

COMMON POSITION (EC) No 12/1999

adopted by the Council on 22 December 1998

with a view to adopting Council Directive 1999/. . /EC amending for the second time Directive 90/394/EEC on the protection of workers from the risk related to exposure to carcinogens at work and extending it to mutagens

(1999/C 55/05)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, 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 (sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)⁽¹⁾,

Having regard to the proposal from the Commission⁽²⁾, submitted after consultation with the Advisory Committee on safety, hygiene and health protection at work,

Having regard to the opinion of the Economic and Social Committee⁽³⁾,

Acting in accordance with the procedure referred to in Article 189c of the Treaty⁽⁴⁾,

(1) 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 guarantee a better level of protection of the safety and health of workers;

(2) 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;

(3) Whereas 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;

(4) Whereas because of their mechanism of action germ cell mutagens are likely to have carcinogenic effects;

(5) Whereas vinyl chloride monomer is classified as a category 1 carcinogen under 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⁽⁵⁾;

(6) Whereas, for the sake of consistency and clarity, the essential provisions of Council Directive 78/610/EEC of 29 June 1978 on the approximation of the laws, regulations and administrative provisions of the Member States on the protection of the health of workers exposed to vinyl chloride monomer⁽⁶⁾ should be included in this Directive, without reducing the level of protection of the health and safety of workers;

(7) Whereas Directive 78/610/EEC can be repealed after implementation of this Directive;

(8) Whereas the carcinogenicity of oak and beech dusts has been confirmed in epidemiological studies on workers exposed; whereas it is highly probable that other types of hardwood dust can also cause cancer in humans; whereas therefore the workers concerned are exposed to a serious potential risk of developing cancer;

(9) Whereas the precautionary principle should be applied in the protection of workers' health; whereas therefore Directive 90/334/EEC should be extended to cover all types of hardwood dusts;

(10) Whereas further research is desirable into the carcinogenicity of other wood dusts; whereas the Commission is to bring forward proposals to protect the health of workers where a risk is identified;

(11) Whereas Article 16 of Directive 90/394/EEC makes provision for the establishment of limit values in

⁽¹⁾ OJ L 196, 26.7.1990, p. 1. Directive as last amended by Directive 97/42/EC (OJ L 179, 8.7.1997, p. 4).

⁽²⁾ OJ C 123, 22.4.1998, p. 21.

⁽³⁾ OJ C 284, 14.9.1998, p. 111.

⁽⁴⁾ Opinion of the European Parliament of 22 October 1998 (OJ C 341, 9.11.1998, p. 132), Council common position of 22 December 1998 and Decision of the European Parliament of ... (not yet published in the Official Journal).

⁽⁵⁾ OJ L 196, 16.8.1967, p. 1. Directive as last amended by Directive 97/69/EC (OJ L 343, 13.12.1997, p. 19).

⁽⁶⁾ OJ L 197, 22.7.1978, p. 12.

respect of all those carcinogens for which that is possible, on the basis of the available information, including scientific and technical data;

- (12) Whereas it is appropriate to fix such limit values for hardwood dusts; whereas the current limit values for vinyl chloride monomer should be reduced to reflect best minimum standards for technological practices which reflect feasibility factors while maintaining the aim of ensuring the health of workers at work;
- (13) Whereas workers must be effectively protected from the risks of developing cancer as a result of occupational exposure to hardwood dusts; whereas the aim of this Directive is not to restrict the use of wood either by replacing it with other materials or by replacing the use of certain types of wood with other types of wood;
- (14) Whereas compliance with the minimum requirements on protection of the health and safety of workers from the specific risks related to carcinogens is intended not only to ensure the health and safety protection of each individual worker but also to provide a level of minimum protection for all workers in the Community;
- (15) Whereas a consistent level of protection from the risks related to carcinogens has to be established for the Community as a whole, whereas that level of protection has to be set by a framework of general principles to enable Member States to apply the minimum requirements consistently;
- (16) Whereas the amendments contained in this Directive constitute a practical aspect of the realisation of the social dimension of the internal market;
- (17) Whereas, pursuant to Decision 74/325/EEC⁽¹⁾, 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

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

1. Article 1(4) shall be replaced by the following:

‘As regards asbestos, which is dealt with by Directive 83/477/EEC(*), the provisions of this Directive shall

⁽¹⁾ OJ L 185, 9.7.1974, p. 15. Decision as last amended by the 1994 Act of Accession.

apply when they are more favourable to health and safety at work.

(*) OJ L 263, 24.9.1983, p. 25. Directive as last amended by Directive 98/24/EC (OJ L 131, 5.5.1998, p. 11).’

2. In Article 2, the following point shall be inserted after (a):

‘(aa) “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 (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
 - Annex I to Directive 88/379/EEC where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;’.

3. In Article 1(1), Article 3(1), (2), first and second indents, and (4), Article 5(5)(c), (d), (e) and (j), Article 6(a) and (b), Article 10(1), introductory wording, and point (a), Article 11(2), Article 14(3), Article 16(1) and Article 17(2), the word ‘carcinogens’ shall be replaced by ‘carcinogens or mutagens’.

4. In Article 2(b), Article 4(1), Article 5(2) and (5), heading and point (a), the word ‘carcinogen’ shall be replaced by ‘carcinogen or mutagen’.

