8th meeting of the PSN IUCLID sub-group
22 November 2023

FEEDBACK FROM THE MICRO-ORGANISMS WORKING PARTY

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EUROPEAN FOOD SAFETY AUTHORITY

WHY A WORKING PARTY?

Entry into force of the new regulatory framework in August 2022, mandatory from May 2023 for microbial active substances

→ an improved IUCLID working context **EU PPP Microorganisms - active substance application (product)**

- New and revised documents
- Information on secondary metabolites based on the dedicated guidance document
- Presentation of information in the datasets
- Validation assistant rules

- **22 Members**: 1 EC, 15 experts from MSs (from 9 MSs), 4 from Industry + EFSA
- **4 meetings** held so far (kick-off on 4 July 2023)

WP MAIN GOALS – CLOSED: IUCLID MO MINI-MANUAL]

- ✓ **Revision** of the IUCLID **(mini)manual** on microbial a.s. applications:
  - → to support applicants in compiling **Microbial Pesticide Active Substance dossiers** in line with the **new applicable rules** and with the **relevant changes** released with **IUCLID 6.7**
  - → mini-manual **published** on 15/11/2023 and available at: https://doi.org/10.5281/zenodo.10118202

    - ❖ *Revised introduction based on new Regulatory Framework*
    - ❖ *Instructions on special cases (e.g. deactivated micro-organisms)*
    - ❖ *Submission of information on secondary metabolites*
    - ❖ *Instructions focused on new and revised documents*

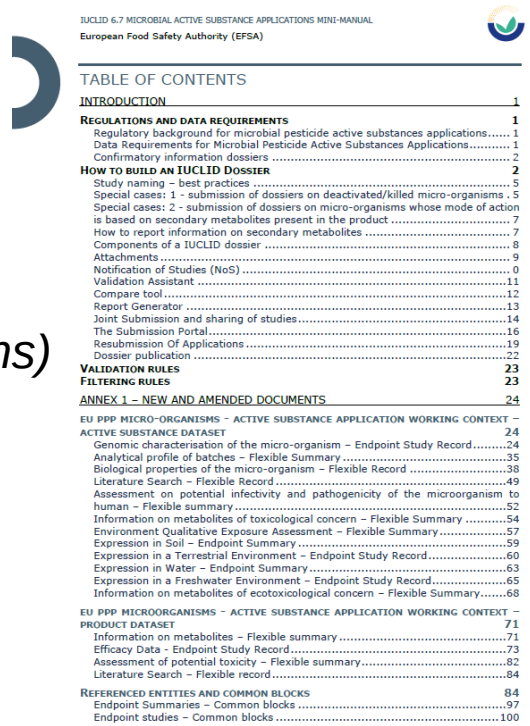

IUCLID 6.7 MICROBIAL ACTIVE SUBSTANCE APPLICATIONS MINI-MANUAL
European Food Safety Authority (EFSA)

TABLE OF CONTENTS

WP MAIN GOALS – CLOSED: LIST OF MANDATORY DOCUMENTS

✓ **Agreed list** of **validation rules for MO working context**:

From **standard** VRs currently applied to **customised VRs → improve quality** of dossiers

There are **different types of validation rules** with different complexity:

- **Type #1: rules just checking that a document is created**
- Type #2: rules checking that specific fields are completed
- Type #3: dynamic rules

  - To facilitate discussion EFSA cross-checked all the IUCLID documents in **the** Crosswalks EU PPP microorganisms and compared them with the **conditionality status** included in the Explanatory notes
  - Based on the indications of the explanatory notes, EFSA prepared:
    - ✓A **list of documents*** for which **rules are proposed (non-conditional documents)**
    - ✓A **list of documents*** for which **rules are not needed (conditional documents)**
    - ✓A **list of documents*** for which **discussion is needed within the WP**

Final lists of mandatory and conditional documents **agreed** with the WP on 14/11

*including Endpoint Study Summaries, Endpoint Study Record and other IUCLID documents (e.g. flexible summaries)

WP MAIN GOALS – ONGOING

- Identification of **data gaps/format changes**
- **Mapping** of IUCLID MOs **working context - Appendix I** Explanatory Notes

  (Identifing existing IUCLID paths and/or data gaps/format changes needed in April 2024)

