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Delegations will find attached document COM(2023) 71 final.

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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

{SEC(2023) 67 final} - {SWD(2023) 34 final} - {SWD(2023) 35 final} -
{SWD(2023) 36 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

One of the objectives of the European Union (EU) is to promote well-being and sustainable development, based on a highly competitive social market economy, aiming at full employment and social progress[1]. The right of every worker to working conditions that respect their health, safety and dignity is enshrined in Article 31 of the Charter of Fundamental Rights of the European Union. Principle 10 of the European Pillar of Social Rights[2] states that workers have the right to a high level of protection of their health and safety at work.

A strong social Europe calls for constant improvements towards safer and healthier work for all. Over the last few years, the EU's occupational safety and health (OSH) policy framework and rules have contributed to considerably improving working conditions, in particular concerning workers' protection from exposure to carcinogens and other hazardous chemicals. In a context where OSH is high on the political agenda[3], exposure limit values and other provisions have been set or revised for many substances or groups of substances under the Carcinogens, Mutagens and Reprotoxic Substances Directive 2004/37/EC[4] (CMRD) and the Chemical Agents Directive 98/24/EC[5] (CAD).

Ensuring healthy and safe work environments is vital to protect workers, support economic activity and productivity, and foster a sustainable economic recovery. Hence, the Commission announced in the European Pillar of Social Rights action plan[6] its intention to ensure a healthy, safe and well adapted work environment. This was confirmed with the adoption of the OSH strategic framework for 2021-2027[7]. Protecting workers from exposure to hazardous

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1 Article 3 of the Treaty on European Union.

2 https://op.europa.eu/webpub/empl/european-pillar-of-social-rights/en/

3 The EU OSH Strategic Framework on Health and Safety at Work 2014-2020, COM (2014) 332 final, 6.6.2014; Commission Communication *Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy*, COM (2017) 12 final, 10.1.2017; Commission Communication *A strong social Europe for just transitions*, COM(2020) 14 final, 14.1.2020, *the EU Strategic Framework on health and safety at work 2021-2027*, COM (2021) 323 final 28.7.2021.

4 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158 30.4.2004, p. 50).

5 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC (OJ L 131, 5.5.1998, p 11).

6 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - *The European Pillar of Social Rights Action Plan.* COM (2021) 102 final.

7 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions *EU strategic framework on health*

substances also contributes to the objectives of the Europe's Beating Cancer plan. Also, the 2020 chemicals strategy for sustainability (CSS)[8] recognises the need to strengthen the protection of workers and identifies lead[9] and diisocyanates[10] among the most harmful chemical substances to act upon.

The substances concerned

Lead and its inorganic compounds (hereafter referred to as 'lead') is an occupational reprotoxicant that can affect sexual function and fertility and the development of the foetus, and cause other health effects. It is stated to be responsible for around half of occupational reprotoxic ill-health cases. Diisocyanates are key respiratory asthmagens. Studies have shown that occupational exposure accounts for 9%-15% of asthma cases in adults of working age[11].

This proposal aims to revise the existing limit values for lead and to introduce for the first time limit values for diisocyanates, helping to achieve a high level of protection of workers' health and safety. More specifically, the proposed amendment of the CMRD and CAD is focused on:

(1) revising the occupational exposure limit (OEL)[12] for lead by amending Annex III to the CMRD and revising its biological limit value (BLV)[13] by amending Annex IIIa;

(2) removing the reference to the established OEL and BLV for lead in Annexes I and II to the CAD;

(3) setting, for the first time, limit values (OEL and short-term exposure limit (STEL[14])) for diisocyanates in Annex I to the CAD.

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and safety at work 2021-2027 Occupational safety and health in a changing world of work. COM (2021) 323 final.

8 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Chemicals Strategy for Sustainability. Towards a Toxic-Free Environment. COM (2020) 667 final.

9 The reproductive health toxicity of inorganic lead compounds is due to their lead content. Therefore, a group approach is supported by the Risk Assessment Committee (RAC) of the European Chemicals Agency to cover a broad range of individual lead containing substances.

10 Diisocyanates is a collective term for a number of individual diisocyanates chemicals. This includes at least 25 different diisocyanates, of which 11 account for over 99% of the registered tonnage under REACH (ECHA 2019).

11 Balmes J, Becklake M, Blanc P et al. (2003) American Thoracic Society Statement: occupational contribution to the burden of airway disease. Am J Crit Care Med. 167:787- 797.

12 An occupational exposure limit (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.

13 A biological limit value (BLV) means the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect.

14 An OEL is measured over an 8-hour period reflecting a working day. A short-term exposure limit (STEL) is usually referenced to a 15-minute period and is used when short duration exposures, such as peaks, are relevant to the onset of ill-health.

The directives concerned

The need to protect workers from exposure to lead and diisocyanates was stated in the EU strategic framework on health and safety at work 2021-2027. Diisocyanates fall under the scope of Directive 98/24/EC[15] (CAD), while lead falls under Directive 2004/37/EC[16] (CMRD). The latter was amended following the adoption of Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 by extending the scope of the Carcinogens and Mutagens Directive (CMD)[17] to reprotoxic substances at work, which were until then solely addressed under the CAD.

The introduction of more protective limit values for lead and of limit values for diisocyanates enhances the level of protection without requiring changes to the general requirements of the Directives. As the OEL for lead and its BLV have been moved to the CMRD following the amendment brought by Directive EU 2022/431, they should be deleted from Annexes I and II to the CAD respectively. This is a technical change that does not affect the scope or general requirements of the two Directives.

- **Setting limit values to protect against reproductive ill-health and asthma**

Lead

Lead is an occupational reprotoxic substance that can affect sexual function and fertility for both men and women, and the development of the foetus or offspring (developmental toxicity). Exposure to lead may result in impaired fertility, miscarriages or serious birth defects, as well as in other harmful 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[18]. Lead currently has a large variety of applications. The main sectors for industrial production and use of lead are primary and secondary lead production (including battery recycling); battery, lead sheet and ammunition production; production of lead oxides and frits; lead glass and ceramics production. Exposure to lead is also possible in other industrial applications, such as in foundries and the production of articles of alloys with lead; and the production and use of pigments for paint and plastics. Besides these applications, exposure may take place further downstream in the product chain and when the articles and materials become waste or during the waste recovery of recycled materials. Examples of downstream activities are applications of paints; use of lead ammunition on shooting ranges (e.g., as part of defence, public order or safety activities); work with lead metal; demolition, repair and scrap management; other waste management and soil remediation; and work in laboratories. In addition, workers may be exposed to lead at significant levels from its historic uses in activities such as renovation, waste collection,

15 See footnote 5.

16 See footnote 4.

17 Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (OJ L 88, 16.3.2022, p. 1.)

18 Study on reprotoxic substances https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8220&furtherPubs=yes

recycling and remediation[19]. Besides, lead is present in a large number of Europe's historic buildings including those of the highest cultural heritage value, and workers engaged in the restoration of Europe's vast heritage could also come into contact with it. In historic buildings, lead can be present in stained glass windows, roofs or decorative features.

Currently, it is estimated that approximately 50 000 to 150 000 workers in the EU are exposed to lead[20]. Around 300 cases of ill-health occur each year as a result of past occupational exposure to lead. This exposure is important because lead can accumulate in the bones of exposed workers, thus contributing to the overall body burden and likelihood of chronic ill-health.

The primary routes of occupational exposure are by inhalation and by ingestion via hand-to-mouth contact due to insufficient housekeeping and personal hygiene. Dermal absorption of inorganic lead is considered to be minimal. Exposure by ingestion is considered significant and this exposure route is an important driver for the development of ill-health. Lowering the OEL concerns the reduction of inhalation exposure and additional measures are needed to minimise ingestion exposure. Blood lead concentrations are recognised as the best exposure metric to assess occupational exposures to lead, including through ingestion, and internal lead levels are decisive for determining the overall risk to health.

The lowering of the occupational exposure limit (OEL) is needed to help reduce occupational exposure, as high air concentrations can also lead to contamination. Compliance with the biological limit value (BLV) is the primary tool for protecting workers from lead toxicity and monitor its accumulation in the body. The BLV and the OEL are therefore complementary.

The EU binding OEL and BLV for lead were first introduced under a specific directive on lead in 1982[21] and have not been updated for over 40 years. The 2007 non-binding practical guidelines on the protection of the health and safety of workers from the risks related to chemical agents at work[22] provide an orientation on health surveillance regarding lead, but they are likely to be outdated.

This proposal takes into account the latest scientific and technical developments and findings, the opinions[23] of the Committee for Risk Assessment (RAC) of the European Chemicals

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19 REACH prohibits the use of lead in paints, subject to certain derogations (Annex 8). However, workers may be exposed to lead when working on buildings and structures that were painted prior to the entry into force of the restriction.

20 RPA (2021), *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 (Asbestos). Final report for lead and its compounds and final report for diisocyanates* (external study supporting the impact assessment report).

21 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)first individual Directive within the meaning of Article 8 of Directive 80/1107/EEC) (OJ L 247, 23.8.1982, p. 12)

22 https://op.europa.eu/en/publication-detail/-/publication/b8827eb0-bb69-4193-9d54-8536c02080c1/language-en

23 RAC opinion on lead (2020) https://echa.europa.eu/documents/10162/ed7a37e4-1641-b147-aaac-fce4c3014037

Agency (ECHA), established by Regulation (EC) No 1907/2006 (REACH)[24], and opinions of the tripartite Advisory Committee on Safety and Health at Work (ACSH)[25], and concludes that a BLV for lead equal to 15 µg/100ml blood, accompanied with an associated OEL equal to 0.03 mg/m^3 as an 8-hour time-weighted average (TWA), should be established.

