SCHEDULE 8

ARTICLE 11 OF THE PPE DIRECTIVE

CHECKING OF PPE MANUFACTURED

"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.

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 harmonised 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.

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,

— 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 organisation 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 harmonised 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 authorise 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.