



CropLife
EUROPE

IUCLID Feedback

13th IUCLID PSN meeting

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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

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



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- **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**

ANALYTICAL PROFILE OF BATCHES

- A new single Endpoint study record can be created for each manufacturing plant and/or for each 5BA submitted, including the administrative information related to the manufacturing plant (Link to point CA 1.2.1) and the production date and batch size (kg)
- A new endpoint summary can be created to collect the outcome of all the 5BA submitted for the active substance, sum up all the technical aspects and lead to a conclusion on the specifications
- **NEW repeatable block 'Substance composition analysis'**

Results and discussion

Analytical profile of representative batches

Manufacturing site

Substance composition analysis

Batch number	Date of manufacture	Batch size	Type of production	Batch composition	Actions
1	14/03/2023	514.4 mg	laboratory scale	Specification of purity of the active substance in g/kg	

IMPURITIES

Document to list all types of impurities included in the dossier, either as substance dataset (if studies provided) or reference substance (no studies).

As from IUCLID 6v9 **NEW** nested repeatable table in the **IMPURITIES** document to report data on each impurity:

- Origin of the impurity
- Manufacturing plants/sites (Link to SITE → used to link to manufacturing and 5BA docs)
- Reaction scheme (Chemical reaction)
- Remarks

New field Toxicological / Ecotoxicological assessment to provide a high-level toxicological and ecotoxicological assessment and conclusion for the impurity

Impurities

Impurities information

List of impurities

Link to impurity dataset

Code/Name of the impurity

Type

Remarks

Information on the formation of the impurity

Origin of the impurity

Manufacturing plants/sites

Reaction scheme

Remarks

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)	EFSA: ongoing contract with MetaPath developers will help improving the format (c.f. backlog #2907)
	ENDPOINT_STUDY_RECORD.MetabolismInCrops_v9.6 (OHT 85-3)	
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)	CLE: Replacement of nested, repeated blocks (making use of the concept developed in OHT 85-5)
	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod (OHT 85-8)	
	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod (85-10)	
OECD	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops (OHT 85-5)	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)
	ENDPOINT_SUMMARY.MagnitudeResiduesPlants (OHT 85-5 S)	
	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessed (OHT 85-9)	
		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)

- **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**

IUCLID - Version 6.9: Changes

Example – Toxicological data – Metabolism: Endpoint Summary Record

Version 6.9 (as of ECHA beta)

Version 6.8

Studies on absorption, distribution, metabolism and excretion in mammals.001

UUID: 2c899445-d57e-4224-87e3-74e60abcce40

Administrative data | Link to relevant study record(s) | Description of key information | Key value for chemical safety assessment | Additional information

Administrative data

Link to relevant study record(s)

Description of key information

Key value for chemical safety assessment

Additional information

Studies on absorption, distribution, metabolism and excretion in mammals.001

UUID: 2c899445-d57e-4224-87e3-74e60abcce40

Administrative data | Description of key information | Key value for assessment | Additional information

Key value for assessment

Absorption

Link to relevant study record(s)

Absorption rate – oral (%) At the time of

Absorption rate – dermal (%) At the time of

Absorption rate – inhalation (%) At the time of

Distribution

Link to relevant study record(s)

Extent of distribution in organs and tissues

Organs with highest levels of substance

Metabolism

Link to relevant study record(s)

Rate of metabolism

Rate of metabolism

In vitro human metabolism

Excretion

Link to relevant study record(s)

Excretion – expired air (%) At the time of

Excretion – faeces (%) At the time of

Excretion – urinary (%) At the time of

Excretion – bile (%) At the time of

Excretion – cage wash (%) At the time of

Excretion – total (%) At the time of

Toxicokinetics

Link to relevant study record(s)

Bioaccumulation

Link to relevant study record(s)

- 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).

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**

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

MRM/ parent m/z	MRM/ fragment m/z
301	
301	

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

The background of the slide is a close-up photograph of lush green leaves, likely from a citrus tree, showing detailed vein patterns and vibrant green hues. A large, dark green rounded rectangle is overlaid on the right side of the image.

Thank You!

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



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,
Gerit 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).**