

Health and Safety Executive Board		Misc Paper No: MISC/09/11	
FoI Status	Fully open	Internet Embargo	None
Exemptions	None	Trim Ref:	2009/307357
OUTCOME OF VOTING AT THE MAY 2009 MEETING OF THE EC STANDING COMMITTEE FOR BIOCIDAL PRODUCTS			

Purpose of the paper

1. To inform the Board of the outcome of the voting that took place at the 15 May 2009 meeting of the EC Standing Committee on Biocidal Products (SCB), to agree whether a number of active substances can be included on Annex I of the Biocidal Products Directive 98/8/EC (BPD).

Background

2. HSE is the designated UK Competent Authority (CA) responsible for operating the framework for authorising the placing on the market of biocidal products, established by the BPD. The CA representatives for each Member State (MS) last met on 13-15 May 2009. A key part of this meeting was to agree whether certain active substances can be included in Annex I of the BPD and under which conditions. Annex I is a list of active substances with requirements agreed at Community level for inclusion in biocidal products. When an active substance is listed here it paves the way for biocidal products containing such active substances to be authorised for placing on the market. Formal decisions on Annex I inclusion are made by qualified majority vote (QMV) in the Standing Committee for Biocidal Products (SCB), which meets immediately after each CA meeting. The SCB met on 15 May, and this paper sets out the outcome for each active substance (**Annex 1**).

3. New arrangements have been established for clearing the voting lines for future CA/SCB meetings and for keeping the Board informed about such business (MISC/09/8 refers). This paper fulfils the commitment to report the outcome of voting to the Board. The voting lines were agreed by the Chair on behalf of the Board and then by the Minister.

Argument

4. Following the votes, the Annex Inclusion Directives will be published in the Official Journal and Member States (MS) will have to transpose them into national law. In the UK this is achieved by the simple use of an ambulatory reference¹ inserted into the definition of the BPD in the Biocidal Products Regulations 2001 (as amended), such that the Annex I inclusion Directives are automatically implemented into UK law. The Annex I inclusion Directive specifies the date the decision enters into force, and the date the active substance will be entered onto Annex I (up to two years later). Applications for authorisation of biocidal products containing the active substance must then be sent to the evaluating CA (HSE in the UK) between these dates.

Consultation

¹ The phrase "as from time to time amended" is inserted such that the amendments do not have to be implemented each time.

5. This paper has been agreed with CRD (biocides), LAO, and International Unit. We have also informed Defra, BIS, DH, FSA and the devolved administrations of the outcomes. When the Annex I inclusion Directives are published the information is placed on the HSE biocides web pages and an e-mail alert is sent to those registered summarising this information.

Presentation

6. No special presentational issues arise from this paper.

Financial/Resource Implications for HSE

7. None arising from this paper.

Paper clearance

8. This Paper was cleared by the Senior Management Team on 5 August 2009.

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Outcome of the voting at the 15 May 2009 meeting of the Standing Committee for Biocidal Products

The SCB agenda listed five draft Commission Directives to include in Annex I of the Biocidal Products Directive 98/8/EC the following active substances:

Name of active substance	Use	Main conditions for Annex I inclusion	Outcome
Tolyfluanid	Wood preservative	<u>Not</u> for <i>in situ</i> outdoor treatment or for treating wood that will be exposed to weathering; products must be used with appropriate PPE; labels and Safety Data Sheets to specify post-treatment storage under shelter or on hard standing to prevent leaching to soil or water	Vote in favour of inclusion in Annex I
Flocoumafen	Control of mice, rats or other rodents	Maximum concentration; product to include aversive agent and if appropriate a dye; no use as a tracking powder; measures to minimise exposure to people and the environment, including professional use only, package size restrictions, and use of tamper resistant and secured bait boxes; before inclusion in Annex I can be renewed, comparative risk assessment	Vote in favour of inclusion in Annex I. The Commission and MS agreed to the UK request to add to the Commission guidance document 'risk mitigation measures for anticoagulants used as rodenticides' the clarification that authorisation in individual MS can be restricted to indoor use only

Name of active substance	Use	Main conditions for Annex I inclusion	Outcome
		to be carried out to assess whether another active substance on Annex I presenting significantly less risk to human/animal health or the environment is available	
Aluminium Phosphide releasing phosphine as an active substance	Control of arthropods (including insects, arachnids and crustaceans). Phosphine is generated <i>in situ</i> from aluminium phosphide as a precursor	Only for sale as 'ready-for-use' products by trained professionals; risk reduction methods for operators and bystanders, including (for operators) use of PPE and applicators, and protective measures on re-entry to confined fumigated areas; also measures to ensure Maximum Residue Levels (MRLs) in fumigated foods are met	Withdrawn from the vote to allow MS more time to consider the implications for food safety and the extent to which maximum residue limits (MRLs) should be set. To be put on the agenda for the SCB meeting in September 2009
Magnesium Phosphide releasing phosphine as an active substance	Control of arthropods as above	As above	Withdrawn from the vote (as above)
Brodifacoum	Control of mice, rats or other rodents	As for flocoumafen above	Withdrawn from the vote following discussion at the earlier CA meeting, which led the Commission to conclude that they would fail to secure a QMV for their proposal. This will return to the September CA/SCB meetings. The Commission stated its intention

Name of active substance	Use	Main conditions for Annex I inclusion	Outcome
			to work in the interim with the MSs abstaining/voting against inclusion in the practice vote to secure an acceptable way forward