

***CHARGING FOR
ACTIVITIES
UNDERTAKEN FOR
THE BIOCIDAL
PRODUCTS
REGULATIONS:
A GUIDE***

FIRST EDITION

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ABBREVIATIONS LIST

BPD	Biocidal Products Directive 1998 (98/8/EC)
BPR	Biocidal Products Regulations 2001
BPU	Biocides and Pesticides Unit
CA	Competent Authority
CoPR	Control of Pesticides Regulations 1986
EA	Experimental Authorisation
EC	European Communities
EU	European Union
FOD	Field Operations Directorate
GIC	General Industry Charge
HM	Her Majesty's
HMSO	Her Majesty's Stationary Office
HSC	Health and Safety Commission
HSE	Health and Safety Executive
MS	Member State(s)
PORD	Process orientated research and development
RIA	Regulatory Impact Assessment
SCB	Standing Committee on Biocides

INTRODUCTION

This guide has been prepared for suppliers of biocidal products or active substances used in biocidal products and others who have an interest in how the charging scheme will operate. It explains how charges will be made and gives an indication of the individual charges an applicant may have to pay. It has been prepared on the basis of The Biocidal Products (Amendment) Regulations 2003 (SI 2003/429), which came into force on 1st April 2003. The guide can be accessed on the Internet at the following website address:

<http://www.hse.gov.uk/charging/index.htm>

1 If you manufacture an active substance or biocidal product and place either on the UK market, then this guide is for you. Whether you are a small, medium or large manufacturer or importer of active substances and/or biocidal products, you will have duties under the Biocidal Products Regulations (BPR). These duties include ensuring the active substance can be used in biocidal products and seeking authorisation from the Health and Safety Executive (HSE) before placing your biocidal product on the UK market. The BPR implements the Biocidal Products Directive (98/8/EC) (BPD) a joint European Council/European Parliament Directive, which has introduced an authorisation scheme for the placing on the market of biocidal products and their subsequent use. Each European Union Member State (MS) is responsible for implementing the BPD according to its own legislative system and for establishing a Competent Authority (CA) to carry out the work under the BPD. The Health and Safety Executive (HSE) acts as the CA on behalf of Ministers in the UK. The BPR came into force in Spring 2001.

2 Information on the key aims of the Biocidal Products Directive can be found on the HSE website (address above).

3 Charges are calculated in accordance with Treasury rules and guidance but must not exceed the total costs reasonably incurred by HSE for the relevant work. Details of these costs are given in Annex C.

CHARGING ARRANGEMENTS

What work will be chargeable?

4 Details of activities attracting charges are set out at Annex A but, broadly speaking, the main chargeable activities are:

- the evaluation of applications and dossiers for Annex I etc. inclusion of active substances, making recommendations to the Commission of the European Communities (EC's) and representing the UK at the Standing Committee on Biocides (SCB);
- examining, on behalf of the UK, recommendations made by other European Union (EU) MS regarding Annex I etc. inclusion;

- the evaluation of biocidal products for authorisation and registration;
- providing information to the EC on biocidal products that HSE authorise or register under BPR;
- providing you and others with information and advice about the BPR and products authorised under it;
- monitoring the use of biocidal products;

What work will NOT be chargeable?

5 Excluded from any charge made under these provisions are:

- enforcement, with Local Authorities and other Agencies, of the BPR and investigation of incidents arising from use/misuse of biocidal products and active substances.

Fees

Basis and amount of fees for applications

6 The exact data requirements for all the different types of application and the procedures for handling them are still being finalised in the EC. This has made the determination of fee levels for specific applications difficult. Therefore fees for many types of application will be determined as follows:

1. on receipt of an application an estimate of the cost of the work is determined;
2. the applicant pays this estimated fee;
3. on completion of the work the actual cost is determined;
4. a further charge, or refund is made as appropriate.

The way in which HSE has approached the identification of the relevant costs for inclusion in the fees follows the guidance in HM Treasury's Fees and Charges Guide¹. The initial estimates of fee(s) for evaluating different types of authorisation / registration and those which it has been possible to fix can be found in Annex C.

Who will be subject to the fees

7 Fees will be charged when the customer for the work is identifiable i.e. where a customer requests a specific piece of work to be undertaken e.g. an application for a product authorisation.

