

# Frequently Asked Questions on Biocides

## **What is the background to the Biocidal Products Directive (BPD)?**

In 1993, the European Commission proposed a Directive to establish a single European market in biocides by introducing a harmonised authorisation system based on assessment of risks to people and the environment, together with consideration of efficacy. This became the Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market - commonly known as the 'Biocidal Products Directive' (BPD) or simply the 'biocides directive'. The BPD entered into force on the 14th May 2000.

The Directive has two central objectives:

- to harmonise the European market for biocidal products and their active substances so that once a product is authorised in one Member State under the Directive that authorisation can be recognised in the other Member States;
- to provide a high level of protection for people, animals and the environment.

Each European Union Member State is responsible for implementing the BPD.

## **What is a biocide/biocidal product?**

The Biocidal Products Directive (BPD) gives a formal definition of biocidal products as:

"Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means."

So despite the name 'biocide', a biocidal product does not actually have to kill. If it is used to destroy, deter, make harmless, or control a harmful organism by chemical or biological means it may be considered to be a biocide. For example a repellent used to 'deter' a mosquito could be considered to be a biocidal product.

## **What types of product are covered by the BPD?**

The scope of the BPD is very wide, covering 23 different product types. This includes disinfectants for home and industrial use; preservatives for manufactured and natural products; non-agricultural pesticides for use against insects, rodents and other vertebrates and specialised products such as embalming/taxidermist fluids and antifouling products. A full list of product types is in Annex V of the BPD.

The BPD excludes the non-biocidal uses of products and active substances. It also does not apply to products regulated under certain other European Directives including plant protection products, human medicines, veterinary medicines, medical devices or cosmetics. Article 1 of the BPD gives a full list of these Directives.

### **How does the BPD work?**

The BPD achieves its aims using a two-stage regime of rigorous evaluation of biocidal active substances and products, to ensure they pose no unacceptable risks to people, animals or the environment.

Ultimately only those biocidal products which contain an active substance which is included in Annex I of the Directive will be authorised for use. Active substances have to be evaluated to ascertain whether or not they will be included in Annex I. This requires industry to submit data which is evaluated by Member States with decisions over Annex I inclusion being taken at the European level. Industry is charged a fee for this process. Once an active substance has been included in Annex I, national Competent Authorities can authorise products containing it in individual Member States (providing that any necessary data have been supplied and any conditions put on Annex I inclusion are met). Once a product has been authorised in the first Member State, it will be possible for it to be mutually recognised and therefore authorised by other Member States (providing relevant conditions are similar). However, there will have to be an application to other Member States, and again there will be a fee for these processes.

### **What is Annex I of the BPD?**

Annex I is a list of active substances that have been assessed and considered to be acceptable for use in biocidal products.

### **What is an existing biocidal active substance and what is a new biocidal active substance?**

All biocidal active substances which have been on the EU market before the 14 May 2000 and which have been Notified or Identified according to the Commission Regulation EC/1896/2000 (the First Review Regulation) are considered as existing biocidal active substances. Biocidal active substances, which have not been on the EU market before the 14 May 2000 and have not been notified or identified, are new biocidal active substances, which have to be assessed according to the BPD before biocidal products containing them can be placed on the EU market.

### **What is Identification and Notification and what is the difference between an identified and a notified existing biocidal active substance?**

The First Review Regulation (EC/1896/2000) required producers and/or formulators of biocidal active substances to inform the EU Commission by 28 March 2002 of their intentions with respect to the biocides review programme. They could either identify or notify an existing active substance.

#### **Identification**

If industry did not intend to support an active substance through the BPD review programme they had the option to Identify that substance by providing the information specified in Annex I of the First Review Regulation. Identification was a relatively simple procedure in which essential information on the identity, uses etc of the active substance had to be sent to the European Chemicals Bureau (ECB). Identification allowed biocidal products containing that substance to continue to be marketed during a 'phase-out' period, which requires such products to have been removed from the EU market by 1 September 2006.

#### **Notification**

An active substance could be Notified where industry intended to support it through the BPD's review programme for possible inclusion in Annex I. They had to supply the information specified in Annex II of the First Review Regulation to the European Chemicals Bureau (ECB). A Notification required submission of summary data on the essential hazards and it required that in the next phase of the review a full dossier is to be provided of all the data and other information needed for the evaluation of the active substance for possible inclusion in Annex I. These notified substances are listed, along with the product types the Notifier intended to support them in, in Annex II of the Second Review Regulation and an updated list in Annex II of the Third Review Regulation. Biocidal Products marketed in the notified product types can stay on the market until the actives have been reviewed and it is decided whether or not they are included on Annex I of the BPD.

### **What happens if an active has been neither Identified nor Notified?**

If an active substance has been neither Identified nor Notified then it cannot be used in biocidal products placed on the EU market. The active substance would be treated as a 'new' active substance, which has to be assessed under the BPD and gain Annex I inclusion before products can be authorised and placed on the EU market.

### **What happens if an active has been Notified for use in my product type?**

If an active substance has been Notified for use in a product type then products containing that active substance can be placed on the EU market (subject to any requirements under existing national legislation), until the review has been completed. If following review, an active substance is included on Annex I of the BPD, then those companies who supply biocidal products containing that active substance will require authorisation if their products are to remain on the market. This will include a requirement to provide a letter of access to the data used to confirm the Annex I entry. If inclusion in Annex I is not possible then products containing that active substance can no longer be placed on the EU market.

### **What is the transitional period?**

Under the BPD the 'Transitional Period' is where existing biocidal active substances are in the process of transferring from EU Member States national legislation to regulation under the BPD. This is being carried out by the biocides review programme, which is expected to run for a period of 10 years from the date of implementation (14 May 2000), Notified biocidal active substances are being reviewed in groups according to their intended uses. During this transition period existing national legislation in Member States on the marketing of biocidal products will continue to apply until such a time as biocidal active substances are included, or a decision is taken to refuse inclusion, in Annex I of the BPD.

### **What do I need to do when applying for a 'new' active substance under the BPD?**

Application dossiers are packages containing all the necessary and relevant information required by a Competent Authority (CA) to evaluate whether Annex I listing is appropriate for that active substance. The application for a new active substance must include a dossier of information on the active substance and a dossier on at least one product for each product type containing the active substance. The data requirements are outlined in Annexes II and III of the BPD.

A company wishing to apply for a new active substance under the BPD should speak to the relevant Competent Authority (CA) regarding the application as they can advise on

any requirements the application may require in addition to those outlined in the core data requirements. Applications for a new active substance may not be given priority as workloads may dictate that a CA must complete evaluations under the review programme prior to beginning evaluations of new active substances.

**Is the information required for a 'new' active substance the same as that for an existing active substance which is being supported in the biocides review programme?**

Yes, the information required for a new active substance and an existing active substance in the biocides review programme is essentially the same. The data requirements are outlined in Annexes II and III of the BPD.

When applying for a 'new' active substance then you can choose when and to which Member State you submit your application to.

In the biocides review programme existing active substances are assigned to a Member State with set deadlines for dossiers.

**What do I need to do if I want to put a new product on the EU market?**

To place a biocidal product on the EU market you need to check if the active substance(s) in your biocidal product has been Identified or Notified for that particular use.

If on checking you find that:

- An active substance has been neither identified nor notified (it is not on the Annexes) then it cannot be used in biocidal products placed on the EU market. The active substance would be treated as a 'new' active substance, which has to be assessed under the BPD and gain Annex I inclusion before products can be authorised and placed on the EU market.
- An active substance has only been identified but not notified, or notified but not for your particular product type, such products can only be placed on the EU market (subject to any existing national legislation), until **1 September 2006**. By this date the products would have to have been removed from the market. Companies wishing to market biocidal products containing these active substances after 1 September 2006 would have to apply for the active substance as a 'new active which has to be assessed under the BPD and gain Annex I inclusion before products products can be placed on the EU market.
- If an active substance has been notified for use in a product type, then products containing that active substance can be placed on the EU market (subject to any requirements under existing national legislation), until the review has been

completed. If the active substance is successful in gaining Annex I inclusion, then products containing the active substance will need to be authorised under the BPD if they are to remain on the market. If inclusion in Annex I is not possible then products containing that active substance can no longer be placed on the EU market.

### **What will happen once an active substance is included on Annex I of the BPD?**

Once an active substance gains Annex I inclusion then those companies who supply biocidal products containing that active substance will be required to gain authorisation for their products under BPD if they intend for them to remain on the market. Applicants for authorisation will require:

- a letter of access to the dossier supporting Annex I inclusion of the active substance in their biocidal product (or they can provide their own active substance dossier) and
- either a product dossier or a letter of access to one, for their biocidal product. The product dossier will need to meet the requirements set out in Annex IIB and relevant parts of IIIB of the BPD.
- There will be a time limit for products containing Annex I listed active substances to be authorised.

### **Once my product is authorised, can I sell it in any Member State?**

Once an authorisation has been granted by one Member State, then authorisation may subsequently be granted in other Member States upon application, unless there are specific grounds to derogate. This is known as mutual recognition.