

7th meeting of the PSN IUCLID sub-group
19-20 June 2023

IUCLID – LATEST NEWS & UPDATES

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TIPS CONCERNING IUCLID DOSSIERS

- It is important to provide adequate contact details within a dossier (generic contact details in the LE and personal contact details in the Contact Entity) and to make sure they are up-to-date
 - EFSA uses these contact details for all communication with the applicant in relation to the dossier
- During the light check for personal data EFSA has identified several over-blackened attachments → applicants should avoid this, bearing in mind that such sanitisation will not be accepted during confidentiality request assessment
- New section on categorisation of resubmissions in the dossier header → an additional business rule will be added to this to ensure that this information is provided



IUCLID SUPPORT

- The manuals are being adapted to IUCLID 6.7 and will be published during the summer
 - Information on microorganisms (introduction + new documents) has been prioritised and will be made available on Knowledge Junction shortly, pending its inclusion in the full manual at a later stage
 - All links will be available in the Applicants Toolkit
- Two trainings will soon be made available on EU Academy:
 - IUCLID for Applicants
 - IUCLID for Evaluators
- We are re-thinking the way we communicate with stakeholders in order to ensure we reach out to a broader audience (the Toolkit will be central to communication: <https://www.efsa.europa.eu/en/applications/toolkit>)



IUCLID SUPPORT

- Contract in place for the design of pesticide demo dossiers
 - 14 different types of dossiers to be prepared (simulating content & complexity of PPP submissions)
 - Will be available for testing, training & manuals
 - Feedback on the manuals/instructions is being provided in parallel
 - Contract runs until February 2024
- IUCLID PSN Working Party on Microorganisms to be kicked off soon – 17 expressions of interest received so far with the intention to organise the kick-off meeting shortly after the PSN and then resume the work after the summer



IUCLID SUPPORT- INFO SESSION ON METAPATH

An event with the aim of supporting Member State Authorities in validating the xml files generated with MSS composers by applicants and containing pesticide metabolism data from plants and livestock metabolism studies has been organized by EFSA:

Info session on MetaPath: how to validate files generated with MSS composers for pesticide metabolism studies

- When: **30 June 2023**, 09.30 - 12.30 (CEST)
- Where: Online
- **Register for participation here:** <https://efsa.blumm.it/event/ar/505/info-session-on-metapath-how-to-validate-files-generated-with-mss-composers-for-pesticides-metabolism-studies>
- **Deadline for registration: 27 June 2023** - 12:00 (CEST)
- More details and Agenda available here: <https://www.efsa.europa.eu/en/events/info-session-metapath-how-validate-files-generated-mss-composers-pesticide-metabolism>



INHERITED TEMPLATES FOR COMPLEX SUBMISSIONS

- EFSA strongly recommends the use of Inherited templates for managing certain complex submissions
- So far suggested for:
 - A complex Copper task force with 5 salts, 5 representative products, main/common dataset with approx. 15 applicants providing supporting information
 - A renewal submission with 1 applicant and 5 “LoA dossiers” with a limited number of supporting studies
 - Joint submission of an MRL dossier
- Facilitates the joint submission of data in situations in which a standard joint submission is not possible/optimal
- Guarantees data segregation among applicants provided a third party is involved
- Each template is an own dataset and can be created/exported as such
- It will be further described in the manuals but applicants should contact EFSA for support if they believe their submission could benefit from this feature





CONFIDENTIALITY ASSESSMENT – KEY MESSAGES

- **Confidentiality claims referring to identical literature reference in different but related dossiers to be aligned** (e.g. joint submission);
- **Duplication of attachments in the endpoint study record and in the literature reference to be avoided;**
- **MSS/DER composer files - as a confidential version, and a PDF file with sanitisation as a non-confidential version.**





CONFIDENTIALITY ASSESSMENT – KEY MESSAGES

- **Precise comments to be provided by the Applicant following EFSA's draft decision** (e.g. page, legal basis, complete justification);
- **Updates on the EFSA User Guide on Confidentiality with, inter alia, a refined concept of personal data are ongoing.**



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