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Subject:	Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC as regards the addition of substances and setting limit values in its Annexes I, III and IIIa *- Letter to the Chair of the European Parliament Committee on Employment and Social Affairs (EMPL)*

Following the Permanent Representatives Committee meeting of 22 July 2026 which endorsed the final compromise text with a view to an agreement, delegations are informed that the Presidency sent the attached letter, together with its Annex, to the Chair of the European Parliament Committee on Employment and Social Affairs (EMPL).

ANNEX

Council of the European Union

SGS 26/02704

Brussels, 22/07/2026

Ms Li ANDERSSON
Chair of the Committee on Employment and Social Affairs
European Parliament
Rue Wiertz 60
B-1047 BRUSSELS

Subject: Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC as regards the addition of substances and setting limit values in its Annexes I, III and IIIa

Dear Ms ANDERSSON,

Following the informal negotiations on this proposal between the representatives of the three institutions, today the Permanent Representatives Committee agreed with the final compromise text.

I am therefore now in a position to inform you that, should the European Parliament adopt its position at first reading, in accordance with Article 294(3) TFEU, in the exact form of the text set out in the Annex to this letter (subject to revision by the lawyer-linguists of the two institutions), the Council, in accordance with Article 294(4) TFEU, will approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the position of the European Parliament.

On behalf of the Council, I also wish to thank you for your close cooperation which should enable us to reach agreement on this file at first reading.

Yours sincerely

Cáit MORAN
Chair of the
Permanent Representatives Committee (Part 1)

Copy:
- Ms Roxana MÎNZATU European Commission Vice-President
- Ms Liesbet SOMMEN, European Parliament rapporteur

Rue de la Loi/Wetstraat 175 – 1048 Bruxelles/Brussel – Belgique/België
Tél./Tel. +32 (0)2 281 61 11

ANNEX

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directive 2004/37/EC as regards the addition of substances and setting limit values in its Annexes I, III and IIIa

(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[2],

Acting in accordance with the ordinary legislative procedure,

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1 OJ C [...], [...], p. [...].
2 OJ C [...], [...], p. [...].

Whereas:

(1) 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 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 workplace across the Union and reflect a broad consensus. Opinions of the ACSH, which are the outcome of tripartite consensus, are of particular importance in this context and should be duly taken into consideration. In accordance with the Interinstitutional Agreement 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 their economic, social, and environmental impacts. Its proposals should respect the principles of subsidiarity and proportionality, in line with the Treaties.***

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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) (codified version), (OJ L 158, 30.4.2004, p. 50).

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).

6 ***OJ L 123, 12.5.2016, p 1***

(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 under 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 the scientific and administrative needs.***

(2a) 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' 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 substances with those of carcinogens and mutagens.

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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).

(2b) ***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 risk). Therefore, it is essential that the existence of such residual risks are communicated to workers in a clear and transparent manner during the training of workers foreseen under Directive 2004/37/EC. A list of residual risks associated with the existing binding OELs for carcinogens under Directives 2004/37/EC and 2009/148/EC was adopted by consensus by the ACSH.***[8]

(2c) ***Workers may be more exposed and more vulnerable to different types of substances depending on their gender, and this should continue to be considered in occupational health and safety research, scientific studies and in the opinions of the RAC and ACSH, while taking into account the objective of participation of men and women in the labour market.***

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8 *ACSH Opinion WPC on Residual Risks-Doc document 016-25 adopted on 10.12.2025. https://osha.europa.eu/en/legislation/directive/directive-200437ec-carcinogens-or-mutagens-work*

(2d) ***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 also essential to ensure that all 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 also recognises the right of workers to a high level of protection of their health and safety at work, which includes protection from the exposure to carcinogens, mutagens and reprotoxic substances at the place of work. In this regard, the process for setting occupational exposure limit values takes into account not only scientific and health considerations, but also socioeconomic aspects, which in some cases justifies the establishment of transitional periods.***

(3) The IARC classified welding fumes as 'carcinogenic to humans' (Group 1 of the IARC classification). According to the ECHA Scoping Study[9] ***report***, welding fumes ***and fumes from other processes that generate fumes in a similar way*** are complex and may 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 regarding the impact on workers' health and safety recommended to include 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 the Regulation (EC) 1272/2008, contribute to a lack of clarity on their possible dangerousness for workers, and therefore a lack of appropriate risk management measures at the workplace. Addressing that absence of classification for welding fumes at Union level would ensure more legal clarity in terms of the application of Directive 2004/37EC. It is therefore appropriate, in line with the opinion of the ACSH[10], 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[11] developed by the Senior Labour Inspectorate Committee in 2018, further EU 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 SMEs including microenterprises, in ensuring compliance with the relevant welding fumes entry in Annex I to Directive 2004/37/EC. Such guidance could serve to***

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9 ECHA (2022), 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, available at: report_welding_fumes_en.pdf (europa.eu)

10 ACSH (2023), Opinion on introducing work involving exposure to fumes from welding processes containing substances that meet the criteria for CMR category 1A/1B set out in Annex I to the CLP Regulation, Doc. 006/23, available at: ACSH Adopted opinion Welding fumes 22.09.23-EN.pdf (europa.eu)

11 ***Senior Labour Inspectors Committee (2018), Guidance for National Labour Inspectors on addressing health risks from Welding Fume. Available at: https://circabc.europa.eu/ui/group/fea534f4-2590-4490-bca6-504782b47c79/library/b13cee56-02e8-4b86-9b39-f4c61af8c98c***

promote, inter alia, a common minimum high level of protection for all workers exposed to welding fumes across the Member States.

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

(5) The ***ACSH***, based on the RAC opinion[12], agreed that exposure to cobalt and its inorganic compounds in the workplace may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish limit values for both the inhalable and respirable fractions of cobalt and its inorganic compounds within the scope of Directive 2004/37/EC and to assign to it a notation for dermal and respiratory sensitisation.

(6) For cobalt and its inorganic compounds, it is foreseeable that it will be difficult to comply with a limit value of 0,01 mg/m³ for the inhalable fraction and 0,0025 mg/m³ for the respirable fraction in the short term. It is therefore appropriate to introduce a transitional period of six years after 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) should apply.

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[12] ***https://echa.europa.eu/oels-activity-list/-/substance-rev/69405***

(6a) ***Cobalt is used in several sectors of strategic importance to reach the goals set out in the European Green Deal and Union Climate Law, such as the batteries sector. 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[13], making it particularly important to ensure a high level of protection of workers' health and safety. OELs for Cobalt and its inorganic compounds are thus necessary to help prevent long-term effects on the health and wellbeing of workers and to support the attractiveness, competitiveness and thus 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 regulation.***

(6b) ***Certain sectors where workers are exposed to substances such as cobalt and PAHs may face difficulties in complying with the occupational exposure limits (OELs). In those sectors where exposure cannot be avoided or adequately reduced by other means, as referred to in Article 5(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 Directive 2004/37/EC, to ensure that workers are appropriately protected. It is necessary that all Member States implement the rules in accordance with the hierarchy of controls set out in Article 5(5), to eliminate or minimise workers' exposure in a consistent manner, in order to ensure a level playing field.***

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13 *Commission Staff Working Document, Impact Assessment Report accompanying the Proposal for a Directive amending Directive 2004/37/EC, SWD(2025) 192 final https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025SC0192#:~:text=Document%2052025SC0192,SWD/2025/192%20final*

(6c) ***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 this context, personal protective equipment (PPE), in particular individual respiratory protection equipment, should be used as a last resort. It is necessary to ensure that PPE is chosen and used in accordance with Article 4 and 5 of Directive 89/656/EEC, including the requirement that all PPE fits the wearer correctly after any necessary adjustment, and complies with the relevant Union provisions on design and manufacture with respect to safety and health, in particular Regulation (EU) 2016/425. 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.***

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

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14 https://echa.europa.eu/oels-activity-list/-/substance-rev/63901

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

(8a) ***Available scientific and technical data, including the RAC[15] and ACSH opinions, indicates that isoprene meets the criteria for classification as carcinogenic (category 1B) 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 longterm occupational exposure limit value of 8,5 mg/m3 (3 ppm), with a view to preventing potential risks to workers' health and to securing a level-playing field across Member States.***

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15 ***https://echa.europa.eu/oels-activity-list/-/substance-rev/62301/term***

(9) 1,4-dioxane meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is therefore appropriate, based on the available information, including scientific and technical data, including the RAC[16] and ACSH opinions, to establish a long- and short-term occupational exposure limit value of 7,3 mg/m³ (2 ppm) and 73 mg/m³ (20 ppm), respectively, supplemented by a skin notation and 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***.

(9a) Directive (EU) 2022/431 of the European Parliament and the Council[17] 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. The term 'mercury and divalent inorganic mercury compounds including mercuric oxide and mercuric chloride (measured as mercury)' should therefore be replaced by the term 'mercury and divalent inorganic mercury compounds that fall within the scope of Directive 2004/37/EC (measured as mercury)'.

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16 https://echa.europa.eu/oels-activity-list/-/substance-rev/61801

17 ***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).***

(9b) ***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 identification of these substances, on 20 February 2025 the Commission published 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 the provisions of Directive 2004/37/EC to safeguard the health and safety of exposed workers'.***

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

(11) 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[18]. When establishing or revising limit values, the Commission should consult the RAC and the ACSH to ensure that they are evidence-based, proportionate and measurable.

(11a) ***The ordinary legislative procedure to set binding limit values under Directive 2004/37/EC is essential because amending that Directive is not a matter for technical consideration alone but requires political assessment.***

(11b) ***Certain workers, in particular emergency services personnel such as firefighters, 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 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 emergency services personnel against inter alia polycyclic aromatic hydrocarbons (PAHs) thereby reducing the risk of occupational diseases. Guidance has already been developed on risks arising from asbestos exposure, including sector-specific guidance for firefighters and emergency services personnel. In view of the specific and high-level risks inherent to emergency services, it is important that 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 that sector.***

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18 OJ L 123, 12.5.2016, p. 1.

