



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food Chain
Chemicals, contaminants, pesticides

SANCO/2012/11251 rev. 4

12 December 2014

DRAFT

Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 (the Renewal Regulation)

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	What
Rev. 4 of 12.12.2014	The procedure and assessment of the specification of the active substance is described in chapters 4.2 and 5.4. The procedure regarding dossier submission, sanitisation and publication is described in chapter 4.9. Appendix II (efficacy information) has been deleted as now reference is made to the relevant section in the dossier. Chapter 4.6 has been amended accordingly.

TABLE OF CONTENTS

1.	BACKGROUND	3
2.	GUIDANCE ON APPLICATION	3
2.1	GENERAL	3
2.2	APPLICATION FORMAT	4
2.3	NEW INFORMATION.....	4
3.	GUIDANCE ON PRE-SUBMISSION MEETINGS	4
4.	GUIDANCE ON DOSSIER SUBMISSION	6
4.1	APPLICATION OF TECHNICAL GUIDANCE DOCUMENTS	6
4.2	SPECIFICATION OF THE ACTIVE SUBSTANCE	6
4.3	REPRESENTATIVE PRODUCT AND USES	6
4.4	DOSSIER FOR CLASSIFICATION AND LABELLING	6
4.5	DOSSIER FOR MRLS REVIEW.....	7
4.6	SUBSTANCE EFFICACY	7
4.7	SUBMISSION OF COPY OF THE ORIGINAL DOSSIER	7
4.8	SCIENTIFIC PEER-REVIEWED OPEN LITERATURE	8
4.9	DOSSIER SUBMISSION, SANITISATION AND PUBLICATION	8
5.	GUIDANCE ON THE PREPARATION OF THE DRAFT RENEWAL ASSESSMENT REPORT	9
5.1	DRAFT RENEWAL ASSESSMENT REPORT FORMAT	9
5.2	RMS AND Co-RMS COOPERATION	10
5.3	FIRST EVALUATION OF APPROVAL CRITERIA	10
5.4	ASSESSMENT OF THE SPECIFICATION OF THE ACTIVE SUBSTANCE	11
	APPENDIX I	12

1. Background

The renewal programme will be based on the provisions of Regulation (EC) No 1107/2009 concerning the placing on the market of plant protection products. The approval criteria in Regulation (EC) No 1107/2009 will apply to decisions to be taken on these substances. It is preferred to include certain elements in a guidance document to supplement the renewal regulation, and also to provide further details on the procedures to be followed.

This guidance document should be read in conjunction with the renewal regulation and Regulation (EC) 1107/2009.

2. Guidance on Application

2.1 General

Specific application provisions are included in the renewal Regulation (EU) No 844/2012. According to those provisions, applicants should use the format described in the Annex to that Regulation and identify the new information they intend to submit. Upon request more detailed information has to be provided according to the format which is laid down in Appendix I of this Guidance document and below described in point 2.3. This can especially be the case when the rapporteur and/or co-rapporteur is/are different from the original RMS or Co-RMS.

The applicants should identify the new information they intend to submit already in this first phase, as any new information submitted need to be justified in terms of change of data requirements, changes to scientific and technical knowledge, development of guidance documents, necessity to amend and/or extend the inclusion restrictions or changes in the range of representative uses. They should also provide a timetable for any new or on-going studies. The finalised studies have to be submitted with the dossier for renewal.

They shall also identify all information (giving reasons) that should be kept confidential and keep it physically separated and submit any data protection claims. The rapporteur Member State shall assess the confidentiality request and shall upon a request for access to information, decide what information is to be kept confidential. Information that normally should be considered confidential is listed in Article 63 of Regulation (EC) No 1107/2009.

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. Thus, any test or study involving vertebrate animals is considered as falling under this definition, where the vertebrate animals suffer any level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice. In the context of renewal dossiers, all studies involving vertebrate animals should be listed separately.

2.2 Application format

The format is given in the Annex to the renewal regulation.

