

12th meeting of the PSN IUCLID sub-group
11 March 2025

IUCLID FORMAT CHANGES PLANNING

FDP, IDATA, PREV

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



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)

IUCLID TEMPLATES ON FATE&BEHAVIOUR (OECD)

Provider	Name	Comment
OECD	ENDPOINT_STUDY_RECORD. BiodegradationInSoil (OHT 30) ENDPOINT_STUDY_RECORD. BiodegradationInWaterAndSedimentSimulationTests (OHT 29) ENDPOINT_STUDY_RECORD. FieldStudies (OHT 39)	CLE: need for reporting 90th percentile confidence intervals according to FOCUS Kinetics. To allow a transparent reporting of kinetic evaluations in IUCLID, we suggest creating a dedicated Endpoint Study Record (backlog #2648, #2650, #2652)
XXX	NEW Endpoint Study Record / OHT ?	CLE: impact of water treatment processes on residues in drinking water (EU) – Generation of a suitable OHT (no OHT available) /ESR EFSA: Additional feedback from PSN members?



IUCLID TEMPLATES ON (ECO)TOXICOLOGY (OECD & EU PPP)

Provider	Name	Comment
OECD	ENDPOINT_STUDY_RECORD. GeneticToxicityVitro (OHT 70) ENDPOINT_STUDY_RECORD. GeneticToxicityVivo (OHT 71)	EFSA: changes according to BfR feedback (c.f. EFSA's genotoxicity db project). Additional feedback from PSN IUCLID members?
OECD	ENDPOINT_STUDY_RECORD. EndocrineDisrupterTestingInAqua (OHT 48-2)	EFSA: possible revision to allow reporting for non-target organisms (as of Sept 2025) Additional feedback from PSN IUCLID members?
OECD	ENDPOINT_STUDY_RECORD. RepeatedDoseToxicityOral (OHT 67)	EFSA: improvement to allow re-use of the data/generate reports needed for different purposes such as endocrine disruption (appendix E), cumulative assessment groups (excel files). Additional feedback from PSN IUCLID members?
OECD	ENDPOINT_STUDY_RECORD. LongTermToxToFish (OHT 42) ENDPOINT_STUDY_RECORD. ToxicityToBirds (OHT 53)	CLE: minor comments EFSA: suggest opening backlogs item accordingly



NEXT STEPS - ACTIONS

- **EFSA to share** the list of format changes in excel file (as provided in slides #3, #4 and #5) with PSN IUCLID members after the PSN meeting
- **PSN IUCLID members** to suggest possible format changes (if not included in the list yet) for both chemicals and micro-organisms by **11 April 2025**
IUCLID backlog file must be used to insert new requests
- **EFSA** to revise PSN IUCLID feedback and discuss with ECHA, considering:
 - ✓ If format changes are applicable to OECD/CORE/DOMAIN, dedicated OECD WG may be established
 - ✓ if format changes are applicable to EU PPP, IUCLID PSN working party may be established



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