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AMENDMENTS
1 - 28

Draft opinion
Joëlle Mélin
(PE625.334v01-00)

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

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

AM_Com_LegOpinion

Amendment 1
Mireille D'Ornano

Proposal for a directive
Recital 1

Text proposed by the Commission	*Amendment*
(1) Principle 10 of the European Pillar of Social Rights[43], 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.	(1) Principle 10 of the European Pillar of Social Rights[43], 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 ***in a suitably safe and hygienic environment*** includes***, in particular,*** protection from carcinogens and mutagens at the workplace.
[43] 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	[43] 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

Or. fr

Amendment 2
Lynn Boylan

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(2) Directive 2004/37/EC of the European Parliament and of the Council[44] aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace.	(2) Directive 2004/37/EC of the European Parliament and of the Council[44] 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. 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.

[44] 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).

Directive 2004/37/EC lays down the relevant minimum requirements on the basis of acquired scientific evidence, and is subject to periodic review in order to improve protection from risks ***arising from*** carcinogens and mutagens. Binding occupational exposure limit values established on the basis of ***scientific*** information 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. 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.

[44] 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).

Or. en

Amendment 3
Mireille D'Ornano

Proposal for a directive
Recital 3

Text proposed by the Commission	*Amendment*
(3) Occupational exposure limit values are part of risk management under Directive 2004/37/EC. Compliance with those limit values is without prejudice to	(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.	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 ***must necessarily*** 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. ***The replacement of carcinogens or mutagens by less dangerous substances seems to be particularly necessary in the case of agricultural workers, who – according to some scientific studies – may have been exposed for long periods to certain dangerous pesticides.***

Or. fr

Amendment 4
Lynn Boylan

Proposal for a directive
Recital 3

Text proposed by the Commission	*Amendment*
(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	(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.

effect. Those measures should include 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 ***such as monitoring systems and rotation by time slot,*** 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. ***It is also crucial that health-checks continue to be arranged for workers beyond the periods in which they are exposed to carcinogens and mutagens.***

Or. en

Amendment 5
Lynn Boylan

Proposal for a directive
Recital 4

Text proposed by the Commission	*Amendment*
(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.	(4) For most carcinogens and mutagens, it is not scientifically possible to identify levels below which exposure would not lead to adverse effects***.*** ***Therefore, actions to phase down, as soon as possible, all relevant agents classified under categories 1A and 1B in accordance with Regulation (EC) 1272/2008, is necessary***. 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.

Or. en

Amendment 6
Mireille D'Ornano

Proposal for a directive
Recital 4

Text proposed by the Commission	*Amendment*
(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.	(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. ***Scientific research to determine the exact value of these limits should be encouraged.***

Or. fr

Amendment 7
Lynn Boylan

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(6) This Directive strengthens the protection of workers' health and safety at	(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***.

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 ***must be ensured***.

Or. en

Amendment 8
Mireille D'Ornano

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(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	(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.	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. ***Particular attention should be paid to agricultural workers, and in particular their exposure to carcinogens and mutagens in certain products regularly used by these workers.***

Or. fr

Amendment 9
Claudiu Ciprian Tănăsescu

Proposal for a directive
Recital 8

Text proposed by the Commission	*Amendment*
(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.	(8) The assessment of health effects of carcinogens subject to this proposal was based on the relevant scientific expertise from the SCOEL ***(for cadmium and its inorganic compounds, beryllium and its inorganic compounds, and formaldehyde)*** and the RAC ***(for arsenic acid and its salts, inorganic arsenic acid compounds and MOCA)***.

Or. ro

Amendment 10
Jadwiga Wiśniewska

Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(12) With regard to cadmium, a limit value of 0,001 mg/m3 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/m3 should apply.	(12) With regard to cadmium, a limit value of 0,001 mg/m3 may be difficult to be complied with in some sectors in the short term. A transitional period of ***ten*** years should therefore be introduced during which the limit value 0,004 mg/m3 should apply.

