

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

Opinion

on an Annex XV dossier proposing restrictions on

LEAD IN GUNSHOT

ECHA/RAC/RES-O-000006671-73-01/F

ECHA/SEAC/RES-O-000006671-73-02/F

**Compiled version prepared by the ECHA Secretariat of RAC's
opinion (adopted 9 March 2018) and SEAC's opinion (adopted 14
June 2018)**

9 March 2018

ECHA/RAC/RES-O-000006671-73-01/F

14 June 2018

ECHA/SEAC/RES-O-000006671-73-02/F

**Opinion of the Committee for Risk Assessment
and
Opinion of the Committee for Socio-economic Analysis**

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

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

Chemical name(s): **Lead**

EC No: 231-100-4

CAS No: 7439-92-1

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

PROCESS FOR ADOPTION OF THE OPINIONS

ECHA on behalf of the Commission has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier.

The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <http://echa.europa.eu/web/guest/restrictions-under-consideration> on **21 June 2017**. Interested parties were invited to submit comments and contributions by **21 December 2017**.

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: *Bert-Ove LUND*

Co-rapporteur, appointed by RAC: *Michael NEUMANN*

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **9 March 2018**.

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

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

ADOPTION OF THE OPINION OF SEAC:

Rapporteur, appointed by SEAC: *Karen THIELE*

Co-rapporteur, appointed by SEAC: *Maria NORING*

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **15 March 2018**.

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

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

The draft opinion was published at <http://echa.europa.eu/web/guest/restrictions-under-consideration> on **21 March 2018**. Interested parties were invited to submit comments on the draft opinion by **21 May 2018**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **14 June 2018**.

The opinion takes into account the comments of interested parties provided in accordance



with Articles 69(6) and 71(1) of the REACH Regulation.

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

Contents

OPINION OF RAC AND SEAC.....	8
THE OPINION OF RAC	8
THE OPINION OF SEAC	10
JUSTIFICATION FOR THE OPINION OF RAC AND SEAC.....	12
IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK	12
JUSTIFICATION IF ACTION IS REQUIRED ON A UNION WIDE BASIS	28
JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE	30
UNCERTAINTIES IN THE EVALUATION OF RAC and SEAC	71
REFERENCES	74
ANNEX.....	75

Tables

TABLE 1.Effects of administered lead pellets on Mallard survival.....	20
TABLE 2. The three cost scenarios as presented by the Dossier Submitter.....	51
TABLE 3.Overview of the benefits resulting from the environmental and human health impact of the proposed restriction	61
TABLE 4. Cost-effectiveness of the proposed restriction in terms of emission reduction.....	64
TABLE 5. Summary of expected costs and benefits of the proposed restriction.....	65
TABLE 6. Costs to hunters resulting from the proposed restriction in total and in percentage of average hunter’s budget.....	66

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Brief title: restriction on the use of lead gunshot in or over wetlands.

Substance Identity	Conditions of restriction
Lead and lead compounds	<ol style="list-style-type: none"> 1. Shall not be used in gunshot for shooting with a shot gun within a wetland or where spent gunshot would land within a wetland. 2. Lead gunshot shall not be in the possession of persons in wetlands. 3. For the purposes of paragraphs 1 and 2: <ul style="list-style-type: none"> • “shot gun” means a smooth-bore gun, • “gunshot” means pellets used in quantity in a single charge or cartridge in a shotgun, • “lead gunshot” means any gunshot made of lead, or any alloy or compound of lead with lead comprising more than 1 % of that alloy or compound, • “wetlands” are defined according to Article 1(1) of the Convention on Wetlands of International Importance especially as Waterfowl Habitat (Ramsar Convention). 4. Paragraphs 1 and 2 shall apply 36 months from entry into force of the restriction. 5. Member States may, on grounds of human health protection and/or environmental protection, impose more stringent measures than those set out in paragraphs 1 and 2. Member States shall inform the Commission of such measures.

THE OPINION OF RAC

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

However, RAC has the following suggestions:

- The scope of the restriction will be clearer if the definition of 'wetland' according to the Ramsar Convention is included in the restriction text (i.e., *wetlands are areas of marsh, fen, peatland or water, whether natural or artificial, permanent or temporary, with water that is static or flowing, fresh, brackish or salt, including areas of marine water with the depth of which at low tide does not exceed six metres*). This would also address any misunderstandings in relation to the scope of the restriction and designated 'Ramsar sites'. The proposed restriction is not limited to designated Ramsar sites, but rather all wetlands that fit the definition, irrespective of their status.
- The REACH definition of 'use' explicitly includes 'keeping' (Article 3(24)).¹ The Dossier Submitter considers that the term keeping is equivalent to 'possession'. Following this rationale, a restriction on 'use', without further qualification, implies a restriction on any of the uses defined under REACH, including 'possession'. The proposed restriction is intended to prohibit any use of lead gunshot within a wetland (including possession) and the shooting of lead gunshot into a wetland from outside of a wetland ('*use [...] where spent gunshot would land within a wetland*'). Other uses, e.g. possession, outside of a wetland are not intended to be restricted on the basis that this would increase the scope of the restriction beyond wetlands; this understanding is supported by the fact that the socio-economic analysis was also made based on the above rationale. However, RAC notes that the proposed wording of paragraphs 1 and 2 may introduce ambiguity as it could be interpreted that the restriction on 'use' outside of a wetland is wider than intended. Thus, the meaning of use and possession are not equivalent or interchangeable in the proposed wording. RAC considers that it is important that the wording of the restriction should unambiguously indicate what precise uses (e.g. shooting/possession) of lead shot are restricted and where (inside or outside of a wetland).
- The proposal by the Dossier Submitter did not include a fixed "buffer zone" around wetlands. Consequently it is the responsibility of the hunter/shooter, based on their expertise and local knowledge, to make sure that no lead is deposited in wetlands when hunting/shooting (see §1). There is some support in RAC for this flexible approach although the FORUM has indicated difficulties with enforcement. There was also support in RAC for quantitatively defining a fixed buffer zone (e.g. 300 metres) around wetlands where shooting towards wetlands would not allowed, although there are also enforcement and scope issues associated with this approach.
- In relation to paragraph 2, RAC has discussed a fixed buffer zone around a wetland where possession of lead gunshot would be prohibited, and noted that this could offer a further enforcement possibility.
- The evaluation of this proposal by RAC is based on the assumption, made by the Dossier Submitter after consultation with the Commission, that possession of lead gunshot by consumers / professionals can be regulated under REACH.

¹ Use under REACH is defined as any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation.

- The proposed restriction on possession should be interpreted as 'possession while hunting/sport shooting'; RAC has not discussed if paragraphs 1 and 2 could be merged and if a) use in gunshot for shooting and b) possession while hunting/sport shooting could be restricted in the same manner and within the same area (e.g. fixed buffer zone).
- Regarding paragraph 4 on entry into force, RAC strongly supports a shorter transitional period than the 3 years proposed by the Dossier Submitter. The reason being that each year of delay results in an estimated additional release of in the order of 4 000 tonnes of lead to wetlands and the associated death of in the order of 1 million birds.
- RAC emphasises the clear advantages of an obligatory labelling requirement for all shotgun cartridges containing lead as is currently the case for shotgun cartridges containing steel gunshot. They could also be labelled to ensure that it is clear that the use of lead gunshot in wetlands is not permitted within the EU and communicate the risks that they are associated with (e.g. poisoning of waterbirds).
- The proposed restriction aims to harmonise the existing diverse Member State approaches, but it is also important that Member States may impose more stringent measures (e.g., with respect to buffer zones or to a total ban).
- The effectiveness and practicality, including enforceability, of the proposed restriction would be further increased by including all uses of lead gunshot within the scope of the proposal (i.e. uses in both wetlands and terrestrial habitats) (option 1 in section E.1.2 of the Background Document²). However, RAC notes that the development of such a restriction proposal was clearly not included in the Commission's request to ECHA.

THE OPINION OF SEAC

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

SEAC proposes the same conditions of the restriction as RAC (see above).

SEAC has the following observations on the conditions of the restriction:

The REACH definition of 'use' explicitly includes 'keeping' (Article 3(24)). The Dossier Submitter considers that the term keeping is equivalent to 'possession'. Following this interpretation, a restriction on 'use', without further qualification, implies a restriction on any of the uses defined under REACH, including 'possession'. Accordingly, the proposed restriction is intended to prohibit any use of lead gunshot within a wetland (including possession) as well as shooting of lead gunshot into a wetland from outside of a wetland

² See also Table 5.1 in Annex XV report.

(‘use [...] where spent gunshot would land within a wetland’). Other uses outside of a wetland, including possession, are not intended to be restricted, because this would increase the scope of the restriction beyond wetlands. This understanding is supported by the fact that the scope of the impact assessment was also defined based on the above interpretation.

SEAC perceives an ambiguity in the proposed restriction with regard to the interpretation of possession in condition no. 2. Since the proposed restriction aims at the impact of shooting, it is necessary to distinguish possession where the intention is to use lead gunshot in wetlands resulting in releases of lead gunshot and where not, e.g. when transporting lead gunshot to another area thereby passing a wetland.

SEAC points out that also RAC notes that the proposed wording of paragraphs 1 and 2 may introduce ambiguity as it could be interpreted that the restriction on ‘use’ outside of a wetland is wider than intended. Thus, the meaning of use and possession are not equivalent in the proposal. RAC considers that it is very important that the wording of the restriction should unambiguously indicate what precise uses (e.g. shooting/possession) of lead shot are restricted and where (inside or outside of a wetland).

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

Description of and justification for targeting of the information on hazard(s) and exposure/emissions (scope)

Summary of proposal:

The proposed restriction aims to address the risks posed by the use of lead gunshot in wetlands. The scope is limited to wetlands as that was set out in the request from the Commission to the Dossier Submitter (ECHA). The Dossier Submitter did not specifically consider any risks from lead gunshot in non-wetland habitats (i.e. in terrestrial habitats). Consequently, the proposed restriction entails a ban on the use of lead gunshot within all European wetlands and where spent (fired) lead gunshot would land within a wetland even if the use (i.e. shooting) takes place outside of a wetland. It includes the use of lead gunshot for both shooting at targets (e.g. clay pigeons) and live quarry. The Dossier Submitter aims to simplify enforcement, and hence maximise the realised risk reduction potential of the restriction, by also prohibiting the possession of lead shot within a wetland. The proposal includes all gunshot containing more than 1 % lead. A transitional period of 36 months after entry into force is proposed to allow producers of cartridges/gunshot to adjust to this restriction.

The proposal describes the risks resulting from the use of lead gunshot in wetlands to both the environment and human health. Concerning human health, lead is considered a non-threshold substance and Annex I of REACH only requires a qualitative assessment of risks to be carried out for such substances (Annex I para 6.5). In contrast, the risk to waterbirds through primary ingestion of spent lead pellets dispersed into wetlands (where pellets are mistaken for food or grit) is assessed quantitatively. The risk assessment also considers a risk, via secondary poisoning, to species that either predate or scavenge birds contaminated with lead gunshot (either as embedded or ingested gunshot, or accumulated lead in tissues from the dissolution of embedded or ingested gunshot).

The proposed restriction aims to harmonise the existing diverse Member State approaches to address the risks from the use of lead gunshot in wetlands. It is primarily justified based on the acute and sub-lethal effects, principally death, that occur in waterbirds after ingesting lead gunshot. As a result of the scope of the restriction, it will only address those risks where ingestion occurs within a wetland. The Dossier Submitter acknowledges that certain species of waterbirds (including certain AEWA-listed waterbirds) are also known to feed outside of wetlands and may therefore still be exposed to lead gunshot should this be used outside of a wetland. The proposed restriction will also reduce the prevalence of 'embedded' or 'shot-in' lead gunshot in waterbirds that may subsequently be consumed by predators/scavengers in either wetland or terrestrial environments, or by humans.

In recognition of these risks, several Member States have already enacted more stringent restrictions on the use of lead gunshot within their territory than proposed here, i.e. restrictions that extend beyond wetlands. The text of the restriction proposed by the

Dossier Submitter does not seek to compel Member States to revoke these existing measures.

The proposed restriction has been justified by the Dossier Submitter primarily on the basis of the identified risks to waterbirds. However, the Dossier Submitter also identifies human health concerns related to the use of lead gunshot in wetlands arising via indirect exposure (humans via the environment). One concern arises by consuming waterbirds that have been shot with lead gunshot. Another is the general condition of wetland environments, including potential contamination of sources of drinking water with lead. For the general population, food and water are considered to be the most important sources of exposure to lead (EFSA, 2013). Consumption of game meat can potentially contribute disproportionately to overall dietary exposure (EFSA, 2013). Addressing these latter concerns are also considered by the Dossier Submitter to be benefits of the proposed restriction. The risks to human health from the use of lead gunshot were not quantitatively assessed in this Annex XV report, as sufficient data were not available to do so.

RAC conclusion(s):

The purpose of the restriction is clear and the reasons for limiting the scope to wetlands as requested by the Commission is understood. RAC is of the opinion that restricting possession of lead shot in addition to restricting its 'use' in wetlands will increase the enforceability and, therefore, the risk reduction potential of the proposal. The effectiveness and practicality, including enforceability, of the proposed restriction would be further increased by including all uses of lead gunshot within the scope of the proposal (i.e. uses in both wetlands and terrestrial habitats) (option 1 in section E.1.2 of the Background Document). However, RAC notes that the development of such a restriction proposal was clearly not included in the Commission's request to ECHA. Similarly, a restriction option to prohibit the use of lead gunshot to hunt specified wetland bird species (e.g. ducks, geese), in line with current regulations in some Member States (option 3 in section E.1.2 of the Background Document), was not within the mandate from the Commission as such hunting can occur outside of wetlands.

The public consultation resulted in supportive comments from individuals, NGOs, scientific organisations, single experts and scientists, but also from national agencies. Also some organisations representing hunters support on a general level the proposed restriction and commented only on specific issues in relation to the scope, the Ramsar definition of a wetland (and specifically the inclusion of peatland), and the impact of the restriction (discussed in the following sections). Some comments explicitly supported the Ramsar Convention definition of a wetland and emphasised the need to address the risks posed by lead gunshot in peatland.

It is acknowledged by RAC, that 24 out of 28 Member States have already implemented different types of restrictions, some of them beyond the scope of the proposed restriction (i.e. total bans on the use and placing on the market of lead gunshot). Many comments also support a wider restriction, e.g. a total ban for the additional protection of soil and terrestrial ecosystems. The merit in having an EU harmonised restriction is clear considering that the breeding and/or overwintering areas (and the flyways between them) for many European waterbird species (including AEWA-listed species) occur across multiple Member States of the European Union, that lead is highly toxic to human health with no

threshold and that any emission to the environment must therefore be minimised.

Ingestion of spent gunshot leads to the poisoning of a large number of waterbirds annually. An EU-wide restriction on the use of lead gunshot in or nearby wetlands, where spent gunshot would fall within a wetland, will therefore prevent waterbird species from ingesting lead pellets whilst foraging in wetland habitats. It will also prevent waterbirds that are shot and wounded (but not killed) in wetlands from having lead shot embedded in their tissues, and subsequently exposing predatory or scavenging species. The proposed restriction also protects wetland ecosystems in general and species that consume waterbirds (scavenging and predatory birds as well as humans).

Wetlands are defined differently in different Member States in relation to hunting restrictions, but the proposed use of an internationally accepted, broad definition is likely to simplify the implementation of the restriction, increasing its effectiveness and is therefore supported by RAC.

The scope of the restriction also includes the use of lead gunshot in areas nearby wetlands when spent gunshot would land within a wetland, but without further defining these areas, for example in terms of distances from the wetland. RAC notes that gunshot can travel up to 300 meters from the point of shooting to the point of deposition. The absence of precise distances from a wetland in the proposal was based on the recognition that many factors will affect the potential for lead gunshot to fall within a wetland when it is used outside of a wetland³, but most notably whether the lead shot was fired in the direction of the wetland or away from it. This may result in uncertainty as to whether a point of shooting outside of a wetland is inside or outside of the scope of the restriction. This uncertainty may complicate understanding by those shooting (affecting compliance) as well as during any enforcement, and could reduce the effectiveness of the proposal.

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

Information on hazard(s)

Summary of proposal:

Mortality can result from either acute (short-term) or chronic (long-term) exposure to lead. Acute lethal poisoning can occur after the ingestion of one shot. In such cases, mortality generally occurs rapidly after ingestion without the bird becoming noticeably intoxicated, typically within 1-3 days. Birds dying from acute lead poisoning are typically found to be in good to excellent condition with good to excellent deposits of fat. Individuals may have a large amount of lead gunshot in the gizzard and show multiple areas of myocardial infarction (areas of pale-pink, dead heart muscle).

Chronic lethal poisoning, as described in USFWS (1986), occurs as the result of a bird ingesting 1 to 15 pellets, most often 1 or 2, and developing a progressive (non-reversible) illness that requires two to three weeks to eventually result in mortality. The most reliable gross indications of lead poisoning are considered to be impaction (blocking) of the alimentary tract with food, submandibular oedema, necrosis of heart muscle and bile

³ e.g. shot size, barrel/chamber pressure generated by the cartridge [standard proof/magnum proof]; trajectory of the shot; barrel choke used, etc.

staining of the liver. Based on extensive field studies, Bellrose (1959) identified specific mortality rates in seven classes defined on the number of ingested lead shot. Mallards with 1, 2, 3, 4, 5, 6, or > 6 ingested shot, were estimated to have a relative mortality increase of 9, 23, 30, 36, 43, 50 and 75 %, respectively, compared to controls.

Lethal or sub-lethal effects are caused in predatory or scavenging birds (as well as other wildlife) by secondary poisoning through eating contaminated waterbirds that have lead gunshot embedded in their tissues (after being wounded) or digestive tract (through ingestion) or where embedded or ingested gunshot results in elevated tissue concentrations.

RAC conclusion(s):

RAC concludes in line with the Dossier Submitter that the ingestion of spent lead shot by waterbirds such as ducks, geese, swans, waders, rails and flamingos causes toxicological effects. Lead exposure may result in mortality, or at lower exposure, in a range of adverse physiological and behavioural effects. Sub-lethal effects occur in waterbirds, as well as in species of birds that either predate or scavenge water birds contaminated with lead gunshot.

RAC concludes that lead is highly toxic and that a threshold for neurodevelopmental effects in children (as well as blood pressure and renal effects in adults) has not been established. RAC has given its opinion on lead toxicity in previous restrictions on lead in jewellery and in consumer articles (RAC, 2011; RAC, 2013), which is in line with the assessment by EFSA (2013). Any exposure to lead, including via the diet, constitutes a risk. This was questioned during public consultation⁴. However, in line with these assessments, the more recent assessment of lead by the Australian NHMRC concludes "Reducing the amount of lead in our environment (e.g. in soil, dust, air and products) as much as possible will reduce the risk of harm to future generations, especially for young children and unborn babies" (NHMRC 2015a and 2015b). During public consultation some comments highlighted the need for regulatory action to protect human health⁵.

RAC concludes that any emission of lead into the environment must be minimised. RAC also notes that the existence of some form of restriction on the use of lead shot in 23 out of 28 Member States confirms that the hazards related to the use of lead gunshot is already well-recognised in Europe.

Based on the methodology developed by Bellrose (1959), the Dossier Submitter estimated that between 400 000 and 1 500 000 waterbirds (across 19 species) die annually across the EU due to ingested lead shot. RAC examined the Bellrose calculations and questioned the appropriateness and reliability of the methods used. However, a reassessment of the Bellrose data using contemporary statistical methods reported by Green (2017, submitted)⁶ was considered to provide a more reliable estimate of annual mortality associated with the ingestion of various quantities of lead gunshot. Nevertheless, acknowledging the large confidence intervals in the Green estimates, and the relatively small differences between the estimates reported by Bellrose and Green, RAC can support with the approach of the Dossier Submitter to use estimates of annual mortality

⁴ comments #1583, #1705

⁵ comments #1560, #1607, #1703, #1802, #1841

⁶ Submitted in ECHA's public consultation, #1612

underpinned by the Bellrose mortality rates for further calculations of total bird mortality.

Key elements underpinning the RAC conclusion(s):

Lead is harmful to the environment. Extensive data on the effects of short and long-term lead exposure on a wide variety of aquatic and terrestrial organisms have been collated in REACH registration dossiers as well as covered in the EU voluntary risk assessment for lead and its compounds (LDAI, 2008). The literature describing the causes and consequences of lead poisoning in birds is extensive and comprehensive.

