Council of the European Union

Brussels, 1 December 2023
(OR. en)

16292/23

Interinstitutional File:
2023/0421 (COD)

CODIF 15
CODEC 2363
SAN 719
SOC 847
EMPL 608

PROPOSAL

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 November 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 738 final
Subject:	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codification)

Delegations will find herewith attached the Commission codification proposal referred to in the subject (COM(2023) 738 final - 2023/0421 (COD) and Annexes 1 to 6).

Delegations are invited to send their comments on the codification proposal by Wednesday, 17 January 2024 to the following addresses:

Codification@consilium.europa.eu AND sj-codification@ec.europa.eu

Delegation's attention is drawn to the Practical Guide on Codification (doc. 14722/14 + COR1).

Encl.: COM(2023) 738 final

EUROPEAN
COMMISSION

Brussels, 27.11.2023
COM(2023) 738 final

2023/0421 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codification)

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. In the context of a people's Europe, the Commission attaches great importance to simplifying and clarifying the law of the Union so as to make it clearer and more accessible to citizens, thus giving them new opportunities and the chance to make use of the specific rights it gives them.

   This aim cannot be achieved so long as numerous provisions that have been amended several times, often quite substantially, remain scattered, so that they must be sought partly in the original instrument and partly in later amending ones. Considerable research work, comparing many different instruments, is thus needed to identify the current rules.

   For this reason a codification of rules that have frequently been amended is also essential if the law is to be clear and transparent.

2. On 1 April 1987 the Commission decided[1] to instruct its staff that all acts should be codified after no more than ten amendments, stressing that this is a minimum requirement and that departments should endeavour to codify at even shorter intervals the texts for which they are responsible, to ensure that their provisions are clear and readily understandable.

3. The Conclusions of the Presidency of the Edinburgh European Council (December 1992) confirmed this[2], stressing the importance of codification as it offers certainty as to the law applicable to a given matter at a given time.

   Codification must be undertaken in full compliance with the normal procedure for the adoption of acts of the Union.

   Given that no changes of substance may be made to the instruments affected by codification, the European Parliament, the Council and the Commission have agreed, by an interinstitutional agreement dated 20 December 1994, that an accelerated procedure may be used for the fast-track adoption of codification instruments.

4. The purpose of this proposal is to undertake a codification of 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, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC[3]. The new Directive will supersede the various acts incorporated in it[4]; this proposal fully preserves the content of the acts being codified and hence does no more than bring them together with only such formal amendments as are required by the codification exercise itself.

5. The codification proposal was drawn up on the basis of a preliminary consolidation, in 24 official languages, of Directive 2004/37/EC and the instruments amending it, carried out by the Publications Office of the European Union, by means of a data-processing system. Where the Articles have been given new numbers, the correlation between the old and the new numbers is shown in a table set out in Annex VI to the codified Directive.

---

1 COM(87) 868 PV.
2 See Annex 3 to Part A of the Conclusions.
3 Entered in the legislative programme for 2023.
4 See Part A of Annex V to this proposal.

↓ 2022/431 Art. 1.1

2023/0421 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codification)

(Text with EEA relevance)

↓ 2004/37/EC (adapted)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty ⌦ on the Functioning of the European Union ⌫, and in particular ⌦ Article 153(2), point (b), in conjunction with Article 153(1), point (a), ⌫ thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[5],

Having regard to the opinion of the Committee of the Regions[6],

Acting in accordance with the ordinary legislative procedure,

Whereas:

↓

(1) Directive 2004/37/EC of the European Parliament and of the Council[7] has been substantially amended several times[8]. In the interests of clarity and rationality, that Directive should be codified.

5 OJ C […], […], p. […].

6 OJ C […], […], p. […].

7 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, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

8 See Part A of Annex V.

↓ 2022/431 recital 1 (adapted)

(2) ⌦ This ⌫ Directive aims to protect workers against risks to their health and safety from exposure to carcinogens, mutagens ⌦ or reprotoxic substances ⌫ at the place of work. A consistent level of protection from the risks related to the occupational exposure to carcinogens, mutagens ⌦ or reprotoxic substances ⌫ is provided for in ⌦ this ⌫ Directive by a framework of general principles to enable Member States to ensure the consistent application of minimum requirements. The aim of these minimum requirements is to protect workers at Union level. More stringent provisions can be set by Member States.

