EUROPEAN CHEMICALS AGENCY

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

Background Document

to the Opinion on the Annex XV dossier proposing restrictions on

Lead in outdoor shooting and fishing

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Note on terminology Various English language terms are commonly used in relation to hunting, shooting and fishing (as well as to birds and their habitats). As these terms sometimes have different meanings for different stakeholders this could potentially result in misunderstandings. Therefore, for the purposes of this document, the use of certain key terms is outlined below. Whilst every effort has been made to ensure the consistent use of terminology in this report, source material may not always have used these terms consistently.	
Barrel or gun barrel	A barrel is the metal tube that the projectile travels through as a result of pressure from burning gunpowder, compressed air, or other like means. The barrel also guides the projectile in the intended direction.
Building	A permanent, closed structure with roof and walls
Bullet trap	Any structure intended to capture and retain fired projectiles
(Bullet) trap chamber	Fully enclosed structure that is isolated from the underlying soil, with the exception of an opening towards the shooting point used to capture and retain fired projectiles. (Bullet) trap chambers can be constructed of various materials but are typically made of metal.
Fishing jig or jig head	A jig or jig-head consists of a sinker with a hook moulded into it and usually covered by a soft body to attract fish. Jig/jig-head might have various sizes, weights and colours.
Fishing lure	Object that is used to attract fish or animals, so that they can be caught. A lure might also function as a 'sinker'.
Fishing sinker	Weight that is attached to a fishing line or a net to keep it under the water, or to keep the fishing line, or net, in a certain position.
Fishing tackle	Fishing tackle is the equipment used by fishers when fishing. Almost any equipment used for fishing can be called fishing tackle. For example, fishing tackle can be rods, reels, lines, hooks, sinkers (or weights), floats, swivels, lures (i.e. artificial baits), jigs, baits, harpoons, nets, gaffs, traps, waders, wire, etc.
Fishing wire	Metal in the form of thin thread often cut in smaller pieces and used as a sinker in certain types of 'lures'.
Game, Large	Includes, roe deer, chamois, mouflon sheep, fallow deer, sika deer, ibex, moose, brown bear, wild boar, red deer, seals, wolf, jackal etc.
Game, Small	Includes waterfowl, pheasants, partridges, hares, squirrels, musk rats, beavers, rabbits, foxes, racoon dogs, wild cats, martens, badgers, polecats etc.
Hunting	Pursuing and killing live quarry using a gun.
Primer	A chemical compound that ignites the propellant in ammunition (e.g. gunpowder) when struck by a firing pin. Primer may be placed either in the rim of the case (rimfire ammunition) or in the centre of the base of the case (centrefire ammunition).

Projectile(s)	Object(s) expelled from the barrel of a gun. Examples of relevant types of projectiles are bullets, gunshot, shotgun 'slugs', airgun pellets and BBs.
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. The term is generally considered to exclude storks, gulls, skuas and penguins, even though these birds are also predators.
Sand trap	Sand traps comprise a mass of sand, or similar material, contained within a concrete or other structure which is open towards the firing point intended to capture and retain fired projectiles.
'Best practice' sand trap	'Best practice' sand trap consists of sand trap (see above) with an impermeable layer to the underlying soil, covered either with an overhanging roof/baffle or other permanent cover combined with a water management system for containment, monitoring and treatment (where necessary) of surface (run-off) water and sub-surface drainage to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive).
Sand/soil berm	Sand/soil berms or sand/gravel berms consist of gravel and/or sand without an impermeable layer to the soil structure below; the berm might be equipped with or without an overhanging roof/baffle.
Soil berm	A berm constructed from soil either with or without a roof/baffle
Scavenging birds (non-raptor)	Other bird species that typically scavenge carrion e.g. vultures, corvids, gulls
Sports shooting	Shooting at any inanimate (non-living) target with a gun. Includes practice, or other shooting, performed in preparation for 'hunting'. Examples of relevant types of targets are 'clay pigeons', paper targets, biathlon targets, silhouettes etc.
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.
Waterfowl	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 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, the term is principally associated with the hunting of game *waterfowl*.
Wildfowling	The hunting of wildfowl, particularly ducks, geese and waders.

Change version history

Version	Change history	Date	Prepared by
1.0	Pre-publication of the Annex XV restriction report and its annexes. Version 1.0 was submitted on 15.01.2021, and published on the ECHA website on 3 February 2021 (this version is not meant for consultation).	15.01.2021	Dossier Submitter
2.0	Revised version of the Annex XV restriction report and its annexes to take into account some of the recommendations of the RAC and SEAC rapporteurs made during the conformity check. This version is intended to be used for the 6-month consultation. The main changes in the Annex XV restriction report and its annex are listed below. The following sections in the Annex XV restriction proposal were updated: - Executive summary: updated to reflect the changes in the main body of the report - Section 1.4 - Information on good hygiene practice to reduce lead exposure of shooters (added) - Section 1.4 - information on lead gunshot, and bullets recovery RMMs incidence (added) - Section 1.4 - information on ferrous chemical amendments (added) - Section 1.4 - information remediation (updated) - Section 1.5 – estimation of lead released from hunting and sports shooting (updated) - Section 1.5 – primary and secondary exposure to birds (updated) - Section 1.5 – risk characterisation for the environment (updated) - Section 1.5 - Additional risks related to sports shooting – clarification on the contamination of recreational areas (added) - Section 1.6 – HH hazard assessment (updated) - Section 1.6 – exposure assessment for lead in game meat (updated) - Section 1.6 – risk characterisation for the HH (updated) - Section 1.8 – baseline for hunting and sports shooting (updated) - Section 1.8 – impact on birds (updated)	24.03.2021	Dossier Submitter

Version	Change history	Date	Prepared by
	- Section 2.1 – impact assessment and RO comparison approach (clarified) - Section 2.2 – outcome of the RO analysis for hunting and sports shooting (clarified) - Section 2.3 – justification of the restriction option (clarified) - Section 2.5 - impact of the restriction on lead in hunting (updated) - Section 2.6 - impact of the restriction on lead in sports shooting (updated) - Section 2.7 - impact of the restriction on other shooting (updated) - Section 3.1 – uncertainties on human health risks, and SEA sensitivity analysis for hunting (added) - Section 3.2 - uncertainties on human health risks, estimated releases, and number of shooting ranges for sports shooting (added) - Section 4.2 – conclusion for sports shooting (updated) The following sections in the Annexes were updated: - Section A.1 - Legislation in the EU related to lead bullets (updated) - Section A.2.- Manufacturing process description (split shots) (added) - Section B.4 - Field evidence of lead and steel shot behaviour in soils (added) - Section B.7 - Toxicity to birds (duplicate information removed) - Section B.9 – Sports shooting (updated) - Section B.10 – Human health (updated) - Section D.1 – Baseline for lead in hunting (updated) - Section D.1 – Alternative for lead in gunshot and bullets (updated) - Section D.1 – Assumptions for the impact assessment (updated) - Section D.4 – Existing EU legislation and other Union-wide risk management options on fishing tackle (clarified) - Section D.4 – Alternatives for fishing tackle (iron added) - Section E.4 (updated) In addition, various spelling mistakes and formatting issues were corrected throughout. Complementary		

Version	Change history	Date	Prepared by
	reference information was added and the wording was reviewed for consistency.		
3.0	Revised version of the Background Document and its annexes to take into account some of the recommendations of the RAC and SEAC rapporteurs and comments received during the consultation on the Annex XV report (until 08.07.2021). This version is intended to be used by RAC and SEAC. The main changes are listed below. The following sections in the main report were updated: - Executive summary: updated to reflect the changes in the main body of the report such as updated releases to the environment, emission reduction, costs, cost effectiveness for hunting and sports shooting and amendments of the proposed restriction entry 4c and 7g. - Section 1.4.4 information amended on good hygiene practice to reduce lead exposure of shooters, on risk management measures for the environment at shooting ranges for lead gunshot and lead bullets, on remediation of shooting ranges, and on the effectiveness of environmental risk management measures - Section 1.5.3 amount of lead releases to the environment updated, primary ingestion of gunshot and fishing tackle by birds amended - Section 1.6.2 human health hazard assessment (minor amendments on absorption and acute toxicity) - Section 1.6.2 on human health exposure assessment amended (inhalation exposure and game meat consumption) - Section 1.6.4 on human health risk assessment amended (inhalation exposure) - Section 1.8 on baseline for lead release to the environment for hunting and sports shooting updated - Section 1.8 on baseline for the impact on birds updated - Section 2.3 on the proposed restriction entry 4c (amendment of sand traps) and 7g (amendment of a transition period of 5 years for 4a, 4b, and 4c, the derogations for sports shooting) - Section 2.5.3 on costs and other economic impacts for hunting updated	15.07.2021	Dossier Submitter

Version	Change history	Date	Prepared by
	- Section 2.6.3 on costs and other economic impacts for sports shooting updated and amended - Section 2.6.5. on other practicality and monitorability considerations for sports shooting amended - Section 2.8.4.2 on other practicality and monitorability considerations for fishing amended (swipe test) The following sections in the Annexes were updated: - Section A.1.1.2 on the use of lead in ammunition for sports shooting amended (short overview) - Section B.9.1.3 on environmental assessment of sports shooting: lead gunshot released to the environment updated - Section B.9.2.2 on human health assessment: information on amount of game meat consumption from game hunted with lead bullets amended - Section C.1.3 on alternative substances for fishing tackle; information on coated lead amended - Section C.3.3 on alternative materials approved by US FWS amended - Section C.3.5.2 on environmental risks of alternative materials to wildlife amended - Section D.1.2.2 on alternative lead bullets for hunting amended - Section D.1.3.2 on main assumptions used in cost calculations amended In addition, various typographic and formatting errors were corrected throughout. Complementary reference information was added and the wording was reviewed for consistency.		
3.1	The following sections in the Background Document were updated (with consequent update of the executive summary). This version is intended to be used by RAC and SEAC: - 1.5.3.1. Release to the environment of lead bullets for hunting, and lead gunshot and lead bullets for sports shooting - 2.3.1 Proposed restriction entry: wording in 4.c changed; 7.d, 7.e, 7.f amended and 7.g., included in the last version, removed, definition of 'bullet containment' defined in 9. - 2.6.2 and 2.6.3 on the impact of a restriction on lead in sports shooting:	18/08/2021	Dossier Submitter

Version	Change history	Date	Prepared by
4.0	The following sections in the Background Document were updated (with consequent update of the executive summary). This version is intended to be used by RAC and SEAC: - Section 1.5 Environmental risk assessment: amended based on information submitted in the consultation on the Annex XV report. - Section 1.6 Human Health Risk assessment: amended based on information submitted in the consultation on the Annex XV report. - Section 1.8 Impact on birds revised based on information received in the Annex XV report consultation. - Section 2.3 conditions of the proposal restriction and accompanying justifications revised based on information received in the consultation on the Annex XV report. - Section 2.5.1, updated the sections on availability of alternatives and economic feasibility based on information received in the consultation on the Annex XV report. - Section 2.5.3 updated the sections on the cost of alternatives, gun renewal as well as additional information on benefits based on information received in the consultation on the Annex XV report. - Section 2.6 updated the section on the risk Management measures used for sports shooting and the accompanying impact assessment based on information received in the consultation on the Annex XV report. - Section 2.7 updated baseline use information for lead in muzzle loading based on information received in the consultation on the Annex XV report. - Section 2.8 Revised based on information received in the consultation on the Annex XV report In addition, various typographic and formatting errors were corrected throughout. Reference information was updated.		

Preface

The proposed restriction of lead in shooting, hunting and fishing was initiated based on Article 69(1) of the REACH Regulation at the request of the European Commission[1].

This report consists of a summary of the proposal, a main report setting out the key evidence justifying the proposed restriction and Annexes with more detailed information and supporting analysis.

ECHA (hereafter referred to as the Dossier Submitter) would like to thank the stakeholders that made contributions to the call for evidence (3/10/2019 until 16/12/2019), the stakeholder workshop on lead in shooting and hunting held in on 10 and 11 of February 2020 and the round table on the use of lead in fishing tackle held on 18 November 2020.

This version of the report has been reviewed for confidential information and any such information has been redacted.

[1] https://echa.europa.eu/documents/10162/13641/rest_lead_ammunition_COM_request_en.pdf

Executive summary

This report details a human health and environmental risk assessment of the use of lead in ammunition[2] and in fishing tackle and describes an assessment of different options to address the identified risks, including a preferred restriction option under REACH. The work was undertaken by ECHA at the request of the European Commission (EU Commission, 2019)[3]. The assessment, and the proposed restriction, is complementary to the existing restriction on the use of lead gunshot in wetlands (Entry 63 of Annex XVII to REACH).

Since 'ammunition' is a generic term that typically describes a complex object comprising of one or more components (e.g. primer, propellant, projectiles and casing), the Dossier Submitter clarified with the Commission after receiving the request that the intended scope of the request was **on the placing on the market and the use of lead in *projectiles* used in firearms and airguns for civilian outdoor activities**. Therefore, the use of lead in other ammunition components such as primers, propellants, wads or casings were outside the scope of the current restriction proposal. Equally, all indoor uses (i.e. the use that takes place in a building) of lead projectiles are excluded from the scope.

In addition, military and other 'non-civilian' uses of lead projectiles such as, for example, by the police, national intelligence agencies and customs authorities were also intended by the Commission to be outside of the scope of the restriction proposal. Nevertheless, it should be noted that the use of lead in full metal jacket ammunition (a type of projectile used by the military and other non-civilians), which can sometimes be used for hunting, is within the scope of the restriction proposal where it is used by civilian.

Regarding the use of lead in fishing tackle, the scope includes tackle used for recreational and commercial fishing irrespective of whether these take place in freshwater (i.e. in rivers, lakes and ponds), estuarine or marine environments. In addition, as fishing tackle can be either purchased from a retailer or manufactured directly by consumers (also known as 'home-casting'), the use of both purchased and home-casted fishing tackle containing lead is in the scope of the Annex XV report and proposed restriction.

Based on the technical function, conditions of use and the potential for substitution, a total of eight uses were identified for risk assessment (environment and human health). Where risks in a use were concluded to not be adequately controlled an impact assessment of different restriction options was conducted (Table 1).

[2] For the purposes of this report the term ammunition comprises gunshot used in terrains other than wetlands as well as projectiles other than gunshot (i.e. bullets and airgun pellets) used both in wetlands and in terrains other than wetlands.
[3] https://www.echa.europa.eu/documents/10162/13641/rest_lead_ammunition_COM_request_en.pdf/f607c957-807a-3b7c-07ae-01151001d939

Table 1: Overview of assessed and out of scope uses

Sector of use	Use #	Use in scope of the Annex XV report
Hunting	1	Hunting with gunshot
	2a	Hunting with bullets – small calibre[1]
	2b	Hunting with bullets – large calibre
Sports shooting	3	Outdoor sports shooting with gunshot
	4	Outdoor sports shooting with bullets
	5	Outdoor shooting using airguns
Shooting with historical weapons	6	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments
Fishing	7	Lead in fishing sinkers and lures
	8	Lead in fishing nets, ropes and lines (where lead in embedded/enclosed in the fishing nets, ropes and lines)
The following uses are intended to be out of scope[2]:		• indoor shooting[3], • police and law enforcement, • military, • protection of critical infrastructure, commercial shipping or high-value convoys, • soft-target and public space protection, and other security purposes, • technical testing and/or proofing, testing and development of materials and products for ballistic (and impact) protection, forensic analysis, historical and other technical research or investigation[4], • self-defence

Notes: [1] this use includes hunting with an airgun; [2] uses out of the scope as per the Commission request (EU Commission, 2019) and subsequent clarifications; [3] should be understood as shooting that takes place entirely inside a permanent building i.e. both the target and the shooter are inside the same building.

Environmental risk assessment

The use of lead ammunition and fishing tackle remains widespread in Europe despite its well documented hazard properties for both wildlife and human health. Approximately 44 000 tonnes of lead are dispersed every year in the environment: 57 % from sports shooting, 32 % from hunting and the rest from fishing activities. Assuming current releases, and if no further regulatory action was taken, approximately 876 000 tonnes of lead would be released to the environment over the next 20 years (see Table 1-58).

The environmental risk assessment is based on a weight of evidence approach and is underpinned by studies on (i) mortality or sub-lethal poisoning of birds after lead projectile or sinker/lure ingestion, (ii) lead concentrations in bird tissues after ingestion of lead objects (including comparison with threshold value for specific adverse effects), (iii) soil, surface water and ground water contamination at shooting ranges, (iv) ammunition-related poisoning of livestock.

Irrespective of the source of lead release to the environment, its hazard (particularly its hazard via ingestion) is similar. Therefore, a generic environmental risk assessment was conducted for all uses that could result in lead poisoning of wildlife (with a focus on birds).

[4] Article 67(1) of REACH states that restriction shall not apply to the manufacture, placing on the market and use of a substance for scientific research and development.

This was done on the basis that it was not practicable or meaningful to disaggregate the risks to birds resulting from the different uses. Other risks relevant for the sports shooting sector only, for example risks to livestock (e.g., ruminants and poultry) and the soil and water compartment in general, were assessed qualitatively.

There is international scientific consensus[5] on the hazards of lead and its toxicokinetics (i.e., bioavailability and absorption). The ingestion of lead objects by birds (including lead projectiles and fishing tackle) result in a range of acute and chronic toxicological effects (including mortality) dependent on the quantity of lead ingested and the body weight of the animal. Lead gunshot and other lead projectiles (e.g., bullets) that remain in the environment after use can be ingested. Lead fishing tackle is also frequently lost during use and affects birds in the same way as lead gunshot and projectiles if ingested. In addition, some contemporary fishing practices, and some fishing tackle suppliers, encourage the deliberate release of lead sinkers during use in some circumstances (termed 'dropping the lead'). Numerous studies have reported the ingestion of lead projectiles and fishing tackle by wildlife, including wildlife whose habitat is outside of wetland areas (i.e. terrestrial bird species).

The principal routes by which animals are exposed to lead from ammunition or fishing tackle are:

- **primary ingestion** defined for the purpose of this report as the ingestion of any lead object *directly* from the environment, e.g. after mistaking it for food or grit (which is deliberately ingested to aid the processing of food);
- **secondary ingestion** defined for the purpose of this report as the *indirect* ingestion of lead that occurs after the consumption of lead-containing food, e.g.
    - o ingestion of embedded fragments/particles of lead that are present in the tissues of prey or carrion,
    - o ingestion of lead fragments/particles that are present in discarded viscera (gut piles) from the field dressing of large game
    - o the ingestion of lead fragments/particles present in contaminated silage.

The primary ingestion route is most relevant for seed eating (granivorous) bird species or those that rely on the ingestion of grit or stones to process their food in the gizzard. For example, lead gunshot and split shot sinkers[6] may appear similar to grit or food items such as seeds. Piscivorous birds are also reported to directly ingest fishing sinkers and lures.

Further to primary (direct) ingestion, predatory or scavenging birds (as well as other wildlife) are at risk of secondary ingestion of lead gunshot, bullet fragments or fishing tackle by eating food that contains these objects.

It is not only small sized lead objects that can be ingested. Various lead objects, including bullets and other projectiles and sinkers and lures, up to 50 g (and even more for some types of birds), have been found in the gizzards, or digestive tracts of birds.

At least 92 species of birds[7] are at risk of lethal and sublethal lead poisoning[8] from lead

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[5] For example, http://www.europeanscientists.eu/ (comment #3506).

[6] Split shot sinkers are spherical sinkers with a small slot through one hemisphere. Split shot sinkers range from 0.01 g to 4.8 g in weight. The smallest split shots (≤0.06 g) are often referred as 'dust shot'.

[7] Waterbird species which may also feed in terrestrial environments have been included.

[8] Lethal and sublethal effects can occur after acute and/or chronic exposure. Sublethal lead poisoning can increase the probability of mortality from hunting (predation), collisions with objects (flying accidents) and illness or death from disease.

ammunition and lead fishing tackle (sinkers and lures). These species are either known to ingest these objects or their feeding ecology makes them particularly likely to ingest these objects.

Table 2: Number of bird species identified to be at risk from the ingestion of lead ammunition and fishing tackle (sinkers and lures) in the EU 27-2020

Exposure route	Number of bird species at greatest risk of lethal and sublethal lead poisoning in the EU 27[9] (EU species on Annex 1 of the EU Birds Directive[10])
Primary ingestion from lead ammunition	41 (19 species on Annex 1 of EU Birds Directive)
Secondary ingestion from lead ammunition	29 (24 species on Annex 1 of EU Birds Directive)
Primary ingestion from fishing tackle (lead sinkers and lead lures)	22 (11 species on Annex 1 of EU Birds Directive)

From these species at risk more than one million birds are expected to die per year due to primary ingestion. The number of birds expected to die as a result of secondary ingestion cannot be quantified because the information needed to do this is not available. A significant number of birds are also expected to be affected by sublethal poisoning, which may also contribute to premature mortality. For long-lived species with low reproductive rates (e.g., raptors and scavengers) mortality of individual birds may be of conservation concern should their populations already be critically endangered.

Although the use of lead gunshot in wetlands is restricted, many waterbird species can be affected by lead poisoning from lead fishing sinkers and lures. Equally, many waterbird species feed outside of wetlands.

Shooting ranges in the EU vary in size and type, ranging from large complexes which may also be intended to host international sport competitions (possibly with state of art environmental risk management measures) to small and mid-sized ranges used for recreational activities by members of the public (potentially with basic or no environmental risk management measures in place). The Dossier Submitter has estimated the total number of outdoor sports shooting ranges in the EU with 20 000. Sports shooting with gunshot frequently takes place in agricultural areas, particularly at temporary sites. Unrecovered lead gunshot may be ingested by many species of birds, especially when shooting ranges or temporary shooting sites are located in Natura 2000[11] (designated) sites or in agricultural areas, resulting in lead poisoning via primary ingestion.

In addition to primary ingestion risks, spent lead projectiles from sports shooting (all uses) can contaminate the environment both during the service life and the end of life of a range[12] potentially leading to a variety of on site and off site risks[13].

[9] A list of 533 wild bird species occurring naturally and regularly in Europe was taken as the starting point for the analysis, to which other criteria were applied to determine individual species risk from lead in ammunition and fishing tackle in a weight of evidence approach (see section 1.5.3.3).
[10] Annex 1 include species and sub-species that are particularly threatened in the EU.
[11] For example, the municipal hunting association of Chambles (Loire) organises an annual shooting event on land classified as a Natura 2000 site (See Section 1.5.3.4).
[12] This includes agricultural soils and soils which may be used for recreational or residential purposes, depending on the use of land at the end of life of a range.
[13] A conceptual source, pathway, receptor model is proposed in Annex B.9.1.3.3.

In areas of lead ammunition deposition, soil lead concentrations are frequently elevated. Lead content in shooting ranges soils may even reach values comparable to those found in lead mining areas, making them unsuitable for any agricultural use (including livestock farming). Lead accumulation at sports shooting ranges may result in leaching of lead polluted surface (runoff) water into local watercourses. Under certain circumstances, groundwater may also be affected. Risks to (or via) groundwater are only likely to materialise many years after use of lead, potentially after the closure of the range.

At EU level no harmonised measure is in place to adequately manage risks to the soil and surface water compartments from uses of lead in ammunition for sports shooting, as well as to other specific receptors such as groundwater, livestock and wildlife (primarily birds).

In addition, risk management measures such as water treatment (if in place) may be discontinued at the end of the service life of a shooting range and there is no guarantee that a full remediation will be carried out at the end of service life as it is not always required by Member State legislation. Adequate risk management measures implemented during the service life of a range are also likely to reduce (to some extent) the need for subsequent remediation at the end of service life.

Human health risk assessment

The detrimental effects of lead on human health are well documented. The range of reported adverse effects includes neurodevelopmental effects, cardiovascular diseases, impaired renal function (including chronic kidney disease – CKD), hypertension, impaired fertility and adverse pregnancy outcomes. However, the greatest public health concern is the neurodevelopmental toxicity of lead in children aged seven and younger.

Direct human exposure to lead occurs via two main routes: inhalation and ingestion. Inhalation exposure may occur during (i) the shooting of lead projectiles, and (ii) the melting of lead for the home-casting of gunshot, projectiles and fishing tackle via lead fumes and dust. Ingestion of lead (as small objects or dust) may happen via (i) direct ingestion, mouthing or chewing, or (ii) via hand to mouth exposure of lead dust at shooting ranges or when manipulating lead gunshot, projectiles or fishing sinkers and lures.

Indirect exposure to lead may occur via the environment through the intake of food and drinking water contaminated from shooting activities, including through the consumption of game meat hunted with lead gunshot or projectiles[14].

Although it is difficult to estimate the extent of groundwater vulnerability to lead contamination at shooting ranges at the EU scale, because many of the contributing factors are local, areas with high intrinsic vulnerability[15] are likely present in all EU Member States.

The human health risk associated with game meat consumption was characterised by calculating the effect of increasing blood lead concentration on:

- Loss of IQ points in young children,

[14] Existing best practices to handle hunted game meat do not eliminate lead contamination. Current EU food regulations do not set a maximum permissible level of lead in wild game intended for consumption. However, should such a level be set, this would not be fully protective as it would not affect exposure of lead via game meat that is consumed outside of the market (i.e. own use, use by friends or family). This measure is also not fully protective for wildlife as the entrails left after the hunt could still contain lead and would contribute to the exposure to lead for raptors and scavengers.

[15] Circumstances leading to higher risk to groundwater include for example: high lead loading in soil (typically found in clay target ranges), shallow water table, preferential flow pathways in the soil, presence of vegetation, especially trees.

- % increase in the prevalence of chronic kidney disease (CKD) in adults, and
- increase in systolic blood pressure in adults.

The Dossier Submitter estimates that in any given year about one million children are likely to be exposed to lead in game meat.

Except for game meat consumption, the available information is not sufficient to quantify the risks to human health from the identified uses. Therefore, the other risks to human health associated with the use of lead gunshot, lead projectiles (other than gunshot) and lead fishing tackle (sinkers and lures) are described and assessed qualitatively. The risk assessment is underpinned by studies reporting potential and actual incidence of lead exposure, as well as elevated blood lead levels observed after shooting, ingestion of lead fishing tackle, or after performing home-casting activities. Where European studies were not available, the Dossier Submitter considered data from outside of Europe.

Justification for risk management

The Dossier Submitter did not identify any risk to human health or the environment associated with the use of lead in fishing nets, ropes and lines where lead is embedded/enclosed. Therefore, no restriction is proposed for use 8.

For all the other uses assessed, the Dossier Submitter concludes that (consistent with the final RAC opinion of the use of lead gunshot in wetlands and other restrictions on lead), the use of lead in gunshot other projectiles not defined as gunshot (i.e. bullets and airgun pellets) , fishing lures and sinkers poses a risk to wildlife, livestock, environment and human health that is **not adequately controlled**, and needs to be addressed at the EU level.

Some Member States, or regions within Member States, have enacted legally binding national measures prohibiting the use of lead in hunting, outdoor sports shooting or fishing to reduce lead emissions and exposure. Notwithstanding these efforts, only Union-wide measures will effectively curb lead emissions, and exposure and address the identified risks.

The four main justifications for an EU-wide restriction measure are:

1. To ensure a harmonised high level of protection of the environment and human health to address the risks identified.
2. To address the lack of EU wide commitment to fulfil the EU Birds Directive, the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA), the (CMS) Convention[16] and the CMS Memorandum of Understanding on the Conservation of Migratory Birds of Prey in Africa and Eurasia (Raptors MOU)[17] to protect birds and their habitats.
3. To ensure the free movement of goods within the Union.

Proposed restriction

To address the identified risks, the Dossier Submitter conducted an analysis of risk management options (RMOs) for each use based on their (i) effectiveness (i.e. in terms of targeting the identified risk, risk reduction achieved and proportionality to the risk), (ii) practicality (including enforceability) and (iii) monitorability (as set out in Annex XV of REACH). The RMOs assessed included regulatory measures under REACH and other existing EU legislation as well as other possible Union-wide RMOs such as voluntary measures or

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[16] Convention on Migratory Species: https://www.cms.int/en/legalinstrument/cms
[17] https://www.cms.int/raptors/en/legalinstrument/birds-prey-raptors

additional training required on the risks of lead before obtaining a hunting/fishing licences, etc. A REACH restriction was considered to be the most appropriate EU-wide measure to address the identified risks. A detailed socio-economic impact assessment of the proposed restriction was undertaken taking into account the costs and benefits of regulation and the availability of alternatives.

As a result of the assessment, the Dossier Submitter is proposing a restriction comprising three main types of measures:

1. A ban on placing on the market combined with a ban on use where continued use of lead ammunition or lead fishing tackle will inevitably result in releases to the environment, irrespective of the conditions of use, and where suitable alternatives are available (i.e., technically and economically feasible and resulting in an overall reduction of the risk for human health and the environment). For some of these uses, a transition period is proposed to allow sufficient time for stakeholders to comply with the restriction. **This includes a ban on the placing on the market and use of lead gunshot for <u>any purpose</u>.**
2. Where a ban on placing on the market would disproportionately affect uses outside of the scope of the proposed restriction (e.g., placing on the market of bullets that would be used indoors or impact on the security of supply for defence) a ban on the specific use associated with the identified risk is proposed, for example the use of lead projectiles (other than gunshot) outdoors. Derogations from the proposed restriction on specific uses were proposed conditional on the implementation of appropriate and effective RMMs (e.g. outdoor sports shooting with projectiles other than gunshot where (bullet) trap chambers or 'best practice' sand traps are used). Further details of derogations are outlined below.
3. An obligation for the retailers to inform consumers at the point of sale about the phase out timelines for uses of lead in ammunition and fishing sinkers as well as information on the presence, toxicity and risk of lead to human health and the environment. Retailers will also be obliged to provide information to customers about the availability of alternatives to lead-containing ammunition and fishing tackle (sinkers and lures). This obligation is underpinned based on studies that highlight the importance of stakeholder awareness to influence purchasing behaviour.

The Dossier Submitter notes that the information submitted in the consultation on the Annex XV report confirmed that, even though non-lead alternatives exist, are being used and are commercially available throughout the EU for many uses, lead is currently difficult to replace in a number of applications, such as in rimfire ammunition (specifically .22 LR), airgun ammunition, ammunition for muzzle loading rifles, full metal jacket bullets for Nordic bird hunting and open tip match bullets for seal hunting.

The largest volumes of projectiles other than gunshot (i.e. bullets and airgun pellets) placed on the market are for sports shooting, where the Dossier Submitter concluded that the risks can be minimised via the use of appropriate RMMs (i.e., shooting in outdoor sports shooting ranges notified to Member States with appropriate bullet containment measures in place). Therefore, a ban on the use of projectiles other than gunshot is not proposed for sports shooting if the risk is appropriately controlled at the point of use.

A derogation for continued use of **lead gunshot for sports shooting** (identified as 'OPTIONAL CONDITIONAL DEROGATION' in Table 3 below) is presented as an option **for the decision-making stage** in the event that policy makers would not wish to impose an EU-wide ban on the placing on the market or use of lead gunshot for sports shooting. The intention of presenting this option is to clarify the costs and benefits of allowing the continued use of lead gunshot for sports shooting under such conditions that the identified risks could be minimised. It is not considered to be the most economically efficient means of addressing the identified risks from the use of lead gunshot for sports shooting and, as such, is **not** the Dossier Submitter's 'PREFERRED OPTION'.

The derogation, 'OPTIONAL CONDITIONAL DEROGATION', would set a minimum standard of RMMs at sites using lead gunshot and would introduce associated obligations for Member States to properly identify and license only those athletes that have a legitimate need to use lead gunshot (for example to train for, or participate in, international competitions that require the use of lead gunshot by virtue of their current rules – i.e. Olympic games / ISSF events). In addition, the optional conditional derogation would be accompanied by a labelling requirement for the supplier and a reporting requirement for the Member States. This will allow the Commission to monitor the continued use of lead gunshot in different EU Member States and facilitate the enforcement of the derogation.

It is important to note that the restriction including the optional conditional derogation for gunshot is not as effective in controlling the identified risks as a ban on use (identified as 'PREFERRED OPTION' in the summary table below), but could be considered as proportionate by decision makers, should the rules of these competitions continue to require the use of lead gunshot.

Table 3 presents for each use, the main risks identified, the estimated releases to the environment and the proposed restriction option.

Table 3: Use overview, main risks identified and proposed restriction

		Use	Main risk(s) identified[18]	Lead releases to the environment [tonnes, 20 years]	Proposed restriction
Hunting	1	Hunting with gunshot	- Poisoning of wildlife (birds) - Humans via consumption of game meat	280 000 (260 000-300 000)	Ban on placing on the market and use – associated with a transition period (5 years)[19] + Information obligation at the point of sale (retailer duty)
	2a	Hunting with bullets – small calibre [1]	- Poisoning of wildlife (birds)	310 (280-340)	Ban on use – associated with a transition period (initially 5 years, with duration subject to a review)[19] + Information obligation at the point of sale (retailer duty) + Labelling obligation (supplier duty) Derogation for: - Seal hunting if the user is permitted by the Member State to hunt seals - Full metal jacket bullets where the Member State allows the use of these bullets [on the date that the restriction proposal was submitted]
	2b	Hunting with bullets – large calibre	- Poisoning of wildlife (birds) - Humans via consumption of game meat - Humans in case of home-casting	2 370 (1 840-2 750)	Ban on use – associated with a transition period (18 months)[19] + Information obligation at the point of sale (retailer duty). + Labelling obligation (supplier duty) Derogation for: - Seal hunting if the user is permitted by the Member State to hunt seals - Full metal jacket bullets where the Member State allows the use of these bullets [on the date that the restriction proposal was submitted]

[18] Only risks identified as "high risks" are included in Table 3. See Sections 1.5.4.4 and 1.6.4.7 for a description of all risks identified.
[19] See Sections 2.3.2.9 and 2.5.4.1 for a discussion on the impacts of different lengths of transition periods for these uses.

		Use	Main risk(s) identified[18]	Lead releases to the environment [tonnes, 20 years]	Proposed restriction
Sports shooting	3	Outdoor sports shooting with gunshot	- Risks to soil, surface water and groundwater - Poisoning of wildlife (birds) - Poisoning of livestock (ruminants and poultry) - Humans - exposure from shooting (lead dust) - Humans (via environment) from drinking water and food	490 000 (280 000-700 000)	**PREFERRED OPTION - same as use 1, i.e.**: Ban on placing on the market and use – associated with a transition period (5 years) + Information obligation at the point of sale (retailer duty) *[OPTIONAL CONDITIONAL DEROGATION* - *Licencing of users by Member States* - *Permitting of locations (with specific risk management measures) by Member States* - *Reporting by Member States to the Commission* + *Labelling obligation (supplier duty)]*
Sports shooting	4	Outdoor sports shooting with bullets	- Risks to soil, surface water and groundwater - Poisoning of livestock (ruminants) - Poisoning of wildlife (birds) and livestock (poultry) (use 5) - Humans - exposure from shooting (lead dust) - Humans in case of home-casting (use 6) - Humans (via environment) from drinking water and food	8 400[20] (110-30 000)	Ban on use – associated with a transition period. Derogation where: - Notification of locations of use to Member States ([18 months] after entry into force) - Implementation of specific risk management measures at use locations ([5] years after entry into force) + Information obligation at the point of sale (retailer duty) + Labelling obligation (supplier duty)
Sports shooting	5	Outdoor shooting using airguns			
Shooting with historical weapons	6	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments			

[20] For specific uses as shooting using air rifle/gun/pistol and shooting activities incl. muzzle-loaders, historical re-enactments, it was not possible to estimate the specific single release

		Use	Main risk(s) identified[18]	Lead releases to the environment [tonnes, 20 years]	Proposed restriction
Fishing	7	Lead in fishing sinkers and lures	- Poisoning of wildlife (birds) (sinkers and lures ≤ 50 g) - Humans in case of home-casting (all weights of sinkers and lures)	60 000 (40 000-140 000)	Ban on placing on the market and use – associated with a transition period depending on the type and weight of the sinkers and lures: - Sinkers and lures ≤ 50 g: 3-year transition period - Sinkers and lures > 50 g: 5-year transition period - Wire: no transition period + Ban on use with drop off techniques (no transition period) + Information obligation at the point of sale (retailer duty)
	8	Lead in fishing nets, ropes and lines (where lead in embedded/enclosed in the fishing nets, ropes and lines)	- No risk to birds or other taxa identified. - No risk to human health identified	34 500 (23 000-46 000)	No restriction proposed.

[1] This use includes hunting with an airgun

Note: as a visual aid for the reader, the proposed restrictions including a comprehensive ban on placing on the market and using are identified with a red background in the final column of the table. Restriction proposals without a ban on placing on the market are in yellow and blue. The blue background indicates that conditional derogations are proposed. Where no restriction is proposed this is shown in green.

Regarding the impact assessment, 2022 was assumed to be the first full year of entry into force of the proposed restriction and a 20-year analytical period was used.

The Dossier Submitter assessed the overall risk reduction potential and the socio-economic impacts of the proposed restriction for each use affected and concluded that the proposed restriction is effective in terms of net risk reduction and proportionate.

The proposed restriction is estimated to result in a cumulative emission reduction of approximately 630 000 tonnes of lead over the 20-year period following its entry into force. This represents a reduction of 72 % of the quantified emissions of lead that would have occurred in the absence of the proposed restriction.

With regards to human health, the most important and most robustly quantified impacts relate to the protection of children in households that frequently consume game meat. Based on reasonable assumptions, it is estimated that a ban of large-calibre lead bullets and lead gunshot could avoid IQ loss in about 7 000 children per year, corresponding to a welfare loss of roughly €70 million. A less robust estimate was made for the reduced risk of CKD in about 1 150 individuals. A tentative valuation value of €7.5 million to €75 million.

Alternatives to lead in the uses identified have in general a better environmental footprint[21] than lead.

The cost-effectiveness of avoided emissions (where possible and meaningful to quantify) was estimated to range between €1 and €525 per kg of lead release avoided depending on the affected use (Table 4). Overall, the restriction is estimated to be more cost-effective than previous REACH restrictions that addressed similar human health concerns.

The costs of the labelling requirement could not be quantified but are considered minor in comparison to other costs estimated.

[21] Considering the following elements: Toxicity and risk for the human health, toxicity and risk for the environment (both aquatic toxicity and wildlife ingestion), sourcing of the raw material (extraction vs recycling), resource depletion (water, energy, chemical) and emission of greenhouse gases

Table 4: Effectiveness of the proposed restriction (central scenarios)

Use #	Use (*non-preferred restriction options in italics*)	Emission reduction (tonnes – 20 years)	Total costs (€ million NPV – 20 years)	Cost-effectiveness (€/kg avoided releases)	Report section
1	Hunting with gunshot	209 000	768	3.7	Section 2.5
2a	Hunting with small calibre bullets[1]	232	122	525	Section 2.5
2b	Hunting with large calibre bullets	2 200	239	109	Section 2.5
3	Sports shooting with gunshot - ban on placing on the market and use[2]	367 500	364	1.0	Section 2.6.2
3	*Sports shooting with gunshot – derogation for athletes only[3]*	*183 750*	*336*	*1.8*	*Section 2.6.2*
3	*Sports shooting with gunshot – derogation under strict conditions for all shooters[3]*	*334 425*	*885-1 309*	*2.6-3.9*	*Section 2.6.2*
3	*Sports shooting with gunshot – derogation under strict conditions for athletes only[3]*	*349 125*	*506-591*	*1.4-1.7*	*Section 2.6.2*
4,6	Sports shooting with bullets – conditional derogation: trap chamber or 'best practice' sand trap[2, 4]	5 800	1 094	189	Section 2.6.2
4,6	*Sports shooting with bullets – ban on use[3]*	*6 300*	*Not calculated*	*Not calculated*	*Section 2.6.2*
7	Fishing (sinkers and lures)	48 300	9 300	193	Section 2.8
	Total for the preferred options	**~633 000**	**~12 000**	**19**	**-**

Notes: [1] This use includes hunting with an airgun [2] Dossier Submitter's preferred option; [3] Not the Dossier Submitter's preferred option; [4] 'Best practice' sand trap comprising a sand trap with a water impermeable barrier between the base of the sand trap and the underlying soil, an overhanging roof or permanent cover, a water management system for containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off);

Table 5: Costs and benefits of the proposed restrictions on hunting

Use #	Use title	Main costs identified (i.e., negative impacts)	Main benefits identified (i.e., positive impacts)
1	Hunting with gunshot	Total cost of the proposed restriction: €768 million over a 20-year period	~ 211 000 tonnes of lead releases avoided over a 20-year period. Prevent further lead accumulation in the environment and thereby reduce incidence of lead poisoning in wildlife. Avoided mortality of more than one million birds per year from primary ingestion of lead gunshot, valued at €114 million (based on a partial assessment of a limited number of species for which data on both mortality rates and restocking costs could be estimated; does not include any monetisation of sub-lethal effects). This corresponds to (considering a transition period of five years) a quantified benefit of €1 042 million over a 20-year period. Positive impact on wildlife, ecosystem, and associated leisure activities (including protection of wildlife species with critical conservation status). Overall positive impact expected based on the environmental footprint of the likely alternatives. EU Birds Directive, CMS and AEWA commitments fulfilled. Avoided exposure to lead for humans (via diet), quantified impact €70 million per year for IQ loss and €7.5 to 75 million per year in chronic kidney diseases (shared benefit across use 1 and 2b). Considering a transition period of 18 months this corresponds to a quantified benefit of €943 to €1 746 million over a 20-year period.
2a	Hunting with bullets – small calibre[1]	Total cost of the proposed restriction: €122 million over a 20-year period	
2b	Hunting with bullets – large calibre	Total cost of the proposed restriction: €239 million over a 20-year period	
Total		**Total societal cost of €1 129 million over 20 years**	**Total societal benefit (quantified for all hunting uses, i.e. use 1, 2a and 2b) of €1 985 to €2 806 million over a 20-year period**

Table 6: Costs and benefits of the proposed restrictions on sports shooting, including shooting with historical weapons

Use #	Use title	Main costs identified (i.e., negative impacts)	Main benefits identified (i.e., positive impacts)
3	Outdoor sports shooting with gunshot	Total cost[2] of the proposed restriction (preferred option) for sports shooting: about €1 500 million over a 20-year period *[If the optional derogation under strict conditions (athletes only) for lead gunshot would be implemented instead of a ban, then the total cost of the restriction for sports shooting would be about €1 600 - 1 700 million over a 20-year period; assuming that only a proportion of existing ranges will implement risk management measures to achieve > 90 % recovery. This does not include the costs of licencing systems for athletes and permitting systems for locations]*	~ 373 300[3] tonnes of lead releases avoided over a 20-year period with the preferred option for sports shooting with gunshot or bullets. *[If the optional derogation under strict conditions (athletes only) for lead gunshot would be implemented instead of a ban, then the total amount of lead releases avoided over the 20-year period would be: 355 000 tonnes.]* Avoided risks to soil, surface water and groundwater. Avoided mortality and sub-lethal effects in birds and other wildlife. Avoided mortality and sub-lethal effects in ruminants (e.g., via contaminated silage) and poultry (via direct ingestion). Avoided future remediation costs for new ranges in Member States/regions that require soil remediation at the end of the lifespan of a shooting range. Overall positive impact expected based on the environmental footprint of the alternatives. EU Birds Directive, CMS and AEWA commitments fulfilled. Avoided exposure of humans to lead from sports shooting (lead dust)(only if optional derogation is not adopted). Avoided exposure of humans to lead from home-casting of lead bullets (use 6). Avoided exposure of humans (via the environment) to lead from contaminated drinking water and food.
4	Outdoor sports shooting with bullets		
5	Other outdoor shooting using airguns		
6	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments		

Notes: [1] This use includes hunting with an airgun [2] Total costs= €364 million + €1 094 million (from Table 4) [3] Total avoided releases 367 500 + 5 800 tonnes (from Table 4)

Table 7: Costs and benefits of the proposed restrictions on fishing

Use #	Use title	Main costs identified (i.e., negative impacts)	Main benefits identified (i.e., positive impact)
7	Lead in fishing sinkers and lures	Total cost of the proposed restriction: €9 300 million over a 20-year period €30 additional expense per fisher per year (i.e., 3 % of average annual fishing budget) Potentially up to 100 workers in SMEs at risk of unemployment	48 300 tonnes of lead releases avoided during a 20-year period. Prevent further lead accumulation in the environment and thereby reduce incidence of lead poisoning in wildlife. Avoided mortality due to sub-lethal effects of birds and other wildlife. Positive impact on wildlife, ecosystem, and associated leisure activities (including protection of wildlife species with critical conservation status). Overall positive impact expected based on the environmental footprint of alternative sinkers and lures. EU Birds Directive, CMS and AEWA commitments fulfilled. Positive impact expected on children’s health if home-casting decreases as expected (not quantified).

The Dossier Submitter concludes that the proposed restriction is practical, enforceable and monitorable for each of the uses affected.

The proposed restriction is practical and implementable because where a ban on placing on the market and/or use is proposed, technically and economically feasible alternatives already exist and are for most uses already widely available.

The transition periods and derogations for certain uses are proposed with the aim to minimise costs to society, without unnecessary delay to risk reduction. The transition periods proposed will ensure that producers, retailers and consumers will have sufficient time to transition to suitable alternatives, including the time needed to scale up production capacity.

Information at the point of sale and/or labelling are proposed for uses where there is a transition period envisaged before a further measure enters into force (e.g., a ban on use). This requirement aims to (i) increase consumer awareness of the hazard and risk of lead, and (ii) prepare end-users to change their purchasing behaviour prior to the entry into effect of the restriction. A labelling requirement is included where a ban is proposed on a specific use (but other uses may continue e.g., sports shooting with bullets).

The proposed restriction is practical for sports shooting with both gunshot and projectiles other than gunshot, as demonstrated by existing practices in Norway, Denmark, Sweden and the Netherlands where limitations on the use of lead gunshot for clay target shooting have already been implemented successfully. Similarly, trap chambers and sand traps have been found to capture lead effectively and are already in use at many shooting ranges throughout the EU, in some instances because of existing legal requirements.

For the above reasons, the proposed restriction is therefore considered implementable and manageable.

The main components of the proposed restriction are also enforceable, and the scope of the proposed restriction is concluded to be clear and unambiguous. Experience with enforcing restrictions on non-lead rifle ammunition already exists in various areas in the EU, and the methods and practices to enforce existing bans on gunshot and other projectiles could also be used for the inspection of restriction on lead fishing tackle (e.g., wipe tests, or ICP-MS[22] testing to check the presence of lead).

The ban on placing on the market proposed for uses #1, #2 and #7, in addition to a ban on use will facilitate the enforceability of the restriction. Indeed, spot checks of imported goods (at customs), but also manufacturer and retailer site inspections are simpler than the enforcement of restrictions at the point of use, particularly for consumer uses. Nevertheless, enforcement at the site of use could be performed by the relevant national enforcement authorities for fishing, hunting or sports shooting. These inspectors are usually fisher/shooters themselves or experienced/trained to perform such inspections (licence, equipment, etc.) and therefore assumed to be sufficiently knowledgeable and skilled to recognise lead articles or 'drop-off techniques' (in the case of fishing for example).

Regarding lead in fishing tackle, a ban on the use of lead fishing tackle cannot be dissociated from a ban on placing on the market. From a practical point of view, it is easier to check compliance with a ban on placing on the market rather than a prohibition of use. However, a ban on the use of lead fishing sinkers and lures is necessary to ensure that the risks associated with the use of home-casted lead fishing tackle are addressed (by

[22] ICP-MS stands for 'Inductively Coupled Plasma Mass Spectrometry'.

discouraging this activity). If the use of lead in fishing tackle continues to be permitted, it could inadvertently provide a greater incentive for casting at home, which could also increase human health risks compared to the current situation. The home-casting of lead fishing sinkers and lures may become particularly attractive for fishers if the price of non-lead fishing tackle in shops and internet webstores increases.

The role of enforcement at all levels of the supply chain (including at the sites of use) is crucial to ensure a level playing field for EU manufacturers and to ensure that the expected release reduction and overall risk reduction (both for the environment and human health) can be achieved.

Monitoring of the effectiveness of the proposed restriction (including compliance) could be achieved through various methods. The most conclusive method is to measure the prevalence of ingested or embedded lead gunshot, projectiles, or fishing tackle in at risk bird species over time. Many of the current studies highlighting the problem of lead poisoning in birds could be readily adapted to monitor the effectiveness of the proposed restriction.

The presence of alternatives to lead on the market could also be monitored using market surveys or mystery shopping.

Finally, in case the derogation for continued use of lead gunshot for sports shooting (‘OPTIONAL CONDITIONAL DEROGATION’) is preferred by **the decision-maker** to an outright ban, the reporting requirement will allow the Commission to monitor the continued used of lead gunshot in different EU Member States. This requirement will also facilitate the enforcement of the sports shooting uses by identifying the permitted locations where lead gunshot can be used under strict conditions.

The proposed restriction entry is the following:

Short title:

Restriction on the placing on the market and use of lead in outdoor shooting and fishing.

Scope description:

The text of the proposed entry in Annex XVII (proposed restriction) has been drafted to describe the intention of the Dossier Submitter. The final legal wording (i.e., to update Annex XVII of REACH) would be decided by the European Commission, and would need to take into account the existing restriction on the use of lead in gunshot in wetlands.

Some elements of the proposal are presented in square brackets [….]. This denotes that the Dossier Submitter has concluded that the proportionality of the proposal is particularly sensitive to these aspects (i.e. duration of transitional periods) but is not able to conclude on a proposal because of policy rather than scientific considerations. This includes elements of the proposal that are not preferred by the Dossier Submitter but may be favoured by the decision maker (i.e., the ‘optional conditional derogation’ for sports shooting with gunshot). In these instances, the Dossier Submitter has assessed the impacts of different options for these elements of the proposal. These assessments should be evaluated by RAC/SEAC during the opinion-making phase.

The text in green describes the ‘optional conditional derogation’, i.e. a ‘non-preferred’ derogation option for the continued used of lead gunshot for sports shooting. The derogation is comprised of four linked parts (i.e., a set of measures that describe the minimum standard of risk management that should be implemented in the event that a derogation for continued use of lead gunshot is **favoured by the decision maker**.

Table 8 Proposed restriction entry

Designation of the substance	Conditions of the restriction
Lead and its compounds	1. Shall not be placed on the market in a concentration equal or greater than 1 % w/w: a. in fishing sinkers and lures b. in fishing wires c. in gunshot 2. Shall not be used[23], in a concentration equal or greater than 1 % w/w: a. in fishing sinkers and lures for fishing b. in fishing wires for fishing c. in gunshot for hunting d. in gunshot for sports shooting e. in any other projectiles not defined as a gunshot for hunting (by way of derogation shall not be used in a concentration equal to or greater than 3 % w/w in copper or copper alloys - this derogation shall be subject to a review prior to entry into force to determine if a concentration less than 1 % can be achieved[24]) f. in any other projectiles not defined as a gunshot for sports shooting (by way of derogation shall not be used in a concentration equal to or greater than 3 % w/w in copper or copper alloys - this derogation shall be subject to a review prior to entry into force to determine if a concentration less than 1 % can be achieved[25]) 3. Shall not be used for fishing, in a concentration equal to or greater than 1 % w/w, in fishing sinkers where the fishing equipment, rig or technique deliberately releases the sinker during use. 4. By way of derogation: *a. [OPTIONAL CONDITIONAL DEROGATION (part 1 of 4): Paragraph 1c shall not apply if:* *- the retailer places lead gunshot on the market only for users licensed by Member States.* *b. [OPTIONAL CONDITIONAL DEROGATION (part 2 of 4):*

[23] For fishing sinkers, lures and wires (paragraph 2a and 2b), 'used' should be understood as 'used for both recreational and commercial fishing irrespective of whether these take place in freshwater (i.e. in rivers, lakes and ponds), estuarine or marine environments'. In addition, as fishing sinkers, lures and wires can be either purchased from a retailer or manufactured directly by consumers (also known as 'home-casting'), the use of both purchased and home-casted fishing tackle containing lead is in the scope of the proposed restriction. It should be noted that the production of lead sinkers, lures and wires either in industrial settings or at home ('home-casting') are not 'uses for fishing' for the purposes of this restriction.

[24] The consequences of setting the concentration limit at 1 or 3 % are explained in Section 2.3.2.4

[25] Idem sopra

Designation of the substance	Conditions of the restriction
	Paragraph 2d shall not apply if: - *the user has a licence, granted by the Member State, to use lead gunshot for sports shooting; AND from EiF + [5] years the use takes place at a location that has a permit granted by the Member State for the use of lead gunshot for sports shooting; AND* - *the following measures are in place:* ▪ *Regular (at least once a year) lead gunshot recovery with >90 % effectiveness (calculated based on mass balance of lead used vs lead recovered in the previous year) to be achieved by appropriate means (such as walls and/or nets and/or surface coverage);* ▪ *Containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off) to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive;* ▪ *Ban of any agricultural use within site boundary;* ▪ *Records of compliance with these conditions shall be maintained by permitted locations and shall be made available to enforcement authorities on request.* c. Paragraph 2e shall not apply to: - Seal hunting if the user is permitted by the Member State to hunt seals - Full metal jacket bullets where the Member State allows the use of these bullets [on the date that the restriction proposal was submitted][26] d. Paragraph 2f shall not apply if: - The use takes place inside a building - The use takes place at a notified (to the Member State) outdoor location for sports shooting; AND no agricultural activities take place at that location; AND - From EiF + [5] years the following measures are in place: ▪ lead projectile containment and recovery via [trap chamber or a 'best practice' sand trap comprising a sand trap with:

[26] See Section 2.3.2.4.

Designation of the substance	Conditions of the restriction
	• a water impermeable barrier between the base of the sand trap and the underlying soil; • an overhanging roof or a permanent cover; • containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off) to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive)]. ▪ Records of compliance with these conditions shall be maintained by notified locations and shall be made available to enforcement authorities on request. 5. Without prejudice to the application of other community provisions on the classification, packaging and labelling of substances, mixtures, and articles: a. Retailers of gunshot, 'projectiles not defined as a gunshot', fishing sinkers and lures of any dimension or weight, and containing lead in concentrations equal to or greater than 0.3 % w/w, shall ensure that, at the point of sale, in close proximity to the retailed lead projectiles, fishing sinkers and lures, the following information is clearly and visibly provided to consumers and professionals: - *'**WARNING**: this product contains lead which is toxic to the environment and may damage fertility or the unborn child. The use of lead in this type of product will be subject to restrictions in the EU from [EiF+TP as specified in paragraph 7]. More information, including on the availability of lead-free alternatives, is available from [www.echa.europa.eu]'*. The information listed above shall be in the official language(s) of the Member State(s) where the products are placed on the market unless the Member State(s) concerned provide(s) otherwise. b. Suppliers of 'projectiles not defined as a gunshot' containing lead in concentrations equal to or greater than 0.3 % w/w, shall ensure, before the placing on the market, that product packaging is clearly, visibly and indelibly labelled with the information listed in paragraph 5a. The labelling shall be in the official language(s) of the Member State(s) where the products are placed on the market unless

Designation of the substance	Conditions of the restriction
	the Member State(s) concerned provide(s) otherwise. If the packaging is too small, and the information listed in paragraph 5a cannot be provided on the packaging, this information can be provided in fold-out labels (leaflet) or on tie-on tags. *c. [OPTIONAL DEROGATION (part 3 of 4): Suppliers of 'gunshot' containing lead in concentrations equal to or greater than 0.3 % w/w, shall ensure, before the placing on the market, that product packaging is clearly, visibly and indelibly labelled with the information listed in paragraph 5a. In addition, individual cartridges shall be labelled:* *- 'Contains lead: do not use for hunting'.* *The labelling shall be in the official language(s) of the Member State(s) where the products are placed on the market unless the Member State(s) concerned provide(s) otherwise. If the packaging is too small, and the information listed in paragraph 5a cannot be provided on the packaging, this information can be provided in fold-out labels (leaflet); or on tie-on tags.]* 6. *[OPTIONAL DEROGATION (part 4 of 4): Member States shall report on an annual basis to the Commission:* *- the number of permits granted to locations in the Member State under paragraph 4b and their location.* *- the number of licences granted to users in the Member State under paragraph 4b.* *- the quantity of lead gunshot used in the Member State under paragraph 4b.]* 7. Entry into force of the restriction: a. paragraph 1a and 2a shall apply 3 years from entry into force of the restriction for sinkers and lures which have a weight equal or less than 50 g. b. paragraph 1a and 2a shall apply 5 years from entry into force of the restriction for all sinkers and lures which have a weight greater than 50 g. c. paragraph 1b, 2b and 3 shall apply as soon as possible from entry into force of the restriction. d. paragraph 1c, 2c and 2d shall apply [5 years][27] from entry into force of the restriction. e. paragraph 2e shall apply [18 months][27] from entry into force of the restriction for centrefire ammunition with a calibre greater than or equal to 5.6 mm.

[27] See Sections 2.3.2.9 and 2.5.4.1 for a discussion on the impacts of different lengths of transition periods for these uses.

Designation of the substance	Conditions of the restriction
	f. paragraph 2e shall apply [5 years][27] from entry into force of the restriction for ammunition not included in paragraph 7e, subject to a review prior to the entry into effect. g. paragraph 2f shall apply 18 months from entry into force of the restriction. h. paragraph 5a shall apply 6 months from entry into force of the restriction. i. paragraph 5b shall apply 18 months from entry into force of the restriction. j. [paragraph 5c shall apply 5 years from entry into force of the restriction.] 8. This restriction on lead in outdoor shooting and fishing shall not apply to the following uses: indoor shooting inside a building, police, law enforcement, military applications, protection of critical infrastructure, commercial shipping or high-value convoys, soft-target and public space protection, self-defence, security purposes, technical testing and/or proofing, testing and development of materials and products for ballistic protection, forensic analysis, historical and other technical research or investigation (i.e., these uses are not associated with the identified risks and are therefore intended to be outside of the scope). 9. For the purposes of this restriction: - 'centrefire ammunition' means ammunition where the primer is located in the centre of the case head or base. - 'fishing wire' means metal in the form of thin thread often cut in smaller pieces and used as a sinker in certain types of 'lures'. - 'gunshot' means the pellets used [or intended for use in quantity] as projectiles in a single charge or cartridge for shooting with a shotgun; it does not include the case, base, primer, wad, propellant etc. - 'hunting' means pursuing and killing live quarry using a projectile expelled from a gun. - 'lure' means an object that is used to attract fish or animals, so that they can be caught. Lures might also have the same technical function as 'sinkers'. - 'projectile': means an object intended to be expelled from a gun, irrespective of the means of propulsion, excluding wads. - 'sand trap' means a mass of sand, or similar material, contained within a concrete or other structure which is open towards the firing point intended to capture and retain fired projectiles.

Designation of the substance	Conditions of the restriction
	- ‘shotgun’ means a smooth bore gun. - ‘sinker’ means a weight that is attached to a fishing line or a net to keep it under the water, or to keep the fishing line, or net, in a certain position. - ‘sports shooting’ means shooting at any inanimate (non-living) target with a gun. It includes practice, or other shooting, performed in preparation for ‘hunting’. - ‘trap chamber’ means a fully enclosed structure that is isolated from the underlying ground, with the exception of an opening towards the firing point, that is used to capture and retain fired projectiles. Trap chambers can be constructed of various materials but are typically made of metal. 10. Member States may maintain national provisions for protection of the environment or human health in force on [EiF] and restricting lead in gunshot, projectiles other than gunshot or in fishing sinkers and lures more severely than provided for in paragraph 1 to 8. The Member State shall communicate the text of those national provisions to the Commission without delay. The Commission shall make publicly available without delay any such texts of national provisions received.

To complement the proposed restriction, other Union-wide initiatives (cf. Annex D) could be implemented (e.g., by national associations), for example:

- Incorporating a mandatory module on the hazards of lead and the risks of using lead ammunition and the use of alternatives into national hunting exams (where these are required to obtain a hunting licence). This could be done at the Member State level whenever such hunting exams takes place.
- The collection of a small fee from fishing licences (whenever existing) in order to support the transition to non-lead alternatives of both the consumers and the EU manufacturers. A fee of 10 cents collected on each licence in Europe would represent a minor increase of the licence fee and could potentially generate an annual revenue of €1.2 million that could be used to help European manufacturers to transition to non-lead alternatives. This fee could also support an education campaign for consumers (see next bullet point).
- A voluntary education and action campaign from sector associations (fishing, hunting and sports shooting) targeted to consumers to promote the use of alternatives and the recovery and recycling of lead containing articles (i.e., fishing tackle and ammunition).

Further explanations on the conditions of this restriction are given in Section 2.3.2.

RAC Box

RAC agrees in general terms with the conditions of the restriction as presented by the Dossier Submitter but proposes a few modifications.

RAC is of the opinion that the concentration threshold of 1% w/w of lead should be applied to the information and labelling requirements (with the exception of the temporary derogation for copper or copper alloys in other projectiles not defined as gunshot, which may contain up to 3% w/w lead).

Regarding the optional derogations §4a and §4b, RAC notes that enforcement of this restriction (and the previous 'wetland' restriction) would be greatly simplified (enabled) if these optional derogations are not implemented. However, if the decision maker would decide that such an optional derogation is still needed, as a secondary option the derogation should be limited to shot sizes used in sports shooting (1.9 to 2.6 mm), as proposed by SEAC.

A five-year transition period for the ban of the use of gunshot in hunting was proposed by the Dossier Submitter in §7d. The view of RAC is that this transition period is too long and could be shortened, taking into account that the use of lead gunshot in wetlands is already regulated in the whole EU. The shorter the transition period is, less lead will be released into the environment.

Furthermore, RAC provides the following recommendations.

RAC recommends to the Commission a further analysis of the possibility to change the Olympics/ISSF/FITASC requirements regarding the use of lead gunshot in international competitions.

RAC recommends remediation at the end of service life of all shooting ranges in addition to the implementation of the specific risk management measures proposed by the Dossier Submitter.

Exposure and risks to shooters caused by lead in ammunition do not result only from the use of bullets and gunshot but also from primers containing lead, e.g., lead styphnate. To minimise such exposure, risk management measures to limit exposure to lead from primers also need to be considered.

Since indoor shooting may result in high exposure of shooters, RAC points out that risk management measures are also needed to tackle the risks to consumers practicing shooting in indoor shooting ranges.

RAC recommends that shooting ranges should also be requested to inform shooters about the risks posed by lead with a similar warning text mentioned in §5a above.

Additionally, RAC recommends setting a regulatory maximum level for lead in game meat, similar to the maximum levels of lead for meat other than game meat already defined by Commission Regulation (EC) 1881/20061*.

RAC also recommends improving the definition of fishing wire to facilitate an effective enforcement of the restriction.

Finally, RAC encourages the decision maker to consider whether there is a need to create a collection system for banned lead ammunition and fishing tackle and/or how to provide information on the safe disposal of these restricted lead-containing articles.

* According to Commission Regulation (EC) 1881/2006, the maximum levels of lead for meat (muscle) and for the offal of cows, sheep, pigs and poultry are 0.10 and 0.50 mg/kg wet weight respectively.

1. Problem analysis

1.1. Background

At the request of the Commission[28], ECHA proposed a restriction on the use of lead in gunshot in wetlands in April 2017. ECHA's scientific committees for risk (RAC) and socio-economic analysis (SEAC) completed their opinions on the proposal in August 2018[29].

In September 2018, as part of the original request of the European Commission to propose a restriction on the use of lead gunshot in wetlands, ECHA published a report on the risks from the use of lead in gunshot in terrestrial environments, in other types of ammunition in any terrain and in fishing tackle (ECHA, 2018a). The report concluded that there is sufficient evidence that risks from these uses are not adequately controlled to justify additional risk management.

On 16 July 2019, the European Commission requested ECHA to prepare a follow-up restriction proposal on 'the placing on the market and use of lead in ammunition, i.e. gunshot used in terrains other than wetlands, and bullets used both in wetlands and in terrains other than wetlands, as well as of lead in fishing tackle, to address the concerns posed by these articles' (EU Commission, 2019)[30].

The request from the Commission noted that the proposed restriction options should be targeted at addressing the risks identified for each of the articles concerned.

In January 2021, the REACH Regulation was amended to include the restriction of lead gunshot in wetlands[31]. This assessment, and proposed restriction for lead gunshot in terrestrial areas, is complementary to the existing restriction on the use of lead in gunshot in wetlands.

1.2. Scope

Concerns to be addressed:

ECHA (ECHA, 2018a) identified concerns for both the environment and human health from the use of lead in ammunition and fishing tackle. Therefore, the scope of this Annex XV report addresses both risks.

Lead in ammunition:

As far as the definition of lead in ammunition is concerned, it is important to note that ammunition can be used both in firearms and airguns[32]. Firearms shoot projectiles by means of pressured gases resulting from a chemical reaction (combustion) whilst airguns shoot projectiles by means of compressed air or other gases that are mechanically pressurised without involving any chemical reaction.

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28 https://www.echa.europa.eu/documents/10162/13641/rest_lead_shot_pvc_tattoo_formaldehyde_request_redacted_en.pdf/f8fb716f-6174-4329-623c-69d8805a2b0d

29 Details of the restriction on the use of lead on gunshot, including assessment reports, committee opinions and consultation comments are available on the ECHA website: https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e180c0ac38

30 https://www.echa.europa.eu/documents/10162/13641/rest_lead_ammunition_COM_request_en.pdf/f607c957-807a-3b7c-07ae-01151001d939

31 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2021.024.01.0019.01.ENG&toc=OJ%3AL%3A2021_%3A024_%3ATOC

32 Firearms and airguns can also be referred to as weapon, gun, handgun, long gun, pistol, revolver, rifle, etc. which are sub-categories of firearms and airguns. These terms might be used specifically in this report to refer to a specific type of ammunition or shooting tool.

Ammunition is a generic term which comprises a wide variety of complex (and less complex) articles[33]. Ammunition may be composed of one or several of the following components depending on the type of ammunition and the type of firearms or airguns used to shoot:

- Primer.
- Explosive materials and propellants.
- Projectile(s).
- Cartridge casing.

Some of the above-mentioned ammunition components can contain lead or lead substances (e.g., lead styphnate is used as a primer whilst lead is a component of brass alloy which is frequently used in cartridge casing). Nevertheless ECHA (2018a), and the Commission's request (EU Commission, 2019)[34] both focussed on lead projectiles (referred to specifically as 'lead gunshot, bullet or pellet'), and upon clarification with the Commission, it was confirmed that the scope of the Annex XV report should only cover projectiles rather than other potentially lead-containing components of ammunition.

However, during the investigation, data indicating that the use of lead or lead substances as primers and propellants in ammunition result in risks that are not adequately controlled became apparent. Whilst remaining outside of the scope of this restriction proposal, these conclusions have been documented in this Annex XV report for information.

Lead projectiles are used in many different applications. The focus of the Annex XV report is on civilian use of ammunition only. Police and military use of ammunition is explicitly excluded from the scope of the Annex XV report. Nevertheless, the Dossier Submitter is aware of the strong interaction between civilian and military use of ammunition in terms of systems design and development, but also in terms of production and production capacity.

Regarding the civilian uses of lead in projectiles, lead projectiles are not only used for hunting but also for indoor and outdoor sports shooting and other outdoor applications. The term 'target shooting' was used in the investigation report but on further consideration was deemed to be too broad. Upon stakeholder advice, the term 'sports shooting' will be used instead as this is better understood by stakeholders and covers more precisely the activities in the scope of the assessment. Only outdoor uses of projectiles are within the scope of the Annex XV restriction report as per the Commission description in its request (i.e., 'wetlands and in terrains other than wetlands'). This means that indoor sports shooting is not within the scope.

The projectiles in the scope of the Annex XV restriction report can be grouped under the following two main categories:

- Gunshot to be shot with a shotgun (also referred as 'gunshot' or 'shot' for simplicity); where multiple shot/pellets are contained in a shotshell
- Other types of projectile (single): bullet is the most common example, but it includes also full metal jacket (if allowed by the local hunting legislation), slug (single shot/pellet in a shotshell), as well as BB (small metallic ball), airgun pellet, etc.

An example of gunshot and other type of projectiles is presented in Figure 1-1.

[33] Cf. Annex A for examples of ammunitions

[34] https://www.echa.europa.eu/documents/10162/13641/rest_lead_ammunition_COM_request_en.pdf/f607c957-807a-3b7c-07ae-01151001d939

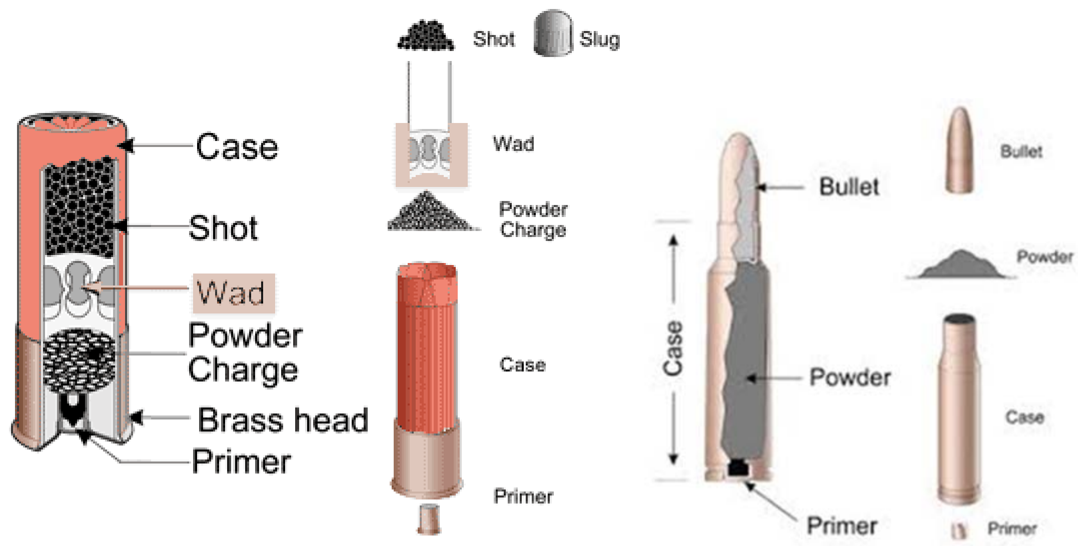

Figure 1-1: Examples of gunshot (left hand-side) and other types of projectiles (e.g., bullet on the right hand-side) within the scope of the proposed restriction

While gunshot can only be shot using firearms, the other type of projectile can be shot using firearms and airguns.

To summarise, with regard to ammunition, the scope of the proposed restriction is the **placing on the market and the use of lead projectiles used in firearms and airguns, for (civilian) outdoor activities.**

Lead in fishing tackle:

In addition, as per the requestion from the Commission (EU Commission, 2019)[35], the Annex XV report also investigates the placing on the market and use of lead in recreational, commercial and subsistence fishing tackle.

Even if the term 'fishing gear' is more common in the context of commercial fishing, the Dossier Submitter uses the term 'fishing tackle' to designate 'the equipment used when fishing for recreational, subsistence or commercial purposes'. In addition, while the demarcation between recreational and commercial fisheries is reasonably clear in Europe, the demarcation between subsistence and recreational fishing is absent (Hyder et al., 2018) Under EU legislation on fisheries, any fishing where catches are sold is considered commercial. Conversely, where catches are not sold, this activity and its impact are generally monitored as recreational fishing. Hence in this report the Dossier Submitter will only refer to recreational and commercial fishing.

There is a large and diverse range of sizes, colours and shapes of fishing tackle containing lead. The lead fishing tackle of interest in this Annex XV report can be categorised into three main types further defined in Section 2.3.2.3:

- Fishing sinkers and wires (also known as 'fishing weights')
- Fishing lures (including jigs)

[35] https://www.echa.europa.eu/documents/10162/13641/rest_lead_ammunition_COM_request_en.pdf/f607c957-807a-3b7c-07ae-01151001d939

- Fishing nets, ropes and lines where lead in embedded/enclosed in the fishing nets, ropes and lines

The scope of the Annex XV report will cover the placing on the market and the use of these three types of tackle for recreational and commercial activities. Both fishing in freshwater (i.e. in rivers, lakes and ponds) and in marine water (i.e. in the sea) are within the scope of this work.

Finally, the understanding of the Dossier Submitter is that the Commission’s request does not cover the manufacture/production of ‘fishing tackle and ammunition’ (at industrial sites). These industrial uses have therefore not been considered as candidates for restriction and are not assessed in this Annex XV report.

Nevertheless, the preparation/manufacturing/processing of fishing tackle or lead bullets at home, or in non-industrial settings (referred to as ‘home-casting’ in this report) was further investigated as the ECHA investigation report (ECHA, 2018a) concluded that risks from this activity may not be adequately controlled.

The Dossier Submitter identified that the casting of lead bullets and lead fishing tackle activity in non-industrial settings presents a concern both for human health and the environment. These activities, either performed by the general public in a private setting (at home), or at larger scale in ‘garage’ type settings or in the backrooms of fishing shops, are carried out without the supervision of the usual national OSH or industrial emission supervisions and regulations. In addition, the fishing tackle and ammunition produced via ‘home-casting’ contributes also to the overall quantity of lead fishing tackle released to the environment. In addition, the effects of different risk management options on the prevalence of home-casting is relevant to consider as part of their effectiveness (in reducing identified risks). Therefore, for all these reasons, the assessment of the risks associated with ‘home-casted’ lead fishing tackle and lead ammunition is within the scope of the Annex XV report.

Finally, from a geographical point of view the scope of the Annex XV report is limited to the European Union composed of 27 Member States as of 2020. It is also referred as ‘EU27-2020’ in this document.

1.3. Identity of the substances, physical and chemical properties

1.3.1. Substance identification

This Annex XV report concerns the use of zero-valent lead massive (particle diameter ≥ 1 mm) or lead alloys used in gunshot, bullets and fishing tackle, and addresses risks to both human health and the environment.

Lead massive is currently the only lead substance (lead compound) associated with use as gunshot, bullets or fishing tackle, including its use as a constituent in lead-containing alloys (which are 'special mixtures' under REACH). However, as the adverse effects resulting from lead exposure are ultimately mediated by dissociated / dissolved lead ions, which could be from any lead compound, the proposed restriction also extends to the use of other lead-containing substances, irrespective of whether they are known to be used in ammunition or fishing tackle or not. As a necessary consequence, the identity of these 'hypothetical' 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 ammunition or fishing sinkers, this approach is analogous to the previous Annex XV reports for lead in gunshot in wetlands, lead in jewellery and lead in consumer articles and is intended to prevent 'regrettable substitution' of lead with other lead substances to circumvent the objectives of this proposed restriction.

Table 1-1: Identification of lead

Identifier	
EC Number	231-100-4
EC name	Lead
CAS number	7439-92-1
Molecular formula	Pb
Molecular weight	207.2

1.3.2. Physical chemical properties

The main physical chemical properties of lead are summarised below, in Table 1-2 based on information from REACH registration dossiers, available in ECHA dissemination portal[36]. Lead is available on the market in both powder and massive forms. In both forms it is a solid, grey-blue element.

Table 1-2: Physical chemical properties of lead

Property	Lead	Other info
Physical state at 20°C and 1013 hPa	Solid (100 %)	
Melting point	326 °C at 101.3 kPa	(CSA, EU A.1 method)
Boiling point	600 °C at 101.3 kPa	(CSA, EU A.2 method)
Relative density	11.45 at 23.8 °C	(CSA, EU A.3 method)
Water solubility	185 mg/L at 20 °C and pH 10.96 [1, 2,3]	(CSA, EU A.6 method)
Flammability	Not classified	
Explosive properties	Non-explosive	
Oxidising properties	Non oxidising	

Notes: [1] in comment #3349 it was noted that according to ECHA Scientific report for evaluation of limit values for lead and its compounds at the workplace, (October 2019), the water solubility of solid lead is 3.2 mg/L at pH 6, 24 h and 185 mg/L at pH 11 (https://echa.europa.eu/documents/10162/68cf7011-9c04-2634-efa6-b712f1b34a85) [2] https://echa.europa.eu/brief-profile/-/briefprofile/100.028.273 [3] In relation to comment #3501, the Dossier Submitter confirms that the pH value was inadvertently excluded from version 2.0 of the Annex XV report.

[36] https://echa.europa.eu/brief-profile/-/briefprofile/100.028.273

1.3.3. Justification for grouping

The various uses of lead in fishing tackle, gunshot and other types of projectiles (e.g. bullets) are grouped because of the following reasons:

- Similarity in substance identity, all three sectors of use utilise lead in the massive form or lead alloys.
- Similar sizes of some lead fishing tackle (e.g. some sinkers and lures) and lead shot ammunition result in similar pathways of exposure and risk.
- The hazards and potential risks posed by lead projectiles, gunshot and some fishing tackle are similar; they ultimately result in lead poisoning of environmental receptors (principally birds).

1.3.4. Classification and labelling

Lead powder (particle diameter <1 mm) and lead massive (particle diameter ≥ 1 mm) are classified for reproductive toxicity, Repr. 1A (H360FD) and lactation, Lact. (H362). In addition, a specific concentration limit for lead powder of 0.03 % applies; for lead massive a generic concentration limit of ≥ 0.3 % applies.[37]

A proposal for a harmonised classification for lead powder and lead massive was adopted by ECHA's Risk Assessment Committee on 30 November 2018. The proposal includes to retain the classifications for Repr. 1A (H360FD) and Lact. (H362) and to add Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).[38] The updated harmonised C&L has been adopted for lead powder in the Commission Delegated Regulation (EU) 2020/1182 and applies from 1 March 2022 (ATP15[39]).

With regard to lead massive it is stated in this amendment to the Regulation that "*in view of the lower dissolution rate of the massive form, the malleable structure of lead, the specific intentional production of the powder and the different environmental classification between massive and powder forms for existing entries in Annex VI for other metals, further assessment needs to be done by RAC on whether to apply the same environmental classification to the massive as to the powder form of lead. In addition, new scientific data has been made available suggesting that the environmental classification for the massive form as recommended in the RAC opinion might not be appropriate. Therefore, the environmental classification for the massive form will not be included in Annex VI to Regulation (EC) No 1272/2008 until RAC has had the opportunity to deliver a revised opinion.*"

On 24 June 2020, RAC[40] received a request from ECHA in accordance with Article 77 (3) (c) of the REACH Regulation to (i) reassess the ERV values for lead using existing data set from the original CLH dossier taking into account the new chronic toxicity study for lead in *Lymnea stagnalis* following OECD TG 243, and (ii) re-examine of whether the powder and massive forms of lead warrant the same classification for hazards to the aquatic environment.

[37] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1179
[38] https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e180db34ea
[39] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=uriserv:OJ.L_.2020.261.01.0002.01.ENG
[40] https://www.echa.europa.eu/documents/10162/13579/rac_mandate_art77_3c_lead_en.pdf/da03fe7b-19a1-5dfa-3086-6e0c2973dc65

Table 1-3: Harmonised classification and labelling according to Regulation 1272/2008 and its amendments

Index No	International Chemical Identification	EC / CAS No	Hazard class category	Hazard statement code(s)	Spec. Conc. Limits, M-factors, ATEs
082-013-00-1	Lead powder [particle diameter <1 mm]	231-100-4 7439-92-1	Repr. 1A Lact. Aquatic Acute 1[1] Aquatic Chronic 1[1]	H360FD H362 H400 H410	Repr. 1A; H360D: C ≥ 0.03 % M = 1 M = 10
082-014-00-7	Lead massive [particle diameter ≥ 1 mm]	231-100-4 7439-92-1	Repr. 1A Lact.	H360FD H362	GCL ≥ 0.3 % applies

Note: [1] shall apply from 1 March 2022 onward

1.4. Manufacture and use

This section summaries the following uses in the EU27-2020 that have been considered in this Annex XV Restriction Report:

- lead in gunshot in terrestrial environments;
- lead in other types of ammunition;
- lead in fishing tackle.

Detailed information on each use is included in Annex A. Some indicative information on the manufacture processes is also provided in Annex A.

1.4.1. Overview of uses

The Dossier Submitter identified various uses of lead in projectiles and in fishing tackle, either from the call for evidence (CfE), literature searches or stakeholder consultation. These uses are identified in Table 1-4 below.

The uses in Table 1-4 are assessed to determine if they pose a risk for human health or the environment that is not adequately controlled. Each of the uses have a different 'substitution profile' and there would be different consequences for society for a restriction on placing on the market or use. These are described in the 'Impact Assessment' outlined in Section 2 of the report with supporting information and analysis presented in Annex D.

Table 1-4: Overview of uses and technical functions

Sector of use	Use #	Use title	Use overview - Brief description of the use of lead and its technical function
Hunting	1	Hunting with gunshot	Used as a projectile, either by itself or in quantity (i.e. gunshot) where the technical function is to provide mass for energy transfer to a target Projectiles can be of various sizes and shapes depending on the desired ballistic properties. They can be used by consumers or professionals The ballistic properties vary depending on whether ammunition is for hunting or sports shooting as well as the size and type of quarry and the type of gun used. Projectiles can sometimes be coated with another metal (termed 'jacketed').
	2a	Hunting with bullets - small calibre[1]	
	2b	Hunting with bullets - large calibre	
Sports Shooting	3	Outdoor sports shooting with gunshot	
	4	Outdoor sports shooting with bullets	
	5	Outdoor shooting using airguns	
Shooting with historical weapons	6	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments	
Fishing	7 and 8	Lead in fishing tackle	Uses of lead in fishing tackle means: - Recreational fishing with lead fishing tackle (Consumer use) - Commercial fishing with lead fishing tackle (Professional use) - Home-casting of lead fishing tackle (Consumer use) The main function of lead in fishing tackle is to provide additional weight in order to (i) cast and set the bait or lure at a certain location and distance (up to 200 m), and/or to (ii) sink the fishing tackle e.g. the line and fishing hook, or the net, while allowing fishing (CfE #1034 - Vlaams Instituut voor de Zee). The following types of fishing tackle can

Sector of use	Use #	Use title	Use overview - Brief description of the use of lead and its technical function
			usually be made of lead: - Sinkers (or weight) including wires (sometimes also referred to as lead core) - Lures including jigs - Nets, ropes or lines in commercial fishing essentially Use 7 covers all the lead uses related to sinkers and lures and use 8 covers the uses where lead is embedded in the fishing tackle (i.e. nets with lead embedded in the nets, ropes or lines).

Notes: [1] This use includes hunting with an airgun

1.4.2. Manufacture of lead gunshot and bullets

The production of lead gunshot and lead bullets is described in Annex A. For gunshot there are two main production processes: tower and Bleimeister. Bullets are made either via cutting or casting.

Lead gunshot is made in various sizes and placed on the market in cartridges of various load weights and gauges (cartridge diameter). Hunters and sports shooters select cartridges that fit in their guns and are suited to the type of shooting undertaken. On average a lead sports shooting cartridge contains about 24 g of lead gunshot (fixed by the International Sports Shooting Federation (ISSF) rules) and a hunting cartridge contains between 30 and 34 g depending on the number of individual gunshot pellets (load) and their size. The latter two (load and size) specifications allow hunters to select a cartridge that is suitable for the intended quarry. For further information see Annex D.

Lead bullets are supplied to the market in various forms: either in ready-to-use cartridges or as separate components for 'reloading' by hunters. Hunters and shooters can choose between various calibres and bullet weights. Calibre size is positively related to the size of game being hunted or is (in sports shooting) set out by the International Sports Shooting Federation such as the International Sports Shooting Federation of the International Biathlon Union. Hunters can furthermore choose the weights of the bullets; again bullet weight is positively related to game size.

Lead bullets are not only used for (recreational) hunting but also in different forms of pest control or wildlife population management. This is done by both volunteers and by professionals in the service of wildlife agencies.

Despite the availability of lead-free alternatives, lead bullets and lead gunshot remain the most popular material for both sports shooting and hunting in jurisdictions where lead has not been regulated.

Where restrictions on lead gunshot and lead bullets are in place, alternatives are more widely available and more competitively priced. Such restrictions are in place (full bans for lead gunshot) in the Netherlands and in Denmark. The implementation of the REACH restriction on the use of lead gunshot in wetlands across the EU should increase availability. Restrictions for bullets are in place in various Federal States in Germany, national parks in Austria and in Italy and France and on a wider scale in Denmark with an upcoming nationwide ban in 2023.

The ammunition value chain can be complex with various interactions between manufacturers, ammunition loaders and cartridge suppliers. Some manufacturers are global players, and some other manufacturers supply only on a local scale; parts and components can be sold together by dedicated assemblers or be put on the market as such for reloading purposes.

1.4.3. Use of lead in hunting

Hunting is performed in various forms: driven, stalking, from the high seat, in groups.

Lead is traditionally used to produce projectiles; it is used as mass to transfer energy. Within hunting such an energy transfer is intended to transfer sufficient energy to a target to result in a rapid kill (where unnecessary suffering is minimised). Hunting regulations often require a minimum calibre or a bullet weight in order to ensure that hunting is performed within what is perceived as ethical limits.

As such, materials other than lead can deliver the same energy as long as the basic parameters of energy transfer are met: sufficient weight combined with sufficient speed to provide at a given distance a sufficient energy transfer.

1.4.4. Use of lead in sports shooting

Sports shooting is usually performed at dedicated locations (temporary or permanent) where individuals practice or compete. Sports shooting is a test of accuracy (target shooting) combined in some disciplines with swiftness of reaction (clay target type sports) or physical endurance (biathlon).

Various types of ammunition are used, ranging from air pellets to small calibres, shot cartridges and larger calibres over longer distances. Rules for the various types of sports shooting are set by international shooting organisations such as the International Biathlon Union (IBU), the International Sports Shooting Federation (ISSF) or by the Federation International des armes de Chasse (FITASC). Concerning the Olympic sports shooting events, the organisation of the sport is delegated to the IBU and to the ISSF.

Training and competitions can take place at sites with varying degrees of risk management measures (e.g. using berms and/or nets, and/or surface coverage).

1.4.4.1. Good hygiene practice to reduce lead exposure of shooters

Lead in the primer and the outer surface of the projectile is vaporized and released into the air after a firearm is discharged. Lead dust and fragments are also released when the projectile impacts solid surfaces. For these reasons, surfaces in shooting ranges may be contaminated with fine lead dust. This dust can also be breathed in and swallowed. Lead dust may be suspended in the air or stick to people's hands, hair, face, clothing, and footwear. This dust may be transported on skin, hair, clothing and equipment from a shooting range into a car and into homes[41].

Good hygiene practice is therefore recommended such as:

[41] https://www.vssclub.org/shooting-hygiene.html

- No eating, drinking or smoking while shooting as this makes swallowing of lead more likely;
- Washing hands, neck and face with soapy cold water before taking breaks and when finished shooting for the day (using warm water should be avoided, as it will open the pores of the skin, enhancing lead exposure);
- Showering after shooting;
- Change of clothes and shoes before leaving the shooting range if possible.

Wearing personal protective equipment is also recommended:

- Using clothing and shoes dedicated to shooting activities or wearing disposable coveralls. Clothes used for shooting should always be washed separately from general laundry.
- Wearing gloves when shooting, handling ammunition, casings or when cleaning handguns.

Furthermore, use of suitable face masks (such as FFP2) has been demonstrated to reduce exposure to lead during indoor shooting (Mühle, 2010).

In the CSR (2020) it is stated that basic hygiene practice to minimise lead exposure should be taught, including prohibitions on smoking and eating in areas where firearms are discharged. Respiratory protection should be available if the type and calibre of the firearm to be used exceeds the capacity of the ventilation systems in place. Precautions regarding "carry home" of lead contaminated dust should also be provided. Such good hygiene practice should also be followed while recovering lead gunshot or lead bullets.

Several comments received during the Annex XV report consultation (e.g. comments #3220, #3244, #3262, #3275, #3326, #3379, #3410; #3426 and #3441) confirmed the required good hygiene practice. Two comments (#3235 and #3254) also highlighted training and education, e.g. for black powder hunting license in Hungary, safe handling of lead is also included.

However, several other comments indicate that the submitters are not aware of lead exposure for outdoor shooters (e.g., #3189, #3194, #3298 and #3309). It is furthermore noted that lead exposure of outdoor shooters can be reduced by using jacketed rifle ammunition for large calibres (#3245, #3257, #3262, #3441 and #3525).

It is to be noted that several comments received in the consultation of the Annex XV report (#3185, #3188, #3189, #3285, #3308, #3309, #3379) challenged the potential exposure of shooters to lead in outdoor sports shooting. According to comment #3221 from FITASC/ISSF, oral exposure to lead in sports shooting disciplines is insignificant while exposure to lead dust using lead gunshot is "impossible". This is further discussed in section 1.6.3.1.

1.4.4.2. Risk management measures for the environment at shooting ranges

In general, different national regulations (implying the use of different types of risk management measures, when actually required) may exist for the operation of shooting ranges, but no EU harmonised measure is in place to manage risks to the environment resulting from sports shooting at shooting ranges. The operation of shooting ranges requires careful planning to minimise environmental pollution related to all involved receptors.

Suggested (but not binding) risk management measures (RMMs) are described in the Chemical Safety report (CSR), as presented in Section 1.4.4.2.1.

In Germany, the legally binding guideline on shooting ranges prescribes risk management measures that need to be implemented (German BMI, 2012).

Based on the comments received in the consultation on the Annex XV report, e.g. in relation to risks for surface water and groundwater, different EU Member States appear to have different approaches and legislations about how to identify risks and subsequently how to deal with them during the entire life cycle of a range (including the end of life).

The Finnish Shooting Sport Federation (Comment #3240) reported that planning of pollutant management at existing shooting ranges requires sufficient data on the site, its emissions and the environmental risk caused by the operations. The assessment procedure involves the study and description of the history of the sites, the emissions and the soil, groundwater and surface water conditions. The goal is to determine how the operations cause an environmental load (e.g., have pollutants migrated into surface waters, or on what timescale is it possible for the pollutants to migrate into the groundwater), and what impact this will have on the environment (e.g. impact on the aquatic ecosystem or changes to groundwater quality). Performing these analyses and assessments requires sufficient expertise and investment. Based on the results of the assessment of the need for pollutant management, the risk management requirement level and objectives are determined, and the required risk management measures are planned based on the risk level of the shooting range. The effectiveness of pollutant management should be followed up through regular environmental monitoring. Comment #3379 notes that in Germany*: "The regular monitoring of the condition of the soil and / or of the water (ground and / or surface water) is for many shooting ranges either included as a requirement in the operating license or specified in a separate order by the licensing authority. The regular examinations are carried out by independent experts".* Comment #3198, also related to Germany, notes that *"If no renovation takes place after a shutdown, the abandoned sites are monitored by means of a monitoring system. At regular intervals (3 to 8 years), soil and groundwater investigations and a risk assessment are carried out in accordance with the laws"*.

Comment #3192 related to Poland notes that *"Despite bullet traps being mandatory, there are additional regulations of the ministry of environment. All outdoor shooting ranges where projectiles containing lead can be used, must have at least 80 % of lead periodically removed from the soil (frequency depends on the depth of the groundwater table) and soil acidity must be monitored and kept within pH range 6.5-8.5."*

Comment #3245, related to Norway, states that *"There are no formal provisions as to how to manage the risk of pollution at the end of life of a shooting range",* thus suggesting that there is no formal provision in relation to the risks to groundwater as well.

Comment #3261, related to Sweden, notes that: *"Test wells adjacent to the backstop are used to monitor lead content in surface water and water drained through the backstop, when requested by local environment regulations or authorities".*

1.4.4.2.1. RMMs in the Chemical Safety Report (CSR)

The REACH registration Chemical Safety Report (CSR) for lead provided in 2020 by the Lead Registrant, describes various professional and consumer uses of lead in ammunition.

Exposure Scenarios (ES) for these various uses of lead in ammunition are described, including an ES for the professional and consumer (non-military) use of lead ammunition. In this ES, the use of lead ammunition in sports shooting is covered in relation to outdoor pistol/rifle shooting and clay target shooting (incl. sporting clays or simulated game hunting). The RMMs identified in the CSR as "required" to prevent releases during service life at different types of shooting ranges are the following:

- Measures to prevent rivers from crossing the lead deposition area
- Bullet containment in the shooting range: "at least one or a combination of bullet traps, sand traps or steel traps"
- Overhanging roof over the lead impact zone to prevent runoff
- Control of water runoff
- Lead shot deposition must be within the boundaries of the shooting range
- Remediation plan upon closure

Specifically, the identified RMMs are supposed to be applied according to the following Table 1-5. No information is provided in the CSR in relation to the expected specific effectiveness of each of the measures.

Table 1-5: RMMs to prevent releases during service life in a outdoor pistol/rifle range and (sporting) clay target range, as indicated in the REACH registration Chemical Safety Report (CSR), 2020

RMMs to prevent releases during service life	Outdoor pistol/ rifle range	Clay target range	Sporting clay target range (simulated game hunting)
Measures to prevent rivers from crossing the lead deposition area	required	required	required
Bullet containment in the shooting range: "at least one or a combination of bullet traps, sand traps or steel trap"	required		
Overhanging roof over the lead impact zone to prevent runoff	required		
Control of water runoff		required	required
Lead shot deposition must be within the boundaries of the shooting range	required	required	required
Remediation plan upon closure	required	required	required

However, the Dossier Submitter considers that the available evidence indicates that these recommended RMMs are not always in place.

For example (as indicated in the Stakeholders Questionnaire, 2020):

- Danish Sports Shooting Association (Skydebaneforeningen), when indicating the measures in place in their rifle/pistol ranges, they only indicated that lead is removed from the ranges to guarantee a safe operation with no mention to the presence of overhanging roof over the impact zone. They clarified that "shooting ranges in Denmark are "very old" and were not built having the protection of the environment as main objective.
- Swedish Shooting Sport Federation (Svenka Skyttesportforbundet) confirmed that permits granted to operate a pistol /rifle range prescribe the characteristics of

berms/backstop (consisting of sand or fine gravel) from a safe operation point of view, with no mention of the presence of overhanging roof over the impact zone in outdoor pistol/rifle ranges.

- Cyprus Shooting Sport Federation, in relation to the control of run off in clay (sporting) target shooting ranges, only stated: "sewage control systems exist in all ranges", not indicating whether installation of controlled surface water intakes with drainage pipes and infiltration systems, possibly with control devices for the analysis of the discharged water, are in place,.
- German Shooting Sport and Archery Federation in relation to the control of run off in clay (sporting) target shooting ranges, stated that: "Typical measures are the installation of a controlled surface water intake with drainage pipes and infiltration systems, in which also control devices for the analysis of the discharged water can be installed. These measures are only required in particularly sensitive locations and their percentage is approx. 25 % of all ranges".
- France: in relation to bullet containment for biathlon: *"But the ranges not equipped with bullet's collectors don't have any wall and the bullets go directly in the berm. Until now the permits granted to operate a range advise to have a wall and bullet collectors, but this is at the moment not yet something mandatory."*

1.4.4.2.2. Guidance for RMMs to be applied at shooting ranges

US EPA published a guidance for best management practices for lead at outdoor shooting ranges (US EPA, 2005).

In the German shooting range guidelines (German BMI, 2012) and its update (German BMI, 2013), which is legally binding, detailed technical guidance are provided on the establishment, approval and operation of shooting ranges (in German language).

The Finnish Ministry of the Environment published a document on best available techniques (BAT) for the management of the environmental impact of shooting ranges (Kajander and Parri, 2014).

The Environmental Protection Authority Victoria, Australia, published a guidance for managing contamination at shooting ranges as well (Environmental Protection Authority Victoria (EPA) (2019)).

The Canadian Wildlife Federation (Canadian_BCWF, 2016) indicated a variety of best management practices to lead management at outdoor shooting ranges, including:

- Control and contain lead bullets and lead fragments.
- Prevent migration of lead to the subsurface and surrounding surface water bodies.
- Remove the lead from the range and recycle.
- Documenting activities and keeping records.

The following sections present different RMMs to control de risks resulting from the use of lead ammunition at shooting ranges. This list of available RMMs is not intended to be exhaustive.

1.4.4.2.2.1. Recovery of lead gunshot

Lead gunshot spreads over a large area. According to the Finnish BAT (Kajander and Parri, 2014), the area for one trap range is ca. 50 000 m^2 and for one skeet range ca. 60 000 m^2. The shot fall zone for one trap station was reported as 35 000 m^2 by the Environmental Protection Authority Victoria (EPA) (2019).

In comment #3240 submitted by the Finnish Shooting Sport Federation it is explained that the rules and nature of shotgun sports place their own requirements on the distances of the structures. At a trap range, the firing stands are located 15 metres behind the thrower trench, and the clay pigeon must be allowed an unobstructed flight distance of at least 76 metres. This means that the minimum distance of the foot of the berm or vertical barrier from the shooter is 91 metres. At a skeet range, the berm can be located significantly closer to the firing stands than at a trap range. However, an unobstructed flight distance of around 67 metres is required for the clay pigeon for it to be possible to calibrate the throwers. In an actual shooting situation, the flight trajectories of the clay pigeons can be restricted, for example with portable nets. If no official competitions are arranged at a range, these distances may be deviated from (comment #3240 from the Finnish Shooting Sport Federation).

Recovery of lead gunshot from soil

In the consultation on the Annex XV report, FITASC/ISSF (comment #3221) provided information on the recovery of lead gunshot from natural soil that requires removal of the impacted soil (see Figure 1-2). On level ground, removal can be performed by mechanical intervention. The reported process consists of the following:

- extraction of the gunshot deposited on the surface and concealed in the ground;
- deposition of material in screening and purification equipment;
- separation of material and soil elements by means of filtering process;
- replacement of processed soil;
- cleaning of recovered gunshot to allow correct melting of lead.

Mechanical recovery might be provided free of charge depending on the quantity of lead collected (as this can be sold for re-use). No information was provided on the effectiveness of lead recovery using this method.

Figure 1-2: Two examples of large screening machines used for mechanical intervention on level ground (FITASC/ISSF comment #3221)

Furthermore, FITASC/ISSF (comment #3221) provided information on examples of manual interventions that can be used to recover lead gunshot from shooting ranges/areas located on difficult terrains such as in forest/woodland/scrub and sloping and/or rocky terrain (see Figure 1-3). With regards to podzolic soils[42], the authors commented that lead collection did not require the total destruction of the vegetation and organic layer and vegetation grew back normally. However, the required infrastructure would be significant for the recovery of lead in a podzolic area where a shooting range is in operation. The recovery of lead from ranges located in difficult terrain would usually only be possible after the final shut down of a range.

[42] Podzols are the typical soils of coniferous or boreal forests.

Figure 1-3: Examples for manual interventions to recover lead gunshot from wooded and rocky areas (FITASC/ISSF comment #3221)

RMMs to improve lead gunshot recovery

At shooting ranges, RMMs can be implemented to reduce the size of the shot fall zone to facilitate the effective recovery of lead gunshot.

In a comment received from the Belgian Weapon Forum (#3403), it was noted that environmental rules are already imposed and that shooting ranges have sufficient measures in place to recover lead or other substances. For trap and/or skeet ranges, the soil has to be covered over 150 m as to be able to recover shot.

The German Shooting Sport and Archery Federation (comment #3379) reported that in general, the pollution management methods suitable for shotgun ranges can be divided into three main categories:

- Reduction of the spreading area of pollutants: terrain contouring, nets and barriers
- Prevention of pollutant migration: soil covering and shot collection
- Water management

Regarding the reduction of the size of the shot fall zone and the prevention of pollutant migration, the following shot retention systems are known to be in use at shotgun shooting ranges in Germany:

1. Vertical shot walls (incl. container solutions) or shot nets (Figure 1-5; Figure 1-6)
2. Earth berms with and without shot-catching surface coverage (Figure 1-4)
3. Combination of earth walls and vertical shot walls.

Vertical barriers

Most frequently used vertical barriers are earth berms. Figure 1-4 presents a scheme for berms at a trap and skeet range.

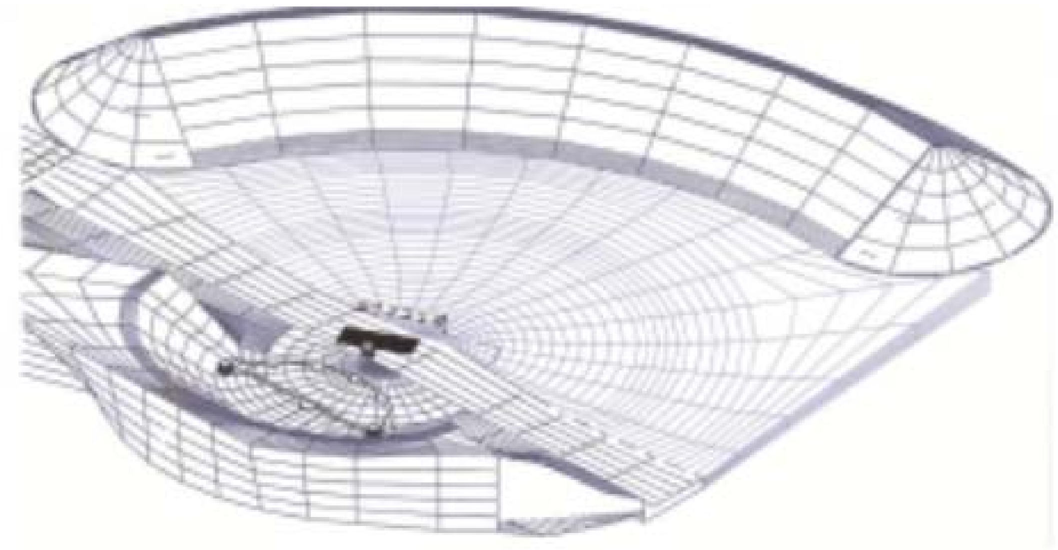

Figure 1-4: Scheme for earth berms for trap and skeet ranges (Bavarian StMLU, 2003)

Nets are also used as a vertical barrier. An example is presented in Figure 1-5. Net systems are available to effectively capture and collect lead gunshot (Bavarian LFU, 2014a).

Vertical barriers have the benefit to reduce the shot fall zone (Figure 1-6) and to concentrate the lead shot to assist lead recovery (Environmental Protection Authority Victoria (EPA), 2019).

Figure 1-5: Example for a vertical barrier in a clay shooting range (Herrmann, 2013)

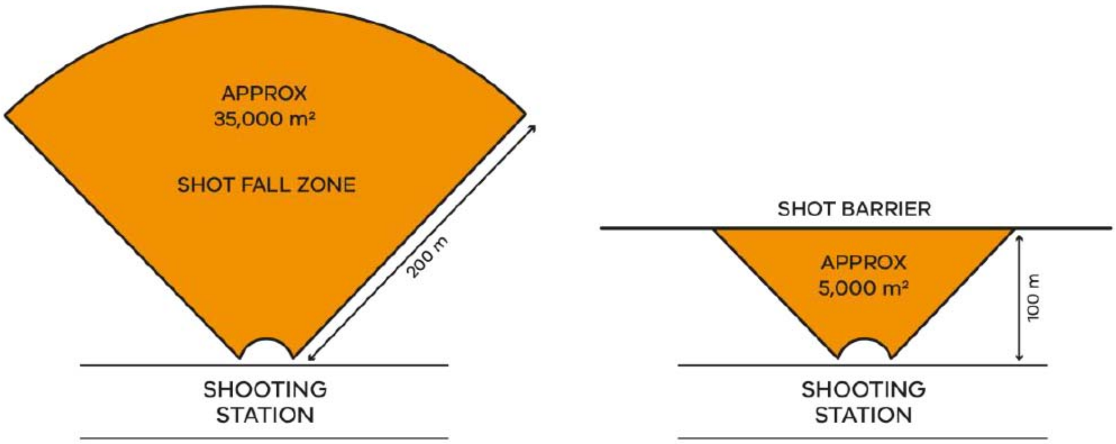

Figure 1-6: Reduction in the shot fall zone by using a barrier at a trap station (Environmental Protection Authority Victoria (EPA), 2019)

Horizontal barriers

To properly recover lead gunshot, horizontal barriers might also be required. Figure 1-7 presents an example of a horizontal barrier. A drawback of a horizontal barrier without a vertical barrier is the large surface area of land that is required to be covered. Furthermore, it would need to be ensured that no lead gunshot would land outside of the range boundaries.

Figure 1-7: Example of a horizontal barrier (Bavarian LFU, 2014a)

In Figure 1-8, a combination of a vertical and horizontal barrier is presented.

Figure 1-8: Example of a range with both a horizontal and vertical barrier (Bavarian StMLU, 2003)

Horizontal barriers may consist of materials such as polymers (e.g. polyethylene), geotextiles or asphalt (Bavarian LFU, 2014a, Kajander and Parri, 2014).

For ranges with lead contaminated soil, an impermeable barrier to cover the soil is likely to be ineffective, as percolation can still occur, and the soil chemistry may be adversely affected by the development of anaerobic soil conditions. Therefore, for existing ranges, before the installation of an impermeable barrier is carried out, removal of any lead contaminated soil is likely to be needed.

Range layout to optimize lead recovery

Overlapping shot fall areas may improve the efficiency of lead recovery (Environmental Protection Authority Victoria (EPA), 2019).

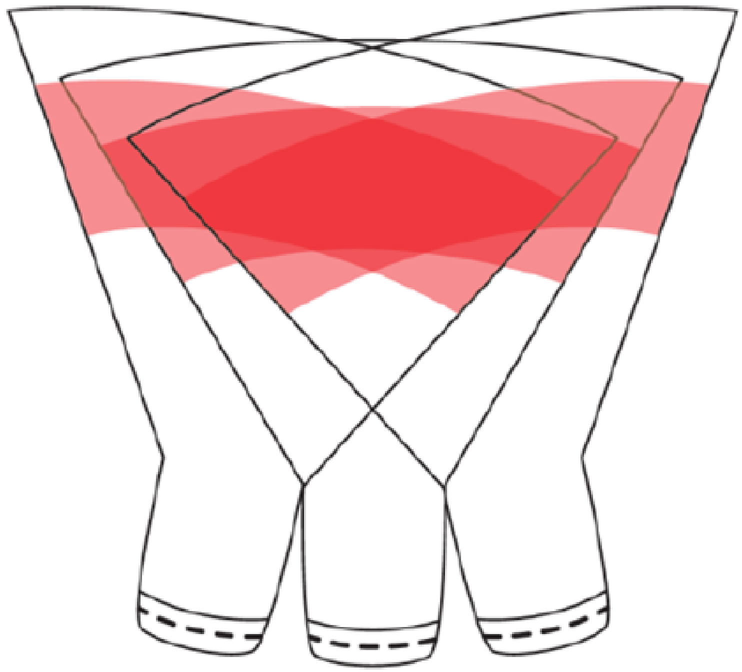

Figure 1-9: Using overlap to reduce shot fall area at trap field (Environmental Protection Authority Victoria (EPA), 2019)

Such measures can be applied to trap and skeet ranges but may not be suitable for all shooting range layouts such as in "sporting" shotgun disciplines.

Effectiveness and frequency of lead gunshot recovery

With regards to lead gunshot recovery, the following specific information was submitted by several stakeholders in the consultation of the Annex XV report:

- In Finland (#3230, #3240), the Czech Republic (#3275), and Norway (#3470, #3257) no trap or skeet range can recover >90 % of spent lead gunshot.
- 40 % of recovery rate was achieved in Cyprus by manually collecting lead gunshot by individuals who have contracts with shooting ranges for recycling (#3394 Cyprus Shooting Sport Federation).
- In Spain (#3431), shooting ranges periodically collect spent lead.
- For shooting ranges with medium or low shooting frequency in the UK, environmental RMMs might not be in place (#3250).
- Almost 100 % recovery is achieved on trap/skeet shotgun ranges, where gunshot net/barrier systems and appropriately prepared deposition areas on earth berms and horizontal surfaces are used (comment #3198 by Bundesverband Schießstätten e.V.and #3379 by German Shooting Sport and Archery Federation).

- FITASC/ISSF (comment #3221) suggested that as long as appropriate techniques are used to stabilise lead *in situ* to prevent it from migrating from the site, shooting ranges have a reasonable period of time to recover deposited lead after initial use. In their view it is, for instance, possible to wait until the quantity of lead deposited is sufficient to finance its collection through its residual value or when quantities are small (small shooting ranges) to recover lead gunshot only every ten years. Furthermore, FITASC noted that lead recovery may be mandatory at the time of closure of shooting ranges and recommended the use of techniques to stabilise lead to reduce its potential to migrate.

Considering the experience of ranges with state of the art RMMs, whilst not currently widely implemented, the Dossier Submitter considers that a regular lead recovery rate of ≥ 90 % (per year) for lead gunshot can be achieved.

With regards to the interval between lead recovery, the German Shooting Sport and Archery Federation (comment #3198) stated that: *"On shotgun ranges with shot trap systems made of vertical nets or walls, the lead shot is collected and reclaimed one to three times a year, depending on the intensity of use. At shot trap systems with nets, the lead shot is recovered by hand using simple devices (broom and shovel) or smaller machines (wheel loader with trailer). This work is usually carried out by shooting range staff or club members in compliance with the relevant occupational health and safety regulations and lasts about one to two days."*

For shotgun ranges without state of the art RMMs, regular lead recovery is expected to be infrequent. Data on the total number (or proportion) of ranges in the EU that currently recover > 90 % lead gunshot (annually) is not available.. Based on the limited examples of sites with state-of-the art risk management measures reported, the Dossier Submitter assumes that fewer than 200 (< 5 %) of shotgun ranges in the EU have state of art environmental risk management measures in place that would allow to recover > 90 % of lead gunshot (annually). Examples are reported in the Finnish guidance on Management of the Environmental Impact of Shooting Ranges (Kajander and Parri, 2014)[43] or by some stakeholders, including the German Shooting Sport & Archery Federation (comment #3198).

Since lead gunshot will remain on top of the soil between removal intervals with the risk of mobilisation of lead to run-off water, the design of the ranges require measures to manage lead-contaminated drainage water (see following sections).

Recovery reduces the lead burden on the soil. However, it is likely that a certain fraction of the lead gunshot and fragments may remain in the soil even following regular lead recovery. The Dossier Submitter notes that the CSR exposure scenario (2020) requires a remediation plan for the end of service life.

Other disciplines

Practical shooting disciplines, also known as dynamic shooting or action shooting, are non-Olympic shooting disciplines, typically simulating combat or self-defence scenarios, where competitors use a firearm to hit targets and score points during the shortest amount of time (or sometimes within a set maximum time). Either handguns, rifles or shotguns may be used. Usually, the competitor must move and shoot from several positions, fire under or over obstacles and in other unfamiliar positions. There are no standard exercises or set

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[43] https://www.enviro.wiki/images/e/ef/2014-Mgmt_of_the_Environmental_Impact_of_Shooting_Ranges_The_Finished_Env..pdf

arrangement of the targets, and the courses are often designed so that the competitor must be inventive, and therefore the solutions of exercises sometimes vary between competitors [44]

In simulated field shooting, also known as 'sporting' or 'COMPAK' clay target shooting, shooters progress from station to station around a set course in natural terrain (e.g. woodland, scrub, agricultural areas). The course uses clay pigeons of various sizes and shapes that are propelled at different speeds, angles and distances to simulate diverse hunting scenarios. There are typically five to nine different shooting stations, sometimes as many as 36, firing in different directions. This results in lead becoming dispersed across a wide area (Environmental Protection Authority Victoria (EPA), 2019).

Figure 1-10: Simulated Field shooting range (Environmental Protection Authority Victoria (EPA), 2019)

The International Practical Shooting Confederation[45] (IPCS; comment #3180) commented that all sports shooting competitions and training are held exclusively within specially equipped, protected and certified facilities (shooting ranges and clubs). The Dossier Submitter notes that IPCS did not provide details of the risk management measures applied for environmental protection and pollution control and their effectiveness, including of lead recovery.

1.4.4.2.2.2. Recovery of lead bullets

According to the Association of European Manufacturers of Sporting Ammunition (AFEMS, 2002) bullets must be contained, controlled and collected both to maintain safety on and off the range and to prevent movement of lead from the site. A rifle/pistol range has the potential to contain all spent bullets, especially if enclosed.

In the CSR (2020), bullet containment in the outdoor shooting range is required by: "at least one or a combination of bullet traps, sand traps or steel traps". An overhanging roof over the lead impact zone to prevent runoff is further required.

In the Annex XV report, in line with the CSR, the Dossier Submitter uses the term 'bullet containment' to refer to all of the different types of measures used to contain bullets and 'bullet trap' for trap chambers, such as steel traps. However, it is understood from the

[44] https://en.wikipedia.org/wiki/Practical_shooting
[45] https://en.wikipedia.org/wiki/International_Practical_Shooting_Confederation

consultation on the Annex XV report that the term 'bullet trap' can also be interpreted in a broader sense, meaning that all projectile containments, including soil and sand berms, are considered to some extent as 'bullet traps'. Consequently, the Dossier Submitter is using the term 'trap chamber' rather than 'bullet trap' in the revisions to the Annex XV report.

The Dosser Submitter further notes that bullet containment serves both safety and environmental purposes at shooting ranges. Within this restriction proposal only the effectiveness of RMMs to minimise the identified risks to the environment are considered.

(Bullet) trap chambers

(Bullet) trap chambers, often made of steel ('steel traps'), are a very effective means to allow controlled containment, easy and frequent collection and recycling of lead projectiles (see Figure 1-11) and therefore minimising the releases to the environment.

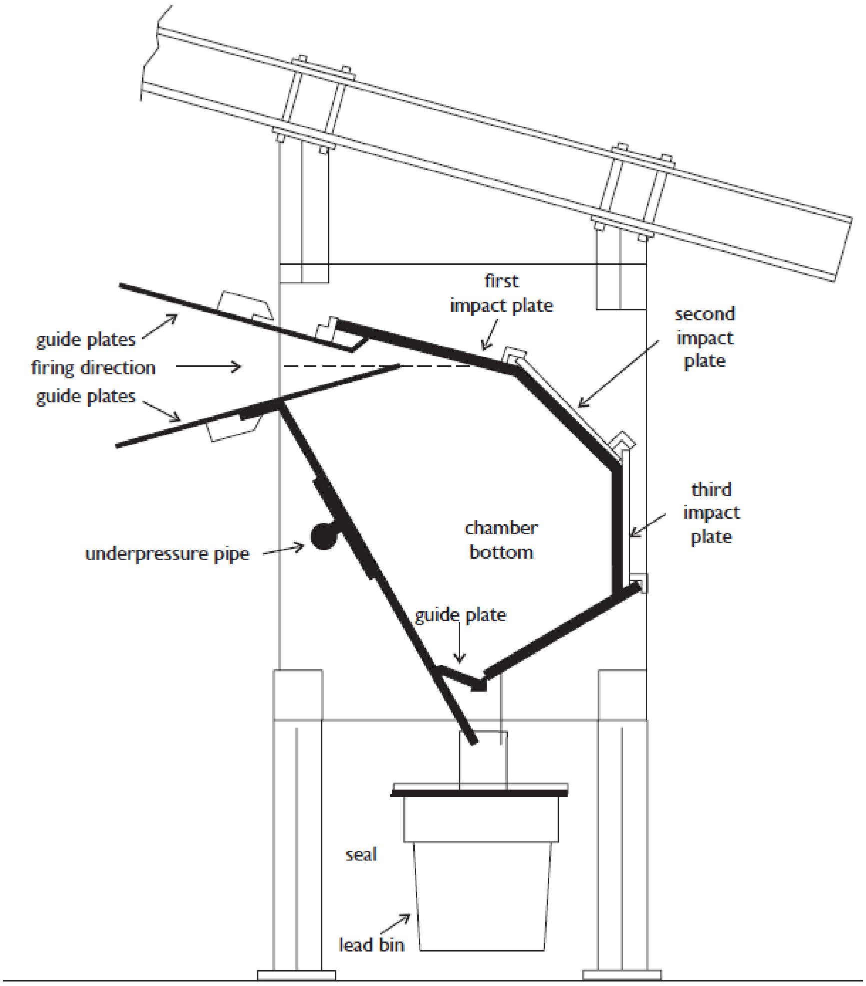

Figure 1-11: Example of a total containment trap chamber (Kajander and Parri, 2014)

According to the German shooting range guidelines (German BMI, 2012) and its update (German BMI, 2013), the following definition of (bullet) trap (chamber) systems are provided (translated to English):

"Bullet trap systems are self-contained assemblies which, as technical equipment or installations in shooting ranges, safely dissipate the bullet energy of impacting bullets. They must be designed and constructed in such a way that:

- the absorption or rejection or conduction of impacting projectiles, of whatever type, takes place reliably and safely

- enable the projectile material to be disposed of and separated from the catch material as far as possible

- safe firing (no dangerous rebound of projectiles and fragments) is ensured for the shooters when shooting at close range

- the removal of bullet trapping material is as simple and safe as possible.

The design and materials used in bullet trap systems must be adapted to the intended use of the respective type of ammunition and weapon and to the shooting technique.

In terms of safety, the bullet trap systems must be coordinated as a self-contained unit with the other structures of the internal safety of a firing range, and in the case of open firing ranges, also with external safety.

The bullet trap systems are classified according to their shooting sport or other intended purpose and the respective energy (E0) of the projectiles.

Examples for the construction of different (bullet) trap chambers are provided in the German shooting range guidelines (German BMI, 2012), the Finnish BAT (Kajander and Parri, 2014) and in the thesis from Kärki (2016).

Figure 1-12: Example of a prototype of biathlon target equipment and trap chambers installed in a shipping container (Kajander and Parri, 2014)

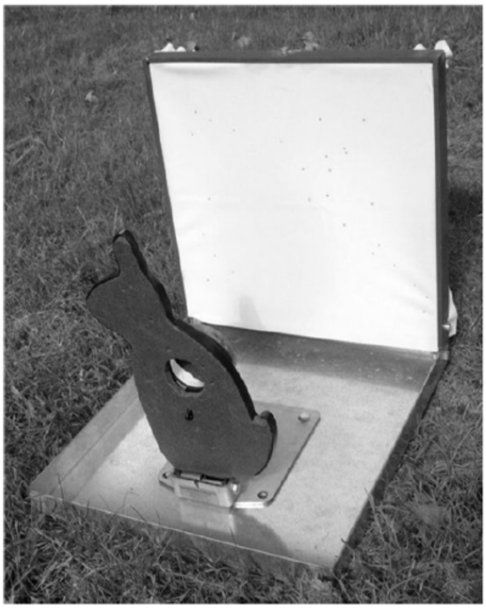

Figure 1-13: Example for field-target trap (German BMI, 2012)

Kärki (2016) found bullet recovery relative to the amount shot of 91.0 to 91.7 % for shooting to cardboard flats and 87.1 to 87.8 % for biathlon.

With regards to lead bullet recovery, the following information has been submitted to ECHA:

- 100 % recovery and recycling: in trap chamber systems (for rifles, pistols and airgun weapons) which are emptied regularly in compliance with the relevant occupational health and safety regulations (German Shooting Sport and Archery Federation);
- 95 to 100 % lead recovered (Royal Netherlands Shooting Sport Association);

In a survey among Member States and stakeholders, lead recovery rates close to 100 % were reported for biathlon where trap chambers were used. The use of berms resulted in much lower recovery rates. Therefore, the Dossier Submitter considers that by using trap chambers a lead recovery rate of >90 % is achievable.

Furthermore, lead can be easily and efficiently reclaimed and recycled, providing an additional stream of revenue for the club (Canadian_BCWF, 2016).

Due to the German shooting range guidelines[46] (requiring the use of bullet trap chambers[47]), all ranges in Germany already have trap chambers in place. In addition, based on the information available, Germany is likely to host half of the rifle and pistol ranges in the EU. Consequently, ca. 50 % of the bullets in the EU would already be recovered by trap chambers.

Sand traps

According to the Association of European Manufacturers of Sporting Ammunition (AFEMS, 2002) sand traps comprise a mass of sand, or similar material, contained within a concrete or other structure which is open towards the firing point. Sand is used to absorb the energy of the bullets and help the separation of spent bullets and fragments during recovery and disposal operations. An overhanging baffle/roof should be fitted to prevent rainwater or snowmelt leaching down through the sand and dissolving lead bullet fragments. The base of

[46] https://www.bundesanzeiger.de/pub/de/amtliche-veroeffentlichung?1

[47] The DS has requested confirmation to the German Competent Authorities, in relation to the current legislation in place in Germany.

the sand should be isolated from the underlying soil to prevent any lead contamination (see Figure 1-14). Salt and peat can be mixed with the sand to stop it freezing which would increase bullet fragmentation and ricochet. Regular removal of accumulated bullets is required to avoid ricochets.

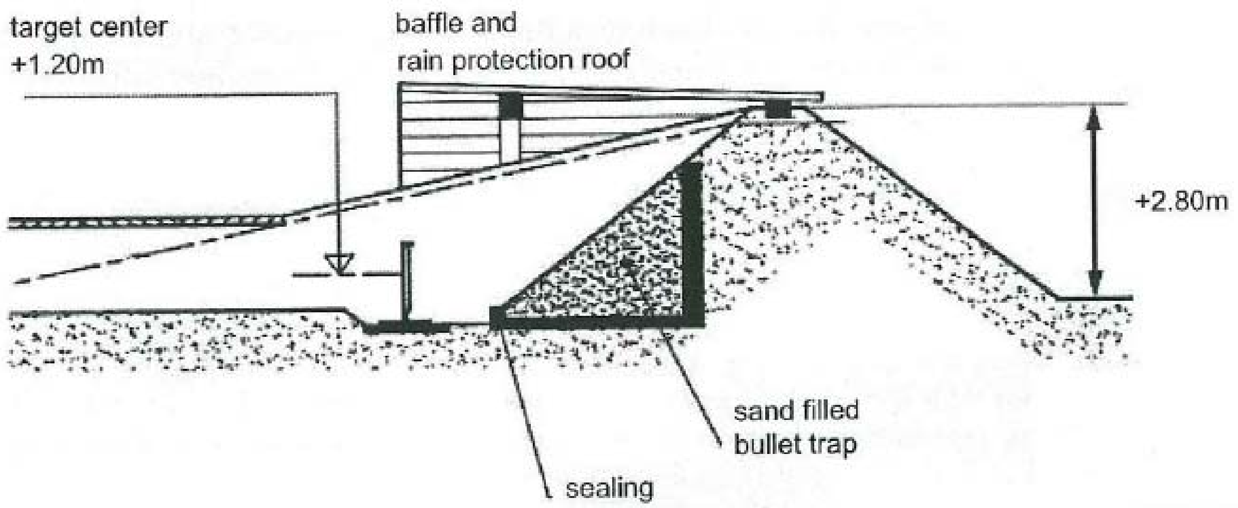

Figure 1-14: Diagram of a sand trap (AFEMS, 2002) as referred to in the CSR

Using a berm made with sand (instead of soil) could slow down lead weathering, but it may increase lead leachability in the long term (Environmental Protection Authority Victoria (EPA), 2019).

In the Finnish BAT (Kajander and Parri, 2014), it is highlighted that in order to function, the sand trap must be a watertight structure where the spreading of lead deeper into the underlying soil and the groundwater is prevented by liners/barriers. It is recommended that in connection with the sand trap structure, infiltration water must be collected from the top of the lining via underground drains and treated if necessary. If the structural solution of the shooting range causes pollutant content in water, the polluted water can be collected depending on the water permeability and structure of the soil either with ditches or with lining and underground drains. Water with pollutant content can be cleaned in a treatment well by filtration or in basins or ditch systems by sedimentation.

Sand/soil berms

In the Nordic countries, sand /gravel berms are used frequently. For the purpose of this report, the Dossier Submitter defines those structures with a sand coverage but without an impermeable layer/barrier to the underlying soil as ‘sand/soil berms’.

In Sweden, most of the approximately 4 000 approved outdoor shooting ranges are for large calibres and are using sand traps (e.g., comments #3249, #3258, #3261). According to comment #3261 from the Swedish Dynamic Sports Shooting Federation, the backstop consists of gravel and/or sand and almost all have the surface covered with a layer of wood chips, sawdust or similar to protect surrounding areas from secondary ricochets. This thick layer (approx. 50 cm) is reported to effectively prevent wildlife from ingesting bullets or shot in the backstop. The backstop itself contains all lead and only emits minute quantities of lead to the surrounding environment, according to a white paper published in 2008

("Vitbok-Om bly i kulfång", Ulf Qvarfort, Per Leffler, Jan Sjöström[48]). In 2020 safety regulations for game shooting (Säkerhetsbestämmelsercivilt skytte, SäkB[49]) were published that specify how bullet containment is to be constructed and maintained, and these are checked regularly by the operators and the Swedish Police Force. Test wells adjacent to the backstop are used to monitor lead content in surface water and water drained through the backstop, when requested by local environment regulations or authorities (comment # 3261). According to the Swedish Shooting Sport Federation (comment #3261) an average of 65 % lead recovery and recycling is achieved in these types of RMMs, depending on the type of range.

The Norwegian Civilian Marksmanship Association (comment #3245) provided information on 'bullet trap systems' (such as sand traps or soil/sand berms) used in Norway (see Figure 1-15 and Figure 1-16). It is specifically mentioned that more than 99 % of the bullets are captured in the area. It is mentioned that possible measures to reduce surface water runoff and to prevent rain from accessing the sand trap would be to install a roof over the sand trap or to cover the sand trap when not in use. Possible measures for runoff control and filtering would be a use of a bentonite membrane, drainage material and pipes (see Figure 1-16).

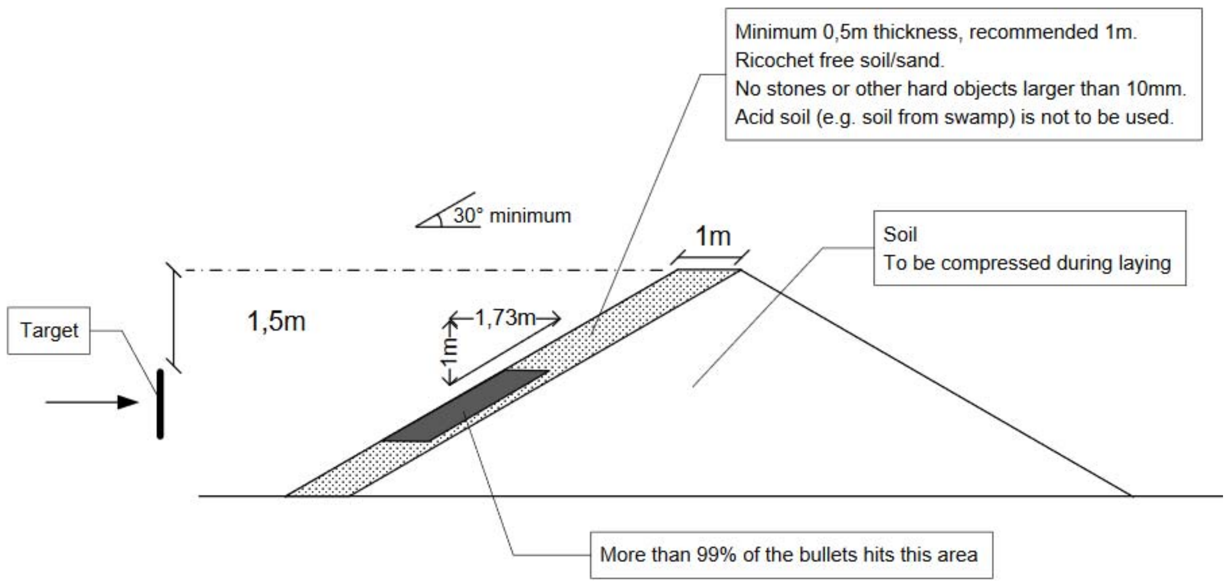

Figure 1-15: Cross section of bullet containment with minimum dimensions (comment #3245)

48 https://www.pistolskytteforbundet.se/produkt-kategori/shop/
49 https://www.skyttesport.se/globalassets/svenska-skyttesportforbundet/regler/sakb/sakb_2020.pdf

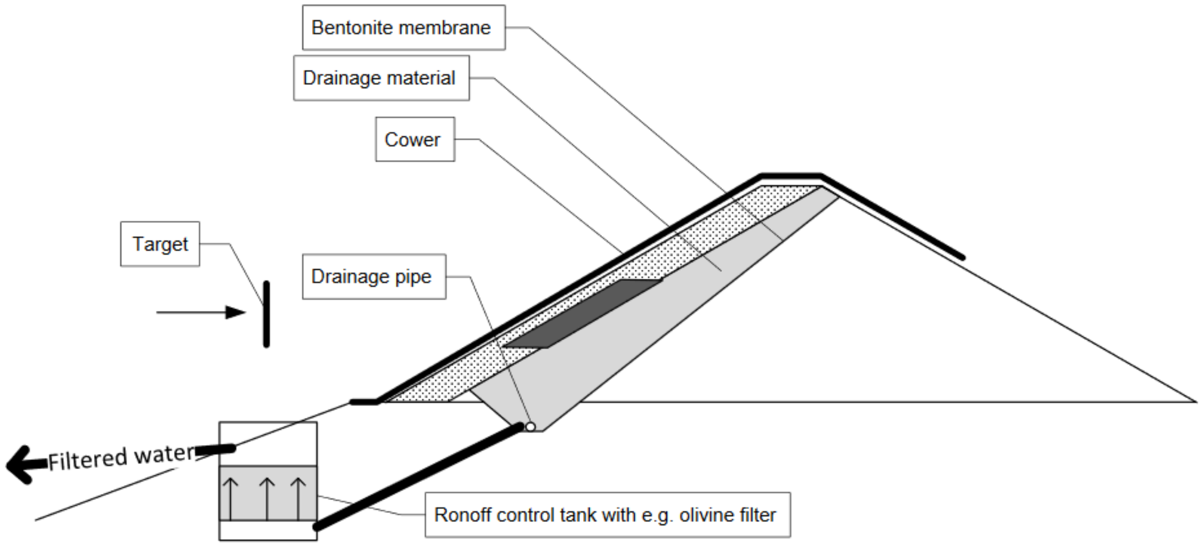

Figure 1-16: Runoff control and water filtering integrated into bullet containment (comment #3245)

The Norwegian Association of Hunters and Anglers (comment #3257) commented that the Norwegian safety regulation for shooting ranges state that 'bullet traps' must consist of sand/soil or other ricochet free material with a minimum slope of 30º and the masses in the bullet trap must consist of a maximum grain size of 10 mm. NIVA (The Norwegian Institute for Water Research, comment #3249), investigated runoff from three rifle ranges. Lead concentrations from the ranges compared to background concentrations for the three ranges were reported as 2.25 versus 0.46 µg/L, 2.89 versus 0.25 µg/L and 0.82 versus 0.20 µg/L. The annual percentage of lead run-off was 0.03, 0.25, and 0.58 % for the three ranges, respectively. The authors concluded that annual leaching was less than 1 % of the lead added. In comment #3257 it was noted that the use of 'bullet traps with sand' can be developed further (runoff control, the use of membranes, filters etc.) to minimize the possibility of leaching.

In a field study with lead sampling at a newly opened shooting range and a laboratory weathering study, it was concluded that 1.5 % of the bullet mass was physically removed by abrasion while firing into sand (Hardison Jr et al., 2004).

In another field study, the effect of weathering of lead bullets in (i) a soil berm (pH 5.3) compared to a sand/soil berm with a 0.6 m sand layer on top of the soil (pH 5.4), (ii) liming of sand (increasing pH from 5.4 to 8.4), and (iii) removing bullets from the soil berm were investigated (Yin et al., 2010). The authors concluded that the conditions of the sand layer with low soil moisture, low organic matter and high pH decreased the weathering of lead bullets; weathering consisted of both chemical (transformation of metallic to ionic lead) and physical reactions (transfer of lead-bullets to soil fraction). Weathering (formation of $PbCO_3$) increased the pH to 7.9. Replacement of a soil berm with sand/soil berm reduced lead bullet weathering by 85 % after 11 months of operation, with the weathering rates (soil lead: bullet loading) being 0.05 and 0.34 for the sand/soil and soil berm, respectively.

Liming in the sand/soil berm reduced lead weathering by 58 % compared to the control after 15 months of application. However, it increased the water-soluble lead in the berm and may have increased lead leaching from the berm. For the limed berms without lime amendment, total lead concentrations in soil were 497 and 777 mg/kg and the water-soluble lead concentrations 2 and 1 mg/kg (0.4 and 0.1 %). For the berms with lime amendment, lead concentrations in soil were 362 and 302 mg/kg and the water-soluble lead concentrations ca. 1.5 and 3 mg/kg (0.4 and 1 %).

Removal of lead bullets impacted the soil lead content in two ways: it removed the sources of lead, thereby reducing the long-term lead build-up potential in shooting ranges. However, at the same time, mechanical sieving broke down weathered metallic lead-bullets into small pieces, increasing total lead concentration in the soil by 2.5 times (Yin et al., 2010).

An experimental study (Liu et al., 2013) reported that total leachable lead in sand (8.48 and 5.25 µg/kg; pH 5.87) is five to seven times lower than in soil (60.6 and 30.4 mg/kg; pH 4.52) under high and low rainfall conditions, respectively. After mixing sand or soil with bullets for 16 weeks, the total lead concentration increased from 6.3 mg/kg to 131 and 105 mg/kg under high and low rainfall conditions, which was 11- and 12-fold greater than that in the sand, indicating a faster weathering of lead bullets from metallic lead to ionic lead in the soil than in sand. Compared to the situation where bullets were mixed with sand or soil, the effect of sand or soil properties on bullet weathering was limited when bullets were placed on the surface of sand or soil. As a result, total lead content in soil (12.9 and 8.41 mg/kg) and sand (3.41 and 2.52 mg/kg) was much lower. In this situation, comparable total leachable lead was observed in soil (11.3 and 3.58 µg/kg) and sand (12.1 and 3.80 µg/kg) under high and low rainfall conditions. Given the fact that not only total leachable lead but also total lead content in soil was greater than those in sand, the authors concluded that under the conditions of this experiment, replacing a soil berm with a sand berm reduced weathering of bullets, resulting in less leachable lead as well as less lead accumulated in the sand. However, it may increase lead leachability in the long term. Based on the provided information with low and high rainfall, the Dossier Submitter assumes that a roof [or a permanent cover] could reduce the weathering of lead projectiles by an average of 50 %.

In an experimental study (Barker et al., 2019), twelve test berms were constructed that comprised of four different types of soil: silt loam, loamy sand, sandy loam, and sand and that covered an area of approximately 2 m^2 each. Each test berm was positioned on a 5 m^2 water-proof plastic geoliner sheet to direct water runoff downslope to one location where samples could be collected. For each type of soil, three berms were established: one control berm and two berms in which 2 000 military-used 5.56 mm bullets were fired. The following total lead concentrations were measured in the soil:

- Silt loam (pH 5.3): 301 and 459 mg/kg compared to 20 mg/kg
- Loamy sand (pH 5.7): 1 256 and 1 679 mg/kg compared to 25 mg/kg
- Sandy loam (pH 6.8): 1 675 2 808 mg/kg and compared to 20 mg/kg
- Sand (pH 8.4): 14 457 and 16 413 mg/kg compared to 30 mg/kg

The highest runoff lead concentrations were reported in the loamy sand runoff. However, numbers or percentages of lead concentrations in the runoff were not reported, only presented in Figure 7 of the publication. From this figure, total aqueous lead concentrations were lowest for the silt loam, higher for sand (median ca. 10 µg/L; 75^{th} percentile ca. 40 µg/L) and highest for sandy loam (median ca. 20 µg/L; 75^{th} percentile around 50 µg/L) and loamy sand (median ca. 20 and 30 µg/L; 75^{th} percentiles around 150 µg/L). The authors argued that sand soil has a relatively high soil pH (8.4) and circumneutral to slightly basic soil pHs have been shown to limit lead solubility, whereas acidic conditions tend to favour lead mobility (Cao et al., 2003). The silt loam soil exhibits a low soil pH (5.3), but has a variety of surfaces for reaction and has a higher organic matter. The Dossier Submitter understands from these data that a maximum of 0.01 % of the lead was measured in runoff from the berm with loamy sand (150 µg/L / ca. 1 500 mg/kg). However, the study only examined particles between 200 nm and 450 nm but no particles smaller than 250 nm.

After firing on average 1 050 bullets into the legacy lead soils there was an observed shift in the fragmentation profiles for the Pb, Sb, and Cu in the soils. There was an observed increase in the smaller sized fragments in the soil profile, providing a potential source for increased mobility of the smaller bullet fragments and oxidized metals (Martin et al., 2014).

Based on the information from (Yin et al., 2010) studying the weathering of bullets on a rifle range for 11 months, the Dossier Submitter takes forward the values for lead bullet weathering of 5 % in sand traps and 34 % in soil berms.

Bullet containments with 'self-healing' surface coverage

In the Finnish BAT (Kajander and Parri, 2014), different rubber granulate bullet traps are presented such as Strapp bullet catchers, SACON structures or rubber granulate structures. Rubber granulate bullet traps are installed in an earthen embankment over support structures. The structure contains a waterproof membrane on top of the soil embankment, drain pipe, rubber granulate for the filler, and a rubber surface layer. The surface layer limits moisture and dirt from getting into the structure and withstands around 15 000 to 20 000 shots. The Shooting Range Association Denmark (#3435) presented an environmental bullet catcher system with a self-healing cover cloth that is based on the patented Swedish STRAPP system (see Figure 1-17). Such bullet containments were tested by the Swedish Defence Forces and by the German Army.

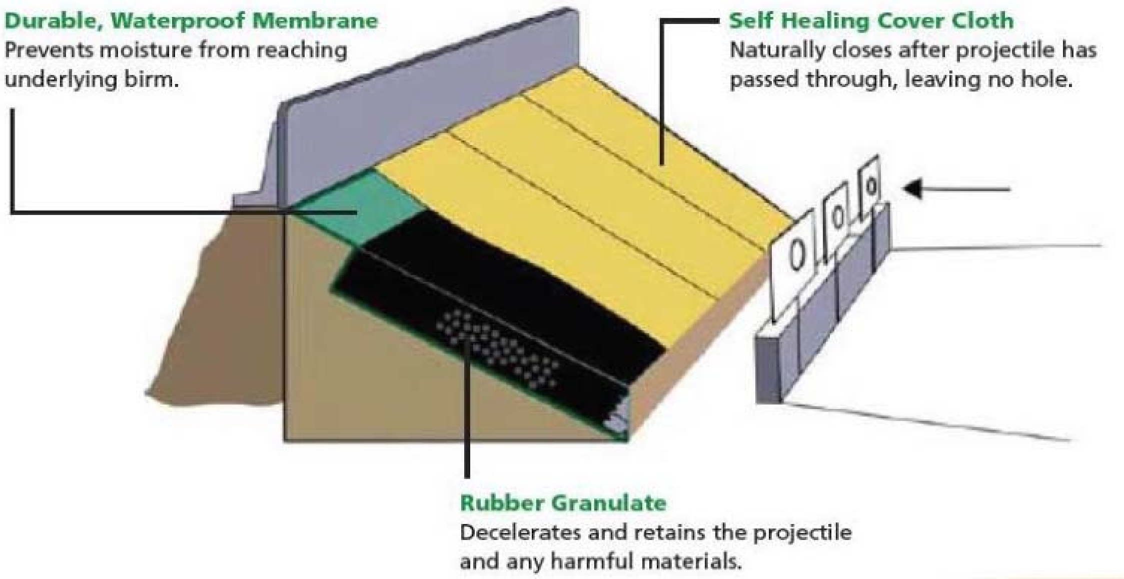

Figure 1-17: Environmental Bullet Catcher (EBC) with self-healing cover cloth (Skydebaneforeningen Danmark #3435)

Movable bullet traps

The Shooting Range Association Denmark (#3435) presented examples of movable bullet traps such as the Polythermo bullet trap (Figure 1-18).

Figure 1-18: Movable polythermo bullet trap (Skydebaneforeningen Danmark #3435)

Soil Berms

Berms are frequently used as a safety related RMM and to trap bullets. y.

In soil berms the bullets are trapped in soil. Contamination hotspots are the target area and the berm (see Figure 1-19).

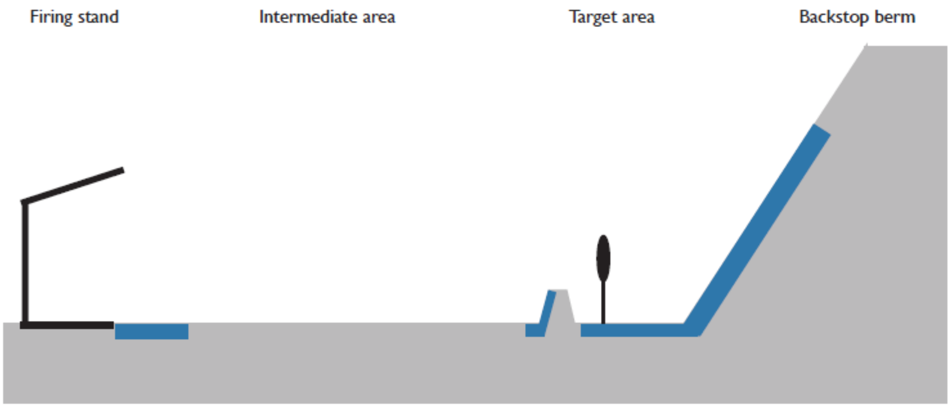

Figure 1-19: Contamination hotspot areas at a rifle or pistol range (Kajander and Parri, 2014)

For outdoor rifle and pistol ranges, impact backstops and target areas may be covered with a roof or other permanent cover to prevent rainwater from contacting berms. However, the roof must be carefully designed to avoid safety issues with ricochets, etc (US EPA, 2005).

Furthermore, if a roof keeps a berm too dry, it could crack and erode. This can increase the risk of contamination spreading through wind as dust.

Removal of lead from earthen backstops usually requires soil removal. Continued use of the backstop without removing the lead may result in increased ricochet of bullets and fragments. In addition, the backstop may lose its slope integrity because of "impact pockets" that develop (US EPA, 2005).

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Furthermore, while recovery of lead bullets removes the sources of lead contamination, X-ray diffraction analysis indicated that its abrasive action transferred metallic lead to the soil fraction (<2 mm), with total lead in soil berm increasing 2.5 times from 4 694 to 11 479 mg/kg (Yin et al., 2010).

In the Finnish report on Best Available Techniques (BAT) for the management of environmental impact of shooting ranges (Kajander and Parri, 2014), three techniques are described for backstop berm renovation:

- Regular removal of the soil in the impact areas containing the most bullet scrap. The removal interval depends on the number of shots and is recommended every three to five years. It is particularly effective at new ranges when used regularly, allowing the removal of the most significant part of the bullets. At old ranges, some of the load is often deeper in the backstop berm and not affected by the technique. This technique is considered suitable for pistol and rifle ranges where the bullets accumulate in the impact areas. However, it is often expensive on the long term.
- Screening of the impact areas. The soil in the impact areas containing the most bullet scrap is removed regularly. The screening interval depends on the number of shots, recommended 3 to 5 years. The bullets are screened out of the soil that can then be returned to the structure or disposed of as waste. The bullets can be recycled. Fine-grained metal remains in the berm and disturbing the soil may increase the solubility of the metals. The spread of dust with metal content must be controlled. This technique is considered of limited suitability for pistol and rifle ranges where the bullets accumulate in the impact areas. At old ranges, there is the risk of the metal particles attached to the soil become mobile.
- Removal of bullet scrap and soil in their entirety. The contaminated soil containing bullet scrap is removed and transported away from the area. Removal in this manner, requires quite extensive earthmoving work. The soil and bullet scrap can be separated by screening. The mass replacement work causes some dust generation and the contamination of clean soil brought to the site. This risk management method is considered effective in principle, but an expensive solution that has poor eco-efficiency.

According to the German shooting range guidelines (German BMI, 2012) and its update (German BMI, 2013), natural hills or walls shall not be used as bullet traps. A berm covered with appropriate material or a wall may be required in addition to the bullet trap for safety reasons as for example for biathlon or for silhouette shooting.

Use of bullet containment for different shooting disciplines

Many comments were received in the consultation on the Annex XV report on the use of specific bullet containments for different disciplines.

(Bullet) trap chambers are frequently used for sports shooting with small calibre projectiles. They may also be used for large calibre projectiles (as required e.g., in Germany) but they require larger dimensions and thicker and stronger steel than trap chambers for small calibre projectiles and are consequently more expensive (#3245; #3262). In Norway, where outdoor shooting is mainly performed with large calibre weapons, sand traps or soil berms are used but not trap chambers.

For practical shooting disciplines, which are popular in northern countries, trap chambers are less suitable and sand traps or soil berms are used frequently (e.g., #3323).

Specific comments on the suitability/practicality of trap chambers for certain shooting disciplines were provided in the consultation on the Annex XV report by Nammo Lapua Oy (#3262), as follows:

- **Disciplines with large target areas**. E.g., in running moose disciplines, the impact area to be covered is 2 m x 23 m. There are a large number of running moose ranges in Nordic countries, where typically even the smallest shooting ranges include a running moose range. In Finland there are 413 running moose ranges, in Norway ca. 700 and in Sweden ca. 1 000 ranges.
- **Disciplines with multiple targets at multiple distances**. E.g. in silhouette shooting disciplines, there are steel targets at four different distances with five targets at each distance. Typically there are 2 – 4 lines (of targets/distances) which corresponds to a total of 40 – 80 targets (each requiring a trap chamber). This may then be multiplied by the number of silhouette disciplines that a range accommodates, each requiring a different target set-up e.g., small/large bore pistol, field pistol, silhouette rifle, hunting rifle, air pistol and air rifle resulting in a total of 240 – 480 targets requiring trap chambers.
- **Steel targets at known or unknown distances**. In rapidly growing Precision Rifle Series (PRS), the steel targets are at distances between 10 and 1 200 meters.
- **Random shooting directions** in e.g. IPSC shooting, field shooting and voluntary military training type disciplines (i.e. practical shooting disciplines, see above).
- **Off-target projectiles**. E.g., in Biathlon (.22 LR), some of the steel target boxes collect bullets hitting the target (hole), but most cannot collect the bullets hitting the frame around the target hole.

In response to these comments, the Dossier Submitter notes that:

- Trap chambers are a suitable measure to effectively contain and recover both large and small calibre projectiles and are already widely used due to existing legal requirements (i.e. in Germany). In other countries sand traps and soil berms are more frequently used, but depending on their design are likely to be (significantly) less effective in preventing release of lead to the environment.
- For disciplines such as running moose or practical shooting that require a large impact area, sand traps or berms may be a more practical measure to contain projectiles, but could be significantly less effective in preventing subsequent release of lead to the environment. The Dossier Submitter notes that for certain shooting disciplines use of alternatives to lead are likely to be technically suitable (and would avoid the need for additional RMMs in response to the proposed restriction).
- For biathlon and silhouette shooting, berms or other structures in addition to trap chambers are already required for safety reasons.

Based on the information submitted in the consultation on the Annex XV report, the Dossier Submitter understands that the sand traps used in Norway, Sweden and Finland are designed to contain and recover lead bullets and may have measures installed to manage contaminated surface water runoff. The Dossier Submitter also understands that the sand traps in Norway, Sweden and Finland may, but not must, have impermeable layers to the underlying soil. According to the Swedish publication "Vitbok-Om bly i kulfång" (#6261), the sand in the bullet trap must have a pH value that exceeds 5 to prevent the mobilisation of lead. If this is not the case, lime must be mixed into the sand.

