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EUROBAT feedback to the public consultation on the Commission's proposal for a Directive revising the Carcinogens, Mutagens and Reprotoxicants Directive *(26 April 2023)*

EUROBAT, the Association of European Automotive and Industrial Battery Manufacturers, welcomes the proposal revising the Carcinogens, Mutagens and Reprotoxicants Directive (CMRD) and the lowering of the occupational (airborne) exposure limit (OEL) and biological limit value (BLV) for lead and its compounds.

The current binding limit values were set in 1982 with a 4-year transposition period and are no longer reflective of scientific evidence of health effects at the workplace[1] or the current performance of industry in managing lead exposures.

Since 2021, Germany his enforcing a 15 µgPb/dL BLV. Denmark implements a 20 µgPb/dL BLV, and Finland, Hungary and Sweden all implement BLVs close to or below 30 µgPb/dL.

Conversely, 11 Member States still implement the maximum 70 µgPb/dL authorised by the current version of the CMRD.

The industry supports a stepwise alignment towards the 15 µgPb/dL target value to ensure a level playing field between operators across Europe and reflect industry best practices.

At the same time, a transitional period of 5 years is needed to ensure that convergence with the German early adopter is achievable from both a business and technical perspective.

In the absence of an appropriate transition period, the new limit value would put several lead-based battery manufacturers established in Member States with high limit values at a strong disadvantage against businesses located in Member States already close to implementing the 15 µgPb/dL target.

A survey conducted in 2020 by the Pb REACH consortium[2] indicates that 10% of workers exposed to lead in lead-based battery manufacturing sites had a blood lead level exceeding 29 µg/dL. Likewise, it was shown that 10% of workers exposed to lead in secondary lead maturing sites, which include lead battery recycling, had a blood lead level exceeding 28 µg/dL.

Those values, along with the extremely long elimination half-life of lead in employees with long service history of exposure to lead, suggest that an important number of sites, most of them located in countries with a BLV at or close to the 70 µgPb/dL EU target, would be at risk of non-compliance in the absence of transitional period.

Besides, EUROBAT maintains that monitoring the BLV (lead in blood) must be the primary method used to control risk. Air lead levels should reflect good hygiene practice and technical feasibility.

[1] Council Directive 82/605/EEC of 28 July 1982 on the protection of workers from the risks related to exposure to metallic lead and its ionic compounds at work

[2] Study on collecting information on substances with the view to analyse health, socio-economic and environmental impacts in connection with possible amendments of Directive 98/24/EC (Chemical Agents) and Directive 2009/148/EC - final report for lead and its compounds.

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In the final Report of the study[3] commissioned by DG EMPL to collect information on exposure to lead and its compounds to support its impact assessment, the study's authors (the Commission's external contractors) indicate that "the OEL option of 50 µgPb/m³ as an achievable level."

The 50 µgPb/m³ correspond to the lowest OEL currently in force in EU Member States (Bulgaria, Czech Republic, Denmark, Estonia, Latvia, Poland, Sweden).

The contractors also acknowledged they could not derive a cost-benefit assessment of lowering the OEL, therefore confirming scientific evidence on the absence of a clear correlation between workplace air levels and employee internal dose (as measured by blood lead).

This concurs with our own assessment that 50 µgPb/m³ is an achievable level for most sectors with significant investments to implement new technologies. Conversely, the study's conclusion signal that achieving a 30 µgPb/m³ maximum concentration will most likely either be technically unachievable for many operators or require costly physical and organisational changes that would make many sites unprofitable, without improving workers' protection.

The co-legislators should therefore amend the proposal in the following way:

- **The OEL should be set no lower than the lowest OEL currently in force in EU Member States [50µg/m3 (8hr time-weighted average)], up from 30 µg/m3 in the proposal**

- **The BLV should be supplemented with a transitional period that allow sufficient time for all industry sectors to achieve a BLV of 15µg Pb/dL blood. We propose a BLV of 20µgPb/dL blood is initially applied until 31 December 2030, thereafter 15µgPb/dL**

Failure to do so would risks putting lead-based manufacturing sites out of business, all this at a time when global demand for batteries – of all chemistries – is increasing to meet decarbonisation and sustainability targets.

Indeed, lead-based batteries support key applications in sectors such as transport, telecoms, and electricity, from start-stop batteries for hybrid vehicles and auxiliary batteries in electric vehicles to uninterrupted power supplies for telecoms and other essential services to energy storage systems.

The EU-based lead battery value chain is proven, economically sustaining and operates in a closed loop, with 99% of lead batteries collected at end of life for recycling, embracing circular economy principles. Accordingly, the average lead battery made in the EU today contains more than 80% recycled materials and more than 80% of the lead in European lead batteries is produced from recycled sources.

