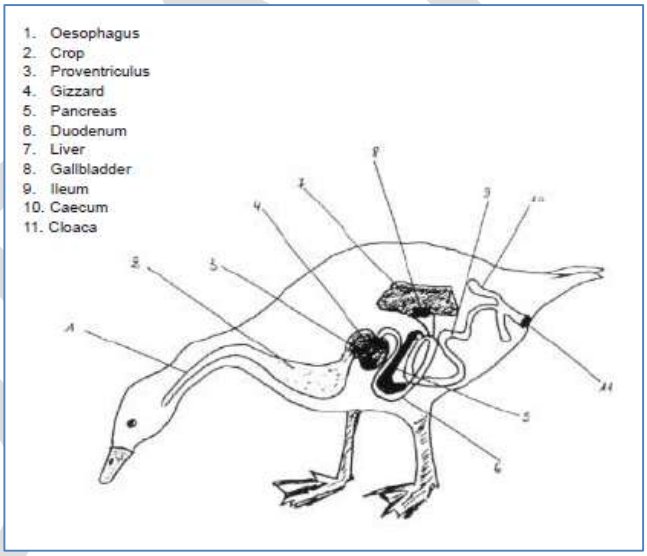

Figure 2.1. Digestive tract of a goose (Source; FAO, 1996)

Grinding in the gizzard facilitates the erosion of any ingested lead gunshot, leading to greater absorption in the gastrointestinal tract (Golden et al., 2016 citing Jordan and Bellrose, 1951). Thus, avian digestive physiology is a key factor leading to the lead poisoning observed in birds. The dissolution of lead shot is also enhanced by the acid environment of the avian stomach. Different species of birds have different stomach pH. For example, the pH of a duck stomach ranges from 2.0 - 2.5, whilst that of an eagle is closer to 1.0 (USFWS, 1986).

Individual pieces of gunshot may be rapidly regurgitated or, alternatively, passed quickly through the gut, both resulting in limited potential for dissolution and absorption of lead.

Other pieces may be retained within the gastrointestinal tract until completely dissolved (Franson and Pain, 2011). Intermediate rates of retention and absorption, between these two states, is also possible (Franson and Pain, 2011). Most lead shot ingested by wildfowl will either pass through the gastrointestinal tract or be completely eroded within 20 days of initial ingestion (Franson et al., 1986; Sanderson and Bellrose, 1986, cited by Pain and Green, 2015; LAG Appendix 4).

Birds of prey typically regurgitate "pellets" comprising the indigestible portions of their food (e.g. bones, hair and feathers). Lead gunshot pellets ingested in food can be regurgitated in these pellets. However, if not ejected from the body within the first 24 hours, gunshot becomes subjected to the grinding within the gizzard and dissolution within the stomach (USFWS, 1986).

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

Absorbed lead is transported around the body in the bloodstream and deposited rapidly into soft tissues, primarily the liver, kidney, bone and also in growing feathers. The greatest lead concentrations are generally found in bone, followed by kidney and liver. Intermediate concentrations are found in brain and blood whilst the lowest concentrations are found in muscle tissues (Longcore et al., 1974; Custer et al., 1984; Garcia Fernandez et al., 1995; cited by Pain and Green, 2015; LAG Appendix 4).

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

Figure 2.2. The gizzard of a Canada goose with lead pellets and corn. Image provided courtesy of the USGS National Wildlife Health Centre (USGS, 1999. Field Manual of Wildlife Diseases: General Field Procedures and Diseases of Birds)

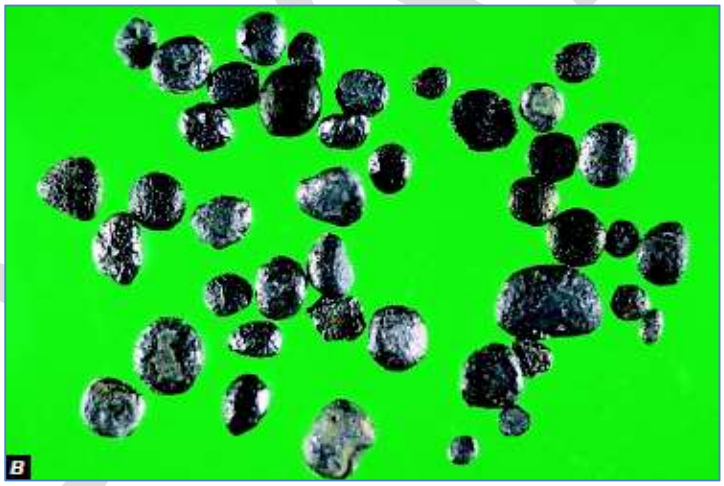

Figure 2.3. Typical "eroded" lead pellets at different stages of erosion. Image provided courtesy of the USGS National Wildlife Health Centre (USGS, 1999. Field Manual of Wildlife Diseases: General Field Procedures and Diseases of Birds)

2.4.1.3 Lethal and sub-lethal endpoints

Mortality can result from either acute (short-term) or chronic (long-term) exposure to lead. Acute lethal poisoning is usually associated with the death of a bird after it has ingested a large number of lead shot within a short period of time, although acute poisoning can occur after the ingestion of just one shot (Pain and Rattner, 1988; Guillemain et al., 2007).

Mortality generally occurs rapidly after ingestion without the bird becoming noticeably intoxicated, typically within 1-3 days. Birds dying from acute lead poisoning are typically found to be in good to excellent condition with good to excellent deposits of fat. Individuals usually have a large amount of lead gunshot in the gizzard and show multiple areas of myocardial infarction (areas of pale-pink, dead heart muscle) (USFWS, 1986).

Chronic lethal poisoning, as described in USFWS (1986), occurs as the result of a bird ingesting 1-15 pellets, most often 1 or 2, and developing a progressive (non-reversible) illness that requires two to three weeks to eventually result in mortality. The average time to death is approximately 20 days (Table 2.5). The most reliable gross indications of lead poisoning are considered to be impaction of the alimentary tract, submandibular edema, necrosis of heart muscle and bile staining of the liver.

Table 2.5. Signs and timeline of chronic lethal poisoning in wildfowl (After USFWS, 1986)

Day	Signs of poisoning
0	Ingestion of shot (may be retained or voided)
1 - 3	Grinding of shot in gizzard. Absorption of lead into blood. Lead excreted by kidneys. AFIB[20] in kidney tubules
4 - 10	Lead moves into liver and bone. Paralysis of upper gastrointestinal tract. Malfunction of gall bladder. Greenish diarrhoea – staining of vent
7 - 10	Depression. Bird seeks isolation and cover
10 - 14	Loss of ability to fly. Change of voice. Loss of weight
14 - 20	Fat deposits exhausted. Marked atrophy of pectoral muscles, "hatchet breast". 30 – 40 % of bodyweight lost
17 - 21	Comatose. Death

Based on extensive field and dosing studies, Bellrose (1959) derived annual mortality rates in seven classes of wild caught mallards, based on the number of lead shot found in their gizzards. Mallards that had 1, 2, 3, 4, 5, 6, >6 ingested shot in their gizzards were estimated to have a relative mortality increase of 9, 23, 30, 36, 43, 50 and 75%, respectively, compared to controls, corresponding to a population loss of 3.98 %. Further details are presented in Section B.7.2.2.1 of Annex B.

Table 2.6. Estimated percentages of North American mallard population lost as a result of lead poisoning (after Bellrose, 1959)

[20] Acid-fast intranuclear inclusion bodies are often present as an early manifestation of lead toxicity (USFWS, 1986).

Shot level	Shot incidence	Hunting bias correction factor	Corrected shot incidence (hunting bias)	Corrected shot incidence 'turnover'	Mortality rate (%)	Population loss (%)
1	4.44	1.5	2.96	17	9	1.60
2	1.14	1.9	0.60	3.60	23	0.83
3	0.47	2.0	0.24	1.44	30	0.43
4	0.18	2.1	0.09	0.54	36	0.19
5	0.14	2.2	0.06	0.36	43	0.15
6	0.05	2.3	0.02	0.12	50	0.06
6+	0.38	2.4	0.16	0.96	75	0.72
Total	**6.80**		**4.13**	**24.78**		**3.98**

RAC box:

During their evaluation, RAC questioned the reliability of the statistical methodology reported by Bellrose (1959), and considered that the reassessment of the Bellrose data using contemporary statistical methods reported by Green[21] was a more robust basis for estimating the mortality associated with the ingestion of different quantities of lead gunshot in mallards. However, acknowledging the large confidence intervals associated with Green's estimates and the relatively small differences between the central estimates reported by Bellrose and Green, RAC agrees with the approach of the Dossier Submitter to use estimates of annual mortality underpinned by the Bellrose mortality rates for further calculations of EU waterbird mortality from ingestion of lead gunshot. Further details of the RAC evaluation are provided in the RAC opinion.

[21] Submitted in ECHA's public consultation (comment #1612).

Figure 2.4. Gizzard lining of a lead-poisoned mallard (green stained, left side) versus a non-poisoned one (right side). Image provided courtesy of the USGS National Wildlife Health Center *(USGS, 1999).*

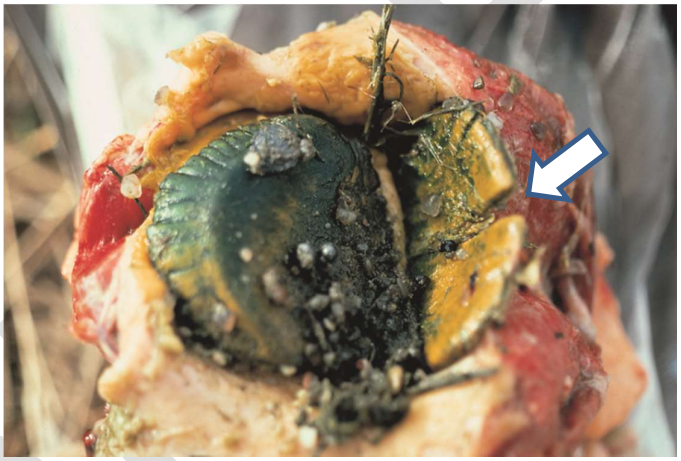

Figure 2.5. Lesions in the gizzard (indicated by arrow) of a lead poisoned mallard. Image provided courtesy of the USGS National Wildlife Health *(USGS, 1999)*

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

- **Haematology**– inhibition of enzymes, including delta-aminolevulinic acid dehydratase (ALAD), involved in haemoglobin synthesis; abnormal morphology of erythrocytes (leading to anaemia); hemosiderin accumulation is tissues leading to hemosiderosis.

- **Cardiovascular system** - myocardial infarcts (dead portions of heart muscle)

- **Kidney histopathology**– presence of 'acid-fast intranuclear inclusion bodies'

- **Growth and body condition** - Newth et al. (2016) recently established a significant association between blood lead concentration and reduced winter body condition above blood lead concentrations of 44 µg/dL. 10% of the wild whooper swans sampled in the study had blood concentrations above this level.

- **Behaviour and learning** –effects (observed in the laboratory and field) on locomotion, begging behaviour, individual recognition, balance, depth perception, thermoregulation (reviewed by Golden et al., 2016).

- **Immune function** – reduced spleen mass and circulating white blood cells (Rocke and Samuel, 1991); inhibition of antibody production (Trust et al., 1990); reduced immune system competence (Vallverdú-Coll et al., 2015a; 2015b; 2016a)

- **Susceptibility to hunting** - Bellrose (1959) reported that mallards dosed with lead shot and released were 1.5 times more vulnerable to being shot by hunters than controls.

- **Reproduction and development** – disruption of the blood-brain barrier (Locke and Thomas, 1996); reduced juvenile survival (Vallverdú-Coll et al., 2015b)

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

Table 2.7 shows the most common thresholds used as indicators of lead exposure (acute or chronic) that can lead to adverse effects in birds and other wildlife. The thresholds can be also used for interpreting tissue concentrations for managing wildlife on contaminated areas[22]. These indicative thresholds should only be interpreted as representative of the likelihood that certain clinical and sub-clinical effects in birds will occur and should not be considered to be equivalent to PNECs. Adverse effects in birds may occur at tissue concentrations below those reported.

Table 2.7. Summary of indicative thresholds for interpreting lead concentrations in various tissues types in birds and other wildlife

[22] E.g. assessing the need for medical treatments in conservation centres.

Endpoint	Lead concentration					Reference
Wildlife monitoring	HC5 = 18 (95% CI 12 – 25) µg/dL blood (mammals) HC5 = 71 (95% CI 26 – 116) µg/dL blood (birds)					Buekers et al. (2008)
General criteria for lead poisoning in wild birds	Blood		Liver		Bone	Rattner et al. (2008); Derived from: Friend 1985, 1999, Franson 1996, Pain 1996 and Pattee and Pain 2003.
	Wet weight µg/dL	Wet weight µg/g or ppm	Wet weight µg/g or ppm	Dry weight µg/g or ppm	Dry weight µg/g or ppm	
Background	<20	<0.2	<2	<8	<10	
Subclinical poisoning	20 to <50	0.2 to <0.5	2 to <6	>20	10 to 20	
Clinical poisoning	50 to 100	0.5 to 1	6 to 15	-	-	
Severe clinical poisoning	>100	>1	>15	>50	>20	
Winter body condition in whooper swans	>44 µg/dL blood					Newth et al. (2016)

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

2.4.1.4 Secondary poisoning

The potential for secondary poisoning of birds and mammals from lead was considered relevant in REACH Registration dossiers. $PNEC_{oral}$ values for birds and mammals were derived deterministically from the lowest observed NOEC from a dataset of long-term (>21 day) studies investigating the effects of lead salts in diet on ecologically relevant endpoints (e.g. growth and reproduction).

The standard assessment factors for deriving these PNECs in the registration were reduced from 30 to 6 on the basis of an accompanying complimentary SSD analysis that demonstrated limited interspecies variability within the dataset. These PNECs, with accompanying back-calculation to soil concentrations, are reported in section B.7.3.2 of Annex B. However, as these $PNEC_{oral}$ values were derived on the basis of lead salts in diet they may only have limited relevance to an assessment of the secondary poisoning of predators or scavengers via the ingestion of lead gunshot in diet.

The methodology presented in the REACH registration dossier for the derivation of $PNEC_{oral}$ has been refined from the methodology originally proposed in the VRAR (LDIA, 2008). However, some of the concerns raised during the evaluation of the VRAR by TCNES (2008) and SCHER (2008) have yet to be addressed, specifically the relevance of neurotoxicity and the need for a dataset comprising wider biological diversity.

The VRAR (LDIA, 2008) includes a study on secondary poisoning by Buekers et al. (2008) that focuses on the derivation of critical tissue concentrations associated with effects on growth, reproduction, physiology or haematology for use in wildlife monitoring. This study

derived threshold (HC_5) values in blood of 71 µg/dL (95% confidence limits 26-116) for birds and 18 µg/dL (95% confidence interval of 10-25) for mammals. As these threshold were based on internal dose, rather than concentrations in food, they are largely independent on the form of lead to which wildlife are exposed and are therefore relevant to the assessment of primary and secondary poisoning of birds and mammals through the ingestion of spent lead gunshot.

2.4.1.5 Hazard conclusions

Ingestion of lead gunshot causes mortality and sub-lethal effects in birds. Ingestion of a single lead gunshot may be sufficient to cause the mortality of a small-sized duck (Pain and Rattner, 1988; Guillemain et al., 2007). Tissue concentrations of lead in birds have been derived that are associated with various lethal and sub-lethal endpoints, but should not be considered to be equivalent to PNECs.

2.4.2 Release of gunshot in or over wetlands

The most comprehensive estimate for the annual tonnage of lead gunshot released to the EU-27 environment from hunting is that reported by AMEC (2012)[23].

Table 2.8. Emissions of lead from hunting estimated by AMEC (2012)

Emissions of lead from hunting	21 216 tonnes of lead per year
Emissions of lead from hunting on wetlands	357 tonnes of lead per year
Emissions of lead from hunting on non-wetland areas	20 859 tonnes of lead per year

Notes: Based on the following assumptions: a) for Member States with a full ban on wetlands, it was assumed that none of the hunters shoot with lead on wetlands b) for Member States with a partial ban, it was assumed that 50% of shooting on wetlands uses lead. c) For Member States with no ban, it was assumed that lead is used at the same level as the average EU proportion of shooting that takes place on wetlands (6.7%) and that all hunters can use lead.

These estimates were confirmed by AFEMS[24] in the ECHA call for evidence (2016) held as part of the preparation of this restriction proposal. According to AFEMS, the annual consumption of shot cartridges in Europe is estimated to be between 600 and 700 million units. This corresponds to a total of 18 000-21 000 tonnes annually dispersed into environment from hunting.

The sum of other estimates for Spain, Italy and the UK range from 15 600 to 29 000 per year[25]. Therefore, there remains some uncertainty in the estimates of the tonnage of lead released in or over wetlands annually. Equally, it is currently unclear how much lead shot is released in or over wetlands from target shooting (e.g. clay pigeon shooting). Whilst target shooting within wetlands is known to occur, the number of shooting ranges located in

[23] Abatement costs of certain hazardous chemicals, lead in shot, final Report 2012 – Study for the European Chemicals Agency (ECHA).

[24] Association of European Manufacturers of Sporting Ammunition.

[25] IT: 6 000 tonnes (Guitart and Mateo, 2006); ES: 1 600 to 10 000 tonnes (Andreotti and Borghesi, 2012); UK: 8 000 to 13 000 tonnes (Pain et al., 2015; based on numbers of birds killed and likely numbers of cartridges used 'per bird', including misses).

wetlands (or where the spent shot from a range outside of a wetland would fall within a wetland) is not known.

Estimates of the risk reduction potential of the restriction is dependent on the number of hunters that would be affected. This is elaborated further in Section 5 of this report.

2.4.3 Lead shot density and availability to wildlife in the environment

Each lead shotgun cartridge may contain several hundreds of pellets (depending on shot size) that are dispersed into the environment during hunting or sports shooting. Only a small proportion of the pellets (e.g. in the order of 1% or fewer) are likely to hit and be retained in a killed or wounded bird (Cromie et al., 2010). Therefore, the remainder are dispersed into the environment. The density of spent lead gunshot in the environment is depending on shooting intensity and is an important factor influencing the likelihood and frequency of ingestion.

The time required for pellets to become unavailable after they have been dispersed in the environment varies in relation to several environmental variables (USFWS, 1986), including:

- the amount of shooting over a particular wetland;
- the firmness/type of the bottom sediment;
- depth of water.

The settlement rate of lead shot in the environment is important. Lead gunshot typically accumulates near the surface of sediments leading to a progressive increase in the total number of lead shot available to waterfowl over time (Mudge, 1984; Pain, 1991; 1992; Anderson, 1986; cited by Peters and Afton, 1993).

Flint (1998) studied settlement rates of lead gunshot in various wetland types to which gunshot was intentionally deposited (i.e. experimentally seeded plots). Most gunshot was still within the top 4 cm of sediment three years after deposition. Similarly, Flint and Schamber (2010) re-sampled experimentally seeded plots in tundra wetlands in the Yukon Delta National Wildlife Refuge (Alaska, USA) for 10 years. After 10 years, they found that about 10% of lead pellets remained within 0-6 cm of the surface and that more than 50% remained within 10 cm of the surface. The authors estimated that more than 25 years would be necessary for gunshot pellets to become completely unavailable to water birds.

The long-term persistence of spent lead in the wetland sediments was also reported for the Camargue marshes (France) by Tavecchia et al. (2001). The authors estimated that, assuming a constant settlement rate, the half-life of pellet availability to waterfowl (within 0-6 cm) would be 46 years and complete settlement would occur after 66 years.

However, some case-studies of lead shot ingestion in wildfowl (reported in Annex B) have indicated relatively rapid declines in lead gunshot ingestion following the introduction of controls on the use of lead gunshot. This suggests that a reduction in the incidence of lead poisoning in wildfowl could occur relatively quickly after the implementation of any restriction on the use of lead gunshot in wetlands. Anderson et al. (2000, cited by Pain et al., 2015) reported that in the fifth and sixth years after a national ban on the use of lead gunshot for shooting waterfowl in the USA, 75.5% of 3 175 gunshot ingested by a sample of 15 147 mallard on the Mississippi flyway were non-lead shot. This suggests that wildfowl are

more likely to ingest the readily available recently deposited shot than previously deposited lead shot.

The available evidence from Europe suggests that lead shot is not evenly distributed across different wetlands, or within the same wetland, and that there are zones with relatively greater density, influenced predominantly by the hunting technique practiced. For example, hunting from fixed 'blinds' or shooting posts, or at shooting ranges, tends to result in greater density of deposited shot than more mobile hunting.

In the Brescia district of northern Italy, an area with more than 5 100 hunting posts, Andreotti and Borghesi (2012) estimated that 5-6 kg of lead pellets are dispersed annually around each post. Based on 92 samples from across eight Member States (IRE, UK, DK, NL, HU, FR, ES, IT), lead shot density within wetlands ranged from 0 to 399 shot/m^2 (Mateo, 2009 – See Annex B). The average, median and 90th percentile densities were 52, 21 and 148 shot/m^2, respectively. The greatest lead densities were observed in southern Europe in the Medina Lagoon in southern Spain where 399 shot/m^2 were found in the upper 30 cm of sediment (Mateo et al., 2007a).

Mateo (2009) reported that high lead shot densities were recorded around shooting ranges located in wetlands. Petersen and Meltofte (1979, cited by Mateo, 2009), reported lead shot densities ranging from 44 to 2 045 shot/m^2 at four Danish shallow water sites with shooting ranges. Smit et al. (1988a, cited by Mateo, 2009), reported 400 and 2 195 shot/m^2 at two clay pigeon grounds in the Netherlands. At Lough Neagh, Co. Antrim, in Ireland, 2 400 spent gunshot/m^2 in the upper 5 cm were found along 100 m of shore in front of a clay pigeon shooting site and on the lake bed up to 60 m from the shore (O'Halloran et al., 1988b; cited by Mateo, 2009). Similarly in the El Hondo Natural Park in Spain, where a shooting range was located in a temporary marshland, a density of 1 432 gunshot/m2 was recorded (Bonet et al., 2004; cited by Mateo, 2009).

Whilst these data give an overview of the range of lead gunshot density that can occur in wetlands where hunting with lead takes place, it should be noted that many of these data are from samples taken in Member States prior to the introduction of restrictions on the use of lead gunshot. Whilst it is uncertain if these data reflect current exposure in these Member States, gunshot may remain available to waterfowl for some time after initial deposition.

2.4.4 Prevalence of primary and secondary lead gunshot ingestion in birds

2.4.4.1 Waterbirds

Numerous European water bird species have been reported as ingesting spent lead gunshot (Mateo, 2009; Pain et al., 2015). These are primarily waterfowl (22 species), e.g. species of duck, goose and swan (Table 2.9), but also include other types of water birds (11 species), such as rails, waders and flamingos (Table 2.10). These bird species are known to inhabit an extensive range of marine, estuarine and inland wetlands, including peatlands (bogs, mires, moors and fens.

The likelihood of ingestion of lead gunshot via primary ingestion depends on:

- availability of lead shot
- feeding ecology of each species

- other environmental and anthropogenic factors

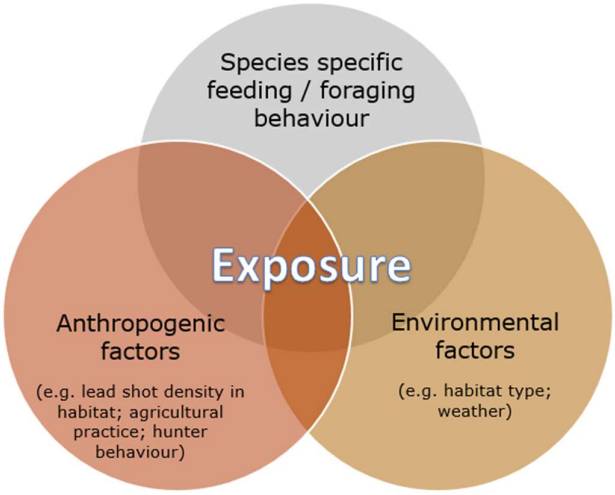

Figure 2.6. Key parameters characterising the likelihood of bird exposure to lead shot, and their interaction.

The feeding ecology of different species is an important variable affecting exposure. For example, up-ending swans and diving ducks may be exposed to shot which is too deep for dabbling ducks, which usually feed in shallow waters (UNEP, 2014)[26].

[26] Review of the ecological effects of poisoning on migratory birds, UNEP/CMS/COP11/Inf.34, 2014

Table 2.9. European species of waterfowl (ducks, geese, swans) reported to have ingested lead gunshot and their inland wetland habitat preference.

Waterfowl species known to ingest lead gunshot	Inland wetland habitat preference[a]										EU 27 Conservation status[b]
	Bogs, Marshes, Swamps, Fens, Peatlands	Permanent Freshwater lakes (> ha)	Permanent Freshwater Marshes/Pools (< ha)	Permanent River, Streams, Creeks (includes waterfalls)	Permanent Saline, Brackish or Alkaline lakes	Permanent Inland Deltas	Seasonal/Intermittent Saline, Brackish or Alkaline Marshes	Seasonal/Intermittent Freshwater Lakes (> ha)	Seasonal/Intermittent Freshwater Marshes/Pools (< ha)	Tundra wetlands (including pools and temporary waters from snowmelt)	
Pink-footed goose *Anser brachyrhynchus*											LC
Greylag goose *Anser anser*											LC
Barnacle goose *Branta leucopsis*											LC
Canada goose *Branta canadensis*											NA
Mute swan *Cygnus olor*											LC
Whooper swan *Cygnus cygnus*											LC
Tundra swan *Cygnus columbianus*											EN
Common shelduck *Tadorna tadorna*											LC
Eurasian widgeon *Anas penelope*											VU
Gadwall *Anas strepera*											LC
Common teal *Anas crecca*											LC
Mallard *Anas platyrhynchos*											LC
Northern pintail *Anas acuta*											VU
Northern shoveler *Anas clypeata*											LC
Marbled teal *Marmaronetta angustirostris*											CR
Red-crested pochard *Netta rufina*											LC
Common pochard *Aythya ferina*											VU
Ferruginous duck *Aythya nyroca*											LC
Tufted duck *Aythya fuligula*											LC
White-headed duck *Oxyura leucocephala*											VU
Goldeneye *Bucephala clangula*											LC
Garganey *Anas querquedula*											VU

Notes - a: based on European Red list of Birds habitat preference classification (http://datazone.birdlife.org/info/euroredlistcom). Light green = suitable habitat; dark green = major habitat; b: LC = least concern; EN = Endangered; VU = Vulnerable; CR = Critically Endangered; NA = Not applicable (introduced species).

Table 2.10. European species of waterbirds reported to have ingested lead gunshot and their inland wetland habitat preference

Waterbird species known to ingest lead gunshot	Inland wetland habitat preference[a]										EU 27 Conservation status[b]
	Bogs, Marshes, Swamps, Fens, Peatlands	Permanent Freshwater lakes (> ha)	Permanent Freshwater Marshes/Pools (< ha)	Permanent River, Streams, Creeks (includes waterfalls)	Permanent Saline, Brackish or Alkaline Marshes/Pools/Lakes	Permanent Inland Deltas	Seasonal/Intermittent Saline, Brackish or Alkaline Marshes	Seasonal/Intermittent Freshwater Lakes (> ha)	Seasonal/Intermittent Freshwater Marshes/Pools (< ha)	Shrub Dominated Wetlands	
Common moorhen *Gallinula chloropus*											LC
Common coot *Fulica atra*											LC
Common snipe *Gallinago gallinago*											LC
Jack snipe *Lymnocryptes minimus*											LC
Avocet *Recurvirostra avosetta*											LC
Northern Lapwing *Vanellus vanellus*[c]											VU
Ruff *Philomachus pugnax*											EN
Black-tailed godwit *Limosa limosa*											EN
Greater flamingo *Phoenicopterus roseus*											LC
Western water rail *Rallus aquaticus*											LC
Purple swamphen *Porphyrio porphyrio*											LC

Notes - a: based on European Red list of Birds habitat preference classification (http://datazone.birdlife.org/info/euroredlistcom). Light orange = suitable habitat; dark orange = major habitat; b: LC = least concern; EN = Endangered; VU = Vulnerable; c:– diagnosis of death from lead poisoning, gizzard was not examined for the presence of lead gunshot

The prevalence of lead shot ingestion typically refers to the presence or absence of lead gunshot in the gizzard of a bird. However, of equal interest is the number of lead gunshot that have been ingested, i.e. the magnitude of the exposure. The prevalence of lead gunshot ingestion has been reported to vary between species and populations, most likely as a function of diet and grit preference (Mateo et al., 2014 citing Pain, 1990; Mateo et al., 2000; Figuerola et al., 2005). Species that prefer larger grits are reported to be at greater risk of ingesting spent lead gunshot (Pain, 1990; Mateo et al., 2000; Figuerola et al., 2005, cited by Franson and Pain, 2011).

Mateo (2009) reports a summary of the prevalence of lead gunshot in 19 species of wildfowl from Europe. The mean prevalence of lead gunshot ingestion in mallards from northern

Europe varies from 2.2% in the Netherlands to 10.9% in Norway, with an overall value of 3.6% for a sample size of 8 683 shot or trapped individuals. In central and southern Europe the prevalence of lead shot ingestion in mallards ranges from 3.2% in Portugal to 36.4% in Greece, with an overall value of 17.3% for 11 239 sampled individuals (Mateo, 2009).

Mateo (2009) also reported prevalence for other European species. In northern Europe the highest prevalence was observed in common goldeneye (*Bucephala clangula*) with 13.8% of 152 sampled birds, followed by tufted ducks (*Aythya fuligula*) with 11.7% of 290 birds.

The highest prevalence in these two species was found in Finland, with 32.1% for common goldeneye and 58.3% in tufted duck (reviewed in Pain, 1990b). The species with the highest prevalence of lead shot ingestion in southern-central Europe were northern pintail (*Anas acuta*) with 45% for 598 birds, followed by the common pochard (*Aythya ferina*) with 24% for 507 birds. In the case of Mediterranean wetlands like the deltas of rivers Ebro, Rhône and Evros, the prevalence in the northern pintail and the common pochard ranges from 50 to 70% (Pain 1990a; Pain and Handrinos 1990; Mateo et al.1997b, 2000b).

More recently, Newth et al. (2012) reported lead poisoning in wildfowl in the UK over the period from 1971 to 2010. The majority of cases of birds diagnosed of dying from lead poisoning (75% of 251) had lead gunshot in various stages of dissolution in their gizzards.

Many wader species across the EU are likely to be susceptible to lead poisoning. For example, in France, studies found that jack snipe and common snipe had shot ingestion levels of 6.5% (of 178 birds) and 15.6% (of 269 birds) (Beck et al., 1995; Veiga, 1984; Beck and Olivier, 1998; Veiga 1985 cited by Oliver, 2006) and it was concluded that lead poisoning could affect waders to a similar extent as wildfowl.

Shot ingestion has also been reported by snipe in the UK (Thomas, 1975) and in other wader species worldwide (Kaiser et al., 1980; Hall and Fisher, 1985; Lock et al 1991; Locke and Friend, 1992).

Upland moorland (a wetland according to the Ramsar definition[27]) is considered as good habitat for many species of wading bird, including common snipe, Eurasian curlew, northern lapwing, dunlin, redshank and golden plover, many of which are of conservation concern because they are declining and/or are AEWA listed species or Birds Directive Annex I species (e.g. golden plover). Table 2.9Table 2.10 outline the habitat preference of various waterbirds known to ingest lead shot. From these tables it is clear that many of these species occur in peatlands. Section B.4.3.3.1 in Annex B includes a further indicative list of EU waterbird species associated with peatland habitats.

2.4.4.2 Predatory and scavenging birds

Only relatively few predatory or scavenging raptors in Europe are predominantly dependent on wetlands for their food. With the exception of the osprey (*Pandion haliaetus*), which feeds exclusively on fish, these species are the white-tailed eagle (*Haliaeetus albicilla*) and the western marsh-harrier (*Circus aeruginosus*) (Mateo, 2009; Pain et al, 2009).

However, some European raptors have a strong association with wetlands, at least at certain times of the year. For example, the hen harrier (*Circus cyaneus*) frequently roots in wetlands

[27] Peatlands under the Ramsar convention comprise "ecosystems with a peat deposit that may currently support a vegetation that is peat-forming, may not, or may lack vegetation entirely"

in the winter and the greater-spotted eagle (*Aquila clanga*) has a strong association with wetlands year round. Many other species feed in a variety of habitats including wetlands. For example, Montagu's harrier (*Circus pygargus*), rough-legged buzzard (*Buteo lagopus*), lesser-spotted eagle (*Clanga pomarina*), Bonelli's eagle (*Hieraaetus fasciatus*), merlin (*Falco columbarius*), hobby (*Falco subbuteo*), peregrine falcon (*Falco peregrinus)* and red-footed falcon (*Falco vespertinus*) (Sterry et al., 1998; Tornberg et al., 2016). For these species feeding areas may be associated with seasonal availability of prey. Various European species of vulture and the golden eagle (*Aquila chrysaetos*) will also have wetlands within their range and will scavenge dead and unretrieved wildfowl (particularly larger wildfowl).

With the important exception of the white-tailed eagle, western marsh-harrier, greater-spotted eagle, peregrine falcon and Bonelli's eagle, which are known to actively prey on waterfowl, birds of prey that occur in European wetlands would generally appear to prefer small mammal, bird and insect prey to larger waterfowl, such as ducks, geese, grebes or coots. Therefore, many birds of prey would appear to have a relatively low likelihood of secondary exposure to lead gunshot via prey obtained from a wetland habitat unless they opportunistically consume carrion that contains lead gunshot.

Other predatory or scavenging birds[28] are also known to feed on waterbirds, albeit not exclusively, and may therefore have greater risk of exposure e.g. Spanish imperial eagle (*Aquila adalberti*) and red kite (*Milvus milvus*) (Mateo, 2009).

In general, predatory or scavenging species are exposed to lead gunshot whenever they consume prey containing embedded shot (in either live prey or carrion). The presence of embedded lead shot in waterfowl is the main cause of lead poisoning for raptors in wetlands (Patte and Hennes, 1983). The percentage of waterfowl with embedded shot differs between species, areas with different hunting pressures and the age of birds (Mateo 2009).

For example, 13 percent of living whooper swans (*Cygnus cygnus*) and 23 per cent of Bewick's swans (*Cygnus columbianus bewickii*) were found to carry shot within their tissues (Newth et al., 2011). Embedded shot prevalence in first winter and adult pink-footed geese (*Anser brachyrhynchus*) are between 7 and 36%, respectively (Noer et al., 2007 cited by Mateo 2009). In an extensive study of some 40 000 common teal (*Anas crecca*) trapped in France, Guillemain et al. (2007) found some 9.6% (7.5%) adult males (females), respectively, carried embedded shot (UNEP, 2014). Pain et al. (2015) report a wide range of European and North American studies in which the prevalence of embedded shot in live waterfowl is frequently >20%.

Western march harriers in Mediterranean wetlands frequently ingest lead gunshot (Mateo, 2009). In Charente-Maritime (France), Pain et al. (1993;1997 cited by Mateo 2009) observed lead shot in 11.5-25% of regurgitated pellets in winter, but only in 1.4% of pellets in May and June. In Spain, the occurrence of lead gunshot in pellets was 10.7% in the Ebro Delta (Mateo et al., 1999 cited by Mateo 2009) and 1.8-4.3% in Donana (Gonzalez 1991; Mateo et al. 2007 cited by Mateo 2009). Elevated blood lead concentrations (>30 µg/dL) in western marsh harrier have also been reported in various studies (Mateo, 2009).

[28] Exposure to lead ammunition in scavenging bird species has been documented worldwide (e.g.: Germany: Nadjafzadeh et al. 2013; Poland: Komosa and Kitowski 2008 ; Spain :Mateo et al. 2001 ; Fernandez et al. 2011; Sweden :Helander et al. 2009; USA: Golden et al. 2016).

Table 2 11. Prevalence of embedded gunshot in live trapped wildfowl from the EU (after Pain et al. 2015)

Species	Member State	Embedded shot (%)
Bewick's swan *Cygnus columbianus bewickii*	UK	31.2
Whooper swan *Cygnus cygnus*	UK	13.6
Pink-footed goose *Anser brachyrhynchus*	DK	9.2 – 36.0
Greylag goose *Anser anser*	ES	44.4
Mallard *Anas platyrhynchos*	UK, FR, NL,	17.6 - 66
Northern pintail *Anas acuta*	UK	27.1
Northern shoveler *Anas clypeata*	UK	25.8
Gadwall *Anas strepera*	UK	26.3
Common teal *Anas crecca*	FR	4.4 – 9.6
Pochard *Aythya ferina*	UK	25.0
Tufted duck *Aythya fuligula*	UK	14.9

2.4.5 Risk characterisation

There is extensive field evidence of the adverse impacts on birds from the ingestion of lead gunshot. Therefore, there is no advantage to undertake a risk characterisation based on comparing PEC/PNEC ratios. This assumption is supported by the many jurisdictions throughout the world, including many EU Member States, which have enacted regulation of one type or another to prohibit the use of lead gunshot in wetlands in response to this risk.

Rather, the risk characterisation summarises information on the following:

1. Estimates of annual waterbird mortality in the EU as a result of primary ingestion of lead gunshot;
2. Selected case studies on the impacts of lead gunshot on birds living in EU wetlands;
3. Comparison of the lead concentration in various tissues of wild birds with indicative thresholds of adverse effect;
4. Information on lead as a co-factor in other causes of mortality in wild birds.

The information presented in relation to points one and two includes data from studies conducted prior in Member States prior to the introduction of national legislation on the use of lead gunshot in wetlands. The use of such data is appropriate as some Member States are yet to implement restrictions on the use of lead gunshot.

Equally, some of the case studies presented were conducted in areas after national legislation of some form or another on the use of lead gunshot in wetlands was introduced. These studies provide insight into the effectiveness of different types of national legislation

on the use of lead gunshot, particularly in relation to risk reduction potential, compliance and enforcement. These studies confirm that in most cases risks to waterbirds from lead gunshot remain after the adoption of national legislation, particularly where this is limited in scope.

In relation to point three, information on the concentration of lead in various lead tissues, relative the indicative thresholds, provides additional evidence of lethal and sub-lethal toxicity occurring in wild birds as a result in lead exposure. These data have been collated to support the conclusions on risk characterisation presented for points one and two.

In addition, evidence of exposure to lead as a co-factor in other causes of mortality in wild birds (e.g. flying accidents, greater probability of predation) is also briefly discussed.

2.4.5.1 Estimates of annual waterbird mortality in the EU due to lead poisoning

RAC box:

During their evaluation, RAC questioned the reliability of the statistical methodology reported by Bellrose (1959), and considered that the reassessment of the Bellrose data using contemporary statistical methods reported by Green[29] was a more robust basis for estimating the mortality associated with the ingestion of different quantities of lead gunshot in mallards. However, acknowledging the large confidence intervals associated with Green's estimates and the relatively small differences between the central estimates reported by Bellrose and Green, RAC agrees with the approach of the Dossier Submitter to use estimates of annual mortality underpinned by the Bellrose mortality rates for further calculations of EU waterbird mortality from ingestion of lead gunshot. Further details of the RAC evaluation are provided in the RAC opinion.

The extent of mortality occurring in waterbirds after ingesting spent lead gunshot has been estimated in several studies. Bellrose (1959) estimated that lead poisoning was responsible for the loss of 2-3 million waterfowl per year in North America (equivalent to 2-3% of the overwintering population of North American waterfowl). The methodology developed by Bellrose (1959) has been used by other authors to underpin estimates of annual mortality occurring in other regions of the world, including Europe, and is described in Annex B.

For example, Mateo (2009) estimated the impact of lead shot ingestion on 17 species of European waterfowl based on data on lead shot ingestion in Europe species collated from 1957-2004. This study estimated that approximately a million individuals from these 17 species would die annually from lead poisoning i.e. 8.7% of the total population. Further details of this study, including a discussion on its uncertainties, is provided in Annex B.

Pain et al. (2015), using the Bellrose (1959) methodology and estimates of the size of British wintering population for 16 species, estimated an annual mortality rate in these species (in the UK) of 3.1%, corresponding to approximately 74 000 birds per year. Further details of the study are presented in Annex B.

An estimate of EU waterfowl mortality of 6.1% is also described by Andreotti et al. (2018).

To estimate current EU mortality from the primary ingestion of lead gunshot in wetland birds for the purposes of this restriction proposal, three scenarios were established based on

[29] Submitted in ECHA's public consultation (comment #1612).

the reported average mortality rates of 3.1% (low), 6.1% (central) and 8.7% (high) in combination with the EU population size estimates for waterbird species (waterfowl, wader and rail species) that have been reported to have ingested lead gunshot in the EU (based on those reported by Mateo, 2009 and Pain et al. 2015)[30].

Complimentary estimates of mortality were made using the reported wintering and breeding population size to account for the fact that certain species are present in different parts of the EU at different times of the year and that some waterbird species are resident within a Member State throughout the year. The analyses assumes that exposure to lead gunshot can occur throughout the year and that the annual mortality rates reported in the literature, which are based on wintering population estimates, can be equally applied to breeding population estimates. These analyses are reported separately to avoid any potential for double counting. Similarly, this analysis assumes that the mortality rate estimates reported for mallard are applicable to other species of waterfowl as well as to species of waders, rails and flamingos that are also reported to have ingested lead gunshot.

As certain Member States have already enacted legislation that completely prohibits the use of lead gunshot within their territory (i.e. NL, BE, DK) the population of birds occurring within these Member States were excluded from the estimates of annual mortality. EU territory with a 'complete' ban on the use of lead gunshot corresponds with approximately 32% of the overwintering population of waterfowl that are reported to have ingested lead gunshot.

Based on wintering population, 5% of waterfowl and 3% of the wader, rail and flamingo populations of species known to have ingested lead gunshot occur in Member States that have no ban in place. Based on breeding population size, this increases to 12% of the waterfowl population and 14% of the wader, rail and flamingo population known to have ingested lead gunshot (Table 2.12). Where a Member State has yet to enact legislation an annual mortality rate of 8.7% was assumed in all three scenarios. Further details of this analysis is provided in Annex B.

[30] Population size estimates (for period 2008 to 2012) were obtained for each Member State from the web tool on population status and trends of birds under Article 12 of the Birds Directive http://bd.eionet.europa.eu/article12/

Table 2.12. Population size of waterfowl, wader and rail species in the EU known to ingest lead gunshot and correspondence with existing legislation prohibiting or reducing the use of lead gunshot.

Population		EU bird population size (% of total)			
		No ban	Partial bans	Complete ban	Total
Wintering population[a]	Waterfowl[b]	633 000 (5%)	7 606 000 (62%)	3 938 000 (32%)	**12 208 000**
	Waders/rails[b]	263 000 (3%)	6 502 000 (84%)	954 000 (12%)	**7 719 000**
Breeding population[a]	Waterfowl[b]	953 000 (12%)	5 866 000 (72%)	1 380 000 (17%)	**8 199 000**
	Waders/rails[b]	1 072 000 (14%)	5 969 000 (73%)	1 257 000 (13%)	**7 869 000**

Notes – a: Based on average of min/max EU Birds Directive Article 12 reporting for period 2008-2012, rounded to the nearest thousand individuals, no data reported by GR or HR; b: based on species reported to have ingested lead gunshot by either Mateo (2009) or Pain et al. (2015), see Annex B for complete list.

Based on wintering population size, between 262 000 and 787 000 waterfowl are estimated to be lethally poisoned as a result of the consumption of lead gunshot in the EU per year (based on 22 species), with a central estimate of 522 000 (Table 2.13). Based on breeding population size of the same species, between 207 000 and 720 000 individuals are estimated to be lethally poisoned per year with a central estimate of 441 000. Between 66 000 and 212 000 of these cases of lethal poisoning in waterfowl are estimates to occur in Member States without existing legislation on the use of lead gunshot (Table 2.14). As there are no population estimates for birds occurring in Greece or Croatia reported under Birds Directive Article 12, this is likely to be an underestimate.

In terms of wintering populations of wader, rail and flamingo species known to ingest lead gunshot, between 204 000 and 638 000 individuals from 11 species are estimated to be lethally poisoned annually, with a central estimate of 420 000. A similar, but moderately greater, number of waders and rails from the same species are estimated to be lethally poisoned annually based on the breeding population size.

When estimates for waterfowl are combined with those for waders, rails and flamingos between 400 000 and 1 500 000 individuals are estimated to die annually throughout the EU from lead poisoning. Of these, between 65 000 and 200 000 are estimated to occur in Member States without legislation prohibiting or reducing the use of lead gunshot in wetlands.

These estimates do not account for sub-lethal poisoning within these species, or for lethal effects on other waterbird species that could also ingest spent lead gunshot. These estimates also do not take into account lethal or sub-lethal effects on predatory or scavenging birds via secondary poisoning.

Table 2.13. Estimated annual mortality of birds in the EU 28 from the ingestion of lead gunshot (based on the population size of waterfowl, wader and rail species known to ingest lead gunshot).

EU 28		**Annual mortality from ingestion of lead shot**		
		3.1%	**6.1%**	**8.7%**
Wintering population[a]	Waterfowl[b]	262 000	522 000	787 000
	Waders/rails[c]	204 000	420 000	638 000
	Total	**466 000**	**941 000**	**1 425 000**
Breeding population[a]	Waterfowl[b]	207 000	441 000	720 000
	Waders/rails[c]	197 000	446 000	775 000
	Total	**404 000**	**886 000**	**1 495 000**

Notes – a: Based on EU Birds Directive Article 12 reporting for period 2008-2012, rounded to the nearest thousand individuals, no data reported by GR or HR; b: 22 species, based on Mateo (2009) and Pain et al. (2015), see Annex B for complete list c: 11 species, based on Mateo (2009) and Pain et al. (2015), see Annex B for complete list.

Table 2.14. Estimated annual mortality of birds in Member States without legislation to control the risks from the use of lead gunshot in wetlands (based on the population size of waterfowl, wader and rail species known to ingest lead gunshot).

MS without existing legislation[a]		**Annual mortality from ingestion of lead shot**		
		3.1%	**6.1%**	**8.7%**
Wintering population[b]	Waterfowl[c]	46 000	58 000	69 000
	Waders/rails[d]	19 000	23 000	27 000
	Total	**65 000**	**81 000**	**96 000**
Breeding population[b]	Waterfowl[c]	64 000	83 000	102 000
	Waders/rails[d]	75 000	93 000	112 000
	Total	**139 000**	**176 000**	**214 000**

Notes – a: IE, RO, PL, SI; b: based on EU Birds Directive Article 12 reporting for period 2008-2012, rounded to the nearest thousand individuals; c: 22 species, based on Mateo (2009) and Pain et al. (2015), see Annex B for complete list; d: 11 species, based on Mateo (2009) and Pain et al. (2015), see Annex B for complete list.

2.4.5.2 Case studies

Newth et al. (2012) reported the results of a large scale assessment of the extent of lead poisoning in the UK based on post mortem analysis of dead waterbirds collected between 1971 and 2010. Over this period a total of 2 365 dead waterfowl were recovered from sites across England, Scotland and Wales. Blood analysis and post mortem examinations were performed and lead poisoning was reported to be responsible for the deaths of 10.6% of the recovered waterfowl. Rates of mortality from lead poisoning varied significantly between species. 27.3% of whooper swan mortality was attributed to lead poisoning. Lead poisoning was attributed as the cause of death in 23% of recovered Bewick's swans and 16.7% of both Canada geese and pochard. Following the introduction of partial bans to reduce the risks from the use of lead gunshot in the UK, no significant difference in the proportion of birds diagnosed as having died of lead poisoning was found (proportion of deaths due to lead poisoning from 2000-2010 was 8.1%, n=1 051). Further case studies are presented in Annex B[31].

2.4.5.3 Tissue concentrations indicative of adverse effect

[31] Whooper swans in the UK, flamingos in Mediterranean countries and white-headed duck and marbled teal in Spain.

Table 2.15 outlines examples of the lead concentration found in wild birds compared with the indicative threshold values outlined in Section 2.4.2.3 of the report. Tissue concentrations regularly exceed threshold concentrations.

2.4.5.4 Sub-lethal effects on birds

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

2.4.6 Summary of risks to birds

The use of lead gunshot in wetlands leads to ingestion by waterbirds, particularly waterfowl. Ingestion by individuals frequently leads to death and at sub-lethal doses may also affect population-relevant endpoints such as recruitment success.

Between 400 000 and 1 500 000 birds are estimated to die annually throughout the EU from lead poisoning. Of these, between 60 000 and 200 000 are estimated to occur in Member States without legislation prohibiting or reducing the use of lead gunshot in wetlands. These estimates do not account for sub-lethal poisoning within these species, or for lethal effects on other waterbird species that could also ingest spent lead gunshot. These estimates also do not take into account lethal or sub-lethal effects on predatory or scavenging birds via secondary poisoning.

Table 2.15. Examples of comparison of the lead concentration in various tissues of wild birds with indicative thresholds of adverse effect.

Details of study (geographical, temporal and species scope)/ Reference	Tissue type and concentration	Interpretation relative to indicative thresholds of adverse effect[a] (See Section B.6.3.3)
Northern pintail after 2007, Spain, n=15, geometric mean value Mateo et al., 2014	**Liver (µg/g d/w)** Mean: 41.6; Range: 6.95-166	Mean concentration observed in liver greater than indicative threshold for sub-clinical poisoning. Maximum level observed greater than indicative threshold for severe clinical poisoning. 100% of the samples had liver concentration > 1.5 µg/g dw, the maximum residue levels for offal for human consumption in the European Union (European Commission, 2006)
Whooper Swans 2010-2014, UK, n=300 Newth et al., 2016	**Blood (µg/dL)** Mean: 23.5; Range: 5.6-132.9	41.7 % of swans with blood concentration greater than indicative threshold for subclinical poisoning. 10 % of swans with blood concertation of ≥44 µg/dL, which was associated with adverse effects of winter body condition. Maximum level observed greater than indicative threshold for severe clinical poisoning. Maximum value exceeds secondary poisoning threshold derived by Buekers et al. (2008)
Flamingos 2006, Italy, n=16 Arcangeli et al.,2007	**Liver (µg/g w/w)** Mean: 108.41; Range:28.8-264.0	100% of flamingos with liver concentration greater than indicative threshold for severe clinical poisoning.
Flamingos 1992-3, Spain, n=106 dead or moribund, mean value Mateo et al., 1997	**Liver (µg/g d/w)** Mean: 192.3 Range < 2.5 - 992.2 µg/g dw 57 of 64 flamingos found dead had live conc. > 77.2	89% dead or moribund flamingos had liver concentrations that were greater than the indicative threshold for severe clinical poisoning.
Whooper swans 2003 – 2005, UK (England and Scotland) O'Connell et al. 2008	**Blood (µg/dL)** >25 µg/dL used as a threshold.	Between 38 and 88% of birds with blood lead concentrations indicative of at least subclinical poisoning.
Whooper swans, Bewick's swans, pintail, pochard 2010/2011, UK, n=285 Newth et al. 2012	**Blood (µg/dL)** 0 to <20: 65.9% 20 to 50: 24.6% 50 to 100: 7.7% >100: 1.8%	25% of birds with blood levels indicative of subclinical poisoning; 8% with blood levels indicative of clinical poisoning; 2% of birds with blood lead levels indicative of severe clinical poisoning.

Notes. a: **Subclinical poisoning**: liver dw: >20 µg/g or w/w 2 to <6 (µg/g); blood: >20.0 to <50 µg/dL; **Clinical poisoning**: liver 6 to 15 µg/g or w/w, blood 50 to 100 µg/dL; **Severe clinical poisoning**: liver w/w>15 (µg/g) or d/w>50 (µg/g); blood: >100 (µg/dL).

2.5 Human health assessment

2.5.1 Hazard

Exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, mortality (mainly due to cardiovascular diseases), impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes. For children, the weight of evidence is greatest, and evidence across studies is most consistent, for an association of blood lead levels with impaired neurodevelopment, specifically reduction of intelligence quotient (IQ). Moreover, this effect has generally been associated with lower blood lead concentrations than those associated with the effects observed in other organ systems (JECFA, 2010).

Lead is most readily absorbed into the body through inhalation or ingestion (KEMI, 2012). Dermal uptake is considered to only make a negligible contribution to systemic lead levels (KEMI, 2012). Once absorbed, lead is not metabolised but will distribute across various tissue types and organs e.g. blood, bone, liver and kidney. Children are particularly vulnerable to lead exposure. Lead is easily transferred to the foetus via the placenta (Carbone et al., 1998). The lead concentration in blood is often the best reflection of the lead exposure status of the individuals (EPA-Denmark, 2014). The human toxicokinetics of lead are further outlined in Section B.5.1 of Annex B.

2.5.1.1 Neurotoxicity

The nervous system is the key target organ for lead toxicity in the developing foetus. Young children are most vulnerable to lead induced neurotoxicity. High levels of lead exposure can have serious effects on the intellectual and behavioural development of individual young children. The Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2010) concluded that negative impact on IQ is the most sensitive endpoint for neurodevelopmental effects and that dose-response analysis does not provide any indication of a threshold. RAC has previously considered the evidence for these effects as part of its evaluation of REACH restriction proposals on lead in jewellery and lead in consumer articles (RAC, 2011; RAC 2013). On both of these occasions, in line with the assessment by EFSA (2013), RAC agreed there is no threshold for the neurotoxicological effects of lead and that any exposure to lead constitutes a risk. In addition, as part of the evaluation of a proposal for a restriction on lead in jewellery (RAC 2011), RAC applied a maximum lead exposure level for children of 0.05 µg lead per kg bw per day (based on the $BMDL_1$ determined by EFSA, 2013). This exposure correlates with an IQ reduction of 0.1 point.

Additional recent studies suggest further neurotoxic effects after lead exposure, such as hyperactivity or attention deficit disorder (Kim et al.,2012; Apostolou et al., 2012), academic performance (Amato et al., 2012) and autism (El-Ansary et al., 2011). An analysis of these studies is provided in Annex B.

2.5.1.2 Other human health effects

Table 2.16 summarises relevant information on other human health endpoints, including acute toxicity, repeated dose toxicity in various target organs and reproductive toxicity. Annex B contains further details of these endpoints.

Table 2.16. Compilation of other human health effects resulting from lead exposure and critical exposure levels

Endpoint	Critical lead exposure levels
Repeated dose toxicity	**Haematological effects** Inhibition of ALAD enzyme is observed at blood lead concentrations <100 µg/L. ALAD is involved in the synthesis of haeme (LDAI, 2008). Decreased haemoglobin production can be observed at blood lead concentrations > 400 µg/L in children. Impacts on haemoglobin production sufficient to cause anaemia are associated with blood lead concentrations > 700 µg/L. (EFSA, 2013).
	Effect on blood pressure and cardiovascular effects A blood lead concentration of 36 µg Pb/L is associated with a 1% increase in systolic blood pressure. This corresponds to a daily lead exposure of 1.50 µg Pb/kg bw per day (EFSA, 2013). Weak positive association between blood lead concentration and blood pressure in general population with average blood lead concentration below 45 µg/dL (REACH Registration, 2015). Potential for a 'societal risk'' as opposed to an 'individual risk'. However, lack of dose-response relationship prevents use of this endpoints within a quantitative risk assessment.
	Kidney effects A blood lead concentration of 15 µg Pb/L is associated with a 10% increase of chronic kidney disease at population level. NOAEL of 60 µg/dL, combined with >5 years of lead exposure (REACH Registration, 2015). EFSA (2013) considered that there is no threshold for renal effects in adults.
Acute toxicity	Symptoms of acute lead poisoning (e.g. headaches, diarrhoea, memory loss, altered mental state etc.) can occur at blood lead concentrations of 800–1000 µg/L in children TNO (2005). USA: LOAEL value of 600–1000 µg/L related to colic in children. ATSDR (2007): LOAEL of 800 µg/L and a NOAEL of 400 µg/L identified for acute effects in children.
Reproductive toxicity	**Male fertility** Cross sectional study of 503 men (UK, Italy and Belgium) indicated a threshold for an effect on semen quality at 45 µg/dL of concurrent blood lead. As blood lead concentrations exceed 50 µg/dL, a progressively greater impact on fertility can be expected (Bonde et al., 2002). **Female fertility**

Endpoint	Critical lead exposure levels
	Effects on female reproduction in animal studies are usually not apparent at the blood lead concentrations that impair male fertility. >> 50 µg/dL blood lead concentrations are generally needed to see an adverse effect on female fertility. Human data are inconsistent and effects thresholds cannot be estimated with precision.

2.5.1.3 Lead gunshot in food

Lead shot that hits an animal will frequently 'fragment' into small particles on impact. The particles are distributed throughout tissues and some may reside in tissues a considerable distance from the primary wound (Green and Pain, 2015). Usually when a gamebird is killed several shot have penetrated it and the lead fragments and high tissue lead concentrations remain even in the event that shot pass in and out of a bird, as sometimes happens (Pain et al., 2010).

It is not possible to successfully remove all fragments of lead gunshot from game during butchery or food preparation (Pain et al., 2010; Green and Pain, 2015). Tiny lead particles would go unnoticed by consumers[32] resulting in their direct ingestion along with food.

Pain et al. (2010) found that a high proportion of samples of game meat had lead concentrations exceeding 100 ppb w.w. (0.1 mg kg w.w.). 100 ppb wet weight is the EU (1881/2006) ML (maximum level) permitted in bovine animals, sheep, pigs and poultry (excluding offal). No level has been set for game. The percentage of mallards exceeding 100 ppb w.w. was: 39.9[33] %.

In addition, cooking methods also appear to 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 its bioavailability. Public awareness of the most appropriate cooking technique for wild game to avoid lead exposure is difficult to evaluate, but is expected to be low.

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 lead in the general diet. This is thought to be because some of the ingested ammunition lead may remain as metallic fragments after cooking and digestion.

2.5.1.4 Conclusions on human health hazard

Lead is associated with multiple adverse heath endpoints in humans, including neurotoxicity in children and renal toxicity in adults for which no threshold has been established. Non-

[32] In the UK, the Food Standards Agency, referring to 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 (would eat into the processor's profit margins) and would cause damage to the birds which would likely make them unsalable."

[33] Adjusted value (approximates what would have been expected if the measurements of concentration in the whole meal derived from each bird had been available).

threshold effects on neurodevelopment was the principal endpoint in recent REACH restrictions for lead in jewellery, lead in consumer articles and lead in PVC.

2.5.2 Direct exposure to humans

There is an indication that some hunters may 'self-fill' their own cartridges with lead gunshot. Although, this exposure route has not been assessed in this report it could be expected there is potential for significant hand-to-mouth exposure of lead if the lead shot is handled without suitable protective equipment and hygiene practices are not followed e.g. washing hands before eating or smoking.

2.5.3 Indirect exposure to humans via the environment

Relevant pathways for human exposure include drinking water and food, indoor / outdoor air (including swallowing household dust or dirt containing lead) and soil. For the general population, food and water are considered to be the most important sources of exposure to lead (EFSA, 2013). Consumption of game meat can potentially contribute disproportionately to overall dietary exposure (EFSA, 2013).

2.5.3.1 Consumption of birds shot with lead gunshot in wetlands

EFSA (2013) undertook an assessment of exposure through the consumption of game meat. However, this assessment did not differentiate between game meat from wetlands (i.e. wildfowl, such as ducks and geese) and other game (such as upland game birds and venison). As such, the EFSA (2013) assessment cannot be used as a basis for an assessment of exposure via food in this restriction report.

Whilst there are some data available on the concentration of lead in waterfowl that are typically consumed, further additional data would be necessary to undertake a quantitative assessment of exposure of human populations to lead in the EU, specifically:

- The proportion of wildfowl in the diets of consumers in the EU, including 'high-level' consumers and children.
- The number of consumers, 'high-level' consumers and children consuming waterfowl in the EU.

This information is not currently available for the EU as the existing dietary studies, such as that underpinning the EFSA (2013) assessment, are not sufficiently detailed to differentiate exposure from different types of game meat, such as waterfowl.

It is expected that wildfowl will typically comprise a small proportion of total game (and total diet) consumed as they tend to be shot in small numbers in comparison with other game birds (upland birds) and other types of game. However, this does not preclude that there will be individuals that consume a high proportion of wildfowl game meat relative to other types of game meat or other meat, for example those undertaking subsistence hunting.

Despite the absence of this specific information for the EU, there is evidence in the literature that consumption of wildfowl can result in exposure to lead. A comprehensive review of specific studies made in the US was reported by Verbrugge et al. (2009). The majority of these studies refer to subsistence hunting.

In a study carried out to analyse the link between lead shot use for subsistence hunting of birds and human exposure, Johansen et al. (2001), cited by Verbrugge et al. (2009), x-rayed 50 carcasses of thick-billed murre (*Uria lomvia*) bought from hunters in Greenland. The birds had been harvested with lead shot and had an average of 3.7 lead pellets per carcass (range 0–12). There was no correlation between the number of gunshot and the lead concentration in meat, which ranged from 0.0074–1.63 ppm wet weight. The authors concluded that even after gunshot were removed, lead shot fragmented to fine dust upon collision with bone. They estimated a potential dose of 50 µg of lead from eating one bird.

Later, Johansen et al. (2006), cited by Verbrugge et al. (2009), monitored blood lead levels in 50 male hunters in Greenland before, during, and after the bird-hunting season to establish the association between bird consumption and blood lead concentrations. The frequency of bird consumption was strongly associated with measured blood lead concentrations in the hunters. Eider duck (*Somateria mollissima*) meals were more important in this case than murre meals as a lead source in the blood. Mean blood lead concentrations (12.8 µg/dL) were more than eight times greater in the group reporting more than 30 bird meals per month than in the group reporting no bird consumption (1.5 µg/dL).

In addition, Bjerregaard et al. (2004), cited by Verbrugge et al. (2009), found blood lead concentrations in Greenlanders to be correlated with reported levels of consumption of seabirds killed using lead gunshot. Blood lead levels in adult Inuit people in arctic Canada were positively correlated with the quantity of hunted waterfowl in the diet. In general, muscle lead concentrations in birds killed using lead gunshot have been shown to be significantly associated with the presence of embedded shot/shot fragments in the body tissues (e.g. Johansen et al., 2004; Pain et al., 2010, cited by Pain et al 2015). Also, a recent field study in ducks found that the presence of both ingested lead shot in the intestine and embedded lead shot in the muscle had separate and additive effects on muscle lead concentrations (Mateo et al., 2014).

Lead shot exposure has also been documented at individual level in humans, using radiography. In Northern Ontario, of 132 randomly selected radiographic charts from a hospital serving six native Cree communities (1990–1995), 15% showed lead shot in the gastrointestinal system (Tsuji and Nieboer 1997, cited by Verbrugge et al. 2009).

In Denmark, Madsen et al. (1988) noted that lead shot in the appendix were seen in lower abdominal x-rays. Seven patients with one or two lead shots retained in the appendix were identified by radiography. For each case, two sex- and age-matched control patients without lead shot in the appendix were identified. None of the seven patients with lead shot in the appendix had blood lead concentrations (median 0.55 µmol/l) approaching toxic levels, but averaged almost twice the concentration in controls (median 0.29 µmol/l). The authors concluded that lead shots may add to individual lead exposures, and blood lead analysis should be performed, at least when more than a few lead shots are present.

2.5.4 Risk characterisation

Green and Pain (2015) estimated minimum and maximum numbers of people in the UK who eat game and are potentially at risk from lead gunshot exposure. They reported that tens of thousands of people from the shooting community are high-frequency consumers of wild-shot game. It was also estimated that thousands of children in the UK (probably in the range 4,000 - 48,000) could potentially be at risk of incurring a one point reduction in IQ, or more, as a result of current levels of exposure to ammunition-derived dietary lead.

This estimate does not distinguish waterfowl consumption from other gamebirds (hunted outside of wetlands) and thus cannot be used to demonstrate a risk to human health from the use of lead gunshot in wetlands. Nevertheless, it is highly likely that some of the gamebirds consumed will have been obtained from hunting in wetlands and will therefore contribute to overall lead exposure. This is particularly relevant given the non-threshold nature of lead toxicity in humans in both adults (kidney effects) and children (neurodevelopmental effects).

On the basis of a qualitative assessment of the risks to humans from the consumption of game waterfowl shot with lead gunshot the risks to consumers cannot be ruled out. A qualitative risk assessment is appropriate according to REACH Annex I (para 6.5), since lead is a non-threshold neurotoxic substance and the risks to humans via the environment cannot be adequately addressed in a quantitative way (e.g. by derivation of DNELs or PNECs).

3. Justification for an EU wide restriction measure

Whilst legislation of one kind or another to prevent or reduce the use of lead gunshot in wetlands is common in EU Member States, the scope of the enacted measures are not harmonised e.g. there are difference in the definition of a wetland used or the proportion of wetland habitats within a Member State that are subject to the conditions of the legislation.

These disparities result in different levels of risk reduction in different Member States. These inconsistencies are sufficiently significant, particular noting that some Member States have no legislation to prevent or reduce the use of lead gunshot in wetlands, that it can be concluded that the risks posed by the use of lead gunshot in wetlands are not adequately controlled on an EU-wide basis.

Non-compliance with existing legislation is also often noted as an issue by Member States and stakeholders and will affect the realised risk reduction of any legislation. However, the proposed restriction under REACH is first and foremost intended to harmonise risk management legislation related to the use of lead gunshot in wetlands across EU Member States at a sufficient high-level to address the identified risks to waterbirds and predatory and scavenging birds that occur in wetlands. Since the flyways of these migratory birds cross several Member States, regulating the risk to them at Union level is likely to ensure the strongest possible protection all over the EU. Whilst 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.

A further reason to act on a Union-wide basis is related to the health risk posed by lead to humans via the consumption of wildfowl. This risk pertains particularly to people in various rural areas of the EU who engage in subsistence hunting.

4. Baseline

4.1 Existing Member State legislation on the use of lead gunshot in wetlands

Legislation to control the risks posed by lead gunshot have been enacted in most, but not all, Member States (or regions in some Member States). These measures range from complete bans on the use and placing on the market of shotgun cartridges continuing lead

gunshot, to restrictions on the use of lead gunshot within or over wetlands (as these are where waterbirds predominantly occur), or restrictions on the use of lead gunshot for hunting certain species, wherever they occur (typically species of waterfowl). Four Member States (Ireland, Poland, Slovenia and Romania), currently have no legislation to control the use of lead shot in wetlands.

The various legislative approaches adopted by Member States to address the risks posed by the use of lead gunshot can be categorised into four groups:

1. **Wide scope area-based partial ban** focusing on preventing the use of lead gunshot in generic wetland habitats (in certain MS based on the Ramsar wetland definition);
2. **Narrow scope area-based partial ban** focusing on preventing the use of lead gunshot in specific wetlands (in certain MS based on existing Ramsar site or Nature 2000 site designations);
3. **Partial ban focusing on the use of lead shot to hunt specific species** (typically waterfowl that spend a significant part of their life in wetlands);
4. **Full (complete) ban** on the use of lead gunshot (in certain MS, including restrictions on possession and sale).

Table 4.1. Scope of existing legislation to control the use of lead shot in Member States

Member State	Ban on use of lead shot	Details	Total number of hunters[b]
AT	Prohibited for hunting designated species	Not permitted for hunting waterfowl; wherever they occur.	118 000
BE[a]	complete	Applies throughout MS, irrespective of habitat or species hunted	34 000
BG	Narrow scope area-based partial ban	Not permitted in wetlands designated as Ramsar sites including a buffer zone of 200 m	110 000
CY	Wide scope area-based partial ban	Not permitted in waterbodies, whether artificial (salt lakes) or not (dams/reservoirs/sewage treatment ponds) – buffer zone of 300 metres	45 000
CZ	Prohibited for hunting designated species	Not permitted for hunting waterfowl; wherever they occur.	100 000
DE	Narrow scope area-based partial ban	Not permitted in waterbodies (all shorelines, lakes and rivers)	351 000
DK	complete	Applies throughout MS, irrespective of habitat or species hunted	165 000
EE	Prohibited for hunting designated species	Use of lead gunshot to hunt waterfowl is prohibited.	16 600
ES	Narrow scope area-based partial ban	Not permitted within designated Ramsar sites, Natura 2000 sites, nature protected sites	980 000
FI	Prohibited for hunting designated species	Not permitted for hunting waterfowl; wherever they occur.	308 000
FR	Wide scope area-based partial ban	(1) Foreshore; (2) marshes not dried; (3) rivers, canals, reservoirs, lakes and ponds.	1 331 000

Member State		Ban on use of lead shot	Details	Total number of hunters[b]
GR		Wide scope area-based partial ban and for hunting birds	-	235 000
HR		Wide scope area-based partial ban	Not permitted in wetlands. Wetland not defined in legislation, but Ramsar convention definition considered to apply.	50 000
HU		Narrow scope area-based partial ban	Not permitted within designated sites. Regulation lists 33 wetland areas, including Ramsar sites	55 000
IE		**No ban in place**	-	350 000
IT		Narrow scope area-based partial ban	Ban on wetlands in SPAs and SACs (with 150 m buffer). Wetland defined as lakes, ponds, marshes, oxbows and lagoons (freshwater, saltwater, brackish)	750 000
LT		Narrow scope area-based partial ban	Hunting forbidden in most important wetlands	32 000
LU		Wide scope area-based partial ban	marshes, lakes, ponds, reservoirs, rivers and canals and a buffer zone of 30 m.	2 000
LV		Narrow scope area-based partial ban	Not permitted for waterfowl hunting protected areas (Ramsar sites, SPAs and nature reserves)	25 000
MT		Narrow scope area-based partial ban)	No wetlands on Malta where hunting is permitted	15 000
NL		complete	Applies throughout MS, irrespective of habitat or species hunted	28 170
PL		**No ban in place**	-	106 000
PT		Narrow scope area-based partial ban	Designated Ramsar sites, Natura 2000 sites and nature protected sites	230 000
RO		**No ban in place**	-	60 000
SE		Wide scope area-based partial ban	Wetlands are defined in the regulation as a vegetation covered area where the water surface is closely under, at the same level or closely over the land surface and where the water level is allowed to vary according to the natural seasonal variations	290 000
SI		**No ban in place**	-	22 000
SK		Wide scope area-based partial ban and for hunting certain species	Wetlands: territory with swamps, low bogs or peat bogs, wet meadows, natural flowing water and natural stagnant water including a water-stream and water area with ponds and water reservoirs; waterbird game species: mallard, greylag goose, bean goose, white fronted goose and coot.	55 000
UK	EN	Narrow scope area-based partial ban and for hunting certain species	Not permitted to be used on foreshore, selected sites of special scientific interest (SSSIs); not permitted for hunting ducks, geese,	800 000

Member State		Ban on use of lead shot	Details	Total number of hunters[b]
			swans, coot, moorhen; wherever they occur.	
	WA	Narrow scope area-based partial ban and for hunting certain species	Not permitted to be used on foreshore, selected sites of special scientific interest (SSSIs); not permitted for hunting ducks, geese, swans, coot, moorhen wherever they occur.	
	SCO	Wide scope area-based partial ban	Not permitted in wetlands based on Ramsar convention definition, but peatlands interpreted to mean 'peatlands with visible water').	
	NI	Wide scope area-based partial ban	Not permitted in wetlands based on Ramsar convention definition, but peatlands interpreted to mean 'peatlands with visible water').	

Notes: a – 18 000 hunters in Wallonia, 16 000 in Flanders; b – data on number of hunters from FACE[34]

Many of the examples of existing national legislation have limited their scope to a subset of identified wetlands; referred to in this report as 'narrow' partial wetland bans.

One reason for such an approach would appear to be linked with the practicality of implementation and enforceability, taking into account that stakeholders should to have a clear understanding of where the use of lead gunshot is or is not permitted. However, any narrow scope partial ban inherently results in a continued risk to waterbirds outside of the designated wetlands, particularly if they offer similar feeding opportunities to designated areas.

Existing networks of protected areas, such as Ramsar and Nature 2000 sites, whilst offering important refuges for migratory species are not sufficient to limit the risks posed by the ingestion of lead gunshot, principally as designated sites only cover a relatively small proportion of the wetland habitat used by waterbirds, including AEWA species (See Annex B).

Similarly, partial bans linked to specific species (typically to prevent the use of lead gunshot to hunt waterfowl) have inherently limited risk reduction potential as they do not prevent the use of lead gunshot to hunt other species where waterbirds subsequently feed.

To effectively limit the risks to birds from the use of lead gunshot in or over wetlands it is evident that any restriction would need to apply in all wetland habitats where waterbirds may be exposed to spent lead gunshot, or where secondary poisoning of predatory and scavenging birds may occur.

Therefore, the observed disparity in the scope of the various existing legislation results in different levels of risk reduction in different Member States. These inconsistencies are sufficiently significant, particular noting that some Member States have no legislation to prevent or reduce the use of lead gunshot in wetlands, that it can be concluded that the

[34] FACE: census of the number of hunters in Europe – September 2010: http://www.face.eu/about-us/members/across-europe/census-of-the-number-of-hunters-in-europe-september-2010

risks posed by the use of lead gunshot in wetlands are not adequately controlled on an EU-wide basis.

4.2 Impacts on birds

Based on wintering population size, between 262 000 and 787 000 waterfowl from 22 species are estimated to die annually from the consumption of lead gunshot in the EU, with a central estimate of 522 000. Based on breeding population size of the same species, between 207 000 and 720 000 individuals are estimated to die annually, with a central estimate of 441 000[35]. Between 66 000 and 212 000 of these cases of lethal poisoning in waterfowl are estimates to occur in Member States without existing legislation on the use of lead gunshot.

In terms of wintering populations of wading and rail species of waterbirds, between 204 000 and 638 000 individuals from 11 species are estimated to die annually, with a central estimate of 420 000. A similar, but moderately greater, number of waders and rails from the same species are estimated to die annually based on the breeding population size.

When estimates for waterfowl are combined with those for waders and rails, between approximately 400 000 and 1 500 000 individuals are estimated to die annually throughout the EU from lead poisoning. Of these, between 65 000 and 200 000 are estimated to occur in Member States without legislation prohibiting or reducing the use of lead gunshot in wetlands. Therefore, imposing measures only on the four Member States without existing legislation on the use of lead gunshot in wetlands would not greatly affect the number of birds estimated to be dying annually.

As there are no population estimates for birds occurring in Greece or Croatia reported under Birds Directive Article 12, these estimates is likely to be an underestimate. Further details are provided in the risk characterisation section of this report and in Annex B.

In addition, these estimates should be considered as minimum impacts as they do not account for sub-lethal poisoning within these species, or for lethal effects on other waterbird species that could also ingest spent lead gunshot. These estimates also do not take into account lethal or sub-lethal effects on predatory or scavenging birds via secondary poisoning.

[35] REACH does not require evidence of 'population level' impacts to demonstrate an unacceptable risk to the environment.

5. Impact assessment

5.1 Introduction

The impact assessment presented in this document employs a semi-quantitative approach to estimating the benefits and costs of the proposed restriction on lead in shot used in or over wetlands. The analysis includes an examination of the compliance costs of the proposed restriction and its cost-effectiveness.

5.2 Risk management options

The preparation of this Annex XV restriction report followed a request from the Commission to ECHA. The conclusion of the risk assessment undertaken by ECHA is that the risk from the use of lead in shot in or over wetlands is not adequately controlled on a union-wide basis. Therefore, ECHA conducted an analysis of diverse risk management options (RMOs), including restriction under REACH, to identify which would be the most appropriate to address the identified risks and to define its scope and conditions.

As a first step, the possibility to address the risks to human health and the environment from the use of lead in gunshot in wetlands using other REACH regulatory measures, existing EU legislation and other possible Union-wide RMOs was examined (see Annex B). These options were all assessed as being inappropriate, as elaborated in Annex E, Section E.1.3.

Therefore, the possibility to impose a restriction under REACH was investigated further and the following restriction options were considered in addition to the proposed option:

1. Restriction on the placing on the market and use of lead gunshot
2. Restriction on the use of lead gunshot for all hunting, irrespective of species
3. Restriction on the use of lead gunshot for all hunting of birds or hunting of waterfowl (e.g. ducks, geese and swans)
4. Restriction on the use of lead gunshot in Ramsar Sites and/or SPAs in Natura 2000 network.
5. Phased approach to implementing a restriction on the use of lead gunshot in wetlands.
6. No additional restrictions on the use of lead gunshot

Each of the options was assessed against the main criteria for a REACH restriction (effectiveness, practicality and monitorability) as well as against the boundaries of the mandate for the restriction proposal establish by the Commission in their request to ECHA (i.e. to investigate a REACH restriction on the use of lead gunshot in wetlands). As a result of this assessment, the restriction option below is proposed and the others summarised in Table 5.1 were discarded. The detailed rationale for not proposing the remaining restriction options is presented in Annex E, Section E.1.2.

Table 5.1. Summary of rejected restriction options (compared to proposed restriction option)

	Restriction option	**Effectiveness** (risk reduction/ proportionality)	**Practicality** (ease of implementation, enforceability, manageability)	**Monitorability**	**Notes**
1	Restriction on the placing on the market and use of lead gunshot	risk reduction (+) proportionality: costs (++), benefits (++)	enforcement (+) implementation (+) manageability (=)	(=)	*Option exceeds the scope of ECHA's mandate from the Commission as would also prevent use of lead gunshot outside of wetlands.*
2	Restriction on the use of lead gunshot for all hunting	risk reduction (+) proportionality: costs (+), benefits (+)	enforcement (+) implementation (+) manageability (=)	(=)	
3	Restriction on the use of lead gunshot for all hunting of birds or hunting of waterfowl (e.g. ducks, geese and swans)	risk reduction (-) proportionality: costs (-), benefits (-)	enforcement (+) implementation (+) manageability (=)	(=)	
4	Restriction on the use of lead gunshot in Ramsar Sites and/or SPAs in Natura 2000 network.	risk reduction (--) proportionality: costs (-), benefits (-)	enforcement (=) implementation (+) manageability (=)	(=)	
5	Phased approach to implementing a restriction on the use of lead gunshot in wetlands	risk reduction (-) proportionality: costs (-), benefits (-)	enforcement (=) implementation (-) manageability (=)	(=)	
6	No additional restrictions on the use of lead gunshot	(-)	(-)	(=)	

Notes**:** (+) increase in relation to the proposed restriction option; (-) decrease in relation to the proposed restriction option; (=) equal to the proposed restriction option.

5.3 Proposed restriction

Brief title: Restriction on the use of lead gunshot in or over wetlands.

Table 5.2. Proposed restriction on the use of lead gunshot in or over wetlands

Lead and lead compounds	1. Shall not be used in gunshot for shooting with a shot gun within a wetland or where spent gunshot would land within a wetland. 2. Lead gunshot shall not be in the possession of persons in wetlands; 3. For the purposes of paragraphs 1 and 2: • "shot gun" means a smooth-bore gun; • "gunshot" means pellets used in quantity in a single charge or cartridge in a shotgun; • "lead gunshot" means any gunshot made of lead, or any alloy or compound of lead with lead comprising more than 1% of that alloy or compound; • "wetlands" are defined according to Article 1(1) of the Convention on Wetlands of International Importance especially as Waterfowl Habitat (Ramsar Convention). 4. Paragraphs 1 and 2 shall apply 36 months from entry into force of the restriction; 5. Member States may, on grounds of human health protection and environmental protection, impose more stringent measures than those set out in paragraphs 1 and 2. Member States shall inform the Commission of such measures.

5.3.1 Justification for the selected scope of the proposed restriction

The proposed restriction aims to address the risks posed by the use of lead gunshot in wetlands, notably to protect birds from the acute and sub-lethal effects resulting from lead exposure via ingestion. The proposed restriction is intended to apply irrespective of the type of shooting that lead gunshot is used for. Therefore, it comprises a ban on any use of lead gunshot for any hunting (irrespective of species) as well as any use of lead gunshot for any sports shooting at targets (e.g. clay pigeons). The proposed restriction is intended to apply within all (generic) wetland habitats (not just designated sites) and is also intended to prevent shooting of lead gunshot outside of a (generic) wetland where the spent gunshot would subsequently land within the wetland.

The intention of the Dossier Submitter, when developing the wording of paragraph 1 of the proposed restriction, was to prevent the deposition and accumulation of lead gunshot in wetlands (addressing the primary poisoning risk) and, equally, to prevent waterbirds from being shot with lead gunshot in wetlands (addressing the secondary poisoning risk). This is in line with the request to develop a restriction from the Commission and the results of the risk assessment.

In more detail, the wording was formulated to explicitly prohibit the following scenarios:

- ***'shooting lead gunshot with a shotgun within a wetland'.*** This is intended to apply to any person that is located within a wetland when they shoot, irrespective of purpose for which the shooting is undertaken. This is justified by the high probability that shooting with lead gunshot with a shotgun within a wetland will result in lead gunshot accumulating within that wetland or being 'shot in' to a waterbird within a wetland, irrespective of whether the waterbird is wounded or killed. Equally, from a risk perspective, the purpose of the shooting (i.e. hunting, clay-pigeon shooting) is irrelevant.

- ***'shooting lead gunshot with a shotgun outside of a wetland where the spent (i.e. fired) lead gunshot would land within a wetland'.*** The intention here is to prevent the deposition and accumulation of lead gunshot within a wetland as a result of the shooting of a shotgun with lead gunshot outside of a wetland. This is intended to apply to any person irrespective of whether they are located inside or outside of a wetland when they shoot or the purpose for which the shooting is undertaken. The intention is only to prevent the use of lead gunshot in a shotgun for shooting outside of a wetland when the lead shot '**would land'** within a wetland. Thus, shooting can take place close to a wetland, or in the direction of a wetland, as long as it can be assured that the lead gunshot would not land within it (i.e. if shooting in the opposite direction to the wetland). Whilst this formulation is acknowledged to rely on the experience, skill and local knowledge of those undertaking the shooting (e.g. in terms of the likely distance that lead gunshot will travel once fired, noting that 'fall-out' distances of 300 metres may not be uncommon) this was considered as the most appropriate means of describing the scope of the restriction in relation to the risks and the request from the Commission. This rationale is further elaborated below, specifically in relation to the potential utility of buffer zones around wetlands to facilitate the implementation of a restriction.

A similar intention, and wording, can be found in existing Member State legislation to prevent the use of lead gunshot in wetlands. For example, the following text is used in the Scottish regulation[36] addressing the use of lead shot and wetlands:

"No person shall use lead shot for the purpose of shooting with a shot gun on or over wetlands"

In an explanatory leaflet published by BASC Scotland[37] this is further explained as:

"The key purpose of the legislation is to stop lead shot falling into wetlands. If your shooting involves shooting "on or over" wetland areas (ponds, lochs, rivers, streams, marshes, fens, bogs etc.) then you must ensure that you either use non-lead shot from 31st March 2005 or modify your shooting behaviour to ensure your shot does not fall into the wetland. Please bear in mind that a 12-bore shotgun shooting a normal cartridge has a maximum fall-out range of approximately 300 metres."

Similarly, with respect to clay pigeon shooting:

[36] Environmental Protection (Restriction on Use of Lead Shot) (Scotland) (No.2) Regulations 2004 (SSI No. 2004/358)

[37] https://basc.org.uk/wp-content/plugins/download-monitor/download.php?id=328 (accessed 24/01/2018)

"Established clay shoots and less formal, occasional shoots will all have to ensure that they are not shooting on or over wetland areas, or will have to use appropriate non-lead shot. 7.2 If there is a wetland feature[38] on the site over which you shoot you may be able to re-arrange your traps and cages to ensure that shooting now takes place away from these features. We are aware of a small number of established sites where there is no alternative but to shoot over wetland features, such as foreshore. In such situations the shoot will only be able to continue if it ensures that non-lead loads are used."

This intention can also be depicted visually. Figure 5.1 describes how to remain compliant with the intention of the proposed restriction.

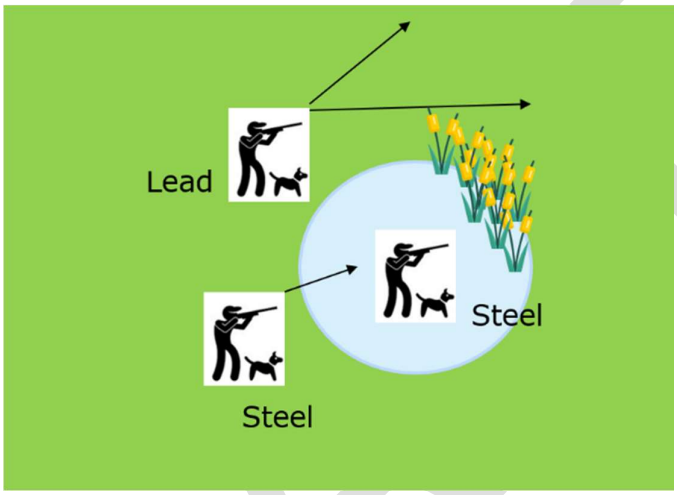

Figure 5.1. Intention of restriction, where to use lead and non-lead ammunition for shooting with a shotgun (in this example steel is the non-lead ammunition used)

As an alternative to the proposed wording *on 'where lead spent gunshot would land within a wetland'*, the Dossier Submitter also considered the usefulness of various types of 'buffer zone' around wetlands to achieve the intention of preventing spent lead gunshot used outside of a wetland from accumulating within a wetland. All of these buffer zone options were dismissed, as described below.

In relation to paragraph 2, the intention of the Dossier Submitter was to make it explicit that the term 'use' in paragraph 1 of the restriction proposal, without further clarification elsewhere in the entry, would imply that the 'possession' of lead gunshot in wetland would also be prohibited by the proposed restriction.

The Dossier Submitter notes that enforcement of the proposed restriction would be made significantly easier where a prohibition on possession was included, but also recognises that in some instances, which are likely to be site-specific, there is not necessarily a clear association between possession within a wetland and an intention to shoot lead shot where it will realise a risk in a wetland. As such, there are both advantages and disadvantages of

[38] Ponds, lochs, rivers, streams, marshes, fens, bogs etc

including a prohibition of the possession of lead gunshot within the scope of the proposed restriction. These issues are further elaborated below.

The proposed restriction would address the risks to birds from the ingestion of lead gunshot where this occurs within a wetland and harmonise existing Member State approaches to address the risk. However, birds (including AWEA listed waterbirds and predatory or scavenging raptors) also feed outside of wetlands and may therefore still be exposed to spent lead gunshot where this is used outside of a wetland. As such, the proposed restriction on use within wetlands (even with a comprehensive definition of wetland environments) cannot completely address the risks associated with the use of lead gunshot to waterbirds.

For example, many species can be hunted while feeding in terrestrial habitats away from wetlands, resulting in deposition of lead shot in feeding areas. Grazing species that primarily feed away from wetlands include migratory swans (whooper swans and Bewick's swans) and species of geese, including the Greenland white-fronted goose *Anser albifrons flavirostris* (the endangered sub-species of greater white-fronted goose) and other threatened species that are listed as priorities under AEWA and CMS. In recognition of these risks, several Member States have already enacted more stringent restrictions on the use of lead gunshot within their territory that extend beyond wetlands.

The proposed restriction does not seek to compel Member States to revoke these existing measures (the risks from the use of lead gunshot in terrestrial habitats and in other types of lead gunshot have not been assessed in this Annex XIV report). This is recognised in paragraph 5 of the restriction proposal.

The restriction is also expected to have various co-benefits, such as to consumers that eat waterfowl, groundwater quality and general environmental quality. These are described in Section E.6.2.2 of Annex E.

The proposed restriction is acknowledged to present some challenges to Member States. These challenges mainly relate to:

- The **definition of wetland areas** within Member States, such that stakeholders can readily comply with the requirements of the restriction.
- **Enforcement/compliance**. Compliance problems are widely reported in relation to partial bans on the use of lead gunshot. Explicitly prohibiting the possession of lead gunshot within a wetland in the restriction proposed is intended to highlight that the 'use' within REACH extends to 'possession' and that it could be used as an enforcement option by Member States.

These challenges and further explanation of the chosen scope are outlined in subsequent sections.

5.3.1.1 Shotgun definition

A shotgun, for the purposes of the proposed restriction, are any smoothbore firearm (meaning the inside of the barrel is not rifled), which use the energy of a fixed shell to fire a number of small pellets called gunshot, or a solid projectile called a slug. The main categories of shotguns are:

- break open double barrels shotguns (either "over-under" or "side-by-side" configurations);
- pump action shotguns;
- semi-automatic shotguns (inertial or gas operated).

5.3.1.2 Proposed wetland definition

Many examples of existing Member State legislation have limited their scope to a subset of identified wetlands; referred to in this report as 'narrow' partial wetland bans.

One reason for such an approach would appear to be linked with the practicality of implementation and enforceability, taking into account that stakeholders should have a clear understanding of where use of lead gunshot is or is not permitted. However, any narrow partial ban inherently results in a continued risk to waterbirds outside of the designated wetlands, particularly if they offer similar feeding opportunities to designated areas.

Similarly, partial bans linked to specific species (typically to prevent the use of lead gunshot to hunt waterfowl) have inherently limited risk reduction potential as they do not prevent the use of lead gunshot to hunt other species where waterbirds subsequently feed e.g. within peatlands or agricultural areas.

To effectively limit the risks to birds, and avoid that conservation efforts in one Member State are undermined by less-optimal measures in another, it is important to deal with the risk posed by lead gunshot in an appropriate and consistent manner with a sufficient scope to reduce the identified risks. As waterbirds range across large areas during their migration and to find food, existing networks of protected areas, such as Ramsar and Nature 2000 sites, whilst offering important refuges for migratory species are not sufficient to limit the risks posed by the ingestion of lead gunshot. Designated sites only cover a relatively small proportion of the habitat used by waterbirds, including AEWA species (See Annex B).

It is therefore appropriate to consider a generic definition of a wetland for the scope of the restriction proposal. The most widely accepted definition of a wetland is that outlined in Article 1(1) of the Ramsar convention:

"areas of marsh, fen, peatland or water, whether natural or artificial, permanent or temporary, with water that is static or flowing, fresh, brackish or salt, including areas of marine water the depth of which at low tide does not exceed six metres".

Therefore, the scope of the proposed restriction is based on the Ramsar definition of a wetland. This is based on the Dossier Submitter's mandate for this restriction from the Commission (to develop a restriction on the use of lead gunshot in wetlands), the fact that the Ramsar convention has been ratified by all EU Member States, the existing obligations of the EU under the AEWA and CMS and the fact that waterbirds are known to use all of the habitat types included in the Ramsar definition of a wetland.

The AEWA requires a complete phase out of the use of lead over wetlands, which is aimed at protecting waterbirds and migratory birds that spend significant parts of their life in wetlands (both during the breeding and wintering seasons).

The term 'wetland' does not typically correspond with cadastral mapping or any other kind of mapping that would allow definitive boundaries to be established for all wetlands, although certain wetland areas such as Ramsar sites and SPAs have well established

boundaries. The mapping of various land classifications that (together) are broadly consistent with the Ramsar definition of a wetland has been undertaken on an EU level under the Corine Land Use programme. Additional information on the definition of wetlands is available in Section B.4.3.3.1 of Annex B.

Making available such maps is beyond the scope of this restriction report but could be undertaken by Member States as part of the implementation of the restriction, particularly for designated sites that would fall within the scope of the proposed restriction, such as many Natura 2000 sites as well as designated Ramsar sites.

It is noteworthy that several Member States (or regions within Member States) with existing legislation prohibiting the use of lead gunshot in 'generic' wetlands (rather than specific sites) have published guidance on the interpretation of a generic wetland definition to aid the implementation of their legislation[39]. Similar guidance could be produced by other Member States or national hunting associations.

5.3.1.3 Buffer zones

The wording proposed in the entry of the restriction "where spent gunshot would land within a wetland" is considered to be a flexible, dynamic and 'fit-for-purpose, approach to address the risk posed from lead gunshot in wetlands in a proportionate way. The Dossier Submitter acknowledges that the approach relies on both a person's knowledge[40] of the area they are shooting in (either from experience or by preparation) and their experience to understand where a possible deposition of lead shot over wetlands may occur.

However, defined 'buffer zones' around wetlands, are often considered to be a necessary component of a restriction on the use of lead gunshot and wetlands to avoid 'spent' (fired) lead gunshot falling within a wetland from a firing position outside of a wetland.

When considering the wording of the proposal the need for a buffer zone (or the advantages that a buffer would offer compared to its disadvantages) was explicitly considered (see below). However, in all circumstances an explicitly defined buffer zone was disregarded in favour of the more flexible approach provided in the wording proposed. In the Dossier Submitters' view little merit would accrue from setting a fixed distance buffer zone rather than the flexible approach that was proposed. This was in recognition that flexibility and discretion is likely to be required to account for the specific local circumstances (e.g. site specific topology, wind conditions, shotgun, ammunition) that will combine to determine the likelihood that spent lead shot would land within a wetland. It also recognises that, based on the generic definition of a wetland proposed as the basis for the restriction, cadastral site boundaries (from which a buffer zone distance would apply) will not be available unless the wetland is also designated for some other purpose e.g. Special Protected Area (SPA) under

[39] A practical guide to the lead shot regulations in Scotland https://basc.org.uk/wp-content/plugins/download-monitor/download.php?id=328

[40] Hunters already have to use their experience and judgement of the effective shooting distance of their combination of shotgun and ammunition to accurately target flying birds. Therefore, it is not unreasonable to assume that hunters can confidently and effectively judge how far the lead shot will travel and if spent shot will land in a wetlands.

the EU Birds Directive, Special Area of Conservations (SAC) under the EU Habitats Regulations or designation 'Ramsar site' under the Ramsar convention.

The term 'buffer zone' has different meanings in different legislation, depending on how they are precisely defined, ranging from a 'transition zone' around certain types of wetlands (to account for the gradual transition from saturated to 'terrestrial' habitat), to a zone of heightened alert on the imminence of wetland to a zone of total exclusion of the use of lead shot[41].

Within the existing national legislations in place in the EU on the use of lead shot over wetlands, three broad categories of buffer zone approaches can be identified: no buffer zones, small buffer zones (20-30m) and large buffer zones (200-300m). These are assessed below. In each case the buffer zone is intended to only prevent shooting towards a wetland i.e. shooting away from a wetland within the buffer zone would be allowed.

Table 5.3. Differences between types of buffer zones

	Flexible/dynamic approach	**20-30 m Buffer Zone**	**200-300 m Buffer Zone**
Risk reduction considerations (in relation to risks arising in wetlands) – assuming compliance with requirements.	Proposed restriction.	Reduced compared to the flexible/dynamic approach as shooting with lead gunshot outside of the buffer zone in the direction of a wetland is likely to result in the deposition of lead gunshot within the wetland. This buffer zone extends the scope of the restriction outside of wetlands as it will prohibit shooting 'over the top' of wetlands where spent lead gunshot will fall into terrestrial areas[42].	Considered to be broadly similar to the flexible/dynamic approach, although could result in reduced risk reduction potential in circumstances where spent lead gunshot is likely to travel >300 metres towards a wetland (e.g. clay-pigeon shooting ranges located near to wetlands). This type of buffer zone extends the scope of the restriction outside of wetlands as it will prohibit shooting 'over the top' of wetlands where spent lead gunshot will fall into terrestrial areas and, dependent on site-specific conditions,

[41] A buffer zone around a wetland that implied a total prohibition on the use of lead shot within it, irrespective of direction of shooting, has not been considered in detail by the Dossier Submitter. This is because any such buffer zone would effectively increase the scope of the restriction beyond a restriction on wetlands.

[42] If a person shoots 'over the top' of a wetland into a terrestrial area they are not within the scope of the proposed restriction, based on the flexible/dynamic approach, but would fall within the scope of a restriction with a buffer zone where shooting towards a wetland was prohibited.

	Flexible/dynamic approach	20-30 m Buffer Zone	200-300 m Buffer Zone
			ignores the potential for spent shot not to always travel 200-300 metres, even when shot in the direction of a wetland.
Enforcement considerations	Proposed restriction, Assumes that person shooting is competent to assess likelihood of risk, based on the skills and experience and local knowledge. Enforcement would need to prove that shot would land in wetland. Giving responsibility to persons shooting may enhance compliance.	Could be easier to enforce than the flexible/dynamic approach as the distance from the boundary of the wetland to the point of shooting is similar to the typical shooting range for hunting with a shotgun and is therefore considered to be relatively more easy to judge by both the person shooting and any enforcement official present (compared to a significantly greater distance, such as >200 metres).	Extent of buffer zone likely to be difficult to estimate in the field for both person shooting and any enforcement present. However, similar challenge posed by flexible/dynamic approach. 200-300m buffer zone may overestimate or underestimate the distance that lead gunshot will travel in practice, prohibiting shooting that would not result in a realised risk in a wetland or allowing shooting that would result in deposition within a wetland. Perception of a disproportionate response to risks could adversely affect compliance.
Socio-economic considerations	As per proposal.	Benefits of restriction may be less than estimated as lead gunshot continues to accumulate in wetlands.	Costs of restriction may be greater than estimated (unnecessary substitution).

Wording similar to the intention of a restriction prohibiting 'shooting on or over' wetlands are used in the following Member States or regions within a Member State: France, Scotland, Northern Ireland, England and Wales where the wording 'shooting over' is used to place responsibility on hunters so as to ensure that the spent shot does not land in wetlands.

Therefore 'shooting towards' is only used in the context of bans where no buffer zones (in the sense of exclusion zones) are in place. Whilst there is a buffer zone in the French legislation it is better understood as a 'transition zone' where lead gunshot can be used, but only under specific circumstances e.g. when they are shooting away from a wetland or in a direction other than towards the wetland.

In addition, the transition zone in France only applies to features with a fixed, definitive boundary. For bogs and swamps (marais sechees without a clear border) hunters are only required to ensure that no lead gunshot is deposited when shooting, i.e. the wording 'shooting in or over' takes effect.

Hunters are advised (See Scottish leaflet[43], French guidance[44]) that distance for hunting are usually around 30 metres (according to public consultation the reason to choose 30 m in France) and that spent lead may deposited (using a 12 gauge calibre) as far as up to 300 m away.

In addition, it appears that buffer zones, in the sense of total exclusion zones, are typically used in Member States where narrow area-based bans are implemented, where indeed the national measure in place only applies to well-defined wetland (sites) with clear cadastral boundaries. Examples of these are found in Italy (150 m, only SPA) Bulgaria (Ramsar **sites** 200 m) and on Hungary (Ramsar **sites** 100 m).

The Dossier Submitter has no specific information on why these choices were made in individual MS but it does seem that, in general, generic habitat based bans are not put in place with an accompanying buffer zone but rather alongside the flexible (on or over) approach.

Table 5.4. Overview of Member State approaches to buffer zones

Member State	Type of existing ban	Buffer zone?	Buffer zone type		shooting towards?
			20-30	200-300	
AT	Species restrictions	n/a			
BE	Complete	n			
BG	Area - narrow			x	exclusion zone
CRO	Area - narrow	n			
CY	Area - wide	y		x	exclusion zone
CZ	Species restrictions	n/a			
DE	Area - narrow	n			
DK	Complete	n			

[43] https://basc.org.uk/wp-content/plugins/download-monitor/download.php?id=328

[44] http://www.oncfs.gouv.fr/Fiches-juridiques-chasse-ru377/Les-munitions-en-zone-humide-ar1342

Member State	Type of existing ban	Buffer zone?	Buffer zone type		shooting towards?
			20-30	200-300	
EE	Area - narrow	n			
ES	Area - narrow	n			
FI	Species restrictions	n/a			
FR	Area - wide	y	x		shooting on or over
GR	Area - wide				
HU	Area - narrow	y		x	exclusion zone
IE	No ban				
IT	Area - narrow	y		x	exclusion zone
LI	Area - narrow	n			
LU	Area - narrow	y	x		exclusion zone
LV	Area - narrow	n			
MT	Area - narrow	n			
NL	Complete	n			
PL	No ban				
PT	Area - narrow	n			
RO	No ban				
SE	Area - wide	n			
SI	No ban				
SK	Area - wide / species				
UK	Area - narrow / species				shooting on or over

5.3.1.4 Enforcement considerations

A large scale study of compliance with the partial ban on the use of lead gunshot in the UK found that 70% of ducks purchased in England had been shot illegally with lead ammunition (Cromie et al. 2010). Alongside this finding, significant mortality of waterbirds continues (Newth et al. 2012). Other studies, although made on local scale, e.g. in some areas of Spain (Ebro Delta), showed that strict controls on the type of ammunition carried by hunters at entry points of hunting areas were necessary to guarantee adequate compliance with the implemented ban (Mateo et. al. 2014).

As such, enforcement of any restriction proposal is clearly important to consider. Feedback from stakeholders[45] was that the enforceability of any restriction proposal, and hence its risk reduction potential, would be enhanced by including the prohibition of possession of lead shot within a wetland that is within the scope of the restriction. Compliance issues in France have been reported to be explicitly linked to enforcement difficulties linked to the legal possession of lead gunshot within a wetland[46].

The definition of 'use' in Article 3(24) of the REACH Regulation, includes 'keeping' and 'any other utilisation', suggests that a restriction under REACH on use would also implicitly allow Member States to restrict 'possession'. However, national legislation on the use of lead gunshot does not tend to cover extend to bans on 'possession'. Therefore including a specific paragraph within the restriction proposal that explicitly outlines that possession within a wetland is within the scope of the proposal ensures that the intention is clear during opinion and decision making (and public consultation).

However, the Dossier Submitter acknowledges that a restriction on the possession of lead gunshot i.e. carrying cartridges containing lead gunshot in wetlands might have additional (unintended) impacts on hunters. These impacts were also raised by several hunting associations in the public consultation. Three main side effects were identified:

1. Transporting or carrying of lead shot (in e.g. the car) on routes through wetlands without the intent to use.
2. Keeping at home where the dwelling is in a wetland.
3. Crossing wetlands to carry out hunting outside of a wetland.

Within examples of existing national legislation, and through the public consultation, several alternative terms that could be used instead of the word 'use' are possible and which would not necessarily be associated with the unintended impacts introduced by the REACH term 'use'. These terms are discussed inTable 5.5. Advantages and disadvantages of various wording options Table 5.5.

Table 5.5. Advantages and disadvantages of various wording options

	'Use'	**'Discharge' / 'fire' / 'shoot'**	**'Loaded'**
Advantage	The word use is a key REACH term which has a clear definition and would include possession, a key factor that was identified to be linked to non-compliance. Inspectors have more possibilities to monitor non compliance – which	The term discharging would imply that lead shot can be carried in both wetland and terrestrial areas but not discharged in a wetland or where lead gunshot would land in a wetland i.e. types of shooting that do not directly impact AEWA species would not be impacted.	Safety rules[47] for shotguns prescribe that shotguns should not be loaded until the hunter is ready to fire. Therefore, a shotgun loaded with a lead gunshot cartridge/s demonstrates a clear intention to discharge the cartridge.

[45] Meeting of the Expert Group on the Birds and Habitats Directives (NADEG), in November 2016.

[46] French report to AEWA (2015). http://www.unep-aewa.org/sites/default/files/document/nr_aewa-mop6_france.pdf

[47] BASC handbook of shooting, an introduction to the sporting shotgun. Quiller press 2013.

	'Use'	'Discharge' / 'fire' / 'shoot'	'Loaded'
	may result in increased risk reduction.	However, as this term is not defined in REACH as subject to a restriction this proposal is not possible.	This would imply that lead shot can be carried in both wetland and terrestrial areas but not loaded (or discharged) within a wetland or where lead gunshot would land in a wetland i.e. types of shooting that do not directly impact AEWA species would not be impacted.
Disadvantage	Possession other than 'personal possession while hunting' (i.e. carry lead shot while hunting) might impact hunters.	Increased enforcement difficulties, hunters need to be 'caught in the act of firing the gun where the shot would land in the wetland'.	When inspected, hunters typically unload guns and any evidence of intent to discharge may disappear.

