European Parliament
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Committee on Employment and Social Affairs

2025/0232(COD)

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COMPROMISE AMENDMENTS 1 - 13

Draft report
Liesbet Sommen
(PE781.362 v01-00)

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

Proposal for a directive
(COM(2025)0418 – C10-0180/2025 – 2025/0232(COD))

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Compromise 1 (Definitions)

Proposed by Rapporteur

Compromise amendment replacing amendments 1, 12, 17, 18, 19, 22, 30, 31, 34, 68, 80, 81, 82, 101

CA1 part 1A
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	*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***;	‘(ii) a substance, mixture or process referred to in ***points 1 to 8 of*** Annex I to this Directive as well as a substance or mixture released by a process referred to in ***those points***;’

Or. en

CA1 part 1B
Proposal for a directive
Article 1 – paragraph 1 – point -1 (new)
Directive 2004/37/EC
Article 2 – paragraph 1 – point a – point iii (new)

Text proposed by the Commission	*Amendment*
	(-1) in Article 2, a new point (a)(iii) is added:
	‘***(iii) a substance, mixture or process referred to in point 9 of Annex I to this Directive as well as a substance or mixture released by a process referred to in that point, where it has carcinogenic effects;***’

Or. en

CA1 part 2A
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	*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***;	*'*(ii) a substance, mixture or process referred to in ***points 1 to 8 of*** Annex I to this Directive as well as a substance or mixture released by a process referred to in ***those points***,;'

Or. en

CA1 part 2B
Proposal for a directive
Article 1 – paragraph 1 – point -1 a (new)
Directive 2004/37/EC
Article 2 – paragraph 1 – point b – point iii (new)

Text proposed by the Commission	*Amendment*
	(-1a) in Article 2, a new point (b)(iii) is added:
	(iii) a substance, mixture or process referred to in point 9 of Annex I to this Directive as well as a substance or mixture released by a process referred to in that point, where it has mutagenic effects;

CA1 part 3

Proposal for a directive
Article 1 – paragraph 1 – point -1 b (new)
Directive 2004/37/EC
Article 2 – paragraph 1 – point ba

Present text	*Amendment*
	(-1b) in Article 2, point (ba) is replaced by the following:
(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	'(ba) "reprotoxic substance" means***:***

Annex I to Regulation (EC) No 1272/2008;

(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 point 9 of Annex I to this Directive as well as a substance or mixture released by a process referred to in that point, where it has reprotoxic effects;'

Or. en

CA1 part 4

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

Present text	*Amendment*
	(-1) in Annex I, the title is replaced by the following:
List of substances, mixtures and processes (Article 2, ***points*** (a)(ii) ***and*** (b)(ii))	List of substances, mixtures and processes (Article 2, ***point*** (a)(ii) ***and (iii), point*** (b)(ii) ***and point (iii) and (ba)(ii))***

Or. en

CA1 part 5 (term mercury definition)
Proposal for a directive
Recital 9a (new)

Text proposed by the Commission	*Amendment*
	(9a) 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)'.

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*[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

CA1 part 6 - Recital 2
Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(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	(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 Council[6] as well as substances, 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 ***that substance***.

published literature on ***those substances, mixtures and processes. It remains essential that the Commission accelerates the procedure for assessment of hazardous substances, mixtures and processes, with a view to setting occupational exposure limit values for a greater number thereof and ensuring the highest level of protection for workers, including by increasing the scientific and administrative capacity of all Union bodies involved***.

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[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

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[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).

Compromise 2 (Use of protective equipment)

Proposed by Rapporteur

Compromise amendment replacing amendments 20, 88, 89, 90, 91

CA2 part 1

Proposal for a directive
Article 1 – paragraph 1 – point -1 e (new)
Directive 2004/37/EC
Article 5 – paragraph 5 a (new)

Present text	*Amendment*
	(-1e) in Article 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 prevention or reduce exposure in accordance with this Article, residual exposure cannot be reduced to levels below the limit values set out in Annex III. In such cases, compliance with the limit values shall be determined taking into account the protection afforded by PPE. PPE shall be correctly maintained, selected and adjusted to fit the wearer, including by means of individual fitting, in accordance with Article 4 of Council Directive 89/656/EEC.'

