



# BIOCIDES FACT SHEET



Biocidal Products Directive  
Biocidal Products Regulations  
Control of Pesticides Regulations

Issue No. 25

January 2006

This is the last paper edition of the Biocides Fact Sheet. Future editions will be available electronically on our website. If you wish to be notified of future Fact Sheet publications by email alert please see Section 1.

## Purpose

This Fact Sheet provides information for manufacturers, suppliers and users of active substances and biocidal products to help keep you up to date with developments in the Biocidal Products Directive (BPD) 98/8/EC and the Biocidal Products Regulations 2001. It also incorporates information concerning the Control of Pesticides Regulations that would previously have appeared in the 'Pesticides Newsletter', which has now ceased publication.

Fact Sheet 25 is **not** a revision of Fact Sheets Nos.1-24 but provides current supplementary information and advice. All Fact Sheets are available on our website at [Biocides Factsheets](#).

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## **General Information**

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### **1. FUTURE AVAILABILITY OF THE FACT SHEET**

This is the last paper edition of the Biocides Fact Sheet. To improve efficiency we will no longer be sending out a paper version to all those people on our mailing list. The fact sheets are already available on our website at [Biocides Factsheets](#) and future editions will be available here too. If you wish to be notified by an email alert when a new edition is published then please email Gavin Rutherford at: [gavin.rutherford@hse.gsi.gov.uk](mailto:gavin.rutherford@hse.gsi.gov.uk) with the following details or you can send him these details to the address at the end of this Fact Sheet.

Your:

- Email address
- Name
- Company/Organisation
- Address
- Telephone Number

## **2. CHANGES AT THE BIOCIDES & PESTICIDES UNIT (BPU)**

The Biocides and Pesticides Unit (BPU) is undergoing a number of changes, which will affect the service we provide to stakeholders and the way we will operate in the future. These changes are as follows:

### Change in Office location

A major impact on staff and the way we work is the relocation of all HSE staff to a new purpose built office, 'Redgrave Court', which is near our current location in Bootle, Merseyside. The move to the new building is scheduled for the weekend of 28<sup>th</sup>-29<sup>th</sup> January 2006. The move may naturally cause some operational teething problems and we ask for your patience over this time, especially the few days before and after the move where there may be a restricted service.

Individual telephone numbers will not be changing and any post delivered to the 'old' building address will be redirected automatically to the new address, which is:

Health & Safety Executive  
Biocides & Pesticides Unit  
Building 1, 3<sup>rd</sup> Floor  
Redgrave Court  
Merton Road  
Bootle  
Merseyside  
L20 7HS

The new office is open plan and one of the implications of this on the way we currently operate is that we will have very limited on site storage space. The files relating to the Control of Pesticides Regulations (COPR) work and many BPD files have been moved off site for storage in a central registry. This means that we no longer have instant access to files and have to recall files back from registry, which can take a number of days.

Whilst we do hold a large amount of information electronically we still need the hard paper files for much of the work we do. This means that we will not always be able to provide replies to certain questions and queries on the same day, something we have been able to do in the past. We will of course always endeavour to meet our agreed service standards.

### Changes in the 'way BPU works'

In order to meet the demands of the BPD, managers in BPU have made changes in the unit structure, which has led to a number of changes to staff roles and responsibilities. Some of the people you may have dealt with on a particular issue in the past may have changed and some familiar faces/voices may have moved on to undertake different areas of work.

### New Staff

BPU has recently undertaken a successful recruitment campaign to fill existing posts that have been vacated due to staff leaving the unit. We have taken on 8 'new' members of staff, who are currently undergoing training in pesticides and biocides work.

### Company Meetings

BPU has had to reconsider the way we can accommodate meetings with industry. Due to the open plan nature of the new building, there will be reduced capacity to hold meetings. There are meeting rooms in the new building but demand for these will naturally be heavy.

Whilst we will endeavour to be flexible we have had to put some limitation on meetings and have decided to introduce an appointment system for company meetings. In addition we are also considering that it may be necessary to make a charge to those companies/consultants who do not pay the General Industry Charge (GIC) for meetings held.

From January 1<sup>st</sup> 2006 the following will apply:

- All requests for meeting should be made by e-mail to:  
[gill.fod.smith@hse.gsi.gov.uk](mailto:gill.fod.smith@hse.gsi.gov.uk)
- You should:
  - Provide details of the issues you want to discuss, preferably in an agenda format.
  - Give an indication of the date you would prefer and we will try and accommodate this.
  - Provide details of the number of people you wish to bring to the meeting (we may have to limit numbers).
  - State if you require car parking space and directions to 'Redgrave Court'.
- Requests will then be agreed or not by BPU management and a meeting coordinator will contact you to confirm arrangements.

