Response to comments document (RCOM)

on the Annex XV dossier

proposing restriction

Lead in outdoor shooting and fishing

Non-confidential

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

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

Substance name	EC number	CAS number
Lead and its compounds	-	-

3 June 2022

General comments and answers to specific information requests

Specific information requests:

Hunting

Q1. **Alternatives to lead for rim calibres**: As indicated in the Annex XV report, there is contradictory information on the accuracy of lead-free ammunition for rim calibres (such as .17 HMR, .22 LR, etc) for hunting. In some studies, lead-free ammunition for these calibres is claimed to be sufficiently accurate while in other studies it is disputed. Please provide information on the accuracy of lead-free ammunition for these calibres in the form of tests, field reports, or similar, as well as information on the development of lead-free alternatives for this type of ammunition in the future.

Q2. **Alternatives to lead for certain types of hunting**: The Annex XV report indicates that the suitability of lead-free ammunition for small game hunting with Full Metal Jacket bullets and **for** the population management of seals (where this is allowed) should be further explored in the consultation.

a. For **small game hunting with Full Metal Jacket bullets** (e.g., Nordic bird hunting), please provide information on (i) whether, and under what circumstances, the use of Full Metal Jacket bullets is permitted in the EEA and (ii) whether lead-free alternatives are available and their technical performance/suitability for this type of hunting.

b. For the **population management of seals**, please provide information that helps ECHA's Committees to better understand in how many EU/EEA states this takes place and whether lead-free alternatives are available and their technical performance/suitability for this type of hunting.

Q3. **Distinction between large and small calibres**: The current cut off between large and small calibres (5.6 mm) is based on a cut off for hunting roe deer found in hunting legislations throughout Europe. The smallest tested alternatives are in the calibre range of .222 and .223 (5.55 mm). Does the proposed cut off between small and large calibres adequately reflect the differences in the suitability and availability of alternatives?

Q4. **Use of shooting ranges / areas for agricultural purposes**:

a. Please provide information on the use of shooting ranges/areas for agricultural purposes, including production of crops or horticultural products for human or animal consumption and other farming activities (e.g., cattle and poultry farming during periods when shooting is not practised). If possible, please provide quantitative information, such as the number of shooting ranges and areas (used either permanently or temporarily) in your country or region (with a focus on the EEA) that are used for agricultural purposes.

b. Does the current legislation in your country set limits to lead concentration in soil used for agricultural purposes?

Q5. **Measures to limit releases to the environment at trap and / or skeet ranges**:

a. What number and proportion of trap and/or skeet ranges (in your country or region or the EEA) have measures in place that allow the regular (at least once a year) recovery of more than 90 % of the spent lead shot? How many individual traps and/or skeet stands are usually available at such a range? Please clarify how the estimates of the number of ranges and stands were derived and provide supporting evidence.

b. Please provide information on the types of measures that are used to reach this recovery rate and information on the costs of such measures (please provide details from example cases).

c. Please provide information on measures required for containment of lead gunshot and the monitoring and, where necessary, treatment of surface (run-off) water – including information on the type and cost of such measures (also in relation to the number of stands covered).

Q6. **Measures to limit releases to the environment at outdoor rifle / pistol ranges**:

a. What number and proportion of outdoor rifle/pistol ranges (covering all firing lines) in your country or region or EEA have bullet traps in place? Please clarify how this estimate was derived and provide supporting evidence. Are measures in addition to bullet traps implemented to limit releases to the environment?

b. If bullet traps are not used, which other measures are in place to limit releases of lead to the environment?

Q7. **Measures to limit exposure of shooters**:

a. Please provide information on the recommendations and measures that are implemented at outdoor shooting ranges to limit lead exposure of the shooters.

b. Are there any recommendations on the blood lead monitoring of sports shooters or any data on the lead exposure of sport shooters in your country or region?

Q8. **Remediation of shooting ranges / areas**:

a. Is remediation of shooting ranges and areas at the end of life foreseen by national legislations in your country or region (with a focus on the EEA)?
b. If this is foreseen, who is responsible for financing and carrying out the remediation?
c. How are risks managed at the end of life if no remediation takes place (considering that runoff water may also contaminate land, groundwater and surface water outside the perimeter of the site)?

Q9. **Substitution of lead ammunition in outdoor sports shooting**:

a. For **gunshot**, are there initiatives (in Europe or elsewhere) to phase out the use of lead ammunition in international sports shooting? What would be a reasonable timeframe to reach a decision on this matter and to implement this in international sports shooting competitions?
b. For **bullets**, the Annex XV report describes limitations in the availability and suitability of lead-free alternatives due to the accuracy requirements in sports shooting. Please provide information in the form of tests, field reports, or similar, as well as information on the development of alternatives for this type of ammunition in the future.

Fishing

Q10. **Home-casting of lead fishing sinkers and lures**: The Dossier Submitter assumes that home-casting is a popular activity among fishers. Furthermore, it is assumed that if a restriction only applied to the placing on the market but not to the use of lead fishing tackle, home-casting would become more popular. Please provide any supporting information that would allow ECHA's Committees to evaluate these assumptions, such as information on the proportion of fishers making their own lead fishing sinkers and lures or information on the proportion of home-cast lead fishing sinkers and lures compared to purchased ones.

Q11. **Alternatives to lead in fishing tackle**: Please provide information and supporting evidence on the availability of lead-free alternatives for the different types of lead fishing tackle (i.e. sinkers and lures ≤ 50 g and > 50 g, as well as lead wires). If no alternatives exist, please explain what analysis this conclusion is based on.

Horizontal issues

Q12. **Impacts of the proposed restriction**: The Annex XV report proposes a concentration limit of 1 % w/w for placing on the market and use, as well as different transition periods for different types of hunting (gunshot / small calibre bullets / large calibre bullets), sports shooting (gunshot / bullets) and fishing tackle (lead wires and 'intentional release weights' / sinkers and lures ≤ 50 g / sinkers and lures > 50 g). Please provide information on the impacts of the proposed restriction (costs and benefits to society, including industry and SMEs) and consider how these impacts would vary dependent on the concentration limit and

the duration of the proposed transition periods. Please refer to Annex XVI of REACH for an overview of the elements that should be included in an impact assessment.

Q13. **Monitoring of environmental exposure**: Please provide information on any organisations in Europe regularly monitoring the impacts related to the exposure of wildlife to lead ammunition and lead fishing tackle.

Q14. **Voluntary military training**: The Annex XV report describes the practice of 'voluntary military training' that is reported to take place in some EU/EEA states. Please provide further information on this practice including a justification for why lead ammunition is required and why a specific derogation for this activity is needed beyond the existing proposed scope and derogations.

Overview of the comments received

In the consultation of the Annex XV report, ECHA received 319 comments from NGOs, academia, Member States, industry organisations and individuals. Figure 1 gives an overview of the comments per type of submitter, the large section of 'blank' items seems to coincide with comments of individual, without any affiliation to a company or organisation.

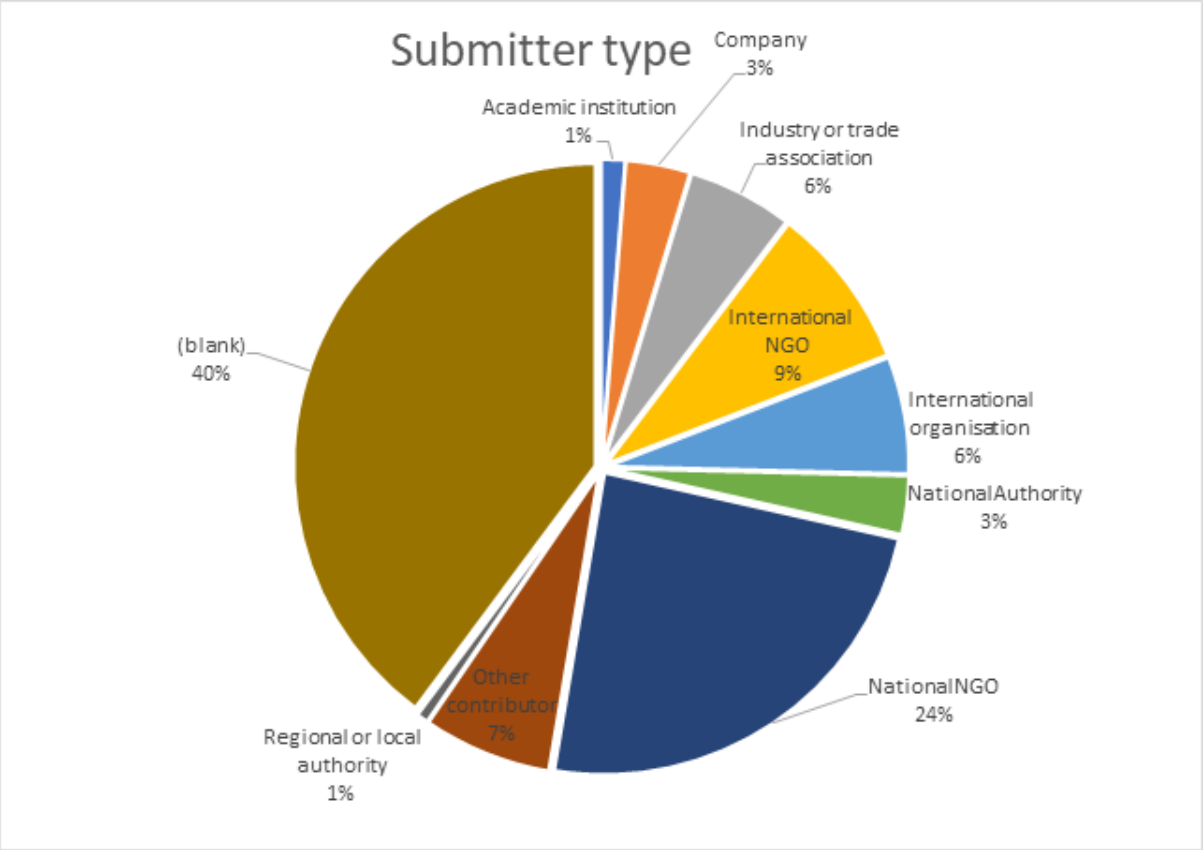

Figure 1: Overview of comments per type of submitter

An overview of the origin of comments that were submitted per Member State is presented given in Figure 2. The group of 'Other contributors' comprises contributions from Australia, Canada, Croatia, Greece, Lithuania, Namibia, Poland, and the United States. Several comments from outside the EU either highlighted their own experience with non-lead ammunition or described the (positive) knock-on effects a regulation in the EU would have on these countries' efforts in wildlife conservation. The highest numbers of comments from EU Member States were received from Finland, France, Germany, and Sweden.

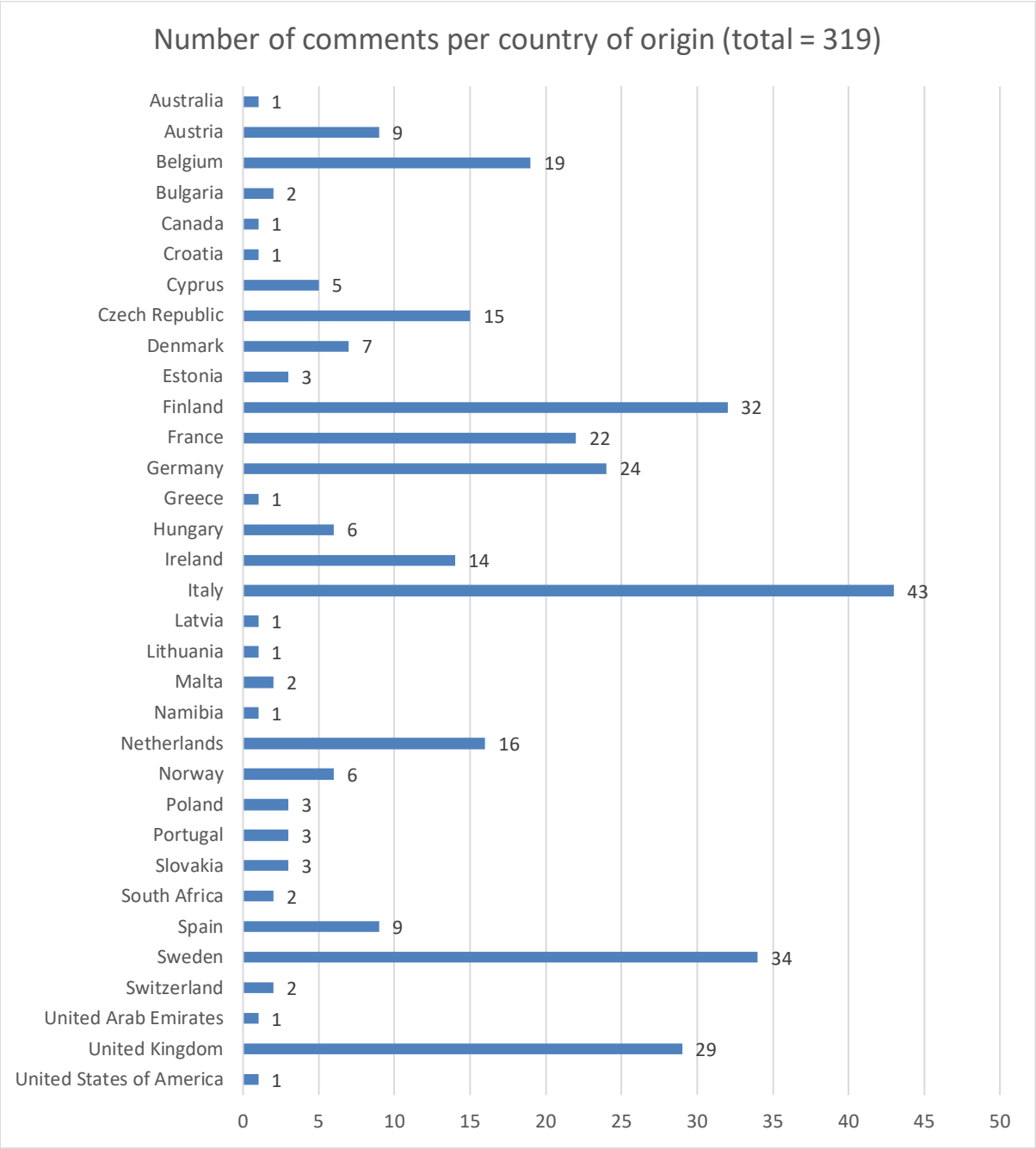

Figure 2: Overview of comments per country of origin

The main areas of interest in the consultation are related to the scope of the restriction, exposure and risks associated with using lead ammunition or fishing tackle, the technical and economic feasibility of lead-free alternatives per sector (hunting, sports shooting and fishing) as well as the risk management measures to control lead emission that can be installed on sport shooting ranges. The structure of this document responding to comments (RCOM) is organised around the main items and issues raised in the consultation.

Response to comments

The Dossier Submitter would like to thank all interested parties that submitted comments and information to the Annex XV consultation. The Dossier Submitter notes that many of the comments received were similar in nature and could be grouped into topics. Given the large number of comments received, and to improve the clarity of the responses, the Dossier Submitter has therefore prepared a set of general responses to common topics addressing multiple individual comments followed, when appropriate, by specific responses to individual comments. These general responses summarise the nature of the comments received and describe, in general terms, how the Dossier Submitter has responded to them, typically by revising specific parts of the Background Document. As such, detailed responses to the comments are often only contained in the Background Document. Where appropriate, for example where there is no update to the Background Document in response to comments on a particular topic, a more elaborated response is provided in this RCOM.

To assist stakeholders to understand how their comments were assessed, the Dossier Submitter has provided an indicative list of comment numbers that are associated with a specific topic(s). Nevertheless, whilst the Dossier Submitter has made best efforts to report these lists for each topic, these lists are not meant to be exhaustive. Therefore, unless a comment has been responded to specifically and individually or within a general response, it should be understood that the Dossier Submitter has considered all of the comments received in the consultation when preparing these general responses.

In some cases, the Dossier Submitter has responded to comments by revising the wording of the 'conditions of the restriction' (i.e., the wording of the restriction entry proposal presented in Table 8 of the Executive Summary and in Table 2-11 in the Background Document). Commenters should note that the wording of the conditions of the restriction in the Background Document is only intended to express the intention of the Dossier Submitter in a concise a form as possible and is not a proposal for legal text in Annex XVII. The European Commission will decide on the legal wording used to update Annex XVII of REACH if a restriction is adopted.

The comments received have been grouped into the following topics:

1. Proposed restriction

1.1. Dossier Submitter response to comments

1.1.1. General comments on the restriction proposal

Numerous comments were submitted in the consultation by sector associations, NGOs, international bodies (incl. UN-AEWA, UN-CMS), competent authorities, scientists, as well as other individuals on many different issues. Comments questioning specific aspects of the restriction or providing supporting information are discussed in subsequent sections of this RCOM or in the Background Document.

Comments supporting the proposal included: #3197, #3274, #3345, #3361, #3364, #3365, #3366, #3370, #3371, #3373, #3374, #3375, #3376, #3383, #3384, #3385, #3386, #3388, #3403, #3404, #3405, #3408, #3409, #3434, #3439, #3454, #3456, #3459, #3461, #3465, #3473, #3475, #3478, #3479, #3483, #3494, #3498, #3499, #3507, #3508, #3510, and #3515. These comments refer to the fact that the adverse effects of lead on human health and the environment have been reported in the scientific literature for many decades; that experiences with partial bans of lead ammunition have not been successful in Europe[1] (such as e.g. #3515); that a harmonised level of protection of the environment and human health is needed to address the identified risks and that the proposed measures are consistent with the EU's policy framework for the environment established as part of the European Green Deal, including the EU biodiversity strategy for 2030, the EU's Zero Pollution Action Plan[2] and the implementation of a 'One Health' approach in the EU[3] that integrates the interdependencies of environmental, animal and human health. Some commenters (e.g., #3478, #3494) expressed concerns about the impacts of possible derogations (for different sectors of use) which may be granted during the process.

Other comments received do not support the need for the proposed restriction, or elements of it, including among other comments: #3174, #3178, #3180, #3186, #3188, #3191, #3199, #3221, #3223, #3242, #3283, #3293, #3295, #3296, #3305, #3335, #3341, #3342, #3357, #3334, #3362, #3416, #3467 and #3501. These included comments from individuals who expressed general malcontent, organisations that were concerned about the broad scope of the proposed restriction, practitioners of certain applications of lead where alternatives are currently not available as well as individuals and organisations that doubted the science and evidence for lead poisoning or environmental contamination arising from the use of lead ammunition or lead fishing tackle. Some commenters considered derogations for different sectors of use or specific uses necessary.

The German competent authority (#3209) as well as the Belgian (#3228), Danish

[1] Comment #3348 provides recent scientific evidence that indicates no effect on the prevalence of lethal poisoning in a bird of prey species over a nine-year period after the enforcement of a partial ban of lead-based shotgun ammunition in Sweden.

[2] https://ec.europa.eu/environment/strategy/zero-pollution-action-plan_en

[3] https://onehealthejp.eu/about/

(#3253) and Norwegian (#3474) competent authority expressed general support for this restriction. The Czech (#3220) and Slovakian (#3349) competent authority expressed concerns as to the need for this restriction and/or the scope of the proposed restriction.

Comments #3473 and #3477 highlighted existing EU legal obligations relating to the Memorandum of Understanding on the Conservation of Migratory Birds of Prey in Africa and Eurasia (Raptors MoU[4]) under the Convention on Migratory Species[5] (CMS). Comment #3478 noted that in addition to the obligations under the Convention on Migratory Species (CMS), AEWA, and Raptors MOU, there are also strict obligations under the EU Birds Directive for EU Member States to protect wildlife (birds) and its habitat. It also notes that the restriction proposal (if implemented without derogations) will fully protect AEWA-listed waterbirds from lead poisoning by addressing the residual risk for terrestrial-feeding waterbirds.

Some comments noted the impact that a restriction on the use of lead in hunting may have on regions outside of Europe. Comments #3482 and #3414 stated that it is likely that a restriction in Europe will increase the availability of lead-free ammunition in African countries such as Namibia and South Africa where a restriction in the EU may thus reduce the amount of lead discharged into the environment in Africa.

Finally, the Dossier Submitter acknowledges the consensus among scientists (comment #3506) on the toxic effects of lead on human and wildlife health.[6]

1.1.2. Scope of the proposed restriction

Numerous comments on the scope of the restriction were submitted by sector associations, supply chain actors and Member State competent authorities as well as individual companies, including comments #3267, #3331 and #3467. Some of these comments have been handled as confidential as per the commenter's request. Below, the Dossier Submitter responds to these high-level comments.

FITASC/ISSF (#3267) commented that they consider an assessment of risks at outdoor shooting ranges not within the scope of the request made by the EU Commission because these sites are 'facilities' and not 'terrains'; furthermore, a shooting sport facility would not be part of 'the environment'. The Dossier Submitter notes that the restriction on the use of lead gunshot in wetlands is considered to apply to shooting ranges in wetlands. Thus, a restriction proposal on 'terrains outside of wetlands' can be reasonably expected to apply to shooting ranges in general. It is the intention of Dossier Submitter that the restriction applies to outdoor shooting ranges as these are the locations where risks are not adequately controlled.

The European Federation for Hunting and Conservation (FACE; #3467) consider that when a gun is discharged at a shooting range, lead pellets and bullets are discarded.

---

[4] https://www.cms.int/raptors/en/signatories-range-states

[5] The Convention on Migratory Species (CMS) is an environmental treaty providing a global platform for the conservation and sustainable use of migratory animals and their habitats.

[6] See http://www.europeanscientists.eu.

Thus, that discarded lead is waste and waste is not within the scope of REACH. Therefore, shooting ranges cannot be subject to restrictions under Article 67(1) of REACH, such as requiring the recovery of 90 % of lead at shooting ranges to benefit from the derogation. In response the Dossier Submitter notes, as recently confirmed by the EU General Court[7], a restriction under REACH can address risks from the use of a substance even if this risk only arises after it has become waste. Specifically, the REACH Restriction on D4 and D5 wash-off cosmetic products was justified based on risks occurring after these substances were disposed down the drain[8].

The Association of European Manufacturers of Sporting Ammunition (AFEMS; #3331) requested that the quality control (QC) of lead ammunition be explicitly outside the scope of the restriction. As this activity would be required to take place to ensure the availability and safety of lead ammunition for uses outside of the scope of the restriction (i.e., indoor uses), or uses derogated from the conditions of the restriction (i.e., outdoor ranges with appropriate risk management measures, RMMs), the Dossier Submitter considers that this activity should be permissible under the conditions of the restriction. However, it should not in itself result in any of the risks identified, e.g., at outdoor shooting ranges. Therefore, if QC testing takes place at an outdoor range, the range should be compliant with the conditions (in terms of RMMs) of the restriction required for the continued use of lead at outdoor shooting ranges. Note that these considerations are compatible with the generic exclusion of scientific research and development from REACH restrictions, where scientific research and development is defined as any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year (Article 3(23) of the REACH Regulation). The use of appropriate RMMs at shooting ranges can be considered as consistent with the concept of controlled conditions.

1.1.3. Specific comments on the wording of the conditions of the restriction (restriction entry)

AFEMS (#3331) requested that the wording of paragraph 1c and paragraph 2c in the conditions of the restriction are revised to clarify that the restriction is on the placing of 'gunshot ammunition' on the market (1c) and the use of this ammunition in outdoor shooting (2c). The Dossier Submitter notes that it has used the same terms in the conditions of the restriction as used in the restriction on the use of lead gunshot in wetlands that is now included in Annex XVII. Therefore, the Dossier Submitter does not consider that it necessary to review the wording at this stage, and that the intention of the wording is consistent with that of the commenters' suggestion.

AFEMS (#3331) also requested that the wording of point 2d *"in any other projectile not defined as gunshot*" is revised to make it clear that the restriction is on the use of ammunition containing a lead projectile in outdoor shooting (unless otherwise derogated or exempted). In response, the Dossier Submitter has amended paragraph 4c to state that "Paragraph 2d shall not apply if: - the use takes place inside a building; or if the use

[7] EUR-Lex - 62018TJ0226 - EN - EUR-Lex (europa.eu)

[8] EUR-Lex - 32018R0035 - EN - EUR-Lex (europe.eu)

takes place at a notified outdoor location for sports shooting where the following measures are in place: […]… "

FACE (#3467) suggest revising the restriction entry summarised as follows:

- To restrict only the use of lead for fishing sinkers and lures, fishing wires and gunshot, not its placing on the market and use. The Dossier Submitter considers that a ban on both the placing on the market and use are important complementary measures that improve the practicality (particularly the enforceability) of the proposed restriction. Enforcement of retailers is considered to be more straightforward than enforcement at the point of use, although enforcement at the point of use is also possible.

- To use a cut-off size between small and large calibres of ≥ 6.8 mm rather than the cut-off of 5.6 mm proposed by the Dossier Submitter. The Dossier Submitter does not consider that the evidence provided in the comment to justify a revision to the proposed cut-off size between small and large calibres is sufficient. The comments against the proposed cut-off size mainly referred to national hunting legislation in some Member States, which do not currently allow the use of lighter, non-lead bullets due to minimum weight requirements. Section 3.1.2.2.1 of this document further elaborates on this subject.

- To omit the concentration limit of 1 % w/w for gunshot and other projectiles and to refer to a concentration limit of 3 % w/w for other projectiles in centrefire ammunition ≥ 6.8 mm with the reference to the restriction report where it was mentioned that the lead content of brass bullets is usually 3 % w/w. The Dossier Submitter has further investigated the issue concerning this concentration limit and has updated the Background Document with new information on this. The updated proposal now contains and option to set the limit at 3 % with a possibility to review this limit in due time with the aim to reduce this to 1 %.

- To derogate the use of lead gunshot and bullets for sports shooting to designated locations where risk management practices are based on best practice for outdoor shooting ranges. The Dossier Submitter notes that in some EU countries (such as Finland) best practices are often taken into account to control some risks at shooting ranges. However, no comprehensive "*best practice*" has been defined at EU level that would guarantee a harmonised high level of protection to the environment (including all environmental compartments and all affected receptors) and humans (including via the environment) applicable to all relevant shooting activities (including temporary shooting practices)[9]. The RMMs included in the conditions of the proposed restriction (including the optional conditional derogation for sports shooting with gunshot) should be considered as the minimum best practice RMMs for outdoor shooting ranges. Therefore, the proposed restriction would not introduce any additional burden to ranges that

[9] See also section 4.1.6.1 for further information.

implement best practice.

- A transition period of 10 years instead of 5 years for paragraph 1c. Please see the Dossier Submitter's responses in Section 3.1.6 (with respect to gunshot used for hunting) and Section 4.1.10 (with respect to gunshot used for sports shooting).

- A transition period of 5 years from the entry into force of the restriction for centre-fire ammunition ≥ 6.8 mm not defined as a gunshot. Please see the Dossier Submitter's responses in Section 3.1.6.

- A derogation for lead projectiles in centre-fire ammunition < 6.8 mm not defined as a gunshot used for hunting. Please see the Dossier Submitter's responses in Section 3.1.3. Furthermore, the Dossier Submitter continues to support a view that there will not be a need to replace large number rifles in the calibre range between 5.6 - 6.5 mm. This is based on advice from hunting associations in Germany and Denmark, see also Section 3.1.2.2.1 of this document. The issues raised by FACE concerning the stability and twist rate of non-lead projectiles apply equally to lead ammunition, and, as such, are not indicative of the technical infeasibility of alternative ammunition *per se*.

- Derogations for hunting with full metal jacket bullets containing lead, other lead bullets not designed to expand, and lead bullets for seal hunting. Please see the Dossier Submitter's responses in Section 3.1.3.

Comment #3380 asked to include the possibility that even after a REACH restriction on lead in ammunition has come into force, it must be possible to maintain and / or adopt national requirements in the Member States on ammunition for use in hunting to ensure a 'reliable killing effect'. In response, the Dossier Submitter considers that even after a REACH restriction would take effect, national provisions to ensure the efficacy of ammunition for hunting will still be in place. However, these national provisions may need to be adapted to ensure that non-lead bullets (which are sometimes lighter than lead bullets of the same calibre size) can be legally used. Such adaptations were already made in Norway and Finland (see also Section 3.1.2.2.1 of this document) and similar adaptations would need to be made in other EU Member States.

1.1.4. Quantifiable and non-quantifiable benefits of the proposed restriction

Comments on the impact on birds from the uses of lead in the scope of the restriction were submitted mainly by sector associations, NGOs researchers and individuals, including: #3307, #3335, #3343, #3348, #3364, #3365, #3367, #3370 , #3372, #3374, #3375, #3377, #3378, #3382, #3388, #3395, #3396, #3397, #3405, #3406, #3411, #3412, #3415, #3418, #3420, #3424, #3425, #3427, #3428, #3432, #3436, #3438, #3439, #3443, #3444, #3446, #3450, #3452, #3458, #3462, #3464, #3473, #3475, #3477, #3478, #3479, #3480, #3484, #3486, #3491, #3497, #3499, #3500, #3510, #3513, #3515.

Some comments were handled as confidential as per respondents' request.

The Dossier Submitter has undertaken a partial quantification of the benefits of the

restriction in relation to birds, focussing on birds that are interesting for hunting and for which therefore a market exists. Other benefits mentioned by the commenters listed above were described qualitatively in the updated Background Document.

In addition to benefits for birds, commenters stated that regulatory action would benefit the environment and human health overall. More specifically, reference was made to several obligations the EU has under different legislative frameworks or international agreements and how the proposed restriction would contribute to fulfilling these international and EU wide obligations:

- Article 7 of the Birds Directive requires EU Member States to ensure that hunting does not jeopardise conservation efforts to preserve huntable and non-huntable bird species and that practice of hunting complies with the principles of wise use.

- In addition, the EU must guarantee the application of the polluter pays principle and Directive 2004/35/CE on environmental liability for remediation of the land impacted by lead pollution.

- Lead poisoning results in clinical effects affecting birds and other animals exposed to lead. This directly contradicts animal welfare standards as provided for in article 13 of the Treaty on the Functioning of the European Union.

- The restriction would be a significant contribution to the aims of the CMS Intergovernmental Task Force and fulfil the EU and its Member States' conservation obligations under CMS Resolution 11.15 (Rev.COP13).

Commenters also highlighted that quantification of additional benefits, beyond those assessed by the Dossier Submitter, would be possible particularly for raptors and scavenging birds. Several commenters referred to a study by Pain, Dickie et al. (2019)[10] which seeks to quantify the effects of lead from ammunition on birds and other wildlife. The study discusses that there is substantial annual expenditure within the EU on non-consumptive uses of these species (e.g., birdwatching and nature tourism) and on delivering legal requirements to maintain their populations in favourable condition by site and species protection. According to the commenters those constitute unquestionable signals of the societal importance of protecting bird species threatened by primary and secondary lead poisoning. The authors of the study note that the costs to society of sublethal poisoning and mortality of wildlife are difficult to quantify, but that this can be approached in a variety of ways, including:

a. Costs of replacing birds that have died. This could be through captive breeding and release or other means of increasing the populations.

b. Costs of treating poisoned birds.

c. Costs of losing the services provided by the wildlife, including tourism, hunting

[10] Pain, D.J., Dickie, I., Green, R.E. et al. Wildlife, human and environmental costs of using lead ammunition: An economic review and analysis. Ambio 48, 969–988 (2019). https://doi.org/10.1007/s13280-019-01157-2.

for food or sport and improvement of environmental health.

d. Society's willingness-to-pay for avoiding these impacts—a way of estimating the value of wildlife to people.

Comment #3367 (national authority) proposed a monetisation of avian scavenger mortality induced by the use of lead ammunition. The comment noted that avian scavengers are listed in Annex I of the EU Birds Directive, implying a legally binding obligation to protect them, also taking into account that lead poisoning can impact the demography of these long-lived species.

Finally, several commenters warned that inaction would severely undermine conservation programmes set up across the EU to protect or reintroduce raptors and scavengers such as the red kite and the Egyptian vulture. These commenters considered that the Dossier Submitter should have included conservation costs and benefits into its assessment of the impacts of the proposed restriction on wildlife.

Whilst the Dossier Submitter acknowledges that these impacts exist, it has refrained from quantifying and monetising them as there are inherent difficulties in monetising a good for which no market exists and the contributions submitted e.g. by #3367.

