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



FEEDBACK FROM WORKING PARTIES

IDATA, PREV

EUROPEAN FOOD SAFETY AUTHORITY

OVERVIEW OF WORKING PARTIES

Working party	Status	Dates
WP on **microorganisms**	Closed	1st round March 2022 to 2nd round May to June 2023
WP on **filtering rules**	Active (ad-hoc)	Sep 2022- February 2023, now ad hoc basis
WP on **Physchem properties and LoEP**	Closed	June to September 2024
WP on **OHT 85**	Closed	June to July 2024
WP on **metabolism studies**	**Ongoing**	May 2025 -
WP on **Confidential Information report**	Closed	October 2025 to January 2026

OUTLINE

1. WP on the Confidential Information report
2. WP on metabolism studies
3. WP on OHT 85

WORKING PARTY ON THE CONFIDENTIAL INFORMATION REPORT

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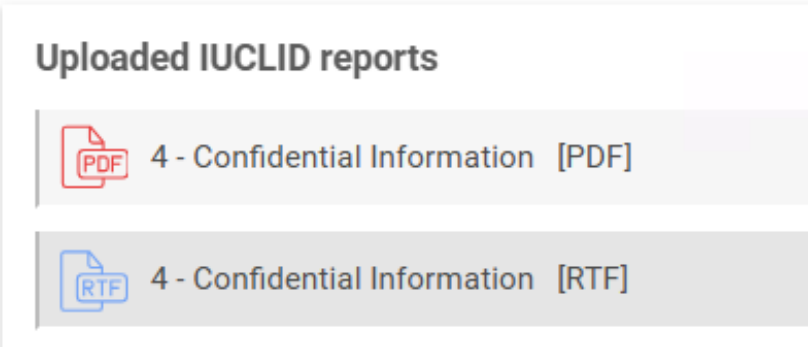
BACKGROUND

- **Jun 2023:** Presentation of **plan for the removal of Document J** at the 7th PSN-IUCLID subgroup meeting, stemming from the WP on filtering rules
- **Jun-Nov 2024**: Preparation of IUCLID **format changes** to accommodate information of DocJ
- **Nov 2024:** Mapping file for the removal of DocJ shared with the PSN and published in EFSA's toolkit
- **Jan 2025**: **Info session for RMS** on the mapping file for the removal of DocJ (incl. Q&A session)
- **Mar 2025: Instructions for applicants** published: Doc J removal - instructions for applicants on data reporting in IUCLID (later further updated)
- **Apr 2025: Open webinar** on the removal of DocJ
- **May 2025**: **IUCLID6 v9** released, including format changes for DocJ
- **Aug 2025**: Collection of **interest to participate** in the WP to test the Confidential Information report, after agreeing at the 13th PSN-IUCLID subgroup (June 2025)
- **May-Oct 2025**: First version of the **Confidential Information report** developed and shared with WP
- **Oct-Jan 2025**: **WP on the Confidential Information report**

THE CONFIDENTIAL INFORMATION REPORT

- The "*4 – Confidential Information*" report follows the official EC template for Volume 4 of the D(R)AR (SANCO/12592/2012)
  - i.e, contains information provided in IUCLID that used to be part of Doc J



- The main purpose of the report is to be used by **RMS,** to support the **preparation of the DAR/RAR Volume 4**
  - The report can also be used by **applicants,** to ensure that all **required data to which confidentiality can be claimed is entered as expected** in the IUCLID dossier before submission, but it should not be attached to the dossier

- The report is applicable to **chemical NAS/AIR** dossiers submitted as from **IUCLID6 v9** (May 2025), which included the necessary format changes to allow the **dismissal of Document J**
  - from this date, Document J should not be submitted anymore by applicants in **new applications**

THE CONFIDENTIAL INFORMATION REPORT (II)

Active substance BC

Volume 4

Confidential Information

Dossier details:

- Dossier name: BC products
- Dossier UUID: 755c88f2-d589-4e74-a7e6-629e5e106e3a
- Dossier creation date and time: Sep 16, 2025, 3:02:36 PM
- Owner legal entity: EFSA IUCLID demo
- Rapporteur Member State: Italy