### Communication with stakeholders

We will be reviewing the way we communicate with our stakeholders particularly industry. We will be making changes to current practices to enable us to communicate more efficiently and effectively.

One example of this is how we feedback from the Competent Authority (CA) and Technical Meetings (TM). We will no longer produce a detailed report of the meetings, but will list the agenda and give a summary of the main items which have been agreed that will directly affect industry.

### Changes at Rose Court

'Rose Court' is the location of the London based policy headquarters of HSE. Many of you will know Stuart Smith 'our man in policy' from the industry seminars. Stuart retired in November 2005 and has now left the world of pesticides and biocides behind him. He has been replaced by Kevin Walken, who will take over some of Stuart's responsibilities.

### Retirement of Paul Oldershaw

Paul Oldershaw retired from HSE in January 2006. For those of you who know Paul, he worked in HSE for more than 30 years, in the field of occupational hygiene. For many years he headed the Division of which the Biocides & Pesticides Unit was part.

## **3. BPU INDUSTRY SEMINAR**

In the past BPU have run Seminars for Stakeholders. These events have provided a forum for HSE to communicate information to stakeholders about developments in Pesticides and Biocides legislation. The last one was held in May 2004 and some stakeholders have suggested that it would be timely to hold another. We are interested to hear your thoughts on this issue and are asking you to provide appropriate items for discussion. We feel that as well as BPU staff giving presentations it would be of benefit for industry to also present their views.

Whilst they are important, there are certain areas which have not developed since they were last discussed and so there is no value in them being the subject of presentations at this stage. These are Post Annex I procedures and what an Annex I entry looks like. These are issues we continue to push forward in Europe and any developments will be reported back to you in the usual way.

We look forward to your replies and will make our decision about a future event based on your responses. If there is insufficient material or an obvious lack of interest we are likely to defer holding a seminar.

Please reply to Mike Potts at the address at the end of this Fact Sheet.

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## **Biocides - European Activities**

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## **4. REPORT ON THE 20<sup>TH</sup> MEETING OF THE COMPETENT AUTHORITIES (12-13 DECEMBER 2005, BRUSSELS)**

### **Agenda Items/Summary**

- Klaus Berend (chair of the CA Meetings) is leaving to take up a position with DG Enterprise at the EC. His replacement is not

- known but will be in place by the next Competent Authority (CA) meeting, which he/she will chair.
- Bobby Arash (legal adviser on biocides) is also leaving to take up a position with industry in the USA; his exact departure date is unknown.
  - UK will lead discussions on guidelines/methods for the chromium efficacy/lack of efficacy issue. We will prepare a paper for the next Technical Meeting (TM) and will evaluate data from UK and German industry on behalf of all Member states.
  - UK, working with Austria & the Netherlands, will prepare a paper explaining Frame Formulations. This will be based on real examples from the UK national scheme with an input from industry. AISE (The international Association for Soaps, Detergents and Maintenance Products) have already sent us their position.
  - The Commission presented a draft Directive for the Annex I entry.
  - The Commission are preparing a database to hold product details to assist in product evaluation and mutual recognition, post Annex I.
  - UK, Sweden & the Netherlands are working on guidelines (which will include timescales) for post Annex I procedures. The guidelines will be presented at the next TM.
  - The Commission presented a paper suggesting what the Annex I entry should look like. We agreed that this should be minimalistic but linked to the CA evaluation on the active substance via an 'Executive Summary'. The UK will draft examples based on sulfuryl fluoride & dichlofluanid.
  - Parallel imports. The Commission presented an information paper on this subject. The UK does not propose to establish any specific procedures and will deal with any requests in the same way as 'normal' requests for the authorisation/registration of biocidal products.
  - Confidentiality and the public version of draft CA report. Procedures will be discussed at the next TM - UK will draft a paper.
  - Commission presented a paper on 'phase out period' for list B. The proposed date of 31 Dec 2007 by which all products containing non-supported actives should be off the market was agreed.
  - Industry fed back their views on the evaluations of sulfuryl fluoride. They wanted an agreed Acceptable Operator Exposure Concentration (AOEC) for all users (including Plant Protection Product uses).
  - Exchange of information on fees. The Commission repeated that this was a national issue. UK suggested that Member states kept a record of time spent and charged accordingly.
  - A proposed common approach for HCHO (formaldehyde) releasing products was presented by Austria and agreed. Industry will be involved re their specific task force on this subject.
  - Next meeting dates: 27-31 March 2006(TM); 10-11 April 2006(CA)

A meeting of the Standing Committee on Biocidal Products was held on 14 December 2005 at which Member states voted on and agreed a Commission

Directive that amends Annexes IVA and IVB of the BPD. This sets out the data requirements for microorganisms including viruses and fungi.

