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► B ► C1 ► M6 **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) ◀**  
**(codified version)**  
**(Text with EEA relevance) ◀**  
**(OJ L 158, 30.4.2004, p. 50)**

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► <u>M1</u>	Directive 2014/27/EU of the European Parliament and of the Council of 26 February 2014	L 65	1	5.3.2014
► <u>M2</u>	Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017	L 345	87	27.12.2017
► <u>M3</u>	Directive (EU) 2019/130 of the European Parliament and of the Council of 16 January 2019	L 30	112	31.1.2019
► <u>M4</u>	Directive (EU) 2019/983 of the European Parliament and of the Council of 5 June 2019	L 164	23	20.6.2019
► <u>M5</u>	Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019	L 198	241	25.7.2019
► <u>M6</u>	Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022	L 88	1	16.3.2022
► <u>M7</u>	Directive (EU) 2024/869 of the European Parliament and of the Council of 13 March 2024	L 869	1	19.3.2024

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► C1 Corrigendum, OJ L 229, 29.6.2004, p. 23 (2004/37/EC)

▼ B▼ C1▼ M6

**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)**

▼ C1

**(codified version)**

**(Text with EEA relevance)**

CHAPTER I

**GENERAL PROVISIONS**

*Article 1*

**Objective**

▼ M6

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.

▼ C1

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.

▼ M1

4. As regards asbestos, which is dealt with by Directive 2009/148/EC of the European Parliament and of the Council <sup>(1)</sup>, the provisions of this Directive shall apply whenever they are more favourable to health and safety at work.

▼ C1

*Article 2*

**Definitions**

For the purposes of this Directive,

▼ M1

(a) ‘carcinogen’ means:

<sup>(1)</sup> 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).

**▼ M1**

- (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 of the European Parliament and of the Council <sup>(1)</sup>;
- (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;

**▼ M7**

- (b) ‘mutagen’ means:
  - (i) 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;
  - (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;

**▼ M6**

- (ba) ‘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;
- (bb) ‘non-threshold reprotoxic substance’ means a reprotoxic substance to which there is no safe level of exposure for workers’ health and which is identified as such in the notation column of Annex III;
- (bc) ‘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;
- (c) ‘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;
- (d) ‘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;
- (e) ‘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.

<sup>(1)</sup> 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).

**▼ C1***Article 3***Scope — determination and assessment of risks****▼ M6**

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.

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.

**▼ C1**

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.

**▼ M6**

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

**▼ C1**

## CHAPTER II

**EMPLOYERS' OBLIGATIONS***Article 4***Reduction and replacement****▼ M6**

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.

**▼ C1**

2. The employer shall, upon request, submit the findings of his investigations to the relevant authorities.

**▼C1***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 must be prevented.

**▼M6**

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.

3a. 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.

3b. 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.

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

5. 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;

**▼C1**

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

**▼M6**

(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;

**▼ M6**

- (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;

**▼ C1**

- (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;

**▼ M6**

- (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;

**▼ C1**

- (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 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:

**▼ M6**

- (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;

**▼ C1**

- (c) the number of workers exposed;
- (d) the preventive measures taken;

**▼C1**

- (e) the type of protective equipment used;
- (f) the nature and degree of exposure;
- (g) the cases of replacement.

**▼M2**

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

**▼C1***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 the first subparagraph of paragraph 1 take place are clearly demarcated and indicated or that unauthorised persons are prevented by other means from having access to such areas.

**▼C1***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 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****▼M6**

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:

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

**▼C1**

- (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 may 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;



**▼C1**

- (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.

**▼M6**

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 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.

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 IIIa, 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.

**▼C1***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:

**▼ C1**

- (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 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 him 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.

**▼ M3***Article 13a***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.

▼ C1

CHAPTER III  
MISCELLANEOUS PROVISIONS

*Article 14*

**Health surveillance**

▼ M2

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 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.

▼ C1

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.

▼ M6

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.

▼ C1

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

▼ M6

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.

