14th meeting of the PSN IUCLID sub-group
4 November 2025

MRL REPORT RESULTS FROM TESTING PHASE

EUROPEAN FOOD SAFETY AUTHORITY

TESTING PHASE OVERVIEW

Request to prolong testing period made during ScoPAFF February 2025

Testing Period: May 28 - July 31

Feedback received from :FR, BE, DE, SE

Comments Received:

- 18 comments included in Excel file (from FR and BE)
- 265 comments received from DE (BfR)
- comments received from Sweden via email/TC

Note: Previous comments from AT, NL, and DE were considered and incorporated into the testing process.

MOST COMMON COMMENTS

Formatting

- Absence of navigation panel
- Absence of automatic landscape orientation
- Absence of page numbers in the ToC (press F9)
- Font size inconsistencies*
- Redundance of titles in SUMMARIES (assessment chapter)*
- Absence of table titles*
- Poor readability of the trials table*
- Poor readability of footnotes when a long list is displayed*

Report length and structure

- Absence of cover page*
- Report is too long **
- Table of Contents (ToC) revision**
- Data waiving justification position **

Comments on specific sections

- Analytical method section commenting box **
- Trials section (see slide 5)*
- GAP table format (see slide 7)
- Tox Reference values **
- Subtitles of Appendix C (OECD format) **

Workflow for report generation

- In case of resubmissions, either an update of the first or the latest generated report can be carried out by the EMS.
- In the current instructions EFSA doesn't recommend one specific option.
- Following commenting phase, EFSA would like to suggest that the new parts (and their commenting boxes) from the newly generated ER should be copied and pasted in the original generated report and commented by the EMS thus avoiding any loss of data.

**under development by EFSA*
***for evaluation by IUCLID PSN Members – Survey to be launched by EFSA*

RESIDUE TRIALS: OHT 85-5 AND 85-9

- As long as they are captured in Excel files, the residue trial tables and the processing factors tables cannot be featured in the MRL report:

[For the detailed result tables, see the Excel files eventually attached in the study record]

- When OHT 85-5 and 85-9 will be fulfilled by applicants it will be possible to generate human readable tables.
- EFSA foresees the following plan:
  - OHT 85-5 and 85-9 are now fit for purpose --> mandatory use as of May 2026 (no more use of Excel attachments)
  - EFSA is currently developing new reports for the trial tables --> will provide trials tables in CSV files (all OHTs of the dossier in the same CSV file). The CSV file will contain all detailed information for risk assessment.
  - High-level trial tables (simplified compared to CSV) will be also provided in an updated version of the MRL report.
  - These reports will be delivered in the major IUCLID release of 2026.

RESIDUE TRIALS: ENDPOINT SUMMARY

- Users have reported some unsatisfactory experience due to migration:
  - Individual values appears in footnotes instead of being in the table

Commodity	Region/Indoor	Residue levels observed in the supervised residue trials (mg/kg)	Calculated MRL (mg/kg)	HR (mg/kg)	STMR (mg/kg)	CF	
Residue definition (for monitoring and risk assessment): [redacted]							
0500010 - Barley		- Mo: 0(1) - RA: 0(1)	0.3	- Mo: 0.25 - RA: 0.25	- Mo: 0.027 - RA: 0.027	1	

(1) Residue levels: RD RA: Barley and wheat grain (NEU + SEU combined): 7x <0.01, 2x 0.012, 2x 0.013, 0.015, 2x 0.016, 2x 0.018, 0.019, 3x 0.020, 0.021, 2x 0.022, 2x 0.023, 3x 0.026, 0.028, 0.029, 0.033, 0.034, 0.039, 0.041, 0.044, 0.045, 0.048, 0.049, 2x 0.050, 0.051, 0.052, 0.056, 0.058, 0.061, 0.063, 2x 0.066, 0.067, 0.082, 0.083, 0.113, 0.158, 0.185, 0.200, 0.250
Residue levels: RD MO: Barley and wheat grain (NEU + SEU combined): 7x <0.01, 2x 0.012, 2x 0.013, 0.015, 2x 0.016, 2x 0.018, 0.019, 3x 0.020, 0.021, 2x 0.022, 2x 0.023, 3x 0.026, 0.028, 0.029, 0.033, 0.034, 0.039, 0.041, 0.044, 0.045, 0.048, 0.049, 2x 0.050, 0.051, 0.052, 0.056, 0.058, 0.061, 0.063, 2x 0.066, 0.067, 0.082, 0.083, 0.113, 0.158, 0.185, 0.200, 0.250