2.3 New information

"New information" referred to in the renewal regulation is intended to set out the state of the art (documentation, decisions and issues) and should be prepared in the format given in Appendix 1. To facilitate the preparation of this document, Member States have to keep available or make available the review report from the approval or subsequent renewals, including the background documents A, B and C and appendices thereto, for consultation by any interested parties (e.g. potential applicants, Rapporteur Member State) or have to make it available to them on their specific request. It is considered that the RMS for the approval or subsequent renewals should assist in the provision of these documents. Review reports can be downloaded from the "EU Pesticides database" (http://ec.europa.eu/food/plant/index_en.htm). Most of the other documents will be available on CIRCA or should preferably be made available via CIRCA, provided that all confidential data have been deleted.

3. **Guidance on pre-submission meetings**

Such meetings can be organised at any time before the submission of the supplementary dossiers (i.e. before the submission of the application, if required). The objective of these meetings is to establish a common understanding between the applicant, RMS and Co-RMS regarding the dossier to be submitted. The discussion should be based upon the document containing the new information to be submitted as prepared by the applicant. A full in-depth evaluation of new data by the RMS –or Co-RMS- is not foreseen at this early stage. It should therefore be noted that the Member States authorities cannot be definitive on data requirements which are ultimately dependent on the full evaluation and peer review. The RMS may wish to discuss specific new issues relevant for the active substance with the European Food Safety Authority (Application Desk of EFSA: APDESK.applications@efsa.europa.eu) and other Member States.

In particular the meeting should:

- clearly identify the reference specification, however it must be ensured that confidential information as business and trade secrets will not be disclosed (in the case of multiple applicants and/or joint applications);
- clearly identify the preparations and range of uses (see Appendix II, table 2) to be supported;
- clearly identify the specifications and test materials used in the new studies; If the new (proposed) representative formulation is different to the former (reference) formulation it should be demonstrated by the applicant that differences are minor for

the different sections (ecotox, tox...) in case that data from the former (reference) formulation should also be used for the assessment of the new (proposed) formulation.

- identify the current classification status of the active substance and any factors that may have a influence on classification;
- reach an understanding of the guidance that will apply to the submission;
- draw attention to the EFSA manuals where relevant and make them available;
- systematically consider the potential issues that may arise in the evaluation with respect to the criteria in Article 4 of Regulation 1107/2009 (discussion can only be very preliminary based on the information given by the applicant at that time, as the decision on the applicability of the cut-off criteria is result of the main evaluation of the dossier) and Annex II to Regulation 1107/2009 including point 4 of Annex II (candidates for substitution);
- consider if the substance is to be proposed by the applicant as a 'low risk' substance;
- consider potential critical issues that may arise in the re-evaluation of the active substance in consequence of the provided new data and/or changes in the scientific and technical knowledge e.g. leading to changes in the previous evaluation of studies and the risk assessment based on those studies.
- take account of the documentation supporting the approval.

The following standard disclaimer should be used by Member States in all presubmission meetings:

This meeting is to assist the applicants in preparing their dossier. The advice given does not bind the Member States, EFSA or the European Commission and should not be seen to create any expectations on the part of the applicants concerned.

The following standard disclaimer should be used by Member States in all records and minutes of pre-submission meetings:

This is a record of pre-submission meeting held to assist the applicant in preparing their dossier. The advice given does not bind the Member States, EFSA or the European Commission and should not be seen to create any expectations on the part of the applicant concerned.

There are no legal restrictions to the number of pre-submission meetings. It is up to the applicant and RMS and Co-RMS to decide what is considered necessary for the respective active substance.

4. Guidance on Dossier Submission

Dossier contents is specified in the renewal regulation.

4.1 Application of technical guidance documents

The technical guidance to be applied should be that applicable at the time of submission of the supplementary dossiers.

