



Plenary sitting

A8-0064/2017

9.3.2017

*****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(2016)0248 – C8-0181/2016 – 2016/0130(COD))

Committee on Employment and Social Affairs

Rapporteur: Marita Ulvskog

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(2016)0248 – C8-0181/2016 – 2016/0130(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2016)0248),
 - having regard to Article 294(2) and Article 153(2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0181/2016),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - after consulting the European Economic and Social Committee,
 - after consulting the Committee of the Regions,
 - having regard to Rule 59 of its Rules of Procedure,
 - having regard to the report of the Committee on Employment and Social Affairs and the opinion of the Committee on Legal Affairs (A8-0064/2017),
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

Proposal for a directive Recital 1

Text proposed by the Commission

(1) Directive 2004/37/EC aims to protect workers against risks to their health and safety from exposure to carcinogens *or* mutagens at the workplace and lays down minimum requirements to that effect including limit values, on the basis of the available scientific and technical data.

Amendment

(1) Directive 2004/37/EC aims to protect workers against risks to their health and safety from exposure to carcinogens, mutagens *and reprotoxic substances* at the workplace and lays down minimum requirements to that effect including limit values, on the basis of the available scientific and technical data, *economic feasibility, a thorough assessment of the socio-economic impact and availability of exposure measurement protocols and techniques in the workplace. The requirements contained in that directive aim to protect workers at Union level and have to be considered to be a minimum. More stringent binding occupational exposure limits can be set by Member States.*

Amendment 2

Proposal for a directive Recital 1 a (new)

Text proposed by the Commission

Amendment

(1a) It is essential to take the precautionary principle into account, especially where there are uncertainties as to the impact of dealing with substances and their mixtures on workers' health or where available scientific and technical data is not sufficient.

Amendment 3

Proposal for a directive

Recital 2

Text proposed by the Commission

(2) ***The limit values should be revised*** when necessary in the light of scientific data.

Amendment

(2) In the light of ***new scientific and technical data and evidence-based best practices, techniques and protocols for exposure levels measurement in the workplace, Directive 2004/37/EC, including the binding occupational limit values provided for, should be reviewed regularly, at least every five years, and, where necessary, revised accordingly. Such revisions should take into account the recommendations and opinions of the Scientific Committee on Occupational Exposure Limits (SCOEL) and the Advisory Committee on Safety and Health at work (ACSH), which is composed of three full members from each Member State, representing national governments, trade unions and employers' organisations, in cooperation with the International Agency for Research on Cancer (IARC). It is also necessary to obtain epidemiological data on the incidence of cancer and on diseases and conditions correlated with exposure to carcinogens, mutagens or reprotoxic substances among workers in the last three decades.***

Amendment 4

Proposal for a directive
Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) ***It is necessary to highlight the importance of protecting workers against exposure to carcinogens, mutagens and reprotoxic substances. In the workplace, men and women are often exposed to a cocktail of substances, which can increase health risks, cause adverse effects on their reproductive systems and 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 as for carcinogens and mutagens. The participation of women in the labour market is necessary to achieve the EU-2020 headline target that 75% of the population aged 20 to 64 be employed by 2020. As not all reprotoxic substances are threshold substances, it is of utmost importance to enlarge the scope of Directive 2004/37/EC to reprotoxic substances in order to bring it into line with Regulation (EC) No 1907/2006 of the European Parliament and of the Council^{1a} and to better protect workers and their offspring and ensure the safer participation of women in the workplace.

^{1a}. *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).*

Amendment 5

Proposal for a directive Recital 2 b (new)

Text proposed by the Commission

Amendment

(2b) Due to the lack of consistent data on substance exposure, it is necessary to protect exposed workers or workers who are at risk of exposure by enforcing

health surveillance, rather than conducting such surveillance only when it is deemed to be necessary. Therefore, health surveillance of workers for whom the results of the assessment referred to in Article 3(2) of Directive 2004/37/EC reveal a risk to health or safety should be resumed even at the end of working life and would be carried out by Member States. Article 14 of Directive 2004/37/EC should be amended to ensure life-long health surveillance for all exposed workers.

Amendment 6

Proposal for a directive Recital 2 c (new)

Text proposed by the Commission

Amendment

(2c) Appropriate and consistent data collection by Member States from employers is necessary to improve and ensure safety and proper care for workers. The Commission should support best practices with regard to data collection between Member States and propose how data collection can be improved. The Member States should provide the Commission with information for the purposes of its reports on the implementation of Directive 2004/37/EC.

Amendment 7

Proposal for a directive Recital 2 d (new)

Text proposed by the Commission

Amendment

(2d) There is no harmonised methodology for measuring workers' exposure to carcinogens, mutagens and reprotoxic substances at Union level. The Commission should develop such a Union

methodology speedily in order to ensure, on the one hand, similar and high-level protection for workers and, on the other, a level playing field.

Amendment 8

Proposal for a directive Recital 2 e (new)

Text proposed by the Commission

Amendment

(2e) More transparency on health risks incurred by workers should be provided by including two new columns to Annex III of the Directive 2004/37/EC in order to indicate the residual carcinogenic risk associated with each Binding Occupational Exposure Limit and the date of the last estimation.

Amendment 9

Proposal for a directive Recital 2 f (new)

Text proposed by the Commission

Amendment

(2f) Following the amendments to Annex III to Directive 2004/37/EC provided for in this Directive, further limit values for additional substances, mixtures and processes will be proposed in early course. Between 50 and 70 substances have been identified by different agencies, stakeholders and the World Health Organization as a priority list of workplace carcinogens, mutagens and reprotoxic substances. Further amendments to the Annex III to Directive 2004/37/EC should include, but should not be limited to, substances, mixtures and processes such as diesel engine exhaust, formaldehyde, cadmium and its compounds, beryllium and its compounds, nickel compounds, arsenic and its

Amendment 10

Proposal for a directive

Recital 3

Text proposed by the Commission

(3) For *some* carcinogens *and* mutagens it is necessary to consider other absorption pathways, including the possibility of penetration through the skin, in order to ensure the best possible level of protection.

Amendment 11

Proposal for a directive

Recital 4

Text proposed by the Commission

(4) The Scientific Committee on Occupational Exposure Limits (‘the Committee’) assists the Commission, in particular, in evaluating the latest available scientific data and in proposing occupational exposure limits for the protection of workers from chemical risks, to be set at EU level pursuant to Council Directive 98/24/EC⁴⁷ and Directive 2004/37/EC. **For** the chemical agents o-toluidine and 2-nitropropane, there were no Committee recommendations available and other sources of scientific information, adequately robust and in the public domain, were considered.^{48, 49}

⁴⁷ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ

Amendment

(3) For *all* carcinogens, mutagens *and reprotoxic substances* it is necessary to consider other absorption pathways, including the possibility of penetration through the skin, in order to ensure the best possible level of protection.