Extracted from the IUCLID dossier: **Dossier header**

Table of Contents

C.1. CONFIDENTIAL INFORMATION 4
C.1.1. DETAILED INFORMATION ON THE MANUFACTURING PROCESS OR PROCESSES FOR THE ACTIVE SUBSTANCE 4
C.1.1.1. Manufacturer of the active substance 4
C.1.1.2. Method of manufacture (synthesis pathway) of the active substance 5
C.1.2. DETAILED SPECIFICATION OF THE ACTIVE SUBSTANCE 9
C.1.2.1. Specification of purity of the active substance in g/kg 9
C.1.2.2. Identity of isomers, impurities and additives 9
C.1.2.2.1. Impurities 9
C.1.2.2.1.1. Relevant impurities 9
C.1.2.2.1.2. Significant impurities 10
C.1.2.2.1.3. Other impurities 12
C.1.2.2.2. Additives 14
C.1.2.3. Analytical profile of batches 15
C.1.2.3.1. Comparison of specifications for Active substance BC 26
C.1.3. DETAILED SPECIFICATION OF THE PLANT PROTECTION PRODUCT(S) 30
C.1.3.1. BC1 200 EC 30
C.1.3.1.1. Manufacturing process of the plant protection product 30
C.1.3.1.2. Composition of the plant protection product 32
C.1.3.1.3. Comparison of the composition of other formulations used in studies 34
C.1.3.1.4. Information on safeners, synergists and co-formulants 38
C.1.3.1.4.1. Safeners 38
C.1.3.1.4.2. Synergists 39
C.1.3.1.4.3. Co-formulants 39
C.1.3.2. BC2 150 DC 42
C.1.3.2.1. Manufacturing process of the plant protection product 42
C.1.3.2.2. Composition of the plant protection product 44
C.1.3.2.3. Comparison of the composition of other formulations used in studies 45
C.1.3.2.4. Information on safeners, synergists and co-formulants 48
C.1.3.2.4.1. Safeners 48
C.1.3.2.4.2. Synergists 48
C.1.3.2.4.3. Co-formulants 49
C.1.4. INFORMATION ON THE BATCHES USED FOR THE MAMMALIAN TOXICITY AND ECOTOXICITY TESTS 51
C.1.4.1. Information on the batches used for the mammalian toxicity tests 51
C.1.4.2. Information on the batches used for the ecotoxicity tests 55
C.1.5. OTHER CONFIDENTIAL INFORMATION 59
C.1.5.1. Analytical methods for determination of impurities in the active substance as manufactured 59
C.1.5.2. Data on impurities 70
C.1.5.2.1. Impurity C (significant) 70
C.1.5.3. Data on co-formulants, safeners and synergists 75
C.2. SUMMARY OF INFORMATION RELATING TO ANY TASK FORCES THAT SUBMITTED TESTS AND STUDY REPORTS 84
C.3. SUMMARY OF INFORMATION RELATING TO AVOIDANCE OF DUPLICATIVE TESTING AND SHARING OF TESTS AND STUDIES INVOLVING VERTEBRATE ANIMALS 85
C.4. REFERENCES RELIED ON 86

Extracted from the IUCLID dossier

To be filled in manually

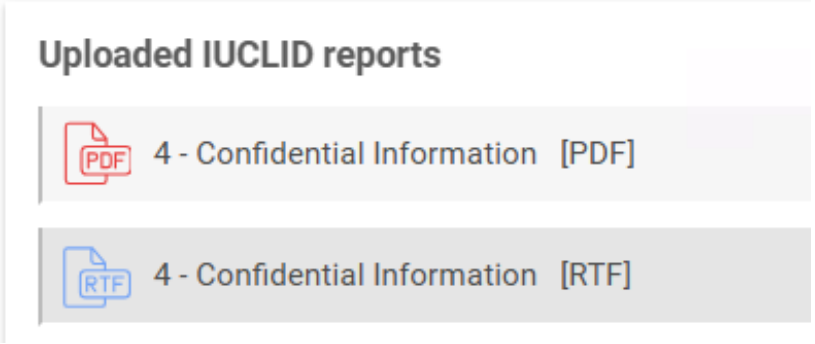
WP CONFIDENTIAL INFORMATION REPORT - INTRODUCTION

- The aim of the Working Party was to **test and provide** feedback on the ***"4 – Confidential Information"*** report in IUCLID developed by EFSA

- Participants were …
  - 8 Member States: BE, DE, EE, ES, FR, NL, SE, PT
  - 4 Industry associations: EACL, ECCA, CLE, IBMA

- WP was carried out from October 2025 to January 2026:
  - **Kick-off** meeting: **Oct 1, 2025** → feedback collected by Oct 24
  - **2nd** meeting: **Nov 14, 2025** → survey launched Nov 20 – Dec 12
  - **3rd** meeting: **Jan 29, 2026** → conclusion

- All materials discussed are available in the PSN-IUCLID subgroup teams



WP CONFIDENTIAL INFORMATION REPORT – 1ST MEETING

- The aim of the meeting was to:
  i. **Present** in detail the report
  ii. Provide **instructions** for testing
  iii. Collect initial **feedback**

- Participants were provided with all necessary materials, including:
  - A **mapping file**, providing a link the official EC template and IUCLID
  - The **meeting presentation**, complementary to the above
  - **FTL templates,** to be uploaded in local instances, if needed
  - A **test dossier** in i6z format: to be uploaded in local instances, if needed (also available in Beta)
  - A **Backlog file**, to provide the feedback on the testing