Or. en

CA2 part 2

Proposal for a directive
Article 1 – paragraph 1 – point -1 f (new)
Directive 2004/37/EC
Article 10 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	(-1f) in Article 10, the following paragraph is added:
	'2a. When wearing personal protective equipment, workers shall be entitled to regular breaks of an appropriate duration in an area where there is no risk of contamination by carcinogens, mutagens or reprotoxic substances.'

Or. en

CA2 part 3

Proposal for a directive
Recital 9c (new)

Text proposed by the Commission	*Amendment*
	(9c) 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 respiratory equipment, should be used where appropriate, as a last resort. It is necessary to ensure that PPE is adjusted to a particular worker's body-type and shape and that it is appropriately maintained, so that it can be an effective tool by which to reduce or eliminate exposure. Employers should therefore ensure that PPE is individually adjusted, including through fitting checks, in accordance with Council Directive 89/656/EEC.

Compromise 3 (Future CMRD revisions / scientific input /gender dimension)

Proposed by Rapporteur

Compromise amendment replacing amendments 10, 16, 27, 28, 33, 51, 63, 70, 72, 74, 77, 79,

CA3 part 1
Proposal for a directive
Recital 1

Text proposed by the Commission	*Amendment*
(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, 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] .	(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. ***It is essential that such*** information 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]. ***Those opinions provide the 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. Rules based on such opinions can therefore be implemented in the Member States in practice. Opinions of the ACSH, which are the outcome of tripartite consensus, are of particular importance***

in this context. In the absence of opinions of the RAC or of the ACSH, the Commission should set out, in its proposal, the reasons underpinning it, on the basis of scientific evidence.

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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).

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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).

Or. en

CA3 part 2

Proposal for a directive
Article 1 – paragraph 1 – point -1 k (new)
Directive 2004/37/EC
Article 18 a – point 11c (new)

Text proposed by the Commission	*Amendment*
	(-1k) in Article 18a, the following point is added:
	'11c. Where the Commission submits a legislative proposal amending the occupational exposure limit values set out in this Directive, it shall take into account any opinions of the Committee for Risk Assessment of the European Chemicals Agency established by Regulation (EC) No 1907/2006 and the opinions of the ACSH, as appropriate. In the absence of any such opinion, the Commission shall set out, in its proposal, the reasons underpinning it, on the basis of scientific evidence.'

CA3 part 3
Proposal for a directive
Recital 11a (new)

Text proposed by the Commission	*Amendment*
	(11a) The occupational exposure limit values set by Directive 2004/37/EC are essential for ensuring minimum standards at Union level to protect workers from dangerous substances. They 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 and further lowered, where appropriate. The ordinary legislative procedure to set binding limit values under Directive 2004/37/ EC is essential because it is not a matter for technical consideration alone but requires political assessment.

Or. en

CA3 part 4
Proposal for a directive
Recital 2a (new)

Text proposed by the Commission	*Amendment*
	(2a) Workers may be more exposed and more vulnerable to different types of substances depending on their gender, and this should be considered in occupational health and safety research, scientific studies and in the opinions of the RAC and ACSH. It is essential that gender mainstreaming is an integral part of the development of all occupational safety and health policies and prevention strategies at Union level and that gender-specific vulnerability and differences in exposure patterns, physiological susceptibility and health outcomes are taken into account in future revisions of Directive 2004/37/EC, especially when setting occupational exposure limits, while ensuring the participation of men and women in the labour market.

Or. en

Compromise 4 (Entry into force of Amending Act)

Proposed by Rapporteur

Compromise amendment replacing amendments 73, 99, 100

Proposal for a directive
Article 2 – paragraph 1

Text proposed by the Commission	*Amendment*
Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by […] [***The time limit for transposition will be as short as possible and, generally, will not exceed*** two years] ***at the latest***. They shall immediately inform the Commission thereof.	Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ***no later than*** […] [two years ***after its entry into force***]. They shall immediately inform the Commission thereof.

Or. en

Compromise 5 (Welding fumes)

Proposed by Rapporteur

Compromise amendment replacing amendments 2, 23, 36, 37, 38, 39, 98, 102, 103

CA5 part 1
Proposal for a directive
Article 1 – paragraph 1 – point -1 k (new)
Directive 2004/37/EC
Article 18 a – point 11 b (new)

Text proposed by the Commission	*Amendment*
	(-1k) in Article 18a, the following point is added:
	'(11b) No later than ... [3 years after the entry into force of this amending directive], the Commission shall, taking into account the latest developments in scientific knowledge, the opinion of RAC and after appropriate consultation with relevant stakeholders, propose, where appropriate, limit value(s) for welding fumes as defined in Annex I to Directive 2004/37/EC.'

