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*Plenary sitting*

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**A9-0114/2021**

7.4.2021

**\*\*\*I**  
**REPORT**

on the proposal for a directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (COM(2020)0571– C9-0301/2020 – 2020/0262(COD))

Committee on Employment and Social Affairs

Rapporteur: Stefania Zambelli

### ***Symbols for procedures***

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

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

### ***Amendments to a draft act***

#### **Amendments by Parliament set out in two columns**

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

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

#### **Amendments by Parliament in the form of a consolidated text**

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

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

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the proposal for a directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (COM(2020)0571 – C9-0301/2020 – 2020/0262(COD))**

**(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2020)0571),
  - having regard to Article 294(2) and Article 153(2)(b) and (1)(a) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0301/2020),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to Rules 59 of its Rules of Procedure,
  - having regard to the opinion of the Committee on Legal Affairs;
  - having regard to the report of the Committee on Employment and Social Affairs (A9-0114/2021)
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments;

Amendment 1

**Draft legislative resolution**  
**Citation 3 a (new)**

*Draft legislative resolution*

*Amendment*

- ***having regard to the Charter of Fundamental Rights of the European Union, and in particular Article 2 (the right to life) and Article 31 (the right to fair and just working conditions),***

## Amendment 2

### Proposal for a directive Recital 1

*Text proposed by the Commission*

(1) Directive 2004/37/EC of the European Parliament and the Council<sup>45</sup> aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. A **consistent** level of protection from the risks related to the occupational exposure to carcinogens and mutagens is provided for in that Directive by a framework of general principles to enable Member States to ensure the consistent application of minimum requirements. The aim of these minimum requirements is to protect workers at Union level. More stringent provisions can be set by Member States.

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<sup>45</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 or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

*Amendment*

(1) Directive 2004/37/EC of the European Parliament and the Council<sup>45</sup> aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. A **high** level of protection from the risks related to the occupational exposure to carcinogens and mutagens is provided for in that Directive by a framework of general principles to enable Member States to ensure the consistent application of minimum requirements. The aim of these minimum requirements is to protect workers at Union level. More stringent provisions can be set by Member States.

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<sup>45</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 or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

## Amendment 3

### Proposal for a directive Recital 1 a (new)

*Text proposed by the Commission*

*Amendment*

***(1a) This Directive clearly shows the added value of the Union and the need to adopt legislation at Union level. In addition to setting similar minimum level of protection across the Union, this Directive also improves clarity and***

*enforcement, and contributes to a better level playing field for the economic actors in the sectors using the substances covered.*

#### Amendment 4

#### Proposal for a directive Recital 1 b (new)

*Text proposed by the Commission*

*Amendment*

***(1b) In the workplace, workers and other persons are often exposed to a cocktail of substances, which can increase health risks, cause adverse effects on their reproductive systems and cause impaired fertility or infertility, and have a negative impact on foetal development and lactation. Substances which are toxic to reproduction are of very high concern and the organisation of workplace prevention should apply the same approach to reprotoxic substances as for carcinogens and mutagens. As not all reprotoxic substances are threshold substances, it is of the utmost importance to enlarge the scope of Directive 2004/37/EC to reprotoxic substances in order to bring it in line with Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>1a</sup>. This is necessary to better protect workers and their children and to ensure the safe participation of all workers in the workplace, in particular female workers who are pregnant or breastfeeding. In Regulation (EC) No 1907/2006, half of the 211 substances identified as substances of very high concern are reprotoxic substances. As is the case in some Member States, the organisation of workplace prevention should therefore apply the same approach to carcinogens, mutagens and reprotoxic substances, thus ensuring legal coherence and a level playing field across Member States.***

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***1<sup>a</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).***

### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

### **Amendment 5**

#### **Proposal for a directive Recital 1 c (new)**

*Text proposed by the Commission*

*Amendment*

***(1c) A high level of human health protection should be ensured in the definition and implementation of all Union policies and activities.***

### **Amendment 6**

#### **Proposal for a directive Recital 2**

*Text proposed by the Commission*

*Amendment*

(2) Principle 10 of the European Pillar of Social Rights<sup>46</sup>, jointly proclaimed by

(2) Principle 10 of the European Pillar of Social Rights<sup>46</sup>, jointly proclaimed by



the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, provides workers' right to a high level of protection of their health and safety at work, which includes the protection from the exposure to carcinogens *and* mutagens at the workplace.

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<sup>46</sup> European Pillar of Social Rights, November 2017, available at : [https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet_en.pdf)

the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, provides workers' right to a high level of protection of their health and safety at work, which includes the protection from the exposure to carcinogens, mutagens *and reprotoxic substances* at the workplace, *irrespective of the arrangements for and duration of the employment or the exposure.*

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<sup>46</sup> European Pillar of Social Rights, November 2017, available at : [https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet_en.pdf)

## Amendment 7

### Proposal for a directive Recital 2 a (new)

*Text proposed by the Commission*

*Amendment*

***(2a) Europe's Beating Cancer Plan, set out in the Commission communication of 3 February 2021, aims to reduce the cancer burden for patients, their families and health systems. Cancer is the primary cause of work-related death in the Union: 52 %<sup>1</sup> of annual occupational deaths are currently attributed to work-related cancers. Exposure at work accounts for 5,3 to 8,4 %<sup>2</sup> cases of cancer and is responsible for approximately 120 000<sup>3</sup> cancers diagnosed and more than 100 000<sup>4</sup> deaths every year. Therefore, following the amendments to Annex III to Directive 2004/37/EC, as set out in this Directive, further limit values for additional substances or group of substances and processes should be introduced by end of 2024. Between 50 and 70 substances or group of substances have been identified by different agencies, stakeholders, and the World Health***

**Organization in priority lists of workplace carcinogens, mutagens and reprotoxic substances for which binding limit values are needed. The Commission should, no later than the end of 2021, put forward an action plan to achieve occupational exposure limits for at least 25 additional substances or group of substances or process generated substances. The additional substances or group of substances referred to in Annex III to Directive 2004/37/EC should include but not be limited to substances and processes such as welding fumes, benzo[a]pyrene/Poly Aromatic Hydrocarbons (PAHs),  $\alpha$ -Chlorotoluene (Benzyl Chloride), Nitrosamines, soot, Silicone carbide fibers, 1,2-Dichloropropane, 1,2-Dihydroxybenzene (pyrocatechol), 2-Chloro-1,3-butadiene (Chloroprene), 2,3-Epoxypropyl methacrylate (glycidyl methacrylate), Anthraquinone, N-(Hydroxymethyl) acrylamide (NMA), 1,2-Dichloropropane, 1,2,3-Trichloropropane, Butanone oxime, Ethylene imine (Aziridine), 1-4dioxane, isoprene. Reprotoxic substances should include lead and lead compounds, Bisphenol-A, Carbon Monoxide, Mercury and divalent inorganic mercury compounds, N-methyl-2-pyrrolidone, N,N-Dimethylacetamide, Nitrobenzene, N,N Dimethylformamide, 2-Methoxy ethanol, 2-Methoxyethyl acetate, 2-Ethoxyethanol, 2-Ethoxyethyl acetate, di(2-ethylhexyl)phthalate, benzyl butyl phthalate and dibutyl phthalate.**

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<sup>1</sup>

[https://ec.europa.eu/commission/presscorner/detail/en/IP\\_20\\_1691](https://ec.europa.eu/commission/presscorner/detail/en/IP_20_1691)

<sup>2</sup>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4551060/>

<sup>3</sup> <https://osha.europa.eu/en/themes/work-related-diseases/work-related-cancer>

<sup>4</sup>

<https://www.ncbi.nlm.nih.gov/pmc/articles>

## Amendment 8

### Proposal for a directive

#### Recital 3

*Text proposed by the Commission*

(3) Binding occupational exposure limit values are important component of the general arrangements for the protection of workers established by Directive 2004/37/EC and must not be exceeded. Limit values and other directly related provisions should be established for all those carcinogens *or* mutagens for which the available information, including scientific and technical data, make this possible.

*Amendment*

(3) Binding occupational exposure limit values are important component of the general arrangements for the protection of workers established by Directive 2004/37/EC and must not be exceeded. Limit values and other directly related provisions should be established for all those carcinogens, mutagens *and reprotoxic substances* for which the available information, including *updated* scientific and technical data, make this possible.

## Amendment 9

### Proposal for a directive

#### Recital 4

*Text proposed by the Commission*

(4) Compliance with binding occupational exposure limit values is without prejudice to other employers' obligations pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens *and* mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens *or* mutagens and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the carcinogen *or* mutagen by a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures aiming to reduce the level of workers'

*Amendment*

(4) Compliance with binding occupational exposure limit values is without prejudice to other employers' obligations pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens, mutagens *and reprotoxic substances* at the workplace, the prevention or reduction of workers' exposure to carcinogens, mutagens *or reprotoxic substances* and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the carcinogen, mutagen *and reprotoxic substance* by a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures

exposure.

aiming to reduce the level of workers' exposure.

### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## **Amendment 10**

### **Proposal for a directive Recital 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***(4a) There is a need for in-depth knowledge on the effect of the substances handled by workers in the healthcare sector. The training that the employer is required to provide pursuant to Article 11 of Directive 2004/37/EC should not only be provided periodically to workers in the healthcare sector but should be provided systematically to all healthcare workers who are exposed to cytotoxic substances or mutagens.***

## **Amendment 11**

### **Proposal for a directive Recital 4 b (new)**

*Text proposed by the Commission*

*Amendment*

***(4b) In addition to the requirements set out in Article 5(5) of Directive 2004/37, employers in the health and social care sectors should prevent the exposure to carcinogens, mutagens and reprotoxic substances of workers, patients and their family members who are pregnant, breast feeding or trying to conceive.***

## Amendment 12

### Proposal for a directive Recital 4 c (new)

*Text proposed by the Commission*

*Amendment*

***(4c) Tackling exposures to dangerous substances at the workplace is particularly relevant for the purpose of fostering prevention and address health inequalities, as some categories of workers among the most vulnerable can be overexposed or more vulnerable to different types of substances. Women, for example, are over-represented among oncology nurses , who are potentially exposed to hazardous medicinal products. In sectors in which workers are exposed to carcinogens, mutagens or reprotoxic substances, gender mainstreaming should be an integral part of the development of occupational safety and health policies and prevention strategies. Member States' authorities should, in consultation with the social partners, take steps to mainstream gender equality and considerations to workers with disabilities and LGBTQI+ in the implementation of Articles 7, 8 and 10 of Directive 2004/37/EC, in particular with regard to sanitary facilities, work equipment and personal protective equipment.***

## Amendment 13

### Proposal for a directive Recital 4 d (new)

*Text proposed by the Commission*

*Amendment*

***(4d) Some workers, such as mobile workers, can additionally face difficulties in accessing healthcare services. Moreover, sectors such as the steel and chemicals industry as well as the cleaning***

*sector in health services rely on posted, mobile and migrant workers. Member States' authorities should ensure, in particular, that the measures on the prevention and reduction of exposure measures for workers set out in Article 5, as well as the information and training requirement provided for in Articles 11 and 12 of Directive 2004/37/EC take into consideration the vulnerable situation of posted, mobile and migrant workers.*

#### **Amendment 14**

##### **Proposal for a directive Recital 4 e (new)**

*Text proposed by the Commission*

*Amendment*

*(4e) Commission Recommendation 2003/670/EC<sup>1a</sup> recommends that Member States introduce into their national laws, regulations or administrative provisions concerning scientifically recognised occupational diseases liable for compensation and subject to preventive measures. Member States should ensure that every worker has the right to compensation in respect of occupational diseases if he or she is suffering from an ailment which can be proved to be occupational in origin and nature.*

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*<sup>1a.</sup> Commission Recommendation 2003/670/EC of 19 September 2003 concerning the European schedule of occupational diseases (OJ L 238, 25.9.2003, p. 28).*

#### **Amendment 15**

##### **Proposal for a directive Recital 4 f(new)**

*Text proposed by the Commission*

*Amendment*

R the

***(4f) However, the reporting and recognition of occupational cancers as occupational diseases are uneven, due, in particular, to a long latency between the exposure to dangerous substances and the diagnosis of the resulting disease, the multifactorial nature of cancer and also to complex procedures for the official recognition of an illness as work-related and for the obtaining of compensation. Data from work-related health problems are often lacking, unreliable or insufficient. Further efforts are therefore needed to improve reporting, prevention, diagnosis, early recognition and compensation of occupational diseases, as well as better medical monitoring throughout life with robust diseases and exposures registries.***

#### **Amendment 16**

##### **Proposal for a directive Recital 4 g (new)**

*Text proposed by the Commission*

*Amendment*

***(4g) Swipe testing in cancer care are rare which means that significant risks of exposure are not identified. If swipe tests were performed systematically, many risks would be identified. The use of such tests should therefore be added to Article 3 of Directive 2004/37/EC with regard to risk assessment.***

#### **Amendment 17**

##### **Proposal for a directive Recital 5**

*Text proposed by the Commission*

*Amendment*

(5) This Directive strengthens the

(5) This Directive strengthens the

protection of workers' health and safety at their workplace. New limit values should be set out in Directive 2004/37/EC **in the light** of available information, including **new** scientific and technical data **and should also be based on** a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the workplace. That information should, if possible, include data on residual risks to the health of workers, opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH). Information related to residual risk, made publicly available at Union level, is valuable for any future work to limit risks from occupational exposure to carcinogens **and** mutagens.

protection of workers' health and safety at their workplace. New limit values should be set out in Directive 2004/37/EC **using a risk-based methodology. Binding occupational exposure limit values should be evidence-based and established on the basis of all** available information, including **updated** scientific and technical data, a thorough assessment of the socioeconomic impact and **the** availability of exposure measurement protocols and techniques at the workplace. That information should, if possible, include data on residual risks to the health of workers, opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH) **and monographs of the International Agency for Research on Cancer (IARC)**. Information related to residual risk, made publicly available at Union level, is valuable for any future work to limit risks from occupational exposure to carcinogens, mutagens **and reprotoxic substances**.

## Amendment 18

### Proposal for a directive

#### Recital 6

##### *Text proposed by the Commission*

(6) In accordance with the recommendations of the RAC and the ACSH, where possible, limit values for the inhalation route of exposure are established in relation to a reference period of eight hours time-weighted average (long-term exposure limit values) and, for certain carcinogens **or** mutagens to a shorter reference period, in general fifteen minutes time-weighted average (short-term exposure limit values), in order to limit, to the extent possible, the effects arising from short-term exposure.

##### *Amendment*

(6) In accordance with the recommendations of the RAC and the ACSH, where possible, limit values for the inhalation route of exposure are established in relation to a reference period of eight hours time-weighted average (long-term exposure limit values) and, for certain carcinogens, mutagens **and reprotoxic substances** to a shorter reference period, in general fifteen minutes time-weighted average (short-term exposure limit values), in order to limit, to the extent possible, the effects arising from short-term exposure.



### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## **Amendment 19**

### **Proposal for a directive**

#### **Recital 7**

##### *Text proposed by the Commission*

(7) It is also necessary to consider **other** absorption pathways than inhalation of all carcinogens **and** mutagens, including the possibility of uptake through the skin, in order to ensure the best possible level of protection.

##### *Amendment*

(7) It is also necessary to consider absorption pathways **other** than inhalation of all carcinogens, mutagens **and reprotoxic substances**, including the possibility of uptake through the skin, in order to ensure the best possible level of protection.

### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## **Amendment 20**

### **Proposal for a directive**

#### **Recital 7 a (new)**

##### *Text proposed by the Commission*

##### *Amendment*

**(7a) In the workplace, workers are often exposed to a cocktail of hazardous substances, which can increase risks and cause adverse health effects. In the case of exposure to a combination of substances acting by the same mode of**

***action or at the same target cell or tissue, it is necessary to adapt the implementation of their possible limit values to take into account the combined effects.***

#### *Justification*

*Workers are often exposed simultaneously to several hazardous chemicals used in or generated by industrial processes. Occupational exposure limit values are established substance by substance with no consideration of possible combined exposure to different substances acting by the same mode of action (e.g., different carcinogenic substances present at the workplace).*

### **Amendment 21**

#### **Proposal for a directive**

##### **Recital 9**

#### *Text proposed by the Commission*

(9) Acrylonitrile meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Council<sup>47</sup> and is therefore carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a long- and short-term limit value for that carcinogen. Acrylonitrile can also be absorbed through the skin. It is therefore appropriate to establish a limit value for acrylonitrile under the scope of Directive 2004/37/EC and to assign a skin notation to it. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for acrylonitrile. This should be considered when developing guidance on the practical use of biomonitoring.

#### *Amendment*

(9) Acrylonitrile meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Council<sup>47</sup> and is therefore carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a long- and short-term limit value for that carcinogen. Acrylonitrile can also be absorbed through the skin. ***Acrylonitrile is acutely toxic and causes neurotoxicity, local irritation of skin, eyes and respiratory tract, and skin sensitisation.*** It is therefore appropriate to establish a limit value for acrylonitrile under the scope of Directive 2004/37/EC and to assign a skin notation to it. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for acrylonitrile. This should be considered when developing guidance on the practical use of biomonitoring.

<sup>47</sup> Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272>.

<sup>47</sup> Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272>.

### *Justification*

*This amendment is based on the opinion of the Risk Assessment Committee of ECHA: <https://echa.europa.eu/documents/10162/102477c9-a961-2c96-5c4d-76fcd856ac19>*

## **Amendment 22**

### **Proposal for a directive Recital 10**

#### *Text proposed by the Commission*

(10) With regard to acrylonitrile, a limit value of 1 mg/m<sup>3</sup> (0.45 ppm) and a short-term limit value of 4 mg/m<sup>3</sup> (1.8 ppm) may be difficult to be complied with in the short term. A transitional period of four years after entry into force of this Directive should be introduced from which these Occupational Exposure Limit (OEL) values shall apply.

#### *Amendment*

(10) With regard to acrylonitrile, a limit value of 1 mg/m<sup>3</sup> (0.45 ppm) and a short-term limit value of 4 mg/m<sup>3</sup> (1.8 ppm) may be difficult to be complied with in the short term. A transitional period of four years after entry into force of this Directive should be introduced from which these Occupational Exposure Limit (OEL) values shall apply. ***Exposure should be reduced as far as technically possible below those limit values.***

### *Justification*

*Where this is not technically possible to replace or substitute the substance, worker exposure must be reduced to as low a level as is technically possible. This is the minimisation obligation under Article 5(2) and Article 5(3) of the Directive 2004/37/EC.*

## **Amendment 23**

### **Proposal for a directive Recital 12**

#### *Text proposed by the Commission*

(12) With regard to nickel compounds, limit values of 0.01 mg/m<sup>3</sup> for the

#### *Amendment*

(12) With regard to nickel compounds, ***based on a consensus between the social***

respirable fraction and 0.05 mg/m<sup>3</sup> for the inhalable fraction may be difficult to be complied with in a number of sectors or processes, including specifically smelting, refineries and welding. Furthermore, since identical risk management measures can be used both for chromium (VI) and nickel compounds, the transitional measures aiming to reduce the exposure to these two groups of carcinogens should be aligned. Therefore, a transitional period until 17 January 2025 inclusive should be introduced during which a limit value of 0.1 mg/m<sup>3</sup> for the inhalable fraction of the nickel compounds should apply. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU<sup>48</sup>.

