Official Journal

of the European Communities

ISSN 0378-6986

C 141

Volume 31

30 May 1988

English edition

Information and Notices

Notice No | Contents | Page

II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive on the introduction of measures to encourage improvements in the safety and health of workers at the workplace

COM(88) 73 final

(Submitted by the Commission to the Council on 11 March 1988)

(88/C 141/01)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the Commission proposal drawn up after consultation with the Advisory Committee on Safety, Hygiene and Health Protection at Work [1],

Having regard to the opinion of the Economic and Social Committee,

In cooperation with the European Parliament,

Whereas Article 118A of the Treaty provides that the Council shall adopt, by means of Directives, minimum requirements for encouraging improvements as regards the health and safety of workers, especially in the working environment;

Whereas Article 118A also recommends that Directives shall avoid imposing administrative, financial and legal constraints which would hold back the creation and development of small and medium-sized undertakings;

Whereas the Communication from the Commission on its programme concerning safety, hygiene and health at work [2] provides for the adoption of Directives designed to guarantee the safety and health of workers;

Whereas the Council Resolution of 21 December 1987 on safety, hygiene and health at work took note of the Commission's intention to submit to the Council in the near future a Directive on the organization of the safety and health of workers at the workplace;

Whereas Member States have a responsibility to ensure the safety and health of persons on their territory, and of workers in particular;

Whereas Member States' legislative systems differ widely with regard to the prevention of work accidents and occupational diseases;

Whereas the incidence of accidents at work is still regrettably high, and preventive measures must be introduced or improved in order to guarantee the safety and health of workers;

Whereas, in order to achieve the maximum degree of protection which is reasonably practicable, it is essential that workers and their representatives be informed of the risks to their safety and health and of the measures required to reduce or eliminate these risks, and be allowed to verify that the necessary protective measures have indeed been taken;

Whereas cooperation between employers and workers and workers' representatives must be strengthened;

Whereas it is recognized as essential to take safety and health considerations into account from the earliest stages of workplace design;

Whereas employers must keep abreast of technological progress in order to provide optimum safety and health protection for their workers;

Whereas this Directive constitutes an overall social complement to various technical harmonization Directives designed to complete the internal market; whereas it supplements the provisions of Directive 80/1107/EEC of 27 November 1980;

Whereas it is planned, as of now, to establish specific provisions containing measures liable to improve safety and health at work;

---

[1] Council Decision 74/325/EEC (OJ No L 185, 9. 7. 1974, p. 15).
[2] Doc. COM(87) 520 final and Council Resolution 88/C 28/01 (OJ No C 28, 3. 2. 1988).

Whereas a Committee composed of members nominated by the Member States needs to be set up to assist the Commission in implementing the supplementary measures provided for by the Directive,

HAS ADOPTED THIS DIRECTIVE:

Object

Article 1

The object of this Directive is the introduction of measures to encourage improvements in the safety and health of workers at the workplace. The Directive contains general principles concerning in particular the prevention of occupational risks, the protection of safety and health and the informing, consultation and training of workers and their representatives, as well as general principles concerning the implementation of such measures.

Definitions

Article 2

For the purposes of this Directive, the following terms have the meaning hereby assigned to them:

— *workplace:*

any place to which the worker has access in the undertaking and/or establishment,

— *worker:*

any person who performs work in some form, including students undergoing training and apprentices,

— *undertaking and/or establishment:*

a public-sector or private-sector entity engaging in particular in industrial, agricultural, commercial, administrative, educational, cultural or service activities,

— *employer:*

the body or person in charge of the undertaking and/or establishment,

— *prevention:*

all the provisions or measures taken or developed at each stage of the activities performed within the undertaking with a view to avoiding or reducing the occupational risks,

— *occupational risk:*

any work-related situation liable to damage the physical or psychological safety and/or health of the worker, excluding accidents on the way to and from work.

Article 3

Member States shall ensure that employers, workers and workers' representatives comply with those provisions of this Directive which apply to them.

Responsibility of the employer

Article 4

1. The employer shall be responsible for the safety and health of the workers in every aspect which is directly or indirectly related to the work in the undertaking and/or establishment.

2. Where an employer calls in a specialist safety and health service or an outside consultant for organization of protective measures, this shall not discharge him from his responsibilities in this area.

3. The obligations of the workers in these fields shall not affect the principle of the employers's responsibility.

Obligations of the employer

Article 5

1. Within the context of his responsibilities, the employer shall take the necessary measures for the protection of the safety and health of workers, including prevention of occupational risks and provision of information and training, as well as provision of the necessary organization and resources. The employer shall be constantly alert to the need to adjust these measures and improve existing situations.

2. The employer shall put the following general preventive principles into practice, adapting them to match the specific conditions applying to his undertaking, including the size of the undertaking:

— combating the risks at source,

— adapting the work to the man,

— adapting to technical progress,

— replacing the dangerous by the non-dangerous or the less dangerous,

— developing a coherent overall prevention policy based on technology, organization of work, working conditions and human relationships.

3. The specific obligations on employers shall be as follows:

(a) The employer shall evaluate the safety and health risks to workers in the choice of work equipment, the chemical substances or preparations used, and the design and fitting out of workplaces.

Subsequent to this evaluation, the preventive measures, working methods and production methods introduced by the employer must provide the maximum protection that is reasonably practicable to achieve in respect of the safety and health of the workers.

(b) The safety and health measures taken by the employer must be integrated into all the activities of the

undertaking and/or establishment and at all hierarchical levels.

(c) The employer must ensure that adequate consideration is given to ergonomic principles, in particular as regards:

— the design of workplaces,

— the choice of plant and equipment,

— the choice of working methods and production methods.

(d) The employer must take the necessary measures to permit workers to organize their work in accordance with their capabilities where reasonably practicable.

(e) In planning and organizing the work, the employer shall ensure that monotonous work involving repetitive activities of brief duration and work where the workrate is governed by a machine or conveyor belt such that the worker is prevented from influencing his workrate himself are avoided where reasonably practicable.

(f) The planning and introduction of new technologies shall be undertaken in close cooperation with the workers and/or their representatives, particularly in respect of the choice of equipment and the working conditions, including those aspects connected with the working environment and the physical and psychosocial well-being of the individual. Workers shall receive appropriate training.

(g) When several undertakings share a workplace, the employers shall coordinate their measures for the prevention of occupational risks, and shall inform one another and their workers and/or workers' representatives of these risks.

Preventive services

Article 6

1. The employer shall designate from the supervisory staff one or more workers to be responsible for the organization of measures for the prevention of occupational risks in the undertaking and/or establishment.

2. If this is not feasible for lack of competent personnel in the undertaking and/or establishment, the employer shall enlist the services of competent outside agencies or individuals.

3. Where the employer calls in competent outside agencies or individuals, he shall inform them of the factors known to affect, or suspected of affecting, the safety and health of the workers.

4. In all cases, the workers designated from within the undertaking and/or the outside agencies or individuals consulted must have the necessary training and be sufficient in number to deal with the organization of preventive measures, taking into account the size of the undertaking and/or the hazards to which the workers are exposed and their distribution throughout the entire undertaking and/or establishment.

5. Member States shall define the size of undertakings in which the employer, provided he is competent, may himself take responsibility for the measures referred to in paragraph 1.

6. Member States shall define the training needed and the number of persons needed to fulfil the conditions set out in paragraph 4 of this Article.

Article 7

1. The employer shall make the requisite arrangements for first-aid, fire-fighting and evacuation of workers and other persons present, and shall arrange the necessary contacts with outside agencies, particularly as regards first-aid, emergency medical care, rescue work and fire-fighting.

2. For first-aid, fire-fighting and the evacuation of personnel, the employer shall designate the workers required to implement such measures.

The number of such personnel, their training and the equipment available to them shall be commensurate with the size and/or specific hazards of the undertaking and/or establishment.

3. The employer shall take precautionary measures to allow the worker to protect himself by immediately leaving the workplace if a serious, imminent, unavoidable danger arises.

4. The employer shall as soon as possible give details of these precautionary measures to all workers exposed, or likely to be exposed, to a risk of serious and imminent danger.

5. In the event of a serious and imminent danger to his own safety and/or that of other persons, each worker shall be in a position to take the necessary measures to avoid the consequences of such a danger, on the basis of his own knowledge and the technical and hierarchical means at his disposal.

Information to be held

Article 8

1. The employer shall:

(a) be in possession of an analysis of existing risks to safety and health at the workplace;

(b) decide on the protective measures to be taken and, if necessary, the protective equipment to be used;

(c) keep a list of accidents and occupational diseases which have resulted in a worker being unfit for work for more than three working days;

(d) draw up a report on accidents and occupational diseases having resulted in, or liable to result in, partial permanent unfitness for work, indicating the causes and the measures taken or to be taken.

2. Member States shall establish the criteria for exempting undertakings from having to draw up the documents required to fulfil the obligations described in paragraph 1 (a) and (b).

Information of workers

Article 9

1. In accordance with the practices adopted in the Member States, which may take account in particular of the size of undertakings, the employer shall take appropriate measures to ensure that the workers and/or their representatives in the undertaking or establishment receive adequate information concerning:

(a) the safety and health risks and the preventive measures and activities in respect of the undertaking in general and in respect of each worker's workstation and/or job;

(b) the measures taken pursuant to Article 7(4).

Such information shall also be provided to temporary workers and the employers of workers from outside firms present in the undertaking.

