



BIOCIDAL PRODUCTS REGULATIONS



THE NEW GENERAL INDUSTRY CHARGE: INFORMATION NOTE

INTRODUCTION

The Biocidal Products Directive 98/8/EC (BPD) sets up a European Community product approval scheme for 'biocidal products' – broadly speaking, non-agricultural pesticides, disinfectants and preservatives. The supply of any such product will eventually be prohibited unless it has been authorised*. Authorisation will be by individual Member States, but there are mutual recognition arrangements to ensure that products marketable in one Member State are marketable in another unless there are good reasons why not. A condition of authorisation is that any active substance contained in the product must be included on a list held centrally at Community level and forming Annex I of the BPD**. A 10 year review programme is being put in place under which existing products and active substances will gradually be brought within the new framework.

The BPD has been almost completely implemented in the UK by the Biocidal Products Regulations 2001 and the Biocidal Products Regulations (Northern Ireland) 2001 (referred to collectively below as 'BPR').

The BPD requires that Member States recover the costs they incur in operating the new system by charging them to those who place biocidal products on the market or who support the inclusion of an active substance on Annex I of the BPD. The BPR have already partly implemented this requirement. Anyone who seeks the authorisation of a product under the Regulations or who applies via the UK authorities for the inclusion of an active substance on Annex I must pay a fee to cover the evaluation and processing of the evaluation

From 1 April 2003 there is also an annual charge, called the 'General Industry Charge' (GIC), additional to the fees charged for the processing of product authorisation and active substance inclusion applications. It covers the ongoing costs incurred by the UK authorities in operating the system as a whole – costs which cannot be attributed to specific applications. Anyone familiar with the present UK product approval regime under the Food and

* A simpler form of approval, called 'registration', is used for some low risk products. Where this note refers to 'authorisation' it should be taken to mean 'registration' in those cases.

** Where this note refers to 'Annex I' of the BPD, it should be taken to mean Annex I, IA or IB as appropriate.

Environment Protection Act and the Control of Pesticides Regulations will see similarities between the existing combination of application fee and annual levy and the new fees and charges regime for biocidal products.

UK Ministers believe that a charging arrangement like this is the fairest way to satisfy the BPD's requirement that the government recovers its costs.

The GIC is introduced by the Biocidal Products (Amendment) Regulations 2003 (SI 2003/429), which came into force on 1 April 2003. The amendment lays down detailed rules specifying who must pay the charge and how the amount is to be calculated.

More information is given in the question & answer sections below. We recommend that you use it in conjunction with the Regulations themselves and the separate Charging Guide, which gives more detailed financial and administrative guidance. The fees and charges regime under the BPR will be operated by HSE's Biocides and Pesticides Unit, which can be contacted at the address in the box below.

Biocides and Pesticides Unit
Health and Safety Executive
Room 123
Magdalen House
Stanley Precinct
Bootle
Liverpool
L20 3QZ
Tel: 0151 951 3535
International: +44 151 951 3535
Email biocides@hse.gsi.gov.uk

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Questions and answers

Basics

Q1. What is the General Industry Charge (GIC)?

A: It is a UK charge on the biocidal products industry, payable on demand annually in arrears. It covers the costs of operating the biocidal products approval regime established by the BPR, other than costs relating to specific products or active substances and charged to individuals by way of a fee.

Q2. What types of work are paid for by the GIC?

A. Chargeable work that cannot be referred to a specific application. This includes the UK input into the European level work of other Member States, providing information to industry, monitoring the effects of biocidal products, and research directly related to the authorisation process.

Q3. Why is there a fee and a GIC?

A. The work that is charged for naturally breaks down into two categories: work related to a specific application, and ongoing general activity. Including a charge for general activity in the fee for a specific application is both difficult (because it has to anticipate and provide for the future) and unfair.

Q4: When does the GIC come into effect?

A: From 1 April 2003.

Q5. What do I need to do?

A. Two things:

(i) notify HSE if you are liable to pay the charge (see Question 7), unless you are:

- the holder of a product authorisation under BPR, or
- the applicant supporting an active substance for which a decision to include on Annex I of the BPD has been made;

(ii) pay the charge when you are asked to do so.

Please note that if you were supplying an active substance (which you have notified within the review programme of the Biocidal Products Directive) or a biocidal product onto the UK market before the 1st April 2003 then you have to inform HSE of your liability within 3 months (by the **30th June 2003**). If you supply an active substance (which you have notified within the review programme of the Biocidal Products Directive) or a biocidal product on to the UK market after the 1st April 2003 you have to inform HSE of your liability prior to placing that active substance or biocidal product onto the UK market. You may wish to do this by completing a [General Industry Charge Registration form \(GIC01\)](#).

Q6. Other Member States aren't making companies pay. Isn't this unfair/not a level playing field/a violation of my human rights?

