



2nd PSN IUCLID subgroup meeting – 31 Jan 2022

Latest updates in the Residues section

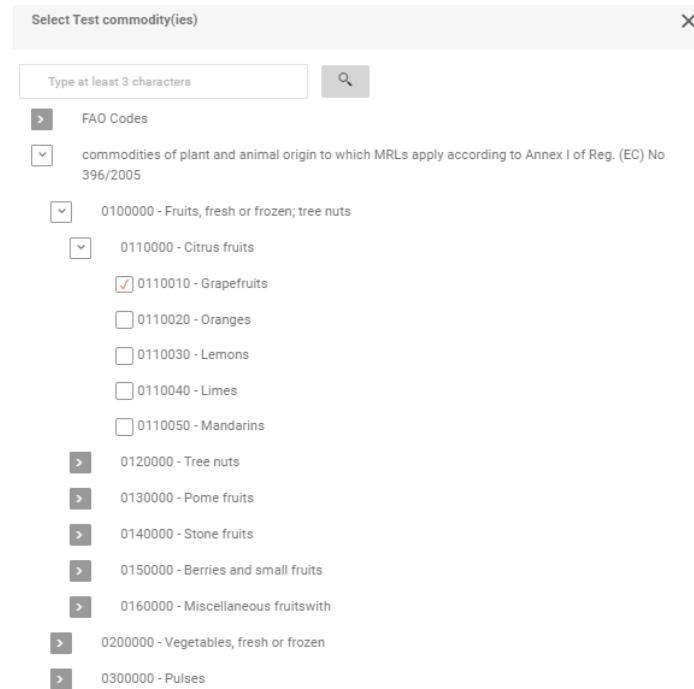
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Trusted science for safe food



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

1

Test commodity
0110010 - Grapefruits (commodities of plant and animal origin to which MRLs apply according to Regulation (EC) No 396/2005)
0110000 - Citrus fruits > 0110010 - Grapefruits)

Other details on test commodity
None

Fortification date (day 0)
2022-01-26

Storage removal date (day X)
2022-04-26

Sample ID
sample 1

Sample description
None

Storage period
3 m

Fortification rate / spike level of stored sample *i* ^ *?* ^
1 mg/kg

Analyte measured *+ New item* *Import file*

1

Analyte identity
ActiveSubstance | GingerExtract

Extraction date
2022-04-27

Analysis date
2022-04-27

Method ID
method IDxxx

Residue level *+ New item* *Import file*

1

Analysed sample ID
001

Residue level
0.91 mg/kg

Residue level (% of nominal spiking level)
91

2

Analysed sample ID
002

Residue level
0.95 mg/kg

Residue level (% of nominal spiking level)
95

Mean residue level *i* ^ *?* ^
0.93 mg/g

Mean residue level (% of nominal spiking level)
93

Example 2: Magnitude of Residues in plants

1 Geographic location and soil characteristics

Test site type

None

Geographic location

None

Trial deviation

None

Year

None

Country or territory

None

Geographic region

None

State/Province

None

County

None

City

None

GPS coordinates

None

Type of crop

None

Type of trial

None

Crop grouping (primary)

None

Crop group

None

Crop

None

Crop code

None

Crop variety

Summary of residues

Sampling and residues

 New item  Import file

1 Trial ID no.

None

Plot ID

None

Sampling ID

None

Sampling timing

None

Growth stage code (BBCH) at sampling

None

Growth stage description at sampling

None

Date of sampling

None

Sampling information

None

Sampled material / commodity (Field RAC sample) code

None

Sampled material / commodity (Field RAC sample) description

None

 This field is mandatory.

Residue levels

 New item  Import file

1 Method ID

None

Analyte identity

None

Analysis sample portion ID

None

Extraction date

None

Analysis date

None

Storage stability factor

None

Use of storage stability factor

None

Correction by storage stability

None

Recovery

None

Correction by recovery

None

Reference portion

None

Residue level (measured)

None

Calculated analyte identity

None

Residue level (calculated)

None

Residue level (calculated and corrected)

None

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 of 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 of 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

Exposure from dietary sources

Model

None

Residue definition(s) for risk assessment

None

Toxicological reference values

None

Chronic exposure

TMDI or IEDI

None

Assumptions

None

Toxicological reference value (ADI) (converted)

None

Total exposure (absolute value)

None

Total exposure (% of ADI)

None

Population / Survey

None

Contribution of commodities

 New item  Import file

1 Commodity - chronic exposure

None

Chronic exposure from this commodity (absolute value)

Chronic exposure from this commodity (% of ADI)

None

Population / Survey

None

Acute exposure

Assumptions

None

Toxicological reference value (ARfD) (converted)

None

Acute exposure

 New item

 Import file

1 Commodity - acute exposure

None

Exposure (absolute value)

Exposure (% of ARfD)

None

2 Commodity - acute exposure

None

Exposure (absolute value)

Exposure (% of ARfD)

None

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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