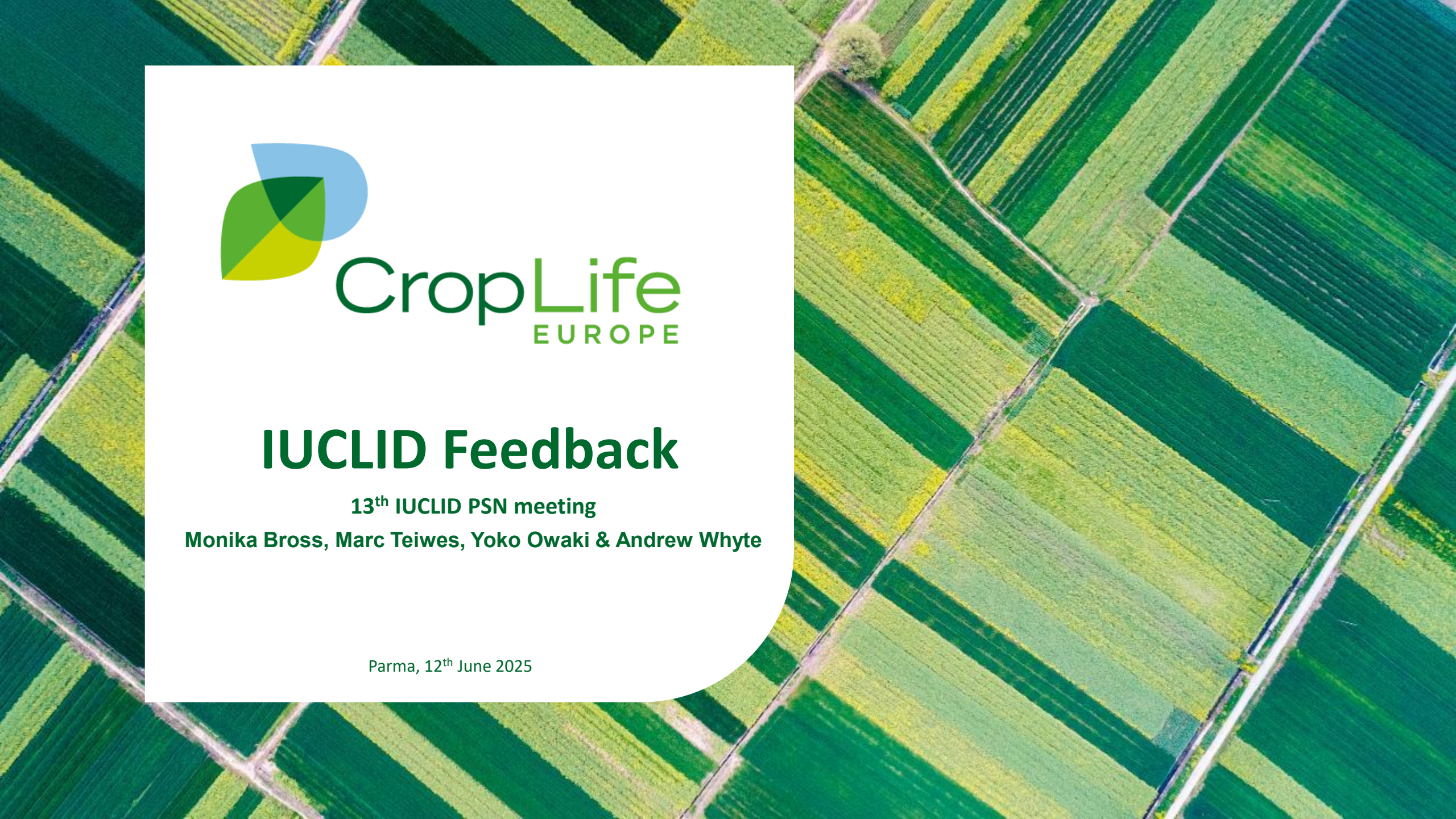

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IUCLID Feedback

13th IUCLID PSN meeting

Monika Bross, Marc Teiwes, Yoko Owaki & Andrew Whyte

Parma, 12th June 2025

Agenda

- Streamlining of evolving data requirements/guidance and IUCLID formats: Implementation of revised OHTs and ESRs in dossier submissions
- Migration issues with IUCLID 6.9