  - This is due to the improvement of the EP summary and the impossibility to migrate previous fields correctly.
  - This should not happen in the new dossiers fulfilled according to the last version of the IUCLID manual

GAP TABLE

- It was reported that the GAP table does not correspond to the GAP table currently in the ER template. Few differences are indeed observed, all of them corresponding to improvements:
  - NEU/SEU and MS were merged in the same cells to simplify the table
  - Product name was removed as not need in MRL application
  - Rate and rate unit split into 2 columns to allow more flexibility (not having a fixed unit in the column title)
  - Conc a.s. in dilution--> a more self-explaining name was added compared to ER template (unit converted in g a.s./**L**) instead of g a.s./**hL**))

Appendix A – Good Agricultural Practices (GAPs) supported in the MRL application

Crop and/or situation (a)	MS Country	NEU SEU G	~~Product name~~	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
						Type (d-f)	Conc. a.s. (i)	method kind (f-h)	Growth Stages & season (j)	number min-max (k)	Interval between application min-max	g a.s /hL min-max (l)	Water L/ha min-max	g a.s./ha min-max (l)		

Crop / situation	MS / country	F, G or I	Pests controlled	Preparation		Application				Application rate per treatment				PHI (days)	Remarks
				Type	Conc. a.s.	Method / kind	Growth stage and season	No. min-max	Interval (days) min-max	Conc. a.s. in dilution min-max (g/L)	Water min-max (L/ha)	A.s. rate min-max	Unit		

CLARIFICATIONS ON MOST COMMON COMMENTS

COLOURS

- Logic of color code (free text in pale violet and commenting boxes for EMS in light blue)
- Results of calculations are in blue font (TBC)
- Instructions to end users are provided in blue

HYPERLINKS

- The MRL Report includes hyperlinks to the IUCLID dossier to facilitate assessment by the EMS. Nevertheless, such links would not work for the general public because pointing to IUCLID Agency environment. The EMS is therefore suggested to inactivate all hyperlinks before publication.

OTHER CLARIFICATIONS

- Tables in free text cannot be edited. To avoid redundancy, do not repeat tables in free text if specific fields are available in IUCLID

- “Confidential data” as displayed in the example was written by the Applicant , it is not generated automatically by the Report. There is no automatic filtering applied to the MRL Report.

Additional information:

Just a test

Assessment and conclusion by Evaluating Member State:

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup *(a)*	Most critical commodity *(b)*	Trigger exceeded (yes/no)
	mg/kg bw per day		mg/kg DM				
	Median	Max	Median	Max			
Cattle (all)	*1.304*	*2.187*	*33.9*	*56.85*	*Dairy*		*yes*
Cattle (dairy)	1.304	2.187	33.9	56.85			yes

Report author	confidential data

ENHANCEMENTS ALREADY AVAILABLE

- Automatic inclusion of the GAP
- Inclusion of specific instructions on how to change orientation layout
- Animal commodity in feeding study summary was improved (code + full name)
- Automatic inclusion of “Version history table"
- Change from “Evaluating competent authority” to “Evaluating Member State” across the report
- Crops displayed in alphabetical order in the GAP table

CONCLUSION AND NEXT STEPS

Conclusion

- The testing phase has been concluded, but EFSA remains committed to continuous improvement and welcomes further input to enhance its quality
- Announced enhancements triggered by testing phase will be implemented by Dec 2025 (tentative) available in Uploaded reports
- Default report will be available by the annual release (May 2026) including the update of the trials table.
- The enhancements will result in a SHORTER and better formatted Report

Next steps and recommendations

- The MRL report use is on a **voluntary basis** for now (several MSs are already using it)
- After May 2026 the Report is expected to remain **stable** with regular updates only based on the annuals IUCLID major release
- EFSA would like to remind stakeholders of the legal requirements that apply. For Applicants (APPL), it is mandatory to prepare a complete and compliant IUCLID dossier, in accordance with Article 6. For Evaluating Member States (EMS), it is required to draft an Evaluation Report, as outlined in Article 8.

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