

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 19 is **not** a revision of Fact Sheets Nos.1-18 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.

Contents

<i>European Activities</i>	<i>Page</i>
1. Report from the December 2003 Competent Authorities meeting	
a. Guidance on Treated Articles	2
b. Update on the Manual of Decisions	2
c. Boundary with Cosmetics	3
d. Data Protection and Freeriders	3
e. Niche Market Initiative	3
f. Emission Scenarios and other Guidance Documents	4
g. Boundary between Veterinary Hygiene Disinfectants (PT3) and Insecticides (PT18)	4
h. Barley Straw	4
i. Product Dossier Issues	5
j. Withdrawals from the Review Programme	5
2. 11th Technical Meeting	5
3. Second Review Regulation and List of Participants published on ECB website	6

UK Activities

4. Biocides/Pesticides Industry Seminar 2004	6
5. Approved Code of Practice for Test Methods for data submitted under the Biocidal Products Regulations (Northern Ireland) 2001	7
6. Insect Repellents used on Animals – Reminder	8
<i>Useful websites and contact details</i>	9

European Activities

1. REPORT FROM THE DECEMBER 2003 COMPETENT AUTHORITIES MEETING

The 15th Meeting of the Biocides Competent Authorities took place on the 14-15 December 2003. The following is a brief summary of the key points discussed and the relevant outcomes:

a) Guidance on Treated Articles

The EC presented Doc-Biocides-2002/04-Rev3 of 31.10.2003 (available on the DG Environment Website). This guidance document clarifies the scope of BPD in a number of specific areas. The particular point concerned 'treated articles', specifically products, treated with an active substance not to protect the article but to be released from it. An example would be a mosquito net treated with an insect repellent. All Member States agreed to the proposed guidance except for Sweden who reiterated their earlier view that they would still only consider treated articles as biocidal products if the principal function was biocidal. They argued that only a limited range of examples should count as the supply of a biocidal product, e.g. insecticidal strips, animal ear tags etc. The rest should be handled as treated materials, the supply of which did not constitute the supply of a biocidal product.

b) Update on the Manual of Decisions

The Manual of Decisions is a 'living' document that is updated to include further decisions as and when they are agreed. Also, at a previous CA Meeting the EC had presented a proposal for restructuring the Manual. The EC presented an updated version that was prepared in accordance with the newly-proposed structure and contained further agreed decisions. The Member States agreed to the updated version, with an amendment to record the Swedish position above, and would be placed on the DG Environment Website.

Industry noted that one decision (point 3.5, sealants) would result in a change in product type for a notified active substance. It was agreed that, for this and any other similar situations that might arise in the future, the company involved should inform the Commission. An amendment to Annex II of the 'Second Review Regulation' (2032/2003/EC) would then have to be made.

c) Boundary with Cosmetics

Products with claims under both CPD and BPD.

The Commission proposed that only products with certain specified secondary claims should be considered to be cosmetics. The others, including sunscreen and repellent products, would require authorisation under BPD. However, following discussion it was agreed that such products would not automatically be considered to require authorisation under BPD and the guidance would be modified to reflect this.

Use of preservatives for cosmetic ingredients.

It was proposed that ingredient preservatives fell within the scope of CPD if they wound up as constituents of the ultimate cosmetic. However, following discussion, the Commission undertook to refer the issue to the next meeting of the cosmetics authorities and report back.

d) Data Protection and Freeriders

It had been intended that the Commission's proposals for the interpretation of BPD Article 12 on Data Protection be presented for agreement. However, a re-examination of the minutes of the 1996 Council meeting agreeing the common position on BPD, had indicated that this interpretation might be challengeable on the grounds that it was not what the Council had intended. The Commission would refer the matter back to their legal services. Nothing more could be done until further legal opinion had been obtained.

On the issue of freeriders, the Commission remained firmly set against the linking of active substances with their suppliers in Annex I. Overall, little progress has been made.

e) Niche Market Initiative

Full details behind the decision to establish the Working Group, primarily to consider the concern about the impact of BPD on active substances used in 'niche markets' (used in low volumes, for 'essential uses' etc.) was included in an earlier Fact Sheet (No 15 of March 2003). The first meeting of the Working Group was held on 14 November 2003 (for detailed report see Fact sheet No 18 of December 2003 on our website). The EC reported to the Competent Authorities the outcome of that meeting and the proposed next steps.

The CA's welcomed the work done to date in this initiative and the proposed next steps It was agreed that there was a clear need to separate essential use

(which could be seen as being specific to individual Member States) and the other areas, where use could be across all Member States. It was agreed that the September 2006 deadline for withdrawal of Identified-only active substances might need to be extended. This could only be until May 2010 (i.e. 10 years after the date BPD had to be implemented). The next meeting of this Working Group is scheduled for 26th March 2004. It is expected that the agenda will further consider the definition of essential use and also the categories of other substances that could benefit from possible derogatory provisions.

f) Emission Scenarios and other Guidance Documents

The following guidance was agreed:

- Emission Scenario Documents (ESD's) for PT 5 (Drinking water disinfectants), PT 11 (Liquid cooling preservatives), PT 12 (Slimicides) and PT 15 (Avicides).
- An addendum to the TNsG on Dossier Preparation to cover the use of Plant Protection Product Monographs in the BPD review programme.
- The amended guidance on waiving data for rodenticides.
- The guidance on Measures to Protect Man and the Environment will be incorporated into the TNsG.

All documents will be placed on the ECB Website as soon as possible

Work, initiated by the OECD, on an ESD for antifoulings, was nearing completion. The contractor would be invited to present the work to the July Competent Authorities Meeting.

The Commission reported that there were still some gaps in the availability of ESD's. However, they had no money to initiate further work until 2005 at the earliest.

The ECB also tabled a detailed timetable for the key actions for the 1st phase of the review programme and proposed meetings to discuss critical issues.

g) Boundary between Veterinary Hygiene Disinfectants (PT3) and Insecticides (PT18)

There had been discussion as to whether products used to control ectoparasites, because they could potentially give rise to residues on food, should be in PT 3. However, because use of similar products as insecticides in animal houses would also give rise to residues on food, it was agreed that ectoparasiticides would be in PT 18.

h) Barley Straw

Barley Straw is used to control algae in ponds, lakes etc. There has been considerable discussion between Industry and some Competent Authorities

(in particular in the UK), and also between UK Industry and the EC, on whether it is within the scope of BPD. Industry submitted a paper to the EC for consideration, which they presented to the Competent Authority Meeting, detailing what Industry believed to be the active substance generated from barley straw. It was agreed by the Commission and the Competent Authorities that the active substance should be considered to be Hydrogen Peroxide, generated from the decomposition of Barley Straw. Data would be required, as appropriate on the active substance and also the other components of the product. The product would be an algaecide, in PT2 on review List 3. The dossier would need to be submitted in 2007.

i) Product Dossier Issues

It was agreed that the product information/dossier to accompany the dossier on the active substance should be included within the IUCLID file for the active substance, not as a separate IUCLID file. A full dossier on the accompanying product was needed, making full use of the opportunities to 'predict' hazard data using the calculation method in Directive 99/45/EC.

j) Withdrawal from the Review Programme

The Commission reported that they had received approx 30 withdrawals so far. 10-12 were sole or all notifiers and affected PT8. As required by the 2nd Review Regulation (2032/2003/EC), the EC will shortly publish on its Website the list of those active substances/cases where all notifications for a given active substance/PT combination have been withdrawn.

2. 11th TECHNICAL MEETING

The 11th Technical Meeting on Biocides took place on 26-27 February 2004. The conclusions of the Technical Meeting will be considered by the Biocides Competent Authorities at their next meeting (April) and further information regarding these items will be provided at that stage. The following items were discussed:

- Environmental emission scenarios for PT 21 Antifouling products, PT 1 Human Hygiene, PT 6 In can preservatives, PT 7 Film preservatives. PT 9 Fibre, leather, rubber and polymerised materials preservatives
- Final Report for EUBEES II
- Substances in accession countries
- Dossier submission including Annex I entry for several applicants (and hence dossiers) of one substance – EINECS rules, a dossier tracking system and data requirements

- Classification and Labelling of Biocides including future co-operation with classification and labelling work in the EC and the classification and labelling of active substances for which certain studies have been waived.
- Informatics issues
- Identification codes for active substances
- Efficacy Test Methods
- Application codes for biocidal products
- Human exposure guidance documents
- Analytical methods

3. SECOND REVIEW REGULATION AND LIST OF PARTICIPANTS PUBLISHED ON ECB WEBSITE

Following the publication of the Second Review Regulation in the Official Journal of the European Union (L307, Vol. 46, 24 November 2003), the text of this regulation has now been reproduced on the European Chemicals Bureau (ECB) website (<http://ecb.jrc.it/biocides>). The ECB has now also placed the list of participants in the review programme on this website, listed by the active substance they are supporting.

