Trusted science for safe food

2nd PSN IUCLID subgroup meeting – 31 Jan 2022

Latest updates in the Residues section

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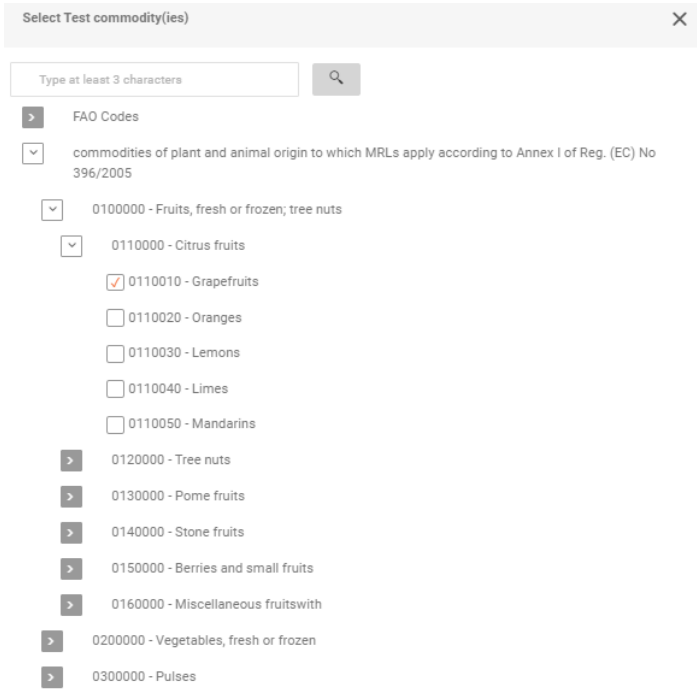
