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

IUCLID REPORT GENERATOR USE FOR DOSSIER LIFECYCLE

efsa
EUROPEAN FOOD SAFETY AUTHORITY

OUTLINE

- IUCLID PPP Dossiers-Datasets: Terminology and Structure Overview
- Run Reports with Report Generator
  - HOW to run Reports
  - WHO should use them
  - WHEN to run Reports in Dossier lifecycle
  - WHICH Report to choose according to the stage (e.g., dossier admissibility)
  - WHY Reports should be used
- IUCLID Demo (GAP Report)

IUCLID PPP DOSSIERS - DATASETS: TERMINOLOGY AND STRUCTURE OVERVIEW

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DATASET-DOSSIER

- **Dataset*** a collection of documents that relate to a particular chemical substance, or grouping of chemical substances. It can be of type:

 *Substance*

 *Mixture/Product*

- **Dossier*** a read-only snapshot of a dataset. It contains a *Dossier header* that has a structure determined by the *working context*.

Datasets are editable**. Dossiers** are read-only.

In IUCLID **EFSA Agency** instance, **MS** have access to **Dossiers**.

GENERALIZED EU PPP DOSSIER STRUCTURE

In **EU PPP** *working contexts* **Dossiers** consist of:*

- One or many Mixture **Datasets**

with

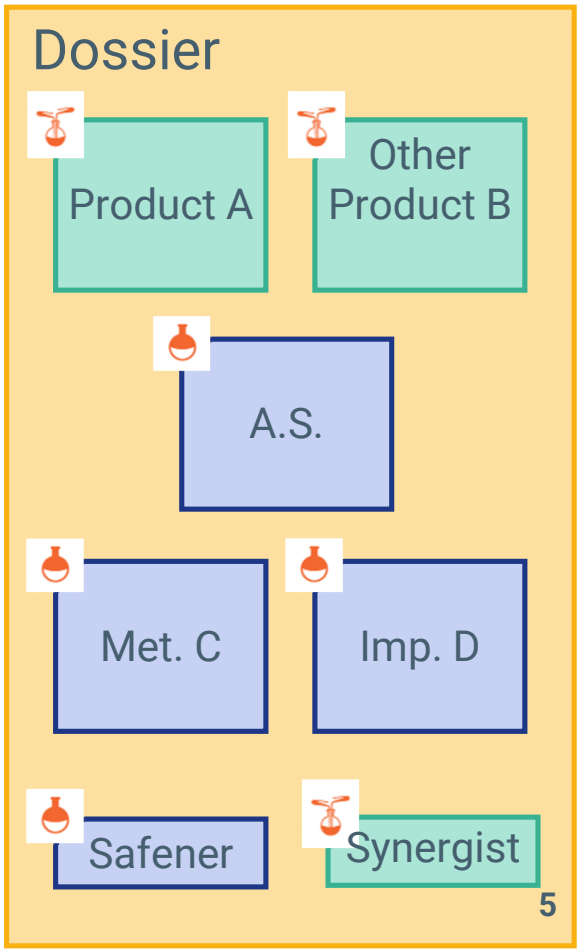
- One and only one Active Substance **Dataset**

plus (where applicable)

- One or many Metabolites and/or Impurities **Datasets**

plus (technically possible but not fully operational)

