Council of the
European Union

Brussels, 5 October 2016

12883/16

Interinstitutional File:
2016/0130 (COD)

SOC 590
EMPL 392
SAN 346
IA 81
CODEC 1381

REPORT

from:	Permanent Representatives Committee (Part 1)
to:	Council (EPSCO)
No. prev. doc.:	12224/16 SOC 525 EMPL 346 SAN 325 IA 69 CODEC 1264 + COR 1
No. Cion prop.:	ST 8962/16 SOC 255 EMPL 158 SAN 187 IA 23 CODEC 666 ADD 1 - ADD 3
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

On 13 May 2016, the Commission submitted its proposal for amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. The proposal is based on Article 153(2) TFEU.

The proposed revision concerns Annex I and III of Directive 2004/37/EC. In Annex I, a provision is added on exposure to respirable crystalline silica dust generated by a work process. With regard to Annex III, while the current Directive includes three carcinogenic agents (hardwood dust, benzene, and vinyl chloride monomer) and their limit values for occupational exposure, the proposal revises the limit value for two of these substances and includes new limit values for eleven substances.

The Commission carried out a two-stage consultation of the European social partners in accordance with Article 154 of the TFEU. The Commission subsequently consulted the tripartite Working Party 'Chemicals at the Workplace' (WPCs), which is part of the tripartite Advisory Committee on Safety and Health at Work (ACSH), taking into account the scientific advice of Scientific Committee on Occupational Exposure Limits for Chemical Agents (SCOEL). The chosen limit values are based on an analysis of economic, social and environmental impacts of the different policy options for each chemical agent, on the criteria of the scientific advice of SCOEL, effectiveness, efficiency and coherence. Those limit values were also agreed by the ACSH. A new package of proposed limit values is expected to be proposed by the Commission at the end of this year.

The legal basis of Article 153(2)(b), in conjunction with Article 153(1)(a) of the Treaty, requires the Council is to act by qualified majority, in accordance with the ordinary legislative procedure with the European Parliament.

The European Parliament has not yet delivered its opinion.

The Committee of Regions has not yet delivered its opinion.

The European Economic and Social Committee adopted its opinion on 21 September 2016.

II. THE COUNCIL'S WORK

The Social Questions Working Party (SQWP) started examining the proposal in May 2016 under the Dutch Presidency. In three meetings the discussions included the related Impact Assessment (IA)[1] and the Member States' replies to the distributed questionnaire.

The Dutch Presidency submitted a progress report (doc. 9625/1/16) to the June EPSCO Council, marking a broad political support for amending the list of carcinogens included in the 2004 Directive on carcinogens and mutagens.

[1] The proposal and the Impact Assessment can be found in docs. 8962/16 + ADD 1 to 3.

Building on this progress, the Slovak Presidency could finalise the technical discussions in a relatively short period of time. While adjusting the recitals taking into account the positions of delegations, the Presidency has suggested maintaining the limit values as proposed by the Commission (doc. 8962/16 ADD 1). At the last Working Party, the majority of delegations supported the Presidency's approach (doc. 11551/16) as a balanced compromise for achieving the objective of reaching a general approach at the Council. Nevertheless, some delegations expressed concerns with regard to the limit values, considering them not ambitious enough (see below under (a)).

On 5 October, Coreper approved the draft proposal as set out in the Annex to this Report with a view to reaching a general approach at the Council (EPSCO) session on 13 October. The Committee took also note of the summary of the discussion on the Impact Assessment (ADD to doc. 1224/16 + COR1) which took place under the Dutch Presidency.

Remaining reservations

(a) Specific reservation: Annex III - Chromium VI (CrVI)

The Commission proposed a limit value of 0,025 mg/m^3. DE, supported by FR, suggested a value of 0,001 mg/m^3 which is the assessment standard for chromium(VI) set in its national law. SE also felt that the limit value for CrVI should be lowered to at least 0,005 mg/m^3. BE has suggested, for the sake of a compromise, the possibility to set a transitional period, whereby the value would be 0,025 mg/m^3 until 1 January 2020 and the value of 0,005 mg/m^3 would be automatically applicable after that date.

In Coreper, BE, DE, DK, FR, NL, LT and SE expressed their view that limit value for Chromium VI maintained in the compromise proposal as proposed by the Commission was not ambitious enough. These delegations announced that they would enter a joint statement on this issue into the Council (EPSCO) minutes on 13 October. At this stage, FR and SE have withdrawn their scrutiny reservations for the sake of compromise. BE and DE were not in a position to do so before the EPSCO Council.

(b) Parliamentary reservations

UK has maintained a parliamentary scrutiny reservation.

III. CONCLUSION

The Council (EPSCO) is invited to reach a General approach on the text, as set out in the Annex to this Report, at its session on 13 October 2016.

