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Committee for Socio-economic Analysis (SEAC)

Background document - Annexes

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

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Contents

Annex A: Manufacture and uses	1
A.1. Lead shot production	1
A.1.1. Tower process	1
A.1.2. Bleimeister process.....	2
A.1.3. Wire process	2
A.2. Use of lead gunshot in or over wetlands	2
A.2.1. Hunting within or over a wetland.....	2
A.2.2. Sports shooting in or over wetlands.....	3
Annex B: Information on hazard, releases, exposure and risk	8
B.1. Identity of the substance and physical and chemical properties	8
B.1.1. Name and other identifiers of the substances	8
B.1.2. Composition of the substances	8
B.1.3. Physicochemical properties	11
B.1.4. Justification for grouping	12
B.2. Manufacture and uses (summary)	13
B.2.1. Lead shot production	13
B.2.2. Use of lead gunshot in or over wetlands	13
B.3. Classification and labelling	14
B.3.1. Regulation (EC) No 1272/2008 (CLP Regulation).....	14
B.3.2. Industry self-classification and labelling	14
B.4. Environmental fate properties	15
B.4.1. Degradation	15
B.4.2. Biodegradation	15
B.4.3. Environmental distribution	16
B.4.4. Bioaccumulation.....	41
B.4.5. Secondary poisoning.....	44
B.5. Human health hazard assessment.....	45
B.5.1. Toxicokinetics	45
B.5.2. Acute toxicity	47
B.5.3. Irritation.....	48
B.5.4. Corrosivity	48
B.5.5. Sensitisation.....	48
B.5.6. Repeated dose toxicity	48
B.5.7. Mutagenicity.....	57
B.5.8. Carcinogenicity	57
B.5.9. Toxicity for reproduction.....	57

B.5.10. Lead gunshot in food.....	58
B.5.11. Derivation of DNEL(s) and other hazard conclusions	59
B.6. Human health hazard assessment of physico-chemical properties.....	61
B.7. Environmental hazard assessment	61
B.7.1. Compartment specific hazard assessment.....	61
B.7.2. Non compartment specific effects.....	62
B.7.3. PNEC derivation and other hazard conclusions.....	86
B.8. PBT and vPvB assessment	90
B.9. Exposure assessment.....	90
B.9.1. Exposure Scenario: use of lead gunshot in or over wetlands	90
B.10. Risk characterisation	112
B.10.1. Environment (risks to birds)	112
B.10.2. Human health	131
Appendix B.1: Bioconcentration / bioaccumulation factors for lead in freshwater organisms and soil	132
Appendix B.2: Benchmark dose estimated and IQ impacts of lead.....	148
Appendix B.3: Summary of the existing legal requirements (and international agreements)	150
Annex C: Justification for action on a union-wide basis	158
Annex D: Baseline	159
D.1. Problem definition – risk to be addressed	159
D.2. Outlook without any additional risk management.....	159
D.2.1. Current quantities of lead dispersed in wetlands	159
D.2.2. Estimates of bird mortality due to lead poisoning.....	159
D.3. Additional consequences of non-action.....	160
Annex E: Impact Assessment	162
E.1. Risk Management Options.....	162
E.1.1. Proposed restriction	162
E.1.2. Other evaluated but discarded restriction options.....	172
E.1.3. Other union-wide risk management options than restriction.....	177
E.2. Alternatives.....	182
E.2.1. Description of the use and function of the restricted substances	182
E.2.2. Identification of potential alternatives/ techniques (overview of existing alternatives)	182
E.3. Risk reduction, technical and economic feasibility and availability of alternatives	184
E.3.1. Most likely alternative: steel.....	184
E.4. Restriction scenario(s).....	233
E.4.1. Proposed restriction	233
E.5. Economic impacts.....	233
E.5.1. Substitution costs.....	233

E.5.2. Enforcement costs	238
E.6. Human health and environmental impacts	238
E.6.1. Human health impacts.....	238
E.6.2. Environmental impacts	243
E.7. Other impacts.....	247
E.7.1. Social impacts.....	247
E.8. Practicality and monitorability.....	255
E.8.1. Implementability, manageability and enforceability	255
E.8.2. Monitorability.....	257
E.9. Proportionality considerations.....	260
E.9.1. Cost-effectiveness of avoiding lead releases to the environment	261
E.9.2. Cost-effectiveness of avoiding premature death in waterbirds through lead ingestion .	262
Appendix E.1 AEWA status per EU Member State	263
Appendix E.2 Analysis of the association between EU wetland habitats (as defined using the Ramsar definition) and the EU Natura 2000 network.....	265
Annex F: Assumptions, uncertainties and sensitivity analysis.....	274
Annex G: Stakeholder information	275
G.1. Consultation with Associated Industry	275
G.1.1. Direct contact with stakeholders	275
G.1.2. Participation in “targeted” meeting with stakeholders	276
<i>Scope of the restriction</i>	277
<i>Enforcement</i>	277
<i>Human and environmental hazard properties</i>	279
<i>Risk to human health, wildlife and the environment</i>	279
Environment (habitat and wildlife)—Emissions.....	279
<i>Human health exposure (humans via the environment)</i>	281
Wildlife (birds)—Population trends.....	281
Vulnerable groups (children, pregnant women and frequent game meat consumers).....	282
Follow-up	285
1. Appendix to annex G	286
Opening remarks by participants	286
G.2. Consultation with international organisations and non-EU Countries.....	289
G.3. Consultation with other EU services and institutions.....	289
G.4. Consultation with Member State Competent Authorities.....	289
G.5. Public Consultations on the restriction report	290
G.6. Public consultation on the SEAC draft Opinion	295
Annex H: REFERENCES	298

Tables

Table B-1 Identification of lead	8
Table B-2 Constituents.....	8
Table B-3 Impurities.....	9
Table B-4 Constituents.....	9
Table B-5 Impurities.....	9
Table B-6 Constituents.....	10
Table B-7 Impurities.....	11
Table B-8 Relevant physico-chemical properties of lead.	11
Table B-9 Harmonised classification for lead massive (particle size ≥ 1 mm) and lead compounds (Annex VI of CLP Regulation).....	14
Table B-10 Human health self-classification in REACH registration.....	14
Table B-11 Environmental self-classification in REACH registration.	14
Table B-12 Reported log KD, SPM values for lead in freshwaters in Europe (LDAI, 2008)	18
Table B-13 Seven general types of wetlands in the European Union (from EU, 1997)...	20
Table B-14 Ramsar Classification System for Wetland Type.	22
Table B-15 Native (regularly occurring) EU bird species associated with tundra, mire and moorland habitat.....	24
Table B-16. Wetland habitats included in Annex I of the Habitats Directive (after EC, 2007)	26
Table B-17 CORINE land cover classifications relevant to wetlands	27
Table B-18. Area of wetland and inland waters compared to Ramsar sites in EU Member States that comprise the Baltic Sea Catchment Area (based on WWF, 2008).	30
Table B-19 Coverage of broad wetland category in the European Ramsar region	31
Table B-20. Bioaccumulation factor estimates (BAF in L/kgww) for lead in freshwater organisms (LDAI, 2008).....	41
Table B-21. The range of bioaccumulation factor (BAF in L/kg ww) of lead in the mixed diet (LDAI, 2008)	42
Table B-22. Representative lead uptake rates (CSRs for lead compounds, 2015).....	46
Table B-23. Benchmark dose calculations for blood lead level (in $\mu\text{g}/\text{dL}$) associated with a 1-IQ point loss.....	51
Table B-24 Description of additional studies listed in REACH Registration	53
Table B-25. DNELs for the general population (REACH registration, 2015).....	60
Table B-26. Signs and timeline of chronic lethal lead poisoning in wildfowl (after USFWS, 1986).	73
Table B-27 Summary of Bellrose (1959) hunting vulnerability release and recovery experiments undertaken at Chautauqua National Wildlife Refuge, Illinois during the autumn and winter of 1949, 1950 and 1951 (after Bellrose, 1959).....	77
Table B-28. Summary of 'year-of-banding' mortality rate experiments Chautauqua National Wildlife Refuge, Illinois during the autumn and winter of 1949, 1950 and 1951 (after Bellrose, 1959).	78
Table B-29. Estimated percentages of North American mallard population lost as a result of lead poisoning (after Bellrose, 1959).....	79

Table B-30. Lead-shot dosage and response of each dosed eagle (after Pattee et al., 1981).	80
Table B-31 Overview of predicted -no effect-concentrations (PNEC values) for the European environmental compartments (Data compilation from by LDAI, 2008; CSRs 2015)	86
Table B-32 PNECs for secondary poisoning.	88
Table B-33 Summary of indicative thresholds for interpreting lead concentrations in various tissues types in birds and other wildlife.....	89
Table B-34. Emissions of lead from hunting (cartridges only) estimated by AMEC (2012), in tonnes.....	90
Table B-35. Lead shot density in European wetlands with waterfowl hunting (modified with data from Italy, original source: Mateo, 2009)	93
Table B-36. European species of water birds reported to have ingested lead shot (according to data available in Mateo, 2009; Pain et al., 2015). This list is not intended to be exhaustive. Other species may be affected by poisoning from lead shot, as dicussed in this section.....	98
Table B-37. Estimated Typical Daily Environmental Lead Exposures and Resulting Incremental Blood Lead Increases From Indirect Exposure via the Environment (LDAI, 2008).	109
Table B-38. Prevalence of lead shot ingestion and estimates of mortality in 17 species of wintering waterfowl in Europe (from Mateo, 2009)	115
Table B-39 Estimates of waterfowl mortality in 16 species of UK waterfowl (from Pain et al. 2015).....	118
Table B-40 Waterbird species known to ingest lead shot included in estimate of EU mortality	120
Table B-41. 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.	122
Table B-42 Estimated annual mortality of birds in the EU 28 from the ingestion of lead gunshot.	124
Table B-43 Estimated annual mortality of birds in Member States without legislation to control the risks from the use of lead gunshot in wetlands.....	124
Table B-44. Examples of comparison of the lead concentration in various tissues of wild birds with indicative thresholds of adverse effect.....	128
Table B-45. The whole-body bioconcentration factor (BCF in L/kg) of lead in freshwater organisms (LDAI, 2008)	132
Table B-46. The whole-body bioaccumulation factor (BAF in L/kg) of lead in freshwater organisms (LDAI, 2008).....	135
Table B-47. Bioaccumulation factors in soil. Lead concentrations in the biota are the product of BAF and soil Pb concentration (LDAI, 2008).	140
Table B-48. Bioaccumulation factors between soil or decomposed leaf litter and isopods. Lead concentrations in the biota are the product of BAF and soil Pb concentration (LDAI, 2008)	146
Table B-49. Benchmark Dose Calculations for the Blood Lead Level in $\mu\text{g}/\text{dL}$ associated with a 1-IQ Point Loss Using Different Model Assumptions and Blood Lead Metrics. ...	148
Table B-50. EU General Legislation controlling lead and its compounds (non-exhaustive list)	150
Table B-51. List of EU legislation related to lead and its compounds associated with human health protection (non-exhaustive list).....	153

Table B-52. List of EU environmental legislation related to lead and its compounds (non-exhaustive list)	155
Table B-53. List of International agreements related to lead and its compounds (non-exhaustive list) (EPA, 2014)	156
Table E-1 Proposed restriction	163
Table E-2 : Advantages and disadvantages of various wording options.....	170
Table E-3 Summary of rejected restriction options (compared to proposed restriction option).....	176
Table E-4. Possible other Union-wide options discarded at this stage	177
Table E-5: Approved 'non-toxic' shot in the US (USFWS).....	183
Table E-6: Shotgun cartridge products identified by a screening of online web shops in a sample of 11 Member States.	185
Table E-7 Basic parameters of lead compared with steel shot. Blue cells apply to both lead and steel. Green apply to lead, and yellow to steel. Arrows indicate the values corresponding to a 0.5 mm change of shot size (=2 US numbers).	191
Table E-8 Comparison of energy retainment of certain lead and steel shot (Source: www.remington.com)	192
Table E-9. Examples of chamber pressure according to information from the manufacturers. The sample is limited to Cal. 12.	199
Table E-10 Operating pressure, cartridge size and proofing	204
Table E-11 Advice from shotgun manufacturers on the use of steel shot in shotguns (non-exhaustive list)	206
Table E-12 Overview of tests performed by ONCFS on use of steel shot (Source: Faune & Sauvage, Avril 2004)	209
Table E-13 Comparative prices for of lead and lead-free shotgun cartridges in the EU in cal. 12 (32 gram load). Summarised after Table E.5).....	218
Table E-14. Comparative prices for lead and lead-free shotgun cartridges, cal. 12. Summarised after Thomas (2015).	219
Table E-15. 'Nontoxic' shot material approved for hunting wildfowl in the US.	220
Table E-16 Examples of advices given in a number of Member States	239
Table E-17: BMDLs derived for IQ, systolic blood pressure and chronic kidney disease (EFSA, 2013).	242
Table E-18 Overview of impacts on shot production supply chain (Source: AFEMS, ECHA's call for Evidence 2016)	252
Table E-19. Methods for monitoring the effectiveness of the proposed restriction (Source: ADAS, 2007)	257
Table E-20 Comparison of the cost-effectiveness of the proposed restriction and previous restrictions under REACH.	261
Table E-21	268

Figures

Figure A-1 Summary of the life cycle of lead in ammunition, including lead gunshot (reproduced from ILA-E, 2010).	1
Figure A-2 Principle of clay target shooting (from ILA-E, 2010)	6
Figure A-3 Diagrammatic layout of a skeet shooting field (from ILA-E, 2010).....	6
Figure A-4 Example of simulated game hunting (from ILA-E, 2010).....	7
Figure B-1 Baltic Sea Catchment Area (after WWF, 2008).	29
Figure B-2 Comparison of SPAs and wetlands in Italy.....	34

Figure B-3 Water budget in a generic wetland (after Welsch et al., 1995).....	36
Figure B-4. Hydrological features of bogs and fens (after Welsch et al., 1995).	37
Figure B-5 Relationship between blood lead levels in children and IQ deficits (KEMI, 2012; after Lanphear et al., 2005).....	50
Figure B-6. Lead exposure routes and receptors animals (adapted from Pain et al. 2015)	65
Figure B-7. Digestive tract of the geese (<i>Source: FAO, 1996</i>)	67
Figure B-8 The gizzard of a Canada goose with lead pellets and corn. <i>Image provided courtesy of the USGS National Wildlife Health Center (USGS, 1999. Field Manual of Wildlife Diseases: General Field Procedures and Diseases of Birds)</i>	69
Figure B-9 Typical “eroded” lead pellets at different stages of erosion. <i>Image provided courtesy of the USGS National Wildlife Health Center (USGS, 1999. Field Manual of Wildlife Diseases: General Field Procedures and Diseases of Birds)</i>	69
Figure B-10 Gizzard lining of a lead-poisoned mallard (green stained, left side) versus a non-poisoned one (right side). <i>Image provided courtesy of the USGS National Wildlife Health Centre (USGS, 1999)</i>	74
Figure B-11 Lesions in the gizzard (indicated by arrow) of a lead poisoned mallard. <i>Image provided courtesy of the USGS National Wildlife Health Centre (USGS, 1999)</i>	75
Figure B-12. Typical signs (e.g. abnormal positioning of the wings and neck) of acute lead poisoning in a whooper swan (<i>Cygnus cygnus</i>). Eroded lead was subsequently found in the bird’s gizzard (during necropsy). <i>Image provided courtesy of WWT (Wildfowl & Wetlands Trust)</i>	82
Figure B-13. Key parameters characterising the likelihood of bird exposure to lead shot.	101
Figure E-1: intention of restriction vis-a-vis direction of shooting	166
Figure E-2. Deviation (miss distance) (cm) between hitting point and target as a function of shooting distance (m) on TROJAN shooting simulator. Each dot represents one shot. Left: “Good” shooter. Right: “Bad” shooter. After Noer et al. (2001).....	194
Figure E-3. Development of wounding of pink-footed goose in Denmark over the period 1997-2015. After Holm et al. (2015).	195
Figure E-4. Harvest of pink-footed geese in Denmark and Norway from 1990-2014. After Madsen et al. (2015).	196
Figure E-5. Progress of chamber pressure during the firing of a shot.	201
Figure E-6. Chamber pressure and proof limits according to CIP regulations.	202
Figure E-7. Proof marks used by CIP.....	203
Figure E-8. A selection of shotgun types typically possessed by European hunters.....	213
Figure E-9 Price distributions for lead and steel shot in the EU	219
Figure E-10. Wad construction in a selection of shotgun cartridges. All calibre 12. Bottom: Lead; Middle: Steel; Top (from left): Hevishot, Tin, Tungsten, Zinc and two Bismuth. See text for details.	228
Figure E-11 Compliance assessment method (<i>Source: ADAS, 2007</i>)	260
Figure E-12: CORINE land cover classes considered to be relevant for scope of restriction	266
Figure 1-1: Comments by origin (country)	291
Figure 1-2: Comments by type of organisation	291

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 use 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.

Annex A: Manufacture and uses

Lead in gunshot and ammunition is used in a range of sporting, military and law enforcement activities. The majority of these uses are registered under REACH. The life-cycle of lead in relation to the production of lead gunshot and other ammunition is shown in Figure A-1.

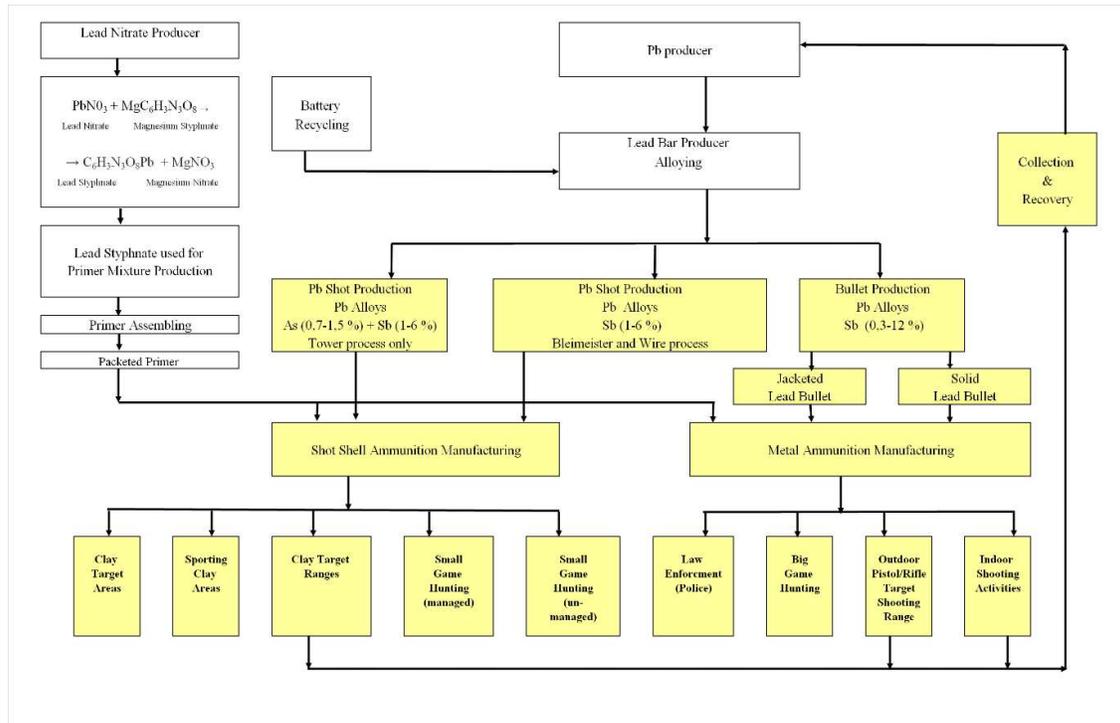


Figure A-1 Summary of the life cycle of lead in ammunition, including lead gunshot (reproduced from ILA-E, 2010).

A.1. Lead shot production

The production of lead gunshot, typically from a lead alloy containing various quantities of arsenic (As), antimony (Sb) and tin (Sn), can be broadly subdivided into tower, Bleimeister and wire processes (ILA-E, 2010; Mann et al., 1994¹ - see Figure A-1). Different processes are used to produce different sizes of lead gunshot. The tower process is included for completeness, but has been widely replaced with other more modern techniques.

A.1.1. Tower process

The tower production process is carried out in a tower typically ranging from 40 to 80 metres in height, dependent on the diameter of the shot required. This process has been largely superseded since the 1960s by the Bleimeister and wire processes described in Section A.1.2.

¹ https://www.fws.gov/lab/pdfs/mann_et.al.1994.pdf: Primary components of lead shot are lead and antimony. The amount of antimony can vary from 0.5% to 6.5% depending on size and desired hardness of the pellet. Arsenic (approximately 0.1% to 0.2%) may be added to the alloy to facilitate sphere formation, tin (approximately 0.1%) may also be an intentional inclusion in the pellet alloy.

Lead (typically as a lead alloy) is heated until molten and 'dropped' through a copper sieve high in a tower. The liquid lead forms spheres through surface tension and solidifies as it falls. The partially cooled spheres are caught at the floor of the tower in a water-filled basin. Thereafter shot are dried and further processed for roundness, size and polished (graphite coating for lubrication and to prevent oxidation). A shot tower with a 40-metre drop can produce up to number six shot (nominally 2.4mm in diameter) while an 80-metre drop can produce number two shot (nominally 3.8mm in diameter) (Lipscombe and Mungan, 2012).

A.1.2. Bleimeister process

The Bleimeister method (U.S. Patent 2978742 A, dated April 11, 1961) is a process for making lead shot in small sizes from about number seven to about number nine. Molten lead (alloy) is dripped from small orifices and dropped approximately 1 inch (2.5 centimetres) into a hot liquid, where it is then rolled along an incline and then dropped another 3 ft. (91 cm). The temperature of the liquid controls the cooling rate of the lead, while the surface tension of the liquid and the inclined surface results in highly regular spheres of lead shot.

The size of the lead shot that is produced is determined by the diameter of the orifice used to initially drop the lead and the specific lead alloy that is used. The roundness of the lead shot depends on the angle of the inclined surfaces as well as the temperature of the liquid coolant. Thereafter shot are dried and further processed for roundness, size and polished (graphite coating for lubrication and to prevent oxidation).

A.1.3. Wire process

Larger shot sizes (than can be produced using the Bleimeister method) are produced from calibrated lengths of extruded lead (alloy) wire that are fed into a die and sized into spheres by hemispherical punches. Thereafter shot are further processed in a tumbling barrel and polished (graphite coating for lubrication and to prevent oxidation).

A.2. Use of lead gunshot in or over wetlands

This Annex XV restriction report is focussed on the uses of lead gunshot in wetland environments. Further uses of lead gunshot occur outside of wetland areas but this will not be assessed as part of this restriction report. Equally, uses of other types of lead-based ammunition (e.g. rifle ammunition) will not be assessed in this restriction report.

A.2.1. Hunting within or over a wetland

Hunting can be divided essentially in two main types: small game (mainly using shotguns and shotgun cartridges) and big game (mainly using rifles and bullets). In several countries (e.g. Sweden, Denmark and Switzerland), roe deer may be hunted with shotguns.

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 most common small game species in wetlands are ducks, geese and some waders, which are mainly hunted using shotgun cartridges.

Hundreds of species of birds are ecologically dependent on wetlands for at least part of their annual cycle. Two hundred and fifty four species of water birds, globally, are protected under the Agreement on the Conservation of African-Eurasian Migratory Water birds (AEWA)². All AEWA species cross international boundaries during their migrations and require good quality habitat for their survival.

The use of lead gunshot within or over wetlands is acknowledged to adversely affect the bird species that live or feed within them. This concern has resulted in numerous national and international measures that are intended to prevent or avoid the use of lead gunshot for hunting in or over wetlands, or for hunting waterfowl species, including measures that have been adopted to meet the obligations of the AEWA. As one of the obligations of AEWA, Parties are obliged to phase out the use of lead shot for hunting in wetlands as soon as possible³.

Whilst the REACH registration Chemical Safety Report (CSR) for lead (prepared by the lead [Pb] REACH consortia) describes various professional and consumer uses of lead in ammunition, the use of lead gunshot for hunting in or over wetlands is not included 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 assessment⁴ for the use of lead in ammunition that is available on request from the Lead Registrant or the International Lead Association, but is not included in the submitted documentation (as detailed on page 489 of the REACH CSR).

This supplementary assessment identified the use of lead gunshot in or over wetlands as a 'use advised against'. This conclusion was reported to have been 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 undertaken by the registrants.

However, 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 include those that have been enacted in some Member States to prohibit or curtail the use of lead gunshot in or over certain wetlands (potentially in response to AEWA), the uses advised against detailed in the CSR is not wholly comparable to the conclusion of the supplementary assessment, and may inadvertently support the use of lead gunshot within wetland areas that are not subject to legal restrictions e.g. under one of the other identified uses (e.g. small game hunting in unmanaged areas).

A.2.2. Sports shooting in or over wetlands

Activities related to sports shooting, when practiced using lead gunshot within or in the proximity of a wetland, may result in risks to water birds and are therefore considered within the scope of this restriction report.

² <http://www.unep-aewa.org/>

³ This aim is codified in Paragraph 4.1.4 of the Action Plan to AEWA.

⁴ 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.

When considering this use a distinction should be made between shooting 'ranges' and shooting 'areas':

A.2.2.1. Shooting ranges

According to ILA-E (2010), a shooting range⁵ is defined as "an area designed and operated specifically for recreational shooting" where:

- the owner/operator of the site⁶ complies with environmental regulations;
- there is a 'remediation upon closure' plan in place; and,
- the range has a clearly defined boundary and it is assumed that lead ammunition is not allowed to be deposited outside the boundaries of the range.

A shooting range can, under this definition, be considered as technical area as defined in the ECHA Guidance document on information requirements.

ILA-E (2010) further elaborate that national environmental or other laws or ordinances in Member States vary in the extent to which deposition of lead shot outside the perimeter of the shooting *range* is permitted and in the extent to which remediation is required upon closure. The general trend is reported to be for increasing national restrictions on ammunition falling outside the range boundary. Four examples from European regions/countries (Finland, Flanders (Belgium), Germany and United Kingdom) were collected by ILA-E (2010) to illustrate the definition of a shooting *range*, as follows:

- In Finland, ownership is an important factor when remedial actions are needed. Finnish environmental legislation follows the polluter pays principle, which places the liability on the polluter (Sorvari et al., 2006). The Environmental Protection Act states that: "Any party whose activities have caused the pollution of soil or groundwater is required to restore said soil or groundwater to a condition that will not cause harm to health or the environment or represent a hazard to the environment". In the case of recreational shooting activities, the polluters are individuals belonging to a non-profit-making club, a circumstance hardly likely to be proven liability for the adverse environmental consequences of their activities. According to the current legislation, if the polluter is indigent, liability can be transferred to the landowner and thence to the municipalities and finally to the state. According to Sorvari's (2006) survey, Finnish shooting ranges are mainly privately owned (40 %). Very often the landowner is a private person or a shooting or hunting club. Communally owned ranges represent 13 %, and state owned ranges 10 %, of the total number. Ownership data were unavailable for one-third of all ranges.
- In Flanders (Belgium), shooting *ranges* for fire arms (excluding paintball shooting) are subject to a preliminary and descriptive soil examination when land is transferred from ownership or every 20 years (Heyman & Smout, 2005; VLAREBO; 1996). A preliminary soil investigation provides indications on the degree of soil pollution. Remediation depends on the degree of pollution and the time it has been established (recently or long ago). The first step in the process of remediation is a

⁵ For clarity, in the UK, "shooting range" has a narrower definition as it only refers to rifles and pistol. "shooting ground" is used for shotguns. In this report, "shooting range" is defined as areas specifically designed and operated for recreational shooting. This usually includes both rifles/pistol and shotgun ranges.

⁶ A site refers to a shooting range.

descriptive soil study which tries to find out about the dispersion of the pollution and its future evolution. Moreover, the risks of the pollution are evaluated. If pollution limits are exceeded, a soil remediation project is worked out in a second step.

- In Germany, clay target ranges need a special permit – following the “Federal Law on Environmental Protection against Noxious Intrusions” (BImSchG Bundes-Immissionsschutz-Gesetz” of March 1, 1975.). That law says in Section 6 that the authority has to check – in any case of closure – whether it is necessary to take legal measures – in the sense of remediation, or not. There are no agricultural used sites within the boundaries of the ranges (shot fall zone) in Germany. There are often agreements (with financial compensation) between the operator and the farmer not to use these sites. In many cases the operator would like to buy the sites (Prof. Crössman, personal communication).
- In the UK, most shooting is done through clubs on permanent shooting grounds that are either owned or leased. Shoots are restricted by local authority requirements about noise and shot not falling outside of shoot boundaries. Most clay target shooting in Britain is controlled by planning legislation and regulations imposed by regulatory bodies. If the land was to be used for other purposes, the responsibility for potential environmental issues is clearly set out in English law.

A.2.2.2. Shooting areas

According to ILA-E (2010), a shooting area is an “area not specifically designed and operated for shooting but where shooting activities can take place”. These areas do not necessarily comply with best practice guidelines and may not be subject to, or comply with, relevant environmental regulations.

ILE-E (2010) note that the definition of a shooting area clearly differs among the EU Member States. For example, under Flemish (Belgium) environmental legislation, shooting *areas* are defined as “shooting contests organised up to a maximum of twice per year on the same piece of land with a maximum duration of four consecutive days”. Shooting areas are exempted from the Flemish soil pollution regulation and can therefore not be considered as technical areas.

The majority of shooting activities use modern firearms with self-contained cartridges.

A.2.2.3. Sporting shooting in clay target ranges (trap and skeet)

Clay target shooting is an outdoor recreational and competitive sport which involves participants firing shotguns using cartridges of spherical pellets of lead to break flying clay targets launched into the air (see Figure A-2). Clay target shooting involves many variations of the sport in the way that targets are presented to the shooters, such as changes in the height and speed of the target, the direction of flight, and the locations of stations where shooters stand. The more common disciplines are ‘trap’ and ‘skeet’.

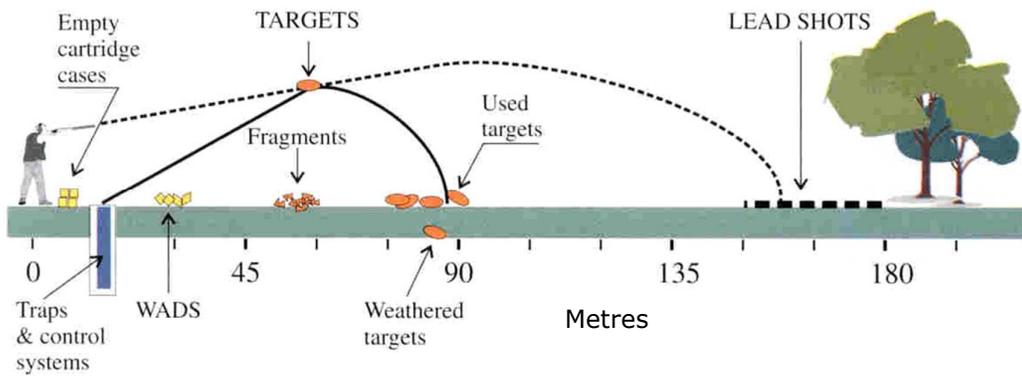


Figure A-2 Principle of clay target shooting (from ILA-E, 2010)

Trap shooting, also referred to as 'down the line' shooting, involves targets launched from machines put in a pit, all within a horizontal spread of approximately 90°. The shooters shoot at the launched target from different positions in five lanes. The five shooting stations must be arranged on a straight line at a distance 15 m behind the pit (ISSF – Rules and Regulations). Lead shot is deposited directly in front of the trap up to a distance some 210 m (AFEMS, 2002; cited by ILA-E, 2010).

Skeet shooting, also referred to as 'across the line' shooting, involves shooting two clay targets launched from two separate traps in towers located about 40 m apart. The targets are released alternately or simultaneously along intersecting flight paths and shooters stand in a series of 8 shooting stations (see Figure A-3).

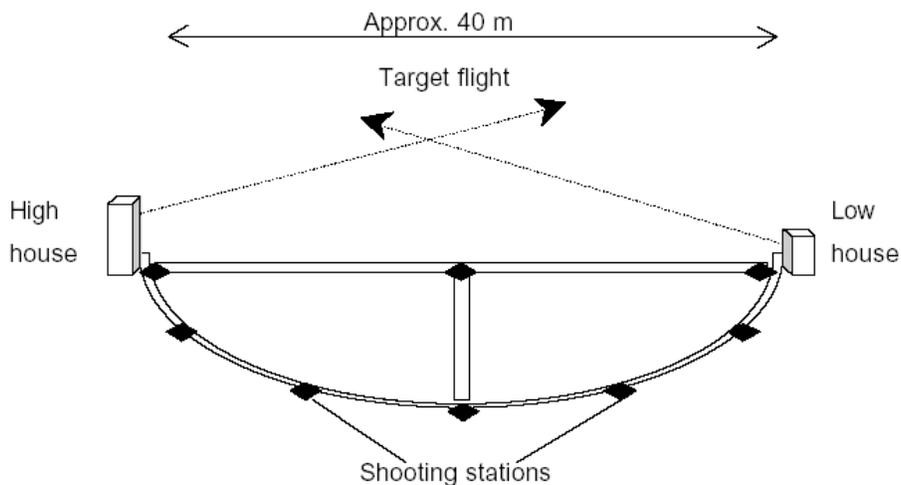


Figure A-3 Diagrammatic layout of a skeet shooting field (from ILA-E, 2010)

A.2.2.4. Sporting shooting in sporting clay ranges (simulated game hunting)

Sporting clays or simulated game shooting is a relatively "new" discipline which simulates actual field hunting by combining different target flight speeds and angles and different target sizes. The target might be crossing, climbing, incoming, outgoing, streaking high

overhead, flying low, or any combination of the above (Rooney, 2002; cited by ILA-E, 2010).

The area of lead shot deposition from sporting clays is not well-defined and a predictable pattern of deposition is unlikely due to the use of mobile traps and target flight variations (Figure A-4).

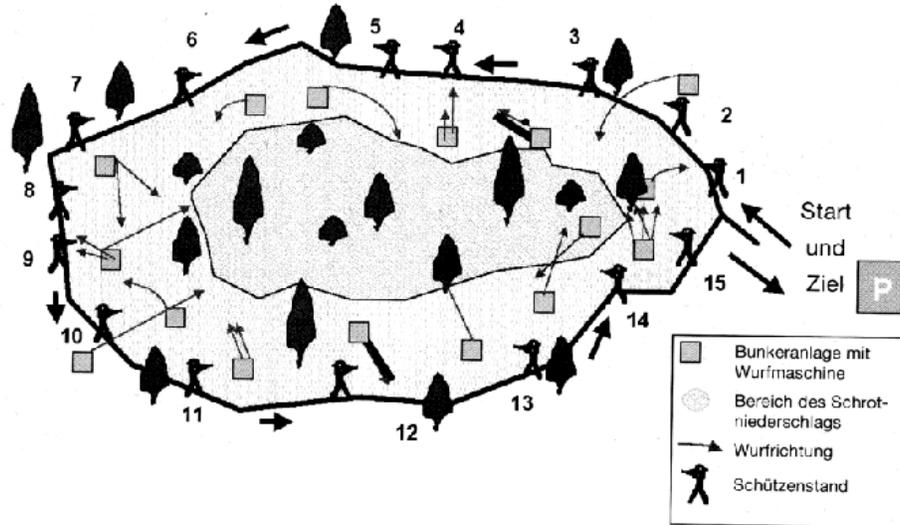


Figure A-4 Example of simulated game hunting (from ILA-E, 2010)

A.2.2.5. Sporting shooting in clay target areas

Outdoor pistol/rifle and clay target (trap and skeet) areas may to a large extent be similar to the respective shooting ranges. However, they are not specifically designed and operated for shooting. These areas do typically not comply with best practice guidelines. These areas are not subject to, or comply with, relevant environmental regulations. However, they are also less frequently used and the number of shooters and the amount used is also much smaller.

Annex B: Information on hazard, releases, exposure and risk

B.1. Identity of the substance and physical and chemical properties

B.1.1. Name and other identifiers of the substances

This Annex XV report concerns the use of zero-valent 'elemental' lead massive (particle diameter ≥ 1 mm) used as gunshot in or over wetlands and describes the risks resulting from this use to both human health and the environment. The principal risk described is that to birds through ingestion.

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 approximately 6 %) and arsenic (up to approximately 1.5 %) to produce specific properties in the lead shot, such as hardness and roundness.

Table B-1 Identification of lead

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

B.1.2. Composition of the substances

The Chemical Safety Reports submitted to ECHA for lead were screened for the relevant information (CSR for lead, 2016).

Several grades of lead massive are reported: high-purity, general and 'with arsenic'

B.1.2.1. Lead metal massive (high purity grades)

Degree of purity: 99.9 % (w/w)

Table B-2 Constituents

Constituent	Typical concentration	Concentration range	Remarks
Lead EC no: 231-100-4	99.9 % (w/w)	≥ 99.8 - ≤ 99.999 % (w/w)	

Table B-3 Impurities

Impurity	Typical concentration	Concentration range	Remarks
Different metal impurities not affecting the classification of the substance		$\geq 0.0001 - \leq 0.2$ % (w/w)	Metal impurities in the range < 0.2 % (w/w): e.g. Sb, Sn, Cu, Al, Zn, Fe, Cr, Se, Mg, Mn, Na, Ba, Sr, In, Ga, Te, Ag, Bi, Au, Ca, Pt; metal impurities in the range < 0.1 % (w/w): Ni, Co, Tl; metal impurities in the range < 0.025 % (w/w): As, Cd, Hg.

B.1.2.2. Lead metal massive (general grades)

Degree of purity: 95.0 % (w/w)

Table B-4 Constituents

Constituent	Typical concentration	Concentration range	Remarks
Lead EC no: 231-100-4	95.0 % (w/w)	$\geq 80.0 - \leq 99.99$ % (w/w)	

Table B-5 Impurities

Impurity	Typical concentration	Concentration range	Remarks
antimony EC no.: 231-146-5		$\geq 0.0 - \leq 15.0$ % (w/w)	
tin EC no.: 231-141-8		$\geq 0.0 - \leq 15.0$ % (w/w)	
sulphur EC no.: 231-722-6		$\geq 0.0 - \leq 10.0$ % (w/w)	only in elemental form
oxygen EC no.: 231-956-9		$\geq 0.0 - \leq 10.0$ % (w/w)	only in elemental form
copper EC no.: 231-159-6		$\geq 0.0 - \leq 10.0$ % (w/w)	
nickel EC no.: 231-111-4		$\geq 0.0 - \leq 1.0$ % (w/w)	
aluminium EC no.: 231-072-3		$\geq 0.0 - \leq 10.0$ % (w/w)	
zinc EC no.: 231-175-3		$\geq 0.0 - \leq 10.0$ % (w/w)	
iron EC no.: 231-096-4		$\geq 0.0 - \leq 10.0$ % (w/w)	
selenium EC no.: 231-957-4		$0.0 - \leq 5.0$ % (w/w)	

Impurity	Typical concentration	Concentration range	Remarks
cobalt EC no.: 231-158-0		≥ 0.0 - ≤ 1.0 % (w/w)	
chromium EC no.: 231-157-5		≥ 0.0 - ≤ 10.0 % (w/w)	
magnesium EC no.: 231-104-6		≥ 0.0 - ≤ 10.0 % (w/w)	
Manganese EC no.: 231-105-1		≥ 0.0 - ≤ 10.0 % (w/w)	
sodium EC no.: 231-132-9		≥ 0.0 - ≤ 10.0 % (w/w)	
Barium EC no.: 231-149-1		≥ 0.0 - ≤ 10.0 % (w/w)	
strontium EC no.: 231-133-4		≥ 0.0 - ≤ 10.0 % (w/w)	
Indium EC no.: 231-180-0		≥ 0.0 - ≤ 10.0 % (w/w)	
gallium EC no.: 231-163-8		≥ 0.0 - ≤ 10.0 % (w/w)	
tellurium EC no.: 236-813-4		≥ 0.0 - ≤ 10.0 % (w/w)	
calcium EC no.: 231-179-5		≥ 0.0 - ≤ 10.0 % (w/w)	
silicon EC no.: 231-130-8		≥ 0.0 - ≤ 10.0 % (w/w)	
Potassium EC no.: 231-119-8		≥ 0.0 - ≤ 10.0 % (w/w)	
bismuth EC no.: 231-177-4		≥ 0.0 - ≤ 2.0 % (w/w)	
Different metal impurities not affecting classification of substance		≥ 0.0 - ≤ 0.25 % (w/w)	Metal impurities in the range < 0.25 % (w/w): e.g. Pt, Ag, Au; metal impurities in the range < 0.1 % (w/w): Tl; metal impurities in the range < 0.025 % (w/w): As, Cd, Hg.

B.1.2.3. Lead metal massive (with arsenic)

Degree of purity: 95.0 % (w/w)

Table B-6 Constituents

Constituent	Typical concentration	Concentration range	Remarks
Lead EC no: 231-100-4	95.0 % (w/w)	≥ 80.0 - ≤ 100.0 % (w/w)	

Table B-7 Impurities

Impurity	Typical concentration	Concentration range	Remarks
antimony EC no.: 231-146-5		≥ 0.0 – ≤ 15.0 % (w/w)	
tin EC no.: 231-141-8		≥ 0.0 – ≤ 15.0 % (w/w)	
sulphur EC no.: 231-722-6		≥ 0.0 – ≤ 10.0 % (w/w)	only in elemental form
oxygen EC no.: 231-956-9		≥ 0.0 – ≤ 10.0 % (w/w)	only in elemental form
copper EC no.: 231-159-6		≥ 0.0 – ≤ 10.0 % (w/w)	
iron EC no.: 231-096-4		≥ 0.0 – ≤ 10.0 % (w/w)	
selenium EC no.: 231-957-4		0.0 – ≤ 5.0 % (w/w)	
cobalt EC no.: 231-158-0		≥ 0.0 – ≤ 1.0 % (w/w)	
chromium EC no.: 231-157-5		≥ 0.0 – ≤ 10.0 % (w/w)	
magnesium EC no.: 231-104-6		≥ 0.0 – ≤ 10.0 % (w/w)	
Manganese EC no.: 231-105-1		≥ 0.0 – ≤ 10.0 % (w/w)	
sodium EC no.: 231-132-9		≥ 0.0 – ≤ 10.0 % (w/w)	
Barium EC no.: 231-149-1		≥ 0.0 – ≤ 10.0 % (w/w)	

B.1.3. Physicochemical properties

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

Table B-8 Relevant physico-chemical 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)	

Property	Results	Value used for CSA / Discussion
	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

B.1.4. 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 gunshot⁷. However, the identity of these lead-containing substances are not elaborated in this Annex XV report.

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

⁷ At least one MS with national legislation covers lead and its compounds.

B.2. Manufacture and uses (summary)

Manufacture and uses of lead gunshot are outlined in detail in Section A.

B.2.1. Lead shot production

The production of lead gunshot (typically from a lead containing alloy) can be broadly subdivided into tower, Bleimeister and wire processes. Different processes are used to produce different sizes of lead gunshot. The tower process is included for completeness, but has been widely replaced with other techniques.

B.2.2. Use of lead gunshot in or over wetlands

This Annex XV restriction report is focussed on the uses of lead gunshot in wetland environments. Further uses of lead gunshot occur outside of wetland areas but this will not be assessed as part of this restriction report. Equally, uses of other types of lead-based ammunition (e.g. rifle ammunition) will not be assessed in this restriction report.

The uses considered are:

- Hunting within a wetland or where spent gunshot would fall within a wetland
- Sports shooting within a wetland or where spent gunshot would fall within a wetland

B.3. Classification and labelling

B.3.1. Regulation (EC) No 1272/2008 (CLP Regulation)

There are harmonised classifications for lead massive (particle diameter ≥ 1 mm) according to Annex VI of the CLP Regulation (9th ATP)⁸. These classifications are given in Table B-9 below:

Table B-9 Harmonised classification for lead massive (particle size ≥ 1 mm) and lead compounds (Annex VI of CLP Regulation).

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		

B.3.2. Industry self-classification and labelling

In addition to the harmonised classifications described in Section B.3.1 the REACH registration dossier for lead includes several additional human health and environmental classifications for the various grades of lead massive described in Section B.1.2.

B.3.2.1. Human health self-classification in REACH registration

Table B-10 Human health self-classification in REACH registration.

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

B.3.2.2. Environmental self-classification in REACH registration

Table B-11 Environmental self-classification in REACH registration.

Hazard class and category code	Hazard Statement
Aquatic Chronic 2	H411: Toxic to aquatic life with long-lasting effects – <i>applicable to lead massive with arsenic grade only</i>

⁸ Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. OJ L 353, 31.12.2008, p.1.

B.4. Environmental fate properties

The information presented in this section includes data from the Voluntary Risk Assessment (VRAR) on lead and lead compounds (LDAI, 2008), the 2014 Danish Environmental Protection Agency (EPA, 2014) survey on lead and lead compounds, REACH registration dossiers as well as the report prepared by the US Sporting Arms and Ammunition Manufacturers' Institute (SAAMI, 1996). Specific information on the environmental fate properties of lead shot in wetlands are presented in Section B.4.3.3.

Lead is naturally present in the environment (resulting in a background concentration of lead in all environmental compartments, including biota). Chemical processes affect the speciation of lead in the environment which, in turn, influences exposure and effects (LDAI, 2008).

Information on the environmental fate and behaviour of lead is based on either monitoring data for lead in water, soil, sediment, suspended matter and biota or the results of speciation studies with lead (di-)nitrate and lead chloride. Data are expressed as elemental (metallic) lead concentrations and grouped together in a read-across approach.

B.4.1. Degradation

The classic standard testing protocols on hydrolysis and photo-transformation are not applicable to lead and inorganic lead compounds. This was recognised in the Guidance to Regulation (EC) No 1272/2008 Classification, Labelling and Packaging⁹, of substances and mixtures (metal annex):

"Environmental transformation of one species of a metal to another species of the same does not constitute degradation as applied to organic compounds and may increase or decrease the availability and bioavailability of the toxic species. However as a result of naturally occurring geochemical processes metal ions can partition from the water column. Data on water column residence time, the processes involved at the water – sediment interface (i.e. deposition and re-mobilisation) are fairly extensive, but have not been integrated into a meaningful database. Nevertheless, using the principles and assumptions discussed above in Section IV.1, it may be possible to incorporate this approach into classification."

B.4.1.1. Abiotic degradation

In general, (abiotic) degradation is not relevant for inorganic substances. The formation of different lead species (e.g. hydroxides) occurs under different environmental conditions. However, the exposure and risk assessment in this restriction report will not differentiate between the properties of the various lead species (pooling of different speciation forms). This "elemental-based" assessment (pooling all speciation forms together) can be considered as a worst-case assumption.

B.4.2. Biodegradation

Similar to abiotic degradation, biotic processes may alter (transform) the speciation of lead in the environment and biota, but will not eliminate it. An elemental-based

⁹ https://echa.europa.eu/documents/10162/13562/clp_labelling_en.pdf

assessment (pooling all speciation forms together), can be considered as a worst-case assumption.

According to Annex VII of REACH and Chapter R.7B of the ECHA REACH Guidance (2008)¹⁰, the requirements for “ready biodegradability” can be waived if the substance is inorganic.

B.4.3. Environmental distribution

B.4.3.1. Lead speciation

Lead ions have more than one oxidation state in the environment. The principal ionic form is Pb (II) (Pb^{2+}), which is more stable than Pb (IV) (Pb^{4+}). In all environmental compartments (water, sediment, soil), the binding affinities of Pb(II) with inorganic and organic matter are dependent on pH, the oxidation-reduction potential in the local environment, and the presence of competing metal ions and inorganic anions.

Lead in its metallic form (Pb^0) needs to be transformed to its ionic forms to become available for uptake by biota. The rate and extent of the transformation/dissolution of lead in massive and various powder form have been assessed in standardised transformation/dissolution tests (in accordance to the OECD guidance, Annex 10 of the GHS). The release of soluble lead- ions from Pb^0 is greater at lower pH, as follows:

For massive lead materials, transformation/dissolution tests were carried out at pH 6 in accordance to the OECD protocol on transformation/dissolution¹¹. The results were used to derive the release of lead-ions from 1 mm particles at loadings of 1, 10 and 100 mg/L.

7-day transformation/dissolution testing of a massive particle of 1 mm diameter at pH 6, and a loading of 100 mg/L results in a total release of 428.9 μg Pb/L.

The results from 28 day transformation/dissolution test of a massive particle of 1 mm diameter at pH 6, and a loading of 1 mg/L, corresponds to 14.2 μg Pb/L.

For lead powders, transformation/dissolution tests were carried out on fine lead powders (< 75 μm ,) in accordance to OECD protocol at pH 6, 7 and 8.

The release of lead to aqueous medium at 24 h for the 100 mg/L loading at pH 6 was 3 211.2 μg /L. For the 100 mg/L loading at pH 7 and 8, the average concentrations of lead released at 24 h was 607 and 187.5 μg /L, respectively.

Lead can precipitate in a variety of forms including hydroxides, sulphates, sulphides, carbonates, and phosphates. The factors that directly control solubility are pH, oxidation-reduction (redox) conditions and the concentration of other components that determine solubility (e.g. dissolved organic carbon). As these parameters are highly variable from one location to another, site-specific conditions determine how much lead can be solubilised in the environment. In general, lead is much more soluble under acidic (low pH) conditions than at neutral or alkaline (high pH) conditions, but this can change under a variety of situations. Some precipitates, especially phosphates and sulphides, are particularly effective at controlling lead solubility, often resulting in maintenance of very low lead concentrations in water. Factors controlling solubility can substantially reduce the

¹⁰ https://echa.europa.eu/documents/10162/13632/information_requirements_r7b_en.pdf

¹¹ http://www.ime.fraunhofer.de/content/dam/ime/de/documents/AE/OECD_ENV_JM_MONO_2001_9.pdf

bioavailability of lead in sediments and/or soils. Physico-chemical conditions establish upper limits on the amount of lead that can be dissolved in surface or ground water.

Lead can be adsorbed by a variety of materials including organic matter, iron and manganese oxyhydroxides, clays, carbonates, and sulphides. In general, neutral or slightly alkaline conditions are expected to give rise to low mobility conditions and only acidic conditions will result in substantial mobility. However, there are exceptions to this generality, as adsorption processes are highly dependent on site-specific conditions.

Complexation/chelation and transport of particulates that contain lead may increase physical movement of lead. Particulate transport mechanisms may be effective in altering the distribution of lead over time but may not have a substantial effect on bioavailability.

In general, site-specific hydrologic and geologic conditions can greatly influence lead mobility and also atmospheric conditions can weather metallic lead into more soluble and mobile forms.

B.4.3.2. Aquatic compartment

Lead enters the aquatic environment via municipal and industrial wastewater, runoff and leaching from natural and anthropogenically burdened soils, atmospheric deposition and corrosion and abrasion of lead containing materials (EPA-Denmark, 2014). Hunting with lead-based shot in wetlands also leads to direct dispersion of lead to the aquatic environment (As described further in Section A.2.1).

The amount of lead that is dissolved in surface waters depends on the pH of the water and the properties of specific lead salts. For example, solid lead dissolves relatively slowly (see section above), whereas the solubility of lead oxide is 107 mg/L at 25°C. At pH values at or below 6.5 most of dissolved lead is in the form of the free Pb^{2+} ion. In waters containing natural organic matter (NOM), organically bound lead also influences speciation and bioavailability, with increasing amounts of NOM generally reducing the concentration of the free Pb^{2+} ion. Sulphate ions limit the dissolved lead concentration through the formation of poorly soluble lead sulphate. At higher pH levels lead carbonates ($PbCO_3$ and $Pb_2(OH)_2CO_3$), determine the amount of lead in solution. The carbonate concentration is in turn dependent upon the partial pressure of carbon dioxide, pH, and temperature.

In most surface and ground waters, the concentration of dissolved lead is low because the lead will form complexes with anions in the water such as hydroxides, carbonates, sulphates, and phosphates that have low water solubility and these complexes will precipitate out of the water column. A significant fraction of lead in surface water is expected to be in an undissolved form, which can consist of colloidal particles or larger undissolved particles of lead carbonate, lead oxide, lead hydroxide, or other lead compounds incorporated in other components of surface particulate matters from runoff. Lead may also occur either as sorbed ions or surface coatings on sediment mineral particles, or it may be carried as a part of suspended organic matter in water. The ratio of lead in suspended solids to lead in dissolved form has been found to vary from 4:1 in rural streams to 27:1 in urban streams (LDAI, 2008).

An overview of the partitioning coefficients ($\log K_D$ (L/kg)) for lead between freshwater and suspended particulate matter (SPM) (LDAI, 2008) is provided in Table B-12.

Table B-12 Reported log K_D , SPM values for lead in freshwaters in Europe (LDAI, 2008)

Location	Log K_D (L/kg)	Remarks	Reference
Four Dutch Lakes	6.0	average	Koelmans and Radovanovic, 1998
Calder River, UK	4.45 - 5.98	min-max range	Lofts and Tipping, 2000
Nidd River, UK	4.69 - 6.25	min-max range	
Swale River, UK	4.58 - 6.20	min-max range	
Trent River, UK	4.61 - 6.06	min-max range	
All rivers	5.41	observed mean	
All rivers	5.71	predicted mean	
Scheldt, Belgium	5.3	salinity of 1.5 ppm	Nolting et al., 1999
Po River, Italy	5.5	median value	Pettine et al., 1994
Dutch freshwater	5.81	mean	Stortelder et al., 1989; in Crommentuyn et al., 1997
Upland-influenced river water, UK	4.6	modelled value	Tipping et al., 1998
Low-salinity water, UK	5.5	modelled value	
7 freshwater locations in The Netherlands	5.93		Venema, 1994; in Crommentuyn et al., 1997
54 Czech rivers / 119 locations	5.44	median K_D	Vesely et al., 2001
	5.18	median $K_A^{(1)}$	
RANGE	4.45 - 6.25		

K_A : based on the acid soluble concentration for the calculation of local and regional exposure concentrations the median log $K_{D, SPM}$ value of 5.47 is selected. This value corresponds with a $K_{D, SPM}$ of 295,121 l/kg. For freshwater sediments, the selected K_D value was 153 848 L/kg (Log K_D : 5.19).

B.4.3.3. 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 depend completely on the hydrological cycle (both natural and regulated by humans) 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 diverse ecosystem services. They are carbon sinks, provide water resources (drinking and agriculture), provide fisheries, act as a buffer against flooding, treat wastewater, support transport conduits, act as a source of hydroelectricity, and provide resources such as peat, game and berries. They also have significant recreational value (EEA, 2000).

B.4.3.3.1. Defining wetlands

Different international bodies often have slightly different definitions of what constitutes a wetland. Wetlands are not exclusively land or water environments. They encompass both environments at the same time, or at least most of the time, as there are also wetlands that can be seasonally aquatic or terrestrial (EC, 2007).

However, in general, wetlands are those areas where water is the primary factor controlling the environment and the associated habitats. They occur where the water table is at or near the surface of the land, or where the land is covered by shallow water.

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

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

Whilst there is no single harmonised definition of a wetland habitat, the most widely accepted definition is the one set out in the text of the Convention on Wetlands, signed in Ramsar, Iran, in 1971 (EC, 2007). As well as the Ramsar Convention, wetlands are conceptually or operationally defined under various existing EU-relevant legislation, such as the Habitats Directive, or EU environmental monitoring schemes, such as the CORINE Land Use programme.

Table B-13 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), the Ebro and Po deltas are among the best known.
Rivers and floodplains	The periodic flooding of the area between the river bed and the raised land on the edge of a valley used to be a common feature of many European rivers and streams. Very few rivers are still allowed to spread out periodically over floodplains that include temporary sand and gravel banks, wet meadows, grassy marshes, flooded forest, and oxbow lakes. Where flooding has been regulated, only small areas of riverine forests and floodplain wetlands remain. The French Loire is probably one of the last remaining larger rivers with substantial parts of its floodplains remaining.
Lakes	Lakes and ponds are characterised by their open water surface. They are formed in basins with badly drained soils or by geological faults, landslides or glacial action. Most European lakes are permanent with freshwater but, especially in the Mediterranean climate of southern Europe, temporary lakes with brackish water are more widespread. Along shallow lakeshores, light that penetrates to the bottom allows the development of rooted vegetation creating biologically rich transition zones between open water and dry land.

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

Ramsar Convention

The Convention on Wetlands of International Importance, generally referred to as the 'Ramsar Convention', is an intergovernmental treaty that provides a framework for the international conservation and wise use of wetlands and their resources.

The Convention was adopted in the Iranian city of Ramsar in 1971 and came into force in 1975. Since then, almost 90 % of UN Member States and all EU Member States have acceded to 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 B-14).

The Ramsar definition of a wetland is acknowledged to be comprehensive and inclusive, comprising marine, coastal, inland and human-made wetlands (including rice fields) as well as many upland habitats, such as 'peatlands' and alpine wetlands (created from snowmelt). Of particular interest in relation to this restriction proposal are peatlands (Ramsar Wetland Types: I, E, K, U, Xp in Table B-14) because of their suitability for many wetland birds (particularly waders) and the fact that they are frequently associated with 'terrestrial' hunting/shooting, rather than waterbird hunting.

Table B-15 lists the 67 native, regularly occurring bird species that are associated with 'tundra, mires and moorland' in the EU according to Birdlife International (Wouter Langhout, pers. com.). This list includes waterbirds (many listed on AEWA) as well as many predatory and scavenging species that could be at risk of secondary poisoning.

Ramsar guidance (Ramsar, 2002) defines peatlands as '*ecosystems with a peat deposit that may currently support a vegetation that is peat-forming, may not, or may lack vegetation entirely*'. Under the Ramsar guidance peatland includes both 'active' peat-forming peatlands (termed mires) and peatlands that are no longer accumulating peat ('dry' peatland, including drained upland moorland). The key characteristic of a peatland is the presence of peat or vegetation capable of forming peat.

Table B-14 Ramsar Classification System for Wetland Type.

Marine/Coastal Wetlands	
A	Permanent shallow marine waters in most cases less than six metres deep at low tide; includes sea bays and straits.
B	Marine subtidal aquatic beds ; includes kelp beds, sea-grass beds, and tropical marine meadows.
C	Coral reefs.
D	Rocky marine shores ; includes rocky offshore islands, sea cliffs.

E	Sand, shingle or pebble shores; includes sand bars, spits and sandy islets; includes dune systems and humid dune slacks.
F	Estuarine waters; permanent water of estuaries and estuarine systems of deltas.
G	Intertidal mud, sand or salt flats.
H	Intertidal marshes; includes salt marshes, salt meadows, saltings, raised salt marshes; includes tidal brackish and freshwater marshes.
I	Intertidal forested wetlands; includes mangrove swamps, nipah swamps and tidal freshwater swamp forests.
J	Coastal brackish/saline lagoons; brackish to saline lagoons with at least one relatively narrow connection to the sea.
K	Coastal freshwater lagoons; includes freshwater delta lagoons.
Zk(a)	Karst and other subterranean hydrological systems; marine/coastal
Inland Wetlands	
L	Permanent inland deltas.
M	Permanent rivers/streams/creeks; includes waterfalls
N	Seasonal/intermittent/irregular rivers/streams/creeks.
O	Permanent freshwater lakes (over 8 ha); includes large oxbow lakes.
P	Seasonal/intermittent freshwater lakes (over 8 ha); includes floodplain lakes.
Q	Permanent saline/brackish/alkaline lakes.
R	Seasonal/intermittent saline/brackish/alkaline lakes and flats.
Sp	Permanent saline/brackish/alkaline marshes/pools.
Ss	Seasonal/intermittent saline/brackish/alkaline marshes/pools.
Tp	Permanent freshwater marshes/pools; ponds (below 8 ha), marshes and swamps on inorganic soils; with emergent vegetation water-logged for at least most of the growing season.
Ts	Seasonal/intermittent freshwater marshes/pools on inorganic soils; includes sloughs, potholes, seasonally flooded meadows, sedge marshes.
U	Non-forested peatlands; includes shrub or open bogs, swamps, fens.
Va	Alpine wetlands; includes alpine meadows, temporary waters from snowmelt.
Vt	Tundra wetlands; includes tundra pools, temporary waters from snowmelt.

W	Shrub-dominated wetlands ; shrub swamps, shrub-dominated freshwater marshes, shrub carr, alder thicket on inorganic soils.
Xf	Freshwater, tree-dominated wetlands ; includes freshwater swamp forests, seasonally flooded forests, wooded swamps on inorganic soils.
Xp	Forested peatlands ; peatswamp forests.
Y	Freshwater springs ; oases
Zg	Geothermal wetlands
Zk(b)	Karst and other subterranean hydrological systems ; inland
Human-made wetlands	
1	Aquaculture (e.g. fish/shrimp) pond .
2	Ponds ; includes farm ponds, stock ponds, small tanks; (generally below 8 ha).
3	Irrigated land ; includes irrigation channels and rice fields.
4	Seasonally flooded agricultural land (including intensively managed or grazed wet meadow or pasture).
5	Salt exploitation sites ; salt pans, salines, etc.
6	Water storage areas ; reservoirs/barrages/dams/impoundments (generally over 8 ha).
7	Excavations ; gravel/brick/clay pits; borrow pits, mining pools.
8	Wastewater treatment areas ; sewage farms, settling ponds, oxidation basins, etc.
9	Canals and drainage channels, ditches.
Zk(c)	Karst and other subterranean hydrological systems , human-made

Note: "floodplain" is a broad term used to refer to one or more wetland types, which may include examples from the R, Ss, Ts, W, Xf, Xp, or other wetland types. Some examples of floodplain wetlands are seasonally inundated grassland (including natural wet meadows), shrublands, woodlands and forests. Floodplain wetlands are not listed as a specific wetland type herein.

Table B-15 Native (regularly occurring) EU bird species associated with tundra, mire and moorland habitat.

Scientific name
<i>Gavia stellate</i> , <i>Gavia arctica</i> , <i>Gavia immer</i> , <i>Gavia adamsii</i> , <i>Cygnus columbianus</i> , <i>Anser fabalis</i> , <i>Anser brachyrhynchus</i> , <i>Anser albifrons</i> , <i>Anser erythropus</i> , <i>Branta leucopsis</i> , <i>Branta bernicla</i> , <i>Anas crecca</i> , <i>Anas acuta</i> , <i>Aythya marila</i> , <i>Clangula hyemalis</i> , <i>Melanitta nigra</i> , <i>Melanitta fusca</i> , <i>Circus cyaneus</i> , <i>Buteo lagopus</i> , <i>Falco columbarius</i> , <i>Falco rusticolus</i> , <i>Falco peregrinus</i> , <i>Lagopus</i> , <i>Lagopus muta</i> , <i>Grus</i> , <i>Eudromias morinellus</i> , <i>Pluvialis apricaria</i> , <i>Pluvialis squatarola</i> , <i>Calidris canutus</i> , <i>Calidris alba</i> , <i>Calidris minuta</i> , <i>Calidris temminckii</i> , <i>Calidris maritima</i> , <i>Calidris alpina</i> , <i>Calidris falcinellus</i> , <i>Calidris</i>

Scientific name

pugnax, Lymnocyptes minimus, Gallinago, Gallinago media, Limosa, Limosa lapponica, Numenius phaeopus, Numenius arquata, Tringa erythropus, Tringa glareola, Arenaria interpres, Phalaropus lobatus, Phalaropus fulicarius, Stercorarius pomarinus, Stercorarius parasiticus, Stercorarius longicaudus, Catharacta skua, Xema sabini, Bubo scandiacus, Eremophila alpestris, Anthos pratensis, Anthus cervinus, Anthus petrosus, Motacilla citreola, Luscinia svecica, Turdus torquatus, Aegithalos caudatus, Carduelis flavirostris, Calcaeus lapponicus, Plectrophenax nivalis, Emberiza pusilla, Emberiza aureola

EU Habitats Directive (92/43/EEC)

The Council Directive 92/43/EEC¹² of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora aims to promote the maintenance of biodiversity, taking account of economic, social, cultural and regional requirements. It forms the cornerstone of Europe's nature conservation policy with the Birds Directive¹³ and establishes the EU wide Natura 2000¹⁴ ecological network of protected areas.

There are various wetland habitats listed in Annex I of the Habitats Directive (92/43/EC). These are outlined in Table B-16, which is based on EC (2007). The Interpretation Manual of European Union Habitats (EC, 2013) aims to clear any ambiguities in the interpretation of the habitat types listed in Annex I of the regulation in the EU-28, including interlinks with corresponding habitat classification under existing national or regional schemes.

These habitats are largely identified by the plant composition and in some cases by a range of ecological characteristics (EC, 2007). In all, the Directive lists some 40 wetland habitat types (EC, 2007).

¹² <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31992L0043>

¹³ http://ec.europa.eu/environment/nature/legislation/birdsdirective/index_en.htm

¹⁴ http://ec.europa.eu/environment/nature/natura2000/index_en.htm

Table B-16. Wetland habitats included in Annex I of the Habitats Directive (after EC, 2007)

Code	Habitat
1. Coastal and halophytic habitats	
1130	Estuaries
1140	Mudflats and sandflats not covered by seawater at low tide
1150*	Coastal lagoons
1160	Large shallow inlets and bays
1630	Boreal Baltic coastal meadows
1650	Boreal Baltic narrow inlets
3. Freshwater habitats	
31, 32	Standing water, running water and all listed habitat sub-types
7. Raised bogs, mires and fens^a	
71, 72, 73	Sphagnum acid bogs (including raised, blanket and quaking bogs), calcareous fens, boreal mires and all listed habitat sub-types
9. Forests	
9030 ^b	Natural forests of primary succession stages of land upheaval coast
91D0 ^b	Bog woodland
91E0 ^b	Alluvial forests with <i>Alnus glutinosa</i> and <i>Fraxinus excelsior</i> (<i>Alno-Padion</i> , <i>Alnion incanae</i> , <i>Salicion albae</i>)
91F0 ^b	Riparian mixed forests of <i>Quercus robur</i> , <i>Ulmus laevis</i> and <i>Ulmus minor</i> , <i>Fraxinus excelsior</i> or <i>Fraxinus angustifolia</i> , along the great rivers (<i>Ulmion minoris</i>)
92A0	<i>Salix alba</i> and <i>Populus alba</i> galleries
92B0	Riparian formations on intermittent Mediterranean water courses with <i>Rhododendron ponticum</i> , <i>Salix</i> and others.
92C0	<i>Plantanus orientalis</i> and <i>Liquidamber orientalis</i> woods (<i>Platanion orientalis</i>)
93D0	Southern riparian galleries and thickets (<i>Nerio-Tamaricetea</i> and <i>Securinegion tinctoriae</i>)

Notes: a: Bogs, fens and mires are also widely referred to as peatlands. b: Priority for conservation

EU CORINE land cover project

The coordination of information on the environment (CORINE) programme was initiated by the European Union in 1985. Parts of the programme, including the CORINE land cover (CLC) project, were subsequently taken over by the European Environment Agency.

The CLC project developed an inventory of EU land cover based on 44 standardised 'classes', initially for 12 EU Member States, including several that directly and indirectly relate to wetlands habitats (Table B-17). The CLC inventory has been extended and updated, most recently in 2016 (2012 data), to cover 39 European Environment Agency countries (including all EU Member States). GIS datasets are freely available via the EEA¹⁵.

Table B-17 CORINE land cover classifications relevant to wetlands

Level 1	Level 2	Level 3
2. Agricultural areas	2.1 Arable land	2.1.3 Rice fields Land developed for rice cultivation. Flat surfaces with irrigation channels. Surfaces regularly flooded.
	2.3 Pastures	2.3.1 Pastures ^a Dense, predominantly graminoid grass cover, of floral composition, not under a rotation system. Mainly used for grazing, but the fodder may be harvested mechanically. Includes areas with hedges
4. Wetlands	4.1 Inland wetland Non-forested areas either partially, seasonally or permanently waterlogged. The water may be stagnant or circulating.	4.1.1 Inland marshes Low-lying land usually flooded in winter, and more or less saturated by water all year round.
		4.1.2 Peatbogs Peatland consisting mainly of decomposed moss and vegetable matter. May or may not be exploited.
	4.2 Coastal wetlands Non-wooded areas either tidally, seasonally or permanently waterlogged with brackish or saline water.	4.2.1 Salt marshes Vegetated low-lying areas, above the high-tide line, susceptible to flooding by sea water. Often in the process of filling in, gradually being colonised by halophilic plants.
4.2.3 Intertidal flats Generally unvegetated expanses of mud, sand or rock lying between high and low water-marks. On contour on maps.		
5. Water bodies	5.1 Inland waters	5.1.1 Water courses

¹⁵ <http://land.copernicus.eu/pan-european/corine-land-cover/clc-2012>

Level 1	Level 2	Level 3
		Natural or artificial water-courses serving as water drainage channels. Includes canals. Minimum width to include: 100 m.
		5.1.2 Water bodies Natural or artificial stretches of water.
	5.2 Marine waters	5.2.1 Coastal lagoons Unvegetated stretches of salt or brackish waters separated from the sea by a tongue of land or other similar topography. These water bodies can be connected with the sea at limited points, either permanently or for parts of the year only.
		5.2.2 Estuaries The mouth of a river within which the tide ebbs and flows.

Notes: a: Wet pasture which may be flooded at certain times of the year (winter waterlogging of between 10 and 30 cm depth) and which is used for grazing is classified under CORINE as pasture rather than wetlands. It is not possible to differentiate dry and wet pastures. Therefore exclusion of this class will underestimate the area of wetlands in the EU, whilst including it would significantly overestimate it.

Ramsar sites and the EU Natura 2000 network

When a country accedes to the Ramsar Convention, it must designate at least one wetland site as a Wetland of International Importance.

According to Article 2.1 of the Convention: 'Each Contracting Party shall designate suitable wetlands within its territory for inclusion in a List of Wetlands of International Importance, hereinafter referred to as "the List"[...] The boundaries of each wetland shall be precisely described and also delimited on a map and they may incorporate riparian and coastal zones adjacent to the wetlands, and islands or bodies of marine water deeper than six metres at low tide lying within the wetlands [...].'

Article 2.2 states: 'Wetlands should be selected for the List on account of their international significance in terms of ecology, botany, zoology, limnology or hydrology.' Any wetland which meets at least one of the Criteria for Identifying Wetlands of International Importance can be designated by the appropriate national authority to be added to the Ramsar List.

Key information about each Ramsar Contracting Party (Member State) and the number of Ramsar sites designated in each Member State, is publicly available¹⁶. Typically, the surface area of wetlands within an EU Member State designated as Ramsar sites is limited

¹⁶ <http://www.ramsar.org/country-profiles>

to a small proportion of the overall surface area within a Member State that would be considered to be a wetland according to the Ramsar definition.

For example, Italy currently has 53 designated Ramsar sites, with a total surface area of 60 759 hectares (608 km²). This is equivalent to 11.8 % of the total territory that is considered to be a wetland in Italy¹⁷ (ISPRA, 2014).

Similarly, WWF (2008) have reported that, as a whole, Ramsar sites in the Baltic Sea Catchment Area¹⁸ (Figure B-1) comprise a total of 3 % of the wetlands in the catchment. The level of representation is similar for most countries; except for Latvia, Estonia and Denmark for which 8 %, 9 % and 21 %, respectively are Ramsar sites. The level of representation for EU Member States within the catchment area is reported to range from zero to 20 %. The mean representation is 6 % ().



Figure B-1 Baltic Sea Catchment Area (after WWF, 2008).

¹⁷ The percentage of the Italian territory classified as wetland (land use) is: 1.7% (ISPRA, 2014). The percentage of Italian territory that would be considered a wetland under the Ramsar convention is likely to be greater than this.

¹⁸ Countries that are part of the Baltic Sea Catchment (WWF, 2008): Belarus, Czech Republic, Denmark, Estonia, Finland, Germany, Norway, Latvia, Lithuania, Poland, Slovakia, Russia, Sweden, Ukraine.

Table B-18. Area of wetland and inland waters compared to Ramsar sites in EU Member States that comprise the Baltic Sea Catchment Area (based on WWF, 2008).

Member State	% of Member State within catchment	% of total catchment area within Member State	Surface areas of wetlands and inland waters within catchment (km ²)	Surface area of wetlands and inland waters within Ramsar sites (km ²)	% of wetlands and inland waters (within the catchment) within Ramsar sites
Czech Republic	10	0.5	800	24	3.0
Denmark	75	1.9	3 000	616	20.5
Estonia	100	2.6	12 300	1 109	9.0
Finland	89	17.6	68 600	2 152	3.1
Germany	8	1.6	2 300	64	2.8
Latvia	100	3.8	9 500	788	8.2
Lithuania	100	3.8	7 700	302	3.9
Poland	99	18.1	23 400	400	1.7
Slovakia	5	5	100	-	-
Sweden	92	24.3	122 900	2 710	2.2
Total	68	8	250 600	8 165	6

According to criterion n.5 of the Ramsar convention, a wetland can be considered to be 'internationally important' if it regularly supports 20 000 or more waterbirds. However, meeting one of the nine criteria of Ramsar convention¹⁹, does not imply that a wetland **must** be designated as a Ramsar site.²⁰ Examples are the Trasimeno and Laghi di Lesina e Varano wetlands in Italy, which are not designated as Ramsar sites despite fulfilling criterion n.5 (ISPRA, 2014).

An assessment of the proportion of European wetlands covered by Ramsar sites is provided by Niviet Frazier (2004), based on 'best estimates' of broad wetland types and the extent that they have been covered by Ramsar sites within the Ramsar Europe region. On the basis of their assessment it can be concluded that approximately 17 % of European wetlands occur within Ramsar sites (see Table B-19). Coverage is variable between Member States, with some having designated all their wetlands (100 % Malta, 2 sites) whilst others have designated as little as 1 % (Bulgaria, 5 sites). The assessment was done on the basis of 2004 data.

¹⁹ http://www.ramsar.org/sites/default/files/documents/library/ramsarsites_criteria_eng.pdf

²⁰ The risk reduction potential of a restriction on the use of lead in gunshot defined on the basis of existing Ramsar sites is discussed in Section E.1.2.