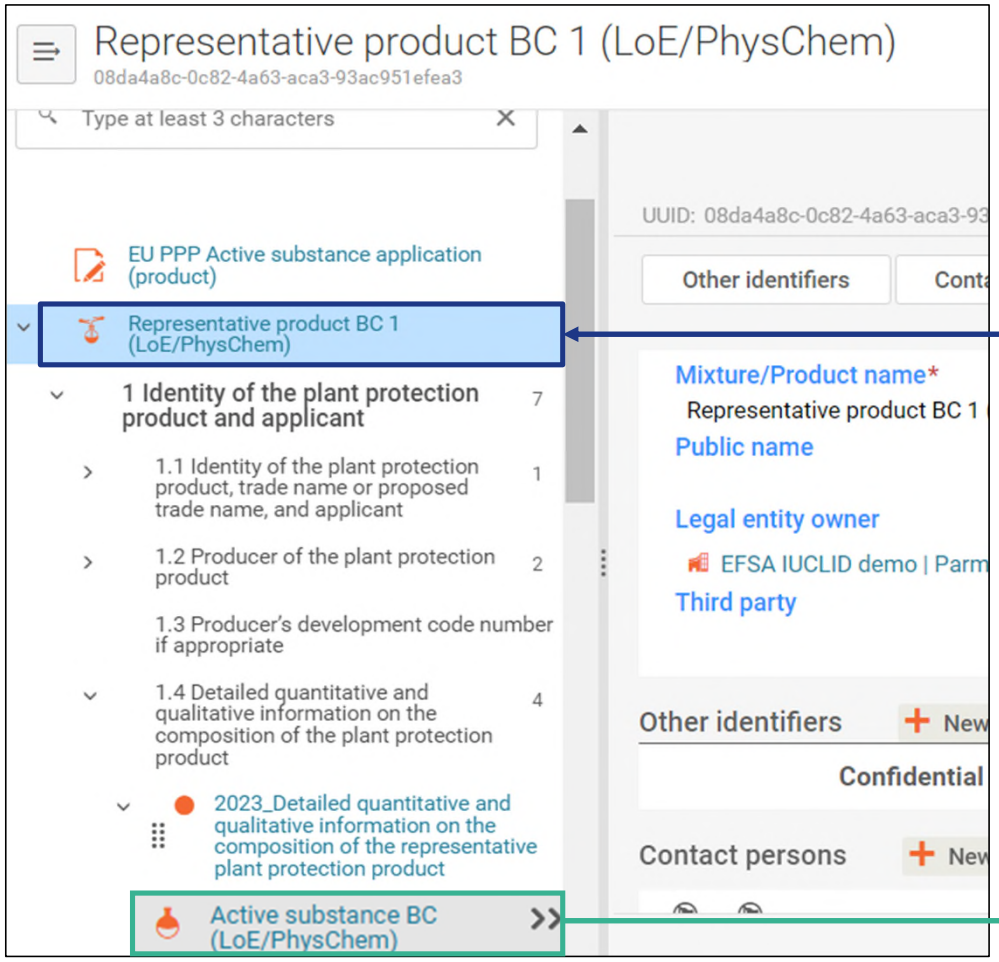
- One or many Co-Formulants, Safeners and Synergists **Datasets**



PRODUCT AND ACTIVE SUBSTANCE DATASETS

Product Dataset

Product Table of Contents (ToC)*



Active Substance (A.S.) Dataset

Active Substance ToC*

MAIN ELEMENTS WITHIN A PPP DOSSIER-DATASET

Dossier Header

EU PPP Active substance application (product)

Metabolite Dataset(s)

1.4.4 Information on metabolites 1
Information on metabolites.001
Active substance BC (LoE/PhysChem)
Metabolite 2
EFSA Tender: Metabolite 1

Impurity Dataset(s)

1.4.6 Impurities 1
Impurities.001
Active substance BC (LoE/PhysChem)
Impurity B

Other Product Dataset(s)

1.4.5 Other representative products 1
Other representative products.001
Other representative product (LoE/PhysChem)

ToC Sections

7 Toxicological studies on the plant protection product 14
7.1 Acute toxicity 10
2023_Summary_Acute Toxicity
7.1.1 Oral toxicity 1
1989_Oral toxicity_01

Documents*

ENDPOINT_Summary

ENDPOINT_Study_Record

1989_Oral toxicity_01
UUID: cc503573-9200-4da6-8cbd-7731b4078a3e
EU: PPP
Administrative data | Data source | Material
Results and discussion
Preliminary study
Not applicable.
Effect levels | New item | Import file

Key result	Sex	Dose descriptor	Effect level	Based on
1	male/female	LD50	> 2000 mg/kg bw	test mat.

