

11th meeting of the PSN IUCLID sub-group  
21 November 2024

# IUCLID – LATEST NEWS & UPDATES



## IUCLID SUPPORT

- **IUCLID manuals** have been updated for IUCLID 6.8 and can be accessed through the Applicants Toolkit
- **Active substance:** <https://doi.org/10.5281/zenodo.5091463>
- **MRL:** <https://doi.org/10.5281/zenodo.4630193>
- **Microorganisms:** <https://doi.org/10.5281/zenodo.4773526>
- **Basic substances:** <https://doi.org/10.5281/zenodo.5172130>
- **EU Academy – Training for Evaluators**
  - During the summer there were some delays in approving access to the training – EFSA has flagged the issue



# VIRTUAL TOUR OF THE MEMBER STATES

- 10 meetings held so far (AT, DK, GR, FR, NL, IT, ES, FI, **DE, SI**)
- Standard draft agenda
- Very similar issues are raised:
  - Initial focus on admissibility now mostly on evaluation (report generator + dossier quality)
- EFSA follows up on any action points agreed during the meetings and informs the PSN where relevant for all *e.g. the admissibility checklist was updated based on input from AT and DK*

No	Indicative time (minutes)	Topic	Presenter
1.	5	Welcome	EFSA (Chair)
2.	5	Adoption of the agenda and scope of the meeting	EFSA (Chair)
3.	15	<b>Use of IUCLID</b> <ul style="list-style-type: none"> <li>• Access and IUCLID navigation (ToC, Working context)</li> </ul>	all
4.	20	<b>Admissibility check:</b> <ul style="list-style-type: none"> <li>• Impact on National process (workload, resources) for Slovenia (if any)</li> <li>• Issues with Admissibility :               <ul style="list-style-type: none"> <li>✓ Notification of Studies check</li> <li>✓ Use of available resources for admissibility check (IUCLID validation assistant, EFSA admissibility checklist, pre-admissibility teleconferences)</li> <li>✓ Light confidentiality check</li> </ul> </li> </ul>	all
5.	45	<b>Evaluation phase</b> <ul style="list-style-type: none"> <li>• Dossier quality</li> <li>• Dossier updates post-admissibility</li> <li>• Use of report generator</li> <li>• Annotations</li> <li>• Dossier formats other than IUCLID</li> </ul>	all
6.	30	<b>AOB &amp; Wrap-up</b>	all



# GENERAL REMARKS

## Applicants

- European Reference Number (ERN): a reminder that it should **not** be changed upon dossier resubmission unless requested by EFSA. New BRs will be in place as of April 2025 to help control this

## Member States

- Admissibility checklist to be updated with a recommendation to run certain reports before declaring a dossier admissible (e.g. MRL report)
- Ignore Filtered dossiers in EFSA Agency IUCLID – they are needed by EFSA for dossier publication and are removed when the process is finalised



## NEW FILTERING RULE – TEST MATERIAL ENTITY

- EFSA proposed changes to the Test Material (TM) Entity also in view of Doc J dismissal
  - Extended list of categories for the components + confidentiality flag added to every entry of the TM composition table
- The new rule checks whether a given component in the TM composition table is flagged confidential and:
  - ALWAYS publishes if there is no flag
  - ALWAYS publishes if the component = active substance (*specific instructions to be provided for microorganisms*)
  - REMOVES the whole row if the component is flagged and does not correspond to the above (*pending assessment of the confidentiality request*)
- The rule was slightly amended and endorsed by the Filtering WP on 13 November 2024



## DOCUMENT J DISMISSAL - OVERVIEW

- Document J will be removed in **April 2025** for **chemical active substance dossiers** (for **Microorganisms April 2026**)
- 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)
- A **new Manufacturer document** will be delivered in replacement of the existing one and will have many more fields for hosting additional data e.g. manufacturing process, starting substances, reaction scheme, etc.
  - For existing submissions (which include a Doc J) there are two possible ways forward:
    - 1) Create a legacy section for hosting the old manufacturer document
    - 2) Migrate only the attachment(s) and confidentiality justification to an existing document (e.g. Summary and Evaluation)



