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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

Delegations will find attached a table containing the Commission 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 (CMRD6), together with the respective mandates of the European Parliament and of the Council. Both the Council mandate and the EP mandate show changes compared to the Commission proposal.

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)

2025/0232(COD)

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
Formula			
1	2025/0232 (COD)	2025/0232 (COD)	2025/0232 (COD)
Document Stage			
2	Proposal for a	Proposal for a	Proposal for a
Document Type			
3	DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
Document Purpose			
4	amending Directive 2004/37/EC as regards the addition of substances and setting limit values in its Annexes I, III and IIIa	amending Directive 2004/37/EC as regards the addition of substances and setting limit values in its Annexes I, III and IIIa	amending Directive 2004/37/EC as regards the addition of substances and setting limit values in its Annexes I, III and IIIa
EEA Relevance			
5	(Text with EEA relevance)	(Text with EEA relevance)	(Text with EEA relevance)
Formula			
6	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
Citation 1			
7	Having regard to the Treaty on the Functioning of the European Union, and in particular	Having regard to the Treaty on the Functioning of the European Union, and in particular	Having regard to the Treaty on the Functioning of the European Union, and in particular

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
	Article 153(2), point (b), in conjunction with Article 153(1), point (a), thereof,	Article 153(2), point (b), in conjunction with Article 153(1), point (a), thereof,	Article 153(2), point (b), in conjunction with Article 153(1), point (a), thereof,
Citation 2			
8	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,
Citation 3			
9	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,
Citation 4			
10	Having regard to the opinion of the European Economic and Social Committee[1], 1. OJ C […], […], p. […].	Having regard to the opinion of the European Economic and Social Committee[1], 1. OJ C […], […], p. […].	Having regard to the opinion of the European Economic and Social Committee[1], 1. OJ C […], […], p. […].
Citation 5			
11	After consulting the Committee of the Regions[1], 1. OJ C […], […], p. […].	After consulting the Committee of the Regions[1], 1. OJ C […], […], p. […].	After consulting the Committee of the Regions[1], 1. OJ C […], […], p. […].
Citation 6			
12	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,
Formula			
13	Whereas:	Whereas:	Whereas:
Recital 1			
14	(1) To improve the protection of workers against risks from exposure to carcinogens, mutagens or reprotoxic substances at the place	(1) To improve the protection of workers against risks from exposure to carcinogens, mutagens or reprotoxic substances at the place	(1) To improve the protection of workers against risks from exposure to carcinogens, mutagens or reprotoxic substances at the place

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
	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[1] 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[2] and opinions of the Advisory Committee on Safety and Health at Work (ACSH)[3]. 1. 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). 2. 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).	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[1] 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*** ~~*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[2] and opinions of the Advisory Committee on Safety and Health at Work (ACSH)[3]. ***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.***	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[1] 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[2] and opinions of the Advisory Committee on Safety and Health at Work (ACSH) ***set up by Council Decision of 22 July 2003[3].*** ~~[3].~~ 1. 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). 2. 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

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	3. 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).	1. 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). 2. 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). 3. 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).	2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj). 3. 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)~~ *1)*.
Recital 2			
15	(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[1] 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	(2) Directive 2004/37/EC covers substances ~~or~~*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[1] as well as substances, mixtures ~~or~~*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	(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~~*reproductive toxicant* set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[1] 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 Directive 2004/37/EC* to demonstrate that ~~these~~*those* substances,

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	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. _____ 1. 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).	~~*under*~~***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. 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*** ~~*that substance*~~. _____ 1. 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 fall under the scope of ***that*** 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*~~***those substances, mixtures and processes***. _____ 1. 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).
Recital 2a			
15a			***(2a) For mutagens and most carcinogens, it is not scientifically possible to identify levels below which exposure would not lead to adverse health effects. Although setting limit values for exposure at the place of work in relation to carcinogens and mutagens in Directive 2004/37/EC does not completely eliminate risks to the health and safety of workers arising from exposure at work***

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			(residual risk), it nonetheless contributes to a significant reduction of risks arising from such exposure by means of the stepwise and goal-setting approach that was adopted in that Directive.
Recital 2b			
15b		***(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.***	
Recital 2c			
15c		***(2b) 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***	

