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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates

Delegations will find attached document SWD(2023) 36 final.

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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Directive of the European Parliament and of the Council

amending Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates

{COM(2023) 71 final} - {SEC(2023) 67 final} - {SWD(2023) 34 final} -
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A. Need for action

Why? What is the problem being addressed?

This initiative addresses occupational ill-health caused by two groups of chemicals, lead and its inorganic compounds (hereinafter 'lead'), and diisocyanates. The regulation of lead in occupational settings falls under the scope of the Carcinogens, Mutagens and Reprotoxic Substances Directive (CMRD) (Directive 2004/37/EC), following an agreement in March 2022 between the European Parliament and Council to expand the scope of the Carcinogens and Mutagens Directive 2004/37/EC (CMD) to include reprotoxic substances. The binding biological limit value (BLV[1]) and occupational exposure limit (OEL[2]) for lead under the CMRD were first introduced in 1982 under a specific directive on lead, and have not been updated since. The regulation of diisocyanates falls under the Chemical Agents Directive (CAD) (Directive 98/24/EC). There is currently no EU OEL or short-term exposure limit value (STEL[3]) for diisocyanates.

Lead is a key occupational reprotoxicant that can affect sexual function and fertility and the development of the foetus or offspring (developmental toxicity)[4]. It can also have harmful health effects such as neurotoxicity, renal toxicity, cardiovascular effects, and haematological effects. Lead accounts for around half of all occupational exposures to reprotoxic substances and associated cases of reproductive ill-health[5]. The risk of exposure to lead occurs in mining and primary processing and subsequent use in products such as batteries, and due to its historical uses in renovations, waste collection, recycling and remediation. Since the primary routes of exposure are inhalation and hand-to-mouth transmission and ingestion, lead concentrations in blood are the best exposure metric, as they cover both exposure routes. Between 50 000 and 150 000 workers in the EU27 are exposed to lead, and around 300 cases of ill-health occur annually due to past occupational exposure. One of the aims in the green and digital transition is to reduce emissions from cars by 55% by 2030 and eliminate emissions from new cars by 2035, while setting a target of 13 million low- and zero-emission vehicles by 2025[6]. In this context, the desire to increase the use of electric transportation and of batteries in electricity grids may result in an increased use of lead (estimated annual growth of 25%[7]), and therefore, in additional occupational exposures.

Diisocyanates are skin and respiratory sensitisers (asthmagens) that can have harmful respiratory health effects such as occupational asthma, isocyanate sensitisation and bronchial hyperresponsiveness, as well as dermal occupational disease[8]. This can happen both after acute and long-term exposure. Occupational factors account for 9-15% of asthma cases in adults of working age.

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[1] BLV means the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect.

[2] 'OEL means the limit of the time-weighted average of the concentration of a chemical agent in the air within the breathing zone of a worker in relation to a specified reference period, normally 8 hours.

[3] Diisocyanate substances have a common mechanism of inducing hypersensitivity mechanisms. Therefore, a group approach is supported by the European Chemicals Agency's (ECHA) Risk Assessment Committee (RAC) to cover a broad range of individual diisocyanate substances.

[4] The reproductive health toxicity of inorganic lead compounds is due to their lead content. Therefore, a group approach is supported by the RAC to cover a broad range of individual lead containing substances.

[5] https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8220&furtherPubs=yes

[6] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal/delivering-european-green-deal_en https://ec.europa.eu/commission/presscorner/detail/en/fs_19_6726

[7] WEF_A_Vision_for_a_Sustainable_Battery_Value_Chain_in_2030_Report.pdf (weforum.org)

[8] Diisocyanate substances have a common mechanism of inducing hypersensitivity mechanisms. Therefore, a group approach is supported by RAC to cover a broad range of individual diisocyanate substances.

The number of annual cases of diisocyanate-related occupational asthma in the EU range from 2 350 to 7 269 cases[9] [10] [11].