Amendment

(4) The Scientific Committee on Occupational Exposure Limits (‘the Committee’) assists the Commission, in particular, in *identifying*, evaluating *and analysing in detail* the latest available scientific data and in proposing occupational exposure limits for the protection of workers from chemical risks, to be set at EU level pursuant to Council Directive 98/24/EC⁴⁷ and Directive 2004/37/EC. **As regards** the chemical agents o-toluidine and 2-nitropropane, there were no Committee recommendations available and other sources of scientific information, adequately robust and in the public domain, were considered.^{48, 49}

⁴⁷ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ

L 131, 05.05.1998, p. 11).

48

<http://monographs.iarc.fr/ENG/Monographs/vol77/mono77-11.pdf>

<http://monographs.iarc.fr/ENG/Monographs/vol99/mono99-15.pdf> and

<http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-11.pdf>

49

<http://monographs.iarc.fr/ENG/Monographs/vol1-42/mono29.pdf> and

<http://monographs.iarc.fr/ENG/Monographs/vol71/mono71-49.pdf>

L 131, 05.05.1998, p. 11).

48

<http://monographs.iarc.fr/ENG/Monographs/vol77/mono77-11.pdf>

<http://monographs.iarc.fr/ENG/Monographs/vol99/mono99-15.pdf> and

<http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-11.pdf>

49

<http://monographs.iarc.fr/ENG/Monographs/vol1-42/mono29.pdf> and

<http://monographs.iarc.fr/ENG/Monographs/vol71/mono71-49.pdf>

Amendment 12

Proposal for a directive

Recital 6

Text proposed by the Commission

(6) Guides and good practice developed through initiatives such as the Social Dialogue "Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it" (NEPSi) are valuable instruments to complement regulatory measures and in particular to support the effective implementation of limit values.

Amendment

(6) Guides and good practice developed through initiatives such as the Social Dialogue "Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it" (NEPSi) are valuable ***and necessary*** instruments to complement regulatory measures and in particular to support the effective implementation of limit values ***and should therefore be given serious consideration.***

Amendment 13

Proposal for a directive

Recital 7

Text proposed by the Commission

(7) The limit values set out in Annex III to Directive 2004/37/EC for vinyl chloride monomer and hardwood dusts should be revised in the light of more recent scientific data.

Amendment

(7) The limit values set out in Annex III to Directive 2004/37/EC for vinyl chloride monomer and hardwood dusts should be revised in the light of more recent scientific data ***and the distinction between hardwood and softwood dust***

should be removed as regards the limit value in Annex III to Directive 2004/37/EC as recommended by the Scientific Committee on Occupational Exposure Limits and the IARC, which concludes in its risk assessment for wood dust (SCOEL/SUM/102 final) that, in light of the available data and with a view to protecting workers' health, it is not pertinent to distinguish between softwood and hardwood dusts.

Amendment 14

Proposal for a directive Recital 8

Text proposed by the Commission

(8) 1,2-Epoxypropane meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen within the meaning of Directive 2004/37/EC. On the basis of the available information, including scientific and technical data, it is possible to identify *a clear* exposure level below which exposure to this carcinogen is not expected to lead to adverse effects. It is therefore appropriate to establish such a limit value for 1,2-epoxypropane .

Amendment

(8) 1,2-Epoxypropane meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen within the meaning of Directive 2004/37/EC. On the basis of the available information, including scientific and technical data, it is possible to identify *an* exposure level below which exposure to this carcinogen is not expected to lead to adverse effects. It is therefore appropriate to establish such a limit value for 1,2-epoxypropane.

Amendment 15

Proposal for a directive Recital 18

Text proposed by the Commission

(18) This amendment strengthens the protection of workers' health at their workplace.

Amendment

(18) This amendment strengthens the protection of workers' health *and safety* at their workplace *subject to the amendments to Directive 2004/37/CE being properly transposed and implemented by the Member States and applied by undertakings and workers. Member States*

should ensure that labour inspectorates have sufficient financial and human resources to carry out their duties while helping undertakings, in particular small and medium-sized enterprises (SMEs), to comply with the new rules and should closely collaborate with the European Agency for Safety and Health at work and dedicate sufficient financial resources to support a proper implementation of this Directive while avoiding any job losses.

Amendment 16

Proposal for a directive Recital 19 a (new)

Text proposed by the Commission

Amendment

(19a) In its opinions, the Advisory Committee on Safety and Health at Work (ACSH) refers to a review period for Binding Occupational Exposure limits for several substances. It is suggested that the Binding Occupational Exposure limits on respirable crystalline silica and hardwood dusts be revised within three to five years, acrylamide and 1,3-butadiene within three years, and chromium VI within an adequate review period. The Commission should therefore ask the ACSH to submit up-to-date opinions with regard to those substances.

Amendment 17

Proposal for a directive Recital 19 b (new)

Text proposed by the Commission

Amendment

(19b) In its opinion on refractory ceramic fibres, ACSH agreed that a Binding Occupational Exposure Limit is necessary but failed to reach a common position on a threshold. The Commission should therefore encourage the ACSH to

submit an opinion on a Binding Occupational Exposure Limit for refractory ceramic fibres.

Amendment 18

Proposal for a directive Recital 20

Text proposed by the Commission

(20) This Directive respects the fundamental rights and principles enshrined in the Charter of Fundamental Rights of the European Union, in particular in Article 31(1) thereof.

Amendment

(20) This Directive respects the fundamental rights and principles enshrined in the Charter of Fundamental Rights of the European Union, in particular **Article 2 (right to life) and Article 31(1) (right to fair and just working conditions with respect to workers' health, safety and dignity)** thereof.

Amendment 19

Proposal for a directive Recital 21

Text proposed by the Commission

(21) The limit values set in this Directive will be kept under review in the light of the implementation of Regulation (EC) No 1907/2006, in particular to take account of the interaction between limit values set out under Directive 2004/37/EC and DNELs (Derived No Effect Levels) derived for hazardous chemicals under that Regulation.