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Guidance Documents and IUCLID

IUCLID FORMAT CHANGES SCREENING EXERCISE

- Ensuring more transparency in the IUCLID format changes **prioritisation** by EFSA
- **Approach** for prioritisation:
  - ✓Input from industry (CLE on tox, ecotox, fate&behaviour)
  - ✓Input from OECD members as part of OECD consultation
  - ✓Input from EFSA experts + IUCLID backlog items
- **Expected PSN IUCLID input on**:
  - ✓List of format changes (OECD, CORE, DOMAIN, EU PPP) to work on in 2025&2026

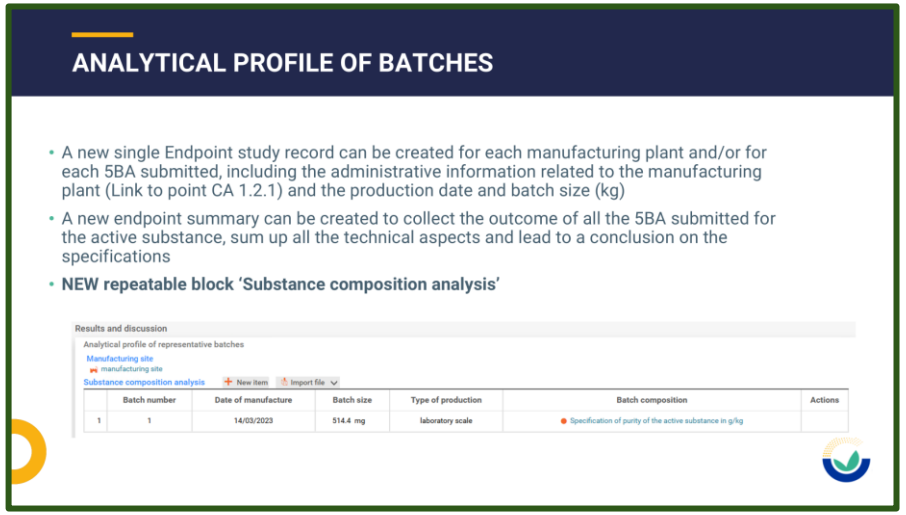
2

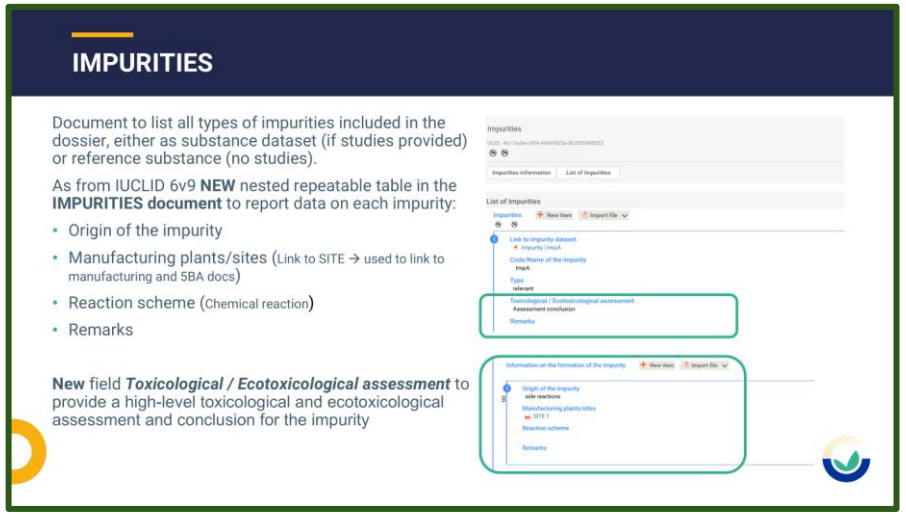
- **Revised versions of OHTs and ESR are essential for improving functionality but also for insertion of information according to applicable guidance documents**
- **CLE actively supports relevant EFSA / OECD activities, but we partly miss guidance on implementation and transition periods**

IUCLID - Version 6.9: Changes

Dismissal of document J: Processes / Impact

- Set-up of a working party
- Early communication of implementation (timelines and applicability by EFSA)
- Generation of several new documents and changes to existing documents
- Step-wise implementation of format changes mostly one year in advance
- Organization of a Stakeholder Webinar

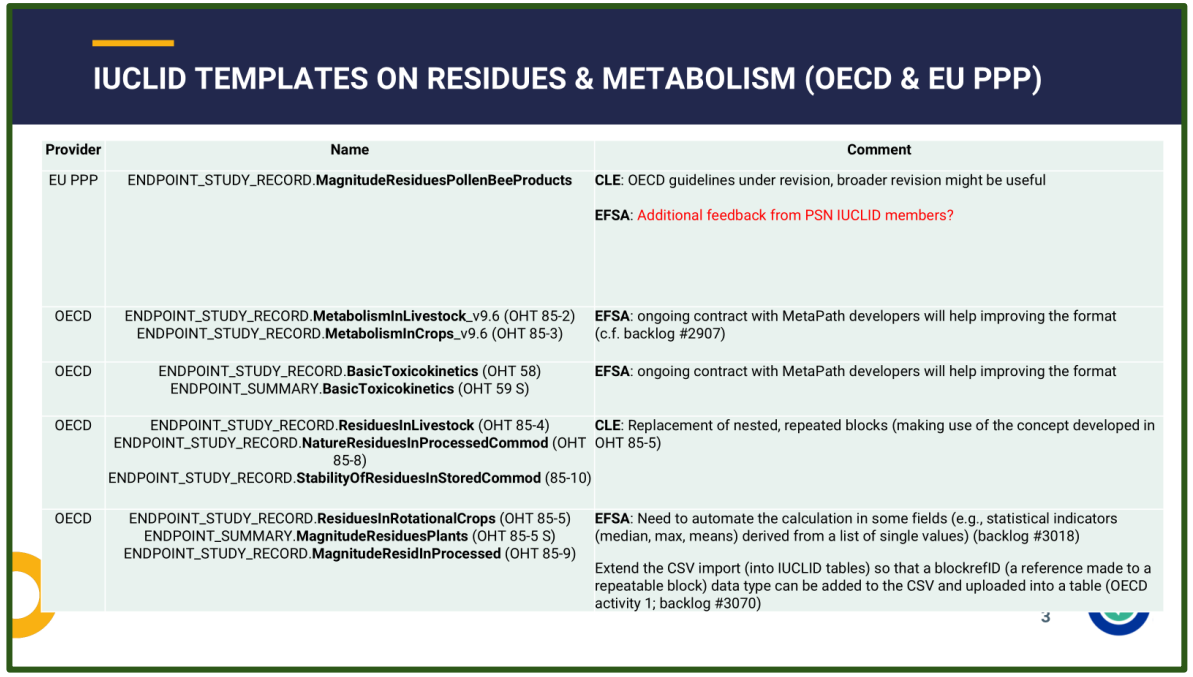




- **Positive example: Applicants can start in time to prepare for upcoming submissions**

4

IUCLID - Version 6.9: Changes



IUCLID TEMPLATES ON RESIDUES & METABOLISM (OECD & EU PPP)

Provider	Name	Comment
EU PPP	ENDPOINT_STUDY_RECORD.**MagnitudeResiduesPollenBeeProducts**	**CLE**: OECD guidelines under revision, broader revision might be useful **EFSA**: Additional feedback from PSN IUCLID members?
OECD	ENDPOINT_STUDY_RECORD.**MetabolismInLivestock**_v9.6 (OHT 85-2) ENDPOINT_STUDY_RECORD.**MetabolismInCrops**_v9.6 (OHT 85-3)	**EFSA**: ongoing contract with MetaPath developers will help improving the format (c.f. backlog #2907)
OECD	ENDPOINT_STUDY_RECORD.**BasicToxicokinetics** (OHT 58) ENDPOINT_SUMMARY.**BasicToxicokinetics** (OHT 59 S)	**EFSA**: ongoing contract with MetaPath developers will help improving the format
OECD	ENDPOINT_STUDY_RECORD.**ResiduesInLivestock** (OHT 85-4) ENDPOINT_STUDY_RECORD.**NatureResiduesInProcessedCommod** (OHT 85-8) ENDPOINT_STUDY_RECORD.**StabilityOfResiduesInStoredCommod** (85-10)	**CLE**: Replacement of nested, repeated blocks (making use of the concept developed in OHT 85-5)
OECD	ENDPOINT_STUDY_RECORD.**ResiduesInRotationalCrops** (OHT 85-5) ENDPOINT_SUMMARY.**MagnitudeResiduesPlants** (OHT 85-5 S) ENDPOINT_STUDY_RECORD.**MagnitudeResidInProcessed** (OHT 85-9)	**EFSA**: Need to automate the calculation in some fields (e.g., statistical indicators (median, max, means) derived from a list of single values) (backlog #3018) Extend the CSV import (into IUCLID tables) so that a blockrefID (a reference made to a repeatable block) data type can be added to the CSV and uploaded into a table (OECD activity 1; backlog #3070)

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- **May 2025 release:**
  - Completely revised versions of residue OHTs 85-5 and OHT 85-9 replacing in future the upload of Excel files
- **2026 release:**
  - New OECD Guidelines / guidance documents:
    - Analytical methods (OHT 87)
    - Storage stability (OHT 85-10)
    - Honey
    - Residue definition
  - Revision of metabolism OHTs / ESRs (developed by the working party)

- **For Residues: Considerable changes to be expected in upcoming years**

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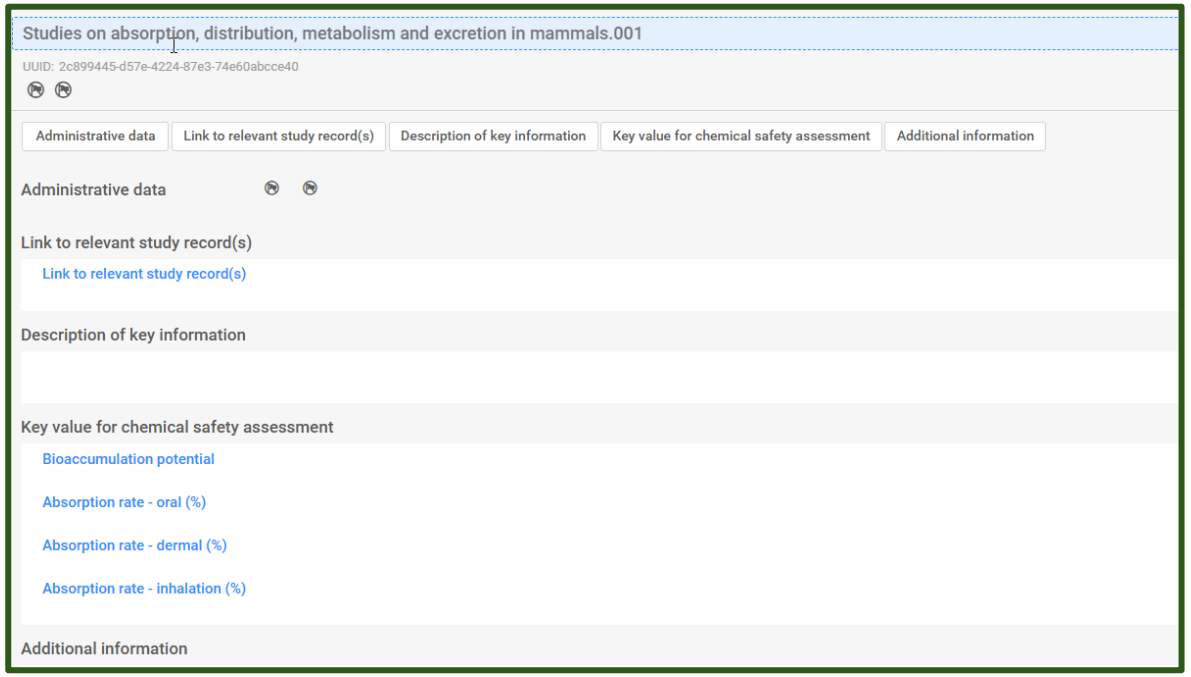
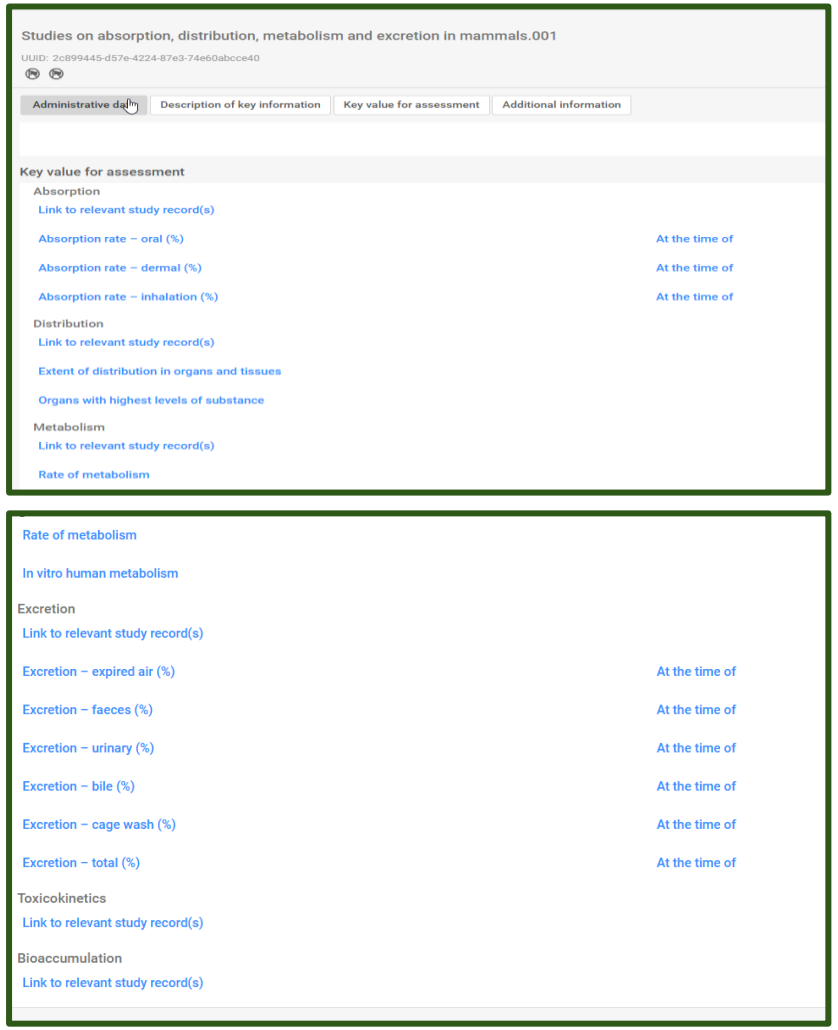
IUCLID - Version 6.9: Changes

Example – Toxicological data – Metabolism: Endpoint Summary Record

Version 6.8



Version 6.9 (as of ECHA beta)



- **Considerable change despite related OHT 58 (rat metabolism / comparative in vitro) is under revision (replacement of previous DER composer by direct data entry into IUCLID).**

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IUCLID - Version 6.9: Applicant's perspective

Situation

- With implementation of version 6.9, considerable progress was made for the residue field trial OHTs 85-5 and 85-9. The completely revised OHTs result in a reduction of nesting, inclusion of tables and a linkage of in-life data with results.
- For **applicants,** next steps would be (avoiding manual data entries into IUCLID):
  - Creation of upload tables
  - If available: Adaption of in-house residue data bases: Content, reporting / export format
- The required actions are in general relevant for future changes / revisions of other OHTs / ESRs.

Needs

- **Alignment / agreement on appropriate implementation / transition periods** considering
  - Availability of data in a suitable format
  - Appropriate upload functionalities (*.csv and IIP)
  - Reporting tools for allowing quality checks
- **Synchronization of implementation: OHTs combined with relevant ESRs**

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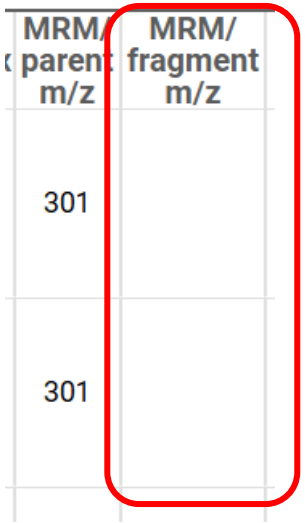
IUCLID - Version 6.9: Migration issue

Situation

- Data losses observed in OHT 87 and 85-5
- In OHT 87: Recovery tables MRM/M/z range field has been split & upper bound values are lost
- In OHT 85-5 Fields “Details on Analytical Method” and “Trial ID No” have been (re)moved
  - ➢ Pre-aligned within the WP on OHT 85-5



CLE position:

- **Data loss in a submitted Dossier….**
  - **is violating Regulation (EC) No 1107/2009**
  - **is detrimental to the currently envisaged process of evaluation**
  - **is not fast and easy to fix despite the open responsibility question**
- **The issue was considered to be resolved by the new strategy to check on data migration options firstly before agreeing to a format change**

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Thank You!

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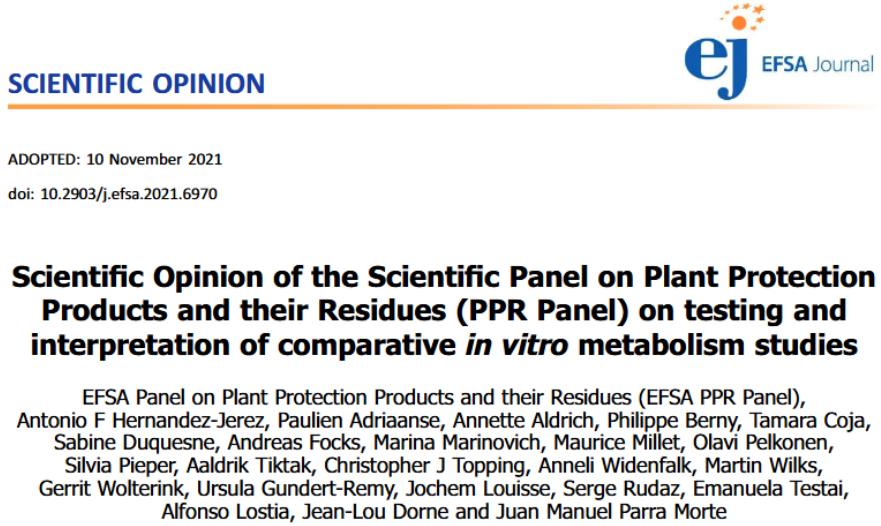
Guidance Documents and IUCLID

- The Scientific Opinion was endorsed as Guidance Document in fall 2023 and will be implemented in IUCLID with the version 6.9.
- In fall 2024, CLE has commented the relevant OECD word document.
- The relevant OHT 58 is modified and is available on the ECHA beta-cloud for testing without considering our comments.



SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 10 November 2021

doi: 10.2903/j.efsa.2021.6970

Scientific Opinion of the Scientific Panel on Plant Protection Products and their Residues (PPR Panel) on testing and interpretation of comparative *in vitro* metabolism studies

EFSA Panel on Plant Protection Products and their Residues (EFSA PPR Panel), Antonio F Hernandez-Jerez, Paulien Adriaanse, Annette Aldrich, Philippe Berny, Tamara Coja, Sabine Duquesne, Andreas Focks, Marina Marinovich, Maurice Millet, Olavi Pelkonen, Silvia Pieper, Aaldrik Tiktak, Christopher J Topping, Anneli Widenfalk, Martin Wilks, Gerrit Wolterink, Ursula Gundert-Remy, Jochem Louisse, Serge Rudaz, Emanuela Testai, Alfonso Lostia, Jean-Lou Dorne and Juan Manuel Parra Morte

- The revised OHT 58 (IUCLID ECHA beta-cloud) does not reflect the complexity of the Scientific Opinion.
- As five different species should be tested, one single study would be distributed across five different OHTs with no option for direct comparison of results.
- **Proposal: The further development of OHT 58 (plus endpoint summary record) might be taken up in a dedicated working party (together with OHT 85-2 and 85-3).**

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