↓ 2022/431 recital 2 (adapted)

(3) By setting minimum requirements for workers' protection across the Union, ⌦ this ⌫ Directive ⌦ provides ⌫ clarity and contributes to a more level playing field for the economic actors in the sectors that use the substances falling within ⌦ its ⌫ scope, thereby demonstrating the importance of Union action in this field.

↓ 2004/37/EC recital 3 (adapted)

(4) This Directive is an individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC[9]. Therefore the provisions of that Directive are fully applicable to the exposure of workers to carcinogens, mutagens ⌦ or reprotoxic substances ⌫, without prejudice to more stringent and/or specific provisions contained in this Directive.

↓ 2004/37/EC recital 5

(5) Germ cell mutagens are substances that can cause a permanent change in the amount or structure of the genetic material of a cell resulting in a change in the phenotypic characteristics of that cell, which may be transferred to descendent daughter cells.

↓ 2004/37/EC recital 6

(6) Because of their mechanism of action, germ cell mutagens are likely to have carcinogenic effects.

↓ 2022/431 recital 3 (adapted)

(7) According to the latest scientific evidence, reprotoxic substances can cause adverse effects on sexual function and fertility in adult males and females, as well as on the development of their offspring. Similarly to carcinogens or mutagens, reprotoxic substances are substances of very high concern which may have serious and irreversible effects on workers' health.

[9] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

↓ 2022/431 recital 4 (adapted)

(8) For most reprotoxic substances, it is scientifically possible to identify levels below which exposure would not lead to adverse health effects. The exposure minimisation requirements laid down in ⌦ this ⌫ Directive should apply only to reprotoxic substances for which it is not possible to identify a safe level of exposure and which are identified as 'non-threshold' in the notation column of Annex III. With regard to all other reprotoxic substances, employers should ensure that the risk related to the exposure of workers is reduced to a minimum.

↓ 2022/431 recital 5 (adapted)

(9) According to the latest scientific data, biological limit values may be necessary in specific cases to protect workers from exposure to some carcinogens, mutagens or reprotoxic substances.

↓ 2022/431 recital 6

(10) Principle 10 of the European Pillar of Social Rights[10], jointly proclaimed by the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, provides for the right of workers to a high level of protection of their health and safety at work, which includes protection from the exposure to carcinogens, mutagens and reprotoxic substances at the place of work.

↓ 2022/431 recital 7 (adapted)

(11) Binding occupational exposure limit values are an important component of the general arrangements for the protection of workers established by ⌦ this ⌫ and must not be exceeded. Limit values and other directly related provisions should be established for all carcinogens, mutagens and reprotoxic substances for which the available information, including up-to-date scientific and technical data, make it possible to do so.

↓ 2022/431 recital 8 (adapted)

(12) For mutagens and most carcinogens, it is not scientifically possible to identify levels below which exposure would not lead to adverse health effects. Although setting limit values for exposure at the place of work in relation to carcinogens and mutagens in ⌦ this ⌫ does not completely eliminate risks to the health and safety of workers arising from exposure at work (residual risk), it nonetheless contributes to a significant reduction of risks arising from such exposure by means of the stepwise and goal-setting approach adopted in ⌦ this ⌫ Directive.

↓ 2022/431 recital 9 (adapted)

(13) Binding occupational exposure limit values are without prejudice to other employers' obligations pursuant to ⌦ this ⌫, such as the reduction of the use of carcinogens,

[10] OJ C 428, 13.12.2017, p. 10.

mutagens and reprotoxic substances at the place of work, the prevention or reduction of workers' exposure to carcinogens, mutagens and reprotoxic substances, or to the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the carcinogen, mutagen and reprotoxic substance by a substance, mixture or process which is not dangerous or which is less dangerous to workers' health, the use of a closed system, or other measures aiming to reduce the level of workers' exposure.

↓ 2022/431 recital 10 (adapted)

(14) There is a need for workers to receive sufficient and appropriate training when they are exposed or are likely to be exposed to carcinogens, mutagens or reprotoxic substances, including those contained in certain hazardous medicinal products. The training that the employer is required to provide pursuant to ⌦ this ⌫ Directive should be adapted to take account of a new or changed risk, in particular when workers are exposed to new carcinogens, mutagens or reprotoxic substances or to a number of different carcinogens, mutagens or reprotoxic substances, including in hazardous medicinal products, or in the case of changing circumstances related to work.

