Trusted science for safe food

3rd PSN IUCLID sub-group meeting – 04 May 2022

IUCLID features: Validation assistant - April and October release

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efsa
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Validation Assistant

The Validation Assistant is a tool available for IUCLID users to check the dossier is technically complete, before submitting it to EFSA

Business Rules (e.g., BR_PPP)

Prevents the applicant from successfully submitting a dossier

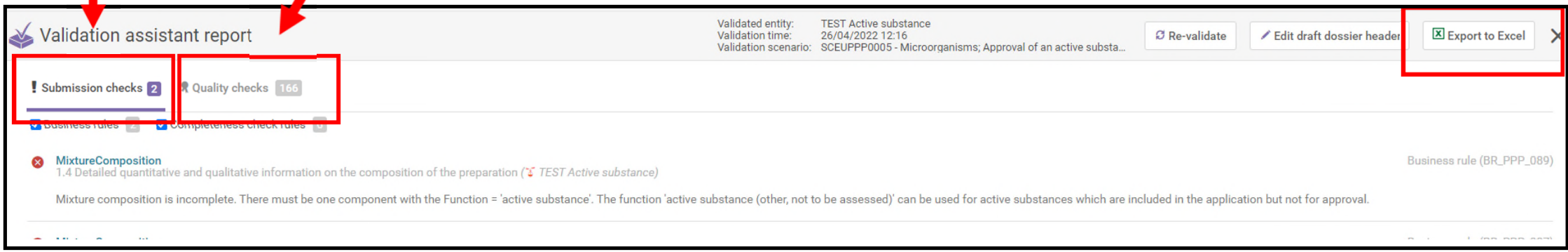
Quality warnings (e.g., QLT_PPP, TCC)

The applicant will be able to submit the dossier but will most likely not pass the admissibility check.

