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/RES-O-0000007178-68-01/F

2 December 2022

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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

2 December 2022

ECHA/SEAC/RES-O-0000007178-68-01/F

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 SEAC and the Committees' justification for their 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

Supporting the Rapporteurs:

Radu BRANISTEANU;
Ignacio DE LA FLOR TEJERO ;
Malcolm DOAK;
Laure GEOFFROY;
Raili MOLDOV ;
Michael NEUMANN;
Pietro PARIS

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

Supporting the Rapporteurs:

Dorota DOMINIAK;

Silke GABBERT;

Eimear LEAHY;

Alex TURVEY;

Klaus URBAN

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 **2 December 2022**.

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

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

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1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Table 1: Proposed restriction

Substance identity	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 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 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 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 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 ono 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.]*

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 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 on the Annex XV report 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:

Table 2: Restriction proposed by RAC

Designation of the substance	**Conditions of the restriction**
Lead and its compounds	Entry as proposed by the Dossier Submitter above, with the following modifications (modifications in **bold red** text): 4. By way of derogation: *a. [OPTIONAL DEROGATION (part 1 of 4): Paragraph 1c shall not apply **for shot sizes between 1.9 and 2.6 mm** if:* (…) b. *[OPTIONAL DEROGATION (part 2 of 4): Paragraph 2d shall not apply **for shot sizes between 1.9 and 2.6 mm** if:* (…) 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 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 (…) 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 *c. [OPTIONAL DEROGATION (part 3 of 4): Suppliers of 'gunshot' containing lead in concentrations equal to or greater than **1** % w/w shall ensure (…)* *7.* Entry into force of the restriction: d. paragraph 1c~~, 2c~~ and 2d shall apply [5 years] from entry into force of

Designation of the substance	Conditions of the restriction
	the restriction. **k. paragraph 2c shall apply [shorter transition period than 5 years] from entry into force of the restriction.**

RAC supports the restriction and agrees in general terms with the proposed conditions 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 paragraphs 5 a, b, and c.

In the opinion of RAC, the enforcement of this restriction (and the previous 'wetland' restriction) would be greatly simplified (enabled) if the optional derogations in paragraph 4a and 4b are **not** implemented. This is fully in line with the preferred option of the Dossier Submitter. In case paragraphs 4a and 4b are not implemented, the optional derogations in paragraphs 5c and 6 become unnecessary. However, if the decision maker would decide that such an optional derogation is still needed, then 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 paragraph 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 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 paragraph 7d. The opinion of RAC is that this transition period is too long and could be shortened because the use of lead gunshot in wetlands is already regulated in the whole EU. The shorter the transition period is, the lower the amount of lead that is released into the environment.

Additional recommendations

RAC strongly 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[1].

RAC recommends to the European Commission that a further analysis of the feasibility for organisations such as the International Olympics Committee, FITASC (Fédération

[1] 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.

Internationale de Tir aux Armes Sportives de Chasse) and ISSF (International Sports Shooting Federation) to change their requirements regarding the use of lead gunshot in international competitions is needed.

RAC recommends the adequate removal of remaining lead fragments 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.

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 paragraph 5a above.

RAC 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 (paragraphs 4a and 4b) is implemented, RAC recommends considering the readability of the labelling of individual cartridges and whether alternative approaches such as colour coding could be more suitable.

RAC encourages the European Commission to consider the implementation of a system for the collection of banned lead ammunition and fishing tackle and/or for the provision of information on the safe disposal of these restricted lead-containing articles.

Other regulatory actions for consideration

Exposure and risks to shooters caused by lead in ammunition does not only result 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.

RAC notes as part of its investigations but outside the scope of this restriction that **indoor** shooting may result in high exposure of shooters, RAC points out that risk management measures may also be needed to tackle the risks to consumers practicing shooting in indoor shooting ranges.

1.2. THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on **lead and its compounds** is the most appropriate Union-wide measure to address the identified risks as concluded by RAC, provided that the conditions are modified as proposed by SEAC. This takes into account the proportionality of its socio-economic benefits to its socio-economic costs, as demonstrated in the justification supporting this opinion.

The conditions of the restriction proposed by SEAC are:

Table 3: Restriction proposed by SEAC

Substance identity	**Conditions of the restriction**
Lead and its compounds	Entry as proposed by the Dossier Submitter above, with the following modifications (modifications in **bold red** text): 4. By way of derogation: *a. [OPTIONAL DEROGATION (part 1 of 4): Paragraph 1c shall not apply **for shot sizes between 1.9 and 2.6 mm** if* (…) *b. [OPTIONAL DEROGATION (part 2 of 4): Paragraph 2d shall not apply **for shot sizes between 1.9 and 2.6 mm** if:* *(…)* c. Paragraph 2e shall not apply to: - (…) - Full metal jacket bullets **(incl. open tip match bullets)** where the Member State allows the use of these bullets [on the date that the restriction proposal was submitted] 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 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 (…) 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 (…)

	*c. [OPTIONAL DEROGATION (part 3 of 4): Suppliers of 'gunshot' containing lead in concentrations equal to or greater than **1** % w/w shall ensure (…)* 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.**

In case the decision-maker would decide that the optional conditional derogation for lead gunshot in sports shooting is needed, SEAC is of the opinion that shot sizes should be limited to those used in sports shooting (between 1.9 and 2.6 mm) in order to retain the advantages of a ban on placing of the market of lead gunshot as much as possible (see discussion in section 3.3).

SEAC notes the Dossier Submitter's intention to propose a derogation for non-expanding ammunition used in hunting (specified as full metal jacket bullets in paragraph 4c). In order to clarify that the derogation includes non-expanding open tip match bullets, SEAC made an addition to make this intention explicit.

SEAC considers that the same concentration threshold of 1 % w/w proposed for restricting the placing on the market and use of lead ammunition and fishing tackle should also apply to the labelling and information requirements to avoid confusion and to facilitate enforcement. SEAC also supports RAC's proposal to apply the labelling requirements specified in paragraphs 5a and 5b for alternatives containing copper and copper alloys only when lead content is equal to or greater than 3 % w/w.

SEAC concludes that for the ban on the use of lead gunshot in hunting a significantly shorter transition period than the five years proposed by the Dossier Submitter is justified (see discussion in section 3.3).

In order to facilitate the enforcement of the ban on the use of lead ammunition in hunting while it is still available on the market (i.e. in the case of lead gunshot if a shorter transition period than five years for use in hunting or the optional conditional derogation for sports shooting is implemented, and in the case of lead bullets), SEAC recommends that the text of the restriction entry includes a ban on 'carrying' of lead ammunition in the field, in line with the restriction on lead gunshot in wetlands. Furthermore, colour-coding or marking of individual bullets or shot cartridges (in addition to labelling on the package) could be considered as a means to support enforcement in the field.

SEAC considers that education can be an effective tool to convince users to switch to lead-free alternatives, in particular if supported by influential groups (peers, associations or clubs). Therefore, it can complement a ban and might be more effective to raise awareness than the proposed information requirement at the point of sale alone.

2. SUMMARY OF PROPOSAL AND OPINION

2.1. Summary of the Dossier Submitter's proposal

Scope

As per the request of the European Commission (2019)[2], the proposed restriction aims to address the risks for human health and the environment posed by the use of lead in:

- ammunition, i.e. gunshot used in terrains[3] other than wetlands and projectiles other than gunshot (bullets and airgun pellets) used both in wetlands and in terrains other than wetlands, as well as of;

- lead in fishing tackle.

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

Environment and wildlife

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 the soil and water. Lead fishing tackle is also frequently lost during use and affects birds in the same way as lead gunshot and projectiles if ingested. In addition, some contemporary fishing practices, and some fishing tackle suppliers, encourage the deliberate release of lead sinkers 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 hazardous 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

[2] https://www.echa.europa.eu/documents/10162/13641/rest_lead_ammunition_COM_request_en.pdf/f607c957-807a-3b7c-07ae-01151001d939 (accessed 27 October 2022)

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

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);

- 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,

    - 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[4] are at risk of lethal and sub-lethal lead poisoning[5] 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 those species at risk more than one million birds are expected to die per year due to primary ingestion. The number of birds expected to die as a result of secondary ingestion cannot be quantified because the information needed to do this is not available. A significant number of birds are also expected to be affected by 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 is 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 the end of life of a shooting range[6] 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

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

[5] 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.

[6] 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.

(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.

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

Human health

Lead 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 – CKD), 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 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 has proposed a restriction comprising three main types of measures:

1. A ban on placing on the market combined with a ban on use where this 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 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), 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.

Derogations

A derogation is proposed for outdoor sports shooting with projectiles other than gunshot conditional on the implementation of appropriate and effective risk management measures. In addition, derogations are proposed for specific uses of bullets (seal hunting) and specific types of non-expanding ammunition used in hunting (specified as full metal jacket bullets) where these uses are allowed.

A derogation for continued use of lead gunshot for sports shooting is presented as an option for the decision-making stage, in the event that the decision-maker would not wish to impose an EU-wide ban on the placing on the market or use of lead gunshot for sports shooting. The intention of presenting this option is to clarify the costs and benefits of allowing the continued use of lead gunshot for sports shooting under such conditions that the identified risks could be minimised. 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 or FITASC 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 the Dossier Submitter's preferred option is a complete ban on the use of lead gunshot in sports shooting. 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 more 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 4 provides a summary of the costs and emission reduction expected from the proposed restriction.

Table 4: Summary of the Dossier Submitter's mean estimates of costs, emission reduction, and costs per kg of avoided releases by sector and/or use (*incl. SEAC's modifications where applicable*)

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 (*SEAC: €342 million*) (range: €28-1 310 million)	209 000 tonnes (range: 159 000-259 000 tonnes)	€3.7/kg *(SEAC: €1.6/kg)* (range: €0.2-5.1/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 opinions

2.2.1. Summary of RAC opinion

Overall, RAC notes that the use of lead in hunting, outdoor shooting and fishing leads to significant local contamination and a wide range of risks to both human health and the environment. The Committee's reasoning is summarised below.

Scope

Regarding the scope of the proposal, RAC agrees that the 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.

RAC agrees that uses by police, military and border control authorities when they are "on duty" should be outside of this scope.

RAC notes that the use of lead -containing primers (lead styphnate) which is not within the scope, will most likely contribute to the exposure to lead of shooters, both outdoors and even more so at indoor shooting locations, where total exposure to lead may be a concern for non-professionals using indoor ranges.

Environment and wildlife

The estimate, made by the Dossier Submitter, of the release of lead to the environment in the EU from hunting, fishing and spors shooting activities is considered to be plausible and in the order of 44 000 tonnes per year.

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. RAC notes that sub-lethal effects in birds are probably even more common but cannot be quantified.

RAC concludes that lead poisoning may affect as many as 92 different species of birds, of which the Committee understands that 54 are red listed by the IUCN, with mortality or sub-lethal effects as consequences.

There is robust evidence for lead toxicity, including mortality of birds through direct (primary) and indirect (secondary) exposure. Primary poisoning may result from ingestion when lead pellets/sinkers are mistaken for food or grit. 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[7], discarded meat or unrecovered game left in the environment by hunters. Direct exposure of birds and increased mortality in these species in the aquatic and terrestrial environments, as a result of ammunition and fishing tackle, as well as indirect exposure of predatory and scavenging birds is well documented. In addition, sub-lethal effects are likely to occur and RAC concludes that indirect exposure of predatory or scavenging bird species to lead is a major concern, especially as it

[7] Discarded entrails after cleaning/butchering the kill outdoors

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.

For fishing, there is ample evidence for 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.

Human health

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.

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.

There is a large variability in game meat Pb levels. However, a relevant proportion of game meat has substantially higher lead concentrations than the regulatory maximum level for lead in meat other than game, which is 0.1 mg Pb/kg. Based on data on game meat consumption and lead concentrations in game meat, a high potential 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.

Non-expanding full metal jacket (FMJ) bullets and small calibre projectiles may not result in similar lead contamination of the game meat.

For hunting, RAC considers that a moderate to high risk exists 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 a 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.

Where **fishing** is concerned, home-casting of fishing sinkers occurs in the EU (and perhaps of ammunition). RAC considers that exposure from home-casting is plausible, especially under uncontrolled conditions, but there no data was presented to support this. Nevertheless, this is likely to pose a risk to human health and restricting the use of home-cast sinkers, is also warranted.

The need for action

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.

Technical aspects of the proposed restriction and derogations

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 % (e.g. 1%) 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 considers 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 considers that this proposal provides the highest risk reduction potential to 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.

Noting that a limit of 1% w/w is set in the condition of the restriction for the maximum content of lead in ammunition and fishing tackle, RAC supports the proposed information requirement for lead ammunition at the point of sale. However, RAC considers that this second 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 harmonised limit of 1 % w/w of lead is also applied to the information requirements.

Alternatives

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, substantially reduces the risks to human health and the

environment.

2.2.2. Summary of SEAC opinion

SEAC agrees that, 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, Union-wide regulatory measures are justified.

SEAC furthermore agrees that the proposed restriction is the most appropriate Union-wide measure to address the identified risks (as concluded by RAC in its opinion including its supplementary opinion), taking into account the proportionality of its socio-economic benefits to its socio-economic costs. However, SEAC identified some areas for which it suggests modifications to the conditions of the proposed restriction:

- SEAC finds that there is insufficient evidence that increasing the production volumes of alternative ammunition to replace lead gunshot in hunting would require a transition period of five years after entry into force. Available information supports that the volumes of lead gunshot used for hunting could be replaced sooner, because alternatives are widely available the market and the supply of steel gunshot can be expected to grow in response to the restriction of lead gunshot in wetlands. Furthermore, the benefits of a ban on lead gunshot are larger than the costs, supporting phase-out as soon as possible. Based on these considerations, SEAC concludes that a significantly shorter transition period than five years is justified for the ban on the use of lead gunshot in hunting. However, substantive and credible evidence to conclude on the specific length of the transition period was not available to SEAC. SEAC considers the minimum transition period required to ensure a smooth transition to alternatives is 18 months (in line with the transition period proposed for large calibre bullets).

- SEAC notes the Dossier Submitter's intention to propose a derogation of non-expanding ammunition used in hunting (specified as full metal jacket bullets in paragraph 4c). In order to clarify that the derogation includes non-expanding open tip match bullets, SEAC made an addition to make this intention explicit.

- SEAC has assessed the derogation for lead gunshot in sports shooting, which is intended by the Dossier Submitter as an option for the decision-maker ('optional conditional derogation') and identified several issues that could negatively affect its implementation and influence its practicality. Furthermore, SEAC considers that if a derogation for lead gunshot in sports shooting is preferred by the decision-maker, it should be limited to the shot sizes used in sports shooting, according to the Fédération Internationale de Tir aux Armes Sportives de Chasse/International Shooting Sport Federation (FITASC/ISSF) rules. This means shot sizes between 1.9 and 2.6 mm, while larger shot sizes that are commonly used for hunting should be excluded. The aim is to retain the advantages of a ban on placing on the market of lead gunshot in terms of simple and effective enforcement as much as possible.

- SEAC considers that the same concentration threshold of 1 % weight by weight (w/w) proposed for restricting the placing on the market and use of lead ammunition and fishing tackle should also apply to the labelling and information requirements to avoid confusion and to aid enforcement. SEAC points out that the threshold in the restriction

of lead gunshot in or around wetlands is also 1 % w/w. SEAC also supports RAC's proposal to apply the labelling requirements specified in paragraphs 5a and 5b for alternatives containing copper and copper alloys only when lead content is equal to or greater than 3 % w/w.

In addition, SEAC has identified the following recommendations for the attention of the decision-maker:

- In order to facilitate the enforcement of the ban on the use of lead ammunition in hunting while it is still available on the market (i.e. in the case of lead gunshot if a shorter transition period than five years for use in hunting or the optional conditional derogation for sports shooting is implemented, and in the case of lead bullets), SEAC recommends that the text of the restriction entry includes the ban of 'carrying' of lead ammunition in the field, in line with the restriction on lead gunshot in wetlands. Furthermore, colour-coding or marking of individual bullets or shot cartridges (in addition to labelling on the package) could be considered as a means to support enforcement in the field.

- SEAC considers that education can be an effective tool to convince users to switch to lead-free alternatives, in particular if supported by influential groups (peers, associations or clubs). Therefore, it can complement a ban and might be more effective to raise awareness than the proposed information requirement at the point of sale alone.

Furthermore, in some areas, SEAC is lacking information to conclude on the potential impacts of the proposed restriction and possible further modifications to the conditions:

- Regarding the labelling requirement where a ban on use only is proposed (paragraph 5b), SEAC considers that this will support enforcement of the ban on use of lead bullets in the field. However, labelling on the package alone does not ensure that a single lead bullet is clearly identifiable, for instance, if bullets are carried without the packaging. Therefore, labelling of individual bullets, e.g. by using markings or colour coding, would facilitate inspections in the field. Comments from stakeholders received in the consultation on the SEAC draft opinion indicated that there are cost-effective ways to achieve this, e.g. by colour-coding of cartridges, but their implementation is likely to be complex. Overall, SEAC does not have sufficient information to conclude on the technical feasibility, the costs involved and the practicality of such means.

- Regarding the ban on the use of lead ammunition in muzzle loaders or other historic firearms outside of shooting ranges, SEAC considers that a conclusion on whether a derogation of this use would be justified based on cultural values is not possible due to lack of information on the socio-economic impacts involved. Hence, this decision will have to be taken based on policy priorities.

- Regarding fishing tackle, SEAC lacks information on the impacts of restricting certain uses, e.g. lead sinkers and lures > 50 g and lead split shots, to conclude whether a derogation from the proposed ban for these uses could be justified on socio-economic grounds.

While SEAC agrees that, overall, the scope of the proposal has been clearly described and

justified, the opinion highlights the following issues:

- SEAC concludes that it is not clear if all forms of shooting undertaken for 'technical testing and development' are covered by the exemption formulated by the Dossier Submitter (paragraph 8) or by the general exemption of scientific research and development (SR&D) under REACH. SEAC elaborated in the Background Document on some forms of technical testing and development which will need to be covered by the exemption according to the Dossier Submitter's intention.

- SEAC has too limited information to conclude whether the effort to introduce an information requirement ('retailer duty' as described in paragraph 5a of the proposed restriction entry) is fully justified or if other educational measures suggested by the Dossier Submitter could be more effective, for example as part of national hunting or fishing exams for those Member States that have such exams.

SEAC agrees with the approach taken by the Dossier Submitter to assess the costs and benefits of the proposed restriction. SEAC identified some shortcomings and uncertainties in the Dossier Submitter's assessment but, generally, considers the ranges of the cost and emission estimates provided by the Dossier Submitter appropriate to indicate the order of magnitude of the impacts to be expected from the proposed restriction. With regard to the monetised benefits estimated by the Dossier Submitter, SEAC considers it important to note that these reflect only part of the impacts to be expected from the proposal and that the unquantified benefits are likely to be significant. SEAC also evaluated potential 'other impacts' of the proposed restriction, including on hunting activities, the distribution of economic impacts from upgrading RMMs at shooting ranges across the various Member States, effects on the availability of shooting ranges for military training, and effects on the supply of lead ammunition for non-civilian use. Based on the available information on the impacts of the proposed restriction, the cost-effectiveness analysis, cost-benefit considerations, as well as the affordability to hunters, sports shooters and fishers, SEAC concludes that the proposed restriction can be considered to be proportionate. However, despite including specific questions in the consultation on the SEAC draft opinion, not all the specific elements mentioned above could be completely resolved.

SEAC concludes that although, in principle, enforcement of the proposed restriction is possible, present enforcement structures are not well suited for this task, particularly if the final implementation of the proposed restriction would necessitate the inspection of private persons or shooting ranges and not only of the sale of ammunition/fishing tackle. SEAC also notes that successful enforcement may call for intensified additional cooperation and agreement between various government control agencies. 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. SEAC considers that new cooperating structures might need to be developed which will add to the complexity of organizing enforcement as well as costs.

SEAC considers the proposed restriction to be monitorable.

3. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

3.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

3.1.1. Information on hazards

Justification for the opinion of RAC

Summary of proposal:

Environmental hazards

Massive lead (as used in lead ammunition and fishing tackle) poses a significant hazard to birds through ingestion. 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:

- 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 conclusion(s):

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]).

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

- 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 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

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

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. 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*" prepared by RAC in support of this opinion.

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 do 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 acutely and chronically 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 (ECHA 2011; ECHA, 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 stoats 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 lead. The limit of 30 mg lead/kg for lead in forage is likely to be breached regularly. There are some published estimates of the NOEC values for different mammalian species but these 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

To characterise the risk of exposure, the Dossier Submitter used quantitative estimates of:

- neurodevelopmental effects;
- chronic kidney disease and;
- cardiovascular (systolic blood pressure) effects.

The EFSA (2010) $BMDL^{10}_{01}$ 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 the previous 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 the 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

[10] Bench Mark Dose Level

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.

However, in the recent RAC opinion on the evaluation of an 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 considered to have a threshold, and a LOAEL[11] 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.

3.1.2. Information on emissions and exposures

Justification for the opinion of RAC

Summary of proposal:

The principal routes by which birds and mammals are exposed to lead from ammunition or fishing tackle are primary ingestion (ingestion of any lead object directly from the

[11] Lowest Observes Adverse Effect Level

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 elaboration.

- 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 Appendixes 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

3.1.3. Characterisation of risk(s)

Justification for the opinion of RAC

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):

Qualitative risk assessment

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 report 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[12] 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).

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 gunshots 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

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

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-lethal 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 published estimates on mortality are available, the Dossier Submitter did not try to provide their own estimate of how many birds will potentially die each year 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 the 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 to result 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.

According to the UNEP CMS ad hoc Expert Group (comment #3343), 634 000 birds (24 % of birds at high or moderate risk)) are affected by lethal or sub-lethal poisoning. For species that are clearly predatory or scavenging, the respondents assume a mortality of 3 %. 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 ecologically threatened species, where mortality and sub-lethal effects may have a much bigger impact on populations. 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. Leaded fishing sinkers (0.06 – 28.35 g) have therefore been banned in the UK, immediately resulting in decreased lethality in British swans. 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).

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 did 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 considers 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 appropriately 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 RAC had 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. The results of this analysis are described in Annex 1: RAC qualitative risk assessment approach and the main conclusions have been taken forward and compiled under chapter RAC conclusions (above).

3.1.4. Uncertainties in the risk characterisation

See section 3.4.1.

3.1.5. 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

Justification for the opinion of RAC

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 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[13]. Authorities such as French ANSES[14] or German BfR[15] 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

[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.

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

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

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 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 conclusion(s):

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 conclusion(s):

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.

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

Justification for the opinion of RAC

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 A UNION-WIDE BASIS

Justification for the opinion of RAC and SEAC

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)[16], and the CMS Memorandum of Understanding on the Conservation of Migratory Birds of Prey in Africa and Eurasia (Raptors MOU)[17] to protect birds and their habitats.

3. To ensure the free movement of goods within the Union.

4. To ensure a level playing field for all engaged in sports shooting within the EU.

SEAC and RAC conclusions:

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

[16] https://www.cms.int/en/legalinstrument/cms (accessed 4 May 2021)

[17] https://www.cms.int/raptors/en/legalinstrument/birds-prey-raptors (accessed 4 May 2021)

hunting and 11 % from fishing. Because these risks are a Union-wide concern, SEAC and RAC agree that initiating 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[18]. Even though the Birds Directive explicitly requires hunting practices to not jeopardise conservation efforts[19], 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 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 sport shooters within the EU.

  Taking part in international competitions (e.g. Olympic Games, ISSF or FITASC events) makes it necessary that participants can prepare for such events under optimal conditions, which represent the conditions during the competition as closely as

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

[19] Article 7 Directive 2009/147/EC

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.

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

3.3.1. 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 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 or airgun pellets takes place under strict conditions, see next point on 'conditional derogation'). Additionally, a ban on the use of fishing sinkers where the fishing equipment, rig or technique deliberately releases the sinker during use is proposed.

- 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 an outdoor location notified (to the Member State) for sports shooting with appropriate risk management measures in place.

- A derogation if the use does not contribute significantly to identified risks. This applies to certain non-expanding ammunition used in hunting (specified as full metal jacket bullets) and lead bullets for seal hunting, for which no suitable alternatives exist yet, 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 of 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 and casings) is 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 intended to be outside the scope of the restriction proposal.

The Background Document makes it clear that the Dossier Submitter prefers a complete ban on the placing on the market and use of lead gunshot. However, the Dossier Submitter also investigated the impacts of an 'optional conditional derogation' to allow the continued placing on the market and 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 currently still required by the rules of these events 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 also be implemented by national associations or national authorities 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.

Justification for the opinion of RAC

RAC conclusion(s):

- 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(s):

Scope of the proposed restriction

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 and were not proposed by the Dossier Submitter. 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[20]. 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.

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.

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

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

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.

Analysis of Risk Management Options

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[21].

The Dossier Submitter concludes that RO1 would be the most effective and enforceable option

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

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 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):

In general, SEAC agrees that the scope of the proposed restriction has been clearly described and justified in the Background Document.

However, SEAC concludes that it is not clear if all forms of shooting undertaken for 'technical testing and development' are covered by the exemption formulated by the Dossier Submitter (paragraph 8) or by the general exemption of scientific research and development (SR&D) under REACH. SEAC will elaborate on some forms of technical testing and development, which will need to be covered by the exemption according to the Dossier Submitter's intention (see SEAC box in the Background Document, section 2.7.3).

With regard to the ban on the use of lead ammunition in muzzle loaders or other historic firearms and their replicas outside of shooting ranges (in particular for hunting), the need for a longer transition period, i.e. 5 years, is supported by information indicating that non-lead alternatives are not generally available for the use in historic firearms yet. SEAC considers that a final conclusion on whether a derogation of this use would be justified based on cultural values is not possible due to lack of information on the socio-economic impacts involved. Hence, this decision will have to be taken based on policy priorities (see also section 3.3.3.4 on proportionality).

SEAC has too limited information to conclude whether the effort to introduce an information requirement ('retailer duty' as described in paragraph 5a of the proposed restriction entry) is fully justified or if other educational measures suggested by the Dossier Submitter (typically outside of the scope of REACH) could be more effective, for example as part of national hunting or fishing exams for those Member States that have such exams.

With regard to the labelling requirement where a ban on use only is proposed (paragraph 5b), SEAC considers that this will support enforcement of the ban on use of lead bullets in the field. However, labelling on the package alone does not ensure that a single lead bullet is clearly identifiable, for instance, if bullets are carried without the packaging. Therefore, it would facilitate inspections if individual lead bullets were identifiable. Comments from stakeholders received in the consultation on the SEAC draft opinion indicated that there are cost-effective ways to achieve this, e.g. by colour-coding of cartridges, but their implementation is likely to be complex. Overall, SEAC does not have sufficient information to assess the technical feasibility, the costs involved, and the practicality of such means in detail.

In response to comments received in the consultation on the Annex XV report indicating difficulties to implement the concentration limit of 1 % for certain types of bullets (copper or copper alloys), the Dossier Submitter proposed a higher limit of 3 % linked to a review before entry into force. As an additional concentration limit may complicate enforcement, SEAC agrees that the proposed review of the concentration limit would be very useful to ensure that the need for a higher limit value is substantiated.

Hunting

With regard to lead gunshot, SEAC finds that the need for a transition period of five years has not been sufficiently substantiated by evidence to support that the increase in production capacities of alternatives would require this much time, in particular taking account of the potential effect of the ban on use of lead in gunshot in wetlands on production capacities of alternative gunshot. Here, more specific information would have been required from industry for SEAC to draw a conclusion on the development of production capacities and the impacts of different transition periods, which was not provided during the consultations. Available evidence indicates that a shorter transition period for the ban of use in hunting is unlikely to result in supply issues. Therefore, SEAC concludes that a significantly shorter transition period than five years is supported by the current availability of alternatives, the expected increase in supply driven by the restriction of lead gunshot in wetlands, and the estimated costs and benefits involved (please see further discussion of the impacts of the ban of lead gunshot in section 3.3.3.4 on proportionality). However, substantive and credible evidence to conclude on the specific length of the transition period was not available to SEAC. SEAC considers the minimum transition period required to ensure a smooth transition to alternatives is 18 months (in line with the transition period proposed for large calibre bullets).

With regard to lead bullets, SEAC agrees with the Dossier Submitter that a longer transition period is required for small calibres/rimfire cartridges, because the availability and performance of alternatives are not yet sufficiently developed compared to large calibres. A review of the availability and technical performance of alternatives for hunting as proposed by the Dossier Submitter is supported by SEAC.

Sports shooting

SEAC understands the intention to provide to the decision-maker the option for a derogation for sports shooting under certain conditions. SEAC has assessed the practicality and expected impacts of the optional conditional derogation as defined by the Dossier Submitter, and has some concerns that are further explained below. SEAC considers that in case a derogation of lead gunshot is preferred by the decision-maker, it should be targeted to the minimum and maximum shot sizes that according to the FITASC/ISSF rules[22] are used in sports shooting, i.e. between 1.9 and 2.6 mm, in order to retain the advantages of a ban on placing on the market of lead gunshot as much as possible.

In relation to the conditional derogation for sports shooting with projectiles other than gunshot (i.e. bullets and airgun pellets) and the optional conditional derogation for sports shooting with gunshot, SEAC considers that the transition period of 5 years that is proposed in the updated Background Document is appropriate for allowing the implementation of the proposed RMMs.

Where lead recovery is part of the conditions proposed, it is implicitly assumed that any lead

[22] The rules for the different FITASC disciplines (Compak sporting, Universal Trench, Sporting, Helice, Combined Game Shooting, Trap1, Universal Skeet) are available at: https://www.fitasc.com/uk/content/10/1 (accessed 3 May 2022). The rules for different shotgun ISSF disciplines (Trap, Double Trap, Skeet, Trap Mixed Team, Skeet Mixed Team) are available at: https://www.issf-sports.org/theissf/rules_and_regulations/shotgun_rules.ashx (accessed 19 May 2022).

recovered under the conditions of the restriction will be recycled in a safe and technically accepted manner.

