EUROPEAN UNION

THE EUROPEAN PARLIAMENT **THE COUNCIL**

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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, MUTAGENS OR REPROTOXIC SUBSTANCES AT WORK

DIRECTIVE (EU) 2026/…
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 21 October 2026

amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work

(Text with EEA relevance)

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],

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1 OJ C, C/2026/73, 30.1.2026, ELI: http://data.europa.eu/eli/C/2026/73/oj.

2 Position of the European Parliament of 6 October 2026 (not yet published in the Official Journal) and decision of the Council of 19 October 2026.

Whereas:

(1) In order to improve the protection of workers against risks from exposure to carcinogens, mutagens or reprotoxic substances at the place of work and ensure the same minimum level of protection across the Union, regular updates of Directive 2004/37/EC of the European Parliament and the Council[3] are necessary. Occupational exposure limit (OEL) values should be established or revised in light of available information, including up-to-date scientific evidence and technical data, and should be based on a thorough assessment of the socio-economic impact and feasibility factors. That information should, where available, include opinions of 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[4] and opinions of the Advisory Committee on Safety and Health at Work (ACSH) established by Council Decision of 22 July 2003[5]. Those opinions provide necessary scientific evidence to substantiate any Commission proposal to amend Directive 2004/37/EC. Moreover, they are based on practical experience and the realities of the place of work across the Union and reflect a broad consensus.

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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, ELI: http://data.europa.eu/eli/dir/2004/37/oj).

4 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, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

5 Council Decision of 22 July 2003 setting up an Advisory Committee on Safety and Health at Work (OJ C 218, 13.9.2003, p. 1).

ACSH opinions, which are the outcome of tripartite consensus, are of particular importance in that context, and should be taken into account. In accordance with the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[6], the Commission should ensure that its proposals are informed by robust evidence and comprehensive stakeholder involvement, and should systematically assess the economic, social and environmental impact of its proposals. Its proposals should respect the principles of subsidiarity and proportionality, in accordance with the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU).

[6] OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

(2) Directive 2004/37/EC covers substances or mixtures which meet the criteria for classification as a category 1A or 1B carcinogen, mutagen or reproductive toxicant set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[7], as well as substances, mixtures or processes referred to in Annex I to that Directive. Robust scientific evidence is to be provided for any new addition to the list of substances, mixtures and processes referred to in Annex I to Directive 2004/37/EC to demonstrate that those substances, mixtures and processes fall within the scope of that Directive, based on available valid scientific sources, such as the ECHA, the International Agency for Research on Cancer (IARC) and national bodies, paying particular attention to peer-reviewed published literature on those substances, mixtures and processes. To ensure the highest level of worker protection, the Commission should enhance its efforts to identify priority substances for setting limit values under that Directive on the basis of the best available information, including scientific and technical data, while making best use of current and future budgetary and administrative resources, taking into account scientific and administrative needs.

[7] 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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

(3) The substances, mixtures and processes referred to in Annex I to Directive 2004/37/EC, and the substances and mixtures released by those processes, vary as to whether they have carcinogenic, mutagenic or reprotoxic effects. It is therefore appropriate to clarify the definitions of 'carcinogen', 'mutagen' and 'reprotoxic substance' provided for in that Directive, to ensure that the relevant substances, mixtures and processes are covered by each of those definitions. It is also appropriate to align the definition of 'reprotoxic substance' with the definitions of 'carcinogen' and 'mutagen'.

(4) For mutagens and most carcinogens, it is not scientifically possible to identify levels below which exposure would not lead to adverse health effects. Although setting limit values for exposure at the place of work in relation to carcinogens and mutagens in Directive 2004/37/EC contributes to a significant reduction of risks arising from such exposure by means of the stepwise and goal-setting approach adopted in that Directive, it nonetheless does not completely eliminate risks to the health and safety of workers arising from exposure at work (residual risks). Therefore, it is essential that the existence of such residual risks be communicated to workers in a clear and transparent manner during the training of workers provided for in that Directive. A list of residual risks associated with the current binding OELs for carcinogens under Directive 2004/37/EC and Directive 2009/148/EC of the European Parliament and of the Council[8] was adopted by consensus by the ACSH in its opinion entitled 'Communication of the residual risks associated with the binding OELs of carcinogens' of 10 December 2025.