Lead also has a harmonised classification under the CLP Regulation as e.g., as toxic to reproduction (H360DF). Unlike many other trace metals it has no physiological function. It acts as a neurotoxin, affecting multiple aspects of behaviour and causing brain damage at low levels of exposure in the absence of other symptoms (EFSA, 2013). Developing individuals (children) are particularly at risk. Lead has also effects on blood pressure and chronic kidney disease. EFSA concluded that there is no evidence for a threshold for neurological effects in children and for renal effects in adults (EFSA, 2013). This was the basis for the restriction on lead compounds in consumer articles that can be mouthed by children and on lead compounds in jewellery (RAC, 2011; RAC, 2013) and is in line with the assessment by EFSA (2013).

The fact that ingesting spent lead gunshot is lethal to waterfowl has been known for over a century, and many important studies are therefore rather old and not always well reported. Nevertheless, based on the experimental studies summarised in the restriction report it is possible to conclude that even the ingestion of a single lead gunshot may be fatal in mallards and small waterfowl, generally causing severe suffering for 2-3 weeks before death occurs (Rodriguez *et al.*, 2010). However, the sensitivity to lead toxicity appears to differ between species, for instance depending on the type of diet and body size, although it is clear that lead is more or less toxic to all species. The toxic effects of lead on organisms are further explained in the Background Document, and these are generally so well-known that it is not further discussed in this RAC opinion.

Whilst there are extensive laboratory data on the potential of lead poisoning to result in mortality, dead birds are not typically observed in the field. This is because carcasses are usually scavenged in a matter of days (USFWS, 1986). However, a few European case-studies have been reported. For example, mortality was observed in populations of flamingos in Spain, Italy and Cyprus (\leq 106 birds, containing 1 to 277 pellets/gizzard). Newth *et al.* (2012) have analysed 2 365 dead waterbirds (including 28 different species) found in the UK between 1971 and 2010, and attributed 10.6 % of the deaths to lead poisoning. Mortality rates for some species were greater, such as for the Whooper swan where 27 % of the deaths were attributed to lead poisoning. Taggart *et al.* (2009) collected dead or moribund birds and found that 21 % of marbled teals (*Marmaronetta angustirostris*) and 71 % of white-headed duck (*Oxyura leucocephala*) had shot in the gizzard.

Bellrose (1959) collected unpublished information from US state and federal conservation agencies on lead poisoning outbreaks among waterfowl and published a summary of die-offs in the US, showing numerous such die-offs involving hundreds of birds (often mallards). A few exceptional cases involving up to 16 000 birds were also reported. The use of lead gunshot to hunt waterfowl was subsequently banned in the USA.

Based on the methodology reported by Bellrose (1959), as used in other recent studies, the Dossier Submitter estimated that between 400 000 and 1 500 000 birds die annually due to ingested lead shot. The Bellrose method estimates the dose-dependent increase in annual mortality in mallard populations caused by the ingestion of different numbers of lead shot; for example, mortality is increased by 9 % in birds having 1 shot in their gizzard and up to 75 % in birds having > 6 lead shot in their gizzard.

The birds studied by Bellrose were wild-caught, dosed with lead shot, provided with leg bands, and released. Hunters were asked to report bands on birds that they had shot. Bellrose (1959) concluded that a considerable proportion of the recovered bands came from bagged (shot) mallards. Experiments were performed in three consecutive years with mallards dosed with 0, 1, 2, or 4 lead pellets.

RAC notes that the method described by Bellrose (1959) does not measure population mortality directly, but was designed to infer changes in relative mortality rates based on the number of band recoveries in control and treatment groups over the period of the study (four years post banding). Bellrose also reported that lead-exposed birds are more frequently shot in the first year after dosing than control birds.

The more lead pellets that mallards were administered, the greater the percentage of birds were shot in the first season, within a few weeks of release. RAC agrees that this is evidence that sub-lethal effects in the mallards, after ingestion of lead shot, makes them more vulnerable to hunting.

The data also show that among the mallards surviving the first year, a lower percentage of treated mallards were shot in the three subsequent years compared to the controls. The difference was presumed by Bellrose to be caused by excess (unobserved) mortality among the treated mallards caused by lead poisoning. However, the mortality rate calculations performed by Bellrose do not appropriately reflect these assumptions, as they were simply the ratio of the number of banded birds recovered after the first year of banding to the total number of banded birds recovered in the four year period after banding. Also, Bellrose's calculations are not consistent with contemporary methodological approaches for estimating mortality rates from studies on the recovery of banded birds. Thus, in the view of RAC, the mortality rates reported by Bellrose associated with the ingestion of lead shot should be interpreted with caution, and more likely reflect sub-lethal effects rather than mortality.

Based on the excess mortality rates for mallards, Bellrose (1959) calculated that 3.98 % of the US mallard population died each year because of lead poisoning. Bellrose also mentions "*The results of twice-weekly surveys of public shooting grounds in central Illinois during recent hunting seasons indicate that the waste, or unharvested loss, due to lead poisoning is about one-fourth less than the 3.98 % calculated as the total loss, or approximately 3 %.*" However, there is no further data or reference given to support this statement.

RAC also notes that the author has used the same data to estimate that mallards dosed with 1, 2, or 4 shot are 1.48, 1.89, and 2.12 times more likely than the controls to be shot the first year, respectively, which he defines as "relative hunting vulnerability". RAC can

support these estimates and notes that an increase in hunting vulnerability (caused by sub-lethal effects) after ingestion of lead shot is supported by:

- the increased risk of being shot was most pronounced the 3 first weeks after the release (Bellrose, 1959), which coincides with when the lead pellets are dissolved, the concentrations in the birds peak (Rodriguez *et al.*, 2010), and the toxicological effects are likely to be worst,
- a larger proportion of the mallards dosed with lead pellets than control birds were shot close to the place of release (< 50 miles). Thus, 77 % of mallards dosed with 2 pellets versus 58 % of controls were shot within 50 miles of the release in the 1950 study, and 96 % of mallards dosed with 4 pellets versus 69 % of controls in the 1951 study (Bellrose, 1959),
- birds killed by hunters are three times more exposed to ingested lead pellets than birds randomly sampled from the same population (Heitmeyer *et al.*, 1993, cited in Tavecchia *et al.*, 2001),
- administration of one lead pellet (size 4) to farmed mallards caused 50 % mortality in a study by Rodriguez *et al.*(2010), a 90 % mortality was observed in farmed mallards administered one lead pellet (size 4) by Brewer *et al.*(2003), and Rattner *et al.*(1989) showed 30 to 60 % mortality in captured wild mallards dosed with 3 to 5 (size 4) pellets and then kept in captivity. Although there are studies showing no mortality after administration of 1 pellet to mallards, the weight of evidence indicates that already ingestion of 1 pellet can be fatal, and at least is likely to result in sub-lethal toxicity,
- a study by Mateo (2009) suggesting a relationship ($r=-0.63$, $p=0.012$) between prevalence of lead pellet ingestion and population trends in 15 species of wintering waterfowl,
- a study by Tavecchia *et al.* (2001) showing that the recovery of rings from 2 740 ringed mallards wintering in southern France was lower in birds that had lead pellets in the gizzard when ringed (as shown by X-ray) than in birds without pellets, which was interpreted as a 19 % decreased survival of birds with lead in the gizzard.

Since the methods used by Bellrose to analyse his extensive dataset are rather dated and simplistic compared to current approaches, Green (2017, submitted) reanalysed the Bellrose dataset using contemporary methods and submitted this to ECHA and RAC through the Public Consultation⁷.

The new calculations use the same data as Bellrose to calculate the mortality associated with lead shot ingestion. Green first estimated total mortality (mortality from lead poisoning plus mortality associated with increased vulnerability to hunting) and then estimated the mortality associated with lead poisoning only, by subtracting the effect associated with the increased vulnerability to hunting. Based on a 50 % reporting rate of recovered bands (from the finding that reporting doubled in an experiment where hunters were paid for reporting recovered bands), Green calculates the increased vulnerability to

⁷ Comment #1612

hunting as being 6, 23, and 21 % in mallards dosed with 1, 2, or 4 lead pellets, respectively.

In contrast to Bellrose (1959), the methodology reported by Green estimated total mortality excluding the available data on the recovery of birds during first year of the study. The total mortality was estimated to be 11 % (95 % confidence limits; 1-20 %), 47 % (95 % confidence limits; 33-59 %) and 55 % (95 % confidence limits; 42-67 %) in mallards dosed with 1, 2 or 4 lead pellets, respectively.

The difference between total mortality and increased vulnerability to hunting represents the mortality caused by lead poisoning, and is 4 % (95 % confidence limits; 0-25 %), 24 % (95 % confidence limits; 9-38 %), and 35 % (95 % confidence limits; 19-48 %) in mallards dosed with 1, 2 or 4 lead pellets, respectively.

In the view of RAC, the new calculations are scientifically sound, and more appropriate than the original calculations reported by Bellrose. However, the new data analysis also indicates that combining data across all three years of the Bellrose study results in large confidence intervals.

Table 1. Effects of administered lead pellets on Mallard survival; a re-analysis of Bellrose (1959) data by Green (comment #1612).

Number of administered lead pellets	Total mortality	Lead poisoning	Increased vulnerability to hunting
	% of birds affected; mean (95 % confidence interval)		
1	11 (1-20)	4 (0-25)	6 (4-10)
2	47 (33-59)	24 (9-38)	23 (15-32)
4	55 (42-67)	35 (19-49)	21 (14-28)

The methodological basis for the mortality rates originally calculated by Bellrose are not considered to be reliable, thus the revised estimates of mortality calculated by Green should preferably be used. However, acknowledging the large confidence intervals and the small difference between the estimates reported by Bellrose and Green (which could be as a result of coincidence), RAC agrees with the approach of the Dossier Submitter to use estimates of annual mortality underpinned by the Bellrose mortality rates for further calculations of total bird mortality in the EU and subsequently for socio-economic calculations, since mortality incidences of 3.1 %, 8.7 %, and 6.1 % calculated by Pain *et al.* (2015), Mateo *et al.* (2009), and Andreotti *et al.* (2018) respectively, are based on the application of the Bellrose methodology.

Although the Dossier Submitter's calculation involves many uncertainties, they indicate that in the order of 1 million birds per year (range 400 000 to 1 500 000) die annually from lead poisoning in the EU. Death of larger wetland birds, such as flamingos or swans has indeed been observed, but it is likely that small dying or dead birds are quickly caught by predatory or scavenging birds (or mammals) and they are therefore not easily observed or found, as reported by USFWS (1986).

All bird species that are hunted and bagged in wetlands are assumed to be for human consumption. Birds that have ingested lead shot have elevated concentrations of lead and are also more vulnerable to hunting. Thus, birds harvested for human consumption are likely to be contaminated with lead (possibly also via fragments of the shot used to kill the bird), even though exposure to humans has not been quantified.

It is noted that lead contains up to 1.5 % arsenic, which is also a well-known toxicant. So if assuming 4 740 tonnes of lead (central estimate) released to wetlands from lead shot, up to 63 tonnes of arsenic is potentially also released. However, this is not further assessed by the Dossier Submitter or by RAC in this opinion.

Information on emissions and exposures

Summary of proposal:

According to the Association of European Manufacturers of Sporting Ammunition (AFEMS), the annual consumption of shot cartridges in Europe is estimated to be, at least, between 600 and 700 million units. This corresponds to a total of at least 18 000-21 000 tonnes of lead being dispersed annually into the environment from hunting. In terms of wetlands, releases of lead from hunting in wetlands in EU-27 was estimated by the Dossier Submitter to be in the range of 1 432 to 7 684 tonnes of lead per year.

Each lead shotgun cartridge may contain several hundred individual pellets that are dispersed into the environment during hunting or sports shooting. Only a small proportion of the pellets (e.g. in the order of 1 % or fewer) are likely to hit and be retained in a killed bird (Cromie *et al.*, 2010), while ≥ 99 % of the shot are spread in the environment. The density of spent lead gunshot in the environment is an important factor influencing the likelihood of ingestion and developing adverse effects.

The available evidence from Europe suggests that lead shot is not evenly distributed within wetlands and that there are zones with higher densities, influenced predominantly by the hunting technique practiced. For example, hunting from fixed blinds or shooting posts tends to result in greater density of shot within a given area than more mobile hunting. In the Brescia district (in northern Italy) in an area with more than 5 100 hunting posts, Andreotti and Borghesi (2012) estimated a conservative mean of 5-6 kg of lead pellets are dispersed annually in the surroundings of each post. Based on 92 samples from across eight Member States, lead shot density within wetlands ranged from 0 to 399 shot/m² (Mateo, 2009). The average, median and 90th percentile densities were 52, 21 and 148 shot/m², respectively.

There is evidence reported in the Background Document that shooting ranges may result in even greater contamination of wetlands, with shot densities in the order of 2 000 shot/m² reported in wetlands from four Member States (Denmark, the Netherlands, Ireland, and Spain).

The time required for pellets to become unavailable (buried beyond the foraging depth of birds) after they have been dispersed in the environment varies in relation to several environmental variables (USFWS, 1986), including the amount of shooting over a particular wetland, the firmness/type of the bottom sediment, and the depth of water. Experimental field studies show that the risk of ingestion decreases over the years as the lead pellets settle in the sediment, but that it may take decades for pellets to become completely unavailable to water birds in some circumstances. Still, it is likely that the majority of gunshot ingested by wildfowl is that most recently deposited and that wildfowl searching for grit are more likely to ingest the readily available recently deposited shot. This is supported by a study by Anderson *et al.* (2000) (cited by Pain *et al.*, 2015), showing that 5-6 years after the US ban on lead gunshot in wetlands, 75 % of the gunshot found in waterfowl gizzards were non-lead shot.

The prevalence of lead shot ingestion typically refers to the presence or absence of lead

gunshot in the gizzard of a bird. However, of equal interest is the number of lead gunshot that have been ingested, i.e. the magnitude of the exposure. The prevalence of lead gunshot ingestion has been reported to vary between species and populations, most likely as a function of diet and grit preference. Species that prefer larger grits are reported to be at greater risk of ingesting spent lead gunshot.

At least 33 European bird species have been reported to ingest spent lead shot. Mateo (2009) reported mean prevalence of lead gunshot ingestion in mallards from northern Europe to be 3.6 % (n=8 683 shot or trapped individuals) and in central and southern Europe to be 17.3 % (n=11 239). Higher prevalences have been reported for other European species. For instance, a prevalence of 32.1 % in common goldeneye (*Bucephala clangula*) and 58.3 % in tufted duck (*Aythya fuligula*) were found in Finland and a prevalence of 50 to 70 % in the northern pintail (*Anas acuta*) and the common pochard (*Aythya ferina*) in Spain. Many wader species across the EU are likely to also ingest lead shot. In France, studies found that the waders jack snipe (*Lymnocyptes minimus*) and common snipe (*Gallinago gallinago*) had shot ingestion levels of 6.5 % (of 178 birds) and 15.6 % (of 269 birds), respectively.

Thus, there is extensive evidence describing the risks to waterbirds from the use of lead gunshot. This is supported by the fact that many jurisdictions throughout the world, including many EU Member States, have already enacted regulation of one type or another to prohibit or reduce the use of lead gunshot in wetlands (or for hunting waterbirds).

RAC conclusion(s):

RAC notes that up to 21 000 tonnes of lead are estimated to be released into the environment (all habitats) per year from hunting with lead gunshot. Within this, the Dossier Submitter estimates that the proposed restriction on wetlands could prevent the release of between 1 432 to 7 684 tonnes of lead per year, depending on the number of hunters affected (best case to worst-case range). RAC notes that the Dossier Submitter's central 'most-likely' estimate of 4 740 tonnes of lead used in wetlands corresponds to approximately 20 % of total lead used in gunshot for hunting). In addition, there is an unquantified, but probably considerable (at least in some EU countries), additional contribution of lead from any shooting ranges located in wetlands⁸.

The occurrence of spent lead shot in wetland sediment is well documented, including in wetlands affected by shooting ranges. Direct exposure of water birds through the ingestion of spent lead shot has been shown in numerous bird species from across the EU, in some cases affecting a very large portion of populations. RAC thus agrees that the use of lead shot in or nearby wetlands results in exposure of water birds to lead, which poses a risk to these birds.

RAC also acknowledges the secondary exposure of scavenging or predatory birds. In addition, since it has been well established that waterbirds having ingested lead shot are more likely to be shot, there is also a potential exposure of humans consuming game (e.g. mallards). Humans may also be exposed via fragmented lead shot particles that is then

⁸ To address this uncertainty, information on shooting ranges in wetlands was specifically requested in the public consultation on the Annex XV Dossier.

present in the harvested bird.

RAC notes that some species of waterbirds like geese and swans to a large extent feed outside of wetlands e.g. in agricultural areas. Since especially geese also are hunted in these areas using lead shot, sometimes after attracting the birds by spreading feed in these areas, agricultural land may also be contaminated with lead pellets available for ingestion. Since this restriction only addresses the use of lead shot inside wetlands, RAC agrees with the Dossier Submitter that waterbird species that feed outside of wetlands will not be protected by this restriction or only partially protected. However, an assessment submitted by the AEWA Secretariat in the Public Consultation⁹ confirmed that the majority of species vulnerable to lead poisoning (85 out of 100 AEWA-listed species) feed primarily in wetlands.

Key elements underpinning the RAC conclusion(s):

For every lead gunshot cartridge fired, all (if missing the target bird) or nearly all pellets (if hitting the target bird) are spread to the environment. If the spent lead pellets land in a wetland, they may be ingested by waterfowl, either as a grit or mistaken as food (seed). The digestive system of many species of European wetland birds has been analysed for the presence of lead pellets. In most cases a few percent of the birds contain lead pellets, but in some species up to 70 % of the birds contain lead pellets. In exceptional cases, the gizzard of a single bird may contain hundreds of lead pellets. The potential for high exposure of waterbirds to lead from spent lead shot is thus well documented.

Birds that have ingested lead pellets have been shown to be more likely to be shot by hunters, probably as a consequence of sub-lethal toxicity caused by exposure to lead. The Bellrose study (1959) showed that mallards dosed with one lead pellets were 1.5 times more likely to be shot in the season of the dosing, and two pellets almost doubled the risk. Heitmeyer *et al.* (1993) showed that birds killed by hunters were three times more exposed to ingested lead pellets than randomly sampled birds from the same population. This suggests that bagged game from wetlands may contain elevated concentrations of lead (also by lead fragments in the bagged game). The contribution to overall human exposure to lead via the consumption of game from wetlands was not quantified by the Dossier Submitter, but it is likely that consuming game from wetlands will contribute to individual lead exposure. Considering the non-threshold effects of lead on neurodevelopment, it seems prudent to minimise human exposure to lead via wetland game.

Waterbirds that have ingested lead pellets are likely to suffer from sub-lethal and lethal toxicity. Waterbirds frequently also contain 'embedded' shot as a consequence of being previously wounded but not killed by a hunter. Embedded shot are not typically considered to result in poisoning of the waterbird, but are available for secondary ingestion by predators/scavengers. Affected/wounded birds will be targets for predatory birds, resulting in exposure of the predatory birds to lead via their prey. Although this specific exposure pathway has not been quantified, it is known that birds of prey often have elevated concentrations of lead (by different reasons). Considering that lead toxicity is likely to

⁹ (#1873)

target neurodevelopment also in birds, and that the hunting technique of many birds of prey require a well-functioning neuronal system, it is likely that a restriction will have beneficial effects also on birds of prey. A recent study in Golden Eagles (*Aquila chrysaetos*) has indeed suggested a correlation between lead blood levels and behaviour (flight height and movement rate) and that eagles found dead due to rail or road collisions usually have higher liver lead levels than eagles dying from other reasons (Ecke *et al.*, 2017).

Characterisation of risk(s)

Summary of proposal:

It is estimated that, based on an assessment of 22 species of waterfowl and 11 species of waders and rails, between 400 000 and 1 500 000 waterbirds currently die every year from ingesting lead shot in EU wetlands. These estimates should be considered as minimum impacts as they do not account for sub-lethal poisoning within these species, or for lethal effects on other waterbird species that could also ingest spent lead gunshot. These estimates also do not take into account lethal or sub-lethal effects on predatory or scavenging birds via secondary poisoning.

There is extensive evidence describing the risks to waterbirds from the use of lead gunshot. As compared to background lead levels in blood of < 20 µg/dL, subclinical poisoning is reported at blood levels of 20-50 µg/dL, clinical poisoning at 50-100 µg/dL, and severe effects or death at > 100 µg/dL blood. This is supported by the fact that many jurisdictions throughout the world, including many EU Member States, have already enacted regulation of one type or another to prohibit or reduce the use of lead gunshot in wetlands (or for hunting waterbirds).

