

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 18 is **not** a revision of Fact Sheets Nos.1-17 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. EU TECHNICAL MEETING - OCTOBER 2003

The latest Technical Meeting took place on the 7-8 October in Ispra, Italy. The key issues covered at this meeting were as follows:

A. Amplification of the procedures outlined in the 2nd Review Regulation

- **Check for Completeness of Dossiers** - individual Rapporteur Member States (RMSs) are responsible for deciding whether a dossier is complete, a task that normally should be completed within 3 months of receipt of the dossier. When a dossier is considered to be incomplete, the RMS should hold a meeting with the Participant. If the matter cannot be resolved, then views from other Member States (MS) would be sought by email consultation and the period for determining whether the dossier is complete can be extended for a further 3 months. There is a lack of agreement between some MSs on the amount of detail required for a completeness check. The ECB proposes to hold a series of meetings of the MSs from June 2004 to discuss practical issues relating to the completeness checks of dossiers and similar issues relating to the evaluation of dossiers.
- **Exceptional circumstances** - where an additional time period can be granted to the participant by the RMS to submit additional information (Article 9.4 of the 2nd Review Regulation) this should be decided on a case-by-case basis.
- **Active substances already reviewed under the Plant Protection Products Directive, 91/414EC (PPPD)**- where there is a monograph and Competent Authority (CA) report already available under PPPD, guidance on the format required for BPD is currently being developed and is to be presented to the next CA meeting for endorsement. Where a CA report is not available the Commission is to check with its Legal Services before an approach can be finalised.

B. Other procedures in the preparation, submission and evaluation of dossiers

- **Submission of multiple dossiers** - a sub-group comprised of Germany, Ireland, Netherlands, Sweden, Austria and Denmark are to work on a strategy on how more than one dossier for the same active substance is to be dealt with by RMSs.
- **Annex I etc. inclusion of active substances** - a sub-group comprised of Ireland, Netherlands, Denmark and Austria, are to develop proposals on the level of detail required.

- **Measures to protect man and the environment** - supplementary forms, drafted by Germany, that are to be completed by the applicant, are to be forwarded to the next CA meeting for endorsement.
- **Safety data sheets** – these will be required for co-formulants in biocidal products. No further data will be required.
- **Literature searches** – RMS *could* undertake literature searches in cases where the RMS has concerns, but will not be required to do so in every case.
- **Testing strategies for rodenticides** – Detailed guidance on strategies for waiving certain long-term mammalian toxicology studies for rodenticides has been agreed by the Technical Meeting. This guidance will be presented to the next CA meeting for endorsement and then included as an addendum to the Technical Notes for Guidance on Data Requirements, Chapter 1.4.
- **Key decisions from the Biocides Working Group on Testing Strategies** - these will go to the EU Technical Meeting and the CAs for endorsement and be included in a chapter on waiving/testing strategies in the Manual of Decisions.
- **Application codes** - a harmonisation of terminology across MSs for application methods has been proposed and a proposal to initiate further work on this will be presented at the next CA for endorsement.
- **EU wide numbering system for biocides** – it is proposed that there will be an EU system for numbering biocides applications. In the first instance, these will be applied to applications for inclusion onto Annex I etc.
- **Allocations of substances from lists 3 and 4 to RMSs** – this is to be considered in Autumn 2004 when the candidate countries have joined the EU and will fully participate in the evaluation of active substances in the review programme.
- **Environmental Issues – Emission Scenario Documents (ESDs)**
 - OECD Wood preservative ESD. Errors in the document will be highlighted as a list on the ECB website and this approach will be adopted for other ESDs.
 - ESDs for Preservatives for liquid cooling systems, slimicides and avicides are to be presented to the next CA meeting for formal adoption.

2. UPDATE ON IUCLID ELECTRONIC DATA SUBMISSION FORMAT PROJECT – BIOCIDES AND BEYOND

The Biocidal Products Directive 98/8/EC requires that a full dossier must be submitted with an application for inclusion of an active substance on Annex I. The European Commission (EC) intends that such dossiers, which must be prepared in accordance with the Technical Notes for Guidance (TNsG) on Dossier Preparation and Study Evaluation, can be submitted by electronic means. At present the database formats for submitting data for biocides by electronic means (HEDSET or IUCLID export files for submission of data to the IUCLID database) are only partly applicable and further work is required. The EC also intends that these database formats should be compatible with the Organisation for Economic Cooperation and Development (OECD) Robust Study Formats so that, once prepared, they can be used for submissions to other Regulatory Authorities.

The European Chemicals Bureau (ECB) established a Working Group to help develop the required data formats. Experts established 3 sub-groups, covering toxicology, ecotoxicology, physical chemistry and exposure with members from both Member States and industry.

A 3rd meeting of the Working Group, organised by the ECB and the German Federal Environmental Agency for the Environment (UBA) took place on November 24th – 25th 2003 in Berlin, Germany. The main purpose of this meeting was to discuss the progress to date and to formalise proposals for harmonisation of the data formats. Developments concerning IUCLID, XML interface and a Data Entry Tool were also considered. The UBA has awarded a contract to the Fraunhofer Institute of Toxicology and Experimental Medicine, Hanover, Germany to ensure consistency across the database fields in all the data formats and to draft new data formats where necessary. This work is due to start in January 2004.

These data formats will not be available for those who have to submit dossiers on active substances used in wood preservation or as rodenticides. Dossiers on these product types will be able to use the currently available formats and, when necessary, attaching documents to the relevant part of the IUCLID database.

3. SECOND REVIEW REGULATION

The 2nd Review Regulation (Commission Regulation 2032/2003/EC) was published in the Official Journal of the European Union (ref) on 24 November 2003 and enters into force on 14 December 2003.

As a consequence of this, biocidal products containing active substances that have been neither Identified nor Notified (i.e. do not appear in Annex I of Regulation 2032/2003/EC) cannot be placed on the market after 14 December 2003.

The 2nd Review Regulation can be viewed on the EU website at http://europa.eu.int/eur-lex/en/archive/2003/l_30720031124en.html

4. NICHE MARKET WORKING GROUP

The first meeting of the 'Niche Market' Working Group took place in Brussels on 14 November 2003. Representatives from 8 Member States and from Industry attended.

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 Factsheet (No. 15 of March 2003). The EC had received comments from a number of stakeholders and had prepared a Working Paper for the meeting.

There was general agreement amongst all those present that the requirements of the Biocidal Products Directive (BPD) caused difficulties for products with essential uses and those used in 'other products' (including those used in niche markets or in low volumes). The agenda worked through the Working Paper and addressed the problems of terminology and definitions, the types of products that could be subject to specific solutions, and the possible solutions (legislative or non-legislative) to deal with them.

The meeting concluded that 'essential uses' and 'other products' were different problems and could require different solutions. There were encouraging ideas for ways of tackling these without resorting to an amendment to BPD. However it was considered that an amendment to BPD in specific areas might be possible (e.g. amending Article 15.1 to allow for certain 'essential' uses to be included and Article 1 to exclude from the BPD active substances used in approved food and feed). It was also agreed that specific guidance on waiving of data for Annex IA inclusion could be developed for some types of active substance used in 'other products'.

The EC would prepare a report for the Competent Authorities Meeting in December and a further meeting of the Working Group was proposed for February 2004. It was suggested that the Working Group should be called 'the Working Group on Essential Uses and Other Specific Categories'. Member States were asked to consider possible criteria for 'essential uses' and provide concrete examples.

5. APPROVED CODE OF PRACTICE FOR TEST METHODS FOR DATA SUBMITTED UNDER THE BIOCIDAL PRODUCTS REGULATIONS

Regulation 37 of the Biocidal Products Regulations 2001 (BPR) requires that any tests carried out in support of an application under BPR are conducted according to guidance issued by the Ministers. The Directive requires that such tests should, as a *general principle* (and so not exclusively), be carried out according to the methods described in Annex V of the Dangerous Substances Directive 67/548/EEC (as amended).

The HSE Consultative Document issued in 1999 on proposals for the draft Regulations included a proposal to adopt Annex V of Directive 67/548/EEC as an Approved Code of Practice in support of regulation 37 but without publishing it separately. Annex V is amended on a regular basis, and adopting it as an ACOP in this way will avoid the need to amend the UK regulations every time Annex V is amended. The alternative, of prescribing test methods in regulations, would be constrictive in that it would remove any discretion to consider whether other test methods were suitable.

A Notice of Approval has been issued signalling the adoption of Annex V to 67/548/EEC as an ACOP, and the text is reproduced below 1. It will be published on the HSE website in due course. The Code of Practice came into effect on 17 November 2003.

