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NOTE

From:	General Secretariat of the Council
To:	Delegations
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

With a view to the meeting of the Social Questions Working Party on 1 October 2025, delegations will find attached a first Presidency compromise text on the above proposal.

Changes compared to the Commission proposal (11823/25 + ADD1) are in **bold** and deletions are marked with **[…]**.

Delegations are invited to examine the Presidency compromise text in the Annex to this note and to provide their feedback at the Social Questions Working Party meeting scheduled for 1 October 2025.

Delegations will also be invited to send their drafting suggestions and written comments via the Consultation in the Delegates Portal by 3 October 2025, 18h00. The related working document with the template in table format will follow.

ANNEX

2025/0232 (COD)

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

(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,

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

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

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, if possible, 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)[5].

(2) Directive 2004/37/EC covers substances or mixtures which meet the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[6] 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 that Annex I to demonstrate that these substances, mixtures and processes fall under the scope of Directive 2004/37/EC, 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 that substance.

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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] 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).

(3) The IARC classified welding fumes as 'carcinogenic to humans' (Group 1 of the IARC classification). According to the ECHA scoping study[7], welding fumes are complex and may include carcinogens, mutagens or reprotoxic substances, such as chromium(VI) compounds, nickel compounds, cadmium and its inorganic compounds. 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[8], to include in Annex I to Directive 2004/37/EC work involving exposure to fumes from welding processes containing substances **or mixtures** that meet **[…]** the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic **substance** set out in Annex I to Regulation (EC) No 1272/2008.

(4) Cobalt metal and several cobalt compounds meet the criteria for classification as carcinogenic and reprotoxicant (category 1B) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens or reprotoxics 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 Advisory Committee on Safety and Health at Work (ACSH) set up by Council Decision of 22 July 2003[9], based on the RAC opinion[10], 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

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[7] 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)

[8] 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)

[9] OJ C 218, 13.9.2003, p. 1.

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

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.

(7) Certain polycyclic aromatic hydrocarbons (PAHs) mixtures, particularly those containing benzo[a]pyrene, meet the criteria for classification as carcinogenic, mutagenic or reprotoxicant (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[11] 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.

(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 six 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 electrode 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.

(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,

[11] https://echa.europa.eu/oels-activity-list/-/substance-rev/63901

including scientific and technical data, including the RAC[12] 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, at the end of exposure or shift.

(9a) Directive (EU) 2022/431 of the European Parliament and the Council 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 under 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 under the scope of Directive 2004/37/EC (measured as mercury)'.

(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[13]. When establishing or revising limit values, the Commission

[12]https://echa.europa.eu/oels-activity-list/-/substance-rev/61801
[13]OJ L 123, 12.5.2016, p. 1.

should consult the RAC and the ACSH to ensure that they are evidence-based, proportionate and measurable.

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

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2004/37/EC is amended as follows:

1) In Article 2, 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 as well as a substance or mixture released by a process referred to in that Annex;'

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

Article 2

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 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 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:

(0) 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** that meet **[…]** the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic **substance** set out in Annex I to Regulation (EC) No 1272/2008[14];

(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	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	ppm	f/ml		
Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are carcinogens, mutagens or reprotoxicants within the meaning of this Directive			0,00007(*2)						Skin (10)	*Limit value 0,00014(*2) until ...[OJ: six years after the date of entry into force of the amending Directive] limited to the following sectors: (1) steel and iron foundries, which includes ferroalloy manufacturers, (2) aluminium manufacturers, (3) carbon and graphite electrode manufacturers, (4)*

[14] 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.

										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/m^3 ([5])	ppm ([6])	f/ml ([7])	mg/m^3	ppm	f/ml		
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/m^3 ([5])	ppm ([6])	f/ml ([7])	mg/m^3	ppm	f/ml		
Cobalt and inorganic cobalt compounds			0,01 […] ([17]) 0,002 5 […] ([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]
1,4-dioxane	**204-661-8**	**123-91-1**	7,3	2		73	20		Skin ([10])	

’;

(cc) 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.’

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*(2-Hydroxyethoxy)acetic acid’.