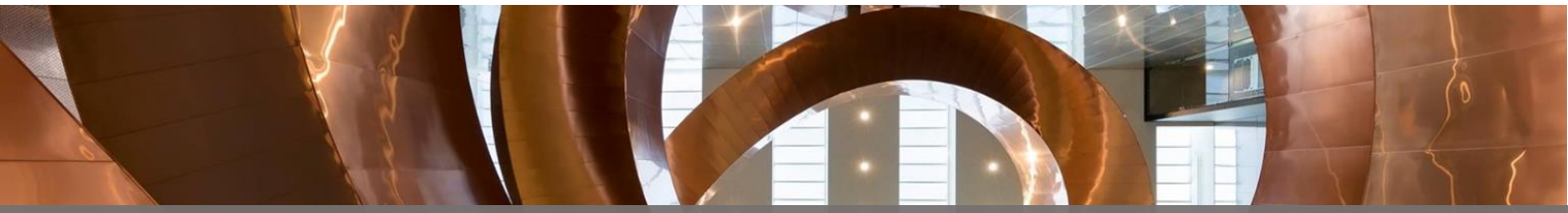
European Copper Institute
Copper Alliance



A Mixture Assessment Factor (MAF) under REACH

European Copper Institute position

31 March 2022

A Mixture Assessment Factor (MAF) will have serious 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 the natural background level. ECI asks for a refined approach to be considered for essential elements, based on the available science. If the absence of mixture risks can be demonstrated, then a MAF equal to 1 must be applied to essential elements.

The Chemicals Strategy for Sustainability will address the combined effect of chemical mixtures by introducing mixture assessment factors in REACH for the chemical safety assessment of substances. Several discussions have been held at CARACAL on how to best implement the MAF, and the EU Commission has recently conducted a stakeholder consultation.

A MAF will have severe and unjustified consequences for the chemical safety assessment of copper, a naturally occurring substance and an essential element. As demonstrated below, a MAF has no scientific basis for such substances and will trigger risk conclusions at the natural background level in water, soils, and sediments. Applying a default MAF to copper will have significant unintended and adverse consequences, such as the adoption of less robust modelled exposure assessment under REACH to artificially mitigate the consequences of the MAF. Instead, a refined scientific approach is available to assess mixture risks related to copper. If the absence of mixture risks can be demonstrated, then a MAF = 1 must be applied to naturally-occurring substances and essential elements.

No scientific basis

Any MAF is a default and precautionary approach that serves to address a potential mixture risk in the absence of more detailed information. For metal mixtures, however, more information has been developed. A framework to assess the combined risks of exposure to different metals is available in the published literature (Nys et al., 2018). Work is presently ongoing to develop a similar framework for the soil compartment. These frameworks will be further developed and applied in MEED [1], a 1M EUR project

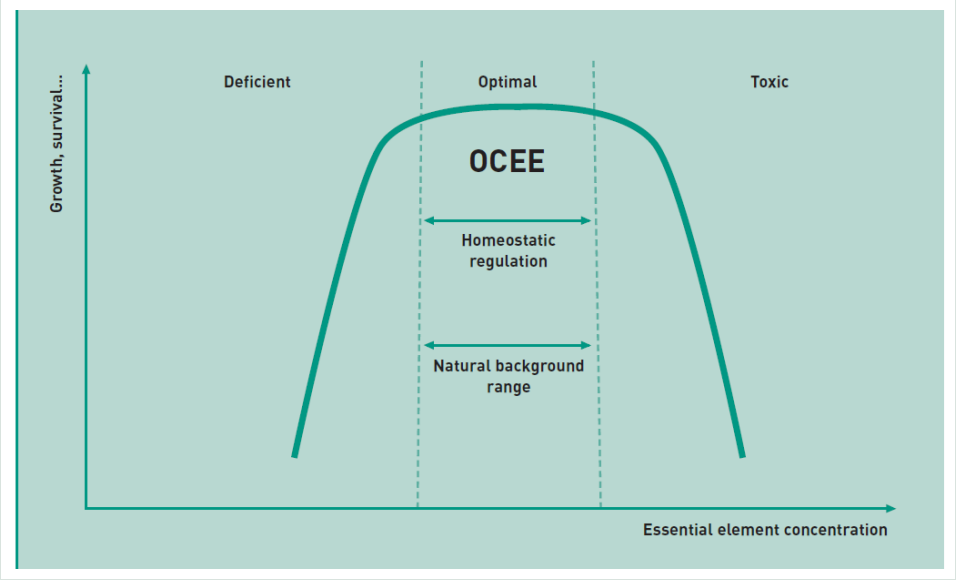
[1] For more information, see https://www.reach-metals.eu/meed/meed-project

by the metals sector to contribute to the Zero Pollution Ambition. This will result in a refined assessment of the mixture risk posed by metals and inorganic substances. In cases where such a framework demonstrates the absence of risk, then a MAF = 1 is justified.

Risk at the background level

Essential elements often have a small window between background and toxicity. This is conceptualized through the Optimal Concentration range for Essential Elements (OCEE, Figure 1). Organisms and ecosystems have developed acclimation, adaptation, and homeostasis mechanisms to regulate the availability of essential elements under different external conditions. Applying a MAF to essential elements can absurdly predict exposure levels should be below the deficiency threshold. For copper, the ranges of natural background and toxicity in the EU environment effectively overlap[2]: even a MAF of 2 will lead to a predicted mixture risk in 5% of Europe's pristine streams due to the natural background levels of copper. Such MAF does not consider that ecosystems are genetically adapted to the local natural background concentrations.

The optimal concentration range for essential elements



The optimal concentration range for essential elements (from ICMM, 2008)

[2] For example, in freshwater, the ambient background level in pristine EU streams is between 0.3 and 3 ug/L (10th and 90th percentile of FOREGS database, Salminen, 2005). The toxicity of copper in freshwater depends on the bioavailability and 10% of European freshwaters have a PNEC below 3 ug /L (Peters et al., 2019).

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The copper chemical safety assessment already considers mixtures

The environmental effects of metals and metal compounds are caused by the dissolved metal, which can be released into the environment after the transformation and dissolution of the metal or metal compound (see Annex IV to the CLP Guidance). The REACH copper chemical safety assessment uses measured data for the exposure assessment in all environmental compartments. Therefore, exposure to the copper metal and all copper compounds from REACH and non-REACH sources, including biocides, plant protection products, cosmetics, fertilizers, and natural sources, is already considered today.

Consequences of a MAF

The copper chemical safety assessment is already supported by a complete and fully refined exposure and effects dataset. Assessment Factors down to 1 have been derived and agreed upon with Competent Authorities through the Copper Voluntary Risk Assessment (2008). No further refinements are possible to mitigate the consequences of a MAF. If a MAF would be applied to the copper chemical risk assessment, then registrants will revert to less robust approaches under REACH, e.g. using modelled (rather than measured) exposure data, to artificially mitigate the consequences of the MAF. Alternatively, risk management measures may be triggered at all copper production sites. Moreover, specific uses may be withdrawn with no benefit for the environment since the science is available to show no mixture risk.

ECI ask: An alternative way forward for essential elements is necessary since a default MAF will have significant unintended adverse consequences without any real environmental or health benefits. This alternative way forward must favour refined scientific assessments over default approaches that do not work for such substances.

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.

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