Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2018/0081(COD)
Protection of workers from the risks related to exposure to carcinogens or mutagens at work: limit values Amending Directive 2004/37/EC 1999/0085(COD) Subject 4.15.15 Health and safety at work, occupational medicine	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	EMPL Employment and Social Affairs		16/05/2018
		EFDD AGEA Laura	
		Shadow rapporteur	
		PPE ROLIN Claude	
		S&D ULVSKOG Marita	
		ECR MCINTYRE Anthea	
		ALDE CALVET CHAMBON Enrique	
		GUE/NGL LE HYARIC Patrick	
		Verts/ALE DELLI Karima	
		ENF MÉLIN Joëlle	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety		02/05/2018
		ENF MÉLIN Joëlle	
	JURI Legal Affairs		
Council of the European Union	Council configuration	Meeting	Date
	Employment, Social Policy, Health and Consumer Affairs	3660	06/12/2018
European Commission	Commission DG	Commissioner	
	Employment, Social Affairs and Inclusion	THYSSEN Marianne	
European Economic and Social Committee			
European Committee of the Regions			

Key events

05/04/2018	Legislative proposal published	COM(2018)0171	Summary
16/04/2018	Committee referral announced in Parliament, 1st reading/single reading		
20/11/2018	Vote in committee, 1st reading/single reading		
20/11/2018	Committee decision to open		

	interinstitutional negotiations with report adopted in committee		
23/11/2018	Committee report tabled for plenary, 1st reading/single reading	A8-0382/2018	Summary
28/11/2018	Committee decision to enter into interinstitutional negotiations announced in plenary (Rule 71)		
10/12/2018	Committee decision to enter into interinstitutional negotiations confirmed by plenary (Rule 71)		
19/02/2019	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE636.044 GEDA/A/(2019)001484	
27/03/2019	Results of vote in Parliament		
27/03/2019	Decision by Parliament, 1st reading/single reading	T8-0307/2019	Summary
22/05/2019	Act adopted by Council after Parliament's 1st reading		
05/06/2019	Final act signed		
05/06/2019	End of procedure in Parliament		
20/06/2019	Final act published in Official Journal		

Technical information

Procedure reference	2018/0081(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Amending Directive 2004/37/EC 1999/0085(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 153-p2; Treaty on the Functioning of the EU TFEU 153-p1
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	EMPL/8/12691

Documentation gateway

Legislative proposal		COM(2018)0171	05/04/2018	EC	Summary
Document attached to the procedure		SWD(2018)0087	05/04/2018	EC	
Document attached to the procedure		SWD(2018)0088	05/04/2018	EC	
Committee draft report		PE623.825	29/06/2018	EP	
Economic and Social Committee: opinion, report		CES2158/2018	19/09/2018	ESC	
Amendments tabled in committee		PE627.584	24/09/2018	EP	

Amendments tabled in committee		PE628.613	09/10/2018	EP	
Committee opinion	JURI	PE625.394	15/10/2018	EP	
Committee report tabled for plenary, 1st reading/single reading		A8-0382/2018	23/11/2018	EP	Summary
Coreper letter confirming interinstitutional agreement		GEDA/A/(2019)001484	15/02/2019	CSL	
Text adopted by Parliament, 1st reading/single reading		T8-0307/2019	27/03/2019	EP	Summary
Draft final act		00042/2019/LEX	05/06/2019	CSL	
Commission response to text adopted in plenary		SP(2019)437	30/07/2019	EC	

Additional information

Research document	Briefing

Final act

Directive 2019/983
OJ L 164 20.06.2019, p. 0023 Summary

2018/0081(COD) - 05/04/2018 Legislative proposal

PURPOSE: to improve the protection of workers against 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: the European Pillar on Social Rights - jointly proclaimed by the European Parliament, the Council and the Commission on 17 November 2017 at the Social Summit in Gothenburg - identifies workers' right to healthy, safe and well adapted work environment, which includes protection from carcinogens, as one of the main principles.

Cancer is the main work-related health problem in the EU-28, causing almost as much damage to workers' lives and health as the two following combined (musculoskeletal disorders and circulatory diseases).

The European Commission took steps to address these issues by adopting two legislative proposals updating the Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. These two proposals addressed 20 carcinogens. The first of these proposals was adopted by the co-legislators on 12 December 2017 as Directive (EU) 2017/2398 and the second is currently subject to discussion within the Council and the Parliament.

The objective of this third proposal is to improve the level of health protection of workers by establishing limit values for five additional carcinogens, with comments in Annex III to Directive 2004/37/EC. The proposal is in line with the Commission's Communication safer and healthier work for all.

