STATUTORY RULES OF NORTHERN IRELAND

2001 No. 422

Biocidal Products Regulations (Northern Ireland) 2001

Part IV

Use of Information

Data protection for active substances

23.—(1) Subject to the following paragraphs, the Executive 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 Executive 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 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 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 1987 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 1987 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 1987 Regulations" means the Control of Pesticides Regulations (Northern Ireland) 1987(**2**);

(c) "submitted in the specified circumstances" means—

(i) submitted under the 1987 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 Executive under these Regulations.

(**1**) 1985 c. 48, as amended by 1989 c. 27 and 1998 c. 26
(**2**) S.R. 1987 No. 414, as amended by S.R. 1991 No. 203 and S.R. 1997 No. 469

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.

Co-operation in the use of information

25.—(1) Subject to paragraph (2), the Executive may give its consent to a new applicant referring to the information contained in the dossiers included in the application submitted to the Executive in respect of an approved biocidal product.

(2) The Executive shall not give its consent under paragraph (1) unless—

(a) the new applicant can provide evidence to the satisfaction of the Executive that—

(i) the biocidal product to which his application relates is sufficiently similar to, and

(ii) the active substance contained in that biocidal product is the same as that contained in,

the approved biocidal product, including in relation to the degree of purity and the nature of the impurities; and

(b) the information referred to in paragraph (1) is information—

(i) in respect of which the new applicant has a letter of access, or

(ii) which the Executive already holds and, by virtue of regulation 23 or 24, is entitled to use for the benefit of that new applicant.

(3) Notwithstanding the obligations contained in these Regulations to submit dossiers in support of an application for the authorisation of a biocidal product under regulation 9, 11, 13 or 17, or the registration of a biocidal product under regulation 10, 12 or 14, before carrying out an experiment on vertebrate animals, a new applicant shall ask the Executive—

(a) whether an authorisation or registration has been granted under these Regulations in respect of a biocidal product similar to that which the new applicant intends to use in such an experiment (whether or not that authorisation or registration has been revoked); and

(b) for the name and address of the authorisation holder in respect of that biocidal product.

(4) When a new applicant makes an enquiry pursuant to paragraph (2), he shall provide evidence that—

(a) he intends to apply on his own behalf for an authorisation of a biocidal product under regulation 9, 11, 13 or 17 or a registration of a biocidal product under regulation 10, 12 or 14; and

(b) the other information, which he has to provide with such an application in accordance with these Regulations, is available.

(5) If the Executive is satisfied that the new applicant intends to apply for an authorisation or a registration referred to in paragraph (4)(a), it shall provide him with the name and address of the authorisation holder and shall inform the authorisation holder of the name and address of the new applicant.

(6) The authorisation holder and the new applicant shall take all reasonable steps to reach agreement on the sharing of information in order to avoid, if possible, the duplication of testing on vertebrate animals.

(7) The Executive shall encourage the authorisation holder to co-operate in the provision of information, with a view to limiting the duplication of testing on vertebrate animals.

(8) In this regulation—

(a) "approved biocidal product" means a biocidal product which has been authorised under regulation 9, 11 or 13 or registered under regulation 10, 12 or 14;

(b) "authorisation holder" means the person to whom—

(i) an authorisation of a biocidal product has been granted under regulation 9, 11, 13 or 17, or

(ii) a registration of a biocidal product has been granted under regulation 10, 12 or 14,

as the case may be;

(c) "dossier" includes a summary of a dossier;

(d) "new applicant" means a person who intends to apply for an authorisation or registration of a biocidal product under these Regulations.

Confidentiality

26.—(1) Information provided to the Executive under these Regulations shall not be treated as relevant information for the purposes of Article 30 of the 1978 Order.

(2) Subject to the following paragraphs, where a person indicates to the Executive in writing that information provided by him to it under these Regulations should be kept confidential because the disclosure of that information might harm his industrial and commercial position—

(a) he shall provide to the Executive full written justification for that indication; and

(b) the Executive shall decide which information shall be kept confidential on the basis of that justification.

(3) Information which a person has indicated should be kept confidential and in relation to which the Executive has not made a decision under paragraph (2)(*b*) shall not be disclosed except—

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

(b) where the information is provided in support of an application made under these Regulations, to the extent necessary to enable the Executive to deal with the application in question.

(4) Where the Executive has made a decision under paragraph (2)(*b*) that certain information shall not be kept confidential, that information shall not be disclosed until there has elapsed a period of 14 days following the day on which the Executive informed the person providing the information of its decision except—

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

(b) where the information is provided in support of an application made under these Regulations, to the extent necessary to enable the Executive to deal with the application in question.

(5) A person who receives information by virtue of paragraph (3)(*b*), (4)(*b*) or (11)(*b*) shall not use that information except for the purposes of the Executive.

