

10th meeting of the PSN IUCLID sub-group

11-12 June 2024

IUCLID – LATEST NEWS & UPDATES



IUCLID SUPPORT

- **IUCLID manuals** are being updated for IUCLID 6.8 and will be linked in the Applicants Toolkit by mid-July at the latest
- **Administrative guidance:**
 - Endorsed by the PAFF on 23 May
 - Published on 3 June, available here:
<https://www.efsa.europa.eu/en/supporting/pub/en-6464>
- **“Virtual Tour of the Member States”** continues
 - 8 meetings held so far (AT, DK, GR, FR, NL, IT, ES, FI)
 - Discussion held with Finland in May and Germany will be next



IUCLID SUPPORT

- IUCLID 6.7 **Test dossiers** have been published
 - Must be upgraded to the latest version of IUCLID
 - Do not contain confidential data
 - Can be used for testing/training purposes
 - <https://zenodo.org/records/11471659>
- Crosswalks IUCLID 6 v8 published on EFSA Toolkit/Zenodo
 - **KCA&KCP**: <https://zenodo.org/records/11402548>
 - **KMA&KMP**: <https://zenodo.org/records/12205874>



RECOMMENDATIONS ON IUCLID DOSSIERS

Applicants

- **Test material in the Product dataset:** the composition/purity refers to the concentration of the active substance in the plant protection product and NOT to the purity of the test material itself
- **ISO name of the substance:** this can be amended at any moment in time by submitting an updated IUCLID dossier (dossier name/header, Reference substance name in the substance composition document)
- The recommendation is to merge this update with other requested updates



RECOMMENDATIONS ON IUCLID DOSSIERS

Peer review dossiers

- **RMS** - Remember to request a **consolidated version of the IUCLID dossier** (which includes any additional data requested during risk assessment) to be published at the public consultation of the assessment report
- **Applicant** – At the dispatch (call for removal), when informing EFSA that the sanitised DAR/RAR is available, **indicate the UUID** of the updated/consolidated IUCLID dossier.
 - If a dedicated update was made, this should be flagged as a “request for update during application evaluation”
- **EFSA** – the non-confidential version of the consolidated dossier will be published in parallel to the launch of the public consultation on the DAR/RAR

MRL dossiers

- A **consolidated version of the IUCLID dossier** must be available for publication together with the **final output**



GENERAL REMARKS

- **Admissibility checklist**
 - It has now been included in Annex A to the Administrative Guidance
 - By now it is considered to be relatively stable however, EFSA always welcomes suggestions from the Member States for including additional elements which can strengthen the process



MIGRATION OF IUCLID CLOUD SUBSCRIPTIONS

- IUCLID 6 v.8 went live on 29 April 2024
- Server & Desktop versions were immediately made available
- Batches of IUCLID Cloud subscriptions are migrated out of office hours by ECHA (>20k hosted IUCLID instances)
- Account migration cannot be controlled/prioritised and takes several weeks (currently estimated to end by mid-June)
- This has caused some delays to two micro-organism dossier submitters
- EFSA & ECHA have provided full support and dossiers can still be submitted with IUCLID 6.7 as no new BRs were added in IUCLID 6.8
- ECHA has committed to improve the migration mechanism before the next major release



DOCUMENT J DISMISSAL

- Document J scheduled for removal in **April 2025** and a “DAR Volume 4” report will be generated in support of the RMS
- The change will apply to **new submissions** made after go-live of the release (i.e. no impact on previously submitted dossiers)
- Mapping of Doc J elements to the fields in the IUCLID dossier is complete and will be made available in the Applicants toolkit shortly
- For any items which are currently still missing in IUCLID a workaround will be suggested and a format change will be scheduled for April 2025
- We are checking the mapped fields against the related filtering rules
- EFSA has an on-going contract with a consultant to support in this task



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