

COMMENT ON**ECHA Scientific report for evaluation of limit values for lead and its compounds at the workplace (“OEL report”)**

WVMetalle appreciates the opportunity to comment on the call launched by ECHA on the report for evaluation of limit values for lead and its 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 in order to maintain and establish measures at a very high level. Today, WVMetalle has about 670 member companies, including producers and processors of most base and special metals and compounds including lead metal and lead compounds. WVMetalle is member of the German Industry Association (BDI) and of the European Non-Ferrous Metals Association (Eurometaux).

WVMetalle welcomes the activity to develop proposals for revised EU health-based exposure limits for lead and its compounds. As a member of the DG Employment Working Party Chemicals who will advise the tripartite Advisory Committee on Health & Safety at Work (ACSH) the signee of this comment has actively contributed to the prioritization of the re-evaluation of the existing EU OELs under the Chemicals Agents Directive (CAD).

- The International Lead Association (ILA) and Pb REACH Consortium provide detailed commentary and criticism on the ECHA report with respect to all aspects regarding health effects, toxicology, epidemiology, and modes of action based on information contained in the REACH Registration dossiers. A special emphasize is given to the quality of the report which included numerous hints on errors, omissions, and shortcomings. We abstain from re-submitting detailed information on this aspect but express our concerns that the report can serve as a valid basis for the discussion within RAC in this status. A thorough re-evaluation should be performed prior the RAC debate. For more details we refer to the ILA comment.
- We would like to re-emphasize that under the umbrella of the German Committee on Hazardous Substances (AGS), a Tripartite Committee advising the Federal Ministry of Labour and Social Affairs (BMAS), a long debate on an update of the national OELs for Lead and its compounds took place recently. Two issues had been assessed. First, the introduction of a limit value on air lead concentrations and, second, the revision of the current biological limit value. As a result, the Subcommittee III on Hazard Risk Assessment developed a scientific opinion for a health based Biological Limit Value (BGW) which was concluded on at AGS level in Mai 2017. With respect to a limit value for air lead concentrations, the UA III considered the uncertainties in the correlation of blood lead values and an air lead concentrations as so relevant that a scientifically sufficient

quality of a corresponding air concentration (AGW) can't be guaranteed. That means that only biomonitoring is considered as scientifically adequate in the case of lead and no air limit value is established. The resulting Biological Limit Value was fixed at the same level as RAC proposes: 150 µg Pb/l blood. ECHA took this information into account but failed to abstain from proposing an occupational exposure limit (OEL). Although WVMetalle recognize that derivation of an OEL may be wished it must much more clearly stated that the level of uncertainty in deriving air levels from blood lead measurements cannot be representative for all workplaces and in any case extremely uncertain. The currently proposed OEL value of 30µg/m³ (8hr TWA) is by no means scientifically sound and would result in nearly impossible demands for affected companies and is at the same time not ensuring a significant reduction of workers with blood lead levels below the target values.

- Regarding actual information on exposure levels WVMetalle already submitted recent information from our own yearly surveys. Of course, WVMetalle is willing to share further information on that database upon request. We urge ECHA to take this into account instead of outdated information from different other sources. ECHA should as well make benefit from the recent "Study to collect recent information relevant to modernizing EU Occupational Safety and Health chemicals legislation with a particular emphasis on reprotoxic chemicals with the view to analyze the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC and Directive 98/24/EC" (<https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8220&furtherPubs=yes>). The study includes illustrative case studies for the following substances including lead and lead compounds. In addition, ECHA should contact DG EMPL in order to receive information from the ongoing study collecting most recent information for inorganic lead and its compounds with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. The Final Report of this report shall be available in due time and might be a valuable piece of information for a sound limit value assessment for inorganic lead and its compounds.
- German AGS recognizes that the envisaged reduction of the blood lead level at workplaces is extremely difficult and needs a thorough analysis of the situation in all affected areas as well as a description of dedicated and state of the art protective measures for relevant uses of Lead and its compounds. Therefore, the recent conclusion on the new Biological Limit Value in Germany for lead in blood to 150 µg/l is not yet legally implemented and will only be installed once the revised Technical Rule on Hazardous Substances (TRGS) 505 "Lead" is updated correspondingly. The TRGS 505 is directed to employers and contains special protective measures for uses involving Lead and inorganic Lead compounds as well as mixtures containing Lead. The process to reevaluate the TRGS 505 on Lead started in 2017 and is envisaged to be finalized end of 2020. WVMetalle emphasizes on this activity as ECHA explicitly requested information on uses and experiences within the call for evidence for the Lead OELs. This practical aspect should as well be reflected within the OEL report for lead and its inorganic compounds.

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