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GUIDANCE DOCUMENT ON THE EVALUATION OF NEW ACTIVE SUBSTANCE DATA POST (RENEWAL OF) APPROVAL

This document has been conceived as a working document of the Commission Services, which was elaborated 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.

Revision history

When	What
Rev. 7 of 21.11.2011	Simplification of text by deleting repetitive paragraphs Update of document to reflect situation under Regulation (EC) No 1107/2009 Inclusion of chapter 5 on data protection
Rev. 8 of 24.01.2012	Some further editorial amendments
Rev.9 of 21.10.2021	Clarification of the assessment process taking into account the kind of new active substance data submitted

Contents

1. Introduction

This guidance document aims to give a systematic overview on the different reasons for submissions of further active substance data after its (renewal of) approval and the handling of such data with respect to (a) authorisation of plant protection products (Regulation (EC) No 1107/2009, Article 29) and (b) potential consequences for the approval of an active substance such as an amendment of the list of end-points or a review of the approval of the respective active substance according to Article 21 of the Regulation (EC) No 1107/2009.

The aim is:

- to establish a harmonised approach when no specific procedure is already established in this area in order to avoid unnecessary duplication of effort,
- to improve co-operation between the Competent Authorities of the Member States (MS) to ensure harmonised national and/or zonal assessments in the framework of authorisation of the plant protection products.

In general, this guidance has been developed in relation to the renewal of plant protection products, but could equally apply to the consideration of new data assessed in the frame of the authorisation of new products or amendment of an existing authorisation. It was originally developed with regard to new active substance data, but could equally apply to the evaluation of key product data in some cases. Finally, the current guidance document could also apply to any other relevant cases, for example information submitted by third parties.

It is highlighted that new active substance data apply to the parent compound and its metabolites.

Cases which are not covered by the current guidance document are detailed in § 4.2, as specific procedures are already established.

2. Revision history and implementation schedule

This document has been finalised in the Standing Committee on the Food Chain and Animal Health on 15.7.2005 and amended on 24.01.2012. It should be implemented as from 24.01.2012 (date of noting of the amended version by the Standing Committee on the Food Chain and Animal Health).

The document was further updated and noted by the Standing Committee on Plants, Animals, Food and Feed (PAFF legislation) on 21.10.2021. The updated version applies to submissions made from 01.11. 2021.

3. Background

There are a number of reasons why it can be necessary to submit further active substance data or why new information can become available to Competent Authorities of the MSs after the approval of an active substance and before its next scheduled renewal:

- New data submitted as part of an application for the authorisation of a product (or its renewal) according to Article 33/43 of Regulation 1107/2009:
  - To support uses other than those supported by available data as listed in appendix

II of the review report or the renewal report.

- To address issues that have been identified as requesting particular attention at Member State level or data gaps identified in the EFSA Conclusion, for which confirmatory information is not listed in the approval (or renewal) regulation. As a matter of principle, human health related effects are to be considered (e.g. relevance assessments of groundwater metabolites and/or metabolites considered for the residue definition of food of animal and plant origin). The scope of this bullet may be extended to other sections if active substance related issues only are concerned.

  For data falling under that point, the following is to be considered:

  - The assessment of the new active substance data shall be prioritised by the respective RMS;
  - The initiation of the assessment of the product submitted in accordance with Article 33 of Regulation (EC) No 1107/2009 shall not be postponed until the RMS has finalised its evaluation, however the product cannot be authorised before the new active substance data necessary for authorisation have been assessed and the resulting outcome/endpoint(s) has been agreed;
  - The Article 33 assessment may be finalised by the zRMS as soon as an agreed outcome/endpoint is available (it is not necessary to await the finalisation of the whole process as described in this guidance document)

- To complete the active substance data leading to the agreed EU end-point, in order to refine the risk assessment for the product.
- To demonstrate access to a complete data package according to Regulation (EU) 283/2013 (with the exception of vertebrate studies; refer to Article 62 of Regulation (EC) No 1107/2009 and to the Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009). All these active substance studies are considered for compliance (“data matching check”); the procedures are laid down in “GD on the Procedures relating to the authorisation of plant protection products following inclusion of an existing active substance in Annex I of Council Directive 91/414/EEC” (SANCO 10796/2003)[1]".

