

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 20 is **not** a revision of Fact Sheets Nos.1-19 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. LATEST POSITION ON DOSSIERS RECEIVED FOR LIST 1

The 2nd Review Regulation (No 2032/2003/EC) established the timetable for the review of active substances used in biocidal products. The deadline for the submission of dossiers for active substances on List 1 (those used in wood preservative or rodenticide products) was 28 March 2004. Out of a total of 81 Notified active substances used in wood preservative and 17 used in rodenticide products only 38 and 13 dossiers respectively were submitted to the Rapporteur Member States by this deadline. Following the procedures in the 2nd Review Regulation the European Commission has now invited industry and/or the Member States to take over the role as Participant in the Review Programme for these active substances for which no dossier was submitted. (Appendix 1 lists all the active substances that were Notified for use in either wood preservative or rodenticide products and indicates if dossiers were submitted. Details can also be found on the EC website at: <http://europa.eu.int/comm/environment/biocides/index.htm>). If nobody comes forward to take over this role then a decision will be taken not to include these active substances in Annex I of the Biocidal Products Directive for use in wood preservative or rodenticide products. It is expected that this decision will take effect on 1 September 2006. From this date such active substances will not be able to be used as active substances in wood preservative or rodenticide products placed on the EU market.

2. WORKING GROUP ON ESSENTIAL USES AND OTHER SPECIFIC CATEGORIES OF BIOCIDES

The full details behind the decision to establish a Working Group and the report of its first meeting were included in earlier Fact Sheets (Numbers 15 of March 2003 and 18 of December 2003).

The Working Group has made substantial progress towards meeting its objective of finding a solution balancing protection of health and the environment with other considerations. It has specifically identified two categories of active substance, those with an essential use and those meeting an 'other specific categories' definition.

For essential uses the Working Group recommended that applications are made by a Member State and will be Member State, substance and use (i.e. not company) specific. If the application is successful, it will be subject to strict limitations, including ongoing comparative assessment and the requirement to meet the requirements of BPD Article 3.7 regarding the substance's use. Finland will trial the process with an application for Pine Tar in Autumn 2004.

For 'other specific categories' (a category of substances that could be considered to possess low hazard and would be candidates for inclusion in Annex IA) the Working Group has recommended the following process.

Industry must make proposals to the EC regarding data that can be waived. These proposals will be discussed in the Working Group on Testing Strategies and agreed guidance published as a Technical Notes for Guidance document. An application dossier for inclusion of the active substance in Annex I/IA must then be submitted, based on the agreed data requirements. The EC will only consider active substances where industry has made proposals.

The recommendations of the Working Group would apply to active substances that have at least been Identified under the 1st Review Regulation. For essential uses the 01.09.06 phase-out deadline would be extended until 14 May 2010. For supply beyond this date BPD would need to be amended. The EC could make proposals for doing this in its 2007 report to the Council and the Parliament. An extended phase-out could also apply to active substances in the 'other specific categories' if a dossier was in preparation and/or the evaluation was not yet finalised.

UK Activities

3. GENERAL INDUSTRY CHARGE FOR 2003-04

The Biocides and Pesticides Unit presented the calculations for the General Industry Charge (GIC) for 2003-04 to the Charging Review Group at a meeting held on 25 May 2004. The final GIC was £301.54 per liable company. This was based on the cost for chargeable activities of £162,227 and 538 liable companies. We anticipate that the invoices will be sent to liable companies in early July 2004.

The cost of chargeable activities is lower than the £200,000 forecast. This is primarily due to staff shortages in BPU. This has resulted in slower progress in implementing our procedures.

The number of liable companies is also lower than originally estimated. BPU is not entirely sure of the reasons for this. One reason is probably that the Regulations currently only place a liability on those who have supported an active substance in the review programme (i.e. made a notification under the 1st Review Regulation) or first place a biocidal product on the UK market. This means that many suppliers of active substances used in biocidal products in the UK are not liable, as they did not make a notification. The same applies to downstream suppliers of biocidal products where another company

manufactures products on their behalf. In this case the manufacturer (who can manufacture for a number of final suppliers), not the final suppliers, is liable.

4. THE BIOCIDES CONSULTATIVE COMMITTEE: REAPPOINTMENT OF EXISTING MEMBERS

The Biocides Consultative Committee (BCC) was established in 2001 to provide The Health and Safety Commission and Executive (HSC/E) and Ministers with independent scientific advice on the evaluation of biocidal products under the Biocidal Products Regulations 2001 (BPR). The BCC is a non-statutory committee, and Members are appointed by HSC subject to the agreement of Ministers. The HSC asked that the composition of the BCC be reviewed 2 years after its inception, and that process is now underway.