↓ 2022/431 recital 11 (adapted)

(15) Certain hazardous medicinal products contain one or more substances which meet the criteria for classification as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B) or toxic for reproduction (category 1A or 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[11] and therefore fall within the scope of ⌦ this ⌫ Directive. However, clear and updated information concerning whether a medicinal product meets those criteria is not easily accessible to workers, employers or enforcement authorities. In order to ensure the proper implementation of ⌦ this ⌫ Directive and to provide clarity with regard to the use of and risks relating to the handling of those hazardous medicinal products, it is necessary to take steps to help employers to identify them. The Commission, in line with the Commission communication of 28 June 2021 on an EU strategic framework on health and safety at work 2021-2027, is to provide guidelines, including on training, protocols, surveillance and monitoring, for protecting workers against exposure to hazardous medicinal products.

↓ 2022/431 recital 12 (adapted)

(16) With regard to the risk assessment provided in ⌦ this ⌫ Directive, when assessing exposure to hazardous medicinal products falling within the scope of ⌦ this ⌫ Directive, employers should pay specific attention to ensure that the requirement to replace such products would not be to the detriment of patients' health.

---

[11] 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).

↓ 2022/431 recital 13 (adapted)

(17) This Directive strengthens the protection of workers' health and safety at the place of work. Limit values should be set out in ⌦ this ⌫ Directive in light of available information, including up-to-date scientific and technical data, and should also be based on a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the place of work. That information should, if possible, include data on residual risks to the health of workers, opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[12] and opinions of the Advisory Committee on Safety and Health at Work established by a Council Decision of 22 July 2003[13] (ACSH). Information related to residual risk that has been made publicly available at Union level is valuable for any future work to limit risks from occupational exposure to carcinogens, mutagens and reprotoxic substances.

↓ 2022/431 recital 15

(18) In accordance with the recommendations of the RAC and the ACSH, where possible, limit values for the inhalation route of exposure are established in relation to a reference period of eight hours time-weighted average (long-term exposure limit values) and, for certain carcinogens, mutagens and reprotoxic substances to a shorter reference period, in general fifteen minutes time-weighted average (short-term exposure limit values), in order to limit, to the extent possible, the effects arising from short-term exposure.

↓ 2022/431 recital 16

(19) It is also necessary to consider absorption pathways other than inhalation for all carcinogens, mutagens and reprotoxic substances, including the possibility of uptake through the skin, in order to ensure the best possible level of protection. Further notations for hazardous substances and mixtures are laid down in Regulation (EC) No 1272/2008.

↓ 2004/37/EC recital 14

(20) The precautionary principle should be applied in the protection of workers' health.

[12] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

[13] Council Decision of 22 July 2003 setting up an Advisory Committee on Safety and Health at Work (OJ C 218, 13.9.2003, p. 1).

↓ 2004/37/EC recital 15 (adapted)

(21) Preventive measures must be taken for the protection of the health and safety of workers exposed to carcinogens, mutagens ⌦ or reprotoxic substances ⌫.

↓ 2022/431 recital 26

(22) The limit values established in this Directive are to be kept under regular scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006. In particular, with regard to benzene, the Commission, in close cooperation with the ACSH, will assess the feasibility of a further reduction of the OEL, taking into account the RAC opinion of 2018 and any new relevant information.

↓ 2022/431 recital 18 (adapted)

(23) The ACSH, based on the RAC opinion, agreed that biological monitoring for acrylonitrile would be useful. This should be considered when developing guidance on the practical use of biological monitoring.

↓ 2022/431 recital 22 (adapted)

(24) The ACSH, based on the RAC opinion, agreed that the biological monitoring for benzene would be useful. This should be considered when developing guidance on the practical use of biological monitoring.

↓ 2019/983 recital 18

(25) Setting a biological limit value for cadmium and its inorganic compounds would protect workers against their systemic toxicity, which mainly affects the kidneys and bones. Biological monitoring can thus contribute to the protection of workers at the workplace, but only as a means of complementing the monitoring of the concentration of cadmium and its inorganic compounds in the air and therefore within the breathing zone of workers. The Commission should issue practical guidelines for biological monitoring.

↓ 2019/130 recital 9 (adapted)

(26) The ACSH is a tripartite body that assists the Commission in the preparation, implementation and evaluation of activities in the field of occupational health and safety. In particular, the ACSH adopts tripartite opinions on initiatives to set occupational exposure limit values at Union level on the basis of the available information, including scientific and technical data as well as data on social aspects and on the economic feasibility of those initiatives.

