

## POSITION PAPER ON COMMISSION PROPOSAL FOR AMENDING EU BOEL AND BLV FOR LEAD AND INORGANIC COMPOUNDS

### SUMMARY

The Commission proposal must be amended to:

- 1. Set the BOEL no lower than the lowest OEL currently in force in EU Member States [0.05 mg/m<sup>3</sup> (8hr TWA)]**
- 2. Include transitional measures that allow sufficient time for all industry sectors to achieve a BLV of 15 µg Pb/100ml blood. We propose a BLV of 20 µg Pb/100 ml blood is initially applied until 31 December 2030, thereafter 15 µg Pb/100 ml or alternatively the inclusion of a footnote in Annex IIIA providing a derogation for workers whose blood lead values exceeded 15 µg Pb/100 ml due to exposure which has occurred before coming into force of this Directive.**

We believe that the new Commission proposal to amend the carcinogens, mutagens or reprotoxic substances at work Directive does not respect the principle of proportionality as it has not adequately assessed technical feasibility and likely cost for all sectors to achieve the BLV and particularly the recommended BOEL. This issue is particularly relevant for European companies processing metallic ores to produce lead and other metals, who will be disproportionately impacted because of the very large capital expenditures required. A longer transition may be required to allow these operations to meet the ambitious standards.

ECHA RAC and all social partners at the ACSH recognized that blood lead concentrations are the best exposure metric to assess occupational exposures to lead and compounds, since internal lead levels are decisive for the chronic toxicity. Moreover, it is acknowledged that there is a poor relationship between an employee's blood lead and workplace air concentrations. We therefore believe that the BOEL proposed by Commission will entail excessive costs for some Industry sectors without achieving any incremental benefits to employee health. The costs and benefits of the BOEL do not appear to have been evaluated in the Commission's impact assessment that focused on achieving target blood lead levels.

Proposing a substantially lower EU BLV without any transitional measures fails to consider the time necessary for Industry sectors to achieve this given many are operating in EU Member States that currently permit much high limits through National legislation. Failure to include any transitional measures also neglects the pharmacokinetics of lead that means that long service workers with lead accumulated in bones due to historical exposures will take much longer to achieve target blood lead levels.

## ORGANISATIONS THAT SUPPORT THIS POSITION PAPER



### Background

We have long supported the Advisory Committee on Safety and Health at Work (ACSH) position of the need to revise downwards the existing biological limit value (BLV) as well as the binding occupational exposure limit value (BOEL) for lead and its Inorganic compounds to better protect workers' health and safety considering scientific and technical developments since the current limit values were adopted in 1982. This is reflected in the adoption of long-standing Industry voluntary initiatives that encourage continuous improvement in the management of workplace lead exposures that currently has a target of 20 µg Pb/100ml blood to be achieved by end of 2025.

On 13th February 2023 the EU Commission published a proposal to amend the Directive 2004/37/EC of the European Parliament and of the Council on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work. This proposal includes a revised binding occupational exposure limit value of 0.03 mg/m<sup>3</sup> (8hr TWA) and a biological limit vale of 15 µg Pb/100 ml blood for lead and its Inorganic compounds with no transitional measures. The proposed binding biological limit value is substantially lower than any that are currently in force in Member States (except Germany) and in most non-EU countries.

### Occupational Exposure Limits

We agree with the conclusion of both RAC and the ACSH that biological monitoring, in the form of regular blood lead testing, is the most effective index for managing the health of workers exposed to lead. Experience of companies over decades has demonstrated that the body burden of lead in individuals following occupational exposure is not well correlated to workplace air concentrations (see Annex 1). Given the significant uncertainties in estimating the air lead levels required to achieve target blood lead limits we believe that any future BOELV should be established to reflect good hygiene practice and technical feasibility rather than attempting to use it as a quantitative measure of exposure linked to a health metric.

