

Public consultation on the targeted revision of the REACH Regulation

European Copper Institute position

April 2022

The European Copper Institute supports the overall objective of the targeted revision, which is to ensure that the provisions of the REACH Regulation reflect the ambitions of the Commission on innovation and a high level of protection of health and the environment.

We believe that the REACH Registration process should aim at collecting relevant and reliable data, to be used within and beyond REACH, while recognising that REACH is primarily substance driven. The implementation of additional information requirements should continue to recognize the specificities of metals. Copper and other metals occur naturally and copper is an essential element.

1. Regarding the introduction of a MAF, a refined approach should be considered for essential elements, based on the available science. If absence of mixture risks can be demonstrated, then a MAF equal to 1 must be applied.
2. Test methods must be robust and reliable. For metals and inorganic compounds, their specific properties may not be sufficiently considered in non-animal methods. In such cases, non-animal methods may be a screening step, but additional animal testing remains necessary.
3. We would not support the introduction of environmental footprint information in REACH as regards the intended ambitions for REACH versus other legislations and initiatives (Climate Transition, Circularity, Safe and Sustainable by Design concept)
4. We support a shared responsibility of reporting over the value chain to cover the lifecycle. In this regard, there may be cases identified where downstream users are responsible for informing ECHA about certain uses and exposures.

We acknowledge the importance of revising the Authorisation and Restriction processes. The copper industry case for lead metal argues that the Authorisation measure would not be proportionate nor effective. This case is illustrating well a proposed set of guiding principles for better risk management.

In addition, we express our support for the response to the public consultation as provided by Eurometaux.

The European Copper Institute welcomes the opportunity to feed into the revision of the REACH Regulation and supports the overall objective of the targeted revision, which is to ensure that the provisions of the REACH Regulation reflect the ambitions of the Commission on innovation and a high level of protection of health and the environment.

We are hereby expressing our support for the response to the public consultation as provided by Eurometaux. In this position paper, we are iterating and providing complementary input on a series of points that are of particular relevance to the copper sector.

In general, we believe that the REACH Registration process should aim at collecting relevant and reliable data, to be used within and beyond REACH, while recognising that REACH is primarily substance driven. Additional information requirements should be implemented if these will contribute to achieving safe use. They should focus on what matters and be justified, making the best use of resources, expertise and methodologies. Furthermore, the implementation of additional information requirements 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 specific comments below refer to the corresponding sections in the Public Consultation questionnaire.

Registration

Information requirements to provide information on endocrine disruption

The request for additional information requirements for the identification of endocrine disruptors should be weighed carefully versus the benefits and how it would help in achieving safe use and control of risks.

Test methods must be robust and reliable. Speed of adoption should not compromise their quality, nor diminishing international recognition relevance. For 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. In such cases, non-animal methods may be a screening step, but additional animal testing remains necessary to confirm a positive result.

Importantly, applying the WHO definition and criteria for the identification of endocrine disruptors to metals is not straightforward. Metals occur naturally, and essential elements like copper may have a role in the endocrine system. Dedicated guidance is needed to ensure that these metal-specific properties are correctly considered in the assessment for endocrine disruption.

Information on environmental footprint

The introduction of information requirements on the environmental footprint in REACH should be carefully assessed for its appropriateness as regards the intended ambitions for REACH on the protection of the environment and achieving safe use. REACH is primarily substance driven and collects data on substances that can input into environmental footprint assessments of products.

We would not support the introduction of environmental footprint information in REACH as regards the intended ambitions for REACH versus other legislations and initiatives (Climate Transition, Circularity, Safe and Sustainable by Design concept).

Information requirements on use and exposure

The key role of downstream users should be recognised and their provision of information should be facilitated when needed. In this regard, specific modalities should aim at simplification and user friendly notification system while taking into account the complexity of supply chains and 'focus on what matters'. Not all users are relevant downstream users (i.e. cases of potential exposure) for the purpose of providing input into the assessments under REACH. In this regard, there may be cases identified where downstream users are responsible for informing ECHA about certain uses and exposures. It will be important to clarify the responsibilities of the registrant versus the downstream user and how to avoid duplication and divergent assessments, e.g. how to ensure that the registrant could access such data. Improving processes for collecting information on use and exposure will be a key opportunity for improving the overall effectiveness of REACH.

