

ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME: Lead

IUPAC NAME: Not applicable

EC NUMBER: 231-100-4

CAS NUMBER: 7439-92-1

CONTACT DETAILS OF THE DOSSIER SUBMITTER:

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VERSION NUMBER: 1

DATE: 7 April 2017

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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: " <i>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</i> ". 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 <i>waterfowl</i> .
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 or 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)
Barnett Rattner (USGS)
David Scallan (FACE)
Debbie Pain (WWT)
John Anthony Swift (LAG)
Kai Tikkinen (Finnish Hunting Association)
Mario Ge (AFEMS)
Matt Ellis (BASC)
Niels Kanstrup (Danish Academy of Hunting)
Rafael Mateo (IREC)
Rhys E. Green (University of Cambridge, UK)
Ruth Cromie (WWT)
Sergey Dereliev (UNEP/AEWA Secretariat)
Steve Binks (ILA)
Torbjörn Lindskog (AFEMS)
Vernon G. Thomas (University of Guelph, Canada)
Wouter Langhout (BirdLife Europe)

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.

<p>Lead and lead compounds</p>	<ol style="list-style-type: none"> 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: <ul style="list-style-type: none"> • “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.
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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 possible².

The proposed restriction is acknowledged to only address part of the risks to waterbirds from the use of lead gunshot as feeding occurs outside of wetlands. Further, the proposed restriction will only prevent around 20% of the estimated annual tonnage of lead used in gunshot for hunting from being dispersed into the environment.

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 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 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 such

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.

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 in EU wetlands. 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 hunting³. This includes releases to both wetlands and non-wetland environments. The available evidence from Europe suggests that lead shot is not evenly distributed within wetlands after releases and that there are areas with 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. 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 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 effective 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 flyways⁴ 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 educational 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. These risks will be the focus of further work by ECHA.

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 €30-60m. 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 €50 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.

⁴ Migration routes

- The estimated cost-effectiveness of the restriction (€12-25 per kg of lead emission avoided, with a central value of €18/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.
- 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 article⁵. However, a specific paragraph has been added to the restriction proposal to explicitly outline that possession within a wetland (or where lead shot would fall 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 poisoning⁶), 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 60 000 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 Greece) 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.

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>

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Wetlands are a characteristic feature of many landscapes, either as a major landform or as small and scattered areas. Their wide range covers marine, coastal and freshwater wetlands (lakes, rivers, bogs and marshes). Wetlands encompass a wide range of hydrological and ecological types and each type of wetland presents unique characteristics.

AEWA species cross international boundaries during their migrations and require good quality habitat for breeding and wintering as well as a network of suitable sites to support their annual journeys. There are close links between the AEWA, CMS, the Ramsar Convention on the conservation and wise use of wetlands 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 a favourable population of a set of 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 possible⁹.

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 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.

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.

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.

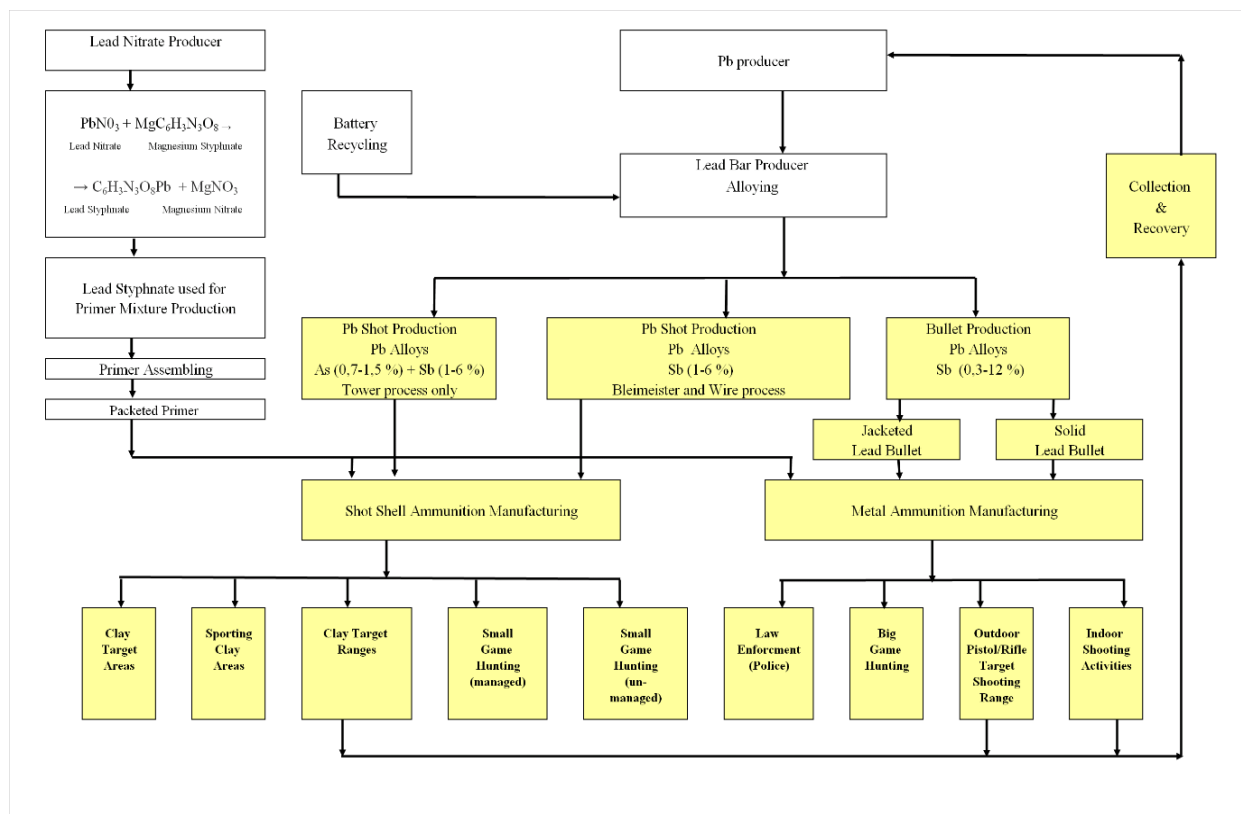


Figure 1.1. Summary of the life cycle of lead in ammunition, including lead gunshot (reproduced from ILA-E, 2010)

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 been 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 and 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 assessment¹² 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'. 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 presents unique characteristics. Wetlands are a characteristic feature of many landscapes, either as a major landform or as small and scattered areas. Their wide range covers marine, coastal and freshwater wetlands (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;

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.

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- Peatlands;
- Man-made wetlands.

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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 (Rhône) 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

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Wetland category	Description
	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.
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

wetlands in europe

Corine land cover classes

- ricefields
- inland marshes
- peatbogs
- salt marshes
- salines
- intertidal flats
- water courses
- water bodies
- coastal lagoons
- estuaries
- sea and ocean
- other



Wetlands depend completely on the hydrological cycle (both natural and regulated by man) 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 enormous 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 peatlands¹⁴ 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 State¹⁵.

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.

¹⁴ 'peatlands' can occur in several categories in the Ramsar Classification System for Wetland Types, i.e. I, E, K, U, Xp (Ramsar, 2002).

¹⁵ The list of Ramsar sites designated in each Member State, is publicly available: <http://www.ramsar.org/country-profiles>

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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 1.2 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.