1.4.4.2.2.3. Reduction of mobilisation of lead

Spent lead bullets and gunshot are most often deposited directly on and into soil during shooting. When lead is exposed to air and water, it may oxidize and form one of several substances. The specific substances created, and their mobility, are greatly influenced by soil characteristics, such as pH and soil types. (US EPA, 2005).

Lead shot will remain on the soil surface between removal intervals with the risk of corrosion and mobilisation of lead to surface run-off water. There are several measures to reduce mobilisation of lead described in the literature.

Lime amendment

The main purpose of applying lime is to adjust the soil pH, with the objective of reducing lead mobility in soils. Lime can be applied around earthen backstops, sand traps, trap and skeet shot fall zones, sporting clay courses and any other areas where the bullets/shots or lead fragments/dust could accumulate.

Phosphate amendment

The main purpose of phosphate amendment is to form pyromorphite[50]. Phosphate amendment can be repeated frequently during a range's lifetime (even on an annual basis). Based on Scheckel et al. (2013) and US EPA (2015), the following should be noted:

- Phosphate amendment is not suitable for all concentration ranges of lead;
- The long-term stability of pyromorphite and the environmental conditions that could cause it to release soluble lead into soil are not fully clear;
- pH level of soil may influence the chemical form of lead in soil, with certain forms of lead not easily reacting with phosphate to form pyromorphite;
- if applied in excess, phosphate may contaminate ground or adjacent surface water (eutrophication);
- there are uncertainties on the effects of phosphate amendment on the mobility of important lead co-contaminants (e.g., arsenic): possible enhanced mobility.
- unclear long term effects on soil quality for agricultural purposes.

Ferrous chemical amendments

The use of ferrous chemical amendments is also reported in the literature, in the form of industrial by-products, as potential stabilisers of metal contaminants (Aboulroos et al., 2006, Berti and Cunningham, 1997, Bertocchi et al., 2006, Kumpiene et al., 2007, Spuller et al., 2007). Such by-products include fly ash, beringite, bauxite and birnessite, which contain not only iron, but also aluminium and manganese oxides, which have been shown to be effective in stabilising lead and other metals through different mechanisms to varying degrees (Sanderson et al., 2012).

Okkenhaug (2012), as cited in Okkenhaug et al. (2016), reports that metallic iron adsorbs

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[50] Pyromorphite is several orders of magnitude less soluble than most common lead minerals in soils, suggesting that transformation of soil lead to pyromorphite would reduce the bioavailability and therefore the toxicity of lead. Soluble lead can be immobilised in pure systems as pyromorphite by adding sources of P but there are uncertainties about the effectiveness of this approach in natural soil systems (Karna et al, 2018).

heavy metals when oxidised and creates binding sites in the form of iron oxyhydroxides. The process is known to be pH dependent (e.g. iron oxyhydroxides adsorbed lead only when lime was added and pH did not decrease). The use of ferrous chemical amendments is further discussed in Annex B (Section.4.2.1).

Ultimately the effectiveness of each of these amendments is modified by soil properties, such as pH, texture, clay content, organic matter, as well as naturally occurring iron and manganese oxides (Dayton et al., 2006).

Vegetation

Vegetative ground covers can impact the mobility of lead and lead compounds. Vegetation absorbs rainwater, thereby reducing the time that the lead is in contact with water. Vegetation also slows down surface water runoff, preventing the lead from migrating off-site. However, recovery activities usually require vegetation to be removed before or during recovery. Furthermore, vegetation that attracts birds and other wildlife should be avoided to prevent potential ingestion of lead by wildlife (US EPA, 2005).

Excessively wooded areas (such as those often used for sporting clay ranges) inhibit lead recovery by making the soils inaccessible to some large, lead-removal machinery (US EPA, 2005).

New shooting ranges should be designed with as few plants as possible to improve lead recovery and to reduce the attractivity for birds and other wildlife (US EPA, 2005).

Surface cover

Removable surface covers may be used at outdoor trap and skeet ranges. In this case, impermeable materials (e.g., plastic liners) can be placed over the shot fall zone during non-use periods. This provides the range with two benefits during periods of rainfall: (1) the shot fall zone is protected from erosion; and (2) the spent lead shot is contained in the shot fall zone and does not come in contact with rainwater (US EPA, 2005).

1.4.4.2.2.4. Management and monitoring of surface runoff and of lead concentration in soil

There are several factors that influence the amount of lead transported offsite by surface runoff, as the amount of lead fragments left on the range and the velocity of the runoff.

Surface runoff control may be of greatest concern when a range is located in an area of heavy annual rainfall because of an increased risk of lead migration due to heavy rainfall events.

Examples of surface runoff controls include (US EPA, 2005):

- filter beds to collect and filter runoff water
- containment traps and detention ponds to settle out lead particles during heavy rainfall
- dams and dikes to reduce the velocity of surface runoff
- ground contouring to prevent lead from being transported off site.

For shotgun and other ranges, synthetic liners (e.g., asphalt, Astroturf™, rubber, other synthetic liners) can also be used beneath the shot fall zone to effectively prevent rainwater or runoff from filtering through lead and lead contaminated soil. Synthetic liners will generate increased runoff, which must be managed (US EPA, 2005).

These runoff controls are especially important at ranges at which the lead accumulation areas are located up-gradient of a surface water body or an adjacent property. Since lead particles are heavier than most other suspended particles, slowing the velocity of surface runoff can reduce the amount of lead transported.

Use of a roof to cover the back-stop berm is an option at rifle and pistol ranges to reduce runoff (CSR, 2020).

After the end of life of a range without remediation, it is unlikely that maintenance will be made to control runoff, with increased risks for nearby surface water and other receptors.

Information gathered by the Member States survey (2020)[51] on monitoring of lead concentration in the soil and surface runoff indicates that monitoring of lead concentration in soil or runoff waters is not a legal requirement included in a site permit or license in many European countries, including (for example) Bulgaria, Cyprus, Denmark, Estonia, Finland, Iceland, Italy, Lithuania, Slovenia, Slovakia[52], Spain, Sweden, Netherlands, Belgium. It is a legal requirement in Germany (authorities can add terms and conditions on a permit), Luxembourg (5 years interval) and Norway (although it varies from case to case). Poland noted that although these measures are not a legal requirement, other measures are adopted to clear the top layer of soil from projectiles: a) projectiles are removed not less frequently than every 3 years at shooting ranges where the depth of the groundwater table is less than 2 m, b) not less frequently than every 5 years at shooting ranges where the depth of the groundwater table is more than 2 m, but less than 3 m, c) not less frequently than every 7 years at shooting ranges where the depth of the groundwater table is more than 3m. In addition, in the areas where projectiles fall, the pH of the soil is maintained within pH values ranging from 6.5 to 8.5.

Comments were also received in the consultation on the Annex XV report regarding this topic. For example: comment #3379 notes that in Germany*: "The regular monitoring of the condition of the soil and/or of the water (ground and / or surface water) is for many shooting ranges either included as a requirement in the operating license or specified in a separate order by the licensing authority. The regular examinations are carried out by independent experts".* Comment #3198, also related to Germany, notes that *"If no renovation takes place after a shutdown, the abandoned sites are monitored by means of a monitoring system. At regular intervals (3 to 8 years), soil and groundwater investigations and a risk assessment are carried out in accordance with the laws"*. Comment #3261, related to Sweden, notes that: *"Test wells adjacent to the backstop are used to monitor lead content in surface water and water drained through the backstop, when requested by local environment regulations or authorities".*

1.4.4.2.2.5. Documentation and record keeping

Documenting activities and keeping good records is of paramount importance for an effective lead management programme at a range. Owners/operators should document all activities done at the range with respect to best management practices and the recycling of lead. Records should be kept on when services were provided and who provided them. The records should be kept for the life of the range. Records may be used to show that owners/operators are doing their part to help prevent lead migration off-site, and that they are doing their part to be stewards of the environment (Canadian_BCWF, 2016).

[51] See Annex E, section E 5.
[52] Specifically, surface water quality monitoring is performed, within which also lead concentration is monitored, but permit does not include such requirement.

1.4.4.2.2.6. Remediation

Recovery reduces the lead burden at shooting ranges. However, depending on the discipline and method of recovery, fragments may remain in the soil even after recovery. Therefore, remediation of a permanent range may be necessary at the end of service life, for example in case of risk to groundwater. Indeed, the requirement for a remediation plan is one of the RMMs specified for shooting ranges using lead ammunition in the CSR (2020).

Remediation is likely to be needed if the site is intended to be used after the end of life for agricultural, recreational or residential use. Remediation is expensive and may cost up to several millions of euros depending on the site.

Remediation may be most necessary for ranges operating for an extended duration and located in or nearby to a water sensitive area. However, in some areas, such as wetlands (which also include lakes and rivers), remediation may not be technically feasible.

The Dossier Submitter further notes that there is no EU-wide obligation for remediation; rather this depends on different legislations in place in the EU at national level to identify contaminated sites and on funding availability. Whilst there is no certainty about the actual implementation of remediating measures, the Dossier Submitter highlights that a remediation plan is indicated in the CSR (2020) as a relevant RMM to prevent lead releases at the end of life of sports shooting ranges. Effective RMMs implemented during the service life of a range will reduce the extent of remediation that would be necessary at the end of the service life of a range.

Based on the information gathered by a Member State survey undertaken by the Dossier Submitter (2020)[53], in some Member States operators/owners of shooting ranges are responsible for remediation expenses when sites are decommissioned (see Table 1-6).

[53] See Annex E, section E5.

Table 1-6: Information on remediation practices in several European countries in relation to the responsibility of operators/owners of shooting ranges.

	Are operators/owners of shooting ranges in your country responsible for remediation expenses when sites are decommissioned?
Belgium	**Walloon region:** In Wallonia, according to the Permis Environnement decree, permits must impose "the measure for rehabilitation", defined as follows: "set of operations, with a view to the reintegration of the establishment into the environment in view of its reassignment to a functional use and/or with a view to the elimination of the risks of pollution from it; rehabilitation is, for the soil, which results from the obligations referred to in Article 19 of the Decree of 1 March 2018 on soil management and soil remediation". **Flemish region:** Yes: according to the Flemish Soil Decree, users/operators/owners have the obligation to carry out an exploratory soil investigation on land where certain risk activities are taking or have taken place. This needs to be done upon transfer of land, periodically, and at closure of the activities. Shooting ranges are on the list of activities for which this needs to be done. If soil or groundwater contamination is detected, the user/operator/owner of the land is responsible for further investigation and remediation of the contamination (including the contamination that might have spread to neighbouring land). He has also the liability according to�much the 'pollute' pays'-principle
Bulgaria	Yes
Cyprus	No. Only for temporary shooting ranges.
Estonia	No
Finland	Yes
Germany	Yes
Iceland	No
Italy	The decontamination is carried out by specialised companies.
Latvia	No
Lithuania	No
Luxembourg	Yes
Netherlands	Yes
Norway	Yes. According to the Pollution Control Act Section 7
Poland	Yes. The manner of liquidating shooting range is specified in administrative decision approving for use.
Slovakia	Yes. They bear costs on lead waste removal and processing under Act on waste
Slovenia	No
Spain	No, it is not establish in the Arms Regulation
Sweden	No. Not regulated in the planning and building legislation. General environmental legislation shall always apply, but there are no specific provisions addressing shooting ranges.

In the case of a regular recovery of lead gunshot or bullets in place, the remediation at the end of service life in ranges using lead ammunition is expected to be less expensive compared to ranges without any recovery of lead gunshot or bullets.

Additional information on remediation was shared in the consultation on the Annex XV report by several stakeholders. A description of this information is provided in the Response to Comments (RCOM) document.

1.4.4.2.2.7. Summary of the effectiveness of environmental RMMs

Considering the available literature (including guidance) on shooting ranges, the identified RMMs are summarised in terms of their effectiveness (at qualitative level) in Table 1-7. The Dossier Submitter notes, based on Steinnes (2013), that no universal RMM for preventing the leaching of lead from ammunition has yet been identified[54].

Table 1-7: Effectiveness of different RMMs applied in shooting ranges

	Generic measure	Effectiveness	Comment
Lead recovery	Wall and/or nets and/or soil coverage to recover lead gunshot	Effective: effectiveness depending on the specific type of shooting practised and corresponding type of shooting ground	To achieve a high percentage of recovery, several measures might need to be in place. It may not be applicable in all types of shooting grounds (e.g. wooded areas for 'sporting' clays). Unrecovered lead gunshot may be ingested by birds.
	Bullet traps such as trap chambers or sand traps with containment of the lead	Effective: effectiveness depending on the specific type of trap (see Annex B.9.1.3.5)	Regular lead recovery is possible. Depending on the type of trap, measures may be needed to control surface and groundwater contamination
	Backstop berm (with or without a cover and without an impermeable layer to soil)	Not effective	Often considered as a "safety" measure, specifically when no cover is present. Mechanical disturbance of the berm during lead recovery may increase soil and surface water contamination
Reduction of lead mobilisation	Lime amendment	Measures may contribute to reduce lead mobilisation but are not confirmed to be effective in all natural soil systems in the long term[55] to prevent lead migration, especially at the end of service life when such measures would b discontinued. Amendment practices are not expected to be applicable in temporary shooting grounds	Adjustment of pH to reduce migration potential of lead expected to be discontinued at the end of service life
	Phosphate amendment[56]		Immobilisation of lead in natural soil systems may not be successful; it may have a negative impact on the environment (eutrophication).
	Vegetation		Vegetation reduces mobilisation of lead but needs to be removed before or during lead recovery. Vegetation increases level of site attractiveness to birds.
Surface water (runoff) control	Such as: - Filter beds - Containment traps and detention ponds - Dams and dikes - Ground contouring	Effective	Especially relevant in clay target ranges or rifle/pistol ranges with sand traps or sand/soil berms

[54] Steinnes E.(2013) refers specifically to lead bullets but the Dossier Submitters considers that this is relevant for all lead ammunition.

[55] Scheckel et al. (2013) have reviewed the available information on the amendment of soil with phosphate. See Annex B, section B.9.1.3.8. Phosphate amendment.

	Generic measure	Effectiveness	Comment
Groundwater monitoring	Measurements (leaching water/groundwater)	Effective	Especially relevant for older shooting ranges located in water sensitive areas or with specific soil conditions that promote leaching of lead to groundwater; if leachate or groundwater measurements show elevated concentrations, remediation of the soil or bullet trap is required
Remediation	Remediation	Effective	Remediation is very expensive

1.4.4.3. Additional information from the Member State survey, 2020

In EU countries that responded to the Member State (MS) survey (2020[57]), **permanent shooting ranges** are reported as usually requiring registration[58]. Apart from Germany[59], mandatory risk management measures or best practices are not typically required. However, general environmental legislation (as for example for noise control or water protection) are usually applicable.

Not all ranges require a licence to operate as, for example, in Slovenia: *"For private clubs you do not need to have a licence"* (MS survey, 2020). The Dossier Submitter is not aware of how many permanent ranges that are considered as "private clubs" exist in the EU. The German Shooting Sport & Archery Federation has more than 14 000 clubs within its federation. They reported (Stakeholder questionnaire, 2020)[60] that most of these clubs are supposed to have their own shooting range (see for additional info Annex B 9.1.3.1). It is unclear whether such shooting clubs in the EU are required to comply with the best practices and the environmental legislation applicable to typical permanent ranges.

Legal permits/licences for permanent ranges can be reviewed with different timelines in Member States: ranging from "no review" (such as in Slovakia, Poland, Norway, Netherlands, Lithuania, Latvia, Cyprus) to "periodical" review (such as in Bulgaria, Denmark, Estonia, Germany, Iceland, Italy, Luxembourg, Spain, Sweden). However, the Dossier Submitter is not aware whether the review (when occurring at a specific site) takes into account the use of adequate environmental risk management measures to address the risks to all relevant receptors.

The registration of a permanent range can occur at municipal, regional or national level, depending on the Member State. It occurs, for example, at municipal level in Denmark, Finland, Germany, Latvia, Poland; at regional level in Slovakia, Norway, Netherlands, Cyprus, Bulgaria; and at national level in Estonia, Lithuania, Slovenia, Spain. However, in general, nationwide databases are not in place, making it difficult to retrieve information related to shooting ranges at MS level.

[57] See section E5 (Annex). Within the European Economic Area (EEA) the following countries replied: Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, Germany, Iceland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Slovakia, Slovenia, Spain, Sweden.
[58] The Dossier Submitter estimated the number of EU ranges based on the number of permanent ranges reported by Member States in the MS survey (2020). Section B 9.1.3.1 (Annex).
[59] However, as mentioned in Section 1.4.4.2, in Germany, there is a legally binding guideline on shooting ranges (German BMI, 2012).
[60] See section E 5 (annex).

To open a **temporary shooting area/range**, different provisions apply in different Member States. For example, in some countries (like in Germany, Estonia, Iceland, Italy, Spain, Belgium, Luxembourg) a legal permit is required. However, it is not clear whether in general there is any obligation to control the environmental pollution from the temporary discharge of lead ammunition[61]. In other Member States, i.e. in Slovenia, a licence for sport activities is needed, or it is not foreseen to have temporary shooting areas (as reported for Latvia).

1.4.5. Manufacture and use of fishing tackle

Lead is used to manufacture various kinds of fishing tackle, such as fishing sinkers and lures, but also fishing nets, ropes and lines.

1.4.5.1. Sinkers and lures

Fishing sinkers and lures are attached in some manner to the fishing line where the lead provides weight to assist in casting, and to carry the fishing line with attached lures or bait and hooks to a certain depth in the water. Annex A presents various examples of fishing sinkers and lures. Sinkers can also be attached to a fishing net (cf. further details below).

Some fishing tackle consists solely of lead, for example sinkers, while in lures, lead has been added to obtain additional functions to the main function of lures which is to attract the fish: lead might indeed be added to give sufficient weight to the lure in the water.

There is no universal shape or size of lead fishing tackle due to differences in the type of fish being sought, the equipment being used, and the environmental / fishing conditions. For example, lead fishing sinkers may have various shapes: split shot (i.e. shots with a notch where the line is attached), triangular, egg, cone, teardrop, elongated oval shapes etc. Lead fishing lures might also encompass various shapes such as jig-head, hard lure, trolling spoon or flies. Lead fishing sinkers and lures which may be lost or discarded in aquatic (freshwater and marine) or terrestrial environments range in weight from 0.01 g (dust split shot size n°13[62], or styl weight n°11) to several kilograms (e.g. downrigger marine weight to catch sharks for example).

The production of lead fishing tackle is relatively simple and may take place in small workshops. There are for example, two main techniques to produce lead fishing sinkers and lures:

1. Melting of lead and casting by gravity (also known as 'à la louche' technique) using iron moulds
2. Melting of lead and casting by injection using silicone moulds

In addition, to these techniques, split shots[63] with a size below 4 mm, are produced using 'hunting' gunshot as a raw material.

Detailed descriptions of the various manufacturing processes are available in Annex A.

In addition to the 'industrial' production, described above, lead fishing sinkers and lures can also be produced by individuals at home, or in the back rooms of fishing shops for retail

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[61] In France, it was recently reported that a regular shooting event was organised in a Natura 2000 site (every year since 1990, the municipal hunting association of Chambles, Loire, organizes a shooting event on a natural site classified as Natura 2000).

[62] Split shot size No13 weights 0.01 g. Split shots range in weight from 0.01 g to 4.8g. The smallest split shots (≤0.06 g) are often referred as 'dust split shot'.

[63] Split shots are a specific types of fishing sinkers. Fishing line is placed into this sliced area and then the sinker is 'pinched' onto the line.

and/or personal use. Production volumes by individuals (aka 'home-casting') is estimated to be substantial in some European countries based on interviews with stakeholders, and information received via the call for evidence. A local survey of fishers in the Netherlands (n=164) reported that approximately 52 % of the respondents casted or are still casting their own lead fishing tackle (CfE –1153 - Modified Materials BV). In some areas, home-casting might account for up to 30 % of the lead fishing tackle (ECHA Market Survey, 2020). Stakeholders indicated that home-casting was still promoted by some fishing associations (CfE –1153 - Modified Materials BV, and ECHA Market Survey, 2020). There is unfortunately no consolidated data to estimate the scale of home-casting across the EU. In 1994, the US EPA estimated that 0.8 – 1.6 million anglers in the U.S. produced their own lead sinkers, representing ca. 5 % of US fishers at that time, and about 30 % of the quantity of lead fishing tackle placed annually on the US market (US EPA, 1994).

Home-casting is very easy to perform. The raw material for home-casting can be lead ingots, lead pieces (including 'old' lead fishing tackle) which are available at home, or from fishing tackle shops, small metal recycling workshops, scrap sellers or directly from the internet. The lead is melted and then poured into moulds to manufacture lead sinkers or lures of any size. Moulds and melting equipment can be readily purchased on the internet or day-to-day kitchenware and home equipment (such as a cooking pot, or silicone baking moulds) may also be used. In addition, individuals may also purchase lead shot (ammunition), and cut a groove in the shot with a special tool sold in fishing tackle shops or on internet creating a split shot fishing sinker. Finally, plenty of instructions (videos, pictures) are freely available on the internet to perform home-casting. Details on home-casting is available in Annex A.

'Home-casters' either use the manufactured lead fishing tackle for their personal use or sell it within the local area to other individuals, angling clubs or small retailers, such as fishing tackle stores (ECHA Market Survey, 2020). Most home manufacturers seem to produce non-split shot fishing sinkers.

The lead fishing tackle value chain is relatively short. Lead fishing sinkers and lures are directly distributed from manufacturing companies to large retail companies or are purchased by a distributor who then supplies smaller retailers. Distributors range in scale from individuals to national or even European-wide companies. A significant amount of lead fishing sinkers and lures are also supplied directly from manufacturers located outside Europe, or 'home-manufacturers' to consumers or small retailers by post in case of purchase via social media or via the internet (e.g. Facebook, Alibaba, ebay, Amazon, Wish, made-in-china.com, etc.).

The general picture emerging from the ECHA market survey (2020) is that the market has evolved from a local market to a more global market since the last report from the European Commission on "Advantages and drawbacks of restricting the marketing and use of lead in ammunition, fishing sinkers and candle wicks" (COWI, 2004). Indeed, on one hand, for logistical reasons (rapid response to market demand), fishing tackle remains supplied by European (global or local) manufacturers[64] of which many are SME foundries, or SMEs specialised in the fishing sector. While for the foundries, the lead fishing tackle manufacturing might represent up to 50 % of their foundry activity, the other SMEs producing lead fishing tackle might be either very specialised, or might have fishing tackle manufacturing as a small part of their activity in the fishing sector. This picture of the EU manufacturing of lead fishing tackle should be nuanced with the fact that European

[64] Including home-manufacturers

manufacturing seems to have been condensed during the past 20 years and that for example it is estimated that about 20 companies remains today as European manufacturers of lead fishing sinkers and lures (with only approximately five major EU manufacturing companies with a global market), while COWI was reporting 159 manufacturing companies in 2004.

On the other hand, the import of fishing tackle from outside Europe seems to have increased. This view is based on information provided by EU manufacturers who have seen their production and sales reduce over the past 20 years. There is some confirmation of this when extrapolating the data from the Prodcom and Comext databases for the past 20 years (see Annex A).[65] The main actors in the supply chain also indicate that 'price competition' and 'fewer environmental constraints' are the main reasons for the significant changes in the market during the past 20 years, and the shift from a European supply of lead fishing tackle to an international one (cf. Annex A).

The Dossier Submitter estimates that (based on 2020 data) approximately 1 300 tonnes of lead sinkers and lures were manufactured each year in the EU for the European market (cf. Annex D). Between 5 to 10 % of European manufacturer production is sent for export. In addition to EU manufacturing, it is estimated that ca. 4 100 tonnes of lead fishing tackle are imported each year to Europe (cf. Annex D). The main importing countries for lead fishing tackle are China, US, Canada, UK and Japan.[66]

To summarise, it is therefore estimated that 5 400 tonnes of lead fishing sinkers and lures are annually placed on the EU market, and that 75 % of this quantity is imported (cf. Annex D).

Following the market survey undertaken by the Dossier Submitter and discussions with various supply chain actors, it is estimated that about half (55 %) of the sinkers and jigs placed on the EU market have a weight below 50 g.

1.4.5.2. Fishing nets, ropes and lines

Lead is used for similar purposes in fishing nets, ropes and lines (CfE –1034 - Vlaams Instituut voor de Zee). It adds weight so the fishing nets, ropes and lines can sink at the desired depth. It is sometimes referred to as 'ballast'. There are two types of ballasts used in fishing nets, ropes and lines: lead sinkers (often barrel shaped ones), and lead cores (often three) braided together and covered with another material (often plastic). The description of the production of fishing nets, ropes and lines is provided in Annex A.

While sinkers and lures may be used for recreational and commercial fishing, the market survey undertaken by ECHA has revealed that fishing nets, ropes or lines containing lead are essentially used for commercial purposes only. This information was also confirmed by the European Fishing Tackle Trade Association (EFTTA).

A few EU companies still manufacture lead fishing nets, ropes or lines in the EU, mostly Southern (Spain, Portugal and Italy) and Northern (Finland, Sweden) Europe. It seems that contrary to the manufacturing of lead sinkers and lures, the manufacturing activities have remained in Europe. This may be because both the manufacturing and the maintenance of

[65] Prodcom provides statistics on the production of manufactured goods. The term comes from the French "PRODuction COMmunautaire" (Community Production) for mining, quarrying and manufacturing: sections B and C of the Statistical Classification of Economy Activity in the European Union (NACE 2). Comext is a statistical database on trade of goods managed by Eurostat, the Statistical Office of the European Commission. It is an important indicator of the performance of the European Union (EU) economy, because it focuses on the size and the evolution of imports and exports.
[66] Source: KOMPASS (2020), information available from www.kompass.com.

the fishing nets, ropes and lines is done in the same factories.

1.5. Environmental risk assessment

1.5.1. Approach to environmental risk assessment

A single, generic, environmental risk assessment was performed for the uses of lead in gunshot, projectiles other than gunshot (i.e., bullets/pellets) and fishing tackle (sinkers and lures). This was done because in most instances it is neither practicable nor meaningful to disaggregate the exposure resulting from the different uses as they comprise a combined source of exposure to environmental receptors. Where relevant, and where data was available, a more detailed assessment of the risks from specific uses was undertaken, e.g. for sports shooting. The approach for the hazard, exposure and risk characterisation is summarised in Table 1-8.

Table 1-8: Approach to environmental risk assessment

Hazard assessment	Information on the hazard of lead for the aquatic and terrestrial compartments. Information on the acute (short-term) and chronic (long-term) toxicity of lead in animals (with a focus on birds) occurring after primary or secondary ingestion from laboratory or field studies; including any relevant thresholds for adverse effects in biota (i.e., blood lead thresholds).
Exposure assessment	Information on the releases of lead to the environment[67] and the resulting environmental concentrations after considering relevant environmental fate, behaviour and transport processes[68]. Information on prevalence/probability (likelihood and frequency) of exposure in wildlife (with a focus on birds) and domestic animals (livestock). Information on biota concentrations i.e., tissue lead concentrations.
Risk characterisation	Incidence of adverse effects in wildlife (with a focus on birds) arising from ingestion of lead, including comparison of biota concentrations with relevant thresholds. Incidence of adverse effects in domestic animals (livestock) grazing on or adjacent to shooting ranges. Qualitative assessment of risks to the soil and aquatic compartments and groundwater (for uses at shooting ranges only)[69]

1.5.2. Environmental hazard assessment

This section provides a summary of the environmental hazard assessment. More detailed information on the hazard of lead for the aquatic and terrestrial compartments are discussed in Annex B. Non-compartment specific effects are discussed both in Annex B and in the following sections. This includes information on the acute (short-term) and chronic

[67] Releases of lead gunshot to wetlands, as defined by the Ramsar Convention, are not included in the assessment as they are already restricted.

[68] The speciation of the lead ion in the environment affects its fate, bioavailability and ecotoxicity and has been taken into account where relevant and appropriate.

[69] Qualitative risks related to sports shooting are considered to occur irrespective considerations related to speciation and bioavailability as locations with 'sensitive' conditions could reasonably be expected to occur in all Member States. In addition, the magnitude of releases from shooting ranges (based on literature case studies) are of concern irrespective of bioavailability considerations.

(long-term) toxicity of lead in animals (with a focus on birds) occurring after primary or secondary ingestion including any relevant thresholds for adverse effects in biota (i.e. blood lead thresholds).

1.5.2.1. Wildlife (birds)

Massive forms of lead (as used in lead ammunition and fishing tackle) pose a significant hazard to birds. Lead poisoning is a general term for acute or chronic toxicity resulting from the ingestion of lead. The probability of a specific species of bird ingesting lead is closely associated with its particular feeding and habitat preferences and physiology (e.g. seed eating, piscivorous or scavenging birds), whilst the probability of an individual bird ingesting lead gunshot also depends on the density of lead objects in the specific areas that it occupies (i.e. whether or not uses of lead in ammunition or fishing tackle take place as well as their intensity).

The principal routes[70] by which animals are exposed to lead from ammunition or fishing tackle are:

- **primary ingestion** defined for the purpose of this report as the ingestion of any lead object *directly* from the environment e.g., after mistaking it for food or grit (which is deliberately ingested to aid the processing of food);
- **secondary ingestion** defined for the purpose of this report as the *indirect* ingestion of lead that occurs after the consumption of lead-containing food, e.g.
  - ingestion of embedded fragments/particles of lead that are present in the tissues of prey or carrion,
  - ingestion of lead fragments/particles that are present in discarded viscera (gut piles) from the field dressing of large game
  - the ingestion of lead fragments/particles present in contaminated silage.

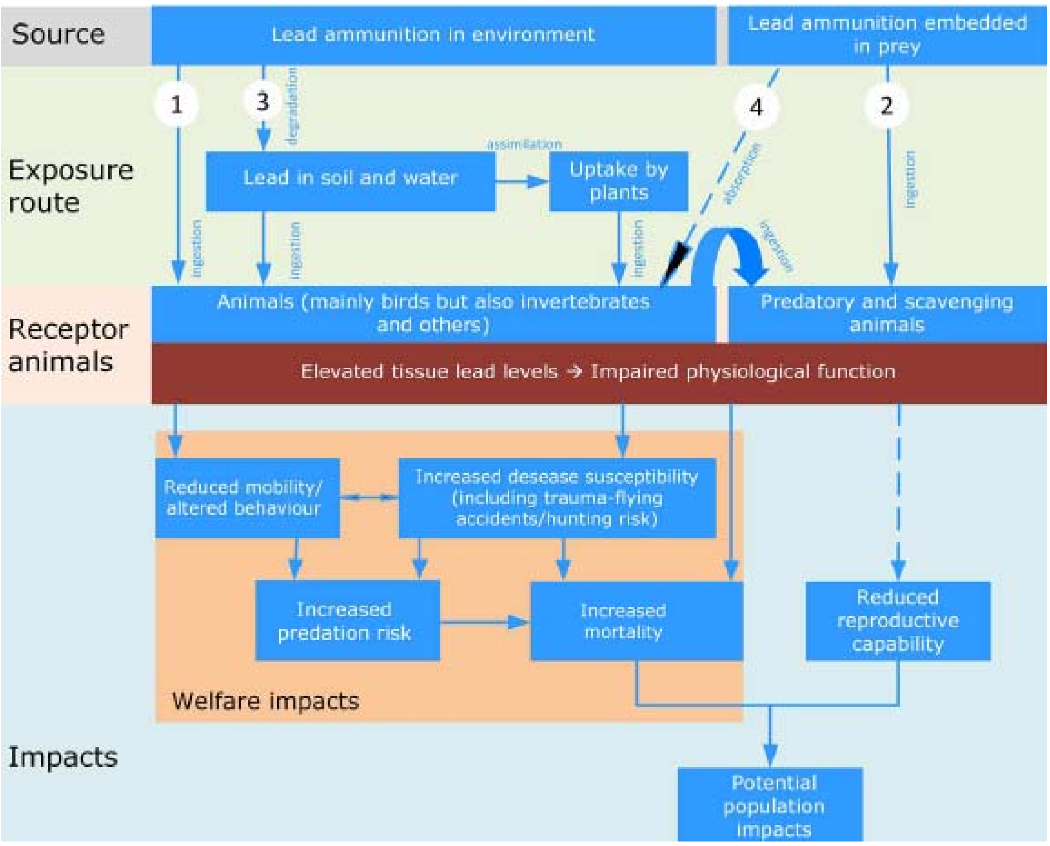
Primary and secondary ingestion of lead objects (including fragments/particles derived from objects) will be the principal focus of this assessment. Other routes of exposure to lead from lead objects are also possible, and relevant, although they have been studied less intensively (Pain et al., 2015), for example, ingestion via contaminated soil, plants or invertebrate prey. Ingestion via soil may be especially relevant in outdoor shooting ranges due to the high concentration of lead in the soil (see Annex B, Section 9.1.3.4). Absorption of lead mobilised from embedded ammunition in animals, notably birds, that have been wounded but survived is also reported[71] (Pain et al., 2019b, Berny et al., 2017).

Primary ingestion is particularly relevant for bird species with muscular gizzards that 'grind/erode' any ingested metallic lead object (which enhances dissolution and subsequent uptake in the intestine). Secondary ingestion is associated with bird species that are susceptible to ingesting fragments of lead when consuming prey or carrion/viscera left in the environment.

The literature describing the causes and consequences of lead poisoning in birds (either through primary or secondary ingestion) is substantial. The first extensive analysis of lead poisoning caused by lead ammunition was initiated as early as the 1930s by the US Fish and

[70] Lead availability for primary and secondary ingestion (uses 1,2,3,7) is discussed in Annex B.9.1.1.
[71] For example, Berny et al. (2017) found that birds of prey in French wildlife centres that had embedded lead projectiles had significantly higher blood lead concentrations than those without (22.4 vs 14.3 µg/dl), suggesting that embedded lead projectiles may release lead.

Wildlife Service (USFWS). Modern scientific reviews evaluating lead-containing ammunition as a cause of lead poisoning include: Rattner et al. (2008), Franson and Pain (2011), Delahay and Spray (2015), Golden et al. (2016), Plaza and Lambertucci (2019), Grade et al. (2019). The relationship between lead poisoning and the use of lead-containing fishing tackle has been reviewed in Franson et al. (2003), Scheuhammer (2003), Haig et al. (2014) and Grade et al. (2019).



Notes: Ingestion Route 1 corresponds to primary ingestion. Route 2 corresponds to secondary ingestion. *Ingestion routes 1 and 2 are also relevant for fishing tackle.*

Figure 1-20: Lead ingestion routes and receptors related to lead ammunition sources (adapted from Pain et al. (2015))

1.5.2.1.1. Toxicokinetics (birds)

The toxicokinetics of lead in birds are closely associated with 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 neither 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 pieces (shot, bullets, fishing tackle) by birds after ingestion 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 (Schulz et al., 2006), diet and gender. Any lead ingested becomes more soluble in the stomach and is subsequently absorbed in the intestine as lead salts (US FWS, 1986).

Stomach characteristics

Following ingestion, lead particles pass down the oesophagus, through the proventriculus (stomach), the primary function of which is gastric secretion, and enters the ventriculus, which is modified into a gizzard in birds. The gizzard is a muscular organ that often contains stones or 'grit' that is used, in the absence of teeth, to grind up food during digestion.

The characteristics of gizzards differ between species, e.g. the well-muscled gizzard of 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).

According to Golden et al. (2016) citing Farner (1960), species 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.

Grinding of ingested food material in the gizzard, whilst necessary for normal digestion, facilitates the erosion of any ingested lead particles, leading to greater absorption in the gastrointestinal tract than would occur if the lead remained as ingested (Golden et al., 2016). Thus, the particularity of avian digestive physiology is key factor in the lead poisoning observed in birds after the consumption of lead objects.

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 (US FWS, 1986). In scavengers, highly acidic gastric juices (for rapidly dissolving bones) can promote rapid lead dissolution (Fisher et al., 2006, Berny et al., 2015a).

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 pieces (Franson and Pain, 2011). Individual pieces of lead may either be rapidly regurgitated or, alternatively, passed rapidly through the gut; both 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).

Most lead ingested will either pass through the gastrointestinal tract or be completely eroded within 20 days of initial ingestion (Sanderson et al., 1986, Franson, 1986) cited by Pain and Green (2015). However, if not ejected from the body within the first 24 hours, lead objects become subjected to grinding within the gizzard and/or dissolution within the stomach (US FWS, 1986).

Birds of prey typically regurgitate 'pellets' comprising the indigestible portions of their food (e.g. bones, hair and feathers). Lead pieces present in prey can be regurgitated in these pellets.

Falconiformes, with an average gastric pH of 1.6, regurgitate pellets with no bones. Owls, in comparison, with a gastric pH of 2.35 regurgitate pellets with nearly all the bones of their prey (Duke et al., 1975).

In addition, according to Duke (1997) cited by Golden et al. (2016) 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.

Diet

The diet of birds is one of the most important factors in determining the extent of lead absorption after ingestion. In general, because of the grinding that occurs in the gizzard, bird species that prefer whole or part-grain diets (granivouous) are more susceptible to lead poisoning than bird species that prefer 'grainless' diets (US FWS, 1986).

Ferrandis et al. (2008) reported that supplying red-legged partridge (*Alectoris rufa*) with large seeds (i.e., corn) may increase the risk of lead shot ingestion.

The nutritional, chemical and physical characteristics of diet are known to affect lead absorption and subsequent deposition in tissues (Jordan and Bellrose, 1951, Longcore, 1974, Sanderson and Irwin, 1976, Koranda et al., 1979, Sanderson et al., 1986, Scheuhammer and Norris, 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 (Rodríguez 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 and Norris, 1996) all cited by Franson and Pain (2011)) For example, calcareous grit consumption can reduce the rate of dissolution of ingested lead gunshot by reducing acidity within the gizzard (Martinez-Haro et al., 2009).

More recently, Runia and Solem (2020) reported a comparative analysis of experimental and wild diets. They stated that diet is probably the most important factor influencing lead absorption and toxicity and that predicting the *c*onsequences of lead ingestion in wild birds based on captive studies (when the food provided is not similar) can be difficult. For example, diets high in protein and calcium can reduce the negative impacts of lead exposure. On the contrary, diets high in carbohydrates such as grain and a variety of seeds can increase symptoms of lead toxicosis. The authors noted that feed and type of grit are usually highly variable among captive bird experiments evaluating lead poisoning. For example, (Gasparik et al., 2012) did not report the specific feed or grit, (Runia and Solem, 2017) fed high-protein poultry food and oyster shell grit, and Runia and Solem (2020)fed high-protein commercial poultry food and gravel as grit. It was considered possible that the high-protein feed could mitigate lead absorption.

Runia and Solem (2020) also noted, after reviewing previous studies, that northern bobwhite showed resilience to lead poisoning when fed on a corn/soybean meal or seed-based diets supplemented with limestone or calcium. In captive chukars, a dose of one or five lead pellets did not cause mortality in birds on commercial feed, but five out of 16 died when on a mixed seed diet. As discussed by Trautman (1982), in wild pheasants, calcium is consumed through calcareous grit or crustaceans. About 20 % of a pheasant's spring diet is mineral matter and animal matter, both of which contain calcium, but the exact percentage of calcium in the diet is difficult to quantify and compare to commercial poultry feed. Calcium intake peaks in spring particularly in females that need increased calcium for egg production Trautman (1982). Runia and Solem (2020) concluded that future research should further investigate pheasant response to lead exposure when provided food that would resemble the season- and sex-specific diets of wild birds.

Other physiological factors

Taylor and Moore (1954) cited by US FWS (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 bones 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 (US FWS, 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 and Norris, 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 in growing feathers. However, 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, 1974, Custer et al., 1984, Garcia-Fernandez et al., 1995) cited by Pain and Green (2015).

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

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, 2006).

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 mammalian and avian systemic regulation of calcium. The most dramatic difference 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).

1.5.2.1.2. Lethal and sub-lethal effects from ingestion of lead ammunition and fishing tackle

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); also cited in Pain and Green (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. (1985) reviewed in Eisler (1988), Pattee and Pain (2003), Franson and Pain (2011) cited in Pain and Green (2015), and 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, 1996, Rattner et al., 2008, Franson and Pain, 2011, Franson and Russell, 2014, Rodríguez et al., 2010) all cited in Golden et al. (2016)

The conclusions of studies using lead gunshot can be considered to also be relevant for lead fishing tackle. As noted by Twiss and Thomas (1998) commonly used lead sinkers and jigs weigh between 0.5 and 15 g. Experiments with mallard ducks (*Anas platyrhynchos*) demonstrated that mortality was dose-related in ducks given commercial lead shot; one #8 shot (0.073 g of lead) caused 35 percent mortality with higher amounts of lead causing 80 to 100 percent mortality (Finley and Dieter, 1978). More recently Brewer et al. (2003) reported a mortality of 90 percent for birds dosed with 0.2 g of lead shot. This suggests that even one lead sinker or jig of the minimum weight, can be lethal. Twiss and Thomas (1998) also noted that birds that died following the ingestion of a lead sinker are usually in good body condition (Pokras and Chafel, 1992), which implies acute toxicity rather than a chronic condition.

The sub-lethal effects associated with ingestion of lead objects can arise after both acute (short-term) and chronic (long-term) exposure. These are elaborated further in Annex B section 7.2.1 and include:

- Haematology
- Cardiovascular system
- Kidney histopathology
- Growth and body condition
- Behaviour and learning
- Immune function
- Susceptibility to hunting
- Reproduction and development

Comment #3343 (CMS, ad hoc Expert Group) notes that clinical signs of lead poisoning in birds include weight loss, muscle wasting and loss of fat reserves, anorexia, diarrhoea, anaemia, lethargy, behavioural deficits, convulsions and muscular incoordination including a range of neurological signs and paralysis. Comment #3409 cites Gillingham et al. (2021) as evidence that lead negatively affects greater flamingo gut microbiota.

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

Table 1-9 shows the most common thresholds used as indicators of lead exposure (acute or chronic) that can result in adverse effects in birds and other wildlife. The thresholds can also be used for interpreting tissue concentrations for managing wildlife on contaminated areas. 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. Pain et al. (2019b) reported that sub-lethal effects have been found at lower blood lead concentrations than previously reported suggesting that previous effect-level 'thresholds' should be abandoned or revised. For example, Espín et al. (2014) cited by Pain et al. (2019b), investigated blood lead concentrations that cause effects on oxidative stress biomarkers using blood taken from 66 griffon vultures *(Gyps fulvus)* in Spain, and found that levels >15 µg/dl can result in oxidative stress, risking damage to cell components.

Additional information is provided in Annex B section B.7.2.1.

Table 1-9: Summary of indicative thresholds for interpreting lead concentrations in various tissue 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. (2009)
General criteria for lead poisoning in wild birds	Blood		Liver		Bone	Rattner et al. (2008) Derived from: Friend (1985), Friend (1999), Franson (1996), Pain (1996), 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	

Endpoint	Lead concentration	Reference
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).*

1.5.2.2. Other taxa

Lead poisoning from ingestion of lead ammunition and fishing tackle has not been extensively studied in mammalian species.

Predatory and scavenging mammal species such as bears, foxes, raccoon dogs, mustelids and wild boar might be exposed to lead through the consumption of contaminated gut piles, discarded meat or unretrieved game left in the environment (Boesen et al., 2019, Kalisinska et al., 2016, Legagneux et al., 2014, McTee et al., 2017). However, information for these wild species is not sufficient to be further elaborated.

Limited information is available on ruminants which is addressed below.

1.5.2.2.1. Toxicokinetics (ruminants)

The physiology of the ruminant digestive system, retention time of lead in the gastrointestinal tract, diet and gender all affect the toxicokinetics of lead.

Absorption

Lead absorption after oral ingestion ranges from 1 to 80 %, and varies considerably depending on the animal species, dose, form of lead (e.g. solid vs dissolved, organic vs inorganic), food/feed composition, nutritional status (e.g. any mineral deficiencies including calcium, iron and zinc or high dietary fat; Smith and George (2009) and age.

Lead gunshot tends to remain lodged in the reticulum (forestomach) of a cow and is not passed on through to the remaining chambers of the rumen, omasum and abomasum. The reticulum is an alkaline environment in which lead gunshot can remain inert for a long time without becoming bioavailable and causing any toxicological issues or visible clinical symptoms (personal communication Bischoff, 2021).

However, lead gunshot as a source of lead poisoning in cattle has been reported (Frape and Pringle, 1984, Rice et al., 1987). Metallic lead in gunshot is unlikely to dissolve in the relatively mildly alkaline environment of the reticulum. However, it is soluble in the more acidic environment of the gastric stomach (abomasum) where lead can become more bioavailable and absorbed.

Lead has a higher bioavailability when exposed as lead acetate rather than as metallic lead as demonstrated in ruminants (Mehennaoui et al., 1997). Oral absorption of lead acetate varied between 6 and 14 % of the administered dose (Fick et al., 1976, Pearl et al., 1983), whereas for lead chloride, this value was approximately 2 % (Mehennaoui et al., 1997).

Similar values were reported in calves (Pinault and Klammerer, 1990).

The greater toxicological hazard from lead poisoning due to ammunition residue would be from feeding and ingestion of contaminated feed such as corn stock/silage. Lead gunshot from rough shooting or organised shooting events can become lodged in broad-leafed vegetation subsequently harvested and processed for silage. The lead shot embedded in feed such as maize can then bypass the rumen reticulum directly to the acidic parts of the gastrointestinal tract. Additionally, the acid conditions produced during the fermentation process of the vegetation provides suitable conditions for the production of lead salts which are more readily absorbed by the ruminant.

Distribution

Although lead is generally poorly absorbed in adult ruminants, blood levels may rise to 200 - 400 µg/dL within 12 hours after ingestion of toxic doses (100 mg/kg body weight) and decline to 0.1 µg/dL within 72h. However, the blood lead levels remain above controls for a period of two months (Allcroft and Laxter, 1950, Allcroft, 1951), due to the slow rate of elimination of lead. In the lactating ewe, the half-life of distribution is short (2 - 3 days, (Mehennaoui et al., 1997)) and these values are lower than those observed in cattle (5 - 9 days, (Oskarsson et al., 1992)). Concentrations of absorbed lead are generally high in the liver and kidney but following long-term exposure, inorganic lead is predominantly stored in bone. There is some excretion of lead into milk, which is another possible mode of entrance into the human food chain (Rumbeiha et al., 2001).

The relationship between lead concentration in blood of exposed cows and lead concentrations in milk was found to be exponential and relatively constant up to a blood lead level of 0.2-0.3 mg/kg (20-30 µg/dL) and increased significantly at higher blood levels (Oskarsson et al., 1992).

Since lead is able to cross the blood brain barrier, cerebellar haemorrhage and oedema associated with capillary damage can occur resulting in the observed neurotoxic effects (Bradbury and Deane, 1993).

Metabolism

Inorganic (metallic) lead is not metabolised but is either passed through the gastro-intestinal tract or retained in the reticulum and rumen. Blood Pb concentrations at any given time depend on the absorption of lead remaining in the gastro-intestinal tract and mobilisation from bone.

Elimination

Elimination of lead from the body is incomplete and very slow, which explains the potential for accumulation in some tissues. The major route of elimination of ingested lead is via faeces. Faecal excretion represents unabsorbed lead with a variable proportion of lead excreted with bile. Urinary excretion is usually <2 % of the ingested dose in ruminant species (Fick et al., 1976, Pearl et al., 1983). The elimination half-life of lead is approximately 250 days in lactating ewes (Mehennaoui et al., 1997) and between 95 and 760 days in cattle (Mehennaoui et al., 1988, Rumbeiha et al., 2001).

1.5.2.2.2. Lethal and sub-lethal effects from ingestion of particulate lead

A review on lead poisoning in cattle and sheep from different sources such as lead batteries or lead paints has been published by Payne et al. (2013). The authors reported that in animals dying of acute poisoning, gross lesions of lead poisoning will be minimal with typically congestion of the liver and the kidneys appear pale. There may be gastrointestinal haemorrhage and possibly grossly visible oedema of the central nervous system. In cases of subacute poisoning, there may be laminar cortical necrosis within the cerebrum, which can sometimes be observed grossly and is similar to changes seen in animals with cerebrocortical necrosis and sulphate poisoning. There may be nephrosis. In cases of chronic poisoning, there may be illthrift, emaciation, muscle wastage and developmental abnormalities in foetuses. In lambs, chronic lead poisoning is typically associated with nephrosis and there may also be osteoporosis and fractures, which can affect the vertebral column.

As mentioned above, lead poisoning of livestock such as cows, especially calves, grazing in areas with deposition of lead from gunshot or bullets or being fed with silage produced from fields located on shooting ranges has been reported (Brown et al., 2005, Rice et al., 1987, Scheuhammer and Norris, 1995, Vermunt et al., 2002)[72]. Symptoms reported in calves (seven to nine months of age) that were put on pasture in the target area of a shooting range consisted of neurological disturbances and included maniacal movements, opisthotonos, drooling, rolling of the eyes, convulsions, licking, champing of the jaws, bruxism, bellowing and breaking through fences (Braun et al., 1997).

In contrast, for sheep grazing on shooting ranges, no mortality has been reported (Johnsen and Aaneby, 2019, Johnsen et al., 2019). This difference in mortality is assumed to be due to differences in oral absorption which is as little as 1 % for sheep but as high as 50 % for calves (Wilkinson et al., 2003). In the CSR (2020) the $NOAEC_{oral}$ for Holstein calves is reported to be 500 mg lead/kg food[73].

1.5.3. Environmental exposure

Information on the releases of lead to the environment and, where relevant, the resulting environmental concentrations[74] from the uses of lead assessed (i.e. hunting, fishing and sports shooting) are discussed in the following sections and in Annex B.

Information on ingestion of lead by wildlife (with a focus on birds) and domestic animals (livestock) is also presented. However, it should be noted that in most instances disaggregating the exposure resulting from the different uses (as they comprise a combined source of exposure to the environment) is not practicable or meaningful e.g., secondary ingestion of ammunition derived lead by wild birds can occur via the ingestion of either embedded lead gunshot or via the presence of bullet fragments in scavenged discarded viscera piles.

Additional information (e.g., on biota concentration) is discussed in Annex B.

Information on environmental monitoring shared in the consultation is discussed in the Response to Comments (RCOM) document.

1.5.3.1. Releases to the environment

In this section the releases of lead to the environment in the EU27-2020 from uses of lead related to different sectors (i.e. hunting, fishing and sports shooting) are reported.

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[72] Regulation (EU) 1275/2013 (animal feed) sets a limit of 10 mg lead/kg (12 % moisture) for animal feed. Regulation (EC) 1881/2006 sets a limit of 0.1-0.3 mg lead/kg food for vegetables and fruits intended for human consumption.
In general, lead concentrations in the harvested material (used as forage) should be below 30 mg/kg (maximum relative to a feed with a moisture content of 12 %) as specified in European Commission DIRECTIVE 2002/32/EC on undesirable substances in animal feed, for this material to be fed to livestock.

[73] For hens, the respective $NOAEC_{oral}$ are reported with 201 to 751 mg/kg food.

[74] Taking into account relevant environmental fate, behaviour and transport processes in line with the approach discussed in section 1.5.1

Information on environmental concentrations are discussed in Annex B.

1.5.3.1.1. Lead from ammunition (hunting)

The Dossier Submitter has estimated the releases to the environment from different uses related to the hunting sector. Estimates are presented in Table 1-10.

Table 1-10: Estimated quantities of lead ammunition released in the EU from hunting per year (tonnes)

Use #	Ammunition type	Estimated releases in EU 27-2020 [tpa in 2020]
1	Lead gunshot for hunting	14 000 (13 000 – 15 000)[1]
2a	Lead bullets for hunting - small calibre	15 (14 – 17)
2b	Lead bullets for hunting - large calibre	119 (92 – 138)
6	Muzzle loading	Muzzle loaders: 0.8

Notes: [1] AMEC (2012) estimated that releases of lead shot from hunting on non-wetland areas accounted for about 20 859 tonnes of lead per year. However, the estimates for Spain and Italy only from other sources are: ES: about 6 000 tonnes (Guitart and Mateo, 2006); IT: 4 600-10 000 tonnes (Andreotti and Borghesi, 2012).

Given that the proposed restriction on the use of lead in wetlands addressed a volume of 5 000 to 7 000 tonnes of lead per year, the Dossier Submitter estimates that total amount of lead gunshot used and released by hunters in the EU-27 per year after the implementation of the wetland restriction is in the order of 13 000 to 15 000 tonnes per year. During the consultation of the Annex XV report a comment from Italy was submitted (#3485), providing an estimate for the use of lead gunshot by Italian hunters according to which the amount estimated by ECHA would be unrealistically low.

Concerning lead bullets, the estimated baseline tonnage of lead use per year is based on hunting statistics (i.e. the number of animals hunted per year in the EU-27) combined with assumptions on the weight and use of lead bullets (Annex D). The total quantity of lead released from small and large calibre bullets used for hunting is estimated to be 106 - 155 tonnes per year.

1.5.3.1.2. Lead from ammunition (sports shooting)

A detailed description on the number of ranges, type of ranges included in the estimates and amount of lead used in the EU in sports shooting (including assumptions and uncertainties) is provided in Annex B (section B 9.1.3.2)

Based on this, the Dossier Submitter has estimated the releases to the environment from different uses related to the sports shooting sector. Estimates are summarised in Table 1-11. For sports shooting with bullets, the calculations for the releases to the environment are reported in Section B.9.1.3.8. and take into account existing risk management measures.

Table 1-11: Estimated quantities of lead ammunition released in the EU from sports shooting per year (tonnes)

Use #	Ammunition type	Number of shooting ranges in EU 27-2020	Estimated releases in EU 27-2020 [tpa in 2020]
3	Lead gunshot	About 4 000	24 500 (14 000 – 35 000)
4, 5, 6	Lead projectiles other than gunshot	About 16 000	420 (6 – 1 500)

The estimates on the numbers of shooting ranges provided by national sports shooting association do not necessarily overlap with the estimates provided by national authorities. The reason for this divergence is not fully clear but may be related to the fact that the Dossier Submitter requested MS information on registered ranges, whereas some ranges may not need to be registered. A cautious approach was adopted to avoid overestimating the number of existing ranges and, where applicable the lower bound of the estimated number of ranges (among different sources and values) was used, as in the case of Germany for rifle and pistol ranges.

Shotgun ranges (lead gunshot)

Specifically it is noted that:

- For shotgun ranges the most likely volume of use of lead gunshot is assumed to be 24 500 tonnes per year (i.e. between 14 000 – 35 000 tonnes per year). This was calculated as the average of the estimates provided by FITASC/ISSF[75] (comment #3221) and of the value calculated by the Dossier Submitter[76] using data described in Section B.9.1.3 (Annex B).
- There is incomplete information at the EU level (and indeed in many Member States) related to a potential annual recovery of lead gunshot at shooting ranges. No RMMs are reported to be mandatory (Member States survey, 2020), including the measures described in the CSR for lead (2020). The available information on lead recovery does not indicate that regular recovery is a typical practice in the EU (Member States survey, 2020).

For shotgun ranges, regular lead recovery is expected to be infrequent and could be assumed to be in place in less than 5 % of EU ranges (see Section 1.4.4.2). Taking into account the low number of such ranges in the EU and the overall uncertainties in the calculation of the quantities of lead shot used (see for details Annex (section B.9.1.3)), the amount of lead released every year has been assumed to be within the estimated amount of lead ammunition used and consequently no further adjustments are made.

Rifle/Pistol range (bullets)

The annual volume of lead bullets used for sports shooting is estimated to be 42 000 tonnes, ranging from 4 000 to 80 000 tonnes (see Section B 9.1.3.2).

To estimate the releases of lead to the environment from rifle/pistol ranges, the performance

[75] Considered as the lower bound of the estimates.
[76] Considered as the upper bound of the estimates.

of the different bullet containments typically implemented in the EU as well as their prevalence were taken into account:

- Identification of different types of bullet containments and layouts;
- Estimation of the number of such types of bullet containment in the EU;
- The effectiveness of the bullet containments to reduce lead emission to soil and surface water.

Detailed explanations of how the emissions were calculated are reported in Section B.9.1.3.5. In the following, the assumptions used are summarised.

Identification of different types of bullet containment and possible permutations

Various bullet containment techniques and structures are available and used in the EU (see Section 1.4.4.2.2.2), such as (bullet) trap chambers, sand traps, sand/soil berms (sand gravel berms) or soil berms. Each type of containment differs, for example, with respect to the material that is used to decelerate and retain the fired projectile (e.g., steel container, sand, soil), whether there is a barrier to the underlying soil (to minimise migration to soil), or a roof or other coverage to minimise water entering the containment. Furthermore, water management systems might be installed to prevent lead released from the retained projectiles to leave the range with surface (runoff) water. For the purposes of the impact assessment, a series of scenarios were developed to represent the variety of bullet containment structures and techniques that could be implemented in the EU (see Table 1-12). Combinations of these scenarios were used to assess the impacts of different restriction options in terms of risk reduction and costs. For example, various permutations of sand trap are described by scenarios 2a, 2b, and 2c. AFEMS (2002) describe sand traps as structures comprising a mass of sand, or similar material, contained within a concrete or other structure (considered as an impermeable barrier to soil) which is open towards the firing point. Sand traps may (scenario 2a and 2b) or may not (scenario 2c) have a roof or cover or a water management system. The Dossier Submitter notes that the term 'sand trap' is frequently used to describe soil berms consisting of a layer of sand on top of a soil berm where the sand is not contained and would therefore not have a barrier between sand and soil. In the absence of a barrier to soil the Dossier Submitter considered these RMMs as "sand/soil berms" (scenario 3). A berm consisting of soil, which are used frequently for safety or noise abatement purposes, were considered in scenario 4 (Table 1-12).

Table 1-12: Scenarios representing different types of bullet containment

Scenario	Type of bullet containment	Material of bullet containment	Impermeable barrier to soil	Roof /coverage	Water management system
1	Trap chamber	Usually metal container	+	+	-
2a	Sand trap	Sand	+	+	+
2b	Sand trap	Sand	+	+	–
2c	Sand trap	Sand	+	–	+
3a	Sand/soil berm	Sand	–	+	–

Scenario	Type of bullet containment	Material of bullet containment	Impermeable barrier to soil	Roof /coverage	Water management system
3b	Sand/soil berm	Sand	–	–	+
3c	Sand/soil berm	Sand	–	–	–
4a	Soil berm	Soil	–	+	–
4b	Soil berm	Soil	–	–	–

Estimation of the number of such types of bullet containment in the EU

The Dossier Submitter attributed a proportion of the total number of EU ranges to each scenario, as follows:

- trap chambers (scenario 1): 50 % (legal requirement in Germany with almost 8 000 ranges which is 50 % of 16 000 ranges in the EU)
- sand traps with impermeable layer to soil (scenario 2): 5 % (estimate)
- sand/soil berms without impermeable layer to soil (scenario 3): 35 % (such type of berm is reported to be frequently used in Nordic countries)
- soil berms (scenario 4): 10 % (estimate).

Calculation of the effectiveness of the bullet containments to reduce lead emission to soil and surface water

Emission to soil and surface water was calculated by using measured or estimated data on:

- weathering of bullets: in sand 5 % and in soil 34 % (Yin et al., 2010)
- effectiveness of a roof or coverage to reduce weathering: 30 to 70 % (estimate)
- effectiveness of water management system to reduce surface water runoff: 80 to 99 % (CEFIC RMM library)
- effectiveness of an impermeable layer to prevent leaching: 84 to 100 % (ECHA Guidance R.18)
- leaching of weathered lead to surface water or soil: 2 to 20 % (estimated to reflect measured lead concentrations leaching from ranges in Norway)

Calculated emissions for the different bullet containments

The following overall release factors to soil and surface water were calculated:

- trap chambers: < 0.1 %
- sand traps with impermeable layer to soil: ca. < 0.1 to 0.4 %
- sand/soil berms: 0.7 to 1.1 %
- soil berms: 5 to 7.5 %

The Dossier Submitter notes that those emission values do not take into account that for sand traps, sand/soil berms or soil berms recovery of lead is every 3 to 5 or even 10 years and for sand/soil berms the recovery effectiveness was reported to be 65 % (see attachment to comment #3261 from the Swedish Dynamic Sportshooting Federation).

Furthermore, it was demonstrated that the process of lead recovery from berms increases the leaching of lead by 2.5 times due to mechanical breakdown of weathered lead bullets (Yin et al., 2010). In comparison, for trap chambers, recovery can be performed several times a year with a recovery effectiveness of up to 100 % without relevant weathering of lead bullets. **Therefore, for sand traps, sand/soil berms or soil berms the calculated emission from the lead remaining in the berm structure could be higher**.

Calculated annual releases

The annual release to the environment (soil and surface water) was calculated to be **420 tonnes (range 6 – 1 500 tonnes)**.

1.5.3.1.3. Groundwater contamination

Lead from ammunition deposited on the ground can migrate towards the groundwater, which may be used for different purposes, including the production of drinking water (also used by livestock), irrigation or even for recreational uses, for example fishing (Environmental Protection Authority Victoria (EPA), 2019). The time when the contamination reaches the groundwater depends on the soil conditions and the distance to the groundwater. However, risk to groundwater is likely to materialise at the end-of-life rather than during the service life of a shooting range. In addition, groundwater travels underground and any contamination can potentially move along with groundwater flow, also reaching areas far away from the hot-spot.

In sites where a potential risk to groundwater has been identified, usually lead concentration in groundwater is monitored to decide on possible risk reduction measures which include remediation. However, published data are scarce, also due to the limited investigations performed by the owners of shooting ranges at the end of a shooting range (service) life.

In an US trap-shooting range running for more than 37 years, water samples from wells located along the bank of the slough contained dissolved lead concentrations higher than 400 µg/L, and as high as 1 000 µg/L. In contrast, a natural background concentration of lead from groundwater in a well upgradient from the site is about 1 µg/L (Soeder and Miller, 2003). In a shooting range in Germany (Mainbullau) with use of lead gunshot for more than 40 years, lead concentrations in leaching water were determined in five different locations with 44.5, 1 460, 198, 64.4, and 12.9 µg/L. The action levels for phase 1 (25 µg/L) requiring supervision was exceeded by 4 out of 5 measurements and action levels for phase 2 (100 µg/L) requiring remediation, was exceeded by 2 out of 5 measurements (Bavarian WWA Aschaffenburg, 2019).

According to investigations performed in Finnish shooting ranges, lead concentrations that are higher than the background level are uncommon. In 5 out of of 24 samples, the total lead concentration in groundwater was > 10 µg/L, whereas the concentration of soluble lead was below 10 µg/L in 13 samples analysed (Kajander and Parri, 2014).

Scheinost (2003) provided an overview of possible mechanisms of vertical distribution of lead in the soil profile. The author concluded that only in a few cases a very small amount of lead (<0.01 %) was transported into the soil profile. Assumed mechanisms involved were transport of soluble lead species along preferential water flow paths (root channels, cracks and other macropores), and transport of lead bound to mobile colloids (in carbonaceous soils). Due to the large amounts of lead commonly present in shooting range soils the quantities of lead migrating into the subsoil may be in the order of kilograms over time.

Dinake et al. (2019) also reported on the synthetic precipitation leaching procedure (SPLP), which is a technique used to simulate possible underground water pollution in areas highly contaminated with lead e.g., Sehube et al. (2017). It simulates acid rain at pH 4.0 that can mobilise high concentrations of Pb and leach to underground water sources. By extension, the SPLP helps assess the mobility, bioavailability and toxicity of lead in shooting range soils. The United States Environmental Protection Agency (US EPA) has set 15 µg/l as the critical level for lead mobility in soils. SPLP lead concentration that exceeds this limit poses a pollution risk to underground water. The SPLP lead concentrations were 6 850 and 19 910 µg/l at two shooting ranges (TRR and MPR) respectively (Cao et al., 2003). The SPLP lead concentrations were more than 400 and 1 000 times the US EPA critical limit for shooting ranges . Dinake et al. (2019) also observed that underground water at three shooting ranges was at risk of being polluted as the determined SPLP lead concentrations at Range-G, Range-O and Range-L were 1.19 × 103 µg/l, 3.62 × 103 µg/l and 3.80 × 103 µg/l respectively and exceeding the set US EPA critical limit by a factor of up to 200.

Other studies have been carried out that revealed that acidic precipitation has the ability to leach sufficient amounts of lead from shooting range soils and thus pose a significant risk to both surface and underground water sources (Cao and Dermatas, 2008, Hardison Jr et al., 2004, Isaacs, 2007, Lafond et al., 2013, Laporte-Saumure et al., 2011, Laporte-Saumure et al., 2012). The high SPLP Pb concentration found in shooting range soils suggest that the lead chemical species that form thin layers on the surface of lead shot and bullets are bioavailable and are susceptible to leaching (Dinake et al., 2019).

In general, the risk of groundwater contamination may vary from very low to high depending on the soil characteristics. The combination of acidic soils, coarse soils, preferential flow pathways or macropores and shallow depths to groundwater (<3m) lead to high vulnerability to lead contamination.

Additional specific information focused on the terrestrial environment is discussed in the *"Assessment of the potential for the use of lead ammunition at shooting ranges to contaminate groundwater and drinking water*", available in Appendix 1 of the Background Document.

1.5.3.1.4. Lead from fishing tackle

Except in some specific fishing practices, essentially those reported for carp fishing (cf. Annex D), lead fishing tackle is not intentionally released to the environment during use. However, releases do occur under reasonably foreseeable conditions of use. The main sources of release identified for fishing sinkers and lures are:

- Unintentional loss of lead fishing tackle, for example when a line breaks, when the tackle is pulled out of the tackle clip/swivel, or when the tackle gets stuck in a natural obstacle (e.g. stones, branches, trees, foliage etc.)
- Unintentional spillage of small lead sinkers on the bank or shore (e.g. split shots)
- Deliberate dropping of 'backlead' or main lead sinker during carp fishing. This practice is recommended by some fishing tackle suppliers in order to improve the catch rate (fish21, 2017).
- Lack of appropriate waste management (i.e., lead fishing tackle ends up in household waste)

With regard to nets, ropes and lines, Deloitte, in a study commissioned by the EU Commission, identified the following three main sources of release to the environment (Deloitte, 2018):

- Accidental loss

- Intentional dumping
- No appropriate formal waste management (e.g. landfilling, difficult to recycle or separate from the plastic)

The estimated releases to the environment are summarised in Table 1-13.

It is important to note that there is no one-to-one relationship between the quantity of lead fishing tackle placed on the market annually, and the quantity lost. The release estimates for fishing sinkers and lures were established using the estimated number of fishers and the estimated annual loss per fisher reported in literature. The loss estimates for lead in nets, ropes and line was made by combining information from the Deloitte study, and the impact assessment for the Single Use Plastic (SUP) Directive (EU Commission, 2018) on estimated incidence of net, rope and line losses, as well as information on the content of lead in nets reported in the literature (Tateda et al., 2014). More details on the calculation can be found in Annex D.

Table 1-13: Estimated amount of lead from fishing tackle released to the environment in 2020 per year

Use #		Estimated releases in EU27-2020 [tpa]
7	Lead from fishing sinkers and lures	3 000 (2 000 – 7 000)
8	Lead from nets, ropes and lines	3 000 (2 000 – 4 000)
	Total lead from fishing tackle	6 000 (4 000 – 11 000)

1.5.3.2. Lead availability for primary and secondary ingestion (use 1,2,3,5,7[77])

Lead availability for primary and secondary ingestion is discussed in Annex B (section B 9.1.1).

1.5.3.3. Primary and secondary lead poisoning of wildlife (birds)

The probability of ingesting lead objects, such as lead ammunition and fishing sinkers and lures, is dependent on: 1) the availability of lead objects in the environment, 2) the specific feeding behaviour of birds, which depends on their ecology, and 3) other environmental and anthropogenic factors (e.g. habitat type).

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

- proximity to hunting or other shooting activities;
- shooting intensity (which may change in different areas);
- compliance with bans (where already in place);

[77] In commercial fishing (use 8) lead is enclosed/embedded/threaded in nets, ropes and lines (CfE #1220 from Danish EPA), and lead from this type of fishing tackle is not considered to be available to enter the food chain.

- 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 specific species of birds;
- local conditions (affecting sinking/movement of gunshot over time);
- land management and land disruption;
- chemical and physical processes in the environment.

An assessment of which EU bird species would be at greatest risk of ingesting lead objects from ammunition or fishing tackle (sinkers and lures) was performed. A list of 533 wild bird species that occur naturally and regularly in Europe (BirdLife International, 2015)[78,79,80] was taken as the starting point for the analysis, to which other criteria were applied to determine individual species risk in a weight of evidence approach.

Specifically, the assessment took into account:

1. The reported **incidence of lead object ingestion (either primary or secondary routes) and/or lead poisoning for a particular species in the scientific literature** (termed direct evidence); based on research done in either the EU-27 (preferred) or outside the EU-27 (assuming that ingestion reported in a study outside of the EU would be indicative of a high probability of ingestion in the same species within the EU).
2. In the absence of direct evidence, the probability that a particular species would ingest lead objects (either primary or secondary routes) based on either:
   (i) **conserved feeding ecology** with species with direct evidence of lead object ingestion or lead poisoning (assuming that species within the same taxonomic family have similar feeding/food and habitat preferences and thus could be reasonably expected to have similar probability to ingest lead objects), or
   (ii) **species preference for grit ingestion;** assuming that deliberate ingestion of grit and stones by a species/family was indicative that lead object ingestion would be likely should lead objects be present.

   In both instances this was termed indirect evidence.
3. **The UNEP/CMS ad hoc Expert Group's assessment**[81] (comment #3343) on the probability and frequency of ingesting (i) lead ammunition in terrestrial environments

[78] European Red List (2015) http://datazone.birdlife.org/info/euroredlist. This dataset was then compared with EU (2020) list of bird species released by the European Environment Agency (EEA). Member states as per the Birds Directive Article 12 reporting requirements (Council directive 2009/147/EC) (once available), in order to confirm which species occur in the EU.
[79] Additional information on species range is available from: Clements, J. F., T. S. Schulenberg, M. J. Iliff, S. M. Billerman, T. A. Fredericks, B. L. Sullivan, and C. L. Wood. 2019. The eBird/Clements Checklist of Birds of the World: v2019. https://www.birds.cornell.edu/clementschecklist/download/
[80] Since 2005, the European Commission has financed European Red Lists for all terrestrial vertebrate groups, except birds. During 2012-2015, a Commission-funded project – led by BirdLife International, and involving a consortium including the European Bird Census Council, Wetlands International, IUCN, BTO, Sovon, RSPB, Czech Society for Ornithology and BirdLife Europe – filled this gap.
[81] At the request of the Dossier Submitter, an *ad hoc* expert group (UNEP/CMS ad hoc Expert Group) of the UNEP-CMS provided specific information on the probability and frequency of ingestion by European bird species of lead ammunition in terrestrial environments and lead fishing weights, including species for which literature information of ingestion is limited. The mandate for the CMS Secretariat to support the request from the Dossier Submitter is provided from UNEP-CMS Resolution 11.15(Rev COP13): *"6. Urges the Secretariat to consult regularly with*

and (ii) lead fishing weights, especially in relation to EU species for which published literature was not available or limited. Similar to the Dossier Submitter's approach, this assessment included an estimate of the probability and frequency of birds to ingest lead objects (based on the literature evidence or an extrapolation based on similar feeding ecology). This approach was termed expert judgement.

Based on these complementary assessments, the approach used to conclude whether a specific species was at risk of lead object ingestion was the following:

- EU species for which multiple lines of evidence (direct, indirect and/or expert judgement) indicated that ingestion had either occurred, or could be reasonably expected to occur, were concluded to be **'at risk'** and have been further discussed in the following sections and in Section 1.8.6.
- All other EU species were concluded to be **'at low risk'** or at **'no risk'** of ingesting lead objects and have not been further discussed. The Dossier Submitter notes that the UNEP/CMS ad hoc Expert Group (comment #3343) reported that some species currently categorised as at 'no risk' or at 'low risk' might be 'potentially at risk' under some circumstances. For example, many birds will scavenge under conditions of environmental stress such as extreme cold or food shortage irrespective of their usual diet, and so could hypothetically be exposed to lead derived from ammunition when doing so.

1.5.3.4. Primary ingestion of lead gunshot and lead fishing tackle (sinkers and lures) by birds (uses 1,3,5,7)

Many species (from different families of birds)[82] are likely to ingest spent lead gunshot and discarded lead fishing tackle (sinkers and lures)[83] [84] across a range of different types of habitats. Exposure to lead objects has been documented in more than 120 species worldwide, the majority being birds (reviewed by Scheuhammer and Norris (1995), Fisher et al. (2006), Mateo (2009), Pain et al. (2009), Tranel and Kimmel (2009), Haig et al. (2014), Pain et al. (2019b) and Grade et al. (2019).

Lead gunshot ingestion may also occur in the terrestrial environment in areas/ranges where sports shooting is practiced[85]. Shooting ranges are likely to have different levels of attractiveness to birds depending on their specific location and the frequency and intensity of any shooting that takes place. The Dossier Submitter notes that comment #3212 (Legis Telum - Združenie vlastníkov strelných zbraní, o.z.) reports that birds and other fauna are

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relevant stakeholders, including government agencies, scientific bodies, non-governmental organizations and the agricultural, pharmaceutical, hunting and fishing sectors, in order to monitor the impacts of poisoning on migratory birds and to support the elaboration of national strategies and sector implementation plans as necessary to minimize detrimental impacts;".

[82] In general, birds with a muscular gizzard may directly ingest spent lead gunshot in the environment (UNEP 2014) such as Anseriformes, Galliformes and granivorous Columbiformes (including many of the most hunted EU species). Other potentially affected orders of birds include e.g.: Gruiformes, Charadriiformes, Pterocliformes, Passeriformes.

[83] Lead fishing tackle come in a variety of different shapes and sizes. They range from the very small (0.01 g) to the very large (>25 g). Widely used types include split shot, worm, egg and pyramid weights. Split shot ranges in size from 0.01 g to about 4.8 g, with the very small ones resembling the shape of lead shot ammunition. In addition, fishers often use jigs. These are fishing lures which consist of a (lead) weight body which is attached to a hook. More information on all types of fishing tackle is provided in Annex D.

[84] In commercial fishing (use 8) lead is enclosed/embedded/threaded in nets, ropes and lines (Danish EPA, CfE #1220 from Danish EPA), and lead from this type of fishing tackle is not considered to be available to enter the food chain.

[85] Ingestion of lead shot in wetlands was assessed in the restriction proposal on the use of lead shot in wetlands. Available data does not allow to assess the specific exposure arising from this "point source" in the terrestrial environment.

not intoxicated or killed by civilian ammunition in sports shooting ranges, although without supporting evidence. Comment #3221 (FITASC/ISSF) proposes that shooting ranges are repulsive to birds, due to the noise. However, the Dossier Submitter notes that this does not take into account that shooting only occurs during a limited period of the day (usually no more than 10 hours) and that when no shooting occurs, birds may forage for food. An example of a natural scenario which may occur in a simulated field shooting range is provided in Figure 1-10.

In addition, some shooting ranges can be located in agricultural areas, as discussed in Annex B, section B.9.1.3, based on information provided by Member States (Member States survey, 2020).

Figure 1-21: Example of sporting clay shooting with no risk management measures in place (comment #3250)

Shooting areas simulating game hunting (or temporary shooting events) are expected to be located in areas that could be very attractive to birds, including sites classified as "Natura 2000" sites.

For example,[86] in France every year since 1990, the municipal hunting association of Chambles (Loire) organises a temporary clay pigeon shooting area on a Natura 2000 site. Comment #3307 (Royal Society for the Protection of Birds) also notes that: "*many Natura 2000 sites have been or are still being contaminated by lead shot*"[87].

Comment #3431 (Real Federacion Espanola de Caza) indicates that in Spain shooting ranges on agricultural land are temporary. In addition, the Dossier Submitter notes that not all ranges/sports shooting areas in the EU are under the FITASC/ISSF umbrella, as presented in Annex B, section B.9.1.3.

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[86] https://www.francetvinfo.fr/monde/environnement/biodiversite/alertepollution-dans-les-gorges-de-la-loire-le-ball-trap-des-chasseurs-plombe-une-foret-natura-2000_4085473.html#xtor=CS2-765-
Published on 06/09/2020.
Based on information publicly available: https://www.ouest-france.fr/bretagne/son-sel-de-guerande-victime-du-ball-trap-5603766
another temporary but regular shooting event in France (in this case occurring in wetlands) was considered responsible of the pollution of commercial salt in one of the salt works of La Turballe (Loire-Atlantique).
[87] References provided in the comment (wetlands were also included, although not relevant for this proposal).

Comment #3367 (ISPRA) confirmed that shooting ranges located in open fields with low grass or bare soil may attract different species (such as pigeons, pheasants, partridges, starlings, geese and lapwings) that are used to feed on seeds, insects in meadows, grasslands or nude terrains. Birds can reach the sites when shooting activities are suspended (for instance at dawn, at dusk or even at night).

In the following paragraphs exposure data is discussed separately for "waterbirds" and "terrestrial species". Many species of waterbirds, although principally associated with wetlands, are known to feed in terrestrial areas when they can be exposed to lead objects.

In addition, in this section, the expected relationship between annual probability of exposure and snapshot prevalence, as noted by UNEP/CMS ad hoc Expert Group (comment #3343) is elaborated.

The UNEP/CMS ad hoc Expert Group noted that the prevalence of ingested gunshot in a particular species (i.e. in gizzards of autopsied birds) is a poor measure of exposure to lead objects throughout the year. The annual probability of exposure (i.e. the proportion of birds ingesting a lead object at least once in the course of a year) would be a better measure of possible exposure.

The most frequent source of data on the exposure of wild birds to ingested lead objects (typically gunshot pellets) is the determination of the proportion of birds in a sample that have gunshot within the alimentary tract by methods such as dissection or X-radiography. This is usually done using a sample of live-trapped or hunted birds. After adjustment, where necessary, for the possibility that birds with ingested gunshot are more or less likely to be sampled, this measure, called snapshot prevalence, is widely used as an index of exposure of the species or population concerned to the hazard from ingested gunshot.

However, the annual probability of exposure could only be determined directly by repeated capture and re-assessment of wild birds. This would be very difficult at a practical level, so snapshot prevalence is generally used. Therefore, it is important to consider the relationship between the annual probability of exposure and the snapshot prevalence.

The UNEP/CMS ad hoc Expert Group proposed to assess annual probability of exposure, as follows:

- A population of birds is assumed to be subjected throughout the year to a constant daily probability k of ingestion of shot. The annual probability of exposure r is given by $r = 1 - (1-k)^{365.25}$
- The snapshot prevalence p for this population can be obtained from a simple simulation model, where birds acquire gunshot at random each day with probability k. Once a bird has acquired gunshot, it is assumed to have a constant daily probability of retaining the gunshot. Gunshot are lost by (i) being eroded in the gizzard, (ii) by being dissolved or (iii) passing out of the body in faeces or (iv) regurgitated pellets.
- The daily probability of an ingested gunshot continuing to be detectable in the alimentary tract is given by $\exp(\log_e(0.5)/h)$ where h is the half-life of gunshot in the alimentary tract in days. This assumes that the presence of detectable gunshot in the alimentary tract declines with time exponentially. The half-life of gunshot in experimentally-dosed captive birds is typically a few tens of days, though it varies among species and with the type of diet. For each value of k and h, simulations were run for 10 days and the average value of p was calculated. The annual risk of exposure r is then plotted against snapshot prevalence p (Figure 1-22) with half-life

(*h)* values of 10 and 20 days*.* It can be seen that *r* increases rapidly with increasing *p* before starting to level off and that *r* is considerably greater than *p* throughout. For example, for a half-life of 10 days, annual probability of ingestion in a population with a snapshot prevalence of 1 % would be 22.1 %. For a snapshot prevalence of 5 % the annual probability of ingestion is 70.3 %. The equivalent values of annual risk for half-life of 20 days are 10.9 % and 45.6 %, respectively.

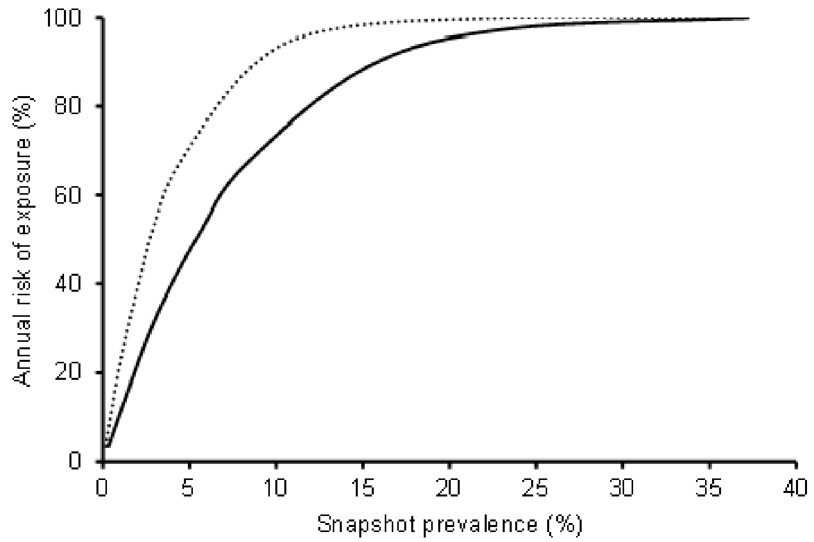

Figure 1-22: Annual probability of ingestion of gunshot in relation to snapshot prevalence with retention half-lives of 10 days (dotted line) and 20 days (solid line), as calculated by UNEP/CMS ad hoc Expert Group.

As noted by the UNEP/CMS ad hoc Expert Group, models can be constructed with much more elaborate assumptions about gunshot retention, the duration of exposure per year and variation among individuals in their risk of acquiring gunshot. However, the annual probability of exposure remains far higher than snapshot prevalence in all circumstances.

Waterbirds

While many species of waterbirds are expected to be protected from exposure to lead gunshot in EU wetlands as a consequence of the restriction on the use of lead gunshot in wetlands[88], some waterbirds are additionally exposed to lead gunshot in terrestrial habitats, for example when feeding in agricultural areas, and may be exposed to lead fishing tackle (lead sinkers and lead lures) in wetlands, specifically, rivers, lakes and marine habitats.

According to an assessment by UNEP/AEWA Secretariat in 2017 of the 150 migratory waterbird species (AEWA-listed species) which occur regularly within the EU, 100 species are vulnerable to lead poisoning from spent lead gunshot. Of these, 85 species were assessed as feeding *primarily* in wetlands. The species that could be expected to be at most risk of exposure to lead gunshot in terrestrial environments are listed in Table 1-14. Geese, swans and cranes are at greatest risk of exposure because they frequently feed in both wet and dry fields. The other species listed may feed in fields which have been flooded.

Table 1-14: AEWA-listed migratory waterbird EU species most likely to be exposed to lead gunshot in terrestrial habitats as assessed by UNEP/AEWA Secretariat in 2017 and by

[88] Commission Regulation (EU) 2021/57 of 25 January 2021 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards lead in gunshot in or around wetlands.

UNEP-CMS ad hoc Expert Group (comment #3343).

Taxonomy	Common name	"IUCN Red List Category (EU)"
Anas acuta	Northern Pintail	VU
Anas crecca	Common Teal	LC
Anas platyrhynchos	Mallard	LC
Anser albifrons	Greater White-fronted Goose	LC
Anser anser	Greylag Goose	LC
Anser brachyrhynchus	Pink-footed Goose	LC
Anser caerulescens	Snow Goose	NE
Anser erythropus	Lesser White-fronted Goose	CR
Anser fabalis	Bean Goose	LC
Branta bernicla	Brent Goose	LC
Branta leucopsis	Barnacle Goose	LC
Branta ruficollis	Red-breasted Goose	NT
Branta canadensis	Canada Goose	NE
Cygnus columbianus	Tundra Swan	EN
Cygnus cygnus	Whooper Swan	LC
Cygnus olor	Mute Swan	LC
Anthropoides virgo	Demoiselle Crane	NE
Grus grus	Common Crane	LC

Notes: The overview was provided by the UNEP/AEWA Secretariat in cooperation with the Wildfowl & Wetlands Trust (WWT) in the consultation on the Annex XV report on the proposed restriction of lead in gunshot in wetlands (comment #1873). This information was confirmed by the UNEP-CMS ad hoc Expert Group in the consultation on the Annex XV report for this proposed restriction (comment #3343).

Waterbird species have been documented to be affected by the ingestion of lead fishing tackle (sinkers and lures) although the available evidence is limited as only a few species have been studied (Grade et al., 2019)[89]. However, worldwide, 33 species of birds have been documented to have ingested lead fishing tackle (Grade et al., 2019)[90]. US EPA (1994)

[89] Grade et al. (2019) also reported (reviewing previous studies) ingestion of fishing tackle by non-avian species, including 3 mammal and 2 reptile species: Humans, *Homo sapiens;* Dog, *Canis lupus familiaris;*Harbor seal, *Phoca vitulina;* Snapping turtle, *Chelydra serpentina;* Painted turtle, *Chrysemys picta*.

[90] Trumpeter swan (*Cygnus buccinators*), Mute swan (*Cygnus olor*), Tundra swan (*Cygnus columbianus*), Whooper swan (*Cygnus cygnus*), Canada goose (*Branta Canadensis*), Wood duck (*Aix sponsa*), Mallard (*Anas platyrhynchos*), American black duck (*Anas rubripes*), Redhead (*Aythya americana*), Greater scaup (*Aythya marila*), White-winged scoter (*Melanitta deglandi*), Long-tailed duck (*Clangula hyemalis*), Red-breasted merganser (*Mergus serrator*), Common merganser (*Mergus merganser*), Great blue heron (*Ardea Herodias*), Great egret (*Ardea alba*), Snowy egret (*Egretta thula*), Green heron (*Butorides virescens*), Black-crowned night-heron (*Nycticorax nycticorax*), White ibis (*Eudocimus albus*), Double-crested cormorant (*Phalacrocorax auritus*), Sandhill

estimated that 75 North American bird species are at risk of lead tackle ingestion due to their feeding behaviour. Scheuhammer (2003) stated that all species of piscivorous birds, as well as species that feed in nearshore soils and sediments, are at risk of lead poisoning from consumption of lost or discarded lead sinkers.

In addition, it is likely to be difficult to distinguish between different lead sources when documenting exposure (for example between gunshot and split shot used for fishing), for example if a split shot has become eroded in the gizzard.

This was confirmed by Mudge (1983) when assessing the incidence and significance of ingested lead poisoning in British wildfowl: *"the majority of pellets found in gizzards were spent shot from shotgun cartridges. Anglers' split shot were only identified with certainty in one pochard and four mute swans. However, in a further three mute swans, and in many cases with other species, the pellets were too heavily eroded for their origin to be reliably judged."*

The feeding behaviour of species (including the tendency to ingest grit and stones) affects the probability to ingest different types and sizes of lead fishing sinkers and lures. UNEP-AEWA (2011) stated that waterbirds usually ingest fishing tackle mistaking them for food or grit.

AEWA-listed species of ducks (Anatidae) will be susceptible to ingesting split shot in the same way that they are susceptible to ingesting spent gunshot. Angler's lead weights have been reported in Greater Scaup (*Aythya marila*) by Grade et al. (2019) and in common pochard (*Aythia ferina*) by Mudge (1983). Species like the mallard and pintail that mostly feed in shallow water and sift through bottom sediments to find food may be especially vulnerable (Eisler, 1988). Twiss and Thomas (1998) reported the deaths of at least six species of waterbirds in Canada after ingesting one or more lead fishing weights, with the common loon (*Gavia immer* – known as the great northern diver in Europe) being the species most often affected. Loons are well known to ingest lead sinkers when they sift through sediment in the water, looking for invertebrates or possibly pebbles that aid in digestion in the gizzard (Michael, 2006). Grade et al. (2019) reported that the majority of fishing tackle objects ingested by loons (in US) that died from lead poisoning, were jigs and sinkers.

Franson et al. (2003) reported findings for 28 species of waterbirds examined for ingested lead fishing weights. Of 2 240 individuals, 23 had ingested tackle, including common loons (*Gavia immer*), brown pelicans (*Pelecanus occidentalis*) and one double-crested cormorant (*Phalacrocorax auritus*) and one black-crowned night heron (*Nycticorax nycticorax*).

More in general, the ingestion of anthropogenic debris in the oceans by birds was studied by Roman et al. (2016). They found that debris ingestion occurred in Procellariiformes, Suliformes, Charadriiformes and Pelecaniformes, across all surveyed habitats, and among birds that foraged by surface feeding, pursuit diving and search-by-sight. Fishing debris (66.7 ± 16.7 %) was the most abundant item ingested by coastal marine birds. Fishing debris, including fishing line, lures, hooks and sinkers (83.3 ± 16.7 %), was also the most common item ingested by diving birds. Fishing debris was found in the digestive contents of all seabird orders, but constituted the most abundant ingested debris type only in Suliformes (83.3 ± 16.7 %).

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crane (*Antigone canadensis*), Brown pelican (*Pelecanus occidentalis*), American white pelican (*Pelecanus erythrorhynchos*), Northern gannet (*Morus bassanus*), Laughing gull (*Leucophaeus atricilla*), Herring gull (*Larus argentatus*), Royal tern (*Thalasseus maximus*), Common loon (*Gavia immer*), Red-throated loon (*Gavia stellate*), Little penguin (*Eudyptula minor*), Bald eagle (*Haliaeetus leucocephalus*), Great horned owl (*Bubo virginianus*).

UNEP-AEWA (2011) concluded that whilst fishing tackle comes in a variety of different shapes, waterbirds usually ingest smaller weights, weighing less than 50 g and being smaller than 2 cm in any dimension. However, larger waterbirds can ingest larger-sized, heavier weights. Available evidence supports this conclusion. For example, Franson et al. (2003) reported the size of ingested lead weights ranging from split shot of 7 mm in the longest dimension to a 22 × 39 mm pyramid sinker, weighing around 2 and 79 g, respectively. Furthermore, Franson et al. (2003) reported that six of the ingested lead weights were more over 25.4 mm in the longest dimension. In loons even jigs exceeding 100 g have been radiographically detected (Grade, 2019). Grade et al. (2019) list the typical weights of tackle found in loons ranging from 0.3 to 30.4 g for sinkers and 0.3 to 20.9 g for eroded jigs. Pokras et al. (2009) concluded based on 522 carcasses of common loons that they mostly ingest objects less than 2.5 cm long and weighing less than 25 g.

According to Franson et al. (2001) the size range of stones ingested as grit in common loons suggests that birds do not ingest lead fishing weights greater than 25.4 mm in any dimension if ingested as grit. It is therefore likely that larger tackle is ingested while consuming fish with attached tackle (i.e. via the secondary ingestion route).

Figure 1-23: Fishing weights found in the stomachs and gizzards of birds that died from lead poisoning (after Field Manual of Wildlife Diseases, General Field Procedures and Diseases of Birds, USGS, 1999)

UNEP-AEWA (2011) concluded that the weights that tend to be ingested are exclusively used for sport angling (i.e. recreational fishing, use 7). In commercial fishing (use 8) lead is enclosed/embedded/threaded in nets, ropes and lines (CfE –1220 - Danish EPA), and lead from this type of fishing tackle is not typically ingested by birds (CfE #936- UK EPA).

Table 1-15 lists the species occurring in the EU27-2020 that are most likely to ingest lead fishing sinkers or lures.

The ingestion of fishing tackle has not been specifically studied in many species. Nevertheless, the probability of exposure for these species can be assessed by extrapolation from other species in the same family where there is a similarity of feeding ecology. In addition, information on the tendency to ingest grit/small stones (gastroliths) can also be used as a proxy for the probability that a species will ingest lead objects.

Information on gastrolith ingestion is for example available in Wings (2004) and the *Birds of the Western Palearctic (BWP), Volumes I-IX*, (Cramp et al., 1977-1994).

The overall approach used in the assessment follows the one indicated in section 1.5.3.3.Primary and secondary lead poisoning of wildlife (birds)

Table 1-15: AEWA-listed migratory waterbird EU species most likely to ingest lead fishing tackle (sinkers or lures) as assessed by the Dossier Submitter

Family	*Taxonomy*[1]	Common name	IUCN Red List Cat.	Supporting evidence and information on lead fishing tackle ingestion /poisoning [2]
Anatidae	*Anas acuta*	Northen Pintail	VU	• Evidence for birds within the same family • Feeding ecology (including grit ingestion) • UNEP/CMS Expert Group assessment
Anatidae	*Anas crecca*	Common Teal	LC	• Evidence for birds within the same family • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Anatidae	*Anas platyrhynchos*	Mallard	LC	• Listed by Grade et al. (2019) • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Anatidae	*Aythya ferina*	Common Pochard	VU	• Listed by Mudge (1983) • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Anatidae	*Aythya fuligula*	Tufted Duck	LC	• Evidence for birds within the same family • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Anatidae	*Aythya marila*	Greater Scaup	VU	• Listed by Grade et al. (2019) • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Anatidae	*Aythya nyroca*	Ferruginous Duck	LC	• Evidence for birds within the same family • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Anatidae	*Cygnus columbianus*	Tundra Swan	EN	• Listed by Grade et al. (2019) • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Anatidae	*Cygnus cygnus*	Whooper Swan	LC	• Listed by Grade et al. (2019) • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment

Family	*Taxonomy*[1]	Common name	IUCN Red List Cat.	Supporting evidence and information on lead fishing tackle ingestion /poisoning [2]
Anatidae	*Cygnus olor*	Mute Swan	LC	• Listed by Grade et al. (2019) • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment (See also case study under Section *1.5.4* "Risk Characterisation")
Anatidae	*Marmaronetta angustirostris*	Marbled Teal	CR	• Evidence for birds within the same family • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Anatidae	*Netta rufina*	Red-crested Pochard	LC	• Evidence for birds within the same family • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Anatidae	*Oxyura leucocephala*	White-headed Duck	VU	• Evidence for birds within the same family • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Anatidae	*Spatula clypeata*	Northern Shoveler	LC	• Evidence for birds within the same family • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Anatidae	*Spatula querquedula*	Garganey	VU	• Evidence for birds within the same family • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Gaviidae	*Gavia adamsii*	Yellow-billed Loon	NE	• Evidence for birds within the same family (common loon (*Gavia immer*) and red-throated loon (*Gavia Stellata*) listed by Grade et al. (2019)) • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment

Family	*Taxonomy*[1]	Common name	IUCN Red List Cat.	Supporting evidence and information on lead fishing tackle ingestion /poisoning [2]
Gaviidae	*Gavia arctica*	Arctic Loon	LC	• Evidence for birds within the same family (common loon (*Gavia immer*) and red-throated loon (*Gavia Stellata*) listed by Grade et al. (2019)) • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Gaviidae	*Gavia immer*	Common Loon	VU	• listed by Grade et al. (2019) • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Gaviidae	*Gavia stellata*	Red-throated Loon	LC	• listed by Grade et al. (2019) • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Pelecanidae	*Pelecanus crispus*	Dalmatian Pelican	LC	• Evidence for birds within the same family (brown pelican (*Pelecanus occidentalis*) and American white pelican (*Pelecanus erythrorhynchos*) listed by Grade et al. (2019) • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Pelecanidae	*Pelecanus onocrotalus*	Great White Pelican	LC	• Evidence for birds within the same family (brown pelican (*Pelecanus occidentalis*) and American white pelican (*Pelecanus erythrorhynchos*) listed by Grade et al. (2019)) • Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment
Threskiornit-hidae	*Platalea leucorodia*	Eurasian Spoonbill	LC	• Feeding ecology (including grit ingestion) • UNEP/CMS ad hoc Expert Group assessment

Notes: [1] Among these species some may be at higher risk than others, e.g. based on specific habitat preferences or feeding behaviour, as swans and loons (see also comment #3343);
[2] When direct evidence of ingestion was not available for a specific species, feeding ecology and evidence for birds within the same family was used. UNEP/CMS ad hoc Expert Group assessment (comment #3343) was also taken into account. UNEP/CMS ad hoc Expert Group considered both likelihood and frequency of ingestion of fishing weights (as part of lead sinkers and lead lures) in their assessment.

Terrestrial birds

Several groups of terrestrial bird species ingest spent lead gunshot deposited in the environment, either accidentally when feeding or intentionally when pellets are mistaken for grit[91]. Evidence of exposure is often reported in terms of prevalence of lead gunshot ingestion, which typically refers to the presence or absence of lead gunshot in the gizzard of a bird. However, as already discussed in section 1.5.3,4, "snapshot prevalence" data does not reflect the overall probability that birds may ingest lead shot on an annual basis.

The number of lead gunshot that have been ingested, i.e. the magnitude of the exposure, is also sometimes available. In addition, lead in various tissues can provide evidence that lead exposure in wildlife is occurring.

The prevalence of lead gunshot ingestion has been reported to vary between species and populations, most likely as a function of diet[92] and grit preference (Mateo et al., 2014) citing Pain (1990), Mateo et al. (2000) and Figuerola et al. (2005). Most birds that eat plant material (as seeds) and some that eat invertebrates ingest grit (Best and Gionfriddo, 1994, Gionfriddo and Best, 1999). Best and Gionfriddo (1994) found that of 90 bird species from 10 orders, 69 % ingested grit. Grit ingestion tends to be highest in granivores and lowest in insectivores, and grit size ingested varies among species and genera. In general, ingested grit size varies with the body weight of birds (larger birds generally eat larger grit) and diet. However, most grit-eating birds will eat quite a wide range of grit sizes.[93]

Butler et al. (2005) studied the ingestion of pellets in common pheasants (N = 437) killed on 32 game farms in the United Kingdom from 1996 to 2002, and as a global prevalence, 3 percent had ingested pellets. Of these, 77 percent had ingested a single pellet, 15 percent two pellets and 8 percent three pellets. The prevalence of pellets ingested in the common pheasant was studied in 14 game farms in Hungary, with rates from 0 to 23.1 percent (N = 947) (all areas: 4.75 %), and the number of pellets ingested varied between one and eight (Imre, 1997). Cases of lead poisoning in pheasants were already discussed by Calvert (1876), who confirmed the presence of lead gunshot in the gizzards of several pheasants with advanced symptoms of lead poisoning.

As reported by Potts (2005), when reviewing previous studies, a pheasant on the Sussex Downs in 1970, had ingested 87 lead gunshot (Beer, 1988) and a grey partridge (*Perdix perdix*) in Denmark in 1976 had ingested 34 (Clausen and Wolstrup, 1979). Butler et al. (2005) reported that one red partridge (*Alectoris rufa*) (0.16 %) of the 637 collected between 1955 and 1992 in the United Kingdom contained lead gunshot in its gizzard, as well as two other partridges (1.4 %) of 144 killed in the 2001-02 hunting season. Rodríguez et al. (2004) also examined seven red partridges in Spain and found 14 gunshot in one of the gizzards.

Romero et al. (2020) reported the presence of lead pellets in the crop, gizzard and intestine

[91] More precisely gastroliths (grit and stones).
[92] Additional information related to diet is discussed in section 1.5.2.1.1.
[93] Frequently used shot for shooting birds include: size 9 shot which is about 2 mm diameter, a number 6 which is 2.6 mm and number 4 which is 3.1 mm. While the smallest lead shot commonly used (no 9) is about 2 mm diameter, eroding shot in the top few cm of the soil can be smaller than this (e.g. Vyas et al 2000). Deposited shot can be of similar size to ingested seeds and grit found in the intestines of several songbird species (<0.2-3.4 mm, cited in Vyas et al 2000). Gionfriddo and Best (1995) found that in 60 House Sparrow gizzards, individual grit particle sizes ranged from 0.1 mm to 2.4 mm. Even some smaller and largely insectivorous birds have been reported to ingest larger gastroliths, e.g. up to 6mm diameter in barn swallows (BWP, Volume V, page 267). Grit size up to 14.9 mm in white-naped cranes from Japan and 14.0 mm in hooded cranes were reported by Uegomori et al. (2018) The body weights of these crane species overlap with the common crane found in Europe.

of birds after an analysis of 530 samples from seven bird species[94]. They included in their study birds killed by hunters with firearms and other means, in different types of territories (and different provinces in Spain) with different hunting intensity (game farm, hunting estates, airport, etc.) and during different moments of hunting seasons. The number of specimens suspected to have ingested lead shot (including red-legged partridges, common woodpigeons, rock doves and stock doves) was 28 (5.6 %), and the geometric mean concentration of hepatic Pb was 0.054 µg g^{-1} (wet weight, ww). A low percentage of samples (4.8 %) were above the abnormal exposure threshold (0.65 µg g^{-1} ww).

Photo (left): Rafael Mateo. Photo (right): E. Pérez-Ramírez. Both figures after (Descalzo and Mateo, 2018).

Figure 1-24: Red partridge (*Alectoris rufa*) and red partridge gizzard with ingested lead shot.

Thomas et al. (2009) when studying red grouse (*Lagopus lagopus scoticus*[95]) analysed leg and foot bones from adults and juveniles collected from hunter-shot birds on different estates in UK in 2003. The lead content of bones was measured by atomic absorption spectrophotometry, and corresponding stable lead isotopes by inductively coupled plasma mass spectrometry. At the Glendye (N=111) and Invermark (N=85) estates, 5.4 % and 3.5 %, respectively of birds had highly elevated bone lead concentrations (>20 µg/g dry weight). In bones of these highly exposed birds, a combination of Pb(206):Pb(207) and Pb(208):Pb(207) ratios was consistent with ingestion of lead gunshot available in Europe. By contrast, Yorkshire grouse experienced a high incidence (65.8 %) of bone lead >20 µg/g. The Pb(206):Pb(207) and Pb(208):Pb(207) ratios in bones of these highly exposed birds were consistent with a combined exposure to ingested lead gunshot and lead from galena mining in the region.

Stamberov et al. (2018) reported that in quail (*Coturnix coturnix*) gathered during the 2016/2017 hunting season in Bulgaria, after the sectioning and revision of the gizzard and its contents, they found a graphite-coloured lead fragment (defined by XRF) of oval shape and diameter of approximately 1.3 mm and weighing 0.018 g. The study suggests that the pellet was ingested. However, the full dataset of gathered information is not available in the

[94] Seven species were studied: 107 common woodpigeons (*Columba palumbus*), 99 rock doves (*Columba livia*), 30 stock doves (*Columba oenas*), 31 European turtle doves (*Streptopelia turtur*), 219 red-legged partridges (*Alectoris rufa*), 13 Barbary partridges (*Alectoris barbara*), 31 common quails (*Coturnix coturnix*).
[95] Red grouse (*Lagopus lagopus scoticus*) is a subspecies of *Lagopus lagopus*. *Lagopus lagopus* is commonly known as willow ptarmigan or willow grouse.

published study.

Mourning Doves (*Zenaida macroura*) are also very likely to ingest spent lead gunshot (Kendall et al., 1996). As reviewed by Franson et al. (2009), in several studies, ingested lead gunshot were found in 0.3 % to 6.4 % of mourning Doves (Castrale, 1991, Kendall et al., 1996, Schulz et al., 2002).

Hanspeter and Kerry (2003) found ingested lead pellets in 5.7 % of 123 gizzards from chukars (*Alectoris chukar*) in Oregon, the first known discovery of ingested lead pellets in this species. Larsen et al. (2007) also reported the ingestion of lead pellets in chukars (*Alectoris chukar*) to be 10.7 %, with ingested lead pellets found from birds harvested in four different counties on several different mountain ranges in the US. Larsen et al. (2007) noted that the ingestion of lead pellets by chukars was not reported in early (pre-1980) research in North America despite several studies which evaluated dietary preferences (Zembal, 1977, Knight et al., 1979).

This suggests that a general accumulation of lead gunshot in the environment over the years might enhance the probability of ingestion for some species and that an absence of wildlife surveillance programmes may explain the apparent lack of evidence of ingestion (Kuiken et al., 2011, Ryser-Degiorgis, 2013).

Overall, data on the incidence and extent of lead ingestion in different species (related to different spatial and temporal datasets in Europe) has been shown to vary significantly, between 0.16 % as reported by (Butler, 2005) and 5.6 % as reported by (Romero et al., 2020).

Examples of lead residues in tissues have been reported by several authors.

As reviewed by Franson and Pain (2011), a wild ring-necked pheasant (*Phasianus colchicus*) found dead with 29 lead shot in its gizzard had 168 mg/kg (wet weight presumed but not stated) of lead in the liver (Hunter and Rosen, 1965). Two female ring-necked pheasants from shooting estates with ingested lead shot had lead concentrations of 378 and 220 mg/kg dry weight in wing bones (Butler et al., 2005). Keymer and Stebbings (1987) reported lead poisoning as the cause of death in a grey partridge (*Perdix perdix*) with 40 mg/kg wet weight of lead in the liver and 100 mg/kg wet weight in the kidney. A grey partridge had lead residues of 130 mg/kg in the liver and 440 in the kidney (wet weight presumed but not stated) with 34 lead pellets in the gizzard (Clausen and Wolstrup, 1979).

Clausen and Wolstrup (1979) reported liver and kidney lead residues of 48 and 200 mg/kg (wet weight presumed but not stated), respectively, in a wood pigeon (*Columba palumbus*) that died of lead poisoning.

To take into account that many individual species have not been specifically and extensively studied in different countries, in relation to the ingestion of lead gunshot, the probability of exposure for these species can be evaluated by extrapolation from other species in the same bird family based on similarity of feeding ecology. In addition, data on grit/small stone (gastrolith) ingestion can also be used as a proxy for the probability that a species will ingest lead gunshot. Information on the ingestion of gastroliths for many species have been taken from Wings (2004), Best and Gionfriddo (1994) and Gionfriddo and Best (1999). Information on gastrolith ingestion is also available in the *Birds of the Western Palearctic (BWP), Volumes I-IX*, (Cramp et al., 1977-1994), as these contain detailed referenced information on food of adults and young for every species.

Based on the method and scale of the hunting and shooting activity, gunshot density in European terrestrial areas (including hunting estates, reserves) may vary significantly and on a local level. However, the Dossier Submitter notes that each lead shotgun cartridge may contain several hundred pellets (depending on shot size) that are dispersed into the environment during hunting or sports shooting. Only a small proportion of the pellets (e.g. in the order of 1 % or fewer) are likely to hit the intended target as reported by (Cromie et al., 2010). The remainder is dispersed in the environment where it accumulates. Comment #3401 notes that in Ireland almost 100 % game shooting/hunting is carried out on agricultural land. Recently, Douglass et al. (2016) based on a field assessment in the US, reported that tillage does not reduce overall lead gunshot concentration. Interestingly, as described by Kirby and Watkins (2015), there are some 29 000 hunting estates in Spain, occupying 36 million ha or 72 % of the Spanish land area.

The Dossier Submitter has taken into account information provided by stakeholders, e.g. in comment #3242 (FACE). However, for all the aforementioned reasons, the scientific evidence reported in Table 1-16 and in Table 1-17 is considered to be representative of the probability of ingestion of lead gunshot (lead poisoning) in the EU for all listed species in the Phasianidae and Columbidae families (both wild and reared individuals), regardless of the specific country or site where the ingestion (lead poisoning) was studied, due to conserved feeding ecology and similarity of use of lead across countries where studies were carried out.

Table 1-16: EU terrestrial bird species belonging to the Phasianidae family (pheasants, grouse and allies) at risk of ingesting lead gunshot

EU species within the Phasianidae family (pheasants, grouse and allies)[1]	Supporting evidence and information on lead gunshot ingestion /poisoning *(literature listed in chronological order covering different species belonging to Phasianidae)*
Barbary partridge *(Alectoris Barbara),* Chukar *(Alectoris chukar),* rock partridge *(Alectoris graeca),* red-legged partridge *(Alectoris rufa),* hazel grouse *(Bonasa bonasia[2]),* common quail *(Coturnix coturnix),* willow grouse *(Lagopus lagopus),* rock ptarmigan *(Lagopus muta),* black grouse *(Lyrurus tetrix),* grey partridge *(Perdix perdix),* common pheasant *(Phasianus colchicus),* western capercaillie *(Tetrao urogallus)*	1) Feeding ecology, including grit ingestion (Cramp et al., 1977-1994, Gionfriddo, 1994, Gionfriddo and Best, 1999, Wings, 2004) 2) Direct evidence of lead shot ingestion or poisoning, as reviewed by Fisher et al. (2006), Tranel and Kimmel (2009), Pain et al. (2009) e.g. in: Calvert (1876); Elder (1955); Hunter and Rosen (1965); Clausen and Wolstrup (1979); Keymer and Stebbings (1987); Imre (1997); Dutton and Bolen (2000); Hanspeter and Kerry (2003); Rodríguez et al. (2004); Butler (2005); Potts (2005); Larsen et al. (2007); Kreager et al. (2008); Ferrandis et al. (2008); Thomas et al. (2009); Stamberov et al. (2018); Romero et al. (2020) 3) UNEP/CMS ad hoc Expert Group final assessment (comment #3343), where both probability and frequency of ingestion of lead gunshot in terrestrial species were considered 4) Evidence from non-EU species reported by Tranel and Kimmel (2009) and Fisher et al. (2006), including ruffed grouse *(Bonasa umbellus),* Japanese quail *(Coturnix coturnix)*, scaled quail *(Callipepla squamata)*

Notes: 1 - Comment #3363 (Germany, MS) notes that Reeve's pheasant (*Syrmaticus reevesii*) and wild turkey (*Meleagris gallopavo*) could be added to the list, since, although introduced, they live wild in Europe and have a similar feeding ecology. The Dossier Submitter agrees that introduced species may also ingest lead gunshot. However, the starting point of the analysis was the list of 533 wild bird species occurring naturally and regularly in Europe; 2 – also known as *Testrastes bonasia*.

Table 1-17: EU terrestrial bird species belonging to the Columbidae family (pigeons and doves) at risk of ingesting lead gunshot

EU species within the Columbidae family (pigeons and doves)	Supporting evidence and information *(literature listed in chronological order covering bird species belonging to Columbidae)*
Rock dove *(Columba livia),* Stock dove *(Columba oenas),* Common woodpigeon *(Columba palumbus),* Eurasian collared-dove *(Streptopelia decaocto),* European turtle-dove *(Streptopelia turtur),* Dark-tailed laurel-pigeon *(Columba bollii),* White-tailed laurel-pigeon *(Columba junoniae),* Madeira laurel-pigeon *(Columba trocaz),*	1) Feeding ecology, including grit ingestion (Cramp et al., 1977-1994, Gionfriddo, 1994, Gionfriddo and Best, 1999, Wings, 2004) 2) Direct evidence of lead shot ingestion or poisoning, as reviewed by Fisher et al. (2006), Tranel and Kimmel (2009), Pain et al. (2009) e.g. in: Clausen and Wolstrup (1979); DeMent et al. (1987); Tavernier et al. (2004); Romero et al. (2020) 3) UNEP/CMS ad hoc Expert Group final assessment (comment #3343), where both probability and frequency of ingestion of lead shot in terrestrial species were considered 4) Evidence from non-EU species reported by Fisher et al. (2006) and Franson et al. (2009), including mourning dove *(Zenaida macroura)*

In addition, based on the feeding ecology and the assessment made by UNEP/CMS ad hoc Expert Group (comment #3343), the following terrestrial bird species are also considered to be likely to ingest lead gunshot:

- Eurasian woodcock (*Scolopax rusticola*), belonging to the Scolopacidae (Sandpipers and allies) family; based on Pain et al. (2009) and read-across from the American woodcock (*Scolopax minor*).
- Pin-tailed sandgrouse (*Pterocles alchata*), black-bellied sandgrouse (*Pterocles orientalis*) belonging to the Pteroclidae (Sandgrouse) family.

1.5.3.5. .Secondary ingestion of lead gunshot, lead bullets and lead fishing tackle by birds: overview (uses 1,2,3,5,7)

Birds may inadvertently ingest lead objects or lead contaminated tissues when feeding. Lead objects may be present within the alimentary tract and/or embedded in tissues (UNEP, 2014). This may occur for example, when:

- Scavenging birds consume offal/viscera or meat (containing either lead gunshot or bullet fragments) discarded by hunters.
- Predatory birds feed on:
    - birds having ingested lead gunshot (Pain et al. (2009);
    - animals with 'embedded' lead ammunition i.e. unretrieved carcasses or previously wounded but recovered animals.
- Piscivorous (fish eating) species ingest fishing tackle attached/ingested to/by fish.
- Predators and scavengers feed on waterbirds poisoned by fishing weights (Goddard et al. (2008), Rattner et al. (2008), (UNEP-AEWA, 2011).

An example of the lead fragments which may become available to birds (from a copper jacketed lead-based bullet) is provided in Figure 1-25 below.

Photo courtesy of Institute for Wildlife Studies, P.O. Box 1137 Tres Pinos, California 95075).

Figure 1-25: Lead fragments from a copper jacket lead-based bullet (left) compared with a copper expanding bullet (right) after Golden et al. (2016)

The probability of secondary ingestion of ammunition or fishing-related lead depends on multiple factors, such as the feeding behaviour of a bird species as well as anthropogenic factors that influence the distribution of lead. In general, all species that are (at least opportunistic) carnivores, i.e. consume the flesh of other animals to some extent, may be exposed to lead from ammunition and fishing tackle via secondary ingestion. When assessing lead exposure in wildlife, a separation between exposure to lead gunshot, bullets or fishing tackle is often not possible, as many species may ingest different sources of lead when feeding.

Bird species susceptible to lead poisoning via secondary ingestion of lead-containing ammunition (gunshot or bullet fragments) or fishing tackle (lead sinkers or lead lures)[96] have been classified based on their feeding ecology (Table 1-18).

Table 1-18: Classification of bird species susceptible to secondary lead ingestion categorised by their feeding behaviour

Bird species susceptible to secondary lead ingestion	Description	Diet
Vultures (obligate scavengers)	Old and New World species (families Accipitridae and Cathartidae, respectively)	Carrion only
Facultative scavengers, raptor species[97]	Species belonging to families Falconidae and Accipitridae	Live prey and carrion

[96] Alternative sources (paint, contaminated water or soils) have also been described in the literature as possible causes of poisoning in wildlife (Katzner et al. (2018)). Confirmation of the source of lead in wildlife can be done with isotope ratio analysis (Scheuhammer and Templeton (1998) However, the growing use of recycled lead may interfere with distinctive isotopic ratios (Sangster et al. (2000)).
[97] Bird species predominantly consuming vertebrates by hunting or scavenging or both are classified as birds of prey, or raptors. In *Commentary: Defining Raptors and Birds of Prey (McClure et al. (2019))* it is stated that no

Bird species susceptible to secondary lead ingestion	Description	Diet
Facultative scavengers, omnivores	Predominantly species that belong to families Laridae and Corvidae	Plant material, carrion
Opportunistic scavengers, other species	Non-scavenging nocturnal raptor species such as owls. Other species with evidence of secondary poisoning due to hunting or fishing related lead	Live prey, possible scavenging accounts less than 10 % of the diet

This assessment considers scavenging as the common denominator among the identified groups. Obligate scavengers are the most specialised species eating carrion only. However, the group "opportunistic scavengers, other species" consists of all species below a 10 % scavenging threshold[98] - but with evidence of scavenging leading to secondary poisoning. Within this group are species, such as common loons, that ingest fishing gear with their catch, as well as nocturnal birds of prey – a subgroup that rarely scavenges.

The specific groups and example species susceptible to exposure to lead by secondary ingestion are listed in Table 1-19. Species with non-European distribution are mainly discussed in the Annex B (section B.9.1.2).

standard definition for raptors and birds of prey exists. However, it is suggested to consider Accipitriformes, Cathartiformes, Falconiformes, Strigiformes and Cariamiformes as birds of prey. For this assessment, only the first four are discussed as there is no known cases of exposure in the last one.

[98] As per defined by Buechley and Sekercioglu (2016)

Table 1-19: Birds susceptible to lead exposure via secondary ingestion

Family	Group	Category	Diet Description	Potential source of exposure
Accipitridae	hawks	Facultative scavenger	Live prey and carrion	Shot, bullets, fishing tackle
	eagles	Facultative scavenger	Live prey and carrion	
	buzzards	Facultative scavenger	Live prey and carrion	
	harriers	Facultative scavenger	Live prey and carrion	
	kites	Facultative scavenger	Live prey and carrion	
	vultures	Vultures (obligate scavengers)	Carrion only	Shot, bullets
Pandionidae	osprey	Piscivorius	Fish only	Fishing tackle
Falconidae	falcons	Facultative scavenger	Live prey and carrion	Shot, bullets
Cathartiformes	vultures	Vultures (obligate scavengers)	Carrion only	Shot, bullets
Strigiformes	owls	Non-scavenging birds of prey	Live prey	Shot, bullets
Laridae	gulls	Facultative scavenger	Live prey, carrion, fish, other	Shot, bullets, fishing tackle
	terns	Piscivorius	Predominantly fish	Fishing tackle
	skimmers	Piscivorius	Predominantly fish	Fishing tackle
Corvidae	crows	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	ravens	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	rooks	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	jackdaws	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	jays	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	magpies	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	treepies	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	choughs	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
	nutcrackers	Facultative scavengers, omnivores	Live prey, plant material, carrion	Shot, bullets
Other	loons	Piscivorius	Fish	Fishing tackle
	albatross	Piscivorius	Fish	Fishing tackle
	storks and herons	Facultative Scavengers	Live prey, plant material, carrion	Shots, bullets
	skuas and jaegers	Facultative Scavengers	Live prey and carrion	Shots, bullets

The information was gathered by identifying the most comprehensive review articles on the matter of ammunition and/or fishing tackle related lead poisoning in birds, assessing the original papers and complementing this with additional relevant information. For European raptor species, one of the most recent and comprehensive reviews and meta-analysis was done by Monclús et al. (2020). For this assessment, the Dossier Submitter extracted the studies reviewed and grouped by Monclús et al. (2020) with either confirmed or suggested (i.e. expert opinion) ammunition related source, consisting of 14 facultative and 4 obligate scavengers as well as one nocturnal bird of prey. However, for many of the remaining species with undetermined source of lead exposure, either lacking expert judgement of the likely source or isotope assessment, the review found a correlation between higher lead levels and hunting season (see Annex B.).

Lead tissue concentrations in these species are presented in Annex B (section B.9.1.2). Furthermore, a global review of lead contamination in vultures (Plaza and Lambertucci, 2019) was used in screening information for vultures in Europe and elsewhere. Other sources such as conference proceedings were also used, when relevant, as well as information from the Call for evidence (2019).

Facultative scavengers that are omnivores, e.g. corvids, are discussed together with the group of opportunistic scavengers and others. Despite corvids being considered as the most common and frequent scavengers, studies on lead poisoning are relatively scarce: 11 species with reported cases of ammunition and/or fishing tackle related lead exposure were identified.

The UNEP/CMS ad hoc Expert Group also provided an assessment relevant for secondary poisoning (comment #3343). The UNEP/CMS ad hoc Expert Group categorised species at risk of secondary poisoning according to feeding ecology and direct evidence of lead ingestion and/or poisoning reported in the peer-reviewed literature. In addition, the assessment extrapolated (read-across) likely risks to other species that had not been specifically assessed for lead exposure/poisoning where habitat use and feeding ecology was considered to be sufficiently similar to a studied species.

At species level, UNEP/CMS ad hoc Expert Group reports 29 species of scavengers and birds of prey in the EU27 in the higher levels of risk of exposure[99]. The evidence identified for these species (within the Accipitridae, Falconidae and Corvidae families) by the Dossier Submitter is discussed in the following sections and in Annex B, section B.9.1.2, together with evidence of secondary poisoning from lead ammunition and fishing tackle for other species.

The approach to conclude on the species having the greatest probability to be poisoned from lead ammunition via secondary routes follows that indicated in Section 1.5.3.3 for primary ingestion i.e. based on both direct and indirect evidence and expert judgment. Based on this approach, the species listed in Table 1-20: have been identified as ‘at risk’ of lead poisoning via secondary exposure routes.

Table 1-20: Raptor/scavenger species at risk of lead poisoning by lead ammunition via secondary poisoning routes in the EU

[99] UNEP/CMS ad hoc Expert Group also provided a classification for birds at low risk of secondary poisoning, including many species of gull.

EU species of raptors and scavengers having the greatest probability to be poisoned by lead ammunition via secondary routes	Supporting evidence and information
Accipitridae family: Spanish imperial eagle *(Aquila adalberti),* golden eagle *(Aquila chrysaetos),* Bonelli's eagle *(Aquila fasciata),* eastern imperial eagle (*Aquila heliacal),* steppe eagle *(Aquila nipalensis),* northern goshawk *(Accipiter gentilis),* Eurasian buzzard *(Buteo buteo),* rough-legged buzzard *(Buteo lagopus),* long-legged buzzard *(Buteo rufinus),* western marsh-harrier *(Circus aeruginosus),* greater spotted eagle *(Clanga clanga),* white-tailed sea-eagle *(Haliaeetus albicilla),* black kite *(Milvus migrans),* red kite *(Milvus milvus),* hen harrier *(Circus cyaneus),* pallid harrier *(Circus macrourus),* Montagu's harrier *(Circus pygargus),* lesser spotted eagle *(Clanga pomarine),* booted eagle *(Hieraaetus pennatus),* cinereous vulture *(Aegypius monachus),* Egyptian vulture *(Neophron percnopterus),* bearded vulture *(Gypaetus barbatus),* griffon vulture *(Gyps fulvus)* **Falconidae family:** Lanner falcon *(Falco biarmicus),* saker falcon *(Falco cherrug),* peregrine falcon *(Falco peregrinus),* gyr falcon *(Falco rusticolus)* **Corvidae family:** Common raven *(Corvus corax),* carrion crow *(Corvus corone)*	1) Direct evidence of lead poisoning, as described in the overall section 1.5.3.5 and Annex B (section B.9.1.2). 2) Evidence for birds within the same families 3) UNEP/CMS ad hoc Expert Group final assessment (comment #3343), where both probability and frequency of ingestion of lead ammunition w considered. 4) Evidence reported for non-EU species (see Annex B, section B.9.1.2)

Vultures

Globally there are 23 vulture and condor species (hereafter "vultures") occurring in the New World (America, Cathartidae family) and the Old World (Europe, Asia and Africa, Accipitridae) (Plaza and Lambertucci, 2019). In this section exposure data related to vultures are discussed, with a focus on species with a European distribution. Additional information is discussed in Annex B.

Vultures, as obligate scavengers, are highly specialised to consume carrion only and are almost entirely dependent on this food source. Due to their social behaviour, and co-evolutionary history of tracking down hunters and other species in search of carrion, the probability to consume lead contaminated carrion, if available in the population's range, can be high for all individuals in the given vulture population (Ogada et al., 2012).

Lead exposure of vultures is most connected to big game hunting where bullets are predominantly used (Hunt et al., 2006). Exposure occurs when hunters leave gut piles and discarded meat containing ammunition or ammunition fragments from their quarry in the environment (Mateo-Tomas et al., 2015). However, lethal exposure to gunshot via secondary ingestion is also possible and seems to be spatio-temporally connected to high density small game hunting (Donázar et al., 2002).

Lead exposure in vultures has been reported and reviewed in many recent scientific papers (Gangoso et al., 2009, Carneiro et al., 2014b, Carneiro et al., 2016, Behmke et al., 2015, Bounas et al., 2016, Garbett et al., 2018, Naidoo et al., 2017, Krüger and Amar, 2018, Ganz et al., 2018, Plaza and Lambertucci, 2019, van den Heever et al., 2019, Roach and Patel, 2019, Miglioranza Rizzi Possignolo, 2019). Vultures are considered to be the most threatened bird guild in the world due to anthropogenic factors (Botha et al., 2017). Due to their threated status, vultures are now being targeted for conservation action in the Convention on Migratory Species Multi-species Action Plan to Conserve African-Eurasian Vultures (CMS-MsAP), and reducing the threat of lead toxicity has been identified as a priority across the range states (CfE #1151, Vulture conservation foundation).

Plaza and Lambertucci (2019) reported that 13/23 vulture species had been studied globally for lead exposure and 88 % of the articles discovered lead concentrations above the threshold in some tissues in these species. The most common reported lead source was ammunition, although this was not always confirmed through isotope studies.[100] The source of lead was confirmed through isotope ratios in 13 % (8/62) of the studies (Plaza and Lambertucci, 2019). Out of 62 reviewed articles of lead poisoning and exposure in vultures by Plaza and Lambertucci (2019), 72 % (45/62) came from North America and 30 % (19/62) from Europe. Fifteen of the European studies came from Spain, likely reflecting that most vultures in Europe live in Spain and, furthermore, that hunting is a significant activity in the country (Plaza and Lambertucci, 2019).

A comprehensive recent review of the effects of lead from ammunition on birds and other wildlife by Pain et al. (2019b) list exposure and poisoning incidents in two different vulture species in Europe; bearded vulture (*Gypaetus barbatus)* and griffon vulture (*Gyps fulvus*) and in four species outside Europe (Table 1-12). Other cases of lead exposure in Egyptian vulture (*Neophron percnopterus*) and cinereous vulture (*Aegypius monachus*) in Europe were listed in Pain et al. (2009).

Overall, all four European vulture species have been reported to ingest lead from

[100] Some articles reported other sources of lead such as mining and pollution or then the source was not investigated.

ammunition (Table 1-21)[101]. Recorded incidents for the four species arise from use of lead ammunition in large game hunting, small game hunting as well as in pest control. Spatio-temporal connection of lead exposure with hunting season and hunting activity has been confirmed in multiple studies in Europe and globally (Plaza and Lambertucci, 2019).

Table 1-21: Vulture species with European distribution and their association to ammunition related lead exposure

Species And Conservation Status (IUCN Red List EU 27)	Details of EU population*	Examples of reported lead poisoning via secondary ingestion[1]
Egyptian vulture (*Neophron percnopterus*) (VU)	Only European vulture that migrates to Africa in winter. Sedentary population in Canary Islands. Majority of European population in Iberian peninsula, 1 300-1 500 pairs. France (80 pairs) and Italy (10 pairs)	Donázar et al. (2002), Gangoso et al. (2009)
Bearded vulture (*Gypaetus barbatus*) (VU)	Rarest vultures in Europe, total population in the area estimated to range from 600 to 1 000 pairs. Pyrenees 100 pairs, Corsica 8 pairs, Crete 9/10 pairs and reintroduced population in the alps, 20 breeding pairs.	Ganz et al. (2018); Hernández and Margalida (2009)
Griffon vulture (*Gyps fulvus*) (LC)	Breeding population in Europe between 19 000 - 21 000 pairs, distributed mostly in Portugal, Spain and French Pyrenees	Berny et al. (2015b) Carneiro et al. (2014b)
Cinereous vulture (*Aegypius monachus*) (LC)	Total European breeding population approximately 1 800 pairs, mainly in Spain. Greece has the only remaining colony in the Balkans with 25+ pairs and France has reintroduced population of about 25 pairs.	Cardiel et al. (2011)

**Source: Vulture conservation foundation https://www.4vultures.org/vultures/ (reviewed 01.09.2020)*

Notes: [1] Either acute poisoning or chronic accumulation

A small, sedentary population of re-introduced bearded vultures in the Alpine region has been connected to lead poisoning and exposure due to ungulate hunting in the area. The IUCN Red List conservation category for the species on European level is considered vulnerable. Ganz et al. (2018) reported high lead concentration in liver and bone from bearded vultures of the Swiss Alps, higher than those found for the same species elsewhere in Europe or North America, reaching the levels compatible with acute poisoning. Two of five bearded vultures had very high bone lead concentrations (58.90 μg/g and 100.04 μg/g). Madry et al. (2015) showed isotope-proven connection to ammunition derived lead burden in golden eagles in the same area, species also known to scavenge. Golden eagles are non-migrant in the area as bearded vultures are, so it is plausible to assume the species scavenge and consume the same resources and furthermore, that the lead burden in

[101] All four European vulture species are exposed to lead ammunition via secondary ingestion. Pain et al. (2009), suggests that feeding ecology can provide a useful proxy for susceptibility to ammunition derived lead exposure in all vulture species. In Annex B tissue concentrations of lead in European vulture species (reviewed by Monclus et al., 2020 are reported.

bearded vulture originates from ungulate hunting in the area[102].

Elevated, above threshold blood lead levels in 14 (24 %) Egyptian vultures from the Canary Islands (n=137 nestlings and adults) were reported by Gangoso et al. (2009). One of the studied birds showed a blood lead concentration of 178 µg/dL. Bounas et al. (2016) reported the first confirmed case of Egyptian vulture lead poisoning in the Balkans where the vulture BLL was recorded at 3 210 µg/L. Dissolved ammunition related lead was suspected as the cause (Bounas et al., 2016).

In the French Pyrenees, embedded lead gunshot was found in 8 out of 120 studied griffon vulture (*G. fulvus*) and lead poisoning was recorded as cause of death for three of the birds (Berny et al., 2015b). Derived isotope signature was considered consistent with an ammunition source. During a five-year study from Aragon, Spain, 691 blood samples were collected from griffon vultures to assess blood lead levels and the source of the lead. The study found spatiotemporal association with high blood lead levels and point sources, such as ammunition and ingestion of ammunition supported by the isotope-ratio analysis was concluded as source (Mateo-Tomás et al., 2016). Nine Egyptian vultures were included in the study and detected during the hunting season in fall and winter, where the density of hunting e.g. pigeons is high, some 170 000 pigeons killed annually (Jean, 1996, Berny et al., 2015b).

The cinereous vulture (*Aegypius monachus*)[103] has two known lead poisoning cases in Europe (Hernández and Margalida, 2009, Cardiel et al., 2011). Cardiel et al. (2011) found 2/3 tested birds exceeding lead bone concentration threshold exceeding subclinical threshold (Franson and Pain, 2011). Outside Europe, In Korea and Mongolia the species have been reported with high concentrations of lead in blood and liver, being higher in individuals trapped in Korea than Mongolia, very likely due to the high levels of hunting activity in the former (Kenny et al., 2015, Kim and Oh, 2016).

Bassi et al. (2021), report an assessment of lead ingestion by facultative and obligate avian scavengers in southcentral Europe. Between 2005 and 2019, 595 tissue samples from 252 carcasses of 4 species, including vultures (golden eagle, bearded vulture, griffon vulture, cinereous vulture) were collected and analysed. Overall, 111 individuals (44.0 %) had lead concentrations above background thresholds in at least one tissue (i.e. >2 mg/kg w.w. in soft tissues, >8.33 in bone) and 66 (26.2 %) had values indicating clinical poisoning (>6 mg/kg w.w. in liver, >4 in kidney, >16.6 in bone).

Overall, different species may exhibit different response to lead exposure. For example, in obligate scavenging birds some variability of symptoms across species has been found. Turkey vultures (*Cathartes aura*) seem to be relatively tolerant of repetitive lead exposure, whereas the mortality of critically endangered California condors from lead poisoning is considered very high and ammunition-related lead is considered to be the cause of the near extinction of the species (Carpenter et al., 2003, Finkelstein et al., 2010).

Facultative scavengers, raptor species

In this section exposure data related to facultative scavengers, raptor species, are discussed, with a focus on species with a European distribution. Non-European cases and additional information is discussed in the Annex B, including recorded tissue concentrations

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[102] The review by Monclús et al. (2020) considers the study by Ganz et al. (2018) as having unknown lead source for studied bearded vultures. However, the authors draw attention very clearly to ammunition related lead. Therefore, the study should be considered as suggesting ammunition related contamination (see Annex).
[103] Sometimes referred to as black vulture.

of the studied birds when available.

The diet of a facultative scavenging raptor consists of live prey in addition to carrion. Predation risks are higher for injured (potentially shot with lead) and intoxicated (potentially lead poisoned and still carrying 'embedded' metallic lead) individuals, therefore debilitated prey may form a large part of the diet of predators. The presence of embedded lead gunshot in waterfowl is the main cause of lead poisoning for raptors in wetlands (Pattee and Hennes, 1983). The percentage of birds with embedded gunshot differs between species, areas with different hunting pressures and the age of birds (Mateo, 2009). 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 %. Therefore, the risk for facultative scavenging raptor species to ingest lead results from the combination of anthropogenic factors that influence the distribution of lead, the preferred prey species and sometimes also even the age and gender of the raptor.[104]

Table 1-22[105] summarises the species reported to have been exposed to ammunition related lead due to secondary ingestion of contaminated carrion and/or prey in Europe.

Table 1-22: Ammunition related lead exposed facultative scavenger raptors with European distribution

Species	Examples of confirmed source of exposure	Examples of spatiotemporal connection suggesting ingestion
European Honey-buzzard (*Pernis apivorus*) LC	Lead shot in the gizzard (Lumeij et al., 1985)	Not available
Common buzzard (*Buteo buteo*)	Suggested ingestion of ammunition supported by isotope-ratio analysis (Taggart et al., 2020) Shotgun pellets in stomach (MacDonald et al., 1983)	Suggested ingestion of ammunition (Komosa and Kitowski, 2008, Mateo et al., 2003)
Rough-legged buzzard (*Buteo lagopus*)	Not available	Suggested ingestion of ammunition (Komosa and Kitowski, 2008)
Spanish Imperial Eagle (*Aquila adalberti*) VU	Two birds with embedded shot (Pain et al., 2005)	Suggested ingestion of ammunition (Pain et al., 2005)
Greater spotted eagle (*Aquila clanga*) VU	Not available	Suggested ingestion of ammunition (Komosa and Kitowski, 2008)
Golden Eagle (*Aquila chrysaetos*) LC	Ingestion of ammunition supported by the isotope ratio analysis (Jenni et al., 2015, Madry et al., 2015, Singh et al., 2021)	Suggested ingestion of ammunition (Kenntner et al., 2007)
Bonneli's eagle (*Aquila fasciata*) LC	Isotope ratio indicating non-mining source (Badry et al., 2019); regurgitated pellets containing lead, prevalence in pellets related to small game hunting (partridge and rabbits)	Descalzo et al. (2021)

[104] In birds of prey it is common for the females being of larger size, e.g. in Eurasian sparrowhawks female can be up to 25 % larger and therefore prey on different species than the male. Furthermore, juvenile birds of prey are suspected occasionally to hunt more prey with embedded shot due to inexperience in hunting in comparison to adults (Pain and Amiardtriquet, 1993, Kitowski et al., 2017).(Pain and Amiardtriquet, 1993, Kitowski et al., 2017).

[105] 21 facultative avian scavenger species globally have been strongly associated with exposure to ammunition related lead. Nocturnal non-scavenging species have been studied for lead exposure, and both European and American cases have been found. For these species, secondary ingestion of embedded lead via prey animal only, rather than carcass, is the assumed exposure route.

Species	**Examples of confirmed source of exposure**	**Examples of spatiotemporal connection suggesting ingestion**
	(Gil-Sanchez et al., 2018)	
Western Marsh-harrier (*Circus aeruginosus*)	Regurgitated pellets containing lead, source overlaps with wetland species and injured mammals (Pain et al., 1993) Lead shot in regurgitated pellets (Mateo et al., 1999)	Suggested ingestion of ammunition (Komosa and Kitowski, 2008, Descalzo et al., 2021)
White-tailed eagle (*Haliaeetus albicilla) LC*	Lead shot and/or ammunition in the gizzard/oesophagus/digestive tract or stomach (Isomursu et al., 2018, Helander et al., 2009, Krone et al., 2009b, Krone et al., 2004, Müller et al., 2007, Kenntner et al., 2001, Helander et al., 2021) Also, concern of fishing tackle ingestion (based on feeding ecology[106] and information reported in CfE #1083 from MME Birdlife Hungary, which includes a picture taken in 2019, in the Danube Ipoly National, where the female eagle brought a large fish with a lead sinker attached to her nest, which was nearly swallowed by one of the chicks).	Suggested ingestion of ammunition (Komosa and Kitowski, 2008, Kitowski et al., 2017)
Red Kite (*Milvus milvus*) NT	One individual with lead shot in the GI-tract (Molenaar et al., 2017) Regurgitated pellets containing shot (Pain et al., 2007)	(Berny et al., 2015b)
Peregrine Falcon *(Falco peregrinus*) LC	Shot in GI-tract (Andreotti et al., 2018)	Suggested ingestion of ammunition (Mateo et al., 2003, Pain et al., 1995)
Eurasian sparrowhawk (*Accipiter nisus*)	Not available	Suggested ingestion of ammunition (Pain et al., 1995)
Northern goshawk (*Accipiter gentilis*) LC	Not available	Suggested ingestion of ammunition (Komosa and Kitowski, 2008, Descalzo et al., 2021)

Notes: Confirmed source of exposure: either presence of lead (embedded and or ingested) and or isotope-ratio analysis confirming source of leaf. Other evidence of exposure may include e.g. expert opinion on the source.

Common buzzard (*Buteo buteo*) has been found with elevated levels of lead in number of individuals in several locations in Europe, such as in the Netherlands (Jager et al., 1996), UK (Pain et al., 1995, Pain and Amiardtriquet, 1993), Italy (Battaglia et al., 2005), Spain (Pérez-López et al., 2008) and Portugal (Carneiro et al., 2014a). Taggart et al. (2020) confirmed the suggested ingestion of ammunition by isotope-ratio analysis. In UK, MacDonald et al. (1983) discovered lead pellets from the stomach of lead-poisoned bird.

Spanish Imperial Eagle (*Aquila adalberti*), an Iberian endemic with a small population, has been reported to have suffered lead exposure on several occasions (Fernandez et al., 2011). Fernandez et al. (2011) found a spatial association with lead tissue concentrations in eagles and intensively hunted areas. However, populations of the Spanish imperial eagle in the vicinity of wintering waterfowl have higher exposure (Mateo et al., 2001, Pain et al.,

[106] Mlíkovský (2009) reported that the food of the White-tailed Sea Eagle (Haliaeetus albicilla) at Lake Baikal (Russia), in a long-term study (1991-2001) revealed that these eagles feed predominantly on water birds, mainly ducks.

2005). Spanish imperial eagle is a typical large raptor, being a long-lived species with individuals breeding relatively late and with one or two chicks only. Therefore the population cannot sustain high mortality, especially in adults (Ferrer et al., 2003, Pain et al., 2005). Pain et al. (2005) discovered two individuals with embedded shot.

Bonneli's eagle (*Aquila fasciata*), an endangered species studied recently by Gil-Sánchez et al. (2018) in south-eastern Spain, was found to have been exposed to lead gunshot likely related to red-legged partridge (*A. rufa*) and European rabbit (*Oryctolagus cuniculus*)-hunting in the studied areas. A negative effect in breeding success was documented and the authors warn it may have an effect in other European populations of the species, as the juveniles dispersing from the study populations are known to act as a source sustaining other populations (Gil-Sanchez et al., 2018). In Portugal, isotope ratio analysis of lead in 80 Bonnelli's eagle feathers (Mean 0.17, range 0.02 - 0.87, n = 80) indicated a non-mining source of lead (Badry et al., 2019).

In Germany, lead poisoning has been identified as the major cause of death in white-tailed eagles (*Haliaeetus albicilla*), with 25 % of carcasses examined having died because of lead toxicosis; lead from both gunshot and bullet fragments was implicated (Krone et al., 2003). Lead poisoning from ammunition is considered to be the single most important cause of mortality in this population (Krone et al., 2009a). White-tailed eagles from both Austria and Germany have been found to be lethally poisoned by lead by Kenntner et al. (2001), with the number of poisoned determined by liver lead concentration as 30 % of 57 studied individuals. Lead fragments were detected in the gizzards of two dead individuals (Kenntner et al., 2007). In Sweden, 22 % of 116 white-tailed eagles collected and examined between 1981 and 2004 had elevated (>6 microg/g d.w.) lead concentrations, indicating exposure to lead ammunition, and 14 % of the individuals had either liver or kidney lead concentrations diagnostic of lethal lead poisoning (Helander et al., 2009). The lead isotope ratios suggested that the source of lead in specimens with lethal concentrations differed from that of ones exhibiting background concentrations of lead (< 6 microg/gd.w.). Furthermore, lead gunshot and fragments were found in the digestive tract of some birds (Helander et al., 2009). In Poland, Kitowski et al. (2017) found 36 % of 22 studied white-tailed eagles had acute lead poisoning according to their liver lead values. Studied individuals were collected during winter from the northern and southern parts of eastern Poland, and in southern areas where waterbodies freeze and the eagles consume more carrion and prey than northern population by water, the levels of lead were higher. When fish availability sharply declines, white-tailed eagles are known to switch to waterfowl and carrion for food (Nadjafzadeh et al., 2013). As white-tailed eagles are also fish consuming, there is also a plausible concern of lead fishing tackle ingestion.

Raptor species that feed on waterbirds are also at risk due to secondary ingestion of lead fishing tackle (Rattner et al., 2008, Ishii et al., 2017, Garvin et al., 2020).

In the Swiss Alps, Madry et al. (2015) demonstrated an isotope-proven connection to ammunition derived lead burden in golden eagles *(Aquila chrysaetos),* species that are also known to scavenge. Jenni et al. (2015) discovered reported episodic and repeated lead intake in golden eagles leading to elevated lead tissue concentrations, likely resulting from ammunition in carcasses foraged in the Swiss Alps. In golden eagles increased mortality in immature and sub-adults exceeding a certain bone lead concentration threshold has been detected, resulting in lower bone lead concentration in the population in younger age groups - falsely suggestive of low exposure or higher tolerance (Madry et al. 2015). Bird scavengers, including raptors, often subsidise their diets by scavenging pests shot on agricultural land. Nesting golden eagles commonly forage in agricultural land during the breeding season and, therefore, both adults and their nestlings are susceptible to lead exposure from scavenging (Herring et al., 2020).

Singh et al. (2021) have recently shown that golden eagles have learned to synchronise the timing of their migration with that of the moose hunt in Sweden at the landscape scale, and therefore match their distribution to the areas with higher number of moose shot. The study also reported that due to this coupling, eagles could ingest lead from moose offal and carcasses. The study highlighted that even sub lethal lead concentrations, below the generally regarded thresholds in eagle blood, can increase the probability of mortality by 3-4 fold.

Northern goshawk (*Accipiter gentilis*) prey on live birds such as partridges and pigeons, which may have lead shot embedded in their tissues. Goshawks studied in Spain had geometric mean lead concentrations in bones equal to 1.57 mg/kg (Mateo et al., 2003) and in France one specimen has been found with a liver lead concentration of 711mg/kg (Pain and Amiardtriquet, 1993). Komosa and Kitowski (2008) reported median bone concentrations of 7 µg g^{-1} d.w. for six studied birds and ingestion of ammunition was suspected as the cause for accumulation.

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For red kites (*Milvus milvus*) there are two references in the literature reporting direct evidence of lead gunshot ingestion, other reporting lead gunshot in regurgitated pellets and other in a GI-tract (Pain et al., 2007, Molenaar et al., 2017). (Molenaar et al., 2017) reported mean lead values in bone exceeding the threshold for severe clinical poisoning in 11 birds.

Andreotti et al. (2018) reported a peregrine falcon (*Falco peregrinus*) ingesting lead gunshot and there are at least two further cases of ingestion in the literature for this species (Mateo et al., 2003, Pain et al., 1995). Pain and Amiardtriquet (1993) suggested the source of lead gunshot to be either small mammals or birds with embedded and/or ingested lead gunshot. A comprehensive review and meta-analysis of lead contamination in raptors in Europe (Monclus et al., 2020) concluded that three species of facultative scavengers (golden eagle, common buzzard and white-tailed sea eagle) accumulated the highest lead concentrations in tissues and generally were the species most at risk of lead poisoning.

Descalzo et al. (2021) reported the results of a study monitoring lead poisoning in birds of prey in Spain by measuring liver (n = 727) and blood (n = 32) lead levels in individuals of 16 species found dead or sick between 2004 and 2020. They also performed an "active" monitoring by measuring blood lead levels and biomarkers of haem biosynthesis, phosphorus (P) and calcium (Ca) metabolism, oxidative stress and immune function in individuals (n = 194) of 9 species trapped alive in the field between 2016 and 2017. Lead poisoning (clinical or lethal) represented 8.1 % of the diagnosed poisonings and affected 5.0 % of the total birds analysed. Clinical lead poisoning was detected in 5 species of birds of prey (first cases in Bonelli's eagle *(Aquila fasciata),* northern goshawk *(Accipiter gentilis)*, andwestern marsh harrier *(Circus aeruginosus))* and represented a significant proportion of the diagnosed poisonings. In addition to mortality, the authors concluded that lead could cause adverse sublethal effects to a much higher proportion of birds of prey, according to the detected blood lead concentrations.

Facultative and opportunistic scavengers (other species)

In this section examples of exposure data related to facultative omnivorous scavengers are discussed. Due to limited information for this group, the review is global and includes all known cases of lead exposure for these species. Facultative omnivorous scavengers with recorded cases of ammunition related lead exposure are mostly species of corvids and gulls. Corvid species are among the most common vertebrates recorded as scavenging large game remains globally and the common raven (*Corvux corax*) is reported as the most common vertebrate scavenger (Mateo-Tomas et al. 2015). Species considered as opportunistically scavenging omnivores, mainly owls, and piscivorous species are also discussed.

Ravens, and corvids in general, are also known to be the first species to arrive to gut piles of moose (Gomo et al., 2017), including species such as magpie (*Pica pica*), Eurasian jay (*Garrulus glandarius*), hooded crow (*Corvus corax)*, Siberian jay (*Perisoreus infaustus*) It is therefore possible that also corvid species other than those with records of exposure are at risk of ingesting lead fragments while scavenging.

Craighead and Bedrosian (2008) examined 302 blood samples from common ravens (*Corvus corax*) scavenging on hunter-killed large ungulates and their offal piles to determine if lead rifle-bullet fragments were a point source for lead ingestion in ravens. They took blood samples during a 15-month period during two hunting seasons. Of the ravens tested during the hunting season, 47 % exhibited elevated blood lead levels (≥10 µg/dL) whereas 2 % tested during the non-hunting season exhibited elevated levels. Females had significantly higher blood lead levels than did males. Results were considered representative of the ingestion of lead during the hunting season and suggesting exposure to lead from rifle-shot large-game offal piles (Craighead and Bedrosian, 2008).

Many species of gulls (family laridae) are considered as scavengers but can also ingest lead gunshot and fishing tackle. Quortrup and Shillinger (1941) found one species of gull with ingested gunshot from US western lake areas, whereas in 1985 two more were reported by National Wildlife Health Laboratory (NWHL, 1985).

Mateo-Tomas et al. (2015) reported scavenging behaviour for two woodpecker species (*Dendrocopos major* and *Dryocopus martius*) in Scandinavian boreal forests indicating a possibility for a scavenging behaviour to result in lead exposure. Therefore, the source of exposure couldl be either primary or secondary ingestion .

An example of "other species" that may ingest fishing tackle by secondary ingestion are loons (known as divers in Europe). As reported by Phillips et al. (2010), loons probably ingest lead sinkers in several ways. Sinkers found in dead loons are sometimes associated with hooks and lines. In such cases, loons may have attempted to prey upon live fish used for bait and ingested the fishing gear directly from anglers. Loons are primarily piscivorous, and can ingest fish or baitfish that have broken free from fishing lines, but still have fishing tackle attached to them. Grade et al. (2018) recorded fishing tackle as the cause of death for 123 common loons (n=253, 48.6 %) in the US. The birds had ingested jigs and sinkers. The timing of the study suggests secondary ingestion rather than grit ingestion and some of the tackle was also outside of the size range of grit. Loons are relatively long lived (some sources estimate a lifespan of up to 30 years) and are slow to mature, not breeding until they at least 4 years old. Females lay only one clutch of 1-3 (usually 2) eggs a year. Both parents incubate the eggs, feed the young, and protect them from predators for the first 3-

4 months of life, so the loss of a breeding adult is likely to cause the loss of the offspring (of the year) (Phillips et al., 2010).