2. Workers or workers' representatives with specific responsibility for the protection of the safety and health of workers shall have access to:

(a) the risk analysis and analysis of protective measures referred to in Article 8 (1) (a) and (b);

(b) the list and the report on accidents and occupational diseases referred to in Article 8 (1) (c) and (d);

(c) the information yielded by preventive measures, inspection agencies and bodies responsible for safety and health.

Consultation of workers

Article 10

1. Workers or their representatives with specific responsibility for safety and health shall be consulted in advance by the employer with regard to:

— any measure which may substantially affect health and safety,

— the designation of persons referred to in Articles 6(2) and 7(2),

— the information referred to in Articles 6(1) and 9;

— the setting up of a specialist safety and/or health service or, where appropriate, the enlistment of an outside preventive service as referred to in Article 6(2);

— the planning and organization of the training referred to in Article 11.

2. The consultation referred to in paragraph 1 may be restricted to the workers' representatives with specific responsibility for the protection of the safety and health of workers, on condition that there are enough of them.

3. Workers and workers' representatives with specific responsibility for the protection of the safety and health of workers shall not be placed at any disadvantage as a result of such activities.

4. The employer shall ensure that workers' representatives with specific responsibility for the protection of the safety and health of workers are allowed time off work without loss of pay and are provided with the necessary equipment to enable them to fulfil their obligations arising from this Directive.

Training of workers

Article 11

1. The employer shall ensure that each worker receives adequate safety and health training specific to his workstation or job;

— on recruitment,

— in the event of a transfer or change of job,

— in the event of a change in the work equipment.

The training shall be adapted to take account of new or changed risks.

2. The training referred to in paragraph 1 shall also be given, under the same conditions, to temporary workers present in the undertaking or establishment. The employer shall also ensure that workers from outside firms engaged in work in the undertaking and/or establishment have received training from their own firms appropriate to the work in which they are engaged.

3. Workers' representatives with specific responsibility for the protection of the safety and health of workers shall be entitled to appropriate training.

4. The training referred to in paragraph 1, 2 and 3 shall be provided during working hours and shall not be at the expense of the workers.

5. Member States:

— shall ensure that guidelines are drawn up concerning the content and duration of the training courses provided for in paragraphs 1 and 3,

— shall establish general rules concerning the conditions under which this training shall be provided.

Obligations on workers

Article 12

1. It shall be the duty of each worker during his working hours to take reasonable care of his own safety and health and that of all other persons affected by his actions or omissions at work.

2. To this end, workers must:

— make correct use of machinery, apparatus, tools, dangerous substances, transport equipment and other means of production,

— make correct use of the personal protective equipment supplied to them and, after use, return it to its proper place,

— refrain from changing or removing unnecessarily safety devices fitted to tools, pieces of apparatus, etc., and use such devices correctly,

— notify the employer immediately of any safety and/or health hazards which they have noticed,

— cooperate with their employer for as long as necessary in order to fulfil any tasks or requirements imposed by the responsible authority to protect the safety and health of workers,

— perform their tasks in accordance with the safety and health training and instructions they have received,

— cooperate in ensuring that the working environment and working conditions are safe and pose no risk to safety and health within their field of activity, and monitor the effectiveness of the safety and health measures taken.

Article 13

The Council, acting on proposals from the Commission, shall adopt individual Directives laying down specific provisions concerning chiefly the technical areas listed in the Annex hereto.

Article 14

For the purposes of adapting this Directive and the Directives provided for in Article 13 under the conditions specified in each of them, to take account of:

— the adoption of Directives in the field of technical harmonization and standardization,

— technical progress, changes in international regulations or specifications, and new findings,

the Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.

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 the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of Decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that article. The Chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of the period to be laid down in each act adopted by the Council under this paragraph but which may not in any case exceed three months from the date of

referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Final provisions

Article 15

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 1991 at the latest and shall forthwith inform the Commission thereof.

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.

3. Member States shall report to the Commission every two years on the practical implementation of the provisions of this Directive, indicating the points of view of employers and workers. The Commission shall inform the Committee and the Tripartite Committee.

Article 16

This Directive is addressed to the Member States.

ANNEX

LIST OF TECHNICAL AREAS REFERRED TO IN ARTICLE 13

— Workplaces.

— Work equipment.

— Personal protective equipment.

— Work with visual display units.

— Handling of heavy loads involving risk of back injury.

Proposal for a Council Directive concerning the minimum safety and health requirements for the workplace

First individual Directive within the meaning of Article 13 of Directive ... [1]

COM(88) 74 final

(Submitted by the Commission to the Council on 11 March 1988)

(88/C 141/02)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the Commission proposal drawn up after consultation with the Advisory Committee for Safety, Hygiene and Health Protection at Work [2],

Having regard to the opinion of the Economic and Social Committee,

In cooperation with the European Parliament,

Whereas Article 118A of the EEC Treaty provides that the Council shall issue Directives containing minimum requirements designed to encourage improvements, especially in the working environment, as regards the health and safety of workers;

Whereas Article 118A also recommends that Directives shall avoid imposing administrative, financial and legal constraints which would hold back the creation and development of SMUs;

Whereas the Communication from the Commission on its programme concerning safety, hygiene and health at

[1] Doc. COM(88) 73 final.
[2] Council Decision 74/325/EEC (OJ No L 185, 9. 7. 1974, p. 15).

work [1] provides for the adoption of Directives designed to guarantee the safety and health of workers;

Whereas the Council Resolution of 21 December 1987 concerning safety, hygiene and health at the workplace noted the Commission's intention to present to it in the near future minimum requirements concerning the safety and health of workers at work;

Whereas it is incumbent on Member States to ensure the safety and health of persons, in particular workers, within their national territory;

Whereas the completion of the internal market [2] entails the drawing up of Directives based on Article 100A, in accordance with the new approach to harmonization and standardization [3], making compliance with essential safety requirements for the design, manufacture or construction of products a condition for their sale and free movement throughout the Community and in view of the fact that some of these products have an effect on workplaces;

Whereas the Member States have very different systems of legislation on safety and health at work; whereas national provisions on the subject, which often include technical specifications and/or self-regulatory standards, may result in different levels of safety and health protection and distort competition;

Whereas compliance with the minimum requirements for health and safety at work is essential to ensure the safety and health of workers and to promote fair competition;

Whereas the minimum requirements for the workplace are basically expressed in terms of intended results; whereas, in implementation of the new approach to technical harmonization and standardization, it is desirable to have technical reports which provide technical details of the aforesaid minimum requirements and give grounds for presumption of compliance with those minimum requirements and for the aforesaid technical reports to be supplemented in some cases by references to measurement methods covered by harmonized standards;

Whereas, pending the adoption of technical reports within the meaning of this Directive, it is advisable to facilitate compliance with the minimum requirements by agreeing to continue using national provisions in the interim combined with a Community monitoring procedure to ensure that the national provisions correspond to the minimum requirements laid down by this Directive; whereas, for this purpose, the Committee is the most appropriate body to assist the Commission in the monitoring at Community level of compliance with the national provisions;

Whereas this Directive is designed to protect the safety and health of workers by laying down essential minimum requirements, without impeding the retention or institution by each Member State of specific measures for safer working conditions;

Whereas it is important to ensure adequate consultation with both sides of industry, and in particular with workers' organizations, on the technical work relating to this Directive;

Whereas, as is widely practised in the Member States, it is advisable to let manufacturers be responsible for complying with the minimum requirements for the design, construction and organization of the workplace or elements thereof;

Whereas it is important to encourage cooperation between management and labour with regard to decision making and measures concerned with the protection of safety and health at the workplace, at all levels;

Whereas there is a need for a committee to assist the Commission in implementing supplementary measures provided for by the Directive,

HAS ADOPTED THIS DIRECTIVE:

Subject

Article 1

1. This Directive, which is an individual Directive within the meaning of Article 13 of Directive ..., lays down minimum requirements for safety and health at work, as defined in Article 2.

2. This Directive does not apply to:

— means of transport,

— temporary or mobile work sites.

3. This Directive does not impede the retention or institution by each Member State of more stringent protection measures for working conditions compatible with the Treaty.

Definitions

Article 2

For the purposes of this Directive, the following terms have the meanings hereby assigned to them:

— *workplace*: any fixed place intended to house permanent workstations on the premises or at the site of the undertaking and/or establishment, including any room or place accessible to a worker,

(1) Doc. COM(87) 520 and Council Resolution 88/C 28/01 (OJ No C 28, 3. 2. 1988).
(2) *White paper* — Doc. COM(85) 310 final.
(3) Council Resolution 85/C 136/01 (OJ No C 136, 4. 6. 1985).

— *undertaking and/or establishment*: a public- or private-sector establishment engaged in industrial, agricultural, commercial, administrative, service, educational or cultural activities,

— *worker*: a person doing work of any sort, including students undergoing training and apprentices.

Workplaces

Article 3

1. The Member States shall take all useful measures to ensure that the workplaces referred to in Article 1, when used as intended and properly maintained, cannot adversely affect the safety and health of workers or of other persons present.

2. The Member States shall carry out any necessary checks in accordance with paragraph 1.

Article 4

Workplaces designed, constructed, fitted out, commissioned or used after the entry into force of this Directive must satisfy the minimum safety and health requirements set out in Annex I.

