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WORKING DOCUMENT

From: To:	General Secretariat of the Council Delegations
N° Cion doc.:	ST 11823 2025 ADD 1 + ST 11823 2025 ADD 2 + ST 11823 2025 ADD 3 + ST 11823 2025 ADD 4 + ST 11823 2025 ADD 5 + ST 11823 2025 INIT
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 – MS written comments on the first Presidency compromise text

Delegations will find attached the written comments received from the CY, CZ, EE, ES, FI, FR, HU, IE, IT, LT, NL, PL, RO and SE delegations on the first Presidency compromise text on the abovementioned proposal.

Presidency compromise text	Drafting suggestions and Comments
General comments	EE (Comments): Estonia has a general scrutiny reservation as we are still forming our national position. Please see EE comment and drafting proposals on recital 9 regarding the measurement of BLV of 1,4-dioxane, as was already questioned in the last SQWP. ES (Comments): - ES would like to thank the PCY for the initial compromise text, which reflects several of the proposals put forward by ES. We welcome the proposal and support the Presidency's efforts to achieve a general approach at the EPSCO Council on 1 December. - Although the text moves in the right direction, some issues remain outstanding, which we set out in this round of written comments. - In order to confirm our commitment to a high level of worker protection, it is important to take into account the ACSH opinion on **isoprene**. We support the inclusion of a limit value for isoprene in the proposal. There are several arguments in favour: a scientific study has already established an OEL, there is a positive assessment from the ACSH, and there is also the legal obligation (established by Article 16.1 of CMRD) to measure. In addition, certain activities would not be sufficiently protected, such as maintenance or cleaning tasks. Furthermore, we should value the consensus on occupational safety and health that has been reached through social dialogue. From a preventive point of view, there is no justification for not setting a limit value. All this work would be in line with the letter addressed to Commissioner Schmidt March 5th 2024 at the initiative of DK, signed by 14 ministers in charge of OSH. At that time, all those ministers believed that a joint effort is needed and could pave the way to advancing European legislation to set limit values for substances in the workplace.

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	The need to reduce administrative burdens is not, in our view, a valid argument in this case, given the extensive preparatory work already carried out and the agreement already adopted: not relying on it would mean not making use of the scientific evidence, the ACSH opinion, and the existing legal obligation. Therefore, ES considers that including a binding OEL for isoprene is both justified and necessary. LT (Comments): *General comments:* *LT thanks the Presidency for the opportunity to submit written comments and suggestions on the text. We continue to maintain a parliamentary reservation.* *LT welcomes and supports all amendments in the compromise text, particularly the determination of a two-year transposition period in Article 2, the amendments regarding cobalt and recital 9a.* *However, we would also support the suggestions of clarifications on the practical implementation of this regulation by providing recommendations for welding fumes.* *Additionally, we consider it crucial to maintain in the text the same definitions as set out in Article 2 of the CMD core directive.* NL (Comments): Isoprene is now left out, the Netherlands and other countries have advocated to leave it in. We would like to emphasize the importance of including Isoprene, as this aligns with the ACSH proposal and the consensus on OSH reached through social dialogue, fully supporting the joint call from 14 OSH ministers in their letter to Commissioner Schmidt (March 5th, 2024) to advance EU legislation on workplace exposure limits. In addition to the arguments we had already used to substantiate our request, we would like to add the following points: - If there is no BOEL, the administrative burden on companies could in fact turn out larger, since they would – at least in the Netherlands – have to derive a company value to evaluate risks; and

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	- There may be future applications of isoprene: establishing a BOEL is an incentive to look for alternatives, also beforehand. SE (Comments): SE welcome and support all amendments in the compromise text, especially regarding the determination of two years of the transposition period in article 2, the amendments regarding cobalt, and the adding to the definition of "reprotoxic substance" in article 1 of the amending directive. However, SE supports the suggested clarifications of the addition to the definition of "reprotoxic substance" made by Finland and Ireland during the working party 1 October 2025. In addition to this, SE suggest clarifying amendments regarding 1,4-dioxane as presented below.
Proposal for a	
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	
amending Directive 2004/37/EC as regards the addition of substances and setting limit values in its Annexes I, III and IIIa	
(Text with EEA relevance)	
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 153(2), point (b), in conjunction with Article 153(1), point (a), thereof,	

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Having regard to the proposal from the European Commission,	
After transmission of the draft legislative act to the national parliaments,	
Having regard to the opinion of the European Economic and Social Committee[1],	
After consulting the Committee of the Regions[2],	
Acting in accordance with the ordinary legislative procedure,	
Whereas:	
(1) To improve the protection of workers against risks from exposure to carcinogens, mutagens or reprotoxic substances at the place of work and ensure the same minimum level of protection across the Union, regular updates of Directive 2004/37/EC of the European Parliament and the Council[3] are necessary. Occupational exposure limit values should be established or revised in light of available information, including up-to-date scientific evidence and technical data, and should be based	

[1] OJ C […], […], p. […].
[2] OJ C […], […], p. […].
[3] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic 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).

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on a thorough assessment of the socio-economic impact and feasibility factors. That information should, if possible, include opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[4] and opinions of the Advisory Committee on Safety and Health at Work (ACSH)[5].	
(2) Directive 2004/37/EC covers substances or mixtures which meet the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[6] as well as substances, mixtures or processes referred to in Annex I to that Directive. Robust scientific evidence is to be provided for any new addition to the list of substances, mixtures and processes referred to in that Annex I to demonstrate that these substances, mixtures and processes fall under the scope of Directive 2004/37/EC, based on available valid scientific sources such as the ECHA, the International	

[4] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

[5] Council Decision of 22 July 2003 setting up an Advisory Committee on Safety and Health at Work (OJ C 218, 13.9.2003, p. 1).

[6] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

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Agency for Research on Cancer (IARC) and national bodies, paying particular attention to peer-reviewed published literature on that substance.	
(3) The IARC classified welding fumes as 'carcinogenic to humans' (Group 1 of the IARC classification). According to the ECHA scoping study[7], welding fumes are complex and may include carcinogens, mutagens or reprotoxic substances, such as chromium(VI) compounds, nickel compounds, cadmium and its inorganic compounds. The complexity and heterogeneity of welding fumes, together with the absence of harmonised classification in the Regulation (EC) 1272/2008, contribute to a lack of clarity on their possible dangerousness for workers, and therefore a lack of appropriate risk management measures at the workplace. Addressing that absence of classification for welding fumes at Union level would ensure more legal clarity in terms of the application of Directive 2004/37EC. It is therefore appropriate, in line with the opinion of the ACSH[8], to include in Annex I to Directive 2004/37/EC work involving exposure to fumes from welding processes containing substances **or mixtures** that meet **[…]** the criteria for classification as a category 1A or 1B	ES (Drafting suggestions): The IARC classified welding fumes as 'carcinogenic to humans' (Group 1 of the IARC classification). According to the ECHA scoping study , 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 , to include in Annex I to Directive 2004/37/EC work involving exposure to fumes from welding processes containing substances or mixtures that meet […] the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic substance set out in Annex I to Regulation (EC) No 1272/2008**.The ACSH, in its opinion of 22 September 2023 on welding fumes, strongly recommends developing a guidance to specify in more detail what is meant with the entry**. ES (Comments):

[7] ECHA (2022), Scoping Study report for evaluation of limit values for welding fumes and fumes from other processes that generate fume in a similar way at the workplace, available at: report_welding_fumes_en.pdf (europa.eu)

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

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carcinogen, mutagen or reprotoxic **substance** set out in Annex I to Regulation (EC) No 1272/2008.	We wish to emphasise that **provision of guidance** for companies, as proposed by the ACSH, is not merely helpful, but consistent with previous EU practice. The Guidelines should not be mandatory in nature, but rather serve as a guiding instrument for the Member States. Their primary purpose is to provide a common framewrk for addessging crucial aspects related to exposure to welding fumes. Although updating existing Guidelines (such as those from SLIC) may be considered, it is essential that the new guidance takes into account the latest scientific evidence and is highly specific. It would be appropriate for Recital 3 to explicitly refer to the preparation of company-oriented guidelines, assigning responsibility to the Commission, supported by ACSH and WPC expertise. Such guidance should include the definition of welding fumes and clarify the scope of Annex I, clarify that there are different types of welding and that not all of them release CMR substances in the same proportion. Therefore, control measures should not be the same for all types of welding. The guidelines should help companies to identify the different types of welding that exist and guide them on the most effective control measures for each of them. FR (Drafting suggestions): (3) The IARC classified welding fumes as 'carcinogenic to humans' (Group 1 of the IARC classification). According to the ECHA scoping study[9], 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

[9] ECHA (2022), Scoping Study report for evaluation of limit values for welding fumes and fumes from other processes that generate fume in a similar way at the workplace, available at: report_welding_fumes_en.pdf (europa.eu)

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	opinion of the ACSH[10], to include in Annex I to Directive 2004/37/EC work involving exposure to fumes from welding processes containing substances ~~**mixtures**~~ that meet **[…]** the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic **substance** set out in Annex I to Regulation (EC) No 1272/2008. FR (Comments): FR: In its comments, Belgium raised a relevant point about the concept of "mixture" that was added to the Commission's proposal. From a regulatory point of view, this concept is specific to chemicals placed on the market, which are considered mixtures when two or more substances are present. It is therefore not relevant to describe the cloud of fumes released during welding as a "mixture" and complicates the text. The French authorities therefore propose to adopt the wording suggested by Belgium: "It is therefore appropriate, in line with the opinion of the ACSH, to include in Annex I to Directive 2004/37/EC work involving exposure to fumes from welding 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 substance set out in Annex I to Regulation (EC) No 1272/2008." The French authorities also support Germany's proposal to include in this recital the need to develop guidance for the application of this entry on welding fumes in Annex I to the Directive. It should to identify welding technics that will release CMR substances and if it is possible for those substances to use biomonitoring. HU (Drafting suggestions): (3) The IARC classified welding fumes as 'carcinogenic to humans' (Group 1 of the IARC classification). According to the ECHA scoping study , welding fumes are complex and may

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

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	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 , to include in Annex I to Directive 2004/37/EC work involving exposure to fumes from welding processes containing substances **or mixtures** that meet […] the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic **substance** set out in Annex I to Regulation (EC) No 1272/2008. **Also in line with the ACSH opinion, the Commission shall develop within two years after the entry into force a non-binding practical guide with detailed information for the assessment of occupational exposure to welding fumes.** HU (Comments): Welding fumes are multi-component mixtures containing harmful chemical substances - including nanoparticles - for which determining the maximum permissible concentration (OEL) in workplace air is extremely complex. Welding processes themselves are diverse and heterogeneous, making the assessment of risks arising from occupational exposure to welding fumes particularly challenging. IE (Drafting suggestions): 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[11], to include in Annex I to Directive 2004/37/EC work involving exposure to fumes from

11 ACSH (2023), Opinion on introducing work involving exposure to fumes from welding processes containing substances that meet the criteria for