(11c) ***Workers are often exposed to a cocktail of hazardous substances at the workplace, 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 organs, tissues or cells, it may be necessary to adapt the implementation of the occupational limit values established pursuant to Directive 2004/37/EC, to take into account their combined effects. This is relevant, inter alia, for firefighters and emergency services personnel. When preparing Union guidelines on the effects of exposure to a combination of substances, the Commission should take into consideration the relevant specificities of these services. Such guidelines should be published on the EU-OSHA website and disseminated in all Member States by the relevant competent authorities.***

(11e) ***There is a need for workers to receive sufficient and appropriate training, on the basis of all available information, when they are exposed 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 Article 11 of 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, and repeated periodically if necessary.***

(11f) ***Union-wide data from work-related health problems due to exposure to cobalt and its inorganic compounds, polycyclic aromatic hydrocarbons, isoprene and 1,4-dioxane are often absent, unreliable or insufficient. Therefore, it could be appropriate for the Commission to consider developing recommendations for data collection by the Member States to improve the reporting and exposures registries.***

(12) 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 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.

(12a) ***Directive 2004/37/EC should therefore be amended accordingly,***

(12b) ***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 this Directive. 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 and microenterprises have the capacity to comply with Directive 2004/37/EC, are not disproportionately affected, in particular with administrative requirements, and can progress towards the elimination of risks relating to exposure to carcinogens, mutagens and reprotoxic substances at the workplace, thus benefitting all workers.***

(12c) ***The ACSH adopted on 29 May 2024 an Opinion[19] on priority chemicals for new or revised occupational exposure limit values under the Union legal framework on occupational safety and health, which contains a list of priority substances to be proposed for 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 dibromid). The ACSH strongly recommended that the Commission use that list when selecting chemicals for developing legislative proposals for new, or revised, limit values under Directive 2004/37/EC.***

HAVE ADOPTED THIS DIRECTIVE:

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[19] ***ACSH document 006-24, https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/1c3986a7-b583-4382-a6bc-d712eace2b47/details***

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;'

(-1g) *in Article 5(5), the following subparagraph is added:*

'Individual protection measures as referred to in point (g) shall include personal protective equipment (PPE), 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, PPE 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. PPE shall be correctly maintained, chosen and individually adjusted to fit the wearer, in accordance with Articles 4 and 5 of Council Directive 89/656/EEC. '

(-1h) *in Article 10, the following paragraph is added:*

'(2a) 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.'

(-1l) *in Article 18a, the following paragraph is added:*

'11c. The Commission shall take into account any new developments in scientific knowledge including the opinion of RAC, and assess after appropriate consultation with relevant stakeholders, where appropriate, whether to set additional limit values for substances contained in welding fumes as defined in Annex I to Directive 2004/37/EC.'

(2) 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 Brussels,

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))"

(1) in Annex I, the following point 9 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[1];

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[1] Exposure shall not exceed the limit value of a carcinogen, mutagen or a reprotoxic substance as set out in Annex III when those substances are released during the welding process.'

(2) 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	ECNo (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)		
Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are			0,00007(*2)						Skin (10)	Limit value 0,00014(*2) until …[OJ: ***seven*** years after the date of entry into force of the amending Directive]

carcinogens, mutagens or reprotoxicants within the meaning of this Directive										limited to the following sectors: (1) steel and iron foundries, which includes ferroalloy manufacturers, (2) aluminium manufacturers, (3) carbon and graphite manufacturers, (4) coking plants, (5) coal tar distillation, (6) refractory products manufacturers, (7) welding of train tracks, (8) other non-ferrous metallurgical processes, and (9) casting of metals.

‘ ’

(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:

‘ ‘

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)		

Mercury and divalent inorganic mercury compounds that fall under 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/m3 (5)	ppm (6)	f/ml (7)	mg/m3 (5)	ppm (6)	f/ml (7)		
Cobalt and inorganic cobalt compounds			0,01(17) 0,0025(18)		□	□	□	□	dermal and respiratory sensitisation(13)	Limit value of 0,02(17) and 0,0042(18) 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])	

';'

(ca) in the footnotes after the Table, the following footnotes ([17]) and ([18]) are added:

''([17]) Inhalable fraction, measured as Cobalt.

([18]) Respirable fraction, measured as Cobalt.' '

(d) in the footnotes after the Table, the following footnote ([*2]) is added:

'([*2]) Measured as benzo[a]pyrene.;'

(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 for 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 for 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.

▌

(10) Substantial contribution to the total body burden via dermal exposure possible.

▌

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

(3) in Annex IIIa, the following point is added:

'1,4-dioxane

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