*partners in the ACSH*, limit values of 0.01 mg/m<sup>3</sup> for the respirable fraction and 0.05 mg/m<sup>3</sup> for the inhalable fraction *are introduced. According to the RAC, the available information on the mechanisms of genotoxicity and cancer support a mode-of-action based threshold for carcinogenic effects. For that reason, the RAC proposed an occupational exposure limit of 0.005 mg/m<sup>3</sup> for the respirable fraction and 0.03 mg/m<sup>3</sup> for the inhalable fraction under which no significant residual cancer risk is expected for workers. Those values* may be difficult to be complied with in a number of sectors or processes, including specifically smelting, refineries and welding. Furthermore, since identical risk management measures can be used both for chromium (VI) and nickel compounds, the transitional measures aiming to reduce the exposure to these two groups of carcinogens should be aligned. Therefore, a transitional period until 17 January 2025 inclusive should be introduced during which a limit value of 0.1 mg/m<sup>3</sup> for the inhalable fraction of the nickel compounds should apply. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU<sup>48</sup>. *Exposure should be reduced as far as technically possible below the limit value introduced and, when possible, below the limit value proposed by the RAC.*

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<sup>48</sup> Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571906530859&uri=CELEX:32017L2398>

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<sup>48</sup> Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571906530859&uri=CELEX:32017L2398>

**Amendment 24**  
**Proposal for a directive**  
**Recital 12 a (new)**

*Text proposed by the Commission*

*Amendment*

***(12a) The green economy is expected to expand in the context of the European Green Deal. It is important to continue to ensure and strengthen occupational safety and health aspects when creating new jobs. Nickel compounds play a considerable role in the development of green alternatives to fossil fuels. As the need for nickel compounds is expected to grow and it is essential to protect workers and ensure the full and effective implementation of the occupational exposure limit values to that chemical agent.***

**Amendment 25**

**Proposal for a directive**  
**Recital 13**

*Text proposed by the Commission*

*Amendment*

(13) Benzene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore carcinogen within the meaning of Directive 2004/37/EC. Benzene can also be absorbed through the skin. The limit value set out in Annex III to Directive 2004/37/EC for benzene should be revised in the light of more recent scientific data and it is appropriate to keep the skin notation. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for benzene. This should be considered when developing guidance on the practical use of biomonitoring.

(13) Benzene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore carcinogen within the meaning of Directive 2004/37/EC. Benzene can also be absorbed through the skin. The limit value set out in Annex III to Directive 2004/37/EC for benzene should be revised in the light of more recent scientific data ***no later than 1 January 2030 in accordance with the ACSH opinion*** and it is appropriate to keep the skin notation. The ACSH, based on the RAC opinion, ***also*** agreed on the usefulness of the biomonitoring for benzene. This should be considered when developing guidance on the practical use of biomonitoring.

**Amendment 26**  
**Proposal for a directive**  
**Recital 14**

*Text proposed by the Commission*

(14) With regard to benzene, a revised limit value of 0.2 ppm (0.66 mg/m<sup>3</sup>) may be difficult to be complied with in some sectors in the short term. A transitional period of 4 years after entry into force of this Directive should be introduced. From two years up to four years after entry into force, a transitional limit value of 0.5 ppm (1.65 mg/m<sup>3</sup>) should apply.

*Amendment*

(14) With regard to benzene, ***based on a consensus between the social partners in the ACSH***, a revised limit value of 0.2 ppm (0.66 mg/m<sup>3</sup>) ***should be introduced. According to the RAC, a mode-of-action-based threshold for chromosomal damage in workers can be used to establish an occupational exposure limit for carcinogenicity, which is considered to have no significant residual cancer risk and to avoid other adverse effects. For this reason, the RAC proposed an Occupational Exposure limit of 0.05 ppm (0.16mg/m<sup>3</sup>), since it*** may be difficult to be complied with in some sectors in the short term. A transitional period of 4 years after entry into force of this Directive should be introduced. From two years up to four years after entry into force, a transitional limit value of 0.5 ppm (1.65 mg/m<sup>3</sup>) should apply. ***Exposure should be reduced as far as technically possible below the limit value introduced and, when possible, below the limit value proposed by the RAC.***

**Amendment 27**

**Proposal for a directive**  
**Recital 14 a (new)**

*Text proposed by the Commission*

*Amendment*

***(14a) The limit value for respirable crystalline silica dust (respirable fraction) set out in Annex III to Directive (EU) 2017/2398 should be revised in the light of the Commission's evaluations pursuant to Directive 2004/37/EC and recent scientific and technical data.***

**Amendment 28**  
**Proposal for a directive**  
**Recital 14 b (new)**

*Text proposed by the Commission*

*Amendment*

***(14b) Cobalt and cobalt compounds meet the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set limit values for that group of carcinogens. Exposure to cobalt and cobalt compounds at workplaces may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish two limit values for both the inhalable and respirable fractions of cobalt and its compounds under the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation.***

**Amendment 29**  
**Proposal for a directive**  
**Recital 14 c (new)**

*Text proposed by the Commission*

*Amendment*

***(14c) Hazardous Medicinal Products can cause adverse health effects, such as certain types of cancer and reproductive disorders, in workers who are exposed to them in the course of work involving their preparation, administration, or disposal. Hazardous Medicinal Products affect workers who handle them directly or indirectly. Such workers include healthcare workers using cytostatic or cytotoxic drugs to treat cancer patients in hospitals or at home and workers who carry out activities relating to the cleaning, transport, laundry, or the waste disposal of hazardous drugs or of material***

*contaminated by such drugs. It is therefore important to protect all workers by including relevant pharmacotherapeutic groups of Hazardous Medicinal Products in Annex I to Directive 2004/37/EC. The reduction and replacement requirements laid down in Article 4 of that Directive do not apply to Hazardous Medicinal Products because they are essential to treat patients. The other provisions of that Directive, in particular Articles 5 to 18a thereof, as amended by this Directive, apply to workers who are exposed to Hazardous Medicinal Products.*

#### *Justification*

*In the healthcare sector alone, 12.7 million workers in Europe (of which 7.3 million nurses), are exposed to Hazardous Medicinal Products at work. Studies show that healthcare workers who handle cytotoxic drugs (all drugs with anti-tumoral activity) are three times more likely to develop cancer (such as breast cancer, haematopoietic cancer) and nurses exposed to cytotoxic drugs are twice as likely to miscarry.*

#### **Amendment 30**

##### **Proposal for a directive Recital 14 d(new)**

*Text proposed by the Commission*

*Amendment*

*(14d) The use at the workplace or while performing job-related duties, of any carcinogens, mutagens or reprotoxic substances, including those referred to in the annexes to Directive 2004/37/EC, as amended by this Directive, should be reported to the national authorities responsible for supervising workers' health. When deciding what substances to report, Member States should take into account the implementation reports submitted to the Commission pursuant to Article 17a of Directive 89/391/EEC.*

#### **Amendment 31**



**Proposal for a directive**  
**Recital 15 a (new)**

*Text proposed by the Commission*

*Amendment*

***(15a) While maintaining equal protection levels for all the workers, it is important to ensure and facilitate operational feasibility and compliance and avoid disproportionate effect on microenterprises and SMEs, also through the assessment of the transposition impact on SMEs, and to take all necessary actions to ensure the safety and health of workers are protected no matter the size of the enterprise. Against that background, specific measures such as incentives and digital tools could help them to better comply with the obligations laid down in the Directive 2004/37/EC. In that regard, the social partners and the European Agency for Health and Safety at Work have an important role to play, in particular to help SMEs assess the risks for their workforce and implement adequate protective measures.***

**Amendment 32**

**Proposal for a directive**  
**Recital 16**

*Text proposed by the Commission*

*Amendment*

(16) The limit values established in this Directive are to be kept under **regular** scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006<sup>49</sup>.

(16) The limit values established in this Directive are to be kept under **ongoing** scrutiny and **regular** review **including making legislative proposals, if appropriate**, to ensure consistency with Regulation (EC) No 1907/2006<sup>49</sup>.

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<sup>49</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. Available at: <https://eur-lex.europa.eu/legal->

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<sup>49</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. Available at: <https://eur-lex.europa.eu/legal->

### Amendment 33

#### Proposal for a directive Recital 17

*Text proposed by the Commission*

(17) Since the objective of this Directive, namely to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens *or* mutagens at work, cannot be sufficiently achieved by the Member States, 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 in order to achieve that objective.

*Amendment*

(17) Since the objective of this Directive, namely to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens, mutagens *or reprotoxic substances* at work, cannot be sufficiently achieved by the Member States, 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 in order to achieve that objective.

