15th meeting of the PSN IUCLID sub-group
15 April 2026



IUCLID REPORT GENERATOR

IDATA, PREV

EUROPEAN FOOD SAFETY AUTHORITY

OUTLINE

1. **Updates to existing reports**
   - 2 – List of References (Chem/Micro)
   - List of substances and metabolites
   - Reports for microorganisms
   - MRL report
2. **New reports:** Residue Trials in Primary Crops
3. **Ongoing and future work**

UPDATES TO EXISTING REPORTS

#OpenEFSA

OVERVIEW OF CHANGES

Two types of changes were implemented in reports:

- Adaptations to format changes
- Additional changes/enhancements (sometimes also linked to the above)

Report / section	Change
2 – List of references	Alignment to official EC templates and clarification on references included (see next slides)
List of substances and metabolites	Moved to HTML/DOCX + inclusion of "compound found in" information (see next slides)
"3 -" reports for microorganisms	Alignment to official EC templates (see next slides) + addition of new documents in 7.4 product and 6 a.s.
MRL report	Inclusion of changes from the testing phase (see next slides)
List of confidentiality claims	Alignment PDF/RFT and CSV versions and addition of new fields in CSV version (Id, Change Log)
Table of analytical methods	Extraction of endpoint study records from ENDPOINT_SUMMARY.AnalyticalMethods, if linked
"3 -" reports: Literature data	Reporting only literature search data relevant to the specific section (based on the new field "Section(s) covered" in FLEXIBLE_RECORD.LiteratureSearch, or linkage in other specific documents) and clarification of text messages
3 – Active substance B-1 (Identity)	Purity and contents of (relevant) impurities and additives extracted from substance compositions of type "reference specification" (if exists, otherwise "legal entity composition…"), and not "technical specification"
"3 -" reports for Ecotox (a.s. & product)	Improvement of layout for dose-responses, effect levels and general results, based on ICPS feedback
GAP Table	Addition of development stage of pest to Pests Controlled column
Sub-entity reports configuration	Limitation of number of reports to be run from "sub-entities", to avoid confusion

2 – LIST OF REFERENCES (CHEM/MICRO) - RECAP

Recap on existing lists of references:

- **PPP Approval or Renewal** applications:
  - standalone report "**2 – List of references**": all sections considered, filtered for confidential references, divided by section and sorted by author name
  - list of references in each **Vol.3 report,** chapter **REFERENCES RELIED ON:** only the relevant section considered, filtered for confidential references, and sorted by IUCLID section (endpoint)

  Both based on the Combined Template for Assessment Reports acc. to Reg (EC) No 1107/2009 and Proposals for Harmonised Classification and Labelling acc. to Reg (EC) No 1272/2008 (SANCO/12592/2012)

- **PPP MRL** applications: list of references in the **MRL Report**, chapter **REFERENCES: ADDITIONAL STUDIES RELIED ON:** all sections considered, not filtered, sorted by author name.
  - No need to generate a standalone report

- **Cross-regulatory**: standalone report "**List of literature references**": standard report, shared with ECHA and available for various working contexts, all references considered, without filtering or particular sorting
  - Not of particular use for PPP (it could potentially be removed from the available list of reports)

2 – LIST OF REFERENCES (CHEM/MICRO)

- Format aligned to the **official EC templates** for the Volume 2, separated by section and sorted by author name, but <u>also including</u>:
  - **Literature data** (literature search) section with included and excluded references
  - **Other references** section, to cover references not linked to any of the above sections (if any)

CHEM

A. LIST OF THE TESTS, STUDIES AND INFORMATION SUBMITTED
- A.1. Identity
- A.2. Physical and Chemical Properties
- A.3. Data on Application
- A.4. Further Information
- A.5. Methods of Analysis
- A.6. Toxicology and Metabolism Data
- A.7. Residues Data
- A.8. Environmental Fate and Behaviour
- A.9. Ecotoxicology Data
- A.10. Literature Data
  - A.10.1. Included
  - A.10.2. Excluded
- A.11. Other References

No separation of references for active substance (+met. & rel. imp.) & references for product(s)

MICRO

A. REFERENCE LISTS
- MA. Reference lists of the active substance-level sections
  - MA.1. Identity of the applicant, identity of the active substance and manufacturing information
  - MA.2. Biological properties of the micro-organism
  - MA.3. Further information
  - MA.4. Analytical methods
  - MA.5. Effects on human health
  - MA.6. Residues in or on treated products, food and feed
  - MA.7. Environmental occurrence of the micro-organism, including fate and behaviour of metabolites of concern
  - MA.8. Ecotoxicology studies
  - MA.9. Literature Data
    - MA.9.1. Included
    - MA.9.2. Excluded
  - MA.10. Other References
- MP. Reference lists of the product-level sections
  - MP.1. Identity of the applicant, identity of the plant protection product and manufacturing information
  - MP.2. Physical, chemical and technical properties of the plant protection product
  - MP.3. Data on application
  - MP.4. Further information on the plant protection product
  - MP.5. Analytical methods
  - MP.6. Efficacy data
  - MP.7. Effect on human health
  - MP.8. Residues in or on treated products, food and feed
  - MP.9. Fate and behaviour in the environment
  - MP.10. Effects on non target organisms
  - MP.11. Literature Data
    - MP.11.1. Included
    - MP.11.2. Excluded
  - MP.12. Other References

Separation of references for active substance (+met. & rel. imp.) & references for product(s)

NEW

2 – LIST OF REFERENCES (CHEM/MICRO) (II)

- Lists all LITERATURE entities linked in studies / documents in the whole dossier, i.e., incl. in datasets for active substance, metabolites, relevant impurities and representative products
  - But <u>filtering out references that correspond to confidential information:</u>
    - Identity section: **method of manufacture** and **analytical profile of batches** subsections
    - Analytical methods section: study records with endpoints:
      - *"methods for significant impurities"*
      - *"screening for impurities"*
      - *"analytical profile of batches"*

NEW

    - Non-relevant impurities datasets (e.g., significant impurities)
    - Co-formulants, safeners and synergists datasets (if any)

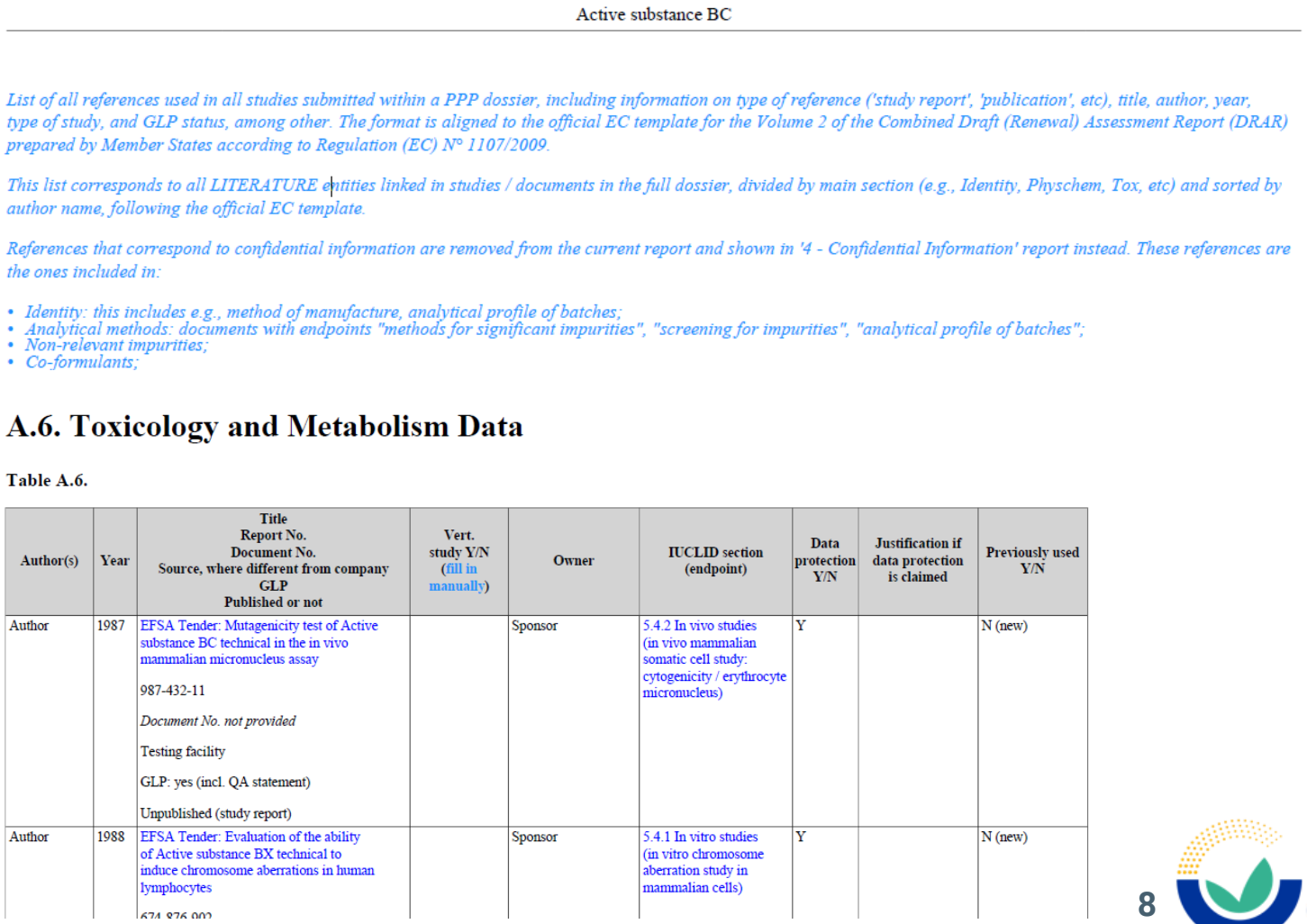
NOTE:

- For **chemicals**, these references are shown in the "4 – Confidential Information" report
- For **microorganisms**, the EC official template does contain a section "**Reference lists of the sections containing confidential information"**, not currently shown in the report:

  Should these section be included in the report for microorganisms?
  Or should the report contain only non-confidential references (like for chemicals)?

2 – LIST OF REFERENCES (CHEM/MICRO) (III)

- An initial introductory page provides a basic description of the report
  - including the filtering of references
- Columns are aligned with the official template
  - Vert. study Y/N needs to be filled in manually: a proposal for format change for 2026 was not accepted, but will be rediscussed



Active substance BC

List of all references used in all studies submitted within a PPP dossier, including information on type of reference ('study report', 'publication', etc), title, author, year, type of study, and GLP status, among other. The format is aligned to the official EC template for the Volume 2 of the Combined Draft (Renewal) Assessment Report (DRAR) prepared by Member States according to Regulation (EC) N° 1107/2009.

This list corresponds to all LITERATURE entities linked in studies / documents in the full dossier, divided by main section (e.g., Identity, Physchem, Tox, etc) and sorted by author name, following the official EC template.

References that correspond to confidential information are removed from the current report and shown in '4 - Confidential Information' report instead. These references are the ones included in:

- *Identity: this includes e.g., method of manufacture, analytical profile of batches;*
- *Analytical methods: documents with endpoints "methods for significant impurities", "screening for impurities", "analytical profile of batches";*
- *Non-relevant impurities;*
- *Co-formulants;*

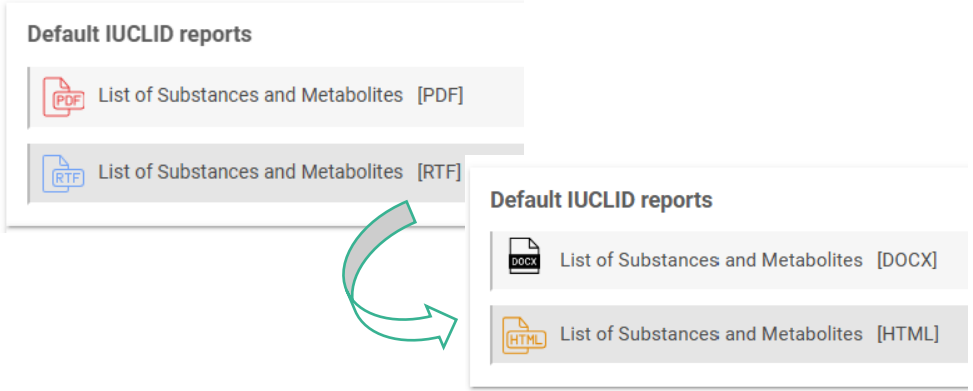
A.6. Toxicology and Metabolism Data

Table A.6.

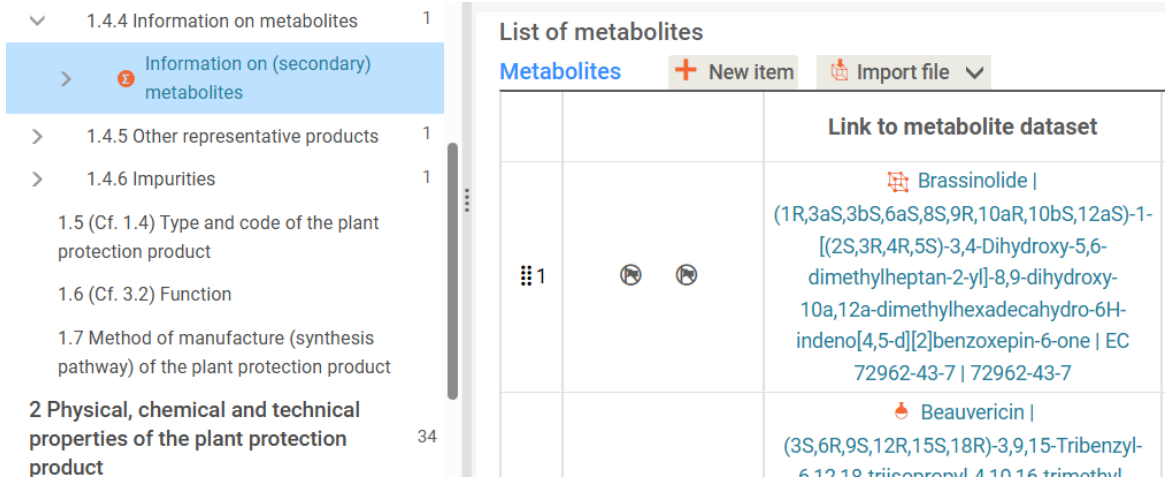
Author(s)	Year	Title Report No. Document No. Source, where different from company GLP Published or not	Vert. study Y/N (fill in manually)	Owner	IUCLID section (endpoint)	Data protection Y/N	Justification if data protection is claimed	Previously used Y/N
Author	1987	EFSA Tender: Mutagenicity test of Active substance BC technical in the in vivo mammalian micronucleus assay 987-432-11 *Document No. not provided* Testing facility GLP: yes (incl. QA statement) Unpublished (study report)		Sponsor	5.4.2 In vivo studies (in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus)	Y		N (new)
Author	1988	EFSA Tender: Evaluation of the ability of Active substance BX technical to induce chromosome aberrations in human lymphocytes 674-876-002		Sponsor	5.4.1 In vitro studies (in vitro chromosome aberration study in mammalian cells)	Y		N (new)

LIST OF SUBSTANCES AND METABOLITES

- Two main changes applied:
  - Change to HTML / DOCX (Word) format
  - Inclusion of new field “compound found in” of *FLEXIBLE_SUMMARY.Metabolites* (in addition to remarks)



- The report currently **lists only metabolites** included in the *FLEXIBLE_SUMMARY.Metabolites* (section 1.4.4 product CHEM, 1.4.1 product MICRO, 1.2.1 product MRL)



Should this report include additional substances, and if so, which ones? E.g.:

- active substance
- relevant impurities
- degradation products
  (although understood as metabolites, they should be included in the metabolites summary)

REPORTS FOR MICROORGANISMS: OVERVIEW

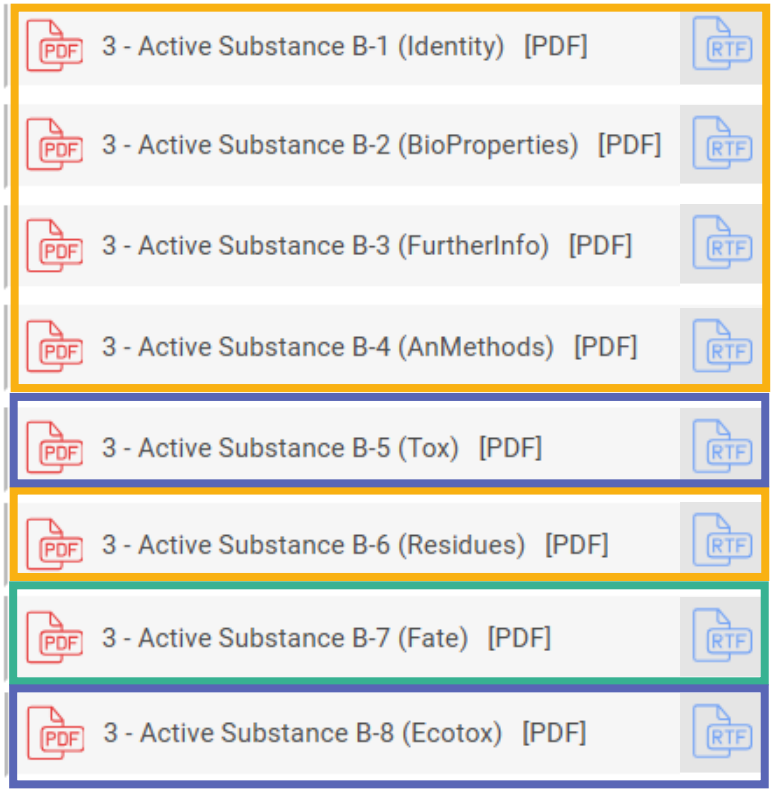
- Based on the feedback from ICPS (Italy) and the new EC templates (see 12th PSN & 14th PSN), Vol.3 reports for **microbial active substance** are being revised and improved
  - To note: several format changes initially planned for 2026 have been postponed since they require further discussion – they might be proposed for 2027

- In parallel, sections for the **microbial product** are being aligned to the official templates
  - To note: without an in-depth analysis (unlike for the a.s.) - further changes might be required in the future

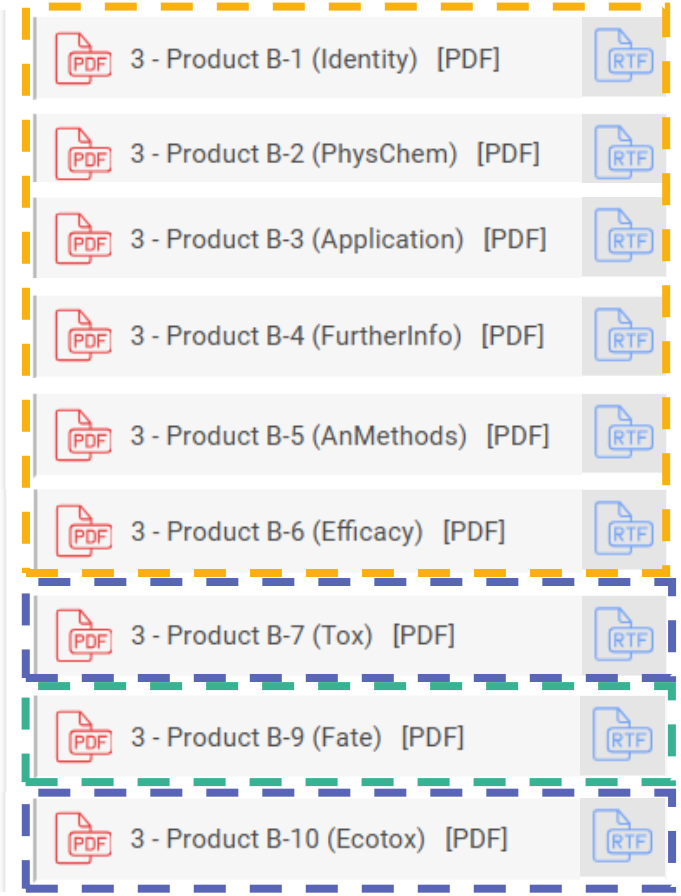
- Summary on the revision of microorganisms reports:
  - **October 2025:** Tox & Ecotox (both a.s. and product)
  - **April 2026:**
    - A.S.: Identity, Biological properties, Further information, Analytical methods & Residues (see next slides)
    - Prod: Identity, Physchem, Application, Analytical methods & Efficacy
  - **October 2026:** Fate (+ other minor changes)

REPORTS FOR MICROORGANISMS: OVERVIEW (II)

- Active substance .Vol3 reports:



- Product.Vol3 reports:



Revised in October 2025

Aligned with templates in October 2025

Revised in April 2026

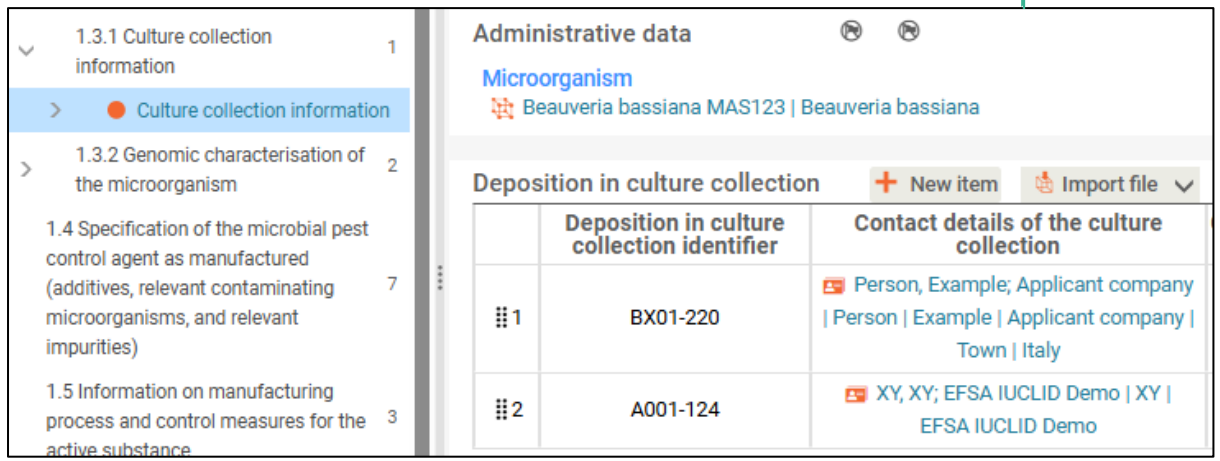
Aligned with templates in April 2026

To be revised in October 2026

To be aligned with templates in October 2026

REPORTS FOR MICROORGANISMS: IDENTITY (I)

