

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

Select Test commodity(ies) ×

Type at least 3 characters 🔍

☐ > FAO Codes

☐ commodities of plant and animal origin to which MRLs apply according to Annex I of Reg. (EC) No 396/2005

☐ 0100000 - Fruits, fresh or frozen; tree nuts

☐ 0110000 - Citrus fruits

☒ 0110010 - Grapefruits

☐ 0110020 - Oranges

☐ 0110030 - Lemons

☐ 0110040 - Limes

☐ 0110050 - Mandarins

☐ > 0120000 - Tree nuts

☐ > 0130000 - Pome fruits

☐ > 0140000 - Stone fruits

☐ > 0150000 - Berries and small fruits

☐ > 0160000 - Miscellaneous fruitswith

☐ > 0200000 - Vegetables, fresh or frozen

☐ > 0300000 - Pulses

Example 1: Storage stability

1 **Test commodity**
0110010 - Grapefruits (commodities of plant and animal origin to which MRLs apply according to Commission Regulation (EC) No 1831/2003)
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 ⓘ ^ ? ^
1 mg/kg

Analyte measured + New item Import file

1 **Analyte identity**
ActiveSubstance | GingerExtract

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 ⓘ ^ ? ^
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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