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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 gunshot¹⁶. 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

¹⁶ At least one MS with national legislation covers lead and its compounds.

is intended to prevent substitution of lead with other lead substances to circumvent the objectives of this proposed restriction.

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 – <i>applicable to lead massive with arsenic grade only</i>

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 proposed 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 available¹⁷.

The first extensive assessment of the relationship between lead poisoning and the use of lead shot for hunting, was initiated as early as the 1930s¹⁸ 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).

¹⁷ Where the scope of review articles includes both lead gunshot and lead bullets, only data referring to lead gunshot has been reported here

¹⁸ http://www.nwhc.usgs.gov/disease_information/lead_poisoning/

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).

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.

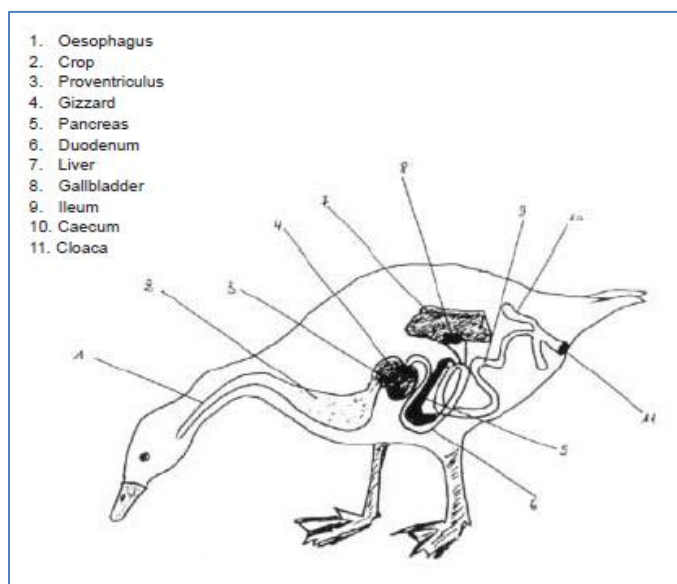


Figure 2.1. Digestive tract of a goose (Source; FAO, 1996)

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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*)

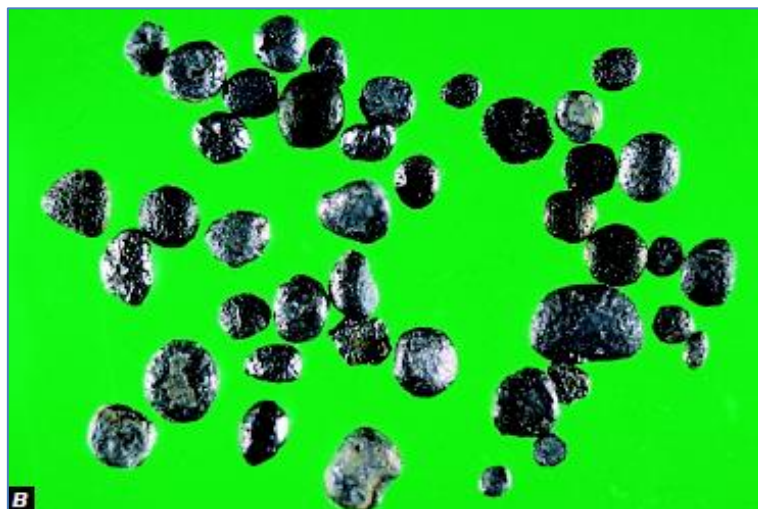


Figure 2.3. Typical "eroded" lead pellets at different stages of erosion. Image provided courtesy of the USGS National Wildlife Health Centre (USGS, 1999. *Field Manual of Wildlife Diseases: General Field Procedures and Diseases of Birds*)

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 ¹⁹ 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 studies, Bellrose (1959) identified specific mortality rates in seven classes dependent on the number of ingested lead shot. Mallards with 1, 2, 3, 4, 5, 6, >6 ingested shot 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.

¹⁹ Acid-fast intranuclear inclusion bodies are often present as an early manifestation of lead toxicity (USFWS, 1986).

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

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



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).

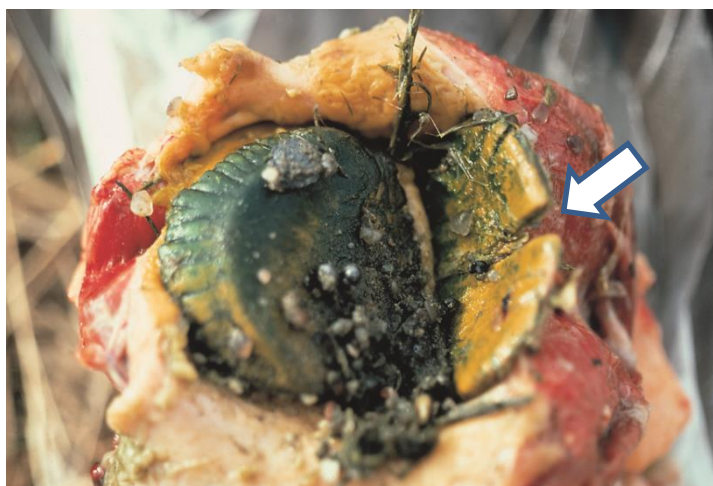


Figure 2.5. Lesions in the gizzard (indicated by arrow) of a lead poisoned mallard. Image provided courtesy of the USGS National Wildlife Health (USGS, 1999)

The sub-lethal endpoints associated with ingestion of lead gunshot can arise after both acute (short-term) and chronic (long-term) exposure, 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 in 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 areas²⁰. 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

²⁰ E.g. assessing the need for medical treatments in conservation centres.

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

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 wider biological diversity has yet to be addressed.

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 (HC₅) 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)²¹.

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 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 AFEMS²² 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.

²¹ Abatement costs of certain hazardous chemicals, lead in shot, final Report 2012 – Study for the European Chemicals Agency (ECHA).

²² Association of European Manufacturers of Sporting Ammunition.

The sum of other estimates for Spain, Italy and the UK range from 15 600 to 29 000 per year²³. 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 sports shooting. Whilst sports shooting within wetlands is likely to be a relatively common activity, the number of sports shooting ranges located in wetlands 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 2.3 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 bird (Cromie et al., 2010). The density of spent lead gunshot in the environment is an important factor influencing the likelihood of ingestion and developing adverse effects.

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 also 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; Pain, 1992; Anderson, 1986; cited by Peters and Afton, 1993).

Flint (1998) found in various wetland types to which gunshot was intentionally deposited to determine settlement rates (i.e. experimentally seeded plots) that most gunshot was still within the top 4 cm of sediment three years after deposition. Flint and Schamber (2010) 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. The authors estimated that more than 25 years would be necessary for pellets to become completely unavailable to water birds.

The long-term persistence of spent lead in the wetland sediments was also reported by Tavecchia et al. (2001). The authors estimated in the Camargue marshes (France), assuming a constant settlement rate, the half-life of pellet availability to waterfowl (within 0-6 cm) to be 46 years and that a complete settlement would occur after 66 years only (lifetime expectancy of lead pellets recalculated from values in Pain, 1991).

²³ 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).

Nevertheless, 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 the majority of gunshot ingested by wildfowl is that most recently deposited and that wildfowl searching for grit are more likely to ingest the readily available recently deposited shot.

The available evidence from Europe suggests that lead shot is not evenly distributed within wetlands and that there are zones with higher densities, influenced predominantly by the hunting technique practiced. For example, hunting from fixed blinds or shooting posts tends to result in greater density of shot within a given area than more mobile hunting (although this should be balanced against the potential for remediation, which is much greater at a shooting range).

