Basic information

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

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
EMPL Employment and Social Affairs	ROLIN Claude (PPE)	14/03/2017
	Shadow rapporteur ULVSKOG Marita (S&D) MCINTYRE Anthea (ECR) CALVET CHAMBON Enrique (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)	20/02/2017
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
AGRI Agriculture and Rural Development	The committee decided not to give an opinion.	

JURI Legal Affairs	The committee decided not to give an opinion.	

Committee for opinion on the legal basis	Rapporteur for opinion	Appointed
JURI Legal Affairs	VOSS Axel (PPE)	05/06/2018

Council of the European Union

Council configuration	Meetings	Date
Employment, Social Policy, Health and Consumer Affairs	3548	2017-06-15
Environment	3666	2018-12-20

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
10/01/2017	Legislative proposal published	COM(2017)0011	Summary
19/01/2017	Committee referral announced in Parliament, 1st reading		
15/06/2017	Debate in Council		
27/03/2018	Vote in committee, 1st reading		
27/03/2018	Committee decision to open interinstitutional negotiations with report adopted in committee		
11/04/2018	Committee report tabled for plenary, 1st reading	A8-0142/2018	Summary
16/04/2018	Committee decision to enter into interinstitutional negotiations announced in plenary (Rule 72)		
18/04/2018	Committee decision to enter into interinstitutional negotiations confirmed by plenary (Rule 72)		
15/11/2018	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE630.596	
10/12/2018	Debate in Parliament		
11/12/2018	Decision by Parliament, 1st reading	T8-0488/2018	Summary
11/12/2018	Results of vote in Parliament		
20/12/2018	Act adopted by Council after Parliament's 1st reading		
16/01/2019	Final act signed		

16/01/2019	End of procedure in Parliament		
31/01/2019	Final act published in Official Journal		

Technical information

Procedure reference	2017/0004(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 2016/0130(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 153-p2
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	EMPL/8/09011

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE613.290	08/11/2017	
Amendments tabled in committee		PE615.368	21/12/2017	
Committee report tabled for plenary, 1st reading/single reading		A8-0142/2018	11/04/2018	Summary
Specific opinion	JURI	PE623.751	03/07/2018	
Text agreed during interinstitutional negotiations		PE630.596	24/10/2018	
Text adopted by Parliament, 1st reading/single reading		T8-0488/2018	11/12/2018	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00060/2018/LEX	16/01/2019	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2017)0011	10/01/2017	Summary
Document attached to the procedure	SWD(2017)0007	12/01/2017	

Document attached to the procedure	SWD(2017)0008	12/01/2017	
Commission response to text adopted in plenary	SP(2019)44	23/01/2019	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	IT_SENATE	COM(2017)0011	15/03/2017	
Contribution	PT_PARLIAMENT	COM(2017)0011	15/03/2017	
Contribution	RO_SENATE	COM(2017)0011	22/03/2017	
Contribution	HR_PARLIAMENT	COM(2017)0011	18/04/2017	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0856/2017	31/05/2017	

Additional information

Source	Document	Date
European Parliament	Briefing	
European Commission	EUR-Lex	

Final act

Directive 2019/0130
OJ L 030 31.01.2019, p. 0112 Summary

Protection of workers from the risks related to exposure to carcinogens or mutagens at work: limit values and skin notations

2017/0004(COD) - 10/01/2017 - Legislative proposal

PURPOSE: to make technical amendments to Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

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: according to latest statistics, **cancer is the first cause of work-related deaths in the EU** (annually, 53 % of occupational deaths are attributed to cancer, notably caused by exposure to carcinogenic substances at work). It is estimated that **every hour in EU, between 7-12 people die of cancer** because of past exposure to carcinogenic substances at work. The Commission took a first step to address these issues by adopting on 13

May 2016 a legislative proposal to amend Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work with a view to revise or to introduce exposure limit values for 13 chemical agents.

It is now proposed to establish **new limit values and/or skin notations for 7 more carcinogens**.

This is estimated to result in increased protection for at least 4 million workers and improved clarity for employers and enforcers. Together it is estimated that both proposals would prevent over 100 000 deaths caused by work-related cancer.

IMPACT ASSESSMENT: this proposal is supported by an impact assessment which compared the social, economic and environmental impacts of a number of different options envisaged for each chemical agent analysed. The preferred option was the one which took account of the following criteria:

- the scientific information (in particular the Scientific Committee on Occupational Exposure Limits recommendations (SCOEL)),
- effectiveness, efficiency and coherence.

Cost and benefits were calculated **over a 60-year period**, in line with the future cancer burden estimated over the same period, to take proper account of the cancer latency period.

CONTENT: the proposed Directive sets a number of general minimum requirements to **eliminate or reduce exposure for all carcinogens and mutagens falling under its scope**.

Minimum requirements of exposure limits: in line with the proposal, employers must identify and assess risks to workers associated with exposure to specific carcinogens (and mutagens) at the workplace, and must prevent exposure where risks occur. Substitution with a non or less-hazardous process or chemical agent is required where this is technically possible. Where substitution is not technically possible chemical carcinogens must, as far as it is technically possible, be manufactured and used in a closed system to **prevent exposure**.

