QUESTIONS AND ANSWERS ON
THE CALL FOR EVIDENCE AND INFORMATION ON
THE USE OF LEAD IN GUNSHOT OUTSIDE OF WETLANDS, BULLETS IN ANY TERRAIN AND IN FISHING TACKLE

VERSION NUMBER: 1.0

DATE: 4 November 2019

PURPOSE:

The purpose of this document is to support the call for evidence on the use of lead in gunshot outside of wetlands, lead in bullets in any terrain and lead in fishing tackle. It aims to clarify the type of information that we would like to receive.

The call for evidence is open from 3 October 2019 until 16 December 2019:

https://echa.europa.eu/calls-for-comments-and-evidence/-/substance-rev/24001/term

This document is complementary to the ECHA webinar that was organised on 15 October 2019. The webinar can be viewed via the following link: https://www.youtube.com/watch?v=YYZVLrrKxrQ

This document is presented in the form of 'questions and answers'. It is based on questions received from stakeholders during the webinar. This document might be revised based on feedback, or if additional questions are received from stakeholders.

If you need further clarification, or if a specific question has not been answered, please contact the ECHA helpdesk[1].

Readers are reminded that the text of the REACH and CLP Regulation is the only authentic legal reference and that the information in this Q&A document does not constitute legal advice.

The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document. Use of the information in this document remains the sole responsibility of the reader.

[1] https://echa.europa.eu/contact/other

TABLE OF CONTENTS

1. REACH Restriction proposal process

1.1. Call for evidence

#	Question	Answer
1.1	How can I participate in the call for evidence?	The purpose of the call for evidence is to collect information that could be used to: (i) assess the risks to the environment and human health posed by the use of lead in ammunition (gunshot and bullets) and fishing tackle and, (ii) assess the impacts on society of a restriction on these uses. Specific questions on the topics that we would like to receive more information on can be found in the background note. Interested parties can submit information via the webform on ECHA website: https://echa.europa.eu/fi/calls-for-comments-and-evidence/-/substance-rev/24001/term The call for evidence is open until 16 December 2019. Please familiarise yourself with the background document and the supporting screening document[2] before sending information.
1.2	What are the next steps after the call for evidence?	ECHA has 12 months to complete their investigation and, if needed, propose a restriction in the form of an Annex XV restriction report. The report would be submitted in October 2020. ECHA is planning an invitation only expert stakeholder workshop in Helsinki in February 2020. Participants will be selected based on the responses to the call for evidence.

[2] https://echa.europa.eu/documents/10162/13641/lead_ammunition_investigation_report_en.pdf/efdc0ae4-c7be-ee71-48a3-bb8abe20374a

#	Question	Answer
1.3	Do I have to reply to all of the general and specific questions in the call for evidence webform?	No, it is not compulsory to answer all the questions. You should submit the information that you have available. Also if you have some information available now but other information only later then you should inform us. It is possible to make more than one submission. However, a minimum amount of compulsory information is requested. This information is marked with an asterisk in the call for evidence webform.
1.4	What is the preferred way of submitting scientific material for the call of evidence? (mail, e-mail, via the ECHA website or something else?)	The only way of submitting information to the call for evidence is via the secure webform on the ECHA website. https://echa.europa.eu/calls-for-comments-and-evidence/-/substance-rev/24001/term Only information submitted via the secure webform will be considered. You can answer the questions in the commenting box but is it also possible to attach any other scientific or technical material to the webform using the attachment button. The information provided should be supported by evidence, and/or reference as much as possible.
1.5	I have confidential business information that I wish to share with ECHA. How can I share this without breaking competiveness or anti-trust laws?	It is possible to provide confidential information, or attach confidential documents to the webform. Your name or your company/association name can also be claimed confidential. We will maintain confidentially in line with the provisions for EU institutions.

#	Question	Answer
1.6	Could the information submitted in the call for evidence influence the scope of a proposed restriction: e.g. derogation or transitional (phase out) period recommended for a specific use?	Yes. Information provided during the call for evidence may have an influence on the need for EU action and the conditions of any restriction proposed, including transitional periods. The conditions of any restriction proposed will be determined based on various factors, including risks and socio-economic considerations, such as the availability of alternatives and the time required to transition to them. Please provide any information to us that you think would be relevant to the need for a derogation or duration of transitional arrangements. Please refer to the guidance on public consultations on restriction proposals for further details on what type of information should be provided in the call for evidence.
1.7	We noticed that the screening report has been edited since its first publication. Could ECHA inform stakeholders where updates were made (ideally indicating which parts have been changed) given the length of the dossier?	The following edits have been made in the screening report since its first publication: Version 1.1 - 13 September 2018: Initial publication Version 1.2 - 17 September 2018: (1) References on pages 38-39 corrected and references list pages 84-85 updated, (2) Findings on new study included on page 39, (3) Advice on game meat from ANSES included in table 6 on page 43. Version 1.3 12 November 2018: Tons of lead for bullets in executive summary corrected on page 4 Version 1.4 27 November 2018: Missing references added
1.8	How can I get the presentation of the webinar?	The presentation of the webinar as well as the recordings are available following this link: https://echa.europa.eu/-/call-for-evidence-on-a-possible-restriction-on-the-placing-on-the-market-and-use-of-lead-in-ammunition-shot-and-bullets-and-fishing-tackle

