EUROPEAN UNION

THE EUROPEAN PARLIAMENT **THE COUNCIL**

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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) 2019/… OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 June 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)

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],

[1] OJ C 440, 6.12.2018, p. 145.

[2] Position of the European Parliament of 27 March 2019 (not yet published in the Official Journal) and decision of the Council of 21 May 2019.

Whereas:

(1) Delivering on the European Pillar of Social Rights[1], proclaimed by the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth in Gothenburg on 17 November 2017, is a shared political commitment and responsibility. Principle 10 of the European Pillar of Social Rights provides that workers have the right to a healthy, safe and well-adapted work environment. The right of workers to a high level of protection of their health and safety at work and to a working environment adapted to their professional needs also includes protection from carcinogens and mutagens at the workplace, irrespective of the duration of the employment or of the exposure.

(2) This Directive respects fundamental rights and observes the principles recognised 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] OJ C 428, 13.12.2017, p. 10.

(3) Directive 2004/37/EC of the European Parliament and of the Council[1] 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 minimum requirements. The aim of those minimum requirements is to protect workers at Union level and to contribute to reducing differences in the levels of protection of workers across the Union and to ensuring a level playing field. Binding occupational exposure limit values are important components of the general arrangements for the protection of workers established by Directive 2004/37/EC. Those limit values need to be evidence-based, proportionate and measurable and should be established on the basis of available information, including up-to-date scientific and technical data, the economic feasibility of implementation and compliance, a thorough assessment of the socioeconomic impact and the availability of exposure measurement protocols and techniques at the workplace. More stringent binding occupational exposure limit values can be set by Member States in close cooperation with the social partners. In addition, Directive 2004/37/EC does not prevent Member States from applying additional measures, such as a biological limit value.

[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).

(4) Directive 2004/37/EC aims to cover substances or mixtures which meet the criteria for classification as a category 1A or 1B carcinogen or mutagen set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[1] as well as substances, mixtures or processes referred to in Annex I to Directive 2004/37/EC. The substances which meet the criteria for classification as a category 1A or 1B carcinogen or mutagen set out in Annex I to Regulation (EC) No 1272/2008 are those with a harmonised classification or classified in accordance with Article 4 or 36 of that Regulation and notified to the European Chemicals Agency (ECHA) pursuant to Article 40 of that Regulation. Those substances are listed in the public Classification and Labelling Inventory maintained by ECHA. For any new addition to the list of substances, mixtures and processes referred to in Annex I to Directive 2004/37/EC in accordance with point (a)(ii) of Article 2 of that Directive, robust scientific evidence of the carcinogenicity of the relevant substance needs to be demonstrated, based on available valid scientific sources such as ECHA's Committee for Risk Assessment (RAC), the International Agency for Research on Cancer (IARC) and national bodies, paying particular attention to peer-reviewed published literature on that substance.

[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).

(5) Occupational exposure limit values are part of the risk-management measures under Directive 2004/37/EC. Those limit values should be revised regularly in accordance with the precautionary principle and the principle of the protection of workers, and in light of sound available scientific and technical data concerning carcinogens and mutagens. Consideration should also be given to improving measurement techniques, risk-management measures and other relevant factors. Compliance with those limit values is without prejudice to other employers' obligations 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 with a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system and other measures aiming to reduce the level of workers' exposure.

(6) Hazardous drugs, including cytotoxic drugs primarily used for cancer treatment, could have genotoxic, carcinogenic or mutagenic properties. It is therefore important to protect workers who are exposed to such drugs through work involving: the preparation, administration or disposal of hazardous drugs, including cytotoxic drugs; services related to cleaning, transport, laundry or waste disposal of hazardous drugs or of materials contaminated by such drugs; or personal care for patients treated with hazardous drugs. Hazardous drugs, including cytotoxic drugs, are subject to Union measures providing for minimum requirements for the protection of health and safety of workers, in particular those provided for in Council Directive 98/24/EC[1]. Hazardous drugs that contain substances that are also carcinogens or mutagens are subject to Directive 2004/37/EC. The Commission should assess the most appropriate instrument for ensuring the occupational safety of workers exposed to hazardous drugs, including cytotoxic drugs. In doing so, access to the best available treatments for patients should not be jeopardised.