4.2 Specification of the active substance

The parts of the dossier related to the specification of the active substance always have to be submitted. The site(s) of manufacture must be clearly identified and changes to methods of analysis, starting materials and the age of the 5 batch analysis data must be considered as this will be subject to detailed scrutiny by the rapporteur (see 5.4 below).

4.3 Representative product and uses

The range of supported uses should reflect a representative use pattern and including whenever possible the uses evaluated for the first approval. Details of the proposed GAP should definitely reflect the outcome of the discussion with the RMS –and Co-RMS- in the pre-submission meeting.

It has to be demonstrated that plant protection products containing the active substance will fulfil the requirements laid down in Article 4 of Regulation (EC) No 1107/2009.

It is preferable that the representative formulation contains only the active substance under review as the active ingredient. However, if no such product exists or is not selected as "representative" for other reasons, a representative formulation can be submitted containing one or more other substances.

Representative use should be on a widely grown crop in each zone, if not a justification has to be submitted.

A full dossier is required for the representative formulation chosen.

The principal uses to be supported should be those required by Regulation (EC) No 1107/2009, Article 8 (1) a – that is one or more representative uses on a widely grown crop in each zone, where commercial authorisations are granted or considered for, of at least one plant protection product. However, for renewal Article 14 establishes that the approval criteria should be satisfied for one or more representative uses of at least one plant protection product. Therefore, the applicants may wish to consider whether they should include additionally uses which will facilitate the authorisation of products in Member States within the zones in subsequent stages, including application of the risk envelope approach according to *Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”* (SANCO/11244/2011 rev 5, 14 March 2011).

4.4 Dossier for classification and labelling

Where it is considered that a change in classification is required (i.e. the revision of an existing classification based on new data/interpretation or a new proposal for classification) that potentially has a bearing on the approval criteria laid out in Annex II to Regulation (EC) No 1107/2009 then the submission of a classification and labelling

dossier (C & L dossier) to the European Chemicals Agency (ECHA) will be required. It should be clear that the applicant should make a proposal and then, if necessary, the RMS will submit an application to ECHA. In that case the RMS should notify ECHA as soon as possible (preferably already at the stage of the pre-submission meeting/completeness check) with a notification –and proposal- in the 'registry of intention' to permit ECHA to plan its activities. As data should be prepared in IUCLID industry should follow the 'Guidance on the preparation of dossiers for harmonised classification and labelling' (http://guidance.echa.europa.eu/docs/guidance_document/clh_en.pdf) and submit the original proposal for C&L to the RMS. The format of the C&L report, to be prepared by the RMS, will have to be integrated to the extent possible in the DAR format. In the case of (proposed) reclassification, the RMS will have to send in parallel to EFSA and ECHA the draft renewal assessment report on the active substance and a proposal for classification or reclassification.

4.5 Dossier for MRLs review

It is strongly recommended that applicants should submit all MRLs applications which they considered necessary for extension of uses or for possible amendment of existing MRLs (not only those relevant to the supported uses), in order to allow an efficient and comprehensive assessment for MRLs setting, including chronic exposure of consumers.

This should include – as far as possible – also applications for minor uses where a second party will be responsible for the application of an authorisation.

An MRL application form should be submitted in case a setting of an MRL for **a new use or a change of an existing MRL** is requested. The assessment of these MRLs will be included in the RAR as prepared by the RMS and peer-reviewed by EFSA.

4.6 Substance efficacy

The dossier should include an overview of the efficacy information concerning representative and supported uses already authorised in Member States according to the format provided in MCA section 3 (see GD SANCO/10181/2013). Information as regards the representative uses and the supported uses has to be reported as part of chapter C 3.3 (MCP section 3). Information about their current authorisation status is reported in Doc D-2.

Considering that the substance is approved and authorisations of plant protection products containing the substance have already been evaluated according to the Uniform Principles (Regulation (EC) No 546/2011), no other efficacy documentation is deemed to be necessary at this stage.