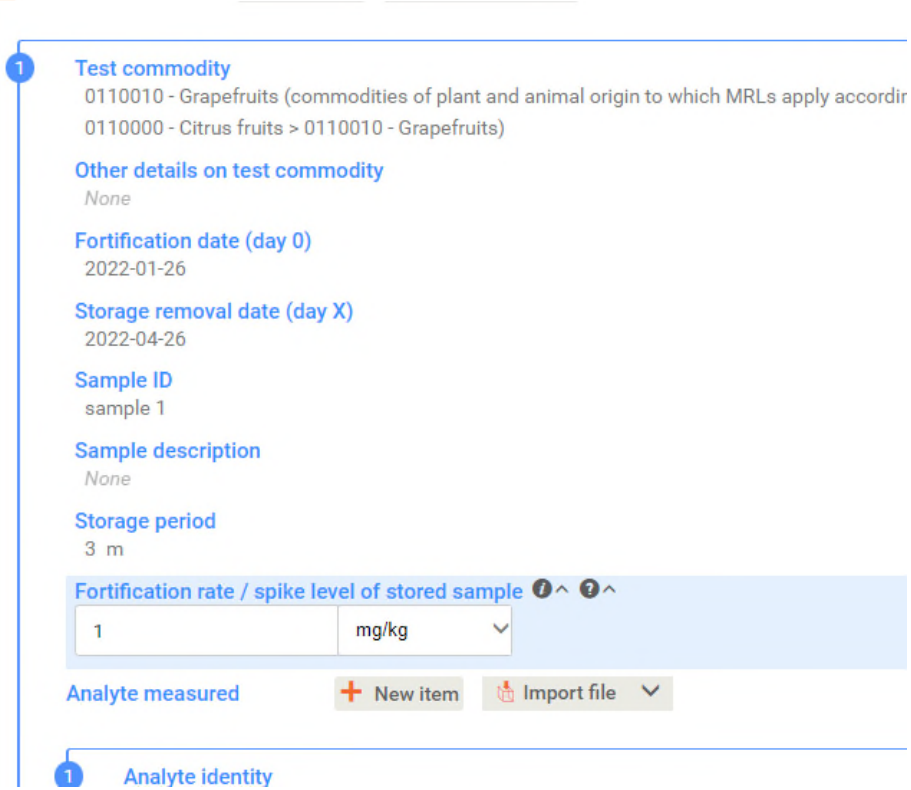
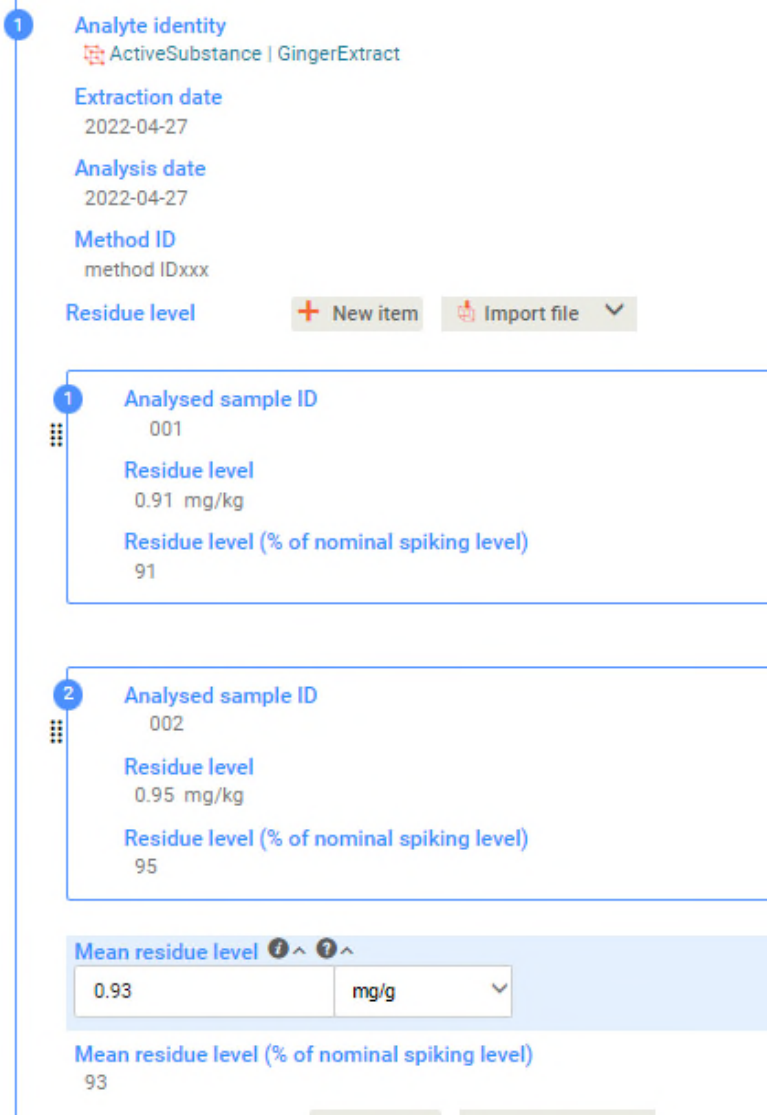
New OHTs: Use the structured template **instead of** attachments/free text fields

