Basic information

2016/0130(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Protection of workers from exposure to carcinogens or mutagens at work: exposure limit values Amending Directive 2004/37/EC 1999/0085(COD) See also 2017/0004(COD) **Subject** 3.40.01 Chemical industry, fertilizers, plastics 4.15.15 Health and safety at work, occupational medicine	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
EMPL Employment and Social Affairs	ULVSKOG Marita (S&D)	02/06/2016
	Shadow rapporteur ROLIN Claude (PPE) MCINTYRE Anthea (ECR) WEBER Renate (ALDE) LE HYARIC Patrick (GUE/NGL) DELLI Karima (Verts/ALE) AGEA Laura (EFDD) MÉLIN Joëlle (ENF)	

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	MÉLIN Joëlle (ENF)	01/07/2016
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
JURI Legal Affairs	CHRYSOGONOS Kostas (GUE/NGL)	11/07/2016

Committee for opinion on the legal basis	Rapporteur for opinion	Appointed

	JURI Legal Affairs	GUTELAND Jytte (S&D)	07/06/2017

Council of the European Union	Council configuration	Meetings	Date
	Employment, Social Policy, Health and Consumer Affairs	3583	2017-12-08
	Employment, Social Policy, Health and Consumer Affairs	3475	2016-06-16

European Commission	Commission DG	Commissioner
	Employment, Social Affairs and Inclusion	THYSSEN Marianne

European Economic and Social Committee

European Committee of the Regions

Key events

Date	Event	Reference	Summary
13/05/2016	Legislative proposal published	COM(2016)0248	Summary
25/05/2016	Committee referral announced in Parliament, 1st reading		
16/06/2016	Debate in Council		
28/02/2017	Vote in committee, 1st reading		
28/02/2017	Committee decision to open interinstitutional negotiations with report adopted in committee		
09/03/2017	Committee report tabled for plenary, 1st reading	A8-0064/2017	Summary
13/03/2017	Committee decision to enter into interinstitutional negotiations announced in plenary (Rule 72)		
15/03/2017	Committee decision to enter into interinstitutional negotiations confirmed by plenary (Rule 72)		
30/08/2017	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE610.591 GEDA/A/(2017)008135	
24/10/2017	Debate in Parliament		
25/10/2017	Decision by Parliament, 1st reading	T8-0410/2017	Summary
25/10/2017	Results of vote in Parliament		
08/12/2017	Act adopted by Council after Parliament's 1st reading		
12/12/2017	Final act signed		
12/12/2017	End of procedure in Parliament		
27/12/2017	Final act published in Official Journal		

Technical information

Procedure reference	2016/0130(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Amendments and repeals	Amending Directive 2004/37/EC 1999/0085(COD) See also 2017/0004(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 153-p2
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	EMPL/8/06557

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE593.996	22/11/2016	
Amendments tabled in committee		PE595.651	12/01/2017	
Committee opinion	JURI	PE592.336	01/02/2017	
Committee report tabled for plenary, 1st reading/single reading		A8-0064/2017	09/03/2017	Summary
Specific opinion	JURI	PE606.153	20/06/2017	
Text agreed during interinstitutional negotiations		PE610.591	12/09/2017	
Text adopted by Parliament, 1st reading/single reading		T8-0410/2017	25/10/2017	Summary

Council of the EU

Document type	Reference	Date	Summary
Coreper letter confirming interinstitutional agreement	GEDA/A/(2017)008135	11/07/2017	
Draft final act	00045/2017/LEX	13/12/2017	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2016)0248	13/05/2016	Summary
Document attached to the procedure	SWD(2016)0152	13/05/2016	
Document attached to the procedure	SWD(2016)0153	13/05/2016	
Commission response to text adopted in plenary	SP(2017)766	06/12/2017	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	PT_PARLIAMENT	COM(2016)0248	19/07/2016	
Contribution	IT_SENATE	COM(2016)0248	25/07/2016	
Contribution	HR_PARLIAMENT	COM(2016)0248	18/04/2017	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES3439/2016	21/09/2016	

Additional information

Source	Document	Date
European Parliament	Briefing	
European Commission	EUR-Lex	

Final act

Directive 2017/2398
OJ L 345 27.12.2017, p. 0087 Summary

Protection of workers from exposure to carcinogens or mutagens at work: exposure limit values

2016/0130(COD) - 13/05/2016 - Legislative proposal

PURPOSE: to improve workers' health protection by reducing occupational exposure to carcinogenic chemical agents.

PROPOSED ACT: Directive of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Directive 2004/37/EC aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace and lays down minimum requirements to that effect including limit values, on the basis of the available scientific and technical data.

The provisions of the Directive apply to any chemical agent that meets the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008 (CLP).

Estimates of the recent and future burden of occupational diseases indicate that work-related cancer is a problem and will remain so in the future as a result of exposure of workers to carcinogens. **Cancer is the first cause of work-related deaths in the EU**. Annually, **53 % of occupational deaths** are attributed to cancer, compared with 28% for circulatory diseases and 6% for respiratory diseases.

Ensuring a safe and healthy work environment for over 217 million workers in the EU is a strategic goal for the Commission according to its recent Communication on the EU Strategic Framework on Health and Safety at Work 2014 – 2020 (setting out an occupational health and safety strategy).

Occupational exposure limit values set under the Directive 2004/37/EC should when appropriate be revised to take into account new scientific data, improvements in measurement techniques, risk management measures and other relevant factors.

IMPACT ASSESSMENT: as regards respirable crystalline silica dust, the option maintained is the one which includes the possibility of inclusion in Annex I to the Directive together with the establishment of a limit value for respirable crystalline silica dust (respirable fraction) in Annex III.

The limit values to be introduced in Annex III proposed in this initiative and agreed by the Advisory Committee on Safety and Health at work (ACSH).

According to the impact assessment, this is estimated to save around **100 000 lives by 2069**. As regards the impact on workers, this proposal should result in benefits in terms of preventing workers from getting avoidable work-related cancer, and thus preventing unnecessary suffering and illness. In addition, this proposal would also prevent **unnecessary health costs**, as follows:

- respirable crystalline silica dust: the proposed limit value at 0.1 mg/m3 will provide for 99,000 avoided cancer cases by 2069 for a total monetized health benefit quantified between EUR 34 and 89 billion;
- hardwood dust: a limit value of 3 mg/m3 will provide for a total monetized health benefit between EUR 12 and 54 million; benefits are also expected in relation to introducing an exposure limit value at 0.025 mg/m3 for all chromium (VI) compounds.

CONTENT: the proposal seeks to revise the limit values in Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work and to revise or to introduce exposure limit values for 13 chemical agents. More specifically, it aims to:

- include in Annex I to the Directive work involving exposure to **respirable crystalline silica dust generated by a work process** and establish a corresponding limit value in Annex III. The words ‘respirable crystalline silica dust’ used in Article 1 refer to the dust particles that reach the alveoli;
- establish in Annex III limit values for further **10 additional carcinogens**: certain chromium compounds (VI); some refractory ceramic fibers; 1,2-epoxypropane, 1,3-butadiene, 2 nitropropane; Acrylamide; Bromoethylene; Chromium VI; Ethylene oxide; Hydrazine; o-toluidine. It is appropriate to establish a limit value for hydrazine and to assign to it a notation indicating the possibility of significant dermal uptake. A **skin notation** assigned to a limit value identifies the possibility of significant uptake through the skin;
- revise the existing limit values for **hardwood dusts and vinyl chloride monomer** in the light of available scientific data.

This proposal leaves Member States the possibility to keep or set more favourable standards for workers and the flexibility to take into account specific features in their national situation.

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.