In this context, the Dossier Submitter notes that Pain et al. (2019)[11] did attempt to monetise several of the impacts identified above, as elaborated below:

- In terms of the replacement cost of birds, the Dossier Submitter considers that this only reflects the supply side of the problem of restocking birds lost to lead poisoning. E.g., while the cost of captive-breeding a vulture can be accurately monetised, by doing so it is not thereby demonstrated that society is willing to pay this cost for a specific number of vultures. Without information on society's demand value, it is analytically not possible to usefully monetise this impact. The Dossier Submitter notes that this contrasts with some of the wildfowl species for which hunters actively pay a market price to release the number of captive-bred birds, i.e., hunters release the number of birds that correspond to market demand. This is different from the release of captive-bred birds reintroduced by conservation projects (even if EU-funded), where societal demand is not directly observable, i.e., there is no market for bird conservation. The Dossier Submitter does not mean to imply that the latter would not have a value to society, but the supply cost does not express this value properly.

- In terms of the view that existing legal obligations in the EU are an expression of society's valuation, and hence the costs arising from existing conservation activities are a useful measure of the benefits of the restriction, the Dossier Submitter notes that—beyond doubt—these have a value to society. However, conservation costs are an inaccurate measure of the existence value of birds since 1) they include a significant overhead for salaries and material that are unrelated

[11] Pain, D. J., et al. (2019). "Wildlife, human and environmental costs of using lead ammunition: An economic review and analysis." Ambio 48(9): 969-988.

to the existence value of birds, 2) using the existing conservation costs as measure of the value of conservation would imply that, once a restriction on lead ammunition was in place, the costed conservation efforts would become redundant. The Dossier Submitter suggests that this is not the case and that there are factors other than lead poisoning which make the continued protection of raptors and scavengers necessary, e.g., habitat loss, persecution (deliberate poisoning) etc.

- As regards human health effects, the Dossier Submitter has provided a more sophisticated modelling of health impacts than the study by Pain et al. and hence does not see a reason to update its approach for estimating the human health impact assessment.

- As regards clean-up costs for lead contaminated shooting ranges, the Dossier Submitter notes that, where remediation actions are mandatory, they will have to occur with and without the proposed restriction; where no such mandate exists, remediation is less likely to occur, and the avoided costs can thus not be attributed to the proposed restriction.

- As regards other cost elements, costs related to research, advocacy, enforcement, collision, food, are notoriously difficult to estimate as demonstrated by the fact that the authors also did not monetise them.

In summary, whilst the Dossier Submitter recognises that several of the impacts described by the commenters are relevant, they cannot be easily monetised. Because of this complication, the Dossier Submitter opted for a qualitative description rather than a monetisation that would draw justified methodological criticism.[12] Nevertheless, the Background Document has been updated to document the comments received, their rationale, and reflect the Dossier Submitter's response.

1.2. RAC Rapporteurs comments

In general, RAC supports the view of the Dossier Submitter on the scope of the restriction. Inclusion of outdoor shooting ranges in the scope is important for limiting the environmental risks resulting from the use of lead in ammunition at shooting ranges. RAC concurs with the Dossier Submitter's responses on the inclusion of lead used at shooting ranges and also on the inclusion of the quality control of lead ammunition in the scope of the restriction proposal. The Dossier Submitter has included in the revised version of the restriction proposal derogations for the use of full metal jacket bullets in hunting and lead bullets for seal hunting. RAC can support the inclusion of these derogations. RAC also supports the derogation for copper-based bullets proposing a concentration limit of 3% but agrees that this should be subject to a review prior to entry into force of the restriction. RAC also supports the Dossier Submitter's decision not to revise the cut-off size between small and large calibres bullets.

[12] On the merits of a qualitative approach to SEA, see the discussion in Scientific basis of conclusions on SEA.

1.3. SEAC Rapporteurs comments

The SEAC rapporteurs point out that the exemptions of uses of lead ammunition in technical testing and research as formulated in paragraph 8 would benefit from further specification to clarify the range of uses to be covered. SEAC has raised this issue in the Background Document (see SEAC box in Section 2.7.3 of the Background Document).

With regard to the societal value of birds, the SEAC rapporteurs would like to add that the market price of birds that are captive-bred to serve hunting purposes cannot (fully) reflect society's willingness to pay (WTP) for a wild bird as the price only covers the value to the hunter and no other relevant values, i.e. use-values where there is no market (e.g. bird watching) or non-use values. Even though the SEAC rapporteurs agree with the Dossier Submitter that the cost for funding conservation projects cannot be directly used as a proxy for society's WTP to monetise the impact of the restriction, we consider that the fact that such projects are funded by public resources does provide an indication that society's WTP is likely to be significant.

2. Hazard and risk characterisation

Numerous comments were submitted by sector associations, supply chain actors and competent authorities as well as individual companies. The Dossier Submitter has grouped these comments into specific topics (note that all comments related to the risk from home-casting are discussed in Section 5 of this document).

2.1. Dossier Submitter response to comments

2.1.1. Risks to birds from the use of lead in outdoor shooting and fishing tackle

Numerous comments were submitted by sector associations, NGOs, international bodies (incl. UN-AEWA, UN-CMS), competent authorities, scientists, as well as other individuals on many different issues related to the risks to birds from the use of lead in outdoor shooting and fishing tackle including comments #3212, #3221, #3223, #3238, #3241, #3242, #3243, #3263, #3343, #3348, #3361, #3364, #3367, #3369, #3372, #3374, #3377, #3392, #3395, #3401, #3405, #3409, #3411, #3412, #3418, #3419, #3424, #3425, #3427, #3428, #3436, #3443, #3455, #3461, #3467, #3468, #3469, #3473, #3477, #3478, #3479, #3480, #3486, #3494, #3496, #3497, #3499, #3502, #3506, #3509, #3510, and #3517.

Some comments were handled as confidential as per respondents' request.

In response to these comments, further information has been added to the Background Document and its annexes (Sections 1.5.1, 1.5.2, 1.5.3, 1.5.4, 1.8.5[13]; B.7.2, B.9.1).

[13] A new summary table for bird species affected by lead poisoning from ammunition and fishing tackle has been added in this section, in addition to information already provided in section 1.5.4.2.

The Dossier Submitter notes that the evidence gathered in the consultation (including[14] direct and indirect evidence from the literature and in addition to that expert judgment as provided by the UN/CMS ad-hoc Expert Group in comment #3343), consolidates the conclusions in the Background Document regarding the risk of lead poisoning in many bird species from the ingestion of lead ammunition and fishing tackle (sinkers and lures).

The Dossier Submitter concluded that 92 species are at risk of lead poisoning[15] (resulting in lethal and/or sublethal effects) from ammunition and fishing tackle in the EU via primary or secondary routes. Fifty-four of these species are listed on Annex 1 of the EU Birds Directive as 'threatened'. This includes species with a very low number of individuals in the EU, including raptors and scavengers with low reproductive rates and for which the mortality of individual birds is of concern to conservation objectives. The Dossier Submitter wishes to highlight that many birds can ingest lead from different uses (lead gunshot, bullets, lures and sinkers) and it is not possible to distinguish the effects (including mortality) due to different sources of lead.[16]

The Dossier Submitter (also in response to comment #3242) further elaborated in the Background Document why the available information can be considered representative for the EU, regardless of the specific region or site where ingestion and subsequent lead poisoning occurs (or where this has been studied). This is due to the conserved feeding ecology of bird species throughout their range and the expected similarity of exposure to lead across the EU as the activities leading to the risk take place across the EU.

The Dossier Submitter also highlights that (as elaborated in comment #3343) the annual probability of exposure of an individual bird to lead objects is greater than that implied by reported 'snapshot prevalence' values in field studies; the Background Document has been updated accordingly (Section 1.5.3.4). Therefore, the Dossier Submitter does not agree with some commenters (e.g., #3242, #3467) suggesting that a negligible proportion of bird populations is at risk of lead poisoning.

Comment #3478 by UN-AEWA notes that *"the numbers of birds, and other wildlife, being affected negatively but non-fatally is an essential aspect of (lead) poisoning"*. The Dossier Submitter agrees that sub-lethal effects are an important element to consider and has discussed this issue in the proposal qualitatively. The Dossier Submitter also notes that several comments (for example #3480 among others) highlighted that the ingestion of lead objects by wildlife may result in poisoning with *"symptoms leading to a painful and long agony for the animals"*. Comment #3455 (as also # 3406 among others) reports that *"there is little to no mention of animal welfare in the report. (..) The range of clinical manifestations of poisoning, whether acute or chronic, represents extensive suffering and the issue of welfare deserves to be reflected within the subsequent opinions from the ECHA Committees"*. The Dossier Submitter wishes to

[14] See for additional details section 1.5.3.3

[15] Because they are either known to ingest these objects or their feeding ecology makes them particularly likely to ingest these objects.

[16] For example, some waterbird species such as the Marbled Teal (Marmaronetta angustirostris) are at a 'critical' conservation status (at risk of extinction) and can be exposed to lead from both fishing weights and gunshot.

highlight that numerous "clinical manifestations" of lead poisoning are discussed in the Annex to the Background Document in Section B.7.2.1.[17]

The Dossier Submitter also notes that some evidence submitted in the consultation (#3409) refers to a specific waterbird species assessed in the restriction on the use of lead shot in wetlands. However, findings have been included in the Background Document, because they may be relevant for other species as well. Comment #3524 proposes to reduce wildlife exposure through organised wildlife management (as a short-term measure), but no details were provided.

In addition, the Dossier Submitter notes the comments from the International Lead Association & Pb REACH Consortium (#3223) reporting the results of population modelling studies: "*all scenarios modelled show relatively small reductions in population size and negligible change in possibility of extinction due to lead shot ingestion".* The Dossier Submitter notes that during the evaluation of the proposed restriction of lead gunshot in wetlands RAC already concluded that "*an environmental risk assessment should not only protect against the risk of extinction of bird populations and species"* (…) "*How large the percentage of the population that would need to be affected for it to be regarded as a problem in conservation terms is not discussed in any guidance[18], perhaps because the concern caused by mortality is greater in a small population, especially if threatened with extinction, than in larger populations".* The Dossier Submitter considers this interpretation to be directly relevant to the risk assessment of lead in ammunition in terrestrial environment and to lead fishing sinkers and lures.

Finally, the Dossier Submitter acknowledges the consensus among scientists (comment #3506) on the toxic effects of lead on wildlife health (including birds). Some additional issues (on impacts) related to birds, are discussed in Section 1.1.4 of this document.

2.1.2. Risk to other species from the use of lead in outdoor shooting and fishing tackle

Numerous comments were submitted (for example #3228, #3250, #3303, #3343, #3361, #3369, #3455, #3489, #3493, #3494, #3510) pointing out that in addition to wild birds and livestock mammals, also other wild and domestic mammals (e.g., hunting dogs or even cats) and domestic avian species (such as chickens, ducks, geese, and turkeys) may be exposed to lead via the use of lead ammunition or fishing tackle. One comment stated that evidence for lead poisoning due to lead ammunition had been found in bears (#3493).

The Dossier Submitter updated the relevant sections of the Background Document (Sections 1.5.3.6, 1.5.3.7.4, 1.5.4) to account for the additional evidence gathered in the consultation.

---

[17] Comment #3343 also notes that clinical signs of lead poisoning in birds include weight loss, muscle wasting and loss of fat reserves, anorexia, diarrhoea, anaemia, lethargy, behavioural deficits, convulsions, and muscular incoordination including a range of neurological signs and paralysis.

[18] The Dossier Submitter notes that under REACH there is no requirement to estimate population-level impacts.

In addition, comment #3343 notes that: *"Published studies document the transfer of lead from ammunition to fish via contaminated water (e.g. Heier et al. 2009; Mariussen et al. 2016), and also the transfer of lead to soil and soil flora and fauna (e.g. Vyas et al. 2000)".* However, the Dossier Submitter could not elaborate further this information based on the limited data available.

Based on comment #3228, the Dossier Submitter notes that mussels and other marine taxa (e.g., shrimps, starfish and swimming crabs) may also be exposed to lead released to marine environments from fishing tackle. However, the Dossier Submitter could not assess the impact of the restriction proposal on these taxa because of the difficulty to distinguish between the sources of lead found in the sediment (marine) compartment.

2.1.3. Other risks (compartments related risks and risks to specific receptors)

Numerous comments were submitted by sector associations, NGOs, international bodies, competent authorities, sharing information relevant to risks related to different environmental compartments (soil, surface water and marine sediment) and to/via specific receptors (e.g., groundwater), including #3187, #3192, #3198, #3200, #3219, #3228, #3233, #3235, #3245, #3250, #3251, #3221, #3240, #3276, #3343, #3364, #3379, #3339, #3378, #3403, #3410, #3451, #3453, #3476, #3478, #3497, #3501 and #3510.

The Dossier Submitter provides general responses to these comment in the following sections. Comment #3198 was treated in a confidential manner as per the submitter's request.

2.1.3.1. Information relevant for risks related to the soil compartment (including agricultural soils)

Comments were either related to the contamination of soil as such or to the risks arising from soil contamination. Comment #3364 notes that in Cyprus: *"National law 517/2002 sets limits on lead concentrations as follows: 50-300 mg/kg"*. Comment #3451 notes that in Switzerland, *"with regard to soil contamination, shooting ranges are released from the "register of contaminated sites" if the soil does not exceed the value for unpolluted excavated material of 50 mg Pb/kg".* Comments #3198 and #3235 note that *"The threshold of lead contamination of soil in Hungary is 100 µg/g".*

Comment #3192 notes that in Poland there are specific regulations regarding soil quality classification, acceptable contamination levels and measurement methods. Comment #3379 notes that in Germany: *"The regular monitoring of the condition of the soil and / or of the water (ground and / or surface water) is for many shooting ranges either included as a requirement in the operating license or specified in a separate order by the licensing authority".*

Comment #3198 notes that in Germany: *"Limit values for lead in soils of agricultural*

land are specified in the Federal Soil Protection and Contaminated Sites Ordinance".[19] Comment #3403 notes that in Belgium: *"A soil examination has to be carried out when closing the range".*

The Hungarian Hunters' National Chamber (#3476) reports data of lead concentration in the soil of three shooting ranges. Based on the soil analysis results, they concluded that the lead contamination of Hungarian soils is acceptable. The Dossier Submitter notes that there is extensive evidence in the literature confirming soil contamination due to the use of lead ammunition, especially in soils in or around shooting ranges[20] and that a limited number of ranges sampled may not be indicative of the scenarios occurring in a whole country.

FITASC/ISSF (comment #3221, #3501) acknowledges that lead mobilisation in soils may occur depending on the characteristic of the sites and proposes different techniques for the monitoring and control of the soil contamination; for example, FITASC/ISSF is recommending to monitor the acid-base soil status and to amend, when indicated, with lime to increase the pH and reduce lead solubility. They also quote a recent study by INERIS (in French) discussing bio accessibility of metals and metalloids in soil. The Dossier Submitter has further elaborated the arguments on risk management measures related to the reduction of lead mobilisation at shooting ranges in Section 1.4.4.2 of the Background Document.

Comment #3478 (UN-AEWA) notes in general that *"Recognizing the importance of uncontaminated soils for agriculture and health of the environment, this should be reflected in the subsequent stages of the ECHA restriction process".* Comment #3510 quotes (among other issues) a study by Schupp et al. (2020) on long-term simulation of lead concentrations in agricultural soils in relation to human adverse health effects: "*annual deposition of Pb onto soil should remain below ~ 100 g/(ha × a) in order not to exceed the critical soil level of 5 mg/kg". The* comment notes that the study proposes *"as efficient measures to reduce Pb input into agricultural soil to lower the Pb content of compost and to use alternatives to Pb ammunition for hunting".* The Study by Schupp et al. (2020) is presented in the Annex to the Background Document in Section B.9.2.1.3.

Comment #3343 notes that *"transfer of lead to soils, sediment and water will generally be greatest in areas of high lead ammunition deposition, such as shooting ranges. Contaminated soil and water can then expose birds either directly or via vegetation, intermediate animals including aquatic or terrestrial invertebrates or vertebrate prey".* However, ingestion of contaminated soil by birds and other taxa was not the focus of the Dossier Submitter's assessment as discussed in Section 1.5.2.1.

In general, based on the received comments, it is unclear whether appropriate monitoring of soil contamination is carried out in all EU countries. For this reason, in response to the comments received, the Dossier Submitter has elaborated a specific

[19] Annex 2 No. 2.2 of the Federal Soil Protection and Contaminated Sites Ordinance of July 12, 1999 (Federal Law Gazette I p. 1554), last amended by Art. 126 V of June 19, 2020 I 1328).

[20] This is discussed in the Background Document (Section 1.5.3.7.2) and more in details in the Annex to the Background Document (B.9.1.3.4).

section in the Background Document (results of the Member States survey 2020, Section 1.4.4.2.2.4) which suggests that monitoring of lead concentration in the soil at shooting ranges is not frequently undertaken at the EU level.

The Dossier Submitter notes that high soil lead concentration[21] are directly linked to the risks discussed in the following sections, in addition to the risks of ingestion of contaminated soil by birds, other taxa and humans[22]. The Dossier Submitter has not further elaborated the conceptual models developed in Section B.9.1.3.3 of the Annex to the Background Document, based on the information received.

Finally, the Dossier Submitter notes that there are no commonly established limits for soil pollutants such as lead at the EU level. The Sewage Sludge Directive defines limits for heavy metals (including lead) in agricultural soils on which sewage sludge is applied. In relation to sewage sludges, comment #3250 mentions that in the United Kingdom the maximum permitted total heavy metal concentrations in agricultural soils receiving sewage sludge are laid out in the Sludge (Use in Agriculture) Regulations 1989 Great Britain and Northern Ireland 1990.

2.1.3.2. Information relevant for risks to/via specific receptors (groundwater)

The Dossier Submitter undertook an additional assessment related to the risks to/via groundwater pollution during the opinion making phase (see Appendix 1 to the Background Document: *Assessment of the potential for the use of lead ammunition at shooting ranges to contaminate groundwater and drinking water*). The circumstances leading to potentially higher risks via groundwater pollution include high lead loading in the soil (typically found on clay target ranges); acidic, coarse textured soils; soils that are low in Fe, Mn and P; soils with shallow water table; preferential flow pathways in the soil; presence of perennial vegetation, especially trees. Circumstances leading to potentially lower risks via groundwater pollution include low lead loading in the soil, calcareous soils (alkaline), fine texture, presence of clay, deep groundwater table, limited preferential pathways in the soil.

Several commenters (for example #3187 or #3251) consider that contamination of groundwater is negligible. However, it is unclear whether this conclusion included a consideration of the circumstances identified above that may lead to potentially higher risks, also for ranges to be built in the future. For instance, FITASC/ISSF (comment #3221) stated that vertical migration of lead to groundwater cannot occur, but this comment does not appear to consider all possible scenarios, as identified above by the Dossier Submitter. However, it is to be noted that FITASC/ISSF (comments #3221 and #3501) acknowledges that lead mobilisation in soils may occur depending on the characteristic of the sites (see also Section 2.1.3.1 above).

Other comments (for example #3240, related to Finland) highlighted that *"the risk level*

[21] Available data are presented in the annex to the Background Document, Section B.9.1.3.4.

[22] After the service life of a shooting range, the ground previously used for shooting, may be used (in some countries) for other purposes, assuming that the land will be zoned accordingly (e.g. for recreational and residential purposes) and undergo some kind of remediation. A "case study" on a shooting range converted in a public park is presented in Section B.9.1.3.4. of the Annex to the Background Document.

can be determined site-specifically" and that *"the possible impact of the pollutants is mainly targeted to the surface and groundwaters"*.

Comment #3494 notes that *"No levels of lead in groundwater should be considered acceptable in line with the EU Water Framework Directive (WFD) 2027 objectives".*

Overall, different EU Member States appear to have different approaches to and legislation for dealing with surface and groundwater-related risks during the entire lifecycle of a range (including end of life). For example, comment #3379 notes that in Germany: "*The regular monitoring of the condition of the soil and / or of the water (ground and / or surface water) is for many shooting ranges either included as a requirement in the operating license or specified in a separate order by the licensing authority. The regular examinations are carried out by independent experts".* Comment #3198, related to Germany, notes that *"If no renovation takes place after a shutdown, the abandoned sites are monitored by means of a monitoring system. At regular intervals (3 to 8 years), soil and groundwater investigations and a risk assessment are carried out in accordance with the laws".* Comment #3192, related to Poland, notes that "*Despite bullet traps being mandatory, there are additional regulations of the ministry of environment. All outdoor shooting ranges where projectiles containing lead can be used, must have at least 80 % of lead periodically removed from the soil (frequency depends on the depth of the groundwater table) and soil acidity must be monitored and kept within pH range 6.5-8.5."*

This information gathered suggests that this type of risk can be relevant in different locations across the EU, although it has not been possible for the Dossier Submitter to quantify the extent to which this is an issue in each of the EU Member States. The Dossier Submitter also notes that monitoring schemes to identify risks which may occur at the end of life of a shooting range are not harmonised across the EEA/EU Member States. For example, comment #3245, related to Norway, states that *"There are no formal provisions as to how to manage the risk of pollution at the end of life of a shooting range",* suggesting that there is no formal provision in relation to the risks of lead pollution via groundwater. A comment by ANSES (#3378) asked whether *"[it] would be possible to further document the vulnerability of groundwater to lead contamination through a mapping exercise cross-referencing data on the location and characteristics of the shooting ranges with the characteristics of the water resources in which they are located".* The Dossier Submitter notes that although this could be a useful exercise, it would require Member States to provide an up-to-date list of the location of existing shooting ranges. However, as noted in the Dossier Submitter's survey carried out in 2020 (referred to as Member States survey 2020, in the Background Document), most Member States do not have a comprehensive national database including such detailed data.

2.1.3.3. Information relevant for compartment related risks (surface water)

Commenters generally acknowledged that contamination of surface run off water may be relevant for certain shooting ranges. For example, comment #3245 suggests an estimation of lead that could leach every year into waterways from certain types of ranges in Norway: "*we can conclude that approx. 150 kg of lead, 70 kg of copper, 20 kg of antimony and 100 kg of zinc are leaked from DFS shooting ranges to the waterways".*

Comments #3261 and #3410 note that: *"Test wells adjacent to the backstop are used to monitor lead content in surface water and water drained through the backstop, when requested by local environment regulations or authorities".* Comment #3221 agrees that the migration of lead into surface water is more likely at shotgun ranges than at pistol and rifle ranges. Comment #3240 highlights that a study by Kajander & Parri (2014) describes the water treatments applicable at shooting ranges.

Comment #3343 notes that*:" Published studies document the transfer of lead from ammunition to fish via contaminated water (e.g. Heier et al. 2009; Mariussen et al. 2016)".* The Dossier Submitter has updated section 1.5.3.7.1 with relevant information.

In general, the Dossier Submitter notes that, based on the results of the Member States survey (see updated Section 1.4.4.2.2.4 of the Background Document), monitoring of lead concentrations in surface water runoff from shooting ranges appears not to be very common.

2.1.3.4. Information relevant for compartment related risks (marine sediment compartment)

In relation to the risks related to the sediment compartment, especially in relation to the potential pollution from lost fishing tackle, the Dossier Submitter acknowledges the comment from Belgium (#3228) to encompass the *"health of environment"* as a whole (*"BE believes that it is important to broaden the basis of the hazard and risk assessment of this restriction to encompass not only human health and wildlife birds, but the environment as a whole"*). However, the Dossier Submitter notes that it is currently not feasible (based on the available data) to distinguish between lead released to the sediment (marine) compartment by the use of lead fishing tackles and other sources of lead not being covered by the restriction proposal.

In general, although some environmental monitoring programmes are carried out at local and national level in the EU, the Dossier Submitter notes the difficulty to distinguish between the sources of lead in the sediment (marine) compartment. For this reason, no specific assessment was carried out. However, this does not imply that risks can be ruled out since many tonnes of lead fishing tackle are released to the environment every year (see Section 2.8.1.2 in the Background Document).

2.1.4. Human health hazards and risks

Several comments were submitted such as #3209, #3212, #3223, #2353, #3267, #3285, #3291, #3361, #3340, #3344, #3361, #3362, #3364, #3372, #3373, #3388, #3401, #3480, #3484, #3485, #3507 related to the hazards and risks of lead for humans.

Some comments flagged the well-known toxicity of lead, such as #3253, #3361, #3364, #3372, #3373, #3388, #3484, #3507. In two comments (#3209, #3485) several studies were brought to the attention of the Dossier Submitter that provide additional evidence to support the conclusion that lead poses a risk for the environment and human health (due to various exposure routes). In other comments the toxicity of lead for humans from the use in fishing (#3340, #3344) and sports shooting (#3362) was questioned. The Dossier Submitter acknowledges those comments.

A comment from the German Member State Competent Authority (#3209) provided further information mainly on toxicokinetics. The Dossier Submitter amended the Background Document accordingly.

The International Lead Association (ILA) and the Lead REACH Consortium (#3223, #3291) provided the following comments amended with responses from the Dossier Submitter:

> "*The Annex XV report fails to systematically and critically assess, correct, and synthesise the lead health effects literature that forms the basis for the human health risk assessment (as described in Section 1.6 of the Annex XV report) to give an accurate synthesis of knowledge and uncertainty about lead health effects.*" The Dossier Submitter notes that the hazards of lead are well known and summarised in several recent restrictions as well as in ECHA's evaluation of limit values for lead and its compounds at the workplace.[23] On this basis a separate assessment for the purposes of this restriction is not necessary.
>
> "*The approach to human health risk assessment (…) relies heavily on the European Food Safety Authority's (EFSA's) Scientific Opinion on lead in food/EFSA Panel on Contaminants in Food Chain report and associated EFSA Journal documents to model lead exposure and health outcomes (…). However, this approach, which uses benchmark dose (BMD) modelling, is too conservative/uncertain for consideration in any final rule on restriction*." The Dossier Submitter notes that in the *ECHA Guidance on information requirements and chemical safety assessment Chapter R.8*[24] the benchmark dose concept is considered as an alternative to dose-response assessment and can be used in parallel to the derivation of a NOAEL.
>
> "*In addition, the EFSA Scientific Opinion is now more than ten years old and may not reflect the most up-to-date information on lead dose-response. For example, Van Landingham et al. (2020) studied the limitations of current regression models in extrapolation to the low dose region of the dose-response curve due to the existence of unrecognised and uncontrolled confounding, using epidemiological data for lead.*" The Dossier Submitter carefully read the paper by Van Landingham et al. (2020) which arrives at the conclusion that "*[t]here is no doubt that there is a negative relationship between lead and IQ; however, given the relatively small effects of lead on IQ at low doses as compared with other factors affecting IQ, it is difficult to believe that the relationship between very low levels of lead and IQ is as large as would be reflected by these log-linear relationships*". However, the Dossier Submitter considers that this conclusion is made based on similar arguments as a previous paper by Wilson and Wilson (2016), which was refuted during the consultation on the restriction on lead gunshot in and over wetlands. Indeed, Van Landingham et al. contemplate the possibility that interaction effects of confounders have been ignored in previous landmark studies

[23] https://echa.europa.eu/documents/10162/68cf7011-9c04-2634-efa6-b712f1b34a85.

[24] https://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf/e153243a-03f0-44c5-8808-88af66223258.

on the lead-IQ relationship. The Dossier Submitter understands the argument of the paper to be the following. Assume that data on IQ were generated by the following data generating process:

IQ = a0 + b0*Pb + c0*CONFOUNDER + d0*Pb*CONFOUNDER + residual0

Suppose that in the analysis the interaction term Pb*CONFOUNDER is overlooked and instead the model fitted to the data is:

IQ = a1 + b1*Pb + c1*CONFOUNDER + residual1

This is not ideal because the analyst will miss the relationship between lead exposure (Pb) and the CONFOUNDER. However, the estimator b1 will converge to b0 + c0*E[CONFOUNDER], where E[CONFOUNDER] denotes the mean value of the CONFOUNDER (or the sample fraction that is characterised by an ordinal confounder). Thus, if the interaction term is ignored, the estimated effect will hold for subjects that are characterizable as average subjects. If the parameter d0 is positive (negative), then the lead effect is less serious for an individual at a higher (lower) CONFOUNDER value. The naive analysis above will estimate the effect for the average individual, which implies that one overestimates the adverse effect for some individuals and underestimates the adverse effect for other individuals but gets it right on average. Therefore, contrary to what Van Landingham et al. (2020) suggest, failure to include interaction terms will not lead to a general overestimation of the exposure effect in the low dose range.

"*Several recent articles have been published from a two-year longitudinal study of adults exposed to low-level lead in the workplace known as SPHERL (Study for the Promotion of Health in Recycling Lead) such as Yang et al. (2018), Mujaj et al. (2019), and Yu et al. (2019).*" The Dossier Submitter amended the Background Document with references to these studies.

"*Inhalation absorption is 95 % and gastrointestinal absorption is more accurately reflected in ranges of 3 -10 % in adults and 40-50 % in children.*" The Dossier Submitter amended the Background Document accordingly.

"*Case reports (mainly for children) prove that even one larger piece of lead ingested orally can create sufficient systemic exposure to produce clinical lead intoxication or even death." Literature citation and statement about the amount of lead should be provided*." The Dossier Submitter notes that this refers to the Voluntary Risk Assessment on lead metal, lead oxide, lead tetraoxide and lead stabilizers (LDAI 2008). A proper reference was added in the Background Document.

With regards to Lanphear et al. (2018), "*it is important to note that Yang et al. (2018) stated, while there is sufficient evidence to infer a causal association of hypertension with lead exposure, the evidence is inconclusive to deduce a causal relation of cardiovascular outcomes with lead exposure. (…) In the Staessen et al. (2020) review of Lanphear et al. (2018), it was noted that the association between cardiovascular mortality and blood lead was statistically significant in all age groups combined, but when analysed by age strata, none of the hazard ratios*

expressing the risk of cardiovascular mortality in the middle or high blood lead categories reached significance; the trend p-value reached significance (p <0.05) only in the age band from 75 to 84 years." The Dossier Submitter amended the information in the Background Document.

"*The statement that lead exposure is associated decreasing GFR at blood lead levels <100 µg/L is not supported by the results of SPHERL.*" The Dossier Submitter amended the Background Document with the SPHERL studies. The Dossier Submitter notes that the conclusion in the Background Document is based on the studies evaluated by EFSA (2010) and supported by the conclusion of ATSDR (2020). However, the Dossier Submitter noted explicitly that the estimates may be inflated by reverse causality for associations between deceasing GFR and increasing lead body burden.

"*The wide range of BMD and BMDL estimates (low of 2.50; high of 80.6) in the table demonstrates the significant effect of modelling assumptions upon benchmark dose calculations.*" The Dossier Submitter noticed a clerical error regarding the decimals reported in the table noted by the commenter. Indeed, as shown in Table II of Budtz-Jørgensen et al. (2013), the BMD and BMDL estimates derived from the linear model should read 8.06 and 5.24, respectively. This was corrected in the Background Document.

FITASC/ISSF (#3267) pointed to the extract from the ISSF presentation sent to the European Chemicals Agency in December 2019: "*There is no evidence for a safe threshold for a number of critical endpoints, including developmental neurotoxicity and nephrotoxicity".* FITASC/ISSF interpreted this sentence in a way that "*means that there is no level of exposure below which effects in humans are not expected*" which would contradict existing standards. A similar comment (#3401) claimed: "*Statements that no level of Lead is safe are clearly incorrect as Lead occurs naturally in the environment and in many industrial and domestic environments where safe levels are documented as part of standard health and safety requirements*." The Dossier Submitter understands the statement from EFSA to mean that the current evidence (data) does not allow the derivation of a threshold for the critical effects mentioned. EFSA therefore extrapolated BMDLs based on available data. The Dossier Submitter considers that for effects on adult members of the general population thresholds for certain adverse effects may exist (see also OEL[25] on lead). However, for the developing nervous system of children any exposure may have an adverse impact on neurological function (typically measured by IQ), and it is therefore commonly assumed that, for this particular endpoint, no safe threshold exists, see also the discussion in Budtz-Jørgensen et al. (2013).

2.1.5. Risk associated with game meat consumption

Several comments were submitted on risks associated with game meat consumption (#3209, #3212, #3220, #3237, #3242, #3303, #3363, #3446, #3460, #3467, #3476, #3479, #3480, #3485, #3494, #3514). These comments covered issues related to the

[25] https://echa.europa.eu/documents/10162/68cf7011-9c04-2634-efa6-b712f1b34a85.

