Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Lead and its compounds

ECHA/RAC/RES-O-0000007115-80-01/F

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

3 June 2022

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON LEAD IN OUTDOOR SHOOTING AND FISHING

2 June 2022

ECHA/RAC/RES-O-0000007115-80-01/F

3 June 2022

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s): **Lead and its compounds**

EC No.: **-**

CAS No.: **-**

This document presents the opinions adopted by RAC and the Committee's justification for its opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

ECHA has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/61901/term on 24 March 2021. Interested parties were invited to submit comments and contributions by 24 September 2021.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: **Tiina SANTONEN**

Co-rapporteur, appointed by RAC: **Bert-Ove LUND**

OPINION ON AN ANNEX XV DOSSIER PROPOSING RESTRICTIONS ON LEAD IN OUTDOOR SHOOTING AND FISHING

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **2 June 2022**.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus.**

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: **Karen THIELE**

Co-rapporteur, appointed by SEAC: **Aart ROUW**

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **3 June 2022.**

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/61901/term on **29 June 2022**. Interested parties were invited to submit comments on the draft opinion by **29 August 2022**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **[date of adoption of the opinion]**. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]]**[1].

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and][5] 71(1) of the REACH Regulation.**] [**No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and][3] 71(1)**]**[6].

The opinion of SEAC was adopted **by [consensus.][a simple majority]** of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion**.]**[6].

[1] Delete the unnecessary part(s)

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1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

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, 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) 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) 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): 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*

Designation of the substance	Conditions of the restriction

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

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:
    - 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

Designation of the substance	Conditions of the restriction
	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 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.]*

Designation of the substance	Conditions of the restriction
	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] 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. 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

Designation of the substance	Conditions of the restriction
	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. - '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.

Note: The original restriction proposal has been revised by the Dossier Submitter based on comments received in the consultation, and the version above is thus the revised proposal that this opinion is referring to.

1.1. THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the restriction proposed by the Dossier Submitter on **Lead and its compounds** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the conditions are modified, as proposed by RAC.

The conditions of the restriction proposed by RAC are:

Designation of the substance	**Conditions of the restriction**
Lead and its compounds	Entry as proposed by the Dossier Submitter above, with the following modifications: 4. By way of derogation: *a. [OPTIONAL CONDITIONAL DEROGATION (part 1 of 4): Paragraph 1c shall not apply for gunshot sizes between **[1.9 to 2.6 mm]** if:* *- the retailer places lead gunshot on the market only for users licensed by Member States.* *b. [OPTIONAL CONDITIONAL DEROGATION (part 2 of 4): Paragraph 2d shall not apply for gunshot sizes between **[1.9 to 2.6 mm]** 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.* 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 **1 % w/w** (3% by way of derogation in copper or copper alloys for

Designation of the substance	Conditions of the restriction
	projectiles not defined as gunshot - this derogation shall be subject to a review prior to entry into force to determine if a concentration less than 1 % can be achieved) **,** 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 **1 % w/w** (3% by way of derogation 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)**,** 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. c. *[OPTIONAL DEROGATION (part 3 of 4): Suppliers of 'gunshot' containing lead in concentrations equal to or greater than **1 % 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*

Designation of the substance	Conditions of the restriction
	be provided in fold-out labels (leaflet); or on tie-on tags.] 7. Entry into force of the restriction: d. paragraph 1c, ~~**2c**~~ and 2d shall apply [5 years] from entry into force of the restriction. *k.* **paragraph 2c shall apply [shorter transition period than 5 years] from entry into force of the restriction**

Explanatory notes:

RAC agrees in general terms with the conditions of the restriction as presented by the Dossier Submitter but proposes several modifications, as described below.

RAC is of the opinion that it is an advantage if the same concentration threshold of 1% w/w for lead is used instead of 0.3% w/w also for the labelling requirements in §5 a, b, and c.

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. This is in line with the preferred option by the Dossier Submitter. In case §4a and §4b are not implemented, also optional derogations §5c and §6 become unnecessary. 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 (between 1.9 and 2.6 mm), as proposed by SEAC.

If a derogation allowing the use of copper or copper alloys containing lead up to 3% in other projectiles not defined as gunshot is implemented, then the labelling requirements specified in §5a and b should be applied for these alternatives only when lead content is ≥3% w/w. This is since the proposed text does not fully apply to these alternatives if they are derogated and also to support the use of copper-based alternatives which are still less hazardous compared to lead bullets.

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 feasibility for organisations such as the International Olympics Committee, FITASC and ISSF to change their 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 its use in bullets and gunshot but also from primers containing lead e.g., lead styphnate. 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 to that 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) 1881/2006[2].

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

Regarding the requirement for the labelling of individual shotgun cartridges in case the optional derogation for the use of gunshot in sports shooting (§4a and §4b) is implemented, RAC recommends to consider the readability of the labelling of individual cartridges and whether alternative approaches such as colour coding could be more suitable.

Finally, RAC encourages decision makers 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.

1.2. THE OPINION OF SEAC

See SEAC opinion

[2] 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.

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of proposal

As per the request of the Commission (EU Commission, 2019)[3] the proposed restriction aims at addressing the risks for human health and the environment posed by the use of lead in ammunition, i.e.

- gunshot used in terrains[4] other than wetlands and
- projectiles other than gunshot (i.e. bullets and airgun pellets) used both in wetlands and in terrains other than wetlands, as well as
- fishing tackle.

This restriction proposal is complementary to the existing restriction on the use of lead gunshot in wetlands (Entry 63 of Annex XVII to REACH).

Ingestion of lead objects by birds (including lead projectiles, fishing sinkers and lures) results in a range of acute and chronic toxicological effects which can lead to death, dependent on the quantity of lead ingested and the size of the animal. Numerous studies have reported incidences of the ingestion of lead projectiles and fishing tackle. The hazards of lead, as well as its bioavailability and absorption are generally well understood and documented for the environment.

Lead gunshot, and the remnants from other lead projectiles (e.g. bullets), that remain in the environment after use become available to be ingested by birds or other wildlife or they can contaminate soil and water. Lead fishing tackle is 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 to the aquatic environment in some circumstances (termed as 'dropping the lead') to ensure a better catch rate.

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 in the environment every year: 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.

Numerous studies have reported the ingestion of lead projectiles and fishing tackle by wildlife, including wildlife whose habitat is outside of wetland areas (e.g. 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 the Background Document 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);

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

[4] In the context of this restriction, the word "terrain" should be interpreted as land.

- **secondary ingestion** defined for the purpose of the Background Document 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.

The Dossier Submitter estimates that, in the EU, at least 135 million birds are at risk of primary poisoning from lead gunshot, 14 million are at risk of secondary poisoning and seven million birds are at risk because of the ingestion (primary poisoning) of fishing sinkers and lures.

At least 92 species of birds[5] are at risk of lethal and sub-lethal lead poisoning[6] from lead 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.

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 because of secondary ingestion cannot be quantified as the information needed to do so is not available. A significant number of birds are also expected to be affected by sub-lethal 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.

In addition to primary ingestion risks, spent lead projectiles from sports shooting can contaminate the environment both during the service life and after the closure of a range[7] potentially leading to a variety of on-site and off-site risks.

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 soil, surface water and groundwater from the use of lead in ammunition for sports shooting, as well as to other specific receptors such as livestock and wildlife (primarily birds).

Lead is not only hazardous for the environment, it is also toxic to humans of all ages and affects various organs. The detrimental health effects of lead are well documented. The range of reported adverse effects includes neurodevelopmental effects in foetuses, babies and small children, cardiovascular diseases, impaired renal function (including chronic kidney disease),

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

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

[7] 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.

hypertension, impaired fertility and adverse pregnancy outcomes in adults. However, the greatest public health concern is the neurodevelopmental toxicity of lead in children aged seven and younger.

Human exposure to lead from ammunition and fishing tackle occurs via inhalation and ingestion. Additionally, humans may be exposed to lead via the environment through the intake of food and drinking water contaminated from shooting activities and via the consumption of game meat hunted with lead gunshot or projectiles. An additional concern is the practise of artisanal casting of fishing weights and bullets in the home or by small businesses, leading to direct exposure to lead through inhalation or hand-to-mouth behaviour.

Based on the assessment performed, the Dossier Submitter concludes that the use of lead in gunshot, other projectiles not defined as gunshot (i.e. bullets and airgun pellets), fishing sinkers and lures poses a risk to wildlife, livestock, environment and human health that is **not adequately controlled**, and needs to be addressed at the EU level.

As a result, 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 use will inevitably result in releases to the environment, irrespective of the conditions of use, and where suitable alternatives are available (i.e. technically, economically feasible and resulting in an overall reduction of the risk for human health and the environment). This includes a ban on the placing on the market and use of lead gunshot, fishing sinkers, lures and fishing wire containing lead in a concentration equal to or greater than 1%. For some of these uses, a transition period is proposed to allow sufficient time for stakeholders to comply with the restriction.
2. Where a ban on placing on the market would disproportionately affect uses outside of the scope of the proposed restriction (such as police and military applications or indoor shooting), a ban on the use only is proposed. This is the case for projectiles not defined as gunshot.
3. There is an obligation for 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 articles (fishing tackle, gunshot, projectiles). This requirement is built on recent studies that highlight the importance of hunters' and fishers' awareness of hazard and risk for changing purchasing behaviour.

A derogation is proposed for outdoor sports shooting with projectiles other than gunshot conditional on the implementation of appropriate and effective RMMs. In addition, derogations are proposed for specific uses of bullets (seal hunting) and specific types of bullets (full metal jacket bullets).

A derogation for continued use of lead gunshot for sports shooting is presented as an option for the decision-making stage if the decision maker does 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. The derogation, referred to by the Dossier Submitter as an 'optional conditional derogation',

would set a minimum standard of RMMs at sites using lead gunshot and would introduce 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 – e.g. Olympic Games, ISSF events). Furthermore, this derogation would be accompanied by a labelling requirement for the supplier and a reporting requirement for the Member States which would grant such a derogation. 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 (i) the Dossier Submitter's preferred option is a complete ban on the use of lead gunshot in sports shooting and (ii) the optional conditional derogation is more costly to society than a complete ban. However, the Dossier Submitter recognises that although the 'optional conditional derogation' for gunshot will not be as effective in controlling the identified risks as a complete ban on use, it may be considered proportionate by the decision-maker, should the rules of international competitions continue to require the use of lead gunshot.

Based on the assessment of the overall risk reduction potential and the socio-economic impacts for each sector and use affected, the Dossier Submitter concluded that overall, the proposed restriction is effective and proportionate. Table 1 provides a summary of the costs and emission reduction expected from the proposed restriction.

Table 1. Summary of the Dossier Submitter's mean estimates of costs, emission reduction, and costs per kg of avoided releases by sector and/or use

Sector/Use	Costs over 20 years[2]	Emission reduction over 20 years[2]	Costs per kg of avoided releases[2]
Hunting with gunshot	€768 million (range: €28-1 484 million)	209 000 tonnes (range: 159 000-259 000 tonnes)	€3.7/kg (range: €0.2-5.7/kg)
Hunting with bullets – small calibres	€122 million (range: €54-179 million)	232 tonnes (range: 208-255 tonnes)	€525/kg (range: €258-705/kg)
Hunting with bullets – large calibres	€239 million (range: €101-412 million)	2 200 tonnes (range: 1 700-2 500 tonnes)	€109/kg (range: €60-162/kg)
Outdoor sports shooting with gunshot	PREFERRED OPTION: €364 million (range: €177-596 million) [OPTIONAL CONDITIONAL DEROGATION: €506-591 million (range: €207-236 million – €913-1 044 million)][3]	PREFERRED OPTION: 367 500 tonnes (range: 210 000-525 000 tonnes) [OPTIONAL CONDITIONAL DEROGATION: 349 125 tonnes][3]	PREFERRED OPTION: €1.0/kg (range: €0.8-1.1/kg) [OPTIONAL CONDITIONAL DEROGATION: €1.4-1.7/kg (range: €0.6-0.7/kg – €2.6-3.0/kg)][3]
Outdoor sports shooting with bullets – all calibres (preferred option)	€1 094 million (range: €859-1 329 million)	5 800 tonnes (range: 83-20 434 tonnes)	€189/kg (range: 65-10 306 €/kg)
Fishing	€9 300 million (range: €~0-48 000 million)	48 300 tonnes (range: 32 200-112 700)	€193/kg (range: €0.01-996/kg)
Total[1]	**~ €12 000 million**	**~ 633 000 tonnes**	**~ €19/kg**

Notes: 1. For the preferred option. 2. Dossier Submitter's central estimates (ranges in parentheses). 3. Optional derogation under strict conditions for licensed individuals only.

2.2. Summary of opinion

2.2.1. Summary of RAC opinion

Regarding the scope, RAC agrees that targeting of the restriction to the use of lead in projectiles, gunshot and fishing tackle in outdoor uses addresses a wide range of risks to the environment, and especially to birds, as well as to human health. As home-casting under uncontrolled conditions is likely to pose a risk to human health, restricting the use of home-cast sinkers, is also warranted.

RAC agrees that uses by police, military and border control when they are "on duty" should be out of this scope. Although presently out of scope, RAC notes that the use of lead -containing primers (lead styphnate) likely contribute to exposure of shooters to lead, both

outdoors but even more so at indoor shooting locations, where total exposure to lead may be a concern for non-professionals using these indoor ranges.

There is robust evidence for lead toxicity, including mortality, to birds through direct (primary) and indirect (secondary) exposure. Primary poisoning may result from either accidental ingestion when lead pellets/sinkers are mistaken for food or intentionally when pellets/sinkers are mistaken for grit ingested to aid digestion in the crop. Secondary poisoning occurs when predatory and scavenging species are 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 hunters. In total, poisoning may affect 92 different species, of which 54 are red listed by the IUCN, with mortality or sub-lethal effects as consequences.

Neurodevelopmental effects are the most critical toxicological endpoint of lead in humans, with no known threshold for these effects. Young children and pregnant females are the sensitive groups for these effects. Other serious effects of lead include chronic kidney disease and increased systolic blood pressure. Similarly, toxicological effects may appear also in domestic animals (livestock) and predatory or scavenging mammalian species.

The estimated release of lead to the environment in the EU made by the Dossier Submitter from hunting, fishing and sporting activities is plausible and in the order of 44 000 tonnes per year. Direct exposure of birds in aquatic and terrestrial environments from ammunition and fishing tackle, as well as indirect exposure of predatory or scavenging birds from ammunition and increased mortality in these species is well documented. In addition, sub-lethal effects are likely to occur. RAC concludes that indirect exposure to lead of predatory or scavenging bird species is a major concern, especially as it affects many threatened bird species. Lead contamination during the service life and at the end of life of shooting ranges is a significant local risk to (surface) soil, and the receiving surface water. If shooting with gunshot takes place on or adjacent to agricultural areas there is a risk of contaminated silage or poisoning of livestock. Outdoor sports shooting may result in elevation of blood lead levels in shooters. Jacketing of lead bullets reduces lead exposure. Airguns seem to result in lower lead exposure. Hunting may result in slight increases in blood lead levels in hunters, but it is not possible to differentiate this from the increase caused by game meat consumption, home-casting or practising shooting.

Home-casting of fishing sinkers occurs in the EU (and perhaps of ammunition), and exposure from home-casting is plausible, especially in uncontrolled conditions, but there is no data to support this.

There is a large variability in the game meat Pb levels. However, a relevant proportion of game meat has a substantially higher lead concentrations than the regulatory maximum level for lead in (other than game) meat (0.1 mg Pb/kg meat). Non-expanding full metal jacket (FMJ) bullets and small calibre projectiles may not result in similar lead contamination of the game meat. Based on data on game meat consumption and lead concentrations in game meat a high exposure of toddlers and infants is noted, resulting in significant increases in blood lead levels in children. A risk of developmental neurotoxicity during pregnancy is also considered relevant since there is no threshold for the developmental neurotoxicity of lead.

For hunting, RAC supports a moderate to high risk for children and pregnant females consuming game meat hunted with lead gunshot/expanding bullets. If home casting of bullets occurs (for large calibre weapons) this can be considered to result in a moderate risk.

For sports shooting, RAC supports a high local risk to surface soil and water, although risks at wider scale are low. The risk of groundwater contamination may vary from very low to high depending on local soil and groundwater characteristics. At sports shooting ranges with a high intensity of shooting, located on or adjacent to agricultural land there is a potential (low-moderate) risk for livestock exposure, and thus to humans consuming dairy products. Lead is likely to cause a low-moderate risk for frequent sports shooters; pregnant (or fertile-age females) being at moderate risk if sports shooting is practised regularly. It is, however, recognised that the exposure (and risk) may vary according to the shooting discipline.

For fishing, there is ample evidence for a very likely exposure and severe effects in certain species (i.e., swans and loons), resulting in a very high risk, but based on limited evidence for other sensitive bird species a moderate risk is concluded. Home-casting of fishing sinkers does occur, and a moderate risk is assumed for adults based on it being likely with exposure resulting in medium severe effects.

A quantitative risk assessment for the environment was performed for bird mortality. RAC supports the Dossier Submitter's estimate of annual mortality in the order of one million terrestrial birds by primary ingestion of gunshot. Sub-lethal effects in birds are probably even more common but cannot be quantified.

A quantitative risk assessment for humans was performed for neurodevelopmental effects in children and for chronic kidney disease in adults. For IQ loss in children, 6% of 1.1 million children from hunting families were estimated to lose >1 IQ point. Regarding risk for chronic kidney disease in adults, RAC supports the use of an estimate of 100-1 000 cases of chronic kidney disease among some 10 million hunters in EU for monetising the risks for adults, although RAC recognises the high uncertainties related to these estimates.

Current risk management measures are not sufficient to control the risks of lead, as shown by a high mortality in many bird species (some red-listed and being threatened) caused by lead used in ammunition or fishing tackle, and by the high levels of lead in game meat sold on the market.

Even if some Member States have already taken specific action to limit or ban the use of lead ammunition for hunting, sports shooting or fishing, the risks posed by lead will still be observed Union-wide without further action. Therefore, based on the key principles of ensuring a consistent level of protection across the Union and maintaining the free movement of goods within the Union RAC agrees that Union-wide regulatory measures are justified.

For hunting, RAC agrees with the Dossier Submitter that a ban under REACH is the only risk management option capable of effectively eliminating the risks for the environment and human health related to the use of lead ammunition. RAC considers that the proposed derogations for seal hunting and for the use of full metal jacket bullets for special hunting uses do not compromise the effectiveness of the restriction. Although there were requests for derogations for muzzle loaders and airguns for hunting, these were not proposed by the Dossier Submitter. However, it is recognised by RAC that the use of both muzzle loaders and airguns in hunting is limited in volume and therefore their impact on the overall risk reduction is low. For copper and copper-based (i.e., brass) bullets, a concentration limit of 3% (w/w_ is proposed with a review before entry into force to determine if a concentration less than 3% can be achieved. Considering that copper-based bullets are the main alternatives for lead bullets, RAC supports this derogation and a review of its need prior to entry into force of the

restriction. RAC notes that the possible need to inspect private persons may present challenges for the enforcement of the restriction of lead ammunition in hunting.

For lead in sports shooting, RAC supports that a ban under REACH on placing on the market of lead gunshot and of the use of lead projectiles would be an effective measure.

As several international sports shooting organisations (e.g., Olympic/ISSF, FITASC) require the use of lead gunshot in competitions, the Dossier Submitter has assessed, but does not prefer, an 'optional derogation' for the use (and thus placing on the market) of lead gunshot if shooters have licenses and the sports shooting location has a permit and fulfils a number of requirements enabling high recovery rates of lead gunshot. Labelling of lead gunshot cartridges will also be required, stating 'Contains lead: do not use for hunting'. RAC supports labelling but notes that other approaches could also be used, such as using a colour coding system. RAC notes that this derogation will adversely affect the enforceability and effectiveness of the restriction of lead gunshot for hunting and may result in non-harmonised conditions for sports shooters over the EU, and rather recommends that the organisations change the sports shooting rules so that alternative (e.g., steel) gunshot can be used as this will enable a more straightforward restriction based on simply preventing (and enforcing) the placing on the market of lead gunshot. 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.

Additionally, for projectiles other than gunshot, since alternatives with equivalent performance to lead are not yet available for all calibres, the Dossier Submitter proposes a derogation of the ban on the use of lead projectiles other than gunshot for sports shooting when specific operational conditions and risk management measures are implemented at the shooting range (adequate risk management measures, monitoring and treatment of surface (run-off) water, compulsory information on the hazard/risk of lead at suppliers, and labelling of ammunition packages, combined with a ban of any agricultural use within the site boundary). RAC can support a time-limited derogation until suitable alternatives are available for all calibres. A ban on potential agricultural use within the site boundary is needed to effectively eliminate the risks for the environment and human health. Permitting (and checking the available risk management systems) of shooting ranges may result in a new workload for some Member States but is needed to ensure high levels of protection of environment and human health. RAC supports the proposed restriction as practical, effective, and enforceable, as use will only be allowed at shooting ranges notified to the Member State.

For fishing sinkers and lures, the Dossier Submitter proposes a ban on placing on the market and use of lead fishing sinkers and lures, without an upper weight limit but a longer transition period for sinkers weighing more than of 50 g. RAC supports that this proposal provides the highest risk reduction potential, as this option reduces the risk both to birds (use of sinkers) and humans (home-casting). Also, it is practical and enforceable since it concerns placing on the market of sinkers. However, enforcing individuals at the point of use may be challenging.

RAC supports the proposed information requirement for the lead ammunition at the point of sale. However, RAC considers that the limit of ≥0.3% w/w of lead that triggers the information requirement may cause confusion and, from a risk perspective, it does not make a significant difference if a limit of 1% w/w of lead is applied to the information requirements instead (which is then in line with the limit that sets up in the condition of the restriction for the maximum content of lead in ammunition and fishing tackle).

