EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

SANTE/10235/2016 Rev. 4.1
23 February 2021

COMMISSION STAFF WORKING DOCUMENT[1]

Evaluation of data submitted to confirm MRLs following the review of existing MRLs

finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 23 February 2021

[1] Does not necessarily represent the views of the Commission.

PREFACE

The Transparency Regulation[2] amended the General Food Law[3] by introducing new requirements in the pre-submission phase and submission application procedure, such as:

- possibility to request for general pre-submission advice;
- obligation to notify information related to studies commissioned or carried out to support an application;
- submission of the application dossier using IUCLID format, including non-confidential version of the dossier;
- public disclosure of non-confidential version of all information submitted in support of the application and related confidentiality decision-making process;
- public consultation on submitted application dossiers.

These new requirements, as implemented by the Practical Arrangements laid down by EFSA, are reflected in the EFSA "Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure": https://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance.

It is noted that the new provisions presented in the above-mentioned guidance apply to all MRL applications submitted as of 27 March 2021. It is therefore advised to consult the EFSA administrative guidance to gather further details on the new procedure and obligations.

The new revision of the guidance document (SANTE/10235/2016 Rev. 4.1) has been presented and discussed at the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) - Section Pesticide Residues on 23 February 2021.

The SCoPAFF agreed that the new revision will apply to all MRL applications submitted as of 27 March 2021. For all applications submitted before 27 March 2021, all procedural steps as described in SANTE/10235/2016 Rev. 4 continue to apply.

[2] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

[3] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1.

Introduction:

Article 12 of Regulation (EC) No 396/2005 provides for a review by the European Food Safety Authority (EFSA) of the existing maximum residue levels (MRLs) for all substances approved as active substances in plant protection products, and for substances non-approved on or after 2 September 2008.

In the outcome of such reviews, EFSA recommends maintaining or amending MRLs, or highlights items for the consideration of risk managers. Within the latter, EFSA derives tentative MRLs that are not fully supported by data but for which no risk to consumers could be identified. EFSA also lists the data required to confirm those MRLs.

In that case, risk managers frequently decide to maintain resp. set the MRL tentatively derived by EFSA and to add a footnote to the MRL in the Annexes to Regulation (EC) No 396/2005. The footnote indicates the information identified as unavailable and that the Commission will take such information into account in a future review of the MRL, if submitted by the given date.

This Commission Working Document sets out the procedures for the evaluation of data submitted to address the lack of information as indicated in the footnotes. Other information identified as unavailable by EFSA but not indicated in a footnote to the MRL is not in the scope of this document.

Such data is referred to in the document as "confirmatory data". It should be stressed that such data must not be confused with confirmatory information in the sense of Article 6(f) of Regulation (EC) No 1107/2009, whose evaluation is the subject of a separate guidance document.

As a matter of principle, confirmatory data should support the cGAP identified in the MRL review.

Alternatively, an adjusted GAP may be supported, if it confirms the tentative MRL or leads to a lower MRL proposal. If the adjusted GAP leads to a higher MRL proposal, it should be evaluated following the standard procedures for setting new or modified MRLs, and this Working Document does not apply.

Member States agree that within the time period provided for submission of the confirmatory data, such data will not be considered as necessary information in a procedure to authorise a plant protection product, and its absence will not lead to a delay in the authorisation procedure, unless concerns are justified on a scientific basis. The same approach applies to the commercial availability of reference standards for substances where an 'A' footnote was added to the residue definition (see below).

General procedure:

- EFSA is involved in the assessment of confirmatory data in all cases, i.e. also when only residue trials are reported and no change of the MRL is needed.
- To achieve and maintain an up-to-date overview of confirmatory data requested and/or submitted, the Rapporteur Member State (RMS)/Evaluating Member State (EMS)

informs EFSA (via the functional mailbox pesticides.mrl@efsa.europa.eu) upon receipt of confirmatory data, through submission of the relevant information in the same format as the overview excel sheet. EFSA updates the overview table that is shared with Member States (read-only) on the EFSA Document Management System (DMS). EFSA will circulate on a regular basis (at least once per year) the overview table to Member States in order to verify completeness.

