CONTENT OF THE PRODUCT DOSSIER ACCOMPANYING THE ACTIVE SUBSTANCE FOR ANNEX I INCLUSION

This document was endorsed at the 22nd meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (7-8 September 2006).

In accordance with Directive 98/8/EC, the dossier for Annex I inclusion of the active substance consists of two parts: a dossier with data on the active substance (Part A) and another dossier with data on a biocidal product (Part B).

The purpose of this product dossier accompanying the active substance for Annex I inclusion is to demonstrate safe use of that active substance in a biocidal product. This means that possible risks from the co-formulants or other active substances are not evaluated at this point.

It should be noted that, as the choice of the accompanying product may affect the data available and thus the risk assessment, the Rapporteur Member State (RMS) will also include in its evaluation report which uses were considered during the review process. In addition, a summary of the evaluated and accepted uses will be made available in the final assessment report for further reference.

This paper aims at providing guidance for the Member States and the applicants on what the requirements for the product dossier are at the Annex I inclusion stage.

Obviously, if the active substance is used as the only active substance in a representative product actually placed on the market, such a product accompanying the active substance for the Annex I inclusion would be preferable. However, this is not always the case, and therefore this document outlines the parts of the product dossier where there is some flexibility, at the Annex I inclusion stage.

The content of the product dossier accompanying the active substance for Annex I inclusion was brought up at the second workshop of the pilot project in 2001, where one of the recommendations in the final report[1] states:

> 1.1.1.1. "Necessary data on the product for Annex I entry of an active substance
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> For wood preservatives multi active formulations are normal and in these products an active substance may have little influence on the product characteristics and therefore a full product dossier would be an unnecessary burden. In most cases it was felt that the data on the product primarily is needed with regard to exposure assessment and efficacy issues and to demonstrate that a safe use of the active substance exists."

The data need for the accompanying biocidal product has since then been discussed at several meetings both at Technical Meeting (TM) level and at Competent Authority (CA) level (e.g. 15th CA meeting and TMI04), but the outcome of the discussions has not yet been added to the existing guidance documents.

During these previous discussions, the TM has agreed that the product dossier for Annex I inclusion does not need to be complete, and that it is possible to submit model data for the biocidal product at the Annex I inclusion stage (dummy product). This is in line with the earlier recommendations of the pilot project.

It is recognised that the content of the product dossier accompanying the active substance at Annex I inclusion stage may influence the content of the Annex I inclusion, and may transfer some discussions to product authorisation in general rather than at Annex I inclusion.

Thus the view expressed by some Member States, that for a decision on Annex I inclusion of an active substance also a full product dossier is necessary with data for a real biocidal product, is not applicable when the required data on safe use of the active substance can be deduced from the data of the active substance. A necessary condition is that all relevant exposure (use pattern) data is provided and efficacy of the active substance for Annex I inclusion is demonstrated. Soundness of extrapolation of data from the active substance to the product has to be demonstrated.

[1] Final report of the project: Pilot evaluation on existing biocidal active substances. Version 1.0. 17 Dec 2001. page 17

In addition, if data on a real product is submitted, there are still parts, which are not relevant at the Annex I inclusion stage (e.g. the storage stability and the trade name). Data on the product accompanying the active substance can therefore be reduced in comparison with the data needed for authorising a product.

As an example, wood preservatives have been discussed in further detail, and typical products often contain more than one active substance. Therefore, several Member States have accepted product dossiers that do not relate to a product placed on the market but is a dossier for a model formulation (dummy product). Such a formulation will give the relevant information with regard to use and exposure of the active substance under evaluation. The rationale behind this decision was that, if the product risk assessment is performed on the basis of a product containing more than one active substance, it would be difficult to draw conclusions relevant for the decision of Annex I inclusion for the active substance under evaluation.

Obviously, at product authorisation stage, a complete dossier for the real products must be submitted for authorisation, keeping in mind that information, which is not necessary owing to the nature of the product or its proposed use, or, which it is not scientifically necessary or technically possible to supply, need not be supplied.

CONCLUSIONS

Thus, in conclusion, if an accompanying product dossier has data gaps, these should be considered also in view of data needs at the Annex I inclusion stage.

It has been agreed that a complete product dossier is not necessary at the Annex I listing stage. Detailed information on use patterns and exposure is essential.