- 6.1 Storage stability of residues
  - Picklist for commodities according to Annex I
- 6.3 Magnitude of residues in plants
  - No longer required to use the Excel file
- 6.4 Feeding studies
  - Detailed results per animal, per feeding level
- 6.5.1 Nature of residues (processed commodities)
  - Better structure for TRR results
  - Representative hydrolysis studies

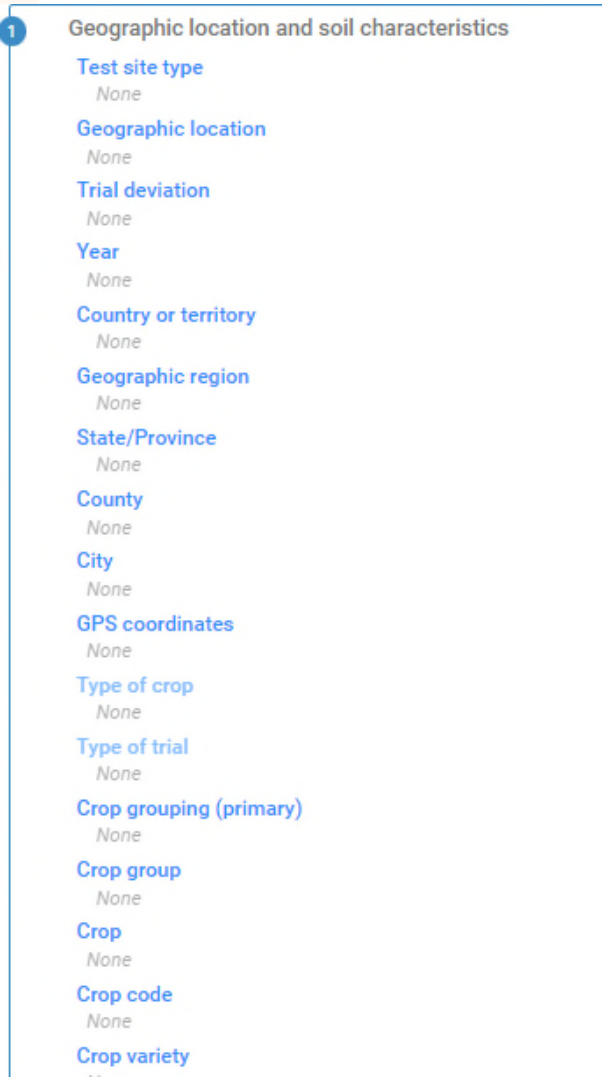


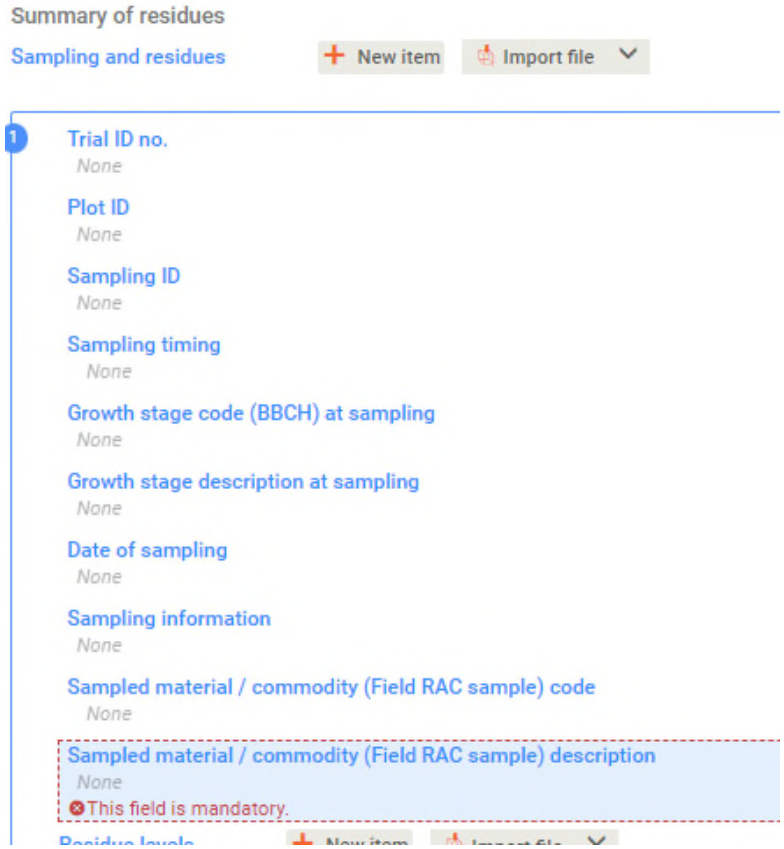
Example 1: Storage stability





Example 2: Magnitude of Residues in plants





New Endpoint summaries: Use the structured template **instead of** free text fields