- **B.1.3** Identity, Phylogeny and Taxonomy
  - **(i) Deposition in culture collection:**
    new *FLEXIBLE_RECORD.CultureCollection*

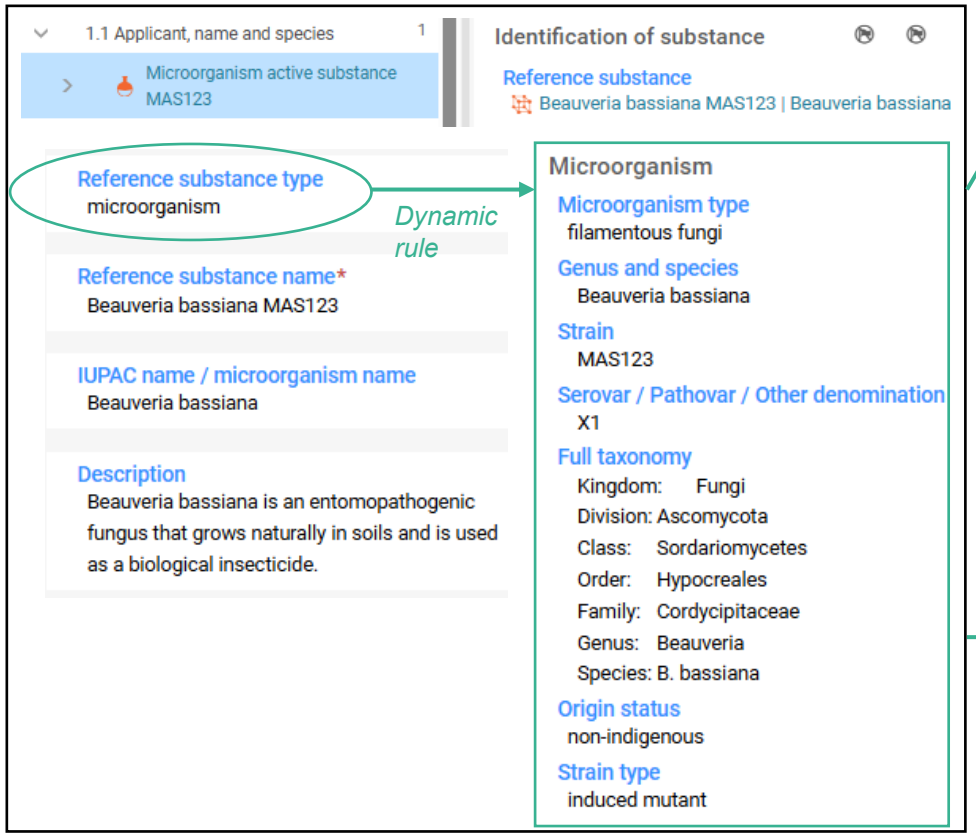


B.1.3. IDENTITY, TAXONOMY AND PHYLOGENY OF THE MICROORGANISM

(i) Deposition in culture collection	
#1	
Identifier	BX01-220
Contact information	Organisation: Applicant company Department: Regulatory affairs Address: Town, Region, Italy [IT] Phone: +01265745 E-mail: contactpersonemail@email.com
#2	
Identifier	A001-124
Contact information	Organisation: EFSA IUCLID Demo Department: Regulatory Department Phone: +351214587963 E-mail: geral.regulatory@dummy.com
(ii) Species to which the micro-organism belongs to	

REPORTS FOR MICROORGANISMS: IDENTITY (II)

- **B.1.3** Identity, Phylogeny and Taxonomy
  - **(ii) Species to which the micro-organism belongs** to **& (v) Wild type, mutant or genetically modified micro-organism: amended** *REFERENCE_SUBSTANCE*

