

7th meeting of the PSN IUCLID sub-group  
19-20 June 2023

# IUCLID FEATURES: VALIDATION ASSISTAN TOOL

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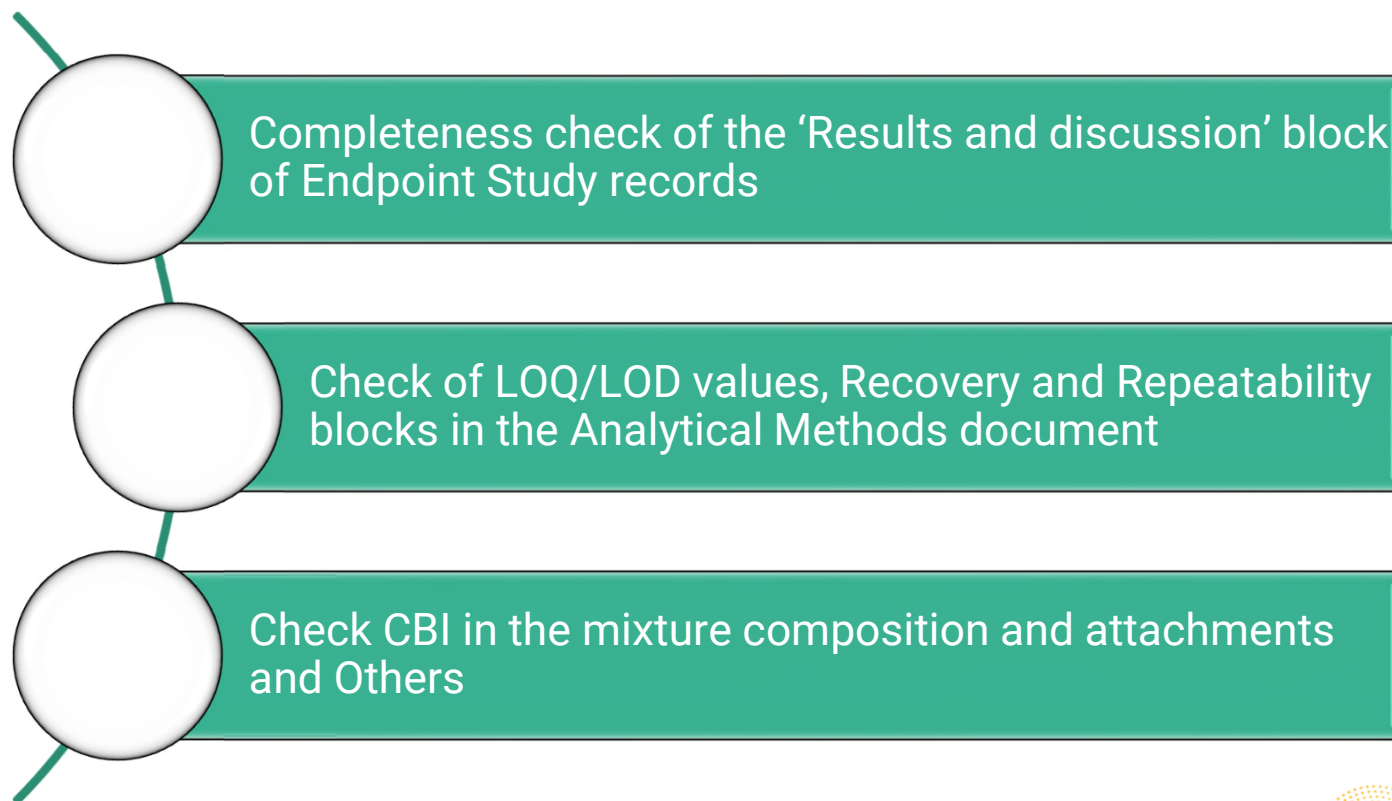
A photograph of a man in a green t-shirt and dark pants harvesting a large, leafy vegetable, possibly a chard or beet, in a vast field. The sun is low on the horizon, creating a warm glow and long shadows. The sky is blue with some wispy clouds and a few white contrails. The field is filled with rows of similar plants. The image is framed by a teal-colored border on the right and bottom sides.

**OCTOBER 2023 RELEASE:  
FOR ADOPTION**



# VALIDATION ASSISTANT: OCTOBER RELEASE

- 13 new QLT\_PPP rules
- Update of 2 rules
- Changes of QLT to BR



# VALIDATION ASSISTANT: OCTOBER RELEASE

## Completeness check of the 'Results and discussion' block of Endpoint Study records



### ENDPOINT\_STUDY\_RECORD.ToxicityToTerrestrialArthropodsOtherThanBees (DEACTIVATED in MAY)

- 'Results and discussion' block
- For each endpoint study record marked as 'key study' or 'weight of evidence', under 'Effect concentrations' heading, the fields 'Duration', 'Dose descriptor', 'Effect conc.' and 'Basis for effect' must be filled in, with unit



### ENDPOINT\_STUDY\_RECORD.Eyelrritation

- 'Results and discussion' block
- An endpoint study record marked as 'key study', 'weight of evidence' or 'supporting study' with the 'Endpoint' selection 'skin sensitisation: in vivo (LLNA)' is expected to have at least one result provided under 'Results (in vivo (LLNA))' heading.



### ENDPOINT\_STUDY\_RECORD.SkinSensitisation

- 'Results and discussion' block
- An endpoint study record marked as 'key study', 'weight of evidence' or 'supporting study' with the 'Endpoint' selection 'eye irritation: in vitro / ex vivo' is expected to have at least one result provided under 'Results (In vitro)' heading.



### ENDPOINT\_STUDY\_RECORD.SkinIrritationCorrosion

- 'Results and discussion' block
- An endpoint study record marked as 'key study', 'weight of evidence' or 'supporting study' with the 'Endpoint' selection 'skin irritation: in vitro / ex vivo' or 'skin corrosion: in vitro / ex vivo' is expected to have at least one result provided under 'Results (In vitro)' heading.





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Key value for chemical safety assessment

Dietary burden

New item

Import file

Field Identifier: FLEXIBLE\_SUMMARY\_ResiduesInLivestock.KeyValueForChemicalSafetyAssessment.DietaryBu  
Field type: Repeatables List

1

RD RA (plant/feed)

Animal species

Median dietary burden

Maximal dietary burden

Median dietary burden

Maximal dietary burden

Trigger exceeded?

~marks



- 

Summary of residues data from the supervised residue trials

New item

Import

Field identifier: ENDPOINT\_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData

Field type: Repeatables List

1

Study name / type

Relevant GAP

Plant back interval (PBI)

Commodity(ies) for which MRL and risk assessment values are derived

Commodity(ies) used in the residue trials

Residue levels: RD RA

Residue levels: RD MO

# VALIDATION ASSISTANT: OCTOBER RELEASE

ENDPOINT\_STUDY\_RECORD.AnalyticalMethods → 'Results using analytical (primary) method' common block

- **Repeatability:** the fields Analyte, Matrix, Number replicates, Mean content, RSD (%) must be completed
- **Recovery:** the fields Analyte, Matrix, Fortification level, Number replicates, Range recovery (%), Mean recovery (%) and RSDr (%) must be completed
- **LOQ/LOD:** for each endpoint study record the Limit of quantification (LOQ) must be provided.

Results and discussion

Results using analytical (primary) method

Recovery [+ New item](#) [Import file](#) [v](#)

#	Analyte	Matrix	MRM/ m/z	Fortification l...	Number repli...	Range recove...	Mean recover...	RSDr (%)	Remarks	Actions
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[Additional details on recovery results](#)

Repeatability [+ New item](#) [Import file](#) [v](#)

#	Analyte	Matrix	Number replica...	Mean content	RSD (%)	RSDr (%)	Horrat value	Remarks	Actions
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LOQ/LOD [+ New item](#) [Import file](#) [v](#)

#	Analyte	Matrix	Limit of quantification	Limit of detection	Remarks	Actions
1						



# VALIDATION ASSISTANT: OCTOBER RELEASE

ENDPOINT\_STUDY\_RECORD.AnalyticalMethods → 'Results using analytical (primary) method' common block

- **Repeatability:** the fields Analyte, Matrix, Number replicates, Mean content, RSD (%) must be completed
- **Recovery:** the fields Analyte, Matrix, Fortification level, Number replicates, Range recovery (%), Mean recovery (%) and RSDr (%) must be completed
- **LOQ/LOD:** for each endpoint study record the Limit of quantification (LOQ) must be provided.

Same rules will be applied at the common blocks *Results using enforcement method (if applicable)* and *Results using confirmatory method (if applicable)*.

