13th meeting of the PSN IUCLID sub-group
12 June 2025

IUCLID OECD ACTIVITIES AND UPDATE ON VALIDATION ASSISTANT RULES

EUROPEAN FOOD SAFETY AUTHORITY

INTRODUCTION

- OECD IUCLID improvement activities
- Update on the VA scope for next IUCLID October release and feedback received from PSN-IUCLID members

OECD IUCLID IMPROVEMENT ACTIVITIES

STATUS OF THE OECD IUCLID IMPROVEMENT ACTIVITIES

In 2022 the OECD IUCLID User Group Expert Panel identified a number of activities aiming at improving IUCLID

Prioritised activities #1-5

- **#1. User interface improvements**
- #2. Reporting (Activity ended);
- **#3. Using the same dataset for multiple recipients**
- #4: Data availability / Dissemination (Activity not started)
- **#5. Picklist management** (just kicked-off)

#1 USER INTERFACE IMPROVEMENTS

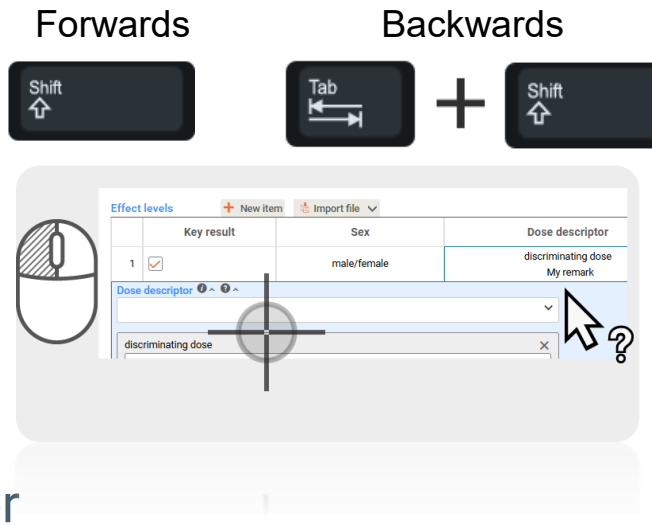
Some context

- **Leads**: ECHA and BIAC
- **Members**: BIAC, AICIS, NZ EPA, EFSA, BfR, BvL
- **Started** in 2023 and extended to 2025
- **Scope**: facilitate and simplify data entry, management and maintenance of data, and improve IUCLID features e.g. comparison tool

#1 USER INTERFACE IMPROVEMENTS

Items identified and prioritised for the IUCLID May 2025 release

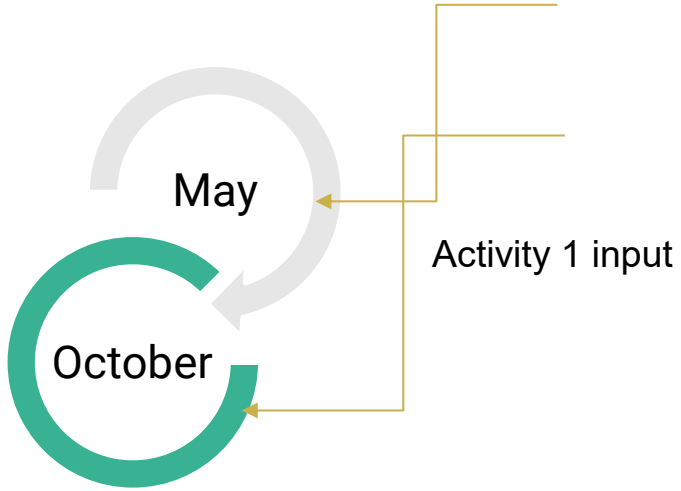
- Inline table editor to facilitate data entry and navigation for all users
- Improvement to the navigation tree (#1620, #3116)
- Make Endpoint summary references to Study Records more relevant by considering Key Results first (#2296 / #2613)
- Display datasets first, then dossiers, when searching by UUID (#3056)
- Display more information about cross-referenced documents than just the name (#3117)
- Extend CSV import to blockRefId field types (indicating target line number of block) (#3115)



#1 USER INTERFACE IMPROVEMENTS

What is next?

