

# **Biocidal Product Authorisation**

## **Guidance for applicants**

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## 1. Introduction

### 1.1. Brief overview of the Biocidal Products Directive and Biocidal Products Regulations

The Biocidal Products Directive (BPD) is a European directive which introduces a common authorisation scheme covering the placing on the market of biocidal products and their subsequent use. The BPD is implemented in each Member State according to their own legislative system. In the UK BPD is implemented through the Biocidal Products Regulations 2001 (BPR). Under BPD each Member State is required to establish a Competent Authority (CA) to carry out the work of the BPD. In the UK the Health and Safety Executive (HSE) acts as the CA on behalf of Ministers.

The scope of the BPD is very wide, covering 23 different product types ([www.hse.gov.uk/biocides/bpd/23products.htm](http://www.hse.gov.uk/biocides/bpd/23products.htm)). This covers non-agricultural pesticides that are covered by the existing UK Control of Pesticides Regulations (COPR), such as wood preservatives, public hygiene insecticides, rodenticides, surface biocides and anti-fouling paints, as well as a wide range of biocidal products not currently covered by any specific legislation, such as disinfectants and preservatives. Any biocidal products that fall into these 23 product types are within the scope of BPD.

The BPD has three main aims; to harmonise the European market for biocidal active substances and products containing them; to provide a high level of protection for humans, animals and the environment; and to ensure that products are sufficiently effective against target species. To achieve this the BPD implements a positive authorisation system for active substances and biocidal products. Active substances are reviewed at European level to assess their risks and efficacy. Those considered acceptable for use in biocidal products are entered into Annex 1 of BPD.

Biocidal products may only contain active substances listed in Annex 1. A biocidal product must be assessed to determine if it can be used effectively without posing unacceptable risks, and be authorised in order to be placed on the market. The authorisation details conditions and restrictions relating to the marketing and use of the product. A product must be authorised by the CA in each Member State that the product is marketed. There are procedures in place to facilitate the acceptance of an authorisation issued in one Member State in other Member States where the product is also marketed (so-called Mutual Recognition).

More information on BPD/BPR is available from <http://ec.europa.eu/environment/biocides/index.htm> and [www.hse.gov.uk/biocides/](http://www.hse.gov.uk/biocides/).

## 1.2. Relationship between BPR and COPR

Pesticidal and biocidal products are regulated in the UK by specific legislation, principally the Control of Pesticides Regulations 1986 (COPR), the Plant Protection Products Regulations 2005, and the Biocidal Products Regulations 2001 (BPR). COPR has been in operation for many years and is a well established regime. The regulation of biocidal products in general, including those currently covered by COPR, is now starting to be harmonised in Europe through the BPD/BPR.

Over the next few years, in accordance with transitional arrangements and procedures operating under the BPR, products covered by COPR will gradually come under the scope of BPR. It is anticipated that by around 2014/2015 COPR will be phased-out and BPR will be the principal legislation covering these products.

Once a product comes into scope of BPR COPR ceases to apply (it “disapplies”) and the product is then subject to the requirements of BPR (see section 4). It must then be authorised under BPR to stay on the market.

## 2. Product authorisation under BPD/BPR

A product must be authorised to be placed on the market. When the requirements for authorisation apply to a particular product depends on the specific active substances in the product. In general terms, BPR will apply to a product once the active substance(s) within the product is listed in Annex 1 of the BPD, and the Annex 1 entry covers the product type appropriate for that product. For instance, if an active substance is listed in Annex 1 for use as a wood preservative (product type 8), it may be authorised for use in a wood preservative product, but may not be authorised for use in an anti-fouling product (product type 21) until that product type is included in the Annex 1 entry.

For products that contain an existing active substance(s) (i.e. a substance which was on the market before 14 May 2000) the BPR transitional provisions will apply (see section 4). A list of existing active substances being supported in the BPD substance assessment programme is available at [http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l\\_325/l\\_32520071211en00030065.pdf#page=37](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_325/l_32520071211en00030065.pdf#page=37). Products containing a new active substance(s) (i.e. a substance which was not on the market before 14 May 2000) must be authorised before they can be placed on the market.

