STATUTORY INSTRUMENTS

2013 No. 1507

HEALTH AND SAFETY

The Biocidal Products (Fees and Charges) Regulations 2013

Made - - - -	*18th June 2013*
Laid before Parliament	*27th June 2013*
Coming into force - -	*1st September 2013*

The Secretary of State is designated for the purposes of section 2(2) of the European Communities Act 1972(**1**) ("the 1972 Act") in relation to measures relating to biocides(**2**).

The Secretary of State makes these Regulations—

(a) in exercise of the powers conferred by section 2(2) of the 1972 Act and sections 43(2), (4), (5) and (6) and 82(3)(a) of the Health and Safety at Work etc. Act 1974(**3**) ("the 1974 Act"), and

(b) for the purposes of giving effect without modifications to proposals submitted to him by the Health and Safety Executive under section 11(3) of the 1974 Act.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Biocidal Products (Fees and Charges) Regulations 2013 and come into force on 1st September 2013.

(2) These Regulations extend to Great Britain.

(3) These Regulations apply outside Great Britain as sections 1 to 59 and 80 to 82 of the 1974 Act apply by virtue of the Health and Safety at Work etc. Act 1974 (Application Outside Great Britain) Order 2013(**4**).

Interpretation

2.—(1) In these Regulations—

(**1**) 1972 c.68. Section 2(2) was amended by section 27 of the Legislative and Regulatory Reform Act 2006 (c.51) and section 3 of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c.7). The power of Ministers to make regulations in relation to matters in or regards Scotland is preserved by section 57(1) of the Scotland Act 1998 (c.46).
(**2**) S.I. 1999/2788.
(**3**) 1974 c.37. Section 43(6) was amended by the Employment Protection Act 1975, ss 116, Sch 15, para 12 and by S.I. 2002/794, art 5(2), Sch 2.
(**4**) S.I. 2013/240.

"the Biocides Regulation" means Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products(**5**);

"competent authority" means any of the competent authorities appointed by regulation 5 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013(**6**);

"liability period" means—

(a) the period beginning on 1st September 2013 and ending on 31st March 2014; or

(b) from 1st April 2014, the period beginning on 1st April and ending on 31st March the following year; and

"the Northern Ireland Regulations" means the Biocidal Products Regulations (Northern Ireland) 2001(**7**).

(2) Expressions used in both these Regulations and the Biocides Regulation have the same meaning in these Regulations as they have in the Biocides Regulation.

Functions of the Member State

3. The functions of the Member State referred to in Article 80(2) of the Biocides Regulation are to be performed by the competent authority.

Fees

4.—(1) Each competent authority shall charge fees for—

(a) work it carries out within the scope of the Biocides Regulation which relates to the activities listed in column 1 of the Table in the Schedule; and

(b) work it carries out in order to evaluate an application under regulation 13 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.

(2) Any fee payable under paragraph (1) shall be calculated in accordance with paragraphs (3) to (9).

(3) Where a fee is payable under paragraph (1), the competent authority shall prepare and send to the applicant, the person providing the information or the person making the request, as the case may be, an estimate of the cost of the work.

(4) The person to whom the estimate of costs specified in paragraph (3) is sent by the competent authority must pay to that authority the amount of that estimate within 30 days of its issue.

(5) Upon completion of the work, the competent authority must prepare a detailed statement of the work carried out and of the cost incurred by the competent authority or any person acting on its behalf in carrying out that work.

(6) If the cost referred to in paragraph (5) is greater than the amount estimated in accordance with paragraph (3), the competent authority must notify the amount of difference to the applicant, the person providing the information or the person making the request as the case may be, who must pay the amount of the difference, which will be the final fee payable, without delay.

(7) If the cost referred to in paragraph (5) is less than the amount estimated in accordance with paragraph (3), the fee shall be adjusted accordingly and the amount of difference shall be paid without delay by the competent authority to the applicant, the person providing the information or the person making the request, as the case may be.

(**5**) OJ No L167, 27.06.2012, p.1.
(**6**) S.I. 2013/1506.
(**7**) S.R. 2001 No. 422, as amended by S.I. 2003/429.

(8) Subject to paragraph (9), in estimating or stating the cost of carrying out any work, the competent authority shall determine that cost by reference to the daily rate specified in column 2 of the Table in the Schedule that corresponds to the activity listed in column 1.

