14th meeting of the PSN IUCLID sub-group
4 November 2025

UPDATE ON VALIDATION RULES

FDP

EUROPEAN FOOD SAFETY AUTHORITY

INTRODUCTION

IUCLID 6 v9.10 release and new validation rules

Validation Assistant rules – 2026 plan

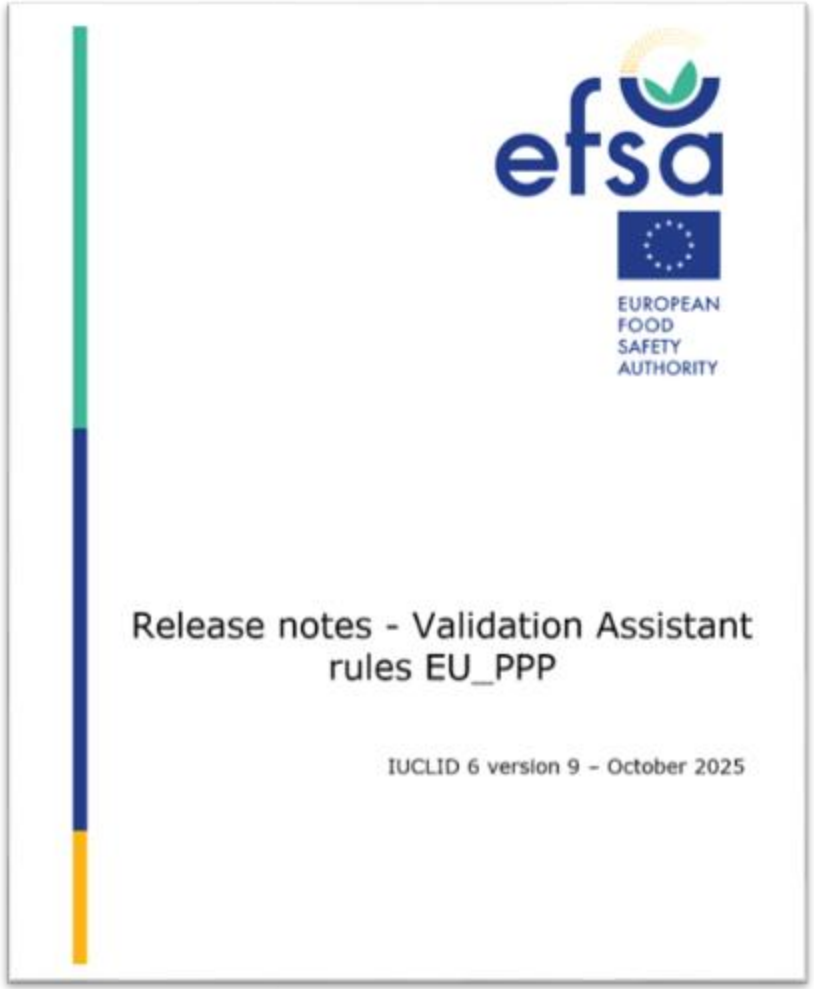
IUCLID SERVICE RELEASE

- IUCLID service release 6.9.10 went live on **30 October 2025** and introduced changes to the Validation Assistant rules

- **13 new QLT rules** checking study results in OHTs of the Chemical Active Substance dataset

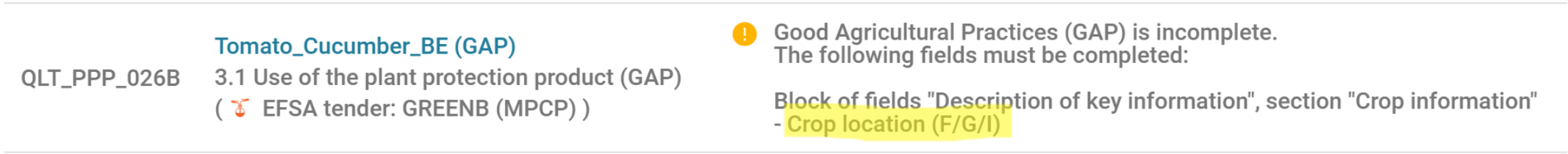
- **Updates to 13 existing rules** which involve
  - Bug fixes
  - Improvement to rule specifications
  - Improvement to message display

https://doi.org/10.5281/zenodo.5141356



VALIDATION RULES – OCTOBER RELEASE

- Based on feedback received during previous PSN–IUCLID meetings, we have piloted message display improvements in QLT_PPP_026B, which checks the completeness of the GAP table.
- Since QLT_PPP_026B validates many fields, it was previously confusing for users to identify which specific field caused the failure.
- With the improvement, only the fields that cause failures are now shown in the VA report



- EFSA aims at applying the same message display improvement to additional rules e.g. rules checking completeness of many fields.

VALIDATION RULES –2026

Strengthening the completeness of IUCLID dossiers and improving the overall quality remains a key success factor for the activities during 2026.

- ❑ **Continuing Development** of new VA rules
- ❑ **Reuse** of existing rules not yet applied to EU_PPP e.g. REACH
- ❑ Early identification of format changes affecting VA rules and
- ❑ Review of VA scenario matrix for EU_PPP MRL applications and introduction of a limited set of rules for minor crops application

NEW VALIDATION RULES – APRIL 2026

High-level specifications (QLT)	IUCLID document
Check that at least one document is created for the active substance dataset with the type of composition = ‘technical specification' and 'batch composition'	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
Commodities under the header 'Summary of key residues data selected from the supervised residue trials' should correspond to the commodities under the header 'Endpoints derived from key residue data'	ENDPOINT_SUMMARY.MagnitudeResiduesPlants
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
If DataSource.DataProtectionClaimed is YES than a justification must be provided in the associated Remarks field	ALL Endpoint study record

UPDATE VALIDATION RULES – APRIL 2026

Validation assistant rules	Reason for update
BR_PPP_062: The reference substance must contain at least one of the following identifiers in the designated fields: EC number, CAS number, IUPAC name. For microorganisms the species and strain should be reported in the IUPAC name. In the case of extracts or other cases where an IUPAC name cannot be defined this field should be completed e.g. 'Extract of ginger' or 'Unknown mixture'	Update needed to reflect the changes in the reference substance entity e.g. new fields to characterize the microorganism
QLT_PPP_013: KS/WoE must be provided for all required sections (Mixture_Active_sub_app)	Update needed to remove some study summary from the list of mandatory documents to be created PROPOSAL FROM CROP LIFE EUROPE
QLT_PPP_170: The concentration unit of the active substance must be expressed in CFU/g in the Mixture composition	Update needed to include other relevant units
BR_PPP_058: The AOEL must be completed otherwise please select 'Not allocated' (MO, MRL, Active sub app) → FLEXIBLE_SUMMARY.ToxRefValues	Should all fields within the AOEL header be completed e.g. oral absorption (%)?

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

VALIDATION RULES – CONSULTATION

PSN-IUCLID members are invited to provide feedback on the proposed changes by November 21st

Feedback are to be provided in the following link

EFSA welcomes additional proposals for new/update validation rules – Submit your proposal through the Ask a Question service

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