When a product contains more than one active substance the product cannot be authorised until all of the active substances in it are in Annex 1. Or in other words, authorisation is possible only when the last of the active substances in the product is entered into Annex 1. As discussed below it may be possible to grant a provisional authorisation earlier than this when the decision to include the active substance(s) in Annex 1 is made but before this decision actually comes into force.

There are three main types of applications that can be made; full product authorisation, provisional product authorisation and mutual recognition of a product authorisation issued by another Member State. In addition, biocidal products may also be allowed on the market for the purposes of research and development. These are described below.

This guidance only refers explicitly to product authorisation. “Low-risk” biocidal products, which only contain active substances listed in Annex 1A of BPD, may be *registered* for placing on the market. The process for seeking product registration is essentially the same as for seeking product authorisation.

## 2.1. Full product authorisation

A full product authorisation can be granted once all the active substances in the product are actually entered into Annex 1 (i.e. when the decisions in the relevant Inclusion directives take effect). To place a product on the market before this stage it may be possible to obtain a provisional authorisation (see below).

It is recognised that for marketing and business purposes the same product (in terms of composition and intended use) may be sold by different companies (i.e. marketing companies) under different trade names. This is possible, although each individual product must still be authorised in order to be placed on the market. The concept of so-called “marketing authorisations” has been introduced to facilitate and expedite the processing of applications for such products. Just to be clear, there is only one type of product authorisation. The term “marketing authorisation” relates to an administrative processes through which an authorisation can be obtained.

In marketing authorisations each version of a product placed on the market, i.e. each individual trade name, is individually authorised. The authorisation holder for each product is the supplier (the manufacturer or formulator) of the product. The application for authorisation should specify the details of the marketing company and the trade name of the product that that marketing company will place on the market. In this case the marketing company simply sells the product and cannot themselves make any changes to it. Any changes to the product must be notified to HSE by the authorisation holder to allow the authorisation to be revised. If the authorisation expires or is revoked then the sale of that product by the marketing company would have to cease.

Where a product has already been authorised subsequent applications for marketing authorisations will usually require little extra assessment in order to grant the authorisation and so will generally be charged a lower fee.

Full product authorisations have a finite duration. The authorisation will normally last until the Annex 1 entry of any of the active substances in the product expires. Most active substances remain in Annex 1 for a period of 10 years (although after re-assessment this may potentially be extended).

## 2.2. Provisional authorisation

A full product authorisation can only be granted once all of the active substance(s) in a product are actually entered into Annex 1. The period of time from when the decision to include an active substance in Annex 1 is made and published in an inclusion directive to when the active substance actually formally enters Annex 1 can be up to 2 years. To cover this interim period the BPR/BPD allow *Provisional Authorisations*, where a product may be provisionally authorised until the active substance(s) formally enters Annex 1.

The provision for provisional authorisation only applies to products which contain new active substances; the product may also contain existing active substances. Any product containing no active substances other than existing substances is subject to the transitional provisions (schedule 13 of BPR) which do not allow for the provisional authorisations of such products.

The earliest stage in the BPD active substance programme that a provisional authorisation can be issued by the UK CA is after the initial review of the Competent Authority Report (CAR) on the active substance (and representative product containing that active substance) by Member State Competent Authorities (during the 90-day consultation period on CIRCA) has been completed and if no adverse comments have been raised. Please note that other Member States may choose to grant provisional authorisation at a different stage in the process to the UK so you should contact the appropriate CA for further details if you intend to apply for provisional authorisation elsewhere.

The information requirements and evaluation criteria for obtaining provisional product authorisation are the same as for obtaining full product authorisation. A provisional authorisation can only be granted if the criteria for a full authorisation (excluding the requirement for actual listing in Annex 1 entry) are met in relation to health and the environment and efficacy.

A provisional authorisation can be granted for up to three years, with a possible extension of a further year if the decision on Annex 1 inclusion is delayed at Commission level, at the discretion of HSE. In most cases a provisional product authorisation will become a full product authorisation once the active substance goes into Annex 1 as most, if not all, of the required assessment will already have been carried out in order to grant the provisional authorisation.

### 2.3. Mutual recognition of a product authorisation granted in another Member State

A company can seek product authorisation in any Member State. It is expected that in most cases the application will be made to the Member State that either was the rapporteur for the active substance in the product when it went through the BPD review process or to the Member State where the product will first be placed on the market. However, in principle, the application can be made to any Member State.