Notice of Approval

By virtue of section 16(1) of the Health and Safety at Work etc. Act 1974 and with the consent of the Minister of State for Work the Health and Safety Commission has on 10 November 2003 adopted as an Approved Code of Practice Annex V to EC Directive 67/548/EEC (as amended).

The Code of Practice is issued on behalf of the Ministers and gives practical guidance in support of regulation 37 of the Biocidal Products Regulations 2001 (SI 2001/880) on the tests for biocidal products that may be required by the competent authority in accordance with the said Regulations.

The Code of Practice comes into effect on 17 November 2003.
Signed

Mark Dempsey
Secretary to the Health and Safety Commission

6. GENERAL INDUSTRY CHARGE

The list of companies that have declared a liability for the General Industry Charge (GIC) is now on our Website at.

<http://www.hse.gov.uk/biocides/giclist.htm>

If you believe that any of the details are incorrect, including company names that are missing, then please let us know by contacting us at the address given at the end of this Fact Sheet. We aim to update this list on a monthly basis.

7. GUIDE FOR PARTICIPANTS

The Biocides and Pesticides Unit will be working closely with the Participants in the review programme for whom the UK is the Rapporteur Member State. We have prepared a Guide for Participants that gives information on dossier preparation and submission and our evaluation processes. Whilst it is primarily intended for those Participants in Priority Lists 1 and 2 submitting dossiers to the UK, it may be of interest to others. Consequently, a copy is included with this Fact Sheet at Appendix 1, for your information.

BPU is always keen to offer help to our industry as much as possible. However, with regards to provision of technical and other advice on BPD review dossiers that are NOT directly allocated to the UK, we have adopted a policy in which ANY issues including as to what data might be required for the Annex I application dossier MUST be referred in the first instance to the relevant Rapporteur Member State (RMS). This policy has been set for a number of reasons one of which is designed to maximise our own limited time and resource on those BPD applications that are specifically assigned to the UK as RMS. Also It would not be constructive to the review process if the UK were appearing to be 'treading on the toes' of the designated Rapporteur Member State and/or pushing a UK line ahead of the start of the review. It is the RMS that has the final say and we cannot impose on them. It should be noted that the UK, as with Other Member States, will have the opportunity to input into the review further down the line.

8. PROPOSED INDUSTRY SEMINAR

The Biocides & Pesticides Unit (BPU) is considering holding another of its one-day seminars for the biocide/pesticide industry around May 2004. As in previous years the aim of the seminar will be to bring companies up-to-date on issues and developments in the regulatory process, promote discussion and to gather feedback from the industry on issues of concern. We will aim to provide the opportunity for delegates to talk to BPU staff informally during the day.

The seminar is likely to cover issues relating to both the national Control of Pesticides Regulations products, and the Biocidal Products Directive/Regulations - though the majority of the content will probably cover the biocides regime - and will be open to delegates from all sectors of the biocide industry. Further details will be provided in the March 2004 Fact Sheet (or via a specific mailout), however, we would like to take this opportunity to ask readers what topics they would like to see covered during the seminar. If you would like to suggest possible topics, please send details by e-mail to :-

biocides@hse.gsi.gov.uk

Whilst this will be a 'one-day' seminar, due to the large number of delegates who wanted to attend the previous event, we will aim to repeat the seminar on the following day, so delegates will be able to choose which of the two dates they wish to attend (the content will be the same for each day), and everyone who wishes to attend should be able to do so.

9. POST ANNEX I etc. INCLUSION ISSUES

After active substances have been included in Annex I, products containing them will need to be authorised. BPU will shortly be starting to consider its procedures etc for dealing with such applications for product authorisations. When finalised, such procedures will be included in our Guide to Applicants.

If there are any issues that you think we should be considering, then we would be very interested to hear from you. Please write to our Biocides Strategy Group at the address at the end of this Fact Sheet.

10. MONITORING PROJECT

The Biocides and Pesticides Unit will shortly commence a project to monitor the supply of biocidal products. This project will check that the products contain only active substances that are on Annex I of the 2nd Review Regulation (2032/2003/EC) and that the company first placing the product on the market has declared a liability to pay the GIC.