(9) The daily rate shall be adjusted pro rata for a period worked of less than 7.4 hours on any one day by—

(a) dividing the daily rate by 14.8 to create a half hourly rate; and

(b) multiplying that figure by the number of half hours worked, rounded up or down to the nearest half hour.

(10) Any unpaid fees may be recovered by a competent authority as a civil debt.

Annual charge

5.—(1) In respect of a given liability period a charge shall be payable to the competent authority on invoice by anyone placing one or more biocidal products on the market.

(2) The charge referred to in paragraph (1) shall be in respect of any costs incurred by or on behalf of—

(a) the competent authorities, in Great Britain; and

(b) the Health and Safety Executive for Northern Ireland, in Northern Ireland,

associated with making biocidal products available on the market, but shall not include any costs in respect of which a fee is payable under regulation 4.

(3) If a person ("P") pays the annual fee under Article 80(1)(a) of the Biocides Regulation in respect of all biocidal products that P places on the market, P shall not be liable to pay the charge referred to in paragraph (1).

(4) No payment shall be required from a person liable to pay the charge referred to in paragraph (1) where that person has made a payment in respect of the same liability to another competent authority under these Regulations or under the Northern Ireland Regulations.

(5) The competent authority may exclude anyone from the requirement to pay a charge where that authority decides that it would not be fair to collect that charge.

(6) Where a person becomes liable to pay a charge in accordance with paragraph (1) at any time during the liability period, that person will be liable to pay a charge for the whole of that liability period.

(7) Any unpaid charge may be recovered by a competent authority as a civil debt.

Calculation of charge and number of persons liable to pay the charge

6.—(1) Upon expiry of the liability period, the competent authority shall calculate the number of persons liable to pay the charge under regulation 5 in accordance with paragraph (2).

(2) The competent authority must calculate the charge by dividing the costs incurred during the liability period in accordance with regulation 5(2) by the number of persons by whom the charge is payable under these Regulations and the Northern Ireland Regulations.

Notification of liability to pay

7.—(1) Subject to paragraph (2), a person who is liable to pay a charge under regulation 5 must notify in writing to the competent authority, or a person designated by the competent authority—

(a) the name of the person liable to pay the charge and the address to which communications should be sent; and

(b) the name of the person to whom requests for payment of the charge should be made,

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

(2) A person is not required to make a notification under paragraph (1) if—

(a) that person has made an application for the authorisation of a biocidal product under the Biocides Regulation and that authorisation has been granted;

(b) that person has been granted a parallel trade permit under Article 53 of the Biocides Regulation;

(c) that person made a notification under paragraph 15 of Schedule 12A to the Biocidal Products Regulations 2001(**8**) or paragraph 15 of Schedule 11A to the Northern Ireland Regulations prior to 1st September 2013; or

(d) that person was granted an authorisation in respect of a biocidal product under the Biocidal Products Regulations 2001 or under the Northern Ireland Regulations prior to 1st September 2013.

(3) The notification in paragraph (1) must be made—

(a) before the biocidal product is placed on the market; or

(b) if the product in question has already been placed on the market before 1st September 2013, by 1st December 2013.

(4) The competent authority must keep the information supplied pursuant to paragraph (1) on a register and, if there is a change to the details required to be notified under paragraph (1), the person liable to pay the charge must inform the competent authority, or the body designated by it under paragraph (1), in writing of the relevant changes, without delay.

Revocations and savings provisions

8.—(1) The following regulations are revoked subject to paragraphs (2) and (3)—

(a) regulations 39 and 39A of, and Schedules 12 and 12A to, the Biocidal Products Regulations 2001; and

(b) regulation 3(c) of, and Schedule 1 to, the Biocidal Product (Amendment) Regulations 2003(**9**).

(2) Regulation 39 of, and paragraphs 2, 3, and 7 to 12 of Schedule 12 to, the Biocidal Products Regulations 2001 continue to apply for the purposes of calculating the fee payable in respect of the evaluation of applications for biocidal product authorisations submitted before 1st September 2013 for the purposes of Directive 98/8/EC(**10**) under Regulation 15(1) of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.

(3) Regulation 39A of, and Schedule 12A to, the Biocidal Products Regulations 2001, as inserted by regulation 3(c) of, and Schedule 1 to, the Biocidal Products (Amendment) Regulations 2003, continue to apply for the purposes of calculating the annual charge payable for the period beginning on 1st April 2013 and ending on 31st August 2013 as if, in Schedule 12A—

(a) the liability period in paragraph 1 means the period beginning on 1st April 2013 and ending on 31st August 2013;

(b) the costs referred to in paragraph 2 mean the costs incurred during the period beginning on 1st April 2013 and ending on 31st August 2013;

(c) in paragraph 7, the words "upon the expiry of the liability period" were replaced with the words "after 31st March 2014"; and

(d) "the Ministers" means the competent authority.

(**8**) S.I. 2001/880, as amended by S.I. 2003/429 and S.I. 2007/293.
(**9**) S.I. 2003/429
(**10**) OJ No. L123, 24.4.98, p.1.

Signed by the authority of the Secretary of State for Work and Pensions.

Mark Hoban
Minister of State,
18th June 2013 Department for Work and Pensions

SCHEDULE Regulation 4

Activities in respect of which a fee is payable and daily rate

Table

1.	*2.*
Activity	*Fee per day worked*
(a) Validation of an application for approval of an active substance.	£447
(b) Evaluation of an application to approve an active substance.	£447
(c) Evaluation of an application to renew an active substance approval.	£447
(d) Work relating to a request for inclusion of an active substance in Annex I on behalf of an economic operator.	£447
(e) Meetings with applicants and prospective applicants.	£447
(f) Evaluation of an application to authorise a biocidal product under the simplified procedure.	£393
(g) Validation of an application for a national authorisation of a biocidal product.	£393
(h) Evaluation of an application for a national authorisation of a biocidal product.	£393
(i) Evaluation of an application to renew a national authorisation of a biocidal product.	£393
(j) Validating, processing and determining an application to mutually recognise a biocidal product in sequence, and subsequent authorisation.	£393
(k) Processing and determining an application for mutual recognition in parallel as a concerned Member State.	£393
(l) Processing and determining an application for mutual recognition by an official or scientific body.	£393
(m) Validating an application for Union Authorisation of a biocidal product.	£393
(n) Evaluation of an application for Union Authorisation of a biocidal product	£393
(o) Evaluation of an application to renew a Union Authorisation.	£393

1.	*2.*
Activity	*Fee per day worked*
(p) Determination of an application to amend an existing biocidal product authorisation.	£393
(q) Determination of an application for a parallel trade permit.	£393
(r) Evaluation of an application for an emergency use permit.	£393
(s) Evaluation of an application under Regulation 13 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.	£393

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations provide the charging regime in relation to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ("the Biocides Regulation"; OJ No L167, 27.06.12, p.1).

The Biocides Regulation replaces Directive 98/8/EC (OJ No. L123, 24.4.98, p.1) of the European Parliament and the Council of 16th February 1998, which laid down harmonised rules for the placing on the market of biocidal products. The Biocides Regulation lays down revised harmonised rules for the approval of active substances and the making available on the market of biocidal products.

Regulation 3 makes provision for the functions of the Member State referred to in Article 80(2) to be performed by the competent authority.

Regulation 4 and the Schedule enables the competent authority to charge fees, at a daily rate, for work carried out within the scope of the Biocides Regulation and within regulation 13 of the Biocidal Products (Appointment of Authorities and Enforcement) Regulations 2013, relating to applications for the authorisation and mutual recognition of biocidal products, the approval of active substances and permits and notifications under specific conditions.

Regulations 5 and 6 provide for an annual charge to be paid to the competent authority by persons placing biocidal products on the market in respect of costs incurred by or on behalf of the competent authorities, associated with any work carried out within the scope of the Biocides Regulation that cannot be attributed to an individual application.

Regulation 7 requires anyone liable to pay the annual charge to notify the competent authority, or a person designated by the competent authority, of information specified in that regulation, subject to exceptions set out in that regulation.

Regulation 8 revokes regulations 39 and 39A of, and Schedules 12 and 12A to, the Biocidal Products Regulations 2001 (and associated amending provisions in the Biocidal Products (Amendment) Regulations 2003), subject to savings provisions which: (i) enable fees to be charged in respect of

the evaluation of biocidal product authorisation applications submitted before 1st September 2013, and (ii) allow the annual charge to be recovered in respect of the period from 1st April 2013 to 31st August 2013.

An impact assessment of the effect that this instrument will have on the costs to business and the voluntary sector is available from the Health and Safety Executive, Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS. A copy of the document has been placed in the Library of each House of Parliament and is annexed to the Explanatory Memorandum which is available alongside this instrument on www.legislation.gov.uk.