

15th meeting of the PSN IUCLID sub-group
15 April 2026

UPDATE ON VALIDATION ASSISTANT RULES

FDP

EUROPEAN FOOD SAFETY AUTHORITY

OUTLINE



IUCLID major release: April



IUCLID service release: October



IUCLID major release: April 2026

IUCLID MAJOR RELEASE: APRIL 2026

Based on the feedback received during the Consultation VA rules – April 2026 , launched in November:

- **10 new QLT rules** originating from **REACH** are made available against PPP dossiers
- **BR_PPP_058,** checking FLEXIBLE_SUMMARY.ToxRefValues, has been **deactivated for MRL applications**
- **QLT_PPP_170** has been **updated** to account for **all units available for microorganism active substances**
- **QLT_PPP_013** has been updated by **removing mandatory checks for some endpoint study records**

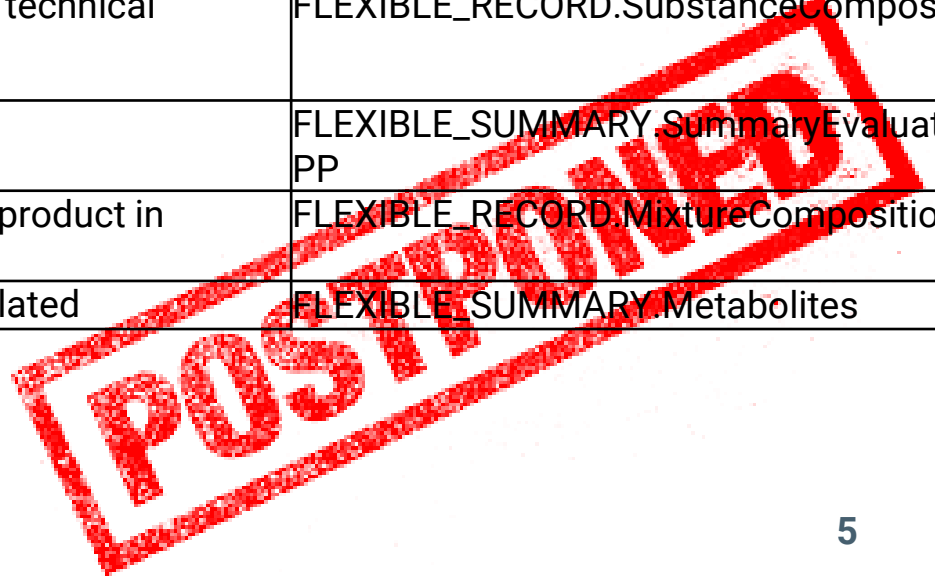
In addition, several rules have been updated due to **format changes affecting their functionality, for example:**

- **BR_PPP_062,** due to changes in the REFERENCE_SUBSTANCE entity
- **QLT_PPP_128,** due to changes in FLEXIBLE_SUMMARY.AquaticToxicityRacReporting

IMPORTANT: Due to the high volume of format changes affecting Validation Assistant (VA) rules, and contrary to what was mentioned at the previous PSN-IUCLID meeting, the implementation of several new VA rules has been postponed

