

## ***Purpose***

These Fact Sheets provide briefings for manufacturers, suppliers and users of active substances and biocidal products to keep you up to date with the implementation of the Biocidal Products Directive (BPD) 98/8/EC and the Biocidal Products Regulations 2001

Fact Sheet 21 is **not** a revision of Fact Sheets Nos.1-20 but instead provides supplementary information and advice. If you would like a copy of earlier Fact Sheets, these can be downloaded from our website. If you cannot do this, then please contact us at the address given at the end of this Fact Sheet.

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## ***European Activities***

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### **1. 12<sup>th</sup> TECHNICAL MEETING ON BIOCIDES 8-11 JUNE 2004**

This meeting was the first to take place after the enlargement of the European Union on 1<sup>st</sup> May 2004, resulting in the participation of an additional 10 Member States. It was also the first meeting after the deadline for submission of dossiers for the first substances (wood preservatives and rodenticides) to be reviewed.

Fifty-one dossiers (38 on active substances used in wood preservation and 13 on rodenticides) had been received altogether and the meeting discussed Member States' experiences when examining these for completeness and the progress that had been made. In general, the majority of dossiers were not entirely satisfactory and would require further work, commonly on areas such as the presentation of arguments for the waiving of data requirements and formatting. It was considered that some issues did not prevent a dossier from being accepted as complete but would have to be addressed during the evaluation phase. Others would need to be addressed in order for a dossier to be considered complete. A number of Member States indicated that they would be extending the deadline (until 28 September 2004, as allowed by Article 9 of the Second Review Regulation) for consideration of the completeness of some dossiers, to allow discussions with the other Member States and with the submitter of the dossier.

The meeting recommended that the 16th Competent Authorities meeting (28th-29th June 2004) endorsed the Users' Guidance to the Technical Notes for Guidance (TNsG) on Human Exposure Estimation. This aims to give more practical advice on how to apply the content of the TNsG on Human Exposure adopted by the Competent Authorities (CAs) at their 11th meeting. The meeting also recommended extending the document for the product types coming up for the second review list - PT16 (Molluscicides) PT18 (Insecticides, acaricides, etc.) PT19 (Attractants and repellents) and PT21 (Antifouling products).

A final draft of the Emission Scenario Document (ESD) (a document setting out guidance on estimation of environmental exposure) for anti-fouling

products was also considered and the meeting agreed to recommend to the CA meeting that, with some minor modifications, this should be used for the assessment of PT 21.

## **2. REPORT FROM THE 16<sup>th</sup> MEETING OF THE COMPETENT AUTHORITIES (28-29 JUNE 2004)**

### **a) UPDATE ON THE MANUAL OF DECISIONS**

There are frequent questions from industry, particularly on the scope of BPD, and Member States and the European Commission participate in the decision-making process via an 'electronic' consultation group. The Manual of Decisions (MoD) presents a compilation of these questions and answers, but is a 'living' document that is updated to include further decisions as and when they are agreed. The Commission presented an updated version of the MoD to the meeting to include recent decisions. These included decisions on the use of disinfectants in cut flower treatments and for use in water, pheromones used in animal housing when combined with insecticides, preservatives for building materials, products authorised for two product types, data requirements for residues for PT's 8 and 14 and an amendment to the guidance on cosmetic products also having a biocidal claim.

The Member States asked for a number of minor amendments to be made. These will be incorporated into the revised MoD, which will then be placed on DG Environment's Website (<http://europa.eu.int/comm/environment/biocides/index.htm>).

### **b) DATA PROTECTION**

The Commission had prepared a paper setting out a revised interpretation of Article 12 of the Directive, which deals with data protection. It departed significantly from the interpretation that had been under discussion since December 2001, under which all information on existing active substances would be granted protection until 10 years after Annex I inclusion. It had been pointed out that this unrestrictive reading was not what the Council of Ministers had had in mind when Article 12 was drafted, and there were legal difficulties with an interpretation that rendered much of Article 12 superfluous. The new paper now proposed that information that had earlier been submitted in any part of the Community for a purpose related to the authorisation of biocidal products under national rules could not be said to satisfy the 'first time' test in Article 12(1)(c)(ii) or 12(2)(c)(ii) (where information submitted 'for the first time in support of the first inclusion in Annex I' would be protected until 10 years after Annex I inclusion), and that its protection would therefore expire, at the latest, in 2010. The difficulties associated with this reading, especially for applicants who had acquired data in good faith with the Directive in mind but had meanwhile submitted it under national rules, were pointed out. The Commission suggested that as a partial remedy it might be feasible to introduce an early amendment such that information submitted

after the coming into force of the Directive (14 May 2000) would be deemed to satisfy the 'first time' test, and we now await a proposal along these lines.