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	[…] processes, **including welding**, containing substances or mixtures that meet the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic substance set out in Annex I to Regulation (EC) No 1272/2008. IE (Comments): **IE Comment**: Concern related to ambiguous nature of the term "welding process", e.g. when does soldering become welding – should a temperature be included or requirement that base metals are fused be used to define a welding process. IE suggested drafting removed the need to address this. **IE Comment:** can support IT proposal to include in this recital the need to develop guidance for the application of this entry on welding fumes in Annex I to the Directive. It should identify welding technics that will release CMR substances and if it is possible for those substances to use biomonitoring and remove IE suggested wording as a result. **IE Comment**: IE would not support the deletion of "or mixtures" due to combined exposures and wide or unknown nature of fume constituents IT (Comments): The inclusion of welding fumes in Annex I of the CMRD is a fundamental step for the protection of workers' health. However, to ensure effective and uniform application of the Directive across Member States, the importance and desirability of issuing Guidelines at the European level should be enphasised. These Guidelines should not be mandatory in nature, but rather serve as a guiding instrument for the MS. Their primary purpose is to provide a common framework for addressing crucial aspects related to exposure to welding fumes. Although updating existing Guidelines (such as those from SLIC) may be considered, it is essential that the new guidance takes into account the latest scientific evidence and is highly specific.

CMR category 1A/1B set out in Annex I to the CLP Regulation, Doc. 006/23, available at: ACSH Adopted opinion Welding fumes 22.09.23-EN.pdf (europa.eu)

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	The aspects to be considered for further in-depth analysis may, for example, concern the following points: - Mandating a risk assessment that explicitly complies with the requirements for carcinogenic agents (e.g., Art. 236 D. Lgs. 81/08 in Italy). A generic hygienic-environmental assessment is not sufficient. - Rigorous environmental/biological monitoring: Exposure monitoring must be targeted and detailed, considering the different welding types (e.g., MMA, MIG/MAG, TIG, Plasma); the material being welded (e.g., stainless steel, aluminum); the presence of coatings or contaminants (e.g., galvanizing, primers). In particular, attention must be focused on the most critical compounds (e.g., Chromium VI, Nickel, Manganese) for a targeted risk control. - Technical criteria for ventilation: The Guidelines must define rigorous technical criteria for proper ventilation (local and general extraction), which is essential for exposure control. - Specific attention to the most insidious particulate fraction (ultrafine) and the systematization of biological monitoring as a verification tool. LT (Drafting suggestions): It is therefore appropriate, in line with the opinion of the ACSH[12], to include in Annex I to Directive 2004/37/EC work involving exposure to fumes from welding processes containing substances **or mixtures** that meet **[…]** the criteria for classification as a category 1A or 1B carcinogen, mutagen or ~~reprotoxic~~ ~~**substance**~~ **reproductive toxicant** set out in Annex I to Regulation (EC) No 1272/2008. LT (Comments): LT suggest to align the terminology used with Article 2 of the CMD core directive.

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

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	LT can support the proposal to include in this recital the need to develop guidance on the application of the entry on welding fumes in Annex I to the Directive. LT considers it important that such guidance should identify welding techniques that may release CMR substances, assess the feasibility of applying biomonitoring for these substances, outline appropriate methods for risk assessment, and specify the health and safety measures to be implemented by employers. The recommendations could build on the 2018 ACSH recommendations. LT underlines that such guidance would be particularly important to ensure proper implementation by small enterprises. NL (Comments): Would it be possible to establish clear guidelines for handling welding fumes, as previously proposed by Italy and other Member States? This would help companies and Member States to better manage risks and reduce administrative burdens, without compromising safety or clarity. There is a diversity of welding fumes which is the reason that no OEL was advised by the ACSH/WPC. At the same time they, signalled the need for a guidance for the same reason, explaining the various types of welding fumes, major components (especially those with excisting OELs), and risk mitigating measures. The comparison with the not always used Guidance on Biomonitoring does not hold: legislation on that subject is very diverse in MS and is perceived differently across MS. Furthermore, there was a discussion on leaving out “mixtures” in the phrase “containing substances or mixtures”, but we suggest to leave the text as is. In welding fumes, for example, there can be a PAH-mixture that is a mixure within the welding fume mixture with its separate classification as a mixture (and separate OEL). RO (Comments): We welcome the addition of the term “mixtures”. We believe it is important to insert at least a sentence on the possibility of the European Commission to develope a guide dedicated to welding fumes.
	FR (Drafting suggestions):

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	Addition of a new recital: (X)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 and ACSH opinions, to establish a long- term occupational exposure limit value of 8,5 mg/m³ (3 ppm). FR (Comments): FR: In order to confirm our commitment to a high level of worker protection, it is important to take into account the ACSH opinion on isoprene, even though this value is already met according to the Commission's impact assessment. For once, we can set a limit value with a residual risk close to 4:100,000, in accordance with the "Commission's methodology for establishing risk-based limit values for carcinogens without a threshold for the purposes of Article 1(18a) of Directive 2004/37/EC," page 6: " ➢ Limit values for non-threshold substances will be set between the predetermined 'upper risk level' and 'lower risk level'. It is agreed that the upper risk level is 4:1,000 (corresponding to 4 predicted cancer cases per 1,000 employees) and the lower risk level is 4:100,000. ➢ … ➢ The proximity of the OEL to the upper or lower risk level will be a key factor in deciding when the OEL should be revised. It is agreed that if the risk is between 4:1,000 and 4:10,000, priority action is needed, while if the risk is between 4:10,000 and 4:100,000, a revision is less necessary. We think it is important to remind CMRD art. 16.1: *"The European Parliament and the Council **shall**, in accordance with the procedure laid down in Article 153(2), point (b), of the Treaty on the Functioning of the European Union (TFEU), **set out limit values** in Directives on the basis of the available information, including scientific and technical data, in respect of **all those***

