Council Directive of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (89/686/EEC)

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.),

— 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,

— **[**[F1]. . . . .**]**

b the EC declaration of conformity referred to in Article 12 for all PPE.

Textual Amendments

F1 Deleted by Council Directive 93/95/EEC of 29 October 1993 amending Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment (PPE).

Article 9

[[F2]1 Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the procedures referred to in Article 8 together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.**]**

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.

Textual Amendments

F2 Substituted by Council Directive 93/68/EEC of 22 July 1993 amending Directives 87/404/EEC (simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC (personal protective equipment), 90/384/EEC (non-automatic weighing instruments), 90/385/EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits).

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.

5 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.

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.

CHECKING OF PPE MANUFACTURED

Article 11

A.
‘EC’ quality control system for the final product

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.

2 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.

3 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.

4 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.

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.

B.
System for ensuring EC quality of production by means of monitoring

The system

1. (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,

— 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.

Supervision

2. (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.

EC DECLARATION OF PRODUCTION CONFORMITY

Article 12

[[F2]The EC declaration of conformity is the procedure whereby the manufacturer or his authorized representative established within the Community:**]**

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 **[**[F2]CE marking**]**of conformity provided for by Article 13 to each PPE.

Textual Amendments

F2 Substituted by Council Directive 93/68/EEC of 22 July 1993 amending Directives 87/404/EEC (simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC (personal protective equipment), 90/384/EEC (non-automatic weighing instruments), 90/385/EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits).