



**FEEDBACK FROM MEMBER STATES
IUCLID PSN MEETING
21 NOVEMBER 2024**

FEEDBACK FROM FR

Analytical methods for residue studies in IUCLID

- Currently, FR sees the need to send a systematic request for additional information to applicants regarding analytical methods in MRL dossiers, especially if there is a need for additional residue trials and/or other residue studies.
- It can be that IUCLID is correctly prepared for the initial dossier, but this is not obvious when new studies are added.
- **Main points for attention:**
 - ❑ Reminders how to fill in IUCLID for the analytical methods section with reference to the user manual
 - ❑ Currently there is no section in IUCLID to report information related to standard and extract stability nor for extraction efficiency that should be addressed for each study.

We propose the applicant to report this information in the field “Remarks” under section “Results and discussion” at the end of the description of the method for each study summarised under § “4 Analytical methods”

- ❑ When a method is already validated in another study, report the test facility of the primary method in the other study.
- ❑ Precise availability of an ILV
- ❑ ALWAYS justify reduced validation data



FEEDBACK FROM FR

Continued:

- ❑ Information on the primary method used in the residues studies should be reported as follows in section “Background information” in IUCLID, if relevant (i.e. the method used in the trial was validated as a primary method in another study)
 - ✓ Reference of the method (code number),
 - ✓ Origin (DAR, RAR or new method, including author, year, report n°),
 - ✓ Validation: primary method ? with or without ILV, analytes, LOQ, matrixes
 - ✓ Test facility involved in the primary validation
- ❑ For new residue studies, detailed information should include the testing facility related to the analytical phase.
- ❑ Please run the report generator in order to check whether all information is correctly extracted.



FEEDBACK FROM FR

- **Removal of document J** -> feedback becomes urgent as this removal will be effective by April 2025.

MS have no insight on how this will be implemented in IUCLID – during last PSN IUCLID meeting it was announced that a work around would be organised in April 2025

=> timing???

=> Could Efsa please clarify and involve MS urgently how this will be visible in IUCLID? The issue has been raised very quickly during the WP on physchem properties, but without discussions.

- **Report generator for MRL applications**

Preparation of the « application report »: As mentioned previously, the ER Article 10 automatically generated by IUCLID does not correspond to the ER template required by EFSA and published on COM's website

Efsa announced during last PSN meeting that the ER generator is ready and used by some MS – could Efsa give some references of MRL applications in this case and confirm that Efsa will accept the ER as generated automatically by IUCLID submitted by the EMS?



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