2024/869

19.3.2024

DIRECTIVE (EU) 2024/869 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 13 March 2024

amending Directive 2004/37/EC of the European Parliament and of the Council and Council Directive 98/24/EC as regards the limit values for lead and its inorganic compounds and for 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 Article 153(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 ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) The scope of Directive 2004/37/EC of the European Parliament and of the Council ([3]) was extended by Directive (EU) 2022/431 of the European Parliament and of the Council ([4]) to cover reprotoxic substances, including lead and its inorganic compounds. As a result, both Council Directive 98/24/EC ([5]), in Annexes I and II thereto, 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 which enable the strengthening of workers' protection from the risks arising from occupational exposure to lead and its inorganic compounds, which is a dangerous reprotoxic substance, as confirmed by the results of a Commission evaluation pursuant to Article 17a(4) of Council Directive 89/391/EEC ([6]).

(2) It is important for Member States to maintain equal protection of all workers and facilitate the compliance of small and medium-sized enterprises (SMEs), including microenterprises, with the obligations introduced by this Directive. SMEs and microenterprises, which represent a large majority of the enterprises in the Union, often have limited financial, technical and human resources. Member States should therefore, in accordance with their national practice, consider the effects of the implementation of this Directive on SMEs and microenterprises, including any burdensome administrative tasks, so that they can, where necessary, facilitate their compliance with the obligations introduced by this Directive, for example by means of technical assistance or financial support through relevant Union funding.

([1]) Opinion of 22 March 2023 (not yet published in the Official Journal).
([2]) Position of the European Parliament of 7 February 2024 (not yet published in the Official Journal) and decision of the Council of 26 February 2024.
([3]) 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).
([4]) 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).
([5]) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).
([6]) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

(3) Pursuant to Article 1(3) of Directive 98/24/EC, that Directive applies to carcinogens, mutagens and reprotoxic substances at work, without prejudice to more stringent or specific provisions set out in Directive 2004/37/EC. It follows that Article 10(4) of Directive 98/24/EC, which imposes requirements on employers in the context of the health surveillance of workers, is without prejudice to Annex IIIa to Directive 2004/37/EC, which sets biological limit values and provides for health surveillance with regard to lead and its inorganic compounds. To ensure legal certainty with regard to the applicable limit values for lead and its inorganic compounds, those Directives should be amended in order to provide for a revised binding occupational exposure limit value and a revised binding biological limit value in Annexes III and IIIa to Directive 2004/37/EC, together with more specific provisions on reprotoxic substances such as lead and its inorganic compounds. Therefore, the specific provisions setting the relevant occupational exposure limit value in Annex I to Directive 98/24/EC and the relevant biological limit value in Annex II to Directive 98/24/EC should be deleted.

(4) New and revised limit values should be set in light of available information, including up-to-date scientific evidence and technical data, and should be 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 (RAC) of the European Chemicals Agency, established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([7]), and the Advisory Committee on Safety and Health at Work (ACSH), 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 substances, limit values are also established in relation 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.

(6) Lead and its inorganic compounds are key occupational reprotoxic substances that can cause adverse effects on both fertility and the development of the foetus and meet the criteria for classification as category 1A reproductive toxicant in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([8]) and are therefore reprotoxic substances as defined in Article 2, point (ba), of Directive 2004/37/EC.

(7) Pursuant to Article 16a of 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 notation 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 to lead and its inorganic compounds 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 biological and occupational exposure limit values for lead and its inorganic compounds. Therefore, a revised biological limit value of 15 µg Pb/100 ml blood, accompanied by a revised occupational exposure limit value of 0,03 mg/m³ as an 8-hour time-weighted average (TWA), should be established.

([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).

([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).

(9) A substantial reduction of the biological limit value to 15 µg Pb/100 ml blood may be difficult to comply with in the short term, due to the time needed to implement risk-management measures and the costly adaptation of production processes. Therefore, a transitional period until 31 December 2028 should be introduced during which a biological limit value of 30 µg Pb/100 ml blood applies.

(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 taken by employers, it is necessary to amend the requirements that apply when workers are exposed to certain levels of lead and its inorganic compounds. To that end, detailed medical surveillance should be carried out where exposure to lead and its inorganic compounds exceeds 0,015 mg/m^3 in the air (50 % of the occupational exposure limit value) or 9 µg Pb/100 ml blood (60 % of the biological limit value).

(11) Lead accumulates in the bones and is released slowly into the circulatory system. The blood lead level could thus remain high for a long time after exposure to lead and its inorganic compounds has been reduced. Regular medical surveillance should therefore be carried out for workers whose blood lead level exceeds the biological limit value in force due to exposure which occurred before 9 April 2026. If a declining trend towards the biological limit value in force is established, it should be possible for those workers to be allowed to continue performing tasks that involve exposure to lead and its inorganic compounds.

(12) Specific measures should be put in place with regard to risk management, including hygiene measures, the use of personal protective equipment and specific health surveillance that takes into consideration the circumstances of individual workers. In addition to technical preventive measures to be taken by employers, medical surveillance is an important protection measure for workers who are exposed to lead and its inorganic compounds. Under the general requirements of Directive 2004/37/EC, employers are obliged to ensure the replacement of the substance where technically possible, the use of closed systems, or the reduction of exposure to as low a level as technically possible.

(13) In addition, the ACSH, in its opinion of 24 November 2021 on lead and its inorganic compounds, suggested 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 and its inorganic compounds in the relevant Member State. The RAC advised that a biological guidance value be used, because there was insufficient scientific evidence to set a biological limit value for women of childbearing age. In its opinion of 11 June 2020, the RAC gives a non-binding recommendation that where national reference levels are not available, the blood lead level in women of childbearing age should not exceed 4,5 µg Pb/100 ml blood because the biological limit value for lead and its inorganic compounds does not protect the foetuses or offspring of women of childbearing age.

(14) Therefore, and given that it is essential that the protection of the health and safety of the foetuses or offspring of female workers does not lead to the unfavourable treatment of women on the labour market and that it is without prejudice to Union law concerning equal treatment for men and women, besides setting biological limit values for all workers, this Directive should provide for medical surveillance to be carried out for female workers of childbearing age whose blood lead level exceeds 4,5 µg Pb/100 ml blood or the national reference value of the general population not occupationally exposed to lead and its inorganic compounds, if such a 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. That value therefore acts as a sentinel marker to alert employers of the need to pay specific attention to that 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 foetuses or offspring of female workers. That provision complements the existing obligations regarding risks assessments, information and training, which are important tools to minimise the risks.

(15) In order to assist Member States, the Commission should draw up Union guidelines on health surveillance, including biological monitoring. Those Union guidelines should focus, inter alia, on the implementation of the provisions of Directive 2004/37/EC regarding blood lead level, taking into account the slow removal of lead from the body, and on the implementation of provisions of that Directive regarding the blood lead level for female workers of childbearing age in order to protect their foetuses and offspring.

(16) Comparable Union-wide data on work-related health problems due to exposure to lead and its inorganic compounds are often lacking, unreliable or insufficient. It is crucial that Member States continue to collect data, especially on workers with historical exposure to lead and its inorganic compounds and female workers of childbearing age. The Commission is best placed to support those efforts by providing technical assistance for the collection of coordinated data from Member States. Those data could be used in the context of the Commission evaluation pursuant to Article 17a(4) 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. To ensure a more comprehensive level of protection, it is also necessary to consider absorption pathways other than inhalation for diisocyanates, including possible adverse health effects following skin exposure at the place of work, which can also result in systemic immunological effects such as sensitisation of the respiratory tract. Appropriate notations for diisocyanates should be introduced in Directive 98/24/EC. Further statements for hazardous substances and mixtures are laid down in Regulation (EC) No 1272/2008. Diisocyanates are considered to be hazardous chemical agents within the meaning of Article 2, point (b), of Directive 98/24/EC and thus fall within the scope of that Directive. Currently there is no binding occupational exposure limit value or short-term exposure limit value for diisocyanates at Union level.

