COUNCIL DIRECTIVE

of 16 December 1988

amending Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work

(88/642/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

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

Whereas, for improved protection of workers with respect to chemical, physical and biological agents at work, it is necessary to strengthen the provisions contained in Council Directive 80/1107/EEC (4), as last amended by the Act of Accession of Spain and Portugal;

Whereas the Council resolution of 27 February 1984 on a second programme of action of the European Communities on safety and health at work (5) provides for the harmonization of provisions and measures regarding the protection of workers with respect to certain chemical, physical and biological agents; whereas, in the interests of balanced development, it is therefore necessary to harmonize and improve those measures, while adapting them to take account of technical progress; whereas this harmonization and improvement should be based on common principles;

Whereas the Council resolution of 21 December 1987 on safety, hygiene and health at work (6) stresses the importance of improving the safety and health of workers at the place of work;

Whereas, in accordance with Decision 74/325/EEC (7), as amended by the Act of Accession of Spain and Portugal, the Advisory Committee on Safety, Hygiene and Health at Work is to be consulted by the Commission with a view to drawing up proposals in this field;

Whereas, for certain agents, the Council will lay down, in individual Directives, the limit values of a binding nature for occupational exposure and, where appropriate, other specific requirements;

Whereas provision should be made at Community level for drawing up for the other agents indicative limit values which the Member States would, *inter alia*, take into account when establishing national limit values;

Whereas representatives of employers and workers have a role to play in the protection of workers;

Whereas the provisions of this Directive are minimum requirements and in no way prevent Member States from maintaining or taking other measures so as to protect workers furhter.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 80/1107/EEC is hereby amended as follows:

1. The following subparagraph is added to Article 3 (1):

'The Council, in accordance with the procedure laid down in Article 118a of the Treaty, may amend Annex I with a view, *inter alia*, to inserting in it agents in respect of which a binding limit value or binding limit values and/or other specific requirements appear necessary.'

2. Article 4 is amended as follows:

(a) point 4 is replaced by the following:

'4. (a) in the case of any activity likely to involve a risk of exposure of workers, determination of the nature and degree of the workers' exposure so that any risk to their safety or health can be assessed and the measures to be taken can be defined;

(b) establishment of limit values and of sampling procedures, measuring procedures and procedures for evaluating results; in the case of chemical agents, the establishment of sampling procedures, measuring procedures and procedures for evaluating results, in accordance with the reference method described in Annex II a or a method yielding equivalent results;

(c) when a limit value is exceeded, identification without delay of the reasons for the limit being exceeded and implementation as soon as possible of appropriate measures to remedy the situation.';

(1) OJ No C 164, 2. 7. 1986, p. 4.
(2) OJ No C 167, 27. 6. 1988, p. 84 and OJ No C 290, 14. 11. 1988.
(3) OJ No C 319, 30. 11. 1987, p. 41.
(4) OJ No L 327, 3. 12. 1980, p. 8.
(5) OJ No C 67, 8. 3. 1984, p. 2.
(6) OJ No C 28, 3. 2. 1988, p. 1.
(7) OJ No L 185, 9. 7. 1974, p. 15.

(b) point 9 is replaced by the following:

'9. appropriate measures shall be taken by the employer to ensure that workers and/or their representatives in undertakings or establishments receive full information on, and instruction in:

(a) the potential risks connected with their exposure, the technical preventive measures to be observed by workers and the precautions taken by the employer and to be taken by workers;

(b) the risk assessment methods used, the existence of a limit value as referred to in point 4 (b) and the need to carry out measurements, and the action to be taken, as laid down in point 4 (c), in the event of a limit value being exceeded.'

3. Article 8 (1) is replaced by the following:

'1. The Council shall, in accordance with the procedure laid down in Article 118a of the Treaty, fix in the individual directives that it adopts with regard to the agents listed in Annex I a binding limit value or binding limit values and/or other specific requirements.'