### Amendment 34

#### Proposal for a directive Recital 18 a (new)

*Text proposed by the Commission*

*Amendment*

***(18a) Articles 153, 154 and 155 of the Treaty on the Functioning of the European Union (TFEU) establish the scope and authority of the social partners to negotiate and enforce agreements relating to occupational health and safety and the Charter of Fundamental Rights of the European Union (Charter) ensures, in particular, the fundamental right to life (Article 2 of the Charter) and the right to fair and just working conditions with***

*respect to health, safety and dignity  
(Article 31(1) of the Charter).*

## **Amendment 35**

**Proposal for a directive**  
**Article 1 – point -1 (new)**  
Directive 2004/37/EC  
Title

*Present text*

*Amendment*

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 *or* mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)

**(-1) The title of Directive 2004/37/EC is replaced by the following:**

"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)"

### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## **Amendment 36**

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

*Present text*

*Amendment*

1. This Directive has as its aim the

**(-1a) In Article 1(1), the first paragraph is replaced by the following:**

"1. This Directive has as its aim the

protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens *or* mutagens at work.

protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens, mutagens *or reprotoxic substances* at work.”

#### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

### **Amendment 37**

#### **Proposal for a directive**

#### **Article 1 – point -1 b (new)**

Directive 2004/37/EC

Article 2 – point b a (new)

*Text proposed by the Commission*

*Amendment*

***(-1b) In Article 2, the following point is inserted:***

***“(ba) 'reprotoxic substance' means: a substance or mixture which meets the criteria for being classified as toxic to reproduction category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008;”***

#### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

### **Amendment 38**

**Proposal for a directive**  
**Article 1 – point -1 c (new)**  
Directive 2004/37/EC  
Article 2 – point c (new)

*Present text*

(c) 'limit value' means, unless otherwise specified, the limit of the time-weighted average of the concentration for a 'carcinogen *or* mutagen' in the air within the breathing zone of a worker in relation to a specified reference period as set out in Annex III to this Directive.

*Amendment*

**(-1c) In Article 2, point (c) is replaced by the following:**

“(c) 'limit value' means, unless otherwise specified, the limit of the time-weighted average of the concentration for a 'carcinogen, mutagen *or reprotoxic substance*' in the air within the breathing zone of a worker in relation to a specified reference period as set out in Annex III to this Directive.”

*Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

**Amendment 39**

**Proposal for a directive**  
**Article 1 – point -1 d (new)**  
Directive 2004/37/EC  
Article 2 – point c a (new)

*Text proposed by the Commission*

*Amendment*

**(-1d) In Article 2, the following point is added:**

“(ca) '*risk-based limit value*' means: a limit value set at an exposure level corresponding to a risk of developing an adverse health effect (e.g. cancer) in the range between an upper and a lower risk level, which is to be set in accordance with the procedure laid down in Article 153(2) TFEU.”

### *Justification*

*Today, there is a broad consensus among stakeholders and governments that the current system to set limit values under the CMD should be revamped to move towards the risk-based methodology. In practice, the current methodology used by the European Commission takes into account a mix of health aspects, technical feasibility and socio-economic factors. Ultimately, the binding OELs proposed for carcinogens are based on cost-benefit analysis.*

### **Amendment 40**

#### **Proposal for a directive**

#### **Article 1 – point -1 e (new)**

Directive 2004/37/EC

Article 3 – paragraph 1

#### *Present text*

1. This Directive shall apply to activities in which workers are or are likely to be exposed to carcinogens *or* mutagens as a result of their work.

#### *Amendment*

***(-1e) In Article 3, paragraph 1 is replaced by the following:***

***"1. This Directive shall apply to activities in which workers are or are likely to be exposed to carcinogens, mutagens *or* reprotoxic substances as a result of their work."***

### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

### **Amendment 41**

#### **Proposal for a directive**

#### **Article 1 – point -1 f (new)**

Directive 2004/37/EC

Article 3 – paragraph 2 – subparagraph 1

#### *Present text*

#### *Amendment*

***(-1f) In Article 3(2), the first subparagraph is replaced by the***

In the case of any activity likely to involve a risk of exposure to carcinogens *or* mutagens, the nature, degree and duration of workers' exposure shall be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken. The assessment shall be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to carcinogens *or* mutagens. *The* employer shall supply the authorities responsible at their request with the information used for making the assessment.

*following:*

"In the case of any activity likely to involve a risk of exposure to carcinogens, mutagens *or reprotoxic substances*; the nature, degree and duration of workers' exposure shall be determined *by way of a systematic risk assessment*, in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken. The assessment shall be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to carcinogens, mutagens *or reprotoxic substances*. The employer shall supply the authorities responsible at their request with the information used for making the assessment."

(02004L0037)

*Justification*

*It is important to name the systematic risk assessment as an obligation.*

## **Amendment 42**

### **Proposal for a directive**

#### **Article 1 – point -1 g (new)**

Directive 2004/37/EC

Article 3 – paragraph 4

*Present text*

4. When the risk assessment is carried out, employers shall give particular attention to any effects concerning the health or safety of workers at particular risk and shall, inter alia, take account of the desirability of not employing such workers in areas where they may come into contact with carcinogens *or* mutagens.

*Amendment*

***(-1g) In Article 3, paragraph 4 is replaced by the following:***

"4. When the risk assessment is carried out, employers shall give particular attention to any effects concerning the health or safety of workers at particular risk and shall, inter alia, take account of the desirability of not employing such workers in areas where they may come into contact with carcinogens, mutagens *or reprotoxic substances*."

### Justification

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

### Amendment 43

#### Proposal for a directive

#### Article 1 – point -1 h (new)

Directive 2004/37/EC

Article 4 – paragraph 1

#### *Present text*

1. The employer shall reduce ***the use of a carcinogen or mutagen at the place of work***, in particular by replacing it, in so far as is technically possible, by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or safety, as the case may be.

#### *Amendment*

***(-1h) In Article 4, paragraph 1 is replaced by the following:***

***"1. Where a carcinogen, mutagen or reprotoxic substance is present at the workplace, the employer shall reduce its use, in particular by replacing it, in so far as is technically possible, by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or safety, as the case may be. This paragraph shall not apply to the use of hazardous medicinal products set out in Annex I."***

### Justification

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

### Amendment 44

#### Proposal for a directive

#### Article 1 – point -1 i (new)



*Present text*

2. Where it is not technically possible to replace the carcinogen *or* mutagen by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen *or* mutagen is, in so far as is technically possible, manufactured and used in a closed system.

*Amendment*

**(-1i) In Article 5, paragraph 2 is replaced by the following:**

“2. Where it is not technically possible to replace the carcinogen, mutagen *or reprotoxic substance* by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen, mutagen *or reprotoxic substance* is, in so far as is technically possible, manufactured and used in a closed system.”

*Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

**Amendment 45**

**Proposal for a directive**  
**Article 1 – point -1 j (new)**  
Directive 2004/37/EC  
Article 5 – paragraph 4

*Present text*

4. Exposure shall not exceed the limit value of a carcinogen as set out in Annex III.

*Amendment*

**(-1j) In Article 5, paragraph 4 is replaced by the following:**

“4. Exposure shall not exceed the limit value of a carcinogen, *mutagen or reprotoxic substance* as set out in Annex III. *In the case of exposure to a combination of substances acting by the same mode of action or at the same target cell or tissue, the implementation of the possible limit values of those substances*

***shall be adapted to take into account the combined effects.”***

*Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

**Amendment 46**

**Proposal for a directive**

**Article 2 – point -1 k (new)**

Directive 2004/37/EC

Article 5 – paragraph 5 – introductory part

*Present text*

*Amendment*

5. Wherever a carcinogen *or* mutagen is used, the employer shall apply all the following measures:

***(-1k) In Article 5(5), the introductory part is replaced by the following:***

***“5. Wherever a carcinogen, mutagen *or* reprotoxic substance is used, the employer shall apply all the following measures:”***

*Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

**Amendment 47**

**Proposal for a directive**

**Article 1 – point -1 l (new)**

Directive 2004/37/EC

Article 5 – paragraph 5 – point a

*Present text*

*Amendment*

(a) limitation of the quantities of a carcinogen *or* mutagen at the place of work;

**(-1l) In Article 5(5), point (a) is replaced by the following:**

“(a) limitation of the quantities of a carcinogen, mutagen *or reprotoxic substance* at the place of work;”

*Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## **Amendment 48**

### **Proposal for a directive**

#### **Article 1 – point -1 m (new)**

Directive 2004/37/EC

Article 5 – paragraph 5 – point c

*Present text*

*Amendment*

(c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens *or* mutagens into the place of work;

**(-1m) In Article 5(5), point (c) is replaced by the following:**

“(c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens, mutagens *or reprotoxic substances* into the place of work;”

*Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## Amendment 49

### Proposal for a directive

#### Article 1 – point -1 n (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point d

#### *Present text*

(d) evacuation of carcinogens *or* mutagens at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;

#### *Amendment*

***(-1n) In Article 5(5), point (d) is replaced by the following:***

“(d) evacuation of carcinogens, mutagens *or reprotoxic substances* at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;”

#### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## Amendment 50

### Proposal for a directive

#### Article 1 – point -1 o (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point e

#### *Present text*

(e) use of existing appropriate procedures for the measurement of carcinogens *or* mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;

#### *Amendment*

***(-1o) In Article 5(5), point (e) is replaced by the following:***

“(e) use of existing appropriate procedures for the measurement of carcinogens, mutagens *or reprotoxic substances*, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;”

### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

### **Amendment 51**

#### **Proposal for a directive**

#### **Article 1 – point -1 p (new)**

Directive 2004/37/EC

Article 5 – paragraph 5 – point i a (new)