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	carcinogens, mutagens or reprotoxic substances for which this is possible*, and, where necessary, other directly related provisions."* So according to this article, we should take into account the proposal from ACSH. Furthermore, we should value the consensus on occupational safety and health (OSH) that has been reached through social dialogue. All this work would be in line with the letter addressed to Commissioner Schmidt March 5th 2024 at the initiative of Denmark, signed by 14 ministers in charge of OSH. At that time, all those ministers believed that a joint effort is needed and could pave the way to advancing European legislation to set limit values for substances in the workplace."
(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.	RO (Comments): Throughout the text, the term 'reprotoxicant' is used in parallel with 'reprotoxic substance', which may be confusing. We propose to keep the text consistent and use only one term or mention specifically that they are synonymous.
(5) The Advisory Committee on Safety and Health at Work (ACSH) set up by Council Decision of 22 July	

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2003[13], based on the RAC opinion[14], agreed that exposure to cobalt and its inorganic compounds in the workplace may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish limit values for both the inhalable and respirable fractions of cobalt and its inorganic compounds within the scope of Directive 2004/37/EC and to assign to it a notation for dermal and respiratory sensitisation.	
(6) For cobalt and its inorganic compounds, it is foreseeable that it will be difficult to comply with a limit value of 0,01 mg/m³ for the inhalable fraction and 0,0025 mg/m³ for the respirable fraction in the short term. It is therefore appropriate to introduce a transitional period of six years after entry into force of this Directive, during which the limit values of 0,02 mg/m³ (inhalable fraction) and 0,0042 mg/m³ (respirable fraction) should apply.	FI (Drafting suggestions): **Add:" As advised by the ACSH the feasibility and need to further reduce the limit values should be duly assessed after enough experience and information has been gathered from the limit values set by this directive".** FI (Comments): The ACSH Opinion, which is a compromise agreement achieved in tripartite negotiations, states that: "The ACSH advises that at the latest 13 years after entry into force of the Directive the Commission should have the result of a study assessing the feasibility to further reduce the respirable OEL to a level corresponding to a residual risk of 4 : 10000 and to check the need of reducing further the inhalable fraction". FI considers it important to respect the tripartite agreement in order to ensure that fruitful compomises can also be achieved in the future. If setting a strict deadline (13 yrs.) is considered inappropriate a more vague description should be aimed at. FR (Drafting suggestions):

[13]OJ C 218, 13.9.2003, p. 1.
[14]https://echa.europa.eu/oels-activity-list/-/substance-rev/69405

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	Addition of a new paragraph: **According to the opinion of the ACSH on the basis of the Commission "Methodology establishing risk-based limit values for non-threshold carcinogens, for the purposes of Article 1 (18a) of Directive 2004/37/EC limit values for non-threshold carcinogens, for the purposes of Article 1 (18a) of Directive 2004/37/EC" as the residual of these OELs are higher than 4 : 10 000, there is a need to assess the possibility to lower the limit value within 13 years after the entry into force of this directive**. FR (Comments): FR: The French authorities maintain that it is important to reiterate, at least in recital (6), the ACSH recommendation to revise the OELs for cobalt. This revision is an integral part of the consensus reached with the social partners and of the Commission's methodology referred to above, given that the residual risks remain very high even with the OEL of 2.5 µg/m^3 for the inhalable fraction. (2:1000)
(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[15] 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.	IE (Drafting suggestions): Certain polycyclic aromatic hydrocarbons (PAHs) mixtures, **[…]** containing benzo[a]pyrene, meet the criteria for classification IE (Comments): See comment in relation to Annex 3 Point A below LT (Comments): The additional sentence "particularly those containing benzo[a]pyrene" could be misleading and should be removed. The limit value is measured as benzo[a]pyrene (BaP) (according to the

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

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	footnote), and if this substance is not present, it cannot be measured. PAHs that do not contain BaP are still relevant for skin labeling. We would also like to underline that it is preferable to adopt a simplified wording for welding fumes and PAHs, in line with the phrasing used in 2.b), second subparagraph, for mercury below.
(8) For PAHs mixtures, it is foreseeable that it will be difficult for some sectors to comply with a limit value of 0,00007 mg/m³ (measured as benzo(a)pyrene) in the short term. It is therefore appropriate to introduce a transitional period of six years after entry into force of this Directive, during which the limit value of 0,00014 mg/m³ (measured as benzo(a)pyrene) should apply. That transitional period should be limited to the following sectors: (a) steel and iron foundries, which includes ferroalloy manufacturers; (b) aluminium manufacturers; (c) carbon and graphite electrode manufacturers; (d) coking plants; (e) coal tar distillation; (f) refractory products manufacturers; (g) welding of train tracks; (h) other non-ferrous metallurgical processes; and (i) casting of metals.	CZ (Comments): CZ welcomes the reduction of the limit. In the current draft directive, the limit set means a 97% tightening of the national limit (for benzo[a]pyrene) for CZ, which seems unrealistic and unachievable. Given the significant reduction in the limit, it is necessary for all sectors to have sufficient time to prepare for such a low limit. For this reason, in the first round of comments on the draft directive, CZ requested a transitional period of 6 years for all employers, regardless of the sector. CZ respects the non-compliance with our comment therefore CZ considers it necessary to apply at least a longer transitional period as also proposed by other Member States. CZ would like to point out that the current limit is critical. IT (Comments): The list in the directive proposal correctly contains all those sectors which were identified by the consultant. However, some of these sectors are overlapping and therefore it would be appropriate to merge some of the points to prepare a more compact list. RO (Comments): We believe that it shoud be notel that the limit value(s) refers to inhalable fraction.
	FI (Drafting suggestions):