For workers exposed to lead, health surveillance, as is currently carried out, will continue to be part of the overall approach to protecting their health. Therefore, Annex IIIa is revised to introduce updated (lower) trigger levels of exposure concentrations of lead in air and blood-lead levels at which medical surveillance should be carried out. This proposal revises the levels that, when exceeded, trigger a need for medical surveillance. These levels are measured in individual workers. Medical surveillance should take place when exposure to a concentration of lead in air is greater than 0.015 mg/m^3, calculated as a time-weighted average over 40 hours per week, or when the blood-lead level exceeds 9 µg Pb/100 ml blood. The relationship between the above levels, which trigger medical surveillance, and the revised OEL and BLV, is proportionately the same as in the current annex to the CMRD.

Lead presents a risk both to reproductive health and to the developmental health of the foetus or offspring of exposed women[26], primarily resulting in a loss of intelligence quotient (IQ)[27]. To protect workers concerned and help employers manage risks, Annex III contains a biological guidance value (BGV[28]) stating that the blood lead level of women of childbearing age should not exceed the reference values of the general population not occupationally exposed to lead in the respective EU Member State. When national reference levels are not available, it is recommended that blood lead levels of the workers concerned do not exceed a

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RAC opinion on diisocyanates (2020) https://echa.europa.eu/documents/10162/4ea3b5ee-141b-63c9-8ffd-1c268dda95e9

24 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC /OJ L 396, 30.12.2006, p. 1.)

25 ACSH opinion on lead (2021) https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/60b206e1-ee10-40c2-9540-fb6510c11a0c/details
ACSH opinion on diisocyanates (2021) https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/0d11d394-b1e8-4e1a-a962-5ad60f4ab2ae/details

26 Estimates show that the majority of the workforce in sectors involving lead is male (around 97%).

27 Data on identifiable health effects are nevertheless insufficient to be properly assessed. (see section below on impact assessment).

28 Biological guidance values (BGVs) are exposure-related values, representing the upper concentration of the chemical agent or one of its metabolites in any appropriate biological medium corresponding to a certain percentile (generally the 90th or 95th percentile) in a defined reference population. Where the available data do not support deriving a BLV, a biological guidance value (BGV) may be established. BGVs are often also called reference values. They may be useful for workers, employers and occupational physicians when dealing with worker protection issues. For instance, they can be an indicator of occupational exposure that may require attention to consider the need for additional risk management measures. BGVs are not a limit for health effects. Source: https://echa.europa.eu/documents/10162/23036412/ircsa_r8_appendix_oels_en.pdf/f1d45aca-193b-a7f5-55ce-032b3a13f9d8

BGV of 4.5 µg/100ml, as recommended by the RAC in its scientific opinion[29] (Section 8.2.4 of the annex to the opinion).

The BGV is used as an indicator of occupational exposure and not of adverse health effects. Therefore, it acts as a sentinel marker to alert the employer that exposure at the workplace has occurred and that remedial action may be required, taking into account the needs of individual workers. In its opinion, the RAC acknowledged the real concerns and potential risks to the foetus posed by exposure to lead. It indicated, however, that based on the available scientific evidence, it is not possible to quantify the degree of risk that could serve as a basis for proposing a BLV for this group of workers. Therefore, the RAC advised that the Directive highlights the concern related to lead exposure and developmental toxicity and based on the available evidence, it recommended the use of a BGV for women of childbearing age.

Diisocyanates

Diisocyanates are hazardous chemical agents in accordance with Article 2(b) of the CAD and fall within the scope of that Directive. Due to the need to address the identified serious health risks specific to diisocyanates, a restriction under Regulation (EC) No 1272/2008 was adopted in August 2020[30]. The restriction requires the mandatory training of workers who use diisocyanates to be put in place by August 2023, in accordance with specified criteria linked to the nature of the work activity.

Diisocyanates are skin and respiratory sensitisers (asthmagens) that have the potential to cause occupational asthma and dermal occupational disease – allergic reactions that can occur due to exposure to such substances. They can cause people's airways to change (the 'hypersensitive state')[31]. Once the lungs become hypersensitive, further exposure to the substance, even at quite low levels, may trigger an asthma attack. The predominant health effects of occupational exposure to diisocyanates are respiratory health effects (occupational asthma, isocyanate sensitisation and bronchial hyperresponsiveness), which are the critical endpoints related to diisocyanate exposure occurring both after acute and long-term exposure.

Diisocyanates are used in manufacture of polyurethane as both solids and foams, and of plastics, coatings, varnishes, two-pack paints and adhesives. Workers in companies manufacturing these materials are exposed to diisocyanates, as are workers using adhesives, sealants, paints and coatings containing diisocyanates. These products are widely used in construction, vehicle repairs, general repairs, and in the manufacturing of textiles, furniture, and of motor vehicles and other means of transport, of domestic appliances, machinery, and computers. Diisocyanates are transformed during the production process, and are no longer

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29 See footnote 23.

30 Commission Regulation (EU) 2020/1149 of 3 August 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards diisocyanates (OJ L 252, 4.8.2020, p. 24).

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

present in the final manufactured product. Therefore, there is no risk to the user of the product (e.g., consumers).

Studies have estimated that occupational factors account for approximately 9-15% of asthma cases in adults of working age[32]. Diisocyanates are one of the most common causes of occupational asthma with an estimated number of annual incidences in the EU in the range of 2 350 to 7 269 cases[333435]. According to estimates[36], approximately 4.2 million workers are exposed to diisocyanates and more than 2.4 million companies in the EU are concerned, the vast majority of them being micro enterprises or SMEs.

Currently, there is no binding OEL or short-term exposure limit value (STEL) for diisocyanates at EU level and there are 19 individual diisocyanate substances registered under the REACH Regulation (Regulation (EC) No 1907/2006). Adverse health effects are caused by a common part of all diisocyanates (the NCO group[37]). Therefore, a grouping approach was considered as it would allow for a common OEL and STEL for all diisocyanates.[38] This is in line with the grouping approach favoured by the recently adopted EU chemicals strategy for sustainability.

Peak exposures (short duration/high exposure levels) are a key factor in the onset of occupational asthma[39]. Therefore, a STEL, which best addresses repeated short-duration high-level exposures, is the most appropriate regulatory measure to address this type of exposure pattern. The external study[40] supporting the impact assessment report, however, could only analyse the impacts of the OEL. A lack of data on the impacts of short-term exposures meant that it was not possible to estimate the related ill-health cases, which in turn likely results in an underestimation of the costs and benefits. For these reasons, the RAC advised that any STEL should be at most twice as high as the OEL.

Therefore, for diisocyanates, this proposal puts forward an OEL equal to 6 µg/m³, accompanied by an associated STEL equal to 12 µg/m³ and a dermal and respiratory sensitisation notation, as well as a skin notation.

However, this proposal allows for a transitional value at 10 µg/m³ with an associated STEL equal to 20 µg/m³ until 31 December 2028. This is to allow employers to obtain the technical

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32 Balmes J, Becklake M, Blanc P et al. (2003) A*merican Thoracic Society Statement: occupational contribution to the burden of airway disease*. Am J Crit Care Med. 167:787- 797.

33 https://www.hse.gov.uk/statistics/causdis/asthma.pdf

34 https://academic.oup.com/annweh/article/65/8/893/6247067

35 RPA (2021), See footnote 20.

36 See footnote 20.

37 The NCO group refers to the nitrogen, carbon, and oxygen atom of the isocyanate group.

38 Several expert committees concluded that a joint assessment for all diisocyanates based on NCO concentration is adequate. The RAC proposes this approach as well, but also states that there is not enough data to assess potency differences for individual diisocyanates.

39 The RAC opinion states that there are indicators that peak exposures are important for the risk of asthma development. However, measuring peaks in human epidemiological studies is not practically possible because of measurement difficulties.

40 RPA (2021), See footnote 20.

means required to measure of such a value and give them the time to implement risk management measures, in particular in downstream sectors. It should be complemented by health surveillance of workers to detect any early onset of ill-health and subsequent management of individual workers to prevent further risks due to exposure to diisocyanates. Together, these measures provide a high level of worker protection.

To achieve the effective protection of workers from the risk of occupational diseases due to exposure to diisocyanates and lead, the limit values are set in this proposal at what can be achieved taking into account technical and economic feasibility.

- **Consistency with existing policy provisions in the policy area**

This proposal is in line with the European Pillar of Social Rights, in particular its principle 10 on the right to a healthy, safe and well-adapted work environment, and its action plan. Revising the existing limit values for lead, which have not been updated since 1982, and introducing, for the first time, limit values for diisocyanates, which fall under the CAD but for which there are currently no limit values at EU level, helps achieve a high level of protection of workers' health and safety.

This initiative also builds on the Commission's commitment in the EU strategic framework on health and safety at work for 2021-2027[41] to further lower the OEL for lead and establish an OEL for diisocyanates in 2022.

The proposal is consistent with Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work[42] (the 'OSH Framework Directive'). The Framework Directive ensures minimum safety and health requirements in all occupational settings, not only when dealing with chemical substances. In addition, it does not preclude other directives, in this case the CAD and CMRD from establishing more stringent provisions or more specific rules that further improve the protection of workers.

- **Fundamental rights and equality, including gender**

The impact on fundamental rights is considered positive, in particular with regard to Article 2 (Right to life) and Article 31 (Fair and just working conditions) of the Charter of Fundamental Rights of the European Union[43].

