EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Safety of the Food Chain
Pesticides and Biocides

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COMMISSION STAFF WORKING DOCUMENT

on the 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 17 June 2016

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.

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.

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). At the time of first implementation of the procedures set out in this working document, EFSA will check and update the overview table, and circulate the updated version to Member States in order to verify completeness.
- Confirmatory data is submitted to EFSA by the RMS/EMS under an Article 10 application, and the RMS/EMS prepares an ER. 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 Evaluation Report (ER) covering both evaluations (combined submission of new use and confirmatory data).
- The applicant/RMS/EMS compiles the MRL application form and submits it to EFSA and DG SANTE. Under section 1 (Purpose of the application), the submission of 'Confirmatory data following Art. 12 review' is indicated by ticking the relevant box. In case of a combined submission, all relevant boxes are ticked in the application form.
- 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 Article10 (new use), or Article 12 Confirmatory data, or both. In case of a combined submission, two separate question numbers are created to ensure transparency and traceability of the different applications.
- The RMS/EMS updates the Pesticide Residue Overview File (PROFile) and submits the PROFile and the supporting ER to EFSA.
- Following receipt of the ER, EFSA amends the status of the application in the EFSA Collaboration table to 'ER available'. 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.
- 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.
- 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.
- EFSA updates the overview table according to the Regulations voted in the Standing Committee and adopted by the Commission.

Specificities for substances in the AIR III process:

- If the confirmatory data contain general data (e.g. metabolism studies), not linked to specific good agricultural practices (GAPs), the confirmatory data is evaluated under the AIR III peer review process (i.e. in a first step by the AIR III RMS). To ensure the link with the confirmatory data request is made during the evaluation, the applicant/RMS/EMS compiles an MRL application form and ticks the relevant box (see above). The assessment should be clearly reported in the Renewal Assessment Report (RAR) and highlighted in the EFSA conclusion.
- If the confirmatory data has been submitted elsewhere (e.g. to the previous RMS) and the AIR III RAR is under preparation, the confirmatory data is forwarded to the AIR III RMS.
- On a case by case basis, deviations from this approach can be agreed. A separate ER should be submitted where the AIR III RAR is already finalised or at a very advanced stage, or where the AIR III evaluation would be in the too distant future.

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.