12th meeting of the PSN IUCLID sub-group
11-12 Mar 2025

IUCLID REPORT GENERATOR

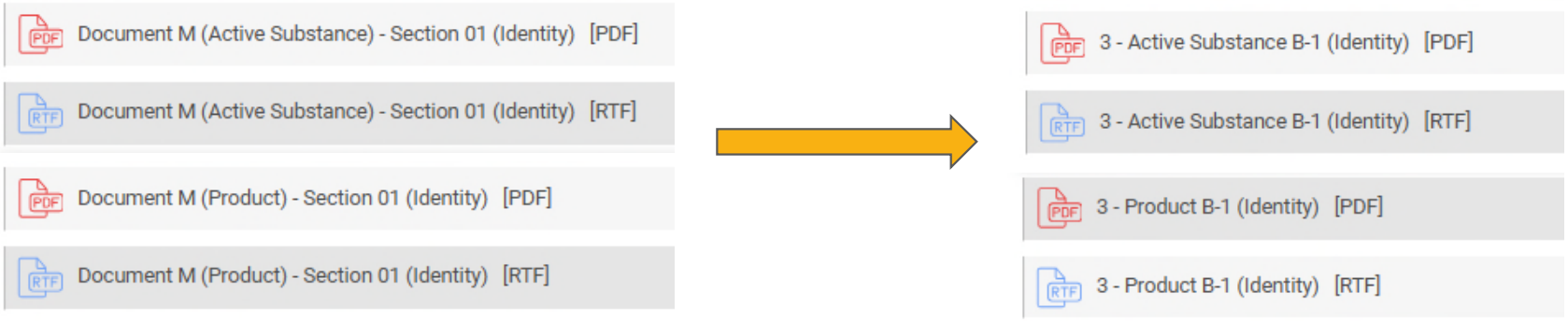
efsa
EUROPEAN FOOD SAFETY AUTHORITY

OUTLINE

- From Document M to DAR Vol3 reports
- Revision of reports by ICPS (Italy)
- List of updates and ongoing work
- Report generator for MRL applications

FROM DOCUMENT M TO DAR VOL3 REPORTS

- In the next IUCLID release (IUCLID 6 9.X, May 2025) **Document M** reports will disappear and will be substituted by the corresponding draft versions of the **D(R)AR Vol3**

