



BIOCIDES FACT SHEET



Biocidal Products Directive
Biocidal Products Regulations
Control of Pesticides Regulations

Issue No. 26

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FUTURE OF THE FACT SHEET – FACT SHEET TO GO!

FUTURE NEWS ARTICLES TO GO ON THE LIVE ISSUES WEBPAGE

The January 2006 fact sheet (No. 25) was the last edition to be sent out as a paper copy and this issue (No. 26) has been placed on our website and an email alert sent out to those who requested it.

Initially the fact sheet was produced on a quarterly basis and more recently it has been produced to coincide with the outcome of Competent Authority or Technical Meetings. We have identified that this practice may lead to a delay in relevant information being disseminated and so to enable information to be published on a more timely basis we have decided that rather than a fact sheet we will in future publish all new articles on the "[Live Issues](#)" page of our website.

Using the email alert system we can notify you when a new article goes on the "Live Issues" page. If you have not sent us your details already and you wish to be notified by email alert then please email them to: 'biocides@hse.gsi.gov.uk'.

Purpose

This fact sheet provides information for manufacturers, suppliers and users of active substances and biocidal products to help keep them up to date with developments in the Biocidal Products Directive (BPD) 98/8/EC and the Biocidal Products Regulations 2001 (as amended). 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 26 is **not** a revision of fact sheets Nos.1-25 but provides current supplementary information and advice. All fact sheets are available on our website at <http://www.hse.gov.uk/biocides/information.htm>.

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Biocides - European Activities

1. REPORT ON THE 21st MEETING OF THE COMPETENT AUTHORITIES (10-11 APRIL 2006)

The following information covers the main points arising from the 21st Competent Authority (CA) Meeting held in Brussels including a report from the Technical Meeting held in Italy. This was the first CA meeting chaired by **Leena Yla Mononen** (she has replaced Klaus Berend).

a) UPDATE ON THE MANUAL OF DECISIONS (MOD)

The new entries to the Manual of Decisions (MOD) were discussed with a view to an updated version being published. The MOD is available at: <http://ec.europa.eu/environment/biocides/manual.htm>. These entries were:

Page 25 – Advanced Oxidation Technology – An ‘in-situ’ generation system to inactivate microbes - MOD decision agreed with a small modification.

Page 26 – Cu²⁺/Ag⁺ from permanently installed copper/silver electrolysis – MOD decision agreed – the electrodes are the biocidal product.

Page 48 – Grafted polymers – MOD not agreed, France to provide more details.

Page 51 – Grains containing a second generation anticoagulant as well as an insect growth regulator – MOD decision agreed - this is PT 14 but needs an explanatory sentence to explain the PT18/‘in can preservative’ issue.

b) REPORT FROM THE TECHNICAL MEETING (HELD IN ARONA 17 - 31 MARCH 2006)

At the 21st CA Meeting the Commission fed back from the Technical Meeting (TM). The main items for discussion for the TM were a number of active substance dossiers for product types 8 (Wood preservatives) and 14 (Rodenticides). The results of the discussions are confidential at present, however the substances discussed were:

Product Type 14

Coumatetralyl	Rapporteur Member State	Denmark
Difenthiolone	Rapporteur Member State	Norway

Product Type 8

Dichlofluanid	Rapporteur Member State	UK
Etofenprox	Rapporteur Member State	Austria

The following agenda items were then discussed:

i. Frame Formulations

The UK presented a paper, outlining the principles of frame formulations. The Netherlands also produced a more detailed paper. Member States (MS) raised a number of questions mostly concerning the details of a proposed frame but overall MS and Industry supported the paper. The Commission will produce a consolidated draft frame formulation paper, which will eventually be used as a guidance document.

ii. Role of Chromium in Wood Preservation

Given the uncertainty over the status of chromium under the BPD, the UK presented a paper to the TM suggesting a simple methodology to help to resolve this issue. Unfortunately, no agreement could be reached on this method. The issue was referred to the CA Meeting (see point D below).

iii. Chemical identity - Oils and Extracts

The chemical identity of oils and extracts (e.g. lavender oil) is an issue that has been previously discussed by Member states (MS), applicants and the ECB as there are several different sources of such extracts. The document presented by the Commission is intended to help inform any future discussion on this subject. MS and industry (via the industry representatives who attend the meetings) were asked to comment on the paper by 31st May 2006.

iv. QUATS (Quaternary Ammonium Compounds)

QUATS are a complex group of substances and which have been allocated to Italy to evaluate. The Italians have encountered many difficulties, and will not start work on the evaluations until these identity problems are sorted out. The Commission presented a paper to try and resolve some of the problems.