Or. en

CA5 part 2
Proposal for a directive
Annex – paragraph 1 – point 1
Directive 2004/37/EC
Annex I – point 9

Text proposed by the Commission	*Amendment*
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 1272/2008[1] ;	9. Work involving exposure to welding ***fumes and fumes from other*** 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[1] ;
[1] Exposure shall not exceed the limit value	[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.

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

CA5 part 3
Proposal for a directive
Recital 3

Text proposed by the Commission	*Amendment*
(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 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.	(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 ***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 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 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 ***welding fumes and fumes from other*** processes ***that generate fumes in a similar way,*** 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. ***That ACSH 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]. The opinion also included a strong 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 [8b] developed by the Senior Labour Inspectorate Committee in 2018, further guidance, on the basis of the latest scientific evidence, could be crucial in assisting 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 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 the usefulness of further guidance in the context of evaluating the current EU Strategic Framework on Health and Safety at Work and developing the possible post-2027 EU Strategic Framework and to promote the exchange of best practices among Member States.

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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)

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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)

[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).***

[8b] ***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/2997b89a-1fbd-4f35-9874-9a9b5ea1a403?p=1&n=-1&sort=name_ASC***

Or. en

Compromise 6 (Isoprene)

Proposed by Rapporteur

Compromise amendment replacing amendments 13, 25, 45, 46, 47, 49, 69, 109, 110, 111, 112

CA 6 part 1
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
Isoprene	***201-143-3***	***78-79-5***	***8,5***	***3***	-	-	-	-		

Or. en

CA 6 part 2

Proposal for a directive
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8 a) 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, on the basis of the available information, including scientific and technical data, including the RAC[1a] and ACSH opinions, to establish a longterm occupational exposure limit value of 8,5 mg/m3 (3 ppm).

[1a] *https://echa.europa.eu/oels-activity-list/-/substance-rev/62301/term*

Or. en

CA6 part 3

Proposal for a directive
Recital 8 b (new)

Text proposed by the Commission	*Amendment*
	(8 b) Short-term or single exposure to isoprene may cause irritation to the nose, throat, and lungs, and can lead to symptoms such as headache or dizziness. Chronic and high exposure may lead to liver cancer but also anaemia, degeneration of olfactory epithelium and degeneration of spinal cord white matter. While for the time being the exposure of workers is still low, a binding occupational exposure limit for isoprene is nevertheless needed to prevent potential risks arising in the future and to secure a level-playing field across Members States.

Or. en

Compromise 7 (1,4-dioxane)

Proposed by Rapporteur

Compromise amendment replacing amendments 4, 26, 48, 113

CA7 part 1

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

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

Or. en

CA7 part 2
Proposal for a directive
Recital 9

Text proposed by the Commission	*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 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.	(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[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, ***measured*** at the end of exposure or shift.
[12] https://echa.europa.eu/oels-activity-list/-/substance-rev/61801	[12] https://echa.europa.eu/oels-activity-list/-/substance-rev/61801

Or. en

Compromise 8 (SMEs)

Proposed by Rapporteur

Compromise amendment replacing amendments 5, 29, 54

CA8 part 1

Proposal for a directive
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12 a) Achieving a high level of protection of workers against risks related to carcinogens, mutagens and reprotoxic substances requires the effective implementation of this Directive. Member States should maintain equal protection for all workers and should 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. Member States should therefore monitor and report the effects of the implementation of this Directive on SMEs including microenterprises, in particular any administrative requirements, in order to ensure that they are not disproportionately affected and have the financial and administrative capacity to 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. Specific measures, such as financial and technical support, could help SMEs including microenterprises.

Or. en

Compromise 9 (firefighters + multi-exposure)

Proposed by Rapporteur

Compromise amendment replacing amendments 11, 14, 52, 56, 64, 65, 67, 71, 96

CA9 part 1

Proposal for a directive
Article 1 – paragraph 1 – point -1 k (new)
Directive 2004/37/EC
Article 18 a – point 11 a (new)

Text proposed by the Commission	*Amendment*
	(-1k) in Article 18a, the following point is added:
	'11a. No later than ... [12 months after the entry into force of this directive] and taking into consideration the recent classification by the World Health Organization of occupational exposure in certain occupations as carcinogenic, the Commission shall begin a consultation with the ACSH on the need to update Commission Recommendation (EU) 2022/2337, with a view to encouraging Member States to introduce provisions ensuring more adequate compensation for diseases suspected of being linked to occupational exposure in certain professions.'

