



## Emission Scenario Documents for disinfectants and preservatives under the EU Biocidal Products Directive

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### Abstract

Active substances used in product types (PT) 1, 2, 3, 4, 5 and 6 are currently being assessed under the review program of the Biocidal Products Directive. An important parameter for the environmental risk assessment of those substances is the estimation of their concentrations in the environment. An EU workshop was organised to establish specific exposure assessment for these PTs. Some of the main issues addressed include the use of tonnage data, the application of the cumulative risk assessment, the refinement of default values and the development of new scenarios. The main outcome of the workshop will be published by ECB in a publicly available report. **Keywords:** Emission Scenario Document, Biocides, Environmental Risk assessment

### Introduction

The Biocidal Products Directive (BPD, 98/8/EC) on the placing on the market of biocidal products aims to evaluate more than 300 active substances distributed over 23 Product Types (PT) and divided into four groups among which the main groups of disinfectants and preservatives. Active substances used in six product types (PT) described below (Fig.1) are currently being assessed by Rapporteur Member States (RMS) leading eventually to a decision on "Annex I inclusion" and product authorisation.

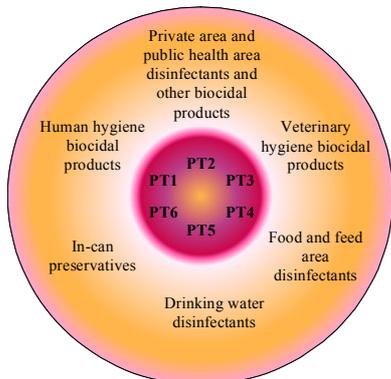


Fig.1\_ Products types currently under evaluation and considered in the workshop

An important parameter for the environmental risk assessment (ERA) is the estimation of the concentrations in the environment. For this purpose emission scenario documents (ESD) were recently updated but some unresolved issues appeared at the light of the first evaluation..

### Materials and Methods

Therefore, an EU workshop was planned to refine and establish specific scenarios for PT1-6 based on the information provided by the applicants and member states. Some of the main issues to be addressed included the exposure assessment based on tonnage or average consumption, the cumulative risk assessment, the refinement of default values and the development of new scenarios.

### Results and Discussions

#### Exposure based on tonnage or average consumption

For PT1-6 a diffuse emission sources are expected and for some uses tonnage based

scenarios were provided in the ESD.

According to the BPD, the applicant must submit information on the likely tonnage to be placed on the market if it is necessary for further evaluation. Pros and cons were identified for tonnage and average consumption approaches (Table 1).

	Tonnage approach	Average consumption approach
<b>Pros</b>	<ul style="list-style-type: none"> <li>global tonnage data available</li> <li>emission directly related to volume of use</li> <li>cumulative risk assessment allowed</li> </ul>	<ul style="list-style-type: none"> <li>simplicity of data required</li> <li>many agreed ESDs</li> <li>modification of default values possible</li> </ul>
<b>Cons</b>	<ul style="list-style-type: none"> <li>confidentiality and dossier manageability</li> <li>lack of data on detailed uses and environmental fractions</li> <li>scenarios available only for wide dispersive uses in current ESDs.</li> </ul>	<ul style="list-style-type: none"> <li>underestimation of the exposure</li> <li>lack of data accuracy leading to uncertain estimates</li> <li>no direct relation with volume of use in case of diffuse emission.</li> </ul>

Table 1. Pros and Cons related to the use of the tonnage and the average consumption approaches for the exposure assessment

It was decided that the RMS will use the average consumption approach based on the worst case scenario as a first tier of the ERA. The tonnage approach can be included for relevant PTs to assess the validity of the average consumption approach and in particular the default values used in the models. The tonnage approach will be kept confidential and can be further used to perform a cumulative risk assessment.

#### Cumulative risk assessment

According to Article 10 of the BPD the evaluation of an active substance should take into account, where relevant, cumulation effects from the use of biocidal products containing the same active substances. RMS asked for clarification on how to perform the cumulative risk assessment (CRA) and on the legal impact with respect to Annex I inclusion.

It was decided to start to perform CRA for PT1-6 to assess multiple uses within one PT and for more PTs. It should be based on the available data and its outcome will not be considered for the Annex I inclusion. An identified risk based on CRA will give the opportunity to refine the risk assessment at the product authorisation stage.

There was a clear need to agree when CRA should be considered relevant and what are the representative uses that need to be assessed. Furthermore there is a need to develop a methodology for CRA.

#### Default value refinement and development of new scenarios

In the second part of the workshop, discussions took place on the most urgent questions raised by the RMS on the environmental risk assessment of PT 1-6. More than 30 themes on issues related to exposure assessment per Product Type and to effect assessment were discussed. The outcome of those discussions will allow to update the ESDs.

### Conclusions

ECB organised a workshop in order to facilitate the evaluation process of the substances used in PT1-6 inside the review program of the BPD. General issues and specific questions were discussed leading to general agreement and/or the identification of further work tracks. The main outcomes of this discussion are compile in a workshop report which will be made publicly available at the following link: <http://ecb.jrc.it/biocides/>

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