- Magnitude of residues in plants
  - One endpoint summary for primary crops
  - One endpoint summary for rotational crops
- Magnitude of residues in livestock
  - Dietary burden in a structured format
  - Derived MRLs, STMR, HR in a structured format
- Exposure through diet and other sources
  - PRIMo 3.1 results in a structured format
  - One endpoint for acute and chronic exposures (to be duplicated if more than one scenario are assessed)

Example 1: Magnitude or residues in plants (primary and rotational crops)

Endpoint
residues in crops (field trials)

Summary of residues data from the supervised residue trials + New item

1 Study name / type
None

Relevant GAP
None

Commodity(ies) for which MRL and risk assessment values are derived
None

Commodity(ies) used in the residue trials
None

Residue levels: RD RA
None

Residue levels: RD MO
None

Conversion factor
None

Highest residue RD-RA

STMR RD-RA

Highest residue RD-Mo

STMR RD-Mo

MRL derived

Provisional
None

Endpoint
residues in rotational crops (limited field studies)

Summary of residues data from the supervised residue trials + New item

1 Study name / type
None

Relevant GAP
None

Plant back interval (PBI)

Commodity(ies) for which MRL and risk assessment values are derived
None

Commodity(ies) used in the residue trials
None

Residue levels: RD RA
None

Residue levels: RD MO
None

Conversion factor
None

Highest residue RD-RA

STMR RD-RA

Highest residue RD-Mo

STMR RD-Mo

MRL derived

Provisional
None

Example 2: Magnitude or residues in livestock

Key value for chemical safety assessment

Dietary burden

+ New item | Import file

1

RD RA (plant/feed)
None

Animal species
None

Median dietary burden (mg/kg bw per day)

Maximal dietary burden (mg/kg bw per day)

Median dietary burden (mg/kg DM)

Maximal dietary burden (mg/kg DM)