ANNEX

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
(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 ('TFEU'), and in particular Article 153(2)(b), in conjunction with Article 153(1)(a), 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,[2]

Having regard to the opinion of the Committee of the Regions,[3]

Acting in accordance with the ordinary legislative procedure,

Whereas:

[2] OJ C , , p.
[3] OJ C , , p.

(1) Directive 2004/37/EC 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 or mutagens is provided for in that Directive by a framework of general principles to enable Member States to ensure the application of the minimum requirements consistently. Binding occupational exposure limit values established on the basis of available information, including scientific and technical data, are important components of the general arrangements for the protection of workers established by that Directive.

(1a) 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 or mutagens at the workplace, prevention or reduction of workers´ exposure to carcinogens or 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 worker´s health, use of a closed system or other measures aimed at the reduction of the level of workers´ exposure.

(1b) For most carcinogens or mutagens it is not scientifically possible to set exposure 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 completely eliminate risks to workers´ health and safety arising from exposure thereto at work (residual risk), it nonetheless contributes to significant reduction of risks arising from such exposure in the stepwise and goal setting approach pursuant to Directive 2004/37/EC. For other carcinogens or mutagens, it is scientifically possible to identify exposure levels below which exposure is not expected to lead to adverse effects.

(1c) Maximum levels of workers`exposure to some carcinogens or mutagens are established by values which pursuant to Directive 2004/37/EC must not be exceeded. Those limit values should be revised and limit values set for additional carcinogens and mutagens.

(2) The limit values set in this Directive should be revised when necessary in the light of available information, including scientific and technical data. That information should, if possible, include data on residual risks to health of the workers and opinions of the Advisory Committee on Safety and Health at Work. Information relating to residual risk, made publically available at the EU level, is valuable for the future work to limit risks from occupational exposure to carcinogens or mutagens, including for future revisions of the limit values set in this Directive.

(3) For some carcinogens and mutagens it is necessary to consider other absorption pathways, including the possibility of penetration through the skin, in order to ensure the best possible level of protection.

(4) The Scientific Committee on Occupational Exposure Limits ('the Committee') assists the Commission, in particular, in evaluating the latest available scientific data and in proposing occupational exposure limits for the protection of workers from chemical risks, to be set at EU level pursuant to Council Directive 98/24/EC[4] and Directive 2004/37/EC. For the chemical agents *o*-toluidine and 2-nitropropane, there were no Committee recommendations available and other sources of scientific information, adequately robust and in the public domain, were considered.[5,6]

---

4 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, 05.05.1998, p. 11).

5 http://monographs.iarc.fr/ENG/Monographs/vol77/mono77-11.pdf http://monographs.iarc.fr/ENG/Monographs/vol99/mono99-15.pdf and http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-11.pdf

6 http://monographs.iarc.fr/ENG/Monographs/vol1-42/mono29.pdf and http://monographs.iarc.fr/ENG/Monographs/vol71/mono71-49.pdf

(5) There is sufficient evidence of the carcinogenicity of respirable crystalline silica dust. On the basis of available information, including scientific and technical data, a limit value for respirable crystalline silica dust should be established. Respirable crystalline silica dust generated by a work process is not subject to classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council.[7] It is therefore appropriate to include work involving exposure to respirable crystalline silica dust generated by a work process in Annex I to Directive 2004/37/EC and to establish a limit value for respirable crystalline silica dust ('respirable fraction').

(6) Guides and examples of good practice produced by the Commission, Member States, social partners, or other initiatives, such as the Social Dialogue "Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it" (NEPSi) are valuable instruments to complement regulatory measures and in particular to support the effective implementation of limit values. These include measures to prevent or minimise exposure such as water assisted suppression to prevent dust from becoming airborne in the case of respirable crystalline silica.

(7) The limit values set out in Annex III to Directive 2004/37/EC for vinyl chloride monomer and hardwood dusts should be revised in the light of more recent scientific and technical data.

(8) 1,2-Epoxypropane meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen within the meaning of Directive 2004/37/EC. On the basis of the available information, including scientific and technical data, it is possible to identify an exposure level below which exposure to this carcinogen is not expected to lead to adverse effects. It is therefore appropriate to establish such a limit value for 1,2-epoxypropane.

[7] 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 (OJ L 353, 31.12.2008, p. 1).

(9) 1,3-Butadiene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for this carcinogen. It is therefore appropriate to establish a limit value for 1,3-butadiene .

(10) 2-Nitropropane meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for this carcinogen. It is therefore appropriate to establish a limit value for 2-nitropropane.

(11) Acrylamide meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for acrylamide. The Committee identified for acrylamide the possibility of significant uptake through the skin. It is therefore appropriate to establish a limit value for acrylamide and to assign to it a notation indicating the possibility of significant dermal uptake.

(12) Certain chromium (VI) compounds meet the criteria for classification as carcinogenic category 1A or 1B in accordance with Regulation (EC) No 1272/2008 and therefore are 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 out a limit value for these chromium VI compounds. It is therefore appropriate to establish a limit value for chromium (VI) compounds that are carcinogens within the meaning of Directive 2004/37/EC.