[8] Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28, ELI: http://data.europa.eu/eli/dir/2009/148/oj).

(5) It is possible that certain workers are more exposed or more vulnerable to different types of substances because of their gender. This should continue to be taken into account in occupational health and safety research, scientific studies and in the opinions of the RAC and the ACSH, while taking into account the objective of participation of men and women in the labour market.

(6) Certain substances covered by Directive 2004/37/EC are used in sectors of strategic importance to the Union. While advancing the industrial transition, stimulating the circular economy and maintaining and enhancing the international strategic autonomy in raw materials are all priorities of the Union, it is essential to ensure that workers receive a high and comparable level of protection against health risks related to occupational exposure. Principle 10 of the European Pillar of Social Rights[9] also recognises the right of workers to a high level of protection of their health and safety at work, which includes protection from exposure to carcinogens, mutagens and reprotoxic substances at the place of work. In that regard, the process for setting OEL values takes into account not only scientific and health considerations, but also socioeconomic aspects, which in some cases justify the establishment of transitional periods.

[9] OJ C 428, 13.12.2017, p. 10.

(7) The IARC classified welding fumes as ‘carcinogenic to humans’ (Group 1 of the IARC classification). According to the ECHA Scoping Study report for evaluation of limit values for welding fumes and fumes from other processes that generate fume in a similar way at the workplace (the ‘ECHA Scoping Study report’), welding fumes and fumes from other processes that generate fumes in a similar way are complex and can include carcinogens, mutagens or reprotoxic substances, such as chromium(VI) compounds, nickel compounds, cadmium and its inorganic compounds. The ACSH, having considered the latest available scientific evidence, including the ECHA Scoping Study report as regards the impact on workers’ health and safety, recommended including in Annex I to Directive 2004/37/EC only work involving exposure to welding fumes. The complexity and heterogeneity of welding fumes, together with the absence of harmonised classification in Regulation (EC) No 1272/2008, contribute to a lack of clarity regarding the extent of their possible danger to workers, and therefore a lack of appropriate risk management measures at the place of work. Addressing that absence of classification for welding fumes at Union level would ensure more legal clarity with regard to the application of Directive 2004/37/EC.

It is therefore appropriate, in line with the opinion of the ACSH, to include in Annex I to Directive 2004/37/EC work involving exposure to fumes from welding processes, containing substances or mixtures which meet the criteria for classification as a category 1A or 1B carcinogen, mutagen or reproductive toxicant set out in Annex I to Regulation (EC) No 1272/2008. That ACSH opinion also included a recommendation to develop guidance on welding fumes. In addition to the existing guidance, such as the Guidance for National Labour Inspectors on addressing health risks from Welding Fume developed by the Senior Labour Inspectors' Committee in 2018, further Union guidance, in line with the EU Strategic Framework on Health and Safety at work on the basis of the latest scientific evidence, could assist labour inspectors and enterprises, especially small and medium-sized enterprises (SMEs), including microenterprises, in ensuring compliance with the welding fumes entry in Annex I to Directive 2004/37/EC. Such guidance could serve to promote, inter alia, a common minimum high level of protection across the Member States for all workers exposed to welding fumes.

(8) Cobalt metal and several cobalt compounds meet the criteria for classification as category 1B carcinogens and reproductive toxicants in accordance with Regulation (EC) No 1272/2008, and are therefore carcinogens or reprotoxic substances as defined in Directive 2004/37/EC. Workers are often exposed to a mixture of cobalt compounds, and OEL values should thus be applied to all inorganic cobalt compounds. It is therefore appropriate, on the basis of available information, including scientific and technical data, to establish a limit value for cobalt and inorganic cobalt compounds in Directive 2004/37/EC.