1.2. Scope of the call for evidence

#	Question	Answer
1.9	Is military use of ammunition going to be in the	The scope of the assessment, as requested by the EU Commission, is on

#	Question	Answer
	scope of the restriction? What about police, customs and other internal security applications?	civilian use of lead in shot and ammunition only. Therefore, this excludes uses by the military, police, customs etc.
1.10	In the background note, 'sports' shooting and hunting are within the scope of your investigation. Does it mean that lead bullets for 'self-defence' will be excluded from restriction?	Outdoor uses of lead ammunition by civilians are within the scope of our investigation. We therefore invite you to provide further details, and information on uses for 'self-defence' by replying to question 1, 3 and 4 in the call for evidence webform.
1.11	Some types of firearms have not been mentioned specifically (e.g. handguns, pistols and revolvers for target shooting on outdoor ranges). Is ammunition for these firearms within the scope of this investigation?	The scope of this assessment would in principle cover all lead shot and lead ammunition for civilian use outdoors and would therefore also cover their use in handguns, pistols and revolvers.
1.12	Indoor ranges have been ruled out-of-scope. Does this mean, that despite any potential restrictions or recommendations - the use of lead ammunition would be still allowed in indoor ranges? (and therefore be commercially available?)	Uses of lead ammunition at indoor ranges are not within the scope of the current investigation.
1.13	Are training and sport shooting in the scope of the assessment?	The scope of the assessment is on all outdoor uses of lead ammunition by civilians. We need to better understand what precisely is meant by 'training and sport shooting' uses. For example, what are the risks and which restriction option would be the most appropriate to address them in case a restriction is needed. We therefore invite you to provide details, and information on these types of use by replying to question 1, 3 and 4 in the call for evidence webform.
1.14	Is it planned to scope the restriction to the pure lead within the shot or also to the cartridge material (potentially brass)?	The principal focus of the investigation are environmental concerns to which the shot and the bullet parts are the main contributors. However, we understand that lead may be present in the bases of cartridges or bullet jackets. We therefore invite you to provide details, and information by replying to

#	Question	Answer
		question 1 in the call for evidence webform.
1.15	Can you please define exactly "non-wetlands areas"?	Non wetland areas are in principle all areas that are not covered by the RAMSAR definition. The RAMSAR definition is as follows: *"…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 the depth of which at low tide does not exceed six metres."*

1.3. REACH Restriction process

#	Question	Answer
1.16	The European Commission has asked ECHA to prepare an Annex XV dossier in view of a possible restriction on placing on the market and use of lead in ammunition. What options are available to ECHA aside from a restriction?	As part of the analysis, ECHA will look at existing legislation to see if this could be used or adapted to control the risk (if so then no restriction proposal would be submitted; instead ECHA would recommend to the Commission that other action could be taken). In addition, existing risk management measures are assessed to see if the risk is already adequately controlled, where again no restriction would be proposed. If a restriction is assessed as the most appropriate means to address a risk then ECHA will perform an assessment of different restriction options. This can assess a variety of restriction options to ensure the most efficient is proposed.
1.17	How often commission's decision follows ECHA findings and recommendations?	ECHA is responsible for developing a scientifically robust assessment taking into account all the relevant scientific and technical evidence. The Commission may deviate from the proposal at its discretion
1.18	Who can propose a restriction under REACH?	The Commission can request ECHA to prepare an Annex XV restriction report. A Member State can initiate a restriction proposal at their own discretion.
1.19	Is it sure that a restriction will be proposed?	At this stage ECHA is gathering information. A decision on whether to propose a restriction, and with which conditions, will depend on the conclusions of our investigation.
1.20	When implementing the restriction, can Member States make their national legislation stricter than the proposed restriction?	In general, this would not be possible as REACH is a single market Regulation directly applicable in all EU/EEA Member States.

