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

IUCLID FEATURES: VALIDATION ASSISTAN TOOL

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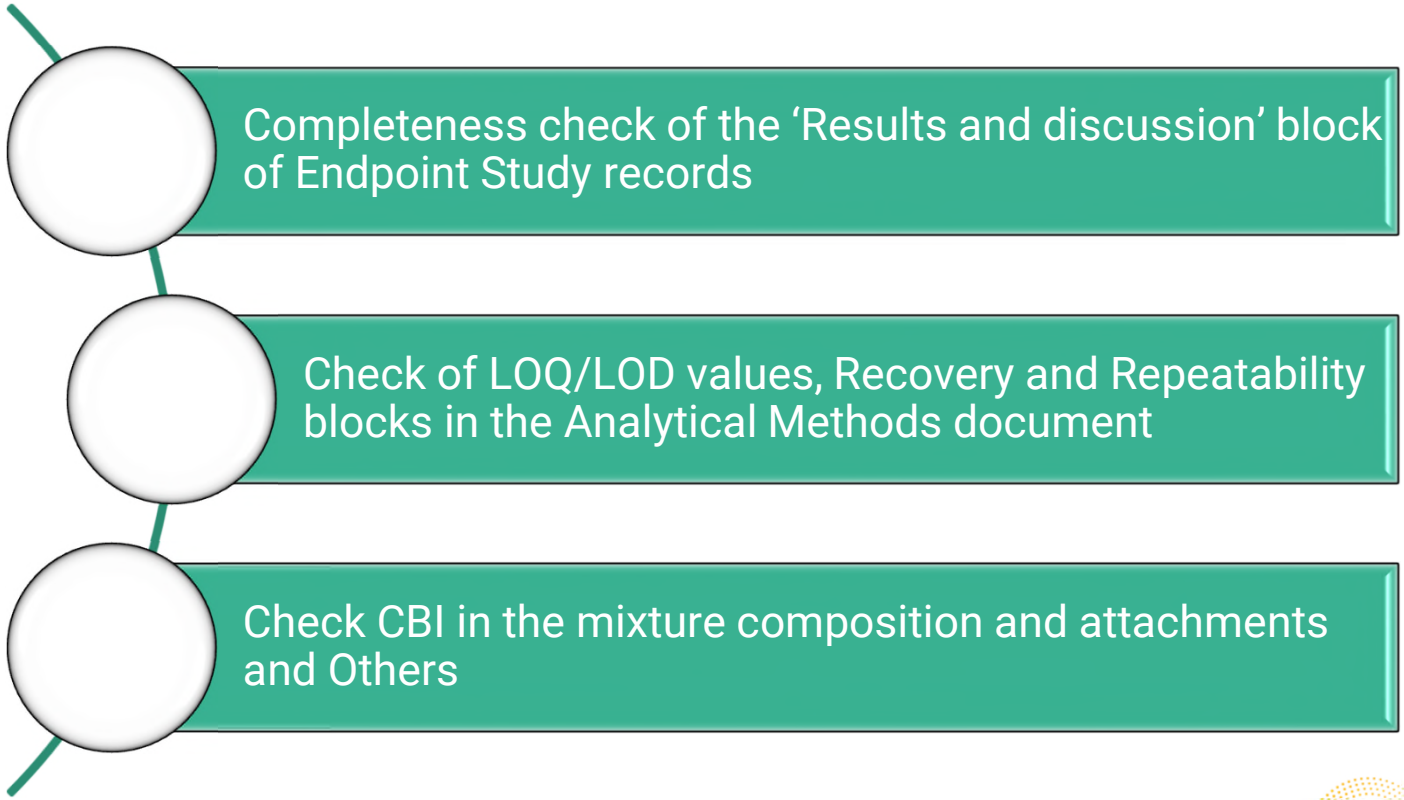
EUROPEAN FOOD SAFETY AUTHORITY

