STATUTORY INSTRUMENTS

2001 No. 880

The Biocidal Products Regulations 2001

PART II

ACTIVE SUBSTANCES

Placing on the market of active substances

4.—(1) Subject to paragraph (2), no person shall place on the market for use in a biocidal product a new active substance unless—

(a) an application has been made to the Ministers or to a competent authority for the inclusion of that new active substance in Annex I, IA or IB; and

(b) the Ministers or that competent authority have agreed to the applicant forwarding a summary of the dossiers submitted in support of the application to the Commission and the member States.

(2) Paragraph (1) shall not apply to a new active substance intended for use in a biocidal product where that new active substance is placed on the market for use in an experiment or test for the purposes of—

(a) scientific research and development; or

(b) process orientated research and development.

(3) No person shall place on the market an active substance intended exclusively for use in a biocidal product for the purpose of any experiment or test in Great Britain which may involve or result in the release into the environment of that active substance unless that active substance has been authorised in accordance with regulation 17.

Applications concerning new active substances

5. A person who applies to the Ministers for the inclusion of a new active substance in Annex I, IA or IB shall submit to the Ministers—

(a) a dossier relating to the new active substance satisfying the requirements of—

(i) Annex IVA, where the new active substance in question is a micro-organism, or

(ii) Annexes IIA and IIIA, where the new active substance in question is not a micro-oganism;

(b) a dossier satisfying the requirements of regulation 9(4) to (6) for at least one biocidal product containing the new active substance; and

(c) a declaration that the new active substance is intended for inclusion in a biocidal product.

Assessment of applications concerning new active substances

6.—(1) When the Ministers receive an application under regulation 5, they shall ensure that the dossiers submitted as part of that application satisfy the requirements of that regulation and, where those dossiers do so, the Ministers shall—

(a) accept the dossiers; and

(b) agree to the applicant forwarding a summary of the dossiers to the Commission and the member States.

(2) Subject to paragraph (5) and subject to regulation 39(2), within the period of 12 months of the Ministers accepting the dossiers in accordance with paragraph (1)(a), the Ministers shall—

(a) evaluate the dossiers submitted in accordance with regulation 5;

(b) make a recommendation as to whether the new active substance in question should, or should not, be included in Annex I, IA or IB; and

(c) send a copy of their evaluation and recommendation to the Commission, the member States and the applicant.

(3) Where necessary for the purpose of carrying out an evaluation required by paragraph (2)(a), the Ministers shall—

(a) request in writing the applicant to provide such additional information relating to the new active substance as they may specify; and

(b) at the same time inform the Commission and the member States of their request.

(4) Where the Ministers request additional information under paragraph (3), the period of time between the date when the Ministers request the information and the date when the applicant responds to their satisfaction shall not be taken into account in calculating the period of 12 months referred to in paragraph (2).

(5) After the Ministers have accepted the dossiers in accordance with paragraph (1)(a), they may make a request to the Commission for the evaluation of the dossiers to be carried out by a competent authority, and, in such a case—

(a) the Ministers shall not be under a duty to evalute those dossiers, unless and until there is a Commission decision to refuse their request; and

(b) where there is such a Commission decision to refuse, the Ministers shall evaluate the dossiers within the period of 12 months of the date of that Commission decision.

(6) Where there is a Commission decision that the Ministers shall evaluate the dossiers submitted to a competent authority in support of an application for the inclusion of a new active substance in Annex I, IA or IB, subject to regulation 39(2), within the period of 12 months of receiving the dossiers, the Ministers shall—

(a) evaluate the dossiers;

(b) make a recommendation as to whether the new active substance should, or should not, be included in Annex I, IA or IB; and

(c) send a copy of their evaluation and recommendation to the Commission, the member States and the applicant.

(7) Paragraphs (3) and (4) shall apply where the Ministers evaluate dossiers under paragraph (6)(a) as if the dossiers had been submitted under regulation 5.

Applications for variation or renewal of the inclusion of active substances in Annex I, IA or IB

7.—(1) A person may apply to the Ministers for a variation of the requirements subject to which an active substance was included in Annex I, IA or IB.

(2) Before the expiry of the initial period, or any renewed period, as the case may be, of the inclusion of an active substance in Annex I, IA or IB, a person may apply to the Ministers for the renewal of the inclusion of that active substance in Annex I, IA or IB for a period not exceeding 10 years.

(3) A person who applies to the Ministers under paragraph (1) or (2) shall submit dossiers in accordance with regulation 5.

(4) Regulation 6(1) to (5) shall apply to an application made under paragraph (1) or (2) as it applies to an application made under regulation 5, save that—

(a) in the case of an application made under paragraph (1), the recommendation to be made under regulation 6(2)(b) shall be as to whether the variation should, or should not, be made; and

(b) in the case of an application made under paragraph (2), the recommendation to be made under regulation 6(2)(b) shall be as to whether the inclusion of the active substance in Annex I, IA or IB should, or should not, be renewed.

(5) Where there is a Commission decision that the Ministers shall evaluate the dossiers submitted to a competent authority in support of an application for—

(a) a variation of the requirements subject to which an active substance was included in Annex I, IA or IB; or

(b) the renewal of the inclusion of an active substance in Annex I, IA or IB,

subject to regulation 39(2), within the period of 12 months of receiving the dossiers, the Ministers shall comply with the requirements specified in paragraph (6).

(6) The requirements referred to in paragraph (5) are that the Ministers shall—

(a) evaluate the dossiers;

(b) make a recommendation as to whether—

(i) the variation should, or should not, be made, or

(ii) the new active substance should, or should not, continue to be included in Annex I, IA or IB,

as the case may be; and

(c) send a copy of their evaluation and recommendation to the Commission, the member States and the applicant.

(7) Regulation 6(3) and (4) shall apply where the Ministers evaluate dossiers under paragraph (6)(a) as if the dossiers had been submitted under regulation 5.