



EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Food and feed safety, innovation
Pesticides and biocides

SANCO/10180/2013– rev. 2
October 2021

GUIDANCE DOCUMENT ON RULES FOR REVISION OF ASSESSMENT REPORTS

**COMMISSION STAFF WORKING DOCUMENT – DOES NOT NECESSARILY
REPRESENT THE VIEW OF THE COMMISSION SERVICES**

This guidance has been developed in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation (EC) No 1107/2009, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

Contents

1. Introduction	3
2. Implementation schedule	3
3. When to update an Assessment Report	3
4. How to revise an Assessment Report	5
Annex	8

1. Introduction

The 'Template to be used for Assessment Reports' (SANCO/12592/2012) will already increase transparency and consistency in the documentation submitted and assessed in light of an application for an approval of an active substance. A next step is to move away from addenda to a consolidated Assessment Report which underpins the approval decision and supports future reviews/renewals.

This document provides guidance on *when* and *how* to update assessment reports and also presents a way to keep track of the different versions and how to name files to identify them in a unique way.

This guidance refers not only to approvals, but also to amendment of approvals, renewal of approvals and the assessment of confirmatory information.

An Assessment Report shall consist of the following parts: Volume 1, Volume 2, Volume 3 Active Substance part, Volume 3 Plant Protection Product part(s), Volume 4 Applicant part(s), as well as a List of Endpoints separated in an Active Substance part and Plant Protection Product part(s).

This Guidance Document is applicable to Assessment Reports in general. When in this document reference is made to 'Assessment Report' it applies as well to 'Draft Assessment Report', 'Draft Renewal Assessment Report' and 'Renewal Assessment Report'.

2. Implementation schedule

This document has been finalised in the Standing Committee on the Food Chain and Animal Health on 15.03.2013 and updated in the Standing Committee on Plants, Animals, Food and Feed on 21 October 2021. This Guidance Document should be used for assessment reports prepared for active substances submitted to the Commission as from 1 November 2021.

3. When to revise an Assessment Report

The Assessment Report (AR) shall be revised to incorporate new data and/or new assessments during the following processes under Regulation (EC) No 1107/2009:

- revision during peer review of AR prior to approval;
- evaluation of confirmatory information submitted according to Article 6f;
- amendment according to Article 7;
- renewal of approval according to Article 14;
- evaluation of new active substance data post (renewal of) approval

A revision may be triggered at different steps in in the process: before or after a decision on approval has been taken.

I. Before DECISION on APPROVAL

Preparation of the AR

Early drafts, such as exchanged between RMS and Co-RMS, are part of the preparation phase and considered internal. Therefore the first version is the AR as finalised and submitted to the Commission and copied to EFSA.

It is envisaged that revisions of the AR –as prepared by the RMS- will be required prior to the decision on approval. Revisions will be associated with the two key steps identified below:

1. Revision to support the expert consultation process (the term ‘expert consultation’ covers both physical meetings and teleconference discussions). Where this has been identified as being necessary for consideration in the expert consultation this will include amendments following the commenting round (as set out in the Reporting Table) and may involve the evaluation of additional information. It should be noted that, as expert meetings/discussions are focussed, revisions made at this stage may not be required to all sections of the AR. Depending on the individual case EFSA and RMS will consult on the extent of revisions required and deadlines taking into account the proposed expert consultation timetable and, where appropriate, the submission dates for additional information.
2. Revision required after the expert consultation process to ensure the AR reflects the agreed outcome of the risk assessment process.

This

- will include any revisions from the commenting round that have not already been done as part of 1. above; post-expert discussion ‘homework’ (i.e. actions identified post-meeting in the Evaluation Table), and;
- may include the evaluation of additional information that was requested by EFSA but not identified as necessary for consideration in the expert consultation process.

It should be noted that if there is no expert consultation scheduled for some disciplines then a single revision, of the relevant section(s), may result from this process to reflect commenting and/or additional information.

Note: Level 3 of Volume 1 should not be updated as this represents the view of the RMS at time of submission of the AR (according to Article 11(1)). Many parts of level 3 are contained either within the EFSA conclusion or in the Commission’s review.

II. AFTER DECISION on APPROVAL

Post approval the AR should be revised under each of the following circumstances:

- Confirmatory information (one or more data submission deadlines may apply): to be evaluated by RMS/DMS (Designated Member State) (see Guidance Document SANCO/5634/2009 rev 4.5 Dated July 2011);
- Amendment of the conditions of approval (as a result of confirmatory information/adverse data/change of reference values); to be evaluated by RMS/DMS/zRMS;
- New data changing reference values (ADI, ARfD, AOEL, or residue definition for commodities of plant and animal origin or any other endpoint related to the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II to Regulation (EC) No 1107/2009); to be evaluated by RMS/zRMS **New active substance data necessary for authorisation and resulting in a change of agreed EU endpoints – in particular for toxicological reference values and residue definitions** (see Guidance Document SANCO/10328/2004 rev. 9).