#	Question	Answer
1.21	What is the expected Entry Into Force (EIF) date of the restriction?	At this stage ECHA is gathering information. A general timeline for this proposal has also been published at the ECHA hot topics page: https://echa.europa.eu/hot-topics/lead-in-shot-bullets-and-fishing-weights. After the call for evidence, ECHA will make its assessment with the objective of justifying the need for a restriction (or no need for a restriction) in an Annex XV report. Should a restriction be needed it will be proposed in October 2020. ECHA's scientific committees require 18 months to evaluate the proposal after agreeing that the proposal is in 'conformity', with the requirements of the REACH Regulation. After which it is sent to the Commission for decision making, which typically takes 12 to 24 months. On this basis the earliest entry into force could be estimated to be 2023 or 2024. Transitional arrangements for specific uses (e.g. to allow sufficient time after the entry into force of a restriction to transition to the use of alternatives) can be considered on a case-by-case basis based on sound justification. Information relevant to establishing the conditions and duration of any transitional arrangements should be provided in the call for evidence.
1.22	If there is a restriction: Is it planned to combine the wetland restriction with the terrestrial restriction in one REACH annex XVII entry?	First, at this stage of the process, it is not possible to conclude if a restriction at EU level is the most appropriate option to address the risk from the use of lead in ammunition outside of wetlands, nor what would be the scope and conditions of this restriction, if any. Based on the information received via the call for evidence, ECHA will undertake an assessment of the available information, and prepare an Annex XV restriction proposal if needed. This restriction proposal will be reviewed by ECHA's Committees. Ultimately, it is the Commission that will decide on the final entry into the Annex XVII.

2. Risk considerations (question 1 and 2 in webform)

2.1. General questions

#	Question	Answer
2.1	How does ECHA handle the evaluation of a diverse product category where different products within the category have different exposure pathways?	We would like to understand how different categories of use of lead would cause different exposure pathways. Issues associated to outdoor shooting ranges might be different from e.g. hunting situations. Different risk management options may be appropriate for different uses. We invite you to provide information on the different types of use, their pathways, and exposure data by replying to question 1 in the call for evidence webform.

#	Question	Answer
2.2	Can ECHA consider proportionality when considering a restriction process, if a restriction was considered the most appropriate option? Based on risk exposure (no-safe limit etc)?	Within the restriction process, proportionality can be understood in different ways. ECHA needs to demonstrate that a risk is not adequately controlled and then proposes various restriction opinions to mitigate that risk. It is possible that after considering its effectiveness and compliance costs one restriction option is more proportionate than the others. Elements that could be important in evaluating the proportionality of these options are for example: the transition period, the availability of alternatives, costs of transition, etc. As part of the restriction we will perform a socio-economic analysis, this is a well-established method of weighing up the pros and cons of an action for society as a whole and plays a vital role in the restrictions processes under REACH. Restriction proposals need to contain a description of the risks as well as information on the health and environmental benefits, the associated costs and other socio-economic impacts Proportionality in REACH restrictions is assessed by comparing the socio-economic benefits of a measure to the socio-economic costs. This is done from the perspective of society, which means that we look at a wide a range of actors and evaluate how these actors are impacted by a measure such as a restriction.

#	Question	Answer
2.3	In terms of ECHA's approach to its risk assessment, do volumes of lead consumption matter from a human health perspective? When ECHA says there is no safe limit?	Although lead is considered as a non-threshold substance (i.e. there is no safe exposure level) the quantity of lead consumed is relevant when characterising the likelihood and magnitude of risk. Low levels of consumption are associated with lower risks than higher levels of consumption. This is described by a dose-response relationship. A commonly used dose-response relationship for lead exposure is that which describes the relationship between blood lead concentrations and reduced Intelligence Quotient (IQ) in children, as described by EFSA in their 2010 opinion on lead in food. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1570 In addition, several food safety agencies have published advice regarding the consumption of game meat. ANSES recently advised consumers to limit themselves to occasional consumption of large wild game (approximately three times a year); and that women of childbearing age and children avoid all consumption of large wild game. https://www.anses.fr/fr/content/consommation-de-gibier-sauvage-agir-pour-r%C3%A9duire-les-expositions-aux-contaminants-chimiques (site content available in French and English)
2.4	There are questions difficult to answer, e.g. about game consumption patterns, meat handling and preparation, tonnage of lead used in different activities etc without undertaking new research. Will you use some sort of confidence assessment for such data?"	We would primarily focus on the available information, and in particular information supported by robust evidence, or reference. Where information is lacking, conflicting or poorly justified we will make reasonable assumptions. These can be replaced or refined if and where better or more accurate information becomes available.
2.5	Are you taking into consideration also cases where a lead ban was lifted (i.e. Norway)?	You may have noticed from the wetlands report, that we took into account a wide range of information. This included information from the Netherlands and Denmark. ECHA has an interest to take into account as much experience available in the Member States as possible. This would then indeed also cover the Norwegian experience, but we would need to understand better why this ban was repealed.

