

Note for the attention of Dr Tim Bowmer, Chairman of the Committee for Risk Assessment

Ref: Request to the Committee for Risk Assessment to review the RAC opinion in relation to the harmonised classification of lead

The Committee for Risk Assessment (RAC) is requested to review the environmental classification of lead as adopted by RAC in its opinion of 30 November 2018.

1. Background

On 30 November 2018, RAC adopted an opinion on the harmonised classification and labelling of lead. The dossier submitter (Denmark) had proposed a classification for environment, for both the massive and the powder form, as Aquatic acute 1 and Aquatic chronic 1, with M factors of 10. The RAC opinion confirmed the dossier submitter's proposal but with an M-factor of 1 for Aquatic acute 1.

Following the adoption of the opinion, manufacturers of the substance provided new information on the chronic toxicity of lead in the pond snail *Lymnea stagnalis* (OECD 243). The new information may have an impact on the classification of lead as *Lymnea stagnalis* was considered as the most sensitive species for chronic toxicity on the basis of the available data when the RAC opinion was developed. In addition, the RAC opinion contains an appendix describing an alternative view, ultimately not supported by RAC, for the classification of lead with a particle diameter ≥ 1 mm (i.e., lead in massive form). During the decision making process, including the consultation of the Commission expert group (i.e., CARACAL) and taking into account the arguments provided in the alternative view, some concerns have been expressed with regard to the final decision of RAC not to have a split classification for the powder and the massive form of lead.

Consequently, the environmental classification of lead should be reviewed by RAC, in accordance with recital 5 (see below) of the draft Commission Regulation updating the entry of lead listed in Annex VI of Regulation (EC) No 1272/2008.

(5) With regard to the substance lead (CAS number 7439-92-1 and index numbers 082-013-00-1 (lead powder; [particle diameter < 1mm];) and 082-014-00-7 (lead massive; [particle diameter ≥ 1 mm];)), RAC proposed in its opinion of 30 November 2018 to apply the same environmental classification to the massive and the powder form. However, in view of the

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lower dissolution rate of the massive form, the malleable structure of lead, the specific intentional production of the powder and the different environmental classification between

massive and powder forms for existing entries in Annex VI for other metals, further assessment needs to be done by RAC on whether to apply the same environmental classification to the massive as to the powder form of lead. In addition, new scientific data has been made available suggesting that the environmental classification for the massive form as recommended in the RAC opinion might not be appropriate. Therefore, the environmental classification for the massive form will not be included in Annex VI to Regulation (EC) No 1272/2008 until RAC has had the opportunity to deliver a revised opinion.

2. Terms of Reference

In accordance with Article 77 (3) (c) of the REACH Regulation, RAC is requested to prepare an opinion on the environmental classification of lead. The opinion should focus on:

1. A reassessment of the ERV values for lead, using the existing data set from the original CLH dossier and taking into account the new chronic toxicity study for lead in *Lymnea stagnalis* following OECD TG 243 (Fox M. (2020) Lead nitrate: Determination of effects on reproduction to *Lymnea stagnalis*, Study number 1077.00101).

2. A re-examination of whether the powder and massive forms of lead warrant the same classification for hazards to the aquatic environment. RAC is requested to provide sufficiently detailed justification and argumentation to support its conclusion. Interested parties should also be requested to submit data relevant to the properties of the powder and massive forms in the consultation mentioned below.

- If RAC concludes that powder and massive lead warrant discrete classifications for hazards to the aquatic environment, RAC shall provide separate classification recommendations for both the powder and massive forms of lead, following the classification scheme for metals.

3. Timescale for the RAC opinion

Considering the limited scope of the request, it is considered that the opinion be prepared in a shorter time than usually required for an opinion on harmonised classification. The European Commission is requesting ECHA to conduct a consultation on the new snail study (Fox, 2020) and to request any relevant data on the properties of the powder and massive forms. The duration could be reduced compared to normal harmonised classification-related consultations given the limited amount of information that is new compared to the information considered in the original CLH dossier.

Within 12 months after the receipt of the request, ECHA should finalise the analysis with a view to developing an opinion on the environmental classification for the massive form of lead.

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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

Jukka Malm
Deputy Executive Director

Cc: Christel Musset, 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.