Article 5

1. The Member States shall presume that any workplaces designed, constructed, fitted out or commissioned in accordance with the national provisions which take into account at least the technical reports for the minimum safety and health requirements, the references for which have been published in the *Official Journal of the European Communities*, comply with the minimum safety and health requirements referred to in Article 4.

2. The Member States shall forward to the Commission the texts of their draft and existing national measures which they regard as complying with the technical reports referred to in paragraph 1, without prejudice to Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations. The Commission shall immediately forward these texts to the other Member States. In accordance with the procedure provided for in Article 9(2), it shall notify the Member States of the national measures which can enjoy presumption of compliance with the minimum safety and health requirements. The Commission shall publish the reference for such national measures in the *Official Journal of the European Communities*.

3. In the absence of the technical reports provided for in paragraph 1, and as a temporary measure, the Member States shall communicate to the Commission the text of their draft and existing national measures which they regard as fulfilling the minimum safety and health requirements listed in Annex I, without prejudice to Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations. The Commission shall immediately forward these texts to the other Member States. In accordance with the procedure provided for in Article 9(2), it shall notify the Member States of the measures which can enjoy presumption of compliance with the minimum safety and health requirements. The Commission shall publish the references for such national measures in the *Official Journal of the European Communities*.

Article 6

The Member States shall take any measures necessary to ensure that employers apply the minimum safety and health requirements set out in Annex II in existing and used workplaces at the latest five years after the entry into force of this Directive, without prejudice to the national provisions on safety and health at work in force when the Directive is adopted and the relevant ergonomic principles.

Article 7

When workplaces undergo modifications, extensions and/or conversions after the entry into force of the Directive, the Member States shall ensure that the employer takes any measures necessary, where this is reasonably practicable, to ensure that these modifications, extensions and/or conversions are in compliance with the corresponding minimum safety and health requirements set out in Annex I.

Article 8

1. The Member States shall take any measures necessary to ensure that employers use only workplaces comply with this Directive. The employer shall ensure: which

— that traffic routes to emergency exits and the exits themselves are kept clear for immediate use,

— that the necessary technical maintenance of the workplace is carried out and that any faults found are rectified as quickly as possible. If the faults entail a serious and immediate risk and cannot be rectified immediately, work must be stopped,

— that the workplace is cleaned to an adequate level of hygiene,

— that the safety equipment intended to prevent or eliminate hazards is regularly maintained and checked.

2. Workers or their representatives shall be consulted on health and safety aspects on the basis of Annex I and/or Annex II, as appropriate.

If measures taken by the employer to ensure the safety of existing workplaces, in use or planned, are, in the opinion of the workers or their representatives, inadequate, they may request a visit by the authorities responsible for health and safety at the workplace.

Article 9

1. When a Member State or the Commission considers that the draft technical reports referred to in Article 5 do not satisfy the minimum requirements which apply to them, referred to in Article 4, the Commission shall refer the matter to the Committee referred to in Article 10, giving its reasons, and shall, if necessary, consult the Advisory Committee for Safety, Hygiene and Health Protection at Work set up by Council Decision 74/325/EEC hereinafter referred to as 'the tripartite Committee'.

In the light of the Committee's opinion, the Commission shall publish the reference for the technical report or request an amendment to the draft.

2. Once it has received the Communications referred to in Article 5(2) and (3), the Commission shall consult the Committee and if necessary, the tripartite Committee. In the light of the Committee's opinion, the Commission shall inform the Member States within three months whether or not the national measure in question can enjoy presumption of compliance with the minimum requirements and be published in the *Official Journal of the European Communities*.

If the Commission or a Member State considers that a national provision no longer fulfils the conditions necessary for it to enjoy presumption of compliance with the minimum safety and health requirements set out in Article 4, the Commission shall consult the Committee and, if necessary, the tripartite Committee. In the light of the Committee's opinion, it shall inform the Member States whether or not the provision in question shall continue to enjoy presumption of compliance, and, if not, whether it shall be withdrawn from the publication referred to in Article 5(1).

Changes to the Annexes

Article 10

1. The Commission shall make changes to the Annexes to this Directive as a result of:

— the adoption of Directives on technical harmonization and standardization of the design, manufacture or construction parts of workplaces,

— technical progress, changes in international regulations or specifications and know-how in the field of workplaces.

2. In making the changes referred to in paragraph 1, the Commission shall be assisted by a committee and shall follow the procedure set out in Article 14 of Directive....

Final provisions

Article 11

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 1991 at the latest. They shall immediately notify the Commission.

2. The Member States shall forward to the Commission the text of the national provisions which they are adopting in the field governed by this Directive.

3. At two-yearly intervals, the Member States shall report to the Commission on the practical implementation at the workplace of the provisions of this Directive, indicating the opinions of the two sides of industry. The Commission shall inform the Committee and tripartite Committee.

Article 12

This Directive is addressed to the Member States.

ANNEX I

MINIMUM REQUIREMENTS FOR THE WORKPLACES REFERRED TO IN ARTICLE 4

1. PRELIMINARY REMARK

The minimal health and safety requirements shall only apply where the workplace is subject to the risk in question.

2. MINIMUM HEALTH AND SAFETY REQUIREMENTS FOR WORKPLACES

2.0. **Structure and stability**

Buildings housing workplaces shall have the structure and stability appropriate to the type of use.

2.1. **Electrical installations**

Electrical installations shall be designed and constructed in such a way that they do not present a fire or explosion hazard; persons must be adequately protected against the risk of accidents caused by direct or indirect contact.

The design, construction, choice of material and protection devices shall be appropriate to the voltage, external conditions and the competence of persons with access to parts of the installation.

2.2. **Emergency exits**

The emergency exits shall lead as directly as possible to the open air or a safe area.

2.2.1. In the event of danger, it must be possible for workers to evacuate all workstations quickly and in complete safety.

2.2.2. The number, distribution and dimensions of the emergency exits shall depend on the use, equipment and surface area of the workplaces and the maximum number of persons that may be present.

2.2.3. Emergency exit doors shall be easy to open and shall open outwards; sliding doors and revolving doors shall not be permitted unless there are sufficient of them.

2.2.4. Emergency exits shall be marked by signs in accordance with the national regulations implementing Directive 77/756/EEC; the signs shall be permanent and shall be placed at appropriate points.

2.3. **Fire detection and fire fighting**

2.3.1. Depending on the dimensions, height, use and equipment of the buildings and on the maximum potential number of people present, the workplaces shall be equipped with fire detectors, suitably distributed, an alarm system and appropriate automatic and/or manual fire-fighting equipment.

2.3.2. Non-automatic fire-fighting equipment shall be marked by signs in accordance with the national regulations implementing Directive 77/756/EEC. Such signs shall be permanent and placed at appropriate points.

2.4. **Ventilation of enclosed workplaces (rooms)**

The air in enclosed rooms shall be naturally or artificially renewed so that workers have a sufficient supply of air of an adequate quality, having regard to the work they are carrying out.

2.5. **Room temperatures**

2.5.1. During working hours, the air temperature in rooms comprising the workplaces shall be comfortable, having regard to the nature of the work carried out and the physical effort required of the workers.

2.5.2. The temperature in rest areas, rooms for duty staff, sanitary facilities, canteens and first aid rooms shall be appropriate to the purpose of these areas.

2.5.3. Climate control installations shall not blow or radiate on to workstations in such a way that workers are exposed to draughts or dangerous temperatures.

2.5.4. Windows, skylights and glass partitions shall be such as to prevent excessive insolation.

2.6. **Natural and artificial room lighting**

2.6.1. Rooms shall as far as possible receive sufficient daylight and be equipped with adequate sufficient artificial lighting.

2.6.2. Rooms in which workers may be exposed to risks in the event of failure of artificial lighting must be provided with adequate emergency lighting.

2.7. **Floors, walls and ceilings of rooms**

2.7.1. The floors of workplaces shall be level, with no unevenness, holes or dangerous slopes, they shall be fixed, stable and non-slip and it shall be possible to clean them to appropriate hygienic requirements in accordance with the purpose for which the rooms are used.

2.7.2. The surfaces of walls and ceilings in rooms shall be such that they can be cleaned or refurbished to appropriate hygienic requirements.

2.7.3. Transparent or translucent walls, in particular all-glass partitions, in rooms or in the vicinity of workstations and traffic routes shall be made of safety material or be shielded from workstations or traffic routes to prevent workers from coming into contact with walls or from being injured should the walls shatter.

2.8. **Windows and skylights**

2.8.1. Workers shall be able to open, close, adjust and secure windows, skylights and ventilation installations in complete safety. When open, they should not be so positioned as to constitute a hazard to workers. Unopenable windows shall not be permitted, unless the work requires it and there is adequate ventilation and artificial lighting.

2.8.2. Windows and skylights must be designed, or equipped to allow them to be cleaned without risk to the workers carrying out this work or to workers present in and around the building.

2.9. **Doors, gates and automatic doors**

2.9.1. The position, number and dimensions of doors and gates shall be determined by the nature and use of the rooms or areas.

2.9.2. Swing doors shall be transparent or have see-through panels.

2.9.3. If transparent or translucent surfaces in doors and gates are not made of unbreakable material and if there is a danger that workers may be injured if a door should shatter, the surfaces shall be protected against breakage.

2.9.4. Sliding doors shall be fitted with a mechanism to secure them from being lifted off their mountings and falling out.

2.9.5. Doors and gates opening upwards shall be fitted with a mechanism to secure them against falling back.

2.9.6. Doors along escape routes shall be appropriately marked. It shall be possible to open them from the inside without the use of any special aid throughout the period that the workplaces are occupied. They shall open outwards.

2.9.7. Doors for pedestrians shall be provided in the immediate vicinity of any gates intended essentially for vehicle traffic.

2.9.8. Mechanical doors and gates shall function in such a way that there is no risk of accident to workers. They shall be fitted with easily identifiable and accessible emergency shut-down devices and it shall be possible to open them by hand.

2.10. **Traffic routes — dangerous areas**

2.10.1. Traffic routes, including stairs, fixed ladders and loading ramps, shall be located and dimensioned to ensure easy, safe and appropriate access for pedestrians or vehicles in such a way as not to endanger workers employed in the vicinity of these traffic routes.

2.10.2. Routes used for pedestrian traffic and/or goods traffic shall be dimensioned in accordance with the number of potential users and the type of undertaking. If means of transport are used on traffic routes, a sufficient safety clearance shall be provided for pedestrians.

2.10.3. Sufficient clearance shall be allowed between vehicle traffic routes and doors, gates, passages for pedestrians, corridors and stairs.

2.10.4. Where the use and equipment of rooms so requires for the protection of workers, traffic routes in workrooms and storerooms shall be identified.

2.10.5. If the workplaces contain areas in which, due to the nature of the work, there is a risk of the worker or objects falling, these places shall be equipped, as far as possible, with devices preventing workers entering such areas.

2.11. **Specific measures for escalators and travolators**

Escalators and travolators shall function in such a way that there is no risk of accidents to workers. They shall be fitted with easily identifiable and accessible emergency shut-down devices.

2.12. **Loading ramps**

2.12.1. Loading ramps shall be wide enough for the dimensions of the loads to be transported.

2.12.2. Loading ramps shall have at least one alighting point. Where technically feasible, ramps over a certain length shall have an alighting point at each end.

2.13. **Room dimensions and air space in rooms, and freedom of movement at the workstation**

2.13.1. Workrooms shall have a sufficient surface area, height and minimum air space.

2.13.2. The dimensions of the free unoccupied area at the workstation shall be calculated to allow workers sufficient freedom of movement to perform their work. If this is not possible due to reasons specific to the undertaking, the worker shall be provided with sufficient freedom of movement near his workstation.

2.14. **Rest rooms**

2.14.1. In undertakings with more than a certain number of employees or where the health of workers or type of activity carried out demand it, workers shall be provided with an easily accessible rest room. This shall not apply if the workers are employed in offices or similar workrooms providing equivalent relaxation during breaks.

2.14.2 Rest rooms shall be large enough and equipped with an adequate number of tables and chairs for the number of workers.

2.14.3. Appropriate measures for the protection of non-smokers shall be taken in staff rest rooms.

2.14.4. If working hours are regularly and frequently interrupted and there is no rest room, rooms shall be provided in which workers can stay during such interruptions. Appropriate measures shall be taken for the protection of non-smokers.

2.15. **Sanitary equipment**

2.15.1. *Changing rooms and lockers*

2.15.1.1. Separate changing rooms shall be provided for men and women if they have to wear special work clothes and where, for reasons of health and propriety, they cannot be expected to change in another room.

2.15.1.2. In undertakings where workers are exposed to high temperatures in the course of their work, the changing rooms shall be in the vicinity of their workstations.

2.15.1.3. Changing rooms shall be sufficiently large and have facilities to enable each worker to lock away his clothes during working hours.

If the circumstances demand it (dangerous substances, humidity, dirt), lockers for work clothes shall be separate from those for ordinary clothes.

2.15.1.4. If changing rooms are not required under paragraph 2.15.1.1, each worker shall be provided with a place to store his clothes.

2.15.2. *Washrooms and washbasins*

2.15.2.1. Washrooms shall be provided for workers if required by the nature of the work or for health reasons. Separate washrooms shall be provided for men and women.

2.15.2.2. The washrooms shall be sufficiently large and equipped with facilities (including warm water if necessary) to permit each worker to wash in conditions of an appropriate standard of hygiene.

2.15.2.3. Where washrooms are not required under paragraph 2.15.2.1, washbasins with running water (warm if necessary) shall be provided in the vicinity of the workstations.

2.15.3. *Toilets and washbasins*

Separate facilities shall be provided in the vicinity of workstations with an adequate number of toilets and washbasins.

2.16. **First-aid installations**

2.16.1. Where there is a high risk of accidents or where there is a large workforce, a first-aid room shall be provided.

2.16.2. Such rooms shall be appropriately equipped, easily accessible and be marked in accordance with the national regulations implementing Directive 77/755/EEC. These signs shall be permanent and placed at appropriate points.

2.17. **Handicapped persons**

Workplaces shall be organized to take into account handicapped workers, if necessary.

2.18. **Outdoor workplaces (special provisions)**

2.18.1. Workstations, traffic routes and other areas or installations outdoors which are used by the workers in the course of their activity shall be so designed that there is no danger to pedestrians and vehicles.

Articles 12, 15 and 16 shall also apply to main traffic routes on the site of the undertaking (traffic routes leading to fixed workstations, to traffic routes used for the regular maintenance and supervision of the undertaking's installation and to loading ramps).

The provisions of 2.10 are also applicable to outdoor workplaces.

2.18.2. Workplaces outdoors shall be adequately lit by artificial lighting if daylight is not adequate.

2.18.3. When workers are employed at workstations outdoors, such workstations shall as far as possible be equipped so that workers are protected against inclement weather conditions.

ANNEX II

MINIMUM REQUIREMENTS FOR WORKPLACES REFERRED TO IN ARTICLE 6

The requirements set out in this Annex only apply where the workplace is subject to the risk in question.

1. Buildings containing workplaces shall be structurally sound and possess a stability appropriate to the nature of their use.

2. Escape routes and emergency exits shall follow the shortest possible route to the outside or a safe area. In the event of danger, it shall be possible to evacuate all workplaces quickly and safely; there shall be an adequate number of escape routes and emergency exits.

3. Emergency exit doors shall be easy to open and shall open outwards; sliding or rotating doors shall not be permitted.

   Escape routes and emergency exits shall be marked in accordance with the national regulations implementing Directive 77/756/EEC. They shall be permanently marked at appropriate points.

   Workplaces shall be equipped with suitable first-aid and fire-fighting equipment. The location of this equipment shall be adequately marked at appropriate points.

4. If the workplaces contain hazardous areas, due to the nature of the work, or involve the risk of workers falling or of falling objects, these workplaces shall be equipped, as far as possible, with devices preventing workers from entering such areas.

5. Rooms in which workers would be exposed to particular risks if the artificial lighting were to fail, and all emergency exits and traffic routes, shall have emergency lighting which provides sufficient illumination.

6. Swing doors shall be transparent or have see-through panels.

7. Workplaces shall be organized in such a way that pedestrians and vehicles can circulate without danger.

8. Workplaces shall be organized in such a way that workers have separate rooms in the vicinity of their workstations equipped with an adequate number of toilets and washbasins (cubicles).

9. Appropriate measures for the protection of non-smokers shall be taken in staff rest rooms.

Proposal for a Council Directive on the approximation of the laws of the Member States relating to personal protective equipment

COM(88) 157 final

(Submitted by the Commission to the Council on 14 April 1988)

(88/C 141/03)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

In cooperation with the European Parliament,

Whereas it is necessary to adopt measures with the aim of progressively establishing the internal market over a period

expiring on 31 December 1992; whereas the internal market comprises an area without internal frontiers in which the free movement of goods, persons, services and capital is guaranteed;

Whereas, in recent years, several Member States have introduced regulations and standards covering numerous items of personal protective equipment with a view, in particular, to safeguarding public health, improving safety at work and ensuring user protection;

Whereas these regulations and standards frequently contain extremely detailed requirements relating to the design, manufacture, quality level, testing and certification of personal protective equipment with a view to the protection of individuals against injury and illness;

Whereas, in particular, the requirements relating to safety at work make the use of personal protective equipment compulsory; whereas many requirements oblige employers to make appropriate personal protective equipment available to their staff in the event of the absence or inadequacy of (priority) public protection measures;

Whereas national provisions relating to personal protective equipment may differ significantly from one Member State to another and may thus constitute a barrier to trade with direct consequences for the creation and operation of the common market;

Whereas it is necessary to harmonize these different national provisions in order to ensure the free movement of these products, without in any way reducing the valid levels of protection already required in the Member States, and to provide for any necessary increase therein;

Whereas the provisions governing the design and manufacture of personal protective equipment laid down in this Directive which are fundamental, in particular, to attempts to ensure a safer working environment are without prejudice to provisions relating to the use of such equipment and the organization of the health and safety of workers at the workplace;

Whereas this Directive defines only the basic requirements to be satisfied by personal protective equipment; whereas, in order to facilitate proof of conformity with those basic requirements, it is essential that harmonized European standards be available relating, in particular, to the design and manufacture of, and the specifications and test methods applicable to, personal protective equipment, since compliance therewith confers on these products a presumption of conformity with the above-mentioned basic requirements; whereas such harmonized European standards are drawn up by private bodies and must retain the status of non-mandatory texts; whereas, to this end, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are the competent bodies which have been authorized to adopt harmonized standards in accordance with the general guidelines governing cooperation between the Commission and those two institutions ratified on 13 November 1984; whereas, for the purposes of this Directive, a harmonized standard is a text containing technical specifications (a European standard or a harmonization document) which has been adopted by one or both of the above-mentioned bodies at the instigation of the Commission in accordance with the provisions of Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations [1] and pursuant to the above-mentioned general guidelines;

