



2025/0232(COD)

11.12.2025

*****I**

DRAFT REPORT

on the 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 (COM(2025)0418 – C10-0180/2025 – 2025/0232(COD))

Committee on Employment and Social Affairs

Rapporteur: Liesbet Sommen

Symbols for procedures

- * Consultation procedure
- *** Consent procedure
- ***I Ordinary legislative procedure (first reading)
- ***II Ordinary legislative procedure (second reading)
- ***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▬ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the 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
(COM(2025)0418 – C10-0180/2025 – 2025/0232(COD))**

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2025)0418),
 - having regard to Article 294(2) and Article 153 (1) and (2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C10-0180/2025),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 60 of its Rules of Procedure,
 - having regard to the report of the Committee on Employment and Social Affairs (A10-0000/2025),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

Proposal for a directive

Recital 2

Text proposed by the Commission

(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 Council⁶ as well as substances,

Amendment

(2) Directive 2004/37/EC covers substances **and** 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 Council⁶ 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*.

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).

mixtures *and* 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 *within* 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 *those substances, mixtures and processes*.

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).

Or. en

Amendment 2

Proposal for a directive

Recital 3

Text proposed by the Commission

(3) The IARC classified welding fumes as ‘carcinogenic to humans’ (Group 1 of the IARC classification). According to the ECHA scoping study⁷, *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

Amendment

(3) The IARC classified welding fumes as ‘carcinogenic to humans’ (Group 1 of the IARC classification). According to the ECHA scoping study, fumes *from welding and from 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 complexity and heterogeneity of welding *and other* fumes, together with the absence of harmonised classification in the Regulation (EC) 1272/2008, contribute to a lack of clarity

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 2004/37/EC. It is therefore appropriate, in line with the opinion of the ACSH⁸, to include in Annex I to Directive 2004/37/EC work involving exposure to fumes from welding processes containing substances that meet ***the criteria for a substance or mixture which meets 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.***

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 2004/37/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 ***and from processes that generate fumes in a similar way, containing substances or mixtures that 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. That ACSH⁸ opinion also identified the need for further measures to reduce health effects of exposure to particulates from welding fumes and other sources, including the establishment of a general dust limit under Council Directive 98/24/EC^{8a}. Furthermore the ACSH recommended the development of guidance on welding fumes. In addition to the existing guidance, such as the Guidance for National Labour Inspectors on addressing health risks from welding fumes developed by the Senior Labour Inspectorate Committee in 2018, further guidance, based on the latest scientific evidence, could be crucial in assisting labour inspectors and enterprises, especially microenterprises and SMEs and, in ensuring compliance with the relevant 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 for all workers exposed to welding fumes across the Member States. It is also appropriate for the Commission to prioritise the assessment of whether further guidance to evaluate the current EU Strategic Framework on Health and Safety at Work and develop the possible post-2027 EU Strategic Framework is***

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)

appropriate.

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)

^{8a} ***Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11, ELI: <http://data.europa.eu/eli/dir/1998/24/oj>).***

Or. en

Amendment 3

Proposal for a directive

Recital 6

Text proposed by the Commission

(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.

Amendment

(6) For cobalt and its inorganic compounds, the limit values of 0,02 mg/m³ (inhalable fraction) and 0,0042 mg/m³ (respirable fraction) should apply.

Amendment 4

Proposal for a directive Recital 9

Text proposed by the Commission

(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 RAC¹² 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.

¹² <https://echa.europa.eu/oels-activity-list/-/substance-rev/61801>

Amendment

(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 RAC¹² 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.

