Guidance Document on
How to utilize PPP Dossiers/Monographs
and
Existing Substances (ESR) Dossiers/Risk Assessments
for the Preparation of BP dossiers/ CAs' reports

21 November 2003

This document was endorsed at the 15th meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placi cing of biocidal products on the market (15-16 December 2003).

Contents

1 GENERAL INTRODUCTION

The Biocidal Products Directive (BPD) has many elements in common with the Plant Protection Products Directive (PPPD). There may also be an overlap between active substances contained in biocidal products (BP) and plant protection products (PPP) in a considerable number of cases, which requires the Commission and the Member States to carefully consider how to best use the effort already made under one directive for the other to avoid duplication of effort. It seems reasonable to utilize data from PPP dossiers and monographs on active substances which are already listed in Annex I of the PPPD (Directive 91/414/EC) or are being evaluated for that purpose.

This document does not contain detailed comparison of dossiers and assessment of existing substances (Regulation 793/93/EC, ESR). However, in chapter 5 (section 5.2) some practical advice is given on how to utilize material from the existing substances review program for the BPD review program. For a quick reader it is recommended to look directly in Chapter 5 for practical advise on the use of PPP and ESR dossier data.

2 OVERVIEW OF THE PPP APPROACH

2.1 DOSSIER DOCUMENTATION

The applicant is required to summarise, evaluate and assess the relevant data and to propose the decision to be made and give reasons for this proposal. A tiered approach is applied to the preparation of a dossier, as illustrated by Figure 1a.

The various document types and the nomenclature used indicate that this approach is very complex and also has some redundancies. This can be demonstrated as follows:

- Tier I (Document L: L-II for a.s. and L-III for preparations) contains so-called quality checks. These are, in principle, summaries only of the methods of the individual tests and studies. Standard formats are used, but two different versions are given for (a) studies conducted in accordance with and (b) studies not conducted in accordance with the test guidelines currently specified.
- Tier II (Documents M: M-II for a.s. and M-III for preparations) again contains summaries of the individual tests and studies, but these are comprehesive summaries of the findings and conclusions, whereas the Material and Methods part is only summarised very concisely.
- Tier II also includes summaries for each main section and the conclusions for each end point and subsections and sections, highlighting the parameters of relevance to decision-making.
- Document L-II and M-II are elements of the "Annex II Dossier" which describes the toxicological and ecotoxicological profile of the a.s., together with relevant data on chemical and physical properties and exposure.
- Based on the data compiled in Documents L-III and M-III and drawing on relevant data and information compiled in the Annex II Dossier, the "Annex III Dossier" is prepared, which includes a complete risk and efficacy assessment for the product.
- Tier III (Document N) comprises an overall summary and assessment of the application as far they are relevant for risk assessment and decision making. It includes a concise summary of the data base presented in the Annex II and Annex III Dossiers establishing the rationale for the envisaged Annex I entry. In addition, proposals for risk management measures in terms of restrictions are made, if appropriate. A listing (standard format) of all relevant end points is appended to the Tier III Document.
- Documents A - J and O are so-called supporting documents (see Table 1).
- Document O comprises a set of forms for the checking of dossiers for completeness.
- Document K consists of the references used, i.e. hard copies or copies stored in electronic systems of all individual test and study reports and articles from literature.

At meetings of the Pesticide Registration Steering Group in 1999 and 2000, a revised version of summaries and evaluations was discussed in the light of a

consensus reached within this Group that more subheadings should be included in the "materials and methods" and the "findings" sections of Tier II summaries. The templates proposed by the Canadian PMRA were given consideration, but regarded as too detailed. However, there is a tendency towards further substructuring of study summaries.