4. The following paragraph is added to Article 8:

'4. Without prejudice to paragraph 1, for agents other than those listed in Annex I, indicative limit values shall be drawn up in accordance with the procedure laid down in Article 10.

The Member States shall take account, *inter alia,* of those indicative limit values when establishing the limit values referred to in Article 4 (4) (b).

Indicative limit values shall reflect expert evaluations based on scientific data.'

5. Article 9 (1) is replaced by the following:

'1. With a view to the adaptation to technical progress referred to in Article 8 (3) and to the establishment of indicative limit values as referred to in Article 8 (4), a committee is hereby established consisting of representatives of the Member States and chaired by a representative of the Commission.'

6. Annex II a, which appears in the Annex to this Directive, is inserted.

Article 2

1. This Directive shall be without prejudice to the right of Member States to apply or adopt other laws, regulations and administrative provisions laying down more stringent standards.

2. Member States shall adopt the laws, regulations and administrative provisions necessary to comply with this Directive not later than two years after its notifiction (1). They shall forthwith inform the Commission thereof.

3. Member States shall communicate to the Commission 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 Brussels, 16 December 1988.

For the Council

The President

G. GENNIMATAS

(1) This Directive was notified to the Member States on 21 December 1988.

ANNEX

'ANNEX II a

REFERENCE METHOD REFERRED TO IN ARTICLE 4 (4) (b)

A. DEFINITIONS

I. Suspended matter

1. *Physico-chemical definitions*

(a) "Dust" means a disperse distribution of solids in air, brought about by mechanical processes or stirred up.

(b) "Fume" means a disperse distribution of solids in air, brought about by thermal and/or chemical processes.

(c) "Mist" means a disperse distribution of liquids in air, brought about by condensation or dispersion.

2. *Occupational medicine and toxicological definitions of particle populations*

(a) Dusts, like fumes and mists, fall into the category of suspended matter.

In assessing the health risks of suspended matter, account must be taken of particle size as well as specific dangerous effect, concentration and exposure time.

(b) Only part of the total suspended matter within a worker's breathing area is inhaled. This is termed the inspirable fraction.

Important factors here are the inspiration rate around the nose and mouth and flow conditions about the head.

(c) Depending on its size, the inspirable fraction may be deposited in various areas of the respiratory tract.

Deposition has, *inter alia,* a considerable effect on the point and nature of noxious effect.

The fraction of the inspirable fraction reaching the alveoli is called the respirable fraction.

The respirable fraction is of particular interest in occupational medicine.

II. Limit value

(a) The limit value is stated as the eight-hour time-weighted average concentration of exposure of a substance in gaseous, vaporous or suspended form in the air at the workplace.

Exposure means the presence of a chemical agent in the air within the breathing area of a worker.

It is described in terms of concentration over a reference period.

This section does not concern limit values for biological indicators.

(b) In addition it may be necessary to limit, for certain substances, permissible upward excursions from the average eight-hour time-weighted exposure to substances for shorter terms.

Monitoring then relates to the average concentration of the substance for the shorter term in question.

(c) The limit value for gases and vapours is stated in terms independent of temperature and air pressure variables in ml/m^3 (ppm) and in terms dependent on those variables in mg/m^3 for a temperature of 20 °C and a pressure of 101,3 kPa.

The limit value for suspended matter is given in mg/m^3 for operating conditions at the workplace.

B. ASSESSMENT OF EXPOSURE AND MEASURING STRATEGY

1. Basics

(a) If the presence of one or more agents in gaseous, vaporous or suspended form in the air at the workplace cannot for certain be ruled out, an assessment must be made to see whether the limit values are complied with.

(b) In this assessment, all points which might be relevant to exposure must be carefully looked into, for example :

— agents used or produced,

— operations, technical installations and processes,

— temporal and spatial distribution of concentrations of agents.

(c) A limit value is complied with if the assessment shows that exposure does not exceed it.

If the information obtained is insufficient to establish reliably whether the limit values are complied with, it must be supplemented by workplace measurements.