(9) The ACSH concluded, on the basis of an opinion of the RAC, that exposure to cobalt and inorganic cobalt compounds at the place of work can also result in dermal sensitisation and the sensitisation of the respiratory tract. It is therefore appropriate to establish limit values for both the inhalable and respirable fractions of cobalt and inorganic compounds thereof within the scope of Directive 2004/37/EC, and to assign to them a notation for dermal and respiratory sensitisation.

(10) For cobalt and inorganic cobalt compounds, it is foreseeable that it will be difficult to comply in the short term with a limit value of 0,01 mg/m³ for the inhalable fraction and 0,0025 mg/m³ for the respirable fraction. It is therefore appropriate to introduce a transitional period of six years after the date of entry into force of this Directive, during which the limit values of 0,02 mg/m³ (inhalable fraction) and 0,0042 mg/m³ (respirable fraction) are to apply.

(11) Cobalt is used in several sectors, such as the batteries sector, which are of strategic importance for reaching the goals set out in the European Green Deal and in Regulation (EU) 2021/1119 of the European Parliament and of the Council[10]. Cobalt is a hazardous metal posing serious health risks to workers, such as respiratory problems, heart, thyroid, liver or kidney damage and potential cancer, and its consumption is projected to rise by approximately 330 % by 2050 as a result of the green transition, making it particularly important to ensure a high level of protection of workers' health and safety. OELs for cobalt and inorganic cobalt compounds are thus necessary to help prevent long-term effects on the health and wellbeing of workers and to support the attractiveness, competitiveness and long-term sustainability of the cobalt industry in the Union, while avoiding the relocation of cobalt-processing enterprises to third countries with less stringent occupational safety and health regulations.

(12) Certain sectors in which workers are exposed to substances such as cobalt and polycyclic aromatic hydrocarbons (PAHs) can face difficulties in complying with the OELs. In those sectors where exposure can neither be avoided nor adequately reduced by other means in accordance with Article 5 of Directive 2004/37/EC, respiratory protective equipment should be available and properly used by workers in accordance with the assessment of risks provided for in Article 3(2) of that Directive, in order to ensure that workers are appropriately protected. It is necessary that all Member States implement the rules in accordance with the hierarchy of control measures set out in Article 5 of that Directive, to eliminate or minimise workers' exposure in a consistent manner, in order to ensure a level playing field across Member States.

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[10] Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law') (OJ L 243, 9.7.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/1119/oj).

(13) In order to prevent or reduce exposure to carcinogens, mutagens and reprotoxic substances, Directive 2004/37/EC sets out a hierarchy of technical and organisational measures. In that context, personal protective equipment (PPE), in particular individual respiratory protective equipment, should be used only as a last resort. It is necessary to ensure that PPE is chosen and used in accordance with Council Directive 89/656/EEC[11], including the requirement that all PPE fit the wearer correctly after any necessary adjustment, and comply with the relevant Union provisions on design and manufacture with respect to safety and health, in particular Regulation (EU) 2016/425 of the European Parliament and of the Council[12]. In addition, it is necessary to ensure that PPE is kept in good working order and satisfactory hygienic condition by means of the necessary maintenance, repair and replacements.

(14) Certain PAH mixtures, particularly those containing benzo[a]pyrene, meet the criteria for classification as a category 1A or 1B carcinogen, mutagen or reproductive toxicant in accordance with Regulation (EC) No 1272/2008, and therefore fall within the scope of Directive 2004/37/EC. The RAC has identified the possibility of significant uptake through the skin for those mixtures, and the ACSH has agreed on the importance of introducing an OEL value for all PAH mixtures falling within the scope of Directive 2004/37/EC, measured as benzo[a]pyrene, and to maintain a skin notation already contained in Annex III to that Directive.

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11 Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 393, 30.12.1989, p. 18, ELI: http://data.europa.eu/eli/dir/1989/656/oj).

12 Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51, ELI: http://data.europa.eu/eli/reg/2016/425/oj).

