9th meeting of the PSN IUCLID sub-group
29 February 2024

IUCLID FORMAT: HARMONISATION & CHANGES

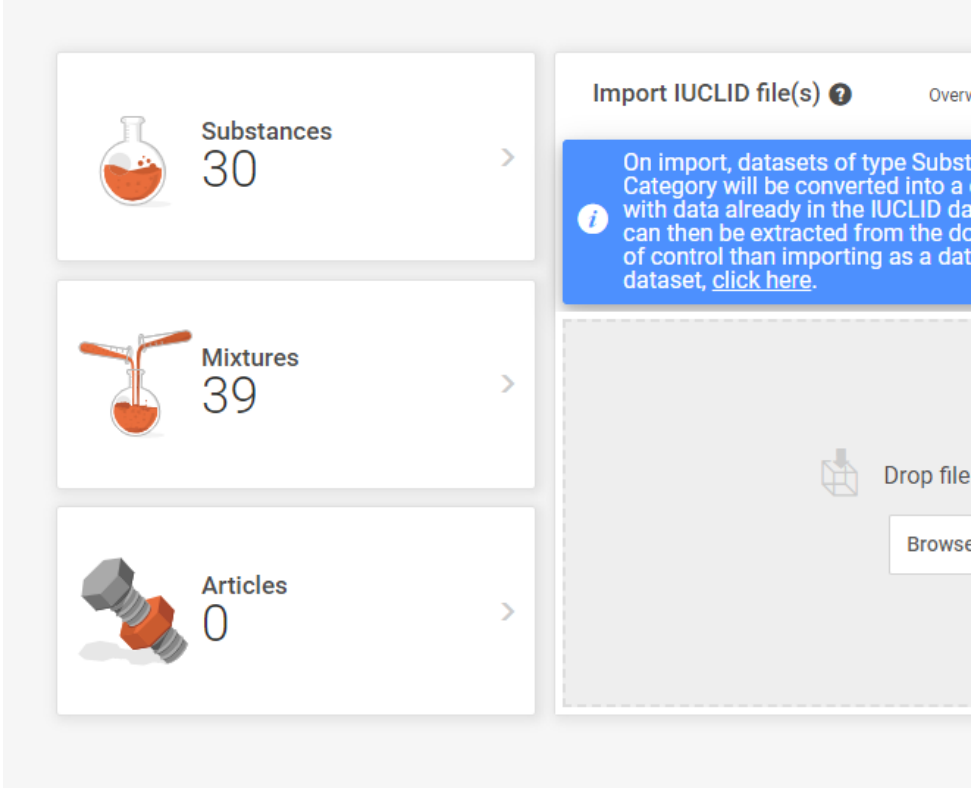
FDP, IDATA

EUROPEAN FOOD SAFETY AUTHORITY

APRIL 2024 IUCLID RELEASE

- IUCLID format release (version 8) will go live on 29 April 2024

  - ca 30 documents revised plus new documents added
  - 14 NEW PPP Validation Assistant rules and update/improvements of 22 rules
  - Overall performance improvement



