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***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(2018)0171 – C8-0130/2018 – 2018/0081(COD))

Committee on Employment and Social Affairs

Rapporteur: Laura Agea

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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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(2018)0171 – C8-0130/2018 – 2018/0081(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM2018/0171),

– having regard to Article 294(2) and Articles 153(2)(b) and 153(1)(a) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0130/2018),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– 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 (A8-0000/2018),

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	*Amendment*
(1) Principle 10 of the European Pillar of Social Rights[43], proclaimed at Gothenburg on 17 November 2017, provides that every worker has the right to healthy, safe and well-adapted work environment. The right to a high level of protection of the health and safety at work, as well as to a working environment adapted to the professional needs of workers ***and which enables them to prolong their participation in the labour market*** includes ***also*** protection from carcinogens and mutagens at the workplace.	(1) ***Delivering on the principles and rights provided for by the European Pillar of Social Rights***[43] proclaimed at Gothenburg on 17 November 2017 ***is a shared political commitment and responsibility of the Union, the Member States and the social partners, in accordance with their respective competences.*** Principle 10 of the European Pillar of Social Rights provides that every worker has the right to healthy, safe and well-adapted work environment. The right to a high level of protection of the health and safety at work, as well as to a working environment adapted to the professional needs of workers ***also*** includes protection from carcinogens and mutagens at the workplace***, irrespective of the arrangements for or duration of the employment or the exposure.***
[43] European Pillar of Social Rights, November 2017, https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en	[43] European Pillar of Social Rights, November 2017, https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en

Amendment 2

Proposal for a directive
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) Articles 153, 154 and 155 TFEU establish the scope and authority of the

social partners to negotiate and enforce agreements relating to occupational health and safety and the Charter of Fundamental Rights of the European Union guarantees, in particular, the fundamental right to life (Article 2), and the right to fair and just working conditions with respect to health, safety and dignity (Article 31(1)).

Amendment 3

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(2) Directive 2004/37/EC of the European Parliament and of the Council[44] aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. A ***consistent*** level of protection from the risks related to carcinogens and mutagens is provided for in Directive 2004/37/EC by a framework of general principles to enable Member States to ensure the consistent application of the minimum requirements. Binding occupational exposure limit values established on the basis of available information, including scientific and technical data, economic feasibility, a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the workplace, are important components of the general arrangements for the protection of workers established by Directive 2004/37/EC. The minimum requirements provided for in Directive 2004/37/EC aim to protect workers at Union level. More stringent binding occupational exposure limit values can be set by Member States.	(2) Directive 2004/37/EC of the European Parliament and of the Council[44] aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. Protection from the risks related to carcinogens and mutagens is provided for in Directive 2004/37/EC by a framework of general principles to enable Member States to ensure the consistent application of the minimum requirements. Binding occupational exposure limit values ***need to be evidence-based, proportionate and measurable and should be*** established on the basis of available information, including ***up-to-date*** scientific and technical data, economic feasibility ***of implementation and compliance***, a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the workplace***. Those limit values*** are important components of the general arrangements for the protection of workers established by Directive 2004/37/EC. The minimum requirements provided for in Directive 2004/37/EC aim to protect workers at Union level. More stringent binding occupational exposure limit values can be set by Member States ***in close cooperation with the social partners***.

	Where a limit-value has been established for a carcinogen or mutagen, workers' exposure should be reduced as far as technically possible below that limit value.

Amendment 4
Proposal for a directive
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) Directive 2004/37/EC aims to cover substances or mixtures which meet the criteria for classification as a category 1A or 1B carcinogen and/or mutagen set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council as well as substances, mixtures or processes referred to in Annex I to this Directive. The substances which meet the criteria for classification as a category 1A or 1B carcinogen or mutagen set out in Annex I to Regulation (EC) No 1272/2008 are those with a harmonised classification or classified in accordance with Article 4 or 36 thereof and notified to the European Chemicals Agency (ECHA) pursuant to article 40 thereof. Those substances are listed in the public Classification and Labelling Inventory maintained by ECHA. Further cooperation with IARC should be sought so that in future substances classified by IARC as carcinogens category 1 or 2A are also deemed to meet the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008.

Amendment 5

Proposal for a directive
Recital 2 b (new)

Text proposed by the Commission	*Amendment*
	(2b) Wide differences in the Member States regarding the setting of limit values for the carcinogens and mutagens persist, which leads to differing levels in the protection of workers across the Union and also distorts competition.

Amendment 6

Proposal for a directive
Recital 3

Text proposed by the Commission	*Amendment*
(3) Occupational exposure limit values are part of risk management under Directive 2004/37/EC. Compliance with those limit values is without prejudice to other obligations of employers pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens or mutagens and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the carcinogen or mutagen by a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures aiming to reduce the level of workers' exposure. ***In that context, it is essential to take the precautionary principle into account where there are uncertainties.***	(3) Occupational exposure limit values are part of risk management under Directive 2004/37/EC***. The limit values should be revised regularly in accordance with the precautionary principle and the principle of the protection of workers, and in light of sound available scientific and technical data concerning carcinogens and mutagens. The limit values for substances listed in Annex III aim to minimise, to the extent possible, the additional risk of cancer arising from working with those substances. On that basis the additional risk is not expected to be more than 1 in 2500 of the time-weighted average of a standard working life. Consideration should also be given to improving measurement techniques, risk management measures, and other relevant factors***. Compliance with those limit values is without prejudice to other obligations of employers pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens or mutagens and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the carcinogen or mutagen

by a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures aiming to reduce the level of workers' exposure.

