Changes and Future Development in the Format of Dossier to be Submitted for the Approval/Renewal of Approval of Active Substances Contained in Plant Protection Products in the European Union: Part 1

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Since the Plant Protection Product (PPP) Directive 91/414/EEC entered into force, an applicant had to submit a dossier meeting Community requirements for the approval of an active substance (AS). Under the PPP Regulation 1107/2009 submission of dossier was also required for the renewal of approval of an AS. The format of dossier was revised several times therefore a considerable amount of time re-writing/re-formatting the existing dossiers was spent for preparation of the dossiers for the renewal of approval of the AS. In this article, the changes in the format of dossier are summarised as 'Part 1', and recent development of the structured and harmonised format and electronic submission of data, *etc*. will be summarised in 'Part 2', which is to be published next time.

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Introduction

In the European Union (EU), an applicant had to submit a dossier, a set of documents and data package of the application, meeting the European Community (EC) requirements for the approval of an active substance (AS) since the Plant Protection Product (PPP) Directive entered into force. After the PPP Directive was replaced by the PPP Regulation, the submission of dossiers was required for the renewal of approval of an AS as well as for the approval of an AS.

Under both the PPP Directive and the PPP Regulation, the format of dossier was revised several times. Based on the revised version of the guidelines for the preparation of dossiers issued in 1998 under the PPP Directive, the Organisation for Economic Co-operation and Development (OECD) dossier format was developed. The OECD dossier format, the format of dossier provided by the guidance on which the OECD agreed, came to be used throughout OECD member countries. However, in the EU, revisions and additions were introduced to the format of dossier on which the OECD dossier format was based.

Since the format of dossier was revised several times, in many cases, the format of dossier to be submitted for the renewal of approval differs from the one of the dossier submitted for the approval. Therefore, re-writing and re-formatting of the dossiers is necessary for many ASs to be applied for the renewal of approval. Since 2021, dossiers have to be prepared using the specified format and software for the submission of dossiers in the EU, which requires time for entering information into the software.

Sumika Technoservice Corporation has been investigating regulatory information on the approval/renewal of approval of ASs used in PPPs in the EU for many years, and providing support during the process of approval/renewal of approval. As such, we have been collecting information on the revisions in the format of dossier to be submitted for approval/renewal of approval of ASs in PPPs. In addition, we had actual experience with compiling dossiers according to the revised version of the guidelines for the preparation of dossiers issued in 1998.

Based on our accumulated experience, this article will give an overview of the changes in the format of

dossier, as 'Part 1'. We will give an overview of the problems concerning the revised version of the EU guidelines for the preparation of dossiers issued in 1998 and the OECD dossier format, and how those problems were responded to in the process of the subsequent revisions to the format of dossier in an upcoming article, which is to be published next time as 'Part 2'.

This article also mentions the guidance on preparation of dossiers, in which formats to be used in dossiers under the Biocidal Product (BP) Directive are given. However, this is only because in the past, the dossiers to be submitted for approval of some ASs in PPPs were prepared in accordance with the guidance on preparation of dossiers for ASs in BPs, and in addition, because the guidance on preparation of dossiers for approval of ASs in BPs was modelled on the guideline for the preparation of dossiers for approval of ASs in PPPs with improvements that would result in revisions in the format of dossier to be submitted for ASs in PPPs. Therefore, this article does not cover the changes in the format of dossier for approval of ASs in BPs.

Changes in the format of dossier to be submitted for the approval of ASs in PPPs under the PPP Directive

The Directive concerning the placing of plant protection products on the market (PPP Directive) 91/414/EEC[1] was published in the Official Journal (OJ) on 19 August 1991.

It provided that Member States should bring into force the laws, regulations, and administrative provisions necessary to comply with this Directive within two years following notification thereof (Article 23(1) of Directive 91/414/EEC), and thereby the provisions of the PPP Directive 91/414/EEC entered into force in Member States as of 26 July 1993.

Annex I 'Active substances authorised for incorporation in plant protection products' to the PPP Directive 91/414/EEC was the Community list of authorised ASs.

Under the PPP Directive 91/414/EEC, inclusion of ASs in Annex I (Article 5 of Directive 91/414/EEC) meant approval of ASs.

For the first approval of a new AS, an AS which was not yet on the market two years after notification of the PPP Directive 91/414/EEC, the requirements should be deemed to be satisfied (Article 5(3) of Directive 91/414/EEC). For the approval of an AS, a dossier which was believed to satisfy the requirements would be submitted by the applicant (Article 6(2) of Directive 91/414/EEC).

With respect to existing ASs, which were already on the market two years after the date of notification of the PPP Directive 91/414/EEC, the European Commission should commence a programme of work for the gradual examination of these ASs, and following the examination of such AS, it might be decided that the AS could be approved—in other words, included in Annex I, or, in cases where the requirements were not satisfied or the requisite information and data had not been submitted within the prescribed period, that such AS would not be approved—in other words, not be included in Annex I (Article 8(2) of Directive 91/414/EEC).

The format of dossier was specified in Document 1663/VI/94 '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 Directive 91/414/EEC (Article 5.3 and 8.2)'.

The guidelines for the preparation of dossiers were revised several times. The dossiers to be submitted for approval of new ASs were normally prepared in accordance with the latest version of the guidelines for the preparation of dossiers at the time of dossier submission. However, the deadline for the submission of dossiers for existing ASs was specified by the Regulations concerning the examination of existing ASs, and dossiers for approval of existing ASs were prepared in accordance with the guidelines for the preparation of dossiers corresponding to the stage by which the existing AS was covered. **Table 1** shows major guidelines for the preparation of dossiers that were used to prepare dossiers for approval of ASs under the PPP Directive 91/414/EEC.

Regulation 933/94[2], published in the OJ on 28 April 1994, provided that the deadline for the submission of dossiers for existing ASs covered by the first stage was set at 30 April 1995 (Article 2 of Regulation 933/94). For this reason, it is considered that the dossiers were prepared in accordance with the guidelines for the preparation of dossiers 1663/VI/94 Rev. 5[3] dated 3 August 1994 or Rev. 6[4] dated 31 January 1995. There was no substantial difference in the format between Rev. 5 and Rev. 6.

Regulation 703/2001[5], published in the OJ on 7 April 2001, provided that the time limit for the

Table 1 Major guidelines/guidance documents on the preparation of the dossiers for the approval of ASs under PPP Directive 91/414/EEC

Guidelines/guidance documents / Category of AS & Dossier submission	1663/VI/94			Guidance documents used for the 4th stage Parts A and D-F AS only*2			OECD Dossier guidance		
	Rev.5 (1994.08.03)	Rev.6 (1995.01.31)	Rev.8 (1998.04.22)	Sanco/10472/2003 Rev.5 (2004.07.06)	Sanco/10473/2003 Rev.4 (2004.07.06)	BP Dossier guidance (2002.03.28)	Chemical substances	Microbials	Pheromones & other Semiochemicals
Existing AS 1st stage (1995.04.30)	○ Either version can be used		–	–	–	–	–	–	–
2nd stage (2002.04.30)	–	–	○	–	–	–	–	–	–
3rd stage Part A (2003.11.30)	–	–	○	–	–	–	–	–	–
3rd stage Part B (2004.11.30)									
4th stage*1 Part A (2005.06.30)	–	–	–	○ (Plant ext. only)	○ (Other than plant ext.)	–	–	–	–
Part B (2005.11.30)	–	–	–	–	–	–	–	–	○
Part C (2005.11.30)	–	–	–	–	–	–	–	○	–
Part D (2005.11.30)	–	–	–	–	–	○	–	–	–
Part E (2005.11.30)	–	–	–	–	–	○	–	–	–
Part F (2005.11.30)	–	–	–	–	–	○	–	–	–
Part G (2005.11.30)	–	–	–	–	–	–	○	–	–
New AS, Dossier submitted before 2004.12.31	○ Depends on the date of submission			–	–	–	–	–	–
New AS, Dossier submitted after 2004.12.31	–	–	–	–	–	–	○ Depends on type of AS		

*1: According to the Part, Sanco/10393/2004 Rev.4 (2004.10.08) indicated guidance document on the preparation of the dossiers

*2: Guidance documents used for the 4th stage Parts A and D-F AS were prepared/used for ASs belonging to specific Parts of the 4th stage. These guidance documents were not updates of 1663/VI/94.

submission of dossiers for existing ASs covered by the second stage was set at 30 April 2002 (Article 2 of Regulation 703/2001). Since there were many existing ASs covered by the third stage, Regulation 1490/2002[6], published in the OJ on 21 August 2002, divided the ASs to be evaluated into two groups, Part A and Part B, respectively, as listed in Annex I, and provided that the dossiers should be submitted by 30 November 2003 at the latest for ASs listed in Annex I, Part A, and by 30 November 2004 at the latest for ASs listed in Annex I, Part B (Article 7(1) of Regulation 1490/2002).