Presidency compromise text	Drafting suggestions and Comments
	(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 and ACSH opinions, to establish a limit value for isoprene in Directive 2004/37/EC. FI (Comments): NL (2018) and DK (2024) have initiated two letters that have been addressed to the Commissioners stressing the need to set limit values for carcinogenic substances. Finland has signed both of the letters. We continue to be committed to set limit values in line with the CMRD article 16.1. which states that limit values shall be set for all those carcinogens, mutagens and reprotoxic substances for which this is possible. The tripartite ACSH proposed to set a limit value for isoprene. Even though the exposures appear to be currently well controlled and the calculated impacts of the OEL thus limited an EU-wide limit value would provide a common reference point for the safe level of exposure and thus a tool for risk assessment. Since all the work has already been carried out at the EU level it would appear justified to make use of the acquired information and the tripartite agreement and also include the value in the directive.
(9) 1,4-dioxane meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is therefore appropriate, based on the available information, including scientific and technical data, including the RAC[16] and ACSH opinions, to establish a long- and short-term occupational exposure limit value of 7,3 mg/m³ (2 ppm) and 73 mg/m³ (20 ppm), respectively, supplemented by a	EE (Drafting suggestions): (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[17] 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**.[…]**

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

Presidency compromise text	Drafting suggestions and Comments
skin notation and a biological limit value of 45 mg HEAA in urine/g creatinine, at the end of exposure or shift.	EE (Comments): We propose deleting the phrase *"at the end of exposure or shift"*, as it creates significant ambiguity regarding the timeframe for conducting biological limit value measurements. The expression *"end of exposure"* is open to several interpretations: it could mean the end of daily exposure, the completion of a specific project or assignment, or even the termination of the employment relationship. Each of these options refers to very different periods of time, ranging from a single workday to several years. Such a broad and unclear formulation creates the potential for inconsistent application across employers. This inconsistency would undermine both legal certainty and the protection of workers' health. Instead, the legal requirement should place emphasis on regular and systematic monitoring that reflects actual exposure conditions. Employers should be required to conduct biological limit value measurements at appropriate intervals, taking into account intensity of exposure, risks assessment and air monitoring results, and determine the optimal measurement frequency in consultation with the occupational health physician. This approach ensures that the timing of measurements is directly linked to the nature and intensity of workers' exposure and not left to broad and potentially unfavorable interpretation. As an alternative wording, we propose considering adding part that is explicitly stating that *"the employer shall conduct regular biological limit value measurements based on the risk assessment."* IE (Drafting suggestions): 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[18] 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 end of **representative** exposure or shift **as part of the workplace**

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

Presidency compromise text	Drafting suggestions and Comments
	sampling strategy. IE (Comments): **IE Comment**: *end of **representative** exposure or shift* - this wording is already used in the 2022 *Asbestos Directive "sampling should reflect the worker's personal exposure to asbestos. Samples should therefore be taken at regular intervals during specific operational phases in representative and realistic situations in which workers are exposed to asbestos dust."* And *"The duration of sampling shall be such that representative exposure can be established for an 8-hour reference period (one shift) by means of measurements or time-weighted calculations" EN689 European Standard specifies a strategy to perform representative measurements of exposure by inhalation to chemical agents in order to demonstrate the compliance with occupational exposure limit values (OELVs.)* EN689 is part of EU Commission HMP Guidance. LT (Comments): LT can support the drafting suggestion proposed by IE. We consider that the time requirements should be clearly and easily understandable for all stakeholders. Additionally, LT considers it useful to include references to the measures to be taken in the event that the results of the test do not meet the required standards. RO (Comments): A sentence should be inserted on the possibility of developing harmonised guidance by the COM on the biological monitoring of exposure to 1,4 dioxan via HEAA in urine and that this is determined at the end of exposure or work shift.
(9a) Directive (EU) 2022/431 of the European Parliament and the Council extended the scope of Directive 2004/37/EC to include reprotoxic substances,	CY (Comments): Agree

Presidency compromise text	Drafting suggestions and Comments
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)'.	CZ (Drafting suggestions): (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 **excluding xxx, yyyy, and zzz** ~~**that fall under the scope of Directive 2004/37/EC**~~ (measured as mercury)'. CZ (Comments): The new recital 9a, based on certain comments from Member States, stipulates that the scope of the directive (the specified limit) should, in the case of mercury, only apply to those mercury compounds that are classified as reprotoxic, i.e. that fall within the scope of Directive 2004/37/EC. Recital 9a also points out that certain (other) inorganic divalent mercury compounds do not meet the conditions for classification as reprotoxic compounds and should therefore be excluded from the scope of Directive 2004/37/EC. The original wording in Directive 2022/431 (CMRD 4) was unambiguous but incorrect, as it did not consider the exclusion of any compounds from the scope of the Directive. The current wording in CMRD 6 rightly proposes a distinction between reprotoxic and non-reprotoxic (inorganic divalent mercury compounds), but it still does not provide any guidance on how to classify individual inorganic divalent mercury compounds. The proposed wording is therefore very general and difficult to apply in practice. In view of the above mentioned, CZ recommends the distinction between compounds that do and do not have these properties be defined more specifically in the draft directive, e.g. on the basis of their physicochemical properties. It is also possible that the entire amendment is proposed only because of a single non-reprotoxic compound or a very small number of specific non-

