European Parliament
2019-2024

Committee on Employment and Social Affairs

2023/0033(COD)

8.5.2023

***I
DRAFT REPORT

on the proposal for a directive of the European Parliament and of the Council amending Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates
(COM(2023)0071 – C9-0022/2023 – 2023/0033(COD))

Committee on Employment and Social Affairs

Rapporteur: Nikolaj Villumsen

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

CONTENTS

Page

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a directive of the European Parliament and of the Council amending Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates
(COM(2023)0071 – C9-0022/2023 – 2023/0033(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2023)0071),

– having regard to Article 294(2) and Article 153(2), point (b), in conjunction with paragraph 1, point (a) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0022/2023),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the Economic and Social Committee of 22 March 2023[1] and the opinion of the Committee of the Regions of xx.xx. 2023[2],

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the report of the Committee on Employment and Social Affairs (A9-0000/2023),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[1] OJ C xxx, xx.xx.xxxx, p. x. / Not yet published in the Official Journal.
[2] OJ C xxx, xx.xx.xxxx, p. x. / Not yet published in the Official Journal.

Amendment 1

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(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.	(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. ***Studies show that lead accounts for around half of all occupational exposure to reprotoxic substances.***

Or. en

Amendment 2

Proposal for a directive
Recital 7

Text proposed by the Commission	*Amendment*
(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.***	(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.

Or. en

Amendment 3

Proposal for a directive
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) The Committee for Risk Assessment of the European Chemicals Agency has recommended an occupational exposure limit (OEL) of 4 µg Pb/m3 as an 8-hour time-weighted average (TWA)[1a]. The Committee also recommended a binding biological limit value (BLV) of 15 µg Pb/100ml (150 µg Pb/L), but concluded that such a BLV for lead does not protect the future children of female workers of childbearing age exposed. The Committee recommended that the blood-lead level in female workers of childbearing age should not exceed the reference values for the general population not occupationally exposed to lead in the relevant Member State. Where national reference levels are not available, blood-lead levels in women of childbearing age should not exceed the biological guidance value (BGV) of 4.5 µg/ml (45 µg/L), the maximal European reference value. The BGV relates to background exposure of the general population not occupationally exposed to lead.
	1a https://echa.europa.eu/documents/10162/ed7a37e4-1641-b147-aaac-fce4c3014037

Or. en

Amendment 4

Proposal for a directive
Recital 7 b (new)

Text proposed by the Commission	*Amendment*
	(7b) In its initiative report on a new Union strategic framework on health and safety at work post 2020 (including better protection of workers from exposure to harmful substances, stress at work and repetitive motion injuries) of 9 February 2022, the European Parliament noted that a BLV of 15 µg Pb/100ml (150 µg Pb/L) "does not protect women and especially pregnant women properly" and called for revised exposure limit values for lead and its compounds while ensuring equal protection for all workers regardless of gender.

Or. en

Justification

source: https://www.europarl.europa.eu/doceo/document/TA-9-2022-0068_EN.pdf

Amendment 5

Proposal for a directive
Recital 7 c (new)

Text proposed by the Commission	*Amendment*
	(7c) This Directive respects the fundamental rights recognised in the Charter of Fundamental Rights of the European Union, in particular the prohibition of discrimination on the ground of sex and the right to fair and just working conditions provided for, respectively, in Articles 21 and 31 thereof. Moreover, it complies with Principle No 10 of the European Pillar of Social Rights, according to which workers have the right to a healthy, safe and well-adapted work environment. The right of workers to the protection of health and safety at work includes the right to protection from the effects of lead and its inorganic compounds on future

generations, such as the negative impacts on the reproductive capacity of men and women, as well as on foetal development. Therefore, a revised BLV equal to 4.5 µg/100ml blood, accompanied by a revised OEL equal to 4 µg Pb/m3 TWA should be established, to ensure the protection of workers who are occupationally exposed to lead, irrespective of their sex. Such a revised BLV is also intended to foster the full participation of women of child-bearing age in economic sectors targeted by the European Green Deal, such as the production of sustainable and circular batteries, in support of the Union's energy transition.