- It was agreed to collect feedback by **Oct 24th EOB**

WP CONFIDENTIAL INFORMATION REPORT – 2ND MEETING

- The aim of the meeting was to **discuss the feedback** received regarding the first version of the report
- **110 comments** were received, in the backlog file and in one commented report
  - Comments were categorized into **different relevance levels** by the participants, and EFSA provided **tentative replies** directly in the backlog file
  - The **sections** that received more comments were:
    - comparison of batches/formulations (21%)
    - identity of isomers, impurities and additives (mostly impurities) (16%)
    - analytical profile of batches (14%)
    - composition of the PPP and information on safeners, synergists, and co-formulants (13%)
- The most relevant topics were **actively discussed** during the meeting
- After the meeting, a **survey** was launched from **Nov 20th to Dec ~~4th~~ 12th** to take a final decision on the remaining open points

WP CONFIDENTIAL INFORMATION REPORT – 3RD MEETING

- The aim of the meeting was to present the **conclusions** of the working party, based on the feedback and the survey, and close any remaining open points
- 12 responses were received in the **survey**: 7 from Member States + 5 from Industry
- Based on the replies to the survey and the feedback collected initially:
  - **Format changes** for April 2026 IUCLID release were proposed (now implemented):
    - **Reference block** in the **method of manufacture** document
    - Fields in the **impurities summary** for the **assessment** of impurities in **(eco)tox batches**
    - **Endpoints** in the **analytical profile of batches** study record for studies on **(eco)tox batches**
    - Additional **concentration** field in the **mixture composition document** allowing to report **% w/w**
  - A **list of changes to the report** was prepared for implementation
- On **March 3rd** the **new version of the report**, the **mapping** file and the revised **test dossier** were shared with the WP and report was made available in **EFSA Agency**

WP CONFIDENTIAL INFORMATION REPORT – WHAT'S NEXT

The "4 – Confidential Information" report is currently available in IUCLID **EFSA Agency**, IUCLID **Beta** and the teams folder of the WP, then:

- **Apr-May 2026**: With **IUCLID6 v10**, the report will incorporate **format changes,** will be reuploaded in **Agency** ("Uploaded reports" section) and the new materials will be re-shared with **WP members**
- **May 2026**: The report and mapping file will be **published in Zenodo**
- **Jun 2026: Manuals** will be updated, including instructions related to the **dismissal of Document J**
- **Oct 2026:** The report becomes "**Default**" in IUCLID

Any feedback or issues can be shared via Ask a Question

WORKING PARTY ON METABOLISM OHT

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WP ON METABOLISM OHT: SCOPE, OBJECTIVES AND TIMELINES

- Scope: Revising **OHTs for metabolism studies** in residues (**OHT 85-2, OHT 85-3**) and toxicology (**OHT 58**).

- Key objectives are:
  - alignment with MSS Composer / MetaPath
  - improved data control and user-friendliness
  - Streamline the OHTs, removing overly complex nested structures.

- Timelines:
  - WP launched in May 2025
  - Initial target for 2026 was abandoned due to the scale of proposed changes
  - Current target is IUCLID release 2027.

- Progress report available here: LINK to Progress report

WP ON METABOLISM OHT: KEY DISCUSSIONS

- **Meeting 1 (June 2025):**

-EFSA presented a first draft of OHT 85-3 (plant metabolism).

-CLE proposed a revised structure introducing a new “sampling” block to resolve issues with treatment groups

-Promising but raised concerns about MetaPath compatibility, leading to postponement of consolidation.

- **Meeting 2 (November 2025):**

-Detailed assessment of the pros and cons of the CLE proposal.

-MetaPath structure cannot be changed.

-CLE was invited to further develop the proposal; OHT 58 was not discussed.

- **Meeting 3 (December 2025):**

-Compatibility between treatment group and new samples block was clarified and considered feasible without jeopardising MetaPath project.

-Discussion covered additional potential blocks (e.g. dosing solution, extraction efficiency) and reporting level for solvent extraction results.

-Agreement to aggregate extraction results by fraction type rather than per solvent.

WP ON METABOLISM OHT: OPEN POINTS AND ACTIONS

- Decision pending on:
  - Whether to develop a dosing solution block.
  - How to address extraction efficiency (EE) (within OHT 85-3/2, analytical methodsOHT, or a separate document).

- CLE and EFSA to further develop OHT 85-3 based on the agreed structure.
- Mapping impact to be assessed by LMC.

- Next Working Party meeting to be planned for April/May 2026
- https://doodle.com/group-poll/participate/b8zNj73e

WORKING PARTY ON OHT 85-5 AND 85-9

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WP ON OHT 85-5 AND 85-9

- Progress report available here: Progress_Report.docx
- WP now closed
- This WP was active between July 2024 and November 2024 (3 meetings)
- Results:
  - Updated 85-5 and its EP summary
  - Updated 85-9 and its EP summary
  - Formats available in IUCLID since 2025 release
- After one year of transition, these OHTs will become mandatory from April 2026 (no longer the alternative of using Excel files)
- EFSA is working on the report generator to prepare the excel files from fulfilled OHTs (see other ppt)

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