The HSC agreed at its 5 April 2004 meeting to carry forward the existing membership of the BCC. The HSC recognised that there is no constitutional need to change the membership at this point, and there is a need to refer to the BCC for its advice on the biocidal product/active substance dossiers received under the 1st phase of the European Commission's review of existing active substances. Ministerial approval has been received for this approach and the HSC Chair has now confirmed the reappointments formally in writing.

The HSC asked for one additional member to be selected with specific expertise in worker protection and the function of making sure that worker safety is given full weight in the BCC's deliberations, and we will be examining how best to recruit for this post and another recently vacated.

Consideration is also being given to whether, in addition to the member to be appointed to cover worker protection, there are other gaps in the Committee's range of experience (e.g. biostatistics and some aspects of environmental protection) and whether there should be a further recruitment exercise to fill them.

5. SUBMISSION OF BIOCIDES DOSSIERS IN THE UK

If your company is intending to submit a dossier on a biocide to BPU as the UK Competent Authority, please provide the paper copies in loose-leaf ring binders. This makes distribution of sections to different experts for evaluation much easier. Please adopt this approach when submitting a dossier on a new active substance or one undergoing review.

6. PAYMENT OF FEES FOR BIOCIDES

We would like to remind you that HSE will accept payment by one of two methods, cheque or payment via a Bankers Automated Clearance (BACS) system.

Cheques should be made payable to :

Health and Safety Executive Only
and crossed 'A/C Payee Only'

BACS payments should be credited to :

Health and Safety Executive
Sort Code 40-12-26
A/c 41453505
Midland Bank PLC
197 Stanley Road
Bootle Merseyside
L20 3DX

Only payment in sterling will be acceptable. Receipts for payments will only be issued if specifically requested.

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/biocides>


Her Majesty's Stationery Office – www.hmso.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 - ACTIVE SUBSTANCES NOTIFIED FOR USE IN WOOD PRESERVATIVES OR AS RODENTICIDES (ENTRIES THAT ARE STRUCK THROUGH ARE THOSE FOR WHICH A DOSSIER WAS NOT SUBMITTED BY 28 MARCH 2004).

A = Austria, B = Belgium, D = Germany, DK = Denmark, E = Spain, EL = Greece
 F = France, FIN = Finland, I = Italy, IRL = Ireland, L = Luxembourg, N = Norway,
 NL = Netherlands, P = Portugal, S = Sweden, UK = United Kingdom.

Active substances for wood preservatives			Rapporteur Member State
Name (EINECS and/or others)	EC Number	CAS Number	
Cyclohexylhydroxydiazene 1-oxide, potassium salt	-	66603-10-9	A
Bis[1-cyclohexyl-1,2-di(hydroxy-kappa.O)diazaniumato(2-)]-copper	-	312600-89-8	A
3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether / Etofenprox	407-980-2	80844-07-1	A
Formic acid	200-579-1	64-18-6	B
Dazomet	208-576-7	533-74-4	B
Zinc oxide	215-222-5	1314-13-2	B
alpha cyano 3-phenoxybenzyl 3-(2,2-dichlorovinyl) 2,2-dimethylcyclopropanecarboxylate / Cypermethrin	257-842-9	52315-07-8	B
[1alpha(S*),3alpha] (alpha) cyano (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl) 2,2-dichlorovinyl) 2,2-dimethylcyclopropanecarboxylate / alpha-cypermethrin	Plant protection product	67375-30-8	B
Propan-2-ol	200-661-7	67-63-0	D
L-(+)-lactic acid	201-196-2	79-33-4	D
Hexa-2,4-dienoic acid / Sorbic acid	203-768-7	110-44-1	D
Calcium dihexa-2,4-dienoate	231-321-6	7492-55-9	D
Trimagnesium diphosphide	235-023-7	12057-74-8	D
Aluminium phosphide	244-088-0	20859-73-8	D