While the workforce exposed to lead is predominantly male, as indicated above, female workers may face additional risks as lead can affect pregnant women and the developing

41 See footnote 3.

42 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work. OJ L 183, 29.6.1989, p. 1.

43 OJ C 326, 26.10.2012, p. 391–407.

foetus[44]. There are existing requirements on implementing protective measures in the Pregnant Workers Directive[45], but they do not provide full protection from developmental effects as they apply from when the worker becomes aware that they are pregnant and inform their employer, typically three months into the pregnancy.

Therefore, within the industry working with lead, it is paramount to raise awareness among workers of childbearing capacity and put in place specific measures to minimise any possible risks, in line with the employers' obligations for risk management. To meet their obligations, employers are obliged to ensure the substitution of the substance when technically possible, the use of closed systems, or the reduction of exposure to as low as technically possible. In addition, as suggested in the opinion of the ACSH[46], the blood lead level in women of childbearing age should not exceed the reference values of the general population not occupationally exposed to lead in the respective Member State. As explained above, when national reference levels are not available, blood lead levels in women of childbearing age should not exceed the BGV of 4.5 µg/100ml[47].

- **Consistency with other Union policies**

Charter of Fundamental Rights of the EU

The objectives of the initiative are consistent with Article 2 (Right to life) and Article 31 (Right to fair and just working conditions) of the EU Charter of Fundamental Rights.

Coherence with the REACH Regulation

The REACH Regulation[48], in force since 2007, establishes among others two distinct EU regulatory approaches, namely, restrictions and authorisations. Improving the interface between REACH and worker protection legislation is an issue being addressed in the context of the ongoing REACH revision[49].

Restrictions enable the EU to impose conditions on the manufacturing, placing on the market and/or use of substances, in mixtures or in articles. Authorisation is designed to ensure that risks from substances of very high concern (SVHCs) are properly controlled while promoting progressive substitution by suitable alternatives that are economically and technically viable.

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44 Lead can pass the placenta resulting in blood lead concentration in the umbilical cord at birth being close to the blood lead level of the mother (source: RPA, 2021 external study section 2.2.4.7, see footnote 19).

45 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding. OJ L 348, 28.11.1992, p. 1–7.

46 See footnote 25.

47 See footnote 23.

48 See RAC opinion, footnote 23.

49 A first joint meeting of the competent authorities for REACH and the interest groups of ACSH/WPC took place on 5 April 2022 to discuss OSH aspects of the current revision of REACH.

A number of uses of lead are restricted under REACH. It is forbidden to use lead in paints (with some exemptions)[50] [51], in jewellery and articles which are intended to come into contact with the skin, and to use lead and its mixtures supplied to the general public[52].

Diisocyanates are restricted under REACH[53]. They can only be used or placed on the market as substances on their own, as a constituent in other substances or in mixtures for industrial and professional uses if the employer or self-employed person ensures that industrial or professional user(s) have successfully completed training on the safe use of diisocyanates before using the substance(s) or mixture(s).

More information about the REACH restrictions for the two substances is available in Annex 8 to the impact assessment report accompanying this proposal.

The ACSH, in its opinion[54], stated that a combination of the REACH restriction (on worker training) and OSH provisions, especially the respect of limit values and carrying out health surveillance, is the most efficient approach for preventing peak exposure, which is the key event leading to asthma from exposure to diisocyanates.

Together, the EU OSH Directives (CMRD and CAD) and the REACH Regulation are relevant for workers' protection from the risks of exposure to lead and diisocyanates.

Coherence with the Batteries Regulation

In December 2020, the Commission proposed a new Batteries Regulation[55] with the aim to ensure that batteries placed on the EU market are sustainable and safe throughout their entire life cycle. This is an integral part of the EU Green Deal, which aims for greater use of modern non-fossil fuelled vehicles, and which could involve an increased use of lead containing batteries, including during their recycling. Updating the limit values for lead ensures that workers in the manufacturing and recycling of batteries will benefit from a high level of health protection, despite a potentially higher production volume in the future.

Coherence with scientific research

Lead and diisocyanates were priority chemicals addressed under the EU human biomonitoring programme (HBM4EU) funded by Horizon 2020[56], a joint effort of 30 countries, the European Environment Agency and the European Commission, that ran from 2017 to 2021. It

50 https://echa.europa.eu/documents/10162/22dd9386-7fac-4e8d-953a-ef3c71025ad4
51 https://echa.europa.eu/documents/10162/ffd7653b-98cc-4bcc-9085-616559280314
52 https://echa.europa.eu/documents/10162/61845f2b-f319-ab2e-24aa-6fc4f8fc150f
53 https://echa.europa.eu/documents/10162/503ac424-3bcb-137b-9247-09e41eb6dd5a
54 See footnote 25.
55 https://ec.europa.eu/environment/pdf/waste/batteries/Proposal_for_a_Regulation_on_batteries_and_waste_batteries.pdf
56 https://www.hbm4eu.eu/about-us/

generated knowledge to provide insight into the safe management of chemicals and so protect human health. A dedicated project on occupational exposure to metals was carried out, with the results showing that exposure to several metals, including lead, occurs during the recycling of e-waste. A dedicated project was also carried out for diisocyanates, leading to a review of the current biomarkers used for biomonitoring diisocyanates, an assessment of the current levels in workers and the identification of research gaps[57].

Coherence with Europe's Beating Cancer plan

The aim of Europe's Beating Cancer Plan is to tackle the entire disease pathway[58]. It is structured around four key action areas where the EU can add the most value: (i) prevention; (ii) early detection; (iii) diagnosis and treatment; and (iv) quality of life of cancer patients and survivors. While rare, exposure to lead can cause cancer, and the reduction in limit values will contribute to preventing these cancers.

For diisocyanates the adverse health effects do not include cancer and the Europe's Beating Cancer plan is not relevant.

Coherence with the Renovation Wave for Europe

Buildings are responsible for 36% of energy-related greenhouse-gas emissions. Given that more than 85% of current buildings will still be standing in 2050, energy-efficiency renovations will be essential to reach the objectives of the European Green Deal. In this context, the renovation wave strategy[59] aims to double the annual energy-renovation rate by 2030. Specialised renovation works to reduce energy consumption can boost the long-term value of properties and create jobs and investment, often rooted in local supply chains. However, workers could become exposed to lead during the removal of lead containing paints, plumbing and roofing materials (amongst others) and to diisocyanates as a result of the increased use of insulating foams and better surface coatings to enhance the thermal insulation of the built environment. This proposal therefore contributes to carrying out renovations that are both positive for the environment and ensure the protection of the safety and health of workers.

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57 For more information see Scholten, B; Kenny, L; Duca, R; Pronk, A; Santonen, T; Galea, K.S; Loh, M; Huumonen, K; Sleeuwenhoek, A; Creta, M; Godderis, L; and Jones, K. 2020. 'Biomonitoring for occupational exposure to diisocyanates: A systematic review. *Annals of Work Exposures and Health* 64(6): 569-585. https://academic.oup.com/annweh/article/64/6/569/5822987?login=true

58 Communication from the Commission to the European Parliament and Council - *Europe's Beating Cancer Plan.* COM (2021) 44 final.

59 Communication from the Commission to the European Parliament and Council, The European Economic and Social Committee and the Committee of the Regions - *A Renovation Wave for Europe - greening our buildings, creating jobs, improving lives.* COM (2020) 662 final

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

Article 153(2)(b) of the Treaty on the Functioning of the European Union (TFEU) provides that the European Parliament and the Council 'may adopt, in the fields referred to in paragraph 1(a) to (i) [of Article of the 153 TFEU], by means of directives, minimum requirements for gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States. Such directives shall avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings'. Article 153(1)(a) TFEU states that the EU must support and complement the activities of the Member States in the field of 'improvement in particular of the working environment to protect workers' health and safety'.

The CMRD and the CAD were both adopted on the basis of Article 153(2)(b) TFEU to improve workers' health and safety. The present proposal aims to strengthen the level of workers' health protection in line with Article 153(1)(a) TFEU, in the form of a revised OEL and BLV for lead to be set in the CMRD and the introduction of an OEL and STEL for diisocyanates in the CAD, accompanied by some technical adaptations. Therefore, Article 153(2)(b) TFEU is the proper legal basis for the Commission's proposal to amend both the CMRD and the CAD.

Pursuant to Article 153(2) TFEU, the improvement in particular of the working environment to protect workers' health and safety is an aspect of social policy where the EU shares competence with the Member States.

• Subsidiarity (for non-exclusive competence)

Scientific knowledge about lead and diisocyanates has developed since the adoption of the CAD in 1998 (and the previous 1982 Directive specific to lead). The change of scope of the CMD resulting from the adoption of the CMRD brings lead, a reprotoxic substance, under the CMRD. Moreover, the added value of EU action is justified due to the problem being widespread across the whole EU. Although competition in the single market is not strongly impacted by the revision of the OEL and BLV for lead and its inorganic compounds and by introducing an OEL and STEL for diisocyanates, the greater harmonisation of minimum requirements would improve the level playing field for operators in the single market.

Data gathered during the preparatory work indicate that there are differences between the Member States on the setting of limit values for lead and diisocyanates. Acknowledging developments in scientific knowledge, some Member States have already reduced their limit values for lead to a varying degree and/or introduced limit values for diisocyanates.

For lead, Member States' BLVs range from 20 µg/100ml blood to 70 µg/100ml blood (the current BLV under the CMRD). 15 Member States have a BLV lower than the current EU

BLV[60]. Some Member States have a lower limit for women, which is age dependent or stated as 'women of childbearing age' and typically ranges between 20 and 40 µg/100ml blood. The OEL ranges from 0.050 g/m^3 up to 0.150 g/m^3 (the current OEL under the CMRD).