Fishing

SEAC agrees in principle with the scope of the Dossier Submitter's proposal for fishing. Derogations requested for certain uses, e.g. lead sinkers and lures > 50 g and lead split shots, were not sufficiently substantiated by evidence of the socio-economic impacts of the ban proposed.

Key elements underpinning the SEAC conclusion(s):

A. General issues

Scope of the proposed restriction

Based on the request by the European Commission, the proposal focusses on uses in shooting and fishing where lead is released to the environment during use. Accordingly, it only covers outdoor activities. Potential risks to human health resulting from lead exposure during indoor shooting are not intended to be addressed by the proposed restriction.

In addition to military uses, other 'on duty' uses by non-civilians are also intended to be excluded from the scope of the proposed restriction, such as those by the police or equivalent law enforcement authorities. In addition, SEAC notes that the Dossier Submitter clarified if and under what circumstances certain other civilian uses are intended to be inside the scope or are intended to be derogated, e.g. for self-defence (intended to be outside scope), or voluntary military training (intended to be inside scope). However, the Dossier Submitter considers that training/practice for excluded uses should only take place on shooting ranges that have the necessary RMMs described for the conditional derogation for using projectiles other than gunshot.

Technical testing and development of materials are also not intended to be covered by the proposal and is considered by the Dossier Submitter to be exempted based on the specific formulation in paragraph 8 of the entry proposal or based on the general exclusion of scientific research and development (SR&D) from restrictions under REACH. As technical shooting goes beyond what is commonly seen as technical testing and proofing of firearms, SEAC sees a need to clarify the range of applications which are indeed exempted by including a box in the final Background Document that shows another example of technical shooting related to the testing of pressurised gas cylinders, as described in e.g. EN 12245.

SEAC also notes that the use of lead-based ammunition would be banned for historic firearms, e.g. muzzle loading or historic breechloading guns, unless used at a shooting range that fulfils the conditions set in the restriction. This means that hunting with such firearms (so-called 'black powder hunting') would no longer be possible, because according to the Dossier Submitter's analysis lead-free ammunition is not generally available for the use in historic firearms or in modern replicas of them. This conclusion is confirmed by comments received in the consultation on the Annex XV report (e.g. #3235) accompanied by requests for a derogation of lead ammunition in muzzle loaders (e.g. #3254). With regard to the development of alternatives, SEAC notes that some manufacturers have developed lead-free muzzle loading ammunition (see Background Document, section 2.7.1). However, no

information was available to evaluate the technical performance of these alternatives and whether they can actually be used in antique guns or only in modern replicas. There have been requests in the consultation on the SEAC draft opinion for a transition period of five years (subject to a review prior to the entry into effect) for hunting with historic firearms using black powder ammunition (e.g. #1041)[23]. SEAC notes that in paragraph 7e of entry text, the Dossier Submitter already proposes a five-year transition period subject to a review prior to the entry into effect for non-centrefire ammunition (e.g. small calibre and rimfire bullets), which also includes black powder ammunition. SEAC considers that the limited availability of alternatives substantiates a longer transition period for black powder ammunition used in hunting bullets.

SEAC assessed the impacts of a potential derogation based on the limited information available on the current use of historic firearms in hunting. However, a final conclusion on whether a derogation of this use would be justified based on cultural values is not possible due to lack of information on the socio-economic impacts involved. Hence, this decision will have to be taken based on policy priorities (please refer to section 3.3.3.4 on proportionality).

It has to be stressed that the proposed restriction does not cover the *manufacture* of ammunition and fishing tackle at *industrial* sites. 'Industrial' uses are therefore not assessed in the Annex XV report.

The Dossier Submitter identified that the casting of lead bullets and lead fishing tackle activity in 'non-industrial' settings presents a risk, especially for human health. These activities, either performed by the general public in a private setting (so-called 'home-casting'), or at larger scale in 'garage' type settings or in the back rooms of fishing shops, are carried out without the supervision of the usual national OSH, and industrial emission regulations. Therefore, the assessment of the risks associated with 'home-casted' lead fishing tackle (and lead ammunition) is within the scope of the Annex XV report and proposed restriction. Because *use* of lead projectiles and fishing tackle that are produced in private settings would also be restricted, the Dossier Submitter expects that the ban on use will effectively discourage this activity. If home-casting as an activity was an explicit part of the scope of the restriction, enforcement would be difficult, because it takes place in the private sphere.

SEAC understands that the Dossier Submitter sees the introduction of warnings to be displayed at the point of sale by the retailer ('retailer duty' as described in paragraph 5a of the proposed restriction entry), which go beyond labelling requirements already needed because of other regulations, as an element that will support a change in the behaviour of the users during the transition (phase out) periods. The available literature on the use of similar warnings on tobacco and alcohol products in Europe and the USA shows mixed effects (Woelbert and d'Hombres, 2018; Hammond, 2011; Williams et al., 2012; Hoek et al., 2011). What seems to be a consistent outcome of various investigations, is the fact that pictures seem to generate a stronger effect with consumers than text-only warnings. It is unclear to what extent these findings are transferrable to lead in outdoor shooting and fishing. In this respect it must be considered that the consumers in this case are hunters, sports shooters or fishers who are likely to already be well aware of the hazards of lead in general, because of

[23] Comments received requested a five-year transition period for lead projectiles in muzzle and breech loading firearms designed for black powder and made before 1899 and their reproductions.

the discussions that have been ongoing already for quite some time, though not necessarily about the risks in the specific outdoor shooting or fishing situation. SEAC considers that the available information is insufficient to reach a conclusion as to whether text-only warnings, as proposed, will significantly influence the purchasing behaviour of consumers during the transition periods. Therefore, it is difficult to conclude if the effort and costs to introduce such an information requirement is justified or if the other approaches to influence purchasing behaviour, outside of REACH, suggested by the Dossier Submitter, such as education, for example as part of national hunting or fishing exams, could be more effective as an alternative or complementary measure for those Member States that have such exams.

Taking into account SEAC's and RAC's assessment of the lead gunshot in wetlands restriction, SEAC considers that the labelling obligation will support enforcement in the field, which contributes to the effectiveness of the proposed restriction. However, labelling on the package does not ensure that lead ammunition is clearly identifiable in the field, for instance if carried without the packaging[24]. Therefore, it would facilitate inspections if also the bullet (or shotgun cartridge) itself was marked. For information to assess the technical and economic feasibility of such a measure, SEAC asked for input from stakeholders in the consultation on the SEAC draft opinion. Comments received indicate that the technical feasibility of marking bullets or cartridges with distinct signs, e.g. 'Pb', is limited. However, the information provided does not allow for a definite conclusion on this issue. According to stakeholders, colour-coding could be a cost-effective means to identify individual lead bullets or cartridges (e.g. #1106, #1098), though its use could be complicated by avoiding overlaps and confusion with colour-coding schemes already in use (e.g. by NATO). In general, labelling seems to be technically less complicated for gunshot cartridges than for bullets.

As a concentration limit value for lead, the Dossier Submitter proposed 1 % along the lines of the restriction of lead gunshot in wetlands. SEAC considers this useful. In the consultation on the Annex XV report it was raised that a 1 % limit would not be achievable for copper or copper alloys without inadvertently affecting existing alternatives to lead ammunition (#3259, #3503). In response to these comments, the Dossier Submitter proposed a limit of 3 % for projectiles made of copper of copper alloys, which should be reviewed before the restriction enters into force. SEAC considers that a harmonised (single) limit value would be the most simple and hence would facilitate enforcement of the restriction. Therefore, any deviation should be well substantiated and SEAC supports the review proposed by the Dossier Submitter before entry into force to ensure that a deviation is strictly necessary.

Regarding the consideration of an optional conditional derogation for sports shooting with gunshot, SEAC understands that the Dossier Submitter included this as an option for the decision-maker, because even if as a result of this restriction a certain willingness of sports shooting federations to change competition rules would emerge, it is unlikely that these rules will be changed in a short period of time. Still, SEAC highlights that the implementation of the present restriction proposal (in particular without, but even with, the optional derogation) could act as a driver for international sporting organisations like the International Olympic Committee to meet the environmental protection and sustainability objectives they have

[24] SEAC notes that in California, where a ban on lead ammunition entered into effect in 2019, hunters are encouraged to carry the packaging with them when hunting: https://wildlife.ca.gov/Hunting/Nonlead-Ammunition#25046248-how-will-wildlife-officers-check-for-compliance (accessed 25 October 2022).

already committed to (IOC, 2020).

However, in the SEAC discussions it appeared that often the optional conditional derogation was considered as a part of the preferred option of the proposed restriction. But it should be strongly emphasised that the Dossier Submitter clearly indicated that a total ban on the placing on the market and use of lead gunshot is the preferred restriction option. The impacts of the optional conditional derogation have been analysed to give relevant information to the decision-maker in case such a derogation will be considered. Moreover, the implementation of the optional conditional derogation in the various Member States has caused some concerns, because many SEAC members consider this to be more complicated than assumed by the Dossier Submitter. This is further discussed below.

Analysis of Risk Management Options

The Background Document does not contain a systematic comparison of various RMOs other than restriction. SEAC understands that the limited scope of the analysis of RMOs results from the fact that the Commission requested ECHA to prepare a restriction proposal, thereby pre-empting potential other conclusions. However, SEAC notes that the Dossier Submitter in their assessment still considered options other than restriction, including non-REACH and voluntary measures. A general overview of these options is given in the Background Document in Annex D.1.5 and in Annex D.4.6. The interpretation of these tables is hindered by the fact that in the descriptions impacts on fishing tackle and lead ammunition are somehow mixed up, leading to a lack of clarity to which use of lead it relates. Also, it is not clear to what extent the analysis includes the use of lead in sports shooting. SEAC recommended that the Dossier Submitter revises these tables and generalises them to the hunting and sports shooting sectors of the restriction. However, this has not been taken up in the Background Document.

Noting the limited RMO analysis and the qualification resulting from this limitation, SEAC overall agrees with the Dossier Submitter's conclusion that, on their own, none of these measures will be effective or practical in addressing all of the risks posed by lead in ammunition and fishing tackle in the described uses. Therefore, a restriction is the most appropriate regulatory action to address the identified risks. However, some of the other options that are mentioned could be used to support the effectiveness of the restriction.

Ranking of Restriction Options

The Dossier Submitter ranked the different restriction options identified by scoring their performance with regard to risk reduction and proportionality. No differentiation was made with regard to practicality (including enforceability) or monitorability arguing that all options assessed would fulfil these criteria. SEAC considers that it is still likely that the options assessed vary in terms of their practicality (including enforceability) or monitorability.

In order to assess risk reduction and proportionality, the Dossier Submitter selected key dimensions[25], in which the performance of the different options was scored from best (highest score) to worst (lowest score). SEAC notes that for the different uses (hunting, sports shooting, fishing) covered by the proposal the key dimensions selected were not applied

[25] Key dimensions: lead emission reduction, other environmental risk reduction (for fishing only), human health risk reduction (for fishing only), overall risk reduction (for outdoor shooting), costs, end user acceptance (for fishing only)

consistently, as some dimensions were exclusively used for one use and not for the others without providing justification for this divergence. Also, the ranking approach was not applied if only one restriction option was found to be effective in terms of risk reduction.

SEAC considers that the ranking approach in principle could be a useful tool to distinguish between the various options. However, overall SEAC considers the ranking as performed by the Dossier Submitter not very useful because (i) it is not applied consistently to all uses and options analysed and (ii) it does not evaluate differences in practicality (incl. enforceability) and monitorability.

B. Hunting (use #1, 2a, 2b)

B1. Hunting with gunshot (use #1)

Scope

The Dossier Submitter proposes a ban on placing on the market and use, i.e. a complete ban of lead gunshot for hunting. As such, the scope of the proposal is clear. SEAC agrees with the Dossier Submitter that the proposed restriction would significantly reduce the environmental and human health risks of the use of lead gunshot in hunting.

As a supporting measure, the Dossier Submitter proposes that information on the hazards of lead and the phase-out timetable has to be provided at the point of sale when purchasing lead containing gunshot until the relevant ban on placing on the market and use enters into effect. Please see 'A. General issues' above for SEAC's view on the 'retailer duty'.

In alignment with lead gunshot in sports shooting, the Dossier Submitter proposes a transition period of five years for the ban on placing on the market and use mainly based on time needed for industry to adapt manufacturing processes and to increase production of non-lead gunshot cartridges to meet total demand (hunting and sports shooting). The Dossier Submitter's proposal is based on general information received from industry and not on explicit information on the investments needed to replace lead gunshot with alternatives. Including the time needed for the decision-making process, a 5-year transition period means that the restriction most likely would not enter into effect before 2029. SEAC considers that the justification for the length of this transition period is insufficient, in particular for the use of lead gunshot in hunting.

The Dossier Submitter did not assess the impacts of a phased ban with different transition periods for the use of lead gunshot in hunting and sports shooting in detail. However, if it is not possible to increase production to cover the total demand for lead gunshot (~38 500 tonnes per year for sports shooting and hunting together) sooner than five years, SEAC considers that it would be justified to have a shorter transition period for the ban on use of lead gunshot in hunting (~14 000 tonnes per year) compared to sports shooting (~24 500 tonnes per year), because hunting with gunshot significantly contributes to the identified risk.

In order to support the decision-maker to conclude on the appropriateness of the length of the transition period, SEAC sought more information on the development of production capacities and necessary investments in the consultation on the SEAC draft opinion. However, no specific information to conclude on this issue was provided by stakeholders. Based on the comments received (e.g. #1106), 850 million units of lead gunshot were produced in 2019 in

total, 350 million units for hunting and 500 million units for sports shooting. Of the 350 million cartridges used in hunting about 100 million[26] can be assumed to be used in wetland hunting and hence will have to be replaced when the restriction of lead gunshot in wetlands enters into effect (February 2023) leaving about 250 million cartridges used in hunting to be substituted to comply with the current proposal. Assuming a steady increase in the production of steel gunshot over a period of five years, it may be feasible to meet market demand of hunters significantly earlier, in particular if the restriction of the use of lead gunshot in wetlands will lead to an increase in current production capacities.

Comments received by industry in the in the consultation on the SEAC draft opinion stated that eight to ten years would be needed to replace the total current production of lead gunshot (for hunting and sports shooting) with alternatives, arguing that steel shot is to a large extent imported from outside the EEA (mainly China) and that major investments and changes in the production are needed to develop new components, to adapt and replace loading machines and to search for new suppliers of alternatives (e.g. #1106, #1077). SEAC notes that the requests for such a long period were not substantiated by sufficient information and conflict with ample evidence showing that technically and economically feasible alternatives are available on the market and used by hunters in Member States where a partial or total ban of lead gunshot was implemented already. All major manufacturers have already introduced non-lead shot to their portfolio and offer a wide range of alternative gunshot cartridges[27], indicating that the time needed for further R&D or product development is likely to be limited. Current supply is likely to increase to meet the demand driven by the restriction of the use of lead gunshot in wetlands, which enters into effect in early 2023.

Analysis of Restriction Options

The Dossier Submitter identified and analysed five different restriction options (ROs) for the use of lead gunshot in hunting (see Table 2-1 in the Background Document):

- RO1: Ban on the placing on the market and use of lead gunshot for hunting
- RO2: Require specific design/construction of lead gunshot
- RO3: Ban on the placing on the market of game meat hunted with lead gunshot or maximum levels of lead in game meat
- RO4: Advice to cut away more meat when handling game and meat hunted with lead gunshot
- RO5: Compulsory information on the hazards of lead and the risks of using lead ammunition, transition periods and availability of alternatives at the point of sale and

[26] Relevant documents on the impact assessment of the wetland restriction can be found here: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e180c0ac38 (accessed 25 October 2022)

[27] Further evidence of current supply was received in a confidential manner in the consultation on the SEAC draft opinion (#1071) and has in the meantime become publicly available: All-Party Parliamentary Group on Lead Ammunition (2022), Alternatives to lead shot: Assessing supply and demand, report researched by Wildlife & Countryside Link and Wildfowl & Wetlands Trust, available at: https://leadammunitionappg.org/wp-content/uploads/2022/09/Alternatives-to-lead-shot-Assessing-supply-and-demand.pdf (accessed 12 October 2022)

incorporated in national hunting exams

SEAC agrees that out of the different measures analysed, RO1 (ban on placing on the market and use of lead gunshot for hunting), is the only option that is sufficiently effective to reduce the risks of lead in gunshot used for hunting. SEAC notes that implementing a ban on placing on the market constitutes a complete ban of lead gunshot, i.e. including for sports shooting, which is also the preferred option proposed by the Dossier Submitter (in combination with compulsory information on the hazards of lead and the risks of using lead ammunition to be provided to users).

SEAC considers that the optional conditional derogation of lead gunshot in sports shooting could undermine the effectiveness of the proposed restriction for lead gunshot in hunting, because it could compromise the advantages of a ban on placing on the market in terms of enforceability as lead gunshot would remain available on the market to a very limited number of actors (see discussion under C1 below). It could also mean that lead gunshot might be more accessible for illegal use in hunting. It is uncertain to what extent this would happen and if it could have a major impact on the effectiveness of the restriction. Nevertheless, this situation would be closer to a 'ban on use only', in which enforcement in the field is decisive for effectiveness. Proper in-field enforcement is likely to require far more resources than enforcement of placing on the market. These potential 'side effects' on the ban of lead gunshot in hunting have to be taken into account when assessing the impacts of the 'optional conditional derogation' in more detail. In this respect, SEAC notes that 'ban on use only' was not a RO that was assessed as part of the Dossier Submitter's analysis. Including this option would have strengthened the RO analysis in the Background Document.

For RO3 (regulation of lead in game meat), effectiveness depends on the share of game meat that is placed on the market rather than consumed (e.g. by hunters and their families) without entering the market. Based on available data on the marketing of game meat, SEAC agrees with the Dossier Submitter that this option is not sufficiently effective, because a considerable share of game meat is consumed privately by hunter families, where any regulation of maximum lead concentrations in game meat would not be practically enforceable. Also, the negative impacts on birds and wildlife will not be addressed by this option.

Similarly, RO2 (require specific design/construction of lead gunshot) and RO4 (advice to cut away more meat when handling game and meat hunted with lead gunshot) will not effectively reduce the risks of using lead gunshot in hunting.

For RO5 (compulsory information on the hazards of lead and the risks of using lead ammunition, transition periods and availability of alternatives at the point of sale and incorporated in national hunting exams), SEAC considers that even though this measure will not be sufficient as a single measure, education can be an effective tool to convince hunters to switch to lead-free alternatives, in particular if supported by influential groups (hunting peers, associations or clubs). Therefore, it can complement a ban and might be more effective than the proposed information requirement at the point of sale alone to raise awareness. In this respect, SEAC notes that the Dossier Submitter suggests educational measures as part of national hunting exams, but this is not reflected in the entry proposal. The main argument for not considering educational measures as part of the proposal is that not all Member States have hunting exams established. SEAC points out that other existing institutional structures such as hunting authorities or associations may also provide a basis to implement educational

measures, even though not as part of a national exam.

B2. Hunting with bullets, incl. airgun pellets (use #2a and 2b)

Scope

The proposed restriction envisages a ban on the use of lead projectiles not defined as gunshot (i.e. bullets and airgun pellets) for hunting. The main reason that a ban on use only is proposed is that it ensures that the placing on the market of lead bullets for other uses, i.e. sports shooting as well as uses that are out of scope (e.g. military uses), will still be possible. The Dossier Submitter complemented the ban on use with the requirement to provide information at the point of sale ('retailer duty') as well as with a labelling obligation ('supplier duty'). Please see 'A. General issues' above for SEAC's view on the 'retailer duty'.

Provided that the ban on use is properly enforced, SEAC considers that the proposed restriction effectively reduces the risks of the use of lead bullets in hunting as hunters will switch to alternative materials, which are considered to entail less risk. However, SEAC considers that a ban on use only is likely to be less effective than a complete ban, because enforcement will be more complicated.

For centrefire ammunition, the Dossier Submitter proposes different transition periods: 5 years for small (< 5.6 mm) and 18 months for large (≥ 5.6 mm) calibres. For rimfire ammunition, 5 years are proposed for all calibres. It is important to note that basically all small calibres used in hunting and sports shooting are rimfire cartridges, e.g. the commonly used .22 LR. SEAC agrees with the Dossier Submitter that a longer transition period is required for small calibres/rimfire cartridges, because the availability and performance of alternatives are not yet sufficiently developed compared to large calibres (see section on costs).

Comments submitted in the consultation on the Annex XV report supported this view on the limited availability of non-lead rimfire bullets as well as their lower performance in terms of precision (#3252). Based on these arguments as well as on a contention that the use of small calibre bullets results in no or much lower risk to the environment and human health, a derogation was requested by several commenters. In response, the Dossier Submitter proposed a review of the ban before the end of the transition period of 5 years, because environmental and human health impacts from the use of small calibre bullets in hunting cannot be ruled out (confirmed by RAC). SEAC agrees with this proposal.

In the consultation on the Annex XV report and on the SEAC draft opinion, further requests for a derogation were received with regard to ammunition, which is used in very specific hunting situations for which no alternatives are available yet, e.g. hunting with muzzle loaders (see discussion under A above), seal hunting and full metal jacket bullets (incl. open tip match bullets). For bullets used for seal hunting as well as full metal jacket bullets, the Dossier Submitter proposed a derogation based on the very low volumes of this ammunition used as well as the limited contribution to the risks to be addressed (for SEAC's evaluation, please refer to section 3.3.3.4 on proportionality). With regard to full metal jacket bullets, SEAC understands that the Dossier Submitter intended to cover non-expanding ammunition used for hunting with the proposed derogation, which also includes non-expanding open tip match bullets. To make this clear, SEAC proposes to specify this in the entry text.

Analysis of Restriction Options

The Dossier Submitter identified and analysed similar ROs as for lead in gunshot (see Table 2-2 in the Background Document), hence SEAC's views on these also apply here:

- RO1a: Ban on the use of small calibre (< 5.6 mm centrefire and rimfire in general) lead bullets for hunting
- RO1b: Ban on the use of large calibre (≥ 5.6 mm centrefire) lead bullets for hunting
- RO2: Require specific bullet design/construction when lead is used (to minimise lead fragmentation)
- RO3: Ban on placing on the market of game meat hunted with lead bullets or maximum levels of lead in game meat
- RO4: Advice to cut away more meat when handling game and meat hunted with lead bullets
- RO5: Compulsory information on the hazards of lead and the risks of using lead ammunition, transition periods and availability of alternatives at the point of sale and on product packaging and incorporated in national hunting exams

The proposed restriction is a combination of RO1a, RO1b and RO5 (with incorporation of information in national hunting exams considered as a complementary measure).

C. Sports shooting (use #3, 4, 5, 6)

C1. Sports shooting with gunshot (use #3)

Scope

SEAC understands from the analysis of various restriction options for lead gunshot in sports shooting in section 2.2.2.1 of the Background Document that the Dossier Submitter considers that RO1 (a ban on the placing on the market and the use of lead gunshot for sports shooting) together with the requirement to provide information at the point of sale ('retailer duty') is the most effective restriction option. In view of the current situation where alternatives for lead gunshot appear to be available already, SEAC agrees with the Dossier Submitter's conclusion that a ban on the placing on the market and use is the preferred risk management option.

SEAC further understands that the Dossier Submitter sees the combination of the optional conditional derogation (involving a combined permit/licence system for shooting ranges and individual athletes and requirements concerning a minimum standard of RMMs) together with a labelling requirement ('supplier duty') and the requirement to provide information at the point of sale ('retailer duty'), as well as a reporting requirement for Member States as a fall-back position, in case the decision-maker would like to avoid impacts on international competitive sports shooting. This option would still allow sports shooters competing at a high level to continue participating in international events and to train for such events as long as international shooting associations only allow the use of lead gunshot, while still reducing the identified risks. Moreover, it would allow continued organisation of such events in Member

States. This option would mean that lead gunshot will remain on the market for a limited number of actors. If the permit/licence system and the conditions are reasonably implemented, this should not have a major impact on the effectiveness of the proposed restriction as the bulk of lead gunshot used today would still be covered by the proposed ban. However, in order to retain the advantages of a ban on placing on the market in terms of simple and effective enforcement, SEAC considers that, should the optional conditional derogation be implemented, it should be limited to the minimum and maximum shot sizes used in sports shooting according to FITASC/ISSF rules[22], i.e. 1.9 to 2.6 mm, and exclude the larger shot sizes that are commonly used for hunting.

In assessing the optional conditional derogation, the Dossier Submitter considered different scenarios on how shooting ranges might respond. These scenarios vary in the number of shooting ranges that would upgrade their RMMs in order to be able to fulfil the condition of > 90 % lead recovery, and thereby be allowed to continue the use of lead gunshot. In addition, the Dossier Submitter assessed options to allow access to these sites for all shooters (RO3) or only for those having a licence issued by the responsible Member State (RO4). However, in each scenario/option this optional conditional derogation would imply high costs for certain actors (see section on costs below).

SEAC would like to point to some issues that have been raised in the course of the opinion development process and which may cast some doubts on the possibilities to implement such an optional derogation as proposed. Most certainly it would mean that the actors involved (sports shooters, shooting clubs and shooting associations) would need flexibility to adjust to the new conditions and would need to structure their sport differently from today. It also involves a permit/licence system and the involvement of many actors at national level (enforcement, shooting clubs, shooting associations, etc) that need to work out how to organize and finance this on a national level, which will not facilitate a speedy implementation, even if this would be considered desirable by the decision-maker. Moreover, it has to be realised that all this would serve to satisfy the needs of a very limited group of sports shooters only – i.e. those participating in international competitions (estimated at a number of 12 000 in the EU, or about 0.5 % of the estimated total of 2 500 000 sports shooters in the EU). It also remains unclear if a transition to "lead shooting status" would present special problems regarding shooting skills once a sports shooter is promoted to the level of international competition.

Furthermore, the Background Document assumes that the proposed permit/licence system for locations and individuals will build on existing systems already in place. It is currently unclear if this is a realistic expectation or if these activities would incur extra costs by authorities. The Background Document describes some basic conditions that the Dossier Submitter envisages as part of a licensing structure for athletes. However, at the same time, it is suggested that the responsibility for organisation and implementation of certain elements of the licensing schemes can be delegated to "national authorities", that are already supervising shooting activities. The decision-maker considering implementing the optional conditional derogation should be aware that this approach, without further specifications that are mandatory and valid for all Member States, may create an outcome that is highly unharmonized across Member States. This would unintentionally run contrary to the objective of a level playing field cited in section 3.2 above.

In the SEAC discussions it was suggested several times that an (optional) derogation which

will allow the use of gunshot for sports shooting should be limited in time. However, in view of the relatively large investments needed to upgrade RMMs at existing ranges, it appears to be rather unattractive to invest in such an upgrade that would be obsolete in a few years. However, SEAC could imagine that such a time-limited derogation would make sense for RO2 (where permitted shooters may continue the use of lead gunshot, but all others have to change to alternatives). Such a time limit may serve as an incentive for sports shooting associations to look for options to allow the use of alternatives to lead gunshot in international competitions. If it is considered that such processes to change rules usually are inherently slow – a transition time of 10 or 15 years (which would be, respectively, 5 and 10 years longer than the transition period proposed by the Dossier Submitter for the preferred option, i.e. a ban on placing on the market and use) may be considered.

SEAC also noted in the comments from the Annex XV report consultation that the sports shooting part of the dossier has been criticised because the impacts on some sports shooting disciplines other than skeet and trap shooting, which also use gunshot, have not been discussed. It is claimed that these other disciplines may have specific problems with a change to steel shot. In SEAC's view, the consultation comments have not shown that other gunshot disciplines have specific problems using steel shot. The mentioned problems of ricochet and problems for the forest industry (because of steel pellets that become embedded in trees and potentially may cause damage to sawing machines) do not seem to be supported by data, at least not for disciplines involving the shooting of clay targets.

Note that, based on comments received in the consultation on the SEAC draft opinion, the uncertainty section of this opinion (section 3.4.2) includes some additional information on other sports shooting disciplines that use gunshot, i.e. practical shooting, and may be impacted by this restriction as well.

Analysis of Restriction Options

The Dossier Submitter compared a number of Restriction Options (ROs) for sports shooting with gunshot and rated these using a scoring system for expected effectiveness complemented with considerations on practicality and monitorability/enforceability (see Table 2-4 in the Background Document).

SEAC notes in the scoring system applied by the Dossier Submitter that the reduction of lead release and overall risks, as well as costs for implementation are rated with the same weight. Unfortunately, the rationale behind this choice is not explained by the Dossier Submitter.

The Dossier Submitter considers that RO1 (ban on placing on the market and use of lead gunshot for sports shooting) is scientifically/technically the preferred restriction option because suitable alternative shot material is available. This restriction option also ranked highest in the Dossier Submitter's analysis. However, this restriction option currently causes problems for the sports shooting sector because rules for international competitions (e.g. Olympic Games, ISSF or FITASC events) currently require the use of lead shot for skeet and trap disciplines.

The Dossier Submitter does not assume that there will be rule changes in the short term that would allow the use of alternative shot materials. The Dossier Submitter also acknowledges that continued participation in international sports shooting competitions is likely to be valued highly by society. Therefore, the Dossier Submitter assumes that decision-makers may

consider a complete ban, without any possibility for continued participation in international sports shooting events, to have an unacceptable socio-economic impact for athletes and the interested public. In the input from stakeholders to the Annex XV report consultation and to the SEAC draft opinion, SEAC found few arguments supporting this assumption other than the desire of European athletes (or their associations) to participate at international events as such and to be able to organize such events in the EU. SEAC considers it a plausible desire to maintain a level playing field for athletes from Europe and other parts of the world. But in the view of SEAC it is questionable if quantifiable socio-economic arguments can be brought forward to support the assumption that hosting events like Olympic games generate a large positive value for society. Data that are available for recent Olympic games do not suggest that organizing such an event is attractive for the organizing city, if only the direct profit/loss balance is considered. However, indirect or follow-up effects may give a more positive picture (McBride, 2018; Malfas et al., 2004).