In addition to environmental risks, there may also be risks to human health from the consumption of wildfowl shot with lead shot. Exposure to lead in humans is associated with a wide range of adverse effects, including various neurodevelopmental effects, mortality (mainly due to cardiovascular diseases), impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes. For children, the weight of evidence is greatest for an association between blood lead concentration and impaired neurodevelopment, specifically reduction of intelligence quotient (IQ).

Use of lead gunshot (especially in shooting ranges) may also endanger water (including ground water) resources at a local level.

RAC conclusion(s):

The large-scale contamination of wetlands with thousands of tonnes of lead annually from the use of lead gunshot for hunting in wetland is clear and well supported. Likewise, the large-scale exposure to lead of numerous wetland bird species by ingestion of spent lead pellets is well documented. Secondary exposure of predatory or scavenging birds (documented for e.g. marsh harrier), as well of humans consuming wetland game, is very likely, but the overall extent of this exposure is not quantified.

Using the Bellrose (1959) methodology, and reported incidences of lead pellets in gizzards, Mateo *et al.* (2009) calculated the annual mortality in European populations across 17

wetland bird species to be 8.7 %. A similar estimation for 16 water bird species in UK (Pain *et al.*, 2015) resulted in an incidence of 3.1 %. Andreotti *et al.* (2017) estimated that 6.1 % of the wintering population of 16 species in the EU die annually, and that 3-fold more birds suffer sub-lethal effects. Based on these incidences, and the European population size of 22 species known to ingest lead pellets (excluding the populations in the four Member States that have banned the use of lead shot), the Dossier Submitter estimated an annual mortality of between 400 000 and 1 500 000 birds (central estimate 900 000). RAC acknowledges that these calculations have been performed using a methodology accepted in the scientific community and despite some uncertainties, they provide a clear indication of mortality and may indeed be minimum impacts. The new assessment of the Bellrose data by Green is in the view of RAC more correct, but results in a similar estimate of the mortality. Thus, RAC supports using the Bellrose numbers and calculations by the DS of an annual mortality of, in the order, of 1 million birds.

The use of lead shot in wetlands is also likely to result in lethal and sub-lethal effects on predatory or scavenging birds via secondary poisoning from eating lead-poisoned wetland bird species. However, it is not possible to quantitatively estimate to what extent this may occur.

Likewise, although not quantified, it is possible that humans eating game from wetlands will be exposed to lead through such food.

The presence of various restrictions on the use of lead shot in wetlands in 24 out of 28 Member States indicates that a concern with this use in wetlands is already recognised in most Member States.

Key elements underpinning the RAC conclusion(s):

Comments in the PC from AFEMS¹⁰ have stated that only population effects should be of concern in environmental risk assessment, and thus the death of individual birds is not a concern. However, against this, there is a common understanding, supported by RAC that an environmental risk assessment should not only protect against the risk for extinction of bird populations and species, and that the issue is more how large a percentage of a population should be affected before this becomes a problem.

A modelling approach by Meyer *et al.* (2016) on the population effects of lead gunshot on three mainly terrestrial bird species showed a 10 % decrease in the size of a grey partridge population, no effects on the size of a common buzzard population, and a reduced growth rate of 1.5 % in a red kite population. For waterbirds, the situation is likely to be worse. Bellrose (1959) suggested a yearly mortality of 4 % of the US mallard population caused by ingestion of lead gunshot, and Mateo *et al.* (2009) suggested a relationship ($r=-0.63$, $p=0.012$) between the prevalence of lead pellet ingestion and population trends in 15 species of wintering waterfowl. Thus, effects have been indicated on the population level.

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, perhaps

¹⁰ Association of European Manufacturers of Sporting Ammunitions, comment #1581

because the concern caused by mortality is greater in a small population, especially if threatened with extinction, than in larger populations. In fact, lead poisoning (through primary or secondary exposure) concerns several European wetland bird species that are considered to have vulnerable or endangered conservation status in the EU, notably the white-headed duck (*Oxyura leucocephala*), marbled teal (*Marmaronetta angustirostris*), and greater spotted eagle (*Clanga clanga*). Thus, the idea that 'acceptable risks', in the form of population-level mortality, among species with such diverse population biology, migration patterns, feeding habits and vulnerability to lead poisoning can in some way be estimated and managed is not supported by RAC.

In the opinion of RAC, the annual mortality estimate of ca. 1 million birds via lead gunshot ingestion, even if this estimate covers 33 species gives sufficient concern in its own right. In addition, a PEC/PNEC comparison indicates similar concern as 25 to 100 % of some studied species have had tissue concentrations of lead above the threshold for subclinical toxicity (i.e. Whooper swans, Bewick's swans, pintail and pochard in the UK; flamingos in Italy and Spain; and Northern pintail in Spain).

RAC concludes that the widespread effects of lead on many waterbird species is sufficient to warrant the restriction, and notes that some waterbird species, for which lead pellet ingestion data were used to estimate the yearly mortality of 1 million waterbirds, are categorised as vulnerable/endangered. For already threatened species, additional mortality caused by lead pellet ingestion can be of concern also for the survival of that species.

Uncertainties in the risk characterisation

Lead pellet ingestion is common among bird species living in wetlands, but the quantification of the extent of lethal and sub-lethal effects in these birds is uncertain. The available quantification of mortality (in the order of 1 million dead birds annually in Europe) seems plausible, but involves many uncertainties that could affect this estimate and the risk characterisation regarding waterbirds. There are also other uncertainties affecting the overall concern caused by the use of lead shot in wetlands, and they are discussed below.

Uncertainties	Effect on concern
The data analysis reported by Bellrose is not consistent with contemporary methodological approaches introducing some uncertainty. However, a recent reanalysis of the extensive Bellrose dataset using contemporary approaches by Green supports the mortality rates reported by Bellrose.	↓ ↑
The re-assessment of the Bellrose study by Green estimates the mortality caused by lead poisoning for mallards, and the large confidence intervals indicates that the resulting numbers are uncertain.	↑ ↓

The Bellrose methodology is based upon mallard data, and Bellrose (1959) suggested that perhaps other species are less sensitive based on most documented die-offs concerning mallards.	↓
Other (smaller/less common/threatened) species could be more vulnerable than mallards to ingesting lead pellets, as indicated by either having much higher prevalence of ingested lead pellets (e.g. 50 to 70 % in northern pintails) or finding individuals with extreme numbers of lead pellets in the gizzard (e.g. < 277 pellets/gizzard in flamingos).	↑
The calculation does not include all species that may ingest lead pellets in wetlands.	↑
For some waterbirds (e.g. geese), it is not clear if the ingestion of lead pellets has occurred inside or outside wetlands.	↓
Secondary effects in predatory or scavenging birds via secondary poisoning are not considered quantitatively.	↑
The extent of lead exposure of humans eating wildfowl has not been considered quantitatively.	↑
Effects caused by lead on threatened/endangered species have not been specifically assessed, and seem particularly important.	↑

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

Summary of proposal:

The use of lead in or over wetlands is not adequately controlled, since four Member States lack any legislation and the legislation implemented in other Member States are inconsistent in terms of their scope. Thus, harmonisation across Member States should be undertaken to ensure a sufficient control of risks.

RAC conclusion(s):

The frequent findings of water birds with lead pellets in their gizzard indicate that lead shot are still used on a large scale in wetlands, and that further risk management measures are needed.

As regards the availability of alternatives to lead gunshot, facilitating voluntary substitution of lead gunshot to alternative (e.g. steel) gunshot, such alternatives have not

been provided (by manufactures/importers) on the market in all Member States.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

Union-wide action is needed to address the environmental risk associated with the use of lead gunshot in EU wetlands since the flyways of migratory birds typically cross several Member States. Regulating the risk to them at Union level is likely to ensure an appropriate level of protection throughout the EU.

In addition, this restriction would ensure an effective implementation of the Agreement on the conservation of African-Eurasian Migratory Waterbirds (AEWA) as managing the risk on a Member State level has resulted in inconsistent national regulations, including four Member States that have not implemented any controls on the use of lead gunshot in wetlands.

RAC conclusion(s):

Lead pellets have been found in the gizzard of many bird species in many Member States, perhaps indicating that the present national restrictions are not sufficiently protective. However, the latest study is from 2014 (Mateo *et al.* 2014), and lead pellets ingested in 2014 could have been shot years previously. Thus, the present situation is unclear. An EU wide restriction, including in those countries presently lacking any restriction, is likely to protect the wetland birds more efficiently, throughout their migratory routes. The public consultation resulted in many supporting comments for the proposed restriction.

JUSTIFICATION IF ACTION IS REQUIRED ON A UNION WIDE BASIS

Justification for the opinion of RAC and SEAC

Summary of the proposal:

Shooting with lead gunshot in wetlands, or where spent (i.e. fired) lead gunshot would land within a wetland, results in various risks all over Europe. Spent lead gunshot is frequently ingested by waterbirds such as ducks, geese and swans that typically inhabit wetlands, leading to a range of acute or chronic toxicological effects (often termed as lead poisoning), including death. Shooting with lead gunshot in wetlands also poses a risk to predatory or scavenging species via secondary poisoning¹¹. The consumption of waterbirds

¹¹ Secondary poisoning occurs by exposure to gunshot embedded in the tissues of birds that were killed but not retrieved, or wounded but not killed, as well as by exposure to lead from the gizzard, or from lead accumulated in their tissues from the dissolution of gunshot after ingestion.

shot with lead gunshot, or with elevated tissue concentrations of lead, may also pose a risk to human health. In addition, deposition of lead gunshot results in general environmental contamination with lead and may locally result in contamination of groundwater resources.

The proposal primarily aims at protecting birds from the aforementioned risks of lead gunshot deposited in wetlands by shooting. The Dossier Submitter concludes that Union-wide action is needed to address the risks associated with the use of lead gunshot in EU wetlands. Managing the risks at Member State level has resulted in a whole range of regulatory actions including a total ban of lead gunshot. However, four Member States have not implemented any regulation on the use of lead gunshot in wetlands. Therefore, risk management measures implemented in Member States are inconsistent in terms of their level of protection of waterbirds and the environment in general. Since the flyways of migratory birds typically cross several Member States, this restriction would ensure the effective implementation of the African-Eurasian Waterbird Agreement (AEWA), to which the EU is a contracting party. Currently, national measures are not sufficiently effective in the protection of migratory birds, and regulating the risk at Union level is more likely to ensure an appropriate level of protection throughout the EU.

Apart from the risks to birds, the Dossier Submitter also highlights the other risks related to shooting with lead gunshot, e.g. to human health, that will be reduced by the proposed restriction.

RAC conclusion(s):

Based on the key principles of ensuring a consistent level of protection across the Union (particularly noting that the flyways of migratory birds typically pass through several Member States), SEAC and RAC support the view that any necessary action to address risks associated with the use of lead shot in wetlands should be implemented in all Member States.

SEAC conclusion(s):

SEAC concludes that further action at Union level is required to address the risks associated with lead gunshot in wetlands. Furthermore, SEAC concludes that the effective implementation of AEWA requires a consistent minimum level of protection of waterbirds across the EU, which would be achieved by the proposed restriction.

Key elements underpinning the RAC and SEAC conclusion(s)

SEAC agrees that the risks posed by the emission of lead gunshot into wetlands are a Union-wide issue, because of the broad geographical distribution of wetlands inhabited by affected bird species all over Europe as well as the use of lead gunshot (shooting), which takes place across the EU. The migration of birds underlines the importance of protecting them from lead exposure in every Member State. More harmonised risk management of lead gunshot at Union level would achieve a consistent level of protection across the EU. Now, the EU risk management is inconsistent and, in breach with AEWA, four Member States have not implemented any controls on the use of lead gunshot in wetlands.

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

Justification for the opinion RAC and SEAC

Considering practicality and enforcement possibilities (see below), a restriction covering all use of lead gunshot (i.e. a total ban) would be the most appropriate measure. However, the mandate given to ECHA by the Commission is acknowledged, and the assessment of RAC and SEAC is accordingly focused on the proposed scope.

As to an EU wide measure, RAC and SEAC are of the view that the suggested restriction is appropriate.

Scope including derogations

Justification for the opinion of RAC

Summary of the proposal:

Lead and lead compounds	<ol style="list-style-type: none"> 1. Shall not be used in gunshot for shooting with a shot gun within a wetland or where spent gunshot would land within a wetland. 2. Lead gunshot shall not be in the possession of persons in wetlands; 3. For the purposes of paragraphs 1 and 2: <ul style="list-style-type: none"> • “shot gun” means a smooth-bore gun, • “gunshot” means pellets used in quantity in a single charge or cartridge in a shotgun; • “lead gunshot” means any gunshot made of lead, or any alloy or compound of lead with lead comprising more than 1 % of that alloy or compound; • “wetlands” are defined according to Article 1(1) of the Convention on Wetlands of International Importance especially as Waterfowl Habitat (Ramsar Convention). 4. Paragraphs 1 and 2 shall apply 36 months from entry into force of the restriction; 5. Member States may, on grounds of human health protection and environmental protection, impose more stringent measures than those set out in paragraphs 1 and 2. Member States shall inform the Commission of such measures.
-------------------------	---

RAC conclusion(s):

The scope of the proposal is clear if the definition of wetland is made clear in the restriction. Accordingly, the FORUM advises to add the definition of wetlands as a footnote to the restriction.

The justification for including peatland in the restriction have been challenged during the public consultation. However, RAC considers that the inclusion of 'wet' peatland within the restriction to be well justified and necessary. This is also supported by many comments during the public consultation. RAC acknowledges that fewer AEWA-listed waterbird species occur in 'dry' peatland habitats but after considering the risks posed by the use of lead gunshot in these habitats, as well as the practical difficulties in differentiating between 'wet' and 'dry' peatland, RAC supports including all peatlands in the scope of the restriction.

The proposal covers use of lead gunshot "where spent gunshot would land within a wetland", without defining this quantitatively. RAC is of the view that the understanding and risk reduction of the restriction would be increased if "where spent gunshot would land within a wetland" is explained further in the entry or expressed as a fixed 'buffer zone'. The buffer zone could be a quantified area in the immediate vicinity of a wetland where restrictions on the use of lead gunshot would apply in order to prevent spent lead gunshot from landing in a wetland.

RAC notes that REACH restrictions may apply to the manufacture, placing on the market or use of substances, mixtures or articles. The definition of 'use', in REACH (Article 3[24]) includes 'keeping' and 'any other utilisation' which implies that a restriction on 'use', without further qualification, implies a restriction on any of the uses defined under REACH, including 'possession'.

The proposed restriction is intended to prohibit any use of lead gunshot within a wetland (including possession) and the shooting of lead gunshot into a wetland from outside of a wetland ('*use [...] where spent gunshot would land within a wetland*'). Other uses, e.g. possession, outside of a wetland are not intended to be restricted on the basis that this would increase the scope of the restriction beyond wetlands; this understanding is supported by the fact that the socio-economic analysis was also made based on the above rationale. However, RAC notes that the proposed wording of paragraphs 1 and 2 may introduce ambiguity as it could be interpreted that the restriction on 'use' outside of a wetland is wider than intended. Thus, the meaning of use and possession are not equivalent or interchangeable in the proposal. RAC considers that it is very important that the wording of the restriction should unambiguously indicate what precise uses (e.g. shooting/possession) of lead shot are restricted and where (inside or outside of a wetland).

A restriction on possession is considered to enhance the enforceability (and therefore risk reduction potential) of the proposed restriction. However, comments in the public consultation have argued that a restriction on the 'possession' of lead gunshot in wetlands (or where spent lead gunshot would land in a wetland), in general, is too broad to be practical. The comments argue that it could also prevent keeping at home or whilst driving or walking through wetlands to hunting/shooting areas, and that refinement of the term 'use' should be considered to be more specific to the shooting/hunting context (e.g. use

could be refined to mean one of more of the following: shall not be discharged..., shall not be loaded into a shotgun..., shall not be possessed whilst shooting). There are examples of national legislation in the EU that prohibit '*possession whilst hunting*' to prevent lead poisoning in wetlands.

The RAC evaluation of this proposal is based on the assumption that possession can be regulated under Reach, but it is outside the expertise of RAC to assess this assumption. RAC supports a clarification of the scope of the restriction as long as it is clear that all types of shooting would be included, and notes that some concern expressed in the public consultation will be addressed by this clarification. Thus, possession should be interpreted as '**possession while hunting/sport shooting**'. RAC has not discussed if paragraphs 1 and 2 could be merged and if use in gunshot for shooting and possession while hunting/sport shooting could be restricted in the same manner and within the same area (e.g. fixed buffer zone).

RAC also notes the need to introduce an obligatory labelling requirement to the restriction for shotgun cartridges containing lead to ensure that it is clear to consumers (or enforcement authorities) that they contain lead. They could also be labelled to ensure that it is clear that the use of lead gunshot in wetlands is not permitted within the EU and communicate the risks that they are associated with (e.g. poisoning of waterbirds).

Considering the risk, there are good reasons to shorten the time period until entry into force (see further below).

Key elements underpinning the RAC conclusion(s):

The suggested scope of the restriction is, in principle, clear.

Article 1(1) of the Ramsar convention (as cited in paragraph 3 the restriction proposal) defines wetlands as:

"areas of marsh, fen, peatland or water, whether natural or artificial, permanent or temporary, with water that is static or flowing, fresh, brackish or salt, including areas of marine water the depth of which at low tide does not exceed six metres".

RAC notes that, although comprehensive and internationally recognised, the Ramsar definition of a wetland might result in misunderstandings as other wetland definitions have previously been implemented as part of controls on the use of lead gunshot in some Member States, which according to comments submitted in the public consultation are well-known and accepted. Thus, RAC considers that the scope of the restriction is clear if read in conjunction with the Ramsar definition of a wetland. The public consultation indicates that certain types of peatland¹², notably 'inactive' (typically dry) or peatlands 'without visible water' may not commonly be understood as wetlands by hunters, despite

¹² Ramsar guidance on peatlands outlines that peat is dead and partially decomposed plant remains that have accumulated *in situ* under waterlogged conditions. Peatlands are landscapes with a peat deposit that may currently support a vegetation that is peat-forming, may not, or may lack vegetation entirely. The presence of peat, or vegetation capable of forming peat, is the key characteristic of peatlands. Peatlands can be differentiated in terms of whether they are 'active' (typically wet) or 'inactive' (typically dry). An active peatland ("mire") is a peatland on which peat is currently forming and accumulating.

being considered as a wetland habitat under the Ramsar definition. The comments have also argued that hunting in peatlands is not associated with risks to waterfowl, and that the inclusion of peatland is not proportionate to the risk. Hunter organisations have therefore requested derogations for (dry) peatland, ostensibly on the basis that such a derogation would make the restriction more understandable and proportionate to risk.

The Background Document estimates that relatively more lead is released during peatland hunting than in other wetland habitats. Active (typically 'wet') peatlands are used by numerous waterbirds known to have ingested lead gunshot, including various species of geese, swans, as well as the common snipe, Jack snipe, common moorhen, common coot, black-tailed godwit and western water rail. Considering that numerous species of wetland birds living in active peatland are known to consume lead gunshot, and the large amounts of spent lead gunshot released into peatland habitats, from a risk point of view RAC is of the opinion that active peatland should clearly be included in the scope of the restriction.

Comments in the public consultation by AEWA indicate that seven waterbird species and marsh harrier (via secondary poisoning) are potentially also at risk of ingesting lead gunshot in dry peatland, especially during the breeding season. In addition, Thomas *et al.* (2009) have reported that 'terrestrial' red grouse (*Lagopus lagopus scoticus*) on UK moors (peatlands) ingest lead pellets. They reported that 4-5 % of 196 birds shot on moors had highly elevated bone lead levels, and lead isotope measurements showed that the lead came from lead gunshot.

Risks to humans from consumption of lead-contaminated birds is the same irrespective if the birds are shot in wet or dry peatlands, being an argument for also including dry peatland within the scope.

Furthermore, it may be difficult to differentiate between 'wet' and 'dry' types of peatland in practice, which is another reason for including all peatland within the scope. Still, it is acknowledged that the inclusion of 'dry' peatland may cause misunderstanding, at least initially, and that hunters and that hunter organisations oppose this inclusion.

The intention of the Dossier Submitter, when developing the wording of paragraph 1 and 2 of the proposed restriction, was to prevent the deposition and accumulation of lead gunshot in wetlands. This is in line with the request to develop a restriction from the Commission and the results of the risk assessment. The reasoning for the wording of paragraph 1 and 2 is described in section 5.3.1. in the background document, as well as the buffer zones analysed (and dismissed in favour for a dynamic/flexible approach).