4. Assessment procedure

4.1. General points

The timing to evaluate the submitted data or information will depend on a number of factors. When data are evaluated, standard procedures are required such to ensure that multiple Member States do not duplicate the evaluation and to ensure harmonised assessments throughout the EU.

The authorisation/renewal of products following the approval (or the renewal) of an active substance should be undertaken in accordance with the scientific and technical knowledge in place at the time of submission of the dossier for the authorisation/renewal (see Articles 1, 29(1), 36(1), 43(1) and 56 of the Regulation (EC) No 1107/2009).

[1] New guidance document on data matching check is currently in progress (july 2020)

In principle the end-points established during the assessment for the approval (or the renewal) of the active substance must be used for the authorisation/renewal of the products.
If new active substance data submitted in the frame of standard active substance procedures (approval, renewal, confirmatory information,…) lead to a modification of the EU agreed end-points and published in the EFSA's conclusions, the list of end-points needs to be updated accordingly and the updated version then must be used.

If new active substance data are submitted in another framework i.e. as part of product applications, then it is necessary to set standard procedures in order to assess those data and to share the evaluations and to verify whether a peer review process at EU level would be necessary, or if a zonal process is sufficient.

MS could request advice from the Commission and the other MS to identify the process to be followed through PAI meetings.

It is important to highlight that in case of zonal processes, the conclusions of the evaluations can differ due to specificities in the zones (e.g. intended uses).

A pre-submission meeting between the applicant and the evaluating Member State (EMS) can be organised before the submission of the data. The EMS can advise on the procedure to be followed:

- The new active substance data should be assessed by the zRMS under the zonal process, see 4.3.1,
- The new active substance data should be assessed by the RMS/EMS at EU level, see 4.3.2.

When the situation is not clear for the MS who is contacted by the applicant, MS can refer to the PAI working group for further consideration.

4.2. New active substance data not triggering an assessment according to § 4.3

4.2.1 Data not to be evaluated prior to next renewal

Some new active substance data, made available by an applicant after the approval (or the renewal) of an active substance are not to be evaluated through a peer review immediately (prior to the next renewal); these data will be considered in the next "scheduled" European peer reviewed procedure for this active substance, i.e. when the approval is reviewed (renewal of approval of the active substance) or in the procedure of MRL setting/review according to Regulation (EC) No 396/2005.

This procedure applies to:
- Data submitted by applicants who are not the applicant for approval/renewal - compliance check ("data matching check"[2]): in principle, such data are not evaluated as not necessary to the product assessment and are only submitted for data access. In case those data trigger the need for an assessment according to Article 56 of Regulation (EC) No 1107/2009, the procedure as described in the corresponding Article has to be followed;
- Active substance data gaps listed in the EFSA conclusion and neither requested as confirmatory data nor necessary for authorisation;
- Additional active substance data submitted by the applicant and not necessary for authorisation;

[2] Guidance document on Data Matching for applications for authorisation of PPPs according to Article 33/43

- Following the implementation of new data requirements

4.2.2 Data evaluated in accordance with a specific procedure

- Any additional residue data required to set an EU MRL for a new crop, a more critical GAP or MRL Art.12 confirmatory data which should be considered under the procedures described in Regulation (EC) No 396/2005 and in the GD SANTE/2015/10595[3].
- Relating to confirmatory information requested in the approval (or renewal) regulation of the active substance; in this case, the assessment of such data must follow the process described in guidance document SANCO/5634/2009[4].
- When submitted for the finalisation of the reference technical specification and for equivalence assessment ; the assessment of such data must follow the processes described respectively in GD SANCO/6075/2009[5] and in guidance document SANCO/10597/2003[6].
- When submitted in the process detailed under Regulation (EC) No 1272/2008 related to classification and labelling.
- When submitted in accordance with Article 56 of Regulation (EC) No 1107/2009

