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REPORT

From: General Secretariat of the Council
To: Permanent Representatives Committee (Part 1)

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COM(2016- 248 final + ADD 1 - ADD 3

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
- *Analysis of the final compromise text with a view to agreement*

Delegations will find in the Annex the provisional agreement on the compromise text on the above proposal, with a view to reaching a first-reading agreement with the European Parliament.

The changes in relation to the Commission proposal are marked as follows:

- General Approach in **bold**; EP amendments *in bold italics* and compromise text in **bold underlined**.

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union ('TFEU'), 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,²

Having regard to the opinion of the Committee of the Regions,³

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Directive 2004/37/EC of the European Parliament and of the Council ¹aims 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, *economic feasibility, a thorough assessment of the socio-economic impact and availability of exposure measurement protocols and techniques in the workplace*, are important components of the general arrangements for the protection of workers established by that Directive. *The minimum requirements contained in that Directive aim to protect workers at Union level. More stringent binding occupational exposure limits can be set by Member States.*

(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, use of a closed system or other measures aimed at the reduction of the level of workers' exposure. *In this context, it is essential to take the precautionary principle into account where there are uncertainties.*

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).

- (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 completely 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 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) On the basis of the implementation reports submitted by MS every five years pursuant to Article 17a of Directive 89/391/EEC, the Commission is to evaluate implementation of the OSH legal framework, including Directive 2004/37/EC, and if necessary, to inform the relevant institutions and ACSH of any initiatives to improve the operation of that framework, including where necessary appropriate legislative proposals.**
- (2) The limit values set in this Directive should be revised when necessary in the light of available information, including *new scientific and technical data and evidence-based best practices, techniques and protocols for exposure levels measurement in 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) and of the Advisory Committee on Safety and Health at Work*. Information relating to residual risk, made publically 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. Transparency of such information should be further encouraged.

(2b) 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 [...] Therefore, it should 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 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.

(2c) 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 between Member States and should propose, as appropriate, further improvements to the data collection required pursuant to Directive 2004/37/EC.

(2d) Employers are required under Directive 2004/37 to use existing appropriate procedures for the measurement of exposure levels to carcinogens or mutagens in the workplace, considering that the Scientific Committee on Occupational Exposure Limit Values notes in its recommendations the feasibility of monitoring exposure at any recommended occupational exposure limit value and biological values. The improvement of the equivalence of methodologies for the measurement of the concentration in the air of carcinogens and mutagens in relation to limit values set out in the Directive 2004/37 is important to reinforce the obligations in the Directive and to ensure a similar and a high-level of workers' health protection and a level playing field in the Union.

(2e) deleted

(2f) Amendments to Annex III to Directive 2004/37/EC provided for in this Directive are the first step in a longer-term process of its updating. As a next part of this process, the Commission has submitted a proposal for the establishment of limit values and/or skin notations with regard to seven additional carcinogens (ST 8962/16 SOC 255 EMPL 158 SAN 187 IA 23 CODEC 666 - COM(2016- 248 final + ADD 1 - ADD 3). Moreover, the Commission stated in its Communication "Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy" (COM(2017) 12 final) that subsequent amendments of Directive 2004/37/EC are foreseen.-The Commission should constantly continue its work on future updates of the Annex III to the Directive 2004/37/EC, in line with the Article 16 of that Directive and established practice. This work should result, where appropriate, in proposals for future revisions of the limit values provided for in Directive 2004/37/EC or in this Directive as well as proposals for additional limit values.

- (3) For *all* carcinogens and mutagens it is necessary to consider other absorption pathways, including the possibility of penetration through the skin, in order to ensure the best possible level of protection.
- (4) The Scientific Committee on Occupational Exposure Limits (‘the Committee’) assists the Commission, in particular, in *identifying*, evaluating *and analysing in detail* the latest available scientific data and in proposing occupational exposure limits for the protection of workers from chemical risks, to be set at EU level pursuant to Council Directive 98/24/EC² and Directive 2004/37/EC. *As regards* the chemical agents o-toluidine and 2-nitropropane, there were no Committee recommendations available and other sources of scientific information, adequately robust and in the public domain, were considered.