Where this is not technically possible, **worker exposure must be reduced to as low a level** as is technically possible (this is the minimisation obligation under the Directive).

Exposure limits: in addition to these general minimum requirements, the Directive clearly indicates that the setting of occupational exposure limit values for the inhalation route of exposure for particular carcinogens and mutagens is an integral part of the mechanism for protecting workers. Those values still need to be set for the chemical agents for which no such values exist and be revised whenever this becomes possible in the light of more recent scientific data.

Occupational exposure limit values set out in Annex III of the Directive should, when appropriate, be revised to take into account new scientific data.

On this basis, it is proposed to take two specific measures:

- include in Annex I to the Directive work involving exposure to oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine and establish a corresponding skin notation in Part B of Annex III to the Directive (used engine oils);
- establish in Annex III limit values supplemented by skin notations for further 5 additional carcinogens, as well as skin notations independently of limit values for 2 carcinogens, including for **mineral oils as used engine oils** (polycyclic aromatic hydrocarbons mixtures which contain benzo [a]pyrene).

Protection of workers from the risks related to exposure to carcinogens or mutagens at work: limit values and skin notations

2017/0004(COD) - 11/12/2018 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 585 votes to 46, with 35 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.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

Diesel engine exhaust: the amended text added to Annex I of Directive 2004/37/EC the work involving exposure to such exhaust gases and set an occupational exposure limit value in Annex III of **50µg/m³ (0.05mg/m³)** calculated on the basis of elemental carbon.

The limit value shall apply from **four years** after the date of entry into force of this amending directive. For underground mining and tunnel construction the limit value shall apply from **seven years** after the date of entry into force of this amending directive.

In a recital, it is recalled that the International Agency for Research on Cancer (IARC), which has classified diesel engine exhaust emissions as carcinogenic to humans (category 1), has clarified that, while the amount of particulates and chemicals are reduced in the newer types of diesel engines, it is not yet clear how the quantitative and qualitative changes will translate into altered health effects.

Mineral oils: it is proposed to include in Annex I to Directive 2004/37/EC work exposed to mineral oils that have previously been used in internal combustion engines to lubricate and cool moving parts of the engine and to include in Annex III to that Directive a **'skin' notation** indicating the possibility of significant absorption through the skin.

To limit dermal exposure, a range of best practices can be used, including the use of personal protective equipment, such as gloves, and the removal and cleaning of contaminated clothing. Strict compliance with these practices, as well as newly emerging best practices, could help reduce this exposure.

Polycyclic aromatic hydrocarbons mixtures (PAHs): these mixtures, in particular those containing benzo[a]pyrene, are carcinogenic within the meaning of Directive 2004/37/EC. Exposure to such mixtures may occur during work involving burning processes, such as from combustion engine exhaust, and high temperature combustion processes, among others. The Advisory Committee on Safety and Health at Work (ACSH) identified the possibility of significant uptake through the skin for those mixtures and the ACSH agreed on the importance of introducing an occupational exposure limit value for PAHs mixtures and has recommended carrying out work to evaluate the scientific aspects with a view to proposing an occupational exposure limit value in the future. It is therefore proposed to **assign in Annex III to Directive 2004/37/EC a 'skin' notation** indicating the possibility of significant absorption through the skin.

Further investigations should also be carried out to assess whether it is necessary to set a limit value for PAHs mixtures in order to better protect workers from those mixtures.

Agreements between social partners: any agreements between social partners concluded in the field covered by the Directive shall be listed on the website of the European Agency for Safety and Health at Work (EU-OSHA). Their list shall be updated regularly.

Revision: no later than in the first quarter of 2019, the Commission, taking into account the latest developments in scientific knowledge, should assess the option of amending the scope of Directive 2004/37/EC **to include reprotoxic substances**. On that basis, the Commission should present a legislative proposal, if appropriate, after consulting management and labour.

The amended text also underlined the importance:

- of protecting workers exposed to carcinogenic or mutagenic substances resulting from the preparation, administration or disposal of **hazardous drugs**, including cytostatic or cytotoxic drugs;
- and from work involving exposure to carcinogenic or mutagenic substances in **cleaning, transport, laundry and waste disposal of hazardous drugs** or materials contaminated by hazardous drugs.

The guidelines published by the Commission to reduce occupational health and safety risks in the healthcare sector shall be without prejudice to possible further legislative proposals or other initiatives.

Protection of workers from the risks related to exposure to carcinogens or mutagens at work: limit values and skin notations

2017/0004(COD) - 16/01/2019 - Final act

PURPOSE: to improve the protection of workers from the risks associated with exposure to carcinogens or mutagens at work.

LEGISLATIVE ACT: Directive (EU) 2019/130 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: the Directive amends Directive 2004/37/EC by introducing exposure limit values for 8 additional carcinogens or mutagens in order to better protect workers at EU level. It is a question of:

- emissions from diesel engines,
- mineral oils that have previously been used in internal combustion engines,
- trichloroethylene,
- 4,4′-methylenedianiline,
- epichlorohydrin,
- ethylene dibromide,
- ethylene dichloride and
- mixtures of polycyclic aromatic hydrocarbons, in particular those containing benzo[a]pyrene.