RUN REPORTS WITH REPORT GENERATOR (RG) - HOW

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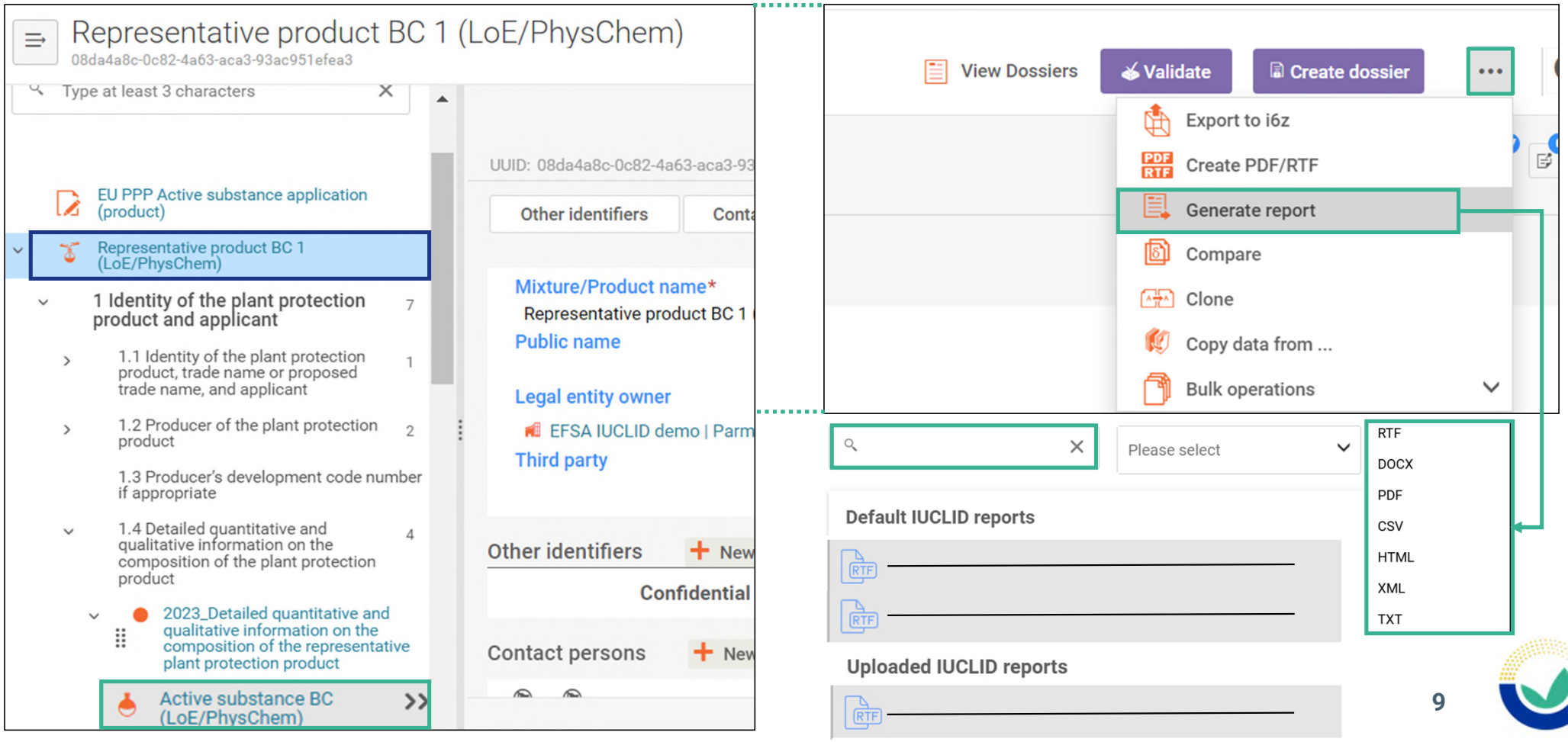