Or. en

Justification

A non-binding guidance value is not suitable to ensure the protection of workers' health and safety in conditions of equality and non-discrimination, with regard in particular to female lead-exposed workers. In order to attain the Directive's stated objective of a high level of protection of worker's health and safety, a binding BLV which offers sufficient protection for all workers irrespective of their sex, is necessary. It must be stressed that this Directive will apply to many economic sectors that possess a great potential for creating green jobs, but at the same time are currently male-dominated: applying the same protective measures to female and male lead-exposed workers will ensure that female workers enjoy equal treatment in matters of employment and occupation, and do not suffer from covert discrimination, for example with regard to access to employment.

Amendment 6

Proposal for a directive
Recital 8

Text proposed by the Commission	*Amendment*
(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	(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).	end, detailed medical surveillance should be required when exposure to lead and its inorganic compounds exceeds ***2 µg/m***^{3} in air (50% of current OEL) or ***2.7*** µg/100ml blood (approx. 60% of the current BLV).
	Or. en

Amendment 7

Proposal for a directive
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) Workers who have been occupationally exposed to lead over several years may have accumulated blood-lead levels well above the revised BLV. In the opinion of Committee for Risk Assessment, adverse health effects can already be observed at blood-lead levels that fall within the current BLV of 70 µg Pb/100ml. It is not acceptable that such workers continue to be exposed to lead in the workplace. Instead, employers should move such workers to other tasksin the workplace to ensure the fastest possible decrease in such workers' blood-lead levels.
	Or. en

Amendment 8

Proposal for a directive
Recital 9

Text proposed by the Commission	*Amendment*
(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	(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***. Since lead is a non-threshold reprotoxic substance, preventive medical surveillance should be one of the most important protection measures for lead-***

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[90], 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[91], 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[92]. 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 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.***

exposed workers, in addition to technical preventive measures to be taken by the employer. 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.

---

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

[91] 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.)

[92] 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

Or. en

Amendment 9

Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(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.	(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.

Or. en

Amendment 10

Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(13) It may be difficult to comply with an occupational exposure limit equal to 6	(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/m***³. 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/m***³ with an associated short-term exposure limit equal to 20 ***µg/m***³ should apply until 31 December 2028.	***µg NCO/m***³ for diisocyanates, accompanied by an associated short-term exposure limit equal to 12 ***µg NCO/m***³. 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 NCO/m***³ with an associated short-term exposure limit equal to 20 ***µg NCO/m***³ should apply until 31 December 2028.

Or. en

Amendment 11

Proposal for a directive
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) Following the adoption of the Commission Delegated Regulation (EU) 2023/707[1a] and the introduction of a new hazard class for endocrine disruptors, such substances should be covered by Union health and safety law. It is therefore necessary to consider extending the scope of Directive 2004/37/EC to endocrine disruptors, which have the ability to interfere with the hormonal system and can therefore induce adverse health effects.
	[1a] Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7)

Or. en

Justification

In its INI report on a new EU strategic framework on health and safety at work post 2020 (including better protection of workers from exposure to harmful substances, stress at work and repetitive motion injuries) of 9 February 2022, the European Parliament stresses that workers should be protected against exposure to endocrine disruptors by EU legislation. Source: https://www.europarl.europa.eu/doceo/document/TA-9-2022-0068_EN.pdf

Amendment 12

Proposal for a directive
Recital 15 b (new)

Text proposed by the Commission	*Amendment*
	(15b) To ensure a comprehensive level of protection, it is necessary to consider the effects of combined exposure to multiple substances. In the workplace, workers are often exposed to a cocktail of hazardous substances, which can increase risks and cause adverse health effects. In the case of exposure to a combination of substances acting by the same mode of action or at the same target cell or tissue, it is necessary to adapt the implementation of their possible limit values to take into account the combined effects.

