EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and biocides

SANTE/2016/11449

7 December 2016

Template for Submission Demonstrating Access to a Complete Package According to Regulation (EU) 283/2013 and for the Data Matching Step

Revision history

When	What

Contents

1. BACKGROUND

Regulation (EC) No 1107/2009 (hereafter the Regulation) provides that application for a product authorisation shall be accompanied by a complete and a summary dossier for each point of the data requirement of the active substances[1]. For renewal of the product authorisations, authorisation holders seeking the renewal of their authorisation shall submit any new information required as a result of amendments in data requirements or criteria.

The template in the appendix should be used by the applicants to list up and justify the access to a full and equivalent data package for the related active substances. It should be used in conjunction with

- the Commission Regulation (EU) No 283/2013 of 1 March 2013, setting out the data requirements for active substances 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;
- the list of studies established according to Art. 60(1) and the related guidance document (SANCO/12580/2012);
- the guidance document on the renewal of authorisations according to Article 43 of Regulation (EC) No 1107/2009 or;
- the guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009

Applicants who were not the applicant supporting the approval (or the renewal of the approval) of the related active substances shall demonstrate that their active substance data package is equivalent to the one used to approve (or renew the approval of) the active substances.

The Rapporteur Member State for the active substance should complete the table with its conclusion whether the data necessary for the approval or the renewal of the approval of the active substance are matched or not. Where relevant, it should state whether the missing data are eligible as Cat.4 data[2] and when they should be submitted. After the submission deadline, it should update the table with its final conclusion on the data matching check.

It should be noted that some pieces of information to be filled out in the annex may be considered as confidential according to Article 63 of the Regulation.

2. IMPLEMENTATION SCHEDULE

This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed on 6-7 December 2016.

This template should be used for applications for product authorisations or renewals submitted as from 1 March 2017.

[1] According to Reg. (EC) No 1107/2009, the same will apply for safeners and synergists once these substances are approved.

[2] See Guidance document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (Document SANCO/2010/13170 rev. 14 or later)

APPENDIX

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE[1] APPROVAL OF [ACTIVE SUBSTANCE] (confidential)

Rapporteur Member State	Month and year	Active Substance[2] (Name)	Notifier

Active substance source =

Data requirement point / reference number	Study or test considered as relied upon and for which data protection has been claimed				Title of alternative study or case referenced / submitted by applicant			Reason for equivalence / justification for non-provision[3,4]	Cat. 4 data[5]		RMS Opinion[4,6,7] a) GLP-compliant? b) Guideline-compliant? c) Equivalent endpoint?
	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not		Y/N	Submission deadline	
											Acceptable/Not acceptable *a) Y/N* *b) Y/N* *c) Y/N*

Notes on completion of table

1) Strike out in case of data matching for a new active substance.

2) Where relevant, please include the variant name of the active substance.

MATCHING ACTIVE SUBSTANCE DATA NECESSARY FOR THE RENEWAL OF THE[1] APPROVAL OF [ACTIVE SUBSTANCE] (confidential)

Rapporteur Member State	Month and year	Active Substance[2] (Name)	Notifier

3) The list of studies according to Article 60(1) of the Regulation for which data protection is sought must be carefully checked. For more information, refer to the specific Guidance Document[3]

4) Any alternative studies / cases submitted or referenced by the applicant must *match* those data requirements. Checks should establish that they satisfactorily address the regulatory requirement:
   a) Does the protocol to the study follow the GLP guidelines?
   b) Does the study follow the appropriate protocol/modelling?
   c) Do(es) the proposed end-point(s) in the study fall within the same range as the EU-agreed end-point(s)[4]?

5) Columns to be filled out only for data matching performed according to art. 43. Where no cat. 4 data are sought, please delete.

6) Opinion of the RMS (see point 4 for criteria)

7) In case cat. 4 data matching studies are agreed, the RMS should update their opinion after the submission deadline.

[3] Guidance document on preparing lists of test and study reports according to Article 60 of Regulation (EC) No 1107/2009 (Document SANCO/12580/2012– rev. 3.1 or later)

[4] Note if another applicant derives a significantly more critical end-point from their study, then they are under obligation to report this to the COM as adverse data, according to art. 56