6th meeting of the PSN IUCLID sub-group
28 March 2023

IUCLID FEATURES: VALIDATION ASSISTAN TOOL

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efsa
EUROPEAN FOOD SAFETY AUTHORITY
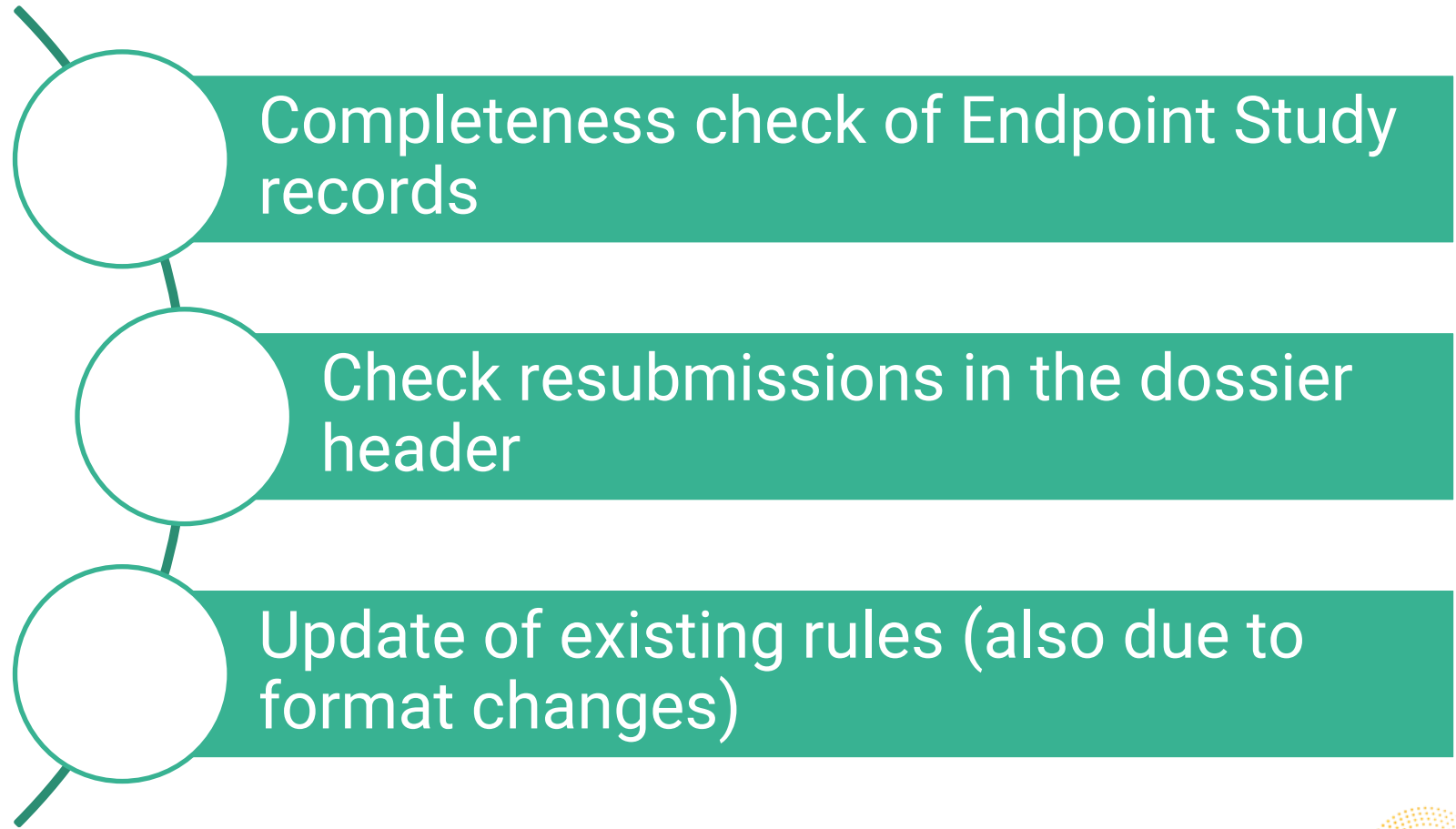
VALIDATION ASSISTANT

IUCLID **April** release

IUCLID **October** release

VALIDATION ASSISTANT: APRIL RELEASE

- ➢ 14 new QLT_PPP rules
- ➢ 1 new BR_PPP
- ➢ Changes due to new format release and bug fixes
- ➢ Changes of QLT to BR

Completeness check of Endpoint Study records

Check resubmissions in the dossier header

Update of existing rules (also due to format changes)