### **c) VERTICAL AGREEMENTS BLOCK EXEMPTIONS**

This was connected with the problem of post-authorisation free-riding, that is to say, the purchase of an active substance by a product formulator from someone other than the person who granted her/him a letter of access at the time of authorisation and not associated with the Annex I inclusion. We had earlier believed that attempts to tackle this problem by tying formulators into restrictive purchase agreements would be regarded as impermissibly anti-competitive and improper in terms of contract law. It emerges however that under Commission Regulation 2790/1999\* certain forms of vertical 'non-compete obligations' of this kind are permissible, and may be a partial aid in dealing with the free-rider problem. There are limitations to their applicability: in particular, the supplier's share of the relevant market must not exceed 30% and the agreement cannot last more than five years. Anyone wanting to take advantage of Regulation 2790/1999 should seek the advice of an expert in competition law.

\*Regulation 2790/1999 can be viewed in the Official Journal of the European Communities L336 of 29<sup>th</sup> December 1999, available on the Europa website (<http://europa.eu.int/eur-lex/en/>)

### **d) EMISSION SCENARIOS AND OTHER GUIDANCE DOCUMENTS**

The Member States endorsed the following:

- Emission Scenario Documents (ESD's) (these are documents setting out guidance on estimation of environmental exposure) on:
  - Product Type (PT) 1 – Human hygiene biocidal products,
  - PT6 – In-can preservatives,
  - PT7 – Film preservatives,
  - PT9 – Fibre, leather, rubber and polymerised materials preservatives.
- The User's Guidance Document to the TNsG on Human Exposure to Biocidal Products – Guidance on Exposure Estimation.
- The draft final report of the ESD on antifouling products produced by the Organisation for Economic Co-operation and Development (OECD).

These documents will be placed on the European Chemical Bureau Website (<http://ecb.jrc.it/biocides/>) as soon as possible.

The European Union Biocides Environmental Emission Scenarios (EUBEES) group had drafted most of the ESD's currently available, working under contract to the European Commission. The Member States also endorsed the final report of the EUBEES Projects. The meeting noted that there were still

product types for which ESD's did not exist. It was possible that the Commission may have funds for a further project in 2005.

#### **e) STATE OF PLAY WITH THE 1<sup>st</sup> PHASE OF THE REVIEW PROGRAMME**

The Member States noted the current state of play of the 1<sup>st</sup> phase of the review programmed, as was discussed at length at the Technical Meeting earlier in June. Dossiers on only 38 active substances out of the 81 originally notified for wood preservatives had been submitted. However, it was noted that in those Member States with a national approval system for wood preservatives there were only some 35-40 active substances available and very few of these would need to be withdrawn. The European Commission has now published on the DG Environment website\* appropriate notices of withdrawal or non-submission of dossiers in accordance with Articles 8 and 9 of the 2<sup>nd</sup> Review Regulation in order to allow other parties to express an interest in taking over the role of participant. The latest information that we have from the Commission is that there are parties interested in taking over the role of Participant for Cypermethrin, Oxine Copper and Copper Naphthenate. At the present time we are unable to say whether this interest will result in a dossier being submitted and these active substances remaining supported in the review programme.

\*(<http://europa.eu.int/comm/environment/biocides/index.htm>)

#### **f) REGULATION OF TREATED ARTICLES**

It is established that articles and materials treated with or incorporating biocides for their own preservation – not for delivery to an external target – fall outside the scope of the Directive. (See guidance document Doc-Biocides-2002/04-Rev3, available on the DG Environment biocides website.) The Commission and some Member States are uneasy about this, fearing that biocides that would not gain authorisation within the community in their own right might make their way on to the market by this route. A particular concern is that such biocides might be manufactured in the Community, exported to a non-EU country where they would be incorporated into treated materials, and then re-imported, so escaping control under the Directive. There was general agreement among industry and Member State representatives that some form of control was desirable. Several options were considered in outline, ranging from a light touch regime involving little more than notification or labelling, to full-blown authorisation. The authorisation system used in the USA was compared. There was a distinct inclination towards the stricter end of the regulatory spectrum. The subject is to be returned to at future Competent Authority meetings.