Table B-19 Coverage of broad wetland category in the European Ramsar region

	BEST ESTIMATES					COVERAGE INFORMATION			RAMSAR INFORMATION	
	Marine/Coastal (ha)	Inland (ha)	Manmade (ha)	Unspecified Wetland Type (ha)	Best Estimate Total (ha)	% of land area (marine areas excluded) covered by these wetlands	# of datasets accessed per country ^{1,2}	# of datasets which can be regarded as comprehensive in cover per country ⁴	Total area of Ramsar sites	# Ramsar sites
EUROPEAN REGION										
ALBANIA	15.000	35.000	unknown	60.215	60.215	2,20%	7	2?	20.000	1
ANDORRA	no data	no data	no data		no data	no data	0	0	0	0
ARMENIA	none	144.206	11.478		155.684	5,48%	4	0	492.239	2
AUSTRIA	none	265.622	435		266.057	3,22%	4	0	115.772	10
AZERBAIJAN ⁵	unknown	unknown	unknown	200.000	200.000	2,32%	4	1?	132.500	1
BELARUS	none	1.199.127	115.515		1.314.642	6,33%	10	2?	204.050	3
BELGIUM	830	42.715	1.670		45.215	1,50%	1	0	7.935	6
BOSNIA-HERZEGOVINA	unknown	unknown	unknown	400.000	400.000	7,81%	2	1?	7.411	1
BULGARIA	unknown	10.000	220.000	7.245	237.245	2,15%	4	1?	2.803	5
CROATIA	unknown	unknown	unknown	116.423	116.423	2,06%	2	0	80.455	4
CYPRUS	unknown	unknown	unknown	10.731	10.731	1,16%	1	0	1.585	1
CZECH REPUBLIC	none	27.000	78.000	11.987	116.987	1,49%	5	1?	41.861	10
DENMARK ⁶	885.142	300.000	unknown		1.185.142	27,97%	4	0	1.184.513	27
ESTONIA	unknown	1.085.900	unknown	366.600	1.452.500	33,62%	9	0	215.950	10
FINLAND	50.143	7.522.000	unknown		7.572.143	24,79%	4	0	138.746	11
FRANCE ⁶	381.280	800.627	3.600	414.493	1.600.000	2,93%	6	0	579.085	15
GEORGIA	unknown	unknown	unknown	220.140	220.140	3,16%	3	0	34.223	2
GERMANY	680.880	751.680	29.871	645.049	2.107.480	6,03%	4	0	672.943	31
GREECE	101.061	65.733	35.824		202.618	1,55%	5	2?	163.501	10
HUNGARY	none	61.500	26.000	97.200	184.700	2,00%	5	1?	154.147	21
ICELAND	unknown	1.080.000	unknown		1.080.000	10,77%	2	0	58.970	3
IRELAND	unknown	unknown	unknown	600.000	600.000	8,71%	3	0	66.994	45
ITALY	unknown	unknown	unknown	450.563	450.563	1,53%	6	0	57.136	46
LATVIA	142.600	1.176.600	14.800		1.334.000	20,81%	9	0	43.300	3
LIECHTENSTEIN	unknown	unknown	unknown	130	130	0,81%	1	1?	101	1
LITHUANIA	41.300	552.000	unknown		593.300	9,10%	9	1?	50.451	5
LUXEMBOURG	unknown	unknown	unknown	1.829	1.829	0,71%	1	0	313	1

	BEST ESTIMATES				COVERAGE INFORMATION			RAMSAR INFORMATION		
	Marine/Coastal (ha)	Inland (ha)	Manmade (ha)	Unspecified Wetland Type (ha)	Best Estimate Total (ha)	% of land area (marine areas excluded) covered by these wetlands	# of datasets accessed per country ^{1,2}	# of datasets which can be regarded as comprehensive in cover per country ⁴	Total area of Ramsar sites	# Ramsar sites
EUROPEAN REGION										
MACEDONIA (TFYROM)	none	47.530	unknown		47.530	1,91%	2	0	18.920	1
MALTA	unknown	unknown	unknown	16	16	0,05%	1	0	16	2
MOLDOVA	unknown	unknown	unknown	250.000	250.000	7,42%	7	1?	19.152	1
MONACO	no data	no data	no data		no data	no data	0	0	10	1
NETHERLANDS ⁶	404.335	391.134	unknown	161.531	795.469	23,45%	6	0	324.918	18
NORWAY	unknown	unknown	unknown	3.300.400	3.300.400	10,72%	4	0	70.150	23
POLAND	unknown	1.762.000	unknown	47.758	1.809.758	5,94%	7	3?	90.455	8
PORTUGAL	79.500	unknown	unknown	51.443	130.943	1,43%	2	0	66.096	12
ROMANIA	529.700	269.080	unknown	308.300	1.107.080	4,81%	3	0	664.586	2
RUSSIAN FEDERATION ³	578.599	217.000.000	57.200		217.635.799	12,81%	7	0	10.323.767	35
SAN MARINO	no data	no data	no data		no data	no data	0	0	0	0
SLOVAK REPUBLIC	none	unknown	unknown	28.628	198.790	4,07%	5	0	37.752	12
SLOVENIA	unknown	91.372	unknown	28.628	120.000	5,92%	3	2?	955	2
SPAIN	104.116	16.421	250.000		370.537	0,74%	6	1?	158.216	38
SWEDEN	unknown	10.100.000	unknown		10.100.000	24,58%	8	3?	382.750	30
SWITZERLAND	none	219.836	unknown		219.836	5,53%	5	0	6.593	8
TURKEY	unknown	unknown	unknown	2.238.000	2.238.000	2,90%	5	2?	159.300	9
UKRAINE	unknown	1.207.000	1.150.000	1.994.000	3.201.000	5,30%	7	1?	716.250	22
UNITED KINGDOM ⁶	596.585	2.380.000	unknown		2.976.585	12,32%	14	0	750.482	152
YUGOSLAVIA	unknown	unknown	unknown	677.200	677.200	6,63%	4	2?	39.861	4
Total estimated wetland cover	4.591.071	248.604.083	1.994.393	12.688.509	266.686.687	11,25%	211	0	18.357.213	655

¹ Excluding the Ramsar sites database.

² Please consult 2.3.1 (in Part I) for a description of how these estimates were generated.

³ Including Asian part of Russia.

⁴ The estimates marked with question marks (?) are given as comprehensive, but no explanation is given on their calculation. They might be outdated or not include all wetland types as given in the Ramsar definition.

⁵ Ramsar Site was designated by the former USSR; Azerbaijan has not yet acceded to the Convention on Wetlands.

⁶ Excluding Ramsar sites in overseas territories.

Many Ramsar sites and other important wetlands are currently, or will be, part of the EU Natura 2000 network²¹. Natura 2000 is the European Union-wide network of nature conservation sites designated, or to be designated, under the EU Habitats Directive (Special Areas of Conservation – SAC) and EU Birds Directive (Special Protected Areas – SPA²²). Areas designated under these Directives receive legal protection from unsustainable utilisation.

The Natura 2000 network extends across all 28 EU Member States, both on land and sea, comprising 18 % of the EU's land area and almost 6 % of its marine territory. The aim of the network is to ensure the long-term survival of Europe's most valuable and threatened species and habitats²³. SPAs are not designated with the purpose to specifically protect wetlands and waterbirds and therefore many wetland areas are not covered by the designated SPAs.

In many regions of Europe the extent of aquatic habitat has reduced appreciably over recent time (Ravenga et al., 2000). For example, Spain has lost more than 60 % of all inland freshwater wetlands since 1970 (EEA 1995). In Portugal about 70 % of the wetlands of the Western Algarve, including 60 % of estuarine habitats, have been converted for agricultural and industrial development (Pullan, 1988), Lithuania has lost 70 % of its wetlands in the last 30 years (EEA, 1999) and the open plains of the southwestern part of Sweden have lost 67 % of their wetlands and ponds to drainage in the last 50 years (EEA 1995).

Therefore, for many species of (migratory) waterbirds, the availability of wintering habitats across Europe has reduced. In most remaining high-quality wetlands (which are often included in protected areas), it is possible to observe very high densities of wintering waterbirds²⁴. In these areas there is typically strong competition for food and many birds are forced to forage outside the main wetland. Many ducks, for instance, have been observed to 'commute', performing nocturnal foraging trips to search for food in marginal/small wetlands, small streams or bogs.

Bengtsson et al. (2014), when studying mobility, home-range size and habitat selection of mallards during autumn migration reported that ducks spent a considerable proportion of darkness hours in small (most less than 50 m in diameter), permanent or seasonal, wetlands.

An indicative example of the extent of SPAs relative to wetlands is available for Italy (Figure B-2), where it is clear that the extent of the SPA network excludes much of the land area that is considered to be a wetland.

²¹ <http://www.ramsar.org/news/natura-2000-and-people-a-partnership>

²² The identification and delimitation of SPAs is based on scientific criteria, such as: "1% of the population of listed vulnerable species" or "wetlands of international importance for migratory waterfowl".

²³ http://ec.europa.eu/environment/nature/natura2000/index_en.htm

²⁴ Andreotti A., ISPRA, personal communication.

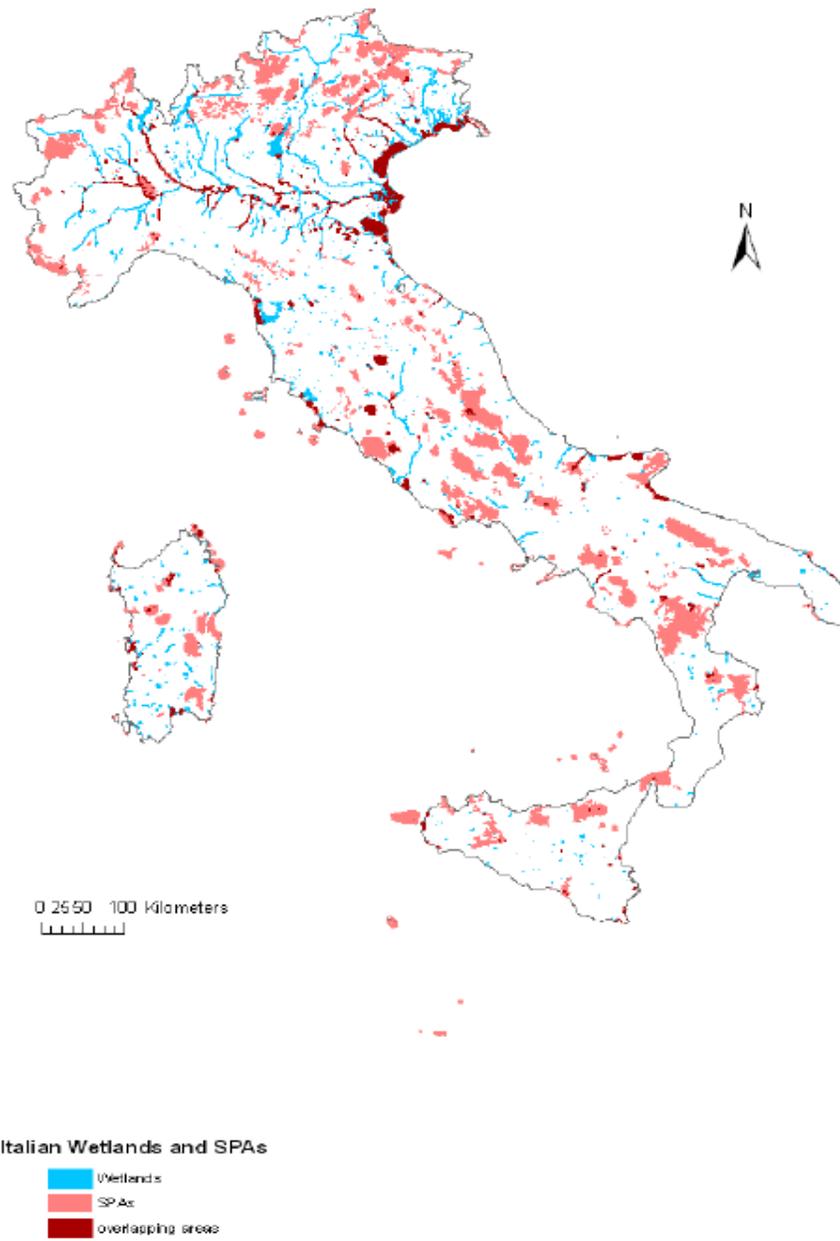


Figure B-2 Comparison of SPAs and wetlands in Italy²⁵.

²⁵ National Report of Italy to AEWA (2008) <http://www.unep-aewa.org/en/documents/national-reports>

Discussion on the definition of wetlands

The various definitions described above are broadly comparable, but clearly differ in terms of their precision, scope and differentiation between some habitat types.

For example, the Ramsar definition comprises a generic high-level description of wetlands, whilst Annex I of the EU Habitats Directive is considerably more precise in its description of wetland habitats. Equally, seasonally flooded pasture is not identified as a wetland in the CORINE Land Use mapping, which would be considered to be a wetland according to the Ramsar convention definition.

Critically, all contemporary EU-relevant definitions of wetlands include peatlands. Ecologically, peatlands are important habitats for many species of waterbirds, including wading birds. Bird species associated with peatland habitats are known to ingest lead gunshot.

B.4.3.3.2. Hydrology of wetlands

Hydrology is one of the most important factors in determining how a wetland will function, what plants and animals will occur within it, and how the wetland should be managed (Welsch et al., 1995). Small differences in the amount, timing or duration of the water supply can result in a profound change in the nature of the wetland and its unique plants, animals and processes (Welsch et al., 1995).

Hydroperiod is the seasonal pattern of the water level that results from the combination of the water budget and the storage capacity of the wetland. The water budget is a term applied to the net of the inflows, all the water flowing into, and outflows, all the water flowing out of, a wetland. The storage capacity of the wetland is determined by the geology, the subsurface soil, the groundwater levels, the surface contours and the vegetation. The hydroperiod of coastal wetlands exhibits the daily and monthly fluctuations associated with tides, whereas inland wetlands tend to show, to a greater degree, the effects of storm and seasonal events such as spring thaw, fall rains and intermittent storm events (Welsch et al., 1995).

Wetlands receiving inflow from groundwater are known as discharging wetlands because water flows or discharges from the groundwater to the wetland. A recharge wetland refers to the reverse case where water flows from the wetland to the groundwater. Recharge and discharge are determined by the elevation of the water level in the wetland with respect to the water table in the surrounding area. Riparian wetlands often have both functions, they are discharge wetlands, receiving groundwater inflow from upslope areas and they are recharge wetlands in that they feed lower elevation groundwater through groundwater outflow. The same wetland may be a discharging wetland in a season of high flow and a recharging wetland in a dry season (Welsch et al., 1995).

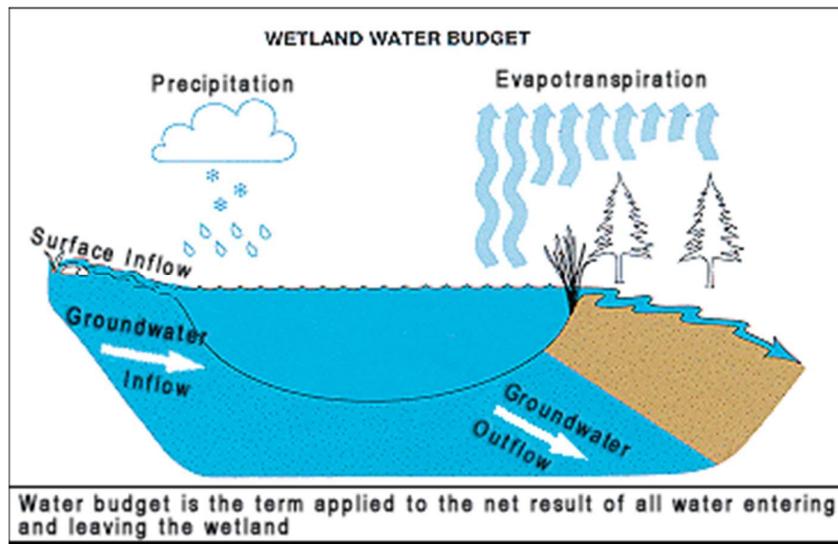


Figure B-3 Water budget in a generic wetland (after Welsch et al., 1995).

Groundwater represents an important link of the hydrological cycle through the maintenance of wetlands and river flows, acting as a buffer through dry periods. It provides the base flow (i.e. the water which feeds rivers all year round) for surface water systems, many of which are used for water supply and recreation. In many rivers indeed, more than 50 % of the annual flow is derived from groundwater. In low-flow periods in summer, more than 90 % of the flow in some rivers may come from groundwater (EC, 2008).

Different types of wetlands have different hydrological characteristics. For example, although bogs and fens share several features (they both accumulate peat and occur in similar climatic and physiographic regions) they generally differ hydrologically.

The main feature that distinguishes fens from bogs is the fact that fens receive water from the surrounding watershed in inflowing streams and groundwater, while bogs receive water primarily from precipitation. Therefore, fens reflect the chemistry of the geological formations through which these waters flow. In limestone areas the water is high in calcium carbonate resulting in fens that are typically buffered to a near neutral pH of 7. However, the level of calcium or magnesium bicarbonate varies widely in fens. At low levels of bicarbonate the pH may be closer to pH 4.6 resulting in an acid fen. At very high levels of bicarbonate, the water may reach a pH of 9. Thus, there is much variation among fens with respect to acidity and they often do not have the extreme acid conditions associated with bogs (Welsch et al., 1995).

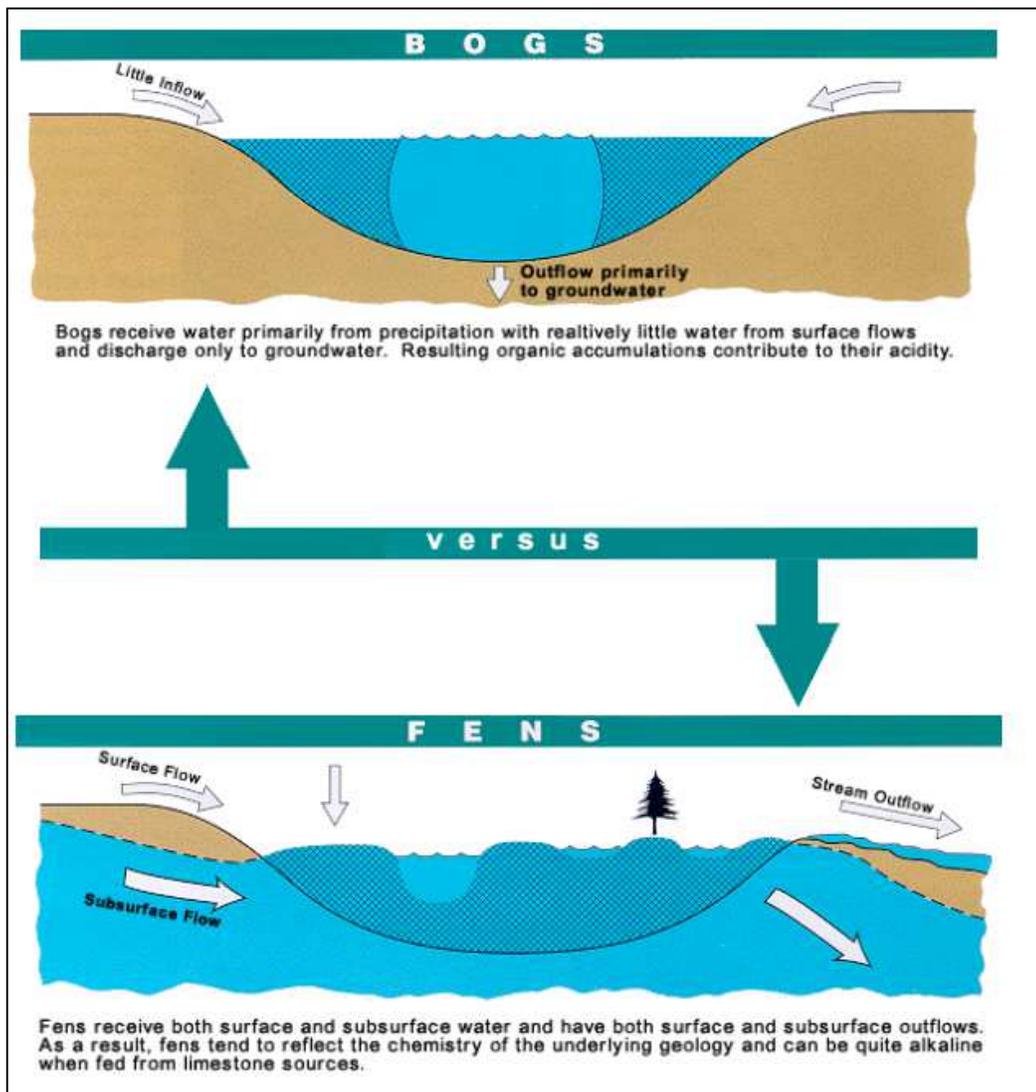


Figure B-4. Hydrological features of bogs and fens (after Welsch et al., 1995).

Bogs receive little or no discharge of water from groundwater aquifers and are mainly dependent on precipitation for moisture. Bogs may recharge small amounts of water to regional groundwater systems (Welsch et al., 1995).

B.4.3.3.3. Wetlands and drinking water catchments

Wetlands provide important ecosystem services, including water supply, since some drinking water catchments are located within wetlands.

An example is the UK, where some drinking water catchments are located within peatlands. Peatlands, particularly blanket bogs, are a significant water supply source in the UK, notably in northern England (Bonn et al., 2009). This ecosystem service is related to high rainfall, low evapotranspiration and upland landscape position. In the UK,

approximately 70 % of drinking water is sourced from surface water that comes mainly from uplands catchments, which are generally peat dominated (Bain et al., 2011).

It is not known (to the Dossier Submitter) the overall number and distribution of drinking water catchments located within peatlands, or other types of wetlands, in the EU. However, a Finnish study related to the potential diffusion of lead into groundwater from shooting ranges is discussed in B.9.1.8.4.

B.4.3.3.4. Dissolution, speciation and mobility of lead from gunshot in wetlands

Physico-chemical conditions in wetlands are generally anoxic. However, chemical reactions in aqueous media are often characterised by pH and the redox potential together with the activity of dissolved chemical species (Scholz, 2016).

Redox potential is the most common parameter used to measure degree of soils wetness or intensity of soil anaerobic conditions. The range of Eh (reduction/oxidation potential), values observed in wetland soils is from +700 to - 300 mV. Negative values represent high electron activity and intense anaerobic conditions typical of permanently waterlogged soils. Positive values represent low electron activity and aerobic to moderately anaerobic conditions typical of wetlands in transition zones (Inglett et al., 2016). Specific Potential-pH diagrams²⁶ for a lead-water system, showing stability of solids and dominant solute species as functions of pH and Eh, indicate which species are likely to exist at various Eh and pH at certain specific conditions.

Lead pellets deposited onto soils and aquatic sediments are not chemically inert. Lead from spent shot can become bioavailable (Scheuhammer and Norris, 1995) although tens or hundreds of years may be required for the complete dissolution of pellets (Scheuhammer and Norris, 1996).

Weathering and dissolution of elemental lead in spent ammunition is influenced by multiple factors (Eisler 1988; IPCS 1989; Scheuhammer and Norris 1995; EC, 2004 cited by Rattner et al., 2008; Scheuhammer and Norris, 1996; Swaine, 1986 cited by Bianchi et al., 2011; SAAMI, 1996), including:

- water chemistry;
- the extent of the mechanical disturbance of sediment (e.g., water flow rate);
- grain size of soils and sediments;
- gaseous aerobic conditions, acidity and alkalinity;
- rainfall, vegetation cover, and;
- the quantity of organic matter in sediment.

The dissolution rate of lead in aquatic environments increases with acidity, low water hardness (< 25 mg/L CaCO₃), and greater water velocity (Eisler, 1988; Scheuhammer and Norris, 1995; EC, 2004 cited by Rattner et al., 2008).

²⁶ The Pourbaix diagram can be used to determine which species is thermodynamically stable at a given Eh and pH. It gives no information about the kinetics.

In aquatic environments with lower water velocities (e.g. lakes), lead particles and artefacts would become buried in bottom sediments, where they would move into the anoxic sediment layer and may be strongly adsorbed onto sediment and soil particles (EC, 2004).

The fate of spent lead in the environment depends on whether it remains exposed in water or buried in sediments or soils (Jacks et al. 2001 cited by Rattner et al., 2008).

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

The fate of lead from lead gunshot is regulated by a number of physico-chemical processes (SAAMI, 1996), including:

- Oxidation/reduction
- Precipitation/dissolution
- Adsorption/desorption
- Complexation/chelation

Lead can precipitate in a variety of forms including hydroxides, sulphates, sulphides, carbonates, and phosphates. Each of these precipitates are soluble, controlled by site-specific water chemistry. The factors that directly control solubility are pH, oxidation-reduction (redox) conditions, and the concentration of the components that determine solubility (the primary solubility controls). As these parameters are highly variable from one location to another, site-specific conditions determine how much lead can be solubilised.

In general, lead is much more soluble under acidic (low pH) conditions than at neutral or alkaline (high pH) conditions, but this can change under a variety of situations. Some precipitates, especially phosphates and sulphides, are particularly effective at controlling lead solubility, often resulting in very low lead concentrations in water. Factors controlling solubility can substantially reduce the bioavailability of lead in sediments and/or soils.

Lead can be adsorbed by a variety of materials including organic matter, iron and manganese oxyhydroxides, clays, carbonates and sulphides. In general, neutral or slightly alkaline conditions are expected to give rise to low mobility conditions and only acidic conditions will result in substantial mobility. However, there are exceptions to this generality, as adsorption processes are highly dependent on site-specific conditions.

Complexation/chelation and transport of particulates that contain lead may increase physical movement of lead. Particulate transport mechanisms may be effective in altering the distribution of lead over time.

The supplementary CSR for the use of lead ammunition developed for the REACH registration of lead (ILA-E, 2010) derived a worst-case corrosion (weathering) rate of lead shot in soil and sediment of 1 % per year, based on reviews of the literature by Scheinost (2004) and others. Scheinost (2004), cited by ILA-E, (2010) concluded that fast initial weathering rates can be considered to be in the range 0.2 to 2 % per year, corresponding

to first order rate constants of 0.002 to 0.02 per annum. Based on these assumptions, large amounts of shotgun pellets deposited on shooting ranges and hunting areas would be transformed every year into lead carbonates and sorbed species, and it would take between 50 and 500 years for lead shot to transform to other lead species. It should be noted that these factors would appear to be derived from data from both bullets and lead gunshot and the precise physico-chemical conditions associated with these factors are not reported in ILA-E (2010).

The 1 % per year dissolution value used in the REACH registration for both soil and sediment was considered by the registrants to be a worst-case assumption because it assumes that the initial corrosion rate will remain constant over time, whilst in reality it decreases (Scheinost, 2004). For example, Linder (2004, cited by ILA-E, 2010) reports that the initial corrosion rate of lead will decrease by about 50 % after 2-3 years.

In a Swedish study, also cited in ILA-E (2010), an upper limit for lead corrosion of 1 % per year is used (Anderberg et al., 1990, cited by ILA-E, 2010). The Dutch emission inventory (VROM, 2002, cited by ILA-E, 2010) also used a worst-case corrosion rate of 1 % per year.

B.4.3.3.5. Lead releases to the environment from shooting ranges

Data collected on site at Prime Hook National Wildlife Refuge, Sussex County, Delaware (US), where a trap-shooting range operated, indicated that 37 years after shooting began (in the early 1960s), lead from a concentrated deposit of shotgun pellets was dissolved and infiltrated into the ground water in the adjacent forested wetland areas. The study confirmed that many site-specific variables were relevant when assessing lead mobility in the environment. One of the main outcome of the study is that soils or sediments containing little or no binding capacity, such as clean sands, can be quite efficient at transporting dissolved lead, especially in areas with acidic rain and low pH ground water (Soeder and Miller 2003). A more detailed description of the specific case is presented in Section B.9.1.8.4.

Jorgensen and Willems (1987 cited by Rattner et al., 2008) examined the dissolution of lead from shot in several different soil types at three shooting ranges in Denmark. Their data suggest that half of a metallic lead pellet would transform to other lead compounds and be released into the soil within 40 to 70 years and that the entire lead shot would transform in 100 to 300 years.

At shooting ranges in Sweden, the amount of lead bound to mineral or organic components in the soil ranged from 0 % to 92 %, depending upon a combination of factors including soil pH, organic matter, cation exchange capacity, and leaching rate (Lin et al. 1995, cited by Rattner et al., 2008).

In the US a study of eight shooting ranges over water, showed that shot density ranged from 1.32×10^6 to 3.7×10^9 /hectare in the upper 7.5 cm of the soil/sediment fall zone (Stansley et al., 1992 cited by Rattner et al., 2008). In this study, lead concentration in water samples reached 581 µg/L and was up to two orders of magnitude greater than the reference site. The authors reported that these values exceeded U.S. EPA water quality criteria for aquatic life (chronic exposure freshwater 2.5 µg/L; U.S. EPA 2007) and safe drinking water criteria for household tap water (<0.015 µg/L; U.S. EPA 2006).

B.4.4. Bioaccumulation

B.4.4.1. Aquatic bioaccumulation

Bioconcentration (BCFs) and bioaccumulation factors (BAFs) for lead from water to aquatic invertebrates and fish are summarised in the Voluntary Risk Assessment for lead (LDAI, 2008) and the REACH registration for lead. A key consideration in these evaluations was whether steady-state tissue concentrations were achieved in studies and whether metal concentrations were measured throughout the exposure period. In that context, the lead concentration from biota sampled from natural environments are assumed to be at equilibrium. In addition, BCF data based on exposure concentrations that resulted in significant effects on the exposed organisms were not included.

An overview of the reliable whole-body BCF/BAF values obtained for freshwater organisms are summarised in Table B-45 and Table B-46 in Appendix B.1.

BAF values are preferred to BCF values since the former include all possible exposure routes (i.e. water, food and soil/sediment) and are therefore considered to be more ecologically relevant.

Within a typical environmental concentration range (i.e. between 0.18 µg/L²⁷ (background concentration) and 15 µg/L (based on the 95th percentile of the PEC_{local} values), BAF values for fish range between 11 and 143 L/kg_{ww} (10 – 90th%) with a median value of 23 L/kg_{ww} while BAF values for molluscs range between 18 and 3 850 L/kg_{ww} (median value of 675 L/kg_{ww}) BAF values for insects range between 968 and 4 740 L/kg_{ww} (median value of 1 830 L/kg_{ww}) and for crustaceans between 1 583 and 11 260 L/kg_{ww} (median value of 3 440 L/kg_{ww}). The results are summarised in Table B-20.

Table B-20. Bioaccumulation factor estimates (BAF in L/kg_{ww}) for lead in freshwater organisms (LDAI, 2008)

Diet	Variable	10 th percentile	50 th percentile	90 th percentile	n
Crustaceans	All exposures	1 187	3 159	10 570	8
	0.18-15 µg/L	1 583	3 440	11 260	7
Molluscs	All exposures	11	473	3 535	14
	0.18-15 µg/L	18	675	3 850	11
Annelids	All exposures	1 620	1 620	1 620	1
	0.18-15 µg/L	1 620	1 620	1 620	1
Acarides	All exposures	1 730	1 730	1 730	1
	0.18-15 µg/L	1 730	1 730	1 730	1

²⁷ The measured aquatic lead concentrations below detection limit of 0.2 µg/L were considered as falling within the typical environmental concentration range.

Diet	Variable	10 th percentile	50 th percentile	90 th percentile	n
Insects	All exposures	968	1 830	4 740	7
	0.18-15 µg/L	968	1 830	4 740	7
Fish	All exposures	11	24	245	16
	0.18-15 µg/L	11	23	143	16

It is assumed that the diet of predators consists entirely of one realistic food type, i.e. fish (EC, 2003; TGD). However, it is recognised that ideally, for a more realistic assessment, refined data on the mixed diet food consumption of birds and mammals should be considered. Thus, a realistic mixed diet BAF value can be calculated using the following formula:

$$BAF_{\text{mixeddiet}} = \sum_{i=1}^n f_i \times BAF_i$$

BAF_i corresponds to the representative bioaccumulation factor (10th, 50th or 90th percentile) for an individual prey species i (L/kg); n: the number of prey species considered in the mixed diet of the predator; f_i: the proportion of the different food types in the mixed diet (value between 0 and 1).

To reflect such mixed diet scenario it is assumed (as no data are available on food type consumption and proportion of the different food types in the mixed diet) that birds/mammals consume equal proportion of the different food types as reported in Table B-20, i.e. crustacean, mollusc, annelid, acaride, insect and fish.

However, based on an observation of relatively greater bioaccumulation for many metals in molluscs, BAF was also considered for a "mollusc food diet". The range of bioaccumulation factors (BAFs in L/kg_{ww}) for lead in the mixed and mollusc food diet is presented in Table B-21.

Table B-21. The range of bioaccumulation factor (BAF in L/kg ww) of lead in the mixed diet (LDAI, 2008)

Diet	Variable	10 th percentile	50 th percentile	90 th percentile	n
Mixed food diet	All exposures	921	1 472	3 740	49
	0.18-15 µg/L	988	1 553	3 890	44
Mollusc food diet	All exposures	11	473	3 535	14
	0.18-15 µg/L	18	675	3 850	11

Table B-21 shows that the median of the mixed diet BAF for aquatic organisms is 1 553 L/kg (90th percentile: 3 890 L/kg) and that the mixed diet scenario is driven by the BAF values observed for invertebrates. The median BAF of the mollusc food diet is somewhat lower, i.e. 675 L/kg (90th percentile: 3 850 L/kg). The mollusc food diet results in lower overall BAF values for lead than the mixed diet.

B.4.4.2. Terrestrial bioaccumulation

A wealth of data are available on terrestrial bioconcentration factors or bioaccumulation factors. Therefore, only a selection of illustrative, representative, BAF data are reported. Data were considered reliable:

- if the data came from field studies or laboratory studies using soil and biota collected at the same field site. This is to ensure that biota lead burdens are in equilibrium with soil lead concentrations. Data from laboratory studies where lead was added to the soil as a lead salt are excluded;
- if lead concentrations were measured in soil and biota. The lead concentration in soil has to be expressed as "total" soil lead (e.g. lead measured after *aqua regia* destruction), extractable lead fractions (e.g. water-extractable lead) are not considered reliable;
- if guts from the biota were voided prior to analysis;
- if it was indicated how BAF values were expressed, i.e. on a dry or wet weight basis.

According to REACH Guidance (Chapter R16)²⁸, the food-chain comprising soil, earthworms and earthworm eating predators was considered. Bioaccumulation factors (BAFs) for lead from soil to earthworms are summarised in the Voluntary Risk Assessment for lead (LDAI, 2008). Results of lead bioaccumulation studies in soil are presented in Table B-47 and Table B-48 of Appendix B.1.

The median BAF for earthworms on a dry weight basis is 0.39 kg_{dw}/kg_{ww} (median of 101 values) and 10-90th percentiles are 0.13-1.17. On a fresh tissue weight basis, BAF values are 0.10 kg_{dw}/kg_{ww} (median) and 0.03-0.27 (10-90th percentiles). The influence of soil properties on the BAF of earthworms (*A. calliginosa*) was studied in different soils and the equation describing the BAF as a function of pH reads, with BAF on a wet weight basis (kg_{dw}/kg_{ww}).

$BAF = 13.9 \cdot \exp(-0.76 \cdot pH)$ (Ma, 1982). This equation predicts that the median BAF of the 101 data points above (BAF = 0.10 kg_{dw}/kg_{ww}) is found at pH=6.5. At pH 4.5, this BAF is 4-fold larger. There is no significant effect of total soil lead on the BAFs (LDAI, 2008).

Literature data are available for bioaccumulation of lead in isopods from soil or litter. Values range from 0.001-0.65 kg_{dw}/kg_{dw}. A median BAF for isopods on a dry weight basis is 0.04 (median of 14 values).

²⁸ Available at: https://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf

From the literature overview, the following bioaccumulation/bioconcentration factors have been derived for lead:

- Aquatic compartment: Bioaccumulation/bioconcentration factors in freshwater: 1 553 L/kg (wet weight);
- Soil compartment: Bioaccumulation/bioconcentration factors in soil: 0.39 kg/kg (dry weight).

B.4.5. Secondary poisoning

The potential for secondary poisoning in birds and mammals was considered to be relevant in REACH Registration dossiers. $PNEC_{oral}$ values for these two groups were derived deterministically from the lowest observed NOEC from a dataset of chronic (> 21 day) studies investigating the effects of lead salts diet on ecologically relevant endpoints (e.g. growth and reproduction). The standard assessment factors for deriving these PNECs 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 B.7.3.2.1. However, as these $PNEC_{oral}$ values were derived on the basis of lead salts in diet they may only have limited relevance to an assessment of the secondary poisoning of predators or scavengers via the ingestion of lead gunshot in diet.

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

As such, a complimentary assessment of the risks of secondary poisoning of predators/scavengers via spent lead gunshot present in food is described in this Annex XV report, alongside the assessment of the risks posed to birds from the primary ingestion of spent lead gunshot.

The VRAR (LDIA, 2008) includes a study on secondary poisoning by Buekers et al. (2008) that focuses on the derivation of critical tissue concentrations for lead associated with adverse effects on growth, reproduction, physiology or haematology for use in wildlife monitoring. This study derived threshold (HC_5) values in blood of 71 $\mu\text{g}/\text{dL}$ (95 % confidence limits 26-116) for birds and 18 $\mu\text{g}/\text{dL}$ (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. However, additional tissue thresholds for lead associated with adverse effects in birds after primary or secondary ingestion of lead gunshot have also been derived by other authors. These are described in Section B.7.3.2.

B.5. Human health hazard assessment

The information in this section has been primarily obtained from the following reports:

- Annex XV report for restriction of lead in consumer articles (KEMI, 2012)²⁹;
- CLH Proposal for Harmonised Classification and Labelling of Lead (KEMI, 2012)³⁰;
- REACH registration dossier for lead (2015);
- Voluntary Risk Assessment Report on lead RAR (LDAI, 2008).

ECHA's Risk Assessment Committee (ECHA, 2014) has previously assessed the health hazards of lead and its compounds for several previous opinions and this has been taken into account in the brief overview given of the relevant hazards.

B.5.1. Toxicokinetics

B.5.1.1. Absorption

The oral and the inhalation routes are the most significant routes of exposure to lead, whereas dermal absorption is considered as minimal (LDAI, 2008). However, even though absorption directly through the skin is considered negligible, the lead can become systemically available through hand-to-mouth behaviour. This route of exposure is possible for both children and adults that come in contact with lead containing articles, both at home and occupationally (Klein and Weilandics, 1996).

The efficiency of oral uptake of lead can vary depending on e.g. particle size and shape (surface area), amount of time spent in the GI tract, concurrent food intake and the iron- and calcium status of the individual. A number of case reports prove that even one larger piece of lead ingested orally can create sufficient systemic exposure to produce clinical lead intoxication or even death. As a worst-case assumption, one can assume that the bioavailability of metallic lead is equivalent to that of soluble lead compounds such as e.g. lead acetate (LDAI, 2008).

Representative uptake rates for lead in adults and children via different exposure routes are presented in Table B-22. These representative uptake rates can be applied to calculate the uptake of lead oxide from individual exposure sources, but are put forward with the caveat that the kinetics of lead uptake can be curvilinear in nature and subject to modification by a number of variables. The uptake estimates given are thus representative values that are only applicable to relatively low exposure levels yielding blood lead levels < 10 – 15 µg/dL.

²⁹ <http://echa.europa.eu/documents/10162/ab0baa9c-29f8-41e2-bcd9-42af796088d2>

³⁰ http://echa.europa.eu/documents/10162/13626/lead_clh_proposal_en.pdf

Table B-22. Representative lead uptake rates (CSRs for lead compounds, 2015)³¹

Intake route	Adults	Children
Oral (food)	10 %	50 %
Oral (soil)	6 %	30 %
Dermal	< 0.01 %	< 0.01 %
Air (deep lung deposition)	100 %	100 %
Air (upper airway deposition)*	Variable	NA

B.5.1.2. Metabolism

The lead ion is not metabolised or bio-transformed in the body, though it does form complexes with a variety of proteins and non-protein ligands. It is primarily absorbed, distributed and then the non-accumulated lead is excreted (WHO, 2003).

B.5.1.3. Distribution

Once it is absorbed, inorganic lead appears to be distributed to both soft tissues (blood, liver, kidney, etc.) and mineralising systems (bones, teeth) in a similar manner regardless of the route of absorption.

The distribution of lead seems to be similar in children and adults, but in adults a larger fraction of lead is stored in skeletal tissue. More than 90 % of the total amount of accumulated lead ends up in bone and tooth in adults, while in children, 75 % is accumulated in bones.

The distribution of lead in the body is initially dependent on the rate of delivery by the bloodstream to the various organs and tissues. A subsequent redistribution may then occur, based on the relative affinity of particular tissues for the element and its toxicodynamics (ATSDR, 2007).

Lead concentration is also related to calcium status; stored lead can therefore be released from bone tissue into the blood stream in situations where a person suffers from calcium deficiency or osteoporosis (LDAI, 2008).

It should be noted that lead is easily transferred to the foetus via the placenta during pregnancy. The foetal/maternal blood lead concentration ratio is approximately 0.9 (Carbone et al., 1998). As explained by Bradbury and Deane, (1993) the blood-cerebral

³¹ Upper airway deposition is expected for many occupational aerosols and uptake will thus vary as a function of pulmonary deposition patterns and the extent of translocation to the gastrointestinal tract where GI uptake kinetics will predominate. Non-linearity as a function of exposure level imparts additional variability into upper airway uptake estimates. Given that upper airway deposition is expected primarily in the occupational setting, upper airway deposition is Not Applicable (NA) to children.

barrier is permeable to lead ions and the most sensitive end-point is connected to neurotoxicity and developmental effects.

B.5.1.4. Elimination

Lead has a different half-life in different tissues. Blood lead and lead in soft tissue is considered the most labile with a half-life of approximately 40 days, while bone lead is very stable with a half-life of several decades (ATSDR, 2007). In lead exposed infants and children, lead is progressively accumulated in the body and is mainly stored in skeletal tissue. As mentioned previously, lead is eliminated from bone very slowly; the half-life can be 10 to 20 years or more. In this way, lead can lead to an internal exposure long after the external exposure has ended, by redistribution between different tissue pools (LDAI, 2008). Elimination takes place mostly via urine (> 75 %), and 15–20 % is excreted via bile and faeces (TNO, 2005).

B.5.1.5. Summary and discussion on toxicokinetics

Lead is most easily taken up into the body through inhalation or ingestion, dermal uptake makes a negligible contribution to systemic lead levels. Once taken up into the body, lead is not metabolised. However, it will distribute to various tissue compartments such as blood, soft tissue and bone. The half-life of lead in the body varies depending on body compartment; lead is retained far longer in bones, up to several decades.

B.5.2. Acute toxicity

Very limited data are available describing lead acute toxicity. According to KEMI (2012a/b), human data for acute toxicity actually describe effects after exposure to lead over a period of weeks or years (sub-acute or chronic duration). The US National Institute of Occupational Safety and Health (NIOSH) estimated the acute lethal dose for an adult to be approximately 21 grams (equivalent to 450 mg/kg bw) by the oral route, and 21 000 mg/m³ for 30 minutes via inhalation (LDAI, 2008).

Acute lead intoxication in children has been reported following the ingestion of lead paint chips containing 1 % or higher of lead (Lin-Fu, 1992). Acute lead intoxication is serious and can be fatal, especially in children. In 2006, a four year old boy in the US died after swallowing a bracelet charm containing 99 % lead. The boy's blood lead level was 180 µg/dL at the time of death (CDC, 2006). It should be noted that during acute lead poisoning (e.g. after oral ingestion of an object composed of lead), the lead blood level reaches a peak, but it does not reflect the total amount present in the body.

Symptoms of acute lead poisoning include but are not limited to: dullness, restlessness, irritation, poor concentration, muscle "vibration" and weakness, headaches, abdominal discomfort and cramping, diarrhoea, memory loss and an altered mental state including hallucinations. These effects can occur at lead blood levels of 800–1 000 µg/L in children (TNO, 2005). Furthermore, the US EPA has identified a LOAEL value of 600–1 000 µg/L related to colic in children as a result of lead poisoning. Then a LOAEL of 800 µg/L (ATSDR, 2007) and a NOAEL of 400 µg/L (TNO, 2005) could be identified for acute effects in children. Due to the long elimination half-life of lead in the body, chronic toxicity should generally be considered a greater risk than acute toxicity.

B.5.3. Irritation

Not relevant for this report

B.5.4. Corrosivity

Not relevant for this report

B.5.5. Sensitisation

Not relevant for this report

B.5.6. Repeated dose toxicity

According to self-classification under REACH (See Section B.3.2), lead massive is classified as 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). EFSA (2013) concluded, based on available human data, that the most critical effects in relation to small increases in blood lead levels were developmental neurotoxicity; effects on blood pressure, and chronic kidney disease. The lead level in blood is often the best reflection of the lead exposure status of the individual (EPA Denmark, 2014). Signs of chronic lead poisoning include among others: sleepiness, irritation, headache, pains and others (LDAI, 2008).

B.5.6.1. Haematological effects

Effects of lead on blood can be detected at low levels of exposure but are not considered to be adverse (KEMI, 2012). As exposure rises, greater impact on haematological parameters can be expected. At blood lead levels < 100 µg/L an inhibition of enzymes such as ALAD is observed, ALAD is an enzyme involved in the synthesis of haeme (LDAI, 2008).

These enzymatic effects are not considered adverse but are sometimes used as biomarkers of lead exposure. At higher levels of lead exposure, the cumulative impacts of lead upon multiple enzymes in the haeme biosynthetic pathway begin to impact the rate of haeme and haemoglobin production (EFSA, 2013). Decreased haemoglobin production can be observed at blood lead levels above 400 µg/L in children. Impacts on haemoglobin production sufficient to cause anaemia are associated with blood lead levels of 700 µg/L or more.

B.5.6.2. Effect on blood pressure and cardiovascular effects

Exposure to lead has been associated with a variety of adverse effects on the cardiovascular system in animals and humans. The most studied dose-response relationship is on the effect of lead exposure on blood pressure; more frequently reported for systolic than for diastolic blood pressure (Victory, 1988).

Based on detailed analyses of five human studies, EFSA (2013) concluded a blood lead level of 36 µg Pb/L was associated to a 1 % increase in systolic blood pressure. This blood lead level was then based on modelling converted to a daily lead exposure of 1.50 µg Pb/kg bw per day. According to data submitted by Industry (REACH Registration), reviews and meta-analyses of the current literature on the blood lead/blood pressure relationship indicate that there is at best a weak positive association between blood lead and blood

pressure in general population and occupational studies with average blood lead levels below 45 µg/dL. However, it can be hypothesised that a modest increase in blood pressure would increase the overall incidence of cardiovascular disease in a large population of individuals.

This consideration of “societal risk” as opposed to “individual risk” thus merits careful examination. As indicated in the REACH Registration, given the findings of the more recent studies that there is a lack of an impact of environmental exposures upon blood pressure, dose response functions cannot be derived that would serve as the basis for any health based limits linked to blood pressure. The lack of dose dependent impacts indicates that lead impacts upon blood pressure are not a health endpoint that should be applied in quantitative risk assessment.

B.5.6.3. Kidney effects

Exposure to lead has been associated with functional renal deficits e.g., changes in proteinuria, glomerular filtration rates or creatinine levels and clearance. EFSA (2013) concluded a blood lead level of 15 µg Pb/L to be associated with a 10 % increase of chronic kidney disease in the population. This blood lead level was then, based on modelling, converted to a daily lead exposure of 0.63 µg Pb/kg bw/d.

The REACH Registration of lead compounds (2015) reviewed relevant studies (e.g. Roels et al., 1994; Weaver et al., 2003) and concluded that blood lead levels at or below 60 µg/dL appears to guard against the onset of lead nephropathy. A NOAEL of 60 µg/dL was therefore adopted for renal effects and provided the basis for the DNEL proposed in the registration dossier. However, it should be noted that EFSA’s CONTAM Panel concluded that there is no evidence for a threshold for renal effects in adults.

B.5.6.4. Neurotoxicity and developmental effects

According to the CLH report submitted by KEMI (2012), the nervous system is the main target organ for lead toxicity. The developing foetus and young children are most vulnerable to lead induced neurotoxicity as the nervous system is still under development and therefore more vulnerable. The immaturity of the blood-brain barrier may also contribute to the vulnerability, as well as the lack of high-affinity lead binding proteins in the brain that trap lead ions in adults (Lindahl et al., 1999). Young children often exhibit hand-to-mouth behaviour and also absorb a larger percentage of orally ingested lead than adults, thus leading to a greater systemic exposure (EFSA, 2013).

Several epidemiological studies have been conducted examining the impacts of pre-natal lead exposure on birth outcome and neurobehavioral development in children. Negative effects of perinatal lead exposure on neurobehavioral performance have been demonstrated both in experimental animals as well as in human prospective studies.

JECFA (2010) and Lanphear et al. (2005) concluded that negative impact on IQ is the most sensitive endpoint for lead exposure and that no safe blood lead level has yet been established. Lanphear et al. (2005) examined data from 1 333 children who participated in seven international population-based longitudinal cohort studies.

A broad picture of the relationship between blood lead levels in children and IQ deficits as established by this study is presented below in Figure B-5 (KEMI 2012). The larger sample size of the pooled analysis permitted the authors to demonstrate that the lead-associated

intellectual decrement was significantly greater for children with a maximal blood lead of $\geq 7.5 \mu\text{g/dL}$ than for those who had a maximal blood lead of $< 7.5 \mu\text{g/dL}$. The authors conclude that *there is no evidence of a threshold for negative effects caused by lead exposure, thus no level of lead exposure can be considered as safe.*

Therefore, lead should be regarded as a non-threshold toxic substance. The central nervous system is still under development well over a decade after birth and lead-induced IQ deficits in children should be considered developmental in nature.

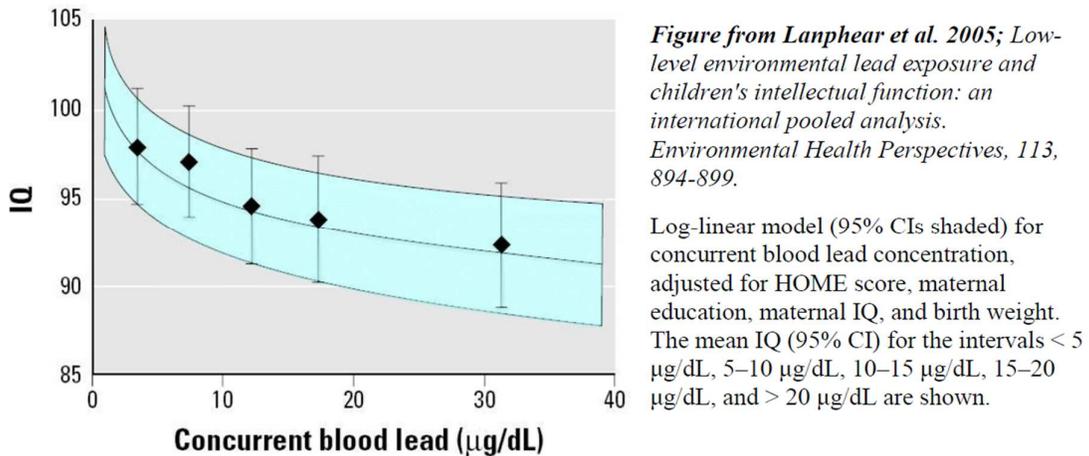


Figure B-5 Relationship between blood lead levels in children and IQ deficits (KEMI, 2012; after Lanphear et al., 2005)

ECHA's Risk Assessment Committee (RAC), based on an assessment by KEMI (2014), have previously concluded that neurotoxicity, specifically neurobehavioral and neurodevelopmental effects from repeated lead exposure, were the principal hazards to human health that should be addressed by restrictions on lead (ECHA, 2014). Small children will be particularly sensitive to this hazard.

In children, an elevated blood lead level is associated with a reduced Intelligence Quotient (IQ) score and reduced cognitive functions up to at least seven years of age. There is some evidence that this subsequently leads to reduced adult grey matter volume, especially in the prefrontal cortex (EFSA, 2013).

The REACH Registration for lead has further developed the EFSA (2013) analysis, based on a study by Budtz-Jorgenson et al. (2010) (see the discussion in Appendix B.2).

Table B-23, reproduced from this analysis, outlines the benchmark dose (BMD) and the lower 90th percentile (BMDL) of the BMD estimated using various regression approaches.

Table B-23. Benchmark dose calculations for blood lead level (in µg/dL) associated with a 1-IQ point loss.

Blood Lead Metric	Nonlinear (logarithmic)		Linear		Piecewise linear	
	BMD	BMDL	BMD	BMDL	BMD	BMDL
Concurrent	0.354	0.260	5.58	4.05	1.80	1.20
Peak	0.393	0.273	9.67	6.57	1.03	0.70
Lifetime Average	0.355	0.250	6.45	4.50	1.48	0.97
Early Childhood	0.558	0.343	8.06	5.24	3.80	1.61

The REACH registrants calculate, using the dose-response function adopted by EFSA (2013) for the impacts of concurrent blood lead levels in a piece-wise linear model, that a population-wide 4.28 IQ point decrement would be associated with a concurrent blood lead level of 7.7 µg/dL. If early childhood blood lead levels were of primary concern, this population wide IQ decrement would require blood lead levels in excess of 16 µg/dL. The registrants conclude that current EU blood levels are significantly lower than those associated with population-wide IQ point decrements used in the Benchmark Dose derivations for other environmental neurotoxins.

However, the overall conclusion that lead should be considered as a non-threshold substance and that current allowable blood lead levels need to be lowered is not disputed. In addition, Budtz-Jorgenson et al. (2010) still conclude that further prevention efforts are needed to protect children from lead toxicity.

In line with EFSA (2013), RAC has previously established a maximum exposure value for children of 0.05 µg/kg bw per day for exposure to lead (ECHA, 2011). This exposure potentially increases the blood lead level by 1.2 µg/L and is equivalent to an IQ reduction of 0.1 point.

A number of studies have been included in the CSRs that were not considered by RAC and the previous Annex XV restriction report from Sweden (Kemi, 2012). These studies are listed in Table B-24).

B.5.6.5. Hyperactivity or attention deficit disorder

In addition to the IQ effects previously described are suggestions that lead exposure may predispose to hyperactivity or attention deficit disorder (Braun, 2008, Hu et al., 2006; Li et al., 2009; Wang et al., 2008). Such a link of lead exposure to these specific health effects continue to be suggested by Nigg et al. (2008), Nie et al. (2011), Nicolescu et al. (2010), Kim et al. (2012) and Liu et al. (2011).

At times the association appears to be expressed with exposure to other environmental toxins such as PCBs (Eubig et al, 2010) or environmental tobacco smoke (Cho et al., 2010;

Apostolou et al., 2012). Interpretation of many of these studies is difficult since most fail to account for family history of the disorder and a strong genetic component is known to exist. As best articulated by Brondum (2009), the strength of the genetic association is such that failing to account for family history in such studies would be similar to not including smoking history in a study of lung cancer causes.

Criminality and anti-social behaviour has also been associated with lead exposure by a number of authors (Fergusson et al., 2008; Mielke and Zahran, 2012; Naiker et al., 2012; Marcus, 2010; Olympio et al., 2009; Plusquelles et al., 2010; Szkup-Jablonska et al., 2012).

Less intensively investigated have been impacts upon academic performance, with some recent studies suggesting associations (Amato et al., 2012; Zhang et al., 2013). Linkages to autism have been suggested by some studies (El-Ansary et al., 2011; Tian et al., 2008; but not others (Albizzati et al., 2012). Mental retardation (Liu et al., 2010; Nevin, 2009) and other neurological disorders (Mahmoudian et al., 2009) are occasionally associated with lead exposure. Altered auditory evoked brainstem responses are also suggested by some studies (Counter et al., 2007, 2012).

However, although perhaps indicative of an effect, the current evidence is not strong enough at present to use further in this assessment.

B.5.6.6. Neurological effects of post-natal exposure in children

The primary target organ for lead toxicity in young children is the brain. High levels of lead exposure can have serious effects on the intellectual and behavioural development of individual young children. Blood lead levels of 80 µg/dL or greater can result in clinical encephalopathy characterised by ataxia (inability to coordinate movements), coma and convulsions and can be fatal. In the absence of encephalopathy, children with symptomatic lead poisoning may show more subtle neurological and behavioural impairments.

Lower levels of lead exposure will affect the nervous system of the child, but the impacts to be expected are qualitatively and quantitatively different from impacts upon the nervous system of the adult. Although the mechanism(s) of neurotoxicity in children have yet to be elucidated, studies of experimental animals suggest that lead can alter developmental and maturation processes that are important to cognitive function. Thus, the dose effect relationships and cognitive impacts observed in adults are not representative of the most sensitive cognitive alterations that have been observed in children.

Overall, the available evidence indicates that exposure to lead causes IQ deficits in children at very low blood lead levels and since no safe blood lead level has been established, lead should be regarded as a non-threshold toxic compound.

Table B-24 Description of additional studies listed in REACH Registration

Reference	Exposure setting	Main characteristics of the population	Exposure assessment, duration and intensity	Observations	Confounders, examined	Study quality score and comments	
Huang et al., 2012	Prospective study of infants in Taiwan	Infant=105 Age 2-3 = 119 Age 5-6 = 76 Age 8-9 = 66	2-3 yr 5-6 yr 8-9 yr	Mean PbB Cord: 1.30 µg/dL Age 2-3: 2.48 µg/dL Age 5-6: 2.49 Age 8 - 9 1.97	Bayley Scales WPPSI-R WISC III	Lagged effect observed between blood lead at age 2-3 and IQ at age 8 - 9. No correlation with material or cord blood lead	2 (reliable with restrictions) Maternal IQ not measured. Significant cohort attrition which introduces potential participation bias. Number of children studied small and power of study to observe the effects reported is low.
Claus-Henn et al., 2012	Young children in Mexico	Infant = 455 12 mo = 275 18 mo = 271 24 mo = 273 30 mo = 260	12 - 36 mo	PbB 12 mo 5.1 +/- 2.6 µg/dL PbB at 24 mo 5.0 +/-2.9 µg/dL	Bayley Scales MDI and PDI	Inverse relationship between PbB and MDI/PDI at blood lead levels less than 10 µg/dL. Co-exposure to manganese seems to increase this effect. Confounder correction for maternal IQ but not SES or Home scores. No later	2 (reliable with restrictions) Mirrors the results of the prospective studies in finding impacts upon MDI and PDI but follow-up inadequate to determine later impact upon more stable measures of cognitive function. Interaction with Mn of interest but long term

Reference	Exposure setting	Main characteristics of the population		Exposure assessment, duration and intensity	Observations	Confounders, examined	Study quality score and comments
		36 mo = 250				measures of developmental or cognitive outcome.	significance not known. Bayley Scales not normalized for Mexico and average values abnormally low.
Al-Saleh et al., 2009	Infants and young children in Saudi Arabia	Infants = 653 6 mo = 107 12 mo = 107 18 mo = 77 24 mo = 43	6 mo interval from birth	Mean blood lead of 2.73 µg/dL at birth increasing to 4.45 +/- 2.31 µg/dL at 24 mo.	Bayley MDI and PDI	Blood lead levels at birth inversely associated with Mental Development Index (MDI) and Psychomotor Development Index (PDI) scores at 24 mo suggesting affects under 10 µg/dL. Confounders restricted to demographic and socioeconomic factors; maternal IQ not included.	2 (reliable with restrictions) Generally mirrors the results of the prospective studies in finding a correlation between PbB at birth and 24 mo MDI and PDI. Cohort attrition was unusually rapid and precludes definitive conclusions since number of children in different exposure ranges is small (e.g. 2 children in low exposure group at 24 mo.). Not able to evaluate significance for IQ or performance at later developmental stages

Reference	Exposure setting	Main characteristics of the population		Exposure assessment, duration and intensity	Observations	Confounders, examined	Study quality score and comments
Lucchini et al., 2012	Italian adolescents aged 11 - 14 years	299	11 - 14	Mean blood lead of 1.17 µg/dL (range 0.44 - 10.2)	WISC III Connor-Wells Adolescent Self-Report test	Small decrements in IQ were associated with blood lead levels less than 5 µg/dL Very limited data on confounders such as alcohol intake, maternal IQ or Home score	2 (reliable with restrictions) Unclear whether concurrent blood lead actually associated with psychometric test performance. Very poor confounder control makes meaningful interpretation difficult.
Pilsner et al., 2010	Mother-child pairs in Mexico	255	2 yr	Cord blood lead: 6.7 +/- 3.6 µg/dL. Maternal patella lead 14.7 +/- 13.7 ppm.	Bayley Scales of Infant Development	MTHFR genotype associated with decrements in MDI at age 2. Lead also affected MDI but no interaction with lead exposure seen. Folate metabolism noted to be an independent predictor of development,	2 (reliable with restrictions) Results mirror findings of prospective studies finding impacts of blood lead upon MDI and PDI but not indication of whether impacts translate into subsequent IQ impacts or other developmental deficits.

Reference	Exposure setting	Main characteristics of the population		Exposure assessment, duration and intensity	Observations	Confounders, examined	Study quality score and comments
Yorifuji et al., 2011	Children in the Faroe Islands	896 age 7	7 and 14	Cord lead 1.57 µg/dL	WISC-R	Study evaluated impacts of mercury and lead exposure. No consistent impact of lead upon overall test performance and no interactions with mercury observed. PCB co-exposure however noted to be of potential concern. Authors report adverse impacts of lead exposure but both positive and negative impacts upon performance were in fact noted.	2 (reliable with restrictions) Confounder correction limited and post-natal lead exposure not determined. No consistent impact of lead is actually present in the analysis.

B.5.7. Mutagenicity

Not relevant for this report.

B.5.8. Carcinogenicity

Not relevant for this report.

B.5.9. Toxicity for reproduction

As discussed in Section B.3, lead massive is classified under CLP in category 1A (H360DF) for reproductive toxicity.

Furthermore, the KEMI CLH report on lead (2012) highlights that strong evidence by studies in both humans and experimental animals have demonstrated negative impacts on male fertility (e.g. semen quality). The report concluded that lead clearly fulfils these criteria for reproductive toxicity and should therefore be classified as reprotoxic category 1A under CLP.

ECHA's Risk Assessment Committee, following the assessment of the KEMI CLH report, has adopted a scientific opinion (RAC 2014)³² concluding that all physical forms of metallic lead should be classified as Repr. 1A; H360DF (Repr. Cat 1) (may damage fertility; may damage the unborn child) similar to the classification that applies for "lead and lead compounds").

The Annex XV report proposing a restriction of lead and its compounds in consumer articles (KEMI, 2012), provided a good review of both animal and human studies on the reproductive toxicity of lead. An overview of these studies is given below:

B.5.9.1. Male fertility

The available data show that moderate to high lead exposure can have a marked adverse impact upon semen quality. Aberrant sperm morphology, decreased sperm count and decreased sperm density have all been demonstrated in exposed individuals. Bonde et al. (2002) conducted a cross sectional study of 503 men employed by 10 different companies in the UK, Italy and Belgium. Among other things, semen volume and sperm concentration were measured. The study group was of sufficient size to model dose-effect relationships and indicated a threshold for an effect upon semen quality at 45 µg/dL of concurrent blood lead. As blood lead levels increase above 50 µg/dL, progressively greater impact on fertility can be expected. According to KEMI (2012), a few studies that did not find an adverse effect of lead upon male fertility have been conducted using very small study populations and confounders have not always been taken into account which can further compromise the study results.

B.5.9.2. Female fertility

Effects of lead on female reproduction have been observed in numerous animal species. These effects include alterations in sexual maturation, hormone levels, reproductive cycles, impaired development of the fertilised egg as well as decreases in fertility (LDAI 2008). Effects on female reproduction in animal studies are usually not apparent at the

³² <http://echa.europa.eu/documents/10162/57ceb1ac-aafc-4852-9aa5-db81bcb04da3>

blood lead levels that impair male fertility; higher blood lead levels are generally needed to see an adverse effect on the fertility of females. In addition, human data are inconsistent.

The reprotoxic effects of lead compounds are also confirmed in the CSRs for lead compounds (2015). The literature review in the REACH registration concluded that:

- (i) an effect upon semen quality at moderate to high levels of lead exposure is likely to manifest itself in a subtle and progressive fashion as evidenced by the relevant human studies;
- (ii) the animal data, and "anecdotal" historical human data, indicate fertility effects in females are probable as well. (Impacts upon female fertility likely occur at blood lead levels in excess of 50 µg/dL as probable side effects of more generalized systemic toxicity).

B.5.10. Lead gunshot in food

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

According to the available evidence, it is not possible for consumers to successfully remove all embedded fragments of lead from the wound channels of shotgun shot game. Tiny lead particles would go unnoticed by consumers.³³

Pain et al. (2010) examined wild shot in gamebirds³⁴ obtained in the UK to determine the potential hazard to human health from exposure to fragments of shot in the tissues. The study found small fragments on X-rays in 76 % of the 121 gamebirds examined. Most fragments were less than about a tenth of a shot in size. The fragments were sometimes clustered around bone, but sometimes appeared to be scattered throughout the bird.

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

Proportions of samples exceeding 100, 1 000 and 10 000 ppb by wet weight (chosen as thresholds), were calculated. The thresholds 100, 1 000 and 10 000 ppb by wet weight (w/w), are equivalent to 0.1, 1.0 and 10 mg/kg or ppm. 100 ppb wet weight is the EU

³³ 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 unsellable."

³⁴ Wild-shot pheasant (*Phasianus colchicus*), red-legged partridge (*Alectoris rufa*), woodpigeon (*Columba palumbus*), red grouse (*Lagopus lagopus*), woodcock (*Scolopax rusticola*) and mallard (*Anas platyrhynchos*).

(1881/2006) ML (maximum level) permitted in bovine animals, sheep, pigs and poultry (excluding offal). No level has been set for game.

Pain et al. (2010) found that a high proportion of samples had lead concentrations exceeding 100 ppb ww. (0.1 mg kg ww). The percentage of mallards exceeding 100 ppb ww was: 39.9³⁵ %.

Another important parameter when consider the bioavailability of lead present in game meat for consumers, is cooking. Cooking methods seem 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 the final lead concentration in meat as well as its bioavailability. Lead particles in game meat can dissolve while cooking, producing soluble lead salts that contaminate parts of the meat. These salts have greater bioavailability and may pose an increased risk compared to metallic lead particles (Mateo et al., 2007).

Green and Pain (2015) reported that, in general, the bioavailability of dietary lead derived from ammunition (the proportion of the ingested amount which is absorbed and enters the blood) can be expected to be lower than that of lead in the general diet³⁶. This is thought to be because some of the ingested ammunition lead may remain as metallic fragments after cooking and digestion. However, despite this, game meat may remain a significant source of lead in the diets of those that consume it regularly.

B.5.11. Derivation of DNEL(s) and other hazard conclusions

B.5.11.1. Tolerable Daily Intake (TDI)

In 1995, a TDI value of 3.6µg/kg bw/day was established for both children and adults by the WHO. This value was established based on the assumption that an intake of 3–4 µg Pb/kg bw/day does not affect the lead levels in blood in children or increase the body burden of lead. In 2003, the WHO (World Health Organisation) reported a possible correlation between blood lead levels below 100 µg/L and a reduction in IQ.

EFSA (2013) concluded that no TDI value³⁷ could be placed upon lead exposure for children due to the fact that no known threshold for the decrease in IQ score in relation to lead exposure has been found. Furthermore, EFSA (2013) reported (i) for children aged one to three years of age, an average lead dietary estimates range from 1.10 to 3.10 µg/kg bw/day. These dietary estimate values were based on lower and upper bound assumptions; (ii) for high consumers an estimated lead exposure range, 1.71 to 5.51 µg/kg bw/day. Dietary exposure is the main source of lead exposure for adults as well as children, although high soil intake can be a factor for children especially in contaminated areas.

³⁵ Adjusted value (approximates what would have been expected if the measurements of concentration in the whole meal derived from each bird had been available).

³⁶ While the absolute bioavailability of ammunition-derived lead may be lower than that of lead in the general diet, the minimum plausible value of absolute bioavailability is nonetheless substantial and capable of causing elevation of blood lead concentrations.

³⁷ The Joint Food and Agriculture Organisation/World Health Organisation Expert Committee on Food Additives withdrew the PTWI in 2010/2011 (WHO 2007, JECFA 2010, WHO 2011).

B.5.11.2. Chronic DMEL (DMEL)

EFSA (2013) proposed a BMDL (benchmark dose level) based on the smallest measurable variation of the blood lead level expressed as daily intake. EFSA reported that “for changes in full scale IQ score a BMDL value of 12 µg/L was derived from the blood lead levels in 6 year old children”. This value corresponds to an exposure of 0.50 µg/kg bw/day. These conclusions were supported by RAC in their 2011 and 2014 scientific opinions, as previously discussed. Budtz-Jorgenson et al. (2013) reported BMDLs of 0.1 – 1.0 µg/dL as the dose leading to the loss of one IQ point.

As already discussed under the Section B.5.6.4, “No exposure threshold has been determined for chronic exposure to lead in regards to neurotoxicity”.

A DNEL of 20 µg lead per dL blood is derived in the REACH Registration CSR for adults in the general population (based on a NOAEL of 40 µg lead per dL blood for effects on adult neurological function and using an assessment factor of 2).

A summary of the DNELs for the general population outlined in the REACH registration is presented in Table B-25.

Table B-25. DNELs for the general population (REACH registration, 2015)

Exposure pattern	Route	Descriptors	DNEL/DMEL (appropriate unit)	Most sensitive endpoint
Acute - systemic effects	Dermal (mg/kg bw /day)	NA	NA	NA
	Inhalation (mg/m ³)	NA	NA	NA
	Oral (mg/kg bw /day)	NA	NA	NA
Acute - local effects	Dermal (mg/cm ²)	NA	NA	NA
	Inhalation (mg/m ³)	NA	NA	NA
Long-term - systemic effects Neurological function	Systemic (µg lead /dL blood)	NOAEL = 40 µg/dL NOAEL = 10 µg/dL	20 µg/dL 5 µg/dL	Adult neurological function Foetal development for a pregnant woman

Exposure pattern	Route	Descriptors	DNEL/DMEL (appropriate unit)	Most sensitive endpoint
		NOAEL = 5 µg/dL	5 µg/dL	IQ development in individual child
		NOAEL = 2 µg/dL	2 µg/dL	IQ development large population of children
Long-term local effects	Dermal (mg/cm ²)	NA	NA	NA
	Inhalation (mg/m ³)	NA	NA	NA

Notes General population includes consumers and humans via the environment. In rare cases it may also be relevant to derive a DNEL for specific subpopulations, such as children. In this case the table need to be repeated. In addition as the respiration rate is taken into account for the derivation of the DNEL, this table need to be repeated in case different exposure scenarios lead to different respiration rate.

However, the risk assessment for human health in this restriction proposal is based on a qualitative assessment, rather than a quantitative assessment using DNELs, due to the acknowledged non-threshold nature of the key effects.

B.6. Human health hazard assessment of physico-chemical properties

Not relevant for this Annex XV report.

B.7. Environmental hazard assessment

B.7.1. Compartment specific hazard assessment

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 previously in the EU voluntary risk assessment for lead and its compounds (LDAI, 2008).

In general, the toxicity of lead in the environment is dependent on the bioavailability of the specific lead substance or form (termed speciation) to which an organism is exposed. Relatively greater toxicity is usually associated with forms that have the greatest bioavailability in the environment, such as forms that are dissolved in aquatic systems, including the 'free-ion'.

Therefore, risk assessments undertaken for REACH registration, and in recent REACH restrictions for lead and its compounds have typically been underpinned by (read-across

from) hazard data derived from ecotoxicity tests that used dissolved forms of lead rather than metallic lead.

Metallic lead (sometimes termed 'massive' lead) transforms/dissociates to liberate soluble/bioavailable species of lead relatively slowly in the environment (see Section B.4). As such, metallic forms of lead are not usually considered to pose a significant ecotoxicological hazard in their own right, but rather act as source of other more mobile lead substances in the environment over time.

However, massive forms of lead (as used in lead gunshot) are known to pose a significant hazard to any bird that ingests it, particularly those bird species with muscular gizzards (such as many waterfowl) that act to 'grind down' any ingested metallic lead particles, enhancing dissolution and subsequent uptake. These hazards are closely associated with the ecology and physiology of particular bird species and the ecological niches (habitats) that they occupy.

As this restriction dossier is focussed on the specific risks to birds posed by the ingestion of spent lead gunshot, general 'compartment specific' ecotoxicity data are of limited relevance in this assessment and are not presented in detail. Instead, effects data directly relevant to the ingestion of lead shot by birds are presented.

For completeness, a summary of derived predicted no effect concentrations (PNECs) for key environmental compartments, collated from previous risk assessments for lead and its compounds, are provided in B.7.3.1. Full details can be obtained in REACH registration dossiers or the voluntary risk assessment report (LDAI, 2008).

B.7.2. Non compartment specific effects

B.7.2.1. Toxicity to birds

Lead poisoning³⁸ in birds (particularly water birds, including waterfowl) caused by the ingestion of lead gunshot has resulted in significant scientific and regulatory concern over many years, including as part of international agreements on wildlife conservation. As a result of these concerns, the use of lead in gunshot is already prohibited under certain circumstances in many countries, including many Member States of the European Union. Most typically in relation to its use to hunt waterfowl or within 'wetland areas'.

The scientific and grey literature describing the causes and consequences of lead poisoning in birds is extensive and comprehensive and would be prohibitive to summarise in detail. Therefore, the assessment presented in this restriction report is comprised of a summary of key data on lethal and sub-lethal avian toxicity resulting from the ingestion of lead gunshot³⁹. These data have been primarily identified from the large number of relevant expert scientific reviews and assessments available⁴⁰.

Where relevant, individual studies have been described in greater detail; as are recently published studies that have not yet been featured in review articles. Whilst every effort

³⁸ '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.

³⁹ In addition, certain species of mammals can be affected by lead poisoning. However, this is not analysed further in this restriction proposal e.g. lead has been reported as a cause of cattle poisoning (Payne et al., 2013)

⁴⁰ According to principle outlined in Annex I, para 0.5 of REACH "Available information from assessments carried out under other international and national programmes shall be included".

has been made to include all pertinent details of studies, readers should consult original source material for further information on individual studies. Where the scope of review articles includes both lead gunshot and lead bullets, only data referring to lead gunshot has been reported here.

The first extensive assessment of the complex relationship between lead poisoning and the use of lead shot for hunting, was initiated as early as the 1930s⁴¹ by the US Fish and Wildlife Service (USFWS). The USFWS subsequently produced two key reports on lead poisoning of birds that were used as the basis for the 1991 US ban on lead shot for hunting waterfowl:

- Final Environmental Statement (FES) on the Proposed Use of Steel Shot for Hunting Waterfowl in the United States, (USFWS, 1976).
- Final supplemental environmental impact statement (SEIS) on the use of lead shot for hunting migratory birds in the United States, (USFWS, 1986). This report incorporated data from the FES 1976 report and summarised additional information gathered on lead poisoning of endangered and non-endangered migratory birds from ingestion of lead gunshot.

The US authorities have subsequently released other information related to lead poisoning in birds, e.g. included in the *Field Manual of Wildlife Diseases, General Field Procedures and Diseases of Birds*⁴² (USGS, 1999).

Other relevant scientific reviews considered include: Bellrose (1959), Sanderson and Bellrose (1986), Rattner et al., (2008), Franson and Pain (2011), UNEP-CMS (2014c), Delahay and Spray (2015) including Pain et al. (2015), LAG (2015), Golden et al. (2016).

B.7.2.1.1. Primary and secondary ingestion of lead gunshot

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

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

⁴¹ http://www.nwhc.usgs.gov/disease_information/lead_poisoning/

⁴² http://www.nwhc.usgs.gov/publications/field_manual/

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-CMS, 2014c).

The primary ingestion exposure pathway has been extensively documented and reviewed (e.g. by Bellrose, 1959; Franson and Pain, 2011).

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 (wounded individuals that survive) differ between species, areas with different hunting pressures and the age of birds (Mateo 2009). Species susceptible to secondary ingestion (such as raptors) usually (based on their ecology) have delayed sexual maturity, therefore they may be poisoned before they reach breeding age.

The following sections describe the hazard of lead ingested via both primary and secondary ingestion. Unless there is a legitimate reason to describe the hazard posed by the two routes separately, they will be discussed together i.e. hazard to water birds (including waterfowl), predators and scavengers. The prevalence of lead shot ingestion in different bird species is described in Section B.9.1.6.

Whilst the primary and secondary ingestion of spent gunshot are considered to be the most significant routes of exposure for lead in gunshot to birds (Pain et al., 2015), and will be the principal focus of this assessment, other routes of exposure to lead from gunshot are also possible although they have been studied less intensively (Figure B-6), for example:

- Ingestion of soil, water, or invertebrate prey contaminated with lead that has dissolved from lead gunshot and entered the aquatic or terrestrial food chain.
- Absorption of lead that has dissolved from pellets shot into the tissues of animals that have been wounded but survived.

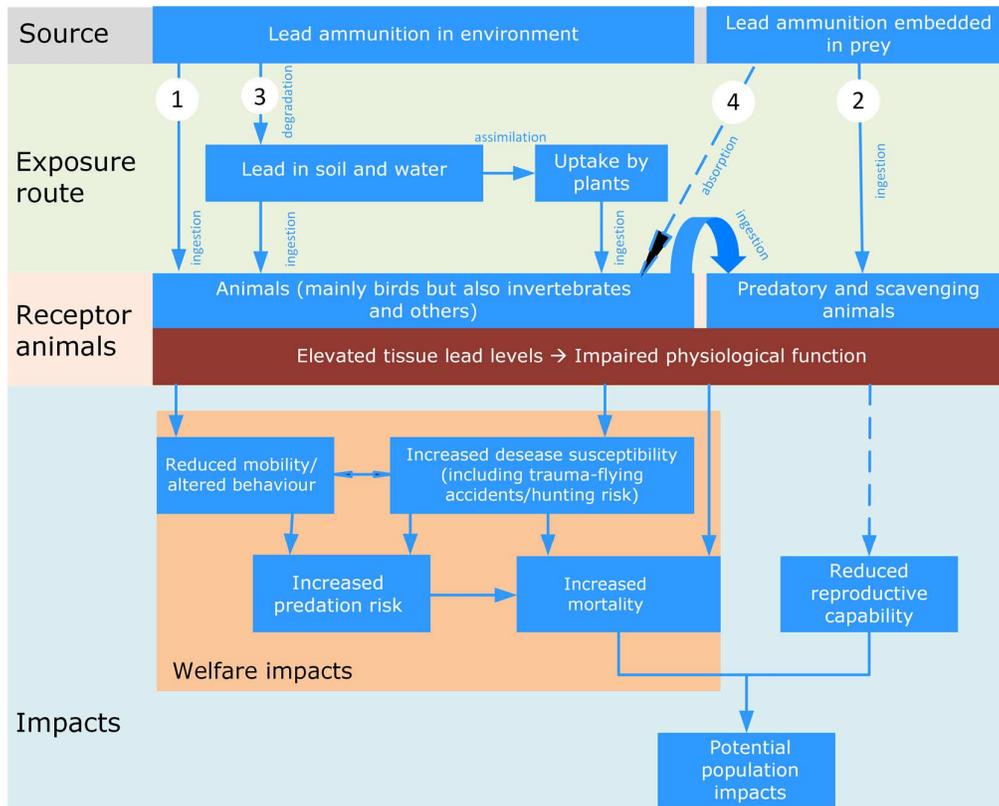


Figure B-6. Lead exposure routes and receptors animals (adapted from Pain et al. 2015)

B.7.2.1.2. Toxicokinetics

In general, the toxicokinetics of lead in birds are closely associated with the biochemical mechanisms and processes that regulate the absorption, distribution and metabolism of calcium. This is a result of the similarity of lead, in terms of atomic structure and mass, to calcium which leads to affinity to calcium uptake channels, enzymes and other biochemical processes that normally involve calcium (Simons, 1993). The lead ion is not metabolised or bio-transformed in birds, though it does form complexes with a variety of proteins and non-protein ligands. It is primarily absorbed, distributed and then the non-accumulated lead is excreted (WHO, 2003).

