Basic information

1999/0085(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Protection of workers from exposure to carcinogens or mutagens at work. Codification Repealing Directive 97/42/EC 1995/0229(SYN) Repealing Directive 1999/38/EC 1998/0093(SYN) Amended by 2013/0062(COD) Amended by 2016/0130(COD) Amended by 2017/0004(COD) Amended by 2018/0081(COD) Amended by 2020/0262(COD) Amended by 2023/0033(COD) Amended by 2025/0232(COD) **Subject** 4.15.15 Health and safety at work, occupational medicine	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
JURI Legal Affairs and Internal Market	GARGANI Giuseppe (PPE-DE)	08/07/2003

Committee for opinion	Rapporteur for opinion	Appointed
EMPL Employment and Social Affairs	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meetings	Date
Agriculture and Fisheries	2578	2004-04-26

European Commission

Commission DG	Commissioner
Legal Service	

Key events

Date	Event	Reference	Summary
08/04/1999	Legislative proposal published	COM(1999)0152	Summary

23/07/1999	Committee referral announced in Parliament, 1st reading		
20/03/2003	Modified legislative proposal published	COM(2003)0127	Summary
08/07/2003	Vote in committee, 1st reading		Summary
08/07/2003	Committee report tabled for plenary, 1st reading	A5-0255/2003	
02/09/2003	Decision by Parliament, 1st reading	T5-0344/2003	Summary
26/04/2004	Act adopted by Council after Parliament's 1st reading		
29/04/2004	End of procedure in Parliament		
30/04/2004	Final act signed		
30/04/2004	Final act published in Official Journal		

Technical information

Procedure reference	1999/0085(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Codification
Legislative instrument	Directive
Amendments and repeals	Repealing Directive 97/42/EC 1995/0229(SYN) Repealing Directive 1999/38/EC 1998/0093(SYN) Amended by 2013/0062(COD) Amended by 2016/0130(COD) Amended by 2017/0004(COD) Amended by 2018/0081(COD) Amended by 2020/0262(COD) Amended by 2023/0033(COD) Amended by 2025/0232(COD)
Legal basis	EC Treaty (after Amsterdam) EC 137-p2 Rules of Procedure EP 52-p1
Stage reached in procedure	Procedure completed

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A5-0255/2003	08/07/2003	
Text adopted by Parliament, 1st reading/single reading		T5-0344/2003 OJ C 076 25.03.2004, p. 0034-0071 E	02/09/2003	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(1999)0152	08/04/1999	Summary

Modified legislative proposal	COM(2003)0127	20/03/2003	Summary
Commission working document (SWD)	SWD(2017)0010	12/01/2017	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0938/1999 OJ C 368 20.12.1999, p. 0018	20/10/1999	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Directive 2004/0037
OJ L 229 29.06.2004, p. 0023-0034 Summary

Protection of workers from exposure to carcinogens or mutagens at work. Codification

1999/0085(COD) - 29/04/2004 - Final act

PURPOSE : to protect workers against exposure to carcinogens of mutagens at work. LEGISLATIVE ACT : Directive 2004/37/EC of the European Parliament and of the Council 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) (codified version). CONTENT : Council Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) has been substantially amended several times. In the interests of clarity and rationality, the Directive is therefore codified. ENTRY INTO FORCE : 20/05/04.

Protection of workers from exposure to carcinogens or mutagens at work. Codification

1999/0085(COD) - 08/04/1999 - Legislative proposal

PURPOSE: the legislative consolidation of Council Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work so as to make it clearer and more accessible to the citizen. CONTENT: The new Directive will supersede the various directives incorporated in it; their content is fully preserved, and they are brought together with only such formal amendments as are required by the codification exercise itself.