Validation Assistant

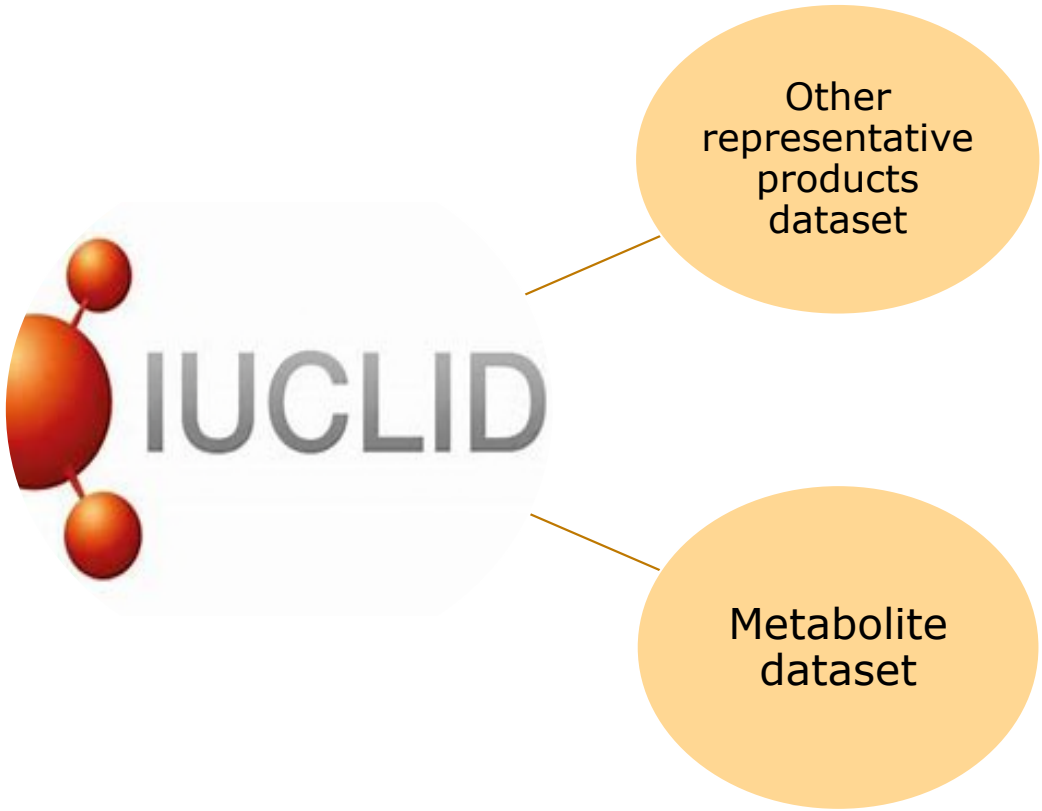
BR_PPP

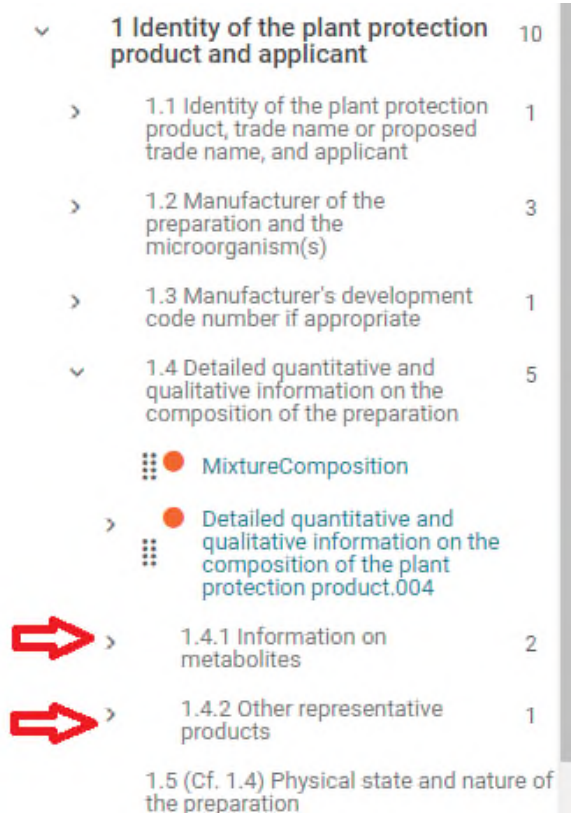
QLT_PPP, TCC



Validation Assistant: April release

- Quality warnings
- 26 new QLT_PPP
- EFSA Agency IUCLID vers. 6.6.14.3

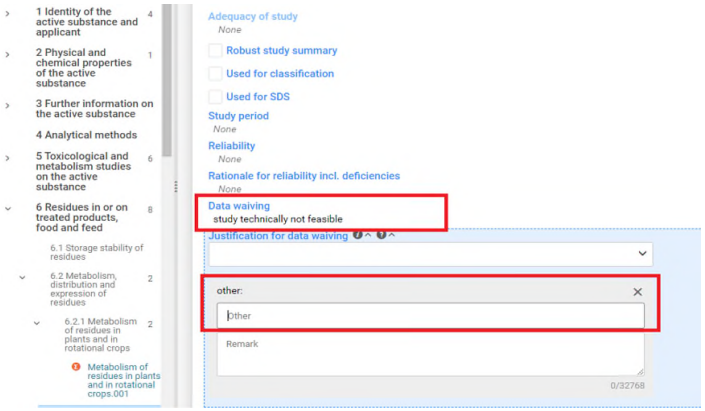




April release: Check Administrative data field

- **QLT_PPP 063/64/65/69** (other representative products)
- **QLT_PPP 091/92/93/97** (metabolites)

- QLT_PPP 063/091: Endpoint must be indicated
- QLT_PPP_064/092: Data waiving must be justified



- QLT_PPP_065/093: Reliability must be provided for Key Study (KS) and Weight of Evidence (WoE)
- QLT_PPP_069/097: Key studies should have reliability 1 or 2

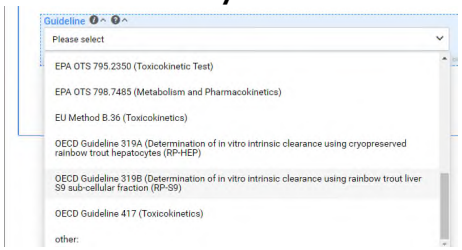
  1-Reliable without restriction
  2-Reliable with restrictions

April release: Check Materials And Method field

- **QLT_PPP 067/68/70** (other representative products)
- **QLT_PPP 095/96/98** (metabolites)