11. READERSHIP SURVEY

With the last issue of the Biocides Fact Sheet there was a short questionnaire seeking your views, as a reader, on the content and format of this Fact Sheet and on the Pesticides Newsletter also produced by the Biocides and Pesticides Unit. We would like to thank all those people who have returned the questionnaire, we are currently collating the responses and will include feedback in a future issue of the Fact Sheet. If you have not yet returned your questionnaire, there is still time to do so and we would value your feedback to help us improve the information we provide to you via these publications. The questionnaire is available on-line at the following web address –

<http://www.hse.gov.uk/biocides/factsheets/biofact17.htm>

12. 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 December 2003. Further details are provided in Fact Sheet 17, September 2003, available on-line at

<http://www.hse.gov.uk/biocides/factsheets/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/>

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:

☎ 0151 951 3535
Fax. 0151 951 3317

e-mail 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

Appendix 1- BIOCIDAL PRODUCTS DIRECTIVE REVIEW PROGRAMME

I. Guidance on the 2nd Review Regulation (2032/2003/EC)

Purpose of the Guidance

This guidance is intended primarily for Participants¹ in the Review Programme who will be submitting dossiers to the UK in the 1st and 2nd Priority Lists. It is particularly aimed at those from the 1st Priority List as we expect that there will be further developments in some procedures and the availability of various tools for preparing and submitting dossiers between now and 2005.

Consequently, participants with active substances on the 2nd and later Priority Lists should check whether there have been changes before commencing the detailed preparation of their dossiers. We will publish new information in our Factsheets as and when it becomes available. Formulators and Participants, for whom other Member States will be acting as Rapporteur Member States (RMS), may find the information useful. The guidance will also be of use to manufacturers who may be considering making an application for the inclusion on Annex I of a new active substance.

However, please note that the guidance given here is on how the UK will implement the requirements of the 2nd Review Regulation. Other Member States may adopt different approaches. Consequently, Participants for whom other Member States will be acting as RMS should discuss specific issues with their RMS.

The 2nd Review Regulation (Commission Regulation (EC) No 2032/2003), made under the Biocidal Products Directive (BPD), was published on 24 November 2003 and entered into force on 14 December 2003.

This Review Regulation confirms the following:

- The submission deadlines as follows for active substances to be reviewed in the following product types.

- Priority List 1:

C. Submission deadline – Must be received no later than 28 March 2004

Product Type 8 – Wood Preservatives

Product Type 14 – Rodenticides

- Priority List 2:

D. Submission deadline - Between 1 November 2005 and 1 March 2006

Product Type 16 – Molluscicides

Product Type 18 – Insecticides, acaricides and products to control other arthropods

Product Type 19 – Repellents and attractants

Product Type 21 – Antifouling products

- The Rapporteur Member State (RMS) for each active substance on the first and second priority lists;
The active substances, on Priority Lists 1 and 2, for which UK will act as RMS are detailed in Appendix 1.

¹ "Participant" means a producer, formulator or association which has submitted a notification that has been accepted by the Commission in accordance with Article 4(2) of Regulation (EC) No 1896/2000 or a Member State which has indicated an interest in accordance with Article 5(3) of that Regulation.

- The submission deadlines and the product types to be reviewed in Priority Lists 3 and 4 are given in Appendix 2. The allocation of RMS to the active substances on these lists will be made at a later date.

Discussions prior to dossier preparation

The 2nd Review Regulation requires that, as RMS, we are available to discuss data requirements and, where relevant, opportunities to waive data, with you. Any advice that we give shall not predetermine the outcome of the completeness check or evaluation.

Additionally, we are available if you wish to discuss other aspects of our work on the evaluation of your dossier. Your particular attention is drawn to the provisions in Article 6 of the 2nd Review Regulation with respect to the efforts you should make to:

- Avoid duplication of testing on vertebrate animals; and
- Establishing a collective dossier, where appropriate.

Details of the efforts made in these areas must, if appropriate, be included in your dossier.

Should you wish to discuss any of these aspects with us, then please do not hesitate to contact us at the address given at the end of this document.

Dossier submission dates

The dossier submission deadlines are detailed in the 2nd Review Regulation (see Purpose of Guidance Section) and we will have a large amount of work to do to complete all our evaluations to the EC's timetable. Consequently, we will have to plan our work very carefully and we would wish to discuss estimated dossier submission dates with Participants individually.

There may be occasions where an applicant, who is not a Participant, wishes to submit a dossier on an active substance included in the review programme. If this is the case, then the dossier should be submitted by the deadline for the product type for which this application is being made.

Preparation of your dossier

Guidance on the format and structure of your dossier is given in the Technical Notes for Guidance (TNsG) on Preparation of Dossiers and Study Evaluation. This is available on the European Chemicals Bureau's (ECB) Website (<http://ecb.jrc.it/biocides>).