For diisocyanates, there is no EU limit value. However, three EU Member States have a general OEL[61] and several have different OELs and STELs for some, but not all, different diisocyanates. Where they exist, OELs range from 3 µg NCO/m^3 to 500 µg NCO/m^3 with a median value of 17.4 µg NCO/m^3. For the STEL, the range is from 10 to 82 µg NCO/m^3.

Given the situation described above, it is clear that workers in the EU are subject to different levels of protection from lead and from diisocyanates.

Significant divergences between national limit values distort competition in the single market. The costs of complying with lower national levels are generally higher and entail therefore a competitive advantage for enterprises operating in markets with no or less stringent national limit values. For lead, companies based in Bulgaria, Czechia, Denmark, Latvia and Poland need to comply with an OEL 3 times lower than the maximum OEL currently set at EU level (0.050 g/m^3 vs 0.150 g/m^3), which could negatively affect their competitiveness and create disparities in the single market. The potential impact on competition is even larger for diisocyanates, for which there are currently no EU limit values. Where national limit values exist, OELs range from 3 µg NCO/m^3 to 500 µg NCO/m^3. Therefore, updating the limit values for lead and introducing, for the first time, limit values for diisocyanates will contribute to greater harmonisation in the single market and create a more level playing field for businesses.

While individual Member States could still introduce lower values, the level playing field for enterprises will improve. Companies willing to operate in the different EU Member States can further benefit from a streamlining of the applicable limit values, potentially providing for savings as common solutions can be adopted across facilities, as opposed to designing site-specific solutions to meet various OEL and BLV requirements.

Risks to workers' health and safety arising from exposure to lead, a dangerous occupational reprotoxicant, and diisocyanates, which are respiratory sensitisers, are broadly similar across the EU and both substances are broadly used in a wide range of sectors and countries. For this reason, there is a clear role for the EU in supporting Member States in addressing such risks.

For lead, the external study[62] accompanying this proposal identifies 18 Member States that produce refined lead and a more limited number of Member States mining lead. The production rate of lead in the EU is in excess of 10 million tonnes per year used for a broad range of processes including lead battery, sheet and powder production, and use in articles.

60 BG, HR, CZ, DK, FI, FR, DE, HU, IT, LV, NL, PL, SK, SI, SE.
61 HR, IE, LT.
62 RPA (2021) See footnote 21.

Diisocyanates are manufactured in 7 Member States and used throughout the EU in 21 relevant downstream sectors.

To ensure that the measures for protecting workers from exposure to lead and diisocyanates are as effective as possible, the Directives need to be kept up to date with the most up-to-date scientific knowledge presented in the RAC opinions[63]. In view of the available scientific evidence, it is necessary to review the OEL and BLV for lead and its inorganic compounds and to introduce an OEL and STEL for diisocyanates. The protection of workers' health against risks arising from exposure to these substances is already covered by EU legislation, in particular by the CAD and CMRD, which can only be amended at EU level. This proposal builds on long and intensive discussions with all stakeholders (representatives of workers' associations, of employers' associations, and of governments). This helps to ensure that the principles of subsidiarity and proportionality are properly respected.

Updating the CAD and the CMRD to take into account newer scientific evidence is an effective way to ensure that preventive measures are updated accordingly in all Member States. This will help achieve a uniform level of minimum requirements designed to guarantee a better standard of health and safety. In turn, this will minimise the disparities in health and safety protection levels of workers between Member States and across the EU single market.

Furthermore, the revision or introduction of limit values is very complex and requires a high level of scientific expertise. Adopting limit values at EU level offers an important advantage by eliminating the need for Member States to conduct their own scientific analysis with likely substantial savings on administrative costs. These resources could instead be dedicated to improving further OSH policies in each Member State.

It follows that, for both lead and diisocyanates, EU-level action to achieve the objectives of this proposal is necessary, as these objectives cannot be sufficiently achieved by the Member States, either at central or at regional and local level, because of the scale and effects of the proposed action. This is in line with Article 5(3) of the Treaty on European Union (TEU). Amending the CMRD and CAD can only be done at EU level and after a two-stage consultation of the social partners (management and labour) in accordance with Article 154 TFEU.

- **Proportionality**

The proposal respects the principle of proportionality, as it does not change the Directives' objectives and general requirements. The action is limited to proposing new and revised limit values taking fully into account up-to-date scientific information and socio-economic feasibility factors. These have been discussed thoroughly with all stakeholders (representatives of workers' organisations, of employers' organisations and of governments). This initiative aims to ensure a balanced approach, i.e., one that prevents companies from

63 See footnote 23.

facing severe economic disadvantages while providing appropriate protection to workers at EU level. Since the proposal for diisocyanates involves establishing limit values for the first time, it includes measures for mitigating burdens and supporting compliance with provisions (such as a transitional period) which have also been discussed with the relevant stakeholders. These transitional measures contribute to the proportionality of the proposed initiative by ensuring a more appropriate time frame for businesses to adapt. For lead, the proposal is part of a stepwise approach[64] to better protecting workers by providing more protective limit values than the existing values.

Furthermore, the setting of these new or revised limit values for both substances would entail limited costs for companies, in particular when compared to their turnovers. The initiative is considered balanced and justified in light of the accrued and long-term benefits in terms of reducing health risks arising from workers' exposure to lead and to diisocyanates and preventing occupational ill-health. In accordance with Article 153(4) TFEU, this proposal lays down minimum requirements and does not prevent any Member State from maintaining or introducing more stringent protective measures compatible with the Treaties, for example, in the form of lower limit values or other provisions ensuring greater protection for workers. This offers the Member States a certain margin of flexibility.

It follows that this proposal does not go beyond what is necessary to achieve its objectives in line with the principle of proportionality, as set out in Article 5(4) TEU. Detailed information on compliance with the principle of proportionality is provided in the impact assessment report accompanying this proposal (point 8.4).

- **Choice of the instrument**

Article 153(2)(b) TFEU specifies that minimum requirements in the field of workers' health and safety protection may be adopted 'by means of directives'.

3. RESULTS OF *EX POST* EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- ***Ex post* evaluations/fitness checks of existing legislation**

The most recent in-depth evaluation of the CAD and CMD (2017 *ex post* evaluation of the EU OSH Directives[65]), concluded that the Directives remain highly relevant and effective according to the available evidence. It highlighted that limit values are an important tool for chemical risk management in the workplace and that there is a need to adopt exposure limit

64 The process for setting and/or revising limit values involves the identification by the Commission of priority substances for scientific evaluation including stakeholder engagement at Member States and Social Partner levels, a scientific evaluation of the Committee for Risk Assessment of the European Chemicals Agency, a public consultation, the tripartite consultation of employers', workers' and governments' representatives via the Advisory Committee on Safety and Health at Work, and an impact assessment based on an external study.

65 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017SC0010&from=en

values for more substances of high concern. Specifically, the evaluation identifies the need to consider the most appropriate approach to managing risks that may arise from exposure to chemical and reprotoxic substances and if and how biomonitoring could be used more effectively for workplace risk management. It further states that sensitisers should be considered as a high priority that merit further consideration to ensure that the risk management requirements are appropriate.

This initiative is also in line with the stocktaking staff working document accompanying the EU strategic framework on health and safety at work 2021-2027 (SWD (2021) 148 final)[66], which identifies the need to increase the focus on addressing occupational diseases. For lead, in particular, it states that the limit values should be reviewed in light of new scientific data.

- **Stakeholder consultations**

Two-stage consultation of European social partners in accordance with Article 154 of the TFEU

In 2020 and 2021, the Commission carried out a two-stage consultation of social partners at EU level pursuant to Article 154(2) of the TFEU. The Commission consulted the social partners on the approach to revising binding occupational exposure limit values for lead and its compounds and to setting occupational exposure limit values for diisocyanates under the CAD.

Workers' organisations

The European Trade Union Confederation (ETUC) replied to the first phase consultation, acknowledging the importance of the existing legislation. While ETUC, in principle, supported reducing the current limit values for lead, it expressed the view that the BLV proposed in the scientific opinion adopted by the RAC would not be sufficiently protective of women of childbearing age in the workplace, nor guarantee equal treatment of women and men at work[67]. They proposed, instead, that a lower BLV be introduced. In addition, they made some general reflections concerning the need to improve workers' protection from exposure to reprotoxic substances and concerning the Pregnant Workers Directive 92/85/EEC[68] in this context.

ETUC agreed that a binding EU OEL for diisocyanates is needed to ensure minimum requirements for the protection of workers exposed to diisocyanates across the EU. At the same time, they expressed the view that this is the first time an EU binding OEL would be established for sensitisers with the main aim of preventing occupational asthma, and therefore

66 See footnote 3.

67 The RAC recommends stating in the CAD that the exposure of fertile women to lead should be avoided or minimised in the workplace because the BLV for lead is not protective of the offspring of women of childbearing age. In ETUC's view, this is discriminatory as it could create a situation where women might not be hired in workplaces where they can be exposed to lead and its compounds.

68 See footnote 45.

proposed that this point be discussed and agreed upon within the ACSH where workers, employers and governments are represented.

The workers' organisations believe that binding EU legislative action is needed on these issues and therefore see no need to launch a negotiation procedure pursuant Article 155 TFEU. ETUC indicates, however, that it might wish to discuss complementary issues with employers and seek convergent positions on certain questions, such as the best legal instrument to protect workers from the risk of exposure to substances that are toxic and affect reproduction or the need for a new methodology to limit the volume of non-threshold substances at EU level.