Table 1-23: Examples of exposure data in different bird species including omnivorous birds

Species	Location	Details of exposure	Reference
Common raven (*Corvus corax)*	US	Increase in BLL along the moose hunting season, isotope ratio analysis indicate ammunition source (Legagneux et al., 2014) Sixfold higher lead median levels in blood during a hunting season (West et al., 2017)	Legagneux et al. (2014); West et al. (2017)
Rook (*Corvus frugilegus*)	Europe	A bird delivered to a rehabilitation centre that subsequently died with a high liver lead content (6.33 ppm dw, N = 1 of 24). Suggested secondary exposure due to the species propensity to scavenge or eat grit/small stones and mistakenly ingest spent ammunition	Kitowski et al. (2017)
Hooded crow (*Corvus Cornixa*)	Europe	A bird delivered to a rehabilitation centre that subsequently died with a high liver lead content (21.77 ppm dw, N = 1 of 6) Suggested secondary exposure due to species propensity to scavenge or eat grit/small stones and mistakenly ingest spent ammunition	Kitowski et al. (2017)
Magpie (*Pica pica*)	Europe	A bird delivered to a rehabilitation centre that subsequently died with a high liver lead content (8.62 ppm dw, N = 1 of 2.) Suggested secondary exposure due to species propensity to scavenge or eat grit/small stones and mistakenly ingest spent ammunition	Kitowski et al. (2017)
California gull (*Larus californicus*)	US	Ingested shot found in autopsy, unclear if due scavenging or/and primary ingestion	Quortrup and Shillinger (1941)
Glaucous-winged gull (*L. glaucescens*)	US	Ingested shot found in autopsy, unclear if due scavenging or/and primary ingestion	NWHL (1985)
Herring gull (*L. argentatus*)	US	Ingested shot found in autopsy, unclear if due scavenging or/and primary ingestion	NWHL (1985)
Eurasian eagle owl (*Bubo bubo)*	Europe	Suggested ingestion of ammunition	Mateo et al. (2003)
Common loon (*Gavia immer*)	US, Europe	Fishing tackle (jig head and sinkers) retrieved from loon carcasses. Timing of the study suggest secondary route instead of grit ingestion. Tackle was the cause of death for 123 birds (n=253, 48.6 %)	Grade et al. (2018)
Wandering albatross (*Diomedea exulans*)	South Georgia	Ingestion of fishing tackle as a bycatch, estimated 1 300–2 048 items of gear are consumed per annum by the wandering albatross population	Phillips et al. (2010)
Woodpeckers (Denrocopus/Dyocopus etc sp.)	Europe	No direct evidence of scavenging, however unknown lead exposure reported by Mörner & Pettersson (1999) and records of woodpecker scavenging by Mateo-Tomas et al. (2015) could indicate a plausible risk.	Mörner and Petersson (1999);Mateo-Tomas et al. (2015)

Notes: Confirmed source of exposure: either presence of lead (embedded and or ingested) and or isotope-ratio analysis confirming source of leaf. Other evidence of exposure may include e.g. expert opinion on the source.

1.5.3.6. Lead poisoning of wildlife (taxa other than birds), domestic animals (dogs) and livestock (other than ruminants)

Predatory and scavenging mammal species may be exposed to lead through the predation and consumption of contaminated game and through contaminated gut piles, discarded meat or unrecovered game left in the environment by the hunters (Pain et al., 2019b).

All carnivorous scavenging mammals consume both prey and scavenge i.e. there is no obligate scavengers in the class Mammalia. As hunting is energetically costly and risky, scavenging is favoured by many predatory mammals when the opportunity arises (Carbone et al., 2007). Predators typically favour debilitated or otherwise weak prey: old, young, pregnant or wounded individuals (Mattisson et al., 2016).

Overall, there are limited data on the incidence of lead poisoning for mammals compared to birds. However, ammunition related lead is often suspected as source of lead poisoning (Rogers et al., 2012, Lazarus et al., 2020). One case of acute lead toxicosis in a cougar (*Puma concolor*) was recorded in Oregon, US in 2010 due to ingestion of ammunition related lead (Burco et al., 2012). Retrieved stomach contents contained mostly of 2-3 mm gunshot and occasional metal bullet jacket and brown glass. Fuchs et al. (2021)[107] found that Scandinavian brown bears are highly exposed to environmental lead despite the general decrease of lead burden on a spatio-temporal scale in Europe and the fact that in Scandinavia, sediment core lead concentrations (dated back to pre-historic metallurgic activities) are very low. The authors concluded that further analysis would be needed to conclude on the exposure sources but berry consumption, ingestion of soil during foraging and lead from large game hunting with lead-based ammunition are most likely the major contributing factors. For suckling offspring, lead in milk was considered the most likely source (blood lead of suckling cubs was positively correlated with their mothers' blood lead).

Comment #3489 provided confidential information (due to ongoing publication work) related to a qualitative risk assessment of the potential Source-Pathway-Receptor linkages for European wild mammal exposure. The study was based on literature reviews, existing evidence and discussions with experts from the fields of wild mammal feeding ecology, behaviour and health. The assessment identified 11 pathways for mammalian exposure to lead, with species likely to be potentially exposed via one or more routes.

Martin (2019) noted that only a small subset of the literature concerning lead toxicosis in marine and land mammals focuses on lead fishing sinkers and tackle (Eisler, 1988, Pokras and Kneeland, 2009). An example of lead toxicosis was reported in a seal. In June 2004, in California researchers examined a harbour seal at a rehabilitation centre. The seal was underweight for its age, dehydrated, and having seizures. After the seal died, a necropsy revealed a lead fishing sinker in the animal's stomach. It was determined the animal died of acute, high-dose lead toxicosis consequent to the ingestion of the sinker. The researchers found it likely that the seal, while foraging for food, ingested a fish attached to fishing tackle used by either recreational or commercial anglers (Zabka et al., 2006).

Exposure of bears to fishing tackle has also been speculated, in cases where they feed on fish with embedded tackle (Rogers et al., 2012).

In addition to wild and livestock mammals, other domestic mammals such as hunters' dogs and domestic avian species referred to as poultry may also be exposed to lead from the use

[107] Also mentioned in comment #3510.

of lead ammunition (as also noted by comment # 3250).

Høgåsen et al. (2016) evaluated the exposure to lead in dogs fed game meat through. Their results suggested that there is a health risk for dogs but also highlighted the lack of data about the amount of game meat eaten and the bioavailability of lead post-ingestion in dogs. The authors recommended that trimmings close to the wound channel should be made inaccessible to dogs, as well as to other domestic or wild animals.

The risk assessment to consumers of cervid meat and hunting dogs undertaken by Knutsen et al. (2019) suggested that the risk for chronic health effects in dogs fed on trimmings of meat/offal from the wound channel from lead killed cervids can be considered as high. On the other hand, they suggested that the risk for adverse effects after a single exposure of lead contaminated meat could be considered as low.

More recently, Fernández et al. (2021) quantified the lead concentrations in blood and hair and other haematological parameters in 31 dogs (from four owners) fed game meat and offal from invasive species wild boar (*Sus scrofa*) and axis deer (*Axis axis*) culled with lead ammunition in El Palmar National Park, Argentina. Findings from this study included detectable lead exposures in the dogs (blood lead concentrations had a median of 18.49 µg/dL). However, all dogs whose owners reported a medium or high frequency of game feeding had blood lead levels below 40 µg/dL. In contrast, the dogs whose owner reported a very low or low frequency of game feeding tended to present higher blood lead concentrations, with 54 % presenting high levels (>40 µg/dL). In the study, most dogs that were fed game meat and offal with medium and high frequencies were adults older than two years (average 50 months old). In contrast, dogs fed game with very low and low frequencies were comparatively younger (average 36 months old). The authors noted that high lead values in dogs fed game only occasionally suggested that variability in ingested versus absorbed lead, frequency of ingestion, and age may explain the apparent discrepancy between game feeding frequency and blood lead concentrations.

The fragmentation of lead ammunition in game meat should also be considered. The health risks of lead absorption are likely to be more dependent on the surface areas of fragments rather than the total lead mass ingested as more lead becomes bioavailable when fragment surface area increases. Interestingly, dogs belonging to owners who reportedly fed them with game meat and offal in a medium or high frequency tended to show higher lead concentrations in their hair, in contrast with the generally low lead concentrations in their blood. The authors concluded that, although the analysis of all diet components and the accurate knowledge of their quantity and frequency of consumption through the study of dogs under controlled conditions, should be considered in future research, their results suggested that high lead blood levels in dogs fed game occasionally could indicate that there might not be a risk-free frequency for the consumption of game meat or offal.

The LAG (Lead Ammunition Group) website[108] contains links to references (updated periodically) including a section on domestic and captive animals (comment #3250).

Due to the very limited data available, lead exposure and related risks to wildlife and domestic mammals other than livestock ruminants (see section 1.5.3.7.3) are not further elaborated by the Dossier Submitter but cannot be ruled out.

Available information on lead exposure of domestic avian species is discussed in section 1.5.3.7.3.

[108] http://www.leadammunitiongroup.org.uk/resources/

Finally, comment #3343 notes that several studies document the transfer of lead from ammunition to fish via contaminated water (Heier et al., 2009, Mariussen et al., 2017) and also the transfer of lead to soil fauna (Vyas et al., 2000). Exposure of fish via surface water runoff is further discussed in Section 1.5.3.7.1.

1.5.3.7. Additional lead exposure related to sports shooting (uses 3, 4, 5 and 6)

Spent lead projectiles from sports shooting (all uses) can contaminate the environment both during the **service life** and at the **end of life** of a range. Lead related contamination may occur both on-site (at the sports shooting range) and away from the point of use (off-site), for example in:

- Agricultural soils (with projectiles landing on grazing, cropping or horticultural areas)
- Soils used for recreational areas (for adults and children) (see also Annex B 9.1.3.4). For example, Urrutia-Goyes et al. (2017) measured lead concentrations in the topsoil of a former range in Greece that had been converted into a public park. Residual lead concentrations of 5 560, 2 043, and 7 160 mg/kg were measured in the soil.[109]
- Soil used for residential areas
- Rivers, lakes and other wetlands (directly or for example via surface run-off or via groundwater)

In general, metallic lead may be released into the environment at shooting ranges via a range of pathways[110]. The relevance and significance of different pathways is often site-specific and may or may not occur at any individual range (US EPA, 2005):

- Lead oxidizes and dissolves when exposed to acidic water or soil.
- Lead particles or dissolved lead can be moved by storm water runoff (horizontal migration.
- Dissolved lead can migrate through soils to groundwater (vertical migration). The risk of groundwater contamination occurring may vary from very low to high depending on the soil characteristics. The combination of acidic soils, coarse soils, preferential flow pathways or macropores and shallow depths to groundwater (<3m) lead to high vulnerability to lead contamination. More specific information focused on terrestrial environment is discussed in Appendix 1 of the Background Document: *"Assessment of the potential for the use of lead ammunition at shooting ranges to contaminate groundwater and drinking water".*

Lead transported by water runoff can represent a risk for off-site receptors (Duggan and Dhawan, 2007). Lead mobility may significantly differ among sites, based on site-specific conditions, as further discussed in Annex B (section B.9.1.3).

Specific differences in terms of risk profiles have to be expected for shooting disciplines using lead gunshot versus shooting disciplines using lead bullets. For example, the migration of lead into surface water is more likely at shotgun ranges than at pistol and rifle

[109] The authors performed a human health risk assessment and concluded that that the main exposure pathway of concern, especially for children, is ingestion, followed by dermal contact and inhalation.

[110] Lead exposure to the aquatic and terrestrial compartments may also occur in areas with intensive hunting with lead shot (use 1). However, limited information is available to further elaborate this. Lead exposure to the aquatic compartment due to the use of fishing tackle (uses 7) may also occur. Specific exposure information related to EU waterbodies are not readily available according to the Dossier Submitter's knowledge. However, Jacks et al. (2001), estimated that dissolution of elemental lead in Swedish rivers amounted to approximately 1 % of the deposited lead, the loss being larger in fast running waters. More recently, the California Research Bureau (2019) stated that the rate at which lead from fishing tackle dissolves in water depends on several factors, including the alkalinity of the water and the dissolved salt content.

ranges because the pollutant load caused by shotgun shooting is wider and the erosion of gunshot is more rapid than that of bullets because of their smaller size (Kajander and Parri, 2014)[111]. In addition, in shooting ranges, spent gunshot and bullets usually fall within an area of deposition which is substantially larger for gunshot compared to bullets. Figure 1-26 and Figure 1-27 provide examples of possible lead deposition areas in a shotgun and rifle/pistol range, respectively.

Figure 1-26: Example of lead gunshot deposition from a shotgun range on lands with different zoning (Environmental Protection Authority Victoria (EPA), 2019)

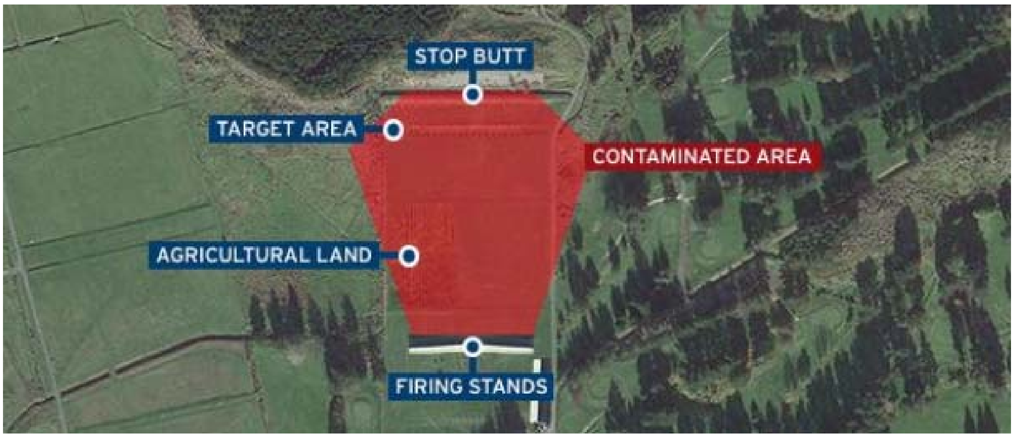

Figure 1-27: Example of lead deposition on agricultural land from a rifle/ pistol range (Environmental Protection Authority Victoria (EPA), 2019)

A simplified model of indirect pathways from a shooting range is shown in Figure 1-28.

[111] Migration is particularly affected by the amount of surface runoff formed in the range area and coming from outside the area (determined by the inclination of the top soil, amount of rainfall, soil types, and vegetation).

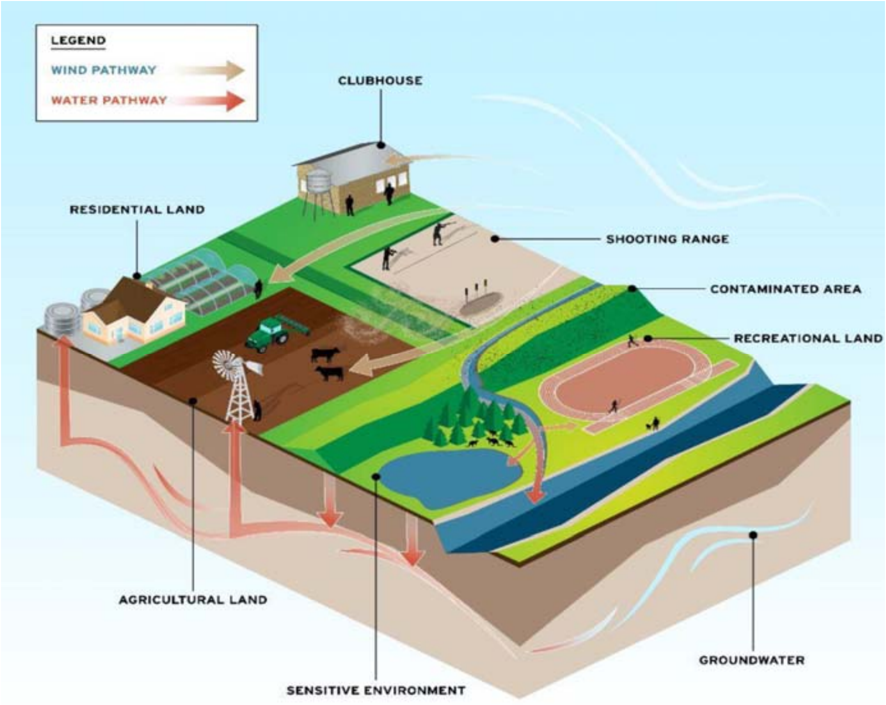

Figure 1-28: Simplified indicative model of water and wind pathways that can spread lead off site from a shooting range (Environmental Protection Authority Victoria (EPA), 2019).

Environmental Protection Authority Victoria (EPA) (2019), when reviewing water and wind pathways, noted that water can move dissolved lead or fine lead in particles which has bonded to soil or organic matter. When lead is in its solid metallic form it is least likely to spread, but after it is weathered and exposed to air, soil and water it can be more mobile. Dissolved lead can be washed away by rainwater and flushed into rivers, lakes, dams and groundwater. Rivers and streams can spread contamination downstream into wetlands, farms, etc. It is important to note that groundwater is both a pathway and a potential receptor. When impacted water reaches groundwater, the contamination can continue to travel underground.

The more rainfall, the more likely it is that surface water will spread contaminants. It is also important to consider how long water remains on the surface of the range. In boggy and wet conditions lead can weather more easily and become more mobile. The slope of the land gives a good indication of how water can spread contamination. It is important to consider both the surface runoff that may flow onto a range as well as runoff leaving a range (Environmental Protection Authority Victoria (EPA), 2019).

Wind can blow dust particles to other areas. There are two kinds of dust which are relevant to shooting ranges, soil dust and lead dust (Environmental Protection Authority Victoria (EPA), 2019). When conditions are suitable, fine particles of contaminated soil may be blown from a shooting range as dust. There are many conditions[112] which influence the likelihood that dust could become airborne and the distance it could travel, including windy conditions, dry soil conditions, such as during summer and drought, fine soil particles, lack of wind breaks (such as trees, which can reduce windy conditions), lack of ground cover such as grasses and other vegetation. Small amounts of lead dust can also be released after firing.

[112] A combination of these conditions can be a strong indicator that wind could carry dust to a receptor. Similarly, if they are not present then it is less likely that wind poses risks.

Distribution of projectiles on the ground

A typical structure of pistol and rifle range can be divided into different segments based on the pollutant load. Different guidance or publications related to shooting ranges suggest slightly different segmentation of a typical (300 m) range. One of these (Swiss BAFU, 2020)[113] proposed a simplified segmentation, also indicating generally expected soil concentrations for different soil sectors:

- Sector including backstop berm, target stand and a band of land about 5 to 10 meters wide around the berm: pollution from lead normally exceeds 1 000 mg Pb/kg. More than 20 000 mg of bullets or their fragments per kg of earthy material can be found in this area. The lead content is in the same order of magnitude as that existing in exploitable deposits of the same metal (i.e. lead mining areas).
- The immediate surroundings of the backstop berm: here lead pollution often fluctuates between 200 and 1 000 mg Pb/kg.
- The areas farthest from the backstop normally show only concentrations of lead less than 200 mg Pb/kg.

Bullets primarily accumulate in the impact area in the backstop berm behind the targets, bullet traps, or other bullet collection structures. A small number of bullets end up in the intermediate area, other parts of the backstop berm, or even outside the range area, if the backstop berm is not sufficiently high or wide, as a result of missed shots or ricochets. At ranges with moving targets and modifiable ranges, the impact areas are not as clearly defined as at traditional rifle ranges; therefore, the metal distribution in the backstop berm is more even.

In sports where metal targets are shot, such as in biathlon and silhouette shooting, the bullet fragments against the target, and fine metal fragments spread to the surface layer of the range in the area surrounding the targets. Metal dust is also generated and accumulates in the surface layer of the target area when certain metal trap chambers are used. At silhouette ranges, the soil contamination spreads more evenly throughout the entire shooting range area, as there are several targets and low intermediate berms in the intermediate area.

At shotgun ranges, gunshot is dispersed across almost the entire surface layer of the range area due to the nature of the shooting activity. The flight distance of shot is directly proportional to their size[114]. Thus, at skeet ranges, gunshot spread over the firing sector to distance of around 200 m from the firing stand, and around 250 m at trap ranges. If larger shot are used at the ranges during practice, the shot may spread as far as over 300 m from the firing stand (Kajander and Parri, 2014). Terrain contours and trees have a significant effect on the spread of the shot, as do wind conditions.

1.5.3.7.1. Soil and surface water contamination

The mean content of lead in uncontaminated soils worldwide is reported to be 17 mg/kg (Steinnes, 2013). Alloway (1995) also reported the lead total metal content in unpolluted soils to be below 20 mg/kg for lead in remote or recently settled areas. Although pollution of surface soils on the local scale associated with mining and smelting of lead metal and addition of organic lead compounds to petrol have often been reported as a major pollution

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[113] The report was made by the Swiss Federal Office for the Environment, Division Soil and biotechnology, Section Contaminated sites. The purpose of the report was to explain the procedure to receive Federal funding for measurements like investigation and remediation of municipal shooting ranges. Lead levels reported were based on the results of fields investigations performed in Switzerland (more than 1 000 fields).

[114] At a rough estimate, gunshot fly many hundreds of metres (Finnish BAT)

source, other significant sources of soil pollution are shooting ranges and sewage sludges[115] (Steinnes, 2013).

The concentration of lead in soil at shooting ranges (and other relevant information) is discussed in detail in Annex B, section B.9.1.3.4. In general, in areas of lead ammunition deposition, soil lead concentrations can be extremely elevated, e.g. from a few to hundreds of times higher than in control soils (also reported in Pain et al. (2015)) and significantly higher than in uncontaminated soils. Lead content in shooting range soils may even reach values comparable to those found in lead mining areas.

Dinake et al. (2019) reviewed literature from 1983 to 2018 to provide an overview on the pollution status of shooting range soils from lead. Lead concentration as high as 97.6 g/kg has been measured in a shooting range soil in the United States of America (Clausen and Korte, 2009), 67.0 g/kg in Canada (Laporte-Saumure et al., 2012), 29.2 g/kg in Japan (Hashimoto et al., 2009), 384 g/kg in Botswana, Africa (Sehube et al., 2017), 300 g/kg in the Netherlands and 206.6 g/kg in New Zealand. One of the first studies with assessment of lead pollution of shooting ranges was carried out by Adsersen et al. (1983) some 35 years ago who found 200 – 300 g of lead per square meter of the studied site which had been in operation for 14 years. The accumulation of lead into shooting range soils and nearby environment has seen drastic surge in recent years reaching highs of 200 g/kg (Rooney and McLaren, 2001) and 300 g/kg in berm soils of a shooting range (Van Bon and Boersema, 1988).

While the areas closest to (< 100 m) and furthest from (> 180 m) the firing position are comparatively less contaminated in shotgun ranges, they are still likely to have high levels of lead contamination compared to normal background levels in agricultural environments. For this reason, shooting ranges should not neglect these areas and actively manage the entire shot fall zone (Environmental Protection Authority Victoria (EPA), 2019).

In agricultural soils close (10 m) to a shooting range, lead was concentrated in the arable layer at total concentrations ranging from 573 to 694 mg/kg (Chrastný et al., 2010)[116].

Lead concentrations in some shooting ranges have also been reported to reduce plant dry weight, photosynthesis, water absorption and root growth (Koeppe, 1977).

A linear correlation between lead in soil and bioaccessible lead concentrations in vegetation has been demonstrated (see Figure 1-29) at rifle and pistol firing ranges (Bennett et al., 2007).

[115] At the EU level no common limits for soil quality or soil pollutants as lead is currently established, apart from one exception: the Sewage Sludge Directive in its annexes defines limits for heavy metals (including lead) in agricultural soils on which sewage sludge is applied.
[116] SPLP lead concentration of up to 24.0 µg/l

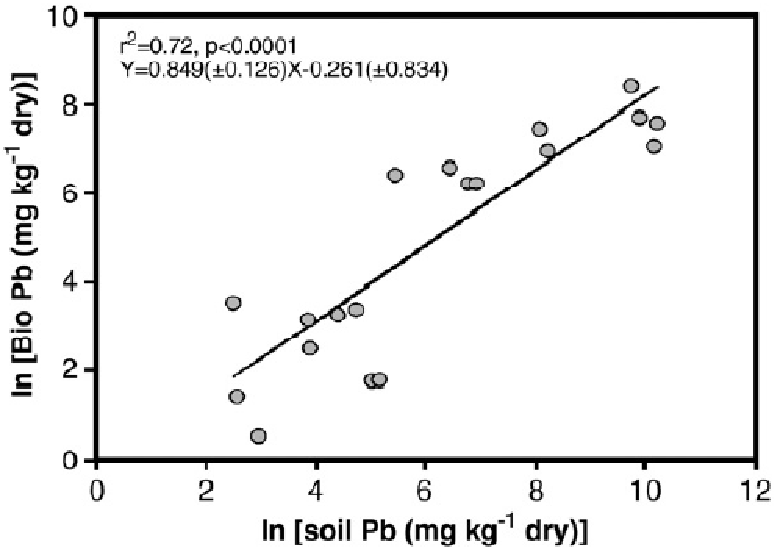

Figure 1-29: Correlation between ln-transformed bioaccessible lead concentrations in vegetation and soil lead concentrations (Bennett et al., 2007)

Concentrations of lead in the oilseed rape plants (*Brassica napus* L.) were largest in the shooting range area of most intense lead shot deposition (>5 000 mg/kg); in root samples the lead concentration exceeded 400 mg/kg. The authors also reported reduced crop density of plants grown within a shot fall zone at soil lead concentrations 1 500 to 10 500 mg/kg (Mellor and McCartney, 1994).

Turpeinen et al. (2000) examined the effects of pine (*Pinus sylvestris*) and liming (pH-change with $CaCO_3$) on the mobility and bioavailability of lead in boreal forest soil, previously used as a shooting range area, under laboratory conditions. Solubility and mobility of lead were measured, and bioavailability of lead was assessed directly using a luminescent bacterial sensor for lead. Lead concentration in the soil (shot removed) was 9 804 ±1 599 mg/kg for top soil (0 - 5 cm) and 325 ± 96.5 mg/kg in mineral soil (5 - 20 cm). Control values were 32.7 ± 5.7 and 17.6 ± 6.3 mg/kg, respectively. Lead concentration in pine seedlings (n = 3) were 2 720.9 ± 471.9 mg/kg in roots, 76.6 ± 62.6 mg/kg in stem, and 5.5 ± 3.1 mg/kg in needles. The pine seedlings reduced lead concentrations of drainage water from 198 ± 13 µg/L without pine seedlings to 101 ± 10 µg/L with pine seedlings.

In agricultural soils very close (10 m) to a shooting range, Chrastný et al. (2010) measured increased lead concentrations in the biomass of spring barley (*Hordeum vulgare* L.) mainly in roots (138 versus 11 mg/mg) and leaves (16 versus 1 mg/kg) but also in stems (4.2 versus 1.6 mg/kg) and spikes (2.4 versus 1.2 mg/kg). The authors identified two possible pathways of lead: (1) through passive diffusion-driven uptake by roots and (2) especially through atmospheric deposition.

Ma et al. (2002) and Cao et al. (2003) performed a study focussing on weathering of lead bullets and its effect on the environment at five outdoor shooting ranges in Florida, US. The lead concentrations in bermudagrass along the central transect of Ranges 3 and 5 are shown in Table 1-24. Generally, lead concentrations in grasses grown close to berms contained more lead, which is attributable to the fact that soils close to the berms contained more total lead and plant-available lead. Compared with the lead concentrations in the roots (up to 1 342 mg/kg), lead concentrations in grass shoots were lower (<806 mg/kg). However, there is still a considerable amount of lead being transported into the aboveground biomass.

Table 1-24: Lead concentration in soil and bermudagrass growing on shooting ranges (Cao et al., 2003)

Range	Distance (m)	Lead concentration (mg/kg dry weight)			
		Soil total	Plant-available	roots	shoots
3 (CWR)	1.5	354	12.1	512	324
	31.5	148	5.61	115	86.7
	61.5	464	73.2	1 166	511
	91.5	6 800	136	1 342	806
5 (MHR)	1.5	1 066	6.75	438	134
	31.5	562	46.3	769	500
	61.5	1 018	28.2	698	518
	91.5	2 715	68.2	952	500

Dallinger (2007) reported the lead concentrations in samples from plants growing in front of berms with 19-34, 1.5-13, and 9.6-17 mg/kg and for plants growing on berms with 175-4 700, 37-835, and 580-715 mg/kg. The type of plants sampled is not mentioned.

The Dossier Submitter notes that within an EU project, metals in topsoil were analysed according to the standards as defined in the Finnish legislation for contaminated soil. For lead, the threshold value that indicates the need for further assessment of the area was set at 60 mg/kg. The lower guidance value indicating a risk for human health has been set at 200 mg/kg and the higher guidance value indicating an ecotoxicological risk at 750 mg/kg (Tóth et al., 2016)[117].

In general, surface water runoff is one of the main pathways for lead and other contaminants to spread from shooting ranges (Environmental Protection Authority Victoria (EPA), 2019).

Lead ammunition accumulated in shooting ranges represents a hot-spot of pollution which may result in leakage of lead polluted water into streams and lakes (Mariussen et al., 2017). Therefore, surface runoff can affect water sources which may also be used for the production of drinking water. In addition to surface water (as rivers, lakes and wetlands), surface runoff can also contaminate nearby land..

The mobility of lead in surface runoff depends on the soil conditions and measures applied to limit lead mobility. The number of shooting ranges where surface runoff is regularly collected and lead concentration measured is not known in the EU. However, as described in Section 1.4.4.2.2.4, monitoring of lead concentration in soil or runoff waters is not a legal

[117] The Dossier Submitter also acknowledges the findings from Carlon (2007) that the *"derivation methods of Soil Screening Values (SVs) have both scientific and political basis and that they differ from country to country. In relation to the common environmental policies in Europe, this variability has raised concern among both regulators and risk assessors".* A new publication by the European Environment Agency and the European Topic Centre on urban, land and soil systems on functional soil quality indicators may become available at the end of 2021 and provide updated information on lead concentration limits in soil in the EU.

requirement included in a site permit or license in many European countries.

Mariussen et al. (2016) (also cited in comment #3343), report about an environmental survey performed in the Lake Kyrtjønn in Norway located within an abandoned shooting range and in the nearby reference Lake Stitjønn, having quite similar water chemistry. The authors note that in Norway (military) ranges can also be located in recreational areas which are popular for game hunting and fishing. The lake Kyrtjønn receives contaminated drainage water from several small creeks (Forsvarsbygg, 2011). Mariussen et al. (2017) indicated that in Lake Kyrtjønn the total water concentrations of lead (14 µg/L) was elevated compared to the nearby reference Lake Stitjønn where the total concentrations was 0.76 µg/L. The authors reported that the brown trout *(Salmo trutta)* from Lake Kyrtjønn had very high concentrations of lead accumulated in bone, kidney and the gills, and ALA-D analysis showed a strong inhibition of the enzyme activity in the blood. The low pH of the water in Lake Kyrtjønn appeared to be the most important factor for the high lead accumulation in the fish tissue. The authors concluded that the adult brown trout as well as fertilized eggs and alevins, may be subjected to chronic exposure to lead as a consequence of the contaminated runoff water from nearby shooting grounds.

In two shooting ranges in Florida, lead concentrations in retention ponds were measured with 289 µg/L and 694 µg/L. In another range, lead concentrations in a retention pond and a lake close to the range were low with 8 µg/L (Ma et al., 2002). According to investigations in Finnish shooting ranges (Kajander and Parri, 2014), lead and the other metals were found to migrate from the shooting range via surface runoff. Total lead concentration was >50 µg/L for 7/18 samples (39 %) and 10-50 µg/L for 4/18 samples (22 %). Soluble lead concentration was >50 µg/L for 3/8 samples (38 %) and 10-50 µg/L for other 3/8 samples (38 %) (Ma et al., 2002). According to investigations in Finnish shooting ranges (Kajander and Parri, 2014), lead and the other metals were found to migrate from the shooting range via surface water. Total lead concentration was >50 µg/L for 7/18 samples (39 %) and 10-50 µg/L for 4/18 samples (22 %). Soluble lead concentration was >50 µg/L for 3/8 samples (38 %) and 10-50 µg/L for other 3/8 samples (38 %).

1.5.3.7.2. Lead poisoning of ruminants and poultry

Braun et al. (1997) reported that five calves were put on pasture in the target area of a shooting range. Acute lead poisoning occurred in one of the calves after five days of grazing, the remainder became ill one to three days later. The concentration of lead in the dry matter of a grass and a soil sample from the target zone of the shooting range were 29 550 mg/kg and 3 900 mg/kg, respectively.

Muntwyler (2010) reported acute poisoning and mortality of two cows that were grazing behind the berm of a shooting range in Aargau (Switzerland). An investigation of the area revealed that the fences were located closer to the berm (2 and 5 m) than allowed (10 m fenced area and an additional 20 m surrounding the fence for which grazing is banned).

In general, the available evidence does not suggest that risks from the direct ingestion of lead gunshot are very likely to occur (Allcroft (1951) cited by Scheuhammer and Norris (1995)). Bjørn et al. (1982) noted no elevation in blood lead concentrations of heifers grazing in pastures where upland bird hunting was common, and Clausen et al. (1981) reported that cattle retaining up to 100 lead pellets in the reticulum nevertheless had normal lead concentrations in liver and kidney tissue.

However, other studies indicate that dairy cattle fed grass or corn silage contaminated with lead gunshot can suffer from lead poisoning (Howard and Braum, 1980, Frape and Pringle, 1984, Rice et al., 1987).

Rice et al. (1987) reported that in 14 steers fed chopped silage prepared from a field that had been used for clay target shooting, one animal died, a second demonstrated clinical signs of lead poisoning, and all animals had substantially inhibited ALAD enzyme activity. It was further noted that even when lead pellets were removed, samples of silage still contained an average of 0.23 % lead, which would have resulted in the ingestion of about 18 g of lead per steer per day, based on the consumption of about 8 kg of silage per animal. Rice et al. (1987) suggested that this concentration of lead would have been sufficient to cause toxicity, independent of ingestion of any lead gunshot pellets. The mechanical/chemical processes of producing silage from material containing lead pellets and/or uptake of lead by plants growing in soils contaminated with metallic lead may be more important risk factors than ingestion of lead shot pellets per se (Scheuhammer and Norris, 1995).

Properly made silage is very acidic (pH< 4.8), and in such an acid environment a proportion of the metallic lead is converted into a more soluble lead salt (St. Clair and Zaslow, 1996, Swain, 2002).

Some case studies are presented in the risk characterisation section. The following table summarises examples of levels of lead in different tissues following ingestion of lead shot.

Table 1-25: Tissue levels of lead in ruminants following ingestion of lead gunshot

Pb source (country)	N	Pb exposure	Tissue Pb levels					Reference
			Blood	Liver	Kidney	Muscle	Milk	
Cattle								
Lead shot (US)	22	NR	290 µg/L (median)	-	-	-	-	Bischoff et al. (2012)
Silage contaminated by lead shot (US)	6	649 mg/kg bw/d	882 – 1220 µg/L (range)	-	-	-	0.0619 – 0.4657 mg/L (range)	Bischoff et al. (2014)
Lead shot (UK)	22	NR	1620 µg/L (mean)	-	-	-	-	Payne et al. (2013)
Lead shot contaminated grass silage (US)	12	NR	2300 µg/L (mean)	-	-	-	-	Rice et al. (1987)
Local bird shooting field (Denmark)	24	NR	28 µg/L (max)	-	-	-	-	Bjørn et al. (1982)
Sheep								

Pb source (country)	N	Pb exposure	Tissue Pb levels					Reference
			Blood	Liver	Kidney	Muscle	Milk	
Grass contaminated by shooting range (Norway)	23	0.33 mg/kg bw[118]	-	0.3 mg/kg (mean)	-	-	-	Johnsen and Aaneby (2019)

Notes: N: Number of animals; NR: Not reported; -: Not measured

Poultry may also ingest lead from ammunition (as also noted by comment #3250).

In relation to different domestic avian species, Payne et al. (2013) discussed a number of case reports associated with clay pigeon grounds where mortality of poultry and some potential food safety incidents were recorded. In one case, lead poisoning was confirmed in a flock of 2000 free range laying hens which were 42 weeks into lay. The hens' range was next to an active clay pigeon area. The flock had never reached its expected production potential and mortality had slowly increased. Post-mortem examinations revealed egg peritonitis and that lead gunshot was consistently present in the gizzards of birds. Subsequent whole egg analyses revealed lead concentrations of up to 2550 µg/kg lead.

In another case, lead poisoning was confirmed in a group of ducks being reared for shooting. There were 1200 (19-week-old) ducks in three groups of approximately 400 birds, each group with a pond. Clinical disease was occurring in approximately 3–5 per cent ducks from one pond. Ducks presented with weight loss and recumbency, and at post-mortem examination numerous lead gunshot were observed in the gizzards. Liver and kidney lead concentrations were 112 and 52 mg/kg wet matter. The source of lead gunshot was a recently set up clay target shooting range approximately 150 m away from the affected pond.

Due to the lack of specific data, exposure of other taxa is not elaborated by the Dossier Submitter, but cannot be ruled out.

1.5.4. Environmental risk characterisation

The identified (main) risks to the environment for each of the uses assessed are summarised in Table 1-26 and are discussed in the following sections.

Table 1-26: Identified environmental risks with regards to uses[119]

Use #	Use name	Identified risk
1	Hunting with gunshot	Primary and secondary poisoning of wildlife (birds)
2a	Hunting with bullets - small calibre[1]	Secondary poisoning of wildlife (birds)
2b	Hunting with bullets - large calibre	Secondary poisoning of wildlife (birds)

[118] Worst case scenario based on a calculated intake from ingestion of soil whilst grazing on the contaminated land. The estimated intake attributed to grass ingestion alone was 0.0074 mg/kg bw

[119] Risks to humans via the environment are discussed within the human health risk assessment.

Use #	Use name	Identified risk
3	Outdoor sports shooting with gunshot	Primary poisoning of wildlife (birds) Ingestion of contaminated soil and vegetation by livestock and secondary poisoning of livestock (ruminants) via silage grown on shooting ranges/areas used as agricultural land. Primary poisoning (ingestion of lead gunshot) by poultry (see also comment #3250) when feeding on land previously/also used for shooting or nearby a shooting range where lead may fall outside the range perimeter. Soil, groundwater and surface water contamination
4	Outdoor sports shooting with bullets	Ingestion of contaminated soil[120] and vegetation by livestock (ruminants) and wildlife on shooting ranges/ areas used as agricultural land. Soil, groundwater and surface water contamination
5	Outdoor shooting using airguns	Same as use 4 with additional potential for primary poisoning of wildlife (birds) if pellets are not contained.
6	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments	Same as use 4
7	Lead in fishing sinkers and lures	Primary and secondary poisoning of wildlife (birds) – when the weight of the sinker or lure is ≤ 50 g
8	Lead in fishing nets, ropes and lines	No risk to birds or other taxa identified[121].

[1] This use includes hunting with an airgun

1.5.4.1. Risk of primary and secondary lead poisoning of wildlife (birds)

In this section a single environmental risk characterisation in relation to the primary and secondary poisoning of wildlife (birds) for the relevant uses (1,2,3,5,7) is presented. This is on the basis that it was not practicable or meaningful to disaggregate the risks to birds resulting from the different uses as they are often the result of a combined source of exposure. Nevertheless, where relevant a more detailed discussion of the risks from specific uses is undertaken.

When considering risks to birds related to the ingestion of lead ammunition and fishing tackle, adverse impacts have been documented worldwide, as discussed in the previous sections. Therefore, there is no advantage to undertake a risk characterisation based on comparing PEC/PNEC ratios.

[120] Mainly soil in the backstop berm area.
[121] In Use 8, lead is enclosed/embedded/threaded in nets, ropes and lines (CfE #1220 from Danish EPA), and lead from this type of fishing tackle is not typically ingested by birds (CfE #936 from UK EPA).

This assumption is also supported by agreements (AEWA, CMS, CMS Raptor MoU[122]), bans[123], wildlife conservation projects[124] and recommendations under UNEP AEWA auspices (UNEP-AEWA, 2011)[125] throughout the world aiming to limit the use of lead ammunition and fishing tackle in response to these risks or to phase out the use of lead ammunition and lead fishing tackle.

Therefore, the risk characterisation related to birds (primary and secondary poisoning) summarises information on the following:

1. Selected case studies on the impacts on birds;
2. Examples of comparison of the lead concentration in various tissues of birds, with indicative thresholds of adverse effect in birds;
3. Mortality in the EU;
4. Information on lead as a co-factor in other causes of mortality.

1.5.4.1.1. Selected case studies on the impacts on birds

- Primary poisoning from ingestion of lead gunshot and fishing tackle: Grey partridges (lead gunshot), mute swans (fishing tackle)
- Secondary poisoning from ingestion of lead ammunition: Eurasian buzzards (lead gunshot), different species (lead ammunition).

Potts (2005) reported the results of an assessment of the extent of lead poisoning in wild grey partridges (*Perdix perdix*) in the UK, based on post mortem analysis of 1 318 birds collected between 1947 to 1992. Grey partridges are granivorous birds, typically ingesting lead gunshot while foraging for seeds or grit.

Over the period between 1947 and 1992, post-mortem examinations were carried out by three successive pathologists, with the only main difference (as regard the applied methodology) that during the period 1947–1958 sublethal ingestion was not recorded. The results of the post-mortems from each period are given in Table 1-27.

Table 1-27: Results of post-mortem per period (Potts, 2005)

Period	Total post-mortems	Ingested lead cited as cause of death
1947-1958	872	3 (0.3 %)

[122] The Memorandum of Understanding on the Conservation of Migratory Birds of Prey in Africa and Eurasia (Raptors MoU). The European Union is a Signatory Party of this not-legally binding agreement since 2011. https://www.cms.int/raptors/en/signatories-range-states

[123] In Europe bans on the use of lead gunshot in the terrestrial environment are in place in Denmark and the Netherlands. In Denmark there is also a ban on the import and placing on the market of fishing tackle.

[124] For example, across Europe there have been several initiatives to reduce the use of lead ammunition and promote non-lead hunting practices. In the Italian Alps the use of lead ammunition has been banned in the Stelvio National Park and Sondrio Province. At Hohe Tauern National Park in Austria, in the Pyrenees, and as part of GypConnect and GypHelp LIFE conservation projects, at the Cévennes National Park in the French Massif Central, and in Haute-Savoie, pilot project where hunters try non-lead ammunition are being carried out. More recently in the Lombardia region (Italy) a regional Decree (n. 13690 dated 11/11/2020) foresees a transition towards non-lead ammunition for hunting ungulates and subsequently birds species in the terrestrial habitats. The Generalitat Valenciana (Spain) has banned the use of lead ammunition in two areas in Maestrazgo to protect vultures there including birds released as part of the new bearded vulture reintroduction project. (https://www.4vultures.org/research-into-the-lead-contamination-of-wild-vultures/)

[125] Under the African-Eurasian Migratory Waterbird Agreement (AEWA) auspices, based on existing data and literature, in 2012 the Technical Committee recommended to the 5th Meeting of the Parties to AEWA (MOP5), to decide to amend the AEWA Action Plan as follows: "Parties shall endeavour to phase out the use of lead shot for hunting in wetlands and the use of lead fishing weights as soon as possible in accordance with self-imposed and published timetables".

Period	Total post-mortems	Ingested lead cited as cause of death
1963-1969	224	9 (4.0 %)
1970-1992	222	6 (2.7 %)
Total	1 318	18 (1.4 %)

The number of gunshot found in the gizzards varied between 1 and 34. It was estimated that all of the birds that contained three or more ingested lead gunshot had died as a result of lead poisoning.

Based on the available data, Potts (2005) compared the incidence of ingested lead gunshot in grey partridge with the situation in waterfowl in the UK where extensive surveys during 1979 – 1981 showed that 8.6 ± 2 % of waterfowl had ingested lead gunshot (Mudge, 1983). The overall incidence in all the grey partridges found dead by Potts (2005) study during 1963 – 1992 was 4.5 ± 1 %.

Potts (2005) also reported the results of a study on chick food from 1968 to 1978 on the Sussex Downs, where the gizzards of 29 wild chicks aged up to 6 weeks were examined. The results of the study on chick, from the examination of gizzard contents, indicated that that two (6.9 ± 4.7 %) of 29 chicks contained lead gunshot.

Meyer et al. (2016) estimated the effects of ingestion of lead gunshot in terrestrial habitats (on small-game hunting areas) for grey partridges at population level. The grey partridge population that the authors chose to model was the continental European population of grey partridges, which was stable in the early 20th century but has declined since the 1970s. Lead gunshot ingestion reduced population size of partridges by 10 %, and when combined with bait and pesticide poisons, by 18 %.

As recently reviewed by Grade et al. (2019), mortality of wildlife from lead fishing tackle ingestion was first documented in mute swans (*Cygnus olor*) in the United Kingdom (UK). Lead fishing tackle accounted for 50 % of documented swan mortalities throughout England in 1980–1981; approximately 3 000–3 500 swans in the UK died annually as a result of lead poisoning. Researchers also documented declines in local populations amid high rates of mortality from lead tackle ingestion. The majority (>70 %) of documented lead poisoned swans had ingested split shots (Birkhead, 1982, Sears, 1988) and about 7 % had ingested larger weights (Sears and Hunt 1991). In comparison, less than 2 % of cases of lead poisoning among mute swans in the UK were attributable to ingested lead gunshot ammunition (Sears and Hunt, 1991). Lead tackle ingestion impacted both adult swans and cygnets (Birkhead, 1982, Wood et al., 2019, Sears, 1988, Kirby et al., 1994). After legislation in England and Wales to ban the sale and use of lead fishing weights took effect in 1987, mute swan deaths from lead poisoning declined from 34 % of documented mortalities between 1971 and 1986 to 6 % between 1987 and 2014 (Wood et al., 2019)

Carneiro et al. (2016) reported three cases of lead poisoning associated with the ingestion of lead gunshot in adult female griffon vultures (*Gyps fulvus*) in the Iberian Peninsula, where their conservation status is considered to be near-threatened. The birds were found prostrate and immediately transferred to a wildlife rehabilitation centre, where they died within 24 hours. Necropsy and histopathological examinations were done in two birds and metal analyses were done in all birds to determine their cause of death. In one vulture, nine uneroded lead pellets were recovered from the stomach, and moderate to severe hemosiderosis was seen histologically in the liver, lungs and kidneys. Diagnosis of lead poisoning was confirmed by results of metal analyses, which revealed extremely high lead concentrations in blood (969-1 384 µg/dL), liver (309-1 077 µg/g dry weight), and kidneys (36-100 µg/g dry weight) in all three vultures.

Taggart et al. (2020) have recently published a comprehensive analysis regarding tissue concentrations and origins of lead in Eurasian buzzards (*Buteo buteo*). The study suggested that most of the lead acquired by Eurasian buzzards is probably obtained when they prey upon or scavenge gamebirds and mammals shot using lead gunshot. Eurasian buzzards found dead in the United Kingdom during an 11-year period were collected and the concentrations of lead in the liver and femur were measured. Concentrations consistent with acute exposure to lead were found in 2.7 % of liver and concentration consistent with exposure to lethal levels were found in the femur of 4.0 % of individuals. Lead concentration in the femur showed no variation among or within years but was greater for old than for young birds. The lead concentration in the liver was not influenced by age but varied among years and showed a tendency to increase substantially throughout the hunting season for gamebirds. The resemblance of the stable isotope composition of lead from buzzard livers to that of lead from the types of shotgun ammunition increased significantly with increasing lead concentration in the liver. Stable isotope results were consistent with 57 % of the mass of lead in livers of all of the buzzards sampled being derived from gunshot, with this proportion being 89 % for the birds with concentrations indicating acute exposure to lead.

Berny et al. (2015b) analysed the cause of death of 170 scavenger birds found dead in the French Pyrenees over a seven-year period (2005-2012). All birds found dead were submitted to full necropsy, X-Ray, parasitological and toxicology screenings (including heavy metals). In total 8 bearded vultures, 120 griffon vultures, 8 Egyptian vultures and 34 red kites were collected and analysed. Results indicated that poisoning was by far the most common cause of death (24.1 %), followed by trauma/fall (12 %), bacterial diseases and starvation (8 %) and electrocution (6 %). Illegal use of banned pesticides was responsible for most of the cases of poisoning (53 % of all poisoning cases) but lead poisoning was also important (17 % of all poisoning cases). Lead isotopic signature could be associated primarily with hunting ammunition. Lead poisoning was also associated with trauma, indicating that lead could be a significant contributor to different causes of death. Lead poisoning cases (all 7 cases) were identified in the fall and winter.

1.5.4.1.2. Comparison of lead concentration in various tissues of wild birds

Table 1-28 compares lead concentrations in various tissues of wild birds with indicative thresholds of adverse effect (examples for primary and secondary poisoning).

Table 1-28: 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 effects
Ferrandis et al. (2008) 2004; n = 2 partridges with ingested shot, Spain (birds shot at the beginning of the hunting season in a driven shooting estate, private upland small-game hunting estate, where frequency of	liver Pb (µg/g)d.w. 2004, mean 21.51 (range 0.19 - 42.83)	Mean concentration observed in liver greater than indicative threshold for subclinical poisoning.

Details of study (geographical, temporal and species scope), Reference	Tissue type and concentration	Interpretation relative to indicative thresholds of adverse effects
partridge hunting events per yearranges 0 - 2). Total sample n = 10 (n = 8 being partridges without lead shot ingested)		
Butler et al. (2005) (1997), n = 95 female pheasants, UK (overall lead shot ingestion rate 3 %)	Bone: 7 - 445 ppm d.w. Median: 48.8 ppm d.w.	Median concentration observed in bone greater than indicative threshold for severe clinical poisoning
Carneiro et al. (2016) N = 3 Griffon vultures, ingestion of lead shot, Iberian Peninsula.	Blood: (969 - 1384 µg/dL) liver (309 - 1077 µg/g d.w.),	Blood and liver: severe clinical poisoning
Franson et al. (2003) 1995 - 1999, n = 2 240 individuals of 28 species, ingestion of lead fishing tackle (US). (Ingested lead fishing tackle was found in eleven Common Loons, ten Brown Pelicans, one Double-crested Cormorant and one Blackcrowned Night Heron)	Of waterbirds with ingested lead sinkers: 64 % and 71 %, respectively, had lead concentrations of ≥ 2 ppm wet weight in their livers or 0.2 ≥ ppm wet weight in blood. Maximum lead concentrations in liver and blood were 26.0 ppm and 13.9 ppm wet weight, respectively. *(In birds without ingested lead liver lead concentrations were ≥ 2 ppm wet weight in 0.7 % of those tested (N = 866) and blood lead concentrations were 0.2 ≥ ppm in 2.2 % (N = 742)*	Liver and blood levels (of waterbirds with ingested lead sinkers, 64 % and 71 %, respectively) greater than indicative threshold for background level, with maximum levels indicating severe clinical poisoning
Monclus et al. (2020)[1]	See Annex B (section B.9.1) Studies with evidence of ammunition related lead exposure recording lead tissue concentrations	See Annex B (section B.9.1) Studies with evidence of ammunition related lead exposure recording lead tissue concentrations

Notes: 1 - Monclus et al. (2020) lists 114 studies of lead contamination in Europe with information of exposure source and tissue concentrations. 54 studies with ammunition related exposure are presented in Annex B. Monclus et al. (2020) concluded that vultures and facultative scavengers (especially golden eagle, common buzzard and white-tailed sea eagle) accumulate the highest lead concentrations in tissues and are at highest risk of lead poisoning.

1.5.4.1.3. Data on bird mortality in the EU

Mortality of wildlife from lead poisoning from ammunition source is often a neglected issue as many (e.g. hunters) state they have never found a lead poisoned animal (Pain et al., 1998). However, it is widely recognised that carcass survival from scavenging and searcher efficiency are two key factors known to bias the mortality estimates of any wild species

(Prosser et al., 2008, Etterson, 2013, Teixeira et al., 2013).

Prosser et al. (2008) lists 19 carcass removal studies where the mean observed carcass survival time ranges from 0.65 to 10.4 days. Carcass persistence seems to be shorter for smaller animals such as small birds (Santos et al., 2011, Ponce et al., 2010). It is likely that the mortality from lead poisoning may often result in frequent and mainly invisible losses of birds, in small numbers, that remain undetected (Stutzenbaker et al., 1986, Scheuhammer, 1987, Newth et al., 2013). Poisoned birds often become reclusive and carcasses may be scavenged before being detected (Sanderson et al., 1986, Stutzenbaker et al., 1986, Newth et al., 2013, Pain, 1991).

Humburg and Babcock (1982) display the difficulty of finding intact waterfowl carcasses in search of documenting non-hunting waterfowl losses; only 22.4 % (934 of 4165) of waterfowl carcasses were found intact in the study and the rest was described as piles of feathers, wings and bones and partially scavenged carcasses.

The available data for lead ingestion in terrestrial bird species is more limited than that for waterbirds (as previously assessed by ECHA in 2017[126]). However, by focussing the assessment on the species identified to be at greatest risk of ingesting lead ammunition (as described in Section 1.5.3.3) it is possible to estimate a plausible annual mortality for terrestrial species in the EU as a result of the use of lead ammunition and fishing tackle.

Pain et al. (2019b), based on a revised Bellrose methodology, estimated that 0.56 % and 0.32 % of the UK pheasant and red-legged partridge population, respectively, die annually from lead ingestion. The authors consider this as an underestimation because juveniles were not included and it does not account for sub-lethal poisoning, possibly leading to additional mortality (see next paragraph). Meyer et al. (2016) indicated that "percentage of deaths from lead shot ingestion for grey partridge were modelled as 4 %, for direct proximal cause of death" based on several studies reviewed by the authors. Potts (2005) based on post-mortem analysis of 1 318 dead wild grey partridges collected between 1947 to 1992, found that mortality over different periods ranged from 0.3 % to 4 %. Therefore, annual mortality (via primary ingestion) for many bird species (all identified as being at greatest risk) might be expected to vary from 0.3 % to 4 %. The Dossier Submitter assumed a range for annual mortality of 0.5 - 2.0 % as the most likely mortality range for the group of terrestrial bird species assessed in Section 1.5.3.4 (and summarised in Section 1.5.4.2); a central value of 1 % has been used for the impact assessment (see Section 1.8.5). Therefore, the 1 % mortality rate for primary ingestion of lead gunshot can be considered as an average applicable across the range of reported mortality rates in the literature. This recognises that there is some variation in species susceptibility to lead exposure (i.e. recognising that some terrestrial bird species may have potentially lower or higher sensitivity to the effects of lead)[127].

As reviewed by Pain et al. (2019b), lead from ammunition is available to predators and scavengers in the flesh of their prey either as whole gunshot/bullets or ammunition fragments. There is extensive literature linking the lead poisoning of predators and scavengers to ammunition sources (via secondary poisoning). This includes significant evidence: for example, temporal and spatial correlations between elevated tissue lead levels in birds and hunting activities and lead isotopic studies to match tissue lead concentrations with sources.

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[126] ECHA (2017). Annex XV restriction report on lead in gunshot.
[127] In Annex B.7.2.1.2. data on experimental lead exposures on some species of gamebirds and the associated caveats when extrapolating findings to the wild setting are discussed.

Mortality related to ingestion of lead ammunition via secondary poisoning is indeed expected to vary between species identified as being at greatest risk (assessed in section 1.5.3.5 and summarised in section 1.5.4.2). In any case, it is not considered possible to estimate the percentage of birds dying due to the secondary ingestion of lead gunshot versus secondary ingestion of bullets fragments because birds may feed on different types of prey.

Comment #3367 (ISPRA) proposes a quantification of the annual mortality for ten European raptor species[128] based on data extracted from published scientific literature. The annual mortality due to the ingestion of lead ammunition is estimated to be in a range between 0.30 % to 1.94 %. The authors note that this should be regarded as an underestimation because additional mortality from sublethal effects was not considered. A fraction of birds with sub-lethal lead concentration in their tissues, would die from collision, starvation or accident as a consequence of the impairment caused by lead poisoning. However, in areas with high exposure, mortality can be much higher than indicated in comment #3367. Helander et al. (2021), comment #3348, found that lethal poisoning occurred in Sweden in 24 % of white-tailed sea eagles *(Haliaeetus albicilla)* in areas with high exposure from hunting activities.

Taking into account data presented in comment #3343 (CMS ad hoc Expert Group) and comment #3367, the Dossier Submitter considers that direct mortality from secondary poisoning with lead ammunition within the overall group of affected species might be expected to vary within the range from 0.3 % to 2 %. Therefore, it could be assumed that at least about 1 % (rounded central value of the identified range) of the species affected by secondary poisoning die as a consequence of ingesting lead ammunition. This would not include additional mortality from sublethal effects. However, as highlighted by comment # 3343, biological impact of secondary lead poisoning should consider that any additional mortality rate in a long-lived species will also reduce population size much more than the same additional mortality rate in a short-lived species.

In general, lead poisoning (and consequent mortality) is likely to have a significant impact on long lived predatory and scavenger species that naturally have low reproductive rates, such as vultures. For predators and scavenging species with a critical conservation status, such as the bearded vulture (*Gypaetus barbatus*) - the rarest vulture in Europe, mortality of even a single individual may be of relevance to the survival of the species.

The available exposure data[129] (widely described in Section 1.5.3.5) confirm that lead continues to cause mortality in many raptor and scavenging species, as determined by diagnosed clinical cases and from the exceedance of lethal threshold levels (Monclus et al., 2020). Sources of lead poisoning are not limited to lead ammunition. For example, raptor species that feed on waterbirds are also at risk due to secondary ingestion of lead fishing tackle (Garvin et al., 2020).

In relation to bird mortality (AEWA-listed species) from ingestion of fishing tackle, no estimate on mortality of EU birds from the ingestion is currently available or possible due to the lack of adequate datasets. Although the extent of waterbirds mortality related to lead fishing tackle ingestion cannot be currently estimated, it can be expected to be high for a

[128] Golden eagle *(Aquila chrysaetos),* Griffon vulture *(Gyps fulvus),* Bearded vulture *(Gypaetus barbatus)*, Cinereous vulture *(Aegypius monachus),* Egyptian vulture *(Neophron percnopterus),* White-tailed eagle *(Haliaeetus albicilla),* Spanish imperial eagle *(Aquila adalberti),* Western marsh-harrier *(Circus aeruginosus),* Red kite *(Milvus milvus)*, Black kite *(Milvus migrans).*

[129] For example, the European Raptor Biomonitoring Facility (comment #3517) monitor contaminants in raptors (birds of prey): lead is one of the key contaminants monitored.

number of waterbird species (especially in relation to lead fishing sinkers) in areas with high fishing activity (UNEP-AEWA, 2011) and can be regarded as additional to the mortality occurring following the ingestion of lead gunshot. It is noteworthy that ingestion of even one lead sinker or jig of the minimum weight, can be lethal, as in the case of the ingestion of a single lead shot.

The Dossier Submitter also notes that lead poisoning from multiple sources (as lead gunshot and fishing tackle) concerns several European bird species that are considered to have vulnerable or endangered conservation status in the EU, notably the white-headed duck *(Oxyura leucocephala*) and marbled teal *(Marmaronetta angustirostris)*, especially in relation to lead fishing sinkers. For already threatened species, any additional mortality caused by lead fishing tackle ingestion may be of concern also for the survival of that species. Based on comment #3343, the inevitability of death following ingestion of the larger fishing weights should be taken into account.

In addition, it is essential to consider that some waterbirds may also feed in terrestrial environments and therefore become exposed to spent lead gunshot outside of wetlands. However, it is not possible to determine the percentage of waterbirds dying due to the ingestion of lead gunshot in terrestrial environment because it is not possible to distinguish between gunshot ingested in wetlands and gunshot ingested outside of wetlands. Waterbird species represent about 5 % of the overall affected birds in terrestrial environments (see Section 1.8.5).

1.5.4.1.4. Lead in ammunition and fishing tackle as a co-factor in other causes of mortality

Sublethal lead poisoning can increase the susceptibility of birds to other causes of death and may be the ultimate, underlying cause of some deaths. Sublethal lead poisoning may impair the immune system, increasing susceptibility to disease or increasing inattentiveness, which in turn increases susceptibility to accidents and predation that are reported as proximal causes of death (Meyer et al., 2016), (comment # 3343).

Sublethal lead poisoning can for example increase the probability of mortality from hunting (predation), collisions with objects (flying accidents) and illness or death from disease (Pain and Green, 2015, Golden et al., 2016, Kelly and Kelly, 2005, Scheuhammer and Norris, 1996). Newth et al. (2016) reported that birds with reduced body condition (being weaker) may be more susceptible to disease and other mortality factors.

In a study by Ecke et al. (2017) on Golden Eagles (*Aquila chrysaetos*), lead levels in blood were correlated with progress of the moose hunting season. Based on analyses of GPS tracking data, the authors found that sublethal lead concentrations in blood (25 ppb, ww) negatively affect movement behaviour (flight height and movement rate) of this scavenging species, increasing the risk of mortality through traffic accidents, collisions with power lines and other infrastructure. In a recent study (Singh et al., 2021), the authors showed that sub lethal concentrations can increase the probability of mortality by 3-4 fold in Golden eagles (comment #3436).

Comment #3359 (European Association of Zoo and Wildlife Veterinarians) notes that *"mortality and morbidity caused by lead from ammunition and fishing tackle in both wild and captive animals are probably underdiagnosed and underreported as the proximal cause of death might be more obvious e.g. predation, trauma or infectious disease, and contaminants surveillance is costly and may not be undertaken routinely."*

The Dossier Submitter considers that the absence of long-term wildlife surveillance programmes may explain the apparent lack of evidence of lead poisoning (and corresponding mortality) for some of the species assessed in the restriction proposal.

1.5.4.2. Species at risk of lead poisoning in the EU (use 1,2,3,5,7)

Based on the analysis provided in the previous sections, the following species are considered to be at greatest risk of lead poisoning from shooting and fishing (Table 1-29 and Table 1-30). It is noteworthy that other species, not in this list, might also be at some risk of lead poisoning. Specifically, based on the assessment made by the UNEP/CMS ad hoc Expert Group (comment #3343), many species (in the order of some hundreds) are at low or very low risk of lead poisoning. The impact assessment (in term of number of birds at highest risk) done by the Dossier Submitter is available in Section 1.8.5.

Table 1-29: EU Waterbird species at most risk of lead poisoning from primary ingestion of lead gunshot in the terrestrial environment and lead fishing tackle

Taxonomy	Common name	EU IUCN Red List Category / primary poisoning source relevant for the current restriction proposal[1]
Anas acuta	Northern Pintail	VU / lead shot in the terrestrial environment and lead fishing tackle
Anas crecca	Common Teal	LC /lead shot in the terrestrial environment and lead fishing tackle
Anas platyrhynchos	Mallard	LC /lead shot in the terrestrial environment and lead fishing tackle
Anser albifrons	Greater White-fronted Goose	LC/ lead shot in the terrestrial environment
Anser anser	Greylag Goose	LC/ lead shot in the terrestrial environment
Anser brachyrhynchus	Pink-footed Goose	LC/ lead shot in the terrestrial environment
Anser caerulescens	Snow Goose	NE/ lead shot in the terrestrial environment
Anser erythropus	Lesser White-fronted Goose	CR/ lead shot in the terrestrial environment
Anser fabalis	Bean Goose	LC/ lead shot in the terrestrial environment
Branta bernicla	Brent Goose	LC /lead shot in the terrestrial environment
Branta leucopsis	Barnacle Goose	LC /lead shot in the terrestrial environment
Branta ruficollis	Red-breasted Goose	NT/ lead shot in the terrestrial environment
Branta canadensis	Canada Goose	NE/lead shot in the terrestrial environment
Cygnus columbianus	Tundra Swan	EN / lead shot in the terrestrial environment and lead fishing tackle
Cygnus cygnus	Whooper Swan	LC / lead shot in the terrestrial environment and lead fishing tackle
Cygnus olor	Mute Swan	LC/ lead shot in the terrestrial environment and lead fishing tackle
Aythya ferina	Common Pochard	VU/ lead fishing tackle
Aythya fuligula	Tufted Duck	LC/ lead fishing tackle
Aythya marila	Greater Scaup	VU/ lead fishing tackle
Aythya nyroca	Ferruginous Duck	LC/ lead fishing tackle
Marmaronetta angustirostris	Marbled Teal	CR/ lead fishing tackle
Netta rufina	Red-crested Pochard	LC/ lead fishing tackle

Taxonomy	Common name	EU IUCN Red List Category / primary poisoning source relevant for the current restriction proposal[1]
Oxyura leucocephala	White-headed Duck	VU/ lead fishing tackle
Spatula clypeata	Northern Shoveler	LC/ lead fishing tackle
Spatula querquedula	Garganey	VU/ lead fishing tackle
Gavia adamsii	Yellow-billed Loon	NE/ lead fishing tackle
Gavia arctica	Arctic Loon	LC/ lead fishing tackle
Gavia immer	Common Loon	VU/ lead fishing tackle
Gavia stellata	Red-throated Loon	LC/ lead fishing tackle
Pelecanus crispus	Dalmatian Pelican	LC/ lead fishing tackle
Pelecanus onocrotalus	Great White Pelican	LC/ lead fishing tackle
Platalea leucorodia	Eurasian Spoonbill	LC/ lead fishing tackle
Anthropoides virgo	Demoiselle Crane	NE/ lead shot in the terrestrial environment
Grus grus	Common Crane	LC/ lead shot in the terrestrial environment

Notes:[1] risks of lead gunshot ingestion in wetlands were analysed in a previous assessment on the use of lead gunshot in wetlands; some species (for example species in the family of loons) may also ingest fishing tackle via secondary ingestion.

Table 1-30: EU Raptors, scavengers and other terrestrial species at most risk of lead poisoning from primary and secondary ingestion of lead ammunition and lead fishing tackle

Taxonomy	Common name	EU IUCN Red List Category / type of lead poisoning[1]
Aquila adalberti	Spanish Imperial Eagle	VU/secondary poisoning
Aquila chrysaetos	Golden Eagle	LC/secondary poisoning
Aquila fasciata	Bonelli's Eagle	NT/secondary poisoning
Aquila heliaca	Eastern Imperial Eagle	NT/secondary poisoning
Aquila nipalensis	Steppe Eagle	NE/secondary poisoning
Accipiter gentilis	Northern Goshawk	LC/secondary poisoning
Aegypius monachus	Cinereous Vulture	LC/secondary poisoning
Neophron percnopterus	Egyptian Vulture	VU/secondary poisoning
Gypaetus barbatus	Bearded Vulture	VU/secondary poisoning
Gyps fulvus	Griffon Vulture	LC/secondary poisoning
Buteo buteo	Eurasian Buzzard	LC/secondary poisoning
Buteo lagopus	Rough-legged Buzzard	EN/secondary poisoning

Taxonomy	Common name	EU IUCN Red List Category / type of lead poisoning[1]
Buteo rufinus	Long-legged Buzzard	LC/secondary poisoning
Circus aeruginosus	Western Marsh-harrier	LC/secondary poisoning
Clanga clanga	Greater Spotted Eagle	CR/secondary poisoning
Haliaeetus albicilla	White-tailed Sea-eagle	LC/secondary poisoning
Milvus migrans	Black Kite	LC/secondary poisoning
Milvus milvus	Red Kite	NT/secondary poisoning
Circus cyaneus	Hen Harrier	LC/secondary poisoning
Circus macrourus	Pallid Harrier	EN/secondary poisoning
Circus pygargus	Montagu's Harrier	LC/secondary poisoning
Clanga pomarina	Lesser Spotted Eagle	LC/secondary poisoning
Hieraaetus pennatus	Booted Eagle	LC/secondary poisoning
Falco biarmicus	Lanner Falcon	VU/secondary poisoning
Falco cherrug	Saker Falcon	VU/secondary poisoning
Falco peregrinus	Peregrine Falcon	LC/secondary poisoning
Falco rusticolus	Gyrfalcon	VU/secondary poisoning
Corvus corax	Common Raven	LC/secondary poisoning
Corvus corone	Carrion Crow	LC/secondary poisoning
Columba livia	Rock Dove	LC/primary poisoning
Columba oenas	Stock Dove	LC/primary poisoning
Columba palumbus	Common Woodpigeon	LC/primary poisoning
Streptopelia decaocto	Eurasian Collared-dove	LC/primary poisoning
Streptopelia turtur	European Turtle-dove	NT/primary poisoning
Columba bollii	Dark-tailed Laurel-pigeon	LC/primary poisoning
Columba junoniae	White-tailed Laurel-pigeon	NT/primary poisoning
Columba trocaz	Madeira Laurel-pigeon	LC/primary poisoning
Pterocles alchata	Pin-tailed Sandgrouse	LC/primary poisoning
Pterocles orientalis	Black-bellied Sandgrouse	EN/primary poisoning
Scolopax rusticola	Eurasian Woodcock	LC/primary poisoning
Alectoris barbara	Barbary Partridge	LC/primary poisoning
Alectoris chukar	Chukar	LC/primary poisoning
Alectoris graeca	Rock Partridge	VU/primary poisoning

Taxonomy	Common name	EU IUCN Red List Category / type of lead poisoning[1]
Alectoris rufa	Red-legged Partridge	LC/primary poisoning
Bonasa bonasia	Hazel Grouse	LC/primary poisoning
Coturnix coturnix	Common Quail	LC/primary poisoning
Lagopus lagopus	Willow Grouse	VU/primary poisoning
Lagopus muta	Rock Ptarmigan	VU/primary poisoning
Lyrurus tetrix	Black Grouse	LC/primary poisoning
Perdix perdix	Grey Partridge	LC/primary poisoning
Phasianus colchicus	Common Pheasant	LC/primary poisoning
Tetrao urogallus	Western Capercaillie	LC/primary poisoning

Notes: [1] some species at risk of secondary poisoning may also ingest fishing tackle via secondary ingestion (for example species feeding on waterbirds)

1.5.4.3. Additional risks related to sports shooting

Based on information discussed in section 1.5.3.7, the Dossier Submitter has undertaken a qualitative assessment of additional risks resulting from the use of lead ammunition in sports shooting, as described in sections 1.5.4.3.1, 1.5.4.3.2 and 1.5.4.4.

The additional risks related to sports shooting ranges have been grouped into two categories: compartment-related risks and risks to specific receptors. When assessing compartment related risks, the Dossier Submitter has considered the ecology of these compartments as a whole[130].

1.5.4.3.1. Compartment-related risks (soil and surface water)

Compartment related risks (soil and surface water) are discussed in section 1.5.4.4.

1.5.4.3.2. Risks to specific receptors

Livestock

Several studies (Braun et al., 1997, Macnicol, 2014, Muntwyler, 2010, Rice et al., 1987, Scheuhammer and Norris, 1995, Vermunt et al., 2002) have discussed lead poisoning in cattle either via ingestion of contaminated soil and grass when grazing on shooting ranges or when being fed with (lead gunshot) contaminated silage (secondary poisoning). A few case studies are discussed below.

- Cattle grazing on shooting ranges (Switzerland):

  Mortality was reported in calves put on pasture on an area containing an old shooting range in Switzerland, for which the concentration of lead in the dry matter of a grass

[130] In response to comment #3223, the Dossier Submitter acknowledges that the speciation of the lead ion in the environment affects its fate, bioavailability and ecotoxicity. The qualitative risks that are identified for the uses related to sports shooting are considered to occur irrespective of these considerations as ‘sensitive’ conditions could reasonably be expected to occur to some extent in all Member States and the magnitude of releases from shooting ranges (based on literature case studies) would, in general, be considered a concern irrespective of any potential modification to ecotoxicity because of bioavailability.

and a soil[131] sample from the target zone of the shooting range were 29 550 mg/kg and 3 900 mg/kg (Braun et al., 1997). As reported by Braun et al. (1997), acute lead poisoning occurred in one of the calves after five days of grazing, the remainder became ill one to three days later. The most important symptoms consisted of neurological disturbances and included maniacal movements, opisthotonos, drooling, rolling of the eyes, convulsions, licking, champing of the jaws, bruxism, bellowing and breaking through fences. All but one calf, which was euthanatized, died within several hours of the occurrence of the first symptoms. Post-mortem examination of this calf revealed acute cardiac, renal and pulmonary haemorrhage, acute tubulonephrosis and acute severe pulmonary emphysema.

- Cattle fed pasture supplemented with maize silage (New Zealand):

  As reported by Vermunt et al. (2002), the herd consisted of 140 spring-calving, Friesian dairy cows fed high-quality pasture, which had been supplemented with maize silage for the previous 4 weeks, at a rate of 4 kg per cow per day.
  In 2001, four pregnant cows showed severe nervous signs. The animals had charged through fences and were agitated. On closer examination three of them appeared to be blind, had muscle tremors and abdominal contractions, and were head pressing when forced into a corner of the cattle yards. The cardinal signs (rectal temperature, heart and respiratory rates) were all within their respective normal ranges. At that stage, differential diagnoses included hypomagnesaemia, nervous ketosis, and polio-encephalomalacia due to thiamine (vitamin B1) deficiency or lead poisoning.
  Blood samples were collected to rule in / out hypomagnesaemia and nervous ketosis, respectively. Each animal was treated with thiamine hydrochloride and also a 20 % magnesium sulphate solution. Sufficient thiamine for additional treatments was left with the owner. The day following the symptoms outbreak, the three clinically affected cows were revisited by veterinary staff. One cow was euthanised because they were moribund. A field necropsy was carried out, but no gross lesions or abnormalities were detected. A kidney sample was taken for further toxicology analysis. The next day another cow was euthanised and a kidney sample was collected for lead analysis. Then also the third cow became extremely ill. This cow was also euthanised and a post-mortem examination carried out. A large amount of lead shot was found in the reticulum and a presumptive diagnosis of lead poisoning was made. Again, a kidney sample was taken for lead analysis. A cursory examination of the fore stomach contents of the carcasses of the other cows also revealed numerous gunshot pellets amongst the digesta. An on-farm investigation identified the maize silage as the source of the lead poisoning. Large numbers of shotgun pellets were found mixed in with the silage. The silage being fed had been purchased from a nearby gun club, which grew the crop beneath the target firing range. A sample of the silage was taken for lead analysis and the farmer was advised to immediately stop feeding this supplement. The lead concentration in the silage, following removal of any lead gunshot, was 32 mg/kg (on a dry matter basis). The sample of maize silage was thoroughly washed at the laboratory, so no lead pellets were present when tested. However, the maize silage fed to the cows was found to be heavily contaminated with lead from the shooting range. The lead shot was harvested and ensiled along with the maize, and became incorporated in the feed.

[131] In bermudagrass growing on a shooting range, lead concentrations as high as 800 mg/kg (dry matter) were also measured (Cao et al., 2003). In plants growing on the berm, concentration in plant was as high as 4 700 mg/kg (Dallinger, 2007)

Properly made silage is very acidic (pH < 4.8), and in such an acid environment a proportion of the metallic lead is converted into a more soluble lead salt, which then leaches into the silage, making it toxic.

- Macnicol (2014) also reported that about 100 Southland dairy cows "had died or been destroyed after contracting lead poisoning" which was later confirmed as the result of lead become embedded in the fodder beet (silage).

Conclusions on livestock

As specified by the European Commission Directive 2002/32/EC[132], lead concentrations in the harvested material (forage) should be below 30 mg/kg (maximum relative to a feed with a moisture content of 12 %) for this material to be fed to livestock. Regulation 1275/2013[133], amending the Annex I to Directive 2002/32/EC, indicates a limit of 10 mg lead/kg (12 % moisture) for lead in animal feed materials with several exceptions, including of 30 mg/kg (maximum relative to a feed with a moisture content of 12 %) for forage. The lead concentrations in material harvested on shooting ranges can have lead concentrations hundred times greater than 30 mg/kg (12 % moisture), constituting therefore a risk and should not be used as animal forage.

In addition, according to the Swiss expert system for risk assessment of contaminated soils (Swiss BUWAL, 2005), it must be assumed that cows could be endangered when grazing on contaminated soil that exceeds 1 000 mg lead/kg (dry matter). Based on this, grazing on shooting ranges may constitute a risk, considering the average soil concentration in a shooting range.

Other receptors

Risks to poultry are discussed in section 1.5.4.4.

Due to the lack of specific data, risks to other taxa could not be elaborated by the Dossier Submitter but cannot be ruled out.

Risks to groundwater are presented in section 1.5.4.4. Comment #3494 noted that no levels of lead in groundwater should be considered acceptable in line with the EU Water Framework Directive (WFD) 2027 objectives.

1.5.4.4. Qualitative assessment of environmental risks

The Dossier Submitter has applied a qualitative approach to assess and compare the identified risks for the use of lead in hunting, sports shooting and fishing.

For sports shooting, the Dossier Submitter has considered the following generic scenarios:

Use of lead gunshot (use #3) for sports shooting under different scenarios

a) Temporary shooting areas (shooting intensity about 5 000 - 10 000 rounds per year) with no environmental RMMs in place

Following the definition of the CSR (2020), shooting areas are "*areas not specifically designed and operated for shooting but where shooting activities can take place*". In most cases, these areas do not comply with best practice guidelines and may not be subject to, or comply with, relevant environmental regulations. The definition of a shooting area differs distinctively among EU Member States. For example, in the Flemish environmental

[132] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02002L0032-20131227&from=EN#E0021
[133] https://eur-lex.europa.eu/eli/reg/2013/1275/oj

legislation (Belgium), shooting *areas* are defined as "shooting contests organised maximum twice per year on the same piece of land with a maximum duration of 4 consecutive days". Shooting areas are exempted from the Flemish soil pollution regulation and can therefore not be considered as technical areas.

No specific data are available on the impact of temporary shooting areas on different environmental compartments and receptors. Assuming limited intensity of shooting, the risk to soil and surface water might be low but might build up over time under certain circumstances, such as annual shooting at the same spot over several years. Lead shot deposited on the soil may be ingested by birds with consequent poisoning but the likelihood and frequency of such poisoning depends on site specific conditions, such as the suitability of habitat for birds.

b) Permanent outdoor shooting areas (shooting intensity about 10 000 rounds per year with a service life of 30 - 40 years) with no environmental RMMs in place (any type);

For this scenario b) the same applies as for scenario a) with the difference of higher contamination due to regular shooting over many years. Therefore, there is a higher likelihood of harm to humans or the environment occurring. An example for a permanent shooting area would be a clay target area which is not specifically designed and operated for shooting. Such areas do typically not comply with best practice guidelines as indicated in the CSR (2020) and are not subject to, or comply with, relevant environmental regulations.

The Dossier Submitter considers that due to the high annual shooting intensity (10 000 rounds) of a sporting clay parcourse that has no environmental RMMs in place and which is usually located in natural surroundings with trees and bushes, there is a relevant risk for soil and surface water contamination as well as for poisoning of birds and possibly of ruminants (if the shooting ground is also used for agricultural purposes).

c) Permanent outdoor shooting ranges (shooting intensity about 10 000 - 100 000 rounds per year with a service life of 30 - 40 years) with environmental RMMs in place such as:
   - Measures to prevent rivers from crossing the lead deposition area
   - Control of water runoff
   - Lead gunshot deposition within the boundaries of the shooting range
   - Remediation plan upon closure[134]

Compared to a temporary clay target area, the CSR (2020) defines a shooting range as an area designed and operated specifically for recreational shooting. The owner/operator of the site complies with environmental regulations. There is a remediation plan upon closure in place. The range has clearly defined boundaries and it is assumed that lead ammunition is not allowed to be deposited outside the boundaries of the range.

This scenario reflects the conditions described in the CSR (2020) for outdoor shooting ranges. Because of accumulation of lead gunshot in and on soil, the Dossier Submitter considers that the environmental RMMs described in the CSR (2020) for permanent shooting ranges are not enough to protect soil and potentially groundwater from contamination and poisoning of birds. The risk of surface water contamination can be considered low because of the required control of runoff water. In case agricultural use (e.g. grassing by ruminants) of the land is allowed there can be a relevant risk.

[134] However, a remediation plan is not providing any guarantee that a remediation will be carried out.

d) Permanent outdoor shooting ranges with the following RMMs implemented (in addition to the RMMs listed in the above scenario):
   - Regular (at least one a year) lead gunshot recovery with ≥ 90 % effectiveness calculated based on mass balance of lead used vs lead recovered to be achieved by appropriate means (such as walls and/or nets, and/or soil coverage);
   - Monitoring and treatment of surface (runoff) water;
   - Ban of any agricultural use within site boundaries.

The Dossier Submitter considers that to minimise the risks from outdoor shooting ranges, further measures than those specified in the CSR (2020) are required.

The Dossier Submitter considers that the identified risks can be minimised by regular (at least one a year) recovery of lead gunshot.. Appropriate measures allow the recovery of more than 90 % lead gunshot as reported by the German 'Bundesverband Schießstätten e.V.' (comment #3198). The Dossier Submitter proposes a 90% recovery rate as a practical threshold with the objective to minimise releases.

Monitoring and treatment of surface water is important to control this risk. Regular lead gunshot collection might reduce but not eliminate the risk to birds. Any agricultural use within the site boundaries should be banned to control the risk for humans (via food) and for ruminants. Even if risks are minimised at such ranges, remediation (e.g., final lead gunshot recovery with topsoil removal) at the cessation of use may still be required, depending on the land future zoning[135].

Use of lead projectiles other than gunshot (uses # 4, 5 and 6) for sports shooting under different scenarios

The environmental risks from lead projectiles other than gunshot (i.e., bullets or pellets) can be minimised by using appropriate trap chambers or 'best practice' sand traps[136] that contain the projectiles and prevent rainwater from entering the trap and lead from leaching to soil. Risks arise from trapping projectiles in soil berms.

a) Temporary shooting areas[137], limited shooting

Due to the limited shooting, the environmental risks to soil, surface water and agricultural use are likely to be low but might rise to a relevant level in case of accumulation of lead projectiles in small areas. In case appropriate trap chambers or 'best practice' sand traps are used to contain the projectiles, the risks are minimised.

b) Permanent outdoor rifle and pistol ranges, intensive shooting, use of berm to trap projectiles

Permanent outdoor rifle and pistol ranges may use sand/soil berms or soil berms to trap projectiles. Sand/soil berms are used frequently in Nordic countries. Soil berms are often used in old ranges that have been in operation for a long time. The contamination of the berm area presents a high environmental risk to soil, surface water and potentially groundwater. Covering berms with a roof reduces the risk from the mobilisation of lead by rain/snow but does not minimise the risk of contamination of soil, groundwater or surface water. The Dossier Submitter notes that those scenarios would not be in accordance with the requirements of the CSR (2020). The effectiveness of recovery of lead bullets from sand/soil berms were reported to be 65 % (comment #3261 from the Swedish Dynamic

[135] Land for example can be used for agricultural uses or even residential or recreational purposes.
[136] Refer to the "Note of terminology" for the definition of "trap chamber" and "best practice sand trap"
[137] Temporary rifle/pistol area might for example apply to biathlon events or for a muzzle loading event, firing with historical weapons.

Sportshooting Federation)

c) Permanent outdoor rifle and pistol ranges with the following RMMs implemented:
   - o trap chambers or
   - o 'best practice' sand trap

This scenario basically reflects the requirements specified in the CSR (2020) with appropriate containment as the main means to control the risk from lead projectiles. Appropriate trap chambers allow recovery of up to 100 % of spent lead ammunition. Data on recovery from 'best practice' sand traps are not available.

The Dossier Submitter considers that in addition to the requirements specified in the CSR (2020) for sand traps (containment with an overhanging roof and a sealing to soil), a water management system to contain, monitor and treat surface water would minimise lead contamination of water runoff. In addition, the required measure such as trap chamber or sand trap with an overhanging roof might not be suitable for dynamic shooting disciplines, for which a permanent cover would be required to reduce rainwater from entering the trap. In addition, any agricultural use at a permanent range should be banned due to the residual risks.

A remediation of the site/facility at the cessation of the use would ensure removal of remaining contaminations.

The qualitative analysis of the level of risks identified during service life of sports shooting ranges in the above listed scenarios, is presented in Table 1-31, together with the risks arising from the use of lead ammunition in hunting and lead tackle in fishing. The risks have been grouped into two categories: compartment-related risks and risks to specific, non-compartment related, receptors.

To describe the level of risks, the following qualitative ranking is used:

Table 1-31: Qualitative assessment of environmental risks related to the use of lead for hunting, outdoor sports shooting and fishing

		Compartment related risks		Risks to specific receptors		
Use	Scenario	Soil [6]	Surface water (including groundwater fed)	Birds [3,4] (including poultry)	Livestock (ruminants) [2]	Groundwater [5]
1	Hunting with gunshot	+ to ++	+ to ++	+++	+ to ++	+
2a	Hunting with bullets - small calibre[1]	+	+	+++	+	+
2b	Hunting with bullets - large calibre	+	+	+++	+	+
3	Outdoor sports shooting - gunshot					
3a	Temporary shotgun areas, no ENV RMM, limited shooting intensity	+ to ++	+ to ++	+++	+ to ++	+
3b	Permanent shotgun areas, no ENV RMM, intensive shooting	+++	+++	+++	+++	+ to +++

		Compartment related risks		Risks to specific receptors		
Use	**Scenario**	**Soil [6]**	**Surface water (including groundwater fed)**	**Birds [3,4] (including poultry)**	**Livestock (ruminants) [2]**	**Groundwater [5]**
3c	Permanent shotgun range, ENV RMMs in place: - prevent rivers from crossing - control water runoff - lead deposition within range - remediation plan upon closure	+++	+	+++	+++	+ to +++
3d	Permanent shotgun range, ENV RMMs in place (in addition to 3c): - regular (annual) collection of lead shot (>90 % effectiveness) - monitoring and treatment of surface (runoff) water - ban of agricultural use within site boundary	+	+	+	+	+
4	Outdoor sports–shooting - bullets					
4a	Temporary rifle/pistol areas, limited shooting intensity:					
	- use of soil berm to trap bullets	++	+ to ++	[2]	+ to ++	+
	- use of trap chambers and/or 'best practice' sand traps combined with a water management system	+	+	N/A	+	+
4b	Permanent rifle/pistol ranges, intensive shooting: - use of soil berm to trap bullets	+++	+++	[2]	+++	+ to +++
4c	Permanent rifle/pistol ranges: - use of trap chambers and/or 'best practice' sand traps combined with a water management system - ban of any agricultural use within site boundary	+	+	N/A	+	+
5	Outdoor shooting using airguns					
	- use of air pellet containment	+	+	N/A	+	+
	- no pellet containment	++	++	+++	+ to ++	++

Use	Scenario	Compartment related risks		Risks to specific receptors		
		Soil [6]	Surface water (including groundwater fed)	Birds [3,4] (including poultry)	Livestock (ruminants) [2]	Groundwater [5]
6	Other outdoor shooting activities (assuming low shooting intensity)					
	- use of trap chambers and/or 'best practice' sand trap combined with a water management system	+	+	N/A	+	+
	- use of soil berm to trap bullets	++	++	[2]	+ to ++	
7	Fishing sinkers and lures	N/A	+	+++ (sinkers and lures ≤ 50 g)	N/A	N/A
8	Fishing nets, lines and ropes	N/A	+	N/A	N/A	N/A

Notes: +: negligible to low risk or risk controlled; ++: moderate risk; +++: high (main) risk; N/A: not applicable. [1] this use includes hunting with an airgun [2] the risk relates to grazing of ruminants on ranges with ingestion of contaminated soil and vegetation and (secondary) poisoning via silage grown on areas used for shotgun shooting (hunting or sports shooting). [3] Some birds may also ingest contaminated soil while feeding. This route has not been assessed due to the lack of specific data. [4] Livestock (poultry) is also at risk, as any other birds, for example in shooting ranges/ areas used as agricultural land or abandoned ranges or if reared in field where lead shot may land from an adjacent shooting range. [5] Groundwater can be considered both as a pathway and receptor (Environmental Protection Authority Victoria (EPA), 2019). When impacted water reaches groundwater, the contamination can continue to travel underground. Groundwater may be used for drinking water (also used by livestock), irrigation, or even used for recreation (for example fishing) (Environmental Protection Authority Victoria (EPA), 2019). Comment #3494 noted that no levels of lead in groundwater should be considered acceptable in line with the EU Water Framework Directive (WFD) 2027 objectives. [6] In relation to the sediment (marine) compartment the Dossier Submitter notes that it is not easily feasible to distinguish between lead released to the sediment compartment by the use of lead fishing tackles and other sources of lead not being covered by the restriction proposal. For this reason, the marine sediment compartment was not assessed.

Groundwater is referred to in publications both as a pathway and a receptor; it may be used for drinking water (also by livestock), irrigation or even used for recreation, for example fishing (Environmental Protection Authority Victoria (EPA), 2019). Therefore, for completeness, risks to groundwater have been qualitatively described in Table 1-31 as a receptor in its own right and as a proxy for risks to groundwater mediated receptors.

Soil compartment: (uses 1, 2, 3, 4, 5 and 6): The contamination of soil from shooting activities depends on the deposition of lead ammunition on the soil and its corrosion and solubility on and in the soil (see Annex B, section B.4.2.1). For hunting with bullets (uses 2a, 2b) the risk level for soil contamination is considered low (+) due to the low intensity of shooting during hunting and because bullets often remain in the carcass. The risk level for soil contamination is also considered low in case of lead gunshot recovery higher than 90 % (uses 3d) or lead projectile recovery by installing suitable trap chambers and/or 'best practice' sand traps (uses 4a, 4c, 5 and 6). The risk level for soil contamination is considered low to medium (+ to ++) for infrequent shooting and/or limited shooting frequency with low to moderate amount of ammunition deposited onto soil. This is assumed for hunting with gunshot (use 1) and for sports shooting on temporary shotgun areas (use 3a) and temporary rifle/pistol ranges that retain bullets in a soil berm (use 4a, 5, 6). High risk level for soil contamination (+++) is assumed for permanent shotgun and rifle/pistol areas or ranges with intensive shooting and deposition of the ammunition to soil (uses 3b, 3c, 4b and 5).

Surface water compartment (uses 1, 2, 3, 4, 5 and 6): Surface water contamination can be assumed for lead ammunition (gunshot and bullets) being deposited on or in the soil and subsequent corrosion and dissolution of the lead (see Annex B, section B.4.2.2). The risk level is assumed to increase with increasing amount of deposition. The risk level is assumed to be low (+) for hunting with bullets (use 2a, 2b) and for sports shooting when projectiles are contained in suitable trap chambers and/or 'best practice' sand traps (uses 4a, 4c, 5, 6). For shotgun ranges a risk for surface water contamination is always present due to the deposition of the gunshot on the soil and its corrosion. In case of limited shooting intensity such as hunting with gunshot (use 1) and on temporary shotgun ranges (use 3a) the level of risk is assumed to vary between low and moderate (+ to ++), depending on the amount of deposition at specific areas. To control the risk of water-runoff (+), the use of specific measures is required to collect, contain, and treat the surface water (uses 3c, 3d). For fishing (use 7 and 8) the risk for water contamination is considered negligible to low. A risk from fishing (use 7 and 8) can be expected when a high lead dissolution rate occurs (due to the waterflow velocity, pH, etc), and is combined with a high rate of lead fishing tackle exposure (i.e. intense fishing practice, and therefore higher loss of fishing tackle).

The dissolution rate of lead in aquatic environments is relatively slow but increases with acidity, low water hardness (< 25 mg/L $CaCO_3$), and greater water velocity (see Annex B, section B.4.2.2). Aquatic environments fulfilling these criteria are specific to some areas. A typical example of such conditions, where lead would dissolve more quickly and would become more bioavailable, is high-flow rivers/rapids populated with salmon. This is why, local bans are for example in place in specific salmon-populated rapids in Sweden where the salmon fishing is a popular activity.

As indicated in Annex B, in aquatic environments with lower water velocities (e.g. lakes), lead particles and artefacts would also be buried in bottom sediments, where they would move into the anoxic sediment layer and may be strongly adsorbed onto sediment and soil particles, and where the dissolution of elemental lead will be reduced, without mechanical disturbance.

For these reasons, the risk for water contamination from use 7 and 8 is considered negligible to low.

Birds (uses 1, 2, 3, 5 and 7): The risks of lead poisoning depend on the availability of spent lead projectiles for birds (see Annex B, section B.9.1.1), with greater risks associated with greater intensity of shooting activity. Birds can ingest (primary poisoning) lead gunshot (mistaken for grit/food) used for hunting (use 1) or sports shooting (3a, 3b, 3c). The risks can be reduced if appropriate risk management measures are in place and no agricultural activities take place at the shooting ranges/area (3d). Unless contained in suitable projectile traps, lead pellets used in airguns for sports shooting (use 5) may pose a risk of primary poisoning, particularly if there is a high intensity of use at a site. Risks can also arise from the consumption of meat containing lead fragments (secondary poisoning) such as viscera and carcasses from large game hunting left in the field (use 2b) or animals wounded or shot with lead ammunition (uses 1, 2a, 2b), animals shot for pest control with lead ammunition (uses 1, 2a, 2b) but not recovered and animal carrying ingested lead shot (uses 1). Direct intake of lead gunshot may also depend on the attractiveness of the area to birds e.g. presence of suitable habitat such as food sources and shelter (US EPA, 2005). Poultry, similar to other birds, may also be at risk of lead poisoning if shooting ranges/areas are subsequently used for agricultural purposes or if poultry are reared in fields where lead gunshot may land from an adjacent shooting range i.e., if lead gunshot is not contained within the boundary of the site during use (as noted in comment #3250).

With regards to fishing (use 7) the risk is related to both primary and secondary lead poisoning (by consumption of prey having ingested split anglers' shot or other types of tackle or while consuming fish with attached fishing tackle). The risk levels for bird poisoning are considered high (+++) for all conditions under which lead (to be considered as lead sinkers and lures ≤50 g, fragments or lead available in tissues) is available to birds[138] for ingestion.

Livestock (ruminants) (uses 1, , 3, 4, 5 and 6): Lead dust from shooting and dissolved lead gunshot are one source of increased lead concentrations in the biomass of grass or crops used for agricultural purposes (Chrastný et al., 2010) or for elevated exposure of ruminants grazing in these areas or being fed with silage from shooting ranges (see Section 1.5.3.7.4). The level of risk is considered to depend on the amount of gunshot deposition on terrestrial areas that might also be used for agricultural purposes. Low risk level (+) is assumed for hunting with bullets (uses 2a, 2b) and for sports shooting when lead projectiles are contained in trap chambers or 'best practice' sand traps (uses 4a, 4c, 5, 6) and in case agricultural use is banned on the range (uses 3d, 4c). Low to moderate risk levels are assumed for areas with frequent hunting with shotguns (use 1), temporary shotgun areas (use 3a), and for temporary or permanent pistol/rifle ranges with low shooting intensity and deposition of the projectiles in soil without a ban of agricultural use of the contaminated area (uses 4a, 5, 6). High risk level is assumed for permanent pistol/rifle ranges with high shooting intensity and deposition of the bullets in soil without a ban of agricultural use of the contaminated area (use 4b).

Groundwater (uses 1, 2, 3, 4, 5 and 6): In general, the risk to groundwater might be negligible or low in the terrestrial environment if shooting occurs far from sensitive areas[139].

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[138] Even a single pellet can be lethal to different species of birds.

[139] The use of lead gunshot (in any type of shooting) will not be allowed in wetlands (as defined by the Ramsar Convention) as a consequence of the restriction on the use of lead shot in wetlands.

Specifically, the risk level for groundwater contamination is assumed to be negligible to low for hunting (uses 1, 2a, 2b) and low at shooting areas with limited shooting intensity (uses 3a, 4a, 5, 6) and for shooting ranges with lead gunshot recovery >90% and appropriate lead projectile containment and recovery (uses 3d, 4c, 5, 6). Groundwater contamination can be relevant in case the deposition of larger quantities of lead result in accumulating in soil and migration to groundwater. The time for contamination to reach groundwater depends on the soil conditions and the distance to the ground water (see Annex B, section B.4.2.1). Consequently, the site-specific risk level can range from low (e.g., high deposition but ground water very deep and soil conditions are not promoting migration), to high (e.g., medium or high deposition with ground water level close to the contamination horizon and/or soil conditions promoting the leaching of lead). This may apply to uses 3b, 3c and 4b.

In addition to the qualitative risk assessment discussed above, the Dossier Submitter has performed a quantitative impact assessment of the risks to birds of lead poisoning which is presented on section 1.8.5.

RAC box

RAC agrees in general with the risk assessment made by the Dossier Submitter. However, RAC's evaluation resulted in small differences in the conclusions concerning some environmental risks. These are as follows:

- Lead contamination occurring during the service life and at the end of life at a shooting range can result in high risks to surface soil at shooting ranges but generally not to deeper soil layers.
- Surface water migrating from shooting ranges without RMMs can be contaminated with lead, and exposure to aquatic organisms would be likely, resulting in a moderate to high risk, depending on dilution. However, any measurable impacts are generally localised, therefore this results in low overall general risk in the RAC conceptual risk assessment model.
- The risk of groundwater (and derived drinking water) contamination may vary from very low to high depending on the soil and groundwater characteristics. It is difficult to estimate the prevalence and extent of groundwater vulnerability to lead contamination at shooting ranges at European, national or even regional scale.

1.6. Human health risk assessment

1.6.1. Approach to human health risk assessment

In this human health risk assessment, the hazards related to lead exposure via hunting, outdoor sports shooting and fishing are described. The speciation of lead (e.g., massive, dust, fume, ions) and the respective bioavailability has been taken into account where relevant.

Since there is no evidence for thresholds for critical lead-induced effects, toxicological reference (BMDL) values for these activities are established. Indirect exposure via the environment from these uses is also assessed, primarily through the consumption of game meat obtained by using lead ammunition, but also via the consumption of milk and meat from cattle suffering from sub-clinical poisoning. Risks to human health via drinking water and the consumption of crops grown on agricultural soils adjacent to or within shooting areas are discussed qualitatively.

Occupational lead exposures arising from the manufacture of ammunition or fishing sinkers, professional shooting or commercial fishing are not explicitly assessed as, for the purposes of this assessment, such risks are considered to be addressed by existing binding occupational limit values for lead and are outside the scope of this restriction proposal.

The exposure pathways of key concern are inhalation and oral intake.

Inhalation exposure results from fumes, aerosols or dusts arising from firing lead-containing gunshot or other projectiles (e.g. bullets) as well as from the melting of lead by consumers to prepare ammunition or fishing tackle (termed 'home-casting').

Oral intake of lead (as lead dust) occurs after handling lead gunshot, other projectiles or fishing tackle (an example of hand-to-mouth exposure) or by the mouthing or unintended ingestion of lead-containing objects, usually by children. Another important source of oral lead intake from the uses assessed occurs indirectly via the environment and occurs either via the consumption of game meat containing fragments of lead gunshots or other lead projectiles or via the consumption of other food or drinking water containing lead.

Only the key studies used as the basis for the assessment are cited in the Annex XV report. Additional studies that were assessed to be less relevant are summarised in Annex B.

Table 1-32: Approach to human health risk assessment

Hazard assessment	Information on toxicokinetics, acute (short-term) and chronic (long-term) toxicity of lead in humans from epidemiological studies; including any relevant thresholds for adverse effects in biota (i.e. blood lead thresholds).
Exposure assessment	Information on lead concentration in human blood following direct exposure to lead by inhalation (shooting) or oral intake (outdoor shooting, fishing) or indirect exposure via the environment from the consumption of game meat (hunting), milk/meat from cattle suffering from sub-clinical poisoning and contaminated drinking water.
Risk characterisation	Incidence of adverse effects in shooters (from hunting and outdoor sports shooting activities), fishers (home-casting), hunter family members (consumption of game meat), children (oral ingestion of lead particles), general population

	(drinking water, food).

1.6.1.1. Integrated assessment model for lead exposure and health outcomes

The analysis presented hereafter is based on an integrated assessment methodology that converts oral or inhalation lead exposure to blood lead levels and then to expected health outcomes. The methodology combines various data sources and relies on numerous model parameters, most of which were provided by EFSA for the purpose of this restriction proposal. In particular, EFSA provided data on game meat consumption, which was further differentiated into (i) game meat from ungulates and other large game that are typically hunted with bullets and (ii) game meat from birds and small mammals, such as rabbits, that are typically hunted with gunshot. The same differentiation was applied to lead concentration data in samples of game meat collected by EFSA. These then served as input data into a traditional integrated assessment model (IAM) that combines intake, resulting exposure, and expected health impacts (Rheinberger and Hammitt, 2012).

Premise of the modelling

Excess lead exposure may lead to a variety of detrimental health effects in children and adults (EFSA, 2010). The most sensitive and best researched endpoint related to lead exposure of children aged 7 or younger is impairment of neurocognitive development, which is typically measured in IQ loss. Such impairments have also been observed in children that were exposed *in utero* via umbilical cord blood. For adolescents and adults, the most sensitive endpoint is impairment of renal function leading to chronic kidney disease (CKD).

Various models have been developed to determine benchmark doses (BMDs) and benchmark dose lower bounds (BMDLs) for the aforementioned endpoints. The models which will be used in this assessment all relate blood lead (PbB) concentrations to health impacts. Therefore, the first task of an integrated assessment is to model lead exposure via ingestion or inhalation. The following generic model is devised to estimate daily exposure:

$$D\ \left[\frac{\mu\text{g}}{\text{kg}_{\text{BW}}\ \text{day}}\right] = I\left[\frac{\text{g}}{\text{kg}_{\text{BW}}\ \text{day}}\right] * C\left[\frac{\mu\text{g}}{\text{kg}}\right],$$

where D denotes the daily lead dose either ingested or inhaled via pathway I with lead concentration C. In a next step, the daily dose needs to be converted into an incremental PbB concentration:

$$\text{PbB}\left[\frac{\mu\text{g}}{\text{L}}\right] = D\ \left[\frac{\mu\text{g}}{\text{kg}_{\text{BW}}\ \text{day}}\right] * \gamma\left[\frac{\mu\text{g}}{\text{L}} / \frac{\mu\text{g}}{\text{kg}_{\text{BW}}\ \text{day}}\right],$$

with γ being a conversion parameter that translates daily lead dose into incremental PbB concentration accounting for the bioavailability of metallic lead. Importantly, γ will differ between different age groups. Once PbB levels are estimated, these can be used to predict health outcomes in the affected population. For this, the following relationships can be derived from EFSA's benchmark doses:

$$\Delta\text{IQ} = \beta_{\text{IQ}}\left[-1\ \text{IQ point}/\frac{\mu\text{g}}{\text{L}}\right] * \text{PbB}\ \left[\frac{\mu\text{g}}{\text{L}}\right],$$

$$\Delta\text{CKD} = \beta_{CKD}\left[-10\ \%\ \text{CKD risk}/\frac{\mu\text{g}}{\text{L}}\right] * \text{PbB}\ \left[\frac{\mu\text{g}}{\text{L}}\right],$$

$$\Delta\text{CVD} = \beta_{CVD}\left[-10\ \%\ \text{CVD risk}/\frac{\mu\text{g}}{\text{L}}\right] * \text{PbB}\ \left[\frac{\mu\text{g}}{\text{L}}\right],$$

where the β's are slope parameters that can be derived from the BMD(L)s for the endpoints

IQ, CKD and CVD (▪) in the following generic way:

$$BMD(L)_{\blacksquare} = \text{b}_{\blacksquare}\ \left[\frac{\mu g}{L}\right] \leftrightarrow \beta_{\blacksquare}\left[-risk/\frac{\mu g}{L}\right] = \text{b}_{\blacksquare}{}^{-1}.$$

Calibration of the model

In order to calibrate these models, the parameters $\langle\beta_{IQ}, \beta_{CKD}, \beta_{CVD}, \gamma\rangle$ must be set as well as the typical habits of hunters and their families. For that purpose, ECHA cooperated with EFSA and obtained information about the concentration of lead in different types of game meat and information about consumption rates of game meat in high frequency consumers (summarised below). Moreover, the EFSA opinion on lead (EFSA, 2010) may be used as a starting point to specify $\langle\beta_{IQ}, \beta_{CKD}, \beta_{CVD}, \gamma\rangle$. All of these elements are subsequently brought together in the impact assessment part (Section 2.5.2.1) of this report.

1.6.2. Hazard assessment

1.6.2.1. Toxicokinetics

Absorption

Oral ingestion and inhalation are the most significant routes of lead exposure, whereas dermal absorption is considered as minimal (LDAI, 2008). However, even though absorption directly through the skin is considered negligible, 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).

Mushak (1991) found that intake and uptake of lead in the general population is mainly via the gastro-intestinal (GI) tract. Therefore, biological and biophysico-chemical factors operating in the Gl tract are the main determinants of lead bioavailability. Lead uptake occurs as ion or complex, from micelles and perhaps by pinocytosis in the infant. Uptake is mainly via the duodenum, but other sites can participate, e.g. ileum (pinocytosis) and colon. Transport to blood is by active, carrier-mediated transport and passive diffusion. Uptake may include movement through intercellular tight junctions. Lead uptake is affected by nutrients in the Gl tract, operating synergistically or antagonistically. Iron and calcium interactions are most important and augment those also occurring *in vivo* in tissues. Liberation of lead from diverse ingested media, e.g. food, paint, soil and dust, mining waste, is affected by their chemical/physical forms, hydrolytic and oxidative processes in gastric fluid and other Gl sites. Such changes *in vivo* are poorly simulated by *in vitro* tests.

Representative uptake rates for lead in adults and children via different exposure routes are presented in Table 1-33. According to the information in the Chemical Safety Report of the REACH Registration (CSR, 2020), inhalation absorption is 100 %, whereas oral absorption from food is 10 % in adults and 50 % in children. ATSDR (2007) reported similar rates for gastrointestinal absorption with 3 to 10 % for adults and 40 to 50 % for children. It is noted that the uptake estimates are only applicable to relatively low exposure levels yielding PbB levels up to 150 µg/L.

In rhesus monkeys administered a single dose of 10 mg (5 µCi) lead acetate, infant monkeys (2 males and 2 females) absorbed 37.9 % of the administered dose of lead acetate whereas four adult females absorbed 26.4 % ($p < 0.1$). The absorbed dose for each animal was calculated as the administered dose minus faecal elimination for 96 hours post-exposure (CSR, 2020).

Table 1-33: Representative lead uptake rates (CSR, 2020)

Route of intake	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)[1]	variable	N/A

Notes: [1] 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 (N/A) to children

In a comment submitted during the Annex XV consultation of the restriction report (#3223),it was noted that inhalation absorption is 95 % and gastrointestinal absorption is more accurately reflected in ranges of 3 to 10 % in adults and 40 to 50 % in children.

The efficiency of oral lead uptake varies depending on e.g. particle size and shape (surface area), amount of time particles spent in the gastrointestinal tract, concurrent food intake and the iron- and calcium status of the individual. There are indications that oral uptake also increases with administration of cholecalciferol (Mykkänen and Wasserman, 1982, Moon, 1994). Small lead-containing particles have a higher surface-to-volume ratio and will undergo more rapid dissolution upon ingestion. Whereas 200 µm particles exhibit gastrointestinal uptake efficiency approximately one order of magnitude lower than for soluble compounds, a decrease in particle size to 6 µm (equivalent to the size of a particle that might be inhaled and subsequently translocated to the gastrointestinal tract) will increase uptake five-fold and largely mitigate potential impacts of speciation upon relative bioavailability (Barltrop and Meek, 1979). Case reports (mainly for children) prove that even one larger piece of lead ingested orally can create sufficient systemic exposure to produce clinical lead poisoning or even death. Precise prediction of the bioavailability that will result from ingestion of an individual lead fragments is thus a complex function of particle size, dissolution rates and residence time in the gastrointestinal tract. As a worst-case assumption, it can be assumed that the bioavailability of metallic lead is equivalent to that of soluble lead compounds such as e.g. lead acetate (LDAI, 2008).

Sahmel et al. (2015) quantified the hand-to-mouth transfer efficiency of lead dust. The saliva of six adult volunteers was collected and poured onto a sheet of wax paper placed on a balance scale. The volunteers handled lead fishing weights with both hands for approximately 15 seconds and then pressed three fingers from the right hand (test hand) into their saliva 10 times, with ~0.45 kg of pressure. The left hand (control hand) was used as a comparison for dermal loading of lead and had no contact with saliva. SKC Full Disclosure® wipes were used to collect lead from the saliva and skin surfaces. Samples were analysed using the NIOSH 7300 method, which was modified for wipes. The mean lead skin-to-saliva transfer efficiency was 24 % (range: 12 – 34 %).

In a recent Swedish study (Swedish NFA, 2014b), the percentage of lead released in stomach-like environment (0.1 M hydrochloric acid) was measured in relation to exposure duration and rocking of the sample. At the start, 8 mg of metallic lead in the form of metal shavings was placed in 40 ml of hydrochloric acid for up to 120 hours either stationary without rocking (Stillastående), slight rocking (Vaggning) or heavy rocking (Ökad vaggning). The results are presented in Figure 1-30.

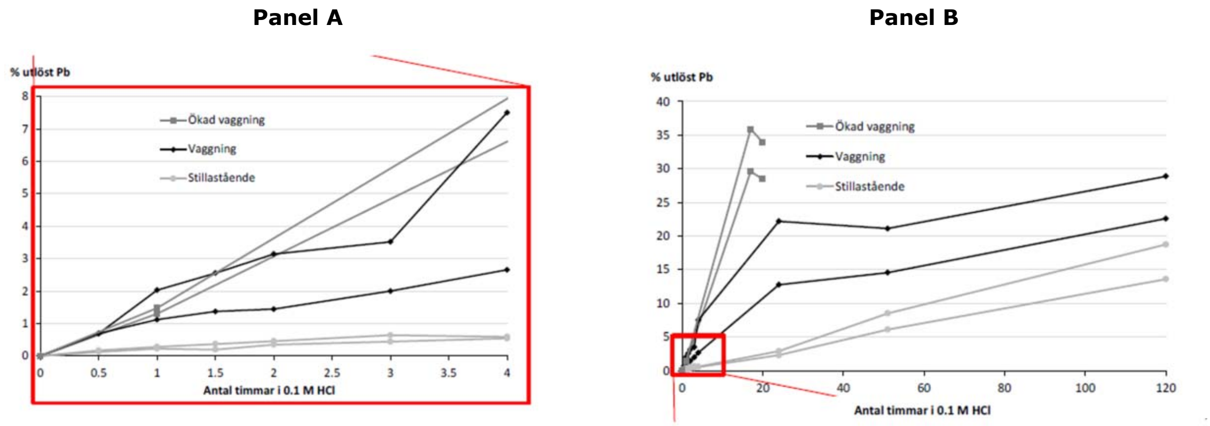

Figure 1-30: Percentage of lead released in stomach-like environment (0.1 M hydrochloric acid) after a certain time with heavy rocking (Ökad vaggning), rocking (Vaggning) or without rocking (Stillastående) (Swedish NFA, 2014b)

Figure 1-30 shows already after half an hour samples with a rocking motion have a higher percentage of lead than stagnant samples. After 1 hour, 1-2 percent of lead was released in the rocked samples while less than 0.5 % of lead dissolved from stationary samples. The difference between stationary samples and rocked samples increased over time. The figure also shows that if the speed in the rocking movement is increased, lead is released faster. After two days, the rocking movement stopped, and all samples were left stationary during the rest of the trial. Consequently, starting from 51 hours all four samples show the same release rate (same slope).

In the "increased rocking" experiment, no sub-samples were taken after 20 hours. The solutions were provided instead, standing still and after three months no visible traces of lead particles could be found in any of the test tubes. This experiment demonstrates that in a stomach-like environment relevant amounts of lead (up to 35 %) can be dissolved. For the *in-vivo* situation, it should be noted though that not all lead in solution may be absorbed due to the usual presence of food in the stomach that might reduce the absorption.

Schulz et al. (2021) determined the absolute bioavailability of lead in growing pigs fed with lead gunshot meat prepared by 24 h marination in wine and vinegar prior to cooking, which is a common method of preparation in the European cuisine. In this study, the acidic marination increased the bioavailability of orally ingested lead from 2.7 to 15 %, resulting in significantly higher blood lead concentrations.

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).

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 in adults ends up in bone and tooth, 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 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 barrier is permeable to lead ions and the most sensitive end-point is connected to neurotoxicity and developmental effects.

Elimination

Elimination takes place mostly via urine (>75 %), and 15 to 20 % is excreted via bile and faeces (TNO, 2005). The half-life of lead in the human body differs across 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 chronically exposed infants and children, lead is progressively accumulated in the body and is mainly stored in skeletal tissue. 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).

It should be noted that the half-life of lead in human blood has a crucial role for the determination of the blood lead level as frequent intake of a constant amount of lead will lead to a steady state blood lead level that may then be taken forward for applying the BMDLs for the various health endpoints. A common misconception pertains to how blood lead levels build up in humans. The Dossier Submitter notes that this is a non-linear accumulation process well studied and discussed in any toxicologic textbook. Indeed, the half-life (i.e. the time it takes until the body has eliminated half of the original intake) of a substance in the human body is defined as $t_{1/2} = \ln(2)/k$, where k is the so-called elimination rate constant. Based on this relationship, one may ask how long it takes until a daily lead intake of x mg/kg bw results in a steady state blood lead level. To answer this question, one may first isolate the elimination rate constant by considering that the half-life of lead in the human blood is 40 days: $k = \ln(2)/40$. Then, the blood lead level PbB can be determined for any exposure duration ED by exploiting the exponential nature of the decay problem:

$$\text{PbB} = (1 - \exp(-k * ED))/k.$$

Using this relationship, one can show that 90/95/99 % of the steady state blood lead level will be reached within 4.5/6/9 months. This again means that even if the daily intake that corresponds to a specific blood lead level is not ingested every day, the blood lead level is poised to steeply raise with frequent lead exposure.

1.6.2.2. Acute toxicity

Acute toxicity of lead in rats is low. The oral LD50 was > 2 000 mg/kg bw, the LC50 following inhalation of a dust of Litharge (Lead oxide) was 5.05 mg/L air, and the dermal LD50 was also > 2 000 mg/kg bw after acute dermal exposure (CSR, 2020).

Very limited data are available on the acute toxicity of lead and its compounds for humans, and it is difficult to accurately establish the dosimetry for physiological effects caused by the inhalation or ingestion of lead and its inorganic compounds after the administration of a single dose. Most data for acute toxicity actually describe the effects of ingestion or inhalation of lead compounds over a period of weeks or years – exposure timeframes that are more accurately regarded as being sub-acute to chronic in duration. Confusion is also caused by traditional definitions in the medical literature which refer to acute and chronic lead poisoning syndromes, both of which are actually the result of sub-chronic or chronic exposure events over extended time frames (CSR, 2020).

Symptoms of lead poisoning may include abdominal pain, constipation, headaches, irritability, memory problems, infertility and tingling in the hands and feet. It causes almost 10 % of intellectual disability of otherwise unknown cause and can result in behavioural problems. Some of the effects are permanent. In severe cases anaemia, seizure, coma or death may occur (CDC, 2018, WHO, 2019).

Acute inhalation of metal fumes including lead (Graeme and Pollack Jr, 1998), copper (Nemery, 1990) and especially zinc oxide (Cooper, 2008) may cause so-called metal fume fever. Metal fume fever is a poorly understood influenza-like or malaria-like reaction. Reported symptoms are the abrupt onset of fever, shaking chills, malaise, excessive salivation, thirst, nausea, myalgia, headache, cough and respiratory distress. The pathogenesis is poorly understood; allergic and immunologic mechanisms are most often postulated. Tolerance to metal fumes develops and symptoms appear only after exposure to metal fumes following a period of abstinence. Metal fume fever will not occur on subsequent successive days of fume exposure.

1.6.2.3. Repeated dose toxicity

Signs of chronic lead poisoning include among others: sleepiness, irritation, headache, pains and others (LDAI, 2008). Blood lead level (PbB) is often the best reflection of the prevailing lead exposure status of the individual (Danish EPA, 2014). EFSA (2010) concluded, based on available human data, that the most critical effects in relation to small increases in PbB levels were developmental neurotoxicity in children aged 7 and younger and effects on blood pressure and chronic kidney disease in adults. The specific effects of lead (haematological effects, effects on blood pressure and cardiovascular effects, kidney effects, neurotoxicity and developmental effects, hyperactivity or attention deficit disorder, and neurological effects of post-natal exposure in children) are summarised in Annex B to the Background Document to the Opinion on the Annex XV dossier proposing restrictions on lead in shot (ECHA, 2018b).

In a recent toxicological profile lor lead, ATSDR (2020) summarised the available information on health effects of lead and concluded that for the most studied endpoints (neurological, renal, cardiovascular, hematological, immunological, reproductive, and developmental), effects occur at the lowest PbB levels studied, which are ≤ 50 µg/L.

Haematological effects

Effects of lead on blood can be detected at low levels of exposure but are not considered to be adverse (ECHA, 2018c). As exposure rises, greater impact on haematological parameters can be expected. At PbB levels < 100 µg/L an inhibition of enzymes such as ALAD is observed; ALAD is 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, 2010). As PbB levels increases, further decreases in blood haemoglobin and loss of erythrocytes due to a lead-induced increased membrane fragility results in the development of anaemia (NAS 2013 as cited in (ATSDR, 2020)). Decreased haemoglobin production can be observed at PbB levels ≥ 400 µg/L in children. Impacts on haemoglobin production sufficient to cause anaemia are associated with PbB levels ≥ 700 µg/L.

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. Based on detailed analyses of five human studies, EFSA (2010) concluded that a PbB level of 36 µg Pb/L was associated with a 1 % increase in systolic blood pressure. Based on modelling, this PbB level was converted to a daily lead exposure of 1.50 µg Pb/kg bw per day.

In a recent study Barry et al. (2019) investigated 211 adult men occupationally exposed to lead with the median age of 61.9 years (range 36.9-85.3 years). Median (IQR) bone, maximum past blood and current blood leads were 13.8 (9.4 – 19.5) µg lead per bone mineral gram, 290 (140 – 380) µg/L and 25 (15 – 44) µg/L, respectively. Bone lead was associated with increased continuous systolic blood pressure, driven by the top two bone lead quartiles.

According to industry data in the REACH registration dossier, 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 the general population and occupational studies with average PbB levels below 450 µg/L. 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" merits careful examination. As indicated in the REACH Registration, given that recent studies find a lack of impact of environmental exposures upon blood pressure, a dose-response function that would serve as the basis for any health-based limit linked to blood pressure cannot be derived. The lack of dose dependent impacts indicates that lead impacts upon blood pressure are not a health endpoint suitable for quantitative risk assessment.

However, in a recent population-based cohort study including 14 289 adults, Lanphear et al. (2018) reported that low-level environmental lead exposure is a risk factor for cardiovascular disease mortality in the US. The geometric mean concentration of lead in blood was 27.1 µg/L (geometric SE 13.1). 3 632 (20 %) participants had a concentration of lead in blood of at least 50 µg/L. During median follow-up of 19.3 years (IQR 17.6 – 21.0), 4 422 people died, 1 801 (38 %) from cardiovascular disease and 988 (22 %) from ischaemic heart disease. An increase in the concentration of lead in blood from 10 µg/L to 67 µg/L, which represents the 10th to 90th percentiles, was associated with all-cause mortality (hazard ratio 1.37, 95 % CI 1.17 – 1.60), cardiovascular disease mortality (1.70, 1.30 – 2.22), and ischaemic heart disease mortality (2.08, 1.52 – 2.85). The population attributable fraction of the concentration of lead in blood for all-cause mortality was 18.0 % (95 % CI 10.9 – 26.1), which is equivalent to 412 000 deaths annually. Respective fractions were 28.7 % (15.5 – 39.5) for cardiovascular disease mortality and 37.4 % (23.4 – 48.6) for ischaemic heart disease mortality, which correspond to 256 000 deaths a year from cardiovascular disease and 185 000 deaths a year from ischaemic heart disease.

Landrigan (2018) drew the conclusion from this analysis that lead has a larger effect on cardiovascular mortality than previously recognised. Lanphear et al. (2018) estimate that lead may account for more than 400 000 deaths annually in the US which represents a tenfold increase over the number of deaths currently attributed to lead exposure. The authors argue that previous estimates have produced lower figures because those analyses assumed that lead has no effect on mortality at levels of lead in blood below 50 µg/L and, thus, did not consider the effects of lower exposures. Landrigan (2018) concluded that these findings have substantial implications for global assessments of cardiovascular disease mortality. ILA and REACH Consortium (comment #3223) provided information on two other publications pointing to shortcomings of the study by Lanphear et al. (2018).

Yang et al. (2018) commented on the study by Lanphear et al. (2018) and concluded that hypertension is unlikely to explain the association between mortality and blood lead, and the underlying mechanisms remain unknown. The authors provided for example the following arguments:

- The focus of this study is exclusively on mortality; it does not account for non-fatal events therefore limits the generalisability of their report.
- The authors did not report on the association of non-cardiovascular mortality with blood lead, an issue of relevance because cardiovascular illness and renal impairment go hand in hand, and environmental exposure to lead might increase the vulnerability of people at risk of chronic kidney disease.
- The effect sizes reported inflate the estimates of the population-attributable risk, because they were computed for the 90th to the 10th percentile intervals of the blood lead distribution. Computing this metric assumes causality, which cannot be deduced from an observational longitudinal study.
- blood lead probably serves as a surrogate for socioeconomic disadvantage and unequal access to health care; the authors adjusted for household income, but this adjustment is insufficient to correct for the differential impact of powerful social and ethnic confounders on morbidity and mortality.

Staessen et al. (2020) noted in its review of Lanphear et al. (2018) that the association between cardiovascular mortality and blood lead was statistically significant in all age groups combined, but when analysed by age strata, none of the hazard ratios expressing the risk of cardiovascular mortality in the middle or high blood lead categories reached significance; the trend p-value reached significance ($p < 0.05$) only in the age band from 75 to 84 years. The authors further noted that Lanphear et al. failed to distinguish relative risk (as captured by hazard ratios) from absolute risk (as captured by incidence rates). Using hypertension as a representative risk factor, relative risk is high and absolute risk is low at younger age, whereas at old age, relative risk is low but absolute risk is high.

Furthermore, ILA and REACH Consortium (comment #3223) provided information on two new studies.

Yu et al. (2019) assessed the association of aortic pulse wave velocity (aPWV) – a measure of arterial stiffness and thus a predictor of cardiovascular complications – with blood lead in 150 young men (mean age 27 years) with a mean blood lead level of 41.4 µg/L; prior to occupational lead exposure (SPHERL). Radial, carotid, and femoral pulse wave recordings were adjusted for ethnicity, age, anthropometric characteristics, mean arterial pressure, heart rate, smoking and drinking, and total and high-density lipoprotein serum cholesterol. At the exposure levels observed in this study, aPWV was not associated with increased blood lead levels.

In a two-year follow up study, (Yu et al., 2020) recorded the responses of office blood pressure (average of 5 consecutive readings) and 24-hour ambulatory blood pressure to first occupational lead exposure in workers newly employed at lead recycling plants. Office blood pressure was measured in 267 participants (11.6 % women; mean age at enrolment = 28.6 years; geometric mean blood lead level 40.9 µg/L for baseline and 33.0 for the last-follow-up-to-baseline blood lead ratio) and ambulatory blood pressure in 137 participants at 2 follow-up visits. In this study, it was concluded that the 2-year blood pressure responses and incident hypertension were not associated with blood lead levels.

Kidney effects

Exposure to lead has been associated with functional renal deficits including changes in proteinuria, glomerular filtration rates or creatinine levels and clearance. EFSA (2010) concluded a PbB level of 15 µg Pb/L to be associated with a 10 % increase of chronic kidney disease (CKD) in the population measured as reduction in the glomerular filtration rate (GFR) to values below 60 mL/min. Based on modelling this PbB level was converted to a daily lead exposure of 0.63 µg Pb/kg bw/d.

ILA and the REACH Consortium (comment #3223) noted that EFSA’s estimated increase in chronic kidney disease was derived from correlational analysis of GFR and blood lead associations in general population studies, specifically, the U.S. Normative Aging Study (NHANES) for the period 1999-2006. They commented that cross-sectional epidemiology studies can only highlight associations and would not provide evidence for causality. ILA and the REACH Consortium are further questioning the dose-response estimate for chronic kidney disease calculated by EFSA by referring to the publication by Evans and Elinder (2011). The authors argue that the association between lead exposure and chronic renal failure would not be evidence based but founded on few narrative reports with statistical associations between lead and serum creatinine or urea.

In the REACH Registration dossier of lead compounds (CSR, 2020), relevant studies (e.g. (Roels et al., 1994, Weaver et al., 2003)) were reviewed. The registrant concluded that blood lead levels at or below 600 µg/L appear to guard against the onset of lead nephropathy. A NOAEL of 600 µg/L was therefore adopted for renal effects and provided the basis for the DNEL proposed in the registration dossier. However, EFSA’s CONTAM Panel concluded that there is no evidence for a threshold for renal effects in adults.

In ATSDR (2020), the most recent studies on effects of lead on kidney are summarised. Several large cross-sectional studies have examined associations between PbB and GFR in adults. Three large studies relied on data collected as part of the US NHANES survey. The Muntner et al. (2003) study, which included 4 813 hypertensive subjects and 10 938 normotensive subjects, found an association between increasing PbB levels and decreasing GFR in the hypertensive group. Navas-Acien et al. (2009) included 14 788 adult subjects and reported decreased GFR (< 60 mL/minute/1.73 m^2) among participants in the highest PbB quartile (mean > 24 µg/L). Spector et al. (2011) included 3 941 adults. In the age group ≥ 60 years, the estimate for the decline in GFR was 4.5 mL/minute/1.73 m^2 per doubling of PbB. The mean PbB level in this group was 22 µg/L.

In a recent study Barry et al. (2019) investigated 211 adult men occupationally exposed to lead with the median age of 61.9 years (range 36.9-85.3 years). Median (IQR) bone, maximum past blood and current blood leads were 13.8 (9.4 – 19.5) µg lead per bone mineral gram, 290 (140 – 380) µg/L and 25 (15 – 44) µg/L, respectively. Bone lead was not associated with a reduction in GFR.

Harari et al. (2018) performed a prospective population-based cohort study with 4 341 individuals enrolled into the Malmö Diet and Cancer Study - Cardiovascular Cohort between 1991 and 1994 and for which blood lead level measurement were performed at that time (referred to as ’baseline’). 2 567 individuals were followed up (2007 – 2012) for changes in

GFR. Blood lead levels were presented in quartiles. Proportion of men, proportion of individuals with low education, alcohol consumption, waist circumference, hypertension and proportion of current smokers were all higher in the highest quartile (Q4; median 46 µg/L; range 33 – 258 µg/L) compared to the three lower quartiles (Q1 - Q3). Mean GFR at baseline and follow-up were 76 and 70 mL/min/1.73 m^2, respectively. At both time points GFR was slightly lower in the group with the highest blood lead level. At baseline, linear regression analyses adjusted for age, sex, smoking, alcohol intake, diabetes mellitus, waist circumference, eGFR at baseline, and education level showed a statistically significant inverse association between lead levels (in quartiles) and eGFRs.

Barry and Steenland (2019) investigated the mortality in a cohort of 58 368 male lead-exposed workers that was followed for a median of 19 years and experienced 6 527 deaths. Average maximum blood lead was 259 µg/L and mean year of first blood lead test was 1997. Findings suggested associations with chronic renal disease, although the trend was not statistically significant.

Mujaj et al. (2019) investigated the association of estimated glomerular filtration rate (eGFR), estimated from serum creatinine, cystatin C or both, with blood lead using the baseline measurements of the (ongoing) 'Study for Promotion of Health in Recycling Lead' (SPHERL) in newly hired workers with average age of 28.7 years prior to significant occupational lead exposure. Blood lead levels were < 30 µg/L (n=147), 31 to 63 µg/L (n=152), and ≥ 63 µg/L (n=148). The geometric blood lead levels was 43.4 µg/L with 5^{th} to 95^{th} percentile interval of 9 to 148 µg/L. The association of GFR with blood lead levels were non-significant. The authors note that reverse causality, a less efficient renal function leading to lead retention, remains an issue at current exposure levels.

Several smaller cross-sectional studies have also found associations between increasing PbB level and decreasing GFR in adult populations in which mean or median PbB levels were <100 µg/L (see references in ATSDR (2020)).

Collectively, these studies indicate that lead exposure is associated with decreasing GFR, and effects on GFR are evident in populations with PbB levels <100 µg/L. People with on-going renal disease or hypertension may be more vulnerable to the effects of lead. Estimates of the decline in GFR associated with increasing PbB levels vary across studies, with some studies indicating declines of 3 to 6 mL/minute/1.73 m^2 at PbB levels <100 µg/L (Pollack et al., 2015, Spector et al., 2011, Yu et al., 2004). However, the estimates may be inflated by reverse causality for associations between deceasing GFR and increasing lead body burden.

ILA and the REACH Consortium (comment #3223) commented that the statement that lead exposure is associated with decreasing GFR at blood lead levels <100 µg/L is not supported by the results of further studies (SPHERL), as noted above, nor by studies that appear to have been excluded in the Annex XV restriction report. For example, occupational studies – where workers typically have blood lead levels far greater than 100 µg/L – indicate a blood lead level below 600 µg/L is associated with glomerular filtration rates equal to individuals without occupational exposure.

The Dossier Submitter notes that the conclusion in the Annex XV report is based on the studies as described above and supported by the conclusion of ATSDR (2020). However, the Dossier Submitter explicitly states that the estimates may be inflated by reverse causality for associations between decreasing GFR and increasing lead body burden.

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. 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, 2010).

Several epidemiological studies have been conducted examining the impacts of prenatal 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. Similarly, studies have demonstrated that postnatal exposure to lead may severely impact scholarly achievements.

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. EFSA (2010) concluded a PbB level of 12 µg Pb/L to be associated with a 1 % reduction on the IQ scale in children. Based on modelling this blood lead level was converted to a daily lead exposure of 0.5 µg Pb/kg bw/d.

Budtz-Jørgensen et al. (2013) published benchmark dose (BMD) calculations underlying the EFSA opinion. BMD results were quite robust to modelling assumptions with the best fitting models yielding lower confidence limits (BMDLs) of about 1.0 to 10 µg/L PbB for the dose leading to a loss of one IQ point. This range is confirmed by Rocha and Trujillo (2019) whose review of effects of low-level lead exposure on behaviour and cognition suggests that PbB levels below 30 µg/L may produce diminished cognitive function and maladaptive behaviour in humans and animal models.

ILA and REACH Consortium (comment #3223) pointed to a recent publication by Van Landingham (2020) who studied the limitations of current regression models. The authors contended that missing confounders may influence IQ estimates in a quantifiable way and that these effects may “exceed or at least obscure previously reported effects of blood lead on IQ with blood lead levels below 50 µg/L”.

1.6.2.4. DNEL/BMDL derivation

1.6.2.4.1. Workers

Chronic DN(M)ELs for workers are presented in Table 1-34.

Table 1-34: DNELs for the workers as reported in the CSR for lead (CSR, 2020)

Exposure pattern	Route	Descriptors	DNEL/DMEL	Most sensitive endpoint
Acute – systemic effects	Dermal (mg/kg bw/d)	NA	NA	NA
	Inhalation (mg/m^3)	NA	NA	NA
	Oral (mg/kg bw/d)	NA	NA	NA
	Dermal (mg/cm^2)	NA	NA	NA

Exposure pattern	Route	Descriptors	DNEL/DMEL	Most sensitive endpoint
Acute – local effects	Inhalation (mg/m^3)	NA	NA	NA
Long-term - systemic effects	Systemic (µg Pb/L blood)	NOAEL = 400 µg/L	400 µg/L	Adult neurological function
		NOAEL = 100 µg/L	100 µg/L	Developmental effects of pregnant women
Long-term - local effects	Dermal (mg/cm^2)	NA	NA	NA
	Inhalation (mg/m^3)	NA	NA	NA

In the CSR, a DNEL of 400 µg lead/L blood for adults is proposed to protect workers from neurological effects in the workplace. This workplace DNEL is lowered to 100 µg lead/L blood for pregnant women (and those that are breastfeeding) which, from a practical standpoint, may apply to all women of reproductive capacity.

The Commission asked the advice of RAC to assess the scientific relevance of occupational exposure limits from some chemicals including lead and its compounds. On 17 October 2019 ECHA provided a draft scientific report for evaluation of limit values for lead and its compounds at the workplace with the proposal of a biological limit value (BLV) of 150 µg Pb/L blood[140]. The consultation on this draft opinion ended on 16/12/2019 and RAC provided an opinion by 26/09/2020[141].

1.6.2.4.2. General population

DN(M)ELs according to the CSR

In the REACH Registration CSR (2020), a DNEL of 200 µg Pb/L blood is derived for adults in the general population based on a NOAEL of 400 µg/L for effects on adult neurological function and using an assessment factor of 2. For children, tenfold lower DNELs have been derived. Table 1-35 summarises the DNELs for the general population outlined in the REACH registration.

Table 1-35: DNELs for the general population[1] as reported in the CSR for lead (CSR, 2020)

Exposure pattern	Route	Descriptors	DNEL/DMEL	Most sensitive endpoint
Acute – systemic effects	Dermal (mg/kg bw/d)	NA	NA	NA
	Inhalation (mg/m^3)	NA	NA	NA
	Oral (mg/kg bw/d)	NA	NA	NA
Acute – local effects	Dermal (mg/cm^2)	NA	NA	NA
	Inhalation (mg/m^3)	NA	NA	NA
Long-term - systemic effects	Systemic (µg Pb/L blood)	NOAEL = 400 µg/L	200 µg/L	Adult neurological function

[140] https://echa.europa.eu/documents/10162/4ce397fa-433f-fa30-af4d-bb2c2f72549b
[141] https://echa.europa.eu/oels-activity-list/-/substance-rev/22917/term

Exposure pattern	Route	Descriptors	DNEL/DMEL	Most sensitive endpoint
Neurological function		NOAEL = 100 µg/L	50 µg/L	Foetal development for a pregnant woman
		NOAEL = 50 µg/L	50 µg/L	IQ development in individual child
		NOAEL = 20 µg/L	20 µg/L	IQ development large population of children
Long-term - local effects	Dermal (mg/cm^2)	NA	NA	NA
	Inhalation (mg/m^3)	NA		NA

Notes: [1] 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.

REACH Annex I, 0.5 requires that "*The chemical safety assessment shall be based on the information on the substance contained in the technical dossier and on other available and relevant information. […] Available information from assessments carried out under other international and national programmes shall be included. [] Deviations from such assessments shall be justified.*"

ECHA notes that the registrant has not taken into account the assessment and conclusion performed by the EFSA CONTAM Panel (EFSA, 2010) and did not justify the deviation from the BMDL values identified for the general population (adults and children) as presented in the following section.

Benchmark doses calculated by EFSA

The EFSA CONTAM Panel (EFSA, 2010) concluded that there is no evidence for a threshold for critical lead-induced effects and used the BMD approach to derive reference points for risk characterisation, where the BMD is defined as that PbB level or tibia bone lead concentration, respectively, which is associated with a pre-specified change in the outcome (i.e. loss in IQ, increase in blood pressure, or increase in the incidence of CKD), denoted the benchmark response (BMR). The lower one-sided 95 % confidence bound of the BMD, denoted BMDL, was taken as the reference point.

IQ loss in children

The EFSA CONTAM Panel (EFSA, 2010) used the complete individual data from the seven studies analysed by Lanphear et al. (2005) to determine the 95th percentile lower confidence limit on the benchmark dose (BMD) of 1 % extra risk (corresponding to 1 IQ point) as a reference point for the risk characterisation of lead when assessing the risk of intellectual deficits in children measured by the Full Scale IQ score. The CONTAM Panel considered several model equations to model this relationship. The logarithmic and piecewise linear models resulted in acceptable and similar fits. The mathematical properties of the logarithmic model and the marked uncertainty associated with the relationship at PbB levels <100 µg/L were such that the CONTAM Panel concluded that the piecewise linear model, using the segment fit to the lower PbB levels, provided a reliable estimate of the **$BMDL_{01}$ of 12 µg Pb/L**.

Chronic kidney disease in adults

The EFSA CONTAM Panel (EFSA, 2010) selected as benchmark response (BMR) for chronic kidney disease (CKD) a 10 % change in the prevalence of chronic kidney disease (CKD), defined as a GFR below 60 mL/1.73 m^2 body surface/min. A 10 % response was selected for the BMR as such a change was within the range of observable values and could have significant consequences for human health on a population basis.

The populations in whom the $BMDL_{10}$ values were derived, consisted of a large number of individuals from NHANES (n=15 000), which are representative of the US general population that accounted for a substantial proportion of inter-individual variation in toxicokinetics. The prevalence of kidney disease was compared with concurrent PbB levels. The EFSA CONTAM Panel noted that this effect would depend on lead exposure over a prolonged interval of time, during which such exposure was declining appreciably. Hence, the $BMDL_{10}$ intake value for this endpoint is likely to be numerically lower than necessary to protect against lead-induced CKD.

The EFSA CONTAM Panel fitted the quantal dose-response models recommended by EFSA to the incidence data as shown in columns 1-3 of Table 1-36. When fitting these data, separately from cadmium, using a BMR of 10 % as recommended by the Scientific Committee of EFSA (2009) and an acceptability criterion of p > 0.01 for the model fit, a $BMDL_{10}$ of 15 µg/L was obtained. The highest PbB quartile of > 24 µg/L (median PbB level of 32 µg/L) was associated with an Odds Ratio (95 % CI) of 1–56 (1.17 - 2.08) adjusted *inter alia* for cadmium.

Table 1-36: Dose-response relationship between PbB levels and CKD prevalence as reported by Navas-Acien et al. (2009)

PbB quartiles (µg/L)[1]	Median µg/L (n)	CKD prevalence number of cases (%)	Odds Ratio (95 % CI)	
			Non-adjusted for cadmium[2]	Adjusted for cadmium[3]
≤11	8 (3 242)	147 (4.5)	1 (reference)	1 (reference)
11-16	13 (3 167)	274 (8.7)	1.08 (0.79-1.47)	1.10 (0.80-1.51)
16-24	19 (3 734)	468 (12.5)	1.25 (0.92-1.69)	1.36 (0.99-1.85)
>24	32 (4 635)	779 (16.8)	1.41 (1.07-1.86)	1.56 (1.17-2.08)

Notes: [1] quartiles of concurrent PbB levels; [2] adjusted for survey year, age, sex, race/ethnicity and BMI; [3] adjusted for survey year, age, sex, race/ethnicity, BMI, education, smoking, alcohol intake, hypertension, diabetes mellitus, menopausal status and blood cadmium level (log-10 µg/L)

Cardiovascular effects in adults

The EFSA CONTAM Panel (EFSA, 2010) considered a 1 % increase of systemic blood pressure (SBP) annually or on average in the whole population a public health issue, since this would result in an increased risk of cardiovascular morbidity and coronary heart disease (CHD) mortality in a population. Assuming an average SBP of 120 mmHg and a benchmark response level of 1 %, the dose associated with an increase of SBP by 1.2 mmHg corresponds to a BMD_{01}. BMD_{01} and $BMDL_{01}$ values were derived based on the slope estimates from five selected studies on blood and tibia bone lead concentration. Longitudinal data allowed the calculation of a BMD_{01} for the mean annual increase of SBP by 1 % in an individual, whereas cross-sectional data allowed only the calculation of the BMD_{01} on a population-based increase of the means. The CONTAM Panel determined four $BMDL_{01}$ values for SBP ranging from 15 to 71 µg/L (longitudinal 27 and 71 µg/L, cross-sectional studies 15 and 21 µg/L). Given the strong overlap of the study results and the absence of any obvious design deficiencies in the studies, the CONTAM Panel proposed a mean **$BMDL_{01}$ for SBP of 36 µg/L** from the four studies and a $BMDL_{01}$ = 8 µg/g for tibia bone lead concentrations.

Toxicological reference values for long-term exposure of the general population

Since the EFSA CONTAM Panel (EFSA, 2010) concluded that there is no evidence for a threshold for critical lead-induced effects, the following BMDL values are considered as toxicological reference values for long-term oral exposure of the general population:

- $BMDL_{01}$ of 12 µg/L for developmental neurotoxicity in children (decrease in IQ by 1 point on the full scale IQ);
- $BMDL_{10}$ of 15 µg/L for 10 % increase in the prevalence of chronic kidney disease (CKD) in adults ;
- Toxicological reference values for lead toxicity by EFSA (2010) $BMDL_{01}$ of 36 µg/L for 1 % increase in systolic blood pressure (SBP) in adults, corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult

A summary of the BMDL values defined by EFSA is given in Table 1-37.

Table 1-37: Toxicological reference values for lead toxicity by (EFSA, 2010)

Endpoint	Popu-lation	BMDL (µg/L)	Slope factor ($\beta_{\blacksquare}$)	Definition
Developmental neurotoxicity	children	**12**	8.33E-2	$BMDL_{01}$: 1 % change in full scale IQ score, i.e. a decrease in IQ by 1 point on the full scale IQ score
Kidney toxicity/ nephrotoxicity	adults	**15**	6.66E-2	$BMDL_{10}$: 10 % change in the prevalence of chronic kidney disease (CKD), defined as a GFR below 60 mL/1.73 m^2 body surface
Cardiovascular effects	adults	**36**	2.77E-2	$BMDL_{01}$: 1 % change in systolic blood pressure (SBP), corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult

Benchmark doses for IQ loss in children calculated by Budtz-Jørgensen et al. (2013)

The study team that had prepared the calculations for the benchmark analysis of the EFSA CONTAM Panel (EFSA, 2010) subsequently published an international pooled analysis for obtaining a benchmark dose for environmental lead exposure in children (Budtz-Jørgensen et al., 2013). In this study, the authors used a BMR of 1 IQ point corresponding to 1 % of the population average IQ of about 100 (as recommended by EFSA). For continuous data, the metric of the BMR is often defined as a percent change in the mean response as compared to the background response (EFSA Scientific Committee, 2017). While the EFSA Guidance on the BMD approach generally recommends a BMR of 5 % for continuous data as a default, EFSA notes that this be modified based on toxicological or statistical considerations. As for IQ loss, a vast literature is available that suggests it is inappropriate to base an exposure limit on a loss of 5 IQ points as this is too serious an effect. Considering that economists are calculating the loss of expected lifetime income per IQ point, the authors considered EFSA's BMR selection defensible, also in light of the public health consequences of population-wide IQ loss.

The authors estimated various models, considering all studies pooled, as fixed or as random effects, with different mathematical expressions to study the dose/response relationship. These resulted in different BMD estimates that are summarised in Table 1-38. The logarithmic model yielded the lowest BMDs and BMDLs, while the linear model gave the highest. The linear model also showed the poorest fit to the data. The weaker fit of the linear model is most clearly seen for concurrent and peak lead. The superiority of the piecewise linear model compared to the linear was confirmed by likelihood ratio testing. The two piecewise linear models produced almost identical BMD results. Both for concurrent and peak lead the 100 µg/L-curve fitted slightly better, and yielded BMDLs that were slightly higher. The logarithmic model generally had a better fit than the piecewise linear model.

A thorough sensitivity analysis showed that the benchmark results were fairly robust and depended only slightly on the specific modelling assumptions. The two best fitting dose-response functions – the Hill model and a logarithmic model – both yielded BMDLs of 1.0 to 2.6 µg/L, while piecewise linear models produced somewhat higher BMDLs of approximately 10 µg/L.

Table 1-38: Benchmark modelling results using standard dose-response models (Budtz-Jørgensen et al., 2013)

Model	Parameter	Breakpoint	No. below break point	PbB (µg/L)	
				BMD	BMDL
Concurrent lead	logarithmic			3.54	2.60
	Linear			55.81	40.54
	piecewise linear	breakpoint 75 µg/L	499	16.47	9.80
	piecewise linear	breakpoint 100 µg/L	688	17.97	**11.99**
Peak lead	logarithmic			3.93	2.73
	Linear			96.70	65.67
	piecewise linear	breakpoint 75 µg/L	103	7.12	4.34
	piecewise linear	breakpoint 100 µg/L	244	10.34	6.89
Lifetime lead	logarithmic			3.55	2.50
	Linear			64.46	44.98
	piecewise linear	breakpoint 75 µg/L	302	9.54	6.09
	piecewise linear	breakpoint 100 µg/L	482	14.84	9.69
Early childhood lead	logarithmic			5.58	3.43
	Linear			8.06	5.24
	piecewise linear	breakpoint 75 µg/L	305	15.02	8.09
	piecewise linear	breakpoint 100 µg/L	488	37.69	16.10

For the piecewise linear dose-response function, which was selected by EFSA (2010) as basis for its recommended $BMDL_{01}$ of 12 µg/L for loss of one IQ point in children, the authors found that the slope can depend on whether the dose is below or above the breakpoint.[142]

Benchmark calculations performed by ECHA

IQ loss in children

In addition to the current opinion of the EFSA CONTAM Panel on lead (EFSA, 2010) ECHA has used BMD and BMDL estimates from a set of more complex models estimated in Budtz-Jørgensen et al. (2013) for the purpose of benchmark modelling.[143] Table 1-39 reports the corresponding BMD_{01} and $BMDL_{01}$ values which are on average four times lower than the $BMDL_{01}$ recommended by the EFSA CONTAM Panel (EFSA, 2010). A **$BMDL_{01,IQ}$ of 4 µg/L** will be used for sensitivity analysis.

Table 1-39: Benchmark modelling for concurrent child lead concentration using sophisticated dose-response models (Budtz-Jørgensen et al., 2013)

Model	Parameter	BMR	PbB (µg/L)	
			BMD	BMDL
Hill model	h = 1		6.77	1.81
	h >1		9.06	1.82
Hybrid approach	P_0 = 5 %	BMR = 1 %	3.54	2.60
	P_0 = 5 %	BMR = 2.5 %	11.35 *(4.54)*[1]	7.81 *(3.12)*[1]
	P_0 = 5 %	BMR = 5 %	35.58 *(7.12)*[1]	21.70 *(4.34)*[1]

Notes: [1] values in italics denote average effect per IQ point and have been converted by dividing the original BMD(L) estimate by the corresponding BMR in order to make them comparable with $BMD(L)_{01}$. They should however not be interpreted as actual $BMD(L)_{01}$ values.

CKD in adults

In addition to the current opinion of the EFSA CONTAM Panel on lead (EFSA, 2010) ECHA has estimated additional BMD and BMDL estimates applying the open source tool PROAST (v. 67.0, accessible under https://proastweb.rivm.nl/). As reported in Table 1-40, most of the obtained $BMDL_{10}$ values are somewhat lower than the $BMDL_{10}$ value for CKD recommended by the EFSA CONTAM Panel (EFSA, 2010). A **$BMDL_{10,\,CKD}$ of 12.7 µg/L** is to be used for sensitivity analysis.

Table 1-40: Benchmark modelling results for CKD obtained with PROAST v. 67.0

Model	No. par	loglik	AIC	Accepted	BMDL	BMDU	BMD	conv
two.stage	3	-4786.12	9578.24	yes	13.8	15.0	14.4	yes
log.logist	3	-4785.22	9576.44	yes	13.7	15.1	14.4	yes
Weibull	3	-4786.07	9578.14	yes	13.7	16.0	14.5	yes

142 Mathematically the dose-response function takes the following form: $f(d) = \beta_1(d 1_{d<d_0} + d_0 1_{d>d_0}) + \beta_2(d - d_0)1_{d>d_0})$, where d_0 is the breakpoint and β_1 and β_2 are the slope parameters below and above the breakpoint, respectively. Although slightly more complex than for logarithmic and linear models, benchmark analysis is still straightforward especially if the exposure-induced loss in outcome reaches the BMR before the breakpoint.

143 It should be noted that these models are compatible with EFSA's most recent guidance on the benchmark dose approach (EFSA 2017).

Model	No. par	loglik	AIC	Accepted	BMDL	BMDU	BMD	conv
log.prob	3	-4783.37	9572.74	yes	13.5	Inf	14.2	yes
gamma	3	-4786.04	9578.08	yes	13.8	16.1	14.5	yes
logistic	2	-4803.74	9611.48	yes	22.0	23.7	22.7	yes
probit	2	-4800.76	9605.52	yes	21.0	22.7	21.8	yes
LVm: Expon. m5-	4	-4780.08	9568.16	yes	12.8	17.3	13.7	yes
LVM: Hill m5-	4	-4780.08	9568.16	yes	**12.7**	18.1	14.5	yes

Cardiovascular effects in adults

No additional modelling was undertaken. EFSA (2010) defined a corresponding $BMDL_{01}$ of 36 µg/L for 1 % increase in systolic blood pressure (SBP) in adults, corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult.

Summary

As noted above, EFSA's guidance on the benchmark dose approach (EFSA Scientific Committee, 2017) has significantly changed since the EFSA CONTAM Panel recommended its BMD(L) values for developmental neurotoxicity, kidney toxicity, and cardiovascular effects of lead exposure (EFSA, 2010). Without implying that the established benchmark values are no longer valid, ECHA has gathered additional modelling data to derive its own set of BMDL values for the purpose of sensitivity analysis. These are summarised in Table 1-41.

Table 1-41: Toxicological reference values for lead toxicity used by ECHA for sensitivity analysis

Endpoint	Population	ECHA 2020		
		BMDL (µg/L)	Slope factor ($\beta_{■}$)	Definition
Developmental neurotoxicity	children	**4**	2.5E-1	$BMDL_{01}$: 1 % change in full scale IQ score, i.e. a decrease in IQ by 1 point on the full scale IQ score
Kidney toxicity/ nephrotoxicity	adults	**12.7**	7.87E-2	$BMDL_{10}$: 10 % change in the prevalence of chronic kidney disease (CKD), defined as a GFR below 60 mL/1.73 m^2 body surface
Cardiovascular effects	adults	**36**	2.77E-2	$BMDL_{01}$: 1 % change in systolic blood pressure (SBP), corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult; Not updated

1.6.3. Exposure assessment

There are several pathways through which consumers can be exposed to lead used in hunting, sports shooting, and fishing activities. Most relevant are inhalation exposure and oral intake, with higher absorption following inhalation. Indeed, inhaled lead lodging deep in the respiratory tract seems to be absorbed equally and totally (95 %), regardless of chemical form, whereas the oral absorption of metallic lead is assumed to be up to 10 % in adults and up to 50 % in children (ATSDR, 2019).

Inhalation exposure can result from lead fumes, aerosols and/or dusts from shooting during sports shooting or hunting, and from melting lead to cast ammunition or fishing sinkers and lures. Oral exposure can result from intake of lead dust (hand-to-mouth) while shooting or handling lead gunshot, bullets or fishing sinkers and lures, when eating, drinking or smoking in an environment containing lead dust, from chewing or swallowing lead fragments. Oral exposure can also occur indirectly via the environment, such as from the consumption of game meat containing fragments of lead gunshot or bullets, or the consumption of milk, meat or drinking water. High lead exposure may also result from swallowed lead particles retained in the Annex or from incorporated lead fragments following a gunshot wound.

Analysis of lead in whole blood (PbB) is the most common and accurate method of assessing lead exposure. PbB reflects recent exposure whereas bone lead measurements are an indicator of cumulative exposure as lead remains in bones for decades (ATSDR, 2019). When evaluating PbB levels the following has to be noted:

- PbB levels provide information on recent exposure; to assess cumulative exposure from previous years or decades, lead levels in bone would need to be measured.
- PbB levels in the EU general population have been decreasing over the last 40 years.
- PbB levels in males are generally higher than in females.
- Based on data from Germany, recent statistically derived reference values (95^{th} percentile) for the general population are 4 µg/L for adult men, 3 µg/L for adult women and 3.5 µg/L for children (HBM4EU, 2019).
- To analyse the risk of a specific exposure scenario, the increase in the PbB level resulting from this exposure source was compared to the reported control/ background level.

1.6.3.1. Inhalation of lead fumes or dusts from outdoor shooting (uses # 1, 2, 3, 4, 5 and 6)

The review by Laidlaw et al. (2017) provides information on the sources of potential lead exposure from shooting guns and firing ranges, mostly indoor shooting ranges. The authors note that most projectiles are made from lead, and a large amount of lead may also be present in the primer, composed of approximately 35 % lead styphnate and lead peroxide (and also contains barium and antimony compounds) that ignites in a firearm barrel to provide the propulsion for the projectile (Tripathi and Llewellyn, 1990, Hawa et el., 2010, Basu, 1982, meng and Caddy, 1997, Romolo and Margot, 2001; references as cited by Laidlaw et al., 2017). A portion of the lead projectile disintegrates into fine fragments while passing through the gun due to misalignments of the gun barrel (Tripathi and Llewellyn, 1990, as cited by Laidlaw et al., 2017).

Lead particles, along with dust and fumes originating from the lead primer and the projectile fragments are ejected at high pressures (18 000 – 20 000 psi; 124 – 128 mpa) from the gun barrel, a large proportion of which occurs at right angles to the direction of fire in close proximity to the shooter (Tripathi and Llewellyn, 1990, as cited by Laidlaw et al., 2017).

Figure 1-31 shows a schematic outline of an outdoor and an indoor shooting range. In this case, the outdoor shooting range has a “roofed area” covering the shooter. Major differences are the larger dimension of an outdoor range compared to an indoor range and usually natural ventilation in the outdoor range and artificial ventilation in the indoor range.

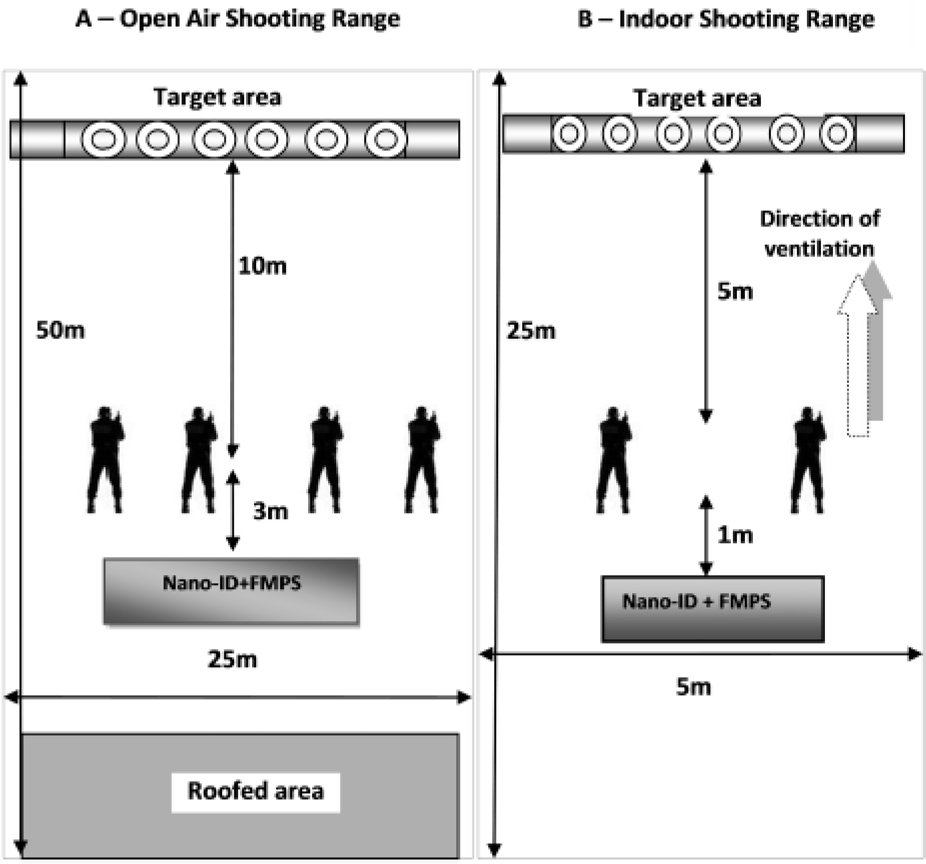

Figure 1-31: Schematic outline of the situation on outdoor [panel A] and indoor [panel B] shooting ranges (Source: Lach et al., 2015)

The shooter can inhale fine lead particulates (mainly from the primer) which constitutes the primary exposure pathway. Fine and coarse particulates from both the primer and projectile fragments also attach to the shooter's hands, clothing, and other surfaces, and can be inadvertently ingested, providing a secondary lead exposure pathway (Dalby et al., 2010, Mathee et al., 2017). Deposition of lead-containing gunshot residues on hands, followed by hand-to-mouth activity, could contribute to elevated PbB levels (Bonanno et al., 2002). Finally, shooters may be exposed to lead that has accumulated in soil dust when changing targets at outdoor firing ranges.

Instructors are generally exposed to the highest concentrations of airborne lead and tend to have the highest PbB levels due to their regular duties, which include supervising the range, cleaning, and test-firing weapons, and preparing training ammunition from commercially purchased components. A positive correlation was reported between exposure of firearm instructors to elemental lead at covered outdoor firing ranges and increased PbB concentrations (Tripathi et al., 1991).

The current Annex XV report and restriction proposal addresses risks from outdoor shooting. Indoor shooting ranges are not intended to be within the scope of this restriction because the request from the Commission refers to "terrains", which is interpreted as referring to 'outdoor' environments. However, specific information collected from indoor shooting ranges provide useful information on the hazard of shooting that need to be adapted to the conditions of outdoor shooting ranges for risk assessment.

Lead concentration in air

Bullets

Lead concentrations were measured in breathing air near the chest and face of two instructors in a covered outdoor shooting range while cadets were firing non-jacketed and jacketed lead ammunition with police revolvers. For the non-jacketed bullets mean lead concentrations were 67.1 µg/m^3 (range 36.7 - 95.6 µg/m^3) and 211.1 µg/m^3 (range 49.1 - 431.5 µg/m^3) for the two instructors, respectively. Using copper-jacketed bullets, lead concentrations in the air were reduced by more than 90 % to 5.4 and 8.7 µg/m^3 (Tripathi et al., 1991).

Bonanno et al. (2002) performed an initial investigation into lead exposure to target shooters using an outdoor covered pistol range. Lead concentration in air was measure in the breathing zone (collar) of the shooters. Airborne lead and lead dust levels were also examined on horizontal surfaces and on the hands of the shooters. The effects of ammunition calibre, ammunition type and shooting season on airborne lead levels were investigated. During summer, the front wall of firing lanes was removed in order to improve ventilation. In two competitions (one in summer, 29 August and one in winter season, 7 November), each participant fired 120 rounds, 60 rounds with 22 calibre and 60 rounds with centre-fire (45 calibre) total firing time was about 1 hour. Lead concentrations in the air were 286 and 235 µg/m^3 for the 22 calibre and 579 and 1 558 µg/m^3 for the 45 calibre weapons. The use of larger calibre also resulted in higher concentrations of lead dust on the hand of the shooter (324 and 353 µg) compared to 233 and 50 µg for the lower calibre. In the third competition (during winter-time 20 November), 60 rounds with centrefire using a specific low lead 45 calibre ammunition (WinClean^{TM}) resulted in a 99 % reduction of lead in the breathing air (ca. 15 µg/m^3).

Lach et al. (2015) studied aerosols formed during shooting events in indoor and outdoor shooting ranges. Conventional (TOX) and so called 'green' ammunition (NON-TOX) was used, where lead is replaced by other metals and substances. Lead concentrations were measured by stationary devices placed one and three meters behind the shooter for the indoor and the outdoor range, respectively. The total measured lead mass aerosol concentration ranged from 2.2 µg/m^3 for indoor shooting with NON-TOX ammunition to 10 µg/m^3 for outdoor shooting with TOX ammunition and to 72 µg/m^3 for indoor shooting with TOX ammunition. The proportion of the total mass of airborne particles deposited in the respiratory tract varied from 34-70 %, with a median of 55.9 % as calculated using the ICRP lung deposition model.

Wang et al. (2017) measured the task-based personal exposure of one shooter to total fume, lead and acidic gasses during two-hour shooting sessions at indoor and outdoor shooting ranges. Pistols with a short barrel (Sig Sauer P226, Newington, NH) and rifles with a long barrel (Rock River Arms AR15, Colona, IL) were used. The pistol used 9 x 19 mm Parabellum (also known as Luger) ammunition (Winchester, Alton, IL), while the rifle used .223 Remington ammunition (Remington, Madison, NC). Both types of ammunition had full-metal-jacketed bullets with brass casings. The respirable airborne lead concentration during two-hour shooting sessions was between 200 and 1 700 µg/m^3, although not directly comparable were exceeding the Occupational Safety and Health Administration 8-h time-weighted-average permissible exposure limit (PEL) of 50 µg/m^3. Indoor ventilation effectively removed gaseous pollutants but was unable to reduce the particulate fume and lead exposure to acceptable levels. Outdoor ventilation relied more upon natural weather and had a larger deviation. The authors discuss the high fume and lead concentrations for outdoor rife shooting with the calm weather condition resulting in little natural dilution.

Gunshot

In a covered outdoor shooting range for clay shooting athletes, Chun et al. (2018) measured lead exposure of 292 µg Pb/m^3 air with personal air samplers and 18.7 µg Pb/m^3 with group samplers. PbB levels measured in the shooters are reported below in the respective section.

FITASC and IFSSF noted in their comments submitted during the consultation (comment #3221) that "*there is no possible emission of lead dust in clay target sports shooting using lead gunshot cartridges. For lead dust to be released on firing, there must be friction between the lead pellets and the barrel's bore. In modern cartridges that use plastic wads, there is no contact between the barrel's bore and the lead load.*" The Dossier Submitter notes however that a Korean study (Chun et al., 2018) measured increased lead concentrations in the air and in the blood of clay target athletes compared to national background blood lead levels. Therefore, in the absence of further reliable measured data and studies, the Dossier Submitter assumes that there is lead exposure from clay target shooting using lead gunshot cartridges.

PbB levels in shooters

Bullets – indoor shooting

Most information on PbB levels in shooters is available from training scenarios in indoor shooting ranges.

Demmeler et al. (2009) observed that the larger the calibre of the weapon, the higher the PbB levels of indoor shooters. The following median PbB levels were reported in 131 sports shooters (9 females, 182 males) from 11 clubs with indoor shooting ranges in relation to the weapon used:

- airguns (n = 20): 33 µg/L (range 18 – 127 µg/L);
- airguns and 0.22 calibre weapons (n = 15): 87 µg/L (range 14 – 172 µg/L);
- 0.22 calibre and large calibre handguns (9 mm or larger) (n = 51): 107 µg/L (range 27 – 375 µg/L)
- large calibre handguns (n = 32): 100 µg/L (range 28 – 326 µg/L)
- only use of large calibre handguns (n = 11; International Practical Shooting Confederation shooters): 192 µg/L (range 32 - 521 µg/L).

The authors did not measure PbB levels in non-shooting persons but discussed that PbB levels for the German population were 33 µg/L in 1998 and further decreased since that time. They reported a clear difference between the uptake of lead from shooters using lead-containing cartridges and airgun users. The former group (n = 110) had a median of 105 µg/L (range 14 – 521 µg/L) whereas the latter (n = 20) had median PbB levels of 33 µg/L. PbB levels of the first group also depended on the training time or rather on the time of exposure within the period of 1 month. The Spearman's rank correlation coefficient of 0.395 ($P < 0.001$) showed an upward trend of PbB levels with the time spent on the range per month. PbB levels did not only depend on the factors mentioned above, but also on the rounds shot each month which were examined by analyses of quartiles. 27 marksmen shooting fewer than 200 rounds per month (1st quartile) had a median of 87 µg/L (range 28 – 314 µg/L). 28 marksmen shooting between 200 and 399 rounds per month (2nd quartile) had a median of 90 µg/L (range 27 – 315 µg/l). Shooters (n = 29) of the 3rd quartile group which included 400–680 rounds per month had 118 µg/l (range 29 – 375 µg/L) whereas shooters (n = 23) of the 4th quartile group (more than 680 rounds per month) had indeed

138 µg/l (range 37 – 521 µg/L).

Mühle (2010) reported in his thesis a high correlation between number of shots per month and increased PbB levels (Figure 1-32), even though the sample was fairly small.

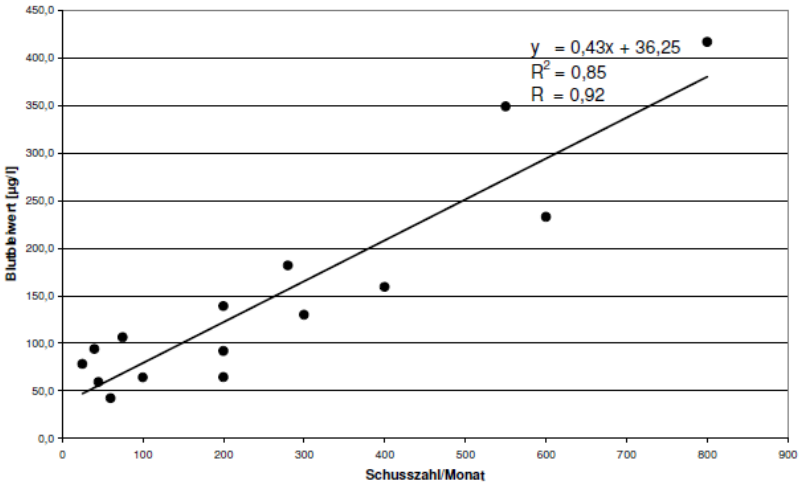

Figure 1-32: Correlation of number of shots per month (Schusszahl/Monat) with PbB levels (Blutbleiwert) in indoor sports shooters (Mühle, 2010)

Laidlaw et al. (2017) reviewed 36 articles that reported blood lead levels from shooters using lead bullets at mainly indoor shooting ranges. In 31 studies, PbB levels > 100 µg/L were reported in some shooters, 18 studies reported PbB levels > 200 µg/L, 17 studies > 300 µg/L, and 15 studies PbB levels > 400 µg/L. For indoor shooting ranges, the quality of the ventilation system has been identified as important measure to limit exposure. Laidlaw et al. (2017) noted that there is a "lack of evidence" gap in the literature demonstrating that ventilation systems can maintain air lead levels at indoor ranges below the US OSHA (50 µg/m^3) or California (0.5 – 2.2 µg/m^3) guideline.

Only very limited relevant information is available on PbB levels measure in sports shooters training in outdoor ranges.

Bullets – outdoor shooting

In a pilot project, which is published only as an abstract, Turmel et al. (2010) measured blood lead levels and pulmonary function in 12 biathletes using a gun powder cartridge containing a lead bullet of 2.6 grams. 12 cross-country skiers of similar for age, sex, anthropometric status, number of training hours per week and prevalence of atopy were used as controls. Lung function did not differ between the groups but mean PbB levels in biathletes (0.087 ± 0.015 µmol/L; 18 ± 3.1 µg/L) was slight but significantly higher compared to the cross-country skiers (< 0.04 ± 0.0 µmol/L; < 8.3 µg/L). The type of ammunition used was not specified. The difference in PbB levels between biathletes and cross-country skiers was ≥ 10 µg/L.

Mathee et al. (2017) investigated in South Africa 87 shooters (80 males, 7 females) from one outdoor and three indoor shooting ranges and as controls 31 archers (23 males, 8 females) from three archery ranges. The mean experience in shooting was 22 years. 92 % of the shooters used non-jacketed lead bullets and 54 % of the shooters were also hunters. Shooters had significantly higher PbB levels compared to archers. The twelve shooters from the outdoor shooting range had on average a 43 µg/L higher PbB level (70 ± 42 µg/L) compared to 20 archers (27 ± 14 µg/L) (of which 19 did not perform gun shooting). Mean PbB levels for shooters training in three indoor shooting ranges were 78, 134 and 165 µg/L higher (105 ± 70 µg/L, 161 ± 98 µg/L, 192 ± 163 µg/L) compared to the 20 archers (27 ± 14 µg/L). Considering all gun shooters, irrespective of indoor or outdoor training, PbB levels were 42 µg/L lower for females compared to males. Shooters with higher shooting frequency (more than monthly) showed higher PbB levels compared to shooters shooting less frequently (less than monthly). Casting of own bullets increased PbB concentrations by 22 µg/L, hunting by 34 µg/L and placing bullets in the mouth by 82 µg/L.

Vandebroek et al. (2019) investigated, among others, 10 police officers (8 males, 2 females) having shooting training only a few times a year (mean 10±5.2 hours per year). The officers used 9 mm ammunition with a lead bullet totally covered by copper and a NON-TOX primer (not containing antimony, barium, or lead) while shooting for "a few hours". It is not specified if shooting was performed in an indoor or outdoor shooting range. Mean PbB levels were 14.1 µg/L before and slightly elevated with 14.7 µg/L after shooting. P50 and P95 reference values for lead were 1.8 µg/L and 4.9 µg/L, respectively.

Information was submitted during the consultation for one shooter with high training volume with a PbB level of 72 µg/L (comment #3277). The reference PbB level for adult males in the general population was reported to be < 90 µg/L. The sports shooter, 55 years of age, was reported to practice since 1999 and to be a member of the Austrian muzzle loading National Team since 2006 with the following shooting activities:

1. Shots per year:
    - Muzzle loading (black powder) training and competition: ca. 5 000 shots
    - Black powder long-range rifle: ca. 800 shots
    - Big bore pistol and Revolver (modern): ca. 4 000 shots
    - Small bore pistol and rifle (modern): ca. 1 000 shots
    - Military rifle (modern): ca. 800 shots
    - Air pistol: ca. 6 000 shots
2. Melting lead for bullet casting: ca. 250 kg per year
3. Casting lead bullets: ca. 8 000 per year
4. Reloading modern ammunition: ca. 5 000 rounds

It should be noted that a reference value of 90 µg/L was identified by the German Federal Environmental Agency[144] for adult males in the year 2003 based on the 95th percentile of the blood lead level in the general adult male population. However, in 2019, the reference value was lowered to 40 µg/L for adult males[145]. Consequently, the measured PbB level of the shooter is well above the current 95th percentile of the PbB level for adult males in Germany.

Gunshot – outdoor shooting

Chun et al. (2018) investigated the exposure to lead and other metals in 9 male and 5 female Korean clay shooting athletes in an outdoor shooting range. Exposure was 292 µg Pb/m^3 air measured with personal air samplers and 18.7 µg Pb/m^3 with group samplers as reported above. Mean PbB level and standard deviation was 45.2 ± 16.0 µg/L for both

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[144] https://www.umweltbundesamt.de/sites/default/files/medien/377/dokumente/aktual-ref-metalle.pdf

[145] https://www.umweltbundesamt.de/sites/default/files/medien/4031/dokumente/blei_aktualisierung_der_referenzwerte.pdf

sexes combined. The differences in PbB levels were significant between the sexes with 36 ± 7.7 µg/L for females and 51 ± 16.4 µg/L for males. According to the authors, the PbB levels were higher than the upper limit of normal levels (data not provided). Mean PbB levels in the general population of Korea (2010 to 2011) were reported with 18.3 ± 7.9 µg/L for females and 22.2 ± 10.4 µg/L for males (Eom et al., 2017). Chun et al. (2018) reported that PbB levels increased with increasing training frequency: 29 µg/L; 4 times/week (n = 1); 36.4±5.5; 5 times/week (n = 7); 58.2±15.5; 6 times/week (n = 6). However, due to the marked sex-related differences in PbB levels, such a separation according to training frequency would have to be performed according to sex. Without such a separation the presented data might be interpreted in a way that females trained less frequently compared to males. The differences in PbB levels between the general population of Korea and the clay shooters were 18 and 29 µg/L for females and males, respectively.

During the consultation, the measured blood lead level of a Slovak Olympic bronze medallist in shotgun shooting, was submitted as an element of comment #3518. The athlete is reported to have been exposed to lead for a total of 20 years, firing an average of 20 000 rounds per year. A single blood lead concentration was reported (32 µg/L < LOQ) (#3518). Whilst the Dossier Submitter acknowledges that this sample does not appear to indicate an elevated blood lead concentration, it notes the relatively high limit of quantification, the absence of any contextual information around the sample (i.e. the intensity of shooting prior to the sampling) as well as the absence of sample information of a longer time period. Such data would be necessary for a more thorough evaluation of the representativeness of these data for the assessed use.

Furthermore, the Dossier Submitter notes that the blood lead levels reported above are single samples without further contextual information on the time between shooting and testing and the amount of shooting that was performed before testing.

During the consultation, several reasons were brought forward (e.g., by FITASC/ISSF comment #3221) contributing to the low exposure of sports shooters using shotguns such as:

- Open air environment with natural ventilation
- Technical measures to limit exposure of outdoor shooters
- lead is contained in the cartridge (#3194)
- shooting positions are minimum 2 to 2.5 metres apart
- minimum firing distance to the target to prevent exposure from the projectile splashing on the target or berm

The Dossier Submitter acknowledges that lead exposure of sports shooters is assumed to be lower for outdoor shooters compared to indoor shooters. However, lead dust formation at outdoor shooting ranges with potential lead dust exposure of outdoor shooters either by inhalation and/or by hand-to-mouth contact are well-known exposure pathways and risk management measures are usually recommended at shooting ranges to minimise exposure.

1.6.3.2. Exposure of hunters (uses # 1 and 2)

Since it is not possible to separate between lead exposure from shooting trainings, hunting, handling of ammunition and consumption of game meat, lead exposure of hunters is considered on its own. However, it should be noted that the database on PbB levels in hunters is very limited and all published studies have certain limitations and uncertainties.

Gunshot and bullets

Iqbal et al. (2009) investigated PbB levels from 736 males and females from six cities in North Dakota, aged 2 to 92 years, 80.8 % of whom reported a history of wild game consumption (venison, other game such as moose, birds; waterfowl excluded) and 55.5 % lead-related hobbies car/boat repair, lead casting, target shooting. PbB levels for males (14.9 µg/L) were 6 µg/L higher compared to females (8.9 µg/L). For lead-related hobbies such as casting bullets, hunting or target shooting the PbB level increment was 5 µg/L compared to persons with no lead-related hobbies. It has to be noted that blood samples were taken 4 to 5 months after the hunting season and that hunting activity as such was not analysed.

In one Italian study (Fustinoni et al., 2017), PbB levels were measured in hunters hunting birds and mammals and consuming game meat. The information on hunters with > 10 hunts per year indicates that hunting (which may include assembling of the ammunition) has a higher impact on PbB levels than the consumption of game meat. In hunters undertaking > 10 hunts per year and consuming game meat (n = 61) the median PbB level was 37 µg/L, 23 µg/L higher compared to the controls with a median PbB level of 14 µg/L. It has to be noted that in this study individuals who had consumed game meat the week before were excluded and that the PbB measurements were performed outside the regular hunting season. Therefore, the measured PbB levels are expected to underestimate the actual exposure from game meat consumption and hunting.

In a study in two groups of native people in Canada with subsistence hunting of migratory birds using gunshot and bullets (Tsuji et al., 2008), mean PbB levels for males (which can be assumed to be the hunters) were 47 and 53 µg/L higher compared to the levels of inhabitants of a highly industrialised city.

Bullets

For 25 male hunters in Switzerland the increase in PbB level compared to the controls was reported to be 2 µg/L (Haldimann et al., 2002). However, since the control group was not characterised with regards to their hunting activities and the consumption of game meat, the result cannot be used for the assessment of hunting activities and game meat consumption.

For gun shooters using non-jacketed bullets training in indoor or outdoor shooting ranges in South Africa, the PbB levels of shooters that are also hunting were on average 34 µg/L higher than those of shooters not hunting (Mathee et al., 2017).

1.6.3.3. Inhalation exposure from melting lead ('home-casting') of ammunition or fishing tackle (mainly uses # 2, 4, and 7)

To home-cast lead bullets or sinkers and lures for fishing, lead is melted down and poured into moulds. Lead melts at the relatively low temperature of 327°C and lead fumes are released at 482°C, which can be inhaled and absorbed. Lead fumes mixed with air forms a fine yellowish/brown dust (lead oxide) which can be inhaled and which also settles on surfaces. The main hazard activities involve hot lead smelting, casting and handling dross (the contaminate residue that is skimmed off in the melting process[146]). Good hygiene and ventilation are mentioned as the best way to reduce lead exposure.

Fishing sinkers and lures (use 7) are often produced by home-casting and small-scale casting by individuals or in the 'back rooms' of fishing tackle shops. This may result in relatively high exposure to lead as the lead is likely to be cast with no or insufficient

[146] https://oem.msu.edu/images/annual_reports/lead%20hazards%20casting%20and%20reloading-sept.pdf

exposure abatements technology (risk management measures). In addition, the casting may have significant health impact of the persons involved.

Many suppliers sell moulds for casting lead bullets, fishing sinkers and lures. However, some suppliers warn that lead dust and fumes can be extremely toxic and recommend that even if melting and casting lead is performed outdoors, protection with a respirator is required.

Several reports or studies have been published describing toxicity symptoms in persons melting lead or in children living in the vicinity of lead melting activities (Bressler et al., 2019, Brown et al., 2005, Mathee et al., 2013, Olivero-Verbel et al., 2007, Yimthiang et al., 2019). As a worst-case example, an Alaskan adult male patient suffered from lead poisoning as a result of inhaling lead dust and fumes from melting and casting lead for several years. This patient was anaemic and showed a high level of neutrophils. The PbB level was 1 330 µg/L, the highest PbB level ever recorded in Alaska (State of Alaska Epidemiology, 2001).

Comment #3237 received from the Finnish Wildlife Agency during the Annex XV report consultation provided information on an unpublised small-scale survey of middle-aged men who had eaten both small and large game for several decades since infancy (several times a week, up to 10 servings/week), engaged in sports shooting, and half of them engaged also in cartridge recharging. Their blood lead levels ranged from 0.09 to 0.19 µmol/L [4 to 39 µg/L], averaging 0.13 µmol/L [27 µg/L]. One person, who also carried out casting work, had a blood lead content of 0.7 µmol/L [145 µg/L], which was clearly higher than the other measurement results. The submitter of the comment noted that the reported lead concentrations would be below the action limit for occupational health care of 1.4 µmol/L [ca. 290 µg/L] and concluded that based on the study, it appears that eating a very large amount of game, shooting as hobby, and reloading cartridges do not cause a dangerous lead exposure to health. The Dossier Submitter acknowledges the information but notes that no further details were reported such as the number, age and sex of the persons investigated, individual information on blood lead levels, frequency, amount and type of game meat consumed, frequency, intensity and type of shooting and casting work, and the time of blood lead level measurement related to exposure to lead.

1.6.3.4. Oral exposure to lead dust (hand-to-mouth) from shooting or handling lead ammunition or fishing tackle (uses 1, 2, 3, 4, 5, 6 and 7)

From occupational settings, the oral uptake of lead dust by the hand-to-mouth route under insufficient hygiene measures and its contribution to the blood lead burden is well known. However, the database is very limited and does not permit to quantify the risk from oral exposure to lead dust (hand-to-mouth) from shooting or handling lead ammunition.

Lead dust associated with shooting may be deposited on all surfaces of a shooting range, with specifically high concentrations in the impact area (Mirkin and Williams, 1998). Lead dust can adhere to shooter’s clothes and potentially contaminate vehicles and homes. The CDC (1996) measured carpet dust lead concentrations in FBI student dormitory rooms and in 14 non–student dormitory rooms at a firing range and training facility. They observed that student dormitory rooms had significantly higher lead levels than non–student dormitory rooms, suggesting that the FBI students were contaminating their living quarters with lead. ‘Take home lead’ has been described mostly for occupational settings but given the fine particle nature and lead concentrations of dust associated with shooting, the ‘take home lead’ pathway of exposure from shooting must be recognised and curtailed (Laidlaw et al., 2017).

In the CSR (2020), the amount of lead ingested from reloading activities (home-casting) was calculated with 14 µg for cleaning spent cartridges and with 4.7 µg for reloading lead bullet or shot. The Norwegian Scientific Committee for Food Safety (VKM) (Knutsen et al., 2013) reported that PbB levels were significantly higher in participants who reported self-assembling of lead-containing bullets (median PbB 31 µg/L compared to 16 µg/L in the control group).

The practice to keep lead bullets in the mouth for shooting was reported for 17 % of the shooters investigated with an average PbB level increment of 82 µg/L (Mathee et al., 2017). Reports of lead poisoning among adults retaining two or more ingested lead gunshot pellets have been published for example by Hillman (1967) or Madsen et al. (1988).

Sahmel et al. (2015) quantified the mean lead skin-to-saliva transfer efficiency with 24 % (range: 12–34 %). Based on this study the hand-to-mouth exposure from lead dust on the skin from fishing sinkers and lures (and lead bullets or shots) is highly plausible.

Therefore, shooters and personnel cleaning shooting ranges or recovering lead shots or bullets can be expected to have high potential for lead exposure in case strict hygiene measures to prevent exposure are not applied.

Depending on the use of land at the end of life of a range (and on the land zoning at local level), oral uptake of lead from contaminated soil might also be possible, in case soil is not fully remediated. For example, Urrutia-Goyes et al. (2017) measured high lead concentrations in the topsoil of a former range in Greece that had been converted into a public park. Lead levels in blood of the residents were not measured. The authors performed a human health risk assessment and concluded that that the main exposure pathway of concern, especially for children, was ingestion, followed by dermal contact and inhalation.

1.6.3.5. Swallowing of lead fragments (uses # 1, 3, 5, and 7)

Grade et al. (2019) reported that poison control centres (outside the EU) are commonly consulted on cases of ingestion of lead and previous studies had noted that some of these are fishing weights (Cole et al., 2010). In the absence of data from the EU, the reported data from outside the EU are used as a surrogate. In 2016, 2 412 of the poisoning cases reported to poison control centres in the US were due to single exposures to lead, typically due to the ingestion of small lead items (Gummin et al., 2017). In many cases the lead item ingested was not defined. However, in 38 cases reported to US poison control centres in 2016 the item ingested was specifically recorded as lead fishing tackle and most of these (28 cases) were due to ingestion by children under 6 years of age (Gummin et al., 2017).

Grade et al. (2019) noted that not all ingestions of lead sinkers will result in reports to poison control centres and the toxic impacts of the exposure may not be immediately evident. It is likely that the poison control centre numbers underestimate the total number of children exposed to lead via this route.

Retention of lead fishing sinkers in the stomach and intestines of children following ingestion has been demonstrated and can result in long-term elevation of lead levels (Mowad et al., 1998).

Significantly elevated blood lead levels from 450 to 690 µg/L have been documented in children ingesting fishing sinkers (Cole et al., 2010, McCloskey et al., 2014, Mowad et al., 1998, St. Clair and Benjamin, 2008). The ingestion of lead pellets by children resulted in PbB levels of 530 to 650 µg/L (Rozier and Liebelt, 2019, Treble and Thompson, 2002).

The practice to bite lead split shot to secure onto the fishing line has frequently been reported (Grade et al., 2019). Carrier et al. (2012) report a 21-year-old man with signs of lead poisoning and PbB levels of 1 410 µg/L. The patient reported that he commonly chewed fishing lead sinker and may sometimes swallow them during the preparation of the fishing rod.

1.6.3.6. Indirect exposure of humans via the environment

1.6.3.6.1. Consumption of game meat hunted with lead ammunition (uses # 1 and 2)

Consumption of meat from game hunted with lead ammunition is likely to be a relevant source of lead exposure. However, only limited information has been found in the scientific literature. For this reason, ECHA collaborated as part of the preparation of this dossier with EFSA in order to estimate the possible impact of (fragments of) lead shots and bullets on high-end consumers of game meat.

1.6.3.6.2. Impact of lead gunshot and bullets on lead concentrations in game meat

Lead gunshot used for hunting can 'fragment' after hitting quarry animals resulting in small particles of lead being distributed within the tissues of an animal. Some of these fragments may reside in edible tissues away from the primary wound and remain there after butchery and food preparation (Green and Pain, 2014). According to the available evidence, it is not possible to successfully remove all embedded fragments of lead from the wound channels of shotgun shot game as tiny lead particles would go unnoticed.

Felsmann et al. (2016) investigated the effect of lead bullets on game meat. The projectile that penetrates the animal body generates a temporary cavity and this phenomenon is accompanied by a change in the pressure within the funnel of a wound and in the adjacent tissues. A cavity is formed behind the projectile and may persist even after the projectile has left the target. Its size is difficult to predict and the momentary shape of the frontal part of a projectile seems to have a major impact on its formation and size (Felsmann et al., 2012). Due to the temporary cavity phenomenon, especially pressure fluctuations in adjacent tissues, it may be assumed that this phenomenon is responsible for lead transfer deep into the tissues that surround the path of a wound.

The highly variable results of studies on the content of lead at the same distance from the path of a wound in individual animals are unsurprising due to this physical phenomena (Dobrowolska and Melosik, 2008). The increased lead levels in animals where projectiles were hitting bones, as reported by other authors, seem to confirm the hypothesised lead transfer from projectiles to animal tissues. After hitting the bone, a projectile may be fragmented, the core may be exposed, and secondary projectiles may be generated. Detached fragments most often move at a different velocity than the projectile core, contaminating a larger area of tissues (Knott et al., 2010). These fragments increase the surface of lead elements that come in contact with the surrounding tissues. Detached projectile fragments and comminute bone become secondary projectiles that generate a temporary cavity and, although an individual "secondary" temporary cavity may coalesce, it always expands the area of contaminated tissues (Felsmann et al., 2016).

The Norwegian Scientific Committee on Food Safety (Norwegian VKM, 2013) reviewed the data on the impact of different ammunition types on the lead concentration in game meat and found that expanding lead-containing bullets produce a cloud of lead particles in the meat around the wound channel. Fragment sizes varied between < 1mm and up to 10 mm. Disruptively-expanding bullets may retain down to 10 % (fragmenting type) or 20-80 % (semi-fragmenting type) of their original weight. Expanding bullets may retain 60-100 % of their original weight, and some bonded types appear to be considerably more stable than unbonded types although great variations exist. Disruptively-expanding, expanding unbonded and some expanding bonded lead-containing bullets produced on average 200 radiographically visible fragments per bullet (range of averages 90 - 370), and up to 800 fragments per bullet were detected for individual bullet types. Very small fragments presumably remain undetected. Other types of bonded expanding lead-containing bullets produced fewer than 10 fragments per bullet. Non-lead disruptively-expanding bullets produced on average 6 to 23 fragments, while non-lead expanding-nose bullets produced 0 to 2 fragments. Lead fragments from disruptively-expanding, unbonded and some bonded expanding lead-containing bullets were found by radiography in various species (roe deer, red deer, wild board, sheep, chamois) with an average radius of 15 cm around the wound channel. The maximal penetration length of visible fragments was on average 29 cm. In a study on sheep, fragments from more stable types of expanding lead-containing bonded bullets were found at distances less than 5 cm. This is comparable to fragments from non-lead disruptively expanding bullets and non-lead expanding-nose bullets measured in the same study. Corresponding studies on moose have not been found. An available study indicates that lead concentrations above 0.1 mg/kg can be found at 25 cm distance from the wound channel in red deer and wild boar shot with various unknown types of lead ammunition (Norwegian VKM, 2013).

Kollander et al. (2017) detected lead nanoparticles in the range 40 to 750 nm in game shot with lead-containing bullets. The median diameter of the detected nanoparticles was around 60 nm. In game meat sampled more than 10 cm away from the wound channel, no lead particles with a diameter larger than 40 nm were detected. The absorption and systemic bioavailability of (nano)particles has already been demonstrated for TiO2 particles (Pele et al., 2015, Jani et al., 1994) and gold nanoparticles (Hillyer and Albrecht, 2001, Zhang et al., 2010) and can in principle not be excluded for lead fragments in the nano range.

Broadway et al. (2020) investigated fragmentation in deer shot with three different types of low velocity lead ammunition (rifled slugs, sabot slugs and modern muzzle-loading bullets). All radiographed deer had evidence of fragmentation, with a geometric mean of 13.1 (95 % CI = 10.3, 16.8) fragments per deer. Most fragments (89 %) were <5 mm from wound channels, and no fragment travelled beyond 205 mm from a wound channel. Fragments were often retained within the muscle tissue of deer with a geometric mean rate of 0.55 (95 % CI = 0.48, 0.65). Muzzleloader bullet fragments were larger than those generated by rifled and sabot slugs, and sabot slug fragments had the shortest dispersal from wound channels. Shoulder-shot placement and bone contact for all ammunition resulted in a significantly larger number of fragments. Shoulder-shots also generated more small fragments and higher fragment retention in muscle tissue. The author concluded that, compared to high-velocity rifle bullets, significantly fewer lead fragments are made available to humans and wildlife that consume game shot with low-velocity ammunition types.

In a recent study by Trinogga et al. (2019), the differences in the fragmentation patterns of lead-based and lead-free hunting rifle bullets using radiographs of 297 wild ungulates shot during regular hunting events in Germany was studied. Compared to lead-free ammunition, both the number of bullet fragments and the maximal distance between fragments and the wound channel increased when bullets were lead-based. The study divided the bullets into five classes depending on their material and ballistic behaviour: type 1 were lead-free deforming bullets, i.e. bullets made of copper or copper alloys that resist fragmentation; type 2 were lead-free partially fragmenting bullets, i.e. copper or brass bullets where the front part is designed to fragment; type 3 were semi-jacketed lead-core bullets, i.e. projectiles with a lead core partially enclosed by a copper jacket; type 4 were semi-jacketed bullets with two lead cores of different hardness that are designed for controlled fragmentation; type 5 were semi-jacketed bullets whose lead core is bonded to the jacket in order to prevent separation of the two components during flight (upon impact, semi-jacketed bullets still impact). For all three types of lead-based semi-jacketed bullets (types 3, 4 and 5) tested, the mean maximal distance of fragments to the wound channel exceeded 10 cm (11.7 cm for type 3, 15.6 cm for type 4, and 11.3 cm for type 5).

In relation to fully metal jacketed lead bullets (often referred to as FMJ), the Dossier Submitter acknowledges that this type of ammunition can be used in a limited set of hunting scenarios, for example on small size animals like grouse, as it is not considered to be technically suitable for large game. Comment #3255 (Finnish Hunters' Association) reported the results of a field test suggesting that FMJ bullets (used for small game) do not cause lead contamination in game meat and would not be available for ingestion to predators (as raptors).

1.6.3.6.3. Best practices to handle game meat

In several European countries, hunters should follow "best practice" as advised by several wildlife authorities. However, there is no evidence to support if "best practice" advice is followed. This basic game meat handling advice is often part of the hunting education prior to any compulsory hunting exam. For example, it is recommended to remove the meat around the gunshot wound defined as any meat that is visibly affected by the bullet and an additional 10 cm of meat visibly unaffected by the bullet (e.g., (Swedish NFA, 2014d).

In that regard, the FACE Guidance on managing risks from lead[147] states: *"All expanding lead core bullets fragment on impact and shed lead particles through the meat as the bullet penetrates. This is also true for lead shot. This gives rise to* microscopic *particles of lead widely distributed throughout the carcase. Expanding lead core bullets typically release thousands of fragments of varying size (including millions of nanoparticles) and the larger ones can be visualized using X-rays (Arnemo et al., 2016, Knott et al., 2010).*

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The lead levels are greatest immediately surrounding the wound channel but may remain detectable up to 30 cm away depending on bullet type, bullet resistance during penetration and bullet velocity upon impact.

Attempts to remove lead ammunition from game meat can be successful at significantly reducing the levels of lead contamination. Research in Sweden has shown that proper handling of game shot with lead ammunition can effectively eliminate the risk (Swedish NFA, 2014a). The Federal Institute for Risk Assessment, Germany (BfR, 2011) states that cutting out large sections of meat around the bullet hole is not always enough to guarantee removal of lead.

Risk management options can include the application of appropriate game meat handling techniques, eating game shot with non-lead ammunition, or reducing their intake of game shot with lead ammunition."

The Dossier Submitter agrees with the FACE Guidance but highlights that (i) based on lead

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[147] https://www.leadammunitionguidance.com/lead-ammunition-in-game-meat/

particles found around wound channels (e.g., Trinogga et al. (2019)), it is uncertain whether removing less than 30 cm of meat around the wound channel is effective in "significantly reducing the levels of lead contamination", and (ii) it is unknown how many hunters would remove that much meat.[148]

1.6.3.6.4. Discard of lead contaminated meat

Lead concentration in the wound channel can be very high. Dobrowolska and Melosik (2008) reported for 16/20 meat samples from the wound channel of wild boar and red deer lead concentrations > 100 mg/kg wet weight, 1/20 even exceeding 1 000 mg/kg wet weight. Swedish NFA (2014a) reported median and maximum lead concentrations from the wound channel of 146 and 1 829 mg/kg wet weight.

Several investigations studied lead concentration in game meat in relation to the distance to the wound channel. In tissues from wild boar and red deer hunted with unspecified different brands of expanding lead-based ammunition routinely used in Poland (Dobrowolska and Melosik, 2008) maximum concentrations measured at the entry wounds were ca. 1 100 mg/kg wet tissue (wild boar) and 480 mg/kg (red deer) and at exit wounds 740 mg/kg (wild boar) and 120 mg/kg (red deer). In all samples taken at 5 cm and 15 cm distance from the wound channel, the tissue concentrations exceeded 0.1 mg/kg. At 25 cm distance, nine of the 10 red deer and eight of the 10 wild boar samples were still greater than 0.1 mg lead/kg, and at 30 cm five (red deer) and eight (wild boar) of the 10 samples in each species were greater than 0.1 mg lead/kg (see Table 1-42).

Table 1-42: Lead concentration in wild boar and red deer at different distance from the bullet pathway (Dobrowolska and Melosik, 2008)

Indiv. No.	Carcass weight	Lead concentration (mg/kg wet weight)[1]						
		Wound		Distance from bullet pathway (cm)				
		entrance	exit	5	15	25	30	control
Wild boar								
1	86	**1 095.9**	**736.0**	**32.2**	**11.2**	**4.2**	**3.3**	0.3
2	82	**189.2**	**67.4**	**18.9**	**6.2**	0.2	0.2	0.2
3	78	**125.2**	**59.8**	**14.2**	**0.8**	0.2	0.2	0.1
4	76	**131.4**	**77.7**	**11.9**	**3.8**	0.2	0.2	0.2
5	43	**361.4**	**633.1**	**47.5**	**6.8**	**3.8**	**3.1**	0.3
6	34	**179.2**	**395.4**	**26.2**	**5.2**	**2.6**	**0.9**	0.1
7	32	**74.0**	**95.0**	**5.1**	**0.9**	0.1	0.1	0.1
8	32	**65.5**	**158.3**	**8.2**	**0.8**	0.2	0.2	0.2
9	29	**76.5**	**212.3**	**10.3**	**0.8**	0.2	0.2	0.2

[148] The Dossier Submitter notes that removal of lead gunshot and lead bullet fragments results in discarding a considerable quantity of meat, especially in large game animals. In Norway, discarding meat close to wound channels results in approximately 200 tonnes of contaminated meat being discarded annually, representing an economic loss of around €3m (Kanstrup et al., 2018) This suggests that less affluent hunters may be tempted to remove less meat.

Indiv. No.	Carcass weight	Lead concentration (mg/kg wet weight)[1]						
		Wound		Distance from bullet pathway (cm)				
		entrance	exit	5	15	25	30	control
10	26	**69.7**	**176.3**	**10.2**	**2.3**	0.1	0.1	0.1
Red deer								
1	116	**234.6**	**76.5**	**43.8**	**8.6**	**0.3**	0.1	0.1
2	113	**364.8**	**102.6**	**53.7**	**5.7**	**1.1**	**0.8**	0.2
3	110	**185.8**	**67.3**	**31.9**	**7.9**	**0.2**	0.1	0.1
4	102	**476.9**	**92.7**	**87.5**	**16.9**	**4.8**	**1.1**	0.3
5	98	**156.6**	**60.4**	**16.9**	**5.1**	0.2	0.2	0.2
6	97	**243.8**	**97.2**	**42.7**	**13.7**	**0.3**	**0.2**	0.1
7	96	**176.8**	**67.9**	**38.7**	**9.6**	**0.2**	0.1	0.1
8	93	**346.5**	**123.7**	**64.2**	**12.5**	**5.8**	**0.9**	0.3
9	89	**198.5**	**64.9**	**32.1**	**2.6**	**0.2**	0.1	0.1
10	88	**135.7**	**59.9**	**23.2**	**4.3**	0.1	0.1	0.1

Notes: [1] lead concentrations exceeding the individual control value are marked in bold

Investigations from Sweden on moose meat samples found lead concentrations ranging from levels below detection limit 0.02 mg/kg up to 31 mg/kg. 54 Percent of the samples (29/54) showed lead concentrations above the detection limit and 33 % of the samples (18/54) exceeded the lead concentration of 0.1 mg/kg. Samples from wild boar showed that up to 10 cm around the wound channel 50 % of the samples exceeded 0.1 mg/kg and 15 cm from the wound channel 27 % of the meat samples exceeded this level (Swedish NFA, 2014b, Swedish NFA, 2014c). More detailed data are provided in Table 1-43.

Table 1-43: Lead content (mg/kg) in the meat of wild boar in relation to the distance to the wound channel (Swedish NFA, 2014c, Forsell et al., 2014, Swedish NFA, 2014b)

	Sample in relation to wound channel	N	Lead concentration (mg/kg)			Samples >0.1 mg/kg (%)[1]
			Min	Median	Max	
Wild boar	Wound channel	18	0.011	**146**	**1 829**	94 %
	0 to 5 cm	18	0.007	**9**	**1 466**	89 %
	5 to 10 cm	18	0.004	**0.11**	**18**	50 %
	10 to 15 cm	15	0.004	0.04	**29**	27 %

Notes: [1] Threshold set by Commission Regulation (EC) 1881/2006 for lead in meat

1.6.3.6.5. Lead in game meat

Animals shot with lead ammunition frequently contain lead fragments in the carcass which contaminate game meat with concentrations of lead substantially above the maximum levels set by the food contamination Regulation (EC) No 1881/2006. The maximum permissible levels for bovine animals, sheep, pig and poultry are 0.1 and 0.5 mg Pb/kg wet weight for meat and offal, respectively. No maximum levels for lead in wild game have been set. However, the Dossier Submitter notes that the thresholds for lead in edible offal have recently been reduced to 0.2 mg/kg for offal from cattle, 0.15 mg/kg for edible offal from pigs, and 0.1 mg/kg for edible offal from poultry (Regulation (EC) No 1881/2006, amendment from 9 August 2021[149]).

There is no scientific reason why the intake of lead via meat from farmed animals should have different health effects than the intake via game meat. Indeed, the Swedish National Food Administration (Swedish NFA, 2020) considers that meat of game with lead contents exceeding this limit value should not be considered as safe food according to Article 14 of EU Regulation No. 178/2002. Röschel et al. (2020) propose that (EC) No 1881/2006 is amended to incorporate a maximum level for game meats as a supplementary measure to the replacement of lead ammunition. This would harmonise food safety standards for lead in meat traded across and imported into the EU.

Studies in which the concentration of lead in game meat, the amount of game meat consumption, and lead concentrations in the blood of high frequent game meat consumers were analysed are reported in detail in Annex B, section B.9.2.1.2 (game meat bagged with gunshot) and B.9.2.2.2 (game meat bagged with bullets). The Dossier Submitter has focussed in the following sections on information provided by EFSA to analyse exposure to lead from game meat consumption throughout the EU.

As input to this restriction proposal, EFSA provided data on both lead concentration in game meat and the frequency of consumption of game meat in the EU (EFSA, 2020). The collection of these data followed specific EFSA protocols; see the guidance on reporting of analytical results of food and feed samples[150] and detailed information on the EFSA Comprehensive European Food Consumption Database[151].

During the data curation process several assumptions needed to be made:

- With regard to lead concentration data, EFSA and the Dossier Submitter assumed that, where not explicitly reported as 'farmed', samples of duck, partridge, pheasant, quail and other game birds as well as hare and rabbit were bagged with lead shot, whilst samples of chamois, deer, moose, roe deer and wild boar were bagged with lead bullets.
- With regard to consumption data, all eating events that concerned foods whose production method was reported as "Farmed / cultivated / aquaculture" were discarded. Samples from rabbit, goose and reindeer were only included where the production method was specified as "Wild or gathered or hunted".

The Dossier Submitter cannot preclude the possibility that some 'farmed' game meat samples were erroneously classified as 'wild'. If that was the case, one might expect that these misclassifications inflated the left tail of the concentration distribution (since farmed game is less likely to be exposed to lead), resulting in somewhat lower median and mean concentration levels for some species. However, since the mean concentration levels taken forward for the purpose of risk characterisation are driven by high concentrations found in a limited number of samples, the impact of any such misclassifications is likely to be marginal.

In the consultation of the Annex XV report, FACE (comment #3467) raised a series of questions with regard to the representativeness of the input data provided by EFSA. For the

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149 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1317&from=EN
150 https://www.efsa.europa.eu/en/supporting/pub/en-6420#related-topics
151 https://www.efsa.europa.eu/en/data-report/food-consumption-data

benefit of stakeholders, the data on lead concentrations can be summarised as follows:

- The lead concentration dataset received from EFSA contained 12 908 samples of various fowl species incl. duck, partridge, pheasant, quail, and a generic category 'game birds' as well as small and large mammals incl. chamois, deer, elk, hare, wild boar and a generic category 'game mammals'. These data were subsequently split into species hunted with shot and bullets as summarised in Table 1-44.

Table 1-44: Descriptive statistics of the lead concentration dataset received from EFSA

Game species—bullets	n	%	Game species—shot	n	%
Chamois	15	0.1 %	Duck	1313	51.0 %
Deer	5034	48.7 %	Partridge	17	0.7 %
Elk	330	3.2 %	Pheasant	713	27.7 %
Roe deer	314	3.0 %	Quail	129	5.0 %
Wild boar	4040	39.1 %	Hare	341	13.2 %
Game mammals	601	5.8 %	Game birds	48	2.3 %
Total	*10334*		*Total*	*2574*	

- The lead concentration dataset received from EFSA pools data collected by individual EU Member States as part of the Chemical Monitoring (ChemMon) reporting following a standardised protocol. It is important to recognise that the data have not been collected according to a purposeful sampling methodology (i.e., samples are not collected to find particularly high or low concentrations of lead) but are part of a more general exercise to understand the level of pesticide residues, veterinary medicinal product residues, and contaminants and additives in game meat.
- For each observation in the dataset used, there is information about (i) the country of origin of the sample, and (ii) whether samples were 'farmed' in which case they were discarded from the analysis.
- As to the representativeness of the concentration data, Figure 1-33 summarises the origin of samples. The pie chart indicates that almost all Member States had provided data but that some countries were over- or underrepresented in terms of the ratio hunter-to-number of samples.

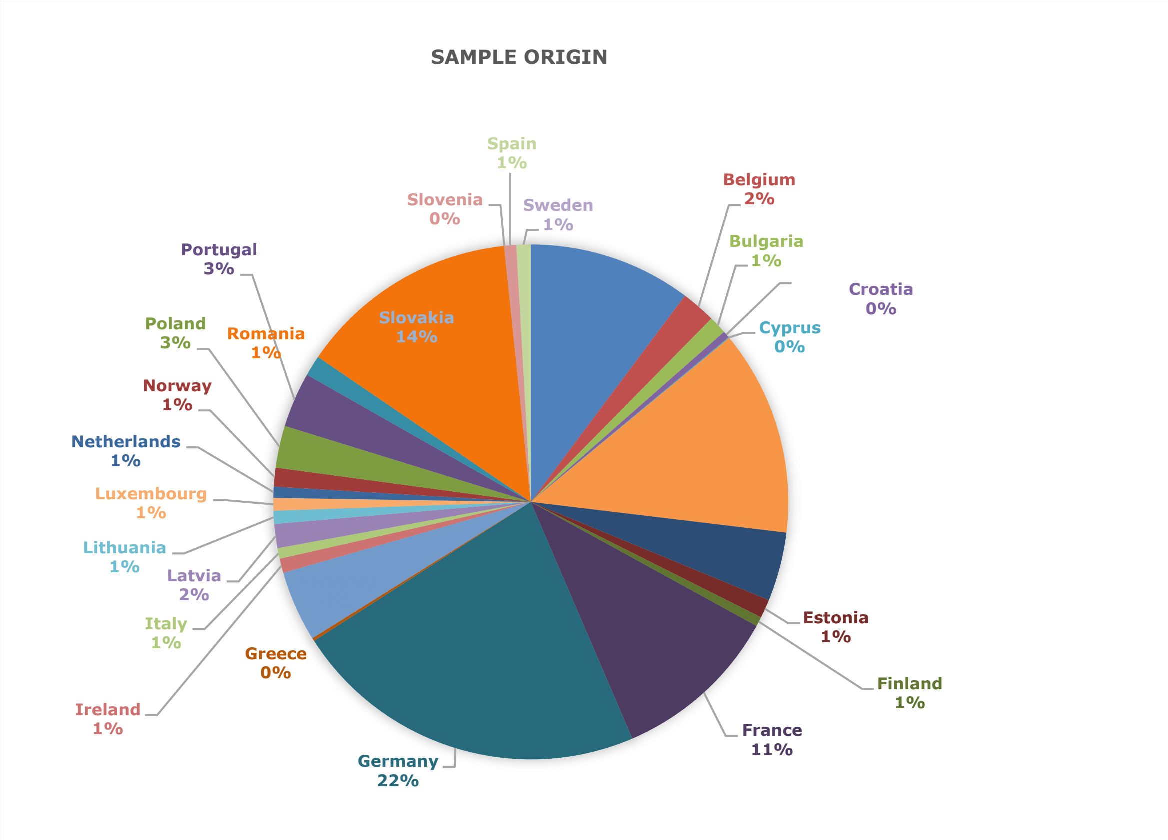

Figure 1-33: Origin of samples in lead concentration dataset received from EFSA

1.6.3.6.5.1. Game meat bagged with lead gunshots

Table 1-45 provides an overview of lead concentrations in game (usually bagged with gunshot) from the dataset EFSA provided to ECHA (EFSA, 2020). About 50 % of the samples (1 313/2 574) pertain to "duck" and might originate from wetland hunting. About 2 % of the samples (48/2 574) are labelled as undefined "game birds". EFSA used lower bound and upper bound concentrations derived from the practice of handling non-quantified or non-detected food chemical concentration results by assigning a value of zero to lower-bound estimate and a value equal to the LOQ for the upper-bound estimate. As reported in Table 1-45, the mean lower bound concentration in the samples analysed was 0.352 mg Pb/kg. Highest mean lower bound lead concentrations were found in hares (0.9 mg/kg) and pheasants (0.7 mg/kg). Highest reported maximum values were 104 and 113 mg/kg for hares and pheasants, respectively. The percentage of samples exceeding the maximum level of lead in meat of 0.1 mg lead per kg meat (according Commission Regulation (EC) 1881/2006) is 13 %. In the absence of a maximum level of lead in game meat, the Dossier Submitter has used the maximum allowable level for lead in meat from bovine animals, sheep, pigs, and poultry.

Table 1-45: Concentration of lead in meat intended for consumption from game hunted with lead shots in the EU (EFSA, 2020)

Species	N	Samples below detection limit (%)	Lead concentration in game meat (mg/kg)			Samples > 0.1 mg/kg (%)[2]
			Mean lower bound	Mean upper bound	Max	
Duck	1 313	73	0.081	0.096	17.900	89 (7 %)
Game birds	48	24	0.207	0.214	1.797	14 (29 %)
Hare	341	60	0.889	0.903	104.000	50 (15 %)
Partridge	17	82	0.054	0.081	0.840	1 (6 %)
Pheasant	713	48	0.676	0.683	113.000	160 (22 %)
Quail	129	74	0.024	0.044	0.400	12 (9 %)
Rabbit	11	64	0.341	0.347	1.000	4 (36 %)
All[1]	**2 574**	**63**	**0.352**	**0.366**	113.000	**330/2 574 (13 %)**

Notes: [1] this row also includes one result from pigeon and one from snipe not displayed in the table; [2] Threshold according to Commission Regulation (EC) 1881/2006 for lead in meat

The Dossier Submitter notes that for several species the mean lead concentrations in the EFSA dataset are lower than those found in the peer reviewed literature.

For the 1 313 samples of '**duck'** in the EFSA data, a mean upper bound of 0.096 mg/kg was found with 7 % of the samples exceeding lead concentrations of 0.1 mg/kg. The Dossier Submitter notes that the dataset may include meat samples taken from wild animals either bagged with lead or steel gunshot as well as meat samples taken from farmed animals. However, the information available to the Dossier Submitter does not allow a correct separation. Of the 1 313 'duck' samples, only 120 samples (ca. 9 %) were specifically flagged to be taken from 'wild duck'. On the other hand, the Dossier Submitter considers it plausible that not all samples taken from wild duck were marked as such, because only 38 % (34/89) of those samples exceeding 0.1 mg Pb/kg were labelled as 'wild duck'.

For '**partridge'** only 17 samples were included in the EFSA data with a mean upper bound and maximum of 0.081 and 0.84 mg Pb/kg, respectively, with one sample exceeding 0.1 mg/kg (6 %). For comparison, Pain et al. (2010) reported 56 % of pheasant samples exceeding 0.1 mg Pb/kg; similarly Mateo et al. (2011) found a mean concentration of 2.55 mg Pb/kg in 128 partridge samples from Spain collected during a driven hunt.

For '**pheasant'** the 713 samples in the EFSA dataset have a mean upper bound of 0.683 mg Pb/kg with 22 % of the samples exceeding 0.1 mg Pb/kg. Pain et al. (2010) reported 47 % of pheasant samples exceeding 0.1 mg Pb/kg. In a recent analysis done by the UK 'Wild Justice'[152], 7 out of 10 samples of 'Holme Farmed Venison packs of Pheasant breasts' had lead concentrations >0.1 mg/kg ww, with median lead levels of 0.41 mg/kg ww, mean lead levels of 0.93 mg/kg ww, and the highest lead level of 3.44 mg/kg ww.

For '**quail'** the Dossier Submitter notes that this species may also be farmed. The distribution of the lead concentration in quail meat of the EFSA dataset indicates that there

[152] https://wildjustice.org.uk/general/sainsburys-game-meat-has-high-lead-levels

might be country specific differences. For example, in 10 out of 33 quail meat samples from Portugal, concentrations exceeded 0.1 mg Pb/kg, which might be an indication that this species is hunted and not farmed.

Overall, the Dossier Submitter considers that the mean lead concentrations reported in the EFSA dataset for duck, partridge, pheasant, and quail may underestimate the lead concentrations in birds hunted with lead shot. This said, the Dossier Submitter considers that sampling of lead-shot birds only would not result in an adequate distribution of lead concentrations in all game birds in the EU either. This is because in several Member States the use of lead shot in the hunt of waterfowl is already banned. Hence one would expect no exposure in samples taken in these Member States.

The Dossier Submitter notes that cooking methods may affect the bioavailability of lead in game meat. Lead particles in game meat can dissolve while cooking, producing soluble lead salts that then contaminate parts of the meat. These salts have greater bioavailability and may pose an increased risk compared to metallic lead particles (Mateo et al., 2007). Cooking small game meat (red-legged partridge breast) under acidic conditions (i.e. using vinegar) has been found to increase the final lead concentration in the meat as well as its bioavailability (Pain et al., 2010). Hence the percentages of samples exceeding certain benchmarks may further increase after cooking and especially after cooking under acidic conditions.

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1.6.3.6.5.2. Game meat bagged with lead bullets

The Swedish National Food Administration (Swedish NFA, 2020) carried out a survey of the lead content in minced meat of game that has been handled in game handling facilities in Sweden. A total of 50 samples of minced meat of moose and 50 samples of minced meat of wild boar were analysed. The samples were taken at 47 different game handling facilities, from Norrbotten to Skåne. The total proportion of samples with levels of lead that were likely to come from lead ammunition was 36 percent (36 samples out of 100). For wild boar, levels of lead with probable origin from lead ammunition were present in 42 percent of the samples (21 of 50 samples) and for moose in 30 percent of the samples (15 of 50 samples). The remaining 64 percent (64 out of 100 samples) were below the detection limit for the analysis (45 samples) or had a content that was within the measurement uncertainty (19 samples).

The results show that 15 % of the 100 samples have lead levels that were above the limit found in current EU legislation for, among other things, meat from domestic animals and poultry (0.10 mg / kg wet weight). For wild boar this limit is exceeded in 16 % of the samples (8 of 50 samples) and for moose in 14 % of the samples (7 of 50 samples). A further 21 % of the samples (21 samples out of 100) had lead contents that are unlikely to originate in a background exposure (26 percent of the wild boar samples and 16 % of the moose samples).

Lead concentrations in game usually bagged with bullets from the dataset EFSA provided to ECHA (EFSA, 2020) are reported in Table 1-46. The mean lower bound concentration in the samples analysed was 2.5 mg Pb/kg. Highest mean lower bound lead concentrations were found in roe deer (mean 10.9 mg/kg), wild boar (2.8 mg/kg) and deer (1.9 mg/kg). Meat from moose showed low mean concentrations of about 0.03 mg/kg. Highest reported maximum values are 588, 3 650, and 5 309 mg/kg for roe deer, wild boar, and deer, respectively. The percentage of samples exceeding the maximum level of lead in meat of 0.1 mg per kg meat (according Commission Regulation (EC) 1881/2006) is 13 %. As mentioned in the previous section, the Dossier Submitter has used the maximum allowable level for lead in meat from bovine animals, sheep, pigs, and poultry.

Table 1-46: Concentration of lead in meat intended for consumption from game hunted with lead bullets in the EU (EFSA, 2020)

Species	N	Samples below detection limit (%)	Lead concentration in game meat (mg/kg)			Samples >0.1 mg/kg (%)
			Mean lower bound	Mean upper bound	Max	
Chamois	15	87	0.002	0.010	0.021	0
Deer	5 034	55	1.992	2.006	5 309.000	514 (10 %)
Moose	330	48	0.026	0.035	2.720	9 (3 %)
Roe deer	314	48	10.893	10.903	588.620	*Included under "deer"*
Wild boar	4 040	47	2.810	2.827	3 650.000	818 (20 %)
All[1]	**10 334**	**52**	**2.501**	**2.515**	5 309.000	**1 341 (13 %)**

Notes: [1] this row also includes results from the generic category "game mammals" not displayed in the table

The Dossier Submitter notes that for some game species the mean lead concentration in the EFSA dataset is lower than those found in the peer reviewed literature:

- The 15 samples of **chamois** in the EFSA dataset show a mean upper bound of 0.01 mg Pb/kg which is more than three magnitudes lower than the concentrations found in 10 chamois samples (Ertl et al., 2016) for which 77±241 mg Pb/kg were reported. (The latter values were associated with ammunition residues.)
- The mean upper bound concentration of 0.035 mg Pb/kg in **moose** meat in the EFSA data is significantly lower than the values reported by Lindboe et al. (2012) that show mean lead concentrations of 5.6 mg Pb/kg (maximum concentration of 110 mg Pb/kg) in 52 samples of ground meat taken from moose shot in Norway. It is also clearly lower than the results reported from 150 moose meat samples randomly bought from food groceries and butchers in different parts of southern Norway (Vogt and Tysnes, 2015), for which the authors reported significant levels of lead in most of the samples analysed. The mean value was 1.79 mg Pb/kg, median value was 0.37 mg Pb/kg, the standard deviation 4.14, and the maximum lead concentration was measured at 35.23 mg Pb/kg.

The mean upper bound concentration for **wild boar** and **wild deer** derived from the EFSA data are in a similar range as concentrations (average of 3.4 mg Pb/kg game meat, mainly wild boar and wild deer) reported for France (ANSES, 2018). Studies from Germany (Gerofke et al., 2018, Martin et al., 2019) investigated lead concentrations in game meat shot under controlled conditions, prepared by trained personal, and inspected for marketability. Three samples of marketable meat (100 g) were taken per animal close to the wound channel, of the saddle and of the haunch. Compared to game shot with non-lead ammunition, the use of lead ammunition significantly increased lead concentrations in game meat of red deer (Table 1-47), roe deer and wild boar (Table 1-48). Mean lead values were lowest for samples taken from the haunch and highest for samples taken close to the wound channel. Even though taken by trained personal, the sample mean concentrations were more than 20 times larger than the upper mean values found in the EFSA data.

Table 1-47: Lead concentration (mg/kg) in marketable meat of red deer in Germany (Martin et al., 2019)

Sample origin	N	Mean (95 % confidence interval)	Lead concentration (mg/kg)				
			Median	P75	P90	P95	Max
Haunch	64	**0.015** (0.012; 0.019)	0.010	0.020	0.030	0.034	0.09
Saddle	64	**0.054** (0.019; 0.101)	0.014	0.023	0.040	0.220	1.14
Close to wound	64	**58.2** (0.970; 168.6)	0.016	0.024	0.820	48.04	3442.00

Table 1-48: Lead concentration (mg/kg) in marketable meat of roe deer and wild boar in Germany (Gerofke et al., 2018)

Sample origin	N	Quantifiable (%)	Lead concentration (mg/kg)					
			Mean	Geometric mean (95 % CI)	Median	P95	P97	Max.
Roe deer								
Haunch	745	296 (39.8)	**0.169**	0.003 (0.002;0.005)	0.006	0.064	0.132	73
Saddle	745	336 (45.1)	**0.968**	0.0043 (0.002;0.008)	0.009	0.164	0.643	189
Close to wound	745	456 (61.2)	**13.958**	0.014 (0.007;0.027)	0.025	2.237	9.676	4 728
Wild boar								
Haunch	514	205 (39.9)	**0.086**	0.004 (0.002; 0.008)	0.014	0.067	0.132	14
Saddle	514	259 (50.4)	**1.716**	0.007 (0.003; 0.016)	0.021	0.691	1.729	650
Close to wound	514	783 (50.8)	**5.367**	0.011 (0.005; 0.075)	0.025	1.446	5.809	1 582

Wilson et al. (2020) analysed ground venison packets from shotgun and archery-harvested white-tailed deer in Illinois in 2013 and 2014. The shotgun venison packets were either processed by three different commercial meat-processing plants ('commercial') or from a custom processor specialised in processing venison only ('custom'). Radiographs indicated that 48 % of 27 ground venison packets from 10 shotgun-harvested deer contained metal fragments, while none of the 15 packets from three archery-harvested deer contained fragments. ICP-MS analysis verified that all metal fragments from seven of the venison samples from shotgun-harvested deer were composed of lead, with average concentrations from 1.04 to 8.42 mg/kg dry weight. Shotgun-harvested venison packets from a commercial processor were more likely ($z = 3.59$; $p < 0.001$) to have fragments and had significantly more ($W = 298.5$; $p = 0.004$) fragments than archery-harvested packets from a commercial processor (see Table 1-49). The author calculated that a single serving of ground venison containing one of these metal fragments embedded in it would be predicted to have a lead concentration ranging from 6.4 to 51.8 mg/kg.

Table 1-49: Data from ground venison packets from white-tailed deer (Wilson et al., 2020)

Type of harvest	processor	Number of packets	% with fragments	Number of fragments per packet
Archery	Commercial	15	0.0±0.0	0.0±0.0
Shotgun	Commercial	21	57.1±10.8	0.86±0.19
Shotgun	Custom	6	16.7±29.8	0.16±0.15

During the Annex XV consultation, further information was submitted regarding the following assumptions:

WWF Spain (#3446) submitted a report on the risk due to consumption of meat from large game in Spain summarising that 47 % of samples from meat product, especially from wild boar, showed lead concentrations above 0.1 mg/kg. The performed risk estimation calculations implied potential risks for extreme consumers and average consumers with regards to cardiovascular effects and chronic nephrotoxicity.

A study from Italy (Lenti et al., 2021) was referenced (#3485) which reports lead concentrations in wild boar meat sold on the Italian market. The median value of lead concentration detected in 48 samples was 0.10 mg/kg with a range from 0.01–18.3 mg/kg. In 23 samples out of 48 (47.9 %), lead levels above 0.10 mg/kg were measured.

Some unpublished reports were submitted during the Annex XV report consultation reporting lead concentrations in game meat. In Spanish meat and meat product samples (#3446) from deer ($n = 37$) and wild boar ($n = 49$), average lead concentrations of 0.52 mg/kg (range 0.1 – 1.06 mg/kg) and 0.33 mg/kg (range 0.1 – 1.47 mg/kg) were reported, respectively. In meat samples (with unknown sampling method) from Hungary (#3476) increased lead concentrations > 0.1 mg/kg were reported for samples from domestic as well as wild animals. For example, in domestic gooses 13.1 % of samples showed lead concentrations > 0.1 mg/kg (maximum 123 mg/kg), in wild roe deer 16.5 % (maximum 352 mg/kg), and in wild boar 5.1 % samples (maximum 304 mg/kg).

In comment #3363, it was highlighted that meat from farmed animals has a homogeneous distribution of lead in muscle tissue, whereas the lead fragments and particles in wild game from lead bullets are unevenly distributed.

Schulz et al. (2021) investigated the effects of acidic marination on the bioavailability of ammunition-derived lead in roe deer meat. The lead content of both game meat preparations was equal with 0.77 to 0.79 mg lead per portion. In pigs ($n = 7$) that received lead-shot game meat cooked in water the bioavailability of lead was 2.7 %, in pigs ($n = 7$) that received lead-shot game meat first marinated (wine and vinegar) and then cooked the bioavailability of lead was 15 %. The authors observed considerable variations in the individual blood lead concentrations which suggests that an inhomogeneous distribution of ammunition-derived lead particles (in terms of size and number) causes individually non-comparable lead intakes from the consumption of game meat.

Summary

Lead concentrations in game meat vary significantly, depending on the cut of meat. However, even if prepared under best practices a relevant proportion of game meat has substantially higher lead concentrations than the regulatory maximum level for lead in meat (0.1 mg Pb/kg meat according Commission Regulation (EC) 1881/2006). Of specific concern are individual samples showing very high lead concentrations even above 1 000 mg/kg.

Meat samples of game bagged with gunshot have frequently lead concentrations exceeding 0.1 mg/kg w/w. For example, 56 % and 47 % of fresh meat samples from partridge and pheasant, respectively, exceeded 0.1 mg Pb/kg, 21 % and 18 % exceeded 1.0 mg Pb/kg, and 5.7 % and 2.4 % exceeded 10 mg Pb/kg (Pain et al., 2010). The mean lead concentration of game meat bagged with lead gunshots in the EFSA dataset was 0.366 mg/kg, with 12.8 % of the samples exceeding 0.1 mg/kg (EFSA data 20.06.2020); however, limitations in the data and comparison with other published data indicate that the lead concentrations reported in the EFSA data for duck, partridge, pheasant and quail may underestimate the lead concentrations in game birds shot with lead.

The mean lead concentration of game meat bagged with lead bullets in the EFSA dataset was 2.515 mg/kg, with 13.0 % of the samples exceeding 0.1 mg/kg (EFSA data 20.06.2020). Other studies have found elevated lead concentrations in marketable game meat. For example, in a recent German study (Martin et al., 2019) the mean lead concentration in red deer meat taken close to the wound channel was 58 mg/kg, whereas lead concentrations in red deer meat from the saddle and haunch had mean concentrations below 0.1 mg/kg. In marketable meat from roe deer, the mean lead concentrations in meat taken close to the wound channel (13.96 mg/kg), from the saddle (0.97 mg/kg) or from the haunch (0.17 mg/kg) all exceeded 0.1 mg/kg. For wild boar meat, the mean concentrations of the samples close to wound channel (5.37 mg/kg) and saddle (1.72 mg/kg) exceeded 0.1 mg/kg (Gerofke et al., 2018).

The Dossier Submitter takes note of other studies and reports referred to by FACE (#3467) that suggest significantly lower lead concentrations in game meat. However, it is unclear how these samples were prepared. For the purpose of this restriction, the EFSA data seem to be best suited since they do not rely on a purposeful sampling methodology, meaning that the sampling protocol is not designed to find high or low lead concentrations (e.g., by sampling meat close or far from the wound channel). Against this background, the Dossier Submitter opts for basing its analysis on the EFSA data, noting that it might not be fully representative of the lead exposures that consumers of game meat may face. However, since the health impact assessment presented in Section 2.5.2.1 is based on the right tail of the respective exposure distributions, it is unlikely that this uncertainty would have a large impact on the results derived.

1.6.3.6.5.3. Game meat consumption

Green and Pain (2019) recently reviewed the published literature on game meat consumption in the EU and concluded that the main consumers of game meat are hunters and their families and associates, and that only a small fraction of the general population in most EU Member States are frequent (a few times per month) or high-level (once per week or more) consumers of game meat. Gerofke et al. (2018) concluded that for the average consumer of game meat in Germany the additional uptake of lead only makes a minor contribution to the average alimentary lead exposure. However, for high-frequency consumers (mainly members of hunter households) the uptake of lead from ammunition fragments may be several times higher than the average alimentary lead exposure.

While other parts of the general population do consume game meat, the focus of this restriction proposal is on game meat consumption of hunters and their families. Game meat consumption of hunter families has been estimated to be 50 g meat/day (Haldimann et al., 2002), up to 91 meals/year or 50 g/day (Gerofke et al., 2018), more than one game meat meal per week, resulting in 50 g/day for adults and 25 g/day for children (ANSES, 2018) and 23 g/day on average with P95 of 97 g/day (AESAN, 2012).

For the purpose of this restriction proposal, EFSA provided recent data on the consumption of game meat in the EU via food recall surveys. Taking into account comments received in the consultation of the Annex XV report (#3467), the Dossier Submitter considers that the median value of chronic consumption of game meat indicated in this dataset is a good proxy of high frequency consumers such as hunter households. The median chronic daily consumption of game meat for different age groups as provided by EFSA is reported in Table 1-50. Of significant importance for this assessment are data on infants (0-12 months of age) and toddlers (1-3 years old), who are specifically sensitive to lead-related IQ loss. Data from pregnant and lactating women were not considered due to the small number of samples.

Table 1-50: Minimum, maximum and median across surveys of the median (P50) of the chronic daily consumption of meat from game hunted with lead gunshot and bullets in the EU (EFSA data 20.06.2020)

Population	Ammun.	N (S)[1]	Daily consumption of game meat (g/kg bw and day)[2]		
			Min P50	Med P50	Max P50
Infants	Shot	1-15 (5)	0.89	1.00	1.67
	Bullet	1-8 (3)	0.14	0.43	4.26
Toddlers	Shot	1-25 (10)	0.11	1.46	4.82
	Bullet	1-30 (7)	0.15	1.01	2.82
Other children	Shot	1-56 (13)	0.44	0.79	4.45
	Bullet	1-27 (11)	0.26	1.18	2.82
Adolescents	Shot	1-84 (14)	0.13	0.89	2.45
	Bullet	1-6 (12)	0.11	0.57	2.83
Adults	Shot	1-218 (20)	0.21	0.58	1.37
	Bullet	1-68 (16)	0.10	0.65	1.76
Elderly	Shot	1-74 (16)	0.42	0.63	1.36
	Bullet	1-27 (11)	0.09	0.58	1.53
Pregnant women	Shot	1-3 (5)	0.40	0.49	0.73
	Bullet	6 (1)	0.22	0.63	0.95
Lactating women	Shot	4 (1)	0.76	0.76	0.76
	Bullet	4 (1)	0.13	0.84	1.56

Notes: [1] range of number of subjects N in (S) surveys; [2] Some of the medians presented in this table were calculated based on information from less than 60 subjects and might hence not be statistically robust.

Based on standard assumptions on the average weight of individuals of different age groups, the values reported in Table 1-50 can be converted in to daily intake of game meat (g/day) and, for the purpose of comparison to other studies, to annual intake of game meat (kg/year), see Table 1-51.

Table 1-51: Chronic daily game meat consumption based on EFSA data (20.06.2020)

Population	Type of ammunition	Daily consumption of game (g/kg bw and day; median)	Daily game meat consumption (g/day)	Implied annual game meat consumption (kg/year)
Infants 0-12 months old; 5 kg bw;	Shot	0.43	2.1	0.8
	Bullet	1.00	5.0	1.8
	All	**1.43**	**7.1**	**2.6**
Toddlers 1-3 years old; 12.0 kg bw	Shot	1.01	12.2	4.4
	Bullet	1.46	17.5	6.4
	All	**2.47**	**29.7**	**10.8**
Adults 70 kg bw	Shot	0.65	45.6	16.6
	Bullet	0.58	40.9	14.9
	All	**1.23**	**86.5**	**31.5**

The Dossier Submitter notes that a daily game meat intake of 50 g/day was assumed by several authors (ANSES, 2018, Gerofke et al., 2018, Haldimann et al., 2002). Ferri et al. (2017) (see also Section B.9.2.1 and B.9.2.2 in the Annex) reported for 766 Italian hunters' intakes of wildfowl meat of 451.7 ± 571.5 g per person and month and 593.2 ± 698.8 g per person and month of wild mammalian meat and boar liver, resulting in a total consumption of 1 044.9 ± 1 264.7 g per person and month. Assuming 30.5 days per months, this corresponds to a daily intake of 14.8 ± 18.7 g/day for feathered game and 19.4 ± 22.9 g/day for wild mammal meat and liver results, in total 34.2 ± 41.6 g per person and day. The maximum values reported in that study were 3 750 and 5 900 g per person per month of feathered game and wild mammalian meat and boar liver, respectively, corresponding to a daily intake of 316 g per day. The Dossier Submitter notes that the chronic daily game meat consumption it estimated based on the EFSA dataset (Table 1-51) results in somewhat higher values of 45.6 g of game meat bagged with gunshot per day and 40.9 g of game meat bagged with bullets per day.

Sevillano Morales et al. (2018) performed a survey on the frequency of consuming meat of the four most representative game species in Spain: wild boar, red deer, rabbit and red partridge, as well as processed meat products (salami-type sausage) made from wild boar or red deer. The survey was carried out among 337 habitual consumers of these types of products (hunters and their relatives). The mean game meat consumption per capita in this population group was 6.9 kg of meat /person/year and 8.6 kg of meat /person/year if the processed meat products were also considered. For the total meat and sausage consumption, the median was calculated at 6.0 kg of meat/year, the 95th percentile at 25.2 kg of meat/year, and the 99th percentile at 38.6 kg of meat/year.

Yet another comparison can be made to the per capita meat consumption in the EU, which was reported to be 63.4 kg in 2010 and 65.8 kg in 2020 (see Table 1-52:).[153] (The EU agricultural outlook report suggests an even higher per capita meat consumption in the EU

[153] https://www.statista.com/statistics/679528/per-capita-meat-consumption-european-union-eu

of 69.0 kg/y.) Against this per capita meat consumption, a game meat consumption of 31.5 kg per year for adults (86.5 g/day) as implied by the median of the EFSA consumption data seems plausible for a group with direct access to game meat.

Table 1-52: Per capita meat consumption forecast in the big five EU countries from 2010 to 2020[153]

Country	Per capita meat consumption (kg)	
	2010	2020
France	70.7	67.2
Germany	68.9	61.3
Italy	65.2	58.6
Spain	60.5	59.0
EU	**63.4**	**65.8**

Summary

Game meat consumption of hunter families has been estimated to be 50 g meat/day for adults (ANSES, 2018, Gerofke et al., 2018, Haldimann et al., 2002) and 25 g/day for children (ANSES, 2018). AESAN (2012) estimated 23 g/day on average and 97 g/day as 95th percentile. Based on EFSA data on chronic consumption of game meat, the median daily game meat consumption of high frequency consumers was pegged at 0.65 and 0.58 g/kg bw/day for adults consuming game harvested with gunshot and bullets, respectively. This corresponds to a daily intake of 45.6 g and 40.9 g for an adult of 70 kg body weight.

For children, only limited data is available from the EFSA database. For infants (0 to 12 months of age) the median value indicated was 0.43 and 1.0 g/kg bw/day. Assuming a body weight of 5 kg, this corresponds to a daily intake of 2.1 and 5.0 g, respectively. For toddlers (1 to 3 years), the median value indicated was 1.01 and 1.46 g/kg bw/day. Assuming a body weight of 12 kg, this corresponds to a daily intake of 12.2 g and 17.5 g, respectively.

1.6.3.6.5.4. Measured PbB levels related to consumption of game meat

Very limited data is available on how frequent game meat consumption affects PbB levels in hunter families. When reviewing the published studies that measured PbB levels in game meat consumers, the following has to be considered:

- Men usually have higher PbB levels compared to females;
- Shooting /hunting has a significant contribution to the PbB level;
- Professional or leisure activities may contribute to PbB levels.
- The available studies investigating PbB levels in hunter and/or members of hunter families usually do not separate the data with respect to sex or shooting/hunting activities. Therefore, it is difficult to draw conclusions on PbB levels.

All reviewed data can be found in Annex B.

Hunt et al. (2009) fed lead fragment-containing venison to four pigs to test bioavailability; four controls received venison without fragments from the same deer. The total amount of lead fed to each pig was unknown, but quantitative analysis of similar packages from other deer in the study showed 0.2 to 168 mg (median 4.2 mg) of lead. Mean blood lead concentrations in pigs peaked at 22.9 µg/L (maximum 38 µg/L) two days following ingestion of fragment-containing venison, significantly higher than the 6.3 µg/L averaged by the controls. The results indicate that after a single feeding of median 4.2 mg lead per pig, the PbB level increase was 17 µg/L. After 7 days the PbB levels returned to the baseline values.

The available data indicate that subsistence hunters living in the circumpolar region show the highest increases in PbB levels. For example, Bjerregaard et al. (2004) reported that sea bird consumption of one to three times per week resulted in an increase of the mean PbB level of more than 30 µg/L, for daily consumption even more than 90 µg/L. However, the data for males and females were not separated and the lead contribution from hunting was not considered. In males with even higher sea bird consumption, PbB level increases were 59 µg/L (5 – 15 bird equivalents per month), 67 µg/L (15 – 30 bird equivalents per week) and >113 µg/L (> 30 bird equivalents per week) (Johansen et al., 2006). Again, the lead contribution from the hunters in this group was not considered separately. Tsuji et al. (2008) separated the data for male and females and reported a clear different in the PbB levels of males and females. Compared to females in an urban area, PbB levels were 6 and 15 µg/L higher in native females. For males, PbB levels were 47 and 53 µg/L higher compared to the controls. Most probably a relevant fraction of the PbB level increase might be due to hunting activities. However, it was not reported how many of the circumpolar residents were hunters.

Males and females from hunter families (n = 115) consuming game meat, mainly moose meat, hunted with lead bullets in Sweden (Swedish NFA, 2014a, Swedish NFA, 2014c) had 5.3 µg/L higher PbB levels compared to the control group. For non-hunting women (n = 35) of hunter families the consumption of game meat resulted in PbB levels about 30 % higher (ca. 3.5 µg/L).

In a more recent publication on hunter families in Sweden, PbB level increase was 3.3 µg/L and 5.6 µg/L for females (n = 16) and males (n = 14), respectively, for moose meat consumption two to three times per week (Wennberg et al., 2017, Swedish NFA, 2014a). Hunting activities were not reported.

No increase in the PbB level was observed in non-hunting family members (possibly 10 females) that consumed game meat hunted with shots or bullets (Fustinoni et al., 2017). However, persons consuming game meat prior to testing were excluded.

In comment #3237 received from the Finnish Wildlife Agency during the Annex XV report consultation, unpublished information on a small-scale survey of middle-aged men who had eaten both small and large game for several decades since infancy (several times a week, up to 10 servings/week), engaged in sports shooting, and half of them engaged also in cartridge recharging. Their blood lead levels ranged from 0.09 to 0.19 µmol/L [4 to 39 µg/L], averaging 0.13 µmol/L [27 µg/L]. One person, who also carried out casting work, had a blood lead content of 0.7 µmol/L [145 µg/L], which was clearly higher than the other measurement results. The submitter of the comment noted that the reported lead concentrations would be below the action limit for occupational health care of 1.4 µmol/L [ca. 290 µg/L] and concluded that based on the study, it appears that eating a very large amount of game, shooting as hobby, and reloading cartridges do not cause a dangerous lead exposure to health. The Dossier Submitter acknowledges the information but notes that no further details were reported such as the number, age and sex of the persons investigated, individual information on blood lead levels, frequency, amount and type of game meat consumed, frequency, intensity and type of shooting and casting work, and the time of blood lead level measurement related to exposure to lead.

Summary

The data on PbB level increments from game meat consumption only (excluding hunting and shooting activities) are very limited. The available data indicate a small increase in PbB level of 3 to 5 µg/L in adults with consumption of moose meat two to three times a week. For groups relying on subsistence hunting, the PbB contribution from game meat consumption seems to be higher; in one study the increment for females (assumed to be non-hunters) was 6 and 15 µg/L (Tsuji et al., 2008). No reliable PbB level measurements in children from hunter families are available.

1.6.3.6.6. Additional sources of indirect exposure to humans via the environment

In addition to the consumption of game meat, it is also relevant to consider the potential for indirect exposure to humans via the environment via other pathways. These pathways are primarily relevant to hunting with lead gunshot (use #1) as well as uses of lead for sports shooting (uses #3, 4 and 5) and other shooting activities (use 6).

1.6.3.6.6.1. Meat and dairy products

The risk of grazing ruminants being exposed to lead gunshot could be more prevalent than anticipated since clay pigeon shooting and the shooting of game birds is an increasingly popular rural business and can result in the contamination of land used for pasture, fodder or silage (Payne et al., 2013).

Lead poisoning of cattle is regularly reported in the US and the UK, arising from various sources: lead-containing paint, batteries as well as spent ammunition. Several studies report exposure of ruminant animals to ammunition derived lead, principally via the consumption of silage (Bjørn et al., 1982, Frape and Pringle, 1984, Howard and Braum, 1980, Payne et al., 2013, Rice et al., 1987).

Payne et al. (2013) present two cases of lead-shot ingestion and subsequent lead poisoning reported in cattle in which quantities of lead shot were retrieved from the reticulum or abomasum. The author postulates that lead shot deposited beyond the perimeter of the shooting zone falls on to grassland or arable fields. In these environments the lead shot becomes trapped in vegetation where it can be consumed by grazing ruminants. In addition, trapped lead shot can be incorporated in silage where the acidic environment of the silage making process can result in the formation of lead compounds that are more readily absorbed then metallic lead.

In contrast, Johnsen and Aaneby (2019) reported that sheep grazing at a shooting range used by the Norwegian Armed Forces were at little or no risk of acute or chronic lead poisoning. These data would suggest that sheep have lower sensitivity to lead poisoning than cattle, although the authors noted that the sheep had reduced soil ingestion rates compared to background information.

1.6.3.6.6.2. Root and leaf crops

Concentrations of lead in the soil of a shooting range can be very high. In the sector including backstop berm, target stand and a band of land about 5 to 10 meters wide around the berm, lead concentrations normally exceed 1 000 mg lead/kg. More than 20 000 mg/kg soil of bullets or their fragments can be found in this area. In the immediate surroundings of the backstop berm lead concentrations often fluctuates between 200 and 1 000 mg lead/kg (Dinake et al., 2019). In agricultural soils close (10 m) to a trap shooting range, total lead concentrations were reported to range from 573 to 694 mg/kg (Chrastný et al., 2010).

A direct correlation between lead in soil and lead in plants has been reported (Bennett et al., 2007). In the biomass of spring barley (*Hordeum vulgare* L.) grown on shooting ranges, lead concentrations were 138 mg/mg in roots, 16 mg/kg in leaves, 4.2 mg/kg in stems and 2.4 mg/kg in spikes (Chrastný et al., 2010). Regulation 1881/2006 limits lead in cereals to 0.2 mg lead/kg food for human consumption.

1.6.3.6.6.3. Drinking water (via surface water or groundwater)

The concentration of lead in **surface (run-off) water** at US shooting ranges has been reported from 8 µg/L to 694 µg/L (Ma et al., 2002). In Finnish shooting ranges (Kajander and Parri, 2014), total lead concentration was > 50 µg/L in more than 60 % of the samples.

Lead concentrations greater than 1 000 µg/L have been reported in **groundwater** affected by US shooting ranges (typically old shooting ranges located in sensitive areas), exceeding the threshold for lead in drinking water by more than 100-times (Soeder and Miller, 2003). In a shooting range in Germany (Mainbullau) with use of lead gunshots for more than 40 years, lead concentrations for leaching water was determined in five different locations with 44.5, 1 460, 198, 64.4, and 12.9 µg/L. The action levels for phase 1 (25 µg/L) requiring supervision was exceeded by 4/5 measurements and action levels for phase 2 (100 µg/L) requiring remediation, was exceeded by 2/5 measurements (Bavarian WWA Aschaffenburg, 2019). According to investigations in Finnish shooting ranges, lead concentrations clearly elevated from the background level are uncommon. In 5 of 24 samples the total lead concentrations in groundwater was > 10 µg/L, whereas the concentration of soluble lead was below 10 µg/L in 13 samples analysed (Kajander and Parri, 2014).

Information related to risks to drinking water focused on terrestrial environment is also discussed in the "Assessment of the potential for the use of lead ammunition at shooting ranges to contaminate groundwater and drinking water ", attached as Appendix 1 of the Background Document.

1.6.4. Human health risk characterisation

Lead affects virtually every system in the body, including the blood, the cardiovascular, renal, endocrine, gastrointestinal, immune and reproductive systems. Nevertheless, the most critical target for lead appears to be the central nervous system (CNS), particularly the developing brain, where it has the potential to cause impaired cognitive development and intellectual performance in children even at low exposure levels (EFSA, 2010).

Lead can accumulate in the body, primarily in the skeleton. From the skeleton, it is released gradually back into the blood stream, particularly during physiological or pathological periods of bone demineralisation such as pregnancy, lactation and osteoporosis, even if lead exposure has already ceased. Lead can be transferred from the mother to the foetus/infant in utero and through breast milk (EFSA, 2010).

Human exposure to lead from gunshots, bullets or fishing sinkers and lures mainly occurs via inhalation (shooting or home-casting) or oral intake of lead dust (hand-to-mouth) or from the consumption of meat bagged with lead shots or bullets. Secondary exposure to lead from such sources via the environment (such as water, soil, plants and animals) is possible but was not investigated quantitatively.

EFSA CONTAM Panel (EFSA, 2010) used the BMD approach to derive references points for risk characterisation :

- $BMDL_{01}$ of 12 µg/L for developmental neurotoxicity in children (decrease in IQ by 1 point on the full scale IQ);
- $BMDL_{10}$ of 15 µg/L for 10 % increase in the prevalence of chronic kidney disease (CKD) in adults;

- $BMDL_{01}$ of 36 µg/L for 1 % increase in systolic blood pressure (SBP) in adults, corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult.

The CONTAM Panel noted that there are many caveats regarding their interpretation and the uncertainty associated with the derivation of the BMDL values. For example, the prevalence of kidney disease was compared with concurrent PbB levels. The EFSA CONTAM Panel noted that this effect would depend on lead exposure over a prolonged interval of time, during which such exposure was declining appreciably. Hence, the $BMDL_{10}$ intake value for this endpoint is likely to be numerically lower than necessary to protect against lead-induced CKD.

In the absence of a threshold for the critical effects, ECHA is reflecting the health impact by calculating the effect of the PbB level increment with respect to:

- IQ decrease in IQ points for children,
- % increase in the prevalence of chronic kidney disease (CKD) in adults, and
- increase in systolic blood pressure (in mmHg) in adults.

In the following sections the risks related to the use of lead ammunition and lead fishing tackle are summarised.

Table 1-53: Identified human health risks with regards to uses

Use number	Use name	Identified risk
1	Hunting with gunshot	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from oral exposure to lead dust (hand-to mouth) Risk from oral exposure and/or swallowing of lead fragments Risk from consumption of meat from game Risk from consumption of contaminated food and drinking water
2a	Hunting–with bullets – small calibre[1]	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from oral exposure to lead dust (hand-to mouth) Risk from consumption of meat from game Risk from consumption of contaminated food and drinking water
2b	Hunting–with bullets – large calibre	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from inhalation exposure from melting lead ('home-casting') Risk from oral exposure to lead dust (hand-to mouth) Risk from consumption of meat from game Risk from consumption of contaminated food and drinking water
3	Outdoor sports shooting with gunshot	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from oral exposure to lead dust (hand-to mouth) Risk from oral exposure and/or swallowing of lead fragments Risk from consumption of contaminated food and drinking water

Use number	Use name	Identified risk
4	Outdoor sports shooting with bullets	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from inhalation exposure from melting lead ('home-casting') Risk from oral exposure to lead dust (hand-to mouth) Risk from consumption of contaminated food and drinking water
5	Outdoor shooting using airguns	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from oral exposure to lead dust (hand-to mouth) Risk from oral exposure and/or swallowing of lead fragments Risk from consumption of contaminated food and drinking water
6	Other outdoor shooting activities incl. muzzle-loaders, historical re-enactments	Risk from inhalation exposure to lead fumes or dusts from shooting Risk from oral exposure to lead dust (hand-to mouth) Risk from consumption of contaminated food and drinking water
7	Lead in fishing sinkers and lures	Risk from inhalation exposure from melting lead ('home-casting') Risk from oral exposure to lead dust (hand-to mouth) Risk from oral exposure and/or swallowing of lead fragments Risk from consumption of contaminated food and drinking water
8	Lead in fishing nets, ropes or lines	No exposure scenario, and risk identified in the literature.

[1] This use includes hunting with an airgun

1.6.4.1. Risk from inhalation exposure to lead fumes or dusts from shooting (uses # 1, 2, 3, 4, 5 and 6)

With regards to shooting the risks for elevated PbB levels depends very much on the frequency and the conditions of shooting and can range from low risks (low increases in PbB levels) to very high increases reaching even toxic PbB levels. Based on the information from

Demmeler et al. (2009), Laidlaw et al. (2017), Mathee et al. (2017), and Mühle (2010) the factors contributing to exposure to lead and elevated PbB levels are:

- use of fire weapons (with lead-containing primer) compared to use of air weapons;
- increasing calibre of the weapon;
- increasing shooting frequency;
- reduced ventilation.

The use of lead-containing primer increases lead exposure significantly (Lach et al., 2015). However, primers are outside the scope because lead styphnate has already been identified as a substance of very high concern (SVHC) and is on the candidate list for authorisation (Annex XIV of REACH).

High exposure and risks have been reported for shooters training indoor and, depending on the shooting intensity, ventilation might not (always) be sufficient to reduce exposure to required levels. However, indoor shooting is out of scope because the request from the Commission to ECHA to develop this restriction speaks about ‘terrains’, which is interpreted as referring to ‘outdoor’. For shooters training outdoor the database is insufficient to draw a firm conclusion. Due to natural ventilation in outdoor shooting ranges, exposure could be expected to be lower than reported for indoor shooting. However, in one study the measured lead concentrations outdoors were even higher than indoors with ventilation and was considered to be due to missing natural ventilation (wind) (Wang et al., 2017).

Insufficient information is available or has been provided on the association between the use of different specified types of shots or bullets under standardised conditions and resulting lead levels in air and/or resulting PbB levels in shooters.

Indoor shooting

High exposure has been demonstrated for indoor sports shooters with PbB levels often >200 µg/L or even >400 µg/L (Laidlaw et al., 2017). PbB levels of 200 and 400 µg/L are associated with an increase in the prevalence of chronic kidney disease of 133 % and 267 %, respectively, and with an increase in systolic blood pressure of 6.7 and 13 mmHg. At such PbB levels, further effects (e.g., clastogenic effects or effects on sperm quality) may occur (ECHA, 2019).

Laidlaw et al. (2017) concluded that shooting lead bullets at firing ranges results in elevated PbB levels at concentrations that are associated with a variety of adverse health outcomes and the topic of health risk is an ongoing topic of study. Of major concern is the number of women and children among recreational shooters, who are not afforded similar health protections as occupational users of firing ranges. Nearly all PbB level measurements compiled in the reviewed studies exceed the level of 50 µg/L recommended by the U.S. CDC/NIOSH, and thus firing ranges, regardless of type and user classification, constitute a significant and currently largely unmanaged public health concern. Primary prevention of this risk requires development of lead-free primers and projectiles. Prevention includes better oversight of ventilation systems in indoor ranges and development of airflow systems at outdoor ranges, protective clothing that is changed after shooting, and cessation of smoking and eating at firing ranges. The mismatch between what is recommended for individuals by the U.S. CDC is in stark contrast to the allowable levels for occupational exposure, and there are no real systematic biomonitoring programmes for firing range users to measure cumulative health effects caused by persistent low and even high-level lead exposure. Recreational shooters and the general public are provided no legal protections from lead exposures at firing ranges.

Also Wang et al. (2017) found that ventilation systems are effective but unable to reduce lead exposure to acceptable exposure levels.

It was demonstrated that by using jacketed lead bullets with lead-free primer (Tripathi et al., 1991), lead-free primer (Lach et al., 2015) or "low-lead" bullets (Bonanno et al., 2002) lead exposure can be reduced by over 90 %.

Outdoor shooting

For outdoor shooting only limited information is available. Lead exposure in outdoor shooting ranges is more heterogeneous compared to indoor shooting because exposure depends more on natural ventilation (wind) (Bonanno et al., 2002).

Usually, lead exposure is considered to be lower in outdoor shooting ranges compared to indoor ranges due to natural ventilation. However, under condition of low natural ventilation (low wind), the lead concentration could even be higher (Wang et al., 2017). To facilitate natural ventilation the Swedish Association for Hunting and Wildlife Management (#3252) noted that the roof over the shooters may not extend more than three metres in front of the shooter. For partially covered shooting ranges, the German shooting range guidelines prescribe ventilation of the shooting range, which conveys fresh air in the direction of the shooting openings and thus keeps the shooter's breathing area free of lead emission (#3198).

For 12 biathletes in Canada using a gun powder cartridge containing a lead bullet of 2.6 g, PbB levels were measured with 18 ± 3.1 µg/L. They were ≥ 10 µg/L higher compared to the PbB level of 12 matched cross-country skiers with <8.3 µg/L (Turmel et al., 2010). A PbB level increase of 10 µg/L is associated with an increase in the prevalence of chronic kidney disease of 7 %, and with an increase in systolic blood pressure of 0.3 mmHg.

For clay shooting athletes in Korea (Chun et al., 2018) the PbB levels were 36±7.7 µg/L for 5 females and 51±16.4 µg/L for 9 males. Mean PbB levels in the general population of Korea (2010 to 2011) were reported with 18.3±7.9 µg/L for females and 22.2±10.4 µg/L for males (Eom et al., 2017). The lead level increment of 17.7 µg/L for females is associated with an increase in the prevalence of chronic kidney disease of 11.8 %, and with an increase in systolic blood pressure of 0.6 mmHg. The increment of 28.8 µg/L for males with an increase in the prevalence of chronic kidney disease of 19 %, and with an increase in systolic blood pressure of 1.0 mmHg.

Twelve shooters training in an outdoor shooting range in South Africa with non-jacketed lead bullets had in mean PbB levels of 70 ± 42 µg/L, which were 43 µg/L higher compared to the PbB levels of 20 archers (27 ± 14 µg/L) of which 19 did not perform gun shooting (Mathee et al., 2017). A PbB level increment of 43 µg/L is associated with an increase in the prevalence of chronic kidney disease of 29 %, and with an increase in systolic blood pressure of 1.4 mmHg.

A risk for the offspring of female sports shooters at reproductive age can be assumed. Lead from sports shooting can accumulate in the body and can be transferred to the offspring during pregnancy and via the milk during lactation. The EFSA CONTAM Panel (EFSA, 2010) concluded that there is no evidence for a threshold for critical lead-induced effects in children.

1.6.4.2. Risk for hunters (uses # 1 and 2)

Since it is not possible for hunters to separate between the risk attributed to shooting trainings, hunting and consumption of game meat, it is considered together.

For 61 Italian hunters with >10 hunts/year and consuming game meat the PbB level was in median 37 μg/L, which was 23 μg/L higher compared to the controls with 14 μg/L (Fustinoni et al., 2017). However, the PbB levels can be assumed not to be representative because persons with recent game meat consumption were excluded and the PbB levels were determined outside the hunting season. A PbB level increment of 23 μg/L is associated with an increase in the prevalence of chronic kidney disease of 15 %, and with an increase in systolic blood pressure of 0.8 mmHg.

For 25 male hunters in Switzerland the increase in PbB level compared to the controls was reported with 2 μg/L (Haldimann et al., 2002). However, since the control group was not characterised with regards to hunting activities and the consumption of game meat, the result cannot be used for the assessment of hunting activities and game meat consumption.

For gun shooters using non-jacketed bullets training in indoor or outdoor shooting ranges in South Africa, the PbB levels of shooters that were also hunting were in mean 34 μg/L higher compared to shooters not hunting (Mathee et al., 2017). A PbB level increment of 34 μg/L is associated with an increase in the prevalence of chronic kidney disease of 23 %, and with an increase in systolic blood pressure of 1.1 mmHg.

In a study in two groups of native people in Canada undertaking subsistence hunting of migratory birds using gunshot and bullets (Tsuji et al., 2008), mean PbB levels for males (which can be assumed to be the hunters) were 47 and 53 μg/L higher compared to the levels of inhabitants of a highly industrialised city. PbB level increments of 47 and 53 μg/L are associated with an increase in the prevalence of chronic kidney disease of 31 and 35 %, and with increase in systolic blood pressure of 1.6 and 1.8 mmHg.

For groups relying on subsidiary hunting in Canada, any type of lead bullets had an increased Relative Risk (RR) of 1.406 for PbB level exceeding 50 μg/L (C.I. 1.044 – 1.894, p = 0.019). The RR of elevated PbB level (> 50 μg/L) for lead shot shell users was reported with 1.510 (C.I. 1.100 – 2.075, p = 0.007). Users of non-lead shot had no significant risk of having elevated PbB levels greater than 50 μg/L (RR = 1.048, C.I. 0.824–1.333, p = 0.702), and no significant differences in PbB levels between users and non-users of non-lead shot shell were found (p = 0.353) (Liberda et al., 2018).

1.6.4.3. Risk from inhalation exposure from melting lead ('home-casting') of ammunition or fishing tackle (mainly uses # 2, 4, and 7)

Lead poisoning with a PbB level of 1 330 μg/L was reported for one man melting and casting lead for several years (State of Alaska Epidemiology, 2001).

For shooters casting their own bullets the statistically non-significant PbB increment was reported with 22 μg/L (Mathee et al., 2017), which is associated with a 15 % increase in the prevalence of chronic kidney disease and with an increase in systolic blood pressure of 0.7 mmHg.

For children living in the vicinity of persons melting lead to cast fishing sinkers, lures or bullets, increases of PbB levels ranged from 36 μg/L to ≥ 100 μg/L (Brown et al., 2005, Mathee et al., 2013, Yimthiang et al., 2019). Such PbB levels are associated with decreases in IQ points from 3 to > 8.

1.6.4.4. Risk from oral exposure to lead dust (hand-to-mouth) from shooting or handling lead ammunition or fishing tackle (uses # 1, 2, 3, 4, 5, 6 and 7)

No data is available to quantitatively characterise the risk.

From occupational settings the oral uptake of lead dust by the hand-to mouth route and its contribution to the lead burden is well known.

Risk can be assumed to be highest from oral uptake of lead dust from shooting in shooting ranges and hygiene measures are an important tool to limit exposure.

Oral uptake of lead from contaminated soil might also be possible, in case soil of a former shooting range or area is not fully remediated and is used for recreational or residential uses. Urrutia-Goyes et al. (2017) performed a human health risk assessment and concluded on a health risk especially for children.

The mean lead skin-to-saliva transfer efficiency was 24 % (range: 12–34 %) (Sahmel et al., 2015). Based on this study the hand-to-mouth exposure from lead dust on the skin from fishing tackle (and lead bullets or shots) is highly plausible.

1.6.4.5. Risk from oral exposure and/or swallowing of lead fragments (uses # 1, 3, 5, and 7)

High PbB levels of 530 and 650 µg/L have been documented for children following ingestion of small lead fragments intended to be used for hunting, sports shooting or fishing (Mowad et al., 1998, Rozier and Liebelt, 2019). Those incidences are acute poisonings that require medical treatment. No information is available on the impact of acute lead poisoning on the chronic lead burden in children and the resulting risk.

The habit to chew lead to attach it to the fishing line has been reported by many recreational fisher (Grade et al., 2019). The case of one recreational fisher who used to chew leaded fishing tackle and unintendedly swallowed tackle was reported with an acutely toxic PbB level of 1410 µg/L (Carrier et al., 2012).

For gun shooters using non-jacketed bullets training in indoor or outdoor shooting ranges, the PbB levels of shooters keeping lead bullets in their mouth were in mean 82 µg/l higher compared to shooters not keeping lead bullets in their mouth (Mathee et al., 2017).

1.6.4.6. Indirect exposure to humans via the environment

1.6.4.6.1. Risk from consumption of game meat hunted with lead ammunition (uses # 1 and 2)

In Table 1-54, ECHA calculated the daily intake of lead from the consumption of game meat, the resulting incremental PbB levels, and the corresponding health impacts based on the following considerations:

- To calculate the daily intake of lead from game meat, ECHA used the median values of the EFSA dataset on chronic daily consumption of game meat in young children (infants and toddlers) and adults as a proxy for the consumption of hunter families that are high-frequency consumers of game meat as summarised in Table 1-50.
- For the lead concentration in game meat, ECHA has used data from EFSA on the mean lower bound concentration of lead in game meat hunted with lead shots (0.366 µg Pb/kg meat; see Table 1-45) and lead bullets (2.516 µg Pb/kg meat; see Table 1-46), respectively. ECHA considers that the EFSA data on median lead concentration in game meat is not representative for the population at risk because this value does not reflect the potential for recurrent consumption of game meat samples with high lead concentration. This is because when considering game meat consumption **over the whole year** hunter families may consume different parts of

the game which may have very different lead concentrations ranging from no increased lead concentration to very high levels for meat produced from the area around the wound channel. Moreover, if a larger cut of meat is minced then it is likely that consumers are exposed over an extended duration of time to high lead concentrations. Such a scenario, which resembles a Pólya urn, is better reflected by using the mean concentration value than the median concentration value.

- ECHA notes that the mean value may be considered a conservative approach. This is because the lead concentration in the EFSA data is highly skewed with a median lead concentration that is orders of magnitude lower than the mean value. Given the above reflections, it seems better suited for risk characterisation. However, for the human health impact assessment presented in Section 2.5.2.1, the full distribution of concentrations found in game meat hunted with both gunshot and bullets was taken forward.
- For the calculation of PbB levels resulting from daily lead intake via game meat, ECHA has adapted the dietary intake values in µg/kg bw that correspond to the BMDLs reported in EFSA (2010) to the bioavailability of metallic lead. Notwithstanding the considerations laid out in Section 1.6.2.1, the following assumptions were made.

For **developmental neurotoxicity in children** aged ≤ 7 (reduction on IQ scale), EFSA (2010) concluded on a $BMDL_{01}$ (decrease in IQ by 1 point on the full scale IQ) of 12 µg Pb/L blood (1 µg/L = 0.083 IQ points). According to EFSA, 12 µg/L corresponds to a lead intake from diet containing soluble lead of 0.5 µg Pb/kg bw/day. Assuming 50 % bioavailability of metallic lead compared to lead ions for children results in the following relationship:

12 µg Pb/L blood ≙ 1 µg/kg bw/day.

For the increase of prevalence of **CKD in adults**, EFSA (2010) concluded on a $BMDL_{10}$ (10 % increase in the prevalence of CKD) of 15 µg Pb/L blood (1 µg/L = 0.667 % increase in the prevalence of CKD). According to EFSA, 15 µg/L corresponds to a lead intake from diet containing soluble lead of 0.63 µg Pb/kg bw/day. Assuming 10 % bioavailability of metallic lead compared to lead ions for adults:

15 µg Pb/L blood ≙ 6.3 µg Pb/kg bw/day ↔
2.4 µg Pb/L blood ≙ 1 µg/kg bw/day.

For the increase in **systolic blood pressure in adults**, EFSA (2010) concluded on a $BMDL_{01}$ (1 % change in SBP corresponding to an increase of 1.2 mmHg from the baseline value of 120 mmHg in a normotensive adult) of 36 µg Pb/L blood (1 µg/L = 0.033 mmHg). According to EFSA, 36 µg/L corresponds to an intake of diet containing soluble lead of 1.5 µg/kg bw/day. Assuming 10 % bioavailability of metallic lead compared to lead ions for adults:

36 µg Pb/L blood ≙ 15 µg Pb/kg bw/day ↔
2.4 µg Pb/L blood ≙ 1 µg/kg bw/day.

Table 1-54 presents the incremental PbB levels and resulting health impacts for children (infants and toddlers) and adults that correspond to the median daily intake of game meat and the mean lead concentration found in game meat. The results indicate that the mean consumption of game hunted with lead shot results in a low impact with a mean IQ loss of 0.16 and 0.37 IQ points for infants and toddler, respectively, whereas the mean consumption of game meat hunted with bullets has a much higher impact with a mean IQ loss of 2.5 and 3.7 IQ points for infants and toddler, respectively. For adults, the mean increase in the prevalence of CKD is 0.4 and 2.4 % for game hunted with shot and bullets, and the mean increase in systolic blood pressure is predicted to be 0.02 and 0.12 mmHg for game hunted with shot and bullets, respectively.

To take into account the strongly skewed underlying distribution, the full distribution of predicted PbB levels was taken forward to quantify the baseline risks and to monetise such risks (see Section 2.5.2.1).

Table 1-54: Calculated mean values for daily intake, incremental PbB levels and health impacts from the consumption of meat from game hunted with lead bullets or shots in the EU based on data from EFSA (20.06.2020)

Popu-lation	Type of ammu-nition	Game meat consumption (g/kg bw and day; P50[1])		Lead conc. In game meat (µg/g meat; mean Ub)[2]	Daily intake of lead (µg/kg bw/d; mean)	PbB level increment (µg/L: mean)	IQ point loss in children	Incr. preval. of CKD (%) in adults	Incr. in SBP (mmHg) in adults
Infants	Shots	Min	0.14	0.366	0.051	0.615	0.05	—	—
		Med	**0.43**	**0.366**	**0.155**	**1.864**	**0.16**	**—**	—
		Max	4.26	0.366	1.558	18.694	1.56	—	—
	Bullet	Min	0.89	2.516	2.241	26.891	2.24	—	—
		Med	**1.00**	**2.516**	**2.508**	**30.095**	**2.51**	—	—
		Max	1.67	2.516	4.193	50.315	4.19	—	—
Toddlers	Shots	Min	0.15	0.366	0.056	0.670	0.06	—	—
		Med	**1.01**	**0.366**	**0.371**	**4.450**	**0.37**	—	—
		Max	4.82	0.366	1.031	12.369	1.03	—	—
	Bullet	Min	0.11	2.516	0.286	3.432	0.29	—	—
		Med	**1.46**	**2.516**	3.663	**43.953**	**3.66**	—	—
		Max	4.82	2.516	12.130	145.562	12.13	—	—
Adults	Shots	Min	0.10	0.366	0.035	0.084	—	0.06	< 0.01
		Med	**0.65**	**0.366**	**0.238**	**0.571**	—	**0.38**	**0.02**
		Max	1.76	0.366	0.645	1.548	—	1.03	0.05
	Bullet	Min	0.21	2.516	0.520	1.247	—	0.38	0.04
		Med	**0.58**	**2.516**	**1.469**	**3.525**	—	**2.35**	**0.12**
		Max	1.37	2.516	3.437	8.250	—	5.50	0.27

Notes: 1 – See Table 1-50.; 2 – See Table 1-45 and Table 1-46: Concentration of lead in meat intended for consumption from game hunted with lead bullets in the EU (EFSA, 2020).

A robustness check of the lead intake values obtained in the above calculations can be made by comparison to a study by Lindboe et al. (2012) that investigated the lead content of ground meat from moose (*Alces alces*) from 52 samples intended for human consumption in Norway and predicted human exposure through this source. In 81 % of the batches, lead levels were above the limit of quantification of 0.03 mg/kg, ranging up to 110 mg/kg. The mean lead concentration was 5.6 mg/kg; i.e., 56 times the EU limit for lead in meat. The lead intake from exposure to moose meat over time, depending on the frequency of intake and portion size, was predicted using Monte Carlo simulation. For consumers eating a moderate meat serving (2 g/kg bw), a single serving would give a lead intake of 11 µg/kg bw on average, with maximum of 220 µg/kg bw. Using Monte Carlo simulation, the median (97.5th percentile) predicted weekly intake of lead from moose meat was 12 µg/kg bw (27 µg/kg bw) for one serving per week and 25 µg/kg bw (45 µg/kg bw) for two servings per week. A weekly intake of 27 µg Pb/kg bw would result in a daily intake of 3.86 µg Pb/kg bw/day. This value corresponds well with the EFSA data for median game meat consumption by adult members of hunting households (3.9 µg Pb/kg bw/day).

Another sensitivity check was made by applying the All Ages Lead Model (AALM, v. 2.0), which is a simulation model developed by U.S. EPA that predicts lead concentration in body tissues and organs of hypothetical individuals based on simulated intake and lifetime of lead exposure.[154] According to U.S. EPA, "the purpose of the model is to provide risk assessors and researchers with a tool for rapidly evaluating the impact of possible sources of lead in a specific human setting where there is a concern for potential or real human exposure to lead". When applying the AALM model to simulate steady state PbB levels in high-frequency game meat consumers, the Dossier Submitter found a close agreement with the values predicted for infants and toddlers based on the EFSA (2010) relationship between chronic dietary intake and PbB level (12 µg Pb/L blood ≙ 1 µg/kg bw/day). For adults, PbB levels simulated with the AALM model were roughly a factor of two larger than those obtained with the EFSA relationship (2.4 µg Pb/L blood ≙ 1 µg/kg bw/day).

The data indicate that game meat consumption by hunter families can have a relevant impact on the neurodevelopment of young children. The performed calculations may be underestimated because they do not include lead exposure *in utero*. Furthermore, even if the estimate includes infants (under the age of 12 months), the mobilisation of the lead accumulated in the body of the lactating female hunter family member and its elimination with the milk might be underrepresented.

The data also indicate that game meat consumption by hunter families can have an impact on the incidence of chronic kidney disease in adults (males and females). The effects on the cardiovascular system might to be lower.

The impact of game meat consumption and the accumulation of lead in the body of female hunter family members at reproductive age on the offspring during pregnancy and the mobilisation of lead with elimination via the milk during lactation as addressed above is of concern. Consequently, advice is provided from national authorities such as French ANSES[155] or German BfR[156] that children and women at childbearing age should not consume game meat shot with lead ammunition (see also sections B.10.2.2 and B.10.2.3).

Number of high-frequency consumers of game meat

Based on national statistics of the number of hunters, ECHA calculated that there are 6.0 million hunters in the EU-27 (Röschel et al., 2020). According to Eurostat data, the average household size in the EU-27 is 2.3. Thus, hunter families comprise about 13.8 million individuals (3.1 % of the EU-27 population). The number of female hunter family members of reproductive age is expected to be the same as in the general population. According to Eurostat (2020), 15.4 % of the total EU population were women aged 20-44. Applying this percentage to hunter families suggests that there are about 2.1 million female hunter family members of reproductive age. In 2019, the crude birth rate was 9.3 live births per 1 000 individuals (Eurostat, 2019). Applying this rate to the population of interest one may assume that approximately 130 000 (9.3e-3*13.8e6) babies are born to hunter families in an average year. A number of factors could be accounted for (a regular pregnancy lasts 9 months whereas a calendar year has 12 months, multiple birth may be the result of one pregnancy, etc.), but for the purpose of this restriction the Dossier Submitter assumes a ballpark estimate of 100 000 pregnancies per year among hunter families.

Moreover, as the share of the EU-27 population aged 7 or younger is approximately 8 % of

[154] The software is downloadable from: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=343670
[155] https://www.anses.fr/en/content/consumption-wild-game-action-needed-reduce-exposure-chemical-contaminants-and-lead
[156] http://www.bfr.bund.de/cm/349/research-project-safety-of-game-meat-obtained-through-hunting-lemisi.pdf

the total population (Eurostat, 2020), and assuming an equal age distribution in hunter families as in the general EU population, the Dossier Submitter estimates that close to 1.1 million children aged 7 or younger are particularly vulnerable to lead exposure.

1.6.4.6.2. Risk from consumption of contaminated drinking water (uses # 1, 2, 3, 4, 5, 6 and 7)

Risks for the consumption of lead contaminated drinking water may originate from the deposition of lead on and in the soils of shooting ranges using lead gunshot or lead bullets, with corrosion of lead and its mobilisation to surface water and groundwater as drivers.

For several shooting ranges a risk for humans via the environment has been demonstrated. For example, in surface (run-off) water of US shooting ranges measured at retention ponds, measured lead concentrations were 8 µg/L, 289 µg/L and 694 µg/L (Ma et al., 2002). Likewise, in Finnish shooting ranges total lead concentration was >50 µg/L in more than 60 % of the samples taken (Kajander and Parri, 2014). Compared to the threshold of 10 µg/L for lead in drinking water (Directive 98/83/EC), such measured lead concentrations demonstrate a potential risk to human health that requires appropriate RMMs to avoid contaminated run-off water to be released to the environment.

In groundwater beneath old shooting ranges in the US and Europe, lead concentrations above 1 000 µg/L have been reported (Soeder and Miller, 2003, Bavarian WWA Aschaffenburg, 2019), exceeding more than 100-times the background level in drinking water (Carlon, 2007). Such contaminations of the groundwater usually require remediation of the soil to eliminate risk to human health via drinking water.

1.6.4.6.3. Risk from consumption of contaminated food (uses # 1, 2, 3, 4, 5, 6 and 7)

Risks from the consumption of lead contaminated food may originate from the deposition of lead on and in soils of shooting ranges or from lead gunshot deposited on agricultural land with consequent uptake of lead by plants used for human consumption as well as the uptake of lead from soil or gras by grazing ruminants delivering milk and meat for human consumption.

A direct correlation between lead in soil and lead in plants has been reported in the literature (Bennett et al., 2007). In the biomass of spring barley (*Hordeum vulgare* L.) grown on shooting ranges, lead concentrations were 138 mg/kg in roots, 16 mg/kg in leaves, 4.2 mg/kg in stems and 2.4 mg/kg in spikes (Chrastný et al., 2010). Regulation 1881/2006 limits lead in cereals to 0.2 mg lead/kg food for human consumption, demonstrating that there can be a risk for humans from the consumption of food grown on shooting ranges, albeit it is unknown how frequent shooting ranges in the EU are used for food production.

In terms of potential for indirect exposure, one cannot preclude that there is potential for cattle, and their dairy products, to contain elevated lead concentrations that may enter the food chain. This would only happen if the animal did not display overt clinical symptoms of lead poisoning, in which case its meat and dairy products would normally be disposed.

The potential exposure of humans to lead via dairy products and meat seems largest for subsistence farmers (and their families) eating meat and dairy products derived entirely from a cattle herd with sub-clinical lead poisoning following exposure to lead ammunition via grazing on land used for shooting or the consumption of silage contaminated with lead shot. Although the Dossier Submitter considers this a rare scenario, it assessed the significance of exposure via this route performing a 'worst-case local scale'[157] exposure assessment that considers the scenario of an adult farmer and a young child consuming all their meat and dairy products from sub-clinically poisoned cattle.

Dietary exposure is typically calculated based on representative consumption rates for a variety of foodstuffs. Meat and dairy products are of most relevance in this scenario and consumption rates are taken from the EUSES model, which uses the highest country-average consumption rate from the EU Member States for each food as input to the assessment of exposure to chemicals from the diet.

- Adult daily intake of meat is 0.301 kg/d ww in EUSES; and
- Adult daily intake of dairy products is 0.561 kg/d ww.

Children are commonly the most sensitive receptors in the assessment of dietary exposure as they consume more in relation to their bodyweight, and they may also be more sensitive to the toxic effects of the substance under assessment. This is a particular issue with lead as neurobehavioural effects in children (as measured by IQ score) are the most critical health effect (Lanphear et al., 2005). EFSA Scientific Committee (2012) guidance on parameter values for dietary exposure assessment indicates that a young child consumes 52.3 % of an adult diet[158], which can be applied to modify the adult consumption values for meat and dairy products given in EUSES, i.e.:

- Child's daily intake of meat is 0.157 kg/d ww; and
- Child's daily intake of dairy products is 0.293 kg/d ww.

Cattle are only likely to show clinical signs of lead poisoning at PbB levels higher than 250 to 400 µg/L; a PbB level of 300 µg/L in cattle exposed to lead from ammunition is therefore unlikely to alert a farmer to the possibility of poisoning and result in its removal from the food chain. Blood lead level is the most common metric to represent lead poisoning but equivalent concentrations in meat and milk are required for dietary exposure assessment. Bischoff et al. (2014) presents a correlation between milk and blood lead concentrations[159] that suggests a cow with a blood lead level of 300 µg/L would produce milk containing 0.3 mg/L lead. Data from APHA indicates that the lead content of animal tissue from cattle with a similar blood lead level would be 10 – 20 mg/kg lead dw (for a mid-range value of 15 mg/kg dw this would equate to approximately 5 mg/kg ww based on water content of roughly 70 %). These calculated concentrations in meat and milk (including milk used for the manufacture of dairy products) are an order of magnitude higher than the maximum levels permitted for lead, which are 0.10 mg/kg ww in meat (0.50 mg/kg ww in offal) and 0.020 mg/kg ww in milk[160].

Table 1-55 and Table 1-56 detail the dietary exposure assessment for a subsistence farmer and a young child consuming meat and milk/dairy produce from cattle with a blood lead level of 300 µg/L. It should be noted that this assessment may underestimate the potential exposure from dairy produce as the concentration of lead in products such as cheese will be higher than that in milk.

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[157] Local scale is a typical worst case since all food products are derived from the vicinity of a point source (see EUSES guidance).
[158] An average European toddler (1-3 years) weighs 12 kg and has a total mean food consumption rate of 114.4 g/kg bw/day; an average adult weights 70 kg and consumes 37.5 g/kg bw/day (EFSA Scientific Committee, 2012)

[160] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1881-20150521&from=EN

Table 1-55: Dietary exposure assessment for subsistence adult (farmer)

Foodstuff	Lead conc. (mg/kg ww)	Consumption rate (kg/d ww)	Lead intake (mg/d)	Bodyweight (kg)	Dietary lead exposure (mg/kg bw/d)
Meat	5	0.301	1.5	70	0.021
Milk/dairy	0.3	0.561	0.17	70	0.002
Total					0.023

The predicted dietary exposure to lead for an adult subsistence farmer under this scenario is 23 µg/kg bw/d, which is 15 times higher than the $BMDL_{01}$ established by (EFSA, 2012) for cardiovascular effects in adults (1.5 µg/kg bw/d) and 37 times higher than the $BMDL_{10}$ for nephrotoxicity effects (0.63 µg/kg bw/d).

Table 1-56: Dietary exposure assessment for the child of a subsistence farmer

Foodstuff	Lead conc. (mg/kg ww)	Consumption rate (kg/d ww)	Lead intake (mg/d)	Bodyweight (kg)	Dietary lead exposure (mg/kg bw/d)
Meat	5	0.157	0.785	12	0.065
Milk/dairy	0.3	0.293	0.088	12	0.007
Total					0.072

Under this scenario predicted dietary exposure to lead for a toddler is 72 µg/kg bw/d, which is more than 140 times higher than the $BMDL_{01}$ of 0.5 µg/kg bw/d established by (EFSA, 2012) for developmental neurotoxicity in young children.

This scenario illustrates that worst-case exposure estimates do not correspond with negligible potential exposure.

However, in the absence of evidence that this scenario could reasonably occur in practice in the EU, the Dossier Submitter considers this to be a hypothetical, illustrative, scenario, and which is not part of the main analysis.

1.6.4.7. Qualitative assessment of human health risks

Except for game meat consumption, the available information is not sufficient to properly quantify the risks from the assessed uses. Therefore, the risks for human health associated with the use of lead gunshot or bullets for hunting and sports shooting and with the use of lead fishing tackle are described and assessed in a qualitative manner by combining the potential for exposure with the frequency of exposure. The outcome of this analysis is reported in Table 1-57.[161]

To describe the level of risks occurring, the following qualitative ranking is used: +: negligible to low risk or risk controlled; ++: moderate risk; +++: high (main) risk; N/A: not applicable.

Table 1-57: Qualitative assessment of human health risks related to the use of lead for

[161] For the description of the different scenarios for sports shooting, please refer to section 1.5.4.4.

hunting, outdoor sports shooting and fishing

Use #	Use description	Inhalation		Oral intake		Via environment	
		Outdoor shooting	Home-casting	Hand-to mouth (dust)	Ingestion (frag-ments)	Game meat cons.	Drinking water [2], food
1	Hunting with gunshot	+	N/A	+ to ++	++	+ (adults); +++ (< 7 years / pregnant)	+
2a	Hunting–with bullets – small calibre[1]	+	N/A	+ to ++	N/A	N/A	+
2b	Hunting–with bullets – large calibre	+	+++	+ to ++	N/A	+ (adults); +++ (< 7 years / pregnant)	+
3	Outdoor sports shooting – gunshot						
3a	Temporary shotgun areas, no RMM, limited shooting intensity	+	N/A	+ to ++	++	N/A	+ to ++
3b	Permanent shotgun areas, no ENV RMM, intensive shooting	++	N/A	+++	++	N/A	+++
3c	Permanent shotgun range, ENV RMMs in place: - prevent rivers from crossing - control water runoff - lead deposition within range - remediation plan upon closure	++	N/A	+++	++	N/A	++ to +++
3d	Permanent shotgun range, ENV RMMs in place (in addition to 3c): - regular (annual) collection of lead shot (>90 % effectiveness) - monitoring and treatment of surface (runoff) water - ban of agricultural use within site boundary	++	N/A	+++	++	N/A	+
4	Outdoor sports shooting – bullets						
4a	Temporary rifle/pistol areas, limited shooting intensity:						
	- use of soil berm to trap bullets	+	N/A	+ to ++	N/A	N/A	+ to ++

Use #	Use description	Inhalation		Oral intake		Via environment	
		Outdoor shooting	Home-casting	Hand-to mouth (dust)	Ingestion (frag-ments)	Game meat cons.	Drinking water [2], food
	- use of trap chamber or 'best practice' sand traps combined with a water management system	+	N/A	+ to ++	N/A	N/A	+
4b	Permanent rifle/pistol ranges, intensive shooting: - use of soil berm to trap bullets	++	N/A	+++	N/A	N/A	+++
4c	Permanent rifle/pistol ranges: - use of trap chamber or 'best practice' sand trap combined with a water management system - ban of any agricultural use within site boundary	++	N/A	+++	N/A	N/A	+
5	Outdoor shooting using airguns (assuming low shooting intensity)	+	N/A	+	++	N/A	+ to ++
6	Other outdoor shooting activities (assuming low shooting intensity)	++	++	+	N/A	N/A	+ to ++
7	Fishing sinkers and lures	N/A	+++	++	++	N/A	+
8	Fishing nets, lines and ropes	N/A	N/A	N/A	N/A	N/A	N/A

Notes: +: negligible to low risk or risk controlled; ++: moderate risk; +++: high (main) risk; N/A: not applicable. [1] This use includes hunting with an airgun [2] Both groundwater and surface water (e.g. rivers, lakes) may be used for the production of drinking water. A specific "Assessment of the potential for the use of lead ammunition at shooting ranges to contaminate groundwater and drinking water" is available in Appendix 1 to the Background Document.

Inhalation of lead from shooting (uses # 1, 2, 3, 4, 5, 6): There is a risk from shooting of increased uptake of lead and consequent health effects. The risk is higher for the use of firearms (with lead-containing primer) compared to use of air weapons and is increasing with (i) the increasing calibre of the weapon, (ii) increasing shooting frequency and (iii) limited ventilation (see Section 1.6.4.1). Considering that this restriction is focussing on outdoor shooting with natural ventilation and does not address the risks from primers, no high risk level is expected. It is assumed that the risk level increases with increasing shooting frequency. Consequently, it is considered that the risk level from inhalation of lead from hunting (uses 1, 2a, 2b) and shooting at temporary areas (uses 3a, 4a, 5, 6) with low shooting intensity is low (+) and moderate (++) for more frequent shooting at permanent outdoor sports shooting ranges (uses 3b, 3c, 3d, 4b, 4c). It has to be noted that FITASC commented (comment #3221) that the risk from inhalation of lead from shooting with a gunshot is expected to be low.

Inhalation of lead from home-casting (mainly uses #2, 4, and 7): In the absence of information on the incidence of home-casting of lead fishing tackle and lead bullets for hunting or sports shooting and the unknown concentration of lead in air from home-casting, a qualitative analysis was performed. Even though not all hunters/shooters/fishers are home-casting, there is a high exposure/risk from home-casting activities for the person performing the home-casting and for vulnerable population such as children who live with hunters/shooters/fishers. Information and case studies are mostly available for home-casting fishing tackle (see Section B.9.2.6) which was promoted a few years ago (see Section D.4.5.7 in the Annex). However, the same high lead exposure and risks can be assumed for home-casting of lead fishing tackle and lead bullets resulting in a high risk level (+++).

With regard to the home-casting of lead ammunition, the Dossier Submitter assumes that home-casting is mainly performed for large calibre bullets that do not require high accuracy such as for hunting (use 2b). For sports shooting where high precision is required and often small calibre bullets are used, home-casing is not likely to take place. However, for sports shooting with older or historical weapons (use 6) home-casting of bullets individually fit to the weapon can still be reasonably assumed to take place.

Lead enclosed in fishing nets, ropes and lines (use 8) is not home-casted.

Hand-to-mouth intake (all uses): For most activities handling lead, there is a general risk for hand-to-mouth intake of lead dust. This risk is specifically high for lead dust formation while shooting with lead gunshot or bullets. Usually, good hygiene measures such as washing of hands, changing clothes, and avoiding smoking, drinking or eating are recommended for shooting activities to limit the risk. It can be reasonably assumed that with increasing shooting intensity the risk will increase. Therefore, the risk level is considered as low to moderate (+ to ++) in case of limited shooting intensity while hunting (uses 1, 2a, 2b) or sports shooting (uses 3a, 4a, 5, 6), and high (+++) in case of intensive shooting at permanent shooting ranges with high shooting intensity and high dust deposition at the range (uses 3b, 3c, 3d, 4b, 4c). For fishing (use 7) no shooting is involved. However, intensive handling of lead fishing tackle can be assumed, for which a skin-to-saliva transfer efficiency of 24 % was reported (Sahmel et al., 2015). Therefore, a moderate risk level (++) is assumed. Good hygiene practice such as hand washing, no smoking, drinking or eating during fishing could be expected to reduce the intake of lead. Nevertheless, these good hygiene practices are not communicated to consumers when they purchase lead sinkers and lures (ECHA market survey), and the guidance on safe use submitted in the REACH registration dossier and published on ECHA dissemination website does not indicate any hygiene measures for consumers[162].

For use 8, lead is enclosed in nets, ropes, and lines and therefore no direct contact between lead and the hand of the fishers occurs.

Poisoning from ingestion (uses # 1, 3, 5, and 7): Incidental case reports for acute poisoning have been published (e.g., small lead shots, fragments) indicating a risk. Due to the low incidence of reported cases, the overall risk level is not considered as high, even if the reported effects are of high concern. A relevant criterion is availability of lead fragments of ingestible size for children; of concern for potential ingestion are lead gunshot (uses 1, 3), lead air pellets (use 5), and small lead fishing tackle (use 7). It is noted that the safe storage of lead gunshot and lead fishing tackle at home is crucial to prevent inadvertent ingestion by children. However, the reported cases of children with intoxication from small lead items (Gummin et al., 2017, Rozier and Liebelt, 2019, Treble and Thompson, 2002) (see Section 1.6.3.5) clearly demonstrate that this might not necessarily be the case. Therefore, a moderate risk level (++) is assumed. This relates also to the habit of many fishers to bite lead sinkers (use 7) to attach them to the fishing line (Grade et al., 2019, Carrier et al., 2012) and the possibility to swallow such fragments.

Indirect exposure via the environment:

Game meat consumption (uses # 1 and 2): European hunters generally follow "best practice", as advised by several wildlife authorities, when handling game meat. Depending on the cut, lead concentrations in game meat intended for consumption can be very different. The available data indicate that even if prepared under best practices a relevant proportion of game meat (Pain et al., 2010) has substantially higher lead concentrations than the regulatory maximum level for lead in meat (0.1 mg Pb/kg meat according Commission Regulation (EC) 1881/2006). Around 13 % of the game meat in the EFSA database showed lead concentrations above this maximum level (see sections B.9.2.1 and B.9.2.2 in the Annex). Of specific concern are individual samples with lead concentrations above 1 000 mg/kg, specifically from deer and wild boar (see Section B.9.2.2). Based on data from the EFSA database on lead concentration in game meat, on the intake of game meat (median used as a proxy for persons of a hunter household), and assuming lead metal bioavailability of 10 % for adults and 50 % for children, ECHA calculated for adult blood lead level that indicate a low risk (+). However, for children 7 years of age or younger a worst-case blood lead level increase was calculated which has a relevant impact (+++) on IQ with a loss of 1.6 to 3.7 IQ points for consumption of game meat bagged with bullets (use 2b). For game bagged with gunshot (use 1), the data indicate a lower risk with IQ losses of 0.2 to 0.4 IQ points (see Section 1.6.4.6.1). However, since there is no evidence for a threshold of lead for developmental neurotoxicity in children, the risk arising from the consumption of game meat bagged with gunshot is also considered to have a relevant impact (+++) for children 7 years and younger and for pregnant females.

There could also be risks to humans via the environment via the intake of **food** grown on soil contaminated from shooting activities and from **drinking** water contaminated from lead from shooting ranges. The risks are assumed to increase with increasing deposition and in case of contaminated food, the use of contaminated areas for agriculture. The risks are assumed to be low (+) in case of hunting with bullets because the bullets (uses 2a and 2b) typically remain in the carcass of the game. For hunting with gunshot (use 1) and for temporary shotgun areas (use 3a), the risk might be low to moderate (+ to ++) depending

[162] Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/16063/9

on the amount of gunshot deposition on terrestrial areas that might also be used for agricultural purposes and the corroding gunshot might lead to contamination of surface water. In the case of permanent shotgun ranges with high shooting intensity but without any environmental risk management measures (use 3b), there is a high risk (+++) of contamination of surface water and potentially groundwater under certain circumstances and in case of agricultural use also a risk for contamination of food. At permanent shotgun ranges (use 3c) the risk is considered moderate (++) due to risk management measures in place to prevent run-off of contaminated surface water; however, accumulation of gunshot in soil (with potential groundwater contamination) and effects on food in case of agricultural use of the range might still occur that might potentially lead to a higher risk (+++). For permanent shotgun ranges (use 3d) the risk is considered low (+) because risk management measures are in place to prevent surface water and ground water contamination and the agricultural use of the range area is banned. For rifle and pistol ranges, the risk is depending on the type of bullet containment. In case appropriate trap chambers and/or 'best practice' sand traps combined with a water management system are used, the risk can be considered as controlled (+), whereas in the case of soil berms used to trap bullets, moderate to high risks (based on shooting intensity) can be assumed due to mobilisation of lead to surface water and to soil. Consequently, for a temporary rifle/pistol range (use 4a) trapping bullets in a soil berm the risk is considered to be between low (+) and moderate (++) and for a permanent rifle/pistol range with intensive shooting (use 4b) high (+++). Depending on the type of bullet trap containment the risks for outdoor shooting with air rifle (use 5) and for other outdoor shooting activities (use 6), the risks vary from low to medium (+ to ++), assuming limited shooting intensity. Depending on the use of land at the end of life of a range (and on the land zoning at local level), oral uptake of lead from contaminated soil might also be possible, in case soil is not fully remediated, within the following scenario: (i) use of land for agricultural purposes, (ii) use of land for recreational areas for adults and children, and (iii) use of land for residential areas.

RAC box

RAC agrees in general with the risk assessment carried out by the Dossier Submitter. However, RAC's evaluation resulted in some slight differences in the conclusions concerning human health risks. These are as follows:

- The risk of groundwater (and derived drinking water) contamination may vary from very low to high depending on the soil and groundwater characteristics. It is difficult to estimate the prevalence and extent of groundwater vulnerability to lead contamination at shooting ranges at European, national or even regional scale.
- The Dossier Submitter did not separately assess risk for pregnant shooters. RAC considers that the act of shooting generally results in only a low risk for adults, while pregnant (or fertile-age females) are at a moderate risk if sports shooting is practiced regularly. RAC also notes that jacketing of bullets reduces the exposure and consequent risk.

1.7. Justification for an EU wide restriction measure

The four main justifications for an EU wide restriction measure are:

1. To ensure a harmonised high level of protection of the environment and human health to address the identified risks;
2. To address the lack of EU wide commitment to fulfil the Birds Directive commitment to the protection of birds and their habitats;
3. To ensure the free movement of goods within the Union;
4. To ensure a level playing field for all engaged in sports shooting.

As demonstrated in the previous sections, lead in ammunition and lead in some uses of fishing tackle (such as sinkers and lures) present risks to the environment and human health, in particular to birds and vulnerable populations such as children, which are not adequately controlled.

A Union-wide action to address the environmental risk associated with the use of lead gunshot outside of EU wetlands is needed to ensure a harmonised level of protection. In the assessment of the proposed restriction on the use of lead gunshot in wetlands it was concluded that despite the comprehensive definition of wetlands applied, the risks to water birds and various AEWA species was not completely addressed as many species feed outside of wetlands and would therefore still be at risk of ingesting spent lead gunshot used outside of wetlands. Since the flyways of these migratory birds and many other species cross several Member States, regulating the risk to them at Union level is likely to ensure the needed protection all over the EU.

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A Union-wide action will also support implementation of the European Birds Directive[163] which states in article 4.4 that ‘ (…) Member States shall take appropriate steps to avoid pollution or deterioration of habitats or any disturbances affecting the birds (…) Member States shall also strive to avoid pollution or deterioration of habitats.’

The EU is a signatory party to the AEWA, CMS[164], and CMS Raptor[165] MOU (since 2005, 1983

[163] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:020:0007:0025:EN:PDF

[164] The Convention on Migratory Species (CMS/Bonn Convention) is an Intergovernmental treaty which aims to conserve terrestrial, marine and avian migratory species throughout their range, on a global scale. Appendix I of CMS lists migratory species threatened with extinction: Parties strive towards strict protection of the species, their habitats and conservation/restoration/mitigation actions. Appendix II lists migratory species that need or would significantly benefit from international co-operation. CMS acts as a framework Convention. The agreements may range from legally binding treaties (called Agreements) to less formal instruments, such as Memoranda of Understanding.

[165] Signatories to the Raptors MOU (Memorandum of Understanding on the Conservation of Migratory Birds of Prey in Africa and Eurasia) commit to adopting and implementing measures to conserve migratory birds of prey and their habitats, including for example, providing a legal framework to protect migratory species, and, developing

and 2011, respectively) Union-wide action would guarantee the effective implementation of these agreements. Managing risks on a Member State level would typically result in national regulations that differ with regards to their effectiveness. A harmonised restriction proposal will ensure a consistent and effective approach.

A further reason to act on a Union-wide basis is related to the health risk posed by lead in particular to children, where no safe level of ingestion for avoiding neurodevelopmental effects has been demonstrated. Adult and child exposure to lead might happen via (i) the exposure to lead fumes during lead fishing tackle home-casting activity, and (ii) the consumption of game meat contaminated with lead from bullets or shot. Regarding this latter risk associated with game consumption, it pertains particularly to hunter families, especially to their children. This is especially the case for those engaged in subsistence hunting.

With regards to contamination of game meat by lead from lead ammunition, no EU-wide maximum levels exists. The maximum levels (ML) of allowable lead in food, under Commission Regulation (EC) 1881/2006, have been set for bovine animals, sheep, pig and poultry as 0.1 and 0.5 mg Pb/kg wet weight for meat and offal, respectively. It has been shown that lead concentrations in game meat frequently exceed the relevant ML of 0.1 mg/kg, set for lead in other meat from domestically raised animals (Pain et al., 2010, EFSA, 2020). For example, EFSA (2020) reported mean upper bound lead concentrations in game meat of 0.366 mg/kg for 2 574 meat samples from small game usually hunted with shot and concentrations of 2.515 mg/kg for 10 334 meat samples from large game hunted with bullets. In Gerofke et al. (2018) the highest concentrations measured were 113 mg/kg for pheasant and 5 309 mg/kg for deer.

Although the issues surrounding the use of lead for hunting are known and, in some cases, lead to voluntary actions, such as in the UK. The conclusion of the Dossier Submitter is that the market will not self-regulate and that regulatory action is required. Given these arguments, there seems to be a justified reason to address the issue at the source: lead bullets and lead shot (Giuggioli et al., 2017). Equally, much hunter consumed game meat is not ‘placed on the market’ prior to consumption, limiting the effectiveness of an ML for lead in game to address the identified risks. Nevertheless, in the event that a restriction is adopted a mandatory ML for game meat on the EU market would be a complementary measure to ensure that risks from imported game meat are adequately controlled.

With regards to sports shooting, action at EU level is warranted to ensure a consistent high level of protection across the EU. The risks posed by the use of lead in shooting ranges affect the receptors (i.e. surface and groundwater) that are typically regulated under EU wide legislation.

With regard to lead in fishing tackle, in the EU27-2020, the voluntary commitment from the sector[166] to phase-out lead from fishing tackle by 2020 did not lead to any action nor reduction of the risk, and there is currently no EU wide measure in place to address the risks of lead in fishing tackle. The only current legally binding ban on lead in fishing tackle in the EU is in Denmark where all types of fishing tackle used in both commercial and

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cooperative international projects and initiatives to promote effective conservation efforts. In December 2019, there were 60 Signatories to the Raptors MoU, including the European Union (since 2011), and 17 individual EU Member States. Of the 93 species covered by the Raptors MOU, 44 occur in Europe.

[166] In June 2015, EFTTA called on the fishing trade and the angling community to voluntarily stop manufacturing, importing, retailing and using angling weights (sinkers) made of lead above the size of 0.06 grams and replace them with suitable lead-free alternatives by 2020 at the latest. https://www.eftta.co.uk/media-centre/news/eftta-position-statement-on-angling-lead-weights-sinkers

recreational fishing are banned from import and placing on the market (cf. Annex D). In addition to the Danish legislation, some local ban also exists in specific rivers or lakes in Sweden, for example.

