

ANNEX 1

STATUTORY INSTRUMENTS

2003 No. []

HEALTH AND SAFETY

The Biocidal Products (Amendment) Regulations 2003

<i>Made</i> - - - -	2003
<i>Laid before Parliament</i>	2003
<i>Coming into force</i> - -	2003

The Secretary of State, being the Minister designated (a) for the purpose of section 2(2) of the European Communities Act 1972(b) in relation to biocides, in exercise of the powers conferred upon him by that section and of all other powers enabling him in that behalf, hereby makes the following Regulations:

Citation Commencement and extent

1. These Regulations may be cited as the Biocidal Products (Amendment) Regulations 2003, come into force on [2003] and extend to the United Kingdom.

Interpretation

2. In these Regulations—

“ the Great Britain Regulations” means the Biocidal Products Regulations 2001(c);

“the Northern Ireland Regulations” means the Biocidal Products Regulations (Northern Ireland) 2001(d).

Amendment of the Great Britain Regulations

3. In the Great Britain Regulations—

(a) in regulation 2(1), after the definition of “feeding stuff” insert—

““the first review regulation” means Commission Regulation (EC) 1896/2000(a)”;

(a) S.I. 1999/2788

(b) 1972 c.68. As regards Scotland, see also section 57(1) of the Scotland Act (c.46), which provides that, despite the transfer to the Scottish Ministers by virtue of section 53 of that Act of functions in relation to observing and implementing Community law, any function of a Minister of the Crown in relation to any matter shall continue to be exercisable by him as regards Scotland for the purposes of section 2(2) European Communities Act 1972.

(c) S.I. 2001/880.

(d) S.R. (N.I.) 2001 No. 422.

- (b) in regulation 2(1), for the definition of “new active substance”, substitute the following—
 ““new active substance” means—
- (a) an active substance which is not an existing active substance, and
 - (b) for the purposes of regulations 4 to 6, both an active substance which is not an existing active substance and an existing active substance not included in the list referred to in Article 6(1) (b) of the first review regulation, in relation to the product type for which application is now being made;”;
 - (c) after regulation 39 add the following regulation—
“General Industry Charge
 39A. Schedule 12A shall have effect.”;
- (c) after Schedule 12 add the Schedule set out in Schedule 1 to these regulations.

Amendment of the Northern Ireland Regulations

4. In the Northern Ireland Regulations—
- (a) in regulation 2(1), after the definition of “feeding stuff” insert—
 ““the first review regulation” means Commission Regulation (EC) 1896/2000”;
 - (b) in regulation 2(1), for the definition of “new active substance”, substitute the following—
 ““new active substance” means—
 - (a) an active substance which is not an existing active substance, and
 - (b) for the purposes of regulations 4 to 6, both an active substance which is not an existing active substance and an existing active substance not included in the list referred to in Article 6(1) (b) of the first review regulation, in relation to the product type for which application is now being made;”; - (c) after regulation 39 add the following regulation—
“General industry charge
 39A. Schedule 11A shall have effect.”;
 - (d) after Schedule 11 add the Schedule set out in Schedule 2 to these regulations.

Signed by authority of the Secretary of State

Address
 Date

Name
 Parliamentary Under Secretary of State
 [Department of Work and Pensions]

(a) OJ No. L 228, 8.9.2000, p.6. When determining what constitutes a notification, the first review regulation should be read together with prolongation regulation OJ L258, 26.09.02, p15 as the prolongation regulation supplements the first review regulation.

SCHEDULE 1

Regulation 3

“SCHEDULE 12A

Regulation 39A

GENERAL INDUSTRY CHARGE

Interpretation

1. In this Schedule—

- (a) “the Northern Ireland Regulations” means the Biocidal Products Regulations (Northern Ireland) 2001;
- (b) “review regulation” means any Commission regulation made pursuant to article 16(2).