Methodology used for calculating the fees

8 The cost of each type of application has been calculated, having referenced the amount of staff time at each grade that will be required to evaluate an application. HSE operates a work recording system to generate the relevant information. The charges are calculated in accordance with HM

¹A priced publication available from HMSO Books : ISBN 0 11 560043 4

Treasury's Fees and Charges Guide and include the full cost of all the resources used in carrying out that chargeable activity. These costs are included in the Memorandum Trading Accounts prepared annually and which are compiled on the basis of five main headings. The costs included in these headings are as follows:

- i) *Gross Salaries of Staff*,
 - w gross salaries of direct staff;
- ii) *Gross Salaries of Operational Management and Strategy*,
 - gross salaries of indirect staff;
- iii) *General Administrative Expenditure*,
 - accommodation costs;
 - travel and subsistence;
 - staff development and training;
 - office services (for example, postage and telecommunications);
 - services bought from external suppliers;
 - any other appropriate costs that may arise;
- iv) *Corporate Services*,
 - common services (for example, finance, personnel);
- v) *Capital Charges*,
 - depreciation of fixed assets, costs of capital and insurance.

Administrative and financial arrangements

9 For assessment of large data packages e.g. a request for inclusion on Annex I etc. of the BPD or a provisional registration or authorisation, payment of an initial non-returnable fee by means of a cheque made payable to "The Health & Safety Executive" should be sent in with your application (other methods of payment are also possible. Please contact the Finance Unit (see paragraph 27 for contact details)). An invoice for the remainder of the estimated fee will be issued once the completeness check on the dossier has been carried out. Invoices will identify:

- i) each separate chargeable activity e.g. fee for an Annex I etc dossier or fees for several product dossiers;
- ii) and the total payable.

Work on the dossiers will not commence until the payment has been cleared through HSE's financial procedures. The applicant will be notified when work will commence. Further information about fees can be found in Annex C of this document.

10 For assessment of smaller data packages e.g. for process orientated research and development (PORD) or experimental authorisations payment of

a fee by means of a cheque made payable to “The Health & Safety Executive” should be sent in with your application (please see paragraph 9 above for alternative methods of payment). Again work on the application will not commence until the payment has been cleared through HSE’s financial procedures. You will be notified when work will commence.

The General Industry Charge (GIC)

Basis and amount of the GIC

11 The GIC will cover other work undertaken by the CA and will be based on recovery of the full costs of the time spent carrying out all activities for which a specific customer cannot be identified. The GIC will be calculated and charged on a yearly basis. The way in which HSE has approached the identification of the relevant costs for inclusion in the GIC follows the guidance in HM Treasury’s Fees and Charges Guide. The rate for the GIC per company for the current year can be found in Annex C.

Who will be subject to the GIC?

12 The GIC will apply to all suppliers on to the UK market of active substances or biocidal products from after the date the charging regulations come into force on 1 April 2003, that is suppliers of all products or active substances used in biocidal products within the scope of BPR, whether or not the products have yet needed to be authorised under BPR; this includes supply to Northern Ireland and all companies outside the UK but within the EC who place products onto the UK market. The GIC will only be payable by suppliers who have supplied active substances or biocidal products on to the UK market for the financial year in question.

Methodology used for calculating the GIC

13 The GIC will be calculated on the basis of the time spent on that particular chargeable activity; plus the cost of any work undertaken by others on behalf of the CA. For further information on calculating the charge see paragraph 8.

Administrative and financial arrangements

14 HSE will issue invoices and receive payments for the GIC. HSE will be responsible for debt recovery.

15 Article 25 of the BPD says that the costs of regulating the industry should be paid by those placing biocidal products on the market and those supporting Annex I etc inclusions. The GIC will be a yearly charge with invoices sent out to companies in June for the preceeding financial year.

16 There is a requirement in the Biocidal Products (Amendment) Regulations 2003 for companies supplying active substances or biocidal products to the UK market to notify HSE.

17 The GIC will be calculated on the basis of the time spent on a particular chargeable activity (see paragraph 8 for further details).

Queries and disputes procedure

18 HSE will prepare annual Memorandum Trading Accounts which will be subject to scrutiny by HSE's Internal Audit and also externally by the National Audit Office.

