



FEEDBACK FROM MEMBER STATES
IUCLID PSN MEETING
22 NOVEMBER 2023

FEEDBACK FROM DE

Communication of the UUID number of the relevant version of the dossier for a certain step in the procedures for approval and renewal of active substances:

- Many versions of an IUCLID dossier exists for the same application. It is sometimes unclear which version is the relevant one for a certain step in the procedure.
- DE proposal: In order to optimize the work with IUCLID dossiers, it would be helpful to include in the communications to all MS the UUID number of the relevant version of the dossier not only at the declaration of the admissibility, but also for the updated dossier after completion of the DAR/RAR and after submission of the additional information. -> Then the MS would know exactly in which versions to look for new documents and will not have to check all available dossier versions.



FEEDBACK FROM DE

Notification of Studies:

- Very oft differences in the required information submitted in the NoS Database and in the dossiers (different title, starting data, etc.);
- Unclear how to deal as RMS with these differences during the admissibility check;
- The applicants and co-notifiers need to keep up-to-date the information notified in the NoS Database.
- Till when is it possible for the notifier to make changes in the NoS Database?
- If a study has been commissioned or started before 27 March 2021, there is no obligation to notify it as an intended study, even if on 27 March 2021 is still ongoing. Is evidence necessary if a study was commissioned before 27 March 2021 but started after this date? Does this evidence need to be submitted in the dossier?



FEEDBACK FROM DE

Questions regarding the announced removal of document J as an attachment in IUCLID dossiers in the IUCLID update from April 2024

- for the dossiers submitted before April 2024:
 - will the already available document J be removed automatically from the dossier?
 - would the applicants need to remove the document J from the dossier for the submission of new versions and fill new fields before submitting?



FEEDBACK FROM DE

Questions related to the Version 4 of the MRL Application manual:

- Are the attachments included in the table at page 8 mandatory, if no “optionally” is included in the description?
- Template 6.3 (Template for reporting trials on magnitude of residues in primary crops and rotational crops): according to the IUCLID Active Substance application Manual Version 4 the template is not used anymore because the structured data should be reported directly in the relevant endpoint study record using the OHT85-5 format. Is it required now to include this document in the MRL dossiers or its use is optional?



FEEDBACK FROM DE

- DE would like to stress once again, that the time and effort to prepare and to update an MRL dossier is disproportionate to the effort needed for an application before the introduction of the IUCLID format. This have a negative impact on the number of applications for minor crops. A more pragmatic approach is needed.
- DE appreciates the on-line training recently made available at <https://academy.europa.eu/>, but advanced hands-on training is needed to support the applicants, especially for minor crops.



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