Active substances for wood preservatives			Rapporteur Member State
Name (EINECS and/or others)	EC Number	CAS Number	
Potassium (E,E) hexa 2,4 dienoate	246-376-1	24634-61-5	D
.alpha. cyano 4 fluoro 3 phenoxybenzyl 3 (2,2-dichlorovinyl) 2,2-dimethylcyclopropanecarboxylate / Cyfluthrin	269-855-7	68359-37-5	D
Margosa ext.	283-644-7	84696-25-3	D
(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine	433-460-1	210880-92-5	D
3-Iodo-2-propynyl butylcarbamate	259-627-5	55406-53-6	DK
1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol / Tebuconazole	403-640-2	107534-96-3	DK
Thiabendazole	205-725-8	148-79-8	E
Hexaboron dizinc undecaoxide / Zinc borate	235-804-2	12767-90-7	E
Dodecylguanidine monohydrochloride	237-030-0	13590-97-1	E
Hexafluorosilicic acid	241-034-8	16961-83-4	E
cis-4-[3-(p-tert-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine	266-719-9	67564-91-4	E
Thiamethoxam	428-650-4	153719-23-4	E
Naphthenic acids, copper salts	215-657-0	1338-02-9	EL
Lignin	232-682-2	9005-53-2	EL
Ethanol	200-578-6	64-17-5	EL
N-Didecyl-N-dipolyethoxyammonium borate / Didecylpolyoxethylammonium borate	Polymer	214710-34-6	EL
Copper oxide	215-269-1	1317-38-0	F
Dicopper oxide	215-270-7	1317-39-1	F
Copper sulphate	231-847-6	7758-98-7	F
Oxine copper	233-841-9	10380-28-6	F
Copper(II) carbonate—copper(II) hydroxide (1:1)	235-113-6	12069-69-1	F

Active substances for wood preservatives			Rapporteur Member State
Name (EINECS and/or others)	EC Number	CAS Number	
Copper dihydroxide	243-815-9	20427-59-2	F
1-(4-(2-chloro-.alpha.,.alpha.,.alpha.-p-trifluorotolyloxy)-2-fluorophenyl)-3-(2,6-difluorobenzoyl)urea / Flufenoxuron	417-680-3	101463-69-8	F
Fipronil	424-610-5	120068-37-3	F
Cyclopropanecarboxylic acid, 3-[(1Z)-2-chloro-3,3,3-trifluoro-1-propenyl]-2,2-dimethyl-, (2-methyl[1,1'-biphenyl]-3-ylmethyl ester, (1R,3R)-rel- / Bifenthrin / Biphenate	Plant protection product	82657-04-3	F
Dichloro-N-[(dimethylamino)sulphonyl]fluoro-N-(p-tolyl)methanesulphenamide / Tolyfluanid	211-986-9	731-27-1	FIN
1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole / Propiconazole	262-104-4	60207-90-1	FIN
Didecyldimethylammonium chloride	230-525-2	7173-51-5	I
Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides	269-919-4	68391-01-5	F
Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides	270-325-2	68424-85-1	I
Quaternary ammonium compounds, di-C8-10-alkyldimethyl, chlorides	270-331-5	68424-95-3	F
Quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides	287-089-1	85409-22-9	F
Quaternary ammonium compounds, C12-14-alkyl[(ethylphenyl)methyl]dimethyl, chlorides	287-090-7	85409-23-0	F
Poly(oxy-1,2-ethanediyl), .alpha.-[2-(didecylmethylammonio)ethyl]-.omega.-hydroxy-, propanoate (salt)	Polymer	94667-33-1	I
Quaternary ammonium compounds (benzylalkyldimethyl (alkyl from C8-C22, saturated and unsaturated, tallow alkyl, coco alkyl, and soya alkyl) chlorides, bromides, or hydroxides) / BKC	Mixture of EINECS substances	listed	I
Quaternary ammonium compounds (dialkyldimethyl (alkyl from C6-C18, saturated and	Mixture of EINECS substances	listed	I