The dossiers for the existing ASs covered by the second and third stages were prepared in accordance with guidelines for the preparation of dossiers 1663/VI/94 Rev. 8[7] dated 22 April 1998.

There are several revised versions of guidelines for the preparation of dossiers 1663/VI/94. There are versions issued earlier than Rev. 5 and versions issued between Rev. 6 and Rev. 8. In case of new ASs, dossiers for some ASs were prepared in accordance with versions not shown in **Table 1**.

ASs contained in PPPs are either ASs for which the dossiers are to be submitted to satisfy the data requirements for chemical substance ASs or ASs for which dossiers are to be submitted to satisfy the data requirements for micro-organism ASs. When the existing ASs were divided into stages, all micro-organism ASs were to be covered by the fourth stage, and therefore the guidelines for the preparation of dossiers 1663/VI/94 do not provide any examples for micro-organism ASs or products containing micro-organism ASs.

Based on the guidelines for the preparation of dossiers 1663/VI/94 Rev. 8, the OECD dossier format was developed. The OECD categorised ASs into three types and provided three guidance documents on the preparation of dossiers.

Chemical substances

OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances (Dossier Guidance)[8]

Microbials

OECD Guidance for Industry Data Submissions for Microbial Pest Control Products and their Microbial Pest Control Agents (Dossier Guidance for Microbials)[9]

Pheromones and other Semiochemicals

OECD Guidance for Industry Data Submissions for Pheromones and other Semiochemicals and their Active Substances (Dossier Guidance for Pheromones and other Semiochemicals)[10]

Table 2 Types of AS covered by the 4th stage of the review programme

Reg. 2229/2004 (OJ 2004.12.24)		SANCO10157/2004 (dated 2004.04.08)		Type of AS (This information was provided in SANCO/10157/2004 Rev.5.2; however, it was not provided in Regulation 2229/2004)
Part A	Group 1	Part A	Group 1	Active substances for which the use is authorised in human foodstuffs or animal feeding stuffs in accordance with EU-legislation
	Group 2		Group 2	Plant extracts
	Group 3		Group 3	Animal products or derived thereof by simple processing
	Group 4		Group 4	Commodity substances
	Group 5		Group 5	Active substances which are used on stored plants or plant products
	Group 6		Group 6	Repellants and attractants (other than pheromones or other semiochemicals)
Part B		Part B		Pheromones or other semiochemicals
Part C		Part C		Micro-organisms including viruses
Part D		Part D		Active substances which are used as rodenticides (products applied in plant growing areas (agricultural field, greenhouse, forest) to protect plants or plant products temporarily stored in the plant growing areas in the open without using storage facilities)
Part E				Active substances which are used on stored plants or plant products
Part F		Part E		Active substances which are Disinfectants *i.e.* products applied indirectly (for example for the disinfection or the disinfestation of empty store rooms or other structures and articles like greenhouses, growing houses, containers, boxes, sacks, barrels *etc.*) provided that the purpose of the use is to destroy organisms exclusively and specifically harmful to plants or plant products and that after the treatment only plants or plants products will be grown or stored in the treated structures
Part G		Part F		Active substances which are on the market in new Member States but are not on the market in existing Member States

Document Sanco/10518/2004 'Guideline developed within the Standing Committee on the Food Chain and Animal Health on the Preparation and Presentation of Complete Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2)' Rev. 3[11] dated 8 October 2004 stated that from 31 December 2004, all dossiers to be submitted should be presented in OECD format. It also stated that for new ASs, dossiers in the OECD format were already acceptable.

Regulation 2229/2004[12] published in the OJ on 24 December 2004 divided the existing ASs covered by the fourth stage into multiple parts according to types of ASs (Annex I to Regulation 2229/2004) and provided that the dossiers should be submitted by 30 June 2005 at the latest for the ASs listed in Part A, and by 30 November 2005 at the latest for the ASs listed in Parts B to G (Article 12 of Regulation 2229/2004). Although Annex I to Regulation 2229/2004 did not give any explanation on types of ASs listed in each part, Annex I to Document SANCO/10157/2004 Rev. 5.2[13] dated 8 April 2004, which was a draft of Regulation 2229/2004, gave an explanation on types of ASs in each part and each group under a part, as shown in **Table 2**.

SANCO/10157/2004 Rev. 5.2 divided the existing ASs covered by the fourth stage into Parts A to F. Later the ASs listed in Part D were divided into Part D and Part E, and as a result, in Annex I to Regulation 2229/2004 published in the OJ the existing ASs covered by the fourth stage were divided into Parts A to G.

Document Sanco/10393/2004 'Guidance document on the preparation of dossiers and draft assessment reports for substances covered in the fourth stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC' Rev. 4[14] dated 8 October 2004 gave guidance on preparation of dossiers for approval of the existing ASs covered by the fourth stage.

Document Sanco/10393/2004 was not the revision of the guidelines for the preparation of dossiers 1663/VI/94 or Sanco/10518/2004, but was specially developed for the preparation of dossiers and draft assessment reports (DARs) for the existing ASs covered by the fourth stage. This document provided requirements for ASs listed in Parts A to F, but a part presented as Part G was not included. Therefore, the document was supposed to be developed based on Document SANCO/10157/2004 Rev. 5.2 dated 8 April 2004, which was the draft of Regulation 2229/2004.

Although the aforementioned guidelines for the preparation of dossiers Sanco/10518/2004 Rev. 3 stated that from 31 December 2004, all dossiers should be presented in OECD format, submission of dossiers presented in other formats specified for certain groups of existing ASs covered by the fourth stage was accepted.

The recital of Regulation 2229/2004 stated that a modified approach was required for the fourth stage of the programme of work to reduce the risk that large numbers of ASs would be withdrawn for economic reasons alone. For certain groups of ASs it was, therefore, appropriate that the format and requirements for the information to be submitted were different from those developed for ASs in the previous three stages of the programme of work (Recital (14) of Regulation 2229/2004).

Regulation 2229/2004 provided specific conditions for submissions of dossiers for ASs listed in Part A (Article 9 of Regulation 2229/2004). ASs listed in Part A were divided into Groups 1 to 6 as shown below and the ASs were expected to constitute a low risk in terms of human and environmental protection.

Group 1

Active substances for which the use is authorised in human foodstuffs or animal feeding stuffs in accordance with EU legislation

Group 2

Plant extracts

Group 3

Animal products or derived thereof by simple processing

Group 4

Commodity substances

Group 5

Active substances which are used on stored plants or plant products

Group 6

Repellants and attractants (other than pheromones or other semiochemicals)

Document Sanco/10393/2004 indicated the information which should appear in dossiers for ASs listed in Part A and the guidance documents which might assist in the preparation of dossiers.

With respect to data requirements for ASs listed in Part A, Document Sanco/10472/2003 'Draft working document concerning the data requirements for active substances of plant protection products made from plants or plant extracts' Rev. 5[15], dated 6 July 2004, defined which data should in principle be submitted with regard to plant extracts, and Document Sanco/10473/2003 'Draft working document concerning the data requirements for certain chemical active substances and plant protection products containing such substances' Rev. 4[16], dated 6 July 2004, defined which data should in principle be submitted with regard to certain chemical substances other than plant extracts. In Document Sanco/10393/2004, these documents were referred to as the guidance documents which might assist in the preparation of dossiers.

For ASs listed in Part B 'Pheromones or other semiochemicals', Document Sanco/10393/2004 indicated that guidance on the preparation of dossiers could be found in the OECD Dossier Guidance for Pheromones and other Semiochemicals.

For ASs listed in Part C 'Micro-organisms including viruses', Document Sanco/10393/2004 indicated that guidance on the preparation of dossiers could be found in the OECD Dossier Guidance for Microbials.

For ASs listed in Part D 'Active substances which are used as rodenticides (products applied in plant growing areas (agricultural field, greenhouse, forest) to protect plants or plant products temporarily stored in the plant growing areas in the open without using storage facilities)', Part E (a group under Part D in the draft) 'Active substances which are used on stored plants or plant products', and Part F (presented as Part E in the draft) 'Active substances which are Disinfectants i.e. products applied indirectly (for example for the disinfection or the disinfestation of empty store rooms or other structures and articles like greenhouses, growing houses, containers, boxes, sacks, barrels, *etc*.) provided that the purpose of the use is to destroy organisms exclusively and specifically harmful to plants or plant products and that after the treatment only plants or plants products will be grown or stored in the treated structures', Document Sanco/10393/2004 indicated that '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 (TNsG on Preparation of Dossiers and Study Evaluation)'[17] dated 28 March 2002 could be followed in principle.

