European Parliament
2014-2019

Committee on Employment and Social Affairs

15.2.2019

PROVISIONAL AGREEMENT RESULTING FROM INTERINSTITUTIONAL NEGOTIATIONS

Subject: Proposal for a directive 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
(COM(2018)0171 – C8-0130/2018 – 2018/0081(COD))

The interinstitutional negotiations on the aforementioned proposal for a directive have led to a compromise. In accordance with Rule 69f(4) of the Rules of Procedure, the provisional agreement, reproduced below, is submitted as a whole to the Committee on Employment and Social Affairs for decision by way of a single vote.

DIRECTIVE 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

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,

[1] OJ C …, …, p. ….

Whereas:

(1) ***Delivering on*** the European Pillar of Social Rights[2], proclaimed at 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 healthy, safe and well-adapted work environment. The right to a high level of protection of the health and safety at work, as well as to a working environment adapted to the professional needs of workers ***also*** includes ▌ protection from carcinogens and mutagens at the workplace***, irrespective of the duration of the employment or the exposure***.

(2) This Directive respects 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.

[2] ***OJ C 428, 13.12.2017, p. 10.***

(3) 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. ***The aim of such 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 ***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 availability of exposure measurement protocols and techniques at the workplace***. Those limit values*** are important components of the general arrangements for the protection of workers established by ***that*** Directive ▌. 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.***

[3] 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[4] 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 thereof and notified to the European Chemicals Agency (ECHA) pursuant to Article 40 thereof. Those substances are listed in the public Classification and Labelling Inventory maintained by ECHA. For the inclusion of new substances in Annex I to Directive 2004/37/EC in accordance with point (ii) of Article 2(a) thereof, robust scientific evidence of the carcinogenicity of the specific substance need to be demonstrated, based on available valid scientific sources such as the Committee for Risk Assessment (RAC) of ECHA, International Agency for Research on Cancer (IARC), national bodies etc., paying particular attention to peer reviewed published literature on the given substance.

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[4] *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 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, as 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 aiming to reduce the level of workers' exposure ▌**.**

(6) ***Hazardous drugs, including cytotoxic drugs that are primarily used for cancer treatment, could have genotoxic, carcinogenic or mutagenic properties. It is therefore important to protect workers exposed to such drugs resulting from the preparation, administration or disposal of hazardous drugs, including cytotoxic drugs, or from work involving services related to cleaning, transport, laundry or waste disposal of (materials contaminated by) hazardous drugs, or personal care for patients treated with hazardous drugs. Hazardous drugs, including cytotoxic drugs, are subject to Union measures providing for minimum requirements of the protection of health and safety of workers, in particular those provided for in Council Directive 98/24/EC[5]. Those drugs that are also carcinogens or mutagens are subject to Directive 2004/37/EC. The Commission should assess the most appropriate instrument for ensuring occupational safety of workers exposed to such drugs. In doing so, in accordance with Article 168(1) Treaty for the Functioning of the European Union (TFEU), 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 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.

(8) 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.

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5 ***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).***

(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 ***RAC***, as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH) ***and monographs of the IARC***. 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***. Transparency ***is a tool for prevention in this context and should be ensured. This Directive follows the specific recommendations of SCOEL, 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 ▌ absorption pathways ***other*** than inhalation of all carcinogens and mutagens, ***in view of observations regarding*** the possibility of uptake through the skin ***- concretely through skin notation***, in order to ensure the best possible level of protection. 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 ▌ RAC.

(12) SCOEL, the activities of which are regulated by the Commission Decision 2014/113/EU[6] 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.

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[6] Commission Decision 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) Pursuant to Regulation ***(***EC***)*** No 1907/2006 of the European Parliament and of the Council[7] RAC delivers opinions of ECHA ***concerning*** the risks of chemical substances to human health and the environment. In the context of this ***Directive***, RAC delivered its opinion as requested in accordance with Article 77(3)(c) of ***that*** Regulation ▌.

(14) The 2018-2019 campaign on "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 works 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.