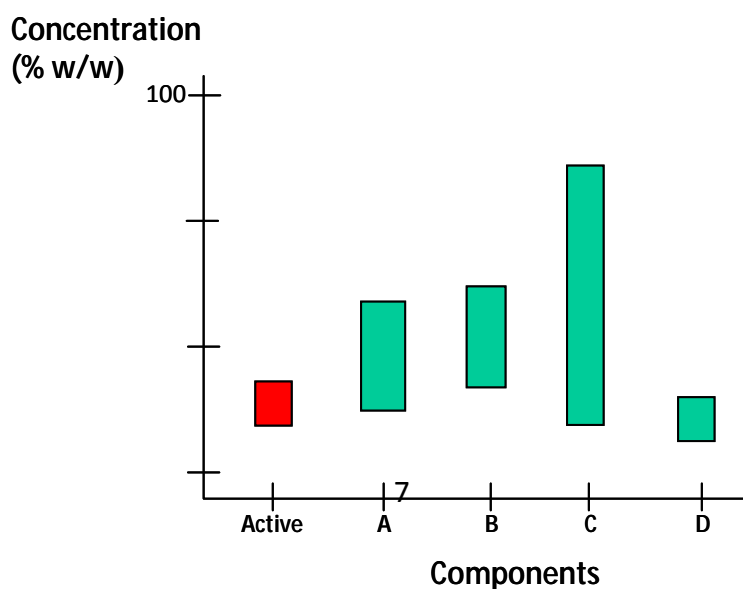
Once a product is successfully authorised in one Member State (the reference Member State) the applicant may apply for that authorisation to be recognised in other Member States. An application for such *mutual recognition* of the authorisation will need to be made to the CA in each Member State where the product will be marketed. The application cannot be made until the product authorisation has been granted in the reference Member State. It is not possible to seek mutual recognition of a provisional authorisation.

### 2.4. Frame formulations

A frame formulation is a generic specification of a biocidal product for a particular use and user type. It defines the composition of the product within specified limits.

A given frame formulation will define the active and non-active substances present and the range of concentration at which each may be present at (Figure 2). It will only cover products containing the same active substance(s) with some degree of flexibility on the presence of other non-active substance components.

The concentration ranges defined for each component in the product will usually be relatively small (perhaps a range of up to around 10% w/w between the lower and upper limit for the concentration of a particular component), depending on the nature of the substance and its properties and how its concentration may affect the product overall. For non-active substances, the concentration range could potentially include 0% to allow for products where the substance is not present. This approach might be useful for instance for products which may be marketed in a range of colours. The frame formulation could be defined to include several dyes which can be incorporated in different amounts to give the desired colours. Products of certain



colours may not need one or more of the dyes but such products would still fall within the frame formulation. A similar situation could be envisaged for products containing different perfumes etc.

Figure 2. A conceptual frame formulation.

A frame formulation will be assessed according to the same criteria as for a single product in terms of risks to health and the environment and efficacy. As a general rule, changes in composition within the frame specification should not significantly change the risks or efficacy of the products within the frame.

In general terms the assessment of the frame formulation will be conducted to assess the maximum risks to health and environment and minimum level of efficacy of products that could fall within the frame formulation. For risks to health and the environment this will usually be where the active substance(s) and any other components with hazardous properties are present at their highest allowable concentrations. Products with lower levels of these substances present will necessarily be of equal or lower risk. Similarly for efficacy, it will be necessary to demonstrate that a product containing the lowest allowable concentration of the active substance(s) is sufficient to achieve the label claims. Products with higher levels of the active substance(s) would be of at least equal efficacy. To help with this assessment it should be clearly indicated what the function (e.g. surfactant, stabiliser) of each component in the product is.

The establishment of a frame formulation will usually be done as part of an application for authorisation of a specific product that falls within that frame. Once a frame formulation is established subsequent applications for product authorisations may refer to that frame formulation. If the product is within the frame formulation then the assessment required should be minimal (presuming the same label claims etc).

