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COLLABORATION WITH EFSA ON OPTIMISATION OF IUCLID REPORT GENERATION

PSN IUCLID subgroup meeting 05 December 2022

1. Presentation of the task

Objectives & duration

- Optimise the « MRL application report » generated by the IUCLID report generator by :

- Commenting on the report generated
- Identifying areas of concern
- Proposing improvements of the reports and the validation rules
- Consulting on the suggestions with stakeholders

- Work on annotations will be performed in a second step

- Task started on 20/07/2022 with kick of meeting and will be concluded by the end of 2023.

2. Working approach

Working approach

- 2 real MRL application dossiers selected as “pilot dossiers”

- Comparison between information/data entered in IUCLID by the applicant, MRL application report generated and OHTs

  → Focus on **formatting** aspects of the report (structure, layout)

  → Identification of IUCLID sections/fields that would require **validation rules** and/or **specific format changes**

- Comments provided in a shared excel file

- EFSA responses provided in the shared excel file and discussed during bi-weekly meetings

3. What has been done?

What have been done?

- Around 70 ANSES comments for the two pilot dossiers:
  - Proposals and priorisation of modification
  - Discussions with EFSA on comments, modification proposals and solutions in accordance with IUCLID functionnalities

- 8 bi-weekly teams meetings

What has been done?

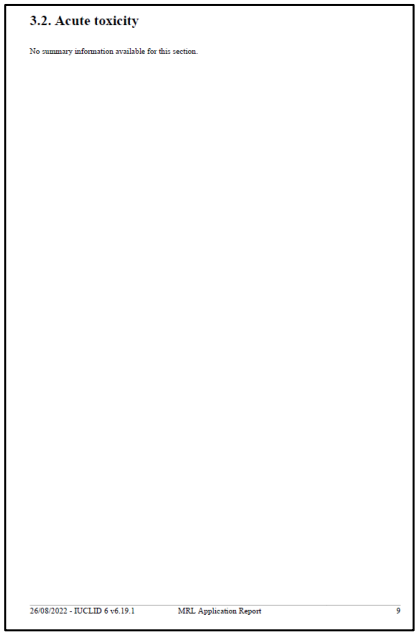
- Creation of working documents for the residue section:

  - Mapping « MRL application report and IUCLID »
  - Comparison of Table of Content (ToC) between MRL application report generated, monograph and actual Evaluation Report → to propose the best ToC
  - Listing of existing summary tables available between MRL application report generated, actual Evaluation Report and table recommended by EFSA (template_6.1_recommended document) → to propose the best table
  - Grouping of similar comments in a summary table with corresponding agreed modifications and alternative solutions pending implementation of modifications.

3. Examples of some proposals/developments

Format of the generated report

- Empty IUCLID sections generating page breaks in the report :



3.2. Acute toxicity

No summary information available for this section.

- Some sections generated in the report are not necessary, for ex:

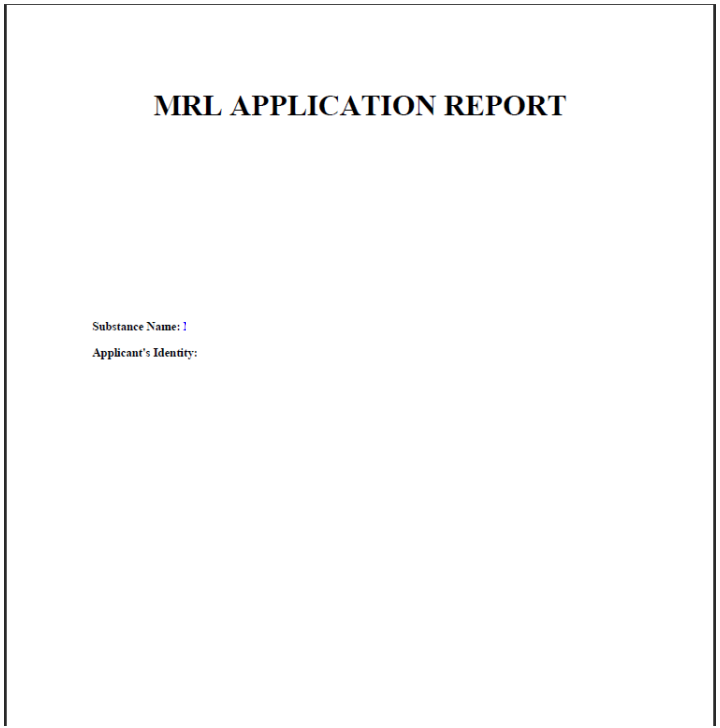
1.2 Method of manufacture
1.3 Specifiction of purity

