

SCHEDULE 2

Regulation 11(1)

PROCEDURE WHERE THE MINISTERS PROPOSE TO TAKE CERTAIN ACTION ON GROUNDS RELATING TO SAFETY OR QUALITY

1. Subject to paragraph 8(1), where the Ministers propose to act in a manner specified in regulation 11(1) (in this Schedule called “the proposed regulation 11(1) action”), the Ministers shall not act in that manner except after consultation with the Board.

2. Where the Board is consulted pursuant to paragraph 1, the Board shall report to the Ministers their advice, and the reasons for their advice.

3. After the Board has reported to the Ministers pursuant to paragraph 2, the Ministers, taking account of that report, may—

- (a) finally determine not to take the proposed regulation 11(1) action, or
- (b) provisionally determine to take that action.

4. Where the Ministers provisionally determine to take the proposed regulation 11(1) action, they shall not act in that manner except after consultation with the Commission.

5.—(1) Where the Commission is consulted pursuant to paragraph 4, and they have reason to think that—

- (a) on an Article 11 ground that concerns the safety or quality of the product, they may have to advise the Ministers that the registration of the product should be refused, or that it should not be registered unless the registration is made subject to certain specific obligations;
- (b) on an Article 11 ground that concerns the safety or quality of the product, they may have to advise the Ministers that registration of the product should not be renewed, or that it should not be renewed unless the renewed registration is made subject to certain specific obligations;
- (c) on a ground specified in Article 36 of Directive 81/851 that concerns the safety or quality of the product, they may have to advise the Ministers that the registration of the product ought to be suspended or revoked; or
- (d) on a ground specified in Article 37.1 of Directive 81/851 that concerns the safety or quality of the product, they may have to advise the Ministers that a notice should be served under regulation 10(1),

the Commission, before giving that advice to the Ministers, shall serve a notice complying with the provisions of sub-paragraph (2) on the applicant, or the person responsible for marketing, as the case may be.

(2) Any notice served under sub-paragraph (1) shall—

- (a) notify the person on whom it is served of the advice that the Commission is minded to give to the Ministers,
- (b) state the reasons why the Commission is minded to give that advice, and
- (c) specify that, on or before the response date specified in the notice, the person on whom the notice is served may make written representations to the Commission with respect to the advice or reasons.

6. Where the Commission is consulted pursuant to paragraph 4, the Commission shall report to the Ministers their findings and advice, and the reasons for their advice, and, in a case where a notice has been served under paragraph 5(1), they shall make that report after considering any written representation made to them on or before the response date specified in that notice.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

7. After the Commission has reported to the Ministers pursuant to paragraph 6, the Ministers shall take that report into account in finally determining whether to take the proposed regulation 11(1) action.

8.—(1) The provisions of paragraph 1 shall not apply where the Ministers consider that it is necessary to take action of the type specified in regulation 11(1)(c) or (d) urgently in order to protect human or animal health or the environment.

(2) Where urgent action is taken by the Ministers, they shall—

- (a) consult the Board within three months of taking the action, and
- (b) comply with such of the provisions of this Schedule as are applicable in the circumstances to that action.