

Please Note: there has been an updated amendment to this edition in section 1.h.ii. regarding teat dips which will not be reflected in the paper copies sent out previously.

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 22 is **not** a revision of Fact Sheets Nos.1-21 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

1. REPORT FROM THE 17th MEETING OF THE COMPETENT AUTHORITIES (6-7 DECEMBER 2004)

a) Update of the Manual of Decisions

The Commission presented an updated version of the Manual of Decisions with the new entries inserted in 'track changes' mode. These were: a product used to control pigeons in cities; the use of silica powder as an insecticide; an antifouling product allegedly acting by physical means; an antifouling product containing micro organisms; slurry additives; the efficacy of products with several potentially active substances; anti-viral paper tissues; hygienic paint coatings for walls and floors; antibacterial paints (borderline between PT2 and PT7); anti-mould paint and the borderline between PT7 and PT8. There was only discussion on one of the items - the anti-fouling product acting by physical means. The UK agreed to contact the USA Environmental Protection Agency to obtain more information on this product and to redraft the text to make it clear that there were actually two products to be considered. The Commission announced that it would be meeting some German companies in an attempt to resolve the biocides/medicines boundary over disinfectants used in Germany; this meeting would involve both DG Environment and DG Enterprise. The Commission also stated that they were still considering the overlap between biocides and medicinal products with regard to a particular product bearing a CE marking that had been taken off the market in Denmark.

b) Report from the Technical Meeting in November 2004

The draft minutes from the Technical Meeting (TM) were circulated. The main items discussed (other than those on the agenda for the Competent Authorities meeting) were:

- (i) The need to agree guidance for micro-organisms.

The Commission will develop a first draft, based on work carried out for the Plant Protection Products Directive.

(ii) The listing of active substances in Annex I/post Annex I procedures

The Commission explained that the proposed listing would be left to the rapporteur Member State to propose but the Commission would check to see whether or not there were any specific legal requirements. After the Annex I listing, Member States will have to authorise products and the Commission stated that industry had expressed differing views as to the desired time required for this. It was impossible to agree now on a 'one size fits all' solution, as the time required would depend on the product type concerned.

(iii) The state of play regarding active substances in Product types 8 and 14

The completeness checks for almost all substances had taken the maximum period allowed of 6 months. Whilst in some ways this was worrying, it could also be interpreted that Member States were showing flexibility and trying to accept the maximum number of dossiers. Major problems were being experienced by Italy with one of the dossiers on Quaternary Ammonium compounds. The Commission suggested that Italy should recommend non-inclusion into Annex I if these could not be resolved. Stopping the clock was not something that Italy should consider.

CEFIC reiterated its request to be present at all Technical Meetings (TM) and regretted the fact it had not been invited to the last TM – this was because it was thought that there would be extensive discussion on individual dossiers at that TM. The Commission would look at future agendas and arrange items so that CEFIC could be present for at least parts of future TMs.

(iv) Guidance on data requirements for pheromones and essential oils

The UK will take the lead in finalising this document with input from a working group involving Austria, Germany and France; the main activity would be on pheromones. All Member States were invited to send comments on the draft document to the Commission and the UK by 20 December 2004.

The Commission suggested that Norway, Portugal, Italy and France get together to look at essential oils in a similar manner.

(v) The draft Guidance on technical equivalence developed for Plant Protection Products

The Plant Protection Products document will be developed separately from that required for biocides (because of timing issues) but the ultimate aim is to have one common document with two annexes (one for biocides and one for PPPs).

c) Draft Third Review Regulation

The Commission presented a draft of the forthcoming third Review Regulation together with an explanatory document. This draft third Review Regulation contains the designation of Rapporteur Member States for the third and fourth lists of active substances to be reviewed. It also allows for so called 'essential active substances'. These are defined where: *'it is necessary for health, safety, protection of cultural heritage or if it is critical for the functioning of*

society (encompassing cultural and intellectual aspects); and there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health'. Norway and Finland had applied for pine tar oil to be an essential active substance - see the next article for further details on this issue.

Member States were essentially content with their allocation of substances, although there were some limited exchanges made at the meeting. For example France agreed with Slovakia, Estonia and Spain to exchange various cresol compounds. The Commission invited Member States to exchange substances if they so wished by bilateral or multilateral agreements. The UK agreed to become rapporteur Member State for sodium nitrite, one of the teat dip substances.

Germany pointed out that the draft Regulation had been circulated only very shortly before the meeting and Member States needed more time to review the proposal. The Commission apologised for the relatively short timescale and assured Member States that there would be further possibilities to comment and to discuss a revised draft at the next CA meeting prior to the vote in the Standing Committee.

CEFIC referred to a letter from industry and suggested that Italy should become rapporteur Member State for calcium hypochlorite. CEFIC also expressed its concern about the lack of enforcement by Member States regarding the phasing out of products containing non-identified active substances.