4.7 Submission of copy of the original dossier

Where requested and the applicant has physical access to the dossier, relevant parts of the original dossier and any relevant updates should be provided to Member States and EFSA in the form they were submitted (EFSA will systematically request the original Annex I dossier). Where the applicant does not have access to the original dossier (for example a new manufacturer is supporting the substance and the original one is not) then the relevant Member States and the Commission will agree how the relevant parts of the dossier can be provided to the Member States who require it or EFSA.

In addition EFSA may request for more elaborated study summaries and/or in some areas (e.g. ecotox) advances in science may trigger the need for a 'new' evaluation of old studies. However, the re-evaluation of old studies should not be required on a routine basis on all studies, but on a case-by-case basis.

4.8 Scientific peer-reviewed open literature

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).

4.9 Dossier submission, sanitisation and publication

In order to avoid unnecessary submissions of documents the **supplementary dossier**, the derived **supplementary summary dossier** and the **sanitised** version of the **supplementary summary dossier** will be submitted at the same time to EFSA, i.e. **after the evaluation and decision of the admissibility by the RMS**. In this way EFSA receives only the final versions and only one shipment is needed from the applicant. Note that EFSA will only accept **electronic versions** of all documents (including the applications).

As EFSA needs to upload **the sanitised supplementary summary dossier** on their web pages, applicants are requested to submit stand-alone pdf files of all documents (A-F, I and L-O).

According to Regulation (EU) No 844/2012 the evaluation of the confidentiality claims for the supplementary summary dossier is performed at RMS level in the beginning of the procedure (Art 8.1) and at the level of EFSA for the updated version of the supplementary summary dossier at the time of the submission of the draft renewal assessment report (dRAR) (Art 11.8). In both cases EFSA should make these sanitised documents available to the public.

To make it clear who (RMS or EFSA) was responsible for the sanitisation of which part of the dossier (original or updated) and which part of the dossier was updated the following procedure should be followed:

- The applicant submits the confidentiality claims for the supplementary summary dossier at RMS level in accordance with Art. 8(1);
- The applicant provides EFSA with the sanitised supplementary summary dossier prepared according to the agreement with the RMS and the justification form with the agreement of the RMS on the sanitisations. EFSA makes the sanitised version available to the public (Art. 8(4));
- At the time of dispatch of the dRAR, EFSA will ask the applicant to supply EFSA with an updated sanitised supplementary summary dossier (detailed instructions on the preparation are provided in the next paragraphs).
- Upon agreement between the applicant and EFSA (Art. 11(8)), EFSA will make this document available to the public in accordance with Art. 12(4). This document will replace the original version.

Some additional procedural and practical aspects related to the submission of the dossiers are listed below:

- At time of the dispatch of the dRAR to the applicant, EFSA will ask for the submission, within 2 weeks, of the **updated sanitised supplementary summary dossier**, together with a **justification form** requesting for information to be kept confidential. This dossier will be presented under the form of a **consolidated version** of the **sanitised supplementary summary dossier** by adding, to the already published version, the additional information requested by the RMS during risk assessment, in highlight. In this dossier the information that is claimed to be confidential in the new, highlighted parts, will be sanitised by the applicant. EFSA will assess these confidentiality claims and inform the applicant of its decision. In case changes would be needed the applicant will submit ASAP a corrected version to EFSA.
- EFSA will replace the original sanitised supplementary summary dossier with the updated sanitised supplementary summary dossier. This in order to avoid confusion, the old version will remain available upon request.
- In order to group the sanitisation processes EFSA will ask to submit sanitisation requests for the new/revised sections in the updated supplementary summary dossier together with the request for sanitisations to the dRAR. Both sanitisation requests will be handled by Application Desk in EFSA as already in place, Applicants are contacted via email to reach an agreement whenever doubts are raised by EFSA on the eligibility of the proposed sanitisations.
- In order to be able to distinguish between the different files uploaded in the EFSA register of questions the following naming convention will be used by EFSA:
Active substance_APPL-XX for the sanitised application in the case there is more than one applicant,
Active substance_SSSD_CA/CP-XX for the original sanitised supplementary summary dossier,
Active substance_SSSD_updated-XX for the updates to the sanitised supplementary summary dossier.
In case there is more than one applicant the files will be numbered (**XX**) in order of publication and the name of the applicant will be specified in the searchable data field of the system (as is the legislation). In case separate dossiers are submitted for the active substance and the plant protection product the conventional codes **CA/CP** will be used to distinguish.