However, these rules will strictly depend on the 'Endpoint' selection in the OHT

Picklist values of Endpoint:

- analysis of the microorganism as manufactured (QC)
- analytical methods
- analytical profile of batches
- methods for post-approval control and monitoring purposes
- methods for providing information on possible variability of seed stock/active micro-organism
- methods for providing information on purity of seed stock/active micro-organism
- methods for relevant impurities and/or metabolites of concern
- methods for risk assessment
- methods for the analysis of the (formulated) product
- methods for the analysis of the active substance as manufactured (QC)
- methods for the determination of residues
- methods to determine storage stability/shelf life
- methods to differentiate a mutant of the microorganism from the parent wild strain
- methods to identify and quantify contaminating microorganisms
- methods used for monitoring purposes to determine and quantify residues (viable or non-viable)
- methods, procedures and criteria used to establish the presence and identity of the microorganism, analysis of the microorganism as manufactured



Analysis still on-going



# VALIDATION ASSISTANT: OCTOBER RELEASE



- ❖ From the Filtering rules Working party, new BR needed:
  - Remove CBI flag from the **FLEXIBLE\_RECORD.MixtureComposition**.

Mixture composition: The composition information for the *active substance*, *safener*, *synergist* or *active substance (other not to be assessed)* cannot be claimed confidential. Please remove CBI flag.

- Additional checks on the Reference substance entity for the function 'Active Substance' are currently under consideration

Components ⓘ  
Field identifier: FLEXIBLE\_RECORD.MixtureComposition.Components  
Field type: Block

+ New item Import file ▾

#	Component...	Name	Function	Typical con...	Concentrati...
1	 	VA_Substance   DifferentSubstance	active substance	ca. 2 ppm	

- ❖ A sanitised version must be provided if Attached document is provided in block 'Attached background material' of the document **FLEXIBLE\_RECORD.Manufacturer\_EU\_PPP**.





# VALIDATION ASSISTANT: OCTOBER RELEASE

- **Update QLT\_PPP\_026** → The rule checks that at least one FLEXIBLE\_RECORD.GAP document is created **and is complete**

The following fields must be completed:

Block “**Administrative data**”

- Product

Block “**Description of key information**”, section “**Crop information**”

- Crop / treated object
- Crop destination is mandatory for GAPs that refer to crops
- Authorisation zone
- MRL zone
- Country or territory
- Crop location

Block “**Description of key information**”, section “**Pest/disease to be treated**”

- Target organisms-scientific name (at least one target organism needs to be defined in a Gap)
- Method of application
- Growth stage (mandatory IF the gap refers to a crop)
- Number of applications (range)
- Application rate per treatment (product)- range
- Safener/synergist adjuvant added: IF YES, the field is mandatory
- Application rate per treatment for target a.s. (range)
- Pre-harvest interval

Purpose of the GAP

[Active substance / microorganism / basic substance applications](#)

✓ intended use supported in the EU for which data are provided (D1)

[MRL applications](#)

✓ MRL application: amendment of existing residue definition

Crop information

[Crop / treated object](#)

✓ 3ASTC (Asteraceous vegetable crops) (crops > 3ASTC (Asteraceous vegetable crops))

[Genetical modification of crop](#)

no

[Crop destination\(s\)](#)

✓ grown for green manure (3GRMAD)

[Authorisation zone](#)

EU

[MRL zone](#)

EU

[Country or territory](#)



# VALIDATION ASSISTANT: OCTOBER RELEASE



**Update QLT\_PPP\_125:** Flexible Summary MRL Proposal must be provided and only once in the Active substance dataset



**Update BR\_PPP\_090:** Block dossiers with the same main mixture as component of the main mixture composition and/or Other representative products mixture



**Conversion Quality warnings to Business rules (108 to 111):**

The Pre-Application\_id in the dossier header must be entered in this format EFSA-ID-YYYY-NNNNNN





# IMPLEMENTATION DATE OR IUCLID VERSION IN IUCLID VALIDATION REPORT



# IUCLID VALIDATION ASSISTANT REPORT

## IUCLID is used by different organisations and for different regulatory purposes

➤ Ad hoc requests cannot be implemented unless agreed by all actors involved

- ❖ The implementation date or IUCLID version in which the rule became operational is consultable in EFSA RulesMasterFile
- ❖ This information could also be included in 'IUCLID Validation Assistant rules for PPP dossiers' available in Zenodo

Summary	Issue type	Message	Target documents	Checked field reference	Impacted area
QLT_PPP_001: Endpoint must be indicated	Quality rules/Warning	Administrative data' is not complete. The 'Endpoint' addressed by the study record must be indicated.	All endpoint study records	Administrative data – common block	<b>Report generator:</b> presentation of information <b>Admissibility:</b> confirmation that all endpoints are addressed
QLT_PPP_002: Data waiving must be justified	Quality rules/Warning	Administrative data' is not complete. If you want to submit a data waiving then the	All endpoint study records	Administrative data – common block	<b>Report generator:</b> presentation of





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