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HEALTH & FOOD SAFETY DIRECTORATE-GENERAL

Food and feed safety, innovation
Pesticides and biocides

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24 March 2021

**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**

This document has been conceived as a guidance document of the Commission Services. It does not represent the official position of the Commission. It does not intend to produce legally binding effects. Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.

Revision history

When	Applicability	What
Rev. 2.1 of 17.05.2013		Reflect the publication of the data requirements Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013, as well as Commission Communications 2013/C 95/01 and 2013/C 95/02. The cross walks for AS and PPP have been included. Chapter 8 on 'public summary dossier and sanitized documents' has been included.
Rev. 3 of 12.12.2014		Doc N2 (List of Endpoints) has been updated.
Rev. 4 of 22.03.2019	For (supplementary) dossiers	The special case of the non-submission of

	submitted on or after 1 October 2019	particular studies required by the EU legislation has been amended. Document N3 has been updated.
Rev. 6 of 24.03.2021	This guidance document is not applicable for applications (including dossiers) submitted on or after 27 March 2021.	On or after 27 March 2021 and concerning the implementation of the Transparency Regulation ¹ , applications must be submitted electronically through a central submission system using the IUCLID (International Uniform Chemical Information Database) software package (freely available online). ^{2 3}

¹ Regulation (EU) No 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency of the EU risk assessment in the food chain and amending Regulations (EU) No 178/2002, (EC) No 1829/2003, No 1831/2003, (EC) No 2068/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283, and Directive 2001/18/EC, (OJ L 231, 6.9.2019, p. 1).

² IUCLID is a software application to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances and is used to prepare application dossiers in a structured format. Available at: <https://iuclid6.echa.europa.eu/it/download>.

³ Unless the active substance is submitted under Regulation (EU) No 844/2012.

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1. Introduction

This guidance document describes how the applicant should submit a dossier for the approval or the renewal of approval of a chemical active substance to comply with the Table of Contents described in Annex to Regulation (EU) No 283/2013 and Annex to Regulation (EU) No 284/2013.

The Guidance Document addresses the following aspects relating to delivering submissions for addressing Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013:

- Cross-walk of data points from OECD Table of Contents to revised EU Table of Contents;
- Documents to be included in the Submission Dossier, including consideration of special situations like the cases where agreed test methods are not yet available for specific data requirement points;
- Electronic Submission (CADDY) Table of Contents.

2. Implementation schedule

This document has been finalised in the Standing Committee on the Food Chain and Animal Health on 17 May 2013 and updated in the Standing Committee on Plants, Animals, Food and Feed on 12 December 2014. This guidance document should be used for dossiers prepared for chemical active substances covered by Commission Regulation (EU) No 844/2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and for chemical active substances for which an application for the approval has been submitted as from 1 January 2014.

3. Cross walk from OECD Table of Contents to revised EU Table of Contents

Applicants should be aware that Annex to Regulation (EU) No 283/2013 and Annex to Regulation (EU) No 284/2013 describe:

- New locations for information and data previously submitted
- New locations for new data requirements
- New locations that contain data and information from a number of previous data points

In addition Annex to Regulation (EU) No 283/2013 and Annex to Regulation (EU) No 284/2013 describe some approaches to addressing annex points contained in the revised EU Table of Contents. Further, the Commission Communications 2013/C 95/01 and 2013/C 95/02, state the test methods and guidance documents applicable for each of the data points. These Communications will be updated regularly in case new test methods and/or guidance documents become available and will be applicable after the publication in the Official Journal.

Active Substance and Plant Protection cross walks:

The cross walks are contained in two Excel files:

- REVISED EU_KCA_XWALKS_2013_04_18.xlsx (Active Substance)
- REVISED EU_KCP_XWALKS_2013_05_09.xlsx (Product)

Each contains the final "REVISED EU CADDY Table of Content"

- KCA_REVISÉD EU (Active Substance)
- KCP_REVISÉD EU (Product)

and complete crosswalks between the different Dossier Numbering Systems (Data Points in the Dossier Table of Content) used so far in the EU

- REVISÉD EU & OECD
- REVISÉD EU & OECD & EU
- REVISÉD EU & EU

All Data Points of a given numbering system are complete with respect to the respective numbering system in the various crosswalks. 'Single to many' and 'many to many' relationships are displayed via repeating the information of one system. If no alignment of data point exists the data point is listed but no crosswalk information is displayed indicated by empty cells in the Excel file.

Inside the tables there is additional information to ease the crosswalk reading. Examples are: "new data requirement" for the revised EU Data Points or "no EC data requirement" for OECD data points.



4. Documents to be included in a submission

The summary and supporting documentation to be included in a submission made within the scope of this guidance document has been revised to reflect the requirements of the revised EU Table of Contents.

