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**NOTE**

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From: General Secretariat of the Council  
To: Permanent Representatives Committee

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Subject: Preparation for the Council (EPSCO) on 1 December 2025:  
Revision of Directive 2004/37/EC on carcinogens, mutagens and  
reprotoxic substances at work (sixth batch)  
*- General approach*

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**I. INTRODUCTION**

On 18 July 2025, the Commission submitted to the Council and the European Parliament a 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 <sup>1</sup>. This is the sixth amendment of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work.

The proposal aims to improve the protection of workers against dangerous chemicals at the workplace inter alia by setting exposure limits for cobalt and its inorganic compounds, for polycyclic aromatic hydrocarbons (PAHs) and for 1,4-dioxane, and by adding welding fumes to the list of substances, mixtures and processes in Annex I to the Directive.

The legal basis of the proposal is Article 153(2), point (b), in conjunction with Article 153(1), point (a) of the Treaty on the Functioning of the European Union (ordinary legislative procedure).

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<sup>1</sup> Doc. 11823/25 + ADD1

The opinions of the European Economic and Social Committee and of the European Committee of the Regions were requested on 16 September 2025. The European Economic and Social Committee delivered its opinion<sup>2</sup> on 23 October 2025. The European Committee of the Regions decided not to deliver an opinion on the proposal, as notified via a renunciation letter<sup>3</sup> on 13 October 2025.

In the European Parliament, the Committee on Employment and Social Affairs has the lead responsibility. Liesbet Sommen (EPP, BE) was appointed Rapporteur. The European Parliament is expected to adopt its negotiating mandate in 2026.

The national parliaments of Italy<sup>4</sup> and Spain<sup>5</sup> issued opinions on the Commission proposal.

## II. STATE OF PLAY IN THE COUNCIL

The Social Questions Working Party discussed the proposal at its meetings on 1 September, 9 September, 1 October, 21 October and 11 November and has agreed on the text in the annex to this note.

Changes in relation to the Commission proposal (as set out in doc. 11823/25 + ADD1) are marked in **bold** and deletions are marked with [...]. In addition, changes of a legal-linguistic nature are marked in ***bold italics*** and deletions with ***[...]***.

The Impact Assessment<sup>6</sup> accompanying the Commission proposal was discussed in the Social Questions Working Party on 1 September and 9 September and delegations' views were gathered through an Impact Assessment questionnaire<sup>7</sup>. A summary of the replies to the Impact Assessment questionnaire is to be found in the Addendum to this note.

## III. PRESIDENCY COMPROMISE PROPOSAL

The main changes in the Presidency compromise text compared to the Commission proposal as a result of examination at Working Party level include the following:

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<sup>2</sup> Doc. 14688/25

<sup>3</sup> Doc. 14318/25

<sup>4</sup> Doc. 14193/25, 15377/25, 15381/25

<sup>5</sup> Doc. 14490/25

<sup>6</sup> Doc. 11823/25 ADD3

<sup>7</sup> Doc. WK 10146/2025

### **Residual cancer risk (Recital 2a)**

In line with previous revisions of Directive 2004/37/EC, a recital was included to state that, while setting limit values for exposure to carcinogens and mutagens does not completely eliminate risks to the health and safety of workers arising from exposure at work (residual risk), it nonetheless contributes to a significant reduction of risks arising from such exposure.

### **Welding fumes guidance (Recital 3)**

A reference was introduced in Recital 3 to stress the importance of the development of further guidance on welding fumes, which was strongly recommended by the Advisory Committee on Safety and Health at Work (ACSH). Such guidance, based on the latest scientific evidence, could serve to assist companies and labour inspectors in ensuring compliance with the welding fumes entry in Annex I to the Directive, and to promote a common minimum high level of protection for all workers exposed to welding fumes.

### **1,4-dioxane biological limit value (Annex IIIa entry, Recital 9)**

In relation to the biological limit value that the revision introduces in Annex IIIa to the Directive for 1,4-dioxane, additional wording was added to indicate that it should be measured at the end of exposure or shift, in accordance with national laws and/or practice. It should be noted that the opinions of both ACSH and the Risk Assessment Committee (RAC) of the European Chemicals Agency referred to the end of exposure or shift in relation to the biological limit value for 1,4-dioxane.

### **Explanation of modification of mercury Annex III entry (Recital 9a)**

A recital was added to explain that the revision corrects the wording of the existing entry for “mercury and divalent inorganic mercury compounds including mercuric oxide and mercuric chloride” in Annex III of the current directive. This change was necessary so that the entry refers only to those mercury and divalent inorganic mercury compounds that fall under the scope of Directive 2004/37/EC.

