Carcinogens, Mutagens and Reprotoxic substances Directive (CMRD)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION
Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 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)

Summary

The objective of this Directive is the protection of 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. This Directive has 3 chapters composed of 22 articles plus 3 annexes. As of 8 March 2022, updates have been approved to include guidance regarding reprotoxic substances in all relevant articles and annexes. This document presents the key updates within CMRD directive.

Key Updates

CHAPTER I, GENERAL PROVISIONS

Articles 1 (Objectives), 2 (Definitions) and 3 (Scope) have been amended to include reprotoxic substances.

- A 'reprotoxic substance' is defined as a substance or mixture which is known (category 1A) to have produced an adverse effect on sexual function and fertility, or on development in humans or when there is evidence from animal studies (category 1B), possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans[1]
- Article 2 now also includes definitions of 'non-threshold reprotoxic substance', 'threshold reprotoxic substance', 'limit value', 'biological limit value' and 'health surveillance'

CHAPTER II, EMPLOYERS' OBLIGATIONS

Articles 4 (Reduction and replacement), 5 (Prevention and reduction of exposure), 6 (Information for the competent authority), 10 (Hygiene and individual protection) and 11 (Information and training of workers) have been amended to include relevant guidance for reprotoxic substances.

- Article 5(3) has been amended to include:

  a) Where it is not technically possible to use or manufacture a threshold reprotoxic substance in a closed system, the employer shall ensure that the risk related to the exposure of workers to that threshold reprotoxic substance is reduced to a minimum.

  b) The employer shall, with regard to reprotoxic substances other than non-threshold reprotoxic substances and threshold reprotoxic substances, apply paragraph 3a of this Article. In such a case, when carrying out the risk assessment referred to in Article 3, the employer shall duly take into account the possibility that a safe level of exposure for workers' health for such a reprotoxic substance might not exist and shall lay down appropriate measures in that regard.

CHAPTER III, MISCELLANEOUS PROVISIONS

Articles 14 (Health surveillance), 15 (Record keeping), 16 (Limit values), 17 (Amendment of Annex II) and 18 (Evaluation) now include relevant guidance for reprotoxic substances

- 14(3) has been amended to include a worker having exceeded the biological limit value as a reason for the health surveillance of others exposed
- 14(4) has been amended to highlight that:

  "Biological monitoring and related requirements may form part of health surveillance"
- 15(1) has been amended to distinguish the length of time required for medical record keeping of carcinogens and mutagens, and reprotoxic substances
- Article 16 has been amended to include both The European Parliament and the Council as regulatory bodies for setting out limit values and biological limit values in Directives. The regulatory bodies shall do this in accordance with the procedure laid down in Article 153(2), point (b), of the Treaty on the Functioning of the European Union (TFEU)[2]
- 16(4) has been added, stating that:

  "Biological limit values and other health surveillance information are set out in Annex IIIa"
- Article 16a (Identification of non-threshold and threshold reprotoxic substances) has been added, it states:

  "The European Parliament and the Council shall, in accordance with the procedure laid down in Article 153(2), point (b), TFEU, identify, on the basis of the available scientific and technical data, in the notations column of Annex III to this Directive whether a reprotoxic substance is a non-threshold reprotoxic substance or a threshold reprotoxic substance."

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- Article 18a has been amended to state that: "The Commission shall develop a definition and establish an indicative list of hazardous medicinal products or the substances contained therein, which meet the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/20081, a mutagen or a reprotoxic substance."
- Article 18a sets 31 December 2022 as the deadline for the Commission to prepare Union guidelines for the preparation, administration, and disposal of hazardous medicinal products at the place of work, after appropriate consultation of relevant stakeholders,

ANNEX II **(Practical recommendations for the health surveillance of workers) now states that:**

The doctor and/or authority responsible for the health surveillance of workers exposed to carcinogens, mutagens or **reprotoxic substances** must be familiar with the exposure conditions or circumstances of each worker.

References

1 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

2 European Union. Consolidated Version of the Treaty on the Functioning of the European Union. *Official Journal of European Union*. 2016;55.