5. Fate and behaviour in the environment

➔ the report generator will skip them and add a line indicating that no data were provided

Format of the generated report

- Not enough information on the cover page:



MRL APPLICATION REPORT

Substance Name: 1

Applicant's Identity:

Add information about commodity involved in the MRL application and type of MRL (import tolerance or classic new MRL)

➔ Those information will be retrieved from the background section

Format of the generated report

- Intended GAP : reference to appendix A and reference to GAP table in appendix A

3. Use of the active substance (GAP)

For details on uses of the active substance please refer to the **Appendix A**.

Appendix A. Good Agricultural Practices (GAP) supported in the MRL application

Please, use the standalone report for Good Agricultural Practices (GAP) available in Report Generator.

➔ Remove appendix A from the report

Format of the generated report

- Too much text in column "remarks"

Dietary burden

1 RD RA (plant/feed)

sum of [redacted]

Animal species

1.2. Dairy (1. Cattle > 1.2. Dairy)

Median dietary burden (mg/kg bw per day)

0.044 mg/kg bw per day

Maximal dietary burden (mg/kg bw per day)

0.124 mg/kg bw per day

Median dietary burden (mg/kg DM)

1.42 mg/kg dry matter

Maximal dietary burden (mg/kg DM)

3.49 mg/kg dry matter

Trigger exceeded?

yes

Remarks

Dietary burdens were calculated using:

- o for the crops related to the current MRL application, the residues expressed according to the current residue definition for RA: [redacted]
- o For other uses, input values reported in [redacted]

For all groups of livestock dietary burden exceed the trigger value of 0.1 mg/kg DM. The available results are in line with the calculations done in the context of Art. 12.

RD RA (plant / feed)	Animal species	Dietary burden				Trigger exceeded	Remarks
		mg/kg bw per day		mg/kg DM			
		Median	Max	Median	Max		
sum of prothioconazole-desthio [redacted]	1.2. Dairy	0.044	0.124	1.42	3.49	yes	Dietary burdens were calculated using: o for the crops related to the current MRL application, the residues expressed according to the current residue definition for RA: sum of prothioconazole-desthio (M04) and all [redacted] EFSA, 2014 For all groups of livestock dietary burden exceed the trigger value of 0.1 mg/kg DM. The available results are in line with the calculations done in the context of Art. 12.

➔ **In the report** : Remove the text from the table and put it as a foot note

Validation rule proposals

- No input values submitted for dietary burden calculation and for PRIMo

  ➔ Validation rule to check if input values are detailed

  ➔ Pending implementation, add instructions in MRL manuals and in IUCLID

- Summary record "toxicological reference values" not created by the applicant

  ➔ Creation of validation rule to check if the summary record "toxicological reference values" was created by the applicant

Validation rule proposals

- Proposed MRL: one summary record created by the applicant per commodity

2. Proposed maximum residue levels (MRLs)

Summary

#1: Proposed maximum residue levels and justification_pome fruits (apple, medlar, quince)

Maximum residue levels:

Table IV.2.