The revision is based on the opinions of the Scientific Committee on Occupational Exposure Limits to Chemical Agents (SCOEL) and the Advisory Committee on Safety and Health at Work (ACSH).

Limit values

- Exhaust gases from diesel engines: the Directive sets an occupational exposure limit value in Annex III of 50µg/m³ (0.05mg/m³) calculated on the basis of elemental carbon. The limit value will apply from 21 February 2023. For underground mining and tunnel excavation, the limit value shall apply from 21 February 2026.

- Mineral oils: the Directive establishes a ‘Skin’ notion for oils that have previously been used in internal combustion engines to lubricate and cool moving parts of the engine, indicating the possibility of significant absorption of the substance through the skin. Dermal exposure may be limited by the implementation of good practices, including the use of personal protective equipment, such as gloves.
- Trichloroethylene: workers' exposure to this substance should be limited to 54.7 mg/m3 over a long period of time and 164.1 mg/m3 over a short period of time. A ‘Skin’ notion indicating the possibility of significant dermal absorption of the substance is established.
- Epichlorohydrin: exposure should be limited to 1.9 mg/m3. A ‘Skin’ notion indicating the possibility of significant dermal absorption is established.
- Ethylene dichloride: the Directive establishes an exposure limit value of 8.2 mg/m3 and a ‘Skin’ notion.
- Polycyclic aromatic hydrocarbons mixtures, in particular those containing benzo[a]pyrene, are carcinogenic within the meaning of Directive 2004/37/EC. Exposure to such mixtures may occur during work involving burning processes, such as from combustion engine exhaust, and high temperature combustion processes, among others.

Agreements between social partners

The Directive provides that any agreements between the social partners concluded in the field covered by the Directive must be listed on the website of the European Agency for Safety and Health at Work (EU-OSHA). Their list should be regularly updated.

Revision

No later than in the first quarter of 2019, the Commission, taking into account the latest developments in scientific knowledge, shall assess the option of amending the scope of Directive 2004/37/EC to include reprotoxic substances. On that basis, the Commission should present a legislative proposal, if appropriate, after consulting management and labour.

The Directive also emphasises the importance of protecting workers who are exposed to carcinogens or mutagens resulting from:

- the preparation, management or disposal of hazardous drugs, including cytostatic or cytotoxic drugs, and
- work involving exposure to carcinogens or mutagens through the cleaning, transport, laundering and disposal of hazardous drugs or equipment contaminated with hazardous drugs, as well as through personal care of patients whose treatment includes the use of hazardous drugs.

ENTRY INTO FORCE: 20.2.2019.

TRANSPOSITION: no later than 20.2.2021.

Protection of workers from the risks related to exposure to carcinogens or mutagens at work: limit values and skin notations

2017/0004(COD) - 11/04/2018 - Committee report tabled for plenary, 1st reading/single reading

The Committee on Employment and Social Affairs adopted the report by Claude ROLIN (EPP, BE) 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 committee recommended that the European Parliament’s position adopted at first reading under the ordinary legislative procedure should amend the Commission proposal as follows:

Diesel engine exhaust: Members proposed including in Annex I work involving exposure to such exhaust gases and **setting an occupational exposure limit value** in Annex III of 50µg/m³ (0.05 mg/m³) calculated on the basis of elemental carbon. They recommended considering emissions from all diesel engines, without distinguishing between them.

By 30 June 2019, the Commission shall, after consulting the Member States and the social partners, **assess** the need to modify the limit values for diesel engine exhaust emissions. The Commission shall propose, where appropriate, necessary amendments related to that process.

Polycyclic aromatic hydrocarbons: in the forthcoming evaluation of the implementation of the Directive, the Commission shall also examine the possibility of extending entry 2 in the Annex I to cover work involving burning processes and high temperature combustion processes and to **set a limit value for benzo[a]pyrene** in order better to protect workers from polycyclic aromatic hydrocarbons mixtures.

Members proposed to extend the ‘skin notation’ to all polycyclic aromatic hydrocarbon mixtures.

Social partners' agreements: the Commission shall encourage the social partners to conclude social dialogue agreements providing guidance and tools to support the effective implementation of the employers' obligations laid down in this Directive. Those agreements shall be listed in Annex IVa. That list shall be regularly updated.

In addition, Members proposed that Member States shall communicate to the Commission the **national law and practices** that ensure that their competent authorities have a sufficient number of trained staff and other resources necessary to carry out their tasks related to proper and effective implementation of this Directive.

Long-term process: the amended text stressed that this Directive, which amends Directive 2004/37/EC, is a further step in a longer process to update that Directive.

Further amendments to that Directive shall address the issue of exposure of workers to carcinogenic or mutagenic substances resulting from the preparation, administration or disposal of **hazardous drugs**, including cytotoxic drugs, and work involving exposure to carcinogenic or mutagenic substances in cleaning, transport, laundry and waste disposal of hazardous drugs of materials contaminated by hazardous drugs and in personal care for patients under treatment of hazardous drugs.