9th meeting of the PSN IUCLID sub-group
29 February 2024

IUCLID – LATEST NEWS & UPDATES

EUROPEAN FOOD SAFETY AUTHORITY

IUCLID SUPPORT

- All IUCLID manuals have been updated and can be accessed via the Applicants Toolkit
  - EFSA will soon start their revamp in view of the IUCLID 6.8 release
  - Indicative delivery by June 2024
- Administrative guidance:
  - Commented by MS in January
  - EFSA is addressing all the comments
  - Guidance to be published in March 2024
- "Virtual Tour of the Member States" continues
  - 7 meetings held so far (AT, DK, GR, FR, NL, IT, ES)
  - March meeting still to be scheduled

RECOMMENDATIONS ON IUCLID DOSSIERS

Applicants

- Appropriate name to be given to the **substance**, considering it will be published too
  - ISO name of the substance
  - AVOID details on product name, company name, versioning, etc

Naming of MRL dossiers

- Note for EMS: to distinguish between different MRL applications for same active substance & same crop(s) -> refer to the "Dossier subject" field (i.e. the Product name) which is always displayed in the IUCLID search results

RECOMMENDATIONS ON IUCLID DOSSIERS

Peer review dossiers

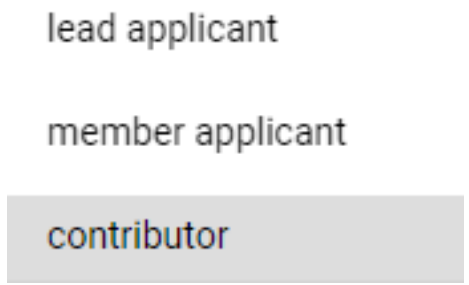
- **RMS** - Remember to request a **consolidated version of the IUCLID dossier** (which includes any additional data requested)
- **Applicant** – At the dispatch (call for removal), when informing EFSA that the sanitised DAR/RAR is available, **indicate the UUID** of the updated/consolidated IUCLID dossier
- **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**

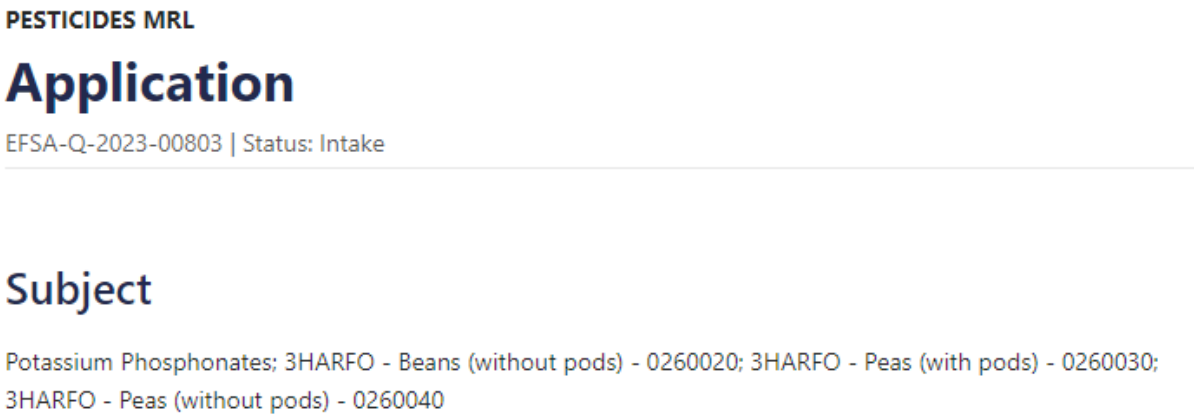
DATA PROVIDED WITH A LOA

- **Studies must always be provided in a dossier** in order to comply with the requirement for a public consultation and to fulfil the proactive transparency requirements
  - Dossiers with only a Letter of Access (LoA) or data sharing agreement cannot be accepted
- It is currently not easy to identify such studies within an IUCLID dossier
- New "Contributor" role added to the dossier header in IUCLID 6.8 – conceptually similar to a Joint Submission but the data submitter will not be considered/published as an Applicant
  - No third party consultant required as data owners can each submit their own studies