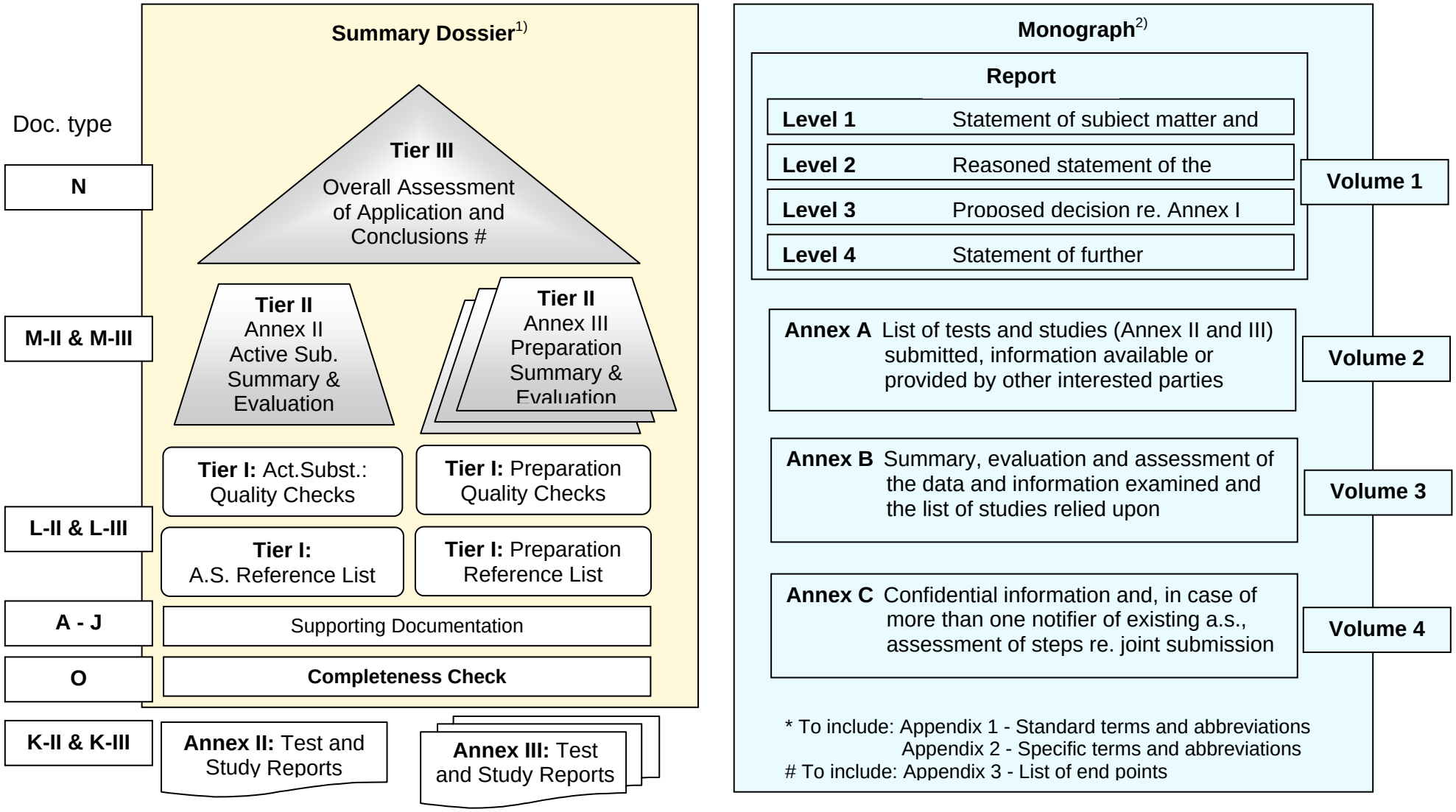
2.2 MONOGRAPH DOCUMENTATION

A PPP monograph contains (Fig. 1):

- a report of the Rapporteur Member State to the Commission, consisting of a statement of the purpose for which the monograph was prepared, a statement of the conclusions reached and a statement of the rationale used in reaching those conclusions, as well as proposals for the decision to be taken by the Commission;
- annexes containing (a) reference lists, (b) a supporting text consisting of a detailed summary, evaluation and assessment of the data base concerned and (c) confidential information.

As shown in Fig. 1, the structure of monographs differs completely from that of dossiers, although most of the individual elements are the same, i.e. summary of the data base, assessment of the data and drawing conclusions for decision-making.

Fig. 1. PPP Approach: structure of applicant's dossier and CA's monograph



To include: Appendix 9 – List of end points

1) Adapted from: EU (1998) Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Dir. 91/414/EEC

2) Adapted from: EU (1998) Guidelines and criteria for the evaluation of dossiers and for the preparation of reports to the European Commission by Rapporteur Member States relating to the proposed inclusion of active substances in Annex I of Dir. 91/414/EEC

3 GENERAL PRINCIPLES OF THE PPP AND BP APPROACHES

With both approaches, dossiers serve as a basis in support of applications from industry for the inclusion of active substances in Annex I (PPPD) or Annex I, IA or IB (BPD), while the evaluation documentation to be prepared by the Rapporteur Member State serves as a basis for deciding whether an active substance is to be included in the respective Annex.

With the PPP approach, the documentation to be prepared by the Rapporteur is called a monograph. According to Article 11 of the BPD, the procedure for the inclusion of an active substance in Annex I, IA or IB requires the receiving competent authority to carry out an "evaluation" of the applicant's dossiers. This evaluation is called "CAs' report" in the TNsG on Preparation of Dossiers and Study Evaluation and corresponds in principle to a PPP monograph, although the structure of the documentation differs.

A comparison of the practicalities concerning the application for authorisation of BP vs. PPP is outside the scope of this paper, since the PPP guidelines concerned only refer to applications for Annex I inclusion of active substances.

3.1 STANDARDISATION OF DOSSIER PREPARATION

The objectives laid down in the PPP guidelines are principally in line with those aimed at with the TNsG on Preparation of Dossiers and Study Evaluation.

Standardisation of dossier preparation is the foremost aim, with a view to:

- ensuring the quality and consistency of the documentation submitted;
- facilitating efficiency and economy in the use of resources necessary for the preparation of that documentation;
- facilitating applicants in checking the completeness and quality of the documentation prior to its submission;

- facilitating the use of electronic media for the submission, archiving and retrieval of the documentation submitted; and
- facilitating efficiency and economy in the use of resources necessary for its evaluation.

With both approaches summaries of the data base have to be prepared, to facilitate:

- checking for completeness by applicants and by the designed authorities of the Member States;
- evaluation and assessment of the documentation concerned by the Rapporteur Member States concerned;
- evaluation and assessment of the documentation concerned by the committees established or convened by the Commission for that purpose; and
- decision making by the Commission.

3.2 STANDARDISATION OF MONOGRAPH OR CAs' REPORT PREPARATION

With both approaches, the Rapporteur Member State has to evaluate and assess the dossiers received from the applicant. This process includes:

- an initial completeness check before conducting any detailed evaluation;
- the preparation of an assessment report which should reflect the information submitted by the applicant and other interested parties and, where appropriate, any other relevant information available to the Rapporteur or made available to them by other Member States.

4 COMMON AND DIFFERING ELEMENTS OF THE PPP AND BP APPROACHES

The BP approach proposed in the TNsG on Preparation of Dossiers and Study Evaluation was modelled on the PPP with following simplifications and improvements:

- reducing the number of main documents;
- simplifying the numbering system and nomenclature of documents;
- clearly distinguishing between summaries of individual tests and studies (Document III) on the one side and summaries of end points which are part of the risk assessment (Document II) on the other side;
- transferring information from Document III to Document II level;
- achieving a uniform structure for dossier and CAs' report documentation;
- allowing the CAs, in a so-called all-in-one-approach, to adopt or adapt the study summaries submitted by the applicant.

In Fig. 2 the structures of BP dossiers and CAs' reports are shown. Comparing these to the corresponding PPP documentations (Fig. 1) , both common and differing elements are apparent.

4.1 DOSSIER PREPARATION

With both approaches, the applicant is required to summarise, evaluate and assess the relevant data and to propose the decision to be made and give reasons for this proposal. The PPP guidelines refer to a so-called tiered approach. The BP approach also includes the step-by-step preparation of different document types. Although there are differences with regard to format and structure on the various dossier levels, the general principles concerning the structure of dossier documentation are similar.

4.1.1 Structure and format of PPP and BP dossiers

For comparison, the structure of BP and PPP dossiers and how the individual dossier documents correspond to each other is shown in Fig. 3 in chapter 5.

4.1.1.1 Supporting documentation

As with the PPP approach, BP dossiers should also contain so-called supporting documents required to describe the context of application. Table 1 shows the supporting documents required with the PPP approach and, for comparison, the corresponding documents in the BP approach. In general, the number of supporting documents has been reduced by integrating some documents in document type III - Study Summaries.

Table 1. Supporting documentation

PPP approach		BP approach	
Type	**Description**	**Type**	**Description**
Doc. A	Statement concerning the dossier submission	Doc. I.1	Application form
Doc. B	Documentation relating to the joint submission	Appendix of Doc. I.1	Documentation relating to the joint submission
Doc. C	Existing or proposed labels	integrated in Doc. III - Study Summaries with overview and risk assessment conclusions in Doc. II	
Doc. D-1	Details of intended uses and conditions of use in the EU		
Doc. D-2	List of authorised uses in the EU and actual uses		
Doc. D-3	Details of intended uses and conditions of use for which import tolerances are required		
Doc. E-1	Listing of EU and Member State MRLs		
Doc. E-2	Listing of MRLs established in exporting countries and in non-EU OECD countries		
Doc. G	Regulatory position (Community legislation) for formulants		
Doc. I	Other available toxicological and environmental data on formulants		
Doc. H	Safety data sheet for formulants in accordance with Directive 67/548/EEC	Appendix of Doc. I.1	Safety data sheet for formulants in accordance with Directive 67/548/EEC
Doc. F	A copy of each notification (Article 8 [2])	Appendix of Doc. I.1	Copies of notifications (in case of existing active substances)
Doc. J	Confidential data and information	Appendix of Doc. III	Confidential data and information