5. Guidance on the preparation of the Draft Renewal Assessment Report

5.1 Draft renewal assessment report format

The Draft renewal assessment report should follow the formatting guidelines for Draft Assessment Reports (DARs), including the "Template to be used for assessment reports regarding Level 3 of Volume 1 (SANCO/11114/2012)". In principle a complete new assessment report should be prepared in stead of an addendum to the original DAR, meaning one single document including the old data. Only new data should be assessed hence the previously submitted and accepted data should not be re-opened, unless such is necessary in the light of current scientific and technical knowledge which may require a re-assessment of old data, e.g. re-evaluation of soil metabolism studies according to

FOCUS degradation kinetics. Studies used for setting of endpoints should be checked and it should be ensured that the endpoint is still valid. This should be reported in a transparent way in the dRAR. Where relevant, the Draft renewal assessment report should include an assessment for MRLs in support of **a new use or a change of an existing MRL**.

Member States should ensure that they take account of all available information including any addenda to the original DAR and evaluations/conclusions presented, for example, in Reporting and Evaluation Tables.

The conclusion in the Draft renewal assessment report should address whether the requirements of Article 4 of Regulation 1107/2009 are satisfied. The report may also consider additional uses submitted according to point 4.3 of this document. The conclusion for these uses must be clearly distinct. The EFSA conclusion may also consider the additional uses.

A complete and up to date list of studies relied upon should also be included in the report. This should be prepared in line with the principles of the *Guidance Document on preparing lists of test and study reports according to Article 60 of Regulation (EC) No 1107/2009* (SANCO/12580/2012).

5.2 RMS and Co-RMS cooperation

Arrangements for working between the RMS and Co-RMS are not prescribed but should be left flexible to accommodate alternative approaches within the legal requirements set out in the renewal regulation. Possibilities include the Co-RMS preparing directly parts of the Draft renewal assessment report or peer reviewing the work of the RMS. It is recommended that the arrangements between RMS and Co-RMS are formalised. All exchanged information, e.g. during pre-submission meetings, should be shared with all parties involved.

5.3 First evaluation of approval criteria

The RMS has to start to examine the compliance to approval criteria as laid down in Article 4 (2) of Regulation 1107/2009 and when the criteria set out in points 3.6.2 to 3.6.4 and 3.7. of Annex II are not satisfied, the RMS shall limit the Draft renewal assessment report to that part (as laid down in Article 11(2) of Regulation (EC) No 1107/2009).

The Draft renewal assessment report should be completed despite the possible non compliance with the approval criteria of Annex II points 3.6.3. to 3.6.5 and 3.8.2. in case the applicant submitted documentation to demonstrate that the derogation of Article 4(7) of Regulation (EC) No 1107/2009) could be applied. Such documentation should be subject to an assessment included in "specific sections" of the Draft renewal assessment report.

5.4 Assessment of the specification of the active substance

In principle, the minimum purity and maximum contents of relevant impurities as originally set for the first approval of the active substance would be kept. However, in justified cases they would be amended as in case of safety concerns.

The rapporteur should evaluate the new data related to the substance identity (point 4.2) to assess whether the new data is in compliance with the reference specification or if it is equivalent according to SANCO/10597/2003. The result of this assessment may require an update of the reference specification. In particular the following should be considered:

- whether a new (relevant) impurity has been revealed by the application of improved analytical methods to technical material of the reference source; i.e. the detection of previously undetected (relevant) impurities;
- whether the reference specification is covered by the batches used in the toxicological and ecotoxicological studies or sufficient information is available that the reference specification does not have any harmful effect on human or animal health or any unacceptable effects on the environment. If this is not the case, than a new reference specification is necessary. In that case it should be checked, whether the new proposed specification could be considered to become the reference specification.

