STATUTORY RULES OF NORTHERN IRELAND

2001 No. 422

Biocidal Products Regulations (Northern Ireland) 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 Executive by, or on behalf of, the person responsible for first placing the biocidal product in question on the market in Northern Ireland.

(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 Executive, an applicant shall submit to it samples of—

(a) the biocidal product in question; and

(b) its ingredients.

(5) The Executive shall communicate its 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 Executive 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 Executive;

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

(d) a summary of those dossiers.

(3) The Executive 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 Executive 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 Department of Enterprise, Trade and Investment if that person is aggrieved by a decision of the Executive—

(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 regulation 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 its consent to him referring to information;

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

(2) A person may appeal to the Department of Enterprise, Trade and Investment if that person is aggrieved by a decision of the Executive—

(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 12;

(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 12.

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

(4) Chapter I of the Schedule to the Deregulation (Model Appeal Provisions) Order (Northern Ireland) 1997(**1**) shall apply where an aggrieved person appeals to the Department of Enterprise, Trade and Investment.

(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 Executive shall not disclose the information except—

(a) to a Government Department, the Great Britain Executive, the Commission or to a competent authority; and

(b) to the extent necessary to enable the Executive 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 Executive.

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 Executive.

Enforcement, offences and civil liability

38. Schedule 10 shall have effect.

Fees

39.—(1) Schedule 11 shall have effect.

(2) The period of time within which the Executive 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 11.

(3) The Executive 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 11, other than those payable in accordance with paragraph 10 of that Schedule.

Transitional provisions

40. Schedule 12 shall have effect.

(**1**) S.R. 1997 No. 269

Application within territorial waters

41. Within territorial waters these Regulations shall apply only to and in relation to the premises and activities mentioned in paragraphs 2 to 6 of Schedule 13.

Amendments

42.—(1) At the end of regulation 3(2) of the Control of Pesticides Regulations (Northern Ireland) 1987 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 (Northern Ireland) 2001, and "biocidal product" shall have the meaning assigned to it in regulation 2(1) of the 2001 Regulations.".

(2) For sub-paragraph (*d*) of regulation 3(2) of the Notification of New Substances Regulations (Northern Ireland) 1994(**2**) there shall be substituted the following sub-paragraph—

"(d) a new substance which is placed on the market exclusively for use as an active substance in one or more of the following, namely—

(i) a biocidal product to which the Biocidal Products Regulations (Northern Ireland) 2001 apply,

(ii) a biocidal product to which the Biocidal Products Regulations (Northern Ireland) 2001 would have applied but for regulation 3(2) of those Regulations,

(iii) a plant protection product to which the Plant Protection Products Regulations (Northern Ireland) 1995(**3**) apply, or

(iv) a pesticide to which the Control of Pesticides Regulations (Northern Ireland) 1987 apply."(**4**).

(3) In regulation 5(6) of the 1995 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 (Northern Ireland) 2001.".

(**2**) S.R. 1994 No. 6, to which there are amendments not relevant to these Regulations
(**3**) S.R. 1995 No. 371, as amended by S.R. 1996 No. 456, S.R. 1997 No. 471, S.R. 1997 No. 507, S.R. 1999 No. 57 and S.R. 1999 No. 282
(**4**) S.R. 1987 No. 414, as amended by S.R. 1991 No. 203 and S.R. 1997 No. 469