4.3. New active substance data submitted as part of an application for the authorisation/renewal of a product to be evaluated prior to renewal of the active substance

4.3.1. New active substance data necessary for authorisation but not resulting in a change of agreed EU endpoints

Such data are needed for the evaluation and decision making of a product, e.g. to support uses other than the representative uses for the active substance approval. They can also be submitted in order to complete the active substance data leading to an EU agreed end-point to refine the risk assessment for the product. In cases where a safe use can only be demonstrated by using this refined end-point, zRMS/cMS will use it for the risk assessment / management (provided that the studies are valid). This means that such data are active substance data, but are handled as product data.

These data will be evaluated under the zonal process by the MS/zRMS receiving that application. It is the responsibility of the applicant to include the same active substance data in the zonal product dossiers and to inform the cMS as well. The assessments should be made available by the MS/zRMS in the format of the registration report (SANCO/6895/2009[7]) via CIRCABC, and all Member States (not only cMS) and EFSA are informed by e-mail (zonal contacts of all MS of the 3 zones + functional mailbox EFSA) that the assessment is available for commenting (Appendix 1) ; this procedure is already described in the Guidance document on zonal evaluation and mutual recognition (see App. 7 for standard form)[8]. The assessment should be made available

[3] SANTE/2015/10595 Rev. 5.4 dated 27 November 2018 and updates : Technical guidelines on the MRL setting procedure in accordance with articles 6 to 11 of regulation (EC) No 396/2005 and article 8 of Regulation (EC) No 1107/2009

[4] SANCO/5634/2009 rev. 6.1 dated December 2013 and updates : Guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009

[5] SANCO/6075/2009 rev. 3 dated July 2009 and updates : DRAFT Guidance document on the finalisation of the reference specification for technical active substances after the peer review

[6] SANCO/10597/2003 rev. 10.1 dated July 2012 and updates : Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009

[7] SANCO/6895/2009 rev. 2.2 dated January 2018 and updates : Technical guidelines on the presentation and evaluation of plant protection product dossiers in the format of a (draft) Registration Report

[8] SANCO/13169/2010 rev. Rev. 10 and updates : Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009

within the timelines specified in Regulation (EC) No 1107/2009, Article 33 or 43 for the authorisation or renewal of the authorisation of the product, respectively.
Although EFSA is informed, there is no involvement of EFSA or the European Commission, no amendment of the list of End-points (LoEP), Review Report or Implementing Regulation until the next renewal of the active substance.