Amendment

(21) The limit values set in this Directive will be kept under review in the light of the implementation of Regulation (EC) No 1907/2006, in particular to take account of the interaction between limit values set out under Directive 2004/37/EC and DNELs (Derived No Effect Levels) derived for hazardous chemicals under that Regulation **in order to protect workers effectively.**

Amendment 20

Proposal for a directive Recital 22

Text proposed by the Commission

(22) Since the objectives of this

Amendment

(22) Since the objectives of this

Directive, which are to improve living and working conditions and to protect the health of workers from the specific risks arising from exposure to carcinogens, cannot be sufficiently achieved by the Member States, but can be better achieved at EU level, the EU may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5(3) of the Treaty on European Union. In accordance with the principle of proportionality, as set out in Article 5(4) of the TEU, this Directive does not go beyond what is necessary in order to achieve those objectives.

Directive, which are to improve living and working conditions and to protect the health of workers from the specific risks arising from exposure to carcinogens, ***mutagens and reprotoxic substances*** cannot be sufficiently achieved by the Member States, but can be better achieved at EU level, the EU may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5(3) of the Treaty on European Union. In accordance with the principle of proportionality, as set out in Article 5(4) of the TEU, this Directive does not go beyond what is necessary in order to achieve those objectives.

Amendment 21

Proposal for a directive

Recital 23

Text proposed by the Commission

(23) Given that the present act concerns the workers' health at their workplace, the deadline for transposition should ***be*** two years.

Amendment

(23) Given that the present act concerns the ***protection of*** workers' health ***and safety*** at their workplace, the deadline for transposition should ***not be later than*** two years ***from the date of entry into force of this Directive.***

Amendment 22

Proposal for a directive

Article 1 – paragraph 1 – point -1 (new)

Directive 2004/37/EC

Title

Present text

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

Amendment

(-1) The title 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 at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)”

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

Amendment 23

Proposal for a directive

Article 1 – paragraph 1 – point -1 a (new)

Directive 2004/37/EC

Article 1 – paragraph 1 – subparagraph 1

Present text

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.

Amendment

(-1a) In Article 1(1), subparagraph 1 is replaced by the following:

“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, *mutagens or reprotoxics* at work.”

Amendment 24

Proposal for a directive

Article 1 – paragraph 1 – point -1 b (new)

Directive 2004/37/EC

Article 2 – paragraph 1 – 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;

Amendment 25

Proposal for a directive

Article 1 – paragraph 1 – point -1 c (new)

Directive 2004/37/EC

Article 2 – paragraph 1 – point c

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.”

Amendment 26

Proposal for a directive

Article 1 – paragraph 1 – point -1 d (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

(-1d) 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.”

Amendment 27

Proposal for a directive

Article 1 – paragraph 1 – point -1 e (new)

Directive 2004/37/EC

Article 3 – paragraph 2 – subparagraph 1

Present Text

Amendment

(-1e) In Article 3(2), the first subparagraph is replaced by the following:

2. 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.

“2. 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 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.”

Amendment 28

Proposal for a directive

Article 1 – paragraph 1 – point -1 f (new)

Directive 2004/37/EC

Article 3 – paragraph 2 – subparagraph 2

Present Text

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.

Amendment

(-1f) In Article 3(2), the second subparagraph is replaced by the following:

“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*.”

Amendment 29

Proposal for a directive

Article 1 – paragraph 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

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*

with carcinogens *or* mutagens.

substances.”

Amendment 30

Proposal for a directive

Article 1 – paragraph 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, preparation 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. The employer shall reduce the use of a carcinogen, mutagen *or reprotoxic substance* 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 31

Proposal for a directive

Article 1 – paragraph 1 – point -1 i (new)

Directive 2004/37/EC

Article 5 – paragraph 2

Present Text

2. Where it is not technically possible to replace the carcinogen *or* mutagen by a substance, preparation 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.”

Amendment 32

Proposal for a directive

Article 1 – paragraph 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.”

Amendment 33

Proposal for a directive

Article 1 – paragraph 1 – point -1 k (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – introductory part

Present Text

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

Amendment

(-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:”

Amendment 34

Proposal for a directive

Article 1 – paragraph 1 – point -1 l (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point a

Present Text

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

Amendment

(-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;”

Amendment 35

Proposal for a directive

Article 1 – paragraph 1 – point -1 m (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point c

Present Text

(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;

Amendment

(-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;”

Amendment 36

Proposal for a directive

Article 1 – paragraph 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;”

Amendment 37

Proposal for a directive

Article 1 – paragraph 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 38

Proposal for a directive

Article 1 – paragraph 1 – point -1 p (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point j

Present Text

(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;

Amendment 39

Proposal for a directive

Article 1 – paragraph 1 – point - 1 q (new)

Directive 2004/37/EC

Article 6 – paragraph 1 – point a

Present Text

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

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;”

Amendment

(-1p) 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*;”

Amendment

(-1q) In 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;”

Amendment 40

Proposal for a directive

Article 1 – paragraph 1 – point - 1 r (new)

Directive 2004/37/EC

Article 6 – paragraph 1 – point b

Present Text

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

Amendment

(-1r) In 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*;”

Amendment 41

Proposal for a directive

Article 1 – paragraph 1 – point -1 s (new)

Directive 2004/37/EC

Article 6 a (new)

Text proposed by the Commission

Amendment

(-1s) The following article is inserted:

“Article 6a

Information for the Commission

The Member States shall provide the Commission with information referred to in Article 6 of this Directive as part of the implementation reports referred to in Article 17a of Directive 89/391/EEC.”

Amendment 42

Proposal for a directive

Article 1 – paragraph 1 – point -1 t (new)

Directive 2004/37/EC

Article 10 – paragraph 1 – introductory part

Present Text

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:

Amendment 43

Proposal for a directive

Article 1 – paragraph 1 – point -1 u (new)

Directive 2004/37/EC

Article 10 – paragraph 1 –point a

Present Text

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

Amendment 44

Proposal for a directive

Article 1 – paragraph 1 – point -1 v (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

Amendment

(-1t) 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:”

Amendment

(-1u) 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*;”

Amendment

(-1v) 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

hazard signs.

warning and hazard signs.”

Amendment 45

Proposal for a directive

Article 1 – paragraph 1 – point -1 w (new)

Directive 2004/37/EC

Article 14 – paragraph 1

Present text

1. The Member States shall establish, in accordance with national laws and/or practice, arrangements for carrying out relevant health surveillance of workers for whom the results of the assessment referred to in Article 3(2) reveal a risk to health or safety.

Amendment

(-1w) In Article 14, paragraph 1 is replaced by the following:

“1. The Member States shall establish, in accordance with national laws or practice, arrangements for carrying out relevant ***life-long*** health surveillance of workers for whom the results of the assessment referred to in Article 3(2) reveal a risk to health or safety.”

