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NOTE

From:	Permanent Representatives Committee (Part 1)
To:	Council
No. prev. doc.:	14252/18
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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 - General approach

I. INTRODUCTION

1. On 5 April 2018, the Commission published its proposal for a directive amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (doc. 7733/18 + ADD1).

2. This directive (third batch) aims to improve workers' health protection by reducing occupational exposure to five carcinogenic chemical agents: cadmium, berylium, arsenic acid, formaldehyde and 4,4' methylene-bis.

3. The Economic and Social Committee adopted its Opinion on the proposal on the 19 September 2018. The Committee of the Regions decided not to issue an Opinion, but replied in a letter dated of 24 July 2018.

4. The Committee on Employment and Social Affairs (EMPL) of the European Parliament adopted a draft report on the proposal on 20 November 2018, followed by the announcement at a next plenary session.

II. STATE OF PLAY

5. Following the work of the Social Questions Working Party the Permanent Representatives Committee has discussed the proposal on 24 October. The Presidency's compromise suggestions (in document 13201/18), regarding Sensitisation (Recital 13 and Recital 17) and Rounding (Formaldehyde Annex III) have been approved. In addition, as a result of the discussion at the meeting, a transitional period of 3 years for Formaldehyde and more precise wording on all transitional measures in the annex to the directive have been also agreed.

   A large number of delegations were in favour of the Presidency compromise proposal. At the same time, some of them also expressed support for an additional combined limit value option on Cadmium suggested by one Member State.

6. The Social Questions Working Party discussed the remaining outstanding issue on 13 November. On this basis, the Presidency prepared a compromise proposal set out in the annex of document 14252/18, which includes: (i) compromise suggestions on the biological limit value for Cadmium and, as requested by some delegations, (ii) a technical clarification in line with the 'Advisory Committee of Safety and Health at Work' opinion, regarding the inhalable fraction for cadmium, beryllium, and arsenic acid of the limit value in footnote (ix) in the annex of the directive.

7. On 23 November, the Permanent Representatives Committee approved this compromise text. Following this meeting, the text of compromise amendments has been reviewed by legal linguists. Their suggestions for improvement, without modifying the substance, have been included in the text set out in the Annex to this document.

III. CONCLUSION

8. Against this background, the Council (EPSCO) is invited to reach a General approach on the text as set out in the Annex to this document to the Council (EPSCO 6 December).

ANNEX I

2018/0081 (COD)

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

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,

Whereas:

[1] OJ C ,, p.

(1) Principle 10 of the European Pillar of Social Rights[2], proclaimed at Gothenburg on 17 November 2017, provides that every worker has 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 and which enables them to prolong their participation in the labour market includes also protection from carcinogens and mutagens at the workplace.

(2) 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 Directive 2004/37/EC 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 Directive 2004/37/EC.

(2a) The minimum requirements provided for in Directive 2004/37/EC aim to protect workers at Union level. More stringent binding occupational exposure limit values can be set by Member States. In addition, Directive 2004/37/EC does not prevent Member States from applying at the national level additional measures, such as a biological limit value.

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2 European Pillar of Social Rights, November 2017, https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en

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).

(3) 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 of employers pursuant to Directive 2004/37/EC, such as 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. In that context, it is essential to take the precautionary principle into account where there are uncertainties.

(4) 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 Directive 2004/37/EC 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 may be scientifically possible to identify levels below which exposure is not expected to lead to adverse effects.

(5) 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.

(6) This Directive strengthens the protection of workers' health and safety at their workplace. New limit values should be set out in Directive 2004/37/EC 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 Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions 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 any future work to limit risks from occupational exposure to carcinogens and mutagens. Transparency of such information should be further encouraged.

(7) It is also necessary to consider other absorption pathways than inhalation of all carcinogens and mutagens, including the possibility of uptake through the skin, 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 Directive 2004/37/EC.

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

(9) SCOEL, the activities of which are regulated by the Commission Decision 2014/113/EU[4] 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.

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

(11) 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 appropriate, on the basis of 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 cadmium and its inorganic compounds under the scope of Directive 2004/37/EC. In addition, cadmium, cadmium nitrate, cadmium hydroxide and cadmium carbonate were identified as substances of very high concern (SVHC) pursuant to 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 for authorisation under the REACH Regulation.

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4 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)

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).

6 Article 77(3)(c) of 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) (OJ L 396, 30.12.2006, p. 1) provides the Commission with a possibility to seek an opinion concerning safety of any substance, including in relation to occupational health and safety.