UK Activities

4. INDUSTRY BIOCIDES/PESTICIDES SEMINAR 2004

Enclosed with this issue of the Biocides Fact Sheet you will find a flyer for this year's industry seminar, which will be held in May at the Maritime Museum in Liverpool. Due to the number of delegates who wished to attend the last event of this kind, we have decided that this year it will still be a one day seminar, but that it will be run twice, once on the 18th May and then again on the 19th. This should allow everyone who wishes to attend the opportunity to do so, and allow for a more comfortable seating arrangement in the lecture theatre. The final details of the programme are still being decided, but it will focus mainly on the Biocidal Products Directive/Regulations scheme, including areas such as the review programme, UK implementation, data waiving and exposure assessments, with a short update on Control of Pesticides Regulations issues. The flyer includes a booking form which should be sent back to the address indicated on the form, and please remember to state

which one of the two available dates you wish to attend.

We also asked in the last Fact Sheet if there were any particular topics you wished us to cover in the seminar, and if you do have any topics which would be relevant to the industry, please send details in an email to biocides@hse.gsi.gov.uk

5. APPROVED CODE OF PRACTICE FOR TEST METHODS FOR DATA SUBMITTED UNDER THE BIOCIDAL PRODUCTS REGULATIONS (NORTHERN IRELAND) 2001

Biocides Factsheet 18 explained that a Notice of Approval had been issued signalling the adoption of Annex V to the Dangerous Substances Directive 67/548/EEC as an Approved Code of Practice (ACOP) for test methods for data submitted under the Biocidal Products Regulations 2001. Similar arrangements have been put into place in Northern Ireland for data submitted under the Biocidal Products Regulations (Northern Ireland) 2001. The Notice of Approval issued by the Health and Safety Executive for Northern Ireland was signed on 2 February 2004 and came into operation on the same date. The text is reproduced below.

NOTICE OF APPROVAL

By virtue of Article 18(1) of the Health and Safety at Work (Northern Ireland) Order 1978^(a) and with the consent of the Department of Enterprise, Trade and Investment, being the Department concerned, the Health and Safety Executive for Northern Ireland (“the Executive”) has on 27 January 2004 adopted as an approved Code of Practice –

Annex V to EC Directive 67/548/EEC^(b) (as amended)

The Code of Practice gives practical guidance in support of regulation 37 of the Biocidal Products Regulations (Northern Ireland) 2001^(c) on the tests for biocidal products that may be required by the competent authority in accordance with those Regulations.

The Code of Practice comes into operation on 2 February 2004.

Dated this 2nd day of February 2004

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TM BLACKER
Head of Corporate Affairs Division

(a) S.I. 1978/1039 (NI 9), as amended by S.I. 1998/2795 (N.I. 18)
(b) O.J. No. L196, 16.8.67, p.1
(c) **S.R. 2001 No. 422**

6. INSECT REPELLENTS USED ON ANIMALS - REMINDER

Companies marketing insect repellents used on animals are reminded of the requirement to gain approval for such products under the national Control of Pesticides Regulations, or as veterinary medicines via the Veterinary Medicines Directorate. The deadline for applications to be received by HSE is 31 March 2003. Further details are provided in Fact Sheet 17, September 2003, available on-line at

<http://www.hse.gov.uk/HTHDIR/NOFRAMES/biofact17.htm>

Useful Websites and Contact Details

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/hthdir/noframes/bioindex.htm>


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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e-mail biocides@hse.gsi.gov.uk

Our address:

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Merseyside L20 3QZ

Our biocides webpages: <http://www.hse.gov.uk/hthdir/noframes/bioindex.htm>

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