In the Brescia district (northern Italy) an area with more than 5 100 hunting posts, Andreotti and Borghesi (2012) estimated a conservative mean of 5-6 kg of lead pellets are dispersed annually in the surroundings of 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/m² (Mateo, 2009 – See Annex B). The average, median and 90th percentile densities were 52, 21 and 148 shot/m², respectively. The greatest lead densities were observed in southern Europe in the Medina Lagoon in southern Spain where 399 shot/m² were found in the upper 30 cm of sediment (Mateo et al., 2007a).

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 and therefore these data are still relevant.

Mateo (2009) reported that high lead shot densities were recorded around shooting ranges located in wetlands. Petersen and Meltofte (1979, cited by Mateo, 2009), found lead shot densities ranging from 44 to 2 045 shot/m² at four Danish shallow water localities with shooting ranges. Smit et al. (1988a, cited by Mateo, 2009), found 400 and 2 195 shot/m² at two clay pigeon grounds in the Netherlands. At Lough Neagh, Co. Antrim, in Ireland, 2 400 spent gunshot/m² 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).

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

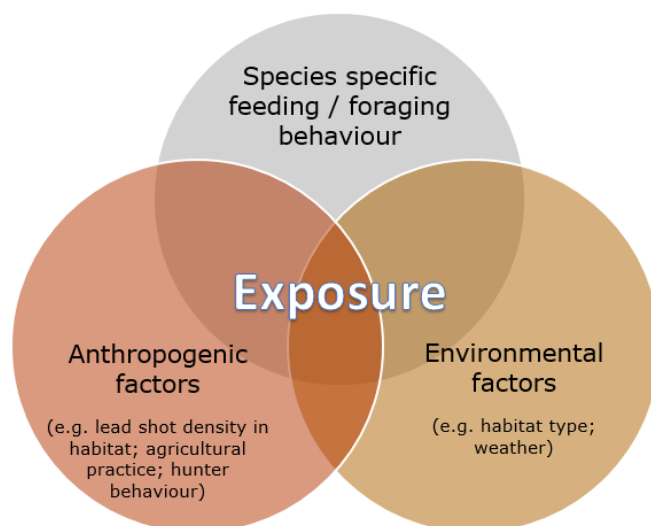


Figure 2.6. Key parameters characterising the likelihood of bird exposure to lead shot, and their interaction.

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)²⁴.

²⁴ Review of the ecological effects of poisoning on migratory birds, UNEP/CMS/COP11/Inf.34, 2014

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

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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, Peatlands	Swamps, Fens	Permanent Freshwater lakes (> ha)	Permanent Marshes/Pools (< ha)	Freshwater	Permanent River, Streams, Creeks (includes waterfalls)	Permanent Saline, Brackish or Alkaline Marshes/Pools/Lakes	Permanent Inland Deltas	Seasonal/Intermittent Brackish or Alkaline Marshes	Saline, Freshwater		Seasonal/Intermittent Lakes (> ha)	Freshwater	Seasonal/Intermittent Marshes/Pools (< ha)	Freshwater	Shrub Dominated Wetlands
Common moorhen <i>Gallinula chloropus</i>																LC
Common coot <i>Fulica atra</i>																LC
Common snipe <i>Gallinago gallinago</i>																LC
Jack snipe <i>Lymnocyptes minimus</i>																LC
Avocet <i>Recurvirostra avoetia</i>																LC
Northern Lapwing <i>Vanellus vanellus</i> ^c																VU
Ruff <i>Philomachus pugnax</i>																EN
Black-tailed godwit <i>Limosa limosa</i>																EN
Greater flamingo <i>Phoenicopterus roseus</i>																LC
Western water rail <i>Rallus aquaticus</i>																LC
Purple swamphen <i>Porphyrio porphyrio</i>																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 definition²⁵) 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 AEW listed species or Birds Directive Annex I (golden plover). Table 2.9Table 2.10 outline the habitat preference of various waterbirds known to ingest lead shot. For these tables it is clear that many of these species occur in peatlands. Section B.4.3.3.1 in Annex B includes an indicative list of EU waterbird species associated with peatland habitats.

²⁵ 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"

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).

Some European raptors also have a strong association with wetlands, at least at certain times of the year. For example, the hen harrier (*Circus cyaneus*) frequently roosts in wetlands 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 (*Hieraetus 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 in a wetland that contains lead gunshot.

Other predatory or scavenging birds²⁶ are also known to feed on water birds, 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

²⁶ 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).

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European and North American studies in which the prevalence of embedded shot in live waterfowl is frequently >20%.

Western marsh 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).

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 <i>Cygnus columbianus bewickii</i>	UK	31.2
Whooper swan <i>Cygnus cygnus</i>	UK	13.6
Pink-footed goose <i>Anser brachyrhynchus</i>	DK	9.2 – 36.0
Greylag goose <i>Anser anser</i>	ES	44.4
Mallard <i>Anas platyrhynchos</i>	UK, FR, NL,	17.6 - 66
Northern pintail <i>Anas acuta</i>	UK	27.1
Northern shoveler <i>Anas clypeata</i>	UK	25.8
Gadwall <i>Anas strepera</i>	UK	26.3
Common teal <i>Anas crecca</i>	FR	4.4 – 9.6
Pochard <i>Aythya ferina</i>	UK	25.0
Tufted duck <i>Aythya fuligula</i>	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 is comprised of a qualitative assessment that summarises information on the following:

1. Analyses of the extent of wild bird mortality in the EU as a result of primary or secondary ingestion of lead gunshot (specifically studies on bird species that are associated with wetlands in the EU);
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 the indicative thresholds of adverse effect;
4. Exposure to 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 to Member State restrictions on the use of lead gunshot entering into force. 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 restrictions of some form or another on the use of lead gunshot in wetlands were enacted. These studies provide insight into the implementation and effectiveness of different types of restrictions 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 legislation.

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 bird mortality in the EU due to lead poisoning

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.

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An estimate of EU waterfowl mortality of 6.1% is also described in the Confidential Annex.

To estimate the magnitude of 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 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)²⁷.

Complimentary estimates of mortality were made based on 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 interpreted separately to avoid any potential for double counting. Similarly, this analysis assumes that the mortality rate estimates reported for mallard after ingestion of lead gunshot are applicable to additional species of waterfowl, waders, rails and flamingos that are 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, HR) 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 11% 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 8.9% was assumed in all three scenarios. Further details of this analysis is provided in Annex B.

²⁷ 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/>

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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	626 000 (5%)	7 644 000 (63%)	3 938 000 (32%)	12 208 000
	Waders/rails ^b	255 000 (3%)	6 510 000 (85%)	954 000 (12%)	7 719 000
Breeding population^a	Waterfowl ^b	941 000 (11%)	5 879 000 (72%)	1 380 000 (17%)	8 199 000
	Waders/rails ^b	1 068 000 (14%)	5 256 000 (66%)	1 545 000 (20%)	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; 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 261 000 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 521 000 (Table 2.13). 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 440 000. Between 66 000 and 212 000 of these cases of lethal poisoning in waterfowl are estimated 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 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 die annually, with a central estimate of 419 000. 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, 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 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.

