EUROPEAN COMMISSION
HEALTH & FOOD SAFETY DIRECTORATE-GENERAL

Food and feed safety, innovation
Pesticides and biocides

SANCO/12580/2012– rev. 4
22 March 2019

GUIDANCE DOCUMENT ON PREPARING LISTS OF TEST AND STUDY REPORTS ACCORDING TO ARTICLE 60 OF REGULATION (EC) No 1107/2009

Revision history

When	Applicability	What
Rev. 3.1 of 17.05.2013		In Chapter 2 the application date has been amended so that now the Guidance Document applies to applications submitted from 1 January 2014 onwards.
Rev. 4 of 22.03.2019	For (supplementary) dossiers submitted on or after 1 October 2019	Amendments made to reflect updates to relevant Regulations and Guidance Documents The format for lists of studies has been updated to ensure that it is indicated whether a study was used in a previous EU assessment or, when the information is

		available, whether the study was already submitted in the framework of national authorisations.

Contents

1. Introduction

The existing *Guidance document on preparation of lists of studies relied upon with a view to Annex I-inclusion of existing active substances* (SANCO/10435/2004 15 April 2005 rev 7) was developed for substances for stages 2 till 4 of the review programme carried out under Directive 91/414/EEC. Because all decisions in the framework of the review programme have been taken it was not considered appropriate to update the existing guidance document but rather prepare a complete new guidance taking into account the provisions of Regulation (EC) No 1107/2009.

The relevant provisions in this respect are laid down in Articles 59 – 62 of Regulation (EC) No 1107/2009.

This Guidance Document will deal with applications for approval submitted under Regulation (EC) No 1107/2009, amendment of approval conditions or renewal of approval of active substances and related first authorisation, amendment of authorisation conditions or renewal of the authorisation of plant protection product. This Guidance Document is applicable to active substances as well as safeners, synergists and adjuvants. When in this document reference is made to 'active substances' it applies as well to safeners, synergist and adjuvants.

2. Implementation schedule

See the revision history for details on implementation of different versions of the document.

3. Responsibilities of the applicant during preparation of the dossier for approval/renewal of the approval of a.s. and preparation of the dossier for authorisation of a plant protection product

When preparing the dossier the applicant, in accordance with the guidance document on the preparation of the dossier[1] should annotate the listing of individual test and study reports to indicate whether or not data protection is claimed in accordance with the requirements of Article 59 of Regulation (EC) No 1107/2009 and which test and study reports should be considered as test and studies involving vertebrates in accordance with Article 62 of Regulation (EC) No 1107/2009. Subsequently if additional data are submitted applicants should at the same time update the list of studies and send it to the RMS.

For renewal or re-authorisation submissions the reference lists should include the newly submitted data relied upon as well as those original submitted tests and studies that are still considered relevant to support the application for renewal or re-authorisation. However these studies should be clearly identified in the reference list.

Therefore, in order to facilitate the compilation of the list of the essential studies and corresponding data protection, the applicant should indicate whether the study was used in the DAR or, when the information is available, whether the study was already submitted in the framework of national authorisations.

[1] 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). Document 663/VI/94 Rev 8, 22 April 1998 (since 01 January 2005 replaced by OECD Dossier Guideline)

4. Test and studies involving vertebrate animals

According to Article 62 of Regulation (EC) No 1107/2009 tests and studies on vertebrates should be avoided. In addition, studies involving vertebrates should be listed in a separate list to be able to easily identify them in order to avoid the duplication of testing and to facilitate the sharing of costs and results. The Directive 2010/63/EU on the protection of animals used for scientific purposes sets rules on how to conduct vertebrate studies and it supersedes the Directive 86/609/EEC which is mentioned in recital (40) of Regulation (EC) No 1107/2009. The terms "tests and studies involving vertebrate animals" should be interpreted as experiments within the scope of Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes and after 1 January 2013 within the scope of Directive 2010/63/EU on the protection of animals used for scientific purposes.

In the context of a first authorisation, amendment of the authorisation conditions or renewal of the authorisation, all studies concerning the active substance, safener or synergist, adjuvant and the plant protection product involving vertebrate animals should be listed separately.

5. Responsibilities of the RMS during preparation of the DAR/RAR

The rapporteur Member State should include in the Draft/Renewal Assessment Report (DAR/RAR) a reference to each test and study for each data requirement relied on for the assessment in the form of a list including the title, author(s), date of study, GLP or GEP status, owners name, if any, the claim made for data protection and if the study should be considered a study on vertebrates. Confidentiality can be claimed for the names and addresses of persons involved in testing of vertebrates.

This is further presented in the Templates to be used for assessments reports and proposals for classification (2018) available on the European Commission website, which requires two lists of tests and studies to be prepared:

- Volume 2 is a list of all information, tests and studies submitted;

For (draft) renewal assessment reports the reference lists for each section should include also those studies that were submitted to support the approval or subsequent renewals.

- Volume 3, at the end of each chapter, a list is required of information, tests and studies evaluated and relied on.

For (draft) renewal assessment reports the reference lists at the end of each section/chapter (sorted by data requirement) should include the newly submitted data relied upon as well as those original submitted tests and studies that are still considered relevant to support the application for renewal. However these studies should be clearly identified in the reference list as well as in the individual study sections. This could be done by consistent use of a statement for each study as presented in the respective Appendix of the EFSA Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances (2019).

It should also be noted that the structure of the DAR/RAR ensures that all confidential information is reported in the separate volume 4. It should be ensured that the study lists themselves do not contain confidential information such as names of impurities, and names and addresses of persons involved in testing on vertebrate animals. Information that

normally should be considered confidential is listed in Article 63 of Regulation (EC) No 1107/2009. A procedure for removal of confidential information and sanitization of documents (summary dossiers, DARs/RARs, etc.) has been elaborated by EFSA with shared responsibilities between EFSA and RMS (Identification and removal of confidential information from documents to be made available to the public by EFSA under Regulation (EC) No 1107/2009) (see EFSA Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances (2019)).

To ensure that these responsibilities are standardised as far as possible the following criteria should be used:

For the lists provided in Volume 2

Volume 2 should include all test and study reports and published papers submitted in support of the application and should include other relevant information available to, or brought to the attention of, the RMS. Special attention should be paid to scientific peer-reviewed open literature (see chapter 8 of this Guidance Document).

For the lists provided in Volume 3

The lists provided in Volume 3 should be compiled having careful regard for the results of the evaluation and assessment(s) of the dossier submitted.

In order to ensure scientifically unacceptable studies are not included in the list of studies relied on it is expected that the RMS will conduct and present a summary, evaluation and assessment of each study. In particular it is expected that for each study the evaluation presented in Volume 3 will contain a brief statement as to the acceptability of the study, as presented in the EFSA Administrative Guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances (2019). In the case of it not being of acceptable quality, a concise statement of the rationale used in reaching that conclusion must be included, having regard to both information contained in the study report and information not so included.

The decision on the acceptability of studies should take into account:

- the applicability of GLP and officially recognised testing facilities according to the provisions in Article 3(19) of Regulation (EC) No 1107/2009 and Article 3 of Annex of Regulation No 283/2013 and 284/2013;
- the suitability of the test method used, having regard to the justification provided for use of methods other than those specified in Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013;
- where there are deviations from the test guidelines specified, or from other methods used, the suitability of the test method actually used, having regard to the justification provided for the deviations concerned;
- where the identity of the test substance or material has not been adequately specified, or its stability in dosing vehicles or solvents used is questionable, the reliability or usefulness of the test or study concerned.

Only information, tests and studies regarded as being scientifically acceptable and relevant for the assessment should be considered for inclusion in the lists provided in Volume 3. Information, tests and studies included in the list are those without which it would not be possible to come to a decision on the approval of the active substance having regard to:

- the criteria specified in Article 4 of Regulation (EC) No 1107/2009;

- the extent that they are relevant, in the context of the supported representative uses, in light of the criteria for evaluations and decisions with regard to authorisation of plant protection products as specified in Regulation (EU) No 546/2011.

The list would therefore include all appropriate studies specified in Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 and required for approval of the substance. It should be noted that:

- higher tier studies which have been provided to refine the risk assessment, for example mesocosm studies and operator biomonitoring studies, should be included. However specific care should be taken to attribute such data to the correct data requirement (for the active substance or for the PPP).

- acceptable studies which, alone, do not address fully a particular requirement or concern identified in the context of approval of the active substance but together contribute to a weight of evidence approach (extent, quality and consistency of data available) should all be included.

The following should not appear in the list:

- studies which are identified in the DAR as being of unacceptable quality.

- studies that are clearly not relevant to the assessment in the context of the supported representative uses in the dossier.

- studies that address a specific Member State's concern and are not a point of the data requirements according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013.

6. Procedure for finalising and making available the list of information, tests and studies relied upon during the peer-review process

The RMS should prepare the list of all references relied upon as a stand-alone document after the peer review has been finalised. The list should be taken from Volume 3 of the DAR/RAR (see "Templates to be used for assessments reports and proposals for classification" (2018)). The following header is added:

List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the (renewal of) approval of the active substance

The finalised list should be available at the latest by the time of voting in the Standing Committee on the Food Chain and Animal Health but ideally should be made available by the rapporteur Member State once the EFSA Conclusion is available. The EU Pesticides Database is updated with the final list provided by the rapporteur Member State alongside the finalised Review Report.

7. Responsibilities of the MS during authorisation of a PPP

The responsibilities as stated in chapter 5 and 6 apply *mutatis mutandis* for every plant protection product which is authorised by a Member state. This concerns a first authorisation, amendment of authorisation conditions or renewal of an authorisation.