(15) For PAH mixtures, it is foreseeable that it will be difficult for some sectors to comply in the short term with a limit value of 0,00007 mg/m³ (measured as benzo[a]pyrene). It is therefore appropriate to introduce a transitional period of seven years after the date of entry into force of this Directive, during which the limit value of 0,00014 mg/m³ (measured as benzo[a]pyrene) is to apply. That transitional period should be limited to the following sectors: (a) steel and iron foundries, which include ferroalloy manufacturers; (b) aluminium manufacturers; (c) carbon and graphite manufacturers; (d) coking plants; (e) coal tar distillation; (f) refractory products manufacturers; (g) train track welding; (h) other non-ferrous metallurgical processes; and (i) metal casting.

(16) Available scientific and technical data, including the opinions of the RAC and the ACSH, indicate that isoprene meets the criteria for classification as a category 1B carcinogen in accordance with Regulation (EC) No 1272/2008, and is therefore a carcinogen as defined in Directive 2004/37/EC. It is therefore appropriate, consistently with the outcome of the tripartite process, to establish a long-term OEL value of 8,5 mg/m^3 (3 ppm), with a view to preventing potential health risks to workers and to ensuring a level-playing field across Member States.

(17) 1,4-dioxane meets the criteria for classification as a category 1B carcinogen in accordance with Regulation (EC) No 1272/2008, and is therefore a carcinogen as defined in Directive 2004/37/EC. It is therefore appropriate, on the basis of the available information, including scientific and technical data, such as the opinions of the RAC and the ACSH, to establish a long-term and a short-term OEL value of 7,3 mg/m³ (2 ppm) and 73 mg/m³ (20 ppm), respectively, supplemented by a skin notation, as well as a biological limit value of 45 mg HEAA in urine/g creatinine, measured at the end of exposure or shift in accordance with national law or practice.

(18) Directive (EU) 2022/431 of the European Parliament and the Council[13] extended the scope of Directive 2004/37/EC to include reprotoxic substances, including mercury and divalent inorganic mercury compounds, which were added to Annex III to Directive 2004/37/EC. Since not all divalent inorganic mercury compounds can be classified as reprotoxic substances, it is necessary to clarify that the limit value applies only to mercury and divalent inorganic mercury compounds that fall within the scope of Directive 2004/37/EC.

(19) Hazardous medicinal products, in so far as they contain carcinogenic, mutagenic or reprotoxic substances, fall within the scope of Directive 2004/37/EC, as acknowledged in the working definitions and examples laid down in the Commission's Guidance of 28 April 2023 for the safe management of hazardous medicinal products at work. To facilitate identifying those substances, the Commission published on 20 February 2025 a communication entitled 'Indicative list of hazardous medicinal products according to Article 18a of 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', thereby enabling the consistent application of Directive 2004/37/EC to safeguard the health and safety of exposed workers.

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[13] 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, ELI: http://data.europa.eu/eli/dir/2022/431/oj).

(20) The Commission has carried out a two-stage consultation of social partners in accordance with Article 154 TFEU. It has also consulted the ACSH. The ACSH has adopted opinions for all substances subject to this Directive, and has recommended one or several binding limit values for each of them, and notations and transitional values for some of them, where appropriate. Transitional values allow employers to make the necessary investments in additional risk management measures and develop technical means by which to ensure compliance. In that regard, existing Union programmes, such as Horizon Europe, could help to develop innovative solutions to protect workers' health.

(21) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. When establishing or revising limit values, the Commission should consult the RAC and the ACSH to ensure that those values are evidence-based, proportionate and measurable.

(22) It is essential that the ordinary legislative procedure be used in order to set binding limit values under Directive 2004/37/EC because amending that Directive is not a matter for technical consideration alone, but also requires a political assessment.

(23) Certain workers, in particular firefighters and other emergency services personnel are at risk of exposure to a variety of hazards resulting from fires and from non-fire events in the course of their work, including to carcinogens, mutagens and reprotoxic substances. It is therefore important that the employers of firefighters and other emergency services personnel assess and reduce the risk of exposure to carcinogens, mutagens and reprotoxic substances in accordance with Directive 2004/37/EC, with a view to strengthening the protection of firefighters and other emergency services personnel against, inter alia, PAHs thereby reducing the risk of occupational diseases. Guidance has already been developed on risks arising from exposure to asbestos, including sector-specific guidance for firefighters and other emergency services personnel. In view of the specific and high-level risks inherent to emergency services, it is important that the European Agency for Safety and Health at Work (EU-OSHA), in cooperation with relevant social partners and national authorities, consider developing a specific Online interactive Risk Assessment (OiRA) tool tailored to the needs of those services.