Regarding alternatives, RAC agrees with the Dossier Submitter that there are alternative materials available for lead gunshot and projectiles other than gunshot both for hunting and for sports shooting as well as for fishing sinkers and lures, and that the use of these alternatives, instead of lead, reduces the human health and environmental risks.

Overall RAC notes that the use of lead in outdoor shooting and fishing leads to significant local contamination and a wide range of risks to both human health and the environment.

2.2.2. Summary of SEAC opinion

See SEAC opinion

3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

3.1.1. Description of the risk(s) addressed by the proposed restriction

3.1.2. Information on hazard(s)

Summary of proposal:

Environmental hazards

Massive lead (as used in lead ammunition and fishing tackle) poses a significant hazard to birds that ingests it. The likelihood of a bird species ingesting lead is closely associated with the ecological niche that it occupies, its feeding habits and its anatomy/physiology.

Many toxicological studies with lead gunshot have been conducted using captive birds, the conclusions of which can also be considered relevant for lead fishing tackle.

However, lead poisoning from ingestion of lead ammunition and fishing tackle has not been extensively studied in mammalian species. Additionally, only limited information is available on ruminants.

Human health hazards

Lead affects virtually every system in the body, including the blood and 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.

In the absence of a threshold for the critical effects, the Dossier Submitter has reflected the health impact by calculating the effect of the increment of blood lead levels with respect to:

- IQ decrease in IQ points for children,
- % increase in the prevalence of chronic kidney disease in adults, and
- increase in systolic blood pressure (in mmHg) in adults.

RAC conclusions:

Environmental hazards:

- The hazardous properties of lead are well-known and have been assessed in many previous opinions of RAC, including the Opinion on an Annex XV dossier proposing restrictions on lead in gunshot in wetlands (ECHA, 2018[8]).

- There is robust evidence for lead toxicity, including mortality, to birds through direct (primary) and indirect (secondary) exposure/mechanisms. Primary poisoning may result from either accidental ingestion when lead pellets/sinkers are mistaken for food (e.g. seeds/grain) or intentionally when pellets/sinkers are mistaken for grit which are ingested to aid digestion. Secondary poisoning occurs when predatory and scavenging species are 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 hunters. In total, poisoning may affect 92 different species of birds, of which 54 are red listed by the IUCN, with mortality or sub-lethal effects as consequences.

- The toxicity of lead to predatory or scavenging mammalian wildlife has not been studied, but the toxicity to other mammals is well-known. EFSA (2013) concluded that there is no threshold for the neurodevelopmental toxicity in humans, and neurodevelopmental and many other toxicological effects appear also in other mammalian species.

- There is robust evidence for lead being very toxic to domestic animals (livestock).

Human health hazards:

- Similarly, hazards of lead to human health are well-known and extensively reviewed for example by EFSA. They have been also addressed in the previous opinions of RAC, most recently in the RAC opinion on occupational exposure limits for lead and its compounds (ECHA 2020[9]).

- RAC agrees with the Dossier Submitter that neurodevelopmental effects are the most critical toxicological endpoint of lead. In addition to small children, developing foetuses are at risk for these effects. Although RAC recognises the related uncertainties at low exposure levels, the use of the EFSA dose response (with $BMDL_{01}$ of 12 µg/L corresponding a decrease in IQ by 1 point for neurodevelopmental effects and more severe effects at higher exposure levels) is supported. Young children and pregnant females are the sensitive groups for these effects and should be covered by the risk assessment.

- Regarding toxic effects in adults, dose responses have been established for the

[8] https://echa.europa.eu/documents/10162/07e05943-ee0a-20e1-2946-9c656499c8f8

[9] https://echa.europa.eu/documents/10162/30184854/oel_lead_final_opinion_en.pdf/1853edfa-da47-c110-106e-2a70c30cef93

association between B-Pb and chronic kidney disease and between B-Pb and increase in systolic blood pressure. The Dossier Submitter has used the EFSA (2010) $BMDL_{10}$ of 15 µg/L for a 10 % increase in the prevalence of chronic kidney disease and a $BMDL_{01}$ of 36 µg/L for a 1 % increase in systolic blood pressure in adults. The increase in systolic blood pressure was used to characterise the risks, but this endpoint was not used in the human health impact assessment.

- RAC recognises the conservative nature and uncertainties related to the EFSA BMDLs for CKD and systolic blood pressure at low B-Pb levels. However, RAC supports the Dossier Submitter's approach to use these EFSA BMDLs for chronic kidney disease and systolic blood pressure for risk assessment.

- The recent RAC opinion on the OEL for lead and its compounds (ECHA, 2020) is based on the neurotoxicity of lead in adults. B-Pb levels higher than 150 µg/l were considered to cause subclinical neurological effects in adults. These effects may become relevant in some high exposure scenarios and needs to be noted. Carcinogenicity of lead seems to be caused via indirect mechanisms and might be relevant only at levels above the proposed OEL (ECHA, 2020).

Key elements underpinning the RAC conclusion(s):

Environmental hazards

Regarding environmental hazards to wildlife and livestock, see the RAC and SEAC Opinion on an Annex XV dossier proposing restrictions on lead in gunshot in wetlands (ECHA, 2018) as well as the work package report WP A.1: Environmental risks to wildlife (birds) and livestock – weight of evidence across all uses.

The hazardous properties of lead are well-known and have been assessed in many previous opinions of RAC. In ECHA (2018), RAC concluded that lead exposure of birds may result in mortality, or at lower exposures, in a range of adverse sub-lethal effects such as physiological and behavioural effects. There are also data correlating tissue concentrations of lead (e.g., blood levels) with toxicological effects, although species differences and a variation of lead concentrations with time after exposure make this correlation rather indicative. Thus, the background concentration of lead in blood is generally <20 µg/dL while severe poisoning is evident at concentrations >100 µg/dL. The lethal effect of lead after primary ingestion of lead shot has been thoroughly studied in waterbirds such as the mallard (*Anas platyrhynchos*) and since RAC assessed the data in the previous opinion (ECHA, 2018) it is not further discussed here. There does not seem to be similar studies on predatory or scavenging bird species, but many studies have correlated (blood) lead levels in these birds with symptoms of toxicity and even mortality, as recently reviewed by Golden et al (2016). RAC concludes that there is robust evidence for lead being toxic to birds.

The toxicity of lead to predatory or scavenging wildlife mammalian species has not been studied, but the toxicity to other mammalian species is well-known. For instance, EFSA (2013) concluded that there is no threshold for the neurodevelopmental toxicity in humans, and many toxicological effects appear in toxicological testing in other mammalian species as discussed in previous RAC opinions (RAC, 2011; RAC, 2013). RAC concludes that there is robust evidence for lead being very toxic to mammalian species, and there is no reason to assume otherwise for predatory or scavenging mammalian wildlife, such as bears, lynx, foxes, badgers

and weasels.

Regarding livestock, there are data on cows and calves showing that grazing on shooting ranges, or use of silage produced at shooting ranges, may cause significant exposure to livestock. The limit of 30 mg lead/kg for lead in forage is likely to be breached regularly. There are some estimates on the NOEC values for different mammalian species but these estimates have not been corroborated by subsequent studies. However, the lead-induced toxic effects in humans (neurotoxicity, hematologic disorders, etc.) are most likely relevant also for mammalian species exposed to environmentally relevant lead concentrations. See further work package report WP A.1: Environmental risks to wildlife (birds) and livestock.

Human health hazards

The Dossier Submitter used quantitative estimates of the neurodevelopmental effects, chronic kidney disease and cardiovascular (systolic blood pressure) effects to characterise the risk of exposure. EFSA (2010) $BMDL_{01}$ of 12 µg/L corresponding to a decrease in IQ by 1 point was used for the characterisation of neurodevelopmental effects in children. This was based on the piecewise linear BMDL model, which was found to give the best fit for the data (Budtz-Jørgensen et al., 2013). In addition to EFSA (2010) modelling, new BMDL calculations using BMD and BMDL estimates from a set of more complex models were included in the restriction dossier. These resulted on average in 4-times lower BMDLs than EFSA (2010) estimates. Based on this modelling, ECHA derived a $BMDL_{01}$ of 4 µg/L used for sensitivity analyses.

When using these BMDL estimates, uncertainties related to the underlying data especially at low exposure levels need to be recognised. The BMDL calculation by EFSA is based on the data by Lanphear et al., (2005) combining the results from seven individual epidemiological studies and showing a significant decrease in IQ at B-Pb levels < 75 µg/l. Although later re-analyses support an association between the B-Pb levels and IQ loss at B-Pb levels of < 75 µg/l and even < 50 µg/l (Crump et al., 2013), there are uncertainties related to the confounders like maternal IQ and education and HOME score (measuring the quality and quantity of stimulation and support available to a child in the home environment), which may have an influence in the dose-response at the B-Pb levels <50 µg/l (van Landingham et al., 2020). Recognising these uncertainties, RAC is still of the opinion that EFSA (2010) BMDL evaluation is acceptable for the characterisation of risks for children caused by lead.

The Dossier Submitter used kidney effects and cardiovascular effects (effects on systolic blood pressure) as critical effects to characterise the risks for adults. There are numerous epidemiologic studies in adults on the association between exposure to lead and altered kidney function. High-dose lead exposure has been established to cause kidney damage but also an increasing number of population studies show association between low-level (<100 µg/l) environmental lead exposure with decreased kidney function. EFSA CONTAM panel (2011) calculated a $BMDL_{10}$ of 15 µg/l for lead-caused chronic kidney disease, defined as a GFR below 60 mL/1.73 m^2 body surface/min). This was based on the large population studies by NHANES (Muntner et al., 2003 and 2005; Navas-Acien et al. 2009, Fadrowski et al., 2010) showing an association with decreased GFR with increasing B-Pb levels. There are also studies showing no clear associations at low exposure levels (e.g. Mujaj et al., 2019, Barry et al., 2019; Barry and Steenland, 2019). Several confounding or modifying factors (like reverse causality) may influence the dose-response relationship of lead-caused kidney impairment. Therefore, it is important to recognise these uncertainties and likely conservative nature of BMDL derived for chronic kidney disease. Regardless of these uncertainties, RAC considers

that the EFSA BMDL is an acceptable estimate for use in risk characterisation.

EFSA also derived a BMDL of 36 µg/L for a 1% increase in systolic blood pressure based on the five different studies showing an association between systolic blood pressure and blood lead levels. Although link between increase in systolic blood pressure and cardiovascular morbidity and mortality can be expected, epidemiological data on these effects and their dose responses at environmentally relevant exposure levels is limited. A recent study by Lanphear et al. (2018) reported an association between the low-level environmental lead exposure and cardiovascular disease mortality in the USA. In this study, an increase in the concentration of lead in blood from 10 µg/L to 67 µg/L was associated with all-cause mortality (hazard ratio 1.37, 95 % CI 1.17 – 1.60), cardiovascular mortality (HR 1.70, 1.30 – 2.22), and ischaemic heart disease mortality (HR 2.08, 1.52 – 2.85). This suggests that lead may have a greater effect on cardiovascular mortality than previously recognized. Further studies are, however, desirable to confirm the findings and dose-responses at low (<70 µg/L) exposure levels.

For renal and systolic blood pressure effects, new BMDL modelling (based on the same datasets) performed by the Dossier Submitter resulted in an almost identical BMDLs ($BMDL_{10}$ of 12.7 µg/L for chronic kidney disease and $BMDL_{01}$ 36 µg/L for systolic blood pressure).

The Dossier Submitter did not consider adult neurotoxicity or carcinogenicity in the restriction proposal. In the recent RAC opinion on the occupational exposure limit (OEL) for lead (ECHA, 2020), neurotoxicity has been selected as a critical endpoint for the toxicity of lead in adults. The proposed BLV of 150 µg/L is based on the subtle (subclinical) neurotoxic effects observed in neuropsychological tests in workers at blood lead levels of ≥180 µg/L. Carcinogenicity was also discussed but lead carcinogenicity was considered to have a threshold, and a LOAEL for chromosomal aberrations observed in some studies was identified at two times higher blood Pb levels than the proposed OEL of 150 µg/L. The epidemiological associations concerning the increased incidence of chronic kidney disease or changes in systolic blood pressure in large general population studies and the BMDLs derived from these studies were not considered in the OEL opinion for occupational settings but may be more relevant for the general population. As discussed above, associations for kidney and cardiovascular (systolic blood pressure) effects are stronger at high exposure levels but less certain at lower exposure levels where some effect of confounders cannot be totally ruled out. This needs to be recognized when using the BMDLs derived for these endpoints.

3.1.3. Information on emissions and exposures

Summary of proposal:

The principal routes by which animals are exposed to lead from ammunition or fishing tackle are primary ingestion (ingestion of any lead object directly from the environment through normal feeding or foraging activity) and secondary ingestion (indirect ingestion of lead via the consumption of food).

An assessment of which EU bird species would be at greatest risk of ingesting lead objects from ammunition or fishing tackle was performed by the Dossier Submitter.

Additionally, the Dossier Submitter identified and assessed in a qualitative way the environmental risks during and after the service life of a shooting range/lands, including risks to soil, risks to surface water and groundwater and risks to livestock in shooting ranges/areas

used as agricultural land.

On the other hand, human exposure to lead occurs mainly via inhalation and ingestion. Inhalation exposure may occur during the shooting, and 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 direct ingestion, mouthing or chewing, or via hand to mouth exposure when manipulating lead gunshot, projectiles or fishing sinkers and lures. Furthermore, human ingestion of lead may occur via the intake of food and drinking water (as groundwater) contaminated from shooting activities and via the consumption of game meat hunted with lead gunshot or projectiles, as the existing best practices to handle hunted game meat do not eliminate all lead in game meat.

According to the Dossier Submitter, the available data allow only a quantification of human exposure to lead via game meat consumption. Human exposure to lead through inhalation or through direct ingestion or hand to mouth contamination cannot be quantified based on the available information.

RAC conclusion(s):

Exposure of birds and other wildlife and livestock:

- The Dossier Submitter's estimates of lead releases to the environment from hunting, fishing and sporting activities are plausible and in the order of 44 000 tonnes per year in EU. The possibilities for wildlife to be exposed to lead is therefore widespread and continuous.

- Direct exposure of birds is well documented both in aquatic and terrestrial environments.

- Indirect exposure of predatory or scavenging birds from ammunition and increased mortality in these species is well documented. Also, sub-lethal effects occur in predatory/scavenging birds (weight loss, lethargy, reduced mobility, reduced migratory and reproductive capacity, impaired flight performance, increased predation risk and enhanced susceptibility to other life-threatening conditions (i.e., hunting, trauma-flying accidents). There is a correlation between lead blood levels and e.g., behaviour (flight height and movement rate).

- Poisoning of waterbirds from lead used in fishing can occur, but it is not well studied, so the magnitude of this problem is difficult to assess.

- It is likely that scavenging mammals are exposed to lead through offal or discarded meat left in the environment. However, there are only a few such documented cases and the Dossier Submitter does not provide any further elaborations.

- Grazing on shooting ranges, or use of grass from shooting ranges for silage, may cause significant exposure to livestock, and RAC notes examples of lead poisoning in cattle. Additionally, the limit of 30 mg Pb/kg in forage harvested on shooting ranges is likely to be breached regularly and constitutes a risk for livestock.

- RAC concludes that indirect exposure to lead of predatory or scavenging bird species is a major concern, especially as it affects many threatened bird species.

- The Dossier Submitter provided a list of 92 bird species that might be considered to be at most risk of lead poisoning from shooting and fishing, and it cannot be excluded that other species currently considered at low risk of lead poisoning, e.g., based on a general feeding habit, might also be adversely affected, if exposed.

Environmental distribution and indirect exposure of humans:

- Lead contamination during the service life and at the end of life of a shooting range presents a significant risk to (surface) soil, and receiving surface water, but generally not to groundwater (or its derived drinking water). Monitoring and treatment of surface water will be important to control this risk, as would the installation of barriers/containment to control lead contaminated run-off and prevent the pollution of any rivers and lakes/lagoons, and surface water in general.

- Limited evidence is provided to substantiate the risk of lead from contaminated food when agriculture is practised on or adjacent to shooting ranges. Yet, the evidence available indicates that there are potential risks in permanent ranges with insufficient risk management measures and intensive shooting.

Exposure of shooters:

- Outdoor sports shooting using firearms (both shotshell and single projectile shooting) may result in exposure to lead and elevation of blood lead levels in shooters. According to the literature, increases in B-Pb levels up to 30 µg/l seem likely and, in some cases, even higher increases in frequent shooters are possible. Jacketing of lead bullets reduces lead exposure but does not prevent this totally. An undefined proportion of lead exposure is caused by lead primers. Shooting with airguns seems to result in clearly lower lead exposure and no clear increases in B-Pb levels have been observed in the available studies. Closed plastic cartridges used in shotguns may also limit the lead exposure, but there is no measured data to confirm this. Overall, the available data, particularly on outdoor shooting, is limited.

- The data on lead exposure due to hunting *per se* is very limited but it suggests that also hunting may result in measurable increases in blood lead levels although it might not be as high as for regular sports shooters.

Human exposure due to home-casting:

- Home-casting of ammunition and fishing sinkers occurs in the EU, as shown by the extensive online sale of moulding forms and also from various surveys. Home-casting of fishing sinkers may be common in some regions, but an overall estimate of how common these practices really are is not available.

- Data from other parts of the world indicate that home-casting can result in substantial exposure to lead, but it is not clear to RAC how relevant these data are for European conditions.

- Thus, RAC concludes that exposure from home-casting is plausible, but the quantitative contribution is probably highly case-specific and no quantitative assessment is currently possible in relation to overall exposure to lead.

Human exposure due to game meat consumption:

- Data related to the concentration of lead in game meat is available from various studies where the concentration of lead in game meat intended for consumption was measured. It is, however, noted that there is a large variability in the game meat lead levels and e.g. a recent meta-analysis of European data (Pain et al., 2022) suggest even higher lead levels in small game than was estimated by the Dossier Submitter based on EFSA data. Overall, the available data indicate that, 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 (other than game) meat (0.1 mg Pb/kg meat).

- Full metal jacket bullets, and small calibre bullets used in some countries for the hunting of small game or seals may, however, result in lower levels of lead contamination of the game meat.

- The data on the concentration of lead in game meat and game meat consumption allows for an estimation of the risk from lead exposure for sensitive population groups such as toddlers and infants, as well as for drawing general conclusions for adults.

- The health risk associated with incremental B-Pb levels from the consumption of meat from game hunted with lead bullets or gunshot was quantitatively estimated by the Dossier Submitter. The values are based on modelling and only limited cross-checking (for adults) can be done with real data adding uncertainty to the results.

- RAC considers that the Dossier Submitter's approach to use mean values for game meat lead levels in the risk characterisation (in contrast to the impact assessment where the full distribution is taken into account) may result in a conservative estimate of risks due to the highly skewed distribution of lead levels in game meat. However, since some pieces of game meat may contain more than one order of magnitude higher amounts of lead when compared to the mean values used by the Dossier Submitter, similar total intakes of lead may follow even after few meals/year of this highly contaminated meat. This may result in significant increases in B-Pb levels in children.

- RAC notes that developmental neurotoxic effects are relevant also in the case of pregnant females. Although in adults increases in B-Pb levels due to game meat consumption are lower than those expected in small children, the risk of developmental neurotoxicity during pregnancy is considered relevant since there is no threshold for the developmental neurotoxicity of lead.

Key elements underpinning the RAC conclusion(s):

The analysis that justifies the conclusions given above is contained in the Annexes prepared by the ad hoc RAC Supporting Group:

WP A.1: Environmental risks to wildlife (birds) and livestock – weight of evidence across all uses

WP A.2: Additional environmental risks related to sports shooting ranges (soil/surface and groundwater)

WP A.3: Human health risks due to shooting

WP A.4: Human health risks related to home-casting

WP A.5: Human health risks related to the consumption of game meat and other meat and dairy products

3.1.4. Characterisation of risk(s)

Summary of proposal:

Environmental risk characterisation

The Dossier Submitter has identified risks for soil, groundwater, surface water, wildlife (birds) and livestock (ruminants and poultry) related to the different uses and scenarios.

According to the Dossier Submitter, the available data is not enough to fully assess the risks in a quantitative manner. Based on the available data, a risk quantification based on bird mortality by primary ingestion of lead gunshot was performed. Other environmental risks, including bird mortality by secondary ingestion of lead ammunition and sublethal effects to birds from lead exposure, risks to livestock and risks resulting from sports shooting ranges during service life and at the end of life, were assessed qualitatively by the Dossier Submitter.

Human health risk characterisation

The Dossier Submitter identified the risks related to human exposure to lead from shot, bullets or fishing sinkers and lures resulting from inhalation (shooting or home-casting) or oral intake of lead dust (hand-to-mouth) and from the consumption of meat bagged with lead shot or bullets. Secondary exposure to lead from such sources via the environment (such as water, soil, plants, animals) was not further investigated by the Dossier Submitter.

The Dossier Submitter performed a quantitative risk assessment for the risks resulting from the consumption of game meat based on data provided by EFSA on its consumption in the EU.

According to the Dossier Submitter, the available information is not sufficient to properly quantify the risks to human health arising from other sources of exposure other than game meat consumption. In the absence of additional data, the Dossier Submitter described and assessed the additional risks for human health in a qualitative manner.

RAC conclusion(s):

RAC agrees with Dossier Submitter that it is not possible or feasible to perform a quantitative risk assessment for all scenarios. RAC has applied a conceptual model to scrutinise the Dossier Submitter's qualitative evaluation of risks (for detailed description see Annex 1: RAC qualitative risk assessment approach). Based on this, the following conclusions are made:

Hunting

- Hunting results in **high risk** to individual birds of sensitive species and is a **very high to high risk** for populations of rare bird species
- Lead contamination of the environment due to hunting results in **low** risks to soil, surface and groundwater (or its derived drinking water).
- Consumption of game meat hunted with lead shot/expanding bullets results in a

moderate to high risk for children and pregnant females. For adults, the risk caused by the consumption of game meat is **low**.

