

## Open Public Consultation on the Targeted Revision of the CLP Regulation

(Regulation (EC) No 1272/2008 on the Classification, Labelling, and Packaging of substances and mixtures)

### Position of the European Copper Institute

FINAL

12 November 2021

The European Copper Institute welcomes the opportunity to feed into the revision of the CLP Regulation. The CLP regulation is a cornerstone of the EU policy on chemicals, with a wide array of downstream legislation depending on it. We are strongly committed to ensuring a correct hazards classification of the substances and mixtures in our industry, and to clearly and correctly communicate this information. This position paper complements our answers to the Open Public Consultation questionnaire.

In general, we believe that a successful classification system is clear, in line with scientific developments, and consistent. The supply chain of our industry is global and therefore we strongly argue for a classification system that is fully consistent with the Globally Harmonized System (GHS) by the United Nations. Such consistency will maximize the protection of health and the environment, minimize confusion along the supply chain, and minimize unnecessary burden on industry (e.g. due to difference in classification criteria, resulting in reclassification and relabelling of products when products cross borders).

Furthermore, the CLP regulation should continue to recognize the specificities of metals. Copper and other metals are different from most chemicals because they occur naturally. Copper is even essential for all life on earth. The application of any new hazard class to metals requires specific considerations. A good example is *Annex IV: Metals and Inorganic Metal Compounds* to the *CLP Guidance*<sup>1</sup> which demonstrates the need to consider metal-specific concepts and properties in the context of classification.

The specific comments below refer to the corresponding sections in the Open Public Consultation questionnaire.

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<sup>1</sup> <https://echa.europa.eu/guidance-documents/guidance-on-clp>

### **New hazard classes – endocrine disruptors**

To achieve a maximal consistency with legislation on chemicals globally, the definition of endocrine disruptors by the World Health Organization (WHO) should be used. Along the same lines, a prior agreement at GHS level would be preferred before adding hazard classes in EU.

Any Endocrine Disruptor category for chemicals should consider the three criteria of the definition of an endocrine disruptor collectively: endocrine activity, adverse effect, and the adverse effect is the consequence of the endocrine activity. A substance fulfilling only two out of the three criteria should not be classified. Along the same lines, a substance for which the level of evidence on any of these three criteria is deemed “low”, should not be classified. All three criteria of the definition of endocrine disruptors need to be clearly demonstrated with a reasonably high level of evidence before a substance can be classified.

Finally, we would like to emphasize that applying the endocrine disrupting classification on metals is not straightforward. Metals occur naturally, and some metals (including copper) are essential elements. They may therefore naturally have a role in the endocrine system. Dedicated guidance is needed to ensure that metal-specific properties are considered correctly in endocrine disruptor assessments. Together with the broader metals sector, we are consulting with various experts to develop such guidance. We are also prepared to provide this guidance to the EU Commission for consideration once it is finalized.

### **New hazard classes – persistent, bioaccumulative, mobile, and/or toxic chemicals**

Under the REACH regulation, the criteria for persistent, bioaccumulative, and toxic (PBT) chemicals, and those for very persistent & very bioaccumulative (vPvB) chemicals, are only applicable to organic substances and organo-metals (see REACH Annex XIII). These criteria are not applicable to metals and inorganic substances: these occur in the natural environment and they are released, transported, bound, and mineralized through natural processes. They are subject to a wide variety of detoxification processes, but they cannot be degraded in the same way as organic substances. If criteria are included in the CLP Regulation, the scope should continue to focus on organic substances and organo-metals. The same argument applies to the potential criteria for persistent, mobile, and toxic (PMT) chemicals, and to those for very persistent & very mobile (vPvM) chemicals: these criteria should only be applicable to organic substances and organo-metals.

### **Other new hazard classes**

The added value of considering terrestrial toxicity is, in our view, low. Metals, including copper, are more toxic in the aquatic environment than in the terrestrial environment. For example, under the REACH regulation, the safe level (Predicted No-Effect Concentration, PNEC) of copper in freshwater is 0,0078 mg/L and the copper PNEC in soil is 65 mg/kg. There may be very specific chemicals which have higher toxicity in the terrestrial environment, but it is not clear how this would justify adding the burden of considering terrestrial toxicity for all chemicals.

### **Harmonized classification**

We support the EU Commission to initiate harmonized classifications, and we support a prioritization mechanism for harmonized classification dossiers. We note however that resources at member state level are constrained, and the agenda of expert committees such as the Committee for Risk

Assessment (RAC) is full. There is limited time for the experts to fully review and assess dossiers. These issues will be amplified with the newly proposed hazard classes, the increased number of dossiers, and other related initiatives. To ensure a high quality assessment, we suggest that policymakers and authorities develop a plan that allocates sufficient resources to the relevant expert committees.

### **Harmonization of DNELs, DMELs and PNECs**

While we support harmonization in general, we think the harmonization of DNELs, DMELs, and PNECs under the CLP regulation does not add value. These values are part of risk assessment, while the focus of the CLP regulation is on hazard classification. In some cases, different values justifiably have different protection goals in specific sectoral legislation, e.g. consumers vs. workers. Furthermore, under the REACH regulation, there is already a legal duty by industry to adopt these values jointly by joint registration where possible and to keep these values up-to-date. A harmonization process under the CLP regulation will likely lead to a more time-consuming and burdensome process.

### **Animal testing**

For the purposes of hazard classification of metals and inorganic compounds, animal testing should be the last resort when alternative tests are not available. However, applying non-animal methods to metals and inorganic compounds may be challenging if such methods have not been developed or validated specifically for metals. Metals occur naturally and have complex detoxification pathways. In addition, essential elements like copper are subject to homeostasis in organisms. Such properties may not be sufficiently considered in non-animal methods if they have not been developed or validated specifically for metals and inorganic compounds. In such cases, non-animal methods may be a screening step, but additional animal testing remains necessary to confirm a positive result.

For the purpose of read-across tools and to assess complex substances, non-animal methods such as transformation-dissolution testing and biosolubility testing are very valuable, e.g. to support the assessment of inorganic substances of Unknown or Variable composition (UVCBs). These methods have been developed with due recognition for the specific properties of metals and inorganic compounds.

### **Classification & Labelling inventory**

We agree that the Classification & Labelling inventory is an important tool and that its consistency can be improved. However, different classifications for the same substance can have valid reasons, e.g. impurity profiles or different physical forms of the same substance. For example, in the case of copper, different physical forms (powder and massive) have been identified under REACH, and additionally two copper substances (copper flakes and copper granulated) have been identified under the Biocidal Products Regulation. The inventory currently has difficulties to transparently communicate information on different forms of the same substance. As a consequence, the current entries for copper in the inventory are confusing and this could not yet be resolved.

The European Copper Institute (ECI) is the European chapter of the International Copper Association (ICA), representing the interests of ICA members towards European Union institutions and stakeholders.

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