Basic information

2020/0262(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 Amending Directive 2004/37 1999/0085(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	ZAMBELLI Stefania (ID)	10/11/2020
	Shadow rapporteur FRANSSEN Cindy (EPP) DANIELSSON Johan (S&D) TRILLET-LENOIR Véronique (Renew) MATTHIEU Sara (Greens/EFA) KOPCIŃSKA Joanna (ECR) VILLUMSEN Nikolaj (GUE/NGL)	

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	
JURI Legal Affairs	LEBRETON Gilles (ID)	12/10/2020

Council of the European Union

European Commission

Commission DG	Commissioner
Employment, Social Affairs and Inclusion	SCHMIT Nicolas

European Economic and Social Committee
European Committee of the Regions

Key events

Date	Event	Reference	Summary
22/09/2020	Legislative proposal published	COM(2020)0571	Summary
05/10/2020	Committee referral announced in Parliament, 1st reading		
25/03/2021	Vote in committee, 1st reading		
25/03/2021	Committee decision to open interinstitutional negotiations with report adopted in committee		
07/04/2021	Committee report tabled for plenary, 1st reading	A9-0114/2021	Summary
26/04/2021	Committee decision to enter into interinstitutional negotiations announced in plenary (Rule 72)		
28/04/2021	Committee decision to enter into interinstitutional negotiations confirmed by plenary (Rule 72)		
25/01/2022	Approval in committee of the text agreed at 1st reading interinstitutional negotiations		
15/02/2022	Results of vote in Parliament		
16/02/2022	Results of vote in Parliament		
17/02/2022	Decision by Parliament, 1st reading	T9-0046/2022	Summary
17/02/2022	Results of vote in Parliament		
17/02/2022	Debate in Parliament		
03/03/2022	Act adopted by Council after Parliament's 1st reading		
09/03/2022	Final act signed		
16/03/2022	Final act published in Official Journal		

Technical information

Procedure reference	2020/0262(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Amendments and repeals	Amending Directive 2004/37 1999/0085(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 153-p2 Treaty on the Functioning of the European Union TFEU 153-p1
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/9/04211

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE661.965	10/01/2021	
Amendments tabled in committee		PE680.880	05/02/2021	
Committee opinion	JURI	PE663.184	24/02/2021	
Committee report tabled for plenary, 1st reading/single reading		A9-0114/2021	07/04/2021	Summary
Text adopted by Parliament, 1st reading/single reading		T9-0046/2022	17/02/2022	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00089/2021/LEX	09/03/2022	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2020)0571	22/09/2020	Summary
Document attached to the procedure	SEC(2020)0302	22/09/2020	
Document attached to the procedure	SWD(2020)0183	22/09/2020	
Document attached to the procedure	SWD(2020)0184	22/09/2020	
Commission response to text adopted in plenary	SP(2022)134	31/03/2022	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	IT_SENATE	COM(2020)0571	04/11/2020	
Contribution	PT_PARLIAMENT	COM(2020)0571	13/11/2020	
Contribution	IT_SENATE	COM(2020)0571	02/12/2020	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary

EESC	Economic and Social Committee: opinion, report	CES5142/2020	02/12/2020	

Additional information		
Source	**Document**	**Date**
EP Research Service	Briefing	29/10/2020
European Commission	EUR-Lex	

Meetings with interest representatives published in line with the Rules of Procedure

Rapporteurs, Shadow Rapporteurs and Committee Chairs

Transparency				
Name	**Role**	**Committee**	**Date**	**Interest representatives**
VILLUMSEN Nikolaj	Shadow rapporteur	EMPL	20/01/2021	Europæiske kræftsygeplejersker
VILLUMSEN Nikolaj	Shadow rapporteur	EMPL	18/01/2021	EUROPEAN TRADE UNION CONFEDERATION
VILLUMSEN Nikolaj	Shadow rapporteur	EMPL	09/12/2020	European Public Service Unions

Final act
Directive 2022/0431 OJ L 088 16.03.2022, p. 0001

Protection of workers from the risks related to exposure to carcinogens or mutagens at work

2020/0262(COD) - 22/09/2020 - Legislative proposal

PURPOSE: to better protect the health and safety of workers by reducing their exposure to three carcinogenic substances or groups of substances in the workplace.

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 of the European Parliament and of the Council aims to protect workers from risks to their health and safety arising from exposure to carcinogens or mutagens at work. Cancer is the leading cause of work-related mortality in the EU: 52% of annual occupational deaths are currently attributed to work-related cancers.

In order to further contribute to a better protection of workers, the Commission pursues its process of updating the Carcinogens and Mutagens Directive to keep abreast with the new scientific and technical developments and take into account of its stakeholders' views.

The Commission has already proposed three directives amending Directive 2004/37/EC. These three Directives were adopted by the European Parliament and the Council in December 2017, January 2019 and June 2019. The three revisions, which addressed 26 substances, included the revision of two existing occupational exposure limit values (OELs), the introduction of 22 new OELs and the establishment of a skin observation for two substances (without setting OELs).