The Commission's own study on health, socio-economic and environmental impacts in connection with possible amendments to binding limit values<sup>[1]</sup> was unable to derive any estimate on cost-benefit of achieving target OELs. It concluded that "analysis of OEL options could not be performed due to missing and uncertain data regarding health effects related to airborne exposures. PbB and PbA relationships depend on various factors within an occupational setting and unambiguous correlation methods are not available. Data indicate the OEL option of 0.05 mg/m<sup>3</sup> as an achievable level."

This conclusion is in line with Industry assessment that 0.05 mg/m<sup>3</sup> is an achievable level for most sectors with significant investments to implement new technologies. However, the 0.03 mg/m<sup>3</sup> [8hr TWA] included in the Commission proposal is likely technically unachievable for many and/or will entail excessive cost that will risk some site closures.

This issue was raised several times during the consultation process, especially in relation to European companies processing metallic ores to produce lead and other metals. We therefore request that as the Commission has not undertaken a cost-benefit analysis, their proposal is amended to better reflect technical feasibility by adopting a value no lower than the lowest OEL currently in force in Member States. Given the lack of any clear relationship between workplace air levels and employee internal dose (as measured by blood lead) this amendment to the Commission proposal will not negatively impact protection or workers health and safety but will significantly reduce the compliance costs for most industry sectors.

## **Biological Limit Value**

Member States currently have national workplace blood lead limits that range from 15 to 70 µg Pb/100ml blood. Trade Association voluntary programs have been implemented to encourage continuous improvement in the management of workplace lead exposures, and although many EU companies now have average blood lead levels in employees below 15 µg Pb/100ml blood, there are still many hundreds of workers with blood lead values currently exceeding this value. A survey conducted by the Pb REACH consortium in 2020 indicated that P90's for worker blood lead levels across the EU in the primary metal producers, battery manufacturers and recyclers were 27, 29 and 28 µg Pb/100ml respectively<sup>[2]</sup>. This information suggests that it will not be technically feasible for many Industrial operations to achieve compliance with a BLV of 15 µg Pb/dL for all workers without the adoption of appropriate transitional measures, especially if workplaces contain a high number of long service employees (see issue of long-service employees described below). Alternatively, in the absence of transitional measures, the Commission proposal should be amended to include provisions for those workers whose blood lead level exceeds the biological limit value of 15 µg/100 ml due to exposure that has occurred before coming into force of the Directive. This could be accommodated by use of a footnote in Annex IIIa that indicates that such workers should be permitted to work if blood lead values exceed 15 µg/100 ml but must be under the close supervision of a medical professional. Continuous improvement should be required so that blood lead levels in this cohort are eventually reduced to 15 µg/100 ml in a reasonable timeframe.

[1] <https://op.europa.eu/en/publication-detail/-/publication/03b0cc5a-5e22-11ec-9c6c-01aa75ed71a1/language-en/format-PDF>

[2] <https://op.europa.eu/en/publication-detail/-/publication/03b0cc5a-5e22-11ec-9c6c-01aa75ed71a1/language-en/format-PDF>

**\*The issue of long-service employees:** More than 90% of the total amount of accumulated lead ends up stored in bone and teeth in adults. The large pool of stored lead in adult bone maintains elevated lead in blood levels long after exogenous exposure has ended. Employees with a long service history of occupational lead exposure will therefore be releasing lead from bone such that their current blood lead level is not reflective of existing risk management measures adopted in the workplace.

Studies have demonstrated that extensive time periods are often required following removal of long service employees with elevated blood lead levels from workplace exposure (e.g., following retirement or medically recommended suspension) before their blood lead levels reach acceptable levels.

According to PBPK modelling undertaken for the Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency, it would take over a year away from any workplace lead exposure for the blood lead level of a long service employee with 25 years exposure and a blood lead level of 30 µg/100ml at the beginning of medical removal for their measured blood-lead to fall to 15 µg/100ml<sup>[3]</sup>.

It is therefore likely that, even with improved risk management measures, these workers would take substantially longer to reach a blood lead of 15 µg/100ml than other staff. This has not been taken into consideration in the Commission proposal that applies to all workers and not just to new workers that are employed in the company after the revised BLV comes into force. This was a measure suggested by the Government Interest Group during ACSH negotiations. Re-allocating long service employees for extensive periods of time (i.e., years) to job functions that do not result in any lead exposure is not a practical measure for most companies and may result in loss of employment for this sub-population in the workforce. Transitional measures, or a derogation that allows temporary exceedance of the BLV are required in the Commission proposal to take into consideration this cohort of workers.