19 For the GIC debt recovery functions and for both Fees and the GIC invoicing functions will be carried out centrally; **scientists will not be responsible for the issuing of invoices nor for any follow up actions relating to non-payment of invoices**. In addition, they will not be well placed to discuss charging policy. Queries on invoices should be referred to the contact point given in paragraph 27.

20 HSE will actively pursue outstanding debts in accordance with its own debt recovery procedures.

Disputes procedure - invoices

Scope

21 The following procedures have been put in place to seek to resolve queries and disputes which may arise as a result of HSE recovering its costs for relevant work in relation to the BPR. The aim of these procedures is to resolve queries and disputes promptly, transparently and fairly. The procedure has three levels. These are set out in broad terms below but a full description of the procedure can be obtained from HSE Finance Unit (see paragraph 27) or is available on HSE's Internet Website (see paragraph 26). Please note there are time limits at each level within which queries should be submitted.

Level One

22 All queries should initially be directed to HSE Finance Unit, Bootle (see paragraph 27) who will record receipt on a query record. Progress on clearance of the query will be monitored and, where the query has been referred to the Biocides and Pesticides Unit (BPU), progress will be checked regularly at intervals of no less than weekly. Finance Unit will be responsible for answering queries relating to the standard information contained in the invoice such as invoice accuracy, method of payment, VAT, address etc.

Level Two

23 If the query cannot be resolved at Level One or the query relates to whether the charge properly relates to the costs incurred carrying out the function or was a chargeable function, the duty holder may refer their query via HSE's Finance Unit to the appropriate member of senior management in Field Operations Directorate (FOD). The senior manager will consider the query and set out their reasons for the decision in writing.

Level Three

24 If the duty holder is not satisfied with the senior manager's decision under Level Two, they may refer the matter in dispute to a 'Disputes Panel' comprising senior officials from FOD, where appropriate, the Head of HSE's Planning, Efficiency and Finance Division and an independent member from industry. [Field Operations Directorate is the current 'home' of BPU.] The Director of HSE's Safety Policy Directorate will normally chair the 'Disputes Panel'. The 'Disputes Panel' shall have the power to uphold or reject the complaint in total or in part and confirm, vary or cancel the charge in dispute. HSE will commence debt recovery action where an invoice has been disputed under the Level Three procedures and the charge in dispute has been upheld and the invoice has not been settled within ten calendar days of the notification of the 'Disputes Panel' determination.

25 HSE will assume that dutyholder's accounting systems allow part payments to be made. If this is not the case, please see paragraph 15. Where a dutyholder's accounting system does not allow part payment of an invoice and there is a dispute over part of the invoice, the original invoice will be cancelled and two invoices substituted - one for the undisputed amount and the other for the disputed amount. The invoice value for the disputed amount will be for a value agreed between the company and FOD. The settlement in relation to the undisputed invoice will become payable in accordance with the date of the original invoice. Once the dispute has been resolved, either through agreement between the company and FOD or via the Disputes Panel, the invoice will be payable within 30 calendar days of the date of the original invoice or, where the original 30 calendar day period has expired, within 10 calendar days of notification of the outcome of the dispute.

26 The HSE Procedure for Queries and Disputes can be accessed on the internet at the following website address:

<http://www.hse.gov.uk/charging/disputes.htm>

Contacts for advice and guidance

27 Should you need advice on the operation of the charging system or have a specific query, please telephone or write to HSE at:

Finance Unit 2
Financial Accounting and Advice
Room 408
St Hugh's House
Stanley Precinct
Bootle
Merseyside
L20 3QY
United Kingdom

Tel: 0151 951 4326 International callers +44 151 951 4326
Fax: 0151 951 4141 International faxes +44 151 951 4141

28 Queries on the application of the Biocidal Products Regulations and charges prior to the issue of an invoice should be referred to:

Biocides and Pesticides Unit
Room 123
Magdalen House
Stanley Precinct
Bootle
Merseyside
L20 3QZ
United Kingdom

Tel: 0151 951 3535 International callers +44 151 951 3535
Fax: 0151 951 3317 International faxes +44 151 951 3317

FEES AND THE GENERAL INDUSTRY CHARGE

INTRODUCTION

1 Article 25 of the BPD requires MS to establish systems for recovering costs from those placing or seeking to place biocidal products on the market, or supporting entries onto Annex I, IA or IB. These charges will correspond as far as possible to the costs incurred in carrying out all the different procedures associated with the provisions of the Directive.