▼ C1

5. Information and advice must 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

**▼C1**

— 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 given in Annex II.

**▼M6**

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.

**▼M2**

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

**▼C1***Article 15***Record keeping****▼M6**

1. With regard to carcinogens and mutagens, the list referred to in Article 12, point (c), and the medical record referred to in Article 14(4) shall be kept for at least 40 years following the end of exposure, in accordance with national law or practice.

1a. With regard to reprotoxic substances, the list referred to in Article 12, point (c), and the medical record referred to in Article 14(4) shall be kept for at least five years following the end of exposure, in accordance with national law or practice.

**▼C1**

2. 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 16***Limit values****▼M6**

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.

**▼ C1**

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

**▼ M6**

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 IIIa.

*Article 16a***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.

**▼ M5***Article 17***Amendment of Annex II****▼ M6**

The Commission is empowered to adopt delegated acts in accordance with Article 17a 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.

**▼ M5**

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 17b shall apply to delegated acts adopted pursuant to this Article.

*Article 17a***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.

**▼M5**

2. The power to adopt delegated acts referred to in Article 17 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 17 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 <sup>(1)</sup>.

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 17 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 17b***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 17a(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.

**▼C1***Article 18***Use of data**

The Commission shall have access to the use made by the competent national authorities of the information referred to in Article 14(8).

<sup>(1)</sup> OJ L 123, 12.5.2016, p. 1.

▼ **M6***Article 18a***Evaluation**

► **M7** 1. ◀ 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.

► **M7** 2. ◀ 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.

► **M7** 3. ◀ No later than 31 December 2022, where appropriate, after consulting the Advisory Committee for Safety and Health at Work (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 16 without delay.

► **M7** 4. ◀ 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.

► **M7** 5. ◀ 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.

► **M7** 6. ◀ 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.

**▼M6**

►M7 7. ◀ 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.

**▼M7**

8. No later than 30 June 2024, the Commission shall initiate an assessment of the effects of exposure to a combination of substances with a view to preparing Union guidelines thereon where appropriate. The Commission shall take into account the latest developments in scientific knowledge, the opinion of the Committee for Risk Assessment of the European Chemicals Agency established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council <sup>(1)</sup>, the opinion of the ACSH and the best practices in the Member States, and shall conduct appropriate consultations of relevant stakeholders. Those guidelines shall be published on the EU-OSHA website and disseminated in all Member States by the relevant competent authorities.

9. No later than 9 April 2026, the Commission shall initiate the procedure to obtain a scientific assessment of endocrine disruptors that can affect the health and safety of workers, with a view to evaluating the appropriateness of including them within the scope of this Directive in order to better protect the health and safety of workers. Where appropriate the Commission shall, after consulting the ACSH, submit a legislative proposal.

10. In the context of its evaluation pursuant to Article 17a(4) of Directive 89/391/EEC, the Commission shall, no later than 9 April 2029, assess the occupational limit values for lead and its inorganic compounds. Where appropriate, the Commission shall, taking into account the latest developments in scientific knowledge and after consulting the ACSH, submit a legislative proposal to amend those limit values.

11. No later than 9 April 2026, the Commission shall, after appropriate consultation of relevant stakeholders, draw up Union guidelines for health surveillance, including biological monitoring. Those guidelines shall include advice on the implementation of provisions regarding blood lead level, taking into account the slow removal of lead from the body and the special protection of female workers of childbearing age.

**▼M6****▼C1***Article 19***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.

<sup>(1)</sup> 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).



**▼C1***Article 20***Repeal**

Directive 90/394/EEC, as amended by the Directives referred to in Annex IV, Part A of this Directive is repealed, without prejudice to the obligations of the Member States concerning the time limits for transposition set out in Annex IV, Part B of this Directive.

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 V.

*Article 21***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 22***Addressees**

This Directive is addressed to the Member States.