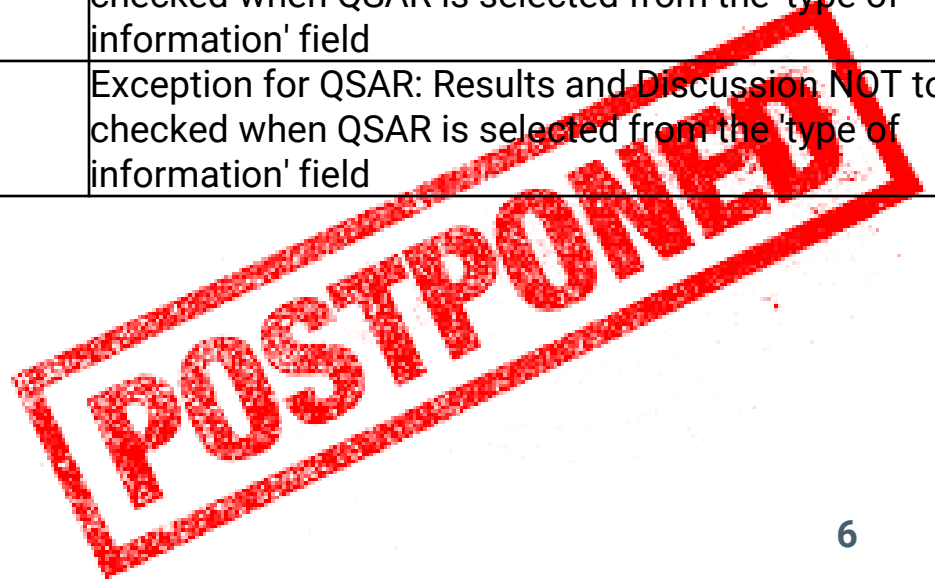
POSTPONED: NEW VALIDATION RULES – APRIL 2026

High-level specifications (QLT)	IUCLID document
It checks that at least two documents are created within the active substance dataset: one with the type of composition set to “batch composition” and another with the type of composition set to either “reference specification” or “technical specification”.	FLEXIBLE_RECORD.SubstanceComposition
IF “fumigating is picked from the picklist “Method of application AND “I- Grown indoor” is indicated in the field “Crop location” THEN the following fields should be completed: • “ventilation practices” • “treatment window • “waiting period handling treated product”	FLEXIBLE_RECORD.GAP
Only the following values are to be selected in the 'Type of composition' field: "technical specification", "reference specification" and "batch composition"	FLEXIBLE_RECORD.SubstanceComposition
Verify that a sanitised LoA is provided if a confidential LoA is attached	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP
Exactly (only) one mixture composition is provided as the main representative product in section 1.4 of the Product dataset	FLEXIBLE_RECORD.MixtureComposition.
If a document is created than the new field 'Compound found in' must be populated	FLEXIBLE_SUMMARY.Metabolites



POSTPONED: UPDATE VALIDATION RULES – APRIL 2026

Validation assistant rules	Reason for update
QLT_PPP_151: Result must be given (ToxicityReproduction)	Exception for QSAR: Results and Discussion NOT to be checked when QSAR is selected from the 'type of information' field
QLT_PPP_152: 'Reproductive effects observed' must be detailed (ToxicityReproduction)	Exception for QSAR: Results and Discussion NOT to be checked when QSAR is selected from the 'type of information' field
QLT_PPP_153: 'Effect levels (maternal animals)' must be detailed (DevelopmentalToxicityTeratogenicity)	Exception for QSAR: Results and Discussion NOT to be checked when QSAR is selected from the 'type of information' field



IUCLID MAJOR RELEASE: APRIL 2026

❑ The VA scenario matrix has been updated for **MRL applications** to account for new fields in the dossier header

- **NEW field 'MRL application on minor crops'**
  - ➢ when selected a limited set of rules is activated
- **Joint Submission fields**
  - ➢ If *Member* or *Contributor* is selected in 'Role of the joint submission' a limited set of rules is activated

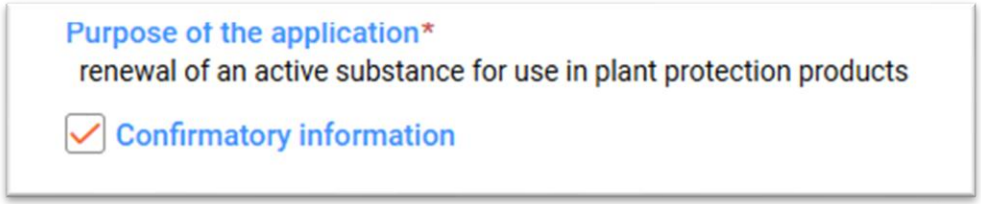
❑ In addition, the updated VA scenario matrix activates a limited set of rules when at least one of the following values is selected in "**Purpose of the application**"