Amendment 46

Proposal for a directive

Article 1 – paragraph 1 – point -1 x (new)

Directive 2004/37/EC

Article 14 – paragraph 2

Present text

2. The arrangements referred to in paragraph 1 shall ***be such that*** each worker ***shall be able*** to undergo, if appropriate, relevant health surveillance:

- prior to exposure,
- at regular intervals ***thereafter***.

Those arrangements shall be such that it is directly possible to implement individual and occupational hygiene measures.

Amendment

(-1x) In Article 14, paragraph 2 is replaced by the following:

“2. The arrangements referred to in paragraph 1 shall ***allow*** each worker to undergo, if appropriate, relevant life-long health surveillance:

- prior to exposure,
- at regular intervals ***during the exposure period,***
- ***after the end of the exposure and the end of their employment.***

Those arrangements shall be such that it is directly possible to implement individual and occupational hygiene measures.

Amendment 47

Proposal for a directive

Article 1 – paragraph 1 – point -1 y (new)

Directive 2004/37/EC

Article 14 – paragraph 3

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. In that event, a reassessment of the risk of exposure shall be carried out in accordance with Article 3(2).

Amendment

(-1y) In Article 14, paragraph 3 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. In that event, a reassessment of the risk of exposure shall be carried out in accordance with Article 3(2).”

Amendment 48

Proposal for a directive

Article 1 – paragraph 1 – point -1 z (new)

Directive 2004/37/EC

Article 14 – paragraph 8

Present Text

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.

Amendment

(-1z) In Article 14, paragraph 8 is replaced by the following:

“8. All cases of cancer 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.”

Amendment 49

Proposal for a directive

Article 1 – paragraph 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) of this Directive as part of the implementation reports referred to in Article 17a of Directive 89/391/EEC.”

Amendment 50

Proposal for a directive

Article 1 – paragraph 1 – point -1 ab (new)

Directive 2004/37/EC

Article 16 – paragraph 1

Present Text

Amendment

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.

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

“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, mutagens *or reprotoxic substances* for which this is possible, and, where necessary, other directly related provisions.”

Amendment 51

Proposal for a directive

Article 1 – paragraph 1 – point -1 ac (new)

Directive 2004/37/EC

Article 17 – paragraph 2

Present Text

Amendment

2. Purely technical adjustments to Annex II in the light of technical progress, changes in international regulations or specifications and new findings in the field of carcinogens *or* mutagens shall be adopted in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC.

(-1acv) In Article 17, paragraph 2 is replaced by the following:

“2. Purely technical adjustments to Annex II in the light of technical progress, changes in international regulations or specifications and new findings in the field of carcinogens, mutagens *or reprotoxic substances* shall be adopted in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC.”

Amendment 52

Proposal for a directive

Article 1 – paragraph 1 – point 1 a(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.

(1a) 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.”

Amendment 53

Proposal for a directive

Annex

Directive 2004/37/EC

Annex III – Part A

Text proposed by the Commission

CAS No	EC No ⁽²⁾	NAME OF AGENT	LIMIT VALUES ⁽³⁾	Notation ⁽⁴⁾
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(¹)			mg/m ³ (⁵)	ppm (⁶)	f/ml(⁷)	
–	–	Hardwood dusts	3 (⁸)	–	–	–
–	–	Chromium (VI) compounds which are carcinogens within the meaning of Article 2 (a) (i) of the Directive (as Chromium)	0,025	–	–	–
–	–	Refractory Ceramic Fibres which are carcinogens within the meaning of Article 2 (a) (i) of the Directive	–	–	0,3	–
–	–	Respirable Crystalline Silica Dust	0,1 (⁹)	–	–	–
71-43-2	200-753-7	Benzene	3,25	1	–	skin
75-01-4	200-831-0	Vinyl chloride monomer	2,6	1	–	–
75-21-8	200-849-9	Ethylene oxide	1,8	1	–	skin
75-56-9	200-879-2	1,2-Epoxypropane	2,4	1	–	–
79-06-1	201-173-7	Acrylamide	0,1	–	–	skin
79-46-9	201-209-1	2-Nitropropane	18	5	–	–
95-53-4	202-429-0	<i>o</i> -Toluidine	0,5	0,1	–	–
106-99-0	203-450-8	1,3-Butadiene	2,2	1	–	–
302-01-2	206-114-9	Hydrazine	0,013	0,01	–	skin
593-60-2	209-800-6	Bromoethylene	4,4	1	–	–

¹ CAS No: Chemical Abstract Service Registry Number.

² EC No, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union, as defined in section 1.1.1.2 in Annex VI, Part 1, of

Regulation (EC) No 1272/2008.

³ Measured or calculated in relation to a reference period of eight hours.

⁴ Substantial contribution to the total body burden via dermal exposure possible.

⁵ mg/m³ = milligrams per cubic metre of air at 20°C and 101,3 kPa (760 mm mercury pressure).

⁶ ppm = parts per million by volume in air (ml/m³).

⁷ f/ml = fibres per millilitre.

⁸ Inhalable fraction: *if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture.*

⁹ Respirable fraction.

Amendment

CAS No (¹)	EC No (²)	NAME OF AGENT	LIMIT VALUES(³)			Notation(⁴)
			mg/m ³ (⁵)	ppm (⁶)	f/ml(⁷)	
–	–	Wood dusts	2 (⁸)	–	–	Hardwood dusts: 3 mg/m³ until XXXX (5 years after entry into force) Softwood dusts: 5 mg/m³ until XXXX (5 years after entry into force)
–	–	Chromium (VI) compounds which are carcinogens within the meaning of Article 2 (a) (i) of the Directive (as Chromium)	0,001	–	–	–
–	–	Refractory Ceramic Fibres which are carcinogens within	–	–	0,3	–

		the meaning of Article 2 (a) (i) of the Directive				
–	–	Respirable Crystalline Silica Dust	0,05 ⁽⁹⁾	–	–	<i>Transition value of 0,1 mg/m³ until XXXX (10 years after entry into force) - to be reviewed 5 years after entry into force</i>
71-43-2	200-753-7	Benzene	3,25	1	–	skin
75-01-4	200-831-0	Vinyl chloride monomer	2,6	1	–	–
75-21-8	200-849-9	Ethylene oxide	1,8	1	–	skin
75-56-9	200-879-2	1,2-Epoxypropane	2,4	1	–	–
79-06-1	201-173-7	Acrylamide	0,1	–	–	skin
79-46-9	201-209-1	2-Nitropropane	18	5	–	–
95-53-4	202-429-0	<i>o</i> -Toluidine	0,5	0,1	–	–
106-99-0	203-450-8	1,3-Butadiene	2,2	1	–	–
302-01-2	206-114-9	Hydrazine	0,013	0,01	–	skin
593-60-2	209-800-6	Bromoethylene	4,4	1	–	–

¹ CAS No: Chemical Abstract Service Registry Number.

² EC No, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union, as defined in section 1.1.1.2 in Annex VI, Part 1, of Regulation (EC) No 1272/2008.

³ Measured or calculated in relation to a reference period of eight hours.

⁴ Substantial contribution to the total body burden via dermal exposure possible.

⁵ mg/m³ = milligrams per cubic metre of air at 20°C and 101,3 kPa (760 mm mercury pressure).

⁶ ppm = parts per million by volume in air (ml/m³).

⁷ f/ml = fibres per millilitre.

⁸ Inhalable fraction.

⁹ Respirable fraction.

EXPLANATORY STATEMENT

On 13 May 2016 the Commission published its proposal for amending Directive 2004/37/EC to better protect workers from exposure to carcinogens and mutagens in the workplace. The European Parliament had called for a revision of the directive at several occasions both in the current and the previous term.

The Rapporteur welcomes the Commission's initiative as an important first step towards addressing the overall problem of exposure to carcinogens and mutagens in the workplace. Cancer is the second largest cause of death in Europe and the largest cause of work-related death. All work related cancers are preventable. An update and precise legislative framework in the European Union will contribute to a better prevention of work-related cancers. The annual cost to Member States is estimated at 334 billion EUR¹.

According to the European Agency for Safety and Health at Work (EU-OSHA), Member States report lack of exposure and toxicological data at national level, and that there is a difficulty reaching consensus regarding occupational exposure limits (OELs). The Rapporteur takes the view that the guiding principle for setting binding OELs (BOELs) is to follow best practice in the Member States as well as globally and to act according to the precautionary principle. This principle should be consistently reflected in the directive as recalled by its Recital 14 ('The precautionary principle should be applied in the protection of workers' health.').

I. The inclusions of reprotoxic substances in the scope of the directive

The rapporteur proposes to broaden the scope of the Directive to allow for the inclusion of reprotoxic substances, which is in line with previous calls from the European Parliament² and with legislation in force in some Member States.

According to a recent French study³ more than 1% of the workers are exposed to reprotoxic substances. Extrapolating those data, there could be between 2 and 3 million workers exposed to reprotoxic substances in the European Union. At present the legislative protection for workers from such substances is very weak because it is basically limited to the general provisions of the Chemical Agents Directive 98/24/EC. Reprotoxic substances are substances of very high concern according to Regulation (EC) No 1907/2006 (REACH). The provisions for workers' protection should be consistent with that finding. The pregnant workers' directive 92/85/EC does not impose preventative measures before a pregnant worker has informed their employer of their pregnancy. That means that there is no specific protection in early weeks of gestation and no protection for male or female fertility. Carcinogens and mutagens are tied to reprotoxic substances in European legislation for instance through REACH. At Member State level six countries have already extended the scope of the directive (FR, AT, FI, DE, SE and CZ) to include reprotoxic substances in transposition.

¹ Work-related cancer in the European Union: Size, impact and options for further prevention Work-related cancer in the European Union: Size, impact and options for further prevention., RIVM, 2016

² European Parliament resolution of 15 December 2011 on the mid-term review of the European strategy 2007-2012 on health and safety at work (2011/2147(INI))

³ Les expositions aux cancérogènes mutagènes et reprotoxiques, INRS, Références en santé au travail, No 144, 2015

In 2004 a survey carried out in France evaluated 50 potential reprotoxic substances scoring them for danger and exposure. The first 10 substances according to this methodology were: di(2-ethylhexyl)phthalate, benzyl butyl phthalate, dibutyl phthalate, cadmium, lead, hexachlorobenzene, toluene, nonylphenol, ethylene glycol ethyl ether, benomyl¹. Examples of effects of reprotoxic substances like phthalates are: testicular toxicity, reduced male and female fertility, foetal toxicity (possibly leading to death or malformations). Alkylphenols and related chemicals have hormone mimicking (imitating) effects and can lead to reduced male fertility, testicular size and sperm quality².

II. Stricter limit values

The Rapporteur has proposed stricter limit values for several of the substances considered. The rapporteur is of the view that the BOELs set by the European Union should mirror the best practice developed in the Member States. As the Commission has highlighted in the impact assessment, decisions on limit values strike a balance between cancer risk and the estimated cost of preventing it. Where practical difficulties exist due to a lack of alternative substances or technical solutions, additional time for implementing the stricter limit values has been proposed. This ensures time for employers to develop solutions and to offset costs for investment. All of the changes proposed by the rapporteur reflect BOELs that are already in force or exist in some Member States.

- *Crystalline silica*

The Scientific Committee for Occupational Exposure Limits (SCOEL) has advised a limit value of 0.05 mg/m³; the rapporteur shares this view and has proposed the same limit value as the SCOEL. According to the Commission's impact assessment, such a limit value would result in 107.350 less deaths in the period 2010-2069 as compared to the current scenario.

- *Chromium VI*

The Rapporteur shares the view expressed by several Member States (Belgium, Germany, Denmark, France, The Netherlands, Lithuania and Sweden) during discussions in the Council that the limit value for Chromium IV should be lowered as compared to the Commission's proposal (0,025 mg/m³). She is concerned that the limit value would be set at a relatively high level despite no up-to-date hexavalent chromium exposure data being available, since the data used to set the proposed limit is from 1995. At present, three Member States have implemented a limit value of 0.001 mg/m³. Again, the precautionary principle should apply.

- *Wood dust*

The rapporteur shares the view of the International Agency for Research on Cancer (IARC) that there is sufficient evidence that no distinction should be made between hard and soft wood dust. As there have been noticeable technical advances in recent years, from a practical perspective it is fully possible to set a stricter limit value for wood dust. As the majority of EU Member States have a limit value set at 2 mg/m³, this should be the common limit value for the European Union until the stricter best practice limit value of 1 mg/m³ (France) can be achieved. An even stricter limit value of 0.5 mg/m³ should be evaluated in the future revision of the Directive based on the health and safety impact, technical feasibility and cost.

¹ AFSSET – Agence française de sécurité sanitaire de l'environnement et du travail, *Identification d'une liste de substances toxiques pour la reproduction et le développement et Proposition d'une méthode de hiérarchisation pour l'analyse des Valeurs Toxicologiques de Référence, Rapport du groupe d'experts 'VTR reprotoxic'*, 2006, p. 58.

² Evans, T.J., 'Endocrine disruptors', Gupta, R.C. (Ed.), *Reproductive and Developmental Toxicity*, Elsevier Inc., 2011, pp. 874-875.

III. Further issues to be addressed

The Rapporteur has not proposed to introduce BOELs for additional substances in light of the Commission's explicit intention to further amend the Directive in the very next future. As there are numerous substances that have been identified as carcinogens, mutagens and reprotoxic agents, the Rapporteur welcomes such plans and urges that additional limit values should be introduced without delay to protect many more workers from exposure, to prevent more risks and save more lives.

Improved data collection also needs to be addressed in the revisions of the Directive, through best practice sharing at a European level and with the aid of social partners, especially employers. At present, the lack of clear and comprehensive data collection by the Member States creates barriers to protection, prevention and proper health care, not to mention responsible policy making.

The gaps in data collection also stress the need to introduce mandatory life-long health surveillance of exposed workers. This has been proposed as an amendment to the directive due to the urgent nature of the problem, without sufficient data on workers' exposure, it is impossible to evaluate when health surveillance is necessary. Until sufficient and comprehensive data is available and can be consistently shared with relevant health professionals, health surveillance must be carried out for all exposed workers, including after the end of exposure and the end of their working life. This includes all workers, trainees, apprentices and maintenance staff who have been exposed. Early detection of cancer is one of the most important factors which contribute to higher survival rates.

On a general note this revision has to be seen as a first step towards a renewed ambition to protect workers from harmful substances in the workplace. It is important to see which additional policy areas can help support the long term goal of protection, for instance through research and innovation initiatives.

1.2.2017

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(2016)0248 – C8-0181/2016 – 2016/0130(COD))

Rapporteur: Kostas Chrysogonos

SHORT JUSTIFICATION

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, which is supported by an impact assessment¹, seeks to guarantee a high level of protection of workers' health and safety in the EU, through the introduction at EU level of better occupation standards, regarding workers' exposure to carcinogens or mutagens at work.

Specifically, the main objectives of the proposal are the following: a) to improve workers' health protection by reducing occupational exposure to chemical agents that may cause cancer or mutations; b) to ensure more clarity and to create a better level playing field for economic operators; and c) to increase the effectiveness of the EU framework for workers' protection by updating it on the basis of available scientific evidence. These objectives are consistent with the fundamental right to life and to fair and just working conditions which respect his/her health, safety and dignity as set out in Articles 2 and 31 respectively of the EU Charter of Fundamental Rights.

As such, this proposal falls within the Commission's EU Strategic Framework on Health and Safety at Work 2014-2020 and fits within the Commission's priority actions in its Work Programme for 2016 for a deeper and fairer single market and for the establishment of a fair and truly pan-European labour market that provides workers with decent protection and sustainable jobs. Cancer is the leading cause (53%) of work-related deaths in the EU. For the workers and their families, cancer results not only in substantial quality of life losses, but also in direct health care costs and indirect loss of present and future earnings. Occupational cancer impacts the economy at large too, reducing labour supply and productivity and

¹ SWD(2016) 152 and SWD(2016) 153.

increasing the burden on public finances through avoidable public expenditure on health care and other benefits. Finally, occupational cancer implies for businesses staff replacement costs, productivity losses and the need to pay higher wages to compensate for the higher occupational risk.

Workers in the EU are currently protected from cancer-causing chemicals under the Carcinogens and Mutagens Directive 2004/37/EC (hereinafter, 'CMD'), which is one of the 24 directives falling under the Occupational Safety and Health Framework Directive 89/391/EEC (hereinafter, 'OSH Framework'). The OSH Framework sets general objectives to eliminate and reduce to a minimum the risks to safety and health of workers. The CMD provides that employers must 'identify and assess risks to workers' associated with carcinogens and 'must prevent exposure where risks occur'. Where it is technically possible, the process or agent concerned must be substituted with a non-hazardous or less hazardous process or agent. Where substitution is not possible, chemical carcinogens must be used in a closed system, or worker exposure must be reduced to as low a level as is technically possible. Employers also have the obligation to ensure that occupational exposure limit values are not exceeded.

The new proposal seeks to bring within the scope of the CMD a number of chemical agents that are recognised as human carcinogens in countries outside the EU or by international organisations, but that are not yet classified under the current EU system. Specifically, it proposes to revise or to introduce EU-wide occupational exposure limit values for 13 chemical agents on the basis of the latest scientific evidence, thus harmonising widely varying national limit values, where existent. According to the impact assessment, this is estimated to save around 100.000 lives by 2069 for a total monetised health benefit quantified between EUR 34 and 89 billion.

As a result, your rapporteur supports strongly the aforementioned proposal, albeit with a number of amendments, which aim mainly at stressing the need for a precautionary approach regarding the implementation of the proposal. The precautionary principle can be defined as a general principle of Union law intended to be applied in order to ensure a high level of protection of health, consumer safety and the environment in all the Union's spheres of activity.¹ This principle is thus particularly important where there are uncertainties as to the impact of dealing with mixtures especially of toxic agents on workers' health or where available scientific and technical data is not sufficient. This calls essentially for the establishment of a new and effective cancer- and related health problems-prevention paradigm that takes into account multiple interacting factors and the latest improvements in measurement techniques, risk management measures and other relevant factors.

Finally, your rapporteur notes that more efforts are required in order to efficiently protect workers from the risks related to carcinogens and mutagens at work, as there are still various substances that are not included in the list of the proposal that can potentially have an adverse impact on workers' health.² All substances that can increase the risk of occupational cancers shall be covered by the EU legislation.

¹ See among others, case T-74/00, *Artegodan v. Commission* [2000] ECR II-02583, paras 183-184.

² See among others H. Wriedt, 'Occupational Health & Safety Advice Centre, Report – Carcinogens that should be subject to binding limits on workers' exposure' (2016).

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 aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace and lays down minimum requirements to that effect including limit values, on the basis of the available scientific and technical data.

Amendment

(1) Directive 2004/37/EC aims to protect **over 217 million Union** workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace and lays down minimum requirements to that effect including limit values, on the basis of the available scientific and technical data.

Amendment 2

Proposal for a directive

Recital 1 a (new)

Text proposed by the Commission

Amendment

(1a) Directive 2004/37/EC needs to be urgently updated in order to provide for new preventive and protective measures.

Amendment 3

Proposal for a directive

Recital 1 b (new)

Text proposed by the Commission

Amendment

(1b) Substances that damage human fertility are just as harmful for the health of workers as carcinogens or mutagens: The scope of Directive 2004/37/EC should therefore also cover substances that

damage human fertility.