IMPACT ASSESSMENT: the measures resulting from the opinions of the Advisory Committee on Safety and Health at Work (ACSH) have been selected as the preferred measures for all chemical agents covered by the proposal, including the transitional periods for three substances: cadmium (7 years), beryllium (5 years) and arsenic acid (2 years).

As regards the impact on workers, the retained policy option for the five substances under consideration should result in benefits in terms of avoided work-related ill-health and cancer cases and related monetised health benefits.

According to estimates, the adoption of the proposal would imply that in the longer term over 1 000 000 EU workers would benefit from improved prevention and protection in relation to occupational exposure to carcinogens and mutagens substances, that can be at the origin of different types of cancers, e.g., lung, bladder, kidney, nasopharyngeal and others, and it would prevent 22 000 cases of ill-health

CONTENT: the European Commission proposes to add five new substances to Annex III of Directive 2004/37/EC extending the list of binding EU limit values, namely:

- cadmium and its inorganic compounds under the scope of the Directive;
- beryllium and inorganic beryllium compounds under the scope of the Directive;
- arsenic acid and its salts, as well as inorganic arsenic compounds under the scope of the Directive;
- formaldehyde (5) 4,4'-Methylene-bis(2-chloroaniline) ("MOCA").

Limit values address the inhalation route of exposure, describing a maximum airborne concentration level for a given chemical agent above

which workers should not be exposed, on average, during a defined time period.

These measures are supplemented by a skin notation for MOCA, a notation for skin sensitisation for formaldehyde, and a notation for skin and respiratory sensitisation for beryllium and its inorganic compounds.

2018/0081(COD) - 23/11/2018 Committee report tabled for plenary, 1st reading/single reading

The Committee on Employment and Social Affairs adopted the report by Laura AGEA (EFDD, 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 proposal aims to improve the protection of workers from the risks related to exposure to carcinogens or mutagens at work. It adds five new substances to Annex III of Directive 2004/37/EC extending the list of binding European limit values, namely: cadmium and beryllium, and their respective inorganic compounds, arsenic acid, formaldehyde and 4,4'-methylene bis (2-chloroaniline) (MOCA).

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

Medical surveillance: the amending Directive shall require Member States to take measures to ensure appropriate health surveillance of workers for whom the results of the risk assessment reveal a risk to their safety or health. Members pointed out that such health monitoring may include biological monitoring for exposure to various substances, where appropriate.

Limit values: binding occupational exposure limit values need to be evidence-based, proportionate and measurable and shall be established on the basis of available information, including up-to-date scientific and technical data. Where a limit-value has been established for a carcinogen or mutagen, workers' exposure shall be reduced as far as technically possible below that limit value.

The limit values should be revised regularly in accordance with the precautionary principle and the principle of the protection of workers, and in light of sound available scientific and technical data concerning carcinogens and mutagens.

Review: by the fourth quarter of 2019, the Commission shall, on the basis of scientific data and appropriate consultation, assess the possibility to amending the scope of this Directive to include a list of hazardous drugs, including cytotoxic drugs, which are carcinogenic or mutagenic, or to propose a more appropriate legal instrument in order to ensure occupational safety of workers handling such drugs

On that basis, the Commission shall present, if appropriate, and after consulting management and labour, a legislative proposal.

Formaldehyde: Members recalled that in some Member States, Formaldehyde is routinely used for the purposes of embalming deceased persons as part of their cultural or religious practices. The funeral sector is likely to find a limit value of 0,3ppm to be difficult to comply with without significant short-term effects on capacity. A transitional period of three years should therefore be introduced for the sector during which the limit-value of 0,5ppm should apply.

Cadmium: in Member States which implement biological monitoring, the biological limit value should be 2?g Cd/g creatinine and the 8-hour TWA limit value should be 0,004 mg/m3 (respirable fraction). The introduction of that limit-value does not require a transitional period. The Commission should draw up guidelines for the practical implementation of such biological monitoring.

More flexible rules for small businesses: Members want to make it easier for SMEs and micro-enterprises to comply with limit values while maintaining the same level of protection for all workers. In this context, specific measures such as incentives and digital tools would help SMEs and micro-enterprises to better comply with the obligations set out in Directive 2004/37/EC and to move towards the elimination of carcinogenic or mutagenic risks.

2018/0081(COD) - 27/03/2019 Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 586 votes to 10 with 26 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

As a reminder, the proposal aims to improve the protection of workers against the risks related to exposure to carcinogens or mutagens at work. It adds five new substances to Annex III of Directive 2004/37 / EC expanding binding European limit values, these being: cadmium and beryllium, as well as their respective inorganic compounds, arsenic acid, formaldehyde and 4,4'-methylenebis (2-chloroaniline) ("MOCA").

