



BIOCIDES FACT SHEET



Biocidal Products Directive
Biocidal Products Regulations
Control of Pesticides Regulations

Issue No. 24

September 2005

Purpose

These Fact Sheets provide briefings 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. From May 2005 the Fact Sheets also incorporate information on the Control of Pesticides Regulations that would previously have appeared in the 'Pesticides Newsletter' – publication of the Newsletter has now ceased.

Fact Sheet 24 is **not** a revision of Fact Sheets Nos.1-23 but instead provides supplementary information and advice. If you would like copies of earlier Fact Sheets, they can be downloaded from our website - the website address is given at the end of this Fact Sheet.

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General Information

1. CONTACTING THE BIOCIDES AND PESTICIDES UNIT

At the Biocides and Pesticides Unit we have to plan our work schedule carefully if we are to meet the deadlines for completing the reviews under the Biocidal Products Directive, whilst maintaining our existing standards for pesticides approvals. One area where our customers can help us is to ensure that enquiries are directed to the most appropriate person. To aid this we would ask that for general enquiries, rather than contacting someone simply because you know their name or they have been helpful previously, instead please contact our Administration Team on the Unit's general phone number - 0151 951 3535. In many cases they can answer your enquiry straightaway, and if they can't they will then redirect the call to the most appropriate member of staff. Similarly for emails, please send them to our general biocides account (biocides@hse.gsi.gov.uk). The exception to this rule is where you have been given a specific named contact for an on-going project, such as a Project Manager for a review or application for a product approval – for enquiries on these specific topics, please continue to use the named contact.

We would also like to remind participants in the review programme that if you have an enquiry relating to your active substance's review, please consult the relevant Rapporteur Member State for that substance – if necessary they can then consult the other Member States, including the UK.

Biocides - European Activities

2. REPORT ON THE 19TH MEETING OF THE COMPETENT AUTHORITIES (4-5 JULY 2005)

The **main** agenda items are summarised below:

(a) Update of the 'Manual of Decisions' (MoD)

The Commission now flag up the 'new' items in the MoD by putting a 'new' annotation next to their entry in the index.

New Items:

- Washing Machines with Silver electrodes
- Wood impregnated with products containing potassium formate
- Chromium in wood preservatives
- Tile cleaners
- Refrigerators

Sweden and Austria indicated that, on occasions, they might wish to state that they do not fully agree with the decision in the MoD. The Commission was reluctant to accept this but agreed that, in exceptional circumstances, this could be included in a footnote to the text.

The Commission have amended the Manual as necessary and published the new version on the EC Environment Directorate web page (given at the end of this fact sheet).

The debate on washing machines raised the question of the need to clarify the definition of 'biocidal product' to cover the case in which the biocidal agent is delivered by treated articles (in the washing machine case, the question is whether the biocidal product is the machine or merely the silver electrodes). The Commission will do this in 2007 when there will be a review of the Directive.

(b) Report from the Technical Meeting (TM) in June 2005

The Commission reported back from the TM, which was held on the 13th –16th June in Arona, Italy (incorporating a leaching workshop on the 13th –14th).

(i) *Outcome of the Leaching Workshop:*

The Workshop was held to try to harmonise the approach taken by the Member States with regard to the leaching of wood preservatives.

There was general agreement at the workshop that part 2 of the OECD draft guideline 'Laboratory method for wooden commodities exposed in use class 4 and 5 (in contact with the ground, fresh water or sea water)' is adequate for leaching tests for use classes 4 and 5.

For use class 3 the OECD draft guideline 'Estimation of Emissions from Preservative treated wood to the environment: Laboratory method for wood held in storage yard after treatment and for wooden commodities exposed in use class 3 (not covered, not in contact with the ground)' had proposed an immersion time of 3 times 1 minute. However, the majority of the workshop participants preferred an immersion time scheme of 2 times 60 minutes for hazard class 3 (which is not currently part of the proposed draft OECD guideline for use class 3). It was also agreed that a decision on the value of an assessment factor on the 3 times 1 minute immersion time scheme is needed. The Netherlands volunteered to draft a discussion paper on the use of assessment factors, Denmark and the UK will assist in this work. Industry will also provide an input.

