IUCLID format udpates: OHTs and Endpoint Summaries migration

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OECD consultation

Sept - Oct 2022
Launch of OECD consultation

Nov – Dec 2022
Final modifications to the Templates

Feb – March 2023
IUCLID adaptations – Beta testing of the new format

26 April 2023
Publication of IUCLID
(+ OECD website)

OHTs

Comments to **OECD** by **24 Oct**:

- At *https://community.oecd.org/docs/DOC-218941*
- **IUCLID team** (iuclid6@echa.europa.eu)

EU_PPP

Comments to EFSA by **30 Oct**:

- PSN Teams folder

IUCLID format updates (EU_PPP/CORE): April 2023 release

- **10 EU_PPP docs:**

Name	IUCLID Backlog (#)
NEW Endpoint_Study_Record_**Magnitude of residues in pollen and bee products**	Update to report studies on residue levels in pollen and bee products (according to the newly developed EU guidance document SANTE/11956/2016rev.9) and to identify key values for risk assessment (#2147 #2468)
FLEXIBLE_SUMMARY.**ToxRefValues**	Changes linked to migration of OpenFoodTox data (#2574; #2576)
FLEXIBLE_SUMMARY.**ResiduesInLivestock**	Small fixes to report MATRIX, MRL at LOQ and fish studies (#2376; #2465;#2481)
ENDPOINT_SUMMARY.**StabilityResiduesCommodities**	Small fixes on picklists (#2464)
Dossier header (MO)	New fields to report submission info (requester, type; reason) (#2357; #2359; #2471)
NEW FLEXIBLE_SUMMARY.**IsomericCompositionRiskAssessment** *	#2583
FLEXIBLE_SUMMARY.**EstConcGroundwater** *	Review the use of the link to a substance (#2360)
FLEXIBLE_SUMMARY.**EstConcWaterSed** *	
FLEXIBLE_SUMMARY.**EstConcOtherRoutes** *	Link to GAP table added
ENDPOINT_SUMMARY.**ResidueFood** *	Addition of "*commodity type*" and "*processing*" fields (#2301)

- **3 CORE docs:**

Name	IUCLID Backlog (#)
FLEXIBLE_RECORD.**AnalyticalInformation**	New field to upload study report/documents (#2223)
ENDPOINT_SUMMARY.**MetabolismInLivestock**	Updates to align with OHT 85-2/MetaPath (#2075)
FLEXIBLE_SUMMARY.**AnalyticalProfileOfBatches**	New section under "*Administrative Data*" for "*Quality Control data*" to report info on (number of batches analysed, max/min conc of each component, manufacturing plant, remarks, etc.); table for CSV uploader (#2489)

* Doc not included in PSN presentation on 22 Sept.

Endpoint Summary (ES) harmonisation (ECHA-EFSA)

Aim: to merge parallel/overlapping Endpoint Summaries (ES) under **EU PPP**, **NZ HSNO** and **CORE** into one single format per endpoint, to be used by all the relevant contexts;

- ✓ Including 105 **ESs** as OECD Harmonised Templates (OHTs):
  - **Newly** created endpoint summary formats;
  - 20 harmonisation proposals (i.e., **20 EU PPP**, 2 NZ HSNO, 18 CORE formats).

Ecotoxicological
- Long-term toxicity to fish
- Long-term toxicity to aquatic invertebrates
- Short-term toxicity to fish
- Short-term toxicity to aquatic invertebrates
- Toxicity to aquatic algae and cyanobacteria
- Toxicity to plants
- Sediment toxicity
- Toxicity to soil macroorganisms except arthropods (Effects on non-target soil meso- and macrofauna)
- Toxicity to terrestrial plants
- Toxicity to soil microorganisms
- Effects on biological methods for sewage treatment
- Toxicity to other above-ground organisms (wild mammals)
- Toxicity to birds
- Bioaccumulation: aquatic / sediment
- Toxicity to terrestrial arthropods (Effects on arthropods including bees)

Fate and behaviour in the environment
- Biodegradation in water and sediment: simulation tests
- Route of degradation in water and sediment
- Biodegradation in soil
- Route of degradation in soil

Toxicological
- Carcinogenicity

- ✓ **Unique key values** (i.e., fixed fields; removal of repeatable blocks);
- ✓ **Datatype of the key values** (only half-bounded numerical values, qualifier + value);
- ✓ **Linking to relevant Endpoint Study Records** (per relevant key section; generating the list of endpoints report);
- ✓ **Streamlined**, **structured information** for assessment purposes;
- ✓ **Microbial pesticide units** added
- ✓ **Long-term toxicity** key values in "Repeated dose toxicity" (including short-term, sub chronic and chronic); "Carcinogenicity" remains.