Directive concerning the placing of biocidal products on the market (BP Directive) 98/8/EC[18] published in the OJ on 24 April 1998 also required the submission of dossiers for approval of ASs.

Regulation 2229/2004 contained the provisions on the dossiers for ASs submitted under the BP Directive 98/8/EC (Article 7 of Regulation 2229/2004), which provided that where an AS had been notified under the BP Directive 98/8/EC, the notifier might submit a copy of the dossier submitted under the BP Directive 98/8/EC.

ASs in BPs used as a rodenticide are ASs in biocidal product type (PT) 14 'Rodenticides' (Annex V to Directive 98/8/EC). Regulation 1896/2000[19] published in the OJ on 8 September 2000 provided that existing AS/PT combinations within PT14 should be included in the first list of existing ASs to be reviewed, and dossiers for existing ASs/PTs in the first list to be evaluated should be submitted not later than 42 months after Regulation 1896/2000 entered into force on 28 September 2000, which was the 20th day following that of its publication in the OJ; this meant that the deadline for submission was 28 March 2004 (Article 7(5) of Regulation 1896/2000). PT2 'Private area and public health area disinfectants and other biocidal products' was also one of biocidal PTs (Annex V to Directive 98/8/EC). Regulation 2032/2003[20] published in the OJ on 24 November 2003 specified the following time periods for the submission of dossiers for existing ASs within the PTs given in Annex V to the BP Directive 98/8/EC, to each of the four parts divided according to the PTs concerned (Annex V to Regulation 2032/2003):

Part A (PT8 and 14): 28 March 2004
Part B (PT16, 18, 19 and 21):
From 1 November 2005 to 30 April 2006
Part C (PT1, 2, 3, 4, 5, 6 and 13):
From 1 February to 31 July 2007
Part D (PT7, 9, 10, 11, 12, 15, 17, 20, 22 and 23):
From 1 May to 31 October 2008

BP dossiers were to be prepared for an existing AS in PPPs if the AS was listed in Part D, E or F of the list of ASs covered by the fourth stage, therefore, it is considered that a copy of the dossier submitted under the BP Directive 98/8/EC may be submitted.

For ASs listed in Part G (presented as Part F in the draft) 'Active substances which are on the market in new Member States but are not on the market in existing Member States', Document Sanco/10393/2004 indicated that dossiers should be submitted in OECD format on the basis of the OECD Dossier Guidance.

The PPP Directive 91/414/EEC contained the provisions on renewal of approval (Article 5(5) of Directive 91/414/EEC). Regulation 737/2007[21], published in the OJ on 29 June 2007, laid down the procedure for the renewal of the approval of ASs of AIR1, Annex I Renewal (AIR) 1st group. Any new data compared to the original dossier relevant to the AS and any new risk assessments to reflect changes in data requirements, or any changes in scientific and technical knowledge since the AS concerned was first approved should be submitted (Article 6(1)(b) of Regulation 737/2007). However, submission of such new data and new risk assessments was described as submission of data, not as submission of dossiers. The new data and new risk assessments should be submitted by 31 August 2008 at the latest (Article 6(1) of Regulation 737/2007).

Guidelines for the preparation of dossiers 1663/VI/94 Rev. 5 and Rev. 6

The guidelines for the preparation of dossiers 1663/VI/94 Rev. 5 or Rev. 6 were mainly used to prepare dossiers for application for approval of the existing chemical substance ASs covered by the first stage of the review programme.

There was no substantial difference in the format between the guidelines for the preparation of dossiers 1663/VI/94 Rev. 5 and Rev. 6. **Fig. 1** shows the structure of dossiers to be prepared according to the guidelines for the preparation of dossiers 1663/VI/94 Rev. 5 or Rev. 6.

A Complete Dossier consisted of Documents A through O, and Summary Dossiers consisted of the Complete Dossier excluding the Document(s) K, individual test and study reports.

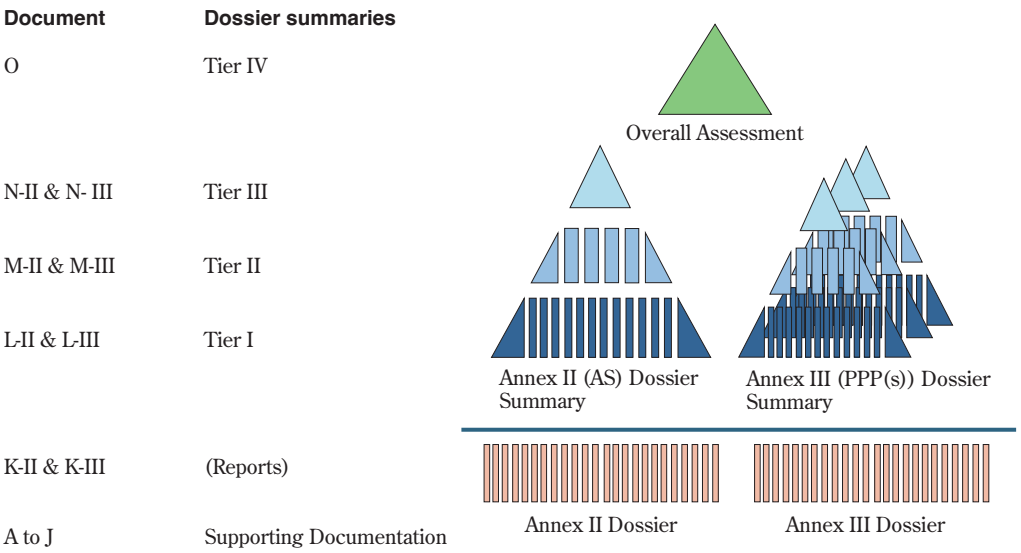
Documents A to J were Supporting Documentation. **Table 3** shows the title of each document.

Documents K to N corresponded to separate data requirements, data requirements for ASs listed in Annex II to the PPP Directive 91/414/EEC and data requirements for PPPs listed in Annex III, so these documents were referred to as, for example, K-II or K-III.

When submitting a complete dossier for the approval of an AS, a dossier complying with the data requirements for ASs had to be submitted together with a dossier on at least one PPP containing that AS (Article 6(2) of Directive 91/414/EEC). For this reason, in some cases there were multiple dossiers complying with the data requirements in Annex III.

Documents L to N were a summary, evaluation and assessment of the Annex II dossier for AS and each Annex III dossier for PPP. Document O was an overall assessment of the submitted dossiers (an Annex II dossier for AS and one or more Annex III dossiers for PPP). Documents L to O were prepared in accordance with the tiered structure as shown in **Fig. 1**.

Document L positioned as Tier I was called a Tier I summary. It was a summary of the individual tests and



A Complete Dossier consists of Documents A through O.
Summary Dossiers consist of the Complete Dossier excluding Document(s) K (Reports).
(Reports): Individual test and study reports
Tier I: Summary of the findings of individual tests and studies
Tier II: Discussion and interpretation of groups of tests and studies
Tier III: Applicant's overall assessment of individual dossier & a reasoned statement of conclusions reached
Tier IV: Applicants overall assessment of the application (Annex II & III Dossiers) and a reasoned statement to justify the conclusions reached and the proposed decision

Fig. 1 Structure of Dossier to be prepared according to the guidelines for the preparation of dossiers 1663/VI/94 Rev.5 or Rev.6

Table 3 Titles of Supporting Documentation (Documents A-J)

Document	Title of document
Document A	Statement of the context in which the dossier is submitted
Document B	Collective dossiers – claim concerning steps taken and documentation
Document C	Labels
Document D	Summary of registrations or authorisations
Document E	Summary of uses and conditions of use Rev. 5 (Two documents: Documents E and E-1) E Details of the uses and conditions of use supported in relation to the proposed inclusion of the active substance in Annex I (GAPs) E-1 Information on approved uses, including those on non-food crops Rev. 6 (Four documents: Documents E-1, E-2, E-3 and E-4) E-1 Details of the uses and conditions of uses (GAPs), on food and feed crops, supported in relation to the proposed inclusion of the active substance in Annex I E-2 Information on all approved uses on non food and feed crops E-3 Concise summary of all uses reported E-4 Listing of Community maximum residue levels (MRLs) established for the active substance and, where relevant, of MRLs established by Member States
Document F	Commission Regulation (EEC) No 3600/92 Notification
Document G	Regulatory position (Community legislation) for formulants
Document H	Directive 67/548/EEC Safety Data Sheet for formulants
Document I	Other data on formulants
Document J	Confidential information

studies together with lists of the documents, a listing of all test and study reports, *etc.* submitted as part of the dossier (Listing by Annex Point and Listing by Author), and a separate listing of test and study reports, *etc.* known to the applicant but not submitted (Listing by Author). For part of the Tier I summary, several formats different from the general requirement for a Tier I summary of each individual test or study were used.