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## **Biocides - UK Activities**

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### **5. THE BIOCIDAL PRODUCTS (AMENDMENT) REGULATIONS 2005**

The Biocidal Products (Amendment) Regulations 2005 (SI 2005/2451) came into force on 1<sup>st</sup> October 2005. They correct an error in the Regulations under which an annual charge (the General Industry Charge) is made to the biocides industry.

The Biocidal Products Directive (article 25) requires that member states recover the costs they incur in operating the system. The Regulations implement this requirement by setting up a two-component charging system:

- i. Individual fees are charged to applicants for the work done in processing their active substance or product dossiers.
- ii. The balance of the other costs for operating the system are covered by means of a General Industry Charge (GIC).

It was intended that two industry sectors would be liable to pay the GIC immediately:

- i. Those supplying biocidal products.
- ii. Those supporting active substances in the review programme.

However suppliers of biocidal products currently on the market were inadvertently excluded from requirements to pay the GIC. All those affected by this exclusion have already been contacted to explain the position.

Because the amendment corrects an error in the 2003 Regulations, the 2005 Regulations containing the correction have been issued free to those who bought copies of the 2003 Regulations (SI 2003 No.429). Copies of the 2005 Regulations are available at: [OPSI Website - Statutory Instrument 2005 No. 2451](#).

### **6. REMINDER – SEPTEMBER 2006 DEADLINE FOR ‘IDENTIFIED’ ONLY ACTIVE SUBSTANCES FOR PRODUCT TYPES 8 (WOOD PRESERVATIVES) AND PRODUCT TYPE 14 (RODENTICIDES)**

We would like to remind stakeholders of the article in the September 2005 edition of the Biocides Fact Sheet concerning future regulatory action BPU will be undertaking on ‘identified’ only active substances

As you should be aware, from **1<sup>st</sup> September 2006** biocidal products containing active substances that have **only** been ‘identified’ under BPD and active substances that have been ‘notified’, but where specific product types

have not been supported by that notification, cannot be placed on the EU market or subsequently stored for any purpose (except for export and disposal).

Approval holders with current COPR registration/s will receive a 'notice' document, which will void the approval with effect from 1<sup>st</sup> September 2006. This 'notice' will be sent out after the 1<sup>st</sup> March 2006, but will not impact until 1<sup>st</sup> September 2006.

Remember it is your responsibility to ensure that biocidal products containing active substances affected by this do not remain on the EU market after the 1<sup>st</sup> September 2006.

## **7. USE OF PHOSPHORIC ACID IN WOOD PRESERVATIVES**

Wood preservative products that contain phosphoric acid cannot be placed on the EU market from 1st September 2006 as phosphoric acid has only been notified in product type 4 (food and feed area disinfectants) but not in product type 8 (wood preservatives). For wood preservative products containing phosphoric acid to remain on the market after 1st September 2006 companies would need to provide evidence such as efficacy data to demonstrate that the phosphoric acid in the product is not acting as an active substance. We would need to have received this evidence by the 1st March 2006 to allow it to be assessed and discussed with other Member States before the September 2006 deadline. This situation is similar to that of chromium, details of which can be found in the last Fact Sheet (Issue No. 24).

## **8. PHASE-OUT PERIOD FOR THE PLACING ON THE MARKET OF BIOCIDAL PRODUCTS IN PRODUCT TYPES 16, 18, 19 & 21 (MOLLUSCICIDES, INSECTICIDES, REPELLENTS/ATTRACTANTS AND ANTIFOULING PRODUCTS) CONTAINING ACTIVE SUBSTANCES FOR WHICH ALL PARTICIPANTS WILL HAVE WITHDRAWN OR FOR WHICH NO DOSSIER WILL HAVE BEEN SUBMITTED**

Further to the feedback from the Competent Authority meeting held in December 2005, the same procedures taken for active substances listed in **Part A of Annex V** of Regulation 2032/2003 (Second Review Reg) have to be followed for those listed in **Part B of Annex V**. This means that the following steps will be followed for product types 16, 18, 19 & 21 (molluscicides, insecticides, repellents/attractants and antifouling products):

- i. The Commission will list those active substance/product type combinations listed in Part B of Annex V, where **no dossier** is submitted or participants withdraw support on its website by **31<sup>st</sup> May 2006**.
- ii. Other companies or Member States then have **three months** to inform the Commission whether they wish to take over the role of

participant for the existing active substance/product type combinations concerned. So the deadline will be at around **31<sup>st</sup> August 2006**.