↓ 2019/130 recital 19 (adapted)

(27) In light of evolving scientific evidence and technical progress, the limit values for ⌦ trichloroethylene ⌫ should be kept under particularly close review.

↓ 2019/130 recital 24 (adapted)

(28) The ‘Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it’, signed by the associations that form the European Network for Silica (NEPSI), and other social partners' agreements, which provide, in addition to regulatory measures, guidance and tools in order to support the effective implementation of the employers' obligations laid down in ⌦ this ⌫ Directive, are valuable instruments to complement regulatory measures. While respecting their autonomy, the Commission should encourage the social partners to conclude such agreements. However, compliance with such agreements should not give rise to a presumption of conformity with the employers' obligations laid down in ⌦ this ⌫ Directive. A regularly updated list of such agreements should be published on the European Agency for Safety and Health at Work (EU-OSHA) website.

↓ 2017/2398 recital 13 (adapted)

(29) The limit values for vinyl chloride monomer and hardwood dusts set out in Annex III to ⌦ this ⌫ Directive should be revised in the light of more recent scientific and technical data. The distinction between hardwood and softwood dust should be further assessed as regards the limit value set out in that Annex, as recommended by the ⌦ Scientific Committee on Occupational Exposure Limits ⌫ and the International Agency for Research on Cancer.

↓ 2017/2398 recital 30

(30) In its opinions, the ACSH has referred to a review period for binding occupational exposure limit values for several substances, such as respirable crystalline silica dust, acrylamide and 1,3-butadiene. The Commission is to take into account those opinions when prioritising substances for scientific evaluation.

↓ 2017/2398 recital 31

(31) In its opinion on refractory ceramic fibres, the ACSH agreed that a binding occupational exposure limit value is necessary but failed to reach a common position on a threshold. The Commission should therefore encourage the ACSH to submit an up-to-date opinion on refractory ceramic fibres with a view to reaching a common position on the limit value for that substance, without prejudice to the working methods of the ACSH and the autonomy of the social partners.

↓ 2004/37/EC recital 18 (adapted)

(32) This Directive ⌦ should be ⌫ without prejudice to the obligations of the Member States ⌦ relating to ⌫ the time-limits for ⌦ the ⌫ transposition ⌦ into national law and the dates of application of the Directives ⌫ set out in Part B of Annex V,

HAVE ADOPTED THIS DIRECTIVE:

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

CHAPTER I

GENERAL PROVISIONS

Article 1

Objective

↓ 2022/431 Art. 1.2

1. This Directive has as its aim 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.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

It lays down particular minimum requirements in this area, including limit values.

2. This Directive shall not apply to workers exposed only to radiation covered by the Treaty establishing the European Atomic Energy Community.

3. Directive 89/391/EEC shall apply fully to the whole area referred to in paragraph 1, without prejudice to more stringent and/or specific provisions contained in this Directive.

↓ 2014/27/EU Art. 5.1 (adapted)

4. As regards asbestos, which is dealt with by Directive 2009/148/EC of the European Parliament and of the Council[14], the provisions of this Directive shall apply whenever they are more favourable to health and safety at work.

[14] Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28).

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23 (adapted)

Article 2

Definitions

For the purposes of this Directive, ⌦ the following definitions shall apply: ⌫

↓ 2014/27/EU Art. 5.2(a)

(a) ‘carcinogen’ means:

(i) a substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008;

(ii) a substance, mixture or process referred to in Annex I to this Directive as well as a substance or mixture released by a process referred to in that Annex;

↓ 2014/27/EU Art. 5.2(b)

(b) ‘mutagen’ means a substance or mixture which meets the criteria for classification as a category 1A or 1B germ cell mutagen set out in Annex I to Regulation (EC) No 1272/2008;

↓ 2022/431 Art. 1.3(a) (adapted)

(c) ‘reprotoxic substance’ means a substance or mixture which meets the criteria for classification as a category 1A or 1B reproductive toxicant set out in Annex I to Regulation (EC) No 1272/2008;

(d) ‘non-threshold reprotoxic substance’ means a reprotoxic substance ⌦ for ⌫ which there is no safe level of exposure for workers’ health and which is identified as such in the notation column of Annex III;

(e) ‘threshold reprotoxic substance’ means a reprotoxic substance for which a safe level of exposure exists below which there is no risk to workers’ health and which is identified as such in the notation column of Annex III;

↓ 2022/431 Art. 1.3(b)