Both workers' and employers' organisations encouraged the Commission to continue the preparatory work for the establishment of OELs for those priority carcinogens: (i) acrylonitrile; (ii) nickel compounds; (iii) benzene, to which more than one million workers are exposed.

The fourth amendment to the proposed Directive is in the context of the COVID 19 pandemic, which has highlighted the importance of health and safety aspects in the workplace, particularly for those on the front line in response to the crisis.

IMPACT ASSESSMENT: an analysis of the economic, social and environmental impacts of the different strategic options considered for each chemical agent has been carried out. The measures resulting from the opinions of the Advisory Committee on Safety and Health at Work (ACSH) were selected and used to draw up the proposal. The costs and benefits were calculated over a period of 60 years.

The Commission considers that the greatest quantifiable benefits should concern nickel compounds and benzene. The chosen option would indeed produce the following results:

- ***acrylonitrile***: up to 12 cases of brain cancer and 408 cases of nasal irritation prevented, saving between EUR 440 000 and EUR 5 800 000 in health costs;

- ***nickel compounds***: 133 cases of lung cancer, 702 cases of pulmonary morbidity and 80 miscarriages avoided, saving between EUR 72 million and EUR 92 million in healthcare costs;

- ***benzene***: 182 cases of leukaemia and 189 cases of leukocytopenia prevented, a monetised health benefit of between EUR 121 and EUR 198 million.

CONTENT: the Commission proposes to amend the Directive of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. It plans to introduce a limit value for acrylonitrile and nickel compounds, and to revise downwards the existing limit for benzene.

Acrylonitrile

The proposal provides for a limit value of 1 milligram per cubic metre (mg/m3) and a short-term limit value of 4 mg/m3, with a transitional period of four years before these values become binding.

Nickel compounds

Limit values of 0.01 mg/m3 for the respirable fraction and 0.05 mg/m3 for the inhalable fraction are foreseen. During a transitional period until 18 January 2025, a limit value of 0.1 mg/m3 for the inhalable fraction should apply.

Benzene

The proposal provides for a limit value of 0.66 mg/m3 , to be applied within four years. A transitional value of 1.65 mg/m3 shall apply between two and four years after the entry into force of the Directive.

In addition to these OELs, it is also proposed to add to Annex III a Skin notation (indicating that significant penetration is possible by the dermal route) for acrylonitrile as well as a notation for dermal and respiratory sensitisation for nickel compounds. The existing skin notation for benzene has also been kept.

Lastly, the Commission will present before the end of 2020, a European plan to reduce the suffering caused by the disease and support Member States to improve cancer control and care in order to ensure more fair access to treatment across the EU.

Protection of workers from the risks related to exposure to carcinogens or mutagens at work

2020/0262(COD) - 17/02/2022 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 686 votes to 4, with 4 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.

Parliament adopted its position at first reading under the ordinary legislative procedure by amending the Commission proposal as follows:

Subject

The purpose of the proposed directive is to protect workers against risks to their health and safety arising from or likely to arise from exposure to carcinogens, mutagens or reprotoxic substances at work, including the prevention of such risks.

Scope – identification and appreciation of risks

This Directive should apply to activities in which workers are or are likely to be exposed to carcinogens, mutagens or reprotoxic substances as a result of their work.

In case of any activity likely to involve a risk of exposure to carcinogens, mutagens or reprotoxic substances, the **nature, degree and duration of workers' exposure** should be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken.

The assessment should be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to carcinogens, mutagens or reprotoxic substances/

When the risk assessment is carried out, employers should give particular attention to any effects concerning the health or safety of **workers at particular risk** and shall, *inter alia*, take account of the desirability of not employing such workers in areas where they may come into contact with carcinogens, mutagens or reprotoxic substances.

Reduction and replacement

The employer should reduce the use of a carcinogen, mutagen or reprotoxic substance at the place of work, in particular by replacing it, in so far as is technically possible, by a **substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or safety**, as the case may be.

If this replacement is not possible, the employer should ensure that the carcinogen, mutagen or reprotoxic substance is, in so far as is technically possible, manufactured and used in a closed system.

Avoid or reduce exposition

Where a closed system is not technically possible, the employer should ensure that the level of exposure of workers to the carcinogen, mutagen or non-threshold reprotoxic substance is **reduced to as low a level as is technically possible**. Where it is not technically possible to use or manufacture a threshold reprotoxic substance in a closed system, the employer should ensure that the risk related to the exposure of workers to that threshold reprotoxic substance is **reduced to a minimum**.

Exposure should not exceed the limit value of a carcinogen, mutagen or a reprotoxic substance as set out in Annex III of the Directive.

Biological limit values and other health surveillance information are set out in Annex IIIa.

Wherever a carcinogen, mutagen or reprotoxic substance is used, the employer should apply all the following measures:

- design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens, mutagens or reprotoxic substances into the place of work;

- evacuation of carcinogens, mutagens or reprotoxic substances at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;

- use of existing appropriate procedures for the measurement of carcinogens, mutagens or reprotoxic substances, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;

- demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens, mutagens or reprotoxic substances;

- ensure that workers do not eat, drink or smoke in working areas where there is a risk of contamination by carcinogens, mutagens or reprotoxic substances.

