



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 24.07.1996

COM(96) 414 final

95/0229 (SYN)

OPINION OF THE COMMISSION

on the amendments proposed by the European Parliament  
to the Council's common position on the

proposal for a  
COUNCIL DIRECTIVE

**on the protection of workers from the risks related to  
exposure to carcinogens at work**

(presented by the Commission pursuant to Article 189 c (d) of the EC Treaty)



## EXPLANATORY MEMORANDUM

The initial proposal for this amendment to the Directive was presented by the Commission to the Council on 14 September 1995<sup>1</sup>.

The main aims are the removal of the existing exclusion in Directive 90/394/EEC of a whole series of preparations containing carcinogens and the laying down of a limit value for occupational exposure to benzene, a well-known carcinogen.

The European Parliament and the Economic and Social Committee gave their opinion on 20 June 1996<sup>2</sup> and 31 January 1996<sup>3</sup> respectively.

In drawing up this amended proposal, the Commission took into account for the most part the amendments from the European Parliament and suggestions put forward by the Economic and Social Committee, and in particular:

- a) the role of biological monitoring in health surveillance for exposed workers;
- b) the need for coherence with other Community acts on the same subject;
- c) the advisability of having a uniform method for measuring benzene concentrations in air and for analysis;
- d) the advisability of including the derogation concerning primary synthesis in the production of materials for perfumes among the temporary derogations relating to limit values for benzene.

This amendment is presented by the Commission under the terms of Article 189a(2) of the Treaty.

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<sup>1</sup> OJ C 317, 28.11.1995, p.16.

<sup>2</sup> OJ .....

<sup>3</sup> OJ C 97, 1.04.1996, p.25.

**Amended Proposal for a Council Directive  
amending for the first time Directive 90/394/EEC  
on the protection of workers from the  
risks related to exposure to carcinogens at work**

**(Text with EEA relevance)**

**COMMISSION PROPOSAL**

**AMENDED COMMISSION  
PROPOSAL**

**THE COUNCIL OF THE EUROPEAN  
UNION,**

**THE COUNCIL OF THE EUROPEAN  
UNION,**

Having regard to the Treaty establishing  
the European Union, and in particular  
Article 118a thereof,

Having regard to Council Directive  
90/394/EEC of 28 June 1990 on the  
protection of workers from the risks related  
to exposure to carcinogens at work<sup>(1)</sup>, and  
in particular Article 16,

Having regard to the proposal from the  
Commission<sup>(2)</sup>, drawn up following  
consultation with the Advisory Committee  
on Safety, Hygiene and Health Protection  
at Work,

In cooperation with the European  
Parliament<sup>(3)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(4)</sup>,

Whereas Article 118a of the Treaty provides that the Council shall adopt, by means of directives, minimum requirements for encouraging improvements, especially in the working environment, to ensure a better level of protection of the safety and health of workers;

Whereas, under the terms of that Article, such directives are to avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings,

Whereas the Commission's communication on its programme in the field of safety, hygiene and health at the workplace (1996-2000)<sup>(5)</sup> provides in particular for the continuation of work on setting limit values for exposure at the workplace;

Whereas Commission Directive 91/325/EEC<sup>(6)</sup> of 1 March 1991 adapting to technical progress for the twelfth time Council Directive 67/548/EEC<sup>(7)</sup> on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances introduces in Annex III new risk phrases to indicate the health hazards resulting from prolonged exposure and the risk of cancer through inhalation;

Whereas in all work situations workers must be protected in respect of preparations containing one or more carcinogens;

Whereas in all work situations workers must be protected in respect of preparations containing one or more carcinogens and from carcinogenic compounds arising at work;

Whereas, 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;

Whereas the wording of point 2 of Annex I to Directive 90/394/EEC relating to polycyclic aromatic hydrocarbons has posed problems of interpretation in many Member States; whereas, therefore, a new, more precise wording is called for;

Whereas Article 16 of the aforementioned Council Directive 90/394/EEC makes provision for the establishment of exposure limit values on the basis of the available information, including scientific and technical data, in respect of all those carcinogens for which this is possible;

Whereas occupational exposure limit values must be regarded as an important component of the general arrangements for the protection of workers; whereas such limit values must be revised whenever this becomes necessary in the light of more recent scientific data;

Whereas benzene is a carcinogen which is present in many work situations whereas, therefore, a large number of workers are exposed to a potential health risk; whereas, 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 benzene will nonetheless reduce these risks;

Whereas the respect of the minimum requirements on the protection of health and safety of workers from the specific risks related to carcinogens ensures not only the protection of the health and safety of each individual worker but also provides a level of minimum protection of all workers in the Community which avoids any possible distortion in the area of competitiveness;

Whereas benzene is a carcinogen which is present in many work situations; whereas, therefore, a large number of workers are exposed to a potential health risk; whereas, although current scientific knowledge classifies benzene among the substances for which a level cannot be established below which risks to health cease to exist, a reduction in exposure to benzene will nonetheless reduce these risks;

Whereas it is important to set biological limit values to carcinogens in order to estimate the level of absorption of other routes than the breath. Because bio-monitoring is an important procedure for assessing benzene exposure, the Commission should propose a biological limit value for benzene without delay;

Whereas the respect of the minimum requirements on the protection of health and safety of workers from the specific risks related to carcinogens aims not only to ensure the protection of the health and safety of each individual worker but also to provide a level of minimum protection of all workers in the Community which avoids any possible distortion in the area of competitiveness;

Whereas all the directives concerning protection of the health of workers at the place of work and the directives concerning protection of public health and of the general environment must reflect a single overall vision of socio-economic development in the European Community whereas the measures taken concerning benzene under the present Directive must therefore be consistent with the aims and provisions of Directive 94/63/EC(\*) on the control of volatile organic compound emissions (and thus of benzene emissions) resulting from the storage of petrol and its distribution from terminals to service stations;

Whereas provision should be made to ensure the protection of the health and safety of workers concerned, in the case of derogations provided for specified activities or sector of activity where the implementation of the limit value proposed for benzene may be difficult to meet within the date proposed;

Whereas in most small and medium sized enterprises where the main use of benzene might be as a solvent, provisions to lower exposure will not be required as legal provisions already exist in nearly all the member States to restrict or prohibit its use.