Amendment 7

Proposal for a directive
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) In pharmacology, hazardous drugs are drugs that are known to cause harm, because of their genotoxicity, carcinogenicity, teratogenicity, reprotoxicity and other forms of toxicity at low doses[1a]. Those drugs include cytotoxic agents, which inhibit or prevent the rapid growth and division of cancer cells, and are primarily used to treat cancer, frequently as part of a chemotherapy regime. However, the cytotoxic drugs available for current use are generally non-selective and are therefore likely to damage normal (non-tumour) cells too. Thus, many cytotoxic drugs are known to be genotoxic, carcinogenetic or mutagenic.
	[1a] IARC monographs on the evaluation of carcinogenic risks to humans, volumes 1-121 http://monographs.iarc.fr/ENG/Classification/index.php.

Amendment 8

Proposal for a directive
Recital 3 b (new)

Text proposed by the Commission	*Amendment*
	(3b) It is therefore important to protect workers exposed 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 the context of providing services relating to cleaning, transport, laundry, waste disposal of hazardous drugs or of materials contaminated by hazardous drugs, and personal care for patients treated with hazardous drugs. As a first step, the Commission has issued dedicated guidance to reduce occupational health and safety risks in the healthcare sector, including on the risks related to exposure to cytotoxic drugs, in a dedicated guide to prevention and good practices.

Amendment 9

Proposal for a directive
Recital 3 c (new)

Text proposed by the Commission	*Amendment*
	(3c) As a second step, the Commission should, taking into account the latest developments in scientific knowledge, assess the possibility of extending the scope of Directive 2004/73/EC to include hazardous drugs, including cytotoxic drugs, which are carcinogenic or mutagenic, or to propose a more appropriate legal instrument, in order to ensure the occupational safety of workers handling those drugs. Accordingly, the Commission should present, if appropriate, and after consulting the social partners, an appropriate legislative proposal. In doing so, it is imperative, however, that, in accordance with Article 168(1) TFEU, access to the best available treatments for patients should not be questioned or jeopardised.

Amendment 10

Proposal for a directive
Recital 5

Text proposed by the Commission	*Amendment*
(5) Maximum levels for the exposure of workers to some carcinogens or mutagens are established by values which, pursuant to Directive 2004/37/EC, must not be exceeded.	(5) Maximum levels for the exposure of workers to some carcinogens or mutagens are established ***in Annex III*** by values which, pursuant to Directive 2004/37/EC, must not be exceeded. ***Practical recommendations for the health surveillance of workers may be laid down in Annex II to Directive 2004/37/EC but are not made mandatory.***

Amendment 11

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(6) This Directive strengthens the protection of workers' health and safety at their workplace. New limit values should be set out in Directive 2004/37/EC in the light of available information, including new scientific and technical data and evidence-based best practices, techniques and protocols for exposure level measurement at the workplace. That information should, if possible, include data on residual risks to the health of workers, recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL) and opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH). Information related to residual risk, made publicly available at Union level***, is valuable for any future work to limit risks from occupational exposure to***	(6) This Directive strengthens the protection of workers' health and safety at their workplace. ***The Commission should review this Directive on a regular basis and make legislative proposals if appropriate***. New limit values should be set out in Directive 2004/37/EC in the light of available information, including new scientific and technical data and evidence-based best practices, techniques and protocols for exposure level measurement at the workplace. That information should, if possible, include data on residual risks to the health of workers, recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL) and opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH) ***and monographs of the International Agency for Research on***

carcinogens and mutagens. Transparency ***of such information*** should be ***further encouraged***.	***Cancer (IARC[1a])***. Information related to residual risk ***is valuable for any future work to limit risks from occupational exposure to carcinogens and mutagens***, ***and should be*** made publicly available at Union level. Transparency ***is a tool for prevention in this context and*** should be ***ensured***. ***This Directive follows the specific recommendations of SCOEL and the ACSH, the importance of which has been highlighted in previous amendments to Directive 2004/37/EC.***
	[1a] The International Agency for Research on Cancer was set up in 1965 by the United Nations World Health Organization.

Amendment 12

Proposal for a directive
Recital 7

Text proposed by the Commission	*Amendment*
(7) It is also necessary to consider other absorption pathways than inhalation of all carcinogens and mutagens, including the possibility of uptake through the skin, in order to ensure the best possible level of protection. Amendments to Annex III to Directive 2004/37/EC provided for in this Directive constitute a further step in a longer term process initiated to update Directive 2004/37/EC.	(7) It is also necessary***, in light of scientific data,*** to consider other absorption pathways than inhalation of all carcinogens and mutagens, in view of ***observations regarding*** the possibility of uptake through the skin - ***concretely through skin notation***, in order to ensure the best possible level of protection. Amendments to Annex III to Directive 2004/37/EC provided for in this Directive constitute a further step in a longer term process initiated to update Directive 2004/37/EC.

Amendment 13

Proposal for a directive
Recital 10 a (new)

Text proposed by the Commission	*Amendment*
	(10a) The 2018-2019 campaign the European Agency for Safety and Health at Work (EU-OSHA) on Healthy Workplaces: Manage Dangerous Substances is a first step. EU-OSHA needs to work closely with Member States and reinforce the exchange of good practices, to provide tailored information and examples of good practices to workers in contact with certain substances, in particular cytotoxic, highlighting policy developments and the legislative framework already in place.

Amendment 14

Proposal for a directive
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) Cadmium (Cd) is a naturally occurring element to which humans are exposed from cigarettes, food and industrial sources. Kidneys, and possibly bones, are the most sensitive target of systemic Cd toxicity following occupational exposure (critical target organs). Cd is a cumulative toxicant; the systemic manifestations associated with chronic exposure are related to the body burden of the element (liver and kidney content). Biological markers such as Cd-U (cadmium excretion in urine) allow the assessment of body burden, and the integration of all sources of Cd exposure, including by means of contaminated food and smoking. The use of such biomarkers in most epidemiological studies conducted in occupational settings has allowed researchers to document reliable dose-effect-response relationhips. A biological limit-value would thus protect workers against systemic toxicity of Cd, mainly renal and bone effects[1a]. Biological

monitoring can thus contribute to the protection of workers at the workplace by but only as a means of complementing the monitoring of the concentration for cadmium (and its inorganic compounds) in the air within the breathing zone of a worker.

