

## SCHEDULE

### COUNCIL DIRECTIVE

of 21 December 1989

on the approximation of the laws of the Member States relating to personal protective equipment (89/686/EEC)

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<sup>(1)</sup>,

In co-operation with the European Parliament<sup>(2)</sup>

Having regard to the opinion of the Economic and Social Committee<sup>(3)</sup>,

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 various Member States have, over recent years, adopted provisions 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 national provisions are often very detailed as regards the 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 national provisions 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 absence or inadequacy of priority public protection measures;

Whereas national provisions relating to personal protective equipment differ significantly from one Member State to another; whereas they 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 abovementioned 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

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(1) OJ No.C141, 30.5.1988, p.14.

(2) OJ No.C12, 16.1.1989, p.109, OJNo.C304, 4.12.1989, p.29.

(3) OJ No.C337, 31.12.1988, p.37.

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Electrotechnical Standardization (Cenelec) are the competent bodies which have been authorized to adopt harmonized standards in accordance with the general guidelines governing co-operation 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(4), as amended by Directive 88/182/EEC(5), and pursuant to the abovementioned general guidelines;

Whereas, pending the adoption of harmonized standards, 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 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 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;

Whereas the legislative framework should be improved so that both sides of industry will make an effective and appropriate contribution to the process of standardization,

HAS ADOPTED THIS DIRECTIVE:

## CHAPTER I

### SCOPE, PLACING ON THE MARKET 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 placing on the market and free movement within the Community and the basic safety requirements which PPE must satisfy in order to ensure the health protection and safety of users.

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

PPE shall also cover:

- (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;

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(4) OJ No.L109, 26.4.1983, p.8.

(5) OJ No.L81, 26.3.1988, p.75.

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- (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 and used exclusively for such equipment.
3. Any system placed on the market in conjunction with PPE for its connection to another external, additional 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 directive designed to achieve the same objectives as this Directive with regard to placing on the market, free movement of goods and safety,
  - the PPE classes specified in the list of excluded products in Annex I, independently of the reason for exclusion mentioned in the first indent.

#### *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 preserves 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 whatsoever until it has been brought into conformity by the manufacturer or his representative established in the Community.

#### *Article 3*

The PPE referred to in Article 1 must satisfy the basic health and safety requirements laid down in Annex II.

#### *Article 4*

1. Member States shall not prohibit, restrict or hinder the placing on the market 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 placing on the market 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*

1. Member States shall regard as in conformity with the basic requirements referred to in Article 3 the PPE referred to in Article 8(3) bearing the EC mark with respect to which the manufacturer is able to produce, on demand, the declaration of conformity referred to in Article 12.

2. Member States shall presume that the PPE referred to in Article 8(2) satisfies the basic requirements referred to in Article 3 if it bears the EC mark with respect to which the manufacturer is

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able to produce, on demand, not only the declaration referred to in Article 12 but also the certificate issued by the body of which notification has been given in accordance with Article 9 attesting to their conformity to the relevant national standards, transposing the harmonized standards, assessed at the EC type examination level in accordance with the first indent of Article 10(4)(a) and (b).

Where a manufacturer has not applied or has only partly applied the harmonized standards or where there are no such standards the certificate issued by the body of which notification has been given must state the conformity to the basic requirements in accordance with the second indent of Article 10(4)(a) and (b).

**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 arrangements already in force on the date of adoption of this Directive, provided that such arrangements are compatible with the provisions of the Treaty.

**4.** The Commission shall publish the references of the harmonized standards in the Official Journal of the European Communities.

Member States shall publish the references of the national standards transposing the harmonized standards.

**5.** Member States shall ensure that by 30 June 1991 appropriate steps are taken to enable both sides of industry to have an influence at national level on the process of formulating the harmonized standards and keeping them under review.

#### *Article 6*

**1.** Should a Member State or the Commission consider that the harmonized standards referred to in Article 5 do not completely satisfy the relevant basic requirements referred to in Article 3, the Commission or the Member State concerned shall refer the matter to the committee created pursuant to Directive 83/189/EEC(6), setting out its reasons. The committee shall deliver an opinion without delay.

In the light of the committee's opinion, the Commission shall notify Member States of whether or not it is necessary to withdraw the standards concerned from publications made pursuant to Article 5.

**2.** The Standing Committee set up by Article 6(2) of Directive 89/392/EEC(7) may be apprised, in accordance with the procedure described below, of any matter to which the implementation and practical application of this Directive give rise.

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, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

#### *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

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(6) OJ No.L109, 26.4.1983, p.8.