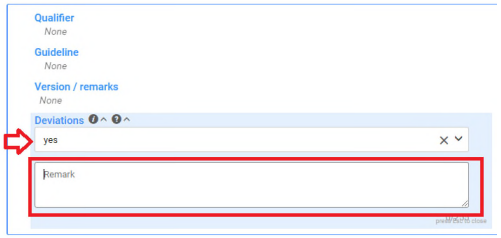
➢ QLT_PPP_067/095: Guideline must be given for Key Study, WoE and testing proposal

For each endpoint study record marked as 'key study' or 'weight of evidence', or indicated as a testing proposal, the test guideline (to be) used in the study must be indicated in the 'Guideline' under the 'Test guideline' heading.



➢ QLT_PPP_070/098: Deviations in the guideline must be explained

- In the entry 'Test guideline' the field 'Deviations' has been set to 'yes'. In this case, you are expected to provide a brief explanation summarising the deviations from the guideline in the below 'Remarks' field.



RJ0

April release: Check Materials And Method field

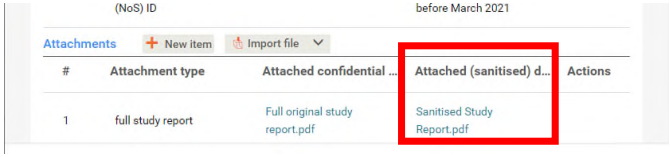
- QLT_PPP_068/096: Test material must be given for Key Study, WoE and testing proposal

  For each endpoint study record marked as 'key study' or 'weight of evidence', or indicated as a testing proposal, the test material (to be) used in the study must be identified by linking a test material information (TMI) record in the 'Test material information' entry.

April release: Check Attachment blocks – sanitised documents

- **QLT_PPP_071/097 -** Check Data Source - Literature reference
  - Attached (sanitised) documents for publication must be provided for each endpoint study record marked as 'key study' or 'weight of evidence'

- **QLT_PPP_079/106 -** Check Data Source - Literature reference
  - For each 'Attachments' block a version of the attachment must be provided under the 'Attached (sanitised) documents for publication' field, in addition, a selection under the field 'Attachment type' must be filled in.



- **QLT_PPP_074 -** Check 'Additional information' field (Summaries)
  - For each Endpoint study summary document a sanitised version must be provided if 'Attached document' is provided

- **QLT_PPP_075 -** Check 'Overall remarks, attachments' field
  - If Attached document or Attached full study report is provided, a sanitised version for publication must be provided as well in the 'Attached (sanitised) documents for publication' field

- **QLT_PPP_076 -** Check FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP document 'Reports and administrative information' field
  - If attachment is provided a sanitised version must be provided as well in SummaryEvaluation_EU_PPP

Validation Assistant: April release

- QLT_PPP_072/100:For each endpoint study record marked as 'key study' or 'weight of evidence', **report the notification of studies status of the submitted study in the Literature reference entity.**

  - If the study has been notified in the Notification of Studies Database then report the number in the 'Other study identifier(s)' - 'Study ID' and indicate Study ID type="notification of Studies (NoS) ID)".

  - If the study has not been notified, then the 'Remarks' field must be completed providing a justification.

Other study identifier(s) + New item | Import file

#	Study ID type	Study ID	Remarks	Actions
1	Notification of Studies (NoS) ID	*None*	Study commissioned before March 2021	

  - If the study has been notified in the Notification of Studies Database then the NoS ID must be reported in the 'Study ID' field of the Literature Reference for the study, and indicate select type = 'notification of Studies (NoS) ID' NoS_ID and must follow the format: EFSA-YYYY-NNNNNNNN (where YYYY-year with minimum value set to 2021 and numeric and N-8digit number).

Other study identifier(s) + New item | Import file

#	Study ID type	Study ID	Remarks	Actions
1	Notification of Studies (NoS) ID	EFSA-2022-12345678	*None*	

October release: Update to existing rules

❑ QLT_PPP_010 Update

Study ID and/or Justification (remarks) must be provided

- There is exactly one entry under the *Other study identifier(s)* table with the field '*Study ID type*' = ***notification of Studies (NoS) ID***
- AND it fulfils at least one of the following:
  - The field '*Study ID*' in the 'Literature reference' (LITERATURE.GeneralInfo.StudyIdentifiers.StudyID) is **not** empty ~~and the entry of the following format: EFSA-YYYY-NNNNNNNN (there YYYY-year with minimum value set to 2021 and numeric and N-8digit number).~~
  - The 'Remarks' field ~~should~~ is **not** be empty.
- AND the field '*Study ID*', if exists, has the format EFSA-YYYY-NNNNNNNN (there YYYY-year with minimum value set to 2021 and numeric and N-8digit number).