Employers' organisations

Three employers' organisations replied to the first-phase consultation: Business Europe, SME United (European Association of Crafts and SMEs) and the European Construction Industry Federation (FIEC).

The employers' organisations supported the objective to effectively protect workers from exposure to hazardous chemicals, including by setting OELs at EU level, where appropriate. They consider this is in the interest of workers and businesses and contributes to a level playing field. However, they also raised some concerns about the approach taken when setting such values.

Concerning the issues identified in the consultation paper, the employers' organisations supported the Commission's general direction towards constant improvement of the protection of workers from exposure to carcinogens and risks arising from chemical agents in the workplace, subject to certain conditions. In their view, the process of setting limit values should be based on sound scientific evidence, technical and economic feasibility, socioeconomic impact assessment, and the opinion of the ACSH, as is done currently by the Commission.

Furthermore, they stressed that a lower limit value does not always mean better protection of workers, as it depends on the feasibility to measure it and for employers to implement it.

Business Europe and SME United stressed the need to assess the impact on small and medium-sized enterprises (SMEs), in particular on micro-enterprises, in terms of proportionality and feasibility of action, and also to take account of sectoral differences.

Concerning the question on the binding instrument to be used for addressing these issues, SME United pointed out that without a deeper analysis of the impact of the new values on crafts, SMEs and employers' obligations, they cannot assess whether such an instrument would be appropriate.

As regards lead and its compounds, Business Europe referred to the voluntary agreements put in place by the industry to continuously lower exposure levels, as far as technology allows it.

It stressed that OSH legislation at EU and national level already provides a good level of protection for workers and highlighted the importance of the existing binding OEL under the CAD together with other protective measures aside from the limit value.

SME United underlined that a concrete proposal on the new planned OEL should be submitted in order to better assess the impact on companies.

As regards diisocyanates, SME United is of the view that a detailed analysis of the risks of diisocyanates justifying setting a limit value is lacking. However, while in principle they did not oppose introducing a proportionate and feasible OEL for diisocyanates in indoor workplaces, for outdoor workplaces they considered that training requirements addressing the possible risks and hazards are sufficient.

Business Europe, although agreeing with the existence of risks for workers, highlighted that the introduction of a new binding OEL would put additional obligations on employers, not only to comply with the limit value, but also with the other protective measures in the CAD.

They also stressed the importance of workers' protection already provided under REACH through the restriction requiring the training of workers who use diisocyanates[69], as well as obligations concerning the training of workers. Moreover, they noted that the RAC mentioned in the context of the restriction that the training of workers is the most effective way of reducing exposure and the impact on them.

Business Europe expressed the need for the EU to provide more information and analysis on how effective a binding OEL would be in addition to the existing restriction under REACH.

The employers' organisations considered that the existing preparatory procedures already involve social partners, including the ACSH consultations. Therefore, they do not want to launch a negotiation procedure pursuant Article 155 TFEU.

Results of the second phase of the social partners consultation

The Commission launched a second-phase consultation of the social partners, which closed on 30 September 2021. This second-phase consultation focused on the envisaged content of possible proposals, as required under the Treaty.

Among workers' organisations, only ETUC replied to the second-phase consultation. They recognised the importance of further improving the protection of workers from exposure to lead and diisocyanates and supported binding action via the revision of the Directives. Having already answered the first-phase consultation, they reconfirmed their statements.

They did not see the need to enter negotiations under Article 155 TFEU.

[69] See footnote 24.

Among employers' organisations, only Business Europe and the Shipyards' & Maritime Equipment Association of Europe (SEA Europe) replied to the second phase consultation.

Business Europe, having already answered the first-phase consultation, reconfirmed their statements.

Business Europe considered that the existing preparatory procedures already involve social partners and that the ACSH is the right place for dialogue with them, jointly with governments, on the next steps in the process. Therefore, they did not want to launch a negotiation procedure pursuant Article 155 TFEU.

SEA Europe stated that diisocyanates are rarely used in their industry and that if they could no longer be used, they would find an alternative substance as a substitute.

Consultation of the Advisory Committee on Safety and Health at Work (ACSH)

The ACSH is composed of representatives of national governments and workers' and employers' organisations. It was consulted on this proposal via its dedicated Working Party on Chemicals, in accordance with the ACSH's mandate. In this mandate, the Commission asks the Working Party on Chemicals to actively participate in recommending priorities for new or revised scientific evaluations. The Working Party on Chemicals' opinion takes into account the RAC's scientific input, and socio-economic and feasibility factors.

The ACSH adopted, on 24 November 2021, an opinion on lead[70] for an EU binding OEL and a binding BLV under the CAD (now under the CMRD), and an opinion on diisocyanates[71] for a binding OEL and STEL under the CAD.

As regards lead, the three ACSH Interest Groups (employers, workers and governments) reached a consensus on the need to revise downwards both the existing BLV and OEL 'to better protect workers' health taking into account scientific and technical developments since the current limit values were adopted'. No consensus was reached on the limit value to be proposed. In their opinion, oral and inhalation exposure are both relevant routes for the uptake of lead into the human body and blood lead concentrations are the best exposure metric to assess occupational exposure. This is because internal lead levels are decisive for chronic toxicity. Therefore, it is important to use the BLV as the primary tool for protecting workers from lead toxicity. The OEL and BLV complement each other, and both should be complied with.

The main differing views concerned (i) how best to tackle workers with higher blood levels due to historic exposure since lead is stored in the bones for a long time; (ii) levels of exposure for women of childbearing age; and (iii) for the OEL, the uncertainties in the models

70 See footnote 25.
71 See footnote 25.

used to derive the values and technical feasibility together with cost-benefit considerations to achieve these levels[72].

The divergent views presented above highlight the importance of health surveillance (already a requirement of the CMRD) for the effective management of individual workers who may have historic exposure, or in the specific case of female workers of childbearing age. The general requirements for health surveillance (which apply to all substances within the scope of the Directive) are complemented by specific requirements when workers are exposed to certain specified levels of lead requiring more detailed medical surveillance when exposure exceeds 0.075 mg/m^3 in air (50% of the current OEL) or 40 µg/100ml blood (approx. 60% of the current BLV).

For lead health/medical surveillance is important because lead is stored in the bones for decades (half-life in bones[73] is 6 to 37 years) and is released gradually into the bloodstream.

As regards diisocyanates, the three ACSH Interest Groups agreed on the numerical values of the OEL and STEL that should be proposed and advised that a phase-in approach is required due to technical measurement feasibility and the time to implement risk management measures, in particular in downstream sectors. The Employers Interest Group highlighted the need to tackle the problem of occupational asthma caused by this agent by preventing peak exposures. They recognised the need to take a pragmatic approach to setting the STEL that will significantly reduce peak exposures resulting in a major improvement of workers' health.

Specific health surveillance is also mentioned as appropriate in line with Articles 6(3) and 10 of the CAD as a means of identifying early signs and symptoms of respiratory sensitisation. These arrangements should be in accordance with national laws and/or practice, as well as in line with the principles and practices of occupational medicine.

Thus, there is consensus on the need to adopt a binding OEL under the CAD to be set at 6 µg/m³, accompanied by an associated STEL equal to 12 µg/m³, a dermal and respiratory sensitisation notation and a skin notation. A transitional value at the level of 10 µg/m³ with an associated STEL equal to 20 µg/m³ that should apply until 31 December 2028 was also proposed.

- **Collection and use of expertise**

In reviewing the binding limit values (OEL and BLV) for lead under the CMRD and establishing, for the first time, a binding OEL and STEL for diisocyanates, the Commission followed a well-established procedure that involves seeking scientific advice and consulting the ACSH. A sound scientific basis is indispensable in underpinning any OSH action, particularly in relation to the dangerous substances. In this regard, the Commission sought advice from the Committee for Risk Assessment (RAC) of the European Chemicals Agency.

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72 For a detailed overview of the differing views, see the ACSH opinion (see footnote 25) and the impact assessment report accompanying this proposal.

73 The time required for its concentration to decrease by half.

The RAC develops high-quality comparative analytical knowledge and ensures that Commission proposals, decisions and policy on the protection of workers' health and safety are based on sound scientific evidence. Members of the RAC are highly qualified, specialised, independent experts selected on the basis of objective criteria. They provide the Commission with opinions that are used to develop EU policy on workers' protection.

The scientific opinions of the RAC[74] necessary for revising the binding limit values (OEL and BLV) for lead and for establishing, for the first time, a binding OEL and STEL for diisocyanates, were adopted on 11 June 2020. In its opinion on lead, the RAC proposes a BLV of 15 µg lead/100 ml blood and an OEL of 0.004 mg lead/m^3 (inhalable fraction).

As regards diisocyanates, the RAC opinion states that a threshold for bronchial hyper-responsiveness or for the development of asthma could not be observed. However, an OEL defined as an 8-hour time weighted average (TWA) exposure based on the 'NCO group'[75] can be obtained from the exposure-risk relationships (ERR) for hyper-responsiveness or diisocyanate asthma, based on excess risk over a working life period.

The ERR presents a range of exposure levels and the corresponding risk of developing occupational asthma due to exposure to diisocyanates.

A 15-minute STEL value is required since peak exposures are important and drive the onset of asthma. However, measuring peaks in epidemiological studies is not practically possible and for this reason the RAC focused on the OEL while concluding on the need for a STEL that should be determined using a multiplication factor of no more than two times the OEL. The RAC recommended that the STEL value should not exceed 6 µg/m^3 NCO.