RO4 (use of lead gunshot is only allowed for licensed individuals at permitted sites with effective RMMs in place, i.e. regular lead gunshot recovery with > 90 % effectiveness, containment, monitoring and treatment of drainage water, ban of any agricultural use within site boundary, and reporting to Commission) ranks second in the Dossier Submitter's analysis. This restriction option would minimise the risks from lead as far as possible but still allowing athletes the participation in international competitions.

RO2 and RO3 rank next. Within RO2 retailers are allowed to sell lead shot to licensed individuals and these would be allowed to use lead shot on all ranges. No further risk management measures are required to reduce lead release. Limiting the use of lead shot in the EU to licensed athletes would reduce lead release by roughly 50 %. Consequently, relevant risks would still remain. Within RO3 the use of lead shot is allowed for all recreational sports shooters and athletes at permitted sites with effective RMMs in place (which are the same as defined for RO4).

RO5 (compulsory information) ranks lowest but is considered useful to disseminate information for the user about the hazard and risks of lead at the point of sale and, in case the optional conditional derogation is implemented, to support enforcement by an indelible labelling of the product packaging and individual cartridges ('Contains lead: do not use for hunting'). The Dossier Submitter considers that the restriction options RO1, RO2, RO3 and RO4 would be most effective and monitorable when combined with RO5.

Taking into account the availability of suitable alternatives, the Dossier Submitter is of the opinion that the socio-economic benefit of the use of lead gunshot in international competitions (e.g. Olympic Games, ISSF or FITASC events) may not outweigh the costs of implementing the risk management measures required to control the risks. SEAC agrees with this conclusion of the Dossier Submitter.

Although, each restriction option was assessed individually, the Dossier Submitter considers that the restriction options assessed within the Background Document are not mutually exclusive and could be proposed in conjunction with one another. After consideration of the various options, the Dossier Submitter concludes that a ban on placing on the market and use of lead gunshot for sports shooting (RO1) would be the most effective way to reduce risks and that this should be combined with compulsory information at the point of sale (part of RO5).

However, if a complete ban (RO1) is not considered appropriate by the decision-maker, the Dossier Submitter considers that the optional conditional derogation as defined by RO4 would be practical to minimise the risks whilst allowing continued use for sports shooting and that this should be combined with compulsory information at the point of sale and the labelling of product packaging and individual cartridges (RO5).

SEAC agrees with the ranking and underlying comparison of ROs 1-5. It shows that a total ban would bring the highest reduction in emissions of lead and for that reason is to be preferred. It is clear that options that would soften this ban in order to avoid a loss of opportunities to participate in international competitions, can be made available, albeit at significant costs if additional RMMs are to be implemented and an inevitable reduction in the effectiveness of the restriction regarding reduction of lead release.

However, SEAC has strong reservations regarding the implementation of such an option in the form of the optional conditional derogation assessed by the Dossier Submitter. Not only does this cause high costs for adapting RMMs of shooting ranges to benefit a small group of people, but as mentioned before, SEAC also has some reservations about the perceived ease to implement and maintain the permit/licence systems related to such an optional conditional derogation, as well as the ease to implement reporting duties that have to be taken up by each Member State. More arguments putting SEAC's reservations in a broader perspective can be found in section 3.3.4 on enforceability below.

In addition, as already explained above, SEAC is uncertain about the supposed effectiveness of the information requirements as far as this is meant to contribute significantly to a change in behaviour of gunshot buyers.

For the decision-maker it is important to realize that implementation of the preferred option RO1 will undoubtedly disrupt the sports shooting sector, because it would no longer allow Member States to host international competitions that require the use of lead gunshot and EU athletes to participate or train for them, effectively excluding them from such events, until a ban on lead would be globally accepted and rules modified accordingly. Unfortunately, there are no indications that the relevant international associations (which also contributed to the consultations on the Annex XV report and the SEAC draft opinion) are considering a move in this direction.

However, choosing RO4 would mean that the sports shooting sector would need to re-structure itself in a significant way. The option would create a 'two-level membership' and foresees only a selected number of sites to be permitted for lead use, which may lead to a situation where some licensed athletes will have to travel long distances in order to practice at a site that allows the use of lead. Others may be in a more favourable position and have such a site nearby. Moreover, it remains unclear how easy it is for athletes to change back and forth between shooting with lead (while practicing for international events) and shooting with steel (in their home competitions). This was not addressed in any of the comments in the Annex XV report consultation.

An option that was not considered by the Dossier Submitter, but which may be a pragmatic approach to circumvent some of the complications that may be connected to the optional conditional derogation, would be to limit the licence of RO2 in time (e.g. 5 or 10 years after entry into force of the restriction). This would incentivise the shooting associations to get steel shot approved for international competitions, but still give sufficient time to work on this

on a global scale. As a result, it would lead to an avoided lead release that although lower than for RO1 is still higher than for RO2 (as proposed by the Dossier Submitter). A comparison of indicative results as calculated by SEAC appears in Table 5 5 below. A time-limited derogation/licence for athletes (indicated by RO2a and RO2b in the table) would lead to considerably higher avoided lead release compared to RO2 at only marginally higher costs and comparable cost-effectiveness ratios.

Table 5: Comparison of possible variations to RO2, as calculated by SEAC

Option	Variation	Lead release avoided over 20 years	Costs over 20 years (NPV, 4 %)	Cost-effectiveness (€/kg)
RO1	As proposed	367 500 t	€364m	1.0
RO2	As proposed	183 750 t	€336m	1.8
RO2a	5-year exemption for athletes after the transition period	306 250 t	€353m	1.1
RO2b	10-year exemption for athletes after the transition period	245 000 t	€343m	1.4

Note that the figures for RO2a and RO2b were calculated from the data on nominal costs per year after the transition period, as supplied by the Dossier Submitter as mid-ranges for RO1 and RO2. In the calculation it is assumed that for each year that the exemption for athletes is in place (i.e. for 5 or 10 years after the end of the transition period), costs would be counted as for RO2 and for each year in the 20-year assessment period that the exemption has expired (respectively 10 and 5 years) costs would be counted as for RO1. The total NPV is then calculated as the sum of the discounted contributions for each year.

Transition periods

The restriction text in the Background Document proposes a 5-year transition period for both the preferred option (RO1) and the optional conditional derogation (RO4). Either option is proposed to be combined with compulsory information at the point of sale (retailer duty) for which a transition period of 6 months is foreseen. According to the Dossier Submitter this is intended to increase consumer awareness and prepare them to change their purchasing behaviour until RO1 or RO4 enter into effect. RO4 is additionally proposed to be combined with the labelling of product packaging and individual cartridges (supplier duty), which would still be needed in this option to aid enforcement of the restriction for hunting, because lead shot will still be available for licensed individuals for sports shooting. A 5-year transition period is proposed for the labelling requirement, in line with the transition period proposed for RO4.

SEAC considers the 6-month transition period for the compulsory information at the point of sale will not present major problems, because this is only an action to visually inform customers.

An issue for RO1 may be that, if sports shooters change to alternative gunshot types (mainly steel) all together, this may lead to transient production and supply chain bottle necks, where at first alternative gunshot may not be as commonly available as the traditional lead shot currently is, or may become, more expensive. However, SEAC has no information that would suggest that such supply chain issues (if any) would persist beyond an initial short period of time.

For RO4, the problems of availability of alternative shot for 50 % of the market may be the same as for RO1, but because amounts are less, any problems are expected to be overcome even sooner.

For RO4 it is more important if for each Member State the 5-year transition period is enough to work out which shooting sites should be upgraded (or will have the means to do so), and to complete the work related to implementing the necessary RMMs. Provided planning for such actions is initiated early enough (i.e. at the latest after the entry into force of the restriction), the time period indicated seems long enough to implement the changes. However, it should be noted that in comment #1146 submitted in the consultation on the SEAC draft opinion, it was pointed out that in some countries (in that particular case in Norway) time to obtain a mandatory permit from the authorities for changes of a shooting site may also have to be included. In the view of SEAC this shows that a 5-year transition period is likely to be the minimum needed and good coordination will be needed to finish the upgrades within this period.

C2. Sports shooting with bullets, incl. airgun pellets (use #4, 5, 6)

Scope

For lead projectiles other than gunshot (i.e. bullets and airgun pellets) the situation is somewhat different. On the one hand, a ban on placing on the market is not possible in view of concerns about unintended impacts on other uses not in scope of the proposed restriction (e.g. indoor uses, uses by military or law enforcement) and, on the other hand, a full ban on use is not (yet) possible because of the lack of availability of suitable alternatives for sports shooting with the highest possible accuracy, which is less critical for hunting. This seems especially the case for small calibre bullets and for airgun pellets. Therefore, the proposed ban on use is combined with a conditional derogation on the use taking place at locations that are notified to the respective Member State and which have effective lead projectile containment and recovery measures in place, as well as having a ban on any agricultural activities at those locations (e.g. grazing by cattle).

SEAC notes that in the consultations on the Annex XV report and on the SEAC draft opinion many comments, mainly from the Nordic countries, point to the importance of the availability of local shooting ranges to allow practicing by reserve soldiers near home. SEAC notes that the Dossier Submitter considers such training as "civilian use" and therefore in scope of the proposed restriction, meaning that the use of lead ammunition is limited to "notified sites" complying with the measures described above. RAC has expressed its agreement with this view. However, this view gives rise to some uncertainties regarding the availability of sufficient sites for training. This uncertainty is further addressed in section 3.4.2 of this opinion. It should be noted that Member States, in the interest of defence, may use REACH Article 2(3) to exempt the activity from the scope of the proposed restriction.

SEAC notes that the current restriction proposal may lead to a situation where the use of lead bullets in sports shooting will continue indefinitely. A time limit for the derogation would prevent this. However, an obligation to install additional or upgraded RMMs to meet the conditions for the derogation at designated sites is difficult to reconcile with a reasonable amortisation time of the significant investments needed to install such RMMs. Therefore, if a time limit for the derogation would be considered by the decision-maker it would need to be sufficiently long (15 or 20 years) to make such investments a realistic option. On the other hand, a time limit (whatever its length) would stimulate further innovation by the ammunition manufacturers.

Analysis of Restriction Options

SEAC notes that the various discussions in the course of the opinion development and in the information received in the Annex XV report consultation have led the Dossier Submitter to analyse restriction options in a different way compared to the approach taken in the initially submitted Annex XV dossier.

A similar comparison of restriction options as for gunshot above was made for sports shooting with bullets, including the same scoring system (see Table 2-7 in the Background Document).

The Dossier Submitter considers that RO1 (general ban on use of lead bullets for sports shooting) is currently not an option because only few alternative bullets of suitable precision are available and the risks from lead bullets in sports shooting can be minimised by using bullet containment, i.e. trap chambers and sand traps. Moreover, it appears that a ban on placing on the market of bullets (even only for sports shooting) would have unintended consequences for non-civilian uses outside the scope of the restriction. Reports from the industry have indicated that the same production lines that serve non-civilian uses also depend on the hunting and sports shooting market to operate economically.

RO2 consists of a ban on the use of lead bullets for sports shooting with a derogation at notified outdoor locations where no agricultural activities take place and specific risk management measures to contain and recover lead bullets are in place. RO2 has four different sub-options, which differ based on the specific risk management measures to be implemented:

- RO2a: Trap chamber, or sand trap (with impermeable barrier) or sand/soil berm (without impermeable barrier), combined with roof or water management system.

- RO2b: Trap chamber, or sand trap (with impermeable barrier), combined with roof or water management system.

- RO2c: Trap chamber, or 'best practice' sand trap with impermeable barrier and roof or permanent cover and water management system.

- RO2d: Trap chamber for static disciplines; AND 'best practice' sand trap for dynamic disciplines.

While the Dossier Submitter considers that all four sub-options are proportionate, it is also noted that they differ in terms of both their costs and effectiveness. Based on the scoring system used by the Dossier Submitter, option RO2c was identified as the preferred option.

The risk management measures of RO2c (trap chambers and 'best practice' sand traps) are required in the CSR for lead (2020), and are implemented within the EU at many, but not all, facilities.

RO3 (compulsory information on the hazards/risks of lead at the point of sale and on product packaging) is not considered effective in reducing lead release by itself but in combination with RO2 it would inform the user about the hazards of lead and the risks of using ammunition at the point of sale ('retailer duty') and through an indelible labelling of the product packaging ('supplier duty') with the information of paragraph 5a of the proposed restriction text. The latter would also support enforcement.

Therefore, the Dossier Submitter concludes that the most effective way to minimise the identified risks would be a ban on the use lead bullets for sports shooting with a derogation at notified outdoor locations where no agricultural activities take place and the measures specified by RO2c are in place (trap chamber, or 'best practice' sand trap with impermeable barrier and roof or permanent cover and water management system). This restriction option should be combined with compulsory information at the point of sale and on product packaging (RO3).

SEAC agrees with the Dossier Submitter that the available information from ammunition manufacturers and stakeholders indicates that RO1 (general ban on use for lead bullets) is currently not yet an option because of the limited availability of alternatives and if alternatives are available these do not always bring the accuracy needed for sports shooting disciplines (especially for small calibres).

Therefore, SEAC agrees to selecting RO2c as the preferred option, because it allows to still use high accuracy projectiles, but will help to limit uncontrolled release of lead into the environment, provided that the recovered lead is either recycled or disposed of in a safe and an accepted manner.

Consultation comments related to this part of the proposed restriction, which may indicate some uncertainty about the costs of the proposed RMMs for dynamic shooting disciplines, are discussed in section 3.4.2.

Transition periods

The Background Document proposes a transition period of 6 and 18 months for the retailer duty and supplier duty, respectively, as described in paragraphs 5a and 5b of the proposed restriction text. Because the retailer duty is only to provide visible information at the point of sale, in the opinion of SEAC it can realistically be expected that this can be completed within 6 months after entry into force of the restriction. The supplier duty involves labelling of product packaging. In this case it is realistic to allow more time for printing new labels and selling off the old ones. SEAC has not received information that suggests that 18 months would not be enough for this action.

SEAC notes that already after a maximum period of 18 months after entry into force, shooting ranges should notify use to the respective Member State and cease any agricultural uses at or within the site. This action does not yet imply a decision to potentially plan for an upgrade (see below). SEAC does not expect major difficulties to comply with this transition period.

Regarding the conditional derogation to allow continued use of lead projectiles for sports shooting, a 5-year transition period is proposed to allow for the upgrading of shooting ranges. Provided planning for such actions is initiated early enough (i.e. at the latest after the entry into force of the restriction), the time period indicated seems long enough to implement the changes. Some comments received in the consultation on the SEAC draft opinion (e.g. #1146), as in the case of gunshot shooting, apart from technical challenges, point to the necessity to include time to obtain permits from the authorities to change a shooting range. Therefore, they claim a 5-year transition time is too short. In the view of SEAC this shows that a 5-year transition period is likely to be the minimum needed and good coordination will be needed to finish the upgrades within this period.

D. Fishing (use #7 and 8)

Scope

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

The lead fishing tackle affected by the proposed restriction can be categorised into three main types:

- Fishing sinkers and wires (also known as 'fishing weights') – covered by use #7
- Fishing lures (including jigs) – covered by use #7
- Fishing nets, ropes and lines where lead is embedded/enclosed in the fishing nets, ropes and lines – covered by use #8

Derived from this, the Dossier Submitter presents the following types of fishing activities:

- Recreational fishing with lead fishing tackle (consumer use)
- Commercial fishing with lead fishing tackle (professional use)
- Home-casting of lead fishing tackle (consumer use)

The main function of lead in fishing tackle is to provide additional weight in order to cast and set the bait or lure at a certain location and distance (up to 200 m, in open sea up to 1 000 m), and/or to sink the fishing tackle, e.g. the line and fishing hook, or the net, while allowing fishing.

The Dossier Submitter proposes a ban on placing on the market and use of lead fishing sinkers and lures, which basically eliminates lead releases and exposures originating from fishing activities. In order to raise awareness among anglers and thus to facilitate the implementation of the ban, retailers are required to provide information on the risks of lead and the proposed restriction to their customers as a complementary measure.

The different transition periods proposed by the Dossier Submitter overall reflect the current market situation. Available information indicates that alternatives for heavier sinkers are less available than for lighter sinkers, supporting a longer transition period for sinkers > 50 g. In general, SEAC agrees with the Dossier Submitter that the requests for longer or shorter transition periods received in the consultation on the Annex XV report were not sufficiently substantiated to justify a change of the proposal. With regard to fishing wire, the Dossier Submitter proposed no transition period, arguing that alternatives are already widely available in the EU. SEAC notes that comments were received in the consultation on the Annex XV report indicating that this may not be the case in all Member States (#3512). Further information on potential impacts of the proposed transition periods would have been needed for SEAC to draw a firmer conclusion on the impacts involved.

With regard to sinkers and lures > 50 g, SEAC notes RAC's conclusion that the main risk to be addressed is the risk to human health from home-casting as the risk to birds and other wildlife from ingesting sinkers and lures of this size seems to be very limited. From the risk point of view, RAC does not see sufficient arguments for a derogation of sinkers and lures made of lead > 50 g from the proposed ban (RO3a HIGH) based on the analysis of restriction options assessed by the Dossier Submitter, although there were no specific data to further determine the risk reduction potential of a ban.

However, SEAC considers the proposed ban of sinkers and lures made of lead > 50 g (RO3a HIGH) may potentially lead to an increase in home-casting of such sinkers and lures if the use of alternatives entails higher costs and/or a lower performance, taking into account the ease of obtaining scrap lead. Even if the use of home-casted lead sinkers and lures is covered by the proposed ban, arguments have been brought forward by Forum that cast doubt on an effective enforcement in the field. A potentially limited effectiveness of a ban combined with the higher costs and a potential decrease of performance of alternatives would support the conclusion that the proposed ban of sinkers and lures > 50 g may not be the most appropriate restriction option in terms of proportionality, in particular if the very limited risk to birds and other wildlife from ingesting sinkers and lures > 50 g is taken into account. Hence, SEAC considers that other measures than a ban, for example setting the condition that sinkers have to be industrially manufactured, i.e. not home-casted, indicated by a specific marking or coating (as suggested in comment #3260 in the consultation on the Annex XV report) could potentially be more effective to prevent an increase in home-casting. This option was not assessed by the Dossier Submitter, only the unconditional exclusion of sinkers and lures > 50 g as RO3a (LOW) (see below). SEAC asked for specific information on this option in the consultation of the SEAC draft opinion. However, not sufficient information to assess the technical feasibility and costs of a permanent coating or marking of sinkers and lures was provided. Therefore, SEAC cannot draw a conclusion on the impacts of this alternative restriction option.

For lead split shots requests for a derogation were received in the consultation on the Annex XV report (#3202, #3259) pointing to the limited technical feasibility of alternatives. SEAC agrees with the Dossier Submitter that these requests were not sufficiently supported by evidence. In addition, SEAC notes that RAC is not in support of this request for a derogation, because split shot is small, difficult to handle, and easily dropped on the shore where they become available for birds. SEAC requested specific information on the availability and technical performance of alternatives and justification for why this performance would result in disproportionate socio-economic impacts in the consultation on the SEAC draft opinion.

However, the information received (#1165) did not allow for a more detailed assessment of the impacts involved.

In addition, a request for a derogation of hard-plastic lures (e.g. plugs or jigs) was received in the consultation on the Annex XV report arguing that it will be very difficult for fishers as well as inspectors to determine whether a hard-plastic lure does contain lead or not. In this regard, SEAC notes that it is uncertain to what extent hard-plastic lures are made with lead and to what extent they contribute to the risk to be addressed. According to the Dossier Submitter there is evidence that lead has already been replaced in these kinds of lures. In order to draw a conclusion on the impacts of including hard-plastic lures in the scope of the proposal further information on the current use of lead would have been needed.

Regarding the scope presented in Background Document, SEAC notes a lack of information on the possible use of lead weights in the sport of 'casting'[28], which is derived from angling. No comments on this issue were received in the consultation on the Annex XV report or the consultation on the SEAC draft opinion.

Analysis of Restriction Options

The Dossier Submitter identified for use #7 and use #8 seven restriction options (RO), one of which has two sub-categories.

After a preliminary evaluation, the Dossier Submitter discarded the following ROs:

- RO1 (ban on placing on the market of material and equipment for home-casting activities) as not targeted enough and not enforceable. SEAC agrees with this assessment, as it seems that obtaining lead from any source is easy and there is no special equipment for home-casting. Any camping cooker and a steel frying pan can be used.

- RO3b (ban on placing on the market and using fishing nets, ropes and lines containing lead) as being disproportionate. SEAC notes the experience of the Danish Environmental Protection Agency. According to this, a change to steel or zinc weights with a lower specific density would mean about one-third less workspace on deck for professional fishermen. Steel would rust and damage the nets and zinc would pollute the aquatic environment too. SEAC agrees with the Dossier Submitter's assessment that this RO is disproportionate, because according to the current knowledge lead exposure risk (both to human and wildlife) from these types of fishing tackle seems neglectable while nets, ropes and lines not containing lead appear to have technical limitations.

- RO5 (ban on using lead fishing sinkers and lures) as not implementable and due to enforceability challenges. The enforcement of RO5 would have to be carried out at the sites of use, i.e. fishing spots. REACH inspectors might not be the most appropriate

[28] Casting (casting sport) is supervised by the International Casting Sport Federation (ICSF) which was founded in 1955 and as of April 2014 has member associations in 31 countries. The ICSF sponsors tournaments and recognises world records for accuracy and distance. This sport uses common fishing rods with weights or hookless flies and can be held on water or on athletic fields.

inspectors. The enforcement at the site of uses could be performed by the existing national relevant enforcement authorities for fishing matters. While these inspectors, usually fishers themselves, are used to perform fishing inspections (licence, equipment, fish), it might be difficult, even for skilled inspectors, to distinguish only visually a lead fishing tackle from one made with an alternative metal. A ban only on the use of fishing tackle might therefore be difficult to enforce. SEAC agrees that a ban on use only would be difficult to implement and to enforce in a harmonised way.

SEAC follows this pre-selection from the Dossier Submitter and evaluates the remaining RO as follows:

- RO2 - Ban on using fishing tackle rig or equipment intended to drop off[29] lead sinkers: RO2 is focussed specifically on the emerging practice in the EU of the intentional drop off of sinkers ('backlead' or main sinker) for carp fishing, for example. In line with the Dossier Submitter, even though a ban on placing on the market and use would be more effective than a ban on use only, SEAC agrees that a ban on placing on the market cannot be proposed as this would be beyond the scope of REACH which can restrict the use of a substance or the presence of a substance in an article, but not a technique or an object intended to be used with the substance, i.e. the tackle designed to release the lead weight (as it could be used to release a weight of any material). As industrial uses of lead are outside the scope of the proposed restriction, the Dossier Submitter has not considered a restriction option covering the production of 'backlead' or main sinker. For sinkers intended for drop off in water, the Dossier Submitter in entry 7c does not propose any transition period. Information received in the consultation on the Annex XV report supports an immediate ban, therefore SEAC agrees with the Dossier Submitter's proposal.

- RO3a (LOW and HIGH) - Ban on placing on the market and using lead fishing sinkers and lures: The distinction of LOW and HIGH refers to the weight limit for sinkers and lures, with RO3a (LOW) applying only to lead fishing sinkers and lures ≤ 50 g and RO3a (HIGH) applying to all fishing sinkers and lures without an upper weight limit. SEAC notes the inclusion of all lead sinkers and lures into the scope (i.e. the HIGH option) and the differentiation into transition periods of 3 years for sinkers and lures ≤ 50 g and 5 years for sinkers and lures > 50 g (see proposed entries 7a and 7b). The cut-off value of 50 g was set because, according to the Dossier Submitter, fishing tackle ingested by birds tends to be below 50 g. Nevertheless, for both weight classes, exposure to humans can occur during home-casting or use (hand-to-mouth exposure). SEAC considers that the analysis would have benefitted from including another option, i.e. a ban on placing on the market and using of sinkers and lures ≤ 50 g and obligatory permanent coating or cover of sinkers and lures > 50 g (see discussion above). SEAC welcomes consideration of RO3a separately from RO3b, because RO3b is about lead embedded in nets, ropes and lines and would unnecessarily burden commercial fisheries with net fishing.

- RO4 - Ban on placing on the market of lead fishing sinkers and lures: SEAC agrees

[29] The drop off practice consists in using a specific tackle or rig in order to detach intentionally the main sinker from the main line (see Figure D.4-9 and Figure D.4-10 in Annex D.4.5.2 of the dossier). The purpose of this drop off is to reduce the weight on the line when landing a large fish, and therefore maximise the catch rate.

with the Dossier Submitter that a ban on placing on the market would not be sufficiently effective, because use of 'home-casted' sinkers and lures would still be possible.

- RO6 - RO3a with a derogation for lead split shots conditional on the placing on the market in spill proof and child resistant packaging: So far, the products seem to be available in bulk packed in plastic bags/cartons. Qualified packaging (child resistant and to protect against spillage of large quantities in the environment) would seem to make sense in any case. In addition, a better dosage of these partly very small parts could lead to benefits for the angler. Feedback from the consultation on the Annex XV report indicated that tungsten kit as alternative to lead split shot is very difficult to work with on very thin fishing lines and that alternative metals damage the thin fishing lines. Therefore, a derogation for lead split shots of sizes 6-14 is requested, also because this part would only represent 0.5 % of lead use in the fishery (Annex XV report consultation, #3259). SEAC would have needed more evidence to assess the impacts of a derogation. However, the transition period for thin fishing lines with lead split shots of sizes 6-14 should be sufficient to allow for the substitution of lead, which was also raised in the consultation on the Annex XV report consultation (#3202).

- RO7 - Compulsory information to consumers at the point of sale (presence, toxicity and risks of lead, as well as availability of alternatives): SEAC generally supports this option as a complementary measure, however its effectiveness still needs to be assessed in more detail (see discussion in Part A above).

  SEAC supports a broad information campaign on the health risks of handling lead because lead for DIY use is likely to be around for a long time as metallic lead seems to be in abundant circulation (e.g. lead sheet from the roofing trade, old rechargeable batteries, remnants of lead piping and sheathing from underground and submarine cables, unrecycled balancing weights from car garages) and because various videos from the home-casting scene (Annex XV report consultation, #3325) give an indication that home-casting takes place with little or no risk awareness. As such, SEAC agrees with the Dossier Submitter's recommendation for a voluntary education and action campaign from the sector associations (fishing and trade) targeted to consumers to promote the use of non-lead fishing tackle, and the recovery and recycling of lead fishing tackle.

The proposed restriction is a combination of RO2, RO3a (HIGH) and RO7, which has been identified by the Dossier Submitter as the most appropriate option.

Regarding use #8 and related to RO3b (ban on placing on the market and using fishing nets, ropes and lines containing lead), the Dossier Submitter does not identify any risk to human health or the environment associated with the use of lead in fishing nets, ropes and lines where lead is embedded/enclosed. Noting RAC's conclusion that indeed there is no risk to be expected from this use, SEAC agrees with the Dossier Submitter and notes that the inclusion of use #8 into the scope of the restriction could also lead to a degradation in technical performance:

1. Poorer working environment for the fishers as a result of a reduction of deck space (lead-free sinking lines take up more than one-third more space) and cause more difficult working conditions.

2. Reduced vessel stability as a result of the increased volume of nets, eventually leading to exceeding what is allowed according to rules by e.g. the Danish Maritime Authority.

3. Net damage due to abrasion of material from nets and lines due to rusty and rough steel weights.

3.3.2. 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 conclusion(s):

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 conclusion(s):

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).

3.3.3. Socio-economic impact

Justification for the opinion of SEAC

3.3.3.1. Costs

Summary of proposal:

Approach to impact assessment

The Dossier Submitter carried out separate impact assessments for the different sectors of use concerned by the proposed restriction, i.e. hunting, sports shooting, and fishing. The geographic scope of the impact assessment is the EU as of 2020 (i.e. excluding the United Kingdom) and impacts are considered over a 20-year assessment period. Costs are expressed in Net Present Value (NPV) terms or in annualised form over the 20-year period. A discount rate of 4 % was chosen.

Hunting

According to the Dossier Submitter, hunters affected by the proposed restriction would have to switch to alternative gunshot and bullets:

- Alternatives to lead gunshot for hunting: The Dossier Submitter concludes that technically and economically feasible alternatives to lead gunshot are available. According to the Dossier Submitter, hunters using steel gunshot can achieve the same results as with lead gunshot, while the current prices for steel and lead gunshot are comparable. Other alternatives, such as bismuth or tungsten-based gunshot, can also be used to replace lead gunshot. They can be used in any shotgun, including historic shotguns that may not be suitable for use with steel gunshot. Bismuth and tungsten-based gunshot cartridges are however more expensive than lead gunshot cartridges and are also likely to remain more expensive than lead (and steel) gunshot cartridges.

- Alternatives to lead bullets for hunting: The Dossier Submitter concludes that technically and economically feasible alternatives to large calibre lead bullets are available. These alternatives are typically composed of copper or brass and, according to the Dossier Submitter, are as effective as and comparable in price to their lead-based counterparts. For small calibre bullets, the Dossier Submitter found that currently only limited alternatives are available in the EU. The Dossier Submitter notes that while non-lead alternatives to small calibre lead bullets (including airgun pellets)

do not yet achieve the same level of performance, it has not been unequivocally demonstrated that currently available alternatives are unsuitable for hunting.