## **2.5. Biocidal products placed on the market for the purposes of research and development**

In some cases a biocidal product may be placed on the market for use in an experiment or test for the purposes of research and development. Where such a product is placed on the market for this use in Great Britain the company must have the following information package :

- a dossier of information containing all available information on the possible effects of the product on human and animal health and on the environment.
- an up to date written record of information relating to that product
  - its identity
  - any data on which the information on its label should be based

- the quantity placed on the market
- the name and address of the persons receiving it

Where the product is placed on the market for scientific research and development\* this information package must be made available to HSE on request. Where the product is intended for process-orientated research and development\*\* this information package must be provided to HSE for assessment before it may be placed on the market. In both cases if HSE consider that the experiment or test is liable to have harmful effects on humans or animals or an unacceptable adverse influence on the environment then it may prohibit the experiment or test or impose conditions considered necessary to prevent those effects.

\*means scientific experimentation, analysis or chemical research carried out under controlled conditions including the determination of intrinsic properties, performance and efficacy as well as scientific investigation relating to product development

\*\* means the further development of a substance or preparation in the course of which pilot plant or production trials are used to test the fields of application of that substance or preparation

### **2.5.1. Experimental authorisation**

Where a biocidal product intended for use in any experiment or test in Great Britain which may involve or result in the release of that product into the environment, and the placing on the market has not already been granted as described above, then an experimental authorisation is required. The applicant should submit the information package described above, together with any other information relevant to the risk assessment, to HSE.

If the application is successful the authorisation will detail conditions limiting the quantity of the biocidal product that can be used and the area that can be treated, as well as any other conditions considered necessary.

When permission to market a substance for research and development purposes is given this will typically be for a period of 12-18 months, with discretion to allow it for shorter or longer periods as appropriate.

### **2.6. Emergency authorisation**

An emergency authorisation allows a biocidal product to be placed on the market for a limited and controlled use to deal with an unforeseen danger which cannot be contained by any other means. In the first instance the authorisation will last up to 120 days, with the possibility of extension or renewal if deemed appropriate.

## **3. Making an application for product authorisation**

An overview of the application process is presented in Figure 3. To make an application for product authorisation the applicant should submit to HSE a completed application form together with the required dossier of information. Applications can either be sent electronically by e-mail (preferred) or in hard copy by post. HSE will confirm receipt of the application. Unless otherwise indicated, all documentation should be in English.

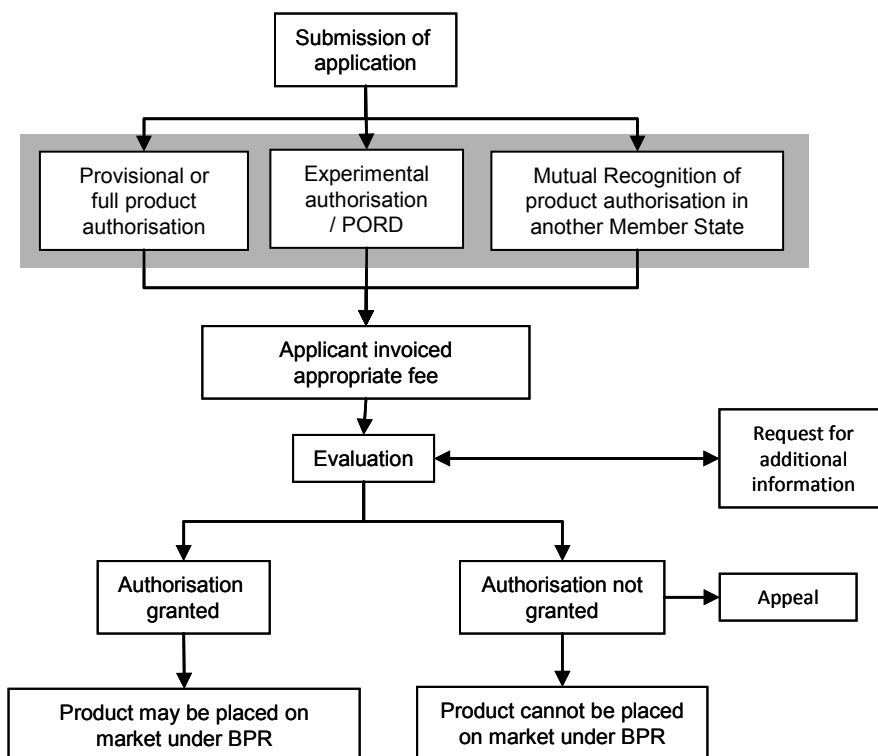


Figure 3. Overview of the product authorisation application process.