(6) After a biocidal product has been authorised or registered under these Regulations, the Executive shall not keep the information specified in Schedule 6 relating to that biocidal product confidential.

(7) If—

(a) the applicant for the authorisation or registration of a biocidal product; or

(b) the manufacturer or the importer of that biocidal product or an active substance contained in that biocidal product,

discloses any information relating to that biocidal product or that active substance which the Executive has decided under paragraph (2)(*b*) shall be kept confidential, that applicant shall inform the Executive accordingly, and such information shall no longer be treated as being confidential for the purposes of these Regulations.

(8) Subject to paragraph (9), where, pursuant to paragraph (2), a person has indicated that he has provided confidential information, he shall forthwith inform the Executive in writing of any change in circumstances which may affect the justification given by him under paragraph (2)(*a*).

(9) Paragraph (8) shall not apply if the Executive has informed the person in question that the information he has provided shall not be kept confidential.

(10) Where—

(a) the Executive has decided to keep information confidential pursuant to paragraph (2)(*b*); and

(b) a person has informed it of a change in circumstances pursuant to paragraph (8),

after consulting that person as appropriate, the Executive shall review whether the information in question should continue to be kept confidential and shall inform that person of the result of that review.

(11) If, following a review referred to in paragraph (10), the Executive decides that the information in question shall not be kept confidential, that information shall not be disclosed until there has elapsed a period of 14 days following the day on which the Executive informed the person providing the information of its decision except—

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

(b) where—

(i) the information is provided in support of an application made under these Regulations, and

(ii) the Executive has not finally disposed of that application,

to the extent necessary to enable the Executive to deal with the application.

(12) This regulation is without prejudice to the provisions of the Environmental Information Regulations (Northern Ireland) 1993(**3**).

Treatment of confidential information

27.—(1) The Executive shall inform the competent authorities and the Commission of the information it has decided shall be kept confidential in accordance with regulation 26.

(2) When the Executive receives information from a competent authority which that competent authority has decided shall be kept confidential, it shall treat that information as confidential and shall not disclose it except to the Commission or to another competent authority.

Exchange of information

28.—(1) The Executive shall inform the Commission and the competent authorities within one month from the end of each quarter of the information, including the information specified in Schedule 7, relating to every biocidal product in respect of which, in that quarter, an authorisation or, as the case may be, a registration has been granted, refused, modified, renewed or revoked under these Regulations.

(2) Where the Executive receives a summary of a dossier submitted in support of an application in a member State for inclusion, or for changes to the inclusion, of an active substance in Annex I, IA or IB and is of the opinion that the dossier is incomplete, it shall—

(a) immediately communicate that opinion to the competent authority which is responsible for the evaluation of that dossier; and

(b) without undue delay inform the Commission and the member States of that opinion.

(3) The Executive shall draw up annually a list of the biocidal products authorised or registered under these Regulations and shall send a copy of that list to the Commission and the member States.

(4) In this regulation, "quarter" means the periods in each year—

(a) commencing on 1st January and ending on 31st March;

(b) commencing on 1st April and ending on 30th June;

(c) commencing on 1st July and ending on 30th September;

(d) commencing on 1st October and ending on 31st December,

and "end of each quarter" shall be construed accordingly.

Notification of information to the Poison Information Service

29.—(1) This regulation shall not apply to a biocidal product on the market in Northern Ireland on 14th May 2000 until 6th May 2003.

(2) The person responsible for first placing a biocidal product on the market in Northern Ireland shall submit to the Poison Information Service written notification of the information specified in Schedule 8 relating to that biocidal product.

(3) Subject to paragraph (4), the notification referred to in paragraph (2) shall be submitted to the Poison Information Service—

(a) within three months after the date on which these Regulations come into operation; or

(b) within one month after the date on which the biocidal product in question was first placed on the market in Northern Ireland,

whichever is the later.

(**3**) S.R. 1993 No. 45, as amended by S.R. 1998 No. 238

(4) In the case of a biocidal product which is on the market in Northern Ireland on 14th May 2000, the notification referred to in paragraph (2) shall be submitted to the Poison Information Service by 13th May 2003.

(5) A person who has submitted a notification under paragraph (2) shall also submit to the Poison Information Service written notification of any change to the information notified by him in accordance with that paragraph.

(6) Notifications to be submitted in accordance with this regulation shall be sent to the Poison Information Service at the Royal Victoria Hospital, Grosvenor Road, Belfast BT12 6BA.

(7) In the event of an emergency referred to in paragraph (4)(*c*) of Schedule 8, the individual to be contacted shall provide such further information relating to the biocidal product in question as the Poison Information Service may require.

(8) The Poison Information Service shall not disclose any information notified to it in pursuance of this regulation except to, and at the request of—

(a) a registered medical practitioner; or

(b) a person working under the direction of a registered medical practitioner,

in connection with the medical treatment of a person who may have been affected by the biocidal product in question.