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[7] 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 set ▌ a limit value for cadmium and its inorganic compounds ***in that*** Directive ▌. In addition, cadmium, cadmium nitrate, cadmium hydroxide and cadmium carbonate were identified as substances of very high concern ***under*** Article 57(a) 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 most sectors will require considerable adaptations in order to comply with*** a limit value of 0,001 mg/m^3 ▌ in the short term. A transitional period of ***eight*** years should therefore be introduced***,*** during which the limit value 0,004 mg/m^3 ***(inhalable fraction) should apply. With a view to protect legitimate expectations and 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, RAC and relevant national bodies, the Commission should assess no later than three years from the entry into force of this Directive the option of amending Directive 2004/37/EC by adding provisions on a combination of an airborne occupational exposure limit with 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 its systemic toxicity, which mainly effects 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 carcinogenic properties beryllium is known to provoke chronic beryllium disease (CBD) and beryllium sensitisation (BeS). It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for that group of carcinogens. It is therefore appropriate to establish a limit value for beryllium and inorganic beryllium compounds ***in*** Directive 2004/37/EC and to assign a notation for skin and respiratory sensitisation.

(20) With regard to beryllium, a limit value of 0,0002 mg/m^3 may be difficult to be complied with in some sectors in the short term. A transitional period of ***seven*** years should therefore be introduced 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*** Directive 2004/37/EC. In addition, arsenic acid, diarsenic pentaoxide and diarsenic trioxide are identified as substances of very high concern ▌ pursuant to Article 57(a) 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, a limit value of 0,01 mg/m^3 may be difficult to be complied with in the copper smelting sector and therefore a transitional period of ***four*** years should 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. On*** the basis of the available information, including scientific and technical data, ***it is possible*** to set a long and short term limit value for that carcinogen. Formaldehyde is also a contact allergen to the skin (skin sensitiser). It is therefore appropriate to establish a limit value for formaldehyde and to assign a notation for skin sensitisation. In addition, ***on*** request of the Commission, ECHA is also gathering existing information to assess the potential exposure from 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 in handling, high degree of accuracy and extreme adaptability. In some Member States, the healthcare sector is likely to have difficulties in complying, in the short term, with the limit value of 0,3 ppm set in this Directive A transitional period of five years should therefore be introduced for the sector during which the limit-value of 0,5 ppm should apply. The healthcare sector should however minimize the exposure to formaldehyde and is encouraged to respect the limit value of 0,3 ppm in the transitional period wherever 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. The funeral sector is likely to have difficulties in complying with the limit value of 0,3 ppm without significant short-term effects on capacity. A transitional period of five years should therefore be introduced for the sector during which the limit-value of 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 the relevant Union legislation. 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 to it a skin notation. In addition, it was identified as a substance of very high concern ▌ pursuant to Article 57(a) of Regulation ***(***EC***)*** No 1907/2006 and included in Annex XIV to that Regulation, requiring authorisation before it can be placed on 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 ***TFEU***. 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 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.

(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 comply with the terms of this Directive. In this context social partner agreements, guidance and other joint action identifying and developing best practice are most welcome.***

(32) As 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 from 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 with a biological limit value for cadmium and its inorganic compounds.

No later than the end of the second quarter of 2020, the Commission shall, taking into account the latest developments in scientific knowledge, and after appropriate consultation, assess whether to amend this Directive to include hazardous drugs, including cytotoxic drugs, or to propose a more appropriate instrument for the purpose of ensuring occupational safety of workers from exposure to such drugs. On that basis, the Commission shall present, if appropriate, and after consulting management and labour, as well as health practitioners and health professionals, 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

Annex III is amended as follows: in point A, the following ***rows are*** added:

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Name of agent	EC No ([1])	CAS No ([2])	Limit values						Notation	Transitional measures
			8 hours ([3])			Short-term ([4])				
			mg/m³ ([5])	ppm ([6])	f/ml ([7])	mg/m³	ppm	f/ml		
Cadmium and its inorganic compounds	–	–	0,001 ***([11])***	–	–	–	–	–		Limit value 0,004 mg/m³ ***([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 ([8])	Limit value 0,0006 mg/m³ until ***… [seven*** years ***after the date of entry into force of this Directive***]**.**
Arsenic acid and its salts, as well as inorganic arsenic compounds	–	–	0,01 ***([11])***	–	–	–	–	–	–	For the copper smelting sector the limit value ***shall*** come into force on ***… [four 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	ppm	f/ml		
Formaldehyde	200-001-8	50-00-0	0,37	0,3	–	***0,74***	0,6	–	dermal senitisation ([9])	***Limit value 0,5ppm*** ([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])	

([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, to 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 time-weighted average (TWA).
([4]) Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.
([5]) mg/m^3 = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).
([6]) ppm = parts per million by volume in air (ml/m^3).
([7]) f/ml = fibres per millilitre.
([8]) The substance can cause sensitisation of the skin and of the respiratory tract.
([9]) The substance can cause sensitisation of the skin.
([10]) Substantial contribution to the total body burden via dermal exposure possible.
([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.

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