### 3.1. The application form and R4BP

The European Commission is currently developing the Register For Biocidal Products (R4BP) as a centralised system for managing much of the biocidal product authorisation work. R4BP will provide a harmonised application form to be used for making applications for product authorisations in any Member State.

The R4BP application form consists of two parts. Part 1 captures essentially administrative information on applications made and their status. Part 2 is more substantive and contains the main detail of the product for which authorisation is sought.

At the moment only Part 1 of the form is operational. This must be completed for all applications for authorisation and/or Mutual Recognition. Until Part 2 is operational, applicants should use HSE's own form (available on request).

## 3.2. Dossier of information

Each application should be accompanied by an appropriate dossier of information. Below is outlined the typical information required for each type of application. This information will in most cases provide sufficient information to assess the application. However, it is possible that additional information considered essential to the assessment may be requested on a case by case basis. The information should be submitted electronically wherever possible.

It should also be noted that the authorisation holder has a standing obligation to make known to HSE any new information of which he is aware, or may reasonably be expected to be aware, concerning the biocidal product or the active substance(s) in that product which is relevant to, and may affect, the authorisation. For instance, any new information relating to the hazardous properties of the active substance or biocidal product, changes in composition of the product, development of resistance to the biocidal product in the harmful organisms it is intended to control or other aspects such as changes to the packaging etc.

### **3.2.1. Full and provisional product authorisation**

For applications for product authorisation in the UK the following information will be required.

- R4BP form (Part 1)
- A completed application form<sup>\*</sup>
- A dossier that satisfies the requirements of the following Annexes to the BPD :-
  - For the product, Annexes IIB and IIIB<sup>\*,\*\*\*</sup>
  - For each active substance in the product, Annexes IIA and IIIA<sup>\*\*</sup>
- A copy of the proposed label (and Safety Data Sheet) for the product as it will be placed on the market in the UK

Note that some Member States require you to inform them that you intend to submit an application for Mutual Recognition at the time you make the application for product authorisation to the reference Member State (usually with at least a cover letter indicating your intentions and the R4BP form (part 1)). You should contact Member States to find out their specific requirements.

### **3.2.2. Mutual recognition**

For applications for mutual recognition in the UK the following information will be required.

For the notice of intention (i.e. when you make the application for authorisation to the reference Member State)

- A cover letter indicating that an application for product authorisation is being made in another Member State and mutual recognition of that product will be sought in the UK once that authorisation is granted (paper or e-mail)
- R4BP form (Part 1)

Once the product has been authorised by the reference Member State and a formal application for Mutual Recognition is being made to the UK

- A copy of the official authorisation granted by the reference Member State. (we receive this just as evidence that the authorisation has been granted. We will not require a version in English as all relevant information will be in the Product Assessment Report)
- A copy of the Product Assessment Report produced by the reference Member State
- A completed application form<sup>\*</sup>
- Summary dossier (Doc I-III; on CD)<sup>\*\*\*</sup>
- A copy of the proposed label (and Safety Data Sheet) for the product as it will be placed on the market in the UK

Additional information, over and above that presented to the reference Member State may be required if there are any aspects to the product or its use specific to the UK, for instance differences in aspects such as climate or type of pests.

Where the application is based on a previously authorised product, for instance when based on a frame formulation or back-to-back, then the application should simply refer to the appropriate authorisation and provide a Letter of Access for that information if appropriate.

<sup>\*</sup> R4BP form (Part 2), if available, otherwise the HSE application form

<sup>\*\*</sup> or Annexes IVA and IVB where the active/product is a micro-organism.

<sup>\*\*\*</sup> For product registrations, a dossier meeting the requirements of Schedule 4 of BPR is required.

### **3.2.3. Data protection issues and Letter of Access**

The applicant must have the legitimate use of the information provided in the application dossier. Where information is under data protection and the applicant does not own that information they must obtain a Letter of Access (LoA) from the information holder to allow them to use this information. This also applies where an applicant is referring to a back-to-back, me-too authorisation or frame formulation. The LoA should be submitted along with the application.