RAC notes that the wording of the proposal by the dossier submitter differs between possession (§2) and use (§1). While possession is only restricted in wetlands, the use is restricted in wetlands and also nearby wetlands where shooting could result in spent gunshot would land within a wetland. The analysis of the Dossier Submitter is also focused on 'use'.

The intention of the Dossier submitter is clear as regards 'use', The Background Document (5.3.1) explains that this formulation relies "*on the experience, skill and local knowledge of those undertaking the shooting (e.g. in terms of the likely distance that lead gunshot will travel once fired, noting that 'fall-out' distances of 300 metres may not be uncommon)*"

and further that *“this was considered as the most appropriate means of describing the scope of the restriction in relation to the risks and the request from the Commission.”* The Dossier submitter states that the proposed wording “where spent gunshot would land within a wetland” *“is considered to be a flexible, dynamic and ‘fit-for-purpose’, approach to address the risk posed from lead gunshot in wetlands in a proportionate way.”* and that *“this was in recognition that flexibility and discretion is likely to be required to account for the specific local circumstances (e.g. site specific topology, wind conditions, shotgun, ammunition) that will combine to determine the likelihood that spent lead shot would land within a wetland.”*

On the other hand, RAC notes that this flexible approach without a fixed buffer zone around a wetland would mean that on one day under specific conditions and for a specific hunter with specific gear a point in space would be inside the restriction and on another day with different conditions, different hunter and different equipment would maybe not be inside the restriction. Also, enforcement will be difficult if compliance depends on the direction the hunter aims at.

Question 2 (b) in the public consultation ask for comments on “how wetlands definition have been implemented in practice and if e.g. buffer zones around wetlands have been used”. This resulted in various comments, including some in favour of a large fixed buffer zone of up to 300 metres. One comment highlighted that the safety requirement to avoid the risk from falling shot on clay target ranges is 300 meters and that - to be meaningful - any buffer zone to prevent lead shot falling into wetlands should be of that order¹³. Another comment points out, that in practice much of the hunting at wetlands takes place while the hunters are not inside the wetland, but rather just outside of it (e.g. lake shore, river bank, etc.). Thus, spent lead shot can be still deposited in the wetland while shooting birds over or nearby the wetland¹⁴. In the federal state Mecklenburg-Vorpommern in Germany¹⁵, there is legislation that prevents the use of lead gunshot in a buffer zone of 400 m enclosing every type of wetland.

There is some variability as to how far gunshot can travel once fired, and thus how far away from a wetland the restriction would need to apply in order to prevent lead shot from landing within a wetland. Comments received in the public consultation indicate that gunshot missing the target may travel up to 400 metres¹⁶. The Dossier submitter notes that *“fall-out’ distances of 300 metres may not be uncommon”* (section 5.3.1). The distance strongly depends on the current weather conditions the trajectory of the shot and the combination of shotgun, propellant, shot load and size of lead shot used. It is also noted that lead shot may spread in an angle of up to 140 degree in front of the hunter (Krebs 2004, p. 552, via comment #1785). However, gunshot is only lethal to birds within a distance of perhaps 30 metres. The intention of the Dossier Submitter is that shooting towards a wetland, where the lead gunshot would land within the wetland, should not be permitted. RAC assumes that the consequence is that there should be no shooting towards a wetland at distances of less than perhaps 300-400 metres from a wetland. When discussing a potential usefulness of a fixed buffer zone versus the flexible approach

¹³ Comment #1607

¹⁴ Comment #1599

¹⁵ Comment #1685

¹⁶ Comments #1685, #1785

proposed by the Dossier Submitter, the arguments can broadly be divided into being related to enforcement, to legal aspects or to risk aspects.

Enforcement-related aspects

The inclusion of possession in the restriction proposal is important. If the proposed restriction will be enforced, it is important that the restriction is enforceable, and comments in the PC have expressed a concern that only hunters 'caught in the act of shooting' outside of a wetland can be enforced in spite of restricting 'possession' of lead gunshot within wetlands.

The scope of the proposed restriction covers use outside wetlands (if spent gunshot can land within a wetland) but not possession outside wetlands. This could hamper enforcement possibilities just outside a wetland (e.g. at a shore).

Below follows some arguments in relation to defining a quantitative buffer zone for possession:

- A fixed quantitative buffer zone around a wetland where possession of lead gunshot is not allowed (independent on in what direction the rifle is pointed) would assist and simplify enforcement no matter to which extent this buffer zone is defined (e.g. 30 metres or 300 metres). However, the scope might be considered to have been increased in relation to the original proposal as any shooting with lead gunshot (irrespective of purpose and direction) will be restricted in this zone (as shooting requires possession). The magnitude of the increase of the scope would depend on the distance from the wetland the buffer zone extends to.
- A fixed wide quantitative buffer zone (e.g. 300 metres) will be more difficult to estimate than a smaller one (e.g. 30 metres). Thus, a large buffer zone may be difficult to enforce if the wetland is not visible (behind trees, hills) from this distance. On the other hand, a large buffer zone around a wetland with a defined border (e.g. a Ramsar site or a wetland Natura 2000 site) could be displayed in maps and on signs close to the wetlands.
- A fixed wide quantitative buffer zone where the possession of lead gunshot is not allowed (e.g. 300 metres) has clear advantages to the enforcement since smaller wetlands patched in the landscape are aggregated to a larger protected area. This supports enforcement and the understanding of the restriction at the local level. This also increases the chance to visualise the protected areas in maps.
- A fixed wide quantitative buffer zone (e.g. 300 metres) might increase the risk of a hunter being illegal when moving inside the buffer zone between non-wetland areas when hunting non-wetland species. This risk is lower when only a fixed small quantitative buffer zone (e.g. 30 metres) is defined.
- Hunters and hunter organisations have argued strongly against the use of any fixed buffer zone. As enforcement is limited in most Member States, risk-reduction is dependent on compliance with the proposed restriction.

- If including any possession of lead gunshot in a fixed wide quantitative buffer zone (e.g. 300 metres), it might cause problems for people living close to wetlands as they may not be able to possess lead gunshot in their house or car.
- For wetlands where the border is uncertain, such as for seasonally flooded land and marshy areas, the definition of where a buffer zone starts and ends (irrespective of how it is defined in size) will also be uncertain. However, this will be a problem with or without a buffer zone and will depend on the interpretation of the Ramsar definition. In contrast, around a lake or river where the shoreline will constitute a clear border any buffer zone could also be clear.

FORUM in their advice has requested that this *“proposed territorial extension of the ban of using lead gunshot to neighborhood areas in order to protect wetland from landing of spent gunshot pellets would make it necessary to define a border line and to determine these neighborhood areas by decree. Otherwise identification and prosecution of offences would pose nearly unresolvable situations for enforcement. It can be assumed that additional 300 m is a reasonable distance for defining neighborhood areas.”* (See final version of advice by FORUM from August 2017).

Enforcement is generally helped by conditions that are as clear as possible. There are many different aspects to consider when it comes to the use of fixed quantified buffer zones. As regards enforcement, arguments in favour for a buffer zone are mainly related to having a small buffer zone (e.g. 30 metres) around objects with clear borders where possession of lead gunshot could be enforced without having to catch the shooter in the act of shooting. Whether this would increase or decrease to scope is a matter of interpretation, but it would decrease the difference in the proposal between restricting use outside wetlands “where spent gunshot would land within a wetland” but not possession outside wetlands. There is some support for a limited buffer zone for possession in RAC.

Risk-related aspects

RAC notes that the risk reduction capacity of the proposed restriction would clearly benefit from a fixed and wide as possible quantitative buffer zone (e.g. 300 metres) around each wetland. This is because it is known that many waterbirds may also feed and pick up lead shots outside a wetland. It is acknowledged that the scope of the present proposal does not cover species feeding outside wetlands, and that the scope as such cannot be increased by the committees. However, limiting shooting with lead gunshot in buffer zones in order to prevent spent gun shot to land in wetlands (or to help enforcement) will as a side effect probably also lead to less gunshot being spent in feeding areas very close to wetlands that may also be used by waterbirds.

When discussing risk-related aspects of a fixed quantitative buffer zone, there are two options: a quantitative buffer zone where shooting in any direction is banned or a quantitative buffer zone where only shooting towards a wetland is banned. Obviously, any ban on possession inside a fixed quantitative buffer zone only complies with the first option (i.e. that shooting in any direction is banned) as there cannot be any shooting if possession is prohibited. A possible exception is to ban possession (and thus all hunting with lead gunshot) within a limited buffer zone and have a fixed larger buffer zone where shooting

towards a wetland is restricted.

Arguments in relation to the two options and the size of a fixed buffer zone on the risk-related aspects and on the scope are given below.

- A fixed wide quantitative buffer zone (e.g. 300 metres) will increase the risk reduction capacity if all shooting (in any direction) is banned. This will lead to less lead being deposited both in the wetland and close to the wetland in potential feeding areas, but will extend the scope.
- A fixed wide quantitative buffer zone (e.g. 300 metres) is viewed by the DS as outside the scope if the buffer zone would concern shooting in any direction. It could also be deemed to increase the scope of the proposed restriction if concerning shooting towards a wetland as spent shot will not in all specific situations and under all specific conditions travel this distance. On the other hand, if it is true, that spent shot reach even further than 300 metres it might be viewed as decreasing the scope. If only including shooting towards a wetland, any deviation from the scope seems rather marginal.
- A fixed small quantitative buffer zone (e.g. 30 metres) would prevent the deliberate hunting of waterfowl (or any shooting) that is in or very nearby the wetland. However, this shooting is also restricted by the original proposed scope of the Dossier Submitter even in the absence of a fixed buffer zone. In contrast, a fixed small quantitative buffer zone (e.g. 30 metres) would not restrict shooting towards wetlands at distances 30 to 300 metres away from the wetland, which is implicitly covered by the original proposed scope of the Dossier Submitter. In other words, a fixed small quantitative buffer zone (e.g. 30 metres) would reduce the scope of the proposed restriction.

In a review of national legislations on the use of lead gunshot in wetlands, the DS has noted that;

- Wording similar to 'shooting on or over' wetlands (without fixed buffer zones) are used in the following Member States or regions within a Member State: France, Scotland, Northern Ireland, England and Wales. The restrictions place responsibility on those shooting to ensure that the spent lead gunshot does not land in wetlands.
- Whilst there is a buffer zone in the French legislation, it is better understood as a 'transition zone' where lead gunshot can be used, but only under specific circumstances e.g. when they are shooting away from a wetland. The transition zone in France only applies to features with a fixed, definitive boundary. For bogs and swamps hunters are required to ensure that no lead gunshot is deposited when shooting, i.e. the wording 'shooting in or over' takes effect.
- It appears that buffer zones in the sense of total exclusion zones are only used in member states where narrow bans are implemented in well-defined wetland sites with clear (mapped) boundaries. Examples of these are found in Italy (150 m, only SPA), Bulgaria (Ramsar sites 200 m), and Hungary Ramsar sites (100 m).

- In general, generic bans are not put in place with an accompanying buffer zone, but rather alongside a flexible (on or over) approach.

There are clearly different approaches in different Member States, and a harmonisation is needed. The compliance can probably become better, but it is not known how the different approaches affect compliance.

If quantitatively defining what is meant with “where spent gunshot would land within a wetland”, RAC is of the view that the travelling distance of lead shot should be an important factor when deciding the size of a fixed quantitative buffer zone. RAC notes that a large buffer zone will increase the risk reduction capacity of the proposed restriction. There is some support in RAC for quantitatively defining the buffer zone, and that it should be in the order of 300 metres.

As mentioned previously, there are also good enforcement-related reasons for a fixed buffer zone for ‘possession whilst hunting/shooting’.

There is also a possibility to propose two different fixed quantitative buffer zones, one for possession (§2) and one for shooting (§1), or just one of them.

Irrespective of the role of any buffer zone within the restriction, awareness campaigns will be needed to explain the restriction to stakeholders. As indicated by paragraph 5 in the proposed restriction, Member States will be allowed to impose more stringent measures than proposed by the DS. RAC assumes that this will also apply to potential buffer zones.

As mentioned above, the scope also includes possession of lead gunshot within a wetland. RAC notes that FORUM has questioned if ‘possession’ legally corresponds to the term ‘keeping’, which is used in REACH, and thus whether possession can be restricted under REACH. However, the definition of ‘use’ in Article 3(24) of the REACH Regulation includes ‘keeping’ and ‘any other utilisation’. This suggests that a restriction under REACH on ‘use’ would also implicitly allow Member States to restrict ‘possession’. Therefore, the Dossier Submitter has proposed to add this specific paragraph on possession in the restriction proposal only to explicitly identify that restricting possession within a wetland is within the scope of the proposal.

If possession is included in the restriction, RAC is of the view that this strengthens the need (see further below) to introduce and require specific labelling of cartridges containing lead gunshot (as opposed to e.g. steel gunshot), as possession of lead gunshot can be more easily demonstrated without dismantling the cartridges (and perhaps analysing the pellets). RAC notes that steel gunshot need to be labelled already, and RAC proposes introducing a similar requirement for cartridges containing lead gunshot. The labelling of lead gunshot could be complemented with information that the use of lead gunshot in wetlands is regulated in the EU.

There have not been any comments regarding the definitions of shotgun, gunshot, and lead gunshot, so RAC concludes that these definitions are clear.

Regarding the ‘entry into force’, there are many comments in different directions in the PC. Hunter organisations request a much longer time period (5-10 years) for hunters to adapt to the restriction, whereas other NGOs note there have been restrictions, of one

kind or another, for many years in most Member States, and that the proposed 3 years therefore is too long. The Dossier Submitter proposed 3 years to give producers of cartridges time to adapt. RAC notes that producers already produce non-lead cartridges, and that adjusting to a growing demand of non-lead gunshot might not need to take 3 years. Additionally, a ban in the US of the use of lead gunshot in wetlands since 1991 might indicate a global production capacity that rather quickly should be able to adjust.

From a risk point of view, for each additional year until entry into force, 4 740 tonnes of lead (central estimate) will be released to wetlands with numerous dead and affected birds as a result. Considering that 24 out of 28 Member States already have some type of restrictions on the use of lead gunshot in wetlands, RAC strongly support a shorter time of entry into force than three years. Various comments were received during the public consultation concerning the proposed transitional period, requesting a longer transitional period¹⁷ or a shorter transitional period¹⁸.

RAC notes the possibility for Member States to impose more stringent measures than the proposed restriction, which RAC supports.

Justification for the opinion of SEAC

Summary of proposal:

The European Commission requested ECHA to prepare an Annex XV restriction proposal for the use of lead gunshot in wetlands in order to harmonise regulation in the EU and to comply with AEWA¹⁹. The request addressed all uses of lead gunshot that would result in releases of lead gunshot to wetlands including hunting as well as sport shooting. Addressing this request, the Dossier Submitter screened variants of a restriction under REACH, and other possible risk management options (RMO), including non-restriction regulatory measures under REACH and other existing EU legislation as well as non-regulatory measures.

The Dossier Submitter rejected all of these options, because they were found not to be practicable, effective and/or proportionate to control the risks resulting from the releases of lead in gunshot to wetlands.

The risks from the use of lead gunshot outside of wetlands, or from other uses of lead ammunition, were not within the mandate given to ECHA by the European Commission and thus they were been assessed in detail.

The RMOs not related to REACH that were considered include voluntary measures, labelling

¹⁷ Comments #1562, #1563, #1581, #1584, #1587, #1588, #1589, #1590, #1593, #1595, #1600, #1601, #1602, #1604, #1731, #1743, #1744, #1745, #1746, #1747, #1749, #1750, #1751, #1752, #1753, #1754, #1756, #1757, #1759, #1760, #1762, #1764, #1766, #1767, #1771, #1775, #1782, #1783, #1784, #1814, #1866, #1870, #1880, #1881

¹⁸ Comments #1564, #1571, #1578, #1579, #1582, #1592, #1599, #1639, #1682, #1684, #1685, #1688, #1689, #1690, #1691, #1692, #1693, #1694, #1695, #1696, #1697, #1698, #1699, #1700, #1701, #1704, #1722, #1733, #1735, #1742, #1748, #1797, #1799, #1800, #1801, #1812, #1821, #1824, #1826, #1835, #1840, #1857, #1862, #1872, #1877

¹⁹ For details on the mandate from the European Commission to ECHA, please refer to https://echa.europa.eu/documents/10162/13641/echa_annex_xv_restriction_proposals_en.pdf

requirements, taxation, existing EU legislation (EU Birds Directive (2009/147/EC), EU Habitats Directive (92/43/EEC)), and international agreements (AEWA, the Bern Convention, and the Ramsar Convention).

Concerning other possible RMOs within REACH, authorisation was assessed. The Dossier Submitter considered this option as not suitable, because it would be disproportionate, as all uses of massive lead would then require an authorisation before use.

With regard to variants of a restriction, the proposal was compared to six other restriction options. These were (see Section E.1.2. of the Annex XV report):

1. Restriction on the placing on the market and use of lead gunshot;
2. Restriction on the use of lead gunshot for all hunting activities;
3. Restriction on the use of lead gunshot for all hunting of birds or hunting of waterfowl (e.g. ducks, geese and swans);
4. Restriction on the use of lead gunshot in Ramsar Sites and/or Special Protected Areas (SPAs) in the Natura 2000 network;
5. Phased approach to implementing a restriction on the use of lead gunshot in wetlands (firstly only Ramsar sites/SPAs covered, after a further implementation period all wetlands according to the Ramsar definition);
6. No additional restrictions on the use of lead gunshot (baseline).

In the Background Document, the Dossier Submitter assessed the different options (1-6) against the main criteria for a restriction given in Annex XV: effectiveness, practicality, and monitorability. Due to the mandate given by the Commission, which is explicitly limited to the use of lead gunshot in wetlands, the Dossier Submitter did not assess the impacts of options 1 to 3 in detail.

The Dossier Submitter still concluded that a total ban of lead gunshot (option 1) or a ban of the use of lead gunshot in hunting (option 2) could be more effective than the proposed restriction (see Table 5.1 in the Background Document). These two options could also be more practical as enforcement would most likely be easier. Apart from these criteria, monitorability is expected to be similar.

Based on a comparison of the proposed restriction with the remaining options (4 to 6), which were within the mandate from the Commission, the Dossier Submitter concluded that the proposed restriction was the most appropriate option in limiting the risks from releases of lead gunshot to wetlands. The Dossier Submitter considered Options 4 and 5 to be less effective in managing the risks and option 6 (baseline) as not appropriate.

Key elements underpinning the SEAC conclusions

SEAC agrees with the conclusions of the Dossier Submitter on the comparison of different RMOs within the mandate of the Commission. Options 4 and 5 are likely to be less effective than the proposed restriction and hence not as appropriate to address the identified risks.

SEAC notes that the scope of the RMO analysis carried out by the Dossier Submitter does not cover a detailed assessment of all relevant options due to the targeted mandate given by the Commission. Therefore, it cannot be excluded that some of the rejected restriction options, such as a total ban on the use of lead gunshot for all purposes (option 1), or only

for hunting (options 2), could address the risks posed by the use of lead gunshot in a more effective way than a restriction targeted on wetlands. SEAC also took note of the fact that the Dossier Submitter considered that a total ban on lead in gunshot could be more effective than the proposed restriction in limiting the identified risks.

In this respect, SEAC notes that the risks of the use of lead gunshot outside of wetlands, which would be important to consider in a more comprehensive approach to the risk management of the use of lead in gunshot and other types of ammunition (e.g. rifle bullets), were not assessed in the Annex XV dossier. An assessment of a total ban would have illustrated the relative impacts on humans and the environment compared to a restriction targeted on wetlands.

In terms of enforceability, a total ban is likely to simplify the enforcement necessary for a targeted restriction in wetlands²⁰ and better fit into existing organisations of enforcement, because the responsibility for compliance would not fall upon individual shooters, but on the producers and retailers of lead gunshot. SEAC considers that such a simplified approach to enforcement would likely result in greater compliance than a targeted restriction on the use in wetlands only. SEAC also notes that enforcement costs are likely to be lower for a total ban compared to the proposed restriction because enforcement would be targeted on retailers (which are more stationary) rather than on hunters while hunting.

In terms of manageability, (confidential) information provided by industry suggests that the market share of lead free gunshot is approximately 50 % of the total market for gunshot. Furthermore, most of the main manufacturers have separate production lines for alternative gunshot as demonstrated by an investigation by the Dossier Submitter (E.3.1.1. in the Annex to the Background Document). Therefore, it can be reasonably assumed that the costs for industry to cope with a total ban would be limited, because there would be no major need for opening new production lines. The availability of lead-free ammunition is first and foremost driven by the demand. The Dossier Submitter highlights a study from the United States, stating that industry indicated that manufacturers would abandon the use of lead gunshot, if a sufficiently competitive shotshell was developed (Friend et al., 2009). This is supported by the fact that the current demand for lead-free gunshot is limited, because waterfowl hunting loads are not the major segment of the shotshell market.