- Continue to receive feedback on inline table editor
- Prioritise and analyse October 2025 release from a User Interface perspective
- Survey on prioritisation finalized – Top three priorities identified:
  - #8 / #39 - keep my working context whenever I am cloning a dataset or importing a dataset
  - #22 - Possibility to force deletion of a dataset with multiple inbound references to avoid make unlink entities by hand.
  - #27 - Introducing colored backgrounds in IUCLID - particularly helpful for users who frequently work with multiple IUCLID windows open at the same time.
- Use OECD webinar on 17/06 to confirm this



#3 USING THE SAME DATASET FOR MULTIPLE RECIPIENTS

Some context

- **Leads**: EFSA and BIAC
- **Members**: ECHA, BIAC, AICIS, NZ EPA, BfR
- **Started** in 2023 and extended to 2025
- **Scope**: Make IUCLID datasets reusable across jurisdictions

#3 USING THE SAME DATASET FOR MULTIPLE RECIPIENTS

Data Standardization and Validation

Ensure that data and data formats are harmonized and compliant, promoting compatibility with regulatory requirements across diverse chemical legislations/jurisdictions

1.Requirements for fields specific to regulation

Comparison of data requirements and validation rules across different jurisdictions

2.Handling of study attachments

- Harmonisation needed for easier accessibility across jurisdictions
- Attachments: Original, marked, sanitised versions.
- Implementation challenges: format changes, migration limitations

3.Language barrier

Facilitate submissions to various regulatory authorities in accordance with national languages

#3 USING THE SAME DATASET FOR MULTIPLE RECIPIENTS

COMPARISON OF INFORMATION REQUIREMENTS AND VALIDATION RULES UNDER REACH, BPR AND PPP: **THE ASSESSMENT OF DICOPPER OXIDE AS CASE STUDY**

- The goal of this study is to compare the endpoint conclusions and information requirements for Cu2O under REACH, BPR and PPP on
  - physicochemical properties
  - environmental fate and pathways
  - ecotoxicological information
  - human health (tox) information (both studies and summaries)

Eurometaux CropLife EUROPE cefic

Support of Copper Consortium

The overall idea is to have a clear overview of data submitted and the data required, and to clarify similarities and discrepancies relevant for further data mining and data dissemination exercise, with attention to the upcoming OSOA initiative

#3 USING THE SAME DATASET FOR MULTIPLE RECIPIENTS

Summary of the report

- REACH, BPR and PPP dossiers updates follow **different regulatory timelines and requirements**, which complicates the comparison of the data at one timepoint
- The **IUCLID databases** are to a certain degree similar under REACH, BPR and PPP compared to the IUCLID OECD framework
- **Phys-chem** requirements show some differences: BPR seems the one with higher number of standard requirements
- **Efate/ecotox/tox**: similar data requirements, but different threshold derivation/checks

Ecotoxicological information						
OECD	**REACH**		**BPR**		**PPP**	
C49. Sediment toxicity	Legal	IUCLID (6.2)	Legal	IUCLID (9.1.9)	Legal	IUCLID (8.2.5.4)
	✓	✓	?	✗	?	✓
	Freshwater NOEC/EC10 = 18.3 to >3158 mg Cu/kg Marine sediment Not assessed		Freshwater NOEC/EC10 = 18.3 to >3158 mg Cu/kg Marine sediment Not assessed		Freshwater NOEC = 16.17 mg Cu/kg Marine sediment Not assessed	
Conclusion: Standard information requirement under REACH. Under BPR/PPP required						

Symbol	Legal requirements	IUCLID requirements*
✓	Standard data requirement	Mandatory
?	Only required under specific situations	/
✗	No data requirement	Not mandatory

- The report shows that **harmonisation is difficult due to different regulatory purposes and assessment methodologies**, which should be considered under the OSOA perspective.

The report is currently undergoing final adjustments and will be presented at the plenary session of the OECD IUCLID User Group Expert Panel in September

#3 USING THE SAME DATASET FOR MULTIPLE RECIPIENTS

Actions for EFSA on Data Validation to be added to the scope of October 2025

PHYSICAL AND CHEMICAL PROPERTIES

- **Spectral data** (UV-VIS, IR, NMR, MS): this information is legally required but not mandatory in IUCLID

ENVIRONMENTAL FATE AND PATHWAYS

- **Biodegradation in soil**: legally required information, but not yet checked by the validation assistant

ECOTOXICOLOGICAL INFORMATION

- **Effects on biotic systems**: legally required but there is no validation assistant rule
- **Toxicity to terrestrial arthropods except bees**: standard information requirement in the PPP legislation but no VA rule
- **Biological effects monitoring**: legally required but not checked by validation assistant

#5 PICKLIST MANAGEMENT

Some context

- **Leads**: Germany (BfR) and EFSA
- **Members**: ECHA, EC DG-ENV, BIAC
- **Started** in March 2025 (with the option to propose a sequential yearly extension at the plenary session in September 2025)
- **Scope**: optimise the management of externally defined lists

#5. PICKLIST MANAGEMENT: OBJECTIVES

- Develop and agree on the most effective approach to manage externally defined lists within IUCLID, with a focus on:
  - **Review the management of internal picklist**: to ensure harmonisation with external defined picklists.
  - **Version Sustainability**: ensuring lists are seamlessly maintained across different IUCLID versions.
  - **Format Stability**: addressing the challenge of external list updates that may not align with IUCLID's governance timelines or release schedules.

