

6th meeting of the PSN IUCLID sub-group
28 March 2023



IUCLID MIGRATION

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INFORMATION ON THE IUCLID APRIL RELEASE

You can download the **information package** (.zip | 29.7 MB, updated 07.03.2023) about format changes to the harmonised IUCLID format. It contains:

- All Word files corresponding to the IUCLID 2023 documents
- XSD files for all IUCLID documents
- The list of all IUCLID 2023 fields
- Excel files listing the difference between the current version of the format and the version planned for April 2023 (in the folder 'Comparison with current format')
- Excel files listing the differences made between the previously shared information package (batch 2) and the latest version of these documents circulated now (batch 6)
- Dynamic content rules (in XML format)
- Migration rules, including phrase groups mapping (in XML format)
- Table of Contents (in XML format)



TEST VERSION IN IUCLID BETA

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<https://echa.europa.eu>

<https://iuclid6.echa.europa.eu>

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IUCLID 6 version 7.0.0.alpha_6, build of 05/03/2023 17:48

KNOWN ISSUES

Selection of units in range fields

Help texts still to be updated

Filtering no yet available



REASON FOR HARMONISATION OF DOCUMENTS

- 1) To ensure that data should only be entered once by linking endpoint studies in endpoint summaries so the information does not need to be repeated (essential that key results in endpoint studies are identified and fully completed)
- 2) Standardisation of the fields used to report key values to facilitate report generation, data analysis and reuse (e.g Metapath & QSARToolbox)
- 3) Reduce barriers to reuse of dossier content in different regulatory contexts
- 4) In the case of arthropods, scientific need to describe in more detail complex / higher tier studies especially for pollinators

IMPORTANT: NO DATA IS LOST, PPP summaries will be included in the Obsolete section of the relevant TOC section



ENDPOINT_STUDIES ARTHROPODS

3 New documents created from
ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods

- ENDPOINT_STUDY_RECORD.ToxicityToBees
- ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganisms
- ENDPOINT_STUDY_RECORD. ENDPOINT_STUDY_RECORD.ToxicityToSoilArthropods (DEFAULT TARGET DOCUMENT)

Mapping based on MaterialsAndMethods.TestOrganisms.TestOrganismsSpecies PhraseGroup_E20-2

All fields mapped Including - Endpoint, Guideline, Application method ,Study Type, Extraction Method, Dose descriptor, Effect concentration, Life Stage, Basis of effect

Manual work:

- 1) **Check for completeness – if necessary copy information from obsolete endpoint study document**



ENDPOINT STUDY TOXICOKINETICS

- Study parameters are now a repeatable block

MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

MaterialsAndMethods.TestAnimals.Sex

Doses / concentrations

+ New item

Import file

#	Treatment gro...	Sex	No. of animals...	Duration and fr...	Dose type	Dose / conc.	Remarks
1	#1	male/female	10		single	100 mg/kg bw/day (nominal)	

Manual work Two additional repeatable blocks should be completed

Distribution of metabolites in matrices

+ New item

Appendix: Metabolites and their parents in treatment groups

Metabolites in treatment groups

+ New item

Import file



PPP SUMMARIES SUBJECT TO HARMONISATION

- ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP replaced by ENDPOINT_SUMMARY-Carcinogenicity
- ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP not harmonised in 2023 no change needed
- ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP and ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP replaced by ENDPOINT_SUMMARY-BiodegradationInSoil
- ENDPOINT_SUMMARY.BiodegradationInWaterAndSedimentSimulationTests_EU_PPP and ENDPOINT_SUMMARY.RouteDegWaterSed_EU_PPP replaced by ENDPOINT_SUMMARY-BiodegradationInWaterAndSedimentSimulationTests
- ENDPOINT_SUMMARY.ToxicityBirds_EU_PPP replaced by ENDPOINT_SUMMARY-ToxicityToBirds

- ENDPOINT_SUMMARY.ToxicityToOtherAboveGroundOrganisms_EU_PPP replaced by ENDPOINT_SUMMARY-ToxicityToOtherAboveGroundOrganisms
- ENDPOINT_SUMMARY.EffectsBioMethodSewageTreatment replaced by ENDPOINT_SUMMARY.ToxicityMicroorganisms

- ENDPOINT_SUMMARY.Short-termToxicityToFish_EU_PPP replaced by ENDPOINT_SUMMARY-ShortTermToxicityToFish
- ENDPOINT_SUMMARY.LongTermToxicityToFish_EU_PPP replaced by ENDPOINT_SUMMARY-LongTermToxicityToFish
- ENDPOINT_SUMMARY.BioaccumulationAquaticSediment_EU_PPP replaced by ENDPOINT_SUMMARY-BioaccumulationAquaticSediment
- ENDPOINT_SUMMARY.ShortTermToxicityAqualInvert_EU_PPP replaced by ENDPOINT_SUMMARY-ShortTermToxicityToAquaticInvertebrates
- ENDPOINT_SUMMARY.LongTermToxicityToAquaticInvertebrates_EU_PPP replaced by ENDPOINT_SUMMARY-LongTermToxicityToAquaticInvertebrates
- ENDPOINT_SUMMARY.SedimentToxicity_EU_PPP replaced by ENDPOINT_SUMMARY-SedimentToxicity
- ENDPOINT_SUMMARY.ToxicityToAquaticAlgae_EU_PPP replaced by ENDPOINT_SUMMARY-ToxicityToAquaticAlgae
- ENDPOINT_SUMMARY.ToxicityPlants_EU_PPP replaced by ENDPOINT_SUMMARY-ToxicityPlants
- ENDPOINT_SUMMARY.ToxicitySoilMacroorganisms_EU_PPP replaced by ENDPOINT_SUMMARY-ToxicityToSoilMacroorganismsExceptArthropods
- ENDPOINT_SUMMARY.ToxicityToSoilMicroorganisms_EU_PPP replaced by ENDPOINT_SUMMARY-ToxicityToSoilMicroorganisms
- ENDPOINT_SUMMARY.ToxicityToTerrestrialPlants_EU_PPP replaced by ENDPOINT_SUMMARY-ToxicityToTerrestrialPlants