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		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.	
Recital 3			
16	(3) The IARC classified welding fumes as 'carcinogenic to humans' (Group 1 of the IARC classification). According to the ECHA	(3) The IARC classified welding fumes as 'carcinogenic to humans' (Group 1 of the IARC classification). According to the ECHA	(3) The IARC classified welding fumes as 'carcinogenic to humans' (Group 1 of the IARC classification). According to the ECHA

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	scoping study[1], 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[2], 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. 1. 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) 2. 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,	scoping study[1], 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[2], to include in Annex I to Directive 2004/37/EC work involving exposure to ***welding fumes and*** fumes from ~~*welding*~~***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***	scoping study[1], 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*~~***No 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[2], 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*~~***or mixtures*** which ~~*meets*~~***meet*** the criteria for classification as a category 1A or 1B carcinogen, mutagen or ~~*reprotoxic*~~***reproductive toxicant*** set out in Annex I to Regulation (EC) No 1272/2008. ***In its opinion of 22 September 2023 on welding fumes, the ACSH strongly 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 Fume[3] developed by the Senior Labour Inspectorate Committee in 2018, further***

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	available at: ACSH Adopted opinion Welding fumes 22.09.23-EN.pdf (europa.eu)	***98/24/EC[3a]. 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[3b] 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.*** _____ 1. 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) 2. 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,	***guidance, based on the latest scientific evidence, may be crucial in assisting labour inspectors and companies, especially SMEs and 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.*** _____ 1. 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) 2. 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) ***3. 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***

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		available at: ACSH Adopted opinion Welding fumes 22.09.23-EN.pdf (europa.eu) ***3a. 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).*** ***3b. 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***	
Recital 4			
17	(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.	(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.	(4) Cobalt metal and several cobalt compounds meet the criteria for classification as carcinogenic and ~~reprotoxicant~~***reproductive toxicant*** (category 1B) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens or ~~reprotoxics~~***reprotoxic substances*** within the meaning of Directive 2004/37/EC. Workers are often exposed to a mixture of cobalt compounds and occupational exposure limit values should be applied to all cobalt inorganic compounds. It is therefore appropriate, based on available information, including scientific and technical data, to establish a limit value for cobalt and its inorganic compounds in Directive 2004/37/EC.
Recital 5			
18	(5) The Advisory Committee on Safety and Health at Work (ACSH) set up by Council Decision of 22 July 2003[1], based on the RAC opinion[2], agreed that exposure to cobalt and its	(5) The Advisory Committee on Safety and Health at Work (ACSH) set up by Council Decision of 22 July 2003[1], based on the RAC opinion[2], agreed that exposure to cobalt and its	(5) The ~~Advisory Committee on Safety and Health at Work (ACSH) set up by Council Decision of 22 July 2003[1]~~***ACSH***, based on the RAC opinion[~~2~~***1***], agreed that exposure to cobalt

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	inorganic compounds in the workplace may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish limit values for both the inhalable and respirable fractions of cobalt and its inorganic compounds within the scope of Directive 2004/37/EC and to assign to it a notation for dermal and respiratory sensitisation. 1. OJ C 218, 13.9.2003, p. 1. 2. https://echa.europa.eu/oels-activity-list/-/substance-rev/69405	inorganic compounds in the workplace may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish limit values for both the inhalable and respirable fractions of cobalt and its inorganic compounds within the scope of Directive 2004/37/EC and to assign to it a notation for dermal and respiratory sensitisation. 1. OJ C 218, 13.9.2003, p. 1. 2. https://echa.europa.eu/oels-activity-list/-/substance-rev/69405	and its inorganic compounds in the workplace may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish limit values for both the inhalable and respirable fractions of cobalt and its inorganic compounds within the scope of Directive 2004/37/EC and to assign to it a notation for dermal and respiratory sensitisation. 1. ~~*OJ C 218, 13.9.2003, p*~~*https://echa.europa*~~*.1.*~~*eu/oels-activity-list/-/substance-rev/69405* ~~*2. https://echa.europa.eu/oels-activity-list/-/substance-rev/69405*~~
Recital 6			
19	(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***	(6) For cobalt and its inorganic compounds, it is foreseeable that it will be difficult to comply with a limit value of 0,01 mg/m³ for the inhalable fraction and 0,0025 mg/m³ for the respirable fraction in the short term. It is therefore appropriate to introduce a transitional period of six years after entry into force of this Directive, during which the limit values of 0,02 mg/m³ (inhalable fraction) and 0,0042 mg/m³ (respirable fraction) should apply.