- There is limited evidence on the home-casting of lead bullets in Europe. If it occurs, home casting of bullets (for large calibre weapons) can be considered to result in a **moderate** risk.

- Lead in hunting is likely to cause a **low** risk for hunters at shooting. RAC notes also that a proportion of the exposure may be caused by the primer. Use of lead in primers is however out of scope of the restriction proposal. Also jacketing of bullets reduces lead emissions.

Shooting at shooting ranges / sports shooting

- Sports shooting results in **high** risk to individual birds of sensitive species and a **very high to high** risk for populations of rare bird species.

- 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 conceptual risk assessment model.

- The risk of groundwater contamination may vary from **very low to high** depending on the soil and groundwater characteristics. The combination of acidic soils, coarse soils, preferential flow pathways or macropores and shallow depths to groundwater (<3m) leads to high vulnerability to lead contamination. 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. Although the number of shooting ranges where these four conditions occur are probably limited to a small fraction of total sites in Europe, this fraction may not be insignificant.

- There are no data on the indirect exposure of humans via dairy products from livestock exposed via shooting ranges. At shooting ranges with a high intensity of shooting, located at or next to agricultural areas there is, however, a potential **(low to moderate)** risk for livestock exposure, and thus to humans eating dairy products.

- There is limited evidence of home-casting of lead bullets in Europe. If it occurs, home casting of bullets (for large calibre weapons) can be considered to result in **moderate** risk.

- Lead exposure in sports shooting when using lead ammunition (either from dust/fumes formed during shooting or from hand contamination caused by eroded lead gunshot and fragmented bullets) is likely to cause a **low to moderate** risk for frequent sports shooters; pregnant (or fertile-age females) being at a moderate risk if sports shooting is practised regularly. It is, however, noted that the risk varies according to shooting

discipline. Many shooting disciplines use jacketed bullets. Jacketing of lead bullets has been shown to reduce lead emissions but does not prevent those totally. The use of closed plastic cartridges in shotgun shooting may also limit exposure by reducing the formation of lead dust/fumes. A currently undefined proportion of lead emissions is caused by lead primers, the use of which is outside the scope of this restriction proposal.

Fishing

- RAC concludes that for swans and loons there is ample evidence for a very likely exposure and severe effects, resulting in a very **high** risk.
- A similar exposure of other (20) sensitive bird species is likely, but there is limited evidence and RAC therefore concludes that there is a **moderate** risk for these species.
- There may be accidental ingestion of sinkers among anglers, but it is difficult to conclude on a risk level for humans exposed to lead fishing tackle.
- There is no data available from Europe on exposure to lead during home-casting, but considering the possible conditions of home-casting, e.g., open conditions and lack of risk management measures, a **moderate** risk is assumed for adults based on it being very likely with exposure resulting in mild effects, and likely with exposure resulting in medium severe effects.

Quantitative risk assessment for the impact assessment

- A quantitative risk assessment for the environment was performed for the bird mortality. RAC supports the Dossier Submitter's estimate of a yearly mortality in the order of one million birds by primary ingestion of gunshot. Sub-lethal effects in birds are probably even more common but cannot be quantified. There is also mortality from secondary ingestion and from ingestion of fishing tackle, but that was only assessed qualitatively.

- A quantitative risk assessment for humans was performed for neurodevelopmental effects in children and for chronic kidney disease in adults. Although the effect on systolic blood pressure was also considered, human health impact assessment was not performed for this endpoint. Considering that the exposure estimates in adults resulted in only a < 1% increase in systolic blood pressure, RAC agrees with Dossier Submitter that no relevant quantifiable effects on systolic blood pressure are assumed to result from game meat consumption.

- RAC agrees with the Dossier Submitter's approach to take the whole distribution of blood lead levels forward in human health impact assessment. This approach is likely to give a more realistic overview on the variability of lead exposure from game meat consumption than a single point estimate.

- For IQ loss the Dossier Submitter used, either the median lead intake by any birth cohort, or only children prone to lose ≥1 IQ points for monetising the risks. It should be noted that both these approaches ignore the upper end of the curve including some exceptionally high (and therefore rather unlikely) lead exposures. RAC agrees with this approach but notes significant uncertainties caused by large variability in game meat

lead levels and lack of data on the B-Pb levels among high game meat consumers. The recent data suggesting high game meat lead levels in small game suggests that risks related to the small game may be even higher than estimated by the Dossier Submitter.

- Regarding chronic kidney disease risk for adults, the Dossier Submitter focuses on the population with an increase in chronic kidney disease risk of ≥ 10 %. The results of this analyses should be, however, interpreted with caution because of the conservative nature of EFSA BMDL, and because of the need for long term (>5 years) constant exposure via highly contaminated game meat. Therefore, RAC agrees with Dossier Submitter that the real numbers are likely to be significantly lower.

Key elements underpinning the RAC conclusion(s):

Environmental risks to wildlife (primary and secondary poisoning of birds)

The restriction proposal estimates that at least 135 million birds are at risk of primary poisoning of lead gunshot, 14 million because of secondary poisoning arising from the ingestion of lead gunshot or other lead projectiles, and 7 million because of ingestion of fishing sinkers and lures. RAC notes that it should be interpreted as number of birds of potentially sensitive species living in the EU.

The Dossier Submitter has used EU data on the number of either breeding birds or wintering birds reported by each Member State as a basis for assessing the number of birds in the EU, and then applied expert judgement (assisted by UNEP /AEWA and UNEP/CMS) to assess which species are likely to: i) primary ingestion of gunshot, ii) secondary ingestion of ammunition-derived lead from prey or carcasses, and iii) primary ingestion of fishing tackle, respectively.

RAC notes the difficulty in assessing the numbers of birds in general since different Member States present different ambition levels in reporting (e.g., only four species are reported for Malta), possibly resulting in an underestimation of number of birds. Although the numbers are uncertain, RAC considers that the selection of 'sensitive' species performed by the Dossier Submitter (41, 29 and 22 respectively, in total 92 species) as well as the estimated number of birds at risk for each of these species (135, 14 and 7 million respectively) are the best data that are available and supports the use of these data for impact assessment

The Annex XV restriction dossier presents the estimated mortality rate and number of birds that die each year from primary ingestion of lead (calculated by the Dossier Submitter as the estimated mortality rate multiplied by the number of birds in the EU that could be potentially exposed to different forms of lead-containing gunshot).

i) Terrestrial[10] birds at risk of primary poisoning from ingesting lead gunshot

The Dossier Submitter has estimated the mortality rate based on Pain et al (2019a), Meyer et al (2016), and Potts (2005).

[10] The denomination of "terrestrial birds" refers to terrestrial and waterbirds that feed in terrestrial environments

Pain et al (2019a) used data from Butler (2005) and Butler et al (2005)) showing that 3% of pheasants at shooting estates and 1.4% of red-legged partridges had ingested lead gunshot. They applied the Bellrose methodology (Bellrose, 1959) and other assumptions, and calculated an annual mortality rate of 0.3-0.6% for these two terrestrial species.

RAC notes that Meyer et al (2016) mention three articles (two by Potts, one being Potts 2005 (see below)) that have estimated the mortality rates in grey partridges at 1-6%. Based on these estimates, Meyer et al (2006) estimated the lead-induced annual mortality in partridges at 7%, but the model was also used for other predictions, i.e., that the annual survival would be reduced by 2% and that the partridge population size would be reduced by 10%. The modelling also concerned red kite and buzzard, and although the modelled effect on population sizes were almost negligible, the modelling indicated that the yearly survival was reduced by 0.6-3.9% in all three species due to lead gunshot poisoning. RAC has not assessed the model.

Potts (2005) reports on investigations of the pathology of 1 318 grey partridges found dead in the UK from 1947-1992. During three periods, it was estimated that ingested lead gunshot was the cause of death in 0.3%, 4.0%, and 2.7% (the latest period 1970-1992) of the dead birds. The lethality of one ingested gunshot was estimated to be 76%, and 100% if three gunshot were ingested.

RAC notes that any estimate of an annual mortality rate is highly uncertain, but the order of magnitude is supported by other studies. The mortality likely varies between species because of different feeding habits and sensitivities to lead. And there are likely to be geographical differences depending on hunting pressure. However, RAC can agree that an annual mortality rate of 1% in terrestrial species due to ingested gunshot, as suggested by the Dossier Submitter, seems plausible. Assuming a close to 100% mortality from the ingestion of one gunshot (Potts 2005 reports a lethality of 76% in partridges), a 1% mortality is also supported by many studies showing that 1% is also a reasonable estimate of the proportion of birds having ingested lead gunshot, also outside shooting estates (Romero et al., 2020, Travis and Solem, 2016). The incidence is likely to be higher in shooting estates and shooting preserves. However, it is acknowledged that the 1% estimate of birds having ingested gunshot is a snapshot as it concerns the percentage of birds that at a given time have ingested lead. However, had the ingestion of lead been investigated at another point of time, other birds may have been found to have lead in the gizzard, so that over the full year a percentage higher than 1% is likely. Considering this aspect, the estimated 1% mortality could therefore be an underestimate. On the other hand, it is likely that the percentage having ingested gunshot is lower outside the hunting season, and ingestion of one gun shot is not 100% lethal in any study. Overall RAC considers that a mortality rate of 1% seems reasonable for terrestrial bird species.

Assuming an annual mortality rate of 1%, RAC finds that the number of terrestrial birds that could die each year due to lead gunshot poisoning is in the order of 1 million, in line with the estimated value presented by the Dossier Submitter. However, RAC acknowledges that this estimation contains uncertainties. Regardless, it is likely that many additional birds will suffer from sub-clinical poisoning. Of concern is that among the 41 species at risk identified by the Dossier Submitter, 19 species are listed under the EU Birds Directive (Directive 2009/147/EC) as requiring highest conservation attention.

ii) Secondary poisoning in birds of prey and scavengers arising from the ingestion of lead gunshot or other lead projectiles

The Dossier Submitter proposal lists 29 predatory and/or scavenging species that could be affected by secondary poisoning arising from the ingestion of lead gunshot or other lead projectiles present in prey or carcasses. RAC supports this selection and particularly notes the presence of many, more or less, endangered species on this list (e.g., vultures and eagles). In fact, 24 of these species are listed in the EU Birds Directive as requiring highest conservation attention.

There is sufficient evidence for e.g., vultures and eagles being poisoned by lead from ammunition, and considering the small population size of these species, any mortality or sub-lethal toxicity is of great concern. According to the Dossier Submitter, about 14 million birds of these species in the EU may be at risk. RAC notes that this number is made up of common species such as crows and endangered species like vultures. As no estimates on mortality is available, the Dossier Submitter did not try to estimate how many birds potentially will die annually after lead exposure. However, there are many studies that show poisoning of predatory and scavenging birds by lead, so RAC considers that many species are indeed at risk. Of extra concern is when endangered species are affected by both mortality and sub-lethal effects potentially affecting the survival of that species. Two recent publications have summarised results from analysing birds of prey found dead in Spain (Descalzo et al, 2021) and Sweden (Helander et al, 2021) in the period 2004-2020 and 2003-2011, respectively. Both studies found highest lead concentrations in the birds during and after the hunting season and suggested that 1-15% of the dead birds of the different species were most likely poisoned by lead. In addition to mortality, blood lead concentrations indicated that many surviving birds suffered from adverse sublethal effects (e.g., 74% of Eurasian griffons (*Gyps fulvus*)).

A recent review (Monclús et al., 2020) of 114 studies published in 1983-2019 on lead exposure of European raptors found a seasonal peak in blood lead concentrations related to the hunting season and that the level of exposure in several species were high and likely resulting in sub-lethal effects. The review found a number of studies that related behavioural changes in raptors to chronic exposure to lead (Krone et al., 2009, Berny et al., 2015 and Ecke et al 2017). A correlation between lead exposure and hunting ammunition was shown by many studies using lead isotope signatures. Helander et al. (2021) (comment #3348) also showed a correlation between the percentage of white-tailed sea eagles (*Haliaeetus albicilla*) poisoned with lead and hunting pressure, and thus that in areas with high exposure to hunting ammunition, 24% of the dead birds showed lethal lead levels.

The UNEP CMS ad hoc Expert Group (comment #3343) suggests using 3% mortality for the species that are clearly predatory or scavenging (representing 79 000 dead birds per year) (and 634 000 birds (24%) affected by lethal or sub-lethal poisoning). RAC notes the large variation in mortality estimates, depending on e.g., species, feeding habits, season and hunting pressure. An overall mortality estimate in the order of 1% seems plausible, which would potentially result in 140 000 birds being poisoned each year by lead. However, RAC is more concerned for the threatened species, where the mortality is possibly higher but the number of poisoned birds still becomes rather small considering the small population sizes. No specific analysis has been made for the 24 species that are listed in the EU Birds Directive as requiring highest conservation attention, but RAC notes that any additional toxic pressure

from lead in ammunition will be of concern for these species.

iii) Poisoning of birds after ingestion of fishing sinkers and lures

The restriction proposal lists 22 species, representing some 7 million birds, potentially exposed to lead from fishing sinkers and lures. Small sinkers are probably most easily ingested, but sinkers up to the size of 100 g have occasionally been ingested by larger birds (loons). The evidence for such exposure is robust for swans in the UK and loons in North America. It should be noted that arctic loons (*Gavia arctica*), red-throated diver (*Gavia Stellata*), and common loons (*Gavia immer)* are widely distributed in North Western Europe; none are regarded as endangered species (IUCN) but the EU Birds Directive stipulates that these species "shall be the subject of special conservation measures concerning their habitat in order to ensure their survival and reproduction in their area of distribution" (Directive 2009/147/EC). Leaded fishing sinkers (0.06 – 28.35 g) have therefore been banned in the UK, immediately resulting in decreased lethality in British swans. The Dossier Submitter proposes a three year transition period for sinkers weighing equal or less than 50 g and five years for sinkers weighing more than 50 g. RAC can support this proposal considering that there are few examples of bird ingestion of heavier objects and that it may take a longer time to find suitable alternative materials for heavier sinkers as most alternatives have a lower density than lead, making heavy sinkers of alternative materials very large. As no data on mortality is available, the Dossier Submitter has not tried to estimate how many birds will potentially die yearly after lead exposure from sinkers and lures.

RAC concludes that mortality and sub-lethal effects can occur in many species (e.g., swans) after ingestion of fishing tackle (e.g., sinkers), but the extent is unknown and probably depends on local fishing/angling techniques and fishing pressure.

Overall, RAC concludes that a massive amount of lead is spread each year in the environment from lead gunshot, leaded ammunition (via wounded prey or carcasses), and fishing tackle, and that about 150 million birds of different species in the EU are at risk of exposure to lead from these sources. Based on known exposure of birds, and assuming an overall mortality rate of 1% (as suggested by the Dossier Submitter for terrestrial species), RAC supports that in the order of 1 million birds are likely to die each year as a consequence of lead poisoning. However, some of these species are very common and rather than focusing on the number of birds that die by lead poisoning, RAC is more concerned for the threatened species, where mortality and also more common sub-lethal poisoning may be critical for the survival of the species. RAC further notes that among the 92 'sensitive' species in total, 54 are listed by the EU Birds Directive as particularly threatened, and which "shall be the subject of special conservation measures" (Directive 2009/147/EC). RAC supports the Dossier Submitter in that limiting the use of leaded ammunition and fishing tackle will be an important conservation measure for these threatened species.

As mentioned above, based on an assumed overall mortality rate of 1% from ingestion of lead from gunshot, RAC considers that mortality in the order of 1 million birds/year because of lead poisoning seems plausible. Another approach to check this estimate is to start from data on how common it is to find birds that have ingested lead, i.e., in the form of lead gunshot. If assuming 135 million terrestrial 'sensitive' birds and 1% as an annual rate of gunshot ingestion in these terrestrial species (which constitute the bulk of the overall 150 million 'sensitive' birds), then more than one million birds will annually ingest lead. The data

on mortality after ingesting gunshot is limited, but according to some studies, 76% of partridges (Potts 2005) and 14% of mallards (Green 2020) were killed by the ingestion of one gunshot. Assuming a lethality of 100% for one gunshot as a worst-case estimate, 1.35 million terrestrial birds will die annually. Assuming a 14% lethality, the figure is 0.19 million. The real figure is likely in between, in the order of 1 million birds without considering sub-lethal effects. Mortality can be higher if ingesting more than 1 gunshot, or larger gunshot/fishing weights are ingested, or if ingesting gunshot often. Mortality is likely to be lower in areas with limited hunting.

RAC supports a yearly mortality in the order of one million birds. However, RAC is more concerned for the many threatened species exposed to lead from ammunition and fishing tackle, where mortality and sub-lethal poisoning may be critical for the survival of the species. RAC thus supports that there is a risk that is not adequately controlled resulting from the use of lead in ammunition in hunting and sports shooting and fishing.

Quantitative risk assessment for humans

In order to quantify the risk of IQ loss for children resulting from the consumption of contaminated game meat, the Dossier Submitter took the whole distribution of game meat lead levels and estimated the distribution of B-Pb levels and the corresponding IQ losses in children of 'hunter' families. This was used to build a cumulative empirical distribution function. From this distribution, it was estimated that 50 % of the exposed population (of the total of 1.1 million children in hunter's families) is at risk to lose > 0.05 IQ points and 6% to lose > 1 IQ point. For the monetizing of health impacts in children, the Dossier Submitter used, either the median lead intake by any birth cohort, or only children prone to lose ≥1 IQ points. It should be noted that both these approaches ignore the upper end of the curve, which includes some exceptionally high repeated lead exposures, which are considered quite unlikely. RAC agrees with this approach and considers that it provides a more realistic overview than any single point estimate. However, it should be noted that it does not eliminate the uncertainties related to the dose-response of lead, the representativeness of the game meat lead concentration data used for the assessment, and the modelling approach used to estimate long-term lead exposure. In relation to the lead concentration in game meat, a recent study suggests higher lead levels in small game than those estimated by the Dossier Submitter based on EFSA data (Pain et al., 2022). This makes the Dossier Submitter assessment less conservative than initially considered.

A similar approach was used to estimate the risk of chronic kidney disease . The size of the exposed population was estimated to be about 10 million. Empirical cumulative distribution functions for excess chronic kidney disease risk from lead ammunition suggested that 50 % of the exposed population face an excess risk larger than 0.1 percent points and 3.1 % of the population bear an excess chronic kidney disease risk of ≥ 10 %. Combining this with the baseline chronic kidney disease prevalence rate, a total of 1 085 additional cases of chronic kidney disease (stages 3-5) among the 10 million exposed hunters (or their family members) was estimated. The results of these analyses should be, however, interpreted with caution. First of all, as discussed under the hazard section, there are significant uncertainties related to the EFSA BMDL at these low B-Pb levels and EFSA BMDL10 can be considered to represent a worst-case value. Secondly, a long-term constant exposure to highly contaminated game meat (with lead levels >5 000 mg/kg) is needed to result in an excess chronic kidney disease risk of >10%. This is likely to represent a rather rare, extreme, situation. Therefore, RAC

agrees with Dossier Submitter that there are significant uncertainties related to the estimation of number of excess chronic kidney disease cases and the real numbers are likely to be significantly lower than estimated using this approach. The Dossier Submitter used 100 cases as a lower bound number of cases. RAC agrees that this represents a more reasonable estimate.

Qualitative risk assessment

To scrutinise the qualitative assessment made by the Dossier Submitter, RAC used a different approach based on a conceptual model considering the potential source of exposure, receptor, pathway and the probability and severity of effects. To assess the probability and severity of effects, a 4x4 risk matrix is used (see Annex 1: RAC qualitative risk assessment approach). The results of this analysis are described in the tables below and the main conclusions have been taken forward and compiled under chapter RAC conclusions (above).

To assess the probability and severity of effects, the 4x4 risk matrix shown below in table 2 is used.

Table 2. Risk matrix for qualitative risk assessment

Risk Category		***Severity of effects***			
		Severe Human Health: B-Pb ↑ >70µg/l in adults and >30 µg/l in children/pregnant females); Environment: Short term risk of pollution of sensitive water resources. Catastrophic damage to buildings or property. Short term risk to an ecosystem or organism forming part of that ecosystem	*Medium* Human Health B-Pb ↑ > 30-70µg/l in adults and 12-30 µg/l in children/pregnant females. Environment: Pollution of sensitive water resources, significant change in an ecosystem or organism forming part of that ecosystem.	*Mild* Human Health B-Pb ↑ >15-30 µg/l in adults, <12 µg/l in children/pregnant females; Environment: Pollution of non-sensitive water resources. Significant damage to crops, buildings, structures and services. Damage to sensitive buildings, structures or the environment	*Minor* Human Health (B-Pb ↑ <15 µg/l in adults); Environment: Harm, not necessarily significant, but that could result in financial loss or expenditure to resolve. Easily repairable damage to buildings, structures and services
Probability	*highly likely*	**very high**	**high**	**moderate**	**low**
	likely	**high**	**moderate**	**moderate / low**	**low**
	low likelihood (possible)	**moderate**	**moderate / low**	**low**	**very low**

	Unlikely	**moderate / low**	**low**	**very low**	**very low**

The risks are summarised in the following Table 3, 4 and 5. Further explanation for the assessment of individual risks is provided in Annex 1. The risks are assessed separately for three main use scenarios relevant for this restriction proposal: 1) Sports shooting in shooting range, 2) Hunting and 3) Use of lead-containing fishing tackle.