Information and training of workers

The training which the employer is required to provide under Article of Directive 2004/37/EC should be **adapted to take account of a new or changed risk**, in particular where workers are exposed to new carcinogens, mutagens or reprotoxic substances, or to a number of different carcinogens, mutagens or reprotoxic substances, including in **dangerous medicinal products**, or where there is a change in the circumstances of the work.

Employers should be required to inform workers about installations and their containers containing carcinogens, mutagens or reprotoxic substances, to ensure that all containers, packaging and installations are labelled clearly and legibly and to display clearly visible warning and hazard signs.

Where a biological limit value has been set in Annex IIIa (e.g. for lead and its ionic compounds), medical surveillance should be compulsory for work with the carcinogen, mutagen or reprotoxic substance in question.

Medical surveillance

If a worker suffers from an abnormality which may be the result of exposure, or if a biological limit value has been exceeded, the doctor or authority responsible for the health surveillance of workers may require that other workers who have suffered similar exposure undergo health surveillance. Where medical surveillance is carried out, an **individual medical record** should be kept for at least 40 years after the end of exposure to carcinogens and mutagens and for at least five years after the end of exposure to reprotoxic substances.

Benzene

As a **transitional measure** for benzene, the limit value of 1 ppm (3.25 mg/m³) should continue to apply until two years after the date of entry into force of the amending directive and a transitional limit value of 0.5 ppm (1.65 mg/m³) should apply from two years after the date of entry into force of the amending directive until four years after the date of entry into force of the amending directive.

Evaluation

The limit value for **respirable crystalline silica dust** should be reviewed in the light of the evaluation made by the Commission and recent scientific and technical data. By 31 December 2022 at the latest, the Commission should (i) present an action plan to achieve new or revised occupational exposure limit values **for at least 25 substances**, groups of substances or process-generated substances; (ii) develop Union guidelines for the preparation, administration and disposal of hazardous medicinal products in the workplace.

Protection of workers from the risks related to exposure to carcinogens or mutagens at work

2020/0262(COD) - 07/04/2021 - Committee report tabled for plenary, 1st reading/single reading

The Committee on Employment and Social Affairs adopted the report by Stefania ZAMBELLI (ID, IT) 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.

As a reminder, the legislative proposal is the fourth concerning Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. It provides for the establishment of new occupational exposure limits for three substances: acrylonitrile, nickel compounds and benzene, to which more than one million workers in the EU are exposed in many different sectors, including the oil, textile, manufacturing, food and chemical industries.

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

Micro-enterprises and SMEs

While maintaining equal levels of protection for all workers, Members considered it desirable to facilitate the operational feasibility and compliance of micro-enterprises and SMEs, avoiding disproportionate impacts on them, in particular by assessing the impact of transposition on these enterprises. Incentives, facilities and digital tools could be the right instruments to address the needs of these businesses.

Reprotoxic substances

Members suggested extending the scope of Directive 2004/37/EC to reprotoxic substances in order to bring it into line with Regulation (EC) No 1907 /2006 of the European Parliament and of the Council (REACH Regulation). Reprotoxic substances are of high concern and the organisation of workplace prevention should apply the same approach to them as to carcinogens and mutagens.

Where a carcinogen, mutagen or reprotoxic substance is present in the workplace, the employer should reduce its use, in particular by replacing it, as far as technically possible, with a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to the health or safety of workers.

Reprotoxic substances can also seriously harm pregnant and breastfeeding workers. Specific measures for this group of workers have therefore been introduced.

Hazardous drugs

In the health care sector alone, 12.7 million workers in Europe (including 7.3 million nurses) are exposed to hazardous drugs at work. The handling, preparation and administration of these drugs exposes healthcare professionals to high health risks.

Members considered it important to protect all workers by including the relevant pharmacotherapeutic classes of hazardous medicines in Annex I of Directive 2004/37/EC.

No later than 1 December 2022, the Commission, after consulting interested parties, should draw up Union guidelines and standards for the preparation, administration and disposal practices of hazardous medicinal products. These guidelines and standards would be published on the website of the European Agency for Safety and Health at Work (EU-OSHA) and disseminated to all Member States by the relevant competent authorities.

Cobalt

No later than 31 December 2023, the Commission should present, after consultation with the Advisory Committee on Safety and Health at Work (ACSH) and taking into account the opinion of the Committee for Risk Assessment (RAC) of the European Chemicals Agency in 2018 and the latest scientific knowledge available, a legislative proposal to introduce a limit value for cobalt and its compounds.

Benzene and nickel

By 1 January 2028, the Commission should assess the feasibility of further reducing the limit value for benzene and the limit value for nickel compounds. No later than 1 January 2030, the Commission should propose, if necessary, the necessary changes for these substances.

Respirable crystalline silica dust

Directive (EU) 2017/2398 requires the European Commission to assess the need to amend the limit value for respirable crystalline silica dust by 2022. Since its inclusion in Annex III of Directive 2004/37/EC, the limit value has remained at 0.1 mg/m³. Members proposed to set a lower limit value (0.05 mg/m³).