- Commodities derived from **EPPO codes** (EPPO Codes Database)
- Raw agriculture commodities (RAC) and processed commodities based on **FoodEx2** codes

UPDATES ON VALIDATION ASSISTANT RULES

#EFSA_EU

UPDATES ON VALIDATION ASSISTANT RULES

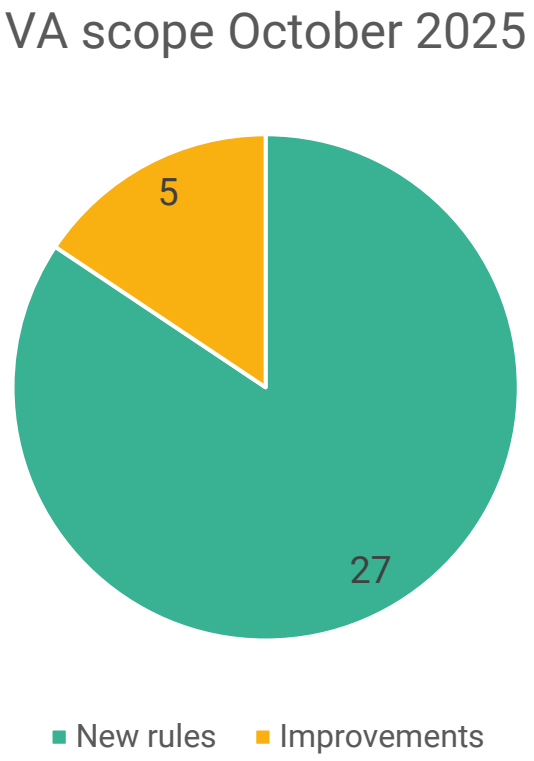
- Consultation on the proposed VA rule for October 2025 was launched at the March PSN-IUCLID meeting
- Feedback received from CLE and EACL. In addition, feedback on VA rules currently operational were also received.

BR_PPP_017, 015	**CLE/ABIM:** The rule relies on en Excel file that lists all mandatory endpoint study records. Some Data points are not addressed with a key study, weight of evidence or data waiving (e.g. CA 3.2, CP 3.2) as those are not required in the NAS or AIR processes. **EFSA: CLE contacted and requested to suggest the endpoints to remove. ABIM to be contacted**
QLT_PPP_027	**CLE**: Some Data points are not addressed with a key study, weight of evidence or data waiving (e.g. CA 3.2, CP 3.2) as those are not required in the NAS or AIR processes. Instead, an information overview is provided. Consequently, the linked Literature Reference if existing is also no study report nor publication. **EFSA: CLE contacted and requested to provide a list of documents to be exempted from the check**
QLT_PPP_026B	**CLE**: Many fields are being checked by the rule making its correction hard to implement. **EFSA: We are exploring the possibility of improving the VA report display by including the specific incomplete fields that trigger the failure in the message.**
XXXX	**EACL**: Rule proposed for October checking metabolism study in livestock. **EFSA: The rule is deprioritised for October due on-going work to revamp the format of the document.**
QLT_PPP_155 & 157	**EFSA: Several feedback have been collected on these rules e.g. Remove 'independent laboratory validation (ILV)' check for matrix soil, air and body fluids when when selecting as endpoint "Methods for post-approval control and monitoring purposes" , and will be prioritized for October release**

UPDATES ON VALIDATION ASSISTANT RULES

Scope of next IUCLID October release includes

- New rules to **strengthen the completeness of dossier** as outlined in VA – rules – Scope 2025
- New rules as identified by the **OECD Improvement Activity** #3
- **Improvements and bug fixes** as identified by stakeholders



Keep sharing your idea/feedback on VA rules - your input matters!

UPDATES ON VALIDATION ASSISTANT RULES

- The IUCLID May release introduced some bugs to the following rules which could not be fixed before the release. A fix is already scheduled for the next IUCLID service release. **RMS/EMS and applicants can disregard these failures until the bugs are fixed.**

QLT_PPP_167

- is found to be checking the incorrect dataset.

QLT_PPP_077.

- contains a bug. Workaround: All fields within the table ‘Summary of residues data from the supervised residue trials’ in the ‘Magnitude of residues in plants’ summary must be completed for the rule to be resolved.

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