Or. en

Justification

This amendment was put forward in the European Parliament report on the proposal for a directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work of 7 April 2021 (CMD4). Source: https://www.europarl.europa.eu/doceo/document/A-9-2021-0114_EN.pdf

Amendment 13

Proposal for a directive
Recital 15 c (new)

Text proposed by the Commission	*Amendment*
	(15c) The World Health Organization classified the occupational exposure of firefighter as carcinogenic to humans (Group 1). Occupational exposure as a firefighter includes a variety of hazards resulting from fires and non-fire events. Firefighters can be exposed to combustion products from fires, building materials, chemicals in firefighting foams, flame retardants and diesel exhaust. The uptake of fire effluents or other chemicals can occur via inhalation and dermal absorption and possibly via ingestion. Such workers should therefore be better protected from such exposure.

Or. en

Justification

source: https://monographs.iarc.who.int/list-of-classifications

Amendment 14

Proposal for a directive
Recital 15 d (new)

Text proposed by the Commission	*Amendment*
	(15d) Union action, such as the European Green Deal launched in the Commission communication of 11 December 2019 and the Critical Raw Material initiative launched in the Commission communication 16 March 2023, entitled 'A secure and sustainable supply of critical raw materials in support of the twin transition', promote sustainable development, which requires a balance between environmental, economic, and social considerations. By enacting binding occupational exposure limits of carcinogens, mutagens and reprotoxic substances, workers are better protected from harm and can continue to

work as safely as possible in industries that produce critical raw materials or contribute to the green economy. This, in turn, promotes a just green and digital transition by ensuring that workers' health are not compromised at the expense of the Union's economic and environmental goals. Protecting workers from exposure to hazardous substances also contributes to the objectives of Europe's Beating Cancer Plan, set out in the Commission communication of 3 February 2021.

Or. en

Amendment 15

Proposal for a directive
Recital 15 e (new)

Text proposed by the Commission	*Amendment*
	(15e) Due to unpredictable exposure to certain substances, a mix of substances or constraints in the organisation of work, some occupations should be considered to be carcinogenic per se. It is difficult in some occupations to predict and prepare for the extent to which workers will be exposed to substances or mixes of substances. It is to be expected that the World Health Organization's list of carcinogenic hazards will be expanded in accordance with the increasing amount of data and the progress of medical and scientific research, which highlight the carcinogenic nature of some occupations. Therefore, a non-exhaustive Union list of occupations that are considered to be carcinogenic would help employers identify recognised professions at risk and would facilitate the implementation of adequate protective measures and training pursuant to Directives 98/24/EC and 2004/37/EC. While the protective measures under Directives 98/24/EC and 2004/37/EC should not be exclusive to occupations on that list, it would provide

employers with guidance.

Or. en

Amendment 16

Proposal for a directive
Recital 15 f (new)

Text proposed by the Commission	*Amendment*
	(15f) The circular economy and the waste collecting, sorting and recovery sectors are growing fast to meet the objectives of the European Green Deal, to ensure the sustainability of European industry and to ensure greater strategic autonomy to the Union. However, those positive developments raise many occupational health and safety issues for workers in that industry, who, by the very nature of their activity, are likely to be disproportionately exposed to harmful substances. Exposure to lead, mercury and other hazardous metals in waste recycling facilities is for example already a reality for many such workers. Ambitious protective measures, adequate prevention policies, as well as good quality working conditions are necessary to reduce the risks of exposure to hazardous substances and to ensure a high level of protection.

Or. en

Amendment 17

Proposal for a directive
Recital 15 g (new)

Text proposed by the Commission	*Amendment*
	(15g) The informal sector is proportionally over-represented in the waste collecting, sorting and recovery sectors. A high exposure to risks, including harmful substances, combined with a low level of social protection place

most informal economy workers in a very vulnerable situation. Preventive measures, in the form of occupational health and safety management systems and a general safety culture, to reduce risks at work often do not reach the informal economy. Special attention should be paid to those precarious workers in order to offer safe working conditions and environments as well as equal treatment with workers in the same sector or in sectors that are better regulated.