Costs have been estimated via the substitution costs incurred by hunters and include operational costs (i.e. costs of alternative gunshot or bullets) and, where relevant, one-off costs in the form of gun testing and replacement:

- Costs related to hunting with gunshot: Different scenarios have been considered, which vary according to the extent of any regulation on the use of lead gunshot that already exists, the average price of steel and other alternatives compared to lead gunshot, and the need for testing and gun replacement. Costs in the central scenario have been estimated at €768 million (range: €28-1 310 million) over 20 years.

- Costs related to hunting with bullets: Different scenarios have been considered regarding the fraction of hunters already using non-lead bullets. Furthermore, for small calibre bullets, it has been assumed that hunters will have to buy new guns or change barrels, with different scenarios representing different assumptions regarding the extent of gun replacement and barrel changes. For small calibre bullets, costs in the central scenario have been estimated at €122 million over 20 years (range: €54-179 million). For large calibre bullets, costs in the central scenario have been estimated at €239 million over 20 years (range: €101-412 million).

Sports shooting

The Dossier Submitter assessed the possibilities for sports shooters affected by the proposed restriction to switch to alternative gunshot and bullets:

- Alternatives to lead gunshot for sports shooting: The Dossier Submitter concludes that alternatives to lead gunshot, in particular steel gunshot, can be used effectively in sports shooting. It is further pointed out that the barriers for further advancing with alternatives are not technical but are rather imposed by the rules of international sports shooting organisations (e.g. ISSF, FITASC) that require lead gunshot to be used and/or have not approved other gunshot material.

- Alternatives to lead bullets for sports shooting: According to the Dossier Submitter's assessment, alternatives to lead bullets (including airgun pellets) exhibit sub-optimal performance in terms of the accuracy required for sports shooting. For muzzle loading guns, the Dossier Submitter notes that various comments from the Annex XV report consultation suggested that no alternatives to lead ammunition would seem to exist.

Costs of the proposed restriction have been estimated either via the substitution costs incurred by sports shooters (for the Dossier Submitter's preferred option for gunshot), the costs related to the implementation of RMMs at shooting areas/ranges (for sports shooting with bullets), or a combination of the two (for the optional conditional derogation for sports shooting with gunshot):

- Costs related to sports shooting with gunshot:

    - PREFERRED OPTION: Costs have been estimated via the substitution costs incurred by sports shooters taking into account the costs of alternatives –

different scenarios regarding the price differences have been considered – and costs for gun replacement – while not expected to be necessary, as a conservative assumption, the Dossier Submitter still assumes that 10 % of sports shooters will replace their gun prematurely (range: 6-14 %). Costs in the central scenario have been estimated at €364 million over 20 years (range: €177-596 million).

- OPTIONAL CONDITIONAL DEROGATION: The Dossier Submitter has considered that a fraction of shooting ranges would upgrade their RMMs to achieve the recovery of more than 90 % of the spent lead gunshot, as required in the optional conditional derogation. These ranges would then be accessible to licensed individuals who could continue to use lead gunshot. All other sports shooters would have to switch to alternatives. The costs of implementing RMMs at a fraction of shooting ranges used by licensed individuals together with the substitution costs incurred by all other sports shooters have been estimated in the central scenario at €506-591 million (range: €207-236 million in the lowest scenario to €913-1 044 million in the highest scenario) over 20 years.

- Costs related to sports shooting with bullets: In the updated analysis the Dossier Submitter assumes that at all permanent rifle/pistol ranges in the EU, RMMs are already in place to contain bullets for safety reasons. The RMMs are either trap chambers, sand traps (with an impermeable barrier to soil) or sand/soil berms (without an impermeable barrier to soil), and soil berms. Compared to the initial approach, it is now assumed that even current practice will already reduce release of spent ammunition into the environment significantly. Costs have been estimated via the costs for upgrading RMMs to fulfil the requirements of the conditional derogation. The costs for RO2c, the Dossier Submitter's preferred option in terms of RMMs to be implemented (i.e. trap chamber or 'best practice' sand trap), have been estimated in the central scenario at €1 094 million (range: €859-1 329 million).

Fishing

According to the Dossier Submitter, technically feasible alternatives to lead fishing sinkers and lures are widely available on the EU market including, for example, bismuth, ceramic/glass, copper and its alloys (such as brass and bronze), concrete, various types of polymers (such as high density polymers, PHA), iron, reinforced bars (rebar), (stainless) steel, stones or pebbles, tin, tungsten, zamac (zinc-aluminium alloy), and zinc.

The costs of the proposed restriction related to fishing have been estimated via the substitution costs incurred by fishers from switching to alternatives, assuming that fishers will continue to purchase the same quantity of fishing tackle (in terms of weight) as today and taking into account the current average price of the alternatives. Costs in the central scenario have been estimated at €9 300 million over 20 years (range: €~0-48 000 million).

Total costs

Table 4 gives a summary of the Dossier Submitter's cost estimates by sector and/or use. The total costs of the proposed restriction across all sectors/uses amount to about €12 billion over the 20-year assessment period.

SEAC conclusion(s):

SEAC considers that the general approach taken by the Dossier Submitter is appropriate to assess the economic impacts of the proposed restriction.

However, uncertainties in the available data may lead to both under- or overestimation of costs reported as central estimates. Therefore, SEAC considers that the costs resulting from the proposed restriction are more reliably reflected by the ranges derived from the cost assessment than by the central estimates.

Key elements underpinning the SEAC conclusion(s):

A. General issues

In the course of the analysis of the calculations performed by the Dossier Submitter, as presented in the Background Document and in additional details supplied to the rapporteurs, some aspects were met that were either not clear to the rapporteurs or where errors may be present. Such cases are further discussed below where needed.

Taking enforcement costs as a general example, SEAC notes that the Dossier Submitter expects these costs to be either zero or up to the standard cost estimate for enforcement typically used in the evaluation of restriction proposals (€55 000 per year). However, SEAC considers that the complexity of implementing and enforcing the proposed restriction may require significantly higher costs. This conclusion is supported by the Forum advice and information submitted in the consultations on the Annex XV report and the SEAC draft opinion. Consequently, this adds to the uncertainties of the cost estimates provided.

B. Hunting (use #1, 2a, 2b)

In the cost assessment for hunting, the Dossier Submitter took into account the following impacts:

- research and development (R&D) costs
- industry compliance costs
- retailer compliance costs
- enforcement costs
- costs to consumers (hunters)

The main focus on the Dossier Submitter's analysis lies on the costs to consumers (hunters). These are further discussed for gunshot and bullets below. SEAC agrees that the cost to hunters is likely to be the most important economic impact to be expected from the proposed restriction. Assuming that at least part of the costs to industry and retailers are passed on in the supply chain these would be reflected in the costs to hunters. However, depending on market structure and competition, industry may not be able to pass on all costs incurred by the proposed restriction.

With regard to R&D costs, SEAC agrees with the Dossier Submitter's conclusion that it is

unlikely that the proposed restriction will generate significant R&D costs, because many EU ammunition manufacturers offer non-lead ammunition and thus R&D investment has already been incurred. It is unclear if the proposed restriction will trigger additional R&D spending in response to the proposed restriction.

The overall costs of the proposed restriction to industry in terms of lost profits depends on the development of the supply of non-lead ammunition by EU manufacturers. If production increased quickly, profits lost to non-EU competitors might be insignificant. The development of EU-production of non-lead ammunition is a major uncertainty. Information received in the consultations on the Annex XV report and on the SEAC draft opinion was not conclusive to substantiate major economic impacts on industry as a result of the proposed restriction (see section 2.5.3.1 in the Background Document). In this regard, SEAC notes that the possible future demand for lead and alternative gunshot in sports shooting significantly depends on the regulatory option taken by the decision-maker: (i) a full ban on placing on the market and use (as preferred by the Dossier Submitter) or (ii) the optional conditional derogation of lead gunshot for sports shooting. If lead gunshot could still be used in sports shooting, it could be feasible for EU manufacturers of steel shot to meet the increased demand in hunting, even earlier than with the 5-year transition period proposed by the Dossier Submitter (see section on scope). Furthermore, the Dossier Submitter assumes that the growing market for target shooting could partly compensate for potentially lost profits in hunting. However, SEAC considers that the impact of market growth cannot be considered as a compensation per se, because the net impact of lost sales due to the ban of lead gunshot for hunting would still remain. Still, it could alleviate the potential negative impacts of profit losses for industry. In addition, industry might incur other costs, such as raw material costs, energy costs, loss of recycling benefits and manufacturing equipment costs (i.e. capital costs), however there is not sufficient information available to assess their significance.

Similarly, potential costs to retailers due to stocks of ammunition that need to be disposed of are likely to be very limited. The scope and transition periods proposed by the Dossier Submitter should allow to sell existing stocks and thus should largely prevent lost sales. In addition, SEAC does not expect that a shorter transition period for the ban of use of lead gunshot in hunting would lead to lost sales, however further information to confirm this assumption would have been desirable to underpin this conclusion.

The Dossier Submitter expects that the proposed restriction can be enforced by using the same resources (inspectors, testing etc.) as for the restriction of lead gunshot in wetlands. Hence, it is assumed that the proposed restriction will not generate additional enforcement costs. SEAC considers that this assumption does not hold, because the geographical area for inspectors to cover is much larger. Therefore, effective enforcement would require additional resources (or otherwise a lack thereof could compromise the effectiveness of the restriction). Based on the information available to SEAC, enforcement costs cannot be assessed in more detail.

All these cost elements were assessed qualitatively. For the economic impact on consumers (hunters) the Dossier Submitter derived quantitative estimates for the use in gunshot and bullets based on available evidence. SEAC notes that the approach to the cost assessment and assumptions made in the cost calculations do not always seem consistent between gunshot and bullets. Also, several uncertainties with regard to the cost figures remain. However, the cost assessment still allows for a conclusion on the overall range of costs to be

expected from the proposed restriction.

B1. Hunting with gunshot (use #1)

Availability and technical and economic feasibility of alternative gunshot

Lead can be substituted in gunshot by different materials, most commonly by steel (soft iron), bismuth, tungsten or copper. With regard to their availability and feasibility, SEAC's assessment on alternatives to lead gunshot drawn in its opinion on the restriction proposal of lead gunshot in wetlands (pp. 51-54)[30] is still valid. Steel gunshot is likely to be the most commonly used alternative, because it is widely available and will entail the lowest or even zero costs to hunters who own a standard- or steel-proofed gun. The price data on lead and steel gunshot gathered by the Dossier Submitter substantiates that the price of steel gunshot is comparable to lead.

With regard to technical feasibility of steel, in both consultations[31] it was raised that the use of steel gunshot will lead to crippling losses and animal suffering, because the game is only injured and not effectively killed. It was also stated that the use of steel shot would not be as safe as lead gunshot, because of an increased risk of injuries from ricochet. These statements were not substantiated by sufficient information to assess their validity. SEAC notes that available scientific evidence does not support a loss in killing efficiency or an increased risk from ricochet.

With regard to the suitability of shotguns to shoot steel, SEAC notes that according to the CIP[32] guns with standard proof (i.e. CIP N) are safe to be used within certain limits of velocity, chamber pressure and pellet size (details on proofing of guns are discussed in the Background Document in section 2.5.1.2 and Annex D.1.2.1.3). Based on the fact that all guns produced after 1970 can be expected to be standard-proofed, it can be concluded that steel can be used as an alternative in the majority of hunting situations. For situations, where the suitability of steel with standard-proofed guns is uncertain, hunters have the option to either test if their gun fulfils the requirements of the CIP steel shot proof ('Fleur de Lys') or to buy a new gun. In both consultations[33], comments were received pointing to the fact that not all Member States are members of CIP and, as such, have no proofing facilities available, meaning that the re-proofing of guns could entail considerable efforts for hunters in these countries. Noting that the actual number of hunters who will re-proof their guns in response to the proposed restriction is uncertain, overall, SEAC considers that available information indicates that not very many hunters are likely to take this effort. However, the potential lack of proofing facilities is an issue, which should be considered during the implementation of the

[30] https://echa.europa.eu/documents/10162/07e05943-ee0a-20e1-2946-9c656499c8f8 (accessed 27 October 2022)

[31] In the consultation on the Annex XV report, for example, in comments #3187, #3189, #3194, #3199 and in the consultation on the SEAC draft opinion, for example, in comments #1014, #1028, #1140.

[32] Commission internationale permanente pour l'épreuve des armes à feu portatives.

[33] In the consultation on the Annex XV report, for example, in comment #3469 and in the consultation on the SEAC draft opinion, for example, in comments #1046, #1089, #1091, #1092, #1136, #1139.

proposed restriction.

Instead of re-proofing or replacing their gun, some hunters will also switch to other alternatives, e.g. bismuth or tungsten, which are much more expensive than lead or steel, because these materials can also be used in guns that are not standard-proofed, for which steel shot is no feasible alternative. Furthermore, bismuth and tungsten are very similar to lead with regard to ballistics and shooting performance meaning that shooters do not need to adapt to new shooting conditions as they have to when switching to steel. As bismuth and tungsten are much more expensive compared to steel, SEAC considers that the number of hunters switching to these alternatives is likely to be very limited. Instead, hunters may choose to buy a new steel-proof gun. This conclusion is supported by comments received in the consultation on the Annex XV report (#3246, #3331).

SEAC notes that the production of some of the alternative materials considered, e.g. bismuth, entails significantly larger environmental impacts in terms of resource use and greenhouse gas emissions than lead (see Background Document Annex C.4).

Cost assessment

The cost assessment is based on the same approach as well as largely on the same assumptions applied in the restriction proposal on the use of lead gunshot in wetlands[34]. The Dossier Submitter updated available information sources and also reflected information received in the call for evidence during the preparation of the proposal as well as the consultation on the Annex XV report by updating several assumptions made in the assessment.

Accordingly, the costs to hunters resulting from the proposed restriction consist of (i) operational costs due to switching to alternative ammunition and (ii) one-off costs to test or to replace existing guns necessary to use alternative gunshot.

As data on the input parameters to estimate costs are limited, the Dossier Submitter had to make several assumptions based on available evidence or plausibility considerations (see Table 6). To reflect the uncertainties underlying these assumptions and to illustrate the range of costs expected to result from the proposed restriction, the Dossier Submitter defined three different cost scenarios (best, central and worst case).

[34] SEAC's assessment and conclusions for the restriction in wetlands are also largely applicable (see link above, pp. 50).

Table 6: Cost scenarios assessed by the Dossier Submitter to substitute lead gunshot in hunting (including variation on the central scenario by SEAC)

Input/Output	Best case	Central case - SEAC	Central case - DS	Worst case
Number of hunters impacted in terrestrial hunting	3.6m (60% of all hunters)	equal to DS	3.8m (65% of all hunters)	4.1m (70% of all hunters)
Relative price of steel shot	100%	equal to DS	101%	103%
Proportion switching to steel shot (remaining hunters are assumed to switch to bismuth or tungsten)	100%	**95%**	85%	85%
Number of shotguns to be replaced in terrestrial hunting (% of hunters affected)	0	equal to DS	190 073 (5%)	413 252 (10%)
One-off cost for premature replacement of shotguns	€0m	equal to DS	€132m	€424m
Annual operational cost (i.e. annual incremental cost to be spent on shot)	€0m	€25m	€72m	€122m
Annualised one-off cost for testing	€3m	equal to DS	€2m	€1m
Annualised one-off cost for new guns	€0m	equal to DS	€10 m	€20m
Total annualised cost to hunters	**€3m**	**€37m**	**€84m**	**€143m**
Total cost (20 years)	**€28m**	**€342m**	**€768m**	**€1 310m**

The Dossier Submitter in general made conservative assumptions with regard to the input parameters used. More specifically, SEAC has the following observations:

- Number of hunters affected: The Dossier Submitter assumes that all hunters that were not covered by the restriction of lead gunshot in wetlands[35] would be affected by the ban. SEAC considers this a conservative assumption, which tends to overestimate the number of affected hunters, because not all hunters might pursue hunting with gunshot, some may exclusively use bullets depending on the kind of game hunted for. The number of hunters using gunshot is likely to depend on the abundance of small game (incl. birds) in the respective region, which has declined significantly for some species in recent years[36], in particular in terrestrial areas.

- Number of lead cartridges used: The Dossier Submitter assumes that lead gunshot accounts for 90 % of all gunshot cartridges currently used in hunting (outside of wetlands). SEAC considers that this share could decrease once the wetland restriction will have entered into effect, because hunters may switch to using steel shot in

[35] The restriction in wetlands was assumed to cover waterfowl hunters as well as all hunters in Member States with a complete national ban and with more than 20% wetlands of the total area.

[36] See, for example: REIMOSER, F. & REIMOSER, S. 2016. Long-term trends of hunting bags and wildlife populations in Central Europe. *Beiträge zur Jagd- und Wildforschung,* 41**,** 29-43.

general, i.e. also outside of wetlands.

- Relative price of steel shot: The updated market analysis carried out by the Dossier Submitter underpins that the price of steel gunshot is the same or can even be lower than lead. Still, the Dossier Submitter assumes a slightly higher price in the central-case scenario.

- Proportion of different alternatives used: The alternatives hunters would use to replace lead is an important driver of the costs of the proposed restriction. In the central-case scenario the Dossier Submitter assumes that 15 % of hunters would switch to other alternatives than steel, i.e. bismuth and tungsten, which are much more costly. SEAC considers it unlikely that this share would be as high, in particular over the whole 20-year period, because of the high price of bismuth and tungsten. This conclusion is supported by information received in the consultation on the Annex XV report (#3246, #3331), which indicates that hunters would rather choose to replace their gun than to use other alternatives than steel. In addition, availability of alternatives like bismuth or tungsten could become limited with increasing demand. To ensure that the central scenario is based on realistic and not overly conservative assumptions, SEAC adapted the proportion of alternatives used to 95 % steel and only 5 % bismuth/tungsten (see Table 6). Based on this assumption, the cost estimate for the central scenario changes from €768 to €342 million. Furthermore, the Dossier Submitter reflected the possibility that hunters who cannot use steel shot would replace their gun instead of using other alternatives than steel in a sensitivity scenario of the central cost estimate (see next bullet point).

- Guns to be replaced in response to the proposed restriction: In the consultation on the Annex XV report comments were received stating that the Dossier Submitter had underestimated the costs of gun replacement resulting from the proposed restriction (e.g. #3331, #3467). In response to these comments, the Dossier Submitter scrutinised the issue by conducting a sensitivity analysis on different drivers of gun replacement costs, i.e. number of hunters affected, share of guns to be replaced and price of a new shotgun (see section 2.5.3.1.1 in Background Document). If the results of this sensitivity scenario are considered in addition to the original cost assessment (Table 6) the gun replacement costs range between €0 and €170 million.

<u>B2. Hunting with bullets, incl. airgun pellets (use #2a and 2b)</u>

Availability and technical and economic feasibility of alternative bullets

Several types of non-lead bullets are available, made with different materials, mainly from copper and brass (see analysis in the Background Document Annex C.1.2). Information presented in the Background Document shows that the availability of alternatives varies between calibres. For large calibres (≥ 5.6 mm) non-lead ammunition is widely available, whereas market supply is more limited for small calibres (< 5.6 mm) (see Background Document Annex D.1.2.2.7). Many comments were received on the suitability and availability of alternatives to lead bullets (see summary of comments received in section 2.5.1.2.1 in the Background Document). These did not change the conclusion of the Dossier Submitter on this issue. SEAC agrees with this analysis of the information received.

SEAC considers that the limited supply of alternatives for small calibre centrefire as well as

rimfire ammunition could be a result of low demand and might change with increasing demand. However, available evidence supports that currently the technical performance of alternatives is indeed limited in terms of precision. It is unclear what exactly the impacts of this performance loss are and how it will develop until the entry into force of the proposal. Therefore, SEAC supports a review of the proposed restriction for small calibre/rimfire ammunition as proposed by the Dossier Submitter.

With regard to the technical feasibility of non-lead large calibre bullets, scientific evidence presented by the Dossier Submitter indicates that in general they are as effective as lead provided that the projectile design is adapted to the lower density of alternative materials compared to lead (see Background Document Annex D.1.2.2.2). SEAC notes that standards set for lead bullets in hunting legislation can act as an obstacle for the use of non-lead projectiles, because these may not achieve the minimum weight required.

Alternative ammunition to be used in airguns (usually zinc alloy) are available. However, these alternatives lack performance in terms of precision. There is only very limited information available to conclude to what extent hunting with airguns is affected by this lower performance. In addition, the price of non-lead airgun pellets is reported to be significantly higher compared to lead. Even though SEAC requested more specific information on the impacts on hunting with airguns in the consultation on the SEAC draft opinion, the evidence base did not significantly improve.

Cost assessment

The costs to hunters of the proposed restriction primarily depend on (i) the number of lead bullets that are currently used in hunting, (ii) the price difference between lead bullets and alternatives and (iii) the number of rifles that will be replaced or re-barrelled in response to the proposed restriction. To estimate these parameters the Dossier Submitter used available data such as hunting bag statistics, an analysis of market prices of lead and non-lead ammunition as well as information on the technical and economic feasibility of alternative ammunition.

Table 7: Cost scenarios assessed by the Dossier Submitter to substitute lead bullets in hunting

Input/Output	Scenario		
	Best case	**Central case**	**Worst case**
Share of hunting with lead-free bullets	15%	10%	5%
Small calibres			
Relative price of non-lead alternatives	± €0	+ €0.2	+ €0.4
Annual operational cost	€1m	€1m	€3m
Number of rifles to be replaced/re-barrelled	178 393	267 590	535 180
One-off cost for premature replacement of rifles/barrels	€66m	€165m	€366m
Annualised one-off cost for new rifles/barrels	€5m	€12m	€17m
Total annualised cost to hunters	€6m	€13m	€20m
Total cost (20 years)	**€54m**	**€122m**	**€179m**
Large calibres			
Relative price of non-lead alternatives	+ €0.75	+ €1.46	+ €2.17
Annual operational cost	€8m	€20m	€34m
Total cost (20 years)	**€101m**	**€239m**	**€412m**

Similar to the assessment for gunshot, also the assumptions made by the Dossier Submitter to estimate the costs to replace lead bullets tend to be conservative. In detail, SEAC notes the following:

- Number of lead bullets used: In the absence of data, the Dossier Submitter made assumptions on the share of hunting that is already carried out with non-lead bullets. SEAC considers that the share of non-lead bullets in hunting could be at the upper end of the range assumed in the assessment based on the fact that in some Member States it is already significantly higher. With regard to the number of small calibre bullets used, some assumptions made, e.g. the share of small game hunted with bullets (compared to shot), were not substantiated by the Dossier Submitter meaning that it is difficult for SEAC to conclude if they are reasonable and appropriate to reflect the range of possible impacts resulting from the proposed restriction.

- Price difference lead and non-lead bullets: The market analysis of lead and non-lead ammunition carried out by the Dossier Submitter generated rather scarce data for small calibre ammunition. Even though SEAC acknowledges that this reflects the limited availability of alternative small calibre bullets, it could compromise the reliability of the price estimates for small calibre non-lead ammunition, in particular as commonly used calibres such as .22 LR were not included. For large calibres, the Dossier Submitter assumed that the price for non-lead ammunition is significantly higher compared to lead based on the results of the market analysis. SEAC notes that other available information sources indicate a more moderate price difference or even similar price levels of lead and non-lead ammunition[37]. Therefore, the price levels used

[37] Ellis, Matt (2019): Availability and price of non-lead ammunition, BASC

by the Dossier Submitter in the cost assessment seem to overestimate the costs of switching to non-lead bullets.

- Rifle or barrel replacement: The Dossier Submitter assumes that rifles using rimfire bullets either need to be replaced or re-barrelled. SEAC notes that there is no clear evidence that rifles or barrels would have to be replaced in response to the restriction and that this would be required for technical reasons. Also, comments received in the consultation on the Annex XV report did not provide information that would allow for a conclusion on the likelihood of these impacts (see discussion on the input received in the consultation in section 2.5.3.1.2 of the Background Document). Hence, it is uncertain if and to what extent replacement costs will result from the proposal.

The Dossier Submitter did not assess the costs resulting from the proposed restriction of lead in airgun pellets or in ammunition used in historic firearms. This is an uncertainty in the cost assessment, which might affect the cost ranges provided in the Background Document. Overall, SEAC considers it to be unlikely that the costs resulting from the ban in airgun pellets and historic firearms would lead to significant changes in the cost ranges.

C. Sports shooting (use #3, 4, 5, 6)

Implementation of the restriction (possibly including derogations) would cause different types of costs to various actors in society, including the manufacturers of firearms and ammunition, the individual sports shooters, and the owners/operators of shooting ranges, as well as national shooting associations and probably national sports associations in general.

The Dossier Submitter has analysed various impacts of the implementation of the proposed restriction. This was helped by extensive information obtained from sports shooting associations and own research into the availability and price of various types of ammunition. In the Background Document the analysis of technical aspects for the use of alternative ammunition mainly focussed on hunting. However, most of the conclusions can be transferred to sports shooting as well. For good order the discussion below is split in a part related to gunshot and in a part related to bullets and other type of ammunition.

C1. Sports shooting with gunshot (use #3)

Availability and technical and economic feasibility of alternative gunshot

In terms of availability and feasibility of alternatives, SEAC's assessment of the use of gunshot in hunting (see above) is transferrable to the situation in sports shooting. Accordingly, steel gunshot is likely to be the most commonly used alternative, because it is available, technically feasible and – if at all – only slightly more expensive compared to lead gunshot. In the Annex XV report consultation, it was confirmed that steel gunshot is already commonly used in competitive sports shooting at national level (e.g. #3189). The latest data available indicate its price will be comparable to that of lead shot, although price and availability may vary depending on the region.

A recurring point of discussion is if the undeniable differences between steel shot and lead shot are so severe that they will prevent general use of steel shot in sports shooting, which in this case mainly relates to different variations of clay target shooting. In international competitions the use of lead shot is still mandatory. In the consultation on the Annex XV

report many comments were received which made statements pro and contra this matter. Moreover, the internet contains many reports about personal experiences. Especially, a voluntary ban on the use of lead shot announced in the United Kingdom has created a lot of comparative testing, both for hunting and clay target shooting. In general, these tests show that initial scepticism gave way to a much more positive opinion in the end. This matches the experiences made in other countries that have been using steel shot already for a longer period of time. On the other side of the spectrum is a comment submitted by FITASC/ISSF (Annex XV report consultation, #3221), where numerical data is supplied about differences in ballistics and other parameters, with the conclusion that steel shot is not suitable for high-level sports shooting. Consequently, there do not seem to be any initiatives that may lead to a change in the rules of international competitions.

A summary of the various points brought up in the discussion is listed below (see also Table 2-38 in the Background Document for more information):

1. Damage to the gun because of abrasion: The argument that steel will damage the gun barrel does not seem to hold in view of its proven use in guns produced after about 1970. Moreover, any abrasive action of steel is prevented by the use of modern plastic wads. In addition, the availably and use of biodegradable wads seems increasing. This is confirmed by practical experience, even with relatively old guns.

2. Damage to the gun because of high pressure: To compensate for the lower density of steel pellets (leading to a faster deceleration after they leave the gun muzzle) powder charges need to be higher, leading to a higher pressure during firing of the gun. Abundant experience has shown that for modern guns the use of standard steel cartridges presents no problem. However, high-performance cartridges with an extra load should only be fired from a modern gun with a fleur-de-lys sign. Provided this is taken care of, no problems are to be expected. For clay target shooting at a certain level, the use of a modern gun seems a given. However, in some cases recreational shooters may have to replace an old gun. Further details on the proofing of guns are discussed under ‘B1. Hunting with gunshot’ above.

3. Higher recoil and noise if steel shot is used: A higher powder charge in the case of steel will inevitably lead to a stronger recoil and a louder bang when firing the gun. FITASC/ISSF presented numerical data on this and claim this will harm the health of the shooter and cause problems with permits of shooting ranges and is therefore not acceptable. Although these issues are mentioned in many other sources comparing lead and steel shot, none of the countries that have a long-term experience with the use of steel shot seems to consider these differences to be so severe that they would prevent the use of steel shot. Problems with noise emissions of shooting ranges using steel shot have not been reported in countries already using steel shot, but it cannot be excluded that these may exist in some cases.

4. Different pattern of steel shot vs. lead shot: The different mechanical properties of steel pellets will cause a difference in spreading out after the pellets leave the gun, which may influence its hitting characteristics. However, there is ample evidence that the choice of a suitable choke (a narrowing of the gun barrel at the muzzle end that allows to control the spatial distribution of the gunshot after it leaves the barrel) will allow to reach a suitable pattern.

5. Difference in ability to destroy a target: The lower density of steel shot will cause the pellets to lose velocity faster than in the case of lead shot. However, experience from practice shows that with the right choice of cartridge, the ability to break a clay target is still sufficient.

6. Less accuracy with steel: The lower density of steel will cause a higher sensitivity towards wind deflection[38]. It is clear that this makes it necessary to adjust the aiming if one wants to hit a moving target (be it a game animal or a clay target). For sports shooting this may give rise to a certain period of intensive training to internalize the new aiming movement and become as proficient as before. The argument brought by FITASC/ISSF that accuracy of steel cartridges decreases to an unacceptable level beyond 30 metres is put in doubt by a test performed by an experienced clay target champion, who demonstrates that even on a windy day he is still able to hit consistently at distances of over 100 metres, although some adjustment is needed[39]. In later comments from FITASC (#1073) and ISSF (#1057) provided in the consultation on the SEAC draft opinion, this source was criticised as being produced as advertising for a particular cartridge brand and therefore should not be given too much weight. However, in the opinion of SEAC the video can at least be considered as "proof of principle", even if not an actual result from competition.

More conflicting comments on the subject of suitability of steel shot were received in response to a specific information request in the consultation on the SEAC draft opinion (e.g. #1031, #1042, #1079, #1083 and #1097 as arguing in favour of steel shot vs. #1057, #1059, #1063, #1073, #1084 and #1142 as arguing against steel shot).