APRIL 2024 FORMAT CHANGES

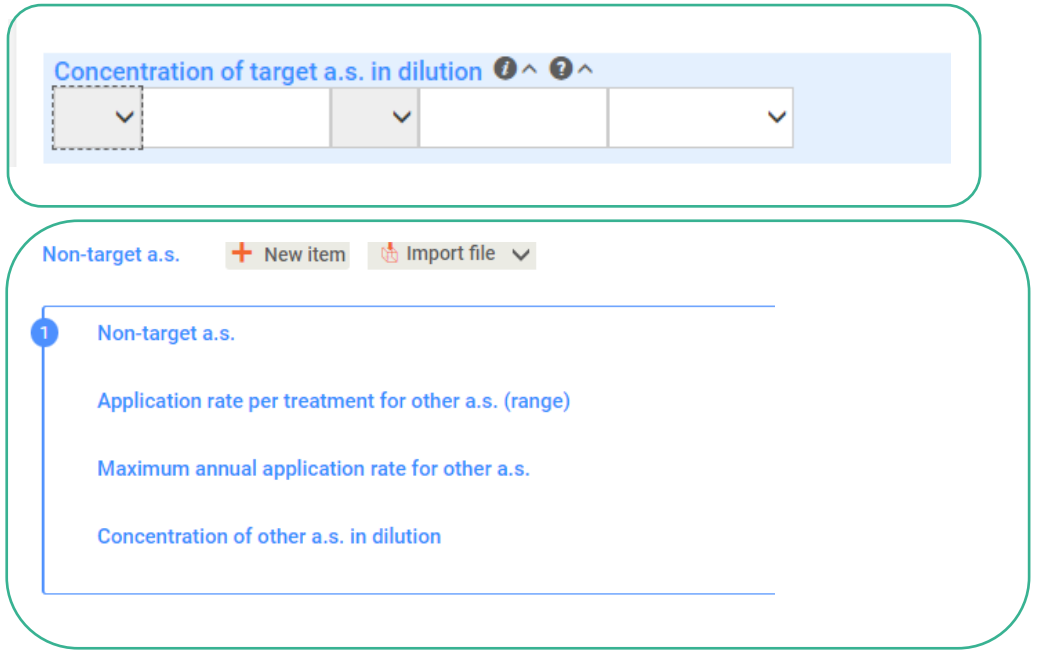
- Harmonisation of results tables across FATE docs
- Introduction of the ‘Contributor’ role in the dossier header (Joint Submission)
- Extension of the structure of relevant OHTs to include more elements concerning the QSAR models
- New ‘sanitised attachment’ fields to comply with the provisions of the Transparency Regulation
- New document on IMPURITIES to comply with Commission Regulation (EU) No 283/2013

Details presented in the PSN-IUCLID meeting held in November 07_IUCLID format_harmonisation and changes.pptx

APRIL 2024 FORMAT CHANGES

- FLEXIBLE_RECORD.GAP

➢ For products applied after dilution with water, NEW fields to report the concentration of the active substance and ‘other active substance’ in the diluted solution.



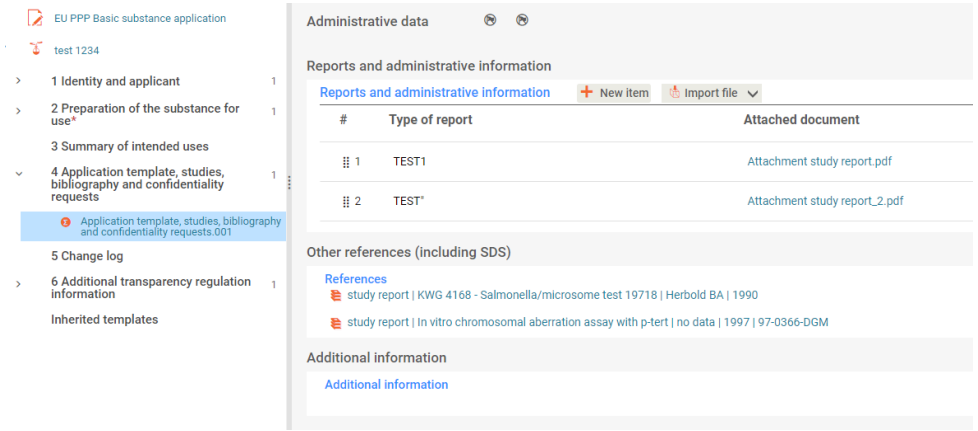
The changes were made in order to fit the GAP table generated via report generator with the GAP table template included in the Combined Template to be used for Assessment Reports according to Regulation (EC) No 1107/2009 and Proposals for Harmonised Classification and Labelling according to Regulation (EC) No 1272/2008 Agreed by Member States' Competent Authorities in the SCoPAFF: Phytopharmaceutical legislation section

APRIL 2024 FORMAT CHANGES

- FLEXIBLE_SUMMARY.SummaryEvaluation
  - ➢New field ‘Complementary information’ under the Administrative block to distinguish the type of bibliography or supporting documentation.