Or. en

Amendment 18

Proposal for a directive
Article 2 – paragraph 1 – introductory wording (new)

Text proposed by the Commission	*Amendment*
	Directive 2004/37/EC is amended as follows:

Or. en

Amendment 19

Proposal for a directive
Article 2 – paragraph -1 – point 1 (new)
Directive 2004/37/EC
Article 2 –point b

Present text	*Amendment*
	(1) in Article 2(1), point (b) is replaced by the following:
(b) 'mutagen' means: a substance or mixture which meets the criteria for classification as a category 1A or 1B germ cell mutagen set out in Annex I to Regulation (EC) No 1272/2008;	"(b) 'mutagen' means:
	(i) a substance or mixture which meets the criteria for classification as a category 1A or 1B germ cell mutagen set out in Annex I to Regulation (EC) No 1272/2008;

(ii) a substance, mixture or process referred to in Annex I to this Directive as well as a substance or mixture released by a process referred to in that Annex;"

Or. en

Justification

Annex I concerns all hazardous substances covered in this directive, including 'mutagens'.

Amendment 20

Proposal for a directive
Article 2 – paragraph -1 – point 2 (new)
Directive 2004/37/EC
Article 2 –point ba

Present text	*Amendment*
	(2) in Article 2(1), point (ba) is replaced by the following:
(ba) 'reprotoxic substance' means a substance or mixture, which meets the criteria for classification as a category 1A or 1B reproductive toxicant set out in Annex I to Regulation (EC) No 1272/2008;	"(ba) 'reprotoxic substance' means:
	(i) a substance or mixture, which meets the criteria for classification as a category 1A or 1B reproductive toxicant set out in Annex I to Regulation (EC) No 1272/2008;
	(ii) a substance, mixture or process referred to in Annex I to this Directive as well as a substance or mixture released by a process referred to in that Annex;"

Or. en

Justification

Annex I concerns all hazardous substances covered in this directive, including 'reprotoxic substances'

Amendment 21

Proposal for a directive
Article 2 – paragraph -1 – point 3 (new)
Directive 2004/37/EC
Article 2 — point e a (new)

Text proposed by the Commission	*Amendment*
	(3) in Article 2(1), the following point is added:
	"(ea) 'hazardous medicinal products' or HMP' means medicinal products that contain one or more substances that meet the criteria for classification as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B) or toxic for reproduction (category 1A or 1B) in accordance with Regulation (EC) No 1272/2008."

Or. en

Justification

This definition is used the European Commission "Guidance for the safe management of hazardous medicinal products at work. Source: https://ec.europa.eu/social/main.jsp?langId=en&catId=89&furtherNews=yes&newsId=10564&pk_source=newsletter&pk_medium=email&pk_campaign=eu_social_newsletter

Amendment 22

Proposal for a directive
Article 2 – paragraph -1 – point 4 (new)
Directive 2004/37/EC
Article 5 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	(4) in Article 5, the following paragraph 4a is inserted:
	"4a. In the case of exposure to a combination of substances acting by the same mode of action or at the same target cell or tissue, the implementation of the possible limit values of those substances shall be adapted to take into account the

combined effects in accordance with Union guidelines to be developed pursuant to Article 18a."

Or. en

Justification

This amendment was put forward in the European Parliament report on the proposal for a directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work of 7 April 2021 (CMD4). Source: https://www.europarl.europa.eu/doceo/document/A-9-2021-0114_EN.pdf

Amendment 23

Proposal for a directive
Article 2 – paragraph - 1 – point 5 (new)
Directive 2004/37/EC
Article 5 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	(5) in Article 5, the following paragraph is added:
	"5a. Biological levels shall not exceed the biological limit value for a carcinogen, mutagen or a reprotoxic substance set out in Annex IIIa."