Amendment 4

Proposal for a directive Recital 1 c (new)

Text proposed by the Commission

Amendment

(1c) *It is essential to take the precautionary principle into account, especially where there are uncertainties as to the impact of dealing with substances and their mixtures on workers' health or where available scientific and technical data is not sufficient.*

Amendment 5

Proposal for a directive Recital 2

Text proposed by the Commission

Amendment

(2) The limit values should be revised *when necessary* in the light of scientific data.

(2) *To improve the efficiency and effectiveness of Union framework provisions for the protection of workers and in accordance with the precautionary principle, the limit values should be revised **regularly in the light of the latest scientific and technical information and data, as well as in the light of the latest improvements in measurement techniques, risk management measures and other relevant factors.***

Amendment 6

Proposal for a directive Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) *It is necessary to highlight the importance of protecting workers against exposure to carcinogens, mutagens and*

substances that are toxic to reproduction. In the workplace, men and women are often exposed to a cocktail of substances, which can increase health risks, cause adverse effects on their reproductive systems and impaired fertility or infertility, and can have a negative impact on foetal development and on development of the children, inter alia through harmful impacts on lactation or harm inflicted through lactation. Substances which are toxic to reproduction and sexual functioning are of very high concern and the same organisation of workplace prevention should be applied as for carcinogens and mutagens. To ensure increased and safe participation of women in the labour market in accordance with the EU-2020 headline target, reprotoxic substances should be covered in the revision of Directive 2004/37/EC. This would bring it in line with Regulation (EC) No 1907/2006 of the European Parliament and of the Council^{1a} as far as the protection of women in the workplace is concerned.

^{1a}. *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).*

Amendment 7

Proposal for a directive Recital 2 b (new)

(2b) *There is a need for the prevention of carcinogenic, mutagenic and reprotoxic chemicals and for an information campaign at Union level following Eurostat's latest chemical production statistics stating that around 31 million tonnes of carcinogenic, mutagenic and reprotoxic chemicals are produced annually in the Union.*

Amendment 8

Proposal for a directive

Recital 3

Text proposed by the Commission

Amendment

(3) ***For some carcinogens and mutagens*** it is ***necessary*** to consider ***other*** absorption pathways, including the possibility of penetration through the skin, in order to ensure the ***best*** possible level of protection.

(3) ***In accordance with the precautionary principle***, it is ***essential*** to consider ***alternative*** absorption pathways ***for carcinogens, mutagens and reprotoxins***, including the possibility of penetration through the skin, in order to ensure the ***highest*** possible level of protection ***for the health and safety of workers***.

Amendment 9

Proposal for a directive

Recital 4

Text proposed by the Commission

Amendment

(4) The Scientific Committee on Occupational Exposure Limits (‘the Committee’) assists the Commission, in particular, in evaluating the latest available scientific data and in proposing occupational exposure limits for the protection of workers from chemical risks, to be set at EU level pursuant to Council Directive 98/24/EC⁴⁷ and Directive 2004/37/EC. For the chemical agents o-

(4) The Scientific Committee on Occupational Exposure Limits (‘the Committee’) assists the Commission, in particular, in ***identifying***, evaluating ***and analysing in detail*** the latest available scientific data and in proposing occupational exposure limits for the protection of workers from chemical risks, to be set at EU level pursuant to Council Directive 98/24/EC⁴⁷ and Directive

toluidine and 2-nitropropane, there were no Committee recommendations available and other sources of scientific information, adequately robust and in the public domain, were considered.^{48, 49}

⁴⁷ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 05.05.1998, p. 11).

48

<http://monographs.iarc.fr/ENG/Monographs/vol77/mono77-11.pdf>
<http://monographs.iarc.fr/ENG/Monographs/vol99/mono99-15.pdf> and
<http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-11.pdf>

49

<http://monographs.iarc.fr/ENG/Monographs/vol1-42/mono29.pdf> and
<http://monographs.iarc.fr/ENG/Monographs/vol71/mono71-49.pdf>

Amendment 10

Proposal for a directive

Recital 5

Text proposed by the Commission

(5) There is sufficient evidence of the carcinogenicity of respirable crystalline silica dust. On the basis of available information, including scientific and technical data, a limit value for respirable crystalline silica dust should be established. Respirable crystalline silica dust generated by a work process is not subject to classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁵⁰. It is therefore appropriate to include work

2004/37/EC. For the chemical agents o-toluidine and 2-nitropropane, there were no Committee recommendations available and other sources of scientific information, adequately robust and in the public domain, were considered.^{48, 49}

⁴⁷ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 05.05.1998, p. 11).

48

<http://monographs.iarc.fr/ENG/Monographs/vol77/mono77-11.pdf>
<http://monographs.iarc.fr/ENG/Monographs/vol99/mono99-15.pdf> and
<http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-11.pdf>

49

<http://monographs.iarc.fr/ENG/Monographs/vol1-42/mono29.pdf> and
<http://monographs.iarc.fr/ENG/Monographs/vol71/mono71-49.pdf>

Amendment

(5) There is sufficient evidence of the carcinogenicity of respirable crystalline silica dust, ***which can travel deep into the lung causing serious health problems***. On the basis of available information, including scientific and technical data, a limit value for respirable crystalline silica dust should be established. Respirable crystalline silica dust generated by a work process is not subject to classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and

involving exposure to respirable crystalline silica dust generated by a work process in Annex I to Directive 2004/37/EC and to establish a limit value for respirable crystalline silica dust ('respirable fraction').

of the Council⁵⁰. It is therefore appropriate to include work involving exposure to respirable crystalline silica dust generated by a work *process or another related* process in Annex I to Directive 2004/37/EC and to establish a limit value for respirable crystalline silica dust ('respirable fraction').

⁵⁰ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1).

⁵⁰ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1).

Amendment 11

Proposal for a directive Recital 6

Text proposed by the Commission

(6) Guides and good practice developed through initiatives such as the Social Dialogue "Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it" (NEPSi) are valuable instruments to complement regulatory measures and in particular to support the effective implementation of limit values.

Amendment

(6) Guides and good practice developed through initiatives such as the Social Dialogue "Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it" (NEPSi) are valuable instruments to complement regulatory measures and in particular to support the effective implementation of limit values, **and update the latter in the light of current practice.**

Amendment 12

Proposal for a directive Recital 7

Text proposed by the Commission

(7) The limit values set out in Annex III to Directive 2004/37/EC for vinyl chloride monomer and hardwood dusts **should** be revised in the light of more

Amendment

(7) **To ensure compliance with and the application of the precautionary principle regarding workers' health and safety,** the limit values set out in Annex III to Directive 2004/37/EC for vinyl chloride

recent scientific data.

monomer, hardwood dusts, **benzene and chromium (VI)** should be **regularly** revised in the light of more recent scientific data.