- Confirmatory data is submitted to EFSA by the RMS/EMS under the procedure set out in Chapter II of Regulation (EC) No 396/2005 (hereinafter "Article 10 application"), and the RMS/EMS prepares an Evaluation Report (ER; case 1). In case an application for a new use on that active substance has been received by the RMS/EMS, the RMS/EMS prepares one single ER covering both evaluations (combined submission of new use and confirmatory data; case 2). Given the complexity of requirements, applicants are strongly encouraged to consider submitting separate applications (for MRL confirmatory data and for new uses), unless confirmatory data and new use data are inherently linked.
    - If the confirmatory data are provided in the context of an application concerning only such confirmatory data (case 1):
        - Guidance documents in place at the time of setting of the confirmatory data request are applied. Reference date is the publication date of the relevant act in the Official Journal of the European Union.
        - Data requirements used in the initial Article 12 review are applied.
        - The same version of the animal dietary burden calculator used in the initial Article 12 review is applied, taking into account additional (more critical) uses assessed after the Article 12 review.
        - PRIMo rev. 3.1 shall be used. For the chronic exposure assessment, the STMR values derived for uses assessed in the framework of confirmatory data assessment shall be used. In addition, the STMR values corresponding to the MRLs established in the MRL legislation shall be used (i.e. STMR value for uses assessed in the MRL review, for MRLs modified after the MRL review, or for Codex MRLs implemented after the MRL review). The acute exposure assessment should focus on the uses subject to confirmatory data assessment. If a concern is identified for a commodity for which confirmatory data has been requested, the clock may be stopped for a maximum of 2 months, for applicant/RMS/EMS to supply information on a fall back GAP.
        - The following PROFile version is applied:

PROFile version in the initial Article 12 assessment	PROFile version to be used in the evaluation of confirmatory data	Main changes between the 2 assessments
2.1	2.3	- use of the OECD calculator for plant MRL - MRL for muscle instead of meat
2.2	2.3	- MRL for muscle instead of meat
2.3	2.3	/
3.0	3.0	/

- If the confirmatory data are provided in the context of an MRL application including additional new elements besides the confirmatory data (case 2):
  - Guidance documents in place at the time of the submission of the Article 10 application to the RMS/EMS is applied, also for assessing the Article 12 confirmatory data. The RMS/EMS unequivocally reports the date of submission by filling in Part C of the application form, which serves as the reference date.
  - Data requirements applicable to the Article 10 application are determined in accordance with Technical Guideline SANTE/2015/10595. The same data requirements then apply for assessing the Article 12 confirmatory data.
  - The version of the animal dietary burden calculator in place at the time of the submission of the Article 10 application is applied, also for assessing the Article 12 confirmatory data.
  - The version of PRIMo used for the Article 10 application and thus also for assessing the Article 12 confirmatory data is: PRIMo version 3.1 for all applications pending with EFSA (opinion or conclusion not yet adopted) on 01 January 2020 or submitted to EFSA as from 01 January 2020.
  - The following PROFile version is applied:

PROFile version in the initial Article 12 assessment	PROFile version to be used in the evaluation of confirmatory data	Main changes between the 2 assessments
2.1	3.0	- use of the OECD calculator for plant MRL - MRL for muscle instead of meat - OECD dietary burden calculator
2.2	3.0	- MRL for muscle instead of meat - OECD dietary burden calculator
2.3	3.0	- OECD dietary burden calculator
3.0	3.0	/

- The applicant should submit an application for Article 12 confirmatory data alongside the dossier containing the data needed for supporting the application using IUCLID format and submit them through the central submission system indicating the Member States to which they intend to submit the application (RMS/EMS) (for further details see the EFSA administrative guidance). Following receipt of the MRL application form, EFSA APDESK creates a folder on DMS and adds the application to the EFSA Collaboration table on DMS, clearly indicating if the application is on Article 10 (new use), or Article 12 Confirmatory data, or both. In case of a combined submission (case 2), two separate question numbers are created to ensure transparency and traceability of the different applications.
- In the context of the admissibility check of the application, the RMS should assess the compliance of the application with all relevant requirements, including with the obligations of study notifications laid down in Article 32b(2) and (3) of Regulation (EC) No 178/2002.

- Once the application is found admissible, the EMS notifies the applicant, EFSA, the European Commission and the Member States.
- At the reception of the notification of admissibility from the EMS, the application is registered in the OpenEFSA portal. Upon admissibility of the application, the non-confidential version of the application is proactively disclosed on the OpenEFSA portal. Following the implementation of the confidentiality decision, the non-confidential version of the application dossier is subject to public consultation.
- The RMS/EMS updates the Pesticide Residue Overview File (PROFile) and submits the PROFile and the supporting ER to EFSA.
- This triggers the inclusion of the application in the monthly Commission mandate. In this mandate, the Commission clearly indicates what the application is referring to (new use, confirmatory data, or both).
- EFSA specifies the deadline in the mandate acceptance letter as this is decided on a case by case level, depending on the amount and nature of the data.
- Both RMS/EMS and EFSA have the possibility to stop the clock for incomplete Article 12 confirmatory data applications. In view of the fact that the applicant was already given an extensive time period for addressing the confirmatory data, the clock stop period at RMS/EMS and EFSA will be limited to a maximum of 2 months each. If additional data are provided, EFSA shall receive an updated dossier in IUCLID format alongside an updated ER uploaded on the EFSA DMS. The confidentiality decision making process on the additional information provided, is performed only once after the output adoption.
- If after 2 months, no additional data have been received, the assessment will resume and RMS/EMS resp. EFSA will proceed with the finalisation of the ER resp. Reasoned Opinion, clearly listing (a) which confirmatory data have been addressed and (b) those confirmatory data for which insufficient information has been received and thus EMS/RMS resp. EFSA could not conclude if the confirmatory data requirement has been addressed. In case the Evaluation Report is combining an assessment of both an Article 10 application for a new use and for Article 12 confirmatory data (case 2), the clock stop shall be limited to 2 months for Article 12 confirmatory data and the standard 6 months for the data pertaining to the new use.
- EFSA provides a reasoned opinion (in the case of combined submission, one reasoned opinion will cover two question numbers) and publishes the ER as a background document to the reasoned opinion. In exceptional cases, an ad hoc MS consultation might be needed before finalising the reasoned opinion. EFSA updates the overview table accordingly.
- In case a consumer risk is identified, EMS and EFSA should report those findings. It is then the task of risk managers to find a solution.
- The Commission submits a draft Regulation deleting the footnote and, where appropriate, amending the MRL to the Standing Committee on Plants, Animals, Food and Feed.

