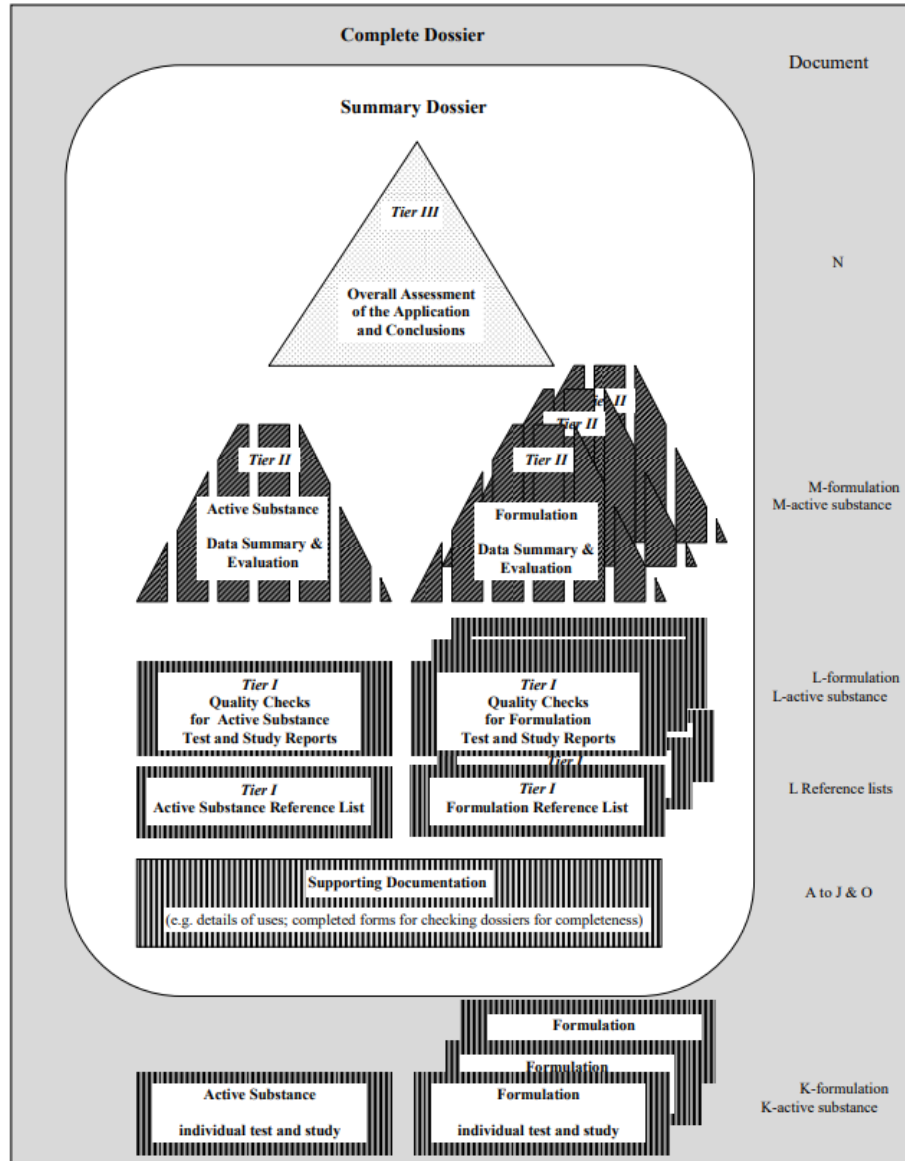


# IUCLID in practice: format and features

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## DOSSIER STRUCTURE AND CONTENT



## IUCLID Dossier



Active substance



Mixture

Submission Type: EU PPP Active substance information



1. Identity of the active substance	8
2. Physical and chemical properties of the active substance	72
3. Further information on the active substance	8
4. Analytical methods	56
5. Toxicological and metabolism studies on the active substance	93
6. Residues in or on treated products, food and feed	61
7. Fate and behaviour in the environment	56
8. Ecotoxicological studies on the active substance	93
10. Classification and labelling of the active substance	3
11. Summary and evaluation	11

## Table of content

- 6 Residues in or on treated products, food and feed 12
- 6.1 Storage stability of residues 3
- 6.2 Metabolism, distribution and expression of residues 3
- 6.2.1 Metabolism of residues in plants and in rotational crops 2
- Metabolism of residues in plants and in rotational crops.001
- Metabolism of residues in plants and in rotational crops.002
- 6.2.2 Metabolism of residues in livestock 1
- 6.3 Magnitude of residue trials 1