*Text proposed by the Commission*

*Amendment*

***(-1p) In Article 5(5), the following point is inserted:***

***"(ia) ensure that personal protective equipment is provided;"***

### **Amendment 52**

#### **Proposal for a directive**

#### **Article 1 – point -1 q (new)**

Directive 2004/37/EC

Article 5 – paragraph 5 – point j

*Present text*

*Amendment*

(j) demarcation of risk areas and use of adequate warning and safety signs including ‘no smoking’ signs in areas where workers are exposed or likely to be exposed to carcinogens *or* mutagens;

***(-1q) In Article 5(5), point (j) is replaced by the following:***

***“(j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens, mutagens *or* reprotoxic substances;”***

### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to*

*at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## **Amendment 53**

### **Proposal for a directive**

#### **Article 1 – point -1 r (new)**

Directive 2004/37/EC

Article 5 – paragraph 5 – point m a (new)

*Text proposed by the Commission*

*Amendment*

***(-1r) In Article 5(5), the following point is added:***

***"(ma) in accordance with Directive 92/85/EC, take the necessary measures to ensure that pregnant workers, workers who have recently given birth and workers who are breastfeeding are duly protected and are in no circumstances required to carry out activities which could jeopardise their safety or health."***

*Justification*

*Reprotoxic substances can seriously harm pregnant and breastfeeding workers therefore we need special measures targeting this group of workers.*

## **Amendment 54**

### **Proposal for a directive**

#### **Article 1 – point -1 s (new)**

Directive 2004/37/EC

Article 6 – paragraph 1– point a

*Present text*

*Amendment*

(a) the activities and/or industrial processes carried out, including the reasons for which carcinogens **or** mutagens are

***(-1s) In the first paragraph of Article 6, point (a) is replaced by the following:***

***"(a) the activities and/or industrial processes carried out, including the reasons for which carcinogens, mutagens **or*****

used;

*reprotoxic substances* are used;”

#### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

### **Amendment 55**

#### **Proposal for a directive**

#### **Article 1 – point -1 t (new)**

Directive 2004/37/EC

Article 6 – paragraph 1 – point b

#### *Present text*

(b) the quantities of substances or mixtures manufactured or used which contain carcinogens *or* mutagens;

#### *Amendment*

***(-1t) In the first paragraph of Article 6, point (b) is replaced by the following:***

***“(b) the quantities of substances or mixtures manufactured or used which contain carcinogens, mutagens *or* reprotoxic substances;”***

#### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

### **Amendment 56**

#### **Proposal for a directive**

#### **Article 1 – point -1 u (new)**

Directive 2004/37/EC

Article 10 – paragraph 1 – introductory part

*Present text*

*Amendment*

1. Employers shall be obliged, in the case of all activities for which there is a risk of contamination by carcinogens *or* mutagens, to take appropriate measures to ensure that:

***(-1u) In Article 10(1), the introductory part is replaced by the following:***

“1. Employers shall be obliged, in the case of all activities for which there is a risk of contamination by carcinogens, mutagens *or reprotoxic substances*, to take appropriate measures to ensure that:”

*Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## **Amendment 57**

### **Proposal for a directive**

#### **Article 1 – point -1 v (new)**

Directive 2004/37/EC

Article 10 – paragraph 1 – point a

*Present text*

*Amendment*

(a) workers do not eat, drink or smoke in working areas where there is a risk of contamination by carcinogens *or* mutagens;

***(-1v) In Article 10(1), point (a) is replaced by the following:***

“(a) workers do not eat, drink or smoke in working areas where there is a risk of contamination by carcinogens, mutagens *or reprotoxic substances*.”

*Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*



## Amendment 58

### Proposal for a directive

#### Article 1 – point -1 w (new)

Directive 2004/37/EC

Article 11 – paragraph 1 – subparagraph 2 – indents 1 and 2

#### *Present text*

- adapted to take account of new or changed risk, **and**
  
- **repeated** periodically if necessary.

#### *Amendment*

**(-1 w) In the second subparagraph of Article 11(1), the indents are replaced by the following:**

- adapted to take account of new or changed risk,
  - **provided periodically in healthcare settings to all workers who are exposed to carcinogens, mutagens or reprotoxic substances, in particular where new drugs occur,**
  - **provided periodically in other settings** if necessary."

## Amendment 59

### Proposal for a directive

#### Article 1 – point -1 x (new)

Directive 2004/37/EC

Article 11 – paragraph 2

#### *Present text*

2. Employers shall inform workers of installations and related containers containing carcinogens **or** mutagens, ensure that all containers, packages and installations containing carcinogens **or** mutagens are labelled clearly and legibly, and display clearly visible warning and hazard signs.

#### *Amendment*

**(-1x) In Article 11, paragraph 2 is replaced by the following:**

“2. Employers shall inform workers of installations and related containers containing carcinogens, mutagens **or reprotoxic substances**, ensure that all containers, packages and installations containing carcinogens, mutagens **or reprotoxic substances** are labelled clearly and legibly, and display clearly visible warning and hazard signs.”

#### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to*

*at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## **Amendment 60**

### **Proposal for a directive**

#### **Article 1 – point -1 y (new)**

Directive 2004/37/EC

Article 14 – paragraph 3 – subparagraph 1

#### *Present text*

3. If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens *or* mutagens, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance.

#### *Amendment*

***(-1y) In Article 14(3), the first subparagraph is replaced by the following:***

“3. If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens, mutagens *or reprotoxic substances*, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance. ”

#### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## **Amendment 61**

### **Proposal for a directive**

#### **Article 1 – point -1 z (new)**

Directive 2004/37/EC

Article 14 – paragraph 8 – subparagraph 1

#### *Present text*

#### *Amendment*

***(-1z) In Article 14(8), the first***

8. All cases of cancer identified in accordance with national laws and/or practice as resulting from occupational exposure to a carcinogen *or* mutagen shall be notified to the competent authority.

*subparagraph is replaced by the following:*

“8. All cases of cancer *and reproductive disorder* identified in accordance with national laws and/or practice as resulting from occupational exposure to a carcinogen, mutagen *or reprotoxic substance* shall be notified to the competent authority. *The Member States shall include the information referred to in this paragraph in their implementation reports submitted to the Commission pursuant to Article 17a of Directive 89/391/EEC.*”

## Amendment 62

### Proposal for a directive

#### Article 1 – point -1 aa (new)

Directive 2004/37/EC

Article 15 – paragraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

*(-1aa) In Article 15, the following paragraph is added:*

*“2a. The Member States shall provide the Commission with the information referred to in Article 14(8) as part of the implementation reports submitted to the Commission pursuant to Article 17a of Directive 89/391/EEC.”*

#### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## Amendment 63

### Proposal for a directive

#### Article 1 – point -1 ab (new)

Directive 2004/37/EC

Article 16 – paragraph 1

#### *Present text*

1. The Council shall, in accordance with the procedure laid down in Article **137(2) of the Treaty**, set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens *or* mutagens for which this is possible, and, where necessary, other directly related provisions.

#### *Amendment*

***(-1ab) In Article 16, paragraph 1 is replaced by the following:***

***"1. The European Parliament and the Council shall, in accordance with the procedure laid down in Article 153(2) TFEU, set out risk-based limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens, mutagens or reprotoxic substances for which this is possible, and, where necessary, other directly related provisions."***

## Amendment 64

### Proposal for a directive

#### Article 1 – point -1 ac (new)

Directive 2004/37/EC

Article 17 – paragraph 1

#### *Present text*

The Commission is empowered to adopt delegated acts in accordance with Article 17a to make strictly technical amendments to Annex II, in order to take account of technical progress, changes in international regulations or specifications and new findings with regard to carcinogens *or* mutagens.

#### *Amendment*

***(-1 ac) In Article 17, the first paragraph is replaced by the following:***

***"The Commission is empowered to adopt delegated acts in accordance with Article 17a to make strictly technical amendments to Annex II, in order to take account of technical progress, changes in international regulations or specifications and new findings with regard to carcinogens, mutagens or reprotoxic substances."***

#### *Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to*

*at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## **Amendment 65**

### **Proposal for a directive**

#### **Article 1 – point -1 ad (new)**

Directive 2004/37/EC

Article 18a – paragraph 2 a (new)

*Text proposed by the Commission*

*Amendment*

***(-1ad) In Article 18a, the following paragraph is inserted after the second paragraph:***

***“No later than 31 December 2021, the Commission shall, taking into account the existing recommendations from different agencies, stakeholders and the World Health Organization on priority carcinogens, mutagens and reprotoxic substances for which limit values are needed, and after consulting the ACSH, present an action plan to achieve occupational exposure limits values for at least 25 substances, groups of substances or process-generated substances additional to those referred to in this Directive. No later than 31 December 2024, the Commission shall, taking into account that action plan, the latest developments in scientific knowledge, and after consulting of the ACSH, present a legislative proposal.”***

## **Amendment 66**

### **Proposal for a directive**

#### **Article 1 – point -1ae (new)**

Directive 2004/37/EC

Article 18a – paragraph 2 b (new)