Appendix A tabulates the summary and supporting document requirements for new active substance and active substance renewal submissions according to Annex to Regulation (EU) No 283/2013 and Annex to Regulation (EU) No 284/2013.

Appendix A also provides indicative templates for summary and supporting information, where appropriate. The templates can be updated to include additional information and changes; particularly on the front page, footers/headers, word styles and appendices.

Special cases:

In some cases, agreed **test methods or guidance documents are not yet available for particular data requirements**. In these cases, the non-submission of particular studies required by the EU legislation should be thoroughly justified and statements (often referred to as 'position papers') must be substantiated with data or information provided by the applicant in the dossier. Applicants should follow on a routine basis the current developments, e.g. activities of the European Food Safety Authority for guidance documents and in particular publications in the Official Journal and the updates of the Commission Communications 2013/C 95/01 and 2013/C 95/02.

In addition, some data requirements imply the **generation of data via long term studies** (e.g. storage stability studies, field studies). If duly justified, it may be considered acceptable to deliver the final reports of long-term studies after submission of the dossier if they have been formally requested by the RMS during the preparation of the Assessment Report or requested by the European Food Safety Authority during the peer-review process. Interim reports submitted at an early phase will facilitate the evaluation process.

5. Inclusion of crop residues data

Under data point 'CA 6.3 Magnitude of Residue Trials in Plants', in in document K and document M, additional sub-headers should be introduced to organise data into relevant crops or crop groups using the crop name or relevant crop identifier, for example:

K document (data location)	M document (summary document)
KCA 6.3 Magnitude of Residue Trials in Plants	CA 6.3 Magnitude of Residue Trials in Plants
KCA 6.3.1 Wheat	CA 6.3.1 Wheat
KCA 6.3.2 Rye	CA 6.3.2 Rye
etc	etc

6. Public summary dossier and sanitized documents

The “Revised EU CADDY Table of Content”, provided in Tab 1 of the CA and CP cross-walk excel files included under Chapter 3, also includes a new data point “Document P – Public Summary Dossier and sanitized documents” which offers the possibility to directly provide at initial submission all documents which may be made available to the public in a dedicated area.

The nodes provided are indicative only and the relevant guidance provided by EFSA on documents for sanitisation should be followed.

7. Electronic Submission (CADDY) Revised EU Table of Contents

A standard CADDY revised EU Table of Contents supporting the revised EU Table of Contents is published on the CADDY website and should be used by all applicants making electronic submissions. A link to the CADDY website is provided here:

<http://esubmission.ecpa.eu>


Examples of the CADDY TOC for the revised EU Table of Contents is included as Tab 1 of the cross walk documents for CA and CP included at Chapter 3 above, Some titles have been shortened to keep them with 100 characters for CADDY compliance.

8. Provision of draft Registration Report aligned with Annex to Regulation (EU) No 283/2013 and Annex to Regulation (EU) No 284/2013


This guidance only considers provision of dossiers to support new chemical active substance submissions and chemical active substance renewal submissions.










It is recognised that similar guidance relating to draft Registration Report dossiers provided for national authorisations and re-authorisations of products is required. This guidance will be developed.








Appendix A Description of documents to be included in a submission










Documents ² :		Document Title	Additional notes	Templates
OECD Document	Revised EU Document			
Document A	Document A	Statement of the context in which the dossier is submitted	<i>Unchanged</i>	<i>Template not required</i>
Document B	Document B	Documentation relating to the joint submission of dossiers	<i>Unchanged</i>	<i>Template not required</i>
Document C	Document C	Existing or proposed labels	<i>Unchanged</i>	<i>Template not required</i>
Document D-1	Document D-1	Intended uses supported in the EU for which data have been provided	<i>Unchanged</i>	<i>Template not required</i>
Document D-2	Document D-2	List of currently authorized uses and extent of use	<i>Unchanged</i>	<i>Template not required</i>
Document D-3	Document D-3	Intended uses supported in the EU for which data will be provided	Required only by request of the RMS or Co-RMS	<i>Template not required</i>
Document E-1	Document E-1	Listing of Community and Member States MRLs	<i>Unchanged</i>	<i>Template not required</i>
Document E-2	Document E-2	Listing of MRLs in exporting countries	<i>Unchanged</i>	<i>Template not required</i>
Document F	Document F	Notification submitted to the Commission	<i>Unchanged</i>	<i>Template not required</i>
Document G	Document G	Permission of each formulant in accordance with EU legislation	<i>Unchanged</i>	<i>Template not required</i>
Document H	Document H	Safety data sheets for the formulants	<i>Unchanged</i>	<i>Template not required</i>
Document I	Document I	Other data on the formulants	<i>Unchanged</i>	<i>Template not required</i>
Document J	Document J	Confidential data and information	Reflecting Annex to Regulation 283/2013 and Annex to Regulation 284/2013	 Document J.docx
Document K ²	Document K²		Reflecting Annex to Regulation 283/2013 and Annex to Regulation 284/2013	<i>CADDY TOC available (CADDY website)</i>
LIIA Section 1	LCA Section 1^{1,2}	Identity of the active substance; Reference list	Should reflect guidance in SANCO/12580/2012 Only required where there are references associated with the M summary document	<i>Template not required</i>