Table 4 Templates/examples provided in 1663/VI/94 Rev.5 or Rev.6 (Guidelines for the preparation of dossiers)

Required documents according to 1663/VI/94 Rev.5 or Rev.6		Template	Example
Document A	Statement of the context in which the dossier is submitted	–	–
Document B	Collective dossiers - claim concerning steps taken and documentation	–	–
Document C	Labels	–	–
Document D	Summary of registrations or authorisations	–	◯ Appendix 3
Document E	Summary of uses and conditions of use	E-1,2 ◯ Appendix 4 E-3 ◯ Appendix 5	–
Document F	Commission Regulation (EEC) No 3600/92 Notification	–	–
Document G	Regulatory position (Community legislation) for formulants	–	–
Document H	Directive 67/548/EEC Safety Data Sheet for formulants	–	–
Document I	Other data on formulants	–	–
Document J	Confidential information	–	–
Document K	Individual test and study reports	–	–
Document L	Tier I summaries of individual tests and studies	◯ Appendix 7 Part 4*1, Part 5*2	◯ Appendix 7 Part 1 (Annex II Point 4.2.2, Point 5.2.2, Point 5.2.5, Point 5.3.2, Point 5.4.1, Point 5.5, Point 6.1, Point 7.1.3.2), Part 2 (Annex II Point 1-3 & 10), Part 3 (Annex II Point 3.4)
	(Tier I Reference list)	–	◯ Appendix 7 Part 6 Reference list
Document M	Tier II summaries and assessments of groups of tests and studies	–	◯ Appendix 8 (Annex II Point 1-3 & 10, Point 5) ◯ Appendix 10 (Annex III Point 1-4 & 12, Point 7)
Document N	Tier III summaries and assessments of Annex II and Annex III dossiers	–	◯ Appendix 9 (Annex II) ◯ Appendix 11 (Annex III)
Document O	Tier IV overall assessment of the application and proposed decision	–	◯ Appendix 12 (Annex II & III)

*1: Tier I summaries of individual supervised residue trials submitted in accordance with the section *residues in treated products, food or feed* (Annex II, point 6) should be compiled using this form
*2: Tier I summaries of soil dissipation studies (Annex II, point 7) should be compiled using this form

In the case of information on identity, physical and chemical properties, data on application, further information, supervised field trials required in the residues section, and soil dissipation studies required in the fate and behaviour in the environment section, examples were shown in different forms or formats. The guidelines provided that in the case of non-submission of particular studies specified in data requirements, full justifications should be provided in Tier II summary.

Document M positioned as Tier II was called a Tier II summary. It was a summary and assessment of groups of tests and studies. Document N positioned as Tier III was called a Tier III summary. It was a summary and assessment of the Annex II dossier or each Annex III dossier. Document O positioned as Tier IV was called a Tier IV summary. It was an overall assessment. The tiered structure consisted of four tiers, Tier I to IV.

The guidelines for the preparation of dossiers 1663/VI/94 Rev. 5 and Rev. 6 provided templates and examples only for some part of Documents A to J and Documents L to O, as shown in **Table 4**.

Guidelines for the preparation of dossiers 1663/VI/94 Rev. 8

The guidelines for the preparation of dossiers 1663/VI/94 Rev. 8 were mainly used to prepare dossiers for application for approval of the existing chemical substance ASs covered by the second and third stages of the review programme.

Major differences from Rev. 5 or Rev. 6, that was used to prepare dossiers for application for approval of the existing chemical substance ASs covered by the first stage of the review programme, were the changes in some part of the components in the Supporting Documentation required as Documents A to J, reduction of number of tiers in the tiered structure of

Table 5 Comparison of required documents according to 1663/VI/94 Rev.5/Rev.6 and Rev.8 (Guidelines for the preparation of dossiers)

	Rev. 5 and Rev. 6		Rev.8
Document A	Statement of the context in which the dossier is submitted	=	Statement of the context in which the dossier is submitted
Document B	Collective dossiers – claim concerning steps taken and documentation	=	Collective dossiers – claim concerning steps taken and documentation
Document C	Labels	=	Labels
Document D	Summary of registrations or authorisations		D-1 Details of intended uses and conditions of use in the EU
			D-2 List of authorised uses in the EU and actual uses
		New	D-3 Details of intended uses and conditions of use for which import tolerances are required
Document E	Summary of uses and conditions of use		E-1 Listing of EU and Member State MRLs
	Rev.5: E Details of the uses and conditions of use supported in relation to the proposed inclusion of the active substance in Annex I (GAPs)		
	Rev.5: E-1 Information on approved uses, including those on non-food crops		
	Rev.6: E-1 Details of the uses and conditions of use (GAPs), on food and feed crops, supported in relation to the proposed inclusion of the active substance in Annex I		
	Rev.6: E-2 Information on all approved uses on non food and feed crops		
	Rev.6: E-3 Concise summary of all uses reported		
	Rev.6: E-4 Listing of Community maximum residue levels (MRLs) established for the active substance and, where relevant, of MRLs established by Member States	New	E-2 Listing of MRLs established in exporting countries and in non-EU OECD countries
Document F	Commission Regulation (EEC) No 3600/92 Notification	=	Article 8 (2) Notifications
Document G	Regulatory position (Community legislation) for formulants	=	Regulatory position (Community legislation) for formulants
Document H	Directive 67/548/EEC Safety Data Sheet for formulants	=	Directive 67/548/EEC Safety Data Sheets for formulants
Document I	Other data on formulants	=	Other available toxicological data on formulants
Document J	Confidential information	=	Confidential information
Document K	Individual test and study reports	=	Individual test and study reports
Document L	(Reference lists) Tier I summaries of individual tests and studies		Tier I quality checks for individual tests and studies and reference lists
Document M	Tier II summaries and assessments of groups of tests and studies		Tier II summaries and assessments of individual tests and studies and groups of tests and studies
Document N	Tier III summaries and assessments of Annex II and Annex III dossiers		Tier III overall summary and assessment, conclusions and proposed decision
Document O	Tier IV overall assessment of the application and proposed decision	New	Completed forms for the checking of dossiers for completeness

former Documents L to O (Tiers I to IV) from four to three, and addition of new forms for use in checking dossiers for completeness as new Document O.

Table 5 shows the outline of changes to Documents A to O.

The Tier I summary was changed from a summary to a quality check of the individual tests and studies. Document L, positioned as Tier I, became the Tier I quality checks together with lists of the documents, a listing of all test and study reports, *etc*. submitted as part of the dossier (Listing by Annex Point and Listing by Author), and a separate listing of all test and study reports, *etc*. not submitted as part of the dossier, of which the applicant was aware (Listing by Author). There were two forms of Tier I quality checks, and depending on whether the test methods used were those currently specified or the test methods used were not those currently specified the form to be used was determined. With respect to a listing of all test and study reports, *etc*., the form of listing was partially changed. In addition, in preparing the listing, applicants should conduct a detailed literature search.

No change was made to the provision that in the case of non-submission of particular studies specified in data requirements, full justifications should be provided in Tier II summary.

It was indicated that a summary of the findings or experimental results obtained should not be included in the Tier I quality checks, except for supervised residue trials and soil dissipation studies. For supervised residue trials and soil dissipation studies, the Tier I summaries, instead of the Tier I quality checks, should be provided by using the forms different from the quality check forms.

In the case of testing as to the physical and chemical properties, the Tier I quality checks were not required. The Tier I quality checks were not required for reports relating to analytical methods, either.

The Tier II summary became a summary and assessment which contained a discussion and interpretation of the results of all tests and studies. In addition, the Tier II summary was required to include a concise but comprehensive summary of each individual test and study, and each summary should include the following elements, as appropriate:

Reference number of the test or study;
Appropriate test or study reference (*e.g.*, author and year);
Test guideline and method used;
Relevant GLP (Good Laboratory Practice)/GEP (Good Experimental Practice) information;
Brief description of the methodology used;
Concise tabular presentation of the findings with supporting text; and
Conclusions reached.

By way of exception to the general rule of the aforementioned Tier II summary, it was indicated that in the case of certain parts of the dossier such as that relating to the physical and chemical properties, and that relating to residue trials (supervised residue trials), a tabular approach to the presentation of the data might be appropriate. It was also indicated that in the case of metabolism studies (animals, plants and soil) and soil dissipation studies, it might be more convenient to provide summaries of groups of tests and studies.