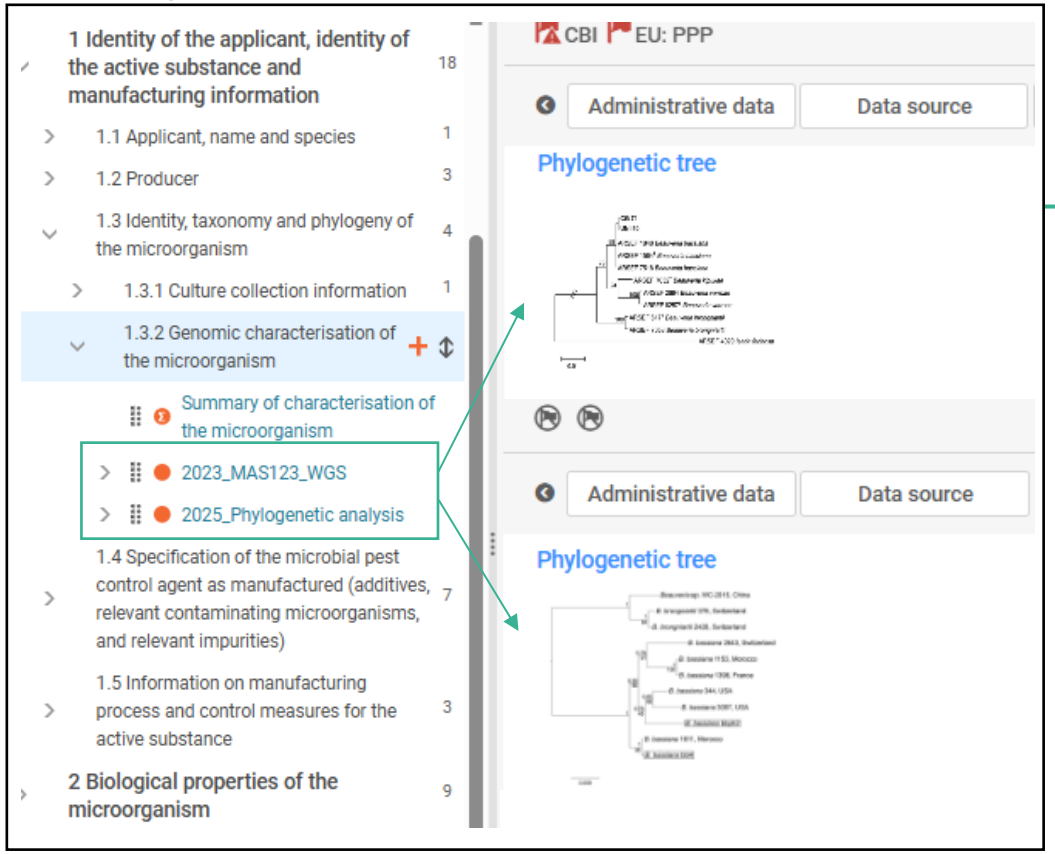


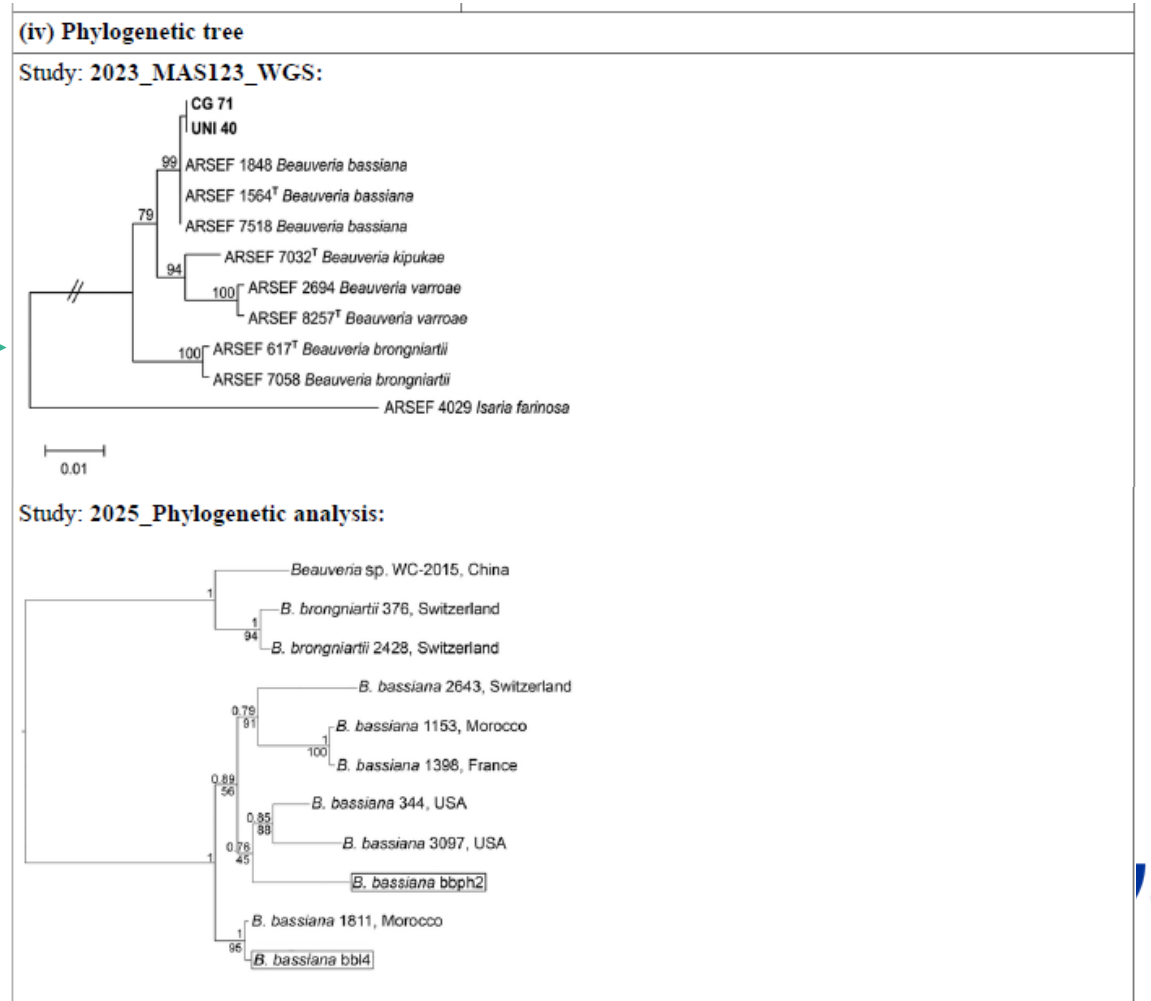
B.1.3. IDENTITY, TAXONOMY AND PHYLOGENY OF THE MICROORGANISM

(ii) Species to which the micro-organism belongs to	
Common name	Beauveria bassiana MAS123
Scientific name	Beauveria bassiana
Description	Beauveria bassiana is an entomopathogenic fungus that grows naturally in soils and is used as a biological insecticide.
Microorganism type	filamentous fungi
Genus and species	Beauveria bassiana
Strain	MAS123
Serovar/Pathovar/Other denomination	X1
Full taxonomy	Kingdom: Fungi Division: Ascomycota Class: Sordariomycetes Order: Hypocreales Family: Cordycipitaceae Genus: Beauveria Species: B. bassiana
Test procedures and criteria used for identification	*Please, refer to the References at the end of this subsection.*
(iii) Synonymous, alternative and superseded names	• basionym: Botrytis bassiana
(v) Wild type, mutant or genetically modified micro-organism	
Strain type (i.e., wild type, spontaneos or induced mutant, genetically modified)	induced mutant
Origin status (i.e., indigenous vs non-indigenous)	non-indigenous

REPORTS FOR MICROORGANISMS: IDENTITY (III)

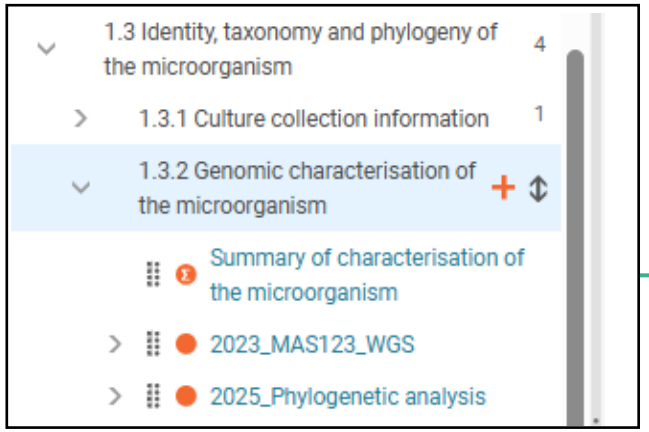
- **B.1.3** Identity, Phylogeny and Taxonomy
  - **(iv) Phylogenetic tree:** all instances of *ENDPOINT_STUDY_RECORD.GenomicCharacterisation Microorganism*





REPORTS FOR MICROORGANISMS: IDENTITY (IV)

- **B.1.3** Identity, Phylogeny and Taxonomy
  - **References**: all instances of
    - *ENDPOINT_SUMMARY.CharacterisationMicroorganisms*
    - *ENDPOINT_STUDY_RECORD.GenomicCharacterisationMicroorganism*:



considering for this case (ESR):

- If flagged as confidential: only administrative information, executive summary and conclusion
- If not flagged as confidential: full contents

B.1.3. IDENTITY, TAXONOMY AND PHYLOGENY OF THE MICROORGANISM

REFERENCES

Summary

Title: Summary of characterisation of the microorganism

Key information:

Two studies are provided demonstrating the identity and the taxonomy of Beauveria bassiana MAS123, one based on Whole Genome Sequencing and one purely in-silico phylogenetic analysis.

Link to relevant study records:

2025_Phylogenetic analysis

2023_MAS123_WGS

Assessment and conclusion by RMS:

Studies

2 individual studies for identity, taxonomy and phylogeny of the microorganism are summarised below:

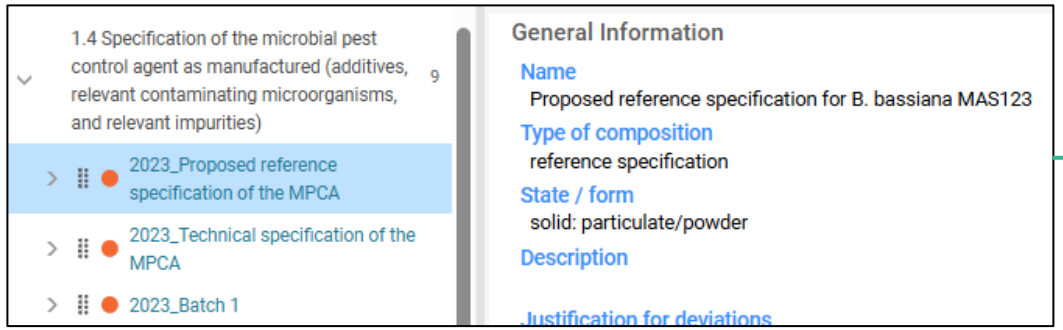
B.1.3./1. 2023_MAS123_WGS

1. Information on the study

Data point	MA 1.3./1.
Study type	genomic characterisation of the microorganism - Genome sequencing
Testing period	Apr 10, 2021 - May 20, 2021

REPORTS FOR MICROORGANISMS: IDENTITY (V)

- **B.1.4** Specification of the microbial pest control agent as manufactured
  - Data from *FLEXIBLE_RECORD.SubstanceComposition* if type of composition = “reference specification” (if not existing, then “legal entity composition…”)



