

Consultation on the European Food Safety Authority (EFSA) data on game meat intake and lead concentrations in game meat used by ECHA for the assessment of the human health risks posed by lead in ammunition in the restriction proposal on lead in outdoor shooting and fishing

1. Background

In January 2021, ECHA (as Dossier Submitter) proposed restrictions on the use of lead in ammunition for outdoor shooting and in fishing sinkers and lures. The proposal was based on risk assessments for both human health and the environment that concluded that risks were not adequately controlled. The proposed restriction was evaluated by ECHA's scientific committees for risk (RAC) and socio-economic analysis (SEAC) and was also subject to a six-month consultation of interested parties. RAC adopted its opinion on the proposed restriction in June 2022. Details of the proposed restriction are provided in the Background Document.

The assessment of the risk to human health from the consumption of game meat hunted with lead ammunition was based on data collated by the European Food Safety Authority (EFSA). EFSA provided ECHA with datasets on (i) game meat intake and (ii) lead concentrations in game meat. Whilst neither of these datasets were publicly available, summary statistics of the data were reported in the Background Document and the reliability and representativeness of the data, as well as the methodology used by ECHA as Dossier Submitter, were fully evaluated by RAC¹.

Certain stakeholders requested these datasets from EFSA to provide comments in the six-month consultation of interested parties. However, these stakeholders did not receive access to these datasets until after the consultation was closed.

The Commission considers that stakeholders should be able to provide comments on the actual EFSA datasets, as well as any relevant additional evidence, and that these comments should be considered by RAC. Therefore, ECHA's Committee for Risk Assessment (RAC) was requested to:

1. Open a three-month targeted consultation on the actual EFSA data in order for stakeholders to provide additional comments and supporting evidence.
2. Ask RAC to re-assess their evaluation of the EFSA data on game meat intake and lead in game meat in the light of any additional stakeholder comments and supporting evidence relating to those data that would be provided during the targeted consultation.
3. Ask RAC to provide a supplementary opinion updating or confirming their conclusions on the risks posed by the intake of lead through consumption of game meat, on the basis of the above re-assessment.

¹ The assessment of the risk to human health from the consumption of game meat hunted with lead ammunition performed by ECHA as the Dossier Submitter is described in section 1.6.3.6.5 and section 1.6.4.6.1 of the Background Document.

The Commission requested that the supplementary RAC opinion should be agreed at the first available RAC meeting after the consultation and sent to the Commission at the same time as the RAC and SEAC opinions on the proposed restrictions on lead in outdoor shooting and fishing.

2. Targeted consultation

The consultation will start on 6 July 2022 and end on 6 October 2022.

The EFSA datasets on game meat intake and lead concentrations in game meat subject to consultation are published on the ECHA website alongside the consultation. The relevant information related to the restriction on the use of lead in ammunition for outdoor shooting and in fishing sinkers and lures is available at: <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1840159e6>.

Information not related to the EFSA datasets subject to consultation will not be taken into consideration by RAC.

Interested parties can provide their comments using the relevant web form on the ECHA website

<https://comments.echa.europa.eu/comments cms/PublicConsultationED.aspx?RObjctId=0b0236e185d702d6>. When submitting comments, please keep in mind that:

- It is usually necessary to provide **supporting evidence** (i.e., in the form of references, data or other information) alongside comments. Without supporting evidence, it is usually not possible for RAC to evaluate the credibility of the comment.
- Information arriving after the closing date or via channels other than the web form will **not be taken into account**.
- It is your responsibility to remove **confidential information** from the comments and attachments submitted with non-confidential status.
- As far as possible, justifications based on non-confidential information are preferred to those based on confidential information. Should the submission of confidential information be considered to be fundamental, then a non-confidential form of the confidential information should be submitted in addition to the confidential information. This is to allow for the most transparent discussion of the justifications in the RAC opinion.

Further information can be found in the consultation guidance available at: https://echa.europa.eu/documents/10162/17233/restriction_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c

Important note: In addition, ECHA's Committee for Socio-Economic Analysis (SEAC) is holding a 60-day consultation for interested parties on its draft opinion on the proposed restriction, which was agreed on 3 June 2022. Comments on the SEAC draft opinion should not be submitted to this targeted consultation but to the specific SEAC draft opinion consultation: <https://www.echa.europa.eu/web/guest/consultations/current>

3. How to submit a comment in the targeted consultation

When you are ready to make your comments, click on the appropriate link on the ECHA website. Please be aware that it is not possible to save your submission and come back to it, so you should already have your comments prepared in an attachment or saved in some other format in advance.

The web form contains the following parts:

- Introduction: containing some general information on the restriction and links to the registry of intentions until outcome entry and SEAC draft opinion consultation.
- Instructions.
- Personal information.
- Organisational information.
- General comments: Your responses can be entered directly into the form or through the following section as an attachment. However, please do not submit the same comments via both means.
- Attachments: Public and confidential attachments can be added here, in the respective fields. Confidential information will only be available to the ECHA Secretariat, the Committees and Member State Competent Authorities. However, if ECHA receives an Access to Documents request, we may come back to you for justifications why the information is confidential. You can also add this information already in the relevant part of the web form.

Once you have finished your submission press the submit button and your comments will be submitted. You will receive a submission number via e-mail, and you should refer to this in any communication with ECHA on this issue. It is not possible for you to retrieve your submission so you may want to take a screen shot, or printed copy for your future reference.