INTEGRATION BETWEEN IUCLID AND OPEN EFSA

- 29 November 2023 we integrated IUCLID with OpenEFSA
- This changes the way data are published on the website:
  - A Question number is automatically created upon first submission of a dossier (and no longer manually upon Admissibility)
  - The Question number contains “placeholder” data in certain fields (as taken from the IUCLID dossier), which will be validated upon Admissibility
  - E.g. the “Subject” is the substance name for an AS dossier and a concatenation of substance name + crop(s) taken from the GAP table for an MRL



ATTACHMENT OF WORD DOCUMENTS IN SUPPORT OF DAR/RAR PREPARATION

Proposed **interim** approach:

- If the dossier is well-built, no need for manually generated Document M, etc because report generator can be used (**ideal scenario**)
- **Under exceptional circumstances** the RMS can ask the applicant to upload word files of these documents **on a voluntary basis** (pending refinement of the reporting)
- The RMS must be mindful of the additional workload this creates for applicants and consider that these files are not officially required to be part of the dossier
- These attachments will not be subject to proactive disclosure and confidentiality requirements, meaning applicants will only have to submit a confidential/full version of the document(s) and no associated confidentiality request(s)
- The above will trigger quality warnings that the applicant can justify in the excel sheet

REPORT GENERATOR (I)

- New reports:

Report	Description	Status	Estimated deadline
DAR Vol1 (Doc. N1)	• CLH report being developed by a contractor for ECHA • Once finished, result to be adapted by EFSA to create DAR Vol1	Ongoing	• CLH: Dec 2024 • DAR Vol 1: 2025
List of Endpoints (Doc. N2)	• draft developed by a contractor, currently being reviewed section by section by EFSA experts • IUCLID PSN to be informed for testing and feedback (also section by section)	Ongoing	• First section: **Apr 2024** • Full LoE: Dec 2024
DAR Vol4 (Doc. J)	• Report to be developed to cover Doc J once dismissed	Awaiting requirements	
Microorganism reports	• Reports to substitute old Doc Ms for micro-organisms	Awaiting requirements	

Any other request?

Volunteers for testing?

REPORT GENERATOR (II)

- Enhancements / modifications:

Report	Description	Status	Estimated deadline
GAP table (Doc. D)	• Amendments already implemented to comply with the official templates (for MRL and approval/renewal) and format changes in the April release (e.g. conc. a.s. in dilution)	Finished	• April 2024
DAR Vol3 Physchem (Doc. M Physchem)	• Amended by EFSA to use the official template (table format) • IUCLID PSN to be informed for testing and feedback	Ongoing	• April 2024
DAR Vol3 Tox, Ecotox (Doc. M Tox, Ecotox)	• Being reviewed by EFSA experts for feedback	Ongoing	
MRL report	• Commenting phase for the use of annotations ended 29/02 • EFSA to analyse the feedback	Ongoing	

Any other request?

Volunteers for reviewing existing reports?

REPORT GENERATOR (III)

- Fixes to errors in rich-text fields implemented in latest service release : see TEAMS post
  - Including:
    - support of a number of special characters which caused the message *"invalid XML content"*
    - support of malformed tables i.e., *"a table-cell is spanning more rows than available in its parent element"* which caused reports crash
  - Not covering 100% of cases – remaining cases being under analysis by ECHA
  - Feedback is welcome!

- To provide feedback / report issues:
  - Urgent fixes: Ask EFSA
  - Feedback and requests: Report_generator_backlog.xlsx
    - Try to avoid generic statements and provide as much detail as possible
    - Try to distinguish issues regarding the report vs issues with the data entered by the applicant

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