Table 3. Qualitative risk assessment for shooting at shooting range / sports shooting

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
'Act of Shooting': fumes and dust formed during shooting, dust from eroded/fragmented shot/ bullets.	Adult Shooter and Observer(s)	Direct Inhalation of fumes and dusts formed during shooting; Dermal contact to settled dust from eroded/fragmented shot /bullets (resulting in hand-to-mouth exposure and ingestion of lead)	+/++ (depending on shooting frequency)	For firearms: Likely For airguns: Low likelihood-Likely	For firearms: Mild For airguns: Minor	**For firearms: Low-Moderate*** **For airguns: Very low-Low**
'Act of Shooting': fumes and dusts formed during shooting, dust from eroded/fragmented shots/ bullets	Foetus (Pregnant Shooter)	See above	not assessed	For firearms: Likely For airguns: Likely	For firearms: Medium For airguns: Mild	**For firearms: Moderate*** **For airguns: Low-Moderate**
Home-casting: fumes and dust, lead massive,	Adult shooter	Direct Inhalation of fumes and dust;	+++	Likely Highly likely	Medium Mild	**Moderate**

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
lead shot/ bullets		Dermal contact with lead (resulting in hand-to-mouth exposure and ingestion of lead)				
Lead shot fallout, lead objects, lead fragments	Birds, Individuals of 70 sensitive species	Ingestion	+++	Likely	Severe	**High**
Lead shot fallout, lead objects, lead fragments	Populations of common bird species	Ingestion	+++	Likely	Minor	**Low**
Lead shot fallout, lead objects, lead fragments	Populations of rare bird species	Ingestion	+++	Likely-Highly likely	Severe	**High-Very high**
Lead shot fallout, lead objects, lead fragments	Humans (> 45m distance), especially farmers and their children	Ingestion via contaminated water or food	+/++/+++	Unlikely-Low likelihood	Medium (for children and fetuses)	**Low-Moderate**
Lead shot fallout, lead objects, lead fragments	Soils: As Topsoil/Surface Soil: Lead contamination of shooting ranges at 200 – 300 g of lead per square meter can be found and constitutes pollution of	Lead gunshot, bullets, fragments, that remain on the soils are available to be ingested. Soluble lead is absorbed by soils, and its mobility in subsoils is limited.	+/++	Highly Likely	Medium	**High**

Potential Source	Potential Receptor	Possible Pathway	DS qualitative risk estimate	RAC qualitative risk assessment		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
	soil surface. Hazard for terrestrial organisms. *Breach of PNEC Pb soil 212 mg/kg*					
Lead shot fallout, lead objects, lead fragments	Soils: (1) > 300m distance[11] from a Shooting Range (2) in Subsoils Hazard for terrestrial organisms. *Breach of PNEC Pb soil 212 mg/kg*	1) Maximum distance of lead shot/projectile from a firing point is 300m. 2) Soluble lead is absorbed by soils, and its mobility is limited. Limited cation and exchange with clays.	+/++	Low likelihood	Minor	**Very low**
Lead shot fallout, lead objects, lead fragments	Local surface waters: *Breach of PNEC aqua (freshwater) 2.4 µg/L and 186 mg/kg sediment, Water Framework Directive EQS 1.2 ug/L*	Runoff/dilution and exposure to aquatic organisms, and/or sedimentation, hence exposure to fish	+++	Likely	Medium	**Moderate-High** (depending on dilution)
Lead shot fallout,	General surface	Runoff/dilution and	+++	Likely	Minor	**Low**

[11] Figure B.9-4 & Table B.9-9 (Background Document): Maximum distance of lead contamination from a skeet or trap range from the firing point is 220m (Victorian EPA, 2019). Also, page 105 (Annex XV Report): The flight distance of shot is directly proportional to their size. At skeet ranges, shot 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. Terrain contours and trees have a significant effect on the spread of the shot, as do wind conditions.

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
lead objects, lead fragments	waters: *Breach of PNEC aqua (freshwater) 2.4 µg/L and 186 mg/kg sediment, Water Framework Directive EQS 1.2 ug/L*	exposure to aquatic organisms, and/or sedimentation, hence exposure to fish				
Lead fragments	Groundwater in geographical areas where the FOUR conditions occur: *Breach of Drinking Water Directive value of 10 µg/l.*	1.Acidic soil (pH <6) 2.Coarse (usually sandy) soils 3.Preferential flow pathways, or macropores 4.Shallow depth to groundwater (< 3m).	+/++/+++	Highly Likely	Medium	**High**
Lead fragments	Groundwater in the more common geographical areas and with the FOUR conditions: *Breach of Drinking Water Directive value of 10 µg/l.*	1.Soils (pH >6) 2. non coarse (non sandy) soils 3. Absence of preferential flow pathways, or macropores 4. Depth to groundwater (> 3m).	+/++/+++	Unlikely	Medium	**Low**

*The use of jacketed bullets reduces the exposure and risk, risk characterisation is focusing on the use of non-jacketed bullets. Part of the exposure may come from lead primer. Closed plastic cartridges used in shotguns may limit the exposure of shooters.

Table 4. Qualitative risk assessment for hunting

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
'Act of Shooting': fumes and dust formed during shooting, dust from eroded/fragmented shot/ bullets.	Adult Shooter and Observer(s)	Direct Inhalation of fumes and dusts formed during shooting; Dermal contact to settled dust from eroded/fragmented shot /bullets (resulting in hand-to-mouth exposure and ingestion of lead)	+	Likely	Minor-Mild	**Low**
'Act of Shooting': fumes and dust formed during shooting, dust from eroded/fragmented shot/ bullets.	Foetus (Pregnant Shooter)	See above	not assessed	Likely	Mild	**Low-Moderate**
Home-casting: fumes and dust, lead massive, lead shot/ bullets	Adult shooter	Direct Inhalation of fumes and dust; Dermal contact with lead(resulting in hand-to-mouth exposure and ingestion of lead)	+++	Likely	Mild	**Low-Moderate**
Game meat	Adults	Ingestion	+	Likely-	Minor-	**Low**

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
consumption				Low likelihood	Mild	
Game meat consumption	Children < 7y Foetuses (pregnant females)	Ingestion	+++	Likely-Highly likely	Medium	**Moderate - High**
Lead shot fallout, lead objects, lead fragments	Birds, Individuals of 70 sensitive species	Ingestion	+++	Likely	Severe	**High**
Lead shot fallout, lead objects, lead fragments	Populations of common bird species	Ingestion	+++	Likely	Minor	**Low**
Lead shot fallout, lead objects, lead fragments	Populations of rare bird species	Ingestion	+++	Likely-Highly likely	Severe	**High-Very high**
Lead shot fallout, lead objects, lead fragments	Soils: Hazard for terrestrial organisms. *Breach of PNEC Pb soil212 mg/kg*	1) Low loading of lead onto soil surface in hunting grounds. 2) Soluble lead is absorbed by soils, and its mobility is limited. Limited Cation and exchange with clays.	+/++	Low likelihood	Mild	**Low**
Lead shot fallout, lead objects, lead fragments	Surface waters: *Breach of PNEC aqua (freshwater) 2.4 µg/L and*	Low loading of lead onto soil surface in hunting grounds hence low		Low likelihood	Minor	**Very low**

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
	186 mg/kg sediment, Water Framework Directive EQS 1.2 ug/L	runoff/dilution and exposure to aquatic organisms, and/or sedimentation, hence exposure to fish				

Table 5. Qualitative risk assessment for fishing.

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very High
Fishing with leaded fishing tackle: sinkers and lures **≤50g**	Birds, general Swans and loons	Ingestion	+++	Birds, general: Likely Swans and loons: Highly likely	Birds, general: Medium Swans and loons: Severe	**Birds, general: Moderate** **Swans and loons: Very high**
Fishing with leaded fishing tackle : sinkers and lures **>50g**	Birds, general Loons	Ingestion	No risk identified	Birds, general: Unlikely Loons: Low likelihood	Birds, general: minor Loons: Severe	**Birds, general: Very low** **Loons: Moderate**
Home casting, fumes and dust, fishing sinkers and lures, all sizes	Adult fisherman	Direct Inhalation; Dermal contact (resulting in hand-to-mouth exposure and ingestion of Pb)	+++	Direct Inhalation: Likely Dermal contact: Highly likely	Direct Inhalation : Medium Dermal contact: Mild	**Moderate**

3.1.5. Uncertainties in the risk characterisation

There are many uncertainties in the estimate of the number of shooting ranges and in the amount of lead released every year. There are various, not always consistent, estimates of the amount of lead used in sports shooting.

There are uncertainties in the estimates of bird mortality in the EU due to secondary ingestion of lead ammunition. Uncertainties also concern the estimate of bird mortality due to secondary poisoning caused by the ingestion of lead fishing tackle given the absence of adequate data sets in the EU. Another uncertainty concerns the occurrence of sub-lethal effects of lead in birds, which are likely to be rather common but cannot be quantified.

Also hunting statistics are incomplete and very uneven in EU Member States. It is likely that scavenging mammals are exposed to lead through offal or discarded meat left in the environment. However, there are only a few such documented cases and RAC agrees with the Dossier Submitter that this cannot be elaborated further.

Risk of lead fishing tackle for the wildlife is not underpinned by extensive exposure data. The scientific documentation on the extent of lead fishing tackle ingestion by birds is in general very poor. It is difficult to identify small lead objects ingested by birds, and to distinguish a lead shot from a lead sinker after it had been eroded into the gizzard of birds.

There are significant uncertainties in the assessment of all human health effects which are largely due to limited information on exposure. In the case of game meat consumption, exposure has been assessed by modelling due to the lack of measured data. Available data on lead concentration in game meat is highly variable. There is no data on exposure caused by home-casting, or by consumption of meat, dairy products, plants or drinking water by farmers living close to shooting ranges. Also, data on exposure of shooters and hunters due to the fumes/dust emitted during shooting outdoors is very limited and may not be only related to the shot/bullets but also to the primers containing lead.

Several uncertainties are also related to the dose-responses and BMDLs derived based on the human epidemiological data. These uncertainties are mainly related to the possible confounders present in underlying epidemiological studies. Especially, dose-response of health effects in adults at low B-Pb levels (≤100 µg/l) are uncertain.

3.1.6. Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

Summary of proposal:

Environmental risks

The Dossier Submitter provides extensive evidence of lead poisoning of birds resulting from ingestion of lead ammunition and fishing tackle. 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 of birds 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). Some evidence of lead poisoning of ruminants (Braun et al., 1997, Macnicol, 2014, Muntwyler, 2010, Rice et al., 1987, Scheuhammer and Norris, 1995, Vermunt et al., 2002) either via ingestion of contaminated soil and grass when grazing on shooting ranges or when being fed with (lead gunshot) contaminated silage is also available.

Suggested (but not binding) risk management measures (RMMs) to control the environmental risks arising from the use of lead ammunition in sports shooting are described in the Chemical Safety report (CSR), as presented in Section 1.4.4.2.1 of the Background Document. However, because of accumulation of lead gunshot in and on soil, the Dossier Submitter considers that the environmental RMMs described in the CSR (2020) for shooting ranges are not enough to protect soil and potentially groundwater from contamination and birds and ruminants from poisoning. The Dossier Submitter proposes additional RMMs to ensure the adequate containment/recovery of lead ammunition and control of water runoff. In addition, any agricultural use at a permanent range should be banned due to the residual risks.

Human health risks

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 according Commission Regulation (EC) 1881/2006[12]. Authorities such as French ANSES[13] or German BfR[14] recommend that children and women at childbearing age should not consume game meat shot with lead ammunition.

Regarding lead exposure resulting from shooting, 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.

The Dossier Submitter 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”.

Many suppliers sell moulds for casting lead bullets, fishing sinkers and lures. 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. According to

[12] 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. No limits in lead content are defined for game meat.

[13] https://www.anses.fr/en/content/consumption-wild-game-action-needed-reduce-exposure-chemical-contaminants-and-lead

[14] http://www.bfr.bund.de/cm/349/research-project-safety-of-game-meat-obtained-through-hunting-lemisi.pdf

a study commissioned by the Dossier Submitter (Appendix 2 of the Background document), although the conditions of use of lead in home-casting are not generally known, the worst case-scenario can be expected to occur for professional users handling relatively large amounts without proper local exhaust and good general ventilation.

RAC conclusions:

A high mortality in many bird species caused by lead used in ammunition or fishing tackle, and assumingly even higher incidence of sub-lethal effects, show that the risk management measures are not sufficient to protect these many bird species, of which many are red-listed as being threatened.

Evidence of poisoning of livestock (ruminants) resulting from the consumption of contaminated soil and/or silage show the potential of soil contamination with lead in shooting areas used for agriculture.

Specifically related to hunting, high levels of lead in the game meat sold in the market further supports the conclusion of the inadequate control of risks.

Limited evidence suggests that frequent shooting even in outdoor shooting ranges (or related to hunting) may result in elevation of B-Pb levels of shooters, which may be a concern especially for pregnant shooters.

Key elements underpinning the RAC conclusions:

The high mortality that has been reported especially in lead-exposed birds of prey (including scavengers) but also in terrestrial and aquatic bird species shows that the risk caused by lead has not been appropriately managed. For instance, Helander et al (2021) indicated that 24% of white-tailed sea eagles (*Haliaeetus albicilla*) found dead in an area with a high hunting pressure was poisoned with lead. Of all studied white-tailed sea eagles, 81% had liver lead concentrations exceeding the current background concentration in other species, and whereas liver lead concentration in other species decreased considerably from 1980 to 2010, the concentration in sea eagles increased. Of 300 radiographed sea eagles, 15% contained visible remains of lead-based ammunition (shotgun pellets or bullet fragments). Similarly, blood lead concentrations in Eurasian griffons (*Gyps fulvus*) indicated that 74% of the birds may have suffered from adverse sub-lethal effects of lead (Descalzo et al, 2021). Many studies have linked the lead exposure to ammunition using lead isotope signatures. Concerning species that feed in terrestrial environments, the conclusion that in the order of 1 million birds die yearly after ingesting lead gunshot and finding dead aquatic bird species having ingested lead sinkers, clearly shows that current risk management measures are not sufficient.

There are plenty of data demonstrating clearly elevated lead concentrations in game meat used for human consumption. This data is further discussed in the work package report WP A.5 and in the Background Document. This is further supported by the recent review submitted to ECHA/RAC during the opinion development process (*Pain et al., How contaminated with ammunition-derived lead is meat from European small game animals? Assessing and reducing risks to human health. Submitted for publication*) suggesting even an increase in game meat lead levels over time during the past 30 years (in small pray hunted with shotgun) in many European countries, except in Denmark where a total ban of lead gunshot is in force and lead levels in small pray are lower compared to pre-restriction levels.

A voluntary “ban” present in the UK from 2020, did not show effects on lead levels in pheasant meat or in the amount of lead gunshot used during the first two hunting seasons.

Regarding livestock, there are data on cows and calves showing that, grazing on shooting ranges, or use of silage produced at shooting ranges, may cause significant exposure to livestock. The limit of 30 mg lead/kg for lead in forage is likely to be breached regularly.

Although risks for adult shooters can be considered as low in outdoor sports shooting, no safe limit is known for foetal risk. Based on the comments from the consultation of the Annex XV report, this issue is not well recognised, and no special precautions have been recommended by the equipment manufacturers to manage these risks for fertile-aged females practising shooting.

There is evidence showing that home-casting of ammunition and fishing sinkers occurs in the EU, and the data (mainly from other parts of the world) suggests that home-casting can result in substantial exposure to lead.

3.1.7. Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

Currently the Netherlands (since 1993) and Denmark (since 1996) are the only EU Member States with a total ban in place on the use of lead gunshot in all types of habitats. In other Member States, the use of lead gunshot is banned in shooting ranges in the entire territory (Sweden and Norway) or in regions or areas within the territory (e.g. Belgium). Additionally, the use of lead-based bullets is regulated in some regions, sites or National Parks in a few EU countries (including Germany, Italy, Spain) in order to avoid contamination of game meat and/or to protect raptors from lead poisoning.

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.

Additionally, there are no limits to the lead content in wild game defined in the EU. In several European countries, hunters should follow “best practice” regarding game meat preparation 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)).

RAC conclusion(s):

RAC agrees with the Dossier Submitter that the many adverse effects caused by lead in wild birds (see above) clearly show that existing risk management instruments are not sufficient. If fact it is hard to see how any risk management measures apart form a ban on lead could be successful across such diverse jurisdictions, habitats and species. The same applies also for contamination of topsoil, surface waters in local scale. There is evidence showing that this have resulted to exposure of livestock grazing on shooting ranges or fed with silage produced at shooting ranges.

RAC also agrees with the Dossier submitter that existing regulatory risk management instruments to limit game meat lead levels are not sufficient. There is for example no maximum residue level for lead in game meat in Europe and no regulatory monitoring required. In addition, there are no labelling requirements to warn of the hazards of lead ammunition for the environment and human health.

Key elements underpinning the RAC conclusion(s):

Concerning exposure from lead in bullets, some Member states have revised the advice to remove a bigger part of the meat around the wound, and to not discard the removed parts in the environment. However, the concentration of lead in meat used for human consumption (see justification under 3.1.7) and continuing mortality in wild birds, shows that these measures are not sufficient. Furthermore, it is not possible to check to what extent this advice is followed, and differences between Member states are possible. This lack of harmonisation within EU applies also to the risk management measures at the shooting ranges to prevent environmental contamination and contamination of the food chain. Therefore, existing regulatory risk management instruments are not sufficient and not harmonised.

3.2. JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

The Dossier Submitter concludes that lead used in gunshot and other types of projectiles (i.e. bullets and airgun pellets) for outdoor shooting (hunting and sports shooting) and in some uses of fishing tackle (such as sinkers and lures) poses risks to the environment and human health, in particular to birds and vulnerable populations such as children, that is not adequately controlled and needs to be addressed at the EU level.

The four main justifications for action on a Union-wide basis put forward by the Dossier Submitter 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 Convention on the Conservation of Migratory Species of Wild Animals (CMS), and the CMS Memorandum of Understanding on the Conservation of Migratory Birds of Prey in Africa and Eurasia (Raptors MOU) to protect 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 within the EU.

SEAC and RAC conclusion(s):

The use of lead in hunting, sports shooting and fishing is widespread and presents a risk to the environment and to human health that is not adequately controlled (either from direct

exposure or from exposure via the environment). Even if some Member States have already taken specific measures to limit or ban the use of lead ammunition for hunting, sports shooting or fishing, the risks posed by lead will still be observed Union-wide without further action. Therefore, based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC agree that Union-wide regulatory measures are justified.

Key elements underpinning the SEAC and RAC conclusion(s):

The Dossier Submitter presents convincing arguments to justify acting on a Union-wide basis:

- *To ensure a harmonised high level of protection of the environment and human health to address the identified risks:*

  The Dossier Submitter reported that the use of lead in ammunition outdoors and in fishing tackle contributes to lead pollution in the environment. The negative impacts of lead in the environment are well-documented, in particular in terms of adverse effects on birds. Birds may ingest spent gunshot, bullet fragments or fishing tackle leading to lead poisoning, which can result in death or sub-lethal toxicity. Moreover, there are negative impacts possible due to secondary poisoning in the food chain. Many species of birds migrate across EU Member States, meaning the negative impacts of lead poisoning are apparent Union-wide, even in Member States that have already introduced regulations preventing or limiting the use of lead in hunting, sports shooting or fishing (e.g., Denmark, The Netherlands).

  The Background Document demonstrates that human health risks of lead in ammunition – mainly related to exposure via food – and of lead in some uses of fishing tackle (e.g. sinkers and lures) – mainly associated with home-casting and hand-to-mouth exposure – are presently not adequately controlled, including in vulnerable populations (e.g. children).

  The use of lead ammunition and fishing tackle in Europe remains widespread despite its risks to 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 11% from fishing. Because these risks are a Union-wide concern, SEAC and RAC agree that initiating a Union-wide regulatory action is appropriate.

- *To address the lack of EU-wide commitment to fulfil the EU Birds Directive and other international agreements towards the protection of birds and their habitats:*

  SEAC and RAC note that several species reported to be regularly affected by lead poisoning are specifically protected by the Birds Directive[15]. Even though the Birds Directive explicitly requires hunting practices to not jeopardise conservation efforts[16], its implementation in most Member States does not sufficiently address the risks to birds arising from the use of lead ammunition. Also, other EU and international

[15] Annex I of Directive 2009/147/EC

[16] Article 7 Directive 2009/147/EC

agreements to protect natural habitats and endangered species have not tackled this regulatory gap (see point 2 of the *Summary of proposal* section above). Therefore, specific regulatory action to address the risks posed by the use of lead in outdoor shooting and fishing is needed to contribute to the goal of the EU Birds Directive to protect wild bird species in the EU.

Moreover, the proposed restriction can be considered to have a positive impact on the implementation of the Water Framework Directive as lead is listed as a priority substance.

- *To ensure the free movement of goods within the Union:*

  Existing national regulations on lead use in shooting and fishing for the protection of human health and the environment across Member States are very diverse. They range from almost-complete bans, to voluntary restrictions, to no regulation at all. This situation also affects the internal market for lead ammunition and fishing tackle. Furthermore, SEAC agrees with the Dossier Submitter that the market for firearms and ammunition used for hunting and sports shooting is served by a limited number of manufacturers operating internationally and thus should be regulated in as harmonised a manner as possible. The same rules throughout the European Union would allow manufacturers and distributors to send a consistent message to their customers about the availability of alternatives and at the same time would allow to simplify offerings of the range of ammunition types in the various Member States, which would allow suppliers to benefit from reduced costs because of economy of scale in production and storage.

- *To ensure a level playing field for all engaged in sports shooting:*

  SEAC agrees with the Dossier Submitter that the proposal will contribute to create harmonised conditions for sports shooters within the EU.

  Taking part in international competitions (e.g. the Olympics) makes it necessary that participants can prepare for such events under optimal conditions, which represent the conditions during the competition as closely as possible. Because for the time being, the rules at international competitions still prescribe the use of lead ammunition, the political decision-maker may consider it as desirable or necessary to create training opportunities for the participation in such events allowing the use of lead ammunition by means of a special derogation as an interim solution.