In addition to a ban on all uses of lead gunshot (option 1), SEAC notes that also a ban on the use of lead gunshot for hunting (option 2) is assumed by the Dossier Submitter to be potentially more effective than the proposed restriction. This would however imply that lead gunshot remains available, since placing on the market and use for non-hunting shooting would be exempted. Hence, enforcement under option 2 might be more difficult than in case of a total ban of lead gunshot. But still for hunters, it would be easier to comply with the legislation compared to the current proposal, because they will not have to identify the area covered by the restriction. Further information on the costs for the different shooters affected and on the risk reduction achieved would be crucial in order to compare costs and benefits and to assess the appropriateness of these other options.

²⁰ In most countries producers and retailers of ammunition need special permission and are often listed in registers. This would further facilitate the enforcement in case of a total ban.

In the public consultation on the Annex XV report, proposals were received suggesting that a ban on using lead gunshot for hunting birds or waterfowl (Option 3) would have been more appropriate than the proposed measure. However, comments received in the public consultation on the SEAC draft opinion noted that a species-specific approach would exclude shooting ranges in wetlands from the remit of the restriction and would therefore not sufficiently address the current risk to waterbirds (e.g. #374/AEWA). SEAC finds that an analysis of a ban for hunting birds or waterfowl (Option 3) by the Dossier Submitter, as well as options 1 (total ban) and 2 (ban for all hunting), would have been beneficial for assessing the effectiveness of the proposed option. As neither of these options have been analysed by the Dossier Submitter, SEAC does not have sufficient information to assess their socio-economic impacts compared to the proposed restriction.

Based on the arguments provided by the Dossier Submitter (summarised in Table 5.1 in the Background Document), SEAC considers that other options could be more effective and/or more practical compared to the proposed targeted restriction on the use of lead shot in wetlands. However, additional information and analysis beyond the scope of the mandate provided by the Commission to the Dossier Submitter would be required to confirm this conclusion and to assess the proportionality of such measures.

SEAC conclusions

Within the targeted scope of the assessment of risk management options, SEAC finds the arguments given by the Dossier Submitter to be valid and agrees with the conclusions made on the different options assessed.

However, in SEAC's view it is likely that there are more effective options to limit the risks posed by the use of lead gunshot to the environment and to human health than the proposed restriction on the use of lead gunshot in wetlands. A broader analysis of different RMOs would be needed to draw a well-informed conclusion on the most appropriate RMO. This was not possible within the confines of the mandate given to ECHA by the European Commission.

Overall, SEAC concludes that the proposed restriction is the most appropriate EU wide measure within the targeted scope of the mandate given to the Dossier Submitter.

Scope including derogations

Summary of the proposal

The aim of the proposed restriction is to address the risks posed by the use of lead gunshot in wetlands. Therefore, all shooting with lead gunshot that might result in lead gunshot landing within a wetland would be prohibited by the proposed restriction. Gunshot has been defined as "pellets used in quantity in a single charge or cartridge in a shotgun". The term "shotgun" has been specified as a smooth-bore gun. The Dossier Submitter proposed a limit value of more than 1 % of lead per pellet in order to define "lead gunshot".

In order to ensure that the risk of lead gunshot in wetlands will be effectively controlled, all wetlands need to be covered by the restriction. The Dossier Submitter proposes to define wetlands according to Article 1(1) of the Ramsar Convention, as follows:

“areas of marsh, fen, peatland or water, whether natural or artificial, permanent or temporary, with water that is static or flowing, fresh, brackish or salt, including areas of marine water the depth of which at low tide does not exceed six metres”.

The Ramsar definition of wetlands is a broad, internationally recognised definition of wetlands. In order to limit the risk in wetlands, the Dossier Submitter considers this definition of wetlands necessary to cover as many feeding and breeding grounds of migratory waterbirds as possible. The areas that are included in the restriction have to be clear in order to facilitate the enforcement of and compliance with the proposal. Various buffer zones were assessed by the Dossier Submitter (Section 5.3.1.3 in the Background Document), however a fixed buffer zone was not included in the restriction proposal. The Dossier Submitter considered the wording proposed in the entry, “where spent gunshot would land within a wetland” to be a flexible, dynamic, and ‘fit-for-purpose’ approach to address in a proportionate way the risks arising inside of a wetland from an original use of lead gunshot outside of a wetland. Whilst the Dossier Submitter acknowledges that this flexible approach relies on the experience, skill and local knowledge of those undertaking the shooting²¹, it is still considered as the most appropriate means of describing the geographical scope of the restriction, taking into account the risks to be addressed and the mandate from the Commission.

In addition to the use of lead gunshot, the restriction prohibits possession of lead gunshot in wetlands in order to facilitate the enforcement of the proposal. Feedback from stakeholders during the preparation of the Annex XV report indicated that the enforceability of the restriction proposal, and hence its risk reduction potential, would be enhanced by including the prohibition of possession of lead gunshot within a wetland. However, the Dossier Submitter acknowledges that a restriction on the possession of lead gunshot, i.e. carrying cartridges containing lead gunshot in wetlands, might have unintended impacts on shooters when transporting or carrying lead gunshot on routes through wetlands without the intent to use them, or when crossing wetlands to carry out shooting outside of a wetland. The Dossier Submitter considers that these impacts can be prevented by further specification of the term ‘possession’ (see 5.3.1 in the Background Document).

The transition period of 36 months proposed by the Dossier Submitter is based on information received from discussions with stakeholders and is considered reasonable to provide sufficient time to EU producers to increase production capacities of alternative gunshot, in particular steel gunshot.

The Dossier Submitter concludes that complementary enforcement, awareness-raising and educational programmes will facilitate compliance, but indicates that these activities would be up to Member States to implement. Although several examples from Member States are described in the Background document, the Dossier Submitter does not elaborate on how such measures could be implemented on an EU wide basis and what costs they would entail.

²¹ In terms of the distance that lead gunshot will travel once fired (‘fall-out’ distances of up to 300 metres are possible).

The proposal explicitly provides the possibility for Member States to introduce (or keep existing) more stringent measures outside of wetlands based on grounds of human health or environmental protection.

Key elements underpinning the SEAC conclusions

Risks to be addressed

During shooting, the major part of lead gunshot is spread into the environment where it may be picked up by waterbirds and contributes to the general environmental background levels of lead. The intention of the proposal is to address the risks posed by the use of lead gunshot, primarily those associated with primary and secondary poisoning of birds. In this respect, the focus of the proposal on wetlands seems appropriate. An assessment submitted by the AEWA Secretariat in the public consultation on the restriction proposal confirmed that the majority of species vulnerable to lead poisoning (85 out of 100 AEWA-listed species) feed primarily in wetlands. However, some waterbirds also feed outside of wetlands meaning the proposed restriction does not completely address the risks to those waterbirds. The Dossier Submitter has not quantitatively assessed this remaining impact. SEAC considers this as a scope-related shortcoming in the evaluation of the appropriateness of the proposal, noting that waterbirds feeding in other areas than wetlands, such as agricultural land, will not be covered by the proposal.

Other relevant impacts such as reduced lead exposure of humans via the environment, and particularly via the consumption of waterfowl, were mentioned by the Dossier Submitter as additional benefits of the restriction on the basis of a qualitative assessment (in the absence of sufficient information for a quantitative assessment). SEAC does not have sufficient information to evaluate the impact on humans, but recognises that RAC considers these risks to be relevant.

Definition of wetlands

In order for the restriction to be effective to protect waterbirds from the ingestion of lead gunshot, "wetlands" as defined by the proposal have to include as many of their feeding/breeding grounds as possible. At the same time, the definition has to be specific and clear enough to be implementable and enforceable. In this respect, SEAC notes that the use of the definition of the Ramsar Convention is appropriate, because it is broad and it has already been accepted at international level. However, the Ramsar definition provides only a description of the generic wetland habitat types, and does not define their precise borders.

SEAC notes that this generic definition of wetlands could cause difficulties in identifying certain types of wetlands in practice, e.g. peatlands, marshes and fens. This could therefore cause difficulties for those shooting to know whether they are in compliance with the restriction or not, e.g. in areas with a large extent of peatland, which is used for agricultural or forestry purposes. Such difficulties are not expected to arise for other generic wetland types included in the Ramsar definition, such as lakes, rivers or other areas of open water, which are more easily identifiable. The Ramsar definition does not include the size of a wetland, which may also complicate the identification of a wetland, in particular in areas that are characterised by a large number of water bodies of varying size, e.g. in Scandinavian forests.

In order to assess the practicality of the definition, the Dossier Submitter conducted a GIS study to explore what areas covered by their wetland definition (based on their corresponding CORINE land cover classes) were also covered by existing Natura 2000²² sites with cadastral borders (see Annex to Background Document, B.4.3.3.1.)²³. The results show that about 70 % of wetlands according to the Ramsar definition (other than waterbodies) lie within Natura 2000 sites²⁴. To SEAC, this indicates that the area subject to the restriction is identifiable in the majority of cases²⁵.

Nevertheless, for those shooting it can be problematic to judge in practice whether an area is a wetland or not, e.g. in landscapes with a large number of smaller puddles and/or more or less dry peatlands. Therefore, SEAC considers that the use of the Ramsar definition could limit the enforceability and compliance with the restriction in certain types of wetlands. Further guidance to assist enforcement and compliance would be advisable for some wetland types in order to facilitate a consistent and effective implementation of the restriction in the different Member States.

In this regard, SEAC notes that the Dossier Submitter has not proposed a fixed buffer zone around the wetland habitats that would be covered by the proposed restriction (i.e. where use and possession of lead gunshot would be prohibited). Accordingly, it is up to those shooting and inspectors to judge in each case if lead gunshot could land within the wetland when fired. However, several comments in the public consultation suggest the need to define a fixed buffer zone. In general, nature conservation organisations argue for a buffer zone of 300 m in order to prevent lead pellets from falling within a wetland, and hunters' organisations argue for not including a buffer zone. Their arguments are mainly focused on practical issues such as enforceability and the ambiguity that hunters might face when hunting. In some countries, there are already fixed buffer zones reaching 30 m from the border of the wetland. SEAC understands that it might be difficult to judge where the actual border of the wetland is, e.g. for peatlands. It therefore can be reasonable to include a buffer zone to clarify what area would be within the scope of the restriction and to safeguard against lead pellets from falling into the wetland. A wider buffer zone of 300 m implies a long distance between the current position of the shooter and the wetland. It may therefore be difficult for shooters and inspectors, to determine whether they are standing within the buffer zone or not. A shorter buffer zone, e.g. 30 metres, could hence be more practical. However, the Dossier Submitter has not assessed the impact of a fixed buffer zone arguing that this would extend the scope of the restrictions beyond wetlands. Therefore, SEAC cannot draw a conclusion on what impact a buffer zone, no matter the size, would have in terms of proportionality.

With regard to the habitats covered by the Ramsar definition, several comments were received during the public consultation of the restriction proposal, in particular from

²² Based on publicly available data from the EEA

²³ The analysis was produced based on the information available to the Dossier Submitter for the purposes of assessing the extent of wetlands that would be covered by the restriction. However, if data are to be used in an official capacity, for example for enforcement or compliance, the relevant Member States would need to update them based on the current situation in their territory.

²⁴ Lakes and rivers were not included in the GIS analysis, because their borders can be easily identified.

²⁵ SEAC notes that some areas (e.g. pastures or forests on dry peatland) were not included in the GIS analysis by the Dossier Submitter, which means that the area of the Corine land cover classes added underestimates the geographical scope of the restriction (see Background Document B 4.3.3.1). This is relevant for the cost assessment of the proposal and further discussed in the following section.

hunters' associations, stating that the inclusion of (dry) peatland in the scope of the restriction would be problematic and not justified. The main arguments are that it is difficult for a shooter to judge whether the land is peatland (i.e. wetland according to the Dossier Submitter's definition), and that in these areas lead gunshot is not imposing a risk to waterbirds. However, information provided by the Dossier Submitter and submitted during the public consultation by UNEP/AEWA (#1873) indicates that the use of lead gunshot spent in peatlands does impose a risk to waterbirds²⁶, as well as to other bird species. This conclusion is confirmed by RAC. In terms of practicality, SEAC acknowledges that it can be difficult for hunters as well as for inspectors to identify peatland as wetland, in particular with regard to dry peatland. In terms of costs of the proposal, SEAC points out that the inclusion of peatlands has been reflected in the cost assessment provided by the Dossier Submitter (see the section on socio-economic impacts below).

Possession

SEAC notes that the proposed restriction is intended to prohibit any use of lead gunshot within a wetland including possession. SEAC agrees that it is important to include 'possession' in the scope of the proposal in order to facilitate the enforceability of the restriction, otherwise it will be very difficult to prove non-compliance in practice. As non-compliance has been a problem in similar restrictions on Member State level, it is important to provide tools for effective enforcement. Possession not related to shooting is not intended to be restricted. This understanding is supported by the fact that the socio-economic analysis was made based on the above rationale. SEAC perceives an ambiguity with regard to the interpretation of possession. Since the proposed restriction aims at the impact of shooting, it is necessary to distinguish possession where the intention is to use lead gunshot in wetlands from where not, e.g. when transporting lead gunshot to another area thereby passing a wetland. Hence, the term 'possession' could be clarified in order to better reflect the aim of the proposal.

Transition period

The arguments on the transition period in the Background Document are based on experiences from the United States and discussions with industry representatives from the EU. Comments received in the public consultation of the restriction proposal indicate that hunters and gun trade associations would like to see a longer transition time. Their arguments are mainly that 36 months are not sufficiently long for the market to adapt and for proofing companies to finish the reproofing of guns in time. However, experiences from Norway received during the public consultation (#1639) suggests that the market can adapt smoothly to changes in the legislation. Some environmental NGOs advocated for a shorter transition period of 18 months since several Member States already have (partial) bans on lead gunshot in place, and that it has been known for a long time that the EU is a party to the AEWA agreement. In SEAC's view, there is evidence indicating that a shorter transition period could be feasible. Since some Member States already have a total or partial ban, lead-free gunshot is produced and available on the market. In addition, the infrastructure for proofing is already in place in nearly all Member States and the speed of work of adapting shotguns where that is necessary, would only be increased. In terms of increased costs for earlier replacement of guns, a shorter transition period would have a

²⁶ According to the AEWA Secretariat, seven of the species listed under AEWA, considered vulnerable to lead poisoning, use "dry" peatlands during the breeding season, which is a particularly sensitive phase in the annual cycle of these birds.

minor impact.

Enforcement

Concerning the conditions of the restriction, SEAC considers that the fact that the set-up and the extent of complementary enforcement and awareness raising measures (this is discussed further in the cost section) is not elaborated on, makes the conclusions on the appropriateness of the scope of the proposal weaker. An elaboration on these aspects would decrease the uncertainty of the effectiveness of this proposal. Neither is there an analysis of what additional labelling of cartridges would imply for the effectiveness and enforcement of the proposed restriction presented in the Annex XV dossier (see section on practicality). Specific information on what additional cost a requirement on labelling lead gunshot would imply, was asked for in the public consultation on the SEAC draft opinion to which some industry associations replied. Overall, SEAC cannot conclude on the impact resulting from the labelling of cartridges.

SEAC conclusion(s)

SEAC agrees that the scope of the proposal is in principal appropriate to significantly mitigate the negative impact of lead gunshot on waterbirds as well as the related secondary effects on predatory and scavenging species as it will reduce their exposure to lead pellets within the boundaries of wetlands.

SEAC agrees with the inclusion of 'possession' and considers that further specification could help to effectively enforce the scope of the restriction in a proportionate way.

SEAC considers that a shorter transition period than proposed by the Dossier Submitter could be reasonable. However, this could pose a challenge to Member States that currently have a narrow or no ban on the use of lead gunshot in wetlands to implement the restriction and to establish the structures for the enforcement of the proposal.

Some uncertainties remain, which may influence the effectiveness of the proposal. These concern the precise border of certain wetland habitats, the significance of the ingestion of lead gunshot by certain species of waterbirds that feed outside of wetlands, the human consumption of waterfowl containing lead, and accompanying measures in the implementation of the restriction (the extent of enforcement and awareness raising measures for shooters using lead shot).

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

The proposed restriction entails a ban on the use of lead gunshot within all wetland habitats within Member States and includes prohibiting the use of lead gunshot where spent lead gunshot would land within a wetland even if the use (i.e. the shooting) takes place outside of a wetland. The proposed restriction applies irrespective of whether the use of lead gunshot relates to hunting live quarry or shooting at targets (e.g. clay pigeons). The Dossier Submitter concludes that the proposed restriction would address the risks to birds

from the ingestion of lead gunshot where this occurs within a wetland and harmonise existing Member State approaches to address the risk.

The scope of the restriction was determined based on the recognition that waterbirds range across large areas during their annual cycle (often travelling between numerous Member States) and that basing the scope of a restriction on the geographical extent of existing networks of protected areas, such as Ramsar sites or the Nature 2000 network, whilst they are acknowledged to offer an important refuge for migratory species, would not be appropriate to limit the risks posed by the ingestion of lead gunshot. Primarily as these risks can occur when lead gunshot is used within any wetland, designated or not. Designated sites only partially cover the wetland habitats used by waterbirds, including AEWA species, at risk of ingesting lead gunshot.

Therefore, to ensure that the scope of the proposed restriction was commensurate to the risks posed by the use of lead gunshot in wetlands, the Dossier Submitter proposed that the scope is underpinned with a generic definition of a wetland (Ramsar definition).

This scope was considered by the Dossier Submitter to be consistent with (i) the mandate for this restriction provided by the Commission (to develop a restriction on the use of lead gunshot in wetlands), (ii) the fact that the Ramsar convention has been ratified by all EU Member States, (iii) the existing obligations of the EU under the AEWA and CMS and (iv) the fact that waterbirds are known to use all of the habitat types included in the Ramsar definition of a wetland.

However, certain species of wetland birds (including AEWA listed waterbirds and predatory or scavenging raptors) also feed outside of wetlands and may therefore still be exposed to spent lead gunshot where this is used outside of a wetland. For example, grazing species of waterbirds that primarily feed away from wetlands include migratory swans (whooper swans and Bewick's swans), species of geese (including the endangered Greenland white-fronted goose (*Anser albifrons flavirostris*) and other threatened species that are listed as priorities under AEWA and CMS. As such, the proposed restriction on use within wetlands (even with a comprehensive generic definition of wetland environments) cannot completely address the risks associated with the use of lead gunshot to waterbirds. An assessment submitted by the AEWA Secretariat in the Public Consultation²⁷ noted that the majority of EU AEWA-listed species vulnerable to lead poisoning (85 out of 100) feed primarily within wetlands clarifying the risk reduction potential of the proposed restriction.

In addition, as compliance problems have been widely reported in certain Member States, the factors affecting compliance (e.g. attitudes of hunters to the identified risks and the suitability of alternatives to the role of enforcement) are clearly relevant to effectiveness of the proposed restriction. Feedback from stakeholders²⁸ was that the enforceability of any restriction proposal would be simplified by prohibiting the possession of lead shot within a wetland. Education and outreach to hunters, in relation to understanding any restriction and the risks it was intended to address, could also improve effectiveness.

The definition of 'use' in Article 3(24) of the REACH Regulation, includes 'keeping' and 'any other utilisation', suggests that a restriction under REACH on use would also implicitly

²⁷ (#1873)

²⁸ Meeting of the Expert Group on the Birds and Habitats Directives (NADEG), in November 2016.

allow Member States to restrict 'possession'. However, national legislation on the use of lead gunshot does not tend to cover extend to bans on 'possession'. Therefore including a specific paragraph within the restriction proposal that explicitly outlines that possession within a wetland is within the scope of the proposal ensures that the intention is clear during opinion and decision making (and public consultation).

RAC conclusion(s):

There are many uncertain factors making it impossible to estimate quantitatively the effectiveness. With full compliance by hunters, which seems based on experience with existing restrictions in Member States to be optimistic, the restriction will prevent the release of 1 432 to 7 684 tonnes of lead to wetlands each year.

However, even assuming full compliance, the restriction will not completely prevent the poisoning of certain species of waterbirds that also feed outside of wetlands.

Considering the uncertainties, it would be reasonable to review the effectiveness of the proposed restriction some years after entry into force.