(f) ‘limit value’ means, unless otherwise specified, the limit of the time-weighted average of the concentration for a carcinogen, mutagen or reprotoxic substance in the air within the breathing zone of a worker in relation to a specified reference period as set out in Annex III;

↓ 2022/431 Art. 1.3(c)

(g) ‘biological limit value’ means the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect;

(h) ‘health surveillance’ means the assessment of an individual worker to determine the state of health of that individual, as related to exposure to specific carcinogens, mutagens or reprotoxic substances at work.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

Article 3

Scope — determination and assessment of risks

↓ 2022/431 Art. 1.4(a)

1. This Directive shall 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.

↓ 2022/431 Art. 1.4(b)

2. In the 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 shall 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 shall 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.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

The employer shall supply the authorities responsible at their request with the information used for making the assessment.

3. When assessing the risk, account shall be taken of all other routes of exposure, such as absorption into and/or through the skin.

↓ 2022/431 Art. 1.4(c) (adapted)

4. When the risk assessment is carried out, employers shall ⌦ pay ⌫ 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.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

CHAPTER II

EMPLOYERS' OBLIGATIONS

Article 4

Reduction and replacement

↓ 2022/431 Art. 1.5

1. The employer shall 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.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23 (adapted)

2. The employer shall, upon request, submit the findings of ⌦ the employer's ⌫ investigations to the relevant authorities.

Article 5

Prevention and reduction of exposure

1. Where the results of the assessment referred to in Article 3(2) reveal a risk to workers' health or safety, workers' exposure ⌦ shall ⌫ be prevented.

↓ 2022/431 Art. 1.6(a) (adapted)

2. Where it is not technically possible to replace the carcinogen, mutagen or reprotoxic substance by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen, mutagen or reprotoxic substance is, in so far as is technically possible, manufactured and used in a closed system.

3. Where a closed system is not technically possible, the employer shall 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.

4. 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.

5. The employer shall, with regard to reprotoxic substances other than non-threshold reprotoxic substances and threshold reprotoxic substances, apply paragraph 4 of this Article. In such a case, when carrying out the risk assessment referred to in Article 3 ⌦ (2) ⌫, 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.

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

↓ 2022/431 Art. 1.6(b)

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

(a) limitation of the quantities of a carcinogen, mutagen or reprotoxic substance at the place of work;

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

(b) keeping as low as possible the number of workers exposed or likely to be exposed;

↓ 2022/431 Art. 1.6(b)

(c) 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;

(d) 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;

(e) 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;

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

(f) application of suitable working procedures and methods;

(g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;

(h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces;

(i) information for workers;

↓ 2022/431 Art. 1.6(b)

(j) 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;

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23 (adapted)

(k) drawing up plans to deal with emergencies likely to result in abnormally high exposure;

(l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers;

(m) means for safe collection, storage and disposal of waste by workers, including the use of sealed and clearly and visibly labelled containers.

Article 6

Information for the competent authority

Where the results of the ⌦ risk ⌫ assessment referred to in Article 3(2) reveal a risk to workers' health or safety, employers shall, when requested, make available to the competent authority appropriate information on:

↓ 2022/431 Art. 1.7

(a) the activities and/or industrial processes carried out, including the reasons for which carcinogens, mutagens or reprotoxic substances are used;

(b) the quantities of substances or mixtures manufactured or used which contain carcinogens, mutagens or reprotoxic substances;

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

(c) the number of workers exposed;

(d) the preventive measures taken;

(e) the type of protective equipment used;

(f) the nature and degree of exposure;

(g) the cases of replacement.

↓ 2017/2398 Art. 1.1 (adapted)

The Member States shall take into account the information ⌦ referred to in ⌫ points (a) to (g) of the first paragraph of this Article in their reports submitted to the Commission ⌦ in accordance with ⌫ Article 17a of Directive 89/391/EEC.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23 (adapted)

Article 7

Unforeseen exposure

1. In the event of an unforeseeable event or an accident which is likely to result in an abnormal exposure of workers, the employer shall inform the workers thereof.

2. Until the situation has been restored to normal and the causes of the abnormal exposure have been eliminated:

(a) only those workers who are essential to the carrying out of repairs and other necessary work shall be permitted to work in the affected area;

(b) the workers concerned shall be provided with protective clothing and individual respiratory protection equipment which they must wear; the exposure may not be permanent and shall be kept to the strict minimum of time necessary for each worker;

(c) unprotected workers shall not be allowed to work in the affected area.