  Whilst the impacts of the proposed restriction with and without a special derogation were assessed by the Dossier Submitter (and are evaluated by SEAC), it is not within SEAC's remit to comment on political reasons for such a derogation or to recommend any particular policy in relation to rule changes at European or international level. Moreover, the impact of any future potential initiative on a political level resulting from the proposal cannot be evaluated by SEAC.

  However, SEAC notes that despite some initiatives in the past to change the international rules in this respect, the international sports shooting federations responsible for setting the rules have been reluctant to consider this, even for cases where non-lead alternatives appear to be available (e.g., for gunshot). The proposed

restriction may give further incentives for a review of competition rules on an international level.

3.2.1. Description of and justification for targeting of the information on hazards and exposure / emissions (scope)

Summary of proposal:

The restriction proposal concerns the use of elemental massive lead (particle diameter ≥ 1 mm) or lead alloys in projectiles (gunshot, bullets, pellets) and in fishing tackle at a concentration equal or greater to 1% w/w.

It covers both outdoor shooting and fishing activities which may result in the distribution of lead in the environment. In addition, it covers both environmental and human health hazards related to these activities. However, the Dossier Submitter's proposal does not include indoor shooting, which does not result in dispersion of lead in the environment although it may result in human exposure.

In addition, the focus of the restriction proposal is on the civilian use of ammunition only. This covers hunting and sports shooting. Police and military use of ammunition is explicitly excluded from the scope of the restriction proposal.

RAC conclusions:

- RAC agrees that targeting of the restriction to the use of lead in projectiles, gunshot, and fishing tackle in outdoor uses is appropriate to address the risks to the environment, and especially to birds.
- RAC supports restricting home-casting, as performing this activity under uncontrolled conditions is likely to result in a high exposure to lead, and thus a high human health risk.
- RAC agrees that non-civilian uses by police, military and border control when they are "on duty" should be out of scope. However, in order to ensure a high level of protection for the environment, training using lead ammunition by these groups at public shooting ranges should be subject to the same conditions (i.e., mandatory RMMs) as those proposed for civilian shooting ranges. This same applies to voluntary military training, which may often take place in civilian shooting ranges. Therefore, RAC agrees that voluntary military training taking place in civilian shooting ranges should be in the scope of restriction.
- However, RAC notes that military shooting ranges exclusively in use for military purposes including training are out of the scope of the restriction proposed by the Dossier Submitter and, even though justified from an environmental protection point of view, it is not possible to include those in the scope of the restriction.
- Exposure and risks to shooters caused by lead in ammunition do not result only from the bullets and gunshot but also from lead-containing primers, containing e.g., lead styphnate. In order to minimise such exposure risk management measures to limit exposure to lead from primers also need to be considered.
- RAC also notes that indoor shooting may result in high exposure of shooters. Although professionals working or practising in indoor shooting ranges are covered by EU OSH legislation (Chemical Agents Directive), this does not cover risks to non-professionals using these shooting ranges. Therefore, RAC points out that risk management measures are also needed to tackle the risks to consumers practising shooting in indoor shooting ranges.

Key elements underpinning the RAC conclusion:

When considering the environmental exposure and risks, the main issue is to limit the distribution of lead-containing bullets, shot, and pellets in the environment where they can be picked up by birds or other wildlife, or where they can contaminate soil and water. Targeting of the restriction to outdoor shooting is justified to prevent these risks. However, if training of professionals, like police, border control personnel or military personnel are not included in the scope, the shooting ranges used exclusively by these groups remain uncontrolled if the requirements for risk management measures introduced by the restriction for civilian ranges are not implemented at shooting ranges for professionals.

It should be noted that the Dossier Submitter's proposal does not ban the use of lead projectiles in shooting ranges if there are appropriate risk management measures in place and agricultural use of the land does not occur within the site boundary. From a human and environmental risk perspective, public shooting ranges used for training of professionals like police, border control personnel or military personnel should also apply the risk management measures proposed to reduce the risks to human health and environment. RAC understands that in many cases non-military professionals like police and border control officers may use shooting ranges which are also used by civilians. In these cases, the conditions of the restriction would also apply for the practising of these professional groups. However, military forces usually have their own shooting ranges. These shooting ranges used exclusively for the training of military forces fall outside the scope of the restriction since military uses are not included in the proposal. Similarly, shooting ranges exclusively in use for other non-civilian forces such as police forces would fall outside the scope of the restriction. Although RAC considers that the risks resulting from the use of lead ammunition in these shooting ranges should be controlled in a similar way to shooting ranges for civilian uses, the Committee recognises that the impacts of these measures have not been assessed by the Dossier Submitter and therefore cannot be addressed in this opinion.

On the other hand, RAC recognises that the use of lead projectiles by professional users while on duty are not associated with the uncontrolled risks identified by the Dossier Submitter. In addition, the use of alternatives to lead projectiles in urban environments may be associated with additional risks, i.e., ricochet from hard surfaces.

The quantity of fumes formed during shooting which arise from primers versus bullets/shot is not clear. The typical substance used in primers is an explosive called lead styphnate. Since this restriction proposal is focused only on projectiles, the Dossier Submitter has chosen not to include other ammunition components. Primers are therefore outside the scope of this restriction. However, RAC notes that all lead release and exposure contribute to the risk. Lead styphnate has been registered under REACH but there are no consumer uses or consumer exposures included in the registration[17]. Given that lead styphnate is mainly used in small arms ammunition and serves as a primary explosive in firearms primers, which will ignite upon impact, the description of uses in the registration dossier seems incomplete, according to RAC. Lead styphnate has been added in the candidate list of SVHC substances for eventual inclusion in Annex XIV already in 2011 (ECHA, 2011) but, according to RAC's knowledge, no actions have been taken to include it in Annex XIV during the past 10 years and no actions are currently on-going.

[17] https://echa.europa.eu/fi/registration-dossier/-/registered-dossier/14733/3/1/4

There is a significant number of literature data showing elevated B-Pb levels in shooters practising in indoor shooting ranges. Although professionals working or practising in these indoor shooting ranges are covered by EU OSH legislation (Chemical Agents Directive), this does not cover risks to amateurs/non-professionals using these shooting ranges. Therefore, from a human health perspective, risk management of the use of lead in indoor shooting ranges would appear to be needed in addition to the proposed restriction.

Especially concerning fishing tackles (but also lead ammunition) there is a relevant concern on the exposure of humans due to the home-casting activity. Home-casting of ammunition and fishing sinkers has been shown to occur in the EU and as discussed earlier, it may result in significant exposure, although the data on exposure levels in Europe is limited.

3.3. JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of SEAC and RAC

Scope including derogations

Summary of proposal:

The Dossier Submitter conducted an analysis of risk management options (RMOs) to identify the most appropriate measure to address the identified risks. The RMOs assessed include regulatory measures under REACH other than restriction, other existing EU legislation, and other possible Union-wide RMOs.

The Dossier Submitter also assessed alternative restriction options (ROs), alone and in combination, for each sector in the scope of the investigation (covering eight uses in total).

As a result, the Dossier Submitter proposes a restriction comprising different types of measures:

- A **ban on placing on the market and use** where the release of lead is impossible or difficult to control by other risk management measures (RMMs), technically and economically feasible alternatives are available, and no disproportionate socio-economic impacts are to be expected from a **complete ban**. A ban on placing on the market and use is proposed to apply to lead in gunshot, fishing wires, sinkers and lures.

- A **ban on use only** where a ban on placing on the market would disproportionately affect uses outside of the scope of the proposed restriction and uses where releases can be controlled by other RMMs and where there are no suitable alternatives yet. A proposed ban on use only is proposed to apply to lead projectiles other than gunshot (i.e. bullets and airgun pellets) used in hunting and sports shooting (unless sports shooting with bullets takes place under strict conditions, see next bullet point).

- A **conditional derogation** of uses if releases can be controlled by other RMMs and where there are no suitable alternatives yet, i.e. the use of lead projectiles other than gunshot (i.e. bullets and airgun pellets) in sports shooting if shooting takes place at a notified (to the Member State) outdoor location for sports shooting with appropriate containment measures in place.

- A **derogation** if the use does not contribute significantly to lead releases. This applies to full metal jacket bullets and lead bullets for seal hunting, for which no suitable alternatives exist, and to lead in fishing nets, ropes and lines.

- An **information obligation** for retailers **at the point of sale** ('retailer duty') to inform consumers about the phase-out timelines for uses banned and in order to raise awareness of the risks of lead among users. Retailers will also be obliged to inform consumers about the availability alternatives to lead-containing gunshot, other types of projectiles, and fishing sinkers and lures.

- A **labelling obligation** for suppliers ('supplier duty') where placing on the market will not be restricted in order to facilitate enforcement of a ban on use in the field. This obligation applies to lead projectiles other than gunshot (i.e. bullets and airgun pellets) in hunting and sports shooting.

For some of the uses banned, a transition period is proposed to allow sufficient time for stakeholders to comply with the restriction, taking into account the availability of alternatives.

The Dossier Submitter proposes different lead concentration limits for placing on the market and using (≥ 1% w/w), and for the labelling ('supplier duty') and information ('retailer duty') obligations (≥ 0.3% w/w). Additionally, the Dossier Submitter proposes by way of derogation a lead concentration limit equal to or greater than 3% w/w for any other projectiles not defined as gunshot made of 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.

The restriction report clarifies that the focus of the restriction proposal is on lead projectiles used in firearms and airguns. Therefore, the use of lead in other ammunition components (e.g. primers, propellants, casings) are outside the scope of the restriction proposal. **Indoor uses** of lead projectiles and military uses of lead projectiles, along with other similar **non-civilian uses** of lead projectiles such as by the police, security services and customs forces, are also **outside the scope** of the restriction proposal.

The Background Document makes it clear that the Dossier Submitter prefers a complete ban of lead gunshot. However, the Dossier Submitter also investigated the impacts of an '**optional conditional derogation**' to allow the continued use of lead gunshot for sports shooting. This option may be considered by the decision-maker to allow the participation of EU athletes in national or international shooting events (or the hosting of such events in EU countries), where the use of lead gunshot is still required and it is deemed important that all participants can train for and practice their sport under equal conditions. The optional conditional derogation identifies a set of minimum RMMs to be implemented at sites using lead gunshot. Implementation of this option by the decision-maker would also introduce specific obligations for the Member States, including the issuing of **permits** for shooting ranges that have implemented specific RMMs for this purpose and **licences** for those users that have a legitimate need to use lead gunshot. In addition, this option would be accompanied by a **labelling requirement** for suppliers ('supplier duty') and a **reporting requirement for the Member States** which would grant such permits and licences.

Finally, the Dossier Submitter lists some Union-wide measures other than a restriction under REACH that could be implemented by national associations to support the proposed restriction.

A summary of the proposed restriction by sector and use can be found in the Background Document (Executive Summary, Table 3).

RAC conclusion(s):

General conclusions on the scope have been already listed under section 3.1.1 of this opinion. The following analysis focuses on the risk management options including derogations and labelling requirements.

Lead ammunition in hunting

The Dossier Submitter proposes to ban the placing on the market of gunshot and the use of gunshot and bullets for hunting. The proposed ban on bullets covers both large calibre and small calibre centrefire and rimfire bullets. However, several comments submitted in the consultation of the Annex XV restriction report requested a derogation for small calibres due to the lack of alternatives with adequate precision. RAC agrees with the Dossier Submitter that this ban is the only risk management option capable to effectively eliminate the risks for the environment and human health related to the use of lead ammunition in hunting.

The Dossier Submitter has proposed derogations for seal hunting and for the use of full metal jacket bullets for special hunting application. There is data suggesting that the contamination of game meat with lead when using non-expandable full metal jacket bullets is likely to be low/negligible. The use of full metal jacket bullets is only allowed in Nordic and Baltic countries for special game hunting. Total use of lead in seal hunting has been estimated to be 20 kg per year in EU. Based on this information, RAC considers that proposed derogations are not compromising the effectivity of the restriction.

Derogations for muzzle loaders and airgun pellets have been also considered. Airguns are mainly used for pest control. The use of both muzzle loaders and airguns in hunting is limited in volume and therefore their impact on the total risk reduction is low.

For copper and copper-based (brass) bullets, a concentration limit of 3% of lead w/w is proposed with a later review to determine if a concentration of less than 1 % of lead w/w can be achieved. There is no quantitative data to estimate the impact of this difference to human exposure via game meat or to risks to wildlife. Impacts might be low especially when considering that in alloys other alloying metals may limit the release of individual metal components. Considering that copper-based bullets are the main alternatives for lead bullets, RAC supports this derogation and agrees with the Dossier Submitter that it should be subject to a a review prior to its entry into force to determine if a concentration of less than 1 % of lead w/w can be achieved.

RAC considers the transition period of five years proposed for the entering into force of the ban on the placing on the market and use of gunshot in hunting is unnecessarily long and recommends shortening it.

Lead in sports shooting

The Dossier Submitter questions how lead gunshot and bullets can be used safely (for the environment and human health) in sports shooting. An optional derogation of the ban on the placing on the market and use of gunshot in sports shooting is proposed by the Dossier

Submitter taking into account that international organisations such as the Olympic/ISSF/FITASC sports shooting rules require using lead gunshot in competitions and the sports regulators may consider this as necessary. Additionally, the Dossier Submitter proposes a derogation of the ban on the use of lead bullets and other ammunition when specific operational conditions and risk management measures are implemented since alternatives are not yet available for all calibres.

RAC does not support the optional derogation for gunshot in sports shooting proposed by the Dossier Submitter and considers that the enforceability of the restriction would be greatly improved if the optional derogation is not implemented. RAC recommends that the Commission undertake a further analysis of the need for this optional derogation and the possibility to change the requirements for sports shooting competitions established by international organisations such as Olympic/ISSF and FITASC. As secondary option the optional derogation should be limited to shot sizes used in sports shooting, as proposed by SEAC.

According to the optional derogation for lead gunshot, the placing on the market and use of lead gunshot in shooting ranges may take place only if the shooter and the shooting range have a licence/permit granted by the Member State, the shooting range has introduced adequate risk management measures to control de risks (regular >90% recovery of lead at least annually, surface water control, and ban of agricultural activities), and the individual lead gunshot cartridges are labelled accordingly. The proposal requires regular recovery of lead at least annually, but RAC notes that if the bookkeeping of used gunshot is properly conducted, regular recovery at longer time intervals than yearly may be as effective as yearly recovery, and acceptable provided that a >90% recovery is obtained.

In the case of ammunition other than gunshot, e.g., bullets and airgun pellets, the Dossier Submitter proposes a derogation from the ban on use of lead-containing ammunition when the shooting range has a permit by the Member State, adequate risk management measures to reduce the risks are implemented and monitoring and treatment of surface (run-off) water take place The Dossier Submitter also recommends compulsory information on the hazard/risk of lead, transition periods and availability of alternatives, and indelible labelling of ammunition packages, combined with a ban of any agricultural use within the site boundary. Since, shooting with lead bullets and airgun pellets is likely to continue also when this restriction will be in place, RAC supports these information/labelling requirements and ban of agricultural uses next to shooting ranges.

RAC concludes in line with the Dossier Submitter that, should a derogation be granted for the use of lead ammunition in sports shooting, both in case of lead gunshot and other lead projectiles (e.g., bullets and airgun pellets), lead containment and a high lead recovery rate must be achieved. This high level of environmental protection is most probably only achievable with a combination of operational conditions (OCs) and risk management measures (RMMs) that will vary depending on the type of shooting range and the type of shooting discipline. For shooting ranges using only gunshot, a >90% lead recovery is required based on a mass balance where the recovered amount of lead is compared with the registered used amount of lead gunshot. The specific OCs and RMMs are not defined as they will depend on site-specific considerations (range layout, impermeable/vertical/horizontal barriers). However, a very detailed bookkeeping system for used gunshot will be required in order to ensure a 90% lead recovery rate. Therefore, RAC supports having the recovery rate expressed

in percentage rather than specifying exactly which OCs and RMM must be implemented. RAC acknowledges that a recovery rate expressed in percentage is significantly more difficult to ensure by enforcement authorities than checking whether specific OCs and RMMs are in place. However, RAC considers that the specific OCs and RMMs needed at a specific site and during a specific discipline to reach > 90% recovery rate of lead are more effectively defined by the permit holder.

For the use of other lead projectiles (e.g., bullets and airgun pellets) at sports shooting ranges, the Dossier Submitter's proposal requires the use of trap chambers or 'best practice' sand traps (comprising of a sand berm with a water impermeable barrier between the sand and the soil, overhanging roof or a permanent cover, and a water management system) to ensure an effective recovery of lead. Lead can frequently be recovered from the trap chambers whereas recovery of lead from the 'best practice' sand traps is typically done every 3-5 years.

RAC agrees with the Dossier Submitter that at specific types of shooting ranges, where all ammunition is collected in trap chambers, containment with bullet trap chambers as a standalone RMM may achieve recovery rates > 90%. This is supported by information from the German Shooting Sport and Archery Federation and the Royal Netherlands Shooting Sport Association. For other types of shooting ranges, a 'best practice' sand trap can be adequate, but other types of backstop berms result in a much lower recovery rate and cannot as standalone RMMs effectively mitigate the risk of soil and aquatic contamination.

RAC supports compulsory information for consumers, especially the labelling of individual gunshot cartridges containing lead. A ban on potential agricultural use within the site boundary is needed to effectively eliminate the risks for the environment and for human health via the ingestion of contaminated food and water. The issuing of permits (and checking the available risk management systems) of shooting ranges may result in an additional workload for some Member States but RAC considers this is needed to ensure high levels of protection of environment and human health. RAC supports the proposed derogation as practical, effective, and enforceable, as use will only be allowed at shooting ranges notified to the Member State.

Fishing sinkers and lures

The Dossier Submitter proposes a ban on the placing on the market and use of lead fishing sinkers and lures, without an upper limit but with a longer transition period for sinkers weighing more than 50 g. RAC supports that this proposal provides the highest emission and risk reduction potential, as this option reduces the risk both to birds (resulting from ingestion of sinkers) and humans (resulting from inhalation of fumes from home-casting and from dermal contact to lead). Also, it is considered practical and enforceable since it concerns not only the use but also the placing on the market of sinkers and lures. RAC notes the due to the high density of lead, a 50 g lead weight is still a rather small sinker, and there are a few findings of birds with pieces of lead weighing >50 g in the gizzard, supporting that no upper limit is warranted. However, RAC supports that the risk to humans resulting from home-casting of sinkers is the main reason for including heavier weights (i.e., >50g) in the restriction. A longer transition period for heavier sinkers may be warranted considering that it may be difficult to substitute lead while not making the sinkers too large (considering the lower density of most alternatives). Limited evidence is provided to show a risk from fishing wire containing lead, but as alternatives are available and a risk cannot be excluded RAC supports the inclusion of fishing wire in the restriction proposal.

Labelling and information requirements

RAC supports the proposed information requirements for lead ammunition and fishing tackle at the point of sale before the ban will come into the force. RAC also supports the labelling requirements for lead bullets at the entry into force of the ban on use since lead-containing bullets will still be on the market for uses outside the scope of the restriction and for derogated sports shooting uses. However, RAC considers that the limit of ≥0.3% w/w of lead that triggers the information and labelling requirements may cause confusion and from a risk perspective, it does not make a significant difference if a limit of 1% w/w of lead is applied to the information and labelling requirements instead (in line with the limit that sets up the condition of the restriction for the use of lead in ammunition and fishing tackle). If a derogation allowing the use of copper or copper alloys containing lead up to 3% in other projectiles not defined as gunshot is accepted, then the information and labelling requirements should be applied for these alternatives only when lead content ≥3% w/w. This is since the proposed text does not fully apply to these alternatives if they are derogated and also to support the use of copper- based alternatives which are still less hazardous compared to lead bullets.

RAC supports the optional derogation requiring the labelling of individual shotgun cartridges with the statement “Contains lead: do not use for hunting.” However, also in this case, RAC supports the use of a limit of 1% w/w of lead instead of 0.3%. Attention should be paid also to the readability of the labelling of individual cartridges, and whether alternative approaches such as colour coding would be better.

Key elements underpinning the RAC conclusion(s):

In the case of hunting the Dossier Submitter analysed essentially five different risk management options:

- RO1: A ban of placing on the market and use of lead gunshot and bullets,
- RO2: A requirement of the specific design/construction of lead gunshot or bullets
- RO3: A ban on the placing on the market of game meat collected with lead gunshot/bullets or maximum levels of lead in game meat
- RO4: Advice to cut away more meat when handling game and meat collected with lead gunshot/bullets
- RO5: Compulsory information on the hazards of lead and the risks of using lead ammunition to be incorporated in national hunting exams and labelling of risks of lead on the package at the point of sale.

The main risks arising from the use of lead gunshot/bullets in hunting are related to the primary and secondary poisoning of birds, and to human health risks to young children and foetuses due to the consumption of contaminated game meat and to adults due to home-casting of bullets. Of the risk management options considered by the Dossier Submitter, RO2 does not prevent the primary and secondary poisoning of wildlife and not necessarily even the contamination of game meat. An exception for this might be non-expandable full metal jacket bullets. These are, however, allowed only for the hunting of specific game in Nordic countries. Thus, the Dossier Submitter did not consider this option as a plausible risk management measure - either for gunshot or bullets. Practicability and monitorability/enforceability were not analysed. RAC agrees with Dossier Submitter that this is not a plausible risk management option.

Similarly, RAC agrees that RO3 (ban of the marketing of game meat hunted with lead ammunition and lead concentration limit for game meat) is likely to result in the reduction of the use of lead ammunition in hunting and subsequent lead emissions in the environment but a significant proportion of hunters may not sell their game meat but rather consume the meat themselves. Therefore, although emissions to the environment are likely to be reduced, they are not fully eliminated and hunters themselves and their families may still be at risk of high exposure to lead either due to game meat consumption or home casting.

