

Note for the attention of Tim Bowmer, Chair of the Committee for Risk Assessment

Ref: Request to the Committee for Risk Assessment to prepare a supplementary opinion on the restriction dossier on lead in outdoor shooting and fishing

In accordance with Article 77(3)(c) of the REACH Regulation, the Committee for Risk Assessment (RAC) is requested to prepare a **supplementary opinion** on the proposed restriction on lead in outdoor shooting and fishing, taking into account certain elements which emerged after the closure of the consultation on the Annex XV report on lead in outdoor shooting and fishing and were not considered in RAC's opinion adopted in June 2022.

Specifically, the RAC is requested to:

1. By means of a three-month targeted consultation on the ECHA website, allow stakeholders to provide comments and supporting evidence on a dataset of lead in game meat and game meat intake provided by the European Food Safety Authority ('EFSA dataset') used by the Dossier Submitter in their assessment of human health risks from lead ammunition, but which was not publically available prior to the closure of the consultation on the Annex XV report.
2. Based on the comments and supporting evidence received in the targeted consultation, re-assess their evaluation of the EFSA dataset.
3. 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. Background

Certain stakeholders encountered difficulties in obtaining access to the European Food Safety Authority (EFSA) data on game meat intake and lead in game meat used by ECHA, as Dossier Submitter, in its assessment of the risks posed by lead in game meat. Whilst the raw data used by ECHA as Dossier Submitter were not publicly available, accurate summary descriptions of the data were reported in the Annex XV report.

The data were available to RAC and their reliability and representativeness, as well as the methodology used by ECHA as Dossier Submitter for risk and impact assessment, were evaluated in detail by RAC and discussed in its opinion. Nevertheless, the Commission believes that it is important to give stakeholders the opportunity to analyse the actual EFSA data

(rather than ECHA's summary descriptions) and provide their comments as well as any relevant additional evidence to ECHA, for consideration by RAC.

2. Terms of Reference

The Committee is requested to prepare a supplementary opinion on the proposed restriction of lead in outdoor shooting and fishing, taking into account of any additional stakeholder comments and supporting evidence relating to those data that would be provided during the aforementioned three-month targeted consultation. RAC is requested 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 (as described above).

3. Timescale for the RAC

Considering the limited scope of the analysis, which should only encompass stakeholder comments and evidence relating to the EFSA data on game meat intake and lead in game meat used by ECHA, the Commission considers that a RAC supplementary opinion can be prepared in a shorter time than usually required for the preparation of a RAC opinion. As the aim of the RAC supplementary opinion is to inform the Commission decision on a possible proposal for a restriction, we would appreciate that it be included in the submission of the RAC and SEAC opinions to the Commission in accordance with Article 72(1) REACH.

Therefore, following receipt of the letter from the Commission (dated 17 June 2022), the aim is to adopt the supplementary opinion at the November/December 2022 RAC meeting. The Commission asks ECHA to ensure the discussion of the above matters in RAC at the first available RAC meeting after the targeted consultation with a view to adopting a RAC supplementary opinion during the same meeting.

4. Remuneration

The task for RAC following from this request is not considered to fulfil any of the requirements of a transfer of funds to the competent authorities of the Member States pursuant to Article 14(1) of Regulation (EC) 340/2008 and therefore no remuneration will be paid by the Agency.

*(e-signed)*¹

Shay O'Malley
Acting Executive Director

Cc: Peter van der Zandt

¹ As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.