1a

https://circabc.europa.eu/sd/a/13cad802-1f3c-40c0-bce4-6838cf5fc4ff/OPIN-336%20Cadmium%20and%20its%20inorganic%20compounds.pd

Amendment 15

Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(12) With regard to cadmium, a limit value of 0,001 mg/m^3 may be difficult to be complied with in some sectors in the short term. A transitional period of seven years should therefore be introduced during which the limit value 0,004 mg/m^3 should apply.	(12) With regard to cadmium, a limit value of 0,001 mg/m^3 may be difficult to be complied with in some sectors in the short term. A transitional period of seven years should therefore be introduced during which the limit value 0,004 mg/m^3 should apply***. In Member States which implement biological monitoring, the biological limit value should be 2µg Cd/g creatinine and the 8-hour TWA limit value should be 0,004 mg/m3 (respirable fraction). The introduction of that limit-value does not require a transitional period. The Commission should draw up guidelines for the practical implementation of such biological monitoring.***

Amendment 16

Proposal for a directive
Recital 17

Text proposed by the Commission	*Amendment*
(17) Formaldehyde meets the criteria for	(17) Formaldehyde meets the criteria for

classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is a local acting genotoxic carcinogen. ***It is possible,*** on the basis of the available information, including scientific and technical data, to set a long and short term limit value for that carcinogen. Formaldehyde is also a contact allergen to the skin (skin sensitiser). It is therefore appropriate to establish a limit value for formaldehyde and to assign a notation for skin sensitisation. In addition, upon request of the Commission, ECHA is also gathering existing information to assess the potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses[48].

48 https://echa.europa.eu/documents/10162/13641/formaldehyde_cion_reqst_axvdossier_en.pdf/11d4a99a-7210-839a-921d-1a9a4129e93e

classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is a local acting genotoxic carcinogen. ***There is sufficient evidence in humans for the carcinogenicity of formaldehyde. Formaldehyde causes cancer of the nasopharynx and leukaemia[47a].*** On the basis of the available information, including scientific and technical data, ***it is possible*** to set a long and short term limit value for that carcinogen. Formaldehyde is also a contact allergen to the skin (skin sensitiser). It is therefore appropriate to establish a limit value for formaldehyde and to assign a notation for skin sensitisation. In addition, upon request of the Commission, ECHA is also gathering existing information to assess the potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses[48].

[47a] https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100F-29.pdf

48 https://echa.europa.eu/documents/10162/13641/formaldehyde_cion_reqst_axvdossier_en.pdf/11d4a99a-7210-839a-921d-1a9a4129e93e

Amendment 17

Proposal for a directive
Recitals 17 a (new)

Text proposed by the Commission	*Amendment*
	(17a) Formaldehyde fixatives are routinely used in Union healthcare centres for the standardised fixation of tissue sample given their convenience in handling, high degree of accuracy and

extreme adaptability, which have, to date, not been reached by any other group of fixative. As a result, a pathologist's diagnosis of a variety of diseases, including cancer, is based on the recognition of microscopic traces in tissue fixed in a formaldehyde fixative. The concentrations of formaldehyde used in healthcare are minimal in comparison with those used in industry and, while healthcare centres in the Union should take all appropriate measures to keep formaldehyde exposure among their staff within safe limits, the healthcare sector is likely to have no difficulty in respecting the limit-value set in this Directive.

Amendment 18

Proposal for a directive
Recitals 17 b (new)

Text proposed by the Commission	*Amendment*
	(17b) In some Member States Formaldehyde is routinely used for the purposes of embalming deceased persons as part of their cultural or religious practices. The funeral sector is likely to find a limit value of 0,3ppm to be difficult to comply with without significant short-term effects on capacity. A transitional period of three years should therefore be introduced for the sector during which the limit-value of 0,5ppm should apply.

Amendment 19

Proposal for a directive
Recital 18

Text proposed by the Commission	*Amendment*
(18) 4,4'-Methylene-bis(2-chloroaniline)(MOCA) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC)	(18) 4,4'-Methylene-bis(2-chloroaniline)(MOCA) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC)

No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. The possibility of a significant uptake through the skin was identified for MOCA. It is therefore appropriate to establish a limit value for MOCA and to assign to it a skin notation. In addition, it was identified as a substance of very high concern (SVHC) pursuant to Article 57(a) of Regulation EC No 1907/2006 and included in Annex XIV to that Regulation, requiring authorisation before it can be placed on market or used. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for MOCA.

No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. ***Its carcinogenicity, together with its manifest genotoxic characteristics, has made it possible to classify that substance as carcinogenic to humans.*** The possibility of a significant uptake through the skin was identified for MOCA. It is therefore appropriate to establish a limit value for MOCA and to assign to it a skin notation. In addition, it was identified as a substance of very high concern (SVHC) pursuant to Article 57(a) of Regulation EC No 1907/2006 and included in Annex XIV to that Regulation, requiring authorisation before it can be placed on market or used. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for MOCA.

Amendment 20

Proposal for a directive
Recital 21

Text proposed by the Commission	*Amendment*
(21) The limit values set out in this Directive are to be kept under review to ensure consistency with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[50] , in particular to take account of the interaction between limit values set out under Directive 2004/37/EC and derived no effect levels for hazardous chemicals under that Regulation in order to protect workers effectively.	(21) The limit values set out in this Directive are to be kept under ***permanent scrutiny and regular*** review to ensure consistency with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[50] , in particular to take account of the interaction between limit values set out under Directive 2004/37/EC and derived no effect levels for hazardous chemicals under that Regulation in order to protect workers effectively.