Whereas, pending the adoption of harmonized standards within the meaning of this Directive, which will be very numerous because of the broad scope of application and the preparation of which within the deadline set for the creation of the internal market will involve a great deal of work, it would be advisable to maintain, on a transitional basis and subject to the requirements of the Treaty, the *status quo* as regards conformity with existing national standards for personal protective equipment not covered by a harmonized standard at the date of adoption of this Directive;

Whereas, given the general and horizontal nature of the role played by the standing Committee set up pursuant to Article 5 of Directive 83/189/EEC in the implementation of the Community standardization policy and, more particularly, its part in the preparation of standardization applications and the operation of the existing European standardization agreements, this standing Committee is especially suited to the task of assisting the Commission in monitoring the conformity of harmonized standards throughout the Community;

Whereas steps should be taken to ensure adequate consultation of the two sides of industry and, in particular, the workers' organizations in the context of the standardizations and administrative activities associated with this Directive;

Whereas compliance with these technical requirements must be monitored in order to ensure adequate user and third-party protection; whereas existing monitoring procedures may differ appreciably from one Member State to another; whereas, in order to avoid numerous checks which merely impede the free movement of personal protective equipment, provision should be made for the mutual recognition of inspections conducted by the Member States; whereas, in order to facilitate such recognition, it is necessary, in particular, to lay down harmonized Community procedures and to harmonize the criteria to be taken into account in selecting the bodies responsible for examination, monitoring and verification,

[1] OJ No L 109, 26. 4. 1983, p. 8.

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

Scope, marketing and free movement

Article 1

1. This Directive applies to personal protective equipment, hereinafter referred to as 'PPE'.

It lays down the conditions governing its marketing and free movement within the Community and the basic safety requirements which PPE must satisfy in order to ensure the safety and health protection of users.

2. For the purposes of this Directive, PPE means any device or appliance designed to be worn or held by an individual for protection against one or more safety and health hazards.

PPE also covers:

(a) a unit constituted by several devices or appliances which have been integrally combined by the manufacturer for the protection of an individual against one or more potentially simultaneous risks;

(b) a protective device or appliance combined, separably or inseparably, with personal non-protective equipment worn or held by an individual for the execution of a specific activity;

(c) interchangeable PPE components which are essential to its satisfactory functioning.

3. Any system marketed in conjunction with PPE for its connection to an external device shall be regarded as an integral part of that equipment even if the system is not intended to be worn or held permanently by the user for the entire period of risk exposure.

4. This Directive does not apply to:

— PPE covered by another Community Directive designed to achieve the same objectives as this Directive with regard to marketing, free movement of goods and safety,

— the PPE classes and types specified in the list of excluded products in Annex I, independently of the above-mentioned reason for exclusion.

Article 2

1. Member States shall take all appropriate measures to ensure that the PPE referred to in Article 1 may be placed on the market and brought into service only if it protects the health and ensures the safety of users without prejudice to the health or safety of other individuals, domestic animals or goods, when properly maintained and used for its intended purpose.

2. This Directive shall be without prejudice to the right of Member States to lay down — in conformity with the Treaty — any requirements which they consider necessary to ensure user protection, provided that this does not give rise to modifications to PPE which could result in its non-conformity with the provisions of this Directive.

3. Member States shall not prevent the presentation at trade fairs, exhibitions and the like of PPE which is not in conformity with the provisions of this Directive, provided that an appropriate notice is displayed drawing attention to this fact and the prohibition on its acquisition and (or) use for any purpose — including tests involving individuals — until it has been brought into conformity by the manufacturer or his representative established in the Community.

Article 3

1. The PPE referred to in Article 1 shall satisfy the basic safety requirements set out in Annex II.

2. The PPE mentioned in Article 8(2) shall conform:

— either to relevant national standards, transposing harmonized standards, the titles and reference numbers of which have been published in the *Official Journal of the European Communities*,

— or to other technical specifications, provided that these give the PPE a level of protection equivalent to that defined in the basic safety requirements, to be assessed by an approved inspection body referred to in Article 9, in accordance with the procedure laid down in Article 10(3).

3. The PPE referred to in Article 8(2), for which harmonized standards are not available, may continue, on a transitional basis until 31 December 1992 at the latest, to be subject to national provisions already in force on the date of adoption of this Directive, provided that any such provisions are compatible with the requirements of the Treaty.

Article 4

1. Member States shall not prohibit, restrict or hinder the marketing of PPE or PPE components which satisfy the provisions of this Directive and which bear the 'EC' mark.

2. Member States shall not prohibit, restrict or impede the marketing of PPE components, which do not bear the 'EC' mark, and which are intended to be incorporated in

PPE, provided that they are not essential to its satisfactory functioning.

Article 5

Member States shall presume that PPE satisfies the basic safety requirements referred to in Article 3 if it bears the 'EC' mark, declaring its conformity:

— with relevant national standards, transposing harmonized standards, the titles and reference numbers of which have been published in the *Official Journal of the European Communities*. The Member States shall publish the appropriate references of these national standards,

— or with other technical specifications providing a level of protection equivalent to that defined in the basic safety requirements of this Directive.

Article 6

If a Member State or the Commission considers that the harmonized standards referred to in Article 5 do not, or no longer, completely satisfy the relevant basic requirements referred to in Article 3, the Commission or the Member State concerned shall refer the matter to the Standing Committee created pursuant to Directive 83/189/EEC, hereinafter referred to as 'the Committee', setting out its reasons. The Committee shall deliver an opinion without delay.

In the light of that opinion, the Commission shall inform the Member States whether the reference to the standards in question need or need not be withdrawn from the publications referred to in Article 5.

Article 7

1. If a Member State discovers that PPE bearing the 'EC' mark and used in accordance with its intended purpose could compromise the safety of individuals, domestic animals or property, it shall take all necessary measures to remove that equipment from the market and prohibit the marketing or free movement thereof.

The Member State concerned shall immediately inform the Commission of such action, indicating the reasons for its decision and, in particular, stating whether non-conformity is due to:

(a) failure to comply with the basic requirements referred to in Article 3;

(b) the unsatisfactory application of the standards referred to in Article 5;

(c) a gap in the standards referred to in Article 5.

2. The Commission shall initiate discussions with the parties concerned as soon as possible. If, after such consultation, the Commission decides that the action taken was justified, it shall immediately inform the Member State concerned and all the other Member States to this effect. If the action referred to in paragraph 1 was taken as a result of a gap in the standards, the Commission shall refer the matter to the Committee within two months if the Member State concerned intends to adhere to its decision and shall initiate the procedures referred to in Article 6.

3. If PPE which is not in conformity with the relevant requirements bears the 'EC' mark, the Member State concerned shall take the appropriate measures with regard to those responsible for affixing the mark and shall inform the Commission and the other Member States accordingly.

4. The Commission shall ensure that the Member States are kept informed of the progress and results of the procedure provided for in this Article.

CHAPTER II

Certification procedures

Article 8

1. Before placing a PPE model on the market, the manufacturer or his authorized representative established in the Community shall assemble the documentation referred to in Annex III (I), so that this can, if necessary, be submitted to the competent authorities.

2. Prior to the series production of PPE other than that referred to in paragraph 3, the manufacturer or his authorized representative established in the Community shall submit a model for 'EC' type-examination in accordance with Article 10.

3. 'EC' type-examination shall not be required in the case of PPE models of simple design where the user can himself assess the level of protection provided against the minimal risks concerned which can be safely identified in good time owing to the gradual nature of their effects.

This category includes PPE models intended for use in domestic, dressmaking and gardening activities and models providing protection against solar radiation, bad weather and dirt.

Prior to marketing, series-manufactured PPE shall be subject to:

(a) the 'EC' verification procedure referred to in Article 11 in the case of PPE of complex design intended to protect the user against mortal danger, the immediate effects of which cannot be identified in sufficient time. This category includes:

— emergency equipment for use in atmospheres rendered unbreathable by oxygen deficiency and (or) serious contamination due to highly toxic or radiotoxic substances, which can harmfully affect

other parts of the body in addition to the respiratory tract,

— emergency equipment for use in high-temperature environments in which the atmospheric temperature is liable to exceed 100 °C and which may or may not be characterized by the presence of flames or the projection of large amounts of molten material,

— emergency equipment for use in low-temperature environments in which the atmospheric temperature is liable to be below −50 °C.

(b) the 'EC' declaration of conformity referred to in Article 12 for all PPE not falling within the category referred to in (a).

Article 9

1. Each Member State shall inform the Commission and the other Member States of the approved bodies responsible for the execution of the certification procedures referred to in Article 8. For information purposes, the Commission shall publish in the *Official Journal of the European Communities* and keep up to date a list giving the names of these bodies and the distinguishing numbers it has assigned to them.

2. Annex III (II) sets out the minimum criteria to be observed by the Member States in approving the above-mentioned bodies.

3. A Member State shall withdraw its approval from such a body if it establishes that the latter no longer satisfies the criteria referred to in Annex III (II). It shall inform the Commission and the other Member States of its action forthwith.

'EC' type-examination

Article 10

'EC' type-examination is the procedure whereby the approved inspection body establishes and certifies that the PPE model in question satisfies the relevant provisions of this Directive.

