STATUTORY RULES OF NORTHERN IRELAND

2001 No. 422

Biocidal Products Regulations (Northern Ireland) 2001

Part III

Biocidal Products

Revocation of authorisations and registrations

- 19.—(1) The Executive shall revoke an authorisation granted under regulation 9 or 11 where—
 - (a) an active substance in the biocidal product to which the authorisation relates—
 - (i) is removed from Annex I, or
 - (ii) is removed from Annex IA and that active substance is not included in Annex I; or
 - (b) a requirement laid down in Annex I or Annex IA in respect of an active substance in the biocidal product to which the authorisation relates is no longer satisfied.
- (2) The Executive shall revoke an authorisation—
 - (a) granted under regulation 9, 11 or 13, where the biocidal product, the subject of the authorisation, no longer satisfies one or more of the requirements referred to in paragraphs 1(a)–(d) and 4(b) of Schedule 3;
 - (b) granted under regulation 9, 11, 13, 15 or 17, where false or misleading information was supplied concerning the facts on the basis of which the authorisation was granted.
- (3) The Executive shall revoke an authorisation of a biocidal product for use by the public, or for placing on the market for use by the public, where that biocidal product is classified as—
 - (a) toxic;
 - (b) very toxic;
 - (c) carcinogenic category 1;
 - (d) carcinogenic category 2;
 - (e) mutagenic category 1;
 - (f) mutagenic category 2;
 - (g) toxic for reproduction category 1; or
 - (h) toxic for reproduction category 2.
 - (4) The Executive shall revoke a registration granted under regulation 10 or 12 where—
 - (a) an active substance in the low-risk biocidal product to which the registration relates is removed from Annex IA; or
 - (b) a requirement laid down in Annex IA in respect of an active substance in the low-risk biocidal product to which the registration relates is no longer satisfied.
 - (5) The Executive shall revoke a registration granted under regulation 10 if—
 - (a) there is a Commission decision referred to in regulation 20(4); and

- (b) following a review of the registration in accordance with regulation 20(4), the Executive decides that the biocidal product in question is not a low-risk biocidal product.
- (6) The Executive shall revoke a registration granted under regulation 10, 12 or 14 where—
 - (a) the biocidal product, the subject of the registration, no longer satisfies one or more of the requirements referred to in paragraphs 1(a)–(d) and 4(b) of Schedule 3;
 - (b) false or misleading information was supplied concerning the facts on the basis of which the registration was granted.
- (7) The Executive shall revoke a registration of a biocidal product for use by the public or for placing on the market for use by the public, where that low-risk biocidal product is classified as toxic or very toxic.
- (8) The Executive shall revoke an authorisation granted under regulation 13 where there is a Commission decision that an active substance in the biocidal product to which the authorisation relates shall not be included in Annex I, and no decision is made to include that active substance in Annex IA.
- (9) The Executive shall revoke a registration granted under regulation 14 where there is a Commission decision that an active substance in the biocidal product to which the registration relates shall not be included in Annex IA.
- (10) The Executive shall revoke an authorisation granted under regulation 15 where a Commission decision does not uphold it.
- (11) The Executive may revoke an authorisation granted under regulation 17 if the experiment or test in question is liable to have harmful effects on human or animal health or an unacceptable adverse effect on the environment.
- (12) The Executive may revoke an authorisation or registration granted under these Regulations at the written request of the holder, who shall state the reasons for that request.
- (13) Before revoking an authorisation or a registration, except following a request made in accordance with paragraph (12), the Executive shall—
 - (a) give to the holder a notice in writing stating that—
 - (i) it is considering revoking that authorisation or registration and the reasons why, and
 - (ii) within a period specified in the notice, the holder may make written representations to the Executive or, if the holder so requests, may make oral representations to the Executive; and
 - (b) consider any representations which are duly made and not withdrawn.
- (14) Before refusing to revoke an authorisation or a registration following a request made in accordance with paragraph (12), the Executive shall—
 - (a) give to the holder a notice in writing stating that—
 - (i) it is considering not revoking that authorisation or that registration and the reasons why, and
 - (ii) within a period specified in the notice, the holder may make written representations to the Executive or, if the holder so requests, may make oral representations to the Executive; and
 - (b) consider any representations which are duly made and not withdrawn.
 - (15) When the Executive revokes—
 - (a) an authorisation or a registration granted under these Regulations in respect of a biocidal product; or

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(b) an authorisation granted under regulation 17 in respect of an active substance intended exclusively for use in a biocidal product,

it may grant a period of grace for the disposal, storage, placing on the market or use of existing stocks of the biocidal product to which the authorisation or the registration relates, or the active substance to which the authorisation relates, as the case may be.

- (16) The period of grace referred to in paragraph (15) shall be of a length commensurate with the reason for the revocation, but shall be without prejudice to any period provided for in connection with the removal from Annex I or Annex IA of an active substance in the biocidal product in question or the active substance in question, as the case may be.
- (17) In this regulation, "holder" means a person to whom an authorisation or a registration has been granted in accordance with these Regulations.