¹² <https://echa.europa.eu/oels-activity-list/-/substance-rev/61801>

Amendment 5

Proposal for a directive Recital 12 a (new)

Text proposed by the Commission

Amendment

(12a) The employers' obligations laid down in this Directive should take into account the fact that microenterprises and SMEs, which represent a large majority of enterprises in the Union, have limited financial, technical and human resources. In order to ensure the highest possible protection of workers in all enterprises, Member States should assess the impact

of the implementation of this Directive and the related administrative burden on those enterprises, in order to ensure that they are not disproportionately affected, with a specific focus on microenterprises, and to publish the results of such assessments. In doing so, Member States should maintain equal protection for all workers and facilitate compliance of microenterprises and SMEs. Against that background, specific measures, such as financial and administrative support, could help microenterprises and SMEs to further comply with the obligations laid down in Directive 2004/37/EC and to progress towards the elimination of risks relating to exposure to carcinogens, mutagens and reprotoxic substances at the workplace, thus benefitting all workers.

Or. en

Amendment 6

Proposal for a directive Recital 12 b (new)

Text proposed by the Commission

Amendment

(12b) 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. 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.

Or. en

Amendment 7

Proposal for a directive Recital 12 c (new)

Text proposed by the Commission

Amendment

(12c) Because of the harmful properties of cobalt and its inorganic compounds, relocation of cobalt-processing enterprises to third countries with less stringent occupational safety and health regulations needs to be avoided at all times.

Or. en

Amendment 8

**Proposal for a directive
Recital 12 d (new)**

Text proposed by the Commission

Amendment

(12d) Some of the substances covered by this Directive, such as cobalt, are considered essential for safeguarding the Union's strategic autonomy and ensuring the resilience of key industrial value chains. For those substances, in the absence of appropriate alternatives, the Commission should assess the socio-economic benefits arising from their continued use against the risks posed to workers in the relevant sectors. In light of evolving geopolitical realities and their potential impact on supply chains and strategic dependencies, such assessments should be reviewed at regular intervals. On the basis of those assessments, and in consultation with the social partners, the Commission should consider targeted and limited exemptions to existing or new limit values, strictly confined to activities where such uses remain indispensable for the Union's strategic interests.

Or. en

Amendment 9

**Proposal for a directive
Recital 12 e (new)**

Text proposed by the Commission

Amendment

(12e) 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. The Commission should develop guidelines and recommendations for data collection by the Member States to improve the reporting and exposures registries.

Or. en

Amendment 10

**Proposal for a directive
Recital 12 f (new)**

Text proposed by the Commission

Amendment

(12f) The limit values established in this Directive should be kept under regular scrutiny and strictly reviewed at least every five years on the basis of advances in knowledge and technologies, in order to ensure ongoing consistency with Regulation (EC) No 1907/2006 and with social, economic and technological developments.

Or. en

Amendment 11

**Proposal for a directive
Recital 12 g (new)**

Text proposed by the Commission

Amendment

(12g) 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 cell or tissue,

it is necessary to adapt the implementation of their possible limit values to take into account the combined effects.

Or. en

Amendment 12

Proposal for a directive Recital 12 h (new)

Text proposed by the Commission

Amendment

(12h) Directive (EU) 2022/431 of the European Parliament and the Council^{1a} 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)’.

^{1a} 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).

Or. en

Amendment 13

Proposal for a directive Recital 12 i (new)

Text proposed by the Commission

Amendment

(12i) Isoprene 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 RAC12 and ACSH opinions, to establish a longterm occupational exposure limit value of 8,5 mg/m³ (3 ppm).

Or. en

Amendment 14

Proposal for a directive Recital 12 j (new)

Text proposed by the Commission

Amendment

(12j) Firefighters and emergency services personnel are at risk of exposure to carcinogens, mutagens and reprotoxic substances in the course of their work. The World Health Organization has classified the occupational exposure of firefighters as carcinogenic. The occupational exposure of firefighters includes a variety of hazards resulting from fires and from non-fire events. It is therefore important that the employers of firefighters, including volunteer firefighters, and emergency services personnel assess, in accordance with Directive 2004/37/EC, the risk of exposure to carcinogens, mutagens and reprotoxic substances and that they take the necessary measures to protect the health and safety of those workers.

Amendment 15

Proposal for a directive Recital 12 k (new)

Text proposed by the Commission

Amendment

(12k) There is a need for workers to receive sufficient and appropriate training 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.

