SCHEDULE

COUNCIL 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;
- (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 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(1), 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(**2**) 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 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.

⁽¹⁾ OJ No.L109, 26.4.1983, p.8.

⁽²⁾ OJ No.L183, 29.6.1989, p.9.