Active substances for wood preservatives			Rapporteur Member State
Name (EINECS and/or others)	EC Number	CAS Number	
unsaturated, and tallow alkyl, coco alkyl, and soya alkyl) chlorides, bromides, or methylsulphates) / DDAC	substances		
Quaternary ammonium compounds (alkyltrimethyl (alkyl from C8-C18, saturated and unsaturated, and tallow alkyl, coco alkyl, and soya alkyl) chlorides, bromides, or methylsulphates) / TMAC	Mixture of EINECS listed substances		I
m-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate / Permethrin	258-067-9	52645-53-1	IRL
Sodium pentachlorophenolate	205-025-2	131-52-2	IRL
1-[2-(allyloxy)-2-(2,4-Dichlorophenyl)ethyl]-1H-imidazole / Imazalil	252-615-0	35554-44-0	L
(±) 1-(β-allyloxy-2,4-dichlorophenylethyl)imidazole / Technical grade imazalil	Plant protection product	73790-28-0	L
Diboron trioxide	215-125-8	1303-86-2	NL
Disodium tetraborate, anhydrous	215-540-4	1330-43-4	NL
Boric acid	233-139-2	10043-35-3	NL
Disodium octaborate tetrahydrate	234-541-0	12280-03-4	NL
Chlorothalonil	217-588-1	1897-45-6	NL
Ethyl [2-(4-phenoxyphenoxy)ethyl]carbamate / Fenoxycarb	276-696-7	72490-01-8	NL
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	219-145-8	2372-82-9	P
3-benzo(b)thien-2-yl-5,6-dihydro-1,4,2-oxathiazine,4-oxide	431-030-6	163269-30-5	P
Esfenvalerate / (S)-α-Cyano-3-phenoxybenzyl (S)-2-(4-chlorophenyl)-3-methylbutyrate	Plant protection product	66230-04-4	P
4-Bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile / Chlorfenapyr	Plant protection product	122453-73-0	P
Sulphuryl difluoride	220-281-5	2699-79-8	S

Active substances for wood preservatives			Rapporteur Member State
Name (EINECS and/or others)	EC Number	CAS Number	
Creosote	232-287-5	8001-58-9	S
.alpha.-cyano-3-phenoxybenzyl [1R-[1.alpha.(S*),3.alpha.]] 3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate / Deltamethrin	258-256-6	52918-63-5	S
Iodine	231-442-4	7553-56-2	S
Bis(tributyltin) oxide	200-268-0	56-35-9	UK
Fenitrothion	204-524-2	122-14-5	UK
Cetylpyridinium chloride	204-593-9	123-03-5	UK
Dichlofluanid	214-118-7	1085-98-9	UK
Diarsenic pentaoxide	215-116-9	1303-28-2	UK
Chromium trioxide	215-607-8	1333-82-0	UK
Sodium dichromate	234-190-3	10588-01-9	UK
2-octyl-2H-isothiazol-3-one	247-761-7	26530-20-1	UK
Stannane, tributyl-, mono(naphthenoxyloxy) derivs.	287-083-9	85409-17-2	UK
Guazatine triacetate	Plant protection product	115044-19-4	UK
Homopolymer of 2-tert-butylaminoethyl methacrylate (EINECS 223-228-44)	Polymer	26716-20-1	UK
Benzothiazole-2-thiol	205-736-8	149-30-4	N

Active substances for rodenticides			Rapporteur Member State
Name (EINECS and/or others)	EC Number	CAS Number	
Trizinc diphosphide	215-244-5	1314-84-7	A
.alpha.,.alpha.,.alpha.-trifluoro-N-methyl-4,6-dinitro-N-(2,4,6-tribromophenyl)-o-toluidine Bromethalin	Plant protection product	63333-35-7	A

Diphacinone	201-434-5	82-66-6	B
Trimagnesium diphosphide	235-023-7	12057-74-8	D
Aluminium phosphide	244-088-0	20859-73-8	D
Coumatetralyl	227-424-0	5836-29-3	DK
Chlorophacinone	223-003-0	3691-35-8	E
Corn cob, powdered	310-127-6	999999-99-4	EL
Carbon dioxide	204-696-9	124-38-9	F
3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin / Difenacoum	259-978-4	56073-07-5	FIN
4-hydroxy-3-(3-(4'-bromo-4-biphenyl)-1,2,3,4-tetrahydro-1-naphthyl)coumarin / Brodifacoum	259-980-5	56073-10-0	I
Warfarin sodium	204-929-4	129-06-6	IRL
Warfarin	201-377-6	81-81-2	IRL
Mixture of: cis-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin; trans-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin / Flocoumafen	421-960-0	90035-08-8	NL
Chloralose	240-016-7	15879-93-3	P
3-[3-(4'-bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2-benzopyrone / Bromadiolone	249-205-9	28772-56-7	S
3-(3-(4'-Bromo-(1,1'-biphenyl)-4-yl)-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxybenzothioipyran-2-one / 3-((RS,3RS;1RS,3SR)-3-(4'-bromobiphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxy-1-benzothioin-2-one / Difethialone	Plant protection product	104653-34-1	N