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NOTE

From:	Permanent Representatives Committee (Part 1)
To:	Council
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Subject:	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 - General approach

I. INTRODUCTION

1. On 13 February 2023, the Commission submitted to the Council and the European Parliament a 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 diisocyanates¹.

¹ Doc. 6417/23.

2. The initiative aims to improve the protection of workers against dangerous chemicals by reducing the exposure limit values for lead and introducing new exposure limit values for diisocyanates. The initiative amends two acts: for lead, Directive (2004/37/EC) on the protection of workers from the risks related to exposure to carcinogens, mutagens and reprotoxic substances at work, and for lead and diisocyanates, the Directive (98/24/EC) on the protection of workers from the risks related to chemical agents at work.
3. The proposal is based on Article 153(2)(b) in conjunction with paragraph 1, point (a) of the Treaty on the Functioning of the European Union. The ordinary legislative procedure is applicable.
4. The European Economic and Social Committee delivered its opinion on 22 March 2023², endorsing the proposal. At its meeting on 20 April 2023, the Committee of the Regions decided not to issue an opinion on this proposal³.
5. In the European Parliament, the Committee on Employment and Social Affairs has the lead responsibility. Nikolaj Villumsen (Left) was appointed rapporteur. The Parliament has not yet decided on its position.

II. STATE OF PLAY

6. The Commission presented the proposal at the Social Questions Working Party meeting of 27 February 2023. The Working Party also discussed the proposal at its meetings on 9 March, 30 March, 21 April and 22 May 2023.

² Doc. 8667/23
³ Doc. 10062/23

7. Based on the input of delegations, the Presidency introduced a transitional period for the biological limit value (BLV) for lead until December 2028. In addition, the Presidency proposed amendments to the text which aim to address the particular situation of workers already exposed to lead ('historical exposure') and women of childbearing age without creating potential grounds for their discrimination at the workplace. In line with the requirement in the applicable legislation, the Presidency clarified in the text that lead is a "non-threshold" reprotoxic substance. Lastly, at the request of delegations, the Presidency introduced an obligation for the Commission to issue guidelines on health surveillance including biomonitoring.
8. On 31 May 2023, the Committee of permanent representatives unanimously supported the final compromise text as set out in document 9607/23 and agreed to forward it to the Council (EPSCO) with a view to reaching a General Approach.
9. The Committee was also informed about the outcome of the examination of the Commission impact assessment, as summarised in the Addendum to document 9607/23.

IV. CONCLUSION

The Council (EPSCO) is invited to reach a General Approach on the text as set out in the Annex to this note and to mandate the Presidency to enter into negotiations on the file with representatives of the European Parliament.

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 diisocyanates and lead and its inorganic compounds

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 Council⁴, was extended by Directive (EU) 2022/431 of the European Parliament and of the Council⁵, to cover also reprotoxic substances, including lead and its inorganic compounds. As a result, both Council Directive 98/24/EC⁶, 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 dangerous reprotoxicant, as also confirmed by the results of an evaluation carried out in accordance with Article 17a of Council Directive 89/391/EEC⁷.

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 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).

⁶ 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).

⁷ 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).

- (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. This applies inter alia to Article 10 (4) of Directive 98/24/EC with regard to Annex IIIa of 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 Council⁸, 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) moved to 10a new
- (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 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 reprotoxic substances within the meaning of Article 2, point (ba), of Directive 2004/37/EC.

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).

- (6a new) Pursuant to Directive 2004/37/EC, the European Parliament and the Council are to identify, on the basis of the available scientific and technical data, in the notations column of Annex III to that Directive whether a reprotoxic substance is a non-threshold reprotoxic substance or a threshold reprotoxic substance. While the biological limit value of 15 µg Pb/100ml blood recommended by RAC and set out in this Directive, protects the health of workers, it is not scientifically possible to identify a safe level of exposure for lead and its inorganic compounds for the development effects of the offspring. A notation as “non-threshold reprotoxic substance” should therefore be introduced for lead and its inorganic compounds.
- (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 Pb/100 ml blood, accompanied by a revised occupational exposure limit value equal to 0,03 mg/m³ as an 8-hour time-weighted average (TWA) should be established.
- (7a) It may be difficult to comply with the biological limit value of 15 µg Pb/100 ml blood. This difficulty is due to the time needed to implement risk management measures and costly adaptation of production processes, especially for companies operating in the sector of primary lead production. Therefore, a transitional value of 35 µg Pb/100 ml blood should apply until 31 December 2028.