VALIDATION ASSISTANT: APRIL RELEASE

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

Rule	Description	ENDPOINT_STUDY_RECORD
QLT_PPP_140	QLT_PPP_140: 'Effect concentrations' must be detailed	ShortTermToxicityToAquaInv
QLT_PPP_141	QLT_PPP_141: 'Effect concentrations' must be detailed	LongTermToxicityToAquaInv
QLT_PPP_142	QLT_PPP_142: 'Effect concentrations' must be detailed	ToxicityToAquaticAlgae
QLT_PPP_143	QLT_PPP_143: 'Effect concentrations' must be detailed	ToxicityToAquaticPlant
QLT_PPP_144	QLT_PPP_144: 'Effect concentrations' must be detailed	ToxicityToTerrestrialArthropodsOtherThanBees
QLT_PPP_145	QLT_PPP_145: 'Effect concentrations' must be detailed	ToxicityToTerrestrialPlants
QLT_PPP_146	QLT_PPP_146: 'Effect levels' must be detailed	ToxicityToBirds
QLT_PPP_147	QLT_PPP_147: 'Effect levels' must be detailed	AcuteToxicityInhalation
QLT_PPP_149	QLT_PPP_149: 'Effect levels' must be detailed	RepeatedDoseToxicityDermal
QLT_PPP_150	QLT_PPP_150: 'Critical effects observed' must be detailed	RepeatedDoseToxicityDermal
QLT_PPP_151	QLT_PPP_151: 'Effect levels' must be detailed	ToxicityReproduction
QLT_PPP_152	QLT_PPP_152: 'Reproductive effects observed' must be detailed	ToxicityReproduction
QLT_PPP_153	QLT_PPP_153: 'Effect levels (maternal animals)' must be detailed	DevelopmentalToxicityTeratogenicity
QLT_PPP_154	QLT_PPP_154: 'Developmental effects observed' must be detailed	DevelopmentalToxicityTeratogenicity

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New feature in the IUCLID dossier header to indicate dossier resubmissions. Please specify '**Official request**' or '**Spontaneous update**'

New **BR_PPP_159** checks completeness of the 'Request', 'Request Type' and 'Reason for resubmission' fields

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- Update of existing BR rules due to bug fixes

- BR_PPP_051: European joint submission number must be provided in UUID format (MO)
- BR_PPP_038 European joint submission number must be provided in UUID format
- BR_PPP_052: If the submission is part of a Joint submission, then it must be indicated whether the submitter is the lead applicant (MO)
- BR_PPP_039 If the submission is part of a Joint submission, then it must be indicated whether the submitter is the lead applicant

- New BR rules Consultation on QLT_PPP to be converted to BR_PPP in April 2023.xlsx

- Update of existing BR rules due to new format changes

- QLT_PPP_045: If attached document is provided a sanitised version must be provided as well in Flexible summaries
- QLT_PPP_117: Transformation products must be identified

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- Update of existing BR rules due to new format changes

New IUCLID documents and modified existing documents (e.g. endpoint summaries) removed from the list of mandatory documents checked by rules such as

BR_PPP_014: Summaries must be provided for all required sections (Mixture_Active_Sub_App)

BR_PPP_016: Summaries must be provided for all required sections (Mixture_MO)

BR_PPP_018: Summaries must be provided for all required sections (Substance_Active_Sub_App)

❑ Documents removed (e.g., ecotox and Tox endpoint study records) will become mandatory again as of October 2023

EU_PPP_ACTIVE_SUBSTANCE_Summaries (MIXTURE) path	Section
ENDPOINT_SUMMARY.GeneralInformation	2.1 appearance
ENDPOINT_SUMMARY.Explosiveness	2.2.1 explosive properties
ENDPOINT_SUMMARY.OxidisingProperties	2.2.2 oxidising properties
ENDPOINT_SUMMARY.FlashPoint	2.3.1 flash point
ENDPOINT_SUMMARY.Flammability	2.3.2 flammability
ENDPOINT_SUMMARY.AutoFlammability	2.3.3 self heating
ENDPOINT_SUMMARY.pH	2.4 acidity alkalinity and ph value
ENDPOINT_SUMMARY.Viscosity	2.5.1 viscosity

