Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 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)

DIRECTIVE (EU) 2017/2398 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 December 2017

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 Committee[(1)],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) Directive 2004/37/EC of the European Parliament and of the Council[(3)] 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. 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.

(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'

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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/EEC[(4)], 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.

(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.

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(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 step 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/EC[(5)] and Directive 2004/37/EC. As regards the chemical agents o-toluidine and 2-nitropropane, there were no SCOEL recommendations available in 2016 and therefore other sources of scientific information, adequately robust and in the public domain, have been considered.

(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.

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(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 Council[6] 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.

(16) With regard to chromium VI, a limit value of 0,005 mg/m^3 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/m^3 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/m^3 should apply during that transitional period, after which the generally applicable limit value of 0,005 mg/m^3 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