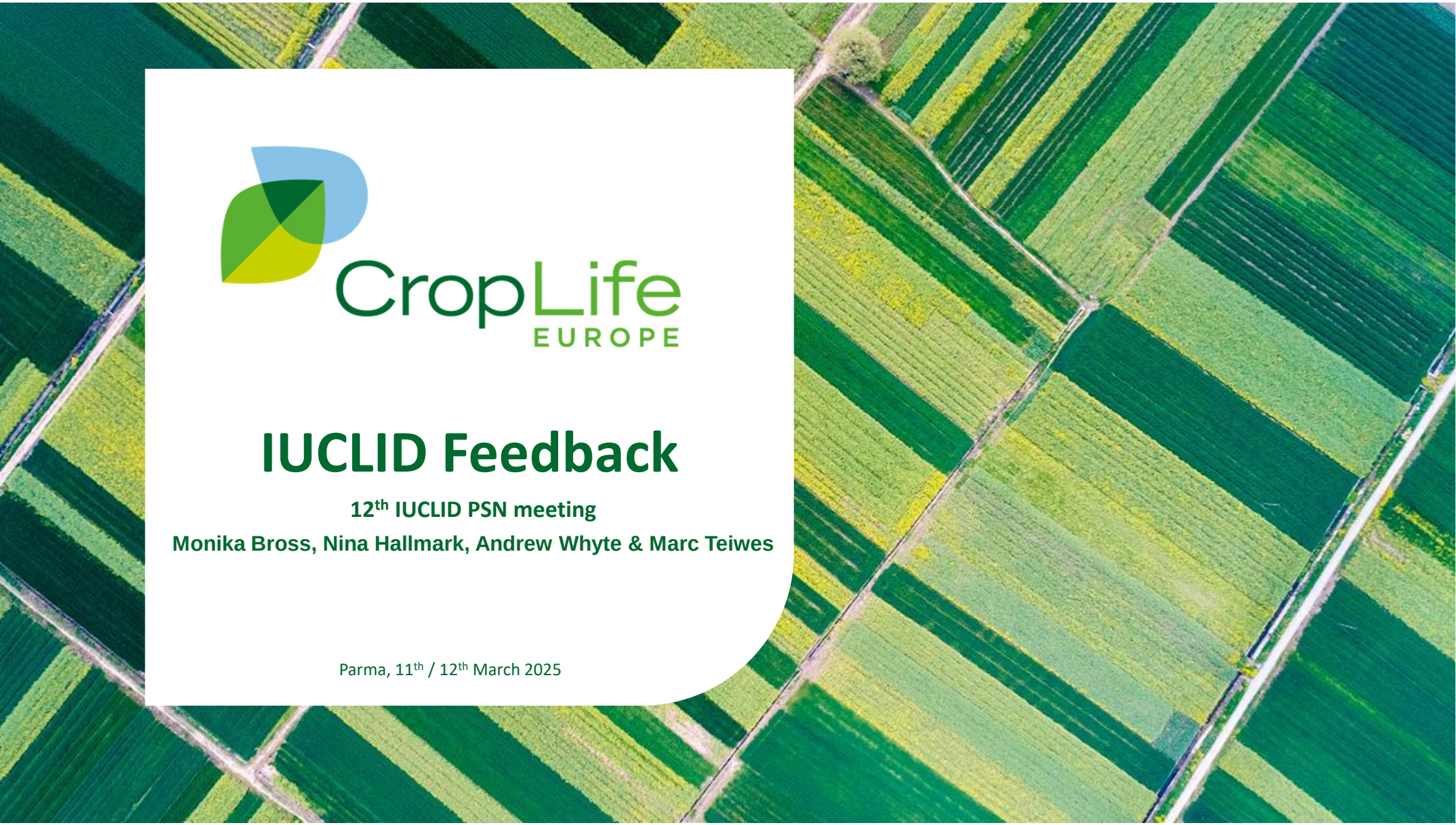

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IUCLID Feedback

12th IUCLID PSN meeting

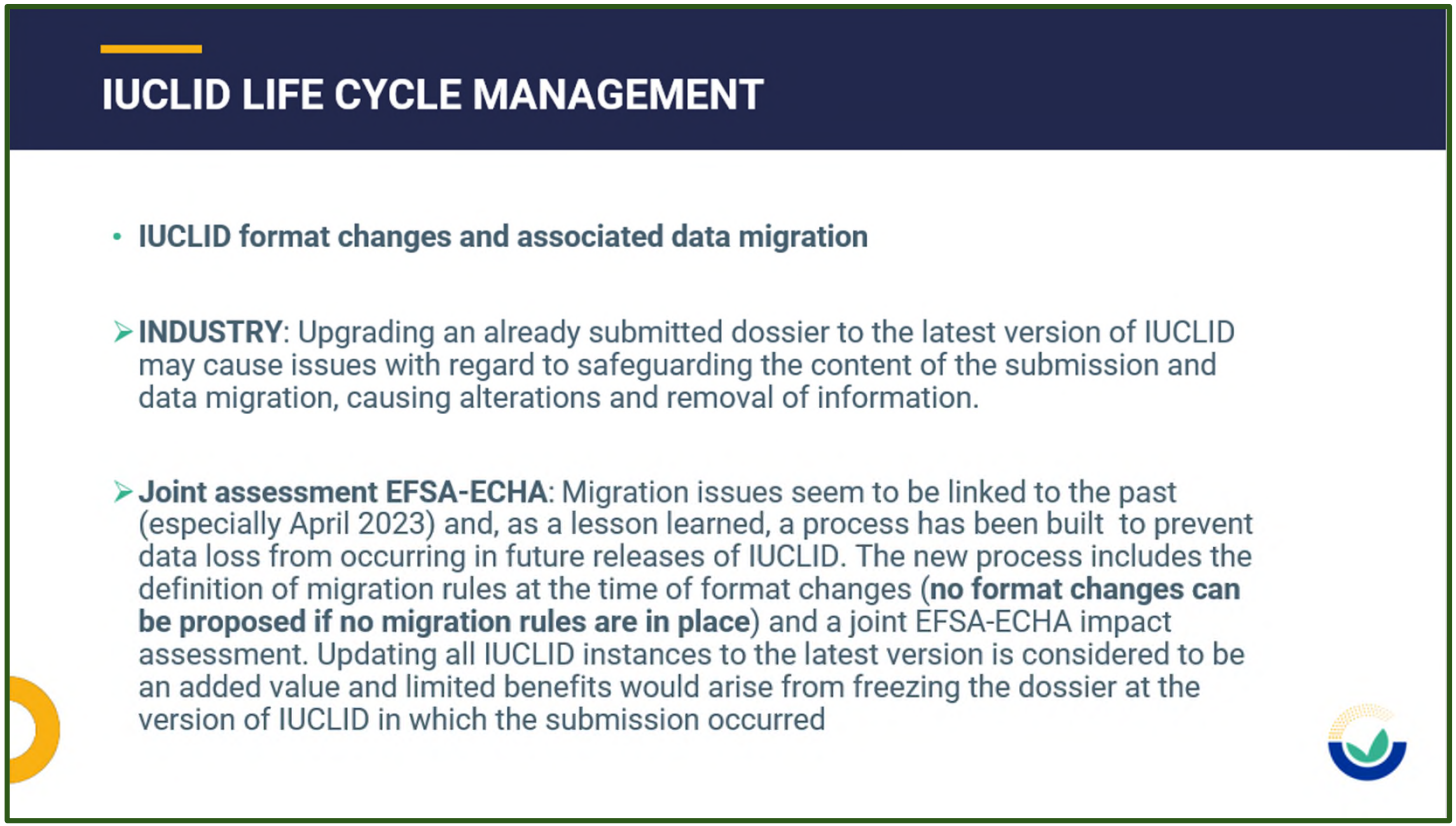
Monika Bross, Nina Hallmark, Andrew Whyte & Marc Teiwes

Parma, 11th / 12th March 2025

Agenda

- Feedback to EFSA presentation on LCM from November 2024 PSN
- Task Force Applications: A proposal how to cover all applicants in IUCLID & Open EFSA
- Streamlining of evolving data requirements/guidance and IUCLID formats

IUCLID LCM – feedback by CLE



- ➢ **Mitigation of the issue but no solution**
- ➢ **Limits option for format changes**

IUCLID LCM – feedback by CLE

IUCLID LIFE CYCLE MANAGEMENT

- **Reuse of the active substance dataset across different/parallel regulatory processes**

➢ **INDUSTRY**: Reusing the same active substance dataset in IUCLID across different/parallel regulatory processes would avoid duplication of work and lead to harmonization of the assessment of these data across different/parallel regulatory processes

➢ **Joint assessment EFSA-ECHA**: The issue is related to the PPP process only and to-date, with the current settings of IUCLID, there is no technical solution to overcome it

- ➢ **With IUCLID as tool to facilitate OSOA the issue will transpire to other areas**
- ➢ **IUCLID is legally mandatory for PPP submissions - therefore issues should be solved**

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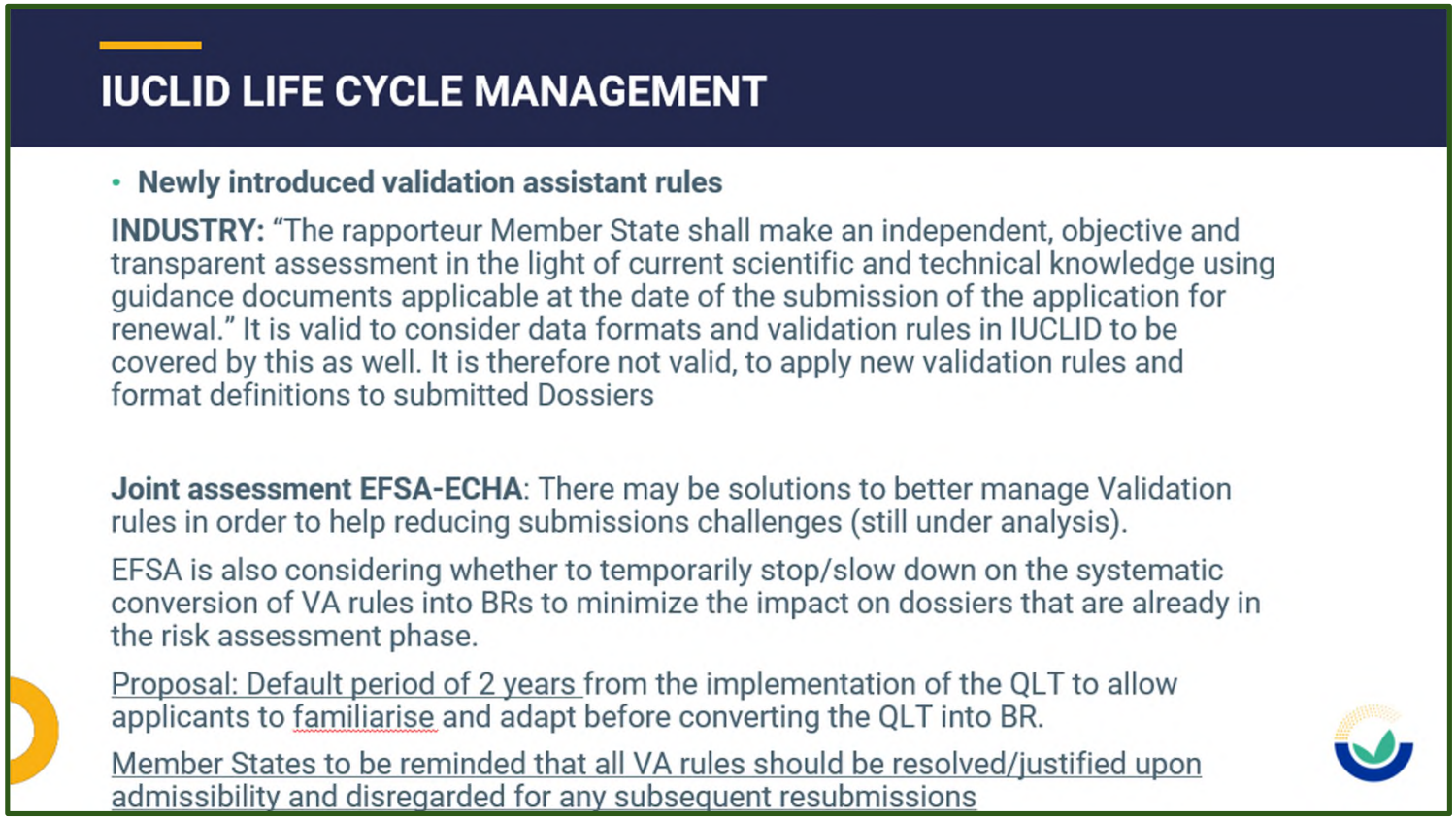
IUCLID LCM – feedback by CLE



IUCLID LIFE CYCLE MANAGEMENT

- **Newly introduced validation assistant rules**

INDUSTRY: "The rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents applicable at the date of the submission of the application for renewal." It is valid to consider data formats and validation rules in IUCLID to be covered by this as well. It is therefore not valid, to apply new validation rules and format definitions to submitted Dossiers

Joint assessment EFSA-ECHA: There may be solutions to better manage Validation rules in order to help reducing submissions challenges (still under analysis).

EFSA is also considering whether to temporarily stop/slow down on the systematic conversion of VA rules into BRs to minimize the impact on dossiers that are already in the risk assessment phase.

Proposal: Default period of 2 years from the implementation of the QLT to allow applicants to familiarise and adapt before converting the QLT into BR.

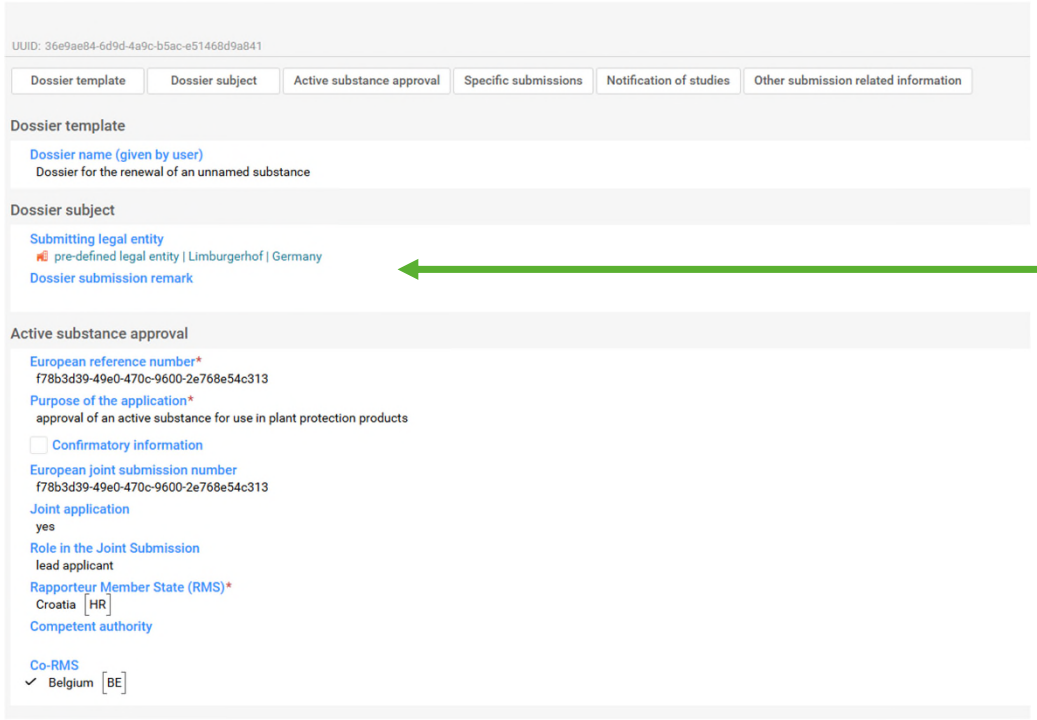
Member States to be reminded that all VA rules should be resolved/justified upon admissibility and disregarded for any subsequent resubmissions

- **EFSA proposal again mitigating the issue, but not solving it**
- **Has the announced analysis been conducted?**

Task Force Applications and applicants information

- In a recent submission not all Task Force members where named as applicants in Open EFSA
- **Reason:** Field is filled from IUCLID Submitting Legal entities – not all Task Force members had to submit an own complimentary Dossier

Solution proposal



Addition of a field additional applicants to name additional legal entities as applicants in case :
Joint application is „yes“ AND
Role in joint submission is set to „lead applicant“

Guidance Documents and IUCLID

- Changes to OECD Harmonized Templates have a cyclical, structured approach, aligning to IUCLID format changes to ensure that OECD test guidelines are in-line with information inserted into IUCLID.
- In the area of Residues (relevant for AI dossiers and MRL applications), several documents are under revision or in discussion:
  - Guidance document - Analytical methods (OHT 87)
  - Guideline - Storage stability (OHT 85-10)
  - Guideline and guidance document - Processing (OHT 85-9)
- The list is not complete .. And might also apply to other areas relevant for crop protection submission

- **For analytical methods, the revision of the guidance offers a good opportunity to split the OHT 87 as proposed before and to increase suitability / functionality**:
  - Residue analytical methods
  - Product chemistry
  - ???

Guidance Documents and IUCLID

- EU (EFSA, ECHA, MS) guidance documents have no such mechanism and lead to divergence between applicant requirements and the format given for insertion
  - This leads to additional manual rework of IUCLID dossiers due to format changes over time
  - Data / Information is ‚grouped' into semi-suitable fields (mainly rich text fields e.g. efate – field studies)

GUIDANCE

ECHA EUROPEAN CHEMICALS AGENCY efsa JOURNAL

APPROVED: 14 July 2023

doi: 10.2903/j.efsa.2023.8194

Guidance document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water

European Chemicals Agency (ECHA) and European Food Safety Authority (EFSA), Roberta Hofman-Caris, Milou Dingemans, Astrid Reus, Sanah Majid Shaikh, Julian Muñoz Sierra, Ursula Karges, Tim aus der Beek, Eugénia Nogueiro, Christopher Lythgo, Juan Manuel Parra Morte, Maria Bastaki, Rositsa Serafimova, Anja Friel, Daniele Court Marques, Andreas Uphoff, Lucie Bielska, Claudio Putzu, Laura Ruggeri and Paschalina Papadaki

Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods

GUIDANCE

efsa JOURNAL

APPROVED: 4 August 2023

doi: 10.2903/j.efsa.2023.8225

Guidance on the assessment of pesticide residues in rotational crops

European Food Safety Authority (EFSA), Luna Greco, Judit Janossy, Samira Jarrah, Aija Kazocina, José Oriol Magrans and Hermine Reich

- **Guidance document generation and IUCLID structure should work holistically**
- **IUCLID entries (OHTs, ESRs) at dossier submission should allow for insertion of information fit to applicable guidance document (efate: DT50/90, kinetic evaluation)**

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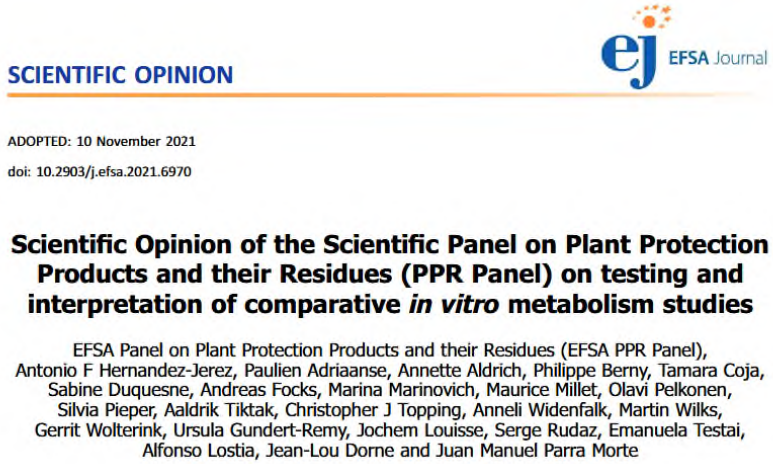
Guidance Documents and IUCLID

- 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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Thank You!