[50] 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

[50] 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).

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 21

Proposal for a directive
Recital 23

Text proposed by the Commission	*Amendment*
(23) In implementing this Directive Member States should ***avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development*** of small and medium-sized undertakings. Member States are therefore invited to assess the impact of their transposition act on SMEs in order to make sure that SMEs are not disproportionately affected, with specific attention for micro-enterprises and for administrative burden, and to publish the results of such assessments.	(23) In implementing this Directive Member States should take into account that ***SMEs and microenterprises, which represent a large majority of enterprises in the Union, have limited financial, technical and human resources.*** Member States are therefore invited to assess the impact of their transposition act on SMEs in order to make sure that SMEs are not disproportionately affected, with specific attention for micro-enterprises and for administrative burden, and to publish the results of such assessments, ***while maintaining levels of equal protection for all workers, compliance of SMEs and microenterprises should be facilitated. Against that background, specific measures such as incentives and digital tools could help SMEs and microenterprises better to comply with the obligations laid down in Directive 2004/37/EC and move towards the elimination of carcinogenic or mutagenic risks. The social partners should exchange best practices in that regard.***

Amendment 22

Proposal for a directive
Article 1 – paragraph -1 (new)
Directive 2004/37/EC
Article 14 – paragraph 1

Present text	*Amendment*
	In Article 14, paragraph 1 is replaced by the following:
1. The Member States shall establish, in accordance with national law 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. ***The doctor or authority responsible for the health surveillance of workers may indicate that health surveillance must continue after the end of exposure for as long as they consider it to be necessary to safeguard the health of the worker concerned.***	"1. 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. ***Such health surveillance may include biological monitoring for substance exposure, where appropriate. Article 10 of Council Directive 98/24/EC shall apply."***

Amendment 23

Proposal for a directive
Article 1 – paragraph -1 a (new)
Directive 2004/37/EC
Article 14 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	In Article 14, after paragraph 1, the following paragraph is inserted:
	"1a. Where Member States choose to implement biological monitoring, the limit values set out in Part B of Annex III shall apply."

Amendment 24

Proposal for a directive
Article 1 – paragraph -1 b (new)
Directive 2004/37/EC
Article 18 b (new)

Text proposed by the Commission	*Amendment*
	The following article is inserted after Article 18a:

	"Article 18b
	By the fourth quarter of 2019, the Commission shall, on the basis of scientific data and appropriate consultation, assess the possibility to amending the scope of this Directive7 to include a list of hazardous drugs, including cytotoxic drugs, which are carcinogenic or mutagenic, or to propose a more appropriate legal instrument in order to ensure occupational safety of workers handling such drugs. On that basis, the Commission shall present, if appropriate, and after consulting management and labour, a legislative proposal."

Amendment 25

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

Text proposed by the Commission	*Amendment*
	In Annex II, the following point is inserted:
	"2a. Where biological monitoring is carried out, such monitoring should take into consideration biological values recommended by SCOEL as well as other available guidance and information at Union and national level."

Amendment 26

Proposal for a directive
Annex
Directive 2004/37/EC
Annex III – Part A – table – row 4

Text proposed by the Commission

Formaldehyde	0,37	0,3	0,7	0,6	Der
			38		mal

					sensitisation (9)	

Amendment

Formaldehyde	0,37	0,3	0,738	0,6	Dermal sensitisation (9)	***Limit value 0,5ppm for the funeral and embalming sectors until xx yyyy 202z [3 years]***

Amendment 27

Proposal for a directive
Annex
Directive 2004/37/EC
Annex III – point B

Text proposed by the Commission	*Amendment*
	Ppoint B of Annex III is replaced by the following:
B. OTHER DIRECTLY RELATED PROVISIONS	**"**B. OTHER DIRECTLY RELATED PROVISIONS
p.m.	***In Member States which implement bio-monitoring for cadmium exposure as set out in Article 14(1) and point 2a of Annex II, such monitoring shall include the measurement of the urine level of cadmium (CdU) using absorption spectrometry or a method giving equivalent results. The biological limit value shall be 2µg Cd/g creatinine and the 8-hour TWA limit-value shall be 0,004 mg/m^3 (respirable fraction). In that case, no transitional period shall be required. "***

EXPLANATORY STATEMENT

Cancer is the main work-related health problem in the EU-28, causing almost as much damage to workers' life and health as the next two combined (musculoskeletal disorders and circulatory diseases). However, the adverse impact of high exposure to carcinogens and mutagens at the workplace is a good deal more far-reaching. In addition to cancers, it can also cause a wide range of other health problems, such as respiratory diseases and neurological disorders.

The European Commission has already taken steps to address these issues by adopting two legislative proposals to update Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work in May 2016 and January 2017.

This third legislative proposal examines five additional carcinogenic chemicals: cadmium, beryllium and their inorganic compounds, arsenic acid, formaldehyde and MOCA (4,4' methylene-bis).

The rapporteur welcomes this third legislative proposal and the limit values that it contains, which, according to estimates, should improve the long-term working conditions of more than a million EU workers, preventing more than 22 000 cases of work-related ill-health (cancers and non-cancers).

The rapporteur has adopted an approach intended to ensure maximum protection for workers without imposing excessive costs on small and medium-sized enterprises. Account can be taken of both these aspects by permitting a transition period for the completion of the necessary changes on the organisational side and more particularly the technical side. Given the weak economic recovery in several European countries, which has persisted for some years, it is considered desirable to grant concessions to businesses which may be divided into two categories:

- active: by paying grants to businesses that comply, including by encouraging planning of EU-subsidised projects, without infringing any European requirements;

- passive: by granting tax relief to businesses that comply.

