### COMMON POSITION (EC) No 3/97

# adopted by the Council on 2 December 1996

with a view to adopting Council Directive 97/.../EC of ... 1997 amending for the first time Directive 90/394/EEC 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)

(97/C 6/03)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the 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), and in particular Article 16 thereof,

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

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),

- Whereas Article 118a of the Treaty provides that (1)the Council is to 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;
- (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-size undertakings;

- Whereas Commission Directive 91/325/EEC of 1 (3) March 1991 adapting to technical progress for the twelfth time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating classification, packaging and labelling of dangerous substances (5) 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 and from carcinogenic compounds arising at work;
- (5) 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 (6)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
- Whereas Article 16 of Directive 90/394/EEC makes (7)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;

<sup>(1)</sup> OJ No L 196, 26. 7. 1990, p. 1.

<sup>(2)</sup> OJ No C 317, 28. 11. 1995, p. 16. (3) OJ No C 97, 1. 4. 1996, p. 25.

<sup>(4)</sup> Opinion of the European Parliament of 20 June 1996 (OJ No C 198, 8. 7. 1996, p. 182), Council common position of 2 December 1996 (not yet published in the Official Journal) and Decision of the European Parliament of ... (not yet published in the Official Journal).

<sup>(5)</sup> OJ No L 180, 8. 7. 1991, p. 1.

- (9) 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;
- (10) 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;
- (11) 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 not by detailed prescriptive requirements but by a framework of general principles to enable Member States to apply the minimum requirements consistently;
- (12) Whereas this amendment constitutes a practical aspect of the realization of the social dimension of the internal market;
- (13) 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. in Article 1, the following paragraph shall be added:
  - '4. As regards asbestos and vinyl chloride monomer, which are dealt with by specific directives, the provisions of this Directive shall apply when they are more favourable to safety and health at work.';
- (1) OJ No L 185, 9. 7. 1974, p. 15. Decision as last amended by the 1994 Act of Accession.

2. Article 2 shall be replaced by the following:

'Article 2

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 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;
  - (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 the time-weighted average of the concentration for a 'carcinogen' in the air within the breathing zone of a worker in relation to a specified reference period as set out in Annex III.';
- 3. Article 3 (3) shall be replaced by the following:
  - '3. Furthermore, when assessing the risk, account shall be taken of all other routes of exposure, such as absorption into and/or through the skin.';
- 4. in Article 5, the following paragraph shall be inserted after paragraph 3:
  - '4. Exposure shall not exceed the limit value of a carcinogen as set out in Annex III.';

former paragraph 4 shall become paragraph 5;

- 5. item 2 of Annex I shall be replaced by the following:
  - '2. Work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or pitch.';
- 6. Part A of Annex III shall be replaced by the following:

## 'A. LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

Name of agent	Einecs (1)	CAS (2)	Limit mg/m³ (³)	values ppm ( <sup>4</sup> )	Notation	Transitional measures
Benzene	200-753-7	71-43-2	3,25 (5)	1 (5)	Skin (6)	Limit value: 3 ppm (= 9,75 mg/m³) until (three years after date in Article 2 (1) of Directive 96//EC (*))

- (1) Einecs: European Inventory of Existing Chemical Substances.
- (2) CAS: Chemical Abstract Service.
- (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
- (\*) OJ No L ..., ..., p. ...'.

#### Article 2

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 provisions, 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 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.

Done at ...

For the Council The President

<sup>(\*)</sup> Three years after adoption of this Directive.

#### STATEMENT OF THE COUNCIL'S REASONS

#### I. INTRODUCTION

- 1. By letter dated 14 September 1995, the Commission submitted to the Council a proposal for a Directive, based on Article 118a of the EC Treaty, amending for the first time Directive 90/394/EEC 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).
- 2. The European Parliament delivered its opinion on 20 June 1996; the opinion of the Economic and Social Committee was delivered on 31 January 1996.

In the light of those opinions, the Commission submitted an amended proposal by letter dated 26 July 1996.