Whilst it is essential to follow this guidance, there are some points to note:

- The ECB is still working to finalise the electronic data entry formats for some of the study summaries in Documents (Docs) IIIA/IIIB and also

similar electronic data entry formats for Docs I, IIA, IIB and IIC. Many of these formats will not be available for use by Participants in the 1st Priority List. Consequently, dossiers on active substances on this list should be prepared using the currently available tools.

- Where an active substance is included in both the review programme under the Plant Protection Products Directive (PPPD) and BPD it is possible to submit information in PPPD format, taking into account relevant differences in the dossier requirements. However, a summary of the dossier must be submitted in IUCLID and additional information related to the biocides use must be submitted in the appropriate biocides format. Guidance on this is being produced by the ECB. If you need further details please contact us.
- Some active substances are also in the EU review programme for existing substances (ESR). Here it is also possible to utilise information provided within the framework of this programme. Again guidance is being produced by the ECB and you should contact us for further details.
- Where you are supporting an active substance that is used in two or more product types being reviewed on the same priority list then we will accept a single dossier with multiple products.

Doc I should also detail:

- The efforts made to avoid duplication of testing on vertebrate animals;
- The efforts made to secure co-operation, and the reasons for failure, if there is more than one Participant for an active substance/product type combination and the Participants concerned do not present a collective dossier.
- Additionally, should you wish to do so, you can also provide information on:
 - The costs entailed in applying for review and on the need for animal testing for the purposes of compiling a complete dossier. This can include a breakdown of the costs of the respective actions and the studies carried out.

We will forward all the above information to the European Commission (EC) with our 'competent authority report'. The EC will collate all information received and present it in a report that they must make to the Council of Ministers in 2007. This report will also make recommendations concerning modification of data requirements in order to reduce to a minimum the need for testing on vertebrate animals, and to ensure cost-effectiveness and proportionality.

Doc IV should contain full copies of all test reports. However, if you are using literature data, then, rather than providing a photocopy of the test report, you can provide its full bibliographical reference.

Literature searches

You should submit the results of a search, with details of the databases searched and search terms used. Copies of all literature need not be submitted because of copyright issues. However, any literature study that is used in your dossier will need a IUCLID entry, with a robust summary if it is a key study, together with an explanation of its relevance where appropriate.

d. Copies of all literature did not need to be submitted b

Product dossiers

When submitting an application for inclusion of an active substance in Annex I the application must contain a dossier that satisfies the requirements of BPD for at least one biocidal product containing the active substance. In addressing which product(s) to prepare a dossier for, Participants should consider the following:

- Support the product(s) of most interest to you.
- Ensure that the product(s) for which (a) dossier(s) is/are submitted can be expected to fulfil the conditions laid down in BPD Art 5.1 (b), (c) and (d).
- If you only wish to support products in a narrow range of uses (i.e. very restricted exposures for humans and/or the environment) in the product type, then you are able to do so. This may enable you to provide justifications for waiving certain studies. However, if you do not provide the full range of toxicological or environmental data required for that product type, then you may have to accept a restricted Annex I inclusion. This restriction is likely to be to a narrow range of uses. To extend the range of uses an application to amend the Annex I inclusion would have to be made.

Language of your dossier

BPD does not specify that your dossier must be submitted to us in English. However, we would strongly encourage you to submit all information in English. If some information is submitted in a language other than English, then we will have to have it translated before we can evaluate it. As BPD requires that we recover our costs, you will be charged for this.

Therefore, if you do submit studies or other information in a language other than English, we will obtain a quotation for its translation and invoice you for this amount. You will be required to pay this before the translation work is started and before we begin our completeness check. Once the translation work is completed, we will then be able to continue our work to determine whether your dossier is complete.

Fees

BPD requires that we recover the costs of this review work. To do this, we will charge a fee. Our approach to this is as follows:

1. An initial fee is payable when you submit your dossier to us. This payment (in full), by means of a cheque, in sterling only, made payable to 'The Health & Safety Executive' and crossed 'A/C Payee only' must be included with your dossier. This fee is non-refundable and we will not commence our work to determine whether your dossier is complete until our Bankers have cleared the cheque.
2. We will then estimate of the cost of the evaluation work. When we are satisfied that your dossier is in compliance with the requirements of BPD we will tell you what this estimate is. You must pay this estimate, full payment as in 1 above, within 30 days¹. At this point your dossier will be considered to be in conformity with the requirements of BPD and we will inform you of this in writing.
3. If the estimate for the balance is not paid within 30 days, then we will be obliged to reject your dossier. If this is the case, then we will write to formally let you know that we have rejected your dossier and the arrangements for its return to you.

