

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

FEEDBACK FROM THE MICRO-ORGANISMS WORKING PARTY

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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)

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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
(Identifying 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/?	<u>Study 1:</u> Effect / test species / strain <u>Study 2, etc...</u>	Metabolite / Effect	Y/N	Y/N/?	<u>MPCA-AM:</u> Y/N or max. <u>PPP:</u> Y/N or max. <u>Induced:</u> 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.

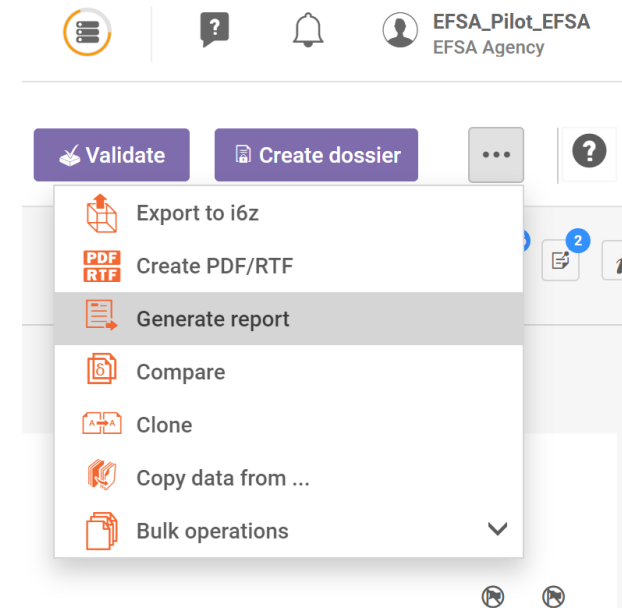
²⁾ For each relevant study (author and year are entered on the 'Study x'-position) the nature of the observed toxic / antimicrobial effect (? = data unavailable; null = no effect observed; ACU = acute toxicity; CYT = cytotoxicity; MUT = mutagenicity; GEN = genotoxicity; CAR = carcinogenicity; REP = reprotoxicity; 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

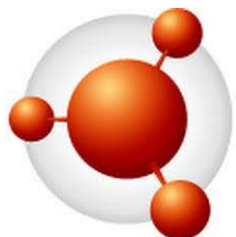
🕒 Propose the **presentation of information by report generator**:

- 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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