
Pesticides Newsletter

Issue Number 63

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Biocides & Pesticides Unit (BPU)

To HSE Approval Holders and Interested Parties.

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1. NEW PRODUCT APPLICATIONS – HELP US TO SPEED UP THE APPLICATION PROCESS BY PROVIDING THE CORRECT INFORMATION/

In order to ensure that the Biocides and Pesticides Unit processes product applications as effectively as possible, applicants are reminded that with **each** new product application (except £300 Back-to-Back applications) in addition to a completed FEPA1 application form, the following information must also be provided:

- a letter of authorisation (if appropriate);
- material Safety Data Sheets for all of the non-active substances;

- a draft product label;
- a *letter of intent from each manufacturer confirming their intention to supply the active substances present in the formulation;
- a *technical specification for all of the active substances present in the formulation, from each source;

(*as further explained in the fifth article in this issue of the Newsletter, and in Newsletter Issue Number 60).

Failure to supply any of the above will result in a delay in processing applications.

If you have any questions on this issue, please contact the Approvals Group at the address given at the end of this Newsletter.

2. COPR FEE REVIEW - BACK-TO-BACK APPLICATIONS

The Biocides and Pesticides Unit's Approvals Group has recently examined the COPR fee band structure to ensure that fees are set at the correct rate.

The findings were that fees should generally remain unchanged. However there were a number of issues concerning the 'Back to Back' category.

Some applications claiming 'Back to Back' status cite a 'parent' product that was approved some time ago, and we are now finding that the work involved in checking the original approval and updating labels to modern standards is taking more time and resource than is covered by the standard 'Back to Back' £300 fee, with the costs involved in this process more in line with a standard secretarial application fee (£500).

As BPU is obliged to recover a proportionate cost for each approval we propose to limit the applications that can be processed under the £300 'Back to Back' fee. This matter was discussed and agreed with the fees and charges review group on the 25th May 2004.

From 1st July 2004 the £300 'Back to Back' application fee will only be allowed in the following situations:

- **when a number of identical product applications are requested at the same time as the original parent application; or**
- **when the original parent product on which the identical Back-to-Back is based was originally approved within the previous 12 months.**

An application that does not fulfill the above criteria can still be processed as a 'Back to Back', but due to the amount of work involved it will have to be charged at £500 rather than the standard £300

3. FINAL REMINDER – LABELLING TO CHIP BY 30th JULY 2004

This article is a final reminder to Approval Holders of their responsibility to include any additional information on their product labels as required by the Chemicals (Hazard Information for Packaging and Supply) Regulations 2002 (CHIP 3) by 30th July 2004.

- This includes all products in the supply chain.
- We would also like to remind you that this responsibility applies to 'classified' products only.
- All new approval applications will continue to be classified and labelled by BPU for COPR using the CHIP 3 criteria.
- It is approval holder's/supplier's responsibility to ensure that the obligatory S phrases as required by CHIP 3 are present on product labels.
- For 'older' approved products in the supply chain you should have already submitted copies of any revised labels to BPU, for inclusion on your BPU product information file.
- The stand-alone transitional CHIP guidance will be removed from the BPU website at the end of July and the main points incorporated into the generic COPR labelling guidance.
- Generic guidance on CHIP 3 is available at www.hse.gov.uk/chip/index.htm.
- BPU will continue to provide information on the classification and labelling of products with respect to the Control of Pesticides Regulations.
- HSE does not approve product labels.

If you have any questions on COPR related labelling, please contact the Approvals Group at the address at the end of the newsletter.

4. AUDIT CERTIFICATES

Several companies have expressed concern at the cost of having to supply auditors certificates, and seem unaware of what is required. Where problems have arisen, the Biocides and Pesticides Unit (BPU) has been in touch with Auditors to explain what is needed, and to find out why problems occur. A simple letter or statement to verify the turnover should not be a cost burden to industry, and it is obviously more cost effective if this verification can be produced at the time of the audit.

When you receive a request for an audit certificate from BPU, it is wise to contact your auditors to arrange for this to be produced when the audit is carried out. If this date does not fit with the BPU deadline please contact us, as in most cases we are able to issue a new deadline date.

If you have any further concerns regarding audit certificates please contact Bobby Bankes or Irene O'Neill at the address given at the end of this Newsletter.

5. WHAT ARE TECHNICAL SPECIFICATIONS AND WHY ARE THEY REQUIRED?

Pesticides Newsletter Issue Number 60 (September 2003) contained an article titled 'Technical Specifications for Active Ingredients to be used in Products Approved under the Control of Pesticides Regulations'. The following paragraphs expand on that article by offering further clarity and guidance as to what the Biocides & Pesticides Unit (BPU) constitutes to be an acceptable technical specification and the reasoning behind the request for such information.

The composition of a technical active ingredient (ai) is defined by certified manufacturing limits. These limits are set for each component that make up the technical ai and consist of a minimum value for the active substance and maximum value for all the relevant impurities and additives as well as a range for the isomeric make-up of the ai.

These limits form the technical specification and are necessary to control the quality of the technical ai, such that any material manufactured outside these limits would not be sold, but discarded as waste or recycled. The composition of the technical ai can vary slightly from batch to batch, so by establishing a technical specification the composition of the technical ai can be singularly defined.

It is important that BPU hold up-to-date technical specifications on the ai's contained in the products it approves, to ensure that we are confident of the active content of the product and that any risk assessment conducted on the product is as robust as is technically possible.