Protection of workers from exposure to carcinogens or mutagens at work: exposure limit values

2016/0130(COD) - 25/10/2017 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 540 votes to 6 with 119 abstentions, a legislative resolution on the 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.

To recall, the proposed directive aims to improve workplace conditions and protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. It introduces 11 carcinogenic substances to the current list of dangerous substances and revises the limit values for two substances that are already listed.

Information for the competent authority: Directive 2004/37/EC provides that where the results of the risk assessment reveal a risk to workers' health or safety, employers shall, when requested, make available to the competent authority appropriate information on:

- the activities and/or industrial processes carried out, including the reasons for which carcinogens or mutagens are used;
- the quantities of substances or preparations manufactured or used which contain carcinogens or mutagens;
- the number of workers exposed;
- the preventive measures taken;
- the type of protective equipment used;
- the nature and degree of exposure.

The amended text provides that **Member States shall take into account the above information in their reports submitted to the Commission** under Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work.

Health surveillance: Member States shall **establish arrangements for carrying out relevant health surveillance of workers** for whom the results of the risk assessment reveal a risk to health or safety. The doctor or authority responsible for the health surveillance of workers may indicate that health surveillance **must continue after the end of exposure** for as long as they consider it to be necessary to safeguard the health of the worker concerned.

Furthermore, all cases of cancer identified in accordance with national law or practice as resulting from occupational exposure to a carcinogen or mutagen shall be **notified** to the competent authority.

The amended text stresses that appropriate and consistent **data collection** by Member States from employers is necessary to ensure the safety and proper care of workers.

Limit values for occupational exposure: Parliament revised the limit values for the following substances:

- **hardwood dusts**: there will be an exposure limit value of 3 mg/m3 for 5 years after the entry into force of the directive and thereafter a **limit of 2 mg/m3**;
- **Chromium VI:** there will be an exposure limit value of 0.010 mg/m3 for a period of 5 years after the date of transposition of the directive; after that period a **limit of 0.005 mg/m3** will apply.

Evaluation: the Commission shall, as part of the next evaluation of the implementation of the Directive, also evaluate the need to **modify the limit value for respirable crystalline silica dust** (set at 0.1mg/m3 in the amended text). The Commission shall propose, where appropriate, necessary amendments and modifications related to that substance.

Parliament also required that by **the first quarter of 2019, the Commission should assess the option of amending the scope of the Directive to include reprotoxic substances**. On that basis, the Commission shall present, if appropriate, and after consulting management and labour, a legislative proposal.

The text goes on to recall that in its opinion on **refractory ceramic fibres**, the Advisory Committee on Safety and Health at Work (ACSH) agreed that a binding occupational exposure limit value is necessary for this substance. The Commission should therefore encourage the ACSH to submit an up-to-date opinion on refractory ceramic fibres with a view to reaching a common position on the limit value for that substance.

Protection of workers from exposure to carcinogens or mutagens at work: exposure limit values

2016/0130(COD) - 12/12/2017 - Final act

PURPOSE: to better protect workers from exposure to carcinogens or mutagens in their workplace.

LEGISLATIVE ACT: Directive (EU) 2017/2398 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.

CONTENT: this Directive amending Directive 2004/37/EC improves workplace conditions and protects workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. It introduces 11 carcinogenic substances to the current list of dangerous substances and revises the limit values for two substances that are already listed.

- crystalline silica dust alveolar,
- 1,2-epoxypropane,
- 1,3-butadiene,
- 2-nitropropane,
- acrylamide,
- certain chromium (VI) compounds,
- ethylene oxide,
- o-toluidine,
- refractory ceramic fibres,
- bromoethylene
- and hydrazine.

Health surveillance: the Member States shall establish, in accordance with national law or practice, arrangements for carrying out relevant health surveillance of workers for whom the results of the assessment reveal a risk to health or safety.