(13) Ethylene oxide meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for this carcinogen. The Committee identified for ethylene oxide the possibility of significant uptake through the skin. It is therefore appropriate to establish a limit value for ethylene oxide and to assign to it a notation indicating the possibility of significant dermal uptake.

(14) *o*-Toluidine meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for this carcinogen. It is therefore appropriate to establish a limit value for *o*-toluidine and to assign to it a notation indicating the possibility of significant dermal uptake.

(15) Certain refractory ceramic fibres meet the criteria for classification as carcinogenic category 1B in accordance with Regulation (EC) No 1272/2008 and therefore are 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 the refractory ceramic fibres which are carcinogens within the meaning of Directive 2004/37/EC. It is therefore appropriate to establish a limit value for these refractory ceramic fibres.

(16) Bromoethylene meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for this carcinogen. It is therefore appropriate to establish a limit value for bromoethylene.

(17) Hydrazine meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for hydrazine. The Committee identified for this carcinogen the possibility of significant uptake through the skin. It is therefore appropriate to establish a limit value for hydrazine and to assign to it a notation indicating the possibility of significant dermal uptake.

(18) This amendment strengthens the protection of workers' health at their workplace.

(19) The Commission consulted the Advisory Committee on Safety and Health at Work, set up by Council Decision of 22 July 2003. It also carried out a two-stage consultation of the European social partners in accordance with Article 154 of the TFEU.

(20) This Directive respects the fundamental rights and principles enshrined in the Charter of Fundamental Rights of the European Union, in particular in Article 31(1) thereof.

(21) The limit values set in this Directive will be kept under review in the light of the implementation of Regulation (EC) No 1907/2006, in particular to take account of the interaction between limit values set out under Directive 2004/37/EC and DNELs (Derived No Effect Levels) derived for hazardous chemicals under that Regulation.

(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 be better achieved at EU level, the EU may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5(3) of the Treaty on European Union. In accordance with the principle of proportionality, as set out in Article 5(4) of the TEU, this Directive does not go beyond what is necessary in order to achieve those objectives.

(23) Given that the present act concerns the workers' health at their workplace, the deadline for transposition should be two years.

(24) 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 Annex I the following point is added:

‘6. Work involving exposure to respirable crystalline silica dust generated by a work process’.

2. Annex III is replaced by the text in 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 not later than two years after the date of entry into force of this Directive. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law that 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: Limit values and other directly related provisions (Article 16)

A. LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

CAS No ([8])	EC No ([9])	NAME OF AGENT	LIMIT VALUES([10])			Notation([11])
			mg/m^3 ([12])	ppm ([13])	f/ml([14])	
–	–	Hardwood dusts	3 ([15])	–	–	–
–	–	Chromium (VI) compounds which are carcinogens within the meaning of Article 2 (a) (i) of the Directive (as Chromium)	0,025	–	–	–
–	–	Refractory Ceramic Fibres which are carcinogens within the meaning of Article 2 (a) (i) of the Directive	–	–	0,3	–
–	–	Respirable Crystalline Silica Dust	0,1 ([16])	–	–	–

[8] CAS No: Chemical Abstract Service Registry Number.

[9] 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, of Regulation (EC) No 1272/2008.

[10] Measured or calculated in relation to a reference period of eight hours.

[11] Substantial contribution to the total body burden via dermal exposure possible.

[12] mg/m^3 = milligrams per cubic metre of air at 20°C and 101,3 kPa (760 mm mercury pressure).

[13] ppm = parts per million by volume in air (ml/m^3).

[14] f/ml = fibres per millilitre.

[15] Inhalable fraction: if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture.

[16] Respirable fraction.

CAS No ([8])	EC No ([9])	NAME OF AGENT	LIMIT VALUES([10])			Notation([11])
			mg/m^3 ([12])	ppm ([13])	f/ml([14])	
71-43-2	200-753-7	Benzene	3,25	1	–	Skin
75-01-4	200-831-0	Vinyl chloride monomer	2,6	1	–	–
75-21-8	200-849-9	Ethylene oxide	1,8	1	–	Skin
75-56-9	200-879-2	1,2-Epoxypropane	2,4	1	–	–
79-06-1	201-173-7	Acrylamide	0,1	–	–	Skin
79-46-9	201-209-1	2-Nitropropane	18	5	–	–
95-53-4	202-429-0	*o*-Toluidine	0,5	0,1	–	Skin
106-99-0	203-450-8	1,3-Butadiene	2,2	1	–	–
302-01-2	206-114-9	Hydrazine	0,013	0,01	–	Skin
593-60-2	209-800-6	Bromoethylene	4,4	1	–	–

B. OTHER DIRECTLY RELATED PROVISIONS

pm"