



Plenary sitting

A8-0142/2018

11.4.2018

*****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(2017)0011 – C8-0010/2017 – 2017/0004(COD))

Committee on Employment and Social Affairs

Rapporteur: Claude Rolin

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(2017)0011 – C8-0010/2017 – 2017/0004(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2017)0011),
 - 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 (C8-0010/2017),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 31 May 2017¹,
 - 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 (A8-0142/2018),
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

Amendment

(1) Directive 2004/37/EC aims to protect workers against risks to their health and safety from exposure to carcinogens or

¹ OJ C 288, 31.8.2017, p. 56.

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.

mutagens at the workplace and lays down minimum requirements to that effect including ***binding occupational exposure*** limit values ***which must not be exceeded***, on the basis of the available ***information, including*** scientific and technical data, ***a thorough impact assessment regarding the social aspects and the economic feasibility and availability of occupational exposure measurement protocols and techniques.***

Amendment 2

Proposal for a directive Recital 1 a (new)

Text proposed by the Commission

Amendment

(1a) Compliance with the limit values is without prejudice to other obligations of employers pursuant to Directive 2004/37/EC which aim to reduce the level of workers' exposure, in particular by reducing the use of carcinogens and mutagens at the workplace, preventing or reducing workers' exposure to carcinogens or mutagens, and implementing measures to that effect. Those measures should include, in so far as technically possible, the replacement of carcinogens or mutagens by substances, mixtures or processes which are not dangerous, or which are less dangerous, to workers' health, the use of closed systems, or other measures that aim to reduce the level of workers' exposure, thereby fostering innovation.

Amendment 3

Proposal for a directive Recital 1 b (new)

Text proposed by the Commission

Amendment

(1b) Small and medium-sized enterprises (SMEs) and microenterprises which represent the large majority of enterprises in the Union, have limited financial, technical and human resources. Compliance of SMEs and microenterprises should be facilitated while maintaining equal protection levels for all workers. In that regard specific measures, incentives and digital tools, could help SMEs and microenterprises more easily to comply with their obligations pursuant to Directive 2004/37/EC and move towards the elimination of carcinogenic or mutagenic risks and the social partners should exchange best practices.

Amendment 4

Proposal for a directive Recital 1 c (new)

Text proposed by the Commission

Amendment

(1c) The requirements laid down in Directive 2004/37/EC aim to protect workers from carcinogens and mutagens at Union level and are to be considered to be minimum requirements. More stringent limit values and protective measures can be set by Member States.

Amendment 5

Proposal for a directive Recital 1 d (new)

Draft legislative resolution

Amendment

(1d) The Commission will assess, by the end of the first quarter of 2019, taking into account latest developments in scientific knowledge, the possibility of

amending the scope of Directive 2004/37/EC to include reprotoxic substances and, on that basis, to present, if appropriate, and after consulting management and labour, a legislative proposal.

Amendment 6

Proposal for a directive

Recital 3

Text proposed by the Commission

(3) The Scientific Committee on Occupational Exposure Limits (***‘the Committee’***)⁵⁵ *assists* the Commission, in particular, in evaluating the latest available scientific data and in proposing occupational exposure limit values for the protection of workers from chemical risks, to be set at Union level pursuant to Council Directive 98/24/EC⁵⁶ and Directive 2004/37/EC. Other sources of scientific information, adequately robust and in the public domain were also considered.

⁵⁵ Commission Decision 2014/113/EU of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC (OJ L 62, 4.3.2014, p. 18).

⁵⁶ Council Directive 98/24/EC of 7 April 1998 on the protection of the

Amendment

(3) The Scientific Committee on Occupational Exposure Limits (***SCOEL***)⁵⁵ ***and the Advisory Committee on Safety and Health at Work (ACSH)***^{55a} *assist* the Commission, in particular, in ***identifying***, evaluating ***and analysing in detail*** the latest available scientific ***and technical*** data and in proposing occupational exposure limit values for the protection of workers from chemical risks, ***which are*** to be set at Union level pursuant to Council Directive 98/24/EC⁵⁶ and Directive 2004/37/EC. Other sources of scientific information, adequately robust and in the public domain were also considered, ***in particular the International Agency for Research on Cancer, the World Health Organization and national agencies.***

⁵⁵ Commission Decision 2014/113/EU of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC (OJ L 62, 4.3.2014, p. 18).

^{55a} ***Council Decision of 22 July 2003 on setting up an Advisory Committee on Safety and Health at Work (2003/C 218/01) (OJ L 218, 13.9.2003, p. 1).***

⁵⁶ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and

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).

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).