#### **g) PROPOSALS FOR THE 3<sup>rd</sup> REVIEW REGULATION**

The meeting discussed the key elements that would need to be included in the 3<sup>rd</sup> Review Regulation. These were:

- The designation of the Rapporteur Member States for the active substances and product types on Lists 3 and 4 (Parts C and D of Annex V) of the 2<sup>nd</sup> Review Regulation.

*List 3* consists of PT1 - Human hygiene biocidal products, PT2 - Private area and public health area disinfectants and other biocidal products, PT3 - Veterinary hygiene biocidal products, PT4 - Food and feed area disinfectants, PT5 - Drinking water disinfectants, PT6 - In-can preservatives and PT13 - Metalworking-fluid preservatives.

*List 4* of PT 7 - Film preservatives, PT9 - Fibre, leather, rubber and polymerised material preservatives, PT10 - Masonry preservatives, PT11 - Preservatives for liquid-cooling and processing systems, PT12 – Slimicides, PT15 – Avicides, PT17 – Piscicides, PT20 - Preservatives for food or feedstocks, PT22 - Embalming and taxidermist fluids and PT23 - Control of other vertebrates)

- To update Annexes II (the list of active substances that have been Notified and the PT's in which they have been Notified) and III (the list of active substance that have only been Identified) of the 2<sup>nd</sup> Review Regulation to reflect the withdrawals and non-submissions of dossiers for the 1<sup>st</sup> List of the 2<sup>nd</sup> Review Regulation.
- A mechanism, possibly a specific Annex, to allow the continued marketing in a new Member State of an active substance that had not been Identified in accordance with the 1<sup>st</sup> Review Regulation but was on the market in that new Member State prior to its joining the EU in May 2004.
- A specific Annex to be used for active substances that had been granted a derogation as an 'essential use' in a particular Member State (for information on 'essential uses' please see Fact Sheet 20 of June 2004).
- A mechanism to allow the continued marketing beyond 01.09.06 for the small number of active substances, only Identified or not Notified in a particular PT, that companies were now expressing an interest in supporting through the review programme.
- A mechanism to allow companies to Notify active substances that had not been Identified because of late decisions as to whether the products they are used in are within scope of BPD. This was of particular importance for some active substances used in teat dips where the decision that they were within scope of BPD was not made until June 2003.

## **h) COMPLIANCE REPORT**

The European Commission presented its draft summary report on compliance with Article 24 (the Article setting out how compliance with BPD is to be monitored). The UK noted that, under its current national legislation (the Food and Environment Protection Act (FEPA)), the UK has quite an extensive monitoring programme, including monitoring for poisonings in wildlife. This had been included in the UK contribution to the Commission report. However, no other Member State had reported on poisonings in wildlife. The Commission agreed to consult with colleagues to see whether Article 24 of

BPD required Member States to record any poisonings of wildlife. The issue would be considered again at the next meeting of the Competent Authorities, scheduled for December 2004.

HSE will continue to develop its programme for the full implementation of Article 24 with respect to human poisonings, but will await the above discussions before considering the monitoring of wildlife.

#### **i) ACTIVITIES UNDER THE PLANT PROTECTION PRODUCTS DIRECTIVE OF RELEVANCE TO BIOCIDES**

Annex VI of BPD (Common Principles for the authorisation of products) is currently only applicable to products based on chemical substances. There will need to be a further section for products based on micro-organisms. Under the Plant Protection Products Directive (PPPD), work on the adoption of such principles for micro-organisms is nearing completion. The European Commission considered that this would be a good basis for similar principles for biocides. Member States were asked to provide comments before 30 September on whether and where the PPPD document would need to be adapted for Biocides. The Commission could then determine whether it would be necessary to hold specific meetings of Member State technical experts to progress the development of the biocides document.

The EC also presented a PPPD guidance document on the 'equivalence of technical materials', which gives guidance on the information and assessment needed when there are changes in the technical specification of an active substance. Individual active substances can be manufactured by different manufacturing routes and to different technical specifications. If there are changes in manufacturing route or specification it is essential that any changes in composition of the active substance used in the biocidal product are properly assessed. The Member States were asked for views on the applicability for biocides of the PPPD guidance. It was agreed that a specific group of experts needed to be established to consider the document.