Finally, the rapporteur wished to tackle in a direct and ambitious manner the problem of workers exposed to carcinogens and mutagens derived from the preparation, administration or disposal of hazardous drugs, including cytotoxic drugs. For that reason she has opted to include in Annex I to the Directive work involving exposure to carcinogenic or mutagenic substances arising from the preparation, administration or disposal of hazardous drugs (including cytotoxic drugs) classified by the IARC as carcinogenic (IARC group 1), probably carcinogenic (IARC group 2A) or possibly carcinogenic (IARC group 2B).

15.10.2018

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(2018)0171 – C8-0130/2018 – 2018/0081(COD))

Rapporteur for opinion: Jiří Maštálka

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, seeks to improve workers' health protection and safety by reducing occupational exposure to five chemical agents. The proposal is supported by an impact assessment.

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 affects th economy at large too, reducing labour supply and productivity and 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.

The social partners, workers 'and employers' organisations confirmed that the five following carcinogens selected for the third amendment of the Directive 2004/37/EC a on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, are of high relevance for the protection of workers and thus encouraged the Commission to continue the preparatory work for the establishment of occupational exposure limit values ("OELs") for:

1. Cadmium and its inorganic compounds under the scope of the Directive
2. Beryllium and inorganic beryllium compounds under the scope of the Directive
3. Arsenic acid and its salts, as well as inorganic arsenic compounds under the scope of the Directive
4. Formaldehyde
5. 4,4'-Methylene-bis(2-chloroaniline) ("MOCA")

The Directive sets a number of general minimum requirements to eliminate or reduce

exposure for all carcinogens and mutagens falling under its scope. Employers must identify and assess risks to workers associated with exposure to specific carcinogens and mutagens at the workplace, and must prevent exposure where risks occur

The present initiative for a modification of Directive 2004/37 is in line with European Pillar of Social Rights. It implements its 10th principle "Healthy, safe and well-adapted work environment" directly contributing to a high level of protection of workers' health and safety. Modernising the legal framework by setting updated OELs on exposure to carcinogens and mutagens was also identified as the key priority in the occupational safety and health (OSH) field by the Commission Communication "Safer and Healthier Work for All" of January 2017.

According to the estimates the adoption of the proposal would imply that in the longer term over 1 000 000 EU workers would benefit from improved prevention and protection in relation to occupational exposure to carcinogens and mutagens substances, that ca be at the origin of different types of cancers and it would prevent 22 000 cases of ill-health.

Your rapporteur supports strongly the aforementioned proposal, with some amendments, which aim mainly at stressing the need for regular overview and update of any potential carcinogens or mutagens, which shall b e- based on scientific date - included in the list. Your rapporteur also believes that all substances, which can increase the risk of occupational cancers, shall be covered by the EU legislation

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	*Amendment*
(1) ***Principle 10*** of the European Pillar of Social Rights[43], proclaimed at Gothenburg on 17 November 2017, provides that every worker has the right to healthy, safe and well-adapted work environment. The right to a high level of protection of the health and safety at work, as well as to a working environment adapted to the professional needs of workers and which enables them to prolong their participation in the labour market includes also protection from	(1) ***One of the top social policy objectives of the European Union is to avoid social fragmentation and social dumping in Europe through renewed convergence towards better living and working conditions in the Union. It is also one of the objectives*** of the European Pillar of Social Rights, proclaimed at Gothenburg on 17 November 2017, ***of which Principle 10*** provides that every worker has the right to healthy, safe and well-adapted work environment. The right

carcinogens and mutagens at the workplace.	to a high level of protection of the health and safety at work, as well as to a working environment adapted to the professional needs of workers and which enables them to prolong their participation in the labour market includes also protection from carcinogens and mutagens at the workplace.
[43] European Pillar of Social Rights, November 2017, https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en	[43] European Pillar of Social Rights, November 2017, https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en

Amendment 2

Proposal for a directive
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) The Charter of Fundamental Rights of the European Union guarantees, in particular, the fundamental right to life in Article 2, and the right to fair and just working conditions with respect to health, safety and dignity under paragraph 1 of Article 31.

Amendment 3

Proposal for a directive
Recital 1 b (new)

Text proposed by the Commission	*Amendment*
	(1b) Articles 153, 154 and 155 TFEU establish the scope and authority of the social partners to negotiate and enforce agreements relating to occupational health and safety.

Amendment 4

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(2) Directive 2004/37/EC of the European Parliament and of the Council[44] ***aims to protect*** workers ***against risks to their*** health and safety from exposure to carcinogens or mutagens at the workplace. A consistent level of protection from the risks related to carcinogens and mutagens is provided for in Directive 2004/37/EC by a framework of general principles to enable Member States to ensure the consistent application of the minimum requirements. Binding occupational exposure limit values established on the basis of available information, including scientific and technical data, economic feasibility, a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the workplace, ***are*** important components ***of the general arrangements for the protection of workers*** established by Directive 2004/37/EC. The minimum requirements provided for in ***Directive 2004/37/EC*** aim to protect workers at Union level. More stringent binding occupational exposure limit values can be set by Member States.	(2) ***The aim of the amendments to*** Directive 2004/37/EC of the European Parliament and of the Council[44] ***provided for in this Directive is to introduce more effective health measures and improve and strengthen the protection of*** workers´ health and safety from exposure to carcinogens or mutagens at the workplace ***in accordance with the precautionary principle***. A consistent level of protection from the risks related to carcinogens and mutagens is provided for in Directive 2004/37/EC by a framework of general principles to enable Member States to ensure the consistent application of the minimum requirements. Binding occupational exposure limit values established on the basis of ***currently*** available information, including scientific and technical data, economic feasibility, a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the workplace***. It is essential that those*** important components established by Directive 2004/37/EC ***are the subject of constant overview, regular revision and updates in light of the most recent scientific studies and data***. The minimum requirements provided for in ***Directive 2004/37/EC*** aim to protect workers at Union level. More stringent binding occupational exposure limit values can be set by Member States.
[44] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the	[44] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the

risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).	risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