Absorption

Factors that influence the absorption of lead have been extensively investigated since the 1950s and reviewed by many authors including Pain and Green (2015). The uptake of lead by birds after ingestion of lead gunshot is known to vary depending on several factors, including the individual digestive physiology of different bird species.

The main factors affecting the absorption of lead include: stomach characteristics, retention time of lead in the gastrointestinal tract, diet and gender. These are outlined, below. However, the absorption of lead occurs in the intestine⁴³. Any lead ingested becomes more soluble in the stomach and after passing into the intestines, is absorbed as lead salts into the body of the bird (USFWS, 1986).

Stomach characteristics

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. A schematic drawing of the digestive tract of a goose is shown in Figure B-7.

⁴³ The dissolution of lead shot is enhanced in the acid environment of the avian stomach.

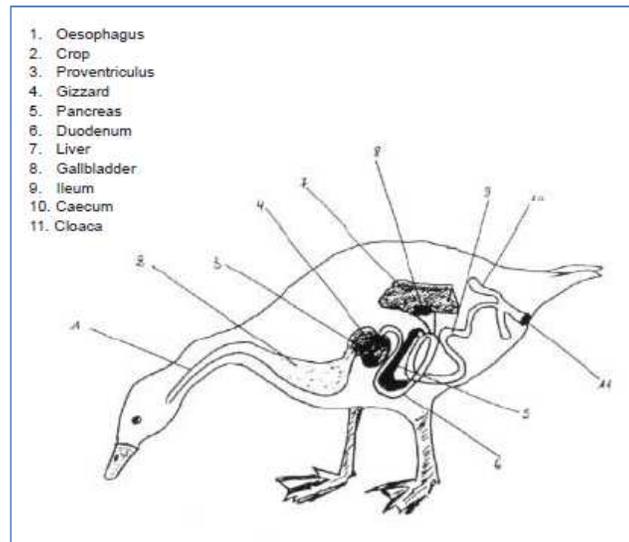


Figure B-7. Digestive tract of the geese (*Source: FAO, 1996*)

The characteristics of gizzards differ between species, e.g. the well-muscled gizzard of a geese can develop pressures of up to 275 mm Hg, which is significantly greater than the pressures of 180 and 125 mm Hg observed for ducks and hens, respectively (FAO, 1996). Species such as waterfowl that feed on coarse objects like grain or plant material have muscular gizzards for grinding that are larger than birds whose diet is largely meat (Farner, 1960, cited by Golden et al., 2016).

Grinding of ingested food material in the gizzard, whilst necessary for normal digestion, facilitates the erosion of any ingested lead gunshot, leading to greater absorption in the gastrointestinal tract than would occur if the gunshot pellets remained as ingested (Golden et al. 2016, citing Jordan and Bellrose, 1951). Thus, the particularity of avian digestive physiology is key factor in the lead poisoning observed in birds after the consumption of gunshot that would perhaps not be observed in other organisms (e.g. mammals).

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).

Retention time in the gastrointestinal tract

The anatomical characteristics of bird species differ and can influence the retention time and thus the absorption of ingested lead gunshot (Franson and Pain, 2011). Individual pieces of gunshot may either be rapidly regurgitated or, alternatively, passed through the gut resulting in limited absorption of lead. Other pieces may be retained within the gastrointestinal tract until completely dissolved and absorbed. Intermediate retention and absorption, between these two states, is also possible (Franson and Pain, 2011).

In general terms, 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 present in prey 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).

In addition, periodic reverse peristalsis moves the contents of the upper ileum and duodenum back into the stomach, an adaptation hypothesized to allow for greater digestion of nutrients without lengthening the gastrointestinal tract, which would be disadvantageous to flying due to added weight (Duke 1997, cited by Golden et al., 2016).

Figure B-8 shows the gizzard of a Canada goose, where both lead gunshot pellets and corn are clearly visible. Figure B-9 shows the erosion of lead shot in the gizzard after ingestion. Lead shot, originally spherical, have been worn down in the waterfowl gizzard. It is possible to note a flattened, disk-like, shape.



Figure B-8 The gizzard of a Canada goose with lead pellets and corn. *Image provided courtesy of the USGS National Wildlife Health Center (USGS, 1999. Field Manual of Wildlife Diseases: General Field Procedures and Diseases of Birds)*

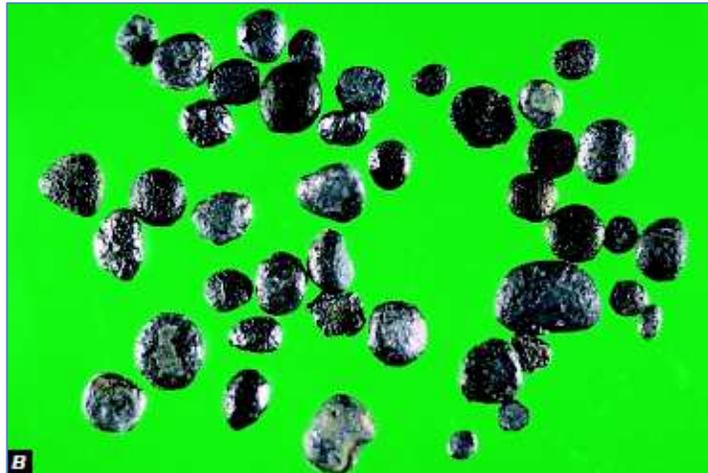


Figure B-9 Typical "eroded" lead pellets at different stages of erosion. *Image provided courtesy of the USGS National Wildlife Health Center (USGS, 1999. Field Manual of Wildlife Diseases: General Field Procedures and Diseases of Birds)*

Diet

The diet of birds is one of the most important factors in determining the extent of lead absorption after lead gunshot ingestion. In general, because of the grinding that occurs in the gizzard, 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.

The nutritional, chemical and physical characteristics of diet are known to affect lead absorption and subsequent deposition in tissues (Jordan and Bellrose, 1951; Longcore et al., 1974a; Sanderson and Irwin, 1976; Koranda et al., 1979, Sanderson and Bellrose, 1986; Scheuhammer, 1996 all cited by Franson and Pain 2011). Differences in the toxicity observed in similarly conducted experimental studies are thought to be related to differences in the diets used in the experiments (Rodriguez et al. 2010).

Diets high in protein and calcium are known to mitigate the effects of lead exposure (Koranda et al., 1979; Sanderson, 1992; Scheuhammer, 1996 all cited by Franson and Pain 2011). Calcareous grit consumption can reduce the rate of dissolution of ingested lead gunshot by reducing acidity within the gizzard (Martinez-Haro *et al.* 2009).

Other physiological factors

Taylor and Moore (1954 cited by USFWS, 1986), reported that the biochemical changes in female birds associated with active laying enhance the accumulation of lead in bones as does a calcium deficient diet. The medullary bones⁴⁴ of birds (i.e. tibia, femur, sternum, ilium, ischium and pubis) supply up to 50 percent of the calcium used in egg production and this rapid turnover of calcium in the laying bird leads to an increased deposition of lead in these bones (USFWS, 1986). Finley and Dieter (1978 cited by Golden et al., 2016), reported that lead concentrations in femurs of laying mallards (*Anas platyrhynchos*) were four times higher than in non-laying females.

When calcium is mobilised for eggshell formation, intestinal absorption of calcium, and concurrently lead, can increase, resulting in greater bone lead concentrations in similarly exposed females than in male birds (Scheuhammer, 1996 cited in Golden et al., 2016). A diet deficient in calcium increases lead absorption in female birds (Scheuhammer and Norris, 1996).

Distribution

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, in relation to the initial amount ingested and the time elapsed since initial ingestion. Lead

⁴⁴ i.e. reservoir of labile Ca for egg production

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).

Metabolism

Lead competes with calcium ions, resulting in substitution for calcium in bone. It also mimics or inhibits many cellular actions of calcium and alters calcium flux across membranes (Simons, 1993; Flora et al., 2006).

Calcium plays two important physiological roles in birds. It provides the structural strength of the avian skeleton and plays a vital role in many of the biochemical reactions within the body via its concentration in the extracellular fluid (Dacke, 2000; Harrison and Lightfoot, 2006⁴⁵).

The control of calcium metabolism in birds has developed into a highly efficient homeostatic system, able to quickly respond to increased demands for calcium during egg production and during rapid growth rate when young (Bentley, 1998).

There are distinct differences between the mammalian and avian systemic regulations of calcium. The most dramatic difference between the two groups is in the rate of skeletal metabolism at times of demand. This is best demonstrated by an egg-laying bird where 10 % of the total body calcium reserves can be required for egg production within a 24-hour period (Klasing, 1998). The calcium required for eggshell production is mainly obtained from increased intestinal absorption and a highly labile reservoir found in the medullary bone. The homeostatic control of the medullary bone involves oestrogen activity (Bentley, 1998).

Lead also binds to sulfhydryl groups in proteins and breaks disulphide bonds that are important for maintaining proper conformation for biological activity. In addition, it can alter many enzymes via its competing effects with other cations, such as ferrous iron and zinc (Speer, 2015).

Effects on specific targets are described in the section describing sub-lethal effects.

Elimination

In general, some of the lead absorbed will be eliminated from the body in waste, but with continuous or repeated exposure some absorbed lead will continue to be retained and bone lead concentrations will increase (Pain and Green, 2015; LAG Appendix 4).

Summary on toxicokinetics

Birds readily ingest lead gunshot through either primary or secondary ingestion. Avian physiology can facilitate the dissolution of lead gunshot and absorption into tissue. Lead competes with calcium ions, resulting in substitution for calcium in bone. It also mimics or inhibits many cellular actions of calcium and alters calcium flux across membranes.

Diet is one of the most important factors determining the severity of lead absorption. However, in addition to diet, there are a number of physiological factors influencing the

⁴⁵ Clinical Avian Medicine - Volume I, chapter 5, calcium metabolism, Michael Stanford.

uptake of lead, e.g. digestive physiology and gender differences (laying females are more susceptible to lead poisoning than male and non-laying females).

After absorption, lead will distribute into various tissue compartments such as blood, soft tissue, bone and feathers. Lead accumulation is greatest in liver and kidney but some accumulation can occasionally also be observed in muscle tissue. Lead in bone is relatively immobile (other than during breeding seasons for females as discussed) accumulating over an animal's lifetime.

B.7.2.2. Lethal and sub-lethal effects

The toxic effects of lead are broadly similar in all vertebrates. These effects are well known from many experimental and field studies and have been the subject of many reviews (e.g. Eisler, 1988; Pattee and Pain 2003; Franson and Pain 2011; Ma, 2011; cited in Pain et al., 2015).

Many toxicological studies with lead shot have been conducted using captive birds. These studies have involved species from various taxa, particularly wildfowl species but some studies have investigated effects on predatory and scavenging species. These studies typically involve dosing of birds with lead gunshot and subsequent monitoring of blood lead concentrations and physiological and other clinical signs, such as altered behaviour (e.g. Hoffman et al. 1981, 1985, reviewed in Eisler 1988, Pattee and Pain 2003, Franson and Pain 2011 cited in Pain et al., 2015; Golden et al. 2016). Many authors have reported the signs of lead poisoning in birds and the dose of lead gunshot necessary to result in either lethal or sub-lethal effects (Locke and Thomas, 1996; Rattner et al., 2008; Franson and Pain, 2011; Franson and Russell, 2014, all cited in Golden et al., 2016; Rodriguez et al., 2010).

B.7.2.2.1. Lethal effects (*occurring after either acute or chronic exposure*)

Lethal effects can result from either acute or chronic 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). Mortality generally occurs rapidly after ingestion without the bird becoming noticeably intoxicated⁴⁶, 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 (average time to death of approximately 20 days). The timelines and main signs that characterise chronic lethal lead poisoning are summarised in Table B-26 (after USFWS, 1986).

One of the first signs of chronic lethal poisoning is the occurrence of a diarrhoea characterised by brilliant, almost fluorescent, green staining of the faeces and the feathers

⁴⁶ Signs of lead intoxication often include wing and tail droop, weakness, anaemia, bile staining of gizzard and vent, emaciation, etc.

around the vent. There is an increasing muscular weakness characterised at first by the abnormal positioning of the wings, followed by a progressive loss of flight. Lead-poisoned waterfowl that are still able to fly do so weakly, often dropping to the ground after going only a short distance. Lead-poisoned waterfowl often exhibit a voice change.

As the condition worsens the bird becomes weaker, loses its ability to walk or fly and seeks refuge in dense cover. Untrained observers often mistakenly believe that lead poisoned birds are "cripples". Finally, the bird loses the ability to swim, or even to walk, and if not caught and eaten by a predator, the bird becomes comatose and dies.

Affected birds lose 30-40, sometimes 60 percent of their weight. Subcutaneous, abdominal and coronary fat deposits are lost and the breast muscles undergo a marked atrophy (wasting away), resulting in the classical "hatchet-breast". These findings have often led untrained observers to believe the birds have died of starvation. The oesophagus is often packed throughout a major portion or its entire length with undigested food. This "impaction" may extend from the angle of the jaw, along the entire length of the neck, into the thoracic (chest) cavity and to the gizzard. Weakened and emaciated lead-poisoned birds, if picked up, will often die after a few brief struggles.

Table B-26. Signs and timeline of chronic lethal lead 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 ⁴⁷ 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.

Birds affected by chronic lethal poisoning often exhibit marked myocardial damage (necrosis of the surface of the heart). Sileo et al.,1973, cited in USFWS, (1986), reported that lead-poisoned Canada geese exhibit electrocardiographic changes similar to those seen in humans suffering from myocardial infarction (i.e. a "heart attack"). Internally, necropsy reveals an emaciated carcass, often with liver atrophy, an enlarged gall bladder distended with thick, dark-green bile and, frequently, an impaction (congestion with food)

⁴⁷ Acid-fast intranuclear inclusion bodies are often present as an early manifestation of lead toxicity (USFWS, 1986).

of the oesophagus, proventriculus and/or gizzard (Locke and Thomas, 1996; Rattner et al., 2008; Franson and Pain, 2011; Franson and Russell, 2014 cited in Golden et al., 2016).

Golden et al. (2016), reported that in a study of 421 lead poisoned waterfowl of various species (Beyer et al. 1998), the most reliable gross indications of lead poisoning were impactions of the alimentary tract, submandibular oedema, necrosis of heart muscle and bile staining of the liver.

Figure B-10 compares the gizzard lining of a lead-poisoned versus a non-poisoned mallard (*Anas platyrhynchos*).

Figure B-11 shows lesions in the gizzard due to lead poisoning together with lead pellets, mixed with grit. The gizzard lining has split (see arrow) because the tissue has become very brittle and it is stained dark-green by regurgitated bile. Frequently, lead shot can be recovered from the lumen of the gizzard.



Figure B-10 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 Centre (USGS, 1999).*

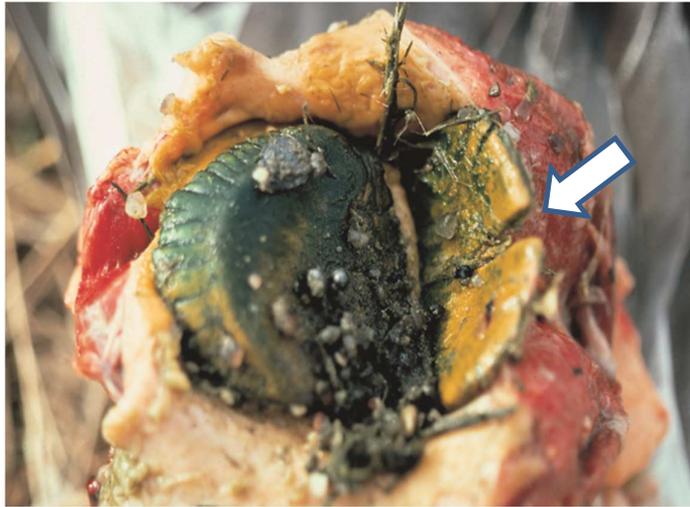


Figure B-11 Lesions in the gizzard (indicated by arrow) of a lead poisoned mallard. *Image provided courtesy of the USGS National Wildlife Health Centre (USGS, 1999)*

Bellrose (1959) reported the results of a series of large scale field experiments into the effects of lead gunshot ingestion on survival, migration and hunting vulnerability in mallards conducted over the course of 1949 to 1955 at Chautauqua National Wildlife Refuge, Illinois. Over the course of these experiments several thousand wild mallards were captured, dosed with lead shot, marked (banded), released and their long-term survival monitored based on their 'recovery' by hunters over the following four seasons.

Over the winters of 1949, 1950 and 1951, groups of wild caught mallards were dosed with either one, two, four or six 'number six' shot pellets and released. On each occasion a control group was marked and released, but were not dosed. During the 1949 and 1950 programmes, mallards were pre-screened using X-ray fluoroscopy to identify individuals that had previously ingested lead gunshot with individuals identified as having previously ingested lead gunshot excluded from the dosing study. Technical difficulties prevented screening during the 1951 programme. Treatment groups primarily comprised adult and juvenile males, dependent on the year of study. A smaller number of studies with female mallards were undertaken.

'Vulnerability' to hunting after ingestion of lead gunshot was also estimated based on the ratio of dosed to non-dosed birds recovered by hunters in the season of banding. Adult drakes were reported to be up to twice as vulnerable to hunting as control animals (Table B-27 Summary of Bellrose (1959) hunting vulnerability release and recovery experiments undertaken at Chautauqua National Wildlife Refuge, Illinois during the autumn and winter of 1949, 1950 and 1951 (after Bellrose, 1959).Table B-27).

Table B-27 Summary of Bellrose (1959) hunting vulnerability release and recovery experiments undertaken at Chautauqua National Wildlife Refuge, Illinois during the autumn and winter of 1949, 1950 and 1951 (after Bellrose, 1959).

Year	Number banded				Number recovered				Relative vulnerability to hunting (dosed: control)		
	Control	Dose (pellets)			Control	Dose (pellets)			1	2	4
		1	2	4		1	2	4			
1949 ^a	560	559	-	-	19	35	-	-	1.84:1.00	-	-
1950 ^b	389	391	392	-	50	60	95	-	1.19:1.00	1.89:1.00	-
1951 ^b	507	504	-	504	47	66	-	99	1.41:1.00	-	2.12:1.00
Total	1 456	1455	392	504	116	161	95	99			

Notes – a: adult drakes; b: adult and juvenile drakes

'Year-of-banding' mortality rates for each treatment group were estimated based on the number of mallards recovered in the year of banding compared to the total number of mallards from within the same treatment group recovered over the subsequent four year period (Table B-28). Average mortality rates were calculated from similar experiments undertaken in different years.

In male mallards, ingestion of one number six gunshot increased mortality rate relative to controls by approximately 9 %, two pellets by approximately 23 %, four pellets by approximately 36 % and six pellets by approximately 50 %. Bellrose concluded that, based on the relatively few studies conducted with female mallards, it was more difficult to appraise the mortality rates in lead poisoning in females but that the available data suggest that among males and females with identical ingested shot levels, females probably suffer twice as much mortality in the autumn and a small fraction of the mortality observed in males in the late winter and the spring.

These 'prevalence-related' mortality rates were then applied to data on the prevalence of shot ingestion in the North American mallard population in a sample of hunter shot birds from the Mississippi flyway to estimate the total annual mortality associated with lead gunshot ingestion.

Observations of lead shot ingestion prevalence in hunter collected birds were first 'corrected' to account for the greater vulnerability of lead poisoned birds to hunting (as observed in the Chautauqua National Wildlife Refuge studies) and for the 'turnover' of lead gunshot in the gizzards of mallards derived from observations of the typical elimination/retention behaviour of lead gunshot in captive wild-caught mallards dosed with one or more number six gunshot⁴⁸.

The turnover correction is based on empirical observations of a typical lead gunshot retention time in mallard of 20 days. Therefore, observations of gunshot prevalence in samples of hunter collected mallards during a 120 day hunting season should be corrected

⁴⁸ factor of six, estimated from a mean turnover of 20 days in a mallard

using a factor of 6 (120/20 = 6) to be representative of levels of ingestion in the underlying population.

Specific mortality rates were then calculated in seven classes dependent on the number of ingested lead shot, corrected for hunting bias and lead shot turnover (Table B-29). 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 %.

Table B-28. Summary of 'year-of-banding' mortality rate experiments Chautauqua National Wildlife Refuge, Illinois during the autumn and winter of 1949, 1950 and 1951 (after Bellrose, 1959).

Year	Sex	Age	Dose (pellet)	N° banded	Recovery in year of banding		Recovery 4 years after banding		Mortality rate (%) ^b	
					n	%	n	%	Year of banding	Dosed vs control
1949	M	A	0	560	19	3.39	143	25.53	13.3	-
	M	A	1	559	35	6.26	155	27.73	22.6	9.3
1950	M	A	0	278	33	11.87	106	38.13	31.1	-
	M	A	1	274	45	16.42	103	37.59	43.7	12.6
	M	A	2	277	74	26.71	99	35.74	74.7	43.6
	M	J	0	111	17	15.32	43	38.74	39.5	-
	M	J	1	117	15	12.82	35	29.91	42.9	3.4
	M	J	2	115	21	18.26	49	42.61	42.9	3.4
	M ^a	A	0	200	-	-	56	28.0	-	-
	M ^a	A	6	200	-	-	19	9.5	-	-
1951	M	A	0	300	24	8.00	77	25.67	31.2	-
	M	A	1	324	42	12.96	91	28.09	46.2	15.0
	M	A	4	284	58	20.42	80	28.17	72.5	41.3
	M	J	0	207	23	11.11	73	35.27	31.5	-
	M	J	1	180	24	13.33	66	36.67	36.4	4.9
	M	J	4	220	41	18.64	65	29.55	63.1	31.6

Notes – a: mallards released from Rocky Mountain Arsenal, Denver, Colorado. The difference in band recoveries between control and treatment groups provide an index to the magnitude of mortality caused by the ingestion of 6 number 6 lead gunshot (approximately 3 to 1); b: 'average' mortality rate increase calculated as the mean of the treatment related difference in mortality observed between adults and juveniles e.g. increase in mortality associated with the ingestion of a single lead gunshot is calculated as the mean of "12.6-3.4 %" and "15.0-4.9 %" = 9.3 % (juveniles are less susceptible to lead poisoning because of their greater food consumption).

Table B-29. 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

RAC box:

During their evaluation, RAC questioned the reliability of the statistical methodology reported by Bellrose (1959), and considered that the reassessment of the Bellrose data using contemporary statistical methods reported by Green⁴⁹ was a more robust basis for estimating the mortality associated with the ingestion of different quantities of lead gunshot in mallards. However, acknowledging the large confidence intervals associated with Green's estimates and the relatively small differences between the central estimates reported by Bellrose and Green, RAC agrees with the approach of the Dossier Submitter to use estimates of annual mortality underpinned by the Bellrose mortality rates for further calculations of EU waterbird mortality from ingestion of lead gunshot. Further details of the RAC evaluation are provided in the RAC opinion.

More recently, Rodriguez et al. (2010) published a comprehensive study on lead toxicity in mallards (*Anas platyrhynchos*). Forty captive mallards of both sexes were separated into five groups and dosed with lead shot; one group was used as a control. Eight birds were dosed with one lead shot, of which half died. Two other groups of eight birds were dosed with either one or two shot on day zero (the first day of dosing), followed by a further single shot on day 70. In these two groups blood lead concentration increased to a greater extent after the second (repeat) lead dosage than after the first. Similarly, the birds' general condition worsened to a greater extent after the second dose than in response to the first shot. However, this relatively greater response was not observed in a fourth group that was given a higher dose of three shot on day zero, followed by one shot on day 70. In all groups subjected to a repeat lead dosage, deaths were recorded

⁴⁹ Submitted in ECHA's public consultation (comment #1612).

after the second dose. In about 90 % of the experimentally dosed mallards, administered shot was retained in the gizzard until it degraded, which took approximately 30 days.

The pattern and severity of clinical signs prior to death in the dosed groups were similar, regardless of the amount of lead ingested and included weight loss (91 %), anorexia (73 %), diarrhoea (73 %), abnormal positions (drop of tail and wings, abduction of one leg, and/or neck "s" lateral shape) associated with motor problems (54 %), in addition to reduced or absent reaction to external stimulus (human presence, light, and sound; 54 %). Further effects were also observed at necropsy: macroscopic signs of anaemia (18 %), compression of the gizzard (36 %), haemorrhagic enteritis (36 %), bile-stained gizzard (27 %), cerebral congestion (27 %), congestion of oesophagus, crop, and proventriculus (18 %) and hepatic congestion (18 %). Control birds all survived with normal blood lead levels.

Pattee et al. (1981) dosed five captive bald eagles (*Haliaeetus leucocephalus*) with lead shot. Initial dosage consisted of 10 (n.4) lead shot. Additional groups of 10 shot were given if all of the previous 10 shot were regurgitated. Frequent radiographs were taken to confirm the presence or absence of shot prior to additional doses. Lead shot dosage and response of each eagle are summarised in Table B-30.

Table B-30. Lead-shot dosage and response of each dosed eagle (after Pattee et al., 1981).

Eagle	Total shot given	Days to death
A	10	20
B	30	10
C	20	12
D	156	125
E	80	133

Four birds died and the fifth became blind and was sacrificed after 133 days. Individual responses to lead-shot ingestion were very variable. The authors found that the interaction of factors such as the duration of shot retention, number of shot retained and amount of lead eroded appeared to affect the time to death. They concluded that while healthy eagles may regurgitate lead shot and survive occasional exposure, repeat exposure of birds would increase the likelihood of reaching a threshold where the eagle would stop eating, retain the ingested shot and die. This threshold may be related to lead erosion rates and shot retention, but the exact factors remain unclear.

Field evidence for bird mortality from lead poisoning

The apparent lack of dead birds in an area does not necessarily indicate that lead poisoning is not occurring as mortality of wild birds is not always easily detected. This has been extensively discussed by USFWS (1986) and is due to several reasons:

- the latency period between ingestion and mortality
- the nature of lead poisoning itself
- the behaviour of lead-poisoned ducks
- lead-poisoned ducks are typically mistaken as "cripples".

The average time to death of waterfowl after lead shot ingestion is approximately three weeks. During this period, the mobility of the affected birds is reduced and they are easy prey for a variety of predators. Lead intoxicated birds seek isolation and protective cover, further reducing their visibility. Studies have shown that duck carcasses are usually scavenged in a matter of days (USFWS, 1986). The effects of lead poisoning may be confused with losses from crippling or those thought to be a result of starvation or some other cause (USFWS, 1986).

Many studies have confirmed the findings described in USFWS (1986). Scheuhammer (1987) and Newth et al. (2012) noted that mortality from lead poisoning may often result in frequent and mainly invisible losses of small numbers of birds that remain undetected. Poisoned birds often become reclusive and carcasses may be scavenged before being detected (Sanderson and Bellrose, 1986; Stutzenbaker et al., 1986, cited by Pain 1991; Pain, 1991; Newth et al., 2012). This supports the potential for risks to scavengers. In addition, in case of acute lethal poisoning, birds may die without showing typical pathology (see Section B.7.2.2.1). In these cases their death may be mistakenly attributed to another cause (Beyer et al. 1998a, Newth et al. 2012).

Summary

Ingestion of lead gunshot causes mortality in birds. Ingestion of a single lead gunshot may be sufficient to cause the mortality of a small-sized duck (Guillemain et al., 2007), although greater quantities are likely to be required to cause mortality in larger birds, such as geese and swans.

The time to death after ingestion of lead gunshot in experimental studies varies between species and dosage regime, with waterfowl generally succumbing within 2–4 weeks of exposure whilst some raptors survive for more than 15 weeks prior to death (Barrett and Karstad, 1971; Pattee et al., 1981; Franson et al., 1986; Beyer et al., 1998; cited in Golden et al. 2016).

An example of typical visible signs (e.g. abnormal positioning of the wings and neck) of acute lead poisoning in a dying whooper swan (*Cygnus cygnus*), is provided in Figure B-12.



Figure B-12. Typical signs (e.g. abnormal positioning of the wings and neck) of acute lead poisoning in a whooper swan (*Cygnus cygnus*). Eroded lead was subsequently found in the bird's gizzard (during necropsy). *Image provided courtesy of WWT (Wildfowl & Wetlands Trust).*

B.7.2.2.2. Sub-lethal effects (occurring after both acute or chronic exposure)

Sub-lethal effects occur as a consequence of acute exposure and of chronic exposure to lead at a level that is not necessarily likely to result in immediate mortality; although death may eventually result from another cause.

While some sub-lethal effects alter health directly, others may render birds more susceptible to causes of mortality such as predation, hunting mortality, collisions with objects, and illness or death from disease (Golden et al., 2016).

Haematological and cardiovascular effects

Lead poisoning in waterfowl, as in other animals, is characterised by the accumulation of non-haeme iron and abnormal blood pigments in malformed red blood cells, often leading to a severe anaemic condition. The resulting anaemia causes a decrease in the amount of oxygen available to the various tissues and, if prolonged, results in progressive weakness, illness and can result in neurological abnormalities and death.

Lead inhibits the activity of at least two major enzymes in the haemoglobin biosynthetic pathway i.e., delta-aminolevulinic acid dehydratase (ALAD or d-ALAD) and haeme synthetase (ferrochelatase) (USFWS, 1986).

The inhibition of ALAD, is considered to be sensitive biomarker of lead exposure in wild birds (Finley et al., 1976; cited in Golden et al., 2016; Locke and Thomas, 1996). Birds tolerate some reduction of ALAD activity without showing signs of reduced haematocrit or haemoglobin concentration, although anaemia may occur following sustained low level ALAD inhibition. Rapid decreases in hematocrit after exposure to a large amount of lead may be associated with haemolytic anaemia, as well as severe (e.g., > 75 %) ALAD inhibition (Pain and Rattner 1988, Mateo et al., 2003; as cited by Franson and Pain 2011).

Lead also inhibits ferrochelatase (haeme synthetase), an enzyme responsible for combining ferrous iron and protoporphyrin IX (PPIX) to form haeme. Blood lead and PPIX concentrations may remain elevated and ALAD activity may remain depressed for several weeks to as long as three months after exposure, as shown in lead shot dosing studies with mallards (*Anas platyrhynchos*) and canvasbacks (*Aythya valisineria*) (Finley and Dieter, 1978; Roscoe et al., 1979 ; Franson et al., 1986, as cited by Golden et al., 2016).

Inhibition of ferrochelatase results in the accumulation of PPIX in the erythrocytes, and its quantification in blood samples has been used as an indicator of lead exposure in birds (Roscoe et al., 1979; Franson et al., 1996, as cited by Golden et al., 2016). Bald eagles dosed with lead shot lost weight and showed reduced haematocrit, haemoglobin, and ALAD activity, as well as changes in serum biochemistries (Hoffman et al., 1981; Pattee et al., 1981, as cited by Golden et al., 2016).

Exposure to lead not only inhibits the production of haemoglobin, but results in abnormal surface membranes in red blood cells (erythrocytes). These erythrocytes are unable to effectively transport oxygen. In addition, abnormal erythrocytes are short-lived and are broken down much more rapidly than normal red blood cells, leading to an accumulation of iron-bearing pigment (hemosiderin) in tissues, particularly in the liver, thus resulting in a condition called hemosiderosis (USFWS, 1986).

Anaemia can lead to damage to the walls of blood vessels and subsequent atrophy of muscles in the heart, resulting in myocardial infarcts (dead portions of heart muscle resulting from blockages of the small arteries going to the heart muscle).

Kidney effects

Locke et al. (1966, cited in USFWS, 1986), reported the presence of 'acid-fast intranuclear inclusion bodies' in histologic sections (also termed 'renal inclusions') of kidney tissue from lead poisoned mallards (*Anas platyrhynchos*). These structures occur within the nuclei of cells in the proximal convoluted tubules of the kidney. This segment (the proximal convoluted tubule) is responsible for the resorption of water, simple sugars and other essential nutrients from the renal filtrate, thus, preserving them for use by the body. Lead interferes with the functioning of these tubular cells causing the lead-poisoned animal to lose excessive water, amino acids, salts and simple sugars in its urinary wastes (USFWS, 1986).

Other gross and microscopic lesions noted with lead poisoning are non-specific and may be observed in association with other conditions, but only lead exposure is known to produce acid-fast intranuclear inclusion bodies in the kidneys of birds. However, even though the presence of renal inclusion bodies are indicative of lead poisoning, they are not present in all cases. (Golden et al., 2016).

Renal inclusions have been reported in different species of birds poisoned by lead, including mute swans (*Cygnus olor*), whooper swans (*Cygnus cygnus*), white-tailed eagle (*Haliaeetus albicilla*) (Simpson et al., 1979; Ochiai et al., 1992; Kenntner et al., 2001; Franson and Russell, 2014, as cited by Golden et al., 2016).

Effects on body condition (weight loss)

Migrating birds can travel thousands of kilometres between summer breeding areas and wintering sites. Migratory journeys impose very high energetic demands since uninterrupted flight may even last several days (e.g. Battley et al., 2000) during which time birds rely exclusively on body energy stores. Due to the birds' ecology, reduction in body weight might affect migratory birds' survival.

Newth et al. (2016) have recently established a relationship between blood lead levels and body condition in free-living whooper swans. In this study, body condition is taken as a measure of the energy capital accumulated in the body, which is assumed to be an indicator of an animal's health (Peig and Green, 2009, cited by Newth et al., 2016). Newth et al. (2016) reported a significant association between blood lead concentration and reduced winter body condition above blood lead concentrations of $44 \mu\text{g dL}^{-1}$. 10 % of the whooper swans had concentrations above this level. More details about this study are available in the risk characterisation chapter. Franson and Pain (2011) had previously estimated the range of blood lead levels within which Anseriformes are predicted to exhibit clinical signs of poisoning, including weight loss, (leading to probable death) at 50-100 $\mu\text{g/dL}$.

Neurotoxicological effects

Neurotoxic effects in response to lead exposure have been extensively observed in birds including on learning and memory. In several experiments made by Burger and Gochfeld (2000, cited by Golden et al., 2016), with young common terns (*Sterna hirundo*) and

herring gulls (*Larus argentatus*), lead exacted behavioural changes on a number of parameters relevant to a chick's survival in the wild e.g. locomotion, begging behaviour, individual recognition, balance, depth perception, behavioural thermoregulation. Burger and Gochfeld (2000) repeated the tests in the field and in lead-injected chicks; both showed similar behavioural deficits and a higher susceptibility to predation.

In addition, lethargy, wing droop, ataxia, anorexia, leg paralysis, and convulsions have been reported as typical signs of lead poisoning (Locke and Thomas, 1996; Rattner et al., 2008; Franson and Pain; 2011). Bellrose (1959) reported that mallards dosed with lead shot and released were 1.5 times more vulnerable to being shot by hunters than controls.

As mentioned in the metabolism section, in the avian body, lead mimics calcium and substitutes for it in many fundamental cellular processes, including nervous-system function (Simons 1993, Flora et al., 2006). Peraza et al. (1998 cited by Golden et al., 2016), noted that the disruption in calcium metabolism can result in neurologic and neuromuscular effects via induction or inhibition of neurotransmitter release, alteration of channels or pumps, and interference with protein kinases.

Effects on immune function

The effect of lead on the immune system of waterfowl has been studied in several field and experimental studies. Rocke and Samuel (1991) studied the effects on mallards exposed in the field to lead shot. Lead-exposed males showed lower spleen mass and levels of circulating white blood cells. Heterophils and, to a lesser extent, lymphocytes and monocytes were the cell types most affected. None of the birds exhibited clinical signs of lead poisoning, which indicates that these effects on the immune system can occur at sub-lethal levels of lead exposure (Rocke and Samuel, 1991). In the same study, mallards experimentally dosed with two pellets of N° 4 lead gunshot also showed reduced spleen mass and levels of circulating white blood cells. Blood and liver lead levels were negatively correlated with monocytes numbers. The number of spleen plaque-forming cells (SPFC) was reduced in the experimentally dosed birds, which indicates an effect on antibody-forming cells after the challenge to specific antigens. Number of SPFC and lead levels in blood and liver in mallards were negatively correlated (Rocke and Samuel 1991).

Trust et al. (1990) experimentally exposed mallards to one lead shot of N° 4 and reported a reduction of the antibody production after a challenge to a specific antigen.

Lead shot ingestion in birds can result in maternal transfer to the offspring that can affect their developing immune system and reduce their survival in early life stages (Vallverdú-Coll et al., 2015b). The authors studied the developmental effect of lead in mallard ducklings hatched from field collected eggs in the Ebro delta (Spain). Blood lead concentration in ducklings was negatively correlated with the skin reaction after subcutaneous injection of phytohaemagglutinin, which indicates a negative effect of lead on the T-cell-dependent immune response of ducklings. Duckling with the greatest blood lead concentrations also showed greater levels of antibodies after a challenge to a specific antigen that can respond to the imbalance produced by lead on Th1/Th2 cells as observed in other studies.

This effect on components of the constitutive immunity have been also experimentally observed after lead gunshot exposure (Vallverdú-Coll et al., 2015a). More recently, Vallverdú-Coll et al. (2016a) also found that blood lead concentrations in wild mallards

were positively related to haemolytic activity of circulating immune system components and negatively related to lysozyme levels.

Effects on reproduction and development

Maternal transfer of lead to chicks can be significant in species with elevated prevalence of lead shot ingestion, as in the case of marbled teals (*Marmaronetta angustirostris*), in which maternal lead transfer has been suggested to be a significant source of exposure for young birds (Mateo et al., 2001).

Juveniles are more susceptible than adults to lead poisoning. This is a consequence of relatively greater lead uptake, incomplete development of detoxifying metabolic pathways and age related differences in the permeability of the blood-brain barrier (Hoffman et al, 2002)

Lead can disrupt the blood–brain barrier in immature animals allowing the entrance of molecules, water, and ions otherwise excluded, leading to cephalic oedema, a condition observed in lead poisoned geese (Locke and Thomas, 1996).

Reduced brain weight has been associated with lead exposure in young mallards (*Anas platyrhynchos*) and American kestrels (*Falco sparverius*), (Hoffman et al., 1985; Douglas-Stroebe et al., 2004; cited by Golden et al., 2016).

Vallverdú-Coll et al. (2015b) studied the developmental effect of lead in mallard ducklings hatched from field collected eggs in the Ebro delta (Spain). The prevalence of lead shot ingestion in this wetland was around 30 %, so mallard hens could frequently be exposed to lead shot before and during the laying season. Lead concentrations in eggshells and blood in ducklings were positively correlated, and both negatively correlated with the activity of d-ALAD. Ducklings with blood lead levels above 180 ng/mL showed reduced body mass and died during the first week post hatching.

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

B.7.3. PNEC derivation and other hazard conclusions

B.7.3.1. PNEC derivation for environmental compartments

Table B-31 Overview of predicted -no effect-concentrations (PNEC values) for the European environmental compartments (Data compilation from by LDAI, 2008; CSRs 2015)

Compartment	LDAI (2008)	CSRs (2015)
PNEC_{freshwater}	<p>PNEC: 4.0 (µg Pb dissolved/L)</p> <p>Species mean HC₅* (log normal distribution, EC₁₆/2 value of 13.5 µg/L for <i>Daphnia magna</i> included in the dataset) = 8.0 µg/L; AF**= 2</p>	<p>PNEC: 3.1 (µg Pb dissolved/L)</p> <p>Based on the use of a species sensitivity distribution approach. A reasonable worst case for freshwater PNEC derived from the HC₅-50 value of 6.2 µg dissolved Pb/L and AF=2.</p>

Compartment	LDAI (2008)	CSRs (2015)
PNEC_{marine}	No PNEC value is provided At TCNES II 07 it was agreed that due to the limited availability of marine toxicity data, further work was required before a robust PNEC could be set.	PNEC: 3.5 (µg Pb dissolved/L) A reasonable worst case for freshwater PNEC derived from the HC5-50 value of 7 µg dissolved Pb/L and AF=2.
PNEC_{sediment}	PNEC: 174 (mg Pb/kg dry wt) Species mean HC ₅ * (log normal distribution)= 522 mg/kg dw; AF**= 3	
PNEC_{sediment bioavailable}	PNEC: 81.0 (mg Pb/kg dry wt) In the VRAL of lead (2008) the statistical distribution method has been used to derive a PNEC bioavailable of 81 mg/kg dry wt. (Species mean HC ₅ * (log normal distribution) of toxicity data expressed as bioavailable Pb = 244 mg/kg dw; AF**= 3)	PNEC: 41 (mg Pb/kg dry wt) SCHER (2009) recommended the use of the classical AF factor approach applying a factor of 10 to the lowest unbounded bioavailable NOEC. In this case the lowest NOEC was 2.0 µmol excess Pb/g dry wt, resulting in a bioavailable PNEC of 0.2 µmol excess Pb/g dry wt or 41 mg Pb/kg dry wt.
PNEC_{sewage treatment plant}	PNEC: 100 (mg/L) According to the assessment performed in the VRAL (LDAI, 2008) an assessment factor of 10 was used for the derivation of PNEC for sewage treatment plant resulting in a PNEC of 0.1 mg/L. This value also recorded in the CSRs	
PNEC_{micro-organisms}	PNEC: 100 (µg Pb dissolved/L) dissolved fraction only; AF**= 10	
PNEC_{soil}	PNEC: 166 (mg Pb/kg dry wt). Species mean HC ₅ * (log normal distribution) = 333 mg/kg dw; AF**= 2	PNEC: 212 (mg Pb/kg dry wt) The generic aged PNEC is 212 mg Pb/kg dry soil (statistical extrapolation method with the log-normal distribution). Taking into account bioavailability of Pb in soil results in PNEC values between 170 and 440 mg Pb/kg soil for the 10 th and 90 th percentile of the eCEC in European arable soils

*HC₅: Hazardous Concentration 5 % (Concentration of a compound that is hazardous to 5 % of the organisms/population tested) **Assessment Factor (AF) (LDAI, 2008).

Lead is identified as a Priority Substance (PS) under the Water Framework Directive (WFD - 2000/60/EC)⁵⁰. The annual average environmental quality standard (EQS) for lead in European freshwaters is currently 7.2 µg/L. A revised limit of 1.2 µg/L bioavailable lead in

⁵⁰ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy [OJ L327 of 22.12.2000].

freshwaters was proposed in January 2012, as part of a wider package of revisions to WFD EQS.

B.7.3.2. PNEC derivation for non-compartment specific hazards

B.7.3.2.1. PNECs for secondary poisoning in REACH Registration CSR

Table B-32 PNECs for secondary poisoning.

Compartment	Value	Reference
PNEC_{oral} (secondary poisoning)	<p>PNEC_{oral} = 10.9 mg/kg food (mammals)</p> <p>PNEC_{oral} = 16.9 mg/kg food (birds)</p> <p>Based on feeding studies with lead salts. Using a standard soil-earthworm bioaccumulation factor of 0.1 these PNEC_{oral} values translate to critical soil lead limits for mammals of 10.9/0.1=109 mg lead/kg soil and for birds of 16.9/0.1=169 mg lead/kg soil.</p>	REACH Registration Dossier

B.7.3.3. Other thresholds for lead poisoning in birds and other wildlife

Tissue concentrations in wild birds provide a good indicator of exposure because they represent actual uptake based on environmental exposure. 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 B-33 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 areas⁵¹, comparing lead concentrations in unexposed wild birds with the concentrations at which clinical effects and mortality may occur. However, they should not be considered to be equivalent to PNECs.

⁵¹ E.g. assessing the need for medical treatments in conservation centres.

Table B-33 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).

According to Franson and Pain (2011), lead concentrations in birds with no history of lead exposure are typically <0.2 ppm wet weight in blood, <2 ppm wet weight in liver and kidney and <10 ppm dry weight in bone.

Franson and Pain (2011) noted that birds exposed to relatively low lead levels on a sustained basis may suffer similar effects (but with lower soft tissue lead concentrations) than birds acutely exposed to higher levels of lead for a short period of time. In addition, the presence of lead shot in the digestive tract and tissue lead concentrations are not always associated in individual birds because of the varying retention time of shot in the gizzard and the uptake/retention dynamics of lead in tissues. However, in live birds sequential blood lead analyses from an individual give a much clearer picture of the significance of contamination as chronicity can be established. Haematological measurements can be used as indicators of biochemical damage, in addition to concentrations of lead in various tissues (such as in liver).

The chronicity of exposure to lead has an important influence upon the concentrations of lead in various tissues of birds. In cases of chronic exposure, the highest lead concentrations are generally found in bone, with lower concentrations in soft tissues such as liver, kidney, and blood (Custer et al., 1984; Pattee 1984, Mautino and Bell 1986, Mautino and Bell 1987; cited by Franson and Pain 2011). However, when birds die

following acute exposure after the ingestion and absorption of large amounts of lead, concentrations in kidney and/or liver may exceed those in bone.

Bone lead concentration is generally considered the best indicator of lead exposure over the total lifetime of the bird, but the least useful indicator of recent lead exposure and absorption. The tissues usually chosen to evaluate recent exposure are blood, liver and occasionally kidney (Franson and Pain, 2011).

However, as noted by Franson and Pain (2011), lead toxicity may depend upon factors other than simply the concentrations in tissues. These factors include the level and duration of lead exposure, previous history of exposure, species variability in response to exposure, the overall health of the bird, the extent of damage already done and the potential interactions between lead and other disease agents. These are in addition to the other factors that influence the concentration of lead in tissues, including: gender, breeding condition, age, stomach type and diet (discussed in the previous sections).

B.8. PBT and vPvB assessment

Not relevant for inorganic substances (with the exception of organo-metals). Therefore this section has not been elaborated for this assessment.

B.9. Exposure assessment

B.9.1. Exposure Scenario: use of lead gunshot in or over wetlands

B.9.1.1. Release of lead gunshot into the environment

The use of lead gunshot (for hunting and sports shooting) results in cumulative and persistent contamination of the environment with lead, particularly in areas of high intensity shooting.

The best estimate currently available for the annual tonnage of lead released to the EU-27 environment is that reported in the AMEC study for the European Chemicals Agency (Abatement costs of certain hazardous chemicals, lead in shot, final Report 2012). This study reported the following estimates for EU-27 region:

Table B-34. Emissions of lead from hunting (cartridges only) estimated by AMEC (2012), in tonnes.

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

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 AFEMS⁵² in the ECHA call for evidence (2016) held as part of the preparations of this report. 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 amount of lead released to the environment of 18 000-21 000 tonnes annually. This estimate is in line with that reported by AMEC (2012) (same data was used).

However, it remains unclear how much lead shot is released in or over wetlands from target shooting. The number of sports shooting ranges located in wetlands is unknown.

Other estimates of annual releases of lead gunshot introduce further uncertainty. The sum⁵³ of 6 000 tonnes and 4 600-10 000 tonnes of lead shot, estimated in Spain and Italy respectively (Guitart and Mateo, 2006; Andreotti and Borghesi, 2012), plus 8 000-13 000 tonnes of lead shot estimated to be used annually in the UK⁵⁴ (Pain et al., 2015) exceeds the value provided by AMEC (2012) for the EU (e.g. 21 216 tonnes), based on only three EU countries. Therefore, there is some uncertainty in the estimates of the tonnage of lead released in or over wetlands annually.

Clay target shooting ranges

Scheuhammer and Norris (1996) reported that significant quantities of lead shot were deposited at clay target shooting ranges. Loadings at large individual ranges can be 10-30 tonnes per year (Ordija, 1993; cited by Scheuhammer and Norris, 1996).

Scheuhammer and Norris (1996) outline that the shotfall areas of shooting ranges may include dryland fields, ravines, creeks, rivers, mudflats, marshes, ponds, and lakes. Spent shot generally remain within the upper 10 cm of soils, and are therefore available for ingestion by waterfowl and other birds at these sites. Therefore, ranges located over or near wetland environments pose a considerable risk to waterfowl and other waterbirds⁵⁵.

Clay target shooting under such environmental circumstances results in a very high local rate of pellet deposition. Under these conditions, the risk of ingestion and poisoning are similar to, or even greater than, those caused by wetland hunting. Roscoe et al. (1989, cited by Scheuhammer and Norris, 1996), reported that within the shotfall zone of a trap and skeet club, in New Jersey, the top 7.5 cm of affected sediments contained over 87 million pellets per acre, which was over 4 000 times the shot density recorded near hunting blinds in the same area.

B.9.1.2. Lead shot density in wetlands

Each lead shotgun cartridge may contain several hundreds of pellets (depending on shot size) that are released 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

⁵² Association of European Manufacturers of Sporting Ammunition.

⁵³ Using average values.

⁵⁴ Based on numbers of birds killed and likely numbers of cartridges used 'per bird', including misses (Pain et al., 2015).

⁵⁵ Scheuhammer and Norris (1996) noted that: "gun clubs which do not shoot over or near water or wetland environments, and have an active programme to recover lead, are least likely to be at risk for environmental impacts".

adverse effects.

In North America, Bellrose (1959) compiled information on the prevalence of lead pellets per square foot and per acre in a number of prime hunting waterfowling areas. These data showed some concentrations greater than one pellet per square foot, being one pellet per 2-3 square feet a common occurrence in shooting areas. Other studies supported these findings: about 30 000 pellets per acre were estimated for soils at Catahoula Lake, Louisiana in 1963 (Wills and Glasgow 1964), while Frederickson et al. (1977) estimated that 23 000 to 122 000 pellets per acre were present in front of duck blinds at the Duck Creek Wildlife Area in Missouri. (USFWS, 1986)

Roscoe et al. (1989 cited by Scheuhammer and Norris, 1996), reported poisoning of northern pintail ducks (*Anas acuta*) that ingested lead shot from a tidal meadow within the shotfall zone of a trap and skeet club, in New Jersey. The top 7.5 cm of affected sediments contained over 87 million pellets per acre, which was over 4 000 times the shot density recorded near hunting blinds in the same area.

In Europe, the available evidence suggests that lead shot is also not evenly distributed across wetlands and that there are zones with higher densities of spent lead. Lead distribution may be influenced by the hunting techniques and by the sport activities run nearby or within the wetlands. Different types of shooting are known to influence the levels of environmental contamination. Hunting wildfowl in wetlands is typically a comparatively low intensity activity compared to clay pigeon shooting (although this should be balanced against the potential for remediation, which is much greater at a shooting range).

As described by Mateo (2009), waterfowl hunting is carried out in Europe using several techniques, depending on the species being hunted and the wetland type. Eurasian Coots (*Fulica atra*) are hunted by pushing them with boats to force birds to fly over the hunters who are located in boats or on the shore of a lagoon. Ducks are mainly hunted from 'blinds'⁵⁶ located on the border of lagoons, marshes, or in rice fields. Hunting is generally carried out during daylight hours in lagoons, but in some places, like the Ebro Delta (Spain), hunting in rice fields is allowed during several nights around the full moon.

Hunters usually use grain to bait around their blinds in rice fields to attract birds several days before hunting. Similarly, hunting in the UK is done on flight ponds to which waterfowl return for food at dawn and dusk from their daytime resting places on estuaries or large water bodies. These flight ponds are repeatedly baited to attract birds and therefore accumulate high lead shot concentrations (Thomas 1982, cited by Mateo 2009).

In Doñana, Spain, one of the largest wetlands in Europe, ducks were followed through marshlands on horseback and hunted with guns capable of shooting heavy loads of pellets. This type of hunting produced a more diffuse contamination of lead shot in the marshes than the techniques based on fixed blinds.

Some stakeholders (local NGOs) in the recent ECHA's call for evidence (2016) have also confirmed that some hunters' habit of feeding wildfowl near shooting posts can concentrate birds in areas that become increasingly polluted with lead shot.

⁵⁶A hunting blind is a cover device for hunters, designed to reduce the chance of detection. There are different types of blinds for different situations, such as deer blinds and duck blinds. Some are exceedingly simple, while others are complex.

The density of lead shot in wetland sediments has been studied in several EU countries. Since late 1970s several authors have compiled information on the concentration of lead pellets in a number of sites used extensively by waterfowl.

One study showed that lead shot fired from fixed hunting posts, unlike shot fired by hunters on foot, falls and accumulates in a limited area and may reach very high densities (millions per hectare) (Andreotti and Borghesi, 2012). In the Brescia district (Northern Italy) an area with more than 5 100 hunting posts, Andreotti and Borghesi (2012) estimated a conservative mean of 5-6 kg of lead pellets dispersed in the surroundings of each post annually.

Maximal lead densities have been 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).

Other data from Italy confirm the high lead densities described by Mateo (2009) in the Mediterranean countries. In the Fucecchio marsh (Florence District, central Italy), hosting more than 200 different species of birds annually, a peak of 3 111 100 gunshot per hectare (404 kg) was measured by Bianchi et al., (2011). In the Margherita di Savoia salt-work (Foggia District, southern Italy) 630 000 to 1 270 000 gunshot per hectare (82-165 kg) were recorded by Tirelli et al., (1996). Lead shot densities (historical data) in European wetlands where waterfowl hunting is practiced, are shown in Table B-35.

Table B-35. Lead shot density in European wetlands with waterfowl hunting (modified with data from Italy, original source: Mateo, 2009)

Country	Area	Site	Depth (cm)	Year/reference	shot/m ²
Ireland	Cork	Kilcolman W. R.	-	1985-86 ^a	7
United Kingdom	Moray/Beaully F.	Longman Bay	15	1981-82 ^b	nd
		Lentral Point			2.57
		Easter Lovat			Nd
	Loch of Strathbeg	Starnakeppie			2.04
		Back Bar			10.29
		Savoch Burn mouth			7.18
		Savoch Farm			2.04
	Caelaverock	Starnafin			3.11
		The Merse			3.95
	Gayton Sands	Marsh End			Nd
		Railing Flash			9.77
	Llyn Ystumllyn	The marsh			3.04
	Gloucestershire	Flight pond			30.00
		Saul Warth			5.45
		The Pill meadow			9.44
		The Pill mud			30.4
Elmley	Shellfleet Creek	7.44			
	Shellfleet Creek	4.88			
	Brick fields	13.08			
Norfolk	Flight pond 1	26.80			

		Flight pond 2			8.22	
	Ouse Washes	The washes			16.00	
Denmark	Western Jutland	Agger Fjord	20	1978 ^c	14.10	
		Thyborøn Fjord			0	
		Harboøre Fjord			25.90	
		Ringkøbing Fjord			35.70	
		Ho Bugt			0	
	Ringkøbing Fjord	Klægbanken			53.30	
		Haurvig Grund			12.20	
		Skjern Ås munding			65.80	
		Tipperne øst			88.30	
		Tippersande			166.80	
Tipperne vest		183.70				
Sjælland, Køge	Nymindestrømmen	145.90				
	Ølsemagle Revle	70.00				
The Netherlands	Overijssel	Ketelmeer	7	1979-84 ^d	20.20	
	Zuid-Holland	Beninger Slikken			18.60	
					14.00	
		Dordtsche Biesboch			23.10	
		43.50				
Hungary	Six areas	Ce.	-	- ^e	0.60	
		So.			10.41	
		Cs.			5.71	
		Ur.			0.07	
		Vá.			2.58	
		Al.			1.82	
France	Camargue	Mejanes 1	15-20	1987 ^f	6.40	
		Mejanes 2			41.90	
		North Vaccares 1			6.40	
		North Vaccares 2			Nd	
		North Vaccares 3			25.00	
		Fangouse 1			6.40	
		Fangouse 2			26.40	
		Cameroun			6.40	
		Pebre			170.30	
		Beluge			12.70	
		Tortue			Nd	
		Paty			199.55	
		Consecan 1			Nd	
		Consecan 2			Nd	
		La Saline			83.90	
	L. de Grand Lieu	La Morne	5	1988 ^g	80.00	
		La Séгнаigerie 1			46.00	
		La Séгнаigerie 1		1989	50.00	
	Spain	Ebro delta	Buda Island 1	20	1991 ^h	28.20
			Buda Island 2			1992
Canal Vell rice			6.00			
Buda Island 3			1993 ⁱ		97.10	
Encanyissada					266.10	

		Punta de la Banya		1996 ^j	Nd	
		La Llanada			48.50	
		L'Aufacada			82.70	
		Migjorn			13.90	
		Dapsa			66.50	
	Tablas de Daimiel	Puesto del Rey		1993 ^k	99.40	
	Alb. de València	Sueca			287.50	
	El Hondo	Embalse de Levante		1993 ^{k,l}	163.00	
		Charca Sur			123.60	
	Cádiz-Sevilla	Medina 1		10	2002 ^m	148.30
		Medina 2	30	398.90		
		Salada del Puerto	10	58.90		
		Chica del Puerto		12.10		
		Jeli de Chiclana		21.60		
		Zorrilla de Espera		2001	27.60	
		Taraje de Sevilla		2002	8.50	
	Guadalquivir M.	Salinas de Sanlúcar		10	2002	18.30
		Santa Olalla			2001	11.80
		Lucio de Marilópez	2002		Nd	
		Veta la Palma	2002		Nd	
Brazo del Este		2001	24.60			
L. Caraviruelas		15	1993 ^k		14.40	
Hato Blanco		1997	Nd			
C. de los Ánsares		20	1997 ⁿ		16.20	
L. Caballero	15	1997 ^o	7.20			
Italy	Toscana	Fucecchio marsh	10	2007-8 ^p	0-331.1 (max)	
	Puglia	Margherita di Savoia		1993 ^q	63 -127	
	Emilia-Romagna	Valli di Comacchio		1995 ^q	4-43	
	Friuli-Venezia Giulia	Marano lagoon		1994 ^q	42	
	Toscana	Orbetello lagoon		1994 ^q	32	
	Toscana	Diaccia Botrona marsh		1994 ^q	8-20	
	Emilia-Romagna	Saline di Cervia		1995 ^q	47-71	
	Emilia-Romagna	Po Delta		1995 ^q	0-20	

a: O'Halloran et al. 1988b; b: Mudge 1984; c: Peterson and Meltofte 1979; d: Smit et al. 1988a; e: Imre 1994; f: Pain 1991a; g: Mauvais and Pinault 1993; h: Guitart et al. 1994a; i: Mateo et al. 1997b; j: Mateo 1998; k: Mateo et al. 1998; l: Bonet et al. 1995; m: Mateo et al. 2007a; n: 2000a; o: Mateo and Taggart 2007; p: Bianchi et al., 2011; q: Tirelli et al. 1996, cited by Bianchi et al., 2011 (note: Margherita di Savoia and Cervia are salt-pans areas).

B.9.1.3. Lead shot density in sports shooting ranges

In general, over the last few decades shooting ranges have received an increasing attention due to the significant quantity of lead deposited in the environment by their activity. Some data about lead shot density recorded in shooting ranges are here reported.

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).

The older and more heavily used the ranges are, the heavier the lead soil loadings, and the greater the risk of lead exposure to wildlife, soil, and water (Stansley et al. 1992; Manninen and Tanskanen 1993; Sorvari et al. 2006; cited by Thomas and Guitart, 2013).

B.9.1.4. Settlement rate of lead shot in sediments (availability of lead shot)

The time required for pellets to become unavailable to waterfowl 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 a critical factor correlated to the exposure of birds to lead. Spent lead availability is affected by water depth and the depth of buried shot within the sediment. Pain (1992) showed that shot accumulates near the surface of sediments and thus the total number of lead shot available to waterfowl increases over time. Other studies corroborated this demonstrating slow settlement rates cause shot to accumulate near the surface over many years resulting in high densities of shot available (Mudge, 1984; Anderson, 1986; cited by Peters and Afton, 1993; Pain 1991).

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, meaning no significant change in the depth distribution of lead pellets had occurred.

Flint and Schamber (2010) sampled plots in tundra wetlands in the Yukon Delta National Wildlife Refuge (Alaska, USA). They sampled experimentally seeded plots 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 a complete settlement, in order to have pellets becoming unavailable to water birds would require more than 25 years.

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).

Mateo et al. (2014) reported that risks for water birds to ingest lead shot were evident within the Ebro delta, Spain, despite being a protected area, due to the high density of lead pellets accumulated in sediments over time. Lead shot densities in the first 20 cm of sediment ranged from < 8 900 to 2 661 000 shot ha⁻¹ (Mateo et al., 1997).

Settlement rates may be also affected by the vegetation present and firmness of the sediment. Mateo et al. (1997) reported that the settlement of pellets in the Encanyissada lagoon (within the Ebro Delta area) seemed to be favoured by the presence of reed. This could be due to the soil breakage made by the roots of plants (Pain, 1991a) or to a higher deposition of sediment in the reed belt.

Assuming that only the superficial pellets are available to birds (top 5 cm), Mateo et al. (1997) noted that the most hazardous area (within the ones studied in the Ebro delta) was the Buda Island where the sediment was hard and compact, being composed primarily of sand, while at the Encanyissada Lagoon the sediment was muddy. However, according to the authors, tillage and desiccation (in the tilled part of the Encanyissada lagoon) appeared to have increased shot densities in the upper layers of sediment and thus their availability to birds. The authors noted that management of the sediment in tilled areas moved shot to the surface and so increased shot availability to birds.

Anderson et al. (2000, cited by Pain et al., 2015) found 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 3175 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.

To summarise, the available evidence described in the literature suggests that due to the many site-specific variables, e.g. amount of lead shot deposited over the past years, type of soil sediment, type of vegetation, soil management (including tillage), it is not possible to conclude on a standard settlement rate for lead pellets, which can be applicable to all wetlands habitats. However, evidence suggests that where hunting with lead shot has been practiced for many years lead pellets will remain available to birds for several years, (even decades) and that bird will ingest recently deposited shot.

B.9.1.5. Likelihood of exposure to lead shot in wetlands

Numerous European species of water birds have been reported as ingesting spent lead gunshot (Table B-36). These are primarily waterfowl, e.g. species of duck, goose and swan, but also include other types of water birds, such as rails, waders and flamingos (Mateo, 2009; Pain et al., 2009).

Table B-36. European species of water birds reported to have ingested lead shot (according to data available in Mateo, 2009; Pain et al., 2015). This list is not intended to be exhaustive. Other species may be affected by poisoning from lead shot, as discussed in this section.

Groups	Species
Dabbling ducks	Eurasian widgeon (<i>Anas penelope</i>), gadwall (<i>Anas strepera</i>), common teal (<i>Anas crecca</i>), mallard (<i>Anas platyrhynchos</i>), northern pintail (<i>Anas acuta</i>), northern shoveler (<i>Anas clypeata</i>), marbled duck/marbled teal (<i>Marmaronetta angustirostris</i>).
Diving ducks	red-crested pochard (<i>Netta rufina</i>), common pochard (<i>Aythya ferina</i>), ferruginous duck (<i>Aythya nyroca</i>), tufted duck (<i>Aythya fuligula</i>).
Stiff-tailed ducks	white-headed duck (<i>Oxyura leucocephala</i>)
Geese	barnacle geese (<i>Anser anser</i>) pink-footed goose (<i>Anser brachyrhynchus</i>), greylag goose (<i>Anser anser</i>).
Swans	mute swan (<i>Cygnus olor</i>), tundra swan (<i>Cygnus columbianus</i>), whooper swan (<i>Cygnus cygnus</i>).
Rails	Eurasian coot (<i>Fulica atra</i>), common moorhen (<i>Gallinula chloropus</i>), purple gallinule (<i>Porphyrio porphyrio</i>).
Waders	avocet (<i>Recurvirostra avosetta</i>), northern lapwing ^a (<i>Vanellus vanellus</i>), ruff (<i>Philomachus pugnax</i>), jack snipe (<i>Lymnocyptes minimus</i>), common snipe (<i>Gallinago gallinago</i>), black-tailed godwit (<i>Limosa limosa</i>).
Others	greater flamingo (<i>Phoenicopterus roseus</i>)

Notes: a – diagnosis of death from lead poisoning, gizzard was not examined for the presence of lead gunshot

Several species (e.g. northern pintail, common pochard) have breeding areas in NE Europe or NW Asia, and after the breeding season they migrate southward and westward for wintering. Conversely, some species (e.g. marbled teal and white-headed duck⁵⁷) spend all the year in the Mediterranean wetlands, which have been found to have the highest densities of lead shot (Section B.9.1.6.1).

According to a recent assessment made in 2017 by UNEP/AEWA Secretariat⁵⁸ on all the 150 migratory waterbird species (AEWA-listed migratory waterbird species) which occur regularly within the EU, **100 species** are considered to be vulnerable to lead poisoning from spent lead shot. This includes ducks, geese, swans, grebes, flamingos, rails, gallinules, coots, cranes, loons/divers, storks, ibises, spoonbills, oystercatchers, avocets, stilts, plovers, sandpipers, snipes and skuas.⁵⁹

Of the 100 AEWA-listed species vulnerable to lead poisoning, 85 species were assessed as feeding primarily in wetlands. In addition, according to the AEWA's assessment, a total of 69 out of 100 of the AEWA-listed species considered vulnerable to lead poisoning, use "wet" peatlands and seven of the species listed under AEWA, considered vulnerable to lead poisoning, use "dry" peatlands. For these species, this "dry" peatland habitat is used mainly during the breeding season, which is a particularly sensitive phase in the annual cycle of these birds.

The likelihood of bird exposure (via primary ingestion) to lead shot depends on:

- availability of lead shot
- feeding ecology of each species
- other environmental and anthropogenic factors

The availability of lead shot is discussed in Section B.9.1.5.

In addition to shot availability, 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 that usually feed in shallow waters (UNEP, 2014⁶⁰).

Waterfowl, like the mallard, that feed on plants and invertebrates in the water column or on the surface of the bottom are less likely to pick up shot that has settled into the substrate than pintails that may dig into the bottom for tubers or invertebrates or other diving ducks that forage for molluscs. Some snow geese and swans will also dig very deep in search of tubers and molluscs; exposing them to lead pellets deposited years earlier (USFWS, 1986)

⁵⁷ Under the Global IUCN category white-headed duck (*Oxyura leucocephala*) is classified at European level as Endangered (BirdLife International. 2016. The IUCN Red List of Threatened Species 2016).

⁵⁸ The overview was provided for the purpose of informing the deliberations within the ECHA processes and was done by the UNEP/AEWA Secretariat in cooperation with the Wildfowl & Wetlands Trust (WWT). The assessment is available in the Public Consultation (2017), comment 1873: <https://echa.europa.eu/it/restrictions-under-consideration/-/substance-rev/17005/term>

⁵⁹ In addition, nine species of heron were considered to potentially be vulnerable to lead poisoning, but this had not been fully studied and the herons were therefore not included in the assessment.

⁶⁰ Review of the ecological effects of poisoning on migratory birds, UNEP/CMS/COP11/Inf.34, 2014

Consumption of shot may be affected by the availability of alternative grit, the absence of which increases rate of shot ingestion (Mateo et al., 2007) and seasonal diet of the bird. For example, during periods of abundance of hard food such as seeds, birds may increase their grit, and thus lead, ingestion (Rocke et al., 1997).

The environmental and anthropogenic factors that influence the distribution of lead shot in the environment and thus exposure can be summarised as follows (UNEP/CMS/COP11/Inf.34, 2014):

- proximity to hunting or other shooting activities
- hunting intensity (which may change in different areas)
- compliance with bans (where already in place)
- time in relation to hunting seasons (exposure towards the end of a hunting season is greater)
- habitat over which lead is used and its attractiveness to birds, e.g. wetland type
- substrate type, water inundation and other local conditions (affecting sinking/movement of shot over time)
- land management and land disruption (e.g. temporary inundation of terrestrial shot-over areas that may attract dabbling ducks; spates and flooding that can erode watercourses and expose historically deposited lead)
- chemical and physical processes in the environment

Figure B-13 illustrates the key parameters characterising the likelihood of bird exposure to lead shot, and their interaction.

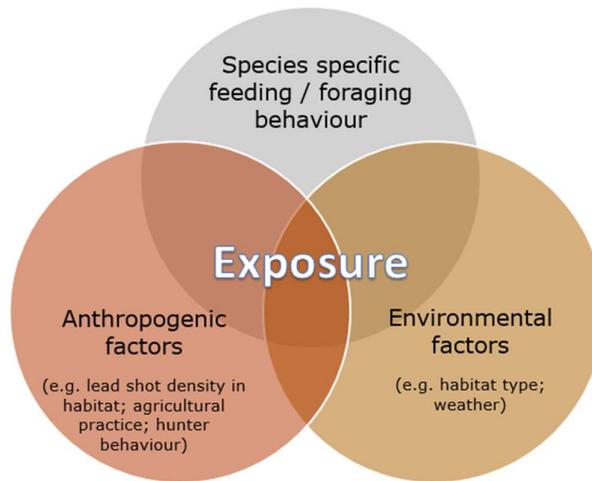


Figure B-13. Key parameters characterising the likelihood of bird exposure to lead shot.

Only relatively few predatory or scavenging raptors in Europe are predominantly dependent on wetlands for their food. With the exception of the osprey (that 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 (*Hieraaetus fasciatus*), merlin (*Falco columbarius*), hobby (*Falco subbuteo*), peregrine falcon (*Falco peregrinus*) and red-footed falcon (*Falco vespertinus*) (Sterry et al., 1998; Tornberg et al., 2016). For these species feeding areas may be associated with seasonal availability of prey. Various European species of vulture and the golden eagle (*Aquila chrysaetos*) will also have wetlands within their range and will scavenge and eat 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 birds⁶¹ 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).

The likelihood of exposure of predatory or scavenging birds to lead shot (via secondary ingestion) depends on:

- Availability of lead shot within food items
- feeding ecology
- other factors

In general, predatory or scavenging species are exposed to lead gunshot whenever they consume prey (in either live prey or carrion) containing embedded shot (or bullet fragments). 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 per cent and 36 per cent, 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 per cent and 7.5 per cent of adult males and females, respectively, carried embedded shot (UNEP/CMS/COP11/Inf.34, 2014). Pain et al. (2015) report a wide range of European and North American studies in which the prevalence of embedded shot in live waterfowl is frequently >20 %.

In addition, predatory or scavenging birds can also have an opportunistic behaviour and they may feed on different types of prey, thus being exposed to lead gunshot (and bullet) fragments.

Other factors that may influence the exposure to lead shot of predatory or scavenging species are:

- scale of hunting with lead in the areas populated by predatory or scavenging birds
- compliance with bans (where already in place)
- degree of debilitation of prey: predation risks are higher for injured (potentially shot with lead) and intoxicated (potentially lead poisoned and still carrying metallic lead) individuals. Debilitated prey may form a large part of the diet of predators and scavengers.

B.9.1.6. Prevalence and magnitude of lead shot ingestion in wild birds

The prevalence of lead shot ingestion typically refers to the presence or absence of lead gunshot in the gizzard of a bird. Of equal interest is the number of lead gunshot that have

⁶¹ 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).

been ingested, the magnitude of the exposure. The prevalence of lead gunshot ingestion is likely to vary between species and populations. Mateo et al. (2014 citing Pain, 1990; Mateo et al., 2000; Figuerola et al., 2005) reported that differences observed in the prevalence of lead shot ingestion between bird species are most likely a function of variability in diet and grit preference. Species of birds that prefer larger grits are at greater risk of ingesting spent lead gunshot (Pain, 1990; Mateo et al., 2000; Figuerola et al., 2005, cited by Franson and Pain, 2011).

The greatest prevalence of lead gunshot ingestion has been found in waterfowl that overwinter in the Mediterranean region, where birds typically concentrate in a limited number of wetlands that have been intensively hunted for decades Mateo (2009). A similar latitudinal trend was observed in North America (Sanderson and Bellrose 1986, cited by Mateo 2009).

Mallard (*Anas platyrhynchos*) have often been used as a sentinel species for lead poisoning, since they hold an almost worldwide distribution (Guitart et al., 1994) and are known to have moderate to high levels of lead gunshot ingestion among waterfowl species (Mateo, 2009). The mortality of mallard in response to varying levels of ingestion of lead gunshot (number of shot consumed) has also been extensively studied (i.e. Bellrose, 1959).

Mateo (2009) provided a summary of the prevalence of lead gunshot in 19 species of wildfowl from Europe, including mallards.

The mean prevalence of lead gunshot ingestion in mallards from northern Europe varies from 2.2 % in Holland 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 cited by Mateo 2009).

The species with the highest prevalence of lead shot ingestion in southern-central Europe are the 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 all cited by Mateo 2009).

As reviewed by Pain et al. (2015), more recently Newth et al. (2012) reported lead poisoning in wildfowl (1971- 2010) in the UK where the majority of cases of birds dying of lead poisoning (75 % of 251) had lead gunshot in various stages of dissolution in their gizzards.

In a study made by Figuerola et al. (2005) with a meta-analysis of lead shot ingestion in 51 locations and 27 waterfowl species from North America and Europe, the authors

concluded that the prevalence in a given species was highly variable between localities, and was not consistently different between dabbling, grazing, and diving species.

B.9.1.6.1. Ebro Delta

Mateo et al. (2014) described the effects of a partial ban (made in 2003) in the Ebro delta, Spain, on several birds' species. The use of lead shot was prohibited in the protected areas (lagoons and marshes) of the Ebro delta (24 % of the delta), but was still allowed in adjacent unprotected crop fields (76 %, mostly rice fields). Between 2007 and 2011, a total of 523 waterfowl carcasses from 11 water bird species⁶² were collected from hunting bags. The hunting season in the Ebro delta begins in mid-October and ends on the first week of March. Carcasses were all X-rayed to detect shots, which were then removed during necropsy. Steel shot was easily distinguished from lead shot because the former is usually larger, rounder and is attracted to a magnet. All the water birds were hunted in the protected lagoons.

The overall prevalence (during the period 2007-2012) of lead shot ingestion decreased significantly when compared to the pre-ban period (1991-1996) for several waterfowl species:

- Northern shoveler (from pre-ban value of 27.8 % to 7.8 %),
- Common teal (from pre-ban value of 22.9 % to 10.6 %),
- Common pochard (from pre-ban value of 69.2 % to 35 %),
- Mallard (from pre-ban value of 30.2 % to 15.5 %).

However, for mallard, during the 2007–08 hunting season shot ingestion was 28.6 %, which was not significantly different to the pre-ban value of 30.2 %. However, a significant decrease in prevalence was found in the 2008–09 season (5.1 %), after an increase in compliance with the ban due to strict enforcement. The effects of strict enforcement are also discussed in Section E.

The prevalence of shot ingestion in northern pintail (*Anas acuta*) in the Ebro Delta remained high, with 76 % of the specimens (N=25) having ingested lead shot, compared to 74.2 % in the pre-ban period. Northern pintail is considered to be one of the European species with the highest observed prevalence of lead shot ingestion (Mateo, 2009).

B.9.1.7. Lead tissue concentrations in wild birds

Following ingestion, lead shot can be voided immediately, partially eroded and then voided, or retained until it is completely eroded and dissolved. As it can be found in various stages of dissolution within the digestive system of a bird blood and body tissue analysis can be useful to confirm lead exposure (Franson and Pain 2011). In individual birds, tissue concentrations (which reflect lead adsorption) rather than simply the presence of ingested lead shot (which reflects exposure) are a good indicator of the likelihood of lead poisoning as a cause of death (Franson and Pain 2011). The confidence with which a diagnosis of lead poisoning as the cause of death can be made, increases with the amount of

⁶² Eurasian wigeon, gadwall, common teal, northern pintail, mallard, northern shoveler, red-crested pochard, common pochard, tufted duck, Eurasian coot, common snipe

information available. For example, a diagnostic evaluation should ideally also include exposure history data, necropsy observations and pathological findings.

Indicative thresholds for lead in tissues that have been associated with lethal and sub-lethal effects in birds are outlined and discussed in Section B.7.3.3.

Many field studies investigating lead tissue concentrations in wild birds have been carried out in the EU over the last fifty years. It is not the purpose of this dossier to list them all. Only the results of several key studies are summarised below, including studies on birds which are not game species i.e. greater flamingo (*Phoenicopterus ruber*) and whooper swans (*Cygnus cygnus*).

Mateo et al. (1997a), reported that between November 1992 to March 1993 and from November 1993 to February 1994, 106 greater flamingos (*Phoenicopterus ruber*) were collected dead or moribund in the wetlands of El Fondo and Salinas de Santa Pola, eastern Spain. Birds still alive were emaciated and had a bile-stained diarrhoea (which is indicative of lead poisoning). On necropsy they showed liquid in the upper digestive tract and the walls of their gizzards were stained dark green. Fifty-three (93 %) of 57 gizzards examined contained lead shot (1 to 277 shot), and fifty-five (96 %) of 57 livers contained levels of lead greater than 5 µg/g dry weight (DW) (median = 192.3 µg/g DW, range < 2.5 to 992.2 µg/g DW).