² 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 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 of the European Parliament and of the Council.³ 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 a review, especially given the number of workers exposed.
- (6) Guides and **examples of good practice produced by the Commission, Member States, 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*. **These 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.**
- (7) The limit values set out in Annex III to Directive 2004/37/EC for vinyl chloride monomer and hardwood dusts 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 in Annex III to Directive 2004/37/EC as recommended by the Scientific Committee on Occupational Exposure Limits and the IARC.**

³ 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).

- (7a) 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 European workers 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 in Annex III for the hardwood dust should apply to all wood dusts present in that mixture.**
- (7b) With regard to Chromium VI a value of 0,005 mg/m³ may be not be appropriate and, in some sectors, difficult to achieve at the moment. 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, an OEL 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.**
- (8) 1,2-Epoxypropane meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen within the meaning of Directive 2004/37/EC. On the basis of the available information, including scientific and technical data, it is possible to identify an [...] exposure level below which exposure to this carcinogen is not expected to lead to adverse effects. It is therefore appropriate to establish such a limit value for 1,2-epoxypropane.
- (9) 1,3-Butadiene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and therefore is 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 this carcinogen. It is therefore appropriate to establish a limit value for 1,3-butadiene.

- (10) 2-Nitropropane meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is 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 this carcinogen. It is therefore appropriate to establish a limit value for 2-nitropropane.
- (11) Acrylamide meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is 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 acrylamide. The Committee 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 dermal uptake.
- (12) Certain chromium (VI) compounds meet the criteria for classification as carcinogenic category 1A or 1B in accordance with Regulation (EC) No 1272/2008 and therefore are 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 out a limit value for these chromium VI compounds. It is therefore appropriate to establish a limit value for chromium (VI) compounds that are carcinogens within the meaning of Directive 2004/37/EC.
- (13) Ethylene oxide meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is 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 this carcinogen. The Committee 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 dermal uptake.

- (14) *o*-Toluidine meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is 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 this 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 dermal uptake.**
- (15) Certain refractory ceramic fibres meet the criteria for classification as carcinogenic category 1B in accordance with Regulation (EC) No 1272/2008 and therefore are 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 the refractory ceramic fibres which are carcinogens within the meaning of Directive 2004/37/EC. It is therefore appropriate to establish a limit value for these refractory ceramic fibres.
- (16) Bromoethylene meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is 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 this carcinogen. It is therefore appropriate to establish a limit value for bromoethylene.
- (17) Hydrazine meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is 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 hydrazine. The Committee identified for this carcinogen 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 dermal uptake.

- (18) **This Directive** strengthens the protection of workers' health *and safety* at their workplace. **Member States should transpose the 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 and/ or practice. Application by employers would be facilitated if they had guidance, where relevant, to identify better ways to achieve compliance with this Directive.**
- (19) 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.
- (19a) *In its opinions, the Advisory Committee on Safety and Health at Work (ACSH) has referred to a review period for Binding Occupational Exposure limits for several substances, such as respirable cristalline silica, acrylamide, and 1,3-butadiene. The Commission is to take into account these opinions when prioritising substances for scientific evaluation.*
- (19b) *In its opinion on refractory ceramic fibres, ACSH agreed that a Binding Occupational Exposure Limit 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 view to reach common position on the limit value for this substance, without prejudice the working methods of the ACSH and autonomy of social partners*

- (19c) In 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 as well as impaired fertility or infertility, and have a negative impact on foetal development and lactation. Substances, which are toxic to reproduction, are subject to the Union measures providing for minimum requirements of the protection of health and safety of workers, in particular those contained in the Directive 98/24/EC and Directive 92/85/ES. Those reprotoxic substances that are also carcinogens are subject to the provisions of the 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 contained in the Directive 2004/37/EC to all reprotoxic substances.**
- (20) This Directive respects the fundamental rights and observes the principles enshrined in the Charter of Fundamental Rights of the European Union, in particular *Article 2 (Right to life) and Article 31 (Fair and just working conditions)*.
- (21) The limit values set in this Directive will be kept under review in the light of the implementation of Regulation (EC) No 1907/2006, in particular to take account of the interaction between limit values set out under Directive 2004/37/EC and DNELs (Derived No Effect Levels) derived for hazardous chemicals under that Regulation *in order to protect workers effectively*.
- (22) 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 EU level, the EU 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.
- (23) Given that this Directive concerns the *protection of workers' health and safety* at their workplace, it should *not be transposed later than two years from the date of entry into force of this Directive*.

