International Lead Association

Position Paper

Lead Metal Harmonised Environmental CLP Classification

We have critical concerns with the latest RAC opinion on a harmonised ENV CLP classification of lead metal issued on 16th September 2021. It does not represent an objective review of the evidence available or follow the existing ECHA CLP guidance on metals. Importantly the methodology used by the committee for deriving the lead metal CLH opinion differs in several critical areas compared with other ongoing metal environmental CLH opinions and these have a significant bearing on the final hazard classification derived. Some aspects of the opinion even appear to go beyond the mandate given the Commission Article 77 (3) request.

As several metals ENV CLH opinions are currently being considered by RAC we would request that Commission considers postponing the inclusion of a revised lead metal CLH in Annex VI to CLP until these are complete. This is necessary to maintain the fundamental principle of CLP that consistent criteria are applied between substances to derive a hazard classification.

There are issues with the Article 77 (3) (c) opinion for lead metal in the following areas:

Assessment of the forms of lead: RAC concluded that lead particles < 1 mm are present in swarf generated from industrial processing – cutting – of lead sheet (an article). This was seen as evidence that powders are formed during reasonably expected use of the substance lead [in massive form] which are relevant for hazard assessment and classification. ***We challenge the conclusion that article releases can be used for the purpose of the hazard classification of the metal (a substance) which would set precedence for many substances even beyond the metal sector***.

Notwithstanding this, the available evidence highlighted that the quantity of lead particles generated from lead sheet processing represents <0.001% of the lead metal placed on the EU market. RAC concluded that ANY quantity of such particles produced is relevant for classification, however small, and adopted a strategy whereby lead in massive form was classified for hazard based on the potential releases of lead ions into solution from a fine powder (75µm). After 28 days, lead ion releases from 75µm powder are 18x greater than a 1mm sphere (default for massive) at pH 5.5 and 200x times greater at pH 8. Given that most of the lead in massive form placed on the market is in the form of large ingots weighing between 25-50kg, significantly larger than 1mm (the default for massive used in T/dP testing), we believe **the RAC assessment clearly fails a test of proportionality**.

<u>Assessment of solubility of the metal</u>: The new RAC opinion extends the pH range of the 28-day T/dP test (OECD TG 29) for the chronic assessment of release of lead ions into solution from pH 6 to pH 5.5. *This **appears to go beyond the mandate provided to the committee by Commission in the Article 77(3) request*** that only asked for an evaluation of the chronic Ecotoxicity Reference Value (ERV) for lead as well as a scientific opinion on how many entries are appropriate to appear in Annex VI to CLP.

Moreover, we believe that assessing releases of metal ion into solution at pH 5.5 is not appropriate for CLP classification. Round Robin testing after publication of OECD TG 29 concluded that testing at pH 5.5 was highly unreliable and not feasible without modifying the speciation aspects of metals due to the pH modifiers used. The OECD Joint meeting agreed with this, and OECD has only validated the 28d T/dP test in the range 6.0-8.5.

*To date all previous metal ENV classifications only examined dissolution into solution down to pH 6, and furthermore the examples in the ECHA CLP Guidance on the Application of the CLP Criteria only use 28d T/dP data in this pH range**.***

***To single out lead for examination of 28-day dissolution at pH 5.5 and no other metals appears to go against a fundamental principle of CLP that consistent criteria are applied**.* It should be recognized that extending the pH range for 28-day T/dP tests would result in classification of many other metals in massive form, including iron, which was felt too precautionary.

Applying the T/dP test in the range 6.0-8.5 is further supported by ecological evidence. Indeed, below pH 6, only species specifically adapted to this extremely stressful physiological condition would reasonably survive and it would therefore not be appropriate to compare dissolution/solubility of metals at this pH with toxicity observed in standard laboratory species. For example, sensitive invertebrate species such *Ceriodaphnia dubia* or *Lymnaea stagnalis* will not reproduce or thrive at pH 5.5 irrespective of presence of test chemical.

<u>Lack of recognition for ecotoxicity data quality</u>: The CLP Regulation states that "for the purposes of CLP classification preference should be given to studies conducted in accordance with the EU test methods (Reg. (EC) 440/2008) or other international test methods validated according to international procedures such as those of the OECD." The chronic Environmental Reference Value (ERV) for lead was however derived by RAC using the single lowest value from a large data set. The critical study selected was from a sensitive life stage of a non-standard species (*Lymnaea stagnalis*, the pond snail) using a protocol that was not conducted in accordance with international test methods validated according to international procedures. This is not an approach taken previously by RAC for other metal harmonized environmental classifications that have typically been restricted to use of "standard species and endpoints from standardised method". **Again, a fundamental principle of CLP appears to have been neglected in that consistent criteria have not be applied**.

Comparison of toxicity and dissolution at different pH bands: The ECHA *Guidance on the Application of CLP Criteria*, Version 5, section IV.2.3 *Comparison of aquatic toxicity data and solubility data*, states "*When a more extensive toxicity/dissolution dataset is available, a split of the acute and chronic ecotoxicity reference values can be performed according to their pH used during T/D test. Meaning that toxicity data and transformation data are in this case always compared at the same pH*."