Combinations of the terms also exist, the Dutch law uses for example *'to have in possession […]. whilst hunting (or being on the hunting ground)'* a term that is used in some of the US states[48] as well where emphasis is put on not having lead gunshot in personal possession while hunting. A clear advantage of this combination is that practical difficulties (keep at home, keep in the car) might be avoided whilst the direct link to shooting with lead gunshot can actually still be assumed.

Future legislative developments in Italy[49] (as reported by several comments in the public consultation) indicate that there is an intention to modify existing legislation to add a ban on the possession of lead ammunition where its use is already not allowed, to ensure an adequate protection of avifauna.

Denmark dealt with the issues of possession/enforcement and risk reduction by restricting the 'placing on the market', which allows inspectors to make easy compliance checks on ammunition retailers rather than on hunters. This unambiguous approach alleviates many of the practical problems associated with partial bans as effective enforcement can be made irrespective of arguments surrounding intent, position with respect to wetlands, etc.

In light of the purpose of the restriction, which is to harmonise risk reduction across the EU, the Dossier Submitter believes that mechanisms for ensuring compliance should facilitate achieving the potential risk reduction (and the accompanying societal benefits), but not impose conditions that are infeasible in practice.

A further element of enforcement relates to the identification of shot material in the field i.e. whether it possible to determine if a cartridge contains lead gunshot or other gunshot material without first disassembling the cartridge.

In this regard, the Dossier Submitter notes that the US Code of Federal Regulations (CFR) relating to Migratory Bird Hunting requires that approved 'nontoxic' shot is used as an alternative to lead gunshot when hunting waterfowl and coots throughout mainland US

[48] E.g. State of Maryland, Alaska, Washington

[49] Action 2.1.1 Piano d'azione nazionale per il contrasto degli illeciti contro gli uccelli selvatici (2017).

state. Approved nontoxic shot must be identifiable by enforcement officers by means of an appropriate 'field testing device', which could comprise regular or rare-earth magnets[50]. As the alternatives to lead shot that are most likely to be used in the EU (e.g. steel, bismuth and tungsten) are already approved as 'non-toxic' in the US, it follows that suitable field testing methods are also available to identify and distinguish lead from alternative shot materials in the field.

5.3.1.5 Entry into force

Upon entry into force, lead gunshot cannot be used anymore in wetlands. The most likely alternative is steel gunshot. No information is available on the production capacity of alternatives outside of EU countries. However, information obtained from stakeholders[51] suggested that for the proposed scope of this restriction (wetlands) a transition time of three years from the date of entry into force of the legislation appears reasonable for EU producers. This is supported by the evaluation reported by Thomas et al. (2014).

Bismuth and other materials are also used in alternative gunshot. Bismuth is derived mainly from the refining of other metals and is increasingly used to substitute lead in various applications (e.g. electronics). The production capacity for bismuth and other alternative gunshot cartridges may have to be increased to satisfy any increase in cartridge demand. Industry would therefore require an adequate phase-in time to implement such capacity increases.

5.3.1.6 Concentration limit

The proposal defines lead gunshot as *'any gunshot made of lead, or any alloy or compound of lead with lead comprising more than 1% of that alloy or compound'*. This concentration limit was selected based on the US 'non-toxic' gunshot approval process that limits the maximum concentration of lead in any 'non-toxic' gunshot to 1% (w/w) in order to avoid a significant toxicity danger to migratory birds and other wildlife, or their habitats.

As such, the proposed concentration limit is considered to sufficiently address the risk posed by containing shot material whilst being readily achievable by producers of alternative gunshot. The Dossier Submitter notes that bismuth/tin-based alternative gunshot materials are more likely to contain lead as an impurity than steel or tungsten-based alternatives. Further details of the environmental and human health risks for alternatives are provided in Section E.3.1.5 in Annex E.

5.4 Assessment of restriction scenario

The expected response of users of lead gunshot to a restriction on the use of lead gunshot in wetlands is to substitute to steel gunshot. However, it is possible that some hunters will chose to use other alternative shot materials, such as bismuth/tin or tungsten-based gunshot, instead. The main elements influencing this choice are outlined below.

[50] For example, the US regulations refer to the Stream Systems 'HOT*SHOT' field testing device as suitable non-invasive means to differentiate between lead, steel, bismuth shot materials during compliance testing. https://www.streamsystems.com/stream_website/hotshot/more_info/hotshot.htm

[51] Personal Communication Baumbach Metalss GmBH, and with Clay 7 Game Relaoders Ltd (2016?)

5.4.1 Alternatives

Users affected by the proposed restriction would have to switch to alternative ammunition. The most commonly used alternatives are steel and bismuth/tin shot (although tungsten-based cartridges are also widely available). These alternatives are already widely used in the EU and internationally. Annex E demonstrates that they are technically and economically feasible (steel gunshot is similarly priced to lead gunshot) and have a more benign human health and environmental hazard and risk profile than lead gunshot; leading to an overall reduction in risk.

5.4.1.1 Availability

As the risks posed by the use of lead shot become known many lead-free and non-toxic shot types have been developed and put into commercial production. Steel shot cartridges are produced by most European manufacturers (in the study of Thomas (2015) by all companies). Whilst steel shot is the most common alternative, particularly in the context of waterbird hunting, many European manufacturers have lines of other lead-free products, including bismuth/tin and tungsten-based. In addition, North American manufacturers sell a variety of lead-free ammunition types in Europe.

A survey of typical online retailers confirm that lead-free shot cartridges are widely available to consumers in most European countries, but stocks of non-lead ammunition held in local retail shops may be limited in quantity, specification, and brand. Hence, a local consumer may not currently be able to purchase the most suitable alternative for their specific needs.

The costs of producing steel shot are comparable to those of producing lead shot even though the raw material is somewhat cheaper. This is because filling a cartridge with steel pellets requires more time than filling with lead pellets. However, one producer of both lead and steel shot commented in the public consultation that technological improvements have been made (comment #1854). For this reason, the Dossier Submitter expects that in the long run the retail prices of steel shot will fall further.

5.4.1.2 Technical feasibility

A user of lead gunshot has several substitution choices when faced with a restriction on lead gunshot in wetlands. These choices are, to a certain extent, informed by the proof marks on their shotgun. Unfortunately, prior to the development of standardised CIP proof marks, other proof marks were commonly used, adding to the uncertainty that a gun owner may find themselves in with relation to substitution.

Some guidance can be found on the BASC website[52]:

> *A standard or superior/magnum-proofed gun can fire standard steel shot cartridges, subject to conditions. To fire 'high performance steel', [a shotgun] has to have passed a steel shot proof, a more rigorous test of the gun's ability to handle the different pressures (same as high performance lead) and shot*

[52] https://basc.org.uk/technical/

hardness of steel/steel-like shot cartridges. A gun successfully passing Steel Shot proof has to be stamped with a Fleur de Lys on its barrel.

Further guidance on when steel shot can be used is given on the website of the Beschussambt Ulm[53], the Ulm proofing house in Germany:

[53] https://www.beschussamt-ulm.de/beschussamt/Interne_Dokumente/Dokumente/VF_504_M_Info-Verwendung-Bleifreie-Schrote.pdf?m=1488869144

Table 5.6. Overview of possibilities to use steel shot

Caliber	**Used ammunition**			**Weapon (type and marking of the gun proof is indicated)**	
Shotguns with smooth barrels	Operation pressure (maximum allowed) In bar	Steelshot Ø In mm		Standard proof 	"Reinforced" With additional steel shot test 
		Column 1	**Column 2 22II**		
		From barrel without restriction of choke	From barrel with choke max.0,5 mm (1/2-Choke)	Since October 2014	
				CIP N	**CIP** 
10/89 High performance cartridge	1050	≤ 4,00	≤ 4,00		**X**
12/70 Standard cartridge	740	≤ 3,25		**X**	
12/70 High performance cartridge	1050	≤ 4,00	≤ 4,00		**X**
12/76 High performance cartridge					
12/89 High performance cartridge					
16 Standard cartridge	780	≤ 3,00		**X**	
16 High performance cartridge	1050	≤ 3,50	≤ 3,50		**X**
20/70 Standard cartridge	830	≤ 3,00		**X**	
20/70 High performance cartridge	1050	≤ 3,25	≤ 3,25		**X**
20/76 High performance cartridge					

Table 5.6 gives an overview on when steel shot can still be used. In line with the findings of (Putz, 2011), standard steel can be used in most shotguns (older, pre-1961 and more modern, post-1961) models.

However, according to the rules of proof, some old (non-standard proofed) shotguns should not be used with steel gunshot of any kind[54]. Nor can any shotgun be proofed to High Performance Steel level with a chamber length less than 70mm (because there is a CIP chamber-length criterion).

In Europe, the regulatory body (CIP) has developed two standards for steel shot shells, called **standard steel** and **high performance steel**. Like America, these standards include limits for chamber pressure, but also include velocity, momentum and shot size. CIP believe these regulatory standards are necessary to ensure the steel shot marketed in CIP countries is matched to the range of firearms that are manufactured and used in Europe.

SAAMI suggest the last three of these CIP standards appear to be controls to limit the chance of choke swelling in thin-wall barrelled and tightly choked guns. The American manufacturers believe these additional controls still may not eliminate the possibility of choke swelling – in their opinion, it is the design of the cartridge wad that is the most significant controlling parameter in this regard.

Ballisticians around the world do agree that there is an increased risk of choke swelling in tightly choked guns and recommend that shotgun owners should consider having chokes opened a little in existing guns when using steel shot, or consider the installation of interchangeable choke tube systems.

European gun manufacturers and retailers often include "proofed for steel" in their advertising for new guns. This means that the barrels and choke tubes have been constructed to ensure choke swelling does not occur, and that 'high performance' ammunition can be used. It does not mean that an existing gun, without this proof stamp, is inherently unsafe to use standard steel gunshot loads, which typically generate lower chamber pressures, comparable to existing lead shot loads.

Given there are always new people taking up shooting, shooters will have a choice (in ascending order of cost) to:

1. Use a standard proofed shotgun (which the majority of shotgun owners will already have) to fire standard steel cartridges (little or no extra cost or even saving);
2. Use a standard proofed shotgun to fire standard bismuth/tin or tungsten-based cartridges (approximately four to five times the cost of existing lead cartridges);
3. Where a very old non-standard proofed shotgun is owned they would have little option but to buy a standard or high performance steel proofed (either new or second hand);
4. Where a standard proofed shotgun is owned, but high performance steel ammunition is required, a standard proofed shotgun can possibly be re-proofed to high-performance steel or a replacement gun already proofed for high-performance ammunition can be purchased.

Most shotgun owners are likely to possess at least one shotgun that is standard proofed since most if not all shotguns sold after 1970 are standard proofed. Hence, most hunters will have to choose whether to use standard bismuth/tin or steel cartridges. Only relatively few are likely to see any merit in sending their gun for re-proofing against the high-

[54] Personal communication John Swift and Niels Kanstrup.

performance steel specification. Some owners of magnum proofed shotguns could feasibly get them re-proofed for high-performance steel.

Hunters shooting goose or coastal wildfowling and who are not prepared to pay for more expensive bismuth or tungsten-based cartridges are more likely to require a gun proofed for high performance steel than more typical wildfowlers.

The exact number of shotguns that would need to be replaced is not precisely known. Many Member States do not keep a register of shotguns or do not require owners to register them.

Lead-like shot types like tungsten-based shot or bismuth/tin shot can be used in any European gun with any type of choke constriction. Also, standard loaded steel shot cartridges can be used in any modern gun suited to fire lead shot. The only possible concern about the use of steel and other hard shot in standard guns pertains to the choke region of the barrel, where large shot (larger 3.5 mm diameter) passing through an abruptly developed, tightly-choked barrel could cause a small ring bulge to appear around the choke cones. However, this is widely considered not to be a safety issue, but rather a cosmetic concern (Coburn, 1991)

As to the use of robust guns, be that side by sides, over and under, semi-automatics or pump-action guns, designed and proofed for high performance cartridges with lead or lead-free shot, there seems to be no limitations in the use of lead-free shot, and steel shot cartridges of either standard or high performance quality is regarded to be the most suited for waterbird hunting depending on quarry size, hunting conditions, shooting distances.

Some hunters may, for different reasons, need to have their gun(s) proofed, modified or, eventually replaced. Based on the Dossier Submitter's analysis the cost of such actions is rather limited compared to the general budget of average European hunters.

5.4.1.3 Claims and our assessment

Throughout the development of the Annex XV report various claims concerning the use of non-lead cartridges have been encountered either in popular media, discussion between hunters in internet fora and other sources.

Following the example of (Thomas et al., 2014) these claims have been listed and compared to the evidence gathered in this dossier.

Table 5.7. Summary of the technical suitability of lead-free gunshot

Claim	Dossier Submitter's Assessment
I cannot hunt as effectively with steel gunshot as I can with lead gunshot.	Although there were initial concerns about the effectiveness of steel shot, the effectiveness of modern steel shot has improved significantly since its introduction. However, the ballistics of steel shot are different

	and hunters will need how to adapt to them. The main difference is in the shot-pattern. Steel shot patterns more tightly and as a result has greater 'killing power' in the middle of the pattern, unlike with lead where many fliers occur. Field studies have shown that hunters using steel gunshot can achieve the same results as with lead gunshot in terms of bird killed per shot, wounded per hit and brought to bag per shot. The effective shooting distance for modern steel gunshot is consistent with the range at which wildfowling (or fowling) is typically unertaken. For some species of larger waterfowl, e.g. geese, shotguns specifically proofed for 'steel' (therefore compatible with high–performance steel cartridges) might be required. Based on these studies (and others mentioned in Annex E), steel and lead give comparable hunting results once hunters have become used to hunting with steel.
I will damage my gun with steel gunshot.	Based on several reports there does not seem to be any evidence that switching to steel gunshot will cause damage to shotguns. It has been noted that the use of steel gunshot can result in minor bulging of the choke region of the barrel, but the evidence concludes that this is a cosmetic rather than a gun safety issue. In general, the use of modern plastic wads prevents damage to barrels in modern steel shot cartridges. The cases where bulging was noted did not describe the context (i.e. correct choice of cartridge or actual genuine bulging to using steel shot). However, this could affect the resale value of the affected guns.
I need a new gun to be able to use steel gunshot.	This might be true in limited circumstances. However, standard steel shot can be used in standard proofed guns. Hunters will need to apply the 'rule of two' and select two shot sizes lower in order to have the equivalent energy per pellet to lead. For hunting geese and birds of similar or larger size, more energy per pellet is required and this may require the use of 'high-performance' steel gunshot cartridges. Unless marked with 'fleur di lis', it is recommended to check with a gunsmith whether your gun is compatible with high-performance steel gunshot cartridges.
There is no steel gunshot cartridges that I can use in my gun.	For most of the shot sizes required for waterfowl hunting (12/70 shot size) most manufactures have suitable cartridges in their product range. Supply of steel gunshot is driven by demand, which in turn is driven by regulation. For example, in

	Member States where restrictions on the use of lead gunshot are in place, the availability and diversity of steel gunshot cartridges on the market is greater.
Steel shot is prohibitively expensive.	Current prices for steel and lead gunshot are comparable (see Table E5 in the Annex E). It can be expected that once there is greater demand for steel gunshot cartridges, their price will go down further.
I cannot use steel gunshot because it is not allowed in the forest where I hunt.	Steel is not the only alternative, bismuth and tungsten are also technically feasible alternatives. They are however more expensive. An additional advantage of bismuth and tungsten is that they can be used in standard (and older) proofed guns.
Steel gives more ricochet	Typical ricochet surfaces do not often occur in wetlands. Research has demonstrated that ricochet occurs using both steel and lead shot and that ricochet energy associated with steel shot is unlikely to result in injury. The experience in Denmark after the introduction of the ban on lead revealed no increase in ricochet / injury (Source: Danish insurance companies).

5.4.1.4 Risk reduction

Alternatives to lead gunshot have been clearly demonstrated to have a more environmentally benign hazard and risk profile than lead gunshot. For example, 'non-toxic' shot in the US must be approved prior to being placed on the market on the basis that their use will not result in risks to migratory birds, other wildlife or the environment. Further details of the human and environmental risks posed by the use of non-lead ammunition refer to Annex E.3.1.5.

The proposed restriction is anticipated to reduce lead emissions to EU wetlands by about 1 400 to 7 700 tonnes per year, depending on how many hunters would be affected. In the central case analysed in Annex E.5, it is estimated that around 4 750 tonnes of lead per year would no longer be dispersed into wetlands.

5.4.1.5 Economic feasibility

The production cost of a shotgun cartridge consists basically of three elements: the material cost, the cost of components, and the cost of assembling the components into a cartridge (loading). This applies to lead as well as lead-free products. In terms of the shell, the primer, the wad, and the powder, there are no significant differences in production costs. Nor is the loading process different, though some components of the machinery may be modified and adjusted to change from one type to another. Hence, the main driver for (production) cost differences is the cost of shot material and shot processing.

In terms of raw material prices: 2 €/kg of lead; 0.07 €/kg of iron[55]; and 20 €/kg of bismuth. Prices vary depending on market demand, purity etc., so these prices should be seen as

[55] London metal exchange reports 300$/ton (cash buyer) for steel and 2 361 $/ton for lead, confirming the order of magnitude of these price differences.

indicative only. However, they illustrate that bismuth is about 10 times more expensive than lead and that lead is approximately 30 times more expensive than iron. This explains why bismuth shot cartridges are generally much more expensive than lead and steel shot cartridges and it indicates that prices of bismuth shot are not likely to fall to levels comparable to lead and steel. The raw material prices also suggest that steel shot may become cheaper than lead shot in the future.

Research on retail prices of loose shot for hand loaders found no large difference (lead shot app. 3 €/kg[56] ; steel shot app. 4 €/kg[57]). The primary reason why the much lower raw material cost of iron does not translate into a pronounced difference in sale prices of shot ammunition is connected to differences in the processing technology, energy consumption, production volumes, market demand, transport, profit etc. Production of lead shot is a traditional technology in many European cartridge manufactory companies, whereas the production of steel shot is done almost exclusively by Chinese manufactures. Hence, the economic and technological conditions vary greatly.

A detailed forecast on the price development of steel shot is beyond the scope of this study. However, it can be assumed that an increased demand for steel shot due to regulatory action should increase the production capacity and gradually influence the production cost such that in the longer run steel shot might become significantly cheaper than lead shot. This assumption is supported by comments received in the public consultation from a large producer of both lead and steel gunshot (comment #1854).

Another factor influencing the cartridge price is the cartridge gauge and the relative market demand for that cartridge. These factors explain why 20 gauge cartridges in both lead and lead-free varieties cost more than the equivalent 12 gauge cartridges. A manufacturer will require a single production run of about one million cartridges to justify the costs of switching the manufacturing equipment settings, product testing for quality assurances, and packaging set-up[58]. Understandably, demand has a major effect on price as well as availability of lesser-used cartridge types, both lead and lead-free. This is why 28 gauge cartridges cost much more than 12 gauge cartridges, despite the lesser content of gunpowder and shot.

Wholesale and retail prices of cartridges will basically depend on production prices, but will also—and to a very high degree—be influenced by volume, transport cost and other basic vectors. Particularly, the profits generated along the value chain from production to retail, taxes, VAT etc. influence the retail prices to be paid by the hunters. To exemplify this, take the example of the product ELEY VIP bismuth cal. 12/70 (shot size 3.2 mm) whose retail price was €1.4 per cartridge on the website of a British supplier[59], but €2.7 per cartridge at a Danish retailer[60]. This just illustrates that the retail price of two identical cartridges may differ by a factor of two depending on market supply and demand (and other relevant factors such as VAT).

Table 5.8 indicates retail prices (including VAT) of lead and various lead-free shot cartridges based on information collated from different European countries. Lead shot cartridge prices

[56] http://www.cabelas.com/

[57] http://www.huntinglife.net/

[58] R. Cove, CEO, Kent Cartridge, pers. comm.

[59] http://www.sportingsupplies.co.uk/contents/en-uk/d194.html

[60] http://www.iversen-import.dk/bismuth-forrest-vip-32-gr-skovpatron-405-m-sek.html

vary from €0.29-0.65 (with a mean price estimate of €0.45), while steel shot cartridges are within a range of €0.23-0.99 (with a mean price estimate of €0.46). Bismuth and tungsten-based cartridges are significantly more costly with prices between approximately €1.7-2.5 per cartridge (with a central price estimate of €2.0). These data support the general finding that prices of lead and steel shot are currently comparable (See also Figure 5.2 below), while bismuth and tungsten, which are produced, sold and used in far lower volumes, are likely to remain more expensive than lead (even though the price of bismuth shot may reduce slightly). These prices are used to underpin the cost scenarios reported in Section 5.5.