Fig. 2. Structure of (a) applicant's dossier and (b) CAs' report

Fig. 2a

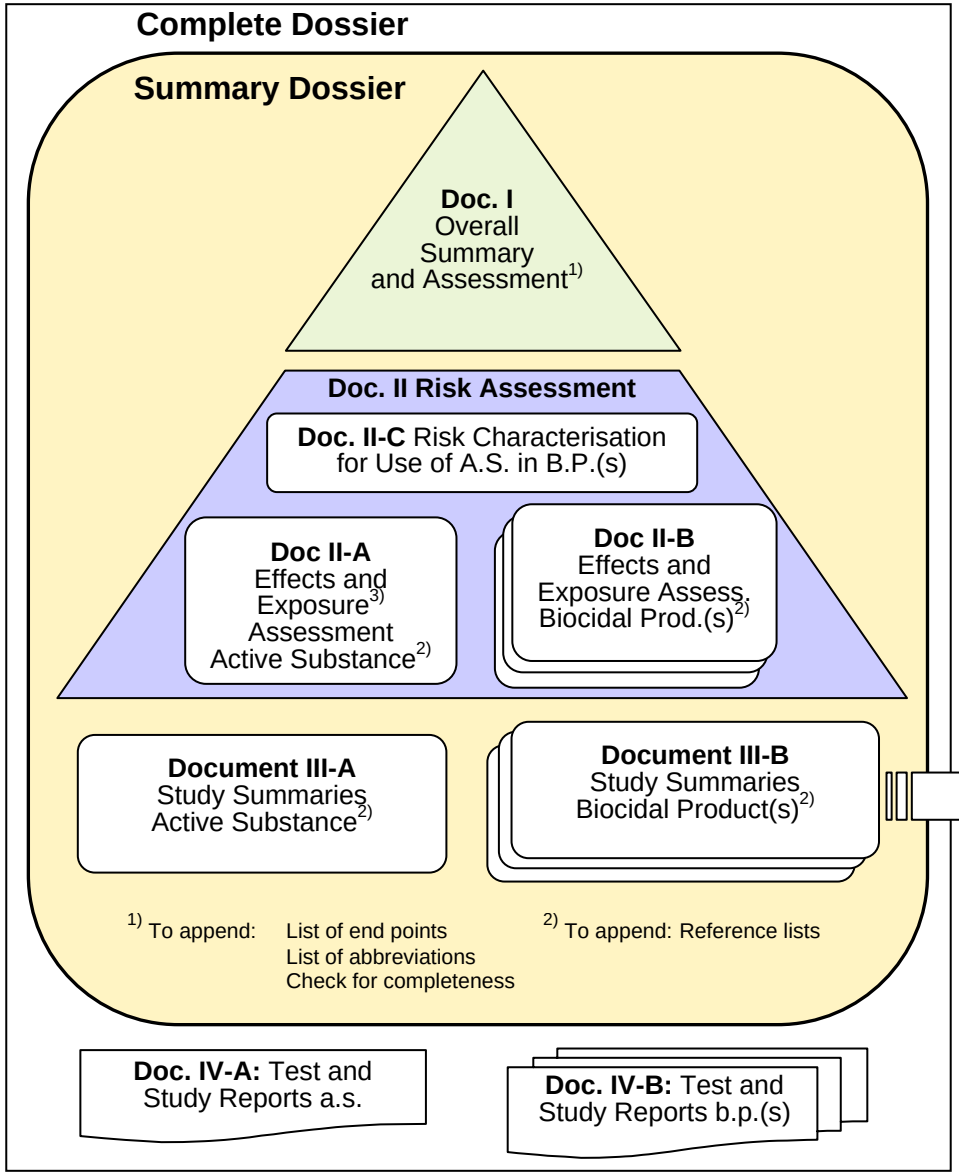
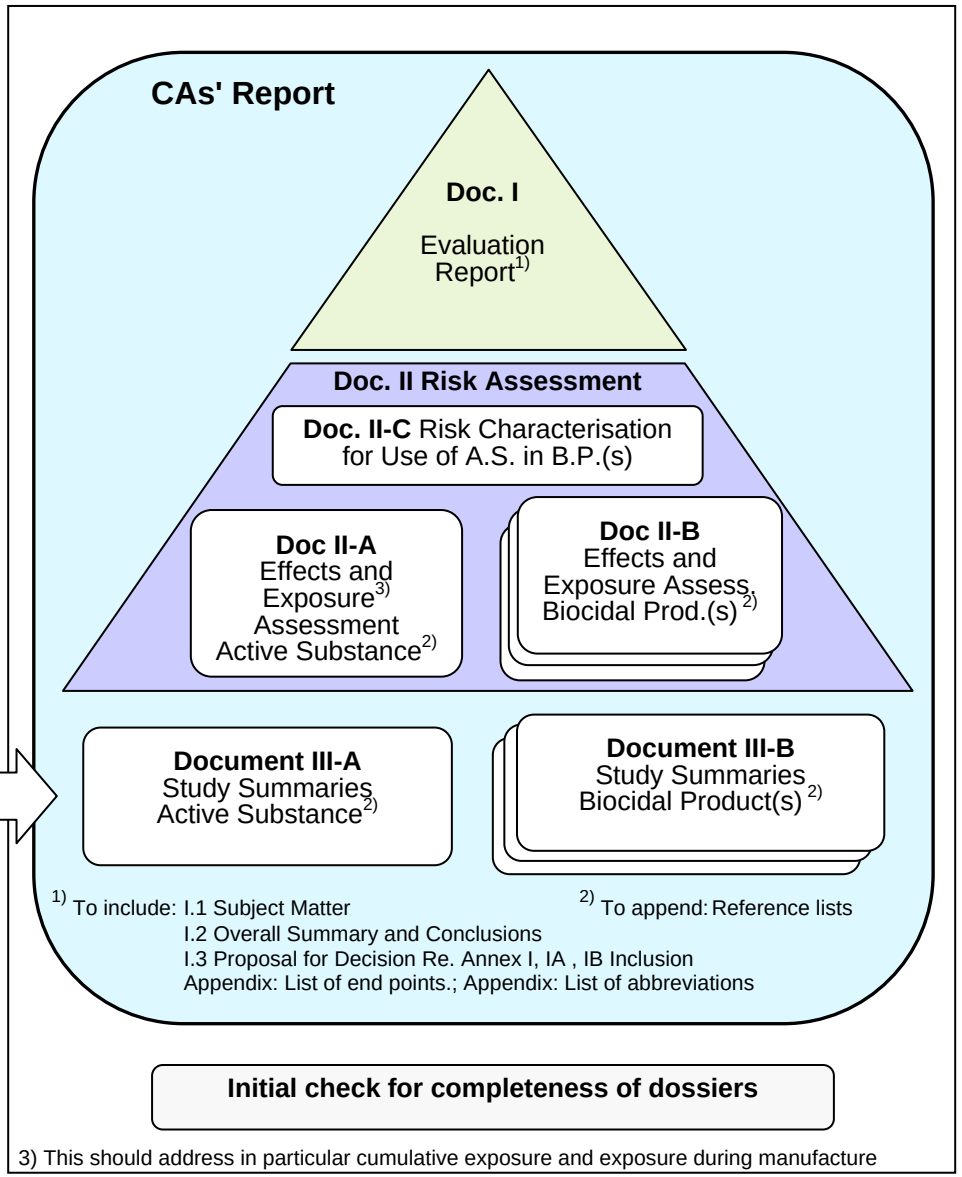


Fig. 2b



4.1.1.2 Summary and overall assessment documentation

With both approaches, the summary dossiers, which are the complete dossiers without the original test and study reports, consist of:

- summaries of data on the level of individual tests and studies;
- summaries and evaluation of end points and sections;
- elements required for risk assessment and
- overall summary and assessment including a proposal for decision.