Or. en

Amendment 16

Proposal for a directive Recital 12 l (new)

Text proposed by the Commission

Amendment

(12l) Gender-specific differences in exposure patterns, physiological susceptibility and health outcomes remain insufficiently reflected in occupational safety and health research, particularly in relation to chemical risks. The Commission should therefore include a systematic integration of the gender dimension in assessments of future revisions of this Directive.

Or. en

Amendment 17

Proposal for a directive

Article 1 – paragraph 1 – point -1 (new)

Directive 2004/37/EC

Article 2 – paragraph 1 – point a – point ii

Present text

(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;

Amendment

(-1) In Article 2, point (a)(ii) is replaced by the following:

‘(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, included in the list set out in that Annex because of its carcinogenic effects;’;

Or. en

Amendment 18

Proposal for a directive

Article 1 – paragraph 1 – point -1 a (new)

Directive 2004/37/EC

Article 2 – paragraph 1 – point b – point ii

Present text

(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;

Amendment

(-1a) In Article 2, point (b)(ii) is replaced by the following:

‘(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, included in the list set out in that Annex because of its carcinogenic effects;’;

Or. en

Amendment 19

Proposal for a directive

Article 1 – paragraph 1 – point -1 b (new)

Directive 2004/37/EC

Article 2 – paragraph 1 – point ba

Present text

(ba) ‘reprotoxic substance’ means 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;

Amendment

(-1b) 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, included in the list set out in that Annex because of its reprotoxic effects;’;

Or. en

Amendment 20

Proposal for a directive

Article 1 – paragraph 1 – point -1 c (new)

Directive 2004/37/EC

Article 10 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

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

‘2a. Workers shall be entitled to proportionate and regular breaks when wearing protective equipment.’;

Or. en

Amendment 21

Proposal for a directive

Article 1 – paragraph 1 – point -1 d (new)

Directive 2004/37/EC
Article 18a – point 7

Present text

7. No later than **31 December 2024**, the Commission shall, taking into account the latest developments in scientific knowledge, **and after appropriate consultation of relevant stakeholders, propose, where appropriate, a limit value** for cobalt and inorganic cobalt compounds.

Amendment

(-1d) in Article 18a, point 7 is replaced by the following:

‘7. No later than ... **[four years after the date of entry into force of this amending Directive]**, the Commission shall, taking into account the latest developments in scientific knowledge, **evaluate the limit value** for cobalt and inorganic cobalt compounds **by carrying out a new impact assessment taking into account evolving geopolitical realities and the Union's strategic independence, while preserving the highest possible protection for exposed workers. Where appropriate, the Commission shall, in consultation with relevant stakeholders, including the social partners, submit a legislative proposal to lower that limit value.**’;

Or. en

(<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004L0037-20240408>)

Amendment 22

Proposal for a directive
Annex – paragraph 1 – point -1 (new)
Directive 2004/37/EC
Annex I – title

Present text

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

Amendment

(-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)**)’;

Or. en

Amendment 23

Proposal for a directive
Annex – paragraph 1 – point 1
Directive 2004/37/EC
Annex I – point 9

Text proposed by the Commission

9. Work involving exposure to fumes from welding processes containing substances that meet ***the criteria for a substance or mixture which meets*** the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic set out in Annex I to Regulation (EC) No 1272/2008¹ ;

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.

Amendment

9. Work involving exposure to fumes from welding ***and from*** processes ***that generate fumes in a similar way,*** containing substances that meet the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic set out in Annex I to Regulation (EC) No 1272/2008¹;

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.