Recently, Newth et al. (2016) noted that the presence of lead in the blood of whooper swans showed a significant detrimental association with their body condition when levels were >44 µg dL⁻¹. They concluded that blood lead concentrations in Whooper Swans were significantly associated with body condition at the lower end of previously proposed clinical thresholds for effect. Franson and Pain (2011) had previously estimated the range of blood lead levels within which Anseriformes are predicted to exhibit clinical signs of poisoning, including weight loss, (leading to probable death) at 50-100 µg dL⁻¹.

Rodrigues et al. (2005 cited by Mateo 2009), found >20 µg/dL of blood lead in 38.6 % of 427 mallards and 20.2 % of 92 common teals from Vouga Lowlands (Portugal) and 38.1 % of 21 mallards from Lagoa dos Patos (Portugal). More recently Rodriguez et al. (2010) reported lead exposure in 135 wild mallards that were trapped between 1998 and 2001 in the Boada and Nava lagoons in the Spanish province of Palencia. X-ray techniques (ventrodorsal and lateral views) were used to detect lead shot in the gizzard and to determine degradation over time. Of the 135 sampled wild mallards, 41 % had blood lead concentration greater than 0.2 µg/g. Lead shot was found embedded in 3.6 % of the wild birds whilst only 1.2 % had lead gunshot in their gizzards.

Kenntner et al. (2005) measured lead concentrations in liver and kidney tissues of 277 immature and adult white-tailed eagles found dead or moribund in Germany between 1979 and 2005 and found levels of lead indicative of lead poisoning (>5 µg/g in wet weight) in 66 (24 %) of the cases originated by the ingestion of lead shot and bullet fragments (cited in Mateo, 2009).

As previously mentioned, raptors such as white-tailed eagle that consume a wide array of prey are usually regarded as opportunistic and generalist predators, thus explaining the possibility to ingest both shot and bullets, according to the prey or carrion available.

B.9.1.8. Indirect exposure to humans via the environment

A comprehensive assessment of indirect exposure to humans via the environment for the use of lead in gunshot in wetlands has not been undertaken. Lead and its compounds, in terms of its neurodevelopmental effects in children (and kidney effects in adults), are non-threshold substances (see Appendix B2) and as such Annex I of REACH only requires a qualitative assessment 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). However, ingestion of contaminated soil, dust and old lead-based paint as a result of hand-to-mouth activities are an important source of lead intake in infants and young children (EFSA, 2013). Consumption of game meat can potentially contribute disproportionately to overall dietary exposure (EFSA, 2013)

B.9.1.8.1. Consumption of game meat

The numbers of hunters in EU27 Member States were published in 2010 (FACE, 2010) and updated data on hunters that use shotguns in the EU27 is estimated to be over 6 million (ECHA, 2013).

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). Therefore, the EFSA (2013) assessment cannot be used as the basis for the assessment in this restriction report.

Whilst there are data available on the concentration of lead in waterfowl typically consumed, further additional data would be necessary to undertake a quantitative assessment of exposure of human populations to lead in the EU as regards waterfowl consumption, 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 in the EU as 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. Typically, it is expected that wildfowl will be a small proportion of total game (and total diet) consumed as they tend to be shot in small numbers in comparison with other game birds (upland birds) and other types of game meat. However, this does not discount that there will be individuals that consume a high proportion of wildfowl game meat relative to other types of game meat.

Despite this absence of this specific information for the EU, there is quantitative evidence that consumption of wildfowl can result in exposure to lead in the literature. 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 in order 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 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.

Often, studies considered game meat generally, when analysing the human exposure to lead. Recently, Green and Pain (2015) estimated minimum and maximum numbers of people in the UK who eat game and are potentially at risk, using information from surveys of gamebird meat consumption by in the general population and of high frequency game consumers (defined as eating game at least once per week). 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.

However, as noted above, this estimate does not distinguish waterfowl consumption from other gamebirds (hunted outside of wetlands) and thus cannot be used as specific evidence of a risk to human health from the use of lead gunshot in wetlands. Nevertheless it is likely that some of the gamebirds consumed (contributing to overall exposure and impacts) will have been obtained from wetlands. This is particularly relevant given the non-threshold nature of lead toxicity in humans, particularly children.

B.9.1.8.2. Lead in soils

Lead in soils continues to be an important source of lead exposure to humans via the EU environment. Sources include particulates from industrial sources, flaking, chipping or weathering of lead-containing paints and improper disposal of waste lead-based paints removed during building renovation and maintenance.

The concentration of lead in the top layer of soils varies considerably because of the deposition and accumulation of atmospheric particulates from anthropogenic sources (ATSDR, 2007). In Europe, lead concentrations in top soils are geographically heterogeneous (EFSA, 2013) and vary from below 10 mg/kg up to > 70 mg/kg. The median value was estimated by WHO (2007) to be 23 mg/kg.

A well-documented correlation exists between lead level in soil and blood lead level in children. Mielke et al. (2007) found a strong curvilinear correlation between blood lead levels of more the 55 000 children coupled with soil measurements (more than 5 400 samples). Thus based on this correlation an increase in lead level in soil from 40 mg Pb/kg to 400 mg/kg would result in an increase in blood lead level of approximately 23 µg Pb/L.

B.9.1.8.3. Lead in drinking water and food

Plants and animals may bioconcentrate lead, but lead is not considered to biomagnify in the aquatic or terrestrial food chain (ATSDR, 2007). This is partly explained by the fact that in vertebrates, lead is stored mainly in bone, which reduces the risk of lead transmission to other organisms in the food chain (EFSA, 2013).

In contaminated areas, high concentrations of lead were observed in roots of vegetables (up to 10.7 mg/kg dry mass), while the lead concentrations in soil were in the range of 129 to 1 996 mg/kg dry mass (Gzyl, 1995).

Lead is commonly present in food and is regulated as a contaminant (EFSA, 2013). EFSA (2013) assessed dietary lead exposure in the European population across the aggregated food categories specified in the EFSA concise European Food Consumption database. According to EFSA (2013). The largest contributor to overall dietary exposure in the average diet of the general population (which contain very little game meat) were vegetables, nuts and pulses (14 to 19 % lower and upper bound estimates) and cereal products (13 to 14 % lower and upper bound estimates). Other food groups that were considered to contribute significantly to overall lead exposure in the average general population diet were starchy roots and potatoes (8 %), meat and meat products, including

offal (8 %), alcoholic beverages (7 %), and milk and dairy products (6 %). Drinking water accounted for 4 % of overall exposure.

Average consumption of lead for typical adults was estimated to be 0.36 – 1.24 µg/kg bw per day. However, specific consumer groups with diets that included relatively greater consumption of game meat and game offal were estimated to have significantly greater lead intake than the general population: 1.98 to 2.44 µg/kg bw per day for game meat and 0.81 to 1.27 µg/kg bw per day for game offal, respectively. A specific estimate for dietary exposure of children the regularly eat game was not calculated.

Overall, dietary exposure was concluded by EFSA to be the major source of exposure to lead in all age groups, although for children ingestion of soil and dust was also an important contributor. Evaluation of the relative contributions of different sources is complex and likely to differ between areas and population groups (von Schirnding YE, 1999). EFSA (2013) clearly indicates that 'above average' consumption of game meat increases dietary lead exposure relative to the average diet.

Sorvari (2011) reported, that consumption of food items produced within the impact area of a shooting range pose a risk of exposure to lead.

The potential diffusion of lead from the use of lead gunshot into the groundwater is further discussed, in Section B.9.1.8.4⁶³.

Table B-37. Estimated Typical Daily Environmental Lead Exposures and Resulting Incremental Blood Lead Increases From Indirect Exposure via the Environment (LDAI, 2008).

Population	Air	Soil/Dust	Water	Food	Total Blood Pb
Adult Urban	0.05 µg/m ³ 0.15 µg/dL	250 mg Pb/kg 0.092 µg/dL	2 µg/d 0.18 µg/dL	25 µg/d 2.3 µg/dL	2.76 µg/dL
Adult Rural	0.01 µg/m ³ (0.032 µg/dL)	40 mg Pb/kg 0.002 µg/dL	2 µg/d 0.2 µg/dL	25 µg/d 2.50 µg/dL	2.73 µg/dL
Child 5-6 yr Urban	0.05 µg/m ³ 0.01 µg/dL	250 mg Pb/kg 0.71 µg/dL	0.8 µg/d 0.08 µg/dL	11.4 µg/d 1.59 µg/dL	2.44 µg/dL
Child 5-6 yr Rural	0.01 µg/m ³ 0.003µg/L	40 mg Pb/kg 0.12 µg/dL	1 µg/L 0.08 µg/dL	11.4 µg/d 1.59 µg/dL	1.84 µg/dL
Child 1-2 yr Urban	0.05 µg/m ³ 0.01 µg/dL	250 mg Pb/kg 1.0 µg/dL	1.0 µg/L 0.03µg/dL	6.5 µg/d 1.28 µg/dL	2.37 µg/dL

⁶³ About 75% of EU inhabitants depend on groundwater for their water supply (EC, 2008). Groundwater is also an important resource for agriculture (irrigation).

Child 1 -2 yr Rural	0.01 µg/m ³ 0.001 µg/dL	40 mg Pb/kg 0.17 µg/dL	1.0 µg/L 0.03 µg/dL	6.5 µg/d 1.18 µg/dL	1.38 µg/dL
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B.9.1.8.4. Groundwater and surface water contamination from lead shot

Groundwater contamination in Prime Hook National Wildlife Refuge in the US was reported by Soeder and Miller (2003).⁶⁴

Prime Hook National Wildlife Refuge (NWR) is located in south-eastern Delaware in coastal lowlands along the margin of Delaware Bay. For 37 years (shooting began in the early 1960s) the Broadkilm Sportsman's Club adjacent to the refuge operated a trap-shooting range, with the clay-target launchers oriented so that the expended lead shot from the range dropped and accumulated into forested wetland areas on the refuge property.

Large numbers of birds, including Canada geese, snow geese, black ducks, mallards, pintails, teal and wood ducks either live on the refuge year round, or pass through the area during spring and fall migrations (U.S. Fish and Wildlife Service, 2000). Because significant numbers of waterfowl use the refuge, the U.S. Fish and Wildlife Service was concerned about the potential environmental impact of large amounts of lead shotgun deposited on the property by a shooting range adjacent to the refuge. As part of the environmental risk assessment for the site, the U.S. Geological Survey investigated the potential for lead contamination in ground water.

The data collected on site indicated that lead from a concentrated deposit of shotgun pellets on the refuge was mobilised through a combination of favourable conditions, dissolved and infiltrated into the ground water.

Water samples from wells located in the contaminated area contained dissolved lead concentrations greater than 400 µg/L, and as high as 1 mg/L. In contrast, a natural background concentration of lead from ground water in an adjacent control site was about 1 µg/L.

The mobility of lead depends upon its transformation/dissolution behaviour in each geochemical environment. The oxidation of metallic lead is rapid under normal environmental conditions, but the oxidised lead reacts readily with other species to form insoluble precipitates that coat and passivate the surface of the metal. However, the mobility of lead, is controlled by processes that may override the passivation. Low pH, in particular, is suspected of being a major agent in the increased solubility of the lead carbonate hydrocerussite.

Relatively low pH was found in the shallow ground water at Prime Hook NWR. Values in the range of about 4.8 to 6.4 were common during the field sampling. The acidic conditions in the wetland, including acid rain, were responsible for dissolving the lead carbonate from the gunshot. Because of the apparent lack of buffering capacity and adsorption sites in the silica-rich sediments, the dissolved lead was mobilised and partitioned into the ground water. In the site many of the stratigraphic horizons are sandy, with little or no clay or

⁶⁴ Daniel J. Soeder and Cherie V. Miller, Ground-Water Contamination from Lead Shot at Prime Hook National Wildlife Refuge, Sussex County, Delaware, water-resources investigation report 02-4282 (2003).

iron oxide coatings that could trap and hold the lead. Once lead was in the ground water, its solubility might have been enhanced by the formation of dissolved organic-carbon complexes.

According to the report, once the shooting area was remediated and the source removed, the lead in the groundwater system would eventually attenuate. However, some of the lead also could be immobilised as it becomes bound to iron oxides at the margins of the sand units, making the natural attenuation process very lengthy. Planned clean-up of the site by the U.S. Fish and Wildlife Service included physical excavation and removal of the gunshot-contaminated soil, offsite disposal, grading, and revegetation of the area. The costs of these remediation activities were not specified in the study.

In the EU, several studies are available describing the environmental contamination occurring at shooting ranges, due to the use of lead ammunition.

According to Sorvari et al. (2006), there are between 2 000 and 2 500 outdoor shooting ranges in Finland. The study reported that a third of all shooting ranges in Finland may result in a risk to groundwater as they were located less than 100 m from the nearest aquifer. However, only very few sites were located adjacent to a domestic water intake. Three cases of groundwater pollution were identified. In these cases, the maximum lead concentration was about 10-fold greater than the guideline value for domestic water (10 µg/ l). Two of the aquifers had been used (previously) for supplying tap water to nearby residential areas. The number of shooting ranges in Finland located within or close to wetlands is not known. Sorvari (2007), attempted to quantify the risks to groundwater and make a prediction of lead leaching in some Finnish shooting ranges. The leaching of soil-bound lead into the aquifer as a function of time, was estimated with the use of a percolation test to be: 70-100 years for sandy soil and 6.5-20 years for peat soil.

Low pH enhances the presence of mobile chemical species of lead in peat soils and could enhance the risk of groundwater contamination from lead (Sorvari (2011)). In addition, shallow groundwater table and melting snow in springtime further enhance the dissolution and distribution of lead and other contaminants to the aquifer. Climatic conditions such as the amount of precipitation, pH of rainwater and site properties, affect the weathering and distribution of contaminants from lead ammunition.

In the EU, the extent to which contamination from high shot deposition is likely to affect sites downstream of shooting areas is unknown. The number of groundwater systems connected to wetlands and therefore exposed to a potential diffusion of dissolved lead (from lead gunshot) is not known.

Surface water

Heier et al. (2009 cited in LAG 2015), showed that trout in cages in a stream in Scandinavia subject to run-off from a shooting range showed elevated lead levels within three weeks. The lead was isotopically traced to the lead pellets used on the range.

Stansley et al. (1992 cited in LAG 2015), examined lead shot densities on eight shotgun (trap and skeet) shooting ranges in the USA where the fall-out areas included wetlands and measured the lead in the surface water, streams and downstream lake. In an acid marsh environment total water lead was as high as 1,270 µg/L and filterable lead was 83

µg/L. They found negligible off-site transport of lead when water pH was 7 or above, but some evidence of lead mobilisation when water pH fell below 7.

B.10. Risk characterisation

B.10.1. Environment (risks to birds)

B.10.1.1. Approach to risk characterisation

The purpose of an environmental risk characterisation under REACH is to describe the likelihood that the identified hazards of a substance are realised in the environment. This includes both compartmental and non-compartmental hazards, such as secondary poisoning. This assessment can be described quantitatively, using a risk characterisation ratio (RCR) or, where a quantitative risk characterisation is not possible or appropriate, the likelihood that risks will occur can be described qualitatively. In the former case an RCR is derived from the predicted environmental concentration (PEC) compared to a predicted no effect concentration (PNEC) derived for an environmental compartment (or food for secondary poisoning assessments). An RCR value greater than one indicates a risk. PNECs are almost exclusively derived from laboratory ecotoxicity studies. In the other case, a qualitative assessment is appropriate for substances that are not considered to have a threshold for adverse effects (such as a PNEC), such as persistent, bioaccumulative and toxic substances (PBTs) or very persistent and very bioaccumulative substances (vPvBs). In addition, a quantitative approach to risk characterisation is most suitable for assessing the risks of substances where there is no, or limited, empirical evidence of impacts linked to the use actually occurring in the environment.

In the case of the use of lead gunshot in wetlands, there is extensive evidence of adverse impacts on birds. Therefore, there is no advantage to undertake a quantitative risk characterisation as the risk from lead shot to birds in wetlands has clearly been demonstrated. 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.

In addition, under the AEWA agreement (MOP 6, 2015)⁶⁵, resolution 6.12 (*Avoiding additional and unnecessary mortality for migratory water birds*) outlines that:

The Meeting of the Parties *Encourages Contracting Parties which are also Parties to CMS*⁶⁶ *to implement, as a matter of priority, CMS Resolution 11.15 on preventing poisoning of migratory birds and utilise, as appropriate, its appended guidance to address risks from:*

- *the incidental poisoning of birds through the use and/or abuse of insecticides and rodenticides to protect crops;*

⁶⁵ <http://www.unep-aewa.org/en/meetings/meetings-of-parties> AEWA has three main bodies: the Meeting of the Parties (MOP), which is the governing body of AEWA, the Standing Committee (StC) and Technical Committee (TC), respectively responsible for steering the operations between sessions of the MOP and for providing scientific advice. The UNEP/AEWA Secretariat supports the Parties and services the bodies of the Agreement.

⁶⁶ Convention on Migratory Species.

- *the deliberate and/or incidental killing of birds through the use of poison baits for predator control and harvesting; and*
- *the use of lead ammunition⁶⁷ and fishing weights.*

The European Union is a Contracting Party of the AEWA agreement since 1 October 2005.

Therefore, the risk characterisation in this Annex XV dossier 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 in individual birds reported in Section B.7.3.3.
4. Exposure to lead as a co-factor in other forms of avian mortality in wild birds.

The information presented in relation to points 1 and 2 above also 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 in this analysis as the proposed restriction, implemented via REACH, will harmonise the risk management implemented in all Member States, regardless of their current implementation status. As such, the risks apparent prior to the implementation of Member State legislation can be considered as part of a baseline scenario.

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 additional insight into the effectiveness of different types of restrictions, particularly in relation to compliance, legacy sources of lead for birds and the potential for exposure of lead from outside of wetland areas. These studies confirm, in some cases, that even after restrictions are enacted risks may still remain to some extent.

In relation to point 3 above, whilst the primary risk assessed in this Annex XIV dossier is that associated with lethal poisoning of birds via primary or secondary ingestion of spent lead gunshot, supplementary information on the concentration of lead in various lead tissues, relative the indicative thresholds reported in B.7.3.3, provides additional evidence of likely sub-lethal effects on wild birds as a result in lead exposure. These data have been collated to support the conclusions on risk characterisation presented for points 1 and 2.

Critically, these indicative thresholds should only be interpreted as representative of the likelihood that certain clinical and sub-clinical effects in birds will occur and should not be considered to be equivalent to PNECs. Adverse effects in birds may occur at tissue concentrations below those reported.

⁶⁷ Including lead shot.

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, increased susceptibility of disease) is also briefly discussed.

B.10.1.2. Annual bird mortality in the EU

The extent of mortality occurring in waterbirds after ingesting spent lead gunshot has been estimated by several authors.

Bellrose (1959) estimated that lead poisoning was responsible for the loss of 2-3 million waterfowl per year in North America (2-3 % of the entire fall population of North American waterfowl). Bellrose's methodology, which is based on studies on mallard (*Anas platyrhynchos*), a species that occurs in both Europe and North America, is discussed in Section B.7.2.2.1. The methodology developed by Bellrose (1959) has been used by other authors to underpin estimates of annual mortality occurring in Europe.

RAC box:

During their evaluation, RAC questioned the reliability of the statistical methodology reported by Bellrose (1959), and considered that the reassessment of the Bellrose data using contemporary statistical methods reported by Green⁶⁸ was a more robust basis for estimating the mortality associated with the ingestion of different quantities of lead gunshot in mallards. However, acknowledging the large confidence intervals associated with Green's estimates and the relatively small differences between the central estimates reported by Bellrose and Green, RAC agrees with the approach of the Dossier Submitter to use estimates of annual mortality underpinned by the Bellrose mortality rates for further calculations of EU waterbird mortality from ingestion of lead gunshot. Further details of the RAC evaluation are provided in the RAC opinion.

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 European species collated from 1957-2004. Species specific mortality, which was explicitly linked to observed rates of lead shot ingestion, was variable. Three of the 17 species were not reported to suffer any mortality as they had not been observed to have ingested lead gunshot (greater white fronted goose, barnacle goose, greater scaup). Of the species with evidence of lead gunshot ingestion, annual mortality rates ranged from 0.2 % (tundra swan) to 32.4 % (white-headed duck). Across the 17 species assessed a total of 8.7 % of the overwintering population in Europe, equivalent to approximately 1 million birds, were estimated to die annually (Table B-38).

Mateo (2009) reports that the relative prevalence of lead shot ingestion is greater in European wildfowl than was observed in the US, which leads to the greater mortality. Mateo (2009) is the only published estimate of the extent of mortality due to lead shot ingestion in European waterfowl populations.

⁶⁸ Submitted in ECHA's public consultation (comment #1612).

Table B-38. Prevalence of lead shot ingestion and estimates of mortality in 17 species of wintering waterfowl in Europe (from Mateo, 2009)

Species	Wintering population	Prevalence (1957 – 2004)		Estimated mortality ^a	
		n	(%)	n	(%)
Tundra swan (<i>Cygnus columbianus</i>)	23 000	516	0.2	45	0.2
Pink-footed goose (<i>Anser brachyrhynchus</i>)	290 000	73	2.7	8 049	2.8
Greater white fronted goose (<i>Anser albifrons</i>)	1 100 000	30	0.0	0	0.0
Greylag goose (<i>Anser anser</i>)	390 000	203	4.4	17 517	4.5
Barnacle goose (<i>Branta leucopsis</i>)	370 000	61	0.0	0	0.0
Eurasian wigeon (<i>Anas Penelope</i>)	1 700 000	1 502	2.0	34 398	2.0
Gadwall (<i>Anas strepera</i>)	96 000	776	4.0	3 885	4.0
Common teal (<i>Anas crecca</i>)	730 000	42 899	4.6	34 271	4.7
Mallard (<i>Anas platyrhynchos</i>)	3 700 000	20 547	11.9	444 942	12.0
Northern pintail (<i>Anas acuta</i>)	120 000	952	30.4	36 905	30.8
Northern shoveler (<i>Anas clypeata</i>)	200 000	1 413	10.5	21 365	10.7
Red-crested pochard (<i>Netta rufina</i>)	84 000	81	12.3	10 506	12.5
Common pochard (<i>Aythya ferina</i>)	790 000	2 313	23.0	184 078	23.3
Tufted duck (<i>Aythya fuligula</i>)	1 200 000	4 203	10.4	126 977	10.6
Greater scaup (<i>Aythya marila</i>)	120 000	11	0.0	0	0.0
Common goldeneye (<i>Bucephala clangula</i>)	310 000	156	16.0	50 329	16.2
White-headed duck (<i>Oxyura leucocephala</i>)	5 700	25	32.0	1 848	32.4
Total	11 228 700	75 761	-	975 115	8.7

Notes: a – Mortality was estimated after Bellrose (1959). The prevalence of lead shot ingestion was assumed based on the mean distribution of the number of ingested pellets found in European waterfowl, as follows: 1 shot = 47.1 %, 2 shot = 15.7 %, 3 shot = 5.4 %, 4 shot = 6.3 %, 5 shot = 3.5 %, 6 shot = 2.0 %, > 6 shot = 19.9 % (data from Mudge, 1983; Pain, 1990; Meteo et al., 1997b, corrected for hunting bias and turnover as described by Bellrose, 1959); mortality associated with each prevalence class was 9, 23, 30, 36, 43, 50 and 75 %, respectively (after Bellrose, 1959).

As a consequence of the study methodology, the estimates do not include mortality caused in these species outside of the hunting season (which can occur but possibly with a lower incidence). It also excludes the sub-lethal effects of lead which can also influence mortality.

As the analysis was only conducted on a limited number of species, the overall mortality of waterbirds is likely to have been greater than the 1 million birds estimated. For example, further species of waterfowl and waterbirds (such as wading birds) are known to ingest lead gunshot in the EU, as discussed in Sections B.9.1.5 and B.9.1.6.

The analysis undertaken by Mateo (2009) also does not include the mortality of raptors or scavenging species that occurs via secondary poisoning. A specific estimate of the number of raptors and scavenging birds dying annually in the EU, resulting from a waterbird diet only, is not available and in all likelihood would be particularly challenging to estimate given the ecology and opportunistic behaviour of these species that means that a range of food types are taken.

Mateo (2009) has been reviewed within other assessments of the risk and impact of the use of lead ammunition (including lead gunshot). Harradine and Leake (2015), as part of the UK's lead in ammunition group, considered that the prevalence data used could overestimate the current incidence of mortality because many of the source data predated the introduction of restrictions on the use of lead gunshot in many Member States. Harradine and Leake (2015) also question the applicability of the Bellrose (1959) methodology, based on effects observed in the mallard, to Europe. However, as mallard occur in both the US and Europe, and the original methodology has been considered to be reliable for many years, this particular aspect of their evaluation appears unsubstantiated.

Pain and Green (2015), in their evaluation of the Mateo (2009) study as part of the UK's lead in ammunition group, acknowledge that contemporary rates of mortality in waterfowl could have been overestimated, but only if shot ingestion levels had indeed declined significantly over time and in response to the legislation enacted in Member States. Newth et al. (2012) report that the incidence of lead poisoning in waterfowl in the UK has not significantly declined since the introduction of partial restrictions on the use of lead gunshot (study elaborated further below).

As such, the estimate reported by Mateo (2009) can still be representative of annual mortality occurring in waterfowl populations where lead shot restrictions have yet to be introduced, or where implemented restrictions are limited in their scope or effectiveness.

Based on an assessment of 16 species using the Bellrose (1959) methodology, Pain et al. (2015) estimated that 3.1 % of the overwintering waterfowl population in the UK could die annually from lead poisoning (equivalent to approximately 74 000 individuals from the 16 species assessed). This estimate was based on gunshot ingestion data obtained from samples of hunter shot birds collected prior to the introduction of the partial restrictions on the use of lead gunshot in the UK. In line with all assessments underpinned by the Bellrose (1958) methodology all species are assumed to have equal sensitivity to lead shot ingestion to mallards (which are a medium sized duck). This assumption leads to some uncertainty as smaller species are likely to be more susceptible to lead poisoning than estimated by Bellrose (1958). Equally, larger species, such as geese and swans, may be less susceptible than estimated. Overall, these uncertainties could be expected to offset one another. According to the authors, mortality may have been underestimated as:

- Only 16 species of waterfowl (with UK data on the incidence of gunshot ingestion) were included.
- The study does not estimate mortality caused by gunshot ingestion outside of the hunting season.
- The study excludes sub lethal effects of gunshot ingestion (birds that have ingested lead shot are more likely to die from other causes).

Equally, the authors acknowledge that the study could have overestimated current levels of mortality. However, they note that compliance with the hunting regulations in the UK is quite low⁶⁹. Pain et al. (2015) do not estimate mortality of raptors or scavenging birds through secondary poisoning.

⁶⁹ Most recent analysis presented in Cromie et al. (2015).

Table B-39 Estimates of waterfowl mortality in 16 species of UK waterfowl (from Pain et al. 2015).

Number of gunshot ingested	% hunter-shot birds with ingested gunshot ^a	Hunting bias correction ^b	% with ingested gunshot after correction for hunting bias	% with ingested gunshot corrected with turnover ^c	Additional mortality rate (annual probability of death) ^d	% of the population estimated as dying of lead poisoning ^e	Number of birds estimated as dying ^f
1	1.89	1.5	1.26	9.45	0.09	0.85	20 039
2	0.525	1.9	0.276	2.07	0.23	0.48	11 230
3	0.081	2	0.041	0.30	0.3	0.09	2 147
4	0.207	2.1	0.098	0.74	0.36	0.27	6 255
5	0.207	2.2	0.094	0.70	0.43	0.30	7 132
≥6	0.578	2.35	0.246	1.84	0.62	1.14	26 947
Totals	3.487		2.015	15.11		3.13	73 750

Notes: a -Incidence from Mudge (1983); b - Correction factor based on the increased likelihood of hunters to shoot waterfowl that have ingested lead shot (after Bellrose, 1959); c - Assuming a 150 day hunting season (Britain) and an average residence time of lead gunshot in the gizzard of 20 days – turnover of $150/20 = 7.5$ (after Bellrose, 1959); d- mortality level is the increase in mortality in mallard caused by ingestion of specific numbers of lead shot (after Bellrose, 1959) – mortality is assumed to be similar in all species; e – per cent with ingested gunshot (after correction for hunting bias and turnover) multiplied by mortality level; f – Using wintering wildfowl estimates from Musgrove et al. (2011) for – mallard (*Anas platyrhynchos*), European widgeon (*Anas penelope*), common teal (*Anas crecca*), northern shoveler (*Anas clypeata*), pochard (*Aythya farina*), northern pintail (*Anas acuta*), tufted duck (*Aythya fuligula*), gadwall (*Anas strepera*), goldeneye (*Bucephala clangula*), pink-footed goose (*Anser brachyrhynchus*), white-fronted goose (*Anser albifrons*), greylag goose (*Anser anser*), barnacle goose (*Branta leucopsis*), mute swan (*Cygnus olor*), whooper swan (*Cygnus cygnus*), Bewick's swan (*Cygnus columbianus bewickii*).

Newth et al. (2012) reported the results of a large scale assessment of the extent of lead poisoning in the UK based on dead waterbirds collected between 1971 and 2010. Over this period a total of 2 365 dead wild water birds were recovered from sites across England, Scotland and Wales. A total of 28 different species of water bird were found from the six subfamilies Anatinae (724 birds), Anserinae (1 358 birds), Aythyinae (151 birds), Merginae (17 birds), Oxyurinae (2 birds) and Tadorninae (113 birds). Lead poisoning was reported to be responsible for the deaths of 10.6 % of the 2 365 recovered wildfowl. Post-mortem examinations found lead gunshot in the gizzards of 74.9 % of water birds that had been diagnosed as having died of lead poisoning. Rates of mortality attributable to lead poisoning were observed to vary significantly between species with 27.3 % of whooper swan mortality, 23 % of Bewick's swans and 16.7 % of Canada geese and pochard deaths in recovered birds attributed to lead poisoning, respectively.

The study also noted that the proportion of birds dying from lead poisoning in England did not vary significantly after the introduction of legislation, accounting for 13.7 % of non-infectious causes of death between 1971 and 1987 (n=204), 20.8 % (n=360) between 1988 and 1999 and 11.8 % (n=423) between 2000 and 2010. This was despite a significant change in lead-related mortality in mute swans found during the same time

period (which is mainly associated with reduced ingestion of lead fishing weights over this period).

A further estimate of EU waterfowl mortality of 6.1 %, based on similar datasets to those used by Mateo (2009) and Pain et al. (2015), is described by Andreotti et al. (2018).

B.10.1.2.1. Contemporary waterbird mortality in the EU

As all these available estimates are underpinned by historic data on lead shot ingestion, a further estimate representative of more contemporary impacts of EU waterbirds has been attempted as part of the development of this restriction proposal.

As there are a range of average annual mortality rates reported, three scenarios (low, central and high) have been developed to estimate the potential range of impacts on EU waterbird populations (waterfowl, wader and rail species). All three scenarios are underpinned by the most recently available (2008 to 2012) EU population size estimates reported under Article 12 of the Birds Directive⁷⁰ for waterbird species reported to have ingested lead gunshot in the EU (as reported by Mateo, 2009 and Pain et al., 2015).

The three scenarios were developed, as follows:

1. **Low scenario** – minimum reported population size for waterbirds combined with annual average mortality rate of 3.1 % after Pain et al. (2015);
2. **Central scenario** – average reported population size for waterbirds combined with annual average mortality rate of 6.1 % reported by Andreotti et al. (2018);
3. **High scenario** – maximum reported population size for waterbirds combined with an annual average mortality rate of 8.7 % after Mateo (2009).

It is acknowledged that the Pain et al. (2015) estimate of average annual mortality of 3.1 % was based on lead ingestion prevalence data specific to UK wildfowl, which have been noted to have relatively lower ingestion prevalence than Southern European wildfowl. Nevertheless, this average mortality rate could be indicative of contemporary impacts from lead gunshot ingestion across the EU in response to the partial restrictions on the use of lead gunshot in wetlands that have been enacted in many Member States. As such, it is considered to be a useful lower bound estimate for assessing indicative contemporary impacts on EU waterbirds.

As discussed above, the estimate of 8.7 % average reported by Mateo (2009) can be considered to be representative of average annual mortality prior to the introduction of restrictions on the use of lead gunshot. As such, it is considered to be a useful upper bound for assessing indicative contemporary impacts on EU waterbirds.

⁷⁰ 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/http://bd.eionet.europa.eu/article12/>. No data were reported by GR or HR.

RAC box:

During their evaluation, RAC questioned the reliability of the statistical methodology reported by Bellrose (1959), and considered that the reassessment of the Bellrose data using contemporary statistical methods reported by Green⁷¹ was a more robust basis for estimating the mortality associated with the ingestion of different quantities of lead gunshot in mallards. However, acknowledging the large confidence intervals associated with Green’s estimates and the relatively small differences between the central estimates reported by Bellrose and Green, RAC agrees with the approach of the Dossier Submitter to use estimates of annual mortality underpinned by the Bellrose mortality rates for further calculations of EU waterbird mortality from ingestion of lead gunshot. Further details of the RAC evaluation are provided in the RAC opinion.

As certain Member States have already enacted legislation that completely prohibits the use of lead gunshot within their territory (i.e. NL, BE, DK) the population of birds occurring within these Member States were excluded from the estimate of contemporary annual mortality. This may underestimate impacts recognising that many waterbirds are migratory and may travel between Member States as part of their migration or in search of food over the winter. Where a Member State has yet to enact any legislation preventing or reducing the use of lead gunshot in wetlands an annual average mortality rate of 8.7 % was assumed under all three scenarios.

Complimentary estimates of annual mortality were made based on both the reported wintering and breeding population sizes. This was to account for the fact that certain species are present in different parts of the EU at different times of the year (where they can be exposed) and that some waterbird species that are known to ingest lead gunshot are resident (rather than migratory) and are not reported as part of overwintering population estimates.

This approach assumes that exposure to lead gunshot can occur throughout the year (not just in the hunting season) 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. Wintering and breeding analyses are reported and interpreted separately to avoid any potential for double counting.

Similarly, this analysis assumes that the mortality rate estimates reported for waterfowl species are applicable to wader and rail species that are also reported to ingest lead gunshot. This assumption is consistent with the conclusions reported for common snipe (*Gallinago gallinago*) and Jack snipe (*Lymnocyptes minimus*) after studies in France (Oliver, 2006).

Table B-40 Waterbird species known to ingest lead shot included in estimate of EU mortality

Type	Common name	Scientific name
Wildfowl	Mallard	<i>Anas platyrhynchos</i>

⁷¹ Submitted in ECHA’s public consultation (comment #1612).

Type	Common name	Scientific name
	Common teal	<i>Anas crecca</i>
	Northern shoveler	<i>Anas clypeata</i>
	Common pochard	<i>Aythya ferina</i>
	Northern pintail	<i>Anas acuta</i>
	Tufted duck	<i>Aythya fuligula</i>
	Gadwall	<i>Anas strepera</i>
	Goldeneye	<i>Bucephala clangula</i>
	Pink-footed goose	<i>Anser brachyrhynchus</i>
	greylag goose	<i>Anser anser</i>
	Barnacle goose	<i>Branta leucopsis</i>
	Canada goose	<i>Branta canadensis</i>
	Common shelduck	<i>Tadorna tadorna</i>
	Eurasian wigeon	<i>Anas penelope</i>
	Garganey	<i>Anas querquedula</i>
	Red-crested pochard	<i>Netta rufina</i>
	White-headed duck	<i>Oxyura leucocephala</i>
	Marbled teal	<i>Marmaronetta angustiorstris</i>
	Ferruginous duck	<i>Aythya nyroca</i>
	Mute swan	<i>Cygnus olor</i>
	Whooper swan	<i>Cygnus cygnus</i>
	Bewick's swan	<i>Cygnus columbianus bewickii</i>
Waders & Rails	Common moorhen	<i>Gallinula chloropus</i>
	Common coot	<i>Fulica atra</i>
	Common snipe	<i>Gallinago gallinago</i>
	Jack snipe	<i>Lymnocyptes minimus</i>
	Avocet	<i>Recurvirostra avosetta</i>
	lapwing	<i>Vanellus vanellus</i>

Type	Common name	Scientific name
	ruff	<i>Philomachus pugnax</i>
	black-tailed godwit	<i>Limosa limosa</i>
	Greater flamingo	<i>Phoenicopterus roseus</i>
	Western water rail	<i>Rallus aquaticus</i>
	Purple swamphen	<i>Porphyrio porphyrio</i>

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 and rail populations of species known to have ingested lead gunshot occur in Member States that have no ban in place. Based on breeding population size, this increases to 12 % of the waterfowl population and 14 % of the wader and rail population known to have ingested lead gunshot (Table B-41).

Table B-41. Population size of waterfowl, wader and rail species in the EU known to ingest lead gunshot and correspondence with existing legislation prohibiting or reducing the use of lead gunshot.

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

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

Based on wintering population size, between 262 000 and 787 000 waterfowl from 22 species are estimated to die annually from the consumption of lead gunshot in the EU, with a central estimate of 522 000 (Table B-42Table B-41). Based on breeding population size of the same species, between 207 000 and 720 000 individuals are estimated to die annually, with a central estimate of 441 000. 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 or Croatia reported under Birds Directive Article 12, this is likely to be an underestimate.

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

When estimates for waterfowl are combined with those for waders and rails between approximately 400 000 and 1 500 000 individuals are estimated to die annually throughout the EU from lead poisoning. Of these, between 65 000 and 200 000 are estimated to occur in Member States without legislation prohibiting or reducing the use of lead gunshot in wetlands (Table B-43).

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

Table B-42 Estimated annual mortality of birds in the EU 28 from the ingestion of lead gunshot.

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

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

Table B-43 Estimated annual mortality of birds in Member States without legislation to control the risks from the use of lead gunshot in wetlands.

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

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

B.10.1.3. Case studies on the impact of lead gunshot on birds living in EU wetlands

The feeding behaviour and overall ecology of each bird species are critical parameters to take into account when assessing risks to water birds from the use of lead shot in wetlands. The differences in the prevalence of lead shot ingestion observed between bird species are most likely to be a function of variability in terms of diet and the type of grit ingested (Figuerola et al., 2005; Mateo et al., 2000; Pain, 1990 cited by Mateo et al. 2014).

Lead shot 'availability' at different wetlands sites will also vary, suggesting that every site may present a unique risk profile to wetland birds. This may result in different mortality rates in different sites, for each species.

However, despite these complex site and species-specific considerations there is clearly a risk to birds that feed or forage for grits in wetlands.

Risks to wetland birds are also influenced by the fact that these birds do not recognise human borders (e.g. protected areas of wetlands where use of lead gunshot is prohibited) as they typically forage across a range of habitats, which are likely to include some that are outside of protected areas (Newth et al., 2016). Further, risks may be influenced by the fact that many water birds are migratory species, thus moving between breeding and wintering sites throughout the year.

A large number of studies have described lethal and sub-lethal effects for many taxa resulting from the ingestion of lead shot. This literature has been reviewed numerous times as recently reported by Pain and Green (2015). A series of case studies, each referring to a different bird species or different type of wetland, are discussed in the following paragraphs.

B.10.1.3.1. Whooper swans in the UK

Within the UK, lead shot can be used in areas where restrictions do not apply, which can be occupied by swans⁷² and other water birds⁷³. Newth et al. (2016) collected a total of 300 blood samples from 260 live whooper swans (including 36 individuals sampled more than once), in winters between 2010-2014.

Lead was detected in all blood samples. Elevated blood lead levels (i.e. > 20 mg/dL) were found in 41.7 % of swans tested. Blood lead levels above 44 mg/dL were associated with a statistically significant detrimental effect on winter body condition⁷⁴ and were found in 10 % (27/260) of swans tested across three winters.

The authors considered that most of the whooper swans had been exposed to lead through the ingestion of spent lead gunshot when foraging within the 35-40 days preceding sampling. Blood lead concentrations usually reflect recent exposure to lead, i.e. within the preceding 35-40 days (O'Halloran et al., 1988, cited by Newth et al., 2016). Franson and Pain (2011) had previously estimated the range of blood lead levels within which Anseriformes are predicted to exhibit clinical signs of poisoning, including weight loss, (leading to probable death) at 50-100 µg/dL. Based on their findings, Newth et al. concluded that sub-lethal impacts of lead on body condition occur at the lower end of previously established clinical thresholds for effect.

⁷² Lead poisoning has been recorded in wild swans globally, with poisoning of mute swans (*Cygnus olor*) attributed to the ingestion of lead fishing weights (Perrins et al., 2003), whereas migratory whooper swans (*Cygnus cygnus*) and Bewick's swans (*Cygnus columbianus bewickii*) more commonly ingest spent lead gunshot (Newth et al., 2016).

⁷³ Within the UK, the use of lead shot was prohibited over all foreshore, over specified Sites of Special Scientific Interest and for hunting ducks, geese, coot and moorhen, wherever they occur in England in 1999 and Wales in 2002; for hunting over wetlands (RAMSAR definition), for any type of shooting activity, in Scotland in 2004 and Northern Ireland in 2009.

⁷⁴ The authors defined the body condition as a measure of the energy capital accumulated in the body as a result of feeding, which is assumed to be an indicator of an animal's health. In general, the energy capital refers to the size of energy reserves such as fat and protein relative to the skeletal body size of the animal. Fats are a major form of energy storage in birds, which are quickly mobilised for energetic purposes.

In general, a reduction in body weight of a migratory bird might affect its survival. Fat accumulation prior to migration can influence migration and survival (e.g. Haramis et al., 1986; Owen and Black, 1989; cited by Newth et al. 2016). In addition, as some migratory birds can travel thousands of kilometres between summer breeding areas and wintering sites, migratory journeys impose very high energetic demands since flight may even last several days (e.g. Battley et al. 2000), during which time birds rely exclusively on body energy stores.

B.10.1.3.2. Flamingos in Mediterranean countries

The diet of flamingos, and their unique feeding behaviour and anatomy, make them especially vulnerable to lead shot ingestion. They can feed on bottom substrates in water that is 120-130 cm deep as a consequence of their long legs and neck.

As reported by Mateo et al. (1997), from November 1992 to March 1993, and from November 1993 to February 1994, 106 dead or moribund greater flamingos (*Phoenicopterus roseus*) were collected in the wetlands of El Fondo and Salinas de Santa Pola, eastern Spain. Birds that were still alive were emaciated and had a bile-stained diarrhoea (which is characteristic of lead poisoning). On necropsy, they had liquid in the upper digestive tract and the walls of their gizzards were stained dark green. Fifty-three (93 %) of 57 gizzards examined contained lead shot (range one to 277 shot).

Another severe event of lead shot poisoning in flamingos is described by Arcangeli et al. (2007)⁷⁵. In autumn 2006, in Italy more than 20 greater flamingos (*Phoenicopterus roseus*) were found dead in the Po Delta. 16 of them were collected for further analysis. Several lead pellets were present in the gizzard of all birds, ranging from 12 to 44. Chemical and histopathological analyses confirmed that lead shot poisoning was the cause of death.

Lead poisoning in flamingos has also been reported in Cyprus as being the cause of death of 52 flamingos on the shores of the Larnaca Salt Lake in February 2003 in the vicinity of a shooting club, which was established in 1979 (Hadjichristoforou, 2004, unpublished data⁷⁶). In 2001 the main Larnaca Salt Lake was declared a Ramsar Site.

The death of the birds was found to be caused by the presence of lead shot in their digestive system with up to 80 lead shot found in the gut of birds.

Sediment analyses showed concentrations of 3 826 mg/kg of lead in the sediment, compared to about 30 mg/kg in other areas of the lake. In 1995, concentrations of 1 316 mg/kg of lead was found in the shooting club area and about 25 mg/kg elsewhere.

The main reasons why flamingos died in 2003 and not in earlier years were considered to be:

1. high rainfall in 2003 resulted in the lake covering a larger than normal area, which meant that the flamingo used the area contaminated with lead shot, near the shooting club, for feeding.
2. high rainfall in the previous year had led to water remaining in the lake over the preceding summer period, upsetting the usual ecological cycles and limiting the quantity of *Artemia* (shrimp) in the lake during the 2003 season. This in turn

⁷⁵ Italian publication (short summary in English).

⁷⁶ This case study was discussed at the 5th European Regional Meeting on the implementation and effectiveness of the Ramsar Convention on 4-8 December 2004, in Yerevan, Armenia.

changed the feeding pattern of the flamingos, with birds foraging for food by stirring the sediment with their feet and ingesting lead shot whilst feeding.

In February 2003, following a debate in the House of Representatives, it was decided that the shooting club should terminate its operations. The clean-up operation was undertaken in August/September 2003 when the lake dried up. The remediation operation was considered successful as the area reverted back to near normality and the mortality of flamingo was reported to be low in 2004, although the lake was flooded to 2003 levels. The cost of the remediation was not specified.

B.10.1.3.3. White-headed duck and marbled teal in Spain

Lead is also known to be a serious threat to certain globally threatened European wildfowl, e.g. white-headed duck (*Oxyura leucocephala*) and marbled teal (*Marmaronetta angustirostris*) (Mateo et al., 2001; Svanberg et al., 2006 all cited by Taggart et al., 2009).

El Hondo, Spain, is one of the most important European wetlands for these species and often holds most of the European population of one or both species at a given moment in time (Svanberg et al., 2006).

Between 1996 and 2001, Taggart et al. (2009) collected dead or moribund birds. Bones and livers were analysed to determine concentrations of lead, copper, zinc, selenium and arsenic. Seven of 34 (21 %) marbled teal adults were found to have lead shot in the gizzard, and in all these cases, only 1 shot was present. Twenty-four of 34 (71 %) white-headed duck adults had shot in the gizzard, 16 had 1 shot, 3 had 2, 1 had 3, 2 had 5, and 2 had 6.

For most metals (lead, copper, zinc, selenium and arsenic), in both bone and liver, levels were consistently higher in the white-headed ducks than in the marbled teals. This seemed to be mainly related to the feeding habits of the two species and were not found to be related to the presence or absence of lead shot in the gizzard, with the exception of lead levels in liver.

Lead in the liver of adult birds was influenced by lead shot ingestion, which was detected in 21 % of marbled teal and in 71 % of white-headed duck. No marbled teal had liver levels indicative of lead poisoning, while 86 % of white-headed ducks did.

Marbled teal tend to feed at the water surface and compared to other European ducks its diet contains a particularly high proportion of seeds. White-headed ducks mainly feed on invertebrates with benthic larvae and pupae being the most common food item. White-headed ducks feed at depth by diving and are more likely to consume both lead shot and sediment particles associated with benthic fauna. Benthic invertebrates in themselves may contain elevated metal levels as they have the potential to bioaccumulate lead, copper, zinc, selenium and arsenic (Flinders, 2006 cited by Taggart et al., 2009). In contrast, marbled teal are less exposed to all of these potential sources of metals because of their feeding behaviour. They also tend to ingest smaller grit particles than white-headed ducks, and hence, less lead shot (Mateo et al., 2001).

This study confirms that for some water birds species, although different exposure routes may be relevant, lead shot ingestion is the main source of lead poisoning, when lead shot is available.

B.10.1.4. Comparison with indicative thresholds of adverse effect

Table B-44 outlines examples from several studies of the lead concentration found in various bird tissues compared with the indicative threshold values discussed in Section B.7.3.3.

The percentage of birds showing subclinical poisoning or severe clinical poisoning is indicated in the column describing the interpretation relative to indicative thresholds of adverse effect.

Table B-44. Examples of comparison of the lead concentration in various tissues of wild birds with indicative thresholds of adverse effect.

Details of study (geographical, temporal and species scope)/ Reference	Tissue type and concentration	Interpretation relative to indicative thresholds of adverse effect^a (See Section B.7.3.3)
<p>Northern pintail after 2007, Spain, n=15, geometric mean value Mateo et al., 2014</p>	<p>Liver ($\mu\text{g/g d/w}$) Mean: 41.6; Range: 6.95-166</p>	<p>Mean concentration observed in liver greater than indicative threshold for sub-clinical poisoning. Maximum level observed greater than indicative threshold for severe clinical poisoning.</p> <p>100 % of the samples had liver concentration > 1.5 $\mu\text{g/g dw}$, the maximum residue levels for offal for human consumption in the European Union (European Commission, 2006)</p>
<p>Whooper Swans 2010-2014, UK, n=300 Newth et al., 2016</p>	<p>Blood ($\mu\text{g/dL}$) Mean: 23.5; Range: 5.6-132.9</p>	<p>41.7 % of swans with blood concentration greater than indicative threshold for subclinical poisoning. 10 % of swans with blood concentration of $\geq 44 \mu\text{g/dL}$, 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)</p>
<p>Flamingos 2006, Italy, n=16 Arcangeli et al., 2007</p>	<p>Liver ($\mu\text{g/g w/w}$) Mean: 108.41; Range: 28.8-264.0</p>	<p>100 % of flamingos with liver concentration greater than indicative threshold for severe clinical poisoning.</p>
<p>Flamingos 1992-3, Spain, n=106 dead or moribund, mean value Mateo et al., 1997</p>	<p>Liver ($\mu\text{g/g d/w}$) Mean: 192.3 Range < 2.5 - 992.2 $\mu\text{g/g dw}$ 57 of 64 flamingos found dead had live conc. > 77.2</p>	<p>89 % dead or moribund flamingos had liver concentrations that were greater than the indicative threshold for severe clinical poisoning.</p>

Details of study (geographical, temporal and species scope)/ Reference	Tissue type and concentration	Interpretation relative to indicative thresholds of adverse effect^a (See Section B.7.3.3)
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).

B.10.1.5. Exposure to lead as a co-factor in other causes of mortality in wild birds

In general, some evidence suggests that sub-lethal lead poisoning can increase the likelihood of mortality from other factors, such as flying accidents in wild mute swans (Kelly and Kelly, 2005) and the susceptibility to being hunted in a wide range of wildfowl (Bellrose, 1959; Demendi and Petrie, 2006; Heitmeyer et al., 1993; cited by Pain et al. 2015).

As reviewed by Newton et al. (2016), in general, birds with reduced body condition may also be more susceptible to disease and other mortality factors and weaker birds may be at increased risk of predation (Kelly and Kelly, 2005; Newth et al., 2012; Scheuhammer and Norris, 1996).

B.10.1.6. Population-level effects

Lead poisoning, through ingestion of spent lead gunshot is a well-established cause of morbidity and mortality in waterbirds. REACH does not require evidence of ‘population level’ impacts to demonstrate that there is an unacceptable risk to either the environment or human health on an EU wide basis, particularly for non-threshold substances. It is clear that the large numbers of individual waterbirds that are estimated to die each year as a result of the use of lead gunshot in wetlands demonstrates that risks from the use of lead gunshot are not adequately controlled. Therefore, a detailed assessment of the population level impacts on water birds due to lead shot ingestion has not been carried out.

Nevertheless, several studies have investigated endpoints in waterbirds that are relevant to the assessment of population-level effects of lead gunshot ingestion, and are briefly described below.

Tavecchia et al. (2001) and Guillemain et al. (2007), found a negative impact on survival rate, when sampling waterfowl in the Camargue, southern France. Vallverdú-Coll et al. (2015b) noted that shot ingestion in birds can result in maternal transfer to the offspring that can affect their developing immune system and reduce early life stage survival. The

adverse effects of lead can be also observed in the reproductive function of male birds, in particular on the integrity of the acrosome and the motility of the spermatozoa (Vallverdú-Coll et al. 2016b).

Mateo (2009) found a statistically significant correlation, across 15 taxonomically similar wildfowl species with broadly comparable life-history characteristics, for species with high levels of shot ingestion to have more negative population trends than species with low shot ingestion levels. While this analysis was based on correlation only, it suggests population level impacts associated with lead gunshot ingestion.

A recent study investigating the hypothesis that lead shot ingestion may affect population levels in some wildfowl species was reported by Green and Pain (2016). The study involved an analysis of winter population trends and shot ingestion prevalence in eight freshwater duck species in the UK (Green & Pain 2016). A correlation was found between wintering population trend over an extended time period and two independent measures of inter-specific variation in the prevalence of ingested lead shot.

Across Europe, some of those species with the highest lead shot ingestion levels are declining very rapidly. Of particular concern is the common pochard (*Aythya farina*). This species typically has high shot ingestion levels and it has long been thought that lead poisoning could be a cause of its decline; females winter predominantly in far southern Europe with higher hunting pressure and lead poisoning prevalence and female survival is far lower than that of males (Owen 1996).

An example of the impacts of lead poisoning on wildfowl populations comes from Britain, where the sedentary mute swan *Cygnus olor* population was affected by ingesting lead fishing weights (which poison birds in a similar way to lead shot). Once lead fishing weights were banned in 1987, lead-induced mortality declined substantially (Newth et al. 2012) and previously declining mute swan populations increased; this increase was quite dramatic on the most heavily affected river systems (Perrins et al. 2003).

B.10.1.7. Conclusions

Lead poisoning, through ingestion of spent lead gunshot (whether primary or secondary), is a well-established cause of morbidity and mortality in water birds that may also adversely affect predatory and scavenging species. Risks to birds from the ingestion of lead shot have led to the enactment of different types of restrictive regulations throughout the world (e.g. in the US), including many EU Member States.

Wherever lead shot is available to birds, poisoning can potentially occur, although at different levels for different species, based on their ecology and especially on their feeding behaviour. Risks are clearly not limited to 'hunted' species. For example, in the UK, swans are frequently diagnosed with lead poisoning. Similarly, in Mediterranean regions, flamingos are also vulnerable to lead poisoning, as discussed in Section B.10.1.3.2.

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

In addition to hunting, activities related to target (i.e. clay pigeon) shooting, when practiced using lead gunshot within wetlands or in their proximity, may affect the quality of wetlands habitat. Lead will accumulate within the environment and the degree of contamination will be proportional to the intensity of release. In addition, environmental conditions (which may vary over time) can affect shot availability and feeding habits of birds, as shown by the case study on flamingo mortality in Cyprus, discussed in Section B.10.1.3.2.

Sub-lethal impacts are difficult to quantify. However, some evidence suggests that sub-lethal lead poisoning can increase the likelihood of mortality from other factors, such as flying accidents and the susceptibility to being hunted. Based on available studies, lead shot ingestion is likely to adversely affect the breeding productivity of birds and could increase the probability of mortality from other causes.

B.10.2. Human health

Exposure to lead results in various non-threshold effects in humans, including neurotoxicity leading to reduced IQ in children. Although the blood lead level of children in Western Europe has decreased to 1.5-2 µg Pb/dL this concentration is still considered to be associated with adverse effects on neurodevelopment. Any incremental reduction in lead exposure will therefore contribute further to reducing adverse effects.

No quantitative risk characterisation for humans consuming game meat from wetlands (wildfowl) killed using lead gunshot has been undertaken. This is due to the lack of data on wildfowl consumption rates relative to other types of game in the EU population. Nevertheless, the available data clearly demonstrates that members of the public that consume relatively greater quantities of game in their diet than average consumers are exposed to significantly greater amounts of lead in their diet. It is not infeasible that a proportion of this additional lead is via game meat from waterfowl hunted in wetlands with lead gunshot.

As lead is a non-threshold substance, any reduction of dietary lead exposure that occurs as a consequence of the proposed restriction will contribute to further reducing the human health risks posed by lead, particularly in specific target populations such as children and subsistence hunters.

In addition, as elaborated in B.9.1.8, taking into account the objectives of the Water Framework Directive (2000/60/EC) and Groundwater Directive (2006/118/EC), further reductions in release of contaminants to the environment that could affect the quality of groundwater (including lead from lead shot at a site-specific level), may also lead to reduced human exposure.

Appendix B.1: Bioconcentration / bioaccumulation factors for lead in freshwater organisms and soil

Table B-45. The whole-body bioconcentration factor (BCF in L/kg) of lead in freshwater organisms (LDAI, 2008)⁷⁷

Species	Organism	Tissue (mg/kg dw)	Tissue (mg/kg ww)	Water (µg/L)	BCF (L/kg dw)	BCF (L/kg ww)	Reference
Crustaceans							
Asellus meridianus	isopod	20 000	4 000	500	40 000	8 000	Brown, 1977
Hyalella azteca	amphipod	1.3	0.26	0.4	3 250	650	Borgmann et al., 1993
Hyalella azteca	amphipod	5.8	1.16	3.3	1 758	352	Borgmann et al., 1993
Hyalella azteca	amphipod	7.1	1.42	2.6	2 731	546	Borgmann et al., 1993
Hyalella azteca	amphipod	15.8	3.16	11.6	1 362	272	Borgmann et al., 1993
Hyalella azteca	amphipod	1.1	0.21	0.2	5 000	1 000	Maclean et al., 1996
Hyalella azteca	amphipod	6.8	1.35	2.1	3 250	650	Maclean et al., 1996
Hyalella azteca	amphipod	25.9	5.18	20.7	1 250	250	Maclean et al., 1996
Hyalella azteca	amphipod	113.9	22.77	207.0	550	110	Maclean et al., 1996
Daphnia magna	cladoceran	4.9	0.98	0.9	5 765	1 153	Cowgill, 1976
Daphnia pulex	cladoceran	3.6	0.72	0.9	4 235	847	Cowgill, 1976
Molluscs							
Dreissenia polymorpha	mussel	0.9	0.09	0.5	1 800	180	Kraak et al., 1994

⁷⁷ Following the assessment on the reliability of the data, all BCF/BAF values in both tables received a Klimisch score of ≥ 2 .

Species	Organism	Tissue (mg/kg dw)	Tissue (mg/kg ww)	Water (µg/L)	BCF (L/kg dw)	BCF (L/kg ww)	Reference
<i>Dreissenia polymorpha</i>	mussel	10	1	4	2 500	250	Kraak et al., 1994
<i>Dreissenia polymorpha</i>	mussel	11	1.1	10	1 100	110	Kraak et al., 1994
<i>Dreissenia polymorpha</i>	mussel	40	4	36	1 111	111	Kraak et al., 1994
<i>Dreissenia polymorpha</i>	mussel	130	13	85	1 529	153	Kraak et al., 1994
<i>Lymnaea palustris</i>	snail	8.5	2.5	1	8 500	2 500	Borgmann et al., 1978
<i>Physa integer</i>	snail	100	20	32	3 125	625	Spehar et al., 1978
<i>Physa integer</i>	snail	400	80	67	5 970	1 194	Spehar et al., 1978
<i>Physa integer</i>	snail	500	100	136	3 676	735	Spehar et al., 1978
<i>Physa integer</i>	snail	500	100	277	1 805	361	Spehar et al., 1978
<i>Physa integer</i>	snail	1 000	200	565	1 770	354	Spehar et al., 1978
Insects							
<i>Brachycentrus</i> sp.	caddisfly	300	60	32	9 375	1 875	Spehar et al., 1978
<i>Brachycentrus</i> sp.	caddisfly	300	60	67	4 478	896	Spehar et al., 1978
<i>Brachycentrus</i> sp.	caddisfly	300	60	136	2 206	441	Spehar et al., 1978
<i>Brachycentrus</i> sp.	caddisfly	600	120	277	2 166	433	Spehar et al., 1978
<i>Brachycentrus</i> sp.	caddisfly	1 000	200	565	1 770	354	Spehar et al., 1978

Species	Organism	Tissue (mg/kg dw)	Tissue (mg/kg ww)	Water (µg/L)	BCF (L/kg dw)	BCF (L/kg ww)	Reference
Pteronarcys dorsata	stonefly	300	60	32	9 375	1 875	Spehar et al., 1978
Pteronarcys dorsata	stonefly	500	100	67	7 463	1 493	Spehar et al., 1978
Pteronarcys dorsata	stonefly	500	100	136	3 676	735	Spehar et al., 1978
Pteronarcys dorsata	stonefly	1 000	200	277	3 610	722	Spehar et al., 1978
Pteronarcys dorsata	stonefly	2 000	400	565	3 540	708	Spehar et al., 1978
Fish							
Poecilia reticulata	fish	4.1	0.82	3.1	265	1 322	Vighi, 1981
Poecilia reticulata	fish	12	2.4	27.5	87	436	Vighi, 1981
Salvelinus fontinalis	brook trout	8	1.6	34	235	47	Holcombe et al., 1976
Salvelinus fontinalis	brook trout	12.7	2.54	58	219	44	Holcombe et al., 1976
Salvelinus fontinalis	brook trout	0.36	0.072	0.9	400	80	Holcombe et al., 1976
Lepomis macrochirus	Blue gill sunfish	1.4	0.28	14.1	100	20	Wiener and Giesy, 1979
Lepomis macrochirus	Blue gill sunfish	1.0	0.20	14.1	70	14	Wiener and Giesy, 1979
Micropterus salmoides	Black bass	0.65	0.13	14.1	45	9	Wiener and Giesy, 1979
Esox niger	Chain Pickerel	1.25	0.08	14.1	25	5	Wiener and Giesy, 1979

Species	Organism	Tissue (mg/kg dw)	Tissue (mg/kg ww)	Water (µg/L)	BCF (L/kg dw)	BCF (L/kg ww)	Reference
Anguilla rostrata	American eel	0.5	0.10	14.1	35	7	Wiener and Giesy, 1979
Erimyzon sucetta	lake chubsuckers	0.5	0.10	14.1	35	7	Wiener and Giesy, 1979
Perca flavescens	Yellow perch	1.1	0.22	0.5	2 025	405	Draves and Fox, 1998
Perca flavescens	Yellow perch	0.5	0.10	0.2	2 120	424	Draves and Fox, 1998

Table B-46. The whole-body bioaccumulation factor (BAF in L/kg) of lead in freshwater organisms (LDAI, 2008)

Species	organism	Tissue (mg/kg dw)	Tissue (mg/kg ww)	Water (µg/L)	BCF (L/kg dw)	BCF (L/kg ww)	Analysis of Pb in aqueous media	Reference
Crustaceans								
Asellus	isopod	3.44	0.688	<0.2	> 17 200	> 3 440	Filtered (0.45 µm)	Timmermans et al., 1989
Gammarus	amphipod	1.65	0.33	<0.2	> 8 250	> 1 650	Filtered (0.45 µm)	Timmermans et al., 1989
Cyclops		3.78	0.756	<0.2	>18 900	> 3 780	Filtered (0.45 µm)	Timmermans et al., 1989
Daphnia magna	cladocera n	23	4.6	3.1	7 400	1 500	Filtered (0.45 µm)	Vighi, 1981
Daphnia magna	cladocera n	68	13.6	27.5	2 500	495	Filtered (0.45 µm)	Vighi, 1981

Species	organism	Tissue (mg/kg dw)	Tissue (mg/kg ww)	Water ($\mu\text{g/L}$)	BCF (L/kg dw)	BCF (L/kg ww)	Analysis of Pb in aqueous media	Reference
Daphnia magna	cladocera n	187	37.4	13	14 380	2 877	Filtered (0.45 μm)	Lu et al., 1975
Daphnia magna	cladocera n	154	30.8	2	77 000	15 400	Filtered (0.45 μm)	Lu et al., 1975
Daphnia magna	cladocera n	85	17	2	42 500	8 500	Filtered (0.45 μm)	Lu et al., 1975
Molluscs								
Amblema plicata	clam	13.5	1.35	2	6 750	675	Filtered (filter size not reported)	Mathis and Cummings, 1973
Dreissena	mussel	0.12	0.024	< 0.2	> 600	> 120		Timmermans et al., 1989
Dreissena polymorpha	mussel	5.1	0.51	35	146	15	Unfiltered	Chevreuil et al., 1996
Dreissena polymorpha	mussel	3.7	0.37	54	69	7	Unfiltered	Chevreuil et al., 1996
Dreissena polymorpha	mussel	3.2	0.32	37	86	9	Unfiltered	Chevreuil et al., 1996
Dreissena polymorpha	mussel	1.9	0.19	12	158	16	Unfiltered	Chevreuil et al., 1996
Dreissena polymorpha	mussel	1.4	0.14	8	175	18	Unfiltered	Chevreuil et al., 1996
Fusconaia flava	clam	18.5	1.85	2	9 250	925	Filtered (filter size not reported)	Mathis and Cummings, 1973
Lymnaea	snail	0.79	0.079	< 0.2	> 3 950	> 395	Filtered (0.45 μm)	Timmermans et al., 1989

Species	organism	Tissue (mg/kg dw)	Tissue (mg/kg ww)	Water ($\mu\text{g/L}$)	BCF (L/kg dw)	BCF (L/kg ww)	Analysis of Pb in aqueous media	Reference
Potamopyrgus	snail	7.7	0.77	< 0.2	> 38 500	> 3 850	Filtered (0.45 μm)	Timmerman s et al., 1989
Quadrula	clam	11	1.1	2	5 500	550	Filtered (filter size not reported)	Mathis and Cummings, 1973
Physa	snail	334	33.4	13	25 692	2 570	Filtered (0.45 μm)	Lu et al., 1975
Physa	snail	88	8.8	2	44 000	4 400	Filtered (0.45 μm)	Lu et al., 1975
Physa	snail	56	5.6	2	28 000	2 800	Filtered (0.45 μm)	Lu et al., 1975
Insects								
Chironomus	midge	1.83	0.366	< 0.2	>9 150	> 1 830	Filtered (0.45 μm)	Timmerman s et al., 1989
Glyptotendipes	midge	0.44	0.088	< 0.2	>2 200	> 440	Filtered (0.45 μm)	Timmerman s et al., 1989
Holocentropus	caddisfly	1.32	0.264	< 0.2	>6 600	> 1 320	Filtered (0.45 μm)	Timmerman s et al., 1989
Ischnura	damselfly	1.75	0.35	< 0.2	>8 750	> 1 750	Filtered (0.45 μm)	Timmerman s et al., 1989
Limnephilus	caddisfly	4.36	0.872	< 0.2	>21800	> 4 360	Filtered (0.45 μm)	Timmerman s et al., 1989
Stictochironomus	chironomid	5.31	1.062	< 0.2	>26 550	> 5 310	Filtered (0.45 μm)	Timmerman s et al., 1989

Species	organism	Tissue (mg/kg g dw)	Tissue (mg/kg g ww)	Water (µg/L)	BCF (L/kg dw)	BCF (L/kg ww)	Analysis of Pb in aqueous media	Reference
Micronecta	corixid	1.87	0.374	< 0.2	> 9 350	> 1 870	Filtered (0.45 µm)	Timmerman s et al., 1989
Annelids								
Erpobdella	leech	1.62	0.324	< 0.2	> 8 100	> 1 620	Filtered (0.45 µm)	Timmerman s et al., 1989
Acarides								
Hygrobates	mite	1.73	0.346	< 0.2	> 8 650	> 1 730	Filtered (0.45 µm)	Timmerman s et al., 1989
Fish								
Astyanax mexicanus	fish	1	0.2	14	71	14	Unfiltere d	Villarreal- Trevino et al., 1986
Astyanax mexicanus	fish	0.9	0.18	12	75	15	Unfiltere d	Villarreal- Trevino et al., 1986
Astyanax mexicanus	fish	0.86	0.172	10	86	17	Unfiltere d	Villarreal- Trevino et al., 1986
Astyanax mexicanus	fish	0.8	0.16	7	114	23	Unfiltere d	Villarreal- Trevino et al., 1986
Astyanax mexicanus	fish	4.74	0.948	4	1 185	237	Unfiltere d	Villarreal- Trevino et al., 1986
Cichlasoma cyanoguttatum	fish	0.5	0.1	9	56	11	Unfiltere d	Villarreal- Trevino et al., 1986
Cichlasoma cyanoguttatum	fish	1.36	0.272	14	97	19	Unfiltere d	Villarreal- Trevino et al., 1986

Species	organism	Tissue (mg/kg dw)	Tissue (mg/kg ww)	Water ($\mu\text{g/L}$)	BCF (L/kg dw)	BCF (L/kg ww)	Analysis of Pb in aqueous media	Reference
<i>Cichlasoma cyanoguttatum</i>	fish	1.3	0.26	10	130	26	Unfiltered	Villarreal-Trevino et al., 1986
<i>Micropterus salmoides</i>	fish	0.46	0.092	9	51	10	Unfiltered	Villarreal-Trevino et al., 1986
<i>Notropis lutrensis</i>	fish	0.8	0.16	14	57	11	Unfiltered	Villarreal-Trevino et al., 1986
<i>Poecilia reticulata</i>	Fish	16	3.2	3.1	5 160	1 032	Filtered (0.45 μm)	Vighi, 1981
<i>Poecilia reticulata</i>	fish	36	7.2	27.5	1 300	260	Filtered (0.45 μm)	Vighi, 1981
<i>Poecilia formosa</i>	fish	0.9	0.18	14	64	13	Unfiltered	Villarreal-Trevino et al., 1986
<i>Poecilia formosa</i>	fish	1.3	0.26	9	144	29	Unfiltered	Villarreal-Trevino et al., 1986
<i>Poecilia formosa</i>	Fish	2.26	0.452	12	188	38	Unfiltered	Villarreal-Trevino et al., 1986
<i>Poecilia formosa</i>	Fish	2.16	0.432	10	216	43	Unfiltered	Villarreal-Trevino et al., 1986
<i>Poecilia formosa</i>	Fish	1.3	0.26	4	325	65	Unfiltered	Villarreal-Trevino et al., 1986
<i>Poecilia formosa</i>	Fish	2.8	0.56	7	400	80	Unfiltered	Villarreal-Trevino et al., 1986

Table B-47. Bioaccumulation factors in soil. Lead concentrations in the biota are the product of BAF and soil Pb concentration (LDAI, 2008).

Test substance	Organism	Medium	Test conditions	Duration (d)	Soil (mg/kg _{dw})	BAF (kg _{dw} /kg _w or kg _{dw} /kg _{dw} ^(a))	References
Pb-soil	<i>Lumbricus terrestris</i>	-control soil of orchard (Long Ashton); pH 6.5; average biomass 113.7 g/m ² ;	control soil	whole life	92	0.32 ^(a)	Wright and Stringer, 1980
	<i>Allolobophora caliginosa</i>		polluted soil		147	0.30 ^(a)	
	<i>Allolobophora tuberculata</i>	Cd 1 µg/g _{dw} ;	control soil		92	0.48 ^(a)	
	<i>Allolobophora chlorotica</i>	Pb 92 µg/g _{dw} ;	polluted soil		147	0.43 ^(a)	
	<i>Allolobophora longa</i>	Zn 89 µg/g _{dw}	control soil		92	0.22 ^(a)	
	<i>Allolobophora rosea</i>	-polluted soil of pasture (Severnside); pH 6.8; average biomass 85.8 g/m ² ;	polluted soil		147	/	
		Cd 10 µg/g _{dw} ;	control soil		92	0.23 ^(a)	
		Pb 147 µg/g _{dw} ;	polluted soil		147	0.57 ^(a)	
		Zn 617 µg/g _{dw}	control soil		92	0.26 ^(a)	
			polluted soil		147	0.51 ^(a)	
Pb-soil	<i>Allalobophora sp.</i>	Top 10 cm of 6 soil series from east Tennessee	Bodine soil	whole life	26	0.18 ^(a)	Van Hook, 1974
	<i>Lumbricus sp.</i>		Captina soil		15	0.30 ^(a)	
	<i>Octolasion sp.</i>		Claiborne soil		24	0.23 ^(a)	
			Emory soil		50	0.11 ^(a)	
			Linside soil		18	0.22 ^(a)	
			Tarklin soil		27	0.15 ^(a)	
Pb-soil	<i>Lumbricus terrestris</i>	polluted soil around a primary smelting place; pH 5.56-7.32; OM 15-29.9 %		whole life	/	0.26 ^(a)	Spurgeon and Hopkin, 1996
	<i>Lumbricus rubellus</i>				0.26 ^(a)		
	<i>Lumbricus castaneus</i>				0.08 ^(a)		
	<i>Allolobophora caliginosa</i>				0.15 ^(a)		
	<i>Allolobophora chlorotica</i>				0.16 ^(a)		

	<i>Allolobophora rosea</i>					0.24 ^(a) 0.24 ^(a) 1.25 ^(a) 0.19 ^(a) 0.18 ^(a) 0.22 ^(a) 0.12 ^(a) 0.25 ^(a) 0.45 ^(a)	
Pb-soil	<i>Lumbricadea sp.</i>	Landsdale1 loam Hagerstown silt loam Landsdale2 loam Readingston silt loam	control; pH 5.9-6.3 sludge; pH 5.5-6.2 control; pH 5.4-6.4; CEC 9 meq/100g; OM 3 % sludge; pH 4.9-6; CEC 13 meq/100g; OM 4.9 % control; pH 4.9-6.4; CEC 8 meq/100g; OM 2.5 % sludge; pH 4.6-6.3; CEC 8 meq/100g; OM 2.8 % control; pH 5.3-6.1; CEC 10 meq/100g; OM 2.6 % sludge; pH 5.5-6.1; CEC 11 meq/100g; OM 3.8 %	whole life	16 16 41 41 34 34 43 43 22 22 23 23 23 22 22	0.85 ^(a) 0.2 0.42 ^(a) 0.1 0.69 ^(a) 0.16 0.65 ^(a) 0.15 0.74 ^(a) 0.17 0.71 ^(a) 0.16 0.96 ^(a) 0.16 0.75 ^(a) 0.23	Beyer et al., 1982
Pb-soil	<i>Lumbricus rubellus</i> <i>Dendrodrilus rubidus</i>	topsoil of control soil and 12 heavily contaminate	control soil polluted soil control soil	whole life	170-24600 170-24600	0.1-0.13 ^(a) 0.5-0.44 ^(a)	Morgan and Morgan, 1988

		d soils of non-ferrous metalliferous mines; pH 4.3-7.8; OC 1-27 %; CEC 8-77 meq/100g	polluted soil				
Pb-soil	<i>Lumbricus terrestris</i> <i>Allolobophora chlorotica</i> <i>Allolobophora trapezoides</i> <i>Allolobophora turgida</i>	topsoil along two highways (Maryland): B-W parkway; silt-clay; pH 6.97; OM 4.96-7.3 US-Highway1 ; pH 6.88-6.96; OM 4.8-6.36	B-W parkway 3 m 6.1 m 12.2 m 24.4 m 48 8 m US-Highway1 3 m 6.1 m 12.2 m 24.4 m 48 8 m	whole life	700 204.3 94.2 60.1 81.6 313.3 90.3 54.1 38.6 34.9	0.47 ^(a) 0.82 ^(a) 1.08 ^(a) 0.82 ^(a) 0.83 ^(a) 0.70 ^(a) 0.84 ^(a) 1.18 ^(a) 1.10 ^(a) 1.18 ^(a)	Gish and Christensen, 1973
Pb-soil	<i>Allolobophora longa</i> <i>Allolobophora caliginosa</i> <i>Allolobophora rosea</i> <i>Allolobophora chlorotica</i> <i>Lumbricus terrestris</i>	experimental plots: soil 1: K-fertilised; pH 5.9 soil 2: NPK-fertilised (300 kg N/ha); pH 5.7 soil 3 Vejen sewage sludge (30 T/ha containing 396 mg Pb/kg _{dw}); pH 5.8 soil 4: Lundtofte sewage	soil 1 soil 2 soil 3 soil 4 soil 3 soil 4 soil 1 soil 2 soil 3 soil 4 soil 3 soil 4 soil 1 soil 3 soil 4	whole life	15.3 16.2 28.2 38.9 28.2 38.9 15.3 16.2 28.2 38.9 28.2 38.9 15.3 28.2 38.9	0.25 ^(a) 0.35 ^(a) 0.16 ^(a) 0.15 ^(a) 0.23 ^(a) 0.24 ^(a) 0.21 ^(a) 0.20 ^(a) 0.17 ^(a) 0.14 ^(a) 0.16 ^(a) 0.15 ^(a) 0.75 ^(a) 0.39 ^(a) 0.13 ^(a)	Andersen, 1979

		sludge (30 T/ha containing 1850 mg Pb/kg _{dw}); pH 6					
Pb-soil	<i>Allolobophora caliginosa</i> (adults)		30 % clay; CEC 26.3 meq/100g; OM 5.8 %; pH 7.1; 0 T compost/ha	whole life	53	0.00 ^(a)	Ma, 1982
			30 % clay; CEC 24.5 meq/100g; OM 6.7 %; pH 7; 20 T compost/ha		100	0.16 ^(a)	
			30 % clay; CEC 25.1 meq/100g; 8.4 %; pH 6.9; 40 T compost/ha		163	0.30 ^(a)	
			10 % clay; CEC 9.4 meq/100g; OM 2.8 %; pH 6.6; 0 T compost/ha		37	0.73 ^(a)	
			10 % clay; CEC 10.5 meq/100g; OM 4 %; pH 7; 20 T compost/ha		87	1.20 ^(a)	
			10 % clay; CEC 12.3 meq/100g; OM 4.9 %; pH 7; 40 T compost/ha		127	0.60 ^(a)	
			40 % clay; CEC 26.4 meq/100g; OM 6.9 %; pH 5.3; 0 T compost/ha		90	0.21 ^(a)	
			40 % clay; CEC 28.7 meq/100g; OM 9.2 %; pH 5.8; 20 T compost/ha		220	0.34 ^(a)	
			40 % clay; CEC 28.7 meq/100g; OM 9.7 %; pH 5.9; 40 T compost/ha		257	0.51 ^(a)	
			10 % humus CEC 20.5 meq/100g; OM 12.4 %; pH 4.7; 0 T compost/ha		40	2.16 ^(a)	
					166	0.77 ^(a)	
					227	0.67 ^(a)	
					23	2.62 ^(a)	
					80	0.93 ^(a)	

			10 % humus CEC 19.2 meq/100g; OM 11.2 %; pH 5.2; 20 T compost/ha		127	0.83 ^(a)	
			10 % humus CEC 18.3 meq/100g; OM 13.6 %; pH 5.8; 40 T compost/ha		20	2.63 ^(a)	
			7 % humus CEC 13.5 meq/100g; OM 6.4 %; pH 5.4; 0 T compost/ha		53	1.24 ^(a)	
			7 % humus CEC 12.7 meq/100g; OM 7.4 %; pH 5.4; 20 T compost/ha		83	0.88 ^(a)	
			7 % humus CEC 23.2 meq/100g; OM 8.1 %; pH 5.7; 40 T compost/ha				
			3 % humus CEC 5.3 meq/100g; OM 2.8 %; pH 4.8; 0 T compost/ha				
			3 % humus CEC 6.1 meq/100g; OM 3.7 %; pH 5.5; 20 T compost/ha				
			3 % humus CEC 7.1 meq/100g; OM 4.3 %; pH 6; 40 T compost/ha				
Pb-soil	<i>Lumbricus rubellus</i>	top soil in region around zinc smelting works in Dutch Kempen region	grassland or heatherland on sandy podzolic soil: pH 3.5- 6.1, % OM 2.2- 8.6	whole life	14-430	1.68- 1.69 ^(a)	Ma et al., 1983
Pb-soil	<i>Lumbricus rubellus</i>	contaminate d site in mid- Wales, Cwmystwyth	Pb 1594-8688 µg/g d.w., pH 5.9-6.3 % OM 31.85-51.19	whole life	1594-8688	0.73- 3.98 ^(a)	Mariño and Morgan, 1999

Pb-soil	<i>Dendrobaena rubida</i>	soil from a mine spoil at Cwmystwyth, mid-Wales	P H 3.6-4.0, % OM 13.5-18.5	whole life	1810	6.86 ^(a)	Ireland, 1975
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Table B-48. Bioaccumulation factors between soil or decomposed leaf litter and isopods. Lead concentrations in the biota are the product of BAF and soil Pb concentration (LDAI, 2008)

Test substance	Organism	Test conditions	Medium	Duration	Soil/litter (mg Pb/kg _{dw})	BAF (kg _{dw} /kg _{dw})	Reference
Pb-soil	<i>Porcellio scaber</i>	15 adult specimen were exposed for 14 days to approximately 600 mL of air-dried experimental soil (polluted and remediated with 2.5, 10, 40 and 4 x 40 EDTA, respectively) in plastic vessels with plastic covers.	polluted soil	14 days	4 603	0.04	Udovic et al., 2009
			polluted soil leached with 2.5 mmol kg ⁻¹ EDTA		4 323	0.04	
			polluted soil leached with 10 mmol kg ⁻¹ EDTA		2 712	0.035	
			polluted soil leached with 40 mmol kg ⁻¹ EDTA		2 112	0.035	
			polluted soil leached with 4 x 40 mmol kg ⁻¹ EDTA		1 239	0.025	
PbCl ₂	<i>Porcellio scaber</i>	Isopods were kept in plastic boxes on a moist gypsum base covered by decomposed leaf litter material, i.e. partly decomposed leaf litter material soaked in an aqueous solution of	Control	21 days	7.1	0.41	Gräff et al., 1997
			100 mg Pb/L		517	0.14	
			500 mg Pb/L		2 777	0.08	
			1 000 mg Pb/L		7 676	0.03	

Test substance	Organism	Test conditions	Medium	Duration	Soil/litter (mg Pb/kg _{dw})	BAF (kg _{dw} /kg _{dw})	Reference
		100, 500 or 1000 mg l ⁻¹ Pb ²⁺ (as PbCl ₂).					
Pb-soil	<i>Trachelipus rathkei</i>	Near a smelting complex a transect of 5 soil sampling sites was taken	0.3 km from the smelting complex	whole life	61 946	0.006	Rabitsch 1995
	<i>Porcellio scaber</i>		0.3 km from the smelting complex		61 946	0.002	
	<i>Trachelipus ratzeburgi</i>		0.5 km from the smelting complex on the other side of the low hill		1 190	0.649	
			1 km from the smelting complex		4 618	0.248	
			2.5 km from the smelting complex		516	0.322	

Appendix B.2: Benchmark dose estimated and IQ impacts of lead

EFSA (2010) proposed that blood lead limits protective of IQ should be indexed to benchmark dose calculations for the impacts of lead upon IQ. The benchmark dose estimates used by EFSA have since been updated (Budtz-Jorgenson et al., 2013). Several types of dose response models were used for benchmark dose calculations. Since there are multiple ways of modelling the dose response for lead, a benchmark dose could be calculated to estimate the blood lead level required to induce one IQ point change assuming a linear dose response, a non-linear dose response or a piece-wise linear dose response that assumes linearity from a blood lead level from 0 to 10 and non-linearity above that point. Since the relationship of blood lead to IQ can use a variety of blood lead metrics (e.g. concurrent blood lead at age 6, early childhood blood lead etc.,) an assortment of benchmark dose estimates can be made. Table B-49 summarises the different benchmark doses associated with different blood lead levels and modelling assumptions. Included in Table B-49. are the benchmark dose (BMD) and the lower one-sided 95th percentile (BMDL) of the BMD estimate.