CA9 part 2
Proposal for a directive
Recital 11 b (new)

Text proposed by the Commission	*Amendment*
	(11b) Firefighters and emergency services personnel are at risk of exposure to a variety of hazards resulting from fires and from non-fire events in the course of their work, including to carcinogens, mutagens and reprotoxic substances. The World Health Organization has classified

the occupational exposure of firefighters as carcinogenic. It is therefore important that the employers of firefighters, including volunteer firefighters and emergency services personnel assess, in accordance with Directive 2004/37/EC, and reduce 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, in particular with regard to decontamination and prevention in accordance with Directive 2009/148/EC following the removal of asbestos. Important guidance has also been developed on risks arising from asbestos exposure, including sector-specific guidance for firefighters and emergency services personnel. This revision should strengthen the protection of firefighters against polycyclic aromatic hydrocarbons (PAHs). To that end, the Commission, in cooperation with EU-OSHA and the ECHA should develop Union guidance for emergency services on PAHs as well as other combustion-related carcinogenic exposures, covering exposure assessment strategies, decontamination, station hygiene, handling, storage and cleaning of personal protective equipment (PPE), and prevention during clean-ups. Guidance should span across both dermal and airborne exposure routes. Employers of firefighters should implement preventive and protective measures on the basis of this guidance, as well as facilitate systematic medical surveillance, particularly after peak events, in order to better monitor medical pathways and improve health hazard data collection. Such data could feed into the ACSH opinions preliminary to future revisions of this directive, ensuring better health and safety for those workers. In addition to the necessary preventive measures provided in this directive, the Commission should consult the ACSH on the need to update its Recommendation (EU) 2022/2337[1a] on

the European schedule of occupational diseases, with a view to encouraging Member States to introduce enhanced prevention measures at the occupational level and provisions allowing for better compensation for conditions suspected to be linked to occupational exposure in certain professions.

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[1a] Commission Recommendation (EU) 2022/2337 of 28 November 2022 concerning the European schedule of occupational diseases (OJ L 309, 30.11.2022, p. 12, ELI: http://data.europa.eu/eli/reco/2022/2337/oj).

Or. en

CA9 part 3
Proposal for a directive

Recital 11c (new)

Text proposed by the Commission	*Amendment*
	(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 cell or tissue, it is necessary to adapt the implementation of their possible limit values to take into account the combined effects. This is particularly relevant for firefighters and emergency services personnel. The Commission and Member States should provide guidance on how inspectors and employers are to evaluate compliance and prevention where multiple carcinogens co-occur and encourage the development and use of appropriate methodologies and tools to address combined exposures.

Compromise 10 (Training)

Proposed by Rapporteur

Compromise amendment replacing amendments 15, 75

Proposal for a directive
Recital 11 e (new)

Text proposed by the Commission	*Amendment*
	(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.

Or. en

Compromise 11 (HMPs and medicinal products)

Proposed by Rapporteur

Compromise amendment replacing amendments 58, 83, 84, 85, 86, 87, 104, 105, 106

CA 11 - Part 1
Proposal for a directive
Article 1 – paragraph 1 – point -1 b (new)
Directive 2004/37/EC
Article 2 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(-1b) in Article 2, the following point is added.
	'(ea) "hazardous medicinal products" means medicinal products that contain one or more substances that meet the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic as set out in Annex I to Regulation (EC) No 1272/2008.'

Or. en

CA 11 - Part 2
Article 1 – paragraph 1 – point -1 c (new)
Directive 2004/37/EC
Article 2 – paragraph 1 – point e b (new)

Text proposed by the Commission	*Amendment*
	(-1c) in Article 2, the following point is added:
	'(eb) "medicinal products" means medicinal products as defined in Article 1 paragraph 2 of Directive 2001/83/EC.'

Or. en

CA 11 - Part 3
Proposal for a directive
Annex – paragraph 1 – point 1
Directive 2004/37/EC
Annex I – point 9 a (new)

Text proposed by the Commission	*Amendment*
	9a. Work involving exposure to hazardous medicinal products containing substances that meet the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic as set out in Annex I to Regulation (EC) No 1272/2008.