3. On 2 December 1996, the Council adopted its common position in accordance with Article 189c of the Treaty.

#### II. OBJECTIVE

The draft Directive seeks to:

- extend the scope of Directive 90/394/EEC to cover all substances meeting the criteria for classification as a category 1 or 2 carcinogen set out in Annex VI to Directive 67/548/EEC and all preparations composed of one or more such substances, where the concentration of at least one individual substance meets the specific requirements for concentration limits,
- provide a definition of 'limit value' for the concentration of carcinogens at work,
- set a limit value for the concentration of benzene at work,
- improve the coherence of Community legislation relating to carcinogens, namely as regards asbestos and vinyl chloride monomer,
- improve the wording of Article 3 (3) of and Annex I (2) to Directive 90/394/EEC.

## III. ANALYSIS OF THE COMMON POSITION

# 1. Council's amendments to the amended Commission proposal

The Council's amendments are intended to facilitate implementation of the Directive.

These amendments are as follows:

1.1. Asbestos and vinyl chloride monomer

(Article 1 (1))

The Council agreed to add a new paragraph to Article 1 of Directive 90/394/EEC, in order to clarify how this Directive shall apply to the abovementioned substances, which are dealt with by specific directives.

1.2. Definition of 'limit value'

(Article 1 (2) (b) and (4))

The Council introduced new wording in order to clarify the proposed definition and to highlight the link with specific limit values set out in Annex III to Directive 90/394/EEC; on the other hand, the Council did not deem it useful to provide a definition of the notion of 'breathing zone'.

The Council agreed that it would be appropriate to insert the provision relating to the binding nature of limit values as a new paragraph in Article 5 of Directive 90/394/EEC (Employers' obligations, prevention and reduction of exposure).

The Council rejected the proposal that a 'biological' limit value be defined at this stage, given the complexity of determining and monitoring such limit values in practice, on the one hand, and taking due account of the binding nature of limit values as defined in the common position, on the other hand.

## 1.3. Transitional measures

(Article 1 (6))

The Council agreed on the principle of transitional measures:

- designed to allow for the technical adjustments needed in order to implement limit values, and
- strictly limited in scope to such limit values.

In light of the fact that the provisions of Directive 90/394/EEC, other than any specific limit values affected by transitional measures, continue to apply in full when transitional measures are in place, the Council rejected a provision on the obligation of Member States to ensure employers' compliance with general protection standards pending transitional measures, which appeared redundant.

The Council set the cut-off date for transitional measures to three years after the date by which Member States must comply with the Directive at the latest.

Given the extensiveness of the scope proposed for transitional measures concerning the limit value for benzene, the Council deleted the reference to specific activities or sectors of activity, so as to facilitate transposition and implementation.

# 1.4. Measuring procedure for benzene

(Article 1 (6))

The Council rejected the proposal that CEN 689:1995 should be used preferentially as a measuring procedure, as it deemed that other methods for measuring benzene concentrations in air are equally suitable.

# 1.5. Implementation date

(Article 2 (1))

The Council set the implementation date at three years after adoption of the Directive, so as to meet the difficulties of some Member States to comply with the Directive at an earlier date.

# 2. European Parliament amendments

## 2.1. Amendments accepted by the Commission

The Council incorporated in full, in part or with textual changes, amendments 2, 8 and 12.

It rejected amendments 1, 5, 6, 9 and 13.

2.2. Amendments not accepted by the CommissionLike the Commission, the Council rejected amendments 3, 4, 7, 10, 15 and 16.It incorporated amendments 11 and 14.

#### IV. ADDITIONAL ELEMENTS CONCERNING THE COMMON POSITION

- 1. In view of the dangers resulting from carcinogens, the Council considers that endeavours to simplify and improve the coherence of existing legislation in this area should be continued and that all carcinogens defined as such in the directives should be listed in a single and easily accessible source.
- 2. When adopting its common position, the Council invited the Commission:
  - to submit, as soon as the scientific and technical knowledge permits and, in any event, not later than 31 December 1997, a proposal to further amend Directive 90/394/EEC with a view to providing appropriate standards of protection for workers against the risks from mutagenic substances not already covered by the Directive, taking account of the particularly dangerous nature of these substances,
  - to put forward the question of carcinogenicity of wood dusts to the Scientific Committee on Occupational Exposure Limits and the Advisory Committee on Safety, Hygiene and Health Protection at Work with a view to putting forward proposals for the inclusion of wood dusts in Directive 90/394/EEC; the Council believes that any such proposals should clarify how the provisions of the Directive could be applied to wood dusts and other substances which could have similar carcinogenic effects.