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COUNCIL DIRECTIVE

of 27 November 1980

on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work

(80/1107/EEC)

(OJ L 327, 3.12.1980, p. 8)

Amended by:

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►**A1**	Act of Accession of Spain and Portugal	L 302	23	15.11.1985
►**A2**	Act of Accession of Austria, Sweden and Finland	C 241	21	29.8.1994
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on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work

(80/1107/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission ([1]), drafted following consultation with the Advisory Committee on Safety, Hygiene and Health Protection at work,

Having regard to the opinion of the European Parliament ([2]),

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

Whereas the Council resolution of 29 June 1978 on an action programme of the European Communities on safety and health at work ([4]), provides for the harmonization of provisions and measures regarding the protection of workers with respect to chemical, physical and biological agents; whereas efforts must therefore be made towards approximation, while the improvement is being maintained, of the laws, regulations and administrative provisions of the Member States in accordance with Article 117 of the Treaty;

Whereas certain differences are revealed by an examination of the measures taken by Member States to protect workers from the risks related to exposure to chemical, physical and biological agents at work; whereas, therefore, in the interests of balanced development, these measures, which directly affect the functioning of the common market, should be approximated and improved; whereas this approximation and improvement should be based on common principles;

Whereas the said protection should as far as possible be ensured by measures to prevent exposure or keep it at as low a level as is reasonably practicable;

Whereas to this end it is appropriate that the Member States should, when they adopt provisions in this field, comply with a set of requirements, including in particular the laying down of limit values; whereas an initial list of agents may be adopted in this Directive for the application of further more specific requirements; whereas the Member States will determine whether and to what extent each of these requirements is applicable to the agent concerned;

Whereas provision should be made, within the time limits set by this Directive, for the implementation, in respect of a limited number of agents, of provisions to ensure, for the workers concerned, appropriate surveillance of their state of health during exposure and the provision of appropriate information;

Whereas the Council will lay down the limit values and other specific requirements for certain agents in individual Directives;

Whereas certain technical aspects concerning the specific requirements established in the individual directives can be reviewed in the light of experience and progress made in the technical and scientific fields;

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

([1]) OJ No C 89, 5. 4. 1979, p. 6.
([2]) OJ No C 59, 10. 3. 1980, p. 73.
([3]) OJ No C 297, 28. 11. 1979, p. 5.
([4]) OJ No C 165, 11. 7. 1978, p. 1.

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Whereas, since the Hellenic Republic is to become a member of the European Economic Community on the 1 January 1981 in accordance with the 1979 Act of Accession, it should be granted a longer period in which to implement this Directive so as to enable it to set up the necessary legislative, social and technical structures, in particular those concerning consultation of both sides of industry, the setting up of a system for monitoring the health of workers as well as the supervision of such implementation,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. The aim of this Directive is the protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise at work from exposure to chemical, physical and biological agents considered harmful.

2. This Directive shall not apply to:

— workers exposed to radiation covered by the Treaty establishing the European Atomic Energy Community,

— sea transport,

— air transport.

Article 2

For the purposes of this Directive:

(a) 'agent' means any chemical, physical or biological agent present at work and likely to be harmful to health;

(b) 'worker' means any employed person exposed or likely to be exposed to such agents at work;

(c) 'limit value' means the exposure limit or biological indicator limit in the appropriate medium, depending on the agent.

Article 3

1. In order that the exposure of workers to agents be avoided or kept at as low a level as is reasonably practicable, Member States shall, when they adopt provisions for the protection of workers, concerning an agent, take:

— the measures set out in Article 4,

— the additional measures set out in Article 5, where the agent appears in the initial list in Annex I.

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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.

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2. For the purposes of paragraph 1, the Member States shall determine the extent, if any, to which each of the measures provided for in Articles 4 and 5 is to apply, taking into account the nature of the agent, the extent and duration of the exposure, the gravity of the risk and the available knowledge concerning it, together with the degree of urgency of the measures to be adopted.

3. Member States shall adopt the measures necessary to ensure:

— in the case of the agents listed in Annex II, Part A, appropriate surveillance of the state of health of workers during the period of exposure,

— in the case of the agents listed in Annex II, Part B, access for workers and/or their representatives at the place of work to appropriate information on the dangers which these agents present.

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4. The adoption of the measures referred to in paragraph 3 by the Member States shall not oblige them to apply paragraphs 1 and 2.

Article 4

The measures referred to in the first indent of Article 3 (1) shall be:

1. limitation of the use of the agent at the place of work;
2. limitation of the number of workers exposed or likely to be exposed;
3. prevention by engineering control;

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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;

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5. protection measures involving the application of suitable working procedures and methods;
6. collective protection measures;
7. individual protection measures, where exposure cannot reasonably be avoided by other means;
8. hygiene measures;

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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;

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10. use of warning and safety signs;
11. surveillance of the health of workers;
12. keeping updated records of exposure levels, lists of workers exposed and medical records;
13. emergency measures for abnormal exposures;
14. if necessary, general or limited ban on the agent, in cases where use of the other means available does not make it possible to ensure adequate protection.