Costs to be charged

2. The Ministers may, subject to and in accordance with the following paragraphs, make an annual charge in respect of any costs incurred by or on behalf of –

- (a) the Ministers in Great Britain; and
 - (b) the Health and Safety Executive for Northern Ireland in Northern Ireland,
- in relation to the carrying out of functions imposed under these Regulations or the Northern Ireland Regulations and in connection with the carrying out of obligations imposed on the United Kingdom by the Directive or by any review regulation.

3. The Ministers shall not charge for any costs under paragraph 2 in respect of which a fee is payable pursuant to regulation 39 and Schedule 12.

Persons liable to pay charge

4. A charge shall be payable to the Ministers by-

- (a) a person who
 - (i) has been granted an authorisation or registration for a biocidal product in accordance with the provisions of regulations 9 to 14, or
 - (ii) is responsible for first placing on the market a biocidal product for which no authorisation or registration has been granted in accordance with the provisions of regulations 9 to 14;
- (b) a person who is named in a dossier submitted under article 11 of the Directive as the applicant in accordance with the data requirements of Annex IIA and IVA, and
 - (i) that person or the manufacturer of the active substance named in accordance with the data requirements of Annex IIA and IVA, has placed on the market the active substance in question, or
 - (ii) the active substance is contained in a biocidal product which is authorised or registered pursuant to Regulations 9 to 14,
where a decision has been made, in accordance with the procedures in articles 27 and 28, that the active substance named in that dossier is included on Annex 1, 1A or 1B;
- (c) a manufacturer who has notified an existing active substance to the Commission under article 4.1 or under articles 4.1 and 8.1 of the first review regulation, or on whose behalf

a notification has been made by a sole representative designated under article 2 of the first review regulation, where—

- (i) the notification has been accepted by the Commission under article 4.2 of the first review regulation,
 - (ii) the notification has not been withdrawn, and
 - (iii) a decision has not been made, in accordance with the procedures in articles 27 and 28, to accept or refuse the inclusion of that active substance on Annex 1, 1A or 1B, and where that manufacturer has placed on the market the active substance in question; and
- (d) a person who has made an application to the Ministers under regulation 5 in respect of a new active substance, where—
- (i) the Ministers have provisionally authorised or registered, under regulations 13 or 14, a biocidal product for placing on the market and use which contains that new active substance;
 - (ii) a decision has not been made to accept or refuse the inclusion of that active substance on Annex 1, 1A or 1B.

Calculation of charge

5. Where a person is liable to pay a charge, in accordance with paragraph 4, at any time from 1 April in any year to 31 March (“the liability period”) in the following year, then he will be liable to pay a charge for that financial year.

6. Upon the expiry of the liability period, the Ministers shall calculate the number of persons liable to pay the charge under paragraph 4 in accordance with the following paragraphs.

7. Where a person falling within paragraph 4(b), (c) or (d) has notified an existing active substance or made an application in respect of a new active substance jointly with one or more other persons then all those persons making that notification or application (“joint applicants”) shall be treated as one person for the purposes of calculating the charge.

8. The joint applicants shall nominate one of their number to pay the charge and shall, notify the Ministers in writing, of the name and address of the person nominated or, if a different person is at any time nominated, of the name and address of that person.

9. Where the joint applicants fail to nominate a person to pay the charge then the Ministers may require payment from any one of them.

10. Where a person is liable to pay a charge under this Schedule—

- (a) in respect of more than one biocidal product;
- (b) in respect of more than one active substance; or
- (c) under more than one sub-paragraph of paragraph 4 ,

then for the purposes of calculating the charge and collecting payments he shall be treated as though he were one person except where he has been nominated by joint applicants to pay the charge on their behalf where he shall be treated as a separate person in respect of that payment.

11. The Ministers shall calculate the charge by dividing the costs incurred in accordance with paragraphs 1 to 3 during the liability period by the number of persons by whom the charge is payable under these Regulations and the Northern Ireland Regulations.