4.3.2. 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

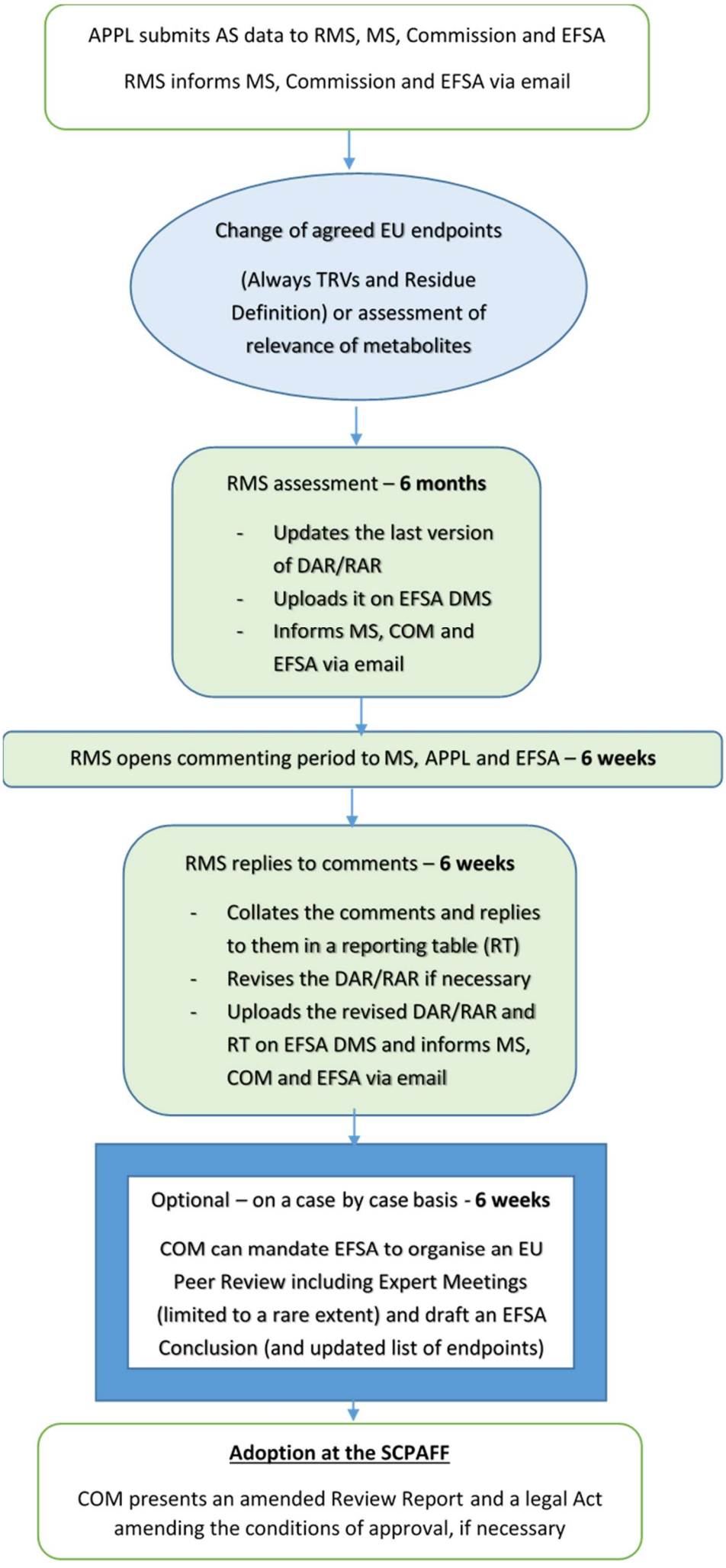
In all cases where the toxicological reference values (TRVs) i.e. ADI, AOEL, AAOEL, ARfD or the residue definitions need to be changed, or the relevance of metabolites needs to be assessed, the evaluation must be performed at EU level by the RMS for the active substance (from the most recent EU evaluation) and include a Peer Review by all MS and EFSA. In addition, changes to other agreed EU endpoints may also need to be evaluated at EU level following the same procedure. The RMS informs MS, EFSA and COM that assessment of active substance data is ongoing under chapter 4.3.2, using the list of contact points used by EFSA for communication to MS on active substance applications. EFSA is asked to create a corresponding folder on the DMS.

In all these cases, the outcomes of the Peer Review should be reported in an updated Review/Renewal Report. In some cases, this could lead to an amendment of the LoEP and/or to revised conditions of approval, which should be adopted by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF = section pesticides legislation).

As for TRVs, data submitted to change the residue definitions should always be assessed following the above procedure and agreed at EU level by the Standing Committee on Plants, Animals, Food and Feed.

The setting of new TRVs or residue definitions could trigger the need to revisit or prioritise the review of existing EU MRLs. A separate mandate for that should be considered by the SCoPAFF (sections pesticide residues and pesticides legislation), on a case-by-case basis.