- iii. For those active substance/product type combinations, for which no company or Member State wishes to take over, the Commission will prepare a formal decision of non Annex I inclusion and establish the phase-out period for products containing the active substances in the product types concerned.

The EU process for adopting the decision is quite lengthy and involves:

- drafting of the text, interservice consultation, translations (around 2 months)
- formal vote in the Standing Committee (1 month)
- information to the European Parliament (standstill 1 month) and notification to the World Trade Organization (WTO) (standstill 2 months)
- procedures for formal adoption (1 month)
- publication in the Official Journal (OJ)(1 month)

So the Decision could be published and enter into force in March 2007 (i.e. 11 month after submission deadline). Given that substances listed in Part B of Annex V have already benefited from longer marketing than those in Part A, the phase-out deadline for placing on the market has been agreed by Member States and the Commission of **31<sup>st</sup> December 2007**. Substances in the product types in Part B, for which submitted dossiers are found to be incomplete, will be given the same deadline.

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## **Control of Pesticides Regulations Specific Information**

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### **9. EVALUATION OF FUTURE APPLICATIONS FOR APPROVAL UNDER COPR**

BPU will no longer be accepting applications for approval under COPR for non-agricultural pesticides containing active substances that have **only** been 'identified' under BPD or for non-agricultural pesticides containing active substances that have been 'notified', but not in the product type that the new product application would fall into. There is little point granting COPR approval this close to the 1<sup>st</sup> September 2006 deadline considering the time needed to obtain approval and get a formulation packaged and ready for the market.

All applications falling into this category will be sent back to the applicant with a note explaining that they cannot be processed.

It is the applicant's responsibility to ensure that any new product applications (including reformulations) made under COPR contain active substances that are being supported through the EU review program and applicants are advised to consult the ECB website ([ECB Website - Biocides](#)) for details of the active substances that are being supported.

Applications containing active substances 'upgraded' after 1<sup>st</sup> March 2006 will be dealt with on a case-by-case basis.

## **10. WILDLIFE INCIDENT INVESTIGATION SCHEME (WIIS) - CURRENT AND FUTURE POSITION ON FUNDING**

Approval Holders will be aware that the funding for WIIS is currently recovered from the pesticides levy. The costs are divided between the agricultural and non-agricultural pesticides industry, and the Pesticides Safety Directorate and HSE.

In the future, as products are authorised under the Biocidal Products Directive, approvals under the Control of Pesticides Regulations will lapse. There will come a time when it will be inappropriate to continue to fund WIIS from the COPR levy.

Therefore, BPU will fund the non-agricultural component of WIIS in 2006/07 from the levy, but will not do so after 1<sup>st</sup> April 2007. BPU have been in contact with relevant Trade Associations and PSD to explain the situation. WIIS will continue to be funded by PSD for Plant Protection Products, but if environmental monitoring for biocides is to continue, that component will require funding either directly by Industry or by Other Government Departments. Some industry sectors have indicated that they would like WIIS to continue.

The BPD does not allow HSE, as the competent authority for Biocides, to charge Industry for environmental monitoring. Article 23 of the Directive relates to "poison control" and the requirement of Member States to monitor for poisonings, the interpretation of this article is that this relates to human poisoning only. The Commission clarified this position when challenged about environmental monitoring.

BPU will continue to discuss the way forward with interested parties and developments will be fed back via the Fact Sheet.

Any questions on this issue should be directed to Mike Potts at the address given at the end of this Fact Sheet.

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## Useful Websites and Contact Details

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As information on the BPD and the UK legislation is held on a number of different websites, the following list details the main sites where information is available.

**European Chemicals Bureau – [ECB Website - Biocides](#)**

**European Commission Environment Directorate website – [Europa Website - Biocidal Products Directive](#)**

**HSE Biocides & Pesticides Unit website – [HSE Website - Biocides](#) ; [HSE Website - Pesticides](#)**

**Her Majesty's Stationery Office – [Office of Public Sector Information](#)**

**HSE Biocides/Pesticides Contacts** - for further information please contact us:

Health & Safety Executive  
Biocides & Pesticides Unit  
Building 1, 3<sup>rd</sup> Floor  
Redgrave Court  
Merton Road  
Bootle  
Merseyside  
L20 7HS

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Fax: 0151 951 3317

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[www.hse.gov.uk/pesticides](http://www.hse.gov.uk/pesticides)