Presidency compromise text	Drafting suggestions and Comments
	reprotoxic compounds, in which case it would be appropriate to list them. Please see the CZ text proposal. ES (Comments): We welcome the inclusion by the Presidency of a new Recital on **mercury.** Nevertheless, It would be useful for a specific Recital on mercury to state clearly that inorganic divalent mercury compounds outside the scope of the CMRD continue to be covered by the indicative OELs laid down in Directive 2009/161. Furthermore, the new Recital should also provide clarification regarding the reference in footnote 7 of Directive 2009/161, namely that, when monitoring exposure to mercury and its divalent inorganic compounds, due consideration should be given to relevant biological monitoring methods as a complement to the IOEL. FR (Comments): FR: The French authorities are satisfied with the new recital proposed by the Presidency. It would be useful to add that the provisions of Directive 98/24/EC on the protection of workers from the risks related to chemical agents at work, and in particular the OEL, remain applicable to non-CMR inorganic mercury compounds. If it is not in line with the rules to write a directive, this information should be added to COM communication when the directive will be published.
(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	

Presidency compromise text	Drafting suggestions and Comments
values should allow employers make the necessary investments in additional risk management measures and develop technical means of ensuring compliance. In this regard, existing Union programmes, such as Horizon Europe, could help to develop innovative solutions to protect workers' health.	
(11) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[19]. 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.	
(12) Since the objective of this Directive, namely to protect workers from exposure to carcinogens, mutagens and reprotoxic substances at work, cannot be sufficiently achieved by the Member States acting alone but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary to achieve	

[19]OJ L 123, 12.5.2016, p. 1.

Presidency compromise text	Drafting suggestions and Comments
that objective. Directive 2004/37/EC should therefore be amended accordingly,	
HAVE ADOPTED THIS DIRECTIVE:	
Article 1	
Directive 2004/37/EC is amended as follows:	
1) In Article 2, point (ba) is replaced by the following:	
'(ba) 'reprotoxic substance' means:	
i) a substance or mixture, which meets the criteria for classification as a category 1A or 1B reproductive toxicant set out in Annex I to Regulation (EC) No 1272/2008;	
ii) a substance, mixture or process referred to in Annex I to this Directive as well as a substance or mixture released by a process referred to in that Annex;'	CY (Drafting suggestions): **ii) a substance or mixture as well as a substance or mixture released by a process referred to in Annex I to this Directive;'** CY (Comments): We believe that a process cannot be set as definition of a reprotoxic substance." FI (Comments):

Presidency compromise text	Drafting suggestions and Comments
	There is a request in the ACSH Opinion stating that: "The ACSH encourages the Commission to clarify within Annex I or in the proposed entry for welding fumes the fact that currently Annex I contains only a list of carcinogenic substances, mixtures and processes and that reprotoxic substances, mixtures and processes need to be included in order to be consistent with the proposed welding fumes entry. It should also be taken into account that there is a need to distinguish between the requirements applying to carcinogens versus those for reprotoxicants.". The same is pointed out in the ECHA scoping study, which states that: "In addition there are some possible complications with an entry. Annex I of CMRD is for carcinogenic substances and mixtures only, so how should potential reprotoxic substances in welding fumes (that are not also carcinogenic) be considered. This may need a future extension of Annex I to include reprotoxic and mutagenic substances and mixtures.". This is challenging to formulate properly. The current addition can be taken to mean that all substances, mixtures and processes listed in Annex I would be also reprotoxic, which is not the case. Options to solve the problem include e.g. adding two subcategories to Annex I: 1) carcinogenic and mutagenic and 2) reprotoxic substances, mixtures and processes. Welding fumes would fit under both subcategories. Another option could perhaps be to modify the (ba) (ii) slightly so that it would only refer to such entries which are indicated as reprotoxic i.e.: *(ba)(ii) a substance, mixture or process**, which is** referred to **and indicated as reprotoxic** in Annex I to this Directive as well as a substance or mixture released by a process referred to **and indicated as reprotoxic** in that Annex;* (What would be the best way to address this depends also on whether other reprotoxic substances, mixtures and processes will be included to Annex I in the future). IE (Comments): **IE Comment** – Following the proposal by FL at SQWP on 1 October in relation to a possible two subcategories, IE would support this proposal and article 1 (ba)(ii) could be retained.
2) Annexes I, III and IIIa to Directive 2004/37/EC are amended in accordance with the Annex to this Directive.	

Presidency compromise text	Drafting suggestions and Comments
Article 2	
Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by […] **[two years after the date of entry into force of this Directive] […]**. They shall immediately inform the Commission thereof.	CY (Comments): Agree
When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.	
Member States shall communicate to the Commission the text of the main measures of national law which they adopt in the field covered by this Directive.	
	HU (Drafting suggestions): **Also in line with the ACSH opinion, the Commission shall develop within two years after the entry into force a non-binding practical guide with detailed information for the assessment of occupational exposure to welding fumes.** HU (Comments): Welding fumes are multi-component mixtures containing harmful chemical substances - including nanoparticles - for which determining the maximum permissible concentration (OEL) in workplace air is extremely complex. Welding processes themselves are diverse and heterogeneous, making the assessment of risks arising from occupational exposure to welding fumes particularly challenging.

Presidency compromise text	Drafting suggestions and Comments
Article 3	
This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.	
Article 4	
This Directive is addressed to the Member States.	
Done at Brussels,	
For the European Parliament *For the Council*	
The President *The President*	
ANNEX	
Annexes I, III and IIIa to Directive 2004/37/EC are amended as follows:	
(0) in Annex I, the title is replaced by the following:	CY (Comments): Agree
'List of substances, mixtures and processes (Article 2, points (a)(ii), (b) (ii)) and (ba) (ii))'	CY

Presidency compromise text	Drafting suggestions and Comments
	(Comments): Agree FR (Comments): FR: we support Finland proposal to separate in to this annex substances and process that are carcinogen from the one that are reprotoxic.
(1) in Annex I, the following point 9 is added:	
'9. Work involving exposure to fumes from welding processes containing substances **or mixtures** that meet **[…]** the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic **substance** set out in Annex I to Regulation (EC) No 1272/2008[20];	CY (Comments): Agree IE (Drafting suggestions): Work involving exposure to fumes from **processes, including** welding, **[…]** containing substances **or mixtures** that meet the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic **substance** set out in Annex I to Regulation (EC) No 1272/2008[21]; IE (Comments): Would remove the need for a welding definition?
(2) in Annex III, point A is amended as follows:	

[20] 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.