Dossier Submitter's assessment of the risk associated with the consumption of game meat, including the following topics:

2.1.5.1. Data from EFSA on lead concentration in and consumption of game meat

Some commentators (e.g., #3460, #3467) expressed concern that they had no access to the data that the Dossier Submitter had received from EFSA. Whilst the Dossier Submitter understands these concerns, it is not able to share data owned by EFSA. The Dossier Submitter made sure to include descriptive statistics of as well as descriptions of the sampling protocols for both datasets that should permit interested parties to replicate its analysis made on the basis of the EFSA data.

2.1.5.2. Lead concentration in game meat

Wildfowl & Wetland Trust (#3303) as well as an individual commenter (#3460) pointed out that they believed that lead concentrations, particular in birds, could be higher than in the EFSA concentration data and provided additional data on lead concentrations found in game meat. FACE (#3467) pointed out that they believed that lead concentrations, particular in large game, could be lower than in the EFSA concentration data and provided additional data on lead concentrations found in game meat. FACE (#3467) and other commenters (e.g., #3460) also requested more information about the representativeness of the data and the sampling methodology. One comment (#3494) noted that the lead levels for some species, especially for species which are widely farmed, are below previously reported levels and proposes to explore this with EFSA. Another comment (#3212) noted that contaminated game meat has been reported in areas with industrial contamination and that lead ammunition increases lead concentration around the wound channel only slightly. Comment #3220 indicated that the State veterinary service of the Czech Republic regularly monitor the contamination of lead in game meat; however, the Dossier Submitter notes that no further information on the monitoring results was provided. Hunting with small calibre lead bullets, very low lead concentration in game meat has been found (#3237); however, no evidence was submitted to support these findings.

Lead concentration in game meat from meat and meat products from deer and wild boar collected in Spain (#3446) and Hungary (#3476) were reported. Comment #3485 referred to a newly published study from Italy on lead levels in wild boar meat sauce. Comment #3363 referred to a recently published study (Schulz et al., 2021) on bioavailability of lead from ammunition in meat fed to pigs.

In response to these comments, the Dossier Submitter added information in the Background Document on the coverage, sampling protocol and geographical representativeness of the EFSA data.[26] Whilst noting that other sources of lead concentration data exist, the Dossier Submitter considers the EFSA data to be the most suitable for the purpose of risk assessment as they were not collected according to a

[26] EFSA data analysed by the Dossier Submitter pools data collected by individual EU Member States as part of the Chemical Monitoring (ChemMon) reporting following a standardised protocol (see https://www.efsa.europa.eu/en/supporting/pub/en-6420#related-topics for details on the most recent version of the sampling protocol).

purposeful sampling methodology (i.e., samples were not collected to find particularly high or low concentrations of lead), but were part of a more general exercise to understand the level of pesticide residues, veterinary medicinal product residues, and contaminants and additives in game meat. The Dossier Submitter also clarified that for the purpose of risk characterisation it had used the mean lead concentration values for small and large game considering that a non-negligible fraction of hunter families might be exposed to high concentrations over a longer period of time[27]; however, for the purpose of impact assessment it used the *full* distribution of concentration data received from EFSA.

In comment #3363 it was noted that it should be discussed that meat from farmed animals has an equal distribution of lead in muscle tissue, whereas the lead fragments and particles in wild game from lead bullets are unevenly distributed. The Dossier Submitter has amended the Background Document accordingly.

2.1.5.3. Game meat intake

Several commentators (#3242, #3467) observed that the daily intakes the Dossier Submitter had assumed in its original analysis were corresponding to unrealistically high annual intake of game meat. A comment (#3485) indicated that in Italy high-frequent consumers might not only be limited to hunter families but due to the expansion of the population of wild ungulates, a large amount of venison is placed on the domestic market and consumed frequently among people living in the countryside. However, no quantitative estimates were provided. Game meat is served in restaurants and country fairs and used for the preparation of sauces and other manufactured products. Furthermore, the consumption of dishes based on game is frequent among people living in the countryside, mainly in mountainous areas where wild ungulates are very abundant.

Based on these comments (#3242, #3467), the Dossier Submitter revised the analysis using the median daily intake value of EFSA consumption data rather than the 95th percentile value assumed in the original analysis. Whilst the implied annual intakes are still somewhat higher than the intakes assumed in other studies, they appear not to be unrealistic. Moreover, it should be emphasised that the daily intake of lead is a toxicokinetic measure whose extrapolation to annual intake values is not entirely appropriate since the daily intake of lead converts into the blood lead level in a non-linear fashion. Indeed, because of the half-life of lead in the human body, the blood lead level of an individual will quickly come close to 90 % of the steady state level even if the individual would not consume game meat on each subsequent day.

2.1.5.4. Risk related to game meat consumption

WWF Spain (#3446) submitted a report on the risk due to consumption of meat from large game in Spain summarising that 47 % of samples from meat product, especially from wild boar, showed lead concentrations above 0.1 mg/kg. The performed risk estimation calculations, implied potential risks for extreme consumers and average

[27] This happens, e.g., if a hunter minces larger cuts of contaminated game meat which the family is subsequently consuming in portions.

consumers with regards to cardiovascular effects and chronic nephrotoxicity. The Dossier Submitter amended the Background Document.

According to a comment from Cyprus (#3514), no health problems caused by the consumption of game meat have been recorded.

FACE (#3467) criticised the Dossier Submitter's assessment of risk related to the intake of game meat hunted with lead ammunition and the corresponding impact assessment and questioned whether, given the prevailing background exposure to lead, any of the excess risks would be attributable to game meat consumption. In conclusion, FACE asserted that the Dossier Submitter had "provided incomplete and suppressed evidence by suppressing unfavourable observations in such a manner that the dietary exposure conclusions appear to be doubtful". In response to this comment, the Dossier Submitter stresses that it had neither provided incomplete evidence, nor had it suppressed unfavourable observations. Instead, the Dossier Submitter took forward the full distribution of ingestion exposure implied by the data provided by EFSA. The Dossier Submitter wishes to emphasise that its analysis is based on excess exposure, i.e., the impacts of being exposed to lead via the consumption of game meat over and above the background exposure. There is robust evidence in the literature (and confirmed multiple times by RAC) for associations between lead exposure and the endpoints (IQ loss in young children, increments in CKD risk in adults) assessed by the Dossier Submitter. Therefore, the Dossier Submitter did not change its methodology. Nevertheless, since the Dossier Submitter changed its assumption on the frequency and quantity of game meat consumption, and thus on daily intake of lead, the quantitative results of both the risk characterisation (Section 1.6) and human health impact assessment (Section 2.5) were updated in the Background Document.

Comment #3209 additionally highlighted that methods for preparing game meat (in acid environments) increase lead absorption and thus the risks related to game meat consumption. Comment #3485 highlighted that in Italy the consumption of game meat has steadily increased over the last decades, leading to a situation in which frequent game meat consumption is no longer limited to hunter families, but has become "frequent among people living in the countryside, mainly in mountainous areas where wild ungulates are very abundant. In a large part of Alps and Apennines, the number of servings per month consumed by non-hunters can be relevant, especially during the hunting season". The Dossier Submitter takes due note of these comments and integrated the reasoning and some of the references provided into the Background Document.

In comment #3296 it was noted that the health risks for children are not sufficiently substantiated; more specifically no scientific source was identified that would demonstrate difference in IQ development for children exposed and non-exposed to meat from animals shot with lead containing ammunition, and those who were not. In the absence of such verifying information, the Dossier Submitter considers the performed calculations as robust because they are based on available information. For example, the calculated risk is based on available data on bioavailability, lead concentration in game meat and amount of game meat consumption within Europe reported from EU Member States to EFSA, and the BMDL of 12 µg/L for IQ changes in children is set by an expert panel from EFSA.

2.1.5.5. Maximum lead concentration in meat

In comment #3363 it was noted that the recommendation for transferring the maximum lead concentration in meat of beef, sheep, pork and poultry, to game meat (mammals), is considered impractical, because so called lead-free alternatives also contain lead which make it impossible to ensure compliance with this value in game meat. The Dossier Submitter notes that no supporting evidence was provided to support the statement that transferring the maximum lead concentration in lead to game meat. The Dossier Submitter considers that game meat shot with alternative ammunition is not expected to contain relevant concentrations of lead. Indeed, alternative shotgun ammunition does not contain any significant amount of lead. Even in game meat shot with alternative bullets no relevant lead concentrations are to be expected as alternatives currently on the market have a maximum lead content of 3 % w/w.

2.1.6. Exposure to lead of shopkeeper and employees

Some comments noted the exposure of shop personnel specifically selling unpackaged lead fishing tackle with potential for hand-to-mouth exposure and that the personnel might not be aware of the hazards of lead (for example, #3178, #3196, #3203). Consequently, these commenters proposed to sell lead fishing tackle only in blisters, to supply PPE, e.g., gloves to the shop personnel, and that potentially exposed personnel are informed about the hazards and risks of lead.

The Dossier Submitter has considered potential exposure of home-casting activities in the Background Document (see Section 1.6.3) but has not investigated lead exposure of shop personnel that sells unpackaged lead items (fishing tackle, ammunition).

2.1.7. Monitoring of environmental exposure

Several comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals covering different aspects. For example, comments #3177, #3181, #3182, #3184, #3189, #3195, #3216, #3217, #3219, #3220, #3225, #3227, #3228, #3235, #3243, #3349, #3250, #3252, #3254, #3263, #3276, #3289, #3299, #3340, #3348, #3359, #3360, #3372, #3377, #3486, #3499. Some of these comments have been handled as confidential as per the commenter's request.

2.1.7.1. Monitoring of lead exposure in wildlife

In relation to the monitoring of lead in wildlife, several countries have existing programmes in place, either at national or local level, which are carried out by authorities, scientific bodies, or other parties. For example, in Finland, the state authority (ELY keskus) is responsible for environmental monitoring. They do regular checks to verify compliance with environmental regulations (#3284), and some monitoring is also carried out by the World Wide Fund For Nature (WWF) together with the Finnish Museum of Natural History (#3182). In Italy, the ISPRA national institute and Parco Nazionale dello Stelvio (National park of Stelvio, comment #3511) have been monitoring the impacts of exposure to lead ammunition in wildlife. Results published in the scientific literature suggest that certain raptor species can be particularly affected (#3377). In Sweden, the National Veterinary Service (Statens Veterinärmedicinska

Anstalt) has a monitoring programme for various health aspects of Swedish wildlife (#3252). As part of that program, the impacts of lead ammunition on wildlife are monitored. Monitoring activities are also carried out by the Department of Contaminant Research of the Swedish Museum of Natural History (#3348) and by the Inland Norway University of Applied Sciences (#3493) which is monitoring environmental lead exposure in several ongoing projects. This includes assessing the effects of calibre and bullet type on wound ballistics, loss of lead and copper from bullets and a comparison of lead-based and non-lead ammunition.

The Lead Ammunition Group (#3250) quotes the United Kingdom's Predatory Bird Monitoring Scheme (PBMS) and the European Raptor Biomonitoring Facility. The European Raptor Biomonitoring Facility (comment #3517) is an open network of researchers and practitioners working towards a coordinated Europe-wide monitoring of contaminants in raptors (birds of prey) with a view to supporting the implementation of EU chemicals regulations. The network has selected lead as one of the key contaminants to be monitored in European raptors: *"Such a network can be used to monitor the current exposure to lead in raptors at a pan-European scale, complementing other national scales studies and will be helpful to evaluate the implementation of the EU regulations on lead ammunition".*

As discussed in Section 2.1.2 of this document, monitoring of lead exposure of other wild mammals is also increasing.

The Dossier Submitter notes that the information received in the consultation highlights that the existence of long-term monitoring schemes of wildlife exposure (covering all species discussed in the Dossier Submitter's assessment) is patchy and not coordinated at the EU level. Short term projects are more likely to be undertaken for a limited number of species, for example when poisoning incidents have occurred. The Dossier Submitter notes the comment #3359 by the European Association of Zoo and Wildlife Veterinarians, stating that mortality and morbidity caused by lead from ammunition and fishing tackle in both wild and captive animals are probably underdiagnosed and underreported as the proximal cause of death might be more obvious (e.g., predation, trauma or infectious disease) and contaminants surveillance is costly and may not be undertaken routinely. The absence of long-term wildlife surveillance programmes may explain the apparent lack of evidence of lead poisoning for some of the species assessed in the restriction proposal.

The Dossier Submitter took note of the submitted comments and integrated the main conclusion in Section 1.5.4.1.4 of the Background Document.

2.2. RAC Rapporteurs comments

Environmental effects

The comments received either emphasised the need to pay more attention to sub-lethal effects of lead in birds or highlighted that the assessment should focus on population effects rather than on effects in individual birds.

RAC acknowledges that it is likely that the sub-lethal effects of lead in birds are even more common than lethal effects and that sub-lethal effects could also be the cause for

accidents resulting in lethality. However, as the sub-lethal effects can be expressed in many ways, and there is no way of quantifying them, RAC supports that they cannot be assessed quantitatively. RAC considers that by focusing on the number of species at risk (92) rather than on bird mortality, sub-lethal effects and welfare issues are also covered.

RAC is of the opinion that effects in individual birds are of concern, and for the 54 red-listed species effects in individual birds may also have population effects (risk for extinction), reinforcing the concern. Both individual risks and population effects have been considered in RAC's qualitative risk assessment.

Regarding comments on risks to other wild and domestic animals, such as hunting dogs, RAC acknowledges this risk but considers that no quantitative assessment of this risk can be performed.

RAC acknowledges the information provided in the consultation on the monitoring of soil and surface/groundwater contamination with lead at the shooting ranges. RAC shares the Dossier Submitter's view that the frequency of monitoring of lead concentration in the soil seem highly variable at the EU level. RAC acknowledges that soil properties highly affect the mobility of lead and potential groundwater contamination and has taken this into account in its qualitative risk assessment. However, it remains unclear how common soil conditions favourable for lead migration are at shooting ranges in EU.

RAC agrees with the Dossier Submitter that there is too limited data to assess the risks to sediments due to fishing tackle.

Human health effects

RAC agrees with the Dossier Submitter that the hazards of lead for humans are well described and EFSA estimations on the BMDLs for different toxic endpoints can be considered still a valid starting point for the risk assessment. However, RAC recognises the uncertainties related to the dose responses of lead especially at lower blood lead (B-Pb) levels. This has been pointed out in the RAC opinion. RAC also agrees with the Dossier Submitter that the current evidence does not allow the derivation of a threshold especially for the developmental toxicity of lead. Therefore, regardless of some uncertainties related to the epidemiological studies behind the calculated BMDLs, RAC considers the approach chosen by the Dossier Submitter justified. However, RAC has discussed the uncertainties in the hazard assessment section of the RAC opinion.

Regarding the EFSA data on the game meat lead levels, RAC has carefully evaluated the EFSA data together with the data available from the literature. Possible underestimation of game meat levels in small game has been pointed out in the opinion. RAC has also recognised the highly skewed distribution of the EFSA data with some single high levels contributing significantly to the arithmetic mean levels of the game meat lead. However, in the quantitative risk assessment, the Dossier Submitter used the whole distribution of the game meat concentrations, and the impacts were capped to the level of ≥ 1 IQ point, which ignores the upper end of the curve including some exceptionally high (and therefore rather unlikely) lead exposure levels.

RAC agrees that the originally calculated game meat intake levels may have been overestimations and supports the Dossier Submitter's updated intake values. Overall,

RAC notes that there are uncertainties related to the assessment of health risks due to game meat consumption since the assessment is based on modelled intake values instead of real measured B-Pb levels in high game meat consuming families. However, recognising this uncertainty, RAC supports the analysis of the Dossier Submitter. This is further discussed in the RAC WP A.5 report on the human health risks related to the consumption of game meat and other meat and dairy products.

RAC considers it important and gives a recommendation to the Commission for the setting of a regulatory maximum level for lead in game meat. If this recommendation is followed, the limit will be set in a separate process.

RAC agrees with the Dossier Submitter that there is too limited data to assess the lead exposure of shopkeepers and employees handling lead fishing tackle.

2.3. SEAC Rapporteurs comments

As hazard and risk characterisation is in RAC's remit, the SEAC rapporteurs do not have any comments.

3. Hunting

3.1. Dossier Submitter response to comments

3.1.1. Use volume

One comment from Italy (#3485) referred to the volume of lead gunshot used and released by hunters that was estimated with 13 000 to 15 000 tonnes per year. The commentor estimated that Italian hunters would release into the environment 4 500 tonnes of lead per year and noted that the amount could even be greater because it did not consider gunshot produced by foreign manufacturers. This amount represents 30 to 35.5 % of the total amount of lead gunshot estimated by ECHA to be used and released by hunters. Because Italian hunters account for just 12.8 % of the overall number of hunters in the EU (data from FACE website), the commenter argues that the total volume of lead that is used on shooting must be higher than the value estimated by the Dossier Submitter.

The Dossier Submitter notes that similar comments on a possible underestimation of the volume of use of lead shot have been made in the dossier on lead in wetlands as well, where diverse national estimates seemed to suggest higher volumes of lead use then the use volumes reported by the Dossier Submitter. The estimation of the Dossier submitter has been based on sales volumes reported by AFEMS[28] and constitute an estimation based on a source that covers in harmonised manner the EU it was therefore used by the Dossier Submitter. The uncertainties around this volume have been documented in the Background Dossier.

3.1.2. Alternatives to lead-based ammunition

Comments on alternatives to lead ammunition (both shot and rifle) were submitted by sector associations, supply chain actors, competent authorities as well as individuals, including: #3173, #3177, #3178, #3181, #3182, #3183, #3184, #3186, #3187, #3188, #3189, #3190, #3194, #3195, #3197, #3198, #3199, #3200, #3201, #3202, #3203, #3204, #3206, #3207, #3210,# 3212, #3213, #3214, #3215, #3216, #3217, #3219, #3220, #3221, #3222, #3223, #3224, #3225, #3226, #3227, #3229, #3230, #3231, #3233, #3234, #3235, #3236, #3237, #3238, #3239, #3240, #3242, #3244, #3245, #3246, #3247, #3248, #3249, #3250, #3252, #3254, #3255, #3257, #3258, #3259, #3261, #3262, #3263, #3265, #3266, #3267, #3275, #3276, #3280, #3285, #3290, #3293, #3298, #3299, #3301, #3303, #3304, #3306, #3310, #3326, #3329, #3331, #3333, #3340, #3341, #3344, #3350, #3358, #3360, #3363, #3364, #3368, #3372, #3373, #3379, #3381, #3389, #3399, #3401, #3402, #3403, #3410, #3411, #3413, #3417, #3418, #3420, #3421, #3422, #3423, #3425, #3426, #3427, #3429, #3431, #3437, #3438, #3440, #3441, #3442, #3445, #3447, #3448, #3449, #3451, #3457, #3458, #3461, #3466, #3467, #3468, #3469, #3470, #3471, #3472, #3474, #3476, #3479, #3480, #3482, #3483, #3488, #3490, #3492, #3498, #3500, #3502,

[28] See, https://echa.europa.eu/documents/10162/13641/restrictions_lead_shot_axv_report_en.pdf/6ef877d5-94b7-a8f8-1c49-8c07c894fff7 , page 70.

#3505, #3507, #3510, #3511, #3512, #3513, #3514, #3518, #3522, #3523, #3525.

The information submitted in these comments presented varying view on the degree of substitution of lead that is possible to achieve in practice ranging from Wildfowl & Wetland Trust (comment #3303) stating that substitution to lead-free ammunition is entirely possible[29] and that lead can be replaced in all applications to comments on certain applications where suitable alternatives to lead might currently not be available; e.g. rimfire rifle ammunition, air guns, muzzle loader and full metal jacket bullets. The different arguments are discussed in specific sections of this document.

3.1.2.1. Alternatives to lead in gunshot

3.1.2.1.1. Availability of bismuth gunshot

In the Annex XV report submitted for consultation, the Dossier Submitter had assumed that hunters could partially replace lead shot by bismuth shot. However, AFEMS (#3246, #3331) and FACE (#3467) commented that bismuth is not a credible drop in alternative and it is therefore not a valid assumption that gun owners will switch to bismuth gunshot rather than replacing their shotguns. They argue that the relative scarcity of bismuth and the massive increase in demand predicted in the event of a restriction would increase costs. They also consider that, as bismuth is not readily recycled, its use in ammunition is not sustainable. A calculation is then presented which – according to the commenter – indicates the non-sustainability of the use of bismuth for hunting.

The Dossier Submitter notes that in hunting, bismuth is typically used in old guns for which replacing lead with steel is often not possible because of concerns of gun suitability for steel.

A further argument AFEMS brings forward relates to the total registered volume of bismuth[30] which is around 10 000 tonnes per year. The argument that is put forward indicates that there are difficulties to increase the share used for ammunition as the use of bismuth in ammunition will need to compete with other uses of bismuth, which AFEMS considers to be more critical.

Stakeholders (#3467, #3331) expressed concern that with a declining lead supply, bismuth (as a by-product of lead mining) would become less available in the future. On this, the Dossier Submitter wants to point to the statistics of the International Lead and Zinc Study Group (ILZGS), see also Figure 3, showing that the dominant end use of lead is in batteries (80 % of total end use by consumption) which is expected to cover 97 % of the market demand for lead until 2030 implying that lead batteries will continue to remain the dominant type of battery for a long period after 2020 as well. Therefore, mining for lead, and a supply of bismuth, will almost certainly continue.

In response to these comments, the Dossier Submitter updated the Background Document with the information provided and has added a sensitivity scenario, describing

[29] https://europeanhuntingexperts.org.

[30] https://echa.europa.eu/fi/substance-information/-/substanceinfo/100.028.343.

the impacts of a lower use of bismuth gunshot and an associated increased replacement of shotguns to use steel gunshot cartridges instead.

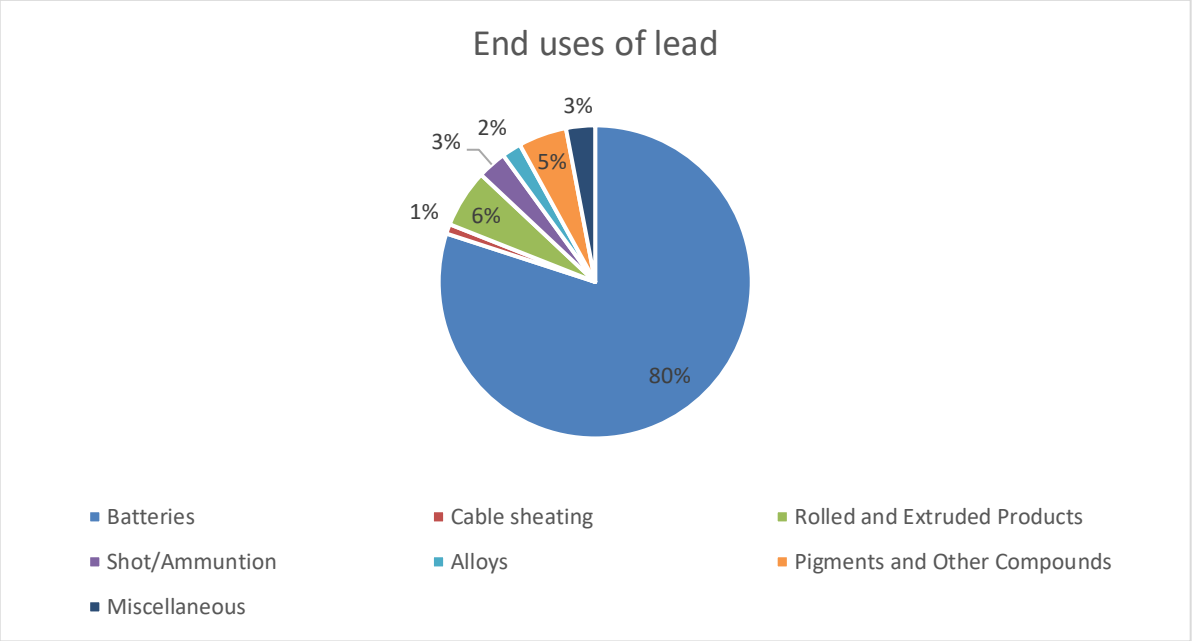

Figure 3: End uses (redacted volumes) of lead by consumption (source: https://www.ilzsg.org/static/enduses.aspx?from=1)

Stakeholder comments (#3467 and #3331) suggested that a few shot-gauge sizes (.410, 20 and 28 gauge) would be particularly impacted by this restriction. These stakeholders consider that bismuth is the only suitable alternative for these gauges and that bismuth shot would be available only in limited quantities. However, to the Dossier Submitter's understanding, one can use standard steel cartridges with suitable muzzle velocities in all standard proofed shotguns (whichever gauge). Also, steel gunshot in the above gauge sizes is growing in demand due to regulations of lead gunshot across different jurisdictions.[31] Alternatives in these gauge sizes are placed on the market, and various companies produce already alternative gunshot (including, for example, steel shot at standard pressure) in this range, for example the brand 'Cartouche Jocker'.[32] Gauges 24, 28 and .410 can therefore be used with steel ammunition of appropriate muzzle velocity, but care must be taken with full or super/extra choke to avoid the risk of a ring bulge.

3.1.2.1.2. Performance of steel gunshot

Several comments were submitted on this topic, for example: #3281, #3293, #3333, #3429, #3467.

Some commenters highlighted that steel gunshot would have a lesser performance then

[31] https://www.ammunitiontogo.com/index.php/cName/410-gauge-steel-shot

[32] http://urubuga.shoothuntingoutdoor.fr/etain-lie/

lead shot. For example, comment (#3429) puts in question the performance of steel shot vis-à-vis lead shot and asks for a restriction to be postponed until suitable alternatives have been identified

On this aspect the Dossier Submitter refers to the numerous studies (discussed and referred to in the Background Document) that have demonstrated based on a systematic, scientific approach that there is no difference in hunting efficiency between lead and steel gunshot if advice on appropriate shot size is correctly followed. More recent research from the BASC has again confirmed these findings.

The Dossier Submitter has updated the section in the Background Document where technical feasibility of non-lead ammunition is discussed (Section 2.5.1.2)

3.1.2.1.3. Price difference between alternatives and lead gunshot cartridges

Several comments were submitted on this topic, for example: #3293, #3295, #3331, #3333, #3350, #3429, #3466, #3467, #3510

Comment #3467 noted a higher price difference between steel and lead gunshot cartridges. A similar remark was made in comment #3293 and in #3429 highlighting the price difference between lead and tungsten, a metal the Dossier Submitter does not consider to be the first choice when substituting lead, but which can be a useful alternative for certain shotguns (similar to bismuth gunshot). Comment #3467 used a price difference found in literature; the Dossier Submitter notes that the source of this price difference is a paper by Kanstrup and Thomas (2019)[33]. The Dossier Submitter performed a more up-to-date market analysis which demonstrated that the cost between steel and lead is negligible, this is explained in Section 2.5.1.3 of the Background Document.

The Dossier Submitter did not change its conclusion on the prices of alternatives. The Dossier Submitter considers that the price difference between steel and lead shot is comparable whilst the price difference between bismuth and lead is more pronounced.

3.1.2.1.4. Replacement of shotguns

Several commenters (e.g., #3467, #3466) suggested that the Dossier Submitter had underestimated the number of shotguns that would need to be replaced in the event of a restriction and consequently had underestimated the corresponding costs. Other comments (#3510, #3329) suggest that there is very little need for gun replacement and the estimation in comment #3467 is too pessimistic as many old guns are suited for firing steel shot if the cartridges used are compatible with the pressure thresholds of the particular shotgun.

Based on the comments received in the Annex XV consultation and previous work on the restriction on lead gunshot in wetlands, the Dossier Submitter highlights that even old

[33] Kanstrup, N. and V. G. Thomas (2019). "Availability and prices of non-lead gunshot cartridges in the European retail market." Ambio **48**(9): 1039-1043.

shotguns may not necessarily need to be replaced but can use bismuth gunshot instead. These alternative shots are more expensive and the optimal response of a hunter to any restriction on lead gunshot thus depends primarily on the total number of shots spent per year. To make this point clearer, consider a hunter who owns a shotgun manufactured before 1961 and is now facing the choice to replace this gun or buy bismuth or tungsten shot instead. Assume that a new shotgun of similar type costs €1 500. As the Dossier Submitter determined that the average price difference between steel shot (average price of €0.46 per cartridge) and bismuth shot (average price of €1.69 per cartridge) was about €1.23 per cartridge, one can calculate that it becomes economically attractive to replace the old shotgun by a new model that can use standard steel shot if the hunter spends more than ~90 shots per year.[34]

On the concept of 'old' guns, the Dossier Submitter notes that there is no fixed definition. The Background Document notes a cut-off date of guns manufactured before 1961 to be considered as 'old' following a study of Putz (2012)[35]. But if standard proof is the benchmark for being able to define old, as according to guidance any standard proofed shot gun can use standard steel shot, then also 1954 can be used as benchmark year for 'old' guns, as in that year nitro proof (i.e., standard proof) was introduced.[36]

FACE (#3333, #3467) had submitted the results of an online survey in which the socio-economic impact of a restriction on the use of lead shot and lead bullets in terms of the need to replace guns was analysed. The report submitted in the consultation presents the following total numbers and shares of shotguns that would be either suitable to use steel gunshot, be of limited suitability or would not be suitable (see Table 1).

Table 1: Numbers of shotguns per category (suitable / limited suitability, unsuitable)

Shotgun category	Number of shotguns in millions	Share of all shotguns
Shotguns SUITABLE	11.17	54 %
Shotguns LIMITED SUITABILITY	4.38	21 %
Shotguns UNSUITABLE	5.09	25 %
Total	20.64	100 %

[34] For this calculation, one may assume that a new shotgun of similar type costs €1 500 and has an expected lifespan of 20 years. Using the PMT command in Excel and assuming a discount rate of 4% as recommended by the EU's Better Regulation guidance, this cost can be converted into an annuity cost of €110. One may then solve the equality €110=x*€1.23, where x is the number of shots spent; x=€110/€1.23=90, meaning that it is economically attractive to buy a new shotgun if the hunter spends more than 90 shots per year with that gun.

[35] Putz (2012). Jäger unter Druck: Bleifreie Munition, Abschlussarbeit im Rahmen des Universitätslehrganges agdwirt/in.

[36] https://www.vintageguns.co.uk/magazine/rules-of-proof-8-re-proof.

The Dossier Submitter would like to make several observations on this survey:

1. The survey posed questions on all shotguns without differentiating between their use for wetland hunting – for which a restriction has already been adopted by the EU institutions – and their use for terrestrial hunting. The survey would have been more informative if it had distinguished between these two uses.

2. The survey collected shotguns users' perceptions of and beliefs about the suitability of steel shot (subjective) rather than collecting information about the properties of the shotguns owned (objective, by e.g., inquiring about the year of manufacture of existing shotguns).

3. Following good practice in socio-economic analysis, the replacement of guns and the need to buy a new shotgun is an important aspect of the overall cost of this regulatory action. However, the analysis should consider that, even in the absence of a restriction on lead gunshot, shotguns have to be periodically replaced. Therefore, the welfare costs brought about by the regulation should see the replacement cost as the advancement of an investment that would have happened anyhow at the end of service life of a shotgun, rather than the total investment cost. In other words, if a hunter would have to replace their shotgun within the next 5 years, then the regulation may force them to buy a new gun five years earlier than they had envisioned. As the cost for the new gun would have accrued anyhow, it is only the extra cost from having to replace the gun earlier that matters. This is explained in more detail in the Background Document.

4. The report emphasises the need to replace shotguns rather than the need for hunters to be able to comply with the conditions of the proposed restriction. The Dossier Submitter agrees that replacing all unsuitable shotguns would, without doubt, generate a far larger cost than focusing on the costs accruing to hunters that need to purchase a compliant shotgun because they do not currently own at least one shotgun suitable to use with alternative ammunition.

AFEMS (#3331) requested that the Dossier Submitter revise the scenarios to exclude the non-credible assumption that 15 % of owners of non-suitable shotguns will switch to bismuth or tungsten shot rather than replace their shotguns. AFEMS further requested that the impact of both increased unit replacement costs and higher percentages for replacement of non-suitable firearms would be considered.