Article 8

Foreseeable exposure

1. For certain activities such as maintenance, in respect of which it is foreseeable that there is the potential for a significant increase in exposure of workers, and in respect of which all scope for further technical preventive measures for limiting workers' exposure has already been exhausted, the employer shall determine, after consultation of the workers and/or their representatives in the undertaking or establishment, without prejudice to the employer's responsibility, the measures necessary to reduce the duration of workers' exposure to the minimum possible and to ensure protection of workers while they are engaged in such activities.

Pursuant to the first subparagraph, the workers concerned shall be provided with protective clothing and individual respiratory protection equipment which they must wear as long as the abnormal exposure persists; that exposure may not be permanent and shall be kept to the strict minimum of time necessary for each worker.

2. Appropriate measures shall be taken to ensure that the areas in which the activities referred to in paragraph 1, first subparagraph, take place are clearly demarcated and indicated or that unauthorised persons are prevented by other means from having access to such areas.

Article 9

Access to risk areas

Appropriate measures shall be taken by employers to ensure that access to areas in which the activities in respect of which the results of the ⌦ risk ⌫ assessment referred to in Article 3(2) reveal a risk to workers' safety or health take place are accessible solely to workers who, by reason of their work or duties, are required to enter them.

Article 10

Hygiene and individual protection

↓ 2022/431 Art. 1.8(a)

1. Employers shall be obliged, in the case of all activities for which there is a risk of contamination by carcinogens, mutagens or reprotoxic substances, to take appropriate measures to ensure that:

↓ 2022/431 Art. 1.8(b)

(a) workers do not eat, drink or smoke in working areas where there is a risk of contamination by carcinogens, mutagens or reprotoxic substances;

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23 (adapted)

(b) workers are provided with appropriate protective clothing or other appropriate special clothing;

(c) separate storage places are provided for working or protective clothing and for street clothes;

(d) workers are provided with appropriate and adequate washing and toilet facilities;

(e) protective equipment is properly stored in a well-defined place and is checked and cleaned if possible before, and in any case after, each use;

(f) defective equipment is repaired or replaced before further use.

2. Workers ⌦ shall ⌫ not be charged for the cost of the measures set out in paragraph 1.

Article 11

Information and training of workers

1. Appropriate measures shall be taken by the employer to ensure that workers and/or workers' representatives in the undertaking or establishment receive sufficient and appropriate training, on the basis of all available information, in particular in the form of information and instructions, concerning:

(a) potential risks to health, including the additional risks due to tobacco consumption;

(b) precautions to be taken to prevent exposure;

(c) hygiene requirements;

(d) wearing and use of protective equipment and clothing;

(e) steps to be taken by workers, including rescue workers, in the case of incidents and to prevent incidents.

↓ 2022/431 Art. 1.9(a) (adapted)

The training shall be:

– adapted to take account of new or changed risk, in particular when workers are or are likely to be exposed to new carcinogens, mutagens or reprotoxic substances or to a number of different carcinogens, mutagens or reprotoxic substances, including those contained in hazardous medicinal products, or in ⌦ the ⌫ case of changing circumstances related to work,

– provided periodically in healthcare settings to all workers who are exposed to carcinogens, mutagens or reprotoxic substances, in particular where new hazardous medicinal products containing those substances are used, and

– repeated periodically in other settings if necessary.

↓ 2022/431 Art. 1.9(b)

2. Employers shall inform workers of installations and related containers containing carcinogens, mutagens or reprotoxic substances, ensure that all containers, packages and installations containing carcinogens, mutagens or reprotoxic substances are labelled clearly and legibly, and display clearly visible warning and hazard signs.

Where a biological limit value has been set in Annex IV, health surveillance shall be mandatory for working with the carcinogen, mutagen or reprotoxic substance in question, in accordance with the procedures laid down in that Annex. Workers shall be informed of that requirement before being assigned to the task involving the risk of exposure to the carcinogen, mutagen or reprotoxic substance indicated.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23 (adapted)

Article 12

Information for workers

Appropriate measures shall be taken to ensure that:

(a) workers and/or any workers' representatives in the undertaking or establishment can check that this Directive is applied or can be involved in its application, in particular with regard to:

  (i) the consequences for workers' safety and health of the selection, wearing and use of protective clothing and equipment, without prejudice to the employer's responsibility for determining the effectiveness of protective clothing and equipment;