The evaluation procedure described above is presented in the following flowchart:


APPL submits AS data to RMS, MS, Commission and EFSA
RMS informs MS, Commission and EFSA via email
Change of agreed EU endpoints
(Always TRVs and Residue Definition) or assessment of relevance of metabolites
RMS assessment – 6 months
- Updates the last version of DAR/RAR
- Uploads it on EFSA DMS
- Informs MS, COM and EFSA via email
RMS opens commenting period to MS, APPL and EFSA – 6 weeks
RMS replies to comments – 6 weeks
- Collates the comments and replies to them in a reporting table (RT)
- Revises the DAR/RAR if necessary
- Uploads the revised DAR/RAR and RT on EFSA DMS and informs MS, COM and EFSA via email
Optional – on a case by case basis - 6 weeks
COM can mandate EFSA to organise an EU Peer Review including Expert Meetings (limited to a rare extent) and draft an EFSA Conclusion (and updated list of endpoints)
Adoption at the SCPAFF
COM presents an amended Review Report and a legal Act amending the conditions of approval, if necessary

Applicability of the amended EU endpoint or residue definition

MS/zRMS can use the amended endpoint/residue definition only after formal adoption in the Standing Committee - the amended endpoint/residue definition will apply to all types of applications/procedures submitted by all applicants as from the date the new endpoint(s) are agreed.

For ongoing applications, updated endpoints can be used when the change was requested as part of a particular application and may also be taken into account by other applicants on request (e.g. in cases where the endpoint would be critical for a decision on authorisation).

MSs and COM may take a decision on the consequences of such amendments on authorised uses and/or the active substance approval, including for ongoing assessments, in particular in cases where safety concerns are indicated.

5. Data protection

Data protection provisions are described in corresponding Commission Notice 2019/C 229/01[9].

6. List of abbreviations

AAOEL	Acute Acceptable Operator Exposure Level
ADI	Acceptable Daily Intake
AOEL	Acceptable Operator Exposure Level
APPL	Applicant
ARfD	Acute Reference Dose
cMS	Concerned Member State
COM	European Commission
DAR	Draft Assessment Report
EFSA	European Food Safety Authority
EFSA DMS	EFSA's Document Management System
EMS	Evaluating Member State
GAP	Good Agricultural Practice
GD	Guidance Document
LoEP	List of End Points
MRL	Maximum Residue Level
MS	Member State
RAR	Renewal Assessment Report
RMS	Rapporteur Member State
RT	Reporting Table
SCoPAFF	Standing Committee on Plants, Animals, Food and Feed
zRMS	Zonal Rapporteur Member State

[9] Technical guidelines on data protection according to Regulation (EC) No 1107/2009, published on 9 July 2019.

Appendix 1 : standard email

Standard e-mail table to notify MS that an assessment is available for commenting (includes a row detailing the zRMS conclusion)

Note: please add EFSA in the mailing list as well as all zonal contacts

New active substance data have been assessed in this dossier according to GD on the evaluation of new AS data post approval (or post renewal) SANCO/10328/2004-rev9 and updates.

All MS (and not only cMS) are invited to comment on these specific data (see 'remarks' below in the following table).

Product code	
Product name	
Formulation type	
Active substance(s) name(s)	
and content(s)	
Low-risk substances	Yes/No
Applicant	
Authorisation holder	
Application reference code of zRMS (if available)	
Application for (type of application)	
Application as low-risk PPP	Yes/No
New / old product data requirement used	
Relevant zone and concerned Member States	
Direct link to the completed assessment uploaded to CIRCABC	
Direct link to part C uploaded to CIRCABC	
6 weeks deadline for comments (3 weeks for Article 43 applications or low-risk PPP)	
zRMS conclusion	
Please send comments to:	
Remarks:	Here precise sections concerned for new AS data: Here precise new AS data to be commented ***Warning**: if in the same dossier, AS data as described in § 4.3.1 and 4.3.2 have been evaluated, indicate that AS data described in § 4.3.2 are evaluated at EU level and should not be commented in this dRR.*