Occupational exposure to diisocyanates occurs primarily in the manufacturing of polyurethane as solids and foams, plastics, coatings, varnishes, two-pack paints, and adhesives. These products are widely used in construction, vehicle repairs, general repairs and the manufacturing of textiles, furniture, motor vehicles and other means of transport, domestic appliances, machinery, and computers. An estimated 42 million workers are exposed to diisocyanates. Actions taken as part of the European Green Deal's Renovation Wave to increase the thermal insulation of the built environment could increase the risk of exposure to diisocyanates.

In case of no action at EU level, based on current exposure data around 298 cases of ill-health and 36 cases of developmental toxicity are predicted annually. Over 40 years, this would mean 12 000 cases of lead-related ill-health and 1 400 cases of developmental toxicity for a workforce of 98 850. As for diisocyanates, 5 000 cases of asthma and 1 300 cases of irritation (e.g. of the skin, mucous membranes, eyes, and the respiratory tract) are estimated to occur annually. The health costs in the EU27 over 40 years would amount to EUR 612.7 million (present value) for lead-related exposure, to EUR 7.2 billion for asthma and to EUR 10.4 million for irritation, as a consequence of exposure to diisocyanates.

What is the initiative expected to achieve?

The overarching objective of this initiative is to further strengthen workers' right to a high level of protection of their health and safety at work by reducing occupational exposure to lead and diisocyanates. This initiative will pursue the following specific objectives:

1. to enhance the effectiveness of the occupational exposure and biological limit values for lead under the CMRD on the basis of scientific and technical knowledge;
2. to enhance the effectiveness of the CAD by introducing limit values for diisocyanates;
3. to achieve a more balanced and effective protection of workers across the EU against lead and diisocyanates thereby contributing to a reduction in the burden of occupational ill-health.

What is the added value of action at EU level?

The current EU limit values of an OEL of 0.150 mg/m³ and a BLV of 70 µg/100 ml blood have not been updated for more than 40 years, meaning that workers in the EU are currently subject to different levels of protection against exposure to lead. Member States have reduced exposure to varying degrees. At present, 15 Member States have an OEL equal or lower than the EU value, with the figures ranging from 0.05 mg/m^3 up to 0.15 mg/m^3 (the current OEL under CMRD).

For diisocyanates, three Member States have a general OEL, and several have different OELs for some, but not all diisocyanates. 17 have a STEL.

Revising the CMRD and the CAD will bring the same minimum standards across all Member States, while they will remain free to set stricter levels. This will lead to greater harmonisation, thus

[9] Work-related asthma in Great Britain 2021 (hse.gov.uk)
[10] Occupational Exposure to Diisocyanates in the European Union | Annals of Work Exposures and Health | Oxford Academic (oup.com)
[11] As per footnote 8 - RPA study 2021 (external study supporting the impact assessment).

contributing to a better protection of workers, especially from diisocyanates. This will also contribute to a more level playing field for businesses across the EU and will likely result in a fairer distribution and reduction of healthcare costs for the different Member States. It also eliminates the need for Member States to conduct their own scientific analyses, with likely substantial savings on administrative costs. Amending the CAD and CMRD can only be done at EU level.

B. Policy options

What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?

Several scenarios have been assessed considering the scientific assessment carried out by the European Chemicals Agency's (ECHA) Risk Assessment Committee (RAC), the opinions from the Advisory Committee for Safety and Health at Work (ACSH), as well as the OELs, BLVs and STELs in place in the different Member States. The scientific evaluation provides a solid evidence base, while the ACSH opinions, which consider also socio-economic and feasibility aspects, provide important information regarding the successful implementation of the revised and new limit values.

For lead, four options for a BLV (µg/100 ml) were considered during the impact assessment: 70 (baseline), 20, 15, and 4.5. It is not possible to establish a clear numerical correlation between levels of lead in air to which workers are exposed and the subsequent levels of lead in their blood. Therefore, it is not possible to identify OEL options and independently assess their impacts with any degree of certainty. However, a numerical value for a revised OEL is presented based on the views of key stakeholders in the ACSH opinion.

For diisocyanates, the following options for an OEL (µg NCO/m^3) were considered: no level (baseline), 10, 6 and 3, together with a STEL. Based on its scientific evaluation including the exposure risk relationship, RAC recommended that the STEL should not exceed 6 µg/m^3 NCO and that it should be no more than two times the OEL.