UAT ON VALIDATION RULES IS ON-GOING

Help us test the rules in IUCLID Beta and report your feedback here

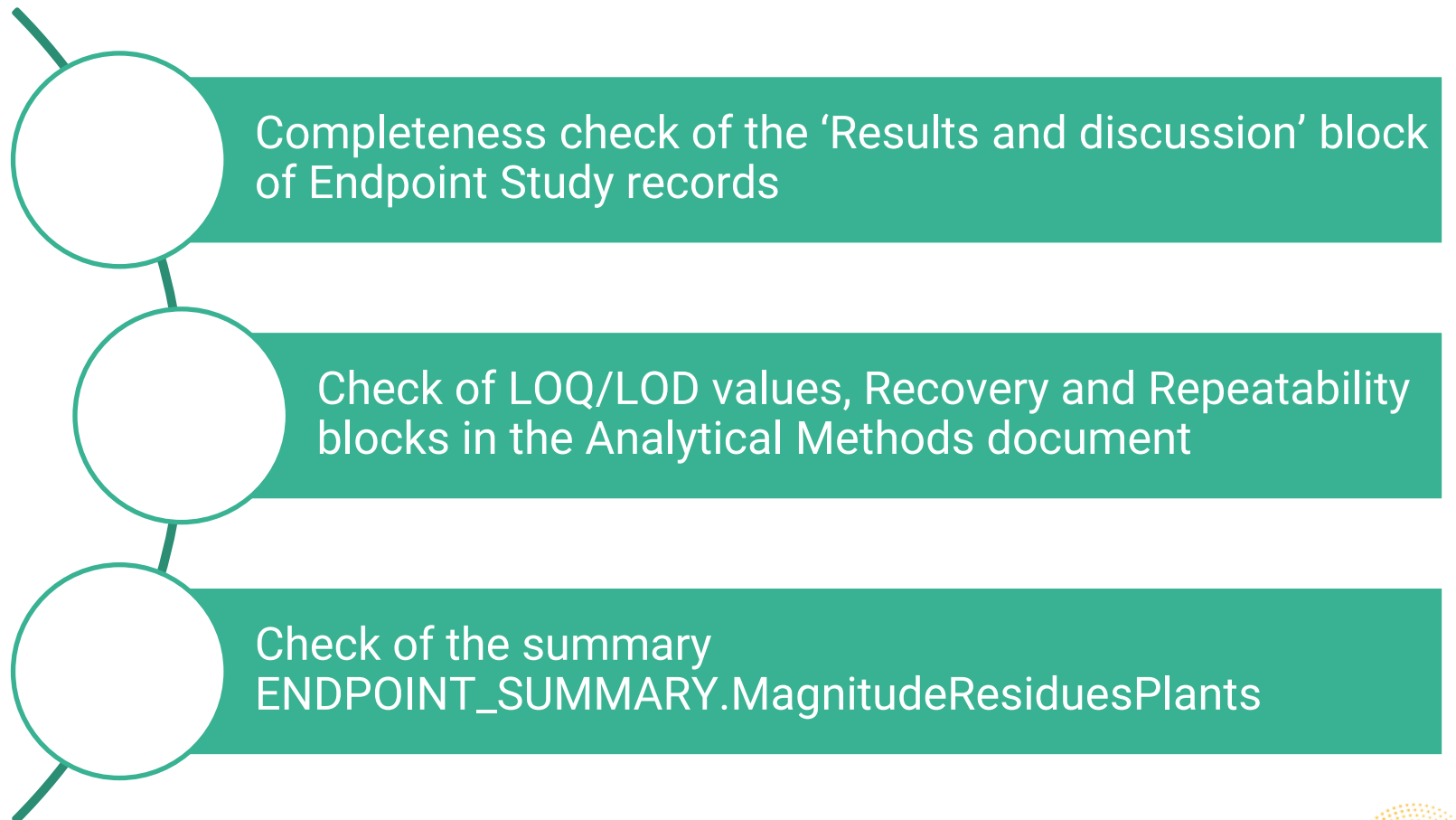IUCLID April 2023 release_VA tests.xlsx

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More information about the October rules can be consulted in the RulesMasterFile

Filter by 'Status'=Planning October 2023 release
EU_PPP_RulesMasterFile_PSN.xlsx

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

Check of LOQ/LOD values, Recovery and Repeatability blocks in the Analytical Methods document

Check of the summary ENDPOINT_SUMMARY.MagnitudeResiduesPlants

VALIDATION ASSISTANT: OCTOBER RELEASE

New Validation rules proposed by ANSES under the on-going partnership for Report generator

Rule	Document
QLT_PPP_164_Only one Proposed maximum residue levels summary can be provided	FLEXIBLE_SUMMARY.MRLProposal
QLT_PPP_165_at least one common block for each summary of residue data must be created	ENDPOINT_SUMMARY.MagnitudeResiduesPlants

VALIDATION ASSISTANT: OCTOBER RELEASE

From the Filtering rules Working party:

- QLT_PPP_162: 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.

YOUR FEEDBACK IS NEEDED

- Several summary documents are reported per section
  - Proposal → QLT_PPP_XXX_Only one summary per section must be reported?

- Summaries of section 2 'Physical, chemical and technical properties of the plant protection product' empty
  - Proposal → 'Key value for chemical safety assessment' block mandatory?

- No BR checking Legal Entity (LE) in the Product dataset
  - Proposal → New BR checking LE in the Product dataset?

YOUR FEEDBACK IS NEEDED

- **QLT_PPP_026** → The rule checks that at least one FLEXIBLE_RECORD.GAP document is created

Make sure to report the key information in the document

Proposal to amend QLT_PPP_026

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

The following fields must be completed:
Block of fields "Administrative data"
- Product

Block of fields "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 of fields "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

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