(12) With regard to cadmium, a limit value of 0,001 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 0,004 mg/m^3 should apply.

(12a) In its opinion on cadmium and its inorganic compounds the ACSH stated that both the combination of an airborne occupational exposure limit (OEL) with a biological limit value and the time-weighted average (TWA) of the concentration in the air, present adequate technical means of protecting workers' health and requested the Commission to investigate this issue further (Doc. 663/17). Therefore, the Commission should assess no later than five years from the entry into force of this Directive the option of amending Directive 2004/37/EC by adding the combination of an airborne OEL with a biological limit value.

(13) 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. 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 under the scope of Directive 2004/37/EC .

(14) 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 five years should therefore be introduced during which the limit value of 0,0006 mg/m^{3}should apply.

(15) 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 appropriate, 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 arsenic acid and its salts, as well as inorganic arsenic compounds under the scope of Directive 2004/37/EC. In addition, arsenic acid, diarsenic pentaoxide and diarsenic trioxide are identified as substances of very high concern (SVHC) 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.

(16) 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 two years should be introduced.

(17) 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. It is a local acting genotoxic carcinogen. It is possible, on the basis of the available information, including scientific and technical data, to set a long and short term limit value for that carcinogen. It is therefore appropriate to establish a limit value for formaldehyde . In addition, upon 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[7].

[7] https://echa.europa.eu/documents/10162/13641/formaldehyde_cion_reqst_axvdossier_en.pdf/11d4a99a-7210-839a-921d-1a9a4129e93e

(18) 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. 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 (SVHC) 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.

(19) 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. ACSH has adopted opinions for all priority substances foreseen by the present proposal and proposed a binding occupational exposure limit value for each of them, supporting the relevant notations for some of them[8].

(20) 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.

[8] The full text of the opinions can be found on CIRCA-BC, https://circabc.europa.eu

(21) The limit values set out in this Directive are to be kept under review to ensure consistency with Regulation (EC) No 1907/2006 of the European Parliament and of the Council [9], in particular to take account of the interaction between limit values set out under Directive 2004/37/EC and derived no effect levels 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 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.

(23) 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. Member States are therefore invited to assess the impact of their transposition act on SMEs in order to make sure that SMEs are not disproportionately affected, with specific attention for micro-enterprises and for administrative burden, and to publish the results of such assessments.

(24) 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.

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

HAVE ADOPTED THIS DIRECTIVE:

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[9] 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).

Article 1

Directive 2004/37/EC is amended as follows:

(1) In Article 18a, the following subparagraph is added:

„No later than … [*OJ: five years from the entry into force of this Directive*] the Commission shall assess the option of amending this Directive to include a combination of an airborne occupational exposure limit with a biological limit value for cadmium and its inorganic compounds.“;

(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…][10]. They shall immediately inform the Commission of the text of those measures.

   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.

[10] Two years after the entry into force of 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 table is added:

Name of agent	EC No ([i])	CAS No ([ii])	Limit values						Notation	Transitional measures
			8 hours ([iii])			Short-term ([iv])				
			mg/m^3 ([v])	ppm ([vi])	f/ml ([vii])	mg/m^3	ppm	f/ml		
Cadmium and its inorganic compounds	–	–	0,001 ([ix])	–	–	–	–	–		Limit value 0,004 mg/m^3 ([ix]) until 7 years after the end of the transposition period.
Beryllium and inorganic beryllium compounds	–	–	0,0002 ([ix])	–	–	–	–	–		Limit value 0,0006 mg/m^3 ([ix]) until 5 years after the end of the transposition period.
Arsenic acid and its salts, as well as inorganic arsenic compounds	–	–	0,01 ([ix])	–	–	–	–	–	–	For the copper smelting sector the limit value will come into force 2 years after the end of the transposition period.
Formaldehyde	200-001-8	50-00-0	0,37	0,3	–	0,74	0,6	–		These limit values will come into force 3 years after the end of the transposition period.
4,4'-Methylene-bis(2-chloroaniline)	202-918-9	101-14-4	0,01	–	–	–	–	–	skin ([viii])	

(i) 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.
(ii) CAS No: Chemical Abstract Service Registry Number.
(iii) Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).
(iv) 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.
(v) mg/m^3 = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).
(vi) ppm = parts per million by volume in air (ml/m^3).
(vii) f/ml = fibres per millilitre.
(viii) Substantial contribution to the total body burden via dermal exposure possible.
(ix) Inhalable fraction.