The Tier III summary was an overall summary and assessment corresponding to the former Tier IV summary. The structure was changed from the former Tier IV summary. The Tier III summary should include the following:

Diagrammatic representation of the metabolic pathway(s) for the AS in animals, plants, soil and water;
Molecular structure of the AS and its metabolites, degradation and reaction products; and
Listing of end points.

Compared with Rev. 5 and Rev. 6, the structure of dossiers was improved to some extent. However, even in Rev. 8 templates and examples were provided only for some part of Documents A to J and Documents L to O as shown in **Table 6**.

Tiers I to IV in Rev. 5 and Rev. 6 were changed to Tiers I to III in Rev. 8, which resulted in reduction of overlapping of summaries and assessments between tiers. However, because the information to be contained in Tier I and Tier II was changed, the information to be contained in the Tier I quality checks considerably overlapped with the information to be contained in the Tier II summary.

Since the Tier II summary, in which a summary and assessment of individual tests and studies were presented, included all the information contained in the Tier I quality checks, Tier I quality checks were not required as documents to be included in dossiers submitted as from 1 January 2014. We will present an overview of this change in 'Part 2' next time.

While the guidelines for the preparation of dossiers 1663/VI/94 were developed for applicants, the guidelines for the evaluation of dossiers, Document 1654/VI/94 '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 Directive 91/414/EEC', were also developed for Rapporteur Member States (RMSs).

The guidelines for the evaluation of dossiers Rev. 7[22], dated 22 April 1998, the same date as the date of the guidelines for the preparation of dossiers Rev. 8, provided the guidance on completeness checks and examination of the Tier I quality checks. However, it was indicated that for completeness checks, a representative selection of the Tier I quality checks submitted from each of the sections of dossiers should be examined, and that it was not necessary that a systematic examination of all Tier I quality checks be carried out, unless on the basis of the examination of a representative selection of them, it became apparent that there were serious deficiencies in the quality of the documentation submitted.

The new forms for checking of dossiers for completeness, added as Document O, comprised five different forms. With respect to Evaluation Form 5 for use in checking that the Tier I quality checks for individual test and study reports conducted in accordance

Table 6 Templates/examples provided in 1663/VI/94 Rev.8 (Guidelines for the preparation of dossiers)

Required Documents according to 1663/VI/94 Rev.8		Template	Example
Document A	Statement of the context in which the dossier is submitted	–	–
Document B	Collective dossiers – claim concerning steps taken and documentation	–	–
Document C	Labels	–	–
Document D-1	Details of intended uses and conditions of use in the EU	○ Appendix 3 Part 1	–
Document D-2	List of authorised uses in the EU and actual uses	○ Appendix 3 Part 2	–
Document D-3	Details of intended uses and conditions of use for which import tolerances are required	○ Appendix 3 Part 1	–
Document E-1	Listing of EU and Member State MRLs	○ Appendix 3 Part 3	–
Document E-2	Listing of MRLs established in exporting countries and in non-EU OECD countries	○ Appendix 3 Part 3	–
Document F	Article 8 (2) Notifications	–	–
Document G	Regulatory position (Community legislation) for formulants	–	–
Document H	Directive 67/548/EEC Safety Data Sheets for formulants	–	–
Document I	Other available toxicological data on formulants	–	–
Document J	Confidential information	–	–
Document K	Individual test and study reports	–	–
Document L	Tier I quality checks for individual tests and studies and reference lists	○ Appendix 5 Part 1*1, Part 2*2	○ Appendix 4 Part 1, 2, ○ Appendix 6 Part 1, 2, 3 (Reference lists)
Document M	Tier II summaries and assessments of individual tests and studies and groups of tests and studies	–	○ Appendix 7 Part 1 (Annex II Point 1 to 3 and 10), Part 2 (Annex II Point 4.1 and 4.2), Part 3 (Annex II Point 5), Part 4 (Annex II Point 6), Part 5 (Annex II Point 7), ○ Appendix 8 Part 1 (Annex III Point 1 to 4 and 12), Part 2 (Annex III Point 7), Part 3 (Annex III Point 10)
Document N	Tier III overall summary and assessment, conclusions and proposed decision	○ Appendix 9 (Annex II & III)	○ Appendix 10 (Annex II &III)
Document O	Completed forms for the checking of dossiers for completeness	○ Appendix 11 Part 1-5	○ Appendix 11 Part 6, 7

*1: Tier I summaries of individual supervised residue trials submitted in accordance with the section *residues in treated products, food or feed* (Annex II, point 6) should be compiled using this form

*2: Tier I summaries of soil dissipation studies (Annex II, point 7) should be compiled using this form

with test methods other than those currently specified, it was not necessary that completed forms be submitted in dossiers. Evaluation Forms 1 and 2 of Document O were for use in checking that the required Documents A to J and Documents L to N, respectively, had been provided. Evaluation Forms 3 and 4 were for use in checking that all test and study reports required had been provided, thus whether information, test or study was provided, whether a justification for non-submission was provided, and whether an undertaking was provided, had to be indicated in each data requirement under Annex II for ASs and data requirement under Annex III for PPPs, respectively. However, the check items shown in Evaluation Forms 3 and 4 included not only the ones corresponding to data requirement points for ASs/PPPs but also the detailed items required under each data requirement point. For this reason, unless a method of presentation was designed to make it easy to find the detailed items required under each data requirement point in the Tier II summary, it took time not only for the applicant to check the documents before submission but also for an RMS to check dossiers for completeness.

BP Dossier Guidance

As previously mentioned, dossiers in accordance with the BP Dossier Guidance dated 28 March 2002 were submitted for some existing ASs covered by the fourth stage. The format of dossier presented in the BP Dossier Guidance was modelled on the format presented in the guidelines for the preparation of dossiers Rev. 8. However, the structure of BP dossiers is not the same as that of PPP dossiers. The BP Dossier Guidance was developed by taking into account solutions for the problem, such as duplicated information, associated with the guidelines for the preparation of dossiers Rev. 8.

'Guidance Document on How to utilize PPP Dossiers/Monographs and Existing Substances (ESR) Dossiers/Risk Assessments for the Preparation of BP dossiers/CAs' reports'[23], dated 21 November 2003, presented differing systems and elements incorporated in the structure of BP dossiers, which was somewhat different from that of PPP dossiers, taking into account the structure of dossiers to be prepared by applicants for approval of ASs in PPPs and the structure of evaluation reports, corresponding to monographs, to be prepared by the Competent Authority (CA) of a Member State evaluating the dossiers for approval of AS/PT of BPs.

ASs to be evaluated under the BP Directive 98/8/EC included not only ASs to be evaluated under the PPP Directive 91/414/EEC but also substances to be assessed under Regulation 793/93[24] on the evaluation and control of the risks of existing substances, which was published in the OJ on 5 April 1993. For existing substances, all studies were summarised in International Uniform Chemical Information Database (IUCLID) software. Therefore, the IUCLID format was also taken into account for BP dossiers.

According to the BP Dossier Guidance, levels of documents were numbered in the opposite order from those required in PPP dossiers. Document I was an overall summary and assessment; Document II was a risk assessment; Document III comprised study summaries; and Document IV contained copies of original test and study reports.

Fig. 2 shows a comparison between the structure of PPP dossiers and that of BP dossiers. Because the PPP Directive 91/414/EEC provided data requirements for ASs in Annex II and data requirements for PPPs in Annex III, test and study reports were referred to as 'Doc. K-II' or 'Doc. K-III'. The BP Directive 98/8/EC provided data requirements for ASs in Part A of each of the relevant Annexes and data requirements for BPs in Part B of each of the relevant Annexes, therefore, test and study reports were referred to as 'Doc. IV-A' or 'Doc. IV-B'.

For BP dossiers, the following simplification and improvements were implemented:

- 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.