  (ii) the measures determined by the employer which are referred to in the first subparagraph of Article 8(1), without prejudice to the employer's responsibility for determining such measures;

(b) workers and/or any workers' representatives in the undertaking or establishment are informed as quickly as possible of abnormal exposures, including those referred to in

Article 8, of the causes thereof and of the measures taken or to be taken to rectify the situation;

(c) the employer keeps an up-to-date list of the workers engaged in the activities in respect of which the results of the ⌦ risk ⌫ assessment referred to in Article 3(2) reveal a risk to workers' health or safety, indicating, if the information is available, the exposure to which they have been subjected;

(d) the doctor and/or the competent authority as well as all other persons who have responsibility for health and safety at work have access to the list referred to in point (c);

(e) each worker has access to the information on the list which relates to ⌦ that worker ⌫ personally;

(f) workers and/or any workers' representatives in the undertaking or establishment have access to anonymous collective information.

Article 13

Consultation and participation of workers

Consultation and participation of workers and/or their representatives in connection with matters covered by this Directive shall take place in accordance with Article 11 of Directive 89/391/EEC.

↓ 2019/130 Art. 1.1

Article 14

Social partners' agreements

Social Partners' agreements possibly concluded in the field of this Directive shall be listed on the website of the European Agency for Safety and Health at Work (EU-OSHA). That list shall be regularly updated.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

CHAPTER III

MISCELLANEOUS PROVISIONS

Article 15

Health surveillance

↓ 2017/2398 Art. 1.2(a) (adapted)

1. The Member States shall establish, in accordance with national law or practice, arrangements for carrying out relevant health surveillance of workers for whom the results of the ⌦ risk ⌫ assessment referred to in Article 3(2) reveal a risk to health or safety. The doctor or authority responsible for the health surveillance of workers may indicate that health

surveillance must continue after the end of exposure for as long as they consider it to be necessary to safeguard the health of the worker concerned.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

2. The arrangements referred to in paragraph 1 shall be such that each worker shall be able to undergo, if appropriate, relevant health surveillance:

– prior to exposure,

– at regular intervals thereafter.

Those arrangements shall be such that it is directly possible to implement individual and occupational hygiene measures.

↓ 2022/431 Art. 1.10(a)

3. If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens, mutagens or reprotoxic substances, or if a biological limit value is found to have been exceeded, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

In that event, a reassessment of the risk of exposure shall be carried out in accordance with Article 3(2).

↓ 2022/431 Art. 1.10(b)

4. In cases where health surveillance is carried out, an individual medical record shall be kept and the doctor or authority responsible for health surveillance shall propose any protective or preventive measures to be taken in respect of any individual workers. Biological monitoring and related requirements may form part of health surveillance.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23 (adapted)

5. Information and advice ⌦ shall ⌫ be given to workers regarding any health surveillance which they may undergo following the end of exposure.

6. In accordance with national laws and/or practice:

– workers shall have access to the results of the health surveillance which concern them, and

– the workers concerned or the employer may request a review of the results of the health surveillance.

7. Practical recommendations for the health surveillance of workers are ⌦ set out ⌫ in Annex II.

↓ 2022/431 Art. 1.10(c)

8. All cases of cancer, adverse effects on sexual function and fertility in adult male and female workers or developmental toxicity in their offspring identified in accordance with national law or practice as resulting from occupational exposure to a carcinogen, mutagen or reprotoxic substance shall be notified to the competent authority.

↓ 2017/2398 Art. 1.2(b) (adapted)

The Member States shall take into account the information ⌦ referred to in ⌫ this paragraph in their reports submitted to the Commission under Article 17a of Directive 89/391/EEC.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

Article 16

Record keeping

↓ 2022/431 Art. 1.11

1. With regard to carcinogens and mutagens, the list referred to in Article 12, point (c), and the medical record referred to in Article 15(4) shall be kept for at least 40 years following the end of exposure, in accordance with national law or practice.

2. With regard to reprotoxic substances, the list referred to in Article 12, point (c), and the medical record referred to in Article 15(4) shall be kept for at least five years following the end of exposure, in accordance with national law or practice.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

3. Those documents shall be made available to the responsible authority in cases where the undertaking ceases activity, in accordance with national laws and/or practice.