Or. en

Amendment 24

Proposal for a directive
Article 2 – paragraph -1 – point 6 (new)
Directive 2004/37/EC
Article 18a – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	(6) in Article 18a, the following paragraph is added:
	"By ... [one year after the date of entry into force of this amending Directive], the Commission shall, taking into account the latest developments in scientific

knowledge and the opinion of the Committee for Risk Assessment of the European Chemicals Agency established by Regulation (EC) No 1907/2006, and after appropriate consultation of relevant stakeholders, prepare Union guidelines on how the implementation of the limit values referred to in Article 5(4) and 5(4b) are to be adapted in the case of exposure to a combination of substances. Those guidelines shall be published on the EU-OSHA website and shall be disseminated in all Member States by the relevant competent authorities."

Or. en

Justification

This amendment was put forward in the European Parliament report on the proposal for a directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work of 7 April 2021 (CMD4). Source: https://www.europarl.europa.eu/doceo/document/A-9-2021-0114_EN.pdf

Amendment 25

Proposal for a directive
Article 2 – paragraph -1 – point 7 (new)
Directive 2004/37/EC
Article 18a – paragraph 7 b (new)

Text proposed by the Commission	*Amendment*
	(7) in Article 18a, the following paragraph is added:
	"By ... [x months after the date of entry into force of this amending directive], the Commission shall review the implementation of this Directive. In the context of that review, its shall consider whether further amendments to this Directive are appropriate, shall assess the feasibility of including endocrine disrupters within the scope of this Directive and, where appropriate, shall present a legislative proposal."

Or. en

Amendment 26

Proposal for a directive
Article 2 – paragraph -1 – point 8 (new)
Directive 2004/37/EC
Article 18a – paragraph 7 c (new)

Text proposed by the Commission	*Amendment*
	(8) in Article 18a, the following paragraph is added:
	"By ... [twelve months after the date of entry into force of this amending Directive], the Commission shall, after consulting the ACSH, develop a definition of 'carcinogenic occupations'. A non-exhaustive list of such occupations shall be annexed to this Directive."

Or. en

Amendment 27

Proposal for a directive
Article 2 – paragraph -1 – point 9 (new)
Directive 2004/37/EC
Article 18a – paragraph 7 d (new)

Text proposed by the Commission	*Amendment*
	(9) in Article 18a, the following paragraph is added:
	"By ... [twelve months after the date of entry into force of this amending Directive], the Commission shall, after consulting the ACSH, develop guidelines as regards historical occupational exposure to lead, in particular the protection and reduction of exposure for workers whose blood-level levels are above the biological limit value. Those guidelines shall be published on the EU-OSHA website and shall be disseminated in all Member States by the relevant competent authorities."

Or. en

Amendment 28

Proposal for a directive
Article 2 – paragraph 1

Text proposed by the Commission	*Amendment*
Annexes III and IIIa to Directive 2004/37/EC are amended in accordance with Annex II to this Directive.	Annexes ***I,*** III and IIIa to Directive 2004/37/EC are amended in accordance with Annex II to this Directive.

Or. en

Amendment 29

Proposal for a directive
Annex I
Directive 98/24/EC
Annex I

Text proposed by the Commission

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			6			12		Skin (8) Dermal and respiratory sensitisation (9)	The limit value of 10 µg/m³ in relation to a reference period of eight hours and a short-term exposure limit value of 20 µg/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/m3 = micrograms per cubic metre of air.

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

(7) f/ml = fibres per millilitre.

(8) The substance can cause sensitisation of the skin.

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

Amendment

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 ***NCO***/m3 (5)	Ppm (6)	f/ml (7)	µg ***NCO***/ m3	ppm		
Diisocyanates			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]) ***Measured as*** µg ***NCO*** /m^3 = micrograms of ***NCO/isocyanate group from diisocyanate*** per cubic metre of air.

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

([7]) f/ml = fibres per millilitre.

([8]) The substance can cause sensitisation of the skin.