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		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.	
Recital 6a			
19a		***(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.*** ***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***	
Recital 6b			

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
19b		***(6b) 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.***	
Recital 7			
20	(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[1] 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. _____ 1. https://echa.europa.eu/oels-activity-list/-/substance-rev/63901	(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[1] 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. _____ 1. https://echa.europa.eu/oels-activity-list/-/substance-rev/63901	(7) Certain polycyclic aromatic hydrocarbons (PAHs) mixtures, particularly those containing benzo[a]pyrene, meet the criteria for classification as carcinogenic, mutagenic or ~~*reprotoxicant*~~***reproductive toxicant*** (category 1A or 1B) in accordance with Regulation (EC) No 1272/2008 and therefore fall under the scope of Directive 2004/37/EC. The RAC[1] 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. _____ 1. https://echa.europa.eu/oels-activity-list/-/substance-rev/63901
Recital 8			
21	(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	(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	(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

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
	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.	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.	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.
Recital 8a			
21a		***(8a) 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***	***(8a) 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 RAC[1] and ACSH opinions, to establish a longterm occupational exposure limit value of 8,5 mg/m³ (3 ppm).*** __________ ***1. https://echa.europa.eu/oels-activity-list/-/substance-rev/62301/term***
Recital 8b			
21b		***(8b) Short-term or single exposure to isoprene may cause irritation to the nose,***	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
		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.	
Recital 9			
22	(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[1] 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. _____ 1. https://echa.europa.eu/oels-activity-list/-/substance-rev/61801	(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[1] 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. _____ 1. https://echa.europa.eu/oels-activity-list/-/substance-rev/61801	(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[1] and ACSH opinions, to establish a long- and short-term occupational exposure limit value of 7,3 mg/m³ (2 ppm) and 73 mg/m³ (20 ppm), respectively, supplemented by a skin notation and a biological limit value of 45 mg HEAA in urine/g creatinine, ***measured*** at the end of exposure or shift***, in accordance with national laws and/or practice***. _____ 1. https://echa.europa.eu/oels-activity-list/-/substance-rev/61801
Recital 9a			

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
22a		***(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)'.*** ***[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).***	***(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)'.***
Recital 9b			
22b		***(9b) 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***	

	CLEAN	Commission Proposal	VS.EC	EP Mandate	VS.EC	Council Mandate
				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.		
Recital 9c						
22c				***(9c) Workers in several sectors, including aviation ground operations, may be exposed to aircraft engine exhaust emissions ("jet exhaust"), a complex mixture of ultrafine particles and hazardous substances. Evidence from inspections, literature reviews and enforcement action shows that aircraft exhaust contains numerous carcinogenic substances and that exposure can reach extremely high levels in real working conditions. In its final ruling of 3 April 2025 concerning Schiphol airport, the Netherlands Labour Authority found that workers were routinely exposed to exceptionally high concentrations of ultrafine particles—sometimes reaching several million particles per cm³—and in many cases were standing directly in the path of aircraft engine exhaust during routine operations. The Netherlands Labour Authority identified 142 substances and 15 substance groups in aircraft exhaust,***		

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
		including 44 classified as carcinogenic, and concluded that exposure posed a serious and urgent risk to workers' health, including increased risks of lung cancer, bladder cancer, COPD and cardiovascular disease. In that ruling, extensive and mandatory measures were imposed to reduce exposure. Given the severity of the health consequences, the demonstrated widespread exposure, and the lack of a harmonised Union-level limit value, it is necessary for the Union to accelerate scientific assessment and move towards establishing an occupational exposure limit value for aircraft engine exhaust emissions.	
Recital 9d			
22d		***(9d) 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.***	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
Recital 10			
23	(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.	(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.	(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.
Recital 11			
24	(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[1]. When establishing or revising limit values, the Commission should consult the RAC and the ACSH to ensure that they are evidence-based, proportionate and measurable. ________ 1. OJ L 123, 12.5.2016, p. 1.	(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[1]. When establishing or revising limit values, the Commission should consult the RAC and the ACSH to ensure that they are evidence-based, proportionate and measurable. ________ 1. OJ L 123, 12.5.2016, p. 1.	(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[1]. When establishing or revising limit values, the Commission should consult the RAC and the ACSH to ensure that they are evidence-based, proportionate and measurable. ________ 1. OJ L 123, 12.5.2016, p. 1.
Recital 11a			

