

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

# ACTIONS FROM PREVIOUS MEETINGS

# COMPLETED ACTIONS



DATE	OWNER	DESCRIPTION	COMMENT
Dec 2022	EFSA	Consider longer period for storing <b>obsolete migrated documents</b> after ToC changes. At least one year should be granted	Ad hoc meeting on Migration held in September 2024 Further information under Agenda item 8b
Dec. 2022	ECHA	Investigate <b>improving search by a substance</b> within a dossier e.g. metabolites	IUCLID backlog item created #2488 <a href="https://docs.google.com/spreadsheets/d/1kFkttA6rXtR2K6LLaauHozq9BSfv6a5EgFDM1GgtmfQ/edit?gid=0#gid=0">https://docs.google.com/spreadsheets/d/1kFkttA6rXtR2K6LLaauHozq9BSfv6a5EgFDM1GgtmfQ/edit?gid=0#gid=0</a>
Jan 2022	ECHA	ECHA to further elaborate on the <b>use of annotations</b> for pesticides dossiers	Discussion with EFSA and IUCLID PSN members concluded in Feb 2024
Jan. 2022	EFSA	To discuss and plan transition from existing PPP templates with <b>report generator outputs</b>	The <u>Report Generator backlog file</u> is dismissed (further details on last slide of this ppt)
June 2023	INDUSTRY ASSOCIATION	CLE to share details of the issues encountered with <b>inherited templates</b>	No follow-up
June 2023	MSs and Industry Associations	Industry and Member States to consider organizing <b>workshop on Notification of Studies</b> . EFSA is available to participate and support	No follow up



# COMPLETED ACTIONS



DATE	OWNER	DESCRIPTION	COMMENT
June 2023	EFSA and Industry	CLE and EFSA to use the OCED Expert Group Multiple jurisdictions activity to analyze improvements to dossier <b>lifecycle management</b>	Further information under Agenda item 9
June 2023	Industry	CLE to propose changes to <b>OHT 85</b> for further discussion at OECD level	Proposal under validation at OECD level. Ad hoc WP held in September 2024 Further information under Agenda item 8a and 10b
June 2023	All	All members to provide feedback on issues experienced during <b>admissibility</b> e.g. NoS related procedures etc. Feedback on admissibility.xlsx	The <u>Admissibility backlog file</u> is dismissed (further details on last slide of this ppt)
Nov. 2023	INDUSTRY ASSOCIATION	CLE to contact EFSA to provide details on the dossiers shown in the presentation of Nov 2023 ( <b>lifecycle management</b> )	Lifecycle management of dossiers discussed under Agenda item 9
Nov. 2023	EFSA	Reflect on how to improve <b>dossier header</b> considering MRL application form dismissal	Changes included under the a.s. Dossier Header Further details under item 8b
Nov 2023	EFSA	Investigate the impact of <b>Document J removal</b> on cases where data within the dossier are owned by different data owners	Updates under Agenda item 4
Feb 2024	EFSA/ECHA	Explore with ECHA generation of <b>aggregated reports</b>	EFSA discussed with ECHA and ran some tests. The current aggregation tool does not work on PPP dossiers. This will be further analyzed in 2025 to see if it can be adapted to work on PPP dossiers



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DATE	OWNER	DESCRIPTION	COMMENT
June 2024	EFSA	EFSA to consider sharing highlights from <b>Virtual Tour with Member States</b>	Updates under Agenda item 4
June 2024	EFSA	EFSA to consider publishing <b>final report from GAB</b>	Report is not going to be published. Test Dossiers are available here: <a href="https://zenodo.org/records/11471659">https://zenodo.org/records/11471659</a>
June 2024	ALL PARTICIPANTS	Sub-group members to give feedback on proposal for <b>change of Dossier header</b> by 28 June	Consultation closed
June 2024	ALL PARTICIPANTS	Sub-group members to give feedback on the <b>proposed VA</b> rules by 28 June	Consultation closed
June 2024	EFSA	EFSA to clarify in writing the <b>steps associated to confidentiality request</b> assessment and the associated timelines	Updates under Agenda item 6
June 2024	EFSA	EFSA to clarify the timeline and the practice related to the submission of confidentiality requests on <b>Additional Data Requests (ADRs)</b>	Updates under Agenda item 6
June 2024	EFSA	EFSA to include instructions on how to compile the new harmonised summaries in ecotox area in the IUCLID manual for microbial active substances	Instructions included in the M.o. IUCLID Manuals Updates under Agenda item 4
June 2024	ALL PARTICIPANTS	sub-group members to give feedback on the <b>use of annotations by 15 July</b>	Consultation closed

# ACTIONS IN PROGRESS



DATE	OWNER	DESCRIPTION	COMMENT
Nov. 2023	EFSA	Advertise changes related to the decommissioning of <b>Document J</b> on the toolkit page	Updates under Agenda item 4
June 2023	EFSA	EFSA to bring to OECD level the discussion on FoodEx	Under discussion with OECD whether to include under activity 5
Feb. 2024	MS	Include specifications for <b>refinement of validation rules regarding in vitro/in vivo studies</b> on the file available for IUCLID PSN members: "Validation Rules_backlog.xlsx"	There is a dynamic rule to hide in vivo fields when in vitro is selected and viceversa



# IUCLID CONTACTS

## SUPPORT

- with **preparation** and/or **submission** of IUCLID **dossiers**
- on related **tools** e.g. Urgent fixes to Report Generator, MetaPath, etc
- to MS during the **admissibility check**



## Ask a question service

(<https://connect.efsa.europa.eu/RM/s/new-ask-efsa-request>)

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GENERAL FEEDBACK on IUCLID improvements  
(e.g. on Report Generator and validation rules)



## ECHA IUCLID backlog file

(open backlogs)

## Google form

(to submit new proposals)

## The following files are **DISMISSED**

[Report\\_generator\\_backlog.xlsx](#)

[Validation Rules\\_backlog.xlsx](#)

[Feedback on admissibility.xlsx](#)



# TERMS OF REFERENCE

- The **Terms of Reference** of the IUCLID PSN network have been updated on 28 August 2024
- Updated version is available online  
<https://www.efsa.europa.eu/sites/default/files/2023-10/terms-of-reference-iuclid-psn-subgroup.pdf>
- Main amendments concern **clarifications on access rules to meetings and nominations of experts**



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