Amendment 5

Proposal for a directive
Recital 3

Text proposed by the Commission	*Amendment*
(3) Occupational exposure limit values are part of risk management under Directive 2004/37/EC. Compliance with those limit values is without prejudice to other obligations of employers pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens or mutagens and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the carcinogen or mutagen by a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures aiming to reduce the level of workers' exposure. In that context, it is essential to take the precautionary principle into account where there are uncertainties.	(3) Occupational exposure limit values are part of risk management under Directive 2004/37/EC***. The limit values should be revised and updated regularly in accordance with the precautionary principle, the principle of the protection of workers and in light of the latest available scientific studies and technical data concerning carcinogens and mutagens. Consideration should also be given to improving measurement techniques, risk management measures, and other relevant factors***. Compliance with those limit values is without prejudice to other obligations of employers pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens or mutagens and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the carcinogen or mutagen by a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures aiming to reduce the level of workers' exposure. In that context, it is essential to take the precautionary principle into account where there are uncertainties.

Amendment 6

Proposal for a directive
Recital 4

Text proposed by the Commission	*Amendment*
(4) For most carcinogens and mutagens, it is not scientifically possible to identify levels below which exposure would not lead to adverse effects. While setting the limit values at the workplace in relation to carcinogens and mutagens pursuant to Directive 2004/37/EC does not completely eliminate risks to the health and safety of workers arising from exposure at work (residual risk), it nonetheless contributes to a significant reduction of risks arising from such exposure in the stepwise and goal-setting approach pursuant to Directive 2004/37/EC. ***For other carcinogens and mutagens, it may be scientifically possible to identify levels below which exposure is not expected to lead to adverse effects.***	(4) For most carcinogens and mutagens, it is not scientifically possible to identify levels below which exposure would not lead to adverse effects. While setting the limit values at the workplace in relation to carcinogens and mutagens pursuant to Directive 2004/37/EC does not completely eliminate risks to the health and safety of workers arising from exposure at work (residual risk), it nonetheless contributes to a significant reduction of risks arising from such exposure in the stepwise and goal-setting approach pursuant to Directive 2004/37/EC.

Amendment 7

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(6) This Directive strengthens the protection of workers health and safety at their workplace. New limit values should be set out in Directive 2004/37/EC in the light of available information, including new scientific and technical data and evidence-based best practices, techniques and protocols for exposure level measurement at the workplace. That information should, if possible, include	(6) This Directive strengthens the ***level of*** protection of workers ***to improve their*** health and safety at their workplace. New limit values should be set out in Directive 2004/37/EC in the light of available information, including new scientific and technical data and evidence-based best practices, techniques and protocols for exposure level measurement at the workplace. That information should, if

data on residual risks to the health of workers, recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL) and opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH). Information related to residual risk, made publicly available at Union level, is valuable for any future work to limit risks from occupational exposure to carcinogens and mutagens. Transparency ***of such*** information should be further encouraged.

possible, include data on residual risks to the health of workers, recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL) and opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH). Information related to residual risk, made publicly available at Union level, is valuable for any future work to limit risks from occupational exposure to carcinogens and mutagens. ***Measures to guarantee t***ransparency ***as well as prevention and*** information ***campaigns at Union level*** should be further encouraged.

Amendment 8

Proposal for a directive
Recital 7

Text proposed by the Commission	*Amendment*
(7) It is also necessary to consider other absorption pathways than inhalation of all carcinogens and mutagens, including the possibility of uptake through the skin, in order to ensure the best possible level of protection. Amendments to Annex III to Directive 2004/37/EC provided for in this Directive constitute a further step in a longer term process initiated to update Directive 2004/37/EC.	(7) It is also necessary***, in the light of scientific data,*** to consider other absorption pathways than inhalation of all carcinogens and mutagens, in view of ***observations regarding*** the possibility of uptake through the skin - ***concretely through skin notation, greater sensitivity of the skin or respiratory tracts and respiratory and skin sensitisation*** - in order to ensure the best possible level of protection. Amendments to Annex III to Directive 2004/37/EC provided for in this Directive constitute a further step in a longer term process initiated to update Directive 2004/37/EC.

Amendment 9

Proposal for a directive
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) It is anticipated that setting EU limits for exposure to carcinogens and mutagens at the workplace will contribute effectively to the prevention of significant health problems and cancer and, in addition, improve the quality of life and well-being of workers and those in their immediate circle, prolonging working life, leading to increased productivity and competitiveness in the EU and helping to ensure a level playing field for businesses in the EU.

Amendment 10

Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(12) With regard to cadmium, a limit value of 0,001 mg/m3 may be difficult to be complied with in some sectors in the short term. A transitional period of ***seven*** years should therefore be introduced during which the limit value 0,004 mg/m3 should apply.	(12) With regard to cadmium, a limit value of 0,001 mg/m3 may be difficult to be complied with in some sectors in the short term. A transitional period of ***five*** years should therefore be introduced during which the limit value 0,004 mg/m3 should apply.

Amendment 11

Proposal for a directive
Recital 14

Text proposed by the Commission	*Amendment*
(14) With regard to beryllium, a limit value of 0,0002 mg/m3 may be difficult to be complied with in some sectors in the short term. A transitional period of ***five*** years should therefore be introduced during which the limit value of 0,0006	(14) With regard to beryllium, a limit value of 0,0002 mg/m3 may be difficult to be complied with in some sectors in the short term. A transitional period of ***four*** years should therefore be introduced during which the limit value of 0,0006

mg/m3should apply.	mg/m3should apply.