Prices of lead-free hunting cartridges have been surveyed in other recent studies. Thomas et al. (2015) compared prices for lead and lead-free cartridges available in the UK market in November 2014 and concluded that, for both shotgun and rifle game shooting in the UK, there is neither a limitation of availability nor a significant price barrier to adopting lead-free ammunition regulation.

Table 5.8. Comparative prices of lead and lead-free shotgun cartridges in the EU in cal. 12 (32 gram load). Summarised after Table E.5 in Annex).

Shot material	Summary statistic	Price (€)
Lead (n=48)	Mean	0.45
	Min	0.29
	Max	0.65
	Median	0.47
Steel (n=23)	Mean	0.46
	Min	0.23
	Max	0.99
	Median	0.38
Bismuth (n=3)	Mean	1.96
	Min	1.68
	Max	2.50
	Median	1.71

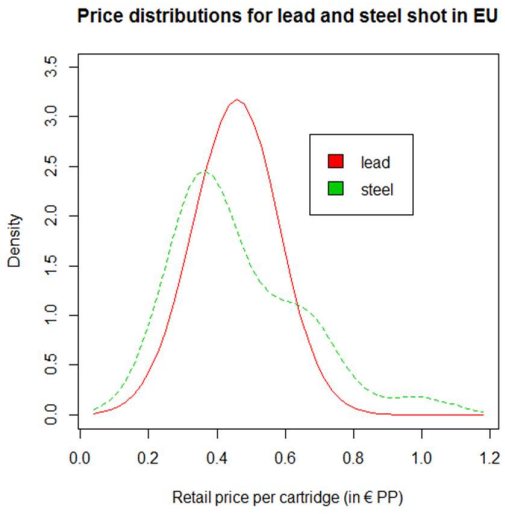

Figure 5.2. Price distribution of lead and steel gunshot cartridges.

5.5 Economic impacts

The main elements included in the substitution cost assessment are (details are presented in Annex E.5):

- **'one-off' costs** for the adaptation and/or replacement of the current stock of shotguns unsuitable to fire steel shot: these include any cost incurred by a hunter to ensure their shotgun can use steel gunshot (e.g. for a choke modification) as well as

the cost for prematurely replacing a shotgun that is unsuitable for use with standard steel gunshot. It also includes the costs some hunters may incur for testing (re-proofing) to ensure that their shotgun is suitable for use with standard or high-performance steel gunshot. Importantly, not all hunters will need to replace, re-proof or modify a shotgun that is not suitable for use with steel gunshot as they may switch over to bismuth shot or other alternative ammunition that can be used in any existing shotgun that is currently used with lead gunshot.

- incremental **'operational' costs** incurred as a continuous consequence of switching to alternative ammunition, including steel, bismuth or tungsten-based loads.

The extent to which an individual has to bear these costs will depend on the scope of the current legislation in their Member States with regard to the use of lead gunshot. Where there is already a legislation in place, it is reasonable to assume that hunters will have taken the necessary measures to comply. The precise scope of the legislation in each Member State will therefore determine the proportion of the number of hunters who will be affected by the restriction. For example, in Member States with existing complete bans on the use and placing on the market of lead gunshot (DK, NL, BE), hunters will already have adopted alternatives and the proposed restriction will have no additional impact on them.

Except in Member States that have a complete ban on the use of lead gunshot, it is acknowledged that applying the Ramsar definition of a wetland (that includes peatland) could affect both wildfowl and non-wildfowl hunting, including fowl hunting (e.g. grouse, pheasant and partridge) and potentially small mammal hunting, depending on where it is practised. Any affected hunter will incur costs from this restriction related to the incremental costs for switching over to alternative ammunition.

To study the costs of the proposed restriction, three scenarios ('best case', 'central case' and 'worst case') were developed. These scenarios are based on different assumptions on the following elements determining the overall cost of the restriction:

a. The total number of hunters impacted by the restriction proposal, taking into account any existing restrictions on the use of lead in the Member States and the extent of peatland habitat that could be used for hunting;

b. The proportion of hunters who would need to buy a new shotgun in order to continue hunting and the average purchase price of such a shotgun;

c. The relative proportion of steel vs bismuth/tungsten ammunition used by hunters once they can no longer use lead gunshot;

d. The expected service-life of a shotgun (as the restriction can be considered to bring forward replacement costs rather than create them *per se*).

The key differences between the three scenarios are related to how the scope of existing legislation in Member States influences the number of existing waterfowl and fowl hunters that would be affected by the proposed restriction.

Under the best case scenario, additional one-off costs would only be incurred by a limited number of hunters in Member States that currently do not have any restrictions on the use of lead gunshot. Alternatively, under the worst case scenario, affected hunters are assumed

to incur one-off costs even though their Member State has an existing wide scope area-based restriction (including peatlands) on the use of lead gunshot in place.

The best and worst case scenarios therefore represent theoretical extremes of potential costs rather than the most likely impacts that will result from the proposed restriction. The central scenario is considered to be more representative of the likely impacts and the costs resulting from the proposed restriction. It assumes that around 141 000 shotguns will have to be prematurely replaced as a result of the restriction[61]. As there is extensive information available from multiple reliable sources (e.g. shotgun manufacturers, hunting/shooting associations, Member States) which acknowledge the suitability of standard steel loads in existing standard proofed shotguns, and given that bismuth and tungsten-based ammunition can be used in all existing shotguns, irrespective of their age, the premature replacement of 141 000 shotguns is likely an overestimate[62].

A summary of the main assumptions going into each of the scenarios is given below. Further details are provided in Table 5.9 and in Annex E. Substitution costs pertaining to each of the scenarios are summarised in Table 5.9. Importantly, all of the scenarios presume that hunters comply with existing legislation in their Member State.

5.5.1 Scenario 1 – 'best case'

The best case scenario assumes that hunting on waterfowl and fowl is assumed to comprise 6.7% and 53.4%, respectively, of all hunting activities. Impacts are expected to occur in Member States (IE, PL, RO, SI) that do not have any measure on lead gunshot in place, and in Member States (DE, LV, EE, LI) in which >10% of wetlands are peatlands and where current bans are area-based and have a narrow geographical scope (e.g. restrictions only apply within certain designated wetland areas, such as the Nature 2000 sites within a Member State). The restriction would result in costs to around 35 000 waterfowl hunters and around 414 000 fowl hunters in those Member States, mainly for having to switch over to steel shot. Assuming that all shotguns in use are standard proofed, there would also be a fraction of 5% of affected hunters who would test their guns to be assured they could use steel shot.

5.5.2 Scenario 2 – 'central case'

The central case scenario assumes that hunting on waterfowl and fowl (primarily in peatlands) is assumed to comprise 8.0% and 53.4%, respectively, of all hunting activities. Impacts are expected to occur in Member States (IE, PL, RO, SI) that do not have any measure on lead gunshot in place, in Member States (DE, LV, EE, LI) in which >10% of wetlands are peatlands and where current bans are area-based and have a narrow geographical scope as well as in Member States (SE, BG, HG, HU, IT, ES, PT, LU, MT, FI and

[61] To put this into perspective, there are almost 7m hunters active in the EU-28. Estimates of the fraction of hunters engaging in waterfowling and fowling are in the range of 8% (0.54m) and from 53% (3.62m), respectively. Not all of these hunters will however be affected since some of the Member States have already a restriction on lead shot in place.

[62] Indeed, it is non-trivial to estimate the number of shotguns that need to be replaced because of the restriction as a waterfowling hunter owns 2.6 shotguns on average (Amec, 2003). Thus, it might well be that—even if they own a shotgun that is not suitable for firing steel shot—they also own a standard proofed gun that is suitable.

parts of the UK) in which >10% of wetlands are peatlands and where there is a ban of lead shotgun to hunt on waterfowl species (but does not exclude fowl hunting with lead shot). Under this scenario, the restriction would result in costs to around 250 000 waterfowl hunters and around 1.24m fowl hunters across those Member States. It is assumed that 10% of the affected hunters will have to prematurely replace their shotgun (i.e. 141 000 shotguns will have to be replaced)[63]; moreover there would be a fraction of 10% of affected hunters who would test their guns to be assured they could use steel shot. As regards flow costs, it is assumed that 85% of all lead shots spent would be replaced by steel shot whilst the remaining 15% would be replaced by bismuth/tungsten shot.

5.5.3 Scenario 3 – 'worst case'

The worst case scenario assumes that hunting on waterfowl and fowl (primarily in peatlands) is assumed to comprise 10.0% and 53.4%, respectively, of all hunting activities. Impacts are expected to occur in all Member States except those which have a full ban in place (BE, DK, NL). The restriction would result in costs to around 645 000 waterfowl hunters and around 1.77m fowl hunters across those Member States. It is assumed that 25% of the affected hunters will have to prematurely replace their shotgun (i.e. 603 000 shotguns will have to be replaced)[64]; moreover there would be a fraction of 15% of affected hunters who would test their guns to be assured they could use steel shot. The evidence found during the dossier development suggests that the number of guns to be replaced under this scenario is based on worst case assumptions and is unlikely to occur. As regards flow costs, it is assumed that 75% of all lead shots spent would be replaced by steel shot whilst the remaining 25% would be replaced by bismuth/tungsten shot. Finally, a price differential between steel and lead shot of 6 € cents per cartridge was assumed. The Dossier Submitter wishes to emphasise that recent information on retail prices for gunshot ammunition suggest that such a large price differential is very unlikely to occur, rendering this scenario worst-case. Since both the stock and flow costs under this scenario are based on worst case assumptions, the Dossier Submitter decided not to take forward Scenario 3 in the proportionality discussion under section 5.12.

[63] The remaining service-life of a shotgun is assumed to be up to 20 years (see Annex E.5 for technical details of bringing forward the replacement costs). However, 5% of the shotguns would not be replaced within the next 50 years, recognising that some shotguns can have long service-lives as they are 'passed down' through families.

[64] It is assumed that these shotguns would not be have been replaced within the next 50 years.

Table 5.9. Assumptions used in the cost scenarios

Scenario	Best case	Central	Worst case
Number of hunters affected			
proportion of total hunting in wetland	6.7%[a]	8%[b]	10%[c]
Waterfowl hunters	Waterfowl hunters <u>included</u> from MS: 1. no ban of any type	Waterfowl hunters <u>included</u> from MS: 1. no ban of any type 2. area-based ban with 'narrow' scope	Waterfowl hunters <u>included</u> from MS: 1. no ban of any type 2. area-based ban with 'wide' or 'narrow' scope 3. waterfowl species ban
	Waterfowl hunters <u>not included</u> from MS: 1. complete ban 2. area-based ban with 'wide' or 'narrow' scope 3. waterfowl species ban	Waterfowl hunters <u>not included</u> from MS: 1. complete ban 2. area-based ban with 'wide' scope 3. waterfowl species ban	Waterfowl hunters <u>not included</u> from MS: 1. complete ban
Fowl hunters[e]	Fowl hunters <u>included</u> from MS where peatlands >10% of total wetland area[d]: 1. no ban 2. area-based ban with 'narrow' scope	Fowl hunters <u>included</u> from MS where peatlands >10% of total wetland area[d]: 1. no ban 2. area-based ban with 'narrow' scope 3. waterfowl species ban[i]	Fowl hunters <u>included</u> from MS where peatlands >1% of total wetland area[d]: 1. no ban 2. area-based ban 3. waterfowl species ban
	Fowl hunters <u>not included</u> from MS where peatlands >10% of total wetland area: 1. complete ban 2. area-based ban with 'wide' scope 3. waterfowl species ban	Fowl hunters <u>not included</u> from MS where peatlands >10% of total wetland area: 1. complete ban 2. area-based ban with 'wide' scope	Fowl hunters <u>not included</u> from MS where peatlands >1% of total wetland area: 1. complete ban[i]
One-off costs			
Average purchase price of a new shotgun[l]	€750	€1 000	€1 500
Counterfactual replacement of existing shotguns that are not standard proofed.	n/a	95% of shotguns to be replaced over the next 20 years[j]; 5% of shotguns not to be replaced within the next 50 years.	No shotguns would be replaced within the next 50 years
Percent of gun owners that re-proof	0%	10%	15%
Cost of proofing test per barrel	€70		

Scenario	Best case	Central	Worst case
Shotguns prematurely replaced[k]	0%	10%	25%
Amortisation period (years)[h]	10 years	20 years	50 years
Operational costs			
Number of lead cartridges consumed in EU-27[g]	663 million		
Retail price of lead shot	€0.35 per cartridge	€0.45 per cartridge	€0.55 per cartridge
Retail price of alternative hot	Steel: €0.35 per cartridge (100% of the price for a lead shot); Bismuth/Tungsten: not relevant	Steel: €0.47 per cartridge (105% of the price for a lead shot); Bismuth/Tungsten: €2 per cartridge (450% of the price for a lead shot)	Steel: €0.61 per cartridge (110% of the price for a lead shot); Bismuth/Tungsten: €3 per cartridge (550% of the price for a lead shot)
Percentage steel	100%	85%	75%
Percentage Bismuth/Tungsten	0%	15%	25%
Emission reduction (t)	Hunters affected/total hunters * 21 216 tonnes (which is equal to number of cartridges * 0.032 kg of lead per cartridge)		

Notes: a – based on Amec (2013); b - Hirschfeld and Heyd (2005); c - Based on market assumptions for steel cartridges; d – based on CORINE land classification; e – term fowl refers to fowl-like birds such as grouse, ptarmigan, capercaillie, partridges, quail, pheasant, dove and pigeons (comprising 53% of hunting in the EU, based on bag statistics: Hirschfeld and Heyd (2005); f – Source, BASC/Niels Kanstrup; g – based on Amec (2013); h – to be consistent with assumptions on the 'lifetime' of shotgun used in the scenario; i – Assumption modified for Finland (FI) recognising the large proportion of peatland in MS. Calculations based on an assumption that **all** non-waterfowl hunting would be affected by the proposed restriction i.e. 283 360 hunters; j - Source: Waarde van de jacht, tijd en geld besteed door jagers aan maatschappelijke diensten, CLM Onderzoek en Advies 2014; k – 25% based on personal communication from stakeholders (BASC & John Swift), 10% based on the fact that the average hunter own 2.6 shotguns (25/2.6 is 10 (rounded) (Amec, 2013) l source: Amec 2013

Further details on the source of assumption can be found in the Background document in section E.5.1.4

5.5.4 Summary of substitution costs to hunters

Based on these assumptions the substitution costs can be calculated for each of the three substitution scenarios. Table 5.9 summarises these costs.[65] It should be noted that all of these costs are based on retail prices and therefore include the Member State specific value-added tax (VAT). The reason for ignoring the VAT in the cost calculation is twofold. First, that way one can estimate the additional cost an individual hunter has to bear if the restriction is implemented; second, the relevant VAT varies from Member State to Member State, making any aggregate calculation cumbersome. It is acknowledged, however, that the current approach overestimates the societal cost of the proposed restriction as the VAT is a distributional cost only. A ballpark estimate of the latter cost may be derived by deducting 20% of the costs reported in Table 5.9, since this would approximate the share of the costs which would flow back to Member States as tax revenues.[66]

Table 5.10. Summary of substitution costs induced by the proposed restriction

	Best-case scenario	**Central-case scenario**	**Worst-case scenario**
Number of waterfowl hunters affected	36 000	252 000	645 000
Number of fowl hunters affected	414 000	1 236 000	1 768 000
Number of shotguns to be replaced	0	141 000	603 000
One-off cost for premature replacement of shotguns	€0	€97m	€680m
Annual operational cost (i.e. annual incremental cost to be spent on shot)	€0m	€35.9m	€158.5m
Annualised one-off cost for testing	€0.4m	€1.5m	€2.4m
Annualised one-off cost for new guns	€0	€7.0m	€31.7m
Total annualised cost to hunters	€0.4m	€44.4m	€192.5m
Annual emission reduction from replacement	1 432 tonnes	4 740 tonnes	7 684 tonnes
Unit abatement cost (p.a.)	€0.3/kg	€9/kg	€25/kg
Additional cost per hunter (p.a.)	--	€25	€66
Average hunter's budget (p.a.)	€ 3 000	€ 3 000	€ 3 000
Fraction of average hunter's budget	**--**	**0.8%**	**2.2%**

[65] Technical details on how the replacement cost for the respective stock of shotguns is calculated and how this estimate is annuitised are relegated to Annex E.5.1.

[66] For an overview of VAT rates (in 2017) applied in the EU-28, see: http://ec.europa.eu/taxation_customs/sites/taxation/files/resources/documents/taxation/vat/how_vat_works/rates/vat_rates_en.pdf.

5.6 Human health and environmental impacts

The environmental and human health impacts that would be avoided with the implementation of the proposed restriction are briefly described below.

5.6.1 Environmental impacts

The number of waterbirds dying annually in the EU as a result of lead shot ingestion has been conservatively estimated (based on figures for 16 species of waterfowl and 11 species of wading and rail species) to range between approximately 400 000 and 1 500 000, depending on the assumptions on wintering population size and underlying mortality rate. In addition, there are likely to be additional effects on other species of waterbirds and on predatory and scavenging birds that consume food containing lead gunshot.

5.6.2 Human health impacts

The restriction is likely to reduce lead exposure in subsistence hunters throughout Europe. Locally, it may also contribute to reduced lead exposure due to groundwater contamination. Lead exposure, at levels commonly observed in the EU today, can impair neurodevelopment and affect cognition and behaviour in children. Moreover, lead exposure has detrimental impacts on cardiovascular diseases as well as other adverse health endpoints in adults (see Annex E.6.1).

5.7 Other impacts

5.7.1 Manufacturers

Steel shot cartridges are produced by most European manufacturers (in this study sample all companies). It is by far the most common alternative to lead gunshot, particularly in the context of waterbird hunting. However, many European manufacturers produce other lead-free ammunition as well, e.g. bismuth and tungsten shot. In addition, North American manufacturers distribute via their European representations a variety of lead-free ammunition types in Europe.

In terms of the shot material itself (not the complete cartridge), if the proposed restriction is introduced, manufacturers that produce lead shots might face a problem due to the fact that the technology used to manufacture their product cannot be adapted to produce alternative shot. Lead shots are produced with either a tower or Bleimeister process.[67] Whereas a moulding process is used to produce steel shots and the production of tungsten and bismuth shot is based on a sintering process. Neither of these processes is in any way comparable with the process used for producing lead shots.

In response to the call for evidence, information was received that the only manufacturer of steel shot in Europe is considering shutting down their production, because they are not able to compete in price with steel shot imported from outside Europe.

Companies manufacturing cartridge components compatible only with lead shots will also lose part of their business. However, they may be able to concentrate on the production of other cartridge components. The economic impact of losing part of business is estimated to

[67] The tower process is the most widely used (95%), while the Bleimeister system has marginal significance today.

be small. For companies producing cartridge components compatible with alternative shots there is no impact expected.

If the material of the shot is changed, other components of a shotgun cartridge (namely the primer, propellant and wad) must be all reconfigured. This is relevant for the companies assembling the components into final cartridges. These companies have to either replace and adapt all other components, or replace some phases and some equipment of the production process. The impacts onto manufacturers are summarised in Table 5.11.

Table 5.11. Impacts on manufacturers

Manufacturer	Impact
Lead shot	Producers of lead shot might encounter problems since other technologies, skills and facilities are needed for producing alternative shots.
Alternative shots/importers	Volume will increase, the vast majority of steel shot is imported from China, there is some production in Europe (3 manufacturers) but their production capacity is unclear. The expectation is that the increased demand for steel shot (needed to produce steel shot cartridges) will be sourced from China.
Component manufacturers	Companies producing components with lead shots will lose part of their business
Assembler of cartridges	Some costs related to adaptation of machinery

The production of steel shot cartridges will remain more expensive than that of lead shot cartridges as the production throughput of steel cartridges is reported to be lower; the harder pellets make the shot more difficult to handle (bounces) and machinery has to be set to a lower speed (vis-a-vis lead shot) in order to deal with this bouncing, resulting in higher production costs.

Confidential information submitted by industry to ECHA suggests that the level of current steel cartridge production is close to the expected increase in demand for steel shot due to further restriction on the use of lead shot over wetlands.

5.7.2 Forestry and veneer industry

Concerns were raised in Denmark in the 1990s that steel shot might damage standing timber when lead was prohibited, and the forestry authorities had recommended against the use of steel. However, LAG (2015) found no documented evidence of any problem with the use of steel ammunition in forestry in the Nordic countries (Denmark in particular).

The Dossier Submitter requested additional information[68] from Metsähallitus (Finnish State Forest Enterprise) about the type of wood-industry that might be affected by the use of steel shot. However, no information was provided to support the contention that the use of steel gunshot could affect forestry.

[68] Personal communication, December 2016.