October release: Dossier header checks

- **QLT_PPP 108-111**
  - Rules checking Pre-Application ID *(BS, A.S. Application, MRL, MO)*

The Pre-Application_id must be entered in this format EFSA-ID-YYYY-NNNNNN

QLT_PPP_108 Pre-Application ID in EFSA format (Active substance application)
QLT_PPP_109 Pre-Application ID in EFSA format (Microorganism)
QLT_PPP_110 Pre-Application ID in EFSA format (MRL application)
QLT_PPP_111 Pre-Application ID in EFSA format (Basic substance)

- **BR_PPP 112-115**
  - Rules checking Notification of Studies (NoS) ID

The Notification of Studies Identifiers must be entered in this format EFSA-YYYY-NNNNNNNN

BR_PPP_112 NoS ID msut be of valid format (Active substance)
BR_PPP_113 NoS ID msut be of valid format (MO)
BR_PPP_114 NoS ID msut be of valid format (MRL)
BR_PPP_114 EFSA study identification must be of valid format (BS)

October release: Flexible summaries check

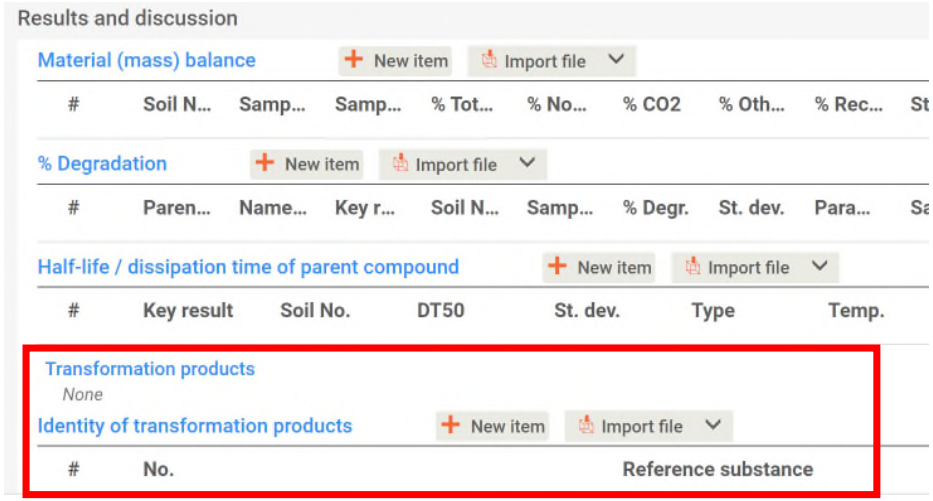
- **QLT_PPP XXX-XXX**

Checks presence of mandatory Flexible summaries (*A.S. Application, MRL, MO)*

EU_PPP_ActiveSubstance_FLEXIBLE_SUMMARY	IUCLID section	Not mandatory
FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP	11.2 Other reports	x
FLEXIBLE_SUMMARY.ToxRefValues	5. Toxicological and metabolism studies on the active substance	
FLEXIBLE_SUMMARY.Metabolites	EU PPP Active substance application (product) 1.4.4 Information on metabolites	
FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest	11.4 Endocrine disrupting properties	
FLEXIBLE_SUMMARY.ResiduesInLivestock	6.4 Feeding studies	
FLEXIBLE_SUMMARY.MRLProposal	6.7.2 Proposed maximum residue levels	
FLEXIBLE_SUMMARY.ExpectedExposure	6.9 Estimation of the potential and actual exposure through diet and other source	
FLEXIBLE_SUMMARY.DefinitionResidueFate	7.4 Residue definition for risk assessment and environmental monitoring	
FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPesticides	8 Ecotoxicological studies on the active substance	
FLEXIBLE_SUMMARY.AquaticToxicityRacReporting	8.2 Effects on aquatic organisms	
FLEXIBLE_SUMMARY.RelevantMetabolitesGroundWater	11.3 Relevance of metabolites in ground water	