Trigger exceeded?
None

Remarks
None

Summary of residues data from feeding studies

+ New item

1

Link to relevant study record(s)
None

Highest residue RD-RA

STMR RD-RA

Highest residue RD-Mo

STMR RD-Mo

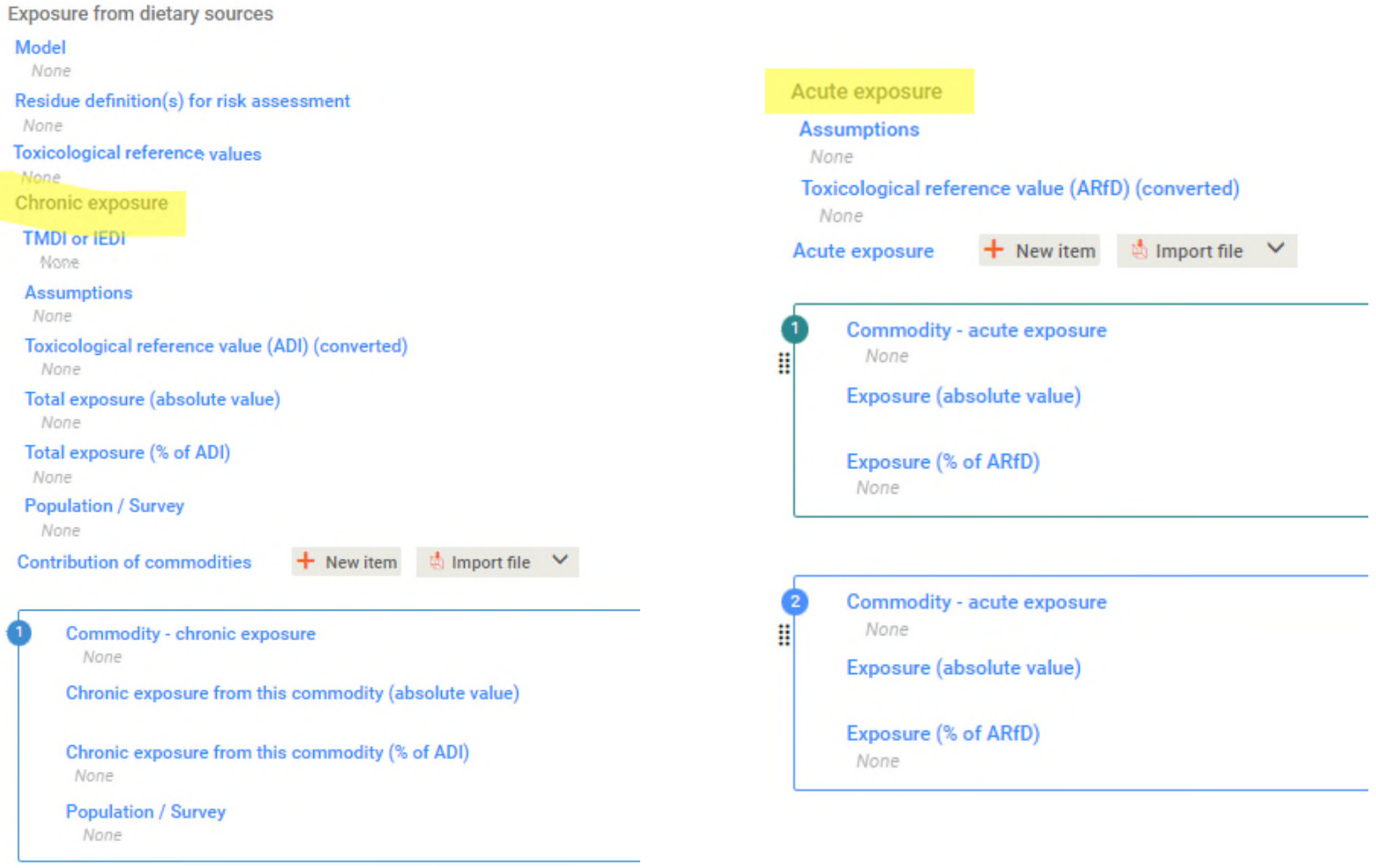
MRL derived

Provisional
None

Remarks
None

Conversion factor (CF)
None

Example 3: Dietary exposure



Still to be done (backlog file and workplan)

- OHTs on metabolism in plant/livestock (interoperability with MetaPath software package)
- Identification of the key values in the endpoint study records to prefill the endpoint summaries (e.g. for Magnitude of Residues plants, Magnitude of Residues processed commodities…)
- OHTs on Magnitude of Residues in processed commodities (interoperability with RUEDIS)
- Endpoint summary residue definition (to be improved)
- Direct link between GAPs and proposed/derived MRLs (not yet possible)
- Endpoint summary on dietary exposure in line with PRIMo 4 (currently under development)
- OHTs for residues in pollen and bee products…
- OHTs for studies on variability factors…

Conclusion

It’s essential to use the new formats developed to:

- Further improve them (concretely contribute to the Backlog)
- Improve automation (interoperability, data uploader, etc)
- Create and contribute to databases
- Make full use of Report Generator
- Get rid of free text and attachments

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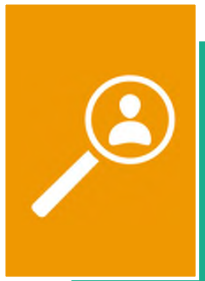

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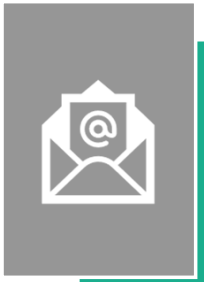

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