View Dossiers

UUID: e1067a6c-ad1a-408e-a1bd-b6b190d05166

### Administrative data

None None

**Endpoint**  
None

**Type of information**  
None

**Adequacy of study**  
None

Robust study summary

Used for classification

Used for SDS

**Study period**  
None

**Reliability**  
None

**Rationale for reliability incl. deficiencies**  
None

**Data waiving**  
None

**Justification for data waiving**  
None

**Justification for type of information**

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View Dossiers Go to search

UUID: 92c1bbe0-1a2b-4627-a831-e90c6120c639 Hide empty

### Administrative data

None None

### Description of key information

None

**Primary crops**

#.	Cro...	Co...	Tre...	Ap...	DAT	L

**Rotational crops**

#.	Crop gr...	Comm...	PBI	Link

### Additional information

None

**Attached background material**

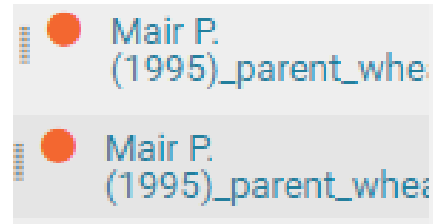
#.	Attached document	Remarks

**Attached (sanitised) documents for publication**

None

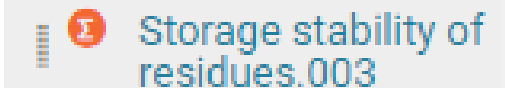
## ■ **Study records:**

- Attached pdf documents (full & sanitized)
- Structure template when available (e.g. OECD harmonised templates (OHT))



## ■ **Summary records (Endpoint summaries)**

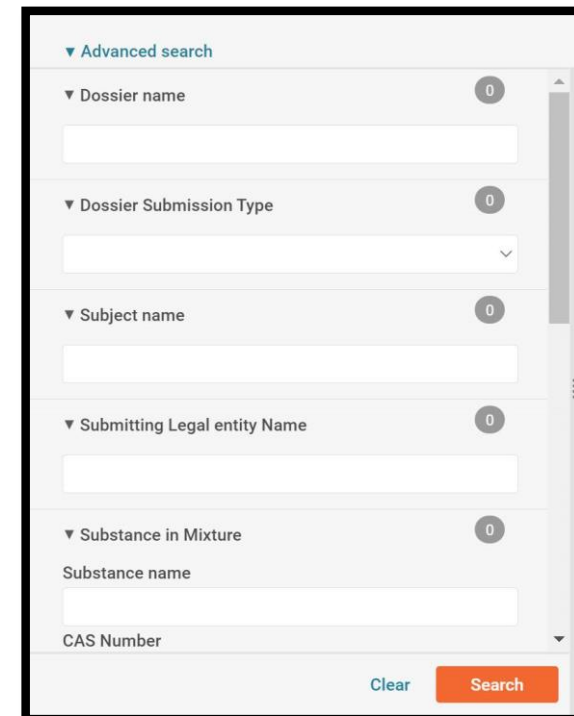
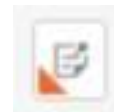
- Reuse of the existing (e.g. tox)
- Creation of new templates based on the LOEP (e.g. residues)



## ■ **Harmonisation** based on current terminologies:

- Use of picklist (e.g. EPPO codes, food classification Reg 396/2005)
- One similar structure for the GAP table in all dossiers

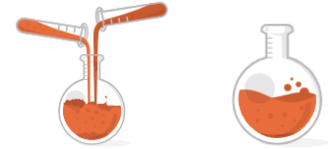
- Validation assistant rules and configuration
  - Check presence of a required document (depending on submission type)
  - Quality check for in document completeness (simple rules)
- PDF creation for each component of the dossier (full dossier in development plan)
- Search for entities and documents (e.g. search dossiers, advanced search)
- Indicate latest dossier/ comparison of the versions of the dossiers
- Filtering of confidential information
  - Dissemination preview
- Commenting/Annotations (to be further developed)



The screenshot shows the 'Advanced search' interface with the following fields and controls:

- ▼ Advanced search (header)
- ▼ Dossier name (0) [input field]
- ▼ Dossier Submission Type (0) [dropdown menu]
- ▼ Subject name (0) [input field]
- ▼ Submitting Legal entity Name (0) [input field]
- ▼ Substance in Mixture (0)
  - Substance name [input field]
  - CAS Number [input field]
- Clear button
- Search button

# Format for reporting GAPs in IUCLID



- Define **data elements/parameters** that are required to describe the GAP;
- One generic format for describing the GAP was developed that can be used for **chemicals** and **microbials**.
- The same GAP format is used for the different submission types
  - **a.s. dossiers** to describe the GAP for the representative formulation/representative use
  - **authorisations of ppp**
  - dossiers for **MRL applications** (also independent from approval/authorisation requests, such as import tolerances).
  - Development of **picklists** for certain parameters (harmonised terminology to describe the use in an unambiguous way)
    - Use picklists that are already available that can be used without further adaptation (e.g. [EPPO codes](#));
    - If no generally accepted picklists are available, new picklists were developed
- Format should be compatible with **PPPAMS**

- Ensure that all information required for the different types of assessments are reported either in the GAP form or in other sections of the IUCLID dossier.
- Instead of a comprehensive document describing all GAPs for the application (“GAP table”), it was agreed to develop a GAP format that would describe the individual GAPs (“**GAP forms**”):
  - if the application covers 3 GAPs, 3 separate documents for each individual GAP would be required.

# DEMO IUCLID for PESTICIDES