In order to better understand this matter, SEAC sought the advice of an independent ballistics expert, in accordance with REACH Article 76(3). For reference, the final report from this work is appended to the final version of the Background Document (Appendix 5). Based on the comments received and this report, SEAC now summarises the available facts as follows:

- The differences in ballistic properties (determined by basic physical properties) between steel and lead shot are acknowledged by all experts and not in dispute.

- Calculations by FITASC and tests by ISSF show that steel shot with a pellet diameter of 2.4-2.7 mm will have a lower impact energy than a lead pellet of diameter 2.4 mm when hitting a clay target at distances beyond 20 m. For a distance of 40 m this is illustrated with pictures in comment #1057 (consultation on SEAC draft opinion). It should be noted, however, that this does not mean that steel shot does not hit the targets, but that there may be more unfavourable situations where, despite a hit, the pellets just pierce or chip away a small part of the target without breaking it, which is not counted as a hit.

- According to the independent expert advice sought by SEAC, which is based on a series of ballistic calculations using a different approach than those of FITASC, the ballistic

[38] https://www.knsa.nl/de-knsa/accommodaties/schieten-met-loodhagel-op-kleiduiven/ (in Dutch; accessed 27 October 2022)

[39] https://www.youtube.com/watch?v=Nl1DLfzOzk8&t=240s (accessed 27 October 2022)

trajectory characteristics of lead shot with a pellet diameter of 2.4 mm can be approximately retained by using steel shot with a pellet diameter larger than 3 mm[40]. By using steel pellets with > 3 mm diameter and keeping the powder charge the same, higher recoil can be avoided, but the larger diameter means that the number of pellets loaded in one cartridge is reduced. Compared to a lead cartridge with a load of 24 g and 2.4 mm pellets, a steel cartridge with a load of 24 g and 3 mm pellets has 26 % less pellets (42 % less in the case of 3.25 mm pellets, 54 % less in the case of 3.5 mm pellets), a steel cartridge with a load of 28 g and 3 mm pellets has 14 % less pellets (32 % less in the case of 3.25 mm pellets, 46 % less in the case of 3.5 mm pellets). Fewer pellets and a slightly smaller shot cloud diameter reduces the probability of a hit, requiring shooters to be more precise.

- Notwithstanding these differences, the responses to the specific information requests in the consultation on the SEAC draft opinion contained reports that steel shot is apparently already successfully used in the various clay target shooting disciplines, including in high-level competitions (comments #1066, #1079, #1097), for those competitions where the use of steel is allowed.

Evidence available to SEAC shows that mixing lead and steel shot shooting in the same competition is likely to lead to a distortion of conditions, which is undesirable from the viewpoint of retaining a level playing field. The importance of retaining a level playing field is stressed in several comments received in the consultation on the SEAC draft opinion (e.g. #1057, #1063, #1084). However, the evidence also shows that steel could effectively be used as an alternative, if it is used exclusively within the same competition (i.e. no lead shot is permitted).

In conclusion, data and experience show that steel can be used as an alternative if it is accepted that its use may result in (i) a reduced probability of an effective hit and increased recoil (when using 2.7 mm steel shot with higher powder charges) or (ii) a reduced overall hit probability, putting more demand on shooter accuracy (when using > 3 mm steel shot with a reduced number of pellets). However, SEAC has no empirical data that may indicate how these factors would work out in practice.

Though not too be taken lightly, the change of competition rules for sports at the top level are not without precedent both within sports shooting (for clay target shooting, past changes are mentioned in comment #1097 of the SEAC draft opinion consultation) and in other sports[41].

In conclusion, SEAC tends to agree with the Dossier Submitter, who concluded that the main barrier preventing a general switch towards the use of steel shot does not seem to be of

[40] According to the expert advice, a change from lead to steel shot while retaining the ballistic trajectory characteristics means that the cross-sectional density of the lead and steel pellets needs to be the same. The cross-sectional density of a 2.4 mm lead pellet is equivalent to the cross-sectional density of 3.43 mm steel pellet. The comparative ballistic calculations for 2.4 mm lead shot and different sizes of steel shot (2.7 mm, 3 mm, 3.25 mm, 3.5 mm) show that 3 mm steel shot would be more suitable than 2.7 mm steel shot and that the ballistic behaviour of 3.25 mm or 3.5 mm steel shot is even more similar to that of 2.4 mm lead shot.

[41] See for example the past controversy and change in rules regarding full-body swimsuits: https://www.swimmingworldmagazine.com/news/one-decade-later-do-we-miss-the-full-body-competition-suit/ (accessed 13 October 2022).

technical nature, but mainly organisational. SEAC also notes that if replacement of lead shot with steel shot were to be approached on a global basis, the chances for success are high. However, this would need a concerted action by the shooting associations.

Cost assessment

The various factors contributing to costs for sports shooting with gunshot can be described as follows:

1. Cost of R&D into development and testing of non-lead ammunition types by gun and ammunition manufacturers and possibly new or modified firearms: For sports shooting with gunshot, this will be very similar to hunting. So, no extra R&D costs in this direction are expected, because modern guns are capable of firing steel shot already. While it is possible that in the future modern guns can be improved even more, making them even better suited to use steel gunshot, this can be considered as normal product development and innovation and should not be counted as costs of this restriction.

2. Costs for manufacturers and retailers which have to broaden their range of products (different materials, larger stocks, limited shelf-life, etc.): Also here there will be close parallels to hunting. The Dossier Submitter argues that these costs will be minor or non-existent because the situation does not really differ from that of today. However, in the Annex XV report consultation some comments were received that refer to a higher risk of corrosion for steel shot and therefore potentially a shorter shelf-life. SEAC considers the information presented is of insufficient quality to determine whether this would indeed be the case.

3. SEAC assumes that costs for enforcement of a full ban on placing on the market and on use will largely be covered by the usual enforcement costs, as argued by the Dossier Submitter. Because sports shooting takes place at specific sites, the argument which was used by SEAC in the section on hunting sector that higher enforcement costs may be caused because of the need to cover a wider geographic area, does not seem valid here.

4. Costs to individual sports shooters:

    a. As one-off costs, as some guns may have to be replaced or modified in order to be able to fire steel shot or need to be re-tested to confirm their safe use with this kind of non-lead ammunition. Although the available information indicates that for use of steel gunshot in most cases a replacement will not be necessary, it cannot be excluded that in some cases (e.g. an old type of gun) users may choose to replace the existing gun earlier than originally planned. For sports shooting, replacement costs are presented in Table 2-43 of the Background Document and in the calculation details supplied to SEAC. However, in view of the above information, the assumption that 10 % of sports shooters may need to replace their gun seems to be rather high and may therefore overestimate costs. SEAC notes that the Dossier Submitter included also scenarios where 6 and 14 % are replaced.

    b. For a total ban, the Dossier Submitter calculates total costs of €264-660 million as costs over 20 years to prematurely replace guns, depending on the number

of guns that need to be prematurely replaced and the price of a new gun. On an annualised basis, this corresponds to costs of €19-49 million. If it is assumed that under the optional conditional derogation about 12 000 out of 2 500 000 sports shooters would qualify for a licence to use lead on permitted sites (so would not have a need to replace their gun), replacement costs would be slightly lower but still in the same range.

In these calculations, the Dossier Submitter uses a price range of €1 000-3 000 for a new gun. Taking into account that a gun is typically used for a long time, the Dossier Submitter states that these costs seem affordable for an individual shooter.

It is likely that for sports shooting at an advanced level, models at the higher end of the range will be preferred. On the other hand, it should be assumed that active sports shooters are likely to already possess a modern gun, reducing the probability that a new purchase will be necessary. Effectively this means that with high probability the gun replacement costs presented by the Dossier Submitter will be an overestimation of reality.

Moreover, costs for equipment in international competitions are often paid for by sponsors or by subsidies. This would mean that part of replacement costs will not be at the burden of the individual but of society as a whole.

c. In some cases, costs will be incurred for renewed proofing of an old gun (about €70) and change of choke (about €70). Compared to the costs for replacing guns, these costs are expected to be of minor importance and SEAC acknowledges these were not explicitly considered in the analysis.

d. Extra costs for steel gunshot in comparison to the traditional lead-based shot types: In the detailed calculations for the area of sports shooting with gunshot provided to SEAC, the Dossier Submitter estimates these extra costs to amount to a mid-value of about €63 based on 10 000 shots at a 1 % higher price for steel shot compared to lead (or a range of €0-126, assuming respectively 0 and 3 % higher price for steel shot compared to lead shot). Recent information seems to indicate that currently there hardly seems to be any price difference between lead and steel shot. So, it may be that these costs are overestimated and in reality will be close to zero. In the most recent calculations on the costs of the different restriction options, a mid-price difference of 1 % was used.

   SEAC notes that for sports shooters a shift to bismuth- or tungsten-based shot does seem an even less attractive option than for hunters. Sports shooters tend to use a higher number of cartridges per year than hunters. In view of the much higher price for this type of shot, a switch to such alternatives is an unattractive option.

   SEAC notes that it remains unclear if the manufacturing sector will be able to meet fast increasing demand for steel shot for sports shooting within the transition period indicated, or whether there may be a transient shortage of such ammunition types. In this case, higher prices may result, at least temporarily.

5. In case the optional conditional derogation to allow further use of gunshot by licensed athletes at permitted sites would come to bear, costs will be incurred by owners/operators of shooting ranges that implement additional RMMs to achieve a lead recovery rate of more than 90 %, in addition to the substitution costs incurred by all other sports shooters. Note that it is likely that all or part of the costs for upgrading RMMs will directly or indirectly be passed on to people using the facility. In case national sports associations or government agencies would step in to subsidise such upgrades, extra costs would be incurred by society as a whole instead. The Dossier Submitter's calculations are further discussed in the following sub-section.

6. Concerning the optional conditional derogation, additional cost elements have to be considered, because regulatory/enforcement authorities are supposed to implement a permit/licence system both for shooting ranges and individuals as well as inspections in the field on the non-use of lead gunshot for hunting. Moreover, as it is not clear whether issuing and checking permits/licences would be done by the same government entities as the "in the field" enforcement, this may potentially increase costs. It remains unclear to SEAC if the costs related to implementing such a permit/licence system would be negligible. The potentially complicating issue about the involvement of different government entities is also mentioned in the Forum advice. It should be noted that experience collected in the restriction of lead gunshot in wetlands (once in force) may give a better view on this matter.

Costs for additional RMMs related to gunshot used in sports shooting (relevant in the context of the optional conditional derogation)

Estimating impacts here is difficult because there is no central EU register of shooting ranges and their measures for risk management. Annex B.9.1.3 (Table B.9-4) of the Background Document gives an overview of information gathered from Member States on the number of shooting ranges in these countries. Based on this information, the Dossier Submitter estimated the total number of shotgun shooting ranges that would be concerned by the proposed restriction at 4 000-5 000 ranges. However, it should be taken into account that some countries did not report data at all and others reported data that are known to be inaccurate because there are no accurate national data available.

Other than for some specific sites in a few Member States, it is unknown to what extent these shooting ranges have already introduced RMMs to control release of lead into the environment.

To be able to calculate the costs of implementing the necessary measures foreseen under the optional conditional derogation, the Dossier Submitter first assigned the 4 000-5 000 shotgun ranges to four groups, where for each group a low and a high figure is assumed:

1. Temporary areas without relevant RMMs (no lead recovery).

2. Permanent ranges without relevant RMMs (lead recovery < 50 %). To satisfy the optional conditional derogation extensive modifications are necessary.

3. Permanent ranges with some RMMs (lead recovery 50-90 %). These will need some modification to increase the level of lead recovery).

4. Permanent ranges with extensive RMMs (lead recovery > 90 %). No further modifications foreseen.

It should be noted that each range will have baseline costs that will occur independent of the introduction of the restriction. These are not included in the calculations. An overview of the number of sites assigned to each of the four groups can be found in Table 2-51 of the Background Document.

Based on information from some real-life examples supplemented with estimations, each range type was assigned certain costs to implement the necessary RMMs. This is summarised in Table 2-50 in the Background Document), which takes into account data that was received from stakeholders in the Annex XV report consultation. In the consultation on the SEAC draft opinion, comment #1096 listed a breakdown of the costs for upgrading a clay target skeet range, by installing extensive RMMs (but without specifying the expected final recovery effectiveness, so it is not clear if this will match the requirement set out in the restriction proposal). This amounted to about €2.3 million, which is somewhat higher than the maximum of €2 million used by the Dossier Submitter in Table 2-50 of the Background Document for a shooting range starting from a level without RMMs. In view of the uncertainties involved in the estimates, this can still be considered satisfactorily close.

The Dossier Submitter estimated that upgrading all shotgun ranges where RMMs that allow the recovery of > 90 % lead are currently not in place (i.e. except permanent ranges with extensive RMMs in place to recover > 90 % lead) would amount to investment costs of €3.5-4.4 billion (central scenario, NPV over 20 years at 4 %). While this is lower compared to the estimates presented in the Annex XV report (€8 527 million, central scenario, NPV over 20 years at 4 %), the Dossier Submitter noted that this estimate is not considered realistic because it also includes costs for the upgrade of temporary shooting areas/ranges, which is not expected to happen in practice. More generally, the Dossier Submitter considers it reasonable to expect that a restriction with the optional conditional derogation would not affect all ranges and shooters evenly and that in reality only a certain fraction of shooting ranges would upgrade their RMMs. In fact, many comments from the Nordic countries in the Annex XV report consultation indicated that many (especially small local) ranges would not be able to afford to implement the proposed RMMs. They would then have the option to go for a "lead free status" or to close. Similar comments were repeated as input to the consultation on the SEAC draft opinion (e.g. #1004, #1010, #1015, #1063, #1096).

Therefore, based on comments from the Annex XV report consultation and on the Dossier Submitter's own research, the Dossier Submitter used an alternative approach to calculate the number of ranges that may upgrade RMMs in order to arrive at a more realistic cost estimate[42]. This approach is based on a regional distribution of shooting ranges in the EU. In this modified calculation, based on a regional breakdown following the NUTS classification for Europe (NUTS = "Nomenclature des unites territoriales statistiques") an important assumption is that in each Member State only a certain number of ranges on a regional level will upgrade their RMMs.

In a first version of this approach, corresponding to RO3 for sports shooting with gunshot (i.e.

[42] The Dossier Submitter provided the Rapporteurs with spreadsheets detailing these calculations.

not the restriction option eventually proposed by the Dossier Submitter for the optional conditional derogation, see section 3.3 for details), it is assumed that in each region at least one shooting range will be available that will be open to all shooters that want to continue using lead shot. Implicitly this assumes that there will be enough of such upgraded sites available so that each shooter can easily reach such a site in his/her region. Because this may not always be the case, it is also assumed that 10 % of shooters may choose to switch to steel shot instead, in order to practice at a range which will not upgrade but opt for a "lead free status".

In a second version of this approach, corresponding to RO4 for sports shooting with gunshot (i.e. the restriction option eventually proposed for the optional conditional derogation, together with RO5,), it is assumed that a smaller number of sites will upgrade RMMs to meet the conditions of the derogation and that these sites will only be accessible for licensed sports shooters who would be allowed to continue using lead gunshot. All other shooters would have to switch to using steel shot and use ranges that are lead free. This would still allow shooters to train in their region for international competitions but would limit the overall costs associated with need to comply with the requirements of the optional conditional derogation.

An overview of the number of ranges expected to be upgraded under the different approaches is given in Table 2-52 in the Background Document).

This approach of upgrading only a fraction of ranges on a regional basis would then result in the cost estimates shown in Table 8 (based on data presented in Table 2-54 in the Background Document). In addition to the costs of upgrading RMMs, the Dossier Submitter considers costs of switching to steel shot for 10 % of sport shooters in the calculations corresponding to RO3 and for all sports shooters without a permit in the calculations corresponding to RO4 (also shown in Table 88). This results in a central cost estimate of €1 097 million (range: €885-1 309 million) for RO3 and €548 million (range: €506-591) for RO4. The latter is also reflected in the summary of the Dossier Submitter's cost estimates above (Table 4).

Table 8: Costs of implementing RMMs and switching to steel shot (NPV over 20 years at 4%)

Scenario	Costs of implementing RMMs to recover > 90 % lead gunshot and costs of switching to steel shot (€ million)					
	low-cost scenario		middle-cost scenario		high-cost scenario	
	Low	high	low	high	low	High
All shooting ranges upgraded (except permanent ranges with all RMMs in place)	RMMs: 1 192	RMMs: 1 490	RMMs: 3 481	RMMs: 4 351	RMMs: 5 343	RMMs: 6 678
Fraction of ranges upgraded to be used by all sports shooters (corresponding to RO3)	RMMs: 148 Steel: 18 **Total: 166**	RMMs: 296 Steel: 18 **Total: 314**	RMMs: 849 Steel: 36 **Total: 885**	RMMs: 1 273 Steel: 36 **Total: 1 309**	RMMs: 1 973 Steel: 60 **Total: 2 033**	RMMs: 2 630 Steel: 60 **Total: 2 690**
Fraction of ranges upgraded to be used by licensed individuals only (corresponding to RO4)	RMMs: 30 Steel: 177 **Total: 207**	RMMs: 59 Steel: 177 **Total: 236**	RMMs: 170 Steel: 336 **Total: 506**	RMMs: 255 Steel: 336 **Total: 591**	RMMs: 395 Steel: 518 **Total: 913**	RMMs: 526 Steel: 518 **Total: 1 044**

SEAC agrees that this representation of the distribution of potential upgrades gives a better picture than just assuming all ranges will upgrade their RMMs. However, in SEAC's view, it should be noted that at least for some large area countries, upgrading only a fraction of ranges on a regional basis may mean much longer travel times for shooters, because such countries may contain very large regions. It is unclear what consequences this will have for the number of sports shooters that need to practice at a certain level and how this will influence the organisation and popularity of the sports shooting disciplines involved in the various Member States.

From the available data it is clear that a change to alternative steel shot ammunition will always be more economical than implementing the required RMMs to reach > 90 % lead recovery, except for those shooting ranges that have already now implemented the necessary RMMs.

C2. Sports shooting with bullets, incl. airgun pellets (use #4, 5, 6)

Availability and technical and economic feasibility of alternative bullets

Even though non-lead rifle ammunition is available for hunting, its technical performance is not sufficient to be suitable for sports shooting, because it does not achieve an equivalent level of accuracy. This is convincingly demonstrated in several contributions to the consultation on the Annex XV report (e.g. #3239).

Cost assessment

Because in the proposed restriction, use of lead bullets would still be allowed, if used on a site with appropriate RMMs in place, which is notified to the respective Member State, some aspects of the cost picture look different from sports shooting with gunshot:

1. Cost of R&D into development and testing of non-lead ammunition types by gun and ammunition manufacturers and possibly developing new or modified firearms: Because no new guns or ammunition would need to be made available, no extra costs are foreseen in the short term. However, stakeholders may perceive this derogation as open for challenge in the future, with the perspective that sooner or later new regulations may emerge that will further tighten the use of lead ammunition. With this in mind, it may be that gun and ammunition manufacturers will resume or intensify their investigations in finding a replacement for lead in bullets, both from the perspective of ammunition and from the type of gun used. However, SEAC does not find it justified to assign any such costs to the present restriction.

2. Costs for manufacturers and retailers which have to broaden their range of products (different materials, larger stocks, limited shelf-life, etc.): Because existing products can be used in the future, no costs will occur. As in the previous point, the situation for the longer term may be less clear, but does not have to be considered further at this stage.

3. Cost of enforcement: SEAC assumes that costs for enforcing a ban on use will largely be covered by the usual enforcement costs for shooting ranges, as already argued by the Dossier Submitter and discussed for gunshot above.

4. Costs to individual sports shooters: For the same reasons as mentioned above no direct costs are to be expected, other than those related to the mandatory use of notified sites. SEAC notes that if implementation of the restriction would significantly reduce the number of sites for shooting with lead bullets, this may cause a shift in membership of shooting clubs or may necessitate longer travel distances of members to reach such a site. SEAC considers the impact of this issue, although not addressed by the Dossier Submitter, to contribute to the uncertainties of the proposal.

   If at a certain point in time, further regulatory action (e.g. a review of this restriction) would still make it necessary to purchase a new gun, internet searches indicate that prices for new guns (also including biathlon) may be rather high – at least higher as for hunting and gunshot shooting. However, SEAC does not consider evaluation of such costs at this moment relevant for this discussion.

5. Costs for additional RMMs related to bullets used in sports shooting (relevant in the context of the conditional derogation): The Dossier Submitter proposes a conditional derogation for lead bullets, allowing further use at notified sites with measures in place for lead projectile containment and recovery. Compared to the original Annex XV report, the Dossier Submitter has made significant changes both in the proposed restriction for sports shooting with bullets and in the assessment of the associated impacts.

   In section 2.6.3.2 of the Background Document, the Dossier Submitter has examined the costs of the proposed restriction option (RO2c) as well as other assessed options (RO2a, RO2b, RO2d) by calculating the impact of the change from RMMs implemented in the baseline to RMMs of higher effectiveness (upgrade) as required by the respective option. The presence of a basic berm structure is taken as a given for each shooting range. Costs related to this structure are not taken into account.

   Based on input from the Annex XV report consultation, Table 2-55 in section 2.6.3.2 of the Background Document gives an overview of the best estimates of the costs associated with the implementation of various projectile containment measures. These vary from €400 for the installation of a simple bullet trap to > €100 000 for sand traps that cover a number of stands. In addition, based on the available input, costs for maintenance and decommissioning, as well as installation of a water management system are estimated. However, for some elements (e.g. decommissioning costs of best practice sand traps) no cost information is available and values are estimated (low and high range given).

   It should be noted that a comment (#1096) received in the consultation on the SEAC draft opinion gave data on a recent upgrade of shooting ranges of the defence forces in Finland, which was completed in 2018. The plan used the Finnish BAT guidelines, which were also used by the Dossier Submitter to develop the "best practice sand trap" description. Therefore, it may be expected that the implemented RMMs are close to what is proposed by the Dossier Submitter in the Background Document, although a detailed description is not given. Total costs amounted to €25 million for 25 sites, i.e. €1 million per site on average. However, the description indicates that a significant part of this amount was used for noise reduction measures, which are not explicitly considered in the present restriction proposal. From the data, for the "share of measures to reduce the load of harmful substances" an amount of €320 000 per site on average can be calculated – close to what the Dosser Submitter has calculated for upgrades that may be assumed to be similar.

   However, other comments (e.g. #1045, #1098, #1129, #1131, #1146) consider the costs for RMMs as presented in the Background Document to be a severe underestimation of reality. Comments #1130 and #1131 advocate the implementation of local best practices solutions instead.

   To calculate the economic impact, estimates of the number of ranges in the EU (outside Germany where the highest standard of RMMs is already in place), taking into account their standard of RMMs implemented in the baseline, are combined with the estimates of upgrading to a higher standard of RMMs as required by respective restriction option. The outcome is presented in Table 2-56 of the Background Document, which is

reproduced below (Table 9) for ease of reference, for the four sub-options RO2a-RO2d. RO2c represents the Dossier Submitter's preferred option for which costs are estimated at €1 094 million (range: €859-1 329 million) over 20 years.

Table 9: Costs of upgrading RMMs to achieve the standard required by the respective restriction option (NPV over 20 years at 4 %)

Restriction option		Estimated number of ranges affected	Costs to change RMMs (million €)
RO2 **Ban on the use of lead bullets for sports shooting with a derogation at notified outdoor locations where no agricultural activities take place and the following measures are in place (see different RO2 options below):**			
RO2a	Trap chamber, or sand trap (with impermeable barrier) or sand/soil berm (without impermeable barrier), combined with roof or water management system	2 440	170 (72-271)
RO2b	Trap chamber, or sand trap (with impermeable barrier), combined with roof or water management system	7 200	435 (212-662)
RO2c	Trap chamber, or 'best practice' sand trap with impermeable barrier and roof or permanent cover and water management system	7 880	1 094 (859-1 329)
RO2d	Trap chamber for static disciplines; AND 'best practice' sand trap for dynamic disciplines	8 000	1 656 (719-2 653)

The Dossier Submitter recognizes that in some areas (e.g. Sweden and Finland) shooting ranges may be located in or next to wetlands and considers that for such shooting ranges RMMs with the highest effectiveness to minimize risks to surface water, soil and groundwater should be installed.

The Dossier Submitter shared details of the calculations with the SEAC rapporteurs. SEAC concludes that compared to the assessment presented in the initially submitted Annex XV report, these calculations are more refined and probably a better representation of reality. Nevertheless, SEAC cannot agree with some aspects of the calculations. In particular, in SEAC's view the Dossier Submitter does not correctly account for the remediation costs of the existing sites as costs resulting from the restriction. Moreover, discounting of the investments related to the installation of RMMs is not used consistently. A recalculation by the rapporteurs for the preferred option RO2c showed some elements go up in costs while others decrease. So for this particular option the resulting differences in total costs are not significant (i.e. < 6 %).

Unintended consequences for the availability of sites for military training purposes have been mentioned before and are discussed as an uncertainty in section 3.4.2 below.

Other types of guns using lead-based ammunition (use #5 and 6)

Although the use of lead projectiles in airgun shooting and in the use of muzzle loading guns is within the scope of the restriction, not enough data are available to perform a similar cost assessment for these uses. For muzzle loaders (either antique or replicas), use of lead for bullets currently seems without alternatives as discussed in several comments received in the Annex XV report consultation (e.g. #3201, #3224, #3235). As already indicated in the scope section above, additional data has been submitted in the Annex XV report consultation on the amount of lead used for muzzle loading guns. However, as long as these are used on the same notified sites as lead bullets, they would fall under the same regulation.

For airguns, information that is available suggests that alternatives may be available for uses other than sports shooting. Insofar as for these guns lead based pellets are used for sports shooting, it is supposed that the same measures proposed for sports shooting with bullets would also control releases from airgun shooting.

D. Fishing (use #7 and 8)

The use of lead fishing tackle is widespread in Europe despite its well documented hazard properties and adverse effects on both wildlife and human health. In terms of lead placed on the market, the Dossier Submitter estimates that fishing tackle accounts for 18 900 tpa, of which 5 400 tpa comes from lead in fishing sinkers and lures. The Dossier Submitter estimates that 1 300 tpa originate from the manufacture of sinkers and lures in the EU while the remainder is imported. The quantity of lead placed on the market in fishing nets, ropes and lines is estimated to be 13 500 tpa.

The Dossier Submitter estimates that of the 44 000 tonnes of lead dispersed in the environment every year, on average 4 725 tonnes/year are derived from fishing tackle. The study by Radomski et al. (2006)[43] cited by the Dossier Submitter illustrates the order of magnitude for the individual, with an estimated loss of at least 165 g lead/year/angler.

Availability and technical and economic feasibility of alternatives in fishing

The Dossier Submitter identified five properties that make metallic lead suitable for use in fishing:

- relative density (compared to water at 4 °C) is D4R = 11.45, making it a heavy metal,
- the relatively low melting point 326 °C, making it suitable for "home-casting",
- the low water solubility at 185 mg/L at 20°C,
- easy mechanical deformability, e. g. when fixing a slit shot ball on the fishing line with tongs, and

[43] The Dossier Submitter cites in the annex of the Annex XV report a study by Radomski et al. (2006). The study estimated the amount of lead lost in five Canadian large lakes using angler interviews to derive some of the assumptions used for the estimation. The angler survey was conducted directly after the fishing trip. For five different categories of lead fishing tackle the loss per hour was estimated (large sinkers, split shots, jigs, lures and hooks). The yearly average fishing tackle loss for every angler was on average 15 fishing lead items with an average weight of 11 g per lost item, that is at least 165 g lead/year/angler.

- metallic gloss for use as a lure due to its similarity with other fish.

Some fishing tackle consists solely of lead, for example sinkers, while in lures, lead has been added to obtain additional functions, such as to attract the fish. Lead is also added to give sufficient weight to the lure in the water. Lead fishing sinkers and lures, which may be lost or discarded in aquatic (freshwater and marine) or terrestrial environments, range in weight from 0.01 g to 4.8 g (≤ 0.06 g are often referred as 'dust split shots') to several kilograms (e.g. downrigger marine weight to catch strong fishes).

According to cited literature of the Dossier Submitter by VLIZ (Flanders Marine Institute) and the Swedish Chemicals Agency (KEMI), the ideal lead alternative (i.e. suitable alternative) should:

- not contain heavy metals such as lead, or zinc, that are toxic to the wildlife,
- match ideally the mass density of lead (11.34 g/cm^3) which contributes to the optimal casting (fishing) properties,
- should be biodegradable, and
- the production process also ideally needed to offer perspective on the (future) elaboration of a do-it-yourself (DIY)/home-casting method.

The Dossier Submitter summarised alternative substances for lead in fishing tackle: bismuth, ceramic/glass, copper and its alloys such as brass and bronze, concrete, high density polymers, iron, reinforced bars (Rebar), (stainless) steel, stones or pebbles, tin, tungsten, zamac (zinc-aluminium alloy), and zinc. In general, the alternatives currently available for fishing tackle are better than lead from a human health and environmental standpoint.

However, some of them are not recommended (as stated by RAC) because of aquatic toxicity (copper, zinc), or being critical raw materials with a concerning environmental footprint (tungsten and bismuth).

This means the large list shrinks on closer inspection because some alternatives seem not available on the EU market or because of environmental concerns (e.g. zinc, brass, thermoplastics with metal powder fillers). Additionally, there are some data gaps for zamac, zinc, ceramic, tin and bismuth, which makes a full comparison difficult.