A. All Member States are required by the BPD to recover their costs. They may use different structures of fees and charges to do so – fees only, for example – but UK experience indicates that a fee plus general charge arrangement of this kind is workable, efficient and fair.

Liability

Q7. How do I know if I am liable to pay the GIC?

Note: where this note uses the term 'liability criteria', it means the five conditions set out below.

A. You are liable to pay if:

(i) you are the person who *first* placed on the market a biocidal product yet to be authorised under BPR, but which is on the market during the financial year for which liability is being assessed;

Note: this *first* placing on the market - the first step in the supply chain - may have taken place before the year for which liability is being assessed if the supply chain spans more than one financial year.

(ii) you are the holder of a current UK authorisation under BPR for a biocidal product;

Note: this will usually, but not always, be the person identified at (i) above for a product that goes from being unauthorised to being authorised.

(iii) you are a manufacturer of an active substance included in the review programme established under BPD who has:

- notified the active substance to the European Commission, or on whose behalf a notification has been submitted, and
- placed the substance on the UK market during the financial year,

provided that *no decision has yet been made* about BPD Annex I inclusion;

Note:

- if you are part of an association notifying jointly then all the members of it are treated collectively as one person;
- formulators who notify active substances to the European Commission are not caught by this rule.

(iv) you have applied for BPD Annex I inclusion for an active substance and a decision to include it *has* been made, provided that

- either you or the manufacturer (usually one and the same) have placed the substance on the UK market during the financial year, or
- the substance has been a component of an BPR authorised product;

Note: as soon as this rule applies, rule (iii) above, if it applied before, now ceases to do so.

(v) you have applied to the UK authorities for BPD Annex I inclusion for an active substance, and

- the substance is a component of a product provisionally authorised under BPR;
- no BPD Annex I inclusion decision has yet been made.

Q8. Why do I have to pay?

A: Because the BPD obliges Member States to recover the costs of administering the biocidal products regime by charging them to product suppliers and to people supporting the inclusion of active substances on Annex I of the BPD.

Q9. My products are not currently approved under any UK legislation but I will require product authorisation under the Biocidal Products Regulations. When do I have to start paying the GIC?

A. You will become liable straightaway if you satisfy any of the criteria set out in the answer to Question 7, and will have to pay for the first time in mid-2004. The fact that you do not fall under any current UK regime does not make a difference.

Q10. What is my position if I supply my product in England, Wales, Scotland and Northern Ireland?

A: The scheme will operate UK-wide, and nobody will be liable to pay the charge more than once each year just because liability arises in more than one UK territory.

Q11. What do I need to do if I stop supplying biocidal products?

A. Let HSE (see box on page 2) know so that you can be removed from the liability register, as long as you are not liable for some other reason. You will still be liable for the year during which you supply, even if you stop part way through.

Q12. I have products currently approved under the Control of Pesticides Regulations and therefore pay the COPR levy and I will also have product authorisations in the future under the Biocidal Products Regulations. Will I be liable to pay both the levy and the GIC?

A. Yes. The two systems are independent. But as the chargeable work carried out by the authorities is gradually transferred from the old system to the new the total will remain approximately constant, so the combined charge to the industry should not increase significantly because of the introduction of the Biocidal Products Regulations.

Q13. Will I have to pay the GIC if I have no products or active substances on the market in the UK?

A. No. Unless you are an active substance supporter and the substance is a component in a product authorised or registered at the request of someone else.

Q14. I don't manufacture any biocidal products in the UK, but just import them and sell them on the UK market – am I liable?

A. Importation on its own counts as placing on the market for the purposes of the Biocidal Products Regulations, and in any case the Regulations apply to supply and not manufacture. You should check whether the liability criteria at Question 7 apply to you.

Q15. I make my own biocides and use them only in my own premises – am I liable?

A: No. Manufacture of a product does not count on its own. Using it exclusively in your own premises does not constitute a 'placing on the market' as defined by the Regulations. Provided you have not been granted an authorisation to market the product, you will not be liable to pay the GIC.

Q16. I supply only active substances that have been identified but not notified under the first Review Regulation. Am I liable?

A: No. You are not supporting the inclusion of your active substances in Annex I of the BPD. See the liability criteria set out at Question 7 above.

Q17. My products contain only active substances that have been identified but not notified under the first Review Regulation. Am I liable?

A. Yes if you are the person first placing a product on the market. Check the liability criteria in Question 7.

Q18. What if I supply more than one product?

A. If you are liable to pay the GIC then you pay only once, regardless of how many products you supply.

Note: someone paying the charge on behalf of an association counts as a separate person for the purpose of that particular payment. They will be liable in their own right if they are supplying products besides those of the association.

Q19. I buy in bulk and then repackage the product for several supermarkets - will I have to pay the charge more than once?

A. No. But see the answer to Question 18.

Q20. I supply an active substance to another who formulates it to be a disinfectant which is then sold. Who pays?