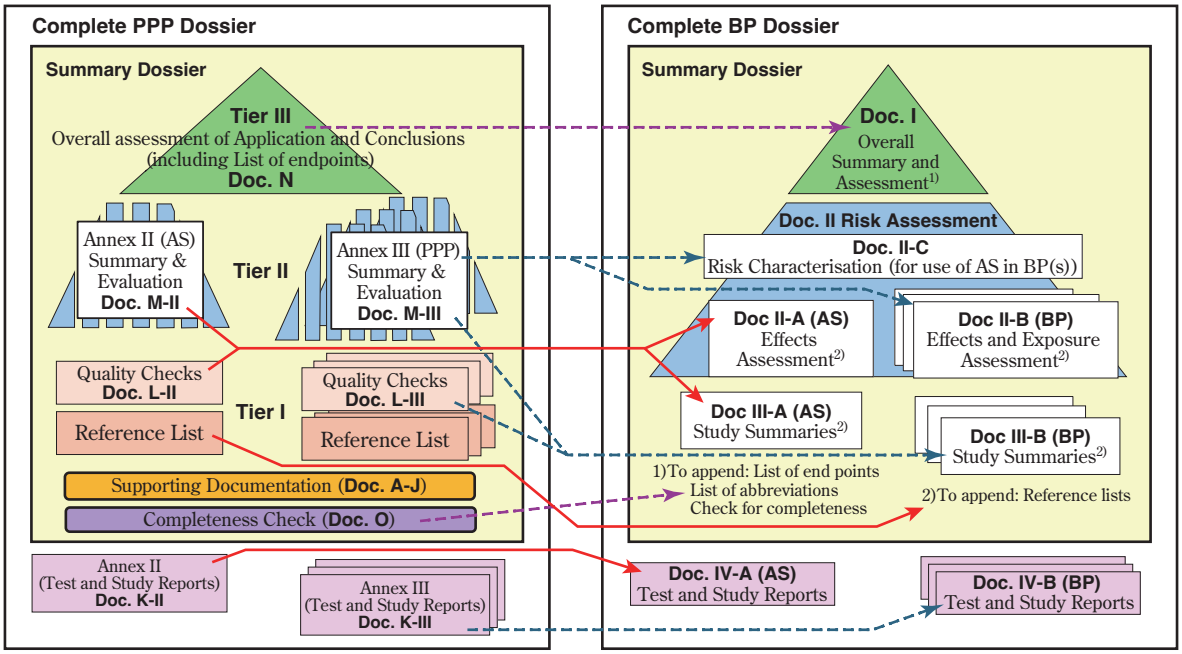


Fig. 2 Structure of PPP Dossier and BP Dossier

Table 7 Comparison of Supporting Documentation required in PPP Dossier and BP Dossier

PPP Dossier		BP Dossier	
Document	Title of the document	Document	Description
Document A	Statement of the context in which the dossier is submitted	Doc. I.1	Application form
Document B	Collective dossiers - claim concerning steps taken and documentation	Appendix of Doc. I.1	Documentation relating to the joint submission
Document C	Labels		
Document D-1	Details of intended uses and conditions of use in the EU		Integrated in Doc. III – Study summaries with overview and risk assessment conclusions in Doc. II
Document D-2	List of authorised uses in the EU and actual uses		
Document D-3	Details of intended uses and conditions of use for which import tolerances are required		
Document E-1	Listing of EU and Member State MRLs		Normally, not needed for BP (Setting MRLs is not normally needed for biocidal use)
Document E-2	Listing of MRLs established in exporting countries and in non-EU OECD countries		
Document G	Regulatory position (Community legislation) for formulants		Integrated in Doc. III – Study summaries with overview and risk assessment conclusions in Doc. II
Document I	Other available toxicological data on formulants		
Document H	Directive 67/548/EEC Safety Data Sheets for formulants	Appendix of Doc. I.1	Safety Data Sheet for formulants in accordance with Directive 67/548/EEC
Document F	Article 8(2) Notifications	Appendix of Doc. I.1	Copies of notifications (in case of existing active substances)
Document J	Confidential information	Appendix of Doc. III	Confidential data and information

The number of documents was reduced mainly by integrating Supporting Documentation, referred to as Documents A to J required in PPP dossiers, in Document III study summaries or Document II risk assessment in BP dossiers, or by incorporating them in Document I as an Appendix of subdocument of Document I. **Table 7** shows which part of BP dossiers each of Documents A to J required in PPP dossiers were integrated in.

Two different forms were provided for the Tier I quality checks required in PPP dossiers, and the form to be used was determined according to whether the test methods used were those currently specified or the test methods used were not those currently specified. The information contained in the Tier I quality checks, in which a summary of the findings or experimental results obtained were not normally included, overlapped with the information contained in the Tier II summary and assessment, which contained a discussion and interpretation of the results of all tests and studies. In BP dossiers, information on individual tests and studies were described in Document III corresponding to summaries and assessment of data on the individual study level. Document III required in BP dossiers was similar to the Tier I summary, a summary of the individual tests and studies, specified by the guidelines for the preparation of PPP dossiers Rev. 5 or Rev. 6. For the presentation of data related to identity, physical and chemical properties, data on application, *etc.*, other types of standard formats different from the standard formats for summaries of individual test and study reports were used.

The guidelines for the preparation of dossiers Rev. 5 or Rev. 6 presented only a limited number of examples of the Tier I summary, and the BP Dossier Guidance also presented limited number of examples of Document III. However, the BP Dossier Guidance presented standard formats, corresponding to almost all data requirement points, which were generally structured with sub-headings in greater detail in the test methods and results part. In addition, it provided tables which gave an overview of the available standard formats proposed to be used to the corresponding data requirement points.

In the presented standard formats, guidance notes explaining the specific data inputs expected in the fields were directly included. In addition, areas for reliability scores indicating the quality of data, and commentary areas and evaluation boxes for the CAs were incorporated into the standard formats.

There was a standard form used to provide detailed justification in the case of non-submission of particular studies specified in data requirements. The standard forms for justification for non-submission of data,

in which justification for non-submission of data was provided, should substitute the standard formats for individual tests and studies designated for particular studies, and take their position in Document III to be submitted. The standard form for justification for non-submission of data also included the guidance notes explaining specific input expected in the relevant fields, and commentary areas and evaluation boxes for the CAs.

Document III was divided into Document III-A for ASs and Document III-B for BPs, and listings of the test and study reports and other documentation (listing by section number and listing by author) to each of them should be provided.

The conclusion of each section, effects assessment, data on exposure, and risk and efficacy assessment were contained in the Tier II summary, a summary and assessment, required in PPP dossiers, however, such information was described in Document II, effects and exposure assessment, required in BP dossiers. Document II was divided into Document II-A, assessment for AS, Document II-B, assessment for BP(s), and Document II-C, risk characterisation for the use of AS in BPs. With respect to Document II, required in BP dossiers, a list of test and study reports, *etc.* cited (listing by author) should be appended to each of Documents II-A, II-B and, if references were given, also to Document II-C.

Document I, the overall summary and assessment, required in BP dossiers, was comparable to the Tier III summary required in PPP dossiers. Unlike the Tier III summary required in PPP dossiers, Document I required in BP dossiers contained an application form with several subdocuments, and documents which were to be appended to the application form.

The BP Dossier Guidance provided two check list forms, which were to be used in checking whether the required information, test or study was provided, whether a justification was provided, whether data were considered as confidential, and the quality of data by means of reliability indicator for each data requirement for ASs in Part A and data requirement for BPs in Part B, respectively. The forms were used to carry out a completeness check covering the data requirements based on the section numbers of Documents III.

Table 8 shows comparison of formats for PPP dossiers and BP dossiers.

As shown in **Fig. 3**, although the structure of BP dossiers was almost the same as the structure of CAs' Reports, the structure of PPP dossiers differed significantly from that of assessment report prepared by the RMS, which was called a monograph, as shown in **Fig. 4**.

As previously mentioned, commentary areas and evaluation boxes for CAs were incorporated into Document III required in BP dossiers, which allowed the use of the documents prepared by applicants by the CAs in the preparation of the assessment reports.

The BP dossier format was proposed with consideration of improvements of the problems associated with

Table 8 Comparison of formats for PPP Dossier and BP Dossier

Item	PPP Dossier	BP Dossier
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: Simple Tier I quality check and detailed Tier I quality check	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 quality check and Tier II study summary and evaluation	
Structure of formats (whether structured with (sub) headings in greater detail in the methods and results part)	Example formats of detailed Tier I quality check 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 of non-submission of data	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