Table 10: Possible alternative substances for fishing sinkers and lure, price index compared to lead (=1.00)

Material	**Remark**
Bismuth alloy (3-6 % tin)	Alloy with tin reduce the frangibility of the bismuth, the density of bismuth (100 % Bi: 9.8 g/cm^3) is similar to lead fishing tackle; melting point: 271 °C - home-casting possible, price index: no data
Tin	Widely used as an alternative for lead split shot fishing sinkers because its softness and ductility/malleability; with 7.3 g/cm^3, tin is not as dense as lead and therefore the tin weights would be larger; melting point 232 °C - home-casting possible, price index: 8.99
Bronze (copper with up to 40 % tin)	Bronze more corrosion resistant than brass (copper with 5 % zinc, sometimes associated with lead); bronze is a very soft metal with high strength; depending of tin content, the melting point and density is between 800 and 1000 °C and 7.7-7.8 g/cm^3, home-casting seems possible, price index: 0.69
Stainless steel	Pure iron is forming iron oxide (rust), stainless steel is less dense (7.9 g/cm^3) than lead, comparable with tin but more brittle as tin, no home-casting, price index: 1.19
Tungsten	Successfully used as a replacement for lead for some fishing tackle applications, density 19.3 g/cm^3, no home-casting with melting point 3.422 °C but tungsten putty available, price index: 15.42
Ceramic/Glass	Less dense (2-6 g/cm^3) than lead and therefore ceramic fishing tackle is larger than lead ones, material seems not useful for DIY processing, seldom marketed in EU, price index: no data
Stones or pebbles	Alternative by Belgian fishers for carp fishing especially in soft or muddy bottoms, density 1.6 g/cm^3, individual processing in DIY possible, price index: no data
High density polymer	Thermoplastic-based formulation with metallic fillers and resins with density up to 11 g/cm^3, very close to the lead one, tungsten, for example, may be used as a filler, composite may be a source of micro plastic, price index: no data

For the alternative substances investigated, the Dossier Submitter reports on regulatory activities that are currently ongoing for copper:

- ED under assessment as Endocrine Disruptor
- CLH: copper granulated: Aquatic Chronic 2 (15th ATP) shall apply from 1 March 2022

SEAC also notes that copper is an approved (approval in progress) active substance under Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR), here in product type 21 (antifouling).

For this reason, SEAC considers that the suitability of copper (pure) and brass (alloy

copper/zinc) as drop-in alternatives are limited.

SEAC expects that technically feasible alternatives to lead in fishing sinkers and lures are available. The materials seem available for industrial production as well as for DIY. The cost of the alternatives for the fisher depends on the material. For example, for simple weights, the cost can range from free (i.e. for stones) to sinkers made of tungsten with a price almost 16 times higher than lead.

The most common lead substitute in, for example, Belgian fishing shops (Annex XV report consultation #3217 and #3325) is tungsten. This material has a specific mass (19.25 g/cm³) that far exceeds that of lead (11.34 g/cm³), which makes it a good lead substitute from a practical point of view. The high price compared to lead explains its limited use. Tungsten (pure) is considered less toxic than lead, but the grade practically used contains toxic nickel and cobalt. The material is not chemically inert and the actual environmental impact seems still unclear.

Of the possible alternatives, only tungsten has a higher density than lead. As a result, future sinkers will tend to be larger in volume than today's lead sinkers. Where the volume gain interferes, tungsten with a density of 19.3 g/cm^3 and bismuth with a density of 9.8 g/cm^3 would be available. Where volume gain is critical, SEAC considers that the choice of feasible materials to substitute lead is limited, which may complicate switching to alternative sinkers.

Tungsten metallic seems reserved for industrial processing for fishing sinkers and lures because of its extremely high melting point and hardness. Bismuth and tin can be considered available for DIY applications and especially for home-casting.

Feedback from the consultation on the Annex XV report (#3207, #3217) suggests that iron powder embedded in a biodegradable plastic (polyhydroxyalkanoates (PHA) or polyhydroxy fatty acids (PHF)) should also be considered as an alternative. These are naturally occurring water-insoluble and linear biopolyesters formed by many bacteria as reserve materials for carbon and energy, which are biodegradable and are used to produce bio-based plastics. SEAC is missing public information on this alternative, especially on market availability and prices.

Casting tests (Annex XV report consultation, #3217) with alternative fishing weights (iron powder with polyhydroxyalkanoates (PHA) binder; mass density of ~5 g/cm³; 3D volume enlargement of approximately 25 %) was found to reduce casting distance by 5 % in tailwinds and approximately 10 % in headwinds. Regarding flow interaction, the same study did not find a negative correlation between flow interaction and flow velocity at the time of angling.

In the consultation on the Annex XV report, the coating of lead sinkers was raised as another option in addition to using alternative materials (e.g. #3518, #3260). The Dossier Submitter concludes that this option is not effective, because available information indicates that so far protective coatings have failed to sustain the conditions of the gizzard of birds. SEAC considers that further information on the technical feasibility of enclosing lead permanently to prevent exposure would have been desirable to draw a firm conclusion on this option (see discussion under scope).

Cost assessment

Central to the cost estimates are the Dossier Submitter's assumptions on the extent of EU production of lead fishing sinkers and lures as well as the number of recreational fishers. Based on interviews undertaken with several EU producers and retailers, the Dossier Submitter assumes that there are four EU manufacturers of lead fishing sinkers and lures with a global market, placing between 150 and 400 tpa on the market. In addition, it is assumed that there are ten EU manufacturers with a local market, each placing on the market circa 50 tpa. The built-in assumption for home-casting is that in every EU country (except Denmark where a ban is already in place), approximately one tpa of lead fishing sinkers and lures is manufactured. Thus, the central assumption is that 1 300 tonnes of lead fishing sinkers and lures are produced in the EU every year.

The Dossier Submitter estimates that there are 23 million recreational fishers in the EU, of which 73 % are freshwater fishers while the remainder engage in marine fishing[44]. These assumptions are based on contacts with various fishing associations as well as literature and internet searches.

The Dossier Submitter estimates that the total cost of the proposed restriction option is €9.3 billion (NPV over a 20-year analytical period). The following broad categories of costs were taken into account to estimate the costs of the restriction within the EU:

- R&D costs

European companies that are currently manufacturing lead fishing tackle will incur R&D costs if they wish to develop alternative technologies. No information was provided on this topic by stakeholders via the call for evidence; however, during the ECHA market survey, information was provided by some stakeholders (mainly retailers and manufacturers) on the costs of previous attempts to develop alternatives to lead fishing tackle, and estimated costs of future R&D.

The Dossier Submitter recognizes that effort and capacity required for R&D will vary depending on the size and market (global vs local) of the EU manufacturers as well as their capacity to invest in R&D. The Dossier Submitter assumes a cost of €75 000 (€50 000-100 000) for European manufacturers with a global market (EU market at least), and a cost of €5 000 for manufacturers with a local market (own country/region) between entry into force of the restriction and the end of the first transition period. This results in an annualised cost for the industry of €22 000 (or NPV of €299 000). It is assumed that R&D costs form part of the overall industry compliance costs. In response to SEAC questioning, the R&D costs estimated by the Dossier Submitter were revised upwards slightly.

- Industry compliance costs

The Dossier Submitter assumes that the industry compliance costs are essentially the reformulation costs and, thus, are strongly linked to the selected alternative(s) to replace lead in fishing tackle. These costs include raw material costs, energy costs, loss of recycling

[44] The Dossier Submitter assumes that 10% of fishers are below the age of 12.

benefits and manufacturing equipment costs (i.e. capital costs). For example, manufacturers would incur higher costs than is presently the case if the price of the alternative raw material is higher than that of lead or if changes to the manufacturing process are required such as the need for new moulds or higher energy costs. The Dossier Submitter assumes that the same machinery will be used for the manufacturing of lead and non-lead fishing tackle[45], and that only different moulds and melting temperatures will be used.

Capital costs are driven by the extent to which new moulds are required and this, in turn, is driven by the replacement rate for different types of moulds (i.e. steel/iron moulds have a much higher melting and casting temperature, as well as a longer life than silicone moulds).

Compliance costs are estimated to be €148 million (NPV), of which:

- R&D costs: €0.3 million
- Cost of switching to silicone moulds: €0.1 million
- Cost of switching to steel moulds: €7.6 million
- Cost of purchasing alternative raw materials and associated energy costs: €140 million

Following SEAC questioning, including a query on the assumed price for one of the alternative raw materials (zamac), compliance costs were revised upwards slightly by the Dossier Submitter.

- Retailer compliance costs

These are costs associated with implementing the restriction condition at point of sale and are assumed to be zero. The Dossier Submitter considers that such costs would be part of the normal business and maintenance of the shops/websites. The transition to non-lead fishing tackle is assumed to have no additional cost for the retailers in terms of stock, or loss of profit since fishing tackle is not expected to remain on shop shelves for a long time. The proposed transition period would give enough time for retailers to switch to non-lead alternatives and sell their stocks of lead fishing tackle.

While retailers and suppliers will not be asked to label or re-label individually all the fishing tackle they sell, it is expected that retailers provide an information 'corner', or a poster sufficiently visible, understandable and in the national language of the customer that would raise awareness and consciousness of the customer. It is assumed that this, in turn, will induce a change of behaviour.

- Enforcement costs

It is assumed that REACH enforcement authorities would conduct spot checks of imported fishing tackle (customs), manufacturers' site inspections, retailers' site inspections, and

[45] The Dossier Submitter assumes that the cost of new machinery would be significant and, as such, if new machinery were to be required, other industrial actors already equipped with such machinery would take over the market.

retailers' website inspections at the end of the transition period. The cost of this includes staff time, laboratory testing, overheads and other inspection-related expenses. In addition, the proposed restriction option would allow inspections at the site of use (e.g. on fishing spots) to be performed as well by the national relevant enforcement authorities. The Dossier Submitter assumes that the costs for enforcement authorities and industry will be ca. €55 000 per year for the duration of the analytical period (20 years). This figure represents the standard cost for enforcement assumed for restriction proposals. However, the Dossier Submitter highlights that this is likely an overestimate in this case: the enforcement costs of such a restriction would likely be incurred in the years following the entry-into-effect and would approach zero by the end of the analytical period as compliance increases.

- Consumers and commercial fishers' costs

The Dossier Submitter assumes that once the restriction enters into force, fishers will continue to purchase the same quantity of fishing tackle as today (based on Danish[46] and UK[47] experience). Thus, 5 400 tpa (4 000-10 000) of fishing sinkers and lures would still be purchased yearly in Europe after the full entry into force of the restriction. The costs for the fishers during the 20-year analytical period take into account:

(i) the transition period proposed for the different sizes of fishing sinkers and lures. This period is assumed to be three years for those ≤ 50 g and five years for those > 50 g;

(ii) the current distribution of sinkers' sizes (those ≤ 50 g are assumed to represent 55 % of the market while those > 50 g are assumed to be 45 %);

(iii) the current average price of the alternatives versus the current average retail price for lead.

The current average price of alternatives is derived from the ECHA market survey and mystery shopping exercise. The latter resulted in almost 1 000 unique data entries representing 40 brands. As a result, in the central scenario, the price per tonne for alternative sinkers and lures ≤ 50 g is estimated by the Dossier Submitter to be €324 000. For the low and high scenarios, the Dossier Submitter applies the 5-95 % percentile which generates a price range of €23 000 - €1.5 million. For alternative sinkers and lures > 50 g, the central cost is considered by the Dossier Submitter to be €43 000, lying within a range of €14 000-285 000. It is assumed that lead sinkers and lures ≤ 50 g retail at €30 000 per tonne while those over 50 g cost retail at approximately half that.

The assumed price of lead sinkers and lures in the central scenario is based on discussions held between the Dossier Submitter and some of the main manufacturers in Europe.

Having discussed these ranges with the Dossier Submitter, SEAC understands that the lower and upper bounds represent an extreme scenario: i.e. all alternatives (bought by fishers) would either be the cheapest or the most expensive one. Thus, the Dossier Submitter

[46] 2002 ban on import and sale of fishing tackle for angling with lead concentration > 0.01%.

[47] 1987 ban on the import and sale of fishing weights between 0.06 g and 28.35 g.

acknowledges that these lower and upper bounds are not realistic but were used for sensitivity analysis and allowed for the calculation of a cost-effectiveness range[48].

The current, relatively expensive, prices of alternatives are noteworthy. This is partly attributed to the cost of raw materials and the associated manufacturing processes. However, the Dossier Submitter explains that there seems to be a significant mark-up within the supply chain for some of alternatives which are marketed as 'lead-free', 'non-lead' or 'non-toxic'. The Dossier Submitter expects a decrease in the selling price of alternatives as demand increases and as more alternatives become available on the market.

Based on a literature review, the Dossier Submitter assumes that recreational fishers fish on average 15 days per year, incurring total annual expenses relating to fishing of €1 000. The average yearly expenses per fisher for the sinkers and lures only is estimated to be €100. The Dossier Submitter estimates that the additional expense per fisher per fishing day as a result of this restriction is €2.

The Dossier Submitter assumes the costs incurred by manufacturers of alternatives will be passed onto consumers through increased prices (experience from the UK and Danish bans shows that this was the case). Thus, the compliance costs, including R&D expenses, and retailer costs should not be counted in addition to the consumer costs.

The Dossier Submitter's central cost estimate of €9.3 billion (range €0-48 billion) for recreational fishers is driven mainly by the cost of replacing lead fishing sinkers and lures ≤ 50 g, which is estimated to be €8.7 billion. The cost of replacing those > 50 g is assumed to be €575 million.

A summary of the cost estimates of the proposed restriction within the EU is shown in Table 11.

Table 11: Cost estimates of the proposed restriction related to fishing within the EU

	Total costs (€) NPV – 20 years	Annualised costs (€)
Cost for fishers	**9 300m**	**680m**
of which:		
EU industry compliance costs (including R&D)	148m	11m
EU retailer compliance costs	0	0
Enforcement costs	0.5m	0.04m

[48] The lower bound in this case would imply cost-savings since the cheapest alternatives have lower prices than lead.

- Other costs

As well as the costs that are monetised, the Dossier Submitter notes that there are other possible costs associated with the restriction. For example, there is a risk that it might not be feasible for EU global and local manufacturers to make the switch to the production of non-lead fishing tackle. Consultations between the Dossier Submitter and manufacturers have indicated that if there is no/too short a transition period, global manufacturers would lose half of their revenue and would have to lay off up to half of their staff. For local businesses, it is expected that most of them would be forced into permanent closure. The Dossier Submitter estimates that up to 100 workers in the industry could lose their job. Since many of these workers have relatively low levels of educational attainment it may be difficult for them to find alternative employment.

There could also be an initial cost for those for whom home-casting is a secondary source of income if alternatives are more expensive than lead or if they cannot easily switch to the use of alternatives. However, since such additional sources of income are not always declared to the tax authorities, this potential impact is not considered further.

Another potential cost noted by the Dossier Submitter is that the proposed restriction option could lead to an increase in the incidence and frequency of home-casting of lead fishing tackle, and the associated exposure to children, if the price of non-lead fishing tackle in shops/on web stores rises, and if enforcement at the point of use is not effective.

Finally, the Dossier Submitter suggests that the proposed restriction option could create a littering effect in the environment because of inevitable loss of fishing tackle, which is inherent to the fishing practice, but will depend on the type of alternative used. The cost of this is not discussed further.

Conclusions related to the cost assessment for fishing

SEAC acknowledges that there is a lack of information available with regard to some elements of the costs and thus, a precise estimation of the total cost of the proposed restriction for the EU is difficult to achieve.

SEAC tends to agree with the general approach taken by the Dossier Submitter in assessing the fishing related costs of the proposed restriction, given the available information. SEAC notes that it has not been possible to monetise all of the possible costs and, as a result, the actual cost of the proposed restriction might be higher than that suggested here. SEAC agrees with the Dossier Submitter that the estimates, nevertheless, are useful in that they can be considered in terms of an order of magnitude.

With regard to enforcement costs, the Dossier Submitter assumes that the costs for enforcement authorities and industry will be ca. €55 000 per year for the duration of the analytical period (20 years). However, as already mentioned, in reality, the enforcement costs of a new restriction would likely be incurred in the years following the entry-into-effect and would approach zero by the end of the analytical period. Thus, SEAC would have welcomed a more realistic estimation of these costs, showing the decreasing trajectory, over the 20-year period. However, SEAC notes that these costs represent only 0.01 % of the total estimated costs.

While SEAC acknowledges that retailer compliance costs will be small given that no relabelling is required, SEAC does not agree that these costs should be assumed to be zero, since the provision of posters/informational signs that are required in order to comply with the restriction will incur a cost that will fall on the retailers. More information regarding the size of such an "informational corner" would have been welcome. SEAC acknowledges, however, that such a cost would not significantly affect the overall cost as currently estimated.

In response to SEAC questioning on the exact number of assumed manufacturers in Europe with a global market and the assumed price of one of the included alternatives (zamac), both the compliance costs and the estimated raw material costs were revised by the Dossier Submitter.

In estimating the costs, it is SEAC's view that the Dossier Submitter implemented appropriate information from consultations with the market through its call for evidence and the ECHA market survey, conducted a thorough literature review and carefully considered the experience from other countries where similar bans have been implemented. SEAC questioned the very large ranges that were applied to the price of alternative sinkers and lures but finds plausible the Dossier Submitter's explanation that these are considered extreme and were applied for illustrative purposes. Thus, SEAC agrees with the Dossier Submitter that the prices applied in the central scenario represent the most plausible estimate of the costs, since it is likely the alternatives bought by the fishers in the future will consist of a wide variety of available alternatives. SEAC is of the view that the Dossier Submitter applied the most appropriate methodologies in order to assess the costs of the proposed restriction.

SEAC agrees with the Dossier Submitter that it is likely that costs incurred by manufacturers of alternatives will be passed onto consumers through increased prices and so, should not be double counted. SEAC also acknowledges the experience of those countries where bans are already in place and agrees that the current price of relatively expensive alternatives should reduce over time as demand and competition increase.

3.3.3.2. Benefits

Summary of proposal:

According to the Dossier Submitter, a conclusive quantification of the benefits expected from the proposed restriction is not possible for most sectors due to the lack of data and the non-threshold character of lead with regard to adverse effects on children (neurotoxicity). Instead, the Dossier Submitter considers releases of lead to the environment as a proxy for risk and complemented this analysis wherever possible with a quantification of benefits (avoided mortality of birds, IQ loss in children, and chronic kidney disease in adults).

The Dossier Submitter estimates the proposed restriction to result in a cumulative emission reduction of approximately 633 000 tonnes of lead over the 20-year assessment period (see Table 4). This represents a reduction of 72 % of the quantified emissions of lead that would have occurred in the absence of the proposed restriction.

These avoided emissions will contribute to prevent further lead accumulation in the environment and thereby avoid mortality and sub-lethal effects in birds and other wildlife as a result of lead poisoning via primary and secondary routes. The Dossier Submitter partially monetised the mortality of birds from primary ingestion of lead gunshot indicating an annual

avoided loss of €114m (central estimate).

Regarding human health, the Dossier Submitter states that the most important impacts relate to the protection of children in households that frequently consume game meat. It is estimated that a ban of large-calibre lead bullets and lead gunshot could avoid IQ loss of ≥ 1 IQ point in about 7 000 children per year, corresponding to an avoided welfare loss of roughly €70 million per year. Furthermore, the Dossier Submitter estimates that the risk of chronic kidney disease (CKD) would be reduced in about 1 150 individuals, valued at €7.5-75 million per year.

A summary of these and other benefits of the proposed restriction is given in Table 12.

Table 12: Summary of benefits of the proposed restriction

Main impacts identified	Uses contributing to impacts	Benefits quantified?
Environment		
Avoided poisoning of wildlife (birds)	Hunting with gunshot (use 1) Hunting with bullets (uses 2a, 2b) Sports shooting with gunshot (use 3) Outdoor shooting using airguns (use 5) Fishing sinkers and lures (use 7)	**Quantified**: Avoided mortality of > 1m birds per year from primary ingestion of gunshot, valued at €114m; 135m birds at risk of primary poisoning from gunshot and 7m from fishing tackle; 14m birds at risk from secondary poisoning (all types of ammunition) **Not quantified**: Avoided sub-lethal effects on birds; effects on other wildlife
Avoided risks to soil, surface water and groundwater	Sports shooting with gunshot (use 3) Sports shooting with bullets (use 4) Outdoor shooting using airguns (use 5) Other outdoor shooting (use 6)	No
Avoided poisoning of livestock	Sports shooting with gunshot (use 3) Sports shooting with bullets (use 4) Outdoor shooting using airguns (use 5) Other outdoor shooting (use 6)	No
Positive impact on wildlife, ecosystem, and associated leisure activities (including protection of wildlife species with critical conservation status)	Hunting with gunshot (use 1) Hunting with bullets (uses 2a, 2b) Fishing sinkers and lures (use 7)	No
Overall positive impact expected based on the environmental footprint of the alternatives	All (uses 1-7)	No
EU Birds Directive, CMS and AEWA commitments fulfilled	All (uses 1-7)	No
Human health		
Avoided exposure to lead via consumption of game meat	Hunting with gunshot (use 1) Hunting with bullets (use 2b)	IQ loss: €70m per year CKD: €7.5-75m per year
Avoided exposure to lead from home-casting	Fishing sinkers and lures (use 7) Hunting with bullets (use 2b) Other outdoor shooting (use 6)	No
Avoided exposure to lead from sports shooting (lead dust)	Sports shooting with gunshot (use 3) Sports shooting with bullets (use 4) Outdoor shooting using airguns (use 5) Other outdoor shooting (use 6)	No

Avoided exposure to lead (via the environment) from drinking water and food	Sports shooting with gunshot (use 3) Sports shooting with bullets (use 4) Outdoor shooting using airguns (use 5) Other outdoor shooting (use 6)	No

SEAC conclusion(s):

In principle SEAC agrees that the approach taken by the Dossier Submitter to use the releases of lead avoided as a proxy for the benefits of the restriction is a viable option to assess the benefits of the proposed restriction taking into account the lack of data to quantify the impacts of lead use on the environment and human health.

Nevertheless, SEAC considers that the benefits resulting from lead emissions avoided are likely to depend on the particular use of lead in hunting, sports shooting and fishing, and the specific risks arising from this use, for example the primary or secondary poisoning of birds, human exposure to lead via game meat consumption or the contamination of soil and groundwater. This conclusion is supported by the qualitative risk assessment carried out by RAC, which indicated different probabilities and severities of the possible risks of the use of lead in outdoor shooting and fishing.

SEAC would like to emphasise that the unquantified benefits of the proposed restriction are likely to be significant. In this respect, it is important to note that the monetised values estimated by the Dossier Submitter only reflect a part of the impacts of lead use in outdoor shooting and fishing. As such, they underestimate the benefits of the proposal and hence should be interpreted as an illustration but not as a comprehensive estimate of the environmental and human health impacts to be expected.

Key elements underpinning the SEAC conclusion(s):

A. Impacts of lead use in outdoor shooting and fishing

Environmental impacts

The main environmental impact of lead use in outdoor shooting and fishing is the primary and secondary poisoning of birds leading to increased mortality as well as sub-lethal effects. According to the Dossier Submitter, 135 million birds are at risk of primary poisoning from lead gunshot and seven million birds because of ingestion of fishing sinkers and lures. In addition, 14 million birds are at risk of secondary poisoning from all types of ammunition.

For assessing the impact of primary poisoning, i.e. via the direct uptake of lead gunshot or fishing tackle by birds, the Dossier Submitter adopted a similar approach as applied in the restriction proposal on lead gunshot in wetlands[49]. The assessment includes an estimate of the annual value of mortality of birds avoided for 17 species (see Background Document Annex D.5.1) based on the replacement costs of 1.2 million birds dying each year of lead poisoning after direct ingestion of lead gunshot.

[49] For details, see SEAC's opinion pp.59-63: https://echa.europa.eu/documents/10162/07e05943-ee0a-20e1-2946-9c656499c8f8

This quantitative estimate only covers a part of the total impact on birds, because numerous factors are not included:

- Bird species affected: Not all species prone to direct ingestion of gunshot are covered by the assessment. As supported by RAC, 41 bird species are considered to be at risk of primary lead poisoning from gunshot.

- Impacts of secondary poisoning: Mortality of birds due to secondary poisoning was not quantified. However, with 14 million birds at risk from 29 species, including several threatened or endangered species, this impact is likely to be substantial. There is ample evidence confirming the socio-economic impacts of secondary poisoning on raptors and scavenging birds. For example, Pain et al. (2019) estimated the annual replacement costs of raptors dying from lead poisoning between €25 million and €457 million for four species (see Background Document, section 2.5.3.3.4).

- Impacts of fishing tackle: Seven million birds may also be affected by lead poisoning from ingesting fishing tackle, including 22 water bird species. These impacts were not quantified by the Dossier Submitter.

- Impacts of sub-lethal effects: Sub-lethal effects, such as physiological or behavioural effects, could have negative consequences on bird populations, especially for threatened or endangered species where population sizes are small.

Furthermore, mortality of birds was monetised based on market prices of captive-bred birds assuming that these would be released to compensate for the loss due to lead poisoning in order to maintain hunting opportunities. SEAC considers that it is uncertain to what extent current market prices reflect the total value of the birds affected by lead poisoning to society. As market prices relate to the use of birds for hunting purposes, other use and non-use values are not reflected, e.g. the value of birds related to other leisure activities (such as bird watching) or the contribution of birds to ecosystem services and the functioning of ecosystems in general. Hence, the market price data used only captures part of the total value related to the bird species assessed. SEAC considers that it is very likely that values indicated by market prices are lower than the marginal willingness-to-pay of society.

In addition to the avoided impacts on birds, it is important to also consider other positive impacts in order to account for total environmental benefits of the proposed restriction, i.e.

- impacts on other wild species than birds, e.g. mammals

- impacts on livestock (ruminants) and other domestic animals

- prevention of soil and groundwater contamination and related remediation costs

- the contribution of the proposed restriction to ecosystem health in general and all related services.

Overall, SEAC underlines that the monetised benefits estimated by the Dossier Submitter should be seen as an illustration of the positive impacts of the proposal, but as such underestimate the total environmental benefit. Therefore, it is crucial to consider monetary estimates in conjunction with the ample qualitative information on environmental impacts of

lead use in outdoor shooting and fishing in the Background Document.

Human health impacts

Humans are exposed to lead originating from outdoor shooting and fishing via two main exposure routes: food and inhalation. The different uses covered by the proposal contribute to the main health impacts identified by the Dossier Submitter (neurotoxicity in children and chronic kidney disease in adults) to varying degree.

Based on EFSA data on the lead content in game meat, the Dossier Submitter estimated the human health impacts that will be avoided by implementing the proposed restriction and monetised these benefits using established methodologies (value of IQ loss for neurotoxicity, value of DALYs for chronic kidney disease). RAC overall supports the quantitative risk assessment provided by the Dossier Submitter, which forms the basis of the human health impact assessment.

The monetised impact of IQ loss avoided estimated by the Dossier Submitter does provide an indication of the socio-economic consequences of lead contamination of game meat. However, SEAC underlines that the figure estimated does not present a precise and robust quantification of these consequences due to the following limitations and uncertainties:

- Blood lead levels: RAC confirmed a large variability in the game meat lead levels and recent evidence (Pain et al., 2022) suggests higher lead levels in small game than the levels estimated by the Dossier Submitter based on EFSA data. Indeed, RAC concluded in its supplementary opinion on this issue that the EFSA dataset is likely to underestimate lead concentrations in small game meat, which may result in an underestimation of the total health impacts on children.

- Correlation between blood lead levels and IQ: In addition to the EFSA Benchmark Dose Levels (BMDL) used by the Dossier Submitter, there are models that indicate IQ loss at much lower BMDLs (see RAC opinion).

- Population included: The Dossier Submitter quantified IQ loss for children up to 7 years of age in the assessment. Unborn children, which are most sensitive for neurotoxic effects resulting from lead exposure, are not covered by the assessment.

- IQ loss covered: The Dossier Submitter assumed an IQ loss of 1 point for those children exposed to or above the equivalent blood lead level. Potential higher IQ losses are not accounted for.

- Valuation of IQ loss: The value of IQ loss is monetised based on the expected decrease in lifetime earnings. The Dossier Submitter assumes a value of one IQ point of €10 000 based on Lin et al. (2018). SEAC notes that in other recent scientific publications (e.g. Remy et al., 2019) this value is assumed to be nearly twice as high. SEAC considers that these values of IQ loss illustrate the cost to society resulting from the adverse neurodevelopmental effects in children, but as such should not be taken as precise monetisation, because (i) other potentially relevant impacts, such as costs for additional educational measures are not included, (ii) they do not capture all impacts of neurodevelopmental effects resulting from lead exposure, e.g. social or behavioural

consequences[50] and (iii) the correlation of IQ and lifetime earnings is a matter of scientific debate (e.g. Grosse and Zhou, 2021).

With regard to the impact on CKD in adults, the range of values estimated can be considered as an indication of the benefits to be expected, similarly as for IQ loss. However, SEAC agrees with the Dossier Submitter that the estimates are likely to be less robust, because basic assumptions (the use of EFSA BMDLs) tend to contribute to an overestimation of impacts (as confirmed by RAC).

Inhalation of lead fumes or dust takes place during the production of fishing tackle or bullets for shooting at home ('home-casting'). There is no conclusive information available on the extent of home-casting activities within the EU. Therefore, it is not possible to quantify the respective health impacts. The Dossier Submitter expects that the proposed restriction will prevent future home-casting as it bans the use of lead fishing tackle as well as bullets for hunting.

Another exposure route of humans to lead from outdoor shooting identified is via food and drinking water, which contains lead through soil and groundwater contamination from shooting ranges. SEAC notes that, according to RAC, there is not enough data to assess the human health risks resulting from these sources and it is uncertain to what extent this route contributes to lead exposure of humans.

B. Emissions and use-specific considerations

Hunting

For gunshot, the Dossier Submitter estimated emissions on the basis of available data on use volumes and an estimate of the number of hunters affected, excluding the impacts of the restriction of lead gunshot in wetlands.

