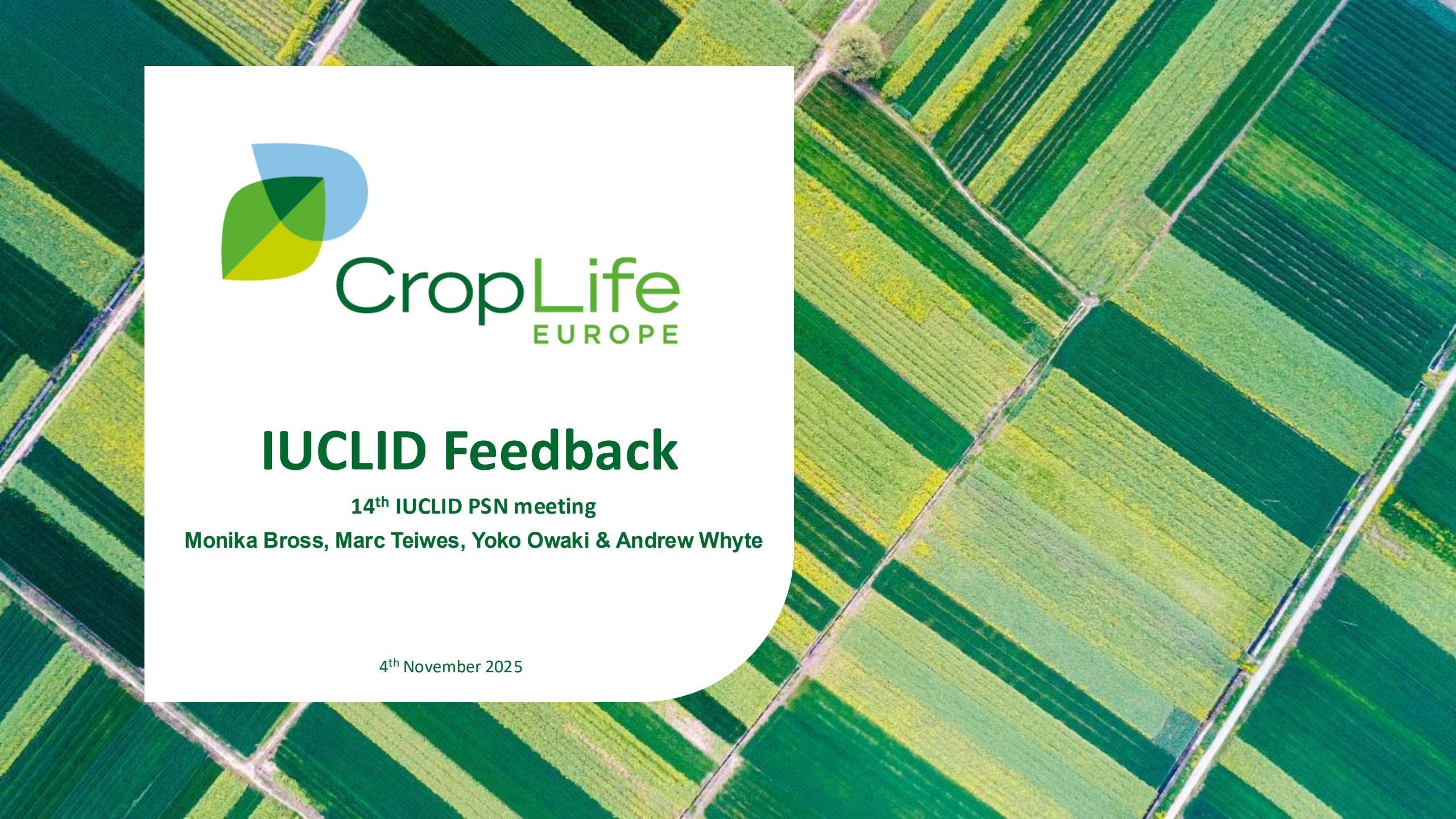

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IUCLID Feedback

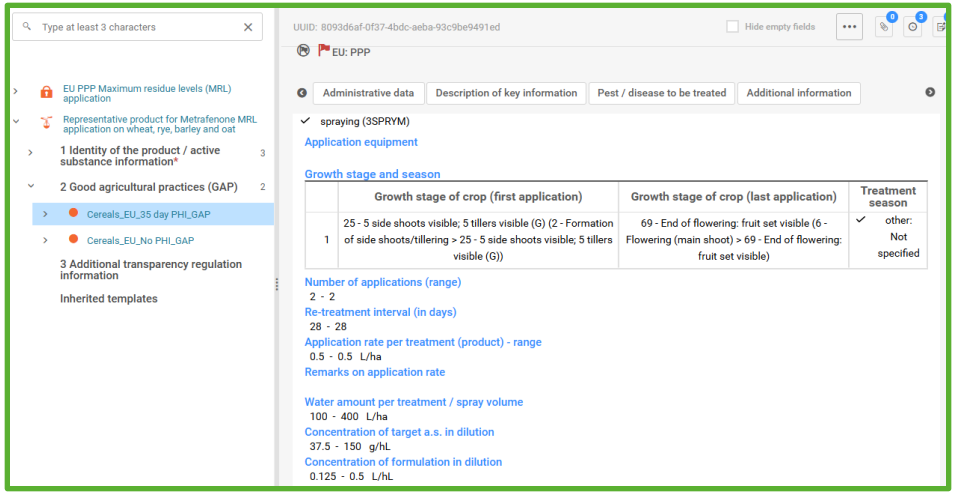
14th IUCLID PSN meeting

Monika Bross, Marc Teiwes, Yoko Owaki & Andrew Whyte

4th November 2025

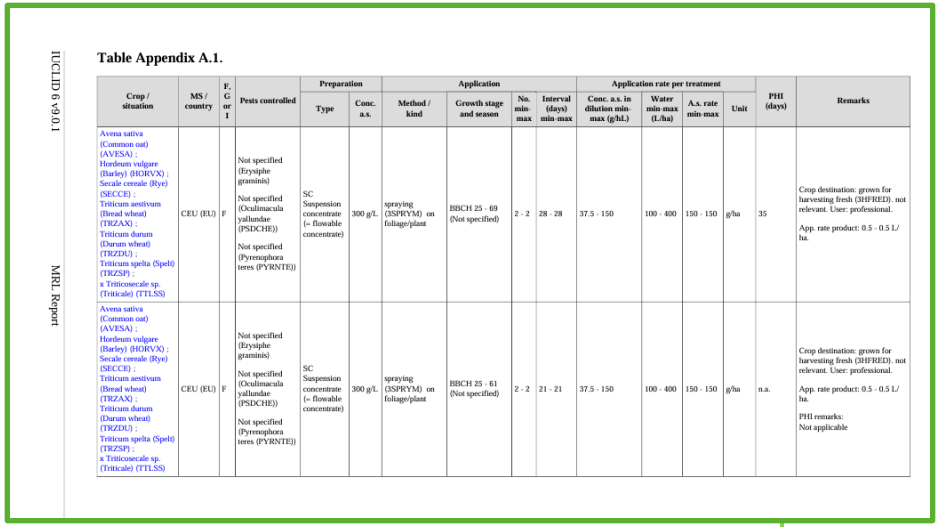
IUCLID DAR & MRL Evaluation reports

- **Several request received to check the completeness and correctness of reports in full**
  - ➢ **Beyond what is described in Admissibility checklist**



Reports can be insufficient/fail for various reasons

- **Dossier has been compiled under an earlier IUCLID Version**
- **Applicant has used different fields than the ones used in the report**
- **Bug in report template**



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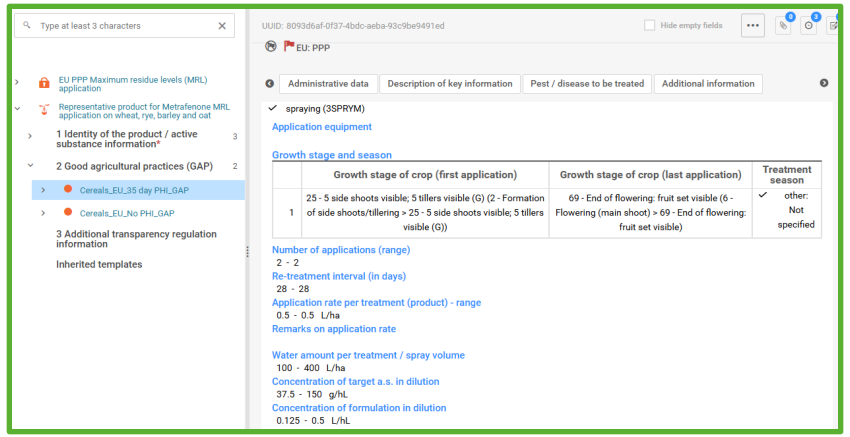
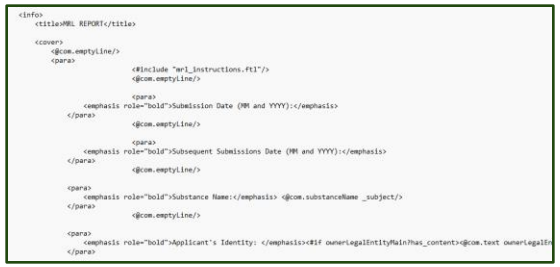
IUCLID DAR & MRL reports

Such requests pose a Problem for applicants

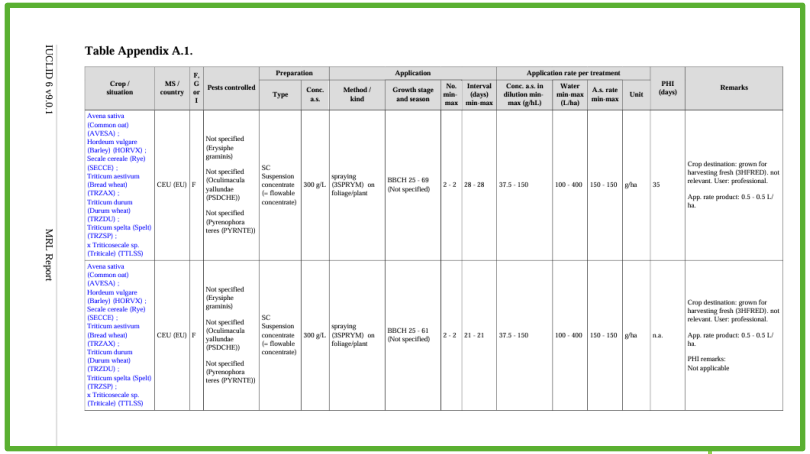
- DAR/RAR/MRL Evaluation report are not in the applicant's responsibility
- Checking of reports is a very time-consuming task
- Report templates (ftl Format) are not human readable hence we search for the needle in the haystack in a black box
- The IUCLID Version issue is currently unsolvable without creating endless update cycles causing a new layer of delays to the processes

RMS/EMS would likely face the same issues





Report generator

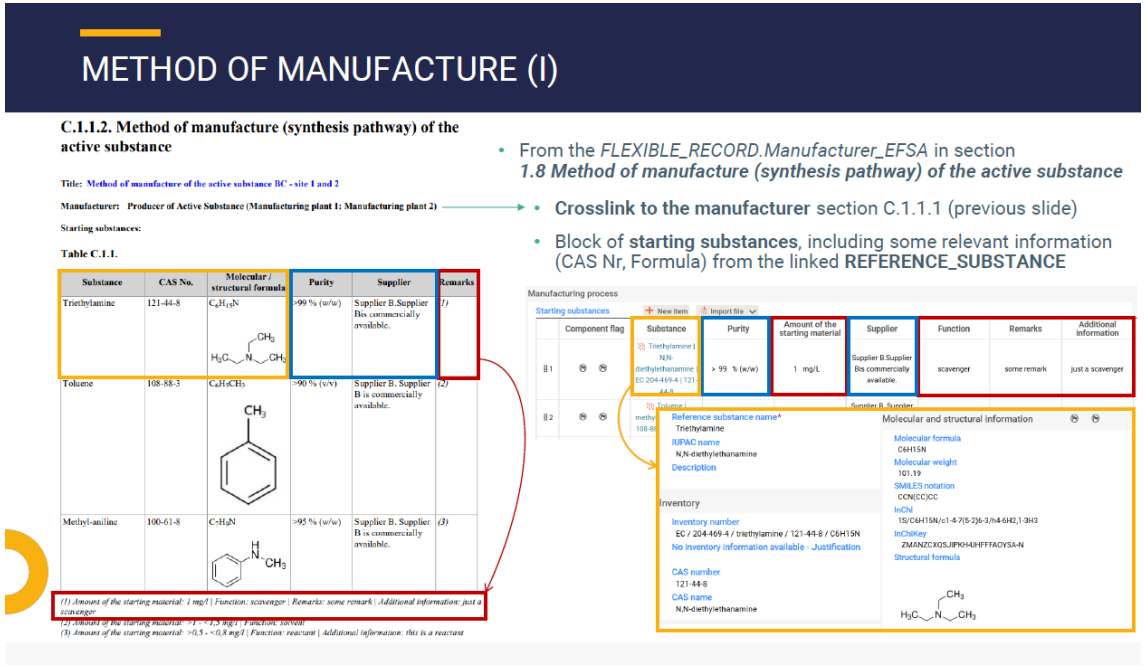


3

IUCLID DAR & MRL reports – next steps

The need for QC of the Report is clear and understood, but pushing it to the applicant is not the solution

- More guidance on how IUCLID and resulting report go together (as e.G. done in the WP on Confidential Volume 4)
- More detailed Validation rules ? – difficult to keep robust to cover for exceptional cases
- Keep older report Versions alive ? – mititgation of the Version issue



Further ideas ??

4

Streamlining MRL Submissions: New Option to Reduce Duplicate Efforts

Current situation:

- If the GAP relevant for the MRL dossier is different from the representative use of the AS dossier, a separate MRL dossier is required.

> **3.1-b:** If the **GAP(s) relevant for the MRL dossier is/are different compared to the GAPS(s) for representative use(s)** of the approval/renewal dossier, **a separate MRL dossier is required.** GAP document(s) relevant for the MRL application (e.g. GAP for non-representative uses) must be created only in the MRL dossier. GAP document(s) relevant for the representative uses (within the approval/renewal application) must be created only in the approval/renewal dossier.

- However, there are cases that same residue data package is used for both AS approval/renewal and critical GAP for MRL setting.

⚠ This creates additional efforts for Applicants to generate two dossiers without new scientific evidence and for RMS to review two dossiers.

Proposal:

- Add/modify „**Other submission related information**“ in the dossier header of AS dossier

- 💡 Add the 4th option
  - ☒ MRL application on non-represenative uses is included in the dossier using the same residue data as representative uses OR
  - ☒ Other + free text field to provide a description
- 💡 Modify the 2nd option to „MRL application on representative uses or non-representative uses is included in this dossier using the same residue data“

Goal: Minimize unnecessary efforts for Applicant and RMS

5

Thank You!

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