(7) 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 in the 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.

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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).

(8) Maximum levels for workers' exposure to some carcinogens or mutagens are established by values which, pursuant to Directive 2004/37/EC, are not to be exceeded.

(9) This Directive strengthens the protection of workers' health and safety at their workplace. The Commission should review Directive 2004/37/EC on a regular basis and make legislative proposals, if appropriate. New limit values should be set out in that Directive 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, recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL) and opinions of the RAC, as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH) and monographs of the IARC. Transparency of information is a tool for prevention in that context and should be ensured. Information related to residual risk is valuable for any future work to limit risks from occupational exposure to carcinogens and mutagens, and should be made publicly available at Union level. This Directive is in line with the specific recommendations of SCOEL, the RAC and the ACSH, the importance of which has been highlighted in previous amendments to Directive 2004/37/EC.

(10) It is also necessary, in light of scientific data, to consider the absorption pathways of carcinogens and mutagens other than inhalation, including the possibility of uptake through the skin, and, in such cases, assign a skin notation for relevant substances in order to ensure the best possible level of protection. The amendments to Annex III to Directive 2004/37/EC provided for in this Directive constitute a further step in a longer-term process initiated to update that Directive.

(11) The assessment of health effects of carcinogens subject to this Directive was based on the relevant scientific expertise from SCOEL and the RAC.

(12) SCOEL, which was set up by Commission Decision 2014/113/EU[1], 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 Directives 98/24/EC and 2004/37/EC.

[1] Commission Decision 2014/113/EU of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC (OJ L 62, 4.3.2014, p. 18).

(13) In accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[1], the RAC draws up ECHA opinions concerning the risks of chemical substances to human health and the environment. In the context of this Directive, the RAC prepared its opinion as requested in accordance with point (c) of Article 77(3) of that Regulation.

(14) The 2018-to-2019 campaign 'Healthy Workplaces Manage Dangerous Substances' is a good example of how the European Agency for Safety and Health at Work (EU-OSHA) can support the implementation of occupational safety and health legislation at Union level. It is desirable that EU-OSHA work closely with Member States to provide tailored information and examples of good practices to workers in contact with certain substances, highlighting policy developments and the legislative framework already in place.

[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).

(15) Cadmium and many of its inorganic compounds 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 therefore appropriate, on the basis of available information, including scientific and technical data, to establish a limit value for cadmium and its inorganic compounds in that Directive. In addition, cadmium, cadmium nitrate, cadmium hydroxide and cadmium carbonate have been identified as substances of very high concern pursuant to point (a) of Article 57 of Regulation (EC) No 1907/2006 and are included in the candidate list referred to in Article 59(1) of that Regulation.

(16) With regard to cadmium, it is foreseeable that it will be difficult to comply with a limit value of 0,001 mg/m^3 in the short term. It is therefore appropriate to introduce a transitional period of eight years, during which the limit value 0,004 mg/m^3 (inhalable fraction) should apply. With a view to protecting legitimate expectations and in order to avoid potential disruptions of existing practices in Member States that implement, on the date of the entry into force of this Directive, a biomonitoring system with a biological limit value not exceeding 0,002 mg Cd/g creatinine in urine, the limit value of 0,004 mg/m^3 should, in those Member States, be measured as respirable fraction during the transitional period, in light of the SCOEL and ACSH opinions on cadmium and its inorganic compounds.

(17) On the basis of available valid scientific sources such as those provided by SCOEL, the RAC and relevant national bodies, the Commission should, no later than three years after the date of entry into force of this Directive, assess the option of amending Directive 2004/37/EC by adding provisions on a combination of an airborne occupational exposure limit and a biological limit value for cadmium and its inorganic compounds.