Or. en

Amendment 24

Proposal for a directive
Annex – paragraph 1 – point 2 – point c
Directive 2004/37/EC
Annex III – point A – table – row 42

Text proposed by the Commission

			<i>Limit values</i>							
			<i>8 hours ⁽³⁾</i>			<i>Short-term ⁽⁴⁾</i>				
Name of agent	EC No ⁽¹⁾	CAS No (2)	mg/m ³ ⁽⁵⁾	ppm ⁽⁶⁾	f/ml ⁽⁷⁾	mg/m ₃	ppm	f/ml	Notation	Transitional measures
Cobalt and inorganic cobalt compounds			0,01⁽¹¹⁾ 0,0025⁽⁹⁾		-	-	-	-	dermal and respiratory sensitisation ⁽¹³⁾	<i>Limit value of 0,02⁽¹¹⁾ and 0,0042⁽⁹⁾ until ...[OJ: six years after the date of entry into force of the amending Directive]</i>

⁽⁹⁾ Respirable fraction.

⁽¹¹⁾ Inhalable fraction.

Amendment

Name of agent	EC No ⁽¹⁾	CAS No (2)	mg/m ³ ⁽⁵⁾	ppm ⁽⁶⁾	f/ml ⁽⁷⁾	mg/m ₃	ppm	f/ml	Notation	Transitional measures
Cobalt and inorganic cobalt compounds			0,02^(16b) 0,0042^(16a)		-	-	-	-	dermal and respiratory sensitisation ⁽¹³⁾	<i>deleted</i>

^(16a) ***Respirable fraction, measured as Cobalt.***

^(16b) ***Inhalable fraction, measured as Cobalt.***

Or. en

Amendment 25

Proposal for a directive

Annex – paragraph 1 – point 2 – point c

Directive 2004/37/EC

Annex III – point A – table – row 42 a (new)

Text proposed by the Commission

Amendment

Name of agent	EC No (1)	CAS No (2)	mg/m ³ (5)	ppm (6)	f/ml(7)	mg/m ₃	ppm	f/ml	Notation	Transitional measures
<i>Isoprene</i>	<i>201-143-3</i>	<i>78-79-5</i>	<i>8,5</i>	<i>3</i>	-	-	-	-		

Or. en

Amendment 26

Proposal for a directive
Annex – paragraph 1 – point 3
Directive 2004/37/EC
Annex IIIa

Text proposed by the Commission

2. The binding biological limit value is 45 mg HEAA*in urine/g creatinine.'

Amendment

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

Or. en

EXPLANATORY STATEMENT

Occupational exposure to hazardous substances remains one of the most serious risks to workers' health in the European Union. Each year about 120,000 work-related cancer cases occur as a result of exposure to carcinogens at work in the EU, leading to approximately 80,000 fatalities annually. Since its first adoption in 2004, the carcinogens and mutagens directive has been reviewed five times and now addresses 28 cancer-causing substances. This revision supports Europe's Beating Cancer Plan and the EU Strategic Framework on Health and Safety at Work 2021–2027, which promotes a “vision zero” approach to work-related deaths.

The sixth revision of Directive 2004/37/EC extends protection for millions of workers across sectors such as manufacturing, construction, healthcare, emergency services, waste management, and the circular economy.

Directive 2004/37/EC has a strong tradition of a multi-stage, evidence-based and consultative legislative procedure. It is very important that revised limit values are based on a scientific evaluation and on the opinion of the Advisory Committee on Safety and Health at Work (ACSH). The ACSH is composed of representatives of the Member States and the social partners. The ACSH reviews the scientific and socio-economic evidence.

Our position is based on the ACSH opinion. This includes the introduction of binding occupational exposure limit (OEL) values for cobalt and inorganic cobalt compounds, polycyclic aromatic hydrocarbons (PAHs), isoprene and 1,4-dioxane, where previously national limit values varied widely or were lacking. Moreover, we should include welding fumes, when they contain CMR substances such as chromium or nickel, among processes covered by the directive. This would mean that employers must apply protective measures when welding.

Substances such as cobalt are used in several sectors of strategic importance to reach the goals set out in the European Green Deal and the EU Climate Law. They are critical for sectors central to the industrial transition, including batteries and advanced manufacturing. The enhancement of international strategic autonomy in raw materials is one of the priorities of the European Union. Moreover, there is clearly a need to avoid relocating cobalt-processing activities to non-EU countries with weaker occupational safety standards.