October release: Set of rules (like REACH)

- **TCC_05_01**: Transformation products must be identified



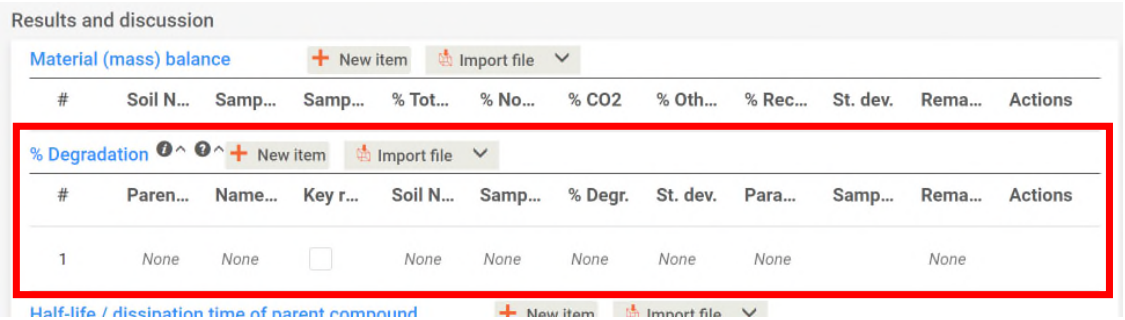
The rule checks that if ENDPOINT_STUDY_RECORD.BiodegradationInSoil has been indicated as a 'key study' or 'weight of evidence' in the field 'Adequacy of study', then a **selection must be made in the field 'Transformation products'**.

If 'yes' was selected, then in the table 'Identity of transformation products' there must be at least one row where the field 'Substance identity' contains a link to a reference substance entity.

PRIORITY

October release: Set of rules (like REACH)

- **TCC_050203_01**: Biodegradation in soil - results tables must be completed



The rule checks **ENDPOINT_STUDY_RECORD.BiodegradationInSoil**. For each endpoint study record marked as 'key study' or 'weight of evidence', at least one entry under the headings '% Degradation' or 'Half-life / dissipation time of parent compound' must be filled in.

Under '% Degradation' heading, the fields '% Degr.', 'Parameter' and 'Sampling time' must be filled in, with unit. Under 'Half-life / dissipation time of parent compound' heading, the fields 'DT50' and 'Temp.' must be filled in, with unit. Each created entry must be complete. If you select 'other:' in any of the picklists, the below field must be filled in.

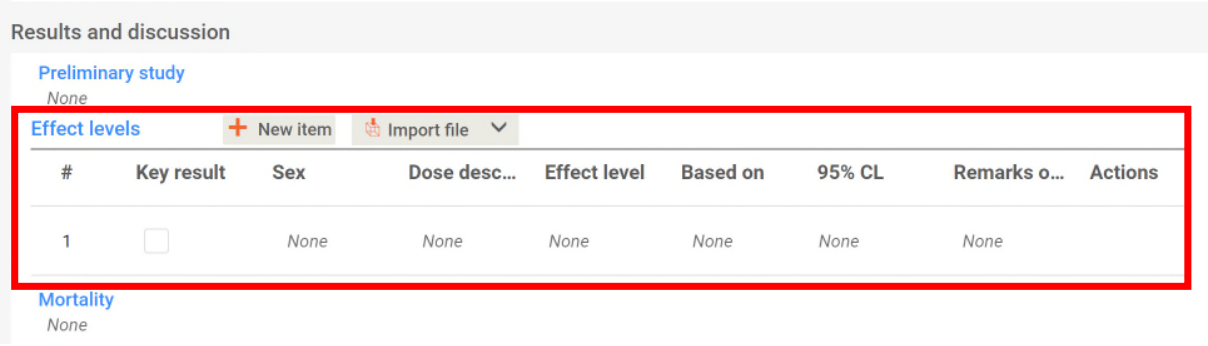
If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.