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### ***UK Activities***

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#### **3. BIOCIDES CONSULTATIVE COMMITTEE OPEN MEETING**

The Biocides Consultative Committee (BCC) is the advisory committee established to provide the UK Competent Authority (HSE) with advice on the evaluation of biocides under the Biocidal Products Directive/Regulations. The Committee comprises an independent Chair and independent expert members as well as lay members to represent consumer, environmental and employee interests. The Committee is to hold its first 'open meeting' on Tuesday 19 October 2004 at 2:00pm at the Maritime Museum, Albert Dock, Liverpool where the Chairman and Members of the Committee will discuss various aspects of the Committee's work with the audience, focusing on the

implementation of the Biocidal Products Directive in the UK. Admission is free, but will be by ticket only.

Requests for tickets should include the names of all attendees and can be submitted either by email ([bcc@hse.gsi.gov.uk](mailto:bcc@hse.gsi.gov.uk)) or in writing to

BCC Secretariat,  
Room 123,  
Magdalen House,  
Stanley Precinct,  
Bootle, L20 3QZ.

by Monday 20<sup>th</sup> September 2004. Tickets will be allocated on a first-come first-served basis and will be sent out after the closing date of 20 September. Attendees are invited to submit written questions in advance, to the above address.

#### **4. TREATMENT OF PRODUCTS USED FOR MOLE CONTROL**

There had been a Community view that products to control moles were covered entirely by the Plant Protection Products Directive (PPPD). However, the UK has identified a number of uses (e.g. to control moles on aircraft landing strips, on gallops and grazing pastures and prior to the preparation of silage) that it believes invalidate this position. The UK considers that products used in mole control can fall within the scope of either PPPD or BPD depending on the ultimate purpose of the product. If the ultimate purpose is to protect plants then it is plant protection product. If products are used to protect e.g. aircraft landing strips then it is a biocidal product. The European Commission has indicated that it is prepared to reconsider the position.

Strychnine is currently used in the UK to control moles. Use of strychnine as a plant protection product has ceased because it was not supported under PPPD. As strychnine has been identified under BPD it can continue to be used to control moles in areas that fall under BPD until 1 September 2006. The suppliers of strychnine are considering presenting to the Biocides & Pesticides Unit a 'case' for strychnine to be dealt with as an essential use substance/product under BPD. Such essential use status, if granted, will only cover the uses of strychnine that fall under BPD. If such a submission is received we will discuss it with other UK Government Departments and determine whether the UK will put up an essential use application to the EC. The provisional Commission view - so far informally expressed - is that 'essentiality' is not proven, in that other products are available.

#### **5. NOTIFICATION OF INFORMATION TO THE NATIONAL POISONS INFORMATION SERVICE**

The Biocidal Products Regulations (2001) (BPR) (as amended) require that the National Poisons Information Service (NPIS) centre in Birmingham

(contact details below) is provided with certain information when a biocidal product is first placed on the UK market. The information you should provide to the NPIS is included in Schedule 8 of BPR. You should provide this information within one month of the date the biocidal product(s) is first placed onto the UK market. A copy of BPR can be found on the following web address:

(<http://www.legislation.hmso.gov.uk/si/si2001/20010880.htm>)

National Poisons Information Service  
Birmingham Centre  
City Hospital NHS Trust  
Dudley Road  
Birmingham B18 7QH

Contact: Ms Rachel Kealey -

E-mail: [r.kealey@npis.org](mailto:r.kealey@npis.org)

Telephone number: 0121 5078 4123

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## ***Useful Websites and Contact Details***

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### Useful websites

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

**European Chemicals Bureau** – <http://ecb.jrc.it/biocides/>

**European Commission Environment Directorate website** –  
<http://europa.eu.int/comm/environment/biocides/index.htm>

**HSE Biocides & Pesticides Unit website** –  
<http://www.hse.gov.uk/biocides>


**Her Majesty's Stationery Office** – [www.hmso.gov.uk](http://www.hmso.gov.uk)


**HSE Books** – [www.hsebooks.co.uk](http://www.hsebooks.co.uk)

### **HSE Biocides Contacts**

For general information on the Directive, progress with implementation or to register your interest in Biocides please contact us on:

Biocides & Pesticides Unit general information number:

 0151 951 3535

 Fax. 0151 951 3317

e-mail [biocides@hse.gsi.gov.uk](mailto:biocides@hse.gsi.gov.uk)

### Our address:

Biocides & Pesticides Unit  
Health & Safety Executive  
Magdalen House  
Stanley Precinct, Bootle  
Merseyside L20 3QZ

Our biocides webpages: <http://www.hse.gov.uk/biocides>

HSE Books: Tel. 01787 881165, Fax. 01787 313995