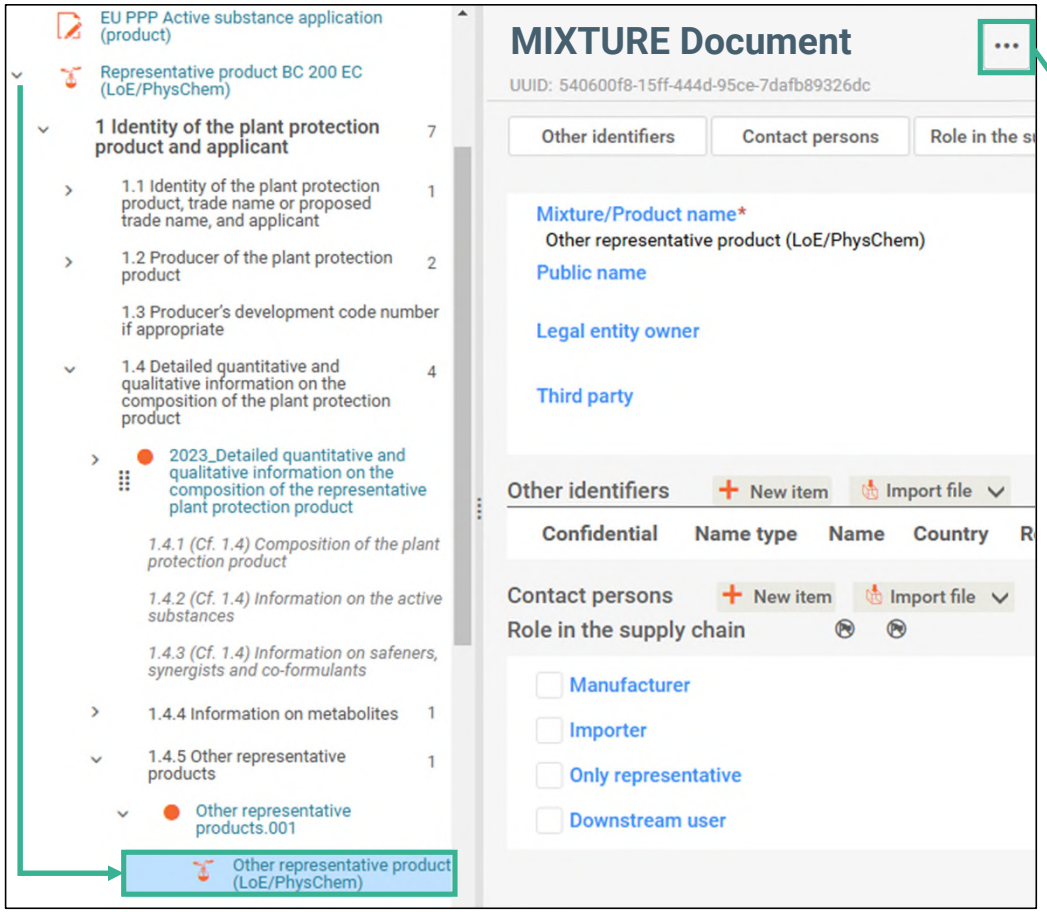
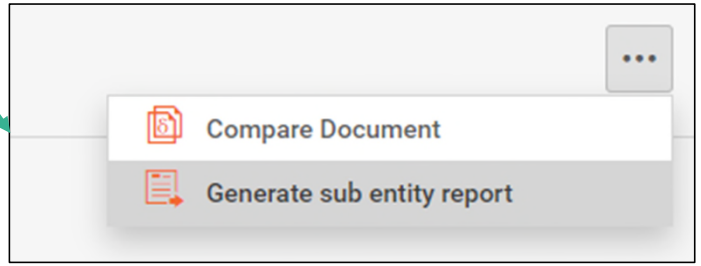
RG TOOL – HOW TO ACCESS IT



HOW TO RUN REPORTS FOR OTHER REPR. PRODUCTS

IUCLID USER INTERFACE





Important Note: sub-entity report generation is required with **Dossiers** and it is needed to generate reports for other representative Products datasets.

RUN REPORTS WITH REPORT GENERATOR (RG) – WHO, WHEN, WHICH, WHY

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RUN REPORTS WITH RG – WHO AND WHEN

Report Generator should be used as much as possible during the entire Dossier lifecycle and in support to the DAR/RAR preparation:

a) To check if IUCLID Datasets are complete during compilation (**Applicant**).

b) To check if IUCLID Dossiers information is complete and consistent during admissibility (**RMS**) – a dossier update might be needed before proceeding to the next steps.

c) Use all available reports in RG to prepare DAR/RAR (**RMS**): this will ensure consistency of information among the Assessment Report and the IUCLID Dossier.

RUN REPORTS WITH RG – WHICH

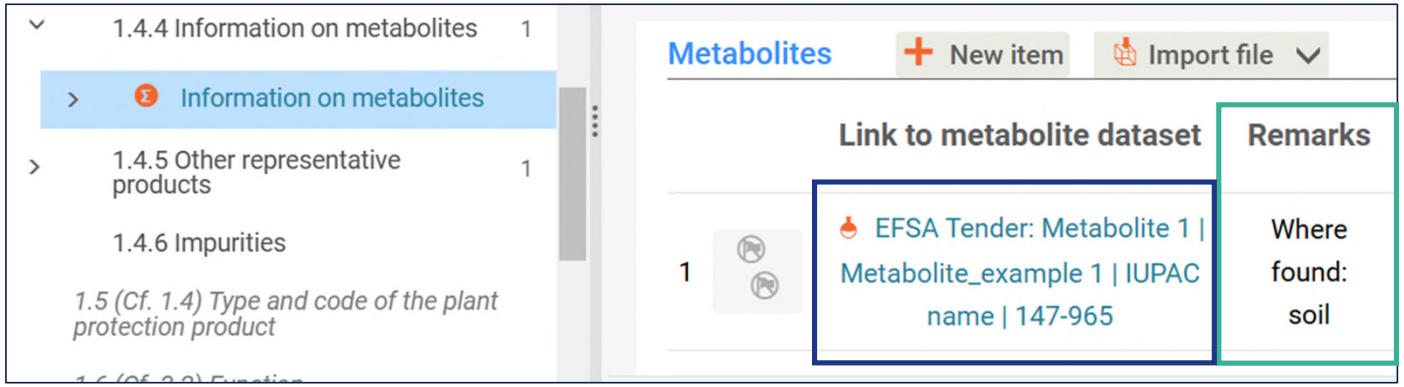
The below reports (at least) are recommended to be used during the admissibility check and in the preparation of the DAR/RAR:

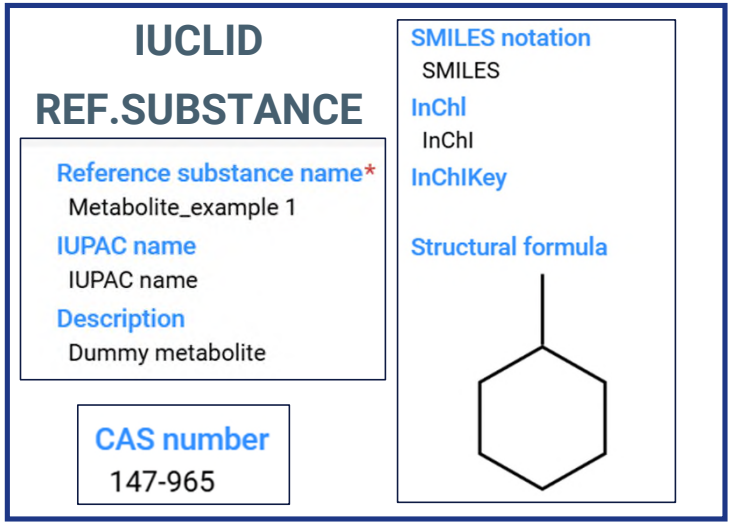
- **GAP Table** (mandatory) – new GAP mapping file will be published in Zenodo in May 2025 following next IUCLID release. A video demonstration on how to use this report will be presented in the final slide.
- **List of Substances and Metabolites** – fill in the “Remarks" field to populate the column “Compound found in” in the report (see next slides).
- **Table of Analytical Methods** – use the cross-reference function to ensure a method is included in the report (see next slides).