It is also important that **all** stakeholders - approval holders, applicants, and formulators know the make-up of the technical ai they are including in the products they are producing/marketing, as good product stewardship should include robust quality control procedures for the manufacture of the product.

Furthermore any manufacturer unable to provide a technical specification for the technical ai they manufacture would raise concern for BPU, particularly with regard to the standard of quality control.

The technical specification must be specific not only to the technical ai, but also to the specific site of manufacture.

A technical specification proforma is available on the BPU website at <http://www.hse.gov.uk/pesticides/> which should be completed as fully as

possible in the first instance. BPU may then contact you again once the specification has been assessed if additional information is required. In order to avoid duplication, if you or the manufacturer of the technical ai believe that BPU already holds a copy of the most up-to-date technical specification then the full reference for that technical specification should be included in section 2a ('source of manufacture' box) on the FEPA1 form.

If you have any comments or questions then please contact Dr Julie Robinson on 0151 951 3279, fax: 0151 951 3317, e-mail: julie.robinson@hse.gsi.gov.uk or by letter to the address at the end of this Newsletter.

6. EXPORTATION OF PESTICIDES

An article was published in the March 2004 edition of the Pesticides Newsletter that outlined the new EC regulation concerning the import and export of dangerous chemicals, (Reference no. EC 304/2003). A list of those pesticides included in the provisions of this regulation was included in this article. HSE's intention was to publicise the new legislation and invite anyone unsure of its scope or implications to contact them. However, the article presented pesticide names only and this evidently caused some confusion. Therefore, to ensure that there is no misunderstanding, we have reproduced the list of pesticides that are affected by the provisions of EC 304/2003.

If you would like to know more about this regulation contact HSE for help.

Contact point:


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Chemical	CAS No
2,4,5-T	93-76-5
Aldrin	309-00-2
Arsenic compounds	-
Azinphos-ethyl	2642-71-9
Binapacryl	485-31-4
Captafol	2425-06-1
Chlordane	57-74-9
Chlordimeform	6164-98-3
Chlorfenapyr	122453-73-0
Chlorobenzilate	510-15-6
Chlozolate	84332-86-5
Cyhalothrine	68085-85-8
DDT	50-29-3

1,2-Dibromoethane (EDB)	106-93-4
Dieldrin	60-57-1
Dicofol containing <78% p,p'-Dicofol or 1g/kg of DDT and DDT-related compounds	115-32-2
Dinoseb, its acetate and salts	88-85-7 and others
Dinoterb	1420-07-1
DNOC	534-52-1
Endrin	72-20-8
Ethylene dichloride (1,2-Dichloroethane)	107-06-2
Ethylene oxide (Oxirane)	75-21-8
Fentin acetate	900-95-8
Fentin hydroxide	76-87-9
Fenvalerate	51630-58-1
Ferbam	14484-64-1
Fluoroacetamide	640-19-7
HCH containing less than 99% of the gamma isomer	608-73-1
Heptachlor	76-44-8
Hexachlorobenzene	118-74-1
Lindane (gamma-HCH)	58-89-9
a) Maleic hydrazide, and its salts, other than choline, potassium and sodium salts;	123-33-1
b) Choline, potassium and sodium salts of maleic hydrazide containing more than 1 mg/kg of free hydrazine expressed on the basis of the acid equivalent	51542-52-0
Mercury compounds, including inorganic mercury compounds, alkyl mercury compounds and alkyloxyalkyl and aryl mercury compounds	10112-91-1, 21908-53-2 and others
Methamidophos (soluble liquid formulations of the substance that exceed 600g active ingredient/l)	10265-92-6
Methyl-parathion (emulsifiable concentrates (EC) with 19.5%, 40%, 50%, 60% active ingredient and dusts containing 1.5%, 2% and 3% active ingredient)	298-00-0
Monocrotophos (soluble liquid formulations of the substance that exceed 600g active ingredient/l)	6923-22-4
Monolinuron	1746-81-2
Nitrofen	1836-75-5
Parathion (all formulations – aerosols, dustable powder (DP), emulsifiable concentrate (Einecs), granules (GR) and wettable powders (WP) – of this substance are included, except capsule suspensions (CS))	56-38-2
Pentachlorophenol	87-86-5
Permethrin	52645-53-1
Phosphamidon (soluble liquid formulations of the substance that exceed 1000g active ingredient/l)	13171-21-6 (mixture, (E) & (Z) isomers) 23783-98-4 ((Z)-isomer) 297-99-4 ((E)-isomer)
Propham	122-42-9

Pyrazophos	13457-18-6
Quintozene	82-68-8
Tecnazene	117-18-0
Toxaphene	8001-35-2
Triorganostannic compounds	-
Zineb	12122-67-7



If you require any further advice or information about any of the articles in this issue of the Pesticides Newsletter, please contact the Biocides and Pesticides Unit at the address below:

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Health and Safety Executive
Room 123 Magdalen House
Trinity Road
Bootle
Merseyside
L20 3QZ.*

Tel: 0151 951 3535, Fax: 0151 951 3317, Email: biocides@hse.gsi.gov.uk

*Back issues of the Pesticides Newsletter and further information on pesticides and biocides can be found on the BPU webpages at :
<http://www.hse.gov.uk/pesticides/> or <http://www.hse.gov.uk/biocides/>*