

Comment on the OEL evaluation for Copper

WVMetalle contribution to the call for comments and evidence related to the scientific evaluation of exposure limits for copper and its inorganic compounds at the workplace

[Wirtschaftsvereinigung Metalle \(WVMetalle\)](#), the German Non-Ferrous Metals Association, represents the German Non-Ferrous (NF) metals industry towards politics and economy to maintain and establish measures at a very high level. Today, WVMetalle has about 625 member companies, including producers and processors of most base and special metals and compounds including copper and copper containing alloys. WVMetalle is member of the German Industry Association (BDI) and of the European Non-Ferrous Metals Association (European Metals).

WVMetalle welcome the opportunity to provide input to the ECHA call for evidence launched on 1st of April 2026 to support the development of a scientific report on health-based exposure limits at the workplace for copper and its inorganic compounds.

Situation and background on OELs for copper and its inorganic compounds

The discussion on OELs for copper is quite long lasting and is mainly connected to the transient acute inflammatory so called “metal fume fever” effect occurring after high exposure to fine copper particle. Hundreds of years’ experience at workplaces shows that during the last centuries only very few anecdotal cases of this illness occurred.

Nevertheless, this effect was already back in 2004 the basis for the German MAK-commission establishing a **MAK-value for the inhalable fraction of 0.1 mg/m³**. MAK based their assessment on a rather old and limited publication from 1968 (Gleason RP. Exposure to copper dust. Am Ind Hyg Assoc J 29: 461-462) and this proposal still seem to be the basis for some existing occupational limit values for copper in the EU like in Hungary, Switzerland and the Netherlands (GESTIS–ILV) although even MAK stated at this time “There is no valid data available that would be suitable for establishing an MAK value, either in humans or from animal studies.”

About 10 years later MAK revised their assessment and concluded 2014 on a **MAK-value of 0.01 mg/m³, this time for the respirable fraction**. Interestingly, part of the rationale for this value is again the Gleason 1968 study, now assuming that the particles occurring during the polishing process described in the study belong to the respirable fraction size. Second part of the rationale for this MAK-value was a 28-day rat inhalation study with dicopperoxide (Cu₂O) (International Copper Association, 2010) in which the appearance of “foamy macrophages” was identified as the driving effect for the MAK-Value derivation. The identical approach was chosen by SCOEL and therefore the **same proposal of 0.01 mg/m³ for the respirable fraction was published in the SCOEL/SUM/171 2014**. This again might be the reason for the existing OELs of 0.01 mg/m³ for the respirable fraction in Spain, and Sweden (GESTIS–ILV).

Discussion and actual OEL on copper and its inorganic compounds in Germany

As a new scientific evaluation of the MAK-commission triggers routinely an OEL discussion in German AGS (Ausschuss für Gefahrstoffe) the proposal on copper created instantly a debate on the discrepancy between what was derived by the MAK-commission on one hand (including the interpretation of the observation of foamy macrophages in the rat study being adverse and relevant for an OEL derivation) and what was known and observed at real workplaces with known copper exposure on the other hand (e.g. the negative results of the occupational health study of Ostiguy: Occupational and Environmental Medicine 1995;52:204-210).

This finally resulted in an agreement in clarifying the somewhat controversial discussion by performing health surveillance study and a cross-sectional study at a European copper smelting plant to investigate more directly the potential chronic effects of copper inhalation exposure in a real (worst case) work life situation.

The results of these on-site human studies are meanwhile published (specifically Haase et al., JOEM [63\(8\):p e480-e489, August 2021](#) and [64\(9\):p e550-e558, September 2022](#)). The health surveillance study indicates that cumulative inhalable copper dust exposure averaging 4.61 mg/m³-years over an exposure duration of ~22 years is not associated with adverse effects on lung function. This is further substantiated by the cross-sectional study in which the absence of detectable effects of copper-containing dust exposure on lung function or chronic inflammation was observed within the investigated cohort. These data were recognized by German AGS as being of high validity and relevance and were used as the main basis to conclude on national OELs (AGW = Arbeitsplatzgrenzwerte) for copper and its inorganic compound of:

- **0.2 mg/m³ for the inhalable fraction**
- **0.045 mg/m³ for the respirable fraction**

The values are established as health based occupational limit values in Germany within TRGS 900 ([BAuA - Regelwerk - TRGS 900 Arbeitsplatzgrenzwerte - Bundesanstalt für Arbeitsschutz und Arbeitsmedizin](#)) together with the rationale behind it ([BAuA - Regelwerk - Begründungen zu Arbeitsplatzgrenzwerten - Bundesanstalt für Arbeitsschutz und Arbeitsmedizin](#)) and represent to our knowledge the most recent and comprehensive assessment of copper and its compounds in the context of OEL setting.

It is important to mention that the AGW derivation considers the data from the human studies as well as the subacute rat inhalation study, complemented by controlled clinical inhalation studies with copper containing welding fumes. The finally derived AGW are therefore consistent with the previous MAK/SCOEL assessments but correctly emphasized on the newly generated high quality human data.

- *WVMetalle urges ECHA to take into the most recent and intensive assessment of German AGS within the scientific evaluation of exposure limits for copper and its inorganic compounds at the workplace and specifically focus on the new workplace studies.*
- *WVMetalle is of course prepared and willing to feed in more details from the course of discussions in Germany including statements from companies' physicians on the absence of any case of metal fume fever in the past and results from a decent measurement campaign from 2010.*

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