(24) Workers are often exposed to a cocktail of hazardous substances at the place of work, 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 acting upon the same target organs, tissues or cells, it can be necessary to adapt the implementation of the OEL values established pursuant to Directive 2004/37/EC, to take into account the combined effects of those substances. This is relevant, inter alia, for firefighters and other emergency services personnel. When preparing Union guidelines on the effects of exposure to a combination of substances, the Commission should take into account the relevant specificities of those services. Such guidelines should be published on the EU-OSHA website and disseminated in all Member States by the relevant competent authorities.

(25) There is a need for workers to receive sufficient and appropriate training, on the basis of all available information, when they are exposed to, or are likely to be exposed to, carcinogens, mutagens or reprotoxic substances, including those contained in certain hazardous medicinal products. The training that the employer is required to provide pursuant to Directive 2004/37/EC should be adapted to take account of a new or changed risk, in particular when workers are exposed to new carcinogens, mutagens or reprotoxic substances or to a number of different carcinogens, mutagens or reprotoxic substances, including in hazardous medicinal products, or in the case of changing circumstances related to work. That training should be repeated periodically if necessary.

(26) Union-wide data from work-related health problems due to exposure to cobalt and inorganic cobalt compounds, PAHs, isoprene and 1,4-dioxane are often unavailable, unreliable or insufficient. It could therefore be appropriate for the Commission to consider developing recommendations for data collection by the Member States to improve the reporting and exposures registries.

(27) Achieving a high level of protection of workers against risks related to carcinogens, mutagens and reprotoxic substances requires that Member States maintain equal protection for all workers and facilitate the compliance of SMEs, including microenterprises, with the obligations stemming from Directive 2004/37/EC. SMEs, including microenterprises, which represent a large majority of enterprises in the Union, have limited financial, technical and human resources. It is important that SMEs, including microenterprises, have the capacity to comply with that Directive, are not disproportionately affected, in particular by administrative requirements, and are able to progress towards the elimination of risks relating to exposure to carcinogens, mutagens and reprotoxic substances at the place of work, thus benefitting all workers.

(28) On 29 May 2024, the ACSH adopted an opinion on priority chemicals for new or revised occupational exposure limit values under EU OSH legislation, which identifies a list of priority substances to be used when developing a proposal for a Union limit value under Directive 2004/37/EC. In particular, the list includes five substances or group of substances classified as 'Immediate priority substances' (Oximes, Butanone oxime, N-(Hydroxymethyl) acrylamide (NMA), Organotins and Ethylene dibromide). The ACSH strongly recommended that the Commission use that list when selecting which chemicals to include in its legislative proposals amending Directive 2004/37/EC for the purpose of including new or revised limit values.

(29) Since the objective of this Directive, namely to protect workers from exposure to carcinogens, mutagens and reprotoxic substances at work, 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 TEU. 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.

(30) Directive 2004/37/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2004/37/EC is amended as follows:

(1) Article 2 is amended as follows:

(a) in point (a), point (ii) is replaced by the following:

‘(ii) a substance, mixture or process referred to in Annex I to this Directive, or a substance or mixture released by a process referred to in that Annex, which has carcinogenic effects;’;

(b) in point (b), point (ii) is replaced by the following:

‘(ii) a substance, mixture or process referred to in Annex I to this Directive, or a substance or mixture released by a process referred to in that Annex, which has mutagenic effects;’;

(c) point (ba) is replaced by the following:

‘(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, or a substance or mixture released by a process referred to in that Annex, which has reprotoxic effects;’;

(2) in Article 5(5), the following subparagraph is added:

‘Individual protection measures as referred to in point (g) of the first subparagraph of this paragraph shall include personal protective equipment, in particular respiratory protective devices, where, despite putting in place the technical and organisational measures for the prevention or reduction of exposure in accordance with this Article, exposure cannot be avoided or adequately reduced by other means. In such cases, personal protective equipment shall be used as a last resort to ensure that workers are adequately protected and, in any case, to avoid exposure exceeding established limit values. Personal protective equipment shall be correctly chosen, individually adjusted to fit the wearer, and maintained, in accordance with Articles 4 and 5 of Council Directive 89/656/EEC*.