Table B-49. Benchmark Dose Calculations for the Blood Lead Level in µg/dL associated with a 1-IQ Point Loss Using Different Model Assumptions and Blood Lead Metrics.

Blood Lead Metric	Nonlinear (logarithmic)		Linear		Piecewise linear	
	BMD	BMDL	BMD	BMDL	BMD	BMDL
Concurrent	0.354	0.260	5.58	4.05	1.80	1.20
Peak	0.393	0.273	9.67	6.57	1.03	0.70
Lifetime Average	0.355	0.250	6.45	4.50	1.48	0.97
Early Childhood	0.558	0.343	8.06	5.24	3.80	1.61

The wide range of BMD estimates above demonstrates the significant impact of modelling assumptions upon BMD calculations. BMD and BMDL estimates made assuming a nonlinear model are well below current EU blood lead levels measured in children, but linear models generally yield BMD's and BMDL's in excess of the 5 µg/dL NOAEL identified here for protection of the individual. Piecewise linear estimates are close to the geometric mean blood lead level of 2 µg/dL suggested here as required to minimize the number of individuals with a blood lead level of 5 µg/dL or greater.

It should further be noted that EFSA (2010) judged the piece-wise linear BMD estimates to be most relevant. These estimates were, however, made based upon Lanphear et al. pooled analysis data now known to contain errors and some alteration of the BMD estimates might occur upon correction of data base errors. Moreover, the BMD estimates for piecewise linear modelling are predicting impacts at low blood lead levels where statistically significant associations no longer exist between blood lead and IQ. Still, given these caveats, it is interesting to note that the BMD and BMDL estimates are similar to the

population geometric mean blood lead levels proposed in this CSR that would be required to maintain the blood lead levels of most children below 5 µg/dL.

It is important to recognise that all of the preceding calculations are estimates of the lead exposure level that would be required to yield a reduction of IQ by one point. In and of itself, one IQ point loss is likely to have no significance for the individual but is hypothesized to have significance if this IQ decrement were to occur population-wide and thereby increase the proportion of individuals in a society judged to have impaired mental capacity. This would be more representative of the health endpoints for which BMD estimates could be made and has been the preferred manner in which to develop BMD's for other neurotoxins such as methylmercury (NAS, 2000).

For example, by definition 5 % of individuals in the general population have an IQ of 70 or lower. BMD estimates can be made of the lead exposure level that would be required to increase this prevalence to 10 %. This would entail a population wide decrement of 4.28 IQ points (Budtz-Jorgenson et al., 2013). Using the dose response functions adopted by EFSA (2010) for the impacts of concurrent blood lead levels in a piece-wise linear model, a population-wide 4.28 IQ point decrement would be associated with a concurrent blood lead level of 7.7 µg/dL. If early childhood blood lead levels were of primary concern, this populations wide IQ decrement would require blood lead levels in excess of 16 µg/dL.

Current EU blood levels are significantly lower than those associated with population-wide IQ point decrements used in the Benchmark Dose derivations for other environmental neurotoxins.

Appendix B.3: Summary of the existing legal requirements (and international agreements)

Lead has been a substance of concern for many years. Due to the well-documented adverse effects of the metallic lead and lead compounds, these have been extensively regulated at national, Union and global level. This is reflected in the large number of sector specific Union legislative acts which restrict the use of lead and or its compounds in mixtures, articles and consumer products with regard to their risks to human health (incl. occupational) and the environment.

A comprehensive (but non-exhaustive) inventory of existing Union legal requirements related to lead, is listed in the following tables:

Table B-50. EU General Legislation controlling lead and its compounds (non-exhaustive list)

EU Legislation	Legal requirements
Regulation (EC) 1123/2009 on cosmetics products	<ul style="list-style-type: none"> List of substances that cosmetic products must not contain (including lead and its compounds)
Directive 98/70/EC on petrol	<ul style="list-style-type: none"> Prohibition of leaded gasoline (except aircraft) Lead content restricted to 0.005 g/L
Directive 1999/45/EC relating to the classification, labelling and packaging of dangerous preparations	<ul style="list-style-type: none"> The label on the packaging of paints and varnishes containing lead in quantities exceeding 0.15 % (expressed as weight of metal) of the total weight of the preparation, as determined in accordance with ISO standard 6503/1984, must show the following particulars: <ul style="list-style-type: none"> 'Contains lead. Should not be used on surfaces liable to be chewed or sucked by children'. In the case of packages the contents of which are less than 125 mL, the particulars may be as follows: <ul style="list-style-type: none"> 'Warning! Contains lead'.
Council Regulation (EEC) 304/2003 on the export and import of dangerous chemicals (Rotterdam Convention)	Sets out the requirements for classification, packaging and labelling of dangerous substances and preparations, including lead compounds, when put on the market in non-EU countries or imported from non-EU countries.
Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators	<ul style="list-style-type: none"> No prohibition on lead in batteries (though prohibitions in place for mercury and cadmium) Sets out measures relating to the collection, treatment, recycling and disposal of waste

EU Legislation	Legal requirements
	batteries and accumulators containing lead, with specific recycling efficiency targets for lead-acid batteries
<p>Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) (to be replaced on 3 Jan 2013 by Directive).</p> <p>Directive 2012/19/EC on waste electrical and electronic equipment (WEEE)</p>	<ul style="list-style-type: none"> • Substances (including lead) restricted in a waste management perspective • Maximum concentration of up to 0.1 % by weight in homogeneous material tolerated • Articles concerned: electrical and electronic equipment including IT and telecommunications equipment, household appliances and consumer equipment, lighting equipment, electrical and electronic tools, toys, leisure and sports equipment, medical devices, monitoring and control instruments, and automatic dispensers • Exemptions include lead in cathode ray tubes; certain electrical and electronic components which contain lead in a glass or ceramic; lead in white glasses for optical applications; in certain printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses; bound in crystal glass; • Lead oxide is specifically exempted for certain applications including in surface conduction electron emitter displays (SED) used in structural elements, notably in the seal frit and frit ring; in seal frit used for making window assemblies for Argon and Krypton laser tubes etc. • Lead is exempted from certain medical devices and monitoring and control instruments • Sets criteria for the collection, recycling and recovery of such equipment and selective treatment of certain materials and components
Directive 2000/53/EC on end-of-life Vehicles	<ul style="list-style-type: none"> • Member State shall ensure that materials and components of vehicles put on the market do not contain lead (certain exemptions apply) • products concerned: passenger vehicles comprising no more than eight seats in addition to the driver's seat, and goods transport vehicles not exceeding 3.5 tons • Maximum concentration of up to 0.1 % by weight in homogeneous material tolerated • Exemptions include lead in alloys and in components such as batteries (to be reviewed in 2015), vulcanising agents and

EU Legislation	Legal requirements
	stabilisers, certain electrical and electronic components which contain lead in a glass or ceramic matrix (compound), pyrotechnic initiators etc.
Directive 2009/48/EC on the safety of toys	<ul style="list-style-type: none"> • Total prohibition of certain substances or preparations in toys except those which are essential to their functioning. In this case, they are submitted to a maximum concentration defined for each substance individually • Bioavailability resulting from the use of toys < 0.7µg/day (EN 71-3) • Lead migration limit from toys = 90 mg/kg (EN 71-3) • Lead migration limit = 13.5 mg/kg dry, brittle, powder-like or pliable toy material • Lead migration limit = 3.4mg/kg liquid or sticky toy material • Lead migration limit = 160mg/kg scraped-off toy material
Directive 2001/95/EC on General Product Safety	<ul style="list-style-type: none"> • Only safe products for consumers are placed on the market (conception and/or information) • Information system (RAPEX)
Directive 94/62/EC on packaging and packaging waste as amended by Directive 2004/12/EC	<ul style="list-style-type: none"> • Requirements on management of packaging and packaging waste effectively eliminated this application of lead by reducing the sum of the amount of lead, cadmium, mercury and hexavalent chromium present in packaging and packaging components to 100 ppm (mg/kg) • Exemption for packaging made of lead crystal glass • Derogation from heavy metal limit for glass packaging and for plastic crates and pallets
Directive 69/493/EEC on crystal glass	<ul style="list-style-type: none"> • Prescription of the use of lead in crystal glass • >30 % of content of lead in "full crystal glass" cat. 1 • [24 %, 30 %] of content of lead in "full crystal glass" cat. 2
<i>Food related EU legislation</i>	
Directive 84/500/EEC on ceramic articles intended to come into contact with foodstuffs as amended by Directive 2005/31/EC	<ul style="list-style-type: none"> • Lays down maximum limits for lead transferred by ceramic objects to the foodstuffs with which they enter into contact • Maximum permitted quantity of lead is 0.8mg/dm² for articles which cannot be filled

EU Legislation	Legal requirements
Framework Regulation EC No. 1935/2004 on materials and articles intended to come into contact with food	or which can be filled but not deep (25 mm), 1.5 mg/L for cooking ware and storage vessels which have a capacity of more than 3 litres and 4.0 mg/L for other articles (+ 50 % of these thresholds tolerated)
Commission Regulation 466/2001 on contaminants in foodstuffs Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs	<ul style="list-style-type: none"> Lead level in milk, meat, fish, shellfish, cereals, vegetables, fruits, berries, oils, fats, fruit juice and wine must be between 0.02mg/kg by wet weight (cow's milk) and 1.5mg/kg w.w. (mussels) Sets maximum levels for lead in a number of different foodstuffs. In various food items the maximum level are between 0.02 and 1.5 mg/kg
Directive 98/83/EC on quality of water intended for human consumption	<ul style="list-style-type: none"> Lead content in water for human consumption must be < 25 µg/L (until 2014) and < 10 µg/L thereafter
Directive 88/344/EEC on extraction solvents in foodstuffs	<ul style="list-style-type: none"> Residues of solvents used in food industry Lead content in extraction solvents < 1 mg/kg
Directive 88/388/EEC on flavourings for use in foodstuffs and to source materials for their production	<ul style="list-style-type: none"> Lead content in flavourings < 10 mg/kg
Directive 2002/32/EC on undesirable substances in animal feed as regards lead, fluorine and cadmium	<ul style="list-style-type: none"> Sets maximum content of lead in different types of feed materials, between 5 and 40 mg Pb/kg.

Table B-51. List of EU legislation related to lead and its compounds associated with human health protection (non-exhaustive list)

EU Legislation	Legal requirements
Annex XVII of REACH: restriction of the use of certain hazardous substances (entries 16, 17, 28, 30, 63)	<ul style="list-style-type: none"> Direct restriction of lead carbonates and lead sulphates in mixtures intended to be used as paints Restriction of lead and its compounds in jewellery and consumer articles that can be placed in the mouth by children Substances classified as CMR may not be sold to the public (lead compounds are Toxic to Reproduction Category 1A and lead hydrogen arsenate is also a Carcinogen Category 1A)

EU Legislation	Legal requirements
<p>Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work</p>	<ul style="list-style-type: none"> • The principal objective is to prevent (personal) exposure to hazardous substances. Where this is not possible, the Directive requires adequate control through engineering and individual protective measures, and in the case of inorganic lead and its compounds, a binding occupational exposure limit value (BOELV) of 0.15 mg/m³ at European level has been set. • The binding biological limit value is 70 µg Pb/dL blood. The Directive requires medical surveillance to be carried out if: <ul style="list-style-type: none"> ○ exposure to a concentration of lead in air is greater than 0.075 mg/m³, calculated as a time-weighted average over 40 hours per week, or ○ a blood-lead level greater than 40 µg Pb/dL blood is measured in individual workers.
<p>Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health of pregnant workers and workers who have recently given birth or are breast-feeding</p>	<ul style="list-style-type: none"> • Sets out measures to protect pregnant workers and workers who have recently given birth or are breast-feeding, including the requirement to assess exposure to health risks including lead compounds due to their reprotoxic effects.
<p>Directive 94/33/EC on the protection of young people at work</p>	<ul style="list-style-type: none"> • Prohibits the use of certain chemical agents, including lead compounds as a reprotoxic agent, by young workers.

Table B-52. List of EU environmental legislation related to lead and its compounds (non-exhaustive list)

EU Legislation	Legal requirements
<p>Directive 2008/1/EC on integrated pollution prevention and control (IPPC)</p> <p>(to be replaced on 7 Jan 2014 by Directive 2010/75/EU on industrial emissions)</p>	<ul style="list-style-type: none"> • Categories of activities subject to IPPC permitting are listed in Annex I of the Directive • Relevant activities controlled include processing of non-ferrous metals; manufacture of glass and ceramic products; chemical installations for the production of organic (e.g. synthetic rubbers, dyes and pigments) and inorganic (e.g. metal oxides) chemicals, and for the production of explosives • Where relevant, emission limit values along with other conditions have to be set in individual plant permits to control the emissions and other impacts to the environment • Best Available Technique Reference (BREF) documents and their BAT conclusions adopted by the Commission provide the reference concerning techniques to control/reduce emissions. Relevant BREFS include those on large volume inorganic chemicals, the ceramic manufacturing industry and the glass manufacturing industry
<p>Regulation No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register (EPRTTR)</p>	<ul style="list-style-type: none"> • Member States have to report on the emissions of industrial facilities regulated (scope is similar to the IPPC Directive). Reporting covers a wide range of pollutants including lead and its compounds.
<p>Directive 2008/50/EC on ambient air quality and cleaner air for Europe</p>	<ul style="list-style-type: none"> • A limit value of the lead concentration in ambient air is established for the protection of human health (expressed as an average over a calendar year) of 0.5 µg/m³. Member States shall ensure that, throughout their zones and agglomerations, levels of lead in ambient air do not exceed this limit value.
<p><i>Waste and water EU legislation</i></p>	

EU Legislation	Legal requirements
Directive 2000/76/EC on the incineration of waste (to be replaced on 7 Jan 2014 by Directive 2010/75/EU on industrial emissions)	<ul style="list-style-type: none"> Total air emission limit values for certain metals and metal compounds (including lead) of 0.5 mg/Nm³ Emission limit value for lead and its compounds in discharges of waste water from the cleaning of waste gases of 0.2 mg/L (expressed as lead)
Directive 2008/98/EC on waste Decision 2000/532/EC establishing a list of wastes	<ul style="list-style-type: none"> Sets out the requirements for the management of hazardous wastes such as wastes containing lead compounds above a certain threshold.
Directive 2000/60/EC establishing a framework for Community action in the field of water policy (Water Framework Directive - WFD) Directive 2008/105/EC on environmental quality standards in the field of water policy Directive 2006/118/EC on the protection of groundwater against pollution and deterioration Directive 2006/11/EC Dangerous Substances Directive (to be integrated into WFD by 2013)	<ul style="list-style-type: none"> In relation to surface water, lead and its compounds are listed as priority substances in Annex X of the WFD and an annual average environmental quality standard of 7.2 µg/L has been set. In relation to groundwater, lead is listed in the minimum list of pollutants and their indicators for which Member States have to consider establishing threshold values.
Directive 86/278/EC on Sewage sludge in agriculture	<ul style="list-style-type: none"> Prohibits sludge from sewage treatment plants being used in agriculture unless specified requirements are fulfilled, including the testing of the sludge and the soil Limit value for lead concentrations in sludge for use in agriculture is 750-1 200 mg/kg dry matter

Table B-53. List of International agreements related to lead and its compounds (non-exhaustive list) (EPA, 2014)

Agreement (entry into force)	Main provisions on lead
The Convention for the Protection of the Marine Environment of the North-East Atlantic/ OSPAR Convention (1992)	Lead in the form of tetraethyl and tetramethyl lead is on the OSPAR list of substances of possible concern, aiming to reduce discharges in order to reach near-background concentrations in the North-East Atlantic. Lead and 8 organic lead compounds are on the Priority action list of OSPAR.

<p>Helsinki Commission /HELCOM (2000)</p>	<p>The Helsinki Commission has issued a range of recommendations regarding lead. This includes the reduction of emissions of lead from leaded fuel, restriction of discharge and emission of lead from treated metal surfaces, proper handling of waste and reduction of discharge from urban areas by the treatment of storm water.</p>
<p>Barcelona convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean (1995)</p>	<p>Lead is listed in Annex II of the, the Annex regards Harmful or Noxious Substances and Materials for which the disposal in the Protocol Area is subject to a special permit.</p>
<p>Bucharest convention on the Protection of the Black Sea Against Pollution (1994)</p>	<p>The Bucharest convention on the protection of the Black Sea, lists heavy metals and its compounds, herein lead and its compounds, with the aim of reducing, controlling, and eliminating use and release of harmful substances in order to prevent the environment of the Black Sea.</p>
<p>Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (1989)</p>	<p>The Basel convention set out control measures of the movements of hazardous waste incl. waste containing lead between nations, and restricts the transfer of hazardous waste from developed to less developed countries (non-adopted). The convention also intends to minimize the amount and toxicity of wastes generated, to ensure their environmentally sound management as closely as possible to the source of generation, and to assist least developed countries (LDCs) in environmentally sound management of the hazardous and other wastes they generate.</p>
<p>Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (rev 2013)</p>	<p>Lead is not directly covered by the on prior informed consent (the PIC-procedure), but tetraethyl lead and tetramethyl lead are, however, covered by Regulation (EC) No 689/2008 implementing the Convention in the EU.</p>

Annex C: Justification for action on a union-wide basis

No further information presented. See Annex XV report.

Annex D: Baseline

D.1. Problem definition – risk to be addressed

Waterfowl that typically inhabit wetlands such as ducks, geese and swans can ingest the 'spent' lead gunshot that is dispersed into the environment by hunting and sports shooting. Ingestion of lead gunshot leads to a range of acute or chronic toxicological effects (often termed as lead poisoning⁷⁸), including death, dependent on the quantity of lead ingested. Ingestion of a single lead gunshot can be sufficient to cause the death of a small waterfowl. Other species of waterbirds, such as wading birds 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, 254 species of migratory waterbirds are included in the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA)⁷⁹. 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 all Member States (except for Malta, Poland and Austria), are Parties.

D.2. Outlook without any additional risk management

Section B.9.1 lists the various legislative frameworks and international agreements that aim at further reducing lead exposure to humans and the environment.

D.2.1. Current quantities of lead dispersed in wetlands

Data related to the amount of lead dispersed in wetlands from hunting and shooting activities are discussed in Section B.9.1.1.

D.2.2. Estimates of bird mortality due to lead poisoning

Estimates of contemporary mortality for the use of lead gunshot in wetlands are discussed in B.10.1.2. These estimates are considered to represent the continued level of mortality that will occur in the absence of a restriction on the use of lead gunshot in wetlands in the EU.

⁷⁸ '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.

⁷⁹ See <http://www.unep-aewa.org/>.

D.3. Additional consequences of non-action

If no action is pursued there is a significant possibility that the following policy objectives might be impeded:

- the EU Biodiversity strategy 2011 (e.g. to halt the deterioration in the status of all species and habitats covered by EU nature legislation and achieve a significant measurable improvement in their status by 2000⁸⁰);
- the policy objectives set out under the Habitat Directive⁸¹ (to ensure biodiversity through conservation of natural habitats and species in the EU) and Birds Directives⁸² (to maintain the population of all wild bird species in the EU at a level which corresponds to their ecological, scientific and cultural requirements).

Furthermore, if no action is pursued, the EU, being a contracting party to various environmental international agreements will be confronted with a situation where it is not able to fulfil its obligations under these international agreements (e.g. AEWA, CMS).

In addition, the benefits described in Section E.6.2.2 will not be achieved, if no action is pursued.⁸³

Conclusion

Under the initial policy objectives of AEWA, contracting parties should have phased out the use of lead shot for hunting in wetlands by the year 2000. However, this has yet to be enacted in some Member States (IE, PL, SI and RO) or fully in others (i.e. Member States that only restrict within designated sites). In 2008, AEWA further called on Contracting Parties to phase out the use of lead over wetlands as soon as possible⁸⁴.

In the EU, the Habitats and Birds Directives, also aim to protect wetland habitats and birds, having as objectives to:

- Contribute towards ensuring bio-diversity through the conservation of natural habitats and of wild fauna and flora in the European territory of the Member States to which the Treaty applies.
- Shall maintain the populations of European bird species at a level that corresponds to ecological, scientific and cultural requirements.

The current adopted instrument to achieve these objectives is the Natura 2000 framework. Natura 2000 sites are of particular importance in protecting breeding, feeding and roosting habitats for wildfowl and raptors. The network of Natura 2000 sites does not cover all wetlands areas existing in the EU. The cost-effectiveness of the Network is reduced by the spent lead gunshot contamination in and around sites, representing a risk to many species

80

http://ec.europa.eu/environment/legal/law/2/2_training_materials/pdf/Introduction_to_the_Birds_Directive_Habitats_Directive_and_Natura_2000.pdf

⁸¹ Idem supra

⁸² Idem supra

⁸³ Taking into account the objectives of the Water Framework Directive (2000/60/EC) and Groundwater Directive (2006/118/EC), further reductions in contaminants (as lead from lead shot) that might affect the quality of groundwater, could also lead to reduced exposure in humans.

⁸⁴ Resolution 4.1 on "Phasing out lead shot for hunting in wetlands" (Meeting of the Parties to AEWA, September 2008, Antananarivo, Madagascar).

of birds, including waterbirds, birds of prey and scavengers (see also Section E.6.2.4) The costs of conservation measures required to maintain bird populations at Favourable Conservation Status are increased by the absence or ineffectiveness of restrictions on the use of lead ammunition in and near wetlands.

The continued use of lead gunshot in wetlands, given the current scope of national measures, will lead to further exposure of many birds (including endangered species) to spent lead gunshot with associated lethal and sub-lethal effects.

Existing national measures are often narrow in scope and are limited to certain wetland areas within a Member State (i.e. not all wetland habitats). Furthermore three Member States (IE, PL, SI and RO) are yet to introduce legislation to prevent or reduce the use of lead shots in wetlands. It is considered unlikely that existing measures will be enhanced to have a more comprehensive scope before the 2020 deadline of the Habitats and Birds Directives.

The status quo is likely to result in the EU failing to achieve the objective of AEWA to phase out the use of lead gunshot in wetlands. Furthermore, the continuation of the use of lead gunshot in wetlands is a strong impediment to Member States achieving the policy objectives of the Birds and Habitats Directives.

Annex E: Impact Assessment

E.1. Risk Management Options

E.1.1. Proposed restriction

An assessment has been made in this proposal whether there is a risk to human health or the environment from the use of lead gunshot in wetlands, especially to birds that are dependent on wetlands, and whether EU measures to address that risk are needed beyond existing national measures.

National measures (such as legislation preventing or reducing the use of lead gunshot in wetlands) have already been enacted by some Member States (or regions in some Member States), but not all. In addition, Member States who have implemented AEWA have done so differently, resulting in a situation within the EU where measures, and their effectiveness, are not harmonised.

The conclusion of this assessment is that the risk from the use of lead in gunshot in wetlands is not adequately controlled. In addition it is concluded that the harmonisation of measures to control the use of lead gunshot in wetlands is necessary to implement the Agreement on the Conservation of African-Eurasian Migratory Water birds (AEWA) and the Convention on the Conservation of Migratory Species of Wild Animals (CMS), to which the EU is a Party.

An analysis of several risk management options (RMOs) was conducted to identify the most appropriate RMO to address the identified risk and that an EU measure was necessary to address that risk beyond existing national measures, including a restriction under REACH and other existing EU legislation. A restriction under REACH was concluded to be the most appropriate EU wide measure to address the identified risk as the other Union-wide risk management measures were not considered to be appropriate to address the identified risk (See Section E.1.3).

The suitability of several restriction options was evaluated based on an analysis of their effectiveness (risk reduction capacity and proportionality to the risk), practicality (implementability, enforceability and manageability) and monitorability.

Based on this analysis the following restriction is proposed. Discarded restriction options are presented in Section E.1.2.

Table E-1 Proposed restriction

Lead and lead compounds	<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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E.1.1.1. Justification for the selected scope of the proposed restriction option

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 lead gunshot where spent lead gunshot would land within a wetland even if the use (i.e. 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 as well as harmonising existing Member State approaches to address this risk. However, birds (including AEWA 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 (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 i.e. restrictions on use that extend beyond wetland environments.

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 have not been assessed in this Annex XIV report). This is recognised in paragraph 5 of the restriction proposal. Equally, the risks from the use of lead in other types of ammunition (e.g. rifle bullets) have not been assessed in this Annex XIV report.

Existing legislative approaches in different Member States in the EU

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

- *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);*
- *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);*
- *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);*
- *Full (complete) ban on the use of lead gunshot (in certain MS, including restrictions on possession and sale).*

The proposed restriction is expected to have various co-benefits in addition to reducing the risks to birds from consuming lead shot and secondary predation, such as to humans that consume waterfowl, groundwater quality and general environmental quality. These are described in Section E.6.2.2.

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

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

- **'shooting lead gunshot with a shotgun within a wetland'**. This is intended to apply to any person that is located within a wetland when they shoot, irrespective of purpose for which the shooting is undertaken. This is justified by the high probability that shooting with lead gunshot with a shotgun within a wetland will result in lead gunshot accumulating within that wetland or being 'shot in' to a waterbird within a wetland, irrespective of whether the waterbird is wounded or

killed. Equally, from a risk perspective, the purpose of the shooting (i.e. hunting, clay-pigeon shooting) is irrelevant.

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

It is important to appreciate that the proposed wording makes no distinction between the purpose of the shooting. All shooting, for whatever purpose, is intended to be restricted. The Dossier Submitter notes that several different terms for shooting have been used in the dossier, some interchangeably e.g. target shooting and sports shooting⁸⁵. It is the intention that all forms of shooting are prohibited by the proposed restriction.

A similar intention, and wording, can be found in existing Member State legislation to prevent the use of lead gunshot in wetlands. For example, the following text is used in the Scottish regulation⁸⁶ addressing the use of lead shot and wetlands:

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

In an explanatory leaflet published by BASC Scotland⁸⁷ this is further explained as:

"The key purpose of the legislation is to stop lead shot falling into wetlands. If your shooting involves shooting "on or over" wetland areas (ponds, lochs, rivers, streams, marshes, fens, bogs etc.) then you must ensure that you either use non-lead shot from 31st March 2005 or modify your shooting behaviour

⁸⁵ Sports/target shooting is intended to mean any shooting with a shotgun that is not hunting. Hunting can be defined, for the purposes of the dossier, as any shooting at an animal.

⁸⁶ Environmental Protection (Restriction on Use of Lead Shot) (Scotland) (No.2) Regulations 2004 (SSI No. 2004/358)

⁸⁷ <https://basc.org.uk/wp-content/plugins/download-monitor/download.php?id=328> (accessed 24/01/2018)

to ensure your shot does not fall into the wetland. Please bear in mind that a 12-bore shotgun shooting a normal cartridge has a maximum fall-out range of approximately 300 metres.”

Similarly, with respect to clay pigeon shooting:

“Established clay shoots and less formal, occasional shoots will all have to ensure that they are not shooting on or over wetland areas, or will have to use appropriate non-lead shot. 7.2 If there is a wetland feature⁸⁸ on the site over which you shoot you may be able to re-arrange your traps and cages to ensure that shooting now takes place away from these features. We are aware of a small number of established sites where there is no alternative but to shoot over wetland features, such as foreshore. In such situations the shoot will only be able to continue if it ensures that non-lead loads are used.”

This intention can also be depicted visually: Figure E-1 describes how to remain compliant with the intention of the proposed restriction where to use lead and non-lead ammunition for shooting with a shotgun (in this example steel is the non-lead ammunition used)

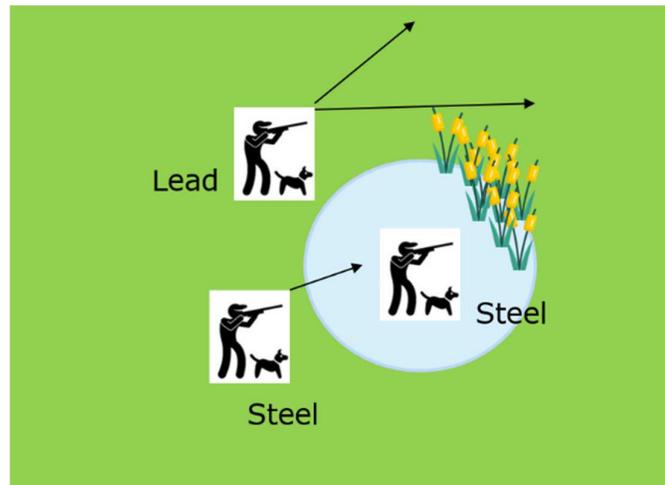


Figure E-1: intention of restriction vis-a-vis direction of shooting

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

In relation to paragraph 2, the intention of the Dossier Submitter was to make it explicit that the term 'use' in paragraph 1 of the restriction proposal, without further clarification

⁸⁸ Ponds, lochs, rivers, streams, marshes, fens, bogs etc

elsewhere in the entry, would imply that the 'possession' of lead gunshot in wetland would also be prohibited by the proposed restriction.

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

- The **definition of wetland areas** within Member States, such that hunters can readily comply with the requirements of the restriction.
- Use of **buffer zones**
- **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 proposed restriction text is intended to highlight that 'use' within REACH extends to 'possession' and that, as such, possession-based enforcement could be applied by Member States.

These challenges and further explanation of the chosen scope are outlined in subsequent sections. Further elaborations on buffer zones and possession can be found in the main report.

E.1.1.1.1. Shotgun definition

A shotgun, for the purposes of the proposed restriction, is any smoothbore firearm (meaning the inside of the barrel is not rifled), which uses 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).

E.1.1.1.2. Wetland definition

Much of the existing MS legislation on the use of lead gunshot in wetlands is constrained to 'specific' identified wetland areas, rather than generic wetland habitats; referred to in this report as 'narrow' area-based partial bans. One reason for such an approach would appear to be linked with 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 area-based partial ban with a limited scope inherently results in a continued risk to waterbirds for use the continued use of lead

gunshot outside of the designated wetlands, particularly if they offer similar feeding opportunities to designated wetlands.

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 in wetlands where waterbirds subsequently feed e.g. hunting of 'terrestrial' game birds, or small mammals using lead gunshot 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 risk. As waterbirds range across large areas during their migration and whilst foraging for 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 (discussed further in E.1.2 below).

To ensure that the identified risks are controlled by the proposed restriction, it is therefore appropriate to consider a generic definition of a wetland. 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 water birds 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 in and over wetlands, which is aimed at protecting water birds 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. It is noteworthy that 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.

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.

E.1.1.1.3. Buffer zones

See main report

E.1.1.1.4. Enforcement considerations

A large scale study of compliance with the partial ban on the use of lead gunshot in the UK found that 70 % of ducks purchased in England had been shot illegally with lead ammunition (Cromie et al., 2010). More recently the level of compliance was found to be 23 % (Cromie et al., 2015).

Alongside this finding, significant mortality of waterbirds continues (Newth et al., 2012). Other studies, although on local scale, e.g. in some areas of Spain (Ebro Delta), have shown that strict controls on the type of ammunition carried by hunters at entry points of hunting areas were sometimes necessary to guarantee adequate compliance with national legislation (Mateo et. al., 2014).

As such, enforcement of any restriction proposal is clearly important to consider. Feedback from stakeholders⁸⁹ was that the enforceability of any restriction proposal, and hence its risk reduction potential, would be enhanced by including an element prohibiting the possession of lead shot within a wetland. Compliance issues in France have been reported to be explicitly linked to enforcement difficulties linked to the legal possession of lead gunshot within a wetland⁹⁰.

The definition of 'use' in Article 3(24) of the REACH Regulation, includes 'keeping' and 'any other utilisation'. This suggests that a restriction under REACH on 'use' would also implicitly allow Member States to restrict 'possession'. Therefore, including a specific paragraph within the proposed restriction text that explicitly details that restricting possession within a wetland is within the scope of the proposal ensures that this intention is clear during opinion and decision making on the proposed restriction (and public consultation).

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

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

Within examples of existing national legislation, and through the public consultation, several alternative terms that could be used instead of the word 'use' are possible and which would not necessarily be associated with the unintended impacts introduced by the REACH term 'use'. These terms are discussed in Table E-2

⁸⁹ Meeting of the Expert Group on the Birds and Habitats Directives (NADEG), in November 2016.

⁹⁰ French report to AEWA (2015). http://www.unep-aewa.org/sites/default/files/document/nr_aewa-mop6_france.pdf

Table E-2 : Advantages and disadvantages of various wording options

	'Use'	'Discharge' / 'fire' / 'shoot'	'Loaded'
Advantage	<p>The word use is a key REACH term which has a clear definition and would include possession, a key factor that was identified to be linked to non-compliance.</p> <p>Inspectors have more possibilities to monitor noncompliance – which may result in increased risk reduction.</p>	<p>The term discharging would imply that lead shot can be carried in both wetland and terrestrial areas but not discharged in a wetland or where lead gunshot would land in a wetland i.e. types of shooting that do not directly impact AEWA species would not be impacted.</p> <p>However, as this term is not defined in REACH as subject to a restriction this proposal is not possible.</p>	<p>Safety rules⁹¹ for shotguns prescribe that shotguns should not be loaded until the hunter is ready to fire.</p> <p>Therefore, a shotgun loaded with a lead gunshot cartridge/s demonstrates a clear intention to discharge the cartridge.</p> <p>This would imply that lead shot can be carried in both wetland and terrestrial areas but not loaded (or discharged) within a wetland or where lead gunshot would land in a wetland i.e. types of shooting that do not directly impact AEWA species would not be impacted.</p>
Disadvantage	<p>Possession other than 'personal possession while hunting' (i.e. carry lead shot while hunting) might impact hunters.</p>	<p>Increased enforcement difficulties, hunters need to be 'caught in the act of firing the gun where the shot would land in the wetland'.</p>	<p>When inspected, hunters typically unload guns and any evidence of intent to discharge may disappear.</p>

Combinations of the terms also exist, the Dutch law uses for example 'to have in possession..... whilst hunting (or being on the hunting ground)' a term that is used in some of the US states⁹² as well where emphasis is put on having in personal possession while hunting. A clear advantage of this combination is that practical difficulties (keep at home,

⁹¹ BASC handbook of shooting, an introduction to the sporting shotgun. Quiller press 2013.

⁹² E.g. State of Maryland, Alaska, Washington

keep in the car) might be avoided whilst the direct link to shooting with lead gunshot can actually still be assumed.

In addition, it is noted that several countries have adopted, or plan to adopt, measures to facilitate the enforcement by including measures in relation to possession. For example, in the earlier quoted Dutch legislation⁹³ under the term 'personal ..whilst hunting' hunters are allowed to keep lead shot at home and during transportation but they cannot be in possession of lead shot when hunting, an approach taken by several US states as well with an emphasis on having lead shot in personal possession while hunting.

Future legislative developments in Italy⁹⁴ (as reported by several comments in the public consultation) indicate that current legislation should be modified to add a ban on the possession of lead ammunition where their use is already not allowed, to ensure an adequate protection of avifauna.

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

In light of the purpose of the restriction, which is to guarantee a harmonised risk reduction across the EU, the Dossier Submitter believes that available mechanisms for ensuring compliance should facilitate achieving the risk reduction and societal benefits described in the proposal, but not impose conditions that are infeasible in practice.

E.1.1.1.5. Entry into force

Upon entry into force, lead gunshot can no longer be used in wetlands, or where spent gunshot will fall within the boundary of a wetland. As discussed below, 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 stakeholders⁹⁵ 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.

⁹³ Circulaire Wapens en Munitie 2016

⁹⁴ Action 2.1.1 Piano d'azione nazionale per il contrasto degli illeciti contro gli uccelli selvatici (2017).

⁹⁵ Personal Communication Baumbach Metals GmbH, and with Clay 7 Game Reloaders Ltd (2016)

E.1.2. Other evaluated but discarded restriction options

This section summarises the discarded restriction options that were considered during the development of the proposed restriction:

1. Restriction on the placing on the market and use of lead gunshot

This restriction option prohibits the placing on the market and use of any lead gunshot, including for sports shooting and the use of shot prepared by hunters (self-filled cartridges).

A preliminary assessment of this option exists (AMEC, 2013). The cost of this restriction option for hunters, sports shooters and the shooting industry is clearly much higher than the proposed option, as significantly more hunters and sports shooters would be affected. However, enforcement and implementation can be expected to be more straightforward since a full ban would no longer require enforcement in the field or for hunters to consider if they are shooting within a wetlands. Instead, enforcement would concentrate on other market actors, such as retailers. A ban on the placing on the market is also likely to create a larger demand for steel shot and for retailers and suppliers to provide sufficient quantity, quality and range of alternatives to lead gunshot to consumers.

The benefits to the environment and human health of a full ban would be much higher (risk reduction capacity is greater) than the proposed restriction as waterfowl that feed outside wetlands would also be protected as would predators exposed through secondary poisoning.

The overall benefits from this restriction option may well outweigh the costs, and it may therefore be more effective than the proposed restriction.

In addition, as stated above, enforcement of the restriction would be easier and the restriction would be more implementable as there would be no possibility for hunters to misinterpret the wetlands definition.

The manageability and monitorability of this option are assumed to be similar to the proposed option.

However, based on the scope of ECHA's current mandate from the Commission, this option was not further assessed.

2. Restriction on the use of lead gunshot for all hunting

This restriction option is similar to the previous option but would only prohibit the placing on the market and use of any lead gunshot for hunting, including the use of shot prepared by hunters (self-filled cartridges). Sports shooting would not be prohibited.

The cost of this restriction option for hunters and the shooting industry is clearly higher than the proposed option but less than discarded option 1, as significantly more hunters would be affected but not sports shooters. Some reduced enforcement costs can be expected (as in option 1) and the larger demand for steel shot would still create a greater incentive for retailers and suppliers to provide sufficient quantity, quality and range of alternatives to lead gunshot to consumers.

The benefits to the environment and human health of this option would be greater (risk reduction capacity is greater) than the proposed restriction as water fowl that feed outside wetlands would also be protected as would predators exposed through secondary poisoning but less than option 1 as risks to wetland habitats and waterbirds from shooting ranges would not be addressed.

The overall benefits from this restriction option may still outweigh the costs and it may therefore be more effective than the proposed restriction.

In addition, as stated above, enforcement of the restriction would be easier and the restriction would be more implementable as there would be no possibility for hunters to misinterpret the wetlands definition.

The manageability and monitorability of this option are assumed to be similar to the proposed option.

However, based on the scope of ECHA's current mandate from the Commission, this option was not further assessed.

3. Restriction on the use of lead gunshot for all hunting of birds or hunting of waterfowl (e.g. ducks, geese and swans).

This restriction option prohibits the use of lead gunshot, including self-filled cartridges, for the hunting of birds or a sub-set of birds (waterfowl). This could include a list of birds that it is prohibited to hunt in case a full prohibition on all birds is not implemented.

The cost of this restriction option for hunters and the shooting industry may well be similar to the proposed option, including enforcement costs. The costs to sports shooters would be minimal.

The benefits to the environment and human health would, however, be less than the proposed option as lead gunshot could still be used for hunting mammals in wetlands with subsequent risks to waterfowl and predators; risks to wetland habitats from shooting ranges would also not be addressed.

The overall benefits from this restriction option may well outweigh the costs but it is unlikely to be as effective as the proposed restriction.

This restriction does not depend on the definition of a wetland. Therefore, the restriction may be simpler for hunters to comply with if they are able to recognise different species of birds from distance (e.g. waterfowl from non-waterfowl) in the case of the option for hunting of waterfowl. Enforcement is likely to be easier in this option as any killed bird in the possession of hunters can be assessed if lead shot has been used.

The manageability and monitorability of this option are assumed to be similar to the proposed option.

However, based on the scope of ECHA's current mandate from the Commission, this option was not further assessed.

4. Restriction on the use of lead shot in or over Ramsar sites and/or SPAs within the Natura 2000 network

This restriction option prohibits the use of any lead gunshot in or over Ramsar **sites** and/or SPAs within the Natura 2000 network, including for sports shooting and the use of shot prepared by hunters (self-filled cartridges). This is comparable to the situation today in many Member States with partial area-based restrictions on the use of lead gunshot in wetlands. It should be noted that Ramsar **sites** are designated by Member States. Many wetland areas are not covered by designated Ramsar sites or SPAs. Details of the extent of Ramsar **sites** and SPAs (within the Nature 2000 network) within Member States are provided in Section B.4.3.3.1.

The cost of this restriction option for hunters, sports shooters and the shooting industry is clearly less than the proposed option, as a similar number of hunters and sports shooters would be affected as the base-line situation.

The risk reduction capacity of such a restriction would be limited and would not ensure that the risk is adequately controlled. The majority of EU wetlands are not designated as either Ramsar sites or SPAs. This would result in a continuing risk to waterbirds and predators within many wetlands. The benefits to the environment and human health of such a ban would be much less than the proposed option.

The enforceability of this option is assumed to be the same as the proposed option whilst the implementability would be improved as the boundaries of Ramsar sites and SPAs are well defined.

The manageability and monitorability of this option are assumed to be similar to the proposed option.

5. Phased approach to implementing a restriction on the use of lead gunshot in wetlands

This restriction option entails a phased approach to the implementation of a wetland ban. Firstly a ban could be implemented on the use of lead gunshot in the wetlands specified in discarded restriction option 4. This would include the Member States without a current ban. Then after a further implementation period (e.g. five years) the ban would be extended to all wetlands similar to the current proposed ban.

This option would have the same costs for hunters, sports shooters and the shooting industry as the proposed restriction, but the costs would be spread over a longer period.

However, this option only results in partial risk reduction and incomplete implementation of the objectives of AEWA and CMS during the implementation of the partial ban. The benefits to the environment and human health would therefore be less over the period of the phase-in.

The overall benefits from this restriction option may well outweigh the costs, but it is unlikely to be as effective as the proposed restriction.

The enforceability of this option will be similar to the proposed option but the implementability would be lower due to the phasing in and possible confusion this could create for hunters adapting to not one but two new situations.

The manageability and monitorability of this option are assumed to be similar to the proposed option

6. No additional restriction on the use of lead gunshot

The effects of no restriction on the use of lead gunshot are discussed under the baseline scenario. This option has been dismissed as, despite national measures to control the use of lead gunshot, there is an identified risk which requires action on a union wide basis.

Table E-3 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 restriction 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.

E.1.3. Other union-wide risk management options than restriction

Possible Union-wide risk management measures other than a restriction are outlined in Table E-4 below. However, none of them were considered to be a realistic, effective and balanced means of solving the problem. As such, none of these risk management options were analysed further.

Table E-4. Possible other Union-wide options discarded at this stage

Option	Reasons for discarding this option
(I) Non-legislative measures	
Voluntary industry agreement.	<p>The sheer number of hunters makes it difficult to negotiate a voluntary agreement and it cannot be effectively enforced. This will also likely affect the timelines for addressing the risks and the possibility to monitor the effectiveness of the proposed measure.</p> <p>In more recent times the European Commission reinvigorated dialogue and cooperation with the hunting community by launching – under the auspices of the Birds Directive - the Sustainable Hunting Initiative in 2001⁹⁶. The objective of this initiative was:</p> <p><i>“to achieve and enhance sustainable hunting under the Birds and Habitats Directives”.</i></p> <p>It was envisaged to be mutually beneficial for the conservation of biodiversity and for responsible hunting, which was to be achieved <i>“by dialogue and cooperation between environmental and hunting organisations, and awareness-raising aimed at grassroots hunters”.</i></p> <p>In 2004, sustainable hunting was given greater legislative precision by the Guide to Sustainable Hunting⁹⁷ under the Birds Directive published by the Commission. This was supported in October 2004 with key delivery objectives, by signature of the Agreement⁹⁸ between BirdLife International and FACE on Directive 79/409/EEC. Under point 9 of the Agreement the organisations agreed to:</p> <p><i>“phase out lead shot for hunting in wetlands throughout the EU as soon as possible, and in any case by 2009 at the latest”.</i></p> <p>The goal mirrored the action agreed between the Commission and Member States in the 25th anniversary Action Plan for the Directive agreed in 2004:</p> <p><i>“Action 5-8. Aim to phase out the use of lead shot in wetlands as soon as possible and ultimately by 2009 (Member States, European Commission)”.</i></p> <p>It further reflected the AEWA commitment, as well as those of the Council of Europe, but remains unrealised, primarily due to non-implementation and/or non-compliance in Member States.</p>
Information campaign / labelling	<p>Cartridges and/or cartridge packaging could be labelled, e.g.:</p> <ul style="list-style-type: none"> • Causes wildlife poisoning - do not use in wetland areas. <p>Labelling could be considered as a relatively inexpensive way of increasing awareness of the risks to the environment associated with the use of lead gunshot.</p> <p>However, there could be issues surrounding the appropriate language/s to be used on any packaging and its effectiveness in modifying behaviour by itself. The size and prominence of labelling would need to be carefully considered. The use of pictorial warnings could also be appropriate.</p> <p>Further relevant information, including on the availability of non-toxic alternatives to lead gunshot, could also be included in any requirements for labelling.</p>

⁹⁶ http://ec.europa.eu/environment/nature/conservation/wildbirds/hunting/index_en.htm

⁹⁷ http://ec.europa.eu/environment/nature/conservation/wildbirds/hunting/docs/hunting_guide_en.pdf

⁹⁸ http://ec.europa.eu/environment/nature/conservation/wildbirds/hunting/docs/agreement_en.pdf

Option	Reasons for discarding this option
	This RMO was considered infeasible, by itself, for the reasons outlined above in relation to a voluntary agreement, but could potentially be usefully incorporated within a more targeted restriction on use.
(II) Legislation other than REACH	
Economic policy instrument (taxation)	<p>It would be possible to propose a tax on lead gunshots at a level that would discourage its use. The revenue could be collected by Member States and used, for instance, to finance the enforcement of existing Member State legislation preventing or reducing the use of lead gunshot in wetlands. This would thus, be a complementary measure to ensure better compliance and the conservation of waterbirds. The tax would be relatively easy to administer as the sale of lead gunshot are typically well regulated, and subject to VAT.</p> <p>It is not clear if REACH Regulation could be used to use an economic instrument. Irrespective of that, an EU wide tax would need to be adopted by unanimity. Some Member States (LU and UK) have thus far taken a principle position that they do not wish to approve EU-wide taxation. Thus, this option is not considered further.</p>
EU Birds Directive (2009/147/EC)	<p>Concerned with the decline of wild bird populations, Member States adopted the Birds Directive (79/409/EEC) in April 1979. It is the oldest piece of EU legislation on the environment and one of its cornerstones. Amended in 2009, it became the Directive 2009/147/EC</p> <p>Habitat loss and degradation are the most serious threats to the conservation of wild birds. The Directive therefore places great emphasis on the protection of habitats for endangered and migratory species. It establishes a network of Special Protection Areas (SPAs) including all the most suitable territories for these species. Since 1994, all SPAs are included in the Natura 2000 ecological network, set up under the Habitats Directive 92/43/EEC.</p> <p>Article 1 of the directive <i>'covers the protection, management and control of these species and lays down rules for their exploitation'</i>. Article 1 also applies <i>'to birds (...) and habitats'</i>.</p> <p>Article 4(4) of the directive refers to member states taking <i>'appropriate steps to avoid pollution or deterioration of habitats of (bird) species requiring special conservation measures'</i>.</p> <p>It could be considered that the general terms expressed in Articles 1 and 4 are consistent with removing lead gunshot from use, as in the exploitation (or take by hunters) and the prevention of accumulation of a toxic pollutant in birds' habitats. However, this is likely to be a too narrow interpretation of these articles, which were included in the original directive of 1979, when avian lead poisoning had yet to become a major conservation issue.</p> <p>Article 14 of the directive <i>'allows member states to introduce stricter protective measures than those provided for under this Directive'</i>, and this is what has occurred when individual countries (such as Denmark, The Netherlands, Spain and the UK) introduced their own national or regional regulations concerning lead gunshot and sinker use (Beintema, 2001), in the absence of provisions at the EU level.</p> <p>The Birds Directive requires uniform action on the conservation of birds and their habitats by Member States. Although the Birds Directive does not mention lead gunshot specifically, it is implied in several articles in which member states are required to prevent pollution and deterioration of major wetlands, and for hunting to be conducted consistent with Wise Use (Thomas and Owen, 1996).</p> <p>The discretion left to the Member States to take appropriate steps could result in dis-harmonisation of the approaches taken by the Member States in manner similar today as with the Implementation to the AEWA</p>

Option	Reasons for discarding this option
	agreement.
EU Habitats Directive (92/43/EEC)	<p>The Habitats Directive protects around 1 200 European species other than birds, which are considered to be endangered, vulnerable, rare and/or endemic. Included in the Directive are mammals, reptiles, fish, crustaceans, insects, molluscs, bivalves and plants.</p> <p>Art 2:</p> <p>1. The aim of this Directive shall be to contribute towards ensuring bio-diversity through the conservation of natural habitats and of wild fauna and flora in the European territory of the Member States to which the Treaty applies.</p> <p>2. Measures taken pursuant to this Directive shall be designed to maintain or restore, at favourable conservation status, natural habitats and species of wild fauna and flora of Community interest.</p> <p>The Habitats Directive (1992) does not include specific provisions on bird hunting, but requires <i>inter alia</i> that in Natura 2000 sites (which include sites designated either under the Birds or the Habitats Directive) “<i>there is no deterioration of the natural habitats and the habitats of the species for which the sites have been designated....</i>” (Art 6).</p>
The African Eurasian Water birds Agreement (AEWA)	<p>The African Eurasian Water birds Agreement (AEWA)⁹⁹ under the Bonn Convention was agreed in 1995 and came into force in 1999. It regulates: “[...] <i>modes of taking, and in particular prohibit the use of all indiscriminate means of taking and the use of all means capable of causing mass destructions, as well as local disappearance of, or serious disturbance to, populations of a species, including: [...] poison</i> (Action Plan 2.1.2 (b)). The original Agreement Text contains a firm obligation for Parties to phase out lead shot for hunting in wetlands before the year 2000 – a provision that since then has been subject to several amendments and at present is formulated: “<i>Parties shall endeavour to phase out the use of lead shot for hunting in wetlands as soon as possible in accordance with self-imposed and published timetables</i>” (Action Plan 4.1.4), and with an agreed target (Resolution 5.23¹⁰⁰) that “<i>by 2017 the use of lead shot for hunting in wetlands is phased out by all Contracting Parties.</i>”</p> <p>Most recently, the 11th Conference of the Parties to the Convention on Migratory Species (in Resolution 11.15) called on Parties to “Phase-out the use of lead ammunition across all habitats (wetland and terrestrial) with non-toxic alternatives within the next three years with Parties reporting to CMS COP12 in 2017.</p>
Council of Europe’s European Charter for Hunting	<p>The Council of Europe’s European Charter for Hunting (2007)¹⁰¹ expanded the commitment outside the EU and specified that “sustainable hunting is the use of wild game species and their habitats in a way and at a rate that does not lead to long term decline of biodiversity or hinder its restoration”.</p> <p>This definition of sustainable hunting was based on the definition of “sustainable use” in Article 2 of the Convention on Biological Diversity¹⁰².</p> <p>The benefits were seen as “the maintenance of hunting as an accepted social, economic and cultural activity”, and that hunting “when conducted sustainably [it] can positively contribute to the conservation of wild populations and their habitats and also benefit society”.</p> <p>Further, the Charter establish guidelines to minimise avoidable suffering by animals, by guiding regulators and managers to “a) Adopt rules, regulations</p>

⁹⁹ <http://www.unep-aewa.org/>

¹⁰⁰ http://www.unep-aewa.org/sites/default/files/document/res_5_23_aewa_contri_aichi_0.pdf

¹⁰¹ [http://www2.nina.no/lcie_new/pdf/634991504714143702_Hunting_Charter\[1\].pdf](http://www2.nina.no/lcie_new/pdf/634991504714143702_Hunting_Charter[1].pdf)

¹⁰² <https://www.cbd.int/>

Option	Reasons for discarding this option
	and incentives that promote methods and equipment that minimise avoidable suffering for animals; b) Communicate to hunters the need to treat game animals with respect; c) Recognise and promote best practices.” (Guideline 3.10.2.1).
Bern Convention	Article 14 of the Bern Convention also called for a ban on the use of lead shot, and introduced recommendations to ensure its success (Thomas and Owen, 1996; Thomas and Guitart, 2005). The recommendations were adopted in 1991, but no provisions for enforcement were developed, and no country was obliged to adopt them.
OECD action	The Organisation for Economic Cooperation and Development (OECD) created policy to reduce lead addition to natural and human environments during the 1990s (OECD, 1993, 1994). The US and the EU proposed an OECD Council Act to effect a reduction in the use of certain specified forms of lead (OECD, 1995), but did not specify lead shot or sinkers. The Lead Working Group of the OECD identified lead shot as a major candidate for inclusion in an OECD Council Act (OECD, 1994), but in the absence of renewed coercion from these and other international agencies (such as the Nordic Council of Ministers (Thomas and Owen, 1996)) political interest waned.
Ramsar convention	<p>Signed in Ramsar, Iran, in 1971, the Ramsar Convention is an intergovernmental treaty which provides the framework for national action and international co-operation for the conservation and wise use of wetlands and their resources.</p> <p>It is the only global environmental convention which specifically aims to conserve one type of ecosystem. It also pays special attention to the conservation of flyway-wide networks of wetlands as water bird habitats.</p> <p>There are presently 169 Contracting Parties to the Ramsar Convention, with over 2200 wetland sites included in the Ramsar List of Wetlands of International Importance.</p> <p>The Ramsar Convention does not specifically address the lead poisoning issue, but addresses it indirectly by urging its contracting parties to conserve wetlands and their species, and to use them sustainably.</p> <p>Recommendation 6.14 on toxic chemicals (6th Meeting of the Conference of the Contracting Parties, COP 1996) provides a framework within which the toxic threats to wetlands should be addressed. The COP 1996 called on Contracting Parties to recognise that: <i>“the adverse impact of toxic substances compromises the ecological character of wetlands and that these threats to ecological character are incompatible with the wise use concept”</i>. The conference also recommended that: <i>“Contracting Parties recognize the importance of the communities’ right to know with respect to hazardous and bioaccumulative chemicals, including pollutant release and transfer registers (PRTRs)”</i></p> <p>Many guidance documents have been officially adopted by the meetings of the Conference of the Contracting Parties from 1990 onwards. Among others have been adopted the <i>“Guidelines for the management of groundwater to maintain wetland ecological character (2005)”</i>, highlighting the need to understand the relationships between wetlands and groundwater. Many wetlands have close associations with groundwater. Where wetlands are sources of groundwater recharge for aquifers, wetland conservation is an essential element in maintaining water resources</p>
(III) Other REACH processes	
REACH Authorisation process	At present massive lead is not on the candidate list but has been recently classified as Repr cat 1b. So in theory it could be identified as a SVHC, included on the candidate list and prioritised for Annex XIV inclusion. However, authorising the use of lead shot would be a disproportionate

Option	Reasons for discarding this option
	measure as it would affect all uses of massive lead, not just the use of lead gunshot in wetlands.
REACH Art. 68.2	Lead gunshot is potentially within the scope of this process (as it is classified as Repr cat 1b) and is used for consumer uses. However, due to the need to carefully consider the impact of any measure proposed (not a requirement of Art 68.2) the Commission decided to request ECHA to prepare a restriction under Article 69(1).

E.2. Alternatives

This section describes the technical and economic feasibility of various alternatives to lead gunshot, notably steel gunshot, which is the most likely alternative to lead gunshot. However, other alternatives are also described (e.g. bismuth and tungsten) as they are likely to be important alternatives in specific circumstances where it is not technically possible to substitute lead gunshot with steel gunshot. Collectively these are called 'lead-free shot', or 'alternative shot', in this report.

E.2.1. Description of the use and function of the restricted substances

The focus of this restriction proposal are shotgun cartridges that are loaded with spherical lead 'shots'. The spherical shots are propelled during the use of the cartridge to reach a target. The spherical shots should penetrate (and may pass through) the target, causing the death or wounding of the target, where it is an animal.

Lead has historically been used as gunshot in cartridges (TemaNord, 1995) because of its:

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

Based on these properties, lead is often considered to be an ideal material for use in ammunition. Other materials often have somewhat different ballistic behaviour to lead but this does not necessarily result in a conclusion that they are technically or economically inferior to lead gunshot. The technical and economic feasibility of the use of alternative to lead in gunshot is outlined in the sections below.

E.2.2. Identification of potential alternatives/ techniques (overview of existing alternatives)

Lead-free shot cartridges are widely available in Member States with existing regulations on the use of lead gunshot (see Section 0). The call for evidence organised by ECHA to support the development of this restriction proposal confirmed that alternatives (e.g. steel, tungsten or bismuth) are already commonly used in wetlands.

In the EU, Denmark has been a testing ground for the introduction and evaluation of alternative gunshot, following the initial regulation for hunting in wetlands in 1985 and the total phase out of lead shot in 1996. Many products have been designed specifically for the Danish market and users (Kanstrup, 2006). There is no indication that a lack of suitable alternative shot types, shot sizes, or other potential drawbacks of the shift from lead to non-lead shot in Denmark has changed the cost of hunting, the number of hunters, or their harvest (Kanstrup, 2015).

Although the risks from the dispersal of lead gunshot in the environment have been known since the late 1800s, the first alternative gunshot materials were only marketed in North America in the 1970s. The availability of alternatives to lead gunshot has increased steadily since this time, corresponding with the introduction of bans on the use of lead gunshot in countries within and outside the EU. Steel gunshot (soft iron) is by far the most commonly used alternative to lead gunshot.

In response to Danish and US regulatory requirements, additional metals were introduced in the early 1990s as alternative to lead shot: specifically bismuth and tungsten. Originally, bismuth was used in shot in an almost pure form; more recently it has been alloyed with tin (6 %) to reduce the tendency of pellets to fragment. Tungsten shot is often based on metal powder embedded in a plastic polymer (Tungsten Matrix) and has ballistic properties very similar to lead shot (Scheuhammer, 1995).

In the US, the environmental safety of alternatives to lead shot is evaluated before they are allowed to be placed on the market. Following extensive testing on captive waterfowl in the US and Canada, zinc gunshot was considered to be toxic, and it is not permitted to be placed on the market in either country (Scheuhammer 1995; Putz, 2012).

Table E-5 gives an overview of the currently allowed shot types in the US. Following extensive testing on captive waterfowl in the US and Canada, zinc gunshot was considered to be toxic, and it is not permitted to be placed on the market in either country (Scheuhammer 1995; Putz, 2012).

Table E-5: Approved 'non-toxic' shot in the US (USFWS¹⁰³)

Alternative	Composition
Bismuth-tin	97 % bismuth, and 3 tin%
Iron (steel)	iron and carbon
Iron-tungsten	any proportion of tungsten, and ≥ 1 iron
Iron-tungsten-nickel	≥ 1 % iron, any proportion of tungsten, and up to 40 % nickel
Copper-clad iron	84 to 56.59 % iron core, with copper cladding up to 44.1 % of the shot mass
Tungsten-bronze	51.1 % tungsten, 44.4 % copper, 3.9 % tin, and 0.6 % iron, or 60 % tungsten, 35.1 % copper, 3.9 % tin, and 1 % iron
Tungsten-iron-copper-nickel	40–76 % tungsten, 10–37 % iron, 9–16 % copper, and 5–7 % nickel
Tungsten-matrix	95.9 % tungsten, 4.1 % polymer
Tungsten-polymer	95.5 % tungsten, 4.5 % Nylon 6 or 11
Tungsten-tin-iron	any proportion of tungsten and tin, and ≥ 1 iron
Tungsten-tin-bismuth	any proportion of tungsten, tin, and bismuth
Tungsten-tin-iron-nickel	65 % tungsten, 21.8 % tin, 10.4 % iron, and 2.8 % nickel
Tungsten-iron-polymer	41.5–95.2 % tungsten, 1.5–52.0 % iron, and 3.5–8.0 % fluoropolymer

E.2.2.1. Steel

This alternative is widely available, but due to its comparatively greater hardness (relative to lead) it requires use in compatible guns. The Dossier Submitter considers that 100 % of new guns currently on the market are compatible with steel gunshot and that a maximum of 25 % of existing (old) guns currently used by consumers would not be compatible with the use of lead gunshot. This issue is further discussed in Section E.3.1.3.

¹⁰³ <https://www.fws.gov/birds/bird-enthusiasts/hunting/nontoxic.php>, accessed 25 January 2017.

Steel gunshot is widely seen to provide equivalent performance to lead or other materials, (Scheuhammer, 1995; Pierce, 2014) without major concerns caused by ricochet (DEVA, 2013). However, some adaptation to the different ballistic properties of steel may be required by hunters to achieve equivalent performance e.g. typically used shot size would need to be increased to account for the lower density of steel.

According to the 'Permanent International Commission for the Proof of small arms' (CIP), which sets standards for firearms and ammunition in the EU, "standard" steel gunshot cartridges are suitable for use in the majority of standard 'nitro-proved' shotguns¹⁰⁴. "High performance" steel cartridges, which generate greater pressures when fired, are only to be used in 'steel shot' proved guns. The difference between standard steel and high performance steel is further explained in Section E.3.1.

Steel shot is the most commonly used alternative due to its price, which is in the same range or even below that of lead shot, making it the cheapest of the known alternatives (ignoring the cost of any gun modification such as modifying choke, barrel change etc.).

E.2.2.2. Bismuth

The ballistics or performance is generally good, provided the shot size is increased to allow for density lower than lead. Bismuth is suitable in all guns. Bismuth can be used as a drop in alternative to lead without concerns over compatibility with guns. Bismuth shot is available in most gauges and with a wide variety of loadings. The shot is available for home loading, including for large-bore guns. However, the price of bismuth shot is relatively high. Bismuth is an alternative that can be used in all guns and is often used in forests where owners limit the possibilities to use steel¹⁰⁵ (see also Section E.7.1.1.5)).

E.2.2.3. Tungsten

The density of tungsten shot is favourable for good ballistics and performance, so the percentage of tungsten in shot material is important. It is suitable for use in appropriately-proved guns and widely available. Tungsten-based shots have been approved as nontoxic by the US Fish and Wildlife Service. However, it is relatively more expensive than lead and steel gunshot, which has restricted its use as an alternative.

E.3. Risk reduction, technical and economic feasibility and availability of alternatives

E.3.1. Most likely alternative: steel

Steel shot is the most likely alternative to lead shot. It is widely available as a raw material and its price is similar to or even less than that of lead shot. Early steel shot products were considered to perform poorly. However, after 20 years of using steel shot for waterfowl hunting, the experience in the US, Canada and in the Netherlands and Denmark have demonstrated that steel gunshot is a viable alternatives to lead gunshot. This section

¹⁰⁴ Standard steel not suitable in certain specific 'standard proofed' shotguns, such as Damascus barrelled shotguns.

¹⁰⁵ Personal communication, Finnish hunting association.

discusses the key questions a hunter may be confronted with, when switching to alternatives for lead shot:

1. Is steel gunshot available? (Section 0)
2. Can I hunt with steel gunshot as well as I can hunt with lead gunshot? (Section 0)
3. Can I use steel gunshot in the gun that I currently own (Section E.3.1.3)
4. How much does it cost to shoot with steel gunshot? (Section E.3.1.4)
5. Are there any other safety concerns associated with the use of steel gunshot (Section E.3.1.5)

E.3.1.1. Availability in the European Union

The Dossier Submitter investigated the availability of steel gunshot in Europe. This was done through an online search of the product catalogues of ammunition manufacturers that are members of AFEMS¹⁰⁶ as well as other companies. Ten manufactures were identified in the following countries: Italy (2), UK (2), Spain (1), Sweden (1), Germany (1), Poland (1), Czech Republic (1), and Greece (1). All of these companies have a line of lead-free shotgun hunting cartridges. All have a steel gunshot production line with a rather varied selection of calibres and loads. Bismuth shot cartridges are also produced by two manufacturers, copper by two, and zinc by one. The manufacturers have agencies in most European countries, hence their products, including lead-free ammunition, are available or can easily become available in any Member State, once the demand is there. In addition, several North American manufacturers produce and export lead-free ammunition to Europe. These companies have a long tradition for production of lead-free hunting cartridges. One (Kent) has specialised in this type (i.e. steel shot) and is directly affiliated with a British company (Gamebore). It has, at present, a significant share in the Danish market of shot cartridges.

Furthermore, the Dossier Submitter has screened the actual availability of lead-free ammunition at the retail level in different Member States. This was carried out by searching for cartridge dealers with online shops in a sample of European countries (Online shops in 13 different Member States were screened)¹⁰⁷. The search was limited to the most relevant calibre in the context of water bird hunting: 12/70 including both 'standard' and 'high performance' cartridge types. Table E-6 shows the result in terms of country, cartridge brand and type, shot material, load weight, and price per cartridge in Euros. Examples of equivalent lead shot cartridges are included to compare prices. It should be underlined that the screening is based on a sample of online shops in a sample of Member States and should therefore not be considered to be a completely representative sample but is likely to generally describe the likely distribution of costs of both lead and lead-free cartridges.

Table E-6: Shotgun cartridge products identified by a screening of online web shops in a sample of 11 Member States.

Member State	Product	Shot material	Load weight (grams)	Price per cartridge (in €)
Austria	Fiocchi PL 32	Lead	32	0.56

¹⁰⁶ <http://www.afems.org/>

¹⁰⁷ Additional search of UK-based online shop undertaken by the Dossier Submitter on 16/01/2018 – prices converted from £ to € at rate of 1.125

Member State	Product	Shot material	Load weight (grams)	Price per cartridge (in €)
Austria	Fiocchi Soft Steel	Steel	32	0.68
Czech Rep	SB Lord	Lead	36	0.32
Czech Rep	SB Steel Shot	Steel	32	0.23
Estonia	Fiocchi Soft Steel	Steel	32	0.39
Finland	Eley VIP Bismuth	Bismuth	36	3.96
Finland	FOB Sweet Copper	Copper	34	1.96
Finland	Remington Nitro Steel	Steel	34	0.66
France	Mary Arm	Lead	36	0.30
France	Solognac	Lead	36	0.48
France	Solognac Impact	Lead	36	0.68
France	Mary arm	Steel	29	0.60
France	Mary arm	Steel	32	0.68
France	TUNET	Steel	32	0.40
Germany	FOREST Ammo	Lead	36	0.36
Germany	B&P HV	Steel	32	0.34
Germany	Rottweil Waidmannsheil	Steel	36	0.77
Germany	Rottweil Steel Trap	Steel	24	0.33
Germany	Rottweil Steel Game HV	Steel	32	0.47
Greece	Ariston	Lead	32	0.29
Greece	Nobel Sport Italia	Steel	32	0.99
Greece	Federal Classic	Steel	39	0.96
Latvia	NSI Classica	Lead	32	0.30
Latvia	NSI Steel Caccia	Steel	32	0.37
Latvia	Gamebore Super Steel	Steel	32	0.37
Portugal	FOB	Bismuth	32	2.50
Portugal	FOB	Steel	28	0.50
Portugal	FOB	Tungsten	36	3.60
Sweden	Gyttorp Bismuth	Bismuth	28	2.40
Sweden	Gyttorp Grouse	Lead	32	0.56
Sweden	Gyttorp Wetland	Steel	32	0.68
The Netherlands	Rottweil	Copper	34	1.65
The Netherlands	Clever Mirage Hunting T4	Steel	32	0.38
The Netherlands	Clever Mirage Hunting T3	Steel	24	0.33
The Netherlands	Rottweil Steel Game HV	Steel	32	0.63
The Netherlands	Gamebore	Steel	32	0.28
UK	Gamebore Clear pigeon	lead	32	0.36

Member State	Product	Shot material	Load weight (grams)	Price per cartridge (in €)
UK	Gamebore Super game hi bird	lead	32	0.43
UK	Gamebore Regal game	lead	32	0.47
UK	Gamebore Black gold game (plastic)	lead	32	0.50
UK	Gambore Black gold game (fibre)	lead	32	0.51
UK	Gamebore Dark strom (fibre)	lead	32	0.52
UK	Gamebore Dark storm (wool)	lead	32	0.65
UK	Gamebore Regal (paper)	lead	32	0.50
UK	Gamebore Buffalo	lead	32	0.54
UK	Purdey	lead	32	0.50
UK	Eley VIP (photo deg)	lead	32	0.50
UK	Eley VIP (fibre)	lead	32	0.50
UK	Eley Pigeon HV (plastic)	lead	32	0.36
UK	Eley Pigeon HV (fibre)	lead	32	0.37
UK	Eley GRAND PRIX HV	lead	32	0.48
UK	Eley HI FLYER	lead	32	0.44
UK	Eley HUSHPOWER	lead	32	0.41
UK	Hull SPECIAL PIGEON LR	lead	32	0.38
UK	Hull DRIVEN GROUSE	lead	32	0.60
UK	Hull HIGH PHEASANT	lead	32	0.49
UK	HIGH PHEASANT EXTREME (plastic)	lead	32	0.50
UK	Hull HIGH PHEASANT EXTREME (fibre)	lead	32	0.50
UK	Hull SUPREME GAME (plastic)	lead	32	0.48
UK	Lyalvale Express SUPREME GAME (fibre)	lead	32	0.50
UK	Lyalvale Express ULTIMATE POWER	lead	32	0.52
UK	Lyalvale Express SPECIAL GAME (fibre)	lead	32	0.44
UK	Lyalvale Express SUPER GAME (plastic)	lead	32	0.43
UK	Lyalvale Express SUPER GAME (fibre)	lead	32	0.46
UK	RC SIPE (plastic)	lead	32	0.44
UK	RC SIPE (fibre)	lead	32	0.46
UK	Fiocchi SPORTING PIGEON (plastic)	lead	32	0.32

Member State	Product	Shot material	Load weight (grams)	Price per cartridge (in €)
UK	Fiocchi SPORTING PIGEON (fibre)	lead	32	0.33
UK	Fiocchi PL	lead	32	0.36
UK	Fiocchi PL (fibre)	lead	32	0.38
UK	Fiocchi F3 GAME (fibre)	lead	32	0.39
UK	Fiocchi GOLDEN PHEASANT	lead	32	0.44
UK	Viri FOB SUPER	lead	32	0.50
UK	Viri FOB STANDARD	lead	32	0.49
UK	Rio SUPER GAME (plastic)	lead	32	0.43
UK	Rio SUPER GAME (fibre)	lead	32	0.44
UK	Rio ROYAL (plastic)	lead	32	0.51
UK	Rio ROYAL (fibre)	lead	32	0.51
UK	Victory EUROPA	lead	32	0.39
UK	Victory STARLIGHT	lead	32	0.38
UK	Gamebore Game and wetlands steel	steel	32	0.33
UK	Steel (fibre)	steel	32	0.63
UK	Eley VIP steel	steel	32	0.33
UK	Eley Lightning steel	steel	32	0.46
UK	Steel game	steel	32	0.34
UK	Lyalvale Express Supreme steel	steel	32	0.35
UK	Steel - game	steel	32	0.36
UK	RC RC3 steel	steel	32	0.36
UK	Bismuth	bismuth	32	1.68
UK	Eley VIP EVO III Bismuth	bismuth	32	1.71

Note: Poland and Ireland were included in the screening but no lead-free ammunition was identified in these countries

It can be seen that lead-free shotgun cartridges are available in most Member States from retail shops with online service. However, the screening showed that the product range of lead-free ammunition is significantly restricted compared to lead shot brands. This is supported by research undertaken by the UK Lead Ammunition Group (2015) who concluded that “the available variety of non-lead shotgun and rifle ammunition is more restricted than currently available for lead, so optimum loads may not yet exist for all circumstances”. This may very well be the situation in other EU Member States with no or partial bans on the use of lead gunshot. Stocks of non-lead ammunition held in local retail shops may be very limited in quantity, specification and brand. Hence, a small-scale local purchaser may not initially be able to buy the most appropriate cartridge for their shotgun or hunting purpose. However, this should not be considered to mean that an appropriate cartridge is not available.