Some voluntary national initiatives and agreements also emerge, for example in Benelux countries (CfE #1034 – Vlaams Instituut voor de Zee), which encourage the use of alternatives to lead fishing tackle. Nevertheless, none of these initiatives set a concrete total phase-out of lead in fishing tackle, and they are currently not legally binding, which means that the compliance with these national agreements and initiatives are not legally enforceable.

Last but not least despite the fact that a number of fishers are willing to pay more to replace their current lead fishing tackle by more environmentally friendly ones (cf. Annex D), stakeholders indicate that there is no incentive to switch to non-lead fishing tackle as long as the use of lead is not banned by a Regulation (e.g. CfE #909 – Sportvisserij Nederland, #1247 – Wildfowl & Wetlands Trust, ECHA market survey). For the manufacturers, further market incentives to develop and place on the market non-lead fishing tackle can be encouraged by announcing a phase-out of lead, with a concrete end date (Grade et al., 2019).

Another important underlying principle to consider is that measures that are introduced at EU level are more effective than a ban in few European countries, as it becomes also better known to non-EU countries importing into the EU, rather than a specific national ban. Compliance is consequently improved. The EU internal market is also promoted by harmonising European Community rules, rather than national specific rules.

Therefore, for all these reasons, an EU wide action is justified.

1.8. Baseline

1.8.1. Baseline for lead in hunting

In the call for evidence, limited information was submitted on the actual quantities of lead used for the different uses within the scope of the proposed restriction, which would have been the best possible data to estimate emissions of lead. The Dossier Submitter therefore estimated lead emissions based on the methodology used for the proposed restriction on the use of lead gunshot in wetlands and hunting statistics.

For some uses (airguns, muzzle loaders) the Dossier Submitter initially did not have enough information to make an estimation of the volume of use. Information submitted in the consultation of the Annex XV dossier has helped to fill this gap only for muzzle loaders.

The baseline scenario describes how the use and emissions of lead for the uses within the scope of the proposed restriction would evolve in the absence of the proposed restriction.

1.8.1.1. Gunshot

The use of lead in shot for hunting is still widespread: its perceived ballistics performance in combination with the lower price of lead has a consequence that many hunters prefer to shoot with lead gunshot and are not typically inclined to start using alternative gunshot on their own initiative.

An observation in a paper from Thomas (2013) states that the use of non-toxic ammunition usually advances only when the use of lead ammunition is regulated. In that respect there are some current actions that could have an impact on the trends in the use of alternatives to lead shot:

1. The use of lead shot is impacted by an upcoming restriction on the use of lead over wetlands[167]. This will have an impact on the extent to which hunters will be able to use lead shot and may encourage them to use alternatives to lead shot also outside of wetlands as alternatives become more attractive, both in terms of availability as well as in price.
2. In the UK a voluntary initiative has been proposed by several of the larger hunting associations to phase out the use of lead within five years (by 2025), inspired by an increasing concern on the effects of lead on wildlife and human health. Also in more practical terms, pressure has increased from supermarkets to supply game meat that is free from lead. Although the UK is outside of the EU as of the first of January 2021, this UK initiative is still of importance for the EU market as their initiative will create an increased demand for non-lead shot and hence increase the availability of alternatives to lead shot and lower their prices. Next to this the organisations leading this voluntary move have asked CIP[168] to approve additional shot size and gauges.

In the dossier concerning the use of lead in wetlands, the Dossier Submitter, based on information from industry, estimated that around 21 000 tonnes of lead were released per year in lead shot cartridges for hunting. A share of that volume is addressed under the proposal on lead over wetlands, the remaining share of that volume is addressed in the current dossier.

Given that the proposed restriction on the use of lead in wetlands addressed a volume of 5 000 to 7 000 tonnes of lead per year, the Dossier Submitter estimates that the total amount of lead that is released by hunters in the EU-27 after the implementation of the wetland restriction is in the order of 14 000 tonnes per year with low and high estimates ranging from about 13 000 to about 15 000 tonnes per year.

Assuming a release over 20 years would result in about 280 000 tonnes (260 000 – 300 000 tonnes). Detailed information on the baseline is available in Annex D.

1.8.1.2. Bullets

Even though most hunters are still considered to be using lead bullets (copper jacketed) there is a moderate growing trend in the use of copper bullets. This trend is inspired by a desire of hunters to have better performance bullets. Copper bullets are considered to perform better as their mass retention is higher. Besides this, there is a growing concern about the consumption of game meat that contains lead. Advice from hunting associations and food safety agencies have led some hunters to use non-lead bullets.

Despite this decrease in the use of lead bullets, the global trend in using non-lead ammunition is in the order of 10 % of bullets used, i.e. an estimated 10 % of all hunters in the EU-27 use non-lead bullets. In some areas, where there are local or regional regulations on the use of lead ammunition this percentage can be higher; in Finland this percentage can

[167] Currently the Commission Regulation (EU) 2021/57 of 25 January 2021 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards lead in gunshot in or around wetlands, has been published. In Annex XVII to Regulation (EC) No 1907/2006, in entry 63, the conditions of the restriction are available.
[168] The Commission internationale permanente pour l'épreuve des armes à feu portatives ("Permanent International Commission for the Proof of Small Arms" – commonly abbreviated as CIP) is an international organisation which sets standards for safety testing of firearms. (The word portatives ("portable") in the name refers to the fact the CIP tests small arms almost exclusively; it is ordinarily omitted from the English translation of the name.) As of 2015, its members are the national governments of 14 countries, of which 11 are European Union Member States. The CIP safeguards that all firearms and ammunition sold to civilian purchasers in Member States are safe for the users.

be as high as 20 % (whilst in neighbouring Sweden the global use is about 2 %). Information received in the call for evidence would suggest that the overall global use in Europe is about 10 %.

Like for lead shot, a few developments are expected to have a positive influence on the availability non-lead rifle ammunition.

1. The Danish hunting association together with ministry of the environment recently announced an initiative to phase out the use of lead in bullets for hunting from 2023.
2. The German Bundesrat has expressed that the use of lead in hunting ammunition should be reduced and that this can be achieved at reasonable cost within foreseeable time as there is sufficient non-lead hunting ammunition on the market.

The estimate baseline tonnage of lead use per year is based on hunting statistics (i.e. the number of animals hunted per year in the EU-27) combined with assumptions on the weight and use of lead bullets. A similar approach for estimating the volume of uses was applied by Environment Canada[169] and an estimate of this kind has also been submitted in the call for evidence by the Finnish hunting association. Based on these sources as well as on the earlier work done in the framework of ECHA's screening report, the Dossier Submitter estimated the amount of lead release to the environment for hunting with **small calibre bullets** to be around 15 tonnes per year with low and high estimates ranging from 14 to 17 tonnes per year. Assuming a release over 20 years would result in 310 tonnes (280 – 340 tonnes).

For hunting with **large calibre bullets** the annual release to the environment is around 119 tonnes per year with low and high estimates ranging from 92 to 138 tonnes per year. Assuming a release over 20 years would result in 2 370 tonnes (1 840 – 2 750 tonnes).

1.8.2. Baseline for lead in sports shooting

Legislations in place to regulate the specific use of lead shot in sports shooting can be summarised as following:

- In Sweden, Norway and Denmark the use of lead shot in shooting ranges is banned in the entire territory (with some derogations in place; see below);
- In the Netherlands the use of lead shot is banned for clay pigeon shooting.
- In Belgium, in the Flemish region, there is a regional ban for the entire territory.

According to the responses of Member State Competent authorities provided in the MS survey 2020 (Annex E.5), the following derogations have been granted:

- in Denmark derogations have been given to the Danish Shooting Union (DSU), for use of lead shot on their shooting ranges, as the International Shooting Sport Federation (ISSF) does not allow the use of alternative shot in such international competitions including the Olympic games. DSU applied a derogation for hosting a Compak sporting competition[170]; the international shooting organizations (FITASC) rules for such competitions require to use lead shot. However, no derogation was granted for training; the Danish athletes in this discipline are training with steel shot.

- In Sweden the following exemptions apply: exemptions in Regulation SFS 1998:944 related to shooting tests, hunting trail shooting, hunter's examination with approved

[169] https://www.canada.ca/en/environment-climate-change/services/management-toxic-substances/list-canadian-environmental-protection-act/lead/using-more-lead-free-ammunition/lead-ammunition-executive-summary.html
[170] According to Wikipedia Compak Sporting is a "compacted" form of sporting clays, which is a shotgun sport usually spread over 12 to 36 stations (shooting areas) occupying around 200 acres (0.81 km^2), presenting 2 or 3 different clay targets at each.

test leaders; and exemptions in Regulation NFS 2002:18 related to licensed shooters representing Sweden at international competitions in skeet, trap and double trap. This derogation applies to both training and competition.

- In Norway derogations have been granted to organisations for training to and participation in international competitions for which lead shot is the only allowed ammunition.
- In the Netherlands derogations are granted for professional athletes.
- In Belgium, in the Flemish region, derogations are granted only if the environmental permit allows this use, and this is only possible if extra measures are in place to collect fired shots.

Other more generic legislation (not specific to address lead contamination related issues) identified by ECHA are the following ones:

- In Cyprus, a national ban on the use of lead bullets at shooting ranges is in place for the entire territory.

In other Member States, the use of lead in sports shooting is not regulated under a specific nationwide legislation. However, some environmental legislations may apply to control or minimize some risks (mainly to groundwater) during the service life and/or end of life of a shooting range. In Finland for example, an environmental permitting system has been set up in which larger ranges are evaluated on the use of lead ammunition. A review of some of the old permits is foreseen (Finnish sports shooting Association, 2020). In Germany a system has been put in place with guidelines (to some extent binding such as German BMI (2012)) that set the conditions under which lead can be used by prescribing the design of shooting ranges.[171]

1.8.2.1. Gunshot

It is estimated that there are about 4 000 clay target shooting ranges in the EU. See Annex B (section B.9.1.3) for details.

The estimated annual amount of lead shot released to the environment at shotgun ranges is about 24 500 tonnes (14 000 – 35 000 tonnes). See Section 1.5.3.1.2 for details.

Assuming a release over 20 years would result in 490 000 tonnes (280 000 – 700 000 tonnes) of lead released to the environment.

In the absence of a restriction it cannot be expected that more risk management measures would be implemented to collect lead gunshot because the measures are costly and would therefore not be implemented without a legal requirement.

1.8.2.2. Bullets

It is estimated that about 16 000 pistol/rifle shooting ranges exist in the EU. This is the best estimate the Dossier Submitter could obtain based on various stakeholders surveys (MS survey 2020 and stakeholders questionnaire 2020 as described in Annex B (section B.9.1.3).

The estimated annual amount of lead bullets used is 42 000 tonnes (4 000 – 80 000 tonnes). See Section 1.5.3.1.2 for details.

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[171] Various guidance documents have been identified by the Dossier Submitter and are listed in the section on Risk Management Measures.

The annual release to the environment (soil and surface water) was calculated to be **420 tonnes (6 – 1 500 tonnes)** (see Section 1.5.3.1.2 and B.9.1.3.8).

Assuming a release over 20 years would result in **8 400 tonnes** of lead deposited in the environment **(110 – 30 000 tonnes)**.

In the absence of a restriction, it is not expected that more risk management measures would be implemented to collect lead bullets in trap chambers and sand traps. In the CSR (2020) bullet traps and sand traps are mentioned as a compulsory measure. According to the information presented in the CSR, the Dossier Submitter understands that the sand traps should be separated from soil by an impermeable layer and covered with an overhanging roof. 2.6.2.2 However, there are indications that such measures are not implemented throughout the EU, but that frequently sand/soil berms are used where the sand is not separated from soil by an impermeable layer and soil berms are still in use where the bullets are accumulating in the soil. Since trap chambers and the implementation of further risk management measures for existing sand/soil berms and soil berms are costly, it is not expected that – without a legal requirement – more trap chambers and more stringent risk management measures for sand/soil berms and soil berms would be installed.

1.8.3. Baseline for lead in fishing tackle

The baseline scenario below describes the situation in the absence of restriction for the different uses identified for lead in fishing activities, i.e. fishing with sinkers and lures, fishing with nets, ropes and lines, and finally home-casting of lead fishing tackle. Detailed information to support the baseline is available in Annex D.

1.8.3.1. Fishing with lead sinkers and lures (recreational and commercial fishing)

Sinkers and lures are used both for recreational and commercial fishing. The market for such fishing tackle has remained stable for the past two decades. Overall, in Europe, the number of fishers remains also stable despite some significant decrease reported in some countries. It is estimated that there are currently between 12 and 23 million recreational fishers in Europe: 6 – 17 million in freshwater and 6 million in marine water (see Annex A). In addition to the recreational fishing, it is estimated that about 14 000 vessels are fishing using lead fishing sinkers and jigs for commercial fishing activities (see Annex A).
It should be noted that even if the number of recreational fishers remains stable, the makeup of the population of fishers changes also over time, with people leaving or entering recreational fishing[172], this phenomenon is also known as the 'Leaky Bucket'. The 'Leaky Bucket' illustrates the annual turn-over of fishing participants, or in other words the fact that some fishers are joining/re-joining the fishing activity and others are quitting every year. For example, in the US (phenomena reported in Europe but no consolidated data available), new participants represents 6 % of the fishers every year, and returning ones about 10 % (after one or several years without any fishing activity) (US, 2018).

During the ECHA market survey, some stakeholders described the market as 'steady' or 'stagnant' with an increased proportion of lead fishing tackle imported from outside Europe. The increase proportion of import could be confirmed when looking at the same Eurostat data between 2004 and 2020 (cf. Annex A and D).

The ECHA market survey, and the call for evidence, confirmed that the market for fishing tackle is still dominated by lead tackle in most of the EU countries, except where a national ban is currently in place (e.g. Denmark, and the UK outside the EU27-2020). Lead remains indeed very popular with fishers because it is cheap, it performs well, it is versatile and none of the non-lead alternatives currently offer the overall performance of lead tackle in terms of mass density, malleability, ease of production and cost.

There are also examples where companies developed, and placed on the market alternatives, but did not achieve a breakthrough in the market despite a functional material and a competitive price. Retailers have indeed no incentive to remove totally lead fishing tackle from their shops as this would imply, in the current situation (i.e. in the absence of regulatory action), a loss of both customers and sales due to the alternative being more expensive and having lower density (experience from a Swedish retailer Fladen Fishing AB in 2007 reported in (KEMI, 2007)).

The market for fishing tackle is changing, even if this change is extremely slow. While lead fishing tackle may still constitute the largest percentage of the fishing tackle market, over the last decade the availability of sinkers and lures made from other materials has expanded, and new non-lead products have entered the market. Nevertheless, despite the production of lead alternatives by several suppliers (cf. Annex D on alternative availability), most retailing shops and websites are not stocking these products and/or carry only a very limited selection (if any). Information submitted during the call for evidence indicates that the use of lead in fishing tackle remains widespread in Europe. For example, a recent survey carried out in Belgium by VLIZ (Flanders Marine Institute) indicates that 6 % of anglers only currently use alternatives (CfE #1034 – Vlaams Instituut voor de Zee).

Considering the Danish or UK situation as an example, one may expect that lead fishing tackle will probably keep on dominating the European market as long as lead is legal because it is widely available, it works well for fishing, it is cheap, there is currently no market incentive at the EU level to switch to alternatives. There is also here a lack of public awareness on lead hazard for the environment and human health.

The underlying drivers of the lead fishing tackle baseline are complex, with several factors leading to one or another direction. The baseline scenario adopted for the analysis is therefore that, in the absence of an EU-wide restriction, lead will continue to be used and placed on the market as fishing sinkers and lures in the same order of magnitude as today. Since the releases in the environment are essentially due to unintentional loss by the fisher (inherent to the fishing practice itself), the Dossier Submitter assumes that the loss of lead fishing tackle in the environment will therefore remain stable during the 20-year analytical period used for the impact assessment.

It is estimated that 3 000 tonnes (2 000 – 7 000 tonnes) of lead sinkers and lures would be lost annually to the environment, which corresponds to a total of 60 000 tonnes (40 000 – 140 000 tonnes) during a 20-year analytical period in the EU27-2020 (cf. Annex D).

1.8.3.2. Fishing with lead nets, ropes and lines

Lead nets, ropes and lines are essentially used for commercial fishing, and in marine water.

Lead is encapsulated in fishing nets in long ropes, head ropes, so that the net is vertical in the water. Sinker lines containing lead are also available. In some trawling, lead is used to weigh the trawl down on the bottom. Purse seine is a long net with floats at the top and lead sinkers at the bottom (cf. Annex A).

The current European use of lead for nets, ropes and lines is estimated between 9 000 and 18 000 tpa and has decreased in the past decade. This quantity is based on assumptions on the fishing fleet of the Member States (Eurostat data) and how much lead is contained in the different commercial lead nets, ropes and lines (Tateda et al., 2014). This figure is probably an overestimate as not all nets, ropes and lines on commercial vessels are made out of lead. The Annex D details the assumptions and calculations performed by the Dossier Submitter.

Lead fishing nets, ropes and lines might be lost in the environment (aka 'ghost nets') but no major wear and tear occurs during the use of these fishing tackle (CfE #1220 – Danish EPA). It is estimated that currently around a fifth of lead fishing nets, ropes and lines are lost yearly by commercial fishers (EU Commission, 2018).

The newly adopted EU 'Single Use Plastic and Fishing Gear' Directive (EU) 2019/904 (aka SUP directive) is also addressing the issue of fishing gear[173] that are lost or disposed in the sea. The SUP Directive sets an extended producer responsibility (EPR) schemes which aims for the fishing gears at setting a minimum collection rate of 50 % and a recycling target of 15 %, both to be met by 2025[174]. This goal is supported by the Directive (EU) 2019/883[175] which aims at protecting the marine environment against the negative effects from discharges of waste from ships, by improving the availability and use of adequate port reception facilities and the delivery of waste to those facilities.

The SUP Directive is also requesting the development of a standard on the circular design of fishing gear, and the duty for Member States to organise and put in place Awareness Raising activities.

Even if the directive is initially intended to reduce plastic waste and is targeting fishing gear containing plastic/polymer (cf. Article 2 of SUP Directive), the scope and intention of the SUP Directive is broad enough to impact in a positive manner the nets, ropes and lines made of both plastic and lead.

The baseline scenario adopted for the analysis is therefore that, in the absence of an EU-wide restriction, and thanks to the implementation of the SUP Directive that could indirectly benefit to this restriction proposal, lead use in fishing nets, ropes and lines will decrease over time. For the same reason, the releases in the environment due to unintentional loss by the fishers is assumed to decrease steadily over a 20-year period from 3 000 tonnes in 2022 to 1 500 tonnes in 2041 (assuming a 50 % drop in loss by 2025), which corresponds to a total release of 34 500 tonnes (23 000 – 46 000 tonnes) during the 20-year analytical period in the EU27-2020 (cf. Annex D).

1.8.3.3. Home-casting of lead fishing tackle (consumer use)

As long as home-casting, and the sale of home-casting equipment and lead ingot and scrap is legal, home-casting will remain a popular Do It Yourself activity for fishers. The main reason is that home-casting is easy and cheap to do, and there is currently a lack of public awareness on lead hazard for human health from home-casting activity.

There is no indication on the scale of the home-casting practice in Europe (cf. Annex A).

For the baseline, it is assumed that this activity will remain stable during a 20-year period. Due to lack of data, no quantification is made, only a trend is given.

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[173] 'fishing gear' is defined in (EU) 2019/904 as 'any item or piece of equipment that is used in fishing or aquaculture to target, capture or rear marine biological resources or that is floating on the sea surface, and is deployed with the objective of attracting and capturing or of rearing such marine biological resources'
[174] https://www.europarl.europa.eu/legislative-train/theme-new-boost-for-jobs-growth-and-investment/file-single-use-plastics-and-fishing-gear-reducing-marine-litter-from-plastics
[175] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L0883&from=EN

1.8.4. Baseline release estimates for all uses

Based on the previous details, the estimated releases and exposures in case of absence of a restriction are summarised in the tables and figures below. The numbers indicated in brackets correspond to the lower and upper boundary of the baseline estimates.

Table 1-58: Baseline release estimate to the environment over the 20-year period

Type of use	Quantity released to the environment over 20 years (tonnes)
Lead in hunting (gunshot)	280 000 (260 000 – 300 000)
Lead in hunting (bullets – small calibre)	310 (280 – 340)
Lead in hunting (bullets – large calibre)	2 370 (1 840 – 2 750)
Lead in sports shooting (gunshot)	490 000 (280 000 – 700 000)
Lead in sports shooting (bullets)	8 400 (110 – 30 000)
Lead in fishing	94 500 (63 000 – 186 000)
Total	**875 580**

1.8.5. Impacts on birds (EU 27)

Member States are required to report to the European Commission the population sizes of all wild bird species that are naturally present in their country every six years (Council Directive 2009/147/EC of April 1979, amended in 2009, on the conservation of wild birds "Birds Directive"). For the latest cycle (2013 to 2018), Member States submitted their information in mid-2019. The results were published in 2020 by the European Environment Agency (EEA).[176].

By virtue of their feeding behaviour or habitat preferences, certain species of birds are more likely to be exposed to ammunition derived lead or to lead in fishing tackle than others. By referring to the population sizes of these species it is possible to quantify the total number of birds that are at greatest risk of lead poisoning from the different uses considered in this assessment (Table 1-59). These estimates considered the different relevant exposure sources, as described in Section 1.5.3. The baseline is based on the species (including species affected by primary and secondary poisoning via different exposure routes) assessed to be at highest risk in Section 1.5.4 (specifically in Section 1.5.4.2). To quantify the population sizes for the species assessed to be at highest risk, the following approach was taken:

a) Bird population sizes can generally be reported as 'breeding populations' and 'wintering populations', depending on time of year by which they were obtained. The breeding population size was used as default estimate, unless the species was defined

[176] See https://www.eea.europa.eu/themes/biodiversity/state-of-nature-in-the-eu/explore-nature-reporting-data and EEA technical report *State of nature in the EU. Results from reporting under the nature directives 2013–2018, Technical report No 10/2020, European Environment Agency, Copenhagen.*(EEA 2020)

as a "key wintering species", as indicated in the reference documents available in the portal for reporting under Article 12 of the Birds Directive[177]. In this case wintering population was used as the default population size for the assessment. On this basis, no 'double counting' by the Dossier Submitter occurred. In the explanatory notes and guidelines provided in the Reference portal for reporting under Article 12 of the Birds Directive[178], it is stated: *"Member States should report on certain key wintering species – especially migratory waterbirds, such as wildfowl (ducks, geese and swans) and waders (shorebirds) – which are significantly more abundant in the EU during the winter and/or whose population size and trend are better monitored in winter".* In general, birds can be much more mobile during the winter season due to weather and food availability, which could potentially complicate the aggregation of the Member States' data (Röschel et al., 2020).

b) No correction was applied to the population sizes provided by Member States, with the exception of corrections discussed in point f), which were considered relevant to avoid potential overestimations.

Total estimates were (in the end) rounded by the Dossier Submitter because, for the purposes of the current assessment, the order of magnitude only was considered to be relevant.

c) Considering that for each (sub)species provided in the EEA dataset, the population size was generally reported as minimum and maximum, the Dossier Submitter used the arithmetic mean to represent the population size for that species[179].

d) To derive the population size of species based on breeding population (where relevant), a multiplying factor of two was used (as breeding population unit is reported as numbers of pairs). However, the individuals calculated in this way are only part of the overall population. For example, long-lived raptors with delayed sexual maturity spend several years in non-breeding areas (Donázar et al., 2016).

e) To derive the population size of species based on wintering population (where relevant), no multiplying factor was necessary/used.

f) In relation to the primary poisoning from the ingestion of lead gunshot, Netherlands and Denmark population estimates were excluded due to total lead gunshot ban in existence in these countries. For Belgium, 50 % of relevant population sizes were included due to the partial lead gunshot ban present in this country.

g) Sub species were aggregated at species level.

In relation to the use of breeding population estimates versus wintering ones, the Dossier Submitter notes that this inadvertently implies risks at different times of the year. This is simply an artefact of often having to use breeding population data as it is sometimes the most robust available or the only one available. The Dossier Submitter notes that these data are used at the EU level (by European Commission) to check the implementation of the Birds Directive and therefore are already used for regulatory purposes in the EU.

Wintering population data could be best for estimating risks from hunting activities. However, it should also be recognised that:

[177] http://cdr.eionet.europa.eu/help/birds_art12
[178] Reporting guidelines Article 12. Available at http://cdr.eionet.europa.eu/help/birds_art12
[179] When population size was indicated as a minimum or maximum value only in the EEA data the value provided was used as both minimum and maximum when calculating the overall EU population size for the species.

- lead gunshot might be available to birds throughout the year for primary ingestion after being deposited on the soil during shooting activities.
- lead projectiles (different types) can also be available via pest control, representing a source of secondary poisoning. Avian scavengers, including raptors, often utilise subsidies from pest shooting[180] in agricultural areas. Pest control might also be practiced outside of hunting seasons e.g., in Italy for some species of pigeons that damage crops[181]. The duration of pest control activities may vary significantly between species, countries and also at regional levels. Some ungulates like wild boar can be hunted all year, as for example in Austria (Reimoser and Reimoser, 2010), Italy and France (Maillard et al., 2010). The length of the hunting season of ungulates may vary among species and countries. This can create a regular source of secondary poisoning for raptors and scavengers.
- Animals may be shot and wounded but survive, thus be available to predators year round. The proportion of live wild birds carrying gunshot can be high in some quarry species (comment #3343).
- Lead availability for primary and secondary ingestion is discussed more in detail in Annex B, section B 9.1.1.

Available information identified by the Dossier Submitter on mortality is reported and discussed in Section 1.5.4.1.3. Information on "annual probability of exposure" is discussed in Section 1.5.3.4. Key information used in the impact assessment is summarised in the following tables.

Table 1-59: Population of birds at risk of primary or secondary lead poisoning via ammunition or fishing tackle in the EU estimated by the Dossier Submitter

Type of risk	**Number of individuals at risk**		**Estimated mortality and number of birds affected by sublethal poisoning (%)**
	EU 26-2020, excluding Romania[1][2][3][5]	**EU 27-2020, including Romania[1][3][5]**	
Primary poisoning (from lead gunshot)	Approximately 129 million	Approximately 135 million	**Estimated mortality:** 1 % Species specific mortality estimated to vary between 0.5 % to 2 % (see Section 1.5.4.1.3). Mortality for waterbirds in terrestrial environment would likely be greater (comment #3343). **Birds affected by sublethal poisoning:** with a (snapshot) prevalence between 1-5 % at least, between 10 to 22 % of the population can be assumed to be affected by sublethal poisoning (comment #3343)[6]
Secondary poisoning (from all types of ammunition	Approximately 14 million		**Estimated mortality:** Mortality can be expected to be at least 1 % within the group of species at risk (see Section 1.5.4.1.3.). Mortality is significantly increased in areas with high hunting pressure[8]. Mortality for 10 at risk species reported between 0.3 % to 1.94 %[9]. Additional mortality in a long-lived species will affect the sustainability of populations more than in a short-lived

[180] For example, individual recreational shooters can shoot >170 squirrels in a single day (Haig et al., 2014) . In Ireland there is a national scheme to control the grey squirrel population, as reported by: https://www.irishtimes.com/news/wait-until-the-squirrel-has-left-the-tree-then-shoot-1.1266810. "The most common way to shoot them is with a shotgun".

[181] Specifically hunting of "colombaccio" species in Emilia Romagna Region as reported in the "Piano faunistico-venatorio regionale dell'Emilia Romagna 2018-2023" https://bur.regione.emilia-romagna.it/bur/area-bollettini/bollettini-in-lavorazione/n-110-del-19-04-2021-parte-seconda.2021-04-19.2279166979/calendario-venatorio-regionale-stagione-2021-2022/cal-ven-2021-completo

		species[10]. Not possible to distinguish between sources of secondary poisoning (e.g., gunshot and bullets). **Birds affected by sublethal poisoning:** not quantified. Sub-lethal poisoning can increase the susceptibility of birds to other causes of death (such as collisions) by 3-4 fold (comment #3436) as discussed in section 1.5.4.1.4.
Primary poisoning (from lead sinkers or lures)[4]	Approximately 7 million	**Estimated mortality:** Not quantified. Dataset insufficient to estimate mortality rates **Birds affected by sublethal poisoning:** not quantified. Sub-lethal poisoning can increase the susceptibility of birds to other causes of death (such as collisions) by 3-4 fold as discussed in section 1.5.4.1.4.

Notes: [1] Based on EEA data – population estimates typically based on breeding population. For certain species the winter estimate is considered to be more relevant; Estimates rounded (order of magnitude only considered to be relevant); [2] EEA 2020 data for Romania was unavailable at the time of the assessment (2020); [3] Netherlands and Denmark population sizes excluded due to lead shot ban. Belgium 50 % of population size excluded due to partial lead shot ban in place; [4] in Denmark there is a ban on the import and placing on the market of fishing tackle. However, since there is no ban on the use, data from Denmark was not excluded. [5] Estimates used arithmetic means of the min and max population size estimates and considered (where relevant) the conversion factor of two for breeding 'unit' data to convert these to individuals, which excludes juveniles and non-breeding individuals. For Portugal and Spain, birds occurring outside of mainland were included. Species breakdown is provided in Annex B (Section B 9.1.4.1); [6] based on UNEP/CMS comment #3343: with a (snapshot) prevalence between 1-5 % and assuming the half-life of shot in the alimentary tract of 10 days about 22-70 %; with a (snapshot) prevalence between 1-5 % and assuming the half-life of shot in the alimentary tract of 20 days about 10-45 % - More information is provided in Section 1.5.3.4; [7] This mortality rate is used as the central scenario for the monetisation of impact on birds (Section D.5.1); [8] For example, high-exposure areas have been reported to have 24 % lethality for white-tailed sea eagles (Haliaeetus albicilla) in Sweden by (Helander et al., 2021) (comment #3348); [9] golden eagle (Aquila chrysaetos), griffon vulture (Gyps fulvus), bearded vulture (Gypaetus barbatus), cinereous vulture (Aegypius monachus), Egyptian vulture (Neophron percnopterus), white-tailed eagle (Haliaeetus albicilla), Spanish imperial eagle (Aquila adalberti), western marsh-harrier (Circus aeruginosus), red kite (Milvus milvus), black kite (Milvus migrans) – comment #3367, excluding additional mortality from sublethal effects; [10] lead ingestion may be responsible for substantial population reduction in several raptors species (comment #3241 – study under publication). The Dossier Submitter notes that under REACH there is no requirement to estimate population-level impacts to demonstrate a risk that is not controlled.

UNEP/CMS ad hoc Expert Group, provided an assessment (comment #3343) on the population sizes of the birds at most risk of lead poisoning in the EU (excluding Romania), using the same EEA Article 12 dataset as used by the Dossier Submitter, to provide a complementary assessment.

The main differences between the two estimates (related to the species at most risk of lead poisoning) were identified by the Dossier Submitter to be the following:

1. The UNEP/CMS ad hoc Expert Group used geometric means of the min and max population size estimates, considered to be more appropriate than arithmetic means.
2. The UNEP/CMS ad hoc Expert Group used a conversion factor of three for "breeding unit data" to convert these to individuals rather than two as used by the Dossier Submitter. This is mainly applicable to calculating the population size at risk of exposure to lead ammunition, because birds exposed to fishing tackle were mainly calculated based on wintering population estimates.
3. Similarly to the Dossier Submitter, the UNEP/CMS ad hoc Expert Group omitted data from DK, NL and 50 % of BE for risks from primary ingestion of gunshot. However, UNEP/CMS also excluded these populations when assessing the risks to scavenging and predatory birds via secondary poisoning.

Based on this, the Dossier Submitter acknowledges that the data presented in Table 1-60 is likely to provide a more refined estimate of the number of birds at most risk compared to the Dossier Submitter's estimate (presented in Table 1-59) , especially considering the inclusion of additional non-breeding individuals (particularly in raptor and scavenging species where delayed sexual maturity is typical) and individuals born during the breeding season that can also ingest lead.

Nevertheless, the Dossier Submitter notes that the data presented in Table 1-60 are likely to be an underestimation of the number of birds at most risk, for the following reasons:

- Data presented in Table 1-60 are related to the EU26, and not the EU27.
- Breeding data may exclude individuals that breed outside of the EU but migrate to and/or through the EU during the winter and non-breeding seasons. For some species this may result in an underestimation of the number of birds at risk (comment #3343).
- Not all juveniles and non-breeding birds are included in the estimates even using a conversion factor of three for "breeding unit data" to convert these to individuals (comment #3343).
- Excluding Denmark and Netherlands and 50 % of Belgian data for exposure assessments of raptors and scavengers underestimates numbers at risk from bullets, which are not currently controlled in those countries or regions (not possible to distinguish risks between shot and bullets for this assessment), as mentioned in comment #3343.
- Data related to birds poisoned by lead fishing tackle (sinkers or lures) refer to the primary poisoning route only. Other (piscivorous) birds might be exposed via secondary poisoning.

Table 1-60: Number of individual birds from species at highest risk of lead related ammunition or fishing tackle poisoning via primary or secondary routes across EU26, as provided by UNEP/CMS ad hoc Expert Group in comment #3343.

Type of risk	UNEP/CMS ad hoc Expert Group estimate of the number of individuals at risk across EU 26-2020 (based on EEA 2020 initial dataset, excluding Romania)[1]
Primary poisoning from lead gunshot	About 171 million
Secondary poisoning (from all type of ammunition)	About 18 million
Primary poisoning from lead fishing sinkers and lures (weights)	About 7 million

Notes: [1] – Estimates used geometric means of the min and max population size estimates and considered (where relevant) a conversion factor of three for "breeding unit data" to take into account juveniles and non-breeding birds and omitted data from DK, NL and 50 % of BE for risks for scavenger/predator risks.

Overall, the estimates provided by UNEP/CMS ad hoc Expert Group are in the same order of magnitude of the estimates calculated by the Dossier Submitter.

Table 1-61 summarises the species identified to be at risk, grouped by type of lead poisoning, already listed in Section 1.5.4.2[182].

[182] The Dossier Submitter wishes to highlight (also in response to comment # 3467, FACE) that section 1.5.4.2 had been made already available in version 2.0 of the Annex XV report, and only amended for one missing species in the subsequent versions.

Table 1-61: EU 27 bird species identified to be at risk, grouped by type of lead poisoning

Type of risk	EU 27 species affected by lead poisoning from ammunition and fishing tackle	Notes
Primary poisoning from lead gunshot only	**Species referred to by the Dossier Submitter as "waterbirds" that can ingest lead shot in terrestrial environments:** northern pintail *(Anas acuta),* common teal *(Anas crecca),* mallard *(Anas platyrhynchos),* greater white-fronted goose *(240entre albifrons),* greylag goose *(240entre answer),* pink-footed goose *(240entre brachyrhynchus),* snow goose *(240entre caerulescens),* lesser white-fronted goose *(240entre erythropus),* bean goose *(240entre fabalis),* brent goose *(Branta bernicla),* barnacle goose *(Branta leucopsis),* red-breasted goose *(Branta ruficollis),* tundra swan *(Cygnus columbianus),* whooper swan *(Cygnus cygnus),* mute swan *(Cygnus olor),* demoiselle crane *(Anthropoides virgo),* common crane *(Grus grus), Canada goose (Branta canadensis)* **Species referred to by the Dossier Submitter as "terrestrial species":** barbary partridge *(Alectoris Barbara),* chukar *(Alectoris chukar),* rock partridge *(Alectoris graeca),* red-legged partridge *(Alectoris rufa),* hazel grouse *(Bonasa bonasia),* common quail *(Coturnix coturnix),* willow grouse *(Lagopus lagopus),* rock ptarmigan *(Lagopus muta),* black grouse *(Lyrurus tetrix),* grey partridge *(Perdix perdix),* common pheasant *(Phasianus colchicus),* western capercaillie *(Tetrao urogallus),* rock dove *(Columba livia),* stock dove *(Columba oenas),* common woodpigeon *(Columba palumbus),* Eurasian collared-dove *(Streptopelia decaocto),* European turtle-dove *(Streptopelia turtur),* dark-tailed laurel-pigeon *(Columba bollii),* white-tailed laurel-pigeon *(Columba junoniae),* Madeira laurel-pigeon *(Columba trocaz),* Eurasian woodcock *(Scolopax rusticola),* pin-tailed sandgrouse *(Pterocles alchata),* black-bellied sandgrouse *(Pterocles orientalis)*	*Waterbirds species represent about 5 % of the overall affected birds in terrestrial environments*[183]
Secondary poisoning from lead ammunition	Spanish Imperial Eagle *(Aquila adalberti),* golden eagle *(Aquila chrysaetos),* Bonelli's eagle *(Aquila fasciata),* eastern imperial eagle (*Aquila heliacal),* steppe eagle *(Aquila nipalensis),* northern goshawk *(Accipiter gentilis),* cinereous vulture *(Aegypius monachus),* Egyptian vulture *(Neophron percnopterus),* bearded vulture *(Gypaetus barbatus),* griffon vulture *(Gyps fulvus),* Eurasian buzzard *(Buteo buteo),* rough-legged buzzard *(Buteo lagopus),* long-legged buzzard *(Buteo rufinus),* western marsh-harrier *(Circus aeruginosus),* greater spotted eagle *(Clanga clanga),* white-tailed sea-eagle *(Haliaeetus albicilla),* black Kite *(Milvus migrans),* red kite *(Milvus milvus),* hen harrier *(Circus cyaneus),* pallid harrier *(Circus macrourus),* Montagu's harrier *(Circus pygargus),* lesser spotted eagle *(Clanga pomarine),* booted eagle *(Hieraaetus pennatus),* lanner falcon *(Falco biarmicus),* saker falcon *(Falco cherrug),* peregrine falcon *(Falco peregrinus),* gyrfalcon *(Falco rusticolus),* common raven *(Corvus corax),* carrion crow *(Corvus corone)*	
Primary poisoning from lead fishing tackle (sinkers or lures)	Northen pintail *(Anas Acuta),* common teal *(Anas crecca),* mallard *(Anas platyrhynchos),* common pochard *(Aythya ferina),* tufted duck *(Aythya fuligula),* greater scaup *(Aythya marila),* ferruginous duck *(Aythya nyroca),* tundra swan *(Cygnus columbianus),* whooper swan *(Cygnus cygnus),* mute swan *(Cygnus olor),* marbled teal *(Marmaronetta angustirostris),* red-crested pochard *(Netta rufina),* white-headed duck *(Oxyura leucocephala),* northern shoveler *(Spatula clypeata),* garganey *(Spatula querquedula),* yellow-billed loon *(Gavia adamsii),* arctic loon *(Gavia arctica),* common loon *(Gavia immer),* red-throated loon *(Gavia stellata),* dalmatian pelican *(Pelecanus crispus),* great white pelican *(Pelecanus onocrotalus),* Eurasian spoonbill *(Platalea leucorodia)*	

Table 1-62 below shows the number of EU bird species at risk and the number of threatened bird species on Annex 1 of EU Birds Directive for each exposure route.

[183] The Dossier Submitter wishes to highlight that some waterbirds may also feed in terrestrial environments, in response to comment #3467. This is also confirmed by comment #3478 (AEWA).

Table 1-63: Number of species identified to be at risk of lead exposure in the EU 27-2020 from different ingestion routes, versus number of species in the Annex 1 of EU Birds Directive.

Exposure route	Number of species at risk of lead poisoning, including lethal and sublethal effects, in the EU 27 (EU species on Annex 1 of the EU Birds Directive)
Primary poisoning from lead ammunition	41 (19 species on Annex 1 of EU Birds Directive)
Secondary poisoning from lead ammunition	29 (24 species on Annex 1 of EU Birds Directive)
Primary poisoning from fishing tackle (lead sinkers and lead lures)	22 (11 species on Annex 1 of EU Birds Directive)

Note: IUCN Red List Categories are specified in comment #3343 for all species.

The Dossier Submitter notes that several of these bird species have a critical conservation status and are therefore in danger of extinction e.g., marbled teal *(Marmaronetta angustirostris),* which can be exposed to lead fishing weights (as part of lead sinkers and lead lures) in addition to lead gunshot.

Furthermore, many EU bird species are listed for their conservation importance in the CMS appendix (the European Union is a signatory party of CMS since 1983). In the CMS appendix, species in the Appendix I are defined as "Endangered migratory species" and species in the Appendix II are defined as "species which have an unfavourable conservation status". Among the bird species assessed to be at greatest risk by the Dossier Submitter, not all species fall into Appendix I and II of the CMS, such as the common raven *(Corvus corax)* and carrion crow *(Corvus corone)*. However, the remaining species include 27 species of raptors and vultures, which are under CMS Appendixes I and II.

All species assessed to be at greatest risk of lead poisoning from lead fishing tackle (lead sinkers or lures) by the Dossier Submitter are listed under CMS Appendixes I and II.

Based on the aforementioned data, the Dossier Submitter concludes the following:

- 41 species (feeding in terrestrial environments) are at risk at the EU level of primary poisoning due to the ingestion of lead gunshot ;19 terrestrial and waterbird species already listed in the Annex 1 of the EU Birds Directive are at risk. Over one million birds (minimum estimates of between 1.4 and 1.7 million birds) are expected to die due to direct lead shot ingestion per year. A significant number of birds is also expected to suffer from sublethal poisoning[184].
- 29 species are at risk at the EU level of secondary poisoning from lead ammunition (all sources). Of these, 24 raptor and scavenger species are listed in Annex 1 of the EU Birds Directive. Mortality due to the ingestion of lead ammunition is expected to vary between species and to increase significantly in areas with high hunting pressure. Sublethal effects can significantly increase a bird's susceptibility to different causes of death (such as collisions with power lines and other

[184] With a (snapshot) prevalence between 1-5 % at least between 10 to 22 % of the population can be assumed to be affected by sublethal poisoning (comment #3343).

infrastructure). More than 14 million birds are estimated to be at risk of lead poisoning via secondary ingestion.

- 22 species are at risk at the EU level of primary poisoning via ingestion of fishing tackle (lead sinkers or lead lures). Of these, 11 waterbirds species are listed in the Annex 1 of the EU Birds Directive. At least 7 million birds are estimated to be at risk.
- For all species with critical conservation status, including long-lived species with low reproductive rates as raptors and scavengers, mortality of even a single individual is of concern.

In addition to the species at highest risk of lead poisoning, other species can also be at some risk as assessed by the UNEP/CMS ad hoc Expert Group. Specifically, UNEP/CMS ad hoc Expert Group in their assessment (comment #3343) provided an estimate of the species at low and very low risk in the EU 27.

2. Impact assessment

2.1. Overview of the restriction options analysis

2.1.1. Identification of the restriction options

In its request to ECHA to prepare an Annex XV restriction dossier on lead in ammunition and in fishing tackle, the European Commission (Commission, 2019) asked the Dossier Submitter (ECHA) to 'provide a thorough assessment of the option(s) that appear more viable, so that RAC and SEAC have all relevant information and analysis at hand in order to be able to define the most appropriate restriction option when elaborating their opinions, so as to inform and support the Commission's risk management decision.'

To address this request, the Dossier Submitter conducted a detailed analysis of a series of diverse restriction options for each sector of use identified in this Annex XV restriction report (i.e. hunting, sports shooting and fishing). These assessments are underpinned by information on uses, releases, availability of alternatives and socio-economic impacts. Each restriction option is also analysed against the criteria outlined in the Annex XV to REACH for assessing the appropriateness of a REACH restriction: effectiveness (i.e. targeting, risk reduction and proportionality to the risk), practicality (e.g. implementability, availability of alternatives, cost, affordability), enforceability and monitorability.

The detailed analysis of each restriction option per sector of use is available in Annex D.

The restriction options for each sector are listed by the Dossier Submitter according to the principle of the hierarchy of control[185]:

- Elimination, i.e. remove the source of hazard
- Substitution, i.e. replace the source of hazard
- Engineering control, i.e. isolate the source of hazard
- Administrative controls, training, procedures, or policies that lessen risks, i.e. information or advice (compulsory or voluntary)

Whenever relevant, the impact of a transition period on sub-category of projectile type (e.g. gunshot vs bullet) or fishing tackle type (e.g. sinkers, lures, of different weight, and nets, ropes and lines) are also part of the restriction option analysis.

Where good quality and detailed information on cost elements was available (albeit with some uncertainties), the Dossier Submitter has undertaken a quantitative impact assessment of the restriction options proposed. Sensitivity analysis has been undertaken on key uncertainties. In most cases, it was not possible to quantify the benefits of a restriction option (e.g. valuation of specific environmental impacts). Instead, a qualitative assessment of the benefits was made and supported with quantitative information where available. For some restriction options information on potential impacts are presented and summarised, but no quantitative estimates of the cost and/or benefit of a potential restriction are provided because: (i) the available information suggested that the potential costs were low in comparison to those of other restriction options (e.g. information to consumers), or (ii) because of the lack of information available to the Dossier Submitter, specifically on sports shooting.

[185] https://echa.europa.eu/documents/10162/13655/pg_15_qualitative-human_health_assessment_documenting_en.pdf

Therefore, the impact assessment of each restriction option per sector of use is comprised of a mix of the available cost information together with a qualitative assessment of other impacts, particularly to identify where a restriction option would have a disproportionate impact from a societal perspective.

2.1.2. Ranking of the restriction options

Once a set of plausible restriction options were identified for a use; i.e. fulfilling all the REACH restriction criteria (effective, practical, enforceable and monitorable), the Dossier Submitter scored them to identify the most appropriate one, or a combination of the most appropriate ones, to address the identified risks.[186]

There are many possible ways of scoring the restriction options analysed for each use. The Dossier Submitter selected a **simple Decision Matrix Analysis approach**.

First, the Dossier Submitter selected key dimensions. The key dimensions selected allowed to compare each restriction option against the others. In addition, the key dimensions selected represents key elements of an effective option in term of overall risk reduction, and proportionality to the risk. No scoring on practicality, enforceability or monitorability were proposed as only restriction options fulfilling these REACH criteria were compared between each other.

The key dimensions selected by the Dossier Submitter for the scoring are:

- **Lead emission reduction**: i.e. ranking according to how much lead releases into the environment will be avoided during the 20-year period of the impact analysis (best score assigned to the largest releases avoided). While this approach cannot describe absolute risk reduction, it is an effective means of comparing the restriction options, as this information provides an indication of the potential for a restriction option to reduce exposure and risk to birds (mainly related to primary and/or secondary poisoning of wildlife). This dimension would also allow to compare the effect of each restriction option with regards to the European commitment towards AEWA to improve the protection of birds (including IUCN) species at the EU level.
- **Other environmental risk reduction (for fishing only)**: this dimension is looking at potential net risk reduction for the environment other than from lead emission reduction. This dimension looks, for example, at the sustainability of the alternatives and/or potential additional/different burden on the environment associated with a restriction option (e.g. environmental footprint, aquatic toxicity, etc.).
- **Human health risk reduction (for fishing only)**: this dimension is looking at what are the potential net risk reduction (or increase) for human health.
- **Overall risk reduction (for outdoor shooting)**: addressing human health and other environmental risk reduction together as described above for the fishing sector.
- **Costs**: this dimension looks more specifically at the costs expected to accrue in the EU for a specific set of stakeholders (depending on the available information). For fishing, it is the cost for the European manufacturers that will be looked at for example. This dimension also looks at the affordability of the proposal for the European industry.

[186] If only one plausible restriction option is identified, then no scoring will be performed.

- **End user acceptance (for fishing only):** end user should be understood here as the end user of the object targeted by the proposed restriction, for example the fisher for the fishing sector. This dimension looks at the assumed end user acceptance of different restriction options and reflects on the discussions held with stakeholders during the preparation of the restriction dossier. The end user acceptance is an important element in the adherence to the restriction option proposed, as the (non)acceptance by the end user could compromise the effectiveness, and in particular the net risk reduction capability, of the restriction option, for example as a consequence of deliberate non-compliance (e.g. increase of home-casting activity as a response to a ban on placing on the market only). Where the acceptance does not affect the effectiveness of the proposed reduction this dimension is ignored, hence this dimension is only applied to the fishing sector.

Once the dimensions were selected, the Dossier Submitter scored each restriction options for each dimension by ranking them. For each dimension, the restriction options were ranked from highest score for best (e.g. 4 points if 4 ROs are compared) to lowest score for poorest (1 point). The ranking of the options is based on the detailed impact assessment of each restriction option presented in the Annex D. Whenever possible the ranking is based on numerical values (e.g. for the releases avoided).

Finally, each score per key dimension is added up for each of the restriction options. The option that scores the highest is presented as the preferred option.

The Dossier Submitter presents its analysis and ranking of the plausible restriction options for hunting with gunshot (Table 2-1) and bullets (Table 2-2), sports shooting with gunshot (Table 2-3) and bullets (Table 2-6), and for the fishing sectors (Table 2-9).

2.2. Outcome of the restriction option analysed per sector

2.2.1. Hunting

The Dossier Submitter wishes to emphasise that none of the restriction options (ROs) proposed amount to a ban of hunting. In fact, this dossier highlights that hunting provides significant social, cultural, economic, and environmental benefits in different regions throughout the European Union. The general framework of hunting as well as the recognition of the role of hunting in nature conservation are both well established[187].

Instead, the ROs that are proposed target the identified problem of lead contamination, consider various possibilities to substitute lead ammunition, ensure that lead remains contained in bullets or is removed from game meat. The analysis of the ROs includes considerations with regards to effectiveness, practicability and monitorability:

- Effectiveness: The restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk (also with regard to the costs).
- Practicality: the restriction must be implementable, enforceable and manageable; it also includes considerations on the transition time required to implement the proposed restriction option.
- Monitorability: it must be possible to monitor the result of the implementation of the proposed restriction.

With regard to effectiveness, the potential to reduce lead emissions, the overall reduction of

[187] https://ec.europa.eu/environment/nature/info/pubs/docs/factsheets/hunting.pdf

risks and the costs the following criteria are addressed:

- Emission reduction is considered as the reduction of the annual amount of lead released to the environment.
- Overall reduction of risks related to the release of lead shot or bullets for hunting, including the reduction of risks for human health (consumption of game meat), the reduction of risks for the environment (birds) and the risks for human health and environment for alternatives(s), where relevant.
- Costs are considered with regard to substitution and possible gun replacement.

For a better overview, the restriction option analysis for sports shooting with lead shot and bullets are addressed separately.

2.2.1.1. Restriction options for hunting with gunshot

List of restriction options considered

Concerning the environmental and human health risk associated with the use of lead gunshot in hunting (covered by use 1), the Dossier Submitter identified and analysed the following restriction options (cf. Annex D):

- RO1: Ban on the placing on the market and use of lead gunshot for hunting
- RO2: Require specific design/construction of lead gunshot
- RO3: Ban on the placing on the market of game meat hunted with lead gunshot or maximum levels of lead in game meat
- RO4: Advice to cut away more meat when handling game and meat hunted with lead gunshot
- RO5: Compulsory information on the hazards of lead and the risks of using lead ammunition, transition periods and availability of alternatives at the point of sale and incorporated in national hunting exams.

The proposed restriction options are listed according to the principle of the hierarchy of control:

- Elimination, i.e. remove the hazard (i.e. RO1) by means of substitution to a substance that has a more benign toxic profile.
- Engineering control, i.e. isolate the hazard (i.e. RO2, RO3, RO4)
- Administrative control (RO4, RO5) putting in place policies, training or advice to ensure address risks.

Outcome of the restriction option analysis

Table 2-1 gives an overview of the qualitative restriction option analysis made by the Dossier Submitter. According to the basic principle described in Section 2.1., and the analysis of the restriction options presented in Annex D, the Dossier Submitter identified only one plausible restriction option (RO1), i.e. fulfilling all the REACH restriction criteria (effectiveness, practicality and monitorability). Regarding the effectiveness of the restriction options, indeed only RO1 would achieve significant emission reduction and a high overall risk reduction (cf. Annex D).

For this reason, no scoring, and no further ranking of the restriction options is presented in this section. Although each restriction option was assessed individually in Annex D, the Dossier Submitter considers that, even if not effective to address the risks by itself, the restriction options are not mutually exclusive and could be proposed in conjunction with one another.

Table 2-1: Restriction option analysis for hunting with gunshot

Dimension		RO1	RO2	RO3	RO4	RO5
Effectiveness	Overall	Yes (very high)	No	No	No	Yes (low)
	Emission reduction (20 years)	High (209 000 tonnes)	No	Medium (reduction in use of lead shot for game marketed)	No	Low (only voluntary)
	Costs per year	Relatively low (steel shot almost same price as lead shot: €3-143m	Higher (costs for different design expected to be higher than use of lead shot)	Relatively low (steel shot almost same price as lead shot)	Relatively low (cost for advice to remove lead shot)	Relatively low (cost for providing information; cost to advise during hunting exams)
	Overall reductions of risks (HH and ENV) incl. risks related to alternative(s)	High (i.e., prevents poisoning of wildlife and HH effects)	Low (does not prevent poisoning of wildlife)	Low (hunter families and birds still at risk)	Low (does not prevent poisoning of wildlife)	Low (only voluntary)
Practicality		Yes (alternatives available)	Not analysed	Yes	No (not practical to remove all shot)	Yes
Monitorability		Yes	Not analysed	Yes	Low	Yes

The Dossier Submitter concludes that the most effective, practical and monitorable way to address the risk posed by lead gunshot to wildlife and the risk for human health posed by consumption of game meat is a combination of the following restriction options:

- **Ban on the placing on the market and use of lead gunshot for hunting**

- **Compulsory information on the hazards of lead and the risks of using lead ammunition, transition periods and availability of alternatives at the point of sale**

Incorporating information on the hazard and risks of lead ammunition in national hunting exams could be an effective complementary risk management measure. However, as not all Member States have mandatory hunting exams it was not considered to be an appropriate element of the conditions of the proposed restriction. As such, only the elements of RO5 on information at the point of sale are taken forward. Member States could take up this as a complementary measure to the proposed restriction.

2.2.1.2. Restriction options for hunting with bullets

List of restriction options considered

Concerning the environmental and human health risk associated with the use of lead bullets in hunting (covered by use 2), the Dossier Submitter identified and analysed the following restriction options (cf. Annex D):

- RO1a: Ban on the use of small calibre (<5.6 mm centrefire and rimfire in general) lead bullets for hunting
- RO1b: Ban on the use of large calibre (≥5.6 mm centrefire) lead bullets for hunting
- RO2: Require specific bullet design/construction when lead is used (to minimise lead fragmentation)
- RO3: Ban on placing on the market of game meat hunted with lead bullets or maximum levels of lead in game meat
- RO4: Advice to cut away more meat when handling game and meat hunted with lead bullets
- RO5: Compulsory information on the hazards of lead and the risks of using lead ammunition, transition periods and availability of alternatives at the point of sale and on product packaging and incorporated in national hunting exams

The proposed restriction options are listed according to the principle of the Hierarchy of control:

- Elimination, i.e. remove the hazard (i.e. RO1a, RO1b) by means of substitution to a substance with a less toxic profile
- Engineering control, i.e. isolate the hazard (i.e. RO2)
- Administrative control (RO3, RO4, RO5) by putting in place policies, training or advice to ensure target groups' attitude.

Outcome of the restriction option analysis

Table 2-2 gives an overview of the qualitative restriction option analysis made by the Dossier Submitter. According to the basic principle described in Section 2.1., and the analysis of the restriction options presented in Annex D, the Dossier Submitter identified two plausible restriction options (RO1a and RO1b), i.e. fulfilling all the REACH restriction criteria (effectiveness, practicality and monitorability). Regarding the effectiveness of the restriction options, indeed only RO1a and RO1b would achieve significant emission and overall risk reduction (cf. Annex D).

For this reason, no scoring, and no further ranking of the restriction options is presented in this section. Although each restriction option was assessed individually in Annex D, the Dossier Submitter considers that, even if not effective to address the risks by itself, the restriction options are not mutually exclusive and could be proposed in conjunction with one another.

Table 2-2: Restriction option analysis for hunting with bullets

Dimension		RO1a	RO1b	RO2	RO3	RO4	RO5
Effectiveness	Overall	Yes (high)	Yes (high)	No	No	No	Yes (low)
	Emission reduction (20 years)	High (232 tonnes)	High (2 200 tonnes)	No reduction	Partial reduction	No reduction	Low (only voluntary)
	Costs per year	Medium (€6-20m)	Medium (€8-34m)	Not analysed	Low (< €6-20m)	Costs to remove more meat higher than costs for use of alternative	Low
	Overall reductions of risks incl. risks related to alternative	Medium (i.e., prevents poisoning of wildlife)	Medium (i.e., prevents poisoning of wildlife and HH effects)	Low (does not prevent poisoning of wildlife)	Low (hunter families and birds still at risk)	Low (does not prevent poisoning wildlife)	Low (only voluntary)
Practicality		Limited (currently only a few alternatives available on the market that are not approved)	Yes (sufficient number of alternatives available)	Not analysed	Yes	No (impractical to remove all impacted meat)	Yes
Monitorability/ Enforceability		Yes	Yes	Not analysed	Yes	Low	Yes

The Dossier Submitter concludes that the most effective way to address the risk posed by lead bullets to wildlife and to address the risk for human health posed by consumption of game meat is a combination of the following restriction options:

- **Ban on the use of large calibre (≥5.6 mm centrefire) lead bullets for hunting**
- **Ban on the use of small calibre (<5.6 mm centrefire and rimfire in general) lead bullets for hunting**
- **Compulsory information on the hazards of lead and the risks of using lead ammunition, transition periods and availability of alternatives at the point of sale and on product packaging**

Incorporating information on the hazard and risks of lead ammunition in national hunting exams could be an effective complementary risk management measure. However, as not all Member States have mandatory hunting exams it was not considered to be an appropriate element of the conditions of the proposed restriction. As such, only the elements of RO5 on information at the point of sale and on product packaging are taken forward. Member States could take up this as a complementary measure to the proposed restriction.

2.2.2. Sports shooting

Concerning the environmental and human health risk associated with the use of lead in sports shooting, the Dossier Submitter identified and analysed different restriction options for the use of lead shot and lead bullets. (cf. Annex D):

In addition, other Union-wide risk management options other than REACH Restriction were also investigated by the Dossier Submitter such as voluntary measures i.e. ISSF code of practice (cf. Annex D).

The Dossier Submitter wishes to emphasise that none of the proposed restriction options amounts to a ban of sports shooting. In fact, this dossier highlights that sports shooting provides significant social, cultural, and economic benefits throughout the European Union. Instead, the restriction options that are proposed target the identified problem of lead contamination, consider various possibilities to substitute lead ammunition, ensure that lead is contained at sports shooting facilities or is minimised otherwise.

The restriction options include also considerations with regards to effectiveness, practicality and monitorability:

- Effectiveness: The restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk (also with regards to the costs)
- Practicality: the restriction must be implementable, enforceable and manageable; it also includes considerations on the transition time required to implement the proposed restriction option
- Monitorability: it must be possible to monitor the result of the implementation of the proposed restriction.

With regards to effectiveness, lead emission reduction, overall reduction of risks and costs are the criteria addressed.

- Emission reduction is considered as the annual amount of lead released to the environment that would need to be recovered from soil. This criterion was used because the Dossier Submitter considers that lead that is frequently collected from a surface without direct contact to soil would minimise the risk to human health and the environment, whereas lead that would need to be recovered from the soil poses a risk to human health and the environment.
- Overall reduction of risks related to the release of lead shot and bullets for sports shooting, including the reduction of risks for human health via environment (drinking water, food), the reduction of risks for the environment (soil, birds wildlife and livestock) and the risks for human health and environment for alternatives(s), where relevant.
- Costs are considered with regards to environmental risk management measured that need to be installed to meet the requirements.

For a better overview, the restriction option analysis for sports shooting with lead shot and bullets are addressed separately.

2.2.2.1. Restriction options for sports shooting with gunshot

List of restriction options considered

Concerning the environmental and human health risk associated with the use of lead in sports shooting (covered by use 3), the Dossier Submitter identified and analysed the following restriction options for shorts shooting with shot (cf. Annex D):

- RO1: Ban on the **placing on the market** and **use** of **lead gunshot** for sports shooting
- RO2: Ban on the **placing on the market** and **use** of **lead gunshot** for sports shooting with a **derogation** for **licenced individuals** to use (e.g. Olympic/ISSF elite level only; training and events) with licencing done by Member States with annual reporting[188] to the Commission
- RO3: Ban on the **placing on the market** and **use** of **lead gunshot** for sports shooting with a **derogation** if the use takes place at a **location that has a permit** granted by the Member State for the use of lead gunshot for sports shooting and the following measures are in place:
    - Regular (at least once a year) lead gunshot recovery with >90 % effectiveness (calculated based on mass balance of lead used vs lead recovered in the previous year) to be achieved by appropriate means (such as walls and/or nets[189], and/or surface coverage);
    - Containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off) to ensure compliance with the Environmental Quality Standards (EQS) for lead specified under the Water Framework Directive;
    - Ban of any agricultural use within site boundary
- RO4: Ban on the **placing on the market** and **use** of **lead gunshot** for sports shooting with a **derogation** for **licenced individuals** to use (e.g. Olympic/ISSF elite level only; training and events) if the use takes place at a **location that has a permit** granted by the Member State for the use of lead gunshot for sports shooting where the following measures are in place:
    - Regular (at least once a year) lead gunshot recovery with >90 % effectiveness (calculated based on mass balance of lead used vs lead recovered in the previous year) to be achieved by appropriate means (such as walls and/or nets[190] and/or surface coverage);
    - Containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off) to ensure compliance with the environmental quality standards (EQS) for lead specified under the Water Framework Directive;
    - Ban of any agricultural use within site boundary;
    - Associated annual reporting[191] to the Commission.
- RO5: Compulsory information on the hazard of lead and the risks of using lead ammunition, transition periods and availability of alternatives at the point of sale and on product packaging. Individual cartridges should be indelibly labelled (‘Contains lead: do not use for hunting’).

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[188] Reporting should cover the number of licences granted to individuals.
[189] In some sources referred to as ‘shot curtains’
[190] In some sources referred to as ‘shot curtains’
[191] Reporting should cover the number of permits granted to locations in the Member State, the number of licences granted to individuals, and the quantity of lead gunshot used in the Member State.

The proposed restriction options are listed according to the principle of the hierarchy of control:

- Elimination, i.e. remove the hazard (i.e. RO1, partly RO2) by means of substitution to a substance with a more benign toxic profile.
- Engineering control, i.e. isolate the hazard (i.e. RO3) ensure that the hazard is contained
- Administrative control (i.e. RO4, RO5) by means of training and or policies.

Outcome of the restriction option analysis

Table 2-3 gives an overview of a ranking of the ROs made by the Dossier Submitter. Table 2-4 and Table 2-5 explain how the ranking was made for each dimension. The Dossier Submitter did the scoring according to the basic principle described in Section 2.1.

Table 2-3: Restriction option analysis for sports shooting with gunshot

Dimension		RO1	RO2	RO3	RO4	RO5
Practicality		**Currently limited**	Yes	Yes	Yes	Yes
Monitorability/Enforceability		Yes	Yes	Yes	Yes	Yes
Effectiveness	Emission reduction (high reduction high score, low reduction low score)	5	2	3	4	1
	Overall reductions of risks incl. risks related to alternative(s) (high reduction high score, low reduction low score)	5	2	3	4	1
	Costs (low cost high score, high cost low score)	4	3	1	2	5
	Overall score	**14**	**7**	**7**	**10**	**7**

Notes: ranking 5 is best and 1 is worst

In Table 2-4 a summary of the restriction option analysis for sports shooting with lead gunshot is presented.

Table 2-4: Restriction option analysis for sports shooting – gunshot

RO Nr	Short description of RO	Effectiveness	Practicality	Monitorability/ enforceability
RO1	Ban on the **placing on the market** and **use** of **lead gunshot** for sports shooting	Lead release avoided in 20 years: 367 500 tonnes (score: 5/5) Overall risk reduction: high (score: 5/5) Total costs (20 years) to switch to alternative: €364m (score: 4/5)	Currently limited due to social reasons (participation at Olympic games)	Yes

RO Nr	Short description of RO	Effectiveness	Practicality	Monitorability/ enforceability
RO2	As RO1, but **derogation** for **licenced individuals** to use; licencing by Member State; reporting to the Commission	Lead release avoided in 20 years: 183 750 tonnes (score: 2/5) ENV and HH risks reduced but still possible (score: 2/5) Total costs (20 years) for shooters without a licence to switch to alternative: €336m plus costs to establish a licencing system (score: 3/5)	Yes	Yes
RO3	Ban on the **placing on the market** and **use** of **lead gunshot** for sports shooting with a **derogation** for use at **permitted locations** with regular lead gunshot recovery (>90 %), containment, monitoring and treatment of drainage water; ban of any agricultural use within site boundary; all shooters allowed	Lead release avoided over 20 years: 334 425 tonnes (score: 3/5) ENV and HH risks minimised (score: 3/5) Total costs (20 years): €885-1 309m (score: 1/5)	Yes	Yes
RO4	As **RO3** but only for **licenced individuals**; reporting to the Commission	Lead release avoided over 20 years: 349 125 tonnes (score: 4/5) ENV and HH risks minimised (score: 4/5) Total costs (20 years): €506-591m (score: 2/5)	Yes	Yes
RO5	Compulsory information on the hazard of lead and the risks of using lead ammunition, transition periods and availability of alternatives at the point of sale and on product packaging. Individual cartridges should be indelibly labelled ('Contains lead: do not use for hunting')	Lead release avoided over 20 years: no change (score: 1/5) ENV and HH risks: awareness raising (score: 1/5) Costs for information and labelling (score: 5/5)	Yes	Yes, supports other RO in enforcement

The Dossier Submitter has performed a scoring of the restriction option. The dimensions "Emission reduction", "Overall reduction of risks", and "Costs" were used for scoring as described at the beginning of this section. The rationale for the scoring is provided in Table 2-5.

Table 2-5: Justification for scoring of restriction options

Dimension	Ranking rationale
Emission reduction	When looking at the potential releases avoided, a ban on placing on the market and use of lead gunshot (RO1) would be the most efficient way of reducing the releases of lead to the environment because it would target the emission at its source (i.e. ammunition), and it would target gunshot that can be purchased at stores. For the restriction options RO2, RO3, and RO4, emission reduction is understood as the reduction of lead that is deposited in or on soil and that requires removal of the soil to recover lead. Lead gunshot that is recovered regularly from surface coverage without direct contact to soil is not considered a release, noting however that such gunshot may still pose a limited risk for birds. Restriction option RO5 does not have an effect on the reduction of releases. Therefore, in terms of releases to soil avoided, the Dossier Submitter ranks the restriction options as follows (best: highest emission reduction): RO1 (5 scores) > RO4 (4 scores) > RO3 (3 scores) > RO2 (2 scores) > RO5 (1 score)
Overall reduction of risks	This dimension addresses the overall reduction of risks related to the release of lead gunshot, including the reduction of risks for human health via environment (drinking water, food), the reduction of risks for the environment (soil, birds wildlife and livestock) and the lower risks for human health and environment for alternatives(s) compared to lead. The reduction of risks related to lead is directly related to the emission reduction (see above). The risks from the alternatives replacing lead might also affect humans and the environment in a negative manner. Indeed, some of the current alternatives have a higher environmental footprint (more energy needed for example to produce lead-free bullets and shot), some alternatives are not recyclable (while lead is), in addition not all alternatives are completely harmless to the environment themselves, and for some alternatives no studies exist to dismiss completely any potential hazard for the environment (cf. Annex C on analysis of alternatives). However, it should be stressed that it is the Dossier Submitter's conclusion that the use of the main alternatives to lead (copper for bullets and steel for shot) would result in a significant net reduction in risk. Therefore, the Dossier Submitter ranks the restriction options as follows (best to worse): RO1 (5 scores) > RO4 (4 scores) > RO3 (3 scores) > RO2 (2 scores) > RO5 (1 score)
Costs	The ranking is mainly based on cost estimates that reflect the relative costs of additional risk management measures required to reduce the release of lead to the environment. The less costly the restriction scenario, the better its ranking. RO1 ranks highest because no further action is required. RO2 and RO5 rank next, for which some actions are required but no expensive costs accrue for risk management measures. RO3 and RO4 are ranking low due to the need for expensive risk management measures. The Dossier Submitter ranks the restriction options as follows (cheapest to most expensive): RO5 (5 scores) > RO1 (4 scores) > RO2 (3 scores) > RO4 (2 scores) > RO3 (1 score)

The Dossier Submitter considers that based on a scientific/technical analysis **RO1** is the preferred restriction option. This option would be a ban on the placing on the market and use of lead gunshot for sports shooting because suitable alternative gunshot material is readily available. This restriction option also had the highest rank overall with a score of 14. As mentioned above, this restriction option would be effective, would introduce the lowest compliance burden, and would have the highest benefit-cost ratio with lowest overall costs. However, this restriction option may be seen as not practical since Olympic and ISSF rules currently require the use of lead gunshot for skeet and trap disciplines. Assuming that there will be no rule changes in the short term that would allow the use of alternative gunshot materials, and acknowledging the importance of participation in international sports shooting competitions to society, the decision maker may consider that a complete ban on placing on the market and use of lead shot, including all sports shooting, has an unacceptable socioeconomic impact on athletes and the public interested in following such sports events.

The restriction option with the next highest score is **RO4** with a total score of 10. Under this restriction options the use of lead gunshot would only be allowed for licenced individuals at a permitted location at which the risks from lead shot for human health and environment are minimised. Therefore, this restriction option could minimise the risks, but would still allow Member States to host international events and EU athletes to participate and train for them.

The restriction options RO2, RO3 and RO5 rank next with a score of 7 each.

Under **RO2**, Member States would licence individuals for the use of lead gunshot; however, no further risk management measures are required to reduce lead release. Limiting the use of lead gunshot in the EU to licenced individuals would reduce total lead releases by roughly 50 %; consequently, relevant risks would remain.

Under **RO3**, the use of lead gunshot would be allowed for all sports shooters at a permitted location at which the risks from lead shot for human health and environment are minimised by >90 %.

RO5 requires useful information to be provided to the user of lead gunshot with regard to the hazard and risks of lead and could support enforcement through an indelibly labelling of the cartridges stating, e.g., "Contains lead: do not use for hunting".

The Dossier Submitter considers that the restriction options RO2, RO3 and RO4 would be most effective and monitorable when **combined with RO5**.

The Dossier Submitter acknowledges that the costs of the described risk management measure to minimise the risks for humans and environment are not insignificant. Taking into account the availability of suitable alternatives, the Dossier Submitter considers that the socio-economic benefit of the use of lead gunshot in international competitions such as the Olympics may not outweigh the costs required to minimise the risk for humans and the environment.

Although, each restriction option was assessed individually, the Dossier Submitter considers that the restriction options assessed are not mutually exclusive and could be proposed in conjunction with one another. The Dossier Submitter concludes that the most effective way (preferred option) to minimise the risks for (i) human health via environment (soil, drinking water), (ii) wildlife, and (iii) ruminants, would be:

- **Ban on the placing on the market and use of lead gunshot for sports shooting**

Considering that participation in international competitions requires the use of lead gunshot, the following option could be practical means to minimise the identified risks, if a ban is not considered to be appropriate by decision makers (optional conditional derogation):

- **Ban on the placing on the market and use of lead gunshot for sports shooting with a derogation for licenced individuals to use if the use takes place at a location that has a permit granted by the Member State for use of lead gunshot for sports shooting where the following measures are in place:**
    - **Regular (at least once a year) lead gunshot recovery with >90 % effectiveness (calculated based on mass balance of lead used vs lead recovered in the previous year) to be achieved by appropriate means (such as wall and/or nets and/or surface coverage);**
    - **Containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off) to ensure compliance with the environmental quality**

standards (EQS) for lead specified under the Water Framework Directive;

- **Ban of any agricultural use within site boundary;**
- **Associated annual reporting to the Commission.**

The following restriction option should be combined with either of the restriction options above:

- **Compulsory information on the hazard of lead and the risks of using lead ammunition, transition periods and availability of alternatives at the point of sale.**

The following restriction option should be combined with any derogation for continued used of lead gunshot for sports shooting (to aid enforcement in the field):

- **Individual cartridges should be indelibly labelled ('Contains lead: do not use for hunting').**

2.2.2.2. Restriction options for sports shooting with bullets

List of restriction options considered

Concerning the environmental risks associated with the use of lead in sports shooting (covered by uses 4, 5 and 6), the Dossier Submitter identified and analysed the following restriction options for shorts shooting with bullets (cf. Annex D):

- RO1: Ban on the **use** of **lead bullets** for sports shooting
- RO2: Ban on the **use** of **lead bullets** for sports shooting with a **derogation** conditional that the use takes place at a notified (to the Member State) outdoor location for sports shooting and no agricultural activities take place at that location and where the following measures are in place for lead projectile containment and recovery:
    - RO2a:
        - Trap chamber, or
        - Sand trap with a water impermeable barrier to soil or a sand/soil berm (without an impermeable layer to soil); combined with an overhanging roof or a water management system for containment, monitoring and, where necessary, treatment of surface (run-off) water to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive
    - RO2b:
        - Trap chamber, or
        - Sand trap with a water impermeable barrier to soil; combined with an overhanging roof or containment, monitoring and, where necessary, treatment of surface (run-off) water to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive
    - RO2c:

- Trap chamber, or
- 'Best practice' sand trap with a water impermeable barrier between the base of the sand trap and the underlying soil; an overhanging roof or a permanent cover; containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off) to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive)

- RO2d:
  - Trap chambers for static disciplines; AND
  - 'Best practice' sand trap as described in RO2c for dynamic disciplines

- RO3: Compulsory information on the hazards of lead and the risks of using lead ammunition at the point of sale and on product packaging

The proposed restriction options are listed according to the principle of the Hierarchy of control:

- Elimination, i.e. remove the hazard (i.e. RO1) by means of substitution to a substance with a more benign toxic profile.
- Engineering control, i.e. isolate the hazard (i.e. RO2)
- Administrative control (RO3).

Outcome of the restriction option analysis

The Dossier Submitter did a scoring of the options according to the basic principle described in Section 2.1. Table 2-6 gives an overview of the ranking made by the Dossier Submitter and Table 2-8 explain how the ranking was made for each dimension.

Table 2-6: Restriction option analysis for sports shooting with bullets

Dimension		RO1	RO2a	RO2b	RO2c	RO2d	RO3
Practicality		Currently limited	Yes	Yes	Yes	Yes	Yes
Monitorability/ Enforceability		Yes	Yes	Yes	Yes	Yes	Yes
Effectiveness	Emission reduction (high reduction high score, low reduction low score)	6	2	3	5	4	1
	Overall reductions of risks incl. risks related to alternative(s) (high reduction high score, low reduction low score)	6	2	3	4	5	1
	Costs (low cost high score, high cost low score)	1	5	4	3	2	6
	Overall score	**13**	**9**	**10**	**12**	**11**	**8**

Table 2-7: Restriction option analysis for sports shooting with bullets

RO Nr	Short description of RO	Effectiveness	Practicality	Monitorability/ enforceability
RO1	Ban on the **use** of **lead bullets** for sports shooting	Emission reduction over 20 years: 6 300 tonnes (score: 6/6) Overall risk reduction: highest (score: 6/6) Costs: not calculated due to missing alternative (score: 1/6)	Currently limited due to missing approved alternatives	Yes
RO2	Ban on the **use** of **lead bullets** for sports shooting with a **derogation** at notified outdoor locations where no agricultural activities take place and the following measures are in place (see different RO2 options below)	See RO2a to RO2d below	See RO2a to RO2d below	See RO2a to RO2d below
RO2a	Trap chamber, or sand trap (with impermeable barrier) or sand/soil berm (without impermeable barrier), combined with roof or water management system	Emission reduction over 20 years: 4 500 tonnes (score: 2/6) Overall risk reduction: risks minimised (score: 2/6) Costs over 20 years: €170m (score: 5/6)	Yes	Yes
RO2b	Trap chamber, or sand trap (with impermeable barrier), combined with roof or water management system	Emission reduction over 20 years: 5 200 tonnes (score: 3/6) Overall risk reduction: risks minimised (score: 3/6) Costs over 20 years: €435m (score: 4/6)	Yes	Yes
RO2c	Trap chamber, or 'best practice' sand trap with impermeable barrier and roof or permanent cover and water management system	Emission reduction over 20 years: 5 800 tonnes (score: 5/6) Overall risk reduction: risks minimised (score: 4/6) Costs over 20 years: €1 100m (score: 3/6)	Yes	Yes
RO2d	Trap chamber for static disciplines; AND 'best practice' sand trap for dynamic disciplines	Emission reduction over 20 years: 5 800 tonnes (score: 4/6) Overall risk reduction: risks minimised (score: 5/6) Costs over 20 years: €1 700m (2/6)	Yes	Yes
RO3	Compulsory information on the hazards/risks of lead at the point of sale and on product packaging	Emission reduction over 20 years: no change (score: 1/6) Overall risk reduction: awareness raising (score: 1/6) Costs: low (score: 6/6)	Yes	Yes

The Dossier Submitter has performed a scoring of the restriction option to allow an independent analysis. The dimensions "Emission reduction", "Overall reduction of risks", and "Costs" were used for scoring as described at the beginning of this section. The rational for the scoring is provided in Table 2-8.

Table 2-8: Justification for scoring of restriction options

Dimension	Ranking rationale
Emission reduction	Looking at the potential releases avoided, a ban on the use of lead bullets (RO1) would be the most effective way of reducing the releases of lead to the environment because it would target the emission at its source (i.e. ammunition), and it would target bullets that can be purchased at stores. However, in the absence of suitable alternative(s), RO1 is currently not an option. RO2 would minimise the release to different levels RO3 does not have an effect on the reduction of releases. Therefore, in terms of releases to soil avoided, the Dossier Submitter ranks the restriction options as follows (best: highest emission reduction): RO1 (6 scores) > RO2c (5 scores) > RO2d (4 scores) > RO2b (3 scores) > RO2a (2 scores) > RO3 (1 score)
Overall reduction of risks	This dimension addresses the overall reduction of risks related to the release of lead bullets, including the reduction of risks for human health via environment (drinking water, food), the reduction of risks for the environment (soil, birds wildlife and livestock). RO1 with a complete ban would be the most effective way of an overall reduction of risks; however, suitable alternative bullets are currently not available. RO3 would be the least effective without any emission reduction. For overall risk reduction of RO2 options, in addition to emission reduction, the effectiveness and efficiency of bullet recovery was considered: for trap chambers lead recovery is most effective (up to 100 %) and most efficient with recovery as frequently as needed, even several times a year, whereas for sand traps effectiveness is lower (no information on effectiveness) as is efficiency because recovery would be only every 3 to 5 years, depending on the amount of lead in the trap. RO2d has the highest fraction of trap chambers with highest effectiveness and efficiency of lead recovery and therefore ranks highest. RO2b and RO2c would be similar in bullet recovery effectiveness and efficiency but RO2c is better than RO2b due to higher emission reduction. RO2a would also allow recovery from sand but without an impermeable barrier to soil, making the recovery less effective. The reduction of risks related to lead is related to the emission reduction (see above) and the fraction of type of containment (trap chamber versus sand trap). Therefore, the Dossier Submitter ranks the restriction options as follows (best to worse): RO1 (6 scores) > RO2d (5 scores) > RO2c (4 scores) > RO2b (3 scores) > RO2a (2 scores) > RO3 (1 score)
Costs	The ranking is mainly based on the cost for the risk management measures to contain bullets. The less costly the restriction option, the better the ranking. In the absence of suitable alternatives, RO1 is currently not an option. RO3 ranks best, for which some actions are required but no expensive costs for risk management measures. RO2 is ranking lower due to the need for risk management measures and RO1 lowest since suitable alternative are currently not available. The Dossier Submitter ranks the restriction options as follows (cheapest to most expensive): RO3 (6 scores) > RO2a (5 scores) > RO2b (4 scores) > RO2c (3 scores) > RO2d (2 score) > RO1 (1 score)

The Dossier Submitter considers that **RO1** is currently not an option because only few alternative bullets of suitable precision are available, and the risks from lead bullets in sports shooting can be minimised by using bullet containment, i.e. trap chambers and sand traps.

Under **RO2** several sub-options with different risk management measures to contain and recover lead bullets were analysed. The Dossier Submitter considers that all options RO2a to RO2d are proportionate based on the analysis presented in Section 2.6.4.1. However, they differ in terms of both their costs and effectiveness. Based on the scoring **RO2c** was identified as preferred sub-option. RO2c was preferred over RO2d due to slightly higher emission reduction and lower costs. The risk management measures of RO2c (trap chambers and 'best practice' sand traps) are required in the CSR (2020) and implemented within the EU at many but not at all facilities.

The Dossier Submitter notes that there might be national legal requirements for specific shooting disciplines (such as silhouette) to use trap chambers and a sand trap.

RO3 informs the user about the hazards of lead and the risks of using lead ammunition at the point of sale and on product packaging.

Therefore, the Dossier Submitter concludes that the most effective way to minimise the risks for (i) human health via environment (soil, surface water and groundwater) and (iii) ruminants, would be:

- **Ban on the use of lead bullets for sports shooting with a derogation conditional that the use takes place at a notified (to the Member State) outdoor location for sports shooting and no agricultural activities take place at that location and where the following measures are in place for lead projectile containment and recovery:**
  - **Trap chamber, or**
  - **'Best practice' sand trap with a water impermeable barrier between the base of the sand trap and the underlying soil; an overhanging roof or a permanent cover; containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off) to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive**

The following restriction option should be combined with the above restriction option:

- **Compulsory information on the hazard of lead and the risks of using lead ammunition at the point of sale and on product packaging**

2.2.3. Fishing

List of restriction options considered:

For the lead in fishing tackle covered by use 7 and 8, based on the identified risks both for the environment and the human health, the following restriction options were analysed by the Dossier Submitter (cf. Annex D):

- RO1: Ban on placing on the market material and equipment for home-casting activities
- RO2: Ban on using fishing tackle rig or equipment intended to drop off lead sinkers
- RO3a: Ban on placing on the market and using lead fishing sinkers and lures
- RO3b: Ban on placing on the market and using fishing nets, ropes and lines containing lead
- RO4: Ban on placing on the market lead fishing sinkers and lures
- RO5: Ban on using lead fishing sinkers and lures
- RO6: RO3a with a derogation for lead split shots conditional to the placing on the market in spill proof and child resistant packaging
- RO7: Compulsory information to consumers at the point of sale (presence, toxicity and risk of lead, as well as availability of alternatives…)

The proposed restriction options are listed according to the principle of the hierarchy of control:

- Elimination, i.e. remove the hazard (i.e. a RO1 and RO2)

- Substitution, i.e. replace the hazard (i.e. RO3 to RO5)
- Engineering control, i.e. isolate the hazard (i.e. RO6)
- Administrative control (RO7)

While RO1, RO3a, RO3b, RO4, and RO6 target the companies placing on the market material and equipment for home-casting (RO1), or different type of lead fishing tackle (RO3a, RO3b, RO4 and RO6); RO2, RO5 and RO7 are targeting only the fishers (consumers or professional fishers).

RO2 is focussing specifically on the emerging practice in EU of the intentional drop off of sinkers (‘backlead’ or main sinker) for carp fishing for example. Even though a ban on placing on the market and use would have been more efficient than a ban on use only, a ban on placing on the market cannot be proposed as a REACH restriction option because this is beyond the scope of REACH which can restrict a substance or a use, but not a technique or an object to use the substance.

RO6 is trying to address with a ‘containment measure’ the issue of the split shots which are very small sinkers[192] and can be easily spilled inadvertently by the fisher on the water shore (CfE #936 – UK EPA). This restriction option was investigated as alternatives for the smallest dust split shots (≤ 0.05 g) were not specifically identified during the ECHA market survey, even if other technical solutions (e.g. tungsten or iron putty) could be applied on fishing line instead of dust split shots (cf. Annex D).

With RO7, retailers will be requested to inform at the point of sale the consumers about the presence, toxicity and risk of lead to human health and the environment. They will also be asked to inform that alternatives to lead fishing tackle are available. RO7 is built on the recent work from Schulz et al on the communication strategies for reducing lead poisoning in wildlife and human health risks (Schulz et al., 2019), which highlight that the initial step to change fishers (and hunters) behaviour toward lead fishing tackle and ammunition is to have stakeholders recognising the importance of the lead issue both for the human health and the environment, and “use that concern as a catalyst for a positive change in their consumer purchasing behaviour”.

RO3a which has been assessed with two different boundaries (LOW and HIGH) and RO3b are very similar. The aim of these restriction options is to ban the placing on the market and the use of different types/dimensions of lead fishing tackle. Nevertheless, RO3a and RO3b differ in term of scope and scale of the ban of lead fishing tackle. RO3b is about lead embedded in nets, ropes and lines, while RO3a is about lead in fishing sinkers and lures. The LOW boundary of RO3a focuses on lead fishing sinkers and lures ≤ 50 g, and the HIGH boundary of RO3a has no size limitation for sinkers and lures. The cut-off value of 50 g was set, because lead fishing tackle that tends to be ingested by birds have a maximum weight of 50 g. Fishing tackle weighing less than 50 g and having a size of less than 2 cm in any dimension are indeed often mistaken for food or grit ((Franson et al., 2001, Grade et al., 2019, Grade et al., 2018, Scheuhammer and Norris, 1995, Pokras et al., 2009) and (CfE #1247- Wildfowl & Wetlands Trust)). Other cut-off values were also investigated (e.g. ban on split shots only, and ban on sinkers and lures ranging from 0.06 g to 28.35 g similar to the UK ban) but dismissed for various reasons that are further explained in Annex D.

The combination of RO3a (HIGH boundary) and RO3b could be seen as a comprehensive ban of all lead fishing tackle used for recreational and commercial fishing as it would include

[192] Split shots range from 0.01 g to 4.8g. The smallest split shots (≤0.06 g) are often referred as ‘dust split shots’.

lead sinkers, and lures but also nets, ropes, and lines made of lead. In practice it means that all types of lead fishing tackle and all sizes of fishing tackle would be banned from being placed on the market, and used, if those two restriction options were combined. While RO3a would affect both recreational and commercial fishers using angling as the main fishing technique, i.e. ca. 14 000 commercial vessels; RO3b would essentially affect commercial fishers., as fishing with nets, ropes and lines is essentially performed by commercial fishers.

Figure 2-1 depicts the difference and interconnection between RO3a and RO3b.

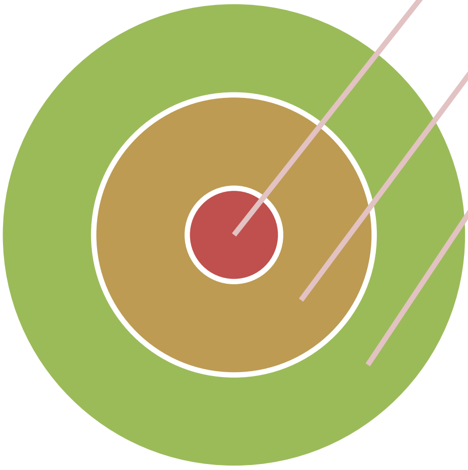

Figure 2-1: Lead fishing tackle – RO3a and RO3b scope

RO4 and RO5 together would be equivalent to RO3a (HIGH): RO4 is indeed a ban on placing on the market only, and RO5 a ban on use only of lead fishing sinkers and lures.

It is important to note that the restriction options including a ban on using lead fishing tackle (i.e. RO3a (LOW and HIGH), and RO5) intend to ban the use of any lead fishing tackle whatever its source of supply: i.e. from retailers or home-casted, while one the other hand a ban on placing on the market only (e.g. RO4) could only target the sold fishing tackle (and not the home-casted ones for personal use).

The Dossier Submitter evaluated each individual restriction option's ability to reduce the number of lead fishing tackle available for exposure to birds, as well as the ability to reduce the human health exposure to lead (essentially during home-casting activity, and ingestion of lead fishing tackle by children).

For some of the restriction options (e.g. RO3a), the need and impact of a transition period was also analysed as part of a sensitivity analysis in Section 3.3.2.

In addition, other Union-wide risk management options other than REACH Restriction were also investigated by the Dossier Submitter such as (i) voluntary educational programmes, (ii) voluntary industry agreement to reduce the use of lead in fishing tackle, (iii) information campaign to promote the use of alternatives, (iv) mandatory training on the risk of lead to obtain a fishing licence, (v) retailer voluntary scheme to sell only fishing tackle from authorised sources (vi) taxation on lead fishing tackle and (vii) fee collected from the licences purchase in order to support the European transition to non-lead alternatives (cf. Annex D).

Outcome of the restriction option analysis

Some options were dismissed at an early stage during the restriction option analysis (cf. Annex D for further details), for the following reasons:

- A 'total ban on fishing activities', even if addressing the risk identified both for human health and wildlife is dismissed as disproportionate and not within the mandate given by the European Commission (EU Commission, 2019). The request from the Commission indeed clearly stated that the proposed restriction proposal should "*identify viable restriction options* *targeted* *at addressing the identified risks*".
- A 'ban on home-casting activities' is also dismissed as the home-casting activities which is performed in the private sphere cannot be enforced.[193]
- RO1, on the placing on the market of material and equipment for home-casting activities, is not targeted enough, does not address all the risks identified (in particular the risks for wildlife) and is not enforceable.
- RO3b, targeted to the fishing nets, ropes and lines, would be disproportionate with regard to the current knowledge of lead exposure risk (both to human and wildlife) from these types of fishing tackle.
- RO5 is not implementable and enforceable in a harmonised way.

All the above-mentioned options were therefore not considered by the Dossier Submitter for the ranking exercise. Only the following restriction options were considered further: RO2, RO3a (LOW and HIGH), RO4, RO6 and RO7.

A ban on all lead fishing sinkers and lures (i.e. RO3a with HIGH boundary) would have probably been unwarranted if the protection of birds would be the only goal of the proposed restriction. Lead fishing tackle heavier than 50 g, are indeed not typically ingested by birds.

However, as the goal of the restriction is to reduce all risks associated to lead, including also to reduce the exposure and risk to lead during home-casting and fishing activities, and more especially the risk for children for whom lead is a non-threshold substance for neurodevelopmental effects, the Dossier Submitter considered both the LOW and HIGH boundary for the ranking exercise. Indeed, RO3a (LOW and HIGH) would ban the use of any lead fishing tackle whatever its source of supply: i.e. from retailers or home-casted ones. A ban on using lead fishing tackle for fishing, would therefore indirectly reduce the incentive for home-casting activity (because a fisher could not use anymore what he would have manufactured), and the associated risk.

The Dossier Submitter considered that the restriction options RO2, RO3a (LOW and HIGH boundary), RO4, RO6 and RO7 are implementable, enforceable, and manageable and the result of the implementation of the proposed restriction can be duly monitored. Therefore, only these options have been ranked according to the key dimensions discussed earlier in this section.

Table 2-9 gives an overview of the scoring made by the Dossier Submitter, and Table 2-10 explains how the ranking and scoring was made for each dimension. The Dossier Submitter did the scoring according to the basic principle described in Section 2.1.

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[193] Note that other restriction options can address indirectly the issue of home-casting. For example: a ban on using lead fishing tackle would capture the use of home-made fishing tackle for fishing. 'If you can't use, don't make it!' principle.

Table 2-9: Restriction option analysis for fishing

	RO2	RO3a LOW	RO3a HIGH	RO4	RO6	RO7
Emission reduction	2	3	6	4	5	1
Other environmental risk reduction	1	4	4	4	1	1
Other human health risk reduction	1	5	6	1	4	1
Costs (for EU industry)	6	2	1	1	1	5
End user acceptance	5	2	1	4	3	6
Unweighted score count	**15**	**16**	**18**	**14**	**14**	**14**
Weighted score count	**17**	**19**	**24**	**18**	**19**	**15**

Table 2-10: Ranking rationale for fishing ROs

Dimension	Ranking rationale
Emission reduction	As indicated in Annex D, it is difficult to evaluate the effect of communication and awareness raising on consumers behaviour, and in particular how much such action, on its own, would impact the releases of lead to the environment. Therefore, taking a conservative approach, RO7 is ranked as the worst option in term of emission reduction efficiency. Using a similar reasoning, RO2 which targets a very specific type of fishing practice (carp fishing with intentional drop of lead) will not reduce drastically releases of lead to the environment on its own. On the contrary, a ban on the placing on the market and on use is the most effective way for reducing the releases of lead fishing tackle to the environment, because it would target the emission at its source (i.e. the fishers). It would target both the lead fishing tackle that could be purchased from a shop or internet, and the home-casted ones. A comprehensive ban both on placing on the market and on use is therefore more effective in term of releases reduction than a ban on placing on the market only, as a ban on placing on the market only (RO4) would not address the release to the environment of home-casted sinkers and lures. Considering also that the larger the scope of the ban, the more releases are avoided, and based on the releases estimates calculated in Annex D for RO3a LOW, RO3a HIGH, RO4 and RO6[194], the Dossier Submitter ranks the restriction options as follows: (Best option) RO3a HIGH > RO6 > RO4 > RO3a LOW > RO2 > RO7 (Worst option).
Other environmental risk reduction	This dimension is looking at what are the other potential positive and negative net risk reduction for the environment **other than lead emission reduction**. While the options RO3a to RO6 would reduce the amount of lead released to the environment, the alternatives, even if much better than lead in term of effects on birds, might also have some negative impact on the environment, and particularly on other environmental compartments. Indeed, some of the currently identified alternatives have a high environmental footprint (more energy needed for example to produce fishing sinkers), some are not recyclable (while lead is), in addition not all alternatives are completely harmless to the environment (e.g. zinc for the aquatic environment), and for some of them no sufficient studies exist to clear completely any potential hazard for the environment (cf. Annex C on analysis of alternative substances). Considering these potential side-effects, and not being able to predict which alternatives will replace lead in the future, RO3a, RO4 and RO6 which all involve lead replacement by alternatives, will be ranked better than the other options, but cannot be ranked with the highest score (i.e. 6 points). RO6 entails the replacement of most of the lead by alternatives, nevertheless lead would still be permitted for the smallest dust split shots (≤

[194] Releases reduction over a 20-year analytical period as reported in Annex D:
RO3a HIGH: 48 300 tonnes
RO6: same order of magnitude of RO3a HIGH but a bit lower than RO3a HIGH (reasoning in Annex D)
RO4: 43 470 tonnes
RO3a LOW: 28 050 tonnes

Dimension	Ranking rationale
	0.06 g), and despite the spill proof design proposed for the packaging, such split shots could still be lost inadvertently during the fishing practice (e.g. if the fishing line breaks). Considering that the smallest lead tackle sizes have the greatest surface area and bioavailability potential, this option is proposed to be ranked worse than RO3a and RO4. RO2 would still allow the use of lead, while prohibiting the intentional drop off which is today a marginal practice. The risk for the environment remains the same as today, therefore RO2 is ranked, together with RO6, as the worst case for the environment compared to any other alternative. RO7 would also be ranked among the worst option: even if the Dossier Submitter believes that an awareness of the risk of lead might trigger the curiosity and the demand of consumers for safer alternatives, the effect of such a measure cannot be quantified. Therefore, taking a conservative approach, RO7 is ranked as the worst option in terms of other environmental impact. Based on all these arguments, and the detailed assessment provided in Annex D for each RO, the following ranking is proposed for this dimension: (Best options) RO3a HIGH / RO3a LOW / RO4 > RO2 / RO6 / RO7 (Worst options).
Human health risk reduction	RO3a is the only option to address the home-casting issue, and the associated risk of lead fumes and lead particles inhalation, this is why RO3a HIGH and RO3a LOW are ranked respectively first and second. Indeed, RO3a prohibit the use of lead sinkers whatever its source of supply (retailer or home-casted ones). RO6 with its spill and child proof packaging is also protecting the children from accessing and ingesting split shot, so this option is ranked third in term of human health benefit. RO4 and RO2 would still allow the use of lead sinkers and lures by fishers, therefore a risk for human health remains. It is assumed also that RO2 might trigger an increase in home-casting lead fishing tackle from fishers who cannot find anymore their usual fishing tackle from retailers. Neither RO2, nor RO4 address the home-casting problem, and an increase of human-health exposure from increased home-casting activity could be expected. These two options would therefore be ranked as the worst ones. In a similar manner as for the awareness raising on the environmental issue, taking a conservative approach, RO7 is ranked among the worst option in terms of human health impact, even if the Dossier Submitter believes that RO7 could have a positive impact in reducing the home-casting habit, and in improving the hygiene habits when manipulating lead fishing tackle. Based on all these arguments, and the detailed assessment provided in Annex D for each RO, the following ranking is proposed for this dimension: (Best option) RO3a HIGH > RO3a LOW > RO6 > RO2 / RO4 / RO7 (Worst option).
Costs	This dimension is looking more specifically at the costs of the restriction options for the European manufacturing activity of fishing tackle. It gives an indication of the affordability potential of the European Industry to roll-out the different restriction options. The less costly the restriction scenario, the better the ranking. Based on the cost estimates for the European Industry, and considering that some options, even if not quantified, would have a low investment costs, the Dossier Submitter concluded on the following ranking based on the assessment provided in Annex D for each RO: (Best option) RO2 >RO7 >>>>RO3a LOW >RO6/RO4/RO3a HIGH (Worst option).
End user acceptance	End user should be understood here as the fisher. This dimension looks at the assumed end user acceptance of different restriction options. For the fishing sector, it is indeed an important element for the adherence of the restriction option proposed, as the (non)acceptance by the end user could compromise the effectiveness, and in particular the net risk reduction capability of the restriction option. Not accepting the proposed restriction, and in particular if the enforcement is not effective, could trigger a different response from the end user: increase the home-casting activity and increase the human health risk, rather than purchasing alternatives. The Dossier Submitter has ranked end user acceptance assuming that end user acceptance usually decreases with perceived constraints to individual freedom. The better the end user acceptance, the best the ranking: RO7 >RO2 >RO4 >RO6 >RO3a LOW >RO3a HIGH

The unweighted score count favours RO3a HIGH over the other five options.

One may object that the key dimension of a restriction on lead in fishing tackle should be emission avoidance. Correspondingly, one may wish to give more weight to this dimension. A weighted score count giving twice as much weight to emission avoidance would then still favours RO3a HIGH (a ban on placing on the market and using fishing sinkers and lures) over the other options. RO3a LOW (a ban on placing on the market lead fishing sinkers and lures below 50 g) and RO6 (i.e. RO3a HIGH with a derogation for split shots) come second and third.

Although, each restriction option was assessed individually, the Dossier Submitter considers that the restriction options assessed within this Annex XV Dossier are not mutually exclusive and could be proposed in conjunction with one another. After consideration of the various options, the available information, the reasonable assumptions, and the above ranking of the options, the Dossier Submitter concludes that the most **effective way** (i) to address and reduce the risks posed by fishing tackle to wildlife, (ii) to address and reduce the risks to human health posed by home-casting and potential exposure and ingestion of lead by children, but also (iii) to support the EU commitment toward the preservation of bird species (AEWA MoU), (iv) and to prepare the fishers to the change, would be a combination of the following restriction options:

- **Ban on placing on the market and using lead fishing sinkers and lures (RO3a HIGH)**. This ban would be accompanied with different transition periods to allow the lead fishing tackle manufacturers, suppliers and retailers to develop and switch to alternatives, i.e. (i) no transition period for lead wire, (ii) a transition period of three years is proposed for lead fishing sinkers and lures with a weight ≤ 50 g, and (iii) a transition period of five years for the sinkers and lures with a weigh > 50 g.
- **Ban on using fishing tackle rig or equipment intended to drop off lead sinkers** (RO2). No transition period granted.
- **Obligation to inform at the point of sale the consumers about the presence, the toxicity and the risk of lead for human health and the environment** (RO7). The information at the point of sale would also include information on the upcoming ban and the availability of alternatives. This obligation would apply to all lead fishing tackle placed on the market (no size restriction), and would be accompanied with a transition period of six months to allow the lead fishing tackle retailers (shops and websites) to put in place the necessary information campaign towards their customers.

In addition, some other Union-wide measures beyond REACH, assessed by the Dossier Submitter (cf. Annex D), could be recommended as complementary measures to support the proposed REACH restriction on lead in fishing tackle, and could be implemented by national associations in order to accompany the European industry and the consumers in this change of fishing practices. These other measures are complementary to each other, as one would allow to finance the other one:

- A collection of a small fee from the fishing licences (where existing) in order to support the change and transition to non-lead alternative of both the consumers and the EU manufacturers. A fee of 10 cents collected on each licence in the EU would represent a marginal increase in the licence fee for an individual, but would generate an annual contribution of €1.2 million, which could be used to support European R&D to develop and place on the market suitable alternatives and/or help the European manufacturers to transition to non-lead alternatives. Alternatively, the income could also be used to support an education campaign towards the consumers (see next bullet point).
- A voluntary education programme and action campaign to promote the use of non-lead fishing tackle, organised and lead by the sector associations (fishing and trade) targeted to the consumers to promote the use of non-lead fishing tackle, and the

recovery and recycling of lead fishing tackle. Efforts encouraging fishers to use non-lead alternatives could benefit from a European-wide coordination by fishing associations for example.

2.3. Proposed restriction

2.3.1. Scope of the proposed restriction

Short title:

Restriction on the placing on the market and use of lead in outdoor shooting and fishing.

Scope description:

The text of the proposed entry in Annex XVII (proposed restriction) has been drafted to describe the intention of the Dossier Submitter. The final legal wording (i.e. to update Annex XVII of REACH) would be decided by the European Commission, and would need to take into account the existing restriction on the use of lead in gunshot in wetlands.

The text *in blue italic font* in the right-hand column is intended to help the reader to understand the purpose of each of the conditions of the proposed restriction. This information is not intended to be part of the final restriction proposal. Note that further detailed explanation of the intention of the Dossier Submitter is also provided in Section 2.3.2.

Some elements of the proposal are presented in square brackets […]. This denotes that the Dossier Submitter has concluded that the proportionality of the proposal is particularly sensitive to these aspects (i.e. duration of transitional periods) but is not able to conclude on a proposal because of policy rather than scientific considerations. This includes elements of the proposal that are not preferred by the Dossier Submitter but may be favoured by the decision maker (i.e., the 'optional conditional derogation' for sprots shooting with gunshot). In these instances, the Dossier Submitter has assessed the impacts of different options for these elements of the proposal. These assessments should be evaluated by RAC/SEAC during the opinion-making phase.

The text in green describes a 'non-preferred' derogation option (identified as 'optional condition derogation') for the continued use of lead gunshot for sports shooting. The derogation is comprised of four linked parts (i.e., a set of measures that describe the minimum standard of risk management that should be implemented in the event that a derogation for continued use of lead gunshot is **favoured by the decision maker**.

Table 2-11: Proposed restriction entry (annotated)

Designation of the substance	Conditions of the restriction	Rationale
Lead and its compounds	1. Shall not be placed on the market in a concentration equal or greater than 1 % w/w:	*A ban on placing on the market is proposed when suitable alternatives are available and ban is not considered to result in disproportionate impacts to society.* *A ban on placing on the market, in addition to a ban on use, enhances the practicality of the proposed restriction (enforceability and implementability) resulting in greater effectiveness.* *Each of the use-specific bans on placing on the market is combined with a corresponding transition period of variable duration to avoid disproportionate impacts from an immediate ban on placing on the market.*
	a. in fishing sinkers and lures b. in fishing wires	*Use of lead fishing sinkers, wires and lures is associated with risks that are not adequately controlled. Lead in these uses can be substituted with technically and economically feasible alternatives that are already available on the market.*
	c. in gunshot	*All uses of lead gunshot are associated with risks that are not adequately controlled and can be substituted with technically and economically feasible alternatives that are already available on the market.* *Nevertheless, the Dossier Submitter has included* ***(as an option for the decision maker when considering the scope and conditions of the restriction in Annex XVII)*** *a derogation from this condition for sports shooting with gunshot for elite level athletes under strict conditions of use that minimise risks to human health and the environment. By describing this option, the Dossier Submitter recognises that this may be the preference of the decision maker – see paragraph 4.* *Note: no ban is proposed for the placing on the market of projectiles other than gunshot as continued use is foreseen under certain conditions (see paragraph 4).*

Designation of the substance	Conditions of the restriction	***Rationale***
	2. Shall not be used, in a concentration equal or greater than 1 % w/w:	
	a. in fishing sinkers and lures for fishing	*In addition to being purchased from the market, lead fishing sinkers and lures may be 'home-casted'. A ban on placing on the market would not control the risks for the environment and human health associated with 'home-casted' fishing sinkers and lures (and may in fact inadvertently encourage the practice of 'home-casting'). To achieve an effective control of risks the ban on placing on the market of fishing sinkers and lures is therefore complemented with a ban on use.*
	b. in fishing wires for fishing	*Lead fishing wire can be cut into small pieces and added to lures (including home-made lures). No transition period for this use is proposed as suitable alternatives are already available.* *For fishing sinkers, lures and wires (paragraph 2a and 2b), 'used' should be understood as 'used for both recreational and commercial fishing irrespective of whether these take place in freshwater (i.e. in rivers, lakes and ponds), estuarine or marine environments'. In addition, as fishing sinkers, lures and wires can be either purchased from a retailer or manufactured directly by consumers (also known as 'home-casting'), the use of both purchased and home-casted fishing tackle containing lead is in the scope of the Annex XV report and proposed restriction. It should be noted that the production of lead sinkers, lures and wires either in industrial setting or at home ('home-casting') are not 'uses for fishing' for the purposes of this restriction.*
	c. in gunshot for hunting d. in gunshot for sports shooting	*A comprehensive ban (paragraph 1+2) on the use of lead in gunshot is proposed as suitable alternatives are available. It implicitly includes* ***both hunting and sports shooting uses****.* *The ban on use is associated with a transition period to allow society to adapt. [Nevertheless, the Dossier Submitter describes* ***as an option*** *a derogation from this condition for certain disciplines of sports shooting at international and Olympic level*

Designation of the substance	Conditions of the restriction	Rationale
		(currently requiring the use of lead gunshot) recognising that this may be the preference of the decision maker – see paragraph 4].
	e. in any other projectiles not defined as a gunshot for hunting (by way of derogation shall not be used in a concentration equal to or greater than 3 % w/w in copper or copper alloys - this derogation shall be subject to a review prior to entry into force to determine if a concentration less than 1 % can be achieved) f. in any other projectiles not defined as a gunshot for sports shooting (by way of derogation shall not be used in a concentration equal or greater than 3 % w/w in copper and copper alloys - this derogation shall be subject to a review prior to entry into force to determine if a concentration less than 1 % can be achieved)	*The ban on the use of projectiles other than gunshot includes projectiles used for both hunting and sports shooting, including muzzle loading ammunition, airgun pellets and 'slugs'.* *Different transition periods are proposed depending on whether the use is for hunting or sports shooting. Different transitional periods for hunting are also proposed for different calibres (< or ≥ 5.6 mm, rimfire vs centrefire) based on the availability of alternatives . Where risks can be minimised (i.e. under controlled conditions for sports shooting) specific derogations from this ban are proposed in paragraph 4.* *A derogation of the concentration limit of 1% w/w is proposed for copper and copper alloys as alternatives made of brass may currently contain up to 3 % lead. Without this derogation many of the existing alternatives to lead ammunition could not be used. Further reduction of the lead content of brass is technically possible. Therefore, this derogation shall be reviewed before the entry into force of the restriction to ensure that the market continues to minimise the lead concentration in alternative ammunition made with copper or copper alloy projectiles.*
	3. Shall not be used for fishing, in a concentration equal to or greater than 1 % w/w, in fishing sinkers where the fishing equipment, rig or technique deliberately releases the sinker during use.	*Relates to the use of lead sinkers in combination with fishing tackle (e.g. swivel) or techniques (rigs) which are intended to intentionally release sinkers into the environment. The use of lead sinkers is associated with uncontrolled risks. No transition period is proposed for this condition as it aims at immediately prohibiting an emerging practice that deliberately disperses lead sinkers. Only a ban on the use of sinkers (rather than the type of tackle/rig) is under the remit of the REACH regulation.*
	4. By way of derogation:	*Derogations in paragraph 4 for sports shooting. The square*

Designation of the substance	Conditions of the restriction	*Rationale*
		brackets apply to the sub-paragraphs related to sports shooting with lead gunshot.
	a. [OPTIONAL CONDITIONAL DEROGATION (part 1 of 4): Paragraph 1c shall not apply if:	***Optional derogation** to allow some sports shooters to purchase lead gunshot for sports shooting. This derogation works in conjunction with the derogation 4b, which allows only licenced individuals to use lead gunshot for sports shooting under strict conditions to minimise the release of lead to the environment, and the requirements set in 5c and 6.*
	- the retailer places lead gunshot on the market only for users licenced by Member States.	*Retailer shall only place lead gunshot on the market for licenced users. See Section 2.3.2.8 where an example licensing system is described.*
	b. [OPTIONAL CONDITIONAL DEROGATION (part 2 of 4): Paragraph 2d shall not apply if:	*This derogation works only in conjunction with the derogation 4a, and the conditions set in paragraph 5c and 6.*
	- the user has a licence, granted by the Member State, to use lead gunshot for sports shooting; AND from EiF + [5] years the use takes place at a location that has a permit granted by the Member State for the use of lead gunshot for sports shooting; AND	*Member states will license only users that are required to use lead gunshot to participate in or train for international shooting events that require (by virtue of their rules) the use of lead gunshot. See Section 2.3.2.8 where an example licensing system is described.*
	- the following measures are in place:	
	▪ Regular (at least once a year) lead gunshot recovery with >90 % effectiveness (calculated based on mass balance of lead used vs lead recovered in the previous year) to be achieved by appropriate means (such as walls and/or nets and/or surface coverage);	*Requiring regular recovery of spent lead gunshot is considered as the most effective means to minimise releases to the environment. Recovered lead is no longer available for ingestion by birds or dissolve. By requiring a high (but achievable) level of effectiveness (via annual mass balance) the permitting member state can be assured that releases of lead are minimised. >90% effectiveness is proposed as a practical threshold indicative of very high rates of recovery, noting that higher levels would be increasingly difficult to demonstrate and enforce. A limit of >90% does not imply that losses of <10% are acceptable or safe.* *In combination with a requirement for recovery the requirement for monitoring and treatment of site drainage water further*

Designation of the substance	**Conditions of the restriction**	***Rationale***
	▪ *Containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off) to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive;* ▪ *Ban of any agricultural use within site boundary;* ▪ *Records of compliance with these conditions shall be maintained by permitted locations and shall be made available to enforcement authorities on request.*	*ensures that releases from a site a minimised to reduce the likelihood of adverse effects.* *Member state enforcement can be based on inspections of mandatory documentation.*
	c. Paragraph 2e shall not apply to: - Seal hunting if the user is permitted by the Member State to hunt seals - Full metal jacket bullets where the Member State allows the use of these bullets [on the date that the restriction proposal was submitted][195]	*Derogation added after the consultation on the Annex XV report to allow the continued use of some types of 'projectiles other than gunshot' where risks to human health and the environment are considered to be low or insignificant and where no alternatives are available with an acceptable level of technical performance. The scope of the derogations are limited to specific scenarios.*
	d. Paragraph 2f shall not apply if: - The use takes place inside a building - The use takes place at a notified (to the Member State)	*Derogation to allow continued use of lead projectiles for sports shooting under conditions of use that minimise risks to the environment and human health. A two-phase approach is foreseen –sites would initially be required to notify their*

[195] See section 2.3.2.4

Designation of the substance	Conditions of the restriction	*Rationale*
	outdoor location for sports shooting; AND no agricultural activities take place at that location; AND' - From EiF + [5] years the following measures are in place: ▪ lead projectile containment and recovery via [trap chamber or a 'best practice' sand trap comprising a sand trap with: • a water impermeable barrier between the base of the sand trap and the underlying soil; • an overhanging roof or a permanent cover; • containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off) to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive)]. ▪ Records of compliance with these conditions shall be maintained by notified locations and shall be made available to enforcement authorities on request.	*continued use to MS and cease any agricultural uses at/within sites (after 18 months). A second phase would require minimum appropriate RMMs to be implemented (if not already). The list of RMMs included in this derogation was extended after the consultation on the Annex XV report to include 'best practice' sand traps, which were confirmed to be of equivalent effectiveness to 'trap chambers' to prevent releases of lead to the environment.* *The derogation requires records of compliance to be kept by operators of these in order to facilitate enforcement of the conditions by Member States. The notification of sites in the 1st phase of the derogation will improve MS knowledge of affected sites, which is currently incomplete.*
	5. Without prejudice to the application of other community provisions on the classification, packaging and labelling of substances, mixtures and articles: a. Retailers of gunshot, 'projectiles not defined as a gunshot', fishing sinkers and lures of any dimension or weight, and	*'Conditions aims to (i) increase consumer awareness of the hazard and risk of lead, and (ii) preparing them to change their*

Designation of the substance	Conditions of the restriction	*Rationale*
	containing lead in concentrations equal to or greater than 0.3 % w/w, shall ensure that, at the point of sale, in close proximity to the retailed lead projectiles, fishing sinkers and lures, the following information is clearly and visibly provided to consumers and professionals: - '***WARNING***: *this product contains lead which is toxic to the environment and may damage fertility or the unborn child. The use of lead in this type of product will be restricted in the EU from [EiF+TP as specified in paragraph 7]. More information, including on the availability of lead-free alternatives, is available from [www.echa.europa.eu]'.* The information listed above shall be in the official language(s) of the Member State(s) where the products are placed on the market, unless the Member State(s) concerned provide(s) otherwise.	*purchasing behaviour. This condition is NOT a labelling requirement, but is consistent with the principles of the CLP regulation. This condition is targeted to the retailers only, and should apply until the relevant ban on placing on the market enters into effect.* *The last statement (The use of lead in [article] will be banned in the EU from [date]) is proposed to boost the uptake of alternatives by the end-users (fishers, hunters, sport-shooters). The warning text is inspired from the CLP Regulation and similar warnings required for lead containing products under California proposition 65* *The link to the ECHA website in intended to allow consumers to seek additional information about the restriction i.e., transitional periods, availability of alternatives etc.*
	b. Suppliers of 'projectiles not defined as a gunshot' containing lead in concentrations equal to or greater than 0.3 % w/w, shall ensure, before the placing on the market, that product packaging is clearly, visibly and indelibly labelled with the information listed in paragraph 5a. The labelling shall be in the official language(s) of the Member State(s) where the products are placed on the market unless the Member State(s) concerned provide(s) otherwise. If the packaging is too small, and the information listed in paragraph 5a cannot be provided on the packaging, this information can be provided in fold-out labels (leaflet); or on tie-on tags.	*Only a labelling proposed for 'bullets or projectiles', as they will continue to be placed on the market with restricted use. The proposed wording is inspired from the CLP Regulation and similar warnings required for lead containing products under California proposition 65.*
	c. [OPTIONAL DEROGATION (part 3 of 4): Suppliers of 'gunshot' containing lead in concentrations equal to or greater than 0.3 % w/w, shall ensure, before the placing on the market, that product packaging is clearly, visibly	*This derogation works only in conjunction with the optional derogation 4a and 4b, and the conditions set in paragraph 6.* ***Optional** additional labelling requirement for shotgun cartridges*

Designation of the substance	Conditions of the restriction	*Rationale*
	and indelibly labelled with the information listed in paragraph 5a. In addition, individual cartridges shall be labelled: - *'Contains lead: do not use for hunting'.* *The labelling shall be in the official language(s) of the Member State(s) where the products are placed on the market unless the Member State(s) concerned provide(s) otherwise. If the packaging is too small, and the information listed in paragraph 5a cannot be provided on the packaging, this information can be provided in fold-out labels (leaflet); or on tie-on tags.]*	*in event that the derogation for use of lead gunshot for sports shooting is preferred to a ban. Labelling was recommended by RAC in their opinion on the proposed restriction of lead in gunshot in wetlands and would aid the enforcement of the restriction for hunting in the event that lead gunshot was still permitted to be placed on the market for sports shooting.*
	6. [OPTIONAL DEROGATION (part 4 of 4): Member States shall report on an annual basis to the Commission: - *the number of permits granted to locations in the Member State under paragraph 4b and their location.* - *the number of licences granted to users in the Member State under paragraph 4b.* - *the quantity of lead gunshot used in the Member State under paragraph 4b.]*	*This derogation works only in conjunction with the derogation 4a, 4b and the conditions set in paragraph 5c.* *In case the derogation for continued use of lead gunshot for sports shooting, set out in paragraph 4b, is preferred to an outright ban the reporting requirement will allow the Commission to monitor the continued used of lead gunshot in different Member States.* *This requirement will also facilitate the enforcement of paragraph 2c and 4 by identifying the permitted locations where lead gunshot can be used under strict conditions.*
	7. Entry into force of the restriction: a. paragraph 1a and 2a shall apply 3 years from entry into force of the restriction for sinkers and lures which have a weight equal or less than 50 g. b. paragraph 1a and 2a shall apply 5 years from entry into force of the restriction for all sinkers and lures which have a weight greater than 50 g. c. paragraph 1b, 2b and 3 shall apply as soon as possible	*Transition periods proposed based on SEA. Transition periods allow the supply chain to put in place the requirements set in the proposal (transition to non-lead alternatives or implementation of RMMs).* *i.e. no transition period for fishing wires, and the use of lead sinkers with tackle or rigs for intentional drop-off, for which many*

Designation of the substance	Conditions of the restriction	*Rationale*
	from entry into force of the restriction.	*alternatives already exists.*
	d. paragraph 1c, 2c and 2d shall apply [5 years] from entry into force of the restriction.	
	e. paragraph 2e shall apply [18 months] from entry into force of the restriction for centrefire ammunition with a calibre greater than or equal to 5.6 mm.	
	f. paragraph 2e shall apply [5 years] from entry into force of the restriction for ammunition not included in paragraph 7e, subject to a review prior to the entry into effect.	*Although alternatives to lead ammunition in calibres <5.6mm are available, there remains some uncertainty as to whether their current technical performance (in terms of precision) is adequate for hunting. The proposed transitional period of [5 years] will allow the further development of these alternatives. However, the inclusion of a review of technical feasibility prior to the entry into effect of this element of the proposed restriction will ensure that socio-economic impacts are not disproportionate. If the technical feasibility of alternatives is not sufficient at the point of review the duration of the transitional period could be extended. This approach is similar to that proposed in the opinion-making on the proposed restriction on intentionally-added microplastics.*
	g. paragraph 2f shall apply 18 months from entry into force of the restriction.	
	h. paragraph 5a shall apply 6 months from entry into force of the restriction.	
	~~i.~~ paragraph 5b shall apply 18 months from entry into force of the restriction.	
	j. [paragraph 5c shall apply 5 years from entry into force of the restriction.]	
	8. This restriction on lead in outdoor shooting and fishing shall not apply to the following uses: indoor shooting inside a building, police, law enforcement, military applications, protection of critical infrastructure, commercial shipping or	*To clearly state that these uses are intended to be out of scope.*

Designation of the substance	Conditions of the restriction	*Rationale*
	high-value convoys, soft-target and public space protection, self-defence, security purposes, technical testing and/or proofing, testing and development of materials and products for ballistic protection, forensic analysis, historical and other technical research or investigation (i.e., these uses are not associated with the identified risks and are therefore intended to be outside of the scope).	
	9. For the purposes of this regulation:	
	- 'centrefire ammunition' means ammunition where the primer is located in the centre of the case head or base.	*The definitions of 'gunshot' and 'shotgun are taken from the restriction on lead gunshot in wetlands.*
	- 'fishing wire' means metal in the form of thin thread often cut in smaller pieces and used as a sinker in certain types of 'lures'.	*Definition of gunshot: the elements in [] are not in the wetland restriction regulation proposed by the Commission. It aims at clarify the definition.*
	- 'gunshot' means the pellets used [or intended for use in quantity] as projectiles in a single charge or cartridge for shooting with a shotgun; it does not include the case, base, primer, wad, propellant etc.	
	- 'hunting' means pursuing and killing live quarry using a projectile expelled from a gun.	
	- 'lure' means an object that is used to attract fish or animals, so that they can be caught. Lures might also have the same technical function as 'sinkers'.	
	- 'projectile': means an object intended to be expelled from a gun, irrespective of the means of propulsion, excluding wads.	
	- 'sand trap' means a mass of sand, or similar material, contained within a concrete or other structure which is open towards the firing point intended to capture and retain fired projectiles.	

Designation of the substance	Conditions of the restriction	*Rationale*
	- 'shotgun' means a smooth bore gun. - 'sinker' means a weight that is attached to a fishing line or a net to keep it under the water, or to keep the fishing line, or net, in a certain position. - 'sports shooting' means shooting at any inanimate (non-living) target with a gun. It includes practice, or other shooting, performed in preparation for 'hunting'. - 'trap chamber' means a fully enclosed structure that is isolated from the underlying ground, with the exception of an opening towards the firing point that is used to capture and retain fired projectiles. Trap chambers can be constructed of various materials but are typically made of metal.	
	10. Member States may maintain national provisions for protection of the environment or human health in force on [EiF] and restricting lead in gunshot, projectiles other than gunshot or in fishing sinkers and lures more severely than provided for in paragraph 1 to 8. The Member State shall communicate the text of those national provisions to the Commission without delay. The Commission shall make publicly available without delay any such texts of national provisions received.	*Same paragraph proposed by the Commission in the final legal text of the lead in wetland restriction*

To complement the proposed restriction, other Union-wide initiatives (cf. Annex D) could be implemented (e.g., by national associations), for example:

- Incorporating a mandatory module on the hazards of lead and the risks of using lead ammunition and the use of alternatives into national hunting exams (where these are required to obtain a hunting licence). This could be done at the Member State level whenever such hunting exams takes place.

- The collection of a small fee from fishing licences (whenever existing) in order to support the transition to non-lead alternatives of both the consumers and the EU manufacturers. A fee of 10 cents collected on each licence in Europe would represent a minor increase of the licence fee and could potentially generate an annual revenue of €1.2 million that could be used to help European manufacturers to transition to non-lead alternatives. This fee could also support an education campaign for consumers (see next bullet point).
- A voluntary education and action campaign from sector associations (fishing, hunting and sports shooting) targeted to consumers to promote the use of alternatives and the recovery and recycling of lead containing articles (i.e., fishing tackle and ammunition).

Further explanations on the conditions of this restriction is given in Section 2.3.2.

2.3.2. Justification for the proposed wording for the restriction entry

2.3.2.1. Identification of the substance (designation)

Substance identity

The substance identity 'lead and its compounds' is consistent with the one in the restriction on the 'use of lead gunshot in or over wetlands'. It covers both lead and lead compounds such as lead alloys.

The proposed identification, combined with the proposed concentration limit (cf. below), would avoid the risk of regrettable substitution of lead by another substance containing lead either as a constituent of another substance, or an alloy.

Concentration limit

The concentration limit in paragraph 1 sets the maximum allowed concentration of lead permitted in the various articles that are within the scope of the restriction.

The proposed concentration limit of 1 % w/w is the same as currently adopted for the restriction on the 'use of lead gunshot in wetlands'. This limit was selected based on the US 'non-toxic' gunshot approval (cf. Annex C) process that limits the maximum concentration of lead in any 'non-toxic' gunshot to 1 % (w/w). This concentration is set to avoid a significant toxicity danger to migratory birds and other wildlife, or their habitats. As such, the proposed concentration limit is considered to sufficiently address the risk for the birds whilst being readily achievable by producers of gunshot alternatives as already implemented in the restriction on the 'use of lead gunshot in wetlands' which entered into force in January 2021.

The consistency of the enforcement of the proposed restriction for the three sectors (hunting, sports shooting, and fishing), and the restriction on 'use of lead gunshot in wetlands' will also be insured, and the proposed concentration limit can be verified using the standardised analytical methods developed for the restriction on the 'use of lead gunshot in wetlands'.

It should nevertheless be noted that, according to the Dossier Submitter's understanding, the maximum content of lead in bullets made of alternative substances varies between 1 to 3 % depending on the alternative material that is used. For example, the lead content of copper bullets is usually ~1 % whereas the lead concentration in brass bullets is usually ~3 %. In setting a concentration limit there are several key points to consider:

- Through stakeholder discussion, the Dossier Submitter was informed that around 20 % of non-lead ammunition in Germany are brass-based bullets.
- The upcoming Danish legislation on lead in ammunition, covering bullets, is likely to set a concentration limit of lead of 3 – 4 %.
- Comments from the consultation on the Annex XV report (#3252) also argue that the maximum concentration limit of lead should be 3 % as this is the limit proposed in Swedish legislation to accommodate the use of non-lead ammunition: some manufacturers produce non lead expanding bullets/ammunition for hunting in centrefire calibres out of brass with a lead content of around 3 % for technical production reasons. Consequently, if a maximum concentration of 1 % lead in "lead free" bullets is allowed, some products on the market would be excluded and it will be more difficult to meet the demand of alternative bullets.

- The California legislation sets the maximum lead content in bullets at 1 % maximum, so compliant ammunition must be available given the size of this market.
- An important consideration with hunting ammunition is that it is designed to expand upon impacting the animal. With lead-based bullets it is precisely this process of expansion that results in the fragmentation of lead and consequent depositing of lead in meat intended for human consumption. This fragmenting of bullet material does not occur with non-lead ammunition such as brass or copper. The section on bullet design in Annex D.1.4.2.3 makes reference to a study of Gremse et al. (2014) where it was concluded that the use of solid bullets made of brass (with about 3-4 % of lead) did not result in a significant deposition of fragments. This conclusion would suggest that the use of both brass and copper-based bullets even with a concentration of 3 to 4 % would not result in significant contamination of game meat.

Similar to the considerations during the development of the restriction on the use of lead gunshot in wetlands, a lower concentration limit (e.g., 0.3 % w/w which corresponds to the generic concentration limit for reprotoxic constituents) might be too stringent to achieve in practice for the manufacturers.

2.3.2.2. Restriction on 'placing on the market' and/or 'use' (paragraphs 1 and 2)

'Placing on the market' should be understood as 'placing on the EEA market (i.e. EU + Iceland, Norway and Liechtenstein)' as defined under REACH Article 3(12), i.e. 'supplying or making available, whether in return for payment or free of charge, to a third party. Import is deemed to be placing on the market'.

'Use' should be understood as 'use' as defined under REACH Article 3(24). The use definition under REACH is broad and includes 'keeping' and 'any other utilisation' such as hunting, shooting, or fishing. The term 'use for fishing' should be understood to correspond to the actual act of using fishing tackle to catch a fish in the field, not to the production of sinkers or lures.

2.3.2.3. Fishing tackle (paragraphs 1, 2 and 3)

The proposed restriction targets fishing tackle that is known to be made from or to contain lead, and for which a risk for human health and the environment needs to be addressed:

- 'Sinker': a weight that is attached to a fishing line or net to keep it under the water, or to keep the fishing line in a certain position. Fishing sinkers can be attached to the fishing line, or net, using a variety of techniques, for example: crimping on the line, tying to a loop on the sinker, or, threading the line through the hole in the centre of the sinker, etc.
- 'Lure': an object that is used to attract fish or animals, so that they can be caught. Lures might in addition perform the same technical function as sinkers.
- 'Wire': metal in the form of thin thread often cut in smaller pieces and used as a sinker in certain types of lures.

The restriction wording does not make any difference regarding how and by whom the lead fishing tackle has been manufactured. For example, home-casted fishing tackle that is sold would be captured by the ban on placing on the market, and home-casted fishing tackle for personal use would be captured by the ban on using lead fishing tackle.

The proposal excludes lead fishing nets, ropes and lines from the scope of the proposal where lead is embedded, because no risk for birds, nor the human health has been identified for these types of fishing tackle. Lead is indeed threaded or enclosed and lead does not wear out, and lead from this fishing tackle is not typically ingested by birds.

It is important to note that if sinkers would be added on fishing nets, e.g., barrel-shaped sinkers added on purse seine nets (cf. Annex A), these would fall under the definition of fishing sinkers and would therefore be subject to a ban with a transition period as described in paragraph 4.

As the sinkers, lures and wires, subject to the proposed restriction, might have different shapes, names or terminology (e.g., 'sinker' can also be called 'weight' or 'ballast' etc), the Dossier Submitter is proposing a broad definition of 'sinker', 'lure', and 'wire' in paragraph 7 of the proposal. Coated lead sinkers, lures and wires would also be captured by this definition if the content of lead is > 1 % w/w.

In addition to lead fishing tackle, the restriction is also targeting the use of 'Fishing tackle and fishing rigs for intentional drop off sinkers' (paragraph 3). This provision should be understood as equipment (e.g., systems that allows lead sinkers to be deliberately released in water by the fisher when fishing) or technique used to intentionally drop-off lead sinkers to the environment. Examples of such equipment or rig are provided in Annex D (section D.4.5.2). The condition set in paragraph 7 can only be enforced at the point of use, i.e., during fishing (for both the equipment and the technique). Even though a ban on placing on the market and use of such equipment would have been more efficient than a ban on use only, a ban on placing on the market cannot be proposed as a REACH restriction option because this is beyond the scope of REACH which can restrict a substance or a use, but not a technique or an object that can be attached or set up on a fishing line in order to handle sinkers.

2.3.2.4. Ammunition (paragraph 1, 2 and 4)

As described in Section 1.2, the term ammunition is not appropriate to designate the lead objects in scope of restriction proposal. The term 'projectile' is more appropriate and more specific.

The projectiles in the scope of the Annex XV restriction report can be grouped under the following two main categories:

- **Gunshot to be shot with a shotgun** (also referred as 'gunshot' 'shot' for simplicity in the restriction entry wording); where multiple shots/pellets are contained in a shotshell
- **Other types of projectile** (single): bullet is the most common example, but it includes also full metal jacket (if allowed by the local hunting legislation), slug (single shot/pellet in a shotshell), as well as BB (small metallic ball), airgun pellet, etc.

2.3.2.5. Cut off between small and large calibre rifle ammunition

The Dossier Submitter proposes a cut-off between large and small calibres with the following definitions:

Large calibres: calibres equal to and larger than 5.6 mm. This is considered to include most centrefire ammunition that is relevant for hunting. This covers calibres .222/.223 and larger

Small calibres: it covers any centrefire ammunition smaller than 5.6 mm as well as rimfire ammunition.

The cut-off between small and large calibres is proposed based on the following considerations:

1) the current market availability of small and large calibres.
2) the size of the alternatives that were tested in the scientific literature.
3) the minimum requirements for hunting roe deer, wild boar and larger species in EU Member States hunting legislation; *in general* the minimum requirement is for a calibre of .222/.223.

As the cut-off is relevant for the ammunition that will be used for hunting roe deer and wild boar, it is directly relevant to the benefits of the restriction in terms of reducing lead exposure via the consumption of lead contaminated game meat.

The input from the consultation on the proposed cut-off was two fold: whereas some commenters argued that the limit should be set at a larger calibre size, other commenters argued that the cut-off (and associated transitional period) ensure a timely realisation of health benefits and reflects the current situation in terms of availability of non-lead alternatives (alternative ammunition for calibres .222/.223 or larger is already considered to be technically feasible and available). Based on the input from the consultation, the Dossier Submitter maintained the initially proposed cut-off between smaller and large calibres of 5.6 mm.

Further explanations are provided in Section 2.5.1.2.1, which discusses the input from the consultation on the technical feasibility of non-lead alternatives.

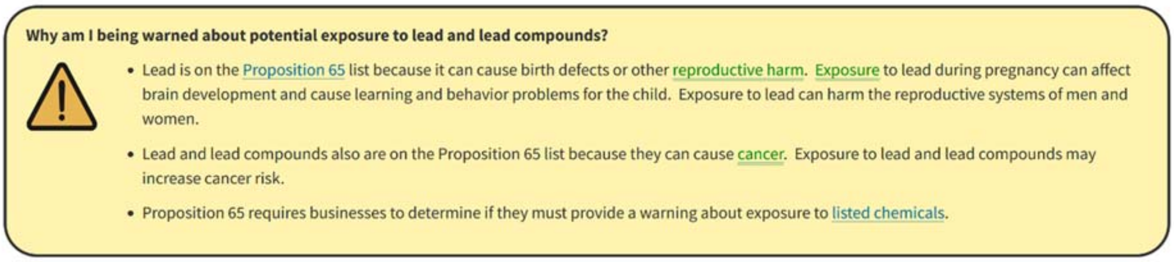
2.3.2.6. Information at the point of sale (paragraph 5a)

This requirement is complementary to the proposed ban on the placing on the market of fishing tackle and lead ammunition (i.e. gunshot and 'projectiles not defined as a gunshot').

It corresponds typically to the first measure in a 'change-management' programme and aims to (i) create consumer awareness of the hazard and risk of lead and (ii) prepare consumers for changing their purchasing behaviour; ideally prior to the end of any transitional period to maximise the human and environmental benefits of the restriction.

The condition on 'information at the point of sale' is NOT a labelling requirement under the CLP requirement, but it is analogous to the CLP regulation (e.g. the 0.3 % concentration limit is from the GCL set in the CLP for Repro 1A substances without SCL, and the proposed wording to be applied at the point of sale is analogous to the relevant CLP hazard and precautionary statements). This condition is targeted to retailers only (only the information is also required to be present on packaging in some instances), and should apply until the relevant ban on placing on the market enters into force.

There might be various ways to 'phrase' such 'information at the point of sale'. The Dossier Submitter is proposing a standard sentence which is inspired from both the CLP Regulation (standard phrases to warn about environmental and fertility toxicity), and the warning requirement to be displayed on lead containing products under the California proposition 65[196]


Why am I being warned about potential exposure to lead and lead compounds?

- Lead is on the Proposition 65 list because it can cause birth defects or other reproductive harm. Exposure to lead during pregnancy can affect brain development and cause learning and behavior problems for the child. Exposure to lead can harm the reproductive systems of men and women.
- Lead and lead compounds also are on the Proposition 65 list because they can cause cancer. Exposure to lead and lead compounds may increase cancer risk.
- Proposition 65 requires businesses to determine if they must provide a warning about exposure to listed chemicals.

Figure 2-2: Warning for lead containing products under California proposition nr 65.

Based on these elements, the Dossier Submitter is therefore proposing the following sentence to be displayed at the 'point of sale':

'***WARNING****: this product contains lead which is toxic to the environment and may damage fertility or the unborn child. The use of lead in this type of product will be restricted in the EU from [EiF+TP as specified in paragraph 7]. More information, including on the availability of lead-free alternatives, is available from [www.echa.europa.eu]'.*

With regard to this requirement, 'point of sale' should be understood as a place where a customer executes the payment for goods or services (and where sales taxes may become payable). The transaction may occur in person (i.e. at a retailers premises) or online. The information should be placed in close proximity to the lead-containing items being sold, such that the consumer would be expected to see it when making their purchase.

2.3.2.7. Labelling requirement (paragraph 5b and 5c)

Lead massive, as well as lead in articles, are exempted from the labelling obligations under the CLP.

Paragraph 5b (projectiles other than gunshot, i.e., bullets and airgun pellets)

The labelling requirement in **paragraph 5b** is analogous to the CLP requirement, and would apply only to projectiles other than gunshot, as these projectiles will continue to be placed on the market with restricted uses (i.e. for sports shooting only):

- the 0.3 % threshold is analogous to the GCL set in the CLP for Repro 1A substance without SCL.
- the type and position of labelling is also analogous to the CLP requirement (cf. CLP Regulation: 'the **product packaging** is clearly, visibly, and indelibly labelled with the information (…). The labelling shall be in the official language(s) of the Member State(s) where the articles, are placed on the market, unless the Member State(s) concerned provide(s) otherwise. If the packaging is too small, and the information (…) cannot be provided on the packaging, this information can be provided in fold-out labels (leaflet); or on tie-on tags).

In addition, the proposed wording to be displayed the label is inspired from the CLP Regulation, and similar warnings required for lead containing products under California

[196] https://www.p65warnings.ca.gov/fact-sheets/lead-and-lead-compounds

proposition 65:

'***WARNING****: this product contains lead which is toxic to the environment and may damage fertility or the unborn child. The use of lead in this type of product will be restricted in the EU from [EiF+TP as specified in paragraph 7]. More information, including on the availability of lead-free alternatives, is available from [www.echa.europa.eu]'.*

Paragraph 5c (gunshot)

The labelling requirement in **paragraph 5c** is somewhat different and is intended to work in conjunction with the optional derogation 4a and 4b, and the conditions set in paragraph 6. This means that additional labelling requirement would apply to shotgun cartridges only in the event that the derogation for use of lead gunshot for sports shooting is preferred to a ban.

Labelling was recommended by RAC in their opinion on the proposed restriction of lead in gunshot in wetlands and would aid the enforcement of the restriction for hunting in the event that lead gunshot was still permitted to be placed on the market for sports shooting. Therefore, in addition to the information listed under paragraph 5a, the Dossier Submitter is proposing the following information is applied to the gunshot cartridge itself containing lead gunshot (i.e. not the product packaging) in case a derogation for sports shooting is preferred to a ban

- 'Contains lead: do not use for hunting'.

Input from the consultation

FACE (#3467) commented that the proposed labelling requirements would constitute a conflict with the 1969 CIP convention and would entail increased costs to manufacturers. AFEMS raised concerns of similar nature and pointed out to further practical obstacles such as e.g. the size of airgun pellets and other smaller sized projectiles where no place is available for any such markings as proposed by the Dossier Submitter.

The Dossier Submitter highlights that the proposed restriction does not require that individual 'projectiles other than gunshot are' labelled, but rather that the product packaging contains the required information. Multi-lingual labels can be used and are already commonly used throughout the single market. See also paragraph 5b of the proposal. The term product packaging is interpreted in line with the CLP regulation.

Should the optional conditional derogation for lead gunshot be preferred by the decision maker, then individual gunshot cartridges would indeed be required to be labelled 'Contains lead: do not use for hunting' – as per the paragraph 5c of the proposed restriction. This is to facilitate enforcement in the field. Alternatively, the plastic parts of lead gunshot cartridges could be required to be made of a single harmonised colour to aid immediate visual identification in the field – for example, red.

2.3.2.8. Licensing scheme for sports shooting with lead gunshot

The licensing of athletes (users) and the permitting of outdoor shooting ranges (sites) is considered to be an essential element of the conditions of the optional derogation for sports shooting with gunshot. The elements are intended to work together to ensure that (i) any continued use of lead gunshot for sports shooting is conducted only by those that are strictly required to do so in order to participate in international shooting competitions (including training for such events) and that (ii) the use takes place under conditions of use that minimise the risks to the environment (and human health via the environment).

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The conditions of the restriction are not prescriptive in terms of how the licensing system should be precisely implemented. This is because Member States specific considerations should be taken into account during the implementation i.e. it may be possible for the requirements to be readily integrated into existing schemes. Nevertheless, the conditions of the proposed restriction establishes a harmonised requirement across Member States for such schemes to be designed and implemented and for regular reporting to the Commission. The rationale for the various elements of the licensing scheme are as follows:

1. It is assumed that the prerequisite for a Member States to license an individual (athlete) to use lead gunshot is that it is required to allow participation in the Olympic games or other international competition, or the qualification for such an event.
2. It is assumed that the prerequisite for retailers to continue to sell lead gunshot is that they operate with an existing licence for the trade of firearms and ammunition in their respective Member State. In the Annex XV report it was initially proposed that retailers would need to be licensed to continue to sell lead gunshot. During the opinion development process, the Dossier Submitter reconsidered the justification for such a condition and in the revised proposal the licensing requirement for retailers has been removed.
3. It is assumed that the prerequisite for a Member States to permit a notified outdoor location for sports shooting with gunshot on which (inter)national events or training for them may take place is that sites meet the minimum conditions of the restriction with respect to record keeping and the regular recovery of lead gunshot (as outlined in paragraph 4b).

The Dossier Submitter notes that sports shooting is typically supervised on a national level by national authorities. Whilst the restriction requires Member States to license individuals and permit sites, close collaboration with national authorities will be necessary. In some instances, it may be practical for Member States to delegate responsibility for the organisation and implementation of certain elements of the licensing scheme to national authorities.

For example, the Dossier Submitter expects that a system of recognition for (inter) national athletes exists in the majority of Member States in order to identify, develop and eventually select athletes to represent the Member State in (inter)national competitions, including the Olympic games. With such a system, a 'pool' of athletes is generally well known to the national authority. As these athletes are striving to participate in ISSF/FITASC events these would then be the athletes that are most likely to be required to use lead gunshot, either in competition or in training.

Such pools of athletes are often created in the run up to Olympic Games or World cups as part of a development programmes of national sports shooting organisations. This pool is likely to be updated annually or more frequently, according to the system the Member States maintains to recognise (inter)nationally competing athletes i.e. as athletes retire they would leave the pool to be replaced by the next generation of athletes.

The licensing scheme envisages that Member States establish a (paper-based) scheme that keeps track of which athletes require a license to use lead gunshot. The Member States would be expected to issue a license for those individuals for use in their Member State for a reasonable duration. Such a system would then allow retailers to 'place on the market' lead gunshot for the identified athletes. Such a system is closely related to existing systems and, as such, would not be expected to cause a disproportionate additional burden to neither public administration nor to commercial operators. Further details of how a system could be implemented by Member States is elaborated in the sections below.

2.3.2.8.1. Individuals (athletes) using lead gunshot

Eligibility

Eligibility for using lead gunshot for training and for participation to competitions is determined based on standard criteria for participation to ISSF/FITASC competitions where the use of lead gunshot is currently required.

Within Member States, shooting federations exist that organise national competitions but also govern, in collaboration with ISSF/FITASC/MLAIC and other international organisations, the participation of the national athletes. These athletes often form the 'national selection': a group of individuals (athletes) that are selected, based on their performance and qualification, to represent national sports shooting federations (or Member States) at international competitions.

Examples of qualification procedures are given on the website of the Dutch shooting association[197], or the German shooting federation[198] of the French qualification system[199].

Application and nomination

The issuing authority is, in principle, the Member States who could develop a scheme that was sufficient for their particular circumstances. However, it is foreseeable that this authority may be delegated in a Member State to national sports shooting federations. Qualification for an international competition, such as the Olympic Games or world championships could automatically result in the issuing of a licence to use lead gunshot in competitions and in practising for competitions.

Member States, in cooperation with national sporting federations, already issue letters/ statements of selection. Such documents, when confirming the type of qualifications achieved (i.e. for an international competition), could be considered de facto as the justification for a Member State to license the use lead gunshot.

Once a license is issued, an individual can use lead gunshot at permitted areas in their Member State and can use their nomination letter/statement to demonstrate that they

[197] https://www.knsa.nl/media/2777/kwalificatieprocedure-deelname-wk-ek-world-cups-in-issf-disciplines-2022.pdf
[198] https://www.dsb.de/fileadmin/DSB.DE/PDF/PDF_2022/Kadernominierungskriterien_2022.pdf
[199] https://www.fftir.org/images/documents/code_de_la_performance_version_finale_20_02_2020_modifie_.pdf

are entitled to use lead ammunition.

Copies of these documents (letters/statements) could be retained by the permitted sites or retailers to demonstrate compliance for enforcement purposes.

A licensing document (letter/statement) could include the following:

1. The achieved nomination/qualification (within the relevant qualification process/es)
2. The international event type(s) the shooter is nominated/qualified for
3. The date of expiry of the nomination and therefore the date of expiry of the authorisation to purchase/use lead gunshot

Comply with a license – demonstrating eligibility

To comply, shooters could demonstrate their eligibility to purchase/use lead gunshot to any enforcement authority (or operator of a permitted site) by showing the original letter of nomination (or an authorised copy of it) and their ID (e.g. identity card, passport and/or any document that according to national legislation is recognised to one's identity).

Enforcement – verify eligibility

The nomination of an athlete is often publicly known and lists of recognised athletes are published on the websites of national shooting federations (see for example the website of the French ministry for sports[200] where it is publicly announced which shooters are in national elite sport programmes, their names and the sites where they practice).

Such lists together with the nomination letter can be used by enforcement authorities to inspect whether a user is entitled to use lead gunshot.

End of a license

Licenses expire upon the end of their validity. Should a shooter no longer be part of the eligible athletes, then their license is revoked and this is then reported on the website of the national sports shooting federation. Alternatively, issued licenses could have an expiration date.

2.3.2.8.2. Retailers

Athletes need to acquire lead gunshot. This can be done via the national sports shooting organisations and/or via individual shops which are both considered to be 'retailers'.

The assumption is that ammunition retailers already have gone through an extensive licensing system to be able to place any gunshot on the market.

The restriction does not require that retailers are permitted to sell lead gunshot in addition to their existing permit to sell gunshot (for all other purposes such as hunting of sports shooting). They would need to ensure that they only placed lead gunshot on the market for use by licensed athletes.

Justify purchase of lead gunshot

[200] https://www.sports.gouv.fr/pratiques-sportives/sport-performance/sport-de-haut-niveau/article/liste-ministerielle-de-sportifs

Retailers/shooting federations[201] could justify lead gunshot purchase by referring to the athletes (specific ones) that are their customers/associated members and therefore inter alia order lead gunshot on the athletes' behalf. Records of ordering, selling and distribution of lead gunshot would typically need to be retained in the event of enforcement, clearly indicating for every order the quantity of lead gunshot as well as the name of all the licensed athletes lead gunshot is intended for.

Any licensed shooter would have to order lead gunshot at a retailer via the normal distribution channels already in place for the purposes of selling gunshot. As the restriction option covers placing on the market, no stock should be kept at a retailer for general selling. Only ordered gunshot should be kept until sold/resold to the licensed shooters. The justification to supply lead gunshot comes from the direct demand of eligible athletes.

Compliance is carried out by means of inspections of the order book which keeps track of the individual athletes that have purchased lead gunshot and the amount of lead gunshot they have ordered. Inspectors could in this manner verify whether any purchase of lead gunshot is in compliance with the derogation proposed.

2.3.2.8.3. Permitted sites

The third layer of the licensing scheme is related to the outdoor shooting range where shooting with lead gunshot takes place. Such a site must meet all the conditions foreseen by the restriction proposal. If so, the site can be permitted by the Member State for the use of lead gunshot. There are numerous existing examples of outdoor shooting ranges that can achieve >90 % recovery of lead gunshot.

Permitted sites - conditions of restriction

Table 2-12 below gives an overview of the conditions of the restriction and explains how these conditions can be demonstrated to be met by operators of a shooting range wishing to be permitted for the use of lead shot by a Member State (MS).

Table 2-12: Conditions and demonstration of compliance

Condition	Means to demonstrate compliance
Permitted by MS after an inspection to ensure that RMMs allow 90 % lead gunshot recovery per year (based on previous year's use) to be achieved	Verifiable well kept system showing records of used and recovered amounts of lead. The records of such a system must be kept always available for enforcement by national authorities The records should allow inspectors to compare element a (see below) with element b (see below) and judge whether the 90 % is met
a) Permitted sites would need to retain records of the quantity of	This will require sites to be auditing the use of lead gunshot and collecting lead

[201] When shooting federations place orders on behalf of athletes, they are essentially acting as a retailer.

lead gunshot used and by whom (training and events)	gunshot prior to the entry into effect of the restriction (at least for 12 months); The standard load weights are known (26 or 24 grams) for sports shooting. Record keeping of a) names of athletes, b) standard load weights used and c) amount of gunshots fired could be readily kept. This would enable a site to estimate the amount of lead gunshot that is used annually.
b) Permitted sites would need to retain records of the amount of lead gunshot recovered	This will require sites to maintain records of the amount of lead that is recovered. A record must be kept of any recovery action, detailing the amount of lead gunshot that is recovered (in kg) and the date at which the recovery took place. Lead gunshot could be readily distinguished from any steel gunshot used at a site by magnetic separation.
Permitted sites would need to retain records of surface water monitoring and treatment (where necessary)	Records of surface water monitoring and treatment must be kept. Compliance with WFD EQS can follow the standard methodology applied under this legislation.
Retain details of athletes	Names of nominated athletes must form part of the bookkeeping under element a)

2.3.2.8.4. Hosting (international) competitions

International competitions where according to ISSF/FITASC rules lead gunshot must be used can be organised at permitted shooting ranges:

- If athletes would be eligible to use lead gunshot within their own Member States, then mutual recognition of EU licencing schemes could entitle them to use lead gunshot at events hosted within another Member State. Alternatively, the Member State hosting the event could issue licenses for all athletes participating in the competition. For all events, the record keeping system required to demonstrate compliance with the conditions of the restriction (number of gunshots fired and quantity of lead recovered) must be kept.
- If (internationally qualified) athletes from outside of the EU would be invited to an event, then the organiser can justify the use of lead gunshot by these non-EU athletes by means of the participation number and the registration of their names, which should appear in the bookkeeping system of the sites at which the event takes place.