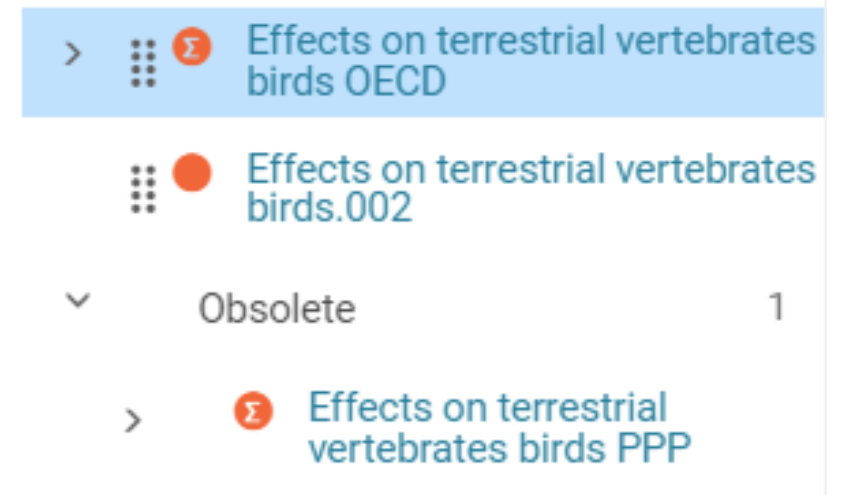
PPP ENDPOINT SUMMARIES

No migration of data in PPP Endpoint summaries in IUCLID Version 6.7

Original documents maintained in 'Obsolete' section information can be copied into new documents as needed

Two options proposed for migration of data after April 2023 but other alternative options can be explored so your input is welcome

- 1) Migration of original summary with repeatable blocks to new summary e.g ecotoxicology endpoint summaries
- 2) Migration of original endpoint summary tabular data to endpoint study record repeatable blocks e.g biodegradation route and rate summaries



OPTION 1 ECOTOX SUMMARIES

Example Toxicity to birds

Data Migrated

- Confidentiality & Description of key information
- Per endpoint block
 - Link to relevant study records (first repeatable row for the parent)
 - DoseDescriptor and EffectConcentration (first repeatable row for the parent)
 - EffectConcentration – lower value and qualifier included in half-bounded value
 - Other fields in the repeatable block deleted

Points still to be analysed

- 1) where more than one study is relied upon for the endpoint then the additional studies must be linked
- 2) metabolite information to be reported in a endpoint summary in the metabolite dataset

Short-term toxicity to birds + New item Import file

#	Stud...	Test ...	Pare...	Subs...	Basi...	Dose...	Effec...	Ac
1	Effects on terrestrial vertebrates birds.002	✓ Coturnix coturnix parent japonica		Active substance	✓ body weight	LC50	100 mg/kg bw	

Birds – short-term

[Link to relevant study record\(s\)](#)
● Effects on terrestrial vertebrates birds.002

[Dose descriptor](#) LC50 [Effect concentration](#) 100 mg/kg bw



OPTION 2 BIODEGRADATION SUMMARIES

Example Biodegradation in water and sediment:simulation studies

Data Migrated

- Link to relevant study records
- Confidentiality & Description of key information
- Attached background material (Attached confidential document & Attached (sanitised) documents for publication) & Remarks

Points still to be analysed

- 1) where more than one study is relied upon for the endpoint then the additional studies must be linked
- 2) metabolite information must be reported in a endpoint summary in the metabolite dataset
- 3) use of csv export and import features to transfer information from route and rate summaries to the relevant tables



RECOMMENDATIONS ON UPDATING DOCUMENTS

- **Dossiers in preparation or not declared admissible:** Strongly recommended to update documents to facilitate the evaluation of the dossier
- **Admissible studies where the dossier is being updated with new studies:** complete new documents according to the latest format and update existing documents which need to be amended (especially endpoint summaries)
- **Older dossiers:** as general principle it is recommended to keep your datasets up to date with the latest IUCLID format so that they can easily be reused in different regulatory actions. **Await further information on the planned migration for PPP Endpoint Summary data**



MAINTAINING OBSOLETE DOCUMENT



Point for discussion

How long should the obsolete documents be retained in the IUCLID PPP format?



IUCLID ROADMAP PPP

2023:

Data integration
Metapath/
QSAR
toolbox

Report
Generator –
report
automation
and use of
annotation

Structured fields to align with reporting requirements & transformation products, genotoxicity studies

2024:

Data integration
Dietary and
Operator
exposure
assessment

Report
Generator
Adoption of
format at
PAFF

Structured fields to align with reporting requirements & GAP, OHT 85-5, OHT 85-9, PRIMO & OPEC

2025

Data
Integration
EU Common
Data
Platform
Chemicals

Report
Generator
Peer review

Structured fields to align with peer review & CDPC format requirements



OECD ROBUST STUDY SUMMARY PROJECT



Study on the role of Robust Study Summaries in hazard assessment

Survey and interviews report

https://echa.europa.eu/documents/10162/17069/study_rss_hazard_assessment_surveys_en.pdf/b2656b6f-7d45-b2e8-f35d-1aa0ef146584?t=1650882479519

**Instructions on
how to complete
study
summaries are
due for
publication this
month!**



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