¹ Whenever we refer to 'days' we mean calendar days

4. On completion of the work we will finalise our costs for the work.
5. Should our costs be less than the estimate that you have already paid, we will refund the difference. If our costs are greater, then we will invoice you for the balance, which must be paid before we send the evaluation and recommendations to the EC, you and other Member States.

For the 1st Priority List the non-refundable initial fee and the estimates for completion are given in the Table below.

Inclusion of active substance on Annex I, IA or IB, together with one supporting product	Non-refundable initial fee - £6,000 Estimate for completion - £59,000-£65,000 ²
Further products <i>in the same product type</i> accompanying the application for inclusion of the active substance on Annex I, IA or IB	Non-refundable initial fee - £800 Estimate for completion - £7,700

¹ The lower figure is for a minimum package of environmental data, the upper figure for a maximum package of environmental data.

There are no cases on the 1st Priority List where there will be an application for inclusion on Annex I of an active substance in two or more product types. However, there may be for later lists. If we receive such an application then the current estimate is a fee of £20,000 for the first product *in a further product type*. This is made up of the non-refundable initial fee of £2,000 and the estimate for completion of £18,000.

Ending your participation or failure to meet the dossier submission deadline

Should you wish to end your participation in the review programme, you must inform the EC and us, in writing and without delay, stating the reasons.

If there are no other complete dossiers for your active substance/product type combination, then the EC will allow a 3-month period during which other producers, formulators or associations can agree to take over the role of Participant. After this period, if nobody takes over the responsibility of Participant, then a decision will be taken not to include the active substance in Annex I for the product type concerned. Once this decision takes effect, biocidal products in that product type containing the active substance can no longer be placed on the market. However, if somebody else takes over the role of Participant, then such products can remain on the market until a decision regarding the Annex I inclusion is taken.

If your dossier, or a satisfactory reason for non-submission, has not been received by the specified deadline then your participation in the review programme with respect to the active substance for the product type in question will cease. Your attention is also drawn to Article 4.4, 4th subparagraph, of the 1st Review Regulation (1896/2000/EC). The EC may make a decision with respect to placing the active substance on the market in other product types.

The 2nd Review Regulation requires that we inform the EC and the other Member States if a dossier has not been received by the specified deadline. Should this happen, then the EC will commence the process outlined above to see if another party wishes to take over the role of Participant.

If you believe that you will be unable to submit your dossier by the deadline, then you should contact us as soon as possible, and give the reasons. The 2nd Review Regulation does allow us to extend the submission deadline in exceptional circumstances if you were unable to submit information in time.

If we agree to a new deadline, then, within 3 months of being informed of the new deadline, you must provide evidence to us that work to provide the missing information is underway.

Number of copies and submission of your dossier

We will require an electronic version and two paper copies of your complete dossier. These should be submitted to the address given at the end of this document.

Your dossier should be complete, with no outstanding information, when you submit it. However, there are a limited number of cases where outstanding data can be submitted after the submission deadline. The 2nd Review Regulation sets out the circumstances under which you may submit further data to us after the deadline. Essentially:

- You must inform us, at the time that you submit your dossier, that you will be submitting the information;
- The information must be submitted no later than nine months after we accepted your dossier;

- By comparison with the data originally submitted, the information is equally or more reliable owing to the application of the same or higher quality standards;
- By comparison with the data originally submitted, the information supports a different conclusion concerning the active substance compared with that in your original dossier.

Completeness check

Once our bankers have cleared your non-refundable initial fee we will commence our completeness check of your dossier. During this process, we will check that:

- All documents that you say have been included are in your dossier;
- All pages are there;
- All the studies that are required by BPD Annexes IIA and IIB and, where appropriate IIIA and IIIB, as amplified by the TNsG on data requirements, are included or that a justification for non-inclusion is presented.

There may be cases where we will require further information to establish whether your dossier is complete. If this is the case, we will contact you with our concerns and invite your comments. If we do this, we will need a response from you within 30 days. If we do not hear from you within this time then we will consider that the dossier is incomplete and formally reject it.