- include an active substance in Annex IV
- amend existing residue definition
- evaluation of confirmatory data following review according to Article 12 of Regulation (EC) No 396/2005

IUCLID MAJOR RELEASE: APRIL 2026

- The VA scenario matrix has been updated for **Chemical and Microorganism active substance applications** to account for:

- Checkbox '**Confirmatory information**'
  - when ticked a limited set of rules is activated







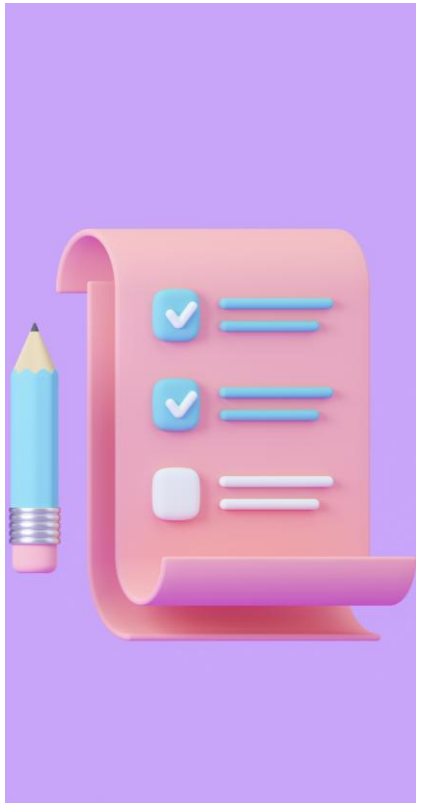
IUCLID service release: October 2026

#EFSA_EU

IUCLID SERVICE RELEASE: OCTOBER 2026

The draft scope of the next IUCLID October release includes

- Implementation of the rules postponed from April
- New rules to **strengthen the completeness of the ecotox and tox sections in chemical active substance applications** (as proposed by IT-ICPS)
- New rules to **strengthen the completeness of the residue section in MRL applications**
- New rules to **enforce proper data entry** following the **removal of DocJ**



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

IUCLID SERVICE RELEASE: OCTOBER 2026

PSN-IUCLID members are invited to provide **feedback** on the draft scope **via written consultation**

The consultation will start at **the beginning of May**; ad-hoc communication will follow

EFSA welcomes **additional proposals for new/update validation** rules – Please **submit your proposal** via the Ask a Question service

VA FAILURES: LIFE CYCLE MANAGEMENT

❑During the admissibility check

- RMS/EMS are responsible for ensuring that the **dossier is complete** and of **adequate quality** before declaring it admissible and moving it to the risk assessment phase.
- **RMS/EMS are responsible for checking VA failures** and ensuring that the **applicant resolves or justifies** them, if any.

❑After the declaration of admissibility

- As discussed and agreed at the **11th PSN-IUCLID meeting**, RMS/EMS should **disregard all VA failures** triggered in any subsequent resubmissions after admissibility, i.e. during the risk assessment phase.
- The applicant must **resolve only BRs**, if any, to successfully submit the dossier.

STAY CONNECTED

SUBSCRIBE TO
efsa.europa.eu/en/news/newsletters
efsa.europa.eu/en/rss
Careers.efsa.europa.eu – job alerts

LISTEN TO OUR PODCAST
Science on the Menu –Spotify, Apple Podcast and YouTube

FOLLOW US ON BLUESKY
@efsa.bsky.social
@efsa-animals.bsky.social @efsa-plants.bsky.social

FOLLOW US ON LINKEDIN
Linkedin.com/company/efsa

FOLLOW US ON INSTAGRAM
@onehealth_eu

CONTACT US
efsa.europa.eu/en/contact/askefsa

efsa
EUROPEAN FOOD SAFETY AUTHORITY