A clear need to finalise the OECD guidelines, including validation was identified.

(ii) *Technical notes for Guidance on the assessment of equivalence for substances regulated under BPD*

This guidance seeks to address the issue of when two (or more) substances can be considered equivalent under the BPD. The UK has made some amendments and the document will now be circulated by the ECB to other Member States for further comments. It was noted that strict equivalence criteria have the advantage of making free-riding more difficult.

(iii) *Data requirements for micro-organisms*

Austria will host a Workshop in Vienna for experts to further debate this issue in September this year (2005). The meeting is hoping to produce guidance for applicants and Member States.

(iv) *Pine Tar: Essential Use*

Norway submitted a paper informing the Technical Meeting how they intend to show whether pine tar is efficacious or not against wood rotting Basidiomycetes. As no clear conclusions were drawn on the best way forward Norway proposed to discuss this issue at the CA meeting.

At the CA meeting Norway stated that they would do some more work (such as efficacy studies) and produce the results of these studies by the end of the

year. However, there was discussion on a possible derogation to the Directive to include the use of pine tar on historic buildings and boats.

(c) Procedures and timescales 'Post Annex I Inclusion'

Papers were provided by the Commission and the UK:

(i) Proposal for procedures and timescales post Annex I

Member States agreed that a harmonised approach needs to be taken for product authorisation and that a common date should be agreed by which products are authorised or removed from the market. A common date by which all products on the market containing the relevant active substance are evaluated would also facilitate mutual recognition.

The Commission commented that this idea is not enforceable legally but agreed to consult the Legal Service on the possibility of inserting a deadline into the draft inclusion directive to allow for mutual recognition applications. Member States could of course harmonise on a voluntary basis. The Commission also agreed that a central database is required so that Member States will know who is working on which product dossier.

More work will be required on this issue and Member States agreed to comment on the document drafted by the Commission.

(ii) Proposal for what an Annex I –inclusion would 'look like'

A 'thought-starter' paper was produced by the UK. CEFIC stressed the need for a harmonised approach for Annex I inclusion. Member States will build upon the UK paper and consider detailed proposals for Annex I listing.

(d) Data protection issues

The Commission presented the latest version of the guidance note on data protection. CEFIC expressed their dissatisfaction with parts of it. The Commission pointed out that all Member States had now agreed it but would record the fact that CEFIC were not content. As already planned, an amendment to Article 12 to solve the problem of data submitted post-2000 under national rules modelled on the BPD will be made at the same time as the amendment to Annex VI to include micro-organisms.

(f) Guidance on Parallel Imports

The Commission introduced their paper which pointed out that there was a theoretical possibility that parallel imports could be requested under the BPD system, though copycat products would be in breach of other Community law on intellectual property. Comments were invited on this paper from Member States.

(g) Relationship between the Biocidal Products Directive (98/9/EC) and The Construction Products Directive (89/106/EC)

There is a potential for conflict between the requirements of these 2 Directives, particularly with regard to the efficacy requirements of wood preservatives. Member States were requested to contact their opposite numbers in their own countries with a view to debating this issue. The UK Government departments with responsibility for these 2 Directives will be meeting in September.

(h) Any Other Business

(i) Clarification of the definition of 'Placing on the Market' in Directive 98/8/EC

At the 18th Competent Authority Meeting, Finland requested a clarification concerning the interpretation of Article 2(1)(h) of Directive 98/8/EC in regard to the definition of 'placing on the market'.

The Commission confirmed that placing on the market includes all subsequent storage following supply, **except for export & disposal**, regardless of when the act of supply took place.

So as of September 1st 2006 products containing active substances that are only identified can be used but not stored for that purpose, even if they were supplied before the deadline. The Commission agreed that this would be difficult to enforce, however they stressed that it is the responsibility of each Member State to take appropriate action under national legislation. NB: please note that this is a departure from the previous UK interpretation, under which a product supplied before the deadline could continue to be stored after the deadline had passed.