Commodity	Residue definition monitoring	MRL proposal	Rationale	Remarks
0130010 - Apples ; 0130030 - Quinces ; 0130040 - Medlars ; 0130050 - Loquats/ Japanese medlars	[redacted]		use on primary crop	

#2: Proposed maximum residue levels and justification_pear

Maximum residue levels:

Table IV.3.

Commodity	Residue definition monitoring	MRL proposal	Rationale	Remarks
0130020 - Pears	[redacted]		use on primary crop	[redacted]

#3: Proposed maximum residue levels and justification_apricot, peach

Maximum residue levels:

Table IV.4.

Commodity	Residue definition monitoring	MRL proposal	Rationale	Remarks
0140010 - Apricots ; 0140030 - Peaches	[redacted]		use on primary crop	

#4: Proposed maximum residue levels and justification_plum

Maximum residue levels:

Table IV.5.

Commodity	Residue definition monitoring	MRL proposal	Rationale	Remarks
0140040 - Plums	[redacted]		use on primary crop	

#5: Proposed maximum residue levels and justification_cherry

Maximum residue levels:

Table IV.6.

Commodity	Residue definition monitoring	MRL proposal	Rationale	Remarks
0140020 - Cherries (sweet)	[redacted]		se on primary crop	

#6: Proposed maximum residue levels and justification_rice

Maximum residue levels:

Table IV.7.

Commodity	Residue definition monitoring	MRL proposal	Rationale	Remarks
0500060 - Rice	[redacted]		se on primary crop	

#7: Proposed maximum residue levels and justification_cucurbits edible peel

Maximum residue levels:

Table IV.8.

Commodity	Residue definition monitoring	MRL proposal	Rationale	Remarks
0232010 - Cucumbers ; 0232020 - Gherkins ; 0232030 - Courgettes	[redacted]		se on primary crop	

#8: Proposed maximum residue levels and justification_cucurbits inedible peel

Maximum residue levels:

Table IV.9.

Commodity	Residue definition monitoring	MRL proposal	Rationale	Remarks
0233010 - Melons ; 0233020 - Pumpkins ; 0233030 - Watermelons	[redacted]		se on primary crop	

➔ Creation of a validation rule to allow only one summary

Validation rule proposals

- Same information present twice since filled in rich text field + in the dedicated picklist:

→ two tables detailed in the MRL application report

Overview of the available residue's trials data

Crop (trial GAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the trials representative for the intended GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Lettuce (extrapolated to watercress)	NEU	Mo/RA: <0.01, 0.01, 2 x 0.02, 2 x 0.03, 0.31	MRL_{OECD}: 0.5/0.501	0.5	0.310	0.020
Lettuce (extrapolated to watercress)	SEU	Mo/RA: <0.01, 2 x 0.01, 4 x 0.02, 0.03	MRL_{OECD}: 0.05/0.048	0.05	0.030	0.020
Lettuce (extrapolated to watercress) Combined datasets (e)	NEU/SEU	Mo/RA: 2 x <0.01, 3 x 0.01, 6 x 0.02, 3 x 0.03, 0.31	MRL_{OECD}: 0.4/0.340	0.4	0.310	0.020
Lettuce (extrapolated to watercress)	Indoor	Mo/RA: <0.01, 0.01, 2 x 0.02, 2 x 0.03, 0.06, 0.120	MRL_{OECD}: 0.2/0.185	0.2	0.120	0.025
Kale (extrapolated to chinese cabbage)	NEU	Mo/RA: <0.01, 0.03, 0.04, 0.08	MRL_{OECD}: 0.2/0.158	0.2	0.080	0.035
Cucumber (extrapolated to Courgette)	NEU	Mo/RA: 2 x <0.01, 0.01, 3 x 0.02, 2 x 0.04	MRL_{OECD}: 0.08/0.071	0.07	0.04	0.02