5.8 Practicability and monitorability

The most conclusive method of monitoring compliance with the restriction is to measure the prevalence of ingested or embedded shot in birds over time. Many of the current studies highlighting the problem of lead poisoning in waterfowl use this method, or varieties of it, to establish the scale of the problem. The method can readily be adapted to monitor the effectiveness of the proposed restriction.[69]

Should the proposed restriction not prove to be effective after its implementation, a further more stringent restriction on the placing on the market of all gunshot cartridges containing lead could be considered. The justification for such a restriction would require further information on the impacts to the wider shooting community (e.g. sports shooting, non-wetland gunshot hunting, etc.) but could be informed by the experiences of Denmark, the Netherlands, Belgium and the Netherlands, which already have such restrictions in place.

5.9 Proportionality considerations

The last stage of the assessment against the criteria for a restriction is an analysis of whether the proposed restriction is a sound regulatory measure. According to the ECHA Guidance on the preparation of an Annex XV dossier for a restriction, this entails among others:

- An analysis of whether the efforts from the actors to implement and enforce the proposed restriction correspond in amount or degree to the adverse effects that are to be avoided;
- An analysis of whether the proposed restriction ensures a good balance between costs and benefits and is cost-effective.

The following sections demonstrate that the proposed restriction is a sound regulatory action by examining its affordability, cost-effectiveness and the benefit-cost ratio.

5.10 Affordability considerations

One of the key arguments to show that the current restriction proposal is justifiable arises from the fact that many EU Member States have already implemented different national legislations to ban the use of lead gunshot, without having a large impact on the number wetland hunters in the regulated areas/Member States. This indicates that switching to non-lead shot is, in principle, affordable to the individual hunter.

Moreover, the proposed measures are estimated to only impose a limited cost on the individual hunter. Based on the cost estimates presented in Annex E.5, it can be expected that the additional cost to an average hunter for purchasing non-lead shot ammunition rather than lead shot ammunition will range from €0 (best case) to €66 (worst case) per year. The worst case corresponds to 2.2% of the average annual hunting budget of a European hunter, which is in the order of €3 000 (Pinet, 1995). This additional cost seems

[69] WWT (2010) describe a protocol for the determination of lead pellets in various species.

economically reasonable even for subsistence hunters with a significantly lower hunting budget.

With regards to the premature replacement of shotguns, the cost calculations detailed in E.5 are based on the assumption that up to 603 000 guns (worst case) would have to be prematurely replaced across the EU as a result of the restriction proposal.[70] This would entail a total replacement cost (in 2016 €) of €97m (central case) to €680m (worst case), depending on the assumptions maintained. These cost estimates can be expressed in terms of the individual cost to a hunter of bringing forward the purchase of a new gun as a result of the restriction proposal, which we expect to be in the range of roughly €650 (central case) to €1 130 (worst case) for the average hunter. This additional cost could pose an extra burden to subsistence hunters with a significantly lower hunting budget. On the other hand, frequent hunters are more likely to have replaced a shotgun not suitable for firing steel shot by a standard proofed shotgun. Therefore, it is readily conceivable that the fraction of active subsistence hunters who would be affected by the proposed restriction is smaller than the fraction among all wetland hunters.

Considering the restriction-induced replacement of guns, consideration has to be given to both the adverse impact on consumer surplus (i.e. some hunters are required to prematurely purchase a new gun if they want to continue hunting in wetlands) and the beneficial impact on producer surplus (i.e. gun manufacturers as well as gun retailers sell more guns). On balance, the former impact is likely to outweigh the latter, but it is unclear by how much.

Hunters also have the possibility to sell guns that are not suitable for use with non-lead shot. From a welfare economic point of view, the residual value of these guns can be deducted from the cost of premature replacement. Again, it is difficult to envisage how much this residual value would be, as it depends on the condition of the individual gun as well as on the demand for lead-firing shotguns after the restriction on lead shot in wetlands is in place. A number of other factors may limit the residual value of a lead-firing shotgun. For example, prices might be driven down by expectations about future extensions of the current restriction or by the cross-price elasticity of demand for lead and steel shot, etc.

The above considerations suggest that, on average, the proposed restriction is affordable to the individual hunter and could be beneficial to European gun manufacturers and retailers. Although affordability considerations do not imply that a regulatory measure entails a net welfare gain, the analysis suggests that the proposed restriction would be unlikely to exert disproportionate costs to society as a whole.

5.11 Cost-effectiveness considerations

The proposed restriction is anticipated to reduce lead emissions to EU wetlands by about 1 400 to 7 700 tonnes per year, depending on how many hunters would be affected. In the central case analysed in Annex E.5, it is estimated that around 4 750 tonnes of lead per year would no longer be dispersed into the wetlands.

Considering the aggregated costs imposed on hunters (in terms of more expensive ammunition and the premature replacement of shotguns that cannot fire non-lead shot

[70] Under the best case scenario, it is assumed that no gun would have to be prematurely replaced due to the proposed restriction.

ammunition), these abatement figures suggest that the total cost per tonne of lead emission avoided is in the range of €0.3/kg to €25/kg.

The central scenario suggests a cost-effectiveness value of €9/kg of lead dispersal avoided, which is far below the cost-effectiveness values estimated many other REACH restrictions (Figure 5.3). If one compares the cost-effectiveness of the current restriction proposal to the one for decaBDE, for example, where one major environmental impact was accumulation of the substance in birds of prey, it is obvious that the current proposal is an order of magnitude more cost-effective. Considering the known hazard properties[71] of lead, it can thus be concluded that the proposed restriction is a cost-effective measure of addressing lead emissions to the environment.

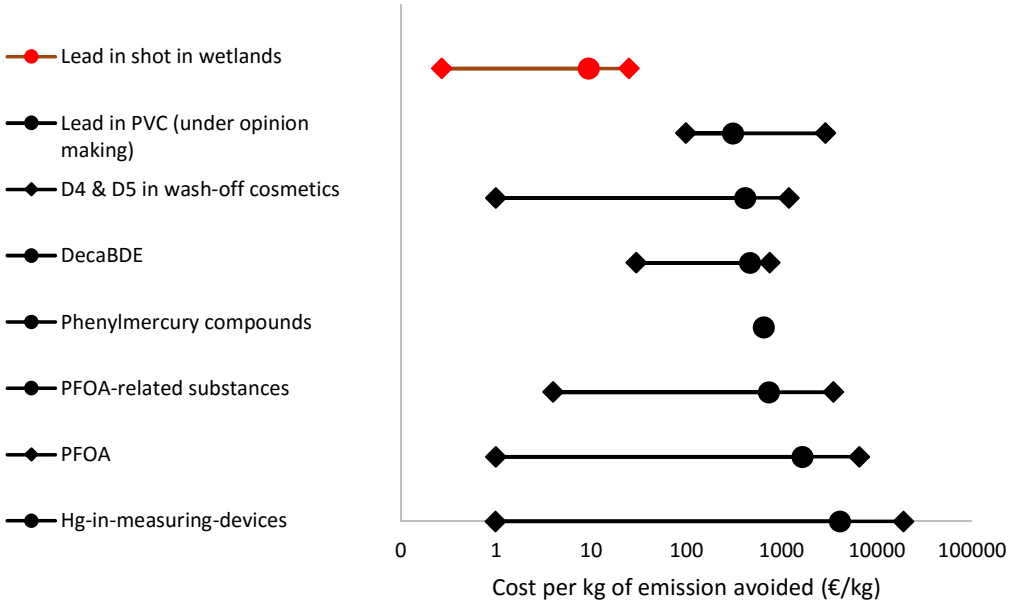

Figure 5.3. Cost-effectiveness of previous restrictions under REACH

5.12 Cost-benefit considerations

Whilst it is difficult to accurately predict all the welfare impacts induced by the current restriction proposal, some elements on both the benefit and the cost side have been quantified. In particular, the estimated cost to wetland hunters from prematurely replacing shotguns when these are not suitable to fire any form of steel gunshot ranges from €0 (best case assuming that shotguns currently used by wetland hunters in the EU are already suitable to using steel shot) to €680m (worst case, assuming that 603 000 shotguns would have to be replaced which would otherwise not have been replaced over the 50 years following the entering into force of the proposed restriction).

[71] Including environmental fate, stock characteristics, hazard and exposure; see SEAC/31/2016/05 Rev.1: https://echa.europa.eu/documents/10162/13580/evaluation_pbt_vpvb_substances_seac_en.pdf.

Both scenarios are based on extreme assumptions and should not be misinterpreted as representing expected regulatory impacts. The central case is that the restriction proposal will require the premature replacement of about 141 000 shotguns, which would have either been replaced over the 20 years following the entering into force of the restriction proposal (95% of these shotguns), or would not have been replaced over the 50 years following the entering into force (5% of these shotguns, see Annex E.5 for detailed assumptions). This central case entails the aforementioned replacement cost of around €88m, which can be made commensurable with the annual cost increment associated with the switching to non-lead (steel, bismuth and tungsten) shot by standard annuitisation.

At a discount rate of 4%, the annuitised replacement cost in the central scenario is close to €7m. This annuity needs to be added to the incremental cost of switching to alternative ammunition, which is estimated at €35.9m per year under the central scenario (assuming that current cartridge prices for lead, steel, and bismuth gunshot remain stable). Adding to this figure the annuitised cost of testing old shotguns for their suitability to using steel shot (€1.5m) results in a central annual cost estimate of €44.4m accruing to wetland hunters in the EU.[72] This cost estimate ignores the residual value of replaced guns. Any such residual value would have to be annuitised and deducted from the above figure to obtain the net cost to hunters.

On the producer side, the quantification of welfare impacts is subject to greater uncertainty. A part of the replacement cost accruing to hunters (i.e. consumer surplus loss) will result in a surplus gain to manufacturers and retailers of shotguns and ammunition. Since the restriction will likely affect current market prices for shotguns and ammunition, it is difficult to estimate the size of this surplus gain. Yet an attempt can be made based on the following assumptions. The mark-up on the ex-factory price of a consumption good is typically in the order of 30% to 50% of the retail price net of any taxes. It is assumed that such a generic mark-up rate would be applied to the selling price of both ammunition and shotguns. Importantly, this mark-up is thought to capture both the income earned as well as the expenses made by manufacturers, wholesalers, and retailers to sell the product (i.e. costs that are not genuinely related to the production, but to the transportation, stocking and selling of shotguns and ammunition).

To approximate the profit made by producers and retailers, one could thus subtract 20% VAT from the €44.4m to arrive at €35.5m, and then multiply this amount by an average 40% to arrive at an estimate of the total mark-up of approximately €14.2m. An unknown fraction of this mark-up will be the actual producer surplus gain and should thus be deducted from the consumer surplus cost to arrive at the net social cost of the restriction.[73] However, information from an application for authorisation made by one EU gun manufacturer[74] suggests that only around 15% of shotguns sold in the European market are EU-manufactured. Likewise the raw material for steel shot is mostly imported from Asia. Hence, a substantial share of the regulation-induced mark-ups might accrue to non-EU actors in the supply chain. Taking all of this together suggests that the total producer

[72] As mentioned in Section 5.5 this cost estimate includes the VAT; if one follows the rule of thumb proposed above and deducts an average VAT rate of 20%, then the central cost estimate shrinks to €35.5m per year.

[73] See Annex E.5.1 for a theoretical discussion of the regulation induced welfare impacts.

[74] https://echa.europa.eu/documents/10162/13637/afa_ct-0070-02-aa_sea_en.pdf

surplus gain to EU manufacturers and retailers is an order of magnitude smaller than the regulation-induced consumer welfare loss.

The primary goal of the restriction proposal is the reduction of lead poisoning in waterbirds and predatory/scavenging birds. Partwise monetisation of this externality is possible under the assumptions outlined in Andreotti et al. (2018). This study proposes to value the premature death of an individual bird by the opportunity cost of not being able to shoot it. This opportunity cost can be approximated by the stocking cost incurred to raise one bird of the same species. Stocking costs for 16 species for which lead gunshot ingestion is known are compiled by Andreotti et al. (2018). Based on the expected reduction of lead dispersal in EU wetlands[75], it is then possible to come up with an aggregate opportunity cost for the approximately 700 000 waterfowl from these 16 species that are currently lost per year due to lead poisoning in the EU. The most comprehensible estimate of this opportunity cost is €105m per year. As discussed in the study, this captures only a fraction of the waterfowl species that are vulnerable to primary lead poisoning (i.e. through swallowing spent lead gunshot), as a consequence of the limited number of species for which comprehensive data on post-release mortality of captive-bred birds was available.[76]

Based on information submitted by the UNEP/AEWA Secretariat and the Wildfowl & Wetlands Trust (WWT) to in the public consultation on the restriction proposal, 100 of the 150 migratory waterbird species listed under the AEWA agreement, which regularly occur within the EU, are considered to be vulnerable to lead poisoning from spent lead shot. Therefore, the monetisation provided by Andreotti et al. (2018), which does not take into account all the waterbird species affected by lead poisoning, clearly underestimates the opportunity costs for waterbirds at risk.

In addition, the study also excludes the opportunity costs for predatory and scavenger birds (and possibly other animals) lost through secondary lead poisoning (i.e. through eating birds that carry lead gunshot [or fragments thereof] in their tissues).

This use value reflects the revealed preferences of hunters who stock birds to increase their hunting success. Applying the stocking costs as a proxy for the use value of birds necessitates the assumption that underlying preferences are shared by other parts of society. In the case of waterfowl and other birds this assumption seems at least not implausible, as there are millions of European citizens who engage in bird watching and other leisure activities in wetlands.[77] For these citizens, protection of wetland birds from the risk of lead poisoning also incurs a use value (albeit different from the one to hunters).[78] For other societal groups, the proposed restriction is likely to entail a non-use value associated

[75] Experiences from the Ebro delta (Mateo et al., 2014) indicate that a measureable reduction in lead shot ingestion in waterbirds can be achieved within 2-3 years, see Annex B.9.2.6.1.

[76] In the public consultation, additional information was shared (comment #1840) on the stocking cost of other bird species, including *Recurvirostra avosetta, Oxyura leucocephala, Somateria mollissima, Aythya nyroca, Marmaronetta angustirostris, Anas querquedula, Tadorna tadorna, Branta canadensis, Cygnus Cygnus, and Cygnus olor.*

[77] Recent market developments suggest that birdwatching tourism is on the rise, see:

https://www.cbi.eu/sites/default/files/market_information/researches/product-factsheet-europe-birdwatching-tourism-2015.pdf.

[78] See Kolstoe and Cameron (2017) for a recent US study on the use value of bird watching that suggests high use values to bird watchers.

with the protection of wildlife and ecosystem services (Bateman et al., 2011) as well as with animal welfare (EU Commission, 2007).

Such non-use values tend to be somewhat smaller than actual use values. In the context of wetland valuation, Brouwer et al. (1999) reviewed the early literature on use and non-use values and found that elicited use values were approximately two times larger than elicited non-use values. This suggests that the use value estimated above might overestimate the societal benefit of avoiding the premature death of wetland birds from lead poisoning. On the other hand, it is clear that reducing the dispersal of lead in wetlands will also have a positive impact on other non-tangible factors for which people have consistently expressed preferences. These include existence values associated with rare bird species as well as non-use values for avoiding the cascading effects that lead intoxication can have on birds of prey and other predators that feed on waterfowl. Moreover, there is abundant evidence that "flagship" species such as eagles or swans attract significantly larger WTP values than less charismatic bird species (see the discussion in Morse-Jones et al. 2012).

Further benefits of the restriction proposal relate to avoided human health impacts through consumption of contaminated game meat and/or potential consumption of contaminated groundwater. Benefits from avoided contamination of drinking water sources would be local.

Taking all the non-quantified benefits into consideration (Table 5.12), it seems plausible to conclude that the societal benefits of the proposed restriction will outweigh its costs even under worst case assumptions (see the sensitivity analysis in the Annex F). A more comprehensive description of the benefits is provided in the Annex E.6.2.2.

Table 5.12. Overview of costs and benefits of a restriction on the use of lead-shot over wetlands.

Costs implied by the proposed restriction		**Benefits of the proposed restriction**	
Annuitised one-off costs		**Use value**	
Replacement of guns	€7.0m	Avoided opportunity cost associated with the annual mortality of approximately 700 000 waterfowl from 16 wetland bird species known to ingest lead shot.	€105m
Testing of guns	€1.5m	Avoided opportunity cost associated with the annual mortality of other waterbirds, predators and scavengers.	non-quantified
Annual operational costs		Beneficial impacts on leisure activities including bird watching	non-quantified
Switching to alternative cartridges	€35.9m	Avoided human health impacts through consumption of contaminated game meat and/or potential consumption of contaminated (ground) water.	non-quantified
Total annual cost to hunters	**€44.4m**	**Non-use values**	
Distributional cost in terms of generated tax revenues assuming an average VAT rate of 20%	€8.9m	Protection of wildlife and ecosystem services	non-quantified
Distributional cost in terms of producer surplus gains (after VAT deduction)	Up to €14.2m	**Existence value**	
		Protection of rare bird species	non-

			quantified
		Cascading effects on birds of prey and predators feeding on waterfowl	non-quantified
Total societal cost	**€21-36m**	**Total societal benefit**	**>€105m**

6. Assumptions, uncertainties and sensitivities

Several assumptions have been maintained when assessing the impact and proportionality of the proposed restriction. The main assumptions are listed below.

- The assessment of the fraction of hunting that takes place on wetlands is assessed on the basis of the number of waterfowl bagged vis-à-vis the total amount of birds bagged. It does not distinguish where the waterfowl and the other birds are bagged. This introduces a bias in the assessment, which is partly counterbalanced by also addressing (in scenarios 3) the market share of lead-free cartridges as a basis to assess costs. It is worth noting that this latter, in turn, also introduces a bias as it can include a bias towards non-compliance. It is not known whether this is an over or an underestimate.

- The assessment of the collateral impact occurring due to a wider wetland definition is carried out assuming that 53% of hunting in certain Member States takes place in peatlands. The actual fraction of hunting that takes place on peatlands is not known and would actually vary by Member State. There are some indications that the number of hunters involved in hunting on peatlands is rather low (47 000 for the UK as opposed to ~400 000 for the UK assumed to be affected in the central case). On the basis of this, it can be argued that the assessment in the report is likely to result in an overestimate of costs. This stands to be verified by other, more Member State specific information.

- The number of guns that need to be replaced due to this restriction largely determines the compliance costs. In the absence of European-wide statistics that specifically describe in detail the number of guns in service, their manufacturer and their proofing, assessment are to a large extent based on available statistics and expert judgement where this issue has been discussed in the past. This inevitably introduces a bias in the assessment.

- The impact assessment assumes an 'average European hunter'. It should be recognised that large heterogeneity exists between different European hunters in terms of annual bag, budget, etc.

- The total amount of lead emitted to the environment could be significantly greater than estimated by the AMEC study.

- The numbers of waterbirds dying annually is based on annual mortality data derived from a study on mallard (Bellrose 1959). The applicability of this method to other species of waterfowl and waterbirds is unknown and may have resulted in either an underestimation or overestimation of impacts.

7. Conclusion

The conclusions of the report are:

1. The number of birds dying annually in the EU as a result of lead shot ingestion has been estimated to be at least 400 000 to 1 500 000 birds, depending on the assumptions maintained on wintering population size, breeding population size and underlying ingestion and mortality rates. Further details are provided in the risk characterisation section of this report and in Annex B.

2. Except in four Member States which have a complete ban on lead shot, current legislative approaches in Member States have up until now focused on waterfowl hunting in wetlands. Applying the Ramsar definition of wetlands is likely to also impact other forms of hunting where this takes place in peatlands (which are considered as wetlands under the Ramsar definition). This is taken into account in the assessment of the costs of the proposed restriction.

3. Alternatives to lead gunshot exist and are technically and economically feasible. The prices of lead and steel shot are currently comparable, while bismuth and tungsten, which are produced, sold and used in far lower volumes, are likely to remain more expensive than lead.

4. The proposed restriction is estimated to result in an overall annual cost in the order of €80m, accruing to EU hunters (including costs for necessary testing, technical adaptations to shotguns, premature replacement of shotguns, and the incremental cost of more expensive alternative ammunition). A substantial share of this cost is distributional in nature (as it goes either as tax revenue to governments or as mark-ups to retailers and manufacturers of shotguns and ammunition). The social cost of the restriction is thus in the order of €21-36m per year.

5. On an individual level, this cost translates into additional costs of approximately €20-30 per year, which is marginal compared to the hunter's overall budget related to their hunting activities. Therefore, the proposed restriction is considered to be affordable to the individual hunter. It also brings forward the sale of shotguns that could be beneficial to European gun manufacturers and retailers. Although affordability considerations do not imply that a regulatory measure entails a net welfare gain, the analysis suggests that the proposed restriction would be unlikely to exert disproportionate costs to society as a whole.

6. Based on the expected impact of the restriction on lead dispersal in EU wetlands, the corresponding benefits of the restriction are estimated to be substantially larger than €105m per year.

7. The proposed restriction is acknowledged to only address part of the risks to waterbirds from the use of lead gunshot as feeding (and therefore ingestion) also occurs outside of wetlands.