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

Limit values

- Cadmium: given that it will be difficult to comply with a limit value of 0.001 mg/m3 in the short term, the amended text introduces introduce a transitional period of eight years, during which the limit value 0.004 mg/m3 (inhalable fraction) should apply. With a view to protecting legitimate expectations and in order to avoid potential disruptions of existing practices in Member States that implement, on the date of the entry into force of the Directive, a bio monitoring system with a biological limit value not exceeding 0.002 mg Cd/g creatinine in urine, the limit value of 0.004 mg/m 3 should, in those Member States, be measured as respirable fraction during the transitional period.
- Beryllium: since it will be difficult to comply with a limit value of 0.0002 mg/m3 in the short term, the Directive introduces a transitional period of seven years, during which the limit value of 0.0006 mg/m3 should apply.
- Arsenic acid: since the copper smelting sector will have difficulties in complying with a limit value of 0.01 mg/m3, a transitional period of four years will be introduced.
- Formaldehyde: since in some Member States, certain sector will have difficulties in complying, in the short term, with a limit value of or

0.3 ppm, the amended text introduces a transitional period of five years, during which the limit value of 0.62 mg/m 3 or 0.5 ppm should apply for the healthcare and funerals and embalming sectors.

Review

No later than three years after the date of entry into force of the Directive, the Commission shall assess the option of amending the Directive to add provisions on a combination of an airborne occupational exposure limit and a biological limit value for cadmium and its inorganic compounds.

No later than 30 June 2020 the Commission shall, taking into account the latest developments in scientific knowledge, and after appropriate consultation with health practitioners and health professionals, assess the option of amending the Directive in order to include hazardous drugs, including cytotoxic drugs, or to propose a more appropriate instrument for the purpose of ensuring the occupational safety of workers exposed to such drugs. On that basis, the Commission shall present, if appropriate, a legislative proposal.

Member States and relevant bodies at Union and national level are encouraged to provide incentives, guidance and advice to micro, small and medium-size enterprises to comply with the terms of the Directive.

2018/0081(COD) - 20/06/2019 Final act

PURPOSE: to ensure better protection of workers from exposure to carcinogens.

LEGISLATIVE ACT: Directive (EU) 2019/983 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 tenth principle of the European Social Rights Pillar provides that workers have the right to a healthy, safe and appropriate working environment.

The purpose of this Directive is to improve the protection of workers from the risks related to exposure to carcinogens or mutagens at work. It adds five new substances to Annex III of Directive 2004/37/EC extending the list of binding European limit values, namely: cadmium and beryllium, and their respective inorganic compounds, arsenic acid, formaldehyde and 4,4'-methylene bis (2-chloroaniline) (MOCA).

The Directive sets new limits that are consistent with new scientific and technical data and evidence-based practices for measuring exposure levels in the workplace.

Limit values

- Cadmium: the limit value is set at 0.001 mg/m3. However, the Directive introduces a transitional period until 11 July 2027, during which a limit value of 0.004 mg/m3 (inhalable fraction) shall apply. In Member States operating a biomonitoring system with a biological limit value not exceeding 0.002 mg Cd/g creatinine in urine, the limit value of 0.004 mg/m shall be measured as a respirable fraction during the transitional period.
- Beryllium: the Directive sets the limit value at 0.0002 mg/m3 but provides for a transitional period until 11 July 2026, during which a limit value of 0.0006 mg/m3 shall apply.
- Arsenic acid: for the copper smelting sector, the limit value of 0.01 mg/m3 (inhalable fraction) shall enter into force on 11 July 2023.
- Formaldehyde: the limit value is set at 0.37 mg/m3 or 0.3 ppm. However, the Directive introduces a transitional period until 11 July 2024 during which a limit value of 0.62 mg/m 3 or 0.5 ppm will apply for the healthcare, funeral and embalming sectors.

Re-examination

No later than 11 July 2022, the Commission shall assess the option of amending this Directive to add provisions on a combination of an airborne occupational exposure limit and a biological limit value for cadmium and its inorganic compounds.

No later than 30 June 2020, the Commission shall assess the option of amending this Directive in order to include hazardous drugs, including cytotoxic drugs, or to propose a more appropriate instrument for the purpose of ensuring the occupational safety of workers exposed to such drugs.

ENTRY INTO FORCE: 10.7.2019.

TRANSPOSITION: no later than 11.7.2021.