Or. pl

Amendment 11
Lynn Boylan

Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(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.	(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 ***five*** years should therefore be introduced during which the limit value 0,004 mg/m^3 should apply.

Or. en

Amendment 12
Luke Ming Flanagan

Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(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**.**	(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 ***for the first three years, then 0,003 mg/m^3 for the following two years, and***

0,002 mg/m³ for the final two years, reducing permanently thereafter to 0,001 mg/m

Or. en

Amendment 13
Lynn Boylan

Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(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. 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 under the scope of Directive2004/37/EC and to assign a notation for skin and respiratory sensitisation.	(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 (category 1) as designated by the International Agency for Research on Cancer,*** 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 under the scope of Directive2004/37/EC and to assign a notation for skin and respiratory sensitisation.

Or. en

Amendment 14
Luke Ming Flanagan

Proposal for a directive
Recital 14

Text proposed by the Commission	*Amendment*
(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**.**	(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 ***for the first three years, reducing then to 0,0004 mg/m^3 for the following two years, and finally and permanently thereafter to 0,0002 mg/m^3;***

Or. en

Amendment 15
Soledad Cabezón Ruiz

Proposal for a directive
Recital 17

Text proposed by the Commission	*Amendment*
(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. 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, 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[48].	(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. On the basis of the available information, including scientific and technical data, ***the concentrations of formaldehyde used in healthcare are minimal in comparison with those used in industry, and 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, 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[48].

48 https://echa.europa.eu/documents/10162/13641/formaldehyde_cion_reqst_axvdossier_en.pdf/11d4a99a7210-839a-921d-1a9a4129e93e

48 https://echa.europa.eu/documents/10162/13641/formaldehyde_cion_reqst_axvdossier_en.pdf/11d4a99a7210-839a-921d-1a9a4129e93e

Or. es

Amendment 16
Soledad Cabezón Ruiz

Proposal for a directive
Recital 17 a (new)

Text proposed by the Commission	*Amendment*
	(17a) Formaldehyde is routinely used in European healthcare centres for the standardised fixation of tissue samples; a pathologist's diagnosis of a variety of diseases, including cancer, is based on the recognition of microscopic traces in tissue fixed in formaldehyde.

Or. es

Amendment 17
Soledad Cabezón Ruiz

Proposal for a directive
Recital 17 b (new)

Text proposed by the Commission	*Amendment*
	(17b) Until such time as other fixatives are available in the EU that are able to perform the crucial role that formaldehyde plays in patient care, the healthcare sector should be exempt from any restrictions on formaldehyde use that could give rise to multiple errors in diagnosis, putting countless European

patients at risk.

Or. es

Amendment 18
Soledad Cabezón Ruiz

Proposal for a directive
Recital 17 c (new)

Text proposed by the Commission	*Amendment*
	(17c) Healthcare centres in the EU should take all appropriate measures to keep formaldehyde exposure among their staff within safe limits.

Or. es

Amendment 19
Lynn Boylan

Proposal for a directive
Recital 21

Text proposed by the Commission	*Amendment*
(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[50] , 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.	(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[50] , 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. ***Systematic, regular and documented revisions must be implemented on the limit values of existing agents.***
[50] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the	[50] 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).	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).

Or. en

Amendment 20
Mireille D'Ornano

Proposal for a directive
Recital 22

Text proposed by the Commission	*Amendment*
(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.	***deleted***

Or. fr

Amendment 21
Luke Ming Flanagan

Proposal for a directive
Recital 23

Text proposed by the Commission	*Amendment*
(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.	(23) In implementing this Directive***, while bearing in mind at all times that worker safety is paramount,*** 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.

Or. en

Amendment 22
Nicola Caputo

Proposal for a directive
Recital 23

Text proposed by the Commission	*Amendment*
(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.	(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 ***–*** ***especially*** on SMEs***, micro-enterprises and young entrepreneurs –*** in order to make sure that SMEs are not disproportionately affected, with specific attention for ***the*** administrative burden, and to publish the results of such assessments.