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* Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 393, 30.12.1989, p. 18,ELI: http://data.europa.eu/eli/dir/1989/656/oj).’;

(3) in Article 10, the following paragraph is added:

‘3. When wearing personal protective equipment, workers shall be entitled to regular breaks in an area where there is no risk of contamination by carcinogens, mutagens or reprotoxic substances. The duration and frequency of the breaks shall be determined by taking into account the assessment of the risks to safety and health at work.’;

(4) in Article 18a, the following paragraph is added:

‘12. The Commission shall take into account any new developments in scientific knowledge, including the opinions of the Committee for Risk Assessment of the European Chemicals Agency, and shall assess, after appropriate consultation of relevant stakeholders, where appropriate, whether to set additional limit values for substances contained in welding fumes as referred to in Annex I, point (9), to this Directive.’;

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

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by … [two years after the date of entry into force of this Directive]. 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 reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. 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 3

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

Article 4

This Directive is addressed to the Member States.

Done at Strasbourg, …

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

ANNEX

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), (b)(ii) and (ba)(ii))';

(2) in Annex I, the following point is added:

'9. Work involving exposure to fumes from welding processes containing substances or mixtures which meet the criteria for classification as a category 1A or 1B carcinogen, mutagen or reproductive toxicant set out in Annex I to Regulation (EC) No 1272/2008*.

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* Exposure shall not exceed the limit value of a carcinogen, mutagen or a reprotoxic substance as set out in Annex III to this Directive when those substances are released during the welding process.';

(3) in Annex III, point A is amended as follows:

(a) in the table, the row related to ‘Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are carcinogens within the meaning of this Directive’, 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 [5]	ppm[6]	f/ml[7]		
Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are carcinogens, mutagens or reprotoxic substances as defined in this Directive			0,00007[17]						Skin[10]	Limit value 0,00014[17] until … [OJ: seven years after the date of entry into force of the amending Directive] limited to the following sectors: (1) steel and iron foundries, which include ferroalloy manufacturers; (2) aluminium manufacturers; (3) carbon and graphite manufacturers; (4) coking plants; (5) coal tar distillation; (6) refractory products manufacturers; (7) train track welding; (8) other non-ferrous metallurgical processes; and (9) metal casting.

[17] Measured as benzo[a]pyrene.’;

(b) in the table, the row related to ‘Mercury and divalent inorganic mercury compounds including mercuric oxide and mercuric chloride (measured as mercury)’ is replaced by the following:

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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 [5]	ppm[6]	f/ml[7]		
Mercury and divalent inorganic mercury compounds that fall within the scope of this Directive (measured as mercury)			0,02							

’;

(c) in the table, the following rows are added:

‘

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 [5]	ppm[6]	f/ml[7]		
Cobalt and inorganic cobalt compounds			0,01[18] 0,0025[19]						dermal and respiratory sensitisation[13]	Limit value of 0,02[18] and 0,0042[19] until … [OJ: six years after the date of entry into force of the amending Directive]
Isoprene	201-143-3	78-79-5	8,5	3						
1,4-dioxane	204-661-8	123-91-1	7,3	2		73	20		Skin[10]	

[18] Inhalable fraction, measured as cobalt.

[19] Respirable fraction, measured as cobalt.’;

(4) Annex IIIa is replaced by the following:

‘ANNEX IIIa

BIOLOGICAL LIMIT VALUES AND HEALTH SURVEILLANCE MEASURES

(Article 16(4))

1. Lead and its inorganic compounds

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

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*

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.

2. 1,4-dioxane

The binding biological limit value is 45 mg HEAA** in urine/g creatinine, measured at the end of exposure or shift, in accordance with national law or practice.

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* 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 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.

** (2-Hydroxyethoxy)acetic acid.'.