The availability of lead-free ammunition is first and foremost limited by the demand at the national, regional, and local level (Thomas, 2013). Manufacturers provide lead-free ammunition and their products are available, or can easily become available in any Member State, regionally and locally, once the demand is there. Another example of this, is in Italy where a partial ban has been put in place (Annex XV Report Table 4.1). Recent industry information suggests that the market share of alternatives for lead was estimated to be up to 50 %¹⁰⁸

In Denmark, ammunition dealers at retail level will offer a very broad selection of lead-free cartridge types. One example is Korsholm¹⁰⁹, who offer 15 different brands of lead-free shot cartridges (mostly steel) in different calibres each with a selection of 3-5 different shot sizes. In contracts, our screening identified that no lead-free gunshot was available online in Poland where a restriction on the use of lead gunshot has yet to be introduced. This is despite the fact that Polish company FAM produces steel gunshot hunting cartridges.

The impact of demand on the availability of non-lead gunshot was discussed in by UK LAG (2015). It was concluded that, based on the development of non-toxic markets in Denmark, the Netherlands and in North-America that "the variety and performance of non-lead ammunition will, if demand exists, improve to meet demand". Also, Thomas (2014) finds that manufacturers in Europe make and distribute cartridges according to hunter demands, which, in turn, is driven by regulations.

E.3.1.2. Technical feasibility of steel shot

This section on the technical feasibility of steel shot outlines whether or not steel shot can be used for hunting, and how it compares to lead gunshot. This issue is discussed from two points of view: a first part on the technical aspects and a second part on the practical aspects.

Technical aspects.

The ability of a hunter to 'put down' a target depends on the distance between the hunter and the target and the energy that is transferred from the gun to the body of the target.

The energy of a shot is well defined and can be expressed by the ability of the powder load to accelerate a shot load of a certain weight to a certain velocity (which in shotgun ballistics is commonly labelled as muzzle velocity (V_0)). The (muzzle) shot energy (E_0) is expressed by the formula:

$$E_0[\text{J}] = \frac{1}{2} M[\text{kg}] \times V_0^2 [\text{m/s}],$$

where M = mass (weight) of the shot load. Corresponding units: Joule [J] for energy, kilogram [kg] for weight and metre per second [m/s] for velocity.

In a standard load (steel or lead) (30 g) with a standard muzzle velocity (400 m/s), the shot energy is about $E_0 = 2\,400$ J. This is comparable to E_0 in standard big game rifle ammunition and more than sufficient to kill an elephant.

¹⁰⁸ Personal Communication AFEMS 2017.

¹⁰⁹ <http://www.korsholm.dk/dk/jagt-produkter/ammunition/halgpatroner.html?m-layered=1>

The technical efficiency describes, without taking into account shooter skill, how the energy that is released into the shot cloud is transferred, via the shot pattern and individual pellets, into the hitting impact on the target. Technical efficiency is related to the shot energy, the shot pattern (radial and longitude dispersal of the shot cloud), and the ability of single pellets to penetrate and release striking energy in the target. It expresses the "shotgun dilemma", i.e. the balance between the size of the pattern (pellet cover) and ensuring that vital parts of a target are hit by a sufficient number of pellets with enough energy to ensure injury (Cochrane 1976). Both variables relate to the shooting distance. The pellet cover relates, in principle, linearly to distance, although both radial and longitude dispersal of shot complicate the relationship, whilst penetration corresponds to the single shot energy, which declines exponentially with distance.

Therefore, in simple terms, shot cover must ensure that the target is hit by a sufficient number of pellets to die upon impact. The number of pellets required to hit the target has been subject to many discussions. A minimum of five hitting pellets will ensure an acceptable likelihood that the vital parts of a bird are hit (Garwood, 1994). Under normal conditions (shot size, choke etc.) this sets a distance limit of approximately 40 metres regardless of shot material (lead or steel), presuming that the target is hit with the central part of the shot pattern.

To ensure sufficient penetration, the single shot must conserve a minimum level of striking energy to penetrate deeply enough to injure vital parts. This requirement is poorly described in the literature. Burrard (1944) finds that 1.08 J is sufficient striking energy to kill small game birds. This is calculated based on the practical experience of hunters in general, that a (lead) shot can "kill" a bird at 41 m (45 yards). Lowry (1974) and Bløtekjær (2011) have further investigated the issue. In summary, both find that the required striking energy of a single shot varies between 1 J and 5 J, depending on, among other things, target body size, anatomy and shooting angles. Also, the position of the bird, i.e. whether vital parts are protected behind tough tissues or by feathers will play a role. Therefore, under normal conditions, the killing of a medium sized water bird requires ≥ 5 shots to hit the target, each with an energy of $> 2 \text{ J}^{110}$.

All this applies equally to lead and non-lead shot. Thomas et al. (2015) summarises in the following quotes how the technical efficiency differs between lead and steel shot:

➤ Pattern

The lead-free shot, Tungsten matrix and Bismuth-tin, have ballistic properties and densities similar to lead shot. Both types are fired from the barrels at approximately the same velocity as lead shot, and in the same shot containers. Both shot types respond to barrel choking as lead shot, and have similar shot string lengths. Manufacturers give steel shot similar muzzle velocities as lead shot, so there is no perceptible difference to shooters. Steel shot, by virtue of their spherical shape and hardness, do not contribute as many fliers (mis-shaped or deformed pellets) to the fringes of shot patterns, and so add more shot to the main killing region of the patterns. Steel shot strings are slightly shorter than lead shot strings. Steel shot cartridges produce slightly tighter patterns than lead shot with a given barrel choke, so do not need to be fired through barrels with much choking.

¹¹⁰ The issue is further complicated by a theory of "synergy" between a hitting shot, meaning that a simultaneous hit of several shots causes a so-called shock-impact, i.e. a physical and lethal impact on the nervous system that causes an instant kill. This has never been verified scientifically, but is commonly accepted by hunters. While some authors like Lampel (1983) believe in the idea, there is little evidence for shot synergy, and killing impact likely boils down to the probability of vital parts of the body being hit and penetrated sufficiently.

➤ Shot impact in body

The lethality of gunshot is not a function of its ability to “mushroom” in the body. This is a common confusion with expanding rifle ammunition. Soft lead pellets that hit large bones in animals’ may lose their round shape, often fragment, and remain in the carcass. The lethality of shotgun shot relates to the number of pellets that penetrate the vital regions of the animal and cause tissue disruption. It is accepted that a minimum of five pellets hitting the vital regions are required to produce rapid humane kills (Garwood 1994), i.e. it is the pattern density of shot rather than the energy in a given shot that defines lethality (Pierce et al. 2014).

Very soft pellets that may deform during passage along the gun barrel also contribute to poorer quality patterns. Gunshot makers will use up to 6 % antimony to harden lead gunshot to ensure that it does not lose its shape during firing and ‘fly away’ from the main shot pattern. Another process involves plating lead shot with nickel to harden the pellet surface, prevent deformation, and generate better killing patterns at distant ranges. In contrast, steel gunshot patterns well on the basis of its relative hardness (compared to lead), and if a shot is on target, kills effectively.

The issue is further summarised in Table E-7 Basic parameters of lead compared with steel shot. Blue cells apply to both lead and steel. Green apply to lead, and yellow to steel. Arrows indicate the values corresponding to a 0.5 mm change of shot size (=2 US numbers)., which gives a comparison between lead and steel shot in terms of the basic parameters: size, weight, number of shot in a 30 g load, and velocities and striking energy at muzzle, 20 and 40 m.

Table E-7 Basic parameters of lead compared with steel shot. Blue cells apply to both lead and steel. Green apply to lead, and yellow to steel. Arrows indicate the values corresponding to a 0.5 mm change of shot size (=2 US numbers).

Diameter	Weight lead	Weight steel	# lead	# steel	V ₀	V ₂₀ lead	V ₄₀ lead	V ₂₀ steel	V ₄₀ steel	E ₂₀ lead	E ₄₀ lead	E ₂₀ steel	E ₄₀ steel
mm	g		per 30 g		m/s	m/s				J			
2,5	0,09	0,06	325	464	400	260	180	225	140	3,1	1,5	1,6	0,6
3	0,16	0,11	188	269	400	280	205	240	165	6,3	3,4	3,2	1,5
3,5	0,25	0,18	118	169	400	290	225	260	180	10,7	6,4	6,0	2,9
4	0,38	0,26	79	113	400	300	235	270	195	17,0	10,5	9,6	5,0

The following conclusions can be drawn

- The lower density of steel compared to lead is reflected in lower values for weight and velocity/energy on distance, but a higher number of shot in the (30 g) load, given the same shot size;
- In general terms, the increase of shot size by 0.5 mm (which is normally recommended when changing from lead to steel – indicated with arrows in the table) compensates for the lower weight, velocity and corresponding energy, without the pattern to be disrupted;
- However, for some of the parameters, the compensation is not complete. This is the reason why V₀ in steel shot cartridges may be increased either by adjusting powder load of reducing shot load weight;
- Small shot (<3 mm), mostly steel but also lead with the demonstrated V₀ (400 m/s) do not fulfil the 2 J demand to kill medium size water birds at great distance.

This is the background for the general recommendation of change to larger shot sizes when changing from lead gunshot to steel gunshot, but also the background for a recommended maximum shooting distance. For example, in Denmark the maximum shooting distance for goose hunting is 25 metres and 30 m for other water bird hunting.

Remington, one of the major manufacturers of shotguns and ammunition, has issued guidance¹¹¹ on the use of shotguns and cartridges, this guidance also describes the difference between lead gunshot and steel gunshot. This guidance outlines that the energy that is retained over distance is comparable between steel and lead gunshot as steel shot has a higher initial velocity than lead when it first exits the muzzle. However, due to its lighter weight, it can lose knockdown power at longer ranges. By using larger steel shot sizes you can maintain a comparable velocity and retained energy to that of lead – even at long distances, see Table E-8 .

Table E-8 Comparison of energy retainment of certain lead and steel shot (Source: www.remington.com)

energy comparison: steel vs lead							
shot type	shot size	velocity (m/s)	retained per pellet energy				
		7.5 cm from muzzle	27 m	36 m	45 m	54 m	
lead	7 1/2	1330	2.17	1.76	1.22		
steel	6	1365	2.44	1.76	1.22		
lead	6	1330	4.20	3.12	2.44		
steel	4	1365	4.75	3.39	2.44		
steel	3	1365	6.24	4.61	3.39		
steel	3	1330	7.59	5.97	4.75	3.66	
lead	4	1330	8.00	5.97	4.47	3.53	
steel	2	1365		10.17	8.27	6.64	
lead	2	1330		7.73	5.97	4.61	
steel	1	1365		12.07	9.49	7.59	
steel	BB	1365		18.71	15.46	12.88	
lead	BB	1260		16.95	13.56	10.85	

The general conclusion on technical efficiency from investigations of basic physical features and field studies over the last 40 years is that commonly available lead-free shot, specifically steel shot with the right adjustment of shot sizes etc., fulfils the needs of ensuring a clean kill to the same extent as lead shot.

The practical efficiency describes the efficiency of ammunition under real and practical field circumstances, i.e. during hunting. It is a simple product of the technical efficiency and the impact of “putting a hunter behind the gun”. Hence the term covers the shot energy combined with constraints of this energy to be transferred to the target via the ballistics of the shot in combination with the constraints of the shooter to hit the target.

The literature on shot gunning is vast. The particularity of shotgun shooting is that one shoots at moving targets and, therefore, the shooter must compensate for the distance (target distance) that the target moves from the time of ignition of the shot until the shot load hits the target (flight time) at the actual shooting distance. The compensation is normally referred to as the “lead”, i.e. the distance the shooter must aim at “in front of” the target to hit.

The target distance depends on simple trigonometric rules with shooting distance, shooting angle and target velocity as the main variables. However, it is complicated by the flight

¹¹¹ https://support.remington.com/General_Information/Guide_to_Shotguns_and_Shotshell_Ammunition

time, which declines exponentially with shooting distance due to deceleration of the shot load. Furthermore, the radial and longitude dispersal of the shot cloud gives per se a compensation that is related also to shooting distance.

In practice the calculation of the target distance is complex and no hunters/shooters base their shooting on such basic formulas, but instead judge the required "lead" from a general subconscious evaluation of the shooting situation (speed, distance and other conditions). To many shooters, the "lead" is not a simple measurement that can be explained.

The technique of "swinging" the gun, thus achieving the required "lead" by moving the aim along the flight direction faster than the target, is commonly practiced. Shooting is an analogue to many other sports and just like for instance football players, shooters depend on their personal talent. However, shooters – like other sportsmen – develop, improve and maintain their skills by training.

It is too far reaching to enter shot gunning in detail here. However, one basic factor should be elaborated: the shooting distance. As mentioned above, technical efficiency is highly dependent on shooting distance of two basic reasons: Shot decelerate and loose energy with distance, and shot disperse three-dimensionally, whereby the pattern density declines and likelihood of the target to be hit by a sufficient number of pellets, declines. Both declines are exponentially related to the shooting distance.

The shooters' ability to hit the target is highly related to the shooting distance. This is not only a general experience but demonstrated in several studies. As a part of the Danish campaign for reducing wounding loss (1997) special emphasis was given to the impact of shooting distances on the hitting frequency. Noer et al. (2001) showed for (all) 14 hunters participating in practical tests a clear dependence between hitting precision and shooting distance. Figure E-2 demonstrates the result for a "good" shooter (left) and a "bad" shooter (right). These results are based on shooting in a simulator (TROJAN).

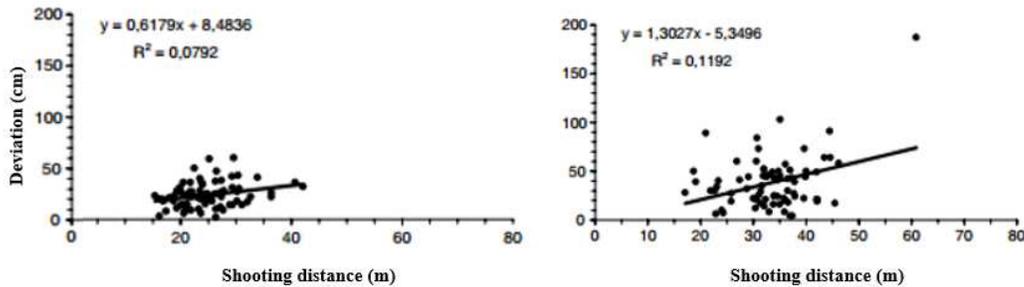


Figure E-2. Deviation (miss distance) (cm) between hitting point and target as a function of shooting distance (m) on TROJAN shooting simulator. Each dot represents one shot. Left: "Good" shooter. Right: "Bad" shooter. After Noer et al. (2001).

Practical aspects

Since the first discussion and regulations on the use of lead gunshot for hunting started in North America and Europe in the 1980s, a major concern has been the question of effectiveness of non-lead shot. Are alternative shot types as effective as lead in killing birds when used by an average bird hunter in practice?

One of the key concerns relates to the potential for an increase in "crippling loss" of birds. This term refers to birds that have been shot, but are un-retrieved, either because they have not been killed outright (wounded birds), or because they have been killed but the carcass cannot be found (Thomas et al., 2015).

The crippling loss for some birds has been reported to be in the range of 10-50 % (Haas, 1977; Nieman et al., 1987). In this case the crippling loss describes the number of wounded birds that survive with pellets in the body (so-called "pellet carriers") plus the number of deadly wounded but non-retrieved birds over the number of all birds hunted.

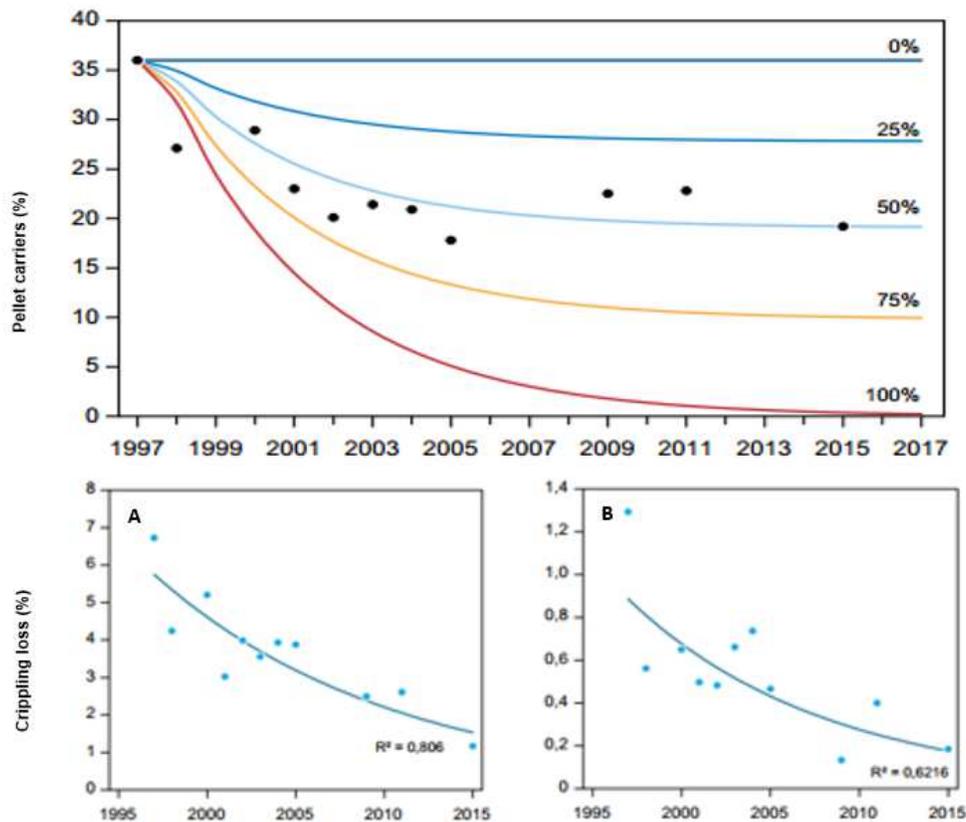
This range is independent of the shot types used. Noer et al. (1996) found in Denmark in a population of Pink-footed Goose (*Anser brachyrhynchus*) a prevalence rate of 36 % of lead shot carriers, and for eider duck (*Somateria mollissima*) a prevalence rate of 34 %. For both species accurate data on population dynamics were available. Based on annual survival rates and the frequency of shot carriers it was estimated that per bagged bird, another bird was wounded (and survived). Moreover, there was an unknown number of mortally wounded but non-retrieved birds. Hence, the estimated crippling loss was well beyond 50 %. Notably, most of the examined birds had been wounded before the Danish ban on lead shot in wetlands (in 1993), and the carried shot was mostly lead shot.

Cartridge consumption per bagged bird varies considerably depending on the skill of the shooter, the shooting distance, the quarry size and many other factors. Haas (1977) found that dove hunters fired an average of 8.6 (lead) shots per bagged bird. Noer et al. (1996) found between 1.5 and 10.50 shots per bagged bird among 14 duck hunters, with an average of 3.3 (steel) shots. These large numbers of shot fired without creating a kill represent a risk not only for missing the target, but for wounding it. Noer et al. (2001) also found a clear correlation between cartridge consumption and the prevailing crippling loss ratio. Here, an ideal situation would be a 1:1 ratio – one bagged bird per shot. Whilst this is not achievable in practical terms, the setting of goals for reducing cartridge consumption has proven to be an effective tool to control crippling. As a result of a Danish campaign (in 1997) a code of maximum three shot per bagged bird was established. In

addition, the shooting distance was found to be crucial for both cartridge consumption and wounding risk. Hence, the recommended shooting distances in the same set of hunting codes were reduced accordingly.

The latest evaluation of the impact of the campaign is presented by Holm et al. (2015). The results are summarised in Notes: Top: The frequency (%) of old (>1 year) with embedded pellets. The curves show the predicted development, if the level of wounding was un-changed (0 %) or declined with, resp. 25 %, 50 %, 75 % and 100 %. The dots show the actual trend. Bottom: Crippling loss (% wounded / % bagged birds). A: Old birds (>1 year); B: Young birds (1 year)

Figure E-3. The top panel shows the development in frequency of pellet carriers from 1997 to 2015 for pink-footed goose. The bottom panels show for old (A) and young specimens (B), the corresponding development in crippling loss (i.e. % wounded birds / % bagged birds), based on the frequency of pellet carriers and data on the total annual bag.



Notes: Top: The frequency (%) of old (>1 year) with embedded pellets. The curves show the predicted development, if the level of wounding was un-changed (0 %) or declined with, resp. 25 %, 50 %, 75 % and 100 %. The dots show the actual trend. Bottom: Crippling loss (% wounded / % bagged birds). A: Old birds (>1 year); B: Young birds (1 year)

Figure E-3. Development of wounding of pink-footed goose in Denmark over the period 1997-2015. After Holm et al. (2015).

Holm et al. (2015) detect a clear and significant reduction in wounding rates over time. The authors attribute this to better organisation and planning of hunting, combined with a better education of hunters. Figure E-4 shows the harvest of pink-footed geese in Denmark and Norway since 1990 (Madsen et al. 2015).

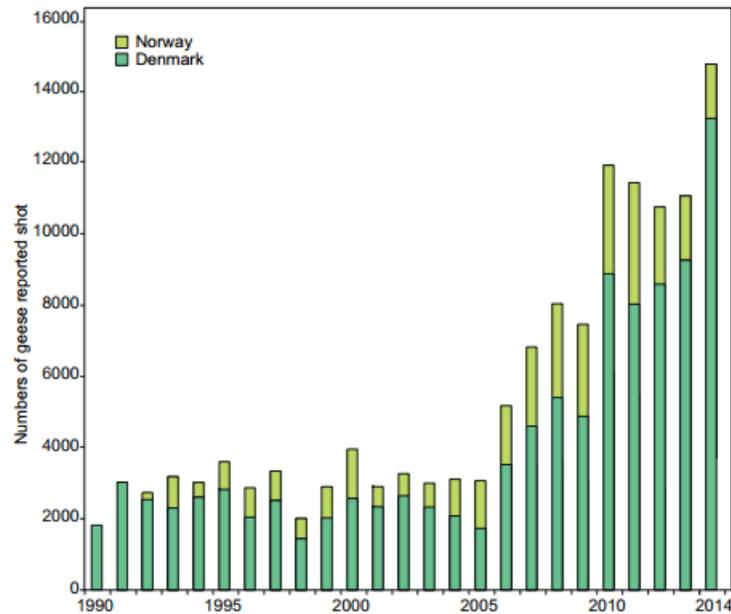


Figure E-4. Harvest of pink-footed geese in Denmark and Norway from 1990-2014. After Madsen et al. (2015).

The time period of this dataset almost completely overlaps with the phasing out of lead gunshot in Denmark. It therefore provides a good basis upon which to assess if a restriction on the use of lead gunshot in wetlands will result in greater crippling loss, i.e. is lead gunshot less or more effective than its alternatives?

Comparative studies on the efficiency of lead versus non-lead shot are abundant in the literature. Nicklaus (1976) reported no difference in crippling loss when using lead or steel. Cochrane (1976) reported that the best lead shot shells available outperformed the best steel shot shells in that they produced fewer cripples at “normal” shooting ranges. Hartmann (1982) concluded that steel shot is suitable for water bird hunting within normal shooting distances (max. 35 m). Kanstrup (1987) reported no difference in the “killing impact” of lead and steel shot in Eider Duck (*Somateria mollissima*) hunting. Morehouse (1992) reported a slight increase in waterfowl crippling loss rates in the US during the early steel shot phase-in over the period 1986-1989, but also that crippling loss for both ducks and geese declined in 1991 towards levels observed during the early 1980s. Strandgaard (1993) concluding that steel shot is just as effective as lead shot when used to kill roe deer and is a valid alternative.

In a more recent study, Gundersen et al. (2006) find that an appropriate combination of shot type and size resulted lead and non-lead ammunition with similar “killing impact”. Likewise, a large-scale European study on the effectiveness of steel gunshot ammunition in hunting waterfowl (Mondain-Monval et al., 2015) indicates performance levels of steel gunshot very similar to lead shot. The study also suggests that hunter behaviour and judgement, the abundance of birds and strong wind conditions are significant determinants of a hunter’s ability to bag birds.

In a recent, large-scale comparative study of the effectiveness of steel and lead shot in shooting mourning doves (*Zenaida macroura*) (Pierce et al., 2014), hunters using lead

shot (cal. 12, with 32g of US #7 1/2 shot) and steel shot (cal. 12, with 28 g of US#6 and US#7 shot) produced the same results in terms of birds killed per shot, wounded per shot, wounded per hit, and bagged per shot. Hunters in this double-blind study wounded 14 % of targeted birds with lead shot, and 15.5 % and 13.9 % with #7 and #6 steel shot, respectively. Hunters missed birds at a rate of 65 % with lead shot, and 60.5 % and 63.6 % with #7 and #6 steel shot, respectively. Pierce et al. (2014) conclude that "[shot] pattern density becomes the primary factor influencing ammunition performance", and that this factor is controlled by the shooter.

During ECHA's call for evidence some concerns were raised on the comparisons made above, arguing that doves are easier to kill than waterbirds and that it would be more useful to repeat the experiment on more resilient game birds such as ducks and geese. This type of research would alleviate concerns about the increased risk of accidentally injuring game birds when using steel shot. However, results similar to the Pierce et al. (2014) study were found in the Norwegian "Testjegerprosjektet"¹¹² – a project where 75 hunters reported more than 3 000 shots of different materials (lead, steel, bismuth, tungsten-matrix and hevi-shot) fired at game mammals, water birds, grouse and dove species, as well as capercaillie and black grouse. It was concluded that as long as one follows recommendations for the size of shot pellets and keeps within a maximum distance of 35 m from the target, there are suitable alternatives to lead shot for all hunting forms.

In light of the above findings, shot material seems to play a secondary role in shooting performance. The issue of crippled game is related primarily to the shooter's habits rather than the ammunition type (COWI, 2004). The right choice of shot size, shooting distance, cartridge quality and conformity plays a more essential role. Based on the literature reviewed the Dossier Submitter concludes that crippling loss is related more to the experience and skill of the shooter, than to the material used in the ammunition. Shooters may need to adapt to different ammunition, but once this has taken place steel shot can be used as effectively as lead shot, without a concurrent increase in the wounding of birds.

As already discussed, flight times and thereby the need for 'lead' can be adjusted by the choice of shot size in combination with muzzle velocity. One difference is that hard shot cartridges, such as steel gunshot, produce slightly tighter patterns than lead shot with a given barrel choke. This may cause a need of higher precision - something that is often reported by shooters that change from lead gunshot to steel gunshot without making the basic adjustments of equipment. On the other hand, the more concentrated shot cloud is an advantage in order ensure pattern cover (efficiency) over longer shooting distances.

The major constraint in optimising the practical efficiency is the ability of the shooter to hit the target precisely. Shooting distance is proven to be one of the crucial factors as it influences both the basic ballistics of the shot (technical efficiency), but first and foremost the practical efficiency in terms of the shooter to hit the target. Hitting and bagging rates decrease with distance, and crippling rates increase with distance, regardless of the ammunition type being used.

¹¹² Report: «Norges Jeger- og Fiskerforbunds Testjegerprosjekt – en vurdering av drepeevne for ulike hagltyper», 2006.

E.3.1.3. Suitability of guns

This section deals with whether hunters can use steel gunshot in the shotgun they currently own.

Construction and condition

For modern guns, those produced after 1960, there are several elements that should be taken into account when considering their suitability for use with steel gunshot. One is the **construction** meaning the strength and thickness of the metal parts used, primarily the barrel, which in simple terms is comprised of three regions: the chamber, the bore and the choke.

Shotguns, like other firearms, have been developed to fulfil many different purposes. Hence, they have been produced in a variety of constructions from very light to heavy (robust) types and in many different calibres.

Examples of light shotguns, typical known as "English guns", are built with thin-walled barrels (although usually thicker than 0.55 mm¹¹³) and are usually chambered for 65 mm cartridges and are intended to be used at short range (much less than 35 yards). Such guns are often regarded as "elegant" and their value is often based on more aesthetics than utility.

As they are often rather costly, owners will limit the use to special types of shooting where the gun can be handled without risk of damage, salt water exposure etc. Apart from driven shooting of mallards and other dabbling ducks in inland ponds and lakes, light English guns are rarely used for water bird hunting, particularly hunting that takes place on the foreshore, coast or sea environments. This is because not only are the physical conditions rougher but also the quarry and shooting conditions typically require more powerful equipment.

The most robust shotguns used regularly by water bird hunters are one-barrelled semi-automatic shotguns or pump-action shotguns constructed to fire heavy loads. Such guns are widely used by European hunters for hunting geese and other flock birds where the hunter can benefit from the possibility of firing more than two shots, which is the limit in most traditional (double barrelled) shotguns¹¹⁴. In addition, semi-automatic and pump-action shotguns are easy to maintain and clean after use in the rough environments that are typical for many types of water bird hunting.

Between the categories of light (English) guns and very robust semi-automatic and pump-action shotguns, there are a variety of more 'standard' shotgun constructions. Typically these are double-barrelled 'side-by-side' shotguns, but during the last decades 'over-and-under' construction shotguns have become widespread. These guns are invariably chambered for either 70 mm or 76 mm cartridges so as to fire modern high-velocity cartridges, whether in 12 or 20 gauge (although calibre can vary between 10 to 36). These standard gun types are constructed to fire 'standard' cartridge loads. Many of the guns currently in service are likely to have been manufactured before the health and environment risks associated with the use of lead gunshot were widely known and were

¹¹³ which is the lower limit for acceptability in calibre 12 with Category 1 [standard] steel properties http://www.cip-bobp.org/sites/default/files/new_file/A-4-1_EN.pdf

¹¹⁴ Many European countries set limits on the number of cartridges that semi-automatic and pump-action shotguns may contain at any time whilst hunting.

therefore not specifically designed for use with alternatives to lead gunshot. However, because alternatives to lead gunshot have been developed to match the technical specification of lead ammunition most 'standard proofed' guns can be used safely with 'standard' steel ammunition defined by the 'standard steel' CIP specification (or with non-steel alternatives, such as bismuth or tungsten-based cartridges).

Another relevant element to consider is the **condition** of a gun, i.e. how worn it is and how well has it been maintained. The wear of guns is a result of the general use and a product of rounds of ammunition fired. This should be considered in combination with gun construction, as some guns are more exposed to wear than others depending of e.g. hardness of the steel types used. Guns may have been attacked by corrosion both outside, in the lock/mechanics and inside the barrel. Furthermore, gun owners may have neglected cleaning and maintenance which will accelerate wear and corrosion. As a consequence, some guns – also modern guns – are in such a condition that they should not be used for any kind of shooting with any type of ammunition, including lead ammunition.

Pressure, wear and temperature

The impact of firing a cartridge on a gun can be divided in three main components: pressure, wear and temperature.

Pressure derives from the burning of the powder load ignited by the primer. The pressure level depends on many (interlinked) features, including powder type, load weight (both powder and shot), construction of wad (buffer features), calibre and powder temperature.

Standard chamber pressures under normal shooting conditions (for instance with standard lead shot cartridges) range between 500 and 700 bar, while high performance cartridges may reach chamber pressures of >1 000 bar. Shotguns must be constructed to withstand the chamber pressure generated by firing a cartridge. This is known as the 'proof' level of a shotgun.

Table E-9 provides examples of the chamber pressures (limited to calibre 12) generated by various gunshot ammunition obtained from internet survey or other available data. Pressure levels reported vary between 650 to 920 bar depending on performance and shot material. Higher velocity, heavier loads, will create greater pressure when fired. This is based on the simple physical rules of acceleration and action-reaction. It applies equally to lead and alternative gunshot ammunition. The relevance of pressure when discussing alternatives to lead gunshot is related to the tendency of manufacturers to produce cartridges that generate greater muzzle velocity to compensate for the (normally) lower density of alternative gunshot materials. To achieve greater muzzle velocity cartridges tend to result in greater chamber pressure.

Table E-9. Examples of chamber pressure according to information from the manufacturers. The sample is limited to Cal. 12.

Product	Calibre	Shot material	Load weight (g)	Velocity (m/s)	Pressure (bar)	Type
Fiocchi PL 32	12/67	Lead	32	385	685	Standard
Fiocchi PL 34	12/70	Lead	34	380	680	Standard
Fiocchi PL 34 HP	12/70	Lead	34	405	800	HP
Fiocchi	12/70	Lead	42	390	920	SEMIMAGNUM

SEMIMAGNUM						
Fiocchi STEEL SHOT 32	12/70	Steel	32	410	830	HP
Fiocchi STEEL SHOT 35	12/70	Steel	34	390	820	HP
B&P F2 Long Range	12/70	Lead	36	410	750	HP
B&P Steel Extra Velocity	12/70	Steel	32	440	900	HP
B&P MG2 TUNGSTEN	12/70	Tungsten	35	410	740	HP
Kent Steel Classic	12/65	Steel	24	400	600	Standard

Notes: HP – high performance

It is important to note the relatively low chamber pressure (600 Bar) generated by the Kent Steel Classic cartridge. This is a 65 mm long 'standard' cartridge that can be fired safely in 65 mm chamber 'standard proofed' gun, such as many of the "English" variety in good condition. Hunters can identify their guns as the chamber length and operating pressure (proof) are typically indicated on the gun itself.

Pressure levels of cartridges (also known as chamber pressure) denote the peak (maximal) pressure achieved during the burning of the powder and whilst the load to passes through the barrel. Figure E-5 shows a typical pressure curve. The impact of the primer can be seen after about 0.1 msec. After that the pressure climbs as the powder burns. A peak of about 800 bar is seen after 0.7 msec after which it declines rapidly after approximately 1 msec. The shot leaves the barrel approximately 3.5 msec after ignition.

Two aspects need to be considered when relating this to lead versus non-lead ammunition. Firstly, the peak chamber pressure achieved is not the primary indicator of the energy and thereby the speed delivered to the shot load. A better indicator is the area below the curve, i.e. the integral of the curve. The area below the curve can be achieved by adjusting the composition of the powder, which has led to improved performance of lead-free cartridges, i.e. to increase velocity and at the same time maintain or even lower the peak pressure. Secondly, the progress of the pressure during the shot, as indicated in Figure E-5, shows that the peak pressure arises when the shot load is still in or very close to the gun chamber, i.e. the part of the barrel that is designed to withstand high pressure.

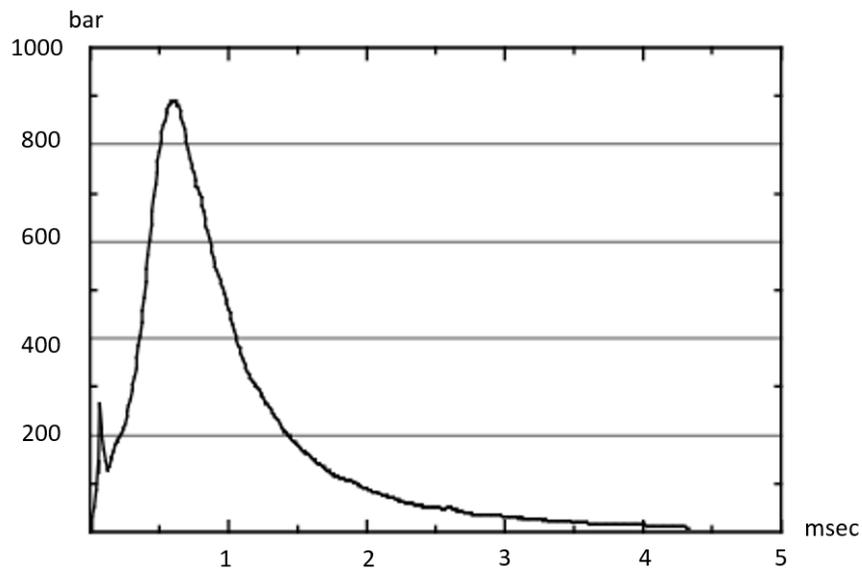


Figure E-5. Progress of chamber pressure during the firing of a shot.

Guns are not only designed but also, normally, 'proofed' to withstand high pressure. The procedure for 'proofing' a gun is to test fire 'proof loads', i.e. special cartridges that exceeding normal chamber pressures. Two well-established institutions, Commission Internationale Permanente Pour L'Preuve des Armes a Feu Portatives (CIP¹¹⁵) in the EU and Sporting Arms and Ammunition Manufactures' Institute, Inc. (SAAMI)¹¹⁶ in the US have set standards for gun proofing.

Figure E-6 shows the chamber pressure levels used to proof shotguns to 'standard' and 'high performance' levels according to CIP regulations. The performance of shot cartridges, particularly the progress of chamber pressure, combined with the construction and proofing of guns is a fundamental security to prevent modern guns from exploding when fired. It is a basic reason why explosion of guns is not regarded as a risk of any significant likelihood.

After more than 30 years' of regulation of lead shot and thus introduction of a variety of lead-free products, e.g. steel shot, Danish experiences have shown no increase in incidents of guns exploding as a result of the change in shot material¹¹⁷. Shotgun barrel blow-ups, when they occur, are caused not by the pressure developed by the shot load, but rather by obstructions in the barrel. Obstructions can take the form of plugs of snow or mud etc. Also, use of shot shells of wrong calibre, for instance 70 mm in 65 mm chamber causes severe stress to the gun chamber and may cause severe damage. Equally, use of the wrong specification of cartridge in a gun, for instance 'high-performance' loads in a 'standard' proofed gun may also lead to damage.

¹¹⁵ <http://www.cip-bobp.org/home>

¹¹⁶ <http://www.saami.org/>

¹¹⁷ http://www.vaabensmeden.dk/sider/jagt/trangboring_staalhagl.htm

CIP sets a maximum velocity for each of the steel shot levels; 400 m/s for Standard Steel Shot, and 430 m/s for High Performance Steel Shot. European members of CIP are: Austria, Belgium, Czech Republic, Finland, France, Germany, Hungary, Italy, Slovakia, Spain and UK.

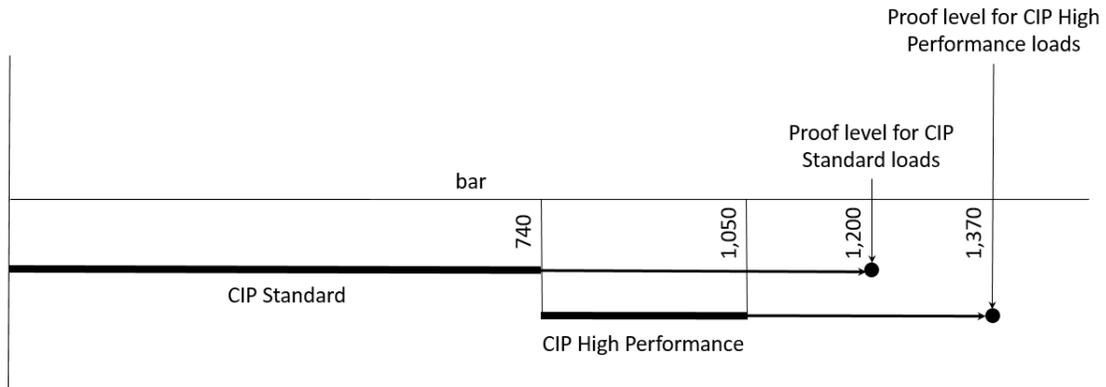


Figure E-6. Chamber pressure and proof limits according to CIP regulations¹¹⁸.

Proofing of guns is accompanied by proof marks that are stamped into the metal of the gun barrel (typically in the parts underneath the chamber). In a European context the most reliable system of proof marking is that used by the CIP. The CIP system uses a "Standard Mark", a "Superior Mark" and a "Steel Mark". These terms apply to the performance (pressure) of the cartridges that can be used in a gun. A general observation is that the marking can be interpreted equally for lead shot and alternative shot types, including steel, bismuth and tungsten (matrix types).

Standard or superior/magnum-proved guns can fire 'standard' steel and other alternative shot cartridges. To fire 'high performance' steel cartridges, the gun is recommended (by the CIP) to be subject to the "Steel Shot" proof, which is a more rigorous test of the gun's ability to handle the pressures and shot hardness of steel/steel-like shot cartridges. A gun successfully passing "Steel Shot" proof will be stamped with a Fleur de Lys on its barrel, se Figure E-7 (right).

¹¹⁸ <http://www.gma.vic.gov.au/education/fact-sheets/non-toxic-shot/steel-shot-standards-pressures-and-proofing>

CIP Standard Mark	CIP Superior Mark	CIP Steel Mark
CIP N	CIP S	CIP 

Figure E-7. Proof marks used by CIP.¹¹⁹

Practical guidance for hunters on how to be sure that steel shot can be used in the shotgun they currently own can be found on the websites of the BASC (UK) and the website of the Victoria Game Authority (AUS):

On the use of steel shot in guns the BASC notes the following¹²⁰:

For steel-like shot the CIP imposes limits on velocity, momentum (weight of load x velocity), and pellet size. For pellets BB and larger it also limits choke, to maximum half choke.

Currently the regulations cover 10 bore, 12 bore, 16 bore and 20 bore guns/ cartridges. There are two types of steel shot cartridges: Standard and High Performance.

- *Standard steel shot cartridges, meeting defined limits of cartridge size, and shot velocity and momentum, can be fired through standard and magnum-proved guns.*
- *High Performance steel cartridges, with their own, higher, size, velocity and momentum limits, are to be fired only through guns which have passed special steel shot proof.*

Some hard tungsten-based shot types are now treated as steel, and are to be used accordingly.

Most tungsten-based shot types, though, including ITM, TMX, Hevi-shot II (but not Hevi-shot I) and others, are made to a similar softness to lead and are treated by CIP as lead.

This is stated again on the website of the Victorian game authority¹²¹

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. If in doubt about your gun - see a competent gunsmith.

¹¹⁹ <http://www.cip-bobp.org/poincons>

¹²⁰ <https://basc.org.uk/wp-content/plugins/download-monitor/download.php?id=722>

¹²¹ <http://www.gma.vic.gov.au/education/fact-sheets/non-toxic-shot/steel-shot-standards-pressures-and-proofing>

Practical guidance is also available for hunters in Germany^{122,123,124}, France^{125,126}, Austria (Putz, 2012) and France (Baron, 2001) and is all of a similar nature, explaining to hunter which sort of cartridges can be used in guns with different proof marks (Summarised in Table E-10).

Table E-10 Operating pressure, cartridge size and proofing¹²⁷

cartridge type	cartridge size	max operational pressure (bar)	max velocity (2.5 m after muzzle) m/s	max impuls (NS)	max shot size	gun proofing
standard	12/65 - 12/70	760	400	12	3.25	normal
high performance	12/70	1050	430	15	no limit	steel proof
high performance	12/76 and above	1050	430		no limit	steel proof

This advice is in line with the CIP specification on the use of steel shot. It must be noted that if any of the limits for the standard proof are exceeded, then the cartridges must be treated as high performance cartridges and can only be used from a steel proofed gun (with fleur de lys).

Using steel gunshot cartridges therefore becomes a matter of carefully selecting cartridges based on the specification of the shotgun that a hunter owns. The CIP specification for standard and high performance steel cartridges, and the BASC's explanation of these specifications, clearly outline the types of steel gunshot cartridges that can be used in different shotguns¹²⁸. Not complying with these rules can result in 'ring bulging', overload and increased wear and tear in guns.

Wear of the gun barrel derives primarily from the friction of the shot load passing through the barrel. The load consists of two elements: The load of shot pellets (in normal cal. 12 loads 30-34 gram) and the wad that provide a seal that prevents gas from blowing through the shot rather than propelling it. Originally, wads were made from felt or paper, but more recently, plastic has become the most used material. At the same time the wad has been developed not only to provide a seal between the powder and shot but also to prevent direct contact between the gunshot pellets (the load) and the inner wall of the barrel, which is achieved by constructing the wad like a cup that contains the load.

This applies for most shot types, including also many lead shot cartridges. For soft materials like lead the primary reason for preventing contact between shot and barrel is to minimise deformation of shot and thereby optimising the pattern of the shot cloud. For

¹²² http://www.flintenschuetze.de/cms/front_content.php?idcat=119

¹²³ http://www.jagd-bayern.de/fileadmin/BJV/Jagd_In_Bayern/jib_2006_07/JiB_7_06_Alternativ_Schrote.pdf

¹²⁴ https://www.beschussamt-ulm.de/beschussamt/Interne_Dokumente/Dokumente/VF_504_M_Info-Verwendung-Bleifreie-Schrote.pdf?m=1488869144

¹²⁵ http://www.fdc54.com/fichiers/munitions_sans_plomb.pdf

¹²⁶ <http://www.syndicatdelachasse.com/actu04/dec/acier.pdf>

¹²⁷ http://www.flintenschuetze.de/cms/front_content.php?idcat=119

¹²⁸ <http://www.chircuprodimpex.ro/produse/alice-non-toxice-de-vanatoare/cip-regulations-on-steel-shot-ammunition.pdf>

hard materials like steel the reason to use a plastic wad is mainly to prevent the hard pellets damaging the barrels of softer and not hardened steel qualities. Due to the use of modern plastic wads the use of hard pellets does not impose an increased risk of wear in the barrel bore. The only point along the barrel where some wear might arise is when hard shot passes through the choke (the narrowed portion at the mouth of the gun barrel).

The chokes used in shotguns produced by different manufactures are not consistent, uniform manner. Concerns relating to the use of steel gunshot pertain to abruptly-developed, as opposed to progressively-developed, chokes¹²⁹.

It is possible that large hard shot (larger than US #4 steel, 3.5 mm diameter) passing through an abruptly developed, tightly-choked barrel, could cause a small **ring bulge** to appear around the choke conus, simply because the hard shot do not deform when passing through the constriction. This does not occur if the barrels are more openly choked, such as "modified" or "improved cylinder". This is the essence of the concerns about wear from hard non lead shot types, such as steel. Ring bulges are also known to occur in shotgun barrels when large lead shot pellets are fired through tight chokes. A gun barrel with a ring bulge can continue to fire any shot type. It is a cosmetic change, and not related to safety or the risk of exploding barrels (Thomas et al. 2015). This might however decrease the value of the gun.

In addition, wear of gun is also caused by the physical impact released by the recoil from heavy loads, which may cause stress to the gun lock and stock Recoil is a function of, powder type, load weight and velocity and, in principle, independent of shot material.

However, as lead-free shot is normally accelerated to a higher velocity there is a general tendency that alternative gunshot may cause a more pronounced recoil, though lighter loads and improved powder composition can compensate for this. Danish gunsmiths have experienced that guns more regularly need maintenance and lock repair when firing large numbers of rounds of high velocity (>420 m/s) cartridges with steel shot. This applies only to standard guns that are not constructed to deal with heavy recoil¹³⁰, but would equally apply to heavy load lead shot cartridges.

The Victoria game authority mentions that the effect of steel shot on the barrels of a selection of 10 English and European manufactured firearms was undertaken by the Royal Military College of Sciences in the UK in 1996 (Report no longer publicly available). The types of firearms used included a Browning U/O, Beretta U/O, Miroku U/O, Purdy SxS, Holland and Holland SxS. All guns used were full choke models, some with integral chokes and some with screw in chokes. After over 9 000 standard steel shot cartridges had been fired through the ten different guns, no measurable damage had occurred to any of the guns. The standard cartridges used recorded muzzle velocities in the range of 377 m/s to 392m/s with shot weights between 24 and 32 grams. These were regarded as being fairly light for game loads. Three of the guns were then tested with cartridges loaded to produce much higher muzzle velocities (438m/s, 28 gram) and in each case deformation of the chokes resulted after approximately 50 cartridges were fired.

¹²⁹ In firearms, a choke is a tapered constriction of a shotgun barrel's bore at the muzzle end. Chokes are almost always used with modern hunting and target shotguns, to improve performance. Its purpose is to shape the spread of the shot in order to gain better range and accuracy. Chokes are implemented as either screw-in chokes, selected for particular applications, or as fixed, permanent chokes, integral to the shotgun barrel.

¹³⁰ Nystrøm & Krabbe, gun and ammunition retailer.

Coburn (1991) reported, from the Winchester perspective, that ring bulging has not been a significant issue over the twenty or so years since steel shot was introduced, although it has occurred, usually in full choked barrels, either as integral chokes or screw-in chokes. Where this has been known to occur, the actual deformation was in the range of three to five one-thousandths of an inch (0.003 to 0.005 inch), which is barely discernible to the naked eye. In the early days for some screw-in chokes, the threading expanded and chokes were difficult to remove, however, today, manufacturers have overcome this problem through redesign.

The third impact factor is temperature, i.e. the heating of the shotgun barrel and lock after firing multiple rounds of ammunition over a short period of time. This is only discussed briefly here but is known particularly from the hunting of game species occurring in large numbers, for instance during driven shoots or excessive pigeon and dove hunting.

Heating derives from the burning of the powder, the pressure and the friction of the shot and wad against the barrel wall. There is very little information about the effect of different shot types and cartridge constructions on temperate. Temperature and heating *per se* is not a significant concern, apart from certain gun types, e.g. semi-automatics where excessive heating may cause increased wear on sliding mechanisms due to reduced effectiveness of greasing. However, in the context of water bird hunting in a Europe context the number and frequency of shots taken is regarded, broadly, to be limited, and the concern of heating of guns seems to be of very low importance. There is no indication that lead-free ammunition should impose a greater impact than leaded ammunition in this regard.

Possibilities for non-steel proofed guns

The advice offered by manufacturers to customers asking if their gun are suitable for use with steel gunshot have been compiled from a selection of manufacturers’ websites (Table E-11).

Table E-11 Advice from shotgun manufacturers on the use of steel shot in shotguns (non-exhaustive list)

Manufacturer	Advice given (direct quotes from websites)
Remington	<p>We do not recommend the use of steel shot through any barrel manufactured before 1963 or through any barrel having a fixed Full choke. Anything larger would not perform well out of a fixed full choke and could open up your muzzle over time.</p> <p>If you have barrels manufactured after 1963, with fixed Modified or Improved Cylinder chokes, you may shoot up to size #2 steel shot. The use of steel shot larger than size #2 is only recommended in modern barrels with the Rem Choke system.</p> <p>If you have the Rem Choke system, you may shoot any size steel through the Improved Cylinder and Modified choke tubes. The Full choke tube must state "For Steel or Lead" to be capable of handling steel shot.</p> <p>Source: https://support.remington.com/General_Information/Can_I_use_steel_shot_in_my_shotgun_barrel%3F</p>

Manufacturer	Advice given (direct quotes from websites)
Winchester	<p>Generally speaking, any shotgun designed for smokeless powder is able to withstand the pressures generated by today's steel shot loads, within the appropriate chambering. As steel shot does not compress like lead, we do not suggest using steel shot through firearms with a full-choke. We do not suggest the use of steel shot in the Winchester Model 59 with a fibre glass barrel.</p> <p>Source: http://www.winchester.com/learning-center/faqs/firearms-guns/Pages/Firearms-and-Guns-Question02.aspx</p>
Browning	<p>1. WILL ACCEPT ALL CURRENT FACTORY STEEL SHOT LOADS: All Browning shotguns with the Standard Invector, Invector-Plus or DS choke tube systems, However, we do not recommend the use of Invector full or extra full chokes with steel shot. They pattern too tightly, and sometimes result in a "blown" pattern.</p> <p>2. WILL ACCEPT ALL CURRENT FACTORY STEEL SHOT LOADS EXCEPT THOSE WITH T, F, BB AND BBB SIZE SHOT: The B-2000 and B-80 shotguns with conventional chokes (Non-Invector)</p> <p>3. DO NO USE ANY STEEL SHOT LOADS: The Belgian-made A-5, Superposed, Leige, and other Belgian Over/Under models, Double Automatic, American-made A-5 and all other models not listed in category 1 or 2. Note: Belgian Auto-5 barrels are interchangeable with the new Invector barrels which are made in Japan. With this new Invector barrel installed on the Belgian-made Auto-5 receiver, steel shot loads can be used.</p> <p>Source: http://www.browning.com/support/frequently-asked-questions/can-i-shoot-steel-shot-in-my-browning-shotgun.html</p>
Beretta	<p>The manual (available at : http://stevespages.com/pdf/beretta_shotguns.pdf¹³¹) explains how to change the choke so as to be able to safely use steel shot in Beretta shot guns</p>
Bernelli	<p>The manual (available at : http://www.benelliusa.com/sites/default/files/originals/product-manuals/ethos_2013.pdf) explains how to change the choke so as to be able to safely use of steel shot in Bernelli shot guns</p>

Furthermore tests conducted by the French hunting association demonstrated that steel shot can be used on a wide variety of shotguns that were available on the market in 2004.

¹³¹ The original manual can be purchased at: <http://estore.beretta.com/en-eu/beretta-overandunders/side-by-sides-owner-manual-ita-fr-eng/>

All guns that were used were successfully used during hunting and shooting with only one gun demonstrating minor bulging (Table E-12).

Table E-12 Overview of tests performed by ONCFS on use of steel shot (Source: Faune & Sauvage, Avril 2004)

Gun type	Degree of choke	Choke type	Sold as steel proof ¹ "	Sold as suitable for steel ² "	Found to be suitable during programme "	Used for hunting ⁴	shot intensively ⁵
AYA juxtaposé	lisse amélioré et ¾					x	
Baikal juxtaposé	½ et full					x	x
Baikal juxtaposé	½ et ½				x	x	x
Baikal superposé	½ et full					x	x
Benelli auto. Super 90	½	VI			x	x	x
Benelli auto. Super 90	¾	VI				x	x
Beretta auto. A 301	¼				x	x	
Beretta auto. A 302	lisse	VE			x	x	
Beretta auto. A 303	lisse	VI			x	x	
Beretta auto. AL 390	full	VI	x			x	x
Beretta superposé Sporting	½ et full	VI		x		x	x
Bettinsoli silver Magnum	lisse et ¼	VI			x	x	
Browning Gold	¾	VI				x	x
Browning Waterfowl	¼ et ½	VI	x			x	x

Gun type	Degree of choke	Choke type	Sold as steel proof ¹ "	Sold as suitable for steel ² "	Found to be suitable during programme "	Used for hunting ⁴	shot intensively ⁵
Fabarm auto. Ellegi	full	VI				x	x
Fabarm superposé Eura mag	lisse amélioré et ½	VI	x			x	x
Fabarm superposé	lisse et ¼	VI			x	x	x
Manufrance auto. Perfex	½					x	
Manufrance semi-auto rapide	½				x	x	x
Manufrance Robust	¼ et ¾					x	
Manufrance Robust (magnum)	½ et full					x	x
Merkel juxtaposé	½ et full					x	x
Remington auto. 11-87	½				x	x	x
Ugartechea Canardouze	full				x	x	
Valmet superposé (900 bars)	½ et ¾					x	
Verney Carron Trap	½ et full					x	x
Verney Carron sagittaire NT premier	¼ et ¾					x	x ⁶
Verney Carron sagittaire NT sous bois	lisse et ½					x	x

Gun type	Degree of choke	Choke type	Sold as steel proof ¹ "	Sold as suitable for steel ² "	Found to be suitable during programme "	Used for hunting ⁴	shot intensively ⁵
Verney Carron auto. AGO	¼					x	x
Verney Carron auto. Super léger	½					x	x
Verney Carron auto. Super léger	full					x	x

Notes: VI ou VE : interchangeable choke (VI : vissage intérieur ; VE : vissage extérieur) ; 1 Guns was bought bearing the fleur-de-Lys Mark); 2 Guns was guaranteed to be suitable for steel, but not steel proofed according to CIP rules); 3 The gun was found to be suitable for steel during the test; 4 The gun was used to hunt; 5 The guns was used to shoot intensively (at shooting range); 6 Gun was found to have some minor bulging.

The conclusion of this assessment, is that if a gun has no steel proof mark then this does not mean that it cannot be used with steel shot on the condition that the right cartridges are used. The shotgun can still be used if attention is paid to selecting the right cartridge type that is compatible with shotgun that is used, especially chamber length, and pressure of the cartridge (Putz, 2012).

As explained by the BASC and the Victorian game Authority, the actual risk depends on the selection of cartridges and ensuring that cartridges are used that match with the proof level of the shotgun.

Putz (2012) argues on the basis of an analysis of the characteristics of the lead-free cartridges provided by one German manufacturer (Rottweil) that hunting ducks and fowl can still continue with steel cartridges of which the maximum diameter of the pellet is not bigger than 3.25 mm. In line with the guidance given as well as the German website and advices that were consulted as well as the findings of Ronholt (1991) that steel shot exhibited somewhat different ballistic properties compared with lead. However, it could be used effectively within normal hunting ranges and Hartmann (1982), concluding that steel shot are suitable for water bird hunting within normal shooting distances (max. 35 m).

For those hunting geese, hare, foxes bigger shot sizes are needed and consequently, following CIP rules, steel proofed guns would be required (Putz, 2012). However, this is subject to debate as many hunters use 'magnum proof' shotguns which are capable of withstanding higher pressures than those generated with standard lead shot. Hence, with suitable cartridges adaptations can be made.

However, the considerations surrounding the proofing of guns may leave a concern that many modern guns may be proofed only to a standard level and owners therefore may hesitate to use them with the most available non lead ammunition, i.e. steel shot in the range of standard and high performance types. This concern in reality is more related to the question of availability of lead-free ammunition suited for their gun, particularly on the local scale. To evaluate this quantitatively the distribution of different gun types among European hunters is needed. Unfortunately, no such statistics are generally available, neither of the types and constructions of guns owned by hunters, nor of the distribution of guns used in different types of hunting, including hunting in wetlands.

In the UK, where all guns are certified, it is assessed that 600 000 hunters and other shotgun certificate holders possess approximately 300 000 "older guns" out of total of 1.35 million shotguns (Lead Ammunition Group 2015). This indicates that fewer than 25 % of the total shotgun population is categorised as "older guns". Furthermore, these figures show that holders by an average possess 2.3 shotguns each, which is an indication that hunters keep guns for different purposes.

Another observation of relevance is that the major gun makers who export a large proportion of their guns to countries that already have lead-free shot regulations in place, such as the US and Canada, already make their guns capable of firing lead-free shot loads. Thus the gun making industry has already responded pro-actively in addressing the present and future needs of the shooting and hunting communities.

COWI (2004) estimated the share of guns that are not suitable for use with steel shot (Standard steel shot) to be around 10-20 % and makes note of the fact that this was a rough estimate as statistical records on the issue were not available.



Notes: **Top:** Belgian double-barrelled 'side-by-side' hammer gun cal. 16 from the "NON POUR BALLE" period 1878-1897 with Damascus barrels. *A vintage gun that should not be fired with any type of modern cartridge without first seeking the advice of a professional gunsmith.* **2nd from top:** A modern Spanish 12/70 double-barrelled 'side-by-side' shotgun proofed for standard ammunition and well-suited for standard loads of lead, steel and other lead-free types. *Used occasionally since 1987 for upland/forest game shooting with bismuth and steel shot loads.* **3rd from top:** Browning Mod L-25, cal. 12/70, double-barrelled 'side-by-side' steel proofed shotgun (suited for standard and high velocity steel shot, as well as lead and other lead-free types). *Used very frequently since 1998 for upland/forest/foreshore hunting, and training with steel shot (> 1 000 rounds annually).* **4th from top:** Beretta semi-auto Mod A. 301 ca. 12/70, steel proofed shotgun. *Used frequently since 1995 for goose hunting on foreshore and sea duck hunting on open sea (> 300 rounds annually).* **Bottom:** American Mossberg cal. 12/76, steel proofed semi-auto. *Used regularly since 1992 for hunting and testing purposes.*

Figure E-8. A selection of shotgun types typically possessed by European hunters.

As to the experiences from Denmark, where the phase-out of lead shot was initiated in 1985, the suitability of guns at that time was a big issue. This was mainly due to the fact that the choice of lead-free cartridges was limited to a few American brands – all steel shot types that were not adapted to the guns commonly used by Danish hunters.

A part of the governmental and private campaign to support the phase out of lead shot was to recommend (and facilitate) hunters to get their guns proofed and checked. In most cases the guns passed the proofing. In other cases, the hunters took the consequence by replacing their gun. In many cases, tight choked guns were modified (opened) to fit better with the available ammunition. Today, most experts regard these modifications as unnecessary as the development of lead-free ammunition went much faster than expected, not least supported by European (including Danish) ammunition manufacturers that started production of types fit to Danish conditions.

During the late 1980s and early 1990s when the decision of a total ban of lead shot was taken (coming into force in 1996), the debate on guns silenced as the severe damages to guns (explosions etc.) caused by lead-free ammunition that was predicted earlier, never became a reality. Also, availability of new shot types as bismuth and tungsten fulfilled the needs of the hunters that could not adapt their guns to use steel gunshot.

In his assessment of the impact of using alternative shot in Austria, Putz (2012) gives no assessment of the number of guns that require replacement. He does refer to personal communication with the Norwegian hunting association indicating that following the ban on the use of lead shot no major deformations (bulging) of guns were registered and no major surge in purchasing new guns was observed. According to that communication most hunters switched to bismuth or other alternatives such as tungsten.

At present, in Denmark, hunters can be broadly categorised into different four groups:

(1) A group of a few but very enthusiastic and knowledgeable hunters that specialise in using vintage guns in some cases only with lead-like shot types mainly bismuth, but also steel shot in light loads typically in vintage designs with paper cases and felt wads.

(2) A (larger but limited) group using light 'side-by-side'¹³² English and Spanish guns proofed to standard levels and with the use of either bismuth or light standard steel loads – mainly for upland and forest hunting.

(3) A very large group of ordinary hunters using a mixture of rather robust, modern guns typically 'over/under'¹³³ with standard or high performance steel shot and for hunting a broad variety of game species in forests, upland, foreshore and sea.

(4) A rather specialised group of water bird hunters using semi-automatic or pump-action guns combined with high performance and magnum steel shot.

Single hunters may be present in more the one group. It is rather normal that hunters possess different guns for different purposes, as indicated earlier for British hunters.

This categorisation is not based on statistics but rather on the views of a range of an experts consulted as part of the preparation of the dossier¹³⁴.

There is no reason to believe that the development that has been seen in Denmark could not take place in other European countries where the regulation of lead shot for hunting

¹³² Where the barrels of a double-barrelled shotgun are arranged one next to the other (left to right),

¹³³ Where the barrels of a double-barrelled shotgun are stacked one on top of the other.

¹³⁴ Personal communication, Per Langvad, PL Guns. <http://www.plguns.dk/>, Niels Kanstrup and John Swift.

has not yet been initiated. An important difference is that the development of non-lead shot cartridges today is much further advanced than 30 years ago, when Denmark and a few other countries initiated the process. A wide variety of non-lead cartridges are now available from most European manufacturers or supplied by North American brands. The further regulation of the use of lead gunshot in member states is expected to stimulate the distribution of wider selection of non-lead shot types, suited for the actual population of guns.

Replacement

There are very few data available on the number of 'old guns' in the EU that may need to be replaced as a result of the proposed restriction. This is because in many Member States shotguns are not registered, especially old guns. Therefore, estimations of the share of old non-suitable guns among hunters could be very biased. It is not known to what extent old guns are actually used in the field e.g. for waterbird hunting.

Some guns may not be suitable for use with certain types of lead-free shot types, particularly hard shots such as steel. Hence, some hunters may choose to replace their shotgun, and a regulation of lead shot ammunition on the European level would impose an extra cost to such hunters.

Shotguns may be purchased either as new guns or second-hand. The cost of a gun is not linked to its utility but mostly to other features, e.g. brand, stock quality and cosmetics (engraving and other decorations). Furthermore, the prices vary between countries.

However, judged from a sample of online stores in five different EU Member States, prices for shotguns suited for the use of lead-free shot, including high performance steel shot cartridges, range from approximately € 500 (for instance a Frankonia Magnum 12/76, over/under, in Slovenia at € 490, second-hand) to several thousand Euros. Typical prices for a suitable new or well-maintained second-hand gun are approximately € 1 000 Euros (for instance a new Beretta A300 Outlander 12/76, semi-automatic in Finland at € 890, or a new Bok FAIR Premier, over/under, in Poland at € 1 000). To many hunters such a cost may not be regarded as negligible. However, as the typical service life of a shotgun is likely to exceed 15 years it is likely to be considered to be affordable given the average annual hunting budget of a European hunter, which is estimated to be € 2 400 (Kenward et al., 2009).

Hunters who are in doubt of the suitability their gun(s) can get advice from a gunsmith, or submit a gun for 'proof testing' (also termed 'pressure testing' or 'proofing'. A typical price for a pressure test is around 70 Euros. The price level for a modification of the choke, if recommended, is also around 70 Euros per barrel¹³⁵.

Guns that can fire standard lead shot cartridges safely can also fire standard lead-free shot cartridges safely, provided that they are the same length, and of an equivalent load weight (Thomas et al. 2015). Thus lead-like shot types like tungsten matrix shot or bismuth-tin can be used confidently in any standard-proofed European gun with any choke constriction.

Also, standard steel gunshot cartridges can be used in any modern gun (most guns built after 1961) typically used to fire lead gunshot cartridges. The only possible concern about

¹³⁵ Mr. Thorkild Voigt, Korsholm Skjern. <http://www.korsholm.dk/>

the use of steel gunshot and other 'hard' gunshot in standard guns pertains to the 'choke region' of the barrel (near the muzzle), where large shot (typically considered to be larger than 3.5 mm diameter) passing through an abruptly developed, tightly-choked, barrel could cause a small ring bulge to appear around the choke conus. However, this is considered a cosmetic, rather than a safety, concern.

As to the use of 'robust guns', be that side-by-side, over-and-under, semi-automatic 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 water bird hunting depending on quarry size, hunting conditions, shooting distances.

Waterbird hunting in Europe is generally performed with robust guns. This is driven by two main factors: 1. That waterbird hunting due to the size of quarry and rather rough environment calls for robust equipment, and 2. That many European countries already have established regulations prohibiting the use of lead gunshot, hence this has motivated hunters to already adopt lead-free hunting, which in terms of waterbird hunting is generally regarded to be using with steel gunshot cartridges.

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.

Thus, the gun making industry has pro-actively responded in addressing the present and future needs, as major gun manufacturers export a large proportion of their guns to countries that already have lead-free shot regulations in place (e.g., the US and Canada), their guns are already now able to firing standard and high performance lead-free shot.

In conclusion, many guns manufactured after 1961 can fire standard steel shot. Guns manufactured before this date would need to be proofed (if not already done) at a one off cost of 70 euro and a modification cost of 70 euro for a new choke. All guns manufactured after 1954 will be stamped with the relevant proofing mark. Furthermore for guns not proofed for steel, using standard cartridges remains a viable option for waterfowl hunting.

E.3.1.4. Economic feasibility of non-lead shot

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) (AFEMS, call for evidence). This applies equally to both lead as well as to 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 fundamentally different, though some components of the machinery may be modified and adjusted to change from one shot type to another. Hence, the main driver for (production) cost differences is the cost of the shot material itself and for shot processing.

As to prices for raw material, these are in the following order of magnitude: lead: 2 €/kg; iron: 0.07 €/kg¹³⁶; and bismuth 20 €/kg. Prices vary depending on market demand, purity etc., so these prices should only be seen as indicative. However, they show that bismuth is 10 times more expensive than lead, but at the same time, that lead is 30 times more expensive than iron. This explains, firstly, 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. Secondly, the prices found indicate a market potential for steel shot to be significantly cheaper than lead shot, though this has not yet been demonstrated in the retail of loaded cartridges in Europe.

Further investigations of retail prices of loose shot for hand loaders found no large difference (lead shot app. 3 €/kg¹³⁷; steel shot app. 4 €/kg¹³⁸).

The reason why the much lower material cost of iron does not translate into a pronounced difference in shot sale prices is connected to processing technologies, 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 based almost exclusively on Chinese manufacture. 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 will most likely increase the production capacity and gradually influence the production cost, such that in the longer term 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. This explains why 20 gauge cartridges in both lead and lead-free varieties cost more than 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-up¹³⁹. Understandably, demand has a major effect on price as well as availability of

¹³⁶ London metal exchange reports 300\$/ton (cash buyer) for steel and 2361 \$/ton for lead, confirming the order of magnitude of these price differences. (accessed April 4 2017)

¹³⁷ <http://www.cabelas.com/>

¹³⁸ <http://www.huntinglife.net/>

¹³⁹ R. Cove, CEO, Kent Cartridge, pers comm.

lesser-used cartridge types, both lead and lead-free. This is why 28 gauge cartridges cost much more than 12 gauge cartridges, despite the smaller 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, the price per cartridge for ELEY VIP Bismuth calibre 12/70 (shot size 3.2 mm) was € 1.4 on the webpage of a UK-based supplier¹⁴⁰, but € 2.7 at a Danish store¹⁴¹. This illustrates that the retail price of two identical cartridges may differ by a factor of two depending on market factors.

Table E-13 summaries the retail prices of lead and various lead-free shot cartridges based on the information from different European countries reported in Table E.5. Lead shot cartridge prices vary from € 0.29-0.65 (mean = € 0.45), while steel shot cartridges vary between € 0.23-0.99 (mean = € 0.46). Bismuth (and tungsten cartridges) are significantly more costly with prices between approximately € 1.7-2.5 per cartridge (with a central price estimate of € 2.0).

Table E-13 Comparative prices for of lead and lead-free shotgun cartridges in the EU in cal. 12 (32 gram load). (Summarised after Table E.5)

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

These data support the general finding that prices of lead and steel shot are currently comparable (See also Figure E-9 below), while bismuth (and tungsten), which are produced, sold and used in lower volumes, are likely to remain more expensive than lead (even though the price of bismuth shot may reduce slightly).

¹⁴⁰ <http://www.sportingsupplies.co.uk/contents/en-uk/d194.html>

¹⁴¹ <http://www.iversen-import.dk/bismuth-forrest-vip-32-gr-skovpatron-405-m-sek.html>

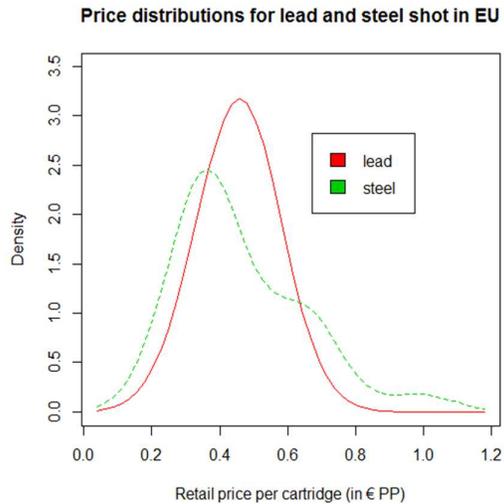


Figure E-9 Price distributions for lead and steel shot in the EU

Prices of lead-free hunting cartridges have been surveyed in other recent studies. For example, Thomas (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 E.14).

Table E-14. Comparative prices for lead and lead-free shotgun cartridges, 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

E.3.1.5. Risks from the use of alternatives to lead gunshot

E.3.1.5.1. Risks to human health and the environment

As previously outlined in Section E.2.2, the US Code of Federal Regulations (CFR) relating to Migratory Bird Hunting¹⁴² (50 CFR part 20) require 'nontoxic' shot to be used as an alternative to lead gunshot when hunting waterfowl and coots throughout mainland US.

Only approved nontoxic shot types can be used and must '*not present a significant toxicity danger to migratory birds and other wildlife or their habitats*'. Approval as nontoxic is obtained by means of an application dossier (and supporting information) submitted to the US Government. Once approved, a nontoxic shot material is listed in the regulations (50 CFR 20.21 – *Illegal hunting methods*).

When the regulations were initially adopted (lead shot was banned nationwide across the US in 1991) the only approved nontoxic shot was steel (iron). The relative safety of steel gunshot was extensively evaluated by the US Fish and Wildlife Service as part of its evaluation of the risks posed by the use of lead gunshot for hunting waterfowl in the US (USFWS, 1976; USFWS, 1986) and concluded that, based on extensive ecotoxicity data, '*there is no evidence that ingested steel shot represents a problem in the management of the waterfowl resource*'. In fact, as elaborated below, steel gunshot is frequently used as the 'negative' control material when assessing the risk of candidate nontoxic shot materials during the US nontoxic approval process.

Since the initial adoption of the regulations various additional shot materials (and coatings) have been approved as nontoxic and, at present, 13 nontoxic shot materials (and coatings) have been approved for hunting migratory wildfowl and coots in the US, as listed below in Table E-15. Approved shot must always contain less than 1 percent residual lead.

Table E-15. 'Nontoxic' shot material approved for hunting wildfowl in the US.

Alternative	Composition
Bismuth-tin	97 % bismuth, and 3 % tin
Iron (steel)	iron and carbon
Iron-tungsten	any proportion of tungsten, and ≥ 1 iron
Iron-tungsten-nickel	≥ 1 % iron, any proportion of tungsten, and up to 40 % nickel
Copper-clad iron	84 to 56.59 % iron core, with copper cladding up to 44.1 % of the shot mass
Tungsten-bronze	51.1 % tungsten, 44.4 % copper, 3.9 % tin, and 0.6 % iron, or 60 % tungsten, 35.1 % copper, 3.9 % tin, and 1 % iron
Tungsten-iron-copper-nickel	40–76 % tungsten, 10–37 % iron, 9–16 % copper, and 5–7 % nickel
Tungsten-matrix	95.9 % tungsten, 4.1 % polymer
Tungsten-polymer	95.5 % tungsten, 4.5 % Nylon 6 or 11
Tungsten-tin-iron	any proportion of tungsten and tin, and ≥ 1 iron
Tungsten-tin-bismuth	any proportion of tungsten, tin, and bismuth

142

https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=5ababa702a49a9d37728a50267453212&ty=HTML&h=L&mc=true&r=PART&n=pt50.9.20#se50.9.20_121 [accessed 01.02.2018]

Alternative	Composition
Tungsten-tin-iron-nickel	65 % tungsten, 21.8 % tin, 10.4 % iron, and 2.8 % nickel
Tungsten-iron-polymer	41.5–95.2 % tungsten, 1.5–52.0 % iron, and 3.5–8.0 % fluoropolymer

Note: Coatings of copper, nickel, tin, zinc, zinc chloride, zinc chrome, and fluoropolymers on approved nontoxic shot types also are approved.

The data required to support an application for approval as nontoxic is specified in part 20.134 of the US Code of Federal Regulations and are organised across three tiers, with increasingly detailed ecotoxicological information required at tiers two and three. In some cases approval may be granted after a relatively straightforward Tier 1 assessment whilst additional, more involved, Tier two and three data on environmental and avian ecotoxicity may be necessary to justify approval as 'nontoxic' if lower tiers of assessment are inconclusive.

Tier 1 information requirements consist of a description of the physico-chemical properties of the shot material as well as information on environmental fate and behaviour (including dissolution in the environment and biological fluids), acute toxicity and ecotoxicity, and a summary of known acute, chronic and reproductive toxicological data with respect to birds, particularly waterfowl. Based on this information a simple risk characterisation is undertaken.

Where a decision cannot be made based on tier 1 information, tier 2 and tier 3 data may be requested comprising, at tier 2, *in vivo* testing of the acute (30 day) effects of exposure via ingestion to mallards as well as additional aquatic ecotoxicity testing with *Daphnia* and fish larvae. Tier 3 data comprise further standardised chronic (at least 60 days) toxicity study with mallards as well as standardised 'chronic dosing' study with mallards to determine the effects from the ingestion of the candidate shot material on reproduction. It is noteworthy that the standardised testing methods required for acute, chronic and reproductive assays with mallards require lead gunshot to be used as the 'positive control', whilst steel gunshot is required to be used as the 'negative control'. A further 'placebo' is used as the standard control material.

Importantly, the regulations state that no material can be approved as nontoxic if the lead concentration is greater than or equal to 1 %. In addition, approved nontoxic shot must be identifiable by enforcement officers by means of an appropriate 'field testing device', which could comprise regular or rare-earth magnets¹⁴³.

The following paragraphs summarise the key relevant information relating to the approval of 'bismuth/tin', 'tungsten-bronze', 'tungsten-iron', 'tungsten-tin-bronze' and 'tungsten-matrix' as nontoxic shot material for hunting wildfowl and coots in the US. Although these are not the only materials that have been approved as 'nontoxic' in the US they are considered, based on market analysis undertaken for the development of this dossier, to

¹⁴³ For example, the US regulations refer to the Stream Systems 'HOT*SHOT' field testing device as suitable non-invasive means to differentiate between lead, steel, bismuth shot materials during compliance testing. https://www.streamsystems.com/stream_website/hotshot/more_info/hotshot.htm

be those, in addition to steel (iron), that are most likely to be used in the EU in response to the proposed restriction.