Key elements underpinning the RAC conclusion(s):

There are currently no restrictions in four Member States, some form of restrictions in 21 Member States, and total bans in three Member States. Thus, for most Member States the proposed restriction will increase the protection level of waterbirds. The actual effectiveness could depend on both compliance and enforcement (although the two are recognised to be linked). In terms of enforcement, this restriction will not be enforced by REACH enforcement authorities (FORUM) and the actual extent of enforcement in different Member States is largely unknown. In light of the potential for limited enforcement, compliance is important to achieve the potential risk reduction. The analysis by the Dossier Submitter indicates that some wetlands are existing official Natura 2000 sites, where high compliance and effectiveness may be expected. The effectiveness in (dry) peatland might be lower, but may increase with time as awareness is increased and those shooting get used to using alternative shot materials. As compliance is difficult to predict, it is not possible to estimate quantitatively the effectiveness. Ideally, the restriction will prevent the release of 1 432 to 7 684 tonnes of lead to wetlands each year.

A factor that could support greater effectiveness, is that an EU wide restriction leading to the protection of European flyways could increase the awareness of the risks posed by lead gunshot to waterbirds and, as a consequence, increase the likelihood of compliance irrespective of the potential for enforcement.

On the other hand, whereas hunter organisations generally support the need to protect waterbirds against lead gunshot poisoning by ingestion of lead pellets, individual hunters and hunter organisations highlight several issues in the public consultation that, in their view, will adversely affect compliance and, therefore, the effectiveness of the proposed restriction:

- Many Member States already have well-known definitions of wetland and a new (broader) one will create problems,

- The inclusion of dry peatland within the scope is not proportionate to the risks,
- The inclusion of possession within the scope will affect the possibilities for hunters to move in between 'legal' hunting areas,
- The potential inclusion of a quantitative buffer zone will increase the scope even further.

Socio-economic impact

Justification for the opinion of SEAC

Costs

Summary of the proposal:

Impacts on hunters

The main cost elements identified by the Dossier Submitter are one-off costs and operational costs to hunters. One-off costs refer to the testing, adaptation and/or replacement of the current stock of shotguns unsuitable to fire alternative steel shot. These can include modifications to ensure the operability, or the premature replacement of a shotgun. Operational costs would occur as a consequence of switching to alternative gunshot. In some cases, there will be no change for hunters, whilst in others the impact will be substantial due to the implementation of an entirely new legislation. There will also be changes of varying kind between those two extreme scenarios.

The level of costs that hunters will have to bear depends on several factors. The available information to estimate these factors varies and is associated with different levels of uncertainty. To illustrate the range of potential costs of the restriction proposal, the Dossier Submitter developed three scenarios (best case, central case, and worst case) based on different sets of assumptions on the following elements:

- The total number of hunters impacted by the restriction proposal. The number of hunters affected is driven by the scope of the existing legislation and the area that will be defined as wetlands in each Member State. The Dossier Submitter estimated the number of hunters affected taking into account waterfowl and fowl hunter populations (derived from hunting bag data), the scope of existing legislation, and the share of peatlands (which would be defined as wetlands by the proposed restriction) in each Member State using different assumptions for each cost scenario. For Member States with a very large share of peatland, all hunters were assumed to be affected in the worst case scenario (if no specific data on the number of affected hunters were available).
- The replacement and testing of guns due to the proposed restriction. The Dossier Submitter estimated the proportion of affected hunters who would test and who would need to replace their shotgun in order to continue hunting. Furthermore, the assessment is based on different assumptions on the expected service-life of a shotgun (as the restriction can be considered to bring forward replacement costs rather than create them *per se*) as well as on the average purchase price of a shotgun.

- The (mix of) alternative gunshots hunters will use to replace lead gunshot. The Dossier Submitter estimated the proportion of steel and bismuth/tungsten ammunition used by hunters once they can no longer use lead gunshot and defined a range of the relative price of these alternatives compared to lead.

The outcomes of the different scenarios are presented in Table 2. The Dossier Submitter considers the central case to illustrate the most likely impacts from the proposal, whereas the worst-case scenario is evaluated as being very unlikely based on available evidence.

Table 2. The three cost scenarios as presented by the Dossier Submitter.

	Best-case scenario	Central-case scenario	Worst-case scenario
Number of waterfowl hunters affected	36 000	252 000	645 000
Number of fowl hunters affected	414 000	1 236 000	1 768 000
Number of shotguns to be replaced	0	141 000	603 000
One-off cost for premature replacement of shotguns	€0	€97m	€680m
Annual operational cost (i.e. annual incremental cost to be spent on shot)	€0m	€35.9m	€158.5m
Annualised one-off cost for testing	€0.4m	€1.5m	€2.4m
Annualised one-off cost for new guns	€0	€7.0m	€31.7m
Total annualised cost to hunters	€0.4m	€44.4m	€192.5m

Shooting activities other than hunting

Shooting practiced at shooting ranges, or other areas that are located in wetlands, will have to replace lead gunshot to comply with the restriction, or to rearrange the way of shooting to ensure that no lead pellets would fall into a wetland. There is no information on the number or location of shooting ranges in the different Member States available that would allow to estimate the economic impact of the proposal on other shooting than hunting, e.g. sport shooting. Hence, this cost has not been assessed by the Dossier Submitter.

Alternative ammunition

As a consequence of the suggested restriction, shooters affected will need to switch to alternative ammunition. According to the Dossier Submitter, alternatives, primarily steel but also others such as bismuth or tungsten, are widely available and in use, both within the EU and internationally. All these alternatives are technically feasible and the Dossier Submitter has not identified any negative environmental or health impacts from their use. Steel shot, according to the Dossier Submitter the alternative most likely to be used, has shown to give comparable results once shooters have become used to it. The ballistics of

steel gunshot are different from lead gunshot and thus the loads need to be adjusted. Moreover, shooters will also need to adapt to steel gunshot, e.g. in terms of patterning. For hunting larger waterfowl, high performance steel gunshot may have to be used, which requires the use of a shotgun that has been proofed accordingly (see below).

Alternative ammunition is expected to be readily available. Many European manufacturers of lead gunshot have production lines of steel gunshot and other lead-free alternatives. There are also non-EU manufacturers selling different types of lead-free ammunition on the European market. Some local retailers might currently not hold stocks of lead-free gunshot though, or have limited quantities.

Alternative ammunition is generally more expensive than lead. However, recent data on the market price of gunshot cartridges indicate that on average there may be no significant difference in price between lead and steel gunshot (Background Document E.3.1.4.). The economic impact on shooters due to different prices of the alternatives is difficult to reliably estimate for the future, because there are several factors affecting the retail price of gunshot including raw material price, production processes, market demand for the ammunition, relative market demand for different cartridge gauges, and taxes, e.g. VAT, in different countries.

The main drivers for differences in production cost are considered by the Dossier Submitter to be the market price of the raw material and the gunshot processing. An internet search made by the Dossier Submitter shows that the price of bismuth gunshot is approximately ten times higher than that of lead gunshot, and lead is about 30 times more expensive than iron. The Dossier Submitter concludes that the prices for bismuth gunshot are less likely to fall to the levels of lead gunshot, and assumes that prices for steel gunshot are likely to become lower once production and market demand increase considering basic market theory.

The Dossier Submitter experienced common obstacles with forecasting all these factors and hence cannot foresee how future market prices will develop. It is concluded by the Dossier Submitter though that the current price difference between lead and steel gunshot – if any – is relatively small, whereas bismuth and tungsten are more expensive than lead gunshot and are likely to remain so.

The Dossier Submitter presents studies and Danish experiences showing that there are no increased risks of ricochets from using other materials than lead gunshot. Shooting in wetlands, in general, is considered to be at low ricochet risk no matter what gunshot type is used because of the high angle above the water surface.

Plastic wads are used as a seal preventing gas from blowing through the gunshot rather than enabling propelling. They are used in all types of cartridges (including lead containing cartridges) and for all kinds of materials. In steel gunshot this has an additional function in preventing contact between the hard shot (i.e. the pellets) and the gun barrel. The wad is shot through the barrel together with the shot. The wad is usually not picked up by the hunter, in comparison to empty shells, which usually are collected. Hunting thus causes dispersal of plastic waste no matter what type of gunshot material is used. The Dossier Submitter has evaluated whether the use of other materials than lead in gunshot will cause increased plastic littering. The conclusion made by the Dossier Submitter is that a change to steel gunshot will not increase plastic littering.

In the public consultation of the restriction proposal there have been comments indicating that steel gunshot would have negative impacts on forestry due to the risk of damage to machinery of the veneer industry (e.g. #1601, #1604, #1624). However, there is no evidence of negative impacts on the forestry and veneer industry. On the contrary, information received in the public consultation of the SEAC draft opinion indicates that impacts of using steel gunshot in the Danish forestry sector have been minor (#348). This is supported by the fact that in Finland restrictions on the use of steel gunshot have been revoked by the Finnish State Forestry Agency recently (#366).

Moreover, the Dossier Submitter points out that in cases where steel gunshot is banned, hunters could still use the softer bismuth or tungsten alternatives.

Manufacturers of gunshot

The Dossier Submitter has identified nine European manufacturers of gunshot. All have production lines of lead-free shotgun cartridges, including a production line of steel gunshot with varied selections of gauges and loads. They all have branches in most European countries and can thus easily provide their products in any Member State. In addition to this, North American manufacturers export lead-free ammunition to Europe. The Dossier Submitter assumes that there might be costs upon (European) manufacturers of lead gunshot, as these will lose a part of their current profits. The Dossier Submitter assumes this loss to be compensated by an increase in the sales of steel cartridges. These costs and compensations are not quantified. Manufacturers producing cartridge components compatible only with lead gunshot are expected to lose part of their business, and there might also be some negative impacts on assemblers of cartridges when they need to adapt their machinery. The Dossier Submitter concludes that since this restriction proposal does not include a total ban, the impact will be limited since information shows that the major part of the lead gunshot production is supplied to other shooting activities than hunting.

Replacement and re-proofing of shotguns

In order to fire steel gunshot, shotguns have to fulfil certain safety standards, which are guaranteed by proofing the gun. There are different levels of proof depending on the capability of the gun. Standard or superior/magnum-proofed shotguns can fire standard steel and other alternative gunshot cartridges. To fire high performance steel cartridges, the gun is recommended (by the CIP²⁹) to be subject to the "Steel Shot" proof, which is a more rigorous test of the gun's ability to handle the pressures and shot hardness of steel/steel-like gunshot cartridges. The majority of shotguns that are currently used can be expected to be standard-proofed as this standard was already introduced in the 1970s. Hunters wanting to be sure, have the choice of re-proofing their guns. Since many Member States do not keep a register of shotguns, or do not require any registration of the number of shotguns owned, the exact number of old guns that would need to be replaced is not known.

When switching to alternatives, shooters may have to adapt somewhat to new conditions. For steel, they will have to increase shot size, or decrease gauge, because of the lower density compared to lead. Also, it is preferable to practice at a shooting range in order to obtain a feeling for how the patterning changes. According to the Dossier Submitter, this

²⁹ Commission Internationale Permanente Pour L'Preuve des Armes a Feu Portatives.

is a natural part of a hunter's annual preparation before hunting season starts. Bismuth can be used as a drop in alternative and requires no adaptations, and tungsten is considered as favourable for good ballistics and performance.

Enforcement costs

The proposed restriction is only likely to be sufficiently effective in reducing the risk to waterfowl and other birds when it is complemented and supported by effective Member State enforcement or educational programmes (as discussed in E.5.2 in the annex to the Background Document). It is stated that there are examples where extensive enforcement has been needed in order to achieve risk reduction. The costs of enforcement will depend on the specific conditions in the different Member States. The Dossier Submitter expects the costs for enforcement mostly to be small in comparison with the substitution costs, but acknowledges that they can be substantial in some Member States.

Key elements underpinning the SEAC conclusions

Impacts on hunters

The Dossier Submitter has used a number of different sources in order to identify relevant estimates for the costs associated with the proposed restriction. For some estimates, such as the proportion of total hunting in wetlands, and number of shotguns prematurely replaced, the Dossier Submitter has used several sources to get an interval illustrating the uncertainties. This is considered by SEAC as a preferred practice. In other cases, this seems to have not been practically achievable, because only one source has been available. For some estimates, assumptions, though transparent, were not substantiated by data due to lack of information, such as the number of waterfowl hunters facing one-off costs. In order to reflect these uncertainties, the Dossier Submitter presented three scenarios to give an interval of the costs of the proposed restriction. SEAC considers that available evidence suggests that some of the assumptions of the worst case scenario are not realistic. This in particular concerns the relative price of steel gunshot compared to lead gunshot, as well as the mix of alternative materials used instead of lead, which are the main driver of the costs to hunters. Therefore, the cost estimate derived from the worst case scenario is likely to significantly overestimate the substitution costs of lead gunshot.

The assumed number of shotguns that need to be replaced (141 000 in the central case scenario for the whole of EU) is based on the share of guns that requires replacement combined with the number of impacted hunters these numbers are based on communication with stakeholders during the preparation of the proposal. Some information from the public consultation indicate that this number could be higher³⁰. It should be noted, however, that these comments were received from Member States with already existing regulations on the use of lead gunshot, therefore the figures mentioned should be taken with caution. No figures for other countries have been received during the public consultation. Therefore, it is difficult for SEAC to evaluate the reliability of the information received.

³⁰ For example, in comment #1562 it has been estimated that 300 000 shotguns would have to be replaced in the UK only. Another comment (#1590), stated that there are up to half a million shotguns not standard proofed in Norway. How many of the latter that needs to be replaced is unknown though.

When it comes to the calculation of the replacement costs, the Dossier Submitter presented annualised costs. The timeframes used are 10, 20, and 50 years for the three scenarios. The standard discount rate of 4 % is used. The reason for the Dossier Submitter to annualise the replacement costs is to make them commensurable with the annual flow cost (i.e. the incremental cost of using alternative shot ammunition).

For the figures on the amount of shotguns that need re-proofing, the Dossier Submitter refers to the AMEC study. That study, however, does not assess the need for re-proofing. Rather, it makes a not well-grounded assumption of the share of shotguns that needs to be replaced.

During the public consultation on the SEAC draft opinion, an assessment of the costs to Irish hunters resulting from the restriction was received (#377). SEAC considers that the assumptions made in this assessment on the replacement of guns are not supported by available information in the Background Document (5.4.1.2 in the Background Document). SEAC also identified several shortcomings in the methodology used concerning the annualisation of costs. Therefore, SEAC considers that the cost assessment received is not as adequate as the cost assessment by the Dossier Submitter.

The analysis in the Background Document of the impact on shooting performance from using alternative materials is thorough and contains substantial evidence to conclude that the impact can be regarded as minor.

The analysis of the cost of switching to alternative gunshot is based on internet search, contacts with industry and hunters, as well as experiences from Denmark, which regulated hunting in wetlands as early as in 1985 and totally phased out lead in gunshot in 1996. Comments received during the public consultation also confirm that there are lead-free alternatives on the market in the EU. Figures provided in the public consultation on the market price of steel gunshot as alternative ammunition indicates both higher and lower prices per cartridge compared to lead gunshot (#1587, #1589, #1604, #1640, #1642, #1653, #1737, #1801, #1881). Noting the distributions in the price per cartridge presented by the Dossier Submitter, SEAC considers that the available evidence suggests there is no substantial difference in the price of lead and steel gunshot.

The conclusion that the amount of plastic waste discarded in the environment by hunters will not increase due to increased use of steel gunshot is considered by SEAC as plausible. The plastic wad will have a similar function in steel gunshot cartridges and will be lost when shooting, as the collecting behaviour by hunters is unlikely to change as a result of a transition to steel gunshot. Evidence provided in the Background Document indicates that all types of gunshot may contain a plastic wad. In addition, the Dossier Submitter also describes in the Background Document that steel and bismuth cartridges without plastic wads are available for use in sensitive areas. However, a comment during the public consultation of the SEAC draft opinion states that the wads in steel gunshot differ from the wads in lead gunshot, with wads in lead gunshots usually made by fibres (#360) and that only steel gunshot contains plastic wads. The comment does not specify what the fibre material is made of though. Furthermore, it is expected that in the future fibres will be used in steel shot as well (#360). Therefore, the conclusion of the Dossier Submitter that there will be no significant impact on plastic littering still stands.

SEAC also notices that RAC does not object to the Dossier Submitter's conclusion that the use of the mentioned alternatives poses no negative impacts on the environment or human

health.

Impacts on shooting activities other than hunting

The costs on sport shooters have not been estimated by the Dossier Submitter due to lack of information on the number of shooting ranges that are located in wetlands, and the corresponding number of sport shooters that would be affected by the restriction³¹.

Some Irish stakeholders identified concerns in the public consultation about the impact on shooting ranges located in Irish peatlands (the number of relevant ranges was not provided). SEAC considers that the proposed restriction may affect sport shooters. To some extent, the impact on shooting ranges can be avoided by changing its layout, e.g. the direction of shooting.

However, a comment from the public consultation of the restriction proposal (#1581) suggest that the impact is marginal. In several Member States e.g. Denmark, the Netherlands, Sweden and Norway (see comment #1639 of the public consultation on the Annex XV report), there is a national ban in place on the use of lead gunshot in shooting ranges, covering the entire territory, not only wetlands. SEAC has no means to assess the significance of these costs.

Impacts on manufacturers of gunshot

The information on the costs on manufacturers is scarce. Not much information has been received during the preparation of the restriction proposal and neither during the public consultation. It is stated in the Background Document that there are about ten European manufacturers of gunshot. The public consultation on the restriction proposal gives indications that it might be around 70 companies, mostly SMEs. It is not clear though whether they are all manufacturers or also retailers, or having other functions in the supply chain. The impacts on these producers are only discussed in a qualitative manner in the Background Document. It seems that the sectors consist of several actors producing multiple or one part to a gunshot. This has not been clarified. From the public consultation on SEAC's draft opinion, some figures on the investment cost on manufacturers that will have to change the machines have been received (#379). SEAC can agree that there are likely to be impacts on manufacturers, but that it is unclear what the magnitude of these impacts would be. All identified producers have separate production lines for alternatives, the suggested restriction does only affect a fraction of all uses of lead gunshot, and several Member States already have total bans. Therefore, the Dossier Submitter concludes that a loss in profit due to decreased demand for lead gunshot will be evened out by an increase in demand for alternative gunshot, and that the production of lead gunshot will not cease because of the proposed restriction. SEAC agrees with this conclusion. The Dossier Submitter has illustrated this distributional impact by estimating the profit gain of ammunition as well as to shotgun manufacturers resulting from the additional spending by hunters.

The Dossier Submitter argues that raw material prices and costs for shot processing are the main driver of the production cost of gunshot cartridges. However, currently that does not translate into lower prices for steel shot. This is likely to be due to the different processes used to manufacture ballistic steel shot (which is a consequence of the different

³¹ This information was specifically requested by the Dossier Submitter in the public consultation run from 21 June until 21 December 2017.

physical properties of the metals). The cartridge production process will be similar for all gunshot types. The Dossier Submitter did not consider the gunshot production process in detail, but it seems likely that processes for the production of ball bearings could be adapted to produce ballistic steel shot. As ball bearing production is highly automated, once adapted to the production of ballistic steel-shot, the price of steel gunshot could fall to reflect the price of the base metal.

During the public consultation on the SEAC draft opinion, some UK manufacturers raised concern about risk for machinery failures due to the hardness of steel shot, which could also put the need for replacement of machinery earlier in time (#360). However, no further quantification of this impacts was given.

Figures provided in the public consultation of the SEAC draft opinion indicate that the majority of the producers offer lead-free alternatives and are planning to further develop non-lead alternatives (e.g. #367). This would indicate that the readjustment to non-lead gunshot would be less costly to producers (#350, #369, #372, #376, and #384).

Enforcement costs and training

Enforcement costs have not been quantified in the Background document. The Dossier Submitter underlines the necessity of enforcement for an effective implementation of the proposal, and it is hinted in several places in the Background Document that the costs might be substantial. Contradictory to this, the Dossier Submitter basically assumes that all hunters would comply with the restriction. There is no analysis to what extent enforcement is needed in order for the proposed restriction to be effective. The effectiveness of a restriction is likely to depend on enforcement activities, as well as information and training activities, and is therefore likely to vary across Member states. The more intense the enforcement activities are the higher effectiveness can be expected up to a certain limit. This is illustrated by an example from Greece where a ban has been in place since 2013, but lead is still used by hunters (#352 in the public consultation of the SEAC draft opinion). From the public consultation of the restriction proposal, it is known that e.g. in France 1 500 wardens are employed to, among other tasks, control hunters. If the proportion put on controlling hunters is known, this could be used to present an estimate on the magnitude of enforcement that might be needed to implement the restriction in those countries where no enforcement is in place at the moment. FORUM concluded that the confinement of the scope of the restriction to wetlands poses considerable problems for enforcement, e.g. by making it necessary to define the area that is within the scope of the restriction, which could indicate that enforcement costs may not be negligible. However, SEAC notes that the expenditure on enforcement activities will not only be driven by the need of enforcement but also by budgetary constraints.