Moreover, the RAC considered that dermal and respiratory sensitisation notations and a 'skin' notation were warranted. The notations indicate that in addition to the need to control inhalation exposure it is important to prevent dermal exposure as the substance can be absorbed through the skin and contribute to overall exposure and elicitation of asthma. Preventing dermal exposure can be achieved, for example, by wearing appropriate gloves and coveralls.

- **Impact assessment**

This proposal is supported by an impact assessment report accompanying the present proposal. The impact-assessment report was supported by an external study that collected information to analyse health, socio-economic and environmental impacts in connection with possible amendments of the CMRD and CAD[76]. The impact assessment report was presented

74 See footnote 23.

75 See footnotes 31 and 37.

76 RPA (2021) See footnote 20. When the study was launched, both the introduction of limit values for diisocyanates and the update of limit values for lead were to be carried out under the CAD. However, the impact assessment report was drafted after the agreement between the European Parliament and Council in January 2022 to expand the scope of the CMD and therefore took account of the inclusion of reprotoxic substances under the CMRD and its implications.

to and reviewed by the Regulatory Scrutiny Board (RSB) on 12 October 2022. It received a positive opinion with reservations dated 14 October 2022. The RSB's comments were addressed in the final impact-assessment report.

The following options for various limit values for lead and diisocyanates were examined:

- a baseline scenario of no further EU action (option 1); and
- options for various OELs and BLVs for lead and OELs and STELs for diisocyanates, taking into account the scientific assessment of the RAC[77], the opinion of the ACSH[78], and the OELs in place in the Member States (the scientific evaluation provides a solid evidence-based approach, while the ACSH's opinion provides important information for the successful implementation of the revised OELs and BLVs options).

Due to insufficient data as regards identifiable effects on health, the impact assessment report did not examine the option of setting a separate BLV for female workers of childbearing age. Consequently, a recommendation is made instead as data on the costs, benefits, and potential overall impacts of a separate BLV is lacking. The recommended guidance value and the requirements for medical surveillance should be considered together to ensureadequate protection for this group of workers.

Several other options were discarded at an early stage as they were considered disproportionate or less effective in reaching the objectives of this initiative. These discarded options related to how to set OELs, STELs and BLVs, to the choice of another instrument, and to the introduction of adapted measures for SMEs. Non-regulatory alternatives such as guidance documents or examples of good practice were not considered effective enough in reaching the objectives of this initiative since they would result in non-binding provisions. On the other hand, existing guidance documents or examples of good practice can be considered as complementary and could provide added value to OELs/STELs/BLVs. Adopting a different solution for SMEs was also discarded. This is because SMEs account for around 99% of companies working with lead and diisocyanates, and should therefore not be exempted from the scope of the initiative. Their exclusion would mean that the vast majority of European workers at risk of exposure to these groups of substances would not be sufficiently protected by health and safety at work legislation, with a clear distortion and inequality in the application of the EU legislative framework and with a risk of compromising the underlying social policy objectives and fundamental rights.

The option to assist SMEs by extending the time by which the limit value needs to be implemented was retained for diisocyanates. A transitional value is considered as necessary for technical measurement feasibility reasons and to give sufficient time to the industry to implement the necessary risk management measures, in particular in downstream sectors,

77 RAC opinion. See footnote 23.
78 See footnote 25.

since there is currently no limit value at EU level. Besides, since most of the companies (99%) working with diisocyanates are SMEs, this transitional value will be particularly beneficial for them.

The Commission also analysed the economic, social and environmental impacts of the various policy options. The results of this analysis are presented in the impact assessment report accompanying the present proposal. The policy options were compared and the preferred option was chosen based on the following criteria: effectiveness, efficiency and coherence. Costs and benefits were calculated over a 40-year period. The health benefits of the revised OEL/STEL/BLV were calculated in terms of the costs of ill-health avoided. All analytical steps were performed in line with the Better Regulation guidelines[79].

The Commission compared the envisaged options and took into account the positions of the various ACSH interest groups. Based on this, the Commission selected the preferred option of setting a BLV for lead equal to 15 µg/100ml blood, accompanied by an associated OEL equal to 0.03 mg/m3 as an 8-hour time-weighted average (TWA) and translated this into a corresponding legislative provision set out in this proposal. This option is considered balanced and justified in light of its accrued and long-term benefits in terms of reducing health risks arising from workers' exposure to lead, without putting a disproportionate burden on businesses in the concerned sectors, including on SMEs and micro-enterprises. As regards diisocyanates, the Commission selected the preferred option of setting an OEL equal to 6 µg/m³, accompanied by an associated STEL equal to 12 µg/m³, a dermal and respiratory sensitisation notation and a skin notation. A transitional OEL value equal to 10 µg/m³ with an associated STEL equal to 20 µg/m³ should apply until 31 December 2028 due to technical measurement feasibility and the time needed to implement risk management measures in particular in downstream sectors. This should be complemented by health surveillance of workers to detect any early onset of ill-health and subsequent management of the individual workers to prevent further risks due to exposure to diisocyanates. Collectively, these measures provide a high level of workers' protection.

Impact on workers

The preferred options should result in benefits in terms of avoided work-related ill-health, and related monetised health benefits (such as the avoidance of intangible costs like reduced quality of life, the suffering of the workers and their families, etc). For lead, it is estimated that about 10 500 cases of ill-health could be prevented, and its monetised health benefit is assessed as ranging from EUR 160 million to EUR 250 million over the next 40 years. Regarding diisocyanates, the lack of data means that it is not possible to quantify the benefits for workers. However, it is largely agreed among relevant stakeholders, including social partners, that setting a STEL would result in a decrease in the number of ill-health cases.

It is expected that the introduction of limit values will, among others, reduce the suffering of workers and their families and lead to healthier and more productive lives.

[79] Available at: https://ec.europa.eu/info/better-regulation-guidelines-and-toolbox_en.

Impact on employers

As regards costs incurred for risk reduction measures, the preferred options will affect operating costs for companies that will have to adjust working practices to comply with the new BLV and OEL for lead and OEL, STEL and notations for diisocyanates. This will consist in incremental costs of risk management measures (RMMs) (including respiratory protective equipment), cost of health surveillance, monitoring costs and training costs[80].

Although the costs outweigh the benefits, the preferred option has not been selected solely on the basis of a comparison of monetised costs and benefits. The costs to business over the next 40 years are estimated to be about EUR 750 million for companies operating with lead and EUR 13.5 billion for companies dealing with diisocyanates.

The costs for businesses regarding lead (an average additional costs per company around EUR 30 000 over 40 years) represent less than 1% of their annual turnover and should therefore not lead to any closures.

Data limitations for diisocyanates implied that costs and benefits were likely underestimated, and for both substances, calculations of costs are easier to obtain than those of benefits, as is usually the case in occupational safety and health. For diisocyanates, the transitional period proposed until 31 December 2028 will contribute to mitigating the costs. Besides, the fact that the proposed value was endorsed by all three Interest Groups of the ACSH, including employers, signals that, despite the costs, it is considered to be an implementable measure.

Each of the companies operating with diisocyanates would spend on average about EUR 6 000 over 40 years, mainly on monitoring tasks, spread over the reference period. However, companies operating in the textiles and apparel sectors would also need to bear one-off costs of EUR 4.5 billion and EUR 10.3 billion respectively, as they would need to invest in additional risk management measures. The one-off costs relate mainly to investments following the need to acquire respiratory protective equipment (this often used in these two sectors as a primary protective measure, before collective protective measures). This involves high one-off costs, yet savings in terms of recurrent costs. Since most of the companies operate in sectors with a high degree of competition, they are unlikely to pass the costs on to consumers, as it could lead to a loss of market share. Therefore, the impacts on consumers will be limited.

The setting of new or revised limit values would certainly benefit companies, including for diisocyanates, although these benefits could not be quantified. For example, this would lead to cost savings related to sick leave, labour productivity and other administrative and legal costs. However, these benefits are far more limited than the additional costs arising from setting limit values. Although monetised costs are higher than monetised benefits, there are a number of significant advantages for companies that could not be quantified, notably in terms of reputation and attractiveness as an employer. Limit values both for lead and diisocyanates can

[80] Companies operating with lead will only face costs of RMMs.

make the sectors more attractive, making it easier to recruit and to increase productivity. Moreover, employers' representatives seem willing to introduce limit values for diisocyanates and reduce the existing limit values for lead, as reflected in the ACSH opinion.

Impacts on company expenses in research and development, and the impacts passed on to consumers, are expected to be very limited.

Environmental impacts and impacts on climate change

This proposal has no identifiable significant impact on the environment. Reducing the limit values for lead is not expected to have an impact either on climate change, though greater use of lead batteries in, for example, electric vehicles will contribute reducing the use of fossil fuels. Similarly, greater use of insulating material based on diisocyanates will improve the thermal insulation of buildings, with a consequent reduction in the use of fossil fuels for heating. This will not be directly impacted by the introduction of limit values for diisocyanates. The proposal is therefore respectful of the 'do no significant harm' principle, as the actions proposed do no harm to the environment and simultaneously contribute to EU efforts against climate change.