12. A person who is otherwise liable to pay a charge, in accordance with paragraph 4, at the time of the regulations coming into force but ceases to be liable within 3 months of that date shall be treated as if they were never liable to pay.

Notification of liability to pay

13. Subject to paragraph 15, a person who is liable to pay a charge in accordance with this Schedule shall notify in writing to the Ministers, or to a person designated by them—

- (a) the name of the person liable to pay the charge and the address to which communications should be sent;
- (b) the name of the person to whom requests for payment of the charge should be sent; and
- (c) the capacity in which they are liable to pay the charge under paragraph 4,

and shall indicate clearly that the notification is for the purposes of this paragraph.

14. Where a person has been nominated by joint applicants to pay a charge on their behalf he shall be treated as a separate person in respect of a notification under paragraph 13.

15. A person shall not be required to make a notification under paragraph 13 if –

- (a) he has made an application for the authorisation or registration of a biocidal product under regulations 9 to 14 and that authorisation or registration has been granted; or
- (b) a decision has been made, in accordance with the procedures in articles 27 and 28, to include the active substance in question on Annex 1, 1A or 1B.

16. The notification in paragraph 13 shall be made—

- (a) before the biocidal product or the active substance in question is placed on the market; or
- (b) if the product or the active substance in question has already been placed on the market before [insert date these regs come into force], then within three months of that date.

17. The Ministers shall keep the information supplied pursuant to paragraph 13 on a register and if there is a change to any of the details required to be notified under paragraph 13, the person liable to pay the charge shall inform the Ministers forthwith in writing or the body designated by them under paragraph 13 of the relevant changes.”

SCHEDULE 2

Regulation 4

“SCHEDULE 11A

Regulation 39

GENERAL INDUSTRY CHARGE

Interpretation

1. In this Schedule—

- (a) “the Great Britain Regulations” means the Biocidal Products Regulations 2001;
- (b) “review regulation” means any Commission regulation made pursuant to article 16(2).

Costs to be charged

2. The Executive may, subject to and in accordance with the following paragraphs, make an annual charge in respect of any costs incurred by or on behalf of—

- (a) the Ministers in Great Britain; and
- (b) the Health and Safety Executive for Northern Ireland in Northern Ireland,
in relation to the carrying out of functions imposed under these Regulations or the Great Britain Regulations and in connection with the carrying out of obligations imposed on the United Kingdom by the Directive or by any review regulation.

3. The Executive shall not charge for any costs under paragraph 2 in respect of which a fee is payable pursuant to regulation 39 and Schedule 11.

Persons liable to pay charge

4. A charge shall be payable to the Executive by-

- (a) a person who
 - (i) who has been granted an authorisation or registration for a biocidal product in accordance with the provisions of regulations 9 to 14, or
 - (ii) is responsible for first placing on the market a biocidal product for which no authorisation or registration has been granted in accordance with the provisions of regulations 9 to 14;
- (b) a person who is named in a dossier submitted under article 11 of the Directive as the applicant in accordance with the data requirements of Annex IIA and IVA, and
 - (i) that person or the manufacturer of the active substance named in accordance with the data requirements of Annex IIA and IVA has placed on the market the active substance in question, or
 - (ii) the active substance is contained in a biocidal product which is authorised or registered pursuant to Regulations 9 to 14,
where a decision has been made, in accordance with the procedures in articles 27 and 28, that the active substance named in that dossier is included on Annex 1, 1A or 1B;
- (c) a manufacturer who has notified an existing active substance to the Commission under article 4.1 or under articles 4.1 and 8.1 of the first review regulation, or on whose behalf a notification has been made by a sole representative designated under article 2 of the first review regulation, where—

- (i) the notification has been accepted by the Commission under article 4.2 of the first review regulation,
 - (ii) the notification has not been withdrawn, and
 - (iii) a decision has not been made, in accordance with the procedures in articles 27 and 28, to accept or refuse the inclusion of that active substance on Annex 1, 1A or 1B, and where that manufacturer has placed on the market the active substance in question.
- (d) a person who has made an application to the Executive under regulation 5 in respect of a new active substance, where—
- (i) the Executive has provisionally authorised or registered, under regulations 13 or 14, a biocidal product for placing on the market and use which contains that new active substance;
 - (ii) a decision has not been made to accept or refuse the inclusion of that active substance on Annex 1, 1A or 1B.