(18) 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 the 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, on the basis of the available information, including scientific and technical data, to set a long-term and a short-term limit value for that group of chemical agents.

(19) 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. Health surveillance carried out pursuant to Article 6(3) and Article 10 of Directive 98/24/EC is important for the purpose of identifying early signs and symptoms of respiratory sensitisation.

(20) With regard to diisocyanates, it may be difficult to comply with an occupational exposure limit of 6 µg NCO/m^3, accompanied by an associated short-term exposure limit of 12 µg NCO/m^3. That is because of technical measurement feasibility issues and the time needed to implement risk management measures, in particular in downstream sectors involving activities such as construction, vehicle repair, general repair, or the manufacturing of textiles, furniture, motor vehicles and other means of transport as well as domestic appliances, machinery, and computers. An occupational exposure limit of 10 µg NCO/m^3 accompanied by an associated short-term exposure limit of 20 µg NCO/m^3 should therefore apply for a transitional period until 31 December 2028.

(21) The Commission has consulted the RAC which provided opinions both on lead and its inorganic compounds, and on diisocyanates. The Commission has also 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 ACSH, which adopted, on 24 November 2021, an opinion on lead and its inorganic compounds and an opinion on diisocyanates, with recommendations for appropriate notations and a review of the limit values for diisocyanates starting in 2029. It is for the Commission, after consulting the ACSH, to evaluate whether there is a need to modify the binding limit values for diisocyanates.

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

(23) The Commission should assess the occupational exposure limit value and the biological limit values for lead and its inorganic compounds. That assessment should be carried out in the context of the next evaluation pursuant to Article 17a(4) of Directive 89/391/EEC. On the basis of developments in knowledge and technology and up-to-date scientific data, the Commission should, where appropriate, propose to amend the limit values for lead and its inorganic compounds in order to better protect the health and safety of workers.

(24) It is important that the Commission, in accordance with the well-established procedure in the field of occupational safety and health, continue its work towards relevant updates of Directive 2004/37/EC, taking into account available scientific information, including progressively acquired scientific and technical data, for the purpose of protecting the health and safety of workers.

(25) It has been proven that endocrine disruption can lead to certain adverse health effects 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 to ensure that endocrine disruptors are recognised in a timely manner and that exposure to them is minimised. Commission Delegated Regulation (EU) 2023/707 ([9]) amended Regulation (EC) No 1272/2008 by introducing hazard classes and labelling requirements for endocrine disruptors and the corresponding scientific criteria to identify them facilitating the identification of those substances and helping carry out an appropriate risk management of the exposure of workers to endocrine disruptors. Against that background, and, inter alia, on the basis of a scientific assessment, the Commission should consider whether additional endocrine disruptors that affect the health and safety of workers should be included in Directive 2004/37/EC.

(26) To ensure a comprehensive level of protection, it is necessary to consider the effects of exposure to a combination of 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 that have the same mode of action or act at the same target organs, tissues or cells, the risk should be assessed on the basis of that combination of substances.

(27) Certain hazardous medicinal products may contain one or more substances which meet the criteria for classification as category 1A or 1B carcinogen, as category 1A or 1B mutagen or as category 1A or 1B reproductive toxicant in accordance with Regulation (EC) No 1272/2008 and therefore fall within the scope of Directive 2004/37/EC. However, it is important to ensure 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 that issue, the Commission is developing a definition and establishing an indicative list of hazardous medicinal products or the substances contained therein pursuant to Article 18a of Directive 2004/37/EC. On 28 April 2023, the Commission also published its Guidance for the safe management of hazardous medicinal products at work. It is crucial that any Union action regarding specific hazardous medicinal products be taken after consulting the ACSH and taking into account the existing scientific advice.

