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THE EUROPEAN PARLIAMENT

THE COUNCIL

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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: 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

DIRECTIVE (EU) 2017/...
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

(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 point (b) of Article 153(2), in conjunction with point (a) of Article 153(1) 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 Committee¹,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure²,

¹ OJ C 487, 28.12.2016, p. 113.

² Position of the European Parliament of 25 October 2017 (not yet published in the Official Journal) and decision of the Council of

Whereas:

- (1) Directive 2004/37/EC of the European Parliament and of the Council¹ 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 socio-economic 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. The minimum requirements provided for in that Directive aim to protect workers at Union level. More stringent binding occupational exposure limit values can be set by Member States.

¹ 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).

- (2) 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 on employers pursuant to that Directive, in particular 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, in so far as 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) 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 this Directive 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 is scientifically possible to identify levels below which exposure is not expected to lead to adverse effects.
- (4) 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. Those limit values should be revised and limit values should be set for additional carcinogens and mutagens.

- (5) On the basis of the implementation reports submitted by Member States every five years pursuant to Article 17a of Council Directive 89/391/EEC¹, the Commission is to evaluate the implementation of the occupational safety and health legal framework, including Directive 2004/37/EC, and, where necessary, to inform the relevant institutions and the Advisory Committee on Safety and Health at Work (ACSH) of initiatives to improve the operation of that framework, including, where necessary, appropriate legislative proposals.
- (6) The limit values set out in this Directive should be revised where necessary 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 and opinions of the Scientific Committee on Occupational Exposure Limits (SCOEL) and of the ACSH. Information related to residual risk, made publicly available at Union level, is valuable for future work to limit risks from occupational exposure to carcinogens and mutagens, including by revising the limit values set out in this Directive. Transparency of such information should be further encouraged.

¹ Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

- (7) Due to the lack of consistent data on substance exposure, it is necessary to protect exposed workers or workers who are at risk of exposure by enforcing relevant health surveillance. It should therefore be possible for appropriate health surveillance of workers, for whom the results of the assessment referred to in Article 3(2) of Directive 2004/37/EC reveal a risk to health or safety, to continue after the end of exposure following an indication by the doctor or authority responsible for the health surveillance. Such surveillance should be carried out in accordance with the national law or practice of the Member States. Article 14 of Directive 2004/37/EC should therefore be amended to ensure such health surveillance for all workers concerned.
- (8) Appropriate and consistent data collection by Member States from employers is necessary to ensure the safety and proper care of workers. The Member States are to provide the Commission with information for the purposes of its reports on the implementation of Directive 2004/37/EC. The Commission already supports best practices with regard to data collection in Member States and should propose, as appropriate, further improvements to the data collection required pursuant to Directive 2004/37/EC.
- (9) Directive 2004/37/EC requires employers to use existing appropriate procedures for the measurement of exposure levels to carcinogens and mutagens at the workplace, in consideration of the fact that SCOEL notes in its recommendations the feasibility of monitoring exposure at any recommended occupational exposure limit value and biological limit values. The improvement of the equivalence of methodologies for measurement of the concentration in the air of carcinogens and mutagens in relation to limit values set out in Directive 2004/37/EC is important in order to reinforce the obligations provided for therein and ensure a similar and a high-level of health protection for workers and a level playing field across the Union.

- (10) Amendments to Annex III to Directive 2004/37/EC provided for in this Directive are the first steps in a longer-term process to update it. 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 seven 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 are to be further amendments to Directive 2004/37/EC. The Commission should, on an ongoing basis, continue its work on updates of Annex III to Directive 2004/37/EC, in line with Article 16 thereof and established practice. 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 limit values.
- (11) It is necessary to consider other absorption pathways of all carcinogens and mutagens, including the possibility of uptake through the skin, in order to ensure the best possible level of protection.
- (12) SCOEL assists the Commission, in particular in identifying, evaluating and analysing in detail 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/EC¹ and Directive 2004/37/EC. As regards the chemical agents o-toluidine and 2-nitropropane, in 2016, there were no SCOEL recommendations available and therefore other sources of scientific information, adequately robust and in the public domain, have been considered.