## DOCUMENT J DISMISSAL – MAPPING FILE

- **Mapping of Doc J** elements to the fields in the IUCLID dossier is complete and will be made available in the Applicants toolkit shortly as well as advertised more broadly
- Currently the Mapping file includes Crosswalks for filling in a dossier and specifications for compiling the report with report generator
- When the Crosswalks are published EFSA will also make available some ad-hoc instructions for compiling certain fields (later to be included in the revision of the manuals)
- The file is available here: [Doc J - crosswalks.xlsx](#)

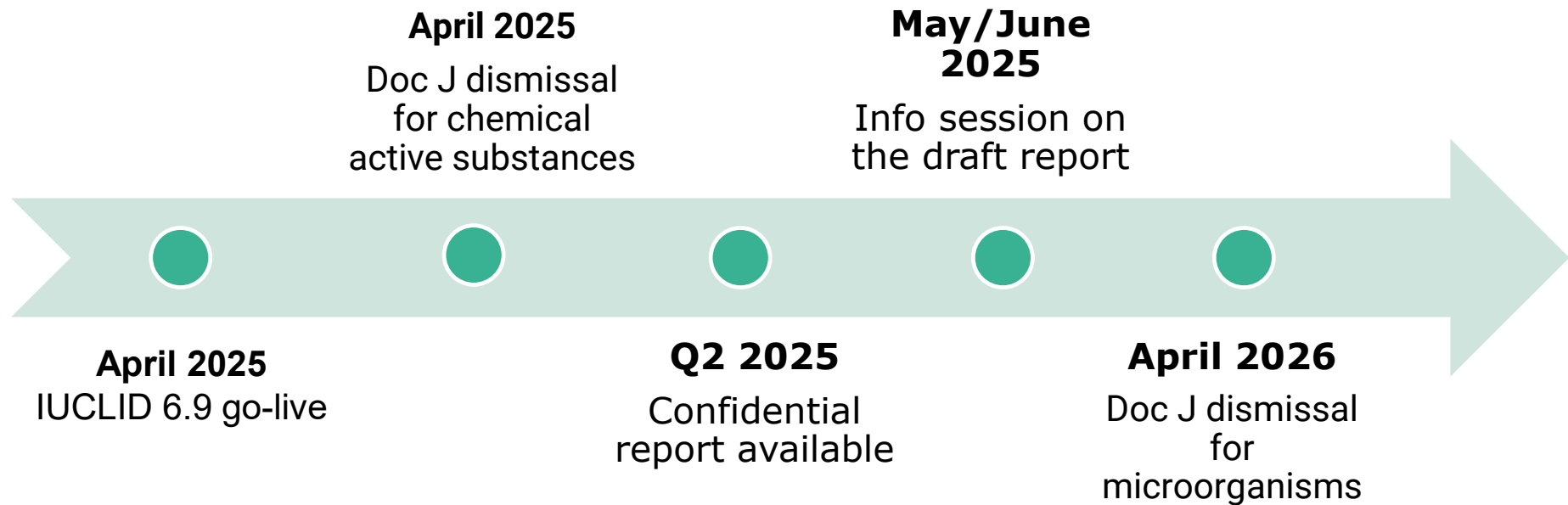


## DOCUMENT J DISMISSAL TIMELINE

- Ad-hoc consultation on the mapping file with the Filtering WP in **November 2024**
- EFSA can organise an ad-hoc **Info session** on the mapping file for IUCLID PSN members before Christmas to address any questions
- The confidential report will be available in **Q2 2025** (i.e. after go-live of IUCLID 6.9)
  - Reminder: only relevant for new submissions
  - Not needed in the early admissibility check phase of any newly received dossiers
- **May/June 2025** expected Info session on the draft report
- **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 TIMELINE



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