***(-1ae) In Article 18a, the following paragraph is inserted after the second paragraph:***

***“No later than 1 March 2022, the Commission shall, taking into account the latest developments in scientific knowledge, and after appropriate consultation of relevant stakeholders, in particular health practitioners and health professionals, develop a definition of Hazardous Medicinal Products and establish the list of substances covered by the related entry in Annex I. The Commission shall review that list every two years. No later than 1 December 2022, the Commission shall, after the appropriate consultation of relevant stakeholders, prepare Union guidelines and standards of practice for the preparation, administration, and disposal of Hazardous Medicinal Products. Those guidelines and standards shall be published on the website of the the European Agency for Safety and Health at Work (EU-OSHA) and shall be disseminated in all Member States by the relevant competent authorities. The consultations undertaken to develop the definition, list, guidelines and standards shall be transparent. The declarations of interests of stakeholders and experts shall be made public in a timely manner.”***

*Justification*

*Studies show that healthcare workers who handle cytotoxic drugs (all drugs with anti-tumoral activity) are three times more likely to develop cancer (such as breast cancer, haematopoietic cancer) and nurses exposed to cytotoxic drugs are twice as likely to miscarry.*

**Amendment 67**

**Proposal for a directive  
Article 1 – point -1af (new)**

Directive 2004/37/EC  
Article 18a – paragraph 2 c (new)

*Text proposed by the Commission*

*Amendment*

***(--1af) In Article 18a, the following paragraph is inserted after the second paragraph:***

***“No later than 1 June 2022, the Commission shall, taking into account the existing methodology to set limit values for carcinogens in some Member States and the opinion of the ACSH, define the upper and lower risk levels referred to in Article 2. No later than 1 December 2022, the Commission shall, after appropriate consultation of relevant stakeholders, prepare Union guidelines on the methodology establishing risk-based limit values under this Directive. Those guidelines shall be published on the EU-OSHA website and disseminated in all Member States by the relevant competent authorities.”***

*Justification*

*Today, there is a broad consensus among stakeholders and governments that the current system to set limit values under the CMD should be revamped to move towards the risk-based methodology. In practice, the current methodology used by the European Commission takes into account a mix of health aspects, technical feasibility and socio-economic factors. Ultimately, the binding OELs proposed for carcinogens are based on cost-benefit analysis.*

## **Amendment 68**

**Proposal for a directive**  
**Article 1 – point -1 ag (new)**  
Directive 2004/37/EC  
Article 18a – paragraph 4 a (new)

*Text proposed by the Commission*

*Amendment*

***(-1 ag) In Article 18a, the following paragraph is added:***

***“No later than 1 December 2022, the Commission shall, taking into account the***

*latest developments in scientific knowledge and the opinion of RAC, and after appropriate consultation of relevant stakeholders, prepare Union guidelines on how the implementation of the limit values referred to in Article 5(4) are to be adapted in the case of exposure to a combination of substances. Those guidelines shall be published on the EU-OSHA website and be disseminated in all Member States by the relevant competent authorities.”*

#### *Justification*

*Workers are often exposed simultaneously to several hazardous chemicals used in or generated by industrial processes. Occupational exposure limit values are established substance by substance with no consideration of possible combined exposure to different substances acting by the same mode of action (e.g., different carcinogenic substances present at the workplace).*

#### **Amendment 69**

##### **Proposal for a directive**

##### **Article 1 – point -1 ah (new)**

Directive 2004/37/EC

Article 18a – paragraph 4 b (new)

*Text proposed by the Commission*

*Amendment*

***(-1ah) In Article 18a, the following paragraph is added:***

***“No later than 31 December 2023, the Commission shall, after consulting the ACSH and taking into account the RAC opinion of 2018 and the latest developments in scientific knowledge, present a legislative proposal to introduce the limit value for cobalt and cobalt compounds.”***

#### **Amendment 70**

##### **Proposal for a directive**

##### **Article 1 – point -1 ai (new)**

Directive 2004/37/EC

Article 18a – paragraph 4 c (new)



*Text proposed by the Commission*

*Amendment*

***(-1ai) In Article 18a, the following paragraph is added:***

***“No later than 1 January 2028, the Commission shall, taking into account the RAC opinion of 2018 and the latest developments in scientific knowledge, start evaluating the feasibility of a further reduction of the limit value for benzene. No later than 1 January 2030, the Commission shall propose, where appropriate, necessary amendments and modifications related to that substance.”***

**Amendment 71**

Proposal for a directive  
Article 1 – point -1 aj (new)  
Directive 2004/37/EC  
Article 18a – paragraph 4 d (new)

*Text proposed by the Commission*

*Amendment*

***(-1aj) In Article 18a, the following paragraph is added:***

***“No later than 1 January 2028, the Commission shall, taking into account the RAC opinion of 2018 and the latest developments in scientific knowledge, evaluate the feasibility of a further reduction of the limit value for nickel compounds. No later than 1 January 2030, the Commission shall propose, where appropriate, necessary amendments and modifications related to that substance.”***

**Amendment 72**

**Proposal for a directive**  
**Article 1 – point -1 ak (new)**  
Directive 2004/37/EC  
Annex I – point 8 a (new)

**(-1 ak) In Annex I the following point is added:**

**“8a. Work involving exposure to Hazardous Medicinal Products meeting the criteria for classification as carcinogenic, mutagenic and/or toxic for reproduction category 1A or 1B set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council.”**

*Justification*

*In the healthcare sector alone, 12.7 million workers in Europe (of which 7.3 million nurses), are exposed to Hazardous Medicinal Products at work. Studies show that healthcare workers who handle cytotoxic drugs (all drugs with anti-tumoral activity) are three times more likely to develop cancer (such as breast cancer, haematopoietic cancer) and nurses exposed to cytotoxic drugs are twice as likely to miscarry.*

**Amendment 73**

**Proposal for a directive**

**Article 1 – point -1 ak (new)**

Directive 2004/37/EC

Annex II – point 1

*Present text*

*Amendment*

1. The doctor and/or authority responsible for the health surveillance of workers exposed to carcinogens **or** mutagens must be familiar with the exposure conditions or circumstances of each worker.

**(-1ak) In Annex II, point 1 is replaced by the following:**

“1. The doctor and/or authority responsible for the health surveillance of workers exposed to carcinogens, mutagens **or reprotoxic substances** must be familiar with the exposure conditions or circumstances of each worker.”

*Justification*

*According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would*

*strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.*

## **Amendment 74**

### **Proposal for a directive**

#### **Annex – point 1 – introductory part**

Directive 2004/37/EC

Annex III – point A – row 4

<i>Present text</i>										
<i>Respirable crystalline silica dust</i>	–	–	<i>0,1</i>	–	–	–	–	–	–	
<i>Amendment</i>										
<i>Respirable crystalline silica dust</i>	–	–	<i>0,05</i>	–	–	–	–	–	–	

#### *Justification*

*Directive (EU) 2017/2398 obligates the EU Commission to evaluate the need to modify the limit value for Respirable Crystalline Silica (RCS) dust by 2022. Since its inclusion in Annex III of Directive 2004/37/EC in 2017, the limit value remains at 0.1 mg/m<sup>3</sup> despite the 341,000 workers expected to die from an exposure at that level between 2010 and 2069. This figure takes solely lung cancer cases into account, even though mortality is expected to be higher due to other diseases caused by exposure. Spain and Finland, and other non-EU countries have a lower limit value nationally (0,05 mg/m<sup>3</sup>) showing that this is technically and economically feasible.*

## EXPLANATORY STATEMENT

Cancer is the first cause of work-related deaths in the European Union. According to the data, some 52% of annual occupational deaths are attributed to work-related cancers, compared to 24% to cardiovascular diseases and 22% to other diseases.

The Commission has made the fight against cancer one of its priorities for 2019-2024. Indeed, according to the Commission, 40 % of cancer cases in Europe can be prevented. Greater protection for workers, together with a reduction or elimination of work-related risks, goes in the right direction in terms of preventing workers' exposure to mutagenic or carcinogenic substances.

The Commission has already addressed the issue of occupational exposure to mutagens and carcinogens through the adoption of three proposals with a view to updating Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work – the first in May 2016, the second in January 2017 and the third in April 2018.

This is the fourth legislative proposal relating to the directive, and it seeks to establish new occupational exposure limits for three substances: acrylonitrile, nickel compounds and benzene.

Your rapporteur welcomed the Commission's proposal and the revision of the new occupational exposure limits. The aim of the new changes to the directive is to ensure a new level of occupational protection for more than one million workers across the EU in many different sectors, including the oil, textile, manufacturing, construction and chemical sectors. The distinction between respirable and inhalable fraction for nickel compounds is also to be welcomed, with different limit values given the different types of exposure and hazard.

Furthermore, the proposal allows for an appropriate transition period for companies, varying according to the substance, so that they can adapt to the new limit values adopted. Your rapporteur considered it important to take an approach that facilitates this transition for small and medium-sized enterprises and micro-enterprises. In attaining the new limit values, a specific approach must be taken for SMEs, which have limited financial and human capacity. Incentives, support and digital tools may be the right way of meeting the needs of these companies.

Lastly, your rapporteur considered it advisable to address the issue of hazardous medicinal products (HMPs) in an ambitious manner. Indeed, every year, more than 12.7 million healthcare workers in Europe, including 7.3 million nurses, are potentially exposed to dangerous drugs. The handling, preparation and administration of these drugs exposes healthcare workers to high health risks, which means that, according to studies, they are three times more likely to get cancer. That is why your rapporteur has opted not only to amend Annex 1 to the directive, in order to include HMPs, but has also called for the introduction of guidelines enabling the exchange of information and best practices between Member States and the establishment of an EU register, comprising a definition of HMPs and a regularly updated list of antineoplastic, immunosuppressant and antiviral HMPs and their active substances. Indeed, studies show that legislative measures are only effective if they are

properly accompanied by non-binding guidelines and explanatory measures.