While the above approach following pH banding of ecotoxicity and solubility data has typically been applied by RAC for other metals, the committee's opinion was that the classification for lead should be determined by comparison of the highest toxicity and maximal solubility across the entire pH range - the most precautionary approach possible and a situation that in practice cannot occur in nature as a water body cannot simultaneously have two pH values.

The rationale for taking this approach equally applies to other metals but has not been applied for lead in practice. **Again, a fundamental principle of CLP appears to have been neglected in that consistent criteria have not be applied.**

Implications for CLP Classification

The final opinion presented by RAC is that lead metal in ALL forms be classified as:

Aquatic Acute 1 (H400), M = 10, Aquatic Chronic 1 (H410), M = 100

Each of the issues raised above has a significant implication for the final ENV CLP classification derived. For example:

1. **Assessment of the forms of lead:** It was accepted that if lead massive should receive a separate classification to powder by using the T/dP data of the massive form, then the classification of lead massive would be **Aquatic Chronic 1 (H410), M=10**. This is highlighted in Annex II to the recent RAC opinion.

2. **Assessment of solubility of the metal:** If the lowest pH value evaluated in the 28d T/dP test was fixed at 6.0, lead powder would be classified as **Aquatic Acute 1 (H400), M = 10, Aquatic Chronic 1 (H410), M = 100** (i.e. no change) but lead massive would be classified as **Aquatic Chronic 1 (H410), M = 1**

3. **Lack of recognition for ecotoxicity data quality:** If only standard species and endpoints from standardised methods were included for the calculation of the chronic ERV, lead powder would be classified as **Aquatic Acute 1 (H400), M = 10, Aquatic Chronic 1 (H410), M = 10** but lead massive would be classified as **Aquatic Chronic 2**

4. **Comparison of toxicity and dissolution at different pH bands:** If toxicity and dissolution were compared at the same pH band, lead powder would be classified as **Aquatic Acute 1 (H400), M = 1, Aquatic Chronic 1 (H410), M = 1** but lead massive would **not be classified** for chronic aquatic toxicity.

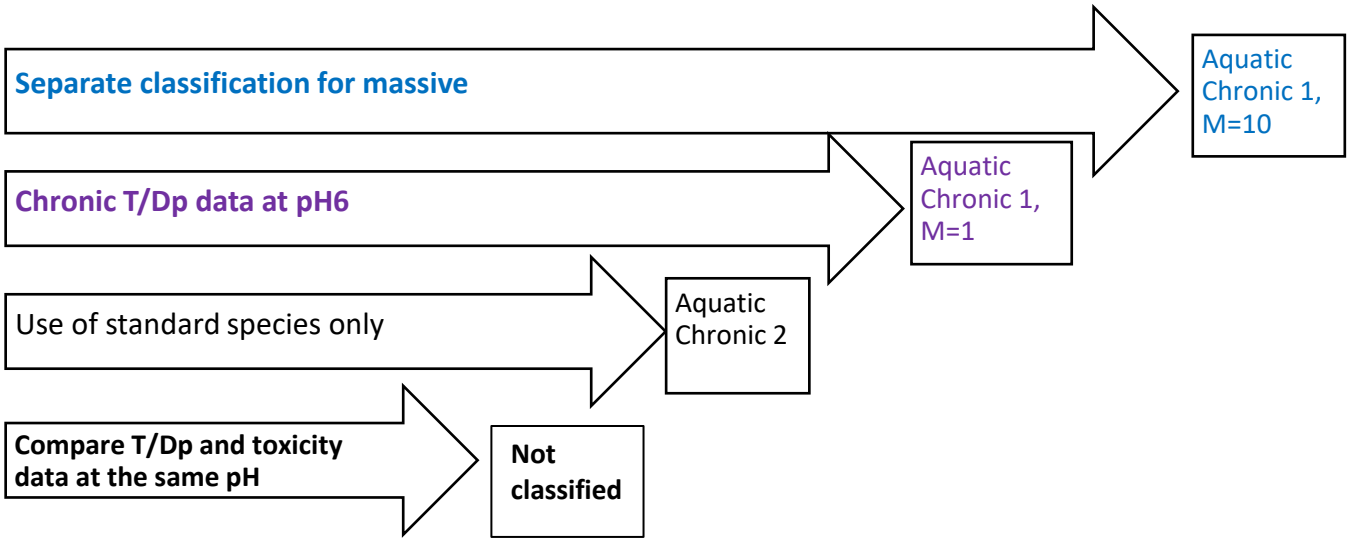

Figure 1: Impacts of classification strategy on classification of lead metal in massive form (>1 mm diameter; <0.529 mm^2/mg specific surface area) for chronic aquatic toxicity.

About the International Lead Association

The International Lead Association (ILA) is the trusted and authoritative global trade association for the lead industry. Its member companies are at the forefront of lead mining, smelting and recycling and through ILA are working towards a vision of a sustainable global lead industry that is recognised for the positive contribution it makes to society. ILA acts as the secretariat for the Lead REACH Consortium that was established in 2008 to help companies meet their REACH obligations for lead metal, lead chloride, and ten lead compounds covered by the Voluntary Risk Assessment for Lead (VRAL).

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