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 2

Sumika Technoservice Corporation
Regulatory Affairs & Chemical Safety Center
Hiroko HARADA
Mio TATSU
Mika OTA

In Part 1 of this article, the changes in the format of the dossier under the Plant Protection Product (PPP) Directive 91/414/EEC were summarised, covering its development from early versions to the introduction of OECD dossier format. Under the PPP Regulation 1107/2009, the submission of a dossier was required for the renewal of approval of an active substance (AS) as well as for the approval of an AS. In Part 2, further changes introduced under the PPP Regulation 1107/2009 are outlined, including the provision of structured data using harmonised templates, electronic submission of summaries of test results, and other relevant information.

Introduction

In the previous article, the changes in the format of the dossier under the Plant Protection Product (PPP) Directive 91/414/EEC were summarised, covering its development from early versions to the introduction of the Organisation for Economic Co-operation and Development (OECD) dossier format. Under the PPP Regulation 1107/2009, the submission of a dossier was required for the renewal of approval of an active substance (AS) as well as for the approval of an AS. Furthermore, modifications to data requirements under the PPP Regulation 1107/2009 made it difficult to prepare dossiers using the once introduced OECD format. As a result, the dossier format incorporating further changes and additions to the OECD dossier format came to be used in the EU. Since 2021, the submission of dossiers has been carried out using the specified format and software for the submission of dossiers.

Due to several revisions, the format of dossiers submitted for approval differs from that required for renewal of approval. This required re-writing and re-formatting of dossiers for renewal purposes. Additionally, the use of software for dossier preparation has introduced further complexity, requiring significant effort to input information into the system.

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. In addition, we have been collecting information on the revisions in the format of dossiers to be submitted for the approval/ renewal of approval of ASs in PPPs.

Based on our accumulated experience, this article provides 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, as well as how those problems were responded to in the process of the subsequent revisions.

It also outlines the structured and harmonised formats currently in use, the electronic submission of summaries of test results, and the submission of

dossiers using the specified format and software for the submission of dossiers. Furthermore, it explains how the entry of information into structured and harmonised templates and the electronic submission of summaries of test results have made it possible to reduce the effort and cost of preparing dossiers for future renewal of approval, as well as other possibility to be provided than dossier preparation.

Revision of the format of dossier in the EU after the introduction of the OECD dossier format

As outlined in Part 1[1], under Directive 91/414/EEC[2] concerning the placing of plant protection products on the market (PPP Directive), it was stated in 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[3] dated 8 October 2004, that from 31 December 2004, all dossiers submitted should be presented in the OECD format. It was also noted that for new ASs, dossiers in the OECD format were already acceptable.

Due to differences in data requirements among OECD member countries, the third and fourth forms within Document O (forms for the checking of dossiers for completeness), which were the forms used to check the presence or absence of information/tests corresponding to the data requirements for AS and the data requirements for each product, respectively, were not included in the Appendix of the OECD Dossier Guidance[4]. Instead, it was stated that these forms were to be developed by the regulatory authorities of individual countries or groups of countries, as appropriate.

The document Sanco/10518/2004 Rev. 3 dated 8 October 2004 indicated the existence of check forms using the OECD numbering system, and stated that these forms must be used from 1 January 2005. It was also mentioned that for new ASs these forms might be used already. These check forms used the OECD numbering system and included data points not required as EU data requirements, while also incorporating the EU numbering system to assist in checking dossiers to be submitted in the EU. However, from 1 January 2005, dossiers should be presented using the OECD numbering system, as stated in the document.

The form for checking data requirements corresponding to the chemical substance AS and the form for checking data requirements corresponding to products containing the chemical substance AS, which were prepared and published as 'Forms for use in checking dossiers for completeness - Part 3: Evaluation Form 3: Annex IIA: Test and Study Reports'[5], and 'Forms for use in checking dossiers for completeness - Part 4: Evaluation Form 4: Annex IIIA: Test and Study Reports'[6], respectively, were the forms which incorporated the OECD data point numbers and information/study titles indicated in Annex 6 of the OECD Dossier Guidance to the third and fourth forms of Document O contained in the Dossier Preparation Guidelines 1663/VI/94 Rev. 8[7] dated 22 April 1998. A number sign '#' was indicated where no EU data requirement point number was available for the OECD data point number concerned.

Unlike the OECD Dossier Guidance for chemicals, the Dossier Guidance for Microbials[8] and the Dossier Guidance for Pheromones and other Semiochemicals[9] provided the third and fourth forms of Document O, which were forms for the checking of dossiers. Regarding the checking forms for dossiers for microbials in the EU, forms for checking data requirements corresponding to microbial AS were prepared and published as 'Forms for use in checking dossiers for completeness - Part 3: Evaluation Form 3: Annex IIB: Test and Study Reports'[10] and forms for checking data requirements corresponding to products containing microbial AS were prepared and published as 'Forms for use in checking dossiers for completeness - Part 4: Evaluation Form 4: Annex IIIB: Test and Study Reports'[11], both of which included the OECD data point numbers as well as EU data requirement point numbers in the same manner as the checking forms for dossiers for chemicals. However, in the EU, pheromones and other semiochemicals are regarded as chemical substance ASs, so no specific forms for use in checking dossiers for pheromones and other semiochemicals were prepared.

Revision of the dossier format due to the replacement of the PPP Directive 91/414/EEC by the PPP Regulation 1107/2009

The PPP Directive 91/414/EEC was repealed with effect from 14 June 2011 by the PPP Regulation 1107/2009[12], which was published in the Official

Journal (OJ) on 24 November 2009 (Article 83 of Regulation 1107/2009). The PPP Regulation 1107/2009 applied from 14 June 2011 (Article 84 of Regulation 1107/2009). The transitional measures under which the PPP Directive shall continue to apply, along with their conditions, have been established (Article 80 of Regulation 1107/2009). Except in cases where the transitional measures applied, the PPP Regulation 1107/2009 applied.

The provisions set out in the Annexes to the PPP Directive 91/414/EEC were to be transferred into separate legal instruments to be adopted by the European Commission within 18 months after the entry into force of the PPP Regulation 1107/2009. The provisions on AS data requirements and PPP data requirements were to be adopted as the Regulation on data requirements for ASs (AS Data Requirements Regulation) and the Regulation on data requirements for PPPs (PPP Data Requirements Regulation) by 14 June 2011 (Article 84(b)(c) of Regulation 1107/2009). The AS Data Requirements Regulation 544/2011[13] and the PPP Data Requirements Regulation 545/2011[14], published in the OJ on 11 June 2011, took over the contents of Annexes II and III of the PPP Directive 91/414/EEC without any substantial modification. Therefore, no changes occurred at this point regarding the EU data requirements listed in Part 4 and Part 5 of Appendix 6 of the OECD Dossier Guidance and the Dossier Guidance for Microbials.

Under the PPP Directive 91/414/EEC, there were no specific provisions regarding the information to be included in the dossier other than the data which was believed to satisfy the data requirements. The information to be included in the dossier was indicated in the Regulations establishing the procedures for the assessment of existing ASs and the dossier preparation guidelines. The information specified to be included in the dossier under the PPP Regulation 1107/2009 included the same information as indicated in the Regulations associated with the PPP Directive 91/414/EEC, but newly required information was also added (Article 8 of Regulation 1107/2009).

Under the PPP Regulation 1107/2009, low-risk ASs, basic substances, and Candidates for Substitution (CfS) were added as derogations from the normal approval of ASs.

A low-risk AS is an AS that meets the criteria laid down in Point 5 of Annex II of the PPP Regulation 1107/2009 (Article 22(2) of Regulation 1107/2009, Point 5 of Annex II). A CfS is an AS that meets one or more of the criteria laid down in Point 4 of Annex II (Article 24(1) of Regulation 1107/2009, Point 4 of Annex II). The provisions regarding the dossier referred to in Article 8 of the PPP Regulation 1107/2009 apply regardless of whether an AS is low-risk or CfS (Article 22(2) and Article 24(2) of Regulation 1107/2009).

However, Article 8 of the PPP Regulation 1107/2009 does not apply to basic substances. Therefore, the preparation and submission of a dossier in the same format as provided for a dossier to be submitted as normal application for approval is not required for a basic substance.

A basic substance is an AS that meets the following criteria and its approval shall be for an unlimited period (Article 23(1)(a)(b)(c)(d) of Regulation 1107/2009):

- is not a substance of concern.
- does not have an inherent capacity to cause endocrine disrupting, neurotoxic, or immunotoxic effects.
- is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent.
- is not placed on the market as a plant protection product.

By way of derogation from the normal application for approval, the information by which an application for approval shall be accompanied is the following (Article 23(3)(a)(b) of Regulation 1107/2009):

- Any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other Community legislation regulating the use of the basic substance.
- Other relevant information on its possible effects on human or animal health or the environment.

The template for the application for approval of a basic substance was provided in Annex I of the document SANCO/10363/2012 'Working Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009' Rev. 7[15] dated 3 April 2013.

According to the description in this working document, the template was based on the structure of the assessment report compiled for ASs. In many cases, not all the items included in the template would be relevant or require supporting data. In cases where an item was considered not applicable or not appropriate by the applicant, the applicant could indicate 'Not

applicable' together with a justification. The explanation concerning each requirement item was provided in the working document.

The documents and data requirements indicated in the template for the application for approval of basic substances, as shown in **Table 1**, were significantly fewer and more simplified compared to those to be included in dossiers for chemical substance ASs. The data requirements were fewer than those set out in the AS Data Requirements Regulation 544/2011 and the PPP Data Requirements Regulation 545/2011. Since the substance is used either directly or in a product consisting of the substance and a simple diluent, the template did not provide separate documents for AS and product data, respectively. Most of the information to be provided in Documents A-J, which were Supporting Documentation to be included in dossiers, was not required. The application template for the approval of a basic substance AS was shaped like a concise summary combining the Tier II summary and the Tier III summary of the dossier, along with a list which was comparable to a listing of all test and study reports, which comprised Tier I. Since it is based on the structure of the assessment report, the Tier I quality check was not included.

The template for the application for approval of a basic substance, which was included in SANCO/10363/2012 Rev. 7, was later updated by Rev. 9[16] dated 21 March 2014, in which some minor changes were made to the template in Annex I.

Under the PPP Directive 91/414/EEC, submission of a Literature Review Report as a document in dossier was not clearly required or stated. Either the Dossier Preparation Guidelines 1663/VI/94 Rev. 5[17] dated 3 August 1994 or Rev. 6[18] dated 31 January 1995, stated that all relevant test and study reports and published papers of which the applicant was aware, but had not been submitted, a separate listing from a listing of those submitted should be provided, but did not require to perform literature search or include reports of literature search in the dossier. The Dossier Preparation Guidelines 1663/VI/94 Rev. 8 dated 22 April 1998, as well as the OECD Dossier Guidance, the Dossier Guidance for Microbials, and the Dossier Guidance for Pheromones and other Semiochemicals, stated that applicants should conduct a detailed literature search when preparing the separate listing. The date on which the reference list was compiled, the identity of the databases searched, the date range established for the purposes of the search, the language constraints, if any, imposed, and the key words used for the purposes of the literature search, should be indicated. However, an

Table 1 Documents (or information to be included in the corresponding Documents) and sections set out as data requirements, which are indicated in the templates provided in the dossier guidelines/guidance for chemical ASs and in the working document for basic substances

Chemical AS (1663/VI/94 Rev.8/OECD)					**Basic substance** (SANCO 10363/2012 Rev.7)	
Doc A to J				Information to be included in Doc A		
Doc M (Tier II)				Information to be included in Doc D-I	1	Purpose of the application
AS		PPP				
1	Identity	1	Identity		2	Identity of the **substance**/**product** as available on the market and predominant use
2	Physical and chemical properties	2	Physical and chemical properties			
3	Further information	3	Data on application		3	Uses of the **substance** and its **product**
		4	Further information	AS only		
4	Analytical methods	5	Analytical methods		4	Classification and labelling of the **substance**
-	(No section allocated)	6	Efficacy data			
5	Toxicological and metabolism studies	7	Toxicological studies		5	Impact on human and animal health (**substance**/**product**)
6	Residues in or on treated products, food and feed	8	Residues in or on treated products, food and feed		6	Residues (Title only)
7	Fate and behaviour in the environment	9	Fate and behaviour in the environment		7	Fate and behaviour in the environment (Title only)
8	Ecotoxicological studies	10	Ecotoxicological studies		8	Effects on non-target species (**substance**/**product** not indicated)
9	Summary and evaluation of Sections 7 and 8	11	Summary and evaluation of Sections 9 and 10	AS only	9	Overall conclusions with respect of eligibility of the substance to be approved as basic substance
10	Classification and labelling	12	Further information (inc. Classification and labelling)			
Doc N (Tier III Over all summary)					Annex I	List of references relied on
Doc N (Tier III List of endpoint)						
Doc L (Tier I Reference list)						
Doc L (Tier I Quality check)						

The arrows indicate how each document or information included in each documents of Chemical AS corresponds to the documents of the Basic substance.
The red arrows represent those related to part of the documents belongs to Doc A-J, while the blue arrows indicate those related to Doc L or N, or particular section of Doc M.
Although 'Efficacy data' is not explicitly stated in the headings or points under each headings of the Basic substance template, if it is to be included, it would correspond to section 3, which is represented by a dashed arrow.

example of how to report the literature search was not provided in the aforementioned guidelines or guidance documents.

According to the provisions concerning dossiers under the PPP Regulation 1107/2009, scientific peer-reviewed open literature, as determined by the European Food Safety Authority (EFSA), on the AS and its relevant metabolites dealing with side-effects on health, the environment, and non-target species, and published within the last 10 years before the date of submission of the dossier, shall be added by the applicant to the dossier (Article 8(5) of Regulation 1107/2009).

The EFSA guidance 'Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009'[19] adopted on 24 February 2011, provides instructions on how to identify and select scientific peer-reviewed open literature and how to report it in a dossier. This guidance also presents tables such as a table for reporting of the search process. **Table 2** shows the sections and tables to be contained in the Literature Review Report, as specified in the guidance.

Copies of the full-text documents listed in Table 4 and Table 5 of the guidance should be provided as Document K of the dossier, and all Literature Review Reports should be incorporated in Document K of the dossier.

The provisions concerning the dossier indicated in Article 8 of the PPP Regulation 1107/2009 do not apply to basic substances. Therefore, the preparation of a Literature Review Report in accordance with the EFSA guidance adopted on 24 February 2011 is not required.

For ASs other than basic substances, the dossier for the approval of an AS or for an amendment to the conditions of an approval under the PPP Regulation 1107/2009 was prepared in accordance with the OECD Dossier Guidance or the Dossier Guidance for Microbials in the early days after the application of the PPP Regulation.

The procedure for the renewal of the approval of the second group of ASs, so-called AIR2 (AIR stands for Annex I Renewal, since inclusion in Annex I meant approval under the PPP Directive 91/414/EEC), of which renewal of the approval was to be decided according to the criteria in Regulation 1107/2009, was laid down by the Renewal Procedure Regulation 1141/2010[20], published in the OJ on 8 December 2010.

The dossiers assessed for the renewal of approval were referred to as supplementary dossiers and should be added to the original dossiers, which were the dossiers submitted for the first approval, with their subsequent updates (Article 9 of Regulation 1141/2010). The supplementary dossiers should be submitted by the date set out for the respective AS in the table of Annex I (29 February, 31 May, or 31 August 2012) (Article

Table 2 Sections and tables to be contained in the literature review report, as specified in the Guidance of EFSA approved on 24 February 2011

Section number	**Section title, content and tables to be included**
1	**Title**
2	**Authors** of the review
3	**Summary**: a brief summary indicating the purpose of the report, the methodology employed and the results obtained.
4	**Protocol**, which should contain: ・ A statement of the objective of the review (i.e. to provide information on side effects of (a) determined active substance(s), metabolite(s), plant protection product(s)); ・ **Table 1**, The criteria for relevance with which decisions to select studies in the dossier were made.
5	**Search methods and results**, including a descriptive summary, together with: ・ **Table 2**, which reports the search process for scientific peer-reviewed open literature in bibliographic databases; ・ A structured text list documenting any searches and related results performed in sources of peer-reviewed literature other than bibliographic databases
6	**Results of the study selection process**, including a descriptive summary, together with: ・ **Table 3**, reporting the results of the study selection process, for each data requirement or group of data requirements searched; ・ **Table 4**, reporting the bibliographic references to all relevant studies and studies whose relevance remains unclear after detailed assessment for relevance of full-text documents (i.e. the second step of the selection process), ordered by data requirement(s); ・ **Table 5**, reporting the bibliographic references to all relevant studies and studies whose relevance remains unclear after detailed assessment for relevance of full-text documents (i.e. the second step of the selection process), ordered by author(s); → Copies of the full-text documents listed in Table 4 and Table 5 should be provided with the dossier (document K). These copies should be placed within the subfolders that contain studies relevant to the data requirements for which the full-text document has been found relevant. If studies are relevant to more than one data requirement, only one copy of the corresponding full-text document should be provided, but cross references would need to be inserted in the other folders for which the full text document is considered relevant. Relevant full-text documents should preferably be provided in English; however, official EU languages would be accepted. Relevant full-text documents in non-EU languages should be translated to English. ・ **Table 6**, reporting the bibliographic references to studies considered non-relevant after detailed assessment of full-text documents (i.e. second step of the selection process).

9(3) of Regulation 1141/2010, Annex I). The guidance document SANCO/10387/2010 Rev. 8[21] dated 28 October 2010, prepared for the ASs covered by AIR2 to be assessed in compliance with Regulation 1141/2010, stated that the dossier format should be used according to the dossier guideline SANCO/10518/2005 Rev. 5[22] dated 27 June 2005. According to Sanco/10518/2005 Rev. 5, the OECD Dossier Guidance Rev. 2 dated May 2005 should be used for chemical substances, and the OECD Dossier Guidance for Microbials dated February 2004 should be used for microbials. Therefore, the supplementary dossier submitted for the AIR2 renewal of approval was prepared in accordance with the OECD dossier format.

Under the PPP Regulation 1107/2009, the summary dossier submitted for the approval, for an amendment of the conditions of an approval, or renewal of the approval of an AS shall be made available to the public by the EFSA, excluding any information in respect of which confidential treatment has been requested and justified pursuant to Article 63 'Confidentiality' (Articles 10 and 16 of Regulation 1107/2009). However, with regard to the application for approval of basic substances, there is no provision stating Article 10 of the PPP Regulation 1107/2009, which is a provision on access to the Summary Dossier, shall apply (Article 23 of Regulation 1107/2009). Therefore, an application for the approval of a basic substance was not made public in the same manner as the dossiers for ASs other than basic substances.

The Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS), which evaluates the approval or amendment to the conditions of an approval of an AS, shall also be made available to the public by the EFSA, except for certain parts of DAR that are required to be kept confidential (Article 12(1) of Regulation 1107/2009). However, it took some time before the DAR, excluding certain parts of the DAR that are required to be kept confidential, was published on the EFSA website actually and could be downloaded directly from the website. As for basic substances, since the procedure for approval is different from that of other ASs, no assessment report corresponding to the DAR is prepared by RMS.

Regarding the DAR, after the EFSA had a role in the evaluation under the PPP Directive 91/414/EEC, the EFSA published the availability of the DAR which it received and made the DAR available at specific request, except the elements thereof which had been requested and accepted as confidential. This provision was introduced by Regulation 1490/2002[23], which laid down further detailed rules for the implementation of the review programme of work for existing ASs in the third stage (Article 11(3) of Regulation 1490/2002). Regulation 1490/2002 also provided amendments to Regulation 451/2000[24], which laid down the detailed rules for the review programme of work for existing ASs covered by the second stage and in the third stage, therefore similar provisions were applied to existing ASs covered by the second stage (Article 20(1) of Regulation 1490/2002, Article 8(6) of Regulation 451/2000). Similar provisions for existing ASs covered by the fourth stage were also set out in Regulation 2229/2004[25] laying down further detailed rules for the implementation of the fourth stage of the programme of work (Article 24(5) of Regulation 2229/2004). Under the PPP Directive 91/414/EEC, there were no such specific provisions for new ASs, however, for new ASs of which the EFSA participated in the evaluation process, the evaluation procedures applied to existing ASs covered by the second stage were applied. Similarly, except the elements that were required to be kept confidential, the DAR was made available upon request to the EFSA.

Under the PPP Regulation 1107/2009, the DAR is made available to the public except certain parts of the DAR which are requested to be kept confidential, so specific request at which the DAR is made available under the PPP Directive 91/414/EEC is no longer necessary.

The assessment report prepared by the RMS which assessed the dossiers submitted for the renewal of approval of the AS is referred to as the Renewal Assessment Report (RAR) under the Renewal Procedure Regulation 1141/2010, which laid down the evaluation procedure for AIR2 (Article 14(1) of Regulation 1141/2010). It was specified that the EFSA should make the RAR available upon request, excluding any information for which confidential treatment had been requested (Article 15(2) of Regulation 1141/2010). However, in practice, since the DAR, excluding any information for which confidential treatment had been requested, could be downloaded directly from EFSA's website, the RAR, like the DAR under the PPP Regulation 1107/2009, was made available to the public via the EFSA's website excluding any information for which confidential treatment had been requested.

As for the assessment report for an AS covered

by AIR2, the format of the RAR prepared by the RMS should follow the formatting guidelines for DARs as provided in the guidance document SANCO/10387/2010 Rev. 8 dated 28 October 2010. Depending on the original DARs, the complexity of the peer review in the first approval process, extent and nature of the new data submitted and assessments required, the RMS might choose to prepare a complete new Assessment Report or prepare addenda to the existing DAR. However, a fully updated Volume 1 should be prepared, and Volume 1 should include the list of endpoints. Furthermore, the conclusion in the RAR should address whether the requirements of Article 4 of Regulation 1107/2009 were satisfied.

Under the PPP Regulation 1107/2009, criteria for the approval were set out in Annex II, and it is stated that an AS shall be approved in accordance with Annex II (Article 4 of Regulation 1107/2009).

A template which was intended to align with the assessment that the RMS had to carry out against the criteria for the approval as set out in the PPP Regulation 1107/2009 was prepared and published as the document SANCO/11114/2012 'Template to be used for Assessment Reports regarding Level 3 of Volume 1'[26] dated 1 June 2012. This template should be used for assessment reports prepared for ASs covered by the Renewal Procedure Regulation 1141/2010 and for ASs for which an application for approval was submitted as from 1 June 2012.

In all of the Guidelines for Dossier Evaluation and Report Preparation 1654/VI/94 Rev. 7[27], the OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances (Monograph Guidance)[28] and OECD Guidance for Country Data Review Reports on Microbial Pest Control Products and their Microbial Pest Control Agents (Monograph Guidance)[29], which were prepared in accordance with the guidelines, Level 3 of Volume 1 presented only three points. In the OECD Monograph Guidance, these three points and their corresponding headings were as follows:

3.1 Background to the proposed decision
3.2 Proposed decision
3.3 Rationale for the postponement of the decision, or for the conditions and restrictions to be associated with any approval or registration, as appropriate

The document SANCO/11114/2012 dated 1 June 2012 introduced subsections under the three points listed in Level 3 of Volume 1 of the Assessment Report which were presented in the aforementioned guidelines or guidance. In addition to the criteria for the approval, it also provided templates to be used to assess the compliance with CfS criteria and low risk AS criteria. The subsections established under Point 3.1 are shown in **Table 3**. Some of these subsections corresponded to the issues dealt with in the EFSA Conclusion, which is prepared based on the DAR or the RAR.

As described above, for a while after the PPP Regulation 1107/2009 applied from 14 June 2011, dossiers and assessment reports were normally prepared in accordance with the OECD format, except for basic substances to which the OECD format for dossiers and assessment reports did not apply. The differences compared to before the application of the PPP Regulation 1107/2009 were that a Literature Review Report which was newly required under the PPP Regulation 1107/2009 had to be included in the dossier, and a template to be used for assessment report regarding Level 3 of Volume 1 was established and should be used for assessment reports.

Table 3 Subsections in the template to be used for assessment reports regarding Level 3 of Volume 1

Subsection	Title	Corresponding issue in EFSA Conclusion
3.1.1	Proposal on acceptability against the decision-making criteria – Article 4 and Annex II of Regulation (EC) No 1107/2009	
3.1.2	Proposal – Candidate for Substitution	
3.1.3	Proposal – Low risk active substance	
3.1.4	List of studies to be generated, still ongoing or available but not peer reviewed	List of studies to be generated, still ongoing or available but not peer reviewed
3.1.5	Issues that could not be finalised	Issues that could not be finalised
3.1.6	Critical areas of concern	Critical areas of concern
3.1.7	Overview table of the concerns identified for each representative use considered	Overview of the concerns identified for each representative use considered
3.1.8	Area(s) where expert consultation is considered necessary	
3.1.9	Critical issues on which the Co-RMS did not agree with the assessment by the RMS	

Revision of the format of dossier due to the replacement of the AS Data Requirements Regulation and the PPP Data Requirements Regulation

In compliance with the provisions concerning amendments to the Regulations on data requirements for ASs and for PPPs, taking into account current scientific and technical knowledge (Article 78(1)(b) of Regulation 1107/2009), the AS Data Requirements Regulation 544/2011 and the PPP Data Requirements Regulation 545/2011 were repealed by the AS Data Requirements Regulation 283/2013[30] and the PPP Data Requirements Regulation 284/2013[31], respectively, published in the OJ on 3 April 2013 (Article 2 of Regulation 283/2013, Article 2 of Regulation 284/2013). Transitional measures and their conditions, where Regulation 544/2011 and/or Regulation 545/2011, respectively, continue to apply were laid down (Articles 3 and 4 of Regulation 283/2013, Articles 3 and 4 of Regulation 284/2013). Unless transitional measures apply, Regulation 283/2013 or Regulation 284/2013 apply from the date of application. There were additional data requirements, such as those related to endocrine disrupting properties, and other additions or amendments regarding data requirements for chemical substance ASs and PPPs containing chemical substance ASs. However, there were almost no substantial changes to the data requirements for micro-organisms ASs or PPPs containing micro-organisms ASs.

As for data requirements for chemical substance ASs, the point listed as '9. Summary and evaluation of Sections 7 and 8' in the AS Data Requirements Regulation 544/2011 was changed to '9. Literature data' in the AS Data Requirements Regulation 283/2013. In the data requirements for PPP containing chemical substance ASs, the point listed as '11. Summary and evaluation of Sections 9 and 10' in the PPP Data Requirements Regulation 545/2011 was changed to '11. Literature data' in the PPP Data Requirements Regulation 284/2013. A summary of all relevant data from the scientific peer reviewed open literature on the AS, metabolites, and breakdown or reaction products and PPPs containing the AS shall be submitted under these data requirement points titled 'Literature data'.

The AS Data Requirements Regulation 283/2013 and the PPP Data Requirements Regulation 284/2013 entered into force on 23 April 2013, twentieth day following that of its publication in the OJ on 3 April 2013, and applied from 1 January 2014 (Article 5(1)(2) of Regulation 283/2013, Article 5(1)(2) of Regulation 284/2013). For procedures concerning the renewal of approval of ASs whose approval expired on 1 January 2016 or later, these Regulations applied (Article 5(2) of Regulation 283/2013, Article 5(2) of Regulation 284/2013).

ASs for the renewal of approval covered by AIR3, the 3rd group of ASs for renewal of the approval, were indicated in Regulation 686/2012[32], allocating to Member States, for the purposes of the renewal procedure, the evaluation of the ASs whose approval expires by 31 December 2018 at the latest, published in the OJ on 27 July 2012. The procedure for the renewal of approval of an AS covered by AIR3 and the subsequent groups, was implemented in accordance with the Renewal Procedure Regulation 844/2012[33], which was published in the OJ on 19 September 2012 and applied from 1 January 2013. Under the Renewal Procedure Regulation 844/2012, an application for the renewal of an approval should be submitted no later than three years before the expiry of the approval, and if the application for the renewal of an approval had been submitted by the date, the supplementary dossiers should be submitted no later than 30 months before the expiry of the approval (Articles 1(1), 3(1), and 6(1)(3) of Regulation 844/2012).

At the time of the publication of Regulation 686/2012, expiry of approval of some ASs covered by AIR3 was earlier than 1 January 2016. As indicated in document SANCO/2012/11284 'Draft Working Document - AIR III Renewal Programme'[34], after the publication of Regulation 686/2012, except for certain ASs, the expiry of approval of the ASs covered by AIR3 were postponed by Amendment Regulations as regards the extension of the approval periods. At the time of the publication of Regulation 686/2012, the expiry of approval of the AIR3 ASs had been set between 1 January 2013 and 31 December 2018. However, the expiry dates of approval of ASs were postponed so that the deadline for the submission of the dossiers for the ASs covered by the first group within AIR3, which was 30 months before the expiry of approval, would be set on 31 January 2014. For any AS of which expiry date of approval was earlier than 1 January 2016, the expiry date of approval was postponed during the year 2012 to a date later than 1 January 2016, unless no application/letter for renewal of approval had been previously submitted.

From 1 January 2014, due to the application of the AS Data Requirements Regulation 283/2013 and the PPP Data Requirements Regulation 284/2013, dossiers submitted after 1 January 2014 must be prepared to include data requirement points not listed in Parts 4 and 5 of Annex 6 of the OECD Dossier Guidance also.

In compliance with the updated data requirements, the document SANCO/10181/2013 'Guidance Document for Applicants on preparing Dossiers for the Approval of a Chemical New Active Substance and for the Renewal of Approval of a Chemical Active Substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013' Rev. 2.1[35] dated 13 May 2013 was issued for chemical substance ASs. This guidance document should be used for dossiers prepared for chemical ASs for the renewal of approval covered by AIR3 and the subsequent groups, and chemical ASs for which an application for the approval was to be submitted as from 1 January 2014.

Appendix A of this guidance document, 'Description of documents to be included in a submission', tabulated the summary and supporting documentation to be included in the dossier. In this table, document names indicated as the OECD Document and the Revised EU Document were listed together with the Document titles.

Under the PPP Directive 91/414/EEC, data requirements for ASs were set out in Annex II, and data requirements for PPPs were set out in Annex III. In each Annex, the data requirements for chemical ASs or products containing chemical ASs were set out under Part A, while the data requirements for micro-organism ASs or products containing micro-organism ASs were set out under Part B. Therefore, for chemical substance ASs and products containing chemical substance ASs, the EU numbering system corresponding to EU data requirements was presented as IIA 1.1 or IIIA 1.1. Similarly, the OECD numbering system used in the OECD dossier format was also presented as IIA 1.1 or IIIA 1.1. However, under Regulation 1107/2009, data requirements were no longer set out in Annexes but in separate Regulations. Therefore, 'CA (Chemical Active)' replaced 'IIA' for chemical substance ASs, and 'CP (Chemical Product)' replaced 'IIIA' for products containing chemical substance ASs. Consequently, a numbering system different from the OECD numbering system was to be used in dossiers.

Indicative MS Word templates were provided for Document J, Document M corresponding to Tier II summary, Document N corresponding to Tier III summary, and two templates of Document O corresponding to Forms for use in checking dossiers in accordance with AS data requirements and PPP data requirements, respectively. In these templates the version history page was introduced following the cover page.

Regarding the reference list, which is a listing of test and study reports, *etc.* and part of Tier I, to which Document L corresponds, the guidance document SANCO/12580/2012 'Guidance Document on preparing lists of test and study reports according to Article 60 of Regulation (EC) No 1107/2009' Rev. 3.1[36] dated 17 May 2013 was provided. Therefore, 'Reference list (should reflect guidance in SANCO/12580/2012)' was indicated in the additional notes, and the template for the list was not provided. The format of the reference list indicated in the guidance document SANCO/12580/2012, Rev. 3.1, was partially modified from the format presented in the OECD Dossier Guidance. Columns that were not included in the OECD format, such as 'Vertebrate study' and 'Justification if data protection is claimed', were added, along with other minor changes. The column to indicate whether the study involved vertebrate animals was added in accordance with the provisions concerning sharing of tests and studies involving vertebrate animals which were newly introduced under the PPP Regulation 1107/2009 (Article 62 of Regulation 1107/2009).

Regarding the Tier I summary and Tier I quality check, which were other parts of Document L, a note below the table in Annex A stated, 'Tier I summaries are not required (OECD study summaries include all the information previously contained in the Tier I summary)', and they were not included in Annex A. Consequently, the Tier I summary was no longer a document to be submitted.

The indicative templates for Document M presented the new data requirement point numbers and titles in accordance with the AS Data Requirements Regulation 283/2013 and the PPP Data Requirements Regulation 284/2013. The templates were provided for each section, except for MCP Section 6 corresponding to efficacy data of products. However, the templates provided contained very little explanation on how to report the information under each data requirement point, and no examples of how to report the information were included.

Regarding efficacy data, it was indicated that it is not

required for either the renewal of approval or approval of an AS. Instead, efficacy summary was required in MCP Section 3 corresponding to, 'Data on application' of product. The template for Section 3 of Document M for product included the indication of guidance from the document SANCO/12592/2012 'Template to be used for Assessment Reports' first edition[37] dated November 2012 mentioned later, and the presented text was similar to that described under Point 2.3 'Data on application and efficacy' in the format for Level 2 of Volume 1 of the assessment report included in the indicated guidance. Therefore, the following two relevant guidance documents mentioned in the indicated guidance were also stated.

- for new ASs 'SANCO E3 Working document (Data requirements on efficacy for the dossier to be submitted for the approval of new active substances as defined under Regulation (EC) No 1107/2009 contained in plant protection products)'
- for renewal of approval of ASs - Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 Appendix II (SANCO/2012/11251)

SANCO E3 Working document was later published as document SANCO/10054/2013 Rev. 3[38] dated 11 July 2013. The latest version of document SANCO/2012/11251 as of November 2012 was Rev. 1.2[39] dated July 2012.

As the OECD study summaries included all the information and therefore Tier I summaries were not required as Document L, the study summaries under each individual data requirement point were to be presented in line with the examples of Tier II summary, which were mentioned as OECD study summaries, in the OECD Dossier Guidance. According to the Appendix E (Template for presenting individual study summaries) of 'Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances'[40] first version adopted on 27 March 2019 mentioned later, summary of the study according to the OECD format was clearly presented after the information on the study.

The Document N included additional documents that did not exist before, and consisted of five documents, N1 to N5. The body text and the list of endpoints, which were included in the previous Document N, had been divided into Document N1 and Document N2. The newly added Documents N3 to N5, as shown below, did not exist in the OECD Dossier Guidance.

Document N3: Substances and metabolites; structures, codes, synonyms

Document N4: Relevance of metabolites in groundwater

Document N5: Consideration of isomeric composition in the risk assessment

The Document O consisted of the following two documents: Document OCA indicated the updated data requirement point numbers and corresponding titles reflecting the AS Data Requirements Regulation 283/2013, and Document OCP indicated the updated data requirement point numbers and corresponding titles reflecting the PPP Data Requirements Regulation 284/2013.

Document OCA: Initial Evaluation Form - Active Substance

Document OCP: Initial Evaluation Form - Plant Protection Product

Unlike the previous check form for chemical substance ASs and the previous check form for products containing chemical substance ASs, the OECD data point numbers presented in Appendix 6 of the OECD Dossier Guidance were not indicated.

The document SANCO/10181/2013 Rev. 2.1 dated 13 May 2013, was subsequently updated by Rev. 3[41] dated 12 December 2014, however, it was only the template of Document N2 that was updated by Rev.3.

For micro-organism ASs, the document SANCO/12545/2014 'Guidance Document for Applicants on preparing Dossiers for the Approval or Renewal of Approval of Micro-organisms including viruses according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013' Rev.1[42] was issued. Since there were few revisions to the data requirements for micro-organisms, only the template for Document N2, List of endpoints for micro-organisms, was provided by this Rev. 1 of the guidance document. Document N3-5 was not indicated in documents to be included for the submission prepared for micro-organism ASs. Since this guidance document was finalised in the Standing Committee on Plants, Animals, Food and Feed on 12 December 2014, it should be used for dossiers prepared for ASs which were micro-organisms, as provided for in the PPP Regulation 1107/2009, for which an application for approval or renewal of approval was submitted as from 1 March 2015. The Rev. 1 of this guidance document was subsequently updated by Rev. 2[43] dated March 2016,

but Rev. 2 did not introduce any changes in the format of the dossier.

Under the PPP Directive 91/414/EEC, data requirements for ASs were set out in Annex II, and data requirements for PPPs were set out in Annex III. In each Annex, the data requirements for chemical substance ASs or products containing chemical substance ASs were set out under Part A, and the data requirements for micro-organism ASs or products containing micro-organism ASs were set out under Part B. Therefore, regarding micro-organism ASs and products containing micro-organism ASs, the EU numbering system corresponding to the EU data requirements was presented as IIB 1.1 or IIIB 1.1. Similarly, the OECD numbering system used in the OECD dossier format was presented as IIM 1.1 or IIIM 1.1. However, under Regulation 1107/2009, the data requirements were no longer set out in Annexes but in separate Regulations. Therefore, 'MA (Microbial Agent)' replaced 'IIB' for micro-organism ASs, and 'MP (Microbial Product)' replaced 'IIIB' for products containing micro-organism ASs. Consequently, a numbering system different from the OECD numbering system was to be used in dossiers.

Revision of the Formats of Dossier and Assessment Report in line with the Harmonisation of the Structure of Dossiers and Assessment Reports

Concerning the ASs covered by AIR3 or subsequent groups, of which renewal of approval were to be assessed in accordance with the provisions set out in the Renewal Procedure Regulation 844/2012, and the ASs for which applications for approval were submitted as from 1 January 2014, new guidance on the templates to be used for assessment reports was applied.

The document SANCO/12592/2012 'Template to be used for Assessment Reports' dated November 2012 introduced several changes to the format presented in the Guideline for Dossier Evaluation 1654/VI/94 Rev. 7 and the OECD Monograph Guidance prepared based on this Rev. 7.

The changes incorporated not only those related to the revised data requirements but also those intended to align the structure of the assessment report with the dossier. It also aimed to reduce duplication of information in different parts of the assessment report and to separate out the AS part from PPP related exposure and risk. Furthermore, it would facilitate the setting of Maximum Residue Levels (MRLs), the preparation of an EFSA Conclusion, as well as a Proposal for Harmonised Classification and Labelling (CLH report). The MS Word indicative template such as those designated for the preparation of each document, as provided in the 'Guidance Document on preparing Dossiers (SANCO/10181/2013)', was not provided. Since the template was presented in the form of a table of contents within the body text, the guidance document was published in two versions, a pdf version and an MS Word version which were the same in content.

The OECD Monograph Guidance consisted of Levels 1 to 4 of Volume 1, Volume 2-Annex A, Volume 3-Annex B, and Volume 4-Annex C. Changes to the structure and additions/modifications of points were introduced in each volume. Similar to the dossier templates, the assessment report template also introduced the version history page immediately after the cover page of each volume. Additionally, explanations and other details regarding the information to be provided were indicated in the template in italics with grey highlights. The changes to the structure and additions/modifications of points in Level 1 of Volume 1 are shown in **Table 4**.

The changes in the structure and the addition/modification of points in Level 2 of Volume 1 are shown in **Table 5**. In Point 2.10 'Classification and labelling' of Level 2 of Volume 1, the tables in line with those included in the template for the CLH report, which is part of the CLH dossier, submitted to the European Chemicals Agency (ECHA) as a proposal for CLH, were included. The addition of Point 2.11 'Relevance of metabolites in groundwater' and Point 2.12 'Consideration of isomeric composition in the risk assessment' in Level 2 of Volume 1 corresponded to the newly introduced Document N4 'Relevance of metabolites in groundwater' and Document N5 'Consideration of isomeric composition in the risk assessment' as part of Document N in the dossier. The body text and the list of endpoints included in Document N in the dossier were split into Document N1 and Document N2, and similarly, in the assessment report, the list of endpoints was separated from Level 2 of Volume 1 and became a stand-alone document to be submitted in addition to Volumes 1 to 4. However, at the time of the preparation of the document SANCO/12592/2012 first version dated November 2012, the template for the list of endpoints was in

Table 4 Comparison of required information in the template to be used for assessment reports regarding Level 1 of Volume 1, as specified in SANCO/12592/2012 and the OECD Monograph Guidance

SANCO/12592/2012 –rev. 0 (2012.11)	OECD Monograph Guidance - Appendix 4
1 Statement of subject matter and purpose for which this report has been prepared and background information on the application	1 Statement of subject matter and purpose for which the monograph was prepared
1.1 Context in which the draft assessment report was prepared	
1.1.1 Purpose for which the draft assessment report was prepared	1.1 Purpose for which the monograph was prepared (Dossier Document A)
1.1.2 Arrangements between rapporteur Member State and co-rapporteur Member State	
1.1.3 EU Regulatory history for use in Plant Protection Products	
1.1.4 Evaluations carried out under other regulatory contexts	
1.2 Applicant(s) information	
1.2.1 Name and address of applicant(s) for approval of the active substance	1.3.1 Name and address of applicant(s)
1.2.2 Producer or producers of the active substance	1.3.7 Manufacturer or manufacturers of the active substance
1.2.3 Information relating to the collective provision of dossiers	1.2 Summary and assessment of information relating to the collective provision of dossiers (Dossier Document B)
1.3 Identity of the active substance	1.3 Identity of the active substance (Dossier Documents J, K-active substance and L-active substance)
1.3.1 Common name proposed or ISO-accepted and synonyms	1.3.2 Common name and synonyms
1.3.2 Chemical name (IUPAC and CA nomenclature)	1.3.3 Chemical name
1.3.3 Producer's development code numbers	1.3.4 Manufacturer's development code number
1.3.4 CAS, EC and CIPAC numbers	1.3.5 CAS, EEC and CIPAC numbers
1.3.5 Molecular and structural formulae, molecular mass	1.3.6 Molecular and structural formulae, molecular mass
1.3.6 Method of manufacture (synthesis pathway) of the active substance	1.3.8 Method or methods of manufacture
1.3.7 Specification of purity of the active substance in g/kg	1.3.9 Specification of purity of the active substance
1.3.8 Identity and content of additives (such as stabilisers) and impurities 1.3.8.1 Additives 1.3.8.2 Significant impurities 1.3.8.3 Relevant impurities	1.3.10 Identity of isomers, impurities and additives
1.3.9 Analytical profile of batches	1.3.11 Analytical profile of batches
1.4 Information on the plant protection product	1.4 Identity of the plant protection product (Dossier Documents J, K-active substance, L-active substance, K-formulation and L-formulation) (to be included for each preparation for which documentation was submitted)
1.4.1 Applicant	
1.4.2 Producer of the plant protection product	1.4.2 Manufacturer or manufacturers of the plant protection product
1.4.3 Trade name or proposed trade name and producer's development code number of the plant protection product	1.4.1 Current, former and proposed trade names and development code numbers
1.4.4 Detailed quantitative and qualitative information on the composition of the plant protection product 1.4.4.1 Composition of the plant protection product 1.4.4.2 Information on the active substances 1.4.4.3 Information on safeners, synergists and co-formulants	1.4.5 Composition of the preparation
1.4.5 Type and code of the plant protection product	1.4.3 Type of the preparation and code
1.4.6 Function	1.4.4 Function
1.4.7 Field of use envisaged	1.5.1 Field of use
1.4.8 Effects on harmful organisms	1.5.2 Effects on harmful organisms
1.5 Detailed uses of the plant protection product (to be included for each preparation for which documentation was submitted)	1.5 Uses of the plant protection product (Dossier Documents C, D and E) (to be included for each preparation for which documentation was submitted)
1.5.1 Details of representative uses	1.5.3 Summary of intended uses
1.5.2 Further information on representative uses	
1.5.3 Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses	
1.5.4 Overview on authorisations in EU Member States	
	1.5.4 Information on registrations in OECD countries

Table 5 Comparison of required information in the template to be used for assessment reports regarding Level 2 of Volume 1, as specified in SANCO/12592/2012 and the OECD Monograph Guidance

SANCO/12592/2012 –rev. 0 (2012.11)	OECD Monograph Guidance - Appendix 4
2 Summary of active substance hazard and of product risk assessment	2. Reasoned statement of the overall conclusions drawn by the regulatory authority
2.1 Identity	2.1.1 Identity
2.1.1 Summary of identity	
2.2 Physical and chemical properties	2.1.2 Physical and chemical properties
2.2.1 Summary of physical and chemical properties of the active substance	
2.2.2 Summary of physical and chemical properties of the plant protection product	
2.3 Data on application and efficacy	2.1.3 Details of uses and further information
	2.7 Efficacy
2.3.1 Summary of effectiveness	2.7.1 Effectiveness against target organisms, or with respect to the effect achieved
2.3.2 Summary of information on the development of resistance	2.7.2 Possible occurrence of the development of resistance
2.3.3 Summary of adverse effects on treated crops	2.7.3 Effects on the quality of plants or plant products 2.7.5 Effects on the yield of treated plants or plant products 2.7.6 Phytotoxicity to target plants or target plant products 2.7.7 Impact on succeeding crops, adjacent crops and on treated plants or plant products used for propagation
2.3.4 Summary of observations on other undesirable or unintended side-effects	2.7.4 Effects on transformation processes 2.7.7 Impact on succeeding crops, adjacent crops and on treated plants or plant products used for propagation
2.4 Further information	2.1.3 Details of uses and further information
	2.7.8 Tank mixing recommendations
2.4.1 Summary of methods and precautions concerning handling, storage, transport or fire	
2.4.2 Summary of procedures for destruction or decontamination	
2.4.3 Summary of emergency measures in case of an accident	
2.5 Methods of analysis	2.2 Methods of analysis
2.5.1 Methods used for the generation of pre-authorisation data	
2.5.2 Methods for post control and monitoring purposes	
	2.2.1 Analytical methods for analysis of the active substance as manufactured
	2.2.2 Analytical methods for formulation analysis
	2.2.3 Analytical methods for residue analysis
2.6 Effects on human and animal health	2.3 Impact on human and animal health
2.6.1 Summary of absorption, distribution, metabolism and excretion in mammals	
2.6.2 Summary of acute toxicity	
2.6.3 Summary of short-term toxicity	
2.6.4 Summary of genotoxicity	
2.6.5 Summary of long-term toxicity and carcinogenicity	
2.6.6 Summary of reproductive toxicity	
2.6.7 Summary of neurotoxicity	
2.6.8 Summary of further toxicological studies on the active substance	
2.6.9 Summary of toxicological data on impurities and metabolites	
2.6.10 Summary of medical data and information	
2.6.11 Toxicological end point for assessment of risk following long-term dietary exposure - ADI	2.3.2 Toxicological end point for assessment of risk following long-term dietary exposure - ADI
2.6.12 Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)	2.3.3 Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)
2.6.13 Toxicological end point for assessment of occupational, bystander and residents risks – AOEL	2.3.4 Toxicological end point for assessment of occupational and bystander risks – AOEL / MOE
	2.3.5 Drinking water limit
	2.3.1 Effects having relevance to human and animal health arising from exposure to the active substance or to impurities contained in the active substance or to their transformation products
	2.3.6 Impact on human or animal health arising from exposure to the active substance or to impurities contained in it
2.6.14 Summary of product exposure and risk assessment	
2.7 Residues	2.4 Residues
2.7.1 Summary of storage stability of residues	
2.7.2 Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish	
2.7.3 Definition of the residue	2.4.1 Definition of the residues relevant to MRLs
2.7.4 Summary of residue trials in plants and identification of critical GAP	
2.7.5 Summary of feeding studies in poultry, ruminants, pigs and fish	
2.7.6 Summary of effects of processing	
2.7.7 Summary of residues in rotational crops	
2.7.8 Summary of other studies	
2.7.9 Estimation of the potential and actual exposure through diet and other sources	
	2.4.2 Residues relevant to consumer safety
	2.4.3 Residues relevant to worker safety
2.7.10 Proposed MRLs and compliance with existing MRLs	2.4.4 Proposed MRLs and compliance with existing MRLs
2.7.11 Proposed import tolerances and compliance with existing import tolerances	2.4.5 Proposed import tolerances and compliance with existing import tolerances
	2.4.6 Basis for differences, if any, in conclusions reached having regard to established or proposed CAC MRLs
2.8 Fate and behaviour in the environment	2.5 Fate and behaviour in the environment
2.8.1 Summary of fate and behaviour in soil	2.5.2 Fate and behaviour in soil
2.8.2 Summary of fate and behaviour in water and sediment	2.5.3 Fate and behaviour in water
2.8.3 Summary of fate and behaviour in air	2.5.4 Fate and behaviour in air
2.8.4 Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products	
	2.5.1 Definition of the residues relevant to the environment
2.8.5 Definition of the residues in the environment requiring further assessment	
2.8.6 Summary of exposure calculations and product assessment	
2.9 Effects on non-target species	2.6 Effects on non-target species
2.9.1 Summary of effects on birds and other terrestrial vertebrates	2.6.1 Effects on terrestrial vertebrates
2.9.2 Summary of effects on aquatic organisms	2.6.2 Effects on aquatic species
2.9.3 Summary of effects on arthropods	2.6.3 Effects on bees and other arthropod species
2.9.4 Summary of effects on non-target soil meso- and macrofauna	2.6.4 Effects on earthworms and other soil macro-organisms
	2.6.5 Effects on soil micro-organisms
2.9.5 Summary of effects on soil nitrogen transformation	
2.9.6 Summary of effects on terrestrial non-target higher plants	
2.9.7 Summary of effects on other terrestrial organisms (flora and fauna)	2.6.6 Effects on other non-target organisms (flora and fauna)
2.9.8 Summary of effects on biological methods for sewage treatment	2.6.7 Effects on biological methods of sewage treatment
2.9.9 Summary of product exposure and risk assessment	
2.10 Classification and labelling	2.1.4 Classification and labelling
2.11 Relevance of metabolites in groundwater	
2.11.1 STEP 1: Exclusion of degradation products of no concern	
2.11.2 STEP 2: Quantification of potential groundwater contamination	
2.11.3 STEP 3: Hazard assessment – identification of relevant metabolites	
2.11.3.1 STEP 3, Stage 1: screening for biological activity	
2.11.3.2 STEP 3, Stage 2: screening for genotoxicity	
2.11.3.3 STEP 3, Stage 3: screening for toxicity	
2.11.4 STEP 4: Exposure assessment – threshold of concern approach	
2.11.5 STEP 5: Refined risk assessment	
2.11.6 Overall conclusion	
2.12 Consideration of isomeric composition in the risk assessment	
2.12.1 Identity and physical chemical properties	
2.12.2 Methods of analysis	
2.12.3 Mammalian toxicity	
2.12.4 Operator, Worker, Bystander and Resident exposure	
2.12.5 Residues and Consumer risk assessment	
2.12.6 Environmental fate	
2.12.7 Ecotoxicology	
2.13 Residue definitions	
2.13.1 Definition of residues for exposure/risk assessment	
2.13.2 Definition of residues for monitoring	

preparation, therefore the template for the list of endpoints was not presented.

Levels 3 and 4 of Volume 1 in the OECD Monograph Guidance were integrated in Level 3. **Table 6** shows how Levels 3 and 4 of Volume 1 were integrated in Level 3, along with the accompanying structural changes and the addition/modification of points. The document SANCO/12592/2012 first version dated November 2012, also indicated that the provided template should be used in conjunction with the template provided by the aforementioned document SANCO/11114/2012 'Template to be used for Assessment Reports regarding Level 3 of Volume 1' dated 1 June 2012. Therefore, Points 3.1.1 to 3.1.9 of Level 3 corresponded to the point numbers and headings presented in the document SANCO/11114/2012 dated 1 June 2012.

The structure of Volume 2-Annex A was also changed, as shown in **Table 7**. At the time of the preparation of the first version of the document SANCO/12592/2012 dated November 2012, the aforementioned guidance document on preparing reference list, SANCO/12580/2012 was in preparation. Therefore, a template for the reference list of submitted study reports and other documents was not provided, but it was indicated that the list should be prepared in accordance with the guidance in preparation.

For RAR, the reference lists for each section should include also those studies that were submitted to support the approval or subsequent renewals of approval.

The Guidelines for the evaluation of dossiers 1654/VI/94 Rev. 7 and the OECD Monograph Guidance Volume 3-Annex B included information on both AS and PPP together. As shown in **Table 8,** with the changes in the structure of the Sections in Volume 3-Annex B, Volume 3-Annex B was divided into Volume 3-Annex B (AS) and Volume 3-Annex B (PPP).

For RAR, the reference lists at the end of each section (sorted by data requirement) were to include the newly submitted data relied upon as well as the original submitted tests and studies that are still considered valid and therefore used to support the application for renewal. However, the newly submitted studies and the original submitted studies should be clearly identified in the reference lists as well as in the individual study sections. This was done by consistent use of a statement concerning previous evaluation for each study. However, the template for the reference list was not provided, and the location in the reference list where the statement for identification to be included was not clearly indicated. The EU Guidelines for the evaluation of dossiers Rev. 7, and the OECD Monograph Guidance prepared based on the EU guidelines were not designed with consideration for renewal of approval. Indications to identify the studies which had been previously submitted and evaluated were necessary for the evaluation of the renewal of approval.

As shown in **Table 9**, the first version of the document SANCO/12592/2012 dated November 2012 harmonised the numbering and titles of subsections between Level 2 of Volume 1, Volume 2-Annex A, Volume 3-Annex B(AS), and Volume 3-Annex B(PPP). The general guidance on content of Volume 1 stated that all section-wise summaries of study evaluations were presented exclusively in Level 2 of Volume 1. For this purpose, section titles and their order in the section-wise summaries of study evaluations in Level 2 of Volume 1, the section-wise lists in Volume 2-Annex A, and the section-wise evaluations of study reports in Volume 3-Annex B(AS) and Volume 3-Annex B(PPP) were needed to be harmonised.

The structure of Volume 4-Annex C was also changed, as shown in **Table 10**.

Regarding Assessment Reports for ASs covered by the aforementioned AIR2, the guidance document SANCO/10387/2010 Rev. 8 dated 28 October 2010, stated that the RMS might choose to prepare a complete new Assessment Report or prepare addenda to the existing Assessment Report. However, the document SANCO/10180/2013 'Guidance Document on Rules for Revision of Assessment Reports' Rev. 1[44] dated March 2013, the revision of Assessment Report moved away from addenda to a consolidated Assessment Report. This guidance should be used for assessment reports submitted to the European Commission as from 1 May 2013. Consequently, a consolidated Assessment Report should be prepared for a part of the ASs covered by AIR2 also.

Concerning the dossiers submitted as from 1 January 2014, the dossier guidance document that should be used was changed from OECD guidance to EU guidance, which meant that dossiers prepared in accordance with the OECD format could no longer be submitted without necessary revisions for approval or renewal of approval in the EU. Additionally, assessment reports prepared for dossiers submitted as from 1 January 2014, significant structural changes from the OECD format were introduced.

Table 6 Comparison of required information in the template to be used for assessment reports regarding Levels 3 and 4 of Volume 1, as specified in SANCO/12592/2012 and the OECD Monograph Guidance

SANCO/12592/2012 –rev. 0 (2012.11)	OECD Monograph Guidance - Appendix 4
3 Proposed decision with respect to the application	3 Proposed decision with respect to the application
3.1 Background to the proposed decision	3.1 Background to the proposed decision
3.1.1 Proposal on acceptability against the approval criteria – Article 4 and Annex II of Regulation (EC) No 1107/2009	
3.1.2 Proposal - Candidate for substitution	
3.1.3 Proposal – Low risk active substance	
3.1.4 List of studies to be generated, still ongoing or available but not evaluated	4 Further information to permit a decision to be made, or to support a review of the conditions and restrictions associated with any approval or registration
3.1.4.1 Identity of the active substance or formulation	4.1 Identity of the active substance or formulation
3.1.4.2 Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation	4.2 Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation
3.1.4.3 Data on uses and efficacy	4.3 Data on application and further information
	4.10 Efficacy
3.1.4.4 Data on handling, storage, transport, packaging and labelling	
	4.4 Classification, packaging and labelling
3.1.4.5 Methods of analysis	4.5 Methods of analysis
3.1.4.6 Toxicology and metabolism	4.6 Toxicology and metabolism
3.1.4.7 Residue data	4.7 Residue data
3.1.4.8 Environmental fate and behaviour	4.8 Environmental fate and behaviour
3.1.4.9 Ecotoxicology	4.9 Ecotoxicology
3.1.5 Issues that could not be finalised	
3.1.6 Critical areas of concern	
3.1.7 Overview table of the concerns identified for each representative use considered	
3.1.8 Area(s) where expert consultation is considered necessary	
3.1.9 Critical issues on which the Co-RMS did not agree with the assessment by the RMS	
3.2 Proposed decision	3.2 Proposed decision
3.3 Rational for the conditions and restrictions to be associated with any approval or authorisation(s), as appropriate	3.3 Rational for the postponement of the decision, or for the conditions and restrictions to be associated with any approval or registration, as appropriate
3.3.1 Particular conditions proposed to be take into account to manage the risks identified	
(Level 4 does not exist)	

Table 7 Comparison of required information in the template to be used for assessment reports regarding Volume 2 (Annex A), as specified in SANCO/12592/2012 and the OECD Monograph Guidance

SANCO/12592/2012 –rev. 0 (2012.11)	OECD Monograph Guidance - Appendix 4
A List of the tests, studies and information submitted	A List of the tests and studies submitted and of information available
A.1 Identity	A.1 Identity
A.2 Physical and chemical properties	A.2 Physical and chemical properties
A.3 Data on application and efficacy	A.10 Efficacy
A.4 Further information	A.3 Further information
- (No section allocated for Classification, packaging and labelling)	A.4 Classification, packaging and labelling
A.5 Methods of analysis	A.5 Methods of analysis
A.6 Toxicology and metabolism data	A.6 Toxicology and metabolism
A.7 Residue data	A.7 Residue data
A.8 Environmental fate and behaviour	A.8 Environmental fate and behaviour
A.9 Ecotoxicology data	A.9 Ecotoxicology

Table 8 Comparison of required information in the template to be used for assessment reports regarding Volume 3 (Annex B), as specified in SANCO/12592/2012 and the OECD Monograph Guidance

SANCO/12592/2012 –rev. 0 (2012.11)		OECD Monograph Guidance - Appendix 4
Volume 3 Annex B (AS)	Volume 3 Annex B (PPP)	Volume 3 Annex B
B.1 Identity	B.1 Identity	B.1 Identity
B.2 Physical and chemical properties of the active substance	B.2 Physical and chemical properties	B.2 Physical and chemical properties
- (No section allocated)	B.3 Data on application and efficacy	B.10 Efficacy
B.3 Data on application		B.3 Data on application and further information
B.4 Further information	B.4 Further information	
B.5 Methods of analysis	B.5 Methods of analysis	B.5 Methods of analysis
B.6 Toxicology and metabolism data	B.6 Toxicology and metabolism data and assessment of risks for humans	B.6 Toxicology and metabolism
B.7 Residue data	B.7 Residue data	B.7 Residue data
B.8 Environmental fate and behaviour	B.8 Environmental fate and behaviour and environmental exposure assessment	B.8 Environmental fate and behaviour
B.9 Ecotoxicology data	B.9 Ecotoxicology data and assessment of risks for non-target species	B.9 Ecotoxicology data and assessment of risks for non-target species
		B.4 Proposals for classification and labelling

Table 9 Titles of subsections in the template to be used for assessment reports regarding Volumes 1-3, as specified in SANCO/12592/2012

Volume 1 Level 2	Volume 2 Annex A	Volume 3 Annex B (AS)	Volume 3 Annex B (PPP)
2.1 Identity	A.1 Identity	B.1 Identity	B.1 Identity
2.2 Physical and chemical properties	A.2 Physical and chemical properties	B.2 Physical and chemical properties of the active substance	B.2 Physical and chemical properties
2.3 Data on application and efficacy	A.3 Data on application and efficacy	B.3 Data on application	B.3 Data on application and efficacy
2.4 Further information	A.4 Further information	B.4 Further information	B.4 Further information
2.5 Methods of analysis	A.5 Methods of analysis	B.5 Methods of analysis	B.5 Methods of analysis
2.6 Effects on human and animal health	A.6 Toxicology and metabolism data	B.6 Toxicology and metabolism data	B.6 Toxicology and metabolism data and assessment of risks for humans
2.7 Residues	A.7 Residue data	B.7 Residue data	B.7 Residue data
2.8 Fate and behaviour in the environment	A.8 Environmental fate and behaviour	B.8 Environmental fate and behaviour	B.8 Environmental fate and behaviour and environmental exposure assessment
2.9 Effects on non-target species	A.9 Ecotoxicology data	B.9 Ecotoxicology data	B.9 Ecotoxicology data and assessment of risks for non-target species
2.10 Classification and labelling			
2.11 Relevance of metabolites in groundwater			
2.12 Consideration of isomeric composition in the risk assessment			
2.13 Residue definitions			

Table 10 Comparison of required information in the template to be used for assessment reports regarding Volume 4 (Annex C), as specified in SANCO/12592/2012 and the OECD Monograph Guidance

SANCO/12592/2012 –rev. 0 (2012.11)	OECD Monograph Guidance - Appendix 4
C Confidential information and, where relevant, details of any task force formed for the purposes of generating tests and studies submitted	C Confidential information and, where relevant, details of any task force formed for the purposes of generating tests and studies submitted
C.1 Confidential information	C.1 Confidential information
C.1.1 Detailed information on the manufacturing process or processes for the active substance	C.1.1 Detailed information on the manufacturing process or processes for the active substance
C.1.2 Detailed specification of the active substance	C.1.2 Detailed specification of the active substance
C.1.3 Detailed specification of the preparations	C.1.3 Detailed specification of the preparations
C.1.4 Information on the batches used for the mammalian toxicity and ecotoxicity tests	
C.1.5 Other confidential information	C.1.4 Other confidential information
C.2 Summary of information relating to any task forces that submitted tests and study reports	C.2 Summary of information relating to any task forces that submitted tests and study reports
C.2.1 Membership of each task force and contact point	C.2.1 Membership of each task force and contact point (Dossier Document B)
C.2.2 Contact point for each member of the task force	C.2.2 Contact point for each member of the task force
C.2.3 Reasonable steps undertaken to form task force	
	C.2.3 List of test and study reports submitted and information relative to the ownership of and rights of access to the test and study reports
C.3 Summary of information relating to avoidance of duplicative testing and sharing of tests and studies involving vertebrate animals	
C.3.1 Detailed information on the avoidance of duplicative testing	
C.3.2 Detailed information on sharing tests and studies involving vertebrate animals	

As described in Part 1, the document titled 'A Vision for the Future - A Global Approach to the Regulation of Agricultural Pesticides'[45] stated that by the end of 2014, through the co-operation of OECD member countries the regulatory system for agricultural pesticides would have been harmonised to the extent that 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 the preparation of data submissions (dossiers) would be co-ordinated globally by industry, to the extent possible, such that opportunities would be maximised for work-sharing between the regulatory authorities of OECD member countries. However, ironically, changes to the format of dossiers and assessment reports in the EU were not reflected in the OECD format. Subsequently, as from 1 January 2014, dossiers submitted in the EU were prepared in a format somewhat different from the OECD format, and assessment reports were to be prepared in a similar way in a format somewhat different from the OECD format.

Revision of the Formats of Assessment Report to align the Assessment Report for Approval/Renewal of Approval of an AS with the report for CLH Assessment

The formats of dossiers and assessment reports in the EU were revised as needed.

The document SANCO/12592/2012 'Template to be used for Assessment Reports' was revised so as to include all the information required for a CLH proposal in the template for Volume 1 of the assessment report. The title of the document was changed to 'Combined Template to be used for Assessment Reports according to Regulation (EC) No 1107/2009 and Proposals for Harmonised Classification and Labelling according to Regulation (EC) No 1272/2008', because the updated template combined the assessment report under the PPP Regulation 1107/2009 and the CLH report under the Classification, Labelling and Packaging (CLP) Regulation 1272/2008[46]. This updated template was issued as the document SANCO/12592/2012 Rev. 1.2[47] dated 6 October 2017. In the first version of the document SANCO/12592/2012 dated November 2012, a template was presented in the form of a table of contents within the body text of the document. In the document SANCO/12592/2012 Rev. 1.2, the template was provided as an appendix. MS Word templates containing a cover page and version history page, which were similar to the dossier document templates provided in the dossier preparation guidance document SANCO/10181/2013, were provided for Volume 1, Volume 2-Annex A, each section of Volume 3-Annex B(AS), each section of Volume 3-Annex B(PPP), Volume 4-Annex C, and the list of endpoint. In the document SANCO/12592/2012 dated November 2012, general guidance on content and instruction of what information should be provided were indicated in the template in italics and highlighted in grey. However, in the document SANCO/12592/2012 Rev. 1.2, such instruction was indicated in red letters. Changes related to the alignment with the CLH report were mainly incorporated into Volume 1.

In Point 2.2.1 'Summary of physical and chemical properties of the active substance' in Level 2 of Volume 1, an equivalent table to that included in the CLH report template was incorporated. In the newly added Point 2.2.1.1 'Evaluation of physical hazards' subpoint numbers were allocated to the physical and chemical properties concerning physical hazards and tables that were included in the equivalent section of the CLH report template were incorporated under such subpoints. In Point 2.6 'Effects on human and animal health' explanations related to classification and labelling were provided. To most of the existing points, subpoint numbers were allocated and tables that were included in the equivalent section of the CLH report template were incorporated, as well as other additional tables. Some subsections were also reconstructed. In areas not related to the CLH proposal, where only instruction, such as information should be provided in a table or table should be inserted, was indicated, the tables in which information was to be included were incorporated into the template. In Point 2.8 'Fate and behaviour in the environment' and Point 2.9 'Effects on non-target species', subpoint numbers were allocated and tables that were included in the equivalent section of the CLH report template were also included for parts related to the CLH proposal. Concerning Point 2.10, the title was changed to reflect the CLH proposal and significant changes, such as the allocation of subpoints and the inclusion of tables, to incorporate equivalent sections and tables of the CLH report template.

Level 3 of Volume 1, in the document SANCO/12592/2012 dated November 2012, only provided section numbers and titles. It was stated that the template should be used in conjunction with the document SANCO/11114/2012 'Template to be used for Assessment Reports regarding Level 3 of Volume 1' dated 1 June 2012. The criteria for the approval of low-risk ASs were amended by Regulation 2017/1432[48] amending the PPP Regulation 1107/2009 as regards the criteria for the approval of low-risk ASs, which was published in the OJ on 8 August 2017. These amended criteria applied as of 28 August 2017 (Article 2 and Annex of Regulation 2017/1432). In the document SANCO/12592/2012 Rev. 1.2, the template of SANCO/11114/2012 was partially revised to reflect the changes in the criteria for the approval of low-risk ASs, and the revised template was incorporated under the corresponding section. The Appendices under which 'Guidance documents used in this assessment' and 'Reference List' were indicated were changed to Point 3.4 'Appendices' and Point 3.5 'Reference List'.

In Volume 2-Annex A, while only section numbers and titles were shown in the document SANCO/12592/2012 dated November 2012, tables of lists were incorporated under each section in the document SANCO/12592/2012 Rev. 1.2. The incorporated tables of lists were slightly different from those indicated in the guidance document for preparing reference list at that time, SANCO/12580/2012 Rev. 3.1 dated 17 May 2013. A column titled 'Previous evaluation' was added as the rightmost column.

As for Volume 3-Annex B(AS) and Volume 3-Annex B(PPP), while only section numbers and

titles were shown in the initial version of the document SANCO/12592/2012 dated November 2012, the same tables of lists incorporated in Volume 2-Annex A were added under the last point 'References relied on' in each section, in the document SANCO/12592/2012 Rev. 1.2.

Regarding Volume 4-Annex C, some structural changes have been made. Point C.4 'References relied on' has been added at the end, and the same table of list included in Volume 2-Annex A has been incorporated.

Regarding 'List of End Points', the template provided was also a stand-alone document similar to the template for Document N2 in the dossier. The document SANCO/12592/2012 Rev. 1.2 should be used for ASs covered by the Renewal Procedure Regulation 844/2012. It should be used for ASs for which an application for approval had been submitted as from 6 October 2017.

Revision of the format of dossier and assessment report associated with the guidance for the identification of endocrine disruptors and the EFSA administrative guidance on submission of dossiers and assessment reports

The scientific criteria for the determination of endocrine disrupting properties were set out in the PPP Regulation 1107/2009 by the Amendment Regulation 2018/605[49], which was published in the OJ on 20 April 2018, and applied as of 10 November 2018 (Article 2 and Annex of Regulation 2018/605).

The 'Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009'[50], prepared by the EFSA/ECHA and applied as of 10 November 2018, the same date as the application of the Amendment Regulation 2018/605, includes an Excel template for reporting the available information relevant for ED assessment as Appendix E. For dossiers submitted as from 10 November 2018, all the parameters which are useful for the ED assessment, identified in each relevant and reliable study, should be reported in the template provided as Appendix E, to be provided by the applicant with the dossier.

Additionally, the guidance for the identification of ED strongly recommended to use the OECD harmonised templates (OHTs) when reporting the studies in the summary dossier. The OHTs are templates incorporated into the International Uniform Chemical Information Database (IUCLID), which is described later.

In 2019, the 'Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances' first version adopted on 27 March 2019, was published by the EFSA. Prior to the publication of this guidance, updated versions of the following documents were released: Combined Template to be used for Assessment Reports and CLH report (SANCO/12592/2012), Guidance Document on preparing Dossiers (SANCO/10181/2013), Guidance Document on preparing reference list (SANCO/12580/2012), and Guidance Document on the renewal of approval in compliance with Regulation 844/2012 (SANCO/2012/11251). These updates introduced further changes to the format of dossiers and assessment reports.

Under the Renewal Procedure Regulation 1141/2010, supplementary dossiers shall be added to the original dossiers (Article 9(1) of Regulation 1141/2010). However, under the provisions for the submission of supplementary dossiers in Renewal Procedure Regulation 844/2012 (Article 6(1) of Regulation 844/2012), 'added to the original dossiers' was no longer stated. However, supplementary dossiers of AIR3 ASs, to which Renewal Procedure Regulation 844/2012 applied, submitted earlier did not include summaries of the studies submitted in the original dossiers or, if included, the summaries contained very brief information. According to the aforementioned document SANCO/10180/2013 Rev. 1 dated March 2013, when preparing assessment reports for the renewal of approval, the preparation of addenda to existing assessment reports could not be chosen anymore; instead, consolidated assessment reports were always prepared. Similarly, for dossiers, the preparation of supplementary dossiers to the original dossier has been replaced by the preparation of consolidated dossiers.

The draft summary of the outcome of the Workshop on improvements in the peer review process was included in the annex to the minutes of the 20th meeting of the Pesticide Steering Network (PSN)[51], held on 14-15 June 2016. In the workshop, the requirements regarding the review of old studies were discussed in Group C of the break-out discussions, and update of the guidance document on the renewal of approval was identified as possible improvement. Key points raised included the submission of a stand-alone

summary dossier from the applicant and the preparation of a stand-alone RAR, highlighting any changes from the previous evaluation, including changes in the List of End Points, and updating the summary to current levels of details considering OECD templates and IUCLID Robust Study Summary (RSS), which were equivalent.

The PSN meeting minutes of the 21st meeting[52] held on 14-15 February 2017 included a follow-up on the workshop on improvements in the peer review process. As actions related to the preparation of dossiers, it was noted that for the renewals of approval, a stand-alone summary dossier should be provided. The AIR3 Guidance Document SANCO/2012/11251 'Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 (the Renewal Regulation)' Rev. 4[53] dated 12 December 2014, was unclear about the handling of old data in the context of the renewals of approval. It was agreed that sufficient details should be provided regarding old studies in order to be able to judge if their assessment was still aligned with current scientific and technical knowledge. Additionally, it was noted that, in the longer term, applicants would need to provide robust OECD study summaries, which would entail all the details needed for presentation of study summaries in a harmonised way. At the same time, it was highlighted that the DAR/RAR should primarily be a systematic summary of the results and conclusions derived from the study reports, with the RMS' critical appraisal of the studies, rather than a collection or copy-paste of robust study summaries provided by applicants. It was generally agreed that, with the publication of the summary dossiers, the DAR/RAR should focus on the significant findings relevant for EU decision-making, representing the views of the RMS.

The AIR3 Guidance Document SANCO/2012/11251 Rev. 5[54] dated 22 March 2019, which was updated to include necessary changes to ensure consistency with the EFSA 'Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances', initial version adopted on 27 March 2019, clarified that the old studies that were part of the original dossier did not need to be resubmitted in the renewal dossier, however, the assessment of old studies against current guidelines and data requirements should be submitted through updated study summaries as part of the supplementary summary dossier. This guidance document Rev.5 dated 22 March 2019, was applied to dossiers for which applications for renewal of approval were submitted after 1 April 2019. Although the formal application was for dossiers with applications for renewal of approval submitted after 1 April 2019, according to the PSN meeting minutes of the 23rd meeting[55] held on 12-13 June 2018, the EFSA indicated that the old studies, that were part of the original dossier, did not need to be resubmitted in the renewal dossier, however, the assessment of old studies against current guidelines and requirements should be submitted through updated summary studies as part of the supplementary summary dossier. The industry association, the European Crop Protection Association (ECPA, now CropLife Europe: CLE), confirmed that an update of the summary studies of the old studies could indeed be provided. Therefore, dossiers for which applications for renewal of approval were submitted before 1 April 2019 also may include updated study summaries of the old studies in supplementary dossiers.

In this way, the preparation of dossiers for renewal of approval of ASs covered by AIR3 and the subsequent groups to be submitted after 1 April 2019, required rewriting the study summaries included in previous dossiers to comply with the requirements of the current guidance documents, which resulted in an increased amount of time and effort to prepare dossiers for renewal of approval.

The Guidance Document on preparing reference list SANCO/12580/2012 Rev. 4[56] dated 22 March 2019, added a new column titled 'Previously used' as the rightmost column to the reference list format presented in the Rev. 3.1 dated 17 May 2013. This reference list format is similar to the one where the column 'Previous evaluation' was added as the rightmost column of the reference lists included in Volume 2-Annex A and each section of Volume 3-Annex B (AS) and Volume 3-Annex B (PPP) of the aforementioned combined template to be used for the assessment reports and CLH reports SANCO/12592/2012 Rev. 1.2. However, there were slight differences in the column titles between these list formats. The guidance document SANCO/12580/2012 Rev. 4 dated 22 March 2019, was applied to dossiers submitted on or after 1 October 2019.

In the combined template to be used for Assessment Reports and CLH reports SANCO/12592/2012 Rev. 2[57] dated 22 March 2019, the reference lists to be included in Volume 2-Annex A and each section of Volume 3-Annex B (AS) and Volume 3-Annex B (PPP)

were formatted according to the format indicated in the SANCO/12580/2012 Rev. 4 dated 22 March 2019. A statement presented in red letters was added to the version history pages of the MS Word templates for Volume 1, Volume 2-Annex A, and each section of Volume 3-Annex B (AS) and Volume 3-Annex B (PPP) to explain how information was presented. Furthermore, revisions were made to the sections related to endocrine disruptor assessments in Volume 1. Point 2.10 'Endocrine disrupting properties' was added to Level 2 of Volume 1 and under the point it was indicated that the completed table, provided as Appendix E to the guidance document for the identification of endocrine disruptors, submitted together with the dossier should be checked and where needed corrected by the RMS, and should be submitted as an Annex to the Assessment Report Volume 1.

The Combined Template to be used for Assessment Reports and CLH reports Rev. 2 dated 22 March 2019, was applicable for dossiers submitted from 1 April 2019. However, for Assessment Reports submitted by Member States from 1 April 2019, it was required that, as a minimum, the revised Volume 1 should be used, and the statement should be added to each section on the page next to the cover page. This was likely due to the need to use the revised Volume 1, which included revisions to sections related to the assessment of endocrine-disrupting properties, because of the application of the scientific criteria for the determination of endocrine-disrupting properties from 10 November 2018.

In the Guidance Document on preparing Dossiers SANCO/10181/2013 Rev. 4[58] dated 22 March 2019, the attached template as Document N3 was updated. Regarding the reference list in Document L, the description in the guidance remains unchanged as 'Reference list (should reflect guidance in SANCO/12580/2012)'. However, the Guidance Document on preparing reference list SANCO/12580/2012 was updated to its Rev. 4 dated 22 March 2019, so the format of the reference list to be included in the dossier had been updated.

There were updates that were not clearly stated in the templates provided in the Combined Template to be used for Assessment Reports and CLH reports Rev. 2, and the Guidance Document on preparing Dossiers SANCO/10181/2013 Rev. 4. These updates were due to the EFSA administrative guidance, first version, adopted on 27 March 2019, which provided additional instructions, guidance, and templates on how data should be presented in the summary dossier and assessment report. The templates provided in the EFSA administrative guidance are shown in **Table 11** below.

In accordance with the document SANTE-10914-2019[59] dated 22 March 2019, EFSA administrative guidance applied for dossiers submitted on or after 1 October 2019. However, the Combined Template to be used for Assessment Reports and CLH reports Rev. 2 dated 22 March 2019, stated that for Assessment Reports submitted from 1 April 2019 as a minimum the revised Volume 1 should be used. Among the templates in Appendices D-J, Appendices D-H are to be used in Volume 3-Annex B of the Assessment Reports, while Appendix J is to be used in Volume 4-Annex C. Therefore, only Appendix I, template for presentation of assessment of endocrine disrupting properties, was to be used in Volume 1 of the Assessment Reports. However, in the Rev. 2 dated 22 March 2019, Point 2.10 'Endocrine disrupting properties' in Level 2 of Volume 1 did not yet incorporate the Appendix I assessment of endocrine disrupting properties, nor indicate its existence.

The EFSA administrative guidance clearly stated that the study summaries of old studies should be included

Table 11 Templates provided as appendices to the EFSA Administrative Guidance on submission of dossiers and assessment reports (original version, 2019)

Corresponding Appendix	Purpose of the template
Appendix D	Template for the overview table for analytical methods used for risk assessment
Appendix E	Template for presenting individual study summaries
Appendix F	Template for presentation of results in tabular format for mammalian toxicology studies
Appendix G	Template for presenting metabolism residues trials
Appendix H	Template for presentation of kinetic fitting
Appendix I	Template for presentation of assessment of endocrine disrupting properties
Appendix J	Template for presentation of assessment for the equivalence of batches

in the dossier, and should be updated in order to have a similar level of information as in the summaries of the new studies submitted for the renewal procedure. It also stated that an assessment of old studies against current guidelines and data requirements through updated summaries, as part of the supplementary summary dossier, should be provided. For reasons of efficiency, certain elements of the assessment report may be taken from the applicant's dossier when the RMS agrees with those parts. Furthermore, the views and conclusions of the RMS should be clearly and transparently reported to differentiate the view of the applicant from that of their own.

The information on the study required in the template for presenting individual study summaries provided as Appendix E is shown in **Table 12** below. The required information was not only common information concerning test or study report, test method and Good Laboratory Practice (GLP), such as Report author, Report year, Report title, Report No., Document No., test guideline, deviations from test guideline, compliance with GLP, etc. indicated in the OECD Document M (Tier II), but also the previous evaluations and Acceptability/Reliability of the studies. It was noted that the sections on Materials and methods and Results should be written according to the OECD format, while concerning Assessment and conclusion two boxes, one was by applicant and the other was by RMS, were provided. The Appendix E template should be used in both the summary dossier and the assessment report. However, in the dossier, the box 'Assessment and conclusions by RMS' should not be used.

The EFSA administrative guidance provided increased amount of guidance regarding the descriptions in dossiers and assessment reports, as well as increased alignment of templates and content

Table 12 Comparison of required information in Tier II and reference list in the EFSA Administrative Guidance (2019) and the OECD Dossier Guidance

EFSA Administrative guidance (2019) Appendix E	**Reference list (2019)** *:not included OECD	**OECD Dossier Guidance Tier II**	**OECD Dossier Guidance: Document L - Tier I quality check** (**:All the important information previously contained in the Tier I quality check is included either in the Tier II or the reference list)
1.Information on the study			
Data point	Data point	Report (Data point)	1.1 the data point addressed**
			1.2 a description of the type of test or study
			2 reference point (location) of the report in the dossier
Report author	Author(s)	Report (Report author)	3.1 the names of the authors**
Report year	Year	Report (Report year)	(year is indicated in 3.1 the names of the authors)
Report title	Title	Report (Report title)	3.2 the title of the test or study report**
	Owner	Report (Report owner)	3.3 the owner of the report**
Report No	Report No	Report (Report No)	3.5 the report number**
			3.6 the date of the report (year is indicated in 3.1 the names of the authors)
	Source (where different from company)	Testing Laboratory and dates (Testing Laboratory)	4.1 the name and address of the testing facility**
Document No	Document No.		4.2 the laboratory report/project number
		Testing Laboratory and dates (Dates)	5 the dates of commencement and completion of experimental work
	Published or not		3.4 an indication as to whether it is a published or unpublished report
	Vertebrate study*		
	Data protection claimed		
	Justification if data protection is claimed*		
Guidelines followed in study		Guideline	7.1 the identity of the test guideline used** 7.2 where test guidelines provide choice as to the method to be used, a reasoned justification for the method used
Deviations from current test guideline		Guideline (Deviation)	7.3 where deviations from the test guidelines specified are employed, a description of and reasoned justification for the deviations**
Previous evaluation	Previously used*		
GLP/Officially recognised testing facilities	GLP/ Officially recognised testing facilities	GLP (GLP/Officially recognised testing facilities)	8 confirmation that the principles of GLP or GEP**, as appropriate, were complied with – in the event of non-compliance a description of the degree of non-compliance and a justification for non-compliance.
		Executive Summary	
Acceptability/Reliability			
2. Full summary of the study according to OECD format			
Materials and methods		I. Materials and methods	6.1 the identity of the test substance or material (ISO common name, batch number and degree of purity)** 6.2 an explicit reference to the relevant specification of composition of the test substance or material
Results		II. Results and discussion	
3. Assessment and conclusion			
Assessment and conclusion by applicant		III. Conclusions	
Assessment and conclusion by RMS			

between dossiers and assessment reports. These changes in the EU concerning dossiers and assessment reports have not yet been reflected in the OECD dossier guidance for now. However, these improvements have contributed to the transition to preparing dossiers using the IUCLID described later.

With the submission of dossiers for the application for approval/renewal of approval using the IUCLID, the Guidance Document on preparing Dossiers SANCO/10181/2013 was updated to its Rev. 6[60] dated 24 March 2021, and the Guidance Document on preparing Dossiers for micro-organisms SANCO/12545/2014 was updated to its Rev. 3[61] dated March 2021. These updates to the guidance documents indicate that the previous guidance documents on preparing dossiers were not applicable for dossiers prepared using the IUCLID.

Applications concerning basic substances also had to be submitted using the IUCLID. However, prior to the submission using the IUCLID, the template for basic substances indicated in Annex I of the document SANCO/10363/2012 Rev. 9 dated 21 March 2014, was updated and presented in Annex II of the Rev. 10[62] dated 25 January 2021.

The Guidance Document on preparing reference list SANCO/12580/2012 Rev. 4 dated 22 March 2019 remains in use, as reference lists are used not only for the dossiers for approval/renewal of approval of AS.

The Combined Template to be used for Assessment Reports and CLH reports SANCO/12592/2012 Rev. 2 dated 22 March 2019, remained in use for some time even after the submission of dossiers using the IUCLID software. It was updated by Rev. 3[63] dated 22 March 2024, but only the template for Volume 1 was updated. This update was primarily due to the need to update sections related to classification and labelling, as new hazard classes were introduced by Regulation 2023/707[64] amending the CLP Regulation 1272/2008, published in the OJ on 31 March 2023. Because of the inclusion of new hazard classes, 'Endocrine disrupting properties' was moved from Point 2.10 to Point 2.12 in Level 2 of Volume 1. Under Point 2.12 template for presentation of assessment of endocrine disrupting properties, which was presented in Appendix I of the EFSA administrative guidance was incorporated.

IUCLID dossier

The Regulation 2019/1381[65] on the transparency and sustainability of the EU risk assessment in the food chain (Transparency Regulation), published in the OJ on 6 September 2019, amended certain provisions of the PPP Regulation 1107/2009. As a result of this amendment, an application for the approval of an AS (including an application for an amendment to the conditions of an approval) or the renewal of the approval should be submitted in accordance with standard data formats. (Article 7(1)(a)(3) of Regulation 2019/1381, Articles 7(1) and 15(1) of Regulation 1107/2009). Before the amendment, the Summary Dossier submitted for approval or renewal of approval of an AS, excluding any information in respect of which confidential treatment had been requested, was made available to the public by the EFSA. However, the distinction between the Summary Dossier and the Complete Dossier was removed by the amendment, and the dossier, including any supplementary information supplied by the applicant, is made available to the public, with the exception of any information to which confidential treatment is granted (Article 7(2)(4) of Regulation 2019/1381, Articles 10 and 16 of Regulation 1107/2009). This means that test or study reports and other documents that were not previously included in the Summary Dossier are to be published except for the information granted confidential treatment. The Transparency Regulation 2019/1381 entered into force on 26 September 2019, which was the 20th day following that of its publication in the OJ on 6 September 2019. Except for certain provisions, it applied from 27 March 2021 (Article 11 of Regulation 2019/1381).

The Renewal Procedure Regulation 2020/1740[66], published in the OJ on 23 November 2020, incorporated updates reflecting the Transparency Regulation 2019/1381. The Renewal Procedure Regulation 2020/1740 entered into force on 13 December 2020, which was the 20th day following that of its publication in the OJ on 23 November 2020. It applied from 27 March 2021, the same date as the Transparency Regulation 2019/1381 applied from (Article 18 of Regulation 2020/1740).

The Renewal Procedure Regulation 844/2012 was repealed by the Renewal Procedure Regulation 2020/1740 (Article 17 of Regulation 2020/1740), however the Renewal Procedure Regulation 844/2012 shall continue to apply to the procedure for the renewal of approval of the ASs for which transitional measures are applied (Article 17 of Regulation 2020/1740).