Occasionally we may seek the views of the EC and the other Member States.

Once we are satisfied that your dossier is in conformity with the requirements of BPD and the full estimate of our fee has been paid, then we will write formally notifying you that your dossier is complete. The 2nd Review Regulation requires that we finalise our completeness check within 3 months of receiving your dossier. However, if we need to consult the EC and the other Member States, then this can be extended for a maximum of a further 3 months.

It is important to understand that, when we accept a dossier as complete, it does not mean that issues will not arise later during our full evaluation of your dossier. [See 'Evaluation of your dossier']

If we conclude that your dossier is incomplete and we cannot accept it we will write formally notifying you of this, together with our reasons. In this situation you will be responsible for organising the collection of copies of your dossier that we do not need to retain.

Copy of summary dossier to EC and other Member States

BPD requires that you forward a summary of your dossier to the EC and all other Member States within one month of us informing you that we have

accepted that your dossier is complete. This summary must be prepared and sent in IUCLID.

From their review of the summary the other Member States may conclude that your dossier is not complete. If this is the case, then they will inform both the EC and us. Should we be informed we would respond to the objection received. We will then write to you explaining the objection and our response to it. If the other Member State still considers that the dossier is incomplete the matter is likely to be referred to the Standing Committee on Biocidal Products for a decision. If this is the case we will continue to keep you informed and give you the opportunity to present your views.

If you submit further information to us after we have finalised our completeness check, then you will have to send an updated summary dossier to the EC and other Member States at the same time.

Evaluation of your dossier

Once we have accepted that your dossier is complete and our Bankers have cleared the full payment for the balance of the estimated cost, we will start our evaluation of your dossier. BPD requires that we finalise our evaluation and recommendations within 12 months of accepting your dossier as complete.

It is important to note that it is only when we start the full evaluation that our scientific staff will have the opportunity to consider the quality of individual studies and the overall dossier. Thus, early in our evaluation of your dossier we may find that the overall quality of the data is poor and unlikely to be acceptable. We may also find significant problems that may mean we will be unable to recommend inclusion on Annex I/IA or IB. In such cases, and so as not to lead to unnecessary costs, we will discuss the issues and your options with you.

There may be times during the evaluation when we need to discuss specific points with you. We will try to keep these to the minimum, but if we need to contact you a prompt response from you will be required if we are to consider your response in our evaluation. There is always the possibility that we will require further data for us to complete our evaluation. This can be for two reasons:

1. We are not satisfied of the quality/relevance of a particular study – a fact that we cannot ascertain during the completeness check as we do not critically evaluate studies at that time; or
2. The results of a particular study or group of studies mean that more information is needed for us to properly assess the risks.

Should we need to discuss specific points with you, we will contact you as soon as possible so that we can discuss the issues with you and give you an opportunity to present your case to us. If necessary, we can refer specific issues to the EC and the other Member States for experts to advise us. Should it be decided that further data are necessary, then we will 'stop the

clock' and the 12-month period referred to above, will be suspended until the data are received.

If we have to 'stop the clock' we would normally do so only when we have completed our evaluation. This will mean that we are in a position to present you with all the data that we consider is needed for us to complete our evaluation.

During our evaluation we may also take into consideration other relevant technical or scientific information regarding the properties of the active substance, metabolites or residues that we are aware of or that are sent to us by other Member States or other interested parties.

Recommendations

At the end of the evaluation, we will prepare our 'competent authority report'. This will also detail our recommendation to either:

- Include the active substance in Annex I/IA or IB, with, where appropriate, conditions, or
- Not include the active substance in Annex I/IA or IB, together with our reasons.

Our evaluation and recommendations will be considered by other Government Departments and the independent Biocides Consultative Committee before they are finalised. You will be given an opportunity to see our draft evaluation and recommendations and provide comments.

Once we have finalised our costs and any outstanding payments have been received, then we will send a copy of our 'competent authority report' to you, as Participant, the EC and all other Member States.

Decision-making procedures

Once the EC has received our 'competent authority report', it will allow yourselves and the other Member States 90 days to comment in writing on our report. The EC may call meetings of experts to discuss specific problems and take advice from its advisory scientific committees.

The Standing Committee on Biocidal Products will consider a proposal for inclusion, or non-inclusion, in Annex I/IA or IB. If the recommendation is for non-inclusion, then you will be given the opportunity to make representations to the EC. A decision should be taken within 12 months of our 'competent authority report' being sent to the EC.