	CLEAN	Commission Proposal	VS.EC	EP Mandate	VS.EC	Council Mandate
24a				***(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.***		
Recital 11b						
24b				***(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***		

	CLEAN	Commission Proposal	VS.EC	EP Mandate	VS.EC	Council Mandate
				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		

	CLEAN	Commission Proposal	VS.EC	EP Mandate	VS.EC	Council Mandate
				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. _____ ***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).***		
Recital 11c						
24c				***(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***		

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
		methodologies and tools to address combined exposures.	
Recital 11d			
24d		***(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***	
Recital 11e			
24e		***(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***	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
		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.	
Recital 11f			
24f		***(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.***	
Recital 12			
25	(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	(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	(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

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
	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,	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,	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,*~~
Recital 12a			
25a			***(12a) Directive 2004/37/EC should therefore be amended accordingly,***
Recital 12a			
25b		***(12a) 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,***	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
		mutagens and reprotoxic substances at the workplace, thus benefitting all workers. Specific measures, such as financial and technical support, could help SMEs including microenterprises.	
Recital 12b			
25c		***(12b) The ACSH adopted on 29 May 2024 an Opinion[1a] on priority chemicals for new or revised occupational exposure limit values under the Union legal framework on occupational safety and health, which contains a list of priority substances to be proposed for developing a proposal for a Union limit value under Directive 2004/37/EC. In particular the list includes five substances or group of substances classified as 'Immediate priority substances' (Oximes, Butanone oxime, N-(Hydroxymethyl) acrylamide (NMA), Organotins and Ethylene dibromid). The ACSH strongly recommended that the Commission use that list when selecting chemicals for developing legislative proposals for new, or revised, limit values under Directive 2004/37/EC.*** ***1a. ACSH document 006-24, https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/1c3986a7-b583-4382-a6bc-d712eace2b47/details***	
Formula			
26	HAVE ADOPTED THIS DIRECTIVE:	HAVE ADOPTED THIS DIRECTIVE:	HAVE ADOPTED THIS DIRECTIVE:

	CLEAN	Commission Proposal	VS.EC	EP Mandate	VS.EC	Council Mandate
Article 1						
27		Article 1		Article 1		Article 1
Article 1, first paragraph						
28		Directive 2004/37/EC is amended as follows:		Directive 2004/37/EC is amended as follows:		Directive 2004/37/EC is amended as follows:
Article 1, first paragraph, point (1)						
28a				‘		***(1) In Article 2, points (a), (b) and (ba) are replaced by the following:***
Article 1, first paragraph, point (1), amending provision, point (a)						
28b						‘ ***(a) 'carcinogen' means:***
Article 1, first paragraph, point (1), amending provision, point (a)(i)						
28c						***(i) a substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council*;*** ****. 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).***
Article 1, first paragraph, point (-1)						
28d				***(-1) in Article 2, point (a)(ii) is replaced by the following:***		
Article 1, first paragraph, point (1), amending provision, point (a)(ii)						

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
28e		***'(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;'***	***(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;***
Article 1, first paragraph, point (-1a)			
28f		***(-1a) in Article 2, a new point (a)(iia) is added:***	
Article 1, first paragraph, amending provision, fourth paragraph - Directive 2004/37/EC, Article 2, point (a)(iia)			
28g		***'(iia) 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;'***	
Article 1, first paragraph, point (1), amending provision, point (b)			
28h			***(b) 'mutagen' means:***
Article 1, first paragraph, point (1), amending provision, point (b)(i)			
28i			***(i) a substance or mixture which meets the criteria for classification as a category 1A or 1B germ cell mutagen set out in Annex I to Regulation (EC) No 1272/2008;***
Article 1, first paragraph, point (-1b)			
28j		***(-1b) in Article 2, point (b)(ii) is replaced by the following:***	
Article 1, first paragraph, point (1), amending provision, point (b)(ii)			
28k		***'(ii) a substance, mixture or process referred to in points 1 to 8 of Annex I to this***	***(ii) a substance, mixture or process referred to in Annex I to this Directive as well***