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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	261 000	521 000	787 000
	Waders/rails ^c	204 000	419 000	638 000
	Total	465 000	940 000	1 425 000
Breeding population^a	Waterfowl ^b	207 000	440 000	720 000
	Waders/rails ^c	196 000	445 000	775 000
	Total	403 000	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; 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	44 000	54 000	65 000
	Waders/rails ^d	19 000	22 000	26 000
	Total	63 000	77 000	91 000
Breeding population^b	Waterfowl ^c	63 000	82 000	100 000
	Waders/rails ^d	74 000	93 000	111 000
	Total	138 000	175 000	212 000

Notes – a: IE, RO, PL, GR; b: based on EU Birds Directive Article 12 reporting for period 2008-2012, rounded to the nearest thousand individuals, no data reported by GR; 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, although this is likely to have also been influenced by the use of lead fishing weights, at least prior to the introduction of bans on certain types of lead fishing weights in the UK during the 1980s. 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 B²⁸.

2.4.5.3 Tissue concentrations indicative of adverse effect

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.

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.

²⁸ Whooper swans in the UK, flamingos in Mediterranean countries and white-headed duck and marbled teal in Spain.

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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, 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 concentration 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). 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 and 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 the dose-response analysis does not provide any indication of a threshold. RAC has given its opinion in previous restrictions on this issue for lead in jewellery and in consumer articles (RAC, 2011; RAC 2013), in line with the assessment by EFSA (2013), it agreed there is no threshold for neurotoxicological effects of lead and that any exposure to lead constitutes a risk. 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 BMDL₁ 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 of lead exposure

Endpoint	Critical lead exposure levels
Repeated dose toxicity	<p>Haematological effects</p> <p>Inhibition of ALAD enzyme is observed at blood lead concentrations <100 µg/L. ALAD is involved in the synthesis of haeme (LDAI, 2008).</p> <p>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):</p>
	<p>Effect on blood pressure and cardiovascular effects</p> <p>Blood lead concentration of 36 µg Pb/L 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).</p> <p>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.</p>
	<p>Kidney effects</p> <p>Blood lead concentration of 15 µg Pb/L associated with a 10% increase of chronic kidney disease in the population. There is no evidence for a threshold in adults (EFSA, 2013).</p> <p>NOAEL of 60 µg/dL, combined with >5 years of lead exposure (REACH Registration, 2015).</p> <p>EFSA (2013) considered that there is no threshold for renal effects in adults.</p>
Acute toxicity	<p>TNO (2005): 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</p> <p>USA: LOAEL value of 600–1000 µg/L related to colic in children.</p> <p>ATSDR (2007): LOAEL of 800 µg/L and a NOAEL of 400 µg/L identified for acute effects in children.</p>
Reproductive toxicity	<p>Male fertility</p> <p>Bonde et al. (2002): 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.</p>

Endpoint	Critical lead exposure levels
	<p>Female fertility</p> <p>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.</p>

2.5.1.3 Lead gunshot in food

Lead shot can ‘fragment’ after hitting the target animal resulting in smaller particles of lead being distributed within the tissues of an animal. Some of these fragments may reside in tissues a considerable distance from the primary wound and remain there after butchery and food preparation (Green and Pain, 2015).

According to the available evidence, it is not possible for consumers to successfully remove all embedded fragments of lead from the wound channels of shotgun shot game (Pain et al., 2010). Tiny lead particles would go unnoticed by consumers²⁹.

Usually when a gamebird is killed several shot have penetrated it and the lead fragments and high tissue lead concentrations remain even when those shot pass in and out of a bird, as sometimes happens (Pain et al., 2010).

Pain et al. (2010) found that a high proportion of samples had lead concentrations exceeding 100 ppb w.w. (0.1 mg kg w.w.). The percentage of mallards exceeding 100 ppb w.w. was: 39.9³⁰ %. 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.

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 final lead concentration in meat as well as 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.

²⁹ 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."

³⁰ Adjusted value (approximates what would have been expected if the measurements of concentration in the whole meal derived from each bird had been available).

2.5.1.4 Conclusions on human health hazard

Lead is associated with multiple adverse health endpoints in humans, including neurotoxicity in children and renal toxicity in adults for which no threshold has been established. Non-threshold effects on neurodevelopment were 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. However, this exposure route has not been further assessed in this report although it could be expected there is some significant hand to mouth exposure if the lead shot is handled without suitable protective equipment and suitable hygiene practices are not kept e.g. washing hands before eating or smoking.

2.5.3 Indirect exposure to humans via the environment

A quantitative assessment of the risks from indirect exposure to humans via the environment from the use of lead in gunshot in wetlands has not been undertaken. As lead is a non-threshold substance Annex I of REACH only requires a qualitative assessment of risks to be carried out (Annex I para 6.5).

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 meats 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

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(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 this 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 thick-billed murre (*Uria lomvia*) carcasses 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 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 found that in ducks 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—a known non-threshold substance—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

Various 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 placing lead gunshot on the market, to restrictions on its use within or over wetland habitats (as these are where waterbirds predominantly occur), or restrictions on its use for hunting certain species wherever they occur (typically waterfowl). Four Member States (Ireland, Greece, Poland and Romania), currently have no legislation to control the use of lead shot in wetlands³¹.

Four legislative approaches to prevent or reduce the use of lead gunshot in wetlands have been implemented in different Member States in the EU:

1. Area-based (wide) partial ban focusing on preventing the use of lead gunshot in generic wetland habitats (in certain MS based on the Ramsar wetland definition);
2. Area-based (narrow) partial ban focussing 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
HR	complete	Applies throughout MS, irrespective of habitat or species hunted	50 000
DK	complete	Applies throughout MS, irrespective of habitat or species hunted	165 000

³¹ Note: additional information was provided just before submission of the Dossier. Slovenia confirmed they had no ban on the use of lead shot in wetlands. This is not expected to change the conclusions of the report but this issue will be further dealt with by the Dossier Submitter when preparing the Background Document.

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Member State	Ban on use of lead shot	Details	Total number of hunters ^b
NL	complete	Applies throughout MS, irrespective of habitat or species hunted	28 170
BE ^a	complete	Applies throughout MS, irrespective of habitat or species hunted	34 000
BG	Prohibited in designed areas (wide scope)	Not permitted in wetlands based on Ramsar convention definition and buffer zone of 200 m	110 000
FR	Prohibited in designed areas (wide scope)	(1) Foreshore; (2) marshes not dried; (3) rivers, canals, reservoirs, lakes and ponds; Hunting and hunting of these game animals are permitted only at a maximum distance of thirty meters from the body of water provided that they have the right to hunt on it.	1 331 000
HU	Prohibited in designed areas (narrow scope)	Not permitted within designated sites. Regulation lists 33 wetland areas, including Ramsar sites	55 000
IT	Prohibited in designed areas (narrow scope)	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
CY	Prohibited in designed areas (wide scope)	Not permitted in waterbodies, whether artificial (salt lakes) or not (dams/reservoirs/sewage treatment ponds) – buffer zone of 300 metres	45 000
AT	Prohibited for hunting designated species	Not permitted for hunting waterfowl; wherever they occur.	118 000
CZ	Prohibited for hunting designated species	Not permitted for hunting waterfowl; wherever they occur.	226 585
DE	Prohibited in designed areas (narrow scope)	Not permitted in waterbodies (all shorelines, lakes and rivers)	351 000
ES	Prohibited in designed areas (narrow scope)	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
LV	Prohibited in designed areas (narrow scope)	Not permitted for waterfowl hunting protected areas (Ramsar sites, SPAs and nature reserves)	25 000
PT	Prohibited in designed areas (narrow scope)	Designated Ramsar sites, Natura 2000 sites and nature protected sites	230 000
SE	Prohibited in designed areas (wide scope)	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	290 000