The National Association of Regional Game Council in Ireland (NARGC; #3466) takes the same line as FACE stating that the number of shotguns that need to be replaced is much higher than estimated by the Dossier Submitter.

Other comments on the same subject (#3329) would suggest that there is less need for gun replacement. The comment states that if it is safe to fire a given lead shot cartridge through the gun, it is safe to fire the equivalent non-lead cartridge of the same cartridge length and shot load through the gun and that applies to all gauges of shotgun, alluding to an overall low need for gun replacement. The Dossier Submitter wishes to highlight that recent recommendations accompanying the voluntary withdrawal of the use of lead shot by the British Association for Shooting and Conservation (BASC) and rural

organisations[37] in the United Kingdom follow similar lines[38] (see also #3329).

Concerning cartridges of 2.5 inch length and considering comment #3209 the Dossier Submitter notes a recent announcement by the company Eley Hawk[39] which intends to place on the market steel cartridges specifically geared towards old shotguns.

Comment #3510 reacts on the survey conducted by FACE among hunters highlighting that an estimated total of 69 million firearms for 7 million hunters in Europe would mean an average of nearly 10 firearms owned by the average hunter. This would show that hunters already dedicate a large budget to their hunting activity. The commenter thus noted that, in this context, comment #3510 state that the perceived costs of shifting to non-lead ammunition and suitable firearms seemed to be rather insignificant compared to the budget dedicated to hunting.

Comment #3510 further highlighted that the FACE survey had indicated that a majority of firearms (66 %) was suitable for non-lead ammunition. Also, 73 % of hunters own at least one shotgun that can be used with non-lead ammunition. The commenter interpreted these figures as showing that the transition to suitable firearms would impact only a minority of hunters. The commenter concluded that the actual replacement costs are lower than stated in the FACE report, as hunters already own suitable firearms; they do not need to replace all the ones that are not suitable.

The issue of replacement of non-proofed shotguns, as highlighted by the Union of Hunters and Anglers in Bulgaria (#3523), is considered an impact that does not originate from this restriction proposal. Indeed, using non-proofed shotguns pose a safety risk for the shooter even when using modern lead loads. The CIP safeguards that all firearms and ammunition sold to civilian purchasers in member states are safe for the users. To achieve this, all such firearms are first proof tested at CIP, without a proof test the safety of a gun cannot be guaranteed neither for steel nor for lead. This is made explicit in the CIP objectives[40].

An important issue the Dossier Submitter wants to underline is the number of hunters that need to replace their shotgun to be able to continue hunting. The FACE survey (#3467, #3333) claimed that as 25 % of existing shotguns are not suited for standard steel shot, around 25 % of all hunters in the EU (~1.5 million) would need to replace their shotguns, the Dossier Submitter argues that the actual need for shotgun replacement is substantially lower than the 25 % proposed in the comments by AFEMS and FACE. Details based on which this conclusion was drawn are reported in Section 2.5.3 of the Background Document.

[37] https://basc.org.uk/a-joint-statement-on-the-future-of-shotgun-ammunition-for-live-quarry-shooting/

[38] https://www.gwct.org.uk/media/1094670/Moving-away-from-lead-shot-QA.PDF

[39] https://www.gunsonpegs.com/articles/cartridges/s/non-toxic-shotgun-cartridges/steel-cartridges-for-older-guns

[40] https://www.cip-bobp.org/en/cip

3.1.2.2. Alternatives to lead rifle ammunition

3.1.2.2.1. Distinction between small and large bullet calibres (i.e., projectiles other than gunshot)

Several comments including #3173, #3189, #3190, #3220, #3225, #3229, #3236, #3237, #3244, #3248, #3249, #3250, #3252, #3255, #3257, #3262, #3280, #3289, #3290, #3333, #3403, #3421, #3449 and #3467 were submitted on the proposed cut-off value (5.6 mm) to differentiate between small and large calibres (which are proposed to have different transitional periods).

The rationale of the Dossier Submitter in setting this cut-off value was based on three elements:

1. The main human health benefits of the proposed restriction would arise when roe deer, wild boar and larger animals would be hunted using non-lead ammunition as these animals are the ones that are most hunted for consumption in the EU.

2. The cut-off in calibre size of 5.6 mm is based on existing hunting legislations in the EU that set the minimum calibre size for hunting roe deer and larger animals to 5.6 mm or .222/.223 calibre.

3. In tests comparing the hunting efficacy of lead with non-lead ammunition the smallest identified alternative for which good results were reported was .222/.223 which would correspond to calibre 5.6 mm.

The critical comments that were brought forward can be divided into three main lines of reasoning:

1. Current hunting legislation in Member States unintentionally preventing the use of non-lead ammunition.

2. Availability of suitable alternatives.

3. Stabilisation of bullets.

To exemplify the critique received on these comments, Table 2 gives an overview of some direct quotes from submitters of comments.

Table 2: Criticism on the cut-off between small and large calibres proposed by the Dossier Submitter

Proposed cut-off	Comment nr	Comments
5.6 mm	Dossier Submitter	See above
6 mm	#3257	Hunting rifles in 6 mm and smaller will more often than the larger calibres need replacement of the barrel to perform with lead free bullets, due to technical issues are related to hunting rifles with barrel twists not designed for the longer and lighter bullets – which results in unstable projectiles and poor precision A cut-off between small and large calibres set at 6 mm will be more appropriate than 5.6 mm.
6.5 mm	#3236, #3333	The cut-off between small and large should be set at 6.5 mm for the following reasons: Above 6.5 mm there is a good range of well tested and proven non-lead ammunition. More time needed to test and develop smaller non-lead calibres. Providing further time to improve the supply and price issues currently being experienced by many hunters in the UK. In some countries, the requirements imposed on roe deer and deer for bullet weight and impact energy do not allow the manufacture and use of functional, for example, copper bullet cartridges in hunting. Therefore, we see an appropriate and better limit of 6.5 mm, which larger calibres are commonly used in large game hunting.
7 mm	#3252	Due to legal requirements, it is not possible to legally hunt large game with calibres such as 6.5x55 with non-lead expanding bullets since the weight and energy requirements are not met.

The importance of this cut-off between small and large calibres vis-à-vis realising health benefits was recognised:

Comment #3262 stated that the limit of 5.6 mm between small and large calibre is artificial and not commonly used within the hunting and sports shooting community. The commenter understands the aim of ECHA to restrict [the] use of lead ammunition for roe deer [hunting] because of the large number of roe deer hunted in Central Europe. There are some first lead-free products available for common hunting calibres .222/223 Rem but the number of products available is small and only little experience of hunting use of them

is available yet.

Or comment #3252, which stated that the smallest calibre normally used in rifles for hunting roe deer is .222 Rem […] The risk for lead contamination with expanding bullets therefore applies with the use of calibres such as .222 Rem. and large and that insofar,, the proposed distinction is relevant when it concerns hunting. Comment #3252 therefore clearly states the cut-off between large and small and calibres as proposed by the Dossier Submitter is relevant for human health concerns; calibres .222/223 would coincide with 5.6 mm centrefire ammunition.

One comment (#3449) states that a similar cut-off of 5.5 mm is expected to be used in the phase out of lead currently discussed by the Danish Competent Authority.

The Dossier Submitter sees no justification to change the cut-off value in the proposal. The possibility to switch to alternatives to lead for calibres that are larger than 6.5 mm seems to be undisputed. Concerning calibre sizes from 5.6 to 6.5 mm the main technical barrier to substitution is related to barrel twists in rifles which results in unstable projectiles and poor precision. However, the available information suggests that avoiding this issue is a matter of carefully selecting cartridges (just like with lead ammunition) and buying ammunition with the correct twist rate. Suitable alternatives are produced and are available on the EU market.

The Dossier Submitter has updated the Background Document with the submitted information and has included the advantages and disadvantages of the proposed cut-off in the section of the Background Document where technical feasibility of non-lead ammunition is discussed (Section 2.5.1.2).

3.1.2.2.2. Current hunting legislation in Member States unintentionally preventing the use of non-lead ammunition

Many commenters from Sweden highlighted that although alternatives exist that would be suitable[41], these are not allowed to be used in Sweden due the national hunting legislation prescribing bullet weight and energy requirements. This is seen as an obstacle for using non-lead bullets (FACE, #3467) and an important element in not maintaining the 5.6 mm separation (#3252).

The Dossier Submitter does not see these energy requirements as an obstacle. Adjustments have been made in the national hunting legislations of Finland and in Norway by allowing lighter bullets for non-lead options, in line with e.g. FACE guidance on replacing lead ammunition[42]. Activities to this end have also started in Sweden (comment #3252; ECHA, personal communication with *Naturvårdsverket).* The Dossier Submitter also notes the primacy of EU law and that adaptations to national legislation could be made with the transitional periods before the measure enters effect, if necessary.

[41] https://jagareforbundet.se/contentassets/7099893fd13b45b98e1900d2ea165fee/65x55_se.pdf

[42] https://www.leadammunitionguidance.com/using-non-lead-ammunition/

3.1.2.2.3. Availability of suitable alternatives

Comment #3467 highlighted the absence of peer-reviewed performance tests for non-lead bullets below 6.5 mm.

The Dossier Submitter notes that the Annex to the Background Document contains an overview of peer-reviewed tests as well as practical tests with non-lead ammunition (large and small calibre) comparing their performance with lead ammunition.

3.1.2.2.3.1. Large calibre bullets

From the available studies it appears that the suitability of non-lead centrefire ammunition from 5.6 mm and up (smallest calibre tested: .222 and .223 which is equivalent to 5.6 mm) is well established. The Background Document (Section 2.5.1) reports on a study by Kanstrup et al. (2016)[43] that describes equivalent performance of lead and non-lead ammunition for .222, .223, .270, .30-06, 6.5x55 and 308 calibres, or by Hackländer et al. (2015)[44] (calibres used: 5.6x50 R, 6x62 Freres Blaser, .243 Win, .300 Win Mag, .300WSM and 9.3x62) finding no statistical difference in the performance of lead and non-lead rifle ammunition.

As also highlighted in another comment (#3329) there is wide availability of rifle bullets in these centrefire calibres (red. below .243 Winchester) in Europe. Table 1 of Thomas et al. (2016) indicates that in 2016 four companies were selling assembled rifle ammunition in small calibres: Hornady (.223 Rem), Sako-Barnes (.222 Rem), Sax KGJ (.223Rem, .22-250 Rem) and Schnetz KG (.22 Hornet, .222 Rem). As of 2021, Lapua, RWS and Nosler provide additional small calibres, a full overview is provided in the Background Document (Section 2.5.1.2).

The above information indicates that given the availability and choice of bullet types currently offered for sale in Europe, the Dossier Submitter considers the transition to non-lead hunting rifle ammunition across all rifle large calibres is likely to be less disruptive than some of the comments received in the consultation suggest.

3.1.2.2.3.2. Small calibre bullets (rimfire)

Comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals, on the use of lead rimfire bullets for hunting, including: #3126, #3137, #3140, #3189, #3190, #3194, #3201, #3210, #3216, #3227, #3220, #3227, #3237, #3244, #3247, #3250, #3252, #3255, #3262, #3329, #3331, #3410, #3426, #3437, #3467. One comment (#3247) was treated in a confidential manner as per the commenters' request.

In the Annex XV report submitted for consultation, the Dossier Submitter had

1. Concluded that the availability of alternatives for small calibre bullets is poor,

[43] Kanstrup, N., et al. (2016). "Efficacy of non-lead rifle ammunition for hunting in Denmark." European Journal of Wildlife Research 62(3): 333-340, https://doi.org/10.1186/s12302-021-00485-z

[44] Hackländer, K., et al. (2015). "Die Eignung bleifreier Büchsenmunition im Jagdbetrieb." Wien: Universität für Bodenkultur.

2. Concluded that the available peer-reviewed tests were inconclusive as regards the suitability of non-lead ammunition for small calibres,

3. Proposed a transition period of five years for the use of small calibre bullets for hunting.

Worldwide only a few jurisdictions have a lead ban that applies to hunting with rimfire bullets. The Danish initiative to phase out the use of lead is set on the initiative of the hunters themselves, but the website[45] of the Danish hunter's association clearly states that rimfire ammunition should not be part of the phase out.

The Dossier Submitter has noted in the Background Document that manufacturers "have found it difficult to develop lead-free bullets in small calibres (e.g., .22 LR, .17 HMR and .22 Winchester magnum) as alternatives pose problems in terms of stabilisation of bullets in flight, which in turn negatively affects bullet accuracy" and that since alternatives are currently not widely available.

The issue of non-lead alternatives for rimfire bullets was widely commented on in the consultation.

The Dossier Submitter found it difficult to separate comments on rimfire ammunition in general to those comments regarding .22 LR. More specific, as some of the commenters on .22 LR used information on this calibre and the (im)possibilities to substitute lead as a proxy for all rimfire cartridges. Some comments addressed rimfire ammunition in general (e.g., #3467, #3331, #3262), whereas other comments addressed .22 LR, in particular (e.g., #3137, #3189, #3190, #3194, #3201, #3210, #3216, #3227, #3220, #3237, #3244, #3247, #3250, #3252, #3255, #3262, #3410, #3426, #3437). However, some of the comments on .22LR used information on this calibre and the (im)possibilities to substitute lead in those calibres.

Several points have been raised:

- Within the use of lead ammunition in hunting, the use of rimfire calibres appears to be limited to applications for which no human consumption of game meat is foreseen. An exception may be the use of certain rimfire calibres in Nordic hunting (along with Full Metal Jacket bullets) (comment #3173).

- The use of rimfire ammunition causes only a limited release to the environment compared to other calibres (comment #3237).

- The use of rimfire is important (as mentioned by several commenters, see e.g., #3262) in the control of invasive species.

- Lead in rimfire ammunition is difficult to replace and successful substitution may take a long time to achieve successfully (comments #3262, #3226, #3331).

- The test results that were submitted in the consultation did demonstrate a lack of

[45] https://www.jaegerforbundet.dk/media/16490/bly-i-riffelammunition-til-jagt-udfases_klj_ok.pdf

accuracy for .22 LR, which is by commenters used as a proxy for all rimfire calibres (comment #3252).

- The lack of accuracy would result in kills that are not immediate and are therefore considered to be unethical (comments #3247, #3190).
- Some commenters pointed out as well that given the dependence on only a few manufacturers it was difficult to see how demand can meet supply (#3189, #3126, #3140).
- Gun compatibility issues due to limited choice of suitable alternatives were mentioned (#3252).
- Other comments were not very specific but in general hinted at similar issues raised as above (#3220, #3227, #3189).
- Other tests on rimfire calibres also showed that rimfire bullets may not deposit lead in the bodies of animals that are taken, which is confirmed for .22LR but not for other rimfire calibres, such as e.g. .17HMR.

The Dossier Submitter verified the main arguments brought forward and notes that one of the manufactures (CIC) of non-lead alternatives for .22 LR lost its CIP homologation, i.e., the calibre is no longer CIP proofed. This leaves only Norma and RWS as brands for non-lead rimfire ammunition. Since both are owned by RUAG Ammotec, this leaves essentially one actor that supplies non-lead .22 LR on the European market.

Upon contacting RUAG Ammotec, the Dossier Submitter verified that the tests performed by RUAG Ammotec showed a systematic disperse on targets that is considered to be too wide for target shooting as well as for hunting with sufficient killing effect. RUAG Ammotec highlighted that the given spread (standard spread, without human intervention) is too large for functional hunting as well and that the typical physical properties of lead are necessary for the use of the weapons currently in circulation and for the design of rimfire ammunition. This results in problems with lead-free bullets with current weapons and current cartridges/calibres.

Concerning the hunting efficiency, the Dossier Submitter refers to another test by McTee et al. (2017)[46]. The study finds that non-lead bullets instantly incapacitated ground squirrels approximately as often as lead bullets. This finding suggests that for calibres .17 HMR, .22 LR and .223, non-lead bullets are comparably lethal to lead ammunition for ground squirrels.

The same study finds that a non-expanding bullet may not have the same magnitude of impact as an expanding bullet because it retains its mass as it passes through the animal, thus carrying energy and momentum through the exit hole. As such the study suggests that some lead may still be deposited in the animal and may pose a risk to

[46] McTee, M., et al. (2017). "Better bullets to shoot small mammals without poisoning scavengers." Wildlife Society Bulletin 41(4): 736-742.

human health.

The Dossier Submitter's initial assessment that the availability of non-lead rimfire ammunition appears to be poor, remains unchanged. As mentioned in #3329 there has been a rapid development in the small-calibre products offered by several European and US rifle ammunition producers. These producers provide a large array of bullet types and weights for the smaller calibre cartridges. However, the Dossier Submitter recognizes that for alternative small calibre ammunition (centrefire smaller than 5.6 mm and rimfire ammunition) further research and development is still required and recognises that there may be a need for a longer transition period accompanied with a potential review (see Section 3.1.6).

The Dossier Submitter has updated the section in the Background Document where technical feasibility of non-lead ammunition is discussed (Section 2.5.1.2)

Stabilisation of bullets

Comment #3467 highlighted possible stability issues with non-lead alternatives in calibres smaller than 6.8 mm and quoted a test from the Danish hunter's association. The complete advice on the website[47] of the Danish hunter's association states that this situation is not different from when using lead ammunition. As a result of the test, the Danish hunter's association advises hunters to carefully examine the twist rate of their barrel and purchase ammunition suitable for that twist rate and consequently state that this is not different when using lead ammunition.

Comment #3329 states that it should be mentioned that all hunters are responsible for selecting the appropriate bullet type and mass that gives them the best accuracy from a given rifle, whether shooting non-lead or lead-based bullets. The same applies to hunters who assemble their own ammunition, especially as it relates to the choice of propellant, bullet mass and type, and the velocity of the bullet. Comment #3329 also explains that manufacturers respond to market demand and have started to develop non-lead ammunition with different twist rates.

The Dossier Submitter has updated Section 2.5.1.1 in the Background Document where availability of non-lead ammunition is discussed.

3.1.2.2.4. Replacement of rifles

Several comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals on the use of alternatives in hunting and raised the issue of gun replacement in response to the proposed restriction. These included comments #3329, #3331, #3333, ##3429, #3466, #3467, #3505, #3514, #3521, #3523.

[47] https://www.jaegerforbundet.dk/om-dj/dj-medier/nyhedsarkiv/2020/lead-free-rifle-ammunition-the-big-test/

Small calibre rifles

Comment #3467 pointed out the high heed for gun replacement in case immediate restrictions would follow on the use of lead in small calibre ammunition. Building on other comments that argue (sometimes tested) the suitability of non-lead ammunition for these calibre group, comments #3467 stated that many of the owners of guns with these calibres would need their guns or adapt them at high costs.

The Dossier Submitter recognizes that for alternative small calibre ammunition (centrefire smaller than 5.6 mm and rimfire ammunition) further research and development is required as explained above (Section 3.1.2.2.3). In that respect, a restriction for small calibre bullets may trigger a need for premature gun replacement.

Large calibre rifles

Concerning rifles, the Dossier Submitter wants to point to its analysis on the cut-off of 5.6 mm used for the restriction. Recognising that this cut-off encompasses most centrefire ammunition for hunting, the Dossier Submitter, given the state of technology in 2014 described by Thomas (2014)[48] , re-analysed in 2016 by Thomas, Gremse et al. (2016)[49] and updated with more information (#3329) on newer bullets and centrefire cartridges put on the market, does not see an immediate need for large-scale gun replacement arising because of the proposed restriction.

The Dossier Submitter re-iterates the German guidance that only thorough cleaning of the rifle is required[50] when using non-lead ammunition and complements this as well with the Danish guidance[51] which states that rifle replacement for large calibres is not foreseen

The Dossier Submitter has updated the section in the Background Document where technical feasibility of non-lead ammunition is discussed (Section 2.5.1.2).

3.1.3. Requested derogations

3.1.3.1. Request for a derogation for small calibre (rimfire) bullets for hunting

Upon contacting RUAG Ammotec, the Dossier Submitter verified that the tests performed by RUAG Ammotec showed a systematic disperse on targets that is considered to be too wide for target shooting and for hunting with sufficient killing effect.

Concerning the hunting efficiency, the Dossier Submitter refers to another test by McTee

[48] Thomas V. G. (2014). Lead-free hunting rifle ammunition: product availability, price, effectiveness, and role in global wildlife conservation. Ambio, 42(6), 737–745. https://doi.org/10.1007/s13280-012-0361-7

[49] Thomas, Vernon George et al. “Non-lead rifle hunting ammunition: issues of availability and performance in Europe.” European Journal of Wildlife Research 62 (2016): 633-641. https://doi.org/10.1007/s10344-016-1044-7.

[50] https://www.jagdverband.de/umstieg-auf-alternative-munition

[51] https://www.jaegerforbundet.dk/om-dj/dj-medier/nyhedsarkiv/2020/lead-free-rifle-ammunition-the-big-test/

et al. (2017)[52]. The study finds that non-lead bullets instantly incapacitated ground squirrels approximately as often as lead bullets. This finding suggests that for calibres .17 HMR, .22 LR and .223, non-lead bullets are comparably lethal to lead ammunition for ground squirrels.

Several commenters such as e.g., #3467, #3262 (from both the hunting community as well as manufacturers) requested a derogation for the use of small calibre (rimfire) bullets for hunting. The evidence provided to support this derogation essentially building upon two lines of argumentation (see Section 3.1.2.2.3.2):

- The absence of risk: it is argued that .22 rimfire ammunition, given the speed at which the ammunition travels, has a lower impact on animals. Therefore, less to no bullet fragmentation takes places that could give rise to lead being deposited in the target.

- The absence of suitable alternatives: despite alternatives being available, the test results that were submitted demonstrated that non-lead .22 LR does not work as accurately as lead containing .22 LR.

Several restriction options are discussed among the commenters: a) permanent derogation (comment #3262), b) rimfire out of scope (#3467), c) time limited derogation with a review clause (comment #3331). The advantages and disadvantages of each option are in Table 3.

Table 3: Advantages and disadvantages of derogating rimfire bullets

	Advantages	Disadvantages
Permanent derogation / rimfire out of scope	Allow the continued use of rimfire bullets where replacement is difficult Continued use appears not to contribute significantly to human health impacts	Loss of incentive to innovate Secondary poisoning cannot be completely ruled out Some alternatives are on the market (.17 HMR) for which fragmentation is a known issue, permanent derogation would not create level playing field for alternatives

[52] McTee, M., et al. (2017). "Better bullets to shoot small mammals without poisoning scavengers." Wildlife Society Bulletin 41(4): 736-742. https://www.jstor.org/stable/90016794

	Advantages	Disadvantages
Time-limited derogation	Allow the temporary use of rimfire bullets until further R&D work is done for possible replacement Keep incentive for innovation Create level playing field for alternatives that exist already (such as .17 HMR)	Uncertainty on whether substitution efforts unlikely to pay off Continued use appears not to contribute significantly to human health impacts

The Dossier Submitter considers that a derogation for rimfire calibres would alleviate much concern within the hunting community especially about gun adaptation and being able to ethically kill game.

A derogation would imply that lead-based rimfire cartridges can be used, even though alternatives exist in some calibres (such as .17HMR). Such a derogation would result in avoided costs of up to ~20 million euro per year, including extra cost for ammunition and investment in new guns.

It would however result in the continuation of ~17 tonnes of lead emissions per year (initially evaluated at 30-40 tonnes) and exposure to human and wildlife cannot be ruled out.

3.1.3.2. Request for a derogation for Full Metal Jacket bullets in hunting

Several comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals on the use of Full Metal Jacket (FMJ) bullets in hunting, for example: #3187, #3189. #3195, #3214, #3215, #3216 #3220, #3231, #3235 #3237, #3244, #3247, #3248, #3250, #3252, #3255, #3257, #3262, # 3449, #3467.

FMJ bullets are a non-fragmenting ammunition type that consists of a soft core (of lead) encased in an outer shell ("jacket").

FACE (#3467) highlighted that this application should be considered as a niche application.

Several commenters pointed out that FMJ bullets would be used in limited volumes in a type of hunting that is done in Finland and Sweden (#3189), Norway (#3474), Denmark (#3446) and, to a lesser extent, in Estonia, Latvia and Lithuania (comment #3262). For this type of hunting, very good accuracy is needed because the target is small (for birds like black grouse, capercaillie and hazel hen, the vital area where the bullet should be placed is only 20 - 60 mm) and distances are quite long (typically 100 - 300 m, sometimes even more).

The comments covered the following subjects:

- Non-expanding ammunition such as FMJ bullets have a low risk of contaminating game meat with lead as bullets go through the target animal (bird species) without depositing lead (#3237).
- FMJ bullets provide the required accuracy for long distances of Nordic bird hunting (#3237).
- Small game, such as red fox, is hunted for the fur and FMJ are allowed and used since they do not expand and destroy the fur. Expanding non-lead bullets would not be an alternative for the same reason. Such animals are not consumed as food.

Based on an absence of risk and a lack of suitable alternatives a derogation was requested.

The Dossier Submitter notes that some national hunting legislations allow the use of FMJ bullets for certain applications: mostly on grouse like species and for applications that are related to pest control as well as for applications where animals are hunted for their fur.

A derogation would therefore pose negligible consequences in terms of risk, whereas it would allow the continuation of niche applications where alternatives are scarce.

The Dossier Submitter does not expect, should a derogation for the use of lead containing FMJ bullets be in place, that hunters would use FMJ bullets as a wide alternative to lead ammunition. The national hunting legislations that are in place demand hunters to use expanding ammunition for hunting roe deer and larger (through which health benefits would be realised) is limited to using expanding ammunition, FMJ bullets are non-expanding ammunition.

Therefore, Dossier Submitter has now proposed a derogation for lead bullets used in seal hunting and has updated the section in the Background Document where technical feasibility of non-lead ammunition is discussed (Section 2.5.1.2)

3.1.3.3. Request for a derogation for the use of lead bullets for seal hunting

Several comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals on the use of lead ammunition in seal hunting. For example: #3187, #3189. #3195, #3214, #3216, #3220, #3231, #3235, #3237, #3244, #3247, #3248, #3250, #3252, #3255, #3257, #3262, #3306, #3467, #3488.

A number of commenters highlighted the niche character of this use, either in general (#3467) or by referring to the annual tonnage of lead involved (8 kg per year in Finland according to comment #3255) or by the referring to the total number of bullets (1 500 per year in Finland, see comment #3488) that are used for this purpose.

Commenters point to several particularities of this use that in their view would justify a

derogation.

Commenters pointed out the demanding environment (which must assure that bullets explode on impact), a characteristic not yet demonstrated to be achievable with non-lead bullets.

Commenters also pointed to the absence of risks for human health due to consumption of contaminated game meat of seals. Placing on the market of seal products such as meat, is already banned by the Regulation (EC) No 1007/2009 of the European Parliament and of the Council of 16 September 2009 on trade in seal products.

The Dossier Submitter's considers that the population management of seals clearly constitutes a niche application, considering the volumes of lead involved. The circumstances under which the hunt takes place requires a specific design of the bullet that until now is only achieved by lead ammunition. No human contamination of seal meat takes place, although this cannot be completely excluded.

Any derogation would be enforceable. The hunt is strictly controlled with individual permits for hunting seals, e.g., in Sweden the hunting of seals is strictly controlled[53] with licenses needed for an individual hunter. Any use of lead can therefore take place under controlled conditions, as individual permission to use lead can be connected to the license to hunt seals.

The demand for this niche application of lead is low, so it is not foreseeable that in the situation that a restriction would enter into effect an alternative would be developed soon.

In sum, a derogation would pose negligible consequences in terms of risk whereas it would allow the continued use of lead in a niche application where alternatives are not available with a similar level of effectiveness.

Therefore, Dossier Submitter has now proposed a derogation for lead bullets used in seal hunting and has updated the section in the Background Document where technical feasibility of non-lead ammunition is discussed (Section 2.5.1.2).

3.1.3.4. Request for a derogation for muzzle loaders and other vintage firearms and replicas

Several comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals on the use of lead in muzzle loading firearms. For example: #3201, #3220, #3224, #3225, #3234, #3235, #3237, #3240, #3254, #3277, #3400, #3467.

The commenters reinforced the conclusions of the Dossier Submitter's analysis as presented in the Annex XV report that alternatives to lead for use in muzzle loading

[53] https://www.naturvardsverket.se/en/topics/hunting/hunting-seals/

firearms are not widely available and are not suitable for use in historic firearms.

The commenters argue that alternatives are not well suited for the use in muzzle loaders, as these types of guns are designed to be used with lead. Other materials that are suitable in other shooting applications, such as tin, bismuth, tungsten and steel, are all harder and shooting them for antique guns generates gas pressures higher than these guns were designed to handle leading to possible damage to the gun.

FACE (#3467) further points out that the C.I.P. proof testing ensuring the safety of those firearms has been carried out with the use of black powder and lead projectiles. There are however no C.I.P. testing protocols for lead-free projectiles as there are no suitable alternatives.

Comment #3224 states that the lead bullets of black powder firearms do not break into parts and do not evaporate or disintegrate when hitting the game due to low impact velocities (approx. max. 550 m/s). The Background Document, based on a study by Sanchez et al. (2016)[54] brought forward evidence that fragmenting indeed occurs to a lesser extent as with modern lead rifle ammunition.

According to a study performed by the Hungarian Black Powder Association (#3400), the total number of muzzle loading shooters and collectors within the EU is estimated at circa 340 000 women and men, out of which circa 27 000 are frequent shooters. The number of muzzle loading hunters is circa 600 based on the data provided by the national associations. However, as a large number of muzzle loading hunters are not visible from the statistics, the Hungarian Black Powder Association assumed that the exact number can be around 1 000 to 1 200 persons.

The estimated yearly lead consumption of muzzle loading shooters in the EU is up to 683 tonnes, out of which up to 682 tonnes of lead ammunition are fired on licensed shooting ranges, and only 0.8 tonnes of lead ammunition are fired for hunting purposes.

Some commenters pointed out the cultural value associated with the use of muzzle loading.

The Dossier Submitter takes note of the submitted information on this subject and notes in particular that in case practicing with muzzle loaders takes place on licensed shooting ranges, it would imply that these are to be considered under the conditions proposed for the use of bullets at shooting ranges.

On the use of muzzle loaders in hunting, the Dossier Submitter on the other hand understands that:

- the use is limited to less than 1 tonne per year in the whole of the EU.
- The size of the bullets would suggest that picking up by bird species is not

[54] Sanchez et al, Estimating Lead Fragmentation from Ammunition for Muzzleloading and Black Powder Cartridge Rifles, Journal of Fish and Wildlife Management (2016). DOI: 10.3996/092015-JFWM-086

possible.

- Fragmenting of bullets occurs significantly less as with typical bullets for modern guns.
- Exposure to lead via diet and the secondary poisoning of wildlife cannot be completely ruled out.
- although claimed to be of high cultural value, no clear evidence was submitted to support this conclusion. References were made to UNESCO classifications in Germany but that seemed more to point out the event of shooting rather than the use of a specific type of firearm.

The Dossier Submitter notes that the proposed ban on the use of lead gunshot and bullets for hunting would prevent muzzle loaders of effectively hunting with lead. Taking into account the provided information, a derogation may be considered by SEAC. The Dossier Submitter has updated the section in the Background Document where technical feasibility of non-lead ammunition is discussed (Section 2.7.1).

3.1.3.5. Request for a derogation for air rifle ammunition

Several comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals on the use of lead ammunition in air rifles, including: #3201, #3236, #3239, #3251, #3260, #3331, #3467, #3268, #3422, #3448, #3468.

Hunting with air rifle ammunition, or air rifle pellets consisting of lead, is legally allowed in the United Kingdom, Sweden, Hungary, and Denmark where air rifles are used for pest control, not for hunting.

FACE (#3467) states that in addition to being inaccurate, non-lead or so-called “green pellets” are also several times more expensive than lead pellets.

A similar concern was raised by AFEMS (#3331) who also stated that alternatives for air rifles work poorly and are expensive.

The Irish Farmers Association (#3251) stated the need for air rifles is solely with the purpose of pest control to take squirrels, corvids and other animals that have the potential to do harm to crops or livestock, a message that is also brought forward by AFEMS (#3331).

The lack of adequate performance is raised as well in comment #3239 and #3422 where tests state that non-lead air rifles have a standard grouping (i.e., spread around the centre) of a target which is wider than with lead because of instability of pellets in flight.