The doctor or authority responsible for the **health surveillance** of workers may indicate that health surveillance must continue after the end of exposure for as long as they consider it to be necessary to safeguard the health of the worker concerned.

All cases of cancer identified in accordance with national law or practice as resulting from occupational exposure to a carcinogen or mutagen shall be notified to the competent authority.

Revision of the exposure limit values: the amending Directive revises the limit values for the following substances:

- **hardwood dust**: the limit value for exposure is set at 3 mg/m3 until 17 January 2023 and at 2 mg/m3 thereafter. The distinction between hardwood and softwood dust should be further assessed as regards the limit value set out in that Annex, as recommended by Scientific Committee on Occupational Exposure Limits (SCOEL) and the International Agency for Research on Cancer;
- **Chromium (VI) compounds which are carcinogens**: the Directive provides an initial exposure limit value of 0.010 mg/m3 until 17 January 2025, after which this value will be lowered to 0.005 mg/m3. A derogation is provided for welding and plasma cutting processes or similar processes that generate fumes: the exposure limit value is fixed at 0.025 mg/m3 until 17 January 2025 and will then be 0.005 mg/m3.

Reprotoxic substances: the Commission shall **assess** the possibility of including reprotoxic substances in the list of dangerous substances by the **first quarter of 2019**. On this basis, it shall submit, if necessary, a legislative proposal, after consulting the social partners.

Lastly, as part of the next evaluation of the implementation of the Directive, the Commission will have to **evaluate** the need to modify the limit value for **respirable crystalline silica dust** (set at 0.1 mg / m³ in the amending Directive). The Commission shall propose, if necessary, the necessary modifications relating to this substance.

ENTRY INTO FORCE: 16.1.2017.

TRANSPOSITON: by 17.1.2020.

Protection of workers from exposure to carcinogens or mutagens at work: exposure limit values

2016/0130(COD) - 09/03/2017 - Committee report tabled for plenary, 1st reading/single reading

The Committee on Employment and Social Affairs adopted the report by Marita ULVSKOG (S&D, SE) on the 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 inclusions of reprotoxic substances: Members proposed broadening the scope of the Directive to allow for the inclusion of reprotoxic substances. They stressed that reprotoxic substances were of great concern and that the organisation of workplace prevention should be **applied as for carcinogens and mutagens**.

The amended text clarifies that the requirements laid down in the Directive should be considered as minimum requirements, with Member States having the possibility of setting more stringent binding occupational exposure limits.

It is essential to take the **precautionary principle** into account, especially where there are uncertainties as to the impact of dealing with substances and their mixtures on workers' health or where available scientific and technical data is not sufficient.

Limit values: the report introduced stricter limit values for several substances:

- **wood dust**: Members do not wish to distinguish between hardwood dust and softwood dust. They consider that the limit value of 2 mg/m3 should constitute the EU's common limit value (the Commission proposed a limit value of 3 mg/m3 for hardwood dust);
- **chromium VI**: a limit value of 0.001 mg/m3 is proposed (instead of 0.025 mg/m3);
- **respirable crystalline silica dust**: a limit value of 0.05 mg/m3 is proposed (instead of 0.1 mg/m3).

The Advisory Committee on Safety and Health at Work (ACSH) should also submit **up-to-date opinions** on the binding occupational exposure limits on respirable cristalline silica, hardwood dusts, acrylamide, 1,3-butadiene, chromium VI and refractory ceramic fibres.

Health surveillance measures: Members considered that health surveillance should be provided for all workers exposed (i) prior to exposure; (ii) at regular intervals during the exposure period; (iii) after the end of the exposure and the end of their employment.

Data collection: Members called on the Commission to:

- **support best practices** with regard to data collection between Member States and propose how data collection can be improved. The Member States should provide the Commission with information for the purposes of its reports on the implementation of Directive 2004/37/EC;
- develop a **harmonised methodology** for measuring workers' exposure to carcinogens, mutagens and reprotoxic substances at Union level.