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Member State		Ban on use of lead shot	Details	Total number of hunters ^b
			vary according to the natural seasonal variations	
UK	EN	Prohibited in designed areas (narrow scope) 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.	800 000
	WA	Prohibited in designed areas (narrow scope) 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	Prohibited in designed areas (wide scope)	Not permitted in wetlands based on Ramsar convention definition, but peatlands interpreted to mean 'peatlands with visible water').	
	NI	Prohibited in designed areas (wide scope)	Not permitted in wetlands based on Ramsar convention definition, but peatlands interpreted to mean 'peatlands with visible water').	
IE	No ban in place	-	350 000	
EE	Prohibited for hunting designated species	Use of lead gunshot to hunt waterfowl is prohibited.	16 600	
LU	Prohibited in designed areas (wide scope)	marshes, lakes, ponds, reservoirs, rivers and canals and a buffer zone of 30 m.	2 000	
LT	Prohibited in designed areas (narrow scope)	Hunting forbidden in most important wetlands	32 000	
MT	Prohibited in designed areas (scope unknown)	No wetlands on Malta where hunting is permitted	15 000	
SI	Prohibited in designed areas (scope unknown) ³²	-	22 000	
SK	Prohibited in designed areas (wide scope) 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	
GR	No ban on place	-	235 000	
PL	No ban in place	-	106 000	

³² Note: additional information was provided just before submission of the Dossier. Slovenia confirmed they had no ban on the use of lead shot in wetlands. This is not expected to change the conclusions of the report but this issue will be further dealt with by the Dossier Submitter when preparing the Background Document.

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Member State	Ban on use of lead shot	Details	Total number of hunters^b
RO	No ban in place	-	60 000

Notes: a – 18 000 hunters in Wallonia, 16 000 in Flanders; b – data on number of hunters from FACE³³

³³ 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>

Many of the existing national implementations 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 subsequent implementation and enforceability of the measure, taking into account the need for hunters to have a clear understanding of where hunting with 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. 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 e.g. within peatlands.

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 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 261 000 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 521 000. 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 440 000³⁴. 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. As there are no population estimates for birds occurring in Greece 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 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 419 000. 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.

³⁴ REACH does not require evidence of 'population level' impacts to demonstrate an unacceptable risk to the environment.

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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 60 000 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.

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.

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 restriction dossier on lead in shot used in or over wetlands followed a request by the Commission to ECHA. As discussed in Annex B, the conclusion of this examination is that the risk from the use of lead in shot is not adequately controlled. Therefore, ECHA conducted an analysis of diverse risk management options (RMOs) to identify the most appropriate to address these 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 lead in shot (see Annex B) under other REACH regulatory measures, existing EU legislation and other possible Union-wide RMOs was examined. However, these were assessed as inappropriate to address all article categories contributing to risk as presented 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
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 restriction: effectiveness, practicality and monitorability. 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. In summary, the proposed restriction, set out in Table 5.2, was found to overall better meet the criteria for restriction in comparison to the other evaluated restriction options.

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

	Type of ban	Effectiveness (risk reduction/ proportionality)	Practicality (implementability, enforceability, manageability)	Monitorability	Other
1	Restriction on the placing on the market and use of lead gunshot	risk reduction (+) proportionality: costs (++), benefits (++)	enforcement (+) implementability (+) manageability (=)	(=)	<i>Note: beyond the scope of ECHA's mandate from the Commission.</i>
2	Restriction on the use of lead gunshot for all hunting	risk reduction (+) proportionality: costs (+), benefits (+)	+ enforcement + implementability manageability (=)	(=)	<i>Note: beyond ECHA's mandate as it can occur beyond wetland habitats.</i>
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 + implementability manageability (=)	(=)	<i>Note: beyond ECHA's mandate as it can occur beyond wetland habitats.</i>
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 related to the proposed restriction option; (-) decrease related 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 within or over wetlands

<p>Lead and lead compounds</p>	<ol style="list-style-type: none"> 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: <ul style="list-style-type: none"> • “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.
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5.3.1 Justification for the selected scope of the proposed restriction

The proposed restriction aims to address the use of lead gunshot in wetlands to protect birds from the acute and sub-lethal effects of lead exposure via ingestion. This proposed restriction entails a ban on the use of lead gunshot within all (generic) wetland habitats that are present within a Member State and includes restricting the use of gunshot where spent gunshot would land within a wetland even if the use (i.e. the shooting) takes place outside of a wetland. The proposed restriction also includes a ban on the use of lead gunshot for shooting at targets (e.g. clay pigeons), rather than live quarry, within a wetland or where spent gunshot would land within a wetland.

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 humans that consume 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 hunters 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 of the existing national implementations 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 subsequent implementation and enforceability of the measure, taking into account the need for hunters to have a clear understanding of where hunting with 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 .

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.

5.3.1.3 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 stakeholders³⁵ 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 wetland³⁶.

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).

5.3.1.4 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 during the discussion with stakeholders³⁷ 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 (such as tungsten) 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.

³⁵ Meeting of the Expert Group on the Birds and Habitats Directives (NADEG), in November 2016.

³⁶ French report to AEWA (2015). http://www.unep-aewa.org/sites/default/files/document/nr_aewa-mop6_france.pdf

³⁷ Personal Communication Baumbach Metalss GmbH, and with Clay 7 Game Reloaders Ltd (2016?)

5.4 Assessment of restriction scenario

The expected response of wetland hunters to the restriction of lead shot in wetlands is to use the main alternative ammunition, i.e. steel shot, but it is possible that some hunters will chose to use other alternatives such as bismuth or tungsten-based materials. The main aspects of this transitional choice are as follows.

5.4.1 Alternatives

Hunters affected by the proposed restriction would have to switch to alternative ammunition. The most commonly used alternatives are steel and bismuth 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 feasible, comparable in price, and having more benign human health and environmental hazard and risk profiles.

5.4.1.1 Availability

Since the concern of dispersal of lead shot in wetlands and the fatal poisoning of waterbirds was raised in the 1970s, several lead-free and non-toxic shot types were developed and put into commercial production. Steel shot cartridges are produced by most European manufacturers (in the study of Thomas (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 and tungsten-based. In addition, North American manufacturers sell a variety of lead-free ammunition types in Europe.

An 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 steel are comparable even though the raw material is at the moment cheaper, the expectation is that in the long run the prices of steel shot will fall further.

5.4.1.2 Technical feasibility

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

Some guidance can be found on the BASC website³⁸:




For steel/steel-like shot, a different process is involved. A standard or superior/magnum-proofed gun can fire standard steel shot cartridges, subject to conditions. To fire high performance steel, it has to have passed steel shot proof, a more rigorous test of the gun's ability to handle the different pressures (same as high performance lead) and shot hardness of steel/steel-like shot cartridges. A gun

³⁸ <https://basc.org.uk/technical/>

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successfully passing Steel Shot proof has to be stamped with a Fleur de Lys on its barrel.