**▼ C1***ANNEX I***▼ M7****List of substances, mixtures and processes (Article 2, points (a)(ii) and (b)(ii))****▼ C1***(Article 2(a)(iii))*

1. Manufacture of auramine.
2. Work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch.
3. Work involving exposure to dusts, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes.
4. Strong acid process in the manufacture of isopropyl alcohol.
5. Work involving exposure to hardwood dusts <sup>(1)</sup>.

**▼ M2**

6. Work involving exposure to respirable crystalline silica dust generated by a work process.

**▼ M3**

7. Work involving dermal exposure to mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine.
8. Work involving exposure to diesel engine exhaust emissions.

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<sup>(1)</sup> A list of some hardwoods is to be found in Volume 62 of the Monographs on the Evaluation of Carcinogenic Risks to Humans 'Wood Dust and Formaldehyde', published by the International Agency for Research on Cancer, Lyon, 1995.

**▼ C1***ANNEX II***Practical recommendations for the health surveillance of workers***(Article 14(7))***▼ M6**

1. 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.

**▼ C1**

2. Health surveillance of workers must be carried out in accordance with the principles and practices of occupational medicine; it must include at least the following measures:
  - keeping records of a worker's medical and occupational history,
  - a personal interview,
  - where appropriate, biological surveillance, as well as detection of early and reversible effects.

Further tests may be decided upon for each worker when he is the subject of health surveillance, in the light of the most recent knowledge available to occupational medicine.

LIMIT VALUES AND OTHER DIRECTLY RELATED PROVISIONS (ARTICLE 16)

A. LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

Name of agent	EC No <sup>(1)</sup>	CAS No <sup>(2)</sup>	Limit values						Notation	Transitional measures
			8 hours <sup>(3)</sup>			Short-term <sup>(4)</sup>				
			mg/m³ <sup>(5)</sup>	ppm <sup>(6)</sup>	f/ml <sup>(7)</sup>	mg/m³ <sup>(5)</sup>	ppm <sup>(6)</sup>	f/ml <sup>(7)</sup>		
Hardwood dusts	—	—	2 <sup>(8)</sup>	—	—	—	—	—	—	Limit value 3 mg/m³ until 17 January 2023
Chromium (VI) compounds which are carcinogens within the meaning of point (i) of Article 2(a) (as chromium)	—	—	0,005	—	—	—	—	—	—	Limit value 0,010 mg/m³ until 17 January 2025  Limit value: 0,025 mg/m³ for welding or plasma cutting processes or similar work processes that generate fume until 17 January 2025
Refractory ceramic fibres which are carcinogens within the meaning of point (i) of Article 2(a)	—	—	—	—	0,3	—	—	—	—	
Respirable crystalline silica dust	—	—	0,1 <sup>(9)</sup>	—	—	—	—	—	—	
Benzene	200-753-7	71-43-2	0,66	0,2	–	–	–	–	Skin <sup>(15)</sup>	Limit value 1 ppm (3,25 mg/m³) until 5 April 2024. Limit value 0,5 ppm (1,65 mg/m³) from 5 April 2024 until 5 April 2026.

▼ **M3**

Name of agent	EC No <sup>(1)</sup>	CAS No <sup>(2)</sup>	Limit values						Notation	Transitional measures
			8 hours <sup>(3)</sup>			Short-term <sup>(4)</sup>				
			mg/m <sup>3</sup> <sup>(5)</sup>	ppm <sup>(6)</sup>	f/ml <sup>(7)</sup>	mg/m <sup>3</sup> <sup>(5)</sup>	ppm <sup>(6)</sup>	f/ml <sup>(7)</sup>		
Vinyl chloride monomer	200-831-0	75-01-4	2,6	1	—	—	—	—	—	
Ethylene oxide	200-849-9	75-21-8	1,8	1	—	—	—	—	skin <sup>(10)</sup>	
1,2-Epoxypropane	200-879-2	75-56-9	2,4	1	—	—	—	—	—	
Trichloroethylene	201-167-4	79-01-6	54,7	10	—	164,1	30	—	skin <sup>(10)</sup>	
Acrylamide	201-173-7	79-06-1	0,1	—	—	—	—	—	skin <sup>(10)</sup>	
2-Nitropropane	201-209-1	79-46-9	18	5	—	—	—	—	—	
o-Toluidine	202-429-0	95-53-4	0,5	0,1	—	—	—	—	skin <sup>(10)</sup>	
4,4'-Methylenedianiline	202-974-4	101-77-9	0,08	—	—	—	—	—	skin <sup>(10)</sup>	