¹ 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, 5.5.1998, p. 11).

- (13) The limit values for vinyl chloride monomer and hardwood dusts set out in Annex III to Directive 2004/37/EC should be revised in the light of more recent scientific and technical data. The distinction between hardwood and softwood dust should be further assessed as regards the limit value set out in that Annex, as recommended by SCOEL and the International Agency for Research on Cancer.
- (14) Mixed exposure to more than one species of wood is very common, which complicates the exposure assessment of different species of wood. Exposure to dust from softwood and hardwood is common among workers in the Union and may cause respiratory symptoms and diseases, with the most serious health effect being the risk of nasal and sinonasal cancers. It is therefore appropriate to establish that if hardwood dusts are mixed with other wood dusts, the limit value set out in the Annex for hardwood dust should apply to all wood dusts present in that mixture.
- (15) Certain chromium (VI) compounds meet the criteria for classification as carcinogenic (category 1A or 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council¹ and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for chromium (VI) compounds that are carcinogens within the meaning of Directive 2004/37/EC. It is therefore appropriate to establish a limit value for those chromium (VI) compounds.

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).

- (16) With regard to chromium VI, a limit value of 0,005 mg/m³ may not be appropriate and, in some sectors, may be difficult to achieve in the short term. A transitional period should therefore be introduced during which the limit value of 0,010 mg/m³ should apply. For the specific situation where the work activity concerns work involving welding or plasma cutting processes or similar such processes that generate fume, a limit value of 0,025 mg/m³ should apply during that transitional period, after which the generally applicable limit value of 0,005 mg/m³ should apply.
- (17) Certain refractory ceramic fibres meet the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for refractory ceramic fibres that are carcinogens within the meaning of Directive 2004/37/EC. It is therefore appropriate to establish a limit value for those refractory ceramic fibres.
- (18) There is sufficient evidence of the carcinogenicity of respirable crystalline silica dust. On the basis of available information, including scientific and technical data, a limit value for respirable crystalline silica dust should be established. Respirable crystalline silica dust generated by a work process is not subject to classification in accordance with Regulation (EC) No 1272/2008. It is therefore appropriate to include work involving exposure to respirable crystalline silica dust generated by a work process in Annex I to Directive 2004/37/EC and to establish a limit value for respirable crystalline silica dust ('respirable fraction') that should be subject to review, in particular in light of the number of workers exposed.

- (19) Guides and examples of good practices produced by the Commission, the Member States or the social partners, or other initiatives, such as the Social Dialogue ‘Agreement on Workers’ Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it’ (NEPSi) are valuable and necessary instruments to complement regulatory measures and in particular to support the effective implementation of limit values, and should therefore be given serious consideration. They include measures to prevent or minimise exposure such as water-assisted suppression to prevent dust from becoming airborne in the case of respirable crystalline silica.
- (20) Ethylene oxide 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 possible, on the basis of the available information, including scientific and technical data, to set a limit value for that carcinogen. SCOEL has identified, for ethylene oxide, the possibility of significant uptake through the skin. It is therefore appropriate to establish a limit value for ethylene oxide and to assign to it a notation indicating the possibility of significant uptake through the skin.
- (21) 1,2-Epoxypropane 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 possible, on the basis of the available information, including scientific and technical data, to identify an exposure level below which exposure to that carcinogen is not expected to lead to adverse effects. It is therefore appropriate to establish a limit value for 1,2-epoxypropane.

- (22) Acrylamide 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 possible, on the basis of the available information, including scientific and technical data, to set a limit value for that carcinogen. SCOEL has identified, for acrylamide, the possibility of significant uptake through the skin. It is therefore appropriate to establish a limit value for acrylamide and to assign to it a notation indicating the possibility of significant uptake through the skin.
- (23) 2-Nitropropane 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 possible, on the basis of the available information, including scientific and technical data, to set a limit value for that carcinogen. It is therefore appropriate to establish a limit value for 2-nitropropane.
- (24) o-Toluidine 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 possible, on the basis of the available information, including scientific and technical data, to set a limit value for that carcinogen. It is therefore appropriate to establish a limit value for o-toluidine and to assign to it a notation indicating the possibility of significant uptake through the skin.