The Commission concluded the item by inviting Member States to submit any additional comments in writing by 16 December 2004 and to inform them about any agreed exchanges of active substances by 15 January 2005.

d) Request from Finland and Norway regarding essential use of Pine Tars

Finland and Norway presented their request for the continued use of pine tars for wood preservation, which they consider essential. Finland explained that the intended uses were important to preserve traditional buildings and boats, which had been treated in this way for hundreds of years.

Member States were not convinced by the arguments put forward and the Commission summarised the discussion by concluding that there were two issues to consider. These were: first whether or not pine tar was a biocidal product and second, whether the criteria for essential use (as stated in the draft third Review Regulation) were fulfilled. Finland and Norway were asked to refine their request - in particular with a better description of the lack of alternatives, to provide a risk assessment for the continued use of pine tars and the results of efficacy testing.

The Commission also informed the meeting that Greece had recently submitted a request for essential use of temephos for mosquito control. However, the request from Greece was not as complete as the one from

Finland and Norway for pine tar and so Greece was asked to submit more detail. Cyprus, Italy and France indicated that they would support Greece in this work.

e) Role of Chromium in wood preservation

The Commission presented a paper with an analysis of the future status of chromium in wood preservation, supported with several documents from industry on the efficacy of chromium. The Commission reminded the meeting that chromium had been notified as an active substance for wood preservatives, but ultimately the participant did not submit a complete dossier for the evaluation. Instead, industry now claim that chromium should not have been identified or notified as an active substance as it has no individual efficacy and is used as a fixative in CCA products.

Whilst chromium was the specific example highlighted, the meeting broadened the discussion in an attempt to decide the criteria by which a substance became an active substance. Whilst no firm conclusion was reached, it was agreed that efficacy was a major deciding factor and that the decision has to be made at the product level under normal condition of use. An important conclusion was that an individual substance could be both an active substance and a substance of concern – its exact status was dependent upon the in use concentration and related efficacy/lack of efficacy data.

f) General Note on Data Protection

The Commission presented the new version of the General Note on Data Protection, which had been slightly modified in the light of the discussions at the last meeting. The document was accepted by the vast majority, subject to some minor issues raised by Sweden (regarding the 'existing active substances' definition) and some clarification provided by Finland. CEFIC repeated its earlier view that it was not satisfied with this document. The Commission acknowledged this, but noted that the interpretation now supported for biocides was also followed in the Plant Protection Products Directive, where a relevant guidance document on protected/unprotected studies was under development. The Commission explained that it had not yet verified with the Legal Services whether the link with the date of entry into force of the Directive could be made, but would do so as this had been previously requested by CEFIC.

g) Report from the second meeting of the OECD Task Force on Biocides

Steve Smith of the OECD Secretariat summarised the current work of the OECD. Essentially this is: harmonisation of efficacy methods for two biocidal product types (hard surface disinfectants and treated article biocides), work on harmonised templates for data submission, Emission Scenarios and the USA human exposure study.

h) Any Other Business

- (i) 'Stopping the clock' of dossier evaluation under the Review Programme
This would not be done except as a very last resort.
- (ii) Teat dips
These are now considered to be biocides unless there is a specific medicinal/therapeutic claim that is accepted by the Veterinary Medicines Directive (VMD) such that they consider the teat dip is a veterinary medicine.
- (iii) Harmonisation of efficacy assessments for wood preservatives.
Following a request from EWPM, the Commission asked EWPM to draft a 'thought starter' paper which will be discussed at the next Technical Meeting.
- (iv) Treated Materials
The Commission will launch a study aimed at the best way to address this issue. Ideas from stakeholders and Member States were requested.

i) Date of future meetings

Technical Meetings	TMI05:	1-4 March 2005
	TMII05:	13-17 June 2005
	TMIII05:	10-14 Oct. 2005
CA Meetings	CA 18:	29 March 2005
	CA 19:	4-5 July 2005
	CA 20:	12-13 Dec
Standing Committee on Biocides	No. 3	30 March 2005
	No. 4	14 Dec 2005 (tentative)

UK Activities

2. BCC Open Meeting Report

The Biocides Consultative Committee (BCC) held their 1st Open Meeting on 19 October 2004 at the Maritime Museum, Liverpool. The Chairman, Dr Tony Cox welcomed the audience to the meeting. He then introduced Dr Harrison of HSE who gave an overview of the Biocidal Products Directive, its implementation in the UK and the role of the BCC. Dr Cox then briefly introduced individual Members and gave a summary of the BCC's Terms of Reference, Code of Practice and the BCC's aims and objectives. This was followed by a short presentation from Prof Anthony Coates covering the potential effects following the implementation of the Directive in the UK, the work the BCC has done so far and the work the BCC is likely to do in the future. The presentations were followed by a lively question and answer session.

3. Environmental Exposure Software: Regulatory Environmental Modelling of Antifoulants (REMA) – Free Internet Download Available

In 1999 HSE released the REMA model software, which was the product of a 3-year research project funded by HSE and the Environment Agency. This validated model was developed for the UK review of the 'booster biocides' used in antifouling paints under the national Control of Pesticides Regulations, but it may also have the potential for use in defining the exposure of antifouling substances under the Biocidal Products Directive review programme.

