CP Carmen Pana

IUCLID for regulators

This course is meant for :
- evaluators assessing pesticide dossiers under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and in accordance with the new requirements of the Transparency Regulation;
- new active substances and renewals for chemicals and microorganisms, MRL applications, and basic substance applications

Lesson 1 of 3

Accessing EFSA Agency IUCLID

CP Carmen Pana

1

Welcome to ECHA Cloud Services

Who are we?

ECHA Cloud Services is a secure online platform used to distribute ECHA's IT applications into a private cloud environment.

The service is built within ECHA's IT infrastructure. The use of encrypted communication, regular security audits and updates of all the components ensures that your cloud data is safe and cannot be accessed by anyone else.

Why should you use ECHA Cloud services?

ECHA Cloud services offer you:

- Access from anywhere, anytime, to the latest release of the IUCLID application, maintained by ECHA;
- Regular and automated data backups by ECHA;
- Easy online collaboration;
- Responsive and 24/7 online support;

How to access ECHA Cloud Sevices

The following steps will guide you through the registration process to create an ECHA industry account for subscription to IUCLID Cloud Services.

ECHA authority Legal Entities and accounts cannot be used to access EFSA Agency IUCLID. They can only be used to access the ECHA secure area, e.g. biocides dossiers.

Step 1

Step 1: How to register to ECHA Cloud Services

The organisation legal entity manager does the registration.

The user must complete the following steps:

1. You need to sign a confidentiality statement

2. You will receive an e-mail requesting validation of your account

3. These credentials should be used to access EFSA Agency IUCLID via ECHA cloud services

Step 2

Step 2: How to reach ECHA Cloud Services

Regulators can access the IUCLID agency using this link:

https://ecs-efsa.echa.europa.eu/cloud/home.html

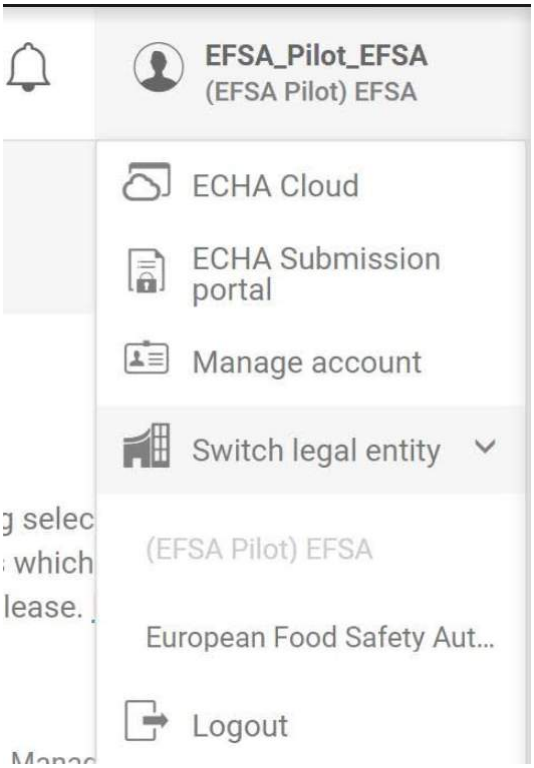
Note! The connection depends on the type of VPN connection your organisation has in place.

It might be necessary to use Cisco AnyConnect sslvpn.efsa.europa.eu before accessing the web link.

If this is the case, see the four steps in the next section.

Step 3

Step 3: Switching foreign entity



To access EFSA Agency IUCLID, you need to switch to the European Food Safety Authority legal entity.

Step 4

Step 4: Access EFSA Agency IUCLID

Click 'Access Service' to enter the EFSA Agency IUCLID

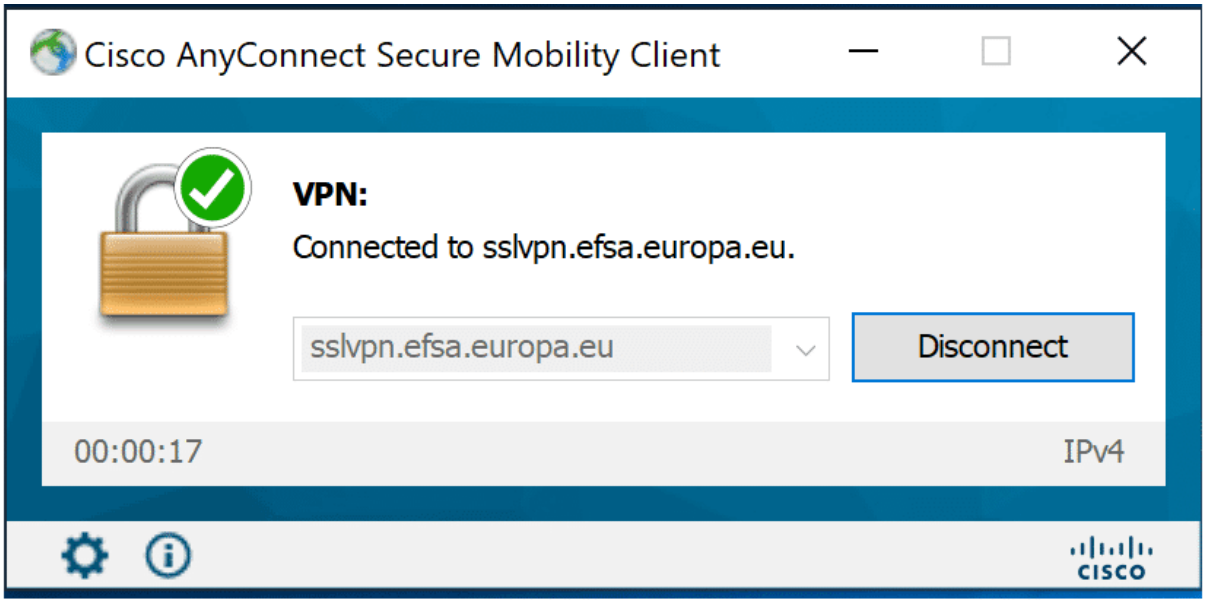
How to connect by VPN if you don't have direct access via the URL

Agency IUCLID is a secure instance of IUCLID hosted on ECHA cloud services.

All valid dossiers received via the Submission portal will be accessible from this instance.

Step 1

Connect via VPN