21 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.

<table>
<tr><th>Presidency compromise text</th><th>Drafting suggestions and Comments</th></tr>
<tr><td></td><td>FR
(Drafting suggestions):
The following entry should be added in the table of Annex III point:
<table><tr><th rowspan="3">EC No</th><th rowspan="3">CAS No</th><th rowspan="3">NAME OF THE CHEMICAL AGENT</th><th colspan="4">LIMIT VALUES</th><th rowspan="3">Notation</th><th rowspan="3">Transitional measures</th></tr><tr><th colspan="2">8 hours</th><th colspan="2">Short-term</th></tr><tr><th>mg/m³</th><th>ppm</th><th>mg/m³</th><th>ppm</th></tr><tr><td>201-143-3</td><td>78-79-5</td><td>Isoprene</td><td>8.5</td><td>3</td><td>-</td><td>-</td><td>-</td><td>-</td></tr></table>
FR
(Comments):
FR: see comment on the proposal to add a recital for isoprene.</td></tr>
<tr><td>(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:</td><td></td></tr>
<tr><td>‘</td><td></td></tr>
<tr><td><u>Name of agent</u>
Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are carcinogens, mutagens or reprotoxicants within the meaning of this Directive</td><td>IE
(Drafting suggestions):
<u>Name of agent</u>
Polycyclic aromatic hydrocarbons mixtures, […] containing benzo[a]pyrene, which are carcinogens, mutagens or reprotoxicants within the meaning of this Directive
IE
(Comments):
By deleting “particularly those” it gives a regulation that is measurable against the stated limit value. If they do not contain benzo[a]pyrene how are they to measured and to what limit?
LT
(Drafting suggestions):</td></tr>
</table>

Presidency compromise text	Drafting suggestions and Comments
	Polycyclic aromatic hydrocarbons mixtures, ~~particularly those containing benzo[a]pyrene, which are carcinogens, mutagens or reprotoxicants within the meaning of this Directive~~ **containing substances that fall under the scope of this Directive** LT (Comments): See comment recital 7
Limit values / 8 hours ([3]) / mg/m^3 ([5]) 0,00007(*[2])	PL (Comments): Consideration should be given to proposing a review of the effectiveness of the implementation of the introduced regulations seven years after the entry into force of this directive. This review should include an analysis of the availability of analytical methods, the costs incurred by companies to adapt technological processes, and an assessment of the impact of the changes on the level of worker health protection. The results of this review should form the basis for a possible revision of the target value to 0.00007 mg/m³. **Poland proposes preparing additional guidelines on measurement methods for PAH to ensure uniform monitoring across the European Union**. RO (Comments): The limit values should be accompanied by the specification that they are measured as benzo[a]pyrene in the inhalable fraction.
Notation Skin ([10])	
Transitional measures *Limit value 0,00014(*[2]) until …[OJ: six years after the date of entry into force of the amending Directive] limited*	IT (Comments):

Presidency compromise text	Drafting suggestions and Comments
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.	The list in the directive proposal correctly contains all those sectors which were identified by the consultant. However, some of these sectors are overlapping and therefore it would be appropriate to merge some of the points to prepare a more compact list. PL (Comments): The proposed limit of 140 ng/m³ until six years after the date of entry into force of the amending Directive, **with no additional transitional period for this value**, is unacceptable in Poland for the large population of workers employed in road construction and other high-temperature processes. **Currently, the maximum allowable concentration (MAC) of polycyclic aromatic hydrocarbons (PAHs) in Poland is 0.002 mg/m³ (2000 ng/m³), with a "skin" notation.** The same MAC value applies to benzo[a]pyrene. The draft directive proposes a significant, approximately 30-fold, reduction of this value – to 0.00007 mg/m³ (70 ng/m³). This limit is intended to apply after a transitional period of six years from the implementation of the directive's provisions. **During the transitional period, only in specific industrial sectors, the draft directive sets a higher MAC value of 0.00014 mg/m³ (140 ng/m³). The introduction of a transitional value is a positive step; however, it still represents an approximately 15-fold reduction compared to the current Polish limit. This transitional value would apply from the moment the directive is implemented without any additional transitional period at the national level.**
’	
(b) in the Table, the row related to mercury and divalent inorganic mercury compounds including mercuric oxide and mercuric chloride (measured as mercury) is replaced by the following:	
‘	
Name of agent	

Presidency compromise text	Drafting suggestions and Comments
Mercury and divalent inorganic mercury compounds that fall under the scope of this Directive (measured as mercury)	
Limit values / 8 hours ([3]) / mg/m^3 ([5]) 0,02	
Notation	
Transitional measures	
’;	
(c) in the table the following rows are added	
‘	
Name of agent Cobalt and inorganic cobalt compounds	
Limit values / 8 hours ([3]) / mg/m^3 ([5]) 0,01[…] **([17])**	
0,00255[…] **([18])**	
Notation dermal and respiratory sensitisation([13])	
Transitional measures	

Presidency compromise text	Drafting suggestions and Comments
Limit value of 0,02 [...] ([17]) and 0,0042 [...] ([18]) until ...[OJ: six years after the date of entry into force of the amending Directive]	
	FI (Drafting suggestions): **Name of agent** **Isoprene** **EC No ([1])** **78-79-5** **CAS No ([2])** **201-143-3** **Limit values** **8 hours ([3]) / mg/m³ ([5])** **8,5** **8 hours ([3]) / ppm ([6])** **3** FI (Comments): For comments see the proposed recital 8(a).
Name of agent 1,4-dioxane	
EC No ([1]) **204-661-8**	