## **International Lead Association**

March 2023

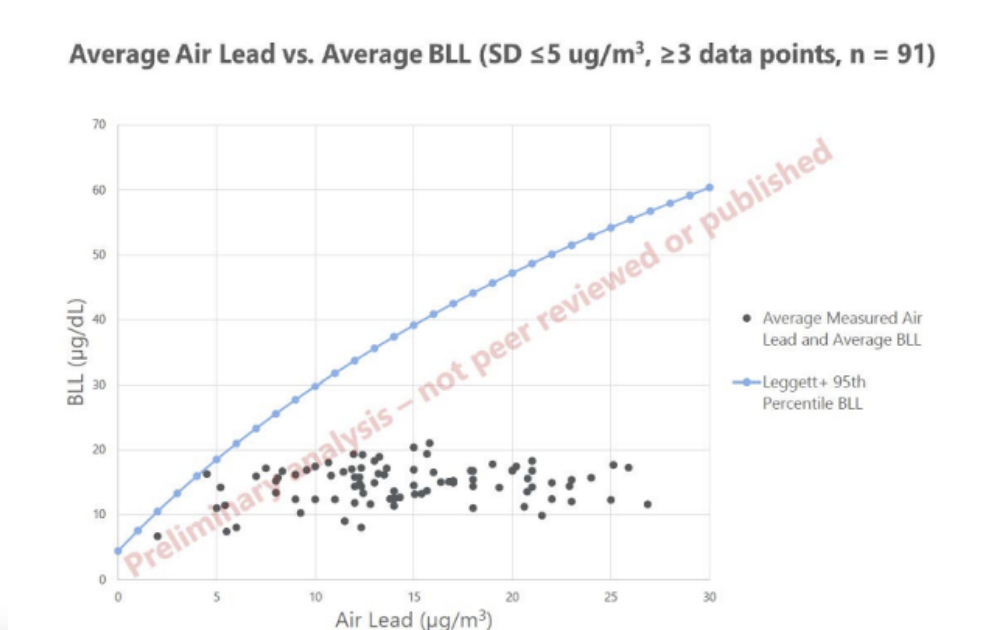
[3] <https://oehha.ca.gov/air/document/estimating-workplace-air-and-worker-blood-lead-concentration-using-updated-pbpb-model>

## ANNEX 1: RELATIONSHIP BETWEEN MEASURE WORKPLACE AIR AND EMPLOYEE BLOOD LEAD LEVELS

The graph below presents preliminary results of a recent analysis of the air to blood lead relationship from a cohort of 91 workers in lead battery manufacturing operations. A peer reviewed publication is in development and is expected to be published in early 2023.

The black dots in the graph represent a plot of average measured air lead concentrations (horizontal axis) vs. average blood lead concentrations (vertical axis) for each of the 91 members of the cohort, and from this plot, it can be concluded that no relationship exists between average air lead concentrations and average blood lead concentrations.

Statistical analyses of these data confirm this conclusion. Specifically, the coefficient of determination ( $R^2$ ) and Mean Square Error (MSE) values calculated for the 91-worker data set of 0.022767 ( $P = 0.081885$ ) and 7.997359, respectively, suggest a poor model fit, and do not support a statistically significant relationship between occupational air lead concentrations and corresponding blood lead concentrations.



[4] M. Kentner, T. Fischer. International Archives of Occupational and Environmental Health volume 66, pages223–228 (1994). Lead exposure in starter battery production: investigation of the correlation between air lead and blood lead levels.

This new data supports the conclusions about the poor relationship between lead in air and measure employee blood lead made in the past in cohorts of workers with much higher workplace lead exposures (e.g. M. Kentner and T. Fischer, 1994<sup>[4]</sup>)

#### Lead in air and relationship with blood lead levels (Kentner & Fischer 1994)