Further guidance on when steel shot can be used is given on the website of the Beschussamt Ulm³⁹, the Ulm proofing house in Germany:

Caliber	Used ammunition		weapon (Type and marking of the gun proof is indicated)	
	Operation pressure (maximum allowed) In bar	Steelshot Ø In mm	Standard proof 	"Reinforced" With additional steel shot test 
		Column 1	Column	
		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

³⁹ https://www.beschussamt-ulm.de/beschussamt/Interne_Dokumente/Dokumente/VF_504_M_Info-Verwendung-Bleifreie-Schrote.pdf?m=1488869144

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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					

Figure 1: overview of possibilities to use steel shot

Figure 9 gives an overview on when steel shot can still be used. In line with the findings of (Putz, 2011), steel (standard) can still be used in most shotguns (older, pre-1961 and more modern, post-1961) models.

According to the rules of proof, some old (not standard proofed) shotguns should not be used with steel gunshot of any kind⁴⁰. 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 wad that is the most significant controlling parameter.

In addition though, ballisticians around the world do agree there is an increased risk of choke swelling in tightly choked guns and recommend hunters should consider having these 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 are often including "proofed for steel" in their advertising for new guns. This means that the barrels and choke tubes have been constructed to ensure choke swelling does not occur, and that higher chamber pressures can be safely used from the CIP's High Performance group. It does not mean that an existing gun, without this proof stamp, is inherently unsafe to use steel loads which generate lower chamber pressures, comparable to existing lead shot loads.

⁴⁰ Personal communication John Swift and Niels Kanstrup.

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Given there are always new hunters taking up this activity and hence having to use non-lead gunshot, hunters will have a choice (ascending order of cost) to:

1. Use a standard proofed shotgun (which the majority of already hunters will have) to fire standard steel cartridges (little or no extra cost or even saving);
2. Use a standard proofed shotgun to fire standard bismuth or tungsten-based cartridges (approximately four to five times the cost of existing lead cartridges);
3. Where the hunter only owned a non-proofed shotgun they would have little option but to buy a new shotgun (either standard or high performance steel proofed);
4. Where a hunter owns a standard proofed shotgun and wants to fire high performance steel ammunition, it can possibly be re-proofed to high-performance steel or a replacement gun can be purchased.

Most hunters will possess at least one shotgun that is standard proofed since most if not all shotguns sold after 1970 are standard proofed. Hence, most hunters will have to choose whether to use standard bismuth or steel cartridges. Only relatively few are likely to see any merit in sending their gun for re-proofing against the high-performance steel specification. Some people with magnum proofed guns *may* 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 old guns that would need to be replaced is not precisely known. Many Member States do not keep a register of shotguns or do not require any registration of the number of shotguns owned per hunter.

Lead-like shot types like tungsten matrix shot or bismuth-tin shot can be used in any European gun with any type of choke constriction. Also, standard loaded steel shot cartridges can be used in any modern gun suited to fire lead shot. The only possible concern about the use of steel and other hard shot in standard guns pertains to the choke region of the barrel, where large shot (larger 3.5 mm diameter) passing through an abruptly developed, tightly-choked barrel could cause a small ring bulge to appear around the choke cones. However, this is widely considered not to be a safety issue, but rather a cosmetic concern (Coburn, 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 several 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 5.3. Summary of the technical suitability of lead-free gunshot

Claim	Dossier Submitter’s Assessment
<p>I cannot hunt as effectively with steel gunshot as I can with lead gunshot.</p>	<p>Although there were initial concerns about the effectiveness of steel shot, the effectiveness of modern steel shot has improved significantly since its introduction.</p> <p>However, the ballistics of steel shot are different and hunters will need how to adapt to them.</p> <p>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.</p> <p>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.</p> <p>The effective shooting distance for modern steel gunshot is consistent with the range at which wildfowling (or fowling) is typically done. For some species of larger waterfowl, e.g. geese, shotguns specifically proofed for ‘steel’ (therefore compatible with high-performance steel cartridges) might be required.</p> <p>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.</p>
<p>I will damage my gun with steel gunshot.</p>	<p>Based on several reports there does not seem to be any evidence that switching to steel gunshot will cause damage to shotguns. It was noted that there are reported cases of where the use of steel gunshot can result in minor bulging of the barrel but the evidence concludes that this is a cosmetic rather than a gun safety issue. The use of modern plastic wads prevents damage in modern steel shot.</p> <p>The cases where bulging was noticed did not describe the context (i.e. correct choice of cartridge or actual genuine bulging to using steel shot).</p> <p>However, this could affect the resale value of the</p>

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	affected guns.
I need a new gun to be able to use steel gunshot.	<p>The evidence suggest that 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 smaller in order to have the equivalent energy per pellet to lead.</p> <p>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 de lis', it is recommended to check with a gunsmith whether your gun is compatible with high-performance steel gunshot cartridges.</p>
There is no steel gunshot cartridges that I can use in my gun.	<p>For most of the shot sizes required for waterfowl hunting (12/70 shot size) most manufactures have suitable cartridges in their product range.</p> <p>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.</p>
Steel shot is prohibitively expensive.	Current prices for steel and lead gunshot are comparable. It can be expected that once there is greater demand for steel gunshot cartridges can go down
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	In wetlands, the typical ricochet surfaces are not often occurring. Furthermore research from (DEVA, 2013) demonstrated that ricochet occurs bot in steel and in lead shot. The experience in Denmark has shown that no increase in ricochet was noted after the introduction of the ban n lead shot (Source; Danish insurance companies) this may also come from the fact that in areas prone to ricochet, softer alternatives like (i.e. bismuth) were used.

5.4.1.4 Risk reduction

The calculation of the risk-reduction capacity follows the methodology set out by AMEC (2013). The annual dispersal of lead into EU wetland environments is estimated based on the current consumption level of lead shot by wetland hunters in the EU (663 million cartridges per year, source: AFEMS). From the annual consumption of cartridges and the average load

per cartridge, it is calculated that (663m* 0.032 kg) 21 216 tonnes of lead are currently emitted per year.

Accounting for the various national and regional legislations in place and how these have impacted hunters and their use of non-lead shot, AMEC estimated that 357 tonnes of lead are annually dispersed into EU wetlands. The risk-reduction capacity of the restriction proposal is then calculated, assuming a reduction in risk linear to the number of hunters impacted under the different scenarios.

5.4.1.5 Economic feasibility

The production cost of a shotgun cartridge consists basically of three elements: the material cost, the cost of construction 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.

As to the price of raw materials, an internet search resulted in the following indicative data: 2 €/kg of lead; 0.07 €/kg of iron⁴¹; and 20 €/kg of bismuth. Prices vary depending on market demand, purity etc., so these prices should be seen as 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 €/kg⁴² ; steel shot app. 4 €/kg⁴³). 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.

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

⁴¹ London metal exchange reports 300\$/ton (cash buyer) for steel and 2361 \$/ton for lead, confirming the order of magnitude of these price differences.

⁴² <http://www.cabelas.com/>

⁴³ <http://www.huntinglife.net/>

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-up⁴⁴. 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 supplier⁴⁵, but €2.7 per cartridge at a Danish retailer⁴⁶. This just illustrate that the retail price of two identical cartridges may differ by a factor of two depending on market supply and demand (and factors such as VAT).

Table 5.4 indicates prices of lead vs lead-free shot cartridges in different European countries. Lead shot cartridge prices vary from €0.29-0.68 (with a central price estimate of €0.43), while steel shot cartridges are within the spectrum of €0.23-0.77 (with a central price estimate of €0.53). Bismuth, copper and tungsten cartridges are found to be significantly more costly with prices between approximately €2-4 per cartridge (with a central price estimate of €3).