Regarding the information on exposure, the use of monitoring data is important in the assessment of copper substances. Challenges exist in collecting such data required for REACH purpose versus well established practices for collecting and reporting monitoring data, e.g. for occupational legislation (OSH) compliance purposes. From this perspective, a better alignment between the assessment and reporting requirements under REACH and OSH would be useful.

Introduction of a Mixture Assessment Factor

Assessment factors are already widely used in REACH to account for uncertainties in data. The introduction of a MAF is proposed as a precautionary and pragmatic approach to address potential unintentional co-exposures. It is important to consider the integration of a MAF into the existing framework of assessment factors under REACH, without entailing less robust assessment approaches or triggering disproportional risk management measures. Neither should the approach duplicate existing functional approaches such as under worker protection legislations.

When introduced, MAFs should be proportional, targeted, and based on a sound scientific knowledge and, in addition, should allow for specific evidence-based refinement. In this regard, the recognition for metals specificities will be required. A validated metal risk assessment framework is available in the published literature (Nys et al., 2018, <https://setac.onlinelibrary.wiley.com/doi/abs/10.1002/etc.4039>) to assess the combined risks of exposure to different metal ions and work is presently ongoing to apply this framework to the soil compartment. Options must be provided to registrants of metals and inorganic substances to consider more refined approaches instead of a default MAF.

A default MAF will have severe and unjustified consequences for the chemical safety assessment of copper, a naturally occurring substance and an essential element. For such substances, a MAF has no scientific basis, and it will trigger risk conclusions at natural background level. ECI asks for a refined approach to be considered for essential elements, based on the available science. If absence of mixture risks can be demonstrated, then a MAF equal to 1 must be applied to essential elements.

‘One substance, on assessment’ concept and harmonised parameters

Aside from REACH, safety assessments of copper and copper compounds are performed under several other sectorial legislations including BPR, PPPR, Water Framework Directive, Cosmetics Regulation, and others. Regarding the EU Commission’s ambition on “one substance, one assessment”, we support more exchange and harmonization of the scientific information that underlies the safe levels. However, we do not support harmonizing the values themselves. Setting toxicological values such as DNEL/DMEL and PNEC is part of the risk assessment under REACH. In general, health-based guidance values justifiably differ by purpose or use, according to different protection goals in the different EU chemicals legislations. Under REACH, there is the legal duty to keep these values up-to-date and the dissemination by ECHA is already making them available for transparency and consideration among different actors.

Authorisation and Restriction

Reform of authorisations and restrictions

We acknowledge the importance of revising the authorisation and restriction processes. In the particular case of lead metal, a critical alloying metal which is ubiquitous in the copper mining, refining and recycling streams, ECI is of the opinion that subjecting lead to Authorisation would not be proportionate nor effective, given the extensive legislative framework already in place. Moreover, it would jeopardise the EU’s recycling and circular economy aspirations and harm EU competitiveness. Instead, the copper industry recommends a regular review and update of the existing set of lead use restrictions as well as an extension of these restrictions if a specific environmental or consumer risk appears (Article 68(1)). For controlling the exposure risk for workers, there is a general industry consensus that the ongoing update of the EU occupational exposure limits is the best-suited measure. In fact, the copper industry case for lead metal is illustrating well the different guiding principles for better risk management put forward by Eurometaux¹.

In addition, the existing and extensive framework of legislation, including the range of product and end-of-life restrictions, should be taken into consideration for their longstanding impact. An alternative system with possible derogations from default restriction should take account of e.g. the review of relevant End-of-Life Vehicle (ELV) and Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directives’ exemptions to avoid overlapping regulatory measures.

About the European Copper Institute

The European Copper Institute (ECI) is the leading advocate for the copper industry in Europe and the European arm of the International Copper Association (ICA). Our members mine, smelt, refine and recycle copper for use across the economy, in the electricity system, buildings, transport and industry. The European Copper Institute acts as the secretariat of the REACH Copper Consortium which provides a coordinated answer to the EU REACH requirements.

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¹ <https://eurometaux.eu/media/oudoprhn/cm-8-guiding-principles-for-risk-management.pdf>



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