Amendment 12

Proposal for a directive
Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(18a) There is sufficient evidence of the carcinogenicity of diesel engine exhaust emissions. Diesel engine exhaust has been classified by the International Agency for Research on Cancer as carcinogenic (Group 1) to humans in 2012, based on sufficient evidence that exposure is associated with an increased risk for lung cancer. New diesel engine technology has changed the quality and quantity of diesel emissions and the associated cancer risks have been reduced but not eliminated. Due to the long transition time to switch from old to new diesel technology, a concomitant exposure to exhaust emissions from old and new diesel engines is expected to occur at work for many years to come. Diesel engine exhaust emissions are process-generated and consequently they are not subject to classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council. On the basis of available information, including scientific and technical data, a limit value for diesel engine exhaust emissions should be established. It is therefore appropriate to include work involving exposure to diesel engine exhaust emissions in Annex I and to establish a limit value for diesel engine exhaust emissions in Annex III to Directive 2004/37/EC. The entries in Annex I and Annex III to that Directive should cover fumes from all types of diesel engines and are thus irrespective of whether the exhaust emissions are from old or new diesel engines. Elemental carbon is known as the relevant marker of

exposure to diesel engine exhaust emissions.

Amendment 13

Proposal for a directive
Recital 18 b (new)

Text proposed by the Commission	*Amendment*
	(18b) Certain polycyclic aromatic hydrocarbons (PAHs) mixtures meet the criteria for classification as carcinogenic in accordance with Regulation (EC) No 1272/2008 and therefore are carcinogens as defined in Directive 2004/37/EC. Exposure to such mixtures may occur during work involving burning processes, such as from combustion engine exhaust, and high temperature combustion processes, among others. The existing entry 2 in Annex I to that Directive should therefore be extended to also cover other occupational exposure situations during which workers are exposed to these substances and their mixtures. In addition, on the basis of available information, including scientific and technical data, it is appropriate to establish a limit value for PAHs mixtures with benzo[a]pyrene as indicator in part A.

Amendment 14

Proposal for a directive
Recital 20 a (new)

Text proposed by the Commission	*Amendment*
	(20a) Similarly, a long-term assessment of the added value of implementing this directive indicates that it will improve working conditions for over 1 000 000 workers in the EU and prevent more than 22 000 occupational illnesses.

Amendment 15

Proposal for a directive
Recital 21

Text proposed by the Commission	*Amendment*
(21) The limit values set out in this Directive are to be kept under review to ensure consistency with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[50], in particular to take account of the interaction between limit values set out under Directive 2004/37/EC and derived no effect levels for hazardous chemicals under that Regulation in order to protect workers effectively.	(21) The limit values set out in this Directive are to be ***verified and*** kept under ***on-going scrutiny and regular*** review to ensure consistency with Regulation(EC) No 1907/2006 of the European Parliament and of the Council[50], in particular to take account of the interaction between limit values set out under Directive 2004/37/EC and derived no effect levels for hazardous chemicals under that Regulation in order to protect workers effectively.
[50] 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).	[50] 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 16

Proposal for a directive
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) Compliance with the transitional periods laid down in this Directive allows

for the adoption of appropriate measures to anticipate any new developments and plan investments so as to avoid any adverse effects for businesses or workers. In the case of SMEs, for example, transitional periods regarding certain substances will help them address any specific technical challenges and plan investments sufficiently well in advance.

Amendment 17

Proposal for a directive
Annex – paragraph -1 (new)
Directive 2004/37/EC
Annex I – point 5 a (new)

Text proposed by the Commission	*Amendment*
	In Annex I of Directive 2004/37/EC the following point is added:
	"5a. Work involving exposure to diesel engine exhaust emissions"

Amendment 18

Proposal for a directive
Annex – paragraph -1 a (new)
Directive 2004/37/EC
Annex I – point 5 b (new)

Text proposed by the Commission	*Amendment*
	In Annex I of Directive 2004/37/EC, the following point is added:
	"5b. Work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch and work involving exposure to carcinogenic polycyclic aromatic hydrocarbons, in particular in any burning process, such as from combustion engine exhaust, and high temperature combustion processes, among others."

Amendment 19

Proposal for a directive
Annex – paragraph 1
Directive 2004/37/EC
Annex III – point A – table – column "Transitional measures" – row 1

Text proposed by the Commission	*Amendment*
Limit value 0,004 mg/m3 until xx yyyy 202z [*7* years]	Limit value 0,004 mg/m3 until xx yyyy 202z [***5*** years]

Amendment 20

Proposal for a directive
Annex – paragraph 1
Directive 2004/37/EC
Annex III – point A – table – column "Transitional measures" – row 2

Text proposed by the Commission	*Amendment*
Limit value 0,0006 mg/m3 until xx yyyy 202z [***5*** years]	Limit value 0,0006 mg/m3 until xx yyyy 202z [***4*** years]

Amendment 21

Proposal for a directive
Annex – paragraph 1
Directive 2004/37/EC
Annex III – point A – table – column "Name of agent" – row 5 a (new)

Text proposed by the Commission	*Amendment*
	Polycyclic aromatic hydrocarbons mixtures containing benzo[a]pyrene which are carcinogens within the meaning of the Directive

Amendment 22

Proposal for a directive
Annex – paragraph 1
Directive 2004/37/EC
Annex III – point A – table – column "Limit values" – column "8 hours" – column "mg/m^3" – row 5 a (new)

Text proposed by the Commission	*Amendment*
	0,00007[10a]
	[10a] benzo[a]pyrene as a marker of total PAH concentration

Justification

This level is applied in Germany and is currently the best practice in the EU.