(d) If the assessment shows that a limit value is not complied with :

— the reasons for the limit being exceeded must be identified and appropriate measures to remedy the situation must be implemented as soon as possible.

— the assessment must be repeated.

(e) If the assessment shows that the limit values are complied with, subsequent measurements at appropriate intervals must, if necessary, be taken to ensure that the situation continues to prevail.

The nearer the concentration recorded comes to the limit value, the more frequently measurements must be taken.

(f) If the assessment shows that, on a long-term basis, owing to the arrangement of the work process, the limit values are complied with and there is no substantial change in conditions at the workplace likely to lead to a change of workers' exposure, the frequency of checks on compliance through measurements may be curtailed.

In such cases, however, it must regularly be checked whether the assessment leading to that conclusion is still applicable.

(g) If workers are exposed simultaneously or consecutively to more than one agent, this fact must be taken into consideration in evaluating the health risk to which they are exposed.

2. **Requirements for persons who carry out measurements**

Those carrying out measurements must possess the necessary expertise and facilities.

3. **Requirements for measuring procedures**

(a) The measuring procedure must give results represesentative of worker exposure.

(b) To ascertain the exposure of the worker at the workplace, where possible personal sampling devices should be used, attached to workers' bodies.

Where a group of workers is performing identical or similar tasks at the same place and has similar exposure, sampling such as to be representative of the group may be carried out within that group.

Fixed-point measuring systems may be used if the results make it possible to assess exposure of the worker at the workplace.

Samples should as far as possible be taken at breathing height and in the immediate vicinity of workers.

If in doubt, the point of greatest risk is to be taken as the measuring point.

(c) The measuring procedure used must be appropriate to the agent to be measured, its limit value and the workplace atmosphere.

The result must show the concentration of the agent exactly and in the same terms as the limit value.

(d) If the measuring procedure is not specific to the agent to be measured, the full value recorded must be counted as applying to the agent to be measured.

(e) The limits of detection, sensitivity and precision of the measuring procedure must be appropriate to the limit value.

(f) The accuracy of the measuring procedure should be ensured.

(g) The measuring procedure must have been tested under practical conditions of use.

(h) If the European Committee for Standardization (CEN) publishes general requirements for the performance of measuring procedures and devices for workplace measurements together with provisions on testing, they should be referred to when selecting appropriate measuring procedures.

4. **Measurement specifications for detecting representative particle populations in the air at the workplace**

(a) Suspended matter concentration should be measured in relation to effect; therefore, when sampling, either the inspirable fraction or the respirable fraction should be measured.

This requires particle separation according to aerodynamic diameter equivalent to the deposition occurring in breathing.

Since appropriate equipment for workplace sampling is not yet available, practical specifications for uniform measurement are needed.

(b) The fraction of suspended matter which can be breathed in by a worker through the mouth and/or the nose is deemed to be inspirable.

By way of example, in measurement practice, devices with an inspiration rate of 1,25 m/s +/− 10 % or devices in conformity with ISO/TR 7708 1983 (E) are used for sampling.

In the first of these two cases, cited by way of example:

— with sampling devices attached to the person, the inlet should be directed parallel to the worker's face throughout sampling,

— with fixed-point sampling, the position and shape of the inlet should enable samples representative of workers' exposure covering various directions of flow to be taken,

— the position of the sampling device inlet is of little significance where there are very low flow rates for the surrounding air,

— with surrounding flow rates of 1 m/s and above, omnidirectional sampling in the horizontal plane is recommended.

(c) The respirable fraction of suspended matter comprises a population passed through a separation system equivalent in its effect to the theoretical separation function of a sedimentation separator giving 50 % separation of particles with an aerodynamic diameter of 5 μm (Johannesburg Convention, 1979).

(d) If the CEN establishes specifications for the collection of suspended material at the workplace, they should be applied, by way of preference.

Other methods may be used provided that they yield the same conclusion or a stricter conclusion in relation to compliance with the limit values.'