Documents²:		Document Title	Additional notes	Templates
LIIA Section 1	LCA Section 2^{1,2}	Physical and chemical properties of the active substance; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	<i>Template not required</i>
LIIA Section 1	LCA Section 3^{1,2}	Further information on the active substance; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	<i>Template not required</i>
LIIA Section 2	LCA Section 4^{1,2}	Analytical methods; Reference list	Reference list (should reflect guidance in SANCO/12580/2012)	<i>Template not required</i>
LIIA Section 3	LCA Section 5^{1,2}	Toxicological and metabolism studies on the active substance; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	<i>Template not required</i>
LIIA Section 4	LCA Section 6^{1,2}	Residues in or on treated products, food and feed and plant metabolism; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	<i>Template not required</i>
LIIA Section 5	LCA Section 7^{1,2}	Fate and behaviour in the environment; Reference list	Reference list (should reflect guidance in SANCO/12580/2012)	<i>Template not required</i>
LIIA Section 6	LCA Section 8^{1,2}	Ecotoxicological studies on the active substance; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	<i>Template not required</i>
Not included	LCA Section 9^{1,2}	Literature data; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	<i>Template not required</i>
LIIA Section 1	LCA Section 10^{1,2}	Classification and labelling of the active substance; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	<i>Template not required</i>
LIIA1 Section 1	LCP Section 1^{1,2}	Identity of the plant protection product; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	<i>Template not required</i>
LIIA1 Section 1	LCP Section 2^{1,2}	Physical and chemical properties of the plant protection product; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	<i>Template not required</i>
LIIA1 Section 1	LCP Section 3^{1,2}	Data on application; Reference list	Reference list (should reflect guidance in SANCO/12580/2012)	<i>Template not required</i>

Documents ² :	Document Title	Additional notes	Templates
		Only required where there are references associated with the M summary document	
LIIIA1 Section 1	LCP Section 4^{1,2}	Further information on the plant protection product; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document <i>Template not required</i>
LIIIA1 Section 2	LCP Section 5^{1,2}	Analytical methods; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document <i>Template not required</i>
LIIIA1 Section 7	LCP Section 6^{1,2}	Efficacy data; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document <i>Template not required</i>
LIIIA1 Section 3	LCP Section 7^{1,2}	Toxicological studies on the plant protection product; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document <i>Template not required</i>
LIIIA1 Section 4	LCP Section 8^{1,2}	Residues in or on treated products, food or feed; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document <i>Template not required</i>
LIIIA1 Section 5	LCP Section 9^{1,2}	Fate and behaviour in the environment; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document <i>Template not required</i>
LIIIA1 Section 6	LCP Section 10^{1,2}	Ecotoxicological studies on the plant protection product; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document <i>Template not required</i>
Not included	LCP Section 11^{1,2}	Literature data; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document <i>Template not required</i>
LIIIA1 Section 1	LCP Section 12^{1,2}	Classification and labelling of the plant protection product; Reference list	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document <i>Template not required</i>
MIIA Section 1	MCA Section 1²	Identity of the active substance	Reflecting Annex to Regulation 283/2013  Document MCA Section 1 rev.2.docx

Documents²:		Document Title	Additional notes	Templates
MIIA Section 1	MCA Section 2²	Physical and chemical properties of the active substance	Reflecting Annex to Regulation 283/2013	 Document MCA Section 2 rev.2.docx
MIIA Section 1	MCA Section 3²	Further information on the active substance	Reflecting Annex to Regulation 283/2013	 Document MCA Section 3 rev.2.docx
MIIA Section 2	MCA Section 4²	Analytical methods	Reflecting Annex to Regulation 283/2013	 Document MCA Section 4 rev.2.docx
MIIA Section 3	MCA Section 5²	Toxicological and metabolism studies on the active substance	Reflecting Annex to Regulation 283/2013	 Document MCA Section 5 rev.2.docx
MIIA Section 4	MCA Section 6²	Residues in or on treated products, food and feed and plant metabolism	Reflecting Annex to Regulation 283/2013	 Document MCA Section 6 rev.3.docx
MIIA Section 5	MCA Section 7²	Fate and behaviour in the environment	Reflecting Annex to Regulation 283/2013	 Document MCA Section 7 rev.2.docx
MIIA Section 6	MCA Section 8²	Ecotoxicological studies on the active substance	Reflecting Annex to Regulation 283/2013	 Document MCA Section 8 rev.2.docx
Not included	MCA Section 9²	Literature data	Reflecting Annex to Regulation 283/2013	 Document MCA Section 9 rev.2.docx
MIIA Section 1	MCA Section 10²	Classification and labelling of the active substance	Reflecting Annex to Regulation 283/2013	 Document MCA Section 10 rev.2.docx

