Council of the European Union

Brussels, 22 March 2023
(OR. en)

7496/23

Interinstitutional File: 2023/0033(COD)

LIMITE

SOC 186
EMPL 132
SAN 140
IA 44
CODEC 390

NOTE

From:	General Secretariat of the Council
To:	Delegations
No. Cion doc.:	6417/23 - COM(2023) 71 final
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

With a view to the Social Questions Working Party meeting on 30 March, delegations will find attached a Presidency compromise text on the above proposal.

Changes in relation to the Commission proposal are marked in **bold** or **[…]**.

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 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.

---

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**,** 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).

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).

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).

(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 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.

---

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).

(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/100 ml 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/100 ml blood (approx. 60% of the current **biological limit value**).

(8a) Lead accumulates in the bones and is released slowly from there into the circulatory system. Therefore, workers whose blood levels exceed the biological limit value of 15 µg/100 ml due to exposure which occurred before the entry into force of this Directive should be subject to regular medical surveillance and biological monitoring to confirm that there is a consistently declining trend towards that limit value. In order to assist Member States with the application of this provision, the Commission should prepare Union guidelines on health surveillance and 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.

(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 as there was insufficient scientific evidence to set a **biological limit value** for women of childbearing age. **In its opinion[9], RAC recommended that** when national reference levels are not available, blood levels of lead and its inorganic compounds in women of childbearing age should not exceed 4~~.~~**,**5 µg/100 ml. Th**is value** 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. **The Commission should prepare Union guidelines on health surveillance and biological monitoring, which should also focus on the implementation of provisions regarding blood lead level for women of childbearing age**. **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.**

---

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

(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 **[…]** 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 **NCO**/m³ and a short-term exposure limit of 12 µg **NCO**/m³ for this group of chemical agents and to assign a skin, dermal and respiratory sensitisation notation to it**, where NCO group refers to nitrogen, carbon, and oxygen group 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.

(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 compounds[10] and establishment of **[…]** occupational limit value**s** for diisocyanates[11], with recommendations for appropriate notations **and a review of the limit values for diisocyanates starting in 2029**.

(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.

(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.

---

10 See footnote **9**.

11 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 and 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/m³ ([5])	Ppm ([6])	f/ml ([7])	µg/m³	ppm		
Diisocyanates **(measured as NCO[10])**			6			12		Skin ([8]) Dermal and respiratory sensitisation ([9])	The limit value of 10 µg **NCO**/m³ in relation to a reference period of eight hours and a short-term exposure limit value of 20 µg **NCO**/m³ 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/m^3 = 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 group refers to nitrogen, carbon, and oxygen group of the diisocyanate compound.'

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])	Ppm ([6])	f/ml ([7])	mg/m^3	ppm	f/ml		
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/m^3 = 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/m^3).

([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))

Lead and its **inorganic** compounds

Biological monitoring must include measuring the blood-lead level (PbB) using absorption spectrometry or a method giving equivalent results. The binding biological limit value is:

15 µg Pb/100 ml blood ([1])

For those workers whose blood lead level exceeds the biological limit value of 15 µg/100 ml due to exposure which has occurred before the entry into force of this Directive, medical surveillance and biological monitoring of blood lead level must be carried out on a regular basis to confirm that there is a consistently declining trend towards the limit value.

Medical surveillance is carried out if 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 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/100 ml or the national reference value of the general population not occupationally exposed to lead, if such value exists.'**

[…]