

Biocides dossiers for subsequent product types

French recommendations for the presentation of dossiers

At the first Technical and Competent Authority Meetings in 2005, discussions took place on the presentation of subsequent product type dossiers. No clear recommendation could be found in the regulation, neither in the Technical Notes for Guidance documents (TNsG). In addition, no consensus could be obtained among the Member States at these meetings. Therefore, the Commission stated that the applicants should discuss directly with the Rapporteur Member States. As a result, discussions took place in France between organizations in charge of the evaluation of dossiers. These talks ended up in a common acceptable solution. This document is intended to explain the proposal for the presentation of subsequent product type dossiers that are submitted in France.

The reasons and objectives for thinking about such a more flexible procedure when submitting subsequent dossiers are:

1. to avoid the applicant providing several times the same study summaries,
2. to avoid the applicant submitting useless copies of the same study,
3. to avoid the RMS evaluating several times the same information,
4. to provide the Commission and the other Member States transparent and relevant evaluation reports, that could be easily read and that are consistent with other evaluation reports previously submitted to the Competent Authorities,

In order to comply with the above objectives, some rules and practical proposals are suggested to allow the applicant submitting a new dossier without repeating information already submitted in a previous dossier (especially for the hazard part of the dossier). It might be quite obvious, but should be reminded that such a procedure would only apply to dossier on active substances already submitted by the same applicant in the scope of another type of product.

- Doc IV: only the new studies not already submitted in the dossier on the other type of product should be provided,
- Doc III A and III B: for the studies already provided in the dossier from the other product type, there is no need providing again the full study summary. A short statement such as “already submitted for <name of active substance> dossier for Product Type x” should be indicated at the beginning of the format, in the reference section. In the same way as for Doc IV, it is obvious that all new data should be submitted for Doc III. Finally, it should be reminded that the key studies might be different from those submitted in the dossier for the former Product Type,
- Doc I, Doc II A II B and II C: These parts of the dossier are specific to the use of the active substance for one product type, and should be submitted as such by the applicant: new documents should be provided. However, if cross references have been used in Doc III, this should be clearly indicated in the formats for check for completeness and quality of data compiled in Doc IIIA and IIIB (e.g. filling the columns “Information test/study provided” with “Y, see PTx”).

French organizations: AFSSE, INERIS and INRS have worked together for the development of this document

Evolution of the structure of the dossier after submission by the applicant:

- Completeness check of dossier: The summary dossier that the applicant has to forward to the Commission and to the other Member States will be exactly the same as the one accepted by the Rapporteur Member States and therefore, it will include in Doc III references to another dossier for a previous Product Type for the relevant sections as described above
- Evaluation of dossiers: Each French organization in charge of one part of the evaluation will be responsible for the consistency of the study summaries between subsequent product type dossiers. The same applies for comments in the evaluation box. This means that complete versions of the dossiers should be provided during the evaluation stage, including detailed study summaries and evaluation box comments for all data submitted. As soon as the evaluation is completed and sent to AFSSE (the French Agency in charge of the coordination of the evaluation process and of the evaluation report), Doc III should no longer display cross reference to other submitted dossier.