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 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 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 nonprotective 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.
- 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.
- 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.

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

- [F1] Member States may not prohibit, restrict or hinder the placing on the market of PPE or PPE components which comply with the provisions of this Directive and which bear the CE marking attesting their conformity to all the provisions of this Directive, including the certification procedures in Chapter II.]
- 2 Member States shall not prohibit, restrict or impede the placing on the market of PPE components which do not bear the [FICE marking, and which are intended to be incorporated in PPE, provided that they are not essential to its satisfactory functioning.

Textual Amendments

F1 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).

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 CE marking with respect to which the manufacturer is able to produce, on demand, the declaration of conformity referred to in Article 12.
- 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 CE marking with respect to which the manufacturer is 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).

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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.

[F36

- a Where the PPE is subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the PPE is also presumed to conform to the provisions of the other Directives.
- However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying such PPE.]

Textual Amendments

- 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).
- **F2** 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).
- F3 Inserted 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).

Article 6

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[F52] The Commission shall be assisted by the Standing Committee, set up by Article 6(2) of Directive 98/37/EC⁽¹⁾, hereinafter referred to as 'the Committee'.

It may be apprised, in accordance with the procedure referred to in this paragraph, of any matter to which the implementation and practical application of this Directive give rise.

Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC⁽²⁾ shall apply, having regard to the provisions of Article 8 thereof.

The Committee shall adopt its rules of procedure.

Textual Amendments

- F4 Deleted by Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (Text with EEA relevance).
- F5 Substituted by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty.

Article 7

If a Member State discovers that PPE bearing the CE markingand 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 shortcoming in the standards referred to in Article 5.
- 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 CE marking], 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.

Textual Amendments

F1 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

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 $terminal\ equipment),\ 92/42/EEC\ (new\ hot-water\ boilers\ fired\ with\ liquid\ or\ gaseous\ fuels)\ and\ 73/23/eq.$ EEC (electrical equipment designed for use within certain voltage limits).

- (1) [F5OJ L 207, 23.7.1998, p. 1. Directive as amended by Directive 98/79/EC (OJ L 331, 7.12.1998, p. 1).]
- (2) [F5Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).]

Textual Amendments

F5 Substituted by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty.