ILA member companies engaged in the mining, smelting, and recycling of lead are committed to ensuring the health and wellbeing of their employees. This is illustrated by the fact that the main lead producing Industries in Europe have long established voluntary lead exposure reduction programmes that go beyond current Regulation and have delivered impressive results in reducing employee lead exposures over time. Companies are obliged to join the voluntary programme as a condition of membership of the International Lead Association and the major lead using sector Association, EUROBAT. This programme currently has a target of having no employees with a measured blood lead exceeding 20µg/dL by the end of 2025.

Industry voluntary lead exposure management targets only apply to companies that are members of the respective Associations and are therefore not adopted by companies in all sectors where lead exposure is possible. Regretfully, as many Member States have not adopted National exposure standards that deviate from the existing EU binding limit values for lead, there are many employees across the EU that will have blood lead levels significantly higher than the 15 µg Pb/dL blood that has been advised by the European Chemicals Agency.

We therefore believe that a stepwise approach to reducing EU binding occupational and biological limit values that considers technical, socio-economic feasibility and the toxicokinetic’s of lead could be adopted. This should reflect current best practice and the available science on health impacts but must allow companies sufficient time to amend existing risk management measures to deliver reductions in employee blood lead levels

We propose the following:

Medical Surveillance
Our experience is that medical surveillance of lead exposed employees is a critical element in an effective risk management programme. In lead producing industries, typically all employees are enrolled in a medical surveillance programme upon start of employment. We therefore believe that the current trigger for medical surveillance requirements in the CAD requires review and must be lowered. We propose that medical surveillance be carried out when a blood-lead level measurement in a worker is greater than 5µg Pb/dL blood above the regional background levels measured in non-occupationally exposed individuals ¹ or when exposure to a concentration of lead in air is greater than 25 µg/m³, calculated as an 8hr time-weighted average over 40 hours per week.

¹ According to the HBM4EU project the geometric mean “background level” for non-occupationally exposed adults in Europe is typically <3µg/dL meaning that medical surveillance should be triggered at 10 µg/dL
**Biological Limit Value**

Our own data analysis, undertaken to support the EU REACH Regulation (see Annex 1), highlights that there is wide range in performance in managing employee lead exposures in companies producing and using lead in the EU. One reason for this is that there is currently a large disparity in the national limits adopted by Member States that range from 15 to 70µg Pb/dL blood. Moreover, as already recognised by the consultant working on behalf of DG Employment, primary metal producers that are processing dusty lead containing ores and concentrates currently have significantly more employees with blood lead levels exceeding 15 ug/dL than recyclers and other sectors. Therefore, whilst a health protective BLV of 15ug/dL may eventually be technically possible for most companies there may be a significant and disproportionate challenge for primary metal producing sites.

Even for companies engaged in operations outside of primary metal production it will be critical to allow sufficient time to allow them to make the necessary changes to work practices and importantly for the blood lead level of employees to fall given the long half-life of lead in the body.

These observations must ultimately be taken into consideration in the establishment of new EU wide Binding Limit Values. It is imperative that there be a reasonable transition period as most EU Member States would need to adopt National exposure limits significantly lower than those currently in force.

We suggest the following EU BLVs may be achievable -subject to a specific impact assessment on the technical and socio-economic implications for Europe’s Primary Lead producers

- **20ug/dL** with a 5-year transition after inclusion in CAD (i.e., no earlier than 2028) *
- **15ug/dL** with an 8-year transition after inclusion in CAD (i.e., no earlier than 2031) *

*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. Studies have demonstrated that extensive time periods are required following removal of long service employees from lead exposure (e.g., following retirement or medically recommended suspension) for their blood lead levels to fall. 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 lead exposure for the blood lead level of a long service employee with 25 years exposure and a blood lead level of 30µg/dL at the beginning of medical removal for their measured blood-lead to fall to 15µg/dL².

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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. It is therefore likely that, even with improved risk management measures, these workers would take substantially longer to reach a blood lead of 15µg/dL than other staff.

To this end we believe that a derogation may be required for long-service employees (defined as ≥ 20 years employment in lead-exposed occupations) to ensure that there is no workplace age related discrimination based upon the inability of this sub-group to reduce blood-lead levels to the BLV in the required time frame. Under the terms for a derogation, it would be important to ensure that BOELVs for the workplace are met by companies and to mandate that such employees be under the supervision of medical staff, enrolled in health surveillance programmes and that efforts be taken to reduce their blood lead levels to the adopted binding biological limit value in the shortest time practicable.

**Occupational Exposure Limit Values**
We agree with the conclusion of both RAC and the consultants 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. 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 rather than attempting to use it as a quantitative measure of exposure linked to a health metric. In that regard, based upon the conclusions of the consultant and our own analysis we believe that the following BOELV’s may ultimately be achievable by well performing companies in all sectors using an appropriate hierarchy of controls:

- 75 ug/m³ (8hr TWA) with a 5-year transition after inclusion in CAD
- 50 ug/m³ (8hr TWA) with an 8-year transition after inclusion in CAD

Adopting a BOELV lower than 50 ug/m³ (8hr TWA) will likely be beyond technical and socio-economic capabilities of many companies and will likely result in a significant number of discontinuations and site closures.

**Protection of sensitive sub-populations (women of child-bearing age)**
Employers are fully committed to equality and non-discrimination at the workplace, including in terms of protecting their workers from health and safety risks at work. We believe EU occupational safety and health (OSH) legislation inherently aims to provide the same level of protection for all workers in a non-discriminatory way, even if this may be achieved through different tailored protective measures, particularly at the workplace. It is important to recall that pregnant and breastfeeding workers are already afforded an extra layer of protection through the Pregnant Workers Directive, in which lead is already listed in Annex II as a substance that such workers must not be in contact with or exposed to.
Also, the EU OSH Framework directive already obliges employers to take account of people with specific risks. We believe that the Biological Guidance Value of 4.5 ug Pb/dL blood recommended in the RAC opinion for women of childbearing age could be used to define a risk of exposure for application of Article 6 of Pregnant Workers Directive as a case when exposure is prohibited but that it would not be appropriate or proportionate to establish this as a BLV for all workers.

Annex 1: Male Worker Blood Lead Measurements for EU Lead Producers Reported in REACH Registration Dossiers

Figure 1: P90 of male worker blood lead measurements in EU lead recyclers for period 2013-2020

At the end of 2020 the P90 blood lead levels for male employees in lead recycling companies in the EU was approximately 24µg/dL, reduced from approximately 30µg/dL in 2013. This suggest that companies in this sector are reducing employees P90 blood lead values at a rate of approximately 1 µg/dL per year and that 20µg/dL could be reached by end 2025 and 15µg/dL after 2030.
At the end of 2020 the P90 blood lead level for male employees in EU companies involved in the production of lead by processing metallic ores in the EU was approximately 30µg/dL. There has been little or no reduction in this P90 for this cohort over time that suggest that this sector will be challenged to achieve BLVs much below 30µg/dL.

About the International Lead Association

The International Lead Association (ILA) is the trusted and authoritative global trade association for the lead industry. Its member companies are at the forefront of lead mining, smelting and recycling and through ILA are working towards a vision of a sustainable global lead industry that is recognised for the positive contribution it makes to society. ILA acts as the secretariat for the Lead REACH Consortium that was established in 2008 to help companies meet their REACH obligations for lead metal, lead chloride, and ten lead compounds covered by the Voluntary Risk Assessment for Lead (VRAL).

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