B.1.4. SPECIFICATION OF THE MICROBIAL PEST CONTROL AGENT AS MANUFACTURED

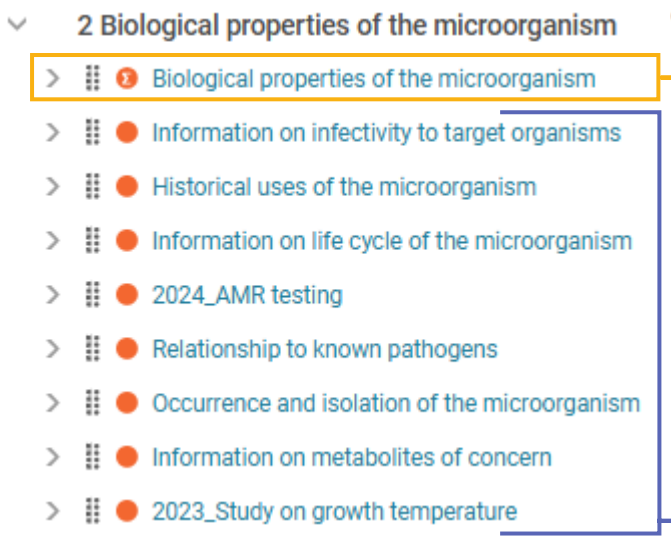
B.1.4.1. Content of the active substance	5.5E8 CFU/g
B.1.4.2 Identity and quantification of additives, relevant contaminating micro-organisms and relevant impurities	
B.1.4.2.1 Identity and quantification of additives	Additive 1 (absorbent) 0.1 % (v/v) *For confidential additives, if any, please refer to Vol. 4.*
B.1.4.2.2 Identity and content of relevant contaminating micro-organisms	*Please, refer to section B.1.4.2.3 below.*
B.1.4.2.3 Identity and quantification of relevant impurities	Impurity C 0.2 % (w/w)
B.1.4.3 Analytical profile of batches	*The analytical profile of batches data package is considered to be CONFIDENTIAL information by default as per Reg. (EC) No 1107/2009, Art. 63(2c). Please refer to Vol. 4, C.1.2.3.*

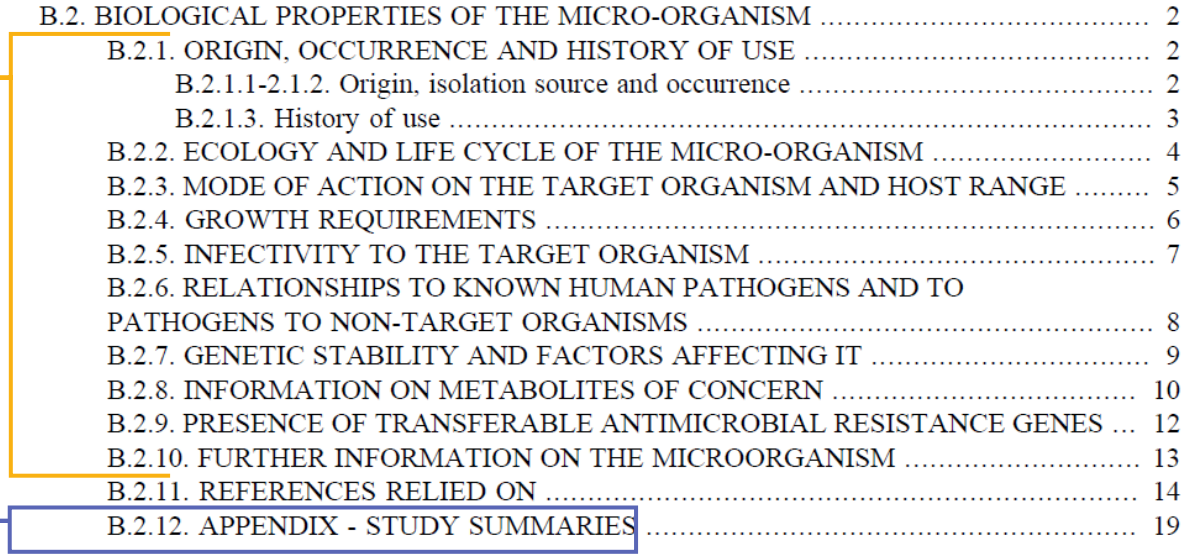
AND:

- **Additives**: if not flagged confidential
- **Impurities**: if flagged as “relevant” in *FLEXIBLE_SUMMARY.Impurities*
- **Contaminating microorganisms**: currently no specific section in IUCLID – extracted only if reported as relevant impurities → *To be discussed?*

REPORTS FOR MICROORGANISMS: BIOLOGICAL PROPERTIES (I)

- From:
  - **amended** *FLEXIBLE_SUMMARY.BioPropertiesMicro* (before IUCLID6 v10: *FLEXIBLE_RECORD)*
    - All sections printed into the **different subchapters of Vol3**
  - **new** *ENDPOINT_STUDY_RECORD.BioPropertiesMicro*
    - All instances printed in **2.12 Appendix – Study summaries,** and cross-referenced in the corresponding sections
      - Alternative: print study summaries in the first section where referenced, and cross-reference in others (if repeated)





REPORTS FOR MICROORGANISMS: BIOLOGICAL PROPERTIES (II)

- Special cases:
  - **2.3 Mode of action on the target organism and host range:**
    - Message printed referring to the **"B-3 (Further information)" report** (section 3.1 in IUCLID)

B.2.3. MODE OF ACTION ON THE TARGET ORGANISM AND HOST RANGE

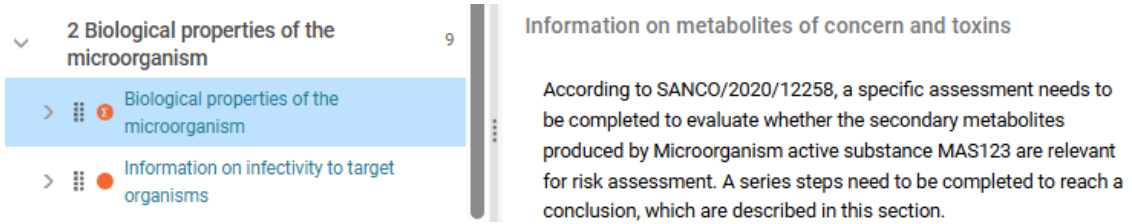
Please, refer to information provided in '3 - Active Substance B-3 (Further Information)'.

  - **2.8 Information on metabolites of concern:**
    - Message printed referring to the **"Metabolites Overview Table"** report (according to annex I SANCO/2020/12258)
    - In addition, *"Information on the production of relevant metabolites and toxins"* section of *FLEXIBLE_SUMMARY.BioPropertiesMicro* is printed

B.2.8. INFORMATION ON METABOLITES OF CONCERN

For the overview table according to annex I of SANCO/2020/12258, please use the standalone report 'Metabolites Overview Table'.

According to SANCO/2020/12258, a specific assessment needs to be completed to evaluate whether the secondary metabolites produced by Microorganism active substance MAS123 are relevant for risk assessment. A series steps need to be completed to reach a conclusion, which are described in this section.
Stage 1:
-The mode of action of MAS123 is based on invasion and competition with plant pathogens, especially arthropods. The presence of the microorganism is necessary for the effectiveness of the plant protection product, therefore the microorganism data requirements (Reg. (EU) 283/2023 Part B) apply.
-The microorganism under assessment is not a virus.
Stage 2:



MRL REPORT – CLOSURE OF TESTING PHASE AND IMPLEMENTED IMPROVEMENTS 1/2

1. Feedback received during testing was consolidated and prioritized (see slides of November PSN)
2. Improvements addressed in three areas:

- Formatting and readability
- Report length and structure
- Section-specific content and instructions



EFSA will continue to update the MRL report in line with any relevant annual format changes and remains available to further improve the report upon request. However, the report is expected to remain **largely stable**, as the major amendments have already been addressed.