### **Amendment of “carcinogen”, “mutagen” and “reprotoxic substance” definitions (Article 1)**

With the inclusion for the first time in Annex I to the Directive of an entry with effects potentially reprotoxic (welding fumes), it became necessary to update the definitions of “carcinogen”, “mutagen” and “reprotoxic substance” in the Directive, as currently only the definitions of

“carcinogen” and “mutagen” make reference to Annex I entries, without differentiating between the carcinogenic, mutagenic or reprotoxic effects of substances, mixtures or processes listed in Annex I.

### **Inclusion of the substance isoprene in the scope of the Directive (Annex III entry, Recital 8a)**

The compromise text features an Occupational Exposure Limit (OEL) for isoprene – a substance that had not been included in the Commission proposal. For isoprene, the Commission decided not to follow the RAC and ACSH recommendations to set an OEL because of the findings of the study underpinning the Commission Impact Assessment, which indicated that, in practice, workers are exposed to lower levels of isoprene than the limit value derived by RAC in its opinion. The Commission therefore concluded that the current prevention of occupational exposure to isoprene is sufficient and decided on that basis not to propose an EU-level OEL.

Nevertheless, in the context of the discussions of the Social Questions Working Party, a significant number of delegations requested the inclusion of isoprene in the scope of the Directive for a multitude of reasons. In the first place, they argued that the text as proposed by the Commission does not protect the workers’ health from the potential exposure to this harmful substance and does not take into account the need for preventive action in this sense. With regard to the conclusions of the study and the Impact Assessment, as acknowledged by the Impact Assessment and the study report, data on exposure to isoprene remains limited and the conclusions are drawn on that limited data. Member States’ experts noted, in that respect, that the current indications – based on that limited data – cannot be considered conclusive and exhaustive; that certain activities take place outside of the closed systems where isoprene is usually handled; that in the future there might be new cases of use, such as emerging sectors or new work processes involving isoprene, for which it would be useful if an EU-level OEL could be taken into account; and that, where there is such doubt as to whether the workers’ health is and will remain sufficiently protected, the decision should be made to act preventively. Discussions likewise took into account the balancing of effects of this potential OEL with the costs and burdens potentially resulting from its inclusion in the Directive. It was underlined in this regard that the study and the Impact Assessment note that the costs related to the introduction of the OEL for isoprene are likely to be very limited, and that – where there is already compliance with the limits – there would be no need for adaptation. The delegations further underlined – as recognised also by the study and the Impact Assessment, given that only five Member State currently have an OEL set for isoprene – that setting an EU-level OEL would ensure legal certainty and a level-playing field. This would also reduce the administrative burden associated with companies and authorities establishing their own limit values and managing

risks, while making use of the technical work already carried out to derive the EU-level OEL. Due consideration was likewise given to the fact that the introduction of the OEL for isoprene was recommended by the tripartite ACSH, where consensus was reached by the social partners and government representatives in this respect.

Taking into account all the above arguments, and in line with the precautionary principle and the objective to protect workers' health, the decision was made to include isoprene in the scope of the Directive, setting the OEL recommended by RAC and ACSH.

#### IV. CONCLUSION

The Presidency considers that the text in the annex represents a balanced compromise, addressing the main issues raised by delegations.

The Permanent Representatives Committee is invited to:

- examine the compromise text as set out in the annex to this note, and
- submit it to the Council (EPSCO) with a view to reaching a general approach at its session on 1 December 2025.

Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Directive 2004/37/EC as regards the addition of substances and setting limit values in its Annexes I, III and IIIa**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 153(2), point (b), in conjunction with Article 153(1), point (a), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>8</sup>,

After consulting the Committee of the Regions<sup>9</sup>,

Acting in accordance with the ordinary legislative procedure,

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<sup>8</sup> OJ C [...], [...], p. [...].

<sup>9</sup> OJ C [...], [...], p. [...].

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<sup>10</sup> 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<sup>11</sup> and opinions of the Advisory Committee on Safety and Health at Work (ACSH) *set up by Council Decision of 22 July 2003*<sup>12</sup>.
- (2) Directive 2004/37/EC covers substances or mixtures which meet the criteria for classification as a category 1A or 1B carcinogen, mutagen or [...] **reproductive toxicant** set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council<sup>13</sup> 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 [...] Annex I to **Directive 2004/37/EC** to demonstrate that [...] **those** substances, mixtures and processes fall under the scope of **that**

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<sup>10</sup>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).

<sup>11</sup>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>).

<sup>12</sup>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).

<sup>13</sup>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).

Directive [...], 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*.