▼ **M3**

Name of agent	EC No <sup>(1)</sup>	CAS No <sup>(2)</sup>	Limit values						Notation	Transitional measures
			8 hours <sup>(3)</sup>			Short-term <sup>(4)</sup>				
			mg/m <sup>3</sup> <sup>(5)</sup>	ppm <sup>(6)</sup>	f/ml <sup>(7)</sup>	mg/m <sup>3</sup> <sup>(5)</sup>	ppm <sup>(6)</sup>	f/ml <sup>(7)</sup>		
Epichlorohydrine	203-439-8	106-89-8	1,9	—	—	—	—	—	skin <sup>(10)</sup>	
Ethylene dibromide	203-444-5	106-93-4	0,8	0,1	—	—	—	—	skin <sup>(10)</sup>	
1,3-Butadiene	203-450-8	106-99-0	2,2	1	—	—	—	—	—	
Ethylene dichloride	203-458-1	107-06-2	8,2	2	—	—	—	—	skin <sup>(10)</sup>	
Hydrazine	206-114-9	302-01-2	0,013	0,01	—	—	—	—	skin <sup>(10)</sup>	
Bromoethylene	209-800-6	593-60-2	4,4	1	—	—	—	—	—	
Diesel engine exhaust emissions			0,05 (*)							The limit value shall apply from 21 February 2023. For underground mining and tunnel construction the limit value shall apply from 21 February 2026.
Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are carcinogens within the meaning of this Directive									skin <sup>(10)</sup>	

▼ **M3**

Name of agent	EC No <sup>(1)</sup>	CAS No <sup>(2)</sup>	Limit values						Notation	Transitional measures
			8 hours <sup>(3)</sup>			Short-term <sup>(4)</sup>				
			mg/m <sup>3</sup> <sup>(5)</sup>	ppm <sup>(6)</sup>	f/ml <sup>(7)</sup>	mg/m <sup>3</sup> <sup>(5)</sup>	ppm <sup>(6)</sup>	f/ml <sup>(7)</sup>		
Mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine									skin <sup>(10)</sup>	

▼ **M4**

Cadmium and its inorganic compounds	—	—	0,001 <sup>(11)</sup>	—	—	—	—	—		Limit value 0,004 mg/m <sup>3</sup> <sup>(12)</sup> until 11 July 2027
Beryllium and inorganic beryllium compounds	—	—	0,0002 <sup>(11)</sup>	—	—	—	—	—	dermal and respiratory sensitisation <sup>(13)</sup>	Limit value 0,0006 mg/m <sup>3</sup> until 11 July 2026
Arsenic acid and its salts, as well as inorganic arsenic compounds	—	—	0,01 <sup>(11)</sup>	—	—	—	—	—	—	For the copper smelting sector, the limit value shall apply from 11 July 2023
Formaldehyde	200-001-8	50-00-0	0,37	0,3	—	0,74	0,6	—	dermal sensitisation <sup>(14)</sup>	Limit value of 0,62 mg/m <sup>3</sup> or 0,5 ppm <sup>(3)</sup> for the health care, funeral and embalming sectors until 11 July 2024
4,4'-Methylene-bis (2-chloroaniline)	202-918-9	101-14-4	0,01	—	—	—	—	—	skin <sup>(10)</sup>	

▼ **M3**

Name of agent	EC No (1)	CAS No (2)	Limit values						Notation	Transitional measures
			8 hours (3)			Short-term (4)				
			mg/m <sup>3</sup> (5)	ppm (6)	f/ml (7)	mg/m <sup>3</sup> (5)	ppm (6)	f/ml (7)		