Article 17

Limit values

↓ 2022/431 Art. 1.12(a)

1. The European Parliament and the Council shall, in accordance with the procedure laid down in Article 153(2), point (b), of the Treaty on the Functioning of the European Union (TFEU), set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens, mutagens or reprotoxic substances for which this is possible, and, where necessary, other directly related provisions.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

2. Limit values and other directly related provisions are set out in Annex III.

↓ 2022/431 Art. 1.12(b)

3. The European Parliament and the Council shall, in accordance with the procedure laid down in Article 153(2), point (b), TFEU, set out biological limit values in Directives on the basis of the available information, including scientific and technical data, together with other relevant health surveillance information.

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

↓ 2022/431 Art. 1.13

Article 18

Identification of non-threshold and threshold reprotoxic substances

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.

↓ 1243/2019 Art. 1 and Annex .III(12)

Article 19

Amendment of Annex II

↓ 2022/431 Art. 1.14

The Commission is empowered to adopt delegated acts in accordance with Article 20 to make strictly technical amendments to Annex II, in order to take account of technical progress, changes in international regulations or specifications and new findings with regard to carcinogens, mutagens or reprotoxic substances.

↓ 1243/2019 Art. 1 and Annex .III(12)

Where, in duly justified and exceptional cases involving imminent, direct and serious risks to workers' and other persons' physical health and safety, imperative grounds of urgency require action in a very short timeframe, the procedure provided for in Article 21 shall apply to delegated acts adopted pursuant to this Article.

↓ 1243/2019 Art. 1 and Annex .III(12)

Article 20

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 19 shall be conferred on the Commission for a period of five years from 26 July 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 19 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[15].

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 19 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 21

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 20(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

15 OJ L 123, 12.5.2016, p. 1.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

Article 22

Use of data

The Commission shall have access to the use made by the competent national authorities of the information referred to in Article 15(8).

↓ 2022/431 Art. 1.15 (adapted)

Article 23

Evaluation

The Commission shall, as part of the next evaluation of the implementation of this Directive in the context of the evaluation referred to in Article 17a of Directive 89/391/EEC, also evaluate the need to modify the limit value for respirable crystalline silica dust. The Commission shall launch this process in 2022 and, where appropriate, shall subsequently propose necessary amendments and modifications related to that substance in a subsequent revision of this Directive.

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 31 December 2022, where appropriate, after consulting the (ACSH) and taking into account the existing recommendations of different agencies, stakeholders and the World Health Organization, on priority carcinogens, mutagens and reprotoxic substances for which limit values are needed, the Commission shall present an action plan to achieve new or revised occupational exposure limits values for at least 25 substances, groups of substances or process-generated substances. Where appropriate, taking into account that action plan, the latest developments in scientific knowledge, and after consulting the ACSH, the Commission shall present legislative proposals pursuant to Article 17 without delay.

Where appropriate and no later than 5 April 2025, taking into account the latest developments in scientific knowledge and after appropriate consultation of relevant stakeholders, 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 1272/2008, a mutagen or a reprotoxic substance.

No later than 31 December 2022, the Commission shall, after appropriate consultation of relevant stakeholders, prepare Union guidelines for the preparation, administration, and disposal of hazardous medicinal products at the place of work. Those guidelines shall be published on the website of EU-OSHA and shall be disseminated in all Member States by the relevant competent authorities.

Where appropriate, after receipt of an opinion from the ACSH, the Commission shall, taking into account the existing methodology for setting limit values for carcinogens in some Member States and the opinion of the ACSH, establish upper and lower risk levels. No later than 12 months after receipt of the ACSH opinion, the Commission shall, after appropriate

consultation of relevant stakeholders, prepare Union guidelines on the methodology establishing risk-based limit values. Those guidelines shall be published on the EU-OSHA website and disseminated in all Member States by the relevant competent authorities.

No later than 31 December 2024, the Commission shall, taking into account the latest developments in scientific knowledge, and after appropriate consultation of relevant stakeholders, propose, where appropriate, a limit value for cobalt and inorganic cobalt compounds.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23 (adapted)

Article 24

Notifying the Commission

Member States shall communicate to the Commission the provisions of national law which they adopt in the future in the field governed by this Directive.

Article 25

Repeal

Directive ⌦ 2004/37/EC ⌫, as amended by the ⌦ acts listed ⌫ in Annex V, Part A, is repealed, without prejudice to the obligations of the Member States ⌦ relating to ⌫ the time-limits for ⌦ the ⌫ transposition ⌦ into national law and the dates of application of the Directives ⌫ set out in Annex V, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VI.

Article 26

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 27

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*