Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version) (Text with EEA relevance)

[[X1]DIRECTIVE 2004/37/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 29 April 2004

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

(codified version)

(Text with EEA relevance)**]**

[[X1]THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 137(2) thereof,

Having regard to the proposal from the Commission,

Having regard to the pinion of the European Economic and Social Committee[(1)],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)[(3)] has been substantially amended several times[(4)]. In the interests of clarity and rationality, the said Directive should therefore be codified.

(2) Compliance with the minimum requirements designed to guarantee a better standard of health and safety as regards the protection of workers from the risks related to exposure to carcinogens or mutagens at work is essential to ensure the health and safety of workers and is also intended to provide a level of minimum protection for all workers in the Community.

(3) This Directive is an individual Directive within the meaning of Article 16(1) of 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[(5)]. Therefore the provisions of that Directive are fully applicable to the exposure of workers to carcinogens or mutagens, without prejudice to more stringent and/or specific provisions contained in this Directive.

(4) A consistent level of protection from the risks related to carcinogens or mutagens has to be established for the Community as a whole and that level of protection has to be set not by detailed prescriptive requirements but by a framework of general principles to enable Member States to apply the minimum requirements consistently.

(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.

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

(7) Annex VI to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[(6)] contains the classification criteria and labelling procedures in respect of each substance.

(8) Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[(7)] contains particulars on the classification criteria and labelling procedures in respect of such preparations.

(9) In all work situations workers must be protected in respect of preparations containing one or more carcinogens or mutagens and from carcinogenic or mutagenic compounds arising at work.

(10) For some agents it is necessary to consider all absorption pathways, including the possibility of penetration through the skin, in order to ensure the best possible level of protection.

(11) Although current scientific knowledge is not such that a level can be established below which risks to health cease to exist, a reduction in exposure to carcinogens or mutagens will nonetheless reduce those risks.

(12) In order to contribute to a reduction in these risks, limit values and other directly related provisions should be established for all those carcinogens or mutagens for which the available information, including scientific and technical data, make this possible.

(13) Occupational exposure limit values must be regarded as an important component of the general arrangements for the protection of workers. Such limit values must be revised whenever this becomes necessary in the light of more recent scientific data.

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

(15) Preventive measures must be taken for the protection of the health and safety of workers exposed to carcinogens or mutagens.

(16) This Directive constitutes a practical aspect of the realisation of the social dimension of the internal market.

(17) Pursuant to Council Decision 74/325/EEC[8], the Commission consulted the Advisory Committee on Safety and Health at Work with a view to drawing up proposals for the Directives taken over in this Directive.

(18) This Directive is without prejudice to the obligations of the Member States concerning the time limits for transposition set out in Part B of Annex IV,

HAVE ADOPTED THIS DIRECTIVE:

Editorial Information

X1 Substituted by Corrigendum to Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version) (Official Journal of the European Union L 158 of 30 April 2004).

CHAPTER I

GENERAL PROVISIONS

Article 1

Objective

1 This Directive has as its aim the protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work.

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.

[[F1]4 As regards asbestos, which is dealt with by Directive 2009/148/EC of the European Parliament and of the Council[9], the provisions of this Directive shall apply whenever they are more favourable to health and safety at work.**]**

Textual Amendments

F1 Substituted by Directive 2014/27/EU of the European Parliament and of the Council of 26 February 2014 amending Council Directives 92/58/EEC, 92/85/EEC, 94/33/EC, 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council, in order to align them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Article 2

Definitions

For the purposes of this Directive,

(a) **[**F1‘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 of the European Parliament and of the Council(10);

(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;**]**

(b) **[**F1‘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;**]**

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

Textual Amendments

F1 Substituted by Directive 2014/27/EU of the European Parliament and of the Council of 26 February 2014 amending Council Directives 92/58/EEC, 92/85/EEC, 94/33/EC, 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council, in order to align them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

Article 3

Scope — determination and assessment of risks

1 This Directive shall apply to activities in which workers are or are likely to be exposed to carcinogens or mutagens as a result of their work.

2 In the case of any activity likely to involve a risk of exposure to carcinogens or mutagens, 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 or mutagens.

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.

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 or mutagens.

CHAPTER II

EMPLOYERS' OBLIGATIONS

Article 4

Reduction and replacement

1 The employer shall reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, **[**F1mixture**]** 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.

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

Textual Amendments

F1 Substituted by Directive 2014/27/EU of the European Parliament and of the Council of 26 February 2014 amending Council Directives 92/58/EEC, 92/85/EEC, 94/33/EC, 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council, in order to align them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

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.

2 Where it is not technically possible to replace the carcinogen or mutagen by a substance, **[**F1mixture**]** 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 or mutagen 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 is reduced to as low a level as is technically possible.