▼ **M6**

Acrylonitrile	203-466-5	107-13-1	1	0,45	–	4	1,8	–	Skin <sup>(10)</sup> Dermal sensitisation <sup>(14)</sup>	The limit values shall apply from 5 April 2026.
Nickel compounds	–	–	0,01 <sup>(15)</sup> 0,05 <sup>(16)</sup>	–	–	–	–	–	Dermal and respiratory sensitisation <sup>(13)</sup>	The limit value <sup>(15)</sup> shall apply from 18 January 2025 The limit value <sup>(16)</sup> shall apply from 18 January 2025. Until then a limit value of 0,1 mg/m <sup>3</sup> <sup>(16)</sup> shall apply.

▼ **M7**

Lead and its inorganic compounds			0,03 <sup>(11)</sup>						Non-threshold reprotoxic substance	
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▼ **M6**

N,N-Dimethylacetamide	204-826-4	127-19-5	36	10		72	20		Skin <sup>(10)</sup>	
Nitrobenzene	202-716-0	98-95-3	1	0,2					Skin <sup>(10)</sup>	
N,N Dimethylformamide	200-679-5	68-12-2	15	5		30	10		Skin <sup>(10)</sup>	
2-Methoxyethanol	203-713-7	109-86-4		1					Skin <sup>(10)</sup>	
2-Methoxyethyl acetate	203-772-9	110-49-6		1					Skin <sup>(10)</sup>	
2-Ethoxy ethanol	203-804-1	110-80-5	8	2					Skin <sup>(10)</sup>	
2-Ethoxyethyl acetate	203-839-2	111-15-9	11	2					Skin <sup>(10)</sup>	
1-Methyl-2-pyrrolidone	212-828-1	872-50-4	40	10		80	20		Skin <sup>(10)</sup>	



▼ **M6**

Name of agent	EC No <sup>(1)</sup>	CAS No <sup>(2)</sup>	Limit values						Notation	Transitional measures
			8 hours <sup>(3)</sup>			Short-term <sup>(4)</sup>				
			mg/m <sup>3</sup> <sup>(5)</sup>	ppm <sup>(6)</sup>	f/ml <sup>(7)</sup>	mg/m <sup>3</sup> <sup>(5)</sup>	ppm <sup>(6)</sup>	f/ml <sup>(7)</sup>		
Mercury and divalent inorganic mercury compounds including mercuric oxide and mercuric chloride (measured as mercury)			0,02							
Bisphenol A; 4,4'-Isopropylidenediphenol	201-245-8	80-05-7	2 <sup>(11)</sup>							
Carbon monoxide	211-128-3	630-08-0	23	20		117	100			

▼ **M3**

<sup>(1)</sup> EC No, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, of Regulation (EC) No 1272/2008.

<sup>(2)</sup> CAS No: Chemical Abstract Service Registry Number.

<sup>(3)</sup> Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).

<sup>(4)</sup> Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.

<sup>(5)</sup> mg/m<sup>3</sup> = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).

<sup>(6)</sup> ppm = parts per million by volume in air (ml/m<sup>3</sup>).

<sup>(7)</sup> f/ml = fibres per millilitre.

<sup>(8)</sup> Inhalable fraction: if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture.

<sup>(9)</sup> Respirable fraction.

<sup>(10)</sup> Substantial contribution to the total body burden via dermal exposure possible.

► **M4** <sup>(11)</sup> Inhalable fraction.

<sup>(12)</sup> Inhalable fraction. Respirable fraction in those Member States that implement, on the date of the entry into force of this Directive, a biomonitoring system with a biological limit value not exceeding 0,002 mg Cd/g creatinine in urine.

<sup>(13)</sup> The substance can cause sensitisation of the skin and of the respiratory tract.

<sup>(14)</sup> The substance can cause sensitisation of the skin. ◀

<sup>(15)</sup> Respirable fraction, measured as nickel.

