

9th meeting of the PSN IUCLID sub-group

29 February 2024

# FEEDBACK FROM THE M.O. WORKING PARTY

Pesticides Peer Review Unit

# HIGHLIGHTS & MILESTONES

August 2022

## 4 implementing Regulations

European Commission adopted [four implementing Regulations](#) amending the **rules** applicable to **micro-organisms** used as **plant protection products**.

1<sup>st</sup> EU Working Party on microbial pesticides

May 2023

## New rules mandatory

Obligation to submit a dossier under the **new regulatory framework** (new DRs) as of **end of May 2023**

May 2023

## IUCLID 6.7 release

A **new format release** was issued on **19 May 2023**, with a revised working context including new and adapted documents accommodating the new rules.

2<sup>nd</sup> EU Working Party on microbial pesticides

April 2024

## IUCLID 6.8 release

The **new format release** is planned to be issued in **April 2024**



	Stage 1		Stage 2					Stage 3			Stage 4	
Metabolite identifier <sup>1)</sup>	Active substance (Y/N)	Claimed active metabolite (Y/N/?)	Verification of MoPC-status				Outcome chemical analysis <sup>4)</sup>	Relevant exposed group <sup>5)</sup>	MoC (Y/N)	Ref. values (TOX) and endpoints (ECOTOX)	Exposure level	Unacceptable risk (Y/N)
			Toxic / antimicrobial effect observed, test species, and strain <sup>2)</sup>	Potential relevance for micro-organism <sup>3)</sup>	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..
<b>The row below presents the SANCO/2020/12258 step-numbers associated with the respective table column</b>												
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

<sup>1)</sup> Typically the name that is unambiguously used throughout the dossier to refer to the metabolite.

<sup>2)</sup> 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 – CLOSED: IUCLID-APPENDIX I MAPPING

## ✓ Mapping of IUCLID MOs working context - Appendix I Explanatory Notes

(Identifying existing IUCLID paths and/or data gaps **New changes** identified and implemented in the 'Flexible\_Summary.Metabolites' document (added in April 2024)

Explanatory notes for micro-

**New changes** identified and implemented in the 'Flexible\_Summary.Metabolites' document

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 <sup>1)</sup>	Active substance (Y/N)	Claimed active metabolite (Y/N/?)	Verification of MoPC-status				Outcome chemical analysis <sup>4)</sup>	Relevant exposed group <sup>5)</sup>	MoC (Y/N)	Ref. values (TOX) and endpoints (ECOTOX)	Exposure level	Unacceptable risk (Y/N)	
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# WP MAIN GOALS – CLOSED: IUCLID-APPENDIX I MAPPING

**TA**  
IUCLID 6

Dashboard > Mixtures / Products > EFSA tender: GREENB (MPCP)

## EFSA tender: GREENB (MPCP)

b93f824e-7398-4c80-b8a0-2ba53949a6b5

### Information on secondary metabolites

UUID: 76c3aaea-a6e7-46b6-b9ca-e4ab68e11b9c

[Metabolites information](#) | [List of metabolites](#)

for genotoxic substances. The risk assessment was not safe. Therefore as refinement, a QSAR study on genotoxicity was conducted, where SecMetB was found not genotoxic which shows acceptable risk. Therefore, SecMetB is considered a metabolite of concern with acceptable risk.

-SecMetC cannot be genomically be produced by the strain. Therefore it is not considered a secondary metabolite of concern.

[Parent of metabolites](#)

### List of metabolites

[Metabolites](#) | [+ New item](#) | [Import file](#)

#	Link to metabolite dataset	Remarks	Toxicological assessment
1	EFSA tender: SecMetA	SecMet A is not present in the MPCP. Not a metabolite of concern.	
2	EFSA Tender: SecMetB (Metabolite of concern)   EFSA Tender: SecMetB   SecMetB	SecMetB is present in the MPCP. Please refer to MA Section 6/ MP Section 7 for the risk assessment.	
3	SecMetC   N/A	SecMetC is known to be produced by this species. However, whole genome analysis shows that the strain MAS123 cannot produce this secondary metabolite.	
4	SecMet D   N/A	Produced at species level, not by this strain	

### Set values

[Link to metabolite dataset](#)  
 EFSA tender: SecMetA

**Remarks**  
SecMet A is not present in the MPCP. Not a metabolite of concern.

**Toxicological assessment**

Please select

- metabolite of potential concern (MoPC)
- metabolite of concern (MoC)
- metabolite of no concern (NoC)

[Close](#)

# WP MAIN GOALS – CLOSED: IUCLID-APPENDIX I MAPPING

✓ Possible new fields or amendments still needed pending testing of the report

Explanatory notes for micro-organisms

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

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# WP MAIN GOALS – CLOSED: FINALISATION OF ECOTOX TOC

## ✓ Finalise a.s. and product ecotox table of contents

- In IUCLID 6.7 release some documents were removed from the ToC upon request of some members of the former working party on microorganisms
- A consultation was launched with the current WP
- WP agreed to re-introduce the documents in next IUCLID 6.8 release on the base of the new data requirements

Section of the Active Substance ToC	Documents reintroduced in 2024 IUCLID format release	Section of the Product ToC	Documents reintroduced in 2024 IUCLID format release
8.2.1.2 Acute Effects on fish	ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish ENDPOINT_SUMMARY.ShortTermToxicityFish	10.2.1.2 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	10.2.2.2 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	10.2.2.3 Aquatic sediment toxicity	ENDPOINT_SUMMARY.SedimentToxicity ENDPOINT_SUMMARY.SedimentToxicity



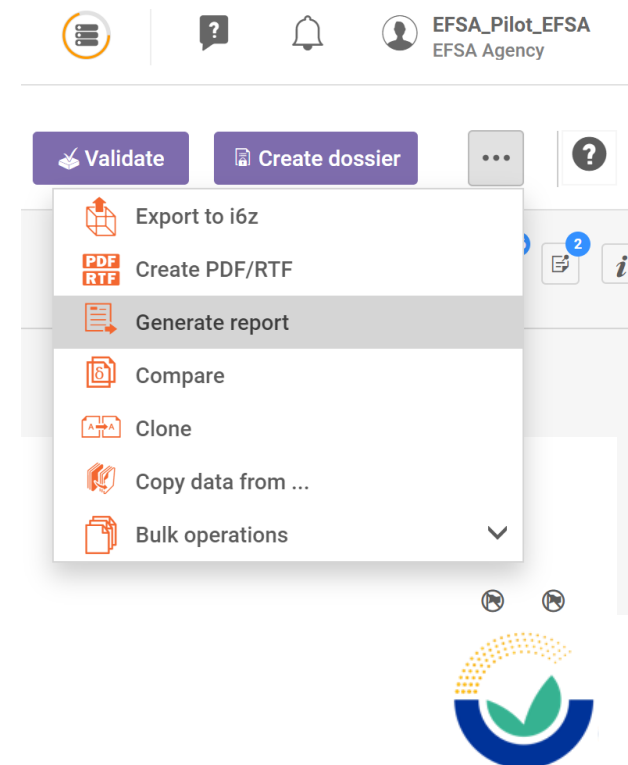
# WP MAIN GOALS – NEXT STEPS



- Final meeting to temporarily close the WP for the moment to be held soon
- Re-open again the WP to proceed with next goals

## 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





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