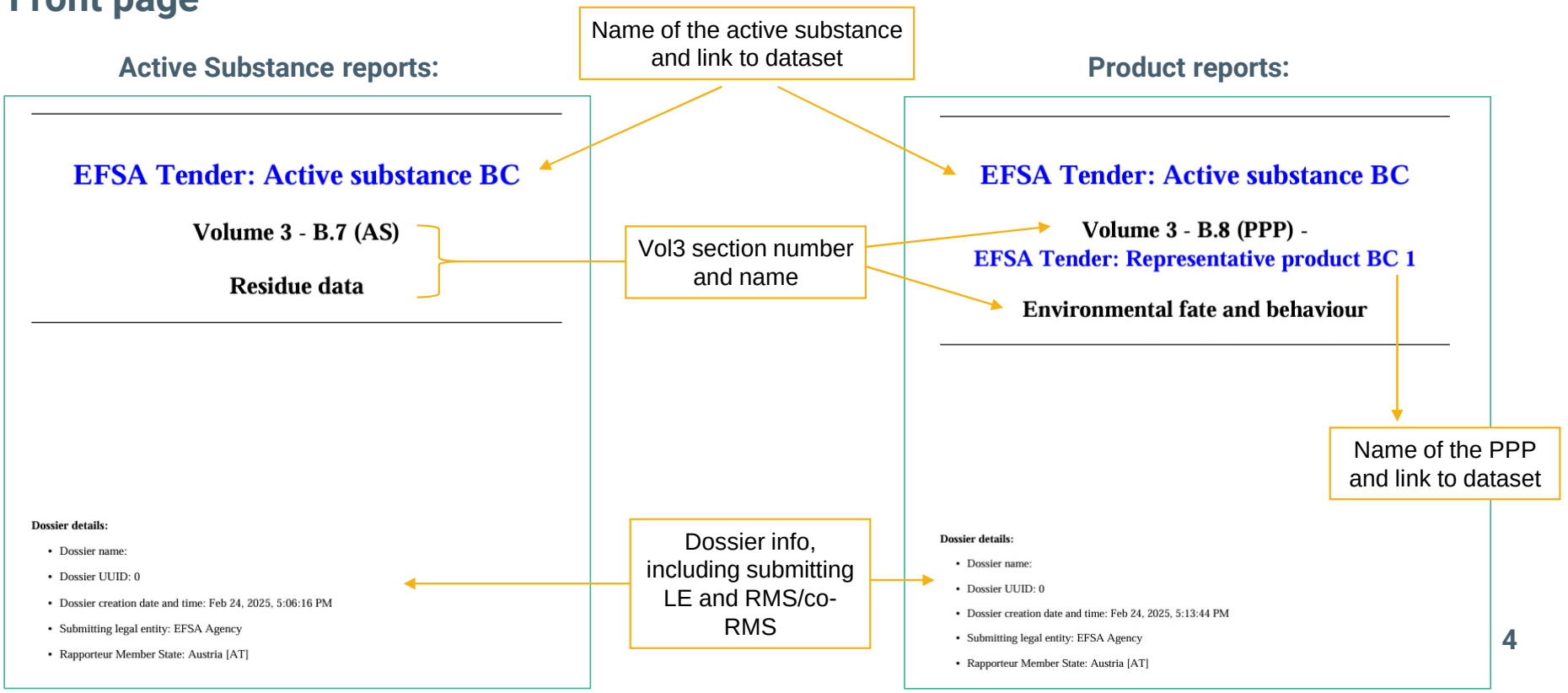


- in some cases changes have been minimal (since the structure of Documents M was already aligned with the DAR), but other cases required more rework
- new templates will be published in Zenodo after the IUCLID release, including some mapping files
- **feedback** is welcome when using these reports – via EFSA's **Ask a question**

FROM DOCUMENT M TO DAR VOL3 REPORTS

Main changes:

1. Front page



FROM DOCUMENT M TO DAR VOL3 REPORTS

Main changes:

2. Tables of Contents (ToC) & merging/splitting of (some) reports

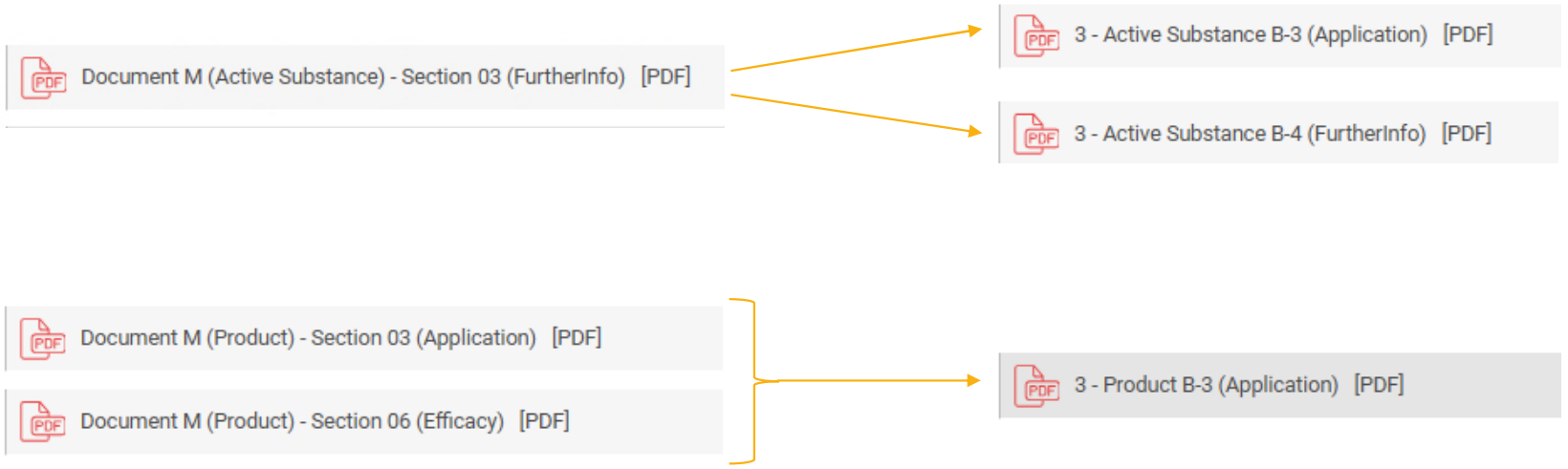
Table of Contents

Table of Contents

FROM DOCUMENT M TO DAR VOL3 REPORTS

Main changes:

2. Tables of Contents (ToC) & merging/splitting of (some) reports (II)



FROM DOCUMENT M TO DAR VOL3 REPORTS

Main changes:

3. **Addition of references,** sorted by section (~data requirement), only for the A.s./product and metabolites datasets (i.e., no impurities, no co-formulants, etc)

B.7.8. REFERENCES RELIED ON

LITERATURE SEARCH

For information on any literature searches performed, please see the standalone 'Literature Search' report.

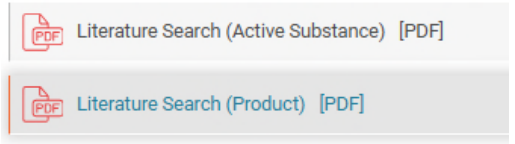
LIST OF REFERENCES

Table B.7.54.

IUCLID section (endpoint)	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	Data protection Y/N	Justification if data protection is claimed	Previously used Y/N
6.1 Storage stability of residues (stability of residues in stored commodities)	Smith, X.	2022	EFSA Tender: Active substance BC: Storage stability in wheat grain and straw XXXXXXXXXX *Document No. not provided* Laboratory A GLP: yes Unpublished (study report)		Applicant	Y	Data submitter is data owner	N
6.2.1 Metabolism of residues in plants and in rotational crops (metabolism of residues in crops)	Richardson J.	2019	EFSA Tender: Active substance BC: Metabolism in spring wheat XXXXXXXXXX No.1243-5 Laboratory C GLP: yes Unpublished (study report)		Applicant	N		N

- **Literature searches** cannot be reported in each Vol3, since the current IUCLID structure does not allow indicating the sections (Tox, Ecotox, etc) for which the search is performed, unless a *format change* is proposed to **FLEXIBLE_RECORD.LiteratureSearch**

  →currently, a standalone report can be run for the A.s. and the product



- **Vertebrate study Y/N** cannot be retrieved automatically, since this information doesn't exist currently in IUCLID; it could also be proposed as format change

- **Data requirements** are not indicated in IUCLID, but the IUCLID Section often corresponds to them

FROM DOCUMENT M TO DAR VOL3 REPORTS

Main changes:

4. **Addition of evaluation boxes,** after each SUMMARY, WAIVER and STUDY for the RMS to perform the evaluation (as done for the MRL report)

3. Assessment and conclusion

a) Assessment and conclusion by applicant:

Conclusion:

Residue levels in control samples of honey were below the LOQ (<0.02 mg/kg). In treated specimens of phacelia honey, taken at maturity, 9-20 DAA, the residues of Active substance BC ranged from 0.080 to 0.270 mg/kg.

b) Assessment and conclusion by RMS

FROM DOCUMENT M TO DAR VOL3 REPORTS

Main changes:

5. **Other general changes,** e.g.,

- Addition of data point, study type, testing period, and testing facility to the summary table of the study

1. Information on the study

Table B.7.2.