2 Also it is government policy to fully recover appropriate costs of regulation from those who create risks, in this case, posed by placing biocidal products on the market, and those who benefit from the products being regulated.

3 The Health and Safety Commission (HSC) considers the work required by the CA in operating the biocides regime to fall into three categories:

- Category A: costs of work for a clearly identified customer, such as the assessment of applications for inclusion of an active substance on Annex I etc, or for authorisation of a particular product;
- Category B: costs of work which it is appropriate to recover from the biocides industry, but not referable to a specific application, such as monitoring the effects of biocides on health and the environment, or the input of the UK into the work of other MS in assessing and reviewing active substance;
- Category C: costs of work, which it is inappropriate to recover from the biocides industry and which should be borne by society through general taxation, such as enforcement of the Regulations.

Fees

4 Category A work is to be recovered by means of fees from individual companies who make applications to the CA. The Health and Safety at Work etc. Act 1974 permits the introduction of a fee of this type. This will be operated on an actuals basis. Following an application BPU will estimate the cost of the work. The applicant will pay this estimate, on completion of the work the actual total cost of the work will be determined and the applicant will be required to pay the difference, or a refund to be made as appropriate.

The General Industry Charge (GIC)

5 The costs of work in Category B cannot be recovered by means of fees because there is no clearly identifiable customer that could be required to pay the fee. Ministers have decided that these costs should be recovered by means of a GIC. Ministers have also agreed that these charges will commence on 1 April 2003, following the amendment to the BPR. The GIC is the mechanism by which HSE will recover the costs of these functions that fall to HSE under BPR. For the costs of work in Category B a charge will be imposed across all companies supplying active substances or biocidal products onto the UK market.

CHARGEABLE ACTIVITIES AND PROPOSED CHARGES

Fees

6 Fees will be charged when work is undertaken for a clearly identified customer, such as the assessment of applications for inclusion of an active substance on Annex I etc or for authorisation of a particular product (including for example an experimental authorisation (EA), a provisional authorisation or a Notification of Process Orientated Research and Development (PORD). The fee charged will reflect the full cost of resources used to assess and evaluate the dossier submitted.

The GIC

7 HSE has estimated a 3 year forecast of projected costs. These can be found in Annex C. These estimates are based on our current understanding of what will be charged to the GIC and also include a number of assumptions as to the size of the biocides industry in the UK. A Regulatory Impact Assessment (RIA) was undertaken for the introduction of the BPR and addressed the introduction of the GIC. A summary of this can be found at Annex D.

8 Regulatory costs are currently incurred under the Control of Pesticides Regulations (CoPR) by certain sectors of the biocides industry both by fees and a levy. Due to this overlap such products will initially incur regulatory costs under both regimes for different services, although this will be at a maximum level at the beginning of the new charging regime. The CoPR levy will subsequently decline over the period 2003/04 - 2009/10 as products move from one regime to the other. Conversely the regulatory costs under BPR will increase, although these will be spread over a wider industry.

9 The regulatory costs are expected to increase in the first 3 years with increasing work associated with the biocides regime. Thereafter, it is expected that they will stabilise at around £700k per annum. By this stage we expect a Charging Review Group to be well established and if any further increases are required, they will be discussed with the Group.

10 The costs of monitoring the effects of biocides, research directly related to the authorisation of biocides, UK input into the European level work of other MS and providing information to industry will be charged to the GIC.

Mandatory arrangements to be put in place to support charging

The GIC

11 The BPR have been amended to give Ministers the powers to recover a GIC and put in place a system to charge a flat rate GIC. This will enable small and medium sized enterprises to budget better for their obligations under BPR. Under the amended Regulations there will be a requirement for suppliers who place biocidal products or active substances onto the UK market to notify the HSE.

12 As the BPR is made under the Health and Safety at Work Act etc. 1974 and the European Communities Act 1972, HSE inspectors or the local weights and measures authority or the local authority for areas where use occurs as specified in BPR schedule 11(5) will have the powers to enforce this aspect of placing biocidal products on the market. Penalties for breaches of the Regulations will be in line with other health and safety legislation. Details of HSE's enforcement policy is set out in the booklet 'Enforcement Policy Statement' - available free from HSE books.