#	Question	Answer
2.6	Did the European Commission ask ECHA to conclude that lead should be restricted in ammunition?	You can find the request from the Commission on ECHA website here: https://echa.europa.eu/documents/10162/13641/rest_lead_ammunition_COM_request_en.pdf/f607c957-807a-3b7c-07ae-01151001d939
2.7	Do you need information on water and drinking water? Which type of information?	In the previous work on wetlands we had come across studies that linked elevated levels of lead in water to the presence of shooting ranges nearby, suggesting that the use of lead in ammunition on shooting ranges may have an impact on water quality, potentially even on drinking water quality. We would be interested in any further studies that might confirm this further and link this to the use of lead or studies that show that this would not occur due to risk management measures that are taken at shooting ranges.
2.8	Has ECHA used any reports from Norway (e.g. NIVA report LNR 4781-2004) in the screening report?	The studies used in our work are reported in the list of references. You can find the screening report following this link: https://echa.europa.eu/documents/10162/13641/lead_ammunition_investigation_report_en.pdf/efdc0ae4-c7be-ee71-48a3-bb8abe20374a In case you notice that some important studies within the scope of the current investigation are missing, we invite you to submit these studies via the call for evidence.
2.9	Concerning how much lead is used in different activities, does these numbers match the production? are they validated by the manufactures?	We recognise that there is uncertainty on the exact volume of lead based ammunition, shot and fishing sinkers paced on the EU market. We have previously used data from a studies by AMEC and COWI. The estimates of market volumes in these studies were based on communication with ammunition manufacturers. These estimates were confirmed by industry stakeholders during the development and evaluation of the proposal to restricted the use of lead gunshot in wetlands. Nevertheless, if you have different or additional information available, we invite you to submit these values by replying to question 1 in the call for evidence webform.

#	Question	Answer
2.10	Do you split the volumes of lead used in ammunition between the ones used in indoor shooting ranges, outdoor shooting ranges and hunting?	Yes. These are distinct uses that need to be assessed based on their own merits. This would require that the volume per use would need to be split in order to compare costs and benefits. Please not that indoor uses of lead ammunition are outside of the scope of our investigation.

2.2. Environmental impacts

#	Question	Answer
2.11	What if there is no impact on populations of birds? How will ECHA approach risk in this respect? look at individual mortality?	This aspect of risk assessment was discussed extensively, by both the Dossier Submitter and RAC, during the development and evaluation of the proposed restriction on the use of lead gunshot in wetlands. In this case individual-levels effects (mortality of ~1 million waterbirds per year in the EU) were considered to be of sufficient magnitude to be of concern irrespective of the available population-level data. In the absence of additional information to the contrary it is likely that a similar approach will be adopted in the current assessment.
2.12	What if there is limited evidence on a particular issue e.g. safety of a type of ammunition? How do you consider limited evidence on key issues?	Please see as well the answer to question 2.4. In the event that we identify data gaps in our assessment, then it may be that we will have to rely on reasonable and justified assumptions. If this is the case then this will be clearly stated in the report.

2.3. Human health impacts

#	Question	Answer
2.13	Shall there be an investigation whether hunters actually suffer any harm from use of lead ammunition?	The aim of the call for evidence is to investigate the risks posed by lead to the environment as well as to humans via the environment (i.e. through the consumption of food). Re. the exposure of humans via the environment, hunters might be a target group, as they might consume the game they hunt. But they are not the only target group: general population, including children, might also consume game. We are therefore interested in any study or information about the consumption of game/fish (by any population group or sub-group) and the associated health effect due to lead consumption. If you have information available on this topic, we invite you to submit these values by replying to question 1 in the call for evidence webform.
2.14	How you will record the lead retention of game eating people in this short time of the investigation?	ECHA will make use of existing scientific or otherwise reliably and formally composed data of game meat consumption. The sources for this type of information can for example include national or EU-level surveys. However, all relevant data can be provided for our assessment. The quantification of the accumulation of lead in the body can be reliably estimated for different population groups with widely applied and proven methods when the estimated levels and ranges of exposure are known. If you have information available on this topic, we invite you to submit these values by replying to question 1 in the call for evidence webform.
2.15	Which information do you need on home casting?	From previous work on lead, such as for example the setting of occupational exposure limits we are aware of measures that need to be taken at workplaces to limit worker exposure to lead. Translating this to private places where home casting takes place, we would like to understand how home casting is done, and under what circumstances (vis-a-vis hygiene) this is taking place. If you have information available on this topic, we invite you to submit these values by replying to question 2 in the call for evidence webform.