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate
		Directive as well as a substance or mixture released by a process referred to in those points;'	***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 mutagenic effects;***
Article 1, first paragraph, point (-1c)			
28l		***(-1c) in Article 2, a new point (b)(iia) is added:***	
Article 1, first paragraph, amending provision, eighth paragraph - Directive 2004/37/EC, Article 2, point (b)(iia)			
28m		***'(iia) 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;'***	
Article 1, first paragraph, point (-1d)			
28n		***(-1d) in Article 2, point (ba) is replaced by the following:***	
Article 1, first paragraph, point (1), amending provision, point (c)			
28o		***'(ba) "reprotoxic substance" means:***	***(ba) 'reprotoxic substance' means:***
Article 1, first paragraph, point (1), amending provision, point (c)(i)			
28p		***(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;***	***(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;***
Article 1, first paragraph, point (1), amending provision, point (c)(ii)			
28q		***(ii) a substance, mixture or process referred to in point 9 of Annex I to this Directive as well as a substance or mixture***	***(ii) a substance, mixture or process referred to in Annex I to this Directive as well as a substance or mixture released by a***

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		released by a process referred to in that point, where it has reprotoxic effects;'	***process referred to in that Annex, included in the list set out in that Annex because of its reprotoxic effects;***
Article 1, first paragraph, point (-1e)			
28r		***(-1e) in Article 2, the following point is added:***	
Article 1, first paragraph, amending provision, twelve paragraph - Directive 2004/37/EC, Article 2, point (ea)			
28s		***'(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.'***	
Article 1, first paragraph, point (-1f)			
28t		***(-1f) in Article 2, the following point is added:***	
Article 1, first paragraph, amending provision, thirteenth paragraph - Directive 2004/37/EC, Article 2, point (eb)			
28u		***'(eb) "medicinal products" means medicinal products as defined in Article 1 paragraph 2 of Directive 2001/83/EC.'***	
Article 1, first paragraph, point (-1g)			
28v		***(-1g) in Article 5(5), the following subparagraph is added:***	
Article 1, first paragraph, amending provision, fourteenth paragraph - Directive 2004/37/EC, Article 5(5) subparagraph 1a			
28w		***'Individual protection measures as referred to in point (g) shall include personal protective equipment (PPE), in particular respiratory***	

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		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.'	
Article 1, first paragraph, point (-1h)			
28x		***(-1h) in Article 10, the following paragraph is added:***	
Article 1, first paragraph, amending provision, fifteenth paragraph - Directive 2004/37/EC, Article 10, paragraph 2a			
28y		***'(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.'***	
Article 1, first paragraph, point (-1i)			
28z		***(-1i) in Article 11(1), subparagraph 1, point (a) is replaced by the following:***	
Article 1, first paragraph, amending provision, sixteenth paragraph - Directive 2004/37/EC, Article 11(1), subparagraph 1, (a)			
28aa		***'a) potential risks to health, including the additional risks due to tobacco consumption and the existence of residual***	

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		risks linked to binding limit values listed in Annex III, with reference to information published by EU OSHA, where available;'	
Article 1, first paragraph, point (-1j)			
28ab		***(-1j) in Article 18a, the following paragraph is added:***	
Article 1, first paragraph, amending provision, seventeenth paragraph - Directive 2004/37/EC, Article 18a, paragraph 11a			
28ac		***'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.'***	
Article 1, first paragraph, point (-1k)			
28ad		***(-1k) in Article 18a, the following paragraph is added:***	
Article 1, first paragraph, amending provision, eighteenth paragraph - Directive 2004/37/EC, Article 18a, paragraph 11b			
28ae		***'11b. The Commission's proposal shall include 'work involving exposure to aircraft engine emissions' in Annex I of Directive 2004/37/EC.'***	
Article 1, first paragraph, point (-1l)			