## **3.3. Evaluation of a product authorisation application and dossier**

### **3.3.1. Evaluation of the product**

Once received HSE will endeavour to process the application to a conclusion as quickly as possible. The submitted application and dossier will be evaluated according to the determinations referred to in Schedule 3 of BPR in relation to risks to health and the environment, intended use and efficacy. This will involve risk assessment for human health and the environment in the context of the intended use and users (e.g. amateur, professional or Industrial), and to establish any necessary conditions and/or restrictions on the use. In addition, the efficacy in relation to the label claims will be evaluated to ensure that the product has the claimed biocidal activity. In short, the evaluation is intended to ensure that the product may be used safely for the intended use and that the product works.

The dossier provided (as specified above) should include all the information required to perform this assessment but HSE may, where necessary, request additional information from the applicant.

If the biocidal product is in the form of a bait station or other physical device then HSE may request a sample to inform the risk assessment.

### **3.3.2. Labelling**

The proposed label will be assessed to ensure that it complies with the requirements of BPR. In general, the label will be considered in terms of whether it correctly and appropriately describes the product; for instance in terms of the correct classification and associated symbols and phrases and label claims etc (see Schedule 9 and Regulation 31 of BPR 2001 for further details).

HSE will not, in general, comment on other aspects of the label, such as marketing aspects or graphics, unless it impacts on the key information.

## **3.4. Outcome of the evaluation**

### ***3.4.1. The application for product authorisation is successful***

Following a successful evaluation of an application HSE will issue a product authorisation certificate to formally document the authorisation. The certificate will formally document the details of the product authorisation; the unique authorisation number, the product name, composition and product type and present any conditions and restrictions that also apply. The certificates will be sent directly to the applicant, usually by e-mail.

Once the authorisation is granted that product may be placed on the market in the UK, in a manner consistent with the conditions and restrictions associated with the authorisation.

### ***3.4.2. The application for product authorisation is not successful***

Where an application does not meet the required standards we will not issue an authorisation. The applicant may have the opportunity to modify/update their application in order to make it acceptable. We have open lines of dialogue with applicants to facilitate this.

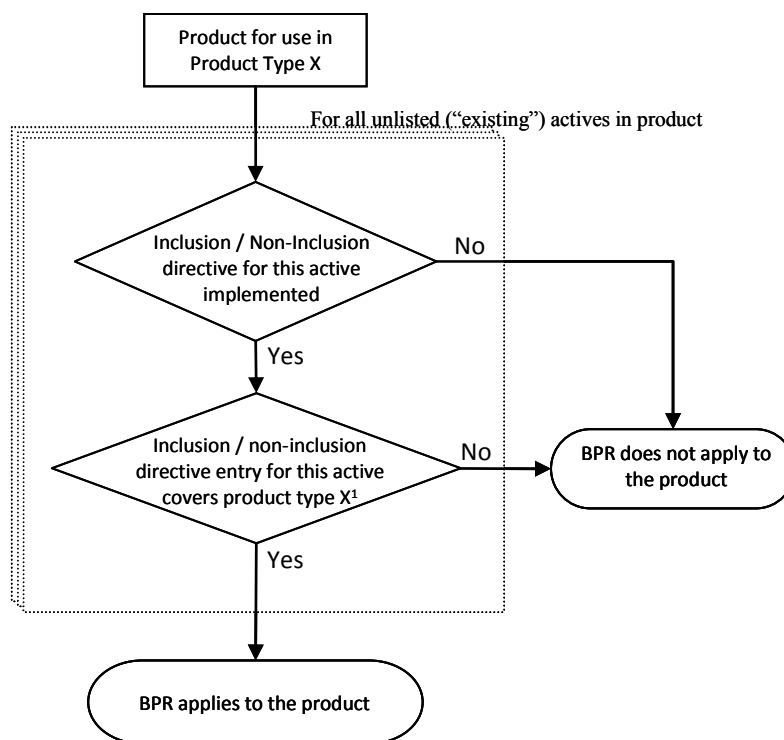
When an authorisation is not granted the product may not be placed on the market in the UK. If the application relates to an existing product (e.g. one containing existing active substances already on the market) then it will need to be removed from the market as soon as possible. HSE will issue a Certificate of Exemption to provide a reasonable amount of time for this to occur.

## **4. Transitional provisions for biocidal products containing “existing” active substances**

### **4.1. General provisions**

Biocidal products that contain only existing active substances are subject to the transitional provisions presented in BPR (Schedule 13). These provisions detail when such products come under the scope of BPR.

