

Statutory Instrument 2003 No. 429

The Biocidal Products (Amendment) Regulations 2003

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This SI has been reprinted to correct errors in the paragraph numbering for Schedule 2 which were present in the published version. This corrected reprint is being issued free of charge to all known recipients.

STATUTORY INSTRUMENTS

2003 No. 429

HEALTH AND SAFETY

The Biocidal Products (Amendment) Regulations 2003

<i>Made</i>	<i>26th February 2003</i>
<i>Laid before Parliament</i>	<i>11th March 2003</i>
<i>Coming into force</i>	<i>1st April 2003</i>

The Secretary of State, being the Minister designated[1] for the purpose of section 2(2) of the European Communities Act 1972[2] 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 1st April 2003 and extend to the United Kingdom.

Interpretation

2. In these Regulations-

" the Great Britain Regulations" means the Biocidal Products Regulations 2001[3];

"the Northern Ireland Regulations" means the Biocidal Products Regulations (Northern Ireland) 2001[4].

Amendment of the Great Britain Regulations

3. In the Great Britain Regulations-

(a) in regulation 2(1), after the definition of "feedingstuff" insert -

" "the first review regulation" means Commission Regulation (EC) 1896/2000[5]";

(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; or

(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."; and**

(d) 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 "feedingstuff" insert -

" "the first review regulation" means Commission Regulation (EC) 1896/2000[6]";

(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; or

(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."; and**

(d) after Schedule 11 add the Schedule set out in Schedule 2 to these Regulations.

Signed by authority of the Secretary of State.

Nick Brown
Minister of State,

**Department for Work and Pensions
26th February 2003**

SCHEDULE 1

Regulation 3

" SCHEDULE 12A

Regulation 39A

GENERAL INDUSTRY CHARGE

Interpretation

1. In this Schedule -

"the Northern Ireland Regulations" means the Biocidal Products Regulations (Northern Ireland) 2001;

"liability period" means the period between 1 April in any year and 31 March in the following year;

"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.

Liability to pay the charge

4. In respect of a given liability period 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 and such authorisation or registration has not expired or been revoked in accordance with the provisions of regulation 19, or

(ii) is responsible for first having placed 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 and that biocidal product is placed on the market during that liability period;

(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 Annexes IIA and IVA, where-

(i) that person or the manufacturer of the active substance named in accordance with the data requirements of Annexes IIA and IVA, has placed on the market during that liability period the active substance in question, or

(ii) the active substance is contained in a biocidal product which is currently authorised or registered during that liability period pursuant to regulations 9 to 14, and

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 of the first

review regulation or under articles 4.1 and 8.1 of that regulation, or on whose behalf a notification has been made by a sole representative designated under article 2 of that 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 during that liability period; and

(d) a person who has made an application to the Ministers under regulation 5 in respect of a new active substance, where-

(i) there is a provisional authorisation or registration pursuant to regulations 13 or 14, for placing on the market a biocidal product and use which contains that new active substance; and

(ii) a decision has not been made to accept or refuse the inclusion of that active substance on Annex 1, 1A or 1B.

5. The Ministers may exclude a person or manufacturer from the requirement to pay a charge where they decide it would not be fair to impose that charge.

6. Where a person becomes liable to pay a charge, in accordance with paragraphs 4 and 5, at any time during the liability period, then he will be liable to pay a charge for the whole of that liability period.

Calculation of charge

7. Upon the expiry of the liability period, the Ministers shall calculate the number of persons liable to pay the charge under paragraphs 4 and 5 in accordance with the following paragraphs.

8. 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 purpose of calculating the charge.

9. 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.

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

them.

11. 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;**
- (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.

12. The Ministers shall calculate the charge by dividing the costs incurred in accordance with paragraphs 2 and 3 during the liability period by the number of persons by whom the charge is payable under these Regulations and the Northern Ireland Regulations.

13. A person who is otherwise liable to pay a charge, in accordance with paragraph 4, at the time of these 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.

14. No payment shall be required from a person liable to pay a charge in accordance with this Schedule where that person has made payment in respect of the same liability under the Northern Ireland Regulations.

Notification of liability to pay

15. Subject to paragraph 17, 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.

16. 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 15.

17. A person shall not be required to make a notification under paragraph 15 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.

18. The notification in paragraph 15 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 1st April 2003, within three months of that date.