Enforcement

The availability and implementation of RMMs can be inspected. However, the element of the restriction that is enforceable is the percentage recovery, and not the specific RMMs implemented to achieve it. Whether or not the RMMs allow the recovery of at least 90 % of lead gunshot used, should be done on the basis of the book-keeping system. This book-keeping system must be up-to-date and be always available to the enforcement authorities and must form part of site inspections.

End of permit

It is envisaged that permits would be granted on an annual basis (after auditing of the recovered quantity of lead). Regular inspection of sites would enable Member States to collate the information needed for annual reporting to the Commission.

2.3.2.8.5. Proportionality

The Dossier Submitter envisions a system that builds on existing systems and would not require setting up different new administrative layers:

- Athletes' eligibility to participate in international events constitutes the baseline to buy lead gunshot.
- Retailers can use existing purchasing channels to buy lead gunshot and use athlete's eligibility documentation to justify buying lead gunshot.
- During periodically planned inspections of shooting ranges (limited to previously permitted ranges), the effectiveness of RMMs can be verified based on record keeping.

Therefore, implementation of such as scheme does not appear disproportionate.

2.3.2.8.6. Checks and balances

The system builds on good practices (in the form of book-keeping) and on the record keeping of existing qualification processes of athletes as well. Both are assumed to be working well. A well-maintained book-keeping is necessary for a retailer for accounting purposes and licenses for selling ammunition. Clear and transparent nomination/qualification processes are necessary for any international qualification process as well as for any funding that may come from a Member State engaged in elite sport programmes.

Additional checks and balances can be carried out during inspections of e.g., the amount of lead gunshot a single athlete uses per year at authorised ranges, compared with the amount of lead gunshot purchased in a year. Large discrepancies would have to be justified.

The requirement for regular reporting to the European Commission envisaged in the conditions of the proposed restriction would highlight if any Member States is licensing/permitting disproportionate amounts of lead gunshot.

2.3.2.9. Transition periods (paragraph 7)

2.3.2.9.1. Transition periods for fishing

Transition periods for fishing sinkers, lures and wires (paragraphs 7a, 7b)

The main drivers to define the length of the transition period are the availability of alternatives, and the capacity for the European industry to switch to the production of alternatives. A ban without any transition period would most probably mean an immediate closure of the remaining European lead fishing tackle producers, and a loss of activities for the retailers as there is currently in Europe not enough capacity in the production of alternatives to absorb the existing market. In addition, enough time is needed for the sector to research and develop new alternatives.

The two-step approach transition period proposed for the sinkers and lures would provide enough time for industry to develop and place on the market alternatives and then to adapt its existing manufacturing equipment. A shorter transition period (3 years) is proposed for lead sinkers and lures ≤ 50 g because this size of fishing tackle can be both ingested by birds, and home-casted, while the lead sinkers and lures > 50 g present essentially a risk for the human health associated to the home-casting practice.

Finally, as alternatives to lead wires are already widely available in retailers' shops, no transition period is proposed for this type of fishing tackle.

Transition period for fishing tackle and fishing rigs for intentional drop off sinkers (paragraph 7c)

Considering that these novel fishing tackle and fishing rigs cause an intentional release of lead to the environment, and considering that techniques, and fishing tackle exist where the sinkers are not drop off. No transition period is granted.

2.3.2.9.2. Transition periods for hunting

Transition period for gunshot (paragraph 7a and 7b)

In the initial assessment of the Dossier Submitter, a transition period of 5 years was proposed due to the wide availability of alternative gunshot. However, some indications exist that, given the scale of lead use, even longer transition period may be required. During the consultation of the Annex XV report, comments were submitted that argued in favour of both a longer and a shorter transition period. Since no specific information was submitted that would justify transition periods longer or shorter than the one proposed by the Dossier Submitter, the initial transition period of five years is therefore retained.

The input from the consultation on this aspect is discussed in section 2.5.1 as well as section 2.5.4.1 which also provides a table with arguments for a short (0-3 year), a medium (3-5 year) and a longer (5-10 year) transition period.

Transition period for bullets (paragraph 7e and 7f)

Large calibres (5.6 mm centrefire and larger)

Alternatives are already widely used throughout Europe and obligatory in several jurisdictions. Most manufacturers have set up production lines that make CIP compliant non-lead bullets. For non-CIP countries, US produced bullets approved by the Sporting Arms and Ammunition Manufacturers' Institute (SAAMI) can be used as well alongside CIP approved ammunition.

Input from the consultation on the Annex XV report

The initial assessment of the Dossier Submitter is that 18 months would be enough time as a transition period. However, information from the consultation suggest that longer transition periods might be warranted. The key argument brought forward is that ammunition manufacturers need more than 18 months to set up new production lines or expand existing lines based on comments that a fully functional ammunition production line takes at least 2 years to set-up and operate. Shorter transition periods were considered to pose challenges in terms of commercial distribution logistics as well as in the acquisition of relevant machinery to produce ammunition. Comments argued that a five-year transition period was considered to be the minimum in order to ensure an adequate supply of ammunition would be available to hunters.

The input from the consultation on this aspect is discussed in section 2.5.1 as well as section 2.5.4.1 which also provides a table with arguments for a short (0-3 year), a medium (3-5 year) and a longer (5-10 year) transition period.

Small calibres (smaller than 5.6 mm centrefire, and rimfire cartridges)

For small calibres further R&D is reported to be required. However, it should be noted that some US companies have reacted to California's regulation and have started to market lead-free ammunition of smaller calibres. The recent introduction of the same size calibres by RWS, Norma and CIC on the European market could result in the rapid adaptation of this calibre group in the EU as well. The Dossier Submitter identified three options to deal with this group of calibres:

a) Exempt altogether the calibres for small game and accept remaining emissions of around 14-17 tonnes per year (previously assessed to be 30-40 tonnes per year).

b) Implement a long transition period (5 years or longer).

c) Recommend a review clause in the conditions of the restriction to ensure that it does not enter into effect until alternatives with sufficient performance are available.

The Dossier Submitter has concluded that (i) based on the present state of the market (some alternatives available) and (ii) the possibility of increased import of US-made calibres a longer transition period than for larger calibres should be proposed. This transition period should be five years long.

Input from the consultation

The following main issues have been raised during the Annex XV consultation:

- Several tests have demonstrated a lack of accuracy of non-lead small calibre ammunition (and in particular for rimfire ammunition, .22 LR) compared to conventional lead ammunition (e.g., comments #3262, #3226, #3252, #3331).
- This level of accuracy may reduce hunting effectiveness compared to lead ammunition (comments #3247, #3190).
- The use of rimfire calibres for hunting appears to be limited to applications for which no human consumption of game meat is foreseen. An exception may be the use of certain rimfire calibres in Nordic hunting (along with Full Metal Jacket bullets) (comment #3173).
- The use of rimfire ammunition causes only a limited release to the environment compared to other calibres (comment #3237).
- The use of rimfire is important (as mentioned by several commenters, see e.g., #3262) in the control of invasive species.
- Gun compatibility issues due to limited choice of suitable alternatives were mentioned (#3252).

The following proposals were made by stakeholders in the consultation:

- Permanent derogation for rimfire bullets (comment #3262 ; #3467)
- A longer transition period, such as 10 years, with a review of the technical feasibility of alternatives, before any further restriction becomes effective comment #3331.

The Dossier Submitter verified the main arguments brought forward and has considered the advantages and disadvantages of each of the options above in Table 2-16 in Section 2.5.1.2.1.

Although alternatives to lead ammunition in calibres <5.6mm are available, there remains some uncertainty as to whether their current technical performance (in terms of precision) is adequate for hunting. The proposed transitional period of [5 years] will allow the further development of these alternatives. However, the inclusion of a review of technical feasibility prior to the entry into effect of this element of the proposed restriction will ensure that socio-economic impacts at the point that the restriction enters into effect are not disproportionate. If the technical feasibility of alternatives is not sufficient at the point of review the duration of the transitional period could be extended. This approach is similar to that proposed in the opinion-making on the proposed restriction on intentionally-added microplastics. The Dossier Submitter acknowledges that there are legal difficulties in proposing review clauses in the conditions of the restriction, but includes here for sake of clarity of intention.

2.3.2.9.3. Transition periods for sports shooting

Transition period for the derogations for sports shooting (paragraph 7g)

The transition periods originally proposed for sports shooting with lead gunshot (5 years) and bullets (18 months for large calibre and 5 years for small calibre) were the same as for hunting and were mainly based on the availability of alternative ammunition.

Input from the consultation

AFEMS (comment #3331) requested a transition period of at least 5 years for sports shooting with all ammunition types; they considered this for practicality reasons due to the overlap in the use of different types of ammunition (rimfire, centrefire, pellets, by different types of users (sports shooters, shooters out of scope of the restriction) on the same shooting ranges.

The Danish Shooting Federation (comment #3516) noted that it is not possible to meet the proposal’s goals and intentions that all sports shooting ranges should be able to collect 90 % lead bullets 18 months after the proposal has been politically adopted.

Following the information submitted during the consultation, the Dossier Submitter considers a revised transition period of 5 years to implement RMMs required for the continued use of lead gunshot and bullet for sports shooting (any calibre) is reasonable and impacts were assessed based on this implementation timeline. However, taking into account additional considerations surrounding the availability of funding/financing, the need for potential remediation of existing contamination and local planning approvals, implementation may feasibly require more than 5 years.

In addition to the timeline for the implementation of the RMMs, the Dossier Submitter further proposes an 18 month transition period for (i) the notification of outdoor sports shooting locations using lead bullets and (ii) to ensure that no agricultural activities take place at that location. The main justification is that such a notification will allow the Member States to get an overview on available locations and to develop a national strategy on the implementation of required RMMs for which a longer transition period will be proposed. With this obligation, the task of enforcement would be alleviated. A problem encountered during the development of the dossier has been that national authorities often have little to no overview of the number of sites where sports shooting takes place. Having a better understanding of where these sports shooting sites are located would allow more targeted enforcement.

It will also allow to restrict the agricultural use of shooting ranges or areas and to prevent potential risks for humans related to this agricultural use.

A step-wise implementation of the requirements ensures that risks begin to be addressed, even in the event that the timeline for full implementation of RMMs is extended beyond the originally foreseen five years.

2.3.2.9.4. Transition periods for information to consumers at the point of sale (paragraph 7h)

A short transition period of 6 months is proposed in order to quickly raise the consumers' awareness regarding the hazard and risk of lead for the environment and the human health. The proposed restriction condition would need to be implemented at the point of sale, i.e. either on the retailing website or at the retailer shop and would not require major revamping or adaptation at the point of sale. Therefore, a short transition period is proposed.

2.4. Approach to impact assessment

There are various uses of lead in ammunition and fishing tackle which involve different sectors and different stakeholders in the value chain. Exposure and releases to the environment vary also depending on the type of use. Because of different technical functions needed for each use, the readiness, availability and costs of suitable alternatives vary also among the uses. For the purpose of this impact assessment, the uses are therefore grouped into three overarching sectors: hunting, sports shooting and fishing.

Because of the differences in the identified uses of lead, different restriction conditions are proposed, and use-specific impacts are expected from the restriction. This is particularly true for the risk reduction capability, the costs, benefits and other socio-economic impacts of the proposed restriction. In order to recognise these specificities, separate impact assessments (incl. risk reduction capability (effectiveness), costs, socio-economic aspects and proportionality) are carried out for the different sectors of use concerned by the proposed restriction, i.e. for the use of lead in hunting, sports shooting and fishing. Details are provided in Annex D.

The practicability of the proposed restriction including its implementation, manageability, enforceability and monitorability is also discussed for each individual sector.

The geographical scope of the impact assessment is the European Union as of 2020 (i.e. excluding the UK); at times the abbreviation EU27-2020 is used in the Annex XV report. The Dossier Submitter recognises and acknowledges that once adopted the proposed restriction will also apply to EEA States, but because of a lack of data for Iceland, Liechtenstein and Norway, impacts in these countries were not assessed specifically.

Regarding the timeline for the impact assessment, 2022 was assumed to be the first full year of entry into force of the proposed restriction, and a 20-year period was assumed as horizon of the impact assessment. Unless otherwise noted, all costs are expressed in 2020 € (i.e. costs are discounted at 4 % discount rate to the study reference year of 2020, and expressed either in Net Present Value (NPV) or in annualised costs over the 20-year period).

For most of the sectors, a conclusive quantification of the benefits expected from the restriction is not possible due to a lack of data and the non-threshold character of lead with regard to children's exposure (neurotoxicity). This specificity makes it challenging to quantitatively demonstrate that the benefits of the proposed restriction outweigh its costs. Instead, the Dossier Submitter has adopted a cost-effectiveness approach considering releases of lead as a proxy for risk and complemented this analysis wherever possible with a quantitative cost-benefit approach.

2.5. Impacts of a restriction on lead in hunting (uses 1 and 2)

The preferred restriction conditions for lead in hunting (uses 1 and 2) are a combination of the following elements:

- Ban on the placing on the market and use of lead gunshot for hunting;
- Ban on the use of lead bullets for hunting to be introduced in a two-step approach, with
    - a transition period of [18 months] for large calibre (≥5.6 mm centrefire) lead bullets for hunting,
    - a transition period of [5 years] for small calibre (<5.6 mm centrefire and rimfire in general) lead bullets for hunting;
- Compulsory information on the hazards of lead and the risks of using lead ammunition at the point of sale and (for use 2) on product packaging..

The choice of the limit of 5.6 mm centrefire is made because:

- 5.6 mm centrefire is in many hunting legislations regarded as the minimum calibre for hunting roe deer and larger animals.
- The smallest calibre size that was successfully tested in comparisons of lead and non-lead ammunition is 5.56 mm centrefire (.222 and .223 calibre).

These arguments are further developed in Annex D.1.1.

The understanding of the Dossier Submitter is that, based on existing hunting legislation, advice from manufacturers etc. three groups of animal species can be distinguished per use: game birds, small game mammals and large game (see Table 2-13). A detailed analysis of species falling into these groups is described in Annex D. From that, the Dossier Submitter infers that a general ban on lead in hunting (gunshot and bullets) would lead to different impacts for the hunting of the different groups as summarised in Table 2-13.

Table 2-13: Groups of animal species relevant per use

Species group	Species or groups of species	Use	Volume of lead releases [tonnes per year] associated w/ hunting
Game birds	Waterfowl, pheasants, partridges	Use 1[202]	13 000 to 15 000
Small game mammals	Hare, squirrel, musk rat, beaver, rabbit, fox, racoon dog, wild cat, martens, badger, polecat (non-exhaustive list)	Use 1, Use 2a	14 to 17

[202] In some Member States game bird species are also hunted with bullets.

Large game	Roe deer[203], chamois, mouflon, fallow deer, sika deer, ibex, moose, brown bear, wild boar, red deer, seals, wolf, jackal (non-exhaustive list)	Use 2b	92 to 138

2.5.1. Conclusions on alternatives and technical solutions

Hunters affected by the proposed restriction would have to switch to alternative ammunition. The most frequently used alternatives for lead gunshot are steel gunshot and bismuth gunshot (although tungsten-based gunshot cartridges are also available). the most commonly used alternatives for lead bullets are copper and brass bullets. These alternatives are already widely used in the EU and internationally. Annex D demonstrates that they are technically feasible, comparable in price, and have more benign hazard and risk profiles than lead ammunition. Annex C shows that the material used as alternatives (steel, bismuth, copper and brass) are safer and therefore pose less risk to human health and the environment.

2.5.1.1. Availability

Gunshot

Since the concerns surrounding the use of lead shot in wetlands and the consequent fatal poisoning of water birds was raised in the 1970s, several non-lead and non-toxic shot types have been developed and put into commercial production. Steel shot cartridges are produced by most European manufacturers (in the study of Thomas (2014) by **all** companies operating in the EU market). Whilst steel shot is the most common alternative, particularly in the context of waterfowl hunting (Thomas, 2014), many European manufacturers also have production lines for other alternatives, including bismuth and tungsten-based gunshot. North American manufacturers sell a variety of non-lead ammunition types in Europe.

Thomas (2014) reports on a survey of typical online retailers confirming that non-lead gunshot cartridges are widely available to consumers in most EU Member States, but stocks of non-lead ammunition held in local retail shops may be limited in quantity, specification or brand. Hence, a local consumer may not always be able to purchase the most suitable alternative for their specific needs. This should be alleviated already to a large degree by market responses to the upcoming restriction on the use of lead shot in wetlands. Later studies by Kanstrup and Thomas (2019) confirm these findings.

The costs of producing steel shot are comparable to those of producing lead shot even though the raw material is somewhat cheaper. This is because the filling of a cartridge with steel pellets requires more loading time per cartridge than the filling with lead pellets. However, in the consultation on the wetland proposal, one producer of both lead and steel shot commented that technological improvements have been made. For this reason, the Dossier Submitter expects that, in the long run, the retail prices of steel shot will fall further, provided supply and demand of the raw material remain in balance.

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[203] Roe deer can in certain MS also be hunted with shotguns.

The Dossier Submitter carried out an investigation into the commercial availability of three of the common medium gauges – 12, 16, and 20 – used in Europe to hunt small-sized game. Of the three gauges, 12 is the most popular among European hunters. It is available under a wide range of brand names drawing upon a host of alternative materials ranging from steel to tungsten. The least widely-used gauge of the three – 16 – is offered by a very limited number of providers of alternatives and ostensibly only in steel and bismuth. Gauge 20 cartridges are available in steel, copper, tungsten, and bismuth versions, similar to gauge 12 cartridges, albeit under fewer brands. Given that the most common cartridges are 70 mm in length, the Dossier Submitter has collected data for the cartridges of that length for all three gauges.

Given its popularity, it is natural that there are far more non-lead alternatives identified for gauge 12 than for the other two gauges. More specifically, there were 13 lead-based brands identified for gauge 12 versus 5 and 6 brands for gauges 16 and 20, respectively. For steel-based alternatives, the differences were even starker, characterised by the presence of up to seventeen different brands for gauge 12, and 2 brands for each of the remaining two gauges. Gauge 16 was not found in copper version, while for gauges 12 and 20 there were two brands and one brand, respectively. For bismuth, an equal number of brands (2) were identified for both gauges 12 and 16, whereas gauge 20 was found to be available from at least 3 different brands. Lastly, for tungsten, the number of identified brands totalled 10 for gauge 12, whilst no brand was available for gauge 16, and only two brands for gauge 20.

It is expected, based on observations with the introduction of past restrictions, that supply will follow demand, and that an introduction of a regulation will stimulate the development and market introduction of alternatives. It must be noted that this analysis was carried out whilst the wetlands dossier was still under discussion, therefore the availability of alternatives is likely to increase with the implementation of the restriction on the use of lead shot in wetlands.

Bullets

The market analysis by Thomas (2013) suggests that alternatives for the most popular bullet cartridges are available on both the EU and US market. The 37 leading ammunition manufacturers produce a wide range of 35 non-lead bullet calibres cover a wide variety of hunting types. Based on a separate analysis of the European market, Thomas et al. (2016) conclude that product availability (i.e. that which is made) of non-lead rifle ammunition in a wide range of calibres[204] is large in Europe and is suited for all European hunting situations. At least 13 major European companies produce non-lead bullets for traditional, rare, and novel rifle calibres. Local retail availability is now a function of consumer demand, which relates, directly, to legal requirements for use.

Notwithstanding the above, the call for evidence comments highlighted that there are no, or limited alternatives to lead for special hunting situations. The present state of industry capabilities suggests that the following types of hunting would be mostly impacted in case of a restriction on the use of all lead bullets:

- Rimfire hunting (22 LR, etc.), used for hunting the smallest game species and when shooting small predators caught in cage traps. Comments from the call for

[204] The term calibre may apply to the diameter of the gun but can also apply to a set of dimensions (including weigh and length) set by the proofing authority (CIP).

evidence suggested that no equally performing alternatives are available.

- Full Metal Jacket (FMJ) bullets in small game hunting, e.g., Nordic bird hunting. This type of bullet is used for long distances and high accuracy is demanded.
- For calibre 5.6 mm (centrefire) and larger, it is generally accepted that modern, well-maintained, rifles can be used to fire accurately non-lead as well as lead bullets within most hunting situations.
- The Dossier Submitter received information that for seal hunting (where this is allowed for population management purposes) lead bullets are required; this is further explained in Annex D.1.2.2.

The Dossier Submitter notes that small lead-containing calibres are scheduled to be phased out with a longer transition period under the Californian regulation, thereby limiting the use of lead ammunition for hunting purposes (Duncan, 2014). Since the introduction of the Californian regulation, alternatives in that same calibre have been developed (Winchester .22/ RW .22 CCI .22). Given that many of the manufacturers in the US also have distributors in Europe, it is expected that in case of a restriction of these small calibres further developments of alternatives will take place. Currently two European manufacturers (Norma and RWS) offer lead-free bullets (based on food safe zinc) in this calibre, one US brand (CCI) offers a non-lead version for this calibre as well. According to the website of CCI, the company has a distribution network encompassing Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Luxembourg, the Netherlands, Malta, Poland, Portugal, Slovakia, and Sweden, thus covering 21 of the 27 EU Member States.

The Dossier Submitter performed an investigation into the availability of non-lead alternatives for some of the most common calibre types used in the EU. Of all the calibres examined only two calibres of rifle ammunition – . 222 REM and 17 HMR – were found to have fewer than five non-lead alternative brands available, whereas the remaining calibres had non-lead alternatives available from at least five, or sometimes even ten, different brands. Some of the non-lead brands were available for most of the calibre types. Of these KJG-SR (Sax Munitions GmbH), Evolution Green (RWS), ZERO (GECO), TUG Nature+ (Brenneke), Naturalis (Lapua), Ecostrike (Norma), HIT (RWS), and GMX (Hornady) were some of the most encountered brands. Much akin to their lead-based counterparts, non-lead alternatives are available in a multitude of varieties for hunters to choose from, depending on their specific hunting needs and preferences.

Air pellets

Hunting with airgun ammunition is legally allowed only in some Member States (Denmark, Hungary, Sweden). In hunting, lead pellets are mostly used for pest control. As pests are generally not considered as “game”, there is no Union-wide risk to humans from ingesting lead fragments although risk via secondary poisoning cannot be excluded.

Unlike for lead bullets, there are no known studies or peer reviewed tests that would compare the performance of lead and non-lead (often tin) based airgun pellets for hunting. Product reviews on hunting and online purchasing would however suggest that the accuracy of airguns for hobby shooting (which would cover a fair share of use) is adequate. However, these tests or reviews are not conclusive enough to come to a firm decision on product suitability.[205]

2.5.1.1.1. Input from the consultation

AFEMS (#3246, #3331) and FACE (#3467) commented that bismuth is not a credible drop in alternative and it is therefore not a valid assumption that gun owners will switch to bismuth gunshot rather than replacing their shotguns. They argue that the relative scarcity of bismuth and the massive increase in demand predicted in the event of a restriction would drive up costs. They also consider that, as bismuth is not readily recycled, its use in ammunition is not sustainable. A calculation is then presented which – according to the commenter – indicates the non-sustainability of the use of bismuth for sports shooting and hunting.

The Dossier Submitter responds to these comments, as follows:

1. The Background Document states that the use of bismuth for sports shooting with shotguns is not considered a suitable alternative as it is relatively expensive, and sports shooters use larger quantities of cartridges relative to hunting. This would render it prohibitive as an alternative for sports shooting. Therefore, the Dossier Submitter assumes that sports shooters would rather use steel gunshot in case of a restriction on lead gunshot.
2. In hunting, bismuth is typically used in old[206] guns for which replacing lead with steel is often not possible because of concerns of gun suitability for steel.

The main argument AFEMS brings forward relates to the total registered volume of bismuth[207] which is around 10 000 tonnes per year. The argument that is put forward alludes that there are difficulties to increase the share used for ammunition as the use of bismuth in ammunition will need to compete with other uses of bismuth, which AFEMS considers to be more critical.

The stakeholders (#3467, #3331) expressed concern that with a declining lead supply, bismuth (as a by-product of lead mining) would become less available in the future. On this, the Dossier Submitter refers to the statistics of the International Lead and Zinc Study Group (ILZGS) (see also Figure 2-3), showing that the dominant end use of lead is in batteries (80 % of total end use by consumption) which is expected to cover 97 % of the market demand for lead until 2030 implying that lead batteries will continue to remain the dominant type of battery for a long period after 2020 as well. Therefore, mining for lead, and a supply of bismuth, will almost certainly continue.

In response to these comments, the Dossier Submitter updated the Background Document with the information provided and has added a sensitivity scenario, describing the impacts of a lower use of bismuth gunshot and an associated increased replacement of shotguns to use steel gunshot cartridges instead.

[205] Some manufacturers market their lead-free air rifle ammunition as suitable for hunting. Examples of these are the H&N Barracude green line: https://www.hn-sport.de/en/air-gun-hunting/baracuda-green-177 and RWS Hypermatch line: https://rws-ammunition.com/en/products/air-gun-pellets.

[206] No precise definitions exist of 'old guns', various characteristics (construction nitro-proof, manufacturers advice) determine a guns suitability for steel, most critically is to use cartridges that match the guns operating pressure.

[207] https://echa.europa.eu/fi/substance-information/-/substanceinfo/100.028.343

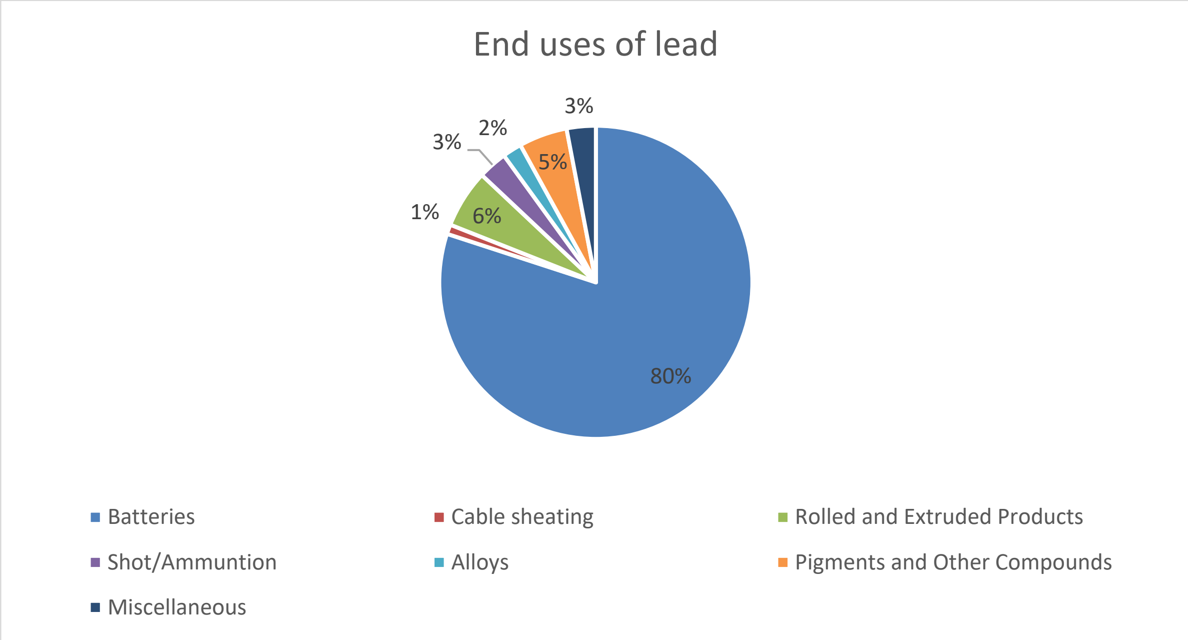

Figure 2-3: End uses (volumes) of lead by consumption (source: https://www.ilzsg.org/static/enduses.aspx?from=1)

Stakeholder comments (#3467 and #3331) suggested that a few shot-gauge sizes (.410, 20 and 28 gauge) would be particularly impacted by this restriction. These stakeholders consider that bismuth is the only suitable alternative for these gauges and that bismuth shot would be available only in limited quantities. However, to the Dossier Submitter's understanding, one can use standard steel cartridges with suitable muzzle velocities in all standard proofed shotguns (whichever gauge). Also, steel gunshot in the above gauge sizes is growing in demand due to regulations of lead gunshot across different jurisdictions.[208] Alternatives in these gauge sizes are placed on the market, and various companies produce already alternative gunshot (including, for example, steel shot at standard pressure) in this range, for example the brand 'Cartouche Jocker'.[209] Gauges 24, 28 and .410 can therefore be used with steel ammunition of appropriate muzzle velocity, but care must be taken with full or super/extra choke to avoid the risk of a ring bulge.

Bulging has been discussed in the Background Document by making reference to a paper from gun manufacturer Winchester published in 1992 by Coburn (Coburn, 1992). The cosmetic nature of this bulging has been re-discussed in various guidance from, for example, the Gun Trade Association[210]. Solutions to avoid bulging exist[211] and would not necessarily imply that hunters would have to buy new guns.

2.5.1.2. Technical feasibility

Gunshot

A hunter has several substitution choices when faced with a restriction on lead gunshot. These choices are, to a certain extent, informed by the proof marks on their gun.

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[208] https://www.ammunitiontogo.com/index.php/cName/410-gauge-steel-shot

[209] http://urubuga.shoothuntingoutdoor.fr/etain-lie/

[210] https://www.gwct.org.uk/media/1094678/GTA_factsheet_shootingnonlead_ver102.pdf

[211] https://www.thefield.co.uk/shooting/adapting-old-guns-for-steel-44454

Unfortunately, prior to the development of standardised CIP proof marks, other proofs were commonly used, adding to the uncertainty hunters may find themselves confronted with in relation to substitution and the suitability of alternative shot for their gun. Some guidance can be found on e.g. the BASC website[212]:

For steel/steel-like shot, a different process is involved. A standard or superior/magnum-proofed gun can fire standard steel shot cartridges, subject to conditions. To fire high performance steel, it must pass a steel shot proof, a more rigorous test of the gun's ability to handle the different pressures (same as high performance lead) and shot hardness of steel/steel-like shot cartridges. A gun successfully passing Steel Shot proof has to be stamped with a Fleur de Lys on its barrel.

Further guidance on when steel shot can be used is given on the website of the Ulm proofing house in Germany, see Table 2-14.

Table 2-14: Overview of possibilities to use steel shot[213]

Calibre	proof		Max operating pressure (bar)	Max allowable shot diameter	Max allowable speed V2.5 (m/s)
	before 2014	since 2014			
20/70	N	CIP N	830	2.6	390
20/70	V	CIP S	1 050	3.25	410
20/76	V	CIP S	1 050	3.25	430
16	N	CIP N	780	3.00	390
16	V	CIP S	1 050	3.5	420
20/76	V	CIP S	1 050	3.25	430
12/70	N	CIP N	740	3.25	425
12/70	V	CIP S	1 050	4.00	430
12/76	V	CIP S	1 050	4.00	430
12/89	V	CIP S	1 050	4.00	430
CIP		All approved non-lead shot can be shot from firearms with this proof mark. It is generally recommended to shoot lead-free shot in larger shot sizes or higher gas pressures; this can only be carried out on weapons with a choke of ≤ 0.5 mm or in connection with the corresponding exchange choke.			

[212] https://basc.org.uk/technical/
[213] Source: https://www.beschussamt-ulm.de/beschussamt/Interne_Dokumente/Dokumente/VF_504_M_Info-Verwendung-Bleifreie-Schrote.pdf

Table 2-14 provides an overview on when steel shot can still be used, highlighting that several possibilities exist to use lead-free ammunition with standard (normal) proofed guns. This is in line with earlier findings (Putz, 2012) that (standard) steel shot can be used in most shotguns (older, pre-1961 and more modern, post-1961) models.

According to the rules of proof, some old (not standard proofed) shotguns should not be used with steel gunshot of any kind[214]; nor can any shotgun be proofed to High Performance Steel level with a chamber length less than 70mm (because of a CIP chamber-length criterion).

In Europe, the regulatory body (CIP) has developed two standards for steel shot shells, called **standard steel** and **high-performance steel**. Similar to standards in the US, the CIP standards set limits for chamber pressure, velocity, momentum and shot size. CIP explained in the call for evidence these regulatory standards are necessary to ensure the steel shot marketed in CIP countries is matched to the range of firearms that are manufactured and used in Europe. The SAAMI standard[215] suggests that the last three of these CIP standards are controls to limit the chance of choke swelling in thin wall barrelled and tightly choked guns.

European gun manufacturers and retailers are often including "proofed for steel" in their advertising for new guns. This means that the barrels and choke tubes have been constructed to ensure choke swelling does not occur, and that higher chamber pressures can be safely used from the CIP's High-Performance group. It does however not mean that an existing gun, without this proof stamp, is inherently unsafe to use standard steel shots that generate lower chamber pressures comparable to those of existing lead shots.

As there are always new hunters taking up this activity, a restriction on lead gunshot means that hunters will have a choice (in ascending order of cost) to:

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

Based on figures provided by FACE during the consultation (#3467), the Dossier Submitter assumes that most hunters will possess at least one shotgun that is standard proofed since most, if not all, shotguns sold after 1970 are standard proofed.[216] Hence, most hunters will have to choose whether to use standard steel or bismuth cartridges.

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[214] Personal communication, John Swift (LAG Group) and Niels Kanstrup (Aarhus University)
[215] https://saami.org/wp-content/uploads/2019/06/ANSI-SAAMI-Z299.2-Shotshell-2015-R2019-Approved-2019-04-23.pdf
[216] Based on a survey of hunters, FACE informed that six million hunters in the EU own 21.62 million shotguns of which 24 % are not suitable for standard steel cartridges. This means that, on average, each hunter owns 3.6 shotguns of which 2.8 are standard proofed.

Only relatively few hunters (assumed to be up to 10-15 %) may see any merit in sending their gun for re-proofing against the high-performance steel specification. Some hunters with magnum proofed guns *may* get them re-proofed for high-performance steel. Further, it is expected that most hunters owning only a gun not suitable for standard steel cartridges will opt for the least costly option and use bismuth (or tungsten) rather than replacing their guns.

Hunters hunting geese or coastal wildfowl who are not prepared to pay for more expensive bismuth or tungsten-based cartridges are more likely to require a gun proofed for high performance steel. However, the Dossier Submitter notes that hunting large birds is even today done with high performance gunshot. Thus, high performance proofing may not be such an issue.

The exact number of guns that would need to be replaced is not known, but the Dossier Submitter reckons that hunters will not replace each shotgun that is not suitable for standard steel cartridges because they own another shotgun that is suitable (see footnote 216). It should be noted that many Member States do not keep a register of shotguns or do not require any registration of the number of shotguns owned per hunter, thus doublechecking the information submitted by FACE against registration data is not possible.

Lead-like shot types like tungsten matrix shot or bismuth-tin shot can be used in any European gun with any type of choke constriction. Also, standard steel shot cartridges can be used in any modern gun suited to fire lead shot. The only possible concern about the use of steel and other hard shot in standard guns pertains to the choke region of the barrel, where large shot (larger 3.5 mm diameter) passing through an abruptly developed, tightly choked barrel could cause a small ring bulge to appear around the choke cones. However, this is widely considered not to be a safety issue, but rather a cosmetic concern (Coburn, 1992).

Practical guidance on the compatibility of steel shot is available for hunters in Germany[217,218,219], France (see also (Baron, 2001)), and Austria (Putz, 2012), and is all of a similar nature, explaining to hunters which sort of cartridges can be used in guns with different proof marks (Table 2-14).

This advice is consistent 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' marking).

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 shotguns.[220] Not complying with these rules can result in 'ring bulging', overload and increased wear and tear in guns.

Hunting success with lead-free alternatives is widely discussed in several studies, a

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[217] http://www.flintenschuetze.de/cms/front_content.php?idcat=119
[218] http://www.jagd-bayern.de/fileadmin/_BJV/Jagd_In_Bayern/jib_2006_07/JiB_7_06_Alternativ_Schrote.pdf
[219] https://www.beschussamt-ulm.de/beschussamt/Interne_Dokumente/Dokumente/VF_504_M_Info-Verwendung-Bleifreie-Schrote.pdf
[220] http://www.chircuprodimpex.ro/produse/alice-non-toxice-de-vanatoare/cip-regulations-on-steel-shot-ammunition.pdf

detailed assessment of which can be found in Annex D. Comments from the call for evidence (Gun Trade Association, British Sports shooting Council) highlighted that non-lead shotgun ammunition has been found to perform effectively in the field.

As for the use of robust guns (side-by-side, over and under, semi-automatics or pump-action guns) designed and proofed for high performance cartridges with lead or non-lead shot, there seems to be no limitations in the use of non-lead shot. Steel shot cartridges of either standard or high-performance quality are regarded to be the most suited option for bird hunting depending on quarry size, hunting conditions, shooting distances.

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

Bullets

From the available studies (Martin et al., 2017, Gremse and Rieger, 2012, Stokke et al., 2019, Trinogga et al., 2013, Kanstrup et al., 2016)[221] it appears that two main factors determine the technical feasibility of alternatives; bullets are compared usually in terms of calibre size ("does the bullet fit in the gun?") and hunting efficiency ("will the bullet not cause unnecessary harm to the animal?"). Evidence suggests that the majority hunters of large game can use lead-free bullets without the need to adapt their guns. Comments from the call for evidence however underline that in specific hunting situations alternatives would require further development.

Non-lead hunting bullets are typically composed of copper or brass (an alloy of copper and zinc) instead of lead. Due to the lower density these bullets are often longer or lighter, and in the latter case need to be faster to transport the same amount of kinetic energy. Non-lead bullets retain most of the mass and produce no or few fragments which pose a health risk to humans.

The suitability of non-lead bullets in hunting is discussed by (Kanstrup et al., 2016) who conclude that for hunting purposes there is no consistent and significant difference between lead containing and non-lead bullet for hunting roe and red deer under normal circumstances. These results are similar to those in other studies (Knott et al., 2009, Gremse and Rieger, 2012). Further studies by Martin et al. (2017) indicate that abandoning of lead as a bullet material for hunting bullets is possible.

In the Italian Alps the use of lead ammunition has been banned in the Stelvio National Park and Sondrio Province, in the Hohe Tauern National Park in Austria, in the Pyrenees, and as part of GypConnect and GypHelp LIFE conservation projects, at the Cévennes National Park in the French Massif Central, and in Haute-Savoie, pilot projects where hunters try non-lead ammunition are being carried out.

These findings on the suitability of non-lead bullets are echoed in the latest advice of the German Bundesrat (German Federal Council, 2020) concluding that more than 15 years of use of lead-free rifle ammunition in large parts of Germany have shown that there are no deficits in terms of killing effect compared to lead-containing rifle ammunition.'

The German Federal Council furthermore concludes that the current minimum legal energy requirements for bullets (1 000 J for Roe Deer[222] and 2 000 J, with 6.5 mm for

[221] A full overview is provided in Annex D.1.2.3

[222] This is understood to be achieved in practice by 5.6 mm centrefire.

large ungulates) can be met by non-lead ammunition. More recently the Danish authorities announced[223] the phase out of lead-based rifle ammunition for hunting, effective from 2023, and then become the first country in the world with a total ban on lead ammunition for hunting (similar to California). This will apply to all calibres and applications but, to the understanding of the Dossier Submitter, not to training and competition shooting (i.e., sports shooting).

The situation is less clear for calibres smaller than 5.6 mm. The recently introduced lead-free ammunition for these calibres has not been extensively tested. Some field tests exist with European hare which did not report equivalent performance to lead (Hampton et al., 2020), whereas other tests exist in the US with the hunting of prairie dogs (McTee et al., 2017, Hampton et al., 2020) which showed that hunting with this type of ammunition can be done without an impediment on hunting success. Some test in the grey literature[224] have indicated that the performance of such non-lead bullets (test performed with Norma .22 Eco strike) has in the meantime improved.

2.5.1.2.1. Input from the consultation on the Annex XV report

Performance of steel gunshot

Several comments were submitted on this topic, for example: #3281, #3293, #3333, #3429, #3467.

Some commenters highlighted that steel gunshot would have a lesser performance than lead shot. For example, comment (#3429) puts in question the performance of steel shot vis-à-vis lead shot and asks for a restriction to be postponed until suitable alternatives have been identified.

On this aspect the Dossier Submitter refers to the numerous studies (discussed and referred to in the Background Document) that have demonstrated based on a systematic, scientific approach that there is no difference in hunting efficiency between lead and steel gunshot if advice on appropriate shot size is correctly followed. More recent research from the BASC has again confirmed these findings.

Bullets

Comments were submitted regarding issues related to several items for which the Dossier Submitter had identified that most impacts from the proposed restriction would occur in relation to:

- Cut-off between small and large calibre ammunition,
- Rimfire ammunition,
- Specific uses of lead such as in full metal jacket bullets, for seal hunting and muzzle loading rifles and (to some extent) in airguns.

<u>Cut-off between small and large calibre ammunition</u>

Extensive feedback was received during the consultation of the Annex XV report on the proposed cut-off between large and small calibre ammunition; in e.g. comments: #3172, #3190, #3220, #3226, #3229, #3236, #3244, #3249, #3250, #3252, #3257, #3290, #3189, #3237, #3248, #3255, #3262, #3257, #3467, #3449. Three main issues were

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[223] https://www.dr.dk/nyheder/regionale/oestjylland/danmark-vil-helt-droppe-blypatroner-i-jagt-som-det-foerste-land-i
[224] https://midwestoutdoors.com/greatoutdoors/norma-ammunition-22-long-rifle-performance-review/

raised concerning the proposed cut-off:

- Hunting legislation does not allow lighter, non-lead ammunition.
- Absence of suitable alternatives: this relates to the current market situation; however, multiple commenters expected that with this restriction the demand for non-lead alternatives will increase.
- Stability of bullets in flight.

Comment #3626 states that although the cut-off is one that the sports shooting and hunting community is unfamiliar with, it is relevant for realising health benefits because of the large number of roe deer that are hunted in Europe. Comment #3626 states that there are some first lead-free products available for common hunting calibres .222/.223 Rem. But the number of products available is small and only little experience of their use in hunting is currently available.

Other commenters found the proposed cut-off. Comment #3252 states that for hunting purposes the smallest calibre normally used in rifles for hunting roe deer is .222 Rem. However, also smaller game is shot with rifles and used for human consumption but in those cases the animals are killed with non-expanding full metal jacket (FMJ) bullets leaving no lead in the animal, according to the commenter. As also mentioned above, the use of expanding bullets for hunting game in Sweden, applies only to game of the size of roe deer and larger. The risk of lead contamination with expanding bullets therefore applies with the use of calibres such as .222 Rem.

One comment (#3449) states that a similar cut-off of 5.5 mm is expected to be used in the phase-out of lead currently proposed in Denmark.

Other comments received were on the following topics:

1. **Hunting legislation:** Many commenters from Sweden highlighted that although alternatives exist that would be suitable[225], these are not allowed to be used in Sweden due the national hunting legislation prescribing bullet weight and energy requirements. This is seen as an obstacle for using non-lead bullets (FACE, #3467), and an important element in maintaining the 5.6 mm separation (#3252).

   The Dossier Submitter does not see these energy requirements as an obstacle. Similar adjustments have been made in the national hunting legislations of Finland and Norway and activities to this end have started in Sweden (comment #3252; ECHA, personal communication with *Naturvårdsverket).* The Dossier Submitter also notes the primacy of EU law and that adaptations to national legislation could be made in the transitional periods before the measure enters effect, if necessary.

2. **Suitable alternatives:** Other comments related to possible stability issues with bullets smaller than 7 mm (#3252), 6.8 mm (#3467) or 6.5 mm (#3236), and the absence of peer-reviewed performance tests for non-lead bullets below 6.5 mm (#3467). On the latter, the Annex XV report contains an overview of peer-reviewed tests as well as practical tests with non-lead ammunition comparing performance with lead ammunition.

[225] https://jagareforbundet.se/contentassets/7099893fd13b45b98e1900d2ea165fee/65x55_se.pdf

From the available studies it appears that the suitability of non-lead centrefire ammunition from 5.6 mm and up (smallest calibre tested: .222 and .223 which is equivalent to 5.6 mm) is well established. The Background Document reports on a study by (Kanstrup, Balsby et al. 2016) that describes equivalent performance of lead and non-lead ammunition for .222, .223, .270, .30-06, 6.5x55 and 308 calibres, or by Hackländer et al. (Hackländer, Hafellner et al. 2015) (calibres used: 5.6x50 R, 6x62 Freres Blaser, .243 Win, .300 Win Mag, .300WSM and 9.3x62) finding no statistical difference in the performance of lead and non-lead rifle ammunition.

As also highlighted in another comment (#3329) there is wide availability of rifle bullets in these centrefire calibres (below .243 Winchester) in Europe. Table 1 of Thomas et al. (2016) indicates that in 2016 four companies were selling assembled rifle ammunition in small calibres: Hornady (.223 Rem), Sako-Barnes (.222 Rem), Sax KGJ (.223 Rem, .22-250 Rem) and Schnetz KG (.22 Hornet, .222 Rem). As of 2021, Lapua, RWS and Nosler provide additional small calibres.

In comment #3329 it is mentioned that there has been a rapid development in the small-calibre products offered by several European and US rifle ammunition producers. These producers provide a large array of bullet types and weights for the smaller calibre cartridges.

The above information indicates that given the availability and choice of bullet types currently offered for sale in Europe, the transition to non-lead hunting rifle ammunition is likely to be less disruptive than some of the comments received in the consultation suggest.

3. **Stability of bullets in flight:** Comment #3467 highlighted possible stability issues with non-lead alternatives in calibres smaller than 6.8 mm and quoted a test from the Danish hunter's association.

   The complete advice on the website[226] of the Danish hunter's association states that this situation is not different from when using lead ammunition.

   As a result of the test, the Danish hunter's association advises hunters to carefully examine the twist rate of their barrel and purchase ammunition suitable for that twist rate and consequently state that this is not different when using lead ammunition.

   Comment #3329 states that it should be mentioned that all hunters are responsible for selecting the appropriate bullet type and mass that gives them the best accuracy from a given rifle, whether shooting non-lead or lead-based bullets. The same applies to hunters who assemble their own ammunition, especially as it relates to the choice of propellant, bullet mass and type, and the velocity of the bullet. Comment #3329 also explains that manufacturers respond to market demand and have started to develop non-lead ammunition with different twist rates.

Considering these arguments, the Dossier Submitter sees no reason to change the proposed cut-off size. The possibility to switch to alternatives that are larger than 6.5 mm seems to be undisputed. Concerning calibre sizes between 5.6 and 6.5 mm the

[226] https://www.jaegerforbundet.dk/om-dj/dj-medier/nyhedsarkiv/2020/lead-free-rifle-ammunition-the-big-test/

claimed main technical issues are related to hunting rifles with barrel twists not designed for longer and lighter bullets – which results in unstable projectiles and poor precision. However, the information submitted by comment #3329 suggests that this is a matter of careful selecting cartridges (just like with lead bullets). Suitable alternatives are produced and are available on the EU market.

Rimfire ammunition

Some comments addressed rimfire ammunition in general: #3467, #3331, #3262, whereas other comments addressed .22 LR, in particular: #3137, #3189, #3190, #3194, #3201, #3210, #3216, #3227, #3220, #3237, #3244, #3247, #3250, #3252, #3255, #3262, #3410, #3426, #3437. One comment (#3247) was treated in a confidential manner as per the commenters' request.

The Dossier Submitter found it difficult to separate comments on rimfire ammunition in general to those comments regarding .22 LR in specific, as some of the commenters on .22 LR used information on this calibre and the (difficulties encountered with the performance of alternatives as a proxy for all rimfire cartridges.

Worldwide, only a few jurisdictions have a lead ban that applies to hunting with rimfire bullets. The Danish initiative to phase out the use of lead is set on the initiative of the hunters themselves, but the website[227] of the Danish hunter's association clearly states that rimfire ammunition should not be part of the phase out.

Comment (#3262), states that there are different rimfire calibres on the market with very different bullet structures, resulting in different possibilities to develop lead-free ammunition. By far the most common is .22 LR. Due to the small diameter and the small bullet volume, the commenter stated that it would be difficult if not impossible to develop accurate non-lead bullets in this calibre. Within the use of lead ammunition in hunting, the use of rimfire calibres appears to be limited to applications for which no human consumption of game meat is foreseen. An exception may be the use of certain rimfire calibres in Nordic hunting (comment #3173). Consequently, the use of rimfire ammunition causes only a limited release to the environment compared to other calibres (comment #3237). The use of rimfire is important (as mentioned by several commenters, see e.g. #3262) in the control of invasive species.

Nammo Schönebeck (comment #3226), a rimfire ammunition manufacturer, has been testing the lead-free .22 LR ammunition currently on the market in their ballistic laboratory and has observed that non-lead .22 LR bullets have consistently a larger spread compared to lead-based .22 LR bullets (detailed test results are provided in comment #3226). The Swedish hunting association has also made a practical study on this topic with very similar results. There are also other studies on this (e.g. from the Czech Republic[228]) which come to a similar conclusion.

One commenter (#3173) brought forward the argument that due to the low speed on impact of the rimfire bullet, lead residues in game meat are practically absent. The commenter highlighted that .22 LR bullets will not disintegrate and will not leave lead in small game but will remain intact, causing no risk to human health and wildlife. A field test was done by the Finnish Hunters' Association comparing full metal jacket and .22 LR bullets used in small game hunting in Finland. Based on this study the Association

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[227] https://www.jaegerforbundet.dk/media/16490/bly-i-riffelammunition-til-jagt-udfases_klj_ok.pdf

[228] https://gunlex.cz/en/3595-comparative-test-of-lead-and-nonlead-ammunition

concluded that the use of these bullets should be allowed in this kind of hunting.[229] The Dossier Submitter incorporated this field test into Annex D.1.2.2.5. Another commenter (#3237) argued that lead emissions from rimfire ammunition are limited (about 300 kg/year in Finland) and that lead is not available to organisms after falling to the ground.

Several individual comments were received on tests of non-lead .22 LR ammunition. Commenters either tested the calibres themselves (#3173, #3194) or made references to tests made by other organisations (e.g. #3237, #3437, #3252) which report that non-lead .22 LR are inadequate for hunting or sports shooting.[230] The Swedish Hunters' Association submitted the results of a field test (#3252) on the basis of which they concluded that the accuracy of non-lead .22 LR was insufficient. Based on these tests (available on the web[231]), several commenters concluded that non-lead .22 LR is not suitable for either hunting or sports shooting. For example, commenter (#3247) concluded that, because of their accuracy, the lead-free alternatives have not yet been proven to be effective for hunting. Calibre .22 LR is commonly used in Sweden in both rifles and one-handed weapons for hunting. It is the most common calibre for killing small game that has been caught in traps (for example foxes and badgers) but also when hunting with dogs below the ground.

It was also pointed out (#3190) that the existing alternatives behave differently to regular lead-bullet ammunition, as they are considerably lighter (1.6g vs 2.6g), and thus their muzzle velocity is considerably higher. This results in noisier shots even when using a noise suppressor and potentially more wear and tear to the barrel of the gun. Also, when considering hunting, lighter bullets are more prone to lose accuracy in windy conditions, which reduces their suitability in many real-life situations.

As for the supply of lead-free .22 LR ammunition, some commenters pointed out that, given the dependence on only a few manufacturers, it was difficult to see how supply can meet demand (#3189, #3126, #3140). Currently only two European manufacturers (Norma and RWS) offer lead-free bullets (based on food safe zinc) in this calibre, one US brand (CCI) offers a non-lead version for this calibre as well but new information from the consultation (#3262) stated that the CIP approval for this product was withdrawn.

One comment from LAG (#3250) states that they are aware of only few published peer-reviewed reports on smaller calibres that are already mentioned in the dossier (McTee et al. 2017 with similar lead vs non-lead results; Hampton et al. 2020 with poor results for the one non-lead bullet tested). However, Hampton et al. (2020) did not suggest their results to be indicative for the performance of other lead-free ammunition and acknowledged the limitations of their study (small sample size, single species shot, use of a single rifle, single type of lead-based and lead-free ammunition, and observing a single shooter). They also acknowledged that considerable differences in the ability of small calibre bullets to instantly incapacitate quarry exist with lead-based bullet types, as illustrated by McTee et al. (2017) for lead-based .22 LR bullets. The results of Hampton et al. (2020) therefore are seen by this commenter (#3250) to provide an important case study which illustrates that animal welfare outcomes will not necessarily be equivalent for all lead-free and lead-based ammunition. Other comments were less

[229] https://metsastajaliitto.fi/luotitestit
[230] See e.g. https://gunlex.cz/en/3595-comparative-test-of-lead-and-nonlead-ammunition; the shooting distance was set at 50 m, and the average dispersion was found to be 31 mm for copper/polymer vs. 7 mm for solid lead. It was suggested that this dispersion is insufficient for target shooting, recreational shooting and small game hunting.
[231] https://metsastajaliitto.fi/luotitestit

specific but hinted at similar issues raised as above (#3220, #3227).

One commenter (#3252) highlighted that there are many manufacturers, brands and versions of .22 LR since it is the most common cartridge in the world, especially for sports shooting. However, they have only found 3 different versions of non-lead .22 LR ammunition available on the market. The commenter remarked that this is problematic since it is a fact that any individual gun is unique due to manufacturing tolerances. This means that to find ammunition that performs well in a particular gun, a wide variety of ammunition should be tested.

Problems in existing hunting legislation in some Member States were mentioned (#3189) and it was pointed out that regarding .22 WMR as a non-lead bullet for hunting capercaillie might prove too light for the classification. Also, the importance of the .22 LR calibre for wildlife management and pest control was pointed out (#3262).

AFEMS (comment #3331) requested, due to the absence of alternatives, that the transition period for .22 LR ammunition be extended to at least 10 years to enable ammunition manufacturers and firearm manufacturers to produce and market an alternative that has comparable ballistic performance. Based on feedback from manufacturers' AFEMS sketches out the steps needed to develop lead-free rimfire ammunition (see Table 2-15).

Table 2-15: Steps to develop lead-free rimfire ammunition (.22 LR)

Steps to develop a non-lead projectile	Estimates for the duration	Estimates for costs
1. Establish non-lead material capable of delivering the same accuracy performance	Minimum 5-10 years. This is the key step as there is no current identified alternative material and it is not clear if there are suitable alternatives.	Ca. €1 million. Best case assuming an alternative can be identified.
2. Design and build projectile manufacturing facility	Can only be started after step 1 has completed (5-10 years).	Ca. €5 million
3. Establish procurement channel for necessary quantities of non-lead raw material	Total substitution 8-10 years. Can be concurrent with step 2.	€0 (internal costs) but it is probable alternatives will be more expensive.
4. Form working partnerships with target shooting firearms manufacturers to establish rifle characteristics that will enable accuracy capability	Some working partnerships are already ongoing. Included in point 1.	Estimates not available
5. Liaise with target shooting organisations to ensure all necessary ranges	2-3 years for liaising and ensuring action at the shooting organisations.	€0.5 million for the collaboration
Backstop modifications have been implemented	5-10 years for modifying all the ranges. Nevertheless, the disposal requirements on the shooting ranges are likely to adapt to require segregation of different waste streams. Today: Mostly lead bullets are used, so collecting and recycling is easy. Future: Many mixed materials (copper, brass, tin, zinc, and so on) of the bullets. Thus, it is necessary to control the use of bullets to enable a useful recycling of the bullet metals.	Additional costs will come from modification of the backstops, bullet catcher etc. in the shooting ranges.
6. Await availability of appropriate firearms in the market	Minimum 5-10 years (see points 1 & 4)	Costs for shooters to purchase new firearms; obsolescence of current firearms.

AFEMS considers the possibility of a review before the expiry of the transition period to be vital in order to determine the status of technical alternatives to allow that the period can be extended. Without this, AFEMS fears, this calibre faces obsolescence.

The Dossier Submitter verified the main arguments brough forward by AFEMS to substantiate their request and notes that one of the manufacturers of non-lead alternatives for the .22 LR calibre (CIC) indeed lost its CIP homologation. This leaves only Norma and RWS as brands for non-lead .22 LR bullets. Since both are owned by RUAG Ammotec, this leaves essentially one manufacturer that supplies non-lead .22 LR on the European market.

Upon contacting RUAG Ammotec, the Dossier Submitter confirmed that the tests performed by the manufacturer demonstrated a wider dispersion on targets than is acceptable for sports shooting. RUAG Ammotec further reported that:

- The given spread (standard spread, without human intervention) is too large for functional hunting.
- The typical physical properties of lead are necessary for the use of the weapons currently in circulation and for the design of rimfire ammunition. This results in problems with lead-free bullets with current weapons and cartridges/calibres.

Concerning hunting efficiency, the Dossier Submitter notes that McTee et al. (2017) reported that non-lead bullets instantly incapacitated ground squirrels approximately as often as lead bullets. This finding suggests that non-lead bullets are comparably lethal to lead ammunition for ground squirrels, when comparing calibres .17 Hm. 22 LR and .223. The same study finds that (i) a non-expanding bullet may not have the magnitude of impact compared with an expanding bullet because it retains its mass as it passes through the animal, thus carrying energy and momentum through the exit hole; (ii) some lead may still be deposited in the animal and may pose a risk to human health upon consumption.

Overall, the Dossier Submitter's initial assessment has been confirmed, i.e. the current feasibility to substitute lead in rimfire ammunition for hunting appears to be limited. A derogation for rimfire calibres could alleviate much of the concern within the hunting community, especially regarding gun adaptation and hunting efficiency. A derogation would imply that lead-based rimfire cartridges can be used, even though alternatives exist for some calibres (such as .17 HMR). Such a derogation would result in a cost saving of up to ~€20 million per year, including extra costs for ammunition and investment in new guns. On the other hand, it would result in the continuation of lead emissions of up to ~17 tonnes per year (initially estimated to be around 30-40 tonnes per year) and lead exposure to human and wildlife cannot be ruled out.

Several other restriction options are discussed in the consultation comments including (i) a permanent derogation (comment #3262), (ii) having rimfire out of scope of the restriction (comment #3467), or (iii) having a time-limited derogation with a review clause (comment #3331). The Dossier Submitter briefly discusses the advantages and disadvantages of each of these options in Table 2-16.

Table 2-16: Advantages and disadvantages of alternative restriction options proposed for rimfire ammunition

	Advantages	Disadvantages
Permanent derogation/ rimfire out of scope	Allow the continued use of a category of bullets where replacement is difficult. Continued use appears not to contribute significantly to human health impacts.	Loss of incentive to innovate Secondary poisoning cannot be completely ruled out. Some alternatives are on the market (.17 HMR) for which fragmentation is a known issue. A permanent derogation would not create a level playing field for alternatives.
Time-limited derogation	Allow the temporary use of rimfire bullets until further R&D work is done for possible replacement. Keep incentive for innovation. Create level playing field for alternatives that exist already (such as .17 HMR).	Uncertainty on whether substitution efforts are likely to pay off. Continued use appears not to contribute significantly to human health impacts.

Niche applications

Several comments highlighted the need to continue using lead ammunition in several niche applications either due to the absence (or minimisation) of risk and/or specific circumstances that demand specific designs to the bullet that until now can only be achieved by lead-based ammunition.

Full Metal Jacket (FMJ)/Open Tip Match (OTM) bullets in hunting

FACE (#3467) highlighted that this application should be considered a niche application. Technical information on the use of FMJ bullets was received in e.g., comments: #3187, #3189. #3195, #3214, #3215, #3216 #3220, #3231, #3235 #3237, #3244, #3247, #3248, #3250, #3252, #3255, #3257, #3262, # 3449, #3467.

FMJ bullets are a non-fragmenting ammunition type that consists of a soft core (of lead) encased in an outer shell ("jacket").

Several commenters pointed out that FMJ bullets are used in limited applications in a type of hunting that is done in Finland, Sweden, and Norway and to a lesser extent in Estonia, Latvia, and Lithuania (e.g. comment #3262). Commenters (#3237, #3262) referred to the test performed by the Finnish Hunter's Association, which demonstrated that the use of rimfire, OTM and FMJ bullets would not lead to a significant deposition of lead in the body of the game (field test of FMJ and .22 LR bullets used in small game hunting in Finland, Finnish Hunter's Association, 2.5.2021[232]). The study compared .22 LR, FMJ and OTM bullets fired at dead pheasants, and no lead residues were found in the

[232] https://metsastajaliitto.fi/luotitestit

birds' carcasses.

In comment #3237 it was stated that FMJ bullets are not allowed for other sorts of hunting (e.g., roe deer with calibre 5.6 mm centrefire or higher). In Sweden, small game hunting is allowed with non-expanding FMJ or other non-expanding bullets such as OTM. Reference is made to the Environmental Protection Agency (Naturvårdsverket) Regulation NFS 2002:18 §§ 13-16 which states that only game from the size of roe deer (class 2) and larger animals up to moose (class 1) require the use of expanding bullets. Also, it was noted that small game like red fox is hunted for its fur and FMJ are allowed and used since they do not expand and destroy the fur. Expanding non-lead bullets would not be an alternative for the same reason. Such animals are not consumed for food.

Non-lead alternatives seem to be poorly available, but one company stated that it makes non-lead alternatives for this application as well. The Dossier Submitter contacted this company and learnt through personal communication that indeed lead-free bullets are made and used for this type of hunting. However, this is the only company the Dossier Submitter has been able to identify to provide non-lead options in this niche market.

Some national hunting legislations allow the use of FMJ bullets for certain applications: mostly on grouse like species and for applications that are related to pest control as well as for applications where animals are hunted for their fur.

A derogation would therefore pose negligible consequences in terms of risk, whereas it would allow the continuation of niche applications where alternatives are scarce.

The Dossier Submitter does not expect that hunters would use FMJ bullets as a wide alternative to lead ammunition, should a derogation for the use of lead containing FMJ bullets be in place. The national hunting legislations that are in place demand hunters to use expanding ammunition for hunting roe deer and larger.

Seal hunting

Several comments were submitted on this topic, e.g.: #3220, #3244, #3248, #3252, #3255, #3237, #3235, #3247, #3250, #3257, #3262, #3231, 3306, #3215, 3467, #3216, #3187, #3189. #3195, #3214, #3214, #3195.

Commenters highlighted the niche character of this use, either in general (#3467) or by referring to the annual tonnage of lead involved (8 kg in Finland according to #3467, and up to 20 kg in total for the EU as per the Dossier Submitter's assessment) or by referring to the annual number of bullets spent in this activity (1 500 bullets according to comment #3488).

Commenters point to several particularities of this use that, in their view, would justify a derogation:

i) The environment in which the use takes place: the hunt takes place in large open bodies of water where a bullet can travel for a long distance before it reaches the surface and stops. The most used bullets for seal hunting are those that fragment drastically upon impact which are very effective upon impact with a seal's skull and the death is instant with a hit.

ii) Accuracy requirements are very high, as the area of impact in the brain is very small and the firing distances are typically long. The seal must die after the main hit immediately, otherwise the catch will be lost at sea. The use of these fast-opening bullets is also of great importance for safety, as when hunting and shooting in the sea archipelago. A (whole or partial) copper bullet, for example, would pose a danger very far behind the target.

iii) Absence of risk for humans due to contamination of game meat: Placing on the market of seal products such as meat, is already banned by the Regulation (EC) No 1007/2009 of the European Parliament and of the Council of 16 September 2009 on trade in seal products. Meat from the head of a seal is not used in human consumption anyway and because seal meat cannot be placed on the market at all, the use of lead bullets here could not cause significant risk of human exposure.

A derogation would therefore have negligible consequences in terms of risk, whereas it would allow the continued use of lead in a niche application where alternatives are not available with the same level as effectiveness. The population management of seals, by volume of lead ammunition consumed, clearly constitutes a niche market. The circumstances under which the hunt takes place require a specific design of the bullet that until now is only achieved by lead ammunition. There is no indication that human contamination via seal meat takes place, although this cannot be completely excluded.

Any derogation would be enforceable. The hunt is strictly controlled with individual permits that are relatively straightforward to use as individual permits for using lead. The demand for this niche application of lead ammunition is low and it is thus not foreseeable that an alternative would be developed soon if this use was restricted.

2.5.1.3. Economic feasibility

Gunshot

In the call for evidence, various commenters had indicated that the prices of steel and lead cartridges are comparable, a similar conclusion had been arrived at in the dossier on wetlands. The Dossier Submitter verified whether this still holds by performing a market analysis. To that end, the Dossier Submitter collected information on prices from retail stores across the EU. For the gauge 12/70 mm, 28 online stores in 8 EU Member States were examined; for the gauge 16/70 mm, 30 online stores in 14 EU Member States were examined; for the gauge 20/70 mm, 34 online stores in 11 EU Member States were examined.

Perhaps the most striking and interesting finding is that for the gauges 12/70 mm and 20/70 mm, the average price of steel-based alternatives is cheaper than that of lead-based shot. Indeed, for the gauge 12/70 mm, steel cartridges were found to be the most price competitive. On average, steel cartridges were 29 % cheaper than lead-based ones. Cartridges with copper shot cost on average 176 % more than lead cartridges, whereas the differences between bismuth and tungsten, on the one hand, and lead, on the other, were even larger. The average prices of bismuth and tungsten cartridges exceeded that of lead cartridge by 306 % and 647 % respectively.

As regards the gauge 16/70 mm, the popularity of which has been in decline globally, lead cartridges were found to be the cheapest, followed by steel and bismuth respectively. Steel cartridges cost on average 17 % more than their lead-based counterparts, whereas those made of bismuth cost 375 % more.

For the gauge 20/70 mm, much akin to the gauge 12/70 mm, steel cartridges were found to be on average 30 % cheaper than lead-based ones. However, the price differences between other alternatives and lead were less accentuated for this gauge than for the 12/70 mm. In particular, the average price of copper cartridges was found to be 91 % more expensive than that of lead cartridges, whereas the figure stood at 126 % and 357 % for bismuth and tungsten, respectively.

Comments from the call for evidence indicated that it might be difficult to source non-lead cartridges for calibre .410[233] (the smallest shotgun size), although other commenters suggested that alternatives for this gauge are available.

Several comments were submitted on this topic in the consultation on the Annex XV restriction report, for example: #3293, #3295, #3331, #3333, #3350, #3429, #3466, #3467, #3510.

Comment #3467 noted a higher price difference between steel and lead gunshot cartridges. A similar remark was made in comment #3293 and in #3429 highlighting the price difference between lead and tungsten, a metal the Dossier Submitter does not consider to be the first choice when substituting lead, but which can be a useful alternative for certain shotguns (similar to bismuth gunshot). Comment #3467 used a price difference found in literature; the Dossier Submitter notes that the source of this price difference is a paper by Kanstrup and Thomas (2019). The Dossier Submitter performed a more up-to-date market analysis which demonstrated that the cost between steel and lead is negligible.

Bullets

A comparison of prices for lead-core and non-lead rifle ammunition was presented by Thomas (2013). That study compared the retail prices of nine commonly used calibres (from .223 to .416) of assembled rifle ammunition in different weights, types, and brands available across the US. It found that prices for the two types of ammunition were generally comparable, and where the non-lead products costed more, the relatively small increase was not enough to deny purchase and use. The same result applies to bulk lead and lead compounds purchase of bullets for ammunition hand-loaders: lead-core and non-lead bullets cost about the same at the retail level.

A regulated use of non-lead rifle ammunition in hunting would increase an economy of scale effect across the most widely used bullet calibres and lower their prices. Kanstrup (2015) concluded that non-lead rifle ammunition is largely available in all normal calibres (particularly 6.5×55, 308 Win. and 30–06) in Danish hunting stores at prices comparable to equivalent lead products. The lowest range of availability was found in the small calibres (<6 mm). In Germany, Gremse and Rieger (2015) found non-lead rifle ammunition in adequate supply across the range of hunting calibres typically used, with ammunition for small calibres (≤6 mm) being offered mostly by specialty manufacturers. Pricing comparisons in Germany mirror the conclusions of Thomas (2013) and Kanstrup and Thomas (2019).

The Dossier Submitter undertook a market analysis of its own to validate some of the comments submitted in the call for evidence as well as to validate arguments brought forward to support or object to substitution. The independent market analysis centred on assessing the market availability and pricing of non-lead alternatives for some of the most popular calibre sizes in the European Union. To this end, the Dossier Submitter surveyed more than 120 online retail stores located across the EU.

While performing online searches, information on prices for both lead-based ammunition

[233] The terms 'calibre .410' and 'gauge 36' are interchangeable, due to tradition gauge 36 is often referred to as .410.

and non-lead alternatives was collected. The result of this analysis confirms the findings by Thomas (2016). Concretely, the Dossier Submitter's analysis found that, on average, the prices of lead bullets and non-lead bullets are comparable, especially for large calibres; for small calibres the prices for non-lead bullets are somewhat higher. In Table 2-17, the price difference between lead bullets and non-lead bullets is documented for different calibres and the respective game type.

Table 2-17: Price difference per cartridge for different calibres found in market analysis between non-lead and lead equivalent (including VAT)

Calibre	Prices lead-containing	Prices non-lead	Price difference with lead equivalent (2020 prices, in euro)	Game type
17 HMR	€1.35	€1.35	€0.00	small
.222 REM	€1.65	€2.50	€0.85	large
.243 Win	€2.35	€2.85	€0.50	large
6.5x55	€2.55	€4.30	€1.75	large
7x64	€3.15	€3.55	€0.40	large
.30-06 Spr.	€3.00	€3.25	€0.25	large
.308 Win.	€2.85	€3.60	€0.75	large
.300 Win. Mag	€3.70	€4.30	€0.60	large
8x57	€3.20	€3.90	€0.70	large
9.3 x 62	€3.65	€4.60	€0.95	large

The price differences found per calibre type were used further in the impact assessment. Given the cut-off between small and large calibre at 5.55 mm (see Section D.1.1.2 of the Annex) the price difference for small calibre was based on calibre .17 HMR and relevant comparisons of minimum and maximum prices, whereas the price difference for large calibres wase based on the average (and minimum and maximum comparison) of all price differences for large calibres. The results of this comparison are presented in Table 2-18.

Table 2-18: Price differences between lead and non-lead (price difference expressed in Euro, including VAT)

Game type	Price difference with lead equivalent (2020 € prices, average over relevant calibres)		
	low	medium	high
Small game	€0.00	€0.20	€0.40
Large game	€0.75	€1.46	€2.17

2.5.1.4. Conclusion on the suitability of alternatives

Table 2-19 presents a summary of the Dossier Submitter's considerations regarding the suitability of alternatives (in terms of their availability, technical and economic feasibility) and hence of the substitutability in case of a restriction on various uses.

Based on stakeholder input from the consultation, the Dossier Submitter would add to the information displayed in Table 2-19 that substitution is problematic in the following areas:

- Rimfire ammunition (and then in particular .22 LR)
- Seal hunting
- Muzzle loaders
- Airguns
- Full metal jackets for specific applications such as Nordic bird hunting

The Dossier Submitter has therefore qualitatively described the consequences of including or derogating these uses in Section 2.5.1.2.1.

Table 2-19: Availability, technical and economic feasibility of alternatives

Restriction Option	Availability	Technical feasibility	Economic feasibility
Ban on placing on the market and use of lead shot for hunting	Good	Good	Good
Ban on use of small calibre (<5.6 mm) bullets for hunting	Poor	Poor	Poor
Ban on use of large calibre (≥5.6 mm) bullet for hunting	Good	Good	Good

2.5.2. Effectiveness and risk reduction

2.5.2.1. Human health impacts

The most relevant health endpoints associated with exposure to lead are neurotoxic effects in children aged 7 and younger (including unborn children via exposure of the mother), as well as increases in the incidence of chronic kidney disease (CKD) and in cardiovascular effects (increase in systolic blood pressure) in adults (EFSA, 2010).

The following main risks to human health resulting from the use of lead ammunition in hunting have been identified within this restriction:

- Home-casting of lead bullets (qualitative assessment)
- Game meat consumption (quantitative assessment)

Home-casting of lead bullets (use 2b)

For home-casting a quantitative assessment was not performed due to missing information on the incidence of home-casting of lead bullets and the concentration of lead in the air from home-casting.

Because of the proposed ban on using lead bullets for hunting, it may be assumed that fewer hunters would have an incentive to home-cast their bullets, and fewer people would therefore be exposed to lead fumes and dust. This would prevent any accidental exposure of children living in the same household as the hunters who are casting lead.

Game meat consumption (uses 1 and 2b)

Different types of game meat can be discerned. Large ungulates (incl. species like deer, moose, and boars) are typically shot with bullets; smaller mammals such as hare and rabbit are shot with either small calibre bullets or gunshot; birds (especially waterfowl) are typically bagged using gunshot. For calibres ≥ 5.6, non-lead bullets are readily available and widely used in practice. Similarly, a wide range of non-lead alternatives for gunshot in standard proofed shotguns are readily available and widely used in practice. A substitution to non-lead ammunition for calibres ≥ 5.6 and for gunshot would thus have an almost immediate effect on the exposure to lead via most types of game meat, the exception being smaller mammals hunted with small calibre bullets. However, a look at the average EU hunting bag by Thomas et al. (2020) suggests that this prey makes up less than 10 % of the weight of mammal kills in the EU. Given that smaller animals such as hare and rabbit have less meat compared to their total body weight than larger animals, it may thus be inferred that the proposed restriction option would eliminate the concern of lead contamination in more than 90 % of mammalian game meat, and in 100 % of bird meat consumed in the EU.

The objective of this section is (i) to quantify the baseline risk of neurotoxic effects in children of hunter families that are assumed to be high-frequency consumers of game meat, and (ii) to monetise the risk reduction that could be achieved by banning lead ammunition (shot and bullets equal to or larger than calibre 5.6). Moreover, an attempt is made to quantify the baseline chronic kidney disease (CKD) risk in adults that belong to hunter families and are assumed to be high-frequency consumers of game meat. For cardiovascular risks, another endpoint associated with chronic lead exposure, the available evidence suggests that exposure via game meat consumption is trivial and hence no quantifiable effects are assumed to result from a ban on lead ammunition.

The impact assessment follows the integrated assessment model outlined in Section 1.6.3.6 of this report and relies on dose-response functions that are derived from the $BMDL_{01}$ of 12 µg Pb/L for neurotoxic effects and the $BMDL_{10}$ for CKD of 15 µg/L as proposed by EFSA (2010).

Impact on IQ

The assessment of neurotoxic impacts in children exposed excessively to lead via game meat consumption follows the well-established link between concurrent blood lead (PbB) levels and full-scale IQ (Budtz-Jørgensen et al., 2013, Crump et al., 2013, Lanphear et al., 2005).

To start with, the vulnerable population was characterised as children aged ≤ 7 that belong to a hunter household. According to figures reported by Thomas et al. (2020), it can be assumed that there are about 6.0 million hunters in the EU-27. The average household size across the EU-27 in 2019 was 2.3 (Eurostat, 2020). There is no reason to assume that the household sizes of hunter families would be systematically different from those of the general population. This suggests that hunter families comprise roughly 13.8 million individuals in the EU-27. Since 15.2 % of the total EU-27 population is aged 14 or younger (Eurostat, 2020), one can extrapolate that each birth cohort corresponds to about 1 % of the population. One thus finds that ~8 % of hunting family members are children aged 7 or younger. In absolute terms, **about 1.1 million children belong to the population at risk**. Each year, 130 000 individuals are newly born into this group and another 130 000 grow out of it, see Section 1.6.4.6.1.

Information about lead intake and resulting PbB levels in this group is scarce and some assumptions are necessary to approximate them. A key assumption made in the original analysis had been that the 95th percentile of chronic game meat consumption frequency (measured in µg Pb/kg bw/day) for children observed in food recall surveys provided by EFSA is an appropriate proxy for the frequency of game meat consumption by children of hunter families. However, during the consultation, FACE (#3467) made a credible case for why the game meat consumption implied by the EFSA food recall data was resulting in exaggerated intake amounts.

Considering the information received, the Dossier Submitter revised its assumptions, relying on the median value of chronic game meat consumption frequency (measured in µg Pb/kg bw/day) as a more appropriate proxy. (The Dossier Submitter notes that this does not preclude that individual hunter families would consume more game meat.) Assuming average bodyweights of 5 kg and 12 kg for infants and toddlers as per EFSA guidance, the assumed daily intake in game meat corresponds to 7.1 g and 29.6 g, respectively. For infants, this amount corresponds to about half of the meat content of a customary baby food char, which contains between 10-20 g of meat (see this example). For toddlers, this amount corresponds to about half of the meat content of a customary hamburger patty, which contains 45-60 g of meat (see example 1 and example 2). Although extrapolations to annual consumption amounts might be misleading, these daily intakes would correspond to 2.6 kg and 10.8 kg of game meat per year, respectively.

EFSA data on lead contamination (measured in µg/kg) in two bundles of game meat—one consisting of meat from species typically hunted with bullets and the other one typically hunted with gunshot—were used to model lead ingestion by children. Importantly, one may expect the lead intake over time to be correlated. E.g., if a hunter has minced the meat from the shoulder of an elk including meat around the wound channel, it is reasonable to assume that the entire batch has elevated lead levels. The implication of consuming this batch over time is that the lead intake by an individual child is unlikely to be independent and identically distributed. To account for such correlations, it is advisable to not focus on a central measure of lead contamination, but to work with the empirical cumulative distribution function (ECDF) of the EFSA contamination data instead.

Using the conversion steps outlined in Section 1.6.1.1, one can combine lead contamination and daily lead intake to derive the predicted PbB levels in children from chronic game meat consumption. When doing so for different moments of the aforementioned ECDF, one obtains a long-tailed distribution with a median incremental

PbB level of 0.3 µg/L in infants and 0.6 µg/L in toddlers, respectively. The corresponding mean incremental PbB levels are more than two orders of magnitude larger (Table 2-20), reflecting the skewed nature of the ECDF.[234]

Table 2-20: IQ loss modelling following the methodology described in Section 1.6.1.1

	Mean	Min	P25	P50	P75	P95	P99
Lead contamination in game meat (µg/kg)							
shot	366	0	10	20	50	500	4 440
bullet	2516	0	10	20	54	420	19 000
Daily intake of lead (µg/kg bw/day)							
Infants							
shot	0.155	0.000	0.004	0.009	0.021	0.213	1.887
bullet	2.508	0.000	0.010	0.020	0.054	0.419	18.941
Toddlers							
shot	0.371	0.000	0.010	0.020	0.051	0.507	4.503
bullet	3.663	0.000	0.014	0.029	0.079	0.611	27.663
Incremental PbB level (µg/L)							
Infants							
shot	1.9	0.0	0.1	0.1	0.3	2.6	22.6
bullet	30.1	0.0	0.1	0.2	0.6	5.0	227.3
total	32.0	0.0	0.2	0.3	0.9	7.6	249.9
Toddlers							
shot	4.4	0.0	0.1	0.2	0.6	6.1	54.0
bullet	44.0	0.0	0.2	0.3	0.9	7.3	332.0
total	48.4	0.0	0.3	0.6	1.6	13.4	386.0
Predicted IQ loss per child (points) based on the EFSA $BMDL_{01}$							
Infants							
shot	0.16	0.00	0.00	0.01	0.02	0.21	1.89
bullet	2.51	0.00	0.01	0.02	0.05	0.42	18.94
Toddlers							
shot	0.37	0.00	0.01	0.02	0.05	0.51	4.50
bullet	3.66	0.00	0.01	0.03	0.08	0.61	27.66

It is well known that the mean value is not a robust measure of centrality for strongly

[234] The predictions were triangulated using the AALM modelling tool. As discussed in a separate Annex, the results were closely aligned.

skewed distributions. For this reason, the full distribution of predicted PbB levels was taken forward for modelling IQ loss in exposed children. More specifically, an age-weighted average for infants and toddlers was used to estimate neurotoxic effects. As PbB levels have to be elevated over a period of several months (see Section 1.6.2.1) to result in detrimental impacts on the developing brain (see Lanphear et al. 2005), it was assumed that for each infant there would be three toddlers exposed.

Applying the EFSA $BMDL_{01}$ for IQ loss (EFSA 2010), the predicted IQ loss for various moments of the ECDF were thus obtained by the following formulas:

IQ loss (shot) = ¼ * IQ loss (shot; infants) + ¾ * IQ loss (shot; toddlers);

IQ loss (bullets) = ¼ * IQ loss (bullets; infants) + ¾ * IQ loss (bullets; toddlers); and

IQ loss (ammunition) = IQ loss (shots) + IQ loss (bullets).

Figure 2-4 depicts the resulting ECDF for IQ loss from lead in gunshot (orange), bullets (light blue) and ammunition (dark blue). Focusing on the aggregate IQ loss (i.e. from both types of ammunition), a closer inspection of the distribution function suggests 50 % of the population at risk lose > 0.05 IQ points and 6 % lose > 1 IQ point.

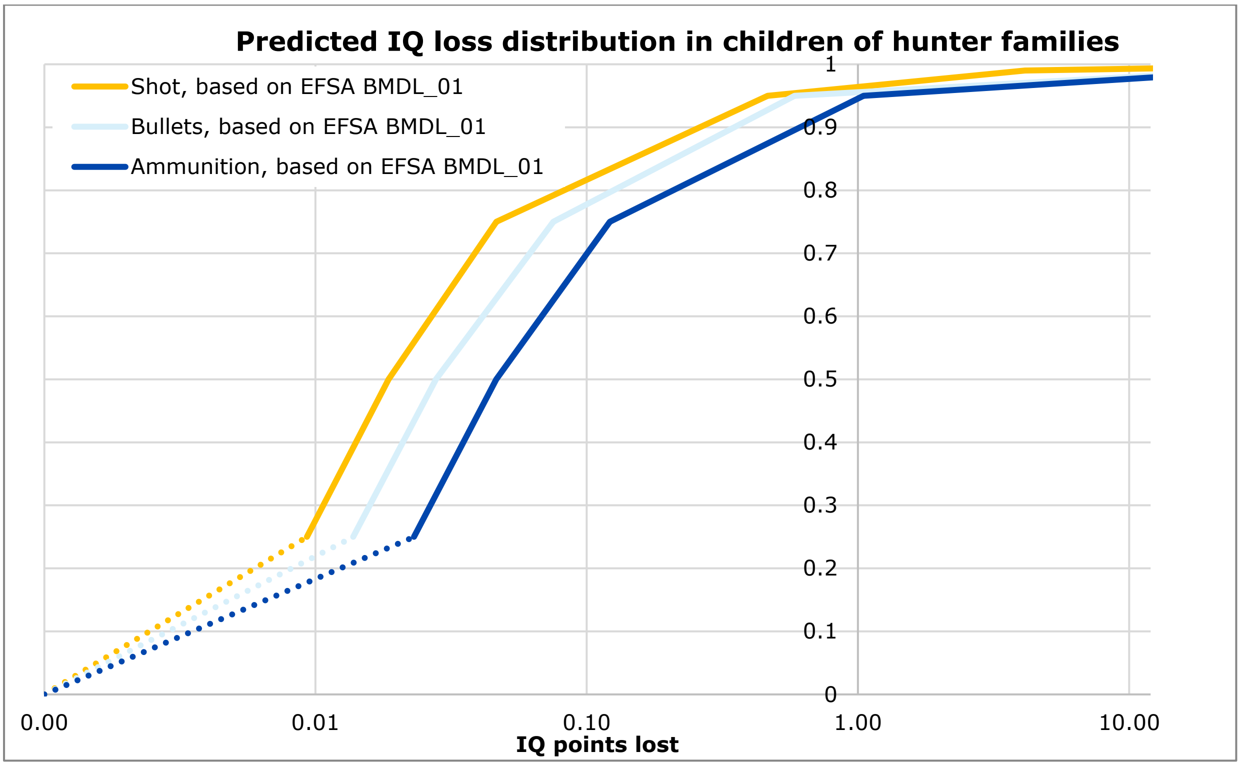

Figure 2-4: Empirical cumulative distribution functions (ECDFs) of IQ loss in high-frequency game meat consumers

These estimates of IQ point loss may be monetised based on the most comprehensive analysis of the IQ-lifetime earnings relationship to date (Lin et al., 2018), which found expected lifetime earning losses between $10 337 and $14 764 per IQ point (in 2014$). When inflation adjusted (https://www.bls.gov/data/inflation_calculator.htm), these values correspond to $11 242 to $16 056 in 2020$, or €9 500 to €13 600 in 2020 €. Based on that, a value of €10 000 per IQ point lost may be assumed. Applied to the above aggregate ECDF, one may then infer that the value of IQ loss associated with the median lead intake by any birth cohort is larger than €32m (50 % * 130k * 0.05 ΔIQ * €10 000 per ΔIQ).

Dating back to the work of Grosse et al. (2002), the methodology for monetising IQ loss is well established in the environmental health literature. Nevertheless, there has been an ongoing debate in SEAC about the valuation of marginal IQ point loss. It is therefore important to stress that the ECDF in Figure 2-4 allows for a more robust monetisation of predicted IQ loss by focusing only on the most exposed individuals. Indeed, if one considers only those children prone to lose 1 or more IQ points, one obtains a corresponding welfare loss of that is larger than €78m (6 % * 130k * 1Δ IQ * €10 000 per ΔIQ).

This value ignores that a proportion of bullets used for hunting ungulates are already lead-free and hence the welfare loss needs to be scaled down by the proportion of lead-free bullets in the market. As per Section 2.5.1.1 (Availability) of this restriction report, the proportion of lead-free ammunition corresponds to 10 %. Therefore, a **baseline welfare gain of €70m** (€78m * 90 %) is assumed by the Dossier Submitter to result from the restriction option proposed.

Risk of CKD

The association between PbB levels and increased CKD risk in adults is less established than the one between PbB levels and neurotoxic effects in children. However, they are still relevant at the population level since the group of highly exposed individuals is larger in the adult population than in the child population. To gauge the size of that population the same sources were used as before. Starting from the assumption that hunter families comprise roughly 13.8m individuals in the EU-27, and excluding those 20 % of family members aged ≤ 20 (Eurostat, 2020) as well as deducting 10 % of hunters who already use lead-free gunshot and bullets, **there are about 10 million individuals at increased risk of developing CKD**.

As for children, it is assumed that the median value of chronic game meat consumption (measured in μg Pb/kg BW/day) frequency observed in the EFSA food recall data is an appropriate proxy for the frequency of game meat consumption by adult members of hunter families. Based on this consideration, the Dossier Submitter revised its assumptions, relying on the median value of chronic game meat consumption frequency (measured in μg Pb/kg bw/day) as a more appropriate proxy. (The Dossier Submitter notes that this does not preclude that individual hunter families would consume more game meat.) Assuming average bodyweights of 70 kg for adults as per EFSA guideline, the assumed daily intake in game meat corresponds to 86.4 g, respectively. This amount can be compared to the daily intake of pork, beef, lamb and poultry meat that corresponds to the per capita meat consumption in the EU. According to the latest EU agricultural outlook report, the per capita meat consumption is about 69 kg/y, which corresponds to 190 g of meat. Although extrapolations to annual amounts of game meat might be misleading (cf. Section 1.6.2.1), the above daily intake of game meat would correspond to about 31 kg of game meat per year. This game meat would correspond to 30-45 % of the individuals total meat consumption.[235]

Following the analysis for children, EFSA data on lead contamination (measured in μg/kg) in two bundles of game meat—one consisting of meat from species typically hunted with bullets and the other one typically hunted with gunshot—were used to

[235] If an individual replaces other sorts of meat, then the share of game meat corresponds to 31 kg / 69 kg = 45 % of the average total meat consumption; if an individual consumes game meat on top of the average meat consumption, the share of game meat corresponds to 31 kg /100 kg = 31 %.

model lead ingestion by adults. One may again expect the lead intake to be correlated over time. Consequently, the analysis below rests on the empirical cumulative distribution function (ECDF) of the EFSA contamination data for adults.

To monetise the impacts associated with excess CKD risk, one has to first determine the prevalence of CKD in the EU population (assuming that members of hunter families have the same background CKD risk than the general population). A recent study by Brück et al. (2016) finds substantial differences in CKD prevalence across the EU. These differences may be driven by the prevalence of various CKD risk factors such as diet, lifestyle, differences in general population age distributions, etc. Focusing on CKD stages 3-5 (defined as estimated glomerular filtration rates (eGFR) < 60 mL/min/1.73 m^2), the age- and sex-adjusted prevalence of CKD varied between 1.0 % (95 %-CI: 0.7 % – 1.3 %) in central Italy and 5.9 % (95 %-CI: 5.2 % – 6 .6 %) in northeast Germany.

Based on this, it stands to reason that any CKD prevalence rate conjectured for the EU-27 general population is subject to uncertainties. Notwithstanding these uncertainties, a general population prevalence rate of 3.5 % (i.e. the mid-point of the CKD prevalence rates found in Brück et al. (2016) will be assumed hereafter. This estimate should be interpreted with caution, however, as it is based on EFSA's $BMDL_{10}$ which has been recognised as a worst-case value due to some methodological choices in its derivation (see EFSA (2010)).

Using the conversion steps outlined in Section 1.6.1.1, one can combine lead contamination and daily lead intake to derive the predicted PbB levels in adults from chronic game meat consumption. When doing so for different percentiles of the aforementioned ECDF, one obtains a long-tailed distribution with a median incremental PbB level of 0.2 µg/L in adults. The corresponding mean incremental PbB levels are 50-fold larger (see Table 2-21), reflecting the skewed nature of the ECDF.[236]

Table 2-21: CKD excess risk modelling following the methodology described in Section 1.6.1.1

	Mean	Min	P25	P50	P75	P95	P99
Lead contamination in game meat (µg/kg)							
shot	366	0	10	20	50	500	4 440
bullet	2516	0	10	20	54	420	19 000
Daily intake of lead (µg/kg bw/day)							
Adults							
shot	0.238	0.000	0.007	0.013	0.033	0.325	2.890
bullet	1.469	0.000	0.006	0.012	0.032	0.245	11.091
Incremental PbB level (µg/L)							
Adults							
shot	0.6	0.0	0.0	0.0	0.1	0.8	6.9
bullet	3.5	0.0	0.0	0.0	0.1	0.6	26.6

[236] The predictions were triangulated using the AALM modeling tool. As discussed in a separate Annex, the results were qualitatively similar.

	Mean	Min	P25	P50	P75	P95	P99
total	4.1	0.0	0.0	0.1	0.2	1.4	33.6
Predicted excess CKD risk (percentage points) per adult based on the EFSA $BMDL_{10}$							
Adults							
shot	0.38	0.00	0.01	0.02	0.05	0.52	4.62
bullet	2.35	0.00	0.01	0.02	0.05	0.39	17.75
total	2.73	0.00	0.02	0.04	0.10	0.91	22.37

Figure 2-5 plots the resulting ECDFs for excess CKD risk from lead in gunshot (orange), bullets (light blue) and ammunition (dark blue). Focusing on the aggregate excess CKD risk (i.e. from both types of ammunition as reported in the last row of Table 2-21), a closer inspection of the distribution function suggests 50 % of the population at risk face an excess risk larger than 0.04 percent points and 3.1 % of the population bear an excess CKD risk of ≥ 10 %.

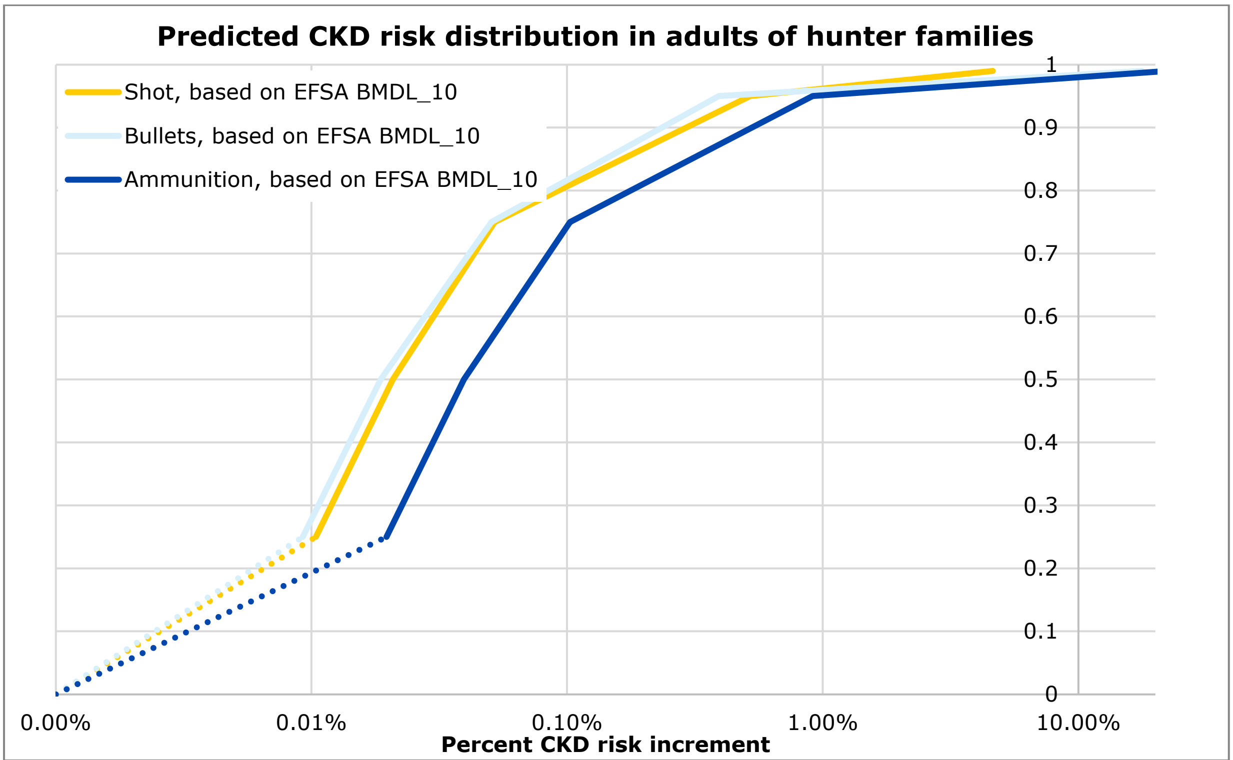

Figure 2-5: Empirical cumulative distribution functions (ECDFs) of excess CKD risk in adult high-frequency game meat consumers

For the monetisation of impacts associated with excess CKD risk, one has to first determine the prevalence of CKD in the EU population (assuming that members of hunter families have the same background CKD risk than the general population). A recent study by Brück et al. (2016) finds substantial differences in CKD prevalence across the EU. These differences may be driven by the prevalence of various CKD risk factors such as diet, lifestyle, differences in general population age distributions, etc. Focusing on CKD stages 3-5 (defined as estimated glomerular filtration rates (eGFR) < 60 mL/min/1.73 m^2), the age- and sex-adjusted prevalence of CKD varied between 1.0 % (95 %-CI: 0.7 % - 1.3 %) in central Italy and 5.9 % (95 %-CI: 5.2 % - 6.6 %) in northeast Germany. Based on this, it stands to reason that any CKD prevalence rate conjectured for the EU-27 general population is subject to uncertainties. Notwithstanding these uncertainties, a general population prevalence rate of 3.5 % (i.e. the mid-point of the CKD prevalence rates found in Brück et al. (2016) will be assumed hereafter.

As shown in Figure 2-5, 3.1 % of the 10 million individuals at risk, or 310 000 individuals, face an excess CKD risk of ≥ 10 %. Without the ingestion of lead via game meat one would expect a general population prevalence of 3.5 % among these individuals. However, one expects a higher prevalence in high-frequency game meat consumers based on the excess risk these individuals bear from lead ingestion. Combining the baseline prevalence rate of 3.5 % with the insights from the ECDF depicted in Figure 2-5, one may expect 1 085 additional cases of CKD (stages 3-5) in this group of extremely exposed individuals.[237]

This estimate should be interpreted with caution, however, as it is based on EFSA's $BMDL_{10}$ which has been recognised as a worst-case value due to some methodological choices in its derivation (see EFSA 2010). Moreover, people need to be permanently exposed over months to build up PbB levels that could lead to them developing CKD, which implies that the population at risk may be overestimated.

For the purpose of an *indicative* valuation, one may instead assume that the etiologic fraction of CKD cases might be as much as an order of magnitude lower. Accordingly, it will here be assumed that the number of attributable cases of CKD across the EU is between 100 and 1 000. These are cases based on prevalence (i.e., the number of current cases of CKD over a specified period) and should not be confused with new cases which would have to be calculated based on incidence (i.e., the number of new cases of CKD during a specified period of time). Hence, instead of valuing new cases, one may turn to disability-adjusted life years (DALYs) and value those.

Both the European Burden of Disease study as well as the Global Burden of Disease study provide collated disability weights for kidney disease (see ECHA 2015). For primary/disseminated/terminate CKD, the EBD study finds average disability weights of 0.27/0.36/0.52. As CKD stage 3 will be more prevalent than CKD stages 4 or 5, an aggregate disability weight of 0.3 will here be assumed. Based on this disability weight, the attributable cases are associated with roughly 30 – 300 DALYs. As an approximation, these may be monetised by multiplication with the value of a statistical life year (VSLY).[238] Following ECHA 2016, the current VSL (€3.5 million – €5 million) endorsed by SEAC corresponds to a VSLY of €200 000 to €290 000. Applying a central value of €250k per VSLY, the DALYs associated with lead intake via game meat correspond to an *indicative* value of €7.5 million to €75 million. Importantly, it should be stressed that many assumptions have been made to arrive at this estimate and the scientific evidence on which those assumptions were based is less robust than the scientific evidence underpinning the neurotoxicity assessment.

2.5.2.2. Environmental impacts

The expected reduction in lead emissions is subject to the underlying assumptions of the assessment. Table 2-22 gives an overview of releases avoided over 20 years following entry into force.

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[237] 310k*3.5 %*110 % – 310k*3.5 %*100 % = 1 085.

[238] explain why this will typically result in a lower bound estimate of the value of disease.

For **gunshot** the baseline release amounts to 14 000 tonnes of lead per year and 280 000 tonnes of lead over 20 years (see Section 1.8.1.1). A full ban on the placing on the market and use of lead gunshot would result in releases of 70 000 tonnes of lead (5 * 14 000 tonnes) during the transition period of 5 years. The avoided total release would thus be 209 000 tonnes of lead over 20 years.

For **small calibre bullets** the baseline is a release of 15 tonnes of lead per year, which results in total releases of about 310 tonnes of lead over 20 years. A full ban on the use of small calibre lead bullets would result in releases only during the transition period of 5 years of 75 tonnes (5 * 15 tonnes) of lead. The avoided releases would be 232 tonnes of lead over 20 years.

For **large calibre bullets** the baseline is a release of 119 tonnes per year, which results in a total release of about 2 370 tonnes of lead over 20 years. A full ban on the use of large calibre lead bullets would result in releases only during the transition period of 18 months (1.5 years) of 119 tonnes (1.5 * 119 tonnes). The avoided releases would be 2 200 tonnes of lead over 20 years.

Table 2-22: Releases to the environment under different scenarios per RO

Restriction option	Avoided release over 20 years (tonnes)
Ban on placing on the market and use of lead gunshot for hunting	209 000 (159 000-259 000)
Ban on use of lead bullets for hunting – small calibre	232 (208-255)
Ban on use of lead bullets for hunting – large calibre	2 200 (1 700-2 500)

Environmental risk reduction

The main environmental risk identified from the use of lead ammunition in hunting relates to the primary and secondary poisoning of birds. Risks to humans via the consumption of lead contaminated game meat are described in section 2.5.2.1.

In terms of risk to wildlife, the risk to birds is especially relevant. Lead ammunition and/or lead contaminated tissues (in prey), when ingested by a bird, typically results in severe adverse effects (poisoning) that can frequently lead to premature death (lethal poisoning). Studies on the sub-lethal effects of lead ingestion suggest that it can affect reproductive success in various bird species (sub-lethal poisoning). Recent studies (Vallverdú-Coll et al., 2016a) indicate that the adverse effects of lead can be observed in the reproductive function of males, in particular on the integrity of the acrosome and the motility of the spermatozoa, which can have consequences on the oocyte fecundation. Although not all species may be equally sensitive to lead, this aspect is considered critical for long-term population effects, especially in species that are not very abundant.

A ban on the placing on the market and use of lead gunshot would significantly reduce the risk of poisoning for species susceptible to ingesting lead gunshot.[239] At least 41 wild bird species (including 19 species on Annex 1 of EU Birds Directive) are at risk of primary poisoning from lead gunshot in terrestrial areas. Of these, more than one million would continue to die annually. Mortality rates are expected to vary between species dependent on their species-specific sensitivity. Nevertheless, many birds would still be affected by sublethal effects as discussed in Section 1.8.5 even if they are not lethally poisoned. The proposed restriction contributes to EU obligations under the AEWA agreement and CMS convention for migratory waterbird species that feed outside of wetland areas (supplementing the existing restriction on lead in gunshot in wetlands).

Without a ban on the placing on the market and use of lead gunshot and on the use of bullets (small and large calibre) for hunting, (at least) 29 wild bird species (including 24 raptor and scavenger species listed in the Annex 1 of the EU Birds) would be at risk of secondary poisoning. Lead poisoning (and consequent mortality) is likely to have a significant impact on predatory and scavenger species that naturally have a low reproductive rate. The number of birds dying from secondary poisoning from both lethal and sublethal effects was not quantified but it can increase significantly in areas with high exposure to lead from hunting (e.g. lethal lead poisoning was registered to be as high as 24 % for white-tailed sea eagles (*Haliaeetus albicilla*) in areas with high exposure by Helander et al. (2021).

For critically endangered species, any additional mortality may be of concern for the survival of that species. Therefore, for raptors and scavengers which usually feed on prey and carcasses (including unretrieved pest species), only a broad restriction on gunshot and bullets (small and large calibre) would guarantee comprehensive protection, in line with the EU obligations under the Birds Directive and the CMS convention (including the CMS Raptors MOU).

The Dossier Submitter further notes that the remnants of hunting (i.e. discarded viscera of large game after 'field dressing') are an important food source (Haig et al., 2014) for many species, especially obligate scavengers (Haig et al., 2014). Burying remnants of hunting, although reducing the potential for lead poisoning, could reduce food availability for some species. Nevertheless, some species (such as certain wild mammals) could be expected to dig up buried contaminated food, which limits the effectiveness of burial as a risk management option.

In addition to the species at high risk of lead poisoning assessed by the Dossier Submitter, other species may be at low or very low risk as assessed by the UNEP/CMS ad hoc Expert Group, specific information is available in comment #3343.

In addition, with a ban on the placing on the market of lead gunshot, a more comprehensive protection of waterbirds (consistent with existing EU obligations under the Birds Directive and AEWA), also taking into account species feeding on terrestrial habitats, would be achieved. Waterbird species represent about 5 % of the overall affected birds in terrestrial environments.

A ban on the placing on the market of lead gunshot will also prevent poisoning of poultry reared in areas used for gunshot shooting or livestock (specifically ruminants) that ingest lead via contaminated silage (grown in areas used for gunshot shooting).

[239] Birds feeding in terrestrial environments may ingest lead gunshot deposited on the land as a result of hunting and sports shooting activities. See section 1.5.3.4. for further details.

An important point concerns rifle calibres smaller than 5.6 mm that are predominantly used for pest control and for which the technical performance of alternatives (i.e. in terms of precision) is currently not equivalent to that achieved with lead ammunition (see Section 2.5.1). An immediate ban on the use of lead-based ammunition for these calibres would require hunters who perform pest control to use relatively more expensive non-lead ammunition without a clear indication that alternatives can be used effectively. In turn, this might have an unwanted negative effect as it could mean that invasive species such as the racoon dog[240] may not be sufficiently controlled, thereby posing a threat to endemic species. This risk-risk trade-off has therefore to be considered carefully when deciding on the proportionality of a ban (or appropriate transitional arrangements) of lead in small calibre rifle ammunition.

2.5.3. Costs and other economic impacts

2.5.3.1. Costs within EU27-2020

The following categories of costs related to the ban on the placing on the market and use of lead shot for hunting and ban on the use of lead bullets – small and large calibres – for hunting have been considered within the EU27-2020.

- Research and Development (R&D) costs
- Industry compliance costs, i.e., raw material costs, energy costs, loss of recycling benefits and manufacturing equipment costs (aka capital costs)
- Retailers' compliance costs
- Enforcement costs
- Consumers costs (costs to hunters)

R&D costs

European companies that are manufacturing lead shot and lead bullets will incur R&D costs to develop new alternatives. Within this context however it has to be noted that many of the European manufacturers already have set up lines for the production of lead-free shot and lead-free bullets, therefore the assumption is that most of the R&D cost have already been incurred before this restriction. On the other hand, retailers and 'brands', to stay innovative and gain market shares, design and develop regularly new products to be placed on the market.

Industry compliance costs

The target shooting market (60-80 %) will not be impacted by the proposed regulations if the strict conditions for lead projectile containment and recovery are met; neither will the ammunition sector's growing exports. Steady growth in the target shooting market is expected to mitigate any shifts in hunting equipment sales. Lead ammunition supplies are expected to continue to be in strong demand by target shooters, personal protection consumers, and hunters outside the EU. With the phase-in of the proposed regulations, hunters may be expected to purchase more non-lead ammunition at higher per-unit

[240] A full list of invasive species is available here: https://ec.europa.eu/environment/nature/invasivealien/list/index_en.htm; out of the mammals on this list species of squirrels, chipmunk, racoon dog, muskrat, mongoose, coypu, etc would be huntable with what the Dossier Submitter identifies as 'small calibres'. Only muntjac deer would be huntable with what the Dossier Submitter defines as 'large calibre' but for large calibres alternatives have already been proven to work.

costs, which should yield higher per-unit margins until manufacturer competition and higher production runs reduce costs.

<u>Input from the consultation</u>

Ammunition manufacturers (bullets)

The input from the consultation on R&D costs and industry compliance costs is closely related to the proposed transition periods. The main arguments put forward relate to:

- Development costs needed for calibres smaller than 5.6 mm;
- Costs for upscaling production to satisfy regulatory driven demand for non-lead calibres larger than 5.6 mm.

Here, most commenters argued for a longer transition period as the proposed 18 months for large calibre bullets was considered to be too short for the following reasons:

- Building of new cartridge lines (#3230, #3255, #3262); commenters explained that:

  'To set up a running bullet production line (a line is much more than a bullet machine) takes typically at least 2 years from the investment decision on normal time, but if there will be an EU-level restriction and all manufacturers need to invest at the same time, there will be a serious lack of capacity among the few manufacturers of bullet machines.' (comment #3262)

  'With normal R&D routines, the industry will not be able to develop, test and get safe and accurate lead-free ammunition in all calibres used for hunting on the market in such a short period of time.' (comment #3256)

- Adaptation to normal cycles of gun renewal; commenters explained that:

  'The planned transition periods are also very short in terms of the rate of renewal of weapons *and cartridges and the product development of cartridges. The transition period should be 5 years for calibres over 6.5 mm and 10 years for medium firing rifle calibre.'* (comment #3237)

Firearm manufacturers

Some comments were submitted that highlighted the impact a ban on the use of lead ammunition in hunting and sports shooting may have on the firearms industry in terms of job losses and loss of profit/revenue (e.g., comments #3330, #3331, #3262).

This is highlighted in comment #3330 from AFEMS and IECAS[241]/ESFAM[242] which summarises the effect a restriction on all uses of lead ammunition would have on firearms producers.

The study by AFEMS and IECAS/ESFAM concludes that 60 % of the firearms industry are likely to continue exporting their current firearm portfolio for lead containing ammunition in case of a restriction.

The study concludes that annually the firearm industry records a revenue of nearly €6 billion and profit of over €0.6 billion and employs nearly 22 thousand employees and that a premature restriction would endanger at least half of this and result in business

[241] Institut Européen des Armes de Chasse et de Sport (European Institute of Hunting and Sporting Arms)
[242] Association of European Manufacturers of Sporting Firearms

closures of approximately 20 % of the companies. According to the study annual monetary losses in terms of revenue and profit are dependent on the manufacturers ability to adapt their portfolio, exports and the share of the EEA sales. The comment states that total socio-economic costs, comprising annual profit losses, would be between €412m and €1 127m. Between 4 130 and 11 304 jobs would be lost in the EEA.

IECAS and ESFAM (#3303) stated that it typically takes more than 1 year to make the necessary changes to the production of a firearm to make it suitable for lead-free ammunition and more than 3 years to make the transition to lead-free ammunition for a firearm product where the impact is more significant. Concerning the entire portfolio, it typically takes more than five years to fully switch the firearm portfolio that is impacted by the scope of the restriction to discharge lead-free ammunition. IECAS and ESFAM stated that to avoid negative impacts, firearms manufacturers need an extension of more than five years to the entry into force.

The impact assessment made by IECAS and ESFAM is focussed on a **complete** ban on the use of lead ammunition. It is clear from Figure 11 of that study (see Figure 2-6) that the impacts on companies can be significant but that the major share of impacts comes from the market for sports shooting. Therefore, the study is not considered specific enough to describe the impacts of the proposed restriction.

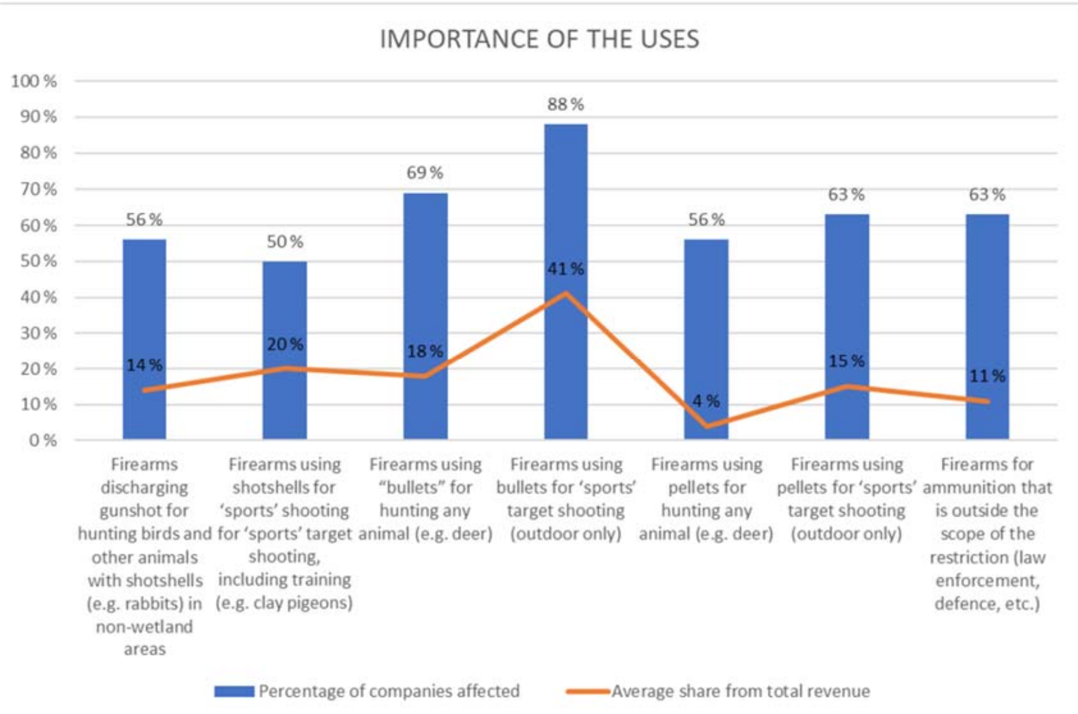

Figure 2-6: Importance of uses (source comment #3303)

However, what is clear from the study, is that, for companies to be compliant with the proposed restriction, extensive R&D work is still required. Consensus between the companies is that at least 5-10 years would be necessary to adapt the portion of their firearm portfolio that is impacted by the scope of the restriction.

The Dossier Submitter notes that the study of AFEMS and IECAS/ESFAM was responded to by 20 of the 150 companies in Europe that have a role in firearm manufacturing and had a response rate of 13 %. The study itself notes that this causes an issue of robustness in the conclusions drawn.

The Dossier Submitter further notes that the study by IECAS/ESFAM is carried out with a focus on firearm manufacturers. The results seem difficult to reconcile with some of the main findings that a) all modern shotguns are already compatible with steel shot (and have been for many years) and that b) most modern rifles are already compatible lead-free ammunition.

The Dossier Submitter furthermore notes that one of the key conclusions of the IECAS/ESFAM study is that 90 % of the impact is expected to occur from a restriction on the use of lead bullets in sports shooting. For this use, however, the Dossier Submitter has already stated that non-lead alternatives do not currently have the same technical performance as lead ammunition and sees the implementation of appropriate and effective RMMs at shooting ranges as the appropriate way to address the identified risks.

The expected impact, as presented in the comment, appears to be related to a premature introduction of the restriction rather than the restriction per se. Similar concerns were raised in comment #3262. However, the comment stated that with a transition period of five years there would be ample time to expand and set up additional production lines which typically takes about 2 years per line. Additional time would then be needed for further logistics, but a five-year transition period was seen as sufficient to avoid negative impacts on industry (#3331).

The Dossier Submitter recognises that for small calibre ammunition (centrefire smaller than 5.6 mm and rimfire ammunition) the performance of non-lead ammunition is not yet equivalent to lead ammunition. However, this is based on the results of performance testing when target shooting (comparative precision of multiple shots whilst target shooting) rather than whilst hunting and it is not clear that the reported performance of alternative ammunition is not technically feasible for hunting.

For rifle ammunition with calibres >5.6 mm, Thomas et al. (2016) present data on lead-free bullet availability from the principal 13 European rifle ammunition makers that have already developed their own brands. Kanstrup (2016) argues that this is in response to the ongoing demand for and evaluation of non-lead rifle ammunition in Germany (Gremse and Rieger 2015), and possibly, for export into the growing North American market. Kanstrup (2016) concludes that the major companies – Blaser, Brenneke, Fiocchi, Geco, Lapua, Norma, Rottweil, RWS, Sako, Sellier & Bellot, Sax, Sauvestre, Schnetz, and Hornady International – list calibres suitable for hunting every European game species and for every commonly used rifle. Kanstrup (2016) concludes from this that the product availability (i.e. that which is manufactured, as opposed to what is commonly available at the retail level) of non-lead rifle ammunition is not a limiting factor in Europe considering also the further growth in the use of non-lead bullets. All the ammunition mentioned above is regarded to be compatible with existing firearms.

The situation is similar for shotgun ammunition. Kanstrup and Thomas (2019) identified 22 European manufacturers of non-lead shot cartridges distributed among the following 8 countries: Italy (6), United Kingdom (4), France (4), Spain (4), Sweden (1), Germany (1), Poland (1), and Czech Republic (1). All companies had a steel shot production line, some with a wide selection of gauges and loads. Bismuth shot cartridges were produced by two, copper by two, and zinc by one company. In addition, six North American manufacturers produced non-lead cartridges. One (Kent Cartridge) had specialised in non-lead cartridges and was directly affiliated with a British company (Gamebore). The 28 manufacturers, including the 22 European and the six North American companies, had distribution agencies in most European countries; hence, their products, including lead-free ammunition, were available, or could easily become available in any region or country, subject to demand. All the ammunition mentioned above is regarded to be compatible with existing shotguns and would not require gun-redesign per se.

The information above has been used as well in Section 2.5.4.

Retailer compliance costs

Retailers are known to keep stocks of ammunition (bullets and gunshot cartridges) to satisfy local customer demand. In the call for evidence many retailers (mostly SMEs) highlighted potential negative consequences of a ban on the use of lead in hunting on their business.

Ammunition has a limited shelf life and cannot be stored for long periods. Several manufacturers give advice on the maximum shelf life their ammunition may have:

Lapua for example advises that its products have been designed to be useable for several years. The durability of cartridges strongly depends on the storage conditions. In good conditions, about 10-15 degrees Celsius and normal humidity, the cartridge can be used for at least 5 years.[243]

Furthermore, in most Member States, regulations are in force concerning the safe storage of ammunition that limit the amount of ammunition a retailer can keep. Especially for SMEs this amount is typically limited and therefore a transition period that is long enough to deplete existing stocks will limit any impact on retailers. In all cases, given the scope of the restriction, lead ammunition can still be used in indoor and outdoor shooting ranges that comply with the RMM conditions set in Section 2.3.

Enforcements costs

In terms of enforcement costs, it is assumed that REACH enforcement authorities would conduct spot checks of imported hunting ammunition (customs), manufacturers site inspection, retailers site inspections, and retailer's website inspection once the restriction option would enter into force (i.e. after the transition period).

In addition, it is assumed that the preferred restriction option would allow inspections at the site of use (e.g., at common hunting locations) to be performed as well by the national relevant enforcement authorities (either hunting associations or local area authorities or ministries depending on the EU country).

It is assumed that the enforcement costs (administrative, testing, and on the field) for enforcement authorities and industry will effectively be zero, existing inspections covered under the wetlands proposal will be used for this proposal as well and no additional cost will arise.

Costs for hunters

Once the restriction enters into force, it is assumed that hunters will continue to consume the same quantity of bullets and shot to continue their activity.

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

- **'one-off' costs** for the adaptation and/or replacement of the current stock of unsuitable guns

[243] https://www.lapua.com/ammunition/faq/

- incremental **'operational' costs** incurred as a continuous consequence of switching to alternative ammunition

The cost for hunters consists of increased prices for alternatives as well as the cost associated with having to buy a new gun earlier than anticipated because of this restriction.

One-off costs

A fraction of the hunters will have to change their shotguns. Even though 'standard proofed' shotguns can fire standard steel cartridges there may still be a fraction of hunters that have shotguns that are not suitable for steel, although these hunters may use bismuth as an alternative. To make a conservative assessment the Dossier Submitter uses assumptions similar to the ones used in the wetlands dossier.

One-off costs consist of any modification that a hunter must make to their shotgun to fire steel shot: these include any cost incurred by a hunter to ensure their shotgun can use steel gunshot (e.g., a choke modification) as well as the cost for prematurely replacing a shotgun that is unsuitable for use with standard steel gunshot. It also includes the costs some hunters may incur for testing (re-proofing) to ensure that their shotgun is suitable for use with standard or high-performance steel gunshot. Importantly, not all hunters will need to replace, re-proof or modify a shotgun that is not suitable for use with steel gunshot as they may switch to bismuth or tungsten gunshot cartridges or other alternative ammunition that can be used in any existing shotgun that is currently used with lead gunshot.

For large calibre rifles, existing non-lead bullets can be used without adaptation. A decision to ban the use of lead bullets would imply that the need would arise to replace certain rifles for small calibre bullets. Small calibre copper bullets may not properly stabilise when fired from a rifle barrel with an incompatible barrel 'twist rate'. In these the rifle may be either substituted or the barrel changed to one with a compatible twist rate (Caudell et al., 2012).

Operational costs

Those hunters that hunt with lead ammunition will face an increased cost for using lead-free alternatives, the cost of such alternatives vary as per the intended game. These differences are described in the section on the economic feasibility of alternatives.

Gunshot

The information submitted in the call for evidence as well as the market analysis performed by the Dossier Submitter highlights that the costs for steel shot are comparable to the costs of lead shot, although there may exist some regional differences.

To study the costs of regulatory action, the Dossier Submitter developed best-, central-, and worst-case scenarios. The scenarios vary according to the extent that regulation on the use of lead gunshot already exists, the average price of steel gunshot compared to lead gunshot, the need for testing/adaptation of existing guns and the need to purchase new guns. The outcome of this assessment is presented in Table 2-23.

The main assumptions concerning the need for gun replacement, the cost associated with using lead-free ammunition and adaptation that hunters already may have made as a consequence of the restriction on lead shot in wetlands are described in Annex D.

Table 2-23: Substitution scenarios for hunting with gunshot (rounded)

Scenario	Best-case	Central-case	Worst-case
Number of hunters impacted in terrestrial hunting	3.6m (60 % of all hunters)	3.8m (65 % of all hunters)	4.1m (70 % of all hunters)
Number of shotguns to be replaced in terrestrial hunting	0	190 000	413 000
One-off costs for premature replacement of shotguns	€0m	€132m	€424m
Annual operational costs (i.e. annual incremental cost to be spent on shot)	€0m	€72m	€122m
Annualised one-off costs for testing	€3m	€2m	€1m
Annualised one-off costs for new guns	€0m	€10m	€20m
Total annual costs	€3m	€84m	€143m
Costs over 20 years (NPV at 4 % discount rate)	€28m	€768m	€1 310m
Annual emission reduction	10 600 tonnes	13 900 tonnes	17 200 tonnes
Emission reduction over 20 years	159 000 tonnes	209 000 tonnes	259 000 tonnes
Additional costs per hunter (p.a.)	€0	€19	€30
Average hunter's budget (p.a.)	€3 000	€3 000	€3 000
Fraction of average hunter's budget	**0 %**	**0.6 %**	**1.0 %**
Note: figures are rounded			

SEAC Box

In the central cost scenario, the Dossier Submitter assumes that 15 % of hunters would switch to alternatives other than steel, i.e. bismuth or tungsten, in response to the ban of lead gunshot.

SEAC considers this assumption as overly conservative for a central scenario. Available evidence supports the conclusion that it is unlikely that as many hunters would switch to bismuth and tungsten, because steel gunshot (i) can be used in the vast majority of shotguns and (ii) would entail no or minor additional costs due to similar price levels as lead gunshot. Comments received in the consultation on the Annex XV report confirmed that hunters would rather buy a new gun than switch to bismuth or tungsten gunshot. As the alternative hunters will switch to is an important driver of the cost estimate, SEAC considered that a change in the assumption made by the Dossier Submitter would be reasonable in order to ensure that the central cost estimate adequately reflects available information. Accordingly, SEAC re-calculated the central cost estimate applying the assumption that only 5 % of hunters would switch to bismuth or tungsten gunshot (see table below).

Cost scenarios assessed by the Dossier Submitter to substitute lead gunshot in hunting including variation on the central scenario included by SEAC rapporteurs

Input/Output	**Best case**	**Central case - SEAC**	**Central case - DS**	**Worst case**
Number of hunters impacted in terrestrial hunting	3.6m (60% of all hunters)	equal to DS	3.8m (65% of all hunters)	4.1m (70% of all hunters)
Relative price of steel shot	100%	equal to DS	101%	103%
Proportion switching to steel shot (remaining hunters are assumed to switch to bismuth or tungsten)	100%	**95%**	85%	85%
Number of shotguns to be replaced in terrestrial hunting (% of hunters affected)	0	equal to DS	190 073 (5%)	413 252 (10%)
One-off cost for premature replacement of shotguns	€0m	equal to DS	€132m	€424m
Annual operational cost (i.e. annual incremental cost to be spent on shot)	€0m	€25m	€72m	€122m
Annualised one-off cost for testing	€3m	equal to DS	€2m	€1m
Annualised one-off cost for new guns	€0m	equal to DS	€10 m	€20m
Total annualised cost to hunters	**€3m**	**€37m**	**€84m**	**€143m**
Total cost (20 years)	**€28m**	**€342m**	**€768m**	**€1 310m**

Bullets

To study the costs of the proposed restriction on lead bullets, three scenarios (‘best case’, ‘central case’ and ‘worst case’) were developed. These scenarios are based on different assumptions on the following elements that determine the overall cost of the restriction.

i) Under the best-case scenario, it is assumed that the fraction of hunters already using non-lead bullets is as high as 15 %, which may be an overestimate in some Member States. Comments in the call for evidence estimated this fraction to be only 10 %, but it is known that many hunters, due to the German legislation and local restrictions in national parks in Austria and Italy, have started to use lead-free bullets. In the central and worst-case scenarios it is assumed that the fraction of hunters already using non-lead bullets is 10 % and 5 %, respectively.

ii) Concerning small calibres, it is assumed that hunters will have to buy new guns or change barrels for calibre sizes smaller than 5.6 mm. Hunters will likely change only the barrel rather than both the stock and the barrel of their guns. The Dossier Submitter has considered this in its cost assessment with the best-case scenario assuming a change of barrel only, and the central and worst-case scenarios assuming a change of the whole gun.

Cost impacts of these assumptions are summarised in Table 2-24.[244] Further assumptions concerning the need for gun replacement, and the cost associated with using alternatives are described in Annex D.

Table 2-24: Substitution scenarios and associated costs for bullets (bullets in small and large calibres, prices per bullet in €)[245]

Scenario	Best case	Central case	Worst case
Small calibre			
Small calibre (smaller than 5.6 mm) Average bullet price increment for non-lead	€0	€0.2	€0.4
Number of guns to be replaced	178 393	267 590	535 180
One-off costs for premature replacement of guns with small calibre	€66m	€165m	€366m
Annualised one-off costs for new guns	€5m	€12m	€17m
Running costs (ammunition)	€1m	€1m	€3m
Total annual costs	€6m	€13m	€20m
Total costs over 20 years (NPV at 4 % discount rate)	€54m	€122m	€179m
Annual emission reduction	14 tonnes	15 tonnes	17 tonnes
Emissions reduction over 20 years	208 tonnes	232 tonnes	255 tonnes
Large calibre			

[244] Technical details on how the replacement cost for the respective stock of shotguns is calculated and how this estimate is annuitized are described in Annex D.
[245] Prices are reported with VAT.

Scenario	Best case	Central case	Worst case
Large calibre (5.6 mm and larger) Average bullet price increment for non-lead	€0.75	€1.46	€2.17
Running costs (ammunition)	€8m	€20m	€34m
Costs over 20 years (NPV at 4 % discount rate)	€101m	€239m	€412m
Annual emission reduction	92 tonnes	119 tonnes	138 tonnes
Emission reduction over 20 years	1 700 tonnes	2 200 tonnes	2 500 tonnes
Note: figures are rounded			

During the call for evidence, the results of a market study by the BASC were submitted to ECHA. This study contained market information on prices of lead bullets. A cost calculation performed with the price differences between lead and non-lead ammunition described in the study by the BASC, resulted in even lower costs for bullets. This analysis is described in detail in Annex D.1.3.2.4.

2.5.3.1.1. Input from the consultation on the Annex XV report on substituting lead in gunshot

Gun renewal

The main comments from the consultation related to the use of bismuth as an alternative to lead gunshot as well as the need to replace existing shotguns. The main contributions on this topic were made by FACE (#3467) and AFEMS (#3331). The Dossier Submitter takes the view that by discussing these two submissions other submissions on the same topic (which sometimes referred to the submissions of FACE and AFEMS) are covered as well.

Several commenters (such as e.g., #3467, #3466) suggested that the Dossier Submitter had underestimated the number of shotguns that would need to be replaced in the event of a restriction and consequently had underestimated the corresponding costs. Other comments (#3510, #3329) suggest that there is very little need for gun replacement and the estimation in comment #3467 is too pessimistic as many old guns can fire steel shot if the cartridges used are compatible with the pressure thresholds of the particular shotgun.

Based on the comments received in the Annex XV consultation and previous work on the restriction on lead gunshot in wetlands, the Dossier Submitter highlights that even old shotguns may not necessarily need to be replaced but can use bismuth gunshot instead. These alternative shots are more expensive and the optimal response of a hunter to any restriction on lead gunshot thus depends primarily on the total number of shots spent per year. To make this point clearer, consider a hunter who owns a shotgun manufactured before 1961 and is now facing the choice to replace this gun or buy bismuth or tungsten shot instead. Assume that a new shotgun of similar type costs €1 500. As the Dossier Submitter determined that the average price difference between steel shot (average price of €0.45 per cartridge) and bismuth shot (average price of €1.69 per cartridge) was about €1.24 per cartridge, one can calculate that it becomes economically attractive to replace the old shotgun by a new model that can use standard steel shot if the hunter spends more than ~90 shots per year.[246]

On the concept of 'old' guns, the Dossier Submitter notes that there is no fixed definition. Guns manufactured before 1961 can be considered as 'old' following a study of Putz (2012). But if standard proof is the benchmark for being able to define old, as according to guidance any standard proofed shotgun can use standard steel shot, then also 1954 can be used as benchmark year for 'old' guns, as in that year nitro proof (i.e., standard proof) was introduced.[247]

FACE had submitted the results of a survey it had organised among its members to analyse the socio-economic impacts of a restriction on the use of lead shot and lead bullets in terms of the need to replace existing guns. Table 2-25 summarises the numbers reported in Table 2 of comment #3467, indicating the absolute and relative numbers of shotguns that hunters believed needed replacement or adaptation in case of a ban of lead gunshot. It should be noted though that in other parts of the submitted comment, the number of existing shotguns in the EU is slightly higher (21.6m as per Table 2 of #3467) or lower (20.1m as per footnote 126 of #3467).

Table 2-25: Information on shotguns in the EU reported by FACE (#3467)

Suitability	Number of shotguns in millions	Share of all shotguns
Shotguns SUITABLE	11.17	54 %
Shotguns LIMITED SUITABILITY	4.38	21 %
Shotguns UNSUITABLE	5.09	25 %
Total	**20.64**	**100 %**

Based on the information displayed in Table 2-25, FACE (#3467) drew the conclusion that one quarter of all hunters may give up hunting in case of a ban on lead gunshot.

[246] For this calculation, one may assume that a new shotgun of similar type costs €1 500 and has an expected lifespan of 20 years. Using the PMT command in Excel and assuming a discount rate of 4 % as recommended by the EU's Better Regulation guidance, this cost can be converted into an annuity cost of €110. One may then solve the equality €110=x*€1.24, where x is the number of shots spent; x=€110/€1.24=90, meaning that it is economically attractive to buy a new shotgun if the hunter spends more than 90 shots per year with that gun.
[247] https://www.vintageguns.co.uk/magazine/rules-of-proof-8-re-proof.

Whilst recognising that there might a fraction of shotguns in use that are not suitable for steel shot, the Dossier Submitter disputes such drastic consequences.

The Dossier Submitter would like to make several observations on this survey:

1. The survey posed questions on all shotguns without differentiating between wetland hunting – for which a restriction has already been adopted by the EU institutions – and terrestrial hunting. The survey would have been more informative if it had distinguished between these two regulatory actions.
2. The survey collected shotguns users' perceptions of and beliefs about the suitability of steel shot (subjective) rather than collecting information about the properties of the shotguns owned (objective, by e.g., inquiring about the year of manufacture of existing shotguns).
3. Following good practice in socio-economic analysis, the replacement of guns and the need to buy a new shotgun is an important aspect of the overall cost of this regulatory action. However, the analysis should consider that, even in the absence of a restriction on lead gunshot, shotguns have to be periodically replaced. Therefore, the welfare costs brought about by the regulation should see the replacement cost as the advancement of an investment that would have happened anyhow at the end of service life of a shotgun, rather than the total investment cost. In other words, if a hunter would have to replace their shotgun within the next 5 years, then the regulation may force them to buy a new gun five years earlier than they had envisioned. As the cost for the new gun would have accrued anyhow, it is only the extra cost from having to replace the gun earlier that matters.
4. The report emphasises the need to replace shotguns rather than the need for hunters to be able to comply with the conditions of the proposed restriction. The Dossier Submitter agrees that replacing all unsuitable shotguns would, without doubt, generate a far larger cost than focusing on the costs accruing to hunters that need to purchase a compliant shotgun because they do not currently own at least one shotgun suitable to use with alternative ammunition.

AFEMS (#3331) requested that the Dossier Submitter revise the scenarios to exclude the non-credible assumption that 15 % of owners of non-suitable shotguns will switch to bismuth or tungsten shot rather than replace their shotguns. AFEMS further requested that the impact of both increased unit replacement costs and higher percentages for replacement of non-suitable firearms would be considered.

The NARGC (#3466) takes the same line as FACE stating that the number of shotguns that need to be replaced is much higher than estimated by the Dossier Submitter.

Other comments on the same subject would suggest that there is less need for gun replacement. Comment #3329 states if it is safe to fire a given lead shot cartridge through the gun, it is safe to fire the equivalent non-lead cartridge of the same cartridge length and shot load through the gun and that applies to all gauges of shotgun, alluding to an overall low need for gun replacement. The Dossier Submitter wishes to highlight that recent recommendations accompanying the voluntary withdrawal of the use of lead shot by the BASC and rural organisations[248] in the United Kingdom follow similar lines[249] (see also #3329).

Concerning cartridges of 2.5 inch length and considering comment #3209 the Dossier Submitter notes a recent announcement by the company Eley Hawk[250] which intends to place on the market steel cartridges specifically geared towards old shotguns.

Comment #3510 reacts on the survey conducted by FACE among hunters highlighting that an estimated total of 69 million firearms for 7 million hunters in Europe would mean an average of nearly 10 firearms owned by the average hunter. This would show that hunters already dedicate a large budget to their hunting activity. The commenter thus noted that, in this context, comment #3510 state that the perceived costs of shifting to non-lead ammunition and suitable firearms seemed to be rather insignificant compared to the budget dedicated to hunting.

Comment #3510 further highlighted that the FACE survey had indicated that a majority of firearms (66 %) was suitable for non-lead ammunition. Also, 73 % of hunters own at least one shotgun that can be used with non-lead ammunition. The commenter interpreted these figures as showing that the transition to suitable firearms would impact only a minority of hunters. The commenter concluded that the actual replacement costs are lower than stated in the FACE report, as hunters already own suitable firearms; they do not need to replace all the ones that are not suitable.

The issue of replacement of non-proofed shotguns, as highlighted by the Union of Hunters and Anglers in Bulgaria (#3523), is considered an impact that does not originate from this restriction proposal. Indeed, using non-proofed shotguns pose a safety risk for the shooter even when using modern lead loads. The CIP safeguards that all firearms and ammunition sold to civilian purchasers in Member States are safe for the users. To achieve this, all such firearms are first proof tested at CIP. Without a proof test the safety of a gun cannot be guaranteed neither for steel nor for lead. This is made explicit in the CIP objectives[251].

An important issue the Dossier Submitter wants to underline is the number of hunters that need to replace their shotgun to be able to continue hunting. The FACE survey (#3467, #3333) claimed that as 25 % of existing shotguns are not suited for standard steel shot, around 25 % of all hunters in the EU (~1.5 million) would need to replace their shotguns. The Dossier Submitter argues that the actual need for shotgun replacement is substantially lower than the 25 % proposed in the comments by AFEMS and FACE.

Based on the above reasoning, the Dossier Submitter argues that the actual need for gun replacement is significantly lower than the 25 % indicated in the comments by AFEMS (#3331) and FACE (#3467). Nevertheless, the Dossier Submitter undertook a sensitivity analysis varying various assumptions, including the number of guns needed to be replaced, the price of replacement per average gun and the actual number of active

[248] https://basc.org.uk/a-joint-statement-on-the-future-of-shotgun-ammunition-for-live-quarry-shooting/

[249] https://www.gwct.org.uk/media/1094670/Moving-away-from-lead-shot-QA.PDF

[250] https://www.gunsonpegs.com/articles/cartridges/s/non-toxic-shotgun-cartridges/steel-cartridges-for-older-guns

[251] https://www.cip-bobp.org/en/cip

hunters engaged in shotgun hunting. In particular, the results presented in Table 2-26, Table 2-27, and Table 2-28 vary the following input parameters:

- Number of hunters affected:
  - 6 million, representing the total number of registered members of hunting associations in the EU (as suggested by FACE);
  - 4.5 million, corresponding to the ballpark estimate of active hunters extrapolating the share of active Finnish hunters to the whole of the EU;
  - 3 million, considering that 50 % of all registered hunters are active hunters engaged in shotgun hunting.
- Share of affected hunters that need to replace their shotgun to be able to continue hunting:
  - 5 %, meaning that between 150 000 and 300 000 hunters have to replace a shotgun;
  - 10 %, meaning that between 300 000 and 600 000 hunters have to replace a shotgun;
  - 15 %, meaning that between 450 000 and 900 000 hunters have to replace a shotgun;
  - 20 %, meaning that between 600 000 and 1 200 000 hunters have to replace a shotgun;
  - 25 %, meaning that between 750 000 and 1 500 000 hunters have to replace a shotgun.
- Price per new shotgun:
  - €1 000 per average shotgun;
  - €1 500 per average shotgun;
  - €2 000 per average shotgun;
  - €2 500 per average shotgun.

Contingent on the number of hunters affected, Table 2-26, Table 2-27 and Table 2-28 indicate the conditions under which the replacement costs brought about by the restriction would be of the same order of magnitude as the benefits derived in Section 2.5.3.3.3 (orange) or would even outweigh these benefits (green). As the tables show, even under the worst-case assumption made by FACE (#3467) that 25 % of hunters would have to replace their shotguns, the monetised benefits of the proposed restriction would be at least as large as the costs implied.

As a side remark, the Dossier Submitter notes that the FACE survey (#3467) does not distinguish between the impacts that can be expected from the restriction on the use of lead shot in wetlands and the *additional* impacts of a restriction on the use of lead shot outside wetlands. Therefore, the Dossier Submitter considers that, of the total number of guns FACE suggests would need to be replaced, a substantial fraction was already accounted for in the earlier restriction on the use of lead gunshot in wetlands. It would be erroneous to attribute the cost of their replacement to this restriction as well.

Table 2-26: Cost of replacement under different prices of guns and different shares of gun replacement (prices in €m) assuming a 20-year service life and an annual replacement rate of 5 %, 5-year TP assuming 6 million hunters affected

	SHARE OF HUNTERS THAT REPLACE SHOTGUN	**5 %**	**10 %**	**15 %**	**20 %**	**25 %**
	shotguns to be replaced	**300 000**	**600 000**	**900 000**	**1 200 000**	**1 500 000**
PRICE OF SHOTGUN (€)	**1 000**	**€185m**	**€369m**	**€554m**	**€739m**	**€924m**
	1 500	**€245m**	**€554m**	**€831m**	**€1 108m**	**€1 385m**
	2 000	**€369m**	**€739m**	**€1 108m**	**€1 478m**	**€1 847m**
	2 500	**€407m**	**€924m**	**€1 385m**	**€1 847m**	**€2 309m**
	1 000	**€14m**	**€27m**	**€41m**	**€54m**	**€68m**
	1 500	**€18m**	**€41m**	**€61m**	**€82m**	**€102m**
	2 000	**€27m**	**€54m**	**€82m**	**€109m**	**€136m**
	2 500	**€30m**	**€68m**	**€102m**	**€136m**	**€170m**

Note: The upper panel refers to total cost, whereas the lower panel refers to annualised costs.

Table 2-27: Cost of replacement under different prices of guns and different shares of gun replacement (prices in €m) assuming a 20-year service life and an annual replacement rate of 5 %, 5-year TP assuming 4.5 million hunters affected

	SHARE OF HUNTERS THAT REPLACE SHOTGUN	**5 %**	**10 %**	**15 %**	**20 %**	**25 %**
	shotguns to be replaced	**225 000**	**450 000**	**675 000**	**900 000**	**1 125 000**
PRICE OF SHOTGUN (€)	**1 000**	**€139m**	**€277m**	**€416m**	**€554m**	**€693m**
	1 500	**€208m**	**€416m**	**€623m**	**€831m**	**€1 039m**
	2 000	**€277m**	**€554m**	**€831m**	**€1 108m**	**€1 385m**
	2 500	**€346m**	**€693m**	**€1 039m**	**€1 385m**	**€1 732m**
	1 000	**€10m**	**€20m**	**€31m**	**€41m**	**€51m**
	1 500	**€15m**	**€31m**	**€46m**	**€61m**	**€76m**
	2 000	**€20m**	**€41m**	**€61m**	**€82m**	**€102m**
	2 500	€26m	€51m	€76m	€102m	€127m

Note: The upper panel refers to total costs, whereas the lower panel refers to annualised costs.

Table 2-28: Cost of replacement under different prices of guns and different shares of gun replacement (prices in €m) assuming a 20-year service life and an annual replacement rate of 5 %, 5-year TP assuming 3 million hunters affected

	SHARE OF HUNTERS THAT REPLACE SHOTGUN	5 %	10 %	15 %	20 %	25 %
	shotguns to be replaced	**150 000**	**300 000**	**450 000**	**600 000**	**750 000**
PRICE OF SHOTGUN (€)	**1 000**	**€92m**	**€185m**	**€277m**	**€369m**	**€462m**
	1 500	**€277m**	**€277m**	**€416m**	**€554m**	**€693m**
	2 000	**€369m**	**€369m**	**€554m**	**€739m**	**€924m**
	2 500	**€462m**	**€462m**	**€693m**	**€924m**	**€1 154m**
	1 000	**€7m**	**€14m**	**€20m**	**€27m**	**€34m**
	1 500	**€20m**	**€20m**	**€31m**	**€41m**	**€51m**
	2 000	**€27m**	**€27m**	**€41m**	**€54m**	**€68m**
	2 500	**€34m**	**€34m**	**€51m**	**€68m**	**€85m**

Note: The upper panel refers to total costs, whereas the lower panel refers to annualised costs.

2.5.3.1.2. Input from the consultation on substituting lead in rifle ammunition

Several topics were brought forward in the consultation most of which related to whether guns are suitable for the use of non-lead rifle ammunition. Most of these issues are also discussed in Section 2.5.1.1.

The survey by FACE (#3467) highlighted that many guns with calibres smaller than 6.5 mm would need to be replaced due to the unsuitability of non-lead ammunition. These comments are already addressed in Section 2.5.1.2.1 where the cut-off between small and large calibres proposed by the Dossier Submitter is discussed. As for the unsuitability of lead-free small calibre ammunition, the Dossier Submitter does not agree with the conclusions made by FACE because of the following considerations:

1. The data of LUKE (cited before) shows that there is a difference between registered members of hunting associations and active hunters. FACE's survey result was extrapolated to all European hunters instead of considering those who engage in the type hunting for which rifles are used.
2. The feedback in the FACE survey came largely from Sweden where Swedish hunters had stated that their rifles would not be suitable for non-lead ammunition given the current weight limitations imposed in the Swedish hunting legislation. Non-lead bullets would be too light to be legally allowed, whereas research[252] has shown that there is no difference in killing effect between lead and non-lead bullets despite the weight difference.
3. Other comments in the consultation indicated that alternative small calibre ammunition with different twist rates is put on the EU market, and that the choice of twist rates and ensuring that the twist rate of a bullet carefully matches the twist rate of a rifle is crucial both for lead and non-lead bullets.

The Dossier Submitter has taken into account the input received from FACE on rimfire and airgun rifles as well as the niche applications of FMJ bullet, muzzle loading in hunting and seal hunting and has taken up the relevant points in its documentation of these subjects (see 2.5.1.2.1 and the conclusion on alternatives).

2.5.3.2. Other impacts for society

2.5.3.2.1. Military uses

While non-civilian uses are outside the scope of the proposed restriction, the restriction may have spillover consequences on the supply of ammunition for military and police use. This is relevant for defence uses where **security-of-supply** considerations necessitate contingency planning to be prepared for a sudden increase in demand (e.g., in a conflict situation). Previous experience of the United States and the United Kingdom armed forces during the Iraq conflict showed that supply was an issue due to the increased demand for ammunition (#3331). In this regard, AFEMS highlighted in the call for evidence that the widely cited 2019 Californian ban on the use of lead ammunition for hunting (Assembly Bill 7111) solely covers hunting whereas sports shooting with bullets is not within the scope of that ban and was therefore disregarded in the regulatory impact analysis conducted.

In the call for evidence, AFEMS stated that many manufacturers offer alternatives at below-cost, at cost, or at a lower profit margin. They do so in order to offer a full range of

[252] https://jagareforbundet.se/contentassets/7099893fd13b45b98e1900d2ea165fee/65x55_se.pdf

products to customers who want or are required to use non-lead ammunition.

2.5.3.2.2. Impact on hunting

Based on the figures that the Dossier Submitter assumed in its original Annex XV report, FACE (#3467) calculated that hunting generates an annual revenue of around €18 000 million to the economies of the EU Member States. FACE criticised that the Dossier Submitter had not estimated how the intended restriction would affect the frequency of hunting in the EU27 and the economic consequence thereof. FACE's calculation is based on an estimation of lost hunting days, which in turn is based on survey results suggesting that 25-30 % of all hunters could stop due to restrictions on the use of lead. On the basis of the number of hunting days in California, FACE estimates that all EU-27 hunters would hunt five days less per season, which evaluated at €176 per day of hunting would result in an economic loss of €1 200 million.

Earlier studies[253] of FACE described the expenditure of hunters and stated that weapons and ammunition together constitute about 10 % of the total hunting budget, more specifically for Germany it stated that average expenditure on arms amounts to €390 of a total budget of €4 320 implying that expenditure on arms corresponds to ~9 % of the total annual hunting budget.

One commenter highlighted that a previous restriction on the use of lead in Spain (comment #3479) did not lead to a reduction in hunting activities. Similar observations have been made in Denmark, where contrary to some hunters' fears, the mandatory switch to non-lead ammunition was not an obstruction to hunting activities (Kanstrup 2015). On the contrary, Kanstrup et al. (2018) argue that the valuable public image of hunters visibly seen to be reducing the dispersal of a recognised contaminant poison (i.e. lead) into the environment has been of paramount importance for the long-term political sustainability of hunting.

More and more German Federal states require the use of non-lead ammunition, yet the number of hunters is increasing in Germany[254],[255]. Specifically, 3 of 16 German Federal States (Schleswig-Holstein, Baden-Württemberg and Saarland) have totally banned the use of lead-core bullets for hunting. In Schleswig-Holstein, the use of lead bullets and shotgun slugs for hunting was banned first in State Forests in 2013 and then state-wide in 2015. In Baden-Württemberg, the use of lead bullets has been banned for hunting ungulates in the State Forests since 2014 and the rest of the region since 2016. In Saarland, the ban on lead-rifle ammunition was implemented in State Forests in 2011 and became state-wide since 2014, with a grace period granted to phase out their use by 2017. The Federal State of North Rhine-Westphalia is in the process of passing legislation to restrict the use of lead bullets and shotgun slugs in hunting, but there is already a ban on lead ammunition for rifles in State Forests since 2013. Other German regions have also banned lead-rifle ammunition in State Forests since 2013 (Berlin, Brandenburg, Lower Saxony and Rhineland-Palatinate), 2014 (Mecklenburg-Vorpommem) and 2015 (Hesse) (Gremse and Rieger 2015). This can be contrasted with data on the number of hunters per federal state in Germany[256] (see Figure 2-7 and Table 2-29), which suggest that there is no decline in hunting since the introduction of these restrictions on the use of lead bullets in hunting.

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[253] https://www.face.eu/sites/default/files/documents/english/economia_della_caccia_27_9_2016_en.pdf
[254] https://gettotext.com/the-day-the-number-of-hunters-in-germany-is-increasing/
[255] https://de.statista.com/statistik/daten/studie/161126/umfrage/anzahl-der-jagdscheininhaber-in-deutschland-seit-1968/
[256] https://de.statista.com/statistik/daten/studie/170022/umfrage/jagdscheininhaber-nach-bundesland/

Figure 2-7: Number of hunters in Germany (Source: statista.com)

Table 2-29: Number of hunters in a given year for selected federal states of Germany (source: statista.com)

	2018	2019	2020
Schleswig-Holstein	22 856	23 328	24 081
Baden-Württemberg	44 375	46 772	49 440
Saarland	4 658	4 756	4 917

2.5.3.3. Cost-effectiveness, affordability, and proportionality to risk

2.5.3.3.1. Affordability considerations

Examples from Denmark and the Netherlands for lead shot and in Germany where similar restrictions of lead in bullets (albeit with different scope) are already in place, indicate that switching to alternative materials is possible and affordable for hunters whether it be based on a regulatory requirement (as in Germany and the Netherlands and Denmark) or based on a desire for bullets whether or not combined with a desire for improved quality of meat (Finland).

Even if the restriction costs would be fully passed through to hunters (via price increments for ammunition), these costs are low compared to the average hunting budget spent yearly by hunters.

Based on the compliance cost estimates reported and the average yearly expenses per hunter presented in Annex D, the purchase of non-lead alternatives for both shot and bullets would induce an additional expense (operational cost only) as per the overview in Table 2-30. The calculations for this table are given in Annex D, Table D.1-46.

Table 2-30: Yearly costs per hunter per restriction option

Restriction Option	Cost of restriction per hunter (€/y)		
	Best case	Central	Worst case
Ban on placing on the market and use of lead gunshot for hunting	€0	€19	€30
Ban on use of lead bullets for hunting – small calibre	€0	€2	€6
Ban on use of lead bullets for hunting – large calibre	€3	€6	€9
Note: the calculated costs are expressed as annual costs			

The proposed measures are estimated to only impose a limited cost on the individual hunter. Based on the cost estimates presented in Table 2-30 of this restriction report, it can be expected that the additional cost to an average hunter for purchasing non-lead shot ammunition rather than lead shot ammunition will range from €0 (best case) to €30 (worst case) per year. The corresponding ranges for small and large calibre bullets are €0-6 and €3-9, respectively.

For small calibre bullets the cost may be higher according to comment #3467, where FACE states, based on a study (Hampton et al., 2020) that due to the inaccuracy of small calibre bullets multiple shots may be needed and the additional cost of using non-lead compared to lead ammunition could be six times higher as more bullets were needed to take game.

For gunshot, the worst-case scenario corresponds to 1 % of the average annual hunting budget of a European hunter which is in the order of €3 000 (Pinet, 1995). For small and large calibre bullets this share is below 0.5%. Other comparisons to the average annual hunting budget of European hunters are reported in Table 2-31.

Table 2-31: Burden relative to the average hunter's annual budget

Restriction option	Low	Central	High
Ban on placing on the market and use of lead gunshot for hunting	0 %	0.6 %	1.0 %
Ban on use of lead bullets for hunting – small calibre	0 %	0.1 %	0.2 %
Ban on use of lead bullets in hunting – large calibre	0.1 %	0.2 %	0.3 %
Note: the calculated costs are expressed as annual costs			

The Dossier Submitter recognises that the budget of a hunter may differ per hunting culture and could vary from as low as €500 per year to €2 000 per year. However, the additional costs that would be incurred by hunters seem economically sustainable even for subsistence hunters with a significantly lower hunting budget than €3 000 per year, which can be broken down into the following cost categories (Pinet, 1995): legal expenditure, expenditure on yearly hunting rights, expenditure on equipment, expenditure on transport, and dog-related expenditure.

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 gamekeepers 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 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 several 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 per year);
- "national" hunters, who hunt less frequently but further away.

In both cases, the travel costs account for around 25 % of total yearly spending.

Dog-related expenditure

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.

On this basis, and using existing regional studies, it is possible to calculate the average annual European hunter's budget. The most recent studies provide the following estimates:

- Belgium €5 800 (1992);
- Spain €2 450 (1993);
- Scotland €1 720 (1990);
- France €1 200 (1993);
- Ireland €350 (1992).

After weighting the figures according to numbers of hunters in each country, the average expenditure comes out at €1 680 per year. 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 a reliable estimate. Correcting for inflation, this is equivalent to about €3 000 in 2020 terms.

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 US spending data where on an average about 6 % of the budget of a hunter is spent on ammunition. Assuming a worst-case scenario where indeed non-toxic shot is more expensive, the average expenditure of €75 would increase to about €100. In the total budget this would imply that the budget needs to increase by less than 1 %.

It is worth noting that this is an average budget and heterogeneity exists among hunters (REGHAB Study, April 2002). 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. Even though 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.

Although affordability considerations do not imply that a regulatory measure entails a net welfare gain, the analysis suggests that the preferred restriction would be unlikely to exert disproportionate costs to society overall, but hunters may be impacted differently across the EU.

2.5.3.3.2. Cost-effectiveness considerations

The proposed restriction is anticipated to reduce lead emissions to the environment according to the estimates in Table 2-32. Over the 20-year study period, the expected impact is a reduced emission of lead of about 211 000 tonnes for gunshot and bullets combined.

Considering the aggregated costs imposed on hunters (in terms of more expensive ammunition and the premature replacement of guns and shotguns that cannot fire non-lead shot ammunition), these abatement figures suggest that the total cost per tonne of lead emission avoided is in the range of 3.7 €/kg to 525 €/kg (central scenario).

Table 2-32: Overview of cost and cost effectiveness

Restriction Option	Yearly costs (million €)	Costs over 20-years (NPV at 4 % discount rate; million €)	Emission avoided over 20-years (tonnes)	Cost-effectiveness[257] (€/kg avoided release)
Ban on placing on the market and use of lead gunshot for hunting	84 (3-143)	768 (28-1 310)	209 000 (159 000-259 000)	3.7 (0.2-5.1)
Ban on use of lead bullets for hunting – small calibre	13 (6-20)	122 (54-179)	232 (208-255)	525 (258-705)
Ban on use of lead bullets for hunting – large calibre	20 (8-34)	239 (101-412)	2 200 (1 700-2 500)	109 (60-162)

Notes: For gunshot and small calibre bullets cost and emission reduction over 20-year period are assumed to occur after the first 5 years, for large calibre bullets after the first 18 months. In the first 5 years (18 months) no costs and no emission reduction are assumed.

If one compares the cost-effectiveness of the current restriction proposal to the one for decaBDE, for example, where one major environmental impact was accumulation of the substance in birds of prey, it is obvious that the current proposal is an order of magnitude more cost-effective. Considering the hazard properties of lead, it can thus be concluded that the proposed restriction is a cost-effective measure of addressing lead emissions to the environment.

Overall, the preferred restriction for lead in shot and bullets appears to be as cost-effective as previous REACH restrictions, including the restriction on lead in PVC which was addressing similar human health concerns (see Figure 2-8). This clearly shows that the proposed measures under this restriction are in the same order of magnitude of other restrictions that were deemed to be proportionate.

[257] Small differences may occur due to rounding and annualisation of impacts over the study period.

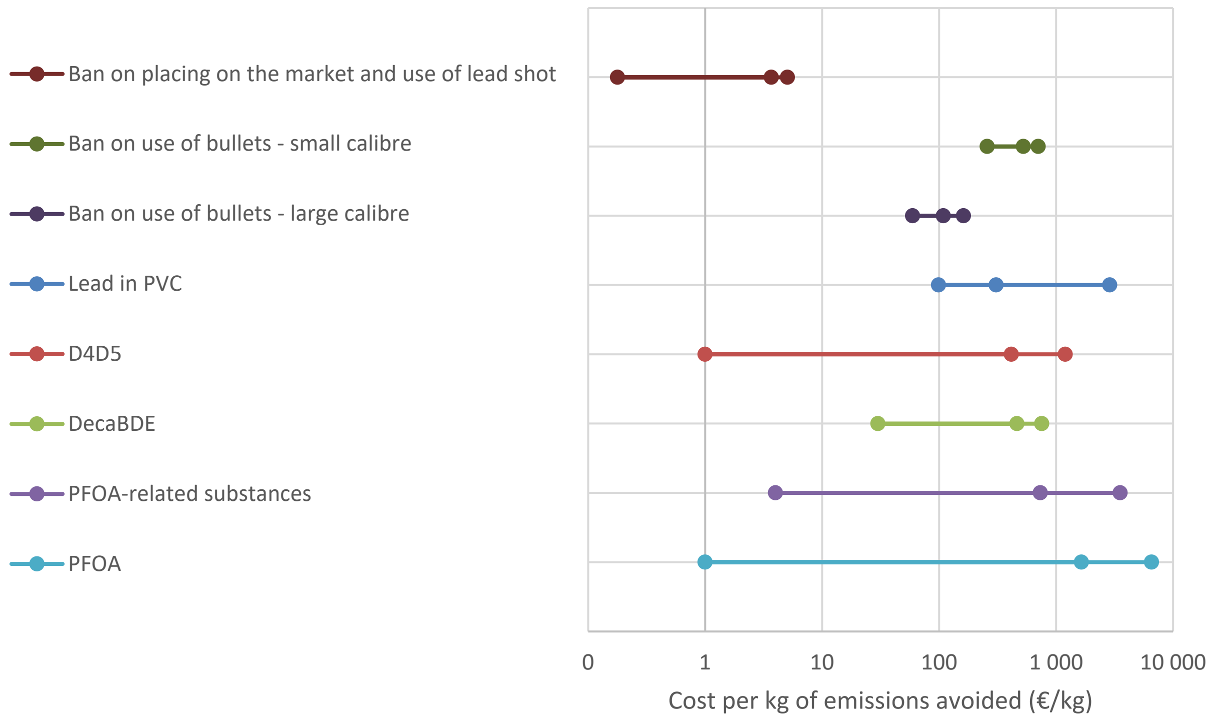


Figure 2-8: Cost-effectiveness comparison with other REACH restriction

2.5.3.3.3. Cost-benefit considerations

Whilst it is difficult to accurately predict all the welfare impacts induced by the current restriction proposal, some elements on both the benefit and the cost side have been quantified.

In particular, the cost to hunters from prematurely replacing guns and shotguns when these are not suitable to fire any form of steel gunshot or alternative bullets have been quantified as well as the cost for using non-lead ammunition such as steel shot and brass or copper bullets.

The central case assumes that the restriction proposal will require the premature replacement of about 190 000 shotguns and 268 000 small rifle guns, which would have either been replaced over the 20 years following the entering into force of the restriction proposal (5 % of these guns) or would not have been replaced over 50 years following the entering into force (95 % of these guns).

On the producer side, the quantification of welfare impacts is subject to greater uncertainty. A part of the replacement cost accruing to hunters (i.e. consumer surplus loss) will result in a surplus gain to manufacturers and retailers of shotguns and ammunition. Since the restriction will likely affect current market prices for shotguns and ammunition, it is difficult to estimate the size of this surplus gain. Yet an attempt can be made based on the following assumptions. The mark-up on the ex-factory price of a consumption good is typically in the order of 30 % to 50 % of the retail price net of any taxes. It is assumed that such a generic mark-up rate would be applied to the selling price of ammunition and shotguns as well.

Importantly, this mark-up is thought to capture both the income earned as well as the expenses made by manufacturers, wholesalers, and retailers to sell the product (i.e. costs that are not genuinely related to the production, but to the transportation, stocking, and selling of shotguns and ammunition).

To approximate the profit made by producers and retailers, one could thus subtract 20 % VAT from the estimated costs and then multiply this amount by an average 40 % to arrive at an estimate of the total mark-up. An unknown fraction of this mark-up will be the actual producer surplus gain and should thus be deducted from the consumer surplus cost to arrive at the net social cost of the restriction. Taking all of this together suggests that the total producer surplus gain to EU manufacturers and retailers is up to €39m.

A key objective of the restriction proposal is the reduction of lead poisoning in both terrestrial birds (including predatory/scavenging birds) and waterbirds in the EU because of the ingestion of lead ammunition and lead fishing tackle.

Partwise monetisation of this externality of the use of lead gunshot is possible at least for terrestrial birds ingesting lead shot under the following assumption. Where there is a market for raising capture-bred birds, it is possible to value the premature death of an individual game bird by the opportunity cost of not being able to shoot it. This opportunity cost can be approximated by the stocking cost incurred to raise one bird of the same species. Stocking costs for 17 game bird species for which lead gunshot ingestion represents a risk have been gathered by the Dossier Submitter through a market survey made in the EU 27-2020[258]. However, these 17 species do not represent the total number of species at risk of lead poisoning in the EU identified by the Dossier Submitter.

The Dossier Submitter assumes that the aggregate opportunity cost for restocking approximately 1.2 million terrestrial birds (related to EU 26) from these 17 species that are currently lost per year due to lead poisoning amounts to approximately €114 million per year. This captures only part of the bird species that are vulnerable to lead poisoning from different sources of lead (in ammunition and fishing tackle) in the EU. It should be noted that this figure does not include benefits to birds beyond the 17 species assessed (refer to Annex D), including some iconic species such as the Eurasian griffon (*Gyps fulvus*), nor does it include other indirect benefits discussed in the restriction report.

Whereas the human health impacts have been quantified in Section 2.5.2.1, there are a number of other values to consider.

In its opinion on lead in shot over wetlands, SEAC considered as well that a restriction will also reduce lethal and sub-lethal effects of lead on predatory and scavenging birds, which are exposed through eating birds, and which have ingested lead gunshot or have embedded lead gunshot in their tissue. The Dossier Submitter was not able to quantify these impacts.

Other non-quantified impacts of the proposed restriction include potential impacts on other wildlife than birds (exposed through the food chain) as well as on wetland ecosystems at large. Also, lead gunshot as a potential source of lead contamination of (drinking) water resources was not assessed by the Dossier Submitter.

In terms of social welfare, the reduction of the adverse effects from the use of lead gunshot in wetlands has multiple consequences, which are summarised below:

[258] The Dossier Submitter carried out an extensive market research to identify market prices of the many hunted bird species in the European Union. The Dossier Submitter identified more than 120 breeders/sellers across 17 countries, from which the pricing information was gathered either by email or by means of online searches. When the prices were available in another currency than €, they were converted using the exchange rate of the day. After the data collection was completed, the Dossier Submitter proceeded to examine the pricing information and to determine the lowest, the highest and the average prices for each of the bird species.

- increased (long-term) opportunities for hunting
- increased (long-term) opportunities for leisure activities, e.g. bird watching
- reduced amount of lead released in the environment and related contamination of water resources (avoided remediation costs)
- better protection of bird populations and wetlands in general (non-use value).

Table 2-33 provides an overview of all cost and benefits considered by the Dossier Submitter.

Table 2-33: Costs and benefits comparison of the preferred restriction

Costs		Benefits	
Annual costs to hunters (gunshot) – use 1	€84m	**Use value**	
Distributional cost in terms of producer surplus gain (after VAT)*	*Up to €27m*	Avoided opportunity cost associated with the annual mortality of terrestrial species	€114m
Annual cost to hunters for hunting with small calibres – use 2a	€13m	Beneficial impacts on leisure activities including bird watching	Non-quantified
Distributional cost in term of producer surplus gain (after VAT)*	*Up to €5m*	Human health benefits of avoided IQ loss (shot and bullets)	€70m
Annual cost to hunters for hunting with large calibres – use 2b	€20m	Human health benefits of avoided CKD	€7.5m-€75m
Distributional cost in term of producer surplus gain (after VAT)*	*Up to €7m*	Human health benefits related to avoided exposure from home-casting of lead bullets	Non-quantified
		Non-use value	
		Protection of wildlife and ecosystem services	Non-quantified
		Protection of rare bird species	Non-quantified
Total societal cost Distributional cost in term of producer surplus gain (after VAT)*	**€117m (incl. VAT)** *Up to €39m*	**Total societal benefit**	**> €191m-259m**
**Calculated to be the annual cost * 0.8 * 0.4*			

However, this restriction should also be looked at in conjunction with the restriction on the use of lead shot in and over wetlands. The two measures are complementary and indeed the benefits of the two proposals should be looked at together. Such a more holistic view is provided in Table 2-34.

Table 2-34: Overview of costs and benefits of the wetland restriction and this restriction proposal together

Costs		Benefits	
Wetlands		**Use value**	
Societal cost*	€35m	Avoided opportunity cost associated with the annual mortality of approximately 700 000 waterfowl from 16 wetland bird species known to ingest lead shot	€105m
Terrains outside of wetlands		Avoided opportunity cost associated with the annual mortality of terrestrial species	€114m
Societal cost*	€67m	Avoided opportunity cost associated with the annual mortality of other waterbirds, predators and scavengers	Non-quantified
Small calibre bullets		Beneficial impacts on leisure activities including bird watching	Non-quantified
Societal cost*	€11m	Human health benefits of avoided IQ loss (shot and bullets)	€70m
Large calibre bullets		Human health benefits of avoided CKD	€7.5m-€75m
Societal cost*	€16m	Human health benefits related to avoided exposure from home-casting of lead bullets	Non-quantified
		Non-use value	
		Protection of wildlife and ecosystem services	Non-quantified
		Protection of rare bird species	Non-quantified
Sum	€129m (societal cost)*	**Sum**	>€296m-364m

**costs without VAT*

2.5.3.3.4. Input from the consultation

Comments on the impact on birds were submitted by sector associations, supply chain actors, competent authorities as well as individuals. For example: #3307, #3335, #3343, #3348, #3364, #3365, #3367, #3372, #3374, #3382, #3388, #3396, #3405, #3406, #3412, #3418, #3424, #3427, #3428, #3420, #3438, #3443, #3444, #3446, #3450, #3458, #3462, #3464, #3473, #3475, #3477, #3478, #3479, #3480, #3484, #3491, #3497, #3499, #3500, #3513, #3486, #3452, #3439, #3436, #3432, #3425, #3415, #3411, #3397, #3395, #3377, #3375, #3370.

One of the comments (#3450) was handled as confidential as per the respondent's request.

In general, comments submitted were on one of the following three subjects:

1. No significant effects on birds occur.
2. General support for regulatory action to prevent primary and secondary lead poisoning in birds and other wildlife.
3. Use and non-use values of birds, especially of flagship species such as vultures and eagles.

Commenters stated that regulatory action would benefit the environment and human health overall. More specifically, reference was made to several obligations the EU has under different legislative frameworks or international agreements and how regulatory action on lead in outdoor shooting and fishing as proposed by the Dossier Submitter would contribute to fulfilling these international and EU wide obligations:

- Article 7 of the Birds Directive requires EU Member States to ensure that hunting does not jeopardise conservation efforts to preserve huntable and non-huntable bird species and that practice of hunting complies with the principles of wise use.
- In addition, the EU must guarantee the application of the polluter pays principle and Directive 2004/35/CE on environmental liability for remediation of the land impacted by lead pollution.
- Lead poisoning results in clinical effects affecting birds and other animals exposed to lead. This directly contradicts animal welfare standards as provided for in article 13 of the Treaty on the Functioning of the European Union.
- The restriction would be a significant contribution to the aims of the CMS Intergovernmental Task Force and fulfil the EU and its Member States' conservation obligations under CMS Resolution 11.15 (Rev.COP13).

Commenters also highlighted that there might be impacts beyond those assessed by the Dossier Submitter, particularly for raptors and scavengers. Several commenters referred to a study by (Pain et al., 2019a) which seeks to quantify effects of lead from ammunition on birds and other wildlife. The study discusses that there is substantial annual expenditure within the EU on non-consumptive uses of these species (e.g., birdwatching and nature tourism) and on delivering legal requirements to maintain their populations in favourable condition by site and species protection. According to the commenters those constitute unquestionable signals of the societal importance of protecting bird species threatened by primary and secondary poisoning. The costs to society of sublethal poisoning and mortality of wildlife are difficult to evaluate, but the authors of the study suggest that this can be approached in a variety of ways, including:

a. Costs of replacing birds that have died. This could be through captive breeding and release or other means of increasing the populations.

b. Costs of treating poisoned birds.

c. Costs of losing the services provided by the wildlife, including tourism, hunting for food or sport and improvement of environmental health.

d. Society's willingness-to-pay for avoiding these impacts—a way of estimating the value of wildlife to people.

Finally, several commentators warned that inaction would severely undermine conservation programmes set up across the EU to protect or reintroduce raptors and scavengers such as the Red kite and the Egyptian vulture. These commenters considered that the Dossier Submitter should have included conservation costs and benefits into its assessment on the impacts of the proposed restriction on wildlife. The Dossier Submitter notes that Pain et al. (2019) tried to monetise several of the impacts identified as displayed in Table 2-35.

Table 2-35: Additional cost items and monetisation submitted in the consultation

Cost Area	Description	Annual cost (€) EU	Annual cost (€) Europe
Wildlife			
Replacement costs—direct mortality	Replacement of 700 000 wildfowl (EU) or 1 million (Europe) of 16 species	€105m	€142m
	Replacement of 4 species of raptor in the EU (530–691 individuals) and Europe (765–1139 individuals)	€25m-457m	€37m-750m
	Replacement of 232 402 released pheasants and red-legged partridges in the UK	€3.4m for UK (not estimated for EU)	Not estimated but > €3.4m
	Replacement of an additional 11 wildfowl species; 12 raptor species, 11 other waterbird and wading species and 2 terrestrial gamebirds known to suffer lead poisoning but for which insufficient information was available to estimate replacement costs	Not estimated	Not estimated
Replacement costs—indirect mortality	Birds that die as a result of sublethal lead poisoning increasing susceptibility to disease and accidents	Not estimated	Not estimated
Treatment costs	Costs for treating 1 % of 700 000 lead-poisoned wildfowl in the EU and 1 million in Europe, plus 1 % of an additional 2.1 (EU) and 3 million (Europe) that suffer sublethal welfare effects	€28m	€40m
	Costs of treating raptors and terrestrial birds that suffer lead poisoning	Not estimated	Not estimated
Reduced IQ in children	Minimum annual costs of risk of reduced IQ in children in the EU that frequently consume game shot with lead. Surveys from other countries suggest that this may be an underestimate, possibly by an order of magnitude	€40m-104m	Not estimated but assumed to be > €40m-104m
Increased incidence of CKD and SBP in adults		Not estimated	Not estimated

Clean-up	Ammunition at shooting ranges—broad estimate	€81m-162m	Not estimated but assumed to be >€81m-162m
Clean-up	Ammunition at hunting blinds with greatest contamination—broad estimate	about €100m	Not estimated but assumed to be >€100m
Research	Investigating lead poisoning; monitoring and surveillance	€1m	Not estimated but assumed to be >€1 million
Advocacy		Not estimated	Not estimated
Enforcement		Not estimated	Not estimated
Collision	Collision of poisoned birds with power lines, other infrastructure and vehicles due to weakened state	Not estimated	Not estimated
Food production	Poisoning of poultry and livestock exposed to lead shot or feed contaminated with lead shot; other food products (e.g. salt) contaminated with shot; wastage of meat around the wound channel of large mammals killed with lead bullets	Not estimated	Not estimated
Health of domestic dogs	Risks to dogs fed trimmings from shot game animals	Not estimated	Not estimated
Total		€383m-€960m	€444m-€130 000m

Source: https://link.springer.com/article/10.1007/s13280-019-01157-2/tables/5 from: Pain, D.J., Dickie, I., Green, R.E. *et al.* Wildlife, human and environmental costs of using lead ammunition: An economic review and analysis. *Ambio* **48,** 969–988 (2019). https://doi.org/10.1007/s13280-019-01157-2

Whilst the Dossier Submitter acknowledges that these impacts exist it has refrained from quantifying and monetising them as there are inherent difficulties in monetising a good for which no market exists:

- As for the replacement cost of birds, the Dossier Submitter considers that this only reflects the supply side of the problem of restocking birds lost to lead poisoning. E.g., while the cost of captive-breeding a vulture can be accurately monetised, it is not thereby demonstrated that society is willing to pay this cost for a specific number of vultures. Without information on society's demand value, it is analytically not possible to usefully monetise this impact. The Dossier Submitter notes that this contrasts with some of the wildfowl species for which hunters actively pay a market price to release the number of captive-bred birds, i.e. hunters release exactly the number of birds that corresponds to market demand. This is different from the release of captive-bred birds by conservation projects (even if EU-funded) where societal demand is not directly observable, i.e. there is no direct societal approval of the amounts spent on bird conservation.
- Some commenters highlighted that legal obligations exist for the EU to protect certain species prone to lead poisoning, that these obligations would be an expression of society's valuation, and hence the costs arising from existing conservation activities would hence be a useful measure of the benefits of the restriction. As regards ongoing conservation efforts, the Dossier Submitter notes that—beyond doubt—these have a value to society. However, conservation costs are an inaccurate measure of the existence value of birds since 1) they include a significant overhead for salaries and material that are unrelated to the existence

value of birds, 2) using existing conservation costs would mean that once a restriction on lead ammunition was in place, the costed conservation efforts would become redundant. The Dossier Submitter suggests that this is not the case and that there are factors other than lead which make the protection of raptors and scavengers necessary, e.g. deliberate poisoning, egg collecting.

- As regards human health effects, the Dossier Submitter provided a more sophisticated modelling of health impacts than the study by Pain et al. and hence does not see a reason to update its approach for estimating the human health impact assessment.
- As regards clean-up costs for lead contaminated shooting ranges, the Dossier Submitter notes that, where remediation actions are mandatory, they will have to occur with and without the proposed restriction; where no such mandate exists, remediation is less likely to occur, and the avoided costs can thus not be attributed to the proposed restriction.
- As regards other cost elements listed in Table 5 of Pain et al. (2019), these are notoriously difficult to estimate as demonstrated by the fact that the authors also did not monetise them.

In sum, while the Dossier Submitter recognises that several of the impacts described by the commenters are relevant, they cannot be easily monetised. Because of this complication, the Dossier Submitter opted for a qualitative description rather than a monetisation that would invariably draw warranted methodological criticism.

2.5.3.4. Proportionality of the proposed restriction

Taking all the non-quantified benefits into consideration (Table 2-33) it seems plausible to conclude that the societal benefits of the proposed restriction will outweigh its costs even under worst case assumptions.

Under worst-case assumptions, the total annual costs of the proposed restriction are close to €200m,[259] which is in the range of the expected benefits of €190-260m. The quantified expected benefits are an underestimate: for only 17 out of 533 species a monetisation has been made whereas a number of the types of benefits were not quantified and/or monetised. This cost-benefit comparison makes it plausible that this restriction is proportionate.

2.5.4. Information on the length of the transition period

The European ammunition industry is very dependent on the EEA market as 69 % of the AFEMS members' turnover is made in the EEA (AFEMS submission). Those manufacturers who mainly produce for the European market face the severest difficulties. They will stop producing ammunition completely, at least temporarily. The duration is dependent on their ability to substitute to another raw material and end-users' willingness to substitute. Only a few companies said they can substitute in the short term (0-3 years). Most manufacturers outlined that they can substitute in the longer term (5-10 years).

These arguments seem to be echoed by recent discussion the United Kingdom where, in reaction to a recent call for a voluntary phase out of the use of lead shot, three (Eley Hawk,

[259] Total annual costs in the worst-case scenario are estimated at €197m, with €143m relating to gunshot, €20m relating to small calibre bullets, and €34m relating to large calibre bullets.

Gameborne, Lyalvale Express) companies reacted[260] by stating that:

We cannot make a complete switch over to these products within a five year period without substantial investment into the industry. BASC and its fellow organisations do not have an understanding of the manufacturing processes involved and are therefore in no position to determine the length of time required to evolve.

Tungsten and Bismuth materials are very limited in their availability and significantly more costly to produce than steel. This will result in huge increases in costs, based on raw material prices, for smaller gauge shooters who cannot use steel. This may price many shooters out of the sport.

Other sources indicated that security of supply of steel shot would be in threat if sports shooting would be in scope of a ban on placing on the market as well.

The length of the transition period is of importance when large investment costs arise. For the restriction options analysed this would mean that the length of the transition period has a significant influence on the costs of substituting lead shot and on the cost of substituting lead bullets.

2.5.4.1. Input from the consultation

In the consultation of the Annex XV report, many commenters argued that the proposed transition period for lead ammunition in hunting uses was too short and argued for longer transition periods for small and large calibre bullets, gunshot and rimfire ammunition.

In relation to large calibre bullets, the arguments presented for a longer transition period are based on the need to expand production lines, which commenters (#3262, #3331) estimated to take at a minimum two years (possibly longer due to shortage in bullet manufacturing machines), the need for compatibility with R&D cycles, as well as the avoidance of a supply shortage of lead-free bullets. The Dossier Submitter notes that even though 12-15 manufacturers already supply the market with alternatives for large calibre bullets (as documented in this report) and there may be more manufacturing companies that provide alternatives (see e.g., DK Bullets and JCP ammo), only a small share of users (10-15 %) currently use these alternatives. Indeed, this would suggest that a significant scaling up of market supply would need to take place. A longer transition period than the proposed 18 months would allow this expansion to be fitted into normal R&D cycles (and therefore into manufacturers' normal R&D budgets).

The main advantage of a the initially proposed transition period for large calibre bullets (i.e. 18 months) is the faster reduction of human health impacts in terms of IQ loss and CKD linked to the consumption of lead-contaminated game meat. In Section 2.5.2.1, these impacts have been estimated at €77.5-145m per year (IQ loss: €70m/year; CKD: €7.5-75m/year). Assuming that these impacts are mainly linked to the use of large calibre bullets, an increase in the transition period from 18 months to 5 years would mean to forgo a reduction in human health impacts of up to €145m per year over a period of 3.5 years. In terms of emissions, 119 tonnes lead per year would continue to be released to the environment during this 3.5-year period. On the other hand, hunters would avoid costs in the order of €20m per year during the same period.

With regards to small calibre bullets (including rimfire ammunition) and gunshot, the arguments put forward in the consultation to underpin requests for longer transition periods

[260] https://www.gunsonpegs.com/articles/cartridges/cartridge-companies-respond-to-the-proposed-phase-out-of-lead-shot

relate mainly to technical feasibility concerns. These are discussed in Section 2.5.1.

For small calibre bullets, an additional 5 years of transition time would mean cost savings in the order of €13m per year for a duration of 5 years. On the other hand, about 15 tonnes of lead per year would continue to be released to the environment during this period.

Similarly, for lead gunshot used in hunting, the avoided costs for hunters associated with a longer transition period needs to be balanced against realising lower benefits in terms of reduced lead poisoning in birds. An additional 5 years of transition time would mean cost savings in the order of €84m per year over a period of 5 years, whereas benefits in the order of €114m per year (in terms of avoided bird mortality) would be forgone during that period. Around 14 000 tonnes of lead per year would continue to be released to the environment during this 5-year period.

Based on input from the consultation on the Annex XV report, Table 2-36 has been updated.

Table 2-36: Considerations regarding the length of transition periods for the proposed restriction

Restriction Option	Short transition period (≤3 years)	Medium transition period (3-5 years)	Long transition period (5-10 years)
Ban on placing on the market and use of lead gunshot for hunting	Quick realisation of benefits in terms of environmental risk reduction (€114m/year forgone for ≤3 years); lead emissions of 14 000 t/year continue for ≤3 years Low cost savings for hunters (€84m/year for ≤3 years) Sudden increase in demand for steel gunshot cartridges may increase their cost	Slower realisation of benefits in terms of environmental risk reduction compared to short transition period (€114m/year forgone for 3-5 years); lead emissions of 14 000 t/year continue for 3-5 years Higher cost savings for hunters compared to short transition period (€84m/year for 3-5 years) Demand effect on the price of steel gunshot is lower compared to a short transition period	Slower realisation of benefits in terms of environmental risk reduction compared to medium transition period (€114m/year forgone for 5-10 years); lead emissions of 14 000 t/year continue for 5-10 years Higher cost savings for hunters compared to medium transition period (€84m/year for 5-10 years) Demand effect on the price of steel gunshot is lower compared to a medium transition period
Ban on use of lead bullets for hunting – small calibre	Lead emissions of 15 t/year continue for ≤3 years Low cost savings for hunters (€13m/year for ≤3 years) Few alternatives available, specifically for popular calibres such as .22LR – technical performance of alternatives not considered to be equivalent to lead Few companies producing alternatives; extra R&D costs for other producers (above normal budget for innovation). Large demand effect. Sudden increase in demand for available alternatives may increase their cost Large number of gun barrels / rifles replaced prematurely (to address twist rate issue)	Lead emissions of 15 t/year continue for 3-5 years Higher cost savings for hunters compared to short transition period (€13m/year for 3-5 years) More time for rifle/barrel replacement results in lower compliance costs (as less premature replacement) Greater availability of alternatives, although remains uncertainty whether they will have achieved an equivalent level technical performance as lead Demand effect on the price of available alternatives is lower compared to a short transition period	Lead emissions of 15 t/year continue for 5-10 years Higher cost savings for hunters compared to medium transition period (€13m/year for 5-10 years) More time to develop further alternatives and for gun replacement compared to medium transition period Outcome of R&D work to develop non-lead alternatives more certain compared to medium transition period

Restriction Option	Short transition period (≤3 years)	Medium transition period (3-5 years)	Long transition period (5-10 years)
Ban on use of lead bullets for hunting – large calibre	Quick realisation of benefits in terms of human health impact reduction (up to 145m/year forgone for ≤3 years); lead emissions of 119 t/year continue for ≤3 years Low cost savings for hunters (€20m/year for ≤3 years) Market already supplies a variety of alternatives Feedback from industry during consultation suggests that 'bottle necks' in supply may arise due to time needed to scale up production Large demand effect. Sudden increase in demand for available alternatives may increase their cost	Slower realisation of benefits in terms of human health impacts compared to short transition period (up to 145m/year forgone for 3-5 years); lead emissions of 119 t/year continue for 3-5 years Higher cost savings for hunters compared to short transition period (€20m/year for 3-5 years) Demand effect on the price of available alternatives is lower compared to a short transition period (feedback from consultation on Annex XV report is that five years is an adequate timespan to scale up production)	Slower realisation of benefits in terms of human health impacts compared to medium transition period (up to 145m/year forgone for 5-10 years); lead emissions of 119 t/year continue for 5-10 years Higher cost savings for hunters compared to medium transition period (€20m/year for 5-10 years) Demand effect on the price of steel gunshot is lower compared to a medium transition period

RAC box

A five-year transition period for the ban of the use of gunshot in hunting was proposed by the Dossier Submitter in §7d. RAC is of the view that this transition period is too long and could be shortened, taking into account that the use of lead gunshot in wetlands is already regulated in the whole EU. The shorter the transition period is, less lead will be released into the environment.

2.5.5. Other practicability and monitorability considerations

2.5.5.1. Implementability and manageability

The restriction is implementable; many examples exist of situations where hunters have already switched to lead-free ammunition (bullets or gunshot) which demonstrates that a restriction on the use of gunshot and bullets is possible and implementable.

2.5.5.2. Enforceability

The wetlands restriction poses similar challenges to enforcement authorities. With a partial restriction pertaining to wetlands only, lead gunshot will still be distributed throughout the EU and will remain available on the market. Field inspections by national authorities to enforce compliance with the restriction on the use of lead gunshot in wetlands are possible but are likely to require coordination across regulatory agencies in Member States (i.e., REACH enforcement, environmental protection, police etc) and would therefore be expensive and potentially inefficient. In its opinion on the proposed restriction of lead gunshot in wetlands SEAC concluded that a total ban would be easier to enforce as it would not be necessary to establish if the use of lead gunshot was in a wetland (or would result in lead gunshot falling within a wetland).

Supplementing a restriction on use with a restriction on 'placing on the market' will facilitate enforcement as this can take place at the point of sale rather than at the point of use. The Forum concluded similarly in their previous advice on the enforceability of the proposal on lead in gunshot over wetlands.

Enforcement at the point of sale can also ensure that any products that are continued to be placed on the market (i.e., projectiles other than gunshot for sports shooting) are compliant with the proposed labelling requirements as well as the 'information at the point of sale' requirements. Should the 'optional conditional derogation' for the continued placing on the market and use of lead gunshot for sports shooting be implemented this can also be enforced at the point of sale, whilst the requirements for individual lead gunshot cartridges to be labelled 'do not use for hunting' should allow relatively easier enforcement in the field compared to the existing restriction on lead in gunshot in wetlands (as it will not be necessary to determine that the use was taking place within 100 metres of a wetland).

Enforcing a ban on lead-containing bullets for hunting may be more difficult in practice. However, the packaging of ammunition carried by hunters should give some indication as to material the projectiles are made of and the packaging of lead containing projectiles that legitimately remain on the market (for sports shooting) are obliged to be labelled as containing lead. On the level of an individual bullet, the differences between lead bullets and copper bullets can be readily seen, except when fully jacketed lead bullets are used.

Should game meat be made commercially available, then certificates of testing obtained already with current testing methods would create an incentive for users to comply with the legislation and at the same time allow enforcers to verify to what extent compliance with the legislation is achieved.

With a restriction entry with different transition periods depending on the calibre/type of bullets, enforcers may be required to verify whether a hunter complies with the regulation:

1. Calibre: enforcers may check the calibre and type of bullets by simple visual inspection Manufacturers place a mark (engraving) on the back of the cartridge to indicate the calibre of the cartridge. Rimfire vs centrefire can be identified at the back of the cartridge (see Figure 2-9 and Figure 2-10)
2. Lead content: lead wipe tests are available[261] that will detect any lead on a projectile; other more modern tests are using solid phase microextraction[262].

In the FAQ on the California legislation on lead ammunition, it states: "*All ammunition in a hunter's possession may be inspected by wildlife officers. In some cases, if a wildlife officer suspects a hunter is in possession of lead ammunition and cannot prove otherwise in the field, he or she may seize a cartridge or bullet for further analysis. Hunters are encouraged to assist in confirming compliance by retaining and carrying in the field ammunition boxes or other packaging.*"

[261] https://dps.mn.gov/divisions/bca/bca-divisions/forensic-science/Pages/forensic-programs-crime-scene-rhodizonate.aspx
[262] https://www.newscientist.com/article/dn13622-gunshot-residue-test-fingers-lead-free-bullets/

Figure 2-9: Calibre markings on the bottom side of a cartridge case (right) and the bottom side of a rimfire cartridge (left), also showing for centrefire ammunition the place of the detonator in the centre of the bottom side of a cartridge

Figure 2-10: Difference between 5.6 mm and .22 LR

Stakeholder information[263] suggested that lead-free bullets for other animals have to be expansible and those can be easily recognised from the visible cavity in the bullet tip (open cavity or cavity with a plastic tip), see also Figure 2-11.

[263] Jussi Partanen, Game shooting manager, Metsastajalitto. personal communication

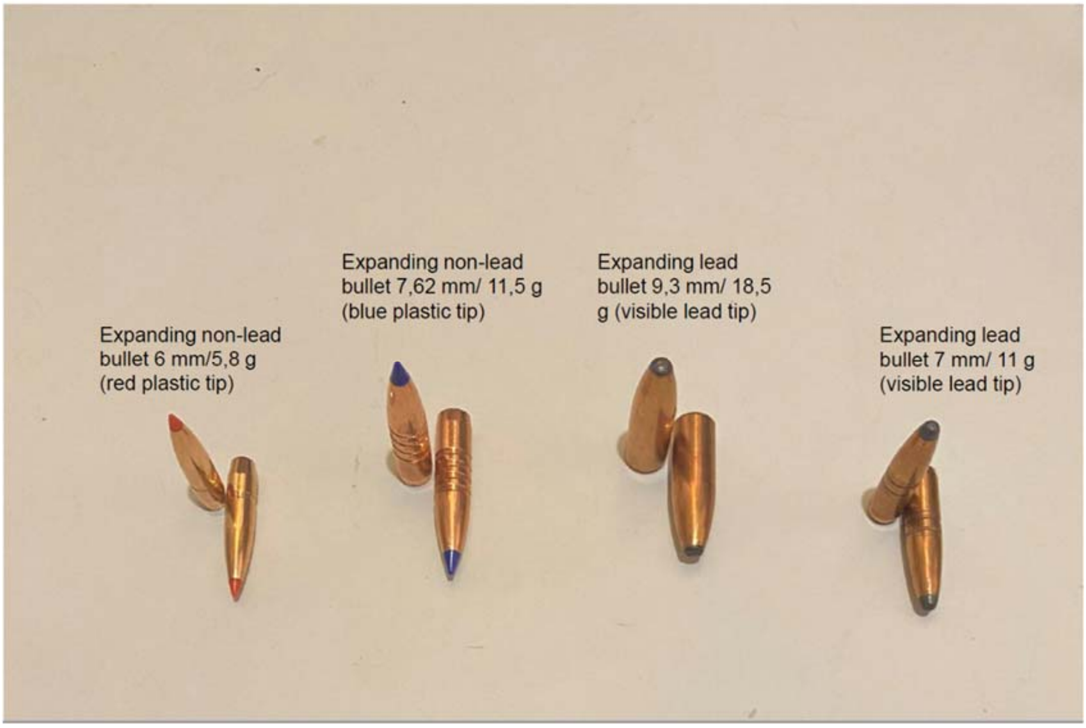
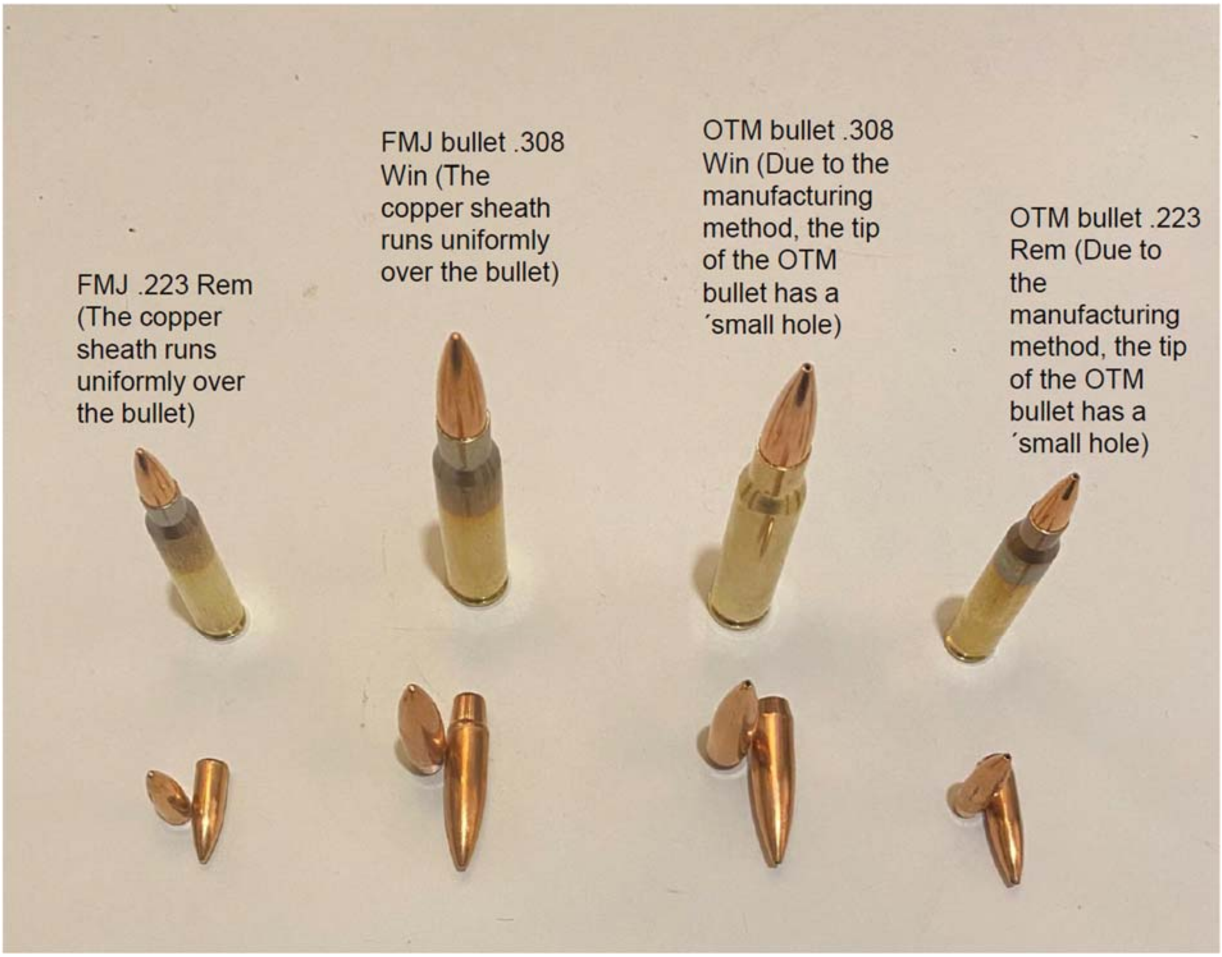


Photo courtesy of Metsastajalitto

Figure 2-11: Difference between expanding lead and non-lead bullets

Based on input from the consultation, a derogation may be warranted for Full Metal Jacket (FMJ) bullets and Open Tip Match (OTM) bullets used for seal hunting.

Stakeholder information suggested that FMJ/OTM bullets can be recognised from the tip closed 95 – 100 % by the copper jacket so that the tissue of the game meat cannot penetrate inside the bullet and start the bullet expansion or fragmentation. See also Figure 2-12 below.



Photograph courtesy of Metsastajalitto

Figure 2-12: Exterior characteristics FMJ and OTM bullets

2.5.5.3. Monitorability

The same tools, methods and equipment that are now used to establish the risk of lead in game meat (see section 1.6.3.6) can be used to monitor any progress on the phasing out of lead. Section 1.6.3.6 describes several studies that establish lead concentrations in game meat; these methods can be used after the restriction enters into force to establish whether any downwards trends in lead concentration in game meat can be observed which would be indicative of the successful implementation of the proposed restriction on the use of lead ammunition in hunting.

2.6. Impacts of a restriction on lead in sports shooting (uses 3 and 4)

The restriction proposal will focus on a balance between substitution of lead shot and bullets and identifying suitable OCs and RMMs that can be put in place to avoid emissions of lead into the environment.

2.6.1. Conclusion on alternatives

2.6.1.1. Gunshot

The rules on firearms and the corresponding ammunition that can be used in Olympic events is given in the "official statutes rules and regulations" developed by the International Sports Shooting Federation (ISSF). These rules have been accepted for the Tokyo Olympics in 2020. For all disciplines, lead or other soft material must be used as the projectile.

The exact rules[264] of the ISSF on shot in skeet and trap (rule 9.4.3.1, c) require that pellets must be made of lead, lead alloy or of any other ISSF approved material. As such, there is no material barrier for competitive shooting using alternative gunshot materials, but an approval of the material by the ISSF is required.

In non-Olympic events, governing rules are set out by the FITASC[265], whom in their rules state that the use of lead is obligatory: chapter 7.8 weapon and ammunition states "the cartridge load must not exceed to 28 grams of lead".

The current situation is that ISSF and FITASC rules encourage the use of lead[266] ammunition at national and local level, with knock-on effects on non-official disciplines/events. For example, the French association for clay target shooting requires[267] the use of lead.

In reaction to this, Thomas (2013) argues that steel would be a suitable alternative because of:

1. the volume of cartridges fired by competitors,
2. the parity with prices for lead cartridges,
3. the suitability of steel shot to be used in trap and skeet events,
4. the ease of substitution for lead-shot in conventional 12- and 20-gauge shotgun cartridges.

According to Thomas and Guitart (2013), Olympic skeet and trap shooting regulations do not stipulate which gauge of shotgun can be used, only the shot load. Consequently, 12-gauge guns dominate the events because of the higher number of shot that can be fired at each target compared to those fired from 20-gauge guns. This facilitates the use of 12-gauge cartridges for Olympic shooting events.

Thomas (2013) presents several factory loads of steel shotgun cartridges (see Table 2-37) that are widely available and that could be considered as alternative for lead shot in shooting.

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[264] https://www.issf-sports.org/getfile.aspx?mod=docf&pane=1&inst=462&file=1.ISSF-Shotgun-Rules_2020.pdf
[265] https://www.fitasc.com/upload/images/Rglts_PCH_01012017_ENG.pdf
[266] http://www.ffbt.asso.fr/assets/filemanager/consignes%20dorganisation%202020.pdf
[267] http://www.ffbt.asso.fr/pages/faire-du-ball-trap/ball-trap-temporaire.html

Table 2-37: Characteristics of steel shotgun cartridges for clay target shooting made by major international cartridge companies in 12 and 20 gauge (ga)

Company and cartridge gauge	Shot mass (oz and g)	Shot size (English) and diameter (mm)	Muzzle velocity (fps and mps)
Kent Gamebore			
12 ga	1 oz 28.4 g	#7 (2.4 mm)	1290 fps: 393 mps
12 ga	7/8 oz 24.8 g	#7 (2.4 mm)	1350 fps: 451 mps
20 ga	7/8 oz 24.8 g	#7 (2.4 mm)	1215 fps: 370 mps
Federal			
12 ga	1 oz 28.4 g	#6, 7 (2.6, 2.4 mm)	1375 fps: 419 mps
12 ga	11/8 oz 31.9 g	#7 (2.4 mm)	1145 fps: 349 mps
20 ga	¾ oz 21.5 g	#7 (2.4 mm)	1210 fps: 369 mps
Winchester			
12 ga	1 oz 28.4 g	#7 (2.4 mm)	1325 fps: 404 mps
20 ga	¾ oz 21.5 g	#7 (2.4 mm)	1325 fps: 404 mps
Remington			
12 ga	1 oz 28.4 g	#7 (2.4 mm)	1325 fps: 404 mps
20 ga	¾ oz 21.5 g	#7 (2.4 mm)	1325 fps: 404 mps
Rio Cartridges			
12 ga	1 oz 28.4 g	#7 (2.4 mm)	1325 fps: 404 mps
20 ga	7/8 oz 24.8 g	#7 (2.4 mm)	1325 fps: 404 mps

Notes: Velocity of shot is given as feet per second (fps), and meters per second (mps). All cartridges are 70 mm; ga= gauge

According to Thomas and Guitart (2013) the loads presented in the table closely fit the ISSF requirements:

1. Given the lower density of steel shot versus lead shot, it is necessary to use steel shot of a larger diameter than the lead equivalent, coupled with an increase in shot velocity, to achieve the same ballistic efficiency and effective range. Thus, a shot diameter of 2.6 mm might be advisable for Olympic trap shooting, in which targets may be broken at a longer distance than in skeet shooting. The ISSF regulations would, already, allow pellets of this diameter to be used (ISSF, 2012).

2. The maximum allowable velocity of steel shot cartridges, as set by the International Proof Commission is 425 m/s (Government of Victoria, 2011). A velocity of 390 m/s, for example, would equate with the same velocity of many lead shot cartridges, and still enable steel shot cartridges to perform well at the distances that trap, and skeet targets are usually hit.

It therefore appears that the possibilities to substitute lead exist but using alternatives would require approval of the ISSF and other federations. The Dossier Submitter concludes that the use of lead shot in sports shooting is not limited by technical barriers but rather by organisational barriers.

Table 2-38: Common misconceptions relating to the suitability of alternatives to lead gunshot for sports shooting

Statement in the consultation	Dossier Submitter's response
Steel gunshot is not suitable for steel shot	The International Shooting Sports Federation (ISSF) places a maximum velocity on shotgun cartridges at 1200 feet/sec, but modern steel target loads use a slightly higher velocity (1350-1450 feet/sec). The difference in velocity is small. The Dossier Submitter has already stated that the evidence suggests that there are no technical barriers to substitute to non-lead shot, only organisational barriers introduced by the ISSF/FITASC rules.
Availability of steel shot	The company Gamebore has a long-standing tradition of making steel shot, their 2021 catalogue lists: 12 gauge Black Gold HV Steel. 24 gram shot load and 28 gram in size 7.5 (2.5 mm). Velocity is 1450 feet/sec (400 m/sec). 12 gauge White Gold Pro Steel. 24 gram in shot size 7.5 and 9. The second load is 28 gram in shot size 9. Velocity of both loads is 1400 feet/sec. 12 gauge Super Steel. 21 gram shot load in size 7.5; 24 gram shot in sizes 7.5 and 9; 28 gram shot load in sizes 7.5 and 9. All three have a velocity of 1350 feet/sec or 390 m/sec. This UK company produces steel shot suitable for all skeet and trap shooting[268] and other events. Other companies in both Europe and overseas produce similar lines.
Gun suitability	Most serious shooters have interchangeable chokes in the gun barrels. This enables them to select the best choke tube for a given cartridge load for a given event. Even if a shooter has a gun with a fixed choke, any of the steel loads sold today for clay shooting can be fired safely through fixed chokes, whether for skeet or trap shooting. If a gun has a full choke for trap shooting, steel shot of size 7.5 and 9 can be fired safely.
Damaging the interior of gun barrels	Modern gunshot loads are supplied with plastic wads which have been introduced specifically to prevent damage to the interior of barrels.
Shooter fatigue from firing steel shot	Steel shot cartridges sound different from lead cartridges when fired, but the recoil from the light loads used for sports shooting is considered to be easily tolerable by users.
Ricochet	Clay targets are broken when in the air, not on the ground, for trap and skeet shooting, so ricochet, although possible, is not likely to occur. There are clay target shooting events such as sporting clays and variations of FITASC where clay targets are thrown along the ground to simulate running rabbits. Clear ground is chosen for the target launch not stony ground (which would surely break the target before the shooter). Traditionally, shooters would view the pattern of their gun/cartridge by firing at a steel plate. This is dangerous with steel shot because it rebounds directly back to the shooter. For patterning, heavy paper sheets in front of a backstop can be used.
Steel shot is more expensive	The price of steel target loads is decreasing because a patent on a process called "atomization" expired a few years ago[269], and so all shot makers can now use this much more efficient process for making small diameter shot. The critical comparison here is the manufactures' costs for making such cartridges, not retail costs. We now see that the costs of high-quality steel shot and comparable lead shot cartridges is similar.

[268] The different weights of shot allow for "handicap" shooting, in which only light loads are allowed to increase difficulty.
[269] https://patents.google.com/patent/US6749662B2/en

During the consultation of the Annex XV report, specific comments were received (such as comment #3189) that steel gunshot could be used as alternative for lead gunshot for trap and skeet shooting. However, other comments noted that the use of alternatives may require gunshot-design changes and re-training (#3216). Other comments noted that no alternatives are available when using steel targets for example for IPCS gunshot (#3326).

Some comments that were made on the use of bismuth for the use of alternatives in hunting are also relevant for the discussion on the use of alternatives for lead gunshot in sports shooting (see section 2.5.1.1.1).

2.6.1.2. Bullets

For the rifle and pistol projectiles, the ISSF rules state that projectiles made of "lead or other (similar) soft material" are permitted.

The information received in the call for evidence and various other sources point to the fact that sports shooting (apart from some specific long ranges shooting events) is mainly done using small calibres.

Very limited quantities of .22 LR ammunition loaded with copper projectiles are available. Independent testing with this copper ammunition shows the enclosing circle diameters for only 5 shots at 45.7m (50 yards) to on average 35.6mm. Stakeholders reported that this would not be considered acceptable for even entry level target shooting.

The bullet calibres used (air and firearms) are .22 LR, .30-.38 and 0.177 Air. These are the basic calibres used in many of the ISSF and IBU events, which are *de facto* standard as well for all sports shooting activities leading to these events, see Table 2-39.

Table 2-39: Popular examples of calibres used in sports shooting

Air	Small bore	Full bore
4.49mm AIR	0.22 LR Precision Rifle	7.62 / 308
4.50mm AIR	0.22 LR Precision Pistol	6mm BR
4.51mm AIR	0.22 LR Rifle	6mm XC
0.22 AIR	0.22 LR Pistol	6.5 x 55
0.177 AIR	0.22 LR Biathlon	7.5 x 55
	0.22 LR High Velocity	6mm x 47
	0.22 LR Heavy Weight	9mm
		38 Super
		45 ACP
		10 mm
		40 CAL
		223 Rifle

Source: eley Ltd, presentation at ECHA workshop 1/11 February 2020[270].

Only international standard .22 in. (5.6 mm)-long rifle rim-fire ammunition may be used, and it is forbidden to bring ammunition not conforming to these rules to the venue. The bullets must be made of a uniform substance, lead or a similar soft material such as a lead alloy. The weight of the bullet must not exceed 2.75 grams and not be less than 2.55 grams.

The muzzle velocity must not exceed 360 m/s, measured 1 m after leaving the muzzle.

The impact momentum of bullets fired from a distance of 50 m must not exceed 0.9 Ns (= 0.09 kg m s^{-1}) with a maximum tolerance of 11 %, i.e., 0.099 Ns. This means that the maximum permitted impulse is 1.0 Ns (= 0.1 kg m s^{-1}).

Stakeholders at the ECHA workshop and in the call for evidence highlighted that tests with lead free bullets have shown that these types of bullets have an accuracy that is sufficient for hunting but that the accuracy achieved with lead-free bullets is not sufficient for sports shooting purposes.

In the winter Olympics, the biathlon is the event that combines excellence in the disciplines in cross-country and shooting. There are also other international events. The rules in terms of the firearm and ammunition are given in the IBU event and competition rules. The biathlete carries a small-bore rifle, which must weigh at least 3.5 kg, excluding ammunition and magazines. The rifles use .22 LR ammunition and are bolt action or "Fortner" ("straight-pull bolt") action. The target range shooting distance is 50 m. There are five circular shooting targets to be hit in each shooting round. When shooting in the prone position, the target diameter is 45 mm; when shooting in the standing position, the target diameter is 115 mm. Manufacturers have engineered .22 LR ammunition to give the shooter the best possibility of using skill to hit the target. All projectiles in competitions are lead based as it has the best ballistic performance. Using a different material would mean poorer ballistic performance and non-competitive shooting. Athletes would also need to learn to shoot with the new ammunition.

The main drawback that lead-free bullets exhibit in sports shooting conditions is that the systematic grouping is larger than the size of the target. In shooting sports, a shot grouping, or simply group, is the pattern of projectile impacts on a target from multiple shots taken in one shooting session. The tightness of the grouping (the proximity of all the shots to each other) is a measure of the precision of a weapon, and a measure of the shooter's consistency and skill. On the other hand, the grouping displacement (the distance between the calculated group centre and the intended point of aim) is a measure of accuracy.

To support the claim of lack of accuracy some commenters submitted test results (Gunlex) which are also available on-line[271].

Rimfire

Gunlex reported on a test with COPPER-22 ammunition with bullets weighing 1.05 g, made from compressed polymer/copper dust material by US company CCI (the only nonlead .22 ammunition on the market – the manufacturer already stopped production, but some is still available). The test results demonstrated the inaccuracy of the ammunition for target

[270] https://echa.europa.eu/fi/-/lead-in-hunting-and-sports-shooting-workshop
[271] https://gunlex.cz/en/3595-comparative-test-of-lead-and-nonlead-ammunition

shooting. The grouping (i.e., the systematic spread of the gun without human intervention) was considerably more spread than with lead bullets (see Table 2-40).

Table 2-40: Results of testing a copper-22 ammunition

Ammunition	Group 1	Group 2	Group 3	Group 4	Group 5	Average dispersion
Copper/polymer	13 mm	29 mm	39 mm	34 mm	40 mm	31 mm
Solid lead	6 mm	7 mm	5 mm	7 mm	10 mm	7 mm

Distance was measured between centres of the two most distant hits. According to the test shooter, this dispersion is insufficient not only for target shooting, but (considering additional disperse caused by average shooter and firearm) even for recreational shooting or small game hunting.

Centrefire

In the same test, Gunlex tested four commonly available non-lead ammunition with lead sporting ammunition as control group. Gunlex chose 308 Win. calibre, as (according to Gunlex) this represents the most common calibre for hunting and target shooting. The tested ammunition was:

- Hornady Superformance International (monolithic copper alloy bullet with plastic tip)
- Hornady Custom International (monolithic copper alloy bullet with uncovered expansion tip)
- Sellier&Bellot XRG (monolithic copper alloy bullet with aluminium tip)
- Sellier&Bellot TXRG (monolithic copper alloy bullet with plastic tip)
- Sako Racehead HPBT (lead core / full metal jacketed bullet) (control group)

The test concluded that the values of dispersion are sufficient for hunting purposes and for short-to-medium distance sports shooting where precision is not critical (for example, disciplines like dynamic rifle or shooting metal silhouettes). Current accuracy of lead-free bullets is regarded to be insufficient for any precision-based shooting discipline.

During the consultation of the Annex XV report, almost all comments received confirmed that for small calibres no lead-free bullets are available that would have sufficient accuracy and stability. However, the Dossier Submitter received also comments from manufacturers (#3306) indicating that for centrefire rifle ammunition for target shooting "*the availability is just a matter of investments in production equipment*" alluding to the possibility that suitable lead-free ammunition could become available in the future.

2.6.2. Effectiveness and risk reduction

2.6.2.1. Human health impact

The following main human health risks have been identified within this restriction:

- Exposure from sports shooting (lead dust)
- Home-casting of lead bullets
- Human exposure via environment from drinking water and food

Exposure from sports shooting (lead dust)

Information on exposure levels in indoor shooting ranges and from blood lead levels in indoor shooters demonstrates that lead exposure increases with shooting frequency, calibre of the weapon, and insufficient ventilation (Demmeler et al., 2009). The frequent use of lead ammunition in large calibre weapons under insufficient ventilation can result in blood lead concentrations in a toxic range (Laidlaw et al., 2017). Only very limited information is available on blood lead levels in shooters performing at outdoor shooting ranges.

Due to limited availability of information and due to relevant limitations in the available studies, no meaningful quantification of inhalation exposure is possible, however. Similarly, there is not enough information available to quantify the oral intake (hand-to mouth) of lead dust deposited on the weapon and the clothes of the shooter or hunters. The proposal to ban the placing on the market and use of lead gunshot and to use alternative shot material(s), which is the Dossier Submitter's preferred option, would prevent such risks to sports shooters.

In case of derogations for lead gunshot and/or lead bullets - even under strict environmental conditions - the risks for sports shooters from lead exposure would remain the same as they are currently.

Recommendations on good hygiene practice (see for example Section 1.4.4.1) to limit lead exposure of the sports shooter and family members are important and are expected to be best practice at all shooting ranges in the EU. However, specific information on best practice recommendations at shooting ranges in the EU was usually not available to the Dossier Submitter. An EU-wide harmonisation of a complete list of recommendations for sports shooters might be beneficial.

Furthermore, recommendations could be provided to sports shooters to use non-lead primers and jacketed bullets (where possible), which can reduce lead exposure by about 90 % (Bonanno et al., 2002, Tripathi et al., 1991).

Home-casting of lead bullets

For home-casting a quantitative assessment was not performed due to missing information on the incidence of home-casting lead bullets for sports shooting and the concentration of lead in the air from home-casting. Due to the proposed derogation for the use of lead bullets for sports shooting under strict environmental conditions, it can be assumed that home-casting of lead bullets for sports shooting will continue; however, as mentioned above, the Dossier Submitter expects that the risk will be limited to shooters with home-casting bullets for specific uses such as old and historic weapons.

Human via the environment from drinking water and food

The risk for human exposure to lead via the environment from food and drinking water is mainly related to soil with lead contamination from shooting activities. Contaminated food may include cereals, fruits or vegetables grown on contaminated soil, dairy products and meat from cows fed e.g. with silage from areas contaminated by shooting.

Directive 98/83/EC sets a threshold of 10 µg/L for lead in drinking water and Regulation 1881/2006 limits lead for example in cereals to 0.2 mg lead/kg food for human consumption. The predicted dietary exposure to lead for an adult subsistence farmer (see Section 1.6.4.6) was calculated with 23 µg/kg bw/d, which is 15 times higher than the $BMDL_{01}$ established by (EFSA, 2012) for cardiovascular effects in adults (1.5 µg/kg bw/d) and 37 times higher than the $BMDL_{10}$ for nephrotoxicity effects (0.63 µg/kg bw/d).

The proposal to ban the placing on the market and use of lead gunshot and a ban on the use of lead bullets for sports shooting would prevent such risks. In case of derogations for gunshot and bullets under strict conditions, the Dossier Submitter considers that an additional ban of any agricultural use within the site boundaries would reduce such risks.

2.6.2.2. Environmental impacts

Gunshot

For sports shooting with gunshot, the Dossier Submitter identified five restriction options (see Section 2.2.2.1). The amount of lead avoided for such restriction options is summarised in Table 2-41.

The baseline is a release of 24 500 tonnes per year and 490 000 tonnes in 20 years (see Section 1.8.2.1).

A full ban on the placing on the market and use of lead gunshot (RO1) would result in releases only during the transition period of 5 years (5 * 24 500) of 122 500 tonnes. This would result in 367 500 tonnes avoided lead.

RO2 is an option that would allow only licenced individuals to use lead shot. This would concern about 12 000 athletes in the EU-27 using about 50 % of the released gunshot. Assuming a transition period of 5 years with a release of 122 500 tonnes (5 * 24 500) and 50 % of the baseline release during 15 years resulting in 183 750 tonnes (15 * 24 500* 0.5), it would result in a total release of 306 250 tonnes in 20 years which would be an avoided release of 183 750 tonnes.

RO3 concerns the ban on the placing on the market and use of lead gunshot with a conditional derogation that stringent risk management measures would need to be in place to, among other things, recover more than 90 % lead shot. The emissions during the transition period of 5 years result in a release of 122 500 tonnes (5 * 24 500). During the following 15 years the release would be limited to 10 % due to risk management measures and to 90 % of shooters, assuming that 10 % of shooters will switch to alternative ammunition. This will result in a release of 33 075 tonnes (15 * 24 500 * 0.1 * 0.9). The total emitted volume would be 155 575 tonnes which would mean an avoided release of 334 425 tonnes in 20 years.

RO4 combines the restriction options RO2 and RO3. The emissions during the transition period result in a release of 122 500 tonnes (5 * 24 500). During the following 15 years the release would be limited to 10 % due to risk management measures and limited to licenced individuals that consume about 50 % of the volume of lead shot. This would result in a release of 18 375 tonnes (15 * 24 500 * 0.1 * 0.5). The total emitted volume would be 140 875 tonnes which would mean avoided releases of 349 125 tonnes in 20 years.

RO5, which foresees compulsory information, is not expected to result in a large reduction of lead releases.

Table 2-41: Avoided releases of lead gunshot for sports shooting for the different restriction options

RO	Short description of RO	Emission reduction (avoided release) over 20 years (tonnes)
	Baseline use of 24 500 tonnes per year over 20 years	490 000
RO1	Ban on the **placing on the market** and **use** of **lead gunshot** for sports shooting	367 500 (210 000-525 000)
RO2	As RO1, but **derogation** for **licenced individuals**[1] to use; licencing by Member State; reporting to the Commission	183 750 (105 000-262 500)

RO	Short description of RO	Emission reduction (avoided release) over 20 years (tonnes)
RO3	Ban on the **placing on the market** and **use** of **lead gunshot** for sports shooting with a **derogation** for use at **permitted locations** with regular lead gunshot recovery (>90 %), containment, monitoring and treatment of drainage water; ban of any agricultural use within site boundary; all shooters allowed	334 425
RO4	As **RO3** but only for **licenced individuals**[1]; reporting to the Commission	349 125

Notes: [1] it is assumed that licenced individuals in the EU (ca. 12 000 athletes) would release ca. 50 % of the total amount of shot used by all sports shooters in the EU

Environmental risk reduction

The main environmental risks identified from the use of gunshot in sports shooting are as follows:

- Primary and secondary poisoning of birds
- Soil, surface water and groundwater contamination
- Poisoning of livestock (ruminants, poultry) resulting from shooting on agricultural areas

In terms of risk reduction to birds, only a ban on the placing on the market and use of lead gunshot for sports shooting together with a ban on the use of lead gunshot for hunting (see section 2.5.2.2) would achieve a full protection of all species susceptible to ingest lead gunshot. All other restriction options would still make lead gunshot available for ingestion to birds, especially in areas which may be attractive to them (including agricultural areas). "Lead contaminated birds" may represent a risk to predators as well.

Soil, surface water and groundwater contamination resulting from shooting activities with gunshot may result in risks to wildlife and livestock (via the ingestion of contaminated soil and vegetation). Silage used for animal fed may also be contaminated with gunshot if harvested from areas where shooting has taken place.

In terms of risk reduction to livestock (as ruminants) which may graze on contaminated land and/or which maybe fed with lead gunshot contaminated silage, there are uncertainties related to the actual extent of these practices. However, a ban of any agricultural use within site boundary would be the minimum RMM to reduce risks to all types of livestock. As regards poultry the Dossier Submitter notes that existing literature including Payne et al. (2013) suggests that lead poisoning may occur, e.g. on agricultural areas where shooting activities occur (even nearby) or on abandoned ranges. A ban of any agricultural use within site boundary would be the minimum RMM to reduce risks to this type of livestock as well. The Dossier Submitter could not assess (due to lack of data) the risks related to the ingestion of lead contaminated soil by wildlife.

Risks (reduction) to humans via the environment are discussed under the human health section.

Bullets

For shooting with both small and large calibre bullets, baseline releases amount on average to 420 tonnes of lead per year (range 6 – 1 500 tonnes) and 8 400 tonnes over 20 years (range 110 – 30 000 tonnes; see Section 1.8.2.2). Various restriction options were considered by the Dossier Submitter (see also Section 2.2.2.2):

RO1 proposes a full ban on the use of lead bullets for sports shooting. However, in the absence of suitable alternatives for sports shooting, such a restriction option is currently not implementable.

RO2 foresees a partial ban on the use of lead bullets with a derogation conditional that the use takes place at a notified (to the Member State) outdoor location for sports shooting and no agricultural activities take place at that location and where measures are in place for lead projectile containment and recovery. The Dossier Submitter has identified several sub-options for RO2 (see also Section 2.2.2.2):

RO2a combines the requirements for trap chambers (such as in Germany) with the basic requirement for sand traps or sand/soil berms (such as in Norway).

RO2b should reflect the information as required in the CSR (1. September 2020) combined with an option for dynamic shooting:

According to the CSR for rifle/pistol ranges "at least one or a combination of bullet traps, sand traps or steel traps" are required to achieve high abatement effectiveness. A sand trap is defined to "comprise of a mass of sand, or similar material, contained within a concrete or other structure which is open towards the firing point". According to the picture of the sand trap in the CSR (Figure 15), the sand trap has a sealing to the underlying soil. The Dossier Submitter understands that in the sand trap as required in the CSR the sand is contained "sealed" to the underlying soil, which would be an impermeable barrier.

The Dossier Submitter further notes that in the CSR for rifle/pistol ranges an "Overhanging roof over the lead impact zone to prevent runoff" is required and in addition is required to prevent rivers from crossing the lead deposition area. However, no control of water run-off is required for rifle/pistol ranges.

With regards to dynamic shooting disciplines, the Dossier Submitter understands that trap chambers and sand traps with an overhanging roof might not be suitable due to safety reasons. Consequently, the Dossier Submitter has added for this restriction option a sand trap without an overhanging roof but with a water management system to reduce surface water leaching from the range (run-off).

RO2c should reflect the highest standard of RMMs with trap chambers or sand traps consisting of a sand trap with an impermeable barrier to soil combined with an overhanging roof (for static disciplines) or a permanent cover (for dynamic disciplines), both combined with a water management system. The Dossier Submitter understand such sand traps to be 'best practice' sand traps.

The Dossier Submitter has included for this restriction option the requirement of a sand trap either with an overhanging roof or a permanent cover. The Dossier Submitter understands that permanent covers are expensive with regards to investment and maintenance costs and that they were reported to be tested for military uses. In the Finnish BAT examples of 1-, 10-, and 20-stand bullet traps ('Stapp rubber grinding bullet traps') are reported. Further information would be welcomed with regards to investment and maintenance costs of sand traps with permanent covers and their applicability for civilian rifle/pistol ranges.

RO2d proposes to require an even higher standard with trap chambers for static shooting disciplines only and 'best practice' sand traps for dynamic shooting disciplines only.

Transition periods for small and large calibre bullets of 5 years are considered most appropriate to allow ranges to be upgraded.

RO3 proposes to require compulsory information on the hazards of lead and the risks of using lead ammunition at the point of sale and on product packaging. Such information does not have an impact on avoided releases.

The Dossier Submitter has calculated the effects to reduce the emissions to the environment (gain in abatement) for the individual restriction options which are summarised in Table 2-42. Details on the emission and emission reduction of specific RMMs are summarised in Section 1.5.3.1.2 and described in Section B.9.1.3.5. Emission reduction was calculated by considering the changes in emission when upgrading from a scenario with less stringent RMMs to a scenario with more stringent RMMs. Details are presented in the Annex (Section D.3.4.2).

Table 2-42: Emission reduction of lead for changing sand/soil berms and soil berms to trap chambers or 'best practice' sand traps

Restriction Option		Estimated number of ranges affected	Emission reduction (tonnes) per year after TP	Emission reduction (tonnes) over 20 years	Relative emission reduction compared to baseline	
					Over 20 years	Over 15 years after TP
RO1	Ban on the **use** of **lead bullets** for sports shooting	16 000	419	6 284		
RO2	Ban on the use of lead **bullets** for sports shooting with a **derogation** at notified outdoor locations where no agricultural activities take place and the following measures are in place (see different RO2 options below)					
RO2a	Trap chamber, or sand trap (with impermeable barrier) or sand/soil berm (without impermeable barrier), combined with roof or water management system	2 440	299	4 487 (71-15 682)	54 %	71 %
RO2b	Trap chamber, or sand trap (with impermeable barrier), combined with roof or water management system	7 200	348	5 226 (78-18 349)	62 %	83 %
RO2c	Trap chamber, or 'best practice' sand trap with impermeable barrier and roof or permanent cover and water management system	7 880	387	5 801 (83-20 434)	69 %	92 %
RO2d	Trap chamber for static disciplines; AND 'best practice' sand trap for dynamic disciplines	8 000	386	5 786 (83-20 374)	69 %	92 %
RO3	Compulsory information on the hazards/risks of lead at the point of sale and on product packaging	n/a	n/a	n/a	n/a	n/a

Based on those calculations, the emission reduction for RO2c, the preferred restriction option, is 5 800 tonnes over 20 years, with a range of 4 500 to 5 800 tonnes for the other restriction options (central scenarios).

Environmental risk reduction

Soil, surface water and groundwater contamination resulting from shooting activities with bullets may result in risks of poisoning for wildlife and livestock (ruminants).

The poisoning of livestock (ruminants) may take place via the ingestion of lead-contaminated soil and vegetation on shooting ranges or areas used as agricultural land. Although there are uncertainties related to the actual extent of the use of shooting ranges as agricultural land, a ban of any agricultural use within site boundary would be the minimum RMM to reduce risks to livestock. The Dossier Submitter could not assess (due to lack of data) the risks related to the ingestion of lead-contaminated soil by wildlife.

Risks reduction to humans via the environment are discussed under the human health section.

2.6.3. Costs and other economic impact

2.6.3.1. Gunshot

As a result of the restriction option analysis, the Dossier Submitter has identified the following preferred restriction option (combined with compulsory information on the hazard of lead and the risks of using lead ammunition, RO5):

- **RO1: Ban on the placing on the market and use of lead gunshot for sports shooting**

Considering that participation in international competition requires the use of lead shot, the following (non-preferred) options (combined with compulsory information on the hazard of lead and the risks of using lead ammunition, RO5) were analysed to provide information for the decision maker:

- **RO2:** Ban on the placing on the market and use of lead gunshot for sports shooting with a derogation for licenced individuals to use (e.g., Olympic/ISSF elite level only; training and events) with licencing done by Member States with annual reporting[272] to the Commission.
- **RO3:** Ban on the placing on the market and use of lead gunshot for sports shooting with a derogation if the use takes place at a location that has a permit granted by the Member State for the use of lead gunshot for sports shooting and the following measures are in place:
    - Regular (at least once a year) lead gunshot recovery with >90 % effectiveness (calculated based on mass balance of lead used vs lead recovered in the previous year) to be achieved by appropriate means (such as walls and/or nets[273] and/or surface coverage);
    - Containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off) to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive;
    - Ban of any agricultural use within site boundary.
- **RO4:** Ban on the placing on the market and use of lead gunshot for sports shooting with a derogation for licenced individuals to use (e.g. Olympic/ISSF elite level only; training and events) if the use takes place at a location that has a permit granted by

[272] Reporting should cover the number of licences granted to individuals.
[273] In some sources referred to as 'shot curtains'.

the Member State for the use of lead gunshot for sports shooting where the following measures are in place:

- Regular (at least once a year) lead gunshot recovery with >90 % effectiveness (calculated based on mass balance of lead used vs lead recovered) to be achieved by appropriate means (such as walls and/or nets[274] and/or surface coverage);
- Containment, monitoring and, where necessary, treatment of drainage water from projectile impact areas (including surface water run-off) to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive;
- Ban of any agricultural use within site boundary;
- Associated annual reporting[275] to the Commission.

The remainder of this section provides an assessment of the costs associated with these restriction options.

RO1: Ban on the placing on the market and use of lead gunshot for sports shooting

The calculations for the cost scenarios involved with a ban on the use of gunshot are presented in Table 2-43. The following considerations were made:

- Bismuth and tungsten are, for their high price, not considered as viable alternatives for lead in sports shooting.
- Although in principle no gun replacement appears to be needed (see section 2.6.1.1 on alternatives) a conservative replacement rate of 10 % was used with a range of 6 % to 14 %.
- Costs and emission reduction over the 20-year assessment period are assumed to occur after the first 5 years, i.e. in the first five years no cost and emission reductions are assumed.
- The annual use volume of lead was based on a low-mid-high estimation based on information from the consultation (low scenario: 14 000 tonnes, source: FITASC/ISSF, comments #3221a) and the estimation made by the Dossier Submitter (high scenario: 35 000 tonnes, based on the Member State survey 2020[276]) as well as the average of these two estimations (mid scenario: 24 500 tonnes).

Similar assumptions were made for RO2 (see Table 2-44).

Table 2-43: Calculation of cost associated with a ban on gunshot for sports shooting

Parameter	Data		
	low	mid	high
Volume of lead used per year (tonnes)	14 000	24 500	35 000

[274] In some sources referred to as 'shot curtains'.
[275] Reporting should cover the number of sites and volume of lead ammunition used at each site.
[276] See section E5 in the Annex for details.

Parameter	Data		
Weight per cartridge	Based on FITASC contribution: 60 % of shooters use a 28-gram cartridge, 40 % of shooters use 24-gram cartridge. 60 % * 28 gram and 40 % * 24 gram = 26.4 gram per cartridge on average		
Number of cartridges used per year	14 000 tonnes / 26.4 gram per cartridge = 530 million cartridges	24 500 tonnes / 26.4 gram per cartridge = 928 million cartridges	35 000 tonnes / 26.4 gram per cartridge = 1 326 million cartridges
Price per cartridge (lead gunshot)	€0.45		
Price difference	low	mid	high
-relative	0 % higher price for steel	1 % higher price for steel	3 % higher price for steel
-absolute	€0	€0.0063	€0.0126
Compliance costs per year	Nr of cartridges * price difference		
	€0m	€5.8m	€16.7m
Number of sports shooters in the EU	2.5 million (based on FITASC information)		
Share of shooters that would have to prematurely replace guns	6 %	10 %	14 %
Number of guns to be replaced prematurely	142 857	250 000	357 143
Rounded costs of replacing guns	€264m	€462m	€660m
Rounded costs for premature gun replacement	€19m	€34m	€49m
Rounded nominal costs per year after the transition period	€19m	€39m	€65m
Rounded costs over 20 years (NPV, 4 %)	€177m	€364m	€596m
Emission reduction over 20 years	210 000 tonnes	367 500 tonnes	525 000 tonnes
Cost-effectiveness based on the PV of restriction costs and the total lead amount affected	0.8 €/kg	1.0 €/kg	1.1 €/kg

RO2: Ban on the placing on the market and use of lead gunshot with a derogation for licenced individuals

The calculations for the costs involved with a ban on the use of gunshot but with a derogation for the continued use of lead gunshot for licenced individuals in the EU is presented in Table 2-44. The following considerations were made:

- The Dossier Submitter assumed that licenced individuals are consuming 50 % of the volume of lead gunshot. With a ban on the use of lead gunshot with a derogation for such individuals, the remaining sports shooters consuming the other 50 % of the volume of gunshot would need to switch to steel gunshot.
- The main costs of this option would be determined by the costs arising from changing to the use of steel gunshot for shooters.

- It is assumed (based on FITASC/ISSF information) that of the 12 000 athletes in the EU-27, 60 % use 28 g cartridges and 40 % use 24 g cartridges, resulting in 26.4 gram per cartridge on average.
- There would be no environmental requirements for the sports shooting locations where the licenced individuals train and compete.

Table 2-44: Calculation of costs for changing to steel shot associated with ban on shot for sports shooting with a derogation for licenced individuals

Parameter	Data		
	low	mid	high
Volume of lead used pear year, all users (tonnes)	14 000	24 500	35 000
Assuming that 50 % of all use would be by licenced individuals and that therefore with a derogation for this group the remaining 50 % (by other shooters) would be affected			
Volume of lead used per year of shooters that would need to switch to steel gunshot (tonnes)	7 000	12 250	17 500
Weight per cartridge	Based on FITASC/ISSF contribution: 60 % of shooters use 28 gram cartridge, 40 % of shooters use 24 gram cartridge. 60 % 28 gram and 40 % 24 gram = 26.4 gram per cartridge on average		
Number of cartridges used per year	265m	464m	663m
Price per cartridge	€0.45		
Price difference	low	mid	high
-relative	0 % higher price for steel	1 % higher price for steel	3 % higher price for steel
-absolute	€0	€0.0063	€0.0126
Compliance costs per year	Nr of cartridges * price difference		
	€0m	€2.9m	€8.4m
Number of sports shooters in the EU	2.5 million (based on FITASC information) shooters minus 12 000 athlete shooters leaves 2 488 000 leisure shooters impacted		
Share of shooters that would have to prematurely replace guns	6 %	10 %	14 %

Parameter	Data		
Number of guns to be replaced prematurely	142 171	248 800	355 429
Rounded costs of replacing guns	€263m	€460m	€656m
Rounded costs for premature gun replacement	€19m	€34m	€48m
Rounded nominal costs per year after the transition period	€19m	€37m	€57m
Rounded costs over 20 years (NPV, 4 %)	€177m	€336m	€518m
Emission reduction over 20 years	105 000 tonnes	183 750 tonnes	262 500 tonnes
Cost-effectiveness based on the PV of restriction costs and the total lead amount affected	1.7 €/kg	1.8 €/kg	2.0 €/kg

SEAC box

SEAC notes that Table 2-43 and Table 2-44 contain some unclear aspects:

1. Values for the "relative price differences" for steel cartridges relative to lead are indicated as +1% and +3%. However, upon closer inspection this does not seem to correspond to the "absolute" numbers given (+€0.0063 and +€0.0126). It appears that the absolute price differences have been taken from the original spreadsheet (available to the rapporteurs), where the relative numbers are, respectively, +1.4% and +2.8% (presented in a rounded form as +1% and +3%).All other numbers in these tables were correctly transferred from the spreadsheet, so that the total impact numbers do not change.
2. SEAC was not able to reach a common understanding with the Dossier Submitter about the fact that in both Table 2-43 and Table 2-44 a lower percentage for gun replacement was combined with a lower volume of lead used per year (and similarly for the high replacement with high lead use). The figures for gun replacement and lead use are plausible by themselves but in SEAC's view it is speculative to link them in the way it has been done in these tables. The quantities of lead are the result of estimates (explained in the Background Document) and may be correct or wrong. The same applies to the percentage of gun replacement. Less (or more) lead used will mean just that. This does not change the need for gun replacement, which would only depend on the current composition of the stock of guns in use. Therefore, SEAC considers that the cost calculations based on these low and high scenarios are of limited value.
3. Moreover, it should be noted that percentages of gun replacement in both tables, Table 2-43 and Table 2-44, (and also in the calculation for RO3 – not shown here, but available in the original spreadsheet), as assumed by the Dosser Submitter, are

the same. However, it should be realized that for these two scenarios the group of sports shooters concerned is a different selection from the total. It cannot a priori be assumed that replacement figures for these groups will be the same. Fortunately, the group of RO4 contains 90% of the group of shooters in RO1, so that any differences in the total impact results will probably not be large. For RO3 (total impact figures presented in Table 2-54) deviations may be higher because this covers only 10% of the total group of shooters.

RO3 and RO4: Derogation under strict conditions

As shooting ranges are a major source of lead emissions to the environment, the restriction options considering a derogation from the ban on placing on the market and the continued use under strict conditions (such as regular lead shot recovery > 90 %) looks at various measures for lead abatement. A site-specific impact assessment for all shooting ranges in the EU/EEA is beyond the scope of this restriction proposal since there is no suitable EU/EEA dataset that identifies all shooting ranges with corresponding information on their operational conditions and risk management measures in place. Instead, the Dossier Submitter, based on the CSR for lead (CSR, 2020), has analysed four representative scenarios to model the likely impacts that the proposed restriction would have on shooting ranges for skeet, trap and sporting/COMPAK throughout the EU.

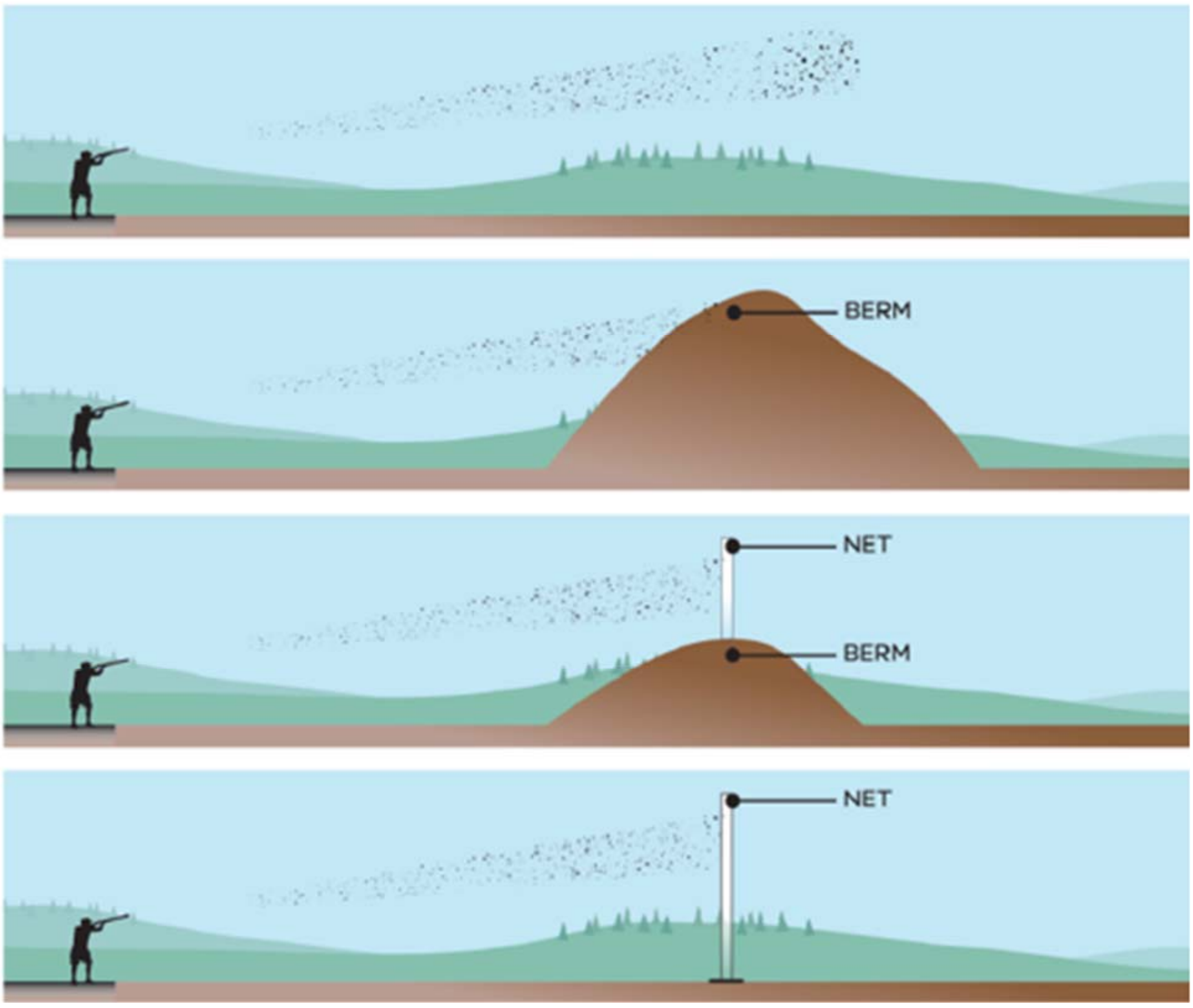

Figure 2-13: How berms and nets limit the spread of gunshot (Kajander and Parri, 2014).

The main principle of containing lead at shooting ranges is to design the range in such a way that lead will not escape, be kept within the boundaries of the range and lead shot recovery is facilitated. In practice this can be achieved by installing berms (with or without nets) of sufficient height, which will stop lead during flight. This is illustrated in Figure 2-13. According to the Finnish BAT (Kajander and Parri, 2014), the area for one trap range is ca. 50 000 m^2 and for one skeet range ca. 60 000 m^2, respectively. The value of 60 000 m^2 is taken forward for further analysis.

The Dossier Submitter assumes that a berm reduces the shotfall zone by 30 % to 70 % of the original area and a berm and/or a net to 50 %. This is a simplified approach, because the reduction in the shotfall zone is dependent on the distance from the shooting stand to the barrier and the type of discipline. For a trap range with a shot net the reduction can be up to 85 % (15 % of the original area), whereas for a skeet range the reduction is only up to 30 % (70 % of the original area) as indicated by Environmental Protection Authority Victoria (EPA) (2019).

By designing ranges in such a way that several stands are next to each other with overlapping shotfall zones, the deposition area can be further limited. Based on Figures 2, 12 and 13 of Environmental Protection Authority Victoria (EPA) (2019) and Figures 4.3 and 4.4 of AFEMS (2002) the Dossier Submitter assumes that for three adjacent ranges the deposition area is about 1.5-times the deposition area of a single range. This has a relevant impact on the cost-effectiveness of risk management measures and the recovery of lead.

Costs of risk management measures

To achieve a lead recovery rate of > 90 % measures such as berms and/or shot nets and/or surface coverage are required to reduce the shot fall zone and to facilitate the regular recovery of lead shot. Information on the costs of such measures is scarce and often limited in scope. Therefore, the following assumptions on costs have to be considered as rough estimates providing an order of the magnitude of costs rather than the exact costs.

According to information submitted during the consultation by the Finnish Shooting Sport federation (#3240) the length of an earthen berm required for one shotgun range is around 100 metres if located at a distance of around 75 metres from the firing stands. A theoretical volume of around 60 000 m^3 of earth (around 3 000 lorries with trailers) is required to build a berm of 20 metres in height. Even if the earth was transported free of charge to the site, e.g. as surplus suitable for construction, the earth works would still incur significant costs. For instance, assuming a unit price of €1.5 per m^3, the cost of earthworks would come up to around €90 000 per berm. If suitable surplus earth is not available in the vicinity, the cost of the earthworks may rise to hundreds of thousands of euros. A berm and net combination that is 23 metres in height, as presented in the sample design of Appendix E2 (Kajander and Parri, 2014), costs around €300 000 to €600 000 depending on the relative heights of the earthen berm and the net, and the cost of the material. In addition to this the earthen berm needs to be covered which increases the costs. For a larger shotgun site (5 ranges), the cost of earthen berms is estimated to be at least €2 250 000, and possibly higher if there are expenses for remediating the existing range structure before building the berm as well as covering the backstop berm. The higher value of €600 000 for one range is taken forward for the impact assessment.

Table 2-45: Costs of berm material and nets according to the Finnish BAT

Berm height (m)	Net height (m)	Total cost for berm length (€)			
		1 m	10 m	100 m	200 m
Berm material and net must be purchased					
23	-	6 300	63 000	630 000	1 260 000
15	8	4 800	48 000	480 000	960 000
10	13	5 800	58 000	580 000	1 160 000
Berm material available for free, only net to be purchased					
23	-	3 000	30 000	300 000	600 000
15	8	3 300	33 000	330 000	660 000
10	13	5 100	51 000	510 000	1 020 000

Costs for the combination of a berm with nets on top are provided in the Finnish BAT (Kajander and Parri, 2014). The costs for 200 m berm and/or net is estimated at **€960 000 to € 1 260 000** (Table 2-45). This cost range is taken forward for the impact assessment.

Another solution which is sometimes opted for is to only place a net at a suitable distance combined with suitable surface coverage of the impact zone. The Finnish BAT does not give the costs of such a net. Other sources (KNSA[277]) have made estimations of the costs of such nets based on a unit price of €250 per m^2 (in 2014 prices). Assuming this to be installed with a height of 5 meters over ¼ of a circle at 150-metre distance and correcting for inflation would result in indicative investment costs of **€300 000 - €400 000** per shot net. There are other types of nets including systems to directly collect lead gunshot. It can be assumed that the costs for such systems are even higher.

Further costs for surface coverages might arise, for which no cost estimates are available for most materials except asphalt as specified in the Finnish BAT. In addition, there will be costs for water containment, monitoring and, where necessary, treatment of surface (run-off) water to ensure compliance with the environmental quality standard (EQS) for lead specified under the Water Framework Directive. The Finnish BAT (Kajander and Parri, 2014) provides a cost estimate of €9 000 for installing a water treatment system covering an area of around 2 000 m^2.

The following examples for the costs of renovation of shooting ranges have been provided:

[277] https://www.knsa.nl/media/1332/122-voorstel-bodembescherming-tegen-loodhagel-kleiduivenschietbaan-emmer-compascuum-knsa-en-milieuadviesbureau-van-den-bos-15-04-2014.pdf

- Costs of renovation of a shooting range from €0.4 million to €1.0 million, costs for a new shooting range €0.5 million to €2.0 million (comment #3198 received by German Bundesverband Schießstätten e.V.).
- German Shooting Sport and Archery Federation (letter to ECHA 25.05.2021) reported and example (German National Training Centre in Wiesbanden) which has a recovery rate of almost 100 % effectiveness by using an earth wall without foil (clay sealing membrane in the soil of the complete range). The costs for the modernisation of the shooting range (3 trap/skeet stands) in 2007 were around €7 million (for the whole modernisation of the range including the bunkers etc.).
- Bavarian LfU (2014b) lists examples for remediation and renovation costs for existing shotgun ranges of €0.26 million, €0.5 million, €0.75 million, €1.3 million, €1.35 million, including work done by club members.

The Finnish BAT provides the total costs for design and implementation of **measures for pollutant management with €1 500 000**, and the costs for **maintenance with €50 000** (for a 10-year period). The Dossier Submitter takes forward those costs and assumes that such measures would be suitable to achieve a recovery rate of > 90 %.

Furthermore, the costs for a final clean-up of the range need to be considered. Two case studies have been found that describe the cost of remediation to remove lead contamination at end of service life:

- Germany, Remscheid shooting range (shot and bullets) in use 1926-1996, remediation of 11 150 m^2 area with costs of €750 000 (Richter and Hohmann, 2019).
- Germany, Lemgo-Lüerdissen, trap and skeet range in use for more than 50 years, ca. 50 000 mg Pb/kg, 37 000 m^2 area to be remediated, 7 500 m^3 contaminated soil, ca. 148 tonnes lead resulted in costs of €950 000 Euro (Lampe, 2012).
- German Shooting Sport and Archery Federation (letter to ECHA 25.05.2021; comment #3379) reported that when converting old systems to a new shot retention system, the costs for the prior renovation of the soil amount €0.2 to 1.0 million on average.

Based on those examples, the total costs of soil removal to recover lead the main impact areas of one range at the end of service life are assumed to be €750 000 - 950 000. For remediation of the whole area of a shooting range (of about 60 000 m^2) more than €1 million must be assumed.

To calculate the costs for regular soil removal each 5 to 15 years, the second example provides information implying that the cleaning of contaminated soil would cost at the minimum **€126 per m^3**.

Costs for the impact on the environment

Contaminating soil with lead has a negative impact on the environment because a fraction of the lead deposited will be mobilised over time leading to increased lead concentrations in water, soil, plants and consequently entering the food chain. No monetisation of this negative impact has been performed.

Scenarios

The Dossier Submitter identified (based on the Chemical Safety Report attached to the registration file) several scenarios for different types of ranges, which are described in Table 2-46.

Table 2-46: Scenarios and range types used for impact assessment

Scenario	Operation conditions	Represents
A: Shooting areas or ranges where steel is used	-	-
B: Temporary areas without relevant RMM (no lead recovery)	Shooting intensity (rounds per year): 5 000-10 000	Temporary ranges such as annual clay target competition on local level
C: Permanent ranges without relevant ENV RMM (lead recovery < 50 %)	Shooting intensity (rounds per year): 5 000-10 000	Ranges organised in open areas
D: Permanent ranges with some ENV RMM (berm reducing the shotfall zone to 70 %; lead recovery 50 - < 90 %)	Shooting intensity (rounds per year): 10 000-100 000	Ranges that are constructed with some RMM possibly used by regional clubs.
E: Permanent ranges with different ENV RMM (reducing the shotfall zone to 50 % (30-70 %); lead recovery > 90 %)	Shooting intensity (rounds per year): 100 000-350 000	Rather large ranges, with well develop RMM where large competitions (even international) could be organised

To investigate the impacts of a restriction (ban on the placing on the market and use of lead shot with derogation to regularly recover > 90 % lead shot) within these types of ranges the Dossier Submitter compared the comparative advantage between the options to continue the use of lead gunshot by installing additional RMMs and avoiding the need to install RMMs by shifting to use non-lead shot.

On many ranges, additional environmental RMMs would need to be installed to ensure lead recovery is sufficiently effective to allow continuation of using lead shot. Following several best practice documents, these RMMs would at least include the construction of a berm, (height and distance to be determined) not only for lead abatement but also for safety and noise abatement, as well as additional measures such as a net on top of the berm (in case the berm does not have a sufficient height) and surface coverage to be able to collect more than 90 % lead shot spent.

The cost of collecting lead varies but it can be assumed that members of shooting clubs help in collecting lead, by organising regular clean-up, such as every six months. Evidence is given, for example, through the explanation on lead collection in France[278] but also by site visits that the Dossier Submitter undertook. In some cases, such as in Finland the additional cost of clean-up that may be incurred, are covered by the members in the form of an eco-contribution.

[278] https://questions.assemblee-nationale.fr/q15/15-3842QE.htm

The Dossier Submitter further assumes that the incremental cost involved in using alternatives at shooting ranges is driven by the (small) price differences between lead and alternatives (steel) and by any cost coming from the use of alternatives.

The most likely alternative to lead gunshot is steel shot (see the section on alternatives), which can be purchased by sports shooters at comparable prices (see the section on suitability of alternatives). The Dossier Submitter assumes that steel shot is at a maximum 3 % more expensive than lead gunshot. This means that while the average market price per lead shot cartridges is €0.45, the average price per steel shot cartridge corresponds to €0.46.

Although the European sports shooting confederation reports wooden structures to prevent ricochets, which have been installed in the Netherlands (personal communication), the German shooting range guidelines (German Bundesministerium der Justiz, 2012) prescribes only the use of safety glasses when using alternative gunshot at shooting ranges. Based on this, the Dossier Submitter concludes that the use of alternative shot does not require additional RMMs compared to the use of lead shot. From an internet search it was learned that the prices of such glasses vary between €5-50 depending on brand, make, etc. The Dossier Submitter assumes a price between €5-50 per shooter.

To evaluate the different scenarios, costs are calculated for a shooting range with one stand only. FITASC and ISSF rules prescribe several shooting stands.

A trap range uses 5 shooting positions to fire at clay targets launched from a centre trap house. The targets are thrown at different angles away from the trap house. A skeet uses 8 shooting positions to fire at clay targets launched from both high and low houses. The targets are thrown at the same pattern, but the angle of shot varies because the shooter moves to the different positions. These shooting angles tend to create a semi-circular pattern of lead shot as it falls to the ground." (US EPA, 2005).

A: Shooting areas or ranges where steel shot is used

Baseline

A few Member States have implemented legislation that restricts the use of lead at shooting ranges. In Sweden, Norway, and Denmark the use of lead shot in shooting ranges is banned in the entire territory (with some derogations in place; see below); in the Netherlands the use of lead shot is not banned for clay pigeon shooting, but lead needs to be collected and soil and water contamination needs to be avoided by means of soil protecting measures. In Belgium, in the Flemish region, there is a regional ban for the entire territory.

Impact

No impacts are expected to arise as a consequence of this restriction. The use of steel and lead gunshot at the same range is not expected to have a negative impact on lead mobilisation as discussed in Annex B (B.4.2.1).

B: Temporary areas where lead is used (without any ENV RMMs)

Baseline

Temporary shooting ranges can be organised at virtually any suitable area of land, typically they are organised for yearly events that last 2-3 days at maximum. For temporary areas, it is assumed that no RMMs are in place to limit lead emissions and/or recover lead shot. Use of RMMs at temporary areas are reported sporadically, as for example reported by the

French ball trap organisation. Incidental use of agricultural foil has been reported[279], but there is insufficient information to model this as part of this scenario.

Lead shot recovery or remediation is usually not performed for temporary ranges and therefore, no running costs emerge. However, the contamination of such temporary shooting areas has an impact on the quality of soil, the quality of agricultural products grown on such areas and for wildlife and livestock. This impact has not been monetised yet.

Impact

The Dossier Submitter calculates that the annual amount of lead dispersed in a typical temporary shooting area is in the order of 120-240 kg corresponding to 5 000-10 000 shots per year (or 2-3 days of shooting per year).

Based on the assumed price difference of €0.01 per cartridge between lead and steel shot, the incremental cost from switching to steel shot is in the order of €60-130 per year, depending on the intensity of shooting. Importantly, this annual cost will be shared by all shooters participating in the use of the area. Using the estimates from Thomas and Guitart (2013) of around 100 shots per person, this would amount to 50-100 participants per event, resulting in an increased cost per person of €1 per shooting participant.

If agricultural foil is used to recover lead shot (assumed price of the foil about €0.2 per m^2[280]), then this would imply costs of up to (50 000 m^2) * €0.2 per m^2 = €10 000 per use. The actual price may vary on the required quality of the foil. Higher quality foil is less likely to break would be more expensive.

The lead that could potentially be recovered would be between (5 000/10 000 * 0.024 kg), i.e. 120-240 kg, against a price for recovered lead of about €0.5 per kg the value of this recovered lead would be in the order of €60-120.

This example is hypothetical, in reality shot will also fall outside the temporary ranges. The practicality of such measures can also be questioned, as the required quantity of foil would be vast and the foil would need to be of sufficient quality to be able to prevent spillages. Furthermore, the temporary character and the envisaged use for other purposes after the event (often for agricultural uses) would result that the foil solution would need to be handled for every, separate event. No re-use of the foil is foreseen.

This leads the Dossier Submitter to assume that the measure is not practical and that the required recovery rate (in case of a condition) would not be met in practice, so not only is the measure not efficient nor practical but will also not lead to the required level of control.

Consequently, for temporary shooting ranges the cost to recover lead shot would be at least €10 000 whereas the incremental cost from using steel shot instead of lead shot would be maximum €130 per year.

[279] https://questions.assemblee-nationale.fr/q15/15-3842QE.htm
[280] https://www.btndehaas.nl/afdekmateriaal/plastic-folie/landbouwplastic

Table 2-47: Baseline and impact costs for temporary areas (B)

Baseline costs	Costs for RMMs required to achieve recovery > 90 %	Costs for use of alternative(s)
Lead recovery or remediation is usually not performed leading to persistent contamination of the area (not monetised yet)	Recovery > 90 % not feasible Cost of foil: €10 000 (minimum)	Use of steel shot At shooting intensity of 5 000 to 10 000 rounds of shot/year €1 000-1 900 over the lifetime of a shooting range (40 years) 20 year cost: €600-1 200

➔ As a full ban of lead shot is less costly and more effective than any conceivable set of RMMs, it is the most proportionate matter for temporary ranges.

C: Permanent ranges without relevant ENV RMMs (low lead recovery)

Baseline

For some permanent ranges no RMMs will be in place. This would, for example, apply to trap and skeet disciplines but also to ranges used for shooting disciplines that are usually located in natural environments with adjunct trees and bushes. The effectiveness of lead recovery under these conditions is assumed to be not higher than 40 % (less than 50 %). It is assumed that for such ranges lead contamination may be removed only at the end of service life with possible infrequent lead collection from the surface or removal of the topsoil during service life. The total costs of soil removal to recover lead at the end of service life are assumed to be far higher than €1 million.

In the case of areas with trees and bushes, the collection of lead from the surface or the removal of topsoil is likely to be more expensive, more difficult and/or even not possible.

Example case

Blackburg shooting range, US; source Craig et al. (2002):

The shotgun range occupies a cleared 60 m long by 60 m wide slightly sloping surface now covered with grass. The shooting ranges are surrounded by second growth forest, last cut over in the 1930s, dominated by red and white oaks that are up to 31 cm in diameter and contain as many as 60 growth rings. Some pines are up to 33 cm in diameter and contain up to 90 growth rings. The shooting range was established in 1993, has been in continuous use since that time, and appears to be increasingly used.

From the description of the case the Dossier Submitter assumes no RMMs are in place. Reference is made to occasional clean-up of the range by means of replacing the topsoil. The claimed disposition rate (assumed to be equal to the possible recovery rate) is in the order of 15 % of the lead, assuming this all falls within the hot zone of 60 m.

The case is exemplary for this class of shooting ranges where no RMMs are put in place.

Impact

To achieve a recovery rate of > 90 % for such a range, the construction of a berm and/or possible installation of shot curtain, shot nets, on the top of the berm (or replacing a berm), together with a surface cover at the impact zone or, alternatively, the installation of nets and surface coverage would be required which are costly.

Costs of €1 500 000 for the implementation of environmental risk management measures and €50 000 for maintenance (for every 10 years) are assumed (Kajander and Parri, 2014). Based on height and position of the berm in relation to the shooting stand, additional shot nets might be required on top of the berm as well as surface coverage of the impact zone. Assuming this to be installed with a height of 5 meters high over ¼ of a circle at 150-meter distance and correcting for inflation would give investment costs of €300 000-400 000 per shot net.

The German Shooting Sport and Archery Federation (letter to ECHA 25.05.2021; comment #3379) reported installation costs ranging from €0.4 million to €2.0 million. **This information together with the information from Kajander and Parri (2014) has been translated into a range from €0.5 million to €1.5 million to €2.0 million.**

To calculate the costs for soil removal at the end of service life, it is assumed that an area of max 30 000 m^2 (50 % reduction in shotfall zone by RMMs) would need to be removed at a soil depth of 5 cm resulting in a soil volume of 1 500 m^3. Assuming €126 per m^3 would result in costs of €189 000.

On the other hand, the use of alternatives to lead shot (such as steel) would, over the lifetime of such a range, lead to an incremental cost of €1 000-1 900 (NPV, 4 %, over 40 years, yearly costs of €60-130). Using the estimates from Thomas and Guitart (2013) of around 100 shots per person, this would amount to 50-100 participants per event, resulting in an increased cost per person of €1.

Table 2-48: Baseline and impact costs for permanent range without ENV RMM (C)

Baseline costs[1]	Costs for RMMs required to achieve lead recovery > 90 %	Costs for use of alternative(s)[2]
Remediation costs (end of service life) >> €1 million	Installation of berm and/or shot nets and/or surface coverage for lead recovery and water containment and treatment: €0.5m – €1.5m – €2m Maintenance of RMMs: €50 000 (for every 10 years) Regular lead recovery: no costs Costs of clean-up (end of service life): €189 000 (€126/m^3 for 30 000 m^2, soil layer of 5 cm) **Total costs over 40 years: €0.5m – €1.3m – €1.7m** **Total cost over 20 years: €0.5m – €1.3m – €1.7m**	Use of steel shot At shooting intensity of 5 000 to 10 000 rounds of shot/year €1 000-1 900 over the lifetime of a shooting range (40 years) 20 year cost: €600-1 200

Notes: [1] costs for the environmental impact not quantified; [2] in case of substituting lead gunshot with steel gunshot, additional clean-up costs might arise, this is considered as advancing the cost of existing end-of life clean-up.

➔ Comparison of the cost of installing environmental RMMs that would result in a lead recovery rate of >90 % to the incremental costs of switching from lead to steel shot suggests that a ban can be the most proportionate matter for this type of shooting range.

D: Permanent ranges with some ENV RMM (lead recovery ~ 50 %)

Baseline

These ranges are assumed to have at least a berm in place that may or may not be covered. The effectiveness of lead recovery is assumed to be around 50 %, i.e. 50 % of all lead used at the site is thought to be recovered. An example of such a range would be the Nokia range in Finland (Kajander and Parri, 2014)[281].

In case of berms already installed, the dispersion zone of lead is reduced by 30 % to an area of 70 % of the original surface (i.e. the original surface of ~60 000 m^2 is reduced to about 42 000 m^2). These facilitates the concentration and subsequent recovery of lead shot from soil.

One cost that would need to be incurred is for periodical soil layer service operations. In feedback from the German Shooting Sport and Archery Federation, the Dossier Submitter learned that: '*In case of shot trap walls made of sand / earth and free deposition areas, the upper soil layer with the lead shot is removed every 5 to 15 years depending on the intensity of use (alternatively: after abandonment of the use of the range) and the lead shot*

[281] NB: this follows a description of the site as in 2014 or earlier. In the meantime, operational conditions of the site may have changed. The example is quoted here for analytical purposes.

is mechanically separated either on site or using a treatment device and recycled. This work is carried out by specialized companies.'

With regards to lead recovery, it is assumed that during service life soil from the *main* shotfall zone will be removed, whereas at end of life the soil of the whole range will be removed. Assuming 10 000 m^2 main shotfall zone removal of the upper 10 cm soil layer (at higher intensity the cleaning of the soil is thought to be needed at greater depth) results in a volume of 1 000 m^3 soil to be removed. Assuming €126 per m^3 costs of €126 000 result, required about every 10 years. For 40 years this would be three time the costs. In addition to the removal of the upper soil from the whole range (60 000 m^2 * 0.7 = 42 000 m^2) at the end of life of (42 000 m^2 * 0.1 m * 126 €/m^3 = €529 200). For this scenario it is assumed that 10 cm of the upper soil would need to be removed due to accumulation of lead on the soil.

The amount of lead that can be recovered every ten years would amount to 100 000 shots/year * 10 years * 0.5 (50 % recovery rate) * 0.024 kg lead/shot = 12 000 kg lead which, against a purchasing price (i.e. the price offered to clients who bring in lead) of 0.5 €/kg lead can deliver a value of €6 000 (max).

Example case

Nokia range, Finland; Source: Finnish BAT (Kajander and Parri, 2014).

The earthen berm at the Nokia shooting range was constructed in 2005, and it is covered with the decommissioned wire of a paper machine for shot collection. The backstop berm is located at around 150 metres from the firing stand, and its height is 4.5 metres measured from the shooting height (Väyrynen 2011 as cited in Finnish BAT). The range is considered to be typical for this class, as some risk management measures are in place to recover lead. A lead shot recovery rate of 55 % is reported.

Impact

To continue operating with lead, further environmental risk management measures would need to be installed to ensure lead recovery > 90 %. Based on height and position of the berm in relation to the shooting stand, addition of shot nets might be required on top of the berm, surface coverage of the impact zone and a system to contain, monitor and treat surface water. Deducting from the costs of €1 500 000 the costs for installing a berm (€600 000), results in installation costs of €900 000 and maintenance costs of €50 000 for every 10 years.

The German Shooting Sport and Archery Federation (letter to ECHA 25.05.2021; comment #3379) reported installation costs ranging from €0.3 million to €1.0 million. **This information together with the information from Kajander and Parri (2014) has been translated into a range from €0.3 million to €0.65 million to €1.0 million.**

To calculate the costs for soil removal at the end of service life, it is assumed that a soil volume of 30 000 m^2 (50 % reduction in shotfall zone by RMMs) would need to be removed at a 5 cm resulting in a soil volume of 1 500 m^3. Assuming €126 per m^3 would result in costs of €189 000.

The total costs for RMMs required to achieve lead recovery of >90 % for one stand are estimated at about €0.6 million (central scenario) over the lifetime of a range (NPV, 4 %).

The costs of using alternatives at the given shooting intensity are estimated at €130-1 300 per year for one stand, resulting in €1 900-19 300 over the lifetime of a range (NPV, 4 %).

Those costs are calculated for one trap or skeet stand. However, for larger ranges where competitions are hosted multiple stands are usually next to each other. As already indicated, this design combines the shotfall zones of multiple stands. As indicated above for 3 stands next to each other the shotfall zone is assumed to be 1.5-times the shotfall zone for one stand. Consequently, risk management measure can be combined reducing the cost. As presented in Table 2-49, total costs for RMMs for three stands are estimated at about €0.9 million (central scenario) over the lifetime of a range, which is only slightly higher than for one stand (€0.6 million). The costs of using alternatives are estimated at €5 800-58 000 over the lifetime of a range.

Table 2-49: Impact on permanent range with some RMM (D)

Baseline costs[1]	Costs for RMMs required to achieve lead recovery > 90 %	Costs for use of alternative(s)[2]
One stand Costs for lead recovery from soil every 10 years (for 40 years lifetime of the range): €0.9m	Berm available; costs for installing further RMMs: €0.3m – €0.65m – €1m Maintenance of RMMs: €50 000 (for every 10 years) Regular lead recovery: no net costs Cost of clean-up (end of service life, 5 cm of soil): €189 000 (60 000 m^2 * 0.5 * 0.05 m = 1 500 m^3 * €126/m^3) **Total cost over 40 years (assigning equal payments over the entire 40-year period): €0.3m – €0.6m – €0.9m** **Total cost over 20 years (assigning equal payments over the entire 20-year period): €0.4m – €0.6m – €0.9m**	Use of steel shot At shooting intensity of 10 000 to 100 000 shots/year 40 years: €1 900-19 300 20 years: €1 200-11 500
Three adjacent stands	Berm available; costs for installing further RMMs: €0.3m – €0.65m – €1m * 1.5 = €0.45m –€0.98m – €1.5m Maintenance of RMMs: €50 000 * 1.5 = €75 000 (for every 10 years) Regular lead recovery: no net costs Cost of clean-up (end of service life): €283 500 (60 000 m^2 * 1.5 * 0.5 * 0.05 m = 2 250 m^3 * €126/m^3) **Total costs over 40 years: €0.5m – €0.9m – €1.3m for three stands** **Total costs over 20 years: €0.5m – €0.9m – €1.4m for three stands**	40 years: €5 800-58 000 20 years: €3 500-34 500

Notes: [1] costs for the environmental impact not quantified; [2] in case of substituting lead gunshot with steel gunshot, additional clean-up costs might arise, this is considered as advancing the cost of existing end-of life clean-up.

- ➔ Comparison of the cost of installing environmental risk management measures that would result in a lead recovery rate of >90 % to the incremental costs of switching from lead to steel shot suggests that a ban can be the most proportionate matter for this type of shooting range.

E: Permanent ranges with ENV RMM (lead recovery >90 %)

Baseline

On these sites where an appropriate boundary exists (berms or nets or any combination) that would allow 90 % recovery of lead and where regular collection of lead takes place including larger soil cleaning operations, the Dossier Submitter does not expect that additional costs (investment or operation) will be incurred. Maintenance costs of €50 000 recurring at a ten-year interval are assumed.

The amount of lead that can be recovered annually would amount to 350 000 shots/year * 0.9 (90 % recovery) * 0.024 kg lead/shot = 7 560 kg lead. Against a purchasing price (i.e. the price offered to clients who bring in lead) of 0.5 €/kg this can deliver a value of €3 780 (max).

It can be assumed that members of shooting clubs help in collecting lead by organising regular clean-up (such as every six months). Evidence is given, for example, through the explanation on lead collection in France[282] but also by site visits that the Dossier Submitter undertook. In some cases, such as in Finland, the additional cost of clean-up that may be incurred are covered by the members in the form of an eco-contribution. Assuming that shooting ranges seek to minimise their cost, the cost of the voluntary clean-up is considered to be effectively zero. Some members will need to take time off from work or spend their free time to do this work, which has a cost as well. But the Dossier Submitter considers that these members express a preference to do this work to keep their hobby or ability to compete in international competitions.

To calculate the costs for soil removal at the end of service life, it is assumed that the soil of the shotfall zone (60 000 m^2 reduced by 50 % due to RMMs) would need to be removed at a depth of 5 cm (1 500 m^3). Assuming €126 per m^3 would result in costs of €189 000.

Example case

Lonata range, Italy; Source: Finnish BAT (Kajander and Parri, 2014).

Mesh-covered earthen berms have been constructed at the Lonato shooting range in Italy to stop the shot. In Lonato, the bottom edge of the berm is at around 90 metres from the firing stands. The height of the berm is around 23 metres. There is a net in the front edge of the berm with PVC plastic underneath to ensure that the shot is stopped and recovered. There is also PVC plastic at the bottom edge of the berm, preventing vegetation from growing and allowing the collection of the shot. The shot is collected from the bottom of the edges of the berms at regular intervals of every six months. There is a low berm in front of the bottom edge, but it is mainly for landscaping purposes (Aarrekivi, 2011; Bufi et al., 2007 as cited in (Kajander and Parri, 2014)).

Impact

For this scenario where risk management measures are already in place to frequently recover lead gunshot > 90 %, maintenance costs of €50 000 for every 10 years arise as well as the costs for the final clean-up at the end of service life (40 years). To calculate the costs for soil removal at the end of service life, it is assumed that a soil volume of 30 000 m^2 (50 % reduction in shotfall zone by RMMs) would need to be removed at a 5 cm resulting in a soil volume of 1 500 m^3. Assuming €126 per m^3 would result in costs of €189 000. Total baseline costs for maintenance and cleaning at the end of service life would therefore sum up to €389 000.

[282] https://questions.assemblee-nationale.fr/q15/15-3842QE.htm

The cost of using alternatives at the given shooting intensity (i.e. 100 000-350 000 shots/year) results in €19 300-67 700 for use over the lifetime of a range (NPV, 4 %). The Dossier Submitter considers that in case of substituting lead gunshot with steel gunshot, additional clean-up costs might arise; this is considered as advancing the cost of existing end-of life clean up.

On such sites the use of alternatives would result in (albeit small) higher costs to shooters.

- ➔ No additional costs for risk management measures would be incurred to meet a lead recovery rate of > 90 %, compared to the incremental costs of switching from lead to steel shot suggests that continuing to use lead would be the most efficient matter.

Synopsis

Table 2-50 gives an overview of the information that was gathered and combined to obtain an order of magnitude estimate regarding the baseline costs and the investment costs needed per site to achieve a minimum recovery rate of > 90 % in comparison to the costs of using steel. In addition, costs for maintenance and final clean up at the end of service life are provided.

It is to be noted that the environmental risk management measures required in scenario C (permanent ranges, no ENV RMMs) would also apply to new ranges.

Table 2-50: Overview of investment costs for different site to achieve a recovery rate of > 90 %

Scenario	Baseline costs[1]	Costs for RMMs required to achieve recovery > 90 %	Costs for the use of alternative(s)[2]
A: Any area or range using steel shot	No lead used	No costs in relation to lead	Only steel used
B: Temporary areas No ENV RMMs 5 000-10 000 rounds per year	No lead recovery assumed Areas often not remediated	Not achievable in practice for a temporary range	€1 000-1 900 per range (40 years)
C: Permanent ranges No ENV RMM 5 000-10 000 rounds per year	< 50 % lead recovery Costs to recover lead from soil (40 years): >> €1m	Costs for RMMs only: €0.5m – €1.5m – €2m Costs for RMMs, maintenance and end-of-life cleaning: €0.5m – €1.3m – €1.7m (40 years)	€1 000-1 900 per range (40 years)
D: Permanent ranges Some ENV RMM available (e.g. berm) 10 000-100 000 rounds per year One stand	> 50 - < 90 % lead recovery Costs to recover lead from soil (40 years): €0.9m	Costs for RMMs only: €0.3m – €0.65m – €1m Costs for RMMs, maintenance and end-of-life cleaning: €0.3m – €0.6m – €0.9m (40 years)	€1 900-19 300 per range (40 years)
E: Permanent ranges ENV RMMs available to recover > 90 % lead 100 000-350 000 rounds per year	> 90 % lead recovery Costs for maintenance and end-of life cleaning: €389 000	No additional costs	€19 300-67 700 per range (40 years)

Notes: [1] costs for the environmental impact not quantified; [2] in case of substituting lead gunshot with steel gunshot, additional clean-up costs might arise, this is considered as advancing the cost of existing end-of life clean-up

To provide more insight into those costs involved at being able to recover lead (at different lead recovery rates), the costs per type of range can be combined with information on the rate of recovery of lead that is theoretically possible into a Marginal Abatement Cost (MAC) curve. Policymakers use MAC-curves to demonstrate how much abatement an economy can afford and the area of focus, with respect to policies, to achieve the emission reductions.

Combining the various cost information with key information on example cases with claimed recovery rates gives some insight in what lead recovery can be achieved at which costs.

However, only few shooting ranges have reported the amount of lead shot that is kept at the shooting range in combination with the RMMs that are installed in order to achieve that.

The marginal abatement cost curve is displayed in Figure 2-14, where (A)-(D) denote the risk management measures described in Table 2-50.

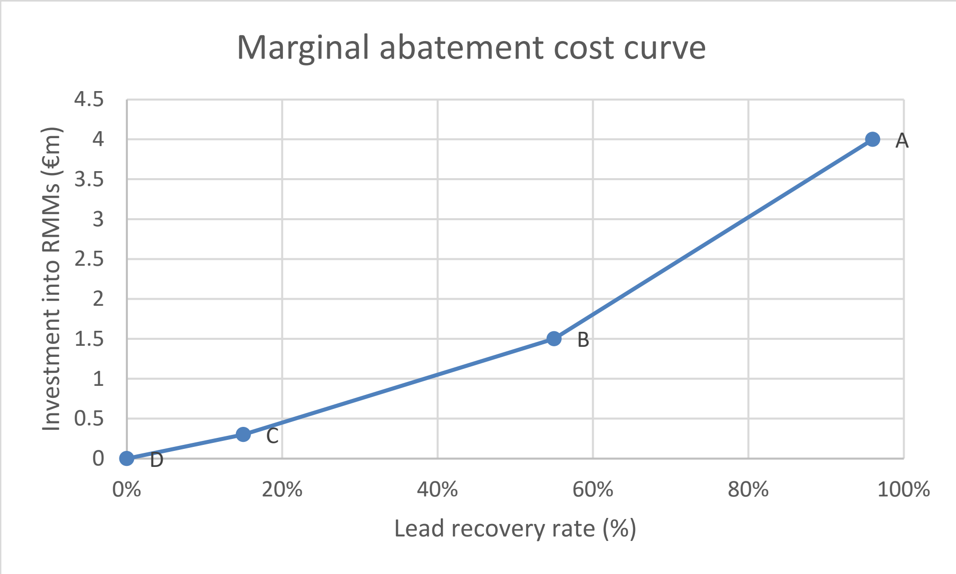

Figure 2-14: Marginal abatement cost curve for shooting ranges

Estimation of the number of ranges in the EU

The precise number of ranges in the EU is unknown but is assumed to be 4 000 (see Section B.9.1.3.1) with an upper limit of 5 000. Reliable information among the EU is not available on the kind of risk management measures implemented. Therefore, the Dossier Submitter has suggested a random distribution of these ranges to define an order of magnitude estimation. This can only give an order of magnitude estimate as the specific requirements per range can vary as per the environment of the range and its specific surroundings and thus investment needs in infrastructure to meet a > 90 % shot capture rate (theoretical recovery rate) may be bespoke for each site. The Dossier Submitter assumes 5 % of the 4 000-5 000 ranges to be temporary ranges. Furthermore, the Dossier Submitter assumes that 30 to 60 % of all ranges are permanent ranges with no RMMs available, 32.5 % to 62.5 % are permanent ranges with some RMMs available, and 2.5 % are ranges with full RMMs available to recover > 90 % of lead gunshot.

In an initial investigation, the Dossier Submitter assumed the number of existing ranges with appropriate risk management measures to recover more than 90 % lead gunshot from 200 to 750. However, in the consultation of the restriction report, information has been provided indicating that such shotgun ranges are mainly located in Germany due to legal requirements and the number may be close to 100. Consequently, the Dossier Submitter assumes that of the existing ranges in the EU 2.5 % have such risk management measures, which would be between 100 (2.5 % of 4 000) and 125 (2.5 % of 5 000) ranges.

Costs to implement risk management measures at all sites

Table 2-51 lists an estimation of existing gunshot ranges with different types of risk management measures implemented that would need to be updated to be able to recover > 90 % gunshot. The assumed 100 to 125 ranges that are already capable to recover > 90 % lead gunshot are not included in the table, resulting in 3 900 to 4 875 ranges that would need to install further RMMs.

Table 2-51: Estimation of number of existing shotgun ranges in the EU and the type of risk management measures implemented

Scenario	Number of sites impacted by the need to install further RMMs					
	Low		Middle		High	
	available	upgrade	available	upgrade	available	upgrade
Temporary area	5 %; 200-250	5 %; 200-250	5 %; 200-250	5 %; 200-250	5 %; 200-250	5 %; 200 - 250
Permanent range, no RMMs	30 %; 1 200-1 500	30 %; 1 200-1 500	45 %; 1 800-2 250	45 %; 1 800-2 250	60 %; 2 400-3 000	60 %; 2 400-3 000
Permanent range, some RMMs (< 90 % recovery)	62.5 %; 2 500-3 125	62.5 %; 2 500-3 125	47.5 %; 1 900-2 375	47.5 %; 1 900-2 375	32.5 %; 1 300-1 625	32.5 %; 1 300-1 625
Permanent range, full RMMs (> 90 % recovery)	2.5 %; 100-125	0	2.5 %; 100-125	0	2.5 %; 100-125	0
Total	4 000-5 000	3 900-4 875	4 000-5 000	3 900-4 875	4 000-5 000	3 900-4 875

Combining the information from Table 2-50 on the costs for RMMs and from Table 2-51 on the estimation of existing gunshot ranges by range type, the estimated costs of implementing RMMs across all affected sites in the EU27 is estimated at €3.5-4.4 billion (mid scenario) over 20 years with a range from €1.2 billion to €6.7 billion. Assuming a total volume of ~330 750 tonnes of lead emissions avoided over 20 years would result in a cost-effectiveness of 10.5-13.2 €/kg (mid scenario).

Costs to implement risk management measures at a fraction of existing sites

Further calculations have been performed assuming that only a fraction of existing sites will be upgraded with RMMs to allow > 90 % lead gunshot recovery.

It is reasonable to expect that a restriction will not affect all shooters or all sites evenly. The costs of investing in extra RMMs is in some cases more affordable than in other cases. Differences in the size of shooting clubs can for example lead to different investment possibilities for club members and can result in some clubs prescribing a switch to alternatives whereas others can invest in the extra RMMs and continue to use lead.

What is likely to be observed is a scale effect resulting in larger sites continuing to use lead for sports shooting.

There are a few sources that can be used to estimate (or make a reasonable estimation) of the number sites that would opt for an update of the RMMs. For the development of Olympic shooting sports in Germany, the Olympic training centres of the regional shooting sports associations are extremely important[283]. At these sites the athletes of the regional associations and national team shooters train under the supervision of highly skilled, experienced coaches and prepare for international competitions:

- World Cup facilities in Munich and Suhl
- Olympic Training Center of Brandenburg, Frankfurt/Oder (BSB)

[283] https://www.meyton.info/en/bilderreferenzen/landesleistungszentren/index.html

- Olympic Training Center of Lower-Saxony, Hannover (NSSV)
- Regional Training Center of Schleswig-Holstein, Kellinghusen (NDSB)
- Regional Training Center of Oberpfalz, Pfreimd (OSB)
- Regional Training Center of Saarland, Saarbrücken (SAAR)
- Olympic Training Center of Hessen, Frankfurt/Main (HSV)
- Regional Training Center of Sachsen-Anhalt, Halle (LSV S-A)
- Olympic Training Center of Baden-Württemberg, Pforzheim (B-W)
- Olympic Training Center of Westphalia (WSB)
- Regional Training Center of Berlin (SV-BB)

Extrapolating this to the EU level would suggest that at the level of Federal states there would be at least one larger training site that athletes would use. The equivalent of Federal states in Europe is at NUTS level 1[284]. On that level there are some 104 units. On NUTS level 2 there are some 283 units and a NUTS level 3 there are 1 345 units. Whereas NUTS level 1 describes major socio-economic regions, NUTS 2 level 2 describes basic regions for the application of regional policies and NUTS level 3 small regions for specific diagnoses.

For the estimation of the number of sits where athletes would train, we consider that NUTS level 1 or NUTS level 2 would be an appropriate scale to consider, given the information mentioned above on the distribution of larger shooting ranges in Germany. Although 'Laender' (Federal States) would typically fall at NUTS level 1 (and less units would need to be considered) we consider that NUTS level 2 would be more appropriate to consider.

NUTS 2 regions usually have between 800 000 and 3 million inhabitants. In Germany this level corresponds to governmental regions known as 'Regierungsbezirke'. NUTS 3 regions generally have a population of 150 000 to 800 000. Considering that about 1 % of the population participates in sports shooting (United Kingdom: 0.14 %[285], Denmark: 1.5 %[286]), on a NUTS 2 level about 8 000-30 000 would participate in sports shooting whereas this would be 1 500-8 000 at NUTS 3 level.

Based on the information above, the Dossier Submitter proposes the number of sites undergoing upgrades as a consequence of this restriction as presented in Table 2-52.

Table 2-52: Number of a fraction of existing sites expected to be upgraded with RMMs to allow > 90 % lead gunshot recovery following the restriction

Scenario	Number of sites expected to be upgraded					
	low cost scenario		mid cost scenario		high cost scenario	
	low	high	low	high	low	high
Fraction of ranges upgraded to be used by all sports shooters (RO3)	500	1 000	1 000	1 500	1 500	2 000

[284] https://ec.europa.eu/eurostat/web/nuts/background
[285] https://www.statista.com/statistics/544640/average-characteristics-outdoor-sport-shooting-sites-areas-united-kingdom-uk/
[286] https://www.statista.com/statistics/1047499/most-popular-sports-among-adults-in-denmark/

Scenario	Number of sites expected to be upgraded					
	low cost scenario		mid cost scenario		high cost scenario	
	low	high	low	high	low	high
Fraction of ranges upgraded to be used by licenced individuals only (RO4)	100	200	200	300	300	400

In Table 2-53 the number of sites assumed to be upgraded with different extent of RMMs are listed, allowing either all sports shooters to continue using lead gunshot or only licenced individuals. For the low-, mid- and high-cost scenario it is assumed that of the number of ranges expected to be upgraded in Table 2-52, respectively 30, 45 and 60 % come from upgrading permanent ranges with no RMMs in place (as per the assumptions in Table 2-51), while respectively 70, 55 and 40 % come from permanent ranges with some RMMs in place. Temporary areas would not be upgraded and no additional costs for ranges that already have measures in place to recover 90 % lead gunshot are expected.

Table 2-53: Number of sites that need to install further RMM to continue using lead gunshot

Scenario	Number of sites that need to install further RMMs		
	low cost scenario	mid cost scenario	high cost scenario
Number of sites upgraded to allow all sports shooters to continue using lead gunshot (RO3)			
B: Temporary area	0	0	0
C: Permanent range, no RMMs, or new range	30 %; 150-300	45 %; 450-675	60 %; 900-1 200
D: Permanent range, some RMMs (< 90 % recovery)	70 %; 350-700	55 %; 550-825	40 %; 600-800
E: Permanent range, full RMMs (> 90 % recovery)	0	0	0
Total	500-1 000	1 000-1 500	1 500-2 000
Number of sites upgraded to allow only licenced individuals to continue using lead gunshot (RO4)			
B: Temporary area	0	0	0
C: Permanent range, no RMMs, or new range	30 %; 30-60	45 %; 90-135	60 %; 180-240
D: Permanent range, some RMMs (< 90 % recovery)	70 %; 70-140	55 %; 110-165	40 %; 120-160

Scenario	Number of sites that need to install further RMMs		
	low cost scenario	mid cost scenario	high cost scenario
E: Permanent range, full RMMs (> 90 % recovery)	0	0	0
Total	100-200	200-300	300-400

In Table 2-54 the total costs for the optional conditional derogation for gunshot are listed either allowing all shooters to continue using lead gunshot (RO3) or only licenced individuals (RO4). The costs include the costs for upgrading RMMs (Table 2-50) combined with the number of ranges expected to be upgraded (Table 2-53) and the costs for a share of sports shooters expected to switch to steel gunshot. For RO3 the share of lead volume used that is assumed to be replaced with to steel shot is conservatively estimated to be 10 %. Similar trends have been observed in Germany where the introduction of stricter RMMs has led to fewer larger sites where lead can still be used and where smaller sites have started to demand steel to be used. For RO4 all sports shooters that are non-licenced individuals would need to switch to steel gunshot; the Dossier Submitter estimated licensed individuals to account for about 50 % of the total lead volume used.

Table 2-54: Costs for the implementation of RO3 and RO4

Type of costs	Nominal costs per year (m€; low / mid / high)	NPV over 20 years (m€; low / mid / high)	Annuity over 20 years (m€; low / mid / high)	C/E (€/kg; low / mid / high)
RO3: Upgrade of ranges for all shooters				
Nominal costs of RMMs for shooting ranges		148-296 / 849-1 273 / 1 973-2 630	13-27 / 76-114 / 177-237	
Costs of shooters to switch to steel (10 % of total lead volume used)	2 / 4 / 6.5	18 / 36 / 60	1.3 / 2.6 / 4.4	
Total		166-314 / **885-1 309** / 2 033-2 690	15-28 / **79-117** / 182-241	0.5-0.9 / **2.6-3.9** / 6.1-8.0
RO4: Upgrade of ranges for licenced individuals				
Nominal costs of RMMs for shooting ranges		30-59 / 170-255 / 395-526	3-5 / 15-23 / 35-47	

Type of costs	Nominal costs per year (m€; low / mid / high)	NPV over 20 years (m€; low / mid / high)	Annuity over 20 years (m€; low / mid / high)	C/E (€/kg; low / mid / high)
Costs of shooters (non-athletes) to switch to steel (50 % of total lead volume used)	19 / 37 / 57	177 / 336 / 518	13 / 25 / 38	
Total		207-236 / **506-591** / 913-1 044	16-18 / **40-48** / 74-85	0.6-0.7 / **1.4-1.7** / 2.6-3.0

2.6.3.2. Bullets

As a result of the restriction option analysis, the Dossier Submitter has identified the following restriction options:

RO1 proposes a full ban on the use of lead bullets for sports shooting. However, in the absence of suitable alternatives for sports shooting, such a restriction option is currently not implementable.

RO2 foresees a partial ban on the use of lead bullets with a derogation conditional that the use takes place at a notified (to the Member State) outdoor location for sports shooting and no agricultural activities take place at that location and where measures are in place for lead projectile containment and recovery. The Dossier Submitter has identified several sub-options for RO2 (see also Section 2.2.2.2).

RO3 proposes to require compulsory information on the hazards of lead and the risks of using lead ammunition at the point of sale and on product packaging.

The Dossier Submitter assumed that at all permanent rifle/pistol ranges in the EU RMMs are already in place to contain bullets for safety reasons. The RMMs are either trap chambers, sand traps (with an impermeable barrier to soil), sand/soil berms (without an impermeable barrier to soil), and soil berms. The Dossier Submitter has examined the costs and other economic impact of the proposed restriction options by calculating the impact of the change from RMMs implemented in the baseline to RMMs of higher effectiveness (upgrade).

The calculations for the costs involved with a conditional derogation under strict conditions are presented in Table 2-56 and are about €170 million for RO2a, €435 million for RO2b, €1 094 million for RO2c and €1 656 million for RO2d (central scenarios).

The following considerations were taken into account:

Trap chambers

FITASC/ISSF (comment #3267) reported the costs for outdoor trap chambers for 20/50 m (SIUS, which are for small calibre ammunition) with €1 000 and for outdoor trap chambers for 300 m (L&H) with €3 000.

The German Shooting Sport and Archery Federation (letter to ECHA 25.05.2021) reported the costs for trap chambers (steel traps with granules filling which could also be used outdoor) are around €300 000 for 30 lines 25/50 m without maintenance costs. They also reported that most shooting ranges in Germany are owned by clubs. For implementation of trap chambers in Bavaria and Baden Württemberg a funding program had successfully been applied. The German Shooting Sport and Archery Federation noted that in case the restriction would be implemented as currently presented, a European public funding programme would be necessary to support the clubs to install the required measures.

Nammo Lapua Oy (comment #3262) estimated that costs (based on enquiry made by the Norwegian hunting federation for manufacturers of bullet traps) are €20 000 per trap (with respect to shooting at multiple targets).

In the Finnish BAT (Kajander and Parri, 2014) it is indicated that the costs of simple steel and pipe bullet traps commissioned for the site vary, but compared to commercial bullet traps, the solutions are affordable. The safety and durability of these structures has not, however, usually been tested. Commercially available trademarked bullet traps (Stapp, SACON^{TM}, Snail, TCT) are significantly more expensive with €20 000 or €44 000 compared to the other bullet trap solutions.

Sand traps

According to the Finnish BAT (Kajander and Parri, 2014) the costs of the cover structure of a sand trap vary a lot depending on the selected material and the size of the cover. According to an analysis by Aalto University, the investment costs of a steel-framed cover (length 50 metres, width 21 metres, column interval 5 metres) are around €260 000. The cover requires constant maintenance, but the maintenance costs are relatively low. The costs of a sand trap structure with a bentonite, plastic membrane, or asphalt liner for a 20-stand shooting range come to around €40 000 to €50 000. These kinds of structures have been implemented at the shooting ranges of the Finnish Defence Forces in 2012–2013.

The mass containing most bullets can be replaced from the impact areas of a covered backstop berm and a sand trap at suitable intervals, for example, every ten years. The replacement time is determined by the increase in ricochet hazard caused by the bullets accumulating in the impact areas. In the case of a sand trap, mass replacement may also be needed if the pollutant concentrations of the percolating water increase to harmful levels, and the operator either does not wish to treat the water, or water treatment does not achieve good enough results.

Covering the backstop berm may make the repair and maintenance work on the backstop berm more difficult, if sufficient working space for the machines is not left underneath the cover. In the case of a liner solution, sufficient movement space for machines should also be left between the targets and the sand trap.

To renovate a sand trap for installation of a sealing, no information is available. The Dossier Submitter assumes such renovations to be about 50 % of the cost of a sand berm with a bentonite, plastic membrane, or an asphalt liner, which would be €20 000-25 000.

Table 2-55: Costs of trap chambers and sand traps

Type, description	Costs (€)	Source
Changing bullet traps from soil/sand to steel or rubber granulates	700-1 400	Skydebaneforeningen Danmark (#3251)
Stapp bullet trap (one)	400	Skydebaneforeningen Danmark (#3435)
Granulate bullet trap Polythermo (individual)	450	Skydebaneforeningen Danmark (#3435)
Bullet trap for 20/50 m	1 000	FITASC/ISSF (#3267)

Type, description	Costs (€)	Source
Bullet trap for 20/50 m (steel traps with granules filling) €300 000 for 30 lines without maintenance costs	10 000	German Shooting Sport and Archery Federation (letter to ECHA 25.05.2021)
Bullet trap with roof and rubber granule	10 000	Comment #3245, 3257
Bullet traps for 300 m	3 000	FITASC/ISSF (comment # 3267)
Bullet trap quality steel with roof (military equipment)	19 000	Comment #3245, 3257
Bullet trap (individual trap for multiple target shooting)	20 000	Nammo Lapua Oy (comment #3262)
Stapp rubber grinding bullet trap (per stand, investment and operational costs over 20 years)	20 000	Finnish BAT
Snail bullet trap (per stand; investment costs, little maintenance)	25 000	Finnish BAT
SACON bullet trap (per stand, investment and operating costs over 20 years)	44 000	Finnish BAT
Sand trap with a bentonite, plastic membrane, or an asphalt liner (for a 20-stand range)	40 000-50 000	Finnish BAT
Stapp standard (10 lines)	47 000	Skydebaneforeningen Danmark (#3435)
Stapp wide (20 lines)	80 000	Skydebaneforeningen Danmark (#3435)
Stapp (20 lines; 20 years costs)	415 000	Finnish BAT
Sand trap with a steel-framed cover (length 50 m, width 21 m; 20-stand)	260 000	Finnish BAT
Renovation of an available berm structure by including a barrier	50 000	Finnish BAT

The Dossier Submitter notes the large variation in the costs reported for trap chambers. For sand traps only limited information is available.

For the cost calculations, the Dossier Submitter takes the following costs forward:

- A basic berm structure is usually in place at rifle/pistol ranges for safety and/or noise abatement reasons. The costs for such a berm structure are indicated with €100 000 in the Finnish BAT and are not considered for the cost calculations. For those, the investment costs of trap chambers or cover structures of sand traps or sand/soil berms as well as maintenance and decommissioning costs are considered. Most of the costs are taken from the Finnish BAT (Kajander and Parri, 2014).
- Investment costs of cover structures:
    - Single trap chamber for small calibre range from €1 000 to €20 000, on average €10 000 (see Table 2-55).
    - Single trap chamber for large calibre range from €3 000 to €44 000, on average €23 000 (see Table 2-55).

  - In the Finnish BAT the costs of a sand trap structure with a bentonite, plastic membrane, or asphalt liner for a 20-stand range are indicated with €40 000 to €50 000. In an analysis referred to in the Finnish BAT, the costs from a 20-stand steel framed sand trap were estimated to be around €260 000. The Dossier Submitter considers those costs as too high to be of practical relevance. The Dossier Submitter uses as upper limit three times the costs of €40 000, which would be €120 000.
  - No information is available for costs of a sand/soil berm without an impermeable barrier. The Dossier Submitter estimates the costs for a sand layer to be €10 000. As upper limit, the Dossier Submitter assumes again three times the investment costs (€30 000).
  - Costs for a 20-stand Stapp rubber grinding bullet trap with a permanent cover (rubber material) over 20 years including maintenance costs are indicated in the Finnish BAT with €415 000. For a 15-year period this would be about €300 000. The Dossier Submitter notes the comment #3435 from Skydebaneforeningen Danmark indicating a cost of €80 000 for a 20-line Stapp bullet containment. The Dossier Submitter understands those costs as investment costs without maintenance.
  - Investment costs for a water management system were assumed to be about €5 000 based on information from the Finnish BAT.
- Maintenance/recovery of lead:
  - Maintenance costs for trap chambers are low and are included within the total 20-year costs as indicated by the Finnish BAT. The recovery of lead bullets from trap chambers is assumed not to be associated with relevant costs.
  - In the Finnish BAT the costs for impact area replacement of a soil berm are estimated at around €10 000 at a 20-stand range (including earthworks, transports, reception of the contaminated soil, and refill materials carried out as work contracted out).
  - In the absence of information on maintenance costs for sand traps, the Dossier Submitter estimates that the replacement of the impact area of a sand trap would be less expensive than for soil. The Dossier Submitter assumes 50 % of the costs, which would be €5 000.
  - The required bullet removal frequency depends on, for instance, the amount of shooting, the bullets used, and the dissolution of lead in the prevailing conditions. For recovery from sand, around 10 000 rounds per firing stand or three to five years could be considered a suitable renovation interval according to the Finnish BAT. For recovery from soil, the Dossier Submitter understands that the frequency might be longer and assumes a frequency of 5 to 7.5 years.
  - Maintenance costs for the change of the filtration mass of a water management system were assumed based on information from the Finnish BAT to be in a range between €600 every 5 years to €600 every 3 years.
- Decommissioning:
  - The renovation costs of the entire soil berm are estimated at €30 000 to €100 000 (Finnish BAT). The Dossier Submitter used those values as decommissioning costs for sand/soil berms and soil berms where additional

soil below the berm structure would need to be removed that contains lead that migrated from the berm.

- For decommissioning of a 'best practice' sand trap, no information is available. Since an impermeable barrier minimises the leaching of lead to soil, decommissioning costs are considered the same as maintenance costs (€5 000), with an upper limit estimated to be three times higher (€15 000).

Costs for upgrading RMMs to meet the conditions of the restriction options are described in Section D.3.4.2. and summarised in Table 2-56 below. As already explained under Section 2.6.2.2, scenarios were created reflecting specific combinations of RMMs. The impact was assessed by calculating the difference in emissions and in costs when changing from one scenario to another scenario.

Table 2-56: Costs and effectiveness to upgrade RMMs

Restriction option		Estimated number of ranges affected	Costs to change RMMs (million €)
RO2a	Trap chamber, or sand trap (with impermeable barrier) or sand/soil berm (without impermeable barrier), combined with roof or water management system	2 440	170 (72-271)
RO2b	Trap chamber, or sand trap (with impermeable barrier), combined with roof or water management system	7 200	435 (212-662)
RO2c	Trap chamber, or 'best practice' sand trap with impermeable barrier and roof or permanent cover and water management system	7 880	1 094 (859-1 329)
RO2d	Trap chamber for static disciplines; AND 'best practice' sand trap for dynamic disciplines	8 000	1 656 (719-2 653)

Rifle/pistol ranges located in or next to a wetland

The Dossier Submitter notes that rifle/pistol ranges may be located in wetlands (see definition in the restriction of lead gunshot in and over wetlands). Due to the sensitive environment, rifle/pistol ranges located in wetlands require case-specific evaluation of the local situation and the implementation of very effective and efficient risk management measures that prevent any lead from leaching to surface water, soil or groundwater.

The Dossier Submitter assumes that 10 % of the current rifle/pistol ranges in the EU are located in a wetland. However, in Sweden and Finland, where most of the rifle/pistol ranges are located, about 50 % of the whole area might be wetlands.

The Dossier Submitter considers that at rifle/pistol ranges located in wetlands, RMMs with highest effectiveness to minimise risks to surface water, soil and groundwater should be installed.

Transition period

The costs over the twenty-year period are assumed to occur after the transition period of five years . An emission reduction is assumed to occur after the respective transition period.

The Dossier Submitter notes that having two different transition periods of 5 and 10 years might be an option to prioritise the renovation of ranges with insufficient RMMs and of ranges for which a high risk to the environment can be assumed within 5 years and a longer transition period for the remaining ranges that require improvement of RMMs. However, the

Dossier Submitter did not investigate two different transition periods.

2.6.4. Cost-effectiveness and cost-benefit considerations

2.6.4.1. Cost-effectiveness considerations

Table 2-57 and Table 2-58 (and Figure 2-15) summarise the cost-effectiveness of the restriction options for sports shooting with gunshot and bullets, respectively, taking forward the assumptions made in Section 2.6.3. Notably, for gunshot, the Dossier Submitter assumed that strict conditions for the derogations under RO3 and RO4 would be met by a specific fraction of existing sites. Whilst a higher or lower fraction of sites might eventually adopt RMMs to fulfil the strict conditions and be eligible for a derogation, the Dossier Submitter notes that the estimated cost-effectiveness ratios reported for the respective ROs are representative as long as there is no structural reason to opt for or against the implementation of RMMs.[287]

Table 2-57: Cost-effectiveness of restriction options for sports shooting with lead gunshot

	Restriction Option	Emissions avoided over 20 years (tonnes)	Costs over 20 years (NPV, 4 %, million €)	Cost-effectiveness (€/ kg avoided release)
RO1	Ban on the **placing on the market** and **use** of **lead gunshot** for sports shooting	367 500 (210 000-525 000)	364 (177-596)	1.0 (0.8-1.1)
RO2	As RO1, but **derogation** for **licenced individuals** to use; licencing by Member State; reporting to the Commission	183 750 (105 000-262 500)	336 (177-518)	1.8 (1.7-2.0)
RO3	Ban on the **placing on the market** and **use** of **lead gunshot** for sports shooting with a **derogation** for use at **permitted locations** with regular lead gunshot recovery (>90 %), containment, monitoring and treatment of drainage water; ban of any agricultural use within site boundary; all shooters allowed	344 425	885-1 309 (166-314 – 2 033-2 690)	2.6-3.9 (0.5-0.9 – 6.1-8.0)
RO4	As **RO3** but only for **licenced individuals**[1]; reporting to the Commission	349 125	506-591 (207-236 – 913-1 044)	1.4-1.7 (0.6-0.7 – 2.6-3.0)

Notes: [1] it is assumed that licenced individuals in the EU (ca. 12 000 athletes) would release ca. 50 % of the total amount of shot used by all sports shooters in the EU

[287] If large ranges would opt to implement RMMs whereas small ranges would not, then the economies of scale mentioned in Section 2.6.3 may slightly affect the cost-effectiveness ratios reported in Table 2-57.

Table 2-58: Cost-effectiveness of restriction options for sports shooting with lead bullets (for the mid scenario)

Restriction Option		Emissions avoided over 20 years (tonnes)	Percentage of emission reduction		Costs over 20 years (NPV, 4 %, million €)	Cost-effectiveness (€/kg avoided release)
			Over 20 years	Over 15 years after the TP		
RO2 **Ban on the use of lead bullets for sports shooting with a derogation at notified outdoor locations where no agricultural activities take place and the following measures are in place (see different RO2 options below):**						
RO2a	Trap chamber, or sand trap (with impermeable barrier) or sand/soil berm (without impermeable barrier), combined with roof or water management system	4 487 (71-15 682)	54 %	71 %	170 (72-271)	38 (17-1 020)
RO2b	Trap chamber, or sand trap (with impermeable barrier), combined with roof or water management system	5 226 (78-18 349)	62 %	83 %	435 (212-662)	83 (36-2 719)
RO2c	Trap chamber, or 'best practice' sand trap with impermeable barrier and roof or permanent cover and water management system	5 801 (83-20 434)	69 %	92 %	1 094 (859-1 329)	189 (65-10 306)
RO2d	Trap chamber for static disciplines; AND 'best practice' sand trap for dynamic disciplines	5 786 (83-20 374)	69 %	92 %	1 656 (719-2 653)	286 (130-8 621)

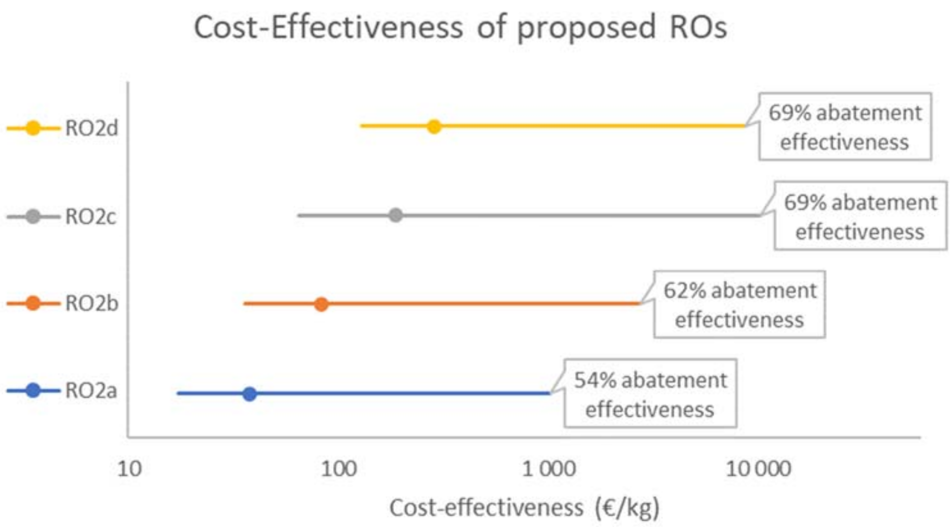

Figure 2-15: Cost-effectiveness of proposed restriction options for sports shooting with bullets

If one compares the cost-effectiveness of the current restriction proposal to the one for decaBDE, for example, where one major environmental impact was accumulation of the substance in birds of prey, it is obvious that the current proposal for lead gunshot is an order of magnitude more cost-effective. Considering the known hazard properties of lead, it can thus be concluded that the proposed restriction is a cost-effective measure of addressing lead emissions to the environment.

Overall, the preferred restriction for lead in shot and in bullets appears to be as cost effective as previous REACH restrictions, including the restriction on lead in PVC which was addressing similar human health concerns (see Figure 2-16). This clearly shows that the proposed measures under this restriction are in the same order of magnitude of other restrictions that were deemed to be proportionate.

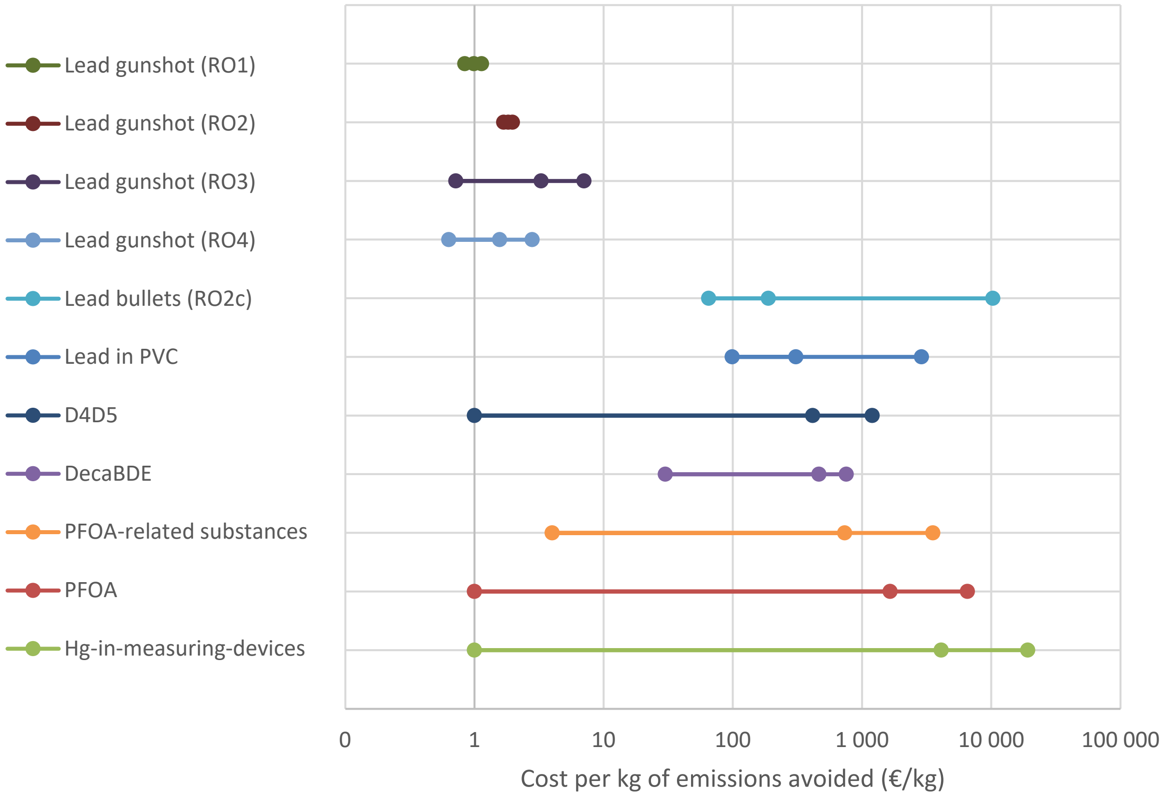

Figure 2-16: Comparing cost-effectiveness of proposed options for sports shooting with other REACH restrictions

2.6.4.2. Cost-benefit considerations

Taken together, the costs for the proposed restriction options for sports shooting with lead shot and lead bullets range from €506m to €2 965m (NPV, over the 20-year analytical period) in the central scenario, depending on the options chosen (see Table 2-57 and Table 2-58).[288] Annuitised at a discount rate of 4 %, these costs correspond to annual costs of €37m to €218m.The Dossier Submitter estimates that through these measures lead emissions could be abated by 9 400 to 18 700 tonnes per year in the central scenario, depending on the restriction options chosen (see Table 2-57 and Table 2-58).[289] Whilst no quantitative benefit assessment could be undertaken for this part of the proposed restriction, a number of non-quantified benefits were identified:

- Avoided exposure of humans to lead from sports shooting (lead dust);
- Avoided exposure of humans to lead from home-casting of lead bullets;
- Avoided exposure of humans (via the environment) to lead, mainly from drinking water (including both surface water and groundwater), especially in the vicinity of shooting ranges;.

[288] The lower/upper bound cost estimate corresponds to the following combination of restriction options: RO2 for lead shot and RO2a for lead bullets in sports shooting/RO3 for lead shot and RO2d for lead bullets in sports shooting.

[289] The lower/upper bound emission reduction estimate corresponds to the following combination of restriction options, divided by 20: RO2 for lead shot and RO2a for lead bullets in sports shooting/RO1 for lead shot and RO2c for lead bullets in sports shooting.

- Avoided risks to soil, surface water and groundwater;
- Avoided mortality and sub-lethal effects in birds and other wildlife;
- Avoided mortality and sub-lethal effects in ruminants (e.g., via contaminated silage) and poultry (via direct ingestion);
- Avoided future remediation costs for new ranges in Member States/regions that require soil remediation at the end of the lifespan of a shooting range;
- Overall positive impact expected based on the environmental footprint of the alternatives;
- EU Birds Directive, CMS and AEWA commitments fulfilled.

Given the abatement potential, the availability of alternatives for various shooting sports disciplines and the limited costs for other disciplines to meet the conditions required for continuing the use of lead ammunition, the Dossier Submitter is convinced that the proposed restriction measures are proportionate.

2.6.5. Other practicality and monitorability considerations

2.6.5.1. Implementability and manageability

Gunshot

Implementability of RO1, the ban on placing on the market and use of lead gunshot for sports shooting, is currently limited due to social reasons because it would not allow athletes to train or participate at international competitions such as the Olympic games.

RO2, the ban on placing on the market and use of lead gunshot for sports shooting with a derogation for licenced individuals is principally implementable. This scenario may resemble the situation in countries with a ban on lead gunshot. However, FITACS commented (3221) and provided an example of Belgium, where athletes training for international competitions need to go to France to be able to train with lead gunshot.

FITASC provided comments (3221) that would favour RO3 over RO4, allowing all shooters instead of licenced individuals to use lead gunshot at a permitted location. The organisation of clay target sports shooting is similar to that of all sports, and can be represented by a pyramid structure. The basis of the pyramid is made up of beginners, junior or adult shooters. The higher you climb the pyramid, the more your competitive qualities are recognised by your sports results. At the top are international shooters or members or national teams who represent their country. This is true for both Olympic and non-Olympic disciplines. To rise or remain at the top of the pyramid, each year the shooters are compulsorily confronted in club, regional and national competitions with all of the shooters constituting the pyramid. Consequently, all the shooters in the pyramid must be able to train and compete with the same sporting regulation, using cartridges with comparable ballistic performance.

Comments were received from Norway (#3257) indicating that derogations from the ban on the use of lead gunshot were granted for disciplines that are using steel targets (such as "game trail" shooting, IPCS shotgun, Cowboy action shooting) or black powder firearms. Such disciplines are usually performed at pistol/rifle ranges, not at trap/skeet ranges. In the comment it was also proposed that derogations for national important disciplines such as "game trail" should be decided at national levels.

Bullets

The conditions of the restriction are considered to be implementable as exemplified by e.g. the current legislation in place in Germany, Norway and Sweden.

2.6.5.2. Enforceability

Gunshot

RO1, the ban on placing on the market and use of lead gunshot for sports shooting, is considered enforceable. The addition of 'placing on the market' would facilitate enforcement, a conclusion already reached by Forum in their advice on the enforceability of the proposal on lead in shot over wetlands

RO3 and RO4, i.e. the ban on the placing on the market and use of gunshot for sports shooting including a derogation at permitted sites with strict risk management measures in place (lead shot recovery [≥90 %], monitoring and treatment of surface (run-off) water; ban of any agricultural use within site boundary), is considered enforceable because:

- the permitting system would be delegated to the Member States to fit with their legal system, the use of lead gunshot would be allowed only at sites approved by national or local authorities to be compliant with the conditions of the restriction (and any other relevant legislation e.g., noise;
- Enforcement of permitted sites can be achieved by means of inspection of the mandatory documentation required under the conditions of the restriction. This documentation should include details of the quantity of lead gunshot used versus that collected (to enable mass balance calculations), as well as details of the site drainage in impact areas. The mandatory documentation should include details of the chemical analysis undertaken to ensure compliance with EQS under the water framework directive, including any treatment undertaken. Analytical methods for WFD compliance can be considered to be readily available given the existing requirements under the WFD in Member States. It is likely that Member States would need to permit sites on an annual basis to ensure that the requirement for 90% annual recovery is achieved.

The condition to allow the use of lead gunshot only for licenced individuals as specified in RO2 and RO4 is considered enforceable because:

- currently 'licencing/permitting/derogation' systems for athletes are already in place in Member States with an existing ban on lead gunshot;
- the licencing system would be delegated to the Member States to fit with their legal system.

The condition of selling/reselling of lead gunshot by retailers only to licenced individuals would be enforceable because retailers need to be licensed to sell ammunition and athletes would need a licence to buy lead gunshot.

The obligation to inform consumers on the hazards and risks of lead at the point of sale and on product packages is considered enforceable; it can be easily verified that the required information is present during retailer inspections by enforcement authorities.

The labelling of individual cartridges as 'not for hunting' will enable game wardens to identify the material used and enforce the illegal use of lead gunshot for hunting.

Bullets

The restriction option, i.e. ban on use of lead bullets with a derogation at outdoor sports shooting locations notified to Member States with strict risk management measures in place (lead projectile containment and recovery, ban of any agricultural use within site boundary), is considered enforceable because:

- the use of lead bullets would be performed at outdoor locations for sports shooting notified to national or local authorities depending on their legal system;
- Enforceability of the proposed minimum RMMs for sports shooting with projectiles other than gunshot can be achieved by means of site visits and inspection of the mandatory documentation that is required under the conditions of the restriction to be held by site operators. The mandatory documentation requires compliance to be demonstrated and could, for example, describe the construction of the trap chamber or 'best practice' sand traps used for lead projectiles in order to satisfy the requirements for an impermeable membrane to soil, roof or surface coverage and collection and treatment of rain/drainage water from the impact areas. The mandatory documentation should include details of the chemical analysis undertaken to ensure compliance with EQS under the water framework directive, as well as any related treatment. Analytical methods for WFD compliance can be considered to be readily available given the existing requirements under the WFD in Member States.

The labelling and information obligation at the point of sale are considered enforceable, as discussed for the restriction of gunshot in sports shooting.

2.6.5.3. Monitorability

Gunshot

The provisions on bookkeeping and recording the mass balance of lead would enable both the inspection and the monitoring of the restriction. Via the record of mass balance, enforcement authorities can monitor whether permitted sites achieve the 90 % recovery rate by comparing the number of gunshots spent (and therefore volume of lead) with the recovered volume of lead. Via the reporting mechanism, MS and the Commission can monitor the number of permitted locations while at the same time monitor the measured recovery rate at these sites.

Bullets

The use of bullets would occur at locations for sports shooting that are notified to the respective Member State, allowing the Member States to monitor the number of locations.

2.7. Impacts of a restriction on others uses of lead ammunition (uses 5 and 6)

Next to the uses in sports shooting and hunting, there are several other uses of lead ammunition. The impacts of a restriction on these uses are summarised below.

2.7.1. Lead used in muzzle loading and historic arms (use 6)

During the dossier development the Dossier Submitter has discussed this use with:

- The vintage arms association (during the opinion making on the wetland proposal);
- The Muzzle Loaders Association of Great Britain;
- The Muzzle Loaders Association international confederation.

Thereby, the Dossier Submitter learnt the following.

Alternatives

It is generally understood that there are limited alternatives available for shooting with muzzle loading. Stakeholders highlighted the impossibility to use material other than lead, out of concerns of prematurely wearing out the rifles these groups of shooters own. Some manufacturers (Barnes, Hornady) have developed lead-free muzzle loading ammunition, but no detailed technical tests have been found that confirm whether these alternatives can be used in antique muzzle loaders or whether their use is only suitable for replica muzzle loaders. The Firearms Directive states that *"reproductions of antique weapons do not have the same historical importance or interest attached to them and may be constructed using modern techniques which can improve their durability and accuracy."* (DIRECTIVE (EU) 2017/853, Art. 27).

FACE (#3467) further pointed out that the CIP proof testing of those firearms has been carried out with the use of black powder and lead projectiles ensuring the safety. There are however no CIP testing protocols for lead-free projectiles as there are currently no suitable versatile alternatives. This view was confirmed during the consultation of the Annex XV report, in which various comments related to shooting with muzzle loaders were received (e.g., #3224, #3227, #3235, #3240, #3254) suggesting that no alternatives to lead ammunition would exist for this use.

Hunting

Although in theory muzzle loading bullets can meet some of the energy requirements set in hunting legislations (as in Finland, France, Spain, Italy, Denmark and Hungary) their use is generally considered a niche use. One reason is that authentic historic arms are rarely used for hunting out of concern for damage. Their design allows the use of lead bullets only and no alternatives are considered suitable.

In some Member States, hunting with muzzle loaders (also known as black powder hunting) is allowed but is not very popular. One author (Sanchez et al., 2016) argues there is less concern of contamination compared to game meat bagged with modern lead ammunition. The authors conclude that:

"*Under regulations banning use of all lead bullets, users of traditional muzzle loading and black powder cartridge rifles could be excluded from hunting because of current limitations in effective non-lead options for those types of firearms (Epps, 2014), and some individuals would be blocked from important cultural and subsistence foraging activities. Similarly, regulations that restrict non-lead bullets prevent muzzle-loading hunters from voluntarily avoiding lead and could discourage hunters from buying fast-twist rifles designed to shoot* *long lead-free bullets with sufficient accuracy. Instead, regulations that allow lead-free bullets of any type (including those which require use of sabots), in addition to traditional non-expanding lead bullet designs could simultaneously reduce lead ingestion risks to humans and wildlife, while also allowing and encouraging primitive weapons hunters to continue participation in hunting*."

Concerning replicas, the 20th and 21st century reproductions of antique guns have been sold with manuals and load markings by the manufacturers based on the traditional lead bullet use. Any change of the bullets used would make the instructions void. Retrospectively, it is not possible to update manufacturer instructions for guns already put on the market. The failures, gun damage, possible injuries caused by non-lead bullet use in these reproductions would raise questions as to the product liability of their manufacturers.

Sports shooting

The stakeholders indicated that most uses of muzzle loaders take place within the confinements of a shooting ranges where spent lead can be recovered.

In the consultation of the Annex XV report, several comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals on the use of lead in muzzle loading firearms. For example: #3201, #3220, #3224, #3225, #3234, #3235, #3237, #3240, #3254, #3277, #3400, #3467.

The commenters confirmed the conclusions of the Dossier Submitter's analysis as presented in the Annex XV report. I.e., alternatives to lead for the use in muzzle loading firearms are not widely available and do not work in historic firearms. Commenters therefore argued that alternatives are not well suited for the use in muzzle loaders, as these types of guns are designed to be used with lead. Alternative materials suitable in other shooting applications such as tin, bismuth, tungsten and steel, are all harder and shooting them with an antique gun generates gas pressures higher than such guns were designed to handle, possibly damaging the gun.

FACE (#3467) further points out that the CIP proof testing ensuring the safety of those firearms has been carried out with the use of black powder and lead projectiles. There are however no CIP testing protocols for lead-free projectiles as there are no suitable alternatives.

Comment #3224 states that lead bullets used in black powder firearms do not break into parts and do not evaporate or disintegrate when hitting the game due to their low impact velocities (max. 550 m/s). The Background Document documented evidence based on a study[290] by Sanchez et al. (2016) that fragmenting indeed occurs to a lesser extent as with modern lead rifle ammunition.

According to a study performed by the Hungarian Black Powder Association (#3400), the total number of muzzle loading shooters and collectors within the EU is estimated at circa 340 000 women and men, out of which about 27 000 are frequent shooters. The number of muzzle loading hunters is about 600 based on data provided by the national associations. However, as a large number of muzzle loading hunters are not visible from the statistics, the Hungarian Black Powder Association assumed that the exact number could be in the order of 1 000-1 200 persons across the EU.

The estimated yearly lead consumption of muzzle loading shooters in the EU is up to 683 tonnes, out of which 682 tonnes of lead ammunition are fired on licensed shooting ranges,

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[290] Dana M. Sanchez et al, Estimating Lead Fragmentation from Ammunition for Muzzleloading and Black Powder Cartridge Rifles, Journal of Fish and Wildlife Management (2016). DOI: 10.3996/092015-JFWM-086

and only 0.8 tonnes of lead ammunition are fired for hunting purposes.

Finally, some commenters pointed out the cultural value associated with the use of muzzle loading (e.g., #3400).

The Dossier Submitter takes note of the information submitted on this subject and finds it particularly noteworthy that practicing with muzzle loaders takes place on licensed shooting ranges, which would imply that these are to be considered under the conditions proposed for continuing the use of lead bullets at shooting ranges.

On the use of muzzle loaders in hunting, the Dossier Submitter understands that:

- The use is limited to less than one tonne per year across the EU.
- The size of the bullets would suggest that the pick up by bird species is not possible.
- Fragmentation of bullets is significantly less frequent as with typical bullets for modern guns.
- Exposure to lead via diet and the secondary poisoning of wildlife cannot be completely ruled out.
- although claimed to be of high cultural value, no clear evidence was submitted to support this conclusion. References were made to UNESCO classifications in Germany but that seemed more to point out the event of shooting rather than the use of a specific type of firearm.

The Dossier Submitter updated Section 2.5.1.2 in the Background Document wherein the technical feasibility of non-lead ammunition is discussed for this and other uses.

2.7.2. Lead ammunition used in airguns for outdoor shooting (use 5)

Hunting

Hunting with air rifle ammunition is legally allowed only in some Member States (Sweden, Denmark, Hungary, Denmark) and in the United Kingdom. When used for hunting, lead pellets are used for pest control. As vermin are not considered "game", there is no risk to humans from ingesting lead fragments in game meat.

Sports shooting

Lead pellets are used extensively in sports shooting where the accuracy and precision of the shot is dependent on the interplay between the gun/pistol/rifle used in terms of rifling and the pellet shape, size, weight, and plasticity. Lead pellets are available in different calibres each with a variety of configurations (e.g., flat-nose, round-nose, pointed, hollow-point). Each calibre may also be available in different weights.

Lead pellets provide the highest accuracy in the rifled barrels of adult precision air rifles and air pistols. Each configuration may be available in different calibres and, for each calibre, in different weights.

Lead is used as pellet material due to its combination of properties (density, plasticity, low melting temperature), meaning that it grips the rifling, deforms into the barrel dimensions and has enough weight for continued momentum. There is no other material that has the same range of properties, plasticity, and low melting temperature. Non-lead pellets are commercially available in low quantities and are generally made of tin-zinc alloys.

As one of the most accurate calibres for long distance shooting, the .177 calibre pellet is by far the most popular on the market today. As the smallest pellet of the available calibres, the .177 can be fired at the highest velocities means greater accuracy for longer distances.

The .22 calibre pellet is larger in weight and size compared to .177 calibre pellets. The .25 calibre is the largest of the common calibres.

The air pellet 0.17 requires extreme precision over a 10 m distance. Similarly, the 0.22 LR requires extreme precision over 50 m. To land a 10.9 (bullseye), the centre of the shot needs to be within a circle diameter of 0.5 mm at 10 m for 0.17 and within 1.6 mm at 50 m for 0.22. As lead is the only material currently allowed in Olympic shooting events for air pistol and air rifle, competitors at local, national, and international events that aim to qualify for the Olympics will need to practice with lead pellets. The rifles and pistols used are engineered for lead pellets where the accuracy and precision of the shot is tailored to the projectile, its intended range, and the spot size.

Lead-free airgun pellets are usually made from zinc alloy. Though harder than lead, this material is still malleable and should not cause damage to the barrel of an air rifle.

In the call for evidence, it was highlighted that there are practically no non-lead air rifle pellets on the Finnish market (or are yet to come on the market). Moreover, non-lead pellets can be up to four times more expensive than lead ones and are less accurate.

One commenter reported that the 15 largest UK online ammunition retailers offered 146 different types of airgun pellets for sale. Of these 76 % were lead, at an average price of £0.030/pellet. The remaining 24 % of non-lead pellets cost on average £0.044/pellet, which would indicate that a switch to lead-free airgun ammunition for hunting could impose extra costs of less than 2 cents per shot.

Assuming that the use is limited to species like pigeons, crows, waders and starlings (Kanstrup and Haugaard, 2020), this price difference seems not to be disproportionally burdensome. Indeed, combining it with the reported hunting bag data suggests a total cost in the order of several tens to hundreds of thousands of euros. On the other hand, a restriction on lead pellets used in air rifles would contribute only marginally to the overall reduction of lead emissions.[291]

Commenters also highlighted that airgun competition shooting requires high precision ammunition, and current non-lead options are not of sufficient quality to meet these requirements. Thus, there is still a significant amount of development work required to produce airgun pellets that behave comparably in the field and at the same ranges as existing lead pellets.

Unlike for large calibre bullets, there are no known studies or peer reviewed tests comparing the performance of lead and non-lead (often tin) based air rifle pellet for hunting. Product reviews on online fora would suggest that the accuracy of air rifles for hobby shooting (which would cover a fair share of the use) is adequate. However, these tests or reviews are not conclusive enough to come to a firm decision on product suitability. Some manufacturers market their lead-free air rifle ammunition as suitable for hunting, examples including the RWS Hypermatch lines and or the H&N Barracude green line.[292]

In the call for evidence one test was submitted by Gunlex which tested EXACT tin pellets of 4.5 mm calibre, weighing 0.44 g, from Czech manufacturer JSB Match Diabolo, using EXACT lead pellets weighing 0.547 g, from the same manufacturer, as a control.[293] The distance

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[291] Assuming an incremental price of 2 cents per pellet implies that €10 000/€100 000 correspond to 500 000/5 000 000 pellets. Considering that one pellet has a weight between 0.5-1 g, the corresponding lead quantity is 250-500 kg/ 2 500-5 000 kg.

[292] https://www.hn-sport.de/en/air-gun-hunting/baracuda-green-177 & https://rws-ammunition.com/en/products/air-gun-pellets

[293] https://gunlex.cz/en/3595-comparative-test-of-lead-and-nonlead-ammunition

was set at 25 metres in an indoor range. For each ammunition, four groups of five pellets were shot, see Table 2-59.

Table 2-59: Results of testing airgun pellets (comparison of tin with lead)

Ammunition	Group 1	Group 2	Group 3	Group 4	Average dispersal
Tin	< 1 mm	5 mm	4 mm	8 mm	4.35 mm
Lead	< 1 mm	< 1 mm	< 1 mm	< 1 mm	1 mm

The distance was measured between the centres of the two most distant hits. According to the testers, this dispersion is sufficient for recreational shooting but insufficient for sports target shooting. The testers concluded that for target shooting alternatives to lead pellets are not suitable. While the test results do show differences in precision, the Dossier Submitter is unable to judge whether the required accuracy could be achieved with other brands that offer lead-free pellets.

Proposed restriction and impact

As part of the restriction option analysis for the use of bullets in sports shooting, the Dossier Submitter examined the cost and other economic impacts of measures to abate lead emissions as a condition for derogation from the ban on the use of lead bullets (such as bullet trap chambers and/or 'best practice' sand trap combined with a water management system), see Section 2.6 of this document.

Although lead-free air pellets are available on the market, no tests have confirmed their efficacy for hunting purposes. Therefore, a separate analysis of air rifle ammunition in hunting could not be undertaken since more information would have been needed to arrive at a firm conclusion on the suitability of alternative pellets in hunting.

Input from the consultation

Several comments on the use of lead ammunition in air rifles were submitted by sector associations, supply chain actors, competent authorities as well as individuals, including the following: #3201, #3236, #3239, #3251, #3260, #3331, #3467, #3268, #3422, #3448, #3468.

FACE (#3467) stated that, in addition to being imprecise, non-lead or so-called "green pellets" are also many times more expensive than lead pellets. Similar concerns were raised by AFEMS (#3331) which also stated that alternatives for air rifles work poorly and are expensive.

Based on their concerns both FACE (#3467) and AFEMS (#3331) explicitly asked to derogate lead ammunition for air rifles from the restriction (without any consideration of risk).

The Irish Farmers Association (#3251) stated the need for lead pellets in air rifles is solely for the purpose of pest control to take squirrels, corvids and other animals that have the potential to do harm to crops or livestock, a message that was echoed by AFEMS (#3331). Other comments stated that hunting with air rifle ammunition, or air rifle pellets, is legally allowed in Sweden and Hungary; in Denmark lead air rifles are used for pest control, but not for hunting.

The lack of adequate performance is raised as well in comments #3239 and #3422, which report on tests finding that non-lead pellets have a standard grouping (i.e., spread around the centre) of a target, which is substantially wider than that achievable with lead because of the instability of such pellets during flight.

No information was submitted in the consultation of the Annex XV report on the total volume of lead used for hunting with airguns. Given the species at stake and the already existing limitations on the use of airguns in hunting, the volume is expected to be low compared to other applications of lead ammunition.

In the Annex XV report, the Dossier Submitter had stated that there were alternatives for the use of lead in ammunition for air rifles, but that these were more expensive without necessarily meeting the same performance as their lead counterparts.

A derogation would avoid the costs related to switching to lead-free ammunition. According to the Dossier Submitter's best knowledge, this cost is in the order of a few cents per pellet. In case of a derogation a volume of lead of several hundred kg per year would continue to be deposited in the environment, causing a (limited) risk of primary and secondary lead poisoning of birds and other animals. On the positive side, a derogation would ensure that farmers have at their disposal an economic means of pest control.

2.7.3. Lead ammunition used for other purposes

Table 2-60 summarises additional uses of lead in ammunition that have been identified by stakeholders. The Dossier Submitter considers them to be out of scope of the proposed restriction.

Table 2-60: Use of lead ammunition for other purposes

Type of shooting	Description
Technical testing and/or proofing	Testing of firearms or ammunition and proofing is aimed at the establishment of technical properties of firearms or ammunition. Institutes of technical expertise, manufacturers, or proof houses (which can be public authorities as well as authorised private entities) practice testing and proofing. Lead ammunition can be required for testing or proofing purposes, e.g., when technical characteristics of firearms designed for the use of lead projectiles are to be established.
Manufacture	Manufacturers of firearms or ammunition are almost exclusively private enterprises even when firearms and ammunition for military or security purposes are concerned.
Testing and development of materials and products for ballistic protection	Means of ballistic protection such as bulletproof vests of such as bullet proof glass windows must be always tested with a relevant array of ammunition including common lead projectiles so that the real-world results are yielded. Manufacturers of means of ballistic protection are almost exclusively private entities.
Forensic analysis, historical and other technical research or investigation	The purpose of these kinds of research or investigation is usually aimed at the establishment of effects of firearms and ammunition on analysed objects or in examined (criminal, historical etc.) contexts. The objectives of the examination determine the means of any professional research or investigation. Most cases of, e.g., forensic analysis is concerned with the use of lead ammunition. Private technical and forensic experts are frequently contracted by police investigators (as well as by the other participants to the criminal proceeding including courts and attorneys). Research as well as expert investigation are usually undertaken by entities other than military forces or police (such as by universities, research institutes or individual researchers/authorised collectors).
Voluntary military training	Voluntary military (or auxiliary police) training includes different types of participation of the public on the training for national defence purposes. The persons included in the voluntary training programmes are either reservists (in systems with general military drafting schemes) or volunteers (in systems consisting of professional armed forces and complementary voluntary reserves). This type of training is characterised by the use of firearms and ammunition which are identical or comparable to those used by the armed forces (or security forces) of the state. On the other hand, the training exercises are usually organised by reservist or volunteer associations which are not (in peace) part of the military or other armed forces. These trainings take place either in shooting ranges run by an official agency or (predominately) in private shooting ranges run by local shooting clubs.
Protection of critical infrastructure, commercial shipping, or high-value convoys	These are uses of ammunition mainly by professional entities such as commercial security agencies. They usually work in close cooperation with official law-enforcing authorities. The choice of ammunition is based on required efficiency and on limitations given by the environment in which the ammunition is used (non-lead projectiles might not be an option, e.g. due to higher penetration and thus higher risk of damage to the protected infrastructure).

Type of shooting	Description
Soft-target and public space protection	These types of use of ammunition are very close to the previous two examples. However, the risk of hitting a third person is critical in these cases. Thus, the risk of either ricochet or shoot-through must be minimalised. It must be noted that the risk of a ricochet in these model situations are significantly higher than in the context of hunting or sports shooting. This is due to the environment in which the soft-target protection takes place (buildings, streets or indoor spaces where the risk of hitting a hard surface is high; dangerous ricochets occur especially at curved hard surfaces such as cobblestones, car wheels or street lampposts). In many instances, there is no non-lead alternative to ammunition for those purposes.
Self-Defence	The meaning of "self-defence" is the use of a firearm for the protection of life, personal integrity or property; the person entitled to the use of a firearm for the legal self-protection usually has to receive an official authorisation to carry a firearm for this purpose. In the EU-context such authorisations are generally granted only in exceptional cases. The use of a firearm for self-defence is limited to the very resisting the imminent threat (attack) as defined by the national law. From the tactical perspective, the use of a firearm in self-defence is relatively close to the use of a firearm by the police. Thus, the technical requirements for firearms and ammunition are similar (including the need for lead projectiles in most cases). It has to be emphasized that a typical self-defence situation encompasses circa 1 to 3 shots and those situations as such are extremely rare. It is understood that, from the perspective of lead emission into the environment, cases of self-defence are negligible.
Non-lead ammunition for security purposes	There are non-lead projectiles for security purposes; however, these projectiles are typically loaded in specialized ammunition. They cannot be regarded a general substitute to lead containing ammunition. Examples of non-lead ammunition for security purposes: - "Frangible" projectiles – this type of bullet is intended to prevent the risk of ricochets and shoot-through especially in highly sensitive places such as power plants; the bullet is usually manufactured from moulded metallic powder; the range and precision are significantly lower than in the case of classic ammunition; the use for self-defence is problematic – when soft tissues are hit, the projectile does not have enough "stopping-power", on the contrary, when bones are hit, the projectile fragments substantially more than a lead projectile and causes enormous devastation of tissues. - Solid expanding bullets – these are projectiles manufactured from solid piece of non-lead metal (zinc, brass, bronze, sintered steel). A typical projectile of this type has an opened (hollowed) tip point, which enables the bullet to expand after the hit of a specified target. These projectiles can be used only under certain conditions; e.g. (i) the use for military or quasi-military purposes, incl. training; (ii) the use is forbidden by international treaties on the law of war; (iii) the use for purposes other than hunting or target-shooting is prohibited by the EU Firearms Directive. On general, these projectiles cause significantly higher destruction of bodily tissues compared to non-expanding lead projectiles.

SEAC box

In the course of developing the SEAC draft opinion, there was a discussion whether the exemption of the use of lead ammunition in 'technical shooting' requires further clarification. The Dossier Submitter argued this would be covered by the exemptions included in paragraph 8, i.e. technical testing and/or proofing, testing and development of materials as well as technical research. In addition, the Dossier Submitter expects that 'technical shooting' will fall under the general REACH exemption for scientific research and development (SR&D) applicable to REACH restriction. SEAC points out that 'technical shooting' covers a wide range of applications that go beyond the development and testing of weapons or other equipment for shooting purposes.

To clarify what the scope of 'technical shooting' includes, SEAC considered it useful to include a specific example of such shooting below. It should be noted that use of an installation as shown may very well lead to a consumption of lead of more than 1 tonne per year, so it may not qualify as SR&D as defined in REACH. However, SEAC considers the exemption as defined in paragraph 8 is sufficiently broad to cover all applications of 'technical shooting'.

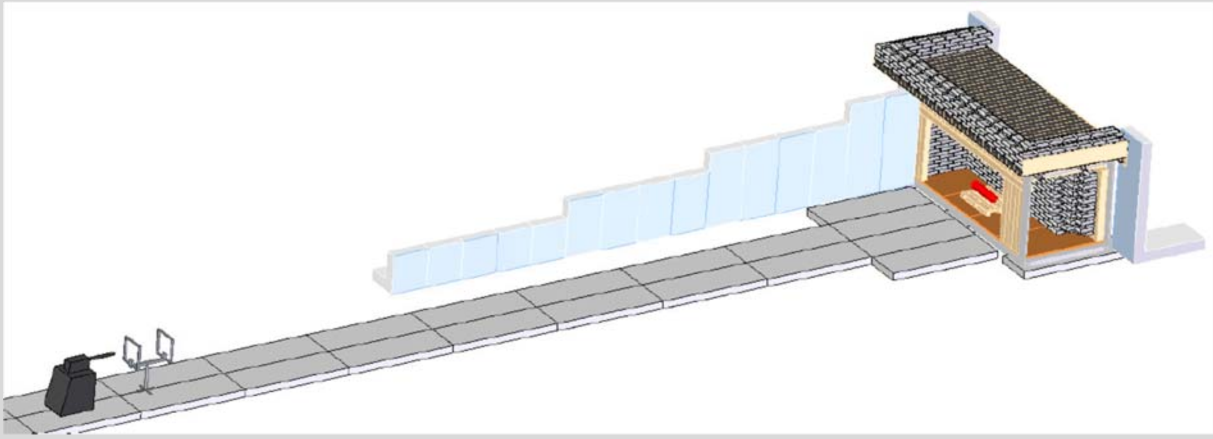
<u>Example for a high-speed-impact-test</u>

For a successful change in automobility, away from the internal combustion engine and towards electric and hydrogen drives, large quantities of lightweight pressurised gas storage systems capable of withstanding operating pressures over 1 000 bar are needed. Such lightweight gas storage systems are made of composite materials. Composites of, for example, carbon fibres and metal foils are considered promising alternatives to the classical heavy solid steel cylinders. Approval of such compressed gas cylinders requires a series of standardized high-speed impact tests: 'Impingement test' (EN 12245), 'Puncture test' (ECE R110), 'High velocity impact' (ISO 11119-4), 'Impact test' (SAE J2579) and 'Penetration test' (ISO 11439).

These tests apply technical bullets and are typically performed with a fixed firing apparatus with interchangeable barrels of varying calibres (e.g. 5.56x45, 7.62x51 and 12.7x99 mm). Depending on the test, usually ammunition with hard jacket bullets is applied. In some cases, hunting ammunition of the same calibre may be used.

Because of the normative basis and to ensure consistent quality and traceability for such tests, the derogation from the ban on the use of lead ammunition seems justified. The technical trial operation requires a permanent supply of such ammunition for technical testing and certification on the market.

Functional drawing of a technical shooting range. Left: The firing apparatus with pre-set measurement of the muzzle speed. Right: adjustable target elevation and bullet trap. (Graphic: BAM Berlin)



Firing apparatus for interchangeable barrels with pre-set measurement of the muzzle speed. The handwheels are used for fine adjustment to the target point. For reproducibility of the distances (muzzle-target) the base is variably adjustable according to different ammunition and associated barrel lengths. (Photo: BAM Berlin)

2.7.4. Costs and other economic impacts

On the uses reported in Section 2.7.1 and 2.7.2 there is less detailed information available as for the other uses of lead documented in this report.

Concerning airguns, the information suggests that alternatives to lead are feasible for uses other than sports shooting where the precision requirements are currently too demanding for pellets made of zinc and other materials. At a price difference of less than 2 cents per pellet, the incremental cost of a ban on lead in airgun ammunition would not be disproportionally expensive. A somewhat dated report (COWI, 2004) suggests that in the beginning of the 2000s about 2.4bn pellets were consumed in the EU15. Assuming that (i) pellet consumption per capita remained approximately constant, (ii) the use in hunting makes up ~10 % of the consumption, and (iii) the figures for the EU15 in 2000 can be scaled up to the EU27 in 2020 by the respective population sizes, one can come up with an indicative substitution cost estimate of €5m per year for hunting and €50m per year for other uses.[294]

Concerning muzzle loaders, stakeholder feedback suggests that a restriction on lead in hunting would technically not be feasible and would be disproportionate. No concrete information on the cost of a restriction on this use was provided in the consultation to support a derogation for antique muzzle loaders and other antique firearms or to confirm the suitability of lead-free ammunition for replicas.

2.7.5. Cost-effectiveness and cost-benefit considerations

Airgun ammunition

Based on the information available, a comprehensive impact assessment could not be conducted for this use. Nevertheless, an indicative assessment can be provided based on the indicative substitution cost estimate derived in Section 2.7.4 and generic information about the weight of lead per pellet. At an average pellet weight of 0.75 g, the total lead abatement potential amounts to about 2 100 tonnes per year and the corresponding cost-effectiveness would be in the order of 20 €/kg.[295] However, since a large fraction of the use takes place on sporting grounds, i.e. under 'sports shooting' conditions, the associated emissions of lead would be controlled by the proposed measures for lead in sports shooting and, therefore, the contribution of a restriction on lead in airgun ammunition to the overall risk reduction would likely be limited.

Muzzle loading ammunition

Given the high value of antique muzzle loaders and the possible destructive effects of the use of non-lead ammunition on the weapon, it is unlikely that antique muzzle loaders are frequently used for hunting and/or contribute significantly to the overall burden of lead from ammunition uses. Based on comments received in the consultation of the Annex XV report, feasible alternative ammunition for muzzle loaders seems not to exist. The Dossier Submitter could not verify whether replicas could use lead-free ammunition and, if so, whether such lead-free ammunition for muzzle loaders is offered on the market. Yet it appears that a ban on the use of lead ammunition in hunting with muzzle loaders would significantly impact this activity, whilst the reduction of lead emission is low—especially

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[294] €0.02*2.4bn*447m [EU27 population in 2020]/378m [EU15 population in 2000] = €56.8m. However, offers by retailers suggest that today lead-free alternatives are widely available (see Section 2.7.2) and thus a non-marginal fraction of the estimated substitution costs are likely to be already born by consumers.

[295] 0.00075kg*2.4bn*447m (EU27 population in 2020)/378m (EU15 population in 2000) = 2 129 t; €56.8m/2 129 t = 20 €/kg.

where use takes place on sporting ranges, i.e. under 'sports shooting' conditions, the associated emissions of lead would be controlled by the proposed measures for lead in sports shooting and, therefore, the contribution of a restriction on muzzle loading ammunition to the overall risk reduction would likely be limited.

2.7.6. Other practicability and monitorability considerations

2.7.6.1. Implementability

A restriction on the use of lead in airgun pellets and muzzle loader ammunition is implementable in principle, as it is not different from other restrictions, either at national or EU level, that have been imposed.

2.7.6.2. Enforceability

Where airguns or muzzle loaders are used for hunting (including pest control) the enforcement of the conditions of the restriction are identical to other hunting uses in scope, specifically hunting with projectiles other than gunshot. As such, readers are referred to the section of the Background Document where the enforcement of these are discussed in the detail.

Similarly, where airguns or muzzle loaders are used for sports shooting the conditions of the proposed restriction for locations undertaking sports shooting can be enforced as foreseen for these locations.

The proposed restriction is therefore considered to be enforceable.

2.7.6.3. Monitorability

The proposed restriction on lead in these uses (airguns and muzzle loading ammunition) can be monitored. The presence of lead and non-lead ammunition on the market could be monitored using the same methodology as the one used by the Dossier Submitter to perform its market survey: contact manufacturers, importers, retailers, consult website and social media pages. Mystery shopping campaigns on websites and in retailers' shops could also be conducted for the same purpose.

2.8. Impacts of a restriction on lead in fishing tackle (use 7)

The proposed restriction option for lead used in fishing tackle is a combination of the following elements:

- **A ban on placing on the market and using lead fishing sinkers and lures.** This action would foresee a ban of lead headed by fishing tackle-specific transition periods to allow manufacturers as well as the suppliers and retailers of fishing tackle to develop and switch to alternatives: (i) no transition period is proposed for lead wire, (ii) a transition period of three years is proposed for lead fishing sinkers and lures with a weigh ≤ 50 g, and (iii) a transition period of five years is proposed for the sinkers and lures with a weight > 50 g.
- **A ban on using fishing tackle rig or equipment intended to drop off lead sinkers**. No transition period proposed.
- **The obligation to inform buyers at the point of sale about the presence, toxicity and risk of lead to human health and the environment, as well as the upcoming ban and the availability of alternatives.** This obligation would apply to all lead-containing fishing tackle placed on the market (no size restriction), and would be headed by a transition period of six months to allow retailers to put in place the necessary information towards their customers.

The following sections summarise the impact assessment of the proposed restriction option. Supporting information, such as detailed calculations, are provided in Annex D. Brief assessments of alternative restriction options are also presented in Annex D.

As the restriction conditions foresee different transition periods to facilitate the adoption of non-lead alternatives, uptake of these alternatives is the assumed response of the supply chain. However, it is noted that a ban on using fishing sinkers and lures is difficult to enforce.

2.8.1. Effectiveness and risk reduction capacity

2.8.1.1. Human health impact

Due to the lack and scarce statistics on exposure (in particular on home-casting), only a qualitative assessment can be made on the human health impact of the proposed restriction option.

The impact on human health of the proposed restriction option is mainly twofold.

First, there will be a reduction of exposure to lead via ingestion, mouthing, chewing and manipulation of lead fishing tackle as lead in fishing tackle will be banned both for sale and use. This will in particular benefit children who may represent in some EU countries up to 20 % of the fishers. On average, the Dossier Submitter estimates that ca. 10 % of the fishers in Europe are below 12. This number should be taken with caution as it is derived from statistics from a few countries only (cf. Annex A).

Second, thanks to the ban on using lead fishing tackle, the use of lead sinkers and lures will be prohibited step-wise (≤ 50 g, and then > 50 g), there will therefore be less opportunity for the fishers to use their home made sinkers and lures (i.e. melted and home-casted). As a consequence of the ban on use, less and less people will have an incentive to home-cast their lead sinkers and lures, and fewer people would therefore be exposed to lead fumes and dust, and in particular the children living in the same household as the fishers who are casting lead.

Overall, the exposure to lead, especially for children, is expected to be reduced. However, as it is difficult to supervise individuals in this area, both in their private home, but also when they fish, the effectiveness of the restriction to guarantee the reduction of the risk for human health cannot therefore be 100 % guarantee.

In order to be successful, it is therefore important to inform and explain to the fishers the risks of lead, and home-casting for their health, and the health of their family, and contextualise the proposed ban. During the transition period preceding the ban on sales and use, an awareness and information campaign, as well as information in retailer's shops and websites on the presence, and toxicity of lead fishing tackle, would probably alter the views of the fishers on lead fishing tackle and consequently the way they act (cf. Annex D).

Last but not least, banning the use of fishing tackle containing lead is required for the prohibition on placing on the market lead fishing tackle to be effective. If the use of lead in fishing tackle continues to be permitted, it could indeed provide a greater incentive for casting at home, which would create a bigger issue in terms of human health than the current situation. Home-casting of lead fishing sinkers and lures may indeed become particularly attractive for fishers if the price of non-lead fishing tackle in shops and internet webstores rises.

2.8.1.2. Environmental risk reduction and releases avoided to the environment

As indicated in Section 1.5, one single lead fishing tackle, when ingested by a bird, triggers severe adverse effects and could generally lead to mortality. Nevertheless, conducting an environmental risk reduction analysis is complicated by a number of factors that have been highlighted in Section 1 of the Annex XV report. For example, (i) the large number of bird species potentially at risk, (ii) the scarcity of available data and studies on birds and lead fishing tackle ingestion, (iii) the deaths from all causes vs the deaths from lead fishing tackle ingestion specifically, (iv) the difficulty to retrieve bird carcasses, make it difficult to estimate current exposures and effects (Grade et al., 2019). It is also difficult to estimate the probability that a lost lead fishing tackle will be picked up and ingested by a bird. Lastly, the accumulation of lead in the environment based on historical fishing, together with uncertainties about its continued availability to birds, are some of the factors that make it difficult to estimate the potential effectiveness of the restriction in reducing exposure and observed effects. Because of these difficulties, the approach taken in the environmental impact assessment is to illustrate the potential sources of exposure (unintentional loss or spillage, deliberate dropping or dumping, and inappropriate waste management) and describe the circumstances that suggest that a number of birds are potentially at risk (i.e. birds at risk because of their feeding ecology), including birds listed as vulnerable, endangered or critically endangered on the IUCN lists.

Even though there has been positive impact on bird mortality in Great Britain after the entry into force of the 1987 law (Kirby et al., 1994), it is difficult for the reasons indicated above to extrapolate such a result to the European scale. The benefits for the environment of the proposed restriction option are therefore essentially presented in terms of quantity of lead fishing tackle releases avoided as a result of the implementation of the proposed restriction option. The proposed restriction would address both the unintentional and the intentional (e.g. drop off sinkers) release of lead fishing tackle, and would also address the releases of purchased and home-casted sinkers thanks to the ban on use contained in the proposed restriction.

The proposed restriction option is anticipated to reduce lead emissions from fishing in the

EU27-2020 by ca. 48 300 tonnes (32 200 – 112 700 tonnes) over the 20-year analytical period. This corresponds to a reduction of releases by approximately 51 % compared to the baseline (Annex D). The remaining releases would come from the lost fishing nets, ropes and line containing enclosed lead.

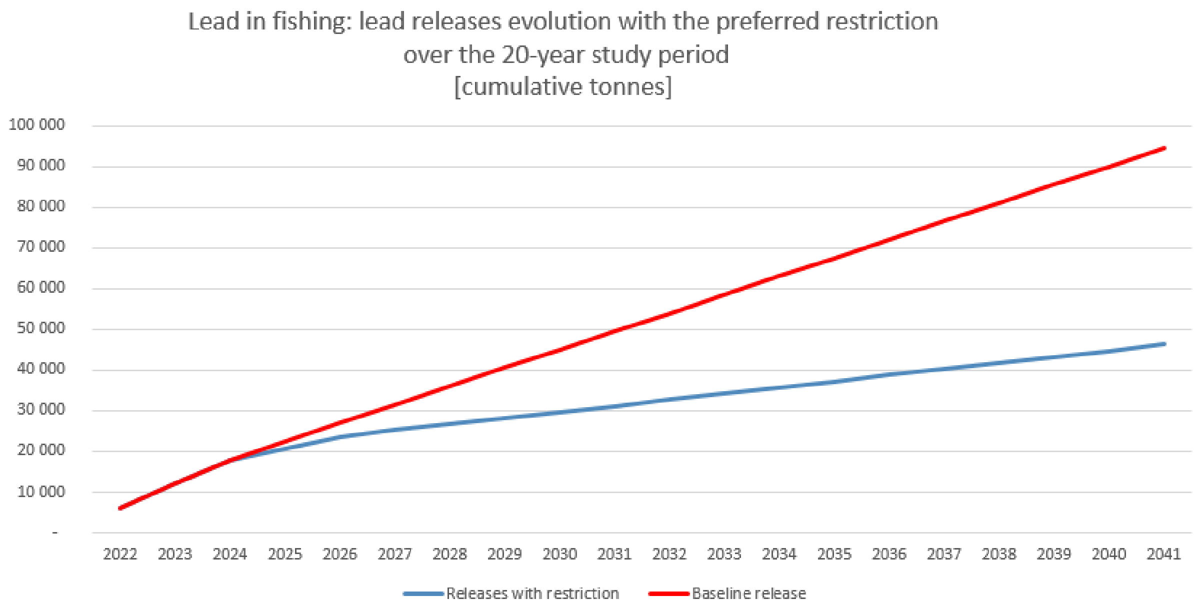

Figure 2-17: Remaining releases of lead in fishing with the proposed restriction in place

2.8.1.3. Conclusions on risk reduction from alternatives and technical solutions

Multiple alternatives[296] to lead in fishing tackle were identified via literature review of recently published articles (Canada, 2018, Thomas, 2019), the ECHA market survey (cf Annex D and E), and information provided via the ECHA call for evidence (CfE #909 from Sportvisserij Nederland, CfE #1034 from VLIZ, CfE #1078 from Belgium - The marine environment department, CfE #1153 from Modified Materials BV, CfE #1170 from an individual, and CfE #1190 from Pallatrax Angling International Ltd), and later during the Annex XV consultation (for example comments #3177, #3178, #3181, #3182, #3190, #3202, #3203, #3207, #3213, #3217, #3219, #3228, #3233, #3259, #3263, #3340, #3358, #3372, #3381, #3389, #3417, #3472, #3492, #3504, #3512, #3518). For example: bismuth, ceramic/glass, copper and its alloys such as brass and bronze, concrete, various types of polymers (such as high density polymers, PHA), iron, reinforced bars (Rebar), (stainless) steel, stones or pebbles, tin, tungsten, zamac (zinc-aluminium alloy), and zinc.

In general, the alternatives currently available for fishing tackle are better than lead from a human health and environmental standpoint, though there are some data gaps for the zamac, zinc, ceramic, tin and bismuth, which makes a full comparison difficult (cf. Annex C).

Potential health effects of alternative metals include respiratory tract irritation (e.g., copper and its alloys), and metal fume fever (mainly zinc) in case of home-casting. To evaluate the

[296] An alternative is a possible replacement for a substance. The alternative should be able to replace the function that the substance performs. An alternative could be another substance or could be a technology, or a combination of both. The word 'alternative' does not imply or mean that the alternative is suitable (i.e. technically, economically feasible and resulting in an overall reduction of the risk for the human health, and the environment).

risk for hunters, sports shooters and fishers following inhalation, occupational exposure limits (OELs) might be the best proxy for the assessment. However, relevant exposure data measuring, for example zinc and copper in the air, are not available.

No risk is identified via skin contact from the handling of fishing tackle made of alternatives.

With regard to the potential effects on the environment, tungsten, which is a common alternative to lead thanks to its high density[297], as well as bismuth and tin were assessed as non-toxic for the wildlife in the US, and are already approved in various formulations by the US Fish and Wildlife services (US FWS, 1997) as alternatives to lead gunshots. Although these substances have been assessed as non-toxic alternatives to lead gunshots only, the same conclusion could apply to fishing tackle.

While none of the alternatives for sinkers and lures are classified for aquatic toxicity (in their massive form), some of them are however not completely harmless to the environment. For example, 'heavy metals' such as zinc and brass (even if less toxic than lead), that may be used as an alternative to lead fishing sinkers and lures, are toxic for the wildlife and birds in particular when ingested (cf. Annex C). Nevertheless, during the Annex XV consultation, some stakeholders indicated that zinc, brass but also copper are in fact seldomely used as alternatives to lead sinkers and lures (comment #3518). Zinc for example 'oxidizes quickly on the surface, which makes it noticeable in the water, and makes fishing difficult' (comment #3518). This is confirming the results from the ECHA market survey presented in the Annex D.4.2.3 to the Background Document.

In addition, some independent analysis revealed the presence of lead in sinkers and lures marketed as 'lead-free', 'non-lead' or 'non toxic' in proportion that can vary between 2 and 100 % (CfE #909 - independent Kiwa inspection report (confidential), and retailer informal communication during the ECHA market survey).

Because fishing lines can break, fishing tackle can be pulled out from the tackle clip/swivel, or might get stuck in a natural obstacle (e.g. stones, branches, trees, foliage etc.), some loss of fishing tackle in the environment during fishing is inevitable and inherent to the fishing activity itself. **This means that accumulation and littering of fishing tackle in the environment is inevitable whatever the alternative used**. The alternative to lead should therefore be considered carefully and with caution.

According to VLIZ (CfE #1034) and the Swedish Chemicals Agency (KEMI, 2007), the ideal lead alternative (aka suitable alternative) should (i) not contain heavy metals such as lead or zinc that are toxic to the wildlife, (ii) match ideally the mass density of lead (11.3 g/cm³) which contributes to the optimal casting (fishing) properties, (iii) should be biodegradable and (iv) the production process also ideally needed to offer perspective on the (future) elaboration of a do-it-yourself (DIY) / home-casting method.

The assessment of the global environmental footprint of the alternatives is outside of the remit of the restriction process. Nevertheless, having in mind the implementation of the future EU Chemicals Strategy, this aspect should not be neglected when looking at the alternatives, and in particular at the overall environmental risk reduction of the alternatives. Using a simplistic approach, the Dossier Submitter described and compared lead and its alternatives against the following criteria that could be used to understand the possible global environmental footprint of the alternatives (cf. Annex C):

- Toxicity and risk for human health

[297] Tungsten has a density of 19.25 g/cm³ that far exceeds that of lead (11.34 g/cm³).

- Toxicity and risk for the environment (both aquatic toxicity and wildlife ingestion)
- Sourcing of the raw material (extraction vs recycling)
- Resource depletion (water, energy, chemical)
- Emission of greenhouse gases

The outcome of this simplistic, relative comparison is summarised in the Table 2-61 for the alternatives that can be used in fishing sinkers and lures.

Table 2-61: Environmental footprint of lead and some of its alternatives (impact)

Material	HH toxicity	Env toxicity (aquatic + wildlife)	Impact on sourcing	Impact on resources depletion	Impact on CO_{2e} emissions
Lead (including coated lead)	High	High	Low	Moderate	Moderate
Alternative metals					
Bismuth	-	-	High	High	High
Copper	Moderate	Moderate	Moderate	Moderate	High
Iron	-	-	Moderate	Moderate	Moderate
Tin	-	-	Low	Moderate	High
Tungsten	-	-	Moderate	Moderate	High
Zinc	Moderate	High	High	Moderate	Moderate
Alternative alloys					
Brass	-	-	Low	Moderate	Moderate
Bronze	-	-	Low	Moderate	High
Zamac	-	-	Low	Moderate	Moderate
Alternative steels					
Rebar, stainless steel, steel	-	-	Low	Moderate	Moderate
Other Inorganic					
Ceramic / glass	-	-	High	Moderate	Moderate
Concrete	-	-	High	High	Low
Stones / pebbles	-	-	Low	Low	Low
Other Organic					
High density polymer	-	High	Moderate	Moderate	High

Source: Annex C

2.8.2. Costs and other economic impacts

Only the costs and impacts within the EU27-2020 area are considered.

The information available, and the assumptions made, does not allow the Dossier Submitter to estimate accurately the total cost of the proposed restriction. In addition, not all costs have been monetised, therefore the overall cost of the proposed restriction conditions might be higher than the one mentioned. Nevertheless, the estimates could be considered in terms of order of magnitude. Detailed information is available in Annex D.

2.8.2.1. Costs within the EU27-2020

The total cost of the proposed restriction option is estimated to be €9.3bn (€NPV – 20 year-analytical period).

The following broad categories of costs were taken into account to estimate the costs of the restriction within EU27-2020:

- R&D costs
- Industry compliance costs, i.e. raw material costs, energy costs, loss of recycling benefits and manufacturing equipment costs (aka capital costs)
- Retailers' compliance costs (i.e. costs to implement the restriction condition related to consumers information at the point of sale)
- Enforcement costs
- Consumers and commercial fishers' costs (cf. Section 2.5.3.2)

Table 2-62 below provides a summary of the cost estimates of the proposed restriction within EU27-2020. The assumptions used to estimate the costs are summarised below and further detailed in Annex D. Note that, where available, assumptions indicated in brackets present lower and upper bounds that could be used for the purpose of a sensitivity analysis.

R&D costs

European companies that are currently manufacturing lead fishing tackle will incur R&D costs from developing new alternative technologies. There was no information provided on this topic by stakeholders via the Call for Evidence, nevertheless, during the ECHA market survey, information was provided by some stakeholders (essentially retailers and manufacturers) on the costs of previous attempts to develop alternatives to lead fishing tackle, and estimated costs of future R&D. The effort and capacity in R&D might vary also depending on the size and market (global vs local) of the EU manufacturers as well as their turn-over and financial capacity to invest in R&D. For the purpose of the analysis, a cost of €75 000 (€50 000 as the lower bound, €100 000 as the upper bound) for European manufacturers with a global market (EU market at least), and a cost of €5 000 for manufacturers with a local market (their own country, or region only) is assumed and will be spread out evenly over the period when the sector is assumed to be developing and implementing alternatives, i.e. before the first transition period ends.

It is important to note that the manufacturers of lead fishing tackle, are usually lead foundries, or SMEs producing lead fishing tackle as a side activity, or as their main activity (ECHA market survey); these types of industry might not have the capacity, in terms of human and financial resources, to engage in a proper R&D programme. On the other hand, retailers and 'brands', in order to stay innovative and gain market shares, design and develop regularly new products to be placed on the market. So, the R&D effort, in case of a restriction on lead in fishing, could also become a joint effort, or could be taken over by other supply chain actors.

Industry compliance costs

Additional costs would be incurred for manufacturers of fishing tackle because of higher raw material prices, changes to the manufacturing process (e.g. new moulds) and higher energy costs.

The call for evidence and the ECHA market survey did not bring much information on how the different actors in the supply chain would react, and to which alternative they would move, therefore the Dossier Submitter has made a series of realistic assumptions which represents a plausible scenario. These assumptions are described and summarised in Annex D.

The industry compliance cost corresponds to the 'reformulation' costs and are strongly linked to the selected alternative(s) to replace lead in fishing tackle. Indeed, as mentioned in Annex D, alternatives to lead have different physical and processing properties which imply that existing tools (e.g. moulds) will have to be replaced, and additional raw material and energy costs will be required.

If the EU manufacturers could move to a better alternative than lead. Several scenarios are possible depending on the alternative selected. In some cases, capital investment costs might be needed in order to buy new tools, such as moulds and machinery. In addition, additional operational costs will be induced, such as higher energy cost due to the higher melting point of the existing alternatives to replace lead.

The current manufacturing of lead fishing tackle and lures is a semi-manual, basic process (cf. Annex A) which consists in the melting and then casting of lead in moulds either via gravity or injection.

With the proposed restriction option, and in particular the transition period proposed for the different weights of fishing sinkers and lures, the Dossier Submitter is assuming that the same machinery will be used for the manufacturing of lead and non-lead fishing tackle, and that only different moulds and melting temperature will be used.

It should be noted that with this assumption, there might be a risk of cross contamination between lead and non-lead alternative during the manufacturing process. This could for example explain why the testing of some already available non-lead alternatives do contain traces of lead (CfE #909 - Sportvisserij Nederland and ECHA market survey).

The Dossier Submitter assumes that existing manufacturers will not switch to a totally different technology (e.g. from lead moulding to plastic injection, or tungsten technology for example), and in case the investment in machinery would be too significant, other industrial actors already equipped with such machinery would take over the market. Therefore, the capital costs considered are essentially linked to the purchase of new moulds. Reusing existing moulds might not be possible as the alternative substance have different density, which implies different size of fishing tackle.

In addition, as indicated in Annex C, some of the alternative substances have a low or non-existing recyclability. Meaning that some residues from the manufacturing process (e.g. manufacturing waste), cannot be sold to fabricators (who manufacture metal from the beginning to the end) or smelters (who recover metals) or are sold at a lower price than lead. This loss of benefits, even if acknowledge by the Dossier Submitter, has not been monetised and accounted for.

Retailer compliance costs

Retailers compliance costs are estimated to be null, because they are considered as part of the normal business and maintenance of the shops or websites.

The transition to non-lead fishing tackle is assumed to have no additional cost for the retailers in term of stock, or loss of profit since fishing tackle is not expected to remain on shop shelves for a long time. The proposed transition period would give also enough time for the retailers to prepare to the transition to non-lead alternatives and sell their stocks of lead fishing tackle.

With the proposed restriction option, retailers will also be requested to inform at the point of sale the consumers about the presence, toxicity and risk of lead to human health and the environment. This is very similar to a price tagging or advertisement campaign that is performed on regular basis by a shop or website owner.

The restriction obligation would apply to all lead fishing tackle placed on the market (no size restriction), and would be accompanied with a transition period of six months to allow the lead fishing tackle retailers to put in place the necessary information for their customers in the shop shelves or on their website.

It should be clear that the retailers will not be asked to label or re-label individually all the fishing tackle they sell, nor request from their suppliers that they would label or re-label individually the fishing tackle supplied. An information 'corner', or a poster sufficiently visible, understandable and in the national language of the customer is expected to raise awareness and consciousness of the customer, which will induce a change of behaviour (cf. Annex D).

Enforcement costs

In terms of enforcement costs, it is assumed that REACH enforcement authorities would conduct spot checks of imported fishing tackle (customs), manufacturers' site inspections, retailers' site inspections, and retailers' website inspections once the restriction option would enter into force (i.e. after the transition period). The estimate includes staff time, laboratory testing, overheads and other inspection-related expenses.

In addition, it is assumed that the proposed restriction option would allow inspections at the site of use (e.g. on fishing spots) to be performed as well by the national relevant enforcement authorities (either fishing associations or local area authorities or ministries, depending on the EU country).

It is assumed that the enforcement costs (administrative, testing, and on the field) for enforcement authorities and industry will be ca. €55 000 per year for the duration of the analytical period (20 years), after the entry-into-effect of the restriction (i.e. after the transition period has elapsed). However, it should be highlighted that this is likely an overestimate, as the enforcement costs of a new restriction would likely be incurred in the years immediately following the entry-into-effect and approach zero by the end of the analytical period as compliance increases.

Costs for the fishers

Once the restriction would have entered into force, it is assumed that the fishers will continue to purchase the same quantity (in term of weight) of fishing tackle as today.

This assumption is based on the UK and Danish experience when they put in place their respective bans on fishing tackle, and might be underestimated for the first years after the entry into force of the proposed ban. For example, in Great Britain, the sales of alternative sinkers increased within the first three years after the entry into force of the ban and returned to the same level as before the ban after that, indicating that the overall demand for alternative sinkers was not affected by increased prices (COWI, 2004).

In practice this would mean that ca. 5 400 tpa (4 000 – 10 000) of fishing sinkers and lures would still be purchased yearly in Europe after the full entry into force of the restriction.

The costs for the fishers during the analytical period (20 year) is calculated considering (i) the transition period proposed for the different sizes of fishing sinkers and lures, (ii) the current distribution of sinkers' sizes, and (iii) the current average price of the alternatives (ECHA market survey, 2020).

With regard to the price of the alternative, the current expensive prices cannot be solely explained by the cost of the raw material or manufacturing process. There seems to be an important mark-up within the supply chain for some of these marketed 'user friendly products' (cf. Annex D). In addition, scale economy would be expected in the future with an increase in European demand, and a decrease of selling price is therefore expected once more alternatives become available on the market.

The restriction costs for the fishers is estimated to be €9 300 million (NPV – 20 year-period). The detailed assumptions and calculations are available in Annex D.

Total costs of the restriction proposal in EU27-2020

When the UK ban came into force in 1987, and the Danish ban came into force, the costs incurred by the manufacturers of alternatives were passed to the consumers. The Dossier Submitter is therefore assuming that such a scenario remains plausible with the proposed restriction, and that all the costs incurred by the manufacturers of fishing tackle (in Europe or elsewhere) will be passed on to the consumers through increased product prices, therefore the R&D/industry compliance/retailers costs, and the consumer cost should not be double-counted.

If the additional manufacturing costs are fully transferred to the prices, as it is currently with the available alternatives on the market, the overall industry compliance costs (EU + outside EU) and the costs to fishers should be equivalent.

The costs for the European Industry (industry compliance costs for the European manufacturers) are also indicated in Table 2-62 as it gives a flavour of the effort and capability of the European Manufacturers to switch to alternatives (cf. Section 2.8.2.2 for further discussion on affordability).

Table 2-62: Summary of costs estimates in EU27-2020

	Total costs [€NPV-20 years]	**Annualised costs [€]**
Costs for the fishers, including:	€9 300 million	€680 million
EU industry compliance costs	€146 million	€11 million
EU retailer compliance costs	0	0
Enforcement costs	€0.5 million	€0.04 million
Total costs of the restriction	**€9 300 million (~0-48 000 million)**	**€680 million (~0-3 500 million)**

2.8.2.2. Affordability considerations

With regard to the affordability, it might be difficult to conclude firmly on this aspect, and to predict for all supply chain actors if the proposed restriction will be affordable or not. The answer is therefore a bit more nuanced: while the Dossier Submitter concludes that the proposed restriction option for lead in fishing tackle is affordable for the fishers and retailers, it might not be the case for the European manufacturers.

Impact and affordability for the European manufacturers

The affordability for the European manufacturers is strongly dependent on three main elements: the proper enforcement of the proposed restriction option, the length of the transition period which should give enough time for the European industry to switch to alternatives, but also the financial capacity of the European Industry to invest in new moulds, and/or technologies. It is therefore difficult to predict and be conclusive on this specific point.

Examples from the UK and Denmark where similar restrictions of lead in fishing tackle (albeit with different scope) are already in place, indicate that switching to alternative materials is possible for both the European fishing tackle industry and fishers.

Indeed, as laid out in Section 2.8.2.1 and in Annex D (for the details), the main drivers for costs to be incurred by the European fishing tackle industry are the raw material prices and the associated energy costs to manufacture fishing tackle (as melting of the raw material is essential in the production process). The changes to the manufacturing process (capital investment) represent a small proportion of the total costs incurred by the European industry. Nevertheless, these costs to replace prematurely (iron) moulds will have to be supported by the companies within a very short period of time before the entry into force of the proposed ban. This premature replacement of moulds will have to be done by the EU manufacturers without having the certitude that their market shares would remain. If enough time is given to industry to transition to alternatives to lead and a market for non-lead alternatives is established through the restriction, the proposed restriction should be affordable for industry as long as they have enough cash flow to engage in this change of tools. Such an assumption would need to be verified during the consultation of the Annex XV proposal. Industry and fishing associations' initiatives could also help the European industry to comply with the proposed restriction by sponsoring or supporting the transition to new tools and equipment. Some financial support to help the European industry to transition to alternatives could also be granted through the financial support mechanisms established through the European Green Deal policy.

Impact and affordability for the recreational fishers

Depending on the type of alternative, non-lead fishing tackle might be more expensive than the lead version. During the ECHA market survey, the Dossier Submitter also noted that alternative fishing tackle ≤ 50 g were in general more expensive than the alternatives for fishing tackle > 50 g (cf. Annex D).

Even if the restriction costs would be fully passed through to the fishers (via price increments for fishing tackle), these costs are low compared to the average fishing budget spent yearly by fishers (e.g. fishing rods, reels and other tackle, licenses, fishing trips, and boats).

Based on the restriction cost estimates reported in Section 2.8.2.1, and the average yearly expenses per fisher presented in Annex A, the purchase of non-lead alternatives would induce an additional expense of €30 per fisher per year, which represents 3 % of the average fishing budget of a fisher (30 % of the average expenses for fishing tackle), and an additional expense of ~ €2 per fisher per fishing day[298] (cf. Annex D).

It should also be noticed that, in contrast to some hunters or sports shooters, fishers do not have to replace their main equipment (i.e. boat, or fishing rod) to be able to use the non-lead fishing tackle.

Affordability for the recreational fishing sector

Some stakeholders have reported a possible performance loss for the fishers in case of inferior fishing tackle quality, or fishing performance, e.g. casting shorter distance, shorter depth (CfE #909 from Sportvisserij Nederland, #1034 from VLIZ and #1078 from Belgium - The marine environment department). The alternatives to lead may indeed behave differently during the casting, or in water as fishing tackle made of alternatives are usually larger than the one made of lead. The Dossier Submitter acknowledges these differences but considers that, with an appropriate design and conception, these differences do not affect the main technical function, and the USbility of the fishing tackle. Similar conclusions were reached by the Environmental Ministry of North Rhine-Westphaliain Germany after a study (Olaf Niepagenkemper, 2015) they commissioned in 2015 on the impact of the fishing tackle material on fishing performance and usability (cf. Annex D).

In addition, from the existing bans on lead in fishing tackle, there is no evidence that the additional cost for the fishers associated with the purchase of alternatives, or a possible loss of performance, would have a negative impact on the fishing participation. For a majority of fishers, according to a recent American survey, the top five main motivations to fish are not to catch a fish but rather to (1) get exercise, (2) be with family and friends, (3) be close to nature, (4) enjoy the sounds and smells of nature and (4) observe scenic beauty (US, 2018). EFTTA, the European Fishing Tackle Trade Association, reported also in 2017 to the European Parliament that the fishers' motivations for fishing is not "catching a fish" but rather "relaxing outdoor, creating social links, experiencing natural settings, enjoying clear water and environment" (EFTTA, 2017). Therefore, no impact from the proposed restriction option is expected on the fishing sector itself, and on the tackle trade sector alone which generates about €2 to 3 billion yearly turnover alone (EFTTA, 2017).

Impact and affordability for commercial fishers

In economic terms, recreational fishing is often discussed in terms of expenditures or total economic value experienced by fishers, in total or per trip. The commercial fishing is, by contrast, often described in terms of the value of fish landed or fleet operating profits.

The commercial fishers' net profit is what remains after other expenses such as the maintenance of physical capital (e.g. fishing gear/tackle and boat). Again, it could reasonably be assumed that commercial fishers net profit would not be too much hampered by a slight increase of consumable such as fishing tackle.

With regard to the value of the fish landed, no performance loss for the commercial fishers has been reported from Denmark on the use of non-lead alternatives for commercial line fishing.

Impact and affordability on the supply chain

In addition to the impact for the manufacturers who would have to reorganise their production to phase out lead from the fishing tackle intended for the internal market, the proposed restriction would also require the importers, only-representatives, retailers and

[298] These additional expenses are in the same order of magnitude as in the US and Canada ((Canada, 2018)).

the web retailers of fishing tackle (including the non-specialised websites such as Amazon, eBay, Wish, or Alibaba) to (i) inform their customers (till the transition period enters into force), but also (ii) ensure and check that lead is not present in the fishing tackle placed on the market. As discussed in Section 2.8.2.1, this is assumed to be affordable by those actors.

2.8.2.3. Other impacts for the society

Impact on EU employment and SMEs

The ECHA market study, and the analysis of the KOMPASS database indicate that the manufacturers of lead fishing tackle could fall essentially under the European SME definition[299]. In addition, the analysis of this information shows that the European manufacturers are separated into three different subgroups: (i) the 'global' manufacturers with significant capital and huge portfolio of lead fishing tackle and other lead products. These manufacturers, usually foundries, have a 'global business' meaning that they supply most of the EU countries (and even export outside Europe), (ii) the 'local' manufacturers which have a smaller portfolio and usually supply lead fishing tackle within their country of origin (local business), these companies are either specialised in the fishing business or manufacture lead fishing tackle among many other fishing equipment or products, and finally (iii) the home manufacturers who might be fishers, fishing associations or fishing shops producing lead fishing tackle for their own use or for selling in small fishing tackle shops.

The impacts on these three sub-groups were examined separately.

Global and local manufacturers could be able to respond and adapt to the restriction proposal if they can switch to alternative processes and/or materials which have similar physical properties as lead (e.g. melting point), if they are given enough time to adapt. In addition they could remain viable if they can use the existing machinery and equipment.

In case of a sudden restriction, i.e. without or with a too short transition period, global manufacturers have indicated that they would lose half of their revenue and would have to lay off up to half of their staff. For local businesses, it is expected that most of them would shut down their business, especially if they are too specialised to be able to afford a restriction without or with a too short transition period.

At the European scale, and assuming four European manufacturers with a 'global market' (i.e. market in multiple EU countries and outside the EU), and 10 European manufacturers with a 'local' market (i.e. market limited to the country where they manufacture), it represents up to 100 employees that could lose their jobs in SMEs. Employees working as smelters have usually a low educational background and might have difficulties in finding another job (see Figure 2-18).

[299] https://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition_en

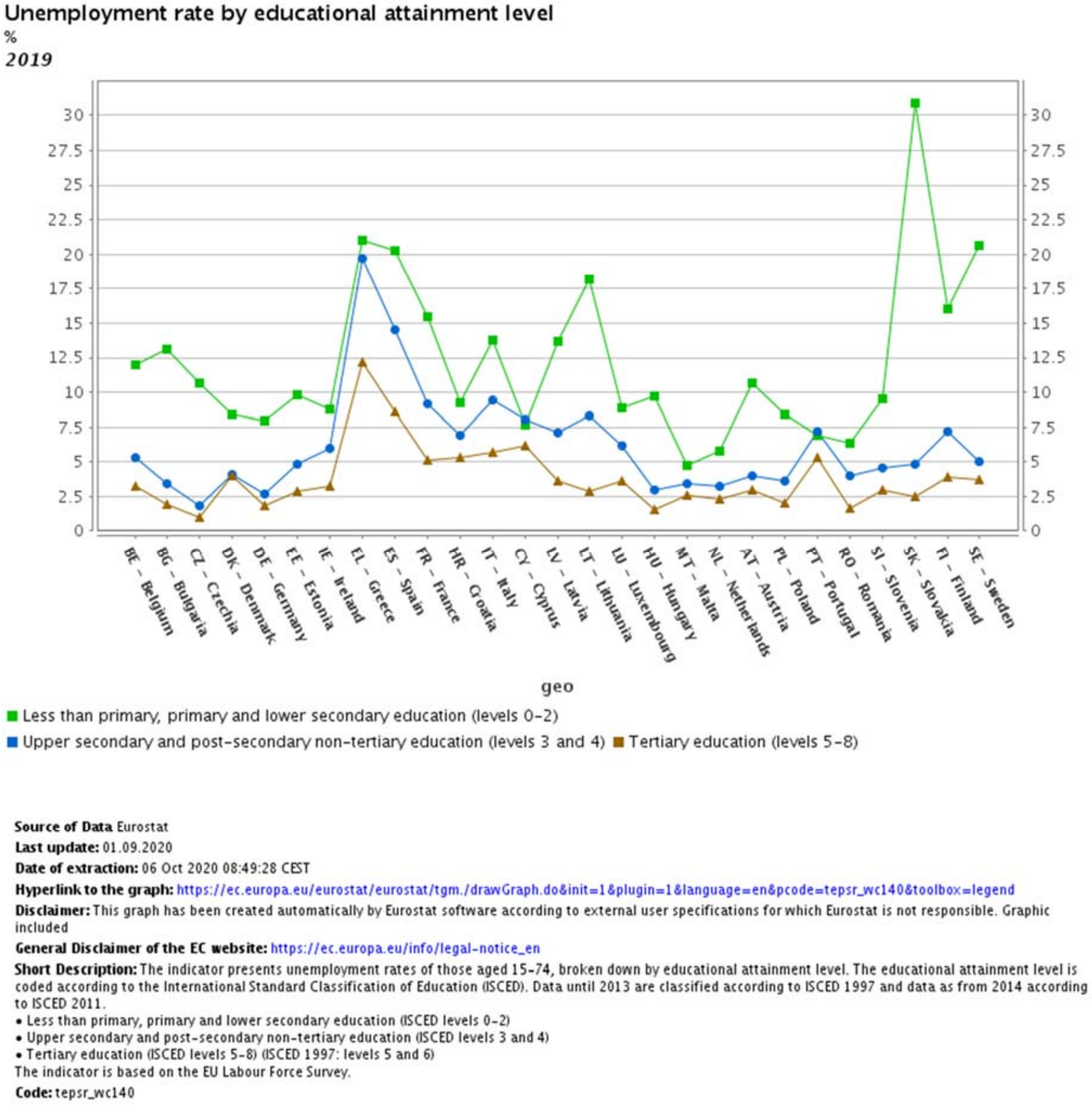

Figure 2-18: Unemployment rate by educational attainment level

Finally, if home manufacturers are unable to easily switch to alternatives, they could also be financially impacted as retail sale of sinkers and lures is usually a second source of income for them. Assuming that this additional source of income might not always be declared by the home-caster to the tax authorities, this potential impact is not considered further.

Impact on trade and competition

The effects of the proposed restriction are expected to have a neutral net effect on trade and competition for the following reasons:

(1) There is a steady and ineluctable erosion of the EU production of lead fishing tackle, while the imports keep on increasing (cf. Annex D).

(2) There is a lack of production capacity of non-lead fishing tackle to answer to the growing demand.

(3) There is a potential for new exports and new markets outside the EU for non-lead alternatives.

No information became available during the call for evidence and the ECHA market survey that would point towards noticeable impacts on trade or competition which would not occur in absence of the restriction.

Indeed, as explained in Annex A, it is suspected that the volumes of imports of lead fishing tackle from outside Europe would have been multiplied by four during the past 20 years. In addition, to confirm this assumption, some important EU manufacturers of lead fishing tackle indicated that their production has been reduced by a factor or two compared to 10 years ago, and for others, by a factor of three to four compared to 20 years ago (ECHA market survey, 2020).

The proposed restriction can be seen as a threat for the European industry, but also as an opportunity as it will create a new market and a new demand for non-lead fishing tackle inside Europe. This opportunity can be supported by the proposed transition period, which should give the European industry sufficient time to adapt. The local production of non-lead fishing tackle can also be seen as a strength as EU manufacturers will be more responsive to the customers' demand than the imports.

Finally, on the export side, the demand for non-lead fishing tackle might also arise outside Europe in the future due to changes of regulations in non-EU countries.

The effect on trade and competition could therefore turn from neutral to positive with an early, strong and systematic enforcement including at the fishing spots (cf. the section on enforcement below).

Impact on innovation

In the long term the restriction proposal can promote the innovation and competitiveness of the European fishing tackle manufacturers as it will force and support, via the additional non-REACH measures, the research and the development of sustainable non-lead alternatives. European manufacturers could become the front runners on non-EU markets if similar lead fishing tackle ban are implemented, for example, in Canada, US, UK.

2.8.3. Cost-effectiveness, and cost-benefit considerations

2.8.3.1. Cost-effectiveness considerations

The proposed restriction is anticipated to reduce lead releases to the environment by about 48 300 tonnes over a 20-year analytical period (cf. Section 2.8.1.2 and Annex D). Considering the total costs of the proposed restriction option, the cost-effectiveness of the proposed restriction is estimated to be €193 per kg of lead release avoided (with a lower bound close to €0 per kg of lead release avoided in case cheaper alternatives are used, and an upper bound of €996 per kg of lead release avoided if considering that all lead fishing tackle would be replaced by the most expensive alternative for the consumer).

Overall, the proposed restriction for lead in fishing tackle appears to be more cost-effective than previous REACH restrictions (Figure 2-19). However, the proposed restriction option for lead in fishing tackle is less cost-effective than the restriction on lead in gunshot in wetlands, which ranged between €0.3/kg to €25/kg and was addressing the same type of environmental impact (ingestion of lead fragments by birds).

Overall, the Dossier Submitter concludes that the proposed restriction is a cost-effective measure for addressing lead releases to the environment from fishing activities.

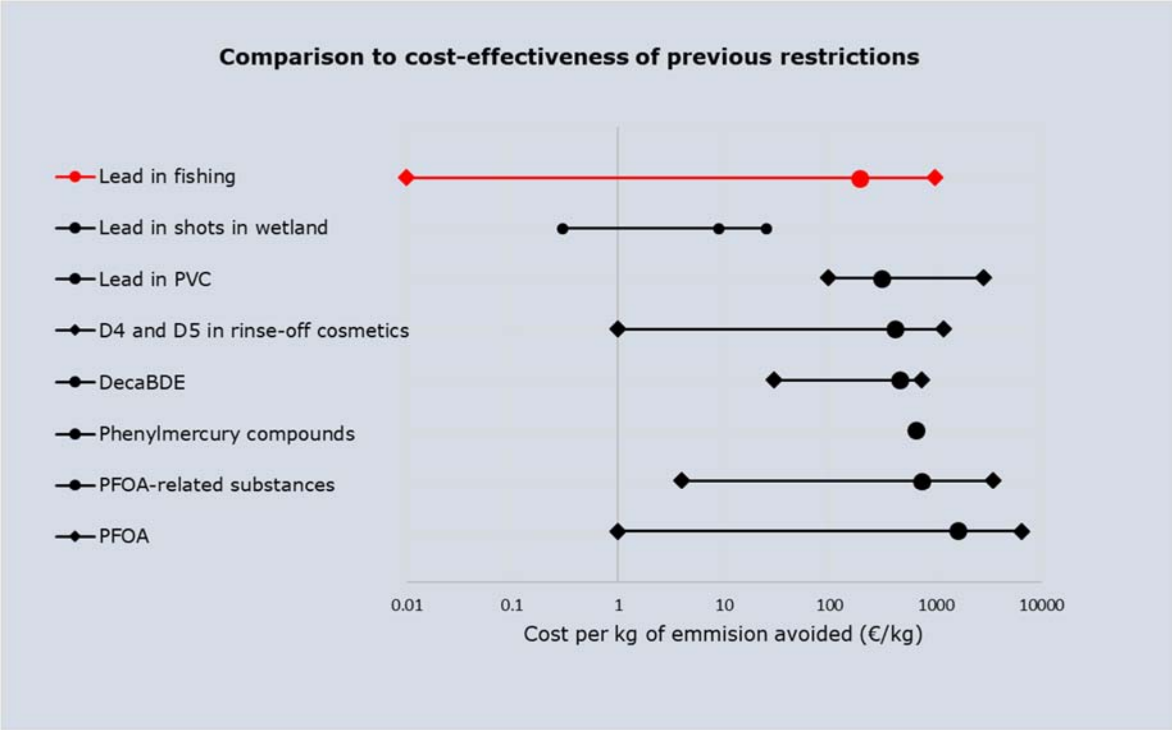

Figure 2-19: Cost-effectiveness comparison with other REACH restrictions

2.8.3.2. Cost-benefit considerations

Table 2-62 summarises the main costs and benefits of the proposed restriction option for lead in fishing tackle that were identified in the previous sections. The analysis also considers additional elements such as welfare impact for the EU producers, and valuation considerations of human health and environmental effects.

Welfare and distributional impact for the EU producers

As a distributional impact, the restriction would result in increased tax generation, and increased profits for importers, retailers and EU manufacturers of alternative fishing tackle: this is based on the assumption that the retailing prices of alternative fishing sinkers and lures are more expensive than the lead ones.

On the European producer side, the quantification of welfare impacts is measured using the manufacturer and retailer surplus. A part of the replacement cost accruing to fishers (i.e. consumer surplus loss) will result in a windfall surplus[300] to fishing tackle manufacturers and retailers. Since the restriction will likely affect current market prices for fishing tackle, it is difficult to estimate the size of this surplus gain. Yet, an attempt can be made based on the assumption that retail price (incl. VAT) of fishing tackle is roughly three times the ex-factory price of fishing tackle (ECHA market survey, 2020). Importantly, this mark-up is thought to capture both the income earned as well as the expenses made by manufacturers, wholesalers, and retailers to sell the product (i.e. costs that are not genuinely related to the production, but to the transportation, stocking and selling of fishing tackle).

To approximate the profit made by producers and retailers, one could thus subtract an average of 20 % VAT from the annualised net cost accruing to fishers (estimated at €680 million) to arrive at €544 million, and then divide this amount by three to arrive at an

[300] (Producer) surplus is defined as the difference between the amount for which the manufacturer/retailer is willing to supply goods and the actual market price. As such it is a measure of company welfare.

estimate of the total mark-up of approximately €180 million. An unknown fraction of this mark-up will be the actual producer surplus gain and should thus be deducted from the consumer surplus cost to arrive at the net social cost of the restriction.

However, one can assume based on COMEXT data that only ~25 % of fishing tackle placed on the common market are produced inside the EU, and most of the metals to produce non-lead fishing tackle are imported from Asia (cf. Annex A and Annex C). Hence, a substantial share of the regulation-induced mark-ups might accrue to non-EU actors in the supply chain. Taking all of this together suggests that the total producer surplus gain to EU manufacturers and retailers is smaller than the regulation-induced consumer welfare loss.

Valuation of human health effects

Given the non-threshold nature of lead for neurotoxic effects in children, and considering that children might be exposed to lead fumes during home-casting activities and possibly via accidental mouthing, detrimental health impacts on them cannot be excluded. However, it is currently not possible to quantify this risk as information that would be needed to underpin a quantitative health impact assessment is not available (cf. Section 1.6).

One would expect that the proposed restriction, and in particular the information towards home-casters of fishing sinkers on the hazard and risk of lead, would have a deterring/discouraging effect on home-casting thereby reducing health risks to children. Indeed, one could assume that if fishers better understand why they should not use lead fishing tackle, then they will refrain from manufacturing them at home. However, because a home-casting ban could hardly ever be enforced, and as the restriction proposal's success is bound to a strong enforcement at the point of use (i.e. at the fishing spots), there is a risk that the proposed restriction on placing on the market of lead fishing tackle would inadvertently increase home-casting and thus increase children's exposure to lead fumes at home. This is a risk that cannot be ignored, especially if alternative sinkers and lures available on the market are substantially more expensive than lead sinkers and lures.

Valuation of environmental effects

As environmental amenities are usually not traded in markets, estimating values for them is inherently difficult. However, some methods to value specific amenities, and empirical estimates are reported in the environmental economics literature[301]. Therefore, a relevant economic value associated with the prevented loss of birds can be considered here.

Birds may be valued for various reasons. These include:

- birdwatching;
- aesthetic value for hikers, campers, anglers, and nature walkers in national and state parks and other natural environments;
- biodiversity value as part of and essential to the health of ecosystems;
- potential future genetic or medical value;
- pest control (e.g. insects, mice) and 'carcass-removal services' (e.g. scavengers); and
- game for hunting.

[301] Environment and Climate Change Canada maintains the Environmental Valuation Reference Inventory (EVRI), which is a searchable online compendium of summaries of environmental and health valuation studies.

Activities related or associated to birds such as birdwatching appear on the rise in Europe[302]. Nevertheless, information on birdwatching activities in Europe is scarce compared to other regions in the world. By way of comparison, a US National yearly Survey[303] reports that in 2016 approximately 45.1 million persons (i.e. ca. 14 % of the US population) engaged in the US in wildlife-watching recreation (incl. watching birds). The recreational benefits measured as expenditure associated with wildlife watching including birdwatching, bird photography, and bird feeding was found to be approximately $1 100 per person[304] (ca. €950). The same study reports that 37 million people engage in bird feeding for an average expenditure of $107 per person (ca. €90).

A concrete example of birds' ecosystem value is as a 'carcase-removal service'. Whelan et al. (2015) suggests that 'carcass-removal services' of vultures in Spain led to minimum annual savings of about €1 million, because without vultures the carcasses of free-ranging livestock would have to be disposed of professionally.

On the assumption that society values both the existence of birds (non-use value) and the services or pleasures they provide (use value), one could attempt to estimate the number of birds which when protected from primary or secondary lead poisoning would correspond to the estimated costs of the restriction proposal. Such a comparison provides a kind of break-even estimate of the number of birds that would need to be protected from ingesting lead so that the restriction proposal would result in a net benefit to society. As discussed above, it seems impossible at this time to obtain a point estimate of either the break-even number of birds to be protected or the value per individual bird protected. However, a ballpark estimate may still be attainable.

Conclusion

While reductions in risk to endangered species and human health have not been monetised, they cannot be ignored.

Regarding the benefit for the wildlife, several endangered species are indeed potentially at risk from the ingestion of the smaller lead fishing sinkers and lures (i.e. ≤ 50 g) as described in Section 1.5. In addition, even if the existence value for the endangered birds have not been accounted for, evidence suggests that part of the society does place a 'high' value on endangered species. For instance, in 2019, a European LIFE project was initiated to restore the habitat in Sicilia of a bird that among other threats is at risk of ingesting lead fishing tackle (cf. 1.5.4.1): €3.4 million will be spent on preservation efforts for the Marble Duck alone[305]. While not a measure of the social value of birds, European LIFE type projects demonstrate that the health and safety of birds is a concern for part of our society.

Regarding the benefits for human health, the proposed restriction option encompasses indirectly the home-casting of lead fishing sinkers and lures. Human health benefits and risk reduction are therefore 'in theory' expected because exposure to lead fumes and dust during home manufacturing would be expected to be reduced. Nevertheless, as explained before, it is important to acknowledge the risks associated with the proposed restriction, and in particular the fact that instead of reducing the exposure to lead fumes and dust, the proposed restriction might inadvertently increase this issue especially if alternative sinkers

[302] https://www.responsibletravel.org/docs/Market/Analysis//Bird-Based/Tourism.pdf
[303] https://www.fws.gov/wsfrprograms/Subpages/NationalSurvey/nat_survey2016.pdf
[304] While this average expense is for all wildlife watching, the U.S. Fish & Wildlife Service study indicates that in the US, 45m people (70 %) engage in birdwatching.
[305] IFE Marbled duck PSSO - Habitat recovery and management actions to increase Marbled duck breeding population in "Pantani della Sicilia SO" area - LIFE18 NAT/DE/000797: https://ec.europa.eu/environment/life/project/Projects/index.cfm?fuseaction=search.dspPage&n_proj_id=7241

and lures available on the market are substantially more expensive than lead sinkers and lures.

Even if benefits exist, the proposed restriction has also a cost both for the fishers and the EU producers that need to be acknowledged.

Table 2-63 summarises the main costs and benefits of the proposed restriction option for lead in fishing tackle that were identified in this document.

Table 2-63: Costs and benefits comparison of the proposed restriction

Costs of the proposed restriction (i.e. negative impacts)		**Benefits of the proposed restriction (i.e positive impacts)**	
Monetised (Annualised)			
Annual costs of the proposed restriction	€680 million	Distributional impact in term of generated tax revenue (with an average VAT rate of 20 %)	€136 million
Including annualised EU industry compliance costs	*€11 million*	Distributional impact in term of supply chain surplus gain (EU and non-EU)	€180 million
Additional yearly expense for a fisher	*€30 per fisher per year (i.e. 3 % of the average yearly fishing budget of a fisher)*		
Quantified			
Workers in lead foundry that are at risk of losing their job	Up to 100 workers with low educational background	Quantity of lead releases avoided to the environment	On average 2 400 tpa
		Protection of birds at risk of ingesting lead fishing tackle	At least 7 million birds are estimated to be at risk including 22 bird species of which 11 are listed in the Annex 1 of the EU Birds Directive. All species at risk are listed under CMS Appendixes I and II[306].
Qualitative			
Risk to inadvertently increase the incidence and frequency of home-casting of lead fishing		Expected to impact positively some children's health due to reduced lead home-casting	

[306] Species under CMS Appendix I are defined as "Endangered migratory species" and species in the CMS Appendix II are defined as "species which have an unfavourable conservation status".

Costs of the proposed restriction (i.e. negative impacts)	Benefits of the proposed restriction (i.e positive impacts)
tackle, and the associated children's exposure, if the price of non-lead fishing tackle in shops and internet webstores rises, and if the enforcement at the point of use is not done effectively.	activities.
Risk to potentially create another littering issue in the environment (inherent to the fishing practice), depending on the type of alternative used.	Overall positive impact expected based on the environmental footprint of alternative sinkers and lures.
	Protection of wildlife and ecosystem services.
	Positive impact on leisure activities including bird watching.
	Fulfilment of European commitment toward the AEWA with regard to protection of endangered bird species.
Summary of the societal costs and benefits:	Monetised costs: at least €364 million (annualised) including €11 million for the EU industry compliance cost. It represents €30 additional expense per fisher per year (i.e. 3 % of the average yearly fishing budget of a fisher) Potentially up to 100 workers in SMEs at risk of losing their job. On average: 2 400 tpa of lead releases avoided. Positive impact expected on children's health if home-casting decreases as expected. Overall positive impact expected based on the environmental footprint of alternative sinkers and lures, despite the risk to potentially create another littering issue in the environment (inherent to the fishing practice), depending on the type of alternative used. Positive impact on wildlife, ecosystem and associated leisure activities (including protection of wildlife species with critical conservation status). EU Birds Directive, CMS and AEWA commitments fulfilled.

2.8.4. Other practicability and monitorability considerations

2.8.4.1. Implementability and manageability

The proposed restriction is considered implementable and manageable.

The proposed restriction includes a ban on using fishing tackle rig or equipment intended to drop off lead sinkers. Such rig techniques and equipment are recent and are promoted by some fishing tackle providers only. As described in Annex D, alternative techniques or equipment are available and economically feasible.

Alternatives[307] are also already available, technically and economically feasible (cf. Annex D) for the fishing sinkers, lures and wire. Multiple alternative substances to lead in fishing tackle were identified via literature review of recently published articles (Environment and Climat Change Canada, 2018, Thomas, 2019), the ECHA market survey (cf. Annex D and E), and information provided via the ECHA call for evidence (CfE #909 from Sportvisserij Nederland, CfE #1034 from VLIZ and CfE #1078 from Belgium - The marine environment department). For example: bismuth, ceramic/glass, copper and its alloys such as brass, concrete, high density polymers, reinforced bars (Rebar), (stainless) steel, stones or pebbles, tin, tungsten, zamac (zinc-aluminium alloy), and zinc.

In general, the alternatives currently available for fishing tackle are better than lead from a human health and environmental standpoint, though there are some data gaps for some alternatives which makes a full comparison difficult.

Among the alternatives, none of them meets the technical performance requirements for every type of fishing tackle, applications or fishing techniques but each alternative could successfully be used for one or more types of sinkers or lures (cf. Annex D). Some alternatives made of steel, stone or pebble, are competitive in price with lead, while others are several times the price of equivalent lead fishing tackle. For example, a sinker or lure in tungsten costs over ten times more than the lead version (cf. Annex D).

In addition, new and more sustainable alternatives could be developed in the future.

Finally, the transition to suitable alternatives could be feasible if a sufficiently long transition period is given to the European industry to adapt their manufacturing equipment and to gear up in terms of capacity of production.

For all these reasons, the proposed restriction is considered implementable and manageable.

2.8.4.2. Enforceability

The three components of the proposed restriction are enforceable, and the scope of the proposed restriction is clear and unambiguous.

Firstly, the enforcement of the ban on placing on the market could be done using one of the following methods:

- Spot checks of imported fishing tackle (customs).
- Manufacturer site inspections.
- Retailers site inspections.
- Retailers/social media website inspections.

Such an enforcement could include one or more of the following checks:

- Wipe test (aka sodium rhodizonate test)

[307] An alternative is a possible replacement for a substance. The alternative should be able to replace the function that the substance performs. An alternative could be another substance or could be a technology, or a combination of both. The word 'alternative' does not imply or mean that the alternative is suitable (i.e. technically, economically feasible and resulting in an overall reduction of the risk for the human health, and the environment).

- Laboratory testing to check the presence of lead in selected fishing tackle. ICP-MS[308] is a common method to detect lead.
- Paper inspection: verification of paper records such as inventory records (purchased goods, sold goods, source of supply, material composition).

The paper inspection could play a key role in order to identify and track non-legal supply chain patterns such as the selling and distribution of 'home-made' lead fishing tackle.

Secondly, the enforcement of the obligation to inform at the point of sale the consumers, could be done together with the retailer inspections via a visual inspection. It can be easily visually verified that information on lead hazard and risk are available, and visible at the points of sale, in the shops and on websites selling lead fishing tackle.

Finally, with regard to the enforcement of the ban on use (use of lead fishing tackle, and use of techniques or equipment to intentionally drop off sinkers), it will have to be carried out on the sites of use, i.e. on fishing spots. REACH inspectors might not be the most appropriate inspectors to ensure the respect of the restriction provision. Nevertheless, the enforcement on the site of uses could be performed by the existing national relevant enforcement authorities for the fishing matters, i.e. either fishing associations or local area authorities or ministries depending on the EU country. These inspectors, usually fishers themselves or used to perform fishing inspections (licence, equipment, fish), are assumed to be knowledgeable, and skilled to recognise lead fishing tackle and drop off techniques or equipment.

With regard to lead in fishing tackle, a ban on using lead fishing tackle cannot be dissociated from a ban on placing on the market. From a practical point of view, it is easier to check compliance with a ban on placing on the market rather than a prohibition of use. However, a ban on using lead fishing tackle is considered necessary to stop the use, exposure and releases of home-casted lead fishing tackle (cf. Annex D).

Despite the proposed restriction, there is a risk of fishers making their own lead fishing tackle (via home-casting), or buying lead fishing tackle from the Internet or abroad (i.e. outside EU). Indeed, while the market among professionals might self-regulate once a restriction is in place, recreational fishers might still be able to purchase lead-fishing tackle directly from other individuals via friends, relatives, but also Facebook, social medial, or shops and websites located outside Europe (cf. examples in Annex D).

For example, Perrins et al. examined lead poisoning of swans in the United Kingdom following the 1987 ban on placing on the market (Perrins et al., 2002). In this study, 13.7 % of fishing tackle with weights that were removed from rescued swans (34/249 swans) included illegal lead weights, suggesting that some anglers may be violating the ban, unless the swans had ingested lead weights that were lost prior to the ban. In addition, an unpublished study using surveys to assess compliance of anglers to the 1987 UK ban found that 7 % of anglers were using banned lead fishing weighs (Rattner et al., 2008).

Even if under the proposed restriction the use of lead fishing tackle will be prohibited, the role of enforcement at all levels of the supply chain (including at the fishing spots) is crucial to ensure a level playing field and a fair competition for the EU manufacturers, but also to achieve the foreseen releases reduction from the proposed restriction. During the call for evidence, the UK competent authorities reported some issues enforcing the current UK ban on internet sales, stock of existing lead tackle, and illegal sale of lead weight in some outlet

[308] ICP-MS stands for 'Inductively Coupled Plasma Mass Spectrometry'. It is a type of mass spectrometry.

(CfE #936 – UK EA). In Denmark, an enforcement campaign revealed in 2010 that almost 10 years after the entry into force of the ban on importing and placing on the market lead fishing tackle, such fishing tackle were still available in stores: the Danish EPA, carried out spot checks, and analysed 266 randomly selected fishing tackle from 20 stores across the country and found there were excessive amounts of lead in 100 cases. In only one store was all the tackle lead-free[309].

2.8.4.3. Monitorability

The proposed restriction on lead in fishing tackle is monitorable.

The presence of lead and non-lead fishing tackle on the market could be monitored using the same methodologies as the one used by the Dossier Submitter to perform the market survey: contact fishing tackle manufacturers, importers, retailers, consult website and social media pages. Mystery shopping campaigns on websites and in retailers' shops could also be conducted for the same purposes.

In addition, the Member States could take advantage of the existing provisions set in the SUP Directive (EU) 2019/904. Indeed, under the SUP Directive, Member States would be required to monitor fishing tackle containing plastic placed on the market, as well as waste fishing tackle collected, with a view to the establishment of binding quantitative EU-wide collection targets[310].

Expanding these monitoring and data requirements to reporting data on lead presence in fishing tackle would be useful for the monitoring of the proposed restriction. This might not be a big additional effort as there is an overlap between the actors in the supply chain placing on the market lead fishing tackle and fishing tackle containing plastic.

[309] https://eng.mst.dk/chemicals/chemicals-in-products/the-chemical-inspection-service/control-of-lead-in-fishing-tackle/

[310] Article 13 (1 and 2): '(1) Member States shall, for each calendar year, report to the Commission (…) data on fishing gear containing plastic placed on the market and on waste fishing gear collected in the Member State each year. The first reporting period shall be the calendar year 2022. (2) The data and information reported by Member States (…) shall be accompanied by a quality check report. The data and information shall be reported in the format established by the Commission'

3. Assumptions, uncertainties and sensitivities

3.1. Lead in hunting ammunition

3.1.1. Main assumptions and uncertainties

Relation to the previous restriction on lead shot in wetlands

The restriction of lead gunshot in wetlands was adopted and published in the Official Journal on 25 January 2021. The final wording of the legal text defines wetlands according to the Ramsar definition, includes a buffer zone of 100m, and offers the possibility to Member States with more than 20 % land cover of wetlands to put in place more stringent measures (e.g., a full ban on the use of lead shot).

As the publication of this restriction was very recent, the Dossier Submitter has no knowledge as to whether a) Member States will make use of the possibility to put in place more stringent measures, and b) to what extent hunters will react to the new legislation beyond the required cease of using lead gunshot in wetlands. The Dossier Submitter has tried to capture this uncertainty by assuming varying scenarios (best case, central case, worst case) of adaptation. These assumptions have an influence on the share of alternatives that are assumed to be used for terrains outside of wetlands (terrestrial compartment) as well as on the estimation of compliance costs for hunting outside wetlands.

Relation to on-going legislation

During the development of the Annex XV report two initiatives were launched that may have an impact on the results of the impact assessment undertaken by the Dossier Submitter. First, Denmark announced a full ban on the use of lead bullets in hunting. Second, the German Bundesrat issued a statement that within a short period of time lead bullets in hunting could be abandoned, at least for hunting ungulates.

These two initiatives may have a positive spillover effect as they may fuel the supply and demand of alternatives to lead ammunition even outside of the respective jurisdictions, and therefore reduce both the costs and overall emission reductions estimated for the proposed restriction.

Need to buy new guns

The Dossier Submitter had analysed the overall need for gun replacement already in the wetlands restriction proposal. This information as well new information submitted in the call for evidence and the consultation of the Annex XV report leads the Dossier Submitter to conclude that there is little need for gun replacement. This conclusion is based on the following observations.

- As for rifles, the Dossier Submitter observes that gun compatibility (and hence the need to replace guns) depends very much on the hunter being able to match the bullet and the rifle. There is little dispute that replacement is needed for rifles above 6.5 mm. For rifles with a calibre between 5.5/5.6 mm and 6.5 mm, some disputes exist, which is due to (i) different interpretations in national hunting legislations that are not all adapted yet to allow lighter bullets (legislative initiatives to fix this are finalised or have been initiated in several MS), and (ii) perceptions on the non-availability of alternatives, whereas many manufacturers already offer non-lead bullets with different twist rates.
- As for shotguns, the Dossier Submitter observes that (i) shotguns manufactured after 1970 are able to fire steel; (ii) according to figures submitted by FACE in the

consultation (#3467), six million hunters own 20.6 million shotguns of which 5.1 million (25 %) are not suited for standard steel cartridges. This implies that on average each hunter owns 3.4 shotguns of which 2.6 are suitable for standard steel cartridges. Whilst this does not preclude that individual hunters would only own one shotgun that is not suitable for standard steel cartridges, the vast majority of hunters will own at least one shotgun that is suitable; (iii) for those individual hunters that own only a shotgun not suitable for standard steel cartridges other alternatives to lead shot (bismuth, tungsten) are available. Whilst these alternatives are 3-4 times more expensive, the extra cost per hunting season is still marginal. To see this, assume an average hunter spends about 100 shots per season. That corresponds to about €45 per season spent on lead shot; if this hunter was now to switch to one of the more costly alternatives, they would have to spent €135-180 which is less than 5 % of the average hunting budget in the EU.

Taking these considerations into account, the compliance cost per hunter is estimated to be lower than in the wetlands restriction dossier. This is expressed by a better cost-effectiveness ratio, i.e. less expenses per tonne of lead abatement.

Human health risks

Information is insufficient on the following elements affecting the human health risk assessment for hunters and their families in the EU:

- potential health risk to hunters from the inhalation of lead dust that is generated during the use of lead ammunition is lacking; data on blood lead levels in hunters in relation to the frequency of shooting and the type of ammunition used could help clarifying the extend of this specific health risk for hunters;
- no information is available on the incidence of home-casting of lead bullets among hunters;
- no information is available on the incidence of accidentally ingesting lead gunshot by small children.

The risk assessment for the consumption of game meat in the EU is based on data from EFSA on the concentration of lead in game meat and the consumption of game meat with the 50^{th} percentile of the consumption distribution taken as an input in modeling the game meat consumption in typical hunter families. Appropriate measurement data on blood lead levels in hunter family members that frequently consume game meat would help verifying the blood lead levels and the resulting risks modelled on the basis of the assumed intake of game meat. Specifically, exposure of female members of hunter families and small children (aged under 7) would be of interest because of the specific concern of developmental neurotoxicity of lead in small children.

The following information would seem to be of particular importance when performing new studies:

- sufficient number of hunter family members and controls;
- identification of the gender;
- identification of the age (children under the age of 7, children older than 7 years, adults, elderly);
- clarification of the hunting status (hunter or non-hunter);
- type of game meat consumed;

- amount and frequency of consumption of game meat;
- identification of other sources of lead intake;
- appropriate control groups of as same gender, same age group, non-hunting status.

Hunting statistics

The Dossier Submitter was unable to find hunting statistics of sufficient detail for all EU Member States. Indeed, large differences in detail—from very detailed information in Finland to rudimentary information in Belgium—were encountered. Interpolations had to be made in order to compile an EU-representative game bag. By nature of the exercise, this introduced uncertainty in the Dossier Submitter's analysis which has been handled by higher and lower end estimates regarding the amount of lead that is used and hence on the estimation of cost-effectiveness estimates for the various restriction options.

Transition period

A sufficiently long transition period may allow more time for hunters and industry to adjust to the use of lead-free ammunition. Therefore, a longer transition period is expected to have a positive impact on compliance but would inevitably lead to a larger emission of lead to the environment (compared to a shorter transition period).

Price of steel shot

Some stakeholders submitted information on the expected demand and supply of steel to produce steel shot. In a UK voluntary agreement to phase out the use of lead in hunting, the UK manufacturers pointed out a similar risk of shortage of supply. Such a shortage of supply would have an influence on the manufacturers' ability to provide ample supply of steel shot. In the short to medium term this could even have an influence on the price of steel shot and hence on the cost to comply with the proposed restriction. However, the information on demand and supply of steel was too limited to allow the Dossier Submitter explore price elasticities and other market effects.

3.1.2. Sensitivity analysis

This section explores in a simple manner the sensitivity of key outcomes of the socio-economic analysis (such as the remaining releases, the average annualised costs of the restriction and its cost-effectiveness) associated with potential variations in a few key input variables. The results of this sensitivity analysis are summarised in Table 3-1, wherein the arrows (🡅/🡇 means the assumption increases/reduces the estimated impact, while **O** indicates that no significant change is expected to result from the variation) indicate the impact that the uncertainty in a key parameter has on the outcome of the socio-economic analysis (such as the average annualised costs of a restriction and its cost-effectiveness).

Table 3-1: Summary of SEA sensitivity analysis (lead in hunting)

Parameter tested	Impact on abatement potential	Impact on annualised costs	Impact on cost-effectiveness
Adaptation to wetlands restriction lower than assumed	🡅	🡅	**O**
More hunters buy a new gun instead of switching to bismuth	**O**	🡇	🡇
Longer transition period	🡅	🡇	🡇

Parameter tested	Impact on abatement potential	Impact on annualised costs	Impact on cost-effectiveness
Higher price of steel shot	O	↑	↑

3.2. Lead in sports shooting

3.2.1. Main assumptions and uncertainties

Despite extensive efforts by the Dossier Submitter (including the conduct of a Member States authority survey in 2020)[311], it was not possible to obtain a detailed overview of the presence of risk management measures (RMMs) already in place at shooting ranges in the EU. Whilst the Dossier Submitter found example cases and identified good practices, no statistics on concrete measures in place was possible as a database of this level of detail and geographic coverage does not exist on an EU-wide level and often not even on a national level.

This has an influence on any conclusion the Dossier Submitter can reach on the extent of the capabilities of shooting range owners and operators to recover a certain fraction of lead spent by shooters. To overcome this, the Dossier Submitter assessed various scenarios covering known types of shooting ranges. By nature of the exercise, this introduced uncertainty in the Dossier Submitter's analysis which has been handled by higher and lower end estimates regarding the amount of lead spent and recovered on shooting ranges with certain RMMs, and hence on the estimation of cost-effectiveness estimates for the various restriction options.

Human health risks

Information is insufficient to conclude on potential health risks in the EU from the use of lead ammunition for outdoor sports shooters, as:

- information on blood lead levels in sports shooters (practicing outdoor) in relation to the type and frequency of ammunition used (including information if a lead-containing primer is used), the discipline and the conditions of shooting (such as covered or open stand) could help clarifying the extend of the specific health risk from outdoor shooting;
- recovery of lead gunshot and lead bullets from trap chambers or 'best practice' sand traps is expected to result in relevant exposure in case that strict personal hygiene measures are not complied with. There might be specific concerns when lead recovery is performed by recreational shooters and not by professionals. No information is however available on how the recovery of spent lead would add to the body burden in recreational shooters;
- no information is available on the incidence of sports shooters that are home-casting lead bullets for sports shooting;
- no information is available on the incidence of small children accidentally ingesting lead gunshot or air pellets used for sports shooting;

[311] See Annex E.5 for details.

- no information is available to assess potential health risks from the consumption of drinking water (or food) contaminated via the environment by lead deposition on shooting ranges.

Number of ranges in Europe

An estimate of the number of shooting ranges in the EU was made based on the results of the Member States survey (2020) as described in Annex B 9.1.3. However, the overall number of ranges arrived at is uncertain. Even though temporary ranges/areas appear to be commonly used in the EU, e.g. in France, the Dossier Submitter could not be establish their number.

Amount of lead used in sports shooting

An estimate of the amount of lead used in the EU was made (as described in Annex B 9.1.3) based on information available from the CSR of the lead REACH registrants (2020) and on information provided by sports shooting associations. However, the overall amount arrived at is uncertain. Comparison with the overall mass balance of ammunition import/export and production in the EU (see Annex A.2 for details), highlights this uncertainty. The amount of lead released, and the uncertainties related to this estimate are discussed in detail in Section 1.5.3.1.2.

Amount of lead released to the environment from bullets

The Dossier Submitter calculated the emission of lead to the environment (surface water and soil) at rifle/pistol ranges in relation to different RMMs installed. Those calculations are subject to several uncertainties as:

- no information was available on the number of soil berms used to trap bullets installed on existing ranges. As this type of RMM is least effective in containing lead, assumptions about the number of sites in need of upgrading has a large impact on the costs of any proposed restriction option. As a central scenario, the Dossier Submitter assumed that 10 % of all shooting ranges have currently soil berms installed. Changing this assumption to 5 % would reduce the calculated emissions to the environment over 20 years from about 5 800 tonnes (mid value for RO2c) to 4 000 tonnes, whereas increasing the assumption to 15 % would increase the calculated emissions over the same period to about 7 700 tonnes.
- The costs to change RMMs would be €950m, €1 100m, and €1 200m assuming 5 %, 10 %, or 15 % of soil berms, respectively. Consequently, it would be useful to receive more information on the share of soil berms used in the EU to trap bullets.
- The reduction in weathering of lead bullets due to a roof or a coverage (30-70 %) is only an estimate. This information would be important to assess whether a roof might provide sufficient minimisation of weathering and leaching of lead, or a water management system would be required in addition.
- The estimated leaching rates of weathered lead to surface water and soil (2 % and 20 % respectively) were selected to achieve leaching rates as measured in 3 rifle/pistol ranges in Norway. However, the RMMs in place were not described in detail.
- The Dossier Submitter’s calculations ignore possible fractioning of bullets in the soil and the consequent increases in lead leaching.
- Calculated emissions do not consider that for sand traps, sand/soil berms or soil berms recovery of lead is typically done every 3-5 years and for sand/soil berms the

recovery effectiveness has been reported to be 65 %. Furthermore, the process of lead recovery from berms increases the leaching of lead by a factor of 2.5 because of the mechanical breakdown of weathered lead bullets (Yin et al., 2010).

In comparison, lead recovery from trap chambers can be performed several times a year with a recovery effectiveness of up to 100 % without relevant weathering of lead bullets. Therefore, the emissions calculated for sand traps, sand/soil berms or soil berms from lead remaining in the structure could be higher. **Transition period**

For sports shooting the Dossier Submitter proposes a provisional transition period of 5 years (see Section 2.3.2.8). The main driver for the proposed transition period is the time required to implement mandatory environmental RMMs to allow regular recovery of lead with high effectiveness and to prevent environmental contamination. In the absence of reliable information on the time needed to implement such measures and taking into account their financing, potential remediation of existing contamination, planning and construction of sites, it may, however, be considered that the implementation would take longer. Therefore, the Dossier Submitter suggests 5 years as a starting point for SEAC's deliberations on an appropriate transition period. Should the SEAC consultation result in a better understanding of the impacts brought about by these options, a longer transition period might be justified.

Price of steel shot

Some stakeholders submitted information on the expected demand and supply of steel to produce steel shot. In a UK voluntary agreement to phase out the use of lead in hunting, the UK manufacturers pointed out a similar risk of shortage of supply. Such a shortage of supply would have an influence on the manufacturers' ability to provide ample supply of steel shot. In the short to medium term this could even have an influence on the price of steel shot and hence on the cost to comply with the proposed restriction. However, the information on demand and supply of steel was too limited to allow the Dossier Submitter explore price elasticities and other market effects.

3.2.2. Sensitivity analysis

This section explores in a simple manner the sensitivity of key outcomes of the socio-economic analysis (such as the remaining releases, the average annualised costs of the restriction and its cost-effectiveness) associated with potential variations in a few key input variables. The results of this sensitivity analysis are summarised in Table 3-2, wherein the arrows (🡹/🡻 means the assumption increases/reduces the estimated impact, while **O** indicates that no significant change is expected to result from the variation) indicate the impact that the uncertainty in a key parameter has on the outcome of the socio-economic analysis (such as the average annualised costs of a restriction and its cost-effectiveness).

Table 3-2: Summary of SEA sensitivity analysis (lead in sports shooting)

Parameter tested	Impact on abatement potential	Impact on annualised costs	Impact on cost-effectiveness
Effective RMMs already in place at more shooting ranges	🡻	🡻	**O**
Amount of lead gunshot used in sports shooting is higher	🡹	🡹	**O**

Parameter tested	Impact on abatement potential	Impact on annualised costs	Impact on cost-effectiveness
Number of shooting ranges in the EU that allow use of lead gunshot is higher	↑	↑	O
Longer transition period	↑	↓	↓
Higher price of steel shot	O	↑	↑

3.3. Lead in fishing tackle

3.3.1. Main assumptions and uncertainties

The lethal and sub-lethal effects of lead on wildlife and humans have been well known and scientifically documented for decades. However, the risk of lead fishing tackle for the wildlife and fishers identified in this restriction proposal could not be underpinned by extensive exposure data. Indeed, the scientific documentation on the extent of both the lead fishing tackle ingestion by birds and the exposure to lead fumes and vapour during home-casting is in general very poor. According to Grade et al., this can be explained by three main reasons: (1) the lack of funding and research on this topic, (2) the difficulty to retrieve bird carcasses that would have died from lead fishing tackle poisoning, and (3) the inaccurate classification of small lead object ingested by birds due to the difficulty to distinguish a lead ammunition from a lead sinkers after it had been eroded in the gizzard of the birds (Grade et al., 2019).

In order to circumvent this lack of scientific data, and in order to be able to conclude on the risk both for the wildlife and the human health, the Dossier Submitter has taken the approach to look at specific case studies performed on well documented birds to confirm the environmental risk, and on specific populations to confirm the human health risk when home-casting.

In addition, as discussed in the previous sections, the three main uncertainties with regard to the impact assessment are:

EU manufacturers' and consumers' reaction to the ban

The Dossier Submitter assumes that the expected reaction from EU manufacturers to the proposed restriction would be 'reformulation', i.e. the EU manufacturers would switch their manufacturing from lead fishing tackle to non-lead ones.

Nevertheless, the continuity of the manufacturing activity of the EU manufacturers are bound essentially to consumer responses to the ban (will they continue buying European products, or will they purchase cheaper products sold on the Internet without guarantee that they do not contain lead, will they do more home-casting?), and the effectiveness of the enforcement. The expected EU manufacturers' reaction to the ban and the impact on the employment in these SMEs is therefore highlighted as an important uncertainty.

The assumption on the expected EU manufacturers' and consumers' reaction to the proposed restriction may therefore overestimate the affordability of the EU manufacturers.

Home-casting

Uncertainties exist both on the extent of the current practice, which are estimated by some stakeholders as representing up to 30 % of the lead fishing tackle placed on the market, but also on the potential response from the fishers to the restriction proposal.

It is indeed assumed and expected that the restriction proposed for lead in fishing tackle would stop 'indirectly' the practice of home-casting. This assumption is plausible considering that the proposed restriction includes a ban on the use of lead fishing tackle (purchased and home-casted ones) at the fishing spots, as well as information to the consumers on the hazard and risk of lead at the point of sale.

Nevertheless, as the home-casting is performed in the private sphere (and not within the scope of the proposed restriction), and as the enforcement at the point of use is uncertain, it is also possible that the quantity of home-casted lead fishing tackle would not decrease. In fact, the home-casting of lead fishing tackle may even increase as fishers would be tempted to avoid purchasing more expensive lead-free sinkers and lure. This could possibly undermine the intended health benefits expected from the proposed restriction.

This uncertainty is also discussed in Section 2.8.3.2.

Enforcement of the proposed restriction

The Dossier Submitter is assuming that the enforcement is feasible, practical and can be done in a harmonised and thorough manner both at the point of sale and at the point of use of the fishing tackle. These assumptions on the enforcement most probably overestimate the benefits, and the risk reduction of the proposed restriction. The uncertainties related to the enforcement are also discussed in Section 2.8.4.2.

In addition, to these three major uncertainties, several assumptions were made due to the limited information provided in the responses to the call for evidence and the ECHA market survey. For some of the assumptions, a sensitivity analysis is performed:

Recreational fishing statistics

There are no consolidated statistics on number of fishers, licences, average fisher expenses at the European level on recreational fishing (cf. Annex A). The general lack of socio-economic data on recreational fishing is also recognised both by EFTTA (European Fishing Tackle Trade association), and EAA (European Angling Association) and was presented and discussed with some members of the EU parliament in 2017[312].

The Dossier Submitter contacted various Fishers Associations, such as the European Angling Association (EAA), the International Sport Fishing Confederation (CIPS), the International Sea Fishing Federation (FIPS-M), the International Game Fish Association (IGFA), the European Federation of Sea Anglers (EFSA) and the European Anglers Federation (EAF), in order to obtain information and statistics on number of fishers, fishing licences and fishing expenses. Via EAA, only the Finnish, Dutch, Slovenian and Spanish national fishing associations responded to the Dossier Submitter questionnaire. Information and country specific statistics were also gathered from literature and internet search and compared with US and Canadian data for which national statistics are available.

The assumptions on number of fishers, fishing licences and fishing expenses per fisher, even if uncertain and not underpinned by an EU wide survey or statistics are considered plausible when comparing all the available data available for specific countries (European or not). The estimated number of fishers was discussed with stakeholders during the Fishing round table (cf. Annex E) and was considered plausible by the participants.

[312] https://www.eaa-europe.org/european-parliament-forum/ep-recfishing-forum-2014-2019/08-march-2017-socio-economic-data.html

The detailed assumptions on fishing-related statistics are described in Annex A.

Estimations of lead fishing tackle manufactured and placed on the EU market

There are currently no statistics, nor consolidated information on the use, and sales of lead in fishing tackle in Europe: customs and Member States do not have any statistics on this topic, the European and national trade and fishing associations do not monitor the use and sales of lead either.

In addition to the traditional supply chain (industrial manufacturer->distributor/wholesaler->retailer->fishers), fishers, angling clubs, or retailers, may also cast their own fishing tackle (aka home-casting) either for their own use or for direct retail to other fishers. EU-wide statistics or precise information of lead in home-casting activity is missing as well. Some plausible and justified estimates and assumptions have therefore been made based on data gathered during the ECHA market survey. All assumptions are described in detail in Annex D.

Baseline assumptions on lead fishing sinkers and lures lost/released to the environment

Information on lead fishing sinkers and lures released to the environment is available in the ECHA investigation report (ECHA, 2018a). This information is, primarily, reproduced from an earlier 2004 European Commission study on 'Advantages and drawbacks of restricting the marketing and use of lead in ammunition, fishing sinkers, and candle wicks' (COWI, 2004). The information is therefore rather old (data from 2004), scarce (limited to some Member States), and all assumptions that were used to estimate the used and released tonnage (from recreational and commercial fishing) not always explicit or fully traceable.

Limited information has been submitted during the call for evidence on lead tonnage lost/released in the environment (CfE#1153 - Modified Materials BV).

There is no European level study to estimate the amount of lead fishing tackle lost yearly in the environment. This might be explained by the fact that the loss of lead tackle is influenced by the intensity of fishing effort, the type of fishing, the fisher skills and experience but also the characteristics of the water body (vegetation, bottom structure, rocky areas), and varies spatially and seasonally.

In order to estimate the losses of lead fishing tackle in the environment, the Dossier Submitter has therefore conducted a literature review, and explored different methodologies in order to estimate the quantity of lead fishing tackle releases yearly in the environment.

Based on this research, which is further detailed in Annex D, the Dossier Submitter presented plausible assumptions. Nevertheless, due to the level of uncertainties, the Dossier Submitter undertook a sensitivity analysis on one of the key input parameters to estimate the quantity of lead released in the environment: the average amount of lead fishing sinkers and lures lost per year/per fisher.

Cost of the restriction proposal

The cost of the restriction proposal is essentially driven by the retailing cost of non-lead fishing tackle. Uncertainty remains regarding which substances/raw materials will be used to replace lead in non-lead fishing tackle, many options are plausible.

In order to estimate the cost of the restriction proposal, the Dossier Submitter considered the current average retailing price of the non-lead fishing tackle (ECHA market survey). Nevertheless, due to the lack of consumers' demand, competition on the market for that type of product, and the potential lack of economy of scale at the manufacturing level, the current retailing prices might be overestimated compared to the future. The outcome of the ECHA market survey reported in Annex D indicates also that the retailing price of non-lead fishing tackle varies depending on its size (≤ or > 50 g). In addition, the retailing prices of some alternatives do not match, and exceed by far, the usual profit margin in the sector. Therefore, the Dossier Submitter undertook a sensitivity analysis on the following parameters: retailing price of non-lead fishing tackle and proportion of lead fishing-tackle ≤ 50 g.

3.3.2. Sensitivity analysis

This section explores in a simple manner the sensitivity of key outcomes of the socio-economic analysis (such as the remaining releases, the average annualised costs of the restriction and its cost-effectiveness) associated with potential variations in a few key input variables. The results of this sensitivity analysis are summarised in Table 3-3, wherein the arrows (🡹/🡻 means the assumption increases/reduces the estimated impact, while **O** indicates that no significant change is expected to result from the variation) indicate the impact that the uncertainty in a key parameter has on the outcome of the socio-economic analysis (such as the average annualised costs of a restriction and its cost-effectiveness).

Table 3-3: Summary of SEA sensitivity analysis (lead in fishing tackle)

Parameter tested	Impact on abatement potential	Impact on annualised costs	Impact on cost-effectiveness
Average quantity of lead lost per year and fisher (sinkers & lures) **lower** than default value	🡻	**O**	🡹
Retailing price of non-lead fishing tackle **lower** than the default value	**O**	🡻	🡻
Proportion of fishing tackle ≤ 50 g **higher** than the default value (55 %)	**O**	🡹	🡹
Longer transition periods	🡻	🡻	**O**
Reversed transition period (i.e., 5y for sinkers and lures >50 g, and 3y ≤50 g)	**O**	🡻	🡻

4. Conclusions

The conclusions for each of the sectors of the proposed restrictions are summarised below.

4.1. Hunting

Identified risk

For all uses of lead that are identified in this dossier, the Dossier Submitter concludes that (consistent with the final RAC opinion of the use of lead gunshot in wetlands and other restrictions on lead), the use of lead in gunshot, bullets, and projectiles poses a risk to wildlife such as birds and to human health that is not adequately controlled and needs to be addressed at the EU level.

Specifically, more than one million birds[313] are expected to die due to direct lead gunshot ingestion (primary poisoning). A significant number of birds are also expected to be affected by sublethal poisoning[314], which may also contribute to premature mortality[315]. For several long-lived species with low reproductive rates (e.g., raptors and scavengers) mortality of even a single individual (as a consequence of lethal or sublethal poisoning) may be concerning in terms of conservation due to the very limited number of individuals in the EU. Several waterbird species can also suffer from lead poisoning from the ingestion of lead gunshot in terrestrial habitats.

Lead poisoning of taxa other than birds (such as wild mammals), domestic animals (such as dogs) and livestock (ruminants, poultry) is also occurring to some extent, although specific data are limited.

The detrimental effects of lead on human health are well documented. The range of reported adverse effects includes neurodevelopmental effects, cardiovascular diseases, impaired renal function (including chronic kidney disease – CKD), hypertension, impaired fertility and adverse pregnancy outcomes. However, the greatest public health concern is the neurodevelopmental toxicity of lead in children aged seven and younger. Calculations indicated a risk for loss of IQ points in young children in case of frequent consumption of game meat (e.g. in hunters’ households).

Additionally, adults and young children are at risk of lead poisoning resulting from home casting of lead bullets.

Availability and suitability of alternatives

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

Where field trials comparing lead and steel gunshot have been conducted, no differences were found in several measures, including the number of birds killed per shot or wounded per shot (e.g., see Pierce et al., 2014). Further, hunters in Denmark, the Netherlands, and the Flemish region of Belgium where the use of lead shot is restricted in all terrains, do not report problems with the effectiveness of non-lead gunshot.

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[313] See section 1.8.5 for details.

[314] Lethal and sublethal effects can occur after acute and/or chronic exposure. Sublethal lead poisoning can increase the probability of mortality from hunting (predation), collisions with objects (flying accidents) and illness or death from disease.

[315] See also comment #3343 (CMS, ad hoc Expert Group).

Alternatives to lead bullets for large game are used, are as effective as their lead-based counterparts and are economically feasible..

Concerning large calibre bullets, various field studies including Gremse and Rieger (2012), Kanstrup et al. (2016), Knott et al. (2009) and Martin et al. (2017), have found no difference in the suitability for hunting between lead and non-lead bullets and conclude that non-lead ammunition is as effectives as lead ammunition.

For small calibre bullets (less than 5.6 mm, rimfire) the Dossier Submitter has identified that currently only limited alternatives are available on the EU market with little evaluation has been done yet of their technical suitability. Alternative small calibres do not yet achieve the same level of precision as lead ammunition. However, whilst this difference in performance is apparent it has not been unequvicolly demonstrated that currently available alternatives are unsuitable for hunting.

Furthermore some uses of lead bullets (FMJ) for Nordic bird hunting and the suitability of non-lead ammunition for seal hunting, airgun ammunition and muzzle loading ammunition has been verified based on comments for the consultation and the Dossier Submitter has evaluated the advantages and disadvantages of possible derogations for these uses.

Economic feasibility

The price difference between lead and non-lead ammunition has gradually declined over the years, to such an extent that the prices for lead and non-lead are comparable. That said, there remain differences either due to local demand (in the absence of regulations), local variations and various calibre or gunshot sizes for which a suitable alternative does not yet exist.

Effectiveness and risk reduction

Using non-lead gunshot and bullets would reduce the lead intake from game meat consumption for adults and children from hunter families and reduce the risks resulting from exposure to lead fumes and dust from home-casting lead bullets

Using non-lead gunshot and bullets would reduce risks to wildlife especially (but not only) birds, in line with the EU obligations under the EU Birds Directive, AEWA, CMS and CMS Raptors MOU. 70 wild bird species (including 43 species on Annex 1 to the EU Birds Directive) would be significantly protected from primary and secondary poisoning from lead ammunition (including both lethal and sublethal effects).

The proposed restriction would also contribute to EU obligations under the AEWA agreement and CMS convention for migratory waterbird species that feed outside of wetland areas (supplementing the existing restriction on lead in gunshot in wetlands).

Practicality

The proposal is deemed to be practical, as demonstrated by the existing limitation on the use of lead gunshot in the Netherlands and in Denmark as well as by existing legislation concerning bullets at Laender level in Germany and various other legislations that are in place in national parks, state forests and other jurisdictions at national levels.

Enforceability

The measure is considered to be enforceable. Methods exist to inspect lead ammunition used by hunters. Enforceability of a total ban on the placing of the market and use of lead gunshot can be done by inspections at the point of sale as well as in the field. Enforcing a ban on lead-containing bullets may be more difficult in practice because of the derogations for continued use under certain conditions and has to be carried out at the point of use.

Should game meat be made commercially available, then certificates of testing obtained already with current testing methods would create an incentive for users to comply with the legislation and at the same time allow enforcers to verify to what extent compliance with the legislation is achieved.

Monitorability

The restriction is monitorable. The existing methods that were used to verify the extent of lead poisoning can also be used to verify and monitor progress of the phase-out of lead. At slaughterhouses, existing methods can be used to detect any lead in game meat.

4.2. Sports shooting

Identified risks

The Dossier Submitter concludes that the use of lead in gunshot and bullets in outdoor sports shooting (all uses) poses risks to the environment and to humans (mainly via the environment) that are not adequately controlled and needs to be addressed at the EU level.

Spent lead projectiles from sports shooting (all uses) can contaminate the environment both during the service life and the end of life of a range, both on site and off site, via different pathways (including surface water runoff).

In areas of lead ammunition deposition, soil lead concentrations can be elevated, e.g., from a few to hundreds of times higher than in control soils and significantly higher than in uncontaminated soils where the mean content of lead worldwide is reported to be 17 mg/kg (Steinnes, 2013). Lead content in shooting ranges soils may even reach values comparable to those found in lead mining areas, making them unsuitable for any related agricultural use (including livestock farming). Despite this, in some EU countries it is possible to have shooting activities (ranges) taking place on agricultural areas.

Unrecovered lead gunshot may be ingested by many species of birds, especially when shooting ranges or temporary shooting are located/takes place in natural (remote) areas, including Natura 2000[316] (designated) sites or in agricultural areas. Lead gunshot can also contaminate the silage used in the fed of livestock (ruminants) when grown on sports shooting ranges or areas used for agricultural activities. Lead gunshot can also be directly ingested by poultry feeding on shooting areas.

Lead ammunition accumulated in shooting ranges may also represent a hot-spot of pollution which may result in leakage of lead polluted surface (runoff) water into local watercourses[317]. Under certain circumstances groundwater may also be affected by lead contamination. However, risks to (or via) groundwater are only likely to materialise many years after use of lead [318].

At EU level no harmonised risk management measure is in place to adequately manage risks to the soil and surface water compartments from lead ammunition, as well as to other specific receptors such as groundwater, wildlife (primarily birds) and livestock (ruminants and poultry).

In addition, risk management measures such as water treatment (if in place) may be discontinued at the end of the service life of a shooting range and there is no guarantee that

[316] For example, as reported in section 1.5.3.4, every year since 1990, the municipal hunting association of Chambles (Loire) organizes a shooting event on a natural site classified as Natura 2000.
[317] Uncontaminated surface water may also be used as a source for the production of drinking water.
[318] In general, any contamination can move (underground) along with groundwater flow, also reaching areas far away from the hot-spot.

a full remediation will be carried out at the end of service life, as it is not always required by Member State legislation.

Shooters may be at high risk of lead poisoning as a result of exposure to lead via inhalation and oral intake (hand to mouth) of lead dust resulting from intensive shooting at shooting ranges. Furthermore, risks to humans via the environment arise from the consumption of contaminated drinking water and food. Adults and children may be at risk as a result of home casting of lead bullets for muzzle loaders.

The Dossier Submitter notes that only a complete ban on the (placing on the market and) use of lead in ammunition for sports shooting would eliminate the risk to the environment and human health. In case of derogations under strict environmental conditions, the risks to the environment will be reduced. However, the risks to birds from gunshot would partially remain. Furthermore, such derogations will not have an impact on the risks for shooters from lead dust exposure while shooting; such risks are usually reduced by recommendations of good hygiene practices.

Indoor shooting is not in the scope of this restriction because it was considered that occupational health and safety measures would be sufficient to also protect recreational shooters. However, the Dossier Submitter has identified potential risks for occupational and recreational shooters from inhaling lead while indoor shooting[319].

The Dossier Submitter notes that the available information on lead exposure in shooting ranges and consequent blood lead levels in shooters are not suitable to separate the increment from lead-containing primers (such as lead styphnate) from the increment coming from lead bullets or from brass alloy which is frequently used in cartridge casing. Lead styphnate (EC number 239-290-0) is already identified as a substance of very high concern[320].

Availability and suitability of alternatives

For sports shooting, the dossier concluded differently per type of ammunition:

1. Alternative gunshot can be used effectively in sports shooting. Alternative shot material has been found to be effective in sports shooting as well as hunting, the barriers for further advancing with alternatives are not technical but are rather imposed by the rules of the ISSF, FITASC and other organisations that require lead gunshot to be used and/or have not approved other shot material.

[319] Blood lead levels in indoor shooters have been demonstrated to increase with increasing calibre of the weapon used (Demmeler et al., 2009) and with increasing shooting frequency (Mühle, 2010). In a more recent review (Laidlaw et al., 2017) 36 studies were compiled reporting blood lead levels mainly from indoor shooters (both occupational and non-occupational) with > 100 µg/L (31 studies), > 200 µg/L (18 studies), > 300 µg/L (17 studies), and > 400 µg/L (15 studies). Such elevated blood lead levels are associated with a variety of adverse health outcomes. The authors noted that there is a "lack of evidence" in the literature demonstrating that ventilation systems can maintain air lead levels at indoor ranges below the required values which is for example 50 µg/m^3 (US OSHA)[319] or 0.5 – 2.2 µg/m^3 (California guideline). The authors consider that of major concern is the number of women and children among recreational shooters, who are not afforded similar health protections as occupational users of firing ranges; regardless of type and user classification, shooting ranges constitute a significant and currently largely unmanaged public health concern. The author also noted that primary prevention of this risk requires development of lead-free primers and projectiles. Prevention includes better oversight of ventilation systems in indoor ranges and development of airflow systems at outdoor ranges, protective clothing that is changed after shooting, and cessation of smoking and eating at shooting ranges. (https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1025)

[320] https://echa.europa.eu/de/proposals-to-identify-substances-of-very-high-concern-previous-consultations/-/substance-rev/3457/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=239-290-0&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true

2. Alternative material for bullets (and airgun pellets) currently exhibits sub-optimal performance in terms of required accuracy in sports shooting. Jacketed large calibre lead bullets may reduce lead exposure of the shooter to lead dust produced in the barrel but do not reduce lead exposure to the environment. In the absence of suitable alternative bullets for sports shooting, the Dossier Submitter did not perform an evaluation of the impact of a ban on the use of lead bullets for sports shooting (the impact of implementing minimum RMMs are proposed instead).

Information submitted in the consultation on the Annex XV report suggested that a ban on the placing on the market of lead bullets in sports shooting would have impacts on the ammunition industry, including supply of ammunition to the defence sector. However, with the current scope of the restriction (which requires implementation of RMMs at shooting sites to minimise risks to the environment) such impacts are in principle avoided.

Economic feasibility

The Dossier Submitter performed an evaluation of the impact of a ban on the use of lead gunshot and compared as well various scenarios under which the transition to alternatives would be less costly than the requirement to install RMMs. From this analysis the Dossier Submitter concluded that in most cases switching to alternatives is more efficient except for ranges where the RMMs are in place and are already sufficiently effective.

The Dossier Submitter performed an evaluation of the economic feasibility of different bullet containments and concluded that the identified restriction options are economically feasible to implement.

Effectiveness and risk reduction

The restriction proposal on the use of lead gunshot in sports shooting is expected to reduce risks to the soil and surface water compartment. In addition, the use of non-lead gunshot would also contribute to reduce risks to birds, which may directly ingest lead gunshot in the fields (especially when the shooting ranges/areas are located in contexts that can be attractive to them, including temporary shooting areas located in Natura 2000 sites). Risks would be consequently reduced also for top predators (as raptors) feeding on species that may ingest lead gunshot. Using non-lead gunshot would also contribute to reduce risks to livestock (ruminants and poultry) reared on rural areas which may be used for shooting. Risks to groundwater (which may occur under certain circumstances) can also be reduced[321]. The implementation of adequate risks management measures for the use of lead bullets at sports shooting together with the ban on the use of the land for agricultural activities is also expected to reduce the identified risks to the environment.

Measures for the containment of lead bullets via trap chambers or sand traps (with a roof or cover and an impermeable barrier to the underlying soil) are already in place at many ranges in the EU, contributing to reduce the identified risk to the environment. However, the effectiveness of existing soil berms or sand/soil berms used frequently does not appear to be sufficient to control the identified risks. Renovation of existing sand traps, sand/soil berms or soil berms[322] to 'best practice' sand traps would effectively contribute to control risks, especially risks related to the soil and surface water compartment.

[321] Comment #3494 noted that no levels of lead in groundwater should be considered acceptable in line with the EU Water Framework Directive (WFD) 2027 objectives.

[322] Renovation can include a permanent layer between sand and soil to protect soil and groundwater, an overhanging roof or a permanent cover to reduce mobilisation of lead, and a water managements system for containment, monitoring, and, when needed, treatment of surface water to prevent water runoff.

Similarly, measures for the containment of lead gunshot as analysed in the optional conditional derogation for the use of gunshot in sports shooting could achieve a high level of containment but would achieve this at a higher cost, impacting the cost-effectiveness ratio. The Dossier Submitter also notes that the optional conditional derogation for the continued use of gunshot is not as effective in controlling the identified risks as a ban on use but may be deemed more proportionate regarding its socio-economic impacts on internationally competing athletes, due to the rules established by the ISSF.

The Dossier Submitter concludes that using non-lead gunshot and adopting adequate containments of bullets (via trap chambers or 'best practice' sand trap with and impermeable barrier and an overhanging roof or a permanent cover combined with a water management system and regular recovery of lead) would significantly reduce environmental impacts on all affected ecosystems.

Practicality

The proposal of the ban on the use of gunshot is deemed to be practical, as demonstrated by the existing examples in Norway, Denmark, Sweden, and the Netherlands were limitations on the use of lead gunshot for clay target shooting have been implemented successfully.

Similarly, trap chambers and 'best practice' sand traps have been found to capture lead effectively and are expected to be already in place in many ranges throughout the EU.

Enforceability

The measures are considered to be enforceable.

Methods exist to inspect shooters for use of lead gunshot. The ban on the placing of the market for lead gunshot is assumed to facilitate enforceability, since inspections may take place at the point of sale.

Should derogations be put in place that rely on RMMs (physical infrastructure), then the presence of this infrastructure can be inspected, and the recovery rate, especially that of lead gunshot, can be determined using the mandatory required documentation by site operators. Environmental monitoring of lead in runoff water and soil could provide further evidence on compliance .

Monitorability

Implementation of the restriction is considered to be monitorable. The notification/permit of shooting ranges required will allow sites to be identified for inspection. The requirement for the monitoring of surface water run-off will allow the effectiveness of the RMMs in place to be monitored.

4.3. Fishing

The proposed restriction for the lead in fishing tackle is three-fold: (1) a ban on placing on the market and using of lead fishing sinkers and lures with different transition periods depending on the weight of the lead fishing sinkers and lures, (2) a ban on using fishing tackle rig or equipment intended to drop off intentionally sinkers, and (3) the obligation to inform the buyers at the point of sale about the presence, toxicity, and risk of lead to human health and the environment.

The proposed restriction, and in particular the phase out of the placing on the market <u>and</u> the use of lead fishing sinkers and lures is the most effective way to reduce at EU level the lead poisoning of birds (22 species are at risk, with 11 listed on Annex 1 of EU Birds

Directive) and exposure of adults and children to home-casting fumes and vapours. It would also support the implementation of the EU Birds Directive, and AEWA agreement, as the main benefit of the proposed restriction for lead fishing tackle is essentially measured in terms of number of lead fishing tackle removed from the market or reduced for exposure to birds. Each lead fishing tackle which does not enter the environment reduces the number of lead fishing tackle available for ingestion and potential bird mortality.

Nevertheless, this ban, to be successful, should be accompanied by an obligation for the retailers to inform at the point of sale the consumers about the presence, toxicity, and risk of lead for human health and the environment during the proposed transition periods. This restriction condition is indeed a crucial element to trigger a change of perception and behaviour regarding lead within the fishing community. It aims at engaging stakeholders about the importance of the lead issue and leverage that concern as a trigger for positive change in their purchasing or DIY behaviour.

A voluntary support from the European and national fishing associations in explaining and educating the fishing community on the hazard and risks of lead would also be an asset for the successful roll-out of the proposed restriction. Such an approach, which would combine both regulatory actions (i.e. the proposed restriction) and voluntary/education programmes is recommended in recent studies (Grade et al., 2019).

The proposed restriction, via the proposed bans and information at the point of sale, would stimulate the availability, sale, and use of non-lead alternatives. Even though it would provide a warranted market incentive to the European industry to invest in non-lead alternatives, European manufacturers of lead sinkers and lures would also require time and financial support to update their production processes and equipment, as they are typically SMEs and might not have sufficient liquidity to switch to the manufacturing of alternatives.

For other producers, such as the manufacturers of alternatives, the proposed restriction could be seen as an opportunity for new markets rather than a burden. They would also need time and financial support to build up their capacity to respond to the demand.

In any case, enough time should be allowed for European manufacturers, retailers, and users to adapt to the changes resulting from any restriction on lead in fishing tackle. Industry and fishing association initiatives could also help the European industry in this transition by sponsoring or supporting the European manufacturers transition via the levy of a small fee from the fishing licences for example. Some additional financial support to help the European industry to transition to alternatives could also be granted through the financial aid mechanisms established by the European Green Deal policy, and the newly adopted Chemicals Strategy.

The enforcement of the proposed restriction at every level of the supply chain including on social media, where home-made fishing sinkers and lures can be purchased, and at the fishing points, where home-casted fishing tackle can also be used, is also critical to ensure the success of the proposed restriction. Experiences from Denmark and the UK, which have had a ban on the import and sales of fishing tackle in place for many years, prove that an active enforcement at every level of the supply chain is the only way to ensure that the ban is applied in practice (CfE #936- UK EA, and Danish enforcement experience[323]).

If the restriction options are prioritised based on economic efficiency and affordability rather than being based on their effectiveness in eliminating or minimising the identified risks,

[323] https://eng.mst.dk/chemicals/chemicals-in-products/the-chemical-inspection-service/control-of-lead-in-fishing-tackle/

then RO7 (Compulsory information to consumers at the point of sale about the presence and toxicity and risk of lead), together with complementary measures undertaken by EU fishers and trade associations, could be the most cost-effective option. However, this would not, in all likelihood, prevent the continued use of lead in fishing tackle or the continued lead poisoning of birds.

Two important issues could not be addressed by the proposed restriction either because they were beyond the boundary of the REACH Regulation, or because they were out of the scope of the Commission request. These two issues that would need to be addressed separately by the legislator are:

1. A ban on placing on the market fishing tackle rig or equipment intended to drop off intentionally sinkers. Such a ban is beyond the REACH mandate which can restrict a substance or its use, but not ancillary equipment or techniques.
2. Because the loss of fishing tackle in the environment during fishing is inevitable and inherent to the fishing activity itself, the accumulation and littering of fishing tackle in the environment is inevitable whatever the alternative used. The alternative to lead should be therefore be considered carefully and with caution. Some identified alternatives, e.g. zinc, are toxic for the wildlife but are not addressed by the current restriction proposal. A restriction on zinc fishing tackle is indeed beyond the scope of the Commission request which was specifically on 'lead' fishing tackle. Only a generic approach banning all substances toxic for the environment would have allowed to tackle the issue of 'toxic' alternatives.

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