EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Safety of the food chain
Chemicals, contaminants, pesticides

SANCO/12545/2014– rev. 2
March 2016

GUIDANCE DOCUMENT FOR APPLICANTS ON PREPARING DOSSIERS FOR THE APPROVAL OR RENEWAL OF APPROVAL OF A MICRO-ORGANISMS INCLUDING VIRUSES ACCORDING TO REGULATION (EU) No 283/2013 AND REGULATION (EU) No 284/2013

Revision history

When	What
March 2016 (rev. 2)	Clarification about the ToC for the dossier. Inclusion of the EU numbering system

Contents

1. Introduction

This guidance document describes how the applicant should submit a dossier for the approval or the renewal of approval of an active substance which is a microorganism[1] to comply with the Table of Contents described in Part B of the Annex to Regulation (EU) No 283/2013 and Part B of the Annex to Regulation (EU) No 284/2013.

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

- Data points from OECD Table of Contents to revised EU Table of Contents;
- Electronic Submission (CADDY) Table of Contents;
- Documents to be included in the Submission Dossier.

2. Implementation schedule

This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed on 12 December 2014. This revision of the guidance document was noted in March 2016 and should be used for dossiers prepared for active substances which are micro-organisms including virus 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 for which an application for the approval or renewal of approval has been submitted as from 1 October 2016.
The current document should be followed also for the supplementary dossiers submitted according to Regulation (EU) 2016/183[2] setting the RMS and co-RMS for the AIR4 programme.

3. Table of Contents

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

- new locations for information and data previously submitted;
- the fact that 'annex points' have become 'data points';
- some approaches how to address data points.

The downloadable file contains the final “Microbials revised EU CADDY Table of Content”

- ToC MA revised EU (Microbial agent)
- ToC MP revised EU (Microbial product)

Click to view file

[1] According to Article 3(15) of Regulation (EC) No 1107/2009 *‘micro-organisms’ means "any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material”*.

[2] Commission Implementing Regulation (EU) 2016/183 of 11 February 2016 amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest.

4. Documents to be included in a submission

The **Appendix** describes the summary and supporting documentation to be included in a submission made within the scope of this guidance document.

It is proposed that applicants provide Document N1 (overall summary) and Document N2 (Endpoints) as separate documents. This is reflected in Table of Contents for the CADDY.

5. 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 are included as Tab 1 and Tab 2 of the CADDY TOC excel document included at Chapter 3 above. Some titles have been shortened to keep them with 100 characters for CADDY compliance.

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

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

The existing microbial dRR templates are available on this link.

Appendix Description of documents to be included in a submission

Documents[1] Revised EU Document	Document Title	Additional notes	Templates
Document A	Statement of the context in which the dossier is submitted	*Unchanged*	*Template not available*
Document B	Documentation relating to the joint submission of dossiers	*Unchanged*	*Template not available*
Document C	Existing or proposed labels	*Unchanged*	*Template not available*
Document D-1	Intended uses supported in the EU for which data have been provided	*Unchanged*	*Template not available*
Document D-2	List of currently authorized uses and extent of use	*Unchanged*	*Template not available*
Document E-1	Listing of EU MRLs	*Unchanged*	*Template not available*
Document E-2	Listing of MRLs in exporting countries	*Unchanged*	*Template not available*
Document F	Notification submitted to the Commission	*Unchanged*	*Template not available*
Document G	Permission of each formulant in accordance with EU legislation	*Unchanged*	*Template not available*
Document H	Safety data sheets for the formulants	*Unchanged*	*Template not available*
Document I	Other data on the formulants	*Unchanged*	*Template not available*
Document J	Confidential data and information	Reflecting Annex to Regulation 283/2013 and Annex to Regulation 284/2013	*Template not available*
Document K[1]	Study reports	Reflecting Annex to Regulation 283/2013 and Annex to Regulation 284/2013	*CADDY TOC available (CADDY website)*
LMA Section 1[1]	Identity of the micro-organism; Reference List	Should reflect guidance in SANCO/12580/2012 Only required where there are references associated with the M summary document	*Template not available*
LMA Section 2[1]	Biological properties of the micro-organism; Reference List	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	*Template not available*
LMA Section 3[1]	Further information on the micro-organism; Reference List	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	*Template not available*
LMA Section 4[1]	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	*Template not available*