MRL REPORT: CLOSURE OF TESTING PHASE AND IMPLEMENTED IMPROVEMENTS 2/2

FORMATTING AND READABILITY

- Font size inconsistencies fixed
- Table titles added (where missing)
- Trials table displayed in landscape mode
- Aggregation of footnotes for long lists
- Improved contrast for free text fields



REPORT LENGTH AND STRUCTURE

- Cover page introduced
- Revised Table of Contents (report shortened)*
- Empty sections suppressed (where applicable)*
- Streamlined displaying of data waiving (moved from Appendix C to the Assessment section) *

COMMENTS ON SPECIFIC SECTIONS

- Analytical method section redundant commenting box deleted*
- Product name added in the GAP table*
- Tox Reference values displaying revised*

UPDATED "INSTRUCTIONS" CHAPTER

Instructions for MSs were updated based on input from the testing phase and new sections on "*MRL Report workflow - When to generate and comment the MRL Report*" and on residue trials were added.

*Changes agreed by respondents to the survey

REVISED TABLE OF CONTENT

Old ToC

I. Background #
II. The active substance and its use pattern #
1. Identity of the active substance #
1.1. Names, identifiers and molecular information of the active substance #
1.2. Method of manufacture (synthesis pathway) of the active substance #
1.3. Specification of purity of the active substance, additives and impurities #
2. Assessments on the active substance #
3. Use of the active substance (GAP) #
4. Effects on harmful organisms, function, mode of action and possible resistance #
III. Assessment #
1. Physical and chemical properties #
2. Methods of analysis #
3. Mammalian toxicology #
3.1. Absorption, distribution, metabolism and excretion (Toxicokinetics) #
3.2. Acute toxicity #
3.3. Short-term toxicity #
3.4. Genotoxicity testing #
3.5. Long-term toxicity and carcinogenicity #
3.6. Reproductive toxicity #
3.7. Neurotoxicity studies #
3.8. Further toxicological studies #
3.9. Medical data #
3.10. Toxicological reference values #
4. Residues #
4.1. Storage stability of residues #
4.2. Residues in plants #
4.2.1. Nature of residues #
4.2.2. Magnitude of residues #
4.2.2.1. Primary crops #
4.2.2.2. Rotational crops #
4.3. Residues in livestock #
4.3.1. Nature of residues #
4.3.2. Magnitude of residues (feeding studies) #
4.4. Residues in processed commodities #
4.5. Other studies #
4.5.1. Residue level in pollen and bee products #
4.6. Consumer risk assessment #
4.6.1. Estimation of the potential and actual exposure through diet and other sources #
5. Fate and behaviour in the environment #
5.1. Fate and behaviour in soil #

Total page nr: **56**

NEW ToC

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2. Mammalian toxicology #
2.1. Toxicological reference values #
3. Residues #
3.1. Storage stability of residues #
3.2. Residues in plants #
3.2.1. Nature of residues #
3.2.2. Magnitude of residues #
3.2.2.1. Primary crops #
3.2.2.2. Rotational crops #
3.3. Residues in livestock #
3.3.1. Nature of residues #
3.3.2. Magnitude of residues (feeding studies) #
3.4. Residues in processed commodities #
3.5. Other studies #
3.5.1. Residue level in pollen and bee products #
3.6. Consumer risk assessment #
3.6.1. Estimation of the potential and actual exposure through diet and other sources #
4. Literature data #
IV. Conclusions and recommendations #
1. Proposed residue definitions #
2. Proposed maximum residue levels (MRLs) #
Appendix A. Good Agricultural Practices (GAP) supported in the MRL application #
Appendix B. Pesticide Residues Intake Model (PRIMo) #
Appendix C. Detailed evaluation of the additional studies relied on #

Total page nr: **49**

NEW COVER PAGE

MRL REPORT

This report is generated from the applicant's IUCLID dossier (UUID: 67aee243-8da3-4098-931d-4ce21909039f) and is intended to be commented by the Evaluating Member State to draw up an evaluation report in accordance with Article 8 of Regulation EC 396/2005. To ensure transparency, there should be clear distinction between the information stemming from the applicant's IUCLID dossier and the assessment and conclusions from the Evaluating Member State.

Purpose and Scope

For post-transparency MRL applications, this Report intends to replace the Evaluation Report template available on the European Commission webpage: https://food.ec.europa.eu/plants/pesticides/maximum-residue-levels/guidelines-maximum-residue-levels_en

Instructions for Evaluating Competent Authorities

Evaluating Competent Authorities are advised to generate this report from the latest version of the applicant's IUCLID dossier and should include their assessment and conclusions in the specific boxes available in the Report.

This template should allow for a certain flexibility. Within the specific boxes for the Evaluating Member State's assessment and conclusions, free text may be added, where necessary, and the content of the section may be adapted to the specific needs required for the different MRL applications. Also, tables can be added, when needed. Ideally, the text, data and tables generated from the dossier as compiled by the Applicant(s) should not be modified. However, if the Evaluating Member State considers easier to amend such entries, e.g. modifying long tables rather than re-drafting new ones, such changes shall be clearly visible. To help clearly distinguishing between Applicants' and Evaluating Competent Authorities' assessment, Evaluators are therefore requested to always highlight any amended text, data or table compared to the original version submitted by the applicant.

The use of the IUCLID "Annotation tool" functionality is not mandatory. However, if the Evaluating Member State used the IUCLID "Annotation tool" functionality, the annotated text will be automatically copied in the

MRL REPORT

Prepared under Article 6 of Regulation (EC) No 396/2005

Submission Date (MM and YYYY):

Subsequent Submissions Date (MM and YYYY):

Evaluating Member State (EMS): [redacted]

Substance Name: [redacted]

Applicant's Identity: [redacted]

Purpose of the application:

- set specific maximum residue level(s) (changing current EU MRL listed in Annex II or III of Regulation (EC) No 396/2005

Commodity:

- 0270030 - Celeries
- 0270040 - Florence fennels
- 0270070 - Rhubarbs

DELETION OF COMMENTING BOX

2. Methods of analysis

Summary

Title: Analytical methods.001

Key information:

valid informations available

Link to relevant study records:
Validation Cellerie 24D15160-01-RACC

Evaluating Competent Authority's assessment on risk assessment methods

Evaluating Competent Authority's assessment on enforcement methods

Evaluating Competent Authority's assessment on other methods

III. Assessment

1. Methods of analysis

Link to IUCLID: Analytical methods.001

Key information:

valid informations available

Link to relevant study records:
Validation Cellerie 24D15160-01-RACC

Evaluating Member State's assessment on risk assessment methods

Evaluating Member State's assessment on enforcement methods

STREAMLINED TRVS

3.10. Toxicological reference values

Summary

Title: Toxicological reference values

Key value for assessment:

Toxicological reference values:

Table III.1.

Reference Value	Study	Route	Uncertainty factor (UF)	Dose descriptor	Justification
AOEL = 0.014 mg/kg bw/day	1-year, dog	oral (28%)	357 - correction for inter and intraspecies defferences as well as for the oral absorption	NOAEL	
ADI = 0.023 mg/kg bw/day	2-year, rat	oral	100 - correction for inter and intraspecies differences	NOAEL	
ARFD = 0.08 mg/kg bw	AKD-2023: blood coagulation time rat - AKD-2023: blood coagulation time rat	oral	100 - correction for inter and intraspecies differences	NOAEL	
AAOEL not allocated not relevant					

2. Mammalian toxicology

2.1. Toxicological reference values

Link to IUCLID: Toxicological reference values

Key value for assessment:

Table III.1. Toxicological reference values

Reference Value	Study	Route	Uncertainty factor (UF)	Dose descriptor	Justification
ADI = 0.023 mg/kg bw/day	2-year, rat	oral	100 - correction for inter and intraspecies differences	NOAEL	
ARFD = 0.08 mg/kg bw	AKD-2023: blood coagulation time rat - AKD-2023: blood coagulation time rat	oral	100 - correction for inter and intraspecies differences	NOAEL	

Assessment and conclusion by Evaluating Member State:

IMPROVED TABLE TITLES

Chapter IV. Conclusions and recommendations

1. Proposed residue definitions

Summary

Title: Proposed residue definitions

Residue definitions:

Table IV.1.