Specificities for substances in the renewal process:

- The following paragraphs pertain to substances in the renewal process, i.e. between submission of the dossier for renewal to the RMS and submission of the RAR to EFSA. However, on a case by case basis, deviations from this approach can be agreed between RMS, EFSA and Commission. A separate ER should be submitted where the RAR is already finalised or at a very advanced stage, or where the renewal evaluation would be in the too distant future. Likewise, flexibility can be applied where confirmatory data was submitted shortly before the submission of the dossier for renewal.
- In the following situations, the evaluation of confirmatory data takes place within the renewal assessment:
    - When the confirmatory data contain information relevant for more than one or few commodities (e.g. metabolism studies).
    - When the confirmatory data contain information relevant for the representative uses.
    - When the confirmatory data contain information relevant for other intended (not representative) uses, but only if all requested confirmatory data is available for evaluation.
- The evaluation of confirmatory data containing information relevant for other intended (not representative) uses takes place outside the renewal assessment (i.e. in a separate Article 10 application), if only part of the requested confirmatory data is available for evaluation.
- To ensure the link with the confirmatory data request is made during the evaluation, the applicant creates a separate dossier (MRL submission) in IUCLID. The link between the active substance dossier and the MRL dossier should be indicated in both dossier headers (i.e. active substance and MRL). In the dossier headers, the applicant should tick the check box under the section "Other submission related information" and specify the submission number of the other dossier. The purpose of the MRL application should be indicated in the dossier header of the MRL submission. In case the applicant considers that some Article 12 confirmatory data will never be submitted (e.g. if the use is no longer supported) this should be clearly indicated in the commenting box next to the purpose of application defined in the dossier header (see further details in the EFSA administrative guidance).
- The assessment should be clearly reported in the Renewal Assessment Report (RAR Volume 1, residues section) and highlighted in the EFSA conclusion.
- If the confirmatory data has been submitted elsewhere (e.g. to the previous RMS) and the RAR is under preparation, the confirmatory data is forwarded to the RMS for the renewal.
- Where the renewal assessment leads to the proposal of revised residue definitions, the evaluation of confirmatory data is based on the existing residue definitions.
- As regards guidance documents, data requirements, animal dietary burden calculator, PRIMo and PROFile versions, the provisions for combined submission (case 2) described in the section "General procedure" apply *mutatis mutandis*.
- Where the renewal assessment leads to the proposal of revised toxicological reference values that are however not yet endorsed by risk managers, the consumer risk assessment is reported in duplicate, i.e. with both the existing and the proposed values.

Specificities for footnotes on missing analytical standards:

- In some cases the European Union Reference Laboratories (EURLs) highlighted that analytical standards were not commercially available and an 'A' footnote was added to the residue definition, stating that the EURLs identified the reference standard for a specific substance as commercially not available and that when re-viewing the MRL, the Commission will take into account the commercial availability of the reference standard 1 year after publication or, if that reference standard is not commercially available by that date, the unavailability of it.
- The Commission systematically follows up on these footnotes, by asking the EURLs whether the standards for the expired footnotes have become available in the meantime. This is done at the end of each calendar year or at the occasion of an Article 6 application of a concerned substance, whatever comes first.
- If the standard is available, the 'A' footnote associated with the residue definition is deleted.
- If the standard is still not commercially available:
    - In the meantime the applicant has made an application for a new MRL under Article 6. In such case the Commission writes a letter to the applicant, reminding that the standard has not been made available yet. The applicant is given 3 months for making the standard commercially available, during which the respective legislative proposal will be put on hold.
        - The standard is finally made available: the 'A' footnote is deleted and the new MRL could be voted provided all other conditions are fulfilled.
        - The standard is not made available: the application for the new MRL is rejected.
    - At the end of each calendar year, the Commission provides an overview on substances with an expired 'A' footnote and makes this information available to authorisation holders, informing that an additional 3 months period is given for making the standard commercially available.
        - The standard is finally made available: the 'A' footnote is deleted.
        - The standard is not made available: all MRLs are reduced to the limit of determination.