(ii) Complaints about discrepancies in Member State fee structure.

CEFIC voiced concerns about the differences in the fees charged by Member States, they were particularly concerned about 3rd list where the same substance had already been looked at and the fee being charged again. The Commission stated that the fee should reflect the work carried out and that Member States should look carefully at their fee structure to reflect this. It was also suggested that a questionnaire on fees should be produced to provide the latest information on the fees.

The UK is currently operating a work recording system to reflect the time spent on dossiers and suggested that Other Member States do the same.

(iii) Other Issues

The 3rd Review Regulation is now on the ECB website

Next meetings:

Technical Meeting	11-14 October 2005
Competent Authority Meeting	12 –14 December 2005

Biocides - UK Activities

3. FEES FOR NEW ACTIVE SUBSTANCES AND REVIEWS IN THE UK

BPU are currently progressing the reviews the UK was allocated for the First List of substances (the First List covered Wood Preservatives and Rodenticides) and consequently are at the stage where we can look at the fees we currently quote and the actual cost of evaluating the dossiers. You will be aware that, unlike the Control of Pesticides Regulations where a fixed fee is charged, the cost of an evaluation under BPD is based on the actual amount of work undertaken.

Industry has indicated that accurate prediction of fees helps with company financial planning. Therefore, in light of our experiences, BPU proposed to increase the fee payable upfront to £84,000 – £89,000, whilst keeping the (non returnable) sift fee constant at £6,000. This will more accurately reflect the cost of the work and should prevent the need for a “top up” fee towards the end of the evaluation. Clearly as before, if the evaluation is done for less than the fee paid, a refund will be made. We will still consider charging a reduced fee for an active substance where it is clear that there is less work to do (e.g. for a reduced data package). Applicants are reminded that the best way to reduce costs is to ensure that their dossiers are of the highest quality.

4. DISINFECTANTS FOR USE ON HUMAN SKIN – BIOCIDES OR MEDICINES?

The Biocidal Products Regulations, in-line with the Biocidal Products Directive itself, exempt products from the requirements of the regulations if they are considered to be medicines. In response to an enquiry from a stakeholder who wants to market a disinfectant product for use on human skin with the claim ‘kills MRSA’ (methicillin resistant *Staphylococcus aureus*) BPU sought the advice of the Medicines and Healthcare products Regulatory Authority (MHRA) who are the UK Competent Authority for medical products.

The MHRA have considered this issue at some length and have consulted existing case law from the European Court of Justice. They have advised us that there is a distinction between products that are for use on human skin as general disinfectants without mentioning any specific form of bacteria/virus or disease – which would be considered to be biocidal products – and those disinfectants for use on human skin that specifically name a disease or type of

bacteria etc. – which would be medicines. Therefore the claim ‘kills MRSA’ (or indeed typhoid, HIV etc.) for a product used on human skin would bring a product within the scope of the medicines legislation rather than the biocides regulations and therefore a Marketing Authorisation from the MHRA would be required before placing the product onto the UK market.

If you or are thinking of marketing a disinfectant for use on human skin that will make claims against a disease or disease causing bacteria/viruses etc. you should contact the MHRA for further advice on the scope and requirements of the medicines legislation (Email - info@mhra.gsi.gov.uk Postal - MHRA Information Centre, 10-2 Market Towers, 1 Nine Elms Lane, London SW8 5NQ Telephone – 0207 084 2000)

5. USE OF CHROMIUM IN WOOD PRESERVATIVE PRODUCTS

Chromium trioxide and sodium dichromate are used in a number of wood preservative products and both these substances were initially notified for review as wood preservatives under the Biocidal Products Directive’s review programme. However, all the participants for these substances withdrew from the review programme, and therefore wood-preserving products containing chromium must be removed from the market by 1st September 2006.

Following discussions amongst Member States and the EU Commission it has been agreed that if companies want to argue that chromium in their products does not act as an active ingredient, they would need to provide evidence to justify this claim. We would need to have received this evidence – such as efficacy data – by the 1st March 2006 to allow it to be assessed and discussed with other Member States before the September 2006 deadline.