Administrative arrangements to be put in place to support charging

Fees

13 Information on administrative arrangements to support the fees can be found in the main document.

The GIC

14 The administration of the new charging system will involve a budget in March of each year where HSE will predict its costings for the next financial year. These will be presented to the Biocides Charging Review Group in May. This budget of predicted figures will then be firmed up by updated forecasts in November based on closely monitored progression throughout the year. The forecasts in November will coincide with a meeting of the Biocides Charging Review Group. Invoices will subsequently be sent out to relevant companies in June, when costs have been finalised for the previous financial year. All costs will be reviewed annually.

Biocides Charging Review Group

15 HSE has set up a Biocides Charging Review Group to review the effectiveness, consistency and operation of the financial and administrative arrangements and their consequences. The Group is intended to provide industry with a mechanism of assurance that the charging scheme is operating as laid down. The remit of this Group will not include setting the rates of charges or what can be charged. The Group will meet biannually, usually in November and May.

THE BIOCIDAL PRODUCTS REGULATIONS (AMENDED) 2003

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(2)for the purpose of section 2(2) of the European Communities Act 1972(3) 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(4);

“the Northern Ireland Regulations” means the Biocidal Products Regulations (Northern Ireland) 2001(5).

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(6);”

(2) S.I. 1999/2788.

(3) 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.

(4) S.I. 2001/880.

(5) S.R. 2001 No. 422.

(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 regulation.

- (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(7)”;
- (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

26th February 2003

Nick Brown
Minister of State
Department for Work and Pensions

(7) 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

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

20. 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

21. 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.

22. 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

23. 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.

24. 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.

25. 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

26. 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.

27. 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.

28. 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.

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

30. 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.

31. 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.

32. 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.

33. 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

34. 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.

35. 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.

36. 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.

37. 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.

38. 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)

39. 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)).

40. 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.

41. 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.

DETAILS OF THE FEES FOR A RANGE OF AUTHORISATIONS OR REGISTRATIONS AND THE GENERAL INDUSTRY CHARGE.

This Annex contains examples of the level of activity that HSE anticipates it will devote to working on the BPR. This information has been provided to help individual companies estimate their charge under these regulations. Companies are asked to bear in mind that the GIC will be dependent on the work HSE is asked to review.

INTRODUCTION AND BACKGROUND

1 Please see Annex A for information on recovering the costs of operating the BPD

Fees for applications

2 The cost of work for a clearly identified customer will be recovered by means of fees, such as the assessment of applications for inclusion of an active substance on Annex I etc or for authorisation of a particular product (including for example an EA or a provisional authorisation or a Notification of PORD. The fee charged will reflect the full cost of resources used to assess and evaluate the dossier submitted.

The exact data requirements for all the different types of application and the procedures for handling them are still being finalised in the EC. This has made the determination of fee levels for specific applications difficult. Because of this fees for many types of application will be determined as follows:

1. on receipt of an application an estimate of the cost of the work is determined;
2. the applicant pays this estimated fee;
3. on completion of the work the actual cost is determined;
4. a further charge, or refund is made as appropriate.

Examples of Estimated Fees

Type of application	Fees
Non refundable deposit of	£6,000
Estimate for completion of an application for Annex I etc inclusion including the first product	£59,000 - £65,000
Non refundable deposit of	£800
Estimate for completion of an application for subsequent products	£7,700
Non refundable deposit of	£500
Application for Experimental Authorisation	£3,000 - £5,800
Notification of Process Orientated Research and Development (<i>This will be a fixed fee</i>)	£650

The GIC

3 The GIC covers the costs of UK input into the European level work of other MS, providing information to industry, monitoring the effects of biocides, and research directly related to the authorisation of biocides. HSE have provided a 3 year forecast of projected costs.

	2003/4	2004/5	2005/6
Estimated total costs to be attributed to the GIC	£400,000	£400,000	£400,000
Estimated per company charge - assuming 1,200 companies and that the charge is a simple mean per company	£330	£330	£330

Illustrative examples of calculating whether a supplier should pay the GIC for a particular financial year.

Example 1

The financial year runs from 1st April to 31st March. Company A supplies an antifouling paint onto the UK market from January 2003 to August 2003. Therefore the company will be liable to pay the GIC for 2003-2004.

02/03	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
										S	S	S
03/04	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
	S	S	S	S	S							

S = supplies onto the market.