Briefly, for a biocidal product for use in a particular product type that contains a single existing active substance BPR applies when the decision to include that active substance in Annex 1 or exclude it from Annex 1, as detailed in the inclusion or non-inclusion directive, respectively, takes effect. The Annex 1 entry or non-inclusion directive should cover the specific product type for the product in question. For products containing more than one existing active, BPR applies when such a decision has come into effect for each and all of the existing actives present (Figure 4).



<sup>1</sup>taking into account any other requirements specified in the inclusion/non-inclusion directive

Figure 4. When products containing existing active substances are subject to BPR

Once BPR applies to a product, that product must be authorised by HSE to be placed on the market and used in the UK or it must otherwise be removed from the market and supply chain.

The transitional provisions provide for the product to be exempt from the requirements of BPR for a period of time during which an application for authorisation is made and assessed, or during which the product is removed from the market and supply chain (“phased-out”). This is facilitated through the Certificate of Exemption.

***Important note. This provision for a transitional period for existing active substances is at variance with the way in which BPD has been implemented in other Member States. Most other Member States require an application for product authorisation to be made by the date of inclusion. Where an application for mutual recognition will be sought most Member States require a formal letter to indicate this together with the summary dossier to be submitted to them by the date of inclusion. If this is not done the Member State may refuse the subsequent application for mutual recognition. You should check the specific requirements with the relevant Member States.***

#### 4.1.1. Products already on the UK market

For products approved under the COPR scheme, these will continue to be covered by COPR until BPR applies. Once BPR applies to a product the COPR approval disappplies immediately. A “notice of revocation” will be issued for these products at least 6 months in advance of this to give COPR approval holders notice of this change. At this stage the approval holder should decide whether they intend to seek authorisation of the product under BPR or whether they will take the product off the market. If an application for authorisation is made the product can stay on the market whilst the application is assessed.

Some products will be on the UK market that are not covered by COPR, for example disinfectants and preservatives. If a company wishes to keep these products on the market and seek authorisation of the product they should submit an application for authorisation by the appropriate date. The application should include some proof that the product was on the UK market prior to the Annex 1 date. The product may then be kept on the market whilst this application is assessed.

#### **4.1.2. Products not currently on the UK market**

The transitional provisions do not apply to products that were not on the UK market when BPR started to apply. Such products may only be placed on the market once an authorisation is obtained.

In cases where a company wish to seek authorisation for a product which is a slightly modified version of an existing COPR-approved product which is already on the market there are two potential approaches.

- i) Seek an amendment of the COPR-approval so that the approval covers the proposed new product. This product would then be subject to the transitional provisions and could be placed on the market immediately without having to wait for an authorisation to be granted.
- ii) Apply for authorisation of the new product whilst phasing-out the COPR-approved product. The authorisation of the new product should be given before the COPR-approved product must be removed from the market providing some degree of continuity.

#### **4.2. Certificates of Exemption**

A Certificate of Exemption (CoE) exempts a person(s) and/or biocidal product(s) from certain requirements of the BPR (relating to placing on the market, use, packaging and labelling, and storage). CoEs are used primarily to allow companies to keep a product on the market whilst they obtain an authorisation under BPR, or to give them a reasonable amount of time to take the product off the market and phase it out of the supply chain.

The duration of the CoE will vary depending on what the CoE is being issued for and the nature of the particular product, but will not exceed a period of 3 years and in

most cases will be considerably shorter than this. A CoE can be revoked at any time if there is due cause (e.g. if new concerns about the product arise).

CoEs for specific cases are described below.

#### ***4.2.1. CoE to cover an application for an authorisation submitted to the UK***

By the date that BPR applies to a product the person responsible for first placing that product on the market in the UK must have submitted an application for authorisation to HSE\*. Once an application is received a CoE will be issued which exempts the product from BPR until the application has been processed by HSE and a decision reached. If the application is successful then the product will then be authorised under BPR and can remain on the market.

If an application is made but is unsuccessful then the product must be removed from the market. Another CoE will be issued to cover a period of time to allow this to happen (see 4.2.3).

\*This is a change from the previous situation where a CoE could be granted to allow the applicant a 3-month period after this date to submit their application. This change is being made to bring the UK into line with the BPD and other Member States and will be incorporated into the next revision of BPR which is due to be implemented in April 2010.