Or. it

Amendment 23
Soledad Cabezón Ruiz

Proposal for a directive
Recital 23

Text proposed by the Commission	*Amendment*
(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.	(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 ***and healthcare facilities***. 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 **–** ***paying*** specific attention ***to*** micro-enterprises and ***the*** administrative burden **–** and to publish the results of such assessments.

Or. es

Amendment 24
Mireille D'Ornano

Proposal for a directive
Recital 23

Text proposed by the Commission	*Amendment*
(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.	(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. ***Public health must nevertheless take priority over other considerations, in particular financial***

considerations, in the assessment of the constraints imposed on undertakings by national rules on exposure to carcinogens and mutagens.

Or. fr

Amendment 25
Jadwiga Wiśniewska

Proposal for a directive
Annex – paragraph 1 – table – column 11 – row 2

Text proposed by the Commission	*Amendment*
Transitional measures	Transitional measures
0,004 mg/m3 until xx yyyy 202z [***7*** years]	0,004 mg/m3 until xx yyyy 202z [***10*** years]

Or. en

Amendment 26
Jadwiga Wiśniewska

Proposal for a directive
Annex – paragraph 1 - table – column 4 – row 4

Text proposed by the Commission	*Amendment*
mg/m3	mg/m3
0,01	0,01 ***(inhalable fraction)***

Or. en

Amendment 27
Jadwiga Wiśniewska

Proposal for a directive
Annex – paragraph 1 - column 7 – row 5

Text proposed by the Commission	*Amendment*
mg/m3	mg/m3

0,738	***0,74***

Or. en

Amendment 28
Lynn Boylan

Proposal for a directive
Annex – paragraph 1 - table

Text proposed by the Commission

Name of agent	EC No	CAS No	Limit values						Notation	Transitional measures
			8 hours			Short-term				
			mg/m3	ppm	f/ml	mg/m3	ppm	f/ml		
Cadmium and its inorganic compounds	–	–	0,001	–	–	–	–	–		Limit value 0,004 mg/m3 until xx yyyy 202z [***7*** years]
Beryllium and inorganic beryllium compounds	–	–	0,0002	–	–	–	–	–	dermal and respiratory sensitisation	Limit value 0,0006 mg/m3 until xx yyyy 202z [***5*** years]
Arsenic acid and its salts, as well as inorganic arsenic compounds	–	–	0,01	–	–	–	–	–	–	For the copper smelting sector the limit value will come into force on xx yyyy 202z [2 Years]
Formaldehyde	200-	50-	0,37	0,3	–	0,73	0,6	–	derma	

	001-8	00-0				8			l senitis ation	
4,4'-Methylene-bis(2-chloroaniline)	202-918-9	101-14-4	0,01	–	–	–	–	–	skin	

Amendment

Name of agent	EC No	CAS No	Limit values						Notation	Transitional measures
			8 hours			Short-term				
			mg/m3	ppm	f/ml	mg/m3	ppm	f/ml		
Cadmium and its inorganic compounds	–	–	0,001	–	–	–	–	–		Limit value 0,004 mg/m3 until xx yyyy 202z [***3*** years]
Beryllium and inorganic beryllium compounds	–	–	0,0002	–	–	–	–	–	dermal and respiratory sensitisation	Limit value 0,0006 mg/m3 until xx yyyy 202z [***3*** years]
Arsenic acid and its salts, as well as inorganic arsenic compounds	–	–	0,01	–	–	–	–	–	–	For the copper smelting sector the limit value will come into force on xx yyyy 202z [2 Years]
Formaldehyde	200-001-8	50-00-0	0,37	0,3	–	0,738	0,6	–	dermal senitisation	
4,4'-Methylene-bis(2-chloroaniline)	202-918-9	101-14-4	0,01	–	–	–	–	–	skin	

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