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STATUTORY INSTRUMENTS

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**2001 No. 880**

**The Biocidal Products Regulations 2001**

**PART IV**

**USE OF INFORMATION**

**Data protection for active substances**

**23.**—(1) Subject to the following paragraphs of this regulation, the Ministers shall not make use of relevant information relating to an active substance 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 Ministers may make use of relevant information relating to an active substance 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 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 15 years from the date on which that new active substance was first included in either Annex I or Annex IA.

(4) In the case of relevant information relating to a new active substance which was submitted for the first time for the purpose of an application under regulation 7 to renew the inclusion of that new active substance in Annex I or Annex IA or to vary the requirements subject to which the new active substance was included 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 of the decision relating to the application under regulation 7; or
- (b) the expiry of the period of 15 years from the date on which that new active substance was first included in either Annex I or Annex IA,

whichever is the later.

(5) In the case of relevant information relating to 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 1986 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 an existing active substance which was also submitted in response to a requirement imposed under section 16(11) of the 1985 Act to supply information relating to the review, revocation or suspension of, or the

amendment of the conditions of, an approval given under the 1986 Regulations (except an approval in the form of an experimental permit), paragraph (1) shall not apply after either—

- (a) the expiry of the period of 5 years from the date of the decision to continue, revoke or suspend, or amend the conditions of, the approval in question; or
- (b) 14th May 2010,

whichever is the sooner.

(7) Subject to paragraph (11), in the case of relevant information relating to an existing active substance which was also submitted in support of an application for approval in the form of an experimental permit under the 1986 Regulations, paragraph (1) shall not apply after 14th May 2010.

(8) In the case of relevant information relating to an existing active substance which was not submitted in the specified circumstances 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.

(9) In the case of relevant information relating to an existing active substance which was not submitted in the specified circumstances but which was submitted for the first time for the purpose of an application under regulation 7 to renew the inclusion of that existing active substance in Annex I or Annex IA, or to vary the requirements subject to which the existing active substance was included 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 of the decision relating to the application under regulation 7; or
- (b) 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 response to a requirement imposed under section 16(11) of the 1985 Act is also submitted in support of an application referred to in paragraph (5).

(11) Paragraph (7) shall not apply where the relevant information submitted in support of an application referred to in that paragraph is also submitted in support of an application referred to in paragraph (5).

(12) In this regulation—

- (a) “the 1985 Act” means the Food and Environment Protection Act 1985(1);
- (b) “the 1986 Regulations” means the Control of Pesticides Regulations 1986(2);
- (c) “submitted in the specified circumstances” means—
  - (i) submitted under the 1986 Regulations, as described in paragraphs (5) or (7), or
  - (ii) submitted in response to a requirement imposed under section 16(11) of the 1985 Act, as described in paragraph (6); and
- (d) “relevant information” means information submitted to the Ministers under these Regulations.

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(1) 1985 c. 48.

(2) S.I.1986/1510, as amended by S.I. 1997/188.