Impact on Member States / national authorities

As regards the impact on Member States / national authorities, the proposal should not entail additional administrative burdens. Member States would need to bear the costs related to transposing the new limit values, which would be EUR 520 000 for lead and EUR 970 000 for diisocyanates. However, the benefits for public authorities outweigh the costs. These benefits are related to reduced healthcare costs, increased tax revenues and, in the case of diisocyanates, the avoided costs of having to set national limit values. A net benefit of EUR 99 480 000 is expected for lead and of EUR 780 000 for diisocyanates. No additional requirements such as new reporting activities for public authorities are anticipated. A two-stage compliance assessment (transposition and conformity checks) will be carried out by the Commission for the transposition of the limit values. At workplace level, there is an obligation for employers to ensure that the exposure does not go above the limit values set out in the annexes to the CAD and CMRD. The monitoring of application and enforcement will be undertaken by national authorities, in particular the national labour inspectorates. At EU level, the Committee of Senior Labour Inspectors (SLIC) keeps the Commission informed of problems relating to the enforcement of the two Directives.

Table 1: Comparison of cost and benefits for options for lead (over 40 years, in EUR million)

	Option 2 (20 µg/100ml)	Option 3 (15 µg/100ml) (Preferred option)	Option 4 (4.5 µg/100ml)
Costs for businesses	350	750	6 300
Benefits for businesses	4	5	6
Costs for public authorities	0.5	0.52	0.54

Benefits for public authorities	90	100	130
Health benefits for workers and families	130 - 200	160 - 250	200 - 310

Table 2: Comparison of cost and benefits for options for diisocyanates (over 40 years, in EUR million)

	Option 2 10 µg NCO/m^3	Option 3 6 µg NCO/m^3 (Preferred option)	Option 4 3 µg NCO/m^3
Costs for businesses	5 600	13 410	14 230
Benefits for businesses	0	0	0.4
Costs for public authorities	0.97	0.97	0.97
Benefits for public authorities	1.75	1.75	2.75
Health benefits for workers and families	N/A	N/A	0.8 - 2.2

Contribution to sustainable development

The initiative will help achieve the Sustainable Development Goals (SDGs) on good health and well-being (SDG 3) and decent work and economic growth (SDG 8). It is also expected to have a positive impact on the SDG on industry, innovation and infrastructure (SDG 9) and on responsible production and consumption (SDG 12).

Impact on digitalisation

None of the policy options for both lead and diisocyanates would have any impacts on digitalisation. The principle of 'digital by default' does not apply to this proposal, as the proposed directive only concerns an update / introduction of limit values and digital developments do not apply to the subject of the proposal.

- **Regulatory fitness and simplification**

Impact on SMEs

99% of the companies working with lead and diisocyanates are SMEs. Therefore, these have been the focus of this report's cost analysis.

This proposal does not contain any exceptions for micro-enterprises or SMEs, which account for around 99% of the companies working with lead and diisocyanates. Their exclusion would mean that the vast majority of European workers who could be exposed to these groups of substances would not be sufficiently protected by health and safety at work legislation, with a clear distortion and inequality in the application of the EU legislative framework and with a risk of compromising the underlying social policy objectives and fundamental rights.

Another option to assist SMEs is to extend the time by which the limit value needs to be implemented. This has been retained for diisocyanates. Although it does not constitute an exception to the measures applying only to SMEs, the transitional period will substantially benefit them, as they represent the majority of companies working with diisocyanates.

Revising the limit values for lead and introducing limit values for diisocyanates, as provided for in this proposal, should have no impact on SMEs located in Member States where the national limit values are either equal to or lower than the proposed values for lead or where national limit values have already been introduced for diisocyanates. However, there may be an economic impact on SMEs and other businesses in Member States that currently have in place higher BLVs and OELs for lead or no limit values for diisocyanates.

SMEs can be more strongly impacted by regulatory changes that introduce substantial adjustment or administrative costs. Their limited size often makes it more difficult to access capital, and most often at a higher cost of capital than large enterprises[81]. SMEs can therefore be exposed to proportionally higher costs than large enterprises.

For all of the above, the analysis presented in the impact assessment report accompanying this proposal has duly taken into account the specificities, limitations and particular challenges of SMEs. When considered appropriate, specific measures to support SMEs have been put forward.

Impact on EU competitiveness or international trade

This initiative will have a positive impact on competition in the single market by: (i) reducing competitive differences between firms operating in Member States with different national OELs and STELs for lead and diisocyanates or BLVs for lead; and (ii) providing greater certainty on an enforceable exposure limit across the EU.

Introducing lower limit values will have a smaller impact on the competitiveness of companies that are already closer to applying any OELs, STELs and BLVs that are being assessed. Such companies operate in Member States where the limit values are lower than the current EU values in the case of lead, and where they are most similar to the limit values proposed for diisocyanates. This is particularly relevant for companies working with diisocyanates in Sweden, which has lower national OELs for a few diisocyanates.

However, while this might make such companies more cost-competitive against companies traditionally working in other Member States, most of the work done with lead and diisocyanates is carried out in fixed installations (for example, lead battery manufacturing and recycling / primary manufacture of diisocyanates). Furthermore, the costs related to compliance with the preferred options should not have significant impacts on competition. However, companies working with lead could be less competitive than those producing lead-free alternative products (e.g., ceramic frit, alloys or crystal glass).

[81] Tool # 22 of the Better Regulation toolbox on SMEs.

On international competitiveness, only three non-EU countries currently have a BLV for lead; these range between the existing EU BLV and the proposed revised EU BLV. Therefore, the impact on competitiveness for companies working with lead should be moderate, although these costs could not be quantified. As for diisocyanates, the EU's main competitors have higher limit values, which could undermine the competitiveness of companies operating in markets characterised by high price sensitivity. However, the potential consequences are mitigated by several factors, including the limited incremental costs for companies and the non-international nature of some of the markets concerned.

4. BUDGETARY IMPLICATIONS

The proposal does not require additional budget and staff resources for the EU budget or bodies set up by the EU.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The core indicators used when monitoring the impacts of this Directive are: (i) the number of occupational diseases and work-related ill-health cases in the EU; and (ii) the reduction of costs related to occupational diseases for businesses and social-security systems in the EU.

Monitoring of the first indicator is based on: (i) available data collected by Eurostat; (ii) data notified by employers to the competent national authorities on occupational diseases; and (iii) data submitted by Member States in their national implementation reports in accordance with Article 17a of Directive 89/391/EEC. The monitoring of the second indicator requires the comparison of the estimated data on the burden of occupational disease in terms of economic loss and health care costs against the data subsequently collected on these matters after the revision is adopted.

The productivity loss and the healthcare costs can be calculated using the number of occupational disease cases.

Compliance with the amended provisions' transposition will be assessed in two stages (transposition and conformity checks). The Commission will evaluate the proposed amendment's practical implementation as part of the periodical evaluation it must carry out pursuant to Article 17a of the OSH Framework Directive. Application and enforcement will be monitored by national authorities, in particular by national labour inspectorates.

At EU level, the Senior Labour Inspectors' Committee (SLIC) informs the Commission of any practical problems relating to the enforcement of the CMRD and CAD, including difficulties regarding compliance with binding limit values.

Collecting reliable data in this area is complex. Therefore, the Commission and the European Agency for Safety and Health at Work (EU-OSHA) are actively working on improving data

quality and availability, so that the proposed initiative's actual impact can be measured more accurately, and additional indicators can be developed.

Ongoing projects generating useful data include cooperation with national authorities on the European Occupational Diseases Statistics data collection[82]. Legislative action needs to be followed by effective implementation in the workplace. Companies can use the broad range of tools, information and good practices provided by EU-OSHA as part of the Healthy Workplaces Campaign on dangerous substances[83].

The existing guidance documents or examples of good practice could be revised and re-disseminated in cooperation with the EU-OSHA and/or the ACSH and its relevant working party. This could also include launching awareness raising campaigns for employers and workers alike on the prevention of risks arising from workers' exposure to lead and diisocyanates. In addition, industry could be encouraged to revise guidance material used to support their voluntary initiatives.

EU-OSHA is currently developing guidance on the use of biomonitoring in the workplace. This will be general guidance and not specific to lead, though the general principles will be relevant and helpful. The guidelines could help Member States and employers, especially SMEs, to implement biomonitoring and health surveillance programmes that support the implementation of the provisions of this proposal, to achieve the highest level of protection.

- **Explanatory documents (for directives)**

Member States must send the Commission the text of national provisions transposing the CMRD and CAD and a correlation table between those provisions and the CMRD and CAD. Unambiguous information on the transposition of the new provisions is needed to ensure compliance with the minimum requirements laid down by this proposal.

Because of the above, it is suggested that Member States notify the Commission of their transposition measures by providing one or more documents explaining the relationship between the components of the CMRD and CAD and the corresponding parts of national transposition instruments.

- **Detailed explanation of the specific provisions of the proposal**

Article 1

Article 1 provides for the amendment of the CMRD, in particular its Annex III and Annex IIIa with regard to updating the OEL and BLV for lead.

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82 https://ec.europa.eu/eurostat/web/experimental-statistics/european-occupational-diseases-statistics

83 The campaign pursued several objectives, including raising awareness on the importance of preventing risks from dangerous substances, promoting risk assessment, heightening awareness of risks of exposure to carcinogens at work, and increasing knowledge of the legislative framework. The campaign ran in 2018-2019. One of its features is a database of guidance and good practices available at https://osha.europa.eu/en/themes/dangerous-substances/practical-tools-dangerous-substances.

It is proposed that Annex III be amended as regards lead, requiring employers to ensure that no worker is exposed to an OEL higher than 0.03 mg/m^3 as an 8-hour time-weighted average (TWA). It is also proposed that Annex IIIa be amended as regards the BLV for lead, ensuring that no worker is exposed to a BLV higher than 15 µg/100ml blood.