Documents[1] Revised EU Document	Document Title	Additional notes	Templates
LMA Section 5[1]	Effects on human health; Reference List	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	*Template not available*
LMA Section 6[1]	Residues in or on treated products, food and feed; Reference List	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	*Template not available*
LMA Section 7[1]	Fate and behaviour on 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	*Template not available*
LMA Section 8[1]	Effects on non-target organism; Reference List	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	*Template not available*
LMA Section 9[1]	Summary and evaluation of environmental impact; Reference List	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	*Template not available*
LMP Section 1[1]	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	*Template not available*
LMP Section 2[1]	Physical, chemical and technical 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	*Template not available*
LMP Section 3[1]	Data on application; Reference List	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	*Template not available*
LMP Section 4[1]	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	*Template not available*
LMP Section 5[1]	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	*Template not available*

Documents[1] Revised EU Document	Document Title	Additional notes	Templates
LMP Section 6[1]	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	*Template not available*
LMP Section 7[1]	Effects on human health; Reference List	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	*Template not available*
LMP Section 8[1]	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	*Template not available*
LMP Section 9[1]	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	*Template not available*
LMP Section 10[1]	Effects on non-target organisms; Reference List	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	*Template not available*
LMP Section 11[1]	Summary and evaluation of environmental impact; Reference List	Reference list (should reflect guidance in SANCO/12580/2012) Only required where there are references associated with the M summary document	*Template not available*
MMA Section 1[1]	Identity of the micro-organism	Reflecting Annex to Regulation 283/2013	*Template not available*
MMA Section 2[1]	Biological properties of the micro-organism	Reflecting Annex to Regulation 283/2013	*Template not available*
MMA Section 3[1]	Further information on the micro-organism	Reflecting Annex to Regulation 283/2013	*Template not available*
MMA Section 4[1]	Analytical methods	Reflecting Annex to Regulation 283/2013	*Template not available*
MMA Section 5[1]	Effects on human health	Reflecting Annex to Regulation 283/2013	*Template not available*
MMA Section 6[1]	Residues in or on treated products, food and feed	Reflecting Annex to Regulation 283/2013	*Template not available*
MMA Section 7[1]	Fate and behaviour on the environment	Reflecting Annex to Regulation 283/2013	*Template not available*
MMA Section 8[1]	Effects on non-target organism	Reflecting Annex to Regulation 283/2013	*Template not available*
MMA Section 9[1]	Summary and evaluation of environmental impact	Reflecting Annex to Regulation 283/2013	*Template not available*
MMP Section 1[1]	Identity of the plant protection product	Reflecting Annex to Regulation 284/2013	*Template not available*
MMP Section 2[1]	Physical, chemical and technical properties of the plant protection product	Reflecting Annex to Regulation 284/2013	*Template not available*
MMP Section 3[1]	Data on application	Reflecting Annex to Regulation 284/2013	*Template not available*
MMP Section 4[1]	Further information on the plant protection product	Reflecting Annex to Regulation 284/2013	*Template not available*

Documents[1] Revised EU Document	Document Title	Additional notes	Templates
MMP Section 5[1]	Analytical methods	Reflecting Annex to Regulation 284/2013	*Template not available*
MMP Section 6[1]	Efficacy data	Reflecting Annex to Regulation 284/2013 (efficacy summary required in MMP Section 3)	*Template not available*
MMP Section 7[1]	Effects on human health	Reflecting Annex to Regulation 284/2013	*Template not available*
MMP Section 8[1]	Residues in or on treated products, food or feed	Reflecting Annex to Regulation 284/2013	*Template not available*
MMP Section 9[1]	Fate and behaviour in the environment	Reflecting Annex to Regulation 284/2013	*Template not available*
MMP Section 10[1]	Effects on non-target organisms	Reflecting Annex to Regulation 284/2013	*Template not available*
MMP Section 11[1]	Summary and evaluation of environmental impact	Reflecting Annex to Regulation 284/2013	*Template not available*
Document N1	Overall summaries	Reflecting Annex to Regulation 283/2013 and Annex to Regulation 284/2013	*Template not available*
Document N2	Endpoints	This LOEP template reflects the new data requirements for microbial agents and products as set out in Commission Regulations (EU) No 283/2013 and 284/2013 of 1 March 2013, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.	*Download template*
Document O	Initial evaluation forms	*Required only by request of the RMS or Co-RMS*	*Template not available*
Document OMA	Microbial pest control agent	Reflecting Annex to Regulation 283/2013	*Template not available*
Document OMP	Microbial pest control product	Reflecting Annex to Regulation 284/2013	*Template not available*

[1] 'AII' and 'AIII' prefixes referred to Directive 91/414/EEC and are no longer appropriate:

- **AII** will be replaced with **MA** (Microbial Agent)
- **AIII** will be replaced with **MP** (Microbial Product).