(28) Firefighters and emergency services personnel are at risk of exposure to carcinogens, mutagens and reprotoxic substances in the course of their work. The World Health Organization has classified the occupational exposure of firefighters as carcinogenic. The occupational exposure of firefighters includes a variety of hazards resulting from fires and from 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 types of material being burned, the duration of the fire and the ventilation conditions. It is therefore important that the employers of firefighters and emergency services personnel assess, in accordance with Directive 2004/37/EC, the risk of exposure to carcinogens, mutagens and reprotoxic substances and that they take the necessary measures to protect the health and safety of those workers.

([9]) 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).

(29) Commission initiatives such as the European Green Deal, launched in the Commission communication of 11 December 2019, and the Critical Raw Materials 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 a 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 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 are able to work as safely as possible, including in industries essential to the Union's sustainable transition and strategic autonomy.

(30) Recommendation No 204 of the International Labour Organization, 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.

(31) Since the objective of this Directive, namely to protect workers from the 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 but can rather, by reason of its scale and effects, be better achieved at Union level, 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.

(32) 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) Article 18a is amended as follows:

(a) the first to seventh paragraphs are numbered 1 to 7;

(b) the following paragraphs are added:

'8. No later than 30 June 2024, the Commission shall initiate an assessment of the effects of exposure to a combination of substances with a view to preparing Union guidelines thereon where appropriate. 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 of the European Parliament and of the Council (*), the opinion of the ACSH and the best practices in the Member States, and shall conduct appropriate consultations of relevant stakeholders. Those guidelines shall be published on the EU-OSHA website and disseminated in all Member States by the relevant competent authorities.

9. No later than 9 April 2026, the Commission shall initiate the procedure to obtain a scientific assessment of endocrine disruptors that can affect the health and safety of workers, with a view to evaluating the appropriateness of including them within the scope of this Directive in order to better protect the health and safety of workers. Where appropriate the Commission shall, after consulting the ACSH, submit a legislative proposal.

10. In the context of its evaluation pursuant to Article 17a(4) of Directive 89/391/EEC, the Commission shall, no later than 9 April 2029, assess the occupational limit values for lead and its inorganic compounds. Where appropriate, the Commission shall, taking into account the latest developments in scientific knowledge and after consulting the ACSH, submit a legislative proposal to amend those limit values.

11. No later than 9 April 2026, the Commission shall, after appropriate consultation of relevant stakeholders, draw up 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 female workers of childbearing age.

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(*) 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).';

(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 by 9 April 2026. 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 Strasbourg, 13 March 2024.

For the European Parliament	*For the Council*
The President	*The President*
R. METSOLA	H. LAHBIB

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]	A limit value of 10 µg NCO/m³ in relation to a reference period of 8 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 Annex VI, Part 1, Section 1.1.1.2, 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 8-hour time-weighted average (TWA).
[4] Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.
[5] µg/m³ = micrograms per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).
[6] ppm = parts per million by volume in air (ml/m³).
[7] f/ml = fibres per millilitre.
[8] Substantial contribution to the total body burden via dermal exposure possible.
[9] The substance can cause sensitisation of the skin and of the respiratory tract.
[10] NCO refers to isocyanate functional groups of the diisocyanate compounds.'.

ANNEX II

Annexes 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]-[6]	f/ml [7]	mg/-m³ [5]	ppm[6]-[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 Annex VI, Part 1, Section 1.1.1.2, 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 8-hour time-weighted average (TWA).
[4] Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.
[5] mg/m³ = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).
[6] ppm = parts per million by volume in air (ml/m³).
[7] f/ml = fibres per millilitre.
[8] Inhalable fraction.';

(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.

1.1.1. 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 9 April 2026, 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, they may be allowed to continue with work involving exposure to lead.

1.1.2. From 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 9 April 2026, 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, they 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 with regard to female workers of childbearing age whose blood lead level exceeds 4,5 µg Pb/100 ml blood or the national reference value of the general population not occupationally exposed to lead, if such a value exists.

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[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.'.