As the Transparency Regulation 2019/1381 specified that applications for renewal of approval shall be submitted in accordance with standard data formats, dossiers for the renewal of approval of ASs, to which the Renewal Procedure Regulation 2020/1740 applies, shall be submitted using the IUCLID software package (Articles 2 and 7 of Regulation 2020/1740). The dossiers submitted for renewal of approval are made public for the submission of written comments (Article 10 of Regulation 2020/1740). Regarding confidential information included in the dossier, the applicant, when requesting certain information to be kept confidential, shall indicate such information using the relevant IUCLID functionality (Article 7(4) of Regulation 2020/1740) and identify the confidential and non-confidential versions of the information submitted (Article 6(7) of Regulation 2020/1740).

Regarding dossiers for approval, the Regulation 2021/428[67] adopting standard data formats for the submission of applications for the approval or the amendment to the conditions of approval of ASs, which was published in the OJ on 11 March 2021, had adopted the standard data formats for the approval of an AS and those for the amendment to the conditions of such an approval, based on the IUCLID software package and it shall apply to dossiers submitted on or after 27 March 2021 (Articles 1 and 2 of Regulation 2021/428).

The provisions concerning the Notification of Studies (NoS), added as Article 32b to the General Food Law (GFL) Regulation 178/2002[68] by the Transparency Regulation 2019/1381 (Article 1(6) of Regulation 2019/1381, Article 32b of Regulation 178/2002), set out the notification to the EFSA and its procedures for studies commissioned or carried out to support an application or notification in relation to which the EFSA is to provide an EFSA Conclusion or a scientific opinion. Under the Renewal Procedure Regulation 2020/1740, information related to the NoS is added as one of the contents which renewal dossier shall include (Article 6(2)(o) of Regulation 2020/1740).

Regarding the application for authorisation of a PPP, the application shall be examined by the zonal Rapporteur Member State (zRMS) in the zone (Articles 35 and 36 of Regulation 1107/2009), and the other Member States concerned in the same zone shall decide on the application at the latest within 120 days of the receipt of the assessment report and the copy of the authorisation of the zRMS (Article 37(4) of Regulation 1107/2009). Therefore, in principle, the process does not involve an examination by the EFSA. Consequently, at this stage, studies conducted solely for the purpose of an application for authorisation are not subject to NoS, and dossiers for application for authorisation are not subject to application dossier using the IUCLID.

However, since MRL applications related to setting a new MRL or modifying an existing MRL are applications for which an EFSA Conclusion or opinion is to be provided, NoS became necessary. Consequently, MRL applications are also submitted via IUCLID. As the requirements relating to applications for MRLs under the MRL Regulation 396/2005[69] (Article 7 of Regulation 396/2005) do not include provisions regarding the format of the application, no Amendment Regulation associated with submission of applications using the IUCLID has been developed for the MRL Regulation.

As dossiers and MRL applications began to be submitted via IUCLID, EFSA administrative guidance was revised to include MRL applications as well. The title was changed to 'Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure', and the revised version[70] adopted on 11 February 2021 was published on 3 March 2021. According to the document SANTE/10182/2021[71] dated 23 February 2021, this 2021 revised version of the administrative guidance applied to all dossiers submitted as of 27 March 2021 and was to be used for the preparation of dossiers intended to be submitted from that date onwards. Regarding assessment reports, it applied to all assessment reports concerning dossiers submitted as of 27 March 2021. The Renewal Procedure Regulation 844/2012 continued to apply to the procedure for the renewal of the approval of the ASs to which transitional measures were to be applied. Therefore, under the Renewal Procedure Regulation 844/2012, supplementary dossiers that did not use IUCLID should be submitted, and the 2021 revised version of the administrative guidance did not apply even if the dossier was submitted after 27 March 2021.

The dossiers for the approval of an AS (including for an amendment to the conditions of an approval) or the renewal of the approval to which the administrative guidance 2021 revised version applies shall be prepared using the IUCLID. Many of the templates presented in Annexes to the first version of the administrative guidance have been incorporated into IUCLID. In the 2021 revised version it is stated that all relevant

templates existed in the Annexes to the first version on how data should be presented as well as further details and instructions on data formats related to the dossier are made available in the IUCLID User Manual. Therefore, many of the templates existed in the Annexes to the first version were not included in the Annexes to the revised version.

The IUCLID User Manuals for AS related applications comprise three types: the Chemical ASs Application Manual, the Microbial ASs Manual, and the Basic Substance Application Manual. Additionally, the MRL Application Manual was prepared. However, most of them were published after 27 March 2021, the date from which the Transparency Regulation 2019/1381 applied.

The first version of the IUCLID application manual for chemical AS application, titled 'IUCLID Active Substance application Manual'[72], was published on 14 July 2021. The first version of the IUCLID application manual for microbial AS application, titled 'IUCLID Microbial Active Substances Manual'[73], was published on 19 May 2021. The first version of the IUCLID application manual for basic substance application, titled 'IUCLID Basic Substance Application Manual'[74], was published on 9 August 2021. The first version of the IUCLID application manual for MRL application, titled 'MRL Applications Manual'[75], was published on 23 March 2021. Regarding the IUCLID application manual for chemical substance AS applications, the second version titled 'IUCLID Active Substance application Manual (IUCLID 6 Version 6.X)'[76], was also published on 14 July 2021. The second version included explanations that were not present in the first version.

The Regulation 2020/2007[77], published in the OJ on 9 December 2020, amended the approved AS list Regulation 540/2011[78], by extension of the approval periods of several ASs. As a result of the amendments, the deadlines for the submission of the dossiers for the renewal ASs, of which applications would be the first IUCLID applications, were extended, and the earliest submission deadline was set for 31 July 2021. The document, titled 'EFSA Pesticide Steering Network sub-group: IUCLID HYPERCARE Programme'[79] dated 30 September 2021, stated that this programme aimed to support Member States and applicants involved in the first submission and evaluation in IUCLID of renewal ASs with an extended legal deadline falling between July and August 2021. The Annex to this document included a list of the selected ASs, the applicants, and the RMSs and Co-RMSs. On 29 October 2020, EFSA contacted all Member States and all applicants for the renewal ASs. A kick-off meeting was held at the end of November 2020, and the IUCLID HYPERCARE Programme would last for 12 months, between December 2020 and December 2021.

The templates existed in the Annexes to the first version of EFSA administrative guidance, adopted on 27 March 2019, were incorporated into IUCLID as shown in **Table 13** below, according to the 'IUCLID Active Substance application Manual (IUCLID 6 VERSION 6.X)' second version published on 14 July 2021. In addition, some of the supporting documentation, which were previously submitted as Documents A-J in dossiers, were not needed to submit because they were incorporated into IUCLID, as shown in **Table 14** below. Furthermore, according to the latest version of the IUCLID Active Substance Application Manual, the seventh version 'IUCLID 6.8 Active Substance Application Manual'[80], published on 20 November 2024, work was ongoing to ensure that all information could be reported in IUCLID documents, and as from April 2025, the pdf documents for Document J would no longer be accepted. The attachment of supporting documentation other than Document J had also reduced, and the 'Crosswalks IUCLID 6 v8 EU PPP Active substance application (product) to KCA&KCP', Rev. 5[81] published on 4 June 2024, indicated that Documents B and Documents D1-3 were incorporated into IUCLID, and only Documents C and Documents G-I could be attached for submission.

In Part 1, we outlined how Biocidal Product (BP) dossiers were structured differently from PPP dossiers, taking into account not only the structure of dossiers to be prepared by applicants for approval of ASs in PPPs but also 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/Product type (PT) of BPs, as described in the 'Guidance Document on How to utilize PPP Dossiers/Monographs and Existing Substances (ESR) Dossiers/Risk Assessments for the Preparation of BP dossiers/CAs' reports'[82] dated 21 November 2003.

ASs to be evaluated under the BP Directive 98/8/EC[83] included not only ASs to be evaluated under the PPP Directive 91/414/EEC but also substances to be assessed under Regulation 793/93[84] on the evaluation

Table 13 Templates provided as appendices to the EFSA Administrative Guidance (original version, 2019) and the corresponding templates used in IUCLID

Appendix to EFSA administrative guidance (2019)	Corresponding template in IUCLID
Appendix D (Template for the overview table for analytical methods used for risk assessment)	Template 4.1 (Template for the overview table for analytical methods for risk assessment)
Appendix E (Template for presenting individual study summaries)	(Dismissed, The Report generator will generate a report shaped on structure of the Appendix E)
Appendix F (Template for presentation of results in tabular format for mammalian toxicology studies)	Template 5.1 (Template for presentation of results in tabular format for mammalian toxicology studies)
Appendix G (Template for presenting metabolism and residue trial)	Template 6.2 (Template for reporting metabolism studies, optional)
	Template 6.3 (Template for reporting trials on magnitude of residues in primary crops and rotational crops)
Appendix H (Template for presentation of kinetic fitting)	Template 7.1 (Template for presentation of kinetic fitting)
Appendix I (Template for presentation of assessment of endocrine disrupting properties)	(Dismissed, A specific document (11.4 - Endocrine Disrupting properties) has been included in IUCLID shaped on the Appendix I)
Appendix J (Template for presentation the assessment for the equivalence of batches)	Template 1.1 (Template for presentation the assessment for the equivalence of batches)

Table 14 Supporting documentation (Documents A-J) to be attached in IUCLID

Supporting documentation		Location in IUCLID
Document A	Purpose	(Dismissed, Information on the application submission are included in the 'Dossier header' document)
Document B	Task force information	Attached to the "Reports and administrative information" field in 13. Summary and evaluation of mixture dataset*1
Document C	Labels and leaflets	Attached to the "Reports and administrative information" field in 13. Summary and evaluation of mixture dataset and 11.2 Other reports of active substance dataset
Document D-1	Supported uses	Attached to the "Reports and administrative information" field in 11.2 Other reports of active substance dataset*2
Document D-2	Registered uses	Attached to the "Reports and administrative information" field in 11.2 Other reports of active substance dataset*2
Document D-3	Supported uses in exporting countries	Attached to the "Reports and administrative information" field in 11.2 Other reports of active substance dataset*2
Document E-1	Existing MRLs	(Dismissed, data to be included in 11.1 Assessment from other authorities of active substance dataset)
Document E-2	MRLs in exporting countries	(Dismissed, data to be included in 11.1 Assessment from other authorities of active substance dataset)
Document F	Statements of intention to submit a dossier	(Dismissed)
Document G	Regulatory position for formulants	Attached to the "Reports and administrative information" field in 13. Summary and evaluation of mixture dataset and 11.2 Other reports of active substance dataset
Document H	Safety data sheets for formulants	Attached to "Other references field" in 13. Summary and evaluation of mixture dataset and 11.2 Other reports of active substance datasest
Document I	Other available toxicological data on formulants	Attached to "Other references field" in 13. Summary and evaluation of mixture dataset and 11.2 Other reports of active substance dataset
Document J	Confidential information	Attached to 1.8 Method of manufacture (synthesis pathway) of the active substance of active substance dataset*3

*1: Information to be included in the 'Dossier header', as specified in, 'Crosswalks IUCLID 6 v8 EU PPP Active substance application (product) to KCA&KCP' version v5 (2024.06.04)
*2: Information to be included in subsection '3.1 Use of the plant protection product (GAP) of mixture data set' and subsection '3.1 Use of the active substance (GAP)', as specified in 'Crosswalks IUCLID 6 v8 EU PPP Active substance application (product) to KCA&KCP' version v5 (2024.06.04)
*3: Work is on-going to ensure that all information can be reported in the IUCLID documents and as from April 2025, the PDF Document J will no longer be accepted.

and control of the risks of existing substances. For existing chemical substances, it was also noted that all studies were summarised in the IUCLID software, and therefore the IUCLID format was also taken into account for BP dossiers. Most of the supporting documentations, referred to as Documents A to J in PPP dossiers, were integrated into Document III - Study Summaries or Document II - Risk Assessment or included as an Appendix in Document I in BP dossiers. By incorporating as much as possible into IUCLID, it can be said that reducing the number of documents attached as Documents A to J was achieved also in PPP dossiers.

As mentioned in the previous chapter, in the Guidance for the identification of ED the use of the OHTs was strongly recommended when reporting the studies in the summary dossier. In the IUCLID, OHTs were used, and formats for data entry were provided for

each requirement. The IUCLID user manual presented the structure of the templates included in the IUCLID for each data requirement, therefore the manual had a considerable number of pages.

The preparation of dossiers for renewal of approval using the IUCLID required re-entering the study summaries, which were included in previous dossier prepared for approval or for renewal of approval, in alignment with the OHT.

The proof of concept pesticides dossier in IUCLID format was performed prior to the IUCLID applications manual and the IUCLID Hypercare Programme. Two reports were prepared and published: the 'Final report: Proof of concept pesticides dossier in IUCLID format'[85], issued on 27 March 2020, and the 'Final report: Proof of concept pesticides dossier for micro-organism in IUCLID format'[86], issued on 24 July 2020. These proof-of-concept studies were also part of a pilot study to test the creation of a PPP AS dossier in IUCLID format. The strengths and weaknesses of IUCLID were listed. The weaknesses identified were as follows; some necessary OHT templates were missing within IUCLID for PPP AS at that time, a template for the Good Agricultural Practices (GAP) table was not available, no template was available for the literature data, and the issues encountered during the preparation of the dossier were the presentation of the studies performed on metabolites and impurities. Recommendations for improvement were also provided in these reports. How the templates provided in the Annexes to the first version of the EFSA administrative guidance could be incorporated into IUCLID was also considered in the reports.

It was reported that even the transfer of study reports available in the original dossier to prepare the dossier for the renewal of approval of a certain chemical substance AS took a significant amount of time, and the overall time spent on the preparation of the dossier in the IUCLID was approximately 840 hours.

It was stated that potential of the IUCLID for the preparation of dossiers was enormous, and examples were provided. The Chemical Safety Report (CSR), which is similar to the DAR for PPP ASs, under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation 1907/2006[87], can be automatically generated from IUCLID and formatting of the CSR takes only approximately four hours. The report generator function was not yet available for biocide dossiers prepared using the IUCLD, but it was stated that the function could be developed and programmed accordingly.

As described in Part 1, the dossier for the application for approval of AS/PT of BP should be submitted using the IUCLID under the BP Regulation 528/2012[88]. Since the IUCLID was also used under the REACH and under the CLP Regulation 1272/2008, OHTs had already been used for reporting the studies for chemical substances subject to the REACH.

Before the IUCLID was used for the approval/renewal of approval of ASs in PPPs, it had already been used under the REACH and other Regulations. Therefore, study reports on the IUCLID exist, and various recommendations have been made.

The 'Study on the role of Robust Study Summaries in hazard assessment'[89] dated 18 January 2022, noted that the study summaries previously used under the PPP Regulations before the use of RSS had issues with quality and lack of standardisation. In the interview RSS authors emphasised that RSS data transfer depended on the endpoint and that it generally needed to be done by an experienced expert or scientist. This is because RSS authors need to understand the study and its parameters. It was suggested that it might be more consistent if the laboratory conducting the study filled out the RSS. Some RSS authors mentioned that it was useful to refer to an RSS of a study completed using the same guidelines as an example when filling in the IUCLID fields. Despite being used for many years under Regulations such as the REACH, several areas for future improvement were pointed out by RSS authors.

The IUCLID application manual presents the structure of the templates included in the IUCLID for each data requirement, therefore the manual has a considerable number of pages. However, it provides few examples of completed forms, particularly those for the study summaries.

The EFSA's procurement, published on 28 June 2022, titled 'IUCLID demonstration dossiers for pesticides'[90], noted that the two dossiers prepared using the IUCLID for the proof of concept previously reported did not cover all currently available submission types.

It was stated on the website announcing this procurement that there was a need for correctly completed/sanitised dossiers to support the development of training materials, for use in system testing and optimisation, and to identify additional

improvements. The contractor was required to produce fourteen dossiers using the materials provided by the EFSA, analyse the problems encountered, and propose improvements. Some of the demonstration dossiers delivered were posted on the website titled 'IUCLID 6.7 test dossiers'[91], published on 4 June 2024, in case they are useful for testing/training purposes.

The report generator function which the IUCLID includes allows for the generation of Document L, the reference list, and Document M, the Tier II summary, of the dossier. Furthermore, it was reported in the minutes of the EFSA PSN-IUCLID Subgroup 11th meeting[92] held on 21 November 2024 that assessment reports could be generated using the Report Generator and work for generation of reports was ongoing. The minutes also noted that the EFSA proposed to rename Document M, which was to be improved, or replaced with new versions that align with the individual volumes of the assessment reports. It can be said that the use of the IUCLID further increased the differences between the dossier format presented in the OECD Dossier Guidance and the EU dossier format.

The minutes of the EFSA PSN-IUCLID Subgroup 11th meeting noted that the EFSA highlighted that structured data in the IUCLID offer an opportunity to enhance the speed of scientific assessments. The current IUCLID data reuse was limited to visualising data in the IUCLID and generating predefined reports from individual dossiers using the IUCLID report generator. The vision for IUCLID data reuse was articulated, with a focus on setting up a data analytics service that would facilitate the identification and use of information in IUCLID dossiers across the whole database, thereby increasing the efficiency of risk assessments.

