Directive (EU) 2019/130 of the European Parliament and of the Council of 16 January 2019 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) 2019/130 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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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. 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 and mutagens at the workplace, prevention or reduction of workers'

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exposure to carcinogens and 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 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 or mutagens pursuant to this Directive does not eliminate risks to the health and safety of workers arising from exposure at work (residual risk), it nonetheless contributes to a significant reduction in 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 of the exposure of workers 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 should be set for additional carcinogens and mutagens.

(5) The limit values set in this Directive should be revised when necessary in 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 the 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 (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 for future revisions of the limit values set in this Directive.

(6) No later than in the first quarter of 2019, the Commission, taking into account the latest developments in scientific knowledge, should assess the option of amending the scope of Directive 2004/37/EC to include reprotoxic substances. On that basis, the Commission should present a legislative proposal, if appropriate, after consulting management and labour.

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

(8) In order to ensure the highest possible level of protection against 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[(4)] and Directive 2004/37/EC. The ACSH is a tripartite body that assists the

Commission in the preparation, implementation and evaluation of activities in the field of occupational health and safety. In particular, the ACSH adopts tripartite opinions on initiatives to set occupational exposure 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 on 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 (IARC), the World Health Organisation and national agencies.

(10) SCOEL's work and the transparency of that work is integral 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 Annexes I and III to Directive 2004/37/EC provided for in this Directive are a further step in a longer term process to update Directive 2004/37/EC. 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 entitled '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 Annexes I and III to Directive 2004/37/EC, in line with Article 16 thereof and established practice, and amend them when necessary in 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 or cytotoxic drugs, and from work involving exposure to carcinogenic or mutagenic substances in cleaning, transport, laundry and waste disposal of hazardous drugs or materials contaminated by hazardous drugs, as well as 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 or cytotoxic drugs, in a dedicated guide to prevention and good practice. This guidance is without prejudice to possible further legislative proposals or other initiatives.

(13) In accordance with the recommendations of SCOEL and of the 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 a shorter reference period, in general fifteen minutes time-weighted average (short-term exposure limit values), in order to limit, to the extent possible, the effects arising from short-term exposure. Skin notations are also set in

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accordance with the recommendations of SCOEL and of the 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 also be promoted in relation to the effects of carcinogens and mutagens on future generations, such as the negative impacts on the reproductive capacity of both men and women, as well as on foetal development. To this end, Member States should 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[(5)]. SCOEL identified the possibility of significant uptake through the skin for those oils, concluded that occupational exposure occurs through the dermal route and strongly recommended the establishment of a skin notation. The ACSH agreed that used mineral engine oils should 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 the use of personal protection equipment such as gloves, and the removal and cleaning of contaminated clothing. Full compliance with those practices, as well as with newly emerging best practices, could help reduce that 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 assign to it a skin notation in Annex III to Directive 2004/37/EC indicating the possibility of significant uptake through the skin.

(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 in accordance with Regulation (EC) No 1272/2008. The ACSH agreed that traditional diesel engine exhaust emissions should 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 IARC as carcinogenic to humans (IARC category 1) and the 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. The 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 in Annex III thereto a limit value for diesel engine exhaust emissions calculated on elemental carbon. The entries in Annexes I and III to Directive 2004/37/EC should cover exhaust emissions from all types of diesel engines.

(17) With regard to diesel engine exhaust emissions, a limit value of 0,05 mg/m^3 measured as elemental carbon may, in some sectors, be difficult to achieve in the short term. Therefore, in addition to the transposition period, a two year transitional period should be introduced before the limit value should apply. However, for the 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 those mixtures and the ACSH agreed on the importance of introducing an occupational exposure limit value for PAHs mixtures and has recommended carrying out work to evaluate the scientific aspects with a view to proposing an occupational exposure limit value in the future. It is therefore appropriate to assign to it a skin notation in Annex III to Directive 2004/37/EC indicating the possibility of significant uptake through the skin. Further investigations should also be carried out to assess whether it is necessary to set a limit value for PAHs mixtures in order to better protect workers from those 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 of fifteen minutes time-weighted average (short-term exposure limit value). SCOEL identified for that carcinogen the possibility of significant uptake through the skin and the 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 and to assign to it a skin notation in Annex III to Directive 2004/37/EC indicating the possibility of significant uptake through the skin. In light of evolving scientific evidence and technical progress, the limit values for that substance should 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 that 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 that carcinogen the possibility of significant uptake through the skin and the 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