- (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/m³ in air (50% of occupational exposure limit value) or 9 µg Pb/100 ml blood (approx. 60% of the biological limit value).
- (8a) Lead accumulates in the bones and is released slowly from there into the circulatory system. Blood lead levels may thus remain high long after exposure to lead has been reduced. Therefore regular medical surveillance should be carried out for workers whose blood levels exceed the biological limit value in force due to exposure which occurred before *[the date of transposition of this Directive]*. If a declining trend towards the limit value in force is established, these workers may be allowed to continue working with tasks that involve exposure to lead.
- (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.

- (9a) In addition, the opinion of the Advisory Committee on Safety and Health at Work⁹ suggested that the blood level of lead 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 Council¹⁰, advised the use of a biological guidance value as there was insufficient scientific evidence to set a biological limit value for women of childbearing age. In its opinion¹¹, RAC recommended that when national reference levels are not available, blood levels of lead in women of childbearing age should not exceed 4,5 µg Pb/100 ml blood because the biological limit value for lead does not protect the foetus or offspring of women of childbearing age.

⁹ ACSH opinion on lead (2021). <https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/60b206e1-ee10-40c2-9540-fb6510c11a0c/details>

¹⁰ 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.)

¹¹ 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>

- (9b) Therefore, medical surveillance should be carried out for women of childbearing age whose blood lead levels exceed 4,5 µg Pb/100 ml blood or the national reference value of the general population not occupationally exposed to lead, if such value exists. The value 4,5 µg Pb/100 ml blood 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 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. This provision complements the existing obligations regarding risks assessment, information and training, which are important tools to minimise risk.
- (9c) In order to assist Member States, the Commission should prepare Union guidelines on health surveillance including biological monitoring, which should also focus on the implementation of provisions regarding blood lead level, taking into account the slow removal of lead from the body. Those Union guidelines should also focus on the implementation of provisions regarding blood lead level for women of childbearing age to protect the foetus and offspring.
- (9d) It is essential that the protection of the safety and health of the foetus or offspring of female workers does not lead to the unfavourable treatment of women on the labour market nor work to the detriment of Union legislation concerning equal treatment for men and women.
- (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. Skin exposure may possibly also result in systemic immunological effects like sensitisation of the respiratory tract. Diisocyanates 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.

- (10a new) To ensure a more comprehensive level of protection, it is also necessary to consider absorption pathways other than inhalation for diisocyanates. This could include possible health effects following skin exposure, including systemic immunological effects. Further notations for hazardous substances and mixtures are laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council¹².
- (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 level of excess risk. As a consequence, limit values for all 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) It is therefore appropriate to establish an occupational exposure limit of 6 µg NCO/m³ and a short-term exposure limit of 12 µg NCO/m³ for all diisocyanates and to assign a skin, dermal and respiratory sensitisation notation to it, where NCO refers to isocyanate functional groups of the diisocyanate compounds. In line with Articles 6(3) and 10 of Directive 98/24/EC, health surveillance is important to identify early signs and symptoms of respiratory sensitisation.
- (13) It may be difficult to comply with an occupational exposure limit equal to 6 µg **NCO**/m³ for diisocyanates, accompanied by an associated short-term exposure limit equal to 12 µg NCO/m³. This difficulty is due to technical measurement feasibility issues and the time needed to implement risk management measures in particular in downstream sectors. Therefore, a transitional value of 10 µg NCO/m³ with an associated short-term exposure limit equal to 20 µg NCO/m³ should apply until 31 December 2028.

¹² 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).

- (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 at Work, which adopted opinions regarding the revision of the limit values for lead and its inorganic compounds¹³ and establishment of occupational limit values for diisocyanates¹⁴, with recommendations for appropriate notations and a review of the limit values for diisocyanates starting in 2029.
- (15) It is crucial to keep the limit values established in this Directive under regular scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006.
- (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.

¹³ See footnote 9.

¹⁴ ACSH opinion on diisocyanates (2021) <https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/0d11d394-b1e8-4e1a-a962-5ad60f4ab2ae/details>

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

Directive 2004/37/EC is amended as follows:

- (1) the following subparagraph is added in Article 18a:

‘No later than [*one year before the transposition deadline*] the Commission shall, after appropriate consultation of relevant stakeholders, prepare Union guidelines for health surveillance including biological monitoring. Those guidelines shall include advice on the implementation of provisions regarding blood lead level, taking into account the slow removal of lead from the body and the special protection of women of childbearing age.’