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

Or. en

Amendment 30

Proposal for a directive
Annex II – introductory wording

Text proposed by the Commission	*Amendment*
Annexes III and IIIa to Directive 2004/37/EC are amended as follows:	Annexes ***I,*** III and IIIa to Directive 2004/37/EC are amended as follows:

Or. en

Justification

Annex I concerns all hazardous substances covered in this directive, including 'mutagens' and 'reprotoxic substances'

Amendment 31

Proposal for a directive
Annex II – point -1 (new)
Directive 2004/37/EC
Annex I – title

Present text	*Amendment*
	(-1) in Annex I, the title is amended as follows:
List of substances, preparations and	List of substances, preparations and

processes	processes
(Article 2(a)(iii))	***(Article 2(a)(ii), 2(b)(ii), 2(ba)(ii))"***

Or. en

Justification

Annex I concerns all hazardous substances covered in this directive, including 'mutagens' and 'reprotoxic substances'

Amendment 32

Proposal for a directive
Annex II – point -1 a (new)
Directive 2004/37/EC
Annex I – point 8 a (new)

Present text	*Amendment*
	(-1a) in Annex I, the following point is added:
	"8 a. Work involving exposure to hazardous medicinal products."

Or. en

Amendment 33

Proposal for a directive
Annex II – point 1 Directive 2004/37/EC
Annex III – point A – row 31

Text proposed by the Commission

(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		
Inorganic lead and its compounds			***0.03***							

([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.';

Amendment

(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		
Inorganic lead and its compounds			***0.004***							

([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.';

Or. en

Amendment 34

Proposal for a directive
Annex II – point 2
Directive 2004/37/EC
Annex IIIa

Text proposed by the Commission	*Amendment*
(2) Annex IIIa is replaced by the following:	(2) Annex IIIa is replaced by the following:
Lead and its ionic compounds	Lead and its ionic 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:	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)	***4.5 µg*** Pb/100 ml blood ***(1)***
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	Medical surveillance is carried out if exposure to a concentration of lead in air is greater than ***0,002*** mg/m^3, calculated as a time-weighted average over 40 hours per week, or a blood-lead level greater than ***2.7 µg Pb/100 ml*** blood is measured in

individual workers.	individual workers.
	If the results of the medical surveillance reveal a blood-lead level of a worker greater than the biological limit value due to historical occupational exposure to lead, the employer and the authority responsible for the health surveillance of that worker shall take the necessary measures to ensure a decrease of the worker's blood-lead level in accordance with the guidelines developed pusuant to Article 18a.
(1) It is recommended that the blood lead level in women of childbearing age does 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 in women of childbearing age do not exceed the Biological Guidance Value of 4.5 µg/100ml.'	

Or. en

EXPLANATORY STATEMENT

The protection of workers' health and safety is enshrined in the Treaties and the Charter of Fundamental Rights and is a key element of an EU economy that works for people. The right to a high level of protection of health and safety at work is reflected in principle 10 of the European Pillar of Social Rights, and is fundamental for reaching the United Nations' sustainable development goals.

No one should suffer from job related deaths, diseases or accidents. The EU occupational safety and health (OSH) legislation is therefore a major regulatory area that concerns almost 170 million workers in the EU. Policy initiatives such as the European Green Deal or the Critical Raw Material Initiative promote sustainable development, which requires a balance between environmental, economic, and social considerations. By enacting binding occupational exposure limits against carcinogens, mutagens and reprotoxic substances, workers are better protected from harm and can continue to work as safely as possible in industries that produce critical raw materials or contribute to the green economy. This, in turn, promotes a just transition by ensuring that workers' health are not compromised at the expense of the Union's economic and environmental goals. Protecting workers from exposure to hazardous substances also contributes to the objectives of Europe's Beating Cancer plan.

In the new 2021-2027 OSH framework, the Union commits to new protective limit values on diisocyanates and lead, which have been identified in the 2020 chemicals strategy as some of the most harmful chemical substances to act upon.