However the paper as presented raised some questions about the future of a number of QUATS due to their generic grouping in relation to their CAS numbers. Member States and industry (via the industry representatives who attend the meetings) were asked to comment on the paper by 31st May 2006.

v. Efficacy testing and proposed Efficacy Workshop

The Netherlands put forward a paper, which provided efficacy guidance documents for biocidal products, in particular, disinfectants, wood preservatives, rodenticides, insecticides and acaricides. The TM agreed that modifications to the technical notes for guidance (TNG's) were required and that this paper would help inform the modification process.

The question of holding an efficacy workshop was raised and the UK expressed an interest in getting involved in participating in such a workshop together with the Netherlands.

vi. Leaching of antifoulants

CEPE (Industrial trade association for paints and coatings) made a detailed presentation of the available methods for predicting the leaching rate from boat hulls. Data for copper paints demonstrated that the ISO laboratory method significantly over predicts the leaching rate of painted surfaces when compared to the CEPE calculation method or in-situ measurements. They wanted to convince the TM that either the ISO or CEPE calculations should be reduced by a factor based on the limited data available.

The ECB had prepared a brief paper covering 2 main issues

- Local initial concentration and
- Leaching rate from a ships hull

Both of these will be critical areas for the risk assessment of antifoulants and their needs to be agreement between Rapporteur Member States if substances used in antifouling products (PT21) are to be accepted for Annex I inclusion. Member States and industry (via the industry representatives who attend the meetings) were asked to comment on the paper by 31st May 2006.

vii. Human Exposure during manufacture

Manufacture covers two different steps: the manufacture of the active substance and the manufacture of the biocidal product. Some MS are asking for very detailed information on human exposure during manufacture as part of the dossier data set. CEFIC have questioned this. The Commission have considered this issue and have made the following conclusions:

- The BPD is concerned with **the placing on the market of biocidal products**, and makes references to other pieces of legislation concerning worker protection. Before asking for detailed exposure information for a manufacturing processes MS should take into account that this is already addressed in other pieces of legislation.

- Only in the cases where a new active substance is **exclusively manufactured for biocidal purposes within the EU** should manufacturing information be required in any detail.
- Information on manufacture is only required for manufacturing sites within the EU

c) DOSSIERS SUBMITTED ACCORDING TO ARTICLE 4b OF THE THIRD REVIEW REGULATION (UPGRADES)

Article 4b of the Third Review Regulation allows for notification of additional active substances/product types. It was agreed that all Member States (MS) need to act in the same way on these upgrades. The ECB will circulate a table for MS to complete – this will then be published as a complete list of all upgrade applications.

d) CHROMIUM

This item was referred to the CA Meeting from the TM. CA agreed that Chromium is an active substance unless product related efficacy data is provided by industry, which proves otherwise. The ‘Burden of proof’ is on industry. See article 2 for further information.

e) LEVEL OF DETAIL REGARDING ANNEX I INCLUSION

The level of detail on an active substance that will be included in the Annex I entry has still not been agreed. Rapporteur Member States are concerned that if there is no agreement made soon on the Annex I entry then it will make product authorisation very difficult. It was agreed that Austria, Denmark and the UK that would present a paper at the next CA Meeting suggesting a way forward.

f) POST ANNEX I INCLUSION

The Commission presented a paper that spells out broadly what needs to be done post Annex I listing with regard to timescales. Member States now need to draw up guidance as to how we go about doing it. The UK has agreed to work with Sweden and the Netherlands on this.

g) STATUS OF WORK CONCERNING COMMON REGISTER/DATABASE

The Commission are working on setting up a common register/database for biocidal products, which could be used for the purposes of information exchange or post Annex I work.

The UK made a plea to keep this as simple as possible and to try not to be too ambitious with it. Some countries (Latvia & Finland) have language issues, by law the national language has to be used for all databases. Member States and industry (via the industry representatives who attend the meetings) were asked to comment on the paper by 31st May 2006.

h) ESSENTIAL USE APPLICATIONS

The process for dealing with essential use applications is still developing. Although a number of individual cases were presented, they were not discussed, as there is a 60 day consultation period in place. The Commission asked Member States for written comments to be sent by 31st May 2006. The Commission also confirmed that essential use only applies in the country/countries who had applied for it.