Presidency compromise text	Drafting suggestions and Comments
CAS No (2) **123-91-1**	
Limit values	
8 hours (3) / mg/m3 (5) 7,3	
8 hours (3) / ppm (6) 2	
Short-term (4) / mg/m3 73	
Short-term (4) / ppm 20	
Notation Skin (10)	
Transitional measures	
’;	
(cc) in the footnotes after the Table, the following footnotes (17) and (18) are added:	CY (Comments): Agree
‘(17) Inhalable fraction, measured as Cobalt.	CY

Presidency compromise text	Drafting suggestions and Comments
	(Comments): Agree
([18]) Respirable fraction, measured as Cobalt.'	CY (Comments): Agree
(d) in the footnotes after the Table, the following footnote (*[2]) is added:	
'(*[2]) Measured as benzo[a]pyrene.';	
([1]) EC No, i.e. Einecs, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, to Regulation (EC) No 1272/2008.	
([2]) CAS No: Chemical Abstract Service Registry Number.	
([3]) Measured or calculated for a reference period of eight hours time-weighted average (TWA).	
([4]) Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is for a 15-minute period unless otherwise specified.	
([5]) mg/m^3 = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).	
([6]) ppm = parts per million by volume in air (ml/m^3).	
([7]) f/ml = fibres per millilitre.	
[…]	

Presidency compromise text	Drafting suggestions and Comments
([10]) Substantial contribution to the total body burden via dermal exposure possible.	
[…]	
([13]) The substance can cause sensitisation of the skin and of the respiratory tract.	
(3) in Annex IIIa, the following point is added:	
'1,4-dioxane	
2. The binding biological limit value is 45 mg HEAA*in urine/g creatinine.'	ES (Drafting suggestions): 2. The binding biological limit value is 45 mg HEAA*in urine/g creatinine **at the end of exposure or shift.** ES (Comments): The timing of sampling for 1,4-dioxane should be included, as set out in Recital 9. Sampling time of the biomonitoring sample is critical for chemicals with short half-lives and affects the resulting data. They are determined by the retention times of the chemical within the human body. As mentioned in the RAC opinion on 1,4-dioxane, sampling needs to take place at the end of exposure or end of shift. FI (Drafting suggestions): Add: ", **at the end of exposure or shift**". FI (Comments):

Presidency compromise text	Drafting suggestions and Comments
	For substances with a relatively short half-life such as 1,4-dioxane, it is crucial that sampling takes place at a correct time. According to RAC "sampling needs to take place at the end of exposure or end of shift". If this information is included only in the recital of the amending directive, the information will not be incorporated to the consolidated version of the CMRD directive. If it is in some MSs unclear what "end of exposure" means those MSs have a possibility to clarify that when transposing the directive to their national legislation. IT (Drafting suggestions): The binding biological limit value is 45 mg HEAA*in urine/g creatinine, at the end of exposure or shift. IT (Comments): The recitals and the annex should be consistent with each other LT (Comments): The timing of sampling for 1,4-dioxane should be duly specified, as referred to in Recital 9. The timing of biomonitoring samples is of particular importance for substances with short biological half-lives, as it significantly influences the reliability and comparability of the resulting data. PL (Comments): **Serious concerns are associated with the introduction of a binding Biological Limit Value (BLV) for 1,4-dioxane without additional provisions regarding health surveillance, definition of measurement methodology in biological material, and the introduction of a transitional period for the BLV value.** **1.** The introduction of a binding BLV for 1,4-dioxane at the level of 45 mg HEAA without an extended transitional period and without provisions specifying how health surveillance should be conducted, raises serious doubts from the perspective of both national and European practices in workers' health protection. This substance is used in industry to a limited extent,

Presidency compromise text	Drafting suggestions and Comments
	and the draft directive sets a binding BLV for it, while for other, much more widespread and toxic agents such as cobalt or polycyclic aromatic hydrocarbons (PAHs), no binding biological values have been established (respectively 113,000 and 1,284,052 workers exposed in the EU vs. 31,150 exposed to 1,4-dioxane, according to the "Explanatory Memorandum" to the draft directive, p. 2). It should also be noted that in Poland, for example, 1,4-dioxane is primarily used in laboratories in small quantities and under strictly controlled conditions. The draft does not include provisions specifying how health surveillance should be conducted (such provisions were included in the case of lead), but only defines the BLV. In practice, this makes it impossible to conduct medical examinations and interpret the results in a standardized manner. **2.** Another issue related to the introduction of the BLV for 1,4-dioxane is the lack of established analytical methods and accredited laboratories for determining HEAA in biological materials, which makes effective and reliable monitoring of workers impossible. **The introduction of a binding BLV for 1,4-dioxane without providing adequate technical and systemic tools could lead to interpretative ambiguities and difficulties in enforcing the regulations, which, in consequence, could weaken rather than strengthen worker protection.** **In the opinion of PL, there should be at least a 5-year transition period for BLV** RO (Comments): We propose to add the clarification in recital 9 that HEAA in urine is determined at the end of exposure or work shift. SE (Drafting suggestions): 2.**1** The binding biological limit value is 45 mg HEAA*in urine/g creatinine.' **2.2 Sampling needs to take place at the end of exposure or end of shift.** SE (Comments):

Presidency compromise text	Drafting suggestions and Comments
	The timing of sampling for 1,4-dioxane should be included, as set out in Recital 9. Sampling time of the biomonitoring sample is critical for chemicals with short half-lives and affects the resulting data.
_____	
*(2-Hydroxyethoxy)acetic acid'.	