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 5.4 summarises the findings of Thomas et al. (2015), which support the general finding that 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 (even though the price of bismuth shot may reduce slightly).

⁴⁴ R. Cove, CEO, Kent Cartridge, pers. comm.

⁴⁵ <http://www.sportingsupplies.co.uk/contents/en-uk/d194.html>

⁴⁶ <http://www.iversen-import.dk/bismuth-forrest-vip-32-gr-skovpatron-405-m-sek.html>

Table 5.4. Comparative prices for lead and lead-free shotgun cartridges in cal. 12. Summarised after Thomas (2015).

Shot type	Manufacturer	Price per box of 25 [in €]
Steel	3 different UK makers	8.3-9.1
Bismuth-tin	Eleyhawk	42.4
Hevi-shot	Loaded in the UK	65.5
Tungsten	Gamebore	70
Lead	Gamebore	8.0-8.1
Lead	Eley	8.1-8.2
Lead	Hull	10.8-11.1
Lead	Lyalvale	9.5-11.3

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 hunter 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 active and inactive peatbogs) 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 the scope of existing legislation in Member States and how this 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 135 000 shotguns will have to be prematurely replaced as a result of the restriction.⁴⁷ As there is extensive information available from multiple reliable sources (e.g. shotgun manufacturers, hunting/shooting associations, Member States) acknowledging the suitability of standard steel loads in existing standard proofed shotguns combined with the fact that bismuth and tungsten-based ammunition can be used in all existing shotguns, irrespective of their age, the premature replacement of 135 000 shotguns is probably a conservative estimate.⁴⁸

⁴⁷ 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.

⁴⁸ 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) and thus it might well be that—even they own a shotgun that is not suitable for firing steel shot—they also own a standard proofed gun.

A summary of the main assumptions going into each of the scenarios is given below. Further details are provided in Table 5.5 and in Annex E. Substitution costs pertaining to each of the scenarios are summarised in Table 5.5. 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, GR, PL, RO) 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 50 000 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, GR, PL, RO) 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 (BG, HU, IT, ES, PT, LU, MT, SI, FI and 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). The restriction would result in costs to around 267 000 waterfowl hunters and around 1.08m fowl hunters in those Member States. It is assumed that 10% of the affected hunters will have to prematurely replace their shotgun (i.e. 135 000 shotguns will have to be replaced)⁴⁹; 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 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, HR, DK, NL). The restriction would result in costs to around 651 000 waterfowl hunters and around 1.83m fowl hunters in those Member States. It is assumed that 25% of the affected hunters will have to prematurely replace their shotgun (i.e. 620 000 shotguns will have to be replaced)⁵⁰; moreover there would be a fraction of 15% of affected hunters who would test

⁴⁹ 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.

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

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their guns to be assured they could use steel shot. 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 shot.

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Table 5.5. Assumptions used in the cost scenarios

Scenario	Best case	Central	Worst case
one-off costs			
proportion of total hunting in wetland	6.7% ^a	8% ^b	10% ^c
Number of waterfowl hunters facing 'one-off' costs	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 ⁱ
Number of 'fowl ^e ' hunters facing 'one-off' costs	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	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
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

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Scenario	Best case	Central	Worst case
Percent of gun owners that re-proof	0%	10%	15%
Cost of proofing test per barrel	€70		
Shotguns prematurely replaced ^k	0%	10%	25%
Operational costs			
Number of lead cartridges consumed in EU-27 ⁹	663 million		
Retail price of lead shot	€0.34 per cartridge		
Retail price of alternatives	Steel: €0.37 per cartridge (110% of the price for lead shot); Bismuth/Tungsten: €1.53 per cartridge (450% of the price for lead shot)		
percentage steel	100%	85%	75%
percentage bismuth	0%	15%	25%
Amortisation period (years) ^h	10 years	20 years	50 years
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 hunters 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 – Sweden also excluded as they have a ban on the use of lead gunshot for hunting birds; 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) | source: Amec 2013

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 5.5 summarises these costs.⁵¹ 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 5.5, since this would approximate the share of the costs which would flow back to Member States as tax revenues.⁵²

Table 5.6. Summary of substitution costs induced by the proposed restriction

	Best-case scenario	Central-case scenario	Worst-case scenario
Number of waterfowl hunters affected	50 000	267 000	651 000
Number of fowl hunters affected	414 000	1 081 000	1 831 000
Number of shotguns to be replaced	0	135 000	620 000
One-off cost for premature replacement of shotguns	€0	€88m	€700m
Annual operational cost (i.e. annual incremental cost to be spent on shot)	€17m	€69m	€161m
Annualised one-off cost for testing	€0.4m	€1.3m	€2.4m
Annualised one-off cost for new guns	€0	€6.3m	€33m
Total annualised cost to hunters	€17.4m	€76.2m	€195.9m
Annual emission reduction from replacement	1 452 tonnes	4 221 tonnes	7 767 tonnes
Unit abatement cost (p.a.)	€12/kg	€18/kg	€25/kg
Additional cost per hunter (p.a.)	€37	€54	€65
Average hunter's budget (p.a.)	€ 3 000	€ 3 000	€ 3 000
Fraction of average hunter's budget	1.2%	1.8%	2.2%

⁵¹ 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.

⁵² 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 water bird 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.

If a restriction on the use of lead shots in wetlands is introduced, manufacturers that produce lead shots might face a problem due to the fact that the technology used for manufacturing their product cannot be adapted to alternative metals. None of the products different from lead can be produced using the skills, technologies and facilities used to produce lead shots. Lead shots are produced with either a tower or Bleimeister process.⁵³ 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 in Europe producing exclusively steel shot is considering shutting down their production, because they are not able to compete in price with steel shot imported from outside Europe.

⁵³ The tower process is the most widely used (95%), while the Bleimeister system has marginal significance today.

Companies manufacturing cartridge components compatible with lead shots will also lose part of their business. However, they can concentrate on the production of other cartridge components, if they do not have alternative shot production machinery already available. The economic impact of losing part of business is estimated to 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 5.7.

Table 5.7. Impacts on manufacturers

Manufacturer	Impact
Lead shot	Lose part of their business
Alternative shots/importers	Volume will increase
Component manufacturers	Companies producing components with lead shots will lose part of their business
Assembler of cartridges	Some costs related to adaptation of machinery

5.7.2 Forestry and veneer industry

Concerns were raised that steel shot might damage standing timber when lead was to be prohibited in the 1990s in Denmark, and the forestry authorities had recommended against the use of steel. However, the LAG report (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 information⁵⁴ to Metsähallitus (Finnish State Forest Enterprise) about the type of wood-industry that might be affected by the use of steel shot but no evidence was provided. Further information on this may be provided in the public consultation.

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.⁵⁵

It could be beneficial to require mandatory training on the need and scope of the proposed restriction before hunting would be permitted in Member States, i.e. the training and examination needed to receive a hunting permit should be amended to that effect. To some

⁵⁴ Personal communication, December 2016.

⁵⁵ WWT (2010) describe a protocol for the determination of lead pellets in various species.

extent this would be consistent with the findings of the Defra commissioned Study (WWT, 2010).

