| Health and Safety Executive SMT Paper | | | SMT/09/82 |
|---|---|---|---|
| **Meeting Date:** | 5 August 2009 | **FOI Status:** | Fully Open |
| **Type of Paper:** | Below the line - for agreement | **Trim Ref:** | 2009/289767 |
| **Exemptions:** | None | | |

**HEALTH AND SAFETY EXECUTIVE**

**Senior Management Team**

**Informing the Board about the outcome of voting at the May 2009 meeting of the Standing Committee for Biocidal Products**

**Advisor: Dr Robin Foster**

**Cleared by Jane Willis**

## Issue

1. To inform the Board about the outcome of the voting at the 15 May 2009 meeting of the 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).

## Timing

2. Routine.

## Recommendation

3. The SMT is invited to consider the attached draft MISC paper and agree its circulation to the HSE Board.

## Background

4. See attached draft paper.

| Health and Safety Executive Board | | Misc Paper No: MISC/09/ | |
|---|---|---|---|
| **FoI Status** | Fully open | **Internet Embargo?** | None |
| **Exemptions** | None | **Trim Ref:** | 2009/ |
| **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 reference[1] 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**

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

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

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].

**Annex 1**

**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 |
|---|---|---|---|
| Tolylfluanid | Wood preservative | Not for *in situ* 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 *in situ* 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 |