Amendment 13

Proposal for a directive

Recital 12

Text proposed by the Commission

(12) Certain chromium (VI) compounds meet the criteria for classification as carcinogenic category 1A or 1B in accordance with Regulation (EC) No 1272/2008 and therefore are 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 out a limit value for these chromium VI compounds. It is therefore appropriate to establish a limit value for chromium (VI) compounds that are carcinogens within the meaning of Directive 2004/37/EC.***

Amendment

(12) Certain chromium (VI) compounds meet the criteria for classification as carcinogenic category 1A or 1B in accordance with Regulation (EC) No 1272/2008 and therefore are carcinogens within the meaning of Directive 2004/37/EC. It is ***therefore possible and necessary to establish a limit value for the chromium VI compounds which are carcinogens within the meaning of Directive 2004/37/EC, on the basis of the most recent available information, including scientific and technical data.***

Amendment 14

Proposal for a directive

Recital 18

Text proposed by the Commission

(18) This amendment strengthens the protection of workers' health at their workplace.

Amendment

(18) ***The aim of the amendment of Directive 2004/37/EC is to improve and strengthen the protection of workers' health and safety at their workplace, via the reinforcement of appropriate means of control. It also increases the effectiveness and clarity of the relevant Union law and ensures a level-playing field.***

Amendment 15

Proposal for a directive Recital 20

Text proposed by the Commission

(20) This Directive respects the fundamental rights and principles enshrined in the Charter of Fundamental Rights of the European Union, in particular in Article 31(1) thereof.

Amendment

(20) This Directive respects the fundamental rights and principles enshrined in the Charter of Fundamental Rights of the European Union, in particular ***the fundamental right to life in Article 2 and the right to fair and just working conditions with respect to people's health, safety and dignity under Article 2 and Article 31(1) thereof.***

Amendment 16

Proposal for a directive Recital 23

Text proposed by the Commission

(23) Given that the present act concerns the workers' health at their workplace, the deadline for transposition should ***be*** two years.

Amendment

(23) Given that the present act concerns the ***protection of*** workers' health ***and safety*** at their workplace, the deadline for transposition should ***not be later than*** two years ***from the date of entry into force of this Directive.***

Amendment 17

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

Present text

"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***

Amendment

(-1) The title 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

mutagens at work"

work"

Amendment 18

Proposal for a directive

Article 1 – paragraph 1 – point -1 a (new)

Directive 2004/37/EC

Article 1 – paragraph 1 – subparagraph 1

Present text

"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.

Amendment

(-1a) In Article 1(1), the first subparagraph 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, mutagens *or substances that damage human fertility* at work.

Amendment 19

Proposal for a directive

Article 1 – paragraph 1 – point -1 b (new)

Directive 2004/37/EC

Article 2 – point c a (new)

Text proposed by the Commission

Amendment

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

“(ca) 'reprotoxin' means a substance which meets the criteria for classification as a category 1A or category 1B substance toxic to reproduction set out in Annex VI to Regulation (EC) No 1272/2008.”

Amendment 20

Proposal for a directive

Article 1 – paragraph 1 – point -1 c (new)

Directive 2004/37/EC

Article 17 a (new)

(-1c) The following Article is inserted:

"Article 17a

Reprotoxic substances

By 1 November 2017, the Commission shall, after consulting the Member States and the social partners, review this Directive and propose any amendments necessary to take into account the inclusion of reprotoxic substances in its scope."

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	Amendment to Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work	
References	COM(2016)0248 – C8-0181/2016 – 2016/0130(COD)	
Committee responsible Date announced in plenary	EMPL 25.5.2016	
Opinion by Date announced in plenary	JURI 25.5.2016	
Rapporteur Date appointed	Kostas Chrysogonos 11.7.2016	
Discussed in committee	8.11.2016	28.11.2016
Date adopted	31.1.2017	
Result of final vote	+: 22 –: 2 0: 0	
Members present for the final vote	Max Andersson, Joëlle Bergeron, Marie-Christine Boutonnet, Jean-Marie Cavada, Kostas Chrysogonos, Therese Comodini Cachia, Mady Delvaux, Rosa Estaràs Ferragut, Lidia Joanna Geringer de Oedenberg, Sajjad Karim, Sylvia-Yvonne Kaufmann, Gilles Lebreton, António Marinho e Pinto, Jiří Maštálka, Emil Radev, Julia Reda, Evelyn Regner, Pavel Svoboda, József Szájer, Axel Voss, Tadeusz Zwiefka	
Substitutes present for the final vote	Sergio Gaetano Cofferati, Angel Dzhambazki, Evelyne Gebhardt	

PROCEDURE – COMMITTEE RESPONSIBLE

Title	Amendment to Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work			
References	COM(2016)0248 – C8-0181/2016 – 2016/0130(COD)			
Date submitted to Parliament	10.5.2016			
Committee responsible Date announced in plenary	EMPL 25.5.2016			
Committees asked for opinions Date announced in plenary	ENVI 25.5.2016	ITRE 25.5.2016	JURI 25.5.2016	
Not delivering opinions Date of decision	ITRE 14.6.2016			
Rapporteurs Date appointed	Marita Ulvskog 2.6.2016			
Discussed in committee	31.8.2016	13.10.2016	8.12.2016	25.1.2017
Date adopted	28.2.2017			
Result of final vote	+: 38 -: 6 0: 0			
Members present for the final vote	Laura Agea, Guillaume Balas, Tiziana Beghin, Vilija Blinkevičiūtė, Enrique Calvet Chambon, Ole Christensen, Lampros Fountoulis, Elena Gentile, Arne Gericke, Marian Harkin, Czesław Hoc, Agnes Jongerius, Jan Keller, Ádám Kósa, Jean Lambert, Jérôme Lavrilleux, Patrick Le Hyaric, Verónica Lope Fontagné, Thomas Mann, Dominique Martin, Anthea McIntyre, Joëlle Mélin, Elisabeth Morin-Chartier, Georgi Pirinski, Marek Plura, Sofia Ribeiro, Maria João Rodrigues, Claude Rolin, Anne Sander, Sven Schulze, Romana Tomc, Marita Ulvskog, Renate Weber, Tatjana Ždanoka, Jana Žitňanská			
Substitutes present for the final vote	Maria Arena, Heinz K. Becker, Sergio Gutiérrez Prieto, Krzysztof Hetman, Paloma López Bermejo, Evelyn Regner, Jasenko Selimovic, Csaba Sógor			
Substitutes under Rule 200(2) present for the final vote	Ulrike Rodust			
Date tabled	9.3.2017			