Protection of workers from exposure to carcinogens or mutagens at work. Codification

1999/0085(COD) - 20/03/2003 - Modified legislative proposal

On 8 April 1999, the Commission presented a proposal for a Council Directive codifying Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related To exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of

Directive 89/391/EEC). In its opinion of 11 May 1999 the Consultative Working Party of the legal services set up under the Interinstitutional Agreement of 20 December 1994 on an accelerated working method for official codification of legislative texts has stated that the above proposal does indeed confine itself to straightforward codification, without any substantive changes to the acts covered by it. In view of the work already carried out in the Council on the proposal, the Commission has decided to present - in accordance with Article 250(2) of the EC treaty - an amended proposal for codification of the Directive in question. This amended proposal also takes account of the purely formal or editorial amendments proposed by the Consultative Working Party of Legal Services, where these are considered justified.

Protection of workers from exposure to carcinogens or mutagens at work. Codification

1999/0085(COD) - 02/09/2003 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Giuseppe GARGANI (EPP-ED, I) and approved the Commission's proposal. The resolution was adopted by 477 votes in favour, 3 against with 13 abstentions.

Protection of workers from exposure to carcinogens or mutagens at work. Codification

1999/0085(COD) - 12/01/2017

The Commission presented a working document accompanying the Commission communication to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the modernisation of the EU occupational safety and health legislation and policy.

The detailed ex-post evaluation of the EU acquis, checking their relevance as well as efficiency, effectiveness, coherence and EU added value, carried out by the Commission confirms that the framework meets its ambition to adequately protect workers.

Main conclusions: the evaluation concluded that the overall structure of the EU occupational safety and health acquis, consisting of a goal-oriented Framework Directive complemented by specific Directives, is generally effective and fit-for-purpose.

However, it pointed to **specific provisions of individual Directives that have become outdated or obsolete**, and highlighted the need to find effective ways to **address new risks**.

The way in which Member States have transposed the EU occupational safety and health Directives varies considerably across Member States. Compliance costs therefore vary and cannot be easily dissociated from more detailed national requirements.

As regards SMEs: the evaluation clearly concluded that compliance with the occupational safety and health Directives is more challenging for SMEs than large establishments, while at the same time the **major and fatal injury rates are higher for SMEs**. Specific support measures are therefore necessary to **reach SMEs** and help them increase their compliance in an efficient and effective way.

Next steps: the evaluation considered that occupational safety and health measures should reach the widest number of people at work, **no matter the type of working relationship they are in, and no matter the size of company they work for**. Compliance with occupational safety and health rules should be manageable for businesses of all sizes and effectively monitored on the ground.

Measures must be result-oriented, instead of paper-driven, and maximum use should be made of **new digital tools** to facilitate implementation.

Characteristics of the evaluation: this exercise also forms part of the Commission's Regulatory Fitness (REFIT) Programme with a special focus on SMEs. In this respect, the evaluation concentrated both on Framework Directive 89/391/EEC and on the other 23 directives related to it.

The evaluation also concerned Directive 2004/37/EC of the European Parliament and of the Council 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 Directive 89/391/EEC).

Directive 2004/37/EC establishes a hierarchy of risk control measures and also sets out obligations for the employers, being the substitution of the carcinogen or mutagen by "a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or safety", the priority measure to implement, to eliminate or reduce the risks provided that this is technically possible.

While some data on occupational exposures is available at national level, a systematic assessment of the effectiveness of the Directive will necessitate the development of better data on occupational exposures to different carcinogens and mutagens.

The following issues will need to be considered:

- the need to adopt limit values for more substances for better chemical risk management in the future, based on duly justified reasoning. For this purpose an updated, simplified and quicker legal procedure for the adoption of occupational exposure limit values (OELs) could be considered. The adoption of these measures should be based on the substance prioritisation approach established and with the scientific advice of the Scientific Committee on Occupational Exposure Limits (SCOEL). Threshold and non-threshold issues need to be addressed and a more detailed explanation of how feasibility factors are taken into account need to be provided;

- the simplification of the procedures to set occupational limit values at EU level could also lead to improving the management of interface and further enhance synergies between OSH and other EU requirements such as REACH and CLP,.
- the need to consider the most appropriate approach to managing risks that may arise from exposure to reprotoxic substances;
- the need to consider if and how biomonitoring could be used more effectively for workplace risk management;
- the need to consider the potential adverse effects arising from exposure to dusts with low specific toxicity;
- developing EU guidance on a range of topics, such as practical risk management, using modern communication methods and tools.