Council of the European Union

Brussels, 30 November 2023
(OR. en)

16071/23
ADD 1

LIMITE

SOC 831
EMPL 596
SAN 705
IA 328
CODEC 2300

Interinstitutional File: 2023/0033(COD)

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
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 981241EC and Directive 20041371EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates

Delegations will find attached the provisional agreement on the above proposal, subject to the agreement by the Committee of Permanent Representatives, with a view to reaching a first-reading agreement with the European Parliament.

Changes compared to the Commission's proposal are marked in **bold** and deletions in ▌.

Lawyer-linguists have performed minor corrections to the document, i.e. ensuring the sequential order of recitals and correcting small typographic mistakes. The full lawyer-linguist revision will follow.

ANNEX

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 *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 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) It is important for Member States to maintain equal protection of all workers and facilitate the compliance of SMEs and microenterprises with the obligations stemming from this Directive. SMEs and microenterprises, which represent a large majority of enterprises in the Union, often have limited financial, technical and human resources. Member States, according to national practice, should therefore consider the effects of the implementation of this Directive on SMEs and microenterprises, including any undue administrative tasks, so they can, when needed, support their compliance with the obligations stemming from this Directive, for example by means of technical assistance and financial support through relevant EU funding.

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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*) 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.

(*4*) 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.

(*5*) 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] 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) 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 [redacted] reprotoxic substances within the meaning of Article 2, point (ba), of Directive 2004/37/EC.

(7) 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. Studies show that lead accounts for around half of all occupational exposure to reprotoxic substances. It is not scientifically possible to identify a level below which exposure to lead and its inorganic compounds would be safe for the development of the offspring of female workers of childbearing age. A notation as "non-threshold reprotoxic substance" should therefore be introduced for lead and its inorganic compounds and employers should ensure that the occupational exposure of workers is reduced to as low a level as is technically possible.

(***8***) 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/m^3 as an 8-hour time-weighted average (TWA) should be established.

(9) It may be difficult to comply with the substantial reduction of 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. Therefore, a transitional limit value of 30 µg Pb/100 ml blood should apply until 31 December 2028.

(***10***) 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 ***occupational exposure limit value***) or 9 ***µg Pb/100 ml*** blood (approx. 60% of the ***biological limit value***).

(11) 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.

(***12***) Specific measures should be put in place with regard to risk management, including***, among others, hygiene measures***, the use of ***personal protective equipment, and specific health surveillance that should take into consideration the circumstances of individual workers. Medical surveillance is an important protection measure for lead-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.***

(13) In addition, the opinion of the Advisory Committee on Safety and Health at Work[6] 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 Council[7], 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, RAC gives a non binding recommendation 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.

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

7 *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).*

(14) Therefore, and given that 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, besides setting biological limit values for all workers, this Directive provides that 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 in order to take account of their specific situation. 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.

(15) 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.

(16) Comparable union-wide data on work-related health problems due to lead exposure are often lacking, unreliable or insufficient. It is crucial that Member States continue to collect data, especially on workers with historical exposure and female workers of childbearing age. The Commission is best placed to support these efforts by providing technical assistance for the collection of coordinated data from Member States. This data could be used in the context of the evaluation of the implementation of this Directive pursuant to Article 17a of Directive 89/391/EEC.

(*17*) 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.

(18) To ensure a more comprehensive level of protection, it is also necessary to consider absorption pathways other than inhalation for diisocyanates. These could include possible health effects following skin exposure at the place of work, including systemic immunological effects like sensitisation of the respiratory tract. Further notations for hazardous substances and mixtures are laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council[8].

(*19*) 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.

(*20*) ▌ It is therefore appropriate to establish an occupational exposure limit of 6 ***µg NCO/m***^{3} and a short-term exposure limit of 12 ***µg NCO/m***^{3} for ***all diisocyanates, where NCO refers to isocyanate functional groups of the diisocyanate compounds,*** and to assign a skin, dermal and respiratory sensitisation notation to it. ***In line with Article 6(3) and Article 10 of Directive 98/24/EC, health surveillance is important to identify early signs and symptoms of respiratory sensitisation.***

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[8] ***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).***

(*21*) It may be difficult to comply with an occupational exposure limit equal to 6 ***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 ***construction, vehicle repairs, general repairs, or manufacturing of textiles, furniture, motor vehicles and other means of transport, of domestic appliances, machinery, and computers***. 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.

(*22*) 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 ***on the functioning of the European Union***. 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[9] ***and the*** establishment of an occupational limit ***values*** for diisocyanates[10], with recommendations for appropriate notations***, and a review of the limit values for diisocyanates starting in 2029***. ***In this regard, it is for the Commission, upon consultation with the ACSH, to evaluate the need to modify the binding limit values for diisocyanates in the future.***

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

(24) The Commission should assess the Occupational Exposure Limit Value and the Biological Limit Values for lead and its inorganic compounds. Such an assessment should be done in the context of the next evaluation exercise provided for in Article 17a of Directive 89/391/EEC. On the basis of developments in knowledge and technologies and up-to-date scientific data, the Commission should, where appropriate, amend the limit values for lead in order to better protect workers' health and safety.

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9 ***See footnote 6.***

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

(25) It is important that the Commission, in line with the well-established procedure in the OSH field, continue its work towards relevant updates of this Directive, considering available scientific information, including progressively acquired scientific and technical data for the purpose of protecting workers' health and safety.

(26) It has been proven that endocrine disruption can lead to certain disorders in humans, such as birth defects, developmental, reproductive or neurodevelopmental disorders, cancer, diabetes and obesity. The Commission communication of 14 October 2020 entitled 'Chemicals strategy for sustainability. Towards a toxic-free environment' highlights the need to establish a comprehensive legal framework in order for disruptors to be recognised in a timely manner and that exposure to them is minimised. Commission Delegated Regulation (EU) 2023/707[11] amended Regulation (EC) No 1272/2008 by introducing hazard classes and labelling requirements for endocrine disruptors and the corresponding scientific criteria to identify them. This will facilitate the identification of these substances and will help to carry out an appropriate risk management of workers' exposure to endocrine disruptors. Against this background, and i.a. on the basis of a scientific assessment, the Commission should consider whether additional endocrine disruptors affecting workers' health and safety should be included in this Directive.

(27) 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, the risk shall be assessed on the basis of the risk presented by all such substances in combination.

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[11] *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).*

(28) Certain hazardous medicinal products (HMPs) may contain one or more substances which 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 and therefore fall within the scope of Directive 2004/37/EC. However, it is important that clear and up to date information concerning whether a medicinal product meets those criteria is easily accessible to workers, employers and enforcement authorities. To address this issue, the Commission is developing a definition and establishing an indicative list of hazardous medicinal products or the substances contained therein in accordance with Article 18a of Directive 2004/37/EC. The Commission also published Guidance for the safe management of hazardous medicinal products (HMPs). It is crucial that any Union action regarding specific hazardous medicinal products is taken after consulting the Advisory Committee for Safety and Health at Work and taking into account the existing scientific advice.

(29) Firefighters and emergency services personnel are at risk of exposure to carcinogen, mutagen and reprotoxic substances in the course of their work. The World Health Organization has classified the occupational exposure of firefighters as carcinogenic. Occupational exposure of firefighters includes a variety of hazards resulting from fires and non-fire events. Firefighters can be exposed to a very wide range of airborne chemical substances. The chemical composition and airborne concentrations of combustion products depend on the materials being burned, the duration of the fire, and the ventilation conditions. It is therefore important that the employers of those workers assess, in accordance with this Directive, the risk to workers of exposure to carcinogen, mutagen and reprotoxic substances and that they take the necessary measures to protect the safety and health of those workers.

(30) The Commission initiatives 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 of 16 March 2023, entitled 'A secure and sustainable supply of critical raw materials in support of the twin transition', promote sustainable development and circular economy. Sectors such as waste collecting, sorting and recovery, and energy renovation as well as the batteries sector are of strategic importance to reach the objective of a climate neutrality. A balance between environmental, economic, and social considerations is crucial. By enacting binding occupational exposure limits for carcinogens, mutagens and reprotoxic substances, workers are better protected from harm and will be able to work as safely as possible, also in industries essential to the Union's sustainable transition and strategic autonomy.

(31) ILO Recommendation 204, adopted on 12 June 2015, recognises that the informal economy is a major challenge to workers' rights, including the right to a safe and healthy working environment. It is therefore important to combat the informal economy.

(***32***) 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.

(***33***) 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.

(***34***) Directives 98/24/EC and 2004/37/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 98/24/EC is amended as follows:

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

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

Article 2

Directive 2004/37/EC is amended as follows:

(1) in Article 2(1), point (b) is replaced by the following:

"(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;";

(2) in Article 18a, the following paragraphs are added:

"By the first semester of 2024 the Commission shall initiate an assessment of the effects of exposure to a combination of substances, with a view to prepare Union guidelines on how to address this matter where appropriate. In this process the Commission shall take into account the latest developments in scientific knowledge, the opinion of the Committee for Risk Assessment of the European Chemicals Agency established by Regulation (EC) No 1907/2006 and of the Advisory Committee on Safety and Health (ACSH), the best practices in the Member States, and conduct appropriate consultations of relevant stakeholders. Those guidelines shall be published on the EU-OSHA website and shall be disseminated in all Member States by the relevant competent authorities.

Within two years from the adoption of this Directive, the Commission shall initiate the procedure to obtain a scientific assessment of endocrine disruptors that can affect workers' health and safety, with a view to evaluate the appropriateness of including them within the scope of the Directive in order to better protect the workers' health. Where appropriate, and after consulting the ACSH, the Commission shall submit to the European Parliament and to the Council a legislative proposal.

The Commission will evaluate the implementation of this Directive pursuant to Article 17a of Directive 89/391/EEC. In this context, within 5 years of the entry into force of this Directive, the Commission shall assess the occupational limit values for lead and its inorganic compounds. The Commission shall propose, where appropriate, legislative amendments to the limit values for lead, considering the latest developments in scientific knowledge and after consulting the ACSH.

No later than [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. ";

(3) Annexes ***I,*** III and IIIa to Directive 2004/37/EC are amended in accordance with Annex II to this Directive.

Article 3

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

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

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

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels,

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

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 ***([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***/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/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.'

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

(1) in Annex I, the title is replaced by the following:

"List of substances, mixtures and processes (Article 2, points (a)(ii) and (b)(ii)";'

(***2***) 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/m³ (5)	ppm (6)	f/ml (7)	mg/m³ ***(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/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.';

(***3***) Annex IIIa is replaced by the following:

'ANNEX IIIa

BIOLOGICAL LIMIT VALUES AND HEALTH SURVEILLANCE MEASURES

(Article 16(4))

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:

30 µg Pb/100 ml blood

For workers whose blood lead level exceeds the biological limit value of 30 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 30 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 ([1])

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 30 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/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 Pb/100 ml blood or the national reference value of the general population not occupationally exposed to lead, if such value exists.***

(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/100 ml.'