(7) OJ No.L183, 29.6.1989, p.9.

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 shortcoming 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 that effect. If, after such consultation, the Commission decides that the action taken was not justified, it shall immediately inform the Member State concerned and the manufacturer or his authorized representative established in the Community to that effect. If the decision referred to in paragraph 1 is in response to a shortcoming in the standards, the Commission shall refer the matter to the Committee referred to in Article 6(1) if the Member State concerned intends to adhere to its decision and shall initiate the procedure referred to in Article 6(2).

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 technical documentation referred to in Annex III so that this can, if necessary, be submitted to the competent authorities.

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

3. EC type-examination shall not be required in the case of PPE models of simple design where the designer assumes the user can himself assess the level of protection provided against the minimal risks concerned the effects of which, when they are gradual, can be safely identified by the user in good time.

This category shall cover exclusively PPE intended to protect the wearer against:

- mechanical action whose effects are superficial (gardening gloves, thimbles, etc.),
- cleaning materials of weak action and easily reversible effects (gloves affording protection against diluted detergent solutions, etc.),
- risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50°C or to dangerous impacts (gloves, aprons for professional use, etc.),
- atmospheric agents of a neither exceptional nor extreme nature (headgear, seasonal clothing, footwear, etc.),

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- minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (light anti-scalping helmets, gloves, light footwear, etc.),
  - sunlight (sunglasses).
4. Production of PPE shall be subject:
- (a) according to the manufacturer's choice, to one of the two procedures referred to in Article 11 in the case of PPE of complex design intended to protect against mortal danger or against dangers that may seriously and irreversibly harm the health, the immediate effects of which the designer assumes the user cannot identify in sufficient time. This category shall cover exclusively:
    - filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radiotoxic gases,
    - respiratory protection devices providing full insulation from the atmosphere, including those for use in diving,
    - PPE providing only limited protection against chemical attack or against ionizing radiation,
    - emergency equipment for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterized by the presence of infra-red radiation, flames or the projection of large amounts of molten material,
    - emergency equipment for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50°C or less,
    - PPE to protect against falls from a height,
    - PPE against electrical risks and dangerous voltages or that used as insulation in high-tension work,
    - motor cycle helmets and visors;
  - (b) the EC declaration of conformity referred to in Article 12 for all PPE.

#### *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. Member States shall apply the criteria laid down in Annex V in assessing the bodies to be indicated in such notification. Bodies meeting the assessment criteria laid down in the relevant harmonized standards shall be presumed to fulfil those criteria.

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 V. It shall inform the Commission and the other Member States of its action forthwith.

### EC TYPE-EXAMINATION

#### *Article 10*

1. 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.

2. 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.

3. 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 technical file referred to in Annex III.

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

4. The inspection body of which notification has been given shall conduct the EC type-examination in accordance with the undermentioned procedures:

(a) Examination of the manufacturer's technical file

- It shall examine the manufacturer's technical file to establish its suitability with respect to the harmonized standards referred to in Article 5.
- Where a manufacturer has not applied, or has only partly applied, the harmonized standards or where there are no such standards, the body of which notification has been given must check the suitability of the technical specifications used by the manufacturer with respect to the basic requirements before examining the manufacturer's technical file to establish its suitability with respect to these technical specifications.

(b) Examination of the model

- When 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.
- It shall conduct the necessary examinations and tests to establish the conformity of the model with the harmonized standards.
- Where a manufacturer has not applied or has only partly applied the harmonized standards or where there are no such standards the body of which notification has been given shall conduct the necessary examinations and tests to establish the conformity of the model with the technical specifications used by the manufacturer, subject to their being suitable with respect to these basic requirements.

**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.**

5. 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.

The file shall be held at the disposal of the competent authorities for 10 years following the placing of the PPE on the market.

6. 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.

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## CHECKING OF PPE MANUFACTURED

### Article 11

#### **‘EC’ quality control system for the final product**

##### **A**

1. A manufacturer shall take all steps necessary to ensure that the manufacturing process, including the final inspection of PPE and tests, ensures the homogeneity of production and the conformity of PPE with the type described in the EC type-approval certificate and with the relevant basic requirements of this Directive.