1. Application for 'EC' type-examination shall be made by the manufacturer or his authorized representative to a single approved inspection body in respect of the model in question. The authorized representative shall be established in the Community.

2. The application shall comprise:

— the name and address of the manufacturer or his authorized representative and of the PPE production plant in question,

— the manufacturer's file referred to in Annex III (I).

It shall be accompanied by the appropriate number of specimens of the model to be approved.

3. The approved inspection body shall conduct the 'EC' type-examination in accordance with the under-mentioned procedures:

(a) It shall examine the manufacturer's technical file to establish its suitability; in the case of technical specifications, other than those of the harmonized standards, referred to in Article 3(2), it shall satisfy itself as to their suitability compared to the basic safety requirements.

(b) In examining the model, the inspection body:

— shall verify that it has been produced in accordance with the manufacturer's technical file and can be used in complete safety for its intended purpose,

— shall conduct the necessary examinations and tests to establish the conformity of the model with the relevant standards or technical specifications and (or) basic requirements.

4. If the model satisfies the relevant provisions, the inspection body shall draw up an 'EC' type-examination certificate and shall notify the applicant to this effect. This certificate shall reproduce the findings of the examination, indicate any conditions attaching to its issue and incorporate the descriptions and drawings necessary for the identification of the approved model.

The Commission, the other approved inspection bodies and the other Member States may obtain a copy of the certificate and, in response to a reasoned request, a copy of the manufacturer's technical file and the reports of the examinations and tests conducted.

5. Any inspection body which refuses to issue an 'EC' type-examination certificate shall inform the other approved inspection bodies of this fact. An inspection body withdrawing an 'EC' type-examination certificate shall inform the Member State which approved it, to this effect. That Member State shall then inform the other Member States and the Commission, setting out the reasons for the decision.

'EC' verification

Article 11

1. 'EC' verification is a procedure for checking and certifying the conformity of production PPE with the approved model. It shall be conducted by the inspection body which drew up the 'EC' type-examination certificate pursuant to the under-mentioned provisions.

2. The verification procedure shall be conducted periodically with reference to PPE batches submitted by the manufacturer or his authorized representative established in the Community. Batches shall be accompanied by the 'EC' type-examination certificate referred to in Article 10.

3. In examining a batch, the inspection body shall establish that the PPE in question has been manufactured and checked in accordance with the manufacturer's file and

shall perform the appropriate tests on the batch specimens; it shall issue an 'EC' verification certificate.

'EC' declaration of conformity

Article 12

The 'EC' declaration of conformity is the procedure whereby the manufacturer who has satisfied the provisions of Article 8(4)(b):

1. draws up a declaration certifying that the PPE model specimens placed on the market are in conformity with the basic requirements of this Directive with a view, where necessary, to its submission to the competent authorities;

2. affixes the 'EC' mark of conformity provided for by Article 13 to each PPE model specimen.

CHAPTER III

'EC' mark

Article 13

1. The 'EC' mark consists of the letters 'EC' followed by the last two figures of the year in which the mark was affixed together, in the event of the involvement of an approved inspection body, with the distinguishing number referred to in Article 9(1).

The two models of the 'EC' mark to be used respectively in the event of the intervention or non-intervention of an approved inspection body are shown in Annex IV.

2. The 'EC' mark shall be affixed to PPE and its packaging so as to be visible, legible and indelible throughout the foreseeable 'useful life' of that PPE.

3. Marks of inscriptions which could be confused with the 'EC' mark shall not be affixed to PPE.

CHAPTER IV

Final provisions

Article 14

Any decision taken by a Member State in implementation of this Directive shall be accompanied by a detailed explanation of the grounds on which it is based. The interested party shall be notified of the decision without delay and informed of the possibilities for appeal under the legislation in force in the Member State concerned and of the deadlines for lodging such appeals.

Article 15

1. By 31 December 1989 Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 July 1990.

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

Article 16

This Directive is addressed to the Member States.

ANNEX I

EXHAUSTIVE LIST OF PPE CLASSES OR TYPES NOT COVERED BY THIS DIRECTIVE [1]

1. PPE designed and manufactured for use by the armed forces or in the maintenance of law and order.
2. PPE for self-private use in bad weather.
3. PPE for self-defence.

---

[1] Independently of the reason for exclusion referred to in Article 1.

ANNEX II

PROPOSAL FOR A DIRECTIVE RELATING TO PERSONAL PROTECTIVE EQUIPMENT

BASIC REQUIREMENTS IN RESPECT OF THE DESIGN AND MANUFACTURE OF PERSONAL PROTECTIVE EQUIPMENT (PPE)

1. GENERAL REQUIREMENTS

1.1. **Design principles**

1.1.1. *Ergonomics*

PPE must be so designed that in the conditions of use for which it is intended and for the foreseeable period of wear the user can perform the risk-related activity in question efficiently and without undue discomfort whilst enjoying the level of protection appropriate to the risks concerned.

1.1.2. *Levels of protection*

Whenever appropriate, PPE must be produced in different classes so as to provide several levels of protection.

1.2. **Innocuousness of PPE**

1.2.1. *Absence of risks and other 'inherent' nuisance factors*

PPE must be so designed and manufactured as to preclude risks and other nuisance factors both under normal conditions of use and under the abnormal conditions which can reasonably be expected to occur.

1.2.1.1. Suitable constituent materials

PPE constituent materials must be so chosen and incorporated that neither they nor any of their decomposition products adversely affect user hygiene or health.

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any PPE part in contact, or in potential contact with the user when such equipment is worn must be free of roughness, sharp edges, projections and the like which could cause excessive irritation or injuries.

1.2.1.3. Minimum uses impediment

Any impediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimized. Nor must PPE cause the user to perform dangerous movements.

1.3. **Comfort and efficiency**

1.3.1. *Adaptation of PPE to user morphology*

PPE must be so designed and manufactured as to facilitate correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, movements to be made and postures to be adopted. For this purpose, it must be possible to optimize PPE

adaptation to user morphology by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate size range.

1.3.2. *Lightness and design strength*

Design strength and efficiency must be appropriate to the levels of risk in question, the conditions of use and the foreseeable 'useful life' of the PPE concerned.

PPE must be as light as possible without unduly prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of such normal ambient phenomena as the physical stresses (abrasions, impact, vibrations, etc.) and chemical attack (from solvents, oil, hydrocarbons, detergents, etc.) to which they may be subject during transport or use, and climatic conditions and their seasonal variations.

1.3.3. *Compatibility of different classes or types of PPE designed for simultaneous use*

If a manufacturer markets several PPE models of different classes or types in order to ensure the simultaneous protection of adjacent parts of the body against combined risks, the composite equipment thus constituted must comply with all the basic requirements applicable to each class or type.

1.4. **Information supplied by the manufacturer**

In addition to the name and address of the manufacturer or his authorized representative established in the Community, the notes drawn up by the former and supplied when PPE is marketed must contain all relevant information on:

1. storage, use, cleaning, maintenance, servicing and disinfection [1];
2. performance as recorded during laboratory conformity tests designed to establish the level of protection (or degree of attenuation) provided by the PPE in question;
3. suitable PPE accessories and the characteristics of appropriate spare parts;
4. the limits beyond which the use of PPE is inappropriate;
5. the obsolescence deadline or period of obsolescence of PPE or certain of its components;
6. the type of packaging suitable for storage or transport;
7. the significance of any markings (see 2.12).

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination.

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

2.1. **PPE incorporating adjustment systems**

If PPE incorporates adjustment systems, the latter must be so designed and manufactured as to remain correctly adjusted under the conditions of use for which that PPE is marketed.

---

[1] Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions.

2.2. **PPE 'enclosing' the parts of the body to be protected**

As far as possible, PPE 'enclosing' the parts of the body to be protected must be sufficiently ventilated to prevent user perspiration; if this is not possible, it must be equipped with devices which absorb perspiration.

2.3. **PPE for the face, eyes and respiratory tracts**

Any restriction of the user's field of vision by PPE for the face, eyes and respiratory tract must be minimized.

The degree of optical neutrality of the vision systems of these PPE classes must be compatible with the type of relatively meticulous and/or prolonged activities for which the equipment is marketed.

If necessary, they must be treated or provided with ventilation facilities designed to prevent moisture formation or to remove moisture.

2.4. **PPE subject to ageing**

If it is known that the design performances of new PPE may be significantly affected by ageing, the date of manufacture or, if possible, the date of obsolescence, must be indelibly inscribed on every PPE item or interchangeable component marketed in such a way as to preclude any misinterpretation; this information must also be indelibly inscribed on the packaging.

If a manufacturer is unable to give an undertaking with regard to the 'useful life' of PPE, his notes must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence date, bearing in mind the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must if possible, affix a mark to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded; failing that, the manufacturer must give this information in his notes.

2.5. **PPE (or PPE components) which may be accidently snagged, jammed or caught up.**

These PPE classes (or components), which may be accidentally snagged, jammed or caught up in external objects, such as moving machine parts, or obstacles when the user changes position, must possess an appropriate tensile-strength threshold above which a constituent part is designed to break so as to protect the user against physical injury.

2.6. **PPE for use in explosive atmospheres**

The constituent materials (and, where relevant, the electric circuits) of such PPE must be so chosen or designed and incorporated as to preclude the production, under normal conditions of use, of an electric arc or spark capable of attaining the level required to ignite an explosive mixture as a result of mechanical impact, friction, (the opening or closing of the electric circuit), or accidental contact of the PPE with energized conductors or exposed conductive parts, or the generation of electrostatic charges.