Refer to Agenda item *6_“IUCLID report generator updates”* to check the status of other reports.

RUN REPORTS WITH RG – LIST OF SUBSTANCES AND METABOLITES

IUCLID METABOLITES DOCUMENT





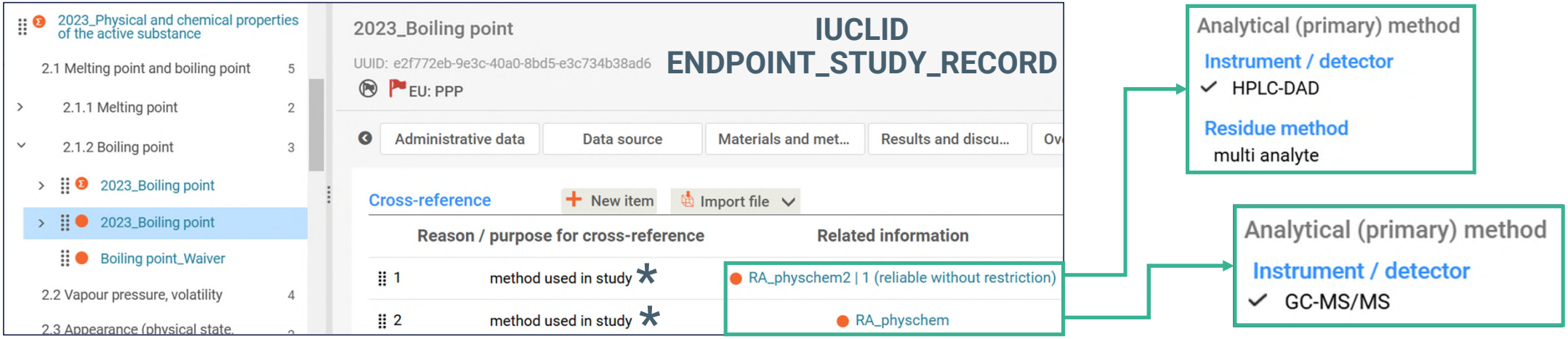
Report

1. Substances and metabolites: structures, codes, synonyms

Table 1.1.

Name and CAS number	IUPAC name, SMILES, InChi	Structural formula	Compound found in
EFSA Tender: Metabolite 1 (ref.: Metabolite_example 1) 147-965	IUPAC name SMILES InChI		Where found: soil

RUN REPORTS WITH RG – TABLE OF ANALYTICAL METHODS



1. Table of Analytical Methods (Appendix D)

Report

Table 1.1. Analytical Methods

#	IUCLID section	Author, date	Study title	Analytical method Author, date, No.	Technique, residue method, LOQ of the method, validated working range	Method meets analytical validation criteria	Remarks	Acceptability of the method
1	2.1.2 Boiling point	Author, 2023	Technical BC: physical and chemical characteristics	1. Me M., 2021, Analytical method physchem 2 2. Serafimova R., 2021, Analytical method physchem1	1. **Primary**: • Instrument: HPLC-DAD • Residue method: multi analyte • LOQ: ISO name active substance BC = 0.07 mg/kg 2. **Primary**: • Instrument: GC-MS/MS • LOQ: ISO name active substance BC = 0.01 mg/kg	1. not specified 2. yes	1. unclear	1. 1 (reliable without restriction)

RUN REPORTS WITH RG – WHY

- **RMS** is reminded to ensure alignment among the information which will be included in the DAR/RAR and the information contained in the IUCLID dossier. The DAR/RAR preparation should start from all available reports. Therefore, we recommend to make full use of the IUCLID Report Generator functionality.

- **EFSA** will ensure alignment among the DAR/RAR and the IUCLID dossier before entering the peer-view phase.

Missing info in this GAP example

- MS/Country codes (therefore assumed to be all EU)
- Crop location according to EPPO codes (F/G/I)
- Formulation Type
- Re-treatment interval in days (min-max)
- Concentration a.s. in dilution (min-max)
- Pre-Harvest Interval in days