- (25) 1,3-Butadiene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for that carcinogen. It is therefore appropriate to establish a limit value for 1,3-butadiene.
- (26) Hydrazine 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 possible, on the basis of available information, including scientific and technical data, to set a limit value for that carcinogen. SCOEL has identified, for hydrazine, the possibility of significant uptake through the skin. It is therefore appropriate to establish a limit value for hydrazine and to assign to it a notation indicating the possibility of significant uptake through the skin.
- (27) Bromoethylene 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 possible, on the basis of available information, including scientific and technical data, to set a limit value for that carcinogen. It is therefore appropriate to establish a limit value for bromoethylene.

- (28) This Directive strengthens the protection of workers' health and safety at their workplace. Member States should transpose this Directive into their national law. They should ensure that competent authorities have a sufficient number of trained staff and other resources necessary to carry out their tasks related to the proper and effective implementation of this Directive, in accordance with national law or practice. Application of this Directive by employers would be facilitated if they had guidance, where relevant, to identify better ways to achieve compliance with this Directive.
- (29) The Commission has consulted the ACSH. It has also carried out a two-stage consultation of management and labour at Union level in accordance with Article 154 of the Treaty on the Functioning of the European Union.
- (30) In its opinions, the ACSH has referred to a review period for binding occupational exposure limit values for several substances, such as respirable crystalline silica dust, acrylamide and 1,3-butadiene. The Commission is to take into account those opinions when prioritising substances for scientific evaluation.
- (31) In its opinion on refractory ceramic fibres, the ACSH agreed that a binding occupational exposure limit value is necessary but failed to reach a common position on a threshold. The Commission should therefore encourage the ACSH to submit an up-to-date opinion on refractory ceramic fibres with a view to reaching a common position on the limit value for that substance, without prejudice to the working methods of the ACSH and the autonomy of the social partners.

- (32) At the workplace, men and women are often exposed to a cocktail of substances, which can increase health risks and cause adverse effects, inter alia on their reproductive systems, including impaired fertility or infertility, and have a negative impact on foetal development and lactation. Substances which are toxic to reproduction are subject to Union measures providing for minimum requirements of the protection of health and safety of workers, in particular those provided for in Directive 98/24/EC and Council Directive 92/85/EEC¹. Those reprotoxic substances that are also carcinogens or mutagens are subject to the provisions of Directive 2004/37/EC. The Commission should evaluate the need to extend the application of the measures for the protection of health and safety of workers provided for in Directive 2004/37/EC to all reprotoxic substances.
- (33) This Directive respects the fundamental rights and observes the principles enshrined in the Charter of Fundamental Rights of the European Union, in particular the right to life and the right to fair and just working conditions provided for, respectively, in Articles 2 and 31 thereof.

¹ Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1).

- (34) The limit values set out 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 Council¹, 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.
- (35) 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 rather, by reason of its scale and effects, 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, this Directive does not go beyond what is necessary in order to achieve those objectives.
- (36) Given that this Directive concerns the protection of the health and safety of workers at their workplace, it should be transposed within two years of the date of its entry into force.
- (37) Directive 2004/37/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

¹ 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).

Article 1

Directive 2004/37/EC is amended as follows:

(1) In Article 6, the following paragraph is added:

‘The Member States shall take into account the information under points (a) to (g) of the first paragraph of this Article in their reports submitted to the Commission under Article 17a of Directive 89/391/EEC.’.

(2) Article 14 is amended as follows:

(a) 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.’;

(b) paragraph 8 is replaced by the following:

‘8. All cases of cancer identified in accordance with national law or practice as resulting from occupational exposure to a carcinogen or mutagen shall be notified to the competent authority.’

