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NOTE

From:	General Secretariat of the Council
To:	Delegations
No. Cion doc.:	ST 5251/17 + ADD 1
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 provisional agreement on the above proposal, subject to the agreement by the Committee of Permanent Representatives, with a view to reaching a first-reading agreement with the European Parliament.

The changes in relation to the Commission proposal are marked *in **bold italics*** and deletions ▌ **.**

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of

amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

▌

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,

[1] OJ C , , p.
[2] OJ C , , p.

Whereas:

(1) Directive 2004/37/EC ***of the European Parliament and of the Council*** 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 that Directive 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 that Directive. In that context, it is essential to take the precautionary principle into account where there are uncertainties. The minimum requirements provided for in that Directive aim to protect workers at Union level. More stringent binding occupational exposure limit values or other protective measures can be set by Member States***.

(2) 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 workers' 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, thereby fostering innovation.

(3) 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.

(4) 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.

(5) The limit values set out in this Directive should be revised when necessary in the light of available information, including 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 health of the workers and opinions of the Scientific Committee on Occupational Exposure Limits (SCOEL)[5] and of the Advisory Committee on Safety and Health at Work (ACSH)[5a]. 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 and mutagens, including for future revisions of the limit values set in this Directive.

(6) No later than in the first quarter of 2019, the Commission should, taking into account the latest developments in scientific knowledge, assess the option of amending the scope of this Directive to include reprotoxic substances. On that basis, the Commission should present, if appropriate, and after consulting management and labour, a legislative proposal.

(7) ***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.***

(8) ***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 ***uptake*** through the skin ▌.

(9) ***SCOEL*** 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, ***which are*** to be set at Union level pursuant to Council Directive 98/24/EC ▌ and Directive 2004/37/EC***. ACSH is a tripartite body assisting the Commission in the preparation, implementation and evaluation of the activities in the fields of health and safety. In particular, the ACSH adopts tripartite opinions on initiatives to set occupational limit values at Union level on the basis of the available information, including scientific and technical data as well as data on social aspects and the economic feasibility of those initiatives***. 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***.

(10) SCOEL's work and transparency of its work is vital with regard to a responsible policy process. If SCOEL's work is to be reorganised, dedicated resources should be guaranteed and specific expertise on epidemiology, toxicology, occupational medicine and occupational hygiene should not be lost.

(11) Amendments to Annex I and Annex III to Directive 2004/37/EC provided for in this Directive are a further step in a longer term process to update that Directive. As the next step in that process, the Commission has submitted a proposal for the establishment of limit values and skin notations with regard to five additional carcinogens. Moreover, the Commission stated in its Communication of 10 January 2017, 'Safer and Healthier Work for All — Modernisation of the EU Occupational Safety and Health Legislation and Policy', that there should be further amendments to Directive 2004/37/EC. The Commission should, on an ongoing basis, continue its work on updates of Annex I and Annex III to Directive 2004/37/EC, in line with Article 16 thereof and established practice, and amend them when necessary in the light of available information, including progressively acquired scientific and technical data such as residual risk data. That work should result, where appropriate, in proposals for future revisions of the limit values set out in Directive 2004/37/EC and in this Directive, as well as proposals for additional substances, mixtures and processes in Annex I and additional limit values in Annex III.

(12) It is important to protect workers exposed to carcinogenic or mutagenic substances resulting from the preparation, administration or disposal of hazardous drugs, including cytostatic/cytotoxic drugs, and work involving exposure to carcinogenic or mutagenic substances in cleaning, transport, laundry and waste disposal of hazardous drugs or materials contaminated by hazardous drugs and in personal care for patients under treatment of hazardous drugs. As a first step, the Commission has issued guidance to reduce occupational health and safety risks in the healthcare sector, including on the risk related to the exposure to cytostatic/cytotoxic drugs, in a dedicated guide to prevention and good practice. This guidance is without prejudice to possible further legislative or other initiatives.

(13) In accordance with the recommendations of ***SCOEL and ACSH***, where available, ▌ 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. ***Skin notations are also set in accordance with the recommendations of SCOEL and ACSH. Additional sources of scientific information that are adequately robust and in the public domain should also be considered.***

(14) The principle of prevention at the workplace should be promoted also in relation to carcinogens and mutagens having effects on future generations such as the negative impacts on both men and women reproductive capacity and the foetal development. Member States should therefore share best practices in this field.

(15) 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 ***mineral*** 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[1]. ***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 processes listed in Annex I to Directive 2004/37/EC and on the possibility of significant uptake through the skin. 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 ***mineral*** 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 ▌ Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

[1] 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).

