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

IUCLID LIFE CYCLE MANAGEMENT AND VALIDATION RULES

efsa
EUROPEAN FOOD SAFETY AUTHORITY

VALIDATION ASSISTANT RULES

- The IUCLID service release (v6.8.13.2) introduced new and updated Validation Assistant (VA) rules
  - ➢5 new Quality warnings
  - ➢Improvement of existing VA rules
  - ➢Conversion from QLT to BR

Release notes and the full list of VA rules are published on Zenodo
https://zenodo.org/records/14069643

SUBMISSION PORTAL RULE

Changing the ‘European Reference Number’ (ERN) across resubmissions creates issues during the processing of applications in EFSA’s internal systems – For this reason the ERN must NOT be changed upon dossier resubmission (unless specifically agreed with EFSA)

- New BRs will be in place as of April 2025 to ensure consistency of the ERN across resubmissions

The rule* will check the following parameters against successful submissions and will fail if discrepancies of the ERN are found

- PPP dossier type
- Legal entity
  - compares legal entity UUID numbers
- Active substance
  - compares EC number/CAS number/IUPAC names of ‘Substance’ and ‘Reference substance’ datasets that are marked to be ‘Active substances’ (BR907 logic)

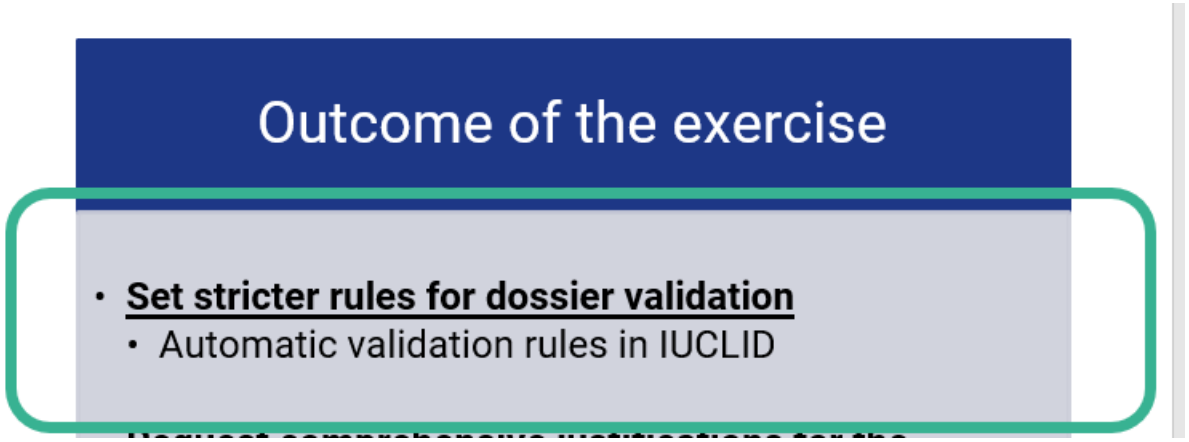
→

- If the ERN is the same the rule passes
- If the ERN is different the rule fails

*The rule is applicable only to EU_PPP Active substance and Microorganisms working contexts

SPEED OF RISK ASSESSMENT AT EFSA

- The automation of the dossier completeness check is one of the improvements identified during an internal EFSA exercise on how to further **speed up risk assessment**



IMPORTANT: EFSA plans to develop more VA rules and encourages **risk assessors to share insights** from the assessment of IUCLID dossiers e.g. most common additional data requests, data gaps, and other relevant observations that can be translated into new VA rules.

Member States may wish to add EFSA in copy of their exchanges with applicants during admissibility and risk assessment/production of DAR/RAR/ER – this is also in line with lean exercise conducted for MRL and presented at the last PSN meeting in October.
Other ideas?

IUCLID LIFE CYCLE MANAGEMENT

EFSA received an Industry position paper on the management of PPP dossiers which over time presents some specific issues on the need for version control and lifecycle management in IUCLID

The main areas of concern described in the paper are the following:

IUCLID format changes and associated data migration	Reuse of the active substance dataset across different/parallel regulatory processes	Newly introduced validation assistant rules

- The issue was thoroughly discussed between EFSA and ECHA, and several potential ways forward have been proposed

IUCLID LIFE CYCLE MANAGEMENT

- **IUCLID format changes and associated data migration**

➢ **INDUSTRY**: Upgrading an already submitted dossier to the latest version of IUCLID may cause issues with regard to safeguarding the content of the submission and data migration, causing alterations and removal of information.

➢ **Joint assessment EFSA-ECHA**: Migration issues seem to be linked to the past (especially April 2023) and, as a lesson learned, a process has been built to prevent data loss from occurring in future releases of IUCLID. The new process includes the definition of migration rules at the time of format changes (**no format changes can be proposed if no migration rules are in place**) and a joint EFSA-ECHA impact assessment. Updating all IUCLID instances to the latest version is considered to be an added value and limited benefits would arise from freezing the dossier at the version of IUCLID in which the submission occurred

IUCLID LIFE CYCLE MANAGEMENT

- **Reuse of the active substance dataset across different/parallel regulatory processes**

➢ **INDUSTRY**: Reusing the same active substance dataset in IUCLID across different/parallel regulatory processes would avoid duplication of work and lead to harmonization of the assessment of these data across different/parallel regulatory processes

➢ **Joint assessment EFSA-ECHA**: The issue is related to the PPP process only and to-date, with the current settings of IUCLID, there is no technical solution to overcome it

IUCLID LIFE CYCLE MANAGEMENT

- **Newly introduced validation assistant rules**

INDUSTRY: “The rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents applicable at the date of the submission of the application for renewal.” It is valid to consider data formats and validation rules in IUCLID to be covered by this as well. It is therefore not valid, to apply new validation rules and format definitions to submitted Dossiers

Joint assessment EFSA-ECHA: There may be solutions to better manage Validation rules in order to help reducing submissions challenges (still under analysis).

EFSA is also considering whether to temporarily stop/slow down on the systematic conversion of VA rules into BRs to minimize the impact on dossiers that are already in the risk assessment phase.

Proposal: Default period of 2 years from the implementation of the QLT to allow applicants to familiarise and adapt before converting the QLT into BR.

Member States to be reminded that all VA rules should be resolved/justified upon admissibility and disregarded for any subsequent resubmissions

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