The Future Use of IUCLID Dossiers

The OECD Dossier Guidance for pesticides, Rev.2 dated May 2005, has not been updated for nearly 20 years. During this time, changes and additions to data requirements for pesticides have occurred in the EU and other OECD member countries. According to the OECD Chemical Safety and Biosafety Progress Report No 39[93] dated December 2019, at the June 2019 Working Group on Pesticides (WGP) meeting, a revised document was developed, by introducing new OECD data point numbers only for ASs based on the additional data requirements provided by member countries. However, the document containing the new OECD data point numbers has not been published as of now. It can be said that the OECD Dossier Guidance has not been able to correspond to the additional data requirements of each member country.

Furthermore, the structure of the templates for reporting the studies in the OECD Dossier Guidance is not presented as detailed or specific as that of the OHTs.

As stated in the previous chapter, in the EU, after the revisions of the format of dossier and the application of the Transparency Regulation 2019/1381, applications related to ASs used in PPPs were to be submitted using the IUCLID. As shown in **Table 15** below, 22 out of the current 38 OECD member countries are EU Member States. In other words, it can be said that in more than half of the OECD member countries, study summaries in accordance with OHTs are being submitted and evaluated.

Due to the large number of data requirements, submissions of applications in the EU tend to be later compared to the non-EU OECD member countries. However, even if a dossier prepared in the OECD format has been submitted to the non-EU OECD member countries, the information contained in that dossier must be transferred to IUCLID for the application in the EU.

At present, use of OHTs when reporting the studies concerning ASs used in PPPs is not required in all the non-EU OECD member countries. However, it is expected that more countries will implement the OHTs in their systems, similar to the approach taken with chemical substances. For submissions to OECD member countries that do not have specific detailed rules or special templates for the format of reporting the studies, it is already possible, though potentially time-consuming, to prepare Tier II study summaries in accordance with OHTs and include them in the dossier.

Even for studies for which no detailed examples of summary are provided in the OECD dossier guidance, the IUCLID dossiers provided as deliverables of the EFSA's procurement, as mentioned in the previous chapter, have been published and can be used as examples of summaries of studies using OHTs in the non-EU OECD member countries.

If summaries of studies are prepared using OHT format for submission to non-EU OECD member countries, the time and effort required to rewrite for the submission in the EU and transfer to IUCLID can be reduced to some extent.

Table 15 The OECD's 38 Member countries

EU Member States - 22 countries	USMCA - 3 countries	Other - 13 countries
Austria (1961)	Canada (1961)	Australia (1971)
Belgium (1961)	Mexico (1994)	Chile (2010)
Czechia (1995)	United States (1961)	Colombia (2020)
Denmark (1961)		Costa Rica (2021)
Estonia (2010)		Iceland (1961)
Finland (1969)		Israel (2010)
France (1961)		Japan (1964)
Germany (1961)		Korea (1996)
Greece (1961)		New Zealand (1973)
Hungary (1996)		Norway (1961)
Ireland (1961)		Switzerland (1961)
Italy (1961)		Türkiye (1961)
Latvia (2016)		United Kingdom (1961)
Lithuania (2018)		
Luxembourg (1961)		
Netherlands (1961)		
Poland (1996)		
Portugal (1961)		
Slovak Republic (2000)		
Slovenia (2010)		
Spain (1961)		
Sweden (1961)		

OHTs are intended to serve as standard formats for summarising data contained in any study report or publication related to particular endpoints. Most OHTs are built around the OECD Test Guidelines (TGs) or particular guidance documents where the studies are conducted according to these guidance documents. Since IUCLID began to be used for applications of ASs used in PPPs in the EU, new OHTs have been developed for studies not required for chemical substances registered under the REACH, and revisions to existing OHTs have been made to ensure their applicability to IUCLID dossiers for ASs used in PPPs.

In the United States, Study Profile Templates for chemical AS are available on the Study Profile Templates site[94], and OECD Data Evaluation Record (DER) templates for microbial AS are provided on the OECD Data Evaluation Record Templates site[95]. Some templates available on the Study Profile Templates website are indicated as DERs. '"How To" Demonstration on using OECD DER templates'[96] dated 18 November 2011, is a document that presents the development of OECD DER templates and demonstrates how to use them. This document includes a brief history of OECD DER templates for microbial ASs, and various uses, as well as examples of DERs for certain data requirements. The DER corresponds to Tier II, Document M, in the OECD dossier format, and Individual test and study reports correspond to Document K, as illustrated in the document. The Tier I quality check, a component of Document L is not shown, so it is presumed that the Tier I quality check is not used in the United States. Regarding the templates corresponding to the Tier II summary in the OECD dossier guidance, those for which test guidelines of the United States Environmental Protection Agency (US EPA) exist are prepared in accordance with the test guidelines. As described in Part 1, in a number of the test guidelines and/or templates taken into account in the process of development of the OHTs, DER templates for reviewing the scientific studies that were submitted to support applications to register pest control products in the area covered by the North American Free Trade Agreement (NAFTA) were included. Therefore, it is considered that there is a certain degree of similarity between the U.S. templates and the OHTs.

The OECD document 'Saving Costs in Chemicals Management: How the OECD Ensures Benefits to Society'[97] issued in 2019 stated that for chemical substances, as countries increasingly implement the OHTs in their IT systems, the costs of preparing different data sets for different national/regional regulatory assessment schemes were reduced. It also noted that OHTs allowed companies to gather and store their chemical test summaries in a single database and submit the same information to different authorities

without having to re-enter or reformat any data.

Regarding language barriers, at the 8th meeting of the EFSA PSN-IUCLID Subgroup held on 22 November 2023, a presentation titled 'OECD IUCLID Expert Group - Prioritised activities: Activity 3 - A Framework for Cross-Jurisdictional Data Usage'[98] proposed that though auto-translate would be a basis for a check by applicants, a central repository in English, with automated translations generated upon request or reporting, was a feasible solution to address language barriers. This approach would avoid the complexities of managing multiple language versions of the same document.

The ability to perform data entry in multiple languages is already described in the 'Customisation Opportunities of IUCLID for the Management of Chemical Data', 2nd edition of the OECD Series on Testing and Assessment No. 297[99] published on 10 June 2021.

Regarding IUCLID, updates have been carried out almost annually in recent years, and OHTs have also been updated and added. However, when OHTs are updated, changes and associated data migration may become necessary from the old OHT to the new OHT. Issues related to changes and associated data migration are noted in the minutes of the 11th meeting of the EFSA PSN-IUCLID subgroup mentioned earlier, and the need for lifecycle management in IUCLID is also noted.

If the issues related to changes and associated data migration are resolved in the future, it is anticipated that summaries of studies using OHTs can be gathered and stored in a single database, and the data are to be extracted and presented in formats in accordance with the requirements of various authorities across different countries. This would potentially reduce the time and effort required to submit applications both in the EU and non-EU countries in the future.

If the use of OHT increases not only in OECD member countries but also in international organisations, summaries of studies using OHT could potentially be used in evaluations conducted by these international organisations.

The standardisation of data reporting formats is also being discussed at the Joint Meeting of the Food and Agriculture Organization of the United Nations (FAO)/the World Health Organization (WHO) on Pesticide Residues (JMPR) and the Codex Committee on Pesticide Residues (CCPR) as a means to improve the efficiency of preparing dossiers to be submitted for assessment at JMPR and preparing assessment reports. The document titled 'Enhancement of the operational procedures of CCPR and JMPR: Opportunities, challenges, and recommendations on next steps'[100] dated April 2023 prepared for consideration by the CCPR 54th Session, presented several themes such as data standardisation, digital templates, and information technology (IT). The use of national reviews and data by JMPR was also considered.

Although evaluation methods are different among various countries and organisations, the increased use of standardised templates for reporting the studies will reduce time and effort in evaluation conducted by not only OECD member countries but also by international organisations.

While some countries are not yet prepared to adopt electronic submissions via the IUCLID, if MS Word templates, like those previously provided for preparation of dossier or assessment report in the EU, in which the format of the OHTs is reflected, are provided, the summaries of studies prepared using these templates are expected to be useful for future data migration to electronic submission systems such as IUCLID.

The EFSA external scientific report 'Extension of the EFSA Pesticides Genotoxicity Database'[101], adopted on 3 March 2025, reported that the EFSA developed a database of genotoxicity extracted from data submitted in the course of regulatory approval, and this database was used for predicting genotoxicity. However, it was also reported that the German Federal Institute for Risk Assessment, Das Bundesinstitut für Risikobewertung (BfR) had developed its own internal database of curated genotoxicity data extracted from original study reports. Several suggestions for improvement were made in the course of performing the data migration to the IUCLID template and the evaluation of the database created. In the course of performing the data migration to the IUCLID/OHT template, several changes to the structure of the OHT 70 (Genetic toxicity in vitro) which would improve its usefulness were recognised. Recommendations were made related to the migration of data, such as a non-IUCLID to IUCLID format migration service. It was proposed that alignment of the data structure and format was needed between the templates currently used by organisations such as the EFSA and IUCLID/OHTs in order to facilitate resource efficient information transfer. This report indicates

that the IUCLID can be used not only for dossier preparation but also as a database, and several changes to the structure of the OHTs which would improve their usefulness were recognised.

The entry of data into the IUCLID is time-consuming and labor-intensive. However, considering that it can be used to prepare dossiers for multiple countries and also serve as a database, it is desirable to make effective use of the information entered into the IUCLID. Analysis of the data in IUCLID dossiers in comparison with the results of existing reviews is helpful for predicting what decisions will be made regarding the findings obtained in the studies of the AS of which dossier is to be submitted.

Conclusion

After the OECD format was introduced in the EU as the format for dossiers submitted for the approval/renewal of approval of ASs used in PPPs and for the assessment reports prepared based on those dossiers, the formats for dossiers and assessment reports were revised and supplemented several times in the EU. Some revisions were made to reflect the data requirements added in the EU, but many of the revisions were made to further improve the OECD format. The use of the IUCLID for dossier submission facilitated the standardisation of data entry formats, such as the template for study summaries based on the OHTs.

The development of OHTs for various studies, along with the development in database systems such as the IUCLID, has made it possible to generate application documents that meet the data requirements of each OECD member country by extracting data entered.

In the future, for submitted study reports, summaries of studies and other relevant information will be occasionally updated with updates of corresponding OHTs, and for the addition of studies corresponding to new data requirements and complying with new standards, additional entry of new study reports and their data and update of risk assessment will be conducted. Thus, the reduction of the time required for the preparation of the dossier before the submission deadline for the dossiers for renewal of approval may be achieved.

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.

References

1) H. Harada *et al.*, SUMITOMO KAGAKU, 2024, 45 (2024). https://www.sumitomo-chem.co.jp/rd/report/files/docs/2024J_5.pdf (Ref. 2025/3/17).
2) EC, "Directive 91/414/EEC (OJ 1991.08.19)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31991L0414 (Ref. 2025/3/17).
3) European Commission, "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), Sanco/10518/2004 rev. 3 (2004.10.08)".
4) OECD, "OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances (Dossier Guidance), Original version (1998.07), Latest version Rev.2(2005.05)", The document has been replaced several times with updated versions. The first published version is considered to be the original version, dated July 1998. The latest updated version is Rev. 2 dated May 2005, but no URL linked to its main document is available now. Appendices are divided into several files and are available at the following URL.https://web-archive.oecd.org/2014-11-19/81844-oecdguidancedocumentsforpesticideregistration.htm#dossier (Ref. 2025/3/17).
5) European Commission, "Forms for use in checking dossiers for completeness - Part 3: Evaluation Form 3: Annex IIA: Test and Study Reports", The document has been replaced several times with updated versions. The first published version is considered to be Rev.4 dated 27 September 2004 and Rev.5 dated 15 April 2005 also exists.
6) European Commission, "Forms for use in checking dossiers for completeness - Part 4: Evaluation Form 4: Annex IIIA: Test and Study Reports", The document has been replaced several times with updated versions. The first published version is considered to be Rev.4 dated 15 October 2004

and Rev.5 dated 15 April 2005 also exists.

7) European Commission, "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), 1663/VI/94 Rev. 8 (1998.04.22)".

8) OECD, "OECD Guidance for Industry Data Submissions for Microbial Pest Control Products and their Microbial Pest Control Agents (Dossier Guidance for Microbials) Original version (2004.02), Latest version Rev.2 (2006.08)",
The document has been replaced several times with updated versions. The first published version is considered to be the original version, dated February 2004. The latest updated version is the version dated August 2006, and its main document is linked to the following URL.
https://web-archive.oecd.org/2012-06-14/115378-43435253.pdf (Ref. 2025/3/17).
Appendices are divided into several files and are available at the following URL.
https://web-archive.oecd.org/2014-11-19/81844-oecdguidancedocumentsforpesticideregistration.htm#dossier (Ref. 2025/3/17).

9) OECD, "OECD Guidance for Industry Data Submissions for Pheromones and other Semiochemicals and their Active Substances (Dossier Guidance for Pheromones and other Semiochemicals)(2003)",
No URL linked to its main document is available now.
Appendices are divided into several files and are available at the following URL.
https://web-archive.oecd.org/2014-11-19/81844-oecdguidancedocumentsforpesticideregistration.htm#dossier (Ref. 2025/3/17).

10) European Commission, "Forms for use in checking dossiers for completeness - Part 3: Evaluation Form 3: Annex IIB: Test and Study Reports",
The first published version is considered to be Rev.3 dated 29 June 2005.

11) European Commission, "Forms for use in checking dossiers for completeness - Part 4: Evaluation Form 4: Annex IIIB: Test and Study Reports",
The first published version is considered to be Rev.3 dated 29 June 2005.

12) EC, "Regulation 1107/2009 (OJ 2009.11.24)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107 (Ref. 2025/3/17).

13) EU, "Regulation 544/2011 (OJ 2011.06.11)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0544 (Ref. 2025/3/17).

14) EU, "Regulation 545/2011 (OJ 2011.06.11)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0545 (Ref. 2025/3/17).

15) European Commission, "Working Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009, SANCO/10363/2012 rev.7 (2013.04.03)",
The document has been replaced with updated versions, and therefore, no URL linked to the document is available now.

16) European Commission, "Working Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009, SANCO/10363/2012 rev.9 (2014.03.21)",
The document has been replaced with updated versions, and therefore, no URL linked to the document is available now.

17) European Commission, "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), 1663/VI/94 Rev. 5 (1994.08.03)".

18) European Commission, "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), 1663/VI/94 Rev. 6 (1995.01.31)".

19) EFSA, "Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009, EFSA Journal 2011;9(2):2092 (2011.02.24)", https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2011.2092 Text
https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2011.2092&file=efs22092-sup-0001-Appendix.pdf Appendix (Ref. 2025/3/17).

20) EC, "Regulation 1141/2010 (OJ 2010.12.08)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010R1141 (Ref. 2025/3/17).

21) European Commission, "Guidance Document on

the renewal of active substances included in Annex I of Council Directive 91/414/EEC to be assessed in compliance with Regulation 1141/2010 (the renewal regulation), SANCO/10387/2010 rev.8 (2010.10.28)", https://food.ec.europa.eu/system/files/2016-10/pesticides_ppp_app-proc_air-2_guide-renewal.pdf (Ref. 2025/3/17).

22) European Commission, "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), Sanco/10518/2005 rev.5 (2005.06.27)".

23) EC, "Regulation 1490/2002 (OJ 2002.08.21)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002R1490 (Ref. 2025/3/17).

24) EC, "Regulation 451/2000(OJ 2000.02.29)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32000R0451 (Ref. 2025/3/17).

25) EC, "Regulation 2229/2004(OJ 2004.12.24)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32004R2229 (Ref. 2025/3/17).

26) European Commission, "Template to be used for Assessment Reports regarding Level 3 of Volume 1, SANCO/11114/2012 –rev. 0 (2012.06.01)", https://food.ec.europa.eu/system/files/2016-10/pesticides_ppp_app-proc_guide_doss_temp-assess-rprts_lvl-3-v1.pdf (Ref. 2025/3/17).

27) European Commission, "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, 1654/VI/94 Rev. 7 (1998.04.22)".

28) OECD, "OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances (Monograph Guidance)",
The document has been replaced several times with updated versions. The first published version is considered to be the original version dated July 1998. The latest updated version is Rev. 3 dated April 2008, and no URL linked to its main document is available now.
Appendices are divided into several files and are available at the following URL.
https://web-archive.oecd.org/2014-11-19/81844-oecdguidancedocumentsforpesticideregistration.htm#dossier (Ref. 2025/3/17).

29) OECD, "OECD Guidance for Country Data Review Reports on Microbial Pest Control Products and their Microbial Pest Control Agents (Monograph Guidance)",
The first published version is considered to be the original version dated February 2004, and its main document is linked to the following URL.
https://web-archive.oecd.org/2012-06-15/174170-30919574.pdf (Ref. 2025/3/17).
Appendices are divided into several files and used to be published, but no URL linked to the set of Appendices is available now.
The document and the part of appendices have been replaced several times with updated versions. The latest updated version is dated August 2006, and its main document is linked to the following URL.
https://web-archive.oecd.org/2012-06-14/115313-43464397.pdf (Ref. 2025/3/17).
Appendices are divided into several files and are available at the following URL.
https://web-archive.oecd.org/2014-11-19/81844-oecdguidancedocumentsforpesticideregistration.htm#dossier (Ref. 2025/3/17).

30) EU, "Regulation 283/2013 (OJ 2013.04.03)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0283 (Ref. 2025/3/17).

31) EU, "Regulation 284/2013 (OJ 2013.04.03)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0284 (Ref. 2025/3/17).

32) EU, "Regulation 686/2012 (OJ 2012.07.27)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0686 (Ref. 2025/3/17).

