STATUTORY INSTRUMENTS

2001 No. 880

The Biocidal Products Regulations 2001

PART VI

MISCELLANEOUS AND GENERAL

General provisions on applications for authorisations and registrations

34.—(1) An application for—

(a) an authorisation of a biocidal product under regulation 9, 11, 13, 15 or 17; and

(b) a registration of a biocidal product under regulation 10, 12, or 14,

shall be made to the Ministers by, or on behalf of, the person responsible for first placing the biocidal product in question on the market in Great Britain.

(2) An application referred to in paragraph (1), and information submitted in support of such an application, shall be in English.

(3) An applicant shall have a permanent office within the Community.

(4) When requested to do so by the Ministers, an applicant shall submit to them samples of—

(a) the biocidal product in question; and

(b) its ingredients.

(5) The Ministers shall communicate their decision in respect of an application referred to in paragraph (1) to the applicant.

(6) Every authorisation and every registration granted under these Regulations shall be in writing.

(7) In this regulation, "applicant" means an applicant for—

(a) an authorisation of a biocidal product under regulation 9, 11, 13, 15 or 17; or

(b) a registration of a biocidal product under regulation 10, 12 or 14.

Files on applications

35.—(1) The Ministers shall ensure that a file is compiled in respect of each application made under regulations 9 to 15 and 17.

(2) A file referred to in paragraph (1) shall include—

(a) a copy of the application to which it relates;

(b) a record of the decision relating to the application taken by the Ministers;

(c) a record of the decision concerning the dossiers submitted in support of that application taken by the Ministers; and

(d) a summary of those dossiers.

(3) The Ministers shall, on request, make available to the competent authorities and the Commission—

(a) a copy of a file compiled in accordance with paragraph (1); and

(b) all information necessary for the full comprehension of the application to which the file relates.

(4) When requested to do so by a competent authority or the Commission, the Ministers shall require an applicant under regulations 9 to 15 and 17, to forward copies of the dossiers submitted in support of his application to that competent authority or to the Commission, as the case may be, and the applicant shall comply with that requirement.

Appeals

36.—(1) Subject to paragraph (3), a person may appeal to the appropriate person if that person is aggrieved by a decision of the Ministers—

(a) not to grant his application for—

(i) the authorisation, or the renewal of an authorisation, of a biocidal product under regulation 9 or 13,

(ii) the authorisation of a biocidal product under regulation 17, or

(iii) the registration, or the renewal of a registration, of a biocidal product under regulation 10 or 14;

(b) to impose a condition or restriction when granting his application for—

(i) an authorisation of a biocidal product under regulation 9, 13 or 17, or

(ii) a registration of a biocidal product under regulation 10 or 14;

(c) made pursuant to regulation 16(6), to prohibit him from conducting an experiment or test or to impose conditions regarding the conduct by him of an experiment or test;

(d) made pursuant to regulation 20(1), to modify a condition of use subject to which an authorisation or registration has been granted to him under regulations 9 to 15 or 17;

(e) not to modify a condition of use, subject to which an authorisation or registration has been granted to him under regulations 9 to 15 or 17, when requested by him to do so under regulation 20(2);

(f) made pursuant to regulation 19, other than paragraph (12) of that regulation, to revoke an authorisation or a registration granted to him under regulations 9 to 15 or 17;

(g) not to revoke an authorisation or registration granted to him under regulations 9 to 15 or 17, when requested by him to do so under regulation 19(12);

(h) not to issue a frame-formulation, when requested by him to do so under regulation 18(1)(a);

(i) made pursuant to regulation 25, not to give their consent to him referring to information; or

(j) made pursuant to regulation 26(2)(b), not to keep confidential information submitted by him to the Ministers.

(2) A person may appeal to the appropriate person if that person is aggrieved by a decision of the Ministers—

(a) not to grant him a period of time longer than 3 months in which to make an application under regulation 9, 10, 11 or 12 pursuant to paragraphs 5 or 8 of Schedule 13;

(b) not to grant him a certificate of exemption;

(c) to impose a condition when granting him a certificate of exemption;

(d) to revoke a certificate of exemption granted to him;

(e) relating to the period of time for which a certificate of exemption is granted to him,

and in this paragraph, "certificate of exemption" means a certificate of exemption referred to in Schedule 13.

(3) Paragraph (1) shall not apply where the decision of the Ministers in question is made to give effect to a Commission decision.

(4) The provisions of Schedule 10 shall apply where an aggrieved person appeals to the appropriate person.

(5) Where an appeal is brought under paragraphs (1)(d), (1)(f) or (2)(d), the decision in question shall be suspended pending the final determination of the appeal.

(6) Where an appeal is brought under paragraph (1)(j), pending final determination of the appeal, the Ministers shall not disclose the information except—

(a) to the Commission or a competent authority; and

(b) to the extent necessary to enable the Ministers to deal with the application in question made under these Regulations.

(7) A person who receives information by virtue of paragraph (6)(b) shall not use that information except for the purposes of the Ministers.

8) In this regulation, "the appropriate person" means—

(a) in the case of a decision of the Secretary of State and the Minister of Agriculture, Fisheries and Food, acting jointly, the Secretary of State; and

(b) in the case of a decision of the Ministers in or as regards Scotland, the Secretary of State and the Scottish Ministers, acting jointly.

Tests

37. Every test carried out in support of an application under regulations 9 to 15 and 17 shall be conducted in accordance with such guidance as may be issued by the Ministers.

Enforcement, offences and civil liability

38. Schedule 11 shall have effect.

Fees

39.—(1) Schedule 12 shall have effect.

(2) The period of time within which the Ministers must—

(a) comply with the provisions of regulation 6(2) when dealing with an application under regulation 5, 7(1) or 7(2);

(b) make a decision relating to an application submitted under regulations 9 to 14 or 17; or

(c) comply with the provisions of regulation 6(6) or 7(5),

shall not begin until there have been paid all fees payable under these Regulations in respect of the application or evaluation in question, other than those fees payable in accordance with paragraph 10 of Schedule 12.

(3) The Ministers shall not be bound to consider a request made under regulation 20(2) until there have been paid the fee or fees payable under paragraph 6 of Schedule 12, other than those payable in accordance with paragraph 10 of that Schedule.

Transitional provisions

40. Schedule 13 shall have effect.

Extension outside Great Britain

41. These Regulations shall apply outside Great Britain as sections 1 to 59 and 80 to 82 of the 1974 Act apply by virtue of the Health and Safety at Work etc. Act 1974 (Application Outside Great Britain) Order 1995(**1**).

Amendments

42.—(1) At the end of regulation 3(2) of the Control of Pesticides Regulations 1986(**2**) there shall be added the following sub-paragraph—

"(j) any biocidal product—

(i) authorised or registered under the 2001 Regulations,

(ii) placed on the market for use in an experiment or test in accordance with regulation 16 of the 2001 Regulations, or

(iii) the placing on the market and use of which are subject to any of the prohibitions specified in regulation 8 of the 2001 Regulations,

and in this sub-paragraph, "the 2001 Regulations" means the Biocidal Products Regulations 2001 and "biocidal product" shall have the meaning assigned to it in regulation 2(1) of the 2001 Regulations."

(2) In regulation 5(6) of the 1994 Regulations, after the words "the Food and Environment Protection Act 1985", there shall be inserted the words "or a biocidal product which has been authorised or registered under the Biocidal Products Regulations 2001".

(**1**) S.I.1995/263.
(**2**) S.I. 1986/1510, amended by S.I. 1997/188.