No information was submitted in the consultation on the total volume of lead used for hunting with airguns. Given the species at stake and the already existing limitations on the use of airguns in hunting, the volume is expected to be low compared to other applications of lead ammunition.

FACE and AFEMS explicitly asked for the of lead ammunition in air rifles to be derogated (without any consideration of risk).

The Dossier Submitter had stated that there were alternatives for the use of lead in ammunition for air rifles but that these were more expensive without necessarily meeting the same performance as their lead counterparts.

A derogation would avoid costs related to switching to lead-free ammunition and possibly gun replacement. An unknown volume of lead would however still be deposited in the environment, with risk of primary and secondary poisoning of wildlife. A derogation would however ensure that farmers would have at their disposal an economic means of pest control. Taking into account the provided information, a derogation may be considered by SEAC. The Dossier Submitter has used the information above to update the sections of the Background Document on air rifle ammunition (Section 2.7.2).

3.1.4. Impact of a restriction on using and placing on the market of lead ammunition on hunting activities

Some comments were submitted relating to the impact of the proposed restriction for hunting activities.

According to FACE (#3467), the Dossier Submitter has not estimated how the intended restriction would affect the frequency of hunting in EU27 and the economic consequence thereof. Based on the Dossier Submitter's own figures, FACE estimates that hunting generates an annual revenue of around €18 000 million per year to the economies of Member States. FACE stated that other impact assessments on similar topics did estimate the lost value to the overall economy. For example, the California Department of Fish and Wildlife estimated the potential economic impact of the prohibition in 2013[55], in terms of lost hunting days and their economic value.

Comment #3172 pointed out that the extra cost in hunting ammunition would be minimal and should not be prohibitive to continue hunting. The commenter exemplifies his argumentation by referring to a study of Stokke et al. (2017)[56] which calculate that for moose hunting in Fennoscandinavia on average 1.7 bullets are used per moose that is hunted. The commenter stated that the safe handling of moose meat (i.e., to handling of meat in such a way that no lead remained) would be more costly than the price difference between lead and non-lead ammunition.

The Dossier Submitter would like to emphasise that earlier studies[57] of FACE describing the expenditure of hunters stated that weapons and ammunition together constitute about 11 % of the total hunting budget of a typical hunter. More specifically, for

[55] Most notably the impact assessment accompanying the introduction of ban on lead in rifle ammunition in California: Standardized Regulatory Impact Assessment Re: Prohibition on the Use of Lead Projectiles and Ammunition Using Lead Projectiles for the Take of Wildlife with Firearms, DOI: 10.13140/2.1.4459.8566

[56] Stokke, S., et al. (2017). "Metal deposition of copper and lead bullets in moose harvested in Fennoscandia." Wildlife Society Bulletin 41(1): 98-106. DOI: 10.1007/s13280-019-01171-4

[57] https://www.face.eu/sites/default/files/documents/english/economia_della_caccia_27_9_2016_en.pdf

Germany it is stated that expenditure on arms is about €390 on a total budget of €4 320 which represents about 9 % of the total annual hunting expenditure. In line with comment #3172, any extra spending on ammunition would result in additional spending of about €1-4 per cull of large game. This would indicate that the cost associated with substitution of lead will not lead to an increase in the costs of hunting of such a nature that it will be prohibitive of hunting as such.

One commenter highlighted that previous restriction on the use of lead ammunition for waterfowl hunting in Spain (comment #3479) did not lead to a reduction in hunting activities. Similar observations have been made in Denmark: contrary to some hunters' fears, change of ammunition type from lead to non-lead was not an obstruction to continued hunting opportunity. On the contrary, it is believed that hunters visibly seen in the public eye to be reducing the dispersal of a recognized contaminant (i.e., lead) into the environment has been of paramount importance for the long-term reputation of hunting (Kanstrup and Thomas, 2019)[58].

An increasing number of German Federal states require the use of non-lead ammunition. Yet, the number of hunters is increasing in Germany[59] as shown in relevant statistics[60]. Data[61] on the number of hunters per Federal state indicated that there's no decline in hunting since the introduction of restriction on the use of lead bullets in hunting in these Federal states.

The Dossier Submitter considers that the submitted information provides an indication that a restriction on the use of lead in hunting, both for shotgun and rifle ammunition would not lead to a decline in hunting participation.

3.1.5. Impact of a ban on European firearms industry

Some comments were submitted that highlighted that a ban on the use of lead ammunition in hunting and sports shooting may have an impact on firearms industry in terms of job losses and loss of profit/revenue. Such comments are: #3330, #3262, #3331.

AFEMS and IECAS/ESFAM (#3330) provided a study that summarises the effects of a restriction on all uses of lead ammunition on firearms producers. In the study it was concluded that 60 % of the firearms industry are likely to continue exporting their current firearm portfolio for lead containing ammunition in case of a complete restriction on the use of lead in hunting and in sprots shooting. It was furthermore concluded that annually the firearm industry records a revenue of nearly €6 billion and profit of over €0.6 billion and employs nearly 22 thousand employees. A premature restriction would endanger at least half of this and undoubtedly results in business closures of

[58] Kanstrup, N. and V. G. Thomas (2019). "Availability and prices of non-lead gunshot cartridges in the European retail market." Ambio 48(9): 1039-1043. DOI: 10.1007/s13280-019-01151-8

[59] https://gettotext.com/the-day-the-number-of-hunters-in-germany-is-increasing/

[60] https://de.statista.com/statistik/daten/studie/161126/umfrage/anzahl-der-jagdscheininhaber-in-deutschland-seit-1968/

[61] https://de.statista.com/statistik/daten/studie/170022/umfrage/jagdscheininhaber-nach-bundesland/

approximately 20 % of the companies. Annual monetary losses in terms of revenue and profit are dependent on the manufacturers ability to adapt their portfolio, exports and the share of the EEA sales. Total socio-economic cost, comprising of annual profit losses, would be between €412M and €1 127M. Between 4 130 and 11 304 jobs would be lost in the EEA.

The Dossier Submitter notes that this study has a response rate of 13 %; only 20 of the 150 companies in Europe that have a role in firearm manufacturing responded. The study itself marks that this causes an issue of robustness in the conclusions that the study draws.

The Dossier Submitter further notes that the study from IECAS/ESFAM is carried out with a focus on firearm manufacturers. The result of that seem difficult to reconcile with some of the main findings that a) modern shotguns can handle steel shot and that b) most modern rifles can handle lead free ammunition.

The Dossier Submitter furthermore notes that one of the key conclusions of the study of IECAS/ESFAM is that 90 % of the impact is expected to occur from a restriction on the use of lead bullets in sports shooting. For this use, however, the Dossier Submitter has already stated the lack of alternative bullets of sufficient precision and considers that improvements of RMMs at rifle/pistol ranges as a more appropriate way forward.

The expected impact as presented in the comment from IECAS/ESFAM appears to be related to a premature introduction of the restriction rather than the restriction per se. Similar concerns were raised in comment #3262, however the commenter stated that with a transition period of five years for large calibre bullets there would be ample time to expand and set up additional production lines which typically takes about 2 years per line. Additional time would then be needed for further logistics, but a five-year transition period was considered to be sufficient to avoid negative impacts on industry (#3331).

Comments from several ammunition manufacturers are discussed in Section 3.1.6 on transition periods.

The Dossier Submitter recognizes that for small calibre ammunition (centrefire smaller than 5.6 mm and rimfire ammunition) the development of non-lead ammunition still requires further R&D and, in that respect, also recognizes that need for a longer transition period accompanied with a potential review. A separate discussion of that topic is described in Section3.1.6. This potentially has an impact on firearm manufacturing.

For rifle ammunition of 5.6 mm and larger, Thomas et al. (2016)[62] present data on lead-free bullet availability from the principal 13 European rifle ammunition makers that have already developed their own brands. Kanstrup et al. (2016)[63] argue that this is in

[62] Thomas, V. G., Gremse, C., & Kanstrup, N. (2016). Non-lead rifle hunting ammunition: Issues of availability and performance in Europe. European Journal of Wildlife Research, 62(6), 633-641, DOI: https://doi.org/10.1007/s10344-016-1044-7

[63] Kanstrup, N., et al. (2016). "Efficacy of non-lead rifle ammunition for hunting in Denmark." European Journal of Wildlife Research 62(3): 333-340. DOI: https://doi.org/10.1007/s10344-016-1006-0

response to the ongoing demand for and evaluation of non-lead rifle ammunition in Germany (Gremse and Rieger 2015), and possibly, for export into the growing North American market. Kanstrup et al. (2016) concludes that the major companies – Blaser, Brenneke, Fiocchi, Geco, Lapua, Norma, Rottweil, RWS, Sako, Sellier & Bellot, Sax, Sauvestre, Schnetz, and Hornady International – list calibres suitable for hunting every European game species and for every commonly used rifle. Kanstrup et al. (2016) concluded that the product availability of non-lead rifle ammunition (i.e. the large variability of alternatives manufactured, as opposed to what is commonly available at the retail level) is not a limiting factor in Europe for increases in the use of non-lead bullets. All the ammunition mentioned above is regarded to be compatible with existing firearms.

The situation is similar for shotgun ammunition. Kanstrup and Thomas (2019)[64] identified 22 European manufactures of non-lead shot cartridges distributed among the following 8 countries: Italy (6), UK (4), France (4), Spain (4), Sweden (1), Germany (1), Poland (1), and Czech Republic (1). All companies had a steel shot production line, some with a wide selection of gauges and loads. Bismuth shot cartridges were produced by two, copper by two, and zinc by one company. In addition, six North American manufacturers produced non-lead cartridges. One (Kent Cartridge) had specialized in non-lead cartridge and was directly affiliated with a British company (Gamebore). The 28 manufacturers, including the 22 European and the six North American companies, had distribution agencies in most European countries; hence, their products, including lead-free ammunition, were available, or could easily become available in any region or country, subject to demand. All the ammunition mentioned above is regarded to be compatible with existing shotguns and would not require gun-redesign per se.

The Dossier Submitter has updated the Background Document (Section 2.5.3) with the information above.

3.1.6. Transition periods for the ban on placing on the market and/or use of lead ammunition for hunting

The Dossier Submitter proposed transition periods of 5 years for the ban on placing on the market and use of lead gunshot, 5 years for the ban on use of small calibre lead bullets, and 18 months for the ban on use of large calibre lead bullets. On the proposed transition periods, several comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals, for example: #3216, #3237, #3250, #3252, #3255, #3256, #3331 #3262, #3467.

In the consultation of the Annex XV report, many commenters argued that the proposed transition period for lead ammunition in hunting uses was too short and argued for longer transition periods for small and large calibre bullets, gunshot and rimfire ammunition.

In relation to large calibre bullets, the arguments presented for a longer transition period

[64] Kanstrup, N. and V. G. Thomas (2019). "Availability and prices of non-lead gunshot cartridges in the European retail market." Ambio 48(9): 1039-1043. DOI: 10.1007/s13280-019-01151-8

are based on the need to expand production lines, which commenters (#3262, #3331) estimated to take at a minimum two years (possibly longer due to shortage in bullet manufacturing machines), the need for compatibility with R&D cycles, as well as the avoidance of a supply shortage of lead-free bullets. The Dossier Submitter notes that even tough 12-15 manufacturers already supply the market with alternatives for large calibre bullets (as documented in this report) and there may be more manufacturing companies that provide alternatives (see e.g. DK Bullets and JCP ammo), only a small share of users (10-15 %) currently use these alternatives. Indeed, this would suggest that a significant scaling up of market supply would need to take place. A longer transition period than the proposed 18 months would allow to fit this expansion into normal R&D cycles (and therefore into manufacturers' normal R&D budgets).

The main advantage of a short transition period for large calibre bullets (i.e. 18 months) is the faster reduction of human health impacts in terms of IQ loss and CKD linked to the consumption of lead-contaminated game meat. In Section 2.5.2.1, these impacts have been estimated at €77.5-145m per year (IQ loss: €70m/year; CKD: €7.5-75m/year). Assuming that these impacts are mainly linked to the use of large calibre bullets, an increase in the transition period from 18 months to 5 years would mean to forgo a reduction in human health impacts of up to €145m per year over a period of 3.5 years. In terms of emissions, 119 tonnes lead per year would continue to be released to the environment during this 3.5-year period. On the other hand, hunters would avoid costs in the order of €20m per year during the same period.

With regard to small calibre bullets (including rimfire ammunition) and gunshot, the arguments put forward in the consultation to underpin requests for longer transition periods relate mainly to technical feasibility concerns. These are discussed in section 3.1.3.1 of this document and have been reported in Section 2.5.1. of the Background Document.

For small calibre bullets, an additional 5 years of transition time would mean cost savings in the order of €13m per year for a duration of 5 years. On the other hand, about 15 tonnes of lead per year would continue to be released to the environment during this period.

Similarly, for lead shot used in hunting, the avoided costs for hunters associated with a longer transition period needs to be balanced against realising lower benefits in terms of reduced lead poisoning in birds. An additional 5 years of transition time would mean cost savings in the order of €84m per year over a period of 5 years, whereas benefits in the order of €114m per year (in terms of avoided bird mortality) would be forgone during that period. Around 14 000 tonnes of lead per year would continue to be released to the environment during this 5-year period. Based on input from the consultation, Table 2-36 in the Background Document has been updated.

3.2. RAC Rapporteurs comments

Related to alternatives, RAC has evaluated the possible risks related to the alternative materials. In the consultation, the high environmental footprint of bismuth-based alternatives was pointed out. RAC agrees with this and has emphasised in its opinion that the main alternative for lead gunshot is steel, and the use of bismuth (and

tungsten) should be limited only to special activities (e.g., use in very old weapons) due to their high environmental footprint.

Several stakeholder comments pointed out that the use of steel gunshot on shooting ranges as an alternative to lead will mobilise lead and other metals in soils at shooting ranges and referred to the recent open-source publication by Lisin et al. (2022). However, the WCA (2022) report (included as Appendix 4 to the Background Document) contradicts this view, showing that field-based evidence does not support the claims in Lisin et al. regarding acceleration of lead migration by iron in soil with subsequent impacts upon surface and ground waters. The weathering of soil and the binding of lead species to 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 sites for lead species than organic matter. Thus, RAC disagrees with these comments. This issue is further discussed in RAC WP A.2 report (Additional environmental risks related to sports shooting ranges: soil/surface and groundwater) and WP B.2 reports (Risks of Alternatives).

Regarding derogations for the use of lead ammunition in hunting, the Dossier Submitter has proposed derogations for lead bullets for seal hunting and for the use of full metal jacket bullets for special hunting applications. 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. In addition, 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.

Should a derogation for hunting with muzzle loaders or pest control with air weapons be considered, RAC notes that the volumes of lead used for these hunting purposes are small.

Several comments submitted in the consultation also requested a derogation for small calibre bullets. Instead of a derogation, the Dossier Submitter proposed a longer transition period for small calibres. RAC agrees with the Dossier Submitter's proposal and points out that the 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.

RAC agrees with the comment on the shorter transition period for the entering into force of the ban on the use of gunshot in hunting. The view of RAC is that the transition period proposed by the Dossier Submitter is too long and could be shortened, considering that the use of lead gunshot in wetlands is already regulated in the whole EU. The shorter the transition period is, less lead will be released into the environment.

3.3. SEAC Rapporteurs comments

With regard to alternative gunshot, the SEAC rapporteurs agree that it is unlikely that a large group of hunters would switch to bismuth instead of steel. The SEAC rapporteurs

have adapted the central cost scenario accordingly (see SEAC box in Section 2.5.3.1 of the Background Document).

With regard to the ban of using lead gunshot in hunting, the SEAC rapporteurs point out that available evidence supports that steel shot is widely available in the majority of sizes and gauges. The 5-year transition period proposed by the Dossier Submitter was mainly based on the argument that production capacities would not be sufficient to allow for an earlier total ban, i.e. in hunting and sports shooting. However, the assessment of the Dossier Submitter has demonstrated that the benefits of a ban of lead gunshot in hunting clearly outweigh the costs. This means that available evidence substantiates a shorter transition period for hunting.

With regard to rifle ammunition, it is important to note that the cut-off value of 5.6 mm between large and small calibres only applies to centrefire ammunition and not to rimfire ammunition.

The SEAC rapporteurs would like to point out that in Sections 3.1.2.2.1 and 3.1.2.2.4 above the remarks of the Dossier Submitter on “buying ammunition with the correct twist rate” and on “non-lead ammunition with a different twist rate” are misleading. The comments from stakeholders and the available literature (e.g. https://www.ammunitiontogo.com/lodge/twist-rate/) clearly indicate that “twist rate” is only used in relation to the rifling in the barrel, not to the projectiles. Nevertheless, the context of this response-to-comments document and the Background Document makes it clear that it is the combination of (rifle) twist rate, bullet size and weight that determines the stabilisation of a projectile.

With regard to the potential negative impact of a restriction on hunting activities, the SEAC rapporteurs consider it unlikely that such an effect would lead to a long-term decrease of hunting activities. To successfully switch to alternative ammunition, it requires further knowledge and skills from the hunter. Therefore, educational measures and training opportunities could be decisive to prevent also a potential short-term drop in hunting activities and associated benefits to society.

For a response to the different derogation requests received the SEAC rapporteurs refer to the discussion in the SEAC draft opinion.

4. Sports shooting

4.1. Dossier Submitter response to comments

4.1.1. Sports shooting disciplines

Several comments were submitted on sports shooting disciplines that were not explicitly mentioned in the Background Document. Comments were received for example from the SAL (Finnish Shooting Sport Federation) (comments #3240, #3323), Firearms United Finland ry (comment #3265), the Finnish Ampumakerho (#3266), or FITASC/ISSF (#3351). In these comments, it was highlighted that, in addition to trap and skeet, also other disciplines such as 'practical shooting' (#3240) are relevant for this restriction proposal. SAL (comment #3323) and FITASC/ISSF (#3346) even provided a link to a video which introduces several shooting disciplines performed in Finland. Specific focus was on dynamic shooting disciplines such as "running moose".

The Dossier Submitter notes the comments and videos that demonstrate the plurality of shooting sport disciplines using gunshot or bullets. The Dossier Submitter notes that such disciplines can be categorised as 'static' and 'dynamic' disciplines and that for these categories different RMMs might be best suited to contain and recover spent lead. Consequently, the Dossier Submitter has taken into account the provided information when it amended the Background Document (see Sections 2.2.2, 2.6.3 and 2.6.4) by considering different combinations of RMMs for 'static' and dynamic' shooting disciplines, respectively.

4.1.2. Use volume and environmental emissions

Some comments (e.g., #3221 and #3379) were submitted by sector associations for sports shooting on the total volume of ammunition spent in sports shooting and the corresponding volume of lead. The Dossier Submitter has grouped these comments into individual topics.

4.1.2.1. Gunshot

FITASC/ISSF (#3221) estimated the annual lead release in EEA+UK from clay target shooting at around 14 000 tonnes based on the following reasoning. The European industry manufactures 1 300 million cartridges in the EEA+UK, of which 60 % are for hunting and 40 % for sport shooting. Thus, 520 million sports cartridges are annually produced for the EEA+UK. The main manufacturing countries are Italy, France, Spain, the United Kingdom and Germany. 28 g sport cartridges (non-Olympic disciplines managed by FITASC/ISSF) account for 60 % of the market, and 24 g sport cartridges (Olympic disciplines managed by ESC) account for 40 %. Furthermore, FITASC/ISSF considered that no significant producer of sport cartridges in the United States has exported to Europe for many years and cartridge self-reloading is prohibited by ISSF and FITASC rules.

The German Shooting Sport and Archery Federation (#3379) commented that the assumption of 10 000 kg/year of lead used 'on a typical outdoor clay target range' may characterise the maximum number of annual shots but cannot be considered 'typical' or

average as much lower volumes of ammunition are consumed at German national training centres. The resulting overestimate of lead released into the environment (35 000 tpa as originally assumed by the Dossier Submitter) does, according to comment #3379, not reflect reality.

Based on these comments, the Dossier Submitter updated the Background Document (Section 1.5.3.1.2). Specifically, the estimate of lead shot used was reassessed. The Dossier Submitter now assumes the lead volume to be in the range of 14 000 to 35 000 tonnes per year, with a calculated average of about 24 500 tonnes per year (instead of 35 000 tonnes per year).

4.1.2.2. Bullets

AFEMS (#3246) criticised the Dossier Submitter's estimates of bullets used for sports shooting, concluding that "AFEMS asks ECHA to use more reliable information, e.g. based on average releases per site or preferably EU sales statistics."

The Dossier Submitter notes that its estimates covered the range of information retrieved in the call for evidence and in information gathering during the preparation of the Annex XV report. Based on comments related to 'Measures to limit release of lead bullets to the environment' (see below) and taking into account the effectiveness of bullet trap chambers and 'best practice sand trap' to reduce the emission to soil and surface water, the Dossier Submitter updated the Background Document (Section 1.5.3.1.2). Specifically, the estimated annual lead releases to the environment (surface water, soil) from bullets were reassessed and the Dossier Submitter now assumes that these releases range from 6 to 1 500 tonnes, with an average of 420 tonnes per year.

4.1.3. Alternative ammunition for sports shooting

Multiple comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals on alternative ammunition for sports shooting. For example, comments #3173, #3177, #3183, #3184, #3187, #3188, #3189, #3190, #3195, #3198, #3200, #3216, #3220, #3224, #3225, #3226, #3227, #3230, #3235, #3237, #3239, #3240, #3245, #3247, #3248, #3249, #3251, #3252, #3254, #3257, #3258, #3261, #3262, #3265, #3266, #3275, #3285, #3290, #3298, #3299, #3301, #3306, #3326, #3331, #3368, #3379, #3399, #3401, #3403, #3410, #3413, #3422, #3426, #3427, #3441, #3447, #3457, #3463, #3467, #3468, #3469, #3470, #3471, #3474, #3490, #3516, #3518, #3525. Some of these comments (#3239, #3413) have been handled as confidential as per the commenter's request.

The Dossier Submitter grouped the comments into the following broad categories.

4.1.3.1. Gunshot

Steel

The Dossier Submitter notes specific comments (e.g., #3189) on the availability of steel gunshot that could be used as alternatives for lead gunshot for trap and skeet shooting. However, in other comments (e.g., #3216) limitations were noted such as a need for the change of gunshot design, required re-training, difference in trajectory, lower target

impact and a baseline and standardised ammunition for world-wide competitions Furthermore, comment #3240 stated that alternatives would not be safe because of ricochet risk and noted that for muzzle loading with historical weapons no alternatives were available. Other commenters also argued that due to the use of steel targets for IPCS gunshot, no safe substitutions are known for lead gunshot to prevent ricochet (#3326). No information was submitted that would give information on initiatives to phase out lead gunshot for international sports shooting competitions.

Based on the available evidence, the Dossier Submitter finds that the differences between lead and steel shot for skeet and trap are predictable and manageable (e.g., re-training) and are not hindered by technical barriers but rather by organisational barriers, namely the ISSF/FITASC rules that prescribe the use of lead shot.

In response to the comments received, the Dossier Submitter updated the parts of the Background Document on the suitability of alternatives for sports shooting (see Section 2.6.1).

Bismuth

AFEMS (#3246, #3331) and FACE (#3467) commented that bismuth is not a credible alternative. The Dossier Submitter refers to the Background Document where it is stated that the use of bismuth for sports shooting with shotguns is not considered a suitable alternative as it is relatively expensive, and sports shooters use larger quantities of cartridges relative to hunting. This would render it prohibitive as an alternative for sports shooting. Therefore, the Dossier Submitter assumes that sports shooters would rather use steel gunshot in case of a restriction on lead gunshot.

4.1.3.2. Alternative bullets for rifle and pistol

For shooting with rifles and pistols, almost all comments received confirmed the Dossier Submitter's view that for small calibres no lead-free bullets are available that would have sufficient accuracy and stability. The comments support the Dossier Submitter's proposal for a derogation on the ban of lead bullets for sports shooting under strict environmental conditions. However, the Dossier Submitter received also comments from manufacturers (#3306) indicating that for centrefire rifle ammunition for target shooting "*the availability is just a matter of investments in production equipment*" alluding on the possibility that suitable lead-free ammunition could become available in the future.

4.1.3.3. Air rifle

Commenter #3379 submitted test results to the Dossier Submitter showing that for air gun pellets the precision of lead-free ammunition is significantly lower than for lead ammunition. The Dossier Submitter incorporated this information into the Background Document (Section 2.7.2).

4.1.3.4. Muzzle loaders

The Dossier Submitter also received various comments (e.g., #3224, #3227, #3235, #3254) related to sports shooting with muzzle loaders, for which there are practically no alternatives to lead ammunition. Based on these comments, the Dossier Submitter

updated the Background Document (Section 2.7.1).

4.1.4. Exposure of sports shooters

Several comments were submitted by sector associations, or individuals on lead exposure of outdoor sports shooters (e.g., #3184, #3185, #3188, #3189, #3221, #3230, #3254, #3277, #3285, #3308, #3309, #3379, #3518). Some of these comments have been handled as confidential as per the commenter's request.

In contrast to known lead exposure from indoor sports shooting (e.g., #3189), several comments considered that lead exposure from outdoor sports shooting is negligible (e.g., #3185, #3188, #3189, #3285, #3308, #3309, #3379). However, one comment indicated that the risks from very frequent shooting are known to the shooters, but these could still be better and more widely informed about associated risks (#3187). It was also noted that frequent blood analysis of athletes participating in shooting competitions have been performed without indicating any health problems (#3230, #3275). For example, it was reported (#3235) that Hungarian sports shooters undergo an annual mandatory health check whereas hunters are periodically monitored (every 2-10 years, depending on their age). The Dossier Submitter notes that in most cases no information on blood lead levels were provided that would allow a more in-depth analysis of lead exposure.

The Muzzle Loaders Associations International Federation (comment #3277) provided information on the blood lead level of one shooter in Austria (concurrent blood lead level of 72 µg/L) who does intensive shooting (muzzle, black powder, big and small-bore pistol and rifle, military rifle, air pistol) and related activities (home casting, re-loading). The Dossier Submitter appreciates the receipt of the measured blood lead level but notes that the reference level of 90 µg/L referred to by the commenter (#3277) is from 2003 and has been lowered since to 40 µg/L (2019) according to the German Federal Environmental Agency (Umweltbundesamt). Therefore, the measured blood lead level is not within but exceeds the current reference value for Germany. Nevertheless, the Dossier Submitter amended the Background Document (Section 1.6.3) with the information received.

In comment #3237, a small-scale survey of middle-aged men eating a lot of game meat was reported. The men had eaten both small and large game for several decades since infancy, several times a week (up to 10 servings/week), engaged in sport shooting, and half of them also engaged in cartridge recharging. Their blood lead levels ranged from 0.09 to 0.19 µmol/L [4 to 39 µg/L], averaging 0.13 µmol/L [27 µg/L]. One person, who also carried out casting work, had a blood lead content of 0.7 µmol/L [145 µg/L], which was clearly higher than the other measurement results. The Dossier Submitter updated the Background Document (Section 1.6.3) with regards to the information received.

FITASC/ISSF (#3221) commented that there is no possible emission of lead dust in clay target sports shooting using lead shot cartridges. They based this view on the argument that, for lead dust to be released on firing, there must be friction between the lead pellets and the barrel's bore. In modern cartridges that use plastic wads, there is no contact between the barrel's bore and the lead load. Furthermore, the commenter explained that, when a lead pellet hits the ground, it has close to zero speed and zero

energy. To support this statement reference was made to a professional Olympic skeet shooter with 'perfectly normal' blood lead levels. Several reasons were brought forward contributing to the low exposure such as:

- Open air environment with natural ventilation
- Technical measures to limit exposure of outdoor shooters (see next issue)
- Lead is contained in the cartridge (#3194)
- Shooting positions are minimum 2 to 2.5 metres apart
- Minimum firing distance to the target to prevent exposure from the projectile splashing on the target or berm

In response to this comment, the Dossier Submitter updated the Background Document (Section 1.6.3) listing these arguments.

The LIGA LIBE (#3518) presented measurement data on the blood lead levels of Danka Barteková, a Slovak Olympic bronze medallist in shotgun shooting. She was exposed to lead for a total of 20 years, firing an average of 20 000 rounds per year, which amounts to 200 million rounds, with an average Skeet 24 cartridge of about 518 shots. The medical blood examination protocol is available here: https://myslivost.cz/Pro-myslivce/Aktuality/Pravdu-mame-my.

While the Dossier Submitter included this information in the Background Document (Section 1.6.3), it notes that in the study by Chun et al. (2018), lead concentrations in the air and in the blood of clay target athletes in Korea were measured that indicated increased lead concentrations in the air and in blood compared to national background blood lead levels, whereas the Slovak shotgun shooter (comment #3518) did not show increased blood lead levels. In the absence of further reliable measured data, it must be assumed that there would be some lead exposure from clay target shooting using lead shot cartridges, even if this might be low.

4.1.5. Measures to limit exposure of outdoor shooters

Multiple comments were submitted on measures to limit lead exposure of outdoor sports shooters. These include comments #3173, #3184, #3185, #3187, #3188, #3189, #3194, #3198, #3200, #3216, #3220, #3223, #3230, #3240, #3244, #3245, #3248, #3252, #3254, #3257, #3261, #3262, #3267, #3275, #3277, #3285, #3289, #3298, #3308, #3309, #3310, #3317, #3326, #3372, #3379, #3394, #3403, #3410, #3413, #3415, #3426, #3441, #3442, #3447, #3468, #3470, #3474, #3518, #3519, #3520, #3525. Some of the comments have been handled as confidential as per the commenter's request.

The Dossier Submitter grouped the comments as follows.

4.1.5.1. Technical measures

Several comments (e.g. #3245, #3257, #3262, #3441, #3525) noted that lead

exposure of shooters can be reduced when using large calibre ammunition jacketed with copper and zinc. The Dossier Submitter acknowledges the significant reduction in lead exposure of shooters using jacketed lead bullets. However, it has to be kept in mind that jacketed lead bullets do not reduce risks to the environment.

Technical measures can be applied to increase air circulation. For partially covered (outdoor) shooting ranges, the German shooting range guidelines prescribe a ventilation of the shooting range, which conveys fresh air in the direction of the shooting openings and thus keeps the shooter's breathing area free of lead emission (#3198, #3379). Commenter (#3252) recommended that on outdoor ranges, the roof over the shooters may not extend more than 3 m in front of the shooter so that any vaporized lead after firing can be ventilated naturally to prevent hazards for the shooters. The Dossier Submitter acknowledges these recommendations to limit lead exposure of outdoor shooters in the Background Document.

4.1.5.2. Personal protection measures

Several comments (e.g., #3200, #3220, #3223, #3224, #3262; #3275; #3326, #3379, #3410; #3426, #3441) were received that addressed issues related to personal protection measures:

Several comments were related to recommendations for good hygiene practice for outdoor shooting ranges such as:

- Careful hand washing (with cold water) after each shooting practice is the main hygiene measure recommended as reflected in many comments received.
- No eating, drinking or smoking at the shooting range after handling lead ammunition; it may be allowed in specific areas (e.g., clubhouse) after careful hand washing.
- Use of gloves when maintaining equipment handling steel targets or bullet traps; the gloves should not be used for any other purpose.
- It is good practice to use separate gloves, shoes and jackets at the shooting range and keep them separated from other clothing.

In addition, training of sports shooters was raised. For example, in comment #3254 it was noted that black powder hunters and shooters understand that handling lead involves health risks. This risk is reduced through education. In most Member States there is a law that using black powder and shooting with muzzle loaders (which implies the use of lead as well) requires a special education and a final examination. The risks from the use of both black powder and lead are warned against. Furthermore, in Hungary a mandatory exam that also focuses on safe handling of lead (#3235) is necessary for obtaining a black powder hunting license.

The Dossier Submitter updated the Background Document considering these personal protection measures.

4.1.6. Sports shooting with lead gunshot

Several comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals on measures to limit the release of lead gunshot to the environment. These include #3186, #3192, #3189, #3195, #3198, #3195, #3216, #3225, #3227, #3230, #3235, #3237, #3240, #3244, #3248, #2350, #3254, #3257, #3265, #3267, #3275, #3285, #3289, #3290, #3301, #3304, #3317, #3328, #3364, #3337, #3338, #3379, #3394, #3403, #3413, #3433, #3435, #3467, #3470, #3474, #3476, #3481, #3501, #3516, #3518, #3522, #3523. Some of these comments have been handled as confidential as per the commenter's request.

The Dossier Submitter grouped the comments as follows.

4.1.6.1. Environmental risks from shotgun ranges

FITASC/ISSF (#3267) commented that due to the low solubility of lead gunshot, shooting sports facilities would not affect the environment outside the proper site of the range that shooting sports facilities would not pose a risk to human health, and that the potential risks that may arise at the facilities with the generation of "migratable" lead are manageable. Similarly, comments (e.g., #3195) stated that no measure would be required because lead does not pollute soil and water.

The Dossier Submitter notes that it is well established in the scientific literature (see the literature summarised in Section 1.5.4.3 of the Background Document) that spent lead gunshot and bullets can be mobilised and may pose a risk to the environment under certain conditions. Furthermore, the Dossier Submitter notes that lead ammunition may currently be used outside designated sports facilities and that shooting sports facilities can pose a risk to the environment if they are not well-managed. Therefore, harmonised criteria throughout the EU are proposed to minimise the risk to the environment from the use of lead ammunition for sports shooting.

Comments #3225 and #3227 referred to the EU LUCAS project, as part of which 220 000 sample points across the EU have been regularly monitored. In 2009 and 2013, 10 % of these points were statistically analysed to obtain a picture about the heavy metal contamination of the topsoil in EU Members States. None of these samples displayed a concentration above the guideline value for agricultural land. The Dossier Submitter used the cited source as background information on lead levels in soils in the EU noting that the LUCAS project did not specifically investigate lead-contaminated soils of shooting ranges.

FITASC/ISSF (#3221) commented that the Dossier Submitter's conclusion that "Measures may contribute in some sites to reduce lead mobilization but are not proved to be effective in natural soil systems in the long term to prevent lead migration" would be wrong because liming is not only applicable for cultivated soils but can also, in the case of the regulation of the soil pH of shooting ranges soils, be repeated as many times as required, and therefore provides an effective means to continuously prevent lead migration. The Dossier Submitter updated the Background Document to clarify that no universal risk management measure (RMM) for preventing leaching of lead ammunition

has yet been identified (see Steinnes 2013[65]), especially in the long term to prevent lead migration after the end of service when such measures would be most likely discontinued, amendment practices are not expected to be applicable in temporary shooting grounds. A summary of the effectiveness of different environmental RMMs, as assessed by the Dossier Submitter, is given in Section 1.4.4.2.2.7 of the Background Document.

FITASC/ISSF (#3328) concluded that all restriction options for sport shooting with lead gunshot would not be feasible. The Dossier Submitter considers that the restriction options are feasible as justified in the Background Document; for example, the RMMs as proposed in the optional conditional derogation are already implemented in several clay target ranges in Germany. In addition, the Dossier Submitter notes that in Sweden, Norway and Denmark the use of lead shot in shooting ranges is already banned in the entire territory with some derogations in place[66].

FITASC/ISSF (#3328) also questioned the Dossier Submitter's risk assessment because no conceptional model was used. The Dossier Submitter considers that a risk assessment does not require the formal use a conceptual model to be appropriate. However, a general conceptual model was made available in Section B.9.1.3.3 of the Annex to the Background Document. Available evidence on risk management measures applied at shooting ranges (and used for the risk assessment) is discussed in Section 1.4.4.2. of the Background Document.

On risk management measures for shooting ranges, FITASC/ISSF (#3328) concluded that the "management methods should be site specific". The Dossier Submitter fully agrees that to achieve a high level of environmental protection at a shooting range the risk management measures need to be site-specific taking into account various factors such as the type of shooting and ammunition used, the slope of the site, the type of soil, vegetation, climate and the location of nearby water sources (surface water and groundwater). However, at EU level no harmonised measure is in place to adequately manage risks to the soil and surface water compartments from lead ammunition (including lead shot), as well as to other specific receptors such as groundwater, livestock, wildlife (primarily birds) and to humans via the environment. The lack of harmonised risk management measures at EU level, for the entire sports shooting sector, is also evident from the Member State survey, 2020[67] carried out by the Dossier Submitter (summarised in Sections 1.4.4.3 and 1.4.4.2.2.4 of the Background Document and in Section B.9.1.3 of the Annex to the Background Document). Finally, the Dossier Submitter wishes to highlight that the restriction proposal aims to propose harmonised measures for the protection of the environment and of humans that cannot be easily achieved without an EU legally binding framework.

FITASC/ISSF (#3328) stated that in non-agricultural land (forest or moor, topsoil, closed

[65] STEINNES 2013. Lead. In: Alloway B. (eds) Heavy Metals in Soils. Environmental Pollution, vol 22. Springer, Dordrecht.

[66] In the Netherlands the use of lead shot is banned for clay pigeon shooting and in Belgium, in the Flemish region, there is a regional ban for the entire territory.

[67] See section E5 (Annex to the Background Document).

meadow, warrens, etc.) where pH is generally below 6.5, if no treatment of the soil is done and pH remains in acidic conditions, a shot recovery with at least 90% effectiveness, at least once a year would be recommended. The Dossier Submitter notes that the use of lead gunshot in wetlands (as defined by the Ramsar definition and thus including moorland) is already banned by a previous restriction. The Dossier Submitter also notes that the available evidence indicates that it is very difficult (or not possible) to reach lead gunshot recovery of 90 % in forests (or in wooded areas) where manual intervention to recover lead gunshot is required or on closed meadows or warrens, where the grass layer would need to be removed to recover the lead gunshot. In addition, the Dossier Submitter considers that soil treatment as a single measure (e.g., liming, discussed in the Background Document, Section 1.4.4.2.2.) would not effectively manage all identified risks (to different environmental compartments and to specific receptors), also taking into account that many risk management measures will not be in place at the end of service life of a shooting range. Finally, lead shot would be available to birds to be ingested, as also discussed in Section 1.5.3.4 of the Background Document.

FITASC/ISSF (#3328) also proposed to work on a European Lead Management Charter for Sport Shooting Ranges taking into account ecological aims and needs of sports shooters. The Dossier Submitter welcomes the contribution of FITASC/ISSF and other stakeholders to the current assessment and wishes to remind that the restriction proposal aims to propose harmonised measures for the protection of the environment and of humans (via the environment) taking into account all types of shooting activities (also temporary shooting) occurring in all types of shooting ranges (or areas) and addressing **all** identified risks.

4.1.6.2. Ban on the use on lead gunshot

Several comments (e.g. #3289) requested a full ban for sports shooting with lead gunshot. Comments were also received from several Member States such as Belgium (#3317), Sweden (#3189, #3301), Norway (#3257) where the use of lead gunshot for trap and skeet is already banned. The Dossier Submitter notes that this information was already included in the Annex XV report and no updates were therefore made to the Background Document.

In a comment of the Belgian Weapon Forum (#3403) it was noted that environmental rules have already been imposed in Belgium and that shooting ranges have sufficient measures in place to recover lead or other substances. The Dossier Submitter has further elaborated the arguments on risk management measures applicable at shooting ranges in Section 1.4.4.2 of the Background Document.

Comment #3257 informed that, in Norway, derogations are in place for disciplines that are using steel targets (such as “game trail” shooting, IPCS shotgun, Cowboy action shooting) or black powder firearms; such disciplines are usually performed at pistol/rifle ranges, not at trap/skeet ranges. The commenter argued that derogations for nationally important disciplines such as “game trail” should be decided at national levels. The Dossier Submitter updated the Background Document (Section 2.6.5.1).

FITASC/ISSF (#3501) commented that in case of a ban of lead gunshot, lead shot would need to be collected and the ranges cleaned up before using steel shot, because they consider that the deposition of steel shot on lead shot generates soil pollution. They also

note that in the EU, many shooting clubs would be affected, and they would not have the funds to bear the costs for clean-up. The Dossier Submitter has not identified any confirmed evidence that the use of steel shot would increase lead mobilisation, as already discussed in the annex to the Background Document (B.4.2.1.1).

One comment (#3248) noted that if it was compulsory for shooting ranges on which currently shooting with lead gunshot is done under a "secure concept" (i.e., in agreement with the relevant authorities) to use steel shot instead, this would mean that many shooting ranges that are important for hunting would lose their approval. The Dossier Submitter refers to the Annex XV report which proposed a ban on marketing and use of lead gunshot in hunting. In case of such a ban, hunting trainings would likely be performed with the preferred alternative gunshot used for hunting (mostly steel, but also bismuth or tungsten shot). On this basis, the Dossier Submitter assessed the impacts on sports shooters in Section 2.6 of the Background Document.

The German Shooting Sport and Archery Federation (#3379) commented that a restriction on the use of lead-containing ammunition would have far-reaching negative influences on the shooting sport for EU athletes participating at international shooting sport competitions and for sports shooters throughout the EU, leading to a significant decrease in the number of sports shooters and clubs with all their important socioeconomic functions within society. It was therefore requested that the Dossier Submitter revise its restriction proposal and foresee a permanent, timely unlimited derogation on the use of all types of lead-containing ammunition for shooting sport on all designated shooting sport facilities. The Dossier Submitter duly documented the request in the updated Background Document.

4.1.6.3. Optional derogation for licenced athletes and permitted ranges

Several comments from Germany (such as #3198, #3248, # 3379, #3413) describe the use of lead gunshot under strict environmental conditions, thus allowing a high recovery rate. In response, the Dossier Submitter highlights that in the revised Background Document it had refined the assessment of several restriction options, including options for continuing the use of lead gunshot under strict environmental conditions and that these options may now be considered by ECHA's scientific committees and eventually by the decision makers.

AFEMS (#3331) requested the full cost of implementing the conditions of this derogation be included in the assessment; specifically, the costs to be borne by national authorities, retailers, suppliers, and range owners. Moreover, options for simplification should be considered to decrease the administrative burden brought about by the proposed restriction. If the intention is to allow for a derogation for competitive sports shooting, then such a derogation needs to be simple to ensure that its implementation is proportionate. For example, a single permitting/licensing scheme as the one proposed for the derogation for non-gunshot sports shooting would be more proportionate. The Dossier Submitter has not been able to develop what the costs and benefits would be of a unified licensing scheme because no information was submitted in the consultation that would have allowed to do so.

This said, the Dossier Submitter does not envision the set-up of an entirely new system but rather a system that would be attached to existing national systems for issuing

hunting licenses or gun ownership along national systems. Therefore, such a system would only incur an incremental cost. E.g., sports athletes with an Olympic or International status are usually nominated by their national sport shooting federation or national Olympic Committee which should then form the basis to receive a license that would allow buying and possessing lead shot for training and competition purposes. Moreover, the Dossier Submitter assumed that, as ammunition shops are already subject to stringent inspections due to requirements on general safety, fire safety etc., additional inspections focused specifically on the selling of lead gunshot to authorised athletes would not impose a significant extra burden. Again, this is explained in more detail in the Background Document (Section 2.3).

4.1.6.4. RMMs for clay target ranges

FITASC/ISSF (#3328) commented that all restriction options for sports shooting with gunshot would not be feasible. Based on German experiences (#3198, #3379, #3413) the Dossier Submitter considers the proposed restriction options to be feasible but acknowledges that all options would require some adaptations and some options might be expensive. Indeed, in the consultation several comments were received from Germany that highlighted the following:

- In Germany, about 20 % of ~350 operated trap or skeet systems organised under 'Bundesverband Schießstätten e.V.' currently have facilities/measures in place with which >90 % of spent lead gunshot can be regularly recovered (#3198).

- There exists a *Technical information on the environmentally friendly construction and operation of clay target shooting ranges DIN 19740 (Part 1 and Part 2)*, which is the key guidance document for site operators in Germany (#3413).

- Existing shot retention systems in Germany (#3198, #3379) that allow recovery of > 90 % spent lead gunshot include: vertical shot-catching walls or shot-catching nets, shot catch wall, shot trap system shot net, earth walls with and without shot-catching foils, shotgun barrier with foils, shotgun barrier with nets, combination of earth walls and vertical shot catch walls.

- The costs for a shooting range to install and maintain appropriate risk management measures are very much shooting-range specific; in Germany the costs for installing shot trap systems are €0.5m-2m per trap / skeet stand for new ranges. When converting old ranges, the costs for the preceding renovation of the topsoil have to be taken into account.

The Dossier Submitter relied on this information when revising the Background Document (Section 1.4.4.2.2.1).

Topical comments were also received from other Member States:

- In Finland (#3230, #3240), the Czech Republic (#3275), and Norway (#3470, #3257) no trap or skeet range can recover >90 % of spent lead gunshot.

- In Cyprus (#3394), no measures are taken to recover lead from the soil.

However, in many ranges lead pellets are collected for recycling (#3481). Some trap and skeet ranges are located in wetland areas (#3394).

- In Spain (#3431) shooting ranges periodically collect spent lead.
- For shooting ranges with medium or low shooting frequency in the UK, environmental RMMs might not be in place (#3250).

The Dossier Submitter took into account all the provided information when revising the Background Document (Section 1.4.4.2.2.1).

4.1.6.5. Effectiveness of recovery and frequency

FITASC/ISSF (#3328) questioned the scientific basis for a recovery effectiveness > 90 %. The Dossier Submitter proposes "> 90 % effectiveness" as an operational threshold with the objective to minimise the environmental releases of lead from ammunition. This practical threshold is meant to allow a high level of protection of the environment and of humans via the environment (via a sufficiently high level of recovery), in relation to all identified risks. For sports shooting with gunshot, the Dossier Submitter considers necessary to specify both the regular recovery frequency (at least once a year) and the effectiveness of recovery (> 90 %) to minimise all identified risks.

It should be noted that the proposed requirement for > 90 % effectiveness of lead gunshot recovery, or any other highly effective set of RMMs to contain and recover lead reflects the EU's "Zero pollution action plan" [68] which targets zero pollution of air, water and soil, but taking into account that measures to regularly recover lead gunshot may in practice not reach 100 % effectiveness, and that a final clean-up of the site at the end of service life might be desirable.

4.1.6.6. Costs of RMMs

Various comments were received on the costs of risk management measures needed to achieve a high level of environmental protection. The following topical comments deserve specific mentioning.

- RMMs to achieve >90 % lead gunshot recovery and their costs are presented in the Finnish BAT (Kajander and Parri, 2014) (#3240, #3379).
- The costs for RMMs amount to an average of €0.4-1.0 million per range (#3379).
- The costs for seepage water catchment, partly with pre-treatment of the surface water by filter devices, are between €20 000 to €30 000 and annual follow-up costs (monitoring) are around €2 500 (#3379).
- EU grants would be required to support the installation of measures as shooting clubs do not have the resources needed to finance such RMMs (#3230).

[68] https://ec.europa.eu/environment/strategy/zero-pollution-action-plan_en

- RMMs to recover lead gunshot are extremely difficult and costly (#3285).

- FITASC/ISSF (#3501): One tonne of lead collected is worth more than €800. By collecting between 80 and 150 tonnes of lead per year, a shooting club can generate between €64 000 and €120 000 which can be used for financing the collection. In case of a ban, the value of lead would drop, and the ranges would have to bear the complete costs of recovery and cleaning, which would be between €166 and €312 million for the 2 600 clubs.

The Dossier Submitter amended the Background Document (Section 2.6.3) based on the received information.

4.1.6.7. Permitting systems for shotgun ranges

Comment (#3248) notes that in Germany the environmentally friendly construction and operation of clay target shooting ranges is legally required. The Dossier Submitter had already included this information in the Annex XV report and thus no changes were made in the Background Document.

4.1.7. Sports shooting with lead bullets

Several comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals on measures to limit the release of lead bullets to the environment. For example, #3173, #3183, #3184, #3185, #3186, #3187, #3188, #3189, #3192, #3194, #3195, #3198, #3200, #3216, #3218, #3225, #3227, #3229, #3230, #3235, #3237, #3240, #3244, #3245, #3247, #3248, #3249, #3250, #3251, #3252, #3254, #3257, #3258, #3261, #3262, #3266, #3267, #3275, #3280, #3285, #3289, #3290, #3292, #3294, #3298, #3299, #3317, #3326, #3347, #3379, #3401, #3403, #3410, #3413, #3420, #3422, #3426, #3435, #3441, #3447, #3449, #3451, #3463, #3467, #3468, #3470, #3488, #3490, #3501; #3512, #3516, #3520, #3525. Some of these comments have been handled as confidential as per the commenter's request.

The Dossier Submitter grouped the comments received into the following main categories and responded to them accordingly.

4.1.7.1. Derogation on the ban on the use of lead bullets

The Dossier Submitter understands that several commenters interpreted the restriction proposal on bullets for sports shooting in such a way that the preferred option would be a ban on the use of lead bullets. However, the Dossier Submitter would like to clarify that, in the absence of suitable alternatives that provide sufficient precision for sports shooting, as confirmed with the information received during the consultation of the Annex XV Dossier (see Section 4.1.3), the Dossier Submitter has not proposed a ban on the use of lead bullets for sports shooting. Instead, the Dossier Submitter has proposed the use of lead bullets under strict environmental conditions at locations designated for sports shooting.

4.1.7.2. Definition of the term 'bullet trap'

The Dossier Submitter notes that in the Annex XV report, the term 'bullet trap' was used and defined according to the German Shooting Range Guideline[69]. According to this guideline, bullet traps consist of either a roofed bullet trap chamber that is only open in direction to the shooter and filled with suitable material (sand, granulate) to trap bullets, or of technical structures that accommodate and capture the bullets (e.g. steel funnels) (see also comment #3198). However, based on the comments received, this term seems to be used and understood in multiple ways, and has been interpreted as a very generic measure to trap bullets. Agreeing with comments #3435 and #3449 that the definition of 'bullet trap' is crucial, the Dossier Submitter updated the Background Document to clarify the terminology used, e.g. by using the term 'trap chamber'.

4.1.7.3. Type of bullet containments

Several commenters mentioned that bullet trap chambers are a legal requirement in some EU Member States such as Germany (e.g., #3198, #3200, #3229, #3379, #3447, #3525) and Belgium (#3403).

'Sand traps' are frequently used in Nordic countries including Norway (#3245, #3257, #3512), Sweden (#3247, #3249, #3252, #3258, #3261, #3410, #3463), or Finland (#3183, #3187, #3194, #3420). In Sweden, national regulations (Säkerhetsbestämmelser för civit skytte 2020) specify how bullet containments (i.e. sand traps) are to be constructed and maintained (e.g., #3249, #3261).

The Norwegian safety regulation for shooting ranges states that bullet traps must consist of sand/soil or other ricochet free substances (#3245, #3257). Comment #3257 stated that in Norway the use of bullet traps with sand may be enhanced by further technical measures (runoff control, the use of membranes, filters etc.) to minimize the possibility of leaching. According to the Finish Ministry of Agriculture and Forestry (#3488), sand berms with protective measures approved by local authorities should always be an alternative to conventional bullet traps.

In Denmark (#3252) official guidelines for bullet traps are given by the Ministry of Justice in "Design criteria for civil shooting ranges by the Ministry of Justice". These guidelines are about safety rules on shooting ranges, which also hold in Norway. In comment #3435, examples of bullet containments were provided.

Commenter #3441 noted that all permanent ranges in Denmark have bullet traps behind the targets. At a minimum, the bullet trap consists of an earth rampart covering the width of the whole target area and even more height as a safety precaution. Moreover, the commenter informed that, for small calibre (22 LR) ranges (target size Ø300 mm), it is a growing trend among shooting clubs to establish environmentally friendly bullet traps that collect projectiles in special constructions where they can easily be separated for reuse/recycling.

Other commenters (e.g. #3326, #3488) noted that bullet trap chambers may not be suitable for dynamic shooting disciplines, e.g. "moose hunting", which are popular in

[69] See https://www.schiessstandrichtlinien.de/wp-content/uploads/2019/07/SRL-190201.pdf

northern European countries. For many shooting disciplines like practising for elk hunting with moving elk targets or for IPSC or other similar dynamic shooting sports. sand berms are the only practical option for trapping bullets (#3420).

The Dossier Submitter amended the Background Document with the information received on the types of bullet containments (Section 1.4.4.2) and assessed the impacts (Section 2.6) on the identified risks via soil, surface water and groundwater that other bullet containment systems than bullet trap chambers such as i) sand traps (with an impermeable layer to soil), ii) sand/soil berms (without an impermeably layer to soil) and iii) soil berms. Based on this assessment, the Dossier Submitter now proposes to add as alternative to a bullet trap chamber a 'best practice sand trap', consisting of a sand trap with an impermeable layer to the soil, an overhanging roof or a coverage, and a water management system to contain, monitor and treat surface water.

4.1.7.4. Costs of RMMs

Several comments were received specifying costs for RMMs to contain bullets (e.g., #3245, #3251, #3257, ##3262, 3267, #3435). The Dossier Submitter amended the Background Document (Section 2.6.3.2) with the provided information.

The Danish Sport Shooting Range Association (#3435) suggested that to lessen the economic burden caused by the implementation of environmental risk management measures (RMMs), a combination of existing and new solutions be deployed over a period of several years and that this is considered in the timeframe needed for the implementation of a restriction. It was also suggested that a provisional arrangement is agreed upon which temporary solutions such as mounting of covers on existing berms to control water run off can be utilized. The cost savings from keeping lead ammunition could possibly be used to install environmental RMMs. The Dossier Submitter took note of this comment.

4.1.7.5. Effectiveness of recovery and frequency

In the Annex XV report, the Dossier Submitter had proposed '*Regular lead recovery with [>90 %] effectiveness (calculated based on mass balance of lead used vs lead recovered)*' as a condition under which the use of lead bullets on designated shooting areas could be derogated from the restriction.

FITASC/ISSF (#3328) questioned the scientific basis for a recovery effectiveness of > 90 % for both lead shot and lead bullets. With the addition of a 'best practice' sand trap as an alternative bullet containment option, the Dossier Submitter considers that this specification of effectiveness is no longer applicable because lead bullet recovery might take place only every 3 to 5 years for a typical 'best practice sand trap'. Where relevant, further information was added and an analysis of the socio-economic impacts of various options was developed in the Background Document (see Section 2.6) to improve the clarity of the proposal and to further elaborate the justification for the restriction options proposed.

4.1.7.6. Permitting systems for rifle / pistol ranges

The International Practical Shooting Confederation (IPCS) (#3180) commented that all its sports shooting competitions and trainings are held exclusively within specially

equipped, protected and certified facilities (shooting ranges and clubs) under the strict control of police and official organisations responsible for environmental protection and pollution control.

Similarly, comment #3516 noted that in several EU Member States environmental rules and regulations are in place that may require an environmental permit for shooting ranges. For example, in Denmark existing shooting ranges are approved if there are no seepages to groundwater or watercourses and lead uptake by wildlife is not expected (comment #3516). In Sweden, all shooting ranges must have an environmental permit that is regularly reviewed by municipalities (#3249). In Finland, an environmental permit system is being implemented (e.g., #3237, #3255). In Germany, all shooting ranges are checked at least every four years by officially appointed shooting range experts (#3198). Some commenters (e.g. #3237) indicated that in case national laws are already in place to ensure that risks to the environment are minimised, this procedure should be allowed to continue in future.

The Dossier Submitter takes note that all IPCS sports shooting competitions and trainings are held under strictly controlled conditions. Moreover, it acknowledges that relevant RMMs are already implemented at many ranges in the EU. However, the Dossier Submitter also considers that currently no EU-wide environmental standards exist for shooting ranges to minimise the release of lead. Furthermore, the Dossier Submitter considers that, even if new ranges meet high environmental standards, this might not be the case for old ranges. The Dossier Submitter considers that the implementation of specific RMMs (taking into account expert advice and relevant technical standards) should always be based on site-specific characteristics. Generic RMMs as prescribed by permits may not be sufficient to ensure a high level of environmental protection. This is further discussed in Section 2.6 of the Background Document.

4.1.8. Clean-up at the end of service life

Multiple comments on the topic of “remediation” were submitted mainly by sport shooting association and individuals. These include comments #2525, #3173, #3182, #3184, #3185, #3187, #3189, #3195, #3198, #3200, #3216, #3220, #3225, #3227, #3230, #3237, #3240, #3244, #3245, #3247, #3248, #3249, #3251, #3252, #3254, #3258, #3261, #3275, #3285, #3289, #3294, #3364, #3379, #3394, #3399, #3403, #3410, #3413, #3415, #3426, #3431, #3437, #3446, #3449, #3451, #3457, #3463, #3467, #3468, #3474, #3507, #3512, #3516. Some of these comments have been handled as confidential as per the commenter’s request.

Comments #3220 and #3275 note that in the Czech Republic *“The description of measures ensuring the recovery of all parts on the ammunition is required within the construction permit”.* However, it is not clear how this is related to possible site remediation requirements, as the Dossier Submitter has not foreseen any such requirement as a condition for a derogation.

Comment #3251 indicates that in Denmark, there are no formal guidelines on how to manage the risk of lead and other pollutants when a shooting range is closed.

Comment #3230 notes that in Finland environmental aspects are usually taken into account by the authorities when shooting range permissions are established. Comment

#3240 further notes that: *"The Environmental Protection Act lays down provisions on the assessment of contaminated areas and the need for remediation of contaminated areas". (..) "Further provisions on the highest permissible concentrations of harmful substances in the soil and the concentrations of harmful substances for the purpose of assessing contamination and the need for treatment, with due consideration to the various purposes for which the land is used are laid down in Government Decree on the Assessment of Soil Contamination and Remediation Needs. According to the Decree, the assessment of soil contamination and remediation needs shall be based on an assessment of the hazards or harm to health, or the environment represented by the harmful substances in the soil." (…) "According to the Environmental Protection Act, when an activity subject to a permit ceases operation, the operator is still obliged to take any necessary actions to prevent pollution and to determine and monitor the impacts of the activity, in accordance with the permit regulations. If the operator is not to be found or cannot be reached, and monitoring of the environment is necessary for supervision of the environmental impacts of the activity that has ceased operations, the party in possession of the activity site is responsible for the monitoring".*

Comments #3198 and #3379 note that in Germany according to the Federal Emission Control Act, paragraph 5 Section 3: *"Ranges requiring a permit are to be built, operated and shut down in such a way that even after operations have ceased 1. no harmful environmental effects and other dangers, significant disadvantages, and considerable nuisance for the general public and the neighbourhood can be caused by the range or the range property, 2. existing waste is recycled properly and without damage or disposed of without harming the public and 3. the restoration of a proper condition of the range property is guaranteed."* Accordingly, the operator of the site is responsible for financing remediation actions after the decommissioning of a site. The commenter noted, however, that the costs of remediations regularly exceed the financial capacity of the operator or owner of a shooting range; it has therefore proven useful to work out remediation concepts and financing options together with the public authorities. If no remediation takes place after the decommissioning of a site, then the abandoned site is monitored at regular intervals (3 to 8 years). In particular, soil and groundwater investigations and a risk assessment are carried out in accordance with the laws/ordinances applicable in Germany (Federal Soil and Contaminated Sites Act).

Comment #3245 notes that the Norwegian Pollution Control Act has provisions that could be used to allow establishing a condition for remediation at the end of life of shooting ranges. However, these provisions are general provisions for all kinds of chemical pollution, and there are – until now – no specific provisions that would set remediation requirements for shooting ranges in Norway. The same comment (#3245) notes that no civilian shooting club has been obliged to remediate their shooting range at the end of life and that the costs of remediation would in any case make it impossible to require the use of such measures before allowing the commissioning of a shooting range.

Comment #3249 notes that the Swedish Defence Research Agency published a paper which includes risk management advice and that the Swedish Environmental Code (SFS 1998:808) covers all persons and operators engaging in environmentally hazardous activities to which shooting range operations are also subject. However, it is not fully clear how this is related to remediation requirements.

Overall, the Dossier Submitter notes that different legislations with regards to remediation of shooting ranges are in place across the EU and that not all shooting ranges may be remediated at the end of life because it is either not required in a specific (region of) a Member State or because of a lack of necessary funding. The Dossier Submitter is aware that "remediation" is beyond the scope of REACH and has therefore not included any requirement for site remediation in its restriction proposal. However, the Dossier Submitter notes that relevant risks to humans and the environment may occur after the end of service life in case no remediation will be performed. Therefore, the Dossier Submitter considers that the current restriction proposal with the implementation of strict RMMs at shooting ranges *during* service life would help to minimise lead mobilisation to the environment and would facilitate an effective "clean-up" of lead at the end of service life. This could contribute to reduce the need for remediation of newly commissioned shooting ranges across the EU. In the Background Document (Section 1.4.4), the Dossier Submitter provides complimentary information on the topic gathered through the Member States survey undertaken in 2020.

4.1.9. Use of shooting areas for agricultural purposes

Multiple comments were submitted, mainly by sector associations and individuals, on the use of shooting areas for agricultural purposes. These include comments #3173, #3184, #3187, #3189, #3192, #3194, #3198, #3200, #3216, #3226, #3230, #3235, #3237, #3240, #3244, #3247, #3248, #3249, #3250, #3254, #3261, #3262, #3275, #3285, #3289, #3290, #3297, #3298, #3308, #3317, #3326, #3334, #3347, #3364, #3379, #3391, #3399, #3402, #3410, #3413, #3415, #3420. #3426, #3431, #3435, #3441, #3442, #3463, #3467, #3471, #3476, #3488, #3516 #3518, #3525. Some of these comments have been handled as confidential as per the commenter's request.

Responses received from the Czech Republic (e.g., #3275, #3391) suggest that shooting ranges/areas are not used for agricultural purposes. In Denmark (#3435, #3441, #3516) and in Germany (e.g., #3198, #3200, #3254, #3379, #3413, #3525) it is not permitted to shoot on agricultural grounds; shooting ranges using lead bullets are exclusively used for shooting; and for trap/skeet ranges, the landing areas shall not be used for agricultural purposes. In Finland (e.g. #3183, #3230, #3237, #3240, #3244, #3262, #3420, #3426, #3488) shooting ranges are already limited by law to require a permit, and there is no possibility to utilise shooting ranges for agricultural purposes. Comments #3235 and #3476 informed that, according to Hungarian firearms laws, all shooting ranges must be designed to safely prevent projectiles exiting the area of the shooting range. This is prevented by bullet traps, ceiling buffers and safety zones. All lead projectiles remain within the boundaries of the safety zone. In one individual comment from Ireland (#3173), no animal grazing was observed by the shooter at the visited ranges. One Polish commenter (#3192) argued that it is not possible to reuse shooting range areas for any other purposes. In Sweden (e.g., #3247, #3261, #3410, #3463, #3471), shooting ranges are not used for agricultural purposes. Shooting ranges are typically located in forest terrain. In Spain (#3431) shooting ranges on agricultural land are temporary only.

In the UK (#3442) clay pigeon shooting can be organised on agricultural fields that (at other times of the year) are grazed by cattle. This seems to be a common practice at least in England. Indeed, the UK Lead Ammunition Group (#3250) commented that it

has no information on the proportion of shooting ranges that are also used for agricultural purposes but that a large proportion of agricultural land, both pastureland and arable land, is likely to be shot over to some extent as part of either pest control (e.g., woodpigeons and rodents) and/or sports shooting (e.g., pheasants and partridges). *"This also includes shooting within and around agricultural buildings. There is also likely to be some deposition of lead gunshot from shooting ranges onto land beyond the range perimeter.*"

The Dossier Submitter notes that although several comments suggest that permanent shooting ranges are (usually) not used for agricultural purposes, complimentary information gathered through the Member State survey, 2020[70] (summarised in Section B.9.1.3 of the Annex to the Background Document) indicates that in some EU Member States it is possible to shoot within a farmland and that in many EU Member States it is possible to shoot nearby. Therefore, the Dossier Submitter considers that if the decision maker considers a derogation for the continued use of lead gunshot for sports shooting to be appropriate, it would be necessary to limit the use of lead gunshot to permitted locations whilst banning any agricultural use within the site boundaries. The Dossier Submitter also considers that agricultural uses should be banned at ranges where lead bullets continue to be used as there is no EU-wide limit for lead concentration in soils used for agricultural purposes.

4.1.10. Transition periods for sports shooting

Some comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals on transitional periods for sports shooting. For example, comments #3331 and #3516. Some content of comment #3516 was handled as confidential as per the commenter's request.

The Danish Shooting Federation (#3516) considered (as non-confidential comment) that:

- It not to be possible to meet the proposal's goals and intentions that all sports shooting ranges should be able to collect 90 % lead 18 months after the proposal has been politically adopted.
- Existing shooting ranges in Denmark will continue to be approved in their current construction, as long as no seepage to groundwater or watercourses is registered, as well as there is no fauna uptake.
- All new shooting ranges should establish environmentally friendly bullet traps/collection, where projectiles and pellets can be easily separated and collected.
- Alternatively, there should be a transitional period of at least 10 years to meet the goals and intentions of the proposal in a professional manner and to ensure there is sufficient time to develop the "*necessary new technology for the area,*

[70] See section E5 (Annex to the Background Document).

which can meet both the environmental and health requirements as well as the accuracy requirements in sports shooting".

- International competitive shooting (the elite sport) should be exempt in line with other areas of application not covered by the proposal, until there are common provisions in this regard worldwide.

AFEMS (#3331) requested a transition period of at least 5 years for sports shooting with all ammunition types; they considered this for practicality reasons due to the overlap in the use of different types of ammunition (rimfire, centrefire, pellets, by different types of users (sports shooters, shooters out of scope of the restriction) on the same shooting ranges. Having different transition times may limit the availability of shooting ranges for activities that are out of scope (see part 8 of the derogation). AFEMS (#3331) also reasoned that the 18-month transition period was too short to enable manufacturers to adapt production lines and ramp up production of lead-free ammunition to meet demand if shooting ranges are unable to comply with the conditions. The same rationale is put forward for large calibre centrefire ammunition used for hunting. AFEMS (#3331) estimated that at least 5 years are needed to ensure alternatives are commercially available in the amounts required.

FACE (#3467) also argued for longer transition periods (of 10 years) for lead in gunshot, although it is not quite clear on what grounds this suggestion was made.

The Dossier Submitter proposed initially a transition period for the use of large calibre bullets for sports shooting of 18 months and 5 years for the use of small calibre bullets for sports shooting and gunshot. Taking into account the comments received, the Dossier Submitter amended the Background Document to propose a transition period of 5 years for the optional derogations on the use of lead gunshot and bullets (small and large calibre) for sports shooting to account for the time required to install RMMs at the ranges. The Dossier Submitter noted the requests for even longer transition periods but, in the absence of evidence proofing the need for longer transition periods, prefers to be cautious on this and remains that a five-year transition period. The relevant sections in the Background Dossier were updated accordingly.

4.1.11. Voluntary military training

Multiple comments were submitted by sector associations, supply chain actors, competent authorities as well as individuals on the use of shooting areas for military training. These include comments #3183, #3184, #3185, #3186, #3188, #3189, #3190, #3194, #3195, #3216, #3220, #3222, #3324, #3230, #3237, #3240, #3244, #3245, #3249, #3252, #3257, #3258, #3275, #3280, #3290, #3326, #3327, #3331, #3372, #3401, #3440, #3441, #3463, #3470, #3472, #3512, #3519. Some of these comments have been handled as confidential as per the commenter's request.

As legislations relevant for voluntary military training vary across EU Member States, topical comments were sorted according to their origin.

4.1.11.1. Voluntary military training

The Dossier Submitter acknowledges the importance of voluntary military training as

highlighted in comments from the Czech Republic (#3220, #3275), Finland (e.g., #3183, #3222, #3230, #3237, #3240, #3224, #3440), Norway (#3245) and Sweden (#3258). The Dossier Submitter notes the following common themes:

- Many of the submitters saw the proposed restriction as a ban on the use of lead ammunition and highlighted the high costs and additional investments needed to accommodate the use of non-lead ammunition on shooting ranges. Section 4.1.7.1 of this document explains that the preferred option for shooting ranges with bullets is to contain and control lead emission via RMMs.

- Commenters pointed out that the main interest at stake is in the upholding of shooting skills among non-active military personnel (volunteers, reserve troops, etc.) using their own ammunition and weapons which should be similar/compatible with government-issued weapons and ammunition that is issued in situations of need. Commenters considered that this need was increasing with the decreasing dependence on obligatory military duty.

The Dossier Submitter understands that such trainings are performed with weapons used for sports shooting and held on shooting ranges, which could be used by civilians and/or for military training. With the emphasis on RMMs to control and contain lead rather than using alternatives, the Dossier Submitter believes that the concerns raised in the comments above are alleviated.

Some commenters also pointed out that the police and military forces use civilian ranges. The Dossier Submitter understands that outdoor shooting ranges are within the scope of this restriction proposal regardless of whether they are used by civilians or for military purposes. The Dossier Submitter highlights that ranges used solely for military purposes are *not* within the scope of this restriction.

4.1.11.2. Spill-over impact of a restriction on ammunition used for civilian use on military uses

AFEMS (#3331) commented that "*Most ammunition manufacturers supply ammunition for both civilian and non-civilian customers. Most military ammunition products have lead projectiles and there are few NATO qualified lead-free products available. This means that EEA defence forces are dependent on EEA manufacturers for their standard supply and their capacity to be able to massively increase supply in case of a conflict situation (surge supply). This production capacity comes from the civilian lines that can be readily adapted to produce military products. Production lines designed for lead-free projectiles cannot be converted to produce lead projectiles. If the derogation given in 4c is not implementable, the restriction on the use of sports shooting ammunition will impact the production capacity for military ammunition in the EEA*".

In the Annex XV report, the Dossier Submitter had already considered the possible spill-over impacts of the proposed restriction on ammunition produced for civilian purposes on the production of military ammunition. As the preferred restriction option for lead bullets in sports shooting foresees a derogation at dedicated sites under strictly controlled conditions (see Section 2.6 of the Background Document), the Dossier Submitter considers that this spill-over impact will be negligible.

4.1.12. Derogation for muzzle loaders and other vintage firearms and replica

AFEMS (#3331) requested that the use of lead ammunition in muzzle loaders and other vintage firearms and replicas be listed under uses outside the scope of the restriction in part 8. They argued that this was warranted as the Dossier Submitter failed to provide a dedicated impact assessment for these uses.

Comments (#3400) from the Hungarian Black Powder Shooters and Hunters Association involved in muzzle loading and vintage firearms suggested that, where muzzle loaders are used for purposes other than hunting (i.e., in competition shooting, etc.) the use takes place at designated sites where RMMs can be installed. The estimated yearly lead consumption of muzzle loading shooters in the EU was estimated by the Hungarian Black Powder Association to be up to 683 tonnes, out of which up to 682 tonnes of lead ammunition are fired on licensed shooting ranges, and only 0.8 tonnes of lead ammunition are fired for hunting purposes.

As with sport shooting in general, suitable alternatives in this category are scarce. FACE (#3467) further pointed out that the CIP proof testing of muzzle loader firearms had to be carried out with the use of black powder and lead projectiles to ensure safety. There are however no CIP testing protocols for lead-free projectiles, as there are no suitable versatile alternatives.

The Dossier Submitter considers that no specific derogation is needed for this type of ammunition for sport shooting, as the use takes place at designated shooting ranges and hence suitable RMM may be installed to ensure that lead emissions are minimised.

4.1.13. Derogation for air weapons

Evidence submitted in the consultation (comment #3221) suggest that air rifles are mainly used for *indoor* sports shooting and as such would fall outside the scope of this restriction proposal (which is focused on *outdoor* uses of lead ammunition). The Dossier Submitter observes that where uses do take place on outdoor sports shooting ranges, these uses would however fall under those parts of the restriction that set conditions for the use of lead in outdoor sports shooting.

The Dossier Submitter considers that no specific derogation is needed for this type of ammunition, as the use takes place at designated shooting ranges and hence suitable RMM are be installed to ensure that lead emissions are minimised.

4.2. RAC Rapporteurs comments

Exposure of shooters

Several comments were submitted by sector associations and individuals on lead exposure of outdoor sports shooters. Many of these considered that lead exposure from outdoor sports shooting is negligible. However, the measurement data provided in the consultation was very limited although it was indicated that regular B-Pb monitoring of sports shooters is routinely performed. As no data was provided, no changes to the RAC conclusions have been made based on these comments.

RAC acknowledges and appreciates the information provided on the measures to limit exposure of sports shooters to lead, including technical measures, good hygiene practices, and training. RAC also acknowledges that the use of jacketed bullets decreases the exposure of sports shooters and that plastic cartridges in shotguns may limit the formation of lead fumes/dusts although no measured data on this was provided. However, although RAC agrees that the risks for adult, non-pregnant shooters are low, RAC cannot exclude risks for the offspring of pregnant/fertile-age females since there is evidence (although limited) on lead exposure in outdoor shooting and no safe level can be identified for the neurodevelopmental effects of lead.

Environmental risks in sports shooting using lead gunshot

RAC disagrees with the statements claiming that sports shooting facilities do not affect the environment outside the range and therefore no measures are needed. RAC notes that the migration of lead in soil is greatly influenced by soil characteristics and therefore the location of the shotgun area has a significant impact on the potential for groundwater pollution. Lead dust may migrate via the air outside the shooting range and there is evidence showing that corrosion and dissolution of lead gunshot may result in the contamination of surface waters nearby the shooting ranges. However, the risk of general contamination of soil and surface waters more distant from the shooting range is considered as low. RAC also considers liming of soils beneficial, but an insufficient measure to prevent the migration of lead in soil and therefore supports the Dossier Submitter's conclusions that additional measures are needed.

As discussed in the RAC and SEAC opinion and in WP A.2 and B.2 reports (annexed to the RAC and SEAC opinion), RAC does not agree that there is evidence showing that the use of steel shots at shooting ranges increases lead mobility in soil.

RAC agrees with the several comments requesting a full ban for sports shooting with lead gunshot – this is indeed the preferred option for RAC as well.

Regarding the comments questioning the 90% collection requirement for gunshot in shooting ranges, RAC refers e.g. to the experience from Germany: about 20 % of ~350 operated trap or skeet systems currently have facilities/measures in place with which >90 % of spent lead gunshot can be regularly recovered (comment #3198). RAC supports this operational threshold as a way of minimising the release of lead from gunshot.

Comments concerning the licencing system for athletes were mainly related to costs and therefore outside of RAC's remit, but RAC has discussed the complexity and the risk that such a system may be implemented differently in different EU Member States.

Environmental risks in sport shooting using lead bullets

RAC acknowledges the various comments mentioning that bullet trap chambers are already a legal requirement in some EU Member States. RAC also recognises that for dynamic shooting disciplines sand berms are the only option available. RAC supports the Dossier Submitter's response to comments and the Dossier Submitter's updated proposal regarding the risk management measures to be implemented at shooting ranges for the use of lead bullets, i.e., bullet trap chambers and best practice sand berms with

impermeable layer, roof and water management system combined with monitoring requirements and water treatment if needed. Further information on RAC's analysis can be found in the WP B.1 report annexed to RAC and SEAC opinion.

RAC also agrees with the Dossier Submitter that even if a significant number of sports shooting competitions and trainings are held under strictly controlled conditions there are currently no EU-wide environmental standards for shooting ranges and especially old ranges may not meet high environmental standards currently. RAC also recognises that there are different legislations in place in EU concerning the remediation of old shooting ranges and that remediation may not occur in all cases. The restriction proposed by the Dossier Submitter will support effective remediation of sports shooting ranges.

RAC agrees with the Dossier Submitter that although permanent shooting ranges are not expected to be used for agricultural purposes, in some Member States it is possible to shoot within or close to farmland. Temporary shooting ranges may also be located in areas also used for agricultural purposes. Therefore, RAC supports the ban of agricultural activities at the location of shooting ranges as proposed by the Dossier Submitter.

RAC agrees with the Dossier Submitter's responses and proposal for the transition periods for the ban of lead ammunition in sports shooting. RAC also agrees with the Dossier Submitter that the strict measures described in the restriction should apply also for voluntary military training, police or military forces using civilian ranges. Although military shooting ranges are outside of the scope of the restriction, for the protection of the environment RAC considers that the risk management measures outlined in this restriction for the shooting ranges are applicable and recommendable also for military shooting ranges.

RAC supports that no derogation should be granted for sports shooting with muzzle loaders or air weapons considering the volumes used for this purpose and that the uses take place at designated shooting ranges with appropriate RMM to minimise lead emissions.

4.3. SEAC Rapporteurs comments

Section 4.1.3.1 above discusses the comments received about the use of steel shot as an alternative to lead shot in sports shooting. The SEAC rapporteurs note that arguments brought by FITASC in comment #3221 about higher recoil and higher noise related to the use of steel shot have not been mentioned at all in the Dossier Submitter's response. The SEAC rapporteurs are of the opinion that these concerns, though probably not presenting an insurmountable barrier to the use of steel shot, are real and need at least to be mentioned.

Section 4.1.11.1 above reacts to comments received from several stakeholders and Member States expressing concerns about the consequences of the proposed restriction for shooting training for military reservists on local civilian shooting ranges, which appears to be part of the defence concepts in some EU countries. The Dossier Submitter expresses their view that the risk management measure concept as proposed will alleviate these concerns. The SEAC rapporteurs would like to point out that this answer does probably not address the main concern as brought forward in the comments cited.

It is clear that upgraded civilian shooting ranges would simply continue to accommodate military training. However, problems might arise if the investments needed would significantly reduce the number of "notified" civilian sites for such training, because they will not be able to afford this burden. Implicitly the Dossier Submitter assumes that all sites will upgrade. If this is not the case (which is not unlikely), some regions may have a problem to offer local training options for the military reservists.

5. Fishing

5.1. Dossier Submitter response to comments

About a fifth of the comments received during the restriction proposal consultation were on the proposed restriction on lead fishing tackle. Comments were submitted by associations (representing industry, fishers, NGO), supply chain actors (manufacturers using lead and/or alternatives, distributors of fishing tackle), competent authorities as well as individuals, essentially fishers (for example, comments #3177, #3178, #3181, #3182, #3190, #3196, #3202, #3203, #3204, #3205, #3206, #3207, #3213, #3215, #3216, #3217, #3219, #3220, #3228, #3233, #3253, #3259, #3260, #3263, #3276, #3278, #3279, #3285, #3286, #3287, #3288, #3289, #3325, #3340, #3343, #3344, #3358, #3372, #3378, #3381, #3384, #3389, #3393, #3407, #3417, #3423, #3442, #3461, #3472, #3474, #3486, #3487, #3492, #3494, #3496, #3503, #3504, #3512, #3513, #3518). Some of these comments were handled by the Dossier Submitter as confidential as per the commenter's request.

The Dossier Submitter notes a general support from the fishing sector for the restriction proposal, and the willingness of different actors in this sector to act in order to reduce the presence of lead fishing sinkers and lures in the environment that could be ingested by birds. In particular, various stakeholders support the combination of a ban on use and a ban on sale accompanied by a strong enforcement to avoid an increase of home-casting and internet purchase of cheap, non-environmentally friendly alternatives (elements most commonly cited by the commenters). Many stakeholders also agree that the drop-off practice (intentional release of lead sinkers) is not acceptable, and that further action needs to be taken to address this practice.

While there is a generic agreement among commenters that lead sinkers and lures should be banned, the scope of the proposed ban is discussed and challenged by some stakeholders. In particular a possible ban on dust split shots, on sinkers and lures above 50 g, and the use of lead in nets, ropes and lines were commented, and additional elements were submitted during the consultation to either support the proposed scope, or argue for a less or more inclusive ban.

Importantly, the Dossier Submitter notes a general support for the assumptions and the baseline scenario established in the restriction proposal (including the assumed number of fishers, estimates of lead loss from fishing sinkers and lures, costs of alternatives). There were no substantiated comments received indicating that these estimates were wrong or not plausible.

The Dossier Submitter has grouped the comments received into the following main categories and has responded to them accordingly: (i) Home-casting, (ii) Alternatives,

(iii) Transition period, (iv) Costs and impacts of the proposed restriction, (v) Monitorability and enforceability of the proposed restriction, and (vi) Suggestions of new or additional restriction options.

Comments were also provided on other horizontal issues such as hazard and risk of lead in the aquatic compartment, birds' ingestion of lead objects (see Section 2.1.1), workers' exposure to lead (see for example Section 2.1.6), or information at the point of sale (see Section 5.1.7). Please refer to other sections of this document for responses by the Dossier Submitter on these specific topics.

Numerous comments were reporting information and scientific studies already available in the Annex XV report and its Annex. Where new and relevant, the information submitted has been added and further developed in the Background Document and its Annex. The main changes made to the Background Document in response to these submissions can be summarised as follows:

- home-casting exposure modelling added as an Annex to the Background Document.

- references to the Annex XV consultation added (availability of alternatives).

- list of potential alternatives updated.

5.1.1. Home-casting

In the restriction proposal, the Dossier Submitter assumed that home-casting is a popular activity among fishers. Furthermore, it is assumed that if a restriction only applies to the placing on the market but not to the use of lead fishing tackle, home-casting would become more popular. In order to corroborate these assumptions, stakeholders were requested to respond to the specific question (Q10) and provide further information on this topic.

Some comments were received on the home-casting practice, most relevantly: #3177, #3178, #3203, #3213, #3215, #3216, #3217, #3220, #3276, #3285, #3286, #3287, #3288, #3325, #3344, #3372, #3474, #3492, #3503, #3512.

5.1.1.1. Popularity and frequency of home-casting in Europe

According to commenters from various Member States, home-casting is a popular practice in Belgium, the Netherlands, Germany, France, Belgium, Ireland and UK (#3203, #3213 and 3325), but less frequently done in other Member States such as Finland, Norway, Sweden, Denmark, Czech Republic, or Estonia (e.g. #3220, #3285, #3325, #3344, #3372, #3474 and #3512).

Some commenters provided also specific information on the home-casting practice in their country. For example, in Ireland and Norway home-casting seems to be essentially performed by sea anglers (#3213 and #3512). In the Netherlands, home-casting is also reported as an activity performed by fishing tackle shop owners themselves in an artisanal manner (#3215, #3325).

The main reasons and incentives for fishers reported to practise home-casting are (i) versatility of size and shape of sinkers that can be manufactured, (ii) low price, and (iii) the pleasure of 'doing it yourself'. One commenter indicated that the home casting puts a price pressure on sinkers and lures that can be purchased from shops, which may force some retailers to either stop proposing on their shelf certain types of sinkers that can be easily produced by home-casting, or become themselves artisanal home casters in order to be able to supply lead sinkers at a lower price. According to the same commenter (#3325), the home casted sinkers and lures in shops are easy to recognise: they are not packaged individually, and they are shinier than the lead sinkers produced in industrial settings.

Some commenters submitted, or were referring in their comment to local home-casting polls, survey or reports (e.g. #3203, #3215, #3217, #3325), the Dossier Submitter thanks the commenters and would like to highlight that these studies on home-casting practices were already reported and mentioned in the restriction proposal (e.g. in Section A.2), so no further update of the Background Document was made on this aspect. One stakeholder (#3203) provided information on the practice of home-casting in Rotterdam. Unfortunately, the Dossier Submitter could not find on the mentioned source website the reported number of 20 000 to 50 000 fishers performing home-casting in the Netherlands. Few commenters confirmed also that there is no additional specific study on the home-casting practice (#3512, #3220). Others indicated, that despite the lack of supporting studies, it is fair to assume that such a practice exists in Europe given the number of commercial web sites selling home-casting equipment but also tutorial and videos available on the Internet (e.g. #3215, #3325, #3512).

The Dossier Submitter takes note of the comments received and concludes that despite a lack of substantiated information, the commenters confirm the assumption of the Dossier Submitter that home-casting is a practice that does exist in the EU, although its popularity differs from one country to another. The key assumption of the Dossier Submitter is therefore plausible, without being quantifiable. No update was thus made in the Background Document.

5.1.1.2. Lead exposure from home-casting practice

Limited information was received on exposure to lead and associated human health impacts from home-casting. One stakeholder (#3325) provided the results of experiments on home-casting performed at different temperature and with different heating material. Even though these tests were most probably not performed in a laboratory under GLP, they demonstrate the impact of the melting temperature and melting tool on the potential release of lead vapour. The experiment was supported by an additional literature review, and concluded that lead melting in home-casting can be done with low emissions of lead vapour. However, under fast heating conditions, this would result in substantial emissions to lead. The Dossier Submitter made use of some of this new information provided on home-casting (video, experiments, literature review). In particular, indications on frequency of home-casting activities, and physico-chemical parameters (e.g. Vp (Vapor Pressure) at elevated temperatures) were used by the Dossier Submitter to refine its exposure scenario modelling and assess in a qualitative manner the exposure of fishers, and artisanal home-casters during home-casting. Results of an additional exposure modelling are reported in a new Annex to the

Background Document.

5.1.1.3. Potential impact of a ban on placing on the market only

Stakeholders were asked to comment the following assumption made by the Dossier Submitter: 'if a restriction is only applied to the placing on the market but not to the use of lead fishing tackle, home-casting would become more popular'.

A limited number of comments were received on this specific question (e.g. #3178, #3512, #3503 and #3492). Most of the commenters to this question recognise that it is difficult to predict if and how much home-casting of lead sinkers could increase as a result of a ban on placing on the market only. Respondents indicate that the fishers' behaviour regarding home-casting would most probably depend on the prices and availability of alternatives compared to the prices and availability of lead (e.g. lead is easily available from lead battery). In a worst-case scenario, and considering that no enforcement would be made at the point of use (i.e. where fishing takes place), a ban on placing on the market only would likely increase home casting 'exponentially' or 'drastically' (see e.g. #3178, #3216, #3276, #3492, #3503, #3512). On the other hand, some commenters were arguing that a ban on placing on the market only, would not increase home-casting (e.g. #3285) because of the high cost of some melting equipment (in case the fisher wants to invest in dedicated home-casting equipment), and the time needed to perform such activities.

The Dossier Submitter takes note of the comments received and concludes that despite the lack of substantiated information, the commenters confirm in general the assumption of the Dossier Submitter that 'if a restriction is only applied to the placing on the market but not to the use of lead fishing tackle, home-casting would become more popular'. This assumption of the Dossier Submitter seems therefore plausible without being quantifiable. No update was made in the Background Document.

5.1.2. Alternatives

Stakeholders were requested to respond to the specific question (Q11) on the availabilities of different alternatives. Numerous comments were received on this topic, for example: #3177, #3178, #3181, #3182, #3190, #3202, #3203, #3207, #3213, #3217, #3219, #3228, #3233, #3259, #3263, #3340, #3358, #3372, #3381, #3389, #3417, #3472, #3492, #3504, #3512, #3518.

5.1.2.1. Availability of alternatives

Comments were submitted by citizens, manufacturers and retailers regarding either the availability or non-availability of alternatives in their country. These statements were often not substantiated, but they provide a good overview on how the market of alternatives is perceived in various EU Member States.

For example, citizens reported that 'alternatives are already available on the market (although limited to certain types of weight range)'. Such comments were submitted by individuals from Finland, Ireland, and Austria (#3182, #3213, #3381, #3417), while others stated that they 'never saw any alternative to lead in local shops' (#3190 from Finland).

The comments submitted by citizens on the availability of alternatives were not supported by any additional evidence, but confirm the assumption from by Dossier Submitter that alternatives already exist on the market, in particular for the smaller weights of sinkers and lures.

With regard to the comments submitted by associations (NGOs, fishers or industry), some are reporting that alternatives are available in general (#3202 from Stichting Gezond Water), while other associations are a bit more specific regarding the current state of play of the sinkers market. Some comments received included examples and even a detailed market study (#3217, #3389 from Flanders Marine Institute (VLIZ)). For example, in Flanders, alternatives are reported to be available for small and large weights – and seem to be working well –for carp fishing, predatory fishing, fly fishing and feeder fishing. For whitefish fishing the availability of alternatives appeared to be rather limited (#3217). In Belgium, a fishing association, Maison Wallonne de la Pêche, indicates that alternatives exist (essentially from Internet webstores) but are not available in sufficient quantity in shops, which are the preferred source of supply of fishing equipment (#3340) in this country. An Austrian fishing association (Österreichisches Kuratorium für Fischerei und Gewässerschutz) indicates that alternatives for larger fishing sinkers are available, and that lead can be easily replaced by less expensive materials such as iron for larger fishing sinkers (#3358). The Norwegian Association of Hunters and Anglers (NJFF) indicates that in Norway alternatives available for sinkers and lures ≤ 50 g are currently limited to bullet sinkers, jigs and jig heads, but that no alternatives are available at the moment for sinkers > 50 g in sea fishing, and for lead wire (#3512).

VLIZ (Flanders Marine Institute) provided a recent market study on the current and future availability of alternatives (#3389). Even though the VLIZ report is focusing essentially on Belgium and the Netherlands, this report is confirming the conclusions of the Dossier Submitter with regard to availability, technical and economic feasibility of alternatives. VLIZ conducted a market study analysis similar to the one carried out by the Dossier Submitter and reported in the Background Document. The report from VLIZ (published in August 2021) is also confirming the current lack of production capacity in the EU, which is supporting the need for a transition period (cf. relevant section in the Background Document). VLIZ conducted interviews with six different alternative producers located in Germany, the Czech Republic and the Netherlands. In addition, a producer located in the United Kingdom was also contacted. The majority of companies contacted have currently a limited production capacity ranging from a maximum of 300 to 10 000 pieces per day. Some of these companies, based on the ECHA market survey, have even a more limited production capacity. The majority of these companies also indicated that they would be ready to scale up and make additional investments (within two years), if the demand increases or if long-term contracts are established. One company indicated waiting for a ban on use coupled with enforcement before considering investments.

Several commenters highlighted the current lack of readily available alternatives for very small split shots indicating that tin is an alternative for some split shots, but difficult when the split shot is too small (aka “dust split shot”) as tin may damage the fishing line (#3389, #3472, #3504, #3518) – cf. also Section 5.1.6.1 below (requested derogation for split shots).

The information provided during the consultation appears to be consistent with the key messages and assumptions made by the Dossier Submitter. Indeed, the Dossier Submitter acknowledges that alternatives are available but not in sufficient quantity to serve the EU market at the moment, and that alternatives for dust split shot do exist. Some commenters also agree with the Dossier Submitter's assumption that alternatives will become more available in the future and may have a positive effect on the price of the alternative sinkers and lures (#3389, #3228, #3512). References to the comments received during the consultation were therefore added in the Background Document.

5.1.2.2. Alternative material

Tungsten is often cited as an alternative already available on the market either on its own, or mixed with other substances (e.g. #3182 in Finland; #3207, #3217, and #3389 in the Netherlands; #3219 and #3233 in Germany; #3259 on the EU market in general; #3263 and #3492 in France, #3340 in Belgium; #3372 in Estonia; #3417 in Austria; #3512 in Norway; #3518 in the Czech Republic).

Other alternatives reported in various comments for sinkers and lures (in particular jigs and jig heads) were stones, tin, zamac, iron, (stainless) steel, PHA (polyhydroxyalkanoates polymers), bismuth, concrete etc. Although the dynamics of alternative sinkers and lures underwater (and in the air) may differ from those of their lead counterparts, they do not appear to have a significant impact on functional performance and switching to alternatives is mainly a matter of habituation according to a recent study (e.g. #3389). Despite this study, some commenters still report the poor workability of some alternatives without providing further details (e.g. #3518).

New alternatives were also reported such as iron putty, or PHA (#3207, #3215) indicating that PHA could be used for home-casting (using 3D print technology). There were no further details provided on the availability of this alternative on the European market. For sake of completeness, PHA and iron putty were added in the list of potential alternatives in the Background Document but not further analysed. The Dossier Submitter notes that (i) PHA is defined as a plastic[71] under the EU's recent Single Use Plastics (SUP) Directive, (ii) and that this Directive is applicable to sinkers and lures. The SUP Directive will therefore trigger extended producer responsibility, monitoring, waste collection and awareness raising campaign obligation for any companies placing PHA sinkers and lures on the market (i.e., there is no ban on placing on the market for the plastic fishing gears in the SUP Directive).

Finally, the Dossier Submitter shall wish to respond to one stakeholder (#3177 and #3203) who alleged that the ECHA mystery shopping and market survey were not exhaustive. The Dossier Submitter stresses that the ECHA market survey never intended to be an exhaustive market survey, nor to provide a list of alternative suppliers, but to prove that alternatives were readily available on the market and to provide an overview

[71] The SUP Directive applies to 'fishing gear containing plastic.' With plastic defined as 'material consisting of a polymer as defined in point 5 of Article 3 of Regulation (EC) No 1907/2006, to which additives or other substances may have been added, and which can function as a main structural component of final products, with the exception of natural polymers that have not been chemically modified'.

of prices and characteristics of these alternatives. With more than 1 000 entries reported, the Dossier Submitter considers that the ECHA market survey serves its foreseen purpose. The Dossier Submitter further highlights that all data sources gathered were shared with the RAC and SEAC rapporteurs for their scrutiny, assessment, and opinion making.

5.1.2.3. Risk of alternatives

Some commenters commented that the alternatives to lead should be 'less harmful than lead' and that the impacts of such alternatives to both the environment and human health should be looked at carefully (for example #3178, #3233, #3263, #3389, #3417, #3472, #3492). Some commenters expressed worries about the potential effects of substances such as high-density polymers, zinc, copper, tungsten and bismuth and were questioning if the toxicity of alternative metals has been properly assessed in both the oxidised and the metal forms, or in the metal only. Additionally, a few statements in the comments received are not supported by any scientific evidence to date (e.g. a statement in #3181 on the potential carcinogenicity of several alternatives could not be confirmed based on the toxicological literature).

The Dossier Submitter looked at the toxicity of the potential alternative materials, and at the overall risk reduction of the alternatives compared to lead. Indeed, the Dossier Submitter has assessed the global environmental footprint including the environmental and human toxicity of available alternative materials for fishing tackle. According to the Dossier Submitter's assessment, the majority of the available alternatives are not toxic. A succinct summary can be found in the Background Document, Section 2.8.1.3, whereas Annex C provides a detailed analysis of the alternatives. The Dossier Submitter acknowledges that not all assessed alternatives are non-toxic (e.g. zinc is toxic for wildlife), but overall the alternatives available on the market have a better global environmental footprint than lead and are less hazardous for humans and the environment than lead (in particular for birds at the risk of ingesting lost sinkers and lures). It is also important to note that, contrary to US regulations, a restriction under the EU's REACH Regulation never provides a list of authorised alternatives.

The Dossier Submitter also agrees with the comments received in the consultation flagging that the environmental impact of lead in fishing should not be limited to its impact at the point of use (i.e. during fishing) (e.g. #3389, #3417 and #3518). This is the reason why the Dossier Submitter conducted a global environmental footprint analysis of lead and its alternatives. Using a simple qualitative approach, the Dossier Submitter described and compared lead and its alternatives against the following criteria:

- toxicity and risk for human health.
- toxicity and risk for the environment (both aquatic and wildlife ingestion).
- sourcing of raw material to manufacture fishing tackle and ammunitions (extraction vs recycling).
- resource depletion associated with the sourcing/production of the raw material, and the manufacturing of fishing tackle and ammunitions (at the end of the

supply chain).

- impact on climate change and in particular emissions of greenhouse gases through the sourcing/production of the raw material as well as through the manufacturing process of fishing tackle and ammunitions.

The outcome of the global environmental footprint comparison is presented in Section 2.8.1.3 of the Background Document.

One commenter (#3518) submitted also an Excel® file with an analysis of potential alternatives, compared them against lead properties in terms of hardness and density and evaluated the impact on the environment of the different alternatives. The comment also indicates if the alternatives are actually used for fishing sinkers and lures. In general the analysis confirms the information gathered in the Background Document (Section 2.8.1.3 and in the Annexes C and D.4.2), specifically the Dossier Submitter's view that zinc and copper are not or seldomly used as alternative to lead sinkers and lures.

The Dossier Submitter took note of the various comments and statements received, but as no new information was brought up in the consultation on the hazards and risks of the alternatives, it did not make any changes in the Background Document.

5.1.2.4. Coated lead

Several commenters cited 'coated lead' as a potential alternative (e.g. #3518, #3260). As indicated in the Background Document, the Dossier Submitter does not consider coated lead to be a viable alternative, in particular for lead sinkers and lures that may be ingested by birds. So far, all attempts to cover lead shot/gunshot to prevent lead toxicity with a protective coating of non-toxic metals or other materials to prevent the degradation and uptake of lead while in the gizzard/stomach of birds have failed. The Dossier Submitter has updated Section C.3.5.2 of the Background Document and added references to scientific studies to clarify why coated lead cannot be considered a viable alternative (i.e. an alternative which is technically and economically feasible and resulting in an overall reduction of risk to human health or the environment).