**A body of which notification has been given, chosen by a manufacturer, shall carry out the necessary checks. Those checks shall be carried out at random, normally at intervals of at least one year.**

##### **2**

**An adequate sample of PPE taken by the body of which notification has been given shall be examined and appropriate tests defined in the harmonized standards or necessary to show conformity to the basic requirements of this Directive shall be carried out to check the conformity of PPE.**

##### **3**

**Where a body is not the body that issued the relevant EC type-approval certificate it shall contact the body of which notification has been given in the event of difficulties in connection with the assessment of the conformity of samples.**

##### **4**

5. The body of which notification has been given shall provide the manufacturer with a test report. If the report concludes that production is not homogeneous or that the PPE examined do not conform to the type described in the EC type-approval certificate or the relevant basic requirements, the body shall take measures appropriate to the nature of the fault or faults recorded and inform the Member State which gave notification thereof accordingly.

6. The manufacturer must be able to present, on request, the report of the body of which notification has been given.

#### **System for ensuring EC quality of production by means of monitoring**

##### **B**

##### **1. The system**

(a) Under this procedure the manufacturer submits an application for the approval of his quality-control system to a body of which notification has been given, of his choice.

That application shall include:

- all the information relating to the category of PPE concerned, including, where appropriate, documentation relating to the model approved,
- documentation on the quality-control system,



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- the undertaking to maintain the obligations arising from the quality-control system and to maintain its adequacy and efficiency.
- (b) Under the quality-control system, each PPE shall be examined and the appropriate tests referred to in Section A paragraph 3 shall be carried out to check their conformity to the relevant basic requirements of this Directive.

The documentation on the quality-control system shall in particular include an adequate description of:

- the quality objectives, the organization chart, the responsibilities of executives and their powers in respect of product quality,
  - the checks and tests which must be carried out after manufacture,
  - the means to be employed to check the efficient operation of the quality-control system.
- (c) The body shall assess the quality-control system to determine whether it satisfies the provisions referred to in paragraph 1(b). It shall assume that quality-control systems applying the relevant harmonized standard satisfy those provisions.
- The body carrying out audits shall make all necessary objective evaluations of the components of the quality-control system and shall check in particular whether the system ensures conformity of PPE manufactured with the approved model.
- The decision shall be communicated to the manufacturer. It shall include the conclusions of the check and the reasoned assessment decision.
- (d) The manufacturer shall inform the body which approved the quality-control system of any plan to alter the quality-control system.

The body shall examine the proposed changes and decide whether the altered quality-control system satisfies the relevant provisions. It shall communicate its decision to the manufacturer. The communication shall include the conclusions of the check and the reasoned assessment decision.

## 2. Supervision

- (a) The purpose of supervision is to ensure that a manufacturer correctly fulfils the obligations arising from the approved quality-control system.
- (b) The manufacturer shall authorize the body to have access, for purposes of inspection, to PPE inspection, testing and storage sites and shall provide the body with all requisite information, in particular:
  - documentation on the quality-control system,
  - technical documentation,
  - quality control manuals.
- (c) The body shall periodically carry out audits to ensure that the manufacturer is maintaining and applying the approved quality-control system and shall provide the manufacturer with a copy of the audit report.
- (d) In addition, the body may make unannounced visits to the manufacturer. In the course of such visits the body shall provide the manufacturer with a report of the visit and, if appropriate, with an audit report.
- (e) The manufacturer must be able to present, on request, the report of the body of which notification has been given.

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## EC DECLARATON OF PRODUCTION CONFORMITY

### *Article 12*

The EC declaration of conformity is the procedure whereby the manufacturer:

1. draws up a declaration using the form laid down in Annex VI certifying that the PPE placed on the market are in conformity with the provisions of this Directive with a view to its submission to the competent authorities;
2. affixes the EC mark of conformity provided for by Article 13 to each PPE.

## CHAPTER III

### EC MARK

#### *Article 13*

1. The EC mark consists of the letters 'CE' followed by the last two figures of the year in which the mark was affixed and, in the event of the involvement of a notified body having carried out an EC examination of the type referred to in Article 10, its distinguishing number shall be added.

The form of the mark to be used is shown in Annex IV.

2. The EC mark shall be affixed to each production PPE and its packaging so as to be visible, legible and indelible throughout the foreseeable useful life of that PPE.
3. Marks or inscriptions which could be confused with the EC mark may not be affixed to PPE.

## CHAPTER IV

### FINAL PROVISIONS

#### *Article 14*

Any decision taken in implementation of this Directive and leading to restrictions on the marketing of PPE 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*

The Commission shall take the necessary steps to ensure that data concerning all the relevant decisions in connection with the management of this Directive are made available.

#### *Article 16*

1. By 31 December 1991, Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 July 1992.

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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 17*

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1989.

For the Council The President

E. CRESSON