Whereas a consistent level of protection from the risks related to carcinogens has to be established for the Community as a whole and whereas 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;

Whereas this amendment constitutes a practical aspect of the realisation of the social dimension of the internal market;

Whereas, pursuant to Decision 74/325/EEC<sup>(9)</sup>, as last amended by the 1985 Act of Accession, the Advisory Committee on Safety, Hygiene and Health Protection at Work is to be consulted by the Commission with a view to drawing up proposals in this field,

**HAS ADOPTED THIS DIRECTIVE:****Article 1****Article 1**

Directive 90/394/EEC is hereby amended as follows:

1. Article 2 shall be replaced by the following:

"For the purposes of this Directive,

- (a) "carcinogen" means:
  - i) a substance which meets the requirements for classification as category 1 or 2 carcinogen according to the criteria of Annex VI of Directive 67/548/EEC<sup>(1)</sup>.
  - ii) a preparation composed of one or more substances referred to in point (a)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 carcinogens set out either:

- in Annex I to Directive 67/548/EEC  
or
  - in Annex I of Directive 88/379/EEC<sup>(10)</sup> where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.
- iii) a substance, preparation or process referred to in Annex I as well as a substance or preparation released by a process referred to in Annex I.
- (b) "limit value" means, unless otherwise specified, the limit of concentration for a "carcinogen" in the air within the breathing zone of a worker."
- (b) "limit value" means, unless otherwise specified, the limit of concentration for a "carcinogen" within the breathing zone of a worker in relation to an appropriate reference period. Breathing zone is the space from where he takes his breath. It shall be forbidden to exceed this value.
- (c) "biological limit value" means the limit of concentration in the appropriate biological medium, of the relevant agent, its metabolite, or an indicator of effect. It shall be forbidden to exceed this value.

2. Article 3(3) shall be replaced by the following:

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

3. In Article 16, the following paragraph shall be added:

"3. In the case of derogations provided for in Annex III, the Member States shall be obliged to ensure that employers comply with procedures and measures in order to take adequate precautions to protect the health and safety of the workers concerned."

4. Item 2 of Annex I shall be replaced by the following:

"Work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch".

5. Part A of Annex III shall be replaced by the following:

**"A. LIMIT VALUES FOR  
OCCUPATIONAL EXPOSURE**

Nome of agent	Einecs (1)	CAS (2)	Limit values mg/m <sup>3</sup> (3) ppm (4)	Notation	Derogations
Benzene	200-753-7	71-43-2	3.25 (5) 1 (5)	Skin (6)	Limit value: 3 ppm (= 9.75 mg/m <sup>3</sup> ) until 31 December 2000 for the following activities or sector of activity: <ul style="list-style-type: none"> <li>- Selected sites in coke plants (primary coolers, benzol/sulphatehouses, benzol storage and loading)</li> <li>- cleaning and maintenance of tanks</li> <li>- loading and unloading of tanker vessels and lorries</li> <li>- marine transport</li> <li>- motor vehicle repair shops</li> <li>- service station with filling</li> <li>- attendant</li> </ul>

Nome of agent	Einecs (1)	CAS (2)	Limit values mg/m <sup>3</sup> (3) ppm (4)	Notation	Derogations	Biological limit value(s)
Benzene	200-753-7	71-43-2	3.25 (5) 1 (5)	Skin (6)	Limit value: 3 ppm (= 9.75 mg/m <sup>3</sup> ) until 31 December 2000 for the following activities or sector of activity: <ul style="list-style-type: none"> <li>- Selected sites in coke plants (primary coolers, benzol/sulphate houses, benzol storage and loading)</li> <li>- cleaning and maintenance of tanks</li> <li>- loading and unloading of tanker vessels and lorries</li> <li>- marine transport</li> <li>- motor vehicle repair shops</li> <li>- service station with filling attendant</li> <li>- primary synthesis in fragrance material production</li> </ul>	p.m.

- (1) EINECS: European Inventory of Existing Chemical Substances  
 (2) CAS: Chemical Abstract Service Number  
 (3) mg/m<sup>3</sup> = 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/m<sup>3</sup>).  
 (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."

Part B of Annex III shall be replaced by the following:

**"B. OTHER DIRECTLY RELATED PROVISIONS**

**Benzene**

For the measuring procedure, CEN 689:1995 should be used preferentially.

In the absence of a uniform analytical method, at Community level, Member States shall provide the method to be used.

**Article 2**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1998. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be laid down by the Member States.

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

**Article 3**

**This Directive is addressed to the Member States.**

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1. OJ No L 196, 26.7.1990, p. 1
  2. OJ C 317, 28.11.1995, p. 16
  3. OJ
  4. OJ C 97, 01.04.1996, p. 25
  5. COM(95) 282 final
  6. OJ No L 180, 8.7.1991, p. 1
  7. OJ No L 196, 16.8.1967, p. 1
  8. OJ No L 365, 31.12.1994, p. 24
  9. OJ No L 185, 9.7.1974, p. 15
  10. OJ No L 187, 16.7.1988, p.14

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# DOCUMENTS

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