2.7. **PPE intended for emergency use or rapid removal**

These PPE classes must be so designed and manufactured as to minimize the time required for attachment and (or) removal.

Any integral systems permitting correct positioning on, or removal from, the user must be susceptible of rapid and easy operation.

2.8. **PPE for use in 'critical' situations**

The information notes supplied by the manufacturer together with PPE for use in the 'critical' situations referred to in Article 8(4) must include, in particular, data reserved for the exclusive

use of competent trained individuals who are qualified to interpret them and ensure their application by the user.

They must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

If PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, this must be so designed and accommodated as to be perceived by the user in the conditions of use for which the PPE is marketed.

2.9. **PPE incorporating components which can be adjusted or removed by the user**

Any PPE components which can be adjusted or removed by the user for the purpose of replacement, must be so designed and manufactured as to facilitate manual adjustment, attachment and removal.

2.10. **PPE for connection to an external device**

If PPE incorporates a system permitting connection to an external device, the attachment mechanism must be so designed and manufactured as to preclude its mounting on inappropriate equipment.

2.11. **PPE incorporating a fluid circulation system**

If PPE incorporates a fluid circulation system, the latter must be so chosen, or designed, and incorporated as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of user gestures, posture or movement under the conditions of use for which the PPE is marketed.

2.12. **PPE bearing one or more identification or recognition marks**

The identification or recognition marks affixed to these types of PPE must remain perfectly legible throughout the foreseeable 'useful life' of this PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, when such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State of destination.

If PPE (or a PPE component) is too small to allow all or part of the necessary marking to be affixed, this fact must be mentioned on the packing and in the manufacturer's notes.

2.13. **PPE in the form of clothing capable of signalling the user's presence**

PPE in the form of clothing intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) external part(s) that are reflective by nature or have a reflective coating. Each reflecting element must be carefully positioned on the PPE so as to reflect back any incident radiation in the direction of its emission source with a suitable coefficient of luminous intensity and appropriate photometric and colorimetric properties.

2.14. **'Multi-risk' PPE**

All PPE designed to protect the user against several potentially simultaneous risks must be so designed and manufactured as to satisfy, in particular, the basic requirements specific to each of those risks (see 3).

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.1. **Protection against mechanical impact**

3.1.1. *Impact caused by falling or projecting objects and collision of parts of the body with an obstacle*

Suitable PPE for this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions and (or) mass of the absorbing device would preclude effective use of the PPE for the foreseeable period of wear.

3.1.2. *Falls*

3.1.2.1. Prevention of falls due to slipping

The outsoles of footwear designed to prevent slipping on loose, irregular or smooth ground or floors made slippery by foreign bodies must be so designed, manufactured or equipped with added elements as to possess for example, an adequate 'tread' and (or) at the same time, provide a sufficient contact surface ensuring satisfactory adhesion by grip and friction.

3.1.2.2. Prevention of falls from a height

PPE designed to prevent falls from a height or their effects must incorporate a body harness and an attachment system which can be connected to a reliable anchorage point by means of an appropriate device. It must be so designed and manufactured that, even under the most unfavourable conditions of use — heavily-built person or person carrying a considerable weight situated at the maximum possible height in relation to the PPE anchorage point at the moment of losing balance —, the vertical drop is minimized so as to preclude collision with obstacles [1], and the braking force nevertheless does not attain the threshold value at which physical injury or the tearing or rupture of any PPE component can be expected to occur.

3.1.2.3. Prevention of drowning

Under the foreseeable conditions of use for which it is marketed, PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible a user who may be exhausted or unconscious after accidentally falling into a liquid medium, and of keeping him afloat in a waiting position which permits respiration.

For this purpose, these PPE classes must be capable of withstanding, without prejudice to their functional capacity, the energy level resulting from impact with the liquid medium, which depends on the height of fall.

Such PPE must inflate automatically, rapidly and completely on impact.

PPE constituent materials and other components must be water-tight and incorporated in such a way that 'buoyancy' derives, in particular, from a system of upward hydrostatic forces, the centres of thrust of which are at the user's thorax and nape of the neck.

If, after impact with the liquid medium, the user is in the 'face-down, head-immersed' position, the system of forces must impart a rotary motion to the body so as to bring it to the 'face-up' position.

The 'buoyancy' provided by PPE must be such that, in the waiting position, the orifices of the user's respiratory tracts are sufficiently above the surface of the liquid medium, due account being taken, in particular, of foreseeable fluctuations in the latter.

---

[1] This vertical drop must always be less than the necessary minimum 'headroom' indicated in the manufacturer's notes.

In addition, this PPE must be so designed and manufactured that it can, if necessary, be worn by a fully-dressed person for as long as the risk of drowning exists.

3.1.3. *Mechanical vibration*

PPE designed to prevent osteoarticular and angioneurotic disorders resulting from mechanical vibrations must be capable of ensuring adequate attenuation of the most harmful vibration components for the part of the body at risk, without dangerously amplifying the vibration components emitted at other frequencies or in other frequency bands. Under no circumstances must the effective value of the accelerations transmitted to the user by those vibrations exceed the limit values recommended in the light of the maximum foreseeable daily exposure of the part of the body at risk.

3.2. **Protection against (static) compression of part of the body**

PPE designed to protect part of the body against (static) compressive stress must be sufficiently capable of attenuating its effects to prevent serious injury or chronic complaints up to compressive-force level above which the dimensions of the shock-absorbing device would preclude effective use during the necessary period of wear.

3.3. **Protection against superficial injury caused by machinery (abrasion, perforation, cuts, bites)**

PPE constituent materials and other components designed to protect all or part of the body against superficial injury caused by machinery, such as abrasion, perforation cuts, or bites must be so chosen or designed and incorporated as to ensure that these PPE classes provide sufficient resistance to abrasion, perforation and gashing (see also 3.1) under the conditions of use for which they are marketed.

3.4. **Protection against the harmful effects of noise**

PPE designed to prevent the harmful effects of noise must be capable of attenuating the latter to such an extent that the equivalent sound levels perceived by the user do not under any circumstances exceed the daily limit values laid down for the protection of workers by the Council Directive of 12 May 1986.

The noise attenuation class of the PPE must be appropriate to the 'typical' noise for which it is marketed.

All PPE and (or, failing this) its packaging must bear labelling indicating the A-weighted overall attenuation level of the 'typical' noise and the value of the comfort index provided by the PPE. The package-insert notes must contain, in particular, the graph of noise attenuation in relation to octave bands.

3.5. **Protection against heat and (or) fire**

PPE designed to protect all or part of the body against the effects of heat and (or) fire must possess thermal insulation capacity and mechanical strength appropriate to the conditions of use for which it is marketed.

In designing these PPE classes, the manufacturer must take account of all parameters of relevance to the evaluation of the heat flow transmitted through PPE by atmospheric radiation and convection or by conduction resulting from contact with elements at high temperature such as the ground, partitions or hot objects and the projection of hot products — incandescent particles, molten materials, etc. — or transmitted by direct contact with flame.

3.5.1. *PPE consituent materials and other components*

Constituent materials and other components suitable for protection against radiant and convective heat must possess the lowest possible coefficient of transmission of incident heat flux

and be sufficiently incombustible (1) to preclude any risk of spontaneous ignition under the foreseeable conditions of use. The reflective power of the outside of these materials and components in the infrared range must increase in line with the intensity of the heat flux due to radiation.

Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as large quantities of molten material, must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed his PPE.

PPE materials and other components which may be splashed by large amounts of hot products must also possess sufficient mechanical-impact absorbency (see 3.1).

PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of fire-fighting equipment must also possess a degree of non-flammability (1) corresponding to the risk class associated with the foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.

3.5.2. *Complete PPE ready for use*

Under the foreseeable conditions of use:

1. the quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;

2. PPE must prevent liquid or steam penetration and must not cause burns resulting from pinpoint contact between its protective integument and the user.

If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, their design must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user.

If PPE incorporates a breathing device, the latter must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's notes accompanying each PPE model intended for brief use in high-temperature environments must provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.

3.6. **Protection against cold**

PPE designed to protect all or part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is marketed.

In designing these PPE classes, the manufacturer must take account of all parameters of relevance to the evaluation of the cold transmitted through PPE, in particular by atmospheric convection or by conduction resulting from contact with elements at an unsuitably low temperature such as the ground, partitions or cold objects or the splashing of cold products.

3.6.1. *PPE constituent materials and other components*

Constituent materials and other components suitable for protection against cold must possess the lowest possible coefficient of transmission of incident cold flux. Flexible materials (and other components) of PPE intended for use in low-temperature environment, must, under the

(1) Measured on an inflammability test bench with reference to the Oxygen Index Limit (ILO) or the minimum oxygen concentration of an oxygen-nitrogen mixture required to maintain flame combustion of a material.

foreseeable conditions of use, retain the degree of flexibility required for the necessary gestures and postures.

PPE materials and other components which may be splashed by large amounts of cold products must also possess sufficient mechanical-impact absorbency (see 3.1).

3.6.2. *Complete PPE ready for use*

Under the foreseeable conditions of use:

1. the flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected (including the tips of fingers and toes in the case of hands or feet) from attaining, under any circumstances, the pain or health-impairment threshold;

2. PPE must prevent the penetration of such liquids as rain water and must not cause injuries resulting from pinpoint contact between its cold protective integument and the user.