(18) Setting a biological limit value for cadmium and its inorganic compounds would protect workers against their systemic toxicity, which mainly affects the kidneys and bones. Biological monitoring can thus contribute to the protection of workers at the workplace, but only as a means of complementing the monitoring of the concentration of cadmium and its inorganic compounds in the air and therefore within the breathing zone of workers. The Commission should issue practical guidelines for biological monitoring.

(19) Beryllium and most inorganic beryllium compounds 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. In addition to having carcinogenic properties, beryllium is known to provoke chronic beryllium disease (CBD) and beryllium sensitisation (BeS). It is therefore appropriate, on the basis of the available information, including scientific and technical data, to establish a limit value for beryllium and inorganic beryllium compounds in that Directive and to assign a notation for skin and respiratory sensitisation.

(20) With regard to beryllium, it is foreseeable that it will be difficult to comply with a limit value of 0,0002 mg/m^3 in the short term. It is therefore appropriate to introduce a transitional period of seven years, during which the limit value of 0,0006 mg/m^3 should apply.

(21) Arsenic acid and its salts, as well as most inorganic arsenic compounds, meet the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is therefore appropriate, on the basis of the available information, including scientific and technical data, to establish a limit value for arsenic acid and its salts, as well as inorganic arsenic compounds in that Directive. In addition, arsenic acid, diarsenic pentaoxide and diarsenic trioxide are identified as substances of very high concern pursuant to point (a) of Article 57 of Regulation (EC) No 1907/2006 and are included in Annex XIV to that Regulation, requiring authorisation before they can be used.

(22) With regard to arsenic acid, it is foreseeable that the copper smelting sector will have difficulties in complying with a limit value of 0,01 mg/m^3. A transitional period of four years should therefore be introduced.

(23) Formaldehyde 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. Formaldehyde is a local acting genotoxic carcinogen and there is sufficient scientific evidence of its carcinogenicity in humans. Formaldehyde is also a contact allergen for the skin (skin sensitiser). It is therefore appropriate, on the basis of the available information, including scientific and technical data, to establish a long- and short-term limit value for formaldehyde in that Directive and to assign a notation for skin sensitisation. In addition, at the request of the Commission, ECHA is also gathering existing information to assess the potential exposure to formaldehyde and formaldehyde releasers at the workplace, including industrial and professional uses.

(24) Formaldehyde fixatives are routinely used in the healthcare sector across the Union because of their convenience of handling, high degree of accuracy and extreme adaptability. In some Member States, it is foreseeable that the healthcare sector will have difficulties in complying, in the short term, with a limit value of 0,37 mg/m^3 or 0,3 ppm. It is therefore appropriate to introduce for that sector a transitional period of five years, during which the limit value of 0,62 mg/m^3 or 0,5 ppm should apply. The healthcare sector should, however, minimise exposure to formaldehyde and is encouraged to respect the limit value of 0,37 mg/m^3 or 0,3 ppm during the transitional period where possible.

(25) In some Member States, formaldehyde is routinely used for the purposes of embalming deceased persons as part of their cultural or religious practices. It is foreseeable that the funeral sector will have difficulties in complying, in the short term, with the limit value of 0,37 mg/m^3 or 0,3 ppm. It is therefore appropriate to introduce for that sector a transitional period of five years, during which the limit value of 0,62 mg/m^3 or 0,5 ppm should apply.

(26) The notations for sensitisation set in this Directive for beryllium and formaldehyde are introduced to improve clarity. When setting such notations during the update of Directive 2004/37/EC, consistency should be ensured with relevant Union law. This may include adding sensitisation notations for substances for which there is already a specific entry in Annex III to that Directive, where relevant.

(27) 4,4'-Methylene-bis(2-chloroaniline) (MOCA) 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. Its carcinogenicity, together with its manifest genotoxic characteristics, has made it possible to classify that substance as carcinogenic to humans. The possibility of a significant uptake through the skin was identified for MOCA. It is therefore appropriate to establish a limit value for MOCA and to assign a skin notation to it. In addition, it was identified as a substance of very high concern pursuant to point (a) of Article 57 of Regulation (EC) No 1907/2006 and included in Annex XIV to that Regulation, requiring authorisation before it can be placed on the market or used. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for MOCA.