#### ***4.2.2. CoE to cover an application for mutual recognition of an authorisation given by another Member State***

Similarly to where an application for authorisation is made directly to the UK, a CoE may also be issued to cover the period of time where an application for authorisation is being made in another Member State following which an application for mutual recognition of that authorisation in the UK will be requested. The product must already be on the UK market, otherwise it cannot be placed on the UK market until it has been authorised by the other Member State and the application for mutual recognition has been received.

In response to a “notice of intention” to seek mutual recognition of such an authorisation in another Member State HSE will issue a CoE which will last until a decision on the application in the UK is made.

#### ***4.2.3. CoE to cover removal of the product from the market***

Where there is no intention to make an application for authorisation under BPR of a product already on the UK market, or where an unsuccessful application for authorisation has been made, the company should seek to take the product off the market and phase it out of the supply chain. A CoE will be granted to cover this

period of time. In general, these CoEs will support a sequential phase out of the product over a total period of 18 months, allowing 6 months to cease first placing on the market (i.e. by the manufacturer/formulator), a further 6 months to cease retail sale (i.e. by distributors and retail outlets), and a final 6 months to cease use (amateur and professional) and for storage and disposal.

Once this CoE has expired it will be illegal to market and use the product. Only storage for disposal and storage for export outside the EU will be allowed. With this in mind companies should aim to have no more product in the supply chain by the end of the 18 month period. In addition, they should try to ensure that any product sold during this period has a reasonable chance of having been used. Obviously a supplier will have less control over this latter aim but a knowledge of how quickly stock is sold from outlets and the use pattern of the product etc will inform when they should stop supplying to the market to try to achieve this.

### **4.3. Applying for a CoE**

An application for a CoE should be made in writing (letter or e-mail) to HSE.

The application just needs to indicate the product for which the CoE is requested, and what type of CoE is requested (e.g. to allow time for an application to be made or for a phase-out period). Where the product is approved under COPR the application need only give the product name and COPR approval number. For other products (i.e. those on the market but not covered by COPR (such as disinfectants), or those not yet on the market) the application should include details of the product name, composition and use details (including a safety data sheet if available).

## **5. Fees and charges**

BPD requires that all Member States recover the costs they incur in operating this regulatory regime. In the UK this is achieved by charging those who place biocidal products on the UK market. The charges are made in terms of a general Industry-wide charge and fees for work related to a specific application for product authorisation ([www.hse.gov.uk/biocides/bpd/charges.htm](http://www.hse.gov.uk/biocides/bpd/charges.htm)).

### **5.1. The General Industry Charge**

The General Industry Charge (GIC) is an Industry-wide charge to cover costs for on-going general activity carried out by the UK authorities in operating the biocidal products regulatory scheme and involvement in related work at Commission level. The GIC is recovered by way of an annual charge. It is mandatory for companies who wish to market biocidal products to pay the GIC.

### **5.2. Fees for product authorisation**

There will be a fee to cover the processing of each application for product authorisation. The exact fee structure is still being developed. In general, the fees will reflect the amount of assessment required to process the application. For the most straightforward cases a basic fee of around £2000 will be charged. For instance where the product is the same or substantially similar to the representative product or where the product is the same as one already authorised (e.g. in a back-to-back application, or based on an existing frame formulation). When more evaluation is needed then the fee will be correspondingly higher to reflect this.

There will be no charge for obtaining a Certificate of Exemption.

## **6. Appeals procedure**

Where an applicant disagrees with a decision reached by HSE or has any other complaints in relation to product authorisation they should first take this up with the product authorisation team to try to resolve the issue. If there is no resolution then the applicant may submit a complaint or a request to start formal appeal proceedings by e-mail or in writing to :

The Director  
Chemical Regulations Directorate  
2.3 Redgrave Court  
Bootle L20 7HS  
[PA.biocides@hse.gsi.gov.uk](mailto:PA.biocides@hse.gsi.gov.uk)

## **7. Contact details**

The biocidal product authorisation team can be contacted using the details below.

Biocidal Product Authorisation Team  
2.3 Redgrave Court  
Bootle L20 7HS  
[PA.biocides@hse.gsi.gov.uk](mailto:PA.biocides@hse.gsi.gov.uk)