- (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 (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.**
- (3) The IARC classified welding fumes as ‘carcinogenic to humans’ (Group 1 of the IARC classification). According to the ECHA scoping study<sup>14</sup>, 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) *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 2004/37/EC. It is therefore appropriate, in line with the opinion of the ACSH<sup>15</sup>, to include in Annex I to Directive 2004/37/EC work involving exposure to fumes from welding processes containing substances **or mixtures which [...]** meet [...]
- the criteria for classification as a category 1A or 1B carcinogen, mutagen or [...] 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**

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<sup>14</sup>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 \(europa.eu\)](#)

<sup>15</sup>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 \(europa.eu\)](#)

the existing guidance, such as the **Guidance for National Labour Inspectors on addressing health risks from Welding Fume**<sup>16</sup> developed by the Senior Labour Inspectorate Committee in 2018, further 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.

- (4) Cobalt metal and several cobalt compounds meet the criteria for classification as carcinogenic and [...] *reproductive toxicant* (category 1B) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens or [...] *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.
- (5) The [...] ACSH [...], based on the RAC opinion<sup>17</sup>, 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/m<sup>3</sup> for the inhalable fraction and 0,0025 mg/m<sup>3</sup> for the

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<sup>16</sup> 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](https://circabc.europa.eu/ui/group/fea534f4-2590-4490-bca6-504782b47c79/library/2997b89a-1fbd-4f35-9874-9a9b5ea1a403?p=1&n=-1&sort=name_ASC)

<sup>17</sup><https://echa.europa.eu/oels-activity-list/-/substance-rev/69405>

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/m<sup>3</sup> (inhalable fraction) and 0,0042 mg/m<sup>3</sup> (respirable fraction) should apply.

- (7) Certain polycyclic aromatic hydrocarbons (PAHs) mixtures, particularly those containing benzo[a]pyrene, meet the criteria for classification as carcinogenic, mutagenic or *[.../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<sup>18</sup> has identified the possibility of significant uptake through the skin for those mixtures and the ACSH has agreed on the importance of introducing an occupational exposure limit value for all PAH mixtures falling under the scope of Directive 2004/37/EC, measured as benzo(a)pyrene, and to maintain a skin notation already contained in Annex III.
- (8) For PAHs mixtures, it is foreseeable that it will be difficult for some sectors to comply with a limit value of 0,00007 mg/m<sup>3</sup> (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/m<sup>3</sup> (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.
- (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<sup>19</sup> and ACSH opinions, to establish a longterm occupational exposure limit value of 8,5 mg/m<sup>3</sup> (3 ppm).**
- (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

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<sup>18</sup><https://echa.europa.eu/oels-activity-list/-/substance-rev/63901>

<sup>19</sup> <https://echa.europa.eu/oels-activity-list/-/substance-rev/62301/term>

Directive 2004/37/EC. It is therefore appropriate, based on the available information, including scientific and technical data, including the RAC<sup>20</sup> and ACSH opinions, to establish a long- and short-term occupational exposure limit value of 7,3 mg/m<sup>3</sup> (2 ppm) and 73 mg/m<sup>3</sup> (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**.

- (9a) **Directive (EU) 2022/431 of the European Parliament and the Council extended the scope of Directive 2004/37/EC to include reprotoxic substances, including mercury and divalent inorganic mercury compounds, which were added to Annex III to Directive 2004/37/EC. Since not all divalent inorganic mercury compounds can be classified as reprotoxic substances, it is necessary to clarify that the limit value applies only to mercury and divalent inorganic mercury compounds that fall under the scope of Directive 2004/37/EC. The term ‘mercury and divalent inorganic mercury compounds including mercuric oxide and mercuric chloride (measured as mercury)’ should therefore be replaced by the term ‘mercury and divalent inorganic mercury compounds that fall under the scope of Directive 2004/37/EC (measured as mercury)’.**
- (10) The Commission has carried out a two-stage consultation of social partners in accordance with Article 154 of the Treaty on the Functioning of the European Union. It has also consulted the ACSH, which has adopted opinions for all substances subject to this Directive and recommended one or several binding limit values for each of them, and notations and transitional values for some of them, where appropriate. Transitional values should allow employers make the necessary investments in additional risk management measures and develop technical means of ensuring compliance. In this regard, existing Union programmes, such as Horizon Europe, could help to develop innovative solutions to protect workers’ health.
- (11) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making<sup>21</sup>. When establishing or revising limit values, the Commission

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<sup>20</sup><https://echa.europa.eu/oels-activity-list/-/substance-rev/61801>

<sup>21</sup>OJ L 123, 12.5.2016, p. 1.

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

- (12) Since the objective of this Directive, namely to protect workers from exposure to carcinogens, mutagens and reprotoxic substances at work, cannot be sufficiently achieved by the Member States acting alone but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary to achieve that objective. [...]