(28) 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. The ACSH has adopted opinions for substances covered by this Directive and proposed a binding occupational exposure limit value for each of them, supporting the relevant notations for some of them.

(29) The limit values established in this Directive are to be kept under regular scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006, in particular to take account of the interaction between limit values established in Directive 2004/37/EC and derived no-effect levels for hazardous chemicals under that Regulation in order to protect workers effectively.

(30) Since the objective of this Directive, namely to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work, 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 that objective.

(31) In implementing this Directive, Member States should avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings. In this regard, Member States and relevant bodies at Union and national level are encouraged to provide incentives, guidance and advice to micro, small and medium-size enterprises to facilitate compliance with this Directive. In that context, social partner agreements, guidance and other joint actions identifying and developing best practices are most welcome.

(32) 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.

(33) 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 18a, the following subparagraphs are added:

'No later than … [three years after the date of entry into force of this Directive], the Commission shall assess the option of amending this Directive to add provisions on a combination of an airborne occupational exposure limit and a biological limit value for cadmium and its inorganic compounds.

No later than 30 June 2020, the Commission shall, taking into account the latest developments in scientific knowledge, and after appropriate consultation with relevant stakeholders, in particular health practitioners and health professionals, assess the option of amending this Directive in order to include hazardous drugs, including cytotoxic drugs, or to propose a more appropriate instrument for the purpose of ensuring the occupational safety of workers exposed to such drugs. On that basis, the Commission shall present, if appropriate, and after consulting management and labour, a legislative proposal.';

(2) 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 by ... [two years after the date of entry into force of this Directive]. They shall immediately inform the Commission thereof.

   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 Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX

In point A of Annex III to Directive 2004/37/EC, the following rows are added:

'

Name of agent	EC No([1])	CAS No([2])	Limit values						Notation	Transitional measures
			8 hours([3])			Short-term([4])				
			mg/m^3([5])	ppm([6])	f/ml([7])	mg/m^3([5])	ppm([6])	f/ml([7])		
Cadmium and its inorganic compounds	–	–	0,001([11])	–	–	–	–	–		Limit value 0,004 mg/m^3([12]) until … [eight years after the date of entry into force of this Directive].
Beryllium and inorganic beryllium compounds	–	–	0,0002([11])	–	–	–	–	–	dermal and respiratory sensitisation([13])	Limit value 0,0006 mg/m^3 until … [seven years after the date of entry into force of this Directive].

Name of agent	EC No([1])	CAS No([2])	Limit values						Notation	Transitional measures
			8 hours([3])			Short-term([4])				
			mg/m^3([5])	ppm([6])	f/ml([7])	mg/m^3([5])	ppm([6])	f/ml([7])		
Arsenic acid and its salts, as well as inorganic arsenic compounds	–	–	0,01([11])	–	–	–	–	–	–	For the copper smelting sector, the limit value shall apply from … [four years after the date of entry into force of this Directive].
Formaldehyde	200-001-8	50-00-0	0,37	0,3	–	0,74	0,6	–	dermal sensitisation([14])	Limit value of 0,62 mg/m^3 or 0,5 ppm([3]) for the health care, funeral and embalming sectors until … [five years after the date of entry into force of this Directive].
4,4'-Methylene-bis(2-chloroaniline)	202-918-9	101-14-4	0,01	–	–	–	–	–	skin([10])	

([11]) Inhalable fraction.
([12]) Inhalable fraction. Respirable fraction in those Member States that implement, on the date of the entry into force of this Directive, a biomonitoring system with a biological limit value not exceeding 0,002 mg Cd/g creatinine in urine.
([13]) The substance can cause sensitisation of the skin and of the respiratory tract.
([14]) The substance can cause sensitisation of the skin.'.