Crop group / Commodity type / Animal	Metabolism group / Commodity	Residue definition	Residue components	Other information
Plant residue definition for monitoring (RD-Mo)				

IV. Conclusions and recommendations

1. Proposed residue definitions

Summary

Title: Proposed residue definitions

Table IV.1. Residue definitions

Crop group / Commodity type / Animal	Metabolism group / Commodity	Residue definition	Residue components	Other information
Plant residue definition for monitoring (RD-Mo)				

IMPROVED CONTRAST OF FREE TEXT FIELDS

4. Residues

Summary

Title: Residues in or on treated products, food and

Key information:

Reference:	Determination of residues o Celeriac – Field trials in Ge
GLP:	Yes
Crop/crop group:	celleriac
Indoor/Outdoor:	outdoor
Formulation:	SC

3. Residues

Title: Residues in or on treated products, food and feed.00

Key information:

Reference:	Determination of residues of Acequ Celeriac – Field trials in Germany 2	
GLP:	Yes	Sample conditi
Crop/crop group:	celleriac	Analyti
Indoor/Outdoor:	outdoor	Limit o (mg/kg
Formulation:	SC	Limit o (mg/kg
Content of active substance (g/kg or g/l):	150 g/L acequioncyl	Residue

MRL REPORT– REFERENCES. ADDITIONAL STUDIES RELIED ON

Currently, the references table include the following columns (in line with the DAR Volume 2 template)

- Author;
- Year;
- Title, type of reference ('study report', 'publication', etc), type of study, and GLP status, among other;
- Vert Study Y/N (**TO BE FILLED MANUALLY**) → Format change not included in April 2026 IUCLID release;
- Owner:
- IUCLID section (endpoint);
- Data protection Y/N;
- Justification if data protection is claimed;
- Previously used Y/N.

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?

[1] In order to facilitate the compilation of the final list of the tests and studies relied upon and the corresponding

MRL REPORT: REFERENCES. ADDITIONAL STUDIES RELIED ON

Proposal for discussion from AT: Removal of column “Justification if data protection is claimed” from the table listing references in MRL report.

Rationale: data protection cannot be granted for studies submitted in the framework of an MRL application. Therefore, the presence of this column appears unnecessary and may create confusion for applicants as well as for evaluators.

Open points: What about the “Data protection Y/N” column itself? Does it need to be removed as well? Technically speaking, the information comes from the same place in IUCLID for both columns.

QUESTION for IUCLID PSN members:

*Should the columns “**Data protection (Y/N)**” and“ **Justification if data protection is claimed**” be **removed** from the list of references included int he **MRL report**?*

NEW REPORTS: RESIDUE TRIALS IN PRIMARY CROPS

#OpenEFSA

RESIDUE TRIALS IN PRIMARY CROPS

- **Since 2025**: OHT 85-5 (residue trials) is fit for purpose and available in IUCLID
- **From May 2026**: it will be mandatory for applicants to fulfill OHT 85-5 (no longer possible to attach Excel files)
- With the “residue trial report”: EMS will be able to generate an excel file combining the results of all residue trials available in a dossier
- **BETA version** is available since **March 2026**, currently under testing by PSN members:
  - Testing lasts until **end of April 2026**
  - APPL can test the report with real data → possibility to share outcome files with PSN members?
  - EMS can test the report with mock datasets
- The consolidation and finalization of the report generator is foreseen in **June 2026**
- The release of the report generator in IUCLID Agency is foreseen in **September 2026**

ONGOING AND FUTURE WORK

UPDATES AND ONGOING WORK

Report	Updates / comments	Status	Estimated deadline
1 – Overall conclusions	• To be adapted by EFSA from the CLH report to create the "1 – Overall conclusions" report, aligned with DAR Vol1, depending on availability of resources	In development	2026
2 – List of references	• Revised (see slides before) – vertebrate study Y/N to be further discussed for next year	Finished	-
3 – Active Substance / Product B-1 (Identity)	• Revised for microorganisms (see slides before)	Finished	-
3 – Active Substance / Product B-2 (PhysChem)		Finished	-
3 – Biological Properties	• Revised including format changes in 2026 April release	Finished	-
3 – Active Substance / Product B-3 (Application)		Finished	-
3 – Active Substance / Product B-4 (FurtherInfo)	• Revised for microorganisms (see slides before)	Finished	-

UPDATES AND ONGOING WORK

Report	Updates / comments	Status	Estimated deadline
3 – Active Substance / Product B-5 (AnMethods)	• Revised for microorganisms	Finished	-
3 – Active Substance / Product B-6 (Tox)		Finished	-
3 – Active Substance B-7 (Residues)	• Revised for microorganisms	Finished	-
3 – Active Substance / Product B-8 (Fate)	• Revised by ICPS for microorganisms, to be implemented	Finished (chem) Under revision (micro)	- ~~Q2~~Q3 2026
3 – Active Substance / Product B-9 (Ecotox)	• Revised for chemicals	Finished (micro)	-
Literature Search (Active Substance / Product)	• Searches are now included in Vol3 reports if the correct value in the "Section(s) covered" is selected - this report provides a full overview – TBD if needed	Finished	-

UPDATES AND ONGOING WORK

Report	Updates / comments	Status	Estimated deadline
4 – Confidential Information	• Report developed, tested by the WP on the Confidential Information report, and available in Agency – will be a default report in October	Finished	-
List of Endpoints (LoE)	• Work to be continued with Ecotox and Fate sections, depending on available resources	In development	2026
MRL report	• Proposals for improvements from the testing phase analysed and implemented	Finished	-
Residue trials	• Testing for residue trials for primary crops • Reports for rotational crops and processed commodities will follow	Testing	Q2 2026
Genotoxicity studies overview table	• Extraction of data from genotoxicity studies in vivo and in vitro (OHT70 and 71), requested by EFSA	In development	Q3 2026
Bee calculator extraction report	• Extraction of all bee-related data from the dose response block of OHT 50-3, requested by EFSA	In development	Q3 2026

PUBLICATION OF REPORTS

- Reports will be published after the April release in Zenodo, as usual
  - They are all listed in EFSA's toolkit, "IUCLID software" section:

Toolkit

IUCLID software

Only for pesticide-related applications

Report generator:

- Summary Reports EU PPP for IUCLID report generator
- List of substances and metabolites EU PPP for IUCLID report generator
- GAP table EU PPP for IUCLID report generator
- MRL Report EU PPP for IUCLID report generator

- Importantly, **more complete mapping files** will be published for reports where they were missing
  - Last one published: MRL report (since February 2026)
  - These mapping files help understanding what are the expected contents of the different reports

MRL Report EU PPP for IUCLID 6 v9.10.4 Report Generator

EFSA

Files

00_MRL_ER_IUCLID9.10.4_v9.zip

Files (245.9 kB)

Name	Size	Download all
00_MRL_ER_IUCLID9.10.4_v9.zip md5:ccafd3b9c45ebdd02f4893f24b80f720	160.2 kB	Preview Download
MRL report EU PPP for IUCLID Report Generator_mapping.xlsx md5:09c105c00db02f66f97bf8be6c81b53b	85.8 kB	Download

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