For the reasons mentioned above and based on experiences made in the Netherlands, Flanders, Sweden and Denmark, a widening the scope of the restriction to entail a complete ban (trade, placing on the market) on all gunshot cartridges containing lead may be considered. However, such a restriction would require a better understanding of its impacts on the wider shooting community (e.g. sports shooting, non-wetland gunshot hunting, etc.).

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 to this restriction report, it can be expected that the additional cost to an average hunter for purchasing non-lead shot ammunition rather than lead shot ammunition will be in the range of €37 (best case) to €65 (worst case) per year. This corresponds to 1.2-2.2% of the average annual hunting budget of a European hunter, which is in the order of €3 000 (Pinet, 1995). This additional cost seems economically reasonable even for subsistence hunters with a significantly lower hunting budget.

With regards to the premature replacement of shotguns, the cost calculations detailed out in E.5 are based on the assumption that up to 620 000 guns (worst case) would have to be prematurely replaced across the EU as a result of the restriction proposal.⁵⁶ This would entail a total replacement cost (in 2016 €) of €88m (central case) to €700m (worst case), depending on the assumptions maintained. These cost estimates can be expressed in terms of the

⁵⁶ Under the best case scenario, it is assumed that no gun would have to be prematurely replaced due to the proposed restriction.

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 well possible that the fraction of active subsistence hunters who would be affected by the restriction proposal 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 1 500 to 7 800 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 4 200 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 ammunition), these abatement figures suggest that the total cost per tonne of lead emission avoided is in the range of €12/kg to €25/kg.

The central scenario suggests a cost-effectiveness value of €18/kg of lead dispersal avoided, which is far below the cost-effectiveness values estimated many other REACH restriction (Figure 5.1). 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 properties⁵⁷ of lead, it can thus be concluded that the proposed restriction is a cost-effective measure of addressing lead emissions to the environment.

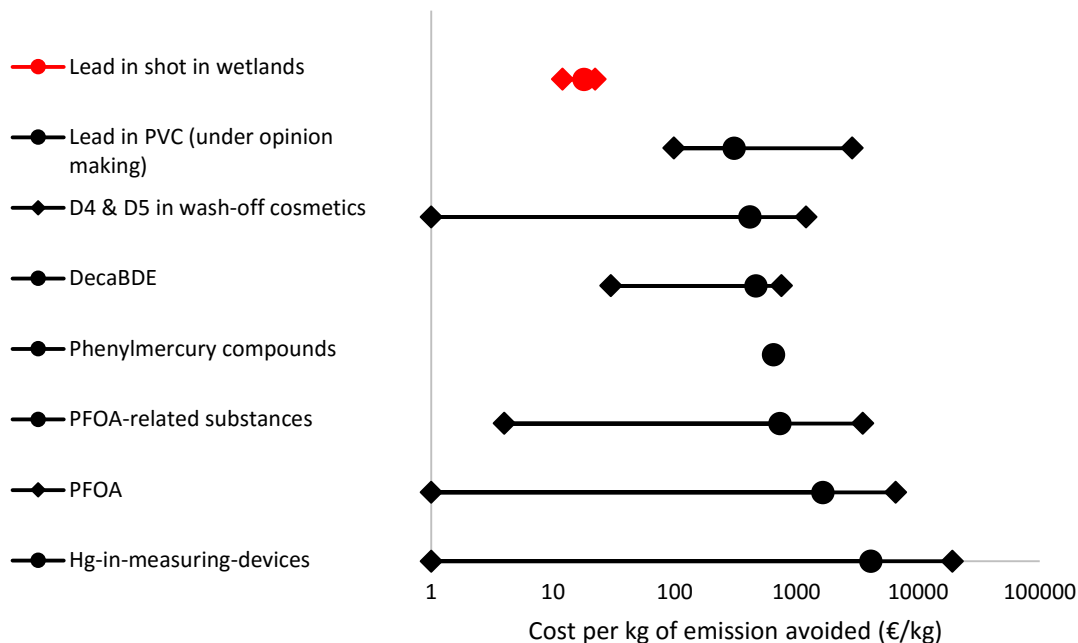


Figure 5.1. Cost-effectiveness of previous restrictions under REACH

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 €700m (worst case, assuming that 620 000 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).

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 135 000 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

⁵⁷ 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.

commensurable with the annual cost increment associated with the switching to non-lead (steel and bismuth) shot by standard annuitisation.

At a discount rate of 4%, the annuitised replacement cost in the central scenario is close to €6.3m. This annuity needs to be added to the incremental cost of switching to alternative ammunition, which is estimated at €68.6m 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 (€1.3m) results in a central annual cost estimate of €76.2m accruing to wetland hunters in the EU.⁵⁸ 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 ammunition and shotguns as well. 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 €76.2m to arrive at €61.0m, and then multiply this amount by an average 40% to arrive at an estimate of the total mark-up of approximately €25m. 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.⁵⁹ However, information from an application for authorisation made by one EU gun manufacturer⁶⁰ 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 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 birds. Partwise monetisation of this externality is possible under the assumptions outlined in the confidential annex to this report. In short, the confidential annex proposes to value the premature death of an individual bird by the opportunity cost of not being able to shoot it.

⁵⁸ 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 €61m per year.

⁵⁹ See Annex E.5.1 for a theoretical discussion of the regulation induced welfare impacts.

⁶⁰ https://echa.europa.eu/documents/10162/13637/afa_ct-0070-02-aa_sea_en.pdf

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 in the confidential annex. Based on the expected reduction of lead dispersal in EU wetlands⁶¹, 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 confidential annex, 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 where both lead ingestion and stocking data were available (16 species with available information vs 38 affected by lead gunshot ingestion).

It is important to note that this estimate does not take into account other waterbird species (for which no such data were available) and 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 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.⁶² 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).⁶³ For other societal groups, the proposed restriction is likely to entail a non-use value associated 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 above use value estimate 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.

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.

⁶¹ 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.

⁶² 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.

⁶³ See Kolstoe and Cameron (2017) for a recent US study on the use value of bird watching.

Taking all the non-quantified benefits into consideration (Table 5.8), it seems plausible to conclude that the societal benefits of the proposed restriction outweigh its costs. A more comprehensive description of the benefits is provided in the Annex E.6.2.2.

Table 5.8. Overview of costs and benefits of a restriction on the use of lead-shot over wetlands.

Costs implied by the central-case scenario		Benefits of the proposed restriction	
Annuitised one-off costs		Use value	
Replacement of guns	€6.3m	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	€1.3m	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	€68.6m	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	€76.2m	Non-use values	
Distributional cost in terms of generated tax revenues assuming an average VAT rate of 20%	€15.2m	Protection of wildlife and ecosystem services	non-quantified
Distributional cost in terms of producer surplus gains (after VAT deduction)	Up to €25m	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	€35-61m	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 the affected type of hunting affects peatland. The actual fraction of hunting taking place on peatbogs is not known and would actually vary by Member State. There are some indications that the number of hunters involved in this would be rather low (47 000 for the UK). On the basis of this, it can be argued that the assessment in the report is likely to result in an overestimate. 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 costs of this restriction. In the absence of any European wide statistics that specifically describe in detail the number of guns available, their make 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 average mortality data derived from a study of the population effects of lead shot ingestion in 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 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.

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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 €30-60m per year.
5. On an individual level, this cost translates into additional costs of approximately €50-60 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 entails some forwarded 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 occurs outside of wetlands. Further, the proposed restriction will only prevent around 20% of the estimated annual tonnage of lead used in gunshot for hunting from being dispersed into the environment.