Article 5

The additional measures referred to in the second indent of Article 3 (1) shall be:

1. providing medical surveillance of workers prior to exposure and thereafter at regular intervals. In special cases, it shall be ensured that a suitable form of health surveillance is available to workers who have been exposed to the agent, after exposure has ceased;

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2. access by workers and/or their representatives at the place of work to the results of exposure measurements and to the anonymous collective results of the biological tests indicating exposure when such tests are provided for;

3. access by each worker concerned to the results of his own biological tests indicating exposure;

4. informing workers and/or their representatives at the place of work where the limit values referred to in Article 4 are exceeded, of the causes thereof and of the measures taken or to be taken in order to rectify the situation;

5. access by workers and/or their representatives at the place of work to appropriate information to improve their knowledge of the dangers to which they are exposed.

Article 6

Member States shall see to it that:

— workers' and employers' organizations are consulted before the provisions for the implementation of the measures referred to in Article 3 are adopted and that workers' representatives in the undertakings or establishments, where they exist, can check that such provisions are applied or can be involved in their application,

— any worker temporarily suspended on medical grounds in accordance with national laws or practices from exposure to the action of an agent is, where possible, provided with another job,

— the measures adopted in implementation of this Directive are consistent with the need to protect public health and the environment.

Article 7

This Directive and the individual Directives referred to in Article 8 shall not prejudice the right of Member States to apply or introduce laws, regulations or administrative provisions ensuring greater protection for workers.

Article 8

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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.

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2. The titles of the individual Directives shall include serial numbers.

3. Adaptation to technical progress in accordance with the procedure in Article 10 shall be restricted to the technical aspects listed in Annex III under the conditions laid down in the individual Directives.

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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.

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Article 9

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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.

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2. The Committee shall draw up its own rules of procedure.

Article 10

1. Where the procedure laid down in this Article is invoked, matters shall be referred to the Committee by the chairman, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on this draft within a time limit which the chairman may set according to the urgency of the matter. Decisions shall be taken by a majority of ►A2 62 ◄ votes, the votes of Member States being weighted as provided for in Article 148 (2) of the treaty. The chairman shall not vote.

3. (a) The Commission shall take the proposed measures where they are in accordance with the opinion of the Committee.

(b) Where the proposed measures are not in accordance with the opinion of the Committee, or if no opinion is delivered the Commission shall without delay propose to the Council the measures to be taken. The Council shall act by a qualified majority.

(c) If the Council has not acted within three months of receiving the proposal, the proposed measures shall be adopted by the Commission.

Article 11

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within a period of three years of its notification and shall forthwith inform the Commission thereof.

However, in the case of Article 3 (3), first indent, this period shall be four years.

In derogation from the above provisions, the time limits laid down in the first and second subparagraphs shall be four and five years respectively in the case of the Hellenic Republic.

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

Article 12

This Directive is addressed to the Member States.

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ANNEX I

List of agents referred to in Article 3 (1), second indent, and Article 8 (1)

Acrylonitrile
Asbestos
Arsenic and compounds
Benzene
Cadmium and compounds
Mercury and compounds
Nickel and compounds
Lead and compounds
Chlorinated hydrocarbons:
— chloroform
— paradichlorobenzene
— carbon tetrachloride

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ANNEX II

A. **List of agents referred to in Article 3 (3), first indent**

1. Asbestos
2. Lead and compounds

B. **List of agents referred to in Article 3 (3), second indent**

1. Asbestos
2. Arsenic and compounds
3. Cadmium and compounds
4. Mercury and compounds
5. Lead and compounds

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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.

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(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

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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.

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ANNEX III

Technical aspects referred to in Article 8 (3)

1. Sampling procedures and measuring methods (including quality control) with respect to the limit values in so far as such procedures and methods have no effect on the quantitative significance of those limit values.

2. Practical recommendations on medical surveillance before and during exposure and after such exposure has ceased and keeping of records on the results of such medical surveillance.

3. Practical procedures regarding the establishment and keeping of records concerning ambient measurement results and lists of exposed workers.

4. Practical recommendations for alarm systems to be installed at workplaces where abnormal exposures are likely to occur.

5. Practical recommendations for emergency measures to be taken in the event of abnormal emissions.

6. Collective and individual protection measures for certain operations (e.g. servicing and repairs) during which it cannot be guaranteed that concentrations or intensities of the agents will be kept below the limit values.

7. Procedures regarding general hygiene requirements, and means of ensuring personal hygiene.

8. Signs to identify areas where significant exposure is likely to occur and to indicate the precautions which have to be taken.