(16) ***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[1]. 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 Annex III thereto for diesel engine exhaust emissions calculated on elemental carbon. The entries in Annex I and Annex III to Directive 2004/37/EC should cover fumes from all types of diesel engine.***

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1 ***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).***

(17) With regard to diesel engine exhaust emissions, a limit value of 0,05 mg/m3 measured as elemental carbon may, in some sectors, be difficult to achieve in the short term. In addition to the transposition period, a two year transitional period should therefore be introduced for all sectors before the limit value should apply. For the specific sectors of underground mining and tunnel construction a five year transitional period, in addition to the transposition period, should be introduced before the limit value should apply.

(18) 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. 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 a view to proposing an occupational exposure limit value in the future***. It is therefore appropriate to set out a skin notation in ▌ 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 set a limit value for polycyclic aromatic hydrocarbons mixtures in order better to protect workers from these mixtures.***

(19) 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. ***SCOEL 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 (long-term limit value) and to a shorter reference period ***fifteen minutes time-weighted average (short-term exposure limit value). 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 ▌ a skin notation in ▌ Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake. In light of evolving scientific evidence ***and technical progress***, the limit values for this substance will be kept under particularly close review.

(20) 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. ***SCOEL concluded that*** it is ***not possible to derive a health-based exposure limit for this non-threshold carcinogen.*** On the basis of available information, including scientific and technical data, ***it is possible, however,*** to set a limit value for 4,4'-Methylenedianiline. ***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 a limit value ▌ for 4,4'-Methylenedianiline and ▌ a skin notation in ▌ Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

(21) 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*** 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 ▌ and ▌ a skin notation in ▌ Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

(22) 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*** 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 ▌ and ▌ a skin notation in ▌ Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

(23) 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. ***SCOEL concluded that it is not possible to derive a health-based exposure limit value for this non-threshold carcinogen.*** On the basis of the available information, including scientific and technical data, ***it is still possible, however,*** 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 ▌ and ▌ a skin notation in ▌ Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

▌

(24) The social partners' agreements, such as the "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. While respecting their autonomy, 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. A regularly updated list of such agreements should be published on the EU-OSHA website.

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

(26) 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.

(27) 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[1] 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***.

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

(28) 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 be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in ***Article 5*** of the Treaty on European Union. In accordance with the principle of proportionality, as set out in ***that Article*** of the TEU, this Directive does not go beyond what is necessary in order to achieve those objectives.

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

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

(31) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents ▌, 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) The following article is inserted

"Article 13a
Social partners' agreements

Social Partners agreements possibly concluded in the field of this Directive shall be listed on the EU-OSHA website. That list shall be regularly updated."

(2) 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***"***.

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

"5b. Work involving exposure to diesel engine exhaust emissions."

(4) 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.

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

To Annex III to Directive 2004/37/EC, the following entries are added:

"

Name of agent	**EC No** ([1])	**CAS No** ([2])	**Limit values**						**Notation** ([8])	**Transitional measures**
			8 hours ([3])			**Short-term** ([4])				
			mg/m³ ([5])	**ppm** ([6])	**f/ml** ([7])	**mg/m³**	**ppm**	**f/ml**		
Benzene	200-753-7	71-43-2							skin	
Trichloroethylene	201-167-4	79-01-6	54,7	10	_	164,1	30	_	skin	
4,4'-Methylenedianiline	202-974-4	101-77-9	0,08	_	_	_	_	_	skin	
Epichlorohydrine	203-439-8	106-89-8	1,9	_	_	_	_	_	skin	
Ethylene dibromide	203-444-5	106-93-4	0,8	0,1	_	_	_	_	skin	
Ethylene dichloride	203-458-1	107-06-2	8,2	2	_	_	_	_	skin	

Name of agent	EC No ([1])	CAS No ([2])	Limit values						Notation ([8])	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****							***The limit value shall apply 2 years after the end of the transposition period. For underground mining and tunnel construction the limit value shall apply 5 years after the end of the transposition period.***
Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are carcinogens within the meaning of the Directive									***skin***	

Name of agent	EC No ([1])	CAS No ([2])	Limit values						Notation ([8])	Transitional measures
			8 hours ([3])			Short-term ([4])				
			mg/m [3] ([5])	ppm ([6])	f/ml ([7])	mg/ m [3]	ppm	f/ml		
Mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine									***skin***	

([1]) 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.

([2]) CAS No: Chemical Abstract Service Registry Number.

([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/m^3 = 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/m^3).

([7]) f/ml = fibres per millilitre.

([8]) Substantial contribution to the total body burden via dermal exposure possible.

* ***Measured as elemental carbon."***