Amendment 7

Proposal for a directive Recital 3 a (new)

Text proposed by the Commission

Amendment

(3a) The Committee's work is vital to a responsible policy process and should be made public in the interests of transparency and evidence-based policymaking. If the Committee's work is to be reorganised, dedicated resources for the work must be guaranteed and specific expertise on epidemiology, toxicology, occupational medicine and occupational hygiene must not be lost.

Amendment 8

Proposal for a directive Recital 3 b (new)

Text proposed by the Commission

Amendment

(3b) This Directive, which amends Directive 2004/37/EC, establishes limit values and skin notations with regard to eight carcinogens additional to those provided for in Directive 2004/37/EC and is a further step in a longer process to update that Directive. For the purpose of achieving better protection for workers, Directive 2004/37/EC should, after consulting SCOEL and ACSH, be reviewed on an ongoing basis and amended when necessary in the light of available information, including progressively acquired scientific and

technical data such as residual risk data, . Further amendments to that Directive should address the issue of exposure of workers to carcinogenic or mutagenic substances resulting from the preparation, administration or disposal of hazardous drugs, including cytotoxic drugs, and work involving exposure to carcinogenic or mutagenic substances in cleaning, transport, laundry and waste disposal of hazardous drugs of materials contaminated by hazardous drugs and in personal care for patients under treatment of hazardous drugs.

Amendment 9

Proposal for a directive Recital 4

Text proposed by the Commission

(4) In accordance with the recommendations of *the Committee*, where available, skin notations and/or 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 shorter reference periods, in general fifteen minutes time-weighted average (short-term exposure limit values), to take account of the effects arising from short-term exposure.

Amendment

(4) In accordance with the recommendations of *SCOEL, ACSH*, where available, skin notations and/or 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 shorter reference periods, in general fifteen minutes time-weighted average (short-term exposure limit values), to *limit, to the extent possible*, the effects arising from short-term exposure. *Additional sources of scientific information that are adequately robust and in the public domain should also be considered.*

Amendment 10

Proposal for a directive Recital 4 a (new)

(4a) The overarching goal of protecting the health of fetuses and future generations implies setting up specific measures for women of childbearing age. Those measures should range from specific, up-to-date, scientific information and guidance documents to employers and workers to temporary prevention of exposure to a number of substances, where appropriate.

Justification

The future of the public health and economic challenges in the EU depends among others on the level of protection of fetuses, which depends on the level of protection of the working environment of women of childbearing potential. Specific national measures such as simple information campaigns are already taking place, for example in Sweden and are a powerful tool for empowering both employers and workers in collectively achieving public health goals.

Amendment 11

Proposal for a directive

Recital 5

(5) There is sufficient evidence of the carcinogenicity of oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine. These used engine oils are process-generated and therefore they are not subject to classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁵⁷. **The Committee** identified the possibility of significant uptake through the skin for these oils, assessed that occupational exposure occurs through the dermal route and strongly recommended the establishment of a skin notation. It is therefore appropriate to include work involving exposure to oils that have been

(5) There is sufficient evidence of the carcinogenicity of oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine. These used engine oils are process-generated and therefore they are not subject to classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁵⁷. **SCOEL** identified the possibility of significant uptake through the skin for these oils, assessed that occupational exposure occurs through the dermal route and strongly recommended the establishment of a skin notation **and ACSH agreed that used engine oils be added to the carcinogenic substances, mixtures and**

used before in internal combustion engines to lubricate and cool the moving parts within the engine in Annex I to Directive 2004/37/EC and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

processes listed in Annex I to Directive 2004/37/EC and on the possibility of significant uptake through the skin. It is therefore appropriate to include work involving exposure to oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine in Annex I to Directive 2004/37/EC and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

⁵⁷ 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).

⁵⁷ 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 12

Proposal for a directive Recital 5 a (new)

Text proposed by the Commission

Amendment

(5a) There is sufficient evidence of the carcinogenicity of diesel engine exhaust emissions arising from the combustion of diesel fuel in compression ignition engines. Diesel engine exhaust emissions are process-generated and therefore not subject to classification pursuant to Regulation (EC) No 1272/2008 of the European Parliament and of the Council^{1a}. ACSH agreed that exposure to traditional diesel engine exhaust emissions be added to the carcinogenic substances, mixtures and processes listed in Annex I to Directive 2004/37/EC and has requested further investigations of the scientific and technical aspects of newer types of engines. Diesel engine exhaust has been classified by the International Agency for Research on Cancer (IARC) as carcinogenic to humans (IARC

category 1) and IARC has specified that while the amount of particulates and chemicals are reduced in the newer types of diesel engines, it is not yet clear how the quantitative and qualitative changes will translate into altered health effects. IARC has also specified that it is common to use elemental carbon, which makes up a significant proportion of those emissions, as a marker of exposure. Given the above and the number of workers exposed, it is appropriate to include work involving exposure to diesel engine exhaust emissions in Annex I to Directive 2004/37/EC and to establish a limit value for diesel in Part A of Annex III thereto for diesel engine exhaust emissions calculated on elemental carbon. The Commission should review that limit value by using the most up-to-date scientific and socio-economic data. The entries in Annex I and Annex III to Directive 2004/37/EC should cover fumes from all types of diesel engine.

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

Amendment 13

Proposal for a directive Recital 5 b (new)

Text proposed by the Commission

Amendment

(5b) For new technology with significantly reduced diesel engine exhaust and elemental carbon mass concentrations, elemental carbon may not be an equally useful exposure indicator.

Nitrogen dioxide is likely to be a more relevant exposure indicator for new technology diesel engine exhaust. Since the age and type of engines and exhaust after-treatment systems applied vary within and between workplaces, it may be appropriate to set an occupational exposure limit value for diesel exhaust both as respirable elemental carbon and as nitrogen dioxide. The Commission should review those limit values by using the most up-to-date scientific and socio-economic data. Both of those values should be fulfilled at workplaces where diesel engines are applied. Although data allowing a direct comparison of the carcinogenic potential of the diesel engine exhaust emitted by new technology and older technology diesel engines are not available, new diesel engine technology has changed the quality and quantity of diesel emissions and the associated carcinogenic risks have been reduced but not eliminated. The significant reduction of the diesel engine exhaust mass concentration in exhaust from new technology diesel engines is expected to reduce the risk of lung cancer (per kWh). This is supported by the findings from a single set of animal studies showing reduced or negligible in vivo lung genotoxicity and oxidative DNA damage after inhalation exposure to diesel exhaust from new technology diesel engines. Determination of relevant exposure indicators for new technology diesel engine exhaust, including consideration of the particle size distribution and different particle exposure metrics (e.g. number vs mass concentration) would be valuable. In addition, it is important to compare the hazard per mass unit of diesel engine exhaust from new and older technology diesel engines. Further information is also needed on exposure levels at workplaces where new diesel engines are in use.

Amendment 14

Proposal for a directive Recital 6

Text proposed by the Commission

(6) Certain polycyclic aromatic hydrocarbons (PAHs) mixtures containing benzo[a]pyrene meet the criteria for classification as carcinogenic (category 1A or 1B) in accordance with Regulation (EC) No 1272/2008 and therefore are carcinogens as defined in Directive 2004/37/EC. **The Committee** identified the possibility of significant uptake through the skin for these mixtures. It is therefore appropriate to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

Amendment

(6) Certain polycyclic aromatic hydrocarbons (PAHs) mixtures, **particularly those** containing benzo[a]pyrene, meet the criteria for classification as carcinogenic (category 1A or 1B) in accordance with Regulation (EC) No 1272/2008 and therefore are carcinogens as defined in Directive 2004/37/EC. **SCOEL** identified the possibility of significant uptake through the skin for these mixtures **and ACSH agreed on the importance of introducing an occupational exposure limit value for PAHs and has recommended carrying out the work to evaluate the scientific aspects with the view to proposing an occupational exposure limit value in the future**. It is therefore appropriate to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake. Further investigations should also be **carried out to assess whether it is necessary to extend entry 2 in the Annex I to cover work involving burning processes and high temperature combustion processes and to set a limit value for benzo[a]pyrene in order better to protect workers from polycyclic aromatic hydrocarbons mixtures**.

Amendment 15

Proposal for a directive Recital 7

Text proposed by the Commission

(7) Trichloroethylene meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. It is possible, on the basis of available information, including scientific and technical data, to set limit values for trichloroethylene in relation to a reference period of eight hours (long-term limit value) and to a shorter reference period (15 minutes). **The Committee** identified for this carcinogen the possibility of significant uptake through the skin. It is therefore appropriate to establish long- and short-term exposure limit values for trichloroethylene in Part A of Annex III and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake. In light of evolving scientific evidence, the limit values for this substance will be kept under particularly close review.

Amendment

(7) Trichloroethylene meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. It is possible, on the basis of available information, including scientific and technical data, to set limit values for trichloroethylene in relation to a reference period of eight hours (long-term limit value) and to a shorter reference period (15 minutes). **SCOEL** identified for this carcinogen the possibility of significant uptake through the skin **and ACSH agreed on a practical limit value on the basis of the available information, including scientific and technical data.** It is therefore appropriate to establish long- and short-term exposure limit values for trichloroethylene in Part A of Annex III and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake. In light of evolving scientific evidence **and technical evolution**, the limit values for this substance will be kept under particularly close review.

Amendment 16

Proposal for a directive Recital 8

Text proposed by the Commission

(8) 4,4'-Methylenedianiline (MDA) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for 4,4'-Methylenedianiline. **The**

Amendment

(8) 4,4'-Methylenedianiline (MDA) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for 4,4'-Methylenedianiline. **SCOEL**

Committee identified for this carcinogen the possibility of significant uptake through the skin. It is therefore appropriate to establish a limit value in Part A of Annex III for 4,4'-Methylenedianiline and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

identified for this carcinogen the possibility of significant uptake through the skin **and agreed on a practical limit value, on the basis of the available information, including scientific and technical data.** It is therefore appropriate to establish a limit value in Part A of Annex III for 4,4'-Methylenedianiline and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

Amendment 17

Proposal for a directive Recital 9

Text proposed by the Commission

(9) Epichlorohydrine (1-chloro-2,3-epoxypropane) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. **The Committee** concluded that that is not possible to derive a health-based exposure limit value for this non-threshold carcinogen and has recommended avoiding occupational exposure. **The Committee** identified for epichlorohydrine the possibility of significant uptake through the skin. **The Advisory Committee on Safety and Health at Work ('ACSH')** has agreed on a practical limit value, on the basis of the available information, including scientific and technical data. It is therefore appropriate to establish a limit value for epichlorohydrine in Part A of Annex III and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

Amendment

(9) Epichlorohydrine (1-chloro-2,3-epoxypropane) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. **SCOEL** concluded that that is not possible to derive a health-based exposure limit value for this non-threshold carcinogen and has recommended avoiding occupational exposure. **SCOEL** identified for epichlorohydrine the possibility of significant uptake through the skin **and ACSH** agreed on a practical limit value, on the basis of the available information, including scientific and technical data. It is therefore appropriate to establish a limit value for epichlorohydrine in Part A of Annex III and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

Amendment 18

Proposal for a directive

Recital 10

Text proposed by the Commission

(10) Ethylene dibromide (1,2-dibromoethane, EDB) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. **The Committee** concluded that that is not possible to derive a health-based exposure limit value for this non-threshold carcinogen and has recommended avoiding occupational exposure. **The Committee** identified for ethylene dibromide the possibility of significant uptake through the skin. **The Advisory Committee on Safety and Health at Work ('ACSH')** has agreed on a practical limit value, on the basis of the available information, including scientific and technical data. It is therefore appropriate to establish a limit value for ethylene dibromide in Part A of Annex III and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

Amendment 19

Proposal for a directive

Recital 11

Text proposed by the Commission

(11) Ethylene dichloride (1,2-dichloroethane, EDC) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. It is possible, on the basis of the available information, including

Amendment

(10) Ethylene dibromide (1,2-dibromoethane, EDB) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. **SCOEL** concluded that that is not possible to derive a health-based exposure limit value for this non-threshold carcinogen and has recommended avoiding occupational exposure. **SCOEL** identified for ethylene dibromide the possibility of significant uptake through the skin **and ACSH** agreed on a practical limit value, on the basis of the available information, including scientific and technical data. It is therefore appropriate to establish a limit value for ethylene dibromide in Part A of Annex III and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

Amendment

(11) Ethylene dichloride (1,2-dichloroethane, EDC) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. It is possible, on the basis of the available information, including

scientific and technical data, to set a limit value for ethylene dichloride. **The Committee** identified for ethylene dichloride the possibility of significant uptake through the skin. It is therefore appropriate to establish a limit value for ethylene dichloride in Part A of Annex III and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

scientific and technical data, to set a limit value for ethylene dichloride. **SCOEL** identified for ethylene dichloride the possibility of significant uptake through the skin **and ACSH agreed on a practical limit value, on the basis of the available information, including scientific and technical data, while stressing the lack of robust and up-to-date scientific data, especially concerning the mode of action.** It is therefore appropriate to establish a limit value for ethylene dichloride in Part A of Annex III and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

Amendment 20

Proposal for a directive Recital 11 a (new)

Text proposed by the Commission

Amendment

(11a) The social partners' agreements, such as the Social Dialogue "Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it" (NEPSI), which provides guidance and tools in order to support, in addition to regulatory measures, the effective implementation of the employers' obligations laid down in the Directive 2004/37/EC, are valuable instruments to complement regulatory measures. The Commission should encourage the social partners to conclude such agreements. However, compliance with such agreements should not give rise to a presumption of conformity with the employers' obligations laid down in this Directive 2004/37/EC.