5. In Annex I the following section shall be added:

‘5. Work involving exposure to hardwood dusts(*).

(*) 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.’

6. In Annex III, Part A shall be replaced by the following:

'A. LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

Name of agent	No Eines (1)	No 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 ... (three years after date in Article 2(1) of Directive 97/42/EC (*))
Vinyl chloride monomer	200-831	75-01-4	7,77 (5)	3 (5)	—	—
Hardwood dusts	—	—	5,0 (5) (7)	—	—	—

(1) Eines: 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.

(*) OJ L 179, 8.7.1997, p. 4.'

Article 2

Directive 78/610/EEC shall be repealed with effect from ... (*).

Article 3

On the basis of the latest available scientific data, the Commission may within two years of the date of the adoption of this Directive, submit a proposal to the Council for the adoption of revised limit values for vinyl chloride monomer and hardwood dusts in accordance with Article 118a of the Treaty.

Article 4

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

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their

official publication. The methods of making such reference shall be laid down by the Member States.

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

Article 5

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 6

This Directive is addressed to the Member States.

Done at ...

For the Council
The President

(*) Four years after the date of the adoption of this Directive.

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. On 19 March 1998, the Commission forwarded to the Council the abovementioned proposal for a Directive, based on Article 118a of the EC Treaty.

The European Parliament and the Economic and Social Committee delivered their opinions on 22 October 1998 and 2 July 1998 respectively.

Following the opinion from the European Parliament, the Commission submitted an amended proposal on 16 November 1998.

2. On 22 December 1998, the Council adopted its common position pursuant to Article 189c of the Treaty.

II. OBJECTIVE

The aim of the draft Directive is:

- to extend the scope of Directive 90/394/EEC to mutagenic substances not already covered by that Directive,
- to extend the scope of Directive 90/394/EEC to cover hardwood dusts,
- to consolidate in that Directive the existing Directive 78/610/EEC relating to vinyl chloride monomer.

Exposure limit values are established in respect of the last two categories of substances.

III. ANALYSIS OF THE COMMON POSITION

1. General remarks

The common position broadly follows the Commission's amended proposal; in particular, it takes up the principal amendment deriving from the European Parliament's opinion, namely the extension of the provisions in respect of beech and oak dusts to hardwood dusts as a whole.

As far as mutagens are concerned, the Council considered that, as it had not been proved that all mutagenic substances were necessarily carcinogenic, those substances should be taken up in the text in their own right and not simply included in Annex I of Directive 90/394/EEC, as proposed by the Commission. For the same reason, it was considered that the title of the Directive should be amended accordingly.

2. Analysis of the Articles

— Article 1

- paragraph 1: this paragraph is unchanged relative to the Commission's proposal,
- paragraph 2: this paragraph provides for a definition of 'mutagens',

- paragraphs 3 and 4: these paragraphs extend the scope of the Directive, where appropriate, to cover mutagens,
- paragraph 5: in accordance with *amendment 6 of the European Parliament*, this paragraph adds a new Item 5 to Annex I in respect of hardwoods.

In order to assist Member States in the implementation of the Directive, a footnote is added containing a reference to the International Agency for Research on Cancer's monograph on 'Wood Dust and Formaldehyde', which contains a list of the most commonly encountered hardwoods and tropical hardwoods,

- paragraph 6: this paragraph, which corresponds to *amendment 7 of the European Parliament*, covers the inclusion in part A of Annex III of the limit values in respect of vinyl chloride monomer and hardwood dusts.

The annual limit value for vinyl chloride monomer, which was included in the Commission's proposal, has been deleted as the Council considered that it could not be applied in practice.

The limit value for hardwood dusts is the same as that suggested by the European Parliament and it is also made clear that the limit value should apply to mixtures of wood dusts. Since the concept of the 'inhalable fraction' derives from agreed international standards and practice, further definition in the present text was considered superfluous.

— *Article 2*

This article is unchanged relative to the Commission's proposal. *Amendment 9 of the European Parliament* was not taken up as it was clear that the date for repeal of Directive 78/610/EEC should correspond to the final date for implementation of the present Directive.

— *Article 3*

This article corresponds to the text to be found in the Commission's amended proposal and consequently includes the two-year review period for the limit values to be found in *amendment 10 of the European Parliament*.

— *Article 4*

In accordance with *amendment 11 of the European Parliament*, the Commission's amended proposal provided for a three-year implementation period.

The Council decided that this period should be extended to four years, principally on account of the cost implications for small and medium-sized enterprises of complying with the new limit value in respect of hardwood dusts.

— *Articles 5 and 6*

Standard provisions.

3. Preamble

The preamble has been adapted to reflect changes in the text relative to that of the Commission's amended proposal.

Amendment 3 of the European Parliament is taken into account in the eighth, ninth and tenth recitals.

Furthermore, the essence of *amendment 5 of the European Parliament* is reflected in the eleventh, twelfth and thirteenth recitals.

4. Other amendments proposed by the European Parliament

Amendment 1: This amendment was not taken up by the Commission in its amended proposal. In any event, the implementation period of four years (Article 4) provides for an adequate transitional period.

Amendment 4: This amendment was not taken up by the Commission in its amended proposal.

IV. CONCLUSION

The Council considers that the text of the common position fulfils the essential aims of the Commission's proposal, notwithstanding certain relatively minor divergences from the text of the amended proposal.