Overview of the available residue's trials data

Crop (trial GAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the trials representative for the intended GAPs (b)	Recommendations/ comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Lettuce (extrapolated to watercress)	NEU	Mo/RA: <0.01, 0.01, 2 x 0.02, 2 x 0.03, 0.31	MRL*OECD*: 0.5/0.501	0.5	0.310	0.020
Lettuce (extrapolated to watercress)	SEU	Mo/RA: <0.01, 2 x	MRL*OECD*: 0.05/0.048	0.05	0.030	0.020

Summary of residues data from the supervised residue trials

1 Study name / type
None
Relevant GAP
None
Plant back interval (PBI)
None
Commodity(ies) for which MRL and risk assessment values are derived
✓ 0254000 - Watercresses (Commodities of plant and animal origin to which MRLs apply according to Annex I of Reg. (EC) No 396/2005 > 0200000 - Vegetables, fresh or frozen > 0250000 - Leaf vegetables, herbs and edible flowers > 0254000 - Watercresses)
Commodity(ies) used in the residue trials
✓ 0251020 - Lettuces (Commodities of plant and animal origin products to which MRLs apply (incl. other products referred to in Part B to Annex I) > 0200000 - Vegetables, fresh or frozen > 0250000 - Leaf vegetables, herbs and edible flowers > 0251000 - Lettuces and salad plants > 0251020 - Lettuces)
Residue levels: RD RA
<0.01; 0.01; 2 x 0.02; 2 x 0.03; 0.31
Residue levels: RD MO
<0.01; 0.01; 2 x 0.02; 2 x 0.03; 0.31
Conversion factor
None
Highest residue RD-RA
0.31 mg/kg
STMR RD-RA
0.02 mg/kg
Highest residue RD-Mo
None
STMR RD-Mo
None
MRL derived
0.5 mg/kg
Provisional
None
Remarks
Sufficient trials to support intended GAP. MRL set based on combined NEU and SEU dataset.

➔ Creation of a validation rule to use the dedicated picklist

Summary of residues data from the supervised residue trials :

Table III.2.

Commodity		Residue levels		MRL derived	Study	Remarks
For MRL / RA	Used in trials	RD-RA	RD-Ro			
0254000 - Watercresses	0251020 - Lettuces	Levels: <0.01; 0.01; 2 x 0.02; 2 x 0.03; 0.31 Max: 0.31mg/kg STMR: 0.02mg/kg	Levels: <0.01; 0.01; 2 x 0.02; 2 x 0.03; 0.31	0.5mg/kg		Sufficient trials to support intended GAP. MRL set based on combined NEU and SEU dataset.
0254000 - Watercresses	0251020 - Lettuces	Levels: <0.01; 2 x 0.01; 4 x 0.02; 0.03 Max: 0.03mg/kg STMR: 0.02mg/kg	Levels: <0.01; 2 x 0.01; 4 x 0.02; 0.03	0.05mg/kg		Sufficient trials to support intended GAP. MRL set based on combined NEU and SEU dataset.
0254000 - Watercresses	0251020 - Lettuces	Levels: <0.01; 0.01; 2 x 0.02; 2 x 0.03; 0.06; 0.120	Levels: <0.01; 0.01; 2 x 0.02; 2 x 0.03; 0.06; 0.120	0.2mg/kg		Sufficient trials to support intended GAP. MRL set based

IUCLID format changes

- No table containing information on livestock metabolism studies in the report:

  ➔ To add new block in IUCLID containing information on livestock metabolism studies (generated in the format of a table) since currently only rich text field available

- No input values submitted for dietary burden calculation and for PRIMo

  ➔ Creation of new blocks for input values for dietary burden and PRIMo calculation (generated in tables)

4. Next steps

On-going and future activities on the task

- Continue commenting on the MRL application report generated
- Continue proposing validation rules and IUCLID format changes or improvements to EFSA if needed
- Explore the use of the Annotation functionality in IUCLID during the MS's assessment and test the generation of annotations
- Test the agreed modifications once implemented by EFSA