October release: Set of rules (like REACH)

- **TCC_070201_01**: Acute oral toxicity - results tables must be completed

The rule checks **ENDPOINT_STUDY_RECORD.AcuteToxicityOral**. For each endpoint study record marked as 'key study' or 'weight of evidence', under 'Effect levels' heading, the fields 'Dose descriptor' and 'Effect level' must be provided, with unit. Each created entry must be complete.

If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'. If none of the available picklist values apply, select 'other:' and provide the reason for not determining a quantitative result in the below field.



October release: Set of rules (like REACH)

- **TCC_070501_01:** Repeated dose toxicity oral - results tables must be completed - *effect levels*

The rule checks **ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral**. For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect levels' the fields 'Dose descriptor', 'Effect level' and 'Basis for effect level' must be provided, with unit. If you add several rows in the table, then all of them must be complete.

- **TCC_070501_02**: Repeated dose toxicity oral - results tables must be completed - *critical effects*

For each endpoint study record marked as 'key study' or 'weight of evidence', a selection must be made in the field 'Critical effects observed' of the table 'Target system / organ toxicity'.

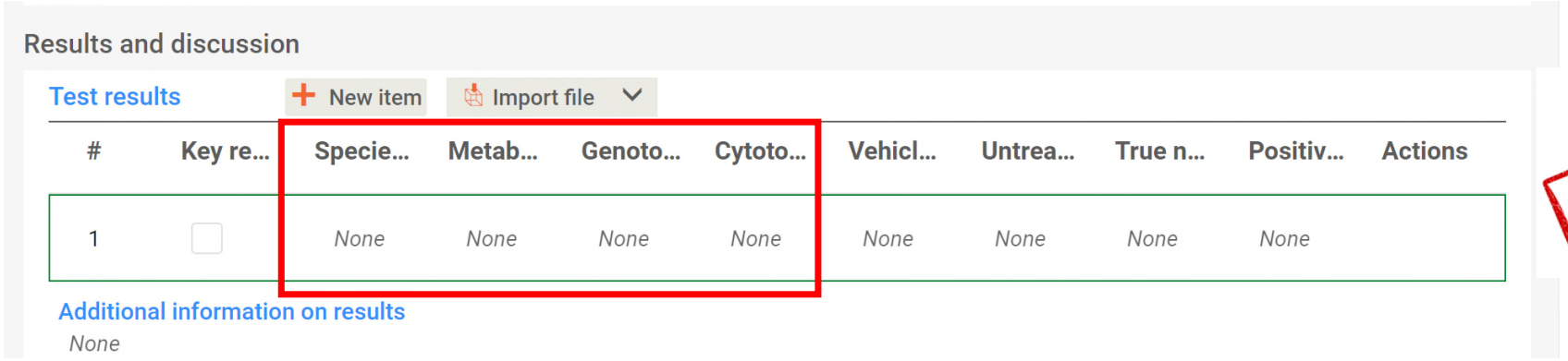
If 'yes' was selected, then the fields 'Lowest effective dose/conc.', 'System', 'Organ' and 'Treatment related' must be provided, with unit, where applicable. Each created row must be complete.

October release: Set of rules (like REACH)

- **TCC_070601_02:** Genetic toxicity in vitro - results tables must be completed

The rule checks **ENDPOINT_STUDY_RECORD.GeneticToxicityVitro**

For each endpoint study record marked as 'key study' or 'weight of evidence', under 'Test results' heading, the fields 'Species/strain', 'Metabolic activation', 'Genotoxicity' and 'Cytotoxicity/choice of top concentrations' must be provided. Each created entry must be complete.



October release: Set of rules (like REACH)

- **TCC_060101_01:** Short term toxicity to fish - results tables must be completed

The rule checks **ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish**

For each endpoint study record marked as 'key study' or 'weight of evidence', under 'Effect concentrations' heading, the fields 'Duration', 'Dose descriptor' and 'Effect conc.' must be filled in, with unit. If 'other:' was selected in any of the picklists, the below field must be filled in. Each created entry must be complete.

If a quantitative result was not determined, an result'. If none of the available picklist values apply, select 'other:' and provide the reason for not determining a quantitative result in the below field.