Calculation of charge

5. Where a person is liable to pay a charge, in accordance with paragraph 4, at any time from 1 April in any year to 31 March (“the liability period”) in the following year, then he will be liable to pay a charge for that financial year.

6. Upon the expiry of the liability period, the Executive shall calculate the number of persons liable to pay the charge under paragraph 4 in accordance with the following paragraphs.

7. Where a person falling within paragraph 4 (b), (c) or (d) has notified an existing active substance or made an application in respect of a new active substance jointly with one or more other persons then all those persons making that notification or application (“joint applicants”) shall be treated as one person for the purposes of calculating the charge.

8. The joint applicants shall nominate one of their number to pay the charge and shall, notify the Executive in writing, of the name and address of the person nominated or, if a different person is at any time nominated, of the name and address of that person.

9. Where the joint applicants fail to nominate a person to pay the charge then the Executive may require payment from any one of them.

10. Where a person is liable to pay a charge under this Schedule—

- (a) in respect of more than one biocidal product;
- (b) in respect of more than one active substance; or
- (c) under more than one sub-paragraph of paragraph 4 ,

then for the purposes of calculating the charge and collecting payments he shall be treated as though he were one person except where he has been nominated by joint applicants to pay the charge on their behalf where he shall be treated as a separate person in respect of that payment.

11. The Executive shall calculate the charge by dividing the costs incurred in accordance with paragraphs 1 to 3 during the liability period by the number of persons by whom the charge is payable under these Regulations and the Great Britain Regulations.

12. A person who is otherwise liable to pay a charge, in accordance with paragraph 4, at the time of the regulations coming into force but ceases to be liable within 3 months of that date shall be treated as if they were never liable to pay.

Notification of liability to pay

13. Subject to paragraph 15, a person who is liable to pay a charge in accordance with this Schedule shall notify in writing to the Executive, or to a person designated by them—

- (a) the name of the person liable to pay the charge and the address to which communications should be sent;
 - (b) the name of the person to whom requests for payment of the charge should be sent; and
 - (c) the capacity in which they are liable to pay the charge under paragraph 4,
- and shall indicate clearly that the notification is for the purposes of this paragraph.

14. Where a person has been nominated by joint applicants to pay a charge on their behalf he shall be treated as a separate person in respect of a notification under paragraph 13.

15. A person shall not be required to make a notification under paragraph 13 if–

- (a) he has made an application for the authorisation or registration of a biocidal product under regulations 9 to 14 and that authorisation or registration has been granted; or
- (b) a decision has been made, in accordance with the procedures in articles 27 and 28, to include the active substance in question on Annex 1, 1A or 1B.

16. The notification in paragraph 13 shall be made–

- (a) before the biocidal product or the active substance in question is placed on the market; or
- (b) if the product or the active substance in question has already been placed on the market before [insert date these regs come into force], then within three months of that date.

17. The Executive shall keep the information supplied pursuant to paragraph 13 on a register and if there is a change to any of the details required to be notified under paragraph 13, the person liable to pay the charge shall inform the Executive forthwith in writing or the body designated by them under paragraph 13 of the relevant changes.”

EXPLANATORY NOTE

(This note is not part of the Regulations)

[] A copy of the regulatory impact assessment prepared in respect of these Regulations can be obtained from the Health and Safety Executive, Economic Adviser's Unit, Rose Court, 2 Southwark Bridge, London SE1 9HS [any extra wording for NI or Scotland]. A copy has been placed in the library of each House of Parliament. [Wording re EU implementation]