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Subject:	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

Delegations will find attached the text of the above Directive, on which the Council (EPSCO) reached a general approach at its session on 15-16 June 2017.

2017/0004 (COD)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure[3],

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1 OJ C , , p.
2 OJ C , , p.
3 Position of the European Parliament of … [(OJ …)/(not yet published in the Official Journal)] and decision of the Council of ….

Whereas:

(1) Directive 2004/37/EC aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. A consistent level of protection from the risks related to carcinogens or mutagens is provided for in that Directive by a framework of general principles to enable Member States to ensure the application of the minimum requirements consistently. Binding occupational exposure limit values established on the basis of available information, including scientific and technical data, are important components of the general arrangements for the protection of workers established by that Directive.

(1a) Occupational exposure limit values are part of the risk management measures under Directive 2004/37/EC. Compliance with those limit values is without prejudice to other employers´ obligations pursuant to that Directive, in particular the reduction of use of carcinogens or mutagens at the workplace, prevention or reduction of workers´ exposure to carcinogens or mutagens and measures which should be implemented to that effect. Those measures should include, in so 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 worker´s health, the use of a closed system or other measures aimed at the reduction of the level of workers´ exposure to a level as low as possible.

(1ab) The minimum requirements contained in Directive 2004/37/EC aim to protect workers at Union level. More stringent binding occupational exposure limits and other protective measures can be set by Member States.

(1b) For most carcinogens or mutagens it is not scientifically possible to set exposure levels below which exposure would not lead to adverse effects. While setting the limit values at the workplace in relation to carcinogens or mutagens pursuant to this Directive does not eliminate risks to workers´ health and safety arising from exposure thereto at work (residual risk), it nonetheless contributes to significant reduction of risks arising from such exposure in the stepwise and goal setting approach pursuant to Directive 2004/37/EC. For other carcinogens or mutagens, it is scientifically possible to identify exposure levels below which exposure is not expected to lead to adverse effects.

(1c) Maximum levels of workers exposure to some carcinogens or mutagens are established by limit values which pursuant to Directive 2004/37/EC must not be exceeded. Those limit values should be revised and limit values set for additional carcinogens and mutagens.

(1d) The limit values set in this Directive should be revised when necessary in the light of available information, including scientific and technical data. That information should, if possible, include data on residual risks to health of the workers and opinions of the Advisory Committee on Safety and Health at Work. Information relating to residual risk, made publicly available at the EU level, is valuable for the future work to limit risks from occupational exposure to carcinogens or mutagens, including for future revisions of the limit values set in this Directive.

(1e)(new) For some non-threshold carcinogens it is not possible to derive a health-based exposure limit value, however it is still possible to set a limit value for these substances based on available information, including scientific and technical data.

(2) In order to ensure the best possible level of protection, for some carcinogens and mutagens it is necessary to consider other absorption pathways, including the possibility of absorption through the skin.

(3) The Scientific Committee on Occupational Exposure Limits ('the Committee'), set up by Commission Decision 2014/113/EU[4], 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/EC[5] and Directive 2004/37/EC. Other sources of scientific information, adequately robust and in the public domain, including those referred to in the Commission Staff Working Document – Impact Assessment *Accompanying the document* 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 (SWD(2017)7 final), were also considered.

(4) In accordance with the recommendations of the Committee, where available, limit values for the inhalation route of exposure 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) are established. Skin notations are also set in accordance with the recommendations of the Committee.

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

(5) There is sufficient evidence of the carcinogenicity of mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine. Those 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 Council[6]. 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. A range of best practices can be used to limit dermal exposure, including, among others, the use of personal protection equipment such as gloves, and the removal and cleaning of contaminated clothing. Full compliance with these, and newly emerging best practices, could help reduce this exposure. 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.

(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. 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 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.

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[6] 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).

(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. The Committee identified trichloroethylene as a genotoxic carcinogen. 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 time-weighted average (long-term exposure limit values), and to a shorter reference period fifteen minutes time-weighted average (short-term exposure limit values). 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.

(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. The Committee concluded that it is not possible to derive a health-based exposure limit value for this non-threshold carcinogen. On the basis of available information, including scientific and technical data, it is still possible, however, to set a limit value for 4,4'-Methylenedianiline. The 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.

(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 it is not possible to derive a health-based exposure limit value for this non-threshold carcinogen. 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.

(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 it is not possible to derive a health-based exposure limit value for this non-threshold carcinogen. 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.

(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. The Committee concluded that it is not possible to derive a health-based exposure limit value for this non-threshold carcinogen. On the basis of available information, including scientific and technical data, it is still possible, however, 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.

(12) In order to ensure internal coherence, it is appropriate to transfer the column "Notation" set out in Part A of Annex III to Directive 2004/37/EC and the notations set out in that column to Part B of Annex III to Directive 2004/37/EC.

(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.

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

(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/EC[7] 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.

(16) Since the objectives of this Directive, which are to improve 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 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.

(17) Given that this Directive concerns the workers' health at their workplace, the deadline for transposition should be two years.

(18) Directive 2004/37/EC should therefore be amended accordingly.

[7] OJ L 396, 30.12.2006, p. 1.

(19) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents[8], Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2004/37/EC is amended as follows:

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

'Work involving dermal exposure to mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine'.

(2) Annex III is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than two years after the date of entry into force of this Directive. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

[8] OJ C 369, 17.12.2011, p.14

2. Member States shall communicate to the Commission the text of the provisions of national law that they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX

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

CAS No ([9])	**EC No** ([10])	**NAME OF AGENT**	**LIMIT VALUES**						**TRANSITIONAL MEASURES**
			8 hours ([11])			**Short-term** ([12])			
			mg/m^3 ([13])	**ppm** ([14])	**f/ml**([15])	**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	_	_	_	_	_	

[9] CAS No: Chemical Abstract Service Registry Number.

[10] 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.

[11] Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).

[12] 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.

[13] mg/m^3 = milligrams per cubic metre of air at 20°C and 101,3 kPa (760 mm mercury pressure).

[14] ppm = parts per million by volume in air (ml/m^3).

[15] f/ml = fibres per millilitre.

CAS No ([9])	EC No ([10])	NAME OF AGENT	LIMIT VALUES						TRANSITIONAL MEASURES
			8 hours ([11])			Short-term ([12])			
			mg/m³ ([13])	ppm ([14])	f/ml([15])	mg/m³	ppm	f/ml	
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	–	–	–	–	

The Column "Notation" in Part A of Annex III to Directive 2004/37/EC and the notations set out in that column are transferred to Part B of Annex III to Directive 2004/37/EC.

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

CAS No ([16])	**EC No** ([17])	**NAME OF AGENT**	**Notation**([18])
–	–	Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[*a*]pyrene, which are carcinogens within the meaning of the Directive	skin
	–	Mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine	skin
71-43-2	200-753-7	Benzene	skin
79-01-6	201-167-4	Trichloroethylene	skin
101-77-9	202-974-4	4,4'-Methylenedianiline	skin
106-89-8	203-439-8	Epichlorohydrine	skin
106-93-4	203-444-5	Ethylene dibromide	skin
107-06-2	203-458-1	Ethylene dichloride	skin

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16 CAS No: Chemical Abstract Service Registry Number.

17 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.

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