    - Picklist values:

      - Application template
      - Purpose of the application
      - Identity of the substance
      - Uses of the substance
      - Classification and labelling
      - Impact on human and animal health
      - Residues
      - Fate and behaviour in the environment
      - Effects on non-target organisms
      - Overall conclusion



- The change will support EFSA and EC during the evaluation process of Basic substance applications

APRIL 2024 FORMAT CHANGES

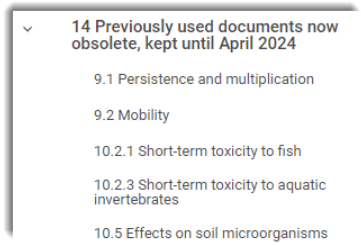
Section of the Active Substance ToC	Documents removed with the 2023 IUCLID format release
8.2.1.2 Acute Effects on fish	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish ENDPOINT_SUMMARY.ShortTermToxicityFish
8.2.2.2 Acute Effects on aquatic invertebrates	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAqualnv ENDPOINT_SUMMARY.ShortTermToxicityToAquaticInvertebrates
8.2.2.3 Aquatic sediment toxicity	ENDPOINT_SUMMARY.SedimentToxicity ENDPOINT_SUMMARY.SedimentToxicity

Section of the ProductToC	Documents removed with the 2023 IUCLID format release
10.2.1.2 Acute Effects on fish	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish ENDPOINT_SUMMARY.ShortTermToxicityFish
10.2.2.2 Acute Effects on aquatic invertebrates	ENDPOINT_STUDY_RECORD.ShortTermToxicityToAqualnv ENDPOINT_SUMMARY.ShortTermToxicityToAquaticInvertebrates
10.2.2.3 Aquatic sediment toxicity	ENDPOINT_SUMMARY.SedimentToxicity ENDPOINT_SUMMARY.SedimentToxicity

Background: With the latest IUCLID format release (May 2023) the following IUCLID documents were removed from the Microorganism Table of Content (ToC) upon request of the former Microbial Working Party

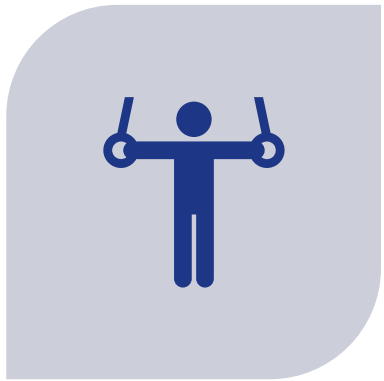
Decision from the current Microbial Working Party: Based on the requirements listed in Regulation 283/2013 and EU Commission communication 2023/C 202/03 it was agreed to reintroduce the documents in the Table of Content

Documents in section 14 will be put back in the ToC



APRIL 2024 FORMAT CHANGES

New fields added in the following documents to support assessment of metabolites in accordance with new data requirements on microorganisms and SANCO/2020/12258 metabolite guidance



FLEXIBLE_SUMMARY.INFORMATIONTOXICITYMETABOLITES

FLEXIBLE_SUMMARY.INFORMATIONECOTOXICITYMETABOLITES

(picklist)Nature of observed toxic effect
(checkbox)Relevant antimicrobial activity

FLEXIBLE_SUMMARY.METABOLITES

(picklist)Toxicological assessment
(checkbox)The metabolite is claimed active metabolite
(checkbox)Metabolite WGS-evidence

NEW VALIDATION ASSISTANT RULES

- BR_PPP_168: the dossier name must be provided
- QLT_PPP_169: Clarify the rationale for choosing the MRL data requirements
- QLT_PPP_170: The concentration unit of the active substance must be expressed in CFU/g
- QLT_PPP_167: Select the type of bibliography or support documentation provided in the literature reference entity
- QLT_PPP_130: Only one Proposed residue definitions summary can be provided
- QLT_PPP_166: GAP table: Report the concentration of the target active substance in the diluted solution or the concentration of water amount per treatment / spray volume
- Rules ensuring Flexible_records and _summaries are provided for Microrganisms

