STATUTORY RULES OF NORTHERN IRELAND

2001 No. 422

Biocidal Products Regulations (Northern Ireland) 2001

Part IV

Use of Information

Data protection for biocidal products

24.—(1) Subject to the following paragraphs, the Executive shall not make use of relevant information relating to a biocidal product for the benefit of a person making an application under these Regulations other than—

(a) the person who submitted; or

(b) the person on whose behalf was submitted,

that relevant information.

(2) The Executive may make use of relevant information relating to a biocidal product for the benefit of a person making an application under these Regulations who has a letter of access to that relevant information.

(3) In the case of relevant information relating to a biocidal product containing a new active substance which was submitted other than for a purpose referred to in paragraph (4), paragraph (1) shall not apply after the expiry of the period of 10 years from the date on which that biocidal product was first authorised or registered, as the case may be, under these Regulations.

(4) In the case of relevant information relating to a biocidal product containing a new active substance which was submitted for the first time in connection with a modification under regulation 20 of a condition of use subject to which was granted the authorisation or registration, as the case may be, relating to that biocidal product, or for the first time in connection with an application under regulation 7 to renew the inclusion of that new active substance in Annex I or Annex IA, paragraph (1) shall not apply after either—

(a) the expiry of the period of 5 years from the date on which the Executive first received that relevant information, or

(b) the expiry of the period of 10 years from the date on which that biocidal product was first authorised or registered, as the case may be, under the Regulations,

whichever is the later.

(5) In the case of relevant information relating to a biocidal product containing an existing active substance which was also submitted in support of an application for an approval (except an approval in the form of an experimental permit) under the 1987 Regulations, paragraph (1) shall not apply after either—

(a) the expiry of the period of 10 years from the date on which the approval was first given on the basis of that relevant information; or

(b) 14th May 2010,

whichever is the sooner.

(6) Subject to paragraph (10), in the case of relevant information relating to a biocidal product containing an existing active substance which was also submitted in support of an application for approval in the form of an experimental permit under the 1987 Regulations, paragraph (1) shall not apply after 14th May 2010.

(7) In the case of relevant information relating to a biocidal product containing an existing active substance which was not submitted under the 1987 Regulations as described in paragraphs (5) or (6) but which was submitted for the first time in support of an application for the first inclusion in Annex I or Annex IA of that existing active substance or of an additional product-type for that existing active substance, paragraph (1) shall not apply after the expiry of the period of 10 years from the date on which that existing active substance, or additional product-type for that existing substance, as the case may be, was first included in either Annex I or Annex IA.

(8) In the case of relevant information relating to a biocidal product containing an existing active substance which—

(a) was not submitted under the 1987 Regulations as described in paragraphs (5) or (6); nor

(b) submitted for the first time in support of an application for the first inclusion in Annex I or Annex IA of that existing active substance or of an additional product-type for that existing active substance,

but which was submitted in support of an application for the grant of an authorisation or a registration under these Regulations, paragraph (1) shall not apply after 14th May 2010.

(9) In the case of relevant information relating to a biocidal product containing an existing active substance which was not submitted under the 1987 Regulations as described in paragraphs (5) or (6), but which was submitted for the first time in connection with a modification under regulation 20 of a condition of use subject to which was granted the authorisation or registration, as the case may be, relating to that biocidal product, or for the first time in connection with an application under regulation 7 to renew the inclusion of that existing active substance in Annex I or Annex IA, paragraph (1) shall not apply after either—

(a) the expiry of the period of 5 years from the date on which the Executive first received that relevant information; or

(b) after the expiry of the period of 10 years from the date on which that existing active substance was first included in either Annex I or Annex IA,

whichever is the later.

(10) Paragraph (6) shall not apply where the relevant information submitted in support of an application referred to in that paragraph was also submitted in support of an application referred to in paragraph (5).

(11) In this regulation, "the 1987 Regulations" and "relevant information" have the same meaning as they have in regulation 23.