Amendment 21

Proposal for a directive Recital 13

Text proposed by the Commission

(13) The Commission consulted *the Advisory Committee on Safety and Health at Work, set up by Council Decision of 22 July 2003*. It also carried out a two-stage consultation of the European social partners in accordance with Article 154 of the TFEU.

Amendment

(13) The Commission consulted *ACSH and* carried out a two-stage consultation of the European social partners in accordance with Article 154 of the TFEU.

Amendment 22

Proposal for a directive Recital 15

Text proposed by the Commission

(15) The limit values established in this Directive will be kept under review in the light of the implementation of 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/EC⁵⁸ and of the opinions of the ECHA Risk Assessment Committee (RAC) and Socio-economic Analysis Committee (SEAC), in particular to take account of the interaction between limit values established in Directive 2004/37/EC and dose-response relations, actual exposure information, and, where available, DNELs (Derived No Effect Levels) derived for hazardous chemicals in accordance with that Regulation.

Amendment

(15) The limit values established in this Directive will be kept under review in the light of the implementation of 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/EC⁵⁸ and of the opinions of the ECHA Risk Assessment Committee (RAC) and Socio-economic Analysis Committee (SEAC), in particular to take account of the interaction between limit values established in Directive 2004/37/EC and dose-response relations, actual exposure information, and, where available, DNELs (Derived No Effect Levels) derived for hazardous chemicals in accordance with that Regulation *in order*

to protect workers effectively.

⁵⁸ OJ L 396, 30.12.2006, p. 1.

⁵⁸ OJ L 396, 30.12.2006, p. 1.

Amendment 23

Proposal for a directive Recital 16

Text proposed by the Commission

(16) 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 Union level, the Union 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

(16) 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 *and mutagens*, cannot be sufficiently achieved by the Member States, but can *rather* be better achieved at Union level, the Union may adopt measures, in accordance with *the precautionary principle as set out in Article 191(2) TFEU*, 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 those objectives.

Amendment 24

Proposal for a directive Article 1 – paragraph 1 – point -1 (new) Directive 2004/37/EC Article 13 a (new)

Text proposed by the Commission

Amendment

(-1) The following article is inserted:

“Article 13a

Social partners' agreements

The Commission shall encourage the social partners to conclude social

dialogue agreements providing guidance and tools to support the effective implementation of the employers' obligations laid down in this Directive. Those agreements shall be listed in Annex IVa. That list shall be regularly updated.”

Amendment 25

Proposal for a directive

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

Directive 2004/37/EC

Article 18a – paragraph 2 a (new)

Text proposed by the Commission

Amendment

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

“The Commission shall, as part of the next evaluation of the implementation of this Directive in the context of the evaluation referred to in Article 17a of Directive 89/391/EEC, also assess the possibility to extend the existing point 2 in Annex I to Directive 2004/37/EC to cover work involving burning processes and high temperature combustion processes and to set a limit value for benzo[a]pyrene in order to better protect workers from polycyclic aromatic hydrocarbons mixtures. The Commission shall propose, where appropriate, necessary amendments related to that substance.

Amendment 26

Proposal for a directive

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

Directive 2004/37/EC

Article 18a – paragraph 2 b (new)

Text proposed by the Commission

Amendment

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

“By 30 June 2019, the Commission shall, after consulting the Member States and the social partners, assess the need to modify the limit values for diesel engine exhaust emissions. The Commission shall propose, where appropriate, necessary amendments related to that process.”

Amendment 27

Proposal for a directive

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

Directive 2004/37/EC

Article 19 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

(-1c) In Article 19, the following paragraph is added:

"Member States shall communicate to the Commission the national law and practices that ensure that their competent authorities have a sufficient number of trained staff and other resources necessary to carry out their tasks related to proper and effective implementation of this Directive. That information shall be part of the implementation reports submitted by Member States every five years pursuant to Article 17a of Council Directive 89/391/EEC".

Amendment 28

Proposal for a directive

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

Directive 2004/37/EC

Annex I – point 5 b (new)

Text proposed by the Commission

Amendment

(1a) In Annex I, the following point is added:

“5b. Work involving exposure to diesel engine exhaust emissions.”