Q&A ON USE OF LEAD IN GUNSHOT OUTSIDE OF WETLANDS, BULLETS IN ANY TERRAIN AND IN FISHING TACKLE

3. Alternatives (question 3 in webform)

#	Question	Answer
3.1	What information do you need on alternatives in the call for evidence?	For the assessment of the technical and economic feasibility of an alternative it is particularly important to have information on the following area: - where the alternative does and does not work (i.e. its performance compared to the use of lead based gunshot, bullets and fishing sinkers); - how much (more) it costs per specified unit to use this alternative rather than using lead (i.e. price differences); - if (and how many) gun owners would need to replace existing shotguns or rifles, and how much would this cost; - how quickly the alternative could be implemented in a company or even a type of use, e.g. the time necessary to develop alternatives; - whether alternatives are available in sufficient quantities on the market or the time necessary for that; - information on hazard and risk of alternatives as well as indirect effects; - other relevant information. Please provide information on the availability of in the specific question 3 in the call for evidence webform.
3.2	ECHA guidance note states that one of the "Elements of an Annex XV assessment" is "An analysis of the availability and technical performance of alternatives": Does that also include evaluation of the toxicity of alternatives?	Indeed, we would like to understand as well the toxicity of any of the alternatives. This is with a view to understand all relevant impacts of switching to alternatives and as such does not constitute another reason to limit or restrict alternatives as well. The toxicity of alternatives is important to understand in relation to the net changes in environmental or human health impacts that would result from the use of alternatives. Information on alternatives, including their hazard and risk can be provided in the specific question 3 in the call for evidence webform.

#	Question	Answer
3.3	All the ammunition alternatives (copper, zinc, tin, steel, tungsten) are harder than lead, so there will be much more projectiles reflections resulting in deadly injuries. This is a physical law principle. How are you going to cope with this?	We refer to the DEVA study published in 2013 as referenced in the restriction proposal on the use of lead in wetlands. The design of the study is not on whether steel shot ricochets but on whether it ricochets differently or more dangerously then lead shot. Both lead and steel shot ricochet. DEVA (DEVA, 2013) concluded that ricochet from lead and steel is comparable. Furthermore, the Danish Hunting Insurance company registers reports on shooting accidents including accidents caused by ricocheting gunshot. The records from the period after the phase-out of lead shot do not indicate any increase in the frequency of ricochet-related accidents. This may be a product of the precautionary steps that were taken in the 1990s, and also that hunters have used lead-like gunshot (bismuth-tin) particularly for forest hunting where the risk of ricochets (e.g. from tree trunks) is larger than in open habitats. Furthermore, hunters are educated to take safety angles into consideration. Information about whether this holds for terrains outside of wetlands and for bullets will need to be evaluated when developing the report.
3.4	Zinc is toxic for fish embryos, copper is toxic for water life, bismuth is toxic, steel is highly corrosive. If lead ammunition is restricted, how are you going to ensure that you do not replace one risk with another?	Please see the answer to question 3.2

4. Socio-economic aspects (question 4 in webform)

4.1. General questions

#	Question	Answer
4.1	How do you assess proportionality?	Proportionality is assessed on a per-use basis (and where information permits even on a product group level). Thereby the costs incurred per use are compared to the potential of emission of lead. See also our reply to question 2.2

4.2. Need for derogation

#	Question	Answer
4.2	I don't think my use should be restricted. How can I ask for an exemption?	In order to consider a derogation for a specific use, a clear justification, including detailed supporting information, must be provided in the call for evidence. Guidance on the information that should be submitted during the call for evidence on a restriction proposal is available on ECHA website: https://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf Specifically, respondents must demonstrate that a restriction of their use would be disproportionate or generate undesirable indirect effects that would not contribute to overall risk reduction. Other relevant information may be considered. Information on the costs and benefits of a possible restriction can be provided in the specific question 4 in the call for evidence webform.

#	Question	Answer
4.3	What about the very old (historic) weapons? Are they in the scope of your work? Which information do you need to consider a derogation?	The scope of the assessment, as requested by the EU Commission, is on all uses of lead in ammunition (gunshot and bullet), this would include historic weapons as well. In order to consider the need for derogations for this type of use, we would need to understand better the use and the socio-economic impact of a possible restriction. Please provide information on the uses (description of the use, quantity of lead used, etc..), alternatives if any, costs and benefits of a possible restriction, in the specific question 1, 3 and 4 in the call for evidence webform.