OCTOBER 2023 RELEASE: FOR ADOPTION

VALIDATION ASSISTANT: OCTOBER RELEASE

- 13 new QLT_PPP rules
- Update of 2 rules
- Changes of QLT to BR



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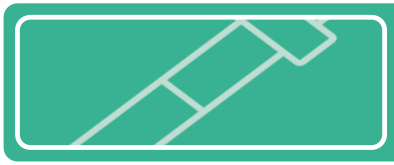
Completeness check of the ‘Results and discussion’ block of Endpoint Study records

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.EyeIrritation

- '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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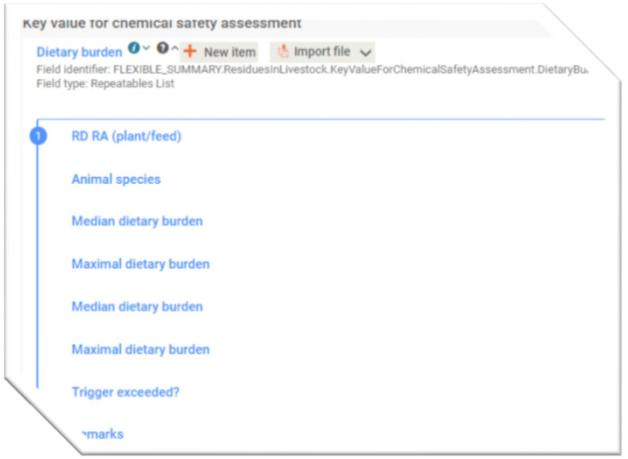
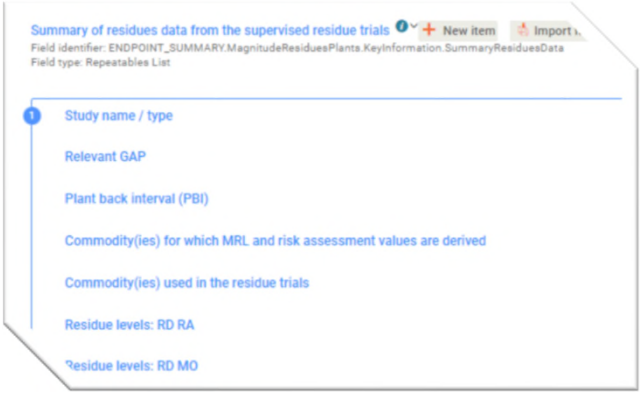
❑FLEXIBLE_SUMMARY.ResiduesInLivestock

- In the **Residues in Livestock** document the '**Dietary burden**' table must be completed unless 'Remarks' is completed with a justification for not completing the table



❑ENDPOINT_SUMMARY.MagnitudeResiduesPlants

- At least one item must be created for each '**Summary of residues data from the supervised residue trials**'. In addition, for each item created the following fields must be filled in:
  - o 'Study name/type'
  - o 'Relevant gap', '
  - o Commodity(ies) for which MRL and Risk Assessment values are derived', and
  - o 'MRL derived'



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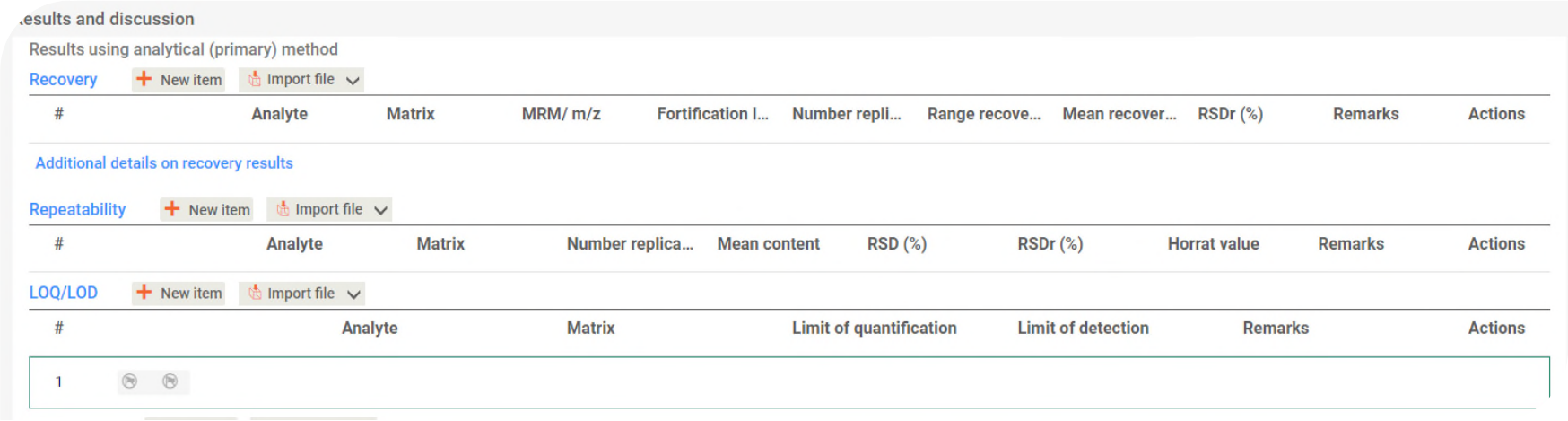
ENDPOINT_STUDY_RECORD.AnalyticalMethods → 'Results using analytical (primary) method' common block