Documents ² :		Document Title	Additional notes	Templates
MIIIA1 Section 1	MCP Section 1²	Identity of the plant protection product	Reflecting Annex to Regulation 284/2013	 Document MCP Section 1 rev.2.docx
MIIIA1 Section 1	MCP Section 2²	Physical and chemical properties of the plant protection product	Reflecting Annex to Regulation 284/2013	 Document MCP Section 2 rev.2.docx
MIIIA1 Section 1	MCP Section 3²	Data on application	Reflecting Annex to Regulation 284/2013	 Document MCP Section 3 rev.2.docx
MIIIA1 Section 1	MCP Section 4²	Further information on the plant protection product	Reflecting Annex to Regulation 284/2013	 Document MCP Section 4 rev.2.docx
MIIIA1 Section 2	MCP Section 5²	Analytical methods	Reflecting Annex to Regulation 284/2013	 Document MCP Section 5 rev.2.docx
MIIIA1 Section 7	MCP Section 6²	Efficacy data	Reflecting Annex to Regulation 284/2013 (Not required for renewal or new active substance submissions; efficacy summary required in MCP Section 3)	<i>Template not required for New AS or AS Renewal submissions. Template not available</i>
MIIIA1 Section 3	MCP Section 7²	Toxicological studies on the plant protection product	Reflecting Annex to Regulation 284/2013	 Document MCP Section 7 rev.2.docx
MIIIA1 Section 4	MCP Section 8²	Residues in or on treated products, food or feed	Reflecting Annex to Regulation 284/2013	 Document MCP Section 8 rev.2.docx

Documents ² :		Document Title	Additional notes	Templates
MIIIA1 Section 5	MCP Section 9²	Fate and behaviour in the environment	Reflecting Annex to Regulation 284/2013	 Document MCP Section 9 rev.2.docx
MIIIA1 Section 6	MCP Section 10²	Ecotoxicological studies on the plant protection product	Reflecting Annex to Regulation 284/2013	 Document MCP Section 10 rev.2.doc
Not included	MCP Section 11²	Literature data	Reflecting Annex to Regulation 284/2013	 Document MCP Section 11 rev.2.doc
MIIIA1 Section 1	MCP Section 12²	Classification and labelling of the plant protection product	Reflecting Annex to Regulation 284/2013	 Document MCP Section 12 rev.2.doc
Document N	Document N1	Overall conclusions	Reflecting Annex to Regulation 283/2013 and Annex to Regulation 284/2013 Required only by request of the RMS or Co-RMS (Template available)	 Document N1 rev.1.docx
Document N	Document N2	Endpoints	Developed from Annex to Regulation 283/2013 and Annex to Regulation 284/2013	 N2_LoEP_rev3.docx
Not included	Document N3	Substances and metabolites; structures, codes, synonyms	New template	 DocN3_rev3.docx
Not included	Document N4	Relevance of metabolites in ground water	New template to match structure of guidance document SANCO/221/2000 – Rev.10 - final (25 Feb 2003) and the 2.11 of the Template Assessment Report (SANCO/12592/2012)	 Document N4 rev.3.docx
Not included	Document N5	Consideration of isomeric composition in the risk assessment	New template to match 2.11 of the Template Assessment Report (SANCO/12592/2012)	 Document N5 rev.3.docx

Documents²:		Document Title	Additional notes	Templates
Document O	Document O	Initial evaluation forms	<i>Required only by request of the RMS or Co-RMS</i>	<i>Template not required</i>
Document O	Document OCA	Active substance	Reflecting Annex to Regulation 283/2013	 Document OCA rev.1.docx
Document O	Document OCP	Plant protection product(s)	Reflecting Annex to Regulation 284/2013	 Document OCP rev.1.docx

¹ Document L Tier 1 summaries are not required (OECD study summaries include all the information previously contained in the Tier 1 summary)

² 'All' and 'AllI' prefixes referred to 91/414 and are no longer appropriate:

- **All** will be replaced with **CA** (Chemical Active)
- **AllI** will be replaced with **CP** (Chemical Product).