Explanatory notes for micro-organisms

New potential changes identified **to be discussed** with the **WP**

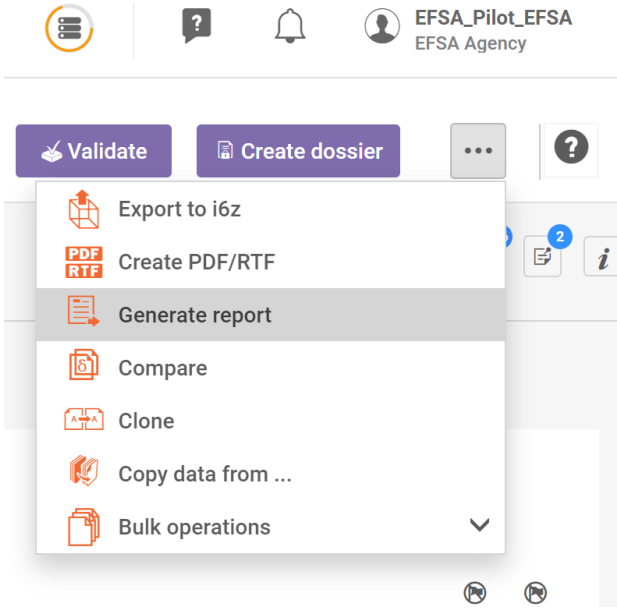
APPENDIX I: OVERVIEW TABLE IN SUPPORT OF THE METABOLITE ASSESSMENT ACCORDING TO SANCO/2020/12258

	Stage 1		Stage 2					Stage 3				Stage 4
Metabolite identifier[1)]	**Active substance (Y/N)**	**Claimed active metabolite (Y/N/?)**	**Verification of MoPC-status**				**Outcome chemical analysis[4)]**	**Relevant exposed group[5)]**	**MoC (Y/N)**	**Ref. values (TOX) and endpoints (ECOTOX)**	**Exposure level**	**Unacceptable risk (Y/N)**
			Toxic / antimicrobial effect observed, test species, and strain[2)]	**Potential relevance for micro-organism [3)]**	**WGS-evidenced (Y/N)**	**MoPC (Y/N/?)**						
Name, CAS, and/or IUPAC	Y/N	Y/N/?	Study 1: Effect / test species / strain Study 2, etc…	Metabolite / Effect	Y/N	Y/N/?	MPCA-AM: Y/N or max. PPP: Y/N or max. Induced: Y/N	TOX; TOX.. / ECOTOX; ECOTOX..	Y/N	TOX; TOX.. / ECOTOX; ECOTOX..	TOX; TOX.. / ECOTOX; ECOTOX..	TOX; TOX.. / ECOTOX; ECOTOX..
The row below presents the SANCO/2020/12258 step-numbers associated with the respective table column												
1, 3, 7, 10	**1**	**1**	**3, 4, 6, 10, 12, 18**	**4, 6, 8, 10, 12**	**9, 10, 12**	**11**	**7, 12**	**13, 14**	**15**	**14, 17, 19**	**14, 16**	**20**

[1)] Typically the name that is unambiguously used throughout the dossier to refer to the metabolite.
[2)] For each relevant study (author and year are entered on the 'Study x'-position) the nature of the observed toxic / antimicrobial effect (? = data unavailable; null = no effect observed; ACU = acute toxicity; CYT = cytotoxicity; MUT = mutagenicity; GEN = genotoxicity; CAR = carcinogenicity; REP = reprotoxicity; NEU = neurotoxicity; AM = antimicrobial activity), the test species (or at least a detailed description of the exposed organism / material), and the name of the strain for which the effect has been observed (could be the micro-organism itself, a closely related strain, or both) is stated.

WP MAIN GOALS – TO BE STARTED

- **Propose** the **presentation** of **information** by **report generator**:
  - adequate use of the report generator to **streamline** the **process** and ensure that **information** is presented in a **clear** and **standardized format** (e. g. headings, sections, and data fields that need to be populated)
  - **evaluate** the **current** report generator reports in IUCLID and identify areas for improvement
  - agree on a starting base for automatic **DAR/RAR generation**
  - possible final **endorsement** of the **reports** at **SCoPAFF** for general use by all parties involved in MO risk assessment



- **Finalise** a.s. and product **ecotox table of contents** (e.g. short-term toxicity aquatic)
- **Provide recommendations** for the **presentation** of **information** in IUCLID for **specific key areas**
  - **microbiological consortia** (after agreement at BPWG)
  - **Deactivated**/killed micro-organisms
  - Other **special cases/new technologies** (e.g. dsRNA-based PPP, peptide-based PPP)

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