

BIOCIDES: RECOMMENDATIONS FOR SUBMITTING A DOSSIER

Inclusion, or subsequent changes to the inclusion, of an active substance in Annex I, IA or IB shall be considered if the applicant sends an application letter written in French, accompanied by 1 paper copy of the complete dossier and 1 electronic copy (on a CD) to the MEDD¹ (competent authority) and submits 5 paper copies of documents I, IIA, IIB, IIC, IIIA, IIIB, 2 paper copies of documents IVA, IVB and 5 electronic copies (on five CDs) of the dossier to the AFSSET².

Whereas the application letter should be written in French, both paper and electronic versions should preferably be written in English in order to be transmitted on request to other member states. In contrast, study reports can be either provided in French or in English.

1 – Reference documents for dossier preparation

According to article 33 of Directive 98/8/EC, the Commission has drawn up technical notes for guidance (TNsG). The applicant should refer to this TNsG for the preparation of the dossier. All the TNsG are available on the ECB website (<http://ecb.jrc.it/biocides/>):

- Technical notes for guidance in support of directive 98/8/EC of the European parliament and the council concerning the placing of biocidal products on the market. Principles and practical procedures for the inclusion of active substances in annexes I, IA and IB (short title: TNsG on Annex I inclusion)
- Technical notes for guidance in support of the directive 98/8/EC concerning the placing of biocidal products on the market. Guidance on data requirements for active substances and biocidal products (short title: TNsG on data requirements)
- Technical notes for guidance on dossier preparation including preparation and evaluation of study summaries under directive 98/8/EC concerning the placing of biocidal products on the market (short title: TNsG on preparation of dossiers and study evaluation)³
- Technical notes for guidance on human exposure to biocidal products – Guidance on exposure estimation (short title: TNsG on human exposure)

¹ Ministère de l'Ecologie et du Développement Durable (A l'attention de Monsieur CHATELIN, DPPR / SDPD/Bureau des Substances et Préparations Chimiques, 20 avenue de Ségur, 75302 PARIS 07 SP).

² Agence Française de Sécurité Sanitaire de l'Environnement et du Travail (A l'attention de Madame TOUFFET, 253 avenue du Général Leclerc, 94701 MAISONS-ALFORT cedex).

³ This TNsG has been recently completed by documents about application codes for rodenticides and wood preservatives in order to standardise and harmonise the terminology used in the dossiers (these documents are also available on the ECB website).

- Technical notes for guidance in support of annex VI of directive 98/8/EC of the European parliament and the council concerning the placing of biocidal products on the market - Common principles and practical procedures for the authorisation and registration of products (short title: TNsG on Product Evaluation)
- Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.

2 – Structure of the dossier

The dossier is based on raw data included in study reports. These reports constitute the **document IV**. Depending on what they are dealing with (active substance or biocidal product), study reports are allocated in document IV-A (active substance) or in document IV-B (biocidal product).

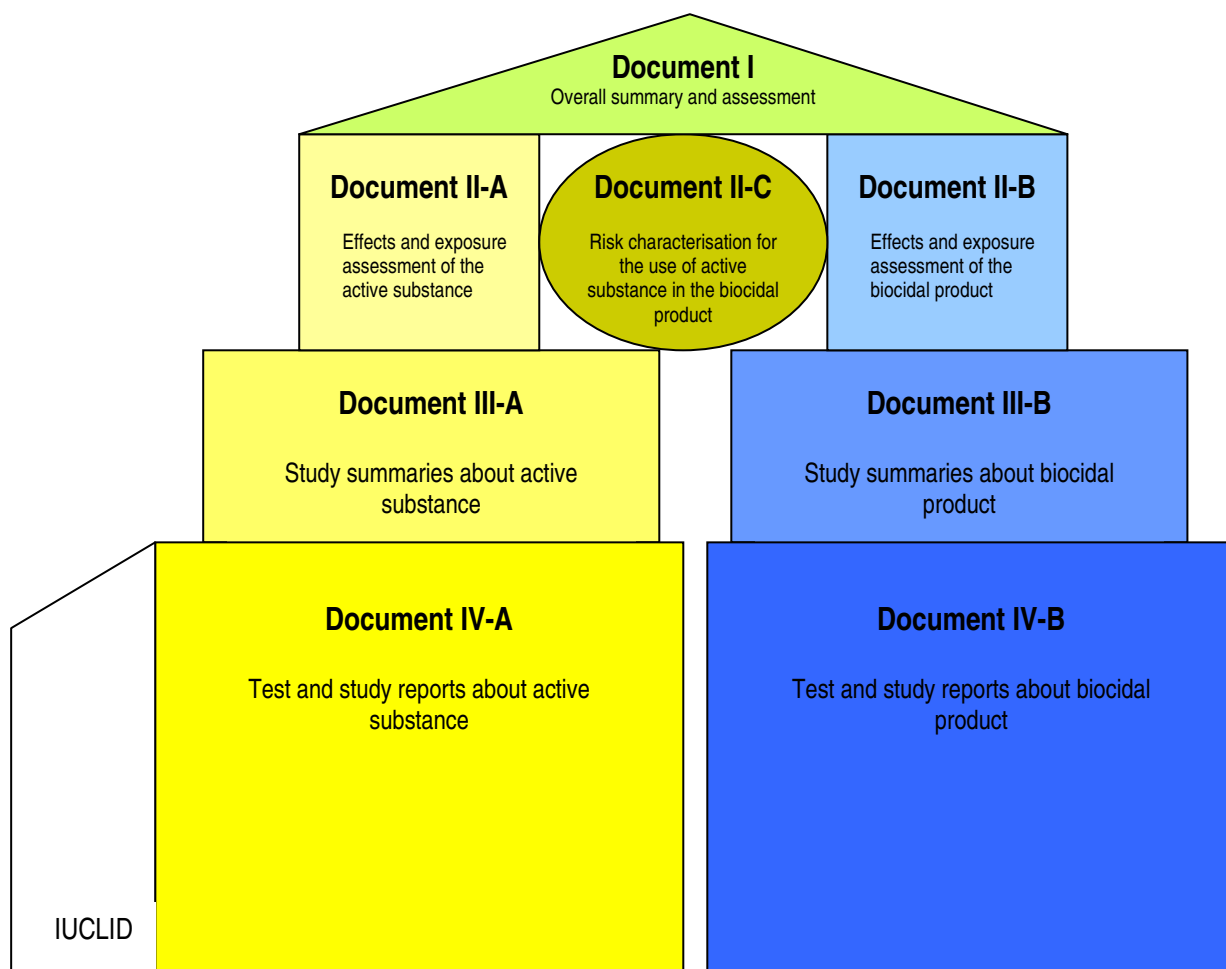
Relevant study reports are summarised in a specific format, called **document III**, which is described in the TNsG on preparation of dossiers and study evaluation. Document III-A and III-B are therefore concise versions of document IV-A and IV-B respectively.

From these study summaries, a synthesis of relevant data is reported in the **document II**. Here again, document II is subdivided into document II-A and document II-B which correspond to active substance and biocidal product data respectively. Additionally, a risk assessment of the use of the active substance in the biocidal product is presented in the document II-C. Here again, the dossier's structure is described in the TNsG on preparation of dossiers and study evaluation.

Finally, an overall summary of the different features of the hazard and risk assessment is provided in the **document I**.

Active substance data should also be summarised in a chemical database called **IUCLID** (International Uniform Chemical Information Database). IUCLID must provide all data available on the substance. The key studies must be reported in a deeply detailed description (called a "robust summary").

The following figure gives an overall picture of the dossier structure:



3 – Paper version

The paper version is composed of different folders.
At least one folder should be dedicated to each document.

3.1. Document I

The document I will always be included in the first folder.

It will present the following parts according to a strict order (*in italics, the reference of the "TNSG on preparation of dossiers and study evaluation" parts, where further information about data presentation can be found*).

- I.1 Application form (*Part I, paragraph 6.2.1, p. 52 + Appendix 6.1*)
- I.2 Overall summary and conclusions (*Part I, paragraph 6.2.2, p.53*)
- I.3 Proposal for the envisaged decision (*6.2.2, p.53*)
- Appendix 1 List of endpoints (*Part I, paragraph 6.2.4, p.54 + Appendix 6.2*)
- Appendix 2 List of abbreviations (*Part I, paragraph 7.2, p.55 + Appendices 7.1 and 7.2*)
- Appendix 3 Check for completeness and quality for document III-A (*Appendix 4.2*)
- Appendix 4 Check for completeness and quality for document III-B (*Appendix 4.3*)
- Appendix 5 Documentation related to the joint submission (if relevant)

- Appendix 6 Copies of notifications
- Appendix 7 Copies of safety data sheets for active substance
- Appendix 8 Copies of safety data sheets for formulants / substances of concern.

3.2. Document II

The document II will always be included in the second folder.

It is divided into the following parts (*in italics, the reference of the "TNsG on preparation of dossiers and study evaluation" parts, where further information about data presentation can be found*):

- II-A Effects assessment of the active substance (*Part I, paragraph 5.2.1, p.46 + Appendix 5.1*)
- II-B Effects and exposure assessment of the biocidal product (*Part I, paragraph 5.2.2, p.46 + Appendix 5.2*)
- II-C Risk characterisation (*Part I, paragraph 5.2.3, p.46 + Appendix 5.3*)

Each part has to present a reference list (*Part I, paragraph 5.3, p.47*).

3.3. Document III-A

The document III-A will always be presented from the third folder.

It will include the following parts (*in italics, the reference of the "TNsG on preparation of dossiers and study evaluation" parts, where further information about data presentation can be found*):

- Reference (*Part I, paragraph 4.8, p.39*)
- Section 1: Applicant (*Part III, p.30*)
- Section 2: Identity (*Part III, p.31-38*)
- Section 3: Physical and chemical properties (*Part III, p.31-42*)
- Section 4: Analytical methods for detection and identification (*Part III, p.43-45*)
- Section 5: Effectiveness against target organisms and intended uses (*Part III, p.46-49*)
- Section 6: Toxicological and metabolic studies (*Part III, p.48-132*)
- Section 7: Ecotoxicological profile including environmental fate and behaviour (*Part III, p.132-252*)
- Section 8: Measures necessary to protect man, animal and the environment
- Section 9: Classification and labelling
- Section 10: Summary and evaluation of sections 2 to 9

This section should display a cross-reference to the document II-A.

Guidance information for filling the above sections are provided in the "TNsG for data requirements".

All sections and sub-sections must be filled. When not possible (section not relevant⁴ or unavailable data), a justification for non submission of data has to be provided according to the format presented in "TNsG on preparation of dossiers and study evaluation", part I, table 4-2, p.28. Note that even obvious justifications have to be reported.

⁴ When a section is considered as being not relevant (e.g. viscosity for a gas, biodegradation for metals,...) the mention "n.a." (standing for "not applicable") should be reported in the completeness check list (column "Information, test, study provided") for the corresponding section.

3.4. Document IV-A

The document IV-A will be presented in the folders following those of document III-A. It will contain copies of all original test and study reports and of any other information compiled and summarised in the entire dossier.

These studies will be classified according to their presentation order and separated by conspicuous divider sheets.

Different sections will be clearly distinguished by specific separators.

All the studies should be written in English (or in French); otherwise the applicant will have to provide translations.

At the end of document IV-A the profile and results of literature searches should be appended (see "TNsG on preparation of dossiers and study evaluation", Part I, Section 3.1).

3.5. IUCLID

The printed version of the IUCLID data set will be presented in the folders following those of document IV-A.

3.6. Document III-B

The document III-B will be presented in the folders following those of document IV-A.

It will include the following parts (*in italics, the reference of the "TNsG on preparation of dossiers and study evaluation" parts, where further information about data presentation can be found*):

Reference list (*Part I, paragraph 4.8, p.39*)

Section 1: Applicant (*Part III, p.253*)

Section 2: Identity (*Part III, p.254-255*)

Section 3: Physical and chemical properties (*Part III, p.256-258*)

Section 4: Methods of identification and analysis

Section 5: Intended uses and efficacy (*Part III, p.259-269*)

Section 6: Toxicological studies (*Part III, p.270-272*)

Section 7: Ecotoxicological data for the biocidal product (*Part III, p.273-275*)

Section 8: Measures to be adopted to protect man, animal and the environment

Section 9: Classification, packaging and labelling

Section 10: Summary and evaluation of sections 2 to 9

This section should display a cross-reference to the document II-B.

Guidance information for filling the above sections is provided in the "TNsG for data requirements".

All sections and sub-sections must be filled. When not possible (section not relevant or unavailable data), a justification for non submission of data has to be provided according to the format presented in TNsG on preparation of dossiers and study evaluation, part I, table 4-2, p.28. Note that even obvious justifications have to be reported.

3.7. Document IV-B

The document IV-B will be presented in the folders following those of document III-B.

It will contain copies of all original tests and study reports and of any other information compiled and summarised in the entire dossier.

These studies will be classified according to their presentation order and separated by conspicuous divider sheets.

Different sections will be clearly distinguished by specific separators.

All the studies should be written in English (or in French); otherwise the applicant will have to provide translations.

In the end of document IV-B the profile and results of literature searches should be appended (see "TNsG on preparation of dossiers and study evaluation", Part I, Section 3.1).

3.8. Confidential information

The last folder will contain all data that are considered as confidential by the applicant.