Based on a thorough impact assessment, a BLV for lead of 15 µg/100ml blood, accompanied by an OEL of 0.03mg/m^3 as an 8-hour time weighted average (TWA) were chosen as the preferred options. For diisocyanates, an OEL of 6µg/m^3 with a STEL of 12 µg/m^3 and a dermal and respiratory sensitisation notation and skin notation are the preferred options. Moreover, for diisocyanates, a transitional value of 10µg/m^3 with a STEL of 20µg/m^3 should apply until 31 December 2028. These represent the best scenarios in terms of effectiveness, efficiency and coherence.

Who supports which option?

The formal two-stage social partner consultation confirmed the need to revise the current BLV and OEL for lead and to propose an OEL and STEL for diisocyanates. In their opinion of November 2021, all three Interest Groups of the ACSH supported the need to revise downwards the limit values for lead and to introduce limit values for diisocyanates. While the preferred option for lead has the support of the Employers' Interest Group and Governments' Interest Group, the Workers' Interest Group supported lower values. The preferred option for diisocyanates is fully supported by all three interest groups in the ACSH.

C. Impacts of the preferred option

What are the benefits of the preferred options?

For lead, thanks to this initiative, 10 500 cases of ill-health could be prevented, with a monetised health benefit ranging between EUR 160 and 250 million over the next 40 years. For diisocyanates, a lack of data means that it is not possible to quantify benefits for workers, but there is strong agreement between stakeholders, including social partners, that a STEL would reduce the number of ill-health cases.

The proposed action will, among others, reduce the suffering of workers and their families and lead them to enjoy longer, better quality and more productive lives. It can also make the sectors more attractive, making it easier to recruit workers and increase productivity.

What are the costs of the preferred options?

Actions to adjust working practices (risk management measures, health surveillance, monitoring and training) to comply with the new values will result in increased costs for companies. The estimated cost of the preferred options is overall bearable for businesses. For lead, the costs would amount to EUR 30 000 per company over 40 years (less than 1% of their turnover). For diisocyanates, a company would have to spend EUR 6 000 over 40 years, which would not represent a significant share of their turnover either. Since these are sectors with a high degree of competition, impacts on consumers are expected to be limited.

How will businesses, SMEs and micro-enterprises be affected?

Businesses will benefit from updated limit values for lead and from the introduction of an OEL for diisocyanates, as this will simplify provisions for compliance across Member States, and it will eliminate the need to conceive and apply tailored measures in each Member State. This will especially benefit companies operating across Member States. Such companies will also benefit from improved labour productivity, lower costs of sick leave and other costs related to the replacement of workers. These benefits would be between EUR 5 million and EUR 6 million in the EU27 over 40 years. Since 99% of companies working with lead and diisocyanates in the EU are SMEs, the impacts identified in this report apply to them too.

Will there be significant impacts on national budgets and administration?

Additional administrative and enforcement costs that might be incurred by enforcing authorities are not expected to be significant. The reduction of ill-health cases will contribute to mitigating financial losses as burdens to social security and health care systems are reduced. The estimated savings for public authorities are around EUR 100 million for lead over 40 years, which outweighs the costs (EUR 500 000). For diisocyanates, public administrations in the EU will have to incur one-off costs of around EUR 970 000, also expected to be offset by the benefits (EUR 1 750 000).

Will there be other significant impacts?

The preferred options will have a positive impact on fundamental rights, especially with regard to Article 2 (right to life), and Article 31 (right to fair and just working conditions which respect their health, safety and dignity) of the Charter of Fundamental Rights of the European Union.

Moreover, this proposal will contribute positively to the Sustainable Development Goals on good health and well-being (SDG 3) and decent work and economic growth (SDG 8). A positive impact is also expected on SDG 9 on industry, innovation and infrastructure and SDG 12on responsible production and consumption.

D. Follow-up

When will the policy be reviewed?

The effectiveness of the proposed revisions of the CMRD and the CAD will be measured as part of of the evaluation of the EU Occupational Safety and Health Directives as set out in Article 17a of Directive 89/391/EEC.