Given the rapidly evolving geopolitical situation and its potential effects on supply chains and strategic dependencies, the Commission should regularly reassess substances such as cobalt. Building on these assessments, and in consultation with social partners and Member States, the Commission should consider targeted and limited exemptions to existing or new OELs. Such exemptions must be strictly limited to activities where these substances remain essential for the Union's strategic interests, and workers' protection must always remain the highest priority.

Firefighters and other emergency personnel are particularly exposed to complex mixtures of carcinogenic, mutagenic and reprotoxic substances. The WHO now classifies firefighters' occupational exposure as carcinogenic. Therefore, we need specific risk assessments, adequate protective measures, and targeted medical surveillance for these high-risk workers.

Reliable EU-wide data on exposures to substances such as cobalt, polycyclic aromatic hydrocarbons, isoprene and 1,4-dioxane remain limited. The Commission should develop guidelines and recommendations to improve national data collection and exposure registries. Enhanced EU guidance should also support labour inspectors and enterprises, particularly SMEs and microenterprises, in applying the directive effectively. This includes guidance on welding fumes and similar exposure processes, building on existing tools such as the SLIC guidance from 2018, ensuring that monitoring is evidence-based and enforcement consistent.

A strong social dialogue is essential for effective implementation. Social partners are indispensable in identifying risks, designing practical prevention measures and ensuring realistic application across sectors. Obligations must remain achievable for SMEs and microenterprises, which often operate with limited financial and technical capacity. Member States should assess administrative impacts and provide targeted support without compromising equal protection for all workers. I have introduced a clear right for workers to take proportionate and regular breaks when using protective equipment, reflecting both safety and well-being considerations.

Gender differences in exposure patterns, physiological responses and health outcomes remain insufficiently integrated into occupational safety research. Therefore, we need to systematically incorporate a gender perspective in future assessments.

Training requirements are crucial to ensure that workers receive clear, up-to-date information whenever new risks arise, including handling multiple hazardous substances or hazardous medicinal products. This approach ensures training is directly relevant to the tasks performed and the risks encountered.

This revision represents a decisive step in preventing occupational cancers and other long-term health effects across the European Union. It strengthens scientific integrity, legal certainty and protection for workers in high-risk sectors while supporting Europe's industrial resilience and strategic autonomy. It ensures that SMEs are supported in applying the rules while maintaining equal protection standards for all workers. Above all, this revision reaffirms the fundamental principle that every worker in the European Union has the right to a safe, healthy and sustainable working environment.

ANNEX: DECLARATION OF INPUT

Pursuant to Article 8 of Annex I to the Rules of Procedure, the rapporteur declares that she included in her report input on matters pertaining to the subject of the file that she received, in the preparation of the draft report, from the following interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register¹, or from the following representatives of public authorities of third countries, including their diplomatic missions and embassies:

1. Interest representatives falling within the scope of the Interinstitutional Agreement on a mandatory transparency register
European Trade Union Confederation (ETUC)
Algemeen Christelijk Vakverbond (ACV)
BusinessEurope
Council of European Employers of the Metal, Engineering and Technology-based Industries (CEEMET)
Agoria
Cobalt Institute
Duracell
European Commission - DG Employment
Permanent Representation of Cyprus to the EU
Permanent Representation of Denmark to the EU
Permanent Representation of Belgium to the EU
2. Representatives of public authorities of third countries, including their diplomatic missions and embassies

The list above is drawn up under the exclusive responsibility of the rapporteur.

Where natural persons are identified in the list by their name, by their function or by both, the rapporteur declares that she has submitted to the natural persons concerned the European Parliament's Data Protection Notice No 484 (<https://www.europarl.europa.eu/data-protect/index.do>), which sets out the conditions applicable to the processing of their personal data and the rights linked to that processing.

¹ Interinstitutional Agreement of 20 May 2021 between the European Parliament, the Council of the European Union and the European Commission on a mandatory transparency register (OJ L 207, 11.6.2021, p. 1, ELI: http://data.europa.eu/eli/agree_interinst/2021/611/oj).