If the revised AR is referred to EFSA further revision may be necessary to reflect the commenting and, if required, expert consultation processes (as detailed above).

It is recognised that further data may be submitted as part of the zonal process or MRL process that will not be reflected in an amendment of the AR.

A procedure is lacking to agree and capture changes in endpoints that may occur from a zonal procedure e.g. related to application of new guidance.

Note: Adverse data may require a revision of the AR. However this will be determined by the COM on a case by case basis taking into account the seriousness and urgency of the concern (Art. 56 Regulation (EC) No 1107/2009).

For a schematic overview see flow chart in the Annex.

Not in all cases it will be necessary to amend the whole assessment report or a complete volume. The smallest piece of document to be submitted as a new version is:

- complete Volume 1 (except level 3);
- complete Volume 2;
- complete LoEP /active substance and/or complete LoEP / product, resp.
- Volume 3 / active substance: complete main chapter (B.1, B.2, ..., B.7,...);
- Volume 3 / product: complete main chapter (B.1, B.2, ..., B.7,...);
- complete Volume 4 (if separate Volumes 4 have been prepared because of multiple applicants only the Volume 4 which is affected by the change)

4. How to revise an Assessment Report

In revising an AR the tracked changes function should not be used. Instead changes to the text should be highlighted. New text should be highlighted yellow shading (text marker for small bits; 'fill with bucket' (fill out with colour) for larger parts). For parts which are no longer

valid the 'strike through' function should be used. When there are many changes in a paragraph the whole paragraph can be deleted by 'strike through' and a new paragraph (highlighted) can be added. Before starting a next revision the document should be cleaned of all shading and all invalid text should be deleted. Corrections of typos do not need to be highlighted.

In the Table of Contents (ToC) the subsections where the LATEST changes (between previous version and the recent one) occurred should be highlighted (yellow shading).

Version history

In the documents as listed above (*smallest piece of document to be submitted as a new version*) a page to be introduced between the cover page and the ToC should list all issue dates of versions in the following format: year, month, dd, such as 2013-02-28, 2013-04-01. In addition it should be indicated for each version why it has been prepared and –if relevant- what the major changes are. Volume 1 should always contain a full version history.

Dates in the header should be avoided because they are often forgotten to be updated and then can cause confusion.

Every document of an 'initial AR' should already contain the following table with the first line completed.

Version history (example Volume 3, chapter B.8)

When	What
2013-02-28	Initial DAR
2013-04-01	Amended subsection B.8.2.2 in light of comments and reporting table
2013-05-14	Amended subsection B.8.1.1 in light of evaluation of additional data on soil degradation. This changed the DT50 soil and accordingly triggered re-calculations of PEC soil and PEC gw. TER values (ref to Volume 1) had to be amended accordingly.
xxx	xxxx

Naming conventions

The following information should allow the reader to identify the file:

Type of document:

- DAR (Draft Assessment Report) – *according to Regulation (EC) No 1107/2009*
- DRAR (Draft Renewal Assessment Report) – *according to Reg. (EU) No 844/2012*
- RAR (Renewal Assessment report) – *according to Regulation (EU) No 1141/2010*
- AR (Assessment Report) – *according to Regulation (EC) No 1107/2009*

Part of document:

- Vol 1 (Volume 1) • Vol 2 (Volume 2)
- Vol 3 (Volume 3)
- CA or MA (Chemical Active or Micro-organism Active)
- CPx or MPx (Chemical Product or Micro-organism Product including manufacturer's code for the preparation or the name of the preparation)
- B-x (Chapter B-1, B-2, B-3, B-4, B-5, B-6, B-7, B-8, B-9)
- Vol 4x (Volume 4 including -in case of multiple applicants- identification of applicant)
- List of endpoints CA/MA or CPx/MPx