6. SEPTEMBER 2006 DEADLINE FOR PRODUCTS CONTAINING SUBSTANCE THAT HAVE ONLY BEEN IDENTIFIED

All stakeholders are reminded that, under Article 4 of the EC Second Review Regulation (No 2032/2003), biocidal products containing active substances that have **only** been ‘Identified’ under BPD **cannot be placed on the EU market or subsequently stored for any purpose (except for export and disposal) from 1st September 2006.**

In addition, the same prohibition also applies to products where the active substances have been ‘Notified’, but where the relevant product types have not been supported by that notification. For example, Substance X has been ‘Notified’ under product types 6, 7, 9, 10, 11, 12 and 13 but **not** product type 8 (wood preservatives). Therefore Substance X is only considered as being ‘Identified’ in relation to product type 8 (wood preservatives), so wood preservatives containing this active substance **cannot be placed on the EU market or subsequently stored (except for export and disposal) from 1st September 2006.**

It is your responsibility to ensure that large stocks of your biocidal products containing such active substances do not remain on the EU market.

There will be no phased withdrawal of products once the 1st September 2006 has been reached. Publication of Regulation No 2032/2003 took place on 24 November 2003 and it is the view of the European Commission that industry has had sufficient time to take appropriate action to ensure a timely phase-out of stocks of products through the supply chain.

- How can you check your active substance status?

Comprehensive lists of Identified/Notified active substances as well as supported product types can be found within the Annexes of the EC Second Review Regulation (2032/2003/EC), as updated by the Third Review Regulation (1048/2005), which can be found by accessing the European Chemicals Bureau website at: www.ecb.jrc.it/biocides then following the specific links in the text.

HSE/BPU web site also contains relevant background information.

- Other action

HSE intends to inform local authority trading standards offices of this forthcoming deadline and its implications. It will be incumbent upon them to decide what, if any, enforcement action is required.

Companies that currently hold approvals under the Control of Pesticides Regulations will find additional information on what will happen to these products in the article immediately below this one, in the COPR Specific Information section of the Fact Sheet.

Control of Pesticides Regulations Specific Information

7. SEPTEMBER 2006 DEADLINE – COPR APPROVALS

Following on from the information given in the article above, COPR Approval Holders should also note the following points:

- Current COPR products - what is the legal status?

If you hold a current approval for a product containing an active substance that has been 'identified' only, **or** have products approved for uses that will not be supported for review under BPD, then all conditions of approval will expire on 31st August as COPR no longer applies to these products. In order to ensure that HSE records are consistent, you will receive a 'notice' voiding your COPR approval with effect from 1st September 2006. This notice will be sent to you from January 2006, but obviously will not impact until 1st September 2006.

- How can you check your active substance status?

BPU has been examining the Second and Third review Regulations against those active substances used in COPR products. The following list details those active substances that have only been identified. Therefore approval under COPR for products containing these active substances will expire on the 31st August 2006. Please note that this list is for guidance purposes only and is not exhaustive, you must check the review regulations on the ECB website if you are unsure of the status of your active.

Acypetacs copper	Acypetacs zinc	Arsenic pentoxide
Azaconazole	Calciferol	Campher
Cedar Oil	Cedarwood Oil	Cholecalciferol
Chromium trioxide	Cinnamomum zeylanicum extract	Citronella Oil
Dimethyl phthalate	Dimethylamine-Epichlorhydrin Polymer	Diphacinone
Eucalyptus Oil	Geranium Oil	Hydroprene
Iron sulphate	Lavender Oil	Lemongrass Oil
Litsea Cubeba extract	Methoprene	Neem
Palmarosa Oil	Penny Royal Oil	Piperonal
Potassium dichromate	Resmethrin	Rotenone
Rue Oil	Sodium dichromate	Sodium perborate
Tea tree oil (as Melaleuca Oil)	Tri (hexylene glycol) baborate	Turpentine Oil

Useful Websites and Contact Details

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 – <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> ; <http://www.hse.gov.uk/pesticides>

Her Majesty's Stationery Office – www.hmsso.gov.uk

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

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