Driving parts of the lead-based battery business out of Europe would increase reliance on lithium-based batteries for energy storage systems, back-up supply systems and automotive applications, with upwards pressure on the price of lithium and other critical raw materials as unwanted consequences.

Background elements on the BLV and OEL are available below.

[3] *Ibid*

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Biological limit value (BLV)

EUROBAT endorses the recommendation of the Advisory Committee on Health and Safety at Work (ACSH) to adopt as soon as possible a revised BLV for lead. There was agreement among all interest groups within the ACSH (governments, employers' and workers' representatives) that a BLV of 15 µg Pb/dL blood is health-protective for male workers that represent the vast majority of the total workforce exposed to lead.

EUROBAT agrees with the Government Interest Group (GIG)'s view presented in the ACSH opinion with regards to the BLV, i.e. that the existing BLV should be revised down from 70 µg Pb/dL blood to 15 µg Pb/dL blood.

However, policy-makers must consider the long elimination half-life of lead in employees with a long service history of workplace exposure to lead when examining the proposal.

As highlighted in the final Report of the study commissioned by DG EMPL to collect information on exposure to lead and its compounds, lead elimination upon cessation of exposure is slow.

The study's contractors pointed out that while blood levels drop with a half-life of up to 36 days during the first phase of elimination, the substance has a half-life of up to 13 years during the following elimination phase.

Besides, a study from the Office of the Environment Health Hazard Assessment of the Environmental Agency of the California Environmental Protection Agency showed that it would take over a year for the blood level of an employee with 25 years of exposure and blood lead of 300 µg/L upon medical removal to drop to 150 µg/L.

As several Member States have not adopted more ambitious BLVs than the 70 µg pb/dL blood limit set by the 1982 Council Directive, the long elimination phase of lead means that many employees in industries across the EU will have blood levels exceeding the 15 µg Pb/dL blood limit proposed by the Commission.

A significant transitional period following the entry force of the revised CMRD should therefore be established for the BLV.

We believe that a 20 µg Pb/dL blood BLV should be implemented until 31 December 2030 before being lowered to 15 µg Pb/dL.

Occupational exposure limit (OEL)

EUROBAT considers that any future airborne limits should be used to reflect good hygiene practice, with blood lead concentration being recognised as the main exposure metric in assessing occupational exposure to lead, as underlined by the Commission's external contractors in the study's final Report[4].

We support the Commission's external contractors conclusion that an OEL of 50 µg/m³ (8-hour time-weighted average) should be achievable.

Raising the airborne limit value to 50 µg/m³ (down from 30 µg/m³ in the Commission's proposal) would not affect workers' protection given the absence of a clear relationship between the concentration of lead particles in the air surrounding the work station and blood lead levels in employees. At the same time, this will significantly reduce the compliance costs for most industry sectors.

[4] *Ibid*

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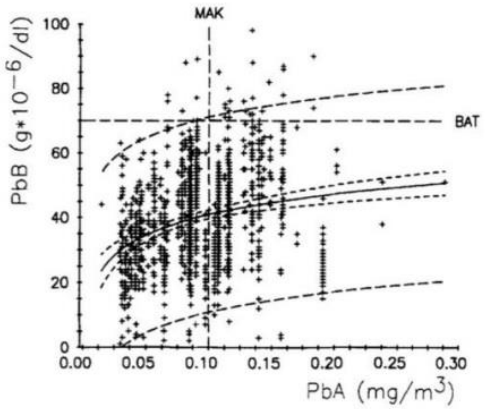
The absence of a clear correlation between air and blood lead levels was notably highlighted by M. Kentner and T. Fischer in a study published in 1994[5] on the results of a 10-year ambient monitoring of 134 battery factory staff and their workplaces.

The authors concluded that "the shape of the regression curve and the wide scattering of values led to the assumption that PbA (lead in air) values above the MAK value (0.1 mg/m3 – the 1994 German threshold limit value (TLV) for lead) do not necessarily result in increased PbB (lead in blood) values. Similarly, PbA values lower than the MAK value do not guarantee PbB levels below the BAT value in every case".

A peer reviewed publication confirming this conclusion is under development and is expected to be published in the coming months.

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



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EUROBAT is the association for the European manufacturers automotive, industrial and energy storage batteries. EUROBAT has more than 50 members from across the continent comprising more than 90% of the automotive and industrial battery industry in Europe. The members and staff work with all stakeholders, such as battery users, governmental organisations and media, to develop new battery solutions in areas of hybrid and electro-mobility as well as grid flexibility and renewable energy storage

[5] 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.