Date: yyyy-mm-dd

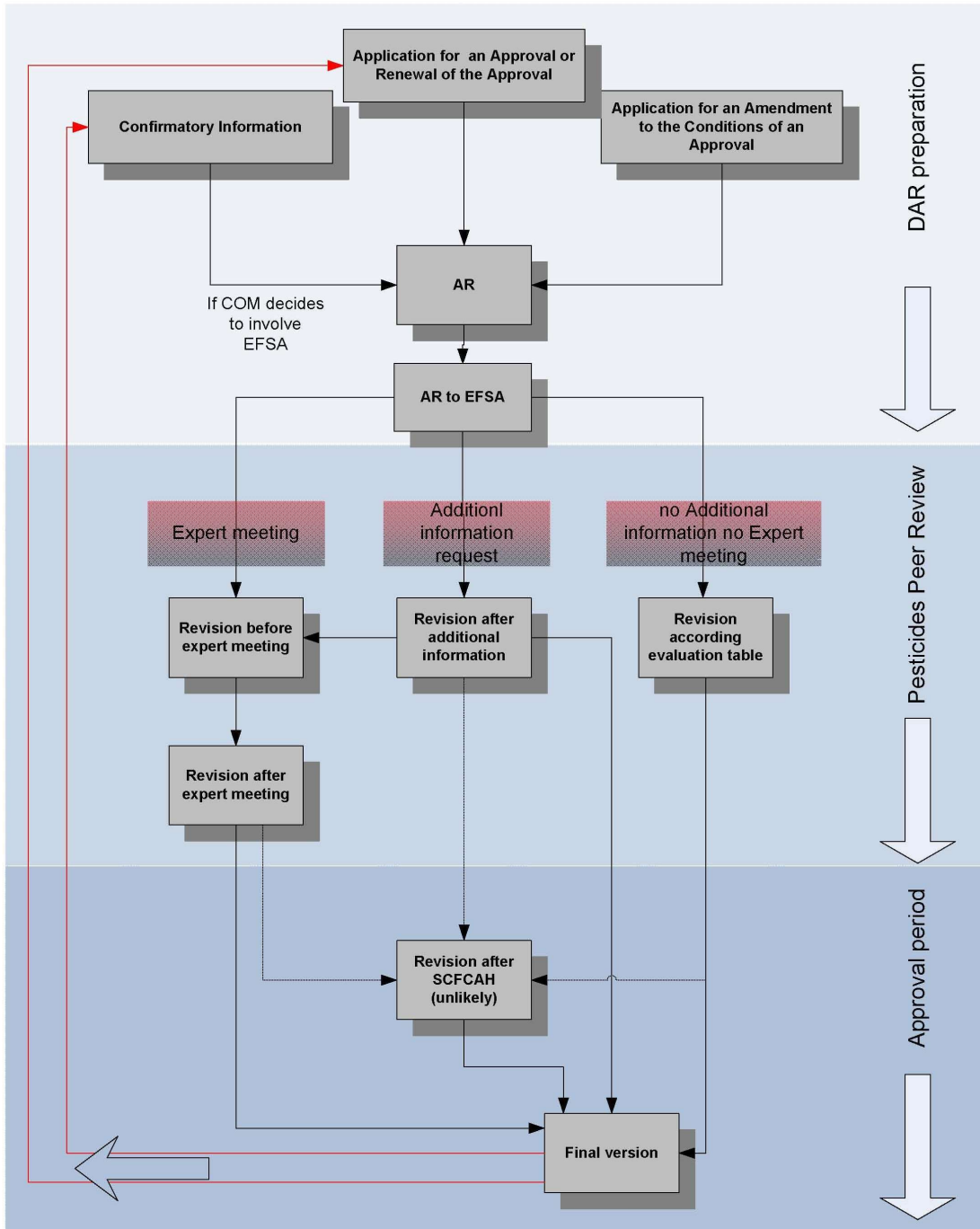
Example:

File: Draft Assessment Report
 Chemical Active: Isopyrazam
 Chemical Product: A15149W
 Applicant: Syngenta
 Date: 15 January 2013

Isopyrazam_DAR_01_Volume_1_2013-01-15
 Isopyrazam_DAR_02_Volume_2_2013-01-15
 Isopyrazam_DAR_03_Volume_3CA_B-1_2013-01-15
 Isopyrazam_DAR_04_Volume_3CA_B-2_2013-01-15
 Isopyrazam_DAR_05_Volume_3CA_B-3_2013-01-15
 Isopyrazam_DAR_06_Volume_3CA_B-4_2013-01-15
 Isopyrazam_DAR_07_Volume_3CA_B-5_2013-01-15
 Isopyrazam_DAR_08_Volume_3CA_B-6_2013-01-15
 Isopyrazam_DAR_09_Volume_3CA_B-7_2013-01-15
 Isopyrazam_DAR_10_Volume_3CA_B-8_2013-01-15
 Isopyrazam_DAR_11_Volume_3CA_B-9_2013-01-15
 Isopyrazam_DAR_12_LoEP_CA_2013-01-15
 Isopyrazam_DAR_13_Volume_3CP_A15149W_B-1_2013-01-15
 Isopyrazam_DAR_14_Volume_3CP_A15149W_B-2_2013-01-15
 Isopyrazam_DAR_15_Volume_3CP_A15149W_B-3_2013-01-15
 Isopyrazam_DAR_16_Volume_3CP_A15149W_B-4_2013-01-15
 Isopyrazam_DAR_17_Volume_3CP_A15149W_B-5_2013-01-15
 Isopyrazam_DAR_18_Volume_3CP_A15149W_B-6_2013-01-15
 Isopyrazam_DAR_19_Volume_3CP_A15149W_B-7_2013-01-15
 Isopyrazam_DAR_20_Volume_3CP_A15149W_B-8_2013-01-15
 Isopyrazam_DAR_21_Volume_3CP_A15149W_B-9_2013-01-15
 Isopyrazam_DAR_22_Volume_4_SYN_2013-01-15
 Isopyrazam_DAR_23_LoEP_CP_A15149W_2013-01-15

2013-01-30

DAR/RAR/AR revision*



*The revision of the DAR/AR/RAR would in most of the cases impact as well the list of end points.