According to the Dossier Submitter, awareness raising and training could have a positive impact on the results from the restriction proposal. SEAC notes that there is no further elaboration on how this training would be designed or what the costs would be (to different actors). SEAC considers that there might be technical and affordable solutions helping hunters to identify their location (e.g. using GPS³² systems), which could also facilitate enforcement, as well as lower the negative impacts of non-compliance on hunters. The costs on guidance for enforcement and compliance are not elaborated on by the Dossier

³² Global Positioning System.

submitter. Member States shared no specific data on costs in the public consultations.

Gun/ammunition retailers and forestry

The Dossier Submitter expects no negative impact on gun and ammunition retailers in the EU. SEAC has no reason to assume otherwise when it comes to ammunition retailers, since it seems reasonable that a loss in sales of lead gunshot would be compensated, at least partly, by profits of lead-free alternatives. Gun retailers, on the other hand, can be expected to gain some positive revenue in the short term from the replacement of shotguns, as also stated in the Background Document. SEAC agrees that it is a likely outcome. Evidence received in the public consultation of the SEAC draft opinion indicates that overall the impact on the forestry and veneer industry is likely to be minor (#348, 366³³). SEAC further considers that due to the focus of wetlands, where forestry is less likely to occur compared to non-wetland areas, as well as the availability of alternatives that are softer than steel shot (e.g. bismuth and tungsten), the impact on forestry and veneer industry is likely to be limited from the proposed restriction.

SEAC conclusions

SEAC concludes that the different cost scenarios presented by the Dossier Submitter cover the range of potential costs to hunters that can be expected from the proposed restriction.

Taking into account all available evidence as well as the different sets of assumptions underlying the different scenarios, SEAC concludes that the central case scenario can be considered as the most realistic to illustrate the order of magnitude of costs that are to be expected from the proposed restriction. The worst-case scenario is likely to significantly overestimate the costs of the proposal, in particular because many hunters from Member States with existing regulation are included, and a significant price difference between lead and steel gunshot is assumed, which is not supported by recent data on retail prices of gunshot.

SEAC notes that the Dossier Submitter has performed a thorough analysis in trying to find the most relevant figures. The calculations made are robust and follow standard practice when it comes to discounting. Due to lack of information, the Dossier Submitter has based the different cost scenarios on several assumptions, e.g. when it comes to number of hunters affected, the number of shotguns that would need to be tested, reproofed or replaced, as well as on the (mix of) alternatives to be used. SEAC understands that it is difficult to get accurate figures on these types of issues. Hunting in general is a private activity and hence is not well monitored. Some estimates lack justification though (see section on uncertainties in the proportionality assessment). Still, SEAC accepts the estimations made on the costs for hunters since they are considered as sound and conservative enough.

SEAC considers that the costs to hunters, as estimated by the Dossier Submitter, constitute private costs and that tax (VAT) needs to be deducted to derive societal costs of the proposed restriction (as the Dossier Submitter does in its proportionality assessment).

³³ As discussed earlier in the section: "Alternative ammunition".

Impacts on hunters and industry seem to be reasonable for most, with several distributional effects, e.g. costs for hunters will lead to gains for producers and retailers of alternative gunshot as well as shotguns.

Enforcement costs have not been quantified by the Dossier Submitter. The enforcement costs are also linked to the effectiveness of the proposal as discussed above. It would have been preferred to have some figures on enforcement costs and its effectiveness, also in relation to other RMOs. SEAC notes that the level of enforcement will depend on the ambition and effectiveness in each Member State. Depending on the design of the enforcement and the conditions in the specific Member State, the costs could be substantial or minor. However, SEAC notes that in practice the extent of enforcement activities is usually driven by the constraints of fixed enforcement budgets. Therefore, Member States will have to find efficient ways to enforce the proposal. Overall, the magnitude of enforcement costs compared to the total costs of the proposal are unknown. In turn, this could negatively affect the effectiveness of the restriction (in terms of higher non-compliance).

SEAC considers that this lack of quantified estimates on the impact on industry and enforcement, as well as its impact on efficiency, weakens the cost assessment presented by the Dossier Submitter.

Benefits

Summary of the proposal:

The use of lead gunshot is a major source of lead releases to the environment. Accordingly, the proposed restriction will reduce lead emissions to wetlands. Based on information received from industry, the Dossier Submitter estimated the total use of lead gunshot in hunting in the EU to more than 21 000 tonnes per year. Of this amount, the Dossier Submitter estimated that about 1 500 to 7 800 tonnes of lead are currently released per year in and to wetlands by shooting with gunshot (during hunting). No estimates are available for the use of lead gunshot in shooting activities other than hunting.

The primary benefit from reducing emissions of lead gunshot is a reduction of lead exposure and consequential adverse effects in birds (especially waterbirds, birds of prey, and scavengers) and other wildlife that are dependent on wetland habitats. In particular, this concerns the effects of lead ingestion by waterbirds leading to increased mortality as well as to sub-lethal effects through lead poisoning. These effects not only lead to premature death of birds and potentially negative impacts on their population sizes, but also reduce animal welfare due to the inflicted suffering, pain and distress of birds that have ingested lead gunshot.

Of these numerous impacts on birds and other wildlife, only the impact of increased annual waterbird mortality was quantified by the Dossier Submitter, whereas the other effects were qualitatively described. In a low, central and high scenario, applying different mortality rates (3.1 %, 6.1 % and 8.7 %), the annual number of birds dying from ingesting lead gunshot was estimated based on the size of the wintering and the breeding population of 33 bird species in the EU-28. In these calculations, the bird populations in Member States with a total ban of lead gunshot were not included. The estimates derived show that between 400 000 and 1 500 000 birds die each year from the ingestion of lead

gunshot. This range does not include birds affected by sub-lethal effects, whose number was estimated to be three times higher (Andreotti et al., 2018).

The impact on waterbird mortality has partly been monetised based on an estimation by Andreotti et al. (2018) of the restocking costs for 700 000 birds lost from 16 species. In this study, the costs to replace the birds that die from lead shot ingestion have been estimated based on the economic value of captive-bred waterbirds and the number of individuals that would have to be released in order to compensate for the annual loss of wild waterbirds dying as a result of ingesting lead gunshot. This opportunity cost reflects the use value for hunters, derived from revealed preferences, who stock birds to increase their hunting success. As a result, at least €105 million would have to be spent to replace waterbirds that have died of lead poisoning. Replacement costs only capture part of the benefit of reduced waterbird mortality in terms of social welfare. Therefore, they have to be considered as a lower-bound estimate of the benefits. Furthermore, this figure derived by Andreotti et al. does not include all waterbird species that are vulnerable to lead poisoning (16 species with available information out of 33 species, for which there is evidence that they are affected by lead gunshot ingestion). According to AEWA, about 100 waterbird species in the EU are considered to be vulnerable to ingesting lead gunshot based on their way of feeding, out of which 85 species are found to feed primarily in wetlands (#1873 in the public consultation on the Annex XV report). Furthermore, the monetised impact of waterbird mortality also does not account for any long-term impact on population sizes due to sub-lethal effects of lead gunshot ingestion.

The restriction will also reduce lethal and sub-lethal effects of lead on predatory and scavenging birds, which are exposed through eating birds, and which have ingested lead gunshot or have embedded lead gunshot in their tissue. The Dossier Submitter was not able to quantify these impacts.

Other non-quantified impacts of the proposed restriction include potential impacts on other wildlife than birds (exposed through the food chain) as well as on wetland ecosystems at large. Also, lead gunshot as a potential source of lead contamination of (drinking) water resources was not assessed by the Dossier Submitter.

In terms of social welfare, the reduction of the adverse effects from the use of lead gunshot in wetlands, on waterbirds and the related effects on ecosystems, have multiple consequences, which are summarised below:

- increased (long-term) opportunities for hunting
- increased (long-term) opportunities for leisure activities, e.g. bird watching
- reduced amount of lead released in the environment and related contamination of water resources (avoided remediation costs)
- better protection of bird populations and wetlands in general (non-use value).

Apart from environmental benefits, the proposed restriction is likely to contribute to a reduction in exposure of humans to lead via the environment (through the consumption of game meat and other potential sources, e.g. groundwater used as drinking water). The impacts of this exposure on human health has been mentioned by the Dossier Submitter. Neurodevelopmental effects are the primary concern of lead exposure, although high-

frequency consumers of game meat, which could potentially be large (evidence presented in the Background Document suggests tens of thousands of people in the UK), could also be at risk from other adverse effects (i.e. cardiovascular and nephrotoxic effects). The Dossier Submitter highlights concerns of lead exposure from consuming meat from game shot with lead gunshot (demonstrated by warnings on the consumption of game meat based on the possible contamination with lead issued by several authorities in the EU).

In summary, Table 3 provides an overview of the benefits resulting from the environmental and human health impact of the proposed restriction as identified by the Dossier Submitter, quantified and not quantified.

Table 3. Overview of the benefits resulting from the environmental and human health impact of the proposed restriction

Use value	
Avoided opportunity cost associated with the annual mortality of approximately 700 000 waterfowl from 16 wetland bird species known to ingest lead gunshot.	€105M
Avoided opportunity cost associated with the annual mortality of other waterbirds.	non-quantified
Avoided opportunity cost associated with the annual mortality of predators and scavengers.	non-quantified
Beneficial impacts on leisure activities, including bird watching.	non-quantified
Avoided human health impacts through consumption of contaminated game meat and/or potential consumption of contaminated (ground) water.	non-quantified
Avoided lead emissions and impacts of environmental contamination.	1 500 to 7 800 t, not monetised
Non-use values	
Protection of wildlife and ecosystems.	non-quantified
Protection of rare bird species.	non-quantified

As a distributional impact, the restriction would result in increased profits for importers and EU manufacturers of alternative gunshot, importers and EU shotgun manufacturers and retailers (for replacing old shotguns), as well as shotgun manufacturers and retailers as a consequences of testing, re-proofing and modifying shotguns (as discussed in the section on costs). Based on the assumption that on average 40 % of the retail price of gunshot, shotguns, as well as the testing of shotguns will be profits for the supply chains concerned, this benefit would be substantial (about €14 million applying the numbers from the central case cost scenario).

Key elements underpinning the SEAC conclusions

SEAC notes that the estimation of annual waterbird mortality due to ingestion of lead shot and the resulting number of birds lost is related to uncertainties (as assessed by RAC), but overall can be considered a realistic estimate (as confirmed by RAC). In this respect,

SEAC takes notice that RAC concurs with the Dossier Submitter's conclusion that the use of the alternatives assessed poses no negative impacts on the environment or human health.

SEAC considers that the quantified monetised benefits in terms of reduced annual waterbird mortality is clearly an underestimate of the benefits of the restriction, in particular because

- less than half (16 from 33 species) of all waterbird species, for which there is evidence of lead shot ingestion, are covered;
- in total up to 100 species of waterbird species could be affected based on their way of feeding;
- sub-lethal effects in waterbirds as well as potentially resulting effects on population sizes were not included.

Furthermore, SEAC points out that the monetised benefits were estimated on the basis of revealed preferences of hunters (market prices of birds), which represent only part of the total value in terms of social welfare (as expressed by stated preferences). Overall, SEAC considers that the non-monetised benefits on waterbirds are likely to be substantial³⁴.

When assessing the total environmental benefits of the proposed restriction, SEAC highlights the multitude of impacts, for which it was not possible to derive a reliable quantitative estimate, which are potentially large:

- The restriction of lead gunshot in wetlands will lead to benefits due to a reduction of lethal and sub-lethal effects on predatory and scavenging birds (as well as other species exposed to lead through the food chain), which were not included in the quantitative assessment. According to RAC, it is very likely that the restriction will contribute to their protection as well.
- The impacts of lead emissions from the use of lead gunshot in wetlands and resulting environmental contamination (i.e. of soil, sediment and aquatic compartments).

From an economics perspective, the impact on waterbirds and other wildlife affects social welfare in different ways. Apart from leisure opportunities like hunting or bird-watching as well as the consumption of game meat, aspects not directly related to the use of waterbirds and wetlands in general, such as animal welfare, biodiversity and the protection of rare bird species and associated ecosystem services are also important to society. SEAC points out that the non-use values of wetlands have been found to be significant³⁵ and are therefore important to consider when assessing the benefits of the proposed restriction.

³⁴ In this respect, SEAC notes that Andreotti et al. (2018) estimated the contribution of one additional species (Common Coot), which was excluded from the value of €105 m, because of limited data on the cost of captive-bred individuals, to €28m in the EU. The calculation was based on the assumption that captive-bred coots have the same post-release mortality of ducks, geese and swans. In addition, in the public consultation on the Background Document, information was shared (#1840) on the stocking cost of other bird species, including *Recurvirostra avosetta*, *Oxyura leucocephala*, *Somateria mollissima*, *Aythya nyroca*, *Marmaronetta angustirostris*, *Anas querquedula*, *Tadorna tadorna*, *Branta canadensis*, *Cygnus Cygnus*, and *Cygnus olor*.

³⁵ In a meta-analysis of 30 contingent valuation studies on wetlands, Brouwer et al. (1999) found that the non-use value of wetlands is on average about half as high as the use value.

SEAC notes that there may be differences in the valuation of these non-use values between Member States, but these differences do not affect this overall conclusion.

In terms of the risks of the use of lead gunshot to human health, SEAC takes note that RAC confirmed that it is very likely that the use of gunshot contributes to human exposure to lead, in particular through the consumption of game meat. This was supported in the public consultation of the SEAC draft opinion³⁶. In the evaluation of other restriction proposals on lead, SEAC has found that the reduction of human exposure to lead can be considered as potentially beneficial to society, which would also be valid for restricting the use of lead in gunshot.

One additional issue that has not been assessed by the Dossier Submitter, and hence has not been evaluated by RAC, is the content of arsenic in lead shot. RAC estimates that up to 63 tonnes of arsenic may be potentially released to wetlands per year based on a 1.5 % content of arsenic in lead. Even though the risks of arsenic emissions is not quantified within this restriction proposal, SEAC acknowledges the potentially decreased exposure to arsenic as a result of the restriction of lead gunshot.

In the public consultation of the SEAC draft opinion, several comments raised that the enhanced societal acceptance and reputation of hunting also has to be considered as a benefit of the proposed restriction. SEAC agrees that the improved image of hunting could be a relevant impact of the proposed restriction.

Some information was received in the public consultation of the SEAC draft opinion, providing examples of shooting ranges in Italy, France, Germany, Finland and Spain, which are recognised as a source of lead pollution for water sources, salt pans and soil (#349, #371, #383, and #385). The avoidance of remediation costs would also be a benefit of the proposed restriction. However, estimates of remediation costs were not available from the public consultation.

SEAC conclusions

In general, SEAC supports the benefits assessment carried out by the Dossier Submitter.

There is clear evidence that the use of lead in gunshot contributes to waterbird mortality and impairment, which has several negative impacts in terms of social welfare. In addition, lead gunshot contributes significantly to the emissions of lead to the environment.

SEAC concludes that the estimate of the economic value of waterbird mortality clearly is an underestimate of the total benefits of the proposed restriction. The benefits are very likely to be considerably higher taking into account that replacement costs only capture part of the benefits in terms of social welfare and in particular the multitude of non-quantified benefits of the proposed restriction.

In this respect, SEAC underlines that it is very likely that the proposed restriction will contribute to a reduction of human exposure to lead, which potentially results in additional benefits to society.

The absence of negative environmental and human health impacts of the alternatives to

³⁶ Comment #357 proposed "An estimate of the annual discounted lifetime value of irreversible damage to the cognitive ability of children in the European Union caused by dietary exposure to lead ammunition due to consumption of wild-shot waterfowl".

lead gunshot is acknowledged by SEAC.

Other impacts

There might be distributional issues between manufacturers and hunters in different Member States. Comments received in the public consultation on the SEAC draft opinion indicate that impacts on hunters and on manufacturers could be higher in Member States that have no regulation on the use of lead gunshot in place, than for countries where there already is a ban on lead gunshot (e.g. #386). Please see also discussion on this issue in the cost section.

Overall proportionality

Summary of proposal

The Dossier Submitter has based the evaluation of proportionality on several elements considering the cost-effectiveness, the costs and benefits, as well as the affordability of the proposed restriction.

Cost-effectiveness

The proposed restriction is anticipated to reduce lead emissions to EU wetlands by about 1 500 to 7 800 tonnes per year, with a central estimate of 4 200 tonnes. Considering the aggregated annual costs imposed on hunters (estimates range from €0.4 to €192.5 million depending on the scenario with €44.4 million as a central estimate), these figures suggest that the total cost per ton of lead emission avoided is in the range of €0.3 to €25 per kg. The central scenario suggests a cost-effectiveness value of € 9 per kg of lead dispersal avoided. These figures are far below the cost-effectiveness values estimated for other REACH restrictions on lead and other substances (e.g. PBT-substances)³⁷.

Table 4. Cost-effectiveness of the proposed restriction in terms of emission reduction

	Best-case scenario	Central-case scenario	Worst-case scenario
Total annualised cost to hunters	€0.4m	€44.4m	€192.5m
Annual emission reduction from replacement	1 432 tonnes	4 740 tonnes	7 684 tonnes
Unit abatement cost (p.a.) € per kg lead emissions avoided	€0.3/kg	€9/kg	€25/kg

Costs and benefits

The quantified and non-quantified cost and benefits are summarised in Table 5. In the assessment, the Dossier Submitter has also considered the surplus gain to manufacturers

³⁷ The Dossier Submitter provided a comparison with the cost-effectiveness of previous restrictions under REACH in the restriction report, section 5.11 *Cost-effectiveness considerations*.

and retailers of shotguns and alternative gunshot as a distributional impact resulting from the restriction partially compensating for the cost accruing to hunters.

In the comparison of costs and benefits, the Dossier Submitter considers the cost estimates based on the central cost scenario being the most realistic. With regard to the benefits, the monetised value is seen as reflecting only a part of the total benefits due to the numerous non-quantified and non-monetised benefits of the restriction.

Table 5. Summary of expected costs and benefits of the proposed restriction

Costs of the proposed restriction				Benefits of the proposed restriction	
Annuitised one-off costs	best case	central case	worst case	Use value	
Replacement of guns	€0	€7.0 m	€31.7 m	Avoided opportunity cost associated with the annual mortality of approximately 700 000 waterfowl from 16 wetland bird species known to ingest lead shot.	€105m
Testing of guns	€0.4 m	€1.5m	€2.4 m	Avoided opportunity cost associated with the annual mortality of other waterbirds, predators and scavengers.	non-quantified
Annual operational costs				Beneficial impacts on leisure activities including bird watching	non-quantified
Switching to alternative cartridges	€0	€35.9 m	€158.5 m	Avoided human health impacts through consumption of contaminated game meat and/or potential consumption of contaminated (ground) water.	non-quantified
Total annual cost to hunters (private cost)	€0.4 m	€44.4 m	€192.5 m	Non-use values	
Distributional cost in terms of generated tax revenues assuming an average VAT rate of 20 %	€0.32 m	€8.9 m	€38.5 m	Protection of wildlife and ecosystem services	non-quantified
Enforcement	Non-quantified			Protection of rare bird species	non-quantified
Total societal cost	€0.8 m	€35m	€154 m	Total societal benefit	>€105m
Distributional cost		Up to €14 m			

in terms of producer surplus gains (after VAT deduction)					
--	--	--	--	--	--

Affordability

Many EU Member States have already implemented different national legislations to ban the use of lead gunshot, without having a large impact on the number of wetland hunters in the regulated areas/Member States. According to the Dossier Submitter, this indicates that switching to non-lead gunshot is, in principle, affordable to the individual hunter. Based on the cost estimates presented in the Background Document, it can be expected that the additional cost to an average hunter for purchasing non-lead gunshot ammunition will be in the range of €0 (best case) to €66 (worst case) per year. This corresponds to 0 to 2.2 % of the average annual hunting budget of a European hunter.