Contacting us

If you wish to contact us regarding data requirements, the possibilities of waiving data, or if you require information on testing on vertebrate animals or any other general enquiries about the review programme you should, in the

first instance, contact us by email (BPD@hse.gsi.gov.uk) or phone +44(0) 151 951 3535).

When you submit your dossier, it should be sent to:

Health and Safety Executive
Biocides Review Programme Dossiers
Room 123
Magdalen House
Stanley Precinct
Bootle
Liverpool
L20 3QZ
United Kingdom

APPENDIX 1

II. Active Substances for which the UK will act as Rapporteur Member State

Priority List 1

Active Substance	Notification No	Product Type	EU Number	CAS Number
2-Propenoic acid, 2-methyl-,2-[1,1-(dimethylethyl) amino] ethyl ester homopolymer	[N391]A	8	-	26716-20-1
2-octyl-2H-isothiazol-3-one	[N090]cA	8	247-761-7	26530-20-1
Fenitrothion	[N356]A	8	204-524-2	122-14-5
Bis(tributyltin)oxide	[N451]J0A/ [N451]J1A	8	200-268-0	56-35-9
Stannane, tributyl-, mono(naphthenoxloxy) derivs	[N452]A	8	287-083-9	85409-17-2
Guazatine triacetate	[N406]A	8	-	115044-19-4
Dichlofluanid	[N114]A	8	214-118-7	1085-98-9
Diarsenic pentaoxide	[N432]A	8	215-116-9	1303-28-2
Sodium dichromate	[N439]A	8	234-190-3	10588-01-9
Chromium trioxide	[N440]A	8	215-607-8	1333-82-0
Cetyl pyridinium chloride	[N615]NC	8	204-593-9	123-03-5

Priority List 2

Active Substance	Notification No	Product Type	EU Number	CAS Number
<i>III. First Review</i>				
N,N,N',N'-Tetramethylethylenediamine-bis(2-chloroethyl)ether copolymer	[N211]A	16	-	31075-24-8
s-Hydroprene	[N261]A	18	-	65733-18-8
Methomyl	[N381]A/ [N506]A	18	240-815-0	16752-77-5
Bendiocarb	[N183]A	18	245-216-8	22781-23-3
Pirimiphos-methyl	[N054]A	18	249-528-5	29232-93-7
Dimethoate	[N131]A	18	200-480-3	60-51-5
Imiprothrin	[N319]cA/ [N358]A	18	428-790-6	72963-72-5
Azamethiphos	[N004]A	18	252-626-0	35575-96-3
Benzyl benzoate	[N390]A	18&19	204-402-9	120-51-4
Anthraquinone	[N051]cA	19	201-549-0	84-65-1
Citriodiol	[N036]A	19	255-953-7	42822-86-6
Naphthalene	[N060]A	19	202-049-5	91-20-3
Zinc sulphide	[N630]A	18&21	215-251-3	1314-98-3
<i>IV. From Priority List 1 - Review in Further Product Types</i>				
Fenitrothion	[N356]A	18	204-524-2	122-14-5
2-Propenoic acid, 2-methyl-,2-[1,1-(dimethylethyl) amino] ethyl ester homopolymer	[N391]A	21	-	26716-20-1
Dichlofluanid	[N114]A	21	214-118-7	1085-98-9
Cetyl pyridinium chloride	[N615]NC	21	204-593-9	123-03-5

APPENDIX 2
Product Types and Submission Deadlines for Priority Lists 3 and 4

3rd Priority List

Submission Deadline between 1 February 2007 and 31 July 2007

Product Types

- 1 - Human hygiene biocidal products
- 2 - Private area and public health area disinfectants and other biocidal products
- 3 - Veterinary hygiene biocidal products
- 4 - Food and feed area disinfectants
- 5 - Drinking water disinfectants
- 6 - In-can preservatives
- 13 - Metalworking-fluid preservatives

4th Priority List

Submission Deadline between 1 May 2008 and 31 October 2008

Product Types

- 7 - Film preservatives
- 9 - Fibre, leather, rubber and polymerised material preservatives
- 10 - Masonry preservatives
- 11 - Preservatives for liquid-cooling and processing systems
- 12 - Slimicides
- 15 - Avicides
- 17 - Piscicides
- 20 - Preservatives for food or feedstocks
- 22 - Embalming and taxidermist fluids
- 23 - Control of other vertebrates