**(12a) 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, points (a), (b) and (ba) [...] are replaced by the following:**

**‘(a) ‘carcinogen’ means:**

**(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\*;**

**(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;**

**(b) ‘mutagen’ means:**

**(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;**

**(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 mutagenic effects;**

**(ba) ‘reprotoxic substance’ means:**

**i) a substance or mixture which meets the criteria for classification as a category 1A or 1B reproductive toxicant set out in Annex I to Regulation (EC) No 1272/2008;**

**ii) a substance, mixture or process referred to in Annex I to this Directive as well as a substance or mixture released by a process referred to in that Annex, included in the list set out in that Annex because of its reprotoxic effects;**

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**\* 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).’**

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

#### *Article 2*

**1.** Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [...] **[two years after the date of entry into force of this Directive]** [...]. They shall immediately inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such [...] reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

**2.** Member States shall communicate to the Commission the text of the main measures of national law which they adopt in the field covered by this Directive.

*Article 3*

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels,

*For the European Parliament*

*The President*

*For the Council*

*The President*

Agence Europe

## ANNEX

Annexes I, III and IIIa to Directive 2004/37/EC are amended as follows:

(0) in Annex I, the title is replaced by the following:

**‘List of substances, mixtures and processes (Article 2, points (a)(ii), (b)(ii) and (ba)(ii))’**

(1) in Annex I, the following point 9 is added:

‘9. Work involving exposure to fumes from welding processes containing substances **or mixtures which [...]** meet [...] the criteria for classification as a category 1A or 1B carcinogen, mutagen or [...] **reproductive toxicant** set out in Annex I to Regulation (EC) No 1272/2008<sup>22</sup>;

(2) in Annex III, point A is amended as follows:

(a) in the Table the row related to polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are carcinogens within the meaning of this Directive, is replaced by the following:

Name of agent	EC No (1)	CAS No (2)	Limit values						Notation	Transitional measures
			8 hours (3)			Short-term (4)				
			mg/m <sup>3</sup> (5)	ppm (6)	f/ml (7)	mg/m <sup>3</sup> (8)	ppm (9)	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)

<sup>22</sup>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.

											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.
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(b) in the Table, the row related to mercury and divalent inorganic mercury compounds including mercuric oxide and mercuric chloride (measured as mercury) is replaced by the following:

Name of agent	EC No (1)	CA S No (2)	Limit values						Notation	Transitional measures
			8 hours (3)			Short-term (4)				
			mg/m <sup>3</sup> (5)	ppm (6)	f/ml (7)	mg/m <sup>3</sup> (8)	ppm (9)	f/ml (10)		
Mercury and divalent inorganic mercury compounds that fall under the scope of this Directive (measured as mercury)			0,02		–	–	–	–		

(c) in the table the following rows are added

Name of agent	EC No (1)	CA S No (2)	Limit values						Notation	Transitional measures
			8 hours (3)			Short-term (4)				
			mg/m <sup>3</sup> (5)	ppm (6)	f/ml (7)	mg/m <sup>3</sup> (8)	ppm (9)	f/ml (10)		
Cobalt and inorganic cobalt compounds			0,01 [...] (17)		–	–	–	–	dermal and respiratory sensitisation (13)	Limit value of 0,02 [...] (17) and 0,0042 [...] (18) until ...[OJ: six

			0,002 5[...] ( <sup>18</sup> )							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	12 3- 91- 1	7,3	2		73	20		Skin ( <sup>10</sup> )	

’;

(ca) in the footnotes after the Table, the following footnotes (<sup>17</sup>) and (<sup>18</sup>) are added:

‘(<sup>17</sup>) Inhalable fraction, measured as Cobalt.

(<sup>18</sup>) Respirable fraction, measured as Cobalt.’

(d) in the footnotes after the Table, the following footnote (<sup>\*2</sup>) is added:

‘(<sup>\*2</sup>) Measured as benzo[a]pyrene.’;

(<sup>1</sup>) 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.

(<sup>2</sup>) CAS No: Chemical Abstract Service Registry Number.

(<sup>3</sup>) Measured or calculated for a reference period of eight hours time-weighted average (TWA).

(<sup>4</sup>) 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.

(<sup>5</sup>) mg/m<sup>3</sup> = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).

(<sup>6</sup>) ppm = parts per million by volume in air (ml/m<sup>3</sup>).

(<sup>7</sup>) f/ml = fibres per millilitre.

[...]

(<sup>10</sup>) Substantial contribution to the total body burden via dermal exposure possible.

[...]

(<sup>13</sup>) 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, **measured at the end of exposure or shift, in accordance with national laws and/or practice.**’

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\*(2-Hydroxyethoxy)acetic acid’.

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