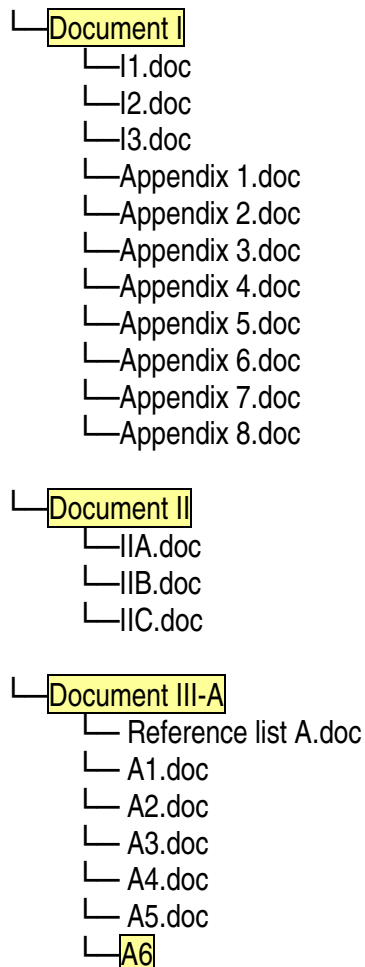
This folder should be easily distinguished from other folders. It is therefore recommended to use a red folder for confidential data and another colour for folders containing non-confidential data.

4 Electronic version

The electronic version has to provide the same information as presented in the paper version. Contrary to documents I, II and III, electronic version of documents IV is not required.

In contrast, unlike the paper version, the IUCLID data must be provided in the shape of an export file with attached documents (and not in the shape of the electronic version of the printed data set).

The presentation of electronic data should comply with the following file tree:



- └─ A6_1
 - └─ A6_1_1.doc
 - └─ A6_1_2.doc
 - └─ A6_1_3.doc
 - └─ A6_1_4.doc
 - └─ A6_1_5.doc
- └─ A6_2.doc
- └─ A6_3.doc
- └─ A6_4.doc
- └─ A6_5.doc
- └─ A6_6
 - └─ A6_6_1.doc
 - └─ A6_6_2.doc
 - └─ A6_6_3.doc
 - └─ A6_6_4.doc
 - └─ A6_6_5.doc
 - └─ A6_6_6.doc
- └─ A6_7.doc
- └─ A6_8
 - └─ A6_8_1.doc
 - └─ A6_8_2.doc
- └─ A6_9.doc
- └─ A6_10.doc
- └─ A6_11.doc
- └─ A6_12
 - └─ A6_12_1.doc
 - └─ A6_12_2.doc
 - └─ A6_12_3.doc
 - └─ A6_12_4.doc
 - └─ A6_12_5.doc
 - └─ A6_12_6.doc
 - └─ A6_12_7.doc
 - └─ A6_12_8.doc
- └─ A6_13.doc
- └─ A6_14.doc
- └─ A6_15.doc
- └─ A6_16.doc
- └─ A6_17.doc
- └─ A6_18.doc

- └─ A7
 - └─ A7_1
 - └─ A7_1_1.doc
 - └─ A7_1_2.doc
 - └─ A7_1_3.doc
 - └─ A7_1_4.doc
 - └─ A7_2.doc
 - └─ A7_3.doc
 - └─ A7_4.doc
 - └─ A7_5.doc

- └─ A7_6.doc
- └─ A8.doc
- └─ A9.doc
- └─ A10.doc

- └─ **IUCLID**
 - └─ Export file.exp
 - └─ Attached document 1.doc (or .bmp)
 - └─ Attached document 2.doc (or .bmp)
 - └─ ...
 - └─ Attached document n.doc (or .bmp)

- └─ **Document III-B**
 - └─ Reference list B.doc
 - └─ B1.doc
 - └─ B2.doc
 - └─ B3.doc
 - └─ B4.doc
 - └─ B5.doc
 - └─ **B6**
 - └─ **B6_1**
 - └─ B6_1_1.doc
 - └─ B6_1_2.doc
 - └─ B6_1_3.doc
 - └─ B6_1_4.doc
 - └─ B6_2.doc
 - └─ B6_3.doc
 - └─ B6_4.doc
 - └─ B6_5.doc
 - └─ B6_6.doc
 - └─ B6_7.doc
 - └─ B7.doc
 - └─ B8.doc
 - └─ B9.doc
 - └─ B10.doc

- └─ **Confidential**

Whenever necessary, the **justification for non submission of data** will be inserted in the file of the corresponding section.

Confidential data will be presented in the "Confidential" directory, which will be subdivided in as many files as necessary. The access to these files will require a password that will be imparted by confidential paper mail to AFSSET.

Unprotected files of the rest of the file tree (where the confidential data were supposed to be presented) will be replaced by a cross-reference to the confidential directory.

IUCLID directory will contain the export file and the corresponding attached documents. These attached documents should be used if only data can not be inserted in appropriate fields or in free text fields.

The applicant should keep in mind that:

- every study presented in the document IV will be summarised in IUCLID,
- among these studies, every key studies, which are necessarily reported in the document III, will be extensively described in IUCLID (constituting thus what is called a "robust summary"). Furthermore, these robust summaries will be emphasized by a "Risk assessment" flag.

N.B. In case of a statistical treatment of data (e.g. statistical PNEC), when no key study is available, the applicant will clearly state it in the document III and will provide short summaries of each related study in IUCLID.