Or. en

CA 11 - Part 4
Proposal for a directive
Recital 9 b (new)

Text proposed by the Commission	*Amendment*
	(9 b) 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 requested the Commission to develop a definition for hazardous medicinal products, publish guidelines and establish an indicative list of hazardous medicinal products or the substances contained therein. While this work has been undertaken, no definition for hazardous medicinal products have to date been included in Union legislation. In order to ensure legal completeness and provide regulatory clarity on the matter, it is therefore appropriate to add such a definition in this Directive.

Or. en

Draft CA 12 on residual risks

Proposed by Rapporteur
Compromise amendment replacing amendments 32, 61, 66, 78

CA12 Part 1
Proposal for a directive
Recital 11d(new)

Text proposed by the Commission	*Amendment*
	(11d) Directive 2004/37/EC sets binding OELs for certain substances for which there is no safe level of exposure for workers' health. However, such binding OELs do not eliminate residual risks. As many of such carcinogens cannot be eliminated, substituted or have exposure to them minimised, it is essential that such residual risks are communicated to workers clearly and openly 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 [1a].

[1a] 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

Or. en

Justification

A list of residual risks associated with Binding Occupational Exposure Limit Values of carcinogens under the CMRD (2004/37/EC) and the Asbestos at Work Directive (2009/148/EC) is available at the following link of the European agency EU-OSHA: https://osha.europa.eu/en/legislation/directive/directive-200437ec-carcinogens-or-mutagens-work

CA12 Part 2

Proposal for a directive
Article 1 – paragraph 1 – point -1 g (new)

Directive 2004/37/EC
Article 11 – paragraph 1

Text proposed by the Commission	*Amendment*
	(-1g) in Article 11, paragraph 1 point (a) is replaced by the following:
	‘
	a) potential risks to health, including the additional risks due to tobacco consumption and the existence of residual risks linked to binding limit values listed in Annex III, with reference to information published by EU OSHA, where available;’

Or. en

Compromise 13 (Cobalt/strategic autonomy)

Proposed by Rapporteur

Compromise amendment replacing amendments 3, 6, 8, 9, 21, 24, 35, 40, 41, 42, 43, 53, 55, 57, 60, 62, 94, 94
Covering 6, 8, 9, 35, 40, 42,53, 55, 57, 60, 62, 94

CA 13 Part 1

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

			Limit values							
			8 hours ([3])			*Short-term ([4])*				
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])	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]

([9]) Respirable fraction.

([11]) Inhalable fraction.

Amendment

			Limit values							
			8 hours ([3])			*Short-term ([4])*				
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])	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]

([9]) Respirable fraction, ***measured as Cobalt.***

([11]) Inhalable fraction, ***measured as Cobalt.***

Or. en

CA 13 Part 2
Proposal for a directive

Recital 6

Text proposed by the Commission	*Amendment*
(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.	(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. ***Some sectors may face difficulties in complying with the occupational exposure limits (OELs). In those sectors it is necessary that respiratory protective equipment is available and used by workers when the lower limit values cannot be complied with otherwise, to ensure that workers are appropriately protected. It is necessary that all Member States implement the rules set out in Article 5, in accordance with the hierarchy of controls, to eliminate or minimise workers' exposure in a consistent manner, in order to ensure a level playing field.***

Or. en

CA 13 Part 3

Proposal for a directive

Recital 11f (new)

Text proposed by the Commission	*Amendment*
	(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. The Commission should develop guidelines and recommendations for data collection by the Member States to improve the reporting and exposures registries.

Or. en

CA 13 Part 4-strategic autonomy

Proposal for a directive
Recital 2 b (new)

Text proposed by the Commission	*Amendment*
	(2 b) 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, in line with the objectives of ensuring a high level of human health protection and, preventing physical illness and diseases, and obviating sources of danger to physical health laid down in Article 168(1) TFEU.

Principle 10 of the European Pillar of Social Rights also provides for 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. For certain substances, the ACSH may recommend that further revisions be considered to allow, in the light of evolving scientific, technical, and socio-economic knowledge, the adoption of solutions that guarantee a level of protection more closely aligned with acceptable levels of risk to workers' health.

Proposal for a directive
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(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 [1a], 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.

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[1a] 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

Or. en