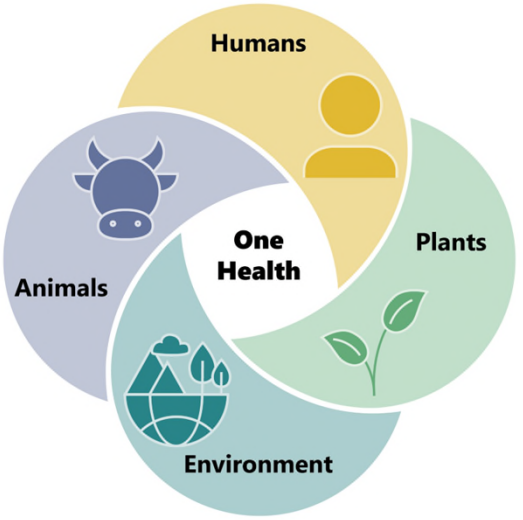
Austrian Agency for Health and Food Safety

Our experiences with the MRL report generated by IUCLID



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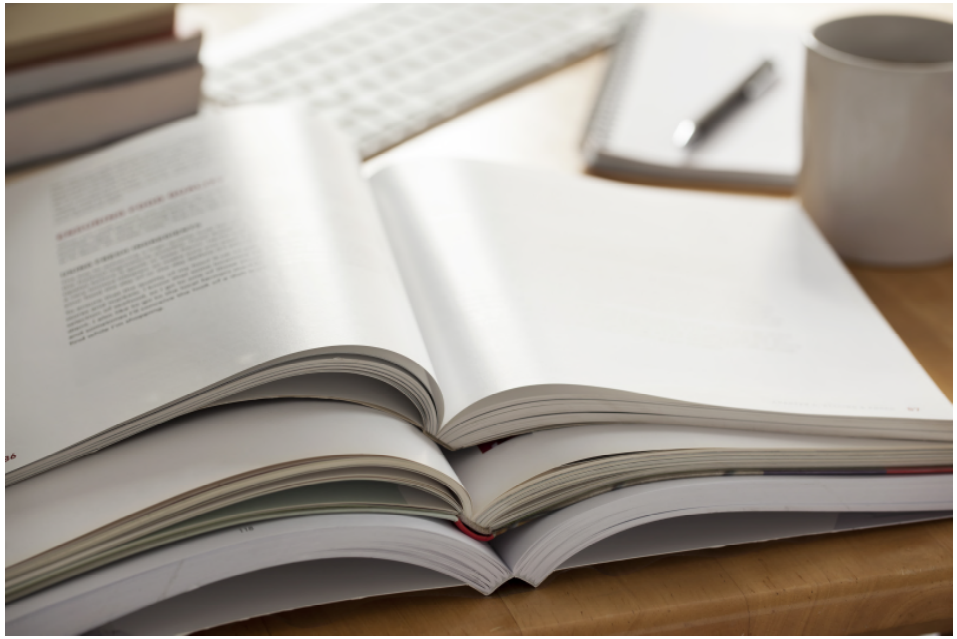
Overview

MRL report generator (IUCLID)

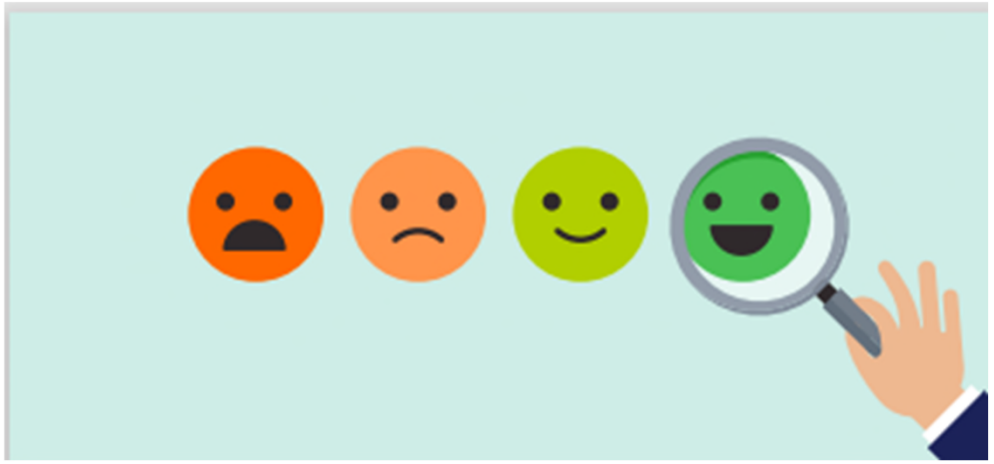
- Overall impression
- Important Considerations
- Comparison old/new report
- Areas for improvement
- Proposals for improvement
- Pro´s and Con´s
- Conclusion and Outlook