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28af		***(-1l) in Article 18a, the following paragraph is added:***	
Article 1, first paragraph, amending provision, nineteenth paragraph - Directive 2004/37/EC, Article 18a, paragraph 11c			
28ag		***'11c. 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.'***	
Article 1, first paragraph, point (-1m)			
28ah		***(-1m) in Article 18a, the following paragraph is added:***	
Article 1, first paragraph, amending provision, twentieth paragraph - Directive 2004/37/EC, Article 18a, paragraph 11d			
28ai		***'11d. 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.'***	
Article 1, first paragraph, point (1), amending provision, fourth paragraph			

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29	‘ Annexes I, III and IIIa to Directive 2004/37/EC are amended in accordance with the Annex to this Directive. ,	Annexes I, III and IIIa to Directive 2004/37/EC are amended in accordance with the Annex to this Directive. ,	***(2)*** Annexes I, III and IIIa to Directive 2004/37/EC are amended in accordance with the Annex to this Directive. ,
Article 2			
30	Article 2	Article 2	Article 2
Article 2(1), first subparagraph			
31	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*** …~~] [The time limit for transposition will be as short as possible and, generally, will not exceed~~ ***[***two years~~] at the latest~~ ***after its entry into force]***. They shall immediately inform the Commission thereof.	***1.*** 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~~ ***after the date of entry into force of this Directive]***. They shall immediately inform the Commission thereof.
Article 2(1), second subparagraph			
32	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.	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.	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.
Article 2(2)			
33	Member States shall communicate to the Commission the text of the main measures of	Member States shall communicate to the Commission the text of the main measures of	***2.*** Member States shall communicate to the Commission the text of the main measures

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	national law which they adopt in the field covered by this Directive.	national law which they adopt in the field covered by this Directive.	of national law which they adopt in the field covered by this Directive.
Article 3			
34	Article 3	Article 3	Article 3
Article 3, first paragraph			
35	This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	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			
36	Article 4	Article 4	Article 4
Article 4, first paragraph			
37	This Directive is addressed to the Member States.	This Directive is addressed to the Member States.	This Directive is addressed to the Member States.
Formula			
38	Done at Brussels,	Done at Brussels,	Done at Brussels,
Formula			
39	For the European Parliament	For the European Parliament	For the European Parliament
Formula			
40	The President	The President	The President
Formula			
41	For the Council	For the Council	For the Council
Formula			
42	The President	The President	The President

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ANNEX			
44	ANNEX	ANNEX	ANNEX
ANNEX, first paragraph			
45	Annexes I, III and IIIa to Directive 2004/37/EC are amended as follows:	Annexes I, III and IIIa to Directive 2004/37/EC are amended as follows:	Annexes I, III and IIIa to Directive 2004/37/EC are amended as follows:
ANNEX, point 1.			
45a		***(-1) in Annex I, the title is replaced by the following:***	***(-1) in Annex I, the title is replaced by the following:***
ANNEX, point 1., amending provision, first paragraph			
45b		‘***‘List of substances, mixtures and processes (Article 2, point (a)(ii) and (iii), point (b)(ii) and point (iii) and (ba)(ii))’***’	‘***‘List of substances, mixtures and processes (Article 2, points (a)(ii), (b)(ii) and (ba)(ii))’***’
ANNEX, point 2.			
46	(1) in Annex I, the following point 9 is added:	(1) in Annex I, the following point 9 is added:	(1) in Annex I, the following point 9 is added:
ANNEX, point 2., amending provision, numbered paragraph (9)			
47	‘ 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 ~~*welding*~~***other*** processes ***that generate fumes in a similar way,*** containing substances ***or mixtures*** 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 fumes from welding processes containing substances ~~*that meet the criteria for a substance or mixture*~~***or mixtures*** which ~~*meets*~~***meet*** the criteria for classification as a category 1A or 1B carcinogen, mutagen or ~~*reprotoxic*~~***reproductive toxicant*** set out in Annex I to Regulation (EC) No 1272/2008[1]; ’