<sup>(16)</sup> Inhalable fraction, measured as nickel.

(\*) Measured as elemental carbon.

B. OTHER DIRECTLY RELATED PROVISIONS

p.m.

▼ **M7***ANNEX IIIa***BIOLOGICAL LIMIT VALUES AND HEALTH SURVEILLANCE MEASURES***(Article 16(4))*

Lead and its inorganic compounds

1.1. Biological monitoring must include measuring the blood lead level (PbB) using absorption spectrometry or a method giving equivalent results.

1.1.1. Until 31 December 2028, the binding biological limit value is:

30 µg Pb/100 ml blood

For workers whose blood lead level exceeds the biological limit value of 30 µg Pb/100 ml blood due to exposure which has occurred before 9 April 2026, but is below 70 µg Pb/100 ml blood, medical surveillance is carried out on a regular basis. If a declining trend towards the limit value of 30 µg Pb/100 ml blood is established in those workers, they may be allowed to continue with work involving exposure to lead.

1.1.2. From 1 January 2029, the binding biological limit value is:

15 µg Pb/100 ml blood <sup>(1)</sup>

For workers whose blood lead level exceeds the biological limit value of 15 µg Pb/100 ml blood due to exposure which has occurred before 9 April 2026, but is below 30 µg Pb/100 ml blood, medical surveillance is carried out on a regular basis. If a declining trend towards the limit value of 15 µg Pb/100 ml blood is established in those workers, they may be allowed to continue with work involving exposure to lead.

1.2. Medical surveillance is carried out if exposure to a concentration of lead in air is greater than 0,015 mg/m<sup>3</sup>, calculated as a time-weighted average over 40 hours per week, or a blood lead level greater than 9 µg Pb/100 ml blood is measured in individual workers. Medical surveillance is also carried out with regard to female workers of childbearing age whose blood lead level exceeds 4,5 µg Pb/100 ml blood or the national reference value of the general population not occupationally exposed to lead, if such a value exists.

<sup>(1)</sup> It is recommended that the blood lead level in women of childbearing age does not exceed the reference values of the general population not occupationally exposed to lead in the respective EU Member State. When national reference levels are not available, it is recommended that blood lead levels in women of childbearing age do not exceed the Biological Guidance Value of 4,5 µg/100 ml.

**▼C1***ANNEX IV***Part A****Repealed Directive and its successive amendments***(referred to by Article 20)*

Council Directive 90/394/EEC (OJ L 196, 26.7.1990, p. 1)

Council Directive 97/42/EC (OJ L 179, 8.7.1997, p. 4)

Council Directive 1999/38/EC (OJ L 138, 1.6.1999, p. 66)

**Part B****Deadlines for transposition into national law***(referred to by Article 20)*

Directive	Deadline for transposition
90/394/EEC	31 December 1992
97/42/EC	27 June 2000
1999/38/EC	29 April 2003



## ANNEX V

## CORRELATION TABLE

Directive 90/394/EC	This Directive
Article 1	Article 1
Article 2(a)	Article 2 (a)
Article 2(aa)	Article 2(b)
Article 2(b)	Article 2 (c)
Articles 3 to 9	Article 3 to 9
Article 10(1)(a)	Article 10(1)(a)
Article 10(1)(b), first sentence	Article 10(1)(b)
Article 10(1)(b), second sentence	Article 10(1)(c)
Article 10(1)(c)	Article 10(1)(d)
Article 10(1)(d), first and second sentences	Article 10(1)(e)
Article 10(1)(d), third sentence	Article 10(1) (f)
Article 10(2)	Article 10 (2)
Articles 11 to 18	Articles 11 to 18
Article 19(1) first subparagraph	—
Article 19(1) second subparagraph	—
Article 19(1) third subparagraph	—
Article 19(2)	Article 19
—	Article 20
—	Article 21
Article 20	Article 22
Annex I	Annex I
Annex II	Annex II
Annex III	Annex III
—	Annex IV
—	Annex V