- (2) Annexes III and IIIa 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

ANNEX I

Annex I to Directive 98/24/EC is replaced by the following:

‘ANNEX I

LIST OF BINDING OCCUPATIONAL EXPOSURE LIMIT VALUES

Name of agent	EC No (¹)	CAS No (²)	Limit values						Notation	Transitional measures
			8 hours (³)			Short-term (⁴)				
			µg/m ³ (⁵)	Ppm (⁶)	f/ml (⁷)	µg/m ³ (⁵)	ppm (⁶)	f/ml (⁷)		
Diisocyanates (measured as NCO ¹⁰)			6			12			Skin (⁸) Dermal and respiratory sensitisation (⁹)	The limit value of 10 µg NCO/m ³ in relation to a reference period of eight hours and a short-term exposure limit value of 20 µg NCO/m ³ shall apply until 31 December 2028.

(¹) EC No, i.e., EINECS, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, to Regulation (EC) No 1272/2008.

(²) CAS No: Chemical Abstract Service Registry Number.

(³) Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).

(⁴) Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.

(⁵) µg/m³ = micrograms per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).

(⁶) ppm = parts per million by volume in air (ml/m³).

(⁷) f/ml = fibres per millilitre.

(⁸) Substantial contribution to the total body burden via dermal exposure possible.

(⁹) The substance can cause sensitisation of the skin and of the respiratory tract.

(¹⁰) NCO refers to isocyanate functional groups of the diisocyanate compounds.’

ANNEX II

Annexes III and IIIa to Directive 2004/37/EC are amended as follows:

(1) in Annex III, point A,

the row related to inorganic lead and its compounds is replaced by the following:

Name of agent	EC No (¹)	CAS No (²)	Limit values						Notation	Transitional measures
			8 hours (³)			Short-term (⁴)				
			mg/m ³ (⁵)	Pp m (⁶)	f/ml (⁷)	mg/m ³ (⁵)	Ppm (⁶)	f/ml (⁷)		
Lead and its inorganic compounds			0.03 ⁽⁸⁾						Non-threshold reprotoxic substance	

(¹) EC No, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, to Regulation (EC) No 1272/2008.

(²) CAS No: Chemical Abstract Service Registry Number.

(³) Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).

(⁴) Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.

(⁵) mg/m³ = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).

(⁶) ppm = parts per million by volume in air (ml/m³).

(⁷) f/ml = fibres per millilitre.

(⁸) inhalable fraction.'

(2) Annex IIIa is replaced by the following:

‘ANNEX IIIa

BIOLOGICAL LIMIT VALUES AND HEALTH SURVEILLANCE MEASURES

(Article 16(4))

1. Lead and its inorganic compounds

1.1. Biological monitoring must include measuring the blood-lead level (PbB) using absorption spectrometry or a method giving equivalent results.

Until 31 December 2028, the binding biological limit value is:

35 µg Pb/100 ml blood

For workers whose blood lead level exceeds the biological limit value of 35 µg Pb/100 ml blood due to exposure which has occurred before *[the date of transposition of this Directive]*, but is below 70 µg Pb/100 ml blood, medical surveillance is carried out on a regular basis. If a declining trend towards the limit value of 35 µg Pb/100 ml blood is established in those workers, those workers may be allowed to continue with work involving exposure to lead.

As of 1 January 2029, the binding biological limit value is:

15 µg Pb/100 ml blood

For workers whose blood lead level exceeds the biological limit value of 15 µg Pb/100 ml blood due to exposure which has occurred before *[the date of transposition of this Directive]*, but is below 35 µg Pb/100 ml blood, medical surveillance is carried out on a regular basis. If a declining trend towards the limit value of 15 µg Pb/100 ml blood is established in those workers, those workers may be allowed to continue with work involving exposure to lead.

1.2. Medical surveillance is carried out if exposure to a concentration of lead in air is greater than 0,015 mg/m³, calculated as a time-weighted average over 40 hours per week, or a blood-lead level greater than 9 µg Pb/100 ml blood is measured in individual workers. Medical surveillance is also carried out for women of childbearing age whose blood lead levels exceed 4,5 µg Pb/100 ml blood or the national reference value of the general population not occupationally exposed to lead, if such value exists.’