5.1.3. Transition period

Some comments were received on the proposed transition period, for example: #3181, #3202, #3217, #3219, #3228, #3233, #3278, #3340, #3389, #3503, #3512, #3518.

The Dossier Submitter is proposing the following transition periods for different types of lead fishing tackle:

- no transition period for lead wire, and for using in fishing sinkers where the combination with any fishing equipment, rig or technique release the sinker during use (intentionally drop off).

- 3-year transition period for lead fishing sinkers and lures with a weight ≤ 50 g.

- 5-year transition period for lead fishing sinkers and lures with a weight > 50 g.

Comments were received on the proposed transition period (TP) for lead wire, in general acknowledging that alternatives do already exist in sufficient quantity on the EU market, and that no TP is needed for lead wires. Only Norwegian commenters flagged that alternatives to lead wires are currently not available on the Norwegian market, but this does not seem to be an issue (#3512).

All commenters who reacted to the use of fishing sinkers where the combination with any fishing equipment, rig or technique release the sinker during use (intentionally drop off) said that they are supporting an immediate ban of the intentional drop-off practice (for example #3358, #3503).

The commenters expressed different views with regard to the proposed TP for the sinkers and lures. Some commenters indicate that the TPs proposed are too short (#3219, #3233 and #3340, #3518), while others indicate that the 3 and 5-year TP proposed are too long "because alternatives are already available on the market" (#3181, #3202, #3217, #3228 and #3278, #3389), and that only shorter TPs would allow to stimulate innovation and allow for industrial investments for scaling up the production of alternatives. One commenter (#3202, #3204) also reported that the proposed TPs are too long, and could 'create a distortion of the market for the companies that already produce lead-free fishing sinkers and lures'. The same type of argument was used by commenters to support the TPs proposed by the Dossier Submitter or advocate for a longer TP, indicating that a too short TP could ''create a distortion of the market for the European companies by favouring a massive import of fishing sinkers and lures from non-EU countries" (e.g. #3389).

Other commenters are proposing that the same TP should be set for all sinkers and lures (i.e. > 50 g and ≤ 50 g). Here again, the view varies among stakeholders: for some the restriction should enter into force as soon as possible with a short TP for all sinkers and lures (#3228), while for other stakeholders a 5-year TP should be granted to all sinkers and lures regardless of their weight (#3503).

Some comments appear to be contradictory: for example, requesting an immediate ban (i.e. no TP) while recognising at the same time that alternatives to bigger sinkers and lures are less frequently available (for example #3202).

One commenter proposed a sort of flexible TP, proposing that 'legacy' fishing sinkers and lures could still be placed on the market and used until existing stocks are depleted (#3260). However, the Dossier Submitter considers that allowing the placing on the market and the use of legacy lead fishing sinkers and lures would hamper the overall risk reduction capacity of the restriction proposal, and therefore did not follow the suggestion. In addition, it would be impossible for the enforcement authorities to differentiate legacy lead sinkers and lures from newly manufactured ones.

Finally, some stakeholders indicated that the TPs proposed by the Dossier Submitter seemed reasonable to allow both industry and fishers to adapt, and that the length of the TP is one of the most important elements for a successful transition from lead to alternatives. On the one hand, consumers must have time to adapt in parallel with a growing market of lead-free alternatives. On the other hand, if the fishing industry cannot meet the demand for alternatives, the number of anglers that practice home-

casting will most likely increase (#3512). Other arguments brought in favour of the TP proposed by the Dossier Submitter or for a longer TP are related to the lack of availability of alternatives, indicating that if the alternatives are not available in sufficient quantity, or are not user-friendly and too expensive, this would hamper the entire restriction proposal.

Various opinions and statements on the TP length are expressed in the comments received, but justifications for a shorter or longer TPs than the ones proposed by the Dossier Submitter were not well substantiated. The Dossier Submitter justifies the lengths of the proposed TPs in Section D.4 of the Background Document; in addition, the Dossier Submitter analysed the impact of various TPs (shorter and longer) on both the release reduction potential, the cost and cost-effectiveness of the proposed restriction using a sensitivity analysis approach (cf. Section 3 of the Background Document). For all these reasons, and because no new information was submitted in the consultation, the Dossier Submitter takes note of the various comments and statements received on the length of the TP, but proposes no change to the Background Document.

5.1.4. Costs and socio-economic impact of the proposed restriction

Some comments were received on the costs and the socio-economic impacts of the proposed restriction, for example: #3178, #3181, #3204, #3228, #3378, #3417, #3492, #3504, #3512.

Some stakeholders expressed concerns that the impacts of the proposed restriction on the fishing sector (EU manufacturers and fishers) would be substantial. Other commenters confirmed what is already indicated in the Background Document, i.e.:

- alternatives to lead sinkers and lures may be four times more expensive than lead (#3178, #3372, #3504, #3512). Note that, based on the market survey carried out by ECHA in 2020, the Dossier Submitter assumes that prices may differ by a factor of 3-10, depending on the weight of the sinker or lure.

- the financial impact of lead alternatives on the yearly budget of recreational fishers is limited (#3228, #3389).

- higher production of alternatives can lead to a lowering of the price (#3228, #3389, #3512).

- the restriction proposal presents a cost-effective means of reducing lead pollution, especially when compared to the cost of lead pollution (#3181).

The Dossier Submitter takes note of the comments received which are consistent with the information described and the assumptions made in the restriction proposal. No update was therefore made to the Background Document.

A few commenters also pointed out that the ‘proposed restriction for sinkers and lures >50 g’ is not proportionate. The Dossier Submitter provides all elements in the restriction proposal to allow ECHA’s scientific committees to evaluate and the European Commission to conclude on the proportionality of the proposed restriction. The Dossier Submitter acknowledges that a ban on sinkers and lures > 50 g may only be justified to

address risks to human health (via home-casting activities) as bigger singers are seldomly reported to be ingested by birds.

One comment was made on the break-even range calculations reported in Section 2.8 of the Background Document (#3378). It was argued if the presented break-even figures were more about the number of people that would need to engage in birdwatching, rather than the number of birds that would need to be prevented from ingesting lead fishing tackle. The Dossier Submitter acknowledges the comment, and therefore has removed the break-even range calculation as strictly speaking the value calculated was presenting the number of people observing birds, rather than a range of birds to be protected.

5.1.5. Monitorability, enforceability of the proposed restriction

Some comments were received on the enforceability, and monitorability of the proposed restriction, for example: #3207, #3215, #3263, #3389, #3474, #3492, #3503.

In the restriction proposal, the Dossier Submitter concludes that the proposed restriction is practical and enforceable (cf. Section 2.8.4.2 of the Background Document) and recognises as well the crucial role of enforcement to achieve the risk reduction expected. The comments received confirm the challenges and uncertainties already flagged by the Dossier Submitter. In particular:

- the challenges to perform inspections at the point of use for unexperienced inspectors (e.g. to identify the presence of lead in certain types of lures).

- the difficulty for fishers to know if the lures they already own contain lead. Indeed, a commenter flagged that many recreational fishers keep lures for many years and may have bought some of them before the restriction would enter into force.

- the difficulty to enforce the restriction on imported articles.

Among the proposed solutions to better enforce and monitor the restriction, some commenters suggested, for example, that lures could be exempted from the scope of the proposed restriction, and that relevant custom code(s) should be established in order to allow enforceability of non-compliant imports of fishing sinkers, lures and other types of fishing tackle. The Dossier Submitter understands the proposed suggestions, and acknowledges the issue related to the customs codes. Indeed, in Section D.4.1 of the restriction proposal, the Dossier Submitter mentions that the existing customs code to identify the import of fishing tackle (#95079000) is not specific enough to differentiate the lead fishing sinkers and lures from all the other types of fishing tackle (e.g. poles, lines, fishing equipment) and should be adapted to help enforcement authorities in performing customs checks. It should be highlighted, however, that enforcement at customs is not the only way proposed by the Dossier Submitter to enforce the restriction proposal; moreover, the establishment of new customs codes is not within the remit of a REACH restriction. It is thus for the European Commission to look at this aspect.

During the opinion making, RAC and SEAC also consulted the FORUM (representing enforcement authorities from all over the EU) in order to get their views on the

enforceability of the proposal. The FORUM advice will be taken into account by the scientific committees in their opinion.

The Dossier Submitter takes note of the various comments and statements received, but proposes no change to the Background Document.

5.1.6. Suggestion of new or different restriction options

Some comments were received which were suggesting new or different restriction options for lead in fishing, for example: #3178, #3196, #3203, #3204, #3228, #3253, #3259, #3260, #3344, #3389, #3417, #3472, #3474, #3492, #3503, #3504, #3518.

The Dossier Submitter grouped the comments received into the following main categories and responded to them accordingly: (i) requested derogation for split shots, (ii) requested derogation for sinkers and lures >50 g, (iii) requested derogation for certain types of lures, (iv) proposal for different cut-off values than 50 g, (v) proposal for a different lead concentration limit, (vi) proposal for a ban on lead in fishing nets, ropes and lines, (vii) proposal to tax lead sinkers and lures, (viii) other suggestions.

5.1.6.1. Requested derogation for split shots

While some commenters clearly support a ban on lead split shots (e.g. #3228), others are asking for a derogation for some split shots, e.g. split shots ≤0.1 g (referred to as size 6 to 14), split shots ≤0.06 g (referred to as size 8 to 14), split shot with a diameter below 3 mm, below 4 mm, etc. The smallest split shots are often known as dust split shots. The main elements provided to support the request for derogation are the following:

- no alternative available for some specific angling and/or competitive practices (e.g. #3259, #3344, #3358, #3472, #3518)

- available alternative may damage the fishing line (#3389, #3472, #3504, #3518)

- limited, and sometimes diverging, quantity placed on the market: 0.5 % of the total lead sinkers and lures market according to #3259, 100 tpa according to #3472, less than 0.3 % of the total lead sinkers and lures market - 16 tpa according to #3503, and 20 % of the market according to #3504

- limited loss in the environment as the rigs are usually prepared at home and therefore the spill does not happen on the shore (#3259)

A ban similar to the one in place in England and Wales and limited to split shots above 0.06 g for example (number 8 split shot) was already considered by the Dossier Submitter, but not justified for the following main reasons:

1. Birds can ingest very small split shot, mistaking them for food and grits.

2. The smaller the size of the split shot, the bigger the surface area per weight unit, and therefore the bigger the bioavailability after ingestion, and the risk of severe acute

effect.

The Dossier Submitter assumed that suitable alternatives for most split shot sizes would be available (cf. Section D.4.2.3 in the Background Document), even though recognising that the smallest size of tin split shots identified during the ECHA market survey was a size #8 (i.e. 0.06 g). Nevertheless, tin styls[72] could also be used as lead split shot alternative and are available up to size n°12 (i.e. 0.02 g). There was no alternative found for the smallest dust split shot (i.e. size n°13 – 0.01 g), but the use of a single split shot size n°13 on a fishing line is questionable. Indeed, a well-known rule of thumb states that 1 g of fishing split shot is needed on a fishing line per foot of water depth (i.e. 0.3 m), ruling out such use.

The Dossier Submitter takes note of the various requests for a derogation for smaller split shots, which would resemble the derogation currently in place in England and Wales for smaller split shot sizes. However, the justifications provided are neither detailed nor sufficiently justified for the Dossier Submitter to consider such a derogation. It is for example unclear what is the market share of the smaller split shot (the information provided varies between 0.3 % and 20 %), what are the competition, and rules referring to the use of lead split shots, what number of people are practicing this type of competition in the EU which would require the use of split shot, could styls replace very small split shots, etc.

For the reasons mentioned above, the Dossier Submitter did not update the proposed restriction entry. SEAC may wish to request further information during the consultation of the SEAC draft opinion in order to consider a potential derogation for lead split shot.

5.1.6.2. Requested derogation for sinkers and lures >50 g

Some commenters proposed a derogation for ‘bigger’ sinkers and lures. For example, derogation for sinkers and lures > 25g > 50 g or > 80 g (#3417, #3492, #3504).

The main elements provided to support the request for derogation are the following:

- birds’ ingestion of sinkers and lures above 50 g is very rare, and above 80 g not reported in the literature.
- the enforcement at point of use cannot be guaranteed and therefore it is not possible to ensure a risk reduction for human health.

Some commenters indicated that big sinkers and lures are more expensive than smaller ones. Such a statement cannot be confirmed by the Dossier Submitter, as the ECHA market survey concluded the exact opposite (cf. Section D.4.2.3 in the Background Document).

The Dossier Submitter acknowledges that a ban on all lead fishing sinkers and lures, as

[72] The styl is a special type of sinker. Whereas split shot is generally round or egg-shaped, the styl is long and thin like a rod with a central split so they can be squeezed on to the line in the same way as a split shot.

currently proposed in the restriction proposal, would have probably been unwarranted if the protection of birds were the only goal of the proposed restriction. Lead fishing tackle heavier than 50 g is indeed not typically ingested by birds. However, as the goal of the restriction is to reduce all risks associated with lead, including those related to lead exposure during home-casting and fishing activities, and especially the risk to children for whom lead is a non-threshold neurotoxin, the Dossier Submitter proposed a ban on all weights of sinker and lures.

Having said that, the proposal to restrict only sinkers and lures ≤50 g was assessed by the Dossier Submitter as a separate restriction option (RO3a-LOW) in the Background Document and was ranked as the second best restriction option. The proportionality of the proposed measure, and the comparison with a ban on sinkers and lures ≤50 g only (RO3a-Low), will be assessed by the scientific committees, which can then propose to review the restriction proposal if they come to the conclusion that the proposed restriction option is less proportionate.

Finally, one commenter suggested a derogation for sinkers and lures > 50 g conditional on the marking and coating of those sinkers and lures. The Dossier Submitter understands the proposal to coat larger lead fishing sinkers and lures with durable metal coating and a clear lead mark on the weight, as a way to easily identify that the larger sinkers and lures have not been home-casted. The Dossier Submitter takes note of such a proposal as it could address the risks identified for the human health. Nevertheless, in order to further elaborate and evaluate such a proposal, additional information on the practicality, costs, and estimated risk reduction of such an option would be needed. This additional information could be submitted during the SEAC draft opinion consultation to support SEAC in the assessment of this option.

5.1.6.3. Requested derogation for certain types of lures

One commenter (#3474) proposed a derogation for lures, which the Dossier Submitter understands as a request for derogating hard-plastic lures from the scope of the restriction proposal. To justify a derogation for hard-plastic lures, the commenter indicates that it might be difficult (even impossible) for fishers to know whether the hard-plastic lures they are using contain lead. Many recreational fishers indeed seem to keep hard-plastic lures for many years and may have a large number of them bought before the proposed ban on placing on the market would start to apply.

While the Dossier Submitter understands and acknowledges the explanations presented by the commenter, the Dossier Submitter would like also to highlight that lead pellets contained in hard-plastic lures have been replaced already by tungsten pellets (cf. Annex Section D.4.2.3.1 of the Background Document), therefore the Dossier Submitter considers a specific derogation not necessary. Nevertheless, the scientific committees may want to deviate from the Dossier Submitter's position, and may wish to exclude hard-plastic lures from the ban on use. In such a case, a clear definition of hard-plastic lures should be proposed by RAC and SEAC, as lures on their own may encompass a wide variety of shapes including jigs, jig-heads or sputniks (and probably other names), for which lead may be directly available to biota (cf. examples below also reported in Section A.2.1.1 of the Background Document).

Name	Description	Picture
Lures	**Used to attract fish**	
Jig or jig-head	A jig or jig-head consists of a sinker with a hook moulded into it and usually covered by a soft body to attract fish. Jigs are intended to create a jerky, vertical motion, as opposed to spinnerbaits which move through the water horizontally. Jig/jig-head might have various sizes, weights and colours.	
Decorated/dressed jig-head	Elaborated version of the jig (cf. description below).	
Pirk	A type of fishing lure consisting of a metal bar with a triple hook attached.	
Plug	Lure with a hard body. Depending on the region, plug might have different names, e.g. crankbait, wobbler, minnow, shallow-diver, etc.	
Spinnerbait		
Sputnik	The name comes from its resembling a satellite with antennas. This bait is popular with surf fishermen as it digs into the sand and is not nearly as affected by wave action and tidal flow as other weights.	

5.1.6.4. Proposal for different cut-off values than 50 g

Two commenters (#3472 and #3417) proposed a different cut-off value of 20 g /25 g instead of 50 g, and no restriction for sinkers and lures >20 g /25 g and below 0.37 g.

Such a restriction would be similar to the ban currently in place in England and Wales where the ban on lead sinkers is limited to the range between 0.06 g (number 8 split shot) and 28.35 g (1 oz). Such a restriction option was shortly assessed by the Dossier Submitter (cf. Section D.4.4.1 of the Background Document) but not considered further because birds can ingest fishing tackle weighing up to 50 g (cf. Section 1 of the Background Document), and for the reasons highlighted above in Section 5.1.6.1 (Requested derogation for split shots).

5.1.6.5. Proposal for a different concentration limit

The concentration limit in paragraph 1 of the proposed Annex XVII restriction entry sets the maximum allowed concentration of lead permitted in the various articles that are within the scope of the restriction. The proposal of the Dossier Submitter is to set this limit to 1 % w/w.

Some commenters argued for a lower concentration limit (e.g. 0.01 % in #3253) indicating that a lower limit is already achieved in Denmark for example, while other commenters advocated for a higher concentration limit (e.g. 4 % #3259, #3503), indicating that a higher concentration limit of lead would allow the possibility to use brass and other alloys as an alternative to lead. Commenters justified a higher limit of 4% indicating that under the ROHS Directive, which restricts the use of hazardous substances in Electrical and Electronic Equipment (EEE), lead is restricted with a

maximum concentration of 0.1 %[73] with the following exemptions: Copper alloy containing up to 4 % lead. The Dossier Submitter takes note of the reference to the ROHS directive, but considered that, based on the ECHA market survey and comments received during the Annex XV consultation (e.g. #3518), brass (copper alloy) and copper have very limited applications in sinkers and lures. Therefore, a change in the proposed concentration limit set for lead in fishing tackle seems not justified.

The concentration limit of 1 % w/w proposed by the Dossier Submitter is also aligned with the one currently adopted for the restriction on the 'use of lead gunshot in wetlands'. As explained in Section 2.3.2.1 of the Background Document, this limit was selected based on the US 'non-toxic' gunshot approval (cf. Annex C of the Background Document) process that limits the maximum concentration of lead in any 'non-toxic' gunshot to 1 % (w/w) in order to avoid a significant toxicity danger to migratory birds and other wildlife, or their habitats. As such, the proposed concentration limit is considered to sufficiently address the risk for the birds whilst being readily achievable by producers of alternatives. The consistency of the enforcement of the proposed restriction for the three sectors (hunting, sports shooting and fishing), and the restriction on 'use of lead gunshot in wetlands' will also be ensured, and the proposed concentration limit can be verified using the standardised analytical methods developed for the restriction on the 'use of lead gunshot in wetlands'.

The Dossier Submitter takes note of the comments and proposals regarding the concentration limit of lead, and considers that this topic is already addressed in the Background Document; therefore, no update was made to the Background Document.

5.1.6.6. Proposal for ban on lead in fishing nets, ropes and lines

With the view of minimising as much as possible the presence of lead in the environment, some commenters propose to include in the scope of the restriction a ban on lead in fishing nets, ropes and lines (e.g., #3228, #3253). Such an option was already analysed by the Dossier Submitter and reported in Section D.4 of the Background Document as restriction option 'RO3b'. The commenters requesting a ban on lead in nets, ropes and lines did not bring new arguments to those already assessed by the Dossier Submitter under RO3b. Therefore, the Dossier Submitter's conclusion that such a ban would not be proportionate to the risk identified remains. However, as indicated in the Background Document, if the goal of the restriction were to reduce the general lead contamination of the environment (rather than addressing the identified risks as requested by the European Commission), then it might be appropriate for the decision maker to consider restricting the use of lead in fishing nets, ropes and lines.

The Dossier Submitter takes note of the comments and proposals regarding a ban on lead in nets, ropes and lines, and considers that this topic is addressed in the Background Document; therefore, no update was made to the Background Document.

[73] According to Annex II to ROHS - consolidated version of ROHS available here: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011L0065-20200301&from=EN

5.1.6.7. Proposal to tax lead sinkers and lures

One commenter suggests that a tax on lead fishing tackle would be an appropriate solution to be further investigated (#3204). The suggestion was not further substantiated.

The Dossier Submitter looked at this option (cf. Section D.4.6 of the Background Document for the details). Assuming that selling prices of today's fishing tackle do not reflect the environmental externalities of the product, it could be possible to internalize these environmental costs by increasing the final product's selling price. The EU could achieve this by implementing an environmental tax on all lead fishing tackle. This tax would be designed to make the lead fishing tackle more expensive than the alternatives. Taxation of lead fishing tackle could steer the purchase behaviour of fishers towards a more environmentally friendly direction. Such a tax could also motivate producers to design more sustainable alternatives. The existence of alternatives is indeed crucial to the prospects of reducing risks to human health and the environment. Such taxes could also generate revenue that could be used to (i) support the European industry in transitioning towards the manufacturing of non-lead fishing tackle, (ii) launch R&D activities to work on 'degradable' alternatives, (iii) launch consumer's awareness campaign, or (iv) support marine/freshwater litter projects such as beach clean-up activities.

Despite being an attractive option, the set up of a harmonised taxation scheme at EU level is extremely complex as taxation in general is not a harmonised measure across the EU (because taxation is in the competence of EU Member States). Therefore, whilst it might be effective in encouraging substitution in theory, it is unlikely that all Member States would introduce relevant taxes thereby undermining the protection of all EU citizens. This option is therefore likely to lead to a non-harmonised situation where different Member States apply different tax rates (if any). In addition, while this option would encourage manufacturers and fishers to switch to non-lead fishing tackle, it is difficult to predict the risk reduction that would result from any given tax rate or fee level, even if case studies exist (e.g. taxes on plastic bags) and have demonstrated that the sale of such products have significantly reduced when applying an environmental tax. In addition, the Dossier Submitter notes that home-casted fishing tackle would not be subject to a fee unless they are sold. As such, the quantity of home-casted sinkers would not be expected to decrease as a result of the tax/fee (in fact, it may increase as consumers attempt to avoid the fee on purchased sinkers), likely undermining its effectiveness. For these reasons, this option was discarded by the Dossier Submitter.

The Dossier Submitter takes note of the comment on taxation and considers that this topic is addressed in the Background Document; therefore, no update was made to the Background Document.

5.1.6.8. Other suggestions

Other restriction options were proposed by some commenters, but due to missing details on practicality, costs, and estimated risk reduction, the suggestions were not further considered by the Dossier Submitter. In addition, some of the proposed suggestions cannot be implemented through a REACH restriction. For completeness, the suggestions

shall still be briefly summarised:

- mandatory packaging in blisters and labelling of sinkers and lures, with warnings of danger and use such as: prohibited use by children, not to be handled by pregnant women, wear gloves etc (#3178, #3196, #3203).

- compulsory use of gloves in shops for the personnel handling sinkers and lures in bulk (#3196, #3203).

- increased transparency regarding the composition of so-called 'non-toxic' or 'lead-free' fishing sinkers and lures with an obligation to mention the exact composition (#3389) (Note that this cannot be implemented through a REACH restriction).

- remediation and cleaning of fishing sites where a lot of sinkers and lures are abandoned (#3344). (Note that this cannot be implemented through a REACH restriction).

- guidance for home-casting to reduce lead exposure (#3344).

Additional information could be submitted during the SEAC draft opinion consultation.

5.1.7. Communication at the point of sale

Limited comments were received regarding the 'communication at the point of sale' requirement in the fishing sector, for example: #3202, #3228.

The commenters, in general, acknowledge the lack of communication on the danger of lead towards the fishers, and the lack of awareness of fishers regarding the risks of lead exposure pose for their health and the environment. While acknowledging this issue, one commenter (#3202) nevertheless criticised the mandatory information at the point of sale during the transition period, indicating that such a measure is 'risible' and a total ban without transition period would be a better option.

During the Annex XV consultation, there was no information submitted regarding the cost of the proposed measure (communication at the point of sale), and the Dossier Submitter did not identify any comments that would be providing arguments against this measure. Therefore, no update to the Background Document was made.

5.2. RAC Rapporteurs comments

Home-casting

The comments submitted clearly show that home-casting of fishing tackle does occur, and seems to be rather common in some Member States. Comment #3325 provided useful information showing that the exposure potential increases dramatically with temperature and with certain melting conditions of lead. RAC supports the response from the Dossier Submitter, and concludes that the comments support an exposure potential to lead and risk when the home-casting is not performed under optimal conditions, warranting a restriction although not allowing a quantitative risk assessment.

Alternatives

The comments indicate that many alternative materials are available, but sometimes the availablility is still limited, especially for heavier sinkers. The suitability of non-lead split shot is also questioned, as they are stated to damage thin fishing lines.

Alternative materials are generally less toxic. Comment #3215 indicates that newer non-lead materials are developed (iron powder in a polyester binder) generally increasing the availability of alternatives with time.

RAC notes the comments, but is of the view that more, less toxic alternatives will become available with time, supporting a restriction.

Transition period

RAC supports the proposed transition periods and the view of the Dossier Submitter that the avaiablibility of alternatives will increase with time, also for heavy sinkers and dust split shot.

Monitorability and enforcability of the proposed restriction

RAC shares the view expressed in the comments that enforcement of use will be very challenging. However, such enforcement is needed in order to limit home-casting and import of articles via internet. A complement to enforcement could be to initiate collection systems in the Member States for lead sinkers and fishing tackle, possibly decreasing the availablility of lead fishing sinkers/tackle at the point of use for the fishers.

Suggestion of new or different restriction options

A derogation has been requested for split shot, but RAC agrees with the Dossier Submitter in not supporting this request. In addition to the arguments provided by the Dossier Submitter, RAC notes that lead split shot are small, difficult to handle, and easily dropped on the shore where they become available for birds. Also, any material, including lead, can damage the fishing line if too much power is used when applying the split shot. Thus, from a risk point of view, there is no reason to derogate split shot.

A derogation has been requested for sinkers and lures >50 grams. RAC acknowledges that enforcement at the point of use will be challenging, but notes the high potential for human exposure when home-casting sinkers and lures >50 grams (rather common in some Member States) and that based on the human health risk a derogation is not supported.

A derogation has been requested for hard-plastic lures, which presently do not usually contain lead, as it will be difficult (or in practice impossible) to know whether they do or do not contain lead. However, as no data to support the derogation request was submitted, and there is a possibility of exposure to lead from this source, RAC does not support this derogation request.

Different concentration limits (than 1%) have been proposed, e.g., to allow use of brass (containing up to 4% lead). However, there seems to be a limited use of brass for sinkers and lures, and if it would be used, RAC notes that there is even lead-free brass on the market and supports the response from the Dossier Submitter. However, RAC proposes to change the lead concentration limit of 0.3 % for the information requirements proposed by the Dossier Submitter to 1% to further increase consistency

in the conditions of the restriction.

Several comments propose a ban on lead in fishing nets, ropes and lines. RAC does not support the proposal in line with the Dossier Submitter's response since no direct exposure potential to lead result from these articles.

RAC supports the Dossier Submitter's response to the other suggestions (5.1.6.8) and the mandatory information requirements at the point of sale during the transition period.

5.3. SEAC Rapporteurs comments

The SEAC rapporteurs refer to the discussion in the SEAC draft opinion on the different issues raised in the comments received.

6. Other comments

6.1. Dossier Submitter response to comments

6.1.1. Request for adaptation of labelling requirement on each projectile/cartridge

6.1.1.1. Labelling and Conflict with CIP regulations

FACE (#3467) submitted that the proposed labelling requirements mentioned in paragraph 5b and 5c would constitute a conflict with the 1969 CIP convention and would entail increased cost to manufacturers. AFEMS raised concerns of similar nature and pointed out to further practical obstacles such as e.g., the size of air rifle pellets and other smaller sized projectiles where no place is available for any such markings.

AFEMS (#3331) explained in detail that:

> The labelling requirement for "projectiles not defined as gunshot" requires that the projectile or cartridge is labelled. Note it is not technically possible to label the projectile without negatively impacting ballistic performance. In addition, the projectile is mostly inside the cartridge case, meaning that the visible part is too small to fit label text in a size that can read. requirement to label the cartridge would create trade barriers as the label would need to be specific to the country of sale as the requirement would be that the label is in the language of that country. Producers would need to hold stock of the same ammunition in as many languages as the countries they supply to. For example, they will need stock with text in the 24 official languages of the EU if they supply to all EU countries. The labelling requirement would be barrier to the free movement of ammunition throughout the EU and goes against a single market concept. This barrier is in contrast to the current situation where ammunition products from any production lot can be placed on any market in any EU country as all necessary information is included with the packaging. Note that cartridges are not sold on an individual basis. Multilingual warnings are already provided on the product packaging of the smallest unit of sale, e.g. for 0.22LR cartridges, the box of 50 cartridges.
>
> In addition, the requirement to label each cartridge would mean that producers

who export ammunition outside the EEA would have to either systematically produce two lots for each production run – one with labels (for each language where the lot will be put on the market) and one without labels for the export market. The variability in EEA languages means that producers could not credibly put a label in e.g., German for a lot that would also be put on the market in the US, Canada, etc. The labelling requirement at the level of each cartridge as a trade barrier for EU based companies exporting outside the EU.

Similarly, for ammunition that is supplied to both military and civilian markets, producers would need to maintain separate inventories for each market.

The Annex XV report has not considered the impact of the labelling requirement on trade within the single market and with the rest of the world. Lot size would need to be small (per country of sale) and this would significantly increase production and logistic costs. One manufacturer estimated that logistic costs may increase by a factor of 10 – 20 as each item will need to be split to 24 items with their own locations in warehouse. Manufacturing costs will increase due to the investment costs to buy and install marking machines (after finding a supplier of the machines).

The investment costs may be ca. 50 000 - 100 000 EUR per line. The additional time needed for marking (5 – 10 X the time of the manufacturing the bullet itself, bullet 2-3 parts per second, marking 2 – 5 seconds each) would be a bottleneck in production. The manufacturer did not consider that it would be economically viable.

Request: AFEMS requests that the labelling requirement be revised to allow for the information to be included with the leaflet included with the packaging only. This would ensure single market access and also avoid creating barriers for international trade.

The Dossier Submitter highlights that the proposed restriction does not require that individual 'projectiles other than gunshot are' labelled, but rather that the product packaging contains the required information. Multi-lingual labels can be used and are already commonly used throughout the single market. See also paragraph 5b of the proposal. The term product packaging is interpreted in line with the CLP regulation.

Should the optional conditional derogation for lead gunshot be preferred by the decision maker then individual gunshot cartridges would indeed be required to be labelled 'contains lead: do not use for hunting' – as per paragraph 5c of the proposed restriction. This is to facilitate enforcement in the field. Alternatively, the plastic parts of lead gunshot cartridges could be required to be made for a single harmonised colour to aid immediate visual identification in the field – for example red.

6.1.2. Other comments on the dossier

Some comments made editorial remarks on Background Documents (#3445) and (#3467) where this was regarded as needed, the Dossier Submitter has implemented corrections.

6.2. RAC Rapporteurs comments

The proposed restriction only requires labelling of the product packaging, which should not be a problem and could include labels in many languages.

In contrast, individual lead gunshot should be labelled ‘contains lead: do not use for hunting’, and RAC is of the opinion that colour coding is an alternative approach to facilitate enforcement in the field.

6.3. SEAC Rapporteurs comments

The SEAC rapporteurs consider that a marking of single bullets would improve the enforceability of the ban on use in hunting of ‘projectiles other than gunshot’, because hunters in the field may carry ammunition without the packaging. This marking does not have to be a sophisticated label or sign, but could be just a mark, e.g. ‘Pb’ at the bottom of the case, which is commonly imprinted stating the brand or the calibre, or a colour coding of certain parts of the projectile (as proposed by the Dossier Submitter for lead gunshot). As highlighted in the SEAC draft opinion the costs of such a means have not been assessed, which means that SEAC cannot conclude whether it would be proportionate. Nevertheless, the SEAC rapporteurs consider that the economic impacts stated above, e.g. that a marking would act as a trade barrier, are likely to be exaggerated.