Bismuth-tin (97 % bismuth, 3 % tin; with < 1 % lead) was approved as 'nontoxic' in March 1997 by means of a decision published in the US federal register¹⁴⁴, which includes a summary of relevant ecotoxicity studies and data and references to original study reports. The decision reports the results of three additional tier 3 ecotoxicity studies (acute, chronic, and reproductive toxicity) undertaken by the applicant (Bismuth Cartridge Company) that '*indicate that bismuth-tin shot is nontoxic when ingested by waterfowl*'. These studies are summarised in the following paragraphs. In the same decision, the US Fish and Wildlife Service notes that it considers that any bismuth-tin shot containing >1 % lead to be toxic. It should also be noted that bismuth metal is not subject to any harmonised (or voluntary) classification in the EU for either human health or environmental hazards¹⁴⁵.

In the acute study (Sanderson et al. 1995, cited in US Federal Register decision), effects on survival, body weight, organ weights (liver, kidney, gonad and gizzard) and haematocrit values were similar between treatment groups receiving either six No. 4 bismuth-tin shot or six No. 4 steel shot and the control (placebo group), indicating no adverse acute effects from ingestion.

The 14-week chronic study (Sanderson et al. 1996, cited in US Federal Register decision), which was conducted during cold weather with a nutritionally deficient diet, comprised 65 male and 65 female mallards dosed on day 0, 20, 60 and 90 with either No. 4 lead, steel or bismuth-tin shot, or a placebo. All birds that had been dosed with lead shot died within 14 days of the initial dosing. All birds dosed with either steel or the placebo survived until the end of the dosing period. A single female from the bismuth-tin treatment group died of undetermined causes 131 days post dosing after laying 16 eggs. In general, the study notes that absence of any deleterious effects from dosing with bismuth-tin shot. The absence of effects noted for the treatment group dosed with steel gunshot supports the conclusions of the previous studies on the toxicity of steel gunshot (reported above).

The reproductive study evaluated effects on reproduction, fertility and egg hatchability and was conducted and reported alongside the chronic study described above (Sanderson et al. 1996, cited in US Federal Register decision). Endpoints assessed for eggs included weight, shell thickness and content analysis. Endpoints for ducklings were body weight, sex-ratio, blood and organ analysis. The study reported no significant differences in the time for either control, steel-dosed or bismuth-tin-dosed mallards to begin to lay or the time required to lay 21 eggs. Similarly, no significant differences were observed between treatment groups on fertility rates, hatchability rates, or the chemical composition of eggs. In ducklings, no significant difference were observed between the steel, bismuth-tin and control groups in the mean body weight (day 7), sex ratio, haematocrit, the mean weights of kidney and liver, elemental content of organs, or in histopathology.

¹⁴⁴ US Federal Register Vol. 62, No. 21, pp. 4874-4876 / Friday 31 January, 1997

¹⁴⁵ <https://echa.europa.eu/brief-profile/-/briefprofile/100.028.343>

Tungsten-matrix (95.9 % tungsten, 4.1 % polymer; <1 % residual lead) shot was approved as 'nontoxic' in September 2000 by means of a decision published in the US federal register¹⁴⁶. As per the approval of bismuth/tin, the decision provides a summary of the environmental risk assessment and ecotoxicological data underpinning the decision, which comprised data from the literature as well as new acute (30 day) and chronic/reproductive (150 day) ecotoxicity studies with mallard performed according to the methods specified in section 20.134 of the US Code of Federal Regulations.

The chronic/reproductive study revealed no adverse effects when mallards were dosed with eight No. 4 size tungsten-matrix shot and monitored over a 150-day period (Gallagher et al. 2000, cited in US Federal Register decision). At initiation of the test (day 0) and on days 31, 60 and 90, 21 male and 21 female adult mallards were dosed with 8 No. 4 tungsten-matrix shot. On the same test days, 22 male and 22 female adult mallards were dosed with 8 No. 4 steel shot (negative control group). An additional four male and female mallards were dosed with a single No.4 lead shot (positive control). Two lead-dosed birds (one female; one male) died from lead toxicosis on test days 10 and 17, respectively; no mortality was observed in any other treatment or control group. Haematological and biochemical results from blood samples collected during tests revealed no biologically meaningful differences between the tungsten-matrix group and the steel shot control group. Low, but measurable levels of tungsten were found in the livers of males from the tungsten-matrix group and in the femurs of females from all treatment groups. For all treatment groups, levels of tungsten were below limits of detection in egg yolks and whites, and all tissues collected from offspring. Liver and kidney tissues collected for histopathological examination revealed no treatment-related abnormalities.

No significant differences between treatment groups were observed in egg production, fertility, or hatchability of eggs. Similarly, no differences were observed in the survival or body weight of ducklings from the various treatment groups. Blood measurements from ducklings from the tungsten-matrix treatment group were similar to those from the steel treatment group. Overall, the decision concludes that *'the results of the 150-day study indicated that tungsten-matrix shot repeatedly administered to adult mallards did not adversely affect them, or the offspring they produced'*.

Tungsten-bronze, tungsten-iron, tungsten-tin-bismuth materials were approved as 'nontoxic' in September 2004 by means of a decision published in the US federal register¹⁴⁷ that concluded that *'none of the types presents a significant toxicity threat to wildlife or their habitats'*. No additional Tier 2 and 3 testing was considered to be necessary in these cases.

The environmental toxicity and carcinogenicity of tungsten-based shot has also been assessed in the scientific literature (Thomas et al., 2009; Thomas, 2015). In these assessments the predicted concentrations in soil and surface water (even at extremely heavy theoretical shot loadings of 69,000 shot/ha) were predicted to be below concentrations associated with toxic/ecotoxic effects.

Thomas (2015) notes that failure to distinguish between elemental tungsten and tungsten alloys has caused confusion when considering the relative toxicity of shotgun ammunition. Whilst tungsten has been linked with carcinogenicity, laboratory studies indicate that

¹⁴⁶ US Federal Register Vol. 65, No. 173, pp. 53936-53940 / Wednesday, September 6, 2000

¹⁴⁷ US Federal Register Vol. 69, No. 152, pp. 48163-48164 / Monday, August 9, 2004

carcinogenicity of embedded tungsten-nickel-cobalt alloys derive from their nickel and cobalt content, and not tungsten. Studies where pure tungsten metal was embedded in animal and human tissue indicates that there is no toxicity or carcinogenicity either locally or systemically. Chronic studies where pure tungsten metal-based shot was embedded into the foregut of ducks for 150 days indicate no adverse physiological effects or effects on reproduction or the development of offspring. However, Thomas (2015) notes that gunshot containing nickel could pose health problems to animals if embedded in tissues. The Dossier Submitter notes that nickel-containing shot material is unlikely to be used as an alternative to lead in the EU.

In summary, the toxicity of alternatives to lead gunshot have been extensively studied and, in some cases, are subject to stringent evaluation assessment prior to regulatory approval and being placed on the market. This assessment clearly indicates that alternatives to lead gunshot are not associated with a risk to the environment. Therefore, the use of alternatives to lead shot will result in high levels of risk reduction.

E.3.1.5.2. Ricochet

All types of shot can ricochet (i.e. deflect) from a hard surface such as water, rocks, or the surface of tree trunks if they hit the surface at an acute angle. Shot made from soft lead, tungsten and bismuth-tin may flatten and even break up on direct contact with rocks. However, steel shot will bounce off hard surfaces, and is not so prone to deformation or fracture, but whether this difference is sufficient to increase the likelihood of injury is not supported by the available evidence.

Ricochet can, roughly, be divided into two components: 1. Ricochet angles and 2. Energy of ricocheting shot. DEVA¹⁴⁸ studies show that ricochet angles do not differ significantly between different types of shot (DEVA, 2013). The same studies show that some types of lead-free shot have greater ricochet energy due to mass stability and that steel and other hard shot has a higher tendency to direct rebound from hard surfaces.

This last element was mentioned particularly by the UK Lead Ammunition Group (LAG, 2015). This was evidenced as the result of pattern testing early steel shot loads at a special pattern testing facility at Holland & Holland's shooting grounds in North London. The Group concluded that in such circumstances precautions need to be taken when firing steel shot at a resilient pattern plate, as steel will rebound to a greater extent than lead. However, for all practical purposes when shooting in the field the group concluded: "An unsafe shot with steel is an unsafe shot with lead".

Under the practical circumstances of hunting the risk of ricochet depends on the physical environment, i.e. the risk of hitting rocky surfaces and obstructions like bush and trees. Water bird hunting in wetlands has a high prevalence of shots in open space with "the sky as background", hence with a low risk of hitting obstructions. Birds (e.g. wounded birds) may be shot/dispatched at the water. Shot of any type will ricochet from water surfaces given that the hitting angle is small (< 5°), but with no difference between shot types. Hunting in wetlands, therefore, seems to be at low ricochet risk no matter the shot type.

¹⁴⁸ <http://www.deva-institut.de/home.php>

Danish experience

Ricochet was a central part of the Danish debate during the transition from lead to lead-free gunshot in the 1990s. Many actors were concerned that particularly steel shot, which was then the only available alternative, would create an increase in ricochet accidents. For this reason, various measures were introduced. Codes of safe hunting were adapted, including that recommended safety angles were increased from 25° to 40°, and hunters were recommended to wear safety glasses when hunting in groups. In addition, a safety campaign was launched under the motto "better red than dead" – meaning that hunters were recommended to wear red caps or hat ribbons to be visible to fellow hunters. The campaign was inspired by the switch from lead to lead-free shot.

Today, two decades later, there is no evidence, that the change from lead to non-lead shot has caused any change in risk of injury. Research from DEVA (DEVA, 2013) concluded that ricochet from lead and steel is comparable. Furthermore, the Danish Hunting Insurance¹⁴⁹ company registers reports on shooting accidents including accidents caused by ricocheting gunshot. However, the records from period after the phase-out of lead shot do not indicate any increase in frequency of such accidents. This may be a product of the precautionary steps that were taken in the 1990s, and also that hunters have used lead-like gunshot (bismuth-tin) particularly for forest hunting where the risk of ricochets (e.g. from tree trunks) is larger than in open habitats. Furthermore, hunters are educated to take safety angles into consideration. This is a mandatory part of education and testing of hunters in Denmark and has been so since 1967.

Since 1985 the use of lead shot for training and competition shooting (clay pigeon) has gradually been phased out in Denmark. Today, lead shot is allowed on a few specially approved shooting grounds. Steel shot has become the only realistic alternative and was from the beginning foreseen to generate an increased risk of accidents caused by shot ricocheting from clay pigeons installations, ground (running target), etc. However, after 20 years and millions of rounds later there has been no detectable change in accidents caused by ricocheting shot¹⁵⁰. So, this initial concern proved groundless. Shooters are recommended to wear safety glasses (in some disciplines this is mandatory). This precaution is mainly introduced to prevent eye injuries from clay pigeon splinters, but will in addition protect against shot – either direct or ricocheting shot. This applies equally to steel and lead shot.

Based on research and experiences there is no indication that a change from lead shot for hunting to other types including steel shot would cause any increased danger due to ricocheting shot.

Danish experiences from hunting accidents do not indicate an increased risk of ricochet caused by non-lead shot, including steel shot. Neither do Danish experiences from clay pigeon shooting indicate a higher danger/risk of ricochets with use of non-lead shot (steel) than with lead shot. In general, there is no evidence from shooting in countries where steel shot has been used for many years of an increase in reported accidents or insurance claims.

As regards the special circumstances of waterfowl hunting, where shooting takes place over water, open saltmarsh or from soft aquatic vegetation cover, the risk of ricochet is

¹⁴⁹ <http://www.danskjagtforsikring.dk/>

¹⁵⁰ Danish Wing Shooting Association, personal communication

considered to be vanishingly negligible. However, continued emphasis on safety angles and education of hunters is highly recommended no matter the shot types used.

E.3.1.5.3. Increased use of plastic wads

Wads used in most modern shot gun ammunition, including lead shot cartridges, are made from plastic. The wad is a seal that prevents gas from blowing through the shot rather than propelling. The need to prevent contact between hard shot, e.g. steel shot, and the gun barrel has accentuated the use of solid wads and until now wads in steel shot cartridges have almost exclusively been made from plastic. The wad construction in other lead-free cartridges may be plastic based, too, but in softer types, for instance bismuth shot, more original types of felt or fibres may be used. Consequently, hunting in wetlands and other habitats cause dispersal of plastic components in the environment.

The question is whether a phase-out of lead shot will cause more plastic waste to be spread from hunting, hence create an increased environmental problem.

The current study has reviewed the wad construction of a sample of shotgun cartridges regarded to be typical for hunting in Europe. In addition, a review of the evidence available in the literature was made alongside an evaluation of the potential for introducing degradable plastic or non-plastic materials to stimulate the phase-out of plastic waste from shotgun hunting in general and put this in context with the ECHA initiative.

Originally, shotgun cartridges were full metal containers but to reduce price and support mass-production the technology changed and paper/card became the basic shell material, and felt was used for wads. When plastic was introduced in modern industry after WWII this material also entered the ammunition industry and during the last 40 years the vast majority of shot gun cartridges have been based on plastic. This applies particularly to cartridges designed for hunting in wetlands where the water resistance qualities of plastic have been obvious. Further it applies to lead as well as lead-free products. In modern cartridges both the wad and the shell is commonly made of plastic.

Normally, empty shells are collected after the shoot, although there is evidence that shells in some cases are left in the hunting habitat¹⁵¹. Wads are part of the shot load and dispersed in the hunting habitat, when the shot is fired. There is no estimate of the total amounts of wads that are dispersed annually in the EU. It was suggested to the UK Lead Ammunition Group (LAG) that the annual waste of plastic to the countryside would have been approximately 500 tonnes if all cartridges fired during hunting in the UK contained steel shot and plastic wads¹⁵². A more recent calculation suggests that if all the cartridges used for shooting ducks and geese contained plastic wads the dispersal of waste plastic wadding might be some 6 tonnes in and around wetlands¹⁵³. A Danish estimate, based on the annual bag of water birds and an average consumption of three rounds per bird, indicates an annual dispersal of 0.5 million wads in coastal habitats¹⁵⁴. This is equivalent to one tonne (average weight of a plastic wad = approximately two grams). This may seem to be a limited contribution compared to other waste sources from society. However,

¹⁵¹ Strandjægernes affald, Netnatur, April 2010 <http://www.netnatur.dk/strandjaegernes-affald/>

¹⁵² See published minutes of 12th LAG meeting 25 June 2014 page 9

¹⁵³ John Swift personal communication 2017.

¹⁵⁴ Niels Kanstrup, unpublished data.

wads are easily recognised and can be connected to hunting. So, the waste is not only about plastic pollution but also about the reputation of hunting.

The LAG discussed waste hazard i.e. the risks to livestock from ingestion of plastic wads, but no members of the group were aware of any recorded instances of death or disease from wad ingestion (albeit that ingestion may occur occasionally without harm).¹⁵⁵

¹⁵⁵ [Published minutes of 12th LAG meeting](#) on 25th June 2014.



Figure E-10. Wad construction in a selection of shotgun cartridges. All calibre 12. Bottom: Lead; Middle: Steel; Top (from left): Hevishot, Tin, Tungsten, Zinc and two Bismuth. See text for details.

Most of the selected cartridges are produced in Europe and regarded to be typical for water bird hunting in most countries. Only calibre 12 is included, but the design of shells and wads would apply equally to other calibres.

It is a general observation that there are no major differences in the wads designed for lead shot (bottom row) compared to lead-free shot (others). However, the felt wads found in two lead shot cartridges (bottom, right) were not found in other types, though the fibre wad in one bismuth shot cartridge (top, 2nd from right) is a similar construction with no cup or other features to prevent contact between gun barrel and load.

As to the plastic wads the main difference between lead and non-lead types is the design of the buffer zone. The buffer function of the wad serves several purposes *inter alia* to regulate the progress of the chamber pressure, to reduce recoil, and to protect soft pellets from deforming during the initial ignition of the powder load. The buffer part is very pronounced (up to 15 mm) in four of the lead shot cartridges (bottom, 1st to 4th from left), the zinc shot cartridge (top, 4th from left) and one bismuth cartridge (top, right), while it

is smaller or absent in the steel shot cartridges (middle row), the hevishot (top, left) and the tin shot (top, 2nd from left) cartridges.

The fundamental reason for this difference is the constraint of shell volume. The lower density of steel and other light non-lead types leads to higher load volume (unless the load weight is reduced). Consequently, less space is left to accommodate a buffer design within the wad. A sample of plastic wads was weighed and lead cartridge wads were found to be slightly lighter (average of 2.5 g) than steel cartridge wads (average of 2.8 g), but this difference does not seem to be of any practical significance in the context of dispersal in the environment. In terms of aesthetics the single wad seems to be more important than the actual weight of the wasted plastic.

Degradable wads

It is fundamental that hunting with modern ammunition causes plastic waste to be dispersed in the hunting habitat no matter what shot type is used. The need to design wads in cartridges with steel and other hard materials in a way that contact between gun barrel and shot load is prevented accentuates this concern and calls on solutions to substitute plastic with other materials or with degradable types of plastic for use in areas where plastic wads are not allowed, whether on wetland or upland sites.

Solutions for this issue are already widely available and used in the commercial production of cartridges. For instance, tungsten-matrix cartridges (not in our sample) and bismuth-tin cartridges are available with shot contained in degradable fibre wads. The UK company, Gamebore, has begun to make a biodegradable wool felt wad that protects the shotgun barrel, and provides an environmentally-friendly material for shooting in sensitive areas. Kent distributes a light steel cartridge with card shell and a biodegradable fibre wad (middle, left), and very recently the Spanish company Mike Hammer, has introduced a steel shot cartridge (Green Shot) with a wad (middle, 2nd from left) made from maize starch that is soluble in water and disappears in few hours in aquatic habitats and in a few weeks in dryer upland habitats. All these types have been thoroughly tested, and there is no evidence that the alternative wad materials influence shot performance or risk of gun damage. In addition, PVA (polyvinyl alcohol) based products are available¹⁵⁶, and European companies have specialised in the development, production and distribution of degradable wads, e.g. Ecowad¹⁵⁷.

Despite the presence of bio- and photodegradable wads for any type of shotgun cartridges, there is still a constraint on the marketing of a price-competitive degradable-wadded steel shot and other hard shot cartridge for use in a standard proofed shotgun. The Lead Ammunition Group (LAG, 2015) stated in its report "... that biodegradable fibre wads commonly used for game shooting with lead are not available for steel". The Group concluded however that "*Biodegradable fibre and photodegradable wads have been available for some time for use in steel game loads; for example those used by Gamebore's 12g Silver Steel Fibre. The technology is certainly available and, if the demand is there, cartridge manufacturers have made clear that brands will be developed and marketed accordingly*".

¹⁵⁶ <https://ec.europa.eu/environment/eco-innovation/projects/en/projects/cartridge-wad>

¹⁵⁷ <http://www.ecowad.com/Home.html>

This UK statement may very well apply to Europe in general: The constraints of availability of degradable wads is not caused by production technology or costs, but only by lack of market demand. This demand seems to be increasing as the concern of waste of plastic from hunting cartridges (including lead shot cartridges) is growing driven by the more general concern of plastic waste in global terms¹⁵⁸, but also by aesthetic concerns in the hunting habitat and by owners of hunting grounds. The development is supported by increasing demands from the sport shooting sector particularly in terms of training and competition on shooting ranges in semi-natural environments.

The increasing demand of lead-free shot caused by *inter alia* the phase out of lead shot for hunting in wetlands and elsewhere is likely to be a driver to develop new technologies that can solve already known problems. The continued and increased need to use solid wads in steel shot cartridges is one example how an increased demand for new materials may stimulate products that can substitute other problematic shot components that the toxic shot.

Shot shells

Shot shells are commonly made from plastic and, thus, represent a potential source of plastic waste in the natural environment if dispersed and not picked and disposed up after the shot. Normally, shells are taken out of the gun chamber after the shot and stored for later deposition. Many guns are equipped with an ejector, and also semi-automatic and pump-action guns will eject the empty shells into the field nearby the shooter. It is a common code, albeit unwritten, in hunting that the shooter picks up such shells for later disposal. However, in certain circumstances, for instance during open sea hunting, shells are frequently lost¹⁵⁹.

This problem seems mainly connected to the use of semi-automatic and pump-action shot guns. Guns can be equipped with so-called "shell catchers" that ensure that empty shells from these gun types can easily be handed by the shooter. However, guns are not equipped with shell catchers as standard, and they are not commonly available on the European market.

Card shot shells are to some degree degradable and degradable plastic shells might be an option in certain circumstances. However, a strategy to make shells degradable could tempt hunters to leave shells in the hunting habitat. This could jeopardise the common conduct of hunters to collect shells and dispose of them appropriately.

Gun technology

There are indications (Putz, 2012), that most hunters use their current guns to shoot non lead ammunition and often without very much concern. Although the switch to non-lead ammunition may stimulate the turnover of guns, a large proportion of the existing guns will be used also in the future, despite further regulation of shot materials. Nevertheless, it is foreseen that guns in the future will be designed and adapted to the required ammunition. Steel shot seems to be the major shot material of the future, though other lead-free materials will also be available. Guns may be developed to withstand impact of steel shot without wads of the traditional design. Kanstrup & Hartmann (1991) investigated this by firing approximately 600 rounds of steel shot (3.4 mm) in a Mossberg cal. 12/76 pump gun and approximately 660 rounds in the lower barrel of a Valmet o/u.

¹⁵⁸ <http://www.plasticpollutioncoalition.org/>

¹⁵⁹ Strandjægernes affald, Netnatur, April 2010: <http://www.netnatur.dk/strandjaegernes-affald/>

The cartridges were loaded with classical felt wads leaving full contact between the shot and gun barrel. Both guns were steel proofed. "Before" and "after" measurements showed no significant changes (diameter, scratches, bulging etc.) in the gun barrel. Since then sophisticated techniques to refine gun barrel steel in terms of hardness, strength, ductility etc. have developed, and the near future will show new generations of guns adapted to the use of 'hard shot', such as steel with no need to use protecting wads.

Conclusion

Wads from shot cartridges cause dispersal of plastic waste in the environment. This applies to lead shot as well as non-lead shot cartridges, though the use of hard shot, e.g. steel shot, calls for an additional concern to prevent contact between the gun barrel and the shot load, thus requiring solid wadding.

Though the amounts of plastic dispersed from hunting ammunition may seem limited compared to the amounts of plastic waste in the natural environment, particularly oceans, hunting waste poses an aesthetic problem that is bad for the reputation of hunting. Hence, there is a considerable interest in reducing plastic waste from all ammunition, including also lead shot cartridges.

Suitable wads made from degradable materials including bio- and photodegradable plastic, fibres, starch etc., are widely available from several European manufacturers. However, due to low market demand, cartridges with degradable wads are not commonly available to hunters. A shift to steel shot will increase the demand and stimulate the further development of wads of degradable material for any type of shot. Hence, the shift from lead to non-lead shot does not create a new source of plastic waste to the environment.

Alternatives for the use of lead whilst hunting over wetlands are viable. The main evidence is that many Member States in Europe and countries outside Europe (most notably US and Canada) have achieved a phase out. The prime alternative, steel, is widely available although it has to be recognised the demand (and consequently supply) is very much driven by the existence of restrictions on the use of lead gunshot. Where alternative gunshot is in demand, the availability is wide and a wide ranges of cartridges are available for hunters to choose from for all types of hunting.

Most standard and steel proofed guns can safely use steel cartridges, despite various claims on possible damages on guns leading to a safety risk. Analysis of the situation after the implementation of restrictions in Denmark show that no major impacts were noticed on guns. Hunting with steel can be done just as efficiently as with lead shot, although the hunter needs to take into account different choices for shot size, compatibility of cartridges and different ballistics. The compromises done with respect to effective shooting distance appear not to impact the effective range over which wild fowling (or fowling) is done. For some species (larger waterfowl birds) consumers may need to replace an existing standard proofed gun, with a 'steel proofed' gun capable of using 'high-performance' steel gunshot cartridges.

The cost of steel gunshot cartridges are currently 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 reduce.

Possible consequences of the use of steel shot (e.g. plastic wads, ricochet) appear to also occur to the same extent when using lead shot.

If a gun does not have a 'steel proof' mark then this does not mean that it cannot be used with steel shot. However, care must be taken that the correct cartridges are used, particularly chamber length and pressure of the cartridge (Putz, 2012). As explained by the BASC and the Victorian game Authority, the actual risk depends on the selection of cartridges and ensuring that cartridges are used that match with the proof level of the shotgun.

This is supported by findings of Scheuhammer, where steel was found to be the preferred shot in the US. Although steel shot exhibited different ballistic properties when compared with lead it could be used effectively within normal hunting ranges (Ronholt, 1991; Hartmann, 1982).

For those hunting geese, hare, foxes bigger shot sizes are needed and consequently, following CIP rules, steel proofed guns would be required (Putz, 2012).

E.4. Restriction scenario(s)

E.4.1. Proposed restriction

The following sections support the justification of the restriction scenario including consideration on the behavioural response(s) of the affected stakeholders.

Brief title: *Restriction of lead in gunshot in or over wetlands.*

The proposed restriction option is presented in Section E.1. Once the restriction enters into force and after the transitional period, it is expected that all EU actors will have completed their transition to the alternative (mainly steel shot) as described in Section E.3.1.

E.4.1.1. Likely responses of hunters

The primary alternative (use of steel shots) has been shown to be technically and economically feasible as it can replace lead shot cartridges at a comparable cost, with comparable performance. The impacts of this proposed restriction have been assessed based on the assumption that the most likely alternative will be steel.

However, an unknown number of hunters might be affected as their shotguns will not support the use of steel shot, this may be fewer than could be initially (see E.3.1.3).

E.4.1.2. Likely responses in Member States

Member States currently have a number of approaches in their current legislation. It is likely that where the current law goes beyond the proposed restriction option, e.g. in Denmark and Netherlands, they will chose to keep their current scope. This will entail no extra work for the Member States, no extra costs etc. as the scope of their current legislation is more extensive than the proposed restriction. The current restriction wording has taken this issue into account. Member States will only need to notify such laws to the Commission.

Some Member States, which currently have a different approach from the proposed restriction option will need to adapt their practices. This will entail some effort by the Member State to communicate this to hunters and enforcement authorities.

It is seen as unlikely that this proposed restriction will mean more Member States implement a more restrictive option than in their current legislation. Therefore no additional costs for this work have been included in the report. However, Member States may give some additional information in the public consultation on this report and this assumption can be updated.

E.5. Economic impacts

E.5.1. Substitution costs

The substitution cost induced by the current restriction proposal is comprised of a stock cost (for testing existing shotguns and prematurely replacing non-standard proofed shotguns) and a flow cost (related to the incremental cost from switching over to non-lead gunshot). In order to make these two cost components commensurable one needs to i) bring forward the replacement of non-standard proofed guns, and ii) convert the stock cost into a constant annuity, which can then be compared to the incremental cost from using steel and bismuth shot. Both steps are explained below (following Sydsæter et al.,

2005), the actual results of the substitution cost assessment are reported in Section 5.5 of the main report.

E.5.1.1. Forwarding the replacement of shotguns

As explained in the main report, the central case scenario and the worst case scenario both presume that a certain number of non-standard proofed shotguns would need to be prematurely be replaced. Under the worst-case scenario it is assumed that these guns would not have been replaced over the 50 years following the entering into force of the restriction; under the central case scenario it is assumed that 95 % of the shotguns that would need to be prematurely replaced, would have been replaced (in equal annual proportions) over the 20 years following the entering into force of the restriction, whereas 5 % would not have replaced over the 50 years following the entering into force of the restriction.

It is useful to introduce the following notation for modelling the forwarding of the investment into new shotguns. Let:

- N denote the total number of non-standard proofed shotguns to be replaced;
- $n = N/(T - \delta)$ be the constant annual fraction of shotguns to be replaced over the relevant period T (taking into account a transitional period to comply of δ years);
- P be the average retail price of a new shotgun; and
- r denote the social discount rate.

Then, the present cost (PC) of forwarding the purchase of those shotguns that would not have been replaced otherwise can be modelled as:

$$PC(\text{not replaced otherwise}) = N * P * (e^{-r\delta} - e^{-rT}),$$

whilst the PC of forwarding the purchase of those shotguns that would have been replaced (in equal annual proportions, i.e. entailing a constant stream of replacement cost) over the next 20 years can be modelled as:

$$PC(\text{replaced otherwise}) = \int_{\delta}^T n * P * e^{-rt} dt = n * P * (e^{-r\delta} - e^{-rT})/\delta.$$

In the calculations presented in Table 5.5 of the main report a transitional period of $\delta = 3$ years and a social discount rate of 4 % (in accordance with the SEA guidance on restrictions) are assumed.

E.5.1.2. Annuitisation of the stock cost

The obtained PC of replacing the stock of non-standard proofed shotguns needs to be converted into a constant annuity to make it commensurable with the annual flow cost (i.e. the incremental cost of using alternative shot ammunition). This can be achieved by annuitising the PC estimates as derived in E.5.1.1 using the standard formula:

$$PC = A \frac{1-(1+r)^{-T}}{r} \leftrightarrow A = PC \frac{r}{1-(1+r)^{-T}}.$$

This results in a constant annuity A , which, when paid each year over the next T years and assuming a constant social discount rate r , corresponds to the PC.

E.5.1.3. Private vs social cost of the restriction

There is obviously a difference between the private cost of the restriction to be borne by the individual hunter and the social cost of the restriction. First, the private cost as calculated in Section 5.5 of the main report contains the VAT, which is a simple transfer from hunters to governments and should therefore be disregarded when calculating the social cost. One may turn to a stylised micro-economic model to think about the welfare impacts of the restriction.

First, it is important to think about the net impact in terms of the elements that it would entail. The restriction is made to address an externality, namely the lead poisoning of waterbirds, the internalisation of which is denoted by ΔE ; it will impose a consumer surplus loss ΔCS as hunters will have to pay more for each cartridge they consume; it will entail a producer surplus change ΔPS (possibly a loss), as producers will sell steel and other non-lead cartridges instead of lead cartridges on which they may earn more (at least that is what the evidence reported in Annex B.3 suggests). The total welfare impact is simply the sum over the three elements: $\Delta W = \Delta E + \Delta PS + \Delta CS$; notably, these elements will have different signs.

As a convention, the social cost will be defined as $\Delta PS + \Delta CS$, while the social benefit equals the externality addressed by the regulation. To better understand the social cost, consider a simple world with one buyer (i.e. the hunters) and one seller (i.e. the gun industry) and abstract from any taxes. Let the indirect utility function of the buyer before (denoted by v_0) and after (denoted by v_1) the regulation be given by:

$$v_0 = y - p_L q \text{ and } v_1 = y - p_S q,$$

where y denotes disposable income; p_L and p_S are the per unit prices (excl. VAT) of lead and steel shot, respectively; q is the number of cartridges consumed per year. The impact of the regulation on the buyer can thus be summarised as:

$$\Delta v = v_1 - v_0 = -q(p_S - p_L) = -q\Delta p,$$

i.e. the buyer suffers a consumer surplus loss that equals the aggregated price differential he is facing due to the restriction.

Next, consider the seller's profit function before (denoted by Π_0) and after (denoted by Π_1) the regulation enters into force:

$$\Pi_0 = p_L q - c_L q - f_L \text{ and } \Pi_1 = p_S q - c_S q - f_S,$$

where c_L and c_S are the per unit production costs for lead and steel shot, respectively; f_L and f_S are costs unrelated to the production (incl. shipping, stocking, selling, etc.). The impact of the regulation on the seller can be summarised as:

$$\Delta \Pi = \Pi_1 - \Pi_0 = (p_S q - c_S q - f_S) - (p_L q - c_L q - f_L) = q(\pi_S - \pi_L) - \Delta f = q\Delta \pi - \Delta f,$$

where $\pi_S = p_S - c_S$ and $\pi_L = p_L - c_L$ are the per unit profits made from selling steel and lead shot, respectively. The sign of the producer surplus change $\Delta \Pi$ depends on both the change in the per unit profit $\Delta \pi$ and the change in other costs Δf .

One may now conclude on the net social cost of the restriction in this model economy:

$$\Delta PS + \Delta CS = \Delta v + \Delta \Pi = -q(\Delta p - \Delta \pi) - \Delta f = -q\Delta c - \Delta f,$$

which just equals the extra resource cost (in terms of material, energy, and labour) implied by the restriction.

E.5.1.4. Assumptions made for assessing the substitution cost

Several assumptions had to be made for the assessment of the substitution cost implied by this restriction proposal (see Table 5.5 in Section 5.5 of the main report). This section gives a justification for these assumptions.

Emission of lead from hunting. Releases of lead from hunting can be estimated in one of two ways: 1) using data on the average annual hunting bag data and the number of cartridges fired per animal; or 2) using total number of cartridges consumed per year and their average lead content. In the absence of data on the total number of waterfowl shot annually in Europe, the total emission of lead from hunting in the EU was estimated using the second approach. (AMEC (2013) used a similar approach.) Using this approach, approximately 21 000 tonnes of lead are estimated to be annually dispersed from hunting in the EU. Using the information below on the number of hunters affected by the restriction, one may then rescale this estimate to the lead emission dispersed in EU wetlands reported in Section 5.5 of the main report.

Proportion of total hunting in wetland. No data is available on the extent to which lead is used for hunting in or over wetlands and non-wetland areas, or how this varies amongst Member States and across the EU. Based on available waterfowl bag data, it is estimated that currently around 6.7 % of hunting takes place in wetland areas in the EU (AMEC, 2013). Other sources suggest different percentages ranging from 8 % (Hirschfeld and Heyd, 2005) to 10 % (AMEC, 2013; based on market information). These figures were used to define the best, central and worst case scenarios described in Section 5.5 of the main report.

Number of waterfowl hunters facing 'one-off' costs. No precise information is available on how many waterfowl hunters may be affected by the proposed restriction. This is due to the fact that the exact number of waterfowl hunters per Member State is unknown and there is no way to single out waterfowl hunting based on shot size as similar shot sizes are used in fowl hunting and in sport shooting. Therefore, it is assumed that the figures on the average hunting bag give an estimate of the extent of hunting in and over wetlands and that the latter data apply evenly to all hunters. This gives an approximation of the size of the activity, but does not account for national or regional differences. For defining the scenarios, these figures were adjusted to account for existing regulations concerning the use of lead in and over wetlands (total ban, wide/ narrow area ban and or species ban). Further explanation on this is provided in the main report (Table 4.1).

Number of fowl hunters facing one-off cost. No precise information is available on how many fowl hunters may be affected by the proposed restriction. This is due to the fact that the exact number of fowl hunters per Member State is unknown and there is no way to single out waterfowl hunting based on shot size as similar shot sizes are used in fowl hunting and in sport shooting. In order to quantify the possible impact of the restriction on fowl hunting in peatbogs, a GIS analysis was conducted using CORINE land cover data. (See appendix E.3¹⁶⁰) In the absence of further Member State specific data, the bag data of Hirschfeld and Heyd (2005) was extrapolated to quantify the impact on fowl hunting in peatbogs. This method is likely to overestimate of the number of affected hunters as it

¹⁶⁰ The results of this analysis are different from the analysis presented in figure B.2 due to a) comparison with all Natura 2000 sites and b) the in-/exclusion of lakes and rivers.

presumes that all fowl hunting takes place in peatbogs, whilst in reality it will also take place in non-wetland areas.

Average price of a new shotgun. In the central scenario, the average price of a shotgun was set to € 1 000 based on figures presented by (AMEC, 2013) and (COWI, 2004). In order to account for the possibility of a lower or higher average price of a shotgun, the best and worst case scenarios are based on prices of € 750 and € 1 500 per shotgun, respectively. A similar value is used in the assessment of impacts of the lead ban in California¹⁶¹

Percentage of shotgun owners who would re-proof a gun. In earlier assessments the percentage of shotguns to be re-proofed was estimated to be up to 95 % (AMEC, 2013). However, it is unknown to the Dossier submitter to what extent this figure relates to the switch over to high performance steel shot. Based on information from Denmark, little to no proofing was required to switch from lead gunshot to steel gunshot (see Section E.3.1.3). The number of hunters who would re-proof their shotgun was therefore assumed to be 0 % (best case) to 15 % (worst case), with 10 % assumed for the best case scenario. The figure is derived from an assessment by (Amec, 2013).

Amortisation period. The value used in this study is derived from a study in the Netherlands on the expenditure which uses a 20 years amortisation period. A similar value is used on the impact assessment of the ban on lead for taking wildlife in California¹⁶².

Shotguns prematurely replaced. The number of shotguns that need to be prematurely replaced if the restriction is implemented was estimated based on expert information. Since several shotgun producers state in their user manuals that shotguns produced after 1970 are suitable for firing standard steel shot (see E.3.1.3), it is assumed that the replacement rate analysed in the worst case scenario (25 % of existing shotguns need to be replaced) represents an absolute upper bound. This replacement rate is based on information about shotguns in the UK that are not proofed¹⁶³ and thus hunters remain uncertain whether or not these guns are suited to use standard steel shot. For Denmark, the fraction of such non-proofed shotguns was pegged at 10-20 %¹⁶⁴. For the central scenario a replacement rate of 10 % of existing shotguns was assumed, considering that a European hunter owns about 2.6 shotguns on average (AMEC, 2013) and therefore might already own a shotgun that is suitable for firing steel shot, even if another one of his shotguns is not. For the best case scenario, the Dossier submitter assumed that all hunters will have access to a shotgun that can fire standard steel shot and therefore no premature replacement of shotguns would be necessary.

Switching to alternative gunshot. In order to quantify the number of lead cartridges that would be replaced by either steel or bismuth gunshot, the following assumptions were made. Under the best case scenario it was assumed that all existing shotguns are suited for firing standard steel shot and consequently 100 % of the affected hunters would switch to standard steel shot. Under the worst case scenario, it was assumed that 25 % of existing shotguns that are deemed unsuitable for firing standard steel shot would not be replaced and their owners would thus have to switch over to bismuth gunshot, whilst the owners of

¹⁶¹ Standardised Regulatory Impact Assessment, implementation of AB771: Fish and Game code section 3004.5

¹⁶² Idem supra.

¹⁶³ Personal communication by John Swift.

¹⁶⁴ Personal communication by Niels Kastrup.

the remaining 75 % of shotguns unsuitable for standard steel shot would buy a new shotgun and switch over to standard steel shot.¹⁶⁵ The central scenario assumes that 15 % of the lead shot spent will be replaced by bismuth shot, acknowledging that some “old timer” guns might still be used even if their owners would buy a standard-proofed shotgun.

E.5.2. Enforcement costs

Non-compliance with partial bans on the use of lead gunshot is known to reduce their potential effectiveness. Case studies are available (e.g. from the Ebro delta in Spain), where partial bans have resulted in significant risk reduction but have required relatively intensive enforcement activities and associated costs to achieve this risk reduction.

The proposed restriction is only likely to be effective in reducing the risk to waterfowl and other birds where it is complemented and supported by effective Member State enforcement or educational programmes. Enforcement costs are not included in the cost assessment of the restriction proposal as Member States with existing legislation already have enforcement measures in place and it is unclear what would be the additional costs due to the enforcement of the proposed restriction. Whilst in most cases these costs are expected to be small compared with the substitution costs, in some cases if specific enforcement projects are undertaken, the costs might be substantial.

E.6. Human health and environmental impacts

The negative impacts that result from the use of lead gunshot in wetlands are wide-ranging and significant. Lead gunshot imposes costs on society through various channels. Direct costs are related to wildlife conservation activities (research, monitoring and surveillance, veterinary care and rehabilitation of lead-poisoned birds) and to the mitigation of negative impacts on human health (research, monitoring and enforcement); indirect costs relate to the contamination of wetlands and the impact this has on wildlife and the concomitant loss in terms of enjoying nature (hunting and fishing, bird watching, etc.) as well as on human health (via the consumption of game meat and other potential sources of contamination such as groundwater used as drinking water).

In this sense, the primary benefit from restricting the use of lead gunshot in and over wetlands is the reduction of lead exposure in the environment and the likelihood of adverse effects in birds (especially waterbirds, birds of prey, and scavengers) and other wildlife that are dependent on wetland habitats. These are discussed in more detail in E.6.2.

Secondary (co-)benefits of the proposed restriction are related to the reduction of indirect exposure of humans to lead via the environment (via the consumption of game meat and other potential sources e.g. groundwater used as drinking water). These are discussed in more detail in E.6.1.

E.6.1. Human health impacts

The impacts of lead on human health are manifold. Lead may affect almost every organ and system in the human body. As mentioned above, young children are particularly

¹⁶⁵ A similar assessment was carried out in COWI (2004) where a mix of steel (50 %), bismuth (20 %), tungsten (20 %) and tin (10 %) was assumed. Based on recent information on tungsten (prohibitively expensive and therefore not a primary alternative and disadvantages of tin shot (brittle pellets), the Dossier submitter believes that a steel-bismuth mix of 75 %-25 % seems justified.

susceptible to the effects of lead and even low-level during childhood may result in a number of adverse health impacts (US EPA, 2013):

- Lower IQ and hyperactivity;
- Behaviour and learning problems;
- Impaired growth;
- Auditory and visual function impairment;
- Motor function impairment.

As lead is stored in bones along with calcium, it may accumulate in humans over time. During pregnancy, lead is released from bones as part of maternal calcium to help form the bones of the foetus. Lead may also cross the placenta barrier exposing the foetus to lead, which may result in reduced growth of the foetus and premature birth. In non-pregnant adults, lead exposure may induce reproductive problems, decrease kidney function and cause cardiovascular diseases. Impacts related to acute lead exposure include dizziness, fatigue, irritability, nausea and, in more severe cases, paralysis, convulsions and cancer.

E.6.1.1. Beneficial impacts of the proposed restriction

Several authorities in the EU have issued warnings on the consumption of game meat pointing out the possible contamination of it with lead as a source of concern, see Table E-16

Table E-16 Examples of advices given in a number of Member States

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

Authority	Date	Scope of advice
Spain http://www.aecosan.mssi.gob.es/AECOSAN/docs/documentos/seguridad_alimentaria/evaluacion_risgos/informes_cc_ingles/L_EAD_GAME.pdf	February 2012	<p>Although the information available in Spain regarding the Pb content in wild game meat and its consumption is incomplete, following the analysis of data available in Spain, it has been shown that the average Pb content in pieces of large and small game exceeds the European Union general limits for meat and offal (there are no specific limits for this food) and these contents are similar to those found throughout Europe and other countries.</p> <p>It has been proven that wild game meat is consumed in Spain, although it is more common in hunters and their families. It is not restricted to the hunting season, and its consumption or products that come from it, such as cured sausage or pâté, by the general public in restaurants is not negligible.</p>
Norway http://www.vkm.no/dav/cbfe3b0544.pdf	June 2013	<p>At the individual level, the risk for adverse effect is likely to be small. At present lead levels, adults with for example normal blood pressure will most likely not experience any clinical symptoms by a small increase, although it may add to the burden of those individuals who are at risk of experiencing cardiovascular disease. A small reduction in the intelligence of children will not be notable at the individual level, but at the population level it can for instance increase the proportion not able to graduate from school. Lead exposure was declining in the population on which the reference value for increased prevalence of chronic kidney disease was based. EFSA noted that this reference value (15 µg/L) is likely to be numerically lower than necessary. The implications of having a concurrent blood lead concentration above the reference value cannot fully be interpreted, since it is not known when and at which level of lead exposure the kidney disease was initiated. However, an eventual increased risk of chronic kidney disease would be higher among those who consume cervid meat regularly or often than those who rarely consume such meat.</p> <p>For these reasons, continued effort is needed in order to reduce lead exposure in the population.</p>
Sweden https://www.livsmedelverket.se/globalassets/rapporter/2014/bly-i-viltkott--del-4-riskhantering.pdf	October 2014	<p>Need not be discarded from a risk perspective, but consumption should be limited up to 1 time per month.</p> <p>Pregnant women planning pregnancy and children under 7 years, however, should continue to avoid consumption.</p>

For decades, the principal approach of public health authorities to assessing health impacts of lead in the diet has been to identify a tolerable rate of dietary intake, which sought to maintain exposure below a no-observed-adverse effect-level (NOAEL) that was assumed to exist.

In 1982, the Joint Food and Agriculture Organisation/World Health Organisation Expert Committee on Food Additives (JECFA) set a Provisional Tolerable Weekly Intake (PTWI) of dietary lead of 25 µg/kg bw for infants and children. The PTWI was extended to all age groups in 1993 and confirmed by JECFA in 1999. In 1992, the PTWI was endorsed by the European Commission's Scientific Committee for Food (SCF 1994). The European Commission carried out an updated lead exposure assessment in 2004 (SCOOP 2004) and, together with the SCF opinion, this formed the basis of setting maximum levels of lead in foods in the EU (Regulation (EC) No 1881/2006).

Today, broad consensus is emerging on the fact that there is no blood lead concentration below which negative physiological effects of lead are known to be absent (EFSA, 2013; ACCLPP, 2012). Hence, the concept of a tolerable intake level has been called into question. In 2007, the European Commission requested the European Food Safety Authority (EFSA) to produce a scientific opinion on the risks to human health related to the presence of lead in foodstuffs. In particular, EFSA was asked to consider new developments regarding the toxicity of lead, and to consider whether the PTWI of 25 µg/kg bw was still appropriate.

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

E.6.1.2. Neurotoxicity

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

E.6.1.3. Cardiovascular effects

Long-term low-level exposure to lead is associated with increased blood pressure in humans. Meta-analyses support a relatively weak, but statistically significant, association between blood lead concentrations and systolic blood pressure, amounting to an increase in systolic blood pressure of approximately 1 mm Hg with each doubling of blood lead

concentration (Nawrot et al. 2002, Staessen et al. 1994), without any clearly identifiable threshold for this effect.

E.6.1.4. Nephrotoxicity

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

The following BMDLs have been derived for these endpoints.

Table E-17: BMDLs derived for IQ, systolic blood pressure and chronic kidney disease (EFSA, 2013).

Benchmark response (BMR)	BMDL (95th percentile lower confidence limit of the benchmark dose – BMD of extra risk) derived from blood lead levels (µg/L)	Corresponding dietary lead intake value (µg/kg bw per day)
A 1 % (1 point) reduction in IQ in young children	BMDL ₀₁ = 12	0.50
A 1 % increase in systolic blood pressure (SBP) in adults (equivalent to a 1.2 mm Hg change)	BMDL ₀₁ = 36	1.50
A 10 % increase in expected incidence of chronic kidney disease in adults	BMDL ₁₀ = 15	0.63

E.6.1.5. Summary

For the purpose of this restriction, neurodevelopmental population effects are the primary concern, although high consumers of game meat in the general population could also be at risk from other adverse effects.

Green and Pain (2015) estimated minimum and maximum numbers of people in the UK who eat game and are therefore potentially at risk, using information from surveys of gamebird (**not only waterfowl**) meat consumption by the general population and of high frequency game consumers (defined as eating game at least once per week). They reported that tens of thousands of people from the shooting community are high-frequency consumers of wild-shot game. Green and Pain (2015) also estimated that 4 000 to 48 000 children in the UK 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.

To assess the impacts at the European level the following uncertainties need to be evaluated:

- The number of high-level game consumers;
- The number of children who could be at potential risk of incurring an IQ reduction.

The CONTAM Panel concluded that adult consumers that frequently ate game meat were at increased risk of adverse cardiovascular and nephrotoxic effects.

In infants, children and pregnant women EFSA recognised a potential concern for effects on neurodevelopment at current levels of dietary exposure to lead. While EFSA did not consider the additional risk of frequent game consumption in these groups, any significant increases in dietary lead exposure would obviously increase health risks in these vulnerable groups.

Furthermore, during pregnancy the foetus can be exposed to greater lead concentrations than the mother. This is attributed to the fact that if the mother does not have sufficient calcium intake, lead is released along with calcium stored in bones resulting in increased exposure for both mother and foetus (BfR, the German Federal Institute for Risk Assessment, 2011) (see table E.8).

Subsequent to EFSA's analysis several national food safety and risk assessment agencies in the EU¹⁶⁶ conducted their own analyses of lead exposure¹⁶⁷ via diet and concluded that vulnerable groups, i.e. pregnant women, those intending to become pregnant, and young children should substantially reduce or abstain from the consumption of game meat shot with lead ammunition. However, public awareness of this advice and its effectiveness in reducing health risks among vulnerable groups has not been assessed and may be difficult to evaluate.

Given the non-threshold nature of the hazard it is very likely that an impact on human health exists. However, it is currently not possible to evaluate its precise magnitude as information that would be needed to underpin a quantitative health impact analysis is not available, as described in Section B.9.1.8.

E.6.2. Environmental impacts

E.6.2.1. Detrimental effects of lead on terrestrial and aquatic ecosystems

In addition to the impacts on birds described throughout this report, lead is associated with more general environmental impacts.

Lead accumulates in the upper layers of the soil surface, particularly in soils with a high organic content. Organic matter in these upper layers retains lead in the soil where it will affect micro-organism and grazing food chains. The uneven distribution of lead in ecosystems might displace other metals from the binding sites on the organic matter (U.S. EPA 2013). Moreover, lead may hinder the chemical breakdown of inorganic soil fragments so that lead in the soil becomes soluble and can be taken up by plants. Plants absorbing lead from the soil retain most of it in their roots, but some lead may also be stored in the plant foliage where it becomes available to grazing animals. At high atmospheric levels,

¹⁶⁶ Germany, Spain, Sweden, Norway and the UK.

¹⁶⁷ From lead ammunition, including both bullets and shot.

lead suppresses plant growth and may kill the plant by reducing its rate of photosynthesis, inhibiting respiration, and causing pre-mature cell aging. Lead concentrations that correspond to those found in plants growing near to smelters or roadsides lead may even affect population genetics.

At greater concentrations (10 000-40 000 ppm dry weight), lead can eradicate populations of bacteria and fungi on leaf surfaces and in soil (U.S. EPA 2013). As many of these micro-organisms are an essential part of the food chain, this may have a significant impact on higher animals as well. In invertebrates, mammals and birds, lead affects the central nervous system and inhibits the synthesis of red blood cells. Plant-feeding animals are exposed to lead: i) directly through their intake of forage and feed contaminated by airborne lead, and ii) indirectly through feeding on plant roots. Predatory animals are exposed through feeding on prey that accumulates lead.

Lead is identified as a Priority Substance (PS) under the Water Framework Directive (WFD - 2000/60/EC)¹⁶⁸. The annual average environmental quality standard (EQS) for lead in European freshwaters is currently 7.2 µg/L. A revised limit of 1.2 µg/L bioavailable lead in freshwaters was proposed in January 2012, as part of a wider package of revisions to WFD EQS.

E.6.2.2. Benefits of the proposed restriction

The benefits of the proposed restriction are related to:

- The reduced adverse effects (including mortality) in birds (waterbirds, birds of prey and scavengers) and other wildlife that are dependent on wetland habitats. Between 50 000-100 000 wildfowl are estimated to die from lead shot ingestion (per winter) in the UK (Pain et al. 2015), with approximately a million estimated to die in total (every winter) across Europe (Mateo 2009)¹⁶⁹. Deaths of wildfowl, from lead shot ingestion, outside of the winter period along with year round deaths of birds of prey, scavengers and other waterbirds (e.g. swans, flamingos)¹⁷⁰ would be additional to these estimates. Birds may even die of lead-related causes (due to effects on behaviour, predation, flying accidents, disease following impacts on the immune system etc., as discussed in Section B.7.2.2.2). Signs occurring prior to death may last weeks and can include: paralysis/impactions of the alimentary tract/upper gastrointestinal tract, malfunction of gall bladder, greenish diarrhoea, myocardial infarction, lesions of the gizzard, haemorrhagic enteritis, anaemia, anorexia, etc., as shown in Section B.7.2.2.1.
- Protection of ecosystem amenities. Ecosystem amenities carry a significant non-use value to people who intrinsically care about animal welfare and the environment (Kling et al. 2012). Lead poisoning of birds from shot ingestion can cause distress and severe pain for days to months (Sainsbury et al. 1995). These authors ranked it as one of the most severe and large-scale welfare problems in Europe related to human activity. Blind studies and field experience (e.g. Pierce,

¹⁶⁸ Directive 2000/60/EC establishing a framework for Community action in the field of water policy.

¹⁶⁹ Estimates done using Bellrose's methodology.

¹⁷⁰ From lead shot ingestion.

2014), illustrate that crippling of birds is related primarily to the shooter and distance at which the shot is taken rather than the ammunition type¹⁷¹ (E.3.1.3). A prolonged use of lead shot over wetlands can be expected to adversely affect welfare of birds, compared to the use of non-lead shot, causing unnecessary mortality and morbidity to birds. The non-use value is hard to quantify in money terms and studies that attempt to provide corresponding WTP¹⁷² values have for multiple reasons been subject to significant bias (Ritov and Kahneman 1997). It is noted in the context of this restriction proposal that a non-use value for better protection of wetlands exists and is potentially large. However, the Dossier submitter refrains from any quantification which would be subject to speculation.

- Increased (long-term) birdwatching opportunities. Birdwatching tourism or avitourism is a fast growing niche market, as Europeans are increasingly becoming involved in birdwatching¹⁷³. The attractiveness of a destination for birdwatching is highly related to birdlife quality and bird species diversity (CBI, 2015). Also rare species of waterbirds (i.e. species where each individual contributes to the survival of the population at a specific wetland site) will be better protected and therefore their stocks may recover, which will be beneficial to bird watchers and other naturalists.
- Increased (long-term) hunting opportunities, related to the reduced mortality of birds¹⁷⁴, for the hunting community. More hunting opportunities can create higher demand for ammunition and other services associated with waterbird hunting compared to a situation where lead shot is not phased out.
- The reduced amount of lead released in the environment. It is expected that the proposed restriction will reduce the emission of lead into wetlands from both hunting and shooting activities. This will help to reduce the potential for future lead contamination of groundwater (and drinking water catchments) and will also help avoiding adverse impacts on humans via the consumption of contaminated game meat¹⁷⁵ (as qualitatively discussed in Sections: B.4.3.3.3 and B.9.1.8.4, for groundwater and drinking water catchments; B.5.10 and B.9.1.8.1 for game meat).
- The avoided or reduced remediation costs at shooting ranges within wetlands (for new shooting ranges and existing ones, respectively), e.g. upon decommissioning. At the European level there is no common definition of contaminated sites agreed. However, the term 'contaminated site' (CS) refers to a well-defined area where the

¹⁷¹ A range of alternatives to lead shot are available which have been used for many years in countries where lead shot was banned, including the US. Good shooting practice can ensure that any animal struck by ammunition is killed quickly. To not do so may involve wounding the animal minimally or seriously i.e. crippling it.

¹⁷² Willingness to pay.

¹⁷³ https://www.cbi.eu/sites/default/files/market_information/researches/product-factsheet-europe-birdwatching-tourism-2015.pdf

¹⁷⁴ Waterbird populations would be maintained in relatively more favourable conservation status by having higher survival and thus preventing more species being banned from hunting.

¹⁷⁵ As suggested by the study of Green and Pain (2015), these benefits may be substantial—albeit too uncertain to quantify with any precision—when scaled to the European level and to all game meat (other than waterfowl only).

presence of soil contamination has been confirmed and this presents a potential risk to humans, water, ecosystems or other receptors (EEA, 2014)¹⁷⁶. Remediation may be needed depending on the severity of the risk of adverse impacts to receptors (under the current or planned use of the site). Shooting ranges would need to be cleaned up under most national legislations, with potentially high costs, when risk of adverse impacts to receptors are identified. The number of shooting ranges which represent a serious source of soil contamination in the EU wetlands is not known.¹⁷⁷ Most European countries have national legislation (or in some cases regional legislation) to deal with local soil contamination, but no legal framework has yet been established at the level of the European Union (EEA, 2014).

One way of capturing the benefits of reduced lead poisoning/mortality in waterbirds is through estimating the repopulation costs. Estimates for a limited number of bird species are given by Andreotti et al. (2018) and suggest that the benefits aggregated over the EU-28 could be in the order of € 100 millions per year.

In addition, the restriction proposal is consistent with the goals of the Sustainable Hunting Initiative. Under the Sustainable Hunting Initiative, promoted by the EU Commission, in 2004 an Agreement between BirdLife International and FACE¹⁷⁸ on Directive 79/409/EEC (Birds Directive) was signed. *Both organisations asked for the phasing out of the use of lead shot for hunting in wetlands throughout the EU as soon as possible, and in any case by the year 2009 at the latest.*

E.6.2.3. Evaluation of other lead-shot restrictions

Within the framework of the North-American waterfowl Management plan (NAWMP) two studies have been to estimate the effectiveness of the measures in terms of the archived goals. The NAWMP is a joint effort between the US and Canada (later expanded to Mexico as well).

The original goal of the NAWMP was to restore 100 million ducks. Within that framework also restrictions have been put in place (n a Federal level) concerning the use of lead shot for waterfowl hunting. IN 1991 a nationwide ban was introduces which made the use of non-toxic shot mandatory. A similar ban was introduced in most parts of Canada in 1999.

In the Mississippi Flyway, losses of mallards due to lead poisoning declined 64 % during the 1996-97 season, five years after lead shot was prohibited for waterfowl hunting (Anderson et al., 2000).

In combination with a predicated mallard population of 14.3 million in 1997, Anderson estimated that around 275 000 - 366 000 mallards died each year due to lead poisoning. Applying then further the analysis of Thomas and Norton (1995), Anderson estimates that to compensate for those losses an additional 187 000-249 000 ha of breeding habitat would be required in order to breed the number of mallards alternatives to lead gunshot saved in the 1997 fall flight.

¹⁷⁶ The term 'potentially contaminated site' (PCS) refers to sites where unacceptable soil contamination is suspected but not verified, and where detailed investigations need to be carried out to verify whether there is an unacceptable risk of adverse impacts on receptors.

¹⁷⁷ In Finland, shooting ranges represent one third of the local sources of soil contamination (EEA, 2014). However, it is unclear how many shooting ranges are located in wetlands.

¹⁷⁸ Federation of Associations for Hunting and Conservation of the EU.

E.6.2.4. Conservation efforts

Another method involves valuing the avoided expenditure on conservation measures to protect or treat wildfowl, due to decreased mortality from lead. The cost of lead poisoning to these projects could potentially be undertaken by calculating the conservation spend per number of individual wildfowl being conserved and then applying that to the number of wildfowl affected negatively by lead poisoning.

Case study on the benefits of banning lead gunshot for the white-headed duck in Spain

The white-headed duck (*Oxyura leucocephala*) is a diving duck species, which in the EU only breeds in Spain, in a small isolated population of around 200 breeding pairs. The species is threatened with extinction, and is listed as Endangered on the global and European IUCN Red List, Vulnerable on the IUCN EU 27 Red List and is listed as Annex I of the Birds Directive. They were more common in the early 20th century but have suffered as a consequence of habitat loss and hunting. Due to conservation actions the population is currently considered to be stable.

The use of lead shot is considered a major cause of mortality the white-headed duck. In studies by Mateo et al. (2001) and Svanberg et al. (2006), over 70 % of the dead individuals found had lead levels in their liver in excess of the levels where lead poisoning occurs.

In addition, Mateo et al. (2001) found that over 30 % of living individuals of the closely related introduced ruddy duck (*Oxyura jamaicensis*) and hybrids¹⁷⁹ carried ingested lead shot. This could be expected to result in a possible monthly mortality rate of over 7.4 % in Spain, based on mortality rates resulting from ingested lead shot in other duck species. Multiplying this with the current population estimate of around 1 500 individuals in Spain, this results in the death of around 75 individuals every month, which suggests that this is likely to be a limiting factor for population recovery.

E.7. Other impacts

E.7.1. Social impacts

E.7.1.1. General information

E.7.1.1.1. Information on potential impacts to various European actors

This section presents available information of the potential impacts on various relevant actors. The analysis is based on information provided by Lead Ammunition group (2016) and by stakeholders in response to various ECHA consultations (see Annex G: Stakeholder consultations).

¹⁷⁹ Hybridisation with ruddy ducks is another major threat to white-headed ducks, and ruddy ducks and hybrids are actively eradicated, usually by shooting. The species are very similar in ecology, and hence the degree of lead poisoning of ruddy ducks and the hybrids is expected to be similar to lead poisoning of white-headed ducks.

E.7.1.1.2. Impact on hunters

As explained in the baseline, there are already national bans in place which restrict the use of lead in wetlands in various ways. The main impacts on hunters are described in the report.

AMEC used a figure of € 9 000/tonne as the cost of removing lead ammunition from the market and replacing it with alternatives; being based on an assumed cost increment of 20 % for non-lead cartridges and 95 % of shotguns would require re-testing. The LAG group applied these figures over the number of guns days and the annual spend for live quarry shooting and estimated that these costs represent a 1.7 % increase in the average live quarry shooter's annually spend.

This global figure can also be seen in the budget of an individual hunter. A hunter typically spends money on a number of items in the pursuits of his activity. These expenditures can be broken down in the following cost items.

➤ Legal expenditure

In most European countries, access to hunting is controlled by the authorities which may impose an exam, a hunting licence (national or not, annual or not), a weapons permit, insurance cover etc. A special licence may sometimes be required to hunt certain game species. Depending on the country, this expenditure accounts for 6 to 10 % of the total. Although relatively low, when repeated every year, it becomes psychologically sensitive and looms disproportionately large in the hunter's mind. Moreover, certain studies have shown that younger hunters, often with more limited financial resources, feel this even more acutely.

➤ Expenditure on yearly hunting rights

Most hunters hunt on territories they do not own, be they private or public areas (state forests or properties). Access to these areas means paying fees or rents. This expenditure is higher in more densely populated countries where free circulation in open spaces is limited. This money goes to the landowners, as well as to the game-keepers and rangers who contribute to the overall hunting quality of the territory. Game breeders also benefit indirectly from hunting rents, as very few hunters buy game themselves. That said, there are hardly any game breeders in Scandinavia. The share of hunting fees in total spending varies from country to country and place to place from 0 to 25 %, with an average between 15 and 18 %.

➤ Expenditure on equipment

The most specific item of hunting expenditure. Firearms (shotguns or rifles) and ammunition (cartridges for small game or bullets for large game) are definitely not the only item of equipment. Whether an economy or luxury model, the firearm is always a long-lasting item written down over a long period of time. In this sense, the impact of this one-off purchase is relatively low compared to overall expenditure on equipment. Specialised equipment (scopes, binoculars, knives), cartridge belts, game bags, gun sleeves and yearly maintenance are included in equipment expenditure, along with smaller items (whistles, decoys, etc.). This expenditure also includes a third line: general clothing (water and windproof clothes, shoes or boots) and special items (headgear, special clothes, shooting sticks, nets, etc.)

This heading covers a large range of equipment, but it is usually inexpensive and long lasting, and therefore written down over a number of years. The overall share of equipment in total spending is around 15 %.

➤ Expenditure on transport

Two major categories of hunters can be identified in this respect:

- "regional" hunters, who do not drive far but hunt often (in some cases over 100 outings a year);

- "national" hunters, who hunt less frequently but further away.

In both cases, this means high overall mileage, and travel costs thus account for around 25 % of total yearly spending.

➤ Dog-related expenditure

"A good hunter never hunts without his dog", in the (translated) words of a French tongue twister. This is fairly true: less than 12 % of European hunters do not have a dog and, conversely, at least 5 % have four or more. Unlike guns, dogs need daily feeding, increasingly on purchased pet food. Specialised breeds (hounds, pointers, bloodhounds or retrievers) are often bought from professionals. They need veterinary care, sometimes following injury. Leashes and other equipment must be bought. The dog therefore represents the biggest expenditure heading in the hunter's budget - around 30 % on average.

➤ Miscellaneous expenditure

Although it breaks down into various lines, this heading accounts for no more than 5 % of the average hunter's budget. It includes membership fees of specialised associations, expenditure on hunting trips outside the home area or abroad (less than 10 % of the hunter population), information (books and magazines), gifts (exceptional purchases of luxury clothing), souvenirs (paintings, prints, sculptures). This miscellaneous spending represents no more than 5 % of the average budget. These budget headings may vary from country to country but the chart below illustrates the typical European average.

On this basis, and using existing regional studies, it is possible to calculate the average annual European hunter's budget.

The most recent studies give the following information:

- Belgium € 5 800 (1992);
- Spain € 2 450 (overestimated, 1993);
- Scotland € 1 720 (1990);
- France € 1 200 (1993);
- Ireland € 350 (underestimated, 1992).

After weighting the figures according to numbers of hunters in each country, the average expenditure comes out at € 1 680. Bearing in mind the methodological differences in terms of coverage and representativeness of the sample, an average of € 1 500 per European hunter could be seen as reliable estimate. Correcting for inflation, in 2016 terms, this is equivalent to about € 3 000 euro.

Pinet (1995) assumes that half of the budget on arms is spent on the annual cost of new guns and the other half on ammunition, implying that on average a European hunter spends per year 5 % of his budget on ammunition, i.e. an annual cost of about € 75. This is not very different from the spending known in the US where on an average about 6 %¹⁸⁰ if the budget of a hunter is spent on ammunition. Assuming a worst case scenario where indeed non-toxic shot is more expensive. The average spending of € 75 would increase to about € 100. In the total budget this would imply that the budget needs to increase with 1.5 %.

It is worth noting that this is an average budget and heterogeneity exists among hunters (REGHAB Study, April 2002)¹⁸¹. For Finland, there are significant differences between the various profiles of hunters with some spending less than € 500 and others spending more than € 2 000 (in 2001 price levels) per year. Despite the fact that the average spending per bird is about equal, the annual hunting bag in Finland was assessed to be 10 birds per hunter, whereas in the UK the annual hunting bag was assessed to be almost 35 bird per hunter (no distinction was made between waterfowl and other types of fowl). In a country where waterfowling is less intensive (such as Finland), the acquisition of a new gun may not be the first choice to adapt to the proposed restriction. Instead, hunters who do not own a standard-proofed shotgun may turn to bismuth or tungsten shot.

E.7.1.1.3. Manufacturers

Companies engaged in the manufacturing of ammunition and related products for sports and hunting purposes in Europe include the following:

- Manufacturers of ammunition components (primers, cases, propellants, wads, lead and alternative shot, lead and alternative bullets);
- Manufacturers of ammunition (assembling of components into final cartridges);
- Manufacturers of machinery used in ammunitions manufacturing (incl. testing equipment);
- Distributors of ammunition and components.

Many of the companies involved in the production of ammunition are involved in one or multiple of the activities above (COWI, 2004). The structure of the Industry is rather complex with many interlinkages between suppliers of components who both supply to other cartridge manufacturers but are also engaged in cartridge manufacturing themselves (COWI, 2005 and Interviews with Industry¹⁸²).

In 2017, among the AFEMS members and other companies ten companies produce both steel and lead shot cartridges in the following countries: Italy(2), UK(2), Sweden(1), Germany(1), Poland(1), Czech Republic(1) and Greece(1)

Producer	Country	Produces steel	Produces lead shot
Fiocchi	Italy	X	X

¹⁸⁰ Fish and wildlife agency, 2001, accessed: http://www.fishwildlife.org/files/Hunting_Economic_Impact.pdf

¹⁸¹ http://cordis.europa.eu/project/rcn/54760_en.html, accessed 10 April 2017

¹⁸² Personal communication Lambo.

RC	Italy	X	X
Gamebore	UK	X	X
Eley	UK	X	X
Sellier & Bellot JSC	Czech Republic	X	X
Rotwell	Germany	X	X
Gyttorp	Sweden	X	X
	Poland		
Lambro	Greece	X	X

There might be other companies who produce components and assemble cartridges that are not associated with AFEMS, we know of at least one: steel-shot.com

An earlier assessment of possible restriction on the use of lead in fishing and hunting (COWI, 2004) concluded that for a transition from producing lead cartridges to steel cartridges a number of changes in the machinery used in cartridge production are required in supply chain changes and machinery. Obviously, from the table above we see that 10 companies have already made that investment and supply the market with lead free (Steel) cartridges. These companies have developed alternatives, set-up production lines, supply chains and systems to market their products and manage an increased number of components and finished products in stock.

Producers of ammunition based on alternative metals and alloys certainly do exist in Europe already (supplying the markets in Netherlands, Denmark and elsewhere) and they would obviously benefit from such a ban, as would also the import to Europe of such ammunition e.g. from the US.

The majority of steel for steel shots comes from China, this makes up half the cost of production. Lead is usually sourced from within Europe (either virgin or recycled material).

The production of steel shot cartridges will stay more expensive as the production throughput of steel cartridges is reported to be lower; the harder pellets make the shot more difficult to handle (bounces) and machinery has to be set to a lower speed (vis-a-vis leadshot) in order to deal with this bouncing. This is why the throughput will be lower and hence the productivity on steel lines will be lower, resulting in higher production costs.

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

Web shop surveys demonstrate that lead-free shot cartridges are widely available to purchasers in most European countries, but stocks of non-lead ammunition held in local retail shops may be very limited in quantity, specification and brand. Hence, a small-scale local purchaser may not be able to purchase what might be best fine-tuned for his/her needs.

However, it is well established that the availability of lead-free ammunition is limited by the demand at the national, regional, and local level. The manufacturers provide lead-free ammunition and their products are available, or can easily become available in any member state, regionally and locally, once the demand is there. The demand for lead-free products will be stimulated by an EU regulation of lead shot for hunting in wetlands. A wider regulation will increase the demand and thus the availability much further.

If a restriction on the use of lead shots is introduced, the manufacturers who produce lead shots will have a problem with the fact that the technology used for manufacturing their product cannot be adapted to alternative metals. None of the alternatives can be produced using technologies and facilities used to produce lead shots. Lead shots can be produced with either a tower process or Bleimeister process. The tower process is the most widely used (95 %). A moulding process is used to produce steel shots, while the production of tungsten and bismuth shots utilises a sintering process.

According to the information received through ECHA’s call for evidence (2016), the only company in Europe manufacturing alternative shot (steel shots) is shutting down their production, being unable to compete with imports from outside of Europe. This may suggest that importers of alternatives may have a positive impact in case of an EU wide restriction.

The 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.

If the material of the shot is changed, the other components of a shotgun cartridge (namely primer, propellant and wad) need to be reconfigured. This is relevant for the companies assembling the components into final cartridge. These companies have to either replace and adapt all other components, or replace some phases and some equipment of the production process. The impacts to manufacturers are summarised in Table E-18.

Table E-18 Overview of impacts on shot production supply chain (Source: AFEMS, ECHA’s call for Evidence 2016)

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

Manufacturers of steel shot indicated that any regulations that would require greater use of lead-free cartridges would require an appropriate phase-in time. The vast majority of steel shot incorporated into cartridges originates in China, and the Chinese companies would need adequate time to increase projected production. The same consideration applies to tungsten originating from Chinese mines and refiners. The cartridge cases and shot cups designed for steel are not the same as those used for lead shot cartridges, and so increasing their production volume takes time. It also takes time for UK makers to make, test, advertise and distribute their cartridges, and for the wholesalers to stock and prepare their products for sale. Given the experiences of the US, Thomas (2015) found that a transition time of three years to the date of entrance of legislation appears reasonable, for both UK and European makers. This estimate was confirmed in discussion with stakeholders¹⁸³.

In an interesting overview and analysis of the lead shot banning on the US, (Friends et al., 2009) indicate that waterfowl hunting loads are not the major segment of the shotshell market and that 'a total ban on lead shot use for any purpose may be more acceptable across industry [...]. Previously, representatives of the ammunition industry had informally indicated that if a sufficiently competitive shotshell could be developed, "...ammunition companies would completely abandon the use of lead even for upland game shooting.'" Also noted was the need for legislation to provide a smooth transition over time and an opportunity to deplete existing lead stocks'. We believe the alternative is available and the thriving US industry is a proof that the ban is not hurting their business.

As concluded in Section E.3.1.1 that most of the main manufacturers have a production line for alternative shot, switching to steel shot and other alternatives therefore is to some extent no longer a question of adaptation of production lines but rather an issue of import of raw materials.

E.7.1.1.4. Gun retailers

There are no major impacts expected on gun retailers. The loss of sales with lead-free shots are assumed to be off-set with the profits in sales on lead-free alternatives.

E.7.1.1.5. Impacts on the forestry and veneer industry

Impacts on the forestry and veneer industry seems to be mainly relevant in regions of the EU with a complex interface between wetland and terrestrial habitats (such as Finnish and Scandinavian forests that comprise a mosaic of forest, lakes, ponds, bogs and mire habitats). The Dossier Submitter requested additional information to Metsähallitus (Finnish State Forest Enterprise)¹⁸⁴ about the type of wood-industry that might be affected by the use of steel shot but no evidence was provided.

In the impact assessment carried out in Sweden (Naturavasverket 2006), the risk of economic losses to the saw-milling and plywood industry, if lead gunshot was banned on forest land, was described. However, the study did not quantify this risk and no other quantified economic costs associated with the use of non-lead shot in forest, is currently available.

¹⁸³ Personal Communication Baumbach Metals GmbH, and with Clay 7 Game Reloaders Ltd (2016)

¹⁸⁴ Personal communication, December 2016.

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

A recent report from Denmark (Kanstrup & Stenkjaer, 2015) highlights that since the introduction of the general lead shot ban it has not been possible to show examples or demonstrate any actual economic loss for forestry companies as a consequence of damage caused by steel shot.

The report concludes that under normal circumstances gunshot does not penetrate sufficiently far into the wood that it poses an actual risk to veneer cutting, generally seen as the most vulnerable branch of wood processing. The added expenditure of forest shot (such as bismuth) is seen not to be proportionate to the annual value of the veneer production in Denmark. Consequently some forest districts have started to waive the woodshot (i.e. alternatives to lead other than steel) requirement and or re-examine this to areas for veneer industry only.

E.8. Practicality and monitorability

E.8.1. Implementability, manageability and enforceability

To be implementable within a reasonable time frame the restriction should be designed so that an existing supervision mechanism exists and is practically implementable for enforcement authorities.

To be enforceable, a restriction needs to be clearly defined so that it is obvious to enforcement authorities and, in this case, the general public which uses are within the scope of the restriction and which are not.

E.8.1.1. Scope of the restriction

The scope of the proposed restriction covers the use (consumer and professional) of gunshot containing lead or lead compounds in wetlands. The definition of what constitutes a wetland is a key factor in determining the implementability and enforceability of the proposed restriction.

In order to have good potential for implementability and enforceability wetland areas should be clearly defined, based on the scope of the restriction. This may need to be addressed by Member States by producing maps or guidance indicating where the restriction would apply. Several Member States (or regions within Member States) with existing legislation prohibiting the use of lead gunshot in 'generic' wetlands (rather than specific sites) have published guidance on the interpretation of the wetland definition to aid the implementation of their legislation¹⁸⁵.

E.8.1.2. Impact of improved enforcement in the Ebro Delta (Spain)

Mateo et al. (2014), assessed compliance with a partial ban on lead gunshot commencing in 2003 by examination of 937 water birds harvested by hunters between 2007 and 2012 in the Ebro delta (Spain). Prevalence of lead gunshot ingestion was determined, as were lead concentrations in liver and muscle tissue to evaluate the potential for lead exposure in game meat consumers. The occurrence of lead gunshot in hunted birds declined from 26.9 % in 2007–08 to ≤ 2 % over the following three hunting seasons (2008-2009, 2009-2010, 2010-2011). However, during the first season of monitoring, relatively high non-compliance rates were observed (26.9 %). The prevalence of lead shot ingestion in mallard in the 2007–08 hunting season (28.6 %) did not differ when compared to the pre-ban value (30.2 %; Mateo et al., 2000). However, a significant decrease in lead shot ingestion was found in the following seasons (mean 2008–12:15.5 %), after ban reinforcement.

Compliance was improved in subsequent seasons through increased enforcement and vigilance by park rangers and, as local authorities threatened to ban hunting completely in the protected areas if noncompliance persisted. Stricter controls on ammunition carried by hunters at entry points to hunting areas were put in place. Random carcass sampling was undertaken at the end of shoots, and national ID numbers were recorded for the

¹⁸⁵ A practical guide to the lead shot regulations in Scotland <https://basc.org.uk/wp-content/plugins/download-monitor/download.php?id=328>

hunters who harvested each bird. Such measures acted as simple but effective deterrents against non-compliance.

The lead gunshot restrictions in the Ebro translated into a significant reduction in the prevalence of lead shot ingestion in four waterfowl species¹⁸⁶, and a significant decrease in lead levels in game meat. This latter decrease can be attributed to both (a) a reduction in the prevalence of lead shot ingestion, and (b) the reduced risk of lead contamination of meat around wounds because of the use of steel shot, rather than lead gunshot.