For bullets, the Dossier Submitter estimated emissions for small and large calibres on the basis of hunting bag statistics making assumptions on the calibre used per type of quarry and the number of shots spent per animal.

Although these estimates are uncertain, SEAC considers that the figures provided are sufficiently robust to indicate the order of magnitude of lead emissions from hunting (uncertainties in the assessment are listed in section 3.4.2).

Sports shooting with lead gunshot

The amounts of lead released as estimated by the Dossier Submitter and by FITASC (Annex XV report consultation, comment #3221) show a large difference. Even with the revisions and explanations from the Dossier Submitter, estimated releases still seem to carry uncertainties and a calculation of the amount of lead used in sports shooting with gunshot which is released into the environment proves to be unexpectedly complex. The amount of 24 500 tonnes/year that is used as a mid-range value by the Dossier Submitter is the average of the initial

[50] For instance, Grandjean and Landrigan (2014) found that factors such as as antisocial behaviour, criminal behaviour, violence are also relevant when assessing the social costs resulting from IQ loss.

estimate by the Dossier Submitter of 35 000 tonnes/year, based on data from the lead CSR (with data from shooting ranges in Cyprus being extrapolated to the total EU) and data submitted by FITASC in the consultation on the Annex XV report (#3221) which reported a total of 14 000 tonnes of lead per year. The data in comment #3221 are based on an annual total of 450 million clay targets sold in the EU (including UK). Considering the ratio of spent cartridges to clay targets will be about 1.2:1, this results in about 520 million cartridges being used in Europe, which in turn will give the amount of lead indicated. Though the Dossier Submitter discusses these arguments, they assume the amounts reported by FITASC are an underestimate because production capacity of clay targets in the EU seems to be higher than reported by FITASC. Moreover, there are gunshot shooting disciplines that do not use clay targets.

However, SEAC notices that available data (Baer, 1995) show that in the United States between 1970 and the mid-nineties, yearly use of clay targets seems to have been on average 560 million, which seems to compare relatively well to the FITASC value for the EU. Moreover, data that can be deduced from REACH applications for authorisation on the EU market for clay targets, also point to a total for the EU of around 500 million targets. These data show that the average tonnage used by the Dossier Submitter means that about 900 million cartridges are used in the EU. If this is correct, there are some 300-400 million cartridges used in other disciplines than clay target shooting. This difference seems rather large and it is questionable if this can be fully explained by use of cartridges in other disciplines like "helice shooting". In this respect it should be noted that FITASC clarified that the number of cartridges being used per year in the EU as stated in comment #3221 in the Annex XV report consultation does include other sports shooting disciplines apart from clay target shooting.

SEAC learned that independent numbers on cartridges used are not easily available (for example from Eurostat's statistics on the production of manufactured goods and international trade in goods), so it has to conclude that the discrepancy between numbers cannot be completely resolved. In view of the available data, SEAC considers the average value of 24 500 tonnes used by the Dossier Submitter as the central estimate, can only be considered an upper limit. A more plausible central estimate may be considered to be somewhere in the range of 14 000-24 500 tonnes/year.

In discussion with the Dossier Submitter, SEAC learned that the number of cartridges that can be estimated from the number of cartridges fired at typical shooting ranges (Table 2-46 in the Background Document, data used in Tables 2-47, 2-48, 2-49 and 2-50), which would indicate a yearly lead release that is even lower than the FITASC estimate, should not be considered reliable enough to be used for this estimate.

Sports shooting with bullets

In the revised analysis of the Dossier Submitter, RMMs that are already in place are taken into account. For the baseline, the Background Document estimates that over a period of 20 years, 8 400 tonnes of lead (range: 110-30 000 tonnes) would be released into the environment. SEAC notes the large tonnage range and considers especially the lower limit as not fully plausible. However, in view of the explanation on the estimates concerning the use of lead for bullet shooting given by the Dossier Submitter in Annex B.9.1.3.2 and in absence of further data, SEAC considers these values as best available estimates.

For the Dossier Submitter's preferred restriction option (RO2c) this release would be reduced

by 5 801 tonnes (central estimate; range: 83-20 434 tonnes). To allow a better overview, an extract of Table 2-42 of the Background Document, which gives estimates for avoided releases of the various sub-options 2a-2d, is shown in Table 13 below.

Table 13: Avoided emissions for the different RO2 sub-options

Restriction option		Estimated number of ranges affected	Emission reduction (tonnes) per year after TP	Emission reduction (tonnes) over 20 years (i.e. in the 15 years after the TP)	Relative emission reduction compared to baseline	
					Over 20 years	Over 15 years after TP
RO2 **Ban on the use of lead bullets for sports shooting with a derogation at notified outdoor locations where no agricultural activities take place and the following measures are in place (see different RO2 options below):**						
RO2a	Trap chamber, or sand trap (with impermeable barrier) or sand/soil berm (without impermeable barrier), combined with roof or water management system	2 440	299	4 487 (71-15 682)	54 %	71 %
RO2b	Trap chamber, or sand trap (with impermeable barrier), combined with roof or water management system	7 200	348	5 226 (78-18 349)	62 %	83 %
RO2c	Trap chamber, or 'best practice' sand trap with impermeable barrier and roof or permanent cover and water management system	7 880	387	5 801 (83-20 434)	69 %	92 %
RO2d	Trap chamber for static disciplines; AND 'best practice' sand trap for dynamic disciplines	8 000	386	5 786 (83-20 374)	69 %	92 %

Fishing

In order to estimate the effect of the proposed restriction on the amount of lead emissions due to fishing, the Dossier Submitter begins by examining the amount of emissions that are being generated at present. In order to do this, the Dossier Submitter takes into account the number of fishers, the number of vessels equipped with sinkers and an estimate of the annual tonnage of lead lost in fishing tackle (based on a literature review).

To estimate the reduction in lead emissions that would result from the proposed restriction,

the Dossier Submitter takes into account the proposed transition period for sinkers and lures ≤ 50 g (i.e. three years) as well as that for sinkers and lures > 50 g (i.e. five years) and finds that the current level of emissions from lead in fishing tackle would be reduced by 48 300 tonnes over the 20-year analytical period considered (51 % reduction compared to the baseline). The remaining releases would come from lost fishing nets, ropes and line containing enclosed lead. If only sinkers and lures ≤ 50 g were banned, avoided emissions would decrease to 28 050 tonnes.

SEAC agrees with the methodology applied by the Dossier Submitter and considers that the figures provided are sufficiently robust to indicate the order of magnitude of lead emissions from fishing.

3.3.3.3. Other impacts

Summary of proposal:

In the Background Document, the Dossier Submitter reports on information received in the Annex XV report consultation on the impact the proposed restriction may have on the frequency of hunting and the economic consequences thereof.

With regard to lead bullets, the Dossier Submitter notes that while non-civilian uses are not within the scope of the proposed restriction, the restriction may have unforeseen consequences on the supply for these uses, because the lead ammunition lines are shared between civilian and military use. This is considered relevant for defence uses where security of supply considerations mean that contingency planning must be in place in the event of a sudden increase in demand (e.g. a conflict situation). However, in the responses to comments from the Annex XV report consultation, the Dossier Submitter considers any impacts on non-civilian uses will be negligible, as the proposed restriction for sports shooting with bullets foresees a derogation conditional on the implementation of appropriate and effective RMMs.

For the fishing sector, the Dossier Submitter reports on the following other impacts to society:

- Distributional impacts:
    - Distributional impact in terms of generated tax revenue (with an average VAT rate of 20 %) estimated to be worth €136 million annually.
    - Distributional impact in terms of supply chain surplus gain (EU and non-EU) of €180 million per annum.

- Impact on trade and competition: The Dossier Submitter reports on the prevailing trends regarding trade and competition (in particular the erosion of EU production of lead fishing tackle and the concurrent growth of imports) and notes that the proposed restriction is not expected to affect trade and competition beyond what is expected to occur in the absence of a restriction. It is noted however that the proposed restriction could be an opportunity for EU manufacturers of fishing tackle as it will create a new market for non-lead fishing tackle in the EU while exports of non-lead fishing tackle might also grow in the future due to regulatory changes in non-EU countries.

- Impact on innovation: The Dossier Submitter considers that the proposed restriction could promote innovation within and competitiveness of European fishing tackle

manufacturers as it will provide a push for the development or non-lead alternatives.

SEAC conclusion(s):

SEAC considers it possible that a short-term drop in hunting activities could result from the proposed restriction; however, there is no evidence indicating a long-term impact on hunting in the EU.

An upgrade of RMMs may need to be undertaken for both sports shooting with gunshot and with bullets, which will require high investments. The impacts of such activities cannot be judged solely by the total amount of investment for the European Union as a whole. Depending on the way this would be organized, different actors in this field would be impacted much more than others.

For sports shooting with bullets, the indirect effect of a reduced availability of civilian shooting ranges for practice of military reserve soldiers has been mentioned already and is discussed further as an uncertainty in section 3.4.2 below.

SEAC concludes that no major impact on the production of ammunition for military and other non-civilian uses are to be expected from the proposed restriction. Hence, defence capabilities will not be negatively affected.

SEAC agrees with the assessment carried out by the Dossier Submitter and considers that available information does not indicate major other impacts to be expected as a result of the proposed restriction.

Key elements underpinning the SEAC conclusion(s):

In the consultation on the Annex XV report, it was raised that the proposed restriction could force hunters to quit or reduce hunting activities with negative impacts for society as a consequence (#3467, #3333). As supporting information, a survey among hunters was provided indicating that about 25 % of hunters would stop hunting if the use of lead ammunition was banned. SEAC considers that a short-term decrease of hunting activities in response to the proposed restriction is possible due to the efforts needed to change shooting practice and to train with non-lead ammunition as well as potential investments for new equipment some hunters will have to make. However, experience from past regulatory measures on lead ammunition does not provide evidence showing a long-term drop in hunting.

SEAC points out that the data presented by the Dossier Submitter indicate that the need to upgrade RMMs at shooting ranges may be very different from region to region, depending on existing regulations and standard of RMMs already in place. For example, existing rules in Germany seem to fulfil the required standard already to a large extent. Smaller shooting ranges as they exist in e.g. the Nordic countries would be much more affected. This means that the economic impacts of an upgrade will be distributed unevenly in the EU.

Potential negative impacts on the production of lead ammunition for uses outside the scope of the proposed restriction (e.g. military uses) were raised in the consultation of the SEAC draft opinion (e.g. #1022, #1046, #1087, #1098, #1106). SEAC notes that manufacturers already supply both alternatives and military ammunition. In normal times (with a regular

supply to the military, e.g. for training), supply to civilian uses is essential for a continued economic operation of such lines. The present restriction would allow for a continued operation of such lines, because also in the future lead-based ammunition would be used for sports shooting. Even though the ban on use of lead bullets in hunting may affect total demand and thus profits generated by the production lines also supplying uses outside the scope, it is unlikely that this would impact the profitability of these lines. As under the conditions of the proposed restriction sports shooting with bullets (annual use volume: 42 000 tonnes) can continue, production is expected to be still economically viable. The decrease in demand from hunting with bullets (annual use volume: 134 tonnes) will only lead to a small – if any – loss in profits generated from these lines. Therefore, a surge in defence orders in times of crisis can be handled and supply to the military will not be affected.

It should be noted that this conclusion is implicitly based on the assumption that the implementation of the proposed restriction will not cause a significant decrease in the volume of lead used for bullets in sports shooting. This might happen if many shooting ranges would choose to close instead of upgrading their RMMs. In that case a significant part of sports shooters may be forced to give up their hobby and thereby the volume of lead ammunition used in sports shooting would be reduced.

In terms of other indirect impacts, one of the comments received in the consultation on the SEAC draft opinion (#1059) mentioned that Cyprus has developed into a centre for foreign sports shooters and international competitions. A lead ban would not only negatively impact the shooting ranges, but also the tourist infrastructure that benefits from the visits of foreigners. A quantification of this impact is not available and therefore has not been taken into account.

3.3.3.4. Overall proportionality

Summary of proposal:

In its assessment of proportionality, the Dossier Submitter compares the cost estimates (summarised in section 3.3.3.1 above) with the identified benefits (summarised in section 3.3.3.2 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 CKD (€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 largely 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 4). 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):

Hunting

The use of lead in hunting is a major contributor to the risks to be addressed by the proposed restriction. Based on available information on these impacts, the cost-effectiveness analysis as well as cost-benefit considerations SEAC concludes that the proposed restriction can be considered to be proportionate.

Overall, SEAC considers that a conclusion on whether a derogation of the use of lead ammunition in historic firearms in hunting (and sports shooting outside of shooting ranges) would be justified on socio-economic grounds or not is not possible due to lack of information on the impacts involved. As the benefits of this niche application are unclear, the conclusion on proportionality of a derogation have to be taken on the basis of policy priorities.

Sports shooting

Based on the assessment of the cost and benefit data presented, SEAC concludes that the proposed restriction as it relates to sports shooting with gunshot can be considered proportionate in all its potential options (RO1, RO2, RO3 and RO4 – see descriptions above). Still, there are considerable differences between the restriction options, which may lead to preference for one or the other. In any case, from a comparison with the restriction on lead in PVC, it becomes clear that eliminating or reducing the role of lead in sports shooting with gunshot is a more cost-effective means of reducing the release of lead into the environment than reducing lead in PVC.

For sports shooting with bullets, it should be noted that the range of the cost-effectiveness ratio for the preferred option is relatively large, with the upper end of the range being comparatively high, which may cause this option to seem less attractive. However, it should be noted that this is driven by the low value of the lower limit of the amount of lead used (which SEAC considers less plausible), which distorts the picture. As far as the central value is concerned, the preferred option seems to be well in line with other restrictions on lead.

Fishing

Based on available information on the impacts of the proposed restriction, the cost-effectiveness analysis as well as cost-benefit considerations, SEAC concludes that the proposed restriction can be considered to be proportionate.

There are some uses for which a ban might be considered disproportionate and where requests for derogations based on socio-economic grounds were received in the consultation on the Annex XV report, e.g. sinkers and lures > 50 g or lead split shots. SEAC sought further

information to conclude on the impacts of a derogation of these uses in the consultation on the SEAC draft opinion. However, no evidence to support a derogation on socio-economic grounds was received.

Key elements underpinning the SEAC conclusion(s):

A. General issues

The Dossier Submitter assessed proportionality of the proposal by considering different factors including costs and benefits, cost-effectiveness of emission reduction as well as affordability for hunters, shooters and fishers. Given the complexities and uncertainties of the assessment, SEAC considers this approach as appropriate to facilitate the evaluation of proportionality.

Given the very limited quantitative information on the benefits of the restriction, the cost-effectiveness analysis is a useful tool to indicate the relative cost per kg emission avoided for the different uses covered. In this respect, SEAC notes that in general the proposed restriction could be considered as a cost-effective measure to reduce lead emissions when compared to other risk management measures on lead that were adopted in the past. However, as only limited information on the socio-economic consequences of these emissions is available and no scientifically- or policy-based emission targets for lead are established that could serve as a benchmark, SEAC can only draw incomplete conclusions on proportionality on the basis of cost-effectiveness. As stated earlier, SEAC underlines that lead emissions covered by the proposal are likely to result in variable impacts depending on the use (e.g. shooting), in which form lead is released (e.g. size) and where emissions occur.

Even though generally accepted benchmarks on the cost-effectiveness ratios to judge proportionality are not available, it is still useful to compare the cost-effectiveness ratios of this restriction with those of other restrictions, in particular those involving lead. So far, a comparison can be made only with the restriction of lead gunshot in wetlands (central estimate: €9/kg; range: €0.3-25/kg) and lead in PVC (central estimate: €308/kg; range: €99-2 884/kg). In the Background Document, data on six other restrictions (D4 and D5 in rinse-off cosmetics, DecaDBE, Phenylmercury compounds, PFOA, PFOA-related substances, and Hg in measuring devices) are available as well and show a range of €1-19 200/kg, but because they refer to different health and environmental impacts, direct comparisons have only limited value.

Following the representation of the Dossier Submitter, the ranges of cost-effectiveness ratios are shown in Figure 1 below.

Given the limitations of cost-effectiveness ratios, SEAC considers that a consideration of the affordability of the proposed restriction for the affected users, i.e. hunters, shooters and fishers, is very useful to complement the assessment and to get a better indication of the consequences of the proposed restriction.

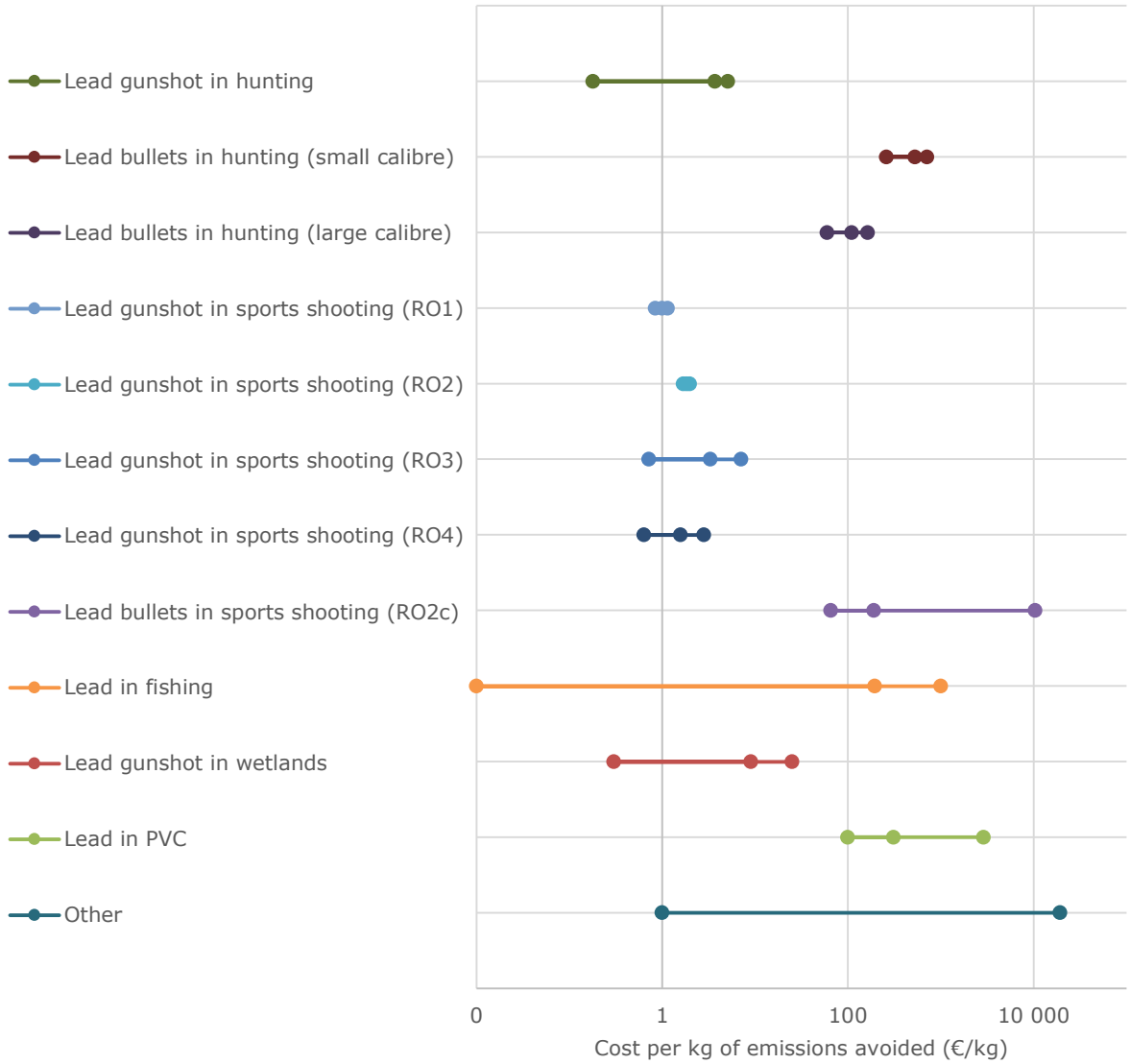

Figure 1: Comparison of cost-effectiveness of this and previous restriction proposals

Note: 'Other' includes D4 and D5 in rinse-off cosmetics, DecaDBE, Phenylmercury compounds, PFOA, PFOA-related substances, and Hg in measuring devices.

The x-axis of this representation is logarithmic. This allows to plot all entries in one graph but tends to mask differences between the various entries.

B. Hunting

B1. Hunting with gunshot

The ingestion of lead gunshot can be considered as the main cause of lead poisoning in birds. The proposed total ban of lead gunshot will effectively reduce this source of risks to the environment, which can be expected to result in numerous benefits (as elaborated by SEAC in its opinion on the restriction of lead gunshot in wetlands). Also, terrestrial bird species are known to pick up lead pellets originating from shot substantiating that benefits can also be

expected from the proposed restriction in addition to the impacts of the wetlands restriction. The quantitative estimate of the benefits indicates that they could be significant, also taking into account that they capture only part of the positive impacts for society. As alternative gunshot is already commonly used by hunters, which can be expected to further increase due to the wetlands restriction, SEAC considers that the costs are likely to be manageable. This conclusion is supported by the assessment of affordability to hunters provided by the Dossier Submitter (see section 2.5.3.3.1 in the Background Document). Moreover, SEAC considers that the cost assessment conducted in the Background Document is rather conservative and that the lower end of the range of cost estimates provided seems more likely to reflect the costs of the proposed restriction.

Apart from these cost-benefit considerations, the cost-effectiveness analysis also supports the proposed restriction as a cost-effective measure to address the risks of lead gunshot for the environment and human health.

B2. Hunting with bullets

Compared to gunshot, the use of lead bullets affects different bird species, i.e. more predatory and scavenging birds, who pick up bullet fragments from the quarry. Bullet fragments also lead to the contamination of the game meat leading to lead exposure of humans. Also here, only part of the benefits of the proposed restriction could be monetised (IQ loss in children and CKD in adults). However, SEAC considers that available evidence supports the conclusion that substantial benefits are to be expected from the proposed restriction.

For large calibres, the supply of alternatives is well developed and in some Member States these are already commonly used. This situation is quite different with regard to small calibre bullets, where alternatives are not as widely available yet. Moreover, for small calibres the switch to alternatives may require further investment by the hunter in terms of replacing the barrel or the whole gun. At the same time lead emissions from small calibres are lower compared to large calibres. This is reflected in the cost-effectiveness estimates indicating that the ban of small calibres is less cost-effective than the ban of large calibres. However, this would not be sufficient for SEAC to conclude that the ban of small calibre bullets would be disproportionate.

The additional costs to hunters' annual budget can be considered as negligible based on the Dossier Submitter's assessment of affordability.

B3. Derogation requests

SEAC evaluated the impacts of derogating certain uses of lead ammunition from the scope of the proposed restriction. With regard to historic firearms, it is reported in the Background Document (Annex D.1.1.3.2) that very limited data are available for this use. However, the use is considered to be very small, both in the number of guns that are concerned and the amount of lead released to the environment that originates from such guns. In a study submitted in the consultation on the Annex XV report (#3400) the use of lead ammunition for muzzle loading guns in the EU is currently estimated at 0.8 tonnes/year for hunting and 682 tonnes/year for use at a shooting range (which would still be possible, if the shooting range fulfils the conditions set by the proposed restriction). For the use in hunting, slightly higher emission estimates (~2 tonnes/year) were received in the consultation on the SEAC draft opinion (#1041). It is unclear to what extent shooting outside of designated shooting

ranges, e.g. historical re-enactments, would be affected by the proposal. In view of the relatively low level of use of such guns, the related comparatively low release of lead to the environment and limited contribution to lead levels in game meat, SEAC considers that the impacts of a derogation for this use would be small. However, there is no information to assess the benefits related to the continued use of muzzle loaders outside of shooting ranges. Therefore, SEAC considers it ultimately depends on policy priorities whether a derogation would be proportionate or not.

Similarly, the environmental and human health impacts of a derogation of other niche applications like ammunition used in seal hunting and non-expanding ammunition used for hunting, like full metal jacket and open tip match bullets, are likely to be minor. As the benefits of these niche applications are unclear, the conclusion on proportionality of these derogations has to be taken on the basis of policy priorities.

C. Sports shooting

C1. Sports shooting with lead gunshot

It should be realized that for sports shooting, the amount of lead released carries an uncertainty. This means that the cost-effectiveness ratio (cost/kg avoided lead) may be different from that in Table 4 above.

To illustrate what differences the use of different values and assumptions that have been mentioned throughout the Background Document may have for the total costs over 20 years and the cost-effectiveness ratio, SEAC performed some calculations of its own for the Dossier Submitter's preferred option (i.e. a total ban of lead gunshot in sports shooting). The following scenarios were distinguished:

1. No price difference between lead and steel gunshot and no replacement of guns

2. Steel gunshot 2 % more expensive than lead gunshot, no gun replacement

3. No price difference between lead and steel gunshot, 10 % replacement of guns (price €3 000/gun), following the calculation of the Dossier Submitter

4. Steel gunshot 2 % more expensive, 10 % replacement of guns (price €3 000/gun), following the calculation of the Dossier Submitter

Calculations of these different scenarios were performed for a yearly release of lead of 14 000 tonnes (FITASC figure), and the 35 000 tonnes (upper limit considered by the Dossier Submitter). This yields the following results with regard to lead reduction, costs, and cost-effectiveness ratios:

Table 14: Cost-effectiveness ratios for sports shooting with gunshot, and their dependence on different input parameters.

Scenario Nr	Lead release [tonnes/year]	Lead release avoided [tonnes/20 years]	Extra cost ammo [million €/year]	Cost guns [million €/year]	Total cost [million €/20 years, NPV, 4 %]	C/E ratio [€/kg]
1	14 000	210 000	0	0	0	0
2	14 000	210 000	4.8	0	43.6	0.2
3	14 000	210 000	0	34.0	310.5	1.5
4	14 000	210 000	4.8	34.0	354.1	1.7
1	35 000	525 000	0	0	0	0
2	35 000	525 000	11.9	0	109.0	0.2
3	35 000	525 000	0	34.0	310.5	0.6
4	35 000	525 000	11.9	34.0	419.5	0.8

Results for 24 500 tonnes/year (the central estimate used by the Dossier submitter) would generally fall in between the range of results obtained from using 14 000 and 35 000 tonnes/year.

The above makes it clear that without further narrowing of the values for the input parameters, it can only be concluded that the cost-effectiveness ratio for a total ban of gunshot in sports shooting will be in a range between €0 and 1.7/kg. Despite the different input values, the range is not that different from the range as given by the Dossier Submitter, which shows that the total analysis is rather robust and the cost-effectiveness ratio will likely remain in the low single digits.

C2. Sports shooting with bullets

The range of estimated lead released in the baseline scenario is rather large. Therefore, also the reduction that is expected to result from the implementation of the proposed restriction will have a rather large range. As discussed above, this will shift the upper limit of the cost-effectiveness ratio to a rather high value. In order to judge the attractiveness of RO2c it is also important to look at the affordability discussion below.

C3. Affordability

Because the impact of the proposed restriction for sports shooting will be mainly felt by a specific group of the public – i.e. the users of ammunition in sports shooting (and not by companies) – it may be appropriate to look at the costs for the individual shooter that are expected to result from the proposed restriction, because it may influence his/her decision to continue or abandon activity in this sports discipline.

For the total ban on the use of gunshot, the data as provided by the Dossier Submitter suggest that costs per active shooter will be between €4 and €12 per year. As indicated above, it may even be argued that costs are overestimated, so in reality costs per shooter may even be

lower.

However, it should be taken into account that individual shooters that need to purchase a new gun may have one-time costs of up to a few thousand euros. On the other hand, such a new gun may last a long time, so that costs per year are not that high.

The picture is different for the restriction option with the optional conditional derogation, where multimillion euros of investments become necessary to upgrade a certain fraction of shooting ranges, mainly at the benefit of a limited group of top shooters.

If the costs of RO4 (mid value €548 million over 20 years) are supposed to be shared by all active sports shooters in the EU (2.5 million) this results in €219 per shooter per 20 years, which gives about €11/year. For an individual this seems quite affordable. However, the situation is different if individual ranges, or clubs operating them, decide to upgrade the available RMMs and have to pay for such costs solely by contributions of their own membership. This may cause significant cost increases for individual members, unless national sports shooting associations will assist in these upgrades. For example, a NPV for an investment over 20 years of €0.9 million, calculated by the Dossier Submitter in Table 2-49 of the Background Document for a shooting range of category D (some RMMs already in place, a site with three stands), to be paid for by a club with 100 members would mean a contribution of €9 000 per member over 20 years (= €450/year), which seems a very high burden for an individual member. For a normal member this burden looks even more unattractive if it is considered that these investments are only performed to accommodate a selected group of top shooters (i.e. if the costs would be calculated per top-level shooter, this would result in a significantly higher number).

For sports shooting with bullets, investments for an upgrade of a range will be much lower. From the data resulting from the calculations of the Dossier Submitter for the preferred option RO2c, as available in detail to the rapporteurs, upgrade costs per site (for those sites that need an upgrade) are found in the central scenario to be between €6 646 and €361 583 over 20 years (average for all sites that need an upgrade: €138 880)[51]. The financial impact for a club with 100 members will now be between €3 and €180 per year (rounded values), with an average of about €70 per year per member. This still seems affordable.

In the above analysis it has to be realized that the costs per shooter will be considerably less for those clubs and ranges (and their members) where appropriate RMMs are already in place, even if only in part. In this respect it also should be taken into account that already now some Member States (e.g. Germany) have regulations in place that require similar RMMs as would be required by the proposed conditional derogation. This means that the regional impacts of the restriction may be felt differently in different countries.

[51] The lower end of this range (€6 646 per site) relates to sites where a sand trap with an impermeable barrier and a roof/permanent cover is already in place and only a water management system needs to be implemented to comply with the RMMs required under restriction option RO2c. The upper end of this range (€361 583 per site) relates to sites where only a soil berm is currently in place and a sand trap with an impermeable barrier, a roof/permanent cover and a water management system need to be implemented to comply with the RMMs required under restriction option RO2c.