For a UK update of essential use applications – see Article 4.

i) FEES

The BPD requires Member States to recoup the costs of running the scheme from the industry and the UK explained that they recorded the time spent on each evaluation & then charged accordingly and suggested that other Member States do the same.

2. STATUS OF CHROMIUM IN WOOD PRESERVATIVE PRODUCTS UNDER BPD

The status of chromium compounds in wood preservative products under the BPD was addressed in our September 2005 fact sheet (Issue No 24). Chromium trioxide and sodium dichromate were initially notified for review as wood preservatives under the BPD's review programme - the industry view was that chromium was an active substance. However, no dossier on chromium was submitted and as a result all wood-preserving products containing chromium must be removed from the market by 1st September 2006. However, some companies subsequently claimed that chromium is not effective as an active substance, and this issue was raised within the EU.

At the Technical Meeting (TM) (27 - 31 March 2006) the UK CA presented a paper to seek the agreement of Member states (MS) and the European Commission to a method for the interpretation of data to show whether or not chromium acts as an active substance when used in wood preservative products. There was no agreement to the methods proposed in the UK paper, and all delegates concluded that chromium IS an active substance when used in wood preservative products currently on the EU market.

The Competent Authority Meeting (10 – 11 April 2006) was invited to consider the opinion of the TM. The TM decision was supported in principle, however if data were provided by companies seeking to demonstrate that chromium is NOT an active substance in a particular wood preservative product this could be evaluated by MS. In the absence of a harmonised method for the evaluation of such efficacy data, MS were invited to consider the methods proposed in the UK TM paper as a first step. In the absence of any efficacy data, the fall back position is that chromium is considered as an active substance in wood preservative products currently on the EU market.

The UK CA has evaluated some data submitted by industry and our preliminary conclusion is that, consistent with label claims made on wood preservatives currently on the market, chromium is an active substance. We have sent our opinion to the EC and informed them that all UK chromium containing wood preservatives will have to be removed from the market by 1st September 2006.

Biocides - UK Activities

3. FINAL NOTICE - 1ST SEPTEMBER 2006 DEADLINE

This is a final reminder concerning the 1st September 2006 deadline for the removal from the EU market of biocidal products containing active substances that have only been identified under the Biocidal Products Directive (BPD). The same deadline also applies to products that contain active substances that have been 'notified', but where that notification does not include the specific product type relevant to these products.

It is industry's responsibility to ensure that biocidal products containing such active substances do not remain on the EU market by this date.

Previous articles relating to this can be found in Fact sheet No 25 (Article 6) and Fact sheet No 24 (Article 6).

What does 'taken off the market' mean in practice?

Suppliers have had advance knowledge of the September deadline and should have taken appropriate steps to ensure that stockpiles of biocidal products have not been allowed to build up. Any stockpiles existing after 1st September 2006 can no longer be placed on the EU market or subsequently stored for any purpose (except for export and disposal).

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.

Products approved under national legislation – The Control of Pesticides Regulations 1986 (COPR)

- As industry has known that products should be being phased out since 2003, under COPR there will be no phased withdrawal of products after the end of August 2006.
- For products containing an active substance that has been 'identified' only, **or** approved for uses that will not be supported for review under BPD, then **all conditions of approval will expire on 31st August 2006**, as COPR no longer applies to these products.

- Approval Holders will receive a 'notice' voiding their COPR product approval(s) with effect from 1st September 2006.
- This notice will not impact on the product approval until 1st September 2006.

What about articles treated with biocides - can they still be placed on the market?

Articles that have been **treated** with biocides that have only been identified, where the treatment is to protect the article itself, for example wood treated with a wood preservative containing identified only active substances, can still be placed on the market as normal. It is only the biocidal product and not the treated article that the BPD and Review Regulations apply to.

How can you check an active substance status?

Lists of Identified/Notified active substances as well as supported product types can be found within the Annexes of the EC Second and Third Review Regulations, found on the [European Chemicals Bureau website](#)

To help you HSE has determined that the following active substances used in products approved under COPR, have only been **Identified**. Please note that this list is for guidance purposes only and is not exhaustive. **You must check the ECB website if you are in any doubt using the specific CAS Number for the substance where appropriate.**

Acypetacs copper	Acypetacs zinc
Arsenic pentoxide	Azaconazole
Calciferol	Camphor
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

Whilst these are substances that have only been Identified, you should remember that if the active substance in your product has been notified, but not in the product type that is relevant for your product, then the 1st September 2006 deadline will also apply to that product. Again, details of the

notified substances and the product types they have been notified in for review are on the [ECB website](#).