Amendment 23

Proposal for a directive
Annex – paragraph 1
Directive 2004/37/EC
Annex III – point A – table – column "Name of agent" – row 5 b (new)

Text proposed by the Commission	*Amendment*
	Diesel engine exhaust emissions

Amendment 24

Proposal for a directive
Annex – paragraph 1
Directive 2004/37/EC
Annex III – point A – table – column "Limit values" – column "8 hours" – column "mg/m^3" – row 5 b (new)

Text proposed by the Commission	*Amendment*
	0,000011[10b]
	[10b] measured as elemental carbon

Justification

This corresponds the 4 deaths per 100 000, for 40 years of occupational exposure, as calculated by Dutch Expert Committee on Occupational Safety. Workers should not be exposed to diesel engine exhaust at levels higher than the background levels.

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	Protection of workers from the risks related to exposure to carcinogens or mutagens at work
References	COM(2018)0171 – C8-0130/2018 – 2018/0081(COD)
Committee responsible Date announced in plenary	EMPL 16.4.2018
Opinion by Date announced in plenary	JURI 16.4.2018
Rapporteur Date appointed	Jiří Maštálka 23.4.2018
Discussed in committee	3.9.2018
Date adopted	10.10.2018
Result of final vote	+: 22 –: 0 0: 0
Members present for the final vote	Max Andersson, Joëlle Bergeron, Jean-Marie Cavada, Kostas Chrysogonos, Mady Delvaux, Rosa Estaràs Ferragut, Enrico Gasbarra, Lidia Joanna Geringer de Oedenberg, Heidi Hautala, Sylvia-Yvonne Kaufmann, Gilles Lebreton, António Marinho e Pinto, József Szájer, Axel Voss, Francis Zammit Dimech, Tadeusz Zwiefka
Substitutes present for the final vote	Geoffroy Didier, Pascal Durand, Angel Dzhambazki, Angelika Niebler, Virginie Rozière, Tiemo Wölken

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

22	+
ALDE	Jean-Marie Cavada, António Marinho e Pinto
ECR	Angel Dzhambazki
EFDD	Joëlle Bergeron
ENF	Gilles Lebreton
GUE/NGL	Kostas Chrysogonos
PPE	Geoffroy Didier, Rosa Estaràs Ferragut, Angelika Niebler, József Szájer, Axel Voss, Francis Zammit Dimech, Tadeusz Zwiefka
S&D	Mady Delvaux, Enrico Gasbarra, Lidia Joanna Geringer de Oedenberg, Sylvia-Yvonne Kaufmann, Virginie Rozière, Tiemo Wölken
VERTS/ALE	Max Andersson, Pascal Durand, Heidi Hautala

0	-

0	0

Key to symbols:
+ : in favour
- : against
0 : abstention

PROCEDURE – COMMITTEE RESPONSIBLE

Title	Protection of workers from the risks related to exposure to carcinogens or mutagens at work
References	COM(2018)0171 – C8-0130/2018 – 2018/0081(COD)
Date submitted to Parliament	5.4.2018
Committee responsible Date announced in plenary	EMPL 16.4.2018
Committees asked for opinions Date announced in plenary	ENVI JURI 16.4.2018 16.4.2018
Rapporteurs Date appointed	Laura Agea 16.5.2018
Discussed in committee	11.7.2018 9.10.2018
Date adopted	20.11.2018
Result of final vote	+: 43 –: 0 0: 2
Members present for the final vote	Laura Agea, Guillaume Balas, Brando Benifei, Mara Bizzotto, David Casa, Ole Christensen, Michael Detjen, Martina Dlabajová, Lampros Fountoulis, Marian Harkin, Czesław Hoc, Danuta Jazłowiecka, Agnes Jongerius, Rina Ronja Kari, Ádám Kósa, Agnieszka Kozłowska-Rajewicz, Jean Lambert, Jérôme Lavrilleux, Patrick Le Hyaric, Jeroen Lenaers, Verónica Lope Fontagné, Thomas Mann, Dominique Martin, Anthea McIntyre, Joëlle Mélin, Miroslavs Mitrofanovs, Elisabeth Morin-Chartier, Emilian Pavel, Georgi Pirinski, Dennis Radtke, Terry Reintke, Robert Rochefort, Claude Rolin, Siôn Simon, Romana Tomc, Marita Ulvskog
Substitutes present for the final vote	Georges Bach, Rosa D'Amato, Tania González Peñas, Paloma López Bermejo, Edouard Martin, Alex Mayer, Sven Schulze, Helga Stevens, Flavio Zanonato

FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

43	+
ALDE	Martina Dlabajová, Marian Harkin, Robert Rochefort
ECR	Czesław Hoc, Anthea McIntyre, Helga Stevens
EFDD	Laura Agea, Rosa D'Amato
ENF	Mara Bizzotto
GUE	Tania González Peñas, Rina Ronja Kari, Patrick Le Hyaric, Paloma López Bermejo
NI	Lampros Fountoulis
PPE	Georges Bach, David Casa, Danuta Jazłowiecka, Agnieszka Kozłowska-Rajewicz, Ádám Kósa, Jérôme Lavrilleux, Jeroen Lenaers, Verónica Lope Fontagné, Thomas Mann, Elisabeth Morin-Chartier, Dennis Radtke, Claude Rolin, Sven Schulze, Romana Tomc
S&D	Guillaume Balas, Brando Benifei, Ole Christensen, Michael Detjen, Agnes Jongerius, Edouard Martin, Alex Mayer, Emilian Pavel, Georgi Pirinski, Peter Simon, Marita Ulvskog, Flavio Zanonato
VERTS/ALE	Jean Lambert, Miroslavs Mitrofanovs, Terry Reintke

0	-

2	0
ENF	Dominique Martin, Joëlle Mélin

Key to symbols:
+ : in favour
- : against
0 : abstention