If PPE incorporates a breathing device, this must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's notes accompanying each PPE model intended for brief use in low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.

3.7. **Protection against electric shock**

PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.

To this end, the constituent materials and other components of these PPE classes must be so chosen or designed and incorporated as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered *in situ* is minimized and, at all events, below a maximum conventional permissible value which correlates with the tolerance threshold.

Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating, in particular, their protection class and (or) corresponding operating voltage, their serial number and their date of manufacture; a space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or inspections to be conducted. The manufacturer's notes must indicate, in particular, the exclusive use for which these PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their 'useful life'.

3.8. **Radiation protection**

3.8.1. *Non-ionizing radiation*

PPE designed to prevent acute or chronic eye-damage from sources of non-ionizing radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.

To this end, protective glasses must be so designed and manufactured as to possess, for each harmful wave, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimized and, under no circumstances, exceeds the maximum permissible exposure value.

Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.

Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's notes must indicate, in particular, the transmission curves which make it possible to select the most appropriate PPE bearing in mind such inherent factors of the effective conditions of use as distance to source and the spectral distribution of the energy radiated at that distance.

All protective glasses must bear the relevant protection-factor number.

3.8.2. *Ionizing radiation*

1. Protection against external radioactive contamination (1)

PPE constituent materials and other components designed to protect all or part of the body against radioactive dust, gases, liquids or mixtures thereof must be so chosen or designed and incorporated as to ensure that this equipment effectively prevents the penetration of the contaminants which it is designed to exclude.

Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective 'integument' and (or) by any other appropriate means, such as ventilation and pressurization systems designed to prevent the back-scattering of these contaminants.

Any decontamination measures to which PPE is subject must not prejudice its re-use during the foreseeable 'useful life' of these classes of equipment.

2. Limited protection against external irradiation

PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak electron (e. g. beta) or weak photon (e. g. X, gamma) radiation.

The constituent materials and other components of these PPE classes must be so chosen or designed and incorporated as to provide the maximum possible degree of user protection without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (see 1.3.2).

PPE must bear a mark indicating the type and thickness of the constituent material(s) suitable for the conditions of use for which it is marketed.

3.9. **Protection against dangerous substances and infective agents**

3.9.1. *Protection against inhalation (respiratory protection)*

PPE intended for the protection of the respiratory tract must make it possible to supply the user with breathable air when the latter is exposed to a polluted atmosphere and (or) an atmosphere having inadequate oxygen concentration.

The breathable air supplied to the user by the PPE is obtained after filtration of the polluted air through the protective device or appliance or by a piped supply from an unpolluted source.

The constituent materials and other components of these PPE classes must be so chosen or designed and incorporated as to ensure appropriate user respiration and respiratory hygiene for

(1) See 3.9.1 for protection against contamination of the respiratory tracts.

the period of wear concerned under the foreseeable conditions of use for which the PPE is marketed.

The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must be such as to minimize contaminant penetration from a polluted atmosphere, without resulting under the least favourable conditions in an overshooting of the maximum permissible concentration values or an oxygen concentration of less than the minimum required by the user.

The PPE must bear the manufacturer's identification mark and details of the specific characteristics of that type of equipment which, in conjunction with the instructions for use, will enable a trained and qualified user to employ the PPE correctly.

The manufacturer's notes must also indicate the deadline for filter storage.

3.9.2. *Protection against epidermal or ocular contact*

PPE intended to prevent the surface contact of all or part of the body with dangerous substances and infective agents must be capable of preventing the penetration or diffusion of such substances through the protective envelope under the conditions of use for which the PPE is marketed.

To this end, the constituent materials and other components of these PPE classes must be so chosen, or designed, and incorporated as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain dangerous substances or infective agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of efficiency. PPE which is considered to be in conformity with the test specifications must bear a mark indicating, in particular, the names or, failing this, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's notes must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

ANNEX III

CERTIFICATION OF PPE CONFORMITY WITH THE BASIC REQUIREMENTS OF THIS DIRECTIVE

I. TECHNICAL DOCUMENTATION SUPPLIED BY THE MANUFACTURER

The documentation referred to in Article 8(1) must comprise:

1. the manufacturer's technical file consisting of:

   (a) overall and detailed plans accompanied, where necessary, by calculation notes and the results of prototype tests conducted prior to manufacture;

   (b) an exhaustive list indicating the basic requirements of this Directive, and harmonized standards or other technical specifications referred to in Article 5, taken into account in the design and manufacture of the PPE; in the case of technical specifications, other than those of the harmonized standards, the manufacturer's technical file must include in particular all the data required to enable the approved inspection body referred to in Article 9(1) to establish the conformity of the PPE to the basic safety requirements referred to in Article 3 of this Directive;

   (c) a list of all the test facilities used to verify maintenance of the minimum permissible quality level of the starting materials, semi-finished products and finished products used in the production of the PPE in question;

2. a detailed description of the control and test facilities used in the manufacturer's plant, for the periodic batch checking or systematic specimen checking of complete PPE ready for use with regard to:

   (a) its conformity to the harmonized or other technical specifications standards referred to in Article 5;

   (b) maintenance of the minimum permissible quality level of series-production PPE.

3. any reports drawn up by a competent body establishing the conformity of the prototype with the harmonized standards or other technical specifications referred to in Article 5;

4. a copy of the information notes referred to in Annex II, 1.4.

II. MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY THE MEMBER STATES IN APPOINTING INSPECTION BODIES

1. The inspection body, its director and the staff responsible for the execution of the verification procedures must be neither the designer, manufacturer or suppliers of the PPE tested nor the authorized representative of one of those individuals. They must not be involved, either directly or as representatives, in the design, manufacture, marketing or maintenance of this PPE. This provision does not preclude the possibility of an exchange of technical information between the manufacturer and the inspection body concerned.

2. The inspection body and the staff responsible for examinations must carry out the verification procedures with the greatest professional integrity and maximum technical competence; they must be free from all pressures and incentives, particularly financial, which could influence their judgment or the results of their examinations, especially where these emanate from individuals or groups of individuals with an interest in the test results.

3. The inspection body must employ the necessary staff and possess the necessary resources for the satisfactory accomplishment of the technical and administrative tasks which form part of the verification procedures; it must also have access to any equipment required for exceptional examinations.

4. The staff responsible for inspection must be:

   — technically and professionally well-qualified,

   — sufficiently familiar with the requirements relating to the tests they carry out and sufficiently experienced in the execution of those tests,

   — capable of completing the certificates, records and reports which constitute the material evidence of the test conducted.

5. The independence of the inspection staff must be guaranteed. The remuneration of each official must be determined neither by the number of tests conducted nor by the results obtained.

6. The inspection body must take out third-party insurance unless its liability is covered by the State under national law or the tests are not directly conducted by the Member State concerned.

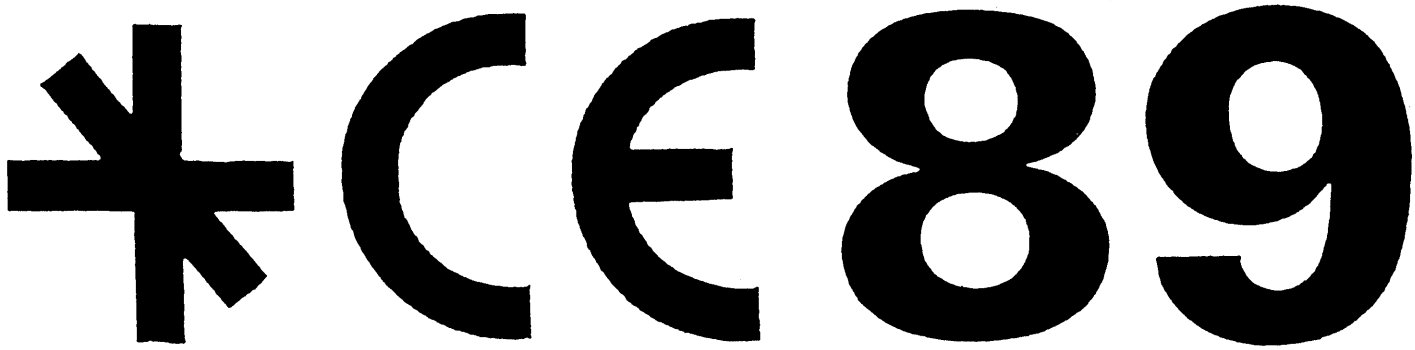
7. The staff of the inspection body must observe professional secrecy as regards everything learned in the performance of their duties (except in relation to the competent authorities of the State in which those duties are performed) in the context of the application of this Directive or of any provisions of national law implementing this Directive.

ANNEX IV

MODEL 'EC' MARKS

A. MODEL FOR USE IN 'EC' TYPE-EXAMINATION OR 'EC' VERIFICATION PROCEDURES
(see Articles 10 and 11)

(1) for example (2)



B. MODEL FOR USE IN THE 'EC' DECLARATION OF CONFORMITY PROCEDURE NOT INVOLVING 'EC' TYPE-EXAMINATION (see Article 12)

for example(2)

The vertical dimension of the different components of the 'EC' mark must be perceptibly the same, namely not less than 2 mm on the PPE and not less than 5 mm on its packaging.

(1) Distinguishing number of approved inspection body (see Article 13).
(2) Last two figures of the year in which the mark was affixed (see Article 13).