Lastly, your rapporteur sought to reiterate Parliament's willingness also to address the issue of reprotoxic substances, which had already been discussed during previous revisions but was still deadlocked. In reopening this discussion, the hope is that co-legislators will be able to find an appropriate and balanced solution to this problem.

### **MINORITY OPINION**

As pro-European and democratic political groups, committed to the protection of workers from risks related to exposure to harmful substances at work, EPP, S&D, Renew Europe, Greens/EFA and The Left, fully support the Revision of the Carcinogens and Mutagens Directive introduced by the European Commission and amended by Members of this Parliament. For this reason, our political groups will support the legislative report attributed to Mrs ZAMBELLI from ID Group. Nevertheless, our support can in no way link us to this political group and the positions it conveys, which we firmly oppose.

## OPINION OF THE COMMITTEE ON LEGAL AFFAIRS

for the Committee on Employment and Social Affairs

on the proposal for a directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work  
(COM(2020)0571 – C9-0301/2020 – 2020/0262(COD))

Rapporteur for opinion: Gilles Lebreton

### SHORT JUSTIFICATION

Cancer, irrespective of whether it is work-related or not, is the second most frequent cause of mortality in the EU Member States, after cardiovascular disease. It accounts for about a quarter of all deaths and is regarded as one of the main causes of premature death. It has an impact not only on individual health, family life, but also on national health and social welfare systems, state budgets, productivity and economic growth.

Against this background, the Commission intends to present a plan designed to reduce the suffering caused by the disease and to help Member States step up the fight against cancer and improve care.

In an occupational context, cancer accounts for 52% of work-related deaths recorded each year, as against 24% for circulatory diseases, 22% for other diseases and 2% for injuries.

Directive 2004/37/EC was adopted on the basis of Article 153(2)(b) TFEU with the aim of improving workers' health and safety. Article 16 provides for the adoption in accordance with the procedure laid down in Article 153(2) TFEU of limit values for all those carcinogens or mutagens for which this is possible.

The aim of the proposal under consideration here is to improve the level of protection provided for by the directive by introducing new or revised limit values.

To that end, four employers' organisations took part in the prior consultation procedure and confirmed their support for measures designed to offer workers effective protection against occupational cancer, including the setting of binding occupational exposure limits (OELs) at EU level, while emphasising the need to set proportionate, technically feasible values. While employers acknowledged that the Commission's criteria for prioritising substances are pertinent, they suggested that the criteria of technical and economic feasibility should also be included.

In keeping with the emphasis on public health, the proposal does not provide for lighter regimes for micro-enterprises or for SMEs. According to the Commission, for all the substances covered by the revision the investments SMEs will have to make will represent only a minimal share of their turnover over the next 60 years. Only a very small number of SMEs that work with nickel compounds might face problems in complying with the preferred

option. For that reason, transitional periods designed to cushion the impact have been included in the package of preferred options.

The companies concerned are generally sensitive to these health priorities. But, in an uncertain economic and social context, they need clarity and legal stability. It is therefore essential, for example, that the definitions of the products and substances covered and inhalation routes be precise and that the timetable for possible revisions be set in advance.

Lastly, it is worth noting the efforts made by the Commission to explain and justify these proposals revising the 2004 directive.

## AMENDMENTS

The Committee on Legal Affairs calls on the Committee on Employment and Social Affairs, as the committee responsible, to take into account the following amendments:

### Amendment 1

#### Proposal for a directive

##### Recital 1

###### *Text proposed by the Commission*

(1) Directive 2004/37/EC of the European Parliament and the Council<sup>45</sup> aims to protect workers against risks to their health and safety from exposure to carcinogens *or mutagens* at the workplace. A consistent level of protection from the risks related to the occupational exposure to carcinogens *and mutagens* is provided for in that Directive by a framework of general principles to enable Member States to ensure the consistent application of minimum requirements. The aim of these minimum requirements is to protect workers at Union level. More stringent provisions can be set by Member States.

###### *Amendment*

(1) Directive 2004/37/EC of the European Parliament and the Council<sup>45</sup> aims to protect workers against risks to their health and safety from exposure to carcinogens, *mutagens or reprotoxic substances* at the workplace. A consistent level of protection from the risks related to the occupational exposure to carcinogens, mutagens *or reprotoxic substances* is provided for in that Directive by a framework of general principles to enable Member States to ensure the consistent application of minimum requirements. The aim of these minimum requirements is to protect workers at Union level. More stringent provisions can be set by Member States. *Those minimum requirements should be established after consulting with the economic and social stakeholders concerned and be based on proportionate and technically feasible values and procedures, in the best interest of the health and safety of the workers.*

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<sup>45</sup> Directive 2004/37/EC of the European

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<sup>45</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 or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

## Amendment 2

### Proposal for a directive

#### Recital 1 a (new)

*Text proposed by the Commission*

*Amendment*

***(1a) The employers' obligations laid down in this Directive should take into account the fact that microenterprises and SMEs, which represent a large majority of enterprises in the Union, have limited financial, technical and human resources. Member States should therefore assess the impact of the implementation of this Directive and the related administrative burden on those enterprises, in order to ensure that they are not disproportionately affected, with specific focus on microenterprises, and to publish the results of such assessments. In doing so, Member States should maintain equal protection for all workers and facilitate compliance of microenterprises and SMEs. Against that background, specific measures, such as incentives and digital tools, could help SMEs and microenterprises further to comply with the obligations laid down in Directive 2004/37/EC and progress towards the elimination of risks relating to exposure to carcinogens or mutagens at the workplace.***

## Amendment 3

### Proposal for a directive

#### Recital 2



*Text proposed by the Commission*

(2) Principle 10 of the European Pillar of Social Rights<sup>46</sup>, jointly proclaimed by the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, provides workers' right to a high level of protection of their health and safety at work, which includes the protection from the exposure to carcinogens and mutagens at the workplace.

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<sup>46</sup> European Pillar of Social Rights, November 2017, available at : [https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet_en.pdf)

*Amendment*

(2) Principle 10 of the European Pillar of Social Rights<sup>46</sup>, jointly proclaimed by the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, provides workers' right to a **safe, healthy and properly adapted working environment, meaning a** high level of protection of their health and safety at work, which includes the protection from the exposure to carcinogens and mutagens at the workplace.

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<sup>46</sup> European Pillar of Social Rights, November 2017, available at: [https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet_en.pdf)

#### **Amendment 4**

##### **Proposal for a directive**

##### **Recital 3**

*Text proposed by the Commission*

(3) Binding occupational exposure limit values are important component of the general arrangements for the protection of workers established by Directive 2004/37/EC and must not be exceeded. Limit values and other directly **related provisions** should be established for all those carcinogens or mutagens for which the available information, including scientific and technical data, make this possible.

*Amendment*

(3) Binding occupational exposure limit values are important component of the general arrangements for the protection of workers established by Directive 2004/37/EC and must not be exceeded. ***In view of social, economic and technological developments***, limit values and other ***provisions*** directly ***relating to mandatory occupational exposure limit values*** should be established for all those carcinogens or mutagens for which the available information, including scientific and technical data, make this possible, ***with a view to stepping up efforts to protect workers and societies from all possible occupational risks.***

## Amendment 5

### Proposal for a directive Recital 4

*Text proposed by the Commission*

(4) Compliance with binding occupational exposure limit values is without prejudice to other employers' obligations pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens or mutagens and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the carcinogen or mutagen by a substance, mixture or process which is not dangerous ***or is less dangerous*** to workers' health, the use of a closed system or other measures aiming to reduce the level of workers' exposure.

*Amendment*

(4) Compliance with binding occupational exposure limit values is without prejudice to other employers' obligations pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens or mutagens and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the carcinogen or mutagen by a substance, mixture or process which is not dangerous to workers' health, the use of a closed system or other measures aiming to reduce ***or eliminate*** the level of workers' exposure. ***Research programmes in that area, in particular on the risks to workers' health, should be eligible to be funded under future national and European recovery plans.***

## Amendment 6

### Proposal for a directive Recital 5 a (new)

*Text proposed by the Commission*

*Amendment*

***(5a) This Directive provides greater clarity for workers, employers and enforcement authorities and helps to create a level playing field for economic operators, impacting positively on employment figures and the economy.***

## Amendment 7

### Proposal for a directive

## Recital 7

*Text proposed by the Commission*

(7) It is also necessary to consider other absorption pathways than inhalation of all carcinogens and mutagens, including the possibility of uptake through the skin, in order to ensure the best possible level of protection.

*Amendment*

(7) It is also necessary to consider other absorption pathways than inhalation of all carcinogens and mutagens, including the possibility of uptake through the skin ***or through the mucous membranes***, in order to ensure the best possible level of protection.

## Amendment 8

**Proposal for a directive**

**Recital 7 a (new)**

*Text proposed by the Commission*

*Amendment*

***(7a) Workers may be exposed to a cocktail of dangerous substances, which can increase the risks to their health. In the event of combined exposure to dangerous substances, the rules should be adapted and the limit values lowered in order to take account of the combined effects.***

## Amendment 9

**Proposal for a directive**

**Recital 13**

*Text proposed by the Commission*

*Amendment*

(13) Benzene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore carcinogen within the meaning of Directive 2004/37/EC. Benzene can also be absorbed through the skin. The limit value set out in Annex III to Directive 2004/37/EC for benzene should be revised in the light of more recent scientific data and it is appropriate to keep the skin notation. The ACSH, based on the RAC opinion, agreed

(13) Benzene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore carcinogen within the meaning of Directive 2004/37/EC. Benzene can also be absorbed through the skin. The limit value set out in Annex III to Directive 2004/37/EC for benzene should be revised in the light of more recent scientific data ***by 1 January 2030 at the latest, in accordance with the opinion of the ACSH***, and it is appropriate

on the usefulness of the biomonitoring for benzene. This should be considered when developing guidance on the practical use of biomonitoring.

to keep the skin notation. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for benzene. This should be considered when developing guidance on the practical use of biomonitoring.