Example 2

The financial year runs from 1st April to 31st March. Company B supplies an insecticide onto the UK market from October 2001 to March 2002 and from April 2003 to Sep 2003. Therefore the company will not be liable to pay the GIC for 2002-2003; but will be liable to pay the GIC for 2003-2004.

01/02	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
							S	S	S	S	S	S
02/03	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
03/04	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
	S	S	S	S	S	S						

S = supplies onto the UK market

REGULATORY IMPACT ASSESSMENT SUMMARY

This RIA covers the introduction of the GIC associated with the implementation of the BPD. Article 25 of BPD essentially requires MS to recover their costs in carrying out all the different procedures associated with the provisions of BPD. Whilst the UK has established a system of fees for applications, there are costs, associated with running the system as a whole, that cannot be recovered in this way. These costs (e.g. monitoring the effects of biocides, research directly related to the authorisation of biocides, UK input into the EU level work of other MS, establishing and maintaining the technical competence of the people who will carry out the assessments as required by BPD, providing information to dutyholders, maintaining an authorisation system and procedures that are efficient and operate well) will be recovered by the GIC. Current estimates are that the GIC will be around £400,000 for the first few years from 2003/04. However, there is uncertainty with respect to both this figure and the size of the market/number of companies who must contribute.

Three possible ways of charging the GIC (based on turnover on biocidal products 'turnover option', a fixed charge per company 'per company option' or a fixed charge per product 'per product option') were considered. HSC held a public consultation exercise on these in summer 2000. The majority of respondents stated that they would prefer the per company option. However, of the companies identifiable as small or medium-sized there was a split between the per company and the turnover options.

The additional costs of complying with the GIC were estimated. These additional costs are incurred both by HSE (ultimately paid for by industry through the charge) and industry and include the costs of establishing the regime in the first year and the recurrent costs. They do not include the actual annual GIC itself. At the time the RIA was prepared, the total costs of the per company option were estimated to be about £167,000 over 10 years in present value terms. For the turnover option the equivalent costs were estimated to be about £1.1 million. Other options (e.g. the per product option and also a per active substance option and a tiered approach to the per company option) were not costed in detail. In all cases the extra costs were estimated to be higher than for the per company option. It was concluded that both in the first year and for recurrent costs, the per company option presented the lowest additional administrative cost over that already incurred. It is also easier to understand and to implement. However, as well as these administrative costs, the total cost to industry will also include the actual annual GIC.

The impact on small businesses was assessed. For those companies the total cost of compliance and the annual GIC were considered together. For those with small annual turnover (less than about £17,000) there would be a

significantly higher total cost with the per company option than with the turnover option. This is because, for them, the GIC with the per company option (estimated to be about £330 per company in the early years) would be significantly higher than with the turnover option (estimated to be less than £25). This might have a significant adverse effect on the viability on individual businesses if they trade in biocidal products alone and if this were the only cost imposed by the new system. However, these costs are insignificant when compared with the compliance costs for the data and authorisation/registration requirements of products (on average £78,000 in 1998/99 prices).

The effects on competition were also assessed. It was not considered that the introduction of the GIC would have any further impact on competition. Any impact on market structure is likely to be due to the costs of the data and authorisation/registration requirements of products.

In establishing the Regulations there will be a duty placed on both those first supplying biocidal products onto the UK market and supporters of entries onto Annex I to inform HSE of their name and address. Once products have been authorised under the new regime, the suppliers of both the product and its active substances can be easily identified.

A Biocides Charging Review Group, of stakeholder representatives, will be established. It will keep under review the effectiveness, consistency and operation of the BPR charging regime's financial and administrative arrangements and their consequences.

It is proposed that the method of collecting the GIC be re-evaluated 3-5 years after the Regulations come into force, depending on the rate of transition from the national to the EU regime, with any changes being introduced for the financial year following the re-evaluation.

The recommendation is for the GIC to be charged using the per company option. Some small and medium sized companies have indicated a preference for the turnover option. However, whilst charging on this basis may result in a lower annual GIC for them, sometimes below the level that is economic to collect, the total cost of the turnover option is, for industry as a whole, higher than the per company option. Additionally, it is considered that, when turnovers are very low, the costs of providing the data to support placing a product on the market is likely to result in these products being withdrawn, independently from the GIC, as the costs of compliance with BPR are high.