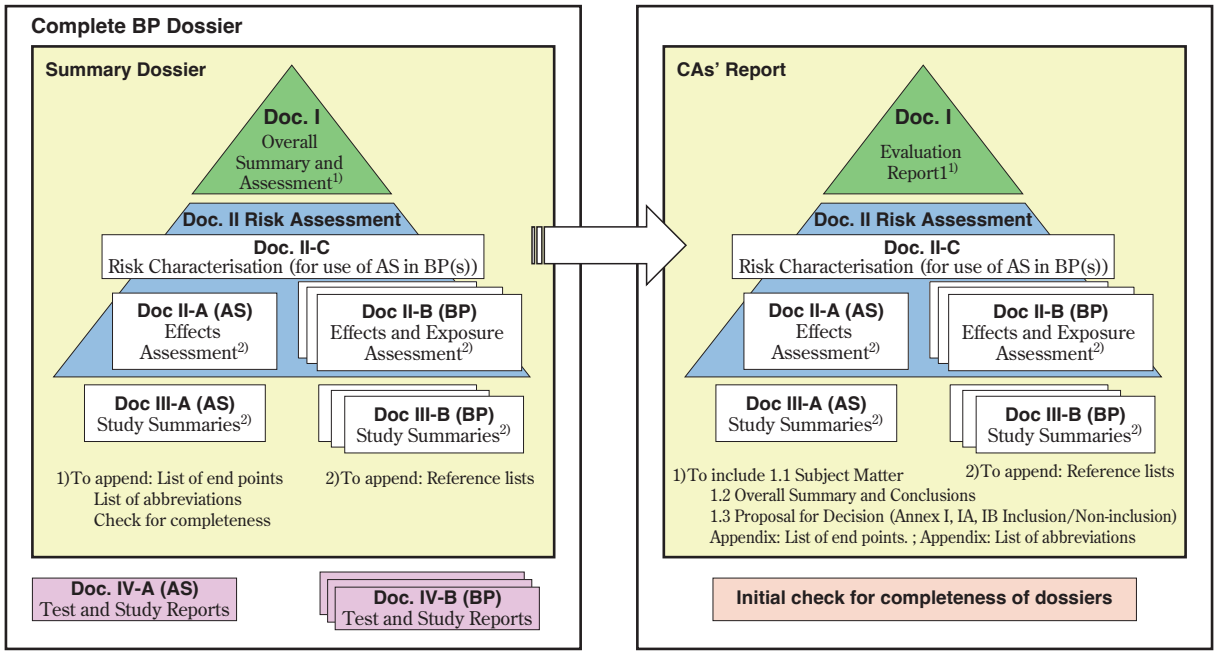


Fig. 3 Structure of BP Dossier and CAs' Report

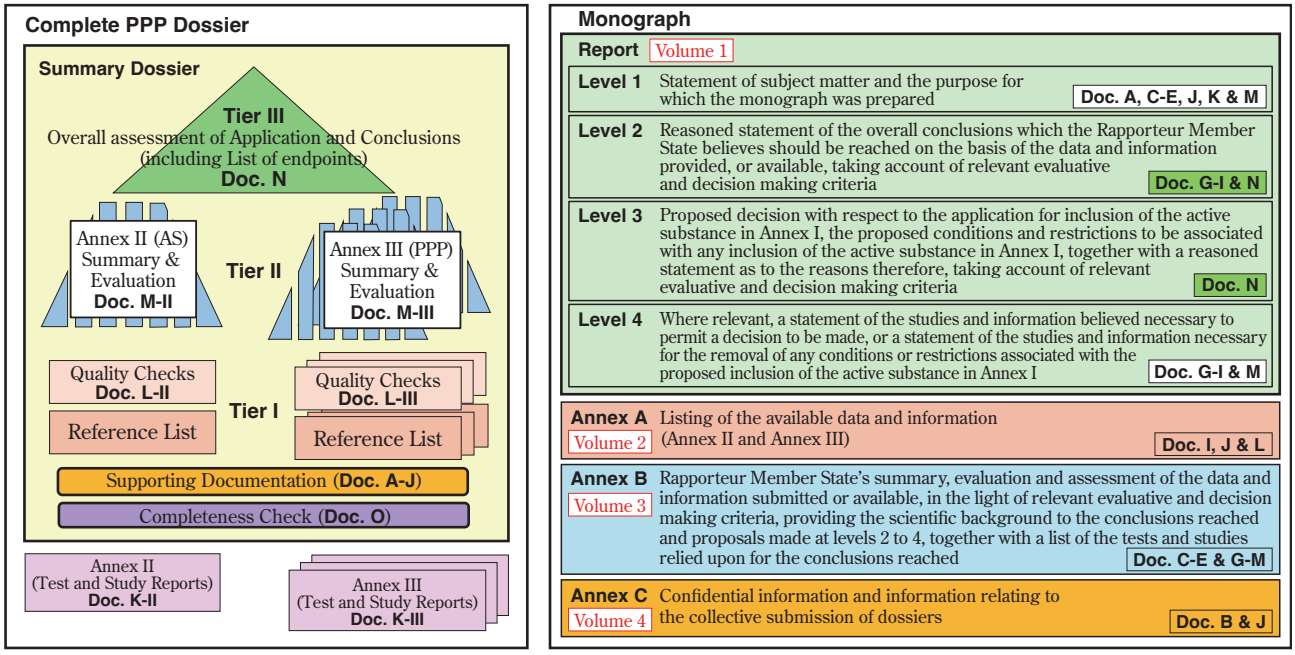


Fig. 4 Structure of PPP Dossier and Monograph

the guidelines for the preparation of dossiers Rev. 8. Nevertheless, the OECD dossier format was developed without major changes from the guidelines for the preparation of dossiers Rev. 8.

The BP Directive 98/8/EC was replaced by the BP Regulation 528/2012[25], published in the OJ on 27 June 2012. Under the BP Regulation 528/2012, the technical dossier should be submitted using the IUCLID software package (Article 79 of Regulation 528/2012).

OECD Dossier Guidance

The OECD dossier format was presented in the OECD Dossier Guidance. The OECD Dossier Guidance was developed based on the EU guidelines for the preparation of dossiers Rev. 8.

The examples presented in appendices to the OECD Dossier Guidance were almost the same as those presented in the EU guidelines for the preparation of

Table 9 Comparison of titles of Supporting Documentation (Documents A-J) required in 1663/VI/94 Rev.8 (EU guidelines for the preparation of dossiers) and the OECD Dossier guidance

	1663/VI/94 Rev 8	OECD Dossier guidance		
		Chemical substances	Microbials	Pheromones & other Semiochemicals
Document A	Statement of the context in which the dossier is submitted	Purpose	Purpose (statement of the context in which the dossier is submitted)	Purpose (statement of the context in which the dossier is submitted)
Document B	Collective dossiers – claim concerning steps taken and documentation	Task force information	Task force information	Task force information
Document C	Labels	Labels and leaflets	Labels and leaflets	Labels and leaflets
Document D-1	Details of intended uses and conditions of use in the EU	Supported uses	Supported uses	Supported uses
Document D-2	List of authorised uses in the EU and actual uses	Registered uses	Registered uses	Registered uses
Document D-3	Details of intended uses and conditions of use for which import tolerances are required	Supported uses in exporting countries	(N/A)	(N/A)
Document E-1	Listing of EU and Member State MRLs	Existing MRLs	(N/A)	(N/A)
Document E-2	Listing of MRLs established in exporting countries and in non-EU OECD countries	MRLs in exporting countries	(N/A)	(N/A)
Document F	Article 8 (2) Notifications	Statements of intention to submit a dossier	Statements of intention to submit a dossier	Statements of intention to submit a dossier
Document G	Regulatory position (Community legislation) for formulants	Regulatory position for formulants	Regulatory position for formulants	Regulatory position for formulants
Document H	Directive 67/548/EEC Safety Data Sheets for formulants	Safety data sheets for formulants	Safety data sheets for formulants	Safety data sheets for formulants
Document I	Other available toxicological data on formulants	Other available toxicological data on formulants	Other available toxicological data on formulants	Other available toxicological data on formulants
Document J	Confidential information	Confidential Information	Confidential information	Confidential information

dossiers with regard to overall formats and structure. However, individual study summaries included more headings and sub-headings and included an executive summary. According to the foreword of the OECD Dossier Guidance, the summaries of data and information included in the appendices to the guidance related to a different AS to that addressed in the EU guidelines for the preparation of dossiers.

Under the OECD Dossier Guidance, dossiers consisted of Documents A to O as in the case of the EU guidelines for the preparation of dossiers. However, the titles of some of Documents A to J were slightly changed as shown in **Table 9** in consideration of use in OECD member countries other than the EU. Some of Documents A to J required under the OECD Dossier Guidance for chemical substances, were not required under the OECD Dossier Guidance for microbials, or for pheromones and other semiochemicals.

With respect to Document O, forms for the checking of dossiers, Evaluation Forms 3 and 4, which were for use in checking that all test and study reports relating to data requirements for AS and data requirements for formulated product, respectively, had been provided, were not provided in the relevant Annex to the OECD Dossier Guidance, due to differences in data requirements among OECD member countries. The Evaluation Forms 3 and 4 were to be developed by the regulatory authorities of individual countries, as appropriate.

Owing to differences among OECD member countries not only in data requirements but also in numbering systems used for required data and studies, applicants were required to use the OECD numbering system for OECD dossiers, in principle. A compilation of the OECD data point numbers and the numbering systems used in major OECD member countries and regions, namely the EU, the United States, Canada, Japan, and Australia, was included in Appendix 6 Part 4 (information on ASs) and Part 5 (information on formulated products) of the guidance.

As previously mentioned, the OECD Dossier Guidance was developed for chemical substances, for microbials, and for pheromones and other semiochemicals. The guidance for chemical substances was first approved in 1998, and new and revised parts were approved in 1999. After Rev. 1 dated March 2001 was approved, Rev. 2 dated May 2005 was approved and became the version providing common formats

Table 10 Templates/examples provided in the OECD Dossier guidance

OECD Dossier guidance (Chemical)		Template	Example
Document A	Purpose	–	–
Document B	Task Force Information	–	–
Document C	Labels and Leaflets	–	–
Document D-1	Supported Uses	○ Appendix 3 Part 1	–
Document D-2	Registered Uses	○ Appendix 3 Part 2	–
Document D-3	Supported Uses in Exporting Countries	○ Appendix 3 Part 1	–
Document E-1	Existing MRLs	○ Appendix 3 Part 3	–
Document E-2	MRLs in Exporting Countries	○ Appendix 3 Part 3	–
Document F	Statements of Intention to Submit a Dossier	–	–
Document G	Regulatory position for formulants	–	–
Document H	Safety data sheets for formulants	–	–
Document I	Other available toxicological data on formulants	–	–
Document J	Confidential Information	–	–
Document K	Individual Test and Study Reports	–	–
Document L	Tier I quality checks for individual tests and studies and reference lists	○ Appendix 5 Part 1*1, Part 2*2	○ Appendix 4 Part 1 (Annex II Point 5.2.2, Point 5.2.3, Point 5.3.2, Point 5.3.3, Point 8.1.2, Point 8.10.1) Part 2 (Annex II Point 5.2.2, Point 5.3.2, Point 6.2.1, Point 7.4.5) ○ Appendix 6 Part 1-5 (Reference lists)
Document M	Tier II summaries and assessments of individual tests and studies and groups of tests and studies	–	○ Appendix 7 Part 1 (Annex II Point 1 to 3 and 10), Part 2 (Annex II Point 4.1, 4.3, 4.4, 4.5, 4.7, 4.8), Part 3 (Annex II Point 5), Part 4 (Annex II Point 6), Part 5 (Annex II Point 7) ○ Appendix 8 Part 1 (Annex III Point 1 to 4 and 12), Part 2 (Annex III Point 7), Part 3 (Annex III Point 10), Part 4 (Annex III Point 6)
Document N	Tier III overall summary and assessment, conclusions and proposed decision	○ Appendix 9 (Annex II & III)	○ Appendix 10 (Annex II & III)
Document O	Completed Forms for the checking of dossiers for completeness	○ Appendix 11 Part 1-3 (Form 1,2,5 only)	–

*1: Tier I summaries of individual supervised residue trials submitted in accordance with the section *residues in treated products, food or feed* (Annex II, point 6) should be compiled using this form

*2: Tier I summaries of soil dissipation studies (Annex II, point 7) should be compiled using this form

used in OECD member countries. With respect to the guidance for microbials, after the publication of the February 2004 version, the partially revised August 2006 version was published. Regarding the guidance for pheromones and other semiochemicals, the September 2002 version was published in 2003.

However, as shown in **Table 10**, the OECD Dossier Guidance for chemical substances Rev. 2 dated May 2005 still provided templates and examples only for some part of Documents A to J and Documents L to O. In addition, by comparing the provided examples using similar formats it was determined that there was partial lack of standardisation. For example, a certain item that seemed to be presented commonly for tests and studies regardless of section was presented in the summary of one section but not presented in the summary of the other section.

As the OECD Dossier Guidance was developed based on the EU guidelines for the preparation of dossiers Rev. 8, the OECD Monograph Guidance was developed based on the guidelines for the evaluation of dossiers Rev. 7. The OECD Monograph Guidance was also developed for chemical substances[26], for microbials[27] and for pheromones and other semiochemicals[28]. The guidance for chemical substances was first approved in 1998, and new and revised parts were approved in 1999. After Rev. 1 dated March 2001 was approved, Rev. 2 dated May 2005 was approved and became the version providing common formats used in OECD member countries. After subsequent revision, the latest version is the one dated April 2008. With respect to the guidance for microbials, after the publication of the February 2004 version, the partially revised August 2006 version was published. Regarding the guidance for pheromones and other semiochemicals, the September 2002 version was published in 2003.

'Environment, Health & Safety News No. 16'[29],

issued by the OECD dated July 2004, stated that a ten-year vision for the harmonisation of regulatory approaches for agricultural pesticides had been agreed upon, and this vision was presented in the document titled 'A Vision for the Future: A Global Approach to the Regulation of Agricultural Pesticides'[30]. According to this document, the vision stated that by the end of 2014, through the co-operation of OECD member countries, the OECD would ensure that the regulatory system for agricultural pesticides would have been harmonised to the extent that country data reviews (monographs) for pesticides prepared in the OECD format on a national or regional basis could be used to support independent risk assessments and regulatory decisions made in other regions or countries, and that the preparation of data submissions (dossiers) was coordinated globally by industry, to the extent possible, such that opportunities were maximised for work-sharing between the regulatory authorities of OECD member countries.

As previously mentioned, from 31 December 2004, all dossiers submitted in the EU should be presented in OECD format, in principle. In the United States, the Pesticide Registration (PR) Notice 'Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)'[31] dated 30 November 2011 stated that the OECD dossier format was an alternative to the submission format for submitters who were planning multi-national submission. In Japan, the format of documents to be submitted for application for registration of pesticide was changed, and the OECD dossier format was introduced. The 'Guidance on dossier to be submitted for application for registration of an agricultural chemical'[32], dated 15 May 2014, presented the format developed based on the format presented in the OECD Dossier Guidance with addition of, or change in, the specific requirements in Japan.

In the 'Guidance Document on the Planning and Implementation of Joint Reviews of Pesticides'[33] published as the Series on Pesticides No. 60, dated 20 May 2011, a dossier submitted in OECD format was described in the implementation phase of a joint review. However, with respect to Document L, this guidance document stated that Tier I study summaries (Tier I quality checks) were not normally required, although the reference lists should continue to be submitted, and this should be confirmed during the project planning phase when determining document expectations.

The 'Report of the OECD Workshop on Electronic Tools for Data Submission, Evaluation and Exchange for the Regulation of new and Existing Industrial Chemicals, Agricultural Pesticides and Biocides, Ottawa, October 2002'[34] published as the Series on Pesticides No. 20, dated 22 May 2003, was the report of the workshop held in October 2002 and was published in the period of 1998 through 2005 during which the OECD Dossier Guidance was being revised. The harmonisation of the structure of study templates across programs wherever possible was recommended, as well as the same formats via test methods, robust summaries and standard templates, and harmonisation of structure. According to the website 'OECD Harmonised Templates - Updates and History'[35] based on the recommendations made by the workshop held in 2002, the OECD Expert Group on Harmonising Templates was established in 2004 and the first four templates, which became the OECD Harmonised Templates (OHTs), were developed and agreed on, and a set of 87 templates was developed in 2006.

In a number of test guidelines and/or templates taken into account in the process of the development of OHTs, Data Evaluation Record (DER) templates for reviewing the scientific studies that were submitted to support applications to register pest control products in the area cover by the North American Free Trade Agreement (NAFTA), the aforementioned BP Dossier Guidance under the BP Directive 98/8/EC, IUCLID used for data entry of electronic submission of summaries of test results under the EU Existing Substances Regulation and the OECD High Production Volume (HPV) Chemicals Programme, and templates for compiling robust study summaries for submission to the OECD HPV Chemicals Programme, were included. However, the OECD Dossier Guidance for pesticides was not included.

For this reason, it can be said that examples of the summary and assessment of the individual tests and studies presented in the OECD Dossier Guidance did not reflect the OHT format.

Conclusion

Because many revisions and additions have been made to the dossier format to be submitted for approval/renewal of approval of ASs in PPPs in the EU, when

finding information in the dossiers submitted in the past or making use of the previously submitted dossiers for the preparation of dossiers to be submitted for the next renewal of approval, it is necessary to identify which guidance was used for the preparation of those dossiers. Since the OECD dossier format came to be used in OECD member countries, the information contained in the dossiers submitted for approval/renewal of approval of ASs in PPPs in the EU can be used for the registration/renewal of registration of pesticide ASs in OECD member countries. However, due to differences in data requirements among OECD member countries, dossiers prepared in the OECD format are accepted in all OECD member countries and used globally as stated in A Vision for the Future issued by the OECD is an ideal and difficult to achieve in practice, except in the case of joint review for new ASs.

Efforts have recently been made to solve this problem, and we will give an overview of recent movement next time. For the content of the article, the URLs linked to the referenced documents are also provided in the 'Reference' section, to the extent that valid URLs currently exist on the Internet, so that the details can be confirmed with the contents of the referenced documents.

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