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	1. Exposure shall not exceed the limit value of a carcinogen, mutagen or a reprotoxic substance as set out in Annex III when those substances are released during the welding process.	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.	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.
ANNEX, first paragraph, amending provision, numbered paragraph (9a) - Directive 2004/37/EC, Annex I, point 9a			
47a		***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.*** ,	
ANNEX, point 3.			
48	(2) in Annex III, point A is amended as follows:	(2) in Annex III, point A is amended as follows:	(2) in Annex III, point A is amended as follows:
ANNEX, point 3.(a)			
49	(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:	(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:	(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:
ANNEX, point 3.(a), amending provision, first subparagraph			
50	‘ ‘	‘ ‘	‘ ‘
ANNEX, point 3.(a), amending provision, Table			
51	Table	Table	Table
ANNEX, point 3.(a), amending provision, second subparagraph			

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52	, ,	, ,	, ,
ANNEX, point 3.(b)			
53	(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:	(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:	(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:
ANNEX, point 3.(b), amending provision, first subparagraph			
54	‘ ‘	‘ ‘	‘ ‘
ANNEX, point 3.(b), amending provision, Table			
55	Table	Table	Table
ANNEX, point 3.(b), amending provision, second subparagraph			
56	’; ,	’; ,	’; ,
ANNEX, point 3.(c)			
57	(c) in the table the following rows are added	(c) in the table the following rows are added	(c) in the table the following rows are added
ANNEX, point 3.(c), amending provision, first subparagraph			
58	‘ ‘	‘ ‘	‘ ‘
ANNEX, point 3.(c), amending provision, Table			
59	Table	Table	Table
ANNEX, point 3.(c), amending provision, second subparagraph			

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60	’; ,	’; ,	’; ,
ANNEX, point 3.(ca)			
60a		***(ca) in the footnotes after the Table, the following footnotes ([11]) and ([9]) are added:***	***(ca) in the footnotes after the Table, the following footnotes ([17]) and ([18]) are added:***
ANNEX, point 3.(ca), amending provision, first paragraph			
60b		‘ ***‘([11]) Inhalable fraction, measured as Cobalt.***	‘ ***‘([17]) Inhalable fraction, measured as Cobalt.***
ANNEX, point 3.(ca), amending provision, second paragraph			
60c		***([9]) Respirable fraction, measured as Cobalt.’*** ,	***([18]) Respirable fraction, measured as Cobalt.’*** ,
ANNEX, point 3.(d)			
61	(d) in the footnotes after the Table, the following footnote (*2) is added:	(d) in the footnotes after the Table, the following footnote (*2) is added:	(d) in the footnotes after the Table, the following footnote (*2) is added:
ANNEX, point 3.(d), amending provision, first paragraph			
62	‘ (*2) Measured as benzo[a]pyrene.; ,	‘ (*2) Measured as benzo[a]pyrene.; ,	‘ (*2) Measured as benzo[a]pyrene.; ,
ANNEX, 3 paragraph			
63	(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.	(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.	(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.

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ANNEX, 2 paragraph			
64	(2) CAS No: Chemical Abstract Service Registry Number.	(2) CAS No: Chemical Abstract Service Registry Number.	(2) CAS No: Chemical Abstract Service Registry Number.
ANNEX, 3 paragraph			
65	(3) Measured or calculated for a reference period of eight hours time-weighted average (TWA).	(3) Measured or calculated for a reference period of eight hours time-weighted average (TWA).	(3) Measured or calculated for a reference period of eight hours time-weighted average (TWA).
ANNEX, 4 paragraph			
66	(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.	(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.	(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.
ANNEX, 5 paragraph			
67	(5) mg/m^3 = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).	(5) mg/m^3 = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).	(5) mg/m^3 = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).
ANNEX, 6 paragraph			
68	(6) ppm = parts per million by volume in air (ml/m^3).	(6) ppm = parts per million by volume in air (ml/m^3).	(6) ppm = parts per million by volume in air (ml/m^3).
ANNEX, 7 paragraph			
69	(7) f/ml = fibres per millilitre.	(7) f/ml = fibres per millilitre.	(7) f/ml = fibres per millilitre.
ANNEX, 8 paragraph			
70	(9) Respirable fraction.	(9) Respirable fraction.	*deleted*
ANNEX, 10 paragraph			