Data point	CA 6.1./1.
Study type	stability of residues in stored commodities - test
Testing period	Mar 27, 2022 - Apr 15, 2023
Report type	study report
Report author	Smith, X.
Report year	2022
Report title	EFSA Tender: Active substance BC: Storage stability in wheat grain and straw
Report No	XXXXXXXXXX
Document No	
Testing facility	Laboratory A

- Moving the executive summary to the first part of section 2

2. Full summary of the study according to OECD format

a) Executive summary:

The storage stability of active substance BC in wheat grain was tested for a time period of 6 months. The residue of active substance BC after 6 months storage amounted to 83% of the initial value. Therefore, it is concluded that the active substance BC residues in grain are stable for 6 months.

b) Materials and methods

- Addition of messages in blue font, e.g., :

Any confidential additives are included in '4 - Confidential Information' report

FROM DOCUMENT M TO DAR VOL3 REPORTS

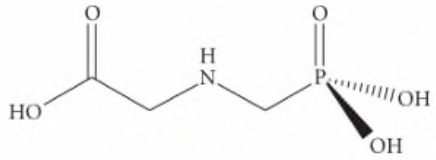
Main changes:

5. **Changes specific to some reports**, aligning them with DAR format:

e.g., ***3 – Active Substance / Product B-1 (Identity):*** tabular format & removal of confidential information that will be part of the Vol4 (manufacture process, 5-batch analysis, identity of impurities, and identity of additives and co-formulants claimed confidential)

B.1.1. IDENTITY OF THE ACTIVE SUBSTANCE

B.1.1.1. Common name proposed or ISO accepted and synonyms	Active substance BC Synonyms: • EC name: EC name Description: Description of active substance BC
B.1.1.2. Chemical name (IUPAC and CA nomenclature)	
IUPAC	IUPAC name
CA	Substance CAS name; Substance CAS name
B.1.1.3. Producer's development code number	
B.1.1.4. CAS, EEC and CIPAC numbers	
CAS	1071-83-6
EEC	1541-5
CIPAC	123456

B.1.1.5. Molecular and structural formula, molecular mass	
Molecular formula	C3H8NO5P
Structural formula	
Molecular mass	1.69E4 g/mol
B.1.1.6. Method of manufacture (synthesis pathway) of the active substance	*Confidential data - see '4 - Confidential Information' report*
B.1.1.7. Specification of purity of the active substance in g/kg	980 g/kg
B.1.1.8. Identity and content of additives (such as stabilisers) and impurities	
B.1.1.8.1. Additives	Additive A 10 g/kg *Any confidential additives are included in '4 - Confidential Information' report*
B.1.1.8.2. Significant impurities	*Confidential data - see '4 - Confidential Information' report*
B.1.1.8.3. Relevant impurities	Impurity B (code: I-B) 2 g/kg
B.1.1.9. Analytical profile of batches	*Confidential data - see '4 - Confidential Information' report*

REVISION OF REPORTS BY ICPS (ITALY)

- ICPS (Italy) accepted 2 tasking grants from EFSA in order to:
  - support the improvement and consolidation of reports created with IUCLID Report Generator for the **toxicology and ecotoxicology** sections for both the **chemical plant protection product(s) and active substance(s)**
  - support the improvement and consolidation of reports created with IUCLID Report Generator for **microbial active substances**
- The work focuses on the revision of RG reports, but also includes the proposal of format changes (if needed), validation rules and support to manuals and training material
- Timeline:
  - By July 2025: ecotox/tox sections for chemical PPP and A.S. and biological properties, human health and ecotox for microbial A.S.
    → Report changes to be implemented by October release 2025 and April release 2026, depending on number and complexity
  - By November 2025: remaining sections for microbial A.S.
    → Report changes to be implemented by April release 2026 and October release 2026, depending on number and complexity