(24) Directive 2004/37/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2004/37/EC is amended as follows:

-1. In Article 6, the following subparagraph is added:

The Member States shall take into account the information under letters a) to g) when submitting their reports to the Commission under Article 17a of Directive 89/391/EEC.

-1a. In Article 14, paragraph 1 is replaced by the following:

The Member States shall establish, in accordance with national laws 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 necessary to safeguard the health of the worker concerned.**

-1b. In Article 14(8), paragraph 8 is replaced by the following:

8. All cases of cancer identified in accordance with national laws and/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 to the Commission under Article 17a of Directive 89/391/EEC".

-1c. After Article 18, a new Article 18a is added:

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 relating to such substances.

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 this basis, the Commission shall present, if appropriate, and after consulting management and labour, a legislative proposal.

1. In Annex I the following point is added:

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

2. 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 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

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

A. LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

CAS No (⁴)	EC No (⁵)	NAME OF AGENT	LIMIT VALUES(⁶)			Notation (⁷)	Transitional measures
			mg/m ³ (⁸)	ppm (⁹)	f/ml(¹⁰)		
–	–	Hardwood dusts	2 (¹¹),	–	–	–	<u>Limit value</u> 3 mg/m³ <u>[insert date:</u> <u>5 years after</u> <u>entry into</u> <u>force of this</u> <u>Directive]</u>

⁴ CAS No: Chemical Abstract Service Registry Number.

⁵ 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.

⁶ Measured or calculated in relation to a reference period of eight hours.

⁷ Substantial contribution to the total body burden via dermal exposure possible.

⁸ mg/m³ = milligrams per cubic metre of air at 20°C and 101,3 kPa (760 mm mercury pressure).

⁹ ppm = parts per million by volume in air (ml/m³).

¹⁰ f/ml = fibres per millilitre.

¹¹ Inhalable fraction: if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture.

–	–	Chromium (VI) compounds which are carcinogens within the meaning of Article 2 (a) (i) of the Directive (as Chromium)	<u>0,005</u>	–	–	–	<u>Limit value</u> <u>0,010 mg/m3</u> <u>[insert date:</u> <u>5 years after</u> <u>the</u> <u>transpositio</u> <u>n date]</u> <u>Limit value:</u> <u>0.025 mg/m3</u> <u>for welding</u> <u>or plasma</u> <u>cutting</u> <u>processes or</u> <u>similar work</u> <u>processes</u> <u>that</u> <u>generate</u> <u>fume until</u> <u>[insert date:</u> <u>5 years after</u> <u>the</u> <u>transpositio</u> <u>n date]</u>
–	–	Refractory Ceramic Fibres which are carcinogens within the meaning of Article 2 (a) (i) of the Directive	–	–	0,3	–	
–	–	Respirable Crystalline Silica Dust	0,1 ⁽¹²⁾	–	–	–	

¹² Respirable fraction.

71-43-2	200-753-7	Benzene	3,25	1	–	skin	
75-01-4	200-831-0	Vinyl chloride monomer	2,6	1	–	–	
75-21-8	200-849-9	Ethylene oxide	1,8	1	–	skin	
75-56-9	200-879-2	1,2-Epoxypropane	2,4	1	–	–	
79-06-1	201-173-7	Acrylamide	0,1	–	–	skin	
79-46-9	201-209-1	2-Nitropropane	18	5	–	–	
95-53-4	202-429-0	<i>o</i> -Toluidine	0,5	0,1	–	skin	
106-99-0	203-450-8	1,3-Butadiene	2,2	1	–	–	
302-01-2	206-114-9	Hydrazine	0,013	0,01	–	skin	
593-60-2	209-800-6	Bromoethylene	4,4	1	–	–	

B. OTHER DIRECTLY RELATED PROVISIONS

pm"