Enforcement

HSE intends to inform Local Authorities by notifying them, in writing, of this forthcoming deadline and its implications. It will be incumbent upon Local Authorities to decide what enforcement action is required.

4. ESSENTIAL USE APPLICATIONS - UPDATE

Article 4a of the Third Review Regulation allows for applications to be made for 'essential use' in individual Member States. If an application is successful, this will allow approved products containing the active substance for the intended essential use to remain on the market, in the Member State where applied, until 14th May 2010. Industry has to actively search for and obtain authorisation for an alternative before this date. In the absence of an agreement to an essential use application the 1st September 2006 deadline for products to be off the market will apply.

The UK has sent the following applications to the Commission:

- Strychnine Hydrochloride
- Methyl Bromide
- Ammonia

Applications received by the Commission can be viewed at: http://ec.europa.eu/environment/biocides/essential_uses.htm and Member States or any person may for a period of 60 days following publication of the applications submit comments in writing to the Commission at the following address:

Directorate-General Environment
Unit B-4, Office Bu-9, 6-163
B-1049 Brussels

Or by e-mail to: ENV-Biocides@ec.europa.eu

5. CHANGES TO THE BIOCIDES WEBPAGES

We have made some recent changes to our biocides webpages on the HSE website. We have added a new frequently asked questions section that you can access via the [homepage](#), just click on the FAQs button on the left hand side. We have given some background to biocides and the Biocidal Products Directive and have tried to cover the main questions that we get asked. Please refer to our website before contacting us as you may find the answer to your question is already available here.

Control of Pesticides Regulations Specific Information

6. STATUS OF PERMETHRIN UNDER COPR

Products regulated under the Control of Pesticides Regulations 1986 (as amended) must contain active substances that are manufactured by a recognised source at specific plant sites.

In January 2006, FMC Corporation (who were then a recognised source/site of permethrin) informed BPU that they would no longer provide permethrin to formulators of COPR-regulated products.

BPU subsequently contacted Approval Holders (in mid January 2006) of products containing permethrin asking that them to **either**:

- confirm that their current source of permethrin comes from an alternative recognised source other than FMC. OR
- confirm the new source that they would be using instead of FMC and provide a Letter of Intent from this new source(s) to confirm the change.

A deadline of 31 March 2006 was set and about 50% of all Approval Holders replied. A reminder was sent out in mid April 2006 to those Approval Holders who had not yet contacted BPU with an indication of how they intend to address this issue. A final deadline of 10 May 2006 was set after which products still containing FMC-permethrin were suspended. Suspended products cannot be marketed legally within the UK and will only be permitted to be stored or supplied for disposal.

If, at a later date, Approval Holders indicate that permethrin is no longer being supplied by FMC and supply documentation to demonstrate supply from alternative, acceptable sources, then BPU will arrange for suspension of relevant products to be lifted.

7. COPR PROCESSING TIMES AND PRODUCT REFORMULATION

In addition to the normal COPR work, staff in BPU are also working on BPD evaluations and so it has been necessary to reprioritise our work to meet the tight demands of the European timetable in relation to BPD.


Consequently we would like to inform applicants that whilst we will always strive to meet our current service standards for processing times, we may be forced to move towards the outer limit of the agreed standard (rather than a shorter process time as has been the norm in the past).

Therefore, applicants are advised to submit any COPR applications as early as possible to allow for any potential delays.

From 1st September 2006, all biocidal products containing active substances that have been 'identified' only must have been removed from the European market. As a result, we are aware that a number of Approval Holders are considering reformulating products, and if you are considering this please

submit any applications as soon as you can. **We can only accept applications to reformulate current products until the 30th June 2006.**

BPU can only process these changes as amendments if applicants can confirm in writing that there will be no stocks of the existing formulation in the supply chain by 1st September 2006.

If applicants are unable to provide such confirmation then the application cannot be processed as an amendment and applicants will need to complete a new [product application form](#)  (as a new approval will be required).

The resulting product will then be issued with its own unique HSE Number and as both the 'new' and 'old' versions of the product may be available to customers at the same time, then the new version will require a unique name to that of its predecessor.

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 – <http://www.hmsso.gov.uk>

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

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

Tel: 0151 951 3535

Fax: 0151 951 3317

E-mail: biocides@hse.gsi.gov.uk

www.hse.gov.uk/biocides

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