Overall Impression

...of the MRL report generated by IUCLID

- Well structured
- Clear organization
- Well advanced
- Ready to be used
- Some minor issues remain to be addressed



Important Considerations

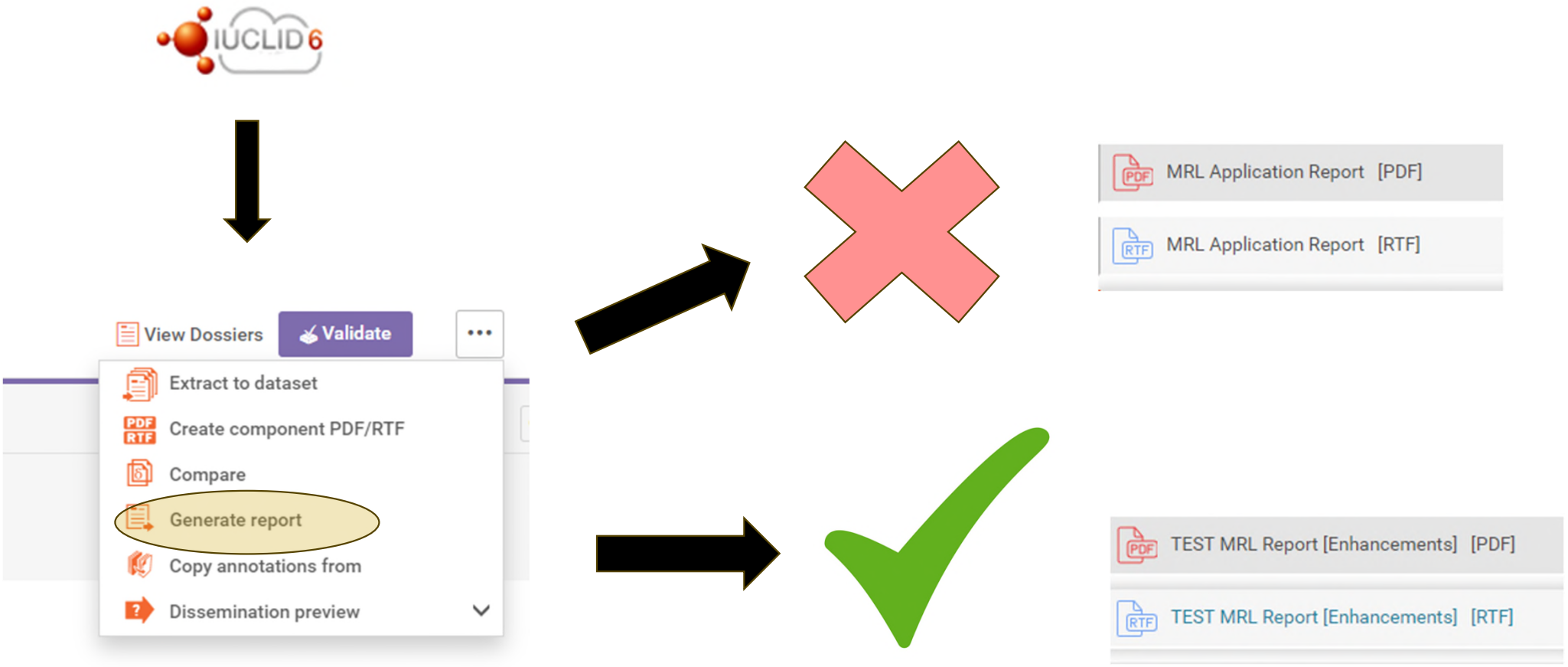
Key Points to Consider

- Correct dossier version (UUID number) = latest version
- Dossier quality → crucial for good quality reports
- Ensure the correct report is generated!

↓

How to generate the (correct) report

TEST MRL Report



MRL REPORT

This report is generated from the applicant's IUCLID dossier (UUID: 4b9bd148-c51b-4e22-95c9-deff9d7ce0ab) and is intended to be commented by the Evaluating Competent Authority to draw up an evaluation report in accordance with Article 8 of Regulation EC 396/2005. To ensure transparency, there should be clear distinction between the information stemming from the applicant's IUCLID dossier and the assessment and conclusions from the Evaluating Competent Authority.

Purpose and Scope

For post-transparency MRL applications, this Report intends to replace the Evaluation Report template available on the European Commission webpage:
https://food.ec.europa.eu/plants/pesticides/maximum-residue-levels/guidelines-maximum-residue-levels_en

Instructions for Evaluating Competent Authorities

Evaluating Competent Authorities are advised to generate this report from the latest version of the applicant's IUCLID dossier and should include their assessment and conclusions in the specific boxes available in the Report.

Assessment and conclusion by Evaluating Competent Authority

4.2. Residues in plants

4.2.1. Nature of residues

Summary

Purpose of the application:

- evaluation of confirmatory data following review according to Article 12 of Regulation (EC) No 396/2005
- set specific maximum residue level(s) (changing current EU MRL listed in Annex II or III of Regulation (EC) No 396/2005

Old evaluation report vs. new MRL report

What is identical? What is different?

- Both reports follow nearly the same chapter structure
- The core findings regarding the active substance residues remain consistent across both reports
- Dossier quality is crucial for both reports but has a greater impact on new report, as any gaps or inconsistencies in the dossier are directly reflected in the final output
- New MRL Report has a more structured format (distinct boxes for the EMS, clear instructions to comment on e.g. waivers or proposed MRLs)
- The old Evaluation Report has more continuous text (might include more clarifying remarks)
- The new version is more technical and formal (making it less narrative)

Areas for improvement

Minor issues

- Most hyperlinks do not work, as they link to local drives
- Font size sometimes incorrect (suddenly 9 instead of 10)
- Symbols such as □? suddenly in the text
- Duplicate text in Appendix C under ‘other studies’ (but it might also be a failure of the applicant)
- Figures of structural formulas have poor quality

Areas for improvement

Minor issues

- After each summary of a residue study, it states: *'Residue trials: [Please, provide this information as attachment (Excel file)]'*
- A similar issue occurs with pictures

Residue trials:

[Please, provide this information as attachment (Excel file)]

Other information:

Illustrations / pictures / graphs:

3. Assessment and conclusion

Proposals

...to improve the report

- Automatic generation of an additional Annex (Annex 3) addressing public consultation
- Automatic insertion of the GAP table in the report
- Automatic insertion of submission date in the report
- Embedding the Excel files from the residue studies into the report (manually)

Pro´s and Con´s

In our view

- Text occasionally lacks fluency
- Tables in grey boxes look very cramped
- Confirmatory data: Full list of footnotes set in Regulation could be very extensive
- Additional work in case of dossier updates

- The report is well-structured
- Clear organization makes it less likely to overlook anything
- Separation between applicants´ and EMS' assessment
- Background section provides good overview (if done properly)

Conclusion and Outlook

Based on our experience with two MRL reports generated so far…

- Makes our work easier
- Some aspects are not yet optimal
- Separation between applicant and EMS much appreciated
- We intend to continue processing the upcoming MRL applications using the MRL report from IUCLID
- Too early to make it mandatory as other MS might still have reservations

→ Only way to improve it is to use it and report problems and improvement proposals

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and Food Safety

Pictures: Christina Fink, Asvola, Monkey Business Images, malshkoff/Shutterstock.com

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