RO4 may only reduce human health risks due to the game meat consumption; risks due to home casting and risks to the wildlife are not prevented. The practicability and monitorability/enforceability of this option are also questionable.

RO5 relies on the education of hunters. The effectivity of this risk management option remains uncertain since the substitution of lead gunshot and bullets remain only voluntary.

Overall, RAC agrees with the Dossier Submitter that only RO1 (a ban of the placing on the market of lead gunshot and of the use of lead gunshot and bullets for hunting can sufficiently address both the environmental risks and human health risks in shooting. It would be also practicable since there are viable alternatives both for gunshot and bullets (see section on alternatives). Although monitoring/enforcement of the use of lead gunshot/bullet might be challenging, it is possible to monitor/enforce the placing on the market of the lead gunshot. However, especially in the case of bullets, possible derogations/uses outside the scope of the restriction may cause challenges for the enforcement (see section on enforcement). Challenges related to the enforcement and monitoring of the use of lead gunshot and bullets by hunters may result in some remaining risk, since it might still be possible to buy lead bullets (and in the case of the potential derogation, also lead gunshot) or lead for home-casting. However, overall this option, especially when combined with labelling/information can be estimated to reduce the risks rated originally as moderate-high to a low level in the qualitative risk assessment due to the reduction in the likelihood of exposure.

RAC agrees that the labelling and information requirements support the ban of the use of bullets for hunting before the ban comes into force since lead-containing bullets will still be on the market for uses outside the scope of this restriction and for derogated sports shooting uses. The Dossier Submitter proposed a limit of ≥0.3% w/w of lead to trigger the labelling and information requirements. This may cause confusion since it is different from the limit of 1% w/w that sets up the condition of the restriction for the use of lead in ammunition and fishing tackle. From the human health and environmental risk perspective, it does not make a significant difference if a limit of 1% w/w of lead (instead of 0.3%) is applied to the labelling and information requirements as well.

The Dossier Submitter has also given a recommendation for Member States to incorporate a mandatory module on the hazards of lead in the hunting exams for new hunters as an action supporting the restriction. The degree of usefulness will depend on the time-schedule of the entry into force of the restriction and of the time-schedule for setting up this kind of education module. Although only new hunters will be affected, RAC supports these educational efforts.

The Dossier Submitter has proposed a five year transition period for the entering into force of the ban of the placing on the market and use of gunshot for hunting. The view of RAC is that this transition period is too long. From a risk perspective, the shorter the transition period is, the less amount of lead will be released into the environment. In addition, the use of lead

gunshot in wetlands is already regulated in the whole EU.

In the case of sports shooting the restriction proposal addresses separately lead gunshot and other lead projectiles (e.g., bullets and airgun pellets).

Five options were analysed for lead gunshot:

- RO1 is a ban on placing on the market and use,
- RO2 is a ban like RO1 but with a derogation for sports shooting combined with a licence system for shooters, and annual reporting to the Commission,
- RO3 is a ban like RO1 but with a derogation for sports shooting at shooting ranges with permits and lead recovery systems (>90% recovery of gunshot) and systems for protecting run-off water (possibly combined with a ban of any agricultural use within the site boundary),
- RO4 is a combination of RO2 and RO3, and like in RO3, possibly combined with a ban of any agricultural use within the site boundary,
- RO5 concerns providing compulsory information, with the aim to result in voluntary substitution of lead gunshot.

The risk management measures relevant for the derogation of the ban on placing on the market and use of gunshot at permitted sports shooting ranges are further described in the work package report WP B.3 report[18].

The Dossier Submitter concludes that RO1 would be the most effective and enforceable option, but noted that this proposal would not allow any further Olympic/ISSF sports shooting using lead gunshot in Europe. The Dossier Submitter further analysed potential derogations limiting human and environmental risks while still allowing competitive sports shooting. In case the final policy decision is to allow continued sports shooting with lead gunshot, the Dossier Submitter introduced an optional derogation that would allow the use of lead gunshot if the shooter and the shooting range were licensed/permitted by the Member State. A combination of RO2, RO3, RO4, and RO5 would ban the placing on the market and use of lead gunshot unless the shooter and the shooting range are permitted by the Member States, the shooting range has introduced risk management measures (e.g., regular >90% recovery of lead and surface water control) and compulsory information to shooters and labelling of the lead gunshot cartridges are implemented.

RAC notes that the Forum advice raises several concerns regarding the licence/permit system as proposed by the Dossier Submitter and that enforcement of many aspects of the proposal is outside the mandate of REACH inspectors and may require the liaison of different inspection authorities. In the Background Document, the Dossier Submitter proposes a transition time of five years before the ban on the placing on the market and use of gunshot for sports shooting enters into force, but the possibilities (if any) to change the requirements for using only lead gunshot in sports shooting competition events such as those established by international organisations like the Olympic/ ISSF and FITASC have not been assessed. If it is not possible to change the requirements within a reasonable time frame (in the order of 5-10 years), RAC supports that a combination of RO2-5 is then an option. However, the RO2-5

[18] WP B.3: Effectiveness of risk management measures at shooting ranges

option will allow retailers to sell lead gunshot to authorised athletes, which will make enforcement of the restriction more difficult, although it might be possible for REACH inspectors to inspect the registry of buyers maintained by the shop. Since lead shot will be still available on the market, enforcement in the field (not by REACH inspectors) will be required. This may hamper the enforcement of this and the previous 'wetland' restriction.

If this optional derogation is considered necessary by the decision maker, SEAC has proposed that the derogation should be limited to shot sizes used in sport shooting. This would limit the use of other shot sizes commonly used in hunting. RAC supports this proposal. RAC notes, however, that this does not totally prevent the use of lead shots in hunting since these shot sizes are used for the hunting of some species.

Introducing a licence/permit system in 27 Member States for shooters and shooting ranges is likely to demand a high workload in the Member States (as pointed out by FORUM). It can also be questioned if such a system will be harmonised as different Member States may choose different ambition levels on requirements and numbers of permits granted. RAC recognises that in principle the requirement for reporting to the European Commission may allow some benchmarking and harmonisation between Member States over time. RAC has, however, no knowledge of any practical experiences from similar systems in the EU.

The proposed recovery rate of >90% of spent lead at permitted shooting ranges may be also difficult to enforce. RAC concludes that >90% of recovery of lead may be achievable but most probably a combination of measures needs to be applied depending on the type of shooting range and the type of shooting activity. Therefore, RAC supports having the recovery rate expressed in percentage rather that specifying exactly which measures will be needed. RAC acknowledges that a percentage is more difficult (perhaps even impossible) to enforce than checking whether specific measures are in place. However, the need for different (combinations) of measures will vary depending on site-specific conditions and can be more effectively defined at each specific site.

In summary, RAC supports the proposed restriction as practical and effective. However, the enforceability would be greatly improved by banning the placing on the market of lead gunshot and a further analysis is recommended of the possibility to change the present requirements established by international organisations such as Olympic/ISSF and FITASC to only use lead gunshot for competitions.

Three options were analysed for other lead projectiles (e.g. bullets and airgun pellets):

- RO1 is a ban on the use of lead bullets for sports shooting
- RO2 is a ban on the use of lead bullets for sports shooting unless it is performed on a shooting range notified to the Member State having appropriate risk management measures in place (and possible a ban on any agricultural use within the site boundary)
- RO3 is compulsory information aiming at voluntary substitution of lead bullets.

The RMMs relevant for derogations are further described in the work package report WP B.3.

RO1 is not further analysed as there are not alternatives available for all calibres.

The final proposal made by the Dossier Submitter is a combination of RO2 and RO3, i.e., banning the use of lead bullets unless the use takes place at a location notified to the Member

State and the site has introduced adequate risk management measures (RMMs) to control the risks, including monitoring and treatment of surface (run-off) water, combined with a ban of any agricultural use within the site boundary. The Dossier Submitter also recommends compulsory information on the hazard/risk of lead, transition periods and availability of alternatives and indelibly labelling of packages.

RAC agrees with the Dossier Submitter and considers bullet trap chambers as an effective and practicable RMM to mitigate lead contamination risks. RAC notes that the use of berms results in a much lower recovery rate and agrees with the Dossier Submitter that berms are not sufficient as a stand-alone RMM. However, 'best practice' sand traps may be rather effective although there is some uncertainty as to how effective they are since their effectivity may also depend on how they are managed and the type of shooting activity. RAC also supports mandatory information on packages containing lead bullets. Since lead bullets will still be available for use in shooting, RAC would like to emphasise the importance of mandatory information and labelling of lead ammunition to prevent the exposure of shooters and especially young (fertile aged) females.

According to the comments received in the consultation of the Annex XV restriction dossier, agricultural use within shooting ranges seems unusual. However, RAC supports the ban proposed by the Dossier Submitter on potential agricultural use within the site boundary as lead may be a risk for e.g., cattle grazing in the area. Checking the available risk management measures at shooting ranges may result in a new workload for some Member States but would be needed to ensure that lead will not affect the environment or human health at these shooting ranges. Some guidance might be needed to ensure a harmonised system.

In summary, although a ban on the placing on the market of lead bullets would be the most effective restriction option, RAC acknowledges that it is currently not possible as alternatives do not exist for all calibres. RAC lacks an analysis of a ban on the placing on the market of such calibres for which alternatives exist, and therefore cannot comment on this possibility. RAC supports the proposed restriction as practical, effective, and enforceable, as use will only be allowed at shooting ranges notified to the Member State.

For the proposal concerning fishing, the Dossier Submitter has evaluated eight different restriction options, albeit to different degrees.

RAC supports that a qualitative assessment is sufficient in some cases because of too limited data and clear shortcomings in effectivity of those options. Thus, restricting the placing on the market of material used for home-casting (RO1), restricting the use of fishing equipment intended to drop off lead sinkers (RO2), and mandatory information to consumers/fishers (RO7), will all only address a very small part of the problem associated with the use of lead in fishing, and the effects of these options are also questionable. A ban on the use of lead fishing sinkers and lures (RO5) also has questionable effectivity as enforcement is difficult (if not impossible).

A ban on placing on the market of lead fishing sinkers and lures (RO4) is indeed possible to enforce but will not affect home-casting and the use of home-cast fishing sinkers. Thus, RAC supports that this option will not sufficiently decrease the risk for birds (exposed to home-casted sinkers) and for persons involved in home-casting. Although speculative, this option may also increase the habit of home-casting fishing sinkers and thus increase human exposure.

RO3b concerns a ban on placing on the market and using fishing nets, ropes and lines containing lead. From a RAC point of view, dismissing this option is supported based on no (or very limited) exposure potential from these articles as the lead is encased in other materials in these articles.

RO3a is a ban on placing on the market and using lead fishing sinkers and lures, with or without an upper limit of 50 g for the sinkers. If no upper limit is used, different transition periods were suggested for weights ≤50 g (3 years) and for weights >50 g (5 years). RAC supports that RO3a provides the highest emission and risk reduction potential, as this option reduces the risk both to birds (resulting from ingestion of sinkers) and humans (resulting from inhalation of fumes from home-casting and from dermal contact to lead) Also, it is practical and enforceable since it concerns not only the use but also the placing on the market of fishing sinkers and lures. It is possible that the end user acceptance is low, but RAC notes that it is an assumption and therefore has no firm opinion on this assumption. As to the weight limit discussed, RAC notes the high density of lead and that 50 g lead is still a rather small weight. There are also a few findings of birds (loons) with pieces of lead weighing >50 g in the gizzard, supporting that no upper limit is warranted. However, a longer transition period for heavier sinkers may be warranted considering that it may be difficult to substitute lead while not making the sinkers too large considering different densities.

RO6 is similar to RO3a but includes a derogation for lead split shot (≤0.06 g), conditional to the placing on the market in spill proof and child resistant packaging. Such tiny sinkers may be lost while attaching them on the line, and losses will occur when the fishing line is broken. Such small lead split shot may perhaps constitute a very small part of all lead put on the market, but they are easily eaten by many bird species and the bioavailability of lead is high in such small particles. All in all, RAC does not support this derogation as it will decrease the environmental protection level.

Justification for the opinion of SEAC

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.3.1. Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal

Human health risk reduction

According to the Background Document, the main human health risks result from home-casting of lead bullets and game meat consumption. The most relevant health endpoints associated with exposure to lead are neurotoxic effects in children aged 7 and younger, as well as increases in the incidence of chronic kidney disease and in cardiovascular effects (increase in systolic blood pressure) in adults (EFSA, 2010).

The Dossier Submitters considers that as a result of the proposed ban on using lead bullets for hunting, fewer hunters will have an incentive to home-cast their bullets, and fewer people would therefore be exposed to lead fumes and dust, and in particular the children living in the same household as the hunters who are casting lead.

Regarding game meat consumption, the Dossier Submitter distinguishes between different scenarios depending on the types of game meat. The meat of large ungulates (incl. species like deer, moose and boars) are typically shot with bullets; the meat of smaller mammals such as hare and rabbit are shot with either small calibre bullets or gunshot; birds (in particular waterfowl) are typically bagged using gunshot. Based on the information available, the Dossier Submitter concludes that the proposed restriction 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.

Environmental risk reduction and releases avoided to the environment

The Dossier Submitter estimates that the proposed restriction would result in a reduction of emissions 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. In terms of risk to wildlife, especially birds, lead ammunition and/or lead contaminated tissues (in prey), when ingested by a bird, trigger severe adverse effects and could lead to mortality. Studies on sub-lethal effects of lead intake are ongoing, but the ones available suggest that lead can also affect reproductive success in various bird species.

According to the Dossier Submitter, without a ban on marketing and use of lead shot for hunting (if taking into account species considered to be at most risk of lead poisoning only) at least 135 million birds would be at risk of primary poisoning from lead gunshot. Of the 135 million birds being at most risk of primary poisoning, over one million birds would die annually due the direct ingestion of lead shot. Other birds (not quantified) would die as a consequence of sublethal effects. The expected risk reduction for many terrestrial (migratory) species from the proposed restriction would also fulfil the EU obligations under the Birds Directive and the CMS convention.

Without a ban on marketing and use of lead shot for hunting and on the use of bullets (small and large calibre) for hunting, 14 million birds (including raptors and scavengers species considered to be at most risk of lead poisoning only) would be at risk of secondary poisoning arising from the combined ingestion of lead gunshot, other lead projectiles and lead contaminated tissues in prey. The number of birds dying from secondary poisoning from both lethal and sublethal effects could not be quantified due to the lack of specific data. However, for already threatened species, any additional mortality caused by the ingestion of lead ammunition or lead contaminated prey may be of concern for the survival of that species.

In addition to the species at most risk of lead poisoning assessed by the Dossier Submitter, other species may still be at some risk as assessed by the UNEP/CMS ad hoc Expert Group (2020), without a restriction. Specifically, based on this assessment, the Dossier Submitter has calculated that additionally about 650 million birds (at least) would be at some risk of lead poisoning from the primary ingestion of lead shot and about 50 million birds (at least) would be at some risk of secondary poisoning from lead ammunition.

RAC conclusions:

Altogether, the Dossier Submitter has estimated that the proposed restriction would result in

a reduction of emissions of approximately 630 000 tonnes of lead over the 20-year period following its entry into force. This value will be scrutinised by SEAC. RAC has assessed the risks of alternatives for lead ammunition used for hunting and lead fishing tackle and concludes the following:

- RAC agrees with the Dossier Submitter that there are alternative materials available for lead shot and bullets in hunting and the use of these alternatives instead of lead reduces the human health and environmental risks related to hunting. RAC also agrees with the Dossier Submitter that there are several alternative materials for fishing sinkers and lures and the use of these will result in the reduction of risks to environment and humans (home-casting).

Regarding the use of lead in shooting ranges/sports shooting:

- RAC agrees that the use of alternative materials for lead shot and bullets in shooting ranges is effective in reducing the risks for environmental and the health of shooters.
- RAC also notes that there is no evidence to support the claim that steel-induced acidity in soils would promote the mobility of lead and therefore increase lead-caused risks to the environment.

Regarding the optional derogation 4a and b, RAC considers that its implementation would significantly complicate enforcement and reduce effectiveness. However, if the decision maker would decide that such an optional derogation is still needed, RAC agrees with SEAC that as a secondary option the derogation should be limited to shot sizes used in sports shooting.

Regarding the derogation proposed for the use of bullets in sports shooting, RAC concludes that trap chambers and/or 'best practice' sand traps will enable recovery of lead, while there is still some uncertainty as to the effectivity of the 'best practice' sand traps in practice. RAC therefore recommends remediation at the end of service life of all shooting ranges.

RAC also notes that there might be a need to create a collection system for banned lead ammunition and fishing tackle and provide information on the safe disposal of these restricted lead-articles.

Key elements underpinning the RAC conclusions:

Hunting

The Dossier Submitter proposes to ban the use of lead shot in hunting. The main alternative for lead shot is steel shot. Steel shot has already been widely used for hunting and although it has been proposed to result in higher ricochet formation, there is no data to support the higher risk to shooters even though steel shot is already widely used (see WP B.2 report). Steel (being mainly iron) presents clearly lower toxicity for humans and for birds compared to lead. Even though there are no data on game meat iron content after use of steel shot, due to homeostatic control of iron absorption from the gastrointestinal tract, slightly elevated game meat iron levels are unlikely to cause any significant health risk.

Other alternatives for lead shot are bismuth and tungsten. Neither of these have classification for human health or environmental hazards, but it should be noted that the hazards of these substances are less well investigated than those of lead. However, based on current

knowledge RAC does not have any strong reason for concern on their potential environmental or human health risks. Since these are critical raw materials and their environmental footprint (when considering the whole lifecycle) is estimated as relatively high, their use may be limited to special activities (see further WP B.2 report).

Additionally, the Dossier Submitter proposes to ban the use of lead bullets in hunting. The main alternatives for lead bullets are copper, zinc and their alloys (brass ad bronze). In the case of brass, it should be noted that currently brass may contain lead up to 3% which is above the limit specified in the restriction proposal. Zinc and copper are essential elements for humans with homeostatic control for their absorption in the gut. There are some measurement data on zinc and copper levels in game meat. The levels of copper were well below the maximum residue levels given for copper in meat. Also zinc levels remained at the level regularly detected in meat (see further WP B.2 report). These data support the low risk. Copper and zinc fumes may result in acute inflammatory reactions and metal fume fever at high exposure levels, however, this risk is related to the shooting in confined spaces with inadequate ventilation and not a relevant risk in hunting scenarios.

Although zinc powder is toxic to water organisms, the toxicity of both zinc and copper to the environment depends on the metal release from shot and bullets and the characteristics of the environment to which these particles are released. Release is reduced with increasing particle size (from fine powder to massive particles like shot) and also with alloying. When zinc is alloyed with copper or tin to make brass or bronze, respectively, its mobility in solution is lowered. Therefore, brass and bronze, whether used in bullets or fishing weights, exhibit less potential toxicity to aquatic environment. However, discarded small fishing weights made of zinc may cause toxicity to waterbirds if ingested.

Based on data provided in the consultation of the Annex XV report the use of full metal jacket bullets is likely to result in lower game meat lead levels. Jacketing of bullets reduces also shooter exposure. However, these full metal jacket bullets are only permitted for special hunting uses in Nordic countries.

Sports shooting

The analysis concerning the risks of alternative materials for shot and bullets applies also to shooting at shooting ranges.

As discussed in the work package report WP B.2, the literature review of field evidence from two lead-contaminated soil types with different soil chemistries (peatland with low pH and high organic matter; sandy moraine with neutral pH low organic matter) presented in the Ramboll report commissioned by the Dossier Submitter (Appendix 3 to the Background Document) shows the addition of steel shot has no significant effect on lead mobilisation, compared to steel-free samples. According to the study, there is no significant theoretical evidence of soil acidification related to the chemical reactions of iron in steel shot, due to both the fundamental chemistry of iron oxidation, the buffering capacity of soils and the greater contribution of other natural processes to soil acidification (e.g., microbes and acid rain).

Several stakeholders' comments on this issue received in the consultation of the Annex XV restriction report refer to the recent open-source evidence produced by Lisin et al. (2022), which they consider supporting the claim that the use of steel gunshot on shooting ranges will mobilise lead and other metals in soils at shooting ranges. This study was carefully

evaluated by WCA (2022, Appendix 4 of the Background Document). The WCA (2022) analysis counters this view showing that field-based evidence does not support the claims in Lisin et al. regarding acceleration of lead migration or iron, impacts upon surface and ground waters. The weathering of soils and the binding of lead species to arising organic matter or iron hydroxide precipitates (from steel shot) reduces the potential for lead to be mobilised or cause toxicity. In fact, where iron hydroxide precipitates are present, they are a more important binding phase for lead species than organic matter.

RAC agrees with the Dossier Submitter and the recent analysis by WCA (2022) that there is no evidence that steel-induced acidity in soils would promote the mobility of lead.

Lime and phosphate amendment of soil is mentioned as risk management measures in several comments received in the consultation of the Annex XV restriction report and although especially lime amendment can decrease the lead mobility in topsoil, RAC concludes that neither method is sufficient as a risk management measure.

Regarding the derogation for the use of lead bullets in shooting ranges which implement specific risk management measures, RAC concludes that trap chambers and/or 'best practice' sand traps will enable recovery of lead, while there is still some uncertainty as to the effectivity of the 'best practice' sand traps in practice. RAC therefore recommends remediation at the end of service life of all shooting ranges.

Fishing

There are a significant number of materials that have been described as alternatives to lead in fishing sinkers and lures, although the use of them in real life seems limited and varies in between countries. Alternatives include bismuth, brass, bronze, ceramic, copper, concrete, high density polymers, stainless steel, stones or pebbles, tin, tungsten, zamac, and zinc. However, some of them are not recommended because of aquatic toxicity (copper, zinc), or being critical raw materials with a concerning environmental footprint (tungsten and bismuth). Alternative, non-toxic materials that can be used thus include brass, bronze, ceramic, concrete, high density polymers, stainless steel, stones or pebbles, and tin, with positive experiences reported for ceramic, stainless steel, tin, and iron polymer putty. RAC concludes that alternatives exist, and that the suitability is clear for some of them but that further use will be needed to fully explore their usefulness in practise (e.g., for different types of weights and lures).