D. Fishing

Cost-effectiveness

The proposed restriction is anticipated to reduce lead releases to the environment by about 48 300 tonnes over a 20-year analytical period while costs in the central scenario have been estimated at €9 300 million, resulting in a central cost-effectiveness estimate of €193 per kg of lead release avoided. The Dossier Submitter estimates a lower bound close to €0 per kg of lead release avoided in case cheaper alternatives are used, and an upper bound of €996 per kg of lead release avoided if all lead fishing tackle would be replaced by the most expensive alternative. SEAC notes that it is more cost-effective to avoid lead releases from fishing sinkers and lures > 50 g than in those ≤ 50 g (~€30 per kg compared to €311 per kg). However, in order to conclude on proportionality also other relevant information on the socio-economic impacts of the proposed restriction will have to be taken into account.

While the proposed restriction for lead in fishing tackle is estimated to be more cost-effective than previous REACH restrictions, it is less cost-effective than the restriction on lead in gunshot in wetlands, which ranged between €0.3/kg to €25/kg and was addressing the same types of environmental impact. Nevertheless, the Dossier Submitter concludes that the proposed restriction is a cost-effective measure for addressing lead releases to the environment from fishing activities.

Affordability

The Dossier Submitter concludes that the proposed restriction is affordable for fishers and retailers but states that it is currently not possible to conclude as to whether this will be the case for EU manufacturers. For the European manufacturers, affordability is, according to the Dossier Submitter, dependent on three main elements:

- proper enforcement of the proposed restriction option;
- the length of the transition period (sufficient time is required for suppliers to transition to non-lead alternatives and for a sufficient level of demand to be established);
- the financial capacity of the industry to invest in new moulds, and/or technologies.

Consultations with manufacturers suggest that global and local manufacturers could adapt if the alternative processes and/or materials have similar physical properties to lead, if they could use existing machinery and equipment, and if they are given sufficient time to adapt. Global manufacturers indicated to the Dossier Submitter that a sudden restriction would result in a loss in revenue and employment (both of which could run to 50 %). Such a scenario would result in closure for most local manufacturers. The Dossier Submitter suggests that some financial support to help the European industry to transition to alternatives could be granted through, for example, the European Green Deal policy.

In terms of recreational fishers, the Dossier Submitter expects that the increased costs associated with the proposed restriction would be fully passed on to consumers and estimates that the purchase of non-lead fishing tackle would induce an additional expense of €30 per fisher per year, equivalent to €2 per day. This figure is derived from estimates of current fishing expenditure (taken from literature reviews and communications with fishing

associations) as well as estimates of the prices of non-lead alternatives (taken from published price indices). The Dossier Submitter notes that alternative fishing tackle ≤ 50 g are in general more expensive than those > 50 g. As such, the additional expense per fisher and year does not change significantly if sinkers and lures > 50 g would be excluded from the ban. According to the Dossier Submitter, this increase represents 3 % of the total expenditure of recreational fishers per year (when equipment, licences, trips etc. are taken into account) and, as such, is deemed affordable.

For commercial fishing, the Dossier Submitter considers that the proposed restriction will have no effect on the value of fish landed while fleet operating profits will not be significantly affected by the projected increase in the price of fishing tackle. Quantitative estimates are not provided by the Dossier Submitter.

With regard to retailers, as previously discussed, both physical and web retailers will have an obligation to comply with the restriction by ensuring that:

- customers are informed of the proposed restriction through information corners/posters etc. (until the transition period enters into force).

- lead is not present in the fishing tackle placed on the market

The Dossier Submitter assumes that these obligations will carry no cost for the retailers.

SEAC agrees with the Dossier Submitter that any increased costs that arise as a result of the proposed restriction option should be affordable for fishers and retailers. Evidence from the United Kingdom and Denmark, where similar restrictions are already in place, indicate that switching to alternative materials is possible for both the European fishing tackle industry and fishers.

In the case of commercial fishers, SEAC agrees with the Dossier Submitter that any price increase would not significantly affect net profits while for recreational fishers the price increase represents only a small proportion of the overall fishing budget and is, therefore, deemed affordable.

While SEAC disagrees with the Dossier Submitter that the cost to retailers will be zero, SEAC acknowledges that the costs associated with the obligation to provide signs and information in stores or on websites is likely to be a one-off expenditure and small relative to a retailer's annual costs.

The data that is available to SEAC indicates that affordability for EU manufacturers will depend on the cost of the alternative chosen and the moulds/technologies that are required for the production process. SEAC acknowledges that there is a risk involved for manufacturers when it is difficult to predict exactly what market will remain for non-lead fishing tackle as a result of the proposed restriction. However, SEAC notes the consultations that were held between the Dossier Submitter and manufacturers and, as a result, SEAC is of the view that the proposed restriction will only be affordable for manufacturers if the alternative processes and/or materials have similar physical properties to lead, if existing machinery and equipment can be used and if the transition period is sufficiently long. Assuming that these conditions are met, the Dossier Submitter expects that manufacturers will continue in the market and any increased costs they face will be passed onto consumers.

3.3.3.5. Uncertainties in the proportionality section

Although the analysis of the proportionality based on cost-effectiveness ratios is common practice in SEAC, it should be realised that generally accepted benchmarks about what cost per kg emission abatement is considered to be proportionate are not (yet) available. This means that conclusions on cost-effectiveness drawn have a certain subjective aspect and are mainly based on a comparison with results of other restrictions. While this may be helpful to compare various proposed options of the current restriction, it is questionable if this is still the case if restrictions with completely different subjects are included.

3.3.4. 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 in any case (i.e. REACH enforcement, environmental protection, police, etc.) and would therefore be expensive and potentially inefficient if only implemented for wetlands. 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 of 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, ISSF or FITASC events). 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 then 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, enforcement structures as they exist in the various Member States are not well suited for this task. The inspection of private persons and possibly to a lesser extent, shooting ranges, could present problems compared to inspections of the placing on the market of ammunition/fishing tackle, because REACH inspectors are not used to/trained for this kind of activity.

In order to facilitate the enforcement of the ban on the use of lead ammunition in hunting while it is still available on the market (i.e. in the case of lead gunshot if a shorter transition period than five years for use in hunting or the optional conditional derogation for sports shooting is implemented, and in the case of lead bullets), SEAC recommends that the text of the restriction entry includes a ban on 'carrying' of lead ammunition in the field, in line with the restriction on lead gunshot in wetlands. Furthermore, colour-coding or marking of individual bullets or shot cartridges (in addition to labelling on the package) could be considered as a means to support enforcement in the field (see discussion in section 3.3).

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 cooperative 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 an 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 'wetlands') 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 book-keeping system of the amount of lead spent in shooting and the amount of lead being recovered. Keeping track of the first part may be a challenge for 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.

In the consultation on the SEAC draft opinion, many comments were received which expressed scepticism if a reliable way of keeping track of spent and recovered lead could be developed and some expressed concerns over an increasingly complex administration and bureaucracy (e.g. #1013, #1016, #1024, #1034, #1060, #1089, #1106, #1134, #1142). However, some (e.g. #1012, #1057, #1059) suggested a pragmatic, low-cost approach to

use the number of clay targets used as the basis for an estimation of spent lead, by linking this to the number of cartridges used. Another comment suggests using the sales of lead cartridges as basis for calculating the recovery rate.

Regarding best practices to reach a 90 % recovery of lead, in the consultation on the SEAC draft opinion, on the one hand statements were made that at a Swedish range that the commenter (#1001) used, 90 % lead recovery was already reached. However, there were no indications on which methods were used. A comment from Germany (#1046) refers to DIN 19470, parts 1 and 2 which apparently describes in some detail the environmental measures that are needed to operate a shooting range in Germany. However, what this would mean for a potential lead recovery rate was not elaborated. On the other hand, some comments (e.g. #1004, #1015) stated that such a recovery rate was impossible to achieve for most smaller shooting ranges, because costs would be excessive. Others (e.g. #996, #1063, #1146) indicated that for new ranges this recovery rate could be achieved, although there was no clear analysis on what this statement was based on.

Some comments received in the consultation on the SEAC draft opinion (e.g. #1063, #1073) claim that annual recovery is not economically viable and suggest allowing for a longer period between lead recovery campaigns. In the opinion of the commenters the very low dissolution rate of lead in the soil may make this acceptable. SEAC also points to the fact that the presence of spent lead shot on a site still carries the risk of ingestion of such pellets by birds, which is part of the environmental risks as described by RAC. This risk would continue to exist as long as gunshot pellets on a range are accessible to birds.

During the development of the Background Document and the RAC and SEAC opinions, the exact formulation and meaning of some definitions has undergone some development. 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 shooters 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 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, RAC and SEAC 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.

3.3.5. 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

In general terms, RAC and SEAC agree with the Dossier Submitter that current activities to monitor the lead concentration in game meat are suitable to monitor the effectiveness of the proposed restriction. However, it is noted that available data on lead content in game meat results from food samples taken during control activities by national authorities and reported to EFSA as part of the Chemical Monitoring (ChemMon) program and are not specifically focused on the monitoring of lead content in game meat hunted with firearms. Potential inconsistencies in the classification of samples have been pointed out in the supplementary RAC opinion[52].

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 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 paragraph 4b and paragraph 6), presents an administrative challenge. This will be especially the case for those countries where 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.

[52] Registry of restriction intentions until outcome - ECHA (europa.eu)

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:

The Background Document includes an overview of the key assumptions made and the main uncertainties identified by the Dossier Submitter separately for hunting, sports shooting, and fishing:

- For hunting, the described assumptions and uncertainties relate to the hunters' and Member States' reaction to the restriction on lead in gunshot in or around wetlands, the reaction to recent initiatives at Member State level, the need for gun replacement, human health risks (see opinion of RAC in section 3.4.1 above), the lack of sufficiently detailed hunting statistics for some Member States, the length of transition periods, and the price of steel gunshot.

- For sports shooting, the described uncertainties relate to the extent to which RMMs are already in place at shooting ranges, human health risks (see opinion of RAC in section 3.4.1 above), the number of shooting ranges in Europe, the amount of lead used, the amount of lead released from bullets, the length of transition periods, and the price of steel gunshot.

- For fishing, the three main uncertainties with regard to the impact assessment described by the Dossier Submitter relate to the EU manufacturers' and consumers' reaction to the proposed restriction, home-casting, and enforcement. Additionally, the Dossier Submitter reports on uncertainties related to the lack of data on recreational fishing, the lack of data on sales and use of lead fishing tackle in Europe, the quantity of lead fishing tackle lost to the environment, and regarding which alternatives will be adopted to replace lead as well as the retail prices of alternatives.

The impact of some of these assumptions and uncertainties on key outcomes of the socio-economic analysis (i.e. release reduction, costs, cost-effectiveness) has been explored in a simple sensitivity analysis.

SEAC conclusion(s):

Overall, the uncertainties related to costs, benefits and proportionality of the proposed restriction are unlikely to have a significant impact on the conclusions reached by SEAC.

Hunting

The main uncertainties recognised by SEAC are summarised in the key elements below.

Sports shooting with gunshot

SEAC notes the following uncertainties. To some extent these have already been mentioned in the respective sections that deal with these subjects:

- The number of guns that need to be replaced.

- The availability and price of steel shot in the short term in all regions.

- The amount of lead released to the environment due to sports shooting with gunshot.

- The consequences of a number of differences between steel shot and lead shot could be underpinned by comments received from stakeholders on both the Annex XV report (#3221) and the SEAC draft opinion (#1057, #1073) and additional expert advice sought by SEAC, but could not yet be resolved in a conclusive way.

- It remains unclear what regional differences for national sports shooting organisations would result if the optional conditional derogation would be implemented.

- The probability and consequences of an "unharmonized" permit and licensing structure as proposed in the concept of an optional conditional derogation remains unclear.

- It is unclear how big the barrier will be for "licensed athletes" that will be forced to switch between steel shot (at their local club range) and lead shot that, in case of the optional conditional derogation, could continue to be used at permitted ranges, when training for and participating in international competitions.

- Based on the comments received in the consultation on the SEAC draft opinion there is uncertainty with respect to how the restriction proposal will impact sports shooting with gunshot in disciplines that do not involve the shooting of clay targets, i.e. practical shooting. These other disciplines use gunshot (at least for some disciplines) but perform their sport on outdoor rifle or pistol ranges where safety rules may explicitly forbid the use of steel shot.

Sports shooting with bullets

This part of the restriction presents uncertainties that are different from the use of gunshot:

- When will alternatives (especially for small calibres) become available?

- It remains unclear to what extent implementation of the restriction would lead to a decrease in the number of civilian shooting ranges that would be available for local military training of reservists.

- Based on the comments received in the consultation on the SEAC draft opinion there is some uncertainty with respect to how the present restriction proposal will impact dynamic shooting disciplines that use lead ammunition, due to concerns regarding the much higher costs of the proposed RMMs, in view of a much larger area that may need to be covered in some cases.

Fishing

Uncertainties related to the impact assessment for the fishing sector are discussed in the different sections of this opinion and summarised below in the key elements.

Key elements underpinning the SEAC conclusion(s):

Hunting

Due to a lack of data, the impact assessment had to be based on several assumptions. Most

uncertainties resulting from that were addressed by considering sensitivity scenarios.

The main uncertainties of the impacts of the proposal identified by SEAC are discussed in the relevant sections of this opinion. These are summarised below:

Scope:

- Transition period for the ban on use of lead gunshot in hunting: Development of production capacities of alternative gunshot, in particular steel (see above, section 3.3 – B1 and section 3.3.3.1 – B).
- Availability of non-lead alternatives for small calibre (rimfire) bullets after the transition period of 5 years (see above, section 3.3 – B2).
- Development of the availability of non-lead alternatives for historic firearms, e.g. muzzle loaders (see above, section 3.3 – A).
- Effectiveness of the ban on use of lead bullets in terms of enforceability (see above, section 3.3 – B2 and section 3.3.4).

Costs:

- Gunshot: Number of hunters affected (see above, section 3.3.3.1 – B1).
- Gunshot: Proportion of alternatives used other than steel, i.e. bismuth and tungsten (see above, section 3.3.3.1 – B1).
- Volumes of lead ammunition used (see above, section 3.3.3.1 – B1, B2).
- Price of alternative ammunition (see above, section 3.3.3.1 – B1, B2).
- Share of hunters who have to replace their gun or to re-barrel their rifle in response to the proposed restriction (see above, section 3.3.3.1 – B1, B2).
- Costs of the proposed restriction of lead in airgun pellets (see above, section 3.3.3.1 – B2).
- Costs of the proposed restriction on lead in ammunition used in historic firearms (see above, section 3.3.3.1 – B2), incl. potential cultural values of shooting outside of shooting ranges (e.g. for hunting) with historic firearms
- Costs to enforce the ban of use of lead bullets (see above, section 3.3.3.1 – A).

Benefits:

- Significance of non-quantified benefits (see above, section 3.3.3.2).

Other impacts:

- Impact of the proposed restriction on hunting activities in the EU (see above, section 3.3.3.3).

Sports shooting with gunshot

- The number of guns to be replaced: As has been discussed by SEAC in the corresponding section above, it is not unrealistic to assume that most sports shooters have rather modern guns, where a switch to steel shot does not present technical problems. The number of 10 % replacements therefore seems a kind of extreme worst-case assumption, because the Dossier Submitter also states that it is likely that for sports shooting with gunshot no replacement will be necessary at all. Regular purchasing of a new gun to keep up with technological development should not be counted as a cost of the restriction, only those purchases that became necessary because the old gun cannot be used for the steel shot alternative and has to be purchased at a point in time earlier than was originally expected. This uncertainty is partly covered by updates made by the Dossiers Submitter in the Background Document, by considering different scenarios with 6, 10 and 14 % replacement of guns. However, SEAC cannot agree to the approach by the Dossier Submitter in this calculation in which a lower replacement percentage of guns is assumed to imply a lower tonnage of lead being used.

- Availability and price of steel shot: As has been described above, recent information seems to indicate that steel shot is similar in price than lead gunshot. So, even the calculations of the Dossier Submitter where a 1-3 % price difference was assumed may be too pessimistic. In combination with the point above this would mean that the cost of changing to alternative steel shot may be lower than that indicated by the Dossier Submitter. From the Annex XV report consultation there are some indications that at present the availability of steel shot is not yet the same in all regions. Although this may be expected to be a transient problem, it is not known how long this situation would continue.

- Amount of lead shot used in sports shooting: This issue was already addressed in section 3.3.3.2 of this opinion. Although SEAC concludes that the Dossier Submitter has clearly explained how they came to the low and high estimates used, the credibility of the highest estimate remains limited. This means that a number of calculations that depend on the tonnage of lead used in sports shooting carry an inevitable uncertainty.

- Differences between steel shot and lead shot were identified by the Dossier Submitter. Further data regarding such differences were submitted in the Annex XV report consultation (#3221) and obtained as responses to the consultation on the SEAC draft opinion (see 'C1. Sports shooting with gunshot (use #3)' in section 3.3.3.1 of this opinion). However, the conclusions drawn by the Dossier Submitter and the relevant sports association still differ widely. There seems to be a need for an effort of the sports shooting sector to approach this on a global scale. It should be possible to use the positive practical experience of countries where steel shot is already in common use for solving what the associations see as problems. In the end this can result in a solution that will allow similar rules to be accepted worldwide. On the basis of the available data, including additional expert advice, SEAC tends to agree with the statement of the Dossier Submitter that a resistance to change seems more of an organisational than a truly technical problem.

- Upgrade of RMMs at shooting ranges on a regional basis: In the assessment of the

optional conditional derogation, the approach taken by the Dossier Submitter seems a pragmatic approach to better account for the (financial) capacity for upgrading shooting ranges at the regional level. However, it does not address the question how the impacts will be distributed across the EU. In the cited examples in Germany, often the national sports associations and/or federal government were involved in financing such centres of excellence. It is unclear if this will also happen in other Member States. Moreover, it is highly uncertain how the sports shooting world will react to this regionalisation concept – i.e. if people will accept longer travel times to/from a training range or if they will simply give up shooting. This may have unforeseen consequences for the implementation of this variant of the restriction, especially in countries where only few of the shooting ranges can afford to upgrade. It also remains unclear which actors need to become involved at a national level to implement such changes.

- Permit and licensing structure: In the assessment of the optional conditional derogation, the Dossier Submitter implicitly seems to assume that issuing and checking new permits will fit into existing structures in the various Member States. However, the Forum advice mentions that the fact that different government agencies may be responsible for such permits and licences may create confusion at least. It is uncertain if additional costs, beyond the assumed normal enforcement costs, will result from this. Although the Dossier Submitter outlined what the conditions of a "licence for athletes" should look like, these are only suggestions. SEAC has some concern that this may give rise to a highly "unharmonized" situation across the EU.

- Switching between using steel shot and lead shot: If the optional conditional derogation as analysed by the Dossier Submitter would come to bear, this would create a situation where "licensed athletes" would shoot with steel at their local clubs and would have to switch to lead when in training for international competitions. Although SEAC does not doubt that such a switch is possible, it remains unclear how quickly such changes back and forth could be made in the available time. This issue did not generate any specific comments in the Annex XV report consultation, which may indicate it is minor after all, or that the commenters have not realised this would be part of this scenario.

  This issue was addressed once more in the form of a specific information request in the consultation to the SEAC draft opinion. A number of answers to this topic were received, but a consensus did not emerge. While some report a high barrier to switch (e.g. #1084), others reported the experience being smooth and not needing much adjustment time, if any (e.g. #1066). An additional aspect that was mentioned (#1057) was the fact that (apart from the issue of using lead or steel) some shooters go to great lengths to reduce sources of variation that may negatively influence their performance. It was mentioned that in such cases they prefer to use cartridges from the same production batch, in order to reduce variability. In this respect, any forced change of ammunition type would be perceived as a problem.

- Use of gunshot in other shooting disciplines: Comments #1019, #1020, #1134, #1142, #1146, #1162 (SEAC draft opinion consultation) refer to the fact that some shooting disciplines (e.g. IPSC shotgun shooting, cowboy action shooting, game-trail shooting) use gunshot on rifle or pistol ranges. Because they shoot at metal targets,

use of steel shot is prohibited by the rules[53] for safety reasons, because of an increased risk of ricochets[54]. The use of gunshot at rifle ranges (even if these would qualify as a "notified range"), is not foreseen in the current restriction proposal as the Dossier Submitter's preferred option is a complete ban on the use of lead gunshot in sports shooting. Moreover, if lead shot would be banned in the EU, such shooters would not have any option to practice for international competitions, because the optional derogation with its licencing system is only defined for "permitted ranges".

SEAC took notice of these comments. However, at this moment, SEAC does not have sufficient data (number of shooters, number of sites, amount of lead released, severity of ricochets on steel targets, possibility to use alternative target plates) to complete a full analysis of the impacts related to these issues. Consequently, a conclusion on the impacts of the restriction for these uses cannot be reached.

The decision-maker may need to pay extra attention to the impacts on such shooting disciplines when discussing the implementation of the restriction.

SEAC will add a summary to the Background Document (see SEAC box in the Background Document section 3.2.1), listing those areas where commenters have indicated they cannot reconcile their practice with the requirements of the current restriction proposal.

Sports shooting with bullets

- Alternatives: Many comments from the Annex XV report consultation point to the fact that for the highest accuracy, gun and ammunition should be closely matched. It is not clear what perspectives are for medium term development (and availability) of modified ammunition and guns (especially for small calibres).

- Military training: The Background Document and the related calculations in connection with a conditional derogation do not give information on how many (if any) of the existing shooting ranges would need to close down, because the investment costs are too high and cannot be shouldered by the local shooting clubs. In countries that depend heavily on local training options for reservists of their armed forces, this may create a problem, because in the conditions of the restriction these local civilian shooting ranges are bound by the restriction as well. In an unfavourable situation, this may cause the need for such soldiers to travel considerable distances to find a range. Because of the differences on how countries organize their national defence, this may become an issue in some countries, but not in others. See, for example, comment #3324 (Annex XV report consultation) from the Finnish ministry of defence. Creating additional shooting ranges or upgrading existing ones just for this purpose, would be an additional burden for the national defence budget. In view of the current geopolitical situation, several comments in the consultation on the SEAC draft opinion stressed this topic more

[53] https://www.ipsc.org/ipsc-rules/rule-books/ (accessed 27 October 2022)

[54] To SEAC it seems plausible that the ricochet problem in this case (if steel hits steel) will be larger than for clay targets, but data are lacking.

prominently than in the consultation on the Annex XV report.

- Dynamic shooting: Dynamic shooting is described in the Background Document (section 1.4.4.2.2.1) and mentioned in the assessed restriction options for sports shooting with bullets (Background Document, e.g. section 2.6.2.2).

  In the comments received in the consultation on the SEAC draft opinion, several reactions (most notably #1081, #1119, #1149 and #1153) were received that pointed to issues and uncertainties which the commenters perceived to exist regarding dynamic shooting with lead bullets. In many cases use of lead bullets is needed to effectively hit the targets. While the Dossier Submitter's proposal would allow the continued use of lead bullets for sports shooting conditional on the implementation of appropriate and effective RMMs, the comments indicate that the used shooting ranges cover a vast area (see for example picture on page 3 in the attachment to #1081) and that the proposed RMMs would lead to excessive costs for such ranges. The Dossier Submitter has already recognised that for dynamic shooting trap chambers and sand traps with an overhanging roof might not be suitable because of safety reasons (Background Document, section 2.6.2.2). Therefore, in the text of the proposed restriction option RO2c, an option for a "permanent cover" instead of an overhanging roof was included by the Dossier Submitter. The Dossier Submitter states that this should prevent water entering the sand trap. However, to SEAC it remains unclear how such a "permanent cover" would need to look like if targets (and therefore bullets and bullet fragments) are spread over a wide area like as in the case of metallic silhouette shooting, where each row may have a sand barrier of its own.

  SEAC took notice of these comments. However, at this moment, SEAC does not have sufficient data (number of shooters, number of sites, amount of lead released, severity of ricochets on steel targets, possibility to use alternative target plates) to complete a full analysis of the impacts related to these issues. Consequently, a conclusion on the impacts of the restriction for these uses cannot be reached.

  SEAC will add a summary to the Background Document (see SEAC box in the Background Document, section 3.2.1), listing those areas where commenters have indicated they cannot reconcile their practice with the requirements of the current restriction proposal.

Fishing

Due to a lack of data, the impact assessment had to be based on several assumptions. Most uncertainties resulting from that were addressed by considering sensitivity scenarios.

The main uncertainties of the impacts of the proposal identified by SEAC are discussed in the relevant sections of this opinion. These are summarised below:

Scope:

- Availability of suitable alternatives for certain applications of sinkers and lures, i.e. dust split shots and large sinkers > 50 g (see above, section 3.3 – D)

Costs:

- Impact on manufacturers of sinkers and lures in terms of investment costs (see above, section 3.3.3.1 – D and 3.3.3.4 – D)

Benefits:

- Impact of the proposed restriction on home casting activities (see above, section 3.3 – D)

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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 1-11-1 is used.

Table 1-1: 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 of 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

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

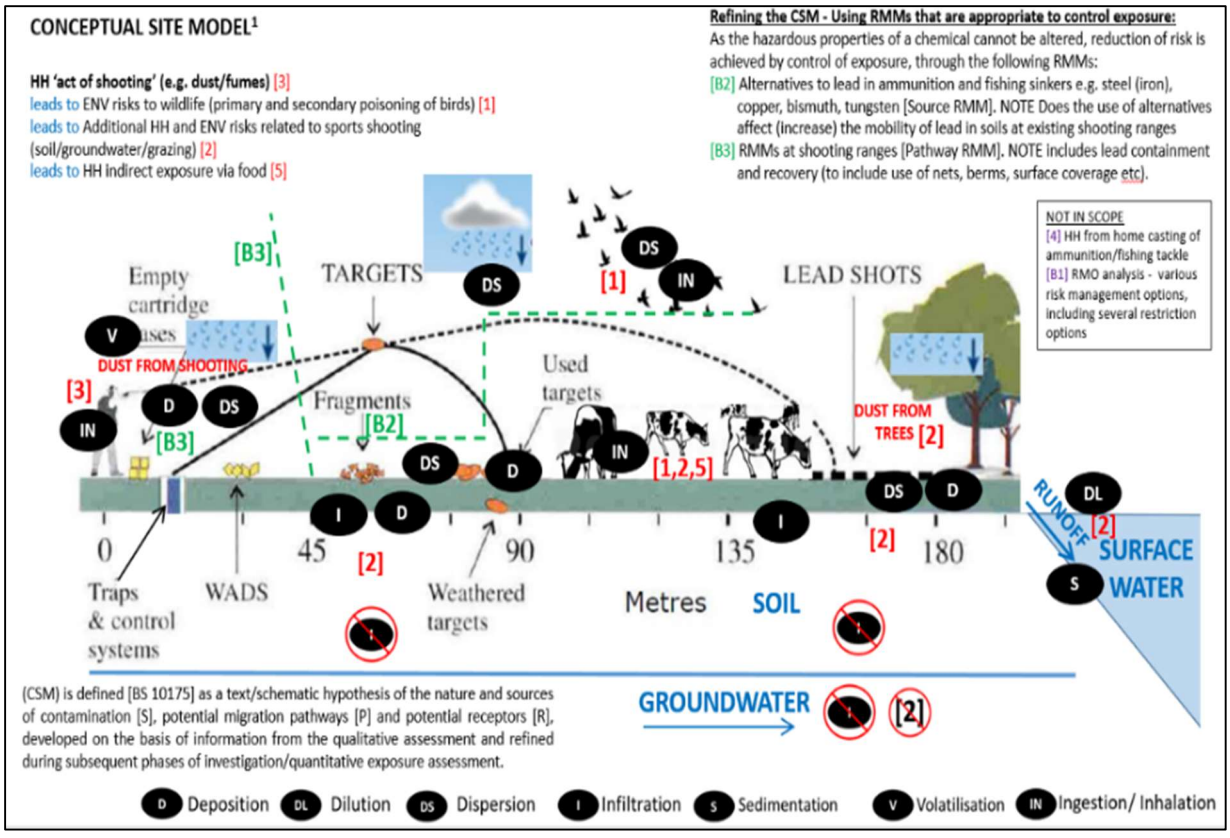

Figure 2: Illustration of the conceptualisation of the risk caused by shooting

Table 1-2: 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, lead shot/ bullets	Adult shooter	Direct Inhalation of fumes and dust; Dermal contact with lead (resulting in hand-to-mouth exposure	+++	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
		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	+/++	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*	limited.				
Lead shot fallout, lead objects, lead fragments	Soils: (1) > 300m distance[55] 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 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)

[55] 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 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 Directive EQS 1.2 ug/L*	Runoff/dilution and exposure to aquatic organisms, and/or sedimentation, hence exposure to fish	+++	Likely	Minor	**Low**
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 groundwate	+/++/+++	Unlikely	Medium	**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
		r (> 3m).				

*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 1-3: 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-	+++	Likely	Mild	**Low-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
		mouth exposure and ingestion of lead)				
Game meat consumption	Adults	Ingestion	+	Likely- Low likelihood	Minor- Mild	**Low**
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	Soils: *Hazard for terrestrial*	1) Low loading of lead onto soil surface in hunting	+/++	Low likelihood	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
fragments	*organisms. Breach of PNEC Pb soil* *212 mg/kg*	grounds. 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	Surface waters: *Breach of PNEC aqua (freshwater) 2.4 µg/L and 186 mg/kg sediment, Water Framework Directive EQS 1.2 ug/L*	Low loading of lead onto soil surface in hunting grounds hence low runoff/dilution and exposure to aquatic organisms, and/or sedimentation, hence exposure to fish		Low likelihood	Minor	**Very low**

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 1-4: 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 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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