UPDATES AND ONGOING WORK

Report	Updates / comments	Status	Estimated deadline
1 – Overall conclusions	• CLH report developed by a contractor for ECHA – currently under revision by ECHA/EFSA before publication • To be adapted by EFSA to create the "1 – Overall conclusions" report, aligned with DAR Vol1	In development	End of 2025
2 – List of references	• Structure aligned with DAR Vol 2 i.e., references separated in different subsections, sorted by Author name • All references in the dossier are listed, without distinction • Note: Vertebrate Y/N and Data point currently not retrievable	Finished	May 2025
3 – Active Substance / Product B-1 (Identity)	• Format aligned to DAR Vol3	Finished	May 2025
3 – Active Substance / Product B-2 (PhysChem)	• Structure aligned with DAR Vol3, discussed and reviewed by the WP in 2024; First report in DOCX/HTML • Work currently ongoing to aligned with some relevant format changes, e.g. new ESR for Spectra	In development	May 2025
3 – Active Substance / Product B-3 (Application)	• Product report including both sections 3 (Application) and 6 (Efficacy) • Other minor content changes/structure – some format changes might be needed to fully align the structure	Finished	May 2025
3 – Active Substance / Product B-4 (FurtherInfo)	• Minor changes to align with DAR format	Finished	May 2025

UPDATES AND ONGOING WORK

Report	Updates / comments	Status	Estimated deadline
3 – Active Substance / Product B-5 (AnMethods)	• Methods with endpoint “methods for significant impurities” not reported (to be part of “4 – Confidential Information”)	Finished	May 2025
3 – Active Substance / Product B-6 (Tox)	• Tasking grant to ICPS (Italy) to review existing reports and propose improvements (including format change proposals)	Under revision	2025-2026
3 – Active Substance B-7 (Residues)	• Changes to several summaries and studies, following extensive format changes	In development	May 2025
3 – Active Substance / Product B-8 (Fate)	• Might require improvements, but not planned for 2025	Finished	May 2025
3 – Active Substance / Product B-9 (Ecotox)	• Tasking grant to ICPS (Italy) to review existing reports and propose improvements (including format change proposals)	Under revision	2025-2026
Literature Search (Active Substance / Product)	• Report available, if format changes to distinguish searches by section are implemented, it could be incorporated to other reports and the standalone report removed	Finished	May 2025

UPDATES AND ONGOING WORK

Report	Updates / comments	Status	Estimated deadline
4 – Confidential Information	• Report to be developed to cover Doc J once dismissed • Requirements collected and being reviewed • Work to develop report to be started in 2025 and finalized after the IUCLID May release	Under analysis	~~Q2~~ Q3 2025
List of Endpoints (LoE)	• New section 3 on residues available • Work to be continued with Ecotox and Fate sections	In development	Q4 2025
MRL report	• Improvements implemented in 2024 – presented at previous PSN • Other changes being implemented, following extensive format changes in residues documents • Discussions at the PAFF for endorsement ongoing (see next slide)	In development	May 2025
Metabolites Overview Table *(for microorganisms)*	• Minor changes implemented based on feedback from Ctgb • Further improvements might require format changes	Finished	May 2025
Microorganism reports	• DAR templates proposed by Ctgb (NL) • Tasking grant to ICPS (Italy) to review existing reports and define new ones (including format change proposals)	Under analysis	2025-2026

REPORT GENERATOR FOR MRL APPLICATIONS

- The MRL report can already be used by EMS to prepare the Evaluation Report of MRL applications
- Some MSs already started using it (feedback will be provided tomorrow)
- The MRL report can give good results if the IUCLID dossier is complete (to be checked by EMS during admissibility step)
- The use of MRL report is not officially endorsed (see discussion at Feb PAFF meeting) but EFSA already accepts Evaluation Reports prepared with the IUCLID report generator
- Until next PAFF meeting, MSs are invited to test the MRL report for preparing ER for MRL applications and to provide feedback via AskEFSA (with examples and practical proposals)
- EFSA continues to improve the MRL report, taking advantage of the formats changes expected in 2025 IUCLID release (e.g. residue and processing trials OHTs and summaries) and considering feedback from MSs
- Reminder: EMS cannot ask the applicant to prepare the dossier in additional formats other than IUCLID as this would impose an undue burden of duplicate work

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