Amendment 29

Proposal for a directive

Annex I – paragraph 1

Directive 2004/37/EC

Annex III – Part A

Text proposed by the Commission

CAS No ⁽¹⁾	EC No ⁽²⁾	NAME OF AGENT	LIMIT VALUES						TRANSITIONAL MEASURES
			8 hours ⁽³⁾			Short-term ⁽⁴⁾			
			mg/m ³ ⁽⁵⁾	ppm ⁽⁶⁾	f/ml ⁽⁷⁾	mg/m ³	ppm	f/ml	
79-01-6	201-167-4	Trichloroethylene	54,7	10	–	164,1	30	–	
101-77-9	202-974-4	4,4'-Methylenedianiline	0,08	–	–	–	–	–	
106-89-8	203-439-8	Epichlorohydrine	1,9	-	-	-	-	-	
106-93-4	203-444-5	Ethylene dibromide	0,8	0,1	–	–	–	–	
107-06-2	203-458-1	Ethylene dichloride	8,2	2	–	–	–	–	

⁽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 time-weighted average (TWA).

⁽⁴⁾ Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.

⁽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.

Amendment

In Part A of Annex III to Directive 2004/37/EC, the following entries are added:

CAS No ⁽¹⁾	EC No ⁽²⁾	NAME OF AGENT	LIMIT VALUES						TRANSITIONAL MEASURES
			8 hours ⁽³⁾			Short-term ⁽⁴⁾			
			mg/m ³ ⁽⁵⁾	ppm ⁽⁶⁾	f/ml ⁽⁷⁾	mg/m ³	ppm	f/ml	
-	-	Diesel engine exhaust emissions	0,05^(7a)	-	-	-	-	-	-
-	-	Diesel engine exhaust emissions		0,5^(7b)	-	-	-	-	-
79-01-6	201-167-4	Trichloroethylene	54,7	10	-	164,1	30	-	-
101-77-9	202-974-4	4,4'-Methylenedianiline	0,08	-	-	-	-	-	-
106-89-8	203-439-8	Epichlorohydrine	1,9	-	-	-	-	-	-
106-93-4	203-444-5	Ethylene dibromide	0,8	0,1	-	-	-	-	-
107-06-2	203-458-1	Ethylene dichloride	8,2	2	-	-	-	-	-

⁽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 time-weighted average (TWA).

⁽⁴⁾ Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.

⁽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.

^(7a) *Measured as elemental carbon.*

^(7b) *Measured as nitrogen dioxide*

Amendment 30

Proposal for a directive

Annex I – paragraph 1
Directive 2004/37/EC
Annex III – Part B – row 1

Text proposed by the Commission

–	–	Polycyclic aromatic hydrocarbons mixtures containing benzo[a]pyrene, which are carcinogens within the meaning of the Directive.	skin
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Amendment

–	–	Polycyclic aromatic hydrocarbons mixtures including those containing benzo[a]pyrene which are carcinogens within the meaning of the Directive	skin
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Amendment 31

Proposal for a directive
Article 1 – paragraph 1 – point 2 a (new)
Directive 2004/37/EC
Annex IV a (new)

Text proposed by the Commission

Amendment

(2a) The following annex is added:

“Annex IVa

List of Social Dialogue Agreements providing guidance and tools in order to support the effective implementation of the employers' obligations

(1) Agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products containing it*.

*** OJ C 279, 17.11.2006.”**

EXPLANATORY STATEMENT

Preamble

On 10 January 2017, the Commission published its proposal for a directive amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Its aim is to improve and clarify the current legal environment in order to enhance the protection of workers' health by reducing occupational exposure to chemical carcinogens or mutagens in the workplace, while promoting a more level playing field for economic operators.

The rapporteur would recall that cancer is the number one cause of work-related deaths in the EU. According to a report by the Netherlands National Institute for Public Health and the Environment (RIVM)¹, between 91 500 and 150 500 new cases of cancer due to exposure to harmful substances at work were diagnosed in Europe in 2012. According to the Commission's figures², seven to twelve people die of work-related cancer every hour in the European Union.

This second proposal for revision could make it possible to improve protection for at least 4 million workers and improve clarity for employers and enforcers. Overall, the first two proposals³ for revising Directive 2004/37/EC should make it possible to prevent more than 100 000 deaths caused by occupational cancer.

Regular and continuous process of revision

While the rapporteur welcomes this proposal for revision of Directive 2004/37/EC and welcomes the decision of the European Commission to propose a third revision of that Directive, he also encourages it to continue in this direction by introducing regular and continuous reviews, in close cooperation with the Scientific Committee on Occupational Exposure Limits for Chemical Agents⁴ ('the Scientific Committee') and the Advisory Committee on Safety and Health at Work⁵ ('the Advisory Committee'). Future revisions must, in particular, make it possible to review the existing limit values, if necessary, set limit values for new substances, and extend the scope of Directive 2004/37/EC to reprotoxic agents, as supported by the European Parliament.

Scientific and Advisory Committees' recommendations

The rapporteur welcomes the consultation process conducted by the Commission in advance of each proposal for revision of Directive 2004/37/EC, as set out in its impact assessment⁶.

The recommendations made by the Scientific and Advisory Committees provide the

¹ 'Work-related cancer in the European Union: Size, impact and options for further prevention', publication on the RIVM's website, p.11

² COM(2017) 11 final

³ First proposal for revision: COM(2016) 248 final

⁴ Commission Decision 2014/113/EU of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC (OJ L 62, 4.3.2014, p. 18).

⁵ Council Decision 2003/C 218/01 setting up an Advisory Committee on Safety and Health at Work (OJ C 2018, 13.9.2003, p. 1-4).

⁶ SWD(2017) 7 final

Commission with scientific and technical data as a basis for proposing or revising occupational exposure limit values.

These recommendations, as well as other scientific information from reliable sources in the public domain, also help the European Parliament and the Council to assess the proposals put forward by the Commission and to make amendments where appropriate. It is on this basis that the rapporteur is submitting this draft report, which combines protection for workers and technical feasibility for businesses.

Diesel engine exhaust fumes

The rapporteur takes note of the reasons given by the Commission in its Impact Assessment for choosing not to include exhaust gases from diesel engines in Annex I to Directive 2004/37/EC and not to impose any corresponding exposure limit value in Annex III.

However, it is necessary to recall that, according to the Institute of Occupational Medicine¹, 3.6 million workers in the EU are potentially exposed to diesel engine exhaust above background levels and that the geometric average of the estimated exposure is 13µg/m³ (or 0.013 mg/m³). Likewise according to the Institute, 4 556 people died from cancer related to occupational exposure to diesel engine exhaust in 2010.

Therefore the rapporteur considers it necessary and urgent to act at European level in order to reduce workers' exposure to diesel engine exhaust by including in Annex I work involving exposure to such exhaust gases and setting an occupational exposure limit value in Annex III of 50µg/m³ (0.05 mg/m³) calculated on the basis of elemental carbon². This marker, which is widely endorsed by the scientific community, is in particular used by Austria and could be used by other Member States, such as Germany and the Netherlands, to determine their limit values for emissions of diesel engine exhaust.

While the Advisory Committee recommends distinguishing between old and new diesel engines, in 2012 the International Agency for Research on Cancer, which is part of the World Health Organisation, classified diesel engine exhaust as carcinogenic to humans. According to the International Agency, changes were required in fuel

‘such as marked decreases in sulphur content, changes in engine design to burn diesel fuel more efficiently and reductions in emissions through exhaust control technology’. The Agency added that ‘while the amount[s] of particulates and chemicals are reduced with these changes, it is not yet clear how the quantitative and qualitative changes may translate into altered health effects’³.

Therefore, and on the basis of Recital 14 of Directive 2004/37/EC stating that the precautionary principle should be applied to the protection of workers' health, the rapporteur recommends considering emissions from all diesel engines, without distinguishing between

¹ IOM Research Project P937/13, May 2011 – Health, socio-economic and environmental aspects of possible amendments to the EU Directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work – Diesel engine exhaust emissions.

² Exhaust from diesel engines, produced by combustion of diesel fuel, is a complex mixture of harmful substances, including elemental carbon. Elemental carbon, which constitutes a significant part of diesel engine exhaust gases, is frequently used as a marker of exposures.

³ IARC press release, 12 June 2012 - IARC: Diesel engine exhaust carcinogenic

them.

Polycyclic aromatic hydrocarbons

The rapporteur takes note of the opinion of the Advisory Committee¹ on benzo[a]pyrene, as an occupational exposure limit value for polycyclic aromatic hydrocarbons (PAHs) is important. Therefore the rapporteur proposes to table an amendment calling on the Commission to continue its work in order to propose an exposure limit value for PAHs calculated on the basis of benzo[a]pyrene.

While the establishment of a skin notation in Annex III, part B, for mixtures of PAHs containing benzo[a]pyrene represents an important step forward in the protection of workers, the rapporteur wishes to point out that other mixtures of PAHs that do not contain benzo[a]pyrene also meet the criteria for classification as carcinogenic category 1A or 1B in accordance with Regulation (EC) No 1272/2008 and can be absorbed through the skin. The rapporteur therefore proposes to extend the 'skin notation' to all mixtures of PAHs, as advocated in the Council's general approach.

Prevention and inspections

Directive 2004/37/EC permits better protection of workers against carcinogens and mutagens in the workplace. The rapporteur would also like to highlight the importance of sectoral or multisectoral agreements negotiated by the social partners. These agreements supplement the provisions of the Directive by listing best practices, enabling business to take precautions to reduce workers' exposure to one or more carcinogens or mutagens. For that reason, the rapporteur welcomes the NEPSI² agreement on 'workers' health protection through the good handling of crystalline silica and products containing it', which, complementing Directive 2004/37/EC, seeks to provide greater protection to workers in the workplace.

The rapporteur also wishes to stress the importance of inspections carried out at the workplace in order to verify that the provisions of Directive 2004/37/EC are correctly applied within companies. The rapporteur encourages the Member States to ensure that the actions of national inspection bodies are not limited to imposing penalties on companies that fail to comply with the aforementioned Directive. Identifying the causes and presenting possible solutions to the undertakings concerned would make it possible to increase the effectiveness of this Directive, in particular in small and medium-sized enterprises.

¹ CCSS, Doc. 727/13

² NEPSI is the acronym for the *European Network for Silica* formed by the Employee and Employer European sectoral associations having signed the Social Dialogue 'Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it' on 25 April 2006.

PROCEDURE – COMMITTEE RESPONSIBLE

Title	Protection of workers from the risks related to exposure to carcinogens or mutagens at work			
References	COM(2017)0011 – C8-0010/2017 – 2017/0004(COD)			
Date submitted to Parliament	12.1.2017			
Committee responsible Date announced in plenary	EMPL 19.1.2017			
Committees asked for opinions Date announced in plenary	ENVI 19.1.2017	ITRE 19.1.2017	IMCO 19.1.2017	AGRI 6.4.2017
	JURI 19.1.2017			
Not delivering opinions Date of decision	ITRE 28.2.2017	IMCO 9.2.2017	AGRI 10.10.2017	JURI 31.1.2017
Rapporteurs Date appointed	Claude Rolin 14.3.2017			
Discussed in committee	13.7.2017	28.11.2017	22.1.2018	
Date adopted	27.3.2018			
Result of final vote	+: 41 -: 0 0: 7			
Members present for the final vote	Guillaume Balas, Tiziana Beghin, Brando Benifei, Mara Bizzotto, Enrique Calvet Chambon, David Casa, Michael Detjen, Lampros Fountoulis, Elena Gentile, Arne Gericke, Marian Harkin, Czesław Hoc, Agnes Jongerius, Adam Kósa, Agnieszka Kozłowska-Rajewicz, Patrick Le Hyaric, Jeroen Lenaers, Thomas Mann, Dominique Martin, Joëlle Mélin, Miroslavs Mitrofanovs, Emilian Pavel, João Pimenta Lopes, Georgi Pirinski, Marek Plura, Sofia Ribeiro, Robert Rochefort, Claude Rolin, Siôn Simon, Yana Toom, Ulrike Trebesius, Marita Ulvskog, Renate Weber			
Substitutes present for the final vote	Georges Bach, Amjad Bashir, Heinz K. Becker, Karima Delli, Tania González Peñas, Krzysztof Hetman, Ivari Padar, Anne Sander, Sven Schulze, Jasenko Selimovic, Neoklis Sylikiotis			
Substitutes under Rule 200(2) present for the final vote	Jude Kirton-Darling, Ana Miranda, James Nicholson, Massimo Paolucci			
Date tabled	11.4.2018			

FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

41	+
ALDE	Enrique Calvet Chambon, Marian Harkin, Robert Rochefort, Jasenko Selimovic, Yana Toom, Renate Weber
EFDD	Tiziana Beghin
ENF	Mara Bizzotto
GUE/NGL	Tania González Peñas, Patrick Le Hyaric, João Pimenta Lopes, Neoklis Sylikiotis
NI	Lampros Fountoulis
PPE	Georges Bach, Heinz K. Becker, David Casa, Krzysztof Hetman, Ádám Kósa, Agnieszka Kozłowska-Rajewicz, Jeroen Lenaers, Thomas Mann, Marek Plura, Sofia Ribeiro, Claude Rolin, Anne Sander, Sven Schulze
S&D	Guillaume Balas, Brando Benifei, Michael Detjen, Elena Gentile, Agnes Jongerius, Jude Kirton-Darling, Ivari Padar, Massimo Paolucci, Emilian Pavel, Georgi Pirinski, Siôn Simon, Marita Ulvskog
VERTS/ALE	Karima Delli, Ana Miranda, Mirosłavs Mitrofanovs

0	-

7	0
ECR	Amjad Bashir, Arne Gericke, Czesław Hoc, James Nicholson, Ulrike Trebesius
ENF	Dominique Martin, Joëlle Mélin

Key to symbols:

+ : in favour

- : against

0 : abstention