October release

- **QLT_PPP 53-60** *Proposed residue definitions and Toxicological reference values*

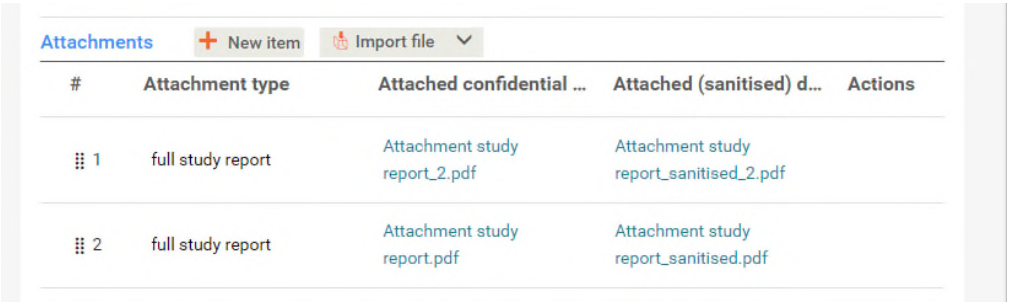
QLT_PPP_053	Proposed residue definitions. A Residue definition for enforcement for unprocessed plant/animal products must be provided
QLT_PPP_054	Proposed residue definitions. A Residue definition for risk assessment for unprocessed plant/animal products must be provided.
QLT_PPP_055	Proposed residue definitions. A Residue definition for risk assessment for processed crops must be provided.
QLT_PPP_056	Proposed residue definitions. A Residue definition for risk assessment for rotational crops must be provided
QLT_PPP_058	Toxicological reference values document the AOEL must be completed
QLT_PPP_059	Toxicological reference values document the ADI must be completed
QLT_PPP_060	Toxicological reference values document the ARfD must be completed

October release:rules 48 & 27 - Feedback needed

- QLT_PPP_048 & QLT_PPP_027

Both rules check **only one row** in the 'Attachments' block with the selection 'full study report' under the field 'Attachment type' and in the literature reference of all EU_PPP_endpoints

Consequently the rule fails/cannot be resolved if more than one attachment (row) is provided



Feedback needed!

Can the constraint that only one literature reference be included in the Endpoint Study Record data source be removed?
Post on TEAMs RICHARDSON Jane: QLT_PPP_027

RJ0

Resources

Rules Master File

	Typ	Parent Rule	DevOps	Summary	Description
QLT_PPP_001	W	QLT_PPP_001	IUCVA-1918	QLT_PPP_001: Endpoint must be indicated	Rule should check Documents owner entities location in the dossier and documents owner entities as s CF_obj_02 (IUCVA-1873). The rule should check documents under the sections described as QLT_PPP_endpoints_all, as specified *QLT_PPP_endpoints_all* Excel attached to IUCVA-1919. Each document under the above specified sections should be checked by calling CF_ESR_001 (IUCVA-1 The rule should fail for a document if the CF_ESR_001 check is FALSE otherwise the rule passes for tha
QLT_PPP_091	W	QLT_PPP_001	279968	QLT_PPP_091: Endpoint must be indicated (Metabc	Rule should check Documents owner entities location in the dossier and documents owner entities as s
QLT_PPP_063	W	QLT_PPP_001	652909	QLT_PPP_063: Endpoint must be indicated (other r	Rule should check Documents owner entities location in the dossier and documents owner entities as s #652961. The rule should check documents under the sections described as EU_PPP_endpoints_all, as specified i EU_PPP_endpoints_all Excel attached to #279967 . Each document under the above specified sections should be checked by calling CF_ESR_001 #279858 The rule should fail for a document if the CF_ESR_001 check is FALSE otherwise the rule passes for tha
QLT_PPP_002	W	QLT_PPP_002	279969	QLT_PPP_002: Data waiving must be justified	Rule should check Documents owner entities location in the dossier and documents owner entities as s
QLT_PPP_092	W	QLT_PPP_002	657051	QLT_PPP_092: Data waiving must be justified (Met	Rule should check Documents owner entities location in the dossier and documents owner entities as s

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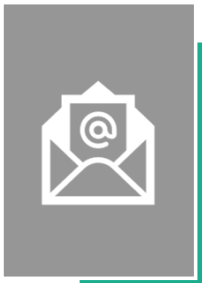

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