3.3.2. Socio-economic impact

Justification for the opinion of SEAC

3.3.2.1. Costs

Summary of proposal:

Add summary of Dossier Submitter proposal from the Impact Assessment section of the Annex XV restriction report.

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.3.2.2. Benefits

Summary of proposal:

See SEAC opinion

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.3.2.3. Other impacts

Summary of proposal:

See SEAC opinion

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.3.2.4. Overall proportionality

Summary of proposal:

In its assessment of proportionality, the Dossier Submitter compares the **cost** estimates (summarised in section 3.3.2.1 above) with the identified **benefits** (summarised in section 3.3.2.2 above) for the different sectors and/or uses.

For hunting some benefits have been monetised, including the **avoided mortality of** more than one million **birds** annually from primary ingestion of lead gunshot, valued at €114 million (€1 billion over 20 years), and the **avoided exposure to lead for humans** (via diet), estimated at €70 million per year for IQ loss (€852 million over 20 years) and €7.5-75 million per year for chronic kidney disease (€91-912 million over 20 years). In total these amount to €192-259 million per year or €2-2.8 billion over 20 years and compare to costs of around €1.1 billion over 20 years.

However, as quantified or monetised estimates for the identified benefits are mostly missing, the Dossier Submitter bases its proportionality assessment mainly on **cost-effectiveness considerations**. Depending on the affected sector/use, these are for the Dossier Submitter's central estimates in a range between €1 and €525 per kg of avoided lead releases (see Table 1). For the restriction proposal as a whole, costs of around €19 per kg of avoided lead releases are indicated. Overall, the Dossier Submitter considers the proposed restriction to be more

cost-effective (i.e., it costs less to reduce lead release by 1 kg) than previous REACH restrictions addressing similar concerns.

In addition, the Dossier Submitter complemented the cost-benefit and cost-effectiveness considerations with considerations about the affordability of the proposed restriction for hunters and fishers.

Based on the assessment of the overall risk reduction potential and the socio-economic impacts for each sector and use affected, the Dossier Submitter concludes that the proposed restriction is, overall, effective and proportionate.

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.3.2.5. Uncertainties in the proportionality section

See SEAC opinion

3.3.3. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

Hunting

According to the Background Document, many examples exist of situations where hunters have already switched to lead-free ammunition (gunshot or bullets) which demonstrates that a restriction on the use of gunshot and bullets is possible and implementable.

The Dossier Submitter states that the restriction on lead in gunshot over wetlands poses similar challenges to national 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. SEAC concluded in its opinion on the wetlands restriction proposal that a ban on lead in gunshot covering all terrains 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). Furthermore, SEAC concluded in the same opinion that restricting the 'placing on the market' in addition to 'use' would facilitate enforcement. This conclusion was also reached by Forum in their advice on the enforceability of the restriction proposal on lead in gunshot over wetlands.

The Dossier Submitter expects that the enforcement of a ban on lead-containing bullets may be more difficult in practice. However, the packaging of ammunition carried by hunters should

give some indication as to what 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.

The Dossier Submitter also points out that bullets are marked with the calibre on the back of the cartridge which will allow enforcers to verify whether hunters comply with the regulation regarding the different transition periods for the entry into force of the restriction for small and large calibres. Additionally, enforcers may use lead swipe tests in the field to detect any lead on a projectile or seize the cartridge or bullet for further analysis at the laboratory.

The Dossier Submitter states that compliance with the proposed information and labelling requirements can be ensured through enforcement at the point of sale and that the labelling of individual lead gunshot cartridges ('do not use for hunting') is intended to facilitate enforcement in the field in case the optional conditional derogation for lead gunshot in sports shooting is implemented.

Sports shooting

For gunshot, implementability is currently considered limited by the Dossier Submitter for its preferred option (complete ban) because it would not allow athletes to train or participate at international competitions (e.g. Olympic games). The other assessed restriction options for sports shooting with gunshot are considered to be more favourable in terms of implementability, with 'licensing/permitting/derogation systems' for athletes already in place in Member States with an existing ban on lead gunshot. For bullets, the conditions of the restriction are deemed to be implementable, as demonstrated by the existing examples in Germany, Norway and Sweden.

According to the Dossier Submitter, its preferred option for sports shooting with gunshot (complete ban) is enforceable. The addition of 'placing on the market' is considered to facilitate enforcement as inspections can be done at the point of sale. The other assessed restriction options for gunshot are also considered enforceable because permitting of sites and/or licensing of individuals would be delegated to Member States to fit with their legal system. The Dossier Submitter notes that enforcement of permitted sites can be achieved by means of inspection of the required documentation and that selling/reselling of lead gunshot by retailers only to licensed individuals would be enforceable because retailers need to be licensed to sell ammunition and athletes would need a licence to buy lead gunshot.

For projectiles other than gunshot, the proposed ban on use with a conditional derogation is considered enforceable because the use would be performed at outdoor locations for sports shooting notified to national or local authorities depending on the Member State's legal system and compliance with the required RMMs can be enforced by means of site visits and inspection of the mandatory documentation.

The Dossier Submitter states that compliance with the proposed information and labelling requirements can be ensured through enforcement at the point of sale.

Fishing

The proposed restriction is considered implementable and manageable by the Dossier Submitter. Alternative techniques or equipment are available and economically feasible. Although none of the available alternatives meet the technical performance requirements for every type of fishing tackle, applications or fishing techniques, each alternative could

successfully be used for one or more types of sinkers or lures.

The Dossier Submitter finds that 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 production capacity.

According to the Background Document, the enforcement of the ban on placing on the market could be done through inspections at manufacturer sites, retailers, customs, or websites, either by paper inspection, laboratory testing or swipe tests.

Additionally, the enforcement of the obligation to inform consumers at the point of sale, could be done together with the retailer inspections. According to the Dossier Submitter, it can be easily visually verified that information on lead hazard and risk is available, and visible at the points of sale, in the shops, and on websites selling lead fishing tackle.

Finally, the enforcement of the ban on use (use of lead fishing tackle, and use of techniques or equipment to intentionally drop off sinkers) will have to be carried out at the sites of use, i.e. fishing spots. This is considered necessary by the Dossier Submitter to prevent the use, exposure and releases of home-casted lead fishing tackle. According to the Dossier Submitter, REACH inspectors might not be the most appropriate inspectors to ensure compliance with the restriction provisions. Instead, enforcement at the sites of use could be performed by the existing relevant national enforcement authorities for fishing matters, i.e. either fishing associations or local authorities or ministries, depending on the EU country. These authorities are assumed to be knowledgeable and skilled to recognise lead fishing tackle and drop off techniques or equipment.

RAC and SEAC conclusion(s):

RAC and SEAC conclude that although in principle enforcement of the restriction as proposed is possible, present enforcement structures as they exist in the various Member States are not well suited for this task. If the final implementation of the proposed restriction would necessitate enforcement to inspect private persons or shooting ranges and not only conduct inspections of the sale of ammunition/fishing tackle, this will present problems because REACH inspectors are not used to/trained for this kind of inspections.

Successful enforcement may call for intensified additional cooperation and agreement between various government control agencies, especially in cases where such cooperation does not yet exist. Moreover, because in different Member States different control agencies may be involved, it might also be difficult to ensure meeting minimum standards throughout the Union. New cooperating structures (whatever their nature) might need to be developed and would certainly add to the complexity of organizing enforcement and will add significant costs, beyond the usual costs associated with enforcing REACH restrictions.

In addition, for an efficient enforcement, it is important that all definitions used have a clear and unambiguous description.

Information and/or labelling requirements for ammunition and fishing tackle containing lead equal to or greater than 0.3% is likely to cause confusion and may cause difficulties in enforcement since otherwise the lead limit used in this (and the ‘wetland’) restriction is 1% w/w. Therefore, RAC and SEAC propose to apply a limit of 1% w/w also for the information and labelling requirements.

Key elements underpinning the RAC and SEAC conclusion(s):

In the course of the RAC and SEAC discussions various aspects have been mentioned that gave rise to the conclusions as shown above. These can be summarized as follows:

In principle, a **ban on placing on the market** as it is proposed for lead in gunshot and in fishing tackle will be much easier to enforce than a ban on use only as implemented for gunshot in the wetlands restriction. However, as the wetlands restriction will only enter into effect in early 2023 there are no experiences from enforcement yet, but it is likely that in many Member States the resources required to allow for effective enforcement will not be available.

Where duties are imposed on local ammunition shops or shooting ranges, enforcement can be combined with existing controls, which will in many Member States already take place regularly (though not necessarily in a REACH framework).

Contrary to this, where **use** is to be banned, enforcement is expected to be problematic where this will involve **checks on private persons** and not on economic entities as it is usual for REACH restrictions. In many, if not all, Member States such checks will involve sections of the civil service that are different from the usual REACH and OSH inspectorates. It is unclear if formal structures exist or can be created that allow the flow of information and expertise between these agencies. If possible at all, it may involve bureaucratic hurdles and significant extra costs. Moreover, **inspections** on private persons will have to be done **in the field**, if hunting and fishing are concerned. Even if control agencies do exist, it is questionable if they will have sufficient human resources to fulfil these new REACH-based duties in addition to their existing ones.

Practical issues may arise if an inspector wants to certify if certain parts used in the field (gunshot cartridges, bullets, fishing gear) do meet the proposed concentration limits for lead. Qualitative detection of lead is possible by the use of e.g. “swipe tests”, even by non-specialised personnel. Although the quantitative determination of lead is not overly complicated as such, handling ammunition that contains lead is not straightforward. Only specialised laboratories have permits and procedures in place to store and handle live ammunition. This may make such analysis time consuming and will add to the costs of enforcement.

Where a **recovery rate of > 90 %** of lead is part of the condition, i.e. for the optional conditional derogation for sports shooting with gunshot, this will call for a detailed book-keeping system of the amount of lead spent in shooting and the amount of lead being recovered after cleaning. Especially keeping track of the first part will be a challenge for most shooting ranges where such a system did not exist before. Consequently, it will be difficult for inspectors to judge if they comply with the condition related to lead recovery.

During the development of the Background Document and the RAC and SEAC opinions, the exact **formulation and meaning of some definitions** have undergone some developments. Examples are the description of appropriate bullet containment/traps (now mentioned in paragraph 4d as trap chambers and best practice sand traps) and how to discriminate between military use (which according to paragraph 8 would be out of scope) and training for such use by reserve soldiers at civilian shooting ranges (which now is considered as “civilian use Apart from these developments, RAC suggests improving the

definition of “fishing wire” to facilitate enforcement.

With regard to the **optional derogation for sports shooting with gunshot**, the foreseen two-tiered system of **permits/licences** (for shooting ranges and individuals) presents complications that will be difficult to handle for inspectors and shooter alike:

a. Again, this may involve checks on private persons which is not part of the normal REACH activities.

b. The system as proposed leaves room for large differences between Member States regarding conditions for such permits/licences. Not only may this give rise to unequal training conditions for athletes across the various Member States, but also the government control agencies that need to be involved may be different, which may cause confusion regarding the permits/licences and what they cover, which would be an undesired effect of the proposed restriction.

c. A yearly reporting system for the number of such permits/licences granted to shooting ranges/individuals and the amount of lead gunshot used would be a new activity for inspectors, made more complex if they belong to different agencies which also may be different across Member States.

d. If the use of licences for individual athletes is supposed to serve their ability to participate in international competitions, mutual recognition of these permits (with potentially varying conditions) between Member States would be required, in order to maintain the “level playing field” that is mentioned as one of the objectives of the restriction. As such, SEAC and RAC welcome that such mutual recognition is suggested in the Background Document, but it is not an integral part of the restriction text.

In all, the permit/licence system has a risk of creating a highly unharmonized situation for the sports shooting field.

More extensive discussion regarding details of many of the aspects mentioned above can be found in the Forum advice.

3.3.3.1. Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

Hunting

According to the Dossier Submitter, the same tools, methods and equipment that are now used to establish the risk of lead in game meat can be used to monitor any progress on the phasing out of lead.

Sports shooting

The Dossier Submitter considers the proposal to be monitorable. The provisions under the optional conditional derogation for gunshot (if implemented) and under the conditional derogation for projectiles other gunshot for permitting/notification of sites and recording compliance with the required RMMs (and reporting in the case of gunshot) are considered to

enable both the inspection and the monitoring of the restriction.

Fishing

According to the Dossier Submitter, the proposed restriction on lead in fishing tackle could be monitored using the same methods as used to perform their market survey, i.e. contact fishing tackle manufacturers, importers, retailers, consult websites 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 which require monitoring of fishing tackle containing plastic placed on the market, as well as waste fishing tackle collected. 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.

RAC and SEAC conclusion(s):

Hunting

RAC and SEAC agree with the Dossier Submitter that current activities to monitor the lead concentration in game meat is suitable to monitor the effectiveness of the proposed restriction. In addition, another method of monitoring compliance is to explore the prevalence of ingested or embedded shot in birds or mortality due to lead poisoning over time.

Sports shooting

RAC and SEAC consider the restriction monitorable. In case the optional conditional derogation for the use of gunshot would be implemented, effective monitoring will depend on the reliability of "bookkeeping of lead use" at permitted shooting ranges. This will require shared reporting standards, which are not yet in place. The restriction also requires monitoring of lead content in drainage water from projectile impact areas (including surface water run-off) to ensure the effectiveness of RMMs at shooting ranges.

Fishing

Monitoring compliance can be performed by assessing the prevalence of ingested lead from fishing tackle in waterbirds over time. Monitorability of the phasing out of home-casting with lead seems to be difficult. Lead is available from a variety of secondary sources (sheet metal from roofing, sheathing from old underground and submarine cables, old balance weights from car rims, car batteries, etc). Thus, home-casting with lead is largely beyond the control of enforcement authorities.

Key elements underpinning the RAC and SEAC conclusion(s):

In the area of sports shooting, the reporting on use and recovery of lead shot (as required in the optional conditional derogation described in par. 4b and par. 6), presents an administrative challenge. This will be especially the case for those countries where so far such obligations do not yet exist. Common standards for reporting may be needed. Moreover, the issue is made more difficult if government departments that are not involved in REACH enforcement will be assigned responsibilities. After all, the availability, comparability and reliability of data regarding the use of lead will be decisive in effective monitoring of this

restriction.

More extensive discussion regarding details of many of the aspects mentioned above can be found in the Forum advice.

3.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

3.4.1. RAC

Summary of proposal:

The Dossier Submitter identified the following uncertainties:

Uncertainties related to lead in hunting ammunition

- Information on blood lead levels in hunters in relation to frequency of hunting (including hunting training) and the type of ammunition used is not available.
- No information is available on the incidence of hunters in the EU that are home-casting lead bullets for hunting.
- No information is available on the incidence of small children in the EU ingesting lead gunshot used for hunting.
- 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 in hunter families. Appropriate measured data on blood lead levels in hunter family members frequently consuming game meat would help to verify the calculated blood lead levels and the resulting risks
- Hunting statistics are not available for all EU Member States with a similar level of detail. Interpolation had to be used to compile an EU wide game bag which introduced additional uncertainty in the assessment.

Uncertainties related to lead in sports shooting

- Insufficient information is available to conclude on potential health risks in the EU from the use of lead ammunition for outdoor sports shooters.
- Recovery of lead gunshot and lead bullets is expected to result in relevant exposure in case strict personal hygiene measures are not applied.
- No information is available on the incidence of sports shooters in the EU that are home-casting lead bullets for sports shooting.
- No information is available on the incidence of small children in the EU ingesting lead gunshot or air pellets used for sports shooting.
- There is also no information to judge on the human health risks in the EU from the consumption of drinking water or food contaminated via the environment by lead deposition on shooting ranges throughout the EU.

- The number of ranges in Europe and the amount of lead used in Europe for sports shooting are not known. Although the Dossier Submitter provided an estimate on the restriction dossier based on a series of assumptions, the overall numbers remain uncertain.

Uncertainties related to lead in fishing tackle

- There is a general lack of data related to the risks resulting from the ingestion of fishing tackle by birds and from human exposure to lead fumes and vapour during home-casting.

- The Dossier Submitter considered that the enforcement of the restriction proposal 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.

- Additional assumptions were made by the Dossier Submitter due to the limited information available. These assumptions relate to recreational fishing statistics (number of fishers, licences, average fisher expenses), the amount of lead fishing tackle manufactured and placed on the market in Europe, and the amount of lead fishing sinkers and lures lost/released to the environment.

RAC conclusion(s):

- RAC agrees with the Dossier Submitter that there are significant uncertainties related to the exposure assessment due to game meat consumption

- There are also uncertainties related to the enforcement of hunting in the case of bullets due to the many derogated uses or uses outside of scope and in case of gunshot if optional derogation proposed by the Dossier Submitter is accepted.

- RAC agrees with the Dossier Submitter that there are significant uncertainties related to the assessment of human health risks due to outdoor shooting and home-casting of ammunition. RAC agrees also on the uncertainties related to risk assessment of groundwater and food contamination especially concerning the number of shooting ranges in vulnerable areas in which contamination may occur.

- RAC agrees with the Dossier Submitter that there is limited information on the human health and environmental risks caused by the fishing tackles which make risk assessment uncertain. There are uncertainties also related to the enforcement of use, for instance of home-casted lead fishing tackles, which requires inspection of individuals.

Key elements underpinning the RAC conclusion(s):

Uncertainties related to the human health and environmental risk assessment have been discussed already under Sections 3.1.5 and 3.1.6 and more in detail in the work package reports WP A.1-5..Uncertainties related to the enforcement issues have been discussed earlier under Section 3.3.3.

3.4.2. SEAC

Summary of proposal:

See SEAC opinion

SEAC conclusion(s):

See SEAC opinion

Key elements underpinning the SEAC conclusion(s):

See SEAC opinion

3.5. REFERENCES

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Annex 1. RAC qualitative risk assessment approach for lead ammunition in hunting and sports shooting and lead fishing tackle

The Dossier Submitter has performed a quantitative risk assessment for primary poisoning of birds and for game meat consumption of hunters' families. The other risks are assessed in a qualitative manner and expressed as low (+), moderate (++) or high (+++) risk. It is not fully transparent how probability of exposure vs severity of effects is weighted in this approach. To scrutinise the qualitative risk assessment made by the Dossier Submitter, RAC has applied an industry best practice approach to qualitative risk assessment based on a conceptual model that takes into account for each scenario the potential source of exposure, the receptor, the pathway and the probability and severity of effects (EC 2010, ISO 21365:2019). This approach allows RAC to evaluate the risks systematically both for human health and the environment. The approach is presented below.

To assess the probability and severity of effects, a 4x4 risk matrix as shown in table 6 is used.

Table 6. Risk matrix for qualitative risk assessment

Risk Category		***Severity of effects***			
		Severe Human Health: B-Pb ↑ >70µg/l in adults and >30 µg/l in children/pregnant females); Environment: Short term risk of pollution of sensitive water resources. Catastrophic damage to buildings or property. Short term risk to an ecosystem or organism forming part of that ecosystem	*Medium* Human Health B-Pb ↑ > 30-70µg/l in adults and 12-30 µg/l in children/pregnant females. Environment: Pollution of sensitive water resources., Significant change in an ecosystem or organism forming part of that ecosystem.	*Mild* Human Health B-Pb ↑ >15-30 µg/l in adults, <12 µg/l in children/pregnant females; Environment: Pollution of non-sensitive water resources. Significant damage to crops, buildings, structures and services. Damage to sensitive buildings, structures or the environment	*Minor* Human Health (B-Pb ↑ <15 µg/l in adults); Environment: Harm, not necessarily significant, but that could result in financial loss or expenditure to resolve. Easily repairable damage to buildings, structures and services
Probability	*highly likely*	very high	high	moderate	low
	likely	high	moderate	moderate/low	low
	low likelihood (possible)	moderate	moderate/low	low	very low
	unlikely	moderate/low	low	very low	very low

Justification for the categorisation of the risks for Human Health:

The following categories for the **severity of effects** are defined:

Severe: considering the background levels in population, an increase in lead in blood (B-Pb) levels above 70 ug/l may result in total B-Pb levels exceeding 100 µg/l in adults. There is strong evidence for an association between these high levels and an increased risk of chronic kidney disease (chronic kidney disease) and cardiovascular effects in adults. Total B-Pb levels above 150 µg/l are associated with neurobehavioural effects even in adults. Levels >30 µg/l in children may result in average of >3 point IQ loss in population level.

Medium: when the B-Pb increase is above 30 µg/l in adults and between 12-30 µg/l in children, total B-Pb levels are likely to increase clearly above the general population reference values (which usually lie between 30-45 µg/l) in adults. For children this corresponds to an IQ loss of 1-3 points.

Mild: when the B-Pb increase is above 15 µg/l in adults, which may cause a 10% increase in the prevalence of chronic kidney disease in adult population.

Minor: when increase in B-Pb is <15 µg/l in adults.

In the case of human health effects, the **Probability** means how likely it is that certain levels of exposure occur in the exposed population. For example, in the case of home- casting, it is estimated that increases in B-Pb levels of medium severity (i.e., in the order of ~30 µg/l) are likely if home-casting is practiced frequently, and at least increases resulting in mild severity are very likely. There is a low likelihood for severe increases, but it could occur if home-casting is performed in large volumes and inadequate conditions. All these combinations result in moderate risk. Thus, the estimated frequency of exposure is partly considered in the probability assessment, although in this specific example it is not possible to estimate the frequency of the occurrence of home-casting activities in the population properly.

Justification for the categorisation of the risks for the Environment:

The approach takes into consideration the risks posed to the environment and the structure and fabric of buildings and infrastructure by land contamination. These aspects are based on CIRIA 552 (2001): Contaminated land risk assessment. A guide to good practice.

