SCHEDULE 4

Modules for conformity assessment

PART 1

General

CHAPTER 1

Miscellaneous

1. A notified body referred to in this Schedule means a notified body appointed by agreement between that body and one or more of the following—

(a) the manufacturer of a listed product;

(b) an authorised representative;

(c) an importer of a listed product.

2. In the remaining provisions of this Schedule, references to a manufacturer include—

(a) an authorised representative; or

(b) an importer of a listed product,

where such person undertakes some or all of a conformity assessment procedure.

3. "Equivalent standards" means standards equivalent to the harmonised standards, including national standards notified by the Commission pursuant to Article 5 of Annex II.B to the Council Resolution of 7 May 1985(**1**).

4. A notified body must carry out tests or examinations—

(a) at such place as the manufacturer and notified body agree; and

(b) so far as appropriate, in accordance with—

(i) the harmonised standards; or

(ii) equivalent standards.

5. A notified body must, under module B—

(a) determine the elements of the listed product, or the design for such a product, which have been made or designed in accordance with a harmonised standard or equivalent standard; and

(b) in respect of elements not made or designed in accordance with a harmonised standard or equivalent standard, determine how those elements conform to the product requirements.

6. A notified body must ensure that—

(a) in module D, at least one member of the team which carries out the determination of the application has experience of the product technology in question;

(b) in module E, at least one member of the team which carries out the determination of the application has experience as an assessor in the product technology in question; and

(c) in modules D and E, it makes at least one inspection visit to the premises of the manufacturer.

(**1**) O.J. No. C136, 4.6.1985, p. 1.

7. Expressions used in this Schedule which are used in Council Decision 93/465/EEC concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives(**2**), have the same meaning as they do in that Decision.

CHAPTER 2

General technical documentation

8. The general technical documentation means the documentation necessary to enable an assessment of the conformity of a listed product to the product requirements, including as appropriate documentation concerning—

(a) the design, manufacture and operation of the product;

(b) the harmonised standards or equivalent standards applied, or to be applied, to the product.

9. The provision of the documentation under paragraph 8 may be satisfied by the supply of equivalent documentation required under Community legislation other than the implementing measure relating to a listed product.

CHAPTER 3

Testing and checking process

10. The testing and checking process means the notified body carries out product checks—

(a) at random intervals; and

(b) on an adequate sample taken on site by the notified body.

11. If the testing and checking process demonstrates that a listed product conforms to the product requirements, the notified body must permit the manufacturer to affix the identification number or symbol of the notified body to the listed product during the manufacturing process.

CHAPTER 4

Notified bodies and non-conformity

12. Where a notified body determines that a listed product does not conform, or will not conform, to the product requirements, it must, subject to paragraph 13, request the manufacturer to provide such further information or to take such additional steps that it believes are necessary to demonstrate conformity.

13. If—

(a) no such further information or steps are possible; or

(b) such information or steps do not demonstrate conformity,

the notified body must give the manufacturer a non-conformity notice.

14. "A non-conformity notice" means a written notice that—

(a) states that the notified body is not satisfied that a listed product conforms, or will conform, to the product requirements; and

(b) gives details of the non-conformity.

15. Where a notified body has given a non-conformity notice and prior to that notice has given to the manufacturer —

(a) an EC type-examination certificate or an EC design examination certificate; or

(b) an approval to a quality assurance procedure under modules D or E,

(**2**) O.J. No. L220, 30.8.1993, p. 23.

the notified body must state in the non-conformity notice if, and the extent to which, the giving of the notice withdraws a certificate or approval, including any additions or modifications to a certificate or approval.