UPDATE VALIDATION ASSISTANT RULES

- QLT_PPP_012: Summaries must be provided for all required sections (Substance_MO)
- BR_PPP_011: KS/WoE must be provided for all required sections (Substance_MO)
- BR_PPP_015: KS/WoE must be provided for all required sections (Mixture_MO)
- BR_PPP_016: Summaries must be provided for all required sections (Mixture_MO)
- BR_PPP_159: Specify if the submission is an update
- QLT_PPP_026B: The GAP must be complete - *checks lower values only in range fields*

Details on rules available in the PPP Validation Assistant Rules_April2024.xlsx

IUCLID DATA RECOVERY TOOL

- IUCLID release May 2023: v7.0.1 and v7.0.2 – Issues with the migration of specific fields ('Description of key information' (KeyInformation) for the following endpoint summaries

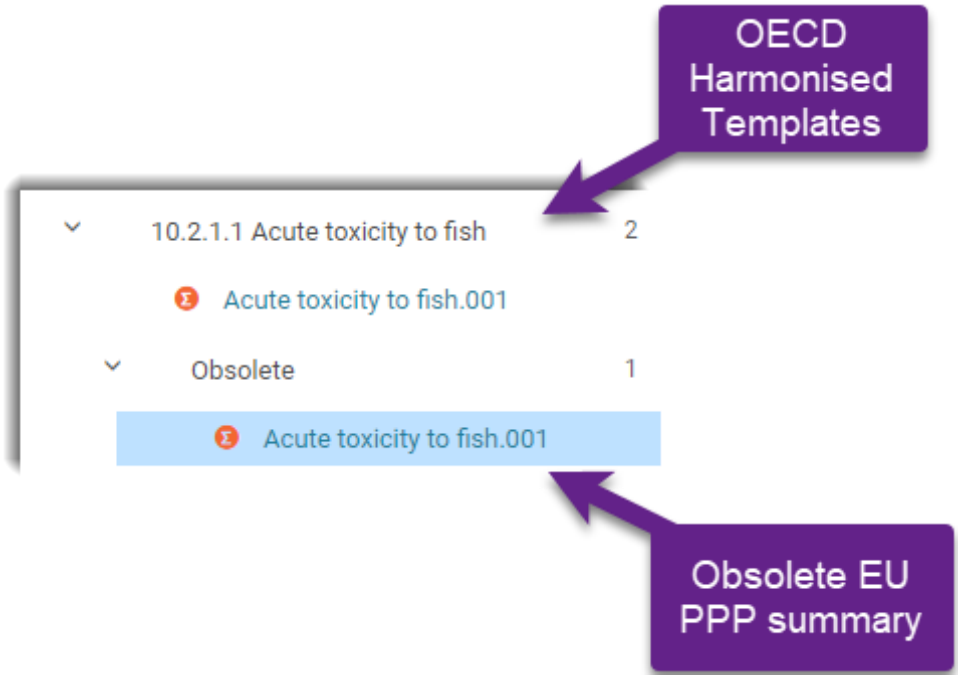
  - Acute Toxicity
  - Repeated dose toxicity
  - Carcinogenicity
  - Neurotoxicity
  - Immunotoxicity

- In January 2024 IUCLID released the data recovery tool to address the issue
- The recovery tool has been run in all IUCLID Cloud instances, inc. EFSA, using pre-migration backups
- We collected the LEs that had IUCLID cloud instances with data actually recovered with the migration and matched with existing PPP submitters

UPDATE ON MIGRATION OF EU_PPP SUMMARIES

- EU PPP specific summaries have been replaced by OECD Harmonised Templates in May 2023
- Most of the EU PPP content has been moved to ‘obsolete’ sections and new OHTs are now available to be filled-in
- Outcome of the analysis: Options for migration will be made available for stakeholder consultation.

NB: ECHA informed that migration implies high risks.



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