Member States when they grant an authorisation are obliged according to article 60.2 to keep and make available to any interested party upon request:

(a) a list of the test and study reports concerning the active substance, safener or synergist, adjuvant and the plant protection product necessary for first authorisation, amendment of the authorisation conditions or renewal of the authorisation; and

(b) a list of test and study reports for which the applicant claimed data protection under Article 59 and any reasons submitted in accordance with that Article.

In preparing such lists MS should rely on the information provided by applicants having in mind that only the data that have been actually been taken into account in the decision for authorisation of the product should be included in the list.

For re-authorisation submissions the reference lists should include the newly submitted data relied upon as well as those original submitted tests and studies that are still considered relevant to support the application for re-authorisation. However these studies should be clearly identified in the reference list.

8. Scientific peer-reviewed open literature

According to Article 8(5) of Regulation (EC) No 1107/2009 the dossier should also contain "*scientific peer-reviewed open literature, as determined by the Authority, on the active substance 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*". To include peer-reviewed open literature the applicant should follow the recommendations included in the European Food Safety Authority guidance on the 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).
The RMS should follow the instructions in the " Templates to be used for assessments reports and proposals for classification" in which is stated that relevant literature references should be included in the list of references relied upon in the chapter of Volume 3 of the assessment report where the literature study has been evaluated.

9. Format for lists of test and study reports

The existing format had to be amended to refer to the data requirements in Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (instead of Annex point).

The following prefixes should be used:

- **AII** will be replaced with **CA** (Chemical Active);
- **AIII** will be replaced with **CP** (Chemical Product);
- For micro-organisms it will be **MA** and **MP**.

According to Article 60 two lists should be prepared: one for the active substance and one for each plant protection product.

Active substance

For each active substance, safener and synergist and adjuvant, the rapporteur Member State shall prepare a list of the test and study reports necessary for first approval, amendment of approval conditions or renewal of the approval and make it available to the Member States and the Commission.

Due to the fact that data protection claims are related to product authorisations a claim for data protection cannot be made at EU-level at the time of approval of the active substance. However, according to Article 7(4) "when submitting the application the applicant shall at the same time join……a list of any claims for data protection pursuant to Article 59."

Plant protection product

For each plant protection product which they authorise, Member States shall keep and make available to any interested party upon request:

- a list of the test and study reports concerning the active substance, safener or synergist, adjuvant and the plant protection product necessary for first authorisation, amendment of the authorisation conditions or renewal of the authorisation;

- a list of test and study reports for which the applicant claimed data protection under Article 59 and any reasons submitted in accordance with that Article.

Due to the fact that the reasoning for data protection claims should be provided an additional column is added to the reference list.

Format for lists with references (DAR/RAR) at EU-level:

References for the active substance: xxx

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?

[1] In order to facilitate the compilation of the final list of the tests and studies relied upon and the corresponding data protection, indicate whether the study was used in the previous DAR/RAR or, when the information is available, whether the study was already submitted in the framework of national authorisations.[2] See Art.3 of Annex of Regulation No 283/2013 and 284/2013.

[3] The RMS shall check that the GLP statement has been properly signed in the study report, that the study results are properly reported in accordance with GLP standards and following the relevant guidance by OECD on the review of the GLP status of non-clinical safety data (currently under development).

References for the plant protection product: xxx

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?

[1] In order to facilitate the compilation of the final list of the tests and studies relied upon and the corresponding data protection, indicate whether the study was used in the previous DAR/RAR or, when the information is available, whether the study was already submitted in the framework of national authorisations.[2] See Art.3 of Annex of Regulation No 283/2013 and 284/2013.

[3] The RMS shall check that the GLP statement has been properly signed in the study report, that the study results are properly reported in accordance with GLP standards and following the relevant guidance by OECD on the review of the GLP status of non-clinical safety data (currently under development).

Format for lists with references (PPP) at national level:

For each plant protection product the following two lists should be prepared:

References for the active substance: xxx

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?

[1] In order to facilitate the compilation of the final list of the tests and studies relied upon and the corresponding data protection, indicate whether the study was used in the previous DAR/RAR or, when the information is available, whether the study was already submitted in the framework of national authorisations..

[2] See Art.3 of Annex of Regulation No 283/2013 and 284/2013.

[3] The RMS shall check that the GLP statement has been properly signed in the study report, that the study results are properly reported in accordance with GLP standards and following the relevant guidance by OECD on the review of the GLP status of non-clinical safety data (currently under development).

References for the plant protection product: xxx

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?

[1] In order to facilitate the compilation of the final list of the tests and studies relied upon and the corresponding data protection, indicate whether the study was used in the previous DAR/RAR or, when the information is available, whether the study was already submitted in the framework of national authorisations..

[2] See Art.3 of Annex of Regulation No 283/2013 and 284/2013.

[3] The RMS shall check that the GLP statement has been properly signed in the study report, that the study results are properly reported in accordance with GLP standards and following the relevant guidance by OECD on the review of the GLP status of non-clinical safety data (currently under development).