Diisocyanates
Diisocyanates are used to produce polyurethane, a key material for a range of applications such as insulation in buildings and appliances, which contributes to the European Green Deal targets by reducing CO2 emissions through energy efficiency. However, Diisocyanates are hazardous chemical agents that can cause occupational asthma and dermal occupational disease – allergic reactions that can occur due to exposure to such substances. According to estimates, approximately 4.2 million workers are exposed to diisocyanates, which makes Diisocyanates one of the most common causes of occupational asthma, and more than 2.4 million companies in the EU are concerned.

Tripartite consensus on limit values.
The limit values (occupational exposure limit / short term exposure limit) for diisocyanates, which are now proposed for the first time at EU level, are supported by the Advisory Committee on Safety and Health at Work (ACSH), consisting of national governments and workers' and employers' organisations. This report therefore proposes to adopt these limit values unamended in the spirit of supporting and advancing solutions that have been agreed between the social partners, jointly with the national administrations.

Lead
Lead currently has a large variety of industrial applications. Lead is an occupational reprotoxic substance that accumulates in the body due to exposure and 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. Currently, it is estimated that approximately 50 000 to 150 000 workers in the EU are exposed to lead. The current EU binding occupational exposure limit (OEL) and biological limit value (BLV) have not been updated for over 40 years.

In the absence of a consensus in the ACSH on the limit values for lead, this report considers it necessary to amend the Commission proposal on a number of points, especially the BLV as regards women of childbearing age.

Women of childbearing age and non-discrimination
Following an opinion of The Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), the Commission has proposed to lower the BLV to 15µg Pb/100ml. However, RAC also concluded that "the BLV is not protective for the offspring of female lead-exposed workers at childbearing age". RAC recommended that 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 EU country - and where national reference levels are not available, blood-lead levels in women of childbearing age should not exceed 4.5µg Pb/100ml, which is the maximal European reference value.

On that background the Commission has proposed to accompany the binding BLV with a non-binding Biological Guidance Value of 4.5µg Pb/100ml for women of childbearing age. While Directive 92/85/EEC provides for the protection of the health and safety of pregnant workers in the work place, its protective measures do not apply until such workers inform their employer of their condition.

In the Vind INI report, on a new EU strategic framework on health and safety at work post 2020 (including better protection of workers from exposure to harmful substances, stress at work and repetitive motion injuries) of 9 February 2022, the European Parliament noted that the RAC recommendation of a BLV of 15µg Pb/100ml does not protect women and especially pregnant women properly. It called on the Commission to ensure that any proposal for revised exposure limit values for lead and its compounds should establish equal protection for all workers regardless of gender.

This report is of the opinion that a non-binding guidance value is not suitable to ensure the protection of workers' health and safety in conditions of equality and non-discrimination, with regard in particular to female lead-exposed workers. In order to attain the Directive's stated objective of a high level of protection of worker's health and safety, a binding biological limit value, which offers sufficient protection for both female and male workers, is necessary.

Historical exposure
Workers who have been occupationally exposed to lead over several years may already have accumulated blood-lead levels well above any new BLV. In such situations, it is not acceptable that such workers continue to be exposed and all necessary measures must be taken to ensure that the blood-levels of such workers decrease as fast as possible.

ANNEX: LIST OF ENTITIES OR PERSONS FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT

The following list is drawn up on a purely voluntary basis under the exclusive responsibility of the rapporteur. The rapporteur has received input from the following entities or persons in the preparation of the [draft report / report, until the adoption thereof in committee]:

Entity and/or person
BusinessEurope
European Trade Union Confederation - ETUC
SMEUnited - European Association of Craft, Small and Medium Sized Enterprises
European Federation of Public Service Unions - EPSU
SGI Europe - European Centre of Employers and Enterprises providing Public Services
European Trade Union Institute - ETUI
ISOPA
ALIPA
Danish Trade Union Confederation - FH
European Commission