Originally the REMA software was made available through distribution via the Health and Safety Laboratories, Sheffield at a cost of £30 per copy. Unfortunately, the distribution contract has now ceased through lack of demand and the original address for this software is no longer valid. Therefore, in order for interested parties to obtain the REMA model, HSE is grateful to the European Chemicals Bureau who have placed the software on their website. The website address is <http://ecb.jrc.it/biocides/> and the REMA software can be located by clicking on the 'Documents' section, then clicking on the 'Environmental Emission Scenarios' link where the software is in the 'REMA ANTIFOULANTS' folder. In addition to the REMA software the ECB has also made a User Guide and an erratum available in this folder, which users will need to be aware of.

It should be noted by intended users that the REMA model is 'unsupported' and recommended for use only by those with previous experience in environmental fate modelling. In situations where down-loading of software is not an option (all technical issues with down-loading from the ECB site should be directed to the ECB) there are a limited number of hard copies of the model available on a 'first come first served' basis. All enquiries for a CD of the software, or issues relating to its use, should be directed to the Biocides and Pesticides Unit at the address given at the end of this Fact Sheet. It should be noted that no further copies or updated versions of REMA will be supplied by HSE once the current stocks are exhausted.

4. Freedom of Information

The Freedom of Information Act 2000 (FOIA) came fully into force on 1st January 2005. The FOIA introduces new statutory rights of access to information held by government bodies, including HSE - replacing the non-statutory Code of Practice on access to Government information. Further information on the FOIA is available at <http://www.foi.gov.uk/>.

The FOIA can create a presumption that the public interest favours disclosure unless this is outweighed by a greater public interest that the information is not disclosed – in which case, one or more of the exemptions available in the FOIA will need to be applied. Some of the FOIA exemptions do not require a public interest test – usually because there is a more appropriate regime

applying to that kind of information – e.g. environmental information, or personal information to which the subject access provisions of the Data Protection Act 1998 apply. More information on the exemptions can be found on the Information Commissioner's website by following this link:

<http://www.informationcommissioner.gov.uk/cms/DocumentUploads/Absolute%20and%20Qualified%20Exemptions.doc>

HSE will be able to consider the public interest in disclosing information it holds, including information provided by duty-holders, and which someone has requested.

The FOIA is fully retrospective. This means that information already provided to HSE became subject to the FOIA access rights from 1 January 2005.

As many readers will have, or will in the future, provide information to the Biocides & Pesticides Unit in compliance with the requirements of the Control of Pesticides Regulations or the Biocidal Products Regulations, you should be aware that information you provide to HSE will be subject to the FOIA, and that decisions on whether or not disclosure of that information is appropriate will be taken by HSE. You will have an opportunity to make representations, though it is HSE, rather than information-providers, who have responsibilities under FOIA

As your organisation may provide information to HSE you may wish to know what will happen if HSE receives a request for such third-party information.

Information requests under FOIA will need to be handled promptly. There is a 20 working days time limit for responding to requests, except where exemptions under the Act apply. Therefore timeliness will be very important. So, on receipt of a request:

1. HSE will establish whether it holds any of the information requested.
2. If yes, HSE will consider the application of any exemptions and the need to consult you about disclosure. If consultation is necessary we will contact you as soon as possible, giving you a deadline by which you need to respond, giving your reasons why any of the requested information should not be disclosed.
3. In the meantime, HSE will keep the requester informed of progress and consider whether there are other reasons why the information should not be disclosed – e.g., ongoing enforcement action, and will also estimate whether the applicant should be charged under the FOIA fees regulations, should disclosure be appropriate.
4. Your response will be considered:
 - as part of deciding whether to neither confirm nor deny the existence of the requested information;
 - in applying the public interest test; and,
 - in applying any exemptions.

5. If HSE considers the information should be disclosed despite your wishes to the contrary, HSE will inform you of this before releasing the information.

This article is to inform you of the changes that the FOIA introduced, but is not intended to give authoritative advice about the FOIA. You can get more information about the FOIA from the Department of Constitutional Affairs website (www.foi.gov.uk), the Information Commissioner's website (www.informationcommissioner.gov.uk), or you may wish to consult your own legal advisers.

5. Future Publication of the Fact Sheet

The Biocides and Pesticides Unit is considering the future publication of the Biocides Fact Sheet and Pesticides Newsletter. The first change that has been decided is that publication will no longer stick to the traditional timetable of the start of March, June, September and December – this is due to the need to report back on the outcome of EU Competent Authority meetings which delayed the publication of this issue of the Fact Sheet – instead publication will be tied more to factors such as EU meetings and to an assessment on whether there is anything useful that needs to be reported to industry. Therefore the publication schedule will be more flexible than previously.

Any other changes will be reported in future issues.

Useful Websites and Contact Details

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.hmsso.gov.uk


HSE Books – 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:

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