- **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.



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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

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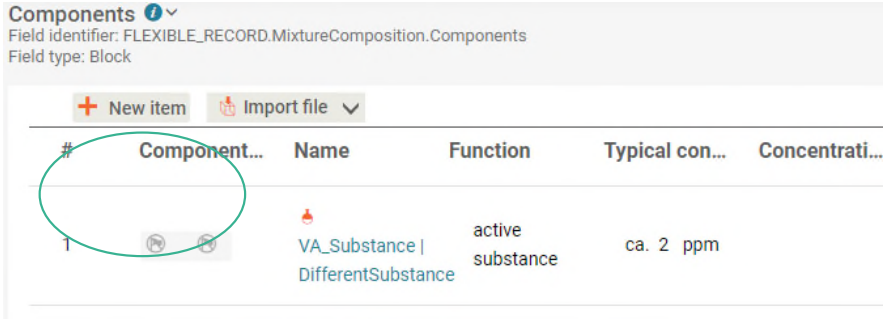
- From the Filtering rules Working party, new BR needed:
  - Remove CBI flag from the **FLEXIBLE_RECORD.MixtureComposition**.

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



- A sanitised version must be provided if Attached document is provided in block 'Attached background material' of the document **FLEXIBLE_RECORD.Manufacturer_EU_PPP**.

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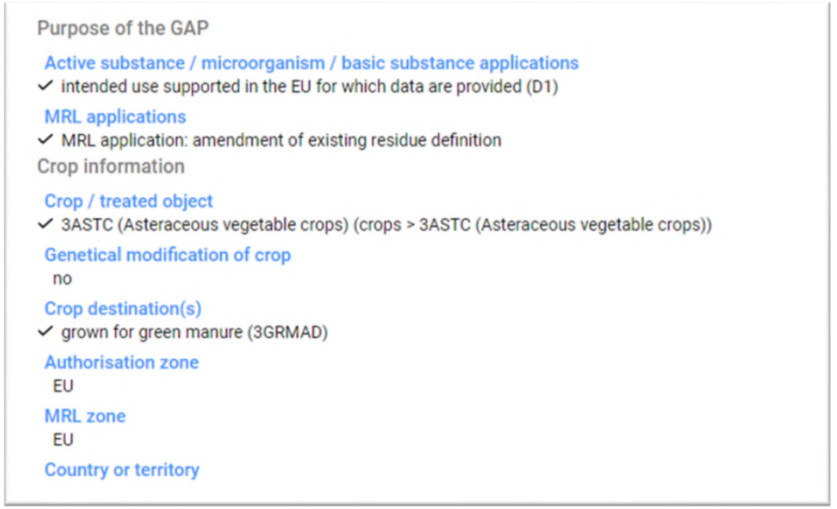
- **Update QLT_PPP_026** → The rule checks that at least one FLEXIBLE_RECORD.GAP document is created **and is complete**