A. Not you, *as far as that product is concerned*. You are not supplying a biocidal product as defined by the regulations because when it leaves you it is not in the form in which it will ultimately be used. (But see the liability criteria at Question 7 if you are supporting inclusion in Annex I of the BPD for the active substance.)

Q21. I buy biocides from a supplier which I then incorporate into an article which I sell, who pays?

A. It depends on the article. If it is designed to deliver a biocide which has an effect on a target organism external to itself (a mosquito net for example), as distinct from just being internally preserved (a fence post), then you will be supplying a biocidal product and may be liable. You should check the liability criteria at Question 7 with that in mind.

How much?

Q22. How much will the charge be?

A. The actual charge will vary from year to year, depending on the actual total costs chargeable to it and the number of companies liable to pay. Our initial estimate is £333 per year for the first few years. It should be noted that this is only an estimate and the actual cost will depend on the actual costs and numbers of liable companies.

Q23. How is it calculated?

A. By adding up all the chargeable costs incurred by the authorities and dividing them between everyone in the UK satisfying, at some point in the year, the liability criteria set out at Question 7.

Q24. I am a small company marketing only small amounts of biocidal product each year. Why do I have to pay the same charge as the large manufacturers?

A. The relative advantages and disadvantages of a flat-rate as opposed to a turnover-based scheme were closely compared during public consultation on the GIC proposals. A flat-rate scheme is much less expensive to operate for industry as a whole, and although it is true that the charge itself is higher for a firm with a very small turnover than it would be under a turnover-based scheme it is still small compared with the costs of product authorisation and Annex I inclusion. Ministers concluded therefore that on balance the advantage lay with the flat-rate option.

Procedures

Q25. When will I know how much I must pay and when do I pay?

A. The financial year (FY) runs from 1 April to 31 March. HSE will prepare a budget in March of each year in which it will predict its costings for the next FY. 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.

At the end of the FY HSE will determine the actual chargeable costs and the number of liable companies for the FY. From this the actual GIC for the FY will be determined. This will be presented to a Charging Review Group in May and, following the agreement of Ministers, invoices will be sent out to relevant companies in June/July for payment within 30 days.

All costs will be reviewed annually. You will be kept informed about the GIC through our Fact Sheets.

Q26. When do I make the first payment and how much will it be?

A. The first invoices, for the FY 2003-04, will be sent out in June/July 2004 for payment within 30 days. See Question 22 also.

Q27. How do I pay?

A. HSE will issue invoices to each liable company in June/July of each year for the Financial Year ending in the previous March.

Full payment, by means of a cheque, in sterling only, made payable to 'The Health & Safety Executive' and crossed 'A/C Payee only', should be sent to:

Financial Accounting and Advice (FU2)
Planning, Efficiency and Finance Division
Room 408
St Hugh's House
Stanley Precinct
Bootle
Liverpool
L20 3QY
United Kingdom

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

Receipts for payments will be issued only if specifically requested.

An alternative method of payment is through the Bankers Automated Clearance System (BACS).

BACS payments should be credited to:

Health and Safety Executive
Sort Code 40-12-26
A/c 41453505
Midland Bank PLC
197 Stanley Road
Bootle
Liverpool
L20 3DX
United Kingdom

HSE's Finance Unit will be able to answer queries once an invoice has been issued. This includes questions on accuracy, method of payment, VAT, address etc.

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

Q28. Can I pay in instalments?

A. No.

Notification of liability to pay the GIC

Q29. I think I am liable to pay the GIC. Do I have to notify anyone?

A. Unless you are in the exempted category you should notify (using the accompanying form if you wish) HSE's Biocides and Pesticides Unit at the address in the box on page 2, *specifying which of the liability criteria applies to you*, and giving

- the name of the person liable to pay the charge and the address to which communications should be sent
- the name of the person to whom requests for payment of the charge should be sent

You are in the exempted category (*you do not have to notify*) if you are:

- the holder of a current BPR product authorisation;
- the supporter of an active substance for which a BPD Annex I inclusion decision has been made.

Q30. Do I have to inform HSE every year if I am liable to pay the GIC?

A. No. But you should let us know if your circumstances change such that the liability criteria that apply to you are different from the ones already notified.

Q31. How do you know who to charge? If my competitors don't pay then I will be at a disadvantage.

A. We have several sources of intelligence about who is liable to pay the GIC, including UK and European Commission records of product authorisation under BPR and BPD Annex I inclusion of active substances. There is also the notification requirement written into the amending regulations (see above), bearing in mind that a person who has a duty to notify and does not is committing an offence. But if you still suspect that a competitor is evading payment you may want to inform HSE.

Offences and penalties

Q32. What will happen if I don't pay?

A: Failure to pay the General Industry Charge when liable to do so is an offence under section 33(1)(c) of the Health and Safety at Work, etc. Act 1974. HSE will take action (including court action where necessary) to recover the debt.