In the light of simplifying the PPP approach and considering the risk assessment approach for new and existing chemicals, the structure and format of the summary documentation of BP dossiers has been modified in such a way that a clear-cut distinction is made between the "summaries of individual tests and studies" level and the "risk assessment" level. In addition, the risk assessment documentation has a modular structure to facilitate the authorisation procedure of biocidal products.

4.1.1.3 Summaries of individual tests and studies

The PPP approach (see Fig. 3) splits this part of the documentation into two separate levels:

- Tier I "Quality Checks for Test and Study Reports": here only the methodology of individual studies is addressed (L-documents).
- Tier II "Data Summary and Evaluation": Tier II summaries contain a summary of the methods plus a discussion and interpretation of the results of all individual tests and studies including conclusion. In addition, the conclusions reached for each section are outlined in Tier II (M-documents).

In the BP approach, a less complicated procedure is proposed (see Fig. 3), which clearly distinguishes between:

- the assessment of data on the individual study level (Document III – Study Summaries) and
- further assessment on an end point or section-related level in Document II-A and II-B (Hazard and Effects Assessment and Exposure Assessment).

This clear distinction principally corresponds to the approach used in the risk assessment of existing industrial chemicals, where a IUCLID data set provides study summaries, which in the future, with improved quality, should be the basis for the evaluation in the risk assessment report. Current information in IUCLID regarding the eixisting substances regulation has been collected for priority setting purposes.

The differences between study summaries of PPP and BP dossiers are summarised in Table 2. The BP approach differs from the PPP approach mainly with regard to the following items:

- Quality checks and summaries of test and study reports are covered by one standard format, i.e. Tier I quality checks and Tier II summaries of the PPP approach have been combined.
- Studies conducted in accordance with standard test guidelines and other studies, i.e. so-called non-guideline studies, are covered by the same standard formats and not by two different formats as in PPP summaries.
- The standard formats are generally structured with (sub)headings in greater detail in the methods and results part.
- Reliability scores indicating the quality of data provided can be given which can be directly transferred to the completeness check form.
- Commentary areas and evaluation boxes for the competent authorities have been incorporated which should allow the synergetic use of the applicant's summaries by the Rapporteur. This so-called all-in-one approach is intended to facilitate the evaluation of this part of the dossier by the competent authorities.

Table 2: Comparison of standard formats of the PPP and BP approach

Item	PPP Approach	BP Approach
Type of formats	Example formats for selected end points	Standard formats for most relevant end points or items
Guideline vs. non-guideline studies	Two different formats	One standard format for both quality check and presentation of results and conclusions (no redundancies)
Quality check and presentation of results and conclusions	Two different formats: Tier I and Tier II	
Structure of formats	Example formats of Tier I have a detailed structure to allow for an appropriate quality check*)	Very detailed structure with guidance on which parameters are to be filled in
Justification	Not included in the formats; to be described as free text	Form provided to be included in case of non-submission of data
Commentary areas for rapporteur	No; dossier as stand-alone approach	Yes; all-in-one approach with specific commentary areas including separate fields for "Evaluation by CAs"
Summary tables	In Tier II, examples of results tables are given	Sample results and summary tables
Guidance notes	Comprehensive, but only general; example formats	Guidance notes integrated in the formats

*) A revision of the PPP guidelines is currently under discussion aiming at including more (sub)headings in Tier II formats

4.1.1.4 Risk assessment

With the PPP approach, the typical structuring into hazard assessment, exposure assessment and risk characterisation is not applied:

- The effects assessment (=hazard identification and dose-response assessment) and data on exposure of the active substance is contained in the Tier II document (Doc. M-II), in addition to the summaries of the individual tests and studies,
- The risk and efficacy assessment is carried out in the Tier II document on the preparation (product) (Doc. M-III).

With the BP approach there is a separate risk assessment document (Doc. II) and this contains the following modules:

- Doc. II-A: Effects and Exposure Assessment Active Substance
- Doc. II-B: Effects and Exposure Assessment Biocidal Product(s)

- Doc. II-C: Risk Characterisation for the Use of the Active Substance in Biocidal Products

As with the PPP approach, the risk characterisation is product-related. In contrast to the PPP, different product types may have to be considered in the exposure assessment and risk characterisation when applying for the Annex I entry of a biocidally active substance.

4.1.1.5 Overall summary and conclusions and list of end points

The overall summary and assessment (Tier III or Doc. N) of the PPP approach is comparable to the overall summary and assessment (Doc. I) of the BP approach. In principle, the reporting format can been adapted for:

- Overall summary and conclusions (Doc. I.2)
- Proposal for decision regarding Annex I, IA or IB inclusion (Doc. I.3)

In addition the BP overall summary and assessment document contains an application form (Doc. I.1).

With the PPP approach, a list of end points is annexed to the overall summary and assessment document. In the BP approach, a similar list should be appended to Doc. I. The format of this list has been adopted from the corresponding PPP guidelines.

4.1.2 Standard units, terms, abbreviations

For the TNsG on Preparation of Dossiers and Study Evaluation, the recommendations given in the corresponding PPP guidelines with regard to the use of standard units, standard terms and standard abbreviations have been adopted.

4.1.3 Codes

For the authorisation procedure of plant protection products, extensive code lists were compiled by EPPO (European and Mediterranean Plant Protection Organization) based on the code lists of the German producer Bayer AG.

A proposal for a similar code system for the authorisation and registration processes for biocidal products is under discussion.

4.1.4 Reference lists

With the PPP approach, listings, ordered by author and annex point, of all test and study reports, test guidelines, and published papers, submitted as part of the dossier are to be provided as part of the Tier I quality checks. In addition, separate listings of such information, if it addresses relevant end points, but is not submitted by the applicant, are to be provided. The listings of test and study reports include also information on data protection and the owner of the reports.

For the BP approach, these types of listings are adopted (see relevant chapters of the TNsG on Preparation of Dossiers and Study Evaluation).

4.1.5 Checking of dossiers for completeness and quality of data

With the PPP approach, the applicant has to confirm that the dossiers are complete. Several evaluation forms to carry out completeness checks are provided with PPP dossier Document O (see Table 3).

Table 3. Evaluation forms for checking PPP dossiers for completeness

Form	**Completeness check for**
Evaluation Form 1	Supporting documentation (A-J)
Evaluation Form 2	Annex II and III dossier summaries and overall assessment (L-N)
Evaluation Form 3	Annex IIA test and study reports
Evaluation Form 4	Annex IIIA test and study reports
Evaluation Form 5	Tier I Quality checks (for non-guideline studies)
Evaluation Form 6	Listing of test guidelines specified and GLP/GEP requirements for Annex IIA tests and studies
Evaluation Form 7	Listing of test guidelines specified and GLP/GEP requirements for Annex IIIA tests and studies

With the BP approach, the applicant should confirm the completeness of the dossier documentation in the application form. For the check of completeness and quality of data (test and study reports), only one single form is used, which can be used to check:

- whether the required information, test or study is provided, or if not,
- whether a justification is provided;
- whether data protection is claimed;
- whether data are considered confidential;
- the quality of data by means of reliability indicators.

4.1.6 Electronic dossier submission

The use of CADDY as an electronic dossier submission system is recommended for PPP dossiers.

In the BPD program IUCLID is used a data input tool. All studies are inserted in the IULID and in addition study summary forms are used for key studies. Some member states may accept the original study reports in CADDY-format, but this must be agreed separately with the raporteur member state.

4.2 MONOGRAPH OR CAs' REPORT PREPARATION

With the PPP approach, dossiers and monographs have completely different structures (Fig. 1). Taking into consideration that most elements of dossier and monograph or CAs' report are equivalent, a harmonisation of the structure of documentation has been achieved as far as possible with the BP approach (see Fig. 2).

The introduction of an all-in-one approach in document type Study Summaries of BP dossiers as discussed above is considered an improvement compared to the PPP approach.

The procedure of the initial completeness check to be carried out by the responsible competent authority has been modelled on the PPP approach.

5 PRACTICAL ADVICE

5.1 HOW TO UTILIZE PPP DOSSIERS / MONOGRAPHS FOR THE PREPARATION OF BP DOSSIERS / CAS' REPORTS

To avoid duplication of work within both companies and CAs the material produced within the PPPD program should be utilized as much as possible. This means that the data generated for the PPP program may be used for the generation of the BPD dossier, but the format of the BPD dossier must in general follow the guidance given in the TNsG on Dossier Preparation and Study Evaluation except for the study reports as indicated later in this Chapter. This is due to the fact that there is always needed some biocides specific data (e.g. on exposure, intended uses, efficacy) that must be incorporated in the documents made for PPPD. So the PPPD documents and text can usually be used as a good basis to be amended for the BPD dossiers.

For comparison, Fig. 3 shows how the individual BP and PPP dossier documents correspond to each other. From this scheme it is evident that some data and summaries can be adopted. This holds true mainly to the data related to the active substance, but in some cases the products may be identical and then product related data may be adopted too. However, several documents are still to be produced specially for the BPD evaluation and all documents and their structure must follow the BPD format.

Several different situations may occur related to the status of an active substance (a.s.) in the PPPD review program. These are:

1. Active substance is already included in the Annex I to the PPPD
2. Active substance not included in the Annex I to the PPPD
    - A. Due to incomplete dossier
    - B. Due to non-acceptability of the substance
3. Active substance is being evaluated according to the PPPD
    - A. CA's monograph is available but not yet adopted
    - B. Only applicant's dossier is available
4. No dossier available (PPPD list 4 substances and new active substances)

If an active substance is already included in Annex I to the PPPD or there is a CA's monograph available, but not yet adopted, an application for inclusion of that substance into BPD Annex I can draw data from the corresponding PPP monograph as much as possible.

The use of product related PPP data for the BPD documents IV B, III B and II B must be judged case by case.

If no CA's monograph is available (situations 2A, 3B, 4) the whole documentation including study summary forms must be prepared according to the guidance given in the TNsG on Dossier Preparation and Study Evaluation. However, even then relevant text from the PPP dossier can be copied or adopted for the BPD dossier.

If an active substance is not included in the Annex I to the PPPD due to in sufficient documentation, special attention must be paid to the substance in the completeness check phase in order to ensure that data requirements of the BPD are fulfilled**.** Non-inclusion of the a.s. for scientific reasons does not necessarily prevent the substance to be evaluated as a biocide since the exposure pattern is different.

Table 4. Document types to be submitted for BPD and the usability of data from the PPP dossier

BPD DOCUMENT	**STATUS OF THE ACTIVE SUBSTANCE (A.S.) IN THE PPPD PROGRAM**
	A.S. in Annex I or CA's monograph available, but not yet adopted (cases 1, 2B, 3A)
Doc. IV A Tests and study reports a.s.	K-II to be submitted [1]
Doc. IV B Tests and study reports b.p.	full BPD dossier to be submitted
Doc. IIIA Study summaries a.s.	- all studies to be summarised in the IUCLID [2] - for key studies already evaluated in the PPP monograph use CA's summary (Vol. 3/Annex B) [3 4] - BPD study summaries for new key studies to be prepared [3]

Doc III B Study summaries b.p.	- all studies to be summarised in the IUCLID [2] - for key studies already evaluated in the PPP monograph use CA's summary (use Vol. 3/Annex B where relevant) [3] - BPD study summaries for new key studies to be prepared [3]
Doc. II A Effects assessment a.s.	adopt information from Vol. 3/Annex B and append, where necessary (NB ! hazard assessment in the PPPD uses different assessment factors)
Doc. II B Effects and Exposure assessment b.p.	all to be prepared according to the TNsG on Preparation of dossiers and study evaluation using text from Vol. 3/Annex B, where relevant
Doc II C Risk Characterisation for use of a.s. in b.p.	to be prepared (use Vol. 2/Annex A, Vol. 3/ Annex B ,Vol. 4/Annex C and Vol.1/level 2 & 3 as a basis)
Doc I Overall summary and assessment	to be prepared (use Vol. 1/levels 1-4 as a basis)
Application forms **Completeness check forms** **Listing of endpoints**	BPD forms always to be prepared (use App. 3 of the monograph and/or Doc. O and App. 9. of the dossier as a basis)
Reference lists	both a PPPD-reference lists with the cross references to the BPD sections and data requirements numbering and one reference list listed by the BPD section numbers to be submitted

[1] unless the rapporteur-CA indicates that they already have access to the test reports
[2] reliability indicators to be used for each study summary in the IUCLID, key studies to be flagged
[3] detailed study summaries are to be inserted in the IUCLID as attached word-files and also delivered separately as word-documents.
[4] The **minimum** requirement for an acceptable biocide study summary based on a PPP monograph is that the section number and heading of the format, information on data protection, the reliability indicator and the box "Evaluation by the CA" follow the biocides format. The rest of the study summary text can be copied from a corresponding part of the CA's PPP monograph.

In all cases, the applicant should contact the responsible competent authorities to ensure that the adoption of parts of a PPP dossier will be accepted due to e.g. variable quality of dossiers received earlier.

It should be noted that within the PPPD procedure the monograph itself is not updated but changes are made in a separate addendum. The applicant should always use the accepted version of the monograph, or if not accepted, the latest version, including the addendum.

5.2 HOW TO UTILIZE EXISTING SUBSTANCES DOSSIERS / RISK ASSESSMENTS FOR THE PREPARATION OF BP DOSSIERS / CAS' REPORTS

In the existing substances review program the test and study reports submitted are comparable to the BPD. All studies are summarised in IUCLID and it is planned for the future that the quality of the summary should be similar to 'keystudy' quality. Risk assessment report contains a short summary of each study used for risk assessment and data on the emissions from production as well as industrial and consumers uses together with risk characterisation i.e. conclusions of the risk assessment.

If a substance for which inclusion to the Annex I of the BPD is applied, has already been evaluated (at least the final draft of the risk assessment available) within the existing substances program, the dossier and evaluation should be used as a data source as much as possible. In addition, there is a IUCLID data set available on numerous existing substances that are not evaluated. These data set may be used as a starting point for the BPD dossier submission.

Table 5. Document types to be submitted for BPD and the usability of existing substances dossier

BPD DOCUMENT	USABILITY OF EXISTING SUBSTANCES DOSSIER
Doc. IV A Tests and study reports a.s.	test and study reports to be submitted [1]
Doc. IV B Tests and study reports b.p.	all to be prepared according to the TNsG on Preparation of dossiers and study evaluation
Doc. IIIA Study summaries a.s.	- all studies should be available in the IUCLID [2] - for key studies already evaluated in the ESR Risk Assessment use CA's summary [3 4] - BPD study summaries for new key studies to be prepared [3]
Doc III B Study summaries b.p.	- all studies should be available in the IUCLID [2] - for key studies already evaluated in the ESR Risk Assessment use CA's summary [3] - BPD study summaries for new key studies to be prepared[3]
Doc. II A Effects assessment a.s.	use hazard assessment, append if necessary
Doc. II B Effects and Exposure assessment b.p.	all to be prepared according to the TNsG on Preparation of dossiers and study evaluation
Doc II C Risk Characterisation for use of a.s. in b.p.	all to be prepared according to the TNsG on Preparation of dossiers and study evaluation
Doc I Overall summary and assessment	all to be prepared according to the TNsG on Preparation of dossiers and study evaluation
Application forms Completeness check forms Listing of endpoints	BPD forms always to be prepared
Reference lists	Reference lists according to the BPD guidance to be prepared

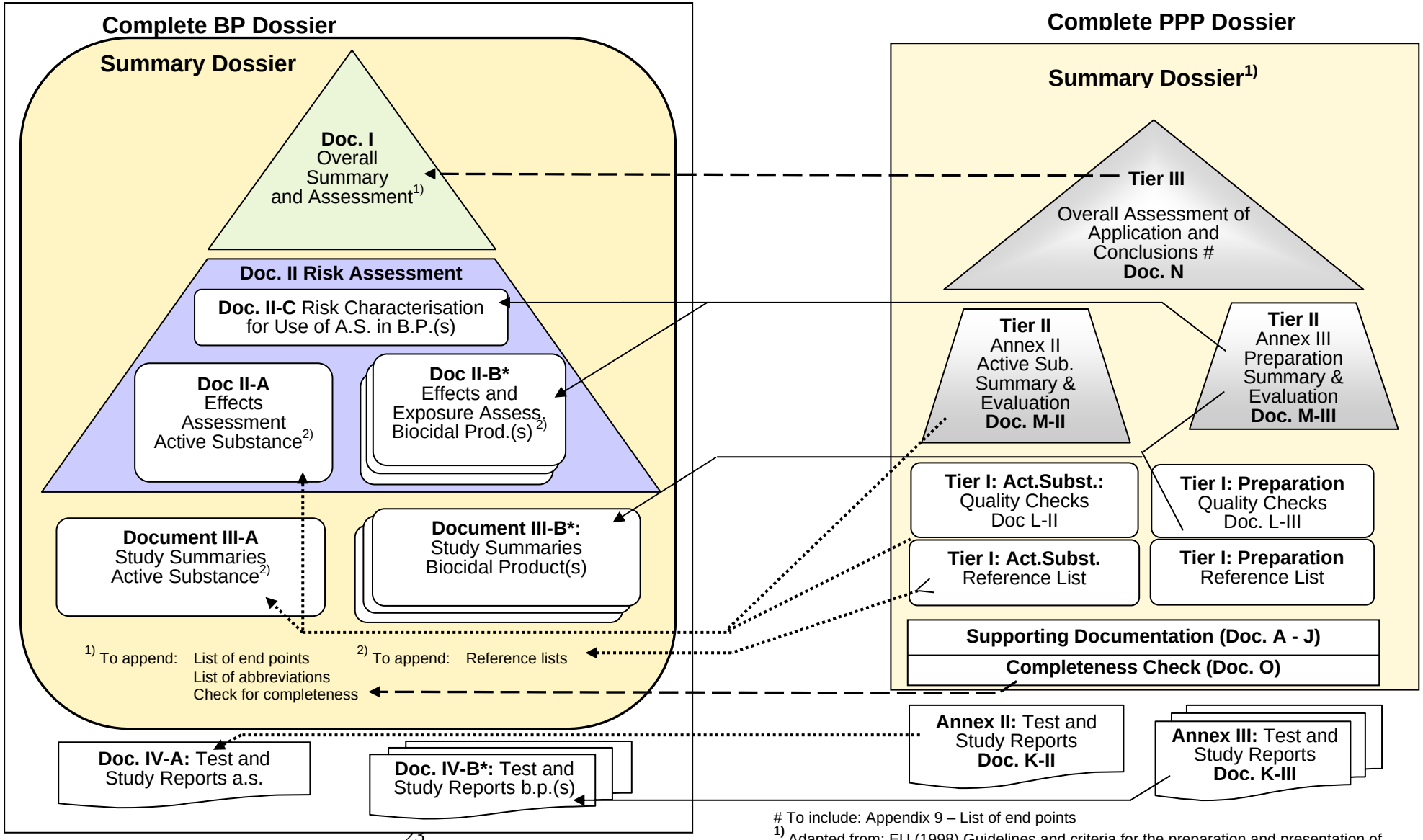
[1] unless the rapporteur-CA indicates that they already have access to the test reports

[2] reliability indicators to be used for each study summary in the IUCLID, key studies to be flagged

[3] detailed study summaries are to be inserted in the IUCLID as attached word-files and also delivered separately as word-documents.

[4] The **minimum** requirement for an acceptable biocide study summary based on a ESR Risk Assessment is that the section number and heading of the format, information on data protection, the reliability indicator and the box "Evaluation by the CA" follow the biocides format. The rest of the study summary text can be copied from a corresponding part of the ESR Risk Assessment.

Fig. 3. Corresponding document types of BP and PPP Dossiers



* Not required in the case of an application for Annex IB inclusion of an a.s.

\# To include: Appendix 9 – List of end points

1) Adapted from: EU (1998) Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Dir. 91/414/EEC