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71	*(10)* Substantial contribution to the total body burden via dermal exposure possible.	(10) Substantial contribution to the total body burden via dermal exposure possible.	(10) Substantial contribution to the total body burden via dermal exposure possible.
ANNEX, 11 paragraph			
72	(11) Inhalable fraction.	(11) Inhalable fraction.	*deleted*
ANNEX, 12 paragraph			
73	*(13)* The substance can cause sensitisation of the skin and of the respiratory tract.	(13) The substance can cause sensitisation of the skin and of the respiratory tract.	(13) The substance can cause sensitisation of the skin and of the respiratory tract.
ANNEX, point 4.			
74	(3) in Annex IIIa, the following point is added:	(3) in Annex IIIa, the following point is added:	(3) in Annex IIIa, the following point is added:
ANNEX, point 4., amending provision, first paragraph			
75	‘ 1,4-dioxane	‘ 1,4-dioxane	‘ 1,4-dioxane
ANNEX, point 4., amending provision, numbered paragraph (2), first subparagraph			
76	2. The binding biological limit value is 45 mg HEAA*in urine/g creatinine.’	2. The binding biological limit value is 45 mg HEAA*in urine/g creatinine***, measured at the end of exposure or shift***.’	2. The binding biological limit value is 45 mg HEAA*in urine/g creatinine***, measured at the end of exposure or shift, in accordance with national laws and/or practice***.’
ANNEX, point 4., amending provision, numbered paragraph (2), second subparagraph			
77	_____	_____	_____
ANNEX, point 4., amending provision, numbered paragraph (2), third subparagraph			
78	*(2-Hydroxyethoxy)acetic acid. ’	*(2-Hydroxyethoxy)acetic acid. ’	*(2-Hydroxyethoxy)acetic acid. ’

Commission Proposal Table

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) 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.

EP Mandate Table

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*~~***ten*** 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) 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.

Council Mandate Table

Name of agent	EC No (1)	CAS No (2)	Limit values						Notation	Transitional measures
			8 hours (3)			Short-term (4)				
			mg/m3 (5)	ppm (6)	f/ml (7)	mg/m3 *(5)*	ppm *(6)*	f/ml *(7)*		
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) 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.

Commission Proposal Table

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		
Mercury and divalent inorganic mercury compounds that fall under the scope of this Directive (measured as mercury)			0,02		□	□	□	□		

EP Mandate Table

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		
Mercury and divalent inorganic mercury compounds that fall under the scope of this Directive (measured as mercury)			0,02		□	□	□	□		

Council Mandate Table

Name of agent	EC No (1)	CAS No (2)	Limit values						Notation	Transitional measures
			8 hours (3)			Short-term (4)				
			mg/m3 (5)	ppm (6)	f/ml (7)	mg/m3 *(5)*	ppm *(6)*	f/ml *(7)*		
Mercury and divalent inorganic mercury compounds that fall under the scope of this Directive (measured as mercury)			0,02		□	□	□	□		

Commission Proposal Table

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		
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]
1,4-dioxane			7,3	2		73	20		Skin (10)	

EP Mandate Table

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		
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]
Isoprene	***201-143-3***	***78-79-5***	***8,5***	***3***	***-***	***-***	***-***	***-***		
1,4-dioxane			7,3	2		73	20		Skin (10)	

Council Mandate Table

Name of agent	EC No (1)	CAS No (2)	Limit values						Notation	Transitional measures
			8 hours (3)			Short-term (4)				
			mg/m3 (5)	ppm (6)	f/ml (7)	mg/m3 ***(5)***	ppm ***(6)***	f/ml ***(7)***		
Cobalt and inorganic cobalt compounds			0,01(~~11~~***17***) 0,0025~~(9)~~***(18)***		□	□	□	□	dermal and respiratory sensitisation(13)	Limit value of 0,02(~~11~~***17***) and 0,0042~~(9)~~***(18)*** until …[OJ: six years after the date of entry into force of the amending Directive]
Isoprene	***201-143-3***	***78-79-5***	***8,5***	***3***	***-***	***-***	***-***	***-***		
1,4-dioxane	***204-661-8***	***123-91-1***	7,3	2		73	20		Skin (10)	