19. The Ministers shall keep the information supplied pursuant to paragraph 15 on a register and if there is a change to any of the details required to be notified under paragraph 15, the person liable to pay the charge shall inform the Ministers, or the body designated by them under paragraph 15, forthwith in writing of the relevant changes."

SCHEDULE 2

Regulation 4

" SCHEDULE 11A

Regulation 39A

GENERAL INDUSTRY CHARGE

Interpretation

1. In this Schedule -

"liability period" means the period between 1 April in any year and 31 March in the following year;

"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 Executive 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.

Liability to pay the charge

4. In respect of a given liability period a charge shall be payable to the Executive 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 and such authorisation or registration has not expired or been revoked in accordance with the provisions of regulation 19, or

(ii) is responsible for first having placed 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 and that biocidal product is placed on the market during that liability period;

(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 Annexes IIA and IVA, where-

(i) that person or the manufacturer of the active substance named in accordance with the data requirements of Annexes IIA and IVA has placed on the market during that liability period the active substance in question, or

(ii) the active substance is contained in a biocidal product which is currently authorised or registered during that liability period pursuant to regulations 9 to 14, and

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 of the first review regulation or under articles 4.1 and 8.1 of that regulation, or on whose behalf a notification has been made by a sole representative designated under article 2 of that 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 during that liability period; and

(d) a person who has made an application to the Executive under regulation 5 in respect of a new active substance, where-

(i) there is a provisional authorisation or registration pursuant to regulations 13 or 14, for placing on the market a biocidal product and use which contains that new active substance; and

(ii) a decision has not been made to accept or refuse the inclusion of that active substance on Annex 1, 1A or 1B.

5. The Executive may exclude a person or manufacturer from the requirement to pay a charge where they decide it would not be fair to impose that charge.

6. Where a person becomes liable to pay a charge, in accordance with paragraphs 4 and 5, at any time during the liability period, then he will be liable to pay a charge for the whole of that liability period.

Calculation of charge

7. Upon the expiry of the liability period, the Executive shall calculate the number of persons liable to pay the charge under paragraphs 4 and 5 in accordance with the following paragraphs.

8. 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 purpose of calculating the charge.

9. 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.

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

11. 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;

(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.

12. The Executive shall calculate the charge by dividing the costs incurred in accordance with paragraphs 2 and 3 during the liability period by the number of persons by whom the charge is payable under these Regulations and the Great Britain Regulations.

13. A person who is otherwise liable to pay a charge, in accordance with paragraph 4, at the time of these 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.

14. No payment shall be required from a person liable to pay a charge in accordance with this Schedule where that person has made payment in respect of the same liability under the Great Britain Regulations.

Notification of liability to pay

15. Subject to paragraph 17, 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.

16. 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 15.

17. A person shall not be required to make a notification under paragraph 15 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.

18. The notification in paragraph 15 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 1st April 2003, within three months of that date.

19. The Executive shall keep the information supplied pursuant to paragraph 15 on a register and if there is a change to any of the details required to be notified under paragraph 15, the person liable to pay the charge shall inform the Executive, or the body designated by them under paragraph 15, forthwith in writing of the relevant changes.."

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations amend the Biocidal Products Regulations 2001 (S.I. 2001/880) and the Biocidal Products Regulations (Northern Ireland) 2001 (S.R. 2001/422) by introducing a general industry charge (thereby implementing Article 25 of Directive 98/8 of the European Parliament and the Council of 16 February 1998 (OJ No. L123, 24.4.98).

2. Regulations 3 and 4 insert new regulations 39A and the Schedules to these Regulations. The Schedules provide for the Ministers and the Executive to make an annual charge, persons liable to pay that charge, calculation of the charge and notification of liability to pay.

3. 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. A copy of the transposition note in relation to implementation of the Directive set out in paragraph 1 can be obtained from the Health and Safety Executive, International Branch at the same address. Copies of both these documents have been placed in the Library of each House of Parliament.

Notes:

[1] S.I. 1999/2788.back

[2] 1972 c. 68. As regards Scotland, see also section 57(1) of the Scotland Act 1998(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.back

[3] S.I. 2001/880.back

[4] S.R. 2001 No. 422.back

[5] 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 1687/2002 OJ L258, 26.09.02, p15 as the prolongation regulation supplements the first review regulation.back

[6] 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 1687/2002 OJ L258, 26.09.02, p15 as the prolongation regulation supplements the first review regulationback

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