The rapporteur should include in the Renewal assessment report a recommendation as to whether the reference specification for first approval requires updating or if the reference specification is still applicable. These considerations will be reflected in the EFSA conclusion, where one is requested, and by the Commission when making the decision for renewal of the substance.

Appendix I

“NEW INFORMATION”

This document should describe the “state-of-the-art” prior to evaluation and preparation of the Draft renewal assessment report, with the purpose to:

- early in the process identify data gaps that need to be fulfilled at dossier submission, and
- identify areas on which the subsequent evaluation must be focussed.

1. BACKGROUND

[Brief overview with dates and decisions related to the approval or subsequent renewals of the active substance including listing of any specific provisions stated in the approval regulations; GAP included in the assessment for the approval; listing of data gaps identified during the previous evaluation and the subsequent peer review; identification of Addenda or evaluations in other forms such as statements in the assessment report of the previous process; details of the application for renewal of the approval. In addition the listing of end points agreed at the approval or subsequent renewals should be provided with any changes proposed (being derived from the assessment of the new studies or revised risk assessments presented in the renewal) being clearly identified by adding to the endpoints table a column to report the changes whenever possible.]

2. THE ACTIVE SUBSTANCE AND THE PLANT PROTECTION PRODUCT

[Identification of additional data needed for the re-assessment, such as batch no. and purity of test substance used for (old and new) toxicological and ecotoxicological studies, and justification for deviations from the profile of the active substance of the application for renewal; identification of the reference specification; potential data requested in case the formulation of the representative product will change since the approval or subsequent renewals of the active substance; justification for the assumption of minor differences between formulation with regard to physico-chemical properties, efficacy, and harmful (eco-)toxicological effects in cases where data from the old (reference) formulation should at least partly be used for the assessment of the new (proposed) formulations.]

3. SPECIFIC CONCLUSIONS BASED ON PREVIOUS EVALUATION

[Brief overview, section by section, of data available for the approval or subsequent renewals of the active substance and the conclusions of the previous evaluation; identification of potential areas of concern; guidance on what will be expected from the re-submission, with a view on new test methods and development of guidance since the approval or subsequent renewals.]

3.1. Identity, physical/chemical/technical properties and methods of analysis

[Subheadings to be added as appropriate.]

3.2. Mammalian toxicology

[Subheadings to be added as appropriate.]

3.3. Residues

[Subheadings to be added as appropriate – include information on current MRL status.]

3.4. Environmental fate and behaviour
[Subheadings to be added as appropriate.]

3.5. Ecotoxicology
[Subheadings to be added as appropriate.]

3.6. Definition of the residues
[Specification of matrices for which residue definition will be needed.]

3.7. Overview of compounds currently identified for the environmental compartments
[EFSA table format with metabolites identified in the previous evaluation, and studies currently available on them.]

3.8 Classification and Labelling
[Subheadings to be added as appropriate- – include information on current classification and labelling status]

4. LIST OF STUDIES TO BE GENERATED, STILL ONGOING BUT NOT EVALUATED AND/OR NOT PEER REVIEWED

[List of data gaps (identified in the previous sections 3.1-3.7) that need to be fulfilled at dossier submission or within the allowed time-frame thereafter; including studies made available during previous peer review but which were not subject to evaluation and reported in Addendum.]

5. IDENTIFIED AREAS FOR WHICH DETAILED RE-EVALUATION IS NEEDED IN DOSSIER FROM APPLICANT AND IN EVALUATION BY RMS/Co-RMS.

[A list of areas proposed to be addressed for which the previous assessment have identified potential concerns for human health or the environment, and/or for which there have been scientific and technical developments since the previous assessment.]