Endpoint Summary (ES) migration – IUCLID ToC

- ✓ We will keep the **original (EU_PPP) ESs** as **obsolete/legacy** docs in the Tables of Contents of IUCLID version 6.7, for a transition period (as was done for the Microorganism update):
  - For example, for the Ecotoxicology summaries and FATE summaries which have been harmonised this would require the future manual transfer of information from the obsolete documents to the summaries in the new format. This would also apply to summaries for metabolites which are located in the Substance dataset.
- ✓ The content of other summaries will be migrated to the new harmonised ones

5.	**Key value for chemical safety assessment**	**Header 1**	
6.	**Freshwater fish**	**Header 2**	
7.	Link to relevant study record(s)	Link to endpoint (multiple) Display: Basic	
8.	Dose descriptor	List (picklist) Display: Basic	**Picklist values:** - EC10 - LC10 - NOEC
9.	Effect concentration	Numeric range (half bounded) Display: Basic	**Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <=

New OHTs #50-3; #50-4; #50-5 – migration

- **Three NEW OHTs** and corresponding **Endpoint Summaries** to replace OHT 50-2 *Toxicity to terrestrial arthropods*:
  - ***i.*** ***OHT 50-3*** - *Toxicity to bees*
  - ***ii.*** ***OHT 50-4*** - *Toxicity to terrestrial arthropods other than bees*
  - ***iii.*** ***OHT 50-5*** - *Toxicity to soil arthropods*

- Information from OHT 50-2 (to be made obsolete) will be migrated to the **new three templates** based on the selection made in the field "***Test organisms (species)***":
  - Where the option "*other:*" is used or no species is specified (data waivers), **OHT 50-4** (most generic of the three split templates) will be used;
  - Backward migration of the three split templates will all be to the original OHT 50-2.

8.3 Effect on arthropods including bees

- 8.3.1 Effect on bees
  - Endpoint summary: Toxicity to bees
  - Endpoint study record: Toxicity to bees
- 8.3.2 Effect on terrestrial arthropods other than bees
  - Endpoint summary: Toxicity to terrestrial arthropods other than bees
  - Endpoint study record: Toxicity to terrestrial arthropods other than bees
- 8.3.3 Effect on soil arthropods
  - Endpoint summary: Toxicity to soil arthropods
  - Endpoint study record: Toxicity to soil arthropods

- **Next steps**, update of:
  - **validation rules** (as per relevant legislation);
  - (EFSA) **IUCLID manuals**

LA document

- Flexible record; Additional Transparency Regulation Information
  - Provides the opportunity to report EFSA IT system identifiers
  - Must be used to nominate contact/s to respond to EFSA legal team during the confidentiality assessment
  - To be used when an applicant intends needs to provide a confidential justification for NoS assessment (optional) - no change to current data entry requirements for NoS assessment

EU_PPP Template Additional Transparency Regulation Information

The following table gives a detailed description of the type of information prompted for by the data entry fields.

Line no.	Field name	Field type Display type	Picklist Freetext template	Help text	Remarks Guidance Cross-reference
1.	**EFSA IT system and regulatory identifiers**	**Block of fields (repeatable) Start**		Provide here identifiers required for integration with EFSA IT systems	
2.	Identifier	List (picklist) Display: Basic	**Picklist values:** - EFSASalesforce - other:	Select the type of identifier you wish to provide using the picklist. If none of pre-defined items apply, select 'other:'. A text field is then activated next to the list field in which you can specify the type of identifier you wish to provide.	
3.	Identity	Text (2,000 char.) Display: Basic		Enter here the identity (name, number, code) corresponding to the identifier type selected.	
4.	Remarks	Text (32,768 char.) Display: Basic			
5.	**EFSA IT system and regulatory identifiers**	**Block of fields (repeatable) End**			
6.	**Contact for confidentiality assessment**	**Block of fields (repeatable) Start**		Report the contact person or persons who will receive communications and decisions on the EFSA confidentiality assessment from the EFSA confidentiality team	
7.	Person	Link to entity (single) Display: Basic			**Cross-reference:** CONTACT
8.	**Contact for confidentiality assessment**	**Block of fields (repeatable) End**			
1.	**Studies requiring confidential NoS justification**			This section provides the possibility to provide justifications with confidential information. A JUSTIFICATION FOR PUBLICATION MUST ALWAYS BE PROVIDED IN THE DOSSIER HEADER OR LITERATURE REFERENCE ENTITY	
2.	**Confidential NoS justification**	**Block of fields (repeatable) Start**			
1.	Component flag	Confidentiality Display: Basic		Set the confidentiality flag and regulatory purpose.	
2.	NoS ID	Text (255 char.) Display: Basic		List the Notification of Studies identifier where more information is provided in a confidential justification.	
	Link to study	Link to lit. reference (single) Display: Basic		If no notification of studies identifier exists link to the study via the literature reference entity	**Cross-reference:** LITERATURE REFERENCE
1.	Confidential justification	Text (2,000 char.) Display: Basic		Confidential Justification for (i) the absence of notification of a study (ii) the delayed notification of a study (iii) the withdrawal of a notification (iv) the non-inclusion in the dossier of a notified study	

Report Generator: issue with HTML checks on rich-text fields

Background: report generator crashing when malformed HTML present in the rich-text field

- New feature to identify rich-text fields with malformed HTML content;
- Not part of report templates but incorporated into Report Generator engine;
- Partially introduced in IUCLID's April 2022 release and extended in October 2022 release;
- However, cases of fields where content are correct, they still display the warning message;
- ECHA currently working of a fix to allow the HTML check to work as indented (patch potentially available in Jan);
- Temporary workaround: to run RP in the local installation of v6.19 of IUCLID.