E.8.1.3. Camargue area (France)

From 1995 to 2005, hunting bags, spent cartridges, and the gizzards of shot ducks were monitored. Using generalised mixed effect models the factors influencing hunter effectiveness were assessed. The prevalence of non-toxic gunshot in duck gizzards increased, probably as a result of rapid accumulation in the sediments. Between 1995 and 2005, the lead shot ban prevented 456 kg of lead gunshot from entering 403 ha of temporary marshes and avoided the contamination of 8 % of the ducks foraging on Tour du Valat (Mondain-Monval et al., 2015).

E.8.1.4. Compliance in North America

The contribution of non-toxic shot regulations to waterfowl conservation has been evaluated in the USA, where the use of lead shot for waterfowl hunting was completely banned in 1991. There, compliance values based on counts of lead and steel shot shell was found in the field ranged from 54.8 to 92.2 % in different US locations, and five years after the lead gunshot ban in Illinois, hunter compliance based on embedded shot was 98.9 % in mallard and 96.5 % in Canada goose (*Branta canadensis*) (Havera et al., 1994). Minimum hunter non-compliance was just 1.1 % (for mallard) and 1.8 % (for goose), which is similar to the compliance values observed in the Ebro delta after improved enforcement was undertaken (Mateo et al., 2014).

In Canada, where ban compliance, based on anonymous hunter surveys was 80 %, bone lead concentrations waterfowl declined significantly from 1989–90 to 2000 (Stevenson et al., 2005). In the US and Canada, legislative compliance appears to be high, which has been attributed to the general support of waterfowl hunters for the non-toxic shot programme and to active enforcement led by conservation police officers (Anderson et al., 2000; Stevenson et al., 2005).

Compliance values from North America contrast quite starkly against the low level of compliance recently documented in England, where 68 % (in 2001–2002) and 70 % (in 2008–2010) of mallards had been shot with lead gunshot despite the fact that this ammunition was banned for hunting over wetlands in 1999 (Cromie et al., 2010). Most recently the level of compliance was found to be 23 % (Cromie et al., 2015).

E.8.1.5. Conclusion on implement ability, manageability and enforceability

The general conclusion is that although a risk reduction (in lead poisoning) to waterfowl may be achieved through a partial ban on the use of lead gunshot, this is only likely to be effective where the ban is accompanied by effective enforcement and supported by

¹⁸⁶ Common teal (*Anas crecca*), Mallard (*Anas platyrhynchos*), Northern shoveler (*Anas clypeata*), Common pochard (*Aythya farina*).

educational programmes, clarifying the multiple benefits of using lead free shot, also to hunters.

The reduction in lead poisoning in some of the case studies described above, were achieved in limited geographical areas alongside effective enforcement and severe deterrents (threatening to restrict all hunting, check points at the entry of the park, etc.), which may prove to be a challenge to reproduce throughout the rest of Europe. For example, France has only 1 500 wardens to monitor a hunting population of about 1 million people. In the UK a lack of enforcement, perceived or real, is likely to contribute to the high rates of non-compliance recorded.

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

E.8.1.6. Transitional period for the restriction

See main report

E.8.1.7. Concentration limit

See main report

E.8.2. Monitorability

Monitoring may cover any means to follow up the effect of the proposed restriction in reducing exposure. This may include monitoring tissue concentrations or the prevalence of lead gunshot ingestion in birds to see if exposure decreases following the restriction. However, as tissue concentrations are the result of many different routes of exposure it might be difficult to attribute changes in blood lead levels to this specific restriction.

- The monitoring of the effectiveness of the proposed restriction could be done through via a number of different monitoring schemes. The advantages and disadvantages of some examples of these are outlined in Table E-19 below (source: ADAS, 2007)

Table E-19. Methods for monitoring the effectiveness of the proposed restriction (Source: ADAS, 2007)

Method	Advantages	Disadvantage
Cartridge wad analysis	Identification by shot type on the basis of difference in wads between lead and steel shot.	The method stems from a period that lead shot was built exclusively with fibre wad and steel shot with plastic wad. As discussed in Section E.3 this is no longer true.
Non-invasive metal detection	Use of a modified metal detectors to identify lead and steel shot in live or	Difficult to procure equipment

	dead birds	Does not distinguish between shot from previous wounding, ingested shot or shot that resulted in mortality of the bird
Survey of waterfowl hunters	Cheap and easy to perform	Bias in sampling and overestimation of own compliance.
Ingested shot study	Evaluate post-mortem of ingested shot is considered to be most conclusive.	Possible biases in obtaining samples
Shot collection in sand buckets	Use of buckets inside the border of wetlands to capture shot pellets and determine actual compliance	Vulnerable to tampering/interference, higher likelihood of shot being washed away

The most conclusive method of monitoring compliance with the restriction is to measure the prevalence of ingested shot in birds over time. Many of the current studies highlighting the current problem of lead poisoning in waterfowl use this method, or varieties of it, to establish the scale or magnitude of the problem. These can readily be adapted to monitor the effectiveness of the proposed restriction. WWT (2010) describe a protocol for the determination of lead pellets in various species.

E.8.2.1. Methodology for differentiating pellet types

Provisional diagnosis of pellet type was made using results of appearance, malleability and melting point (methodology adapted from Cromie et al., 2002). Results of physical and chemical property analyses were considered conclusive. Known pellet types (lead, bismuth, steel and tungsten-based) were used as positive controls throughout the analyses.

Magnetic properties

If magnetic, the pellets were considered to be steel.

Appearance and malleability

The colour and form of the non-magnetic pellets was examined. Those with a slight steely or golden reddish tint were suspected to be bismuth. Those that were dark, dull and deformed were suspected to be lead or possibly bismuth.

When sanded with fine grain sandpaper and cut with a scalpel blade, those exposing shiny surfaces were considered to be either lead or bismuth. If exposed surfaces appeared slightly golden reddish, they were suspected to be bismuth. Those that were relatively soft were suspected of being lead, whilst those that were harder and more brittle were suspected of being bismuth or another compound.

Melting Point

Pellets were heated for 10 minutes in a partitioned porcelain tray in a muffle furnace at 295 °C and 330 °C. Pellets melting at 295°C and forming molten shiny globules upon manipulation were considered to be bismuth. Pellets retaining their shape and remaining hard at 295 °C, yet becoming soft at 330 °C were considered to be lead.

Chemical analysis

Pellets were warmed at 90 °C and simultaneously shaken at 300 rpm on a hot plate in 10 mL of 12.5 % nitric acid for five minutes. Following this period 2 mL of 10 % potassium iodide solution was added. Those forming a bright yellow precipitate (i.e. lead iodide) were considered to be lead. Those forming a dull amber/dark orange yet clear solution (i.e. bismuth iodide) were considered to be bismuth. Based on aspects of this methodology a level of confidence was attached to each lead result.

Sensitivity of this chemical analysis

Lead iodide (PbI_2) is formed as a yellow powder by adding potassium iodide (KI) solution to a solution of lead nitrate or acetate. It is barely soluble in cold water (0.06 % at 15 degrees) but on boiling it dissolves (4.34 gm per litre) and on cooling golden yellow droplets separate. It is soluble in a large excess of KI, forming KPbI_3 but deposits again on dilution (Partington, 1950).

Given this test is qualitative it was not possible to assign sensitivity. However, using standard stock solutions it was possible to determine the limits of detection (LOD). 1mL of standard stock solutions (manufactured for Atomic Absorption Spectrometry) of lead nitrate (50 ppm, 100 ppm and 200 ppm) was added to 1mL for KI 10 %. At 50 ppm no visual colour change was observed, at 100 ppm some precipitation was observed and using 200 ppm more precipitation was observed. Thus, at 100 ppm (100 μg) lead can be detected.

Scanning electron microscopy (SEM)

Each sample was prepared by mounting individual pellets onto aluminium blocks held in place by adhesive. Four sample mounts were loaded into a carrier and placed inside the specimen chamber of the SEM. A high energy beam of electrons scanned each sample surface by interacting with the sample atoms to produce signals. Resulting characteristic X-rays were then assessed to identify the composition and measure the relative abundance of elements in the sample using each peak. Topographic images were also taken. Magnification of 50 times was chosen as standard to examine each sample. In this instance SEM was considered non-destructive as pellet samples are electrically conductive on the surface requiring no additional coating substance.

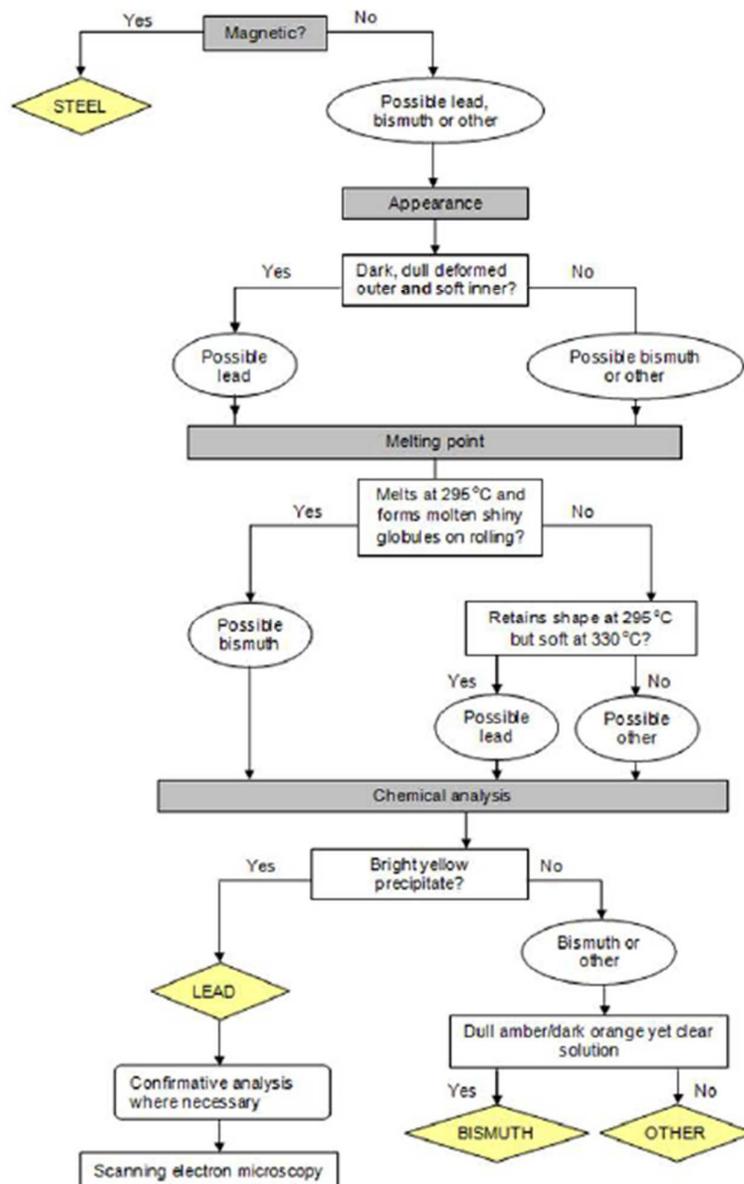


Figure E-11 Compliance assessment method (Source: ADAS, 2007)

E.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. The main report demonstrates that the proposed restriction is a sound regulatory action by examining its affordability, cost-effectiveness and the benefit-cost ratio.

In this Annex further considerations and detail are given here to the cost effectiveness of the measure.

The cost-effectiveness of the proposed restriction can be estimated in relation to the quantities of lead release that would be avoided by the restriction. This is the typical format for estimates of cost-effectiveness that have been used to support the proportionality of previous REACH restrictions on PBTs and PBT-like substances. In the context of this restriction proposal, it is even possible to estimate the cost-effectiveness in terms of social cost per waterbird death avoided (based on estimates of waterbird mortality reported in Section B.10.1.2).

E.9.1. Cost-effectiveness of avoiding lead releases to the environment

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 Section E.5.1, it is estimated that around 4 200 tonnes of lead per year would no longer be dispersed into the environment.

As explained in E.5, the aggregated costs imposed on hunters (in terms of more expensive ammunition, possible testing, and the premature replacement of shotguns) can be annuitised to derive an annuity cost of the proposed restriction in the range of € 0.4m (best case) to € 192.59m (worst case) per year, with a central estimate of € 44.4m per year.¹⁸⁷ These 'abatement cost'-like figures suggest that the total cost per tonne of lead emission avoided is in the range of € 0.3/kg to € 25/kg (with a central value of € 9/kg) of lead emission avoided.

It can be seen from Table E-20 Comparison of the cost-effectiveness of the proposed restriction and previous restrictions under REACH. that these estimates are an order of magnitude lower than cost-effectiveness estimates found in previous restrictions of PBT and PBT-like substances under REACH.

Table E-20 Comparison of the cost-effectiveness of the proposed restriction and previous restrictions under REACH.

Restrictions under REACH	Central value	Range	Remarks
Proposed restriction on lead in shotgun (€/kg avoided)	18	0 - 25	
Lead in PVC (€/kg of emission avoided)	308	99 - 2 484	This restriction proposal is currently under evaluation by RAC and SEAC
Mercury-in-measuring-devices (€/kg of Hg used)	4 100	0 - 19 200	If the calculations were done for Hg emitted, the value of the cost-effectiveness would be higher.
Phenylmercury compounds (€/kg of emission avoided)	649	n/a	
DecaBDE (€/kg of emission avoided)	464	30-756	

¹⁸⁷ It should be noted that this central estimate is likely to be an overestimate since it is based on the assumption that some 8 % of all wetland hunters would have to prematurely replace their shotgun due to the restriction. As discussed under Section E.

PFOA(€/kg of emission avoided)	< 1 649	0-6 551	SEAC considered that the changes proposed to the scope improved the cost-effectiveness of the restriction.
PFOA-related substances (€/kg of emission avoided)	734	4-3 533	
D4/D5 in wash-off cosmetic products (€/kg of emission avoided)	400-430	0-1 200	The central values were estimated for a compliance period of 2 and 5 years respectively.

Source: <https://echa.europa.eu/previous-consultations-on-restriction-proposals>

E.9.2. Cost-effectiveness of avoiding premature death in waterbirds through lead ingestion

As discussed in Section B.10.1.2., between 207 000 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 in the range of 441 000 (estimate based on breeding population) to 522 000 (estimate based on wintering population). As there are no population estimates for birds occurring in Greece or Croatia reported under Birds Directive Article 12, these estimates is likely to be an underestimate.

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 from lead gunshot ingestion, with a central estimate of 420 000. A similar, but moderately greater, number of waders and rails from the same species are estimated to die annually based on the breeding population size.

When estimates for waterfowl are combined with those for waders and rails, between approximately 400 000 and 1 500 000 birds (with a central estimate of 900 000 individuals) are estimated to die annually throughout the EU from ingestion of lead gunshot. However, 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. They also ignore lethal or sub-lethal effects on predatory or scavenging birds via secondary poisoning.

Keeping these caveats in mind, the central estimate of 900 000 premature deaths in waterbirds avoided per year can be taken forward to derive conservative cost-effectiveness estimates in terms of money spent per bird saved. For this purpose, the annuity cost of the proposed restriction (see E.5) is to be divided by 900 000, resulting in costs ranging from € 0.33 per case of lethal poisoning avoided (best case) to € 213 per case of lethal poisoning avoided (worst case), with a central estimate of € 49 per case of lethal poisoning avoided.

These estimates may then be compared to the market price of a captive-bred waterfowl, which may range from € 18 (for a mallard) to € 451 (for a Tundra swan) (Andreotti et al. (2018)).

Appendix E.1 AEWA status per EU Member State

Country	Status	Date of Accession	Region
Austria	Non-Party Range State		Europe
Belgium	Contracting Party	01-Jun-06	Europe
Bulgaria	Contracting Party	01-Feb-00	Europe
Croatia	Contracting Party	01-Sep-00	Europe
Cyprus	Contracting Party	01-Sep-08	Europe
Czech Republic	Contracting Party	23-Jun-06	Europe
Denmark	Contracting Party	01-Jan-00	Europe
Estonia	Contracting Party	01-Nov-08	Europe
Finland	Contracting Party	01-Jan-00	Europe
France	Contracting Party	01-Dec-03	Europe
Germany	Contracting Party	01-Nov-99	Europe
Greece	Signed but not ratified		Europe
Hungary	Contracting Party	01-Mar-03	Europe
Ireland	Contracting Party	01-Aug-03	Europe
Italy	Contracting Party	01-Sep-06	Europe
Latvia	Contracting Party	01-Jan-06	Europe
Lithuania	Contracting Party	01-Nov-04	Europe
Luxembourg	Contracting Party	01-Dec-03	Europe
Malta	Non-Party Range State		Europe
Netherlands	Contracting Party	01-Nov-99	Europe
Poland	Non-Party Range State		Europe
Portugal	Contracting Party	01-Mar-04	Europe
Romania	Contracting Party	01-Oct-00	Europe

Country	Status	Date of Accession	Region
Slovakia	Contracting Party	01-Jul-01	Europe
Slovenia	Contracting Party	01-Oct-03	Europe
Spain	Contracting Party	01-Nov-99	Europe
Sweden	Contracting Party	01-Nov-99	Europe
Switzerland	Contracting Party	01-Nov-99	Europe
United Kingdom of Great Britain and Northern Ireland	Contracting Party	01-Nov-99	Europe
Iceland	Contracting Party	01-Jun-13	Europe
Liechtenstein	Non-Party Range State		Europe
Norway	Contracting Party	01-Sep-08	Europe
European Union	Contracting Party	01-Oct-05	Europe

Appendix E.2 Analysis of the association between EU wetland habitats (as defined using the Ramsar definition) and the EU Natura 2000 network

Introduction and purpose

Evaluation of ECHA's proposal for a restriction on the use of lead in gunshot in or over wetlands has involved various discussions in relation to the 'enforceability' of the measure and how this could influence its effectiveness (risk-reduction capacity).

The 'generic' definition of a wetland proposed in the restriction was that adopted by the Ramsar convention (article 1(1), as follows:

'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.'

When evaluating the enforceability of the restriction one of the key questions is whether it is possible, by hunters or those engaged in enforcement activities, to appropriately distinguish between wetland areas consistent with the Ramsar definition (within the scope of the proposed restriction) and non-wetlands areas (outside of the scope of the restriction).

Guidance documents have been prepared to assist hunters interpret the various generic definitions of wetlands that have been applied in Member State legislation on the use of lead gunshot in wetlands. Notable examples are the practical guidance developed for hunters in Scotland¹⁸⁸, Northern Ireland¹⁸⁹ and France¹⁹⁰.

During the initial stages of the evaluation of the restriction it was highlighted by the Forum that 'official' boundaries around wetland areas would be needed for the restriction to be enforceable. However, as highlighted above it is possible for generic definitions of wetlands to be used in legislation prohibiting the use of lead gunshot in wetlands. Nevertheless, we agree that uncertainty will be minimised in situations where wetland areas are also identified within 'official' boundaries i.e. within sites designated for conservation reasons.

As such, a GIS-based analysis was undertaken to assess what proportion (by area) of 'generic' wetlands in the EU already occur within designated sites within the EU Natura 2000 network. It can be assumed that when hunting in wetland areas within the boundaries of a Natura 2000 site, particularly a site designated under the Birds Directive, there will only be very limited ambiguity as to whether the use of lead gunshot is permitted.

¹⁸⁸ <https://basc.org.uk/wp-content/plugins/download-monitor/download.php?id=328>

¹⁸⁹ <https://www.nidirect.gov.uk/publications/guide-protecting-waterfowl-lead-shot-wetlands>

¹⁹⁰ <http://www.oncfs.gouv.fr/Fiches-juridiques-chasse-ru377/Les-munitions-en-zone-humide-ar1342>

GIS analysis¹⁹¹

Defining land area consistent with the Ramsar definition of a wetland

Land use classes of the CORINE database were selected that are understood to be consistent within the RAMSAR definition. A precise description of this can be found in the Annex XV dossier (page 28), see also Figure E-12 for the purposes of this analysis only class 4 Wetlands was taken into account.

4 Wetlands	41 Inland wetlands	411 Inland marshes
		412 Peat bogs
	42 Maritime wetlands	421 Salt marshes
		422 Salines
		423 Intertidal flats
5 Water bodies	51 Inland waters	511 Water courses
		512 Water bodies
	52 Marine waters	521 Coastal lagoons
		522 Estuaries
		523 Sea and ocean

Figure E-12: CORINE land cover classes considered to be relevant for scope of restriction

Data preparation

1. Correcting spatial references and creating spatial indexes
2. Removing SPA that are not relevant
 - a. Removing marine areas (Doggersbank)
 - b. Remove Natura2000 sites that are outside EU land barriers
 - c. Remove CORINE data outside of boundaries of the EU/EEA (For impact assessment Norway, Switzerland and Liechtenstein are maintained)

The results is a dataset that contains all that relevant inland CORINE land use classes within the EU.

Spatial analysis

3. Clipping the data on the Natura2000 sites with the merged files on relevant CORINE landcovers yields a datalayer of all CORINE mapping that also are Natura2000 sites
 - a. QGIS ->Vector -> Geoprocessing -> Clip-> input layers CORINE mapping, CLIP layer the layer obtained in step 2c
4. Transferring attributes (ISOCODE per MS i.e. NL, AT, DE, FR, etc.) to these datalayer obtained in step 1 adds an explicit reference per MS.
 - a. QGIS -> Vector -> Data management tools -> join attributes per location, target vector:data layer obtained under 3a , join vector: data

¹⁹¹ This is produced based on the information available to the DS for the purposes of assessing the extent of wetlands that would be covered by the restriction. However, if data are to be used in an official capacity, for example for enforcement or compliance, the relevant Member States would need to update them based on the up to date situation in their territory.

from layer containing all EU Member States.

The data set obtained under 4a has (as with all spatial datasets, a spatial and a tabular component). The tabular component can be opened with Excel and using pivot tables the data can be analysed further.

Results and discussion

The results reported in Table 1 indicate that from the broader definition of inland wetland which consists of the relevant CORINE categories, 64 % is actually covered within the boundaries of an existing Natura 2000 site.

This implies that

1. Approximately 2/3 of the CORINE wetland categories consistent with the Ramsar definition occur within Nature 2000 sites and are therefore associated with an 'official' border (and usually clear indications in the field). A list of Nature 2000 sites associated with wetland habitats could be easily prepared by Member States (or EU institution) and communicated to stakeholders
2. A large proportion of the remaining wetland area is likely to be comprised of wetlands with relatively unambiguous boundary features, such as rivers, lakes or shorelines.

Conclusions

1. Uncertainties in relation to the identification of wetland areas based on a generic definition exist, but could be considered to be minimal where wetlands sites exist within an existing Nature 2000 site, or wetland types that are readily identifiable (such as rivers, lakes and foreshore).

Important disclaimer:

These maps are produced based on the information available to us for the purposes of assessing the extent of wetlands that would be covered by our restriction. However, if they are to be used in an official capacity, for example for enforcement or compliance, the relevant Member States would need to update them based on the up to date situation in their territory.

Table E-21

	Area of CORINE wetland per MS (km2)	Area of CORINE also Natura 2000 per MS (km2)	% Of CORINE covered by being Natura 2000 site
AT	13.21	11.32	86 %
AX	0.14	0.01	4 %
BE	13.70	13.08	96 %
BG	8.62	6.55	76 %
CY	0.34	0.17	52 %
CZ	8.00	5.85	73 %
DE	64.34	54.38	85 %
DK	15.79	12.45	79 %
EE	42.50	37.23	88 %
ES	57.13	50.03	88 %
FI	544.95	317.73	58 %
FR	68.58	59.48	87 %
GB	87.15	57.68	66 %
GR	29.75	26.03	88 %
HR	5.54	5.13	93 %
HU	54.48	23.39	43 %
IE	114.35	88.16	77 %
IT	66.35	59.81	90 %
LT	23.61	11.23	48 %
LU	0.04	0.04	92 %
LV	27.48	17.01	62 %
MT	0.00	0.00	100 %
NL	31.20	28.63	92 %
PL	58.09	40.31	69 %
PT	17.83	10.97	62 %
RO	62.92	52.42	83 %
SE	662.15	342.35	52 %
SI	0.53	0.43	81 %
SK	2.29	1.17	51 %
Total	2081.04	1333.03	64 %

Data sets used:

Natura 2000

Natura 2000 is an ecological network composed of sites designated under the Birds Directive (Special Protection Areas, SPAs) and the Habitats Directive (Sites of Community Importance, SCIs, and Special Areas of Conservation, SACs).

The European database on Natura 2000 sites consists of a compilation of the data submitted by Member States to the European Commission. This European database is generally updated once per year, so as to take into account any updating of the content of the national databases by Member States. However, the release of a new EU-wide database does not necessarily entail that a particular national dataset has recently been updated.

The **descriptive data** in the European database are based on the information that national authorities have submitted, for each of the Natura 2000 sites, through a site-specific standard data form (SDF). Amongst other site-specific information, the standard data form provides the list of all species and habitat types (under Bird Directive) for which a site is officially designated.

The **spatial data (borders of sites)** submitted by each Member State are validated by the European Environment Agency (EEA), including as regard their consistency with the descriptive data.

Any problems identified through the above validation procedures in the national datasets are brought to the attention of the Member States concerned. However, it remains up to the Member States to decide whether or not to submit a revised dataset before the European database is updated. As a consequence, the EEA cannot guarantee that all inconsistencies detected in national datasets are removed in the European dataset.

The dataset is available on the website of the EEA via the following link:

<https://www.eea.europa.eu/data-and-maps/data/natura-8#tab-gis-data>

Data projection

```
PROJCS["ETRS89 / LAEA Europe",
  GEOGCS["ETRS89",
    DATUM["European_Terrestrial_Reference_System_1989",
      SPHEROID["GRS 1980",6378137,298.257222101,
        AUTHORITY["EPSG","7019"]],
      TOWGS84[0,0,0,0,0,0,0],
      AUTHORITY["EPSG","6258"]],
    PRIMEM["Greenwich",0,
      AUTHORITY["EPSG","8901"]],
    UNIT["degree",0.0174532925199433,
      AUTHORITY["EPSG","9122"]],
```

```

    AUTHORITY[ "EPSG", "4258" ]],
PROJECTION[ "Lambert_Azimuthal_Equal_Area" ],
PARAMETER[ "latitude_of_center", 52 ],
PARAMETER[ "longitude_of_center", 10 ],
PARAMETER[ "false_easting", 4321000 ],
PARAMETER[ "false_northing", 3210000 ],
UNIT[ "metre", 1,
    AUTHORITY[ "EPSG", "9001" ]],
AUTHORITY[ "EPSG", "3035" ]]

```

CORINE database

CORINE Land Cover (CLC) was specified to standardize data collection on land in Europe to support environmental policy development. The reference year of first CLC inventory was 1990 (CLC1990), and the first update created in 2000. Later the update cycle has become 6 years. The number of participating countries has increased over time – currently includes 33 European Environment Agency (EEA) member countries and six cooperating countries (EEA39) with a total area of over 5.8 Mkm². Ortho-corrected high spatial resolution satellite images provide the geometrical and thematic basis for mapping. In-situ data (topographic maps, ortho-photos and ground survey data) are essential ancillary information. The project is coordinated by the EEA in the frame of the EU Copernicus programme and implemented by national teams under the management and quality control (QC) of the EEA. The basic technical parameters of CLC (i.e. 44 classes in nomenclature, 25 hectares minimum mapping unit (MMU) and 100 meters minimum mapping width) have not changed since the beginning, therefore the results of the different inventories are comparable.

The layer of CORINE Land Cover Changes (CLCC) is produced since the second CLC inventory (CLC2000). CLCC is derived from satellite imagery by direct mapping of changes taken place between two consecutive inventories, based on image-to-image comparison. Change mapping applies a 5 ha MMU to pick up more details in CLCC layer than in CLC status layer. Integration of national CLC and CLCC data includes some harmonization along national borders. Two European validation studies have shown that the achieved thematic accuracy is above the specified minimum (85 %). Primary CLC and CLCC data are in vector format with polygon topology. Derived products in raster format are also available. The seamless European CLC and CLCC time series data (CLC1990, CLC2000, CLC2006, CLC2012 and related CLCC data) are distributed in the standard European Coordinate Reference System defined by the European Terrestrial Reference System 1989 (ETRS89) datum and Lambert Azimuthal Equal Area (LAEA) projection (EPSG: 3035). Results of the CLC inventories can be downloaded from Copernicus Land site free of charge for all users.

CLC data can contribute to a wide range of studies with European coverage, e.g.: ecosystem mapping, modelling the impacts of climate change, landscape fragmentation by roads, abandonment of farm land and major structural changes in agriculture, urban sprawl, water management.

<http://land.copernicus.eu/pan-european/corine-land-cover/clc-2012/view>

For the purposes of the report we have used the 2006 (latest update February 2017) data set which is located here:

<https://www.eea.europa.eu/data-and-maps/data/clc-2006-vector-4>

Metadata on Natura 2000 sites

Field name	Field definition	Note	Data type
COUNTRY_CODE	Two digit country code the site belongs to		text(4)
SITECODE	Unique code wich forms the key-item within the database.	The unique code comprises nine characters and consists of two components. The first two codes are the country code the remaining seven characters, which serve to create a unique alphanumeric code for each site.	text(9)
SITENAME	Site name in the local language.		text(240)
SITETYPE	Type of classification for the site.	A: SPA (Special Protection Areas); B: SCI (Special Conservation Interest); C: both SPA and SCI.	text(1)
DATE_COMPILATION	The date information has been recorded in the Standard Data Form. The data field takes the form of the year (four digits) followed by the month in numeric form (two digits)		date/time
DATE_UPDATE	The date when the information reported for the site was last changed. The data field takes the form of the year (four digits) followed by the month in numeric form (two digits)		date/time
DATE_SPA	Date site classified as SPA		date/time
SPA_LEGAL_REFERENCE	The legal statement by the national authority in which the site was amended as SPA		memo
DATE_PROP_SCI	Date site proposed as eligible for identification as a Site of Community importance (SCI)		date/time
DATE_CONF_SCI	Date site has been confirmed as a Site of Community importance (SCI)		date/time
DATE_SAC	Date site designated as SAC		date/time
SAC_LEGAL_REFERENCE	The legal statement by the national authority in which the site was amended as SAC		memo
EXPLANATIONS	Additional explanations given by the country to support the dates designations.		memo
AREAHA	Surface area of a site in hectares. Although it is an obligatory field, the value -99 is given for sites for witch the areas is unknown. A value of 0 cab be correct if the site is a cave or cliff. In this case the field 2.3 is obligatory.		decimal
LENGTHKM	Site length is entered in kilometres.		decimal
MARINE_AREA_PERCENTAGE	Percentage of the site considered as marine		decimal
LONGITUDE	The geographic coordinate in decimals of the site centre. (ETRS89 projection)		double
LATITUDE	The geographic coordinate in decimals of the site centre. (ETRS89 projection)		double
DOCUMENTATION	Additional documentation existing as a reference for the site		memo

QUALITY	Description of the site in terms of ecological quality		memo
DESIGNATION	The local name of the official designation of the site		memo
OTHERCHARACT	Additional description in the local language about the site		memo

Annex F: Assumptions, uncertainties and sensitivity analysis

Table FX. Sensitivity analysis for the comparison of costs and benefits of a restriction on the use of lead-shot over wetlands under worst-case assumptions.

Worst-case costs implied by the proposed restriction		Benefits of the proposed restriction	
Annuitised one-off costs		Use value	
Replacement of guns	€ 31.7m	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	€ 2.4m	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	€ 158.5m	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	€ 192.6m	Non-use values	
Distributional cost in terms of generated tax revenues assuming an average VAT rate of 20 %	€ 38.5m	Protection of wildlife and ecosystem services	non-quantified
Distributional cost in terms of producer surplus gains (after VAT deduction)	Up to € 61.6m	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	€ 92-154m	Total societal benefit	> € 105m

Annex G: Stakeholder information

G.1. Consultation with Associated Industry

G.1.1. Direct contact with stakeholders

In order to get stakeholders feedback on the proposal as well as their input on the issues to consider the following activities have been organised: call for evidence, stakeholders workshop and a consequent follow up discussion.

Call for evidence.

The call for evidence was organised as a consultation on ECHA's website and ran from 21 April 2016 until 21 June 2016: <https://echa.europa.eu/documents/10162/4d696b50-7c41-44aa-b1aa-bab656eef2a5>.

The following specific questions were asked:

- 1. Can you please provide information on the suitability of alternatives to lead shot, in terms of hunting efficiency and safety of hunting?*
- 2. Would a restriction on lead shot have an impact (positive or negative) on your industry (as manufacturer, distributor, importer, SME)? What would be the impact on consumers (e.g. hunters)? Please be as specific as possible and provide where possible quantitative information.*
- 3. What has been the experience with existing (national or regional) regulations on lead-shots: are there difficulties in compliance with existing restrictions?*
- 4. What will be the effects on wildlife and water ecosystems if a ban on using lead shot will **not** be introduced?*
- 5. Do you have any other information that would be relevant for the preparation of this Annex XV report (including case studies and lead pollution in wetlands, remediation costs and hunting activities leading to high concentrations of lead)?*

G.1.2. Participation in “targeted” meeting with stakeholders

As a follow up from the call for evidence a workshop was organised at the ECHA’s premises at 29 September 2016. The following is the Chairman’s summary of the discussions that took place.

G.1.2.1. Introduction

The European Commission requested ECHA on 3 December 2015 to start the preparation of an Annex XV restriction dossier concerning the use of lead shot over wetlands¹⁹². The development of the Annex XV restriction report will require ECHA to determine if the risk from the use of lead shot is not adequately controlled and that the risk needs to be controlled at a union level. Therefore, ECHA will need to assess the risks to human health and the environment associated to the use of lead shot over wetlands and assess the impacts of any such restriction, including the availability of suitable alternatives. More information on the restriction process can be found on ECHA’s website¹⁹³.

The harmonisation of the conditions for the use of lead in shot in wetlands is a priority at EU level. This is because national legislation has already been enacted by some Member States (or regions in some Member States) to implement the Agreement on the Conservation of African-Eurasian Migratory Water birds (AEWA) under the auspices of the UN Environment Programme (UNEP); to which the EU is a Party.

As part of the preparation of the restriction dossier, ECHA held a ‘call for evidence’ from 1 April to 21 July 2016. The evidence that ECHA looked to obtain included information on the tonnage of lead used in shot, emissions to the environment and exposure to humans and wildlife. The call was also intended to obtain relevant information on costs, uses of lead shots where substitution may be challenging and issues related to enforceability.

Forty one comments were received from EU countries (of which 15 were from the UK, 10 were from Italy and the rest were from other countries). Responses were received from industry and hunting associations, national and international authorities and institutions, scientists, international and local NGOs as well as a consultancy company. The comments received covered all aspects of the restriction proposal and, in addition to information relevant to the use of lead shot, provided information on other types of lead derived ammunition, e.g. lead bullets and their alternatives¹⁹⁴.

Following the call for evidence, ECHA hosted a workshop on 29 September 2016 with invited participants selected from those that had responded to the call. A document highlighting key discussion points was prepared by ECHA before the meeting and shared with participants. The aims of the workshop were to:

1. ensure that ECHA has correctly interpreted the available information;
2. understand on which issues there is agreement between key stakeholders (and where there is not); and
3. assess which knowledge gaps still exist.

¹⁹² https://echa.europa.eu/documents/10162/13641/echa_annex_xv_restriction_proposals_en.pdf

¹⁹³ <https://echa.europa.eu/addressing-chemicals-of-concern/restriction>

¹⁹⁴ At a later stage, ECHA will assess if there is a risk that is not adequately controlled that needs to be dealt with at a Union level for other uses of lead ammunition, including hunting in other terrains than wetlands and target shooting, and for the use of lead weights for fishing.

This document is a summary of the discussions at the workshop, organised according to the discussion points identified in the preparatory discussion document. A short summary of each of the participants experience and expectations is provided in an annex to the report. The European Federation of Associations for Hunting and Conservation (FACE) were invited to participate in the workshop, but did not attend.

G.1.2.2. Summary of discussions

Scope of the restriction

Discussion points from preparatory document:

- Should the restriction include lead compounds?

Summary of discussions:

- Shot and projectiles are lead alloys – there is no evidence that lead compounds are used in shot. However, some lead compounds are used in lead shot ammunition for other purposes (e.g. as propellants / initiators in shotgun cartridges: lead styphnate and lead azide).
- Bismuth shot can contain lead as an impurity (approximately 1 %). It was noted that California (US) has a threshold limit of 1 % lead in shot.
- The restriction text in the discussion document was based on the UK legislation and refers to lead and lead compounds. The inclusion of lead compounds within the scope is not likely to result in an increase in the scope compared to lead only but, equally, would not have any negative implications. A suggestion to include lead alloys in the scope of the restriction was made. The likelihood of shot using lead compounds (rather than lead or lead alloys) being developed in the future was briefly discussed. Inclusion of lead compounds in the scope could avoid this, currently hypothetical, issue that could undermine the effectiveness of the restriction in the future.
- Some Member States have implemented national restrictions on the use of lead shot using 'lead-free' or 'non-toxic' terminology. Lead coated with nickel or other substances would be included in ECHA's proposed scope.
- The restriction proposal does not explicitly mention sports shooting ranges situated within wetlands, but the intention is that these uses would fall within the scope of the restriction. Several stakeholders noted that a definition of shooting should also be provided in the restriction proposal, to clearly include lead shooting ranges located within wetlands. Such shooting ranges are known to exist.

Enforcement

Discussion points from preparatory document:

- Which is the most appropriate definition for a "wetland"? Is the Ramsar definition suitable for enforcement purposes and to guarantee an adequate level of protection to water birds? Or should rice fields and fed flight ponds be included?
- Should the restriction cover possession of lead shot in wetlands or is there another equally effective way of ensuring compliance with the restriction?
- Would it be useful to define a comprehensive list of species that should not be hunted using lead shot, in addition to the defined geographical "wetland criterion"?

Summary of discussions:

- The Ramsar convention definition of a wetland is considered to be sufficiently wide to cover all relevant types of habitats, including rice fields and fed flight ponds. However, some participants reported regional differences in the interpretation of the Ramsar definition in the EU. For example, in some regions of Spain rice fields are not considered to be within the Ramsar definition. To address this issue, and avoid misinterpretation, a list of Ramsar wetland types (or wetland types from other EU legislation, such as the Habitats Regulation) could, if necessary, be included in the restriction. Other existing networks of wetland sites (those within the EU Natura 2000 network) could be used as the basis for the scope of the restriction, but this was not discussed in detail.
- The creation of buffer zones surrounding wetlands was also discussed (distances of 100-300 metres were mentioned). Buffer zones limit the possibility to shoot from outside to inside of a wetland area. In any eventuality, the scope of the restriction must be clear to both hunters and enforcement authorities.
- In regions of the EU with a complex interface between wetland and terrestrial habitats (such as Finnish forests that comprise a mosaic of forest, lakes, ponds, bogs and mire habitats) any geographically defined scope could be problematic from an enforcement perspective (including issues surrounding possession, see below) as hunters are likely to frequently move between wetland and forest areas, even when not hunting waterfowl. This was noted to be of particular concern where steel shot is not permitted to be used due to restrictions to prevent damage to forestry equipment (as is the case in some Finnish forests). This seems typical for hunting in some northern European countries where forests and wetlands are adjacent to one another and hunting types (waterfowl, terrestrial) are interlinked. The suitability of alternatives to lead for terrestrial habitat hunting (including alternatives other than steel such as bismuth), which could address this concern, was briefly discussed.
- It was noted that there are very limited resources available for enforcement in the EU. In Member States (e.g. Italy) where the national legislation allows possession of lead shot in wetlands (at a national or regional level), enforcement problems have been reported. Significant non-compliance has also been reported in the UK and Spain. A restriction on the possession of lead shot (e.g. US legislation where lead cartridges are not allowed on the body) could result in a more effective and enforceable restriction. A case study was discussed (the Ebro Delta area in Spain) where possession was successfully regulated and contributed to a high level of compliance with the local restrictions on lead in shot. However, prohibiting possession of lead shot within designated areas as part of the restriction might also raise issues (for example to move freely and to camp during multi-day / multi-quarry hunting trips) although it was noted that this may only be relevant in some countries (e.g. Finland). The challenge is to define possession in a sufficiently meaningful way, recognising the different hunting practice / geography in different member states.
- Some Member States have implemented the AEWA agreement by means of a list of species for which the use of lead shot for hunting is prohibited. Such an approach is considered to facilitate enforcement as the type of shot present in wildfowl can be checked (70 % of ducks shot in England are still illegally shot with lead). Equally, it could also reduce risks to waterfowl from consumption of lead shot outside of wetlands (e.g. in agricultural areas). It was also discussed that any hunting with lead

within a wetland (for non-listed or non-waterfowl species) would result in lead being directly available to waterfowl via ingestion. A restriction based solely on a list of species, without also considering wetland habitat, may not address all risks to waterfowl.

Human and environmental hazard properties

In general, the human health and environmental hazards of lead are well understood. As such, discussions at the workshop were restricted to sub-lethal effects on wildlife.

Discussion points:

- What is the current level of knowledge concerning the sub lethal effects of lead exposure, particularly concerning endpoints that are potentially relevant to population-level impacts, such as immunotoxicity and reproductive effects?
- Is it possible to make associations between immunotoxicity, and reproductive toxicity and population trends?

Summary of discussions:

- Sub-lethal effects of lead poisoning are recognised at individual level and are known to result in (non-exhaustive list):
 - a. Effects on coordination: leading to increased risk of predation and other types of traumatic mortality (e.g. flying accidents).
 - b. Effects on reproduction: reduced sperm quality (which can also affect population growth). Three ppb lead (from consumption of a single shot) can affect sperm quality in partridges.
 - c. Effects on immune-competence: potentially leading to reduced overwintering survival rates.

Risk to human health, wildlife and the environment

Environment (habitat and wildlife)—Emissions

Discussion points from preparatory document:

- It is unclear if the available information on lead releases reflects the current situation in the EU 28. Considering the lower values of the ranges provided for Spain, Italy and UK would already account for 18 600 tonnes per year (aquatic and terrestrial environment) against 21 216 tonnes per year estimated for the EU by AMEC report. What is the best approach to produce a realistic estimate for both the aquatic and terrestrial environment?

Summary of discussions:

- This was acknowledged to be a problematic area. However, AFEMS considered that the estimates reported in the previous AMEC study give the right order of magnitude. Many participants considered that the available data are only likely to be sufficient to define an emission range. The same approach could be applied to the cost assessment.
- Estimates from market data can be corroborated using 'bag statistics' and assumptions on the number of shots taken per bird shot (1 kg per 10 birds shot was

proposed). Data available via Article 12 of the Birds Directive (where reporting obligations are set for Member States) could also be used to support the estimations (latest reporting round ends 2018). The Commission offered to provide help to identify the key data available in the reports made under the Bird Directive. Additional data are available in the lead VRAR (supplementary CSR for hunting).

Distribution of lead shot in the environment

Discussion points from preparatory document:

- Is there recent detailed mapping of the lead shot density in wetlands at European level? Is there detailed information on the number of hunting posts in Europe?

Summary of discussions:

- The density of lead shot in wetland sediments has been studied in several countries, with greatest densities observed in southern Europe.
- It was noted that the area with greatest lead shot density overlaps with the wintering grounds of many bird species. Northern European countries are predominantly a breeding area for water birds and hunting intensity is reported to be lower than in other European countries. The length of the hunting seasons also varies across different EU Member States.
- It was noted that lead shot is persistent for long periods in sediments / soils and that there are extensive studies on the settlement rates of lead pellets and the time required for lead shot to vacate soil / sediment depths accessible to birds as they feed. In some cases, e.g. salt marshes, shot may remain available to waterfowl almost indefinitely. Some bird species (e.g. diving ducks) access deep sediments when searching for food.

Fate, behaviour and effects of lead in the aquatic environment

Discussion points from preparatory document:

- Is there detailed mapping of wetlands dependent on groundwater bodies at European level? Are you aware of existing contamination of groundwater systems connected to wetlands in Europe (EU 28)?
- Is the transformation/dissolution behaviour of lead shot coated with nickel or other substances different to conventional lead shot, and does this affect bioavailability in wildlife?

Summary of discussions:

- There was limited knowledge of groundwater contamination associated with use of lead shot among the participants and a view that there were a lack of specific studies. Participants noted that the physico-chemistry of wetlands is different to other ecosystems, which have been more extensively studied, and that this could be important.
- Invertebrates, fish and plants were also recognised to be sensitive receptors and as they were also part of birds' diet, they could contribute to the overall exposure of birds to lead. Some relevant information is included in the LAG reports (e.g. information on bioaccumulation in trout).

- The US has a long history of investigating the toxicity of coated shot (began testing in 1974). Conclusions of these studies was that coated shot was equally as toxic as lead shot (coatings removed by action of the gizzard).

Human health exposure (humans via the environment)

Discussion points from preparatory document:

- What is the best approach to estimate lead exposure in the European general population from the consumption of wildfowl, including children, pregnant women and high frequency consumers?
- Available studies on lead fragments from bullets, show that acidic conditions during cooking can increase the final lead concentrations in meat along with its bioavailability. Would this scenario be relevant for waterfowl meat killed with lead shot?

Summary of discussions:

- Lead is present in wildfowl killed with lead shot (both as unremoved fragments and the background concentration from lifetime exposure, including from the consumption of lead shot). However, care must be exercised when analysing the available data on lead intake rates from food as it may not be straightforward to extract 'waterfowl' consumption from overall consumption (or consumption of game).
- Acidic conditions during cooking can increase the final lead concentrations in meat along with its bioavailability. This scenario was recognised to be relevant for lead shot.
- How can the effectiveness of the advice to reduce health risks associated with game meat consumption in vulnerable groups be assessed in EU Member States? Has this been evaluated elsewhere?
- Can embedded pellets remain undetected before cooking? Or generate fragments that are difficult to be removed?
- There was no information available on the effectiveness of the European Institutions' advice to protect consumers from the risks of eating game meat (shot with lead). However, published studies suggest that consumers (even those experienced with eating game) are not able to identify and remove all the pellets and fragments from the game meat before consuming it. It was also mentioned that lead is present in the meat (muscle tissues) of birds because of a combination of processes, including fragments of shot, bioaccumulation from diet and the metabolism of ingested lead shot. The bioavailability of lead present as a result of these various processes is different, but all lead is likely to be eventually bioavailable to some extent.
- Due to changes in consumer preference (game meat marketed as healthy) the baseline could include an upwards trend in the consumption of game.

Impacts

Wildlife (birds)—Population trends

Discussion points from preparatory document:

- Can the results of the studies on population trends mentioned above be transferred to other bird species?

- Could continued use of lead in shot in wetlands result in further bird species being listed as 'of concern' e.g. inclusion on the IUCN (International Union for Conservation of Nature) red list?

Summary of discussions:

- Population level impacts on wildfowl are difficult to evaluate due to the lack of specific data sets. However, available studies indicate impacts on some species (e.g. buzzards, red kites, red grouse, grey partridge).
- "Source pathway receptor" data for one species (e.g. Pochard) is transferrable to others. However, extrapolating impacts on population demographics from one species to another is more difficult.
- Some species are more vulnerable than others to lead poisoning due to the different biological strategies that they employ. For example, some species (notably raptors) only produce low numbers of offspring per year and require long lifespans to ensure a sustainable population. Sub-lethal effects on these species that affect either individual longevity or reproductive success therefore potentially pose a risk to population demographics. There are a limited number of raptor species associated with wetlands (e.g. white-tailed eagle), but there are other species employing similar reproductive strategies within wetlands.
- In terms of endangered species, individuals can be critically important in terms of species recovery and avoiding the risk of extinction, e.g. the marble teal / white-headed duck. Some bird species also spend more time in highly contaminated areas (e.g. in some specific wintering Mediterranean areas) and therefore can suffer from greater impacts than others.
- Data available from the Birds Directive (where reporting obligations are set for Member States) could also be used to evaluate population trends, especially for vulnerable and endangered species. The Commission offered to provide help to identify the key data available in the reports made under the Art. 12 of the Bird Directive. It was also noted that the Birds Directive required that Member States maintain bird population at an adequate level of conservation.
- The welfare issue of prolonged suffering prior to death as a consequence of lead poisoning was discussed. It was also discussed that it would be unethical to wound (cripple) an animal without killing it, as could potentially occur more frequently when using alternatives to lead shot. Available evidence on the incidence of crippling in the US suggests that crippling rates associated with the use of steel shot decreased after a few years to lower levels than those recorded for lead.

Vulnerable groups (children, pregnant women and frequent game meat consumers)

Discussion points from preparatory document:

- What is the best approach to estimate the number of high-frequency game consumers at European level?
- What is the best approach to estimate the number of children at risk of effects on IQ at European level?

- The number of children exposed at EU level to lead from waterfowl consumption is difficult to estimate with the available information. The number of children at risk is likely to be relatively small (280-650 estimated for the UK based on simple assumptions on the size of the relevant hunting population). However, consumption of small quantities of game can potentially lead to significantly (four times) increased lead intake rates for these individuals relative to those that do not.
- Exposure via waterfowl could be considered 'avoidable' and as the consequence of a recreational activity.
- A restriction may not lead to an immediate reduction in lead levels as a consequence of legacy environmental contamination (reduction in ambient exposure likely within a relatively short period of time – 5 to 10 years).

G.1.2.3. Availability of alternatives

Discussion points from preparatory document:

- Is lead shot coated with nickel and other chemicals considered as an alternative?
- Which are the key factors influencing hunting efficiency? Is training a significant factor?
- Does reducing the distance to a quarry necessarily imply a reduction in the probability of hunting success? Why this is not considered an issue in NL and DK?

Summary of discussions:

- It was stated by several participants that there are several factors that influence hunting success: how good you know the area where you hunt, how good one is at hunting (finding and tracking quarry) and what ones hunts with.
- In general, heavier pellets (i.e. lead) demonstrate greater accuracy over longer distances, but it is questionable what accuracy is required when shooting at distances of up to 40 metres. It was mentioned that the quality/performance of steel shot has increased in recent years and that increasing the size of pellets can compensate for the difference in density between lead and steel.
- The main alternatives for hunting in wetlands are steel, bismuth and tungsten. Further information on their toxicity can be learned from US where the focus is on non-toxic shot and shot types need to be pre-approved before being used by consumers.
- Several stakeholders claimed that not all hunters are satisfied with the performance of alternatives, but that this may be because they have not received adequate training in their use, thus also triggering concerns about safety issues (e.g. ricochet). It was noted that younger hunters seem to be more favourable to the use of alternatives than older hunters. US and Danish hunting populations are good case studies for transition to alternatives. Hunting bags appear stable in areas (national or regional level) where steel shot is used i.e. use of different shot material has not reduced the number of birds shot.
- The results of blind testing (using both lead and alternatives) had been reported in the literature.

- Nickel coated shot (and in general lead shot coated with any chemicals) cannot be considered as an alternative since the gizzard of waterfowl can destroy the coating and make the lead available.

G.1.2.4. Costs

Discussion points from preparatory document:

- Is it so that most hunters should already comply with national legislation, therefore the cost of this restrictions is likely to be smaller in the countries with existing legislation?
- Are the incurred costs probably easily affordable for hunters, given the amount they spend on other items necessary for hunting?
- Does a wider scope (i.e. covering possession of lead cartridges over wetlands) pose additional costs to hunters?

Summary of discussions:

- Concerning old guns it was pointed out that steel shot exists for all types of guns (old or not). Most (if not all) guns currently on the market are suitable for steel shot. During the meeting a reference was made to the BASC recommendations¹⁹⁵ on which guns can be used with steel shot. In many Member States that have adopted regulations on the use of lead shot over wetlands hunters should already have replaced old guns with steel proof guns, so a REACH restriction for use of lead shot in wetlands would not represent a significant additional cost for hunters.
- It was stated that the general cost increase associated with the use of alternatives to lead shot for the UK is about 1.7 %, which is considered to only be a marginal increase and affordable.
- It was pointed out that bird mortality (from lead poisoning) is sometimes compensated by the introduction of captive-reared birds. The cost of this re-stocking represents a cost to society, which could be avoided.
- AFEMS confirmed that if the restriction proposal is limited to the wetlands only, no major issues are expected for lead shot manufacturers, due to the limited amount of lead involved. On the other side, AFEMS asserted that an extension to other environment than wetlands could trigger significant losses for lead shot manufacturers.

G.1.2.5. Benefits

Summary of discussions:

- The investments made in nature conservation (e.g. LIFE projects) would not be reduced/lost
- A restriction on the use of lead could increase the reputation of hunting as a sustainable activity.
- The benefits to landowners who own wetlands used for recreational purposes, including hunting, could be evaluated. Landowners can use wetlands populated with wild birds to make profit: e.g. with paid hunting permits. Having wild ducks in

¹⁹⁵ <https://basc.org.uk/technical/>

wetlands allows landowners to possibly make greater profits because a wild duck has a higher value than a captive reared one.

- Avoidance of costly measures to preserve and conserve threatened species suffering from lead poisoning.
- Increased value of ecosystem services, provided by water birds. Wetlands are recognised as major recreational areas in the EU.
- Some bird species would have greater benefits than others according to their conservation status.
- Waterbird populations would be maintained in relatively more favourable conservation status by having higher survival and thus preventing more species being banned from hunting. Reduced mortality of birds will provide more hunting opportunities and will create higher demand for ammunition and other services associated with waterbird hunting compared to a situation where lead shot is not phased out.

Follow-up

1. ECHA will make a short chairman's summary of the workshop to which participants can provide comments.
2. Participants were invited to send ECHA any additional material and information that was referred to in the workshop.
3. ECHA will further develop the Annex XV report will send a draft version to the participants of this workshop for feedback in the middle of February.
4. A WebEx will be organised to gather further feedback (4th week of February).

1. Appendix to annex G

Opening remarks by participants

Participants were invited at the opening of the workshop to provide an opening statement on why they were participating and what their expectations for the workshop were. These are briefly summarised below.

Niels KANSTRUP - Danish Academy of Hunting

- First and foremost a hunter - insight and comments are based on experience
- 30 years' experience with restriction on lead shot for shooting in wetlands (since 1996 in NL), 20 years on total ban for all shooting
- Here to give advice. Happy to assist ECHA

Rafael MATEO - University of Castilla-La Mancha, Spain

- Sustainability of hunting is one focus of research group
- Working on lead poisoning for 25 years
- Lead very interesting - one of the few environmental contaminants that can produce lethal poisoning in wildlife (perhaps some pesticides are others)

Mario GE - Association of European Manufacturers of Sporting Ammunition (AFEMS)

- 32 European Countries / 600 000 workers / 7 million hunters / 3 million sports hunters
- Turnover of sector is € 18-20 billion per year (just in relation to products themselves)
- Members of REACH lead consortia
- NGO status under the auspices of the UN

Torbjörn LINDSKOG - Association of European Manufacturers of Sporting Ammunition (AFEMS)

- Lead is "ideal" material for ammunition based on its ballistic properties
- Debate is open on the impact on environment and human health from lead ammunition
- Alternatives for specific applications are available
- lead-free does not mean "problem free"; industry will only release products when they are assured that they are safe for human health and the environment
- Expectation from this workshop
 - Distinguish facts and figures from emotions
 - Industry stands ready to provide more information if necessary

Alessandro ANDREOTTI - Institute for Environmental Protection and Research (ISPRA), Italy

- Initially involved in the implementation of legislation for biodiversity protection (Habitats and Birds Directives), lead poisoning in 2006
- AEWA adoption: worked on Egyptian vulture (scavenging birds)
- 2007: Italian ban of lead shot in Natura 2000 sites
- CMS (Conference on Migratory Species) conference of parties (2014 - IT presidency of EU)
- Expectations:
 - Surprised that restriction scope is limited to wetlands as there is overwhelming evidence of adverse effects of lead
 - AEWA called for phase out of lead ammunition
 - Sustainable hunting is possible
 - Can we agree that a restriction is urgently required?

Kai Tikkenen - Finnish hunters association

- Finland has a ban on lead shot for waterfowl hunting, wherever they occur
- Objectives for workshop: try and avoid an unfair restriction
 - Finnish forests – “wetlands” are very prevalent – any restriction based on “wetlands” would prevent use in Finnish Government Owned Forests as all steel shot is banned because of damage to forestry equipment.
 - Only bismuth would be available: expensive
- Bans for rifle ammunition (lack of ballistically good alternatives)
 - Moose hunting using alternatives is viable as less precision is required (not for small game)
- Hunters in wetlands initially not happy with steel shot, but growing acceptance
- Ethical aspects important to consider (if they need to shoot at shorter distances)

Steve BINKS - International Lead Association (ILA)

- Lead ammunition is a small use: 2 % of overall lead tonnage
- 95 % of use is in automotive and industrial batteries

Wouter LANGHOUT – Birdlife International

- Would like to take a step forward
- lead poisoning is “most pressing and easily solvable” issue in bird conservation
- Need to come up with something that makes a difference
- Partial bans are not the way forward - problems in MEMBER STATE where these are enacted (from an enforcement perspective)
- Acknowledges that the mandate is what it is, but would urge participants to consider a more ambitious scope

Sergey DERELIEV - African-Eurasian Water bird Agreement (AEWA)

AEWA established in 1995

- 76 Parties to the agreement, including the EU
- Original text of the treaty envisaged a full phase out of lead ammunition by 2000
- Legal text amended post 2000 - phase out "as soon as possible"
- Strategic timeline - phase out of lead in wetlands by 2017

Ruth CROMIE - African-Eurasian Water bird Agreement (AEWA)

- Wildlife health professional (also humans and livestock), vice chair of AEWA technical committee
- 18 years at Wildfowl and Wetland trust (WWT)
- Preventing poisoning working group
- Risk mitigation issues
- Worked on compliance and risk mitigation issues in the UK, including the Lead in Ammunition group (LAG)
- Considers that issue has moved from biology to social

John SWIFT – Lead in Ammunition Group (LAG)

- Chair of Lead Ammunition Group (previously chair of BASC / FACE)
- four risk assessments produced (looked at hazards, sources, pathways and receptors)
- Developed a risk mitigation register
- Concluded, based on the evidence available, that a progressive replacement of lead ammunition was required
- Submitted June 2015
- Group continued - looking at the available science
- Likelihood of wildlife population level effects

Deborah PAIN - Wildfowl and Wetlands Trust (WWT)

- Extensive experience with lead poisoning issue and publication
- 1983 Royal Commission on Environmental Pollution
- Wetlands International report 1991
- Individual, population and human health issues
- Expectations are for an evidence-based debate (issues known about for 50 years)
- Considers that there is much misinformation in the debate

G.2. Consultation with international organisations and non-EU Countries

Representatives of the AEWA secretariat have participated to the call for evidence and have been attending the workshop in September.

G.3. Consultation with other EU services and institutions

G.4. Consultation with Member State Competent Authorities

As a follow-up of ECHA's workshop on a possible restriction of the use of lead shot over wetlands, ECHA was invited to the NADEG meeting to give a presentation of its work on the restriction proposal.

The objective of that presentation was:

- a) To raise awareness on the work carried out in ECHA
- b) To get feedback from the Member States on ECHA's proposal.

ECHA received feedback on the following points:

1. The importance of defining wetlands and making it clear to the hunters where lead shot can and cannot be used.
2. The need to draw buffer zones around wetlands so as to minimise the emission from spent pellets into the wetlands.
3. Positive reactions for having possession (1 Member State) in the scope of the proposal. It was recognized as a main factor contributing to non-compliance.
4. Germany asked whether Member States might go beyond the scope of the restriction. The Commission (DG ENV) informed that under the Birds Directive more stringent conservation measures would be allowed.
5. The importance of the knock-on effects of lead in waterfowl and terrestrial birds was also highlighted. These knock-on effects concerns the secondary poisoning of raptors and scavengers. CMS secretariat may provide additional information on this.

Several questions were made to the Member States, stressing the urgency of having the correct information on the state of play in each Member State.

The chair of the meeting urged the members to respond to ECHA's questions as a restriction on the use of lead shot over wetlands (and possibly later over terrestrial areas) is of great importance to achieve the policy objectives of the EU Nature Directives.

G.5. Public Consultations on the restriction report

After submission of the Annex XV restriction report, ECHA organised a six-month public consultation on the restriction report from 21/06/2017 until 21/12/2017¹⁹⁶.

278 comments were received in the public consultation. The figures below provide an overview of the countries of origin and types of organisations that submitted comments.

Respondents were made up of individual members of the public¹⁹⁷ as well as numerous stakeholder organisations representing a range of interests (i.e. hunting organisations/associations, wildlife conservation organisations, organisations supporting the improvement of animal welfare, industry or trade associations, academic or research institutions). Comments were also submitted by international organisations (e.g. UNEP/AEWA, UNEP/CMS, etc.), National Authorities and some Member States.

One comment (n. 1802) provided a consensus statement from 45 scientists from 13 countries. A few comment were also sent by non-EU countries.

¹⁹⁶ The comments received, as well as the responses from the Dossier Submitter (ECHA) and from the rapporteurs of the Committees for Risk Assessment and Socio-economic Analysis are available on the ECHA website: <https://echa.europa.eu/it/restrictions-under-consideration/-/substance-rev/17005/term>

¹⁹⁷ Some comments were submitted by members of the general public in response to organised campaigns on social media.

Figure 1-1: Comments by origin (country)

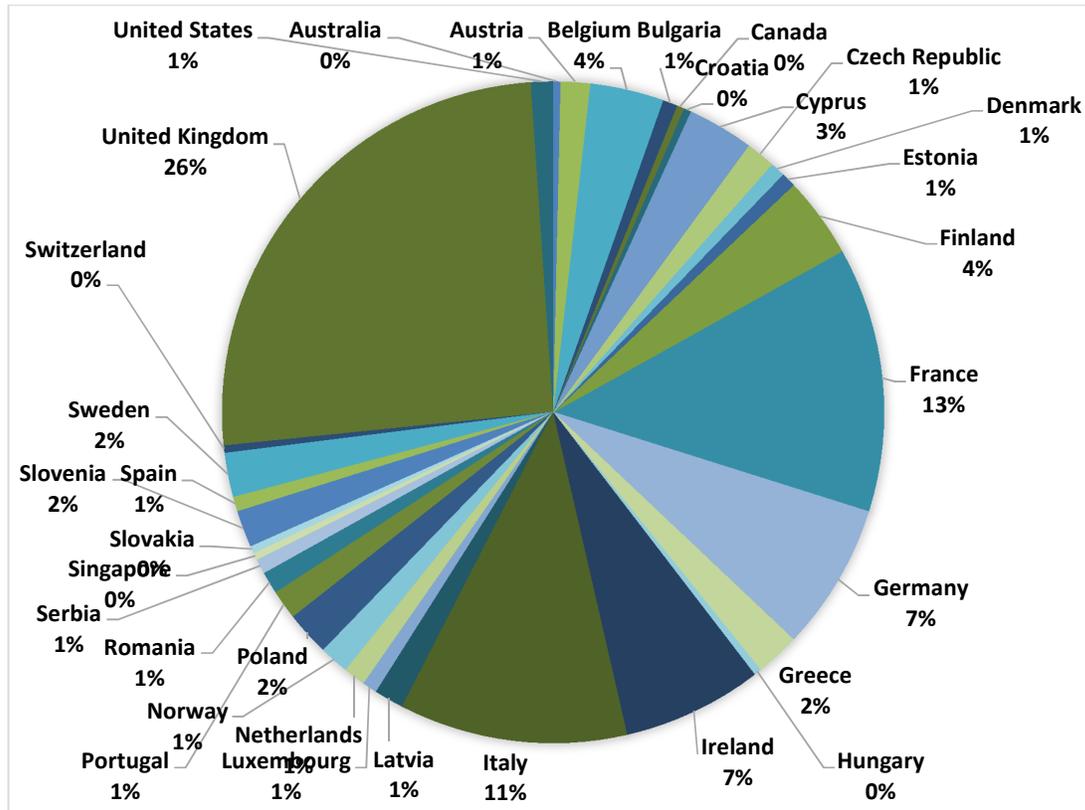
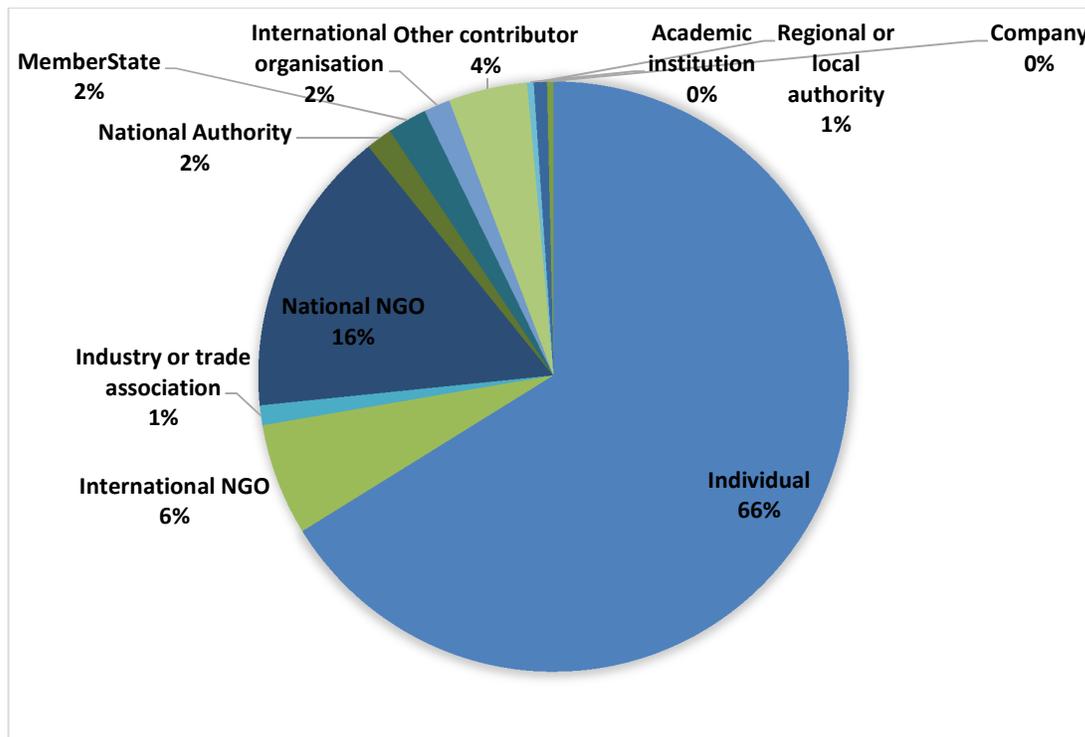


Figure 1-2: Comments by type of organisation



The Dossier Submitter and the Rapporteurs in their opinion have taken these comments into account, as appropriate, in updates to relevant sections of the Background Document.

The key themes highlighted by respondents were as follows:

- the **scope of the restriction**, including the **proposed definition** for a wetland (Ramsar Convention definition) and the **wording of the entry** (specifically the word 'use', which under REACH includes 'any keeping' i.e. possession),
- the **transitional period for compliance**,
- the **suitability of alternatives**, and
- the **proportionality of the restriction proposal**.

Several comments from hunting organisations questioned whether the inclusion of peatlands in the scope would be appropriate. UNEP/AEWA and other stakeholders provided supporting evidence that the inclusion of peatlands would be justified.

In addition, comments from hunting organisations typically highlighted 'practical problems' with respect to both the scope and the restriction of 'possession' of lead gunshot in addition to a restriction on the 'firing/discharge' of lead gunshot.

However, other respondents highlighted that the lack of compliance associated with many existing restrictions on the use of lead gunshot in wetlands has been due to ineffective or impractical enforcement. Some Member States (e.g. Denmark, Norway) also shared their experiences in relation to the scope and enforcement issues.

Several comments from members of the public and stakeholder organisations received from Ireland (e.g. comment 1706) requested that a national derogation from the proposed restriction was justified, based on proportionality and lack of evident risks.

Some comments focussed on the technical and economic feasibility of alternatives to lead gunshot cartridges. Certain comments questioned the conclusion that alternatives to lead gunshot were available (e.g. comment 1581), whilst others supported the analysis of the Dossier Submitter that alternatives were technically and/or economically feasible, including Denmark, Norway (Member States), and a company¹⁹⁸ manufacturing lead-free cartridges (comment 1854).

In relation to the transitional period, requests for a longer time period were typically noted among hunting organisations whilst requests for a shorter time period (i.e. 18 months) were noted in comments from conservation/environmental organisations. International organisations such as UNEP/AEWA and UNEP/CMS were also in favour of a shorter transitional time than that proposed by the Dossier Submitter.

Some comments from hunting organisations and industry or trade association also focused on acceptable levels of risk (especially for humans consuming game meat).

¹⁹⁸ Kent Gamebore Corporation.

A comment was received from a Finnish National Authority (# 1825) noting the possible impacts of the use of alternatives to lead gunshot on the Finnish forestry industry and requesting an exemption, although without providing a comprehensive socio economic analysis.

Several comments also highlighted the importance of protecting raptors, scavengers (suffering from secondary poisoning) and water sources as groundwater.

Although specifically requested, no detailed information on the number of shooting ranges located in wetlands in the EU was submitted during the consultation. However, several examples of shooting ranges located within or nearby wetlands were provided. Some Member States (e.g. Sweden, Norway, comments #1639 and #1608) clarified that sport shooting with lead shot was already totally banned, irrespective of the shooting ranges being located over/nearby a wetlands or not. A more detailed overview of the shooting ranges in the EU¹⁹⁹, is given in the following section.

Shooting ranges in the EU

Based on the information received in the Public Consultation, Member States have in place different risk management measures or no measures at all.

Sweden and Norway have a total ban in place for the use of lead at shooting ranges, as they reported in the PC. They therefore do not differentiate between shooting ranges within and outside of wetlands.

In Sweden, for shooters who compete on the Olympic level in the games trap and skeet there is a derogation but these shooters represent only a very small fraction of all shooters. In Norway, a few exemptions from the ban on lead shot at shooting ranges have been granted upon application for safety reasons for figure shooting (steel targets) and some similar activities, amounting to ca. 7.5 tons per year of lead shot.

In Greece, there are no shooting ranges that are located within or nearby to wetlands, based on information provided by the Hellenic Hunters Confederation (Greece), since the existing legislation prevents their construction in such areas.

In the UK, according to British Association for Shooting & Conservation, any shooting ranges shooting over the foreshore in England and Wales, or over any wetland in Scotland and Northern Ireland are already required to use non-lead shot under the various Environmental Protection regulations. However, based on comment #1821, most shooting parties in England operate on private land rather than permanent ranges, with agricultural fields as well as moors and peatlands all being used as temporary shooting ranges.

Evidence of shooting ranges located nearby a wetland was shared from Italy, comment #1781. In Slovenia, based on comment #1722, there is no legislation preventing the use of lead gunshot at these sites. However, some of the hunting clubs have internal rules and do not allow using lead gunshot cartridges at the clay pigeon shooting ranges they are managing (not only those close to the wetlands).

In Germany, based on comment #1605, in the last decades there was much effort to

¹⁹⁹ See also section E.6.2.2 on benefits for further information on shooting ranges.

establish risk management measures (such as drainage or catch fences) and other measures to prevent poisoning of ground water (e.g. soil replacement). Shooting range operators and authorities conduct investigations to monitor the state of soil and water around shooting ranges. Some shooting ranges allow only lead-free shot for clay pigeon shooting.

In Finland, based on the information shared by the Finnish Hunters' Association, the shooting range and the distribution area of the shotgun pellets are defined as the shooting range structure that is required to be cleansed when the shooting activity is ceased. A guidebook for Environmental Impact Management at Shooting Ranges – Best Available Techniques (BAT), suggests that the risk assessment is the key to control the risks to distribution/dispersal of contamination. In most cases, the risk is controlled by monitoring the water quality and in some high-risk cases by purifying the water in a draining ditch. The Latvian Hunters' Association noted that there is no ban of lead ammunition in shooting ranges. However, they mentioned that there are no shooting ranges that are located in wetlands, based on their information.

A comment from Ireland, comment #1734, mentioned that the vast majority of shooting ranges in Ireland are built on or within shot range of wetlands and that the relocation²⁰⁰ and related compensation costs of moving such shooting ranges would cost millions of euro.

Based on information shared by the Cavan Regional Game Council Ireland, there are 8 shooting ranges in County Cavan where clay targets are on peatland or marginal land where a farmer has granted permission based on the fact the land is unworkable.

Wildfowl & Wetlands Trust noted that Payne et al. (2013) highlighted some recent case studies of the livestock risks from shooting ranges which includes mortalities of ducks reared on land previously used as a clay shoot.

AEWA Secretariat reported that there are a small number of reports (mainly from the US) about remediation activities but also a report of some environmental clean-up actions (by stripping and removing sediment) at Larnaca salt lake Ramsar site in Cyprus following a mortality of Greater Flamingos (*Phoenicopterus roseus*) which was reported to AEWA as an 'emergency situation'.

According to the European Association of the Civil Commerce of Weapons, all or most new shooting ranges in Europe are implementing a lead recovery program that eliminates or greatly reduces the lead pollution impact.

AFEMS (Association of European Manufacturers of Sporting Ammunitions) highlighted that the correct management rules applied in managing the activity of the shooting ranges should prevent the origin of both contamination of groundwater and poisoning of birds.

Based on the information received in the Public Consultation no detailed information is currently available on the number and size of shooting ranges in different EU Member States, located within or nearby wetlands. Therefore no quantification of possible emissions is currently possible for this source.

²⁰⁰ However, it was not explained why a relocation would be needed as a consequence of the restriction.

G.6. Public consultation on the SEAC draft Opinion

The consultation on the SEAC draft opinion was held between 21/03/2018 and 21/05/2018. The consultation consisted of both specific questions proposed by the rapporteurs and a general section to allow the submission of any kind of comments and observations on the SEAC draft.

The specific questions raised by the rapporteurs addressed the following issues

1. Further quantification of the possible impact on forestry industry
2. Further quantification of the increase in production cost and on the additional costs implications of a possible requirement on labelling lead shot,
3. Further quantification of additional benefits.

In total 39 comments were submitted

NGOs Nature Conservation	16
NGOs Hunting/Shooting	5
Industry associations	2
MS/Authorities/Int. Organisations	5
Academic Institutions	1
Individuals	8
Other	2

Impact on forestry industry

During the Public consultation on the proposal, concerns were raised on the impact of steel shot on machineries used in the forestry industry. Evidence received in the SEAC consultation however (based on experiences in DK and FI), suggested that there is no impact on forestry industry to be expected at the EU level. ECHA followed up on this aspect with the Finnish forestry authorities, who, upon investigation with their clients concluded that hard shot (such as steel) poses no problem in forestry machinery such as saws.. Consequently, the Finnish Forest Authorities will lift the existing ban on the use of steel shot in Finnish forests in autumn 2018

Impact on producers of shot

SEAC requested additional information on the extra productions costs involved with the production of steel shot cartridges. No information was submitted to SEAC that allowed quantifying the possible (if any) increase at the EU level in the production costs of lead

shot due to the more extensive use of steel shot in wetlands. Confidential²⁰¹ information submitted to the ECHA that the required increase in production would be minimal for this restriction, as current production levels of steel shot would cover largely the expected increase in demand.

Some cost information was submitted however this often referred to past investments and SEAC regarded these as sink costs = The majority of the producers already offer a wide range of lead-free alternatives and are planning to further develop non-lead ammunition (as summarised by a web research provided in comment #367 of the SEAC consultation).

In addition, stakeholders did not submit detailed information on labelling costs that would allow SEAC to conclude on the additional costs implied by a possible requirement on labelling lead cartridges.

Non-quantified benefits

Several comments were submitted that contained further quantification on the human health impact of the consumption of lead contaminated game meat (#357) and on the impact on the environment of lead exposure.

SEAC however, did not have the possibility to verify all the assumptions and arguments provided.

Additional information was submitted and other non-quantified benefits of this proposal, such as:

- Examples of shooting ranges in Italy, France, Germany, Finland and Spain as a source of lead pollution for water sources (including groundwater), salt pans for human consumption and soil (e.g. comments #349, 371, 383, 385).
- The avoidance of remediation costs (no estimate provided)
- The enhanced societal acceptance and reputation of hunting as a direct benefit of the proposed restriction.
- Several millions of people practice occasionally or regularly birdwatching, making also birdwatching tourism a growing market in the EU (#350).

Further observations were submitted by a hunting NGO (#386) on the use of lead shot over peatlands but no socio-economic analysis was submitted that would support a need for a derogation.

Comments and observations were also submitted on the transition period and on the use of buffer zones. International organisations (like AEWA) and environmental NGOs asked for a shorter transitional period, justified by the many national bans partial bans implemented that most of the Member States have already implemented. FACE (#386) asked for a longer transition period, especially mentioning the current situation in Ireland. Answers to these issues are provided in the ORCOM

²⁰¹ Personal communication with AFEMS.

In relation to shooting ranges, several comments (e.g. # 374) highlighted the implications of this restriction on shooting ranges from where lead shot could fall into wetlands.

The abovementioned items did not change the opinion of SEAC that this restriction is proportional.

Annex H: REFERENCES

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Data used

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