## Amendment 10

### Proposal for a directive Recital 14

#### *Text proposed by the Commission*

(14) With regard to benzene, a revised limit value of 0.2 ppm (0.66 mg/m<sup>3</sup>) may be difficult to be complied with in some sectors in the short term. A transitional period of 4 years after entry into force of this Directive should be introduced. From two years up to four years after entry into force, a transitional limit value of 0.5 ppm (1.65 mg/m<sup>3</sup>) should apply.

#### *Amendment*

(14) With regard to benzene, a revised limit value of 0.2 ppm (0.66 mg/m<sup>3</sup>), **down from a previous value of 1 ppm (3,25mg/m<sup>3</sup>)**, may be difficult to be complied with in some sectors **and by some undertakings, in particular microentreprises and SMEs**, in the short term. A transitional period of 4 years after entry into force of this Directive should **therefore** be introduced. From two years up to four years after entry into force, a transitional limit value of 0.5 ppm (1.65 mg/m<sup>3</sup>) should apply.

## Amendment 11

### Proposal for a directive Recital 14 a (new)

#### *Text proposed by the Commission*

#### *Amendment*

**(14a) Cobalt and cobalt compounds meet the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set limit values for those carcinogens. Exposure to cobalt and cobalt compounds at workplaces may 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 of cobalt compounds in the context of Directive 2004/37/EC.*

## Amendment 12

### Proposal for a directive Recital 16

*Text proposed by the Commission*

(16) The limit values established in this Directive are to be kept under regular scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006<sup>49</sup>.

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<sup>49</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. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006R1907>

*Amendment*

(16) The limit values established in this Directive are to be kept under regular scrutiny and ***strictly reviewed at least every five years on the basis of advances in knowledge and technologies, in order to ensure ongoing consistency with Regulation (EC) No 1907/2006<sup>49</sup> and with social, economic and technological developments.***

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<sup>49</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. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006R1907>

## Amendment 13

### Proposal for a directive Recital 16 a (new)

*Text proposed by the Commission*

*Amendment*

***(16a) The transitional periods provided for in this Directive should guarantee the possibility of taking appropriate measures to anticipate the changes and investment planning required, averting negative repercussions for companies and workers.***

*In the case of SMEs and microenterprises, for example, transitional periods for certain substances should help them address specific technical challenges and plan investments sufficiently well in advance.*

## Amendment 14

### Proposal for a directive

#### Recital 17

*Text proposed by the Commission*

(17) Since the objective of this Directive, namely to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work, **cannot** be **sufficiently** achieved by the Member States, 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 in order to achieve that objective.

*Amendment*

(17) Since the objective of this Directive, namely to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work, **can** be achieved by the Member States, but can, by reason of its scale and effects, be **even** 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 in order to achieve that objective. **Such measures are in any event minimum requirements, which do not deprive the Member States of the right to introduce more protective provisions.**

## Amendment 15

### Proposal for a directive

#### Recital 17 a (new)

*Text proposed by the Commission*

*Amendment*

**(17a) As the provisions of this Directive are intended to set out minimum requirements, this Directive does not prevent Member States from introducing more protective provisions.**



## PROCEDURE – COMMITTEE ASKED FOR OPINION

<b>Title</b>	Amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.
<b>References</b>	COM(2020)0571 – C9-0301/2020 – 2020/0262(COD)
<b>Committee responsible</b> Date announced in plenary	EMPL 5.10.2020
<b>Opinion by</b> Date announced in plenary	JURI 5.10.2020
<b>Rapporteur</b> Date appointed	Gilles Lebreton 12.10.2020
<b>Date adopted</b>	22.2.2021
<b>Result of final vote</b>	+: 13 –: 5 0: 1
<b>Members present for the final vote</b>	Manon Aubry, Gunnar Beck, Geoffroy Didier, Pascal Durand, Angel Dzhambazki, Ibán García Del Blanco, Jean-Paul Garraud, Esteban González Pons, Mislav Kolakušić, Gilles Lebreton, Karen Melchior, Jiří Pospíšil, Franco Roberti, Marcos Ros Sempere, Ernő Schaller-Baross, Stéphane Séjourné, Raffaele Stancanelli, Marie Toussaint, Adrián Vázquez Lázara, Axel Voss, Marion Walsmann, Tiemo Wölken, Lara Wolters, Javier Zarzalejos
<b>Substitutes present for the final vote</b>	Andrzej Halicki, Javier Nart, Emil Radev



## FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

13	+
PPE	Geoffroy Didier, Esteban González Pons, Jiří Pospíšil, Ernő Schaller-Baross, Axel Voss, Marion Walsmann, Javier Zarzalejos
ID	Gunnar Beck, Jean-Paul Garraud, Gilles Lebreton
ECR	Raffaele Stancanelli
The Left	Manon Aubry
NI	Mislav Kolakušić

5	-
Renew	Pascal Durand, Karen Melchior, Stéphane Séjourné, Adrián Vázquez Lázara
ECR	Angel Dzhambazki

1	0
Verts/ALE	Marie Toussaint

**Key to symbols:**

+ : in favour

- : against

0 : abstention

## PROCEDURE – COMMITTEE RESPONSIBLE

<b>Title</b>	Amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.	
<b>References</b>	COM(2020)0571 – C9-0301/2020 – 2020/0262(COD)	
<b>Date submitted to Parliament</b>	22.9.2020	
<b>Committee responsible</b> Date announced in plenary	EMPL 5.10.2020	
<b>Committees asked for opinions</b> Date announced in plenary	ENVI 5.10.2020	JURI 5.10.2020
<b>Not delivering opinions</b> Date of decision	ENVI 12.10.2020	
<b>Rapporteurs</b> Date appointed	Stefania Zambelli 10.11.2020	
<b>Discussed in committee</b>	27.1.2021	23.2.2021
<b>Date adopted</b>	25.3.2021	
<b>Result of final vote</b>	+: –: 0:	46 0 6
<b>Members present for the final vote</b>	Atidzhe Alieva-Veli, Abir Al-Sahlani, Marc Angel, Dominique Bilde, Gabriele Bischoff, Vilija Blinkevičiūtė, Milan Brglez, Sylvie Brunet, Jordi Cañas, David Casa, Margarita de la Pisa Carrión, Özlem Demirel, Klára Dobrev, Jarosław Duda, Estrella Durá Ferrandis, Lucia Ďuriš Nicholsonová, Rosa Estaràs Ferragut, Nicolaus Fest, Loucas Fourlas, Cindy Franssen, Elisabetta Gualmini, Alicia Homs Ginel, France Jamet, Agnes Jongerius, Radan Kanev, Stelios Kympouropoulos, Katrin Langensiepen, Miriam Lexmann, Elena Lizzi, Kira Marie Peter-Hansen, Dragoş Pîslaru, Manuel Pizarro, Dennis Radtke, Elżbieta Rafalska, Guido Reil, Mounir Satouri, Monica Semedo, Beata Szydło, Eugen Tomac, Romana Tomc, Marie-Pierre Vedrenne, Nikolaj Villumsen, Marianne Vind, Maria Walsh, Stefania Zambelli, Tomáš Zdechovský	
<b>Substitutes present for the final vote</b>	Konstantinos Arvanitis, Marc Botenga, Johan Danielsson, Gheorghe Falcă, Sara Matthieu, Véronique Trillet-Lenoir	
<b>Date tabled</b>	7.4.2021	

## FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

46	+
ECR	Lucia Ďuriš Nicholsonová
ID	Dominique Bilde, France Jamet, Elena Lizzi, Stefania Zambelli
PPE	David Casa, Jarosław Duda, Rosa Estaràs Ferragut, Gheorghe Falcă, Loucas Fourlas, Cindy Franssen, Radan Kanev, Stelios Kypouropoulos, Miriam Lexmann, Dennis Radtke, Eugen Tomac, Romana Tomc, Maria Walsh, Tomáš Zdechovský
Renew	Atidzhe Alieva-Veli, Sylvie Brunet, Jordi Cañas, Dragoş Pîslaru, Monica Semedo, Véronique Trillet-Lenoir, Marie-Pierre Vedrenne
S&D	Marc Angel, Gabriele Bischoff, Vilija Blinkevičiūtė, Milan Brglez, Johan Danielsson, Klára Dobrev, Estrella Durá Ferrandis, Elisabetta Gualmini, Alicia Homs Ginel, Agnes Jongerius, Manuel Pizarro, Marianne Vind
The Left	Konstantinos Arvanitis, Marc Botenga, Özlem Demirel, Nikolaj Villumsen
Verts/ALE	Katrin Langensiepen, Sara Matthieu, Kira Marie Peter-Hansen, Mounir Satouri

6	0
ECR	Margarita de la Pisa Carrión, Elżbieta Rafalska, Beata Szydło
ID	Nicolaus Fest, Guido Reil
Renew	Abir Al-Sahlani

### Key to symbols:

+ : in favour

- : against

0 : abstention