The Member States shall take into account the information under this paragraph in their reports submitted to the Commission under Article 17a of Directive 89/391/EEC.’.

- (3) The following Article is inserted:

*‘Article 18a
Evaluation*

The Commission shall, as part of the next evaluation of the implementation of this Directive in the context of the evaluation referred to in Article 17a of Directive 89/391/EEC, also evaluate the need to modify the limit value for respirable crystalline silica dust. The Commission shall propose, where appropriate, necessary amendments and modifications related to that substance.

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

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

‘6. Work involving exposure to respirable crystalline silica dust generated by a work process’.

- (5) Annex III is replaced by the text in 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 by ... [two years after the date of entry into force of this Directive]. They shall immediately inform the Commission of the text of those measures.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the measures of national law which 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 ...,

For the European Parliament
The President

For the Council
The President

ANNEX

Annex III: Limit values and other directly related provisions (Article 16)

A. LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

Name of agent	EC No ⁽¹⁾	CAS No ⁽²⁾	Limit values ⁽³⁾			Notation	Transitional measures
			mg/m ³ ⁽⁴⁾	ppm ⁽⁵⁾	f/ml ⁽⁶⁾		
Hardwood dusts	–	–	2 ⁽⁷⁾	–	–	–	Limit value 3 mg/m ³ until ... [5 years after the date of entry into force of this amending Directive]
Chromium (VI) compounds which are carcinogens within the meaning of point (i) of Article 2(a) (as chromium)	–	–	0,005	–	–	–	Limit value 0,010 mg/m ³ until ... [7 years after the date of entry into force of this amending Directive] Limit value: 0,025 mg/m ³ for welding or plasma cutting processes or similar work processes that generate fume until ... [7 years after the date of entry into force of this amending Directive]

Name of agent	EC No ⁽¹⁾	CAS No ⁽²⁾	Limit values ⁽³⁾			Notation	Transitional measures
			mg/m ³ ⁽⁴⁾	ppm ⁽⁵⁾	f/ml ⁽⁶⁾		
Refractory ceramic fibres which are carcinogens within the meaning of point (i) of Article 2(a)	–	–	–	–	0,3	–	
Respirable crystalline silica dust	–	–	0,1 ⁽⁸⁾	–	–	–	
Benzene	200-753-7	71-43-2	3,25	1	–	Skin ⁽⁹⁾	
Vinyl chloride monomer	200-831-0	75-01-4	2,6	1	–	–	
Ethylene oxide	200-849-9	75-21-8	1,8	1	–	skin ⁽⁹⁾	
1,2-Epoxypropane	200-879-2	75-56-9	2,4	1	–	–	
Acrylamide	201-173-7	79-06-1	0,1	–	–	skin ⁽⁹⁾	
2-Nitropropane	201-209-1	79-46-9	18	5	–	–	
o-Toluidine	202-429-0	95-53-4	0,5	0,1	–	skin ⁽⁹⁾	

Name of agent	EC No ⁽¹⁾	CAS No ⁽²⁾	Limit values ⁽³⁾			Notation	Transitional measures
			mg/m ³ ⁽⁴⁾	ppm ⁽⁵⁾	f/ml ⁽⁶⁾		
1,3-Butadiene	203-450-8	106-99-0	2,2	1	–	–	
Hydrazine	206-114-9	302-01-2	0,013	0,01	–	skin ⁽⁹⁾	
Bromoethylene	209-800-6	593-60-2	4,4	1	–	–	

- (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.
- (4) mg/m³ = milligrams per cubic metre of air at 20°C and 101,3 kPa (760 mm mercury pressure).
- (5) ppm = parts per million by volume in air (ml/m³).
- (6) f/ml = fibres per millilitre.
- (7) Inhalable fraction: if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture.
- (8) Respirable fraction.
- (9) Substantial contribution to the total body burden via dermal exposure possible.

B. OTHER DIRECTLY RELATED PROVISIONS

p.m.