On top of this annual cost, hunters that do not own a standard-proofed gun that can be used with steel gunshot would incur costs for testing and/or costs for the premature replacement of their gun. For the testing of shotguns the Dossier Submitter estimates a cost of €140 per test. The cost estimates for the premature replacement of guns can be expressed in terms of the individual one-off cost to a hunter of bringing forward the purchase of a new gun as a result of the restriction proposal. The Dossier Submitter expects this cost to be in the range of roughly €750 (central case) to €1 130 (worst case) for the average hunter. This additional cost could pose an extra burden to hunters with a significantly lower hunting budget. On the other hand, frequent hunters are more likely to have replaced a shotgun not suitable for firing steel gunshot by a standard proofed shotgun, which is already capable of shooting steel gunshot. This is because they are likely to replace their shotguns more often than infrequent hunters due to the service life of a shotgun being affected by the number of shots fired. As a consequence, no further investment would have to be made by these hunters because of the proposed restriction. This makes the Dossier Submitter assume that subsistence hunters will be less affected than other hunters.

Table 6. Costs to hunters resulting from the proposed restriction in total and in percentage of average hunter's budget

	Best-case scenario	Central-case scenario	Worst-case scenario
Additional cost per hunter (p.a.)	€0	€25	€66
Average hunter's budget (p.a.)	€3 000	€3 000	€3 000
Fraction of average hunter's budget	--	0.8 %	2.2 %

SEAC conclusions

Overall, SEAC concludes, based on the evidence presented by the Dossier Submitter and

the comments received during the public consultation, that the proposed restriction is a proportionate measure to control the risks of the use of lead gunshot in wetlands. In this conclusion, SEAC highlights the numerous non-quantified benefits, which are likely to be significant.

There are some uncertainties in this analysis, which are presented in the following chapter.

Key elements underpinning the SEAC conclusions

SEAC notes that the use of lead in gunshot contributes substantially to lead emissions compared to other uses (e.g. lead in PVC). In other restriction proposals on lead, emissions were used as a proxy of risk given the non-threshold nature of the toxic effects of lead in humans. Taking into account the multitude of non-quantified impacts of the restriction including the effect on human exposure to lead through the consumption of game meat, SEAC considers the cost-effectiveness of reduced lead emission resulting from the proposed restriction important to consider in the assessment of proportionality.

Overall, SEAC considers that the available information on the costs and the benefits provides sufficient justification for the proportionality of the restriction. Taking into account all uncertainties, SEAC considers that generally it has been demonstrated that the benefits of the restriction to society will outweigh the costs. This conclusion is supported by the fact that the monetised part of the benefits of the restriction:

- is a lower-bound estimate of the impact of prevented mortality of the waterbirds (16 species) included in the study by Andreotti et al. (2018), because it is based on revealed preferences of hunters, which do not include all relevant values in terms of social welfare, e.g. non-use values, and
- does not cover other positive impacts of the proposed restriction, in particular on waterbirds, on scavenging and predatory birds (as well as other predators within the food chain) as well as on human exposure to lead resulting from the use of lead gunshot.

There is evidence that indicates that these non-quantified benefits are likely to be substantial (see section on benefits). This is illustrated by the fact that Andreotti et al. (2018) estimated the impact on only one additional species (*Common Coot*), which was excluded from the value of €105 m because of limited data on the cost of captive-bred individuals, to € 28 million in the EU. Hence, SEAC considers the value of €105 million clearly as an underestimate of the total benefit of the restriction.

On the cost side, SEAC notes that the upper-bound societal cost estimate of €154 million (worst-case cost scenario) is within the same order of magnitude as the monetised estimate of the benefits of the restriction. Based on the considerations above and taking into account that the evidence provided by the Dossier Submitter and submitted in the public consultation, SEAC considers that this worst-case cost estimate is an unlikely scenario, and hence is likely to overestimate the costs. On the other hand, relevant cost elements, e.g. enforcement costs have not been included in the cost estimates given by the Dossier Submitter. In sum, SEAC however considers it unlikely that these cost elements will significantly change the range of costs given in the Background Document.

Based on these considerations, SEAC considers proportionality to be demonstrated.

In addition, taking into account that the costs of the restriction are borne largely by a limited group, namely the hunters, the affordability of the costs to hunters is an important aspect to take into account in the overall assessment of proportionality. Overall, SEAC concludes that the assessment by the Dossier Submitter indicates that the cost to hunters seem to be reasonable, in particular when compared to the average budget of a hunter. This conclusion has not been challenged in the public consultation. However, SEAC highlights that there could be differences in terms of affordability between hunters in different Member States. The Dossier Submitter has not elaborated on the price elasticity of the demand in different groups of hunters, nor the affordability related to differing income levels in different Member States. Neither is the assumption that the share of subsistence hunters would be smaller, verified by the Dossier Submitter. Therefore, SEAC cannot evaluate the relevance of those issues.

One general uncertainty regarding the restriction proposal is its effectiveness. The Dossier Submitter assumes in its assessment that the restriction will effectively prevent the use of lead in gunshot in and over wetlands. SEAC considers that this essentially depends on the compliance and enforcement of the restriction in the different Member States. Effective enforcement may require extensive investment from Member States, which could constitute additional costs of the proposal. As SEAC has not sufficient information to assess these costs, no conclusion on their significance in terms of proportionality can be made.

SEAC, in principle, agrees that the proposed restriction is a cost-effective measure to reduce lead emissions to the environment, as indicated by the cost-effectiveness estimates given by the Dossier Submitter³⁸. On the other hand, the lack of comparable risk management options for this particular aim (reducing the risk to waterbirds and to wetlands), makes it difficult for SEAC to say whether this is the most cost-effective measure. Moreover, SEAC underlines that the cost-effectiveness estimates are not comparable to other REACH restrictions in terms of the expected human health and environmental impact of the emission reduction. In this respect, SEAC points out that the emission of lead as pellets may not be directly comparable to emissions of lead to air or dissolved in water.

Uncertainties in the proportionality section

The assessment of costs and benefits made by the Dossier Submitter is based on many parameters and assumptions. An overview of key parameters and assumptions and related uncertainties used can be found in Table A1 in the Annex. These are also discussed in the relevant sections above (costs, benefits, proportionality).

With regard to the cost assessment, variability related to the different relevant parameters (e.g. number of hunters affected, price difference between lead and alternative shot, mix of alternatives used, number of shotguns tested and/or replaced) are reflected in the different cost scenarios. There are some more general sources of uncertainty, which are not (fully) addressed by the cost assessment, i.e. the assumption of full compliance to current (baseline) and future (proposed restriction) legislation, enforcement costs as well

³⁸ As discussed in the section "Overall proportionality".

as costs to other shooters than hunters. These issues and their significance for the costs of the proposed restriction are discussed in corresponding sections above.

With regard to the benefits assessment, SEAC considers the non-quantified benefits to be the major source of uncertainty compared to other sources.

To assess affordability, the Dossier Submitter assumes an 'average European hunter'. This average does not account for the large heterogeneity that exists between different European hunters in terms of their budget available for hunting.

Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of the proposal:

The Dossier Submitter considers the definition of what constitutes a wetland a key factor in determining the implementability and enforceability of the proposed restriction. This would require that wetland areas are clearly defined, based on the scope of the restriction, e.g. by producing detailed maps showing areas within which the restriction would apply. Furthermore, it could be beneficial to require mandatory training on the need and scope of the proposed restriction before hunting would be permitted, i.e. the training and examination needed to receive a hunting permit should be amended to that effect. The Dossier Submitter points out that these issues need to be addressed by Member States and acknowledges that the restriction will need to be complemented and supported by effective Member State enforcement in order to be effective. It is unclear what efforts would be required for effective enforcement, but it could be substantial.

Steel shot cartridges are produced by most European manufacturers (in this study sample all companies). It is by far the most common alternative to lead gunshot, particularly in the context of waterbird hunting. However, many European manufacturers produce other lead-free ammunition as well, e.g. bismuth and tungsten-based shot. In addition, North American manufacturers distribute via their European representations, a variety of lead-free ammunition types in Europe. If a restriction on the use of lead shots in wetlands is introduced, manufacturers that produce lead gunshots might face a problem due to the fact that the technology used for manufacturing their product cannot be adapted to alternative metals. None of the products different from lead can be produced using the skills, technologies and facilities used to produce lead shots.

Concerns have been raised that steel gunshot might damage standing timber when lead was to be prohibited in the 1990s in Denmark, and the forestry authorities had recommended against the use of steel. However, the LAG report (2015) found no documented evidence of any problem with the use of steel ammunition in forestry in the Nordic countries (and Denmark in particular).

RAC and SEAC conclusion(s):

RAC and SEAC are of the view that the proposed restriction in principle is practical, as also indicated by already having similar restrictions in many Member States. Alternative

gunshot is already on the market, and sufficiently increased amounts for a larger scale substitution should be available within a few years. Awareness raising campaigns, training of hunters, and labelling of lead gunshot cartridges are additional factors that can increase the practicality. These factors have not been included in the cost assessment of the proposal.

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

The restriction proposal expresses concern for the manufacturers of cartridges. However, RAC and SEAC note that there are already restrictions since many years on the use of lead gunshot in wetlands in 23 out of 28 Member States, so the substitution of lead gunshot (and shotguns in some instances) should already be well underway in most Member States. It is unclear how much the proposal will broaden the need to substitute lead gunshot with steel (1 452-7 767 tonnes of lead/year is the estimate), and to what extent compliance will result in actual substitution. The producers may need some time to adjust, but there should be no practical problems.

As to forestry and the use of steel gunshot, the former ban on the use of steel gunshot in Finnish forests has been revoked (comment #366 in the public consultation on SEAC's draft opinion). There has been no proof that steel gunshot would harm the machinery in neither the sawmills nor in the veneer industry. The Finnish industry has now authorised the use of shot other than lead gunshot including steel gunshot (effective in August 2018).

Many comments in the public consultation highlight the lack of enforcement in most Member States, and that a successful restriction requires that hunters accept the restriction and the reasons for it. The restriction proposal identified that education/training of hunters would be helpful, and comments in the public consultation support that theoretical training (e.g., with respect to wetland definition) would increase acceptance and that practical shooting training with new non-lead gunshot would improve the hunter's success and decrease the risk for crippling prey. For instance, this training could be part of licencing. RAC supports the need for awareness campaigns and educational programmes, and that hunters could benefit from training with new ammunition, e.g. steel gunshot with clay pigeons.

Regarding enforceability, see above in the section of scope regarding enforcement aspects on buffer zones and possession of lead gunshot. In the view of RAC and SEAC, and supported by FORUM, obligatory labelling of cartridges containing lead gunshot is needed to help enforcement, as the need for dismantling of cartridges and subsequent chemical analysis will be avoided. Information received from industry in the public consultation of the SEAC draft opinion indicates that the cost could be around £125 000 for one UK manufacturer for designing, re-writing and replacing existing designs and packaging (#360). This figure has not been verified from any other source though. As costs for labelling has not been analysed by the dossier submitter, SEAC has not been able to assess such costs more than concluding that there is likely to be a costs for manufacturers.

FORUM also notes that a restriction covering all uses of lead gunshot would rather enable enforcement to focus on the 'placing on the market' of lead gunshot in contrast to field inspections of hunters. In this respect, FORUM concluded that the confinement of the scope of the restriction to wetlands poses considerable problems for enforcement, e.g. by making

it necessary to define the area that is within the scope of the restriction.

This view is acknowledged by SEAC, who also notes that enforcement costs associated with a total ban are likely to be lower than for the proposed restriction.

Monitorability

Justification for the opinion of RAC and SEAC

Summary of the proposal:

The most conclusive method of monitoring compliance with the restriction is to measure the prevalence of ingested or embedded gunshot in birds over time. Many of the current studies highlighting the problem of lead poisoning in waterfowl use this method, or varieties of it, to establish the scale of the problem. The method can readily be adapted to monitor the effectiveness of the proposed restriction.³⁹

It could be beneficial to require mandatory training on the need and scope of the proposed restriction before hunting would be permitted in Member States, i.e. the training and examination needed to receive a hunting permit should be amended to that effect.

The costs of monitoring have not been assessed in the proposal.

RAC and SEAC conclusion(s):

RAC supports that the most conclusive method of monitoring compliance with the restriction is to measure the prevalence of ingested or embedded shot in birds over time.

The costs of monitoring have not been assessed in the proposal.

UNCERTAINTIES IN THE EVALUATION OF RAC and SEAC

RAC

Summary of proposal:

The amount of lead released to the environment, and specifically to wetlands, could be significantly greater than estimated.

The number of waterbirds dying annually is based on a study from the US concerning mallards. The applicability of this method to other species than mallards could result in either an underestimation or overestimation of impacts.

Various sub-lethal effects could also be occurring that have not been quantified e.g. on reproduction.

³⁹ WWT (2010) describe a protocol for the determination of lead pellets in various species.

RAC conclusion(s):

RAC agrees that the estimate of number of waterbirds dying per year is subject to uncertainties. Also, the effectiveness is difficult to estimate as it depends on both enforcement and compliance of those affected by restriction (see above under effectiveness).

Key elements underpinning the RAC conclusion(s):

The amount of lead estimated to be released to wetland, to be restricted by this proposal, is uncertain as indicated by the large interval (1 432 to 7 684 tonnes per year). However, as the estimate is based on the assumption that present restrictions in 19 Member States are fully complied with, which is not likely the case, the amount of lead prevented from being released could therefore be larger (assuming full compliance with the proposed restriction).

The recalculation of the Bellrose mallard data by Green has on the one hand increased the confidence in the estimates, but on the other hand indicated large confidence intervals. The order of magnitude seems reliable, but it assumes that other species are equally sensitive as mallards to lead poisoning. Other species could be more or less sensitive than mallards, and the sensitivity may also vary over time within a species (e.g. depending on choice of feed). Overall, it is certain that a huge number of waterbirds die annually after ingesting lead pellets, although the actual number is uncertain. It is of particular concern when the mortality affects threatened or endangered species, and although this is known to occur, this has not been specifically analysed.

SEAC

Summary of proposal

Key assumptions and uncertainties of the analysis are summarised by the Dossier Submitter in Section 6 of the Background Document. These concern:

- The fraction of hunting that takes place on wetlands. The estimate is based on bagged waterfowl, but does not distinguish where the birds are shot.
- Hence, it is assumed that the share of waterfowl in the total hunting bag is the same in the different Member States. This simplification has implications for the cost estimates, and further, on compliance.
- The fraction of hunting taking place on peatland.
- The number of shotguns that needs to be replaced.
- The amount of lead emitted in or over wetlands could potentially be greater than assumed. In addition, emissions from shooting activities other than hunting are not known.
- The use of mortality data for mallards for estimating the number of waterbirds

dying might result in an over- or underestimation.

- The quantification of welfare impacts on the producers.

SEAC conclusions

Benefits not quantified are likely to be significant if the proposed restriction is implemented. For other aspects of uncertainty, SEAC does not have enough data to judge whether they would increase or decrease the impacts.

One general uncertainty is the risk of non-compliance, which could compromise the effectiveness of the proposed restriction. The experience from existing regulation in Member States implies that non-compliance has been a problem in the implementation of partial bans of lead gunshot, i.e. in wetlands. As discussed in the section on proportionality, enforcement has the potential of increasing the costs but it is not known to what extent. On the other hand, improved enforcement can increase benefits as compliance would improve.

Key elements underpinning the SEAC conclusions

On top of the uncertainties mentioned by the Dossier Submitter, SEAC has identified some additional uncertainties:

- Other risks, such as man via environment, man via birds, and risk to the environment (including birds outside wetlands) are not included.
- The definition of wetland makes analysis and implementation more difficult since it does not describe the size of the wetland. Identifying dry peatland is a difficult task for both hunters and inspectors.
- How enforcement could be implemented and hence the cost is not assessed.
- Awareness raising (i.e. the adaptation of the hunter when shooting with an alternative ammunition) is not assessed in detail.
- Labelling of cartridges is not assessed which would have enabled an improved analysis of compliance and enforcement.
- Emissions from shooting activities other than hunting is not included in the analysis, a potentially significant impact on the environment.
- Experience of non-compliance from Member States with existing regulation and implications for the effectiveness of the proposal.
- Extent to which Member States would introduce more stringent measures.
- See also the Proportionality section for a deeper discussion on uncertainties.

REFERENCES

Andreotti, A., Guberti, V., Nardelli, R., Pirrello, S., Serra, L., Volponi, S., Green, R.E. (2018). Economic assessment of wild bird mortality induced by the use of lead gunshot in European wetlands. *Science of the Total Environment*, 610–611, 1505-1513.

Brewer, L., Fairbrother, A., Clark, J. and Amick, D., 2003. Acute toxicity of lead, steel, and an iron-tungsten-nickel shot to mallard ducks (*Anas platyrhynchos*). *Journal of wildlife diseases*, 39(3), pp.638-648.

Ecke, F., Singh, N.J., Arnemo, J.M., Bignert, A., Helander, B., Berglund, Å.M., Borg, H., Brogger, C., Holm, K., Lanzone, M. and Miller, T., 2017. Sublethal lead exposure alters movement behavior in free-ranging golden eagles. *Environmental Science & Technology*, 51(10), pp.5729-5736.

Meyer *et al.* (2016), Can ingestion of lead shot and poisons change population trends of three European birds: grey partridge, common buzzard, and red kite? *PLoS ONE* 11(1):e0147189. Doi:10.1371/journal.pone.0147189.

NHMRC 2015a. Evaluation of evidence related to exposure to lead. Downloaded from https://www.nhmrc.gov.au/files/nhmrc/publications/attachments/nhmrc_evaluation_of_evidence_related_to_exposure_to_lead_May_2015_0.pdf on 26th April 2017

NHMRC 2015b. NHMRC Information Paper: Evidence on the effects of lead on human health. Downloaded from https://www.nhmrc.gov.au/files/nhmrc/publications/attachments/eh58a_information_paper_effects_lead_human_health_a.pdf on 26th April 2017

Thomas, V.G., Scheuhammer, A.M. and Bond, D.E., 2009. Bone lead levels and lead isotope ratios in red grouse from Scottish and Yorkshire moors. *Science of the Total Environment*, 407(11), pp.3494-3502.

ANNEX

Table A1. Key parameters and assumptions in the assessment of costs and benefits

Key parameters and assumptions
Cost assessment
Number of waterfowl and fowl hunters affected. Based on the existing legislation, bag data and GIS analysis. Hunting of mammals is not assumed to be affected (only for countries with a very high share of peatland it has been included in the worst case cost scenario).
Proportion of total hunting in wetland: Assessed on the basis of the number of waterfowl bagged vis-à-vis the total amount of birds bagged (hunting bag statistics) without distinguishing where the waterfowl and the other birds are bagged. Based on the assumption that (i) hunters that predominantly undertake one type of hunting over another and that (ii) the distribution of bag data across species is proportionate to the number of hunters in each of these cohorts. This could under- or overestimate the number of hunters affected.
Baseline: Effectiveness of current regulation in the different Member States. There is no comprehensive information on this issue available, however examples from some Member States indicate that compliance with partial bans could be low. This has partly been reflected in the worst-case scenario of the cost assessment, which includes more hunters than to be expected if compliance to existing national legislation was assumed.
Use of Corine land cover classes as a basis to estimate the significance of peatland in different Member States and to make assumptions on the number of hunters affected. Not all peatland according to the Ramsar definition is covered by the Corine land cover classes used, in particular peatlands used for forestry and agricultural purposes were not included (see Background Document B 4.3.3.1)
Number of cartridges consumed in EU-28. Based on one reference.
Retail prices of different kinds of gunshot. Based on web searches.
Assumptions on the percentages of steel, bismuth and tungsten are based on one references and assumptions.
The number of shotguns that will have to be prematurely replaced is based on data from literature, hunters' association, manufacturers, and personal communication. These figures can include bias.
Average purchase price of a new shotgun. Based on limited and old data, market changes could have occurred.
Percent of gun owners that will re-proof. Based on one reference.
Cost of proofing test per barrel. Based on one reference.
Costs to other shooters than hunters. Not sufficient information available to derive quantified estimates.
Costs for manufacturers. Not sufficient information available to derive quantified estimates
Enforcement costs and training. Enforcement costs have not been estimated by the Dossier Submitter. It is indicated that enforcement is of major importance for compliance. The costs for effective enforcement could be substantial
Gun retailers and forestry. Based on assumptions, a report, and no comments from public consultation.
The impact assessment assumes an 'average European hunter'. It should be recognised with regard to affordability that large heterogeneity exists between different European hunters in terms of annual bag, budget, etc.
Benefit assessment
Non-quantified benefits (related to the environment and human health, as described in Table 3).
The number of waterbirds dying annually is based on average mortality data derived from a study of the population effects of lead shot ingestion in mallard (Bellrose 1959). The applicability of this method to other species of waterfowl and waterbirds is unknown and may have resulted in either an underestimation or overestimation of impacts.