12th meeting of the PSN IUCLID sub-group
11 – 12 March 2025

IUCLID – LATEST NEWS & UPDATES

efsa
EUROPEAN FOOD SAFETY AUTHORITY

GENERAL UPDATE

- 11 meetings of the Virtual Tour with the Member States held so far (AT, DK, GR, FR, NL, IT, ES, FI, DE, SI, **LV**)
  - Confidentiality request assessment added to the standard agenda in case the RMS has new AS dossiers
- Filtering configuration file is currently being aligned with IUCLID 6.9 → the Working Party on Filtering Rules will be consulted in writing before it is finalised
- IUCLID manuals: do you have any suggestions on how the manuals could be improved/be made more user friendly?

IUCLID MANUALS

- EFSA has started the systematic review of the **Purpose fields** within each Endpoint Study Record
  - Example below of the before & after

5. Toxicological and metabolism studies on the active substance – Flexible summary

Purpose
To report Health-based guidance values than under the pesticides peer review are called toxicological reference values. These are the Acceptable operator exposure level (AOEL), Acceptable daily intake (ADI), Acute reference dose (ARfD) and Acute Acceptable operator Exposure Level (AAOEL) values derived for the active substance or metabolite (if applicable).

FLEXIBLE_SUMMARY.ToxRefValues – v1.1 (Final) [September 2020]			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	See Confidentiality request Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Header 1	FLEXIBLE_SUMMARY.ToxRefValues.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.ToxRefValues.AdministrativeDataSummary.DataProtection

5. Toxicological and metabolism studies on the active substance

Introduction

For EU pesticides, when compiling the dossier for active substances the applicant should consult programme-specific guidance under Commission Communication on list of test methods and guidance documents for active substances available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013XC0403(02)[21].

It is important than when presenting the results in tabular format for mammalian toxicology studies the applicant follows the recommendations of the IUCLID templates for PPP Risk Assessment - Template 5.1 - Template for presentation of results in tabular format for mammalian toxicology studies. [http://doi.org/10.5281/zenodo.4557274]. For presenting the results in tabular format for repeated dose toxicity studies by the oral route the applicant should use the common block detailed toxicological results implemented in OHT 67.

In cases that there are not specific study records fit for purposes please consider the use of the study record for intermediate effects if the aim of the study is mechanistic or the study record for other toxicological studies if the aim is not mechanistic (e.g. hazard identification), both under 5.8.

In cases (Q)SARs are submitted please also attached in the respective study record a summary assessment report of a (Q)SAR. See IUCLID templates for PPP Risk Assessment - Template 5.2 - Summary assessment report of a (Q)SAR and example. [http://doi.org/10.5281/zenodo.4557311].

The following templates should be used when compiling documents in this section:

Template name and link	Information
Template 5.1 Template for presentation of results in tabular format for mammalian toxicology studies	This word file contains the template for presentation of results in tabular format for mammalian toxicology studies, replacing the appendix F of the EFSA administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances (EFSA, 2019). The template shall be used when compiling tables in the **"Any other information on results incl. tables"** field in the relevant **endpoint study record(s)**.
Template 5.2 Template for a summary	The word file contains the template for a summary assessment report of a (Q)SARs.

MANAGEMENT OF A NAS DOSSIER [1/2]

- After a dossier is declared admissible, the next step is the confidentiality request assessment (CFD) → for a NAS this task is a responsibility of the RMS
- EFSA will inform the RMS upon publication of the dossier post-admissibility → this step guarantees that the light check for personal data has passed and that the dossier version should be stable for assessment
- In accordance with the Practical Arrangements concerning confidentiality, the CFD should be carried out before dossier evaluation begins

MANAGEMENT OF A NAS DOSSIER [2/2]

- Should the CFD be carried out in parallel to the evaluation, it is **important to maintain a sequence in relation to dossier submissions** → the RMS should first request a dossier update covering only the implementation of the confidentiality decision (if required) and subsequently ask the applicant to amend/add to the scientific data in IUCLID by means of a separate/sequential resubmission
  - This will enable the distinction between the data that were submitted upon admissibility/provided at a later stage and their management within the evaluation and CFD processed

DOCUMENT J DISMISSAL - OVERVIEW

- Document J will be removed in **May 2025** for **chemical active substance dossiers**
  - For microorganisms dossiers we will keep this activity on hold for the time being
- The change **will apply to new submissions** made after go-live of the release (i.e. no impact on previously submitted dossiers in which the existing Doc J will be kept)
  - Next AS renewal deadline on 25 October 2025
- **RMS are reminded to no longer accept new dossiers with a Doc J attachment as from IUCLID 6.9 go-live** *(in case applicants try to attach Doc J elsewhere in the dossier)*

DOCUMENT J DISMISSAL – SUPPORT TO APPLICANTS

- EFSA has published the **Mapping of Doc J** elements to the fields in the IUCLID dossier (i.e. the Crosswalks clarifying in which IUCLID sections/fields to enter the data previously included in Doc J) as well as some ad-hoc instructions in the Applicants toolkit: https://www.efsa.europa.eu/en/applications/toolkit#iuclid-software
  - The instructions will subsequently be included in the revision of the manuals
- A live **Webinar is scheduled on 2 April 2025**: full details and registration form available here (registration open until 31 March): https://www.efsa.europa.eu/en/events/webinar-removal-document-j-iuclid-how-report-data-pesticide-dossiers

DOCUMENT J DISMISSAL – SUPPORT TO RMS

- Ad-hoc **Info session** held on 15 January (60+ attendees)
- The scope of the current phase was clarified (i.e. focus on data entry/availability in the dossier)
- Once the draft "Confidential report" is available MS will be invited to join dedicated session(s) to ensure that the contents and format of the report are useful for compiling DAR Vol 4
  - The first info session will be held in June – July 2025 (more details will follow)

ENGAGEMENT TOOLS IN THE AREA OF PESTICIDES

Support during the pre-submission phase

- General pre-submission advice (GPSA); Renewal pre-submission advice (RPSA); Pre-submission meetings/advice; Pre-admissibility teleconference

Support during/after the peer review phase

- Clarification teleconference; Applicant's technical hearing; Post-adoption teleconference

Engagement initiatives available to applicants – at any stage

- Dedicated support to SMEs on the use if IT tools; Ask a Question; Info sessions & webinars; Ad-hoc meetings with industry representatives

Additional initiatives

- PSN IUCLID; LinkedIn & communication campaigns; Info stands at conferences; Mass mailing, Newsletters, collaboration with Industry Associations; community on applications

COMMUNICATION RELATED TO IUCLID DOSSIERS

- EFSA would like to be aware of issues related to IUCLID dossiers
- EFSA invites PSN Members (Member States and Applicants) to keep us in the loop for communications related to issues concerning IUCLID dossiers
  - Technical issues, dossier completeness/quality, reports, etc
- This will enable us to provide ad-hoc support if needed and to identify common problems

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