The following categories for the **severity of effects** are defined:

Severe: short term risk of pollution of sensitive water resources. Catastrophic damage to buildings or property. Short term risk to an ecosystem or organism forming part of that ecosystem.

Medium: pollution of sensitive water resources. Significant change in an ecosystem or organism forming part of that ecosystem.

Mild: pollution of non-sensitive water resources. Significant damage to crops, buildings, structures and services. Damage to sensitive buildings, structures or the environment; and

Minor: harm, not necessarily significant, but that could result in financial loss or expenditure

to resolve. Easily repairable damage to buildings, structures and services.

The **Probability o**f these environmental effects are defined (according to CIRIA 552) as:

Highly likely: the event appears very likely in the short term and almost inevitable over the long term or there is evidence at the receptor of harm or pollution.

Likely: it is probable that an event will occur or circumstances are such that the event is not inevitable, but possible in the short term and likely over the long term.

Low likelihood: circumstances are possible under which an event could occur, but it is not certain even in the long term that an event would occur and it is less likely in the short term.

Unlikely: circumstances are such that it is improbable the event would occur even in the long term.

The main use scenarios relevant for this restriction proposal are:

1) Shooting at shooting range/sports shooting
2) Hunting
3) Use of lead-containing fishing tackle

Three separate models are considered to characterise the risks related to each use scenarios.

1) Conceptual model for shooting at shooting range / sports shooting

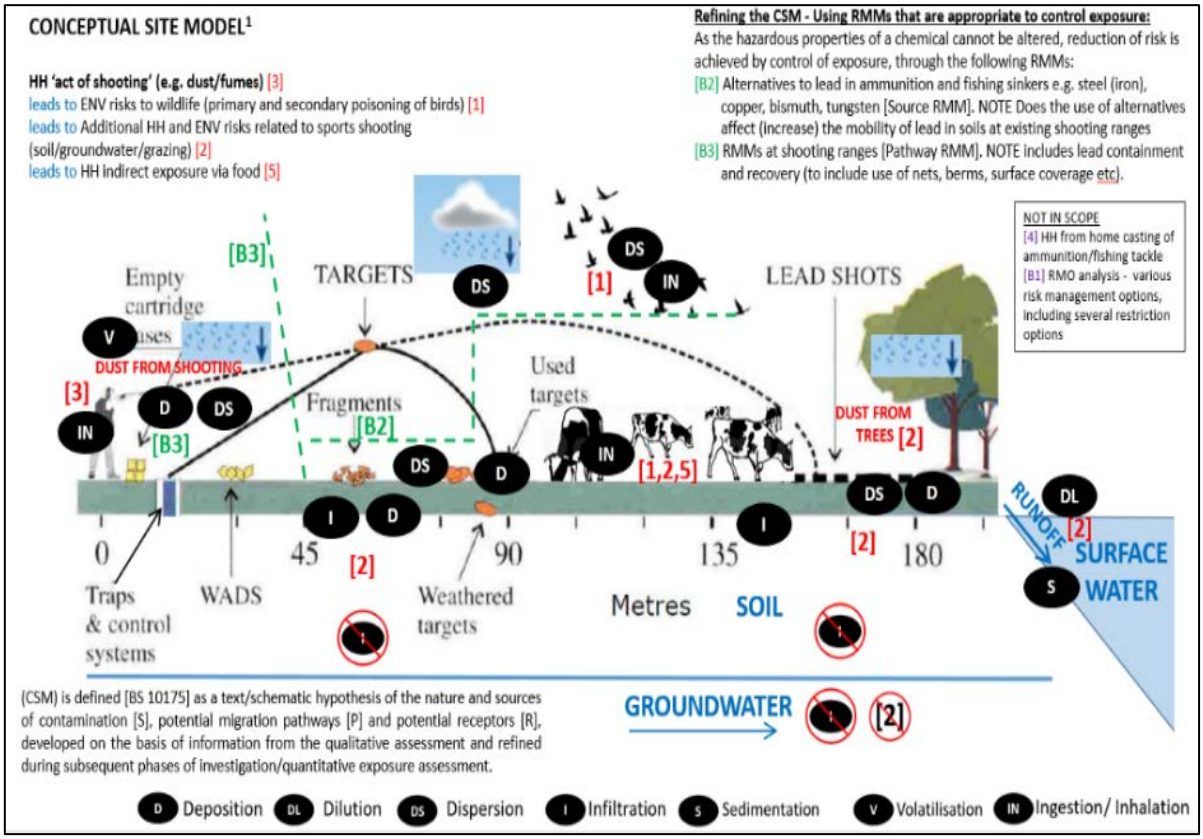

Figure 1. Illustration of the conceptualisation of the risk caused by shooting.

Table 7. Qualitative risk assessment for shooting at shooting range / sports shooting

Potential Source	Potential Receptor	Possible Pathway	DS qualitative risk estimate	RAC qualitative risk assessment		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
'Act of Shooting': fumes and dust formed during shooting, dust from eroded/fragmented shot/ bullets.	Adult Shooter and Observer(s)	Direct Inhalation of fumes and dusts formed during shooting; Dermal contact to settled dust from eroded/fragmented shot	+/++ (depending on shooting frequency)	For firearms: Likely For airguns: Low likelihood-Likely	For firearms: Mild For airguns: Minor	**For firearms: Low-Moderate*** **For airguns: Very low-Low**

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
		/bullets (resulting in hand-to-mouth exposure and ingestion of lead)				
'Act of Shooting': fumes and dusts formed during shooting, dust from eroded/fragmented shots/ bullets	Foetus (Pregnant Shooter)	See above	not assessed	For firearms: Likely For airguns: Likely	For firearms: Medium For airguns: Mild	**For firearms: Moderate*** **For airguns: Low-Moderate**
Home-casting: fumes and dust, lead massive, lead shot/ bullets	Adult shooter	Direct Inhalation of fumes and dust; Dermal contact with lead (resulting in hand-to-mouth exposure and ingestion of lead)	+++	Likely Highly likely	Medium Mild	**Moderate**
Lead shot fallout, lead objects, lead fragments	Birds, Individuals of 70 sensitive species	Ingestion	+++	Likely	Severe	High
Lead shot fallout, lead objects, lead	Populations of common bird species	Ingestion	+++	Likely	Minor	**Low**

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
fragments						
Lead shot fallout, lead objects, lead fragments	Populations of rare bird species	Ingestion	+++	Likely-Highly likely	Severe	**High-Very high**
Lead shot fallout, lead objects, lead fragments	Humans (> 45m distance), especially farmers and their children	Ingestion via contaminated water or food	+/++/+++	Unlikely-Low likelihood	Medium (for children and fetuses)	**Low-Moderate**
Lead shot fallout, lead objects, lead fragments	Soils: As Topsoil/Surface Soil Lead contamination of shooting ranges at 200 – 300 g of lead per square meter can be found and constitutes pollution of soil surface. *Hazard for terrestrial organisms. Breach of PNEC Pb soil 212 mg/kg*	Lead gunshot, bullets, fragments, that remain on the soils are available to be ingested. Soluble lead is absorbed by soils, and its mobility in subsoils is limited.	+/++	Highly Likely	Medium	**High**
Lead shot fallout, lead objects, lead fragments	Soils: (1) > 300m	1) Maximum distance of lead shot/projectile from a firing point	+/++	Low likelihood	Minor	**Very low**

Potential Source	Potential Receptor	Possible Pathway	DS qualitative risk estimate	RAC qualitative risk assessment		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
	distance[19] from a Shooting Range (2) in Subsoils Hazard for terrestrial organisms. *Breach of PNEC Pb soil 212 mg/kg*	is 300m. 2) Soluble lead is absorbed by soils, and its mobility is limited. Limited cation and exchange with clays.				
Lead shot fallout, lead objects, lead fragments	Local surface waters: *Breach of PNEC aqua (freshwater) 2.4 µg/L Water and 186 mg/kg sediment, Framework Directive EQS 1.2 ug/L*	Runoff/dilution and exposure to aquatic organisms, and/or sedimentation, hence exposure to fish	+++	Likely	Medium	**Moderate-** **High** (depending on dilution)
Lead shot fallout, lead objects, lead fragments	General surface waters: *Breach of PNEC aqua (freshwater) 2.4 µg/L and 186 mg/kg sediment, Water Framework*	Runoff/dilution and exposure to aquatic organisms, and/or sedimentation, hence exposure to fish	+++	Likely	Minor	**Low**

[19] Figure B.9-4 & Table B.9-9 (Background Document): Maximum distance of lead contamination from a skeet or trap range from the firing point is 220m (Victorian EPA, 2019). Also, page 105 (Annex XV Report): The flight distance of shot is directly proportional to their size. At skeet ranges, shot 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. Terrain contours and trees have a significant effect on the spread of the shot, as do wind conditions.

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
	Directive EQS 1.2 ug/L					
Lead fragments	Groundwater in geographical areas where the FOUR conditions occur: *<u>Breach</u> of Drinking Water Directive value of 10 µg/l.*	1.Acidic soil (pH <6) 2.Coarse (usually sandy) soils 3.Preferential flow pathways, or macropores 4.Shallow depth to groundwater (< 3m).	+/++/+++	Highly Likely	Medium	**High**
Lead fragments	Groundwater in the more common geographical areas and with the FOUR conditions: *<u>Breach</u> of Drinking Water Directive value of 10 µg/l.*	1.Soils (pH >6) 2. non coarse (non sandy) soils 3. Absence of preferential flow pathways, or macropores 4. Depth to groundwater (> 3m).	+/++/+++	Unlikely	Medium	**Low**

*The use of jacketed bullets reduces the exposure and risk, risk characterisation is focusing on the use of non-jacketed bullets. Part of the exposure may come from lead primer. Closed plastic cartridges used in shotguns may limit the exposure of shooters.

RAC agrees with the Dossier Submitter that there is a moderate risk for frequent shooters arising from lead emissions when lead-based ammunition is used even in outdoor shooting. This is based on the evidence on increased B-Pb levels in humans related to shooting. At least mild increases in B-Pb levels are likely, and medium increases are possible in very frequent

shooters. Both options will result in low-moderate risk. When considering pregnant females practicing shooting, mild increases in B-Pb levels result in moderate risk. However, it should be noted that part of the lead exposure comes from the primer, not only from the projectile. Fully jacketed bullets have been shown to result in lower lead exposure of the shooter. When airguns are used, only minor increases in B-Pb levels are likely, resulting in low risk. The human health risks due to shooting are further discussed in the Work Package report WP A.3.

For home-casting, at least mild increases in B-Pb levels are very likely if this is done frequently and even higher (medium) increases are likely, depending on the conditions during the home-casting. Therefore, RAC agrees that home-casting presents at least a moderate risk when it is performed frequently. However, it is not possible to give a reliable estimate on how frequent home-casting is among shooters. Thus, this aspect cannot be fully considered in the assessment. If pregnant females are practicing home-casting, risks to the foetus can be considered high but it is not possible to assess how likely this scenario is due to lack of data. Home-casting conditions and resulting exposure are further discussed in the Work Package report WP A.4.

Regarding contamination of agricultural land, cattle and groundwater resulting in exposure of humans via the environment, RAC notes that there is no data on human exposure via this route and agrees with the Dossier Submitter that the situation may vary depending on the risk management measures in place at the shooting range (see further discussion on human health indirect exposure in Work Package report WP A.5). When there is no agricultural land next to the shooting range and groundwater contamination is unlikely (soil not favorable for the transfer of lead to groundwater; see last line in the above table) the probability of exposure can be considered unlikely. Higher probability (high concern) for environmental contamination is related to shooting ranges with high intensity of shooting, next to agricultural land, and with soil favorable for lead movement to surface water and groundwater. Considering the apparent lack of evidence supporting this exposure route, this is not considered a frequent case and is therefore judged to be a low probability resulting in low-moderate risk, highest risks being related to the exposure of children and pregnant females.

Regarding groundwater, as discussed in the Work Package report WP A.2, hydrogeological conditions of the sites control the potential for transport of lead through the vadose zone and into groundwaters. There appears to be limited general risk to groundwater in aquifers with overlying depths of soil, as migration of lead in soil can be very limited. But there are cases, such as at a shooting range lying close to a discharge zone (shallow water table and groundwater mixing with surface runoff), and/or on acidic thin layers of soil above the aquifer, and/or on coarse (usually sandy) soils, and/or through preferential flow paths bypassing the soil matrix, where contamination may occur. The risk for contamination increases as more of these four criteria are met. Although such water may not be used generally as drinking water, the situation may vary depending on the EU countries. Since RAC does not have specific data on the number of sites located in areas favoring lead migration, the frequency of either “high mobility” and “low mobility” scenarios cannot be taken fully into account in the assessment. However, it can be speculated that conditions favoring groundwater contamination (when all four conditions favoring lead migration apply) are likely to be less common than the opposite cases.

For livestock, there are data showing that lead exposure and toxicity may occur if livestock are allowed to graze at shooting ranges, and subsequent exposure of humans via food is then

also likely. However, it is not clear how often this may occur, and it is assumed to be rather exceptional cases. But if occurring, there is a risk for the livestock and maybe also for children and pregnant women consuming the livestock as food. RAC supports the Dossier Submitter's proposal to restrict access of livestock to shooting ranges.

There is evidence that surface water can be contaminated at shooting ranges and exposure to aquatic organisms would be likely/very likely resulting in a moderate to high risk at local level. However, as any measurable impacts are very localised, the risks to the surface water in general are categorised as low.

There is evidence that the soil surface can be contaminated at shooting ranges by lead deposition and surface dispersion. Lead gunshot, bullets and fragments that remain on the soils are available to be ingested. Soluble lead is absorbed by soils, and its mobility in subsoils is limited. Hence the topsoil/surface soil is highly likely to be contaminated at a shooting range, where a lead loading rate of 200 – 300 g of lead per square meter can be found, and this constitutes pollution of the soil surface by e.g., a breach of the generic PNEC of 212 mg Pb/kg dry soil as derived in CSR (2020, see further Annex to Background document). However, for soils at a higher than 300 m distance from a shooting range, the lead concentration is lower and its mobility is limited; there is a low likelihood of impact on soil, and hence a very low risk for soil.

Direct exposure of birds is well documented both in aquatic and terrestrial environments. Indirect exposure of predatory or scavenging birds from ammunition and increased mortality in these species is well documented, as well. Also sublethal effects may affect the predatory birds. Population effects become relevant especially for rare species as death of individuals will affect a small population more than a large population.

2) Conceptual model for hunting

Table 8. Qualitative risk assessment for hunting

Potential Source	Potential Receptor	Possible Pathway	DS qualitative risk estimate	RAC qualitative risk assessment		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
'Act of Shooting': fumes and dust formed during shooting, dust from eroded/fragmented shot/ bullets.	Adult Shooter and Observer(s)	Direct Inhalation of fumes and dusts formed during shooting; Dermal contact to settled dust from eroded/fra	+	Likely	Minor-Mild	**Low**

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
		gmented shot /bullets (resulting in hand-to-mouth exposure and ingestion of lead)				
'Act of Shooting': fumes and dust formed during shooting, dust from eroded/fragmented shot/ bullets.	Foetus (Pregnant Shooter)	See above	not assessed	Likely	Mild	**Low-Moderate**
Home-casting: fumes and dust, lead massive, lead shot/ bullets	Adult shooter	Direct Inhalation of fumes and dust; Dermal contact with lead (resulting in hand-to-mouth exposure and ingestion of lead)	+++	Likely	Mild	**Low-Moderate**
Game meat consumption	Adults	Ingestion	+	Likely- Low likelihood	Minor- Mild	**Low**

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
Game meat consumption	Children < 7y Foetuses (pregnant females)	Ingestion	+++	Likely-Highly likely	Medium	**Moderate - High**
Lead shot fallout, lead objects, lead fragments	Birds, Individuals of 70 sensitive species	Ingestion	+++	Likely	Severe	High
Lead shot fallout, lead objects, lead fragments	Populations of common bird species	Ingestion	+++	Likely	Minor	**Low**
Lead shot fallout, lead objects, lead fragments	Populations of rare bird species	Ingestion	+++	Likely-Highly likely	Severe	**High-Very high**
Lead shot fallout, lead objects, lead fragments	Soils: *Hazard for terrestrial organisms. Breach of PNEC Pb soil* *212 mg/kg*	1) Low loading of lead onto soil surface in hunting grounds. 2) Soluble lead is absorbed by soils, and its mobility is limited. Limited Cation and exchange with clays.	+/++	Low likelihood	Mild	**Low**
Lead shot fallout,	Surface	Low loading of		Low	Minor	**Very low**

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very high
lead objects, lead fragments	waters: *Breach of PNEC aqua (freshwater) 2.4 µg/L and 186 mg/kg sediment, Water Framework Directive EQS 1.2 ug/L*	lead onto soil surface in hunting grounds hence low runoff/dilution and exposure to aquatic organisms, and/or sedimentation, hence exposure to fish		likelihood		

RAC agrees with the Dossier Submitter that there might be a risk for hunters from lead emissions at the act of shooting when lead ammunition is used. However, evidence on increased B-Pb levels in humans related to shooting is limited. It should be noted that in the case of hunters any increase in B-Pb levels (biomonitoring) reflects combined exposure from the act of shooting and game meat consumption (together with possible exposure due to home-casting). At least minor increases in B-Pb levels are likely and mild increases are possible (low likelihood). This will result in a low risk. However, in the case of pregnant females, there might be a moderate risk for foetuses (see also WP A.3 report).

For home-casting, as discussed for sports shooting, at least mild increases in B-Pb levels are very likely if it is done frequently and even higher (medium) increases are likely if done under poor conditions. Therefore, RAC agrees that home-casting presents at least a moderate risk when it is done frequently. However, considering that the quantity of bullets/shot needed for hunting is very much smaller than for sports shooting, large scale home-casting is not likely and RAC concludes that the risk is low-moderate. RAC further notes that it is not possible to give a reliable estimate on how frequent home-casting is performed by shooters, thus this aspect cannot be fully considered in the assessment. Home-casting conditions and resulting exposure are further discussed in the Work Package report WP A.4.

In the case of consumption of game meat, the risks for adults and children need to be considered separately. For adults, exposure modelling shows only minor increases in B-Pb levels even in high consumption scenarios. This is in accordance with the limited biomonitoring data showing no clear association between game meat consumption and B-Pb levels. Therefore, for adults, the risk from game meat consumption is considered low.

For children, exposure modelling suggests that up to medium increases in B-Pb levels are

highly likely in high game meat consumption scenarios (basically hunter families). In some cases, even severe increases (>30 µg/l) are possible (low likelihood) if highly contaminated meat is consumed. Overall, this scenario results in moderate to high risk for children. Developmental neurotoxic effects are relevant also in the case of offspring of pregnant females. As discussed, increases in B-Pb levels due to game meat consumption are lower in adults than those expected in small children. However, considering that there is no threshold for the developmental neurotoxicity of lead, also for pregnant females the risk is considered at least moderate since at least mild increases in B-Pb levels are expected in case of frequent consumption. Further assessment of the risks resulting from game meat consumption, including a quantitative risk assessment, are presented in the Work Package report WP A.5. As discussed in WP A 5, non-expanding full metal jacket bullets may result in lower levels of lead contamination of the game meat as non-jacketed or partially (or semi-) jacketed expanding bullets.

The environmental risk related to hunting mainly concerns birds, for which there is sufficient data on exposure to conclude a high risk on an individual level (for individuals of the 70 species that are of risk from shooting because of their feeding behaviour) and for some species in areas with intensive hunting a very high risk (see also WP A.1 report). Exposure to lead may result from eating gunshot mistaken for grit or grain, scavenging, and eating prey carrying embedded gunshot. Exposure of wildlife other than birds is less documented (but may occur as some wildlife species are known to be scavengers and therefore may be exposed to lead remaining in corpses) so no risk characterisation is possible.

Regarding ground and surface water as well as soil, the risks related to water or soil contamination due to hunting are considered very low since, in addition to the soil characteristics favoring lead mobilisation and migration to surface or groundwater, this requires very concentrated hunting in a small area. Moreover, hunting grounds are widespread and possibly may be used once a year, if not infrequently.

3) Conceptual model for fishing

Table 9. Qualitative risk assessment for fishing

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very High
Fishing with leaded fishing tackle: sinkers and lures ≤50g	Birds, general Swans and loons	Ingestion	+++	Birds, general: Likely Swans and loons: Highly likely	Birds, general: Medium Swans and loons: Severe	**Birds, general: Moderate** **Swans and loons: Very high**

Potential Source	**Potential Receptor**	**Possible Pathway**	**DS qualitative risk estimate**	**RAC qualitative risk assessment**		
				Probability Unlikely; Low likelihood; Likely; Highly likely	**Severity** Minor; Mild; Medium; Severe	**Risk Category** Very low; Low; Moderate; High; Very High
Fishing with lead fishing tackle : sinkers and lures >50g	Birds, general Loons	Ingestion	No risk identified	Birds, general: Unlikely Loons: Low likelihood	Birds, general: minor Loons: Severe	**Birds, general: Very low** **Loons: Moderate**
Home-casting: fumes and dust,, fishing sinkers and lures (all sizes)	Adult fisherman	Direct Inhalation; Dermal contact (resulting in hand-to-mouth exposure and ingestion of Pb)	+++	Direct Inhalation: Likely Dermal contact: Highly likely	Direct Inhalation: Medium Dermal contact: Mild	**Moderate**

RAC concludes that exposure to fishing tackle of sensitive species is likely, and that for swans and loons there is ample evidence to also assume a very likely exposure and severe effects, resulting in a very high risk for swans and loons, and a moderate risk for the other twenty sensitive species (see also WP A.1 report). This applies especially to small sinkers. Although ingestion of sinkers and lures >50 g may also happen, it becomes more unlikely.

For home-casting, the same conclusions already discussed for hunting and sports shooting apply.

References

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