Article 2

Article 2 provides for the amendment of the CAD, in particular its Annex I, by setting an OEL for diisocyanates that should not exceed 6 µg/m³, accompanied with an associated STEL equal to 12 µg/m³ and a dermal and respiratory sensitisation notation as well as a skin notation. A transitional value of 10 µg/m³ with an associated STEL equal to 20 µg/m³ should apply until 31 December 2028 due to technical measurement feasibility and the time needed to implement risk management measures in particular in downstream sectors.

Ensuring legal certainty and clarity at the same time requires the removal of the specific OEL for lead in Annex I to the CAD and its specific BLV, by amending Annex II to the CAD. This is because both the OEL and BLV for lead will be established at a revised lower level in the more specific provision of the CMRD.

Articles 3 to 5

Articles 3 to 5 contain provisions on transposition into the Member States' national law. Article 3 lays down the date of entry into force of the proposed directive.

2023/0033 (COD)

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 153(2), point (b), in conjunction with paragraph 1, point (a), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The scope of Directive 2004/37/EC of the European Parliament and of the Council[1], was extended by Directive (EU) 2022/431 of the European Parliament and of the Council[2], to cover also reprotoxic substances, including lead and its inorganic compounds. As a result, both Council Directive 98/24/EC[3], Annexes I and II to which already cover that chemical agent and its compounds, and Directive 2004/37/EC establish the same occupational exposure limit value and biological limit value for lead and its inorganic compounds. Those limit values do not take into account the latest scientific and technical developments and findings enabling the strengthening of workers' protection against the risk arising from occupational exposure to that

[1] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

[2] Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (OJ L 88, 16.3.2022, p. 1).

[3] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p 11).

dangerous reprotoxicant, as also confirmed by the results of an evaluation carried out in accordance with Article 17a of Council Directive 89/391/EEC[4].

(2) Pursuant to its Article 1(3), Directive 98/24/EC is to apply to carcinogens, mutagens and reprotoxic substances at work without prejudice to more stringent or specific provisions set out in Directive 2004/37/EC. To ensure legal certainty and avoid ambiguities and possible confusion over the applicable limit values for lead and its inorganic compounds, those Directives should be amended. This will provide for a revised binding occupational exposure limit value and biological limit value in Directive 2004/37/EC only, more specifically its Annexes III and IIIa containing more specific provisions on reprotoxic substances such as lead and its inorganic compounds. Therefore, the specific provisions setting the occupational exposure limit value for lead and its inorganic compounds in Annex I to Directive 98/24/EC and a biological limit value for lead and its ionic compounds in Annex II to Directive 98/24/EC should be deleted.

(3) New and revised limit values should be set out in light of available information, including up-to-date scientific evidence and technical data, based on a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the place of work.

(4) In accordance with the recommendations of the Committee for Risk Assessment of the European Chemicals Agency, established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[5], and the Advisory Committee on Safety and Health at Work, limit values for the inhalation route of exposure are usually established in relation to a reference period of an 8-hour time-weighted average (long-term exposure limit values). For certain chemicals, limit values are also set with reference to a shorter reference period, in general a 15-minute time-weighted average (short-term exposure limit values) in order to limit, to the extent possible, the effects arising from short-term exposure.

(5) To ensure a more comprehensive level of protection, it is also necessary to consider absorption pathways other than inhalation for diisocyanates, including the possibility of uptake through the skin. Further notations for hazardous substances and mixtures are laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council[6].

(6) Lead and its inorganic compounds are key occupational reprotoxicants that can affect both fertility and the development of the foetus and meet the criteria for classification

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4 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.06.1989, p.1).

5 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1.)

6 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

as toxic for reproduction (category 1A) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council and are therefore a reprotoxic substances within the meaning of Article 2, point (ba), of Directive 2004/37/EC.

(7) Oral and inhalation exposure are both relevant routes for the uptake of lead and its inorganic compounds into the human body. Taking into account the most recent scientific data and new findings with regard to lead and its inorganic compounds, it is necessary to improve the protection of workers exposed to a potential health risk, by reducing both the occupational exposure and biological limit values for lead. Therefore, a revised biological limit value equal to 15 µg/100ml blood, accompanied by a revised occupational exposure limit value equal to 0.03 mg/m^3 as an 8-hour time-weighted average (TWA) should be established.

(8) Moreover, to strengthen the health surveillance of workers exposed to lead and its inorganic compounds and thus contribute to the prevention and protection measures to be undertaken by the employer, it is necessary to amend the existing requirements that apply when workers are exposed to certain levels of lead and its inorganic compounds. To that end, detailed medical surveillance should be required when exposure to lead and its inorganic compounds exceeds 0.015 mg/m^3 in air (50% of current OEL) or 9 µg/100ml blood (approx. 60% of the current BLV).

(9) Specific measures should be put in place with regard to risk management, including specific health surveillance that should take into consideration the circumstances of individual workers. Under the general requirements of Directive 2004/37/EC, employers are obliged to ensure the substitution of the substance when technically possible, the use of closed systems, or the reduction of exposure to as low as technically possible. In addition, as suggested in the opinion of the Advisory Committee on Safety and Health at Work[7], the blood level of lead and its inorganic compounds in women of childbearing age should not exceed the reference values of the general population not occupationally exposed to lead and its inorganic compounds in the respective Member State. The Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[8], advised the use of a biological guidance value (BGV) as there was insufficient scientific evidence to set a BLV for women of childbearing age. When national reference levels are not available, blood levels of lead and its inorganic compounds in women of childbearing age should not exceed the BGV of 4.5 µg/100ml, as recommended by the opinion of the RAC[9]. The BGV is an indicator of exposure but not of identifiable adverse health effects. Therefore, it acts as a sentinel marker to alert employers on the need to pay specific

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7 ACSH opinion on lead (2021). https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/60b206e1-ee10-40c2-9540-fb6510c11a0c/details

8 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1.)

9 On the evaluation of the occupational exposure limits for lead and its compounds, delivered on 11 June 2020. (See section 8.2.4. of the annex to the opinion). https://echa.europa.eu/documents/10162/ed7a37e4-1641-b147-aaac-fce4c3014037

attention to this specific potential risk and to introduce measures to ensure that any exposure to lead and its inorganic compounds does not result in adverse developmental health effects in the foetus or offspring of female workers.

(10) Diisocyanates are skin and respiratory sensitisers (asthmagens) that can have harmful respiratory health effects such as occupational asthma, isocyanate sensitisation and bronchial hyper-responsiveness, as well as dermal occupational disease. They are considered as hazardous chemical agents within the meaning of Article 2, point (b), of Directive 98/24/EC and thus fall within its scope. Currently there is no binding occupational exposure limit value or short-term exposure limit value for diisocyanates at Union level.

(11) It is not scientifically possible to identify levels below which exposure to diisocyanates would not lead to adverse health effects. Instead, an exposure-risk relationship can be established, facilitating the setting of an occupational exposure limit by taking into account an acceptable level of excess risk. As a consequence, limit values for diisocyanates should be established in order to reduce the risk by lowering exposure levels. It is therefore possible, based on the available information, including scientific and technical data, to set a long-term and short-term limit value for that group of chemical agents.

(12) Diisocyanates can be absorbed through the skin and exposure to diisocyanates at the place of work may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish an occupational exposure limit of 6 µg/m³ and a short-term exposure limit of 12 µg/m³ for this group of chemical agents and to assign a skin, dermal and respiratory sensitisation notation to it.

(13) It may be difficult to comply with an occupational exposure limit equal to 6 µg/m³ for diisocyanates, accompanied by an associated short-term exposure limit equal to 12 µg/m³. This difficulty is due to technical measurement feasibility issues and the time needed to implement risk management measures in particular in downstream sectors involving activities such as applications of paints, work with lead metal, demolition, repair and scrap management, other waste management and soil remediation. Therefore, a transitional value of 10 µg/m³ with an associated short-term exposure limit equal to 20 µg/m³ should apply until 31 December 2028.

(14) The Commission has consulted the Committee for Risk Assessment) which provided opinions on both substances. The Commission has carried out a two-stage consultation of management and labour at Union level in accordance with Article 154 of the Treaty. It has also consulted the Advisory Committee on Safety and Health, which adopted opinions regarding the revision of the limit values for lead and its inorganic compounds[10] and establishment of an occupational limit value for diisocyanates[11], with recommendations for appropriate notations.

(15) The limit values established in this Directive should be kept under regular scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006.

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10 See footnote 8.

11 ACSH opinion on diisocyanates (2021) https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/0d11d394-b1e8-4e1a-a962-5ad60f4ab2ae/details

(16) The objective of this Directive, namely to protect workers against risks to their health and safety arising from or likely to arise from exposure to chemical agents and reprotoxic substances at work, including the prevention of such risks, cannot be sufficiently achieved by the Member States acting alone. Rather, by reason of its scale and effects, it can be better achieved at Union level. Therefore, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary to achieve that objective.

(17) Since this Directive concerns the protection of the health and safety of workers at the place of work, it should be transposed within two years of the date of its entry into force.

(18) Directives 98/24/EC and 2004/37/EC should therefore be amended accordingly.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 98/24/EC is amended as follows:

(1) Annex I is amended in accordance with Annex I to this Directive;

(2) in Annex II, points 1, 1.1, 1.2 and 1.3 are deleted.

Article 2

Annexes III and IIIa to Directive 2004/37/EC are amended in accordance with Annex II to this Directive.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within two years of the date of entry into force of this Directive at the latest. They shall immediately inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Member States shall communicate to the Commission the text of the main measures of national law which they adopt in the field covered by this Directive.

Article 4

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*