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



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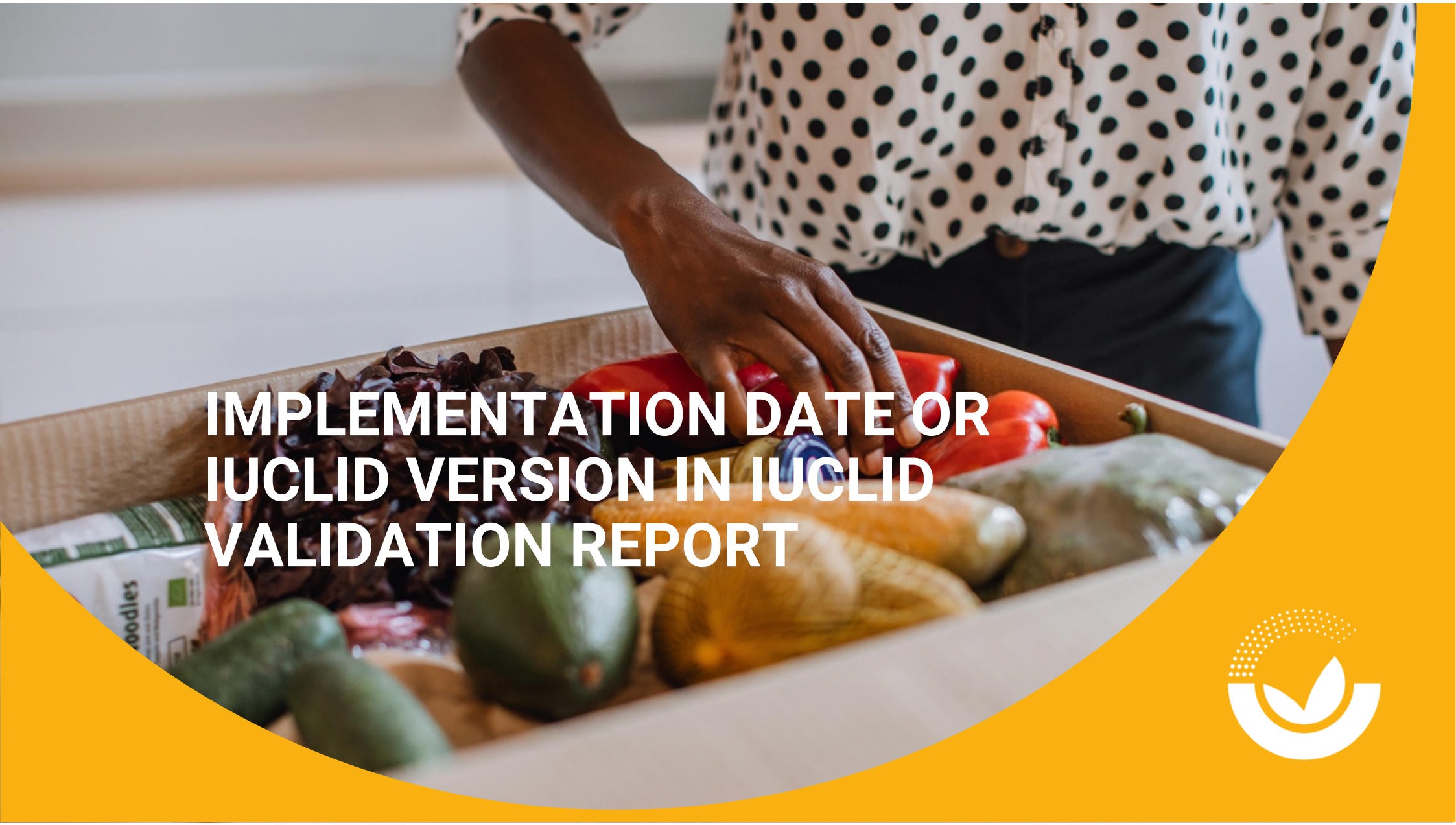
Update QLT_PPP_125: Flexible Summary MRL Proposal must be provided and only once in the Active substance dataset

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	**Report generator:** presentation of information **Admissiblity:** 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	**Report generator:** presentation of

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