4 Exposure shall not exceed the limit value of a carcinogen as set out in Annex III.

5 Wherever a carcinogen or mutagen is used, the employer shall apply all the following measures:

a limitation of the quantities of a carcinogen or mutagen at the place of work;

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

c design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens or mutagens into the place of work;

d evacuation of carcinogens or mutagens 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 or mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;

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;

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 or mutagens;

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.

Textual Amendments

F1 Substituted by Directive 2014/27/EU of the European Parliament and of the Council of 26 February 2014 amending Council Directives 92/58/EEC, 92/85/EEC, 94/33/EC, 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council, in order to align them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

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:

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

(b) the quantities of substances or **[**[F1]mixtures**]** manufactured or used which contain carcinogens or mutagens;

(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.

[[F2]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.**]**

Textual Amendments

F1 Substituted by Directive 2014/27/EU of the European Parliament and of the Council of 26 February 2014 amending Council Directives 92/58/EEC, 92/85/EEC, 94/33/EC, 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council, in order to align them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

F2 Inserted by Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Text with EEA relevance).

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.

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

1 Employers shall be obliged, in the case of all activities for which there is a risk of contamination by carcinogens or mutagens, 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 or mutagens;

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;

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.

The training shall be:

— adapted to take account of new or changed risk, and

— repeated periodically if necessary.

2 Employers shall inform workers of installations and related containers containing carcinogens or mutagens, ensure that all containers, packages and installations containing

carcinogens or mutagens are labelled clearly and legibly, and display clearly visible warning and hazard signs.

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 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.

[F3 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.**]**

Textual Amendments

F3 Inserted by Directive (EU) 2019/130 of the European Parliament and of the Council of 16 January 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Text with EEA relevance).

CHAPTER III

MISCELLANEOUS PROVISIONS

Article 14

Health surveillance

[F4 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.**]**

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.

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

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

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.

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

— 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.

[[F4]8 All cases of cancer identified in accordance with national law or practice as resulting from occupational exposure to a carcinogen or mutagen shall be notified to the competent authority.

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.**]**

Textual Amendments

F4 Substituted by Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Text with EEA relevance).

Article 15

Record keeping

1 The list referred to in point (c) of Article 12 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 laws and/or practice.

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

1 The Council shall, in accordance with the procedure laid down in Article 137(2) of the Treaty, set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens or mutagens for which this is possible, and, where necessary, other directly related provisions.

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

[[F5]*Article 17*

Amendment of Annex II

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 or mutagens.

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.**]**

Textual Amendments

F5 Substituted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

[F6 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.

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[(11)].

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.

Textual Amendments

F6 Inserted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

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.**]**

Textual Amendments

F6 Inserted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).

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).

[*F2**Article 18a*

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 propose, where appropriate, necessary amendments and modifications related to that substance.

No later than in the first quarter of 2019, the Commission shall, taking into account the latest developments in scientific knowledge, assess the option of amending the scope of this Directive to include reprotoxic substances. On that basis, the Commission shall present, if appropriate, and after consulting management and labour, a legislative proposal.

[F7No later than 11 July 2022, the Commission shall assess the option of amending this Directive to add provisions on a combination of an airborne occupational exposure limit and a biological limit value for cadmium and its inorganic compounds.

No later than 30 June 2020, the Commission shall, taking into account the latest developments in scientific knowledge, and after appropriate consultation with relevant stakeholders, in particular health practitioners and health professionals, assess the option

of amending this Directive in order to include hazardous drugs, including cytotoxic drugs, or to propose a more appropriate instrument for the purpose of ensuring the occupational safety of workers exposed to such drugs. On that basis, the Commission shall present, if appropriate, and after consulting management and labour, a legislative proposal.**]]**

Textual Amendments

F2 Inserted by Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Text with EEA relevance).

F7 Inserted by Directive (EU) 2019/983 of the European Parliament and of the Council of 5 June 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Text with EEA relevance).

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.

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.

ANNEX I

List of substances, **[**F1mixtures**]** and processes
(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(12).

[F26. Work involving exposure to respirable crystalline silica dust generated by a work process.**]**

[F37. 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.**]**

ANNEX II

Practical recommendations for the health surveillance of workers
(Article 14(7))

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

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.

[F8ANNEX III

LIMIT VALUES AND OTHER DIRECTLY RELATED PROVISIONS (ARTICLE 16)

Textual Amendments

F8 Substituted by Directive (EU) 2019/130 of the European Parliament and of the Council of 16 January 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Text with EEA relevance).

A.LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

Name of agent	EC No[a]	CAS No[b]	Limit values						Notation	Transitional measures
			8 hours[c]			Short-term[d]				
			mg/m^3[e]	ppm[f]	f/ml[g]	mg/m^3[e]	ppm[f]	f/ml[g]		
Hardwood dusts	—	—	2[h]	—	—	—	—	—	—	Limit value 3 mg/m^3 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/m^3 until 17 January 2025 Limit value: 0,025 mg/m^3 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[i]	—	—	—	—	—	—	
Benzene	200-753-7	71-43-2	3,25	1	—	—	—	—	skin[j]	
Vinyl chloride monomer	200-831-0	75-01-4	2,6	1	—	—	—	—	—	
Ethylene oxide	200-849-9	75-21-8	1,8	1	—	—	—	—	skin[j]	
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[j]	
Acrylamide	201-173-7	79-06-1	0,1	—	—	—	—	—	skin[j]	
2-Nitropropane	201-209-4	79-46-9	18	5	—	—	—	—	—	
o-Toluidine	202-429-0	95-53-4	0,5	0,1	—	—	—	—	skin[j]	
4,4′-Methylenedianiline	202-974-4	101-77-9	0,08	—	—	—	—	—	skin[j]	
Epichlorohydrin	203-439-8	106-89-8	1,9	—	—	—	—	—	skin[j]	
Ethylene dibromide	203-444-1	106-93-4	0,8	0,1	—	—	—	—	skin[j]	
1,3-Butadiene	203-450-8	106-99-0	2,2	1	—	—	—	—	—	
Ethylene dichloride	203-458-1	107-06-2	8,2	2	—	—	—	—	skin[j]	

Hydrazine	206-114-9	302-01-2	0,013	0,01	—	—	—	—	skin[j]	
Bromoethylene	209-800-6	593-60-2	4,4	1	—	—	—	—	—	
Diesel engine exhaust emissions			0,05[o]							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[j]	
Mineral oils that have been used before in									skin[j]	

internal combustion engines to lubricate and cool the moving parts within the engine										
[F7Cadmium and its inorganic compounds	—	—	0,001[k]	—	—	—	—	—		Limit value 0,004 mg/m^{3}[l] until 11 July 2027
Beryllium and inorganic beryllium compounds	—	—	0,0002[k]	—	—	—	—	—	dermal and respiratory sensitisation	Limit value 0,0006 mg/m^{3}[m] until 11 July 2026
Arsenic acid and its salts, as well as inorganic arsenic compounds	—	—	0,01[k]	—	—	—	—	—	—	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	Limit value of 0,62 mg/m^{3} or 0,5 ppm[e] 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[j]	]

a	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.
b	CAS No: Chemical Abstract Service Registry Number.
c	Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).
d	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.
e	mg/m^3 = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).
f	ppm = parts per million by volume in air (ml/m^3).
g	f/ml = fibres per millilitre.
h	Inhalable fraction: if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture.
i	Respirable fraction.
j	Substantial contribution to the total body burden via dermal exposure possible.
k	[F7Inhalable fraction.
l	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.
m	The substance can cause sensitisation of the skin and of the respiratory tract.
n	The substance can cause sensitisation of the skin.]
o	Measured as elemental carbon.

B. OTHER DIRECTLY RELATED PROVISIONS

p.m.]

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]

(1) **[**[X1]OJ C 368, 20.12.1999, p. 18.**]**

(2) **[**[X1]Opinion of the European Parliament of 2 September 2003 (not yet published in the Official Journal) and Council Decision of 30 March 2004.**]**

(3) **[**[X1]OJ L 196, 26.7.1990, p. 1. Directive as last amended by Directive 1999/38/EC (OJ L 138, 1.6.1999, p. 66).**]**

(4) **[**[X1]See Annex IV, Part A.**]**

(5) **[**[X1]OJ L 183, 29.6.1989, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).**]**

(6) **[**[X1]OJ 196, 16.8.1967, p. 1. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).**]**

(7) **[**[X1]OJ L 200, 30.7.1999, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.**]**

(8) **[**[X1]OJ L 185, 9.7.1974, p. 15. Decision as repealed by the Council Decision of 22 July 2003 (OJ C 218, 13.9.2003, p. 1).**]**

(9) **[**[X1]**[**[F1]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).**]]**

(10) **[**[X1]**[**[F1]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).**]]**

(11) **[**[X1]**[**[F6]OJ L 123, 12.5.2016, p. 1.**]]**

(12) **[**[X1]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.**]**

Editorial Information

X1 Substituted by Corrigendum to Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version) (Official Journal of the European Union L 158 of 30 April 2004).

Textual Amendments

F1 Substituted by Directive 2014/27/EU of the European Parliament and of the Council of 26 February 2014 amending Council Directives 92/58/EEC, 92/85/EEC, 94/33/EC, 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council, in order to align them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

F6 Inserted by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (Text with EEA relevance).