33) EU, "Regulation 844/2012 (OJ 2012.09.19)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0844 (Ref. 2025/3/17).

34) European Commission, "Draft Working Document - AIR III Renewal Programme, SANCO/2012/11284",
The document has been replaced several times with updated versions, and the latest updated version is Rev.22 dated December 2018, available at the following URL.
https://food.ec.europa.eu/document/download/3ff7eef9-1dac-4f92-baaa-ddc8949c219f_en?filename=pesticides_ppp_app-proc_air-3_sanco-2012-11284.pdf (Ref. 2025/3/17).

35) European Commission, "Guidance Document

for Applicants on preparing Dossiers for the Approval of a Chemical New Active Substance and for the Renewal of Approval of a Chemical Active Substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013, SANCO/10181/2013– rev. 2.1 (2013.05.13)",
The first published version, considered to be Rev.1 dated 15 March 2013, was prepared before the publications of Regulations 283/2013 and Regulation 284/2013 in the OJ, therefore, the title of Rev.1 was slightly different

36) European Commission, "Guidance Document on preparing lists of test and study reports according to Article 60 of Regulation (EC) No 1107/2009, SANCO/12580/2012– rev. 3.1 (2013.05.17)",
The first published version, considered to be Rev.3 dated 15 March 2013. In Rev.3, it was stated that it would apply to applications submitted from 1 May 2013 onwards, but this was revised in Rev.3.1 dated 17 May 2013, to apply to applications submitted from 1 January 2014 onwards.

37) European Commission, "Template to be used for Assessment Reports, SANCO/12592/2012 –rev. 0 (2012.11)",
As the template was updated with Rev.1.2 dated 6 October 2017 to the combined template to be used for the assessment report and the CLH report, no URL linked to the document is available.

38) European Commission, "Guidance Document on Data Requirements on Efficacy for the Dossier to be submitted for the Approval of New Active Substances contained in Plant Protection Products, SANCO/10054/2013 - rev. 3 (2013.07.11)",
The first published version is considered to be Rev.3 dated 11 July 2013. However, a version believed to be earlier than this is referenced as a SANCO E3 working document with a slightly different title and a date prior to 11 July 2013.
https://food.ec.europa.eu/system/files/2016-10/pesticides_ppp_app-proc_guide_efficacy_nas.pdf (Ref. 2025/3/17).

39) European Commission, "Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 (the Renewal Regulation), SANCO/2012/11251 rev. 1.2 (2012.07)",
The document has been replaced with updated versions, and therefore, no URL linked to the document is available now.

40) EFSA, "Administrative guidance on submission of dossiers and assessment reports for the peer review of pesticide active substances. EFSA Supporting publication 2019:EN-1612 (approved:2019.03.27)", https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2019.EN-1612 (Ref. 2025/3/17).
The appendices are available at the following URL.
https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fsp.efsa.2019.EN-1612&file=efs31612e-sup-0001-SupInfo.zip (Ref. 2025/3/17).

41) European Commission, "Guidance Document for Applicants on preparing Dossiers for the Approval of a Chemical New Active Substance and for the Renewal of Approval of a Chemical Active Substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013, SANCO/10181/2013– rev. 3 (2014.12.12)",
Since the document has been replaced with updated versions, no URL linked to the document is available now.

42) European Commission, "Guidance Document for Applicants on preparing Dossiers for the Approval or Renewal of Approval of a Microorganisms including viruses according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013, SANCO/12545/2014– rev. 1 (2014.12.12)".
Since the document has been replaced with updated versions, no URL linked to the document is available now.

43) European Commission, "Guidance Document for Applicants on preparing Dossiers for the Approval or Renewal of Approval of a Microorganisms including viruses according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013, SANCO/12545/2014– rev. 2 (2016.03)".
Since the document has been replaced with updated versions, no URL linked to the document is available now.

44) European Commission, "Guidance Document on Rules for Revision of Assessment Reports, SANCO/10180/2013– rev. 1 (2013.03)",
The document was updated with Rev. 2 dated October 6, 2017, and therefore, no URL linked to the document is available now.

45) OECD, "A Vision for the Future - A Global Approach to the Regulation of Agricultural Pesticides",

https://web-archive.oecd.org/fr/2012-06-15/155114-33854658.pdf (Ref. 2025/3/17).

46) EC, "Regulation 1272/2008 (OJ 2008.12.31)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272 (Ref. 2025/3/17).

47) European Commission, "Combined Template to be used for Assessment Reports according to Regulation (EC) No 1107/2009 and Proposals for Harmonised Classification and Labelling according to Regulation (EC) No 1272/2008, SANCO/12592/2012 –rev. 1.2 (2017.10.06)", Since the document has been replaced with updated versions, no URL linked to the document is available now.

48) EU, "Regulation 2017/1432 (OJ 2017.08.08)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R1432 (Ref. 2025/3/17).

49) EU, "Regulation 2018/605 (OJ 2018.04.20)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0605 (Ref. 2025/3/17). Corrigendum to Regulation 2018/605 (OJ 2018.05.02) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0605R(01) (Ref. 2025/3/17).

50) ECHA/EFSA, "Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC)No 1107/2009, EFSA Journal 2018;16(6):5311, 2018.06.05", https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5311 (Ref. 2025/3/17).

51) EFSA, "Network on Pesticide Steering Minutes of the 20th meeting held on 14-15 June 2016, Parma (Agreed on 2016.08.17)", https://www.efsa.europa.eu/sites/default/files/event/160614b-m.pdf (Ref. 2025/3/17).

52) EFSA, "Network on Pesticide Steering meeting Minutes of the 21st meeting held on 14-15 February 2017, Parma (Agreed on 2017.04.18)", https://www.efsa.europa.eu/sites/default/files/event/170214-m_0.pdf (Ref. 2025/3/17).

53) European Commission, "Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 (the Renewal Regulation), SANCO/2012/11251 rev. 4 (2014.12.12)", Since the document has been replaced with updated versions, no URL linked to the document is available now.

54) European Commission, "Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 (the Renewal Regulation), SANCO/2012/11251 rev. 5 (2019.03.22)", https://food.ec.europa.eu/system/files/2019-03/pesticides_ppp_app-proc_guide_pai_11251.pdf (Ref. 2025/3/17).

55) EFSA, "Network on Pesticide Steering meeting Minutes of the 23rd meeting Held on 12-13 June 2018, Parma (Agreed on 2018.07.11)", https://www.efsa.europa.eu/sites/default/files/event/180612-m_0.pdf (Ref. 2025/3/17).

56) European Commission, "Guidance Document on preparing lists of test and study reports according to Article 60 of Regulation (EC) No 1107/2009, SANCO/12580/2012– rev. 4 (2019.03.22)", https://food.ec.europa.eu/system/files/2019-03/pesticides_ppp_app-proc_guide_doss_12580.pdf (Ref. 2025/3/17).

57) European Commission, "Combined Template to be used for Assessment Reports according to Regulation (EC) No 1107/2009 and Proposals for Harmonised Classification and Labelling according to Regulation (EC) No 1272/2008, SANCO/12592/2012 –rev. 2 (2019.03.22)", Since the document has been replaced with updated versions, no URL linked to the document is available now.

58) European Commission, "Guidance Document for Applicants on preparing Dossiers for the Approval of a Chemical New Active Substance and for the Renewal of Approval of a Chemical Active Substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013, SANCO/10181/2013– rev. 4 (2019.03.22)" Since the document has been replaced with updated versions, no URL linked to the document is available now.

59) European Commission, "Implementation schedule - Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances, SANTE-10914-2019 rev. 0 (2019.03.22)" Because of the adoption and application of the 2021 revised version of the administrative guidance, the document related to the implementation schedule of the 2019 version was replaced with such document prepared for the 2021 revised version. Therefore, no URL linked to the document related to the 2019 version.

60) European Commission, "Guidance Document for Applicants on preparing Dossiers for the Approval of a Chemical New Active Substance and for the Renewal of Approval of a Chemical Active Substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013, SANCO/10181/2013– rev. 6 (2021.03.24)", https://ec.europa.eu/food/system/files/2021-03/pesticides_ppp_app-proc_guide_doss_10181.pdf (Ref. 2025/3/17).
61) European Commission, "Guidance Document for Applicants on preparing Dossiers for the Approval or Renewal of Approval of a Microorganisms including viruses according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013, SANCO/12545/2014– rev.3 (2021.03)", https://food.ec.europa.eu/system/files/2021-03/pesticides_ppp_app-proc_guide_applicants-microbial_en.pdf (Ref. 2025/3/17).
62) European Commission, "Working Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009, SANCO/10363/2012 rev.10 (2021.01.25)", Since the document has been replaced with updated versions, no URL linked to the document is available now.
63) European Commission, "Combined Template to be used for Assessment Reports according to Regulation (EC) No 1107/2009 and Proposals for Harmonised Classification and Labelling according to Regulation (EC) No 1272/2008, SANCO/12592/2012 –rev. 3 (2024.03.22)", https://food.ec.europa.eu/system/files/2024-04/pesticides_ppp_app-proc_guide_doss_12592-2012.pdf (Ref. 2025/3/17). The templates in the appendices are available at the following URL. https://food.ec.europa.eu/system/files/2024-04/pesticides_ppp_app-proc_guide_doss_12592-2012.zip (Ref. 2025/3/17).
64) EU, "Regulation 2023/707 (OJ 2023.03.31)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0707 (Ref. 2025/3/17).
65) EU, "Regulation 2019/1381 (OJ 2019.09.06)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1381 (Ref. 2025/3/17).
66) EU, "Regulation 2020/1740 (OJ 2020.11.23)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1740 (Ref. 2025/3/17).
67) EU, "Regulation 2021/428 (OJ 2021.03.11)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0428 (Ref. 2025/3/17).
68) EC, "Regulation 178/2002 (OJ 2002.02.01)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002R0178 (Ref. 2025/3/17).
69) EC, "Regulation 396/2005 (OJ 2005.03.16)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005R0396 (Ref. 2025/3/17).
70) EFSA, "Administrative guidance on submission of dossiers and assessment reports for the peer review of pesticide active substances and on the maximum residue level (MRL)application procedure. EFSA Supporting publication 2021: EN-6464 (approved: 2021.02.11)", The document at the following URL is the updated version, dated 3 June 2024, with the updated sections highlighted in gray. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6464 (Ref. 2025/3/17). The document at the following URL is Annex A of the updated version dated 3 June 2024, which includes a list of changes from the 2021 version. https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fsp.efsa.2021.EN-6464&file=efs36464e-sup-0004-Annex-A.pdf (Ref. 2025/3/17).
71) European Commission, "Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure, SANTE/10182/2021 (2021.02.23)", https://food.ec.europa.eu/system/files/2021-03/pesticides_ppp_app-proc_guide_peer-review-active-subs_en.pdf (Ref. 2025/3/17).
72) EFSA, "IUCLID Active Substance application Manual, Version 1 (2021.07.14)", https://zenodo.org/records/5091464 (Ref. 2025/3/17).
73) EFSA, "IUCLID Microbial Active Substances Manual, Version 1 (2021.05.19)", https://zenodo.org/records/4773527 (Ref. 2025/3/17).
74) EFSA, "IUCLID Basic Substance application Manual, Version 1 (2021.08.09)", https://zenodo.org/records/5172131 (Ref. 2025/3/17).
75) EFSA, "MRL Applications Manual, Version 1 (2021.03.23)", https://zenodo.org/records/4630194 (Ref. 2025/3/17).
76) EFSA, "IUCLID Active Substance application Manual

(IUCLID 6 VERSION 6.X), Version 2(2021.07.14)", https://zenodo.org/records/5864849(Ref. 2025/3/17).
77) EU, "Regulation 2020/2007 (OJ 2020.12.09)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R2007 (Ref. 2025/3/17).
78) EU, "Regulation 540/2011 (OJ 2011.06.11)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540 (Ref. 2025/3/17).
79) EFSA, "EFSA Pesticide Steering Network subgroup - IUCLID HYPERCARE Programme (2021.09.30)", https://www.efsa.europa.eu/sites/default/files/documents/IUCLID-hypercare-terms-reference.pdf (Ref. 2025/3/17).
80) EFSA, "IUCLID 6.8 Active Substance Application Manual, Version 7 (2024.11.20)", https://zenodo.org/records/14185538 (Ref. 2025/3/17).
81) EFSA, "Crosswalks IUCLID 6 v8 EU PPP Active substance application (product) to KCA&KCP, Version 5 (2024.06.04)", https://zenodo.org/records/11402548 (Ref. 2025/3/17).
82) European Commission, "Guidance Document on How to utilize PPP Dossiers/Monographs and Existing Substances (ESR) Dossiers/Risk Assessments for the Preparation of BP dossiers/CAs' reports (2003.11.21)", https://echa.europa.eu/documents/10162/983772/bpd_guid_guidance_use_ppp_esr_for_bpd_dossier_preparation_en.pdf (Ref. 2025/3/17).
83) EC, "Directive 98/8/EC (OJ 1998.04.24)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0008 (Ref. 2025/3/17).
84) EC, "Regulation 793/93 (OJ 1993.04.05)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31993R0793 (Ref. 2025/3/17).
85) knoell Germany GmbH, "Final report: Proof of concept pesticides dossier in IUCLID format. Version 1.0 (2020.03.27)", https://zenodo.org/records/3937381 (Ref. 2025/3/17).
86) knoell Germany GmbH, "Final report: Proof of concept pesticides dossier for micro-organism in IUCLID format. Version 1.0 (2020.07.24)", https://zenodo.org/records/4040679 (Ref. 2025/3/17).
87) EC, "Regulation 1907/2006 (OJ 2006.12.30)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1907 (Ref. 2025/3/17). Corrigendum to Regulation 1907/2006 (OJ 2007.05.29) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1907R(01) (Ref. 2025/3/17).
88) EU, "Regulation 528/2012 (OJ 2012.06.27)", https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0528 (Ref. 2025/3/17).
89) ECHA, "Study on the role of Robust Study Summaries in hazard assessment - Survey and interviews report (2022.01.18)", https://echa.europa.eu/documents/10162/17069/study_rss_hazard_assessment_surveys_en.pdf (Ref. 2025/3/17).
90) EFSA, "IUCLID demonstration dossiers for pesticides (2022.06.28)", https://www.efsa.europa.eu/en/call/iuclid-demonstration-dossiers-pesticides(Ref. 2025/3/17).
91) EFSA, "IUCLID 6.7 test dossiers, Version 1 (2024.06.04)", https://zenodo.org/records/11471659(Ref. 2025/3/17).
92) EFSA, "Pesticide Steering Network – IUCLID Subgroup 11th meeting - 21 November 2024 09:30-17:30 (agreed on 2024.12.11)", https://www.efsa.europa.eu/sites/default/files/2024-12/Meeting%20minutes_11th%20PSN%20IUCLID_Network_final.pdf (Ref. 2025/3/17).
93) OECD, "Chemical Safety and Biosafety Progress Report, No.39 (2019.12)", https://web-archive.oecd.org/2019-12-12/538938-progress-report-on-chemical-safety-and-biosafety-november-2019.pdf(Ref. 2025/3/17).
94) US EPA, "Study Profile Templates (last updated on 2024.08.15)", https://www.epa.gov/pesticide-registration/study-profile-templates (Ref. 2025/3/17).
95) US EPA, "OECD Data Evaluation Record Templates (last updated on 2024.09.16)", https://www.epa.gov/pesticide-registration/oecd-data-evaluation-record-templates (Ref. 2025/3/17).
96) US EPA, ""How To" Demonstration on using OECD DER templates (2011.11.18)", https://www.epa.gov/sites/default/files/documents/how-to-on-oecd-der.pdf (Ref. 2025/3/17).
97) OECD, "Saving Costs in Chemicals Management: How the OECD Ensures Benefits to Society (2019)", https://www.oecd-ilibrary.org/environment/saving-costs-in-chemicals-management_9789264311718-en(Ref. 2025/3/17).
98) Teiwes, Marc, "OECD IUCLID Expert Group - Prioritised activities: Activity 3 - A Framework for Cross-Jurisdictional Data Usage (2023.11.22)", https://www.efsa.europa.eu/sites/default/files/2024-01/13-activity-3-oecd-iuclid-expert-group_0.pdf (Ref. 2025/3/17).
99) OECD, "Customisation Opportunities of IUCLID

for the Management of Chemical Data – 2nd edition, Series on Testing and: Assessment No. 297, ENV/JM/MONO(2019)6/REV1 (2021.06.10)", https://one.oecd.org/document/ENV/JM/MONO(2019)6/REV1/en/pdf (Ref. 2025/3/17).

100) CCPR, "Enhancement of the operational procedures of CCPR and JMPR: Opportunities, challenges, and recommendations on next steps, CX/PR 23/54/15 (2023.04)", https://www.fao.org/fao-who-codexalimentarius/sh-proxy/jp/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-54%252FWDs%252Fpr54_15e.pdf (Ref. 2025/3/17).

101) EFSA/BfR, "Extension of the EFSA Pesticides Genotoxicity Database. EFSA Supporting publication 2025:EN-9311 (approved: 2025.03.03)", https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2025.EN-9311 (Ref. 2025/3/17).

PROFILE

Hiroko Harada

Sumika Technoservice Corporation
Regulatory Affairs & Chemical Safety Center
Section manager

Mika Ota

Sumika Technoservice Corporation
Regulatory Affairs & Chemical Safety Center
Director

Mio Tatsu

Sumika Technoservice Corporation
Regulatory Affairs & Chemical Safety Center