

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)**

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 Opinion of the European Economic and Social Committee¹,
Having consulted the Committee of the Regions,
Acting in accordance with the procedure laid down in Article 251 of the Treaty²,

¹ OJ C 368, 20.12.1999, p. 18.

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

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)¹ has been substantially amended several times². 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 work³. 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.

¹ 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).

² See Annex IV, Part A.

³ 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).

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- (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 substances¹ 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 preparations² 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.

¹ 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).

² OJ L 200, 30.7.1999, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

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- (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/EEC¹, 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,

¹ 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).

HAVE ADOPTED THIS DIRECTIVE:

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.

4. As regards asbestos, which is dealt with by Directive 83/477/EEC¹, the provisions of this Directive shall apply whenever they are more favourable to health and safety at work.

Article 2

Definitions

For the purposes of this Directive,

- a) "carcinogen" means:
- i) a substance which meets the criteria for classification as a category 1 or 2 carcinogen set out in Annex VI to Directive 67/548/EEC;
 - ii) a preparation composed of one or more substances referred to in point (i) where the concentration of one or more of the individual substances meets the requirements for concentration limits for the classification of a preparation as a category 1 or 2 carcinogen set out either:

in Annex I to Directive 67/548/EEC; or

in Part B of Annex II to Directive 1999/45/EC where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

¹ Council Directive 83/477/EEC of 19 September 1983 on the protection of workers from the risks related to exposure to asbestos at work (second individual Directive within the meaning of Article 8 of Directive 80/1107/EEC) (OJ L 263, 24.9.1983, p. 25). Directive as last amended by Directive 2003/18/EC of the European Parliament and of the Council (OJ L 97, 15.4.2003, p. 48).

- iii) a substance, preparation or process referred to in Annex I to this Directive as well as a substance or preparation released by a process referred to in that Annex;
- b) "mutagen" means:
- i) a substance which meets the criteria for classification as a category 1 or 2 mutagen set out in Annex VI to Directive 67/548/EEC;
 - ii) a preparation composed of one or more substances referred to in point (i) where the concentration of one or more of the individual substances meets the requirements for concentration limits for the classification of a preparation as a category 1 or 2 mutagen set out in either:

Annex I to Directive 67/548/EEC; or

Part B of Annex II to Directive 1999/45/EC where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;
- 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.

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, preparation 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.

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, preparation 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.

*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 preparations 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.

*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.

CHAPTER III

MISCELLANEOUS PROVISIONS

Article 14

Health surveillance

1. The Member States shall establish, in accordance with national laws and/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.
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.

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

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.

*Article 17***Annexes**

1. Annexes I and III may be amended in accordance only with the procedure laid down in Article 137(2) of the Treaty.
2. Purely technical adjustments to Annex II in the light of technical progress, changes in international regulations or specifications and new findings in the field of carcinogens or mutagens shall be adopted in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC.

*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).

*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.

Done at Strasbourg, 29 April 2004.

For the European Parliament
The President
P. COX

For the Council
The President
M. McDOWELL

ANNEX I**List of substances, preparations 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 dusts¹.

¹ 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.

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.

ANNEX III**Limit values and other directly related provisions***(Article 16)***A. LIMIT VALUES FOR OCCUPATIONAL EXPOSURE**

Name of agent	EINECS ⁽¹⁾	CAS ⁽²⁾	Limit values		Notation	Transitional measures
			mg/m ³ ⁽³⁾	ppm ⁽⁴⁾		
Benzene	200-753-7	71-43-2	3,25 ⁽⁵⁾	1 ⁽⁵⁾	Skin ⁽⁶⁾	Limit value: 3 ppm (=9,75 mg/m ³) (until 27 June 2003)
Vinyl chloride monomer	200-831	75-01-4	7,77 ⁽⁵⁾	3 ⁽⁵⁾	—	—
Hardwood dusts	—	—	5,0 ⁽⁵⁾⁽⁷⁾	—	—	—

B. OTHER DIRECTLY RELATED PROVISIONS

p.m.

¹ EINECS: European Inventory of Existing Chemical Substances.

² CAS: Chemical Abstract Service Number.

³ mg/m³ = milligrams per cubic metre of air at 20°C and 101,3 kPa (760 mm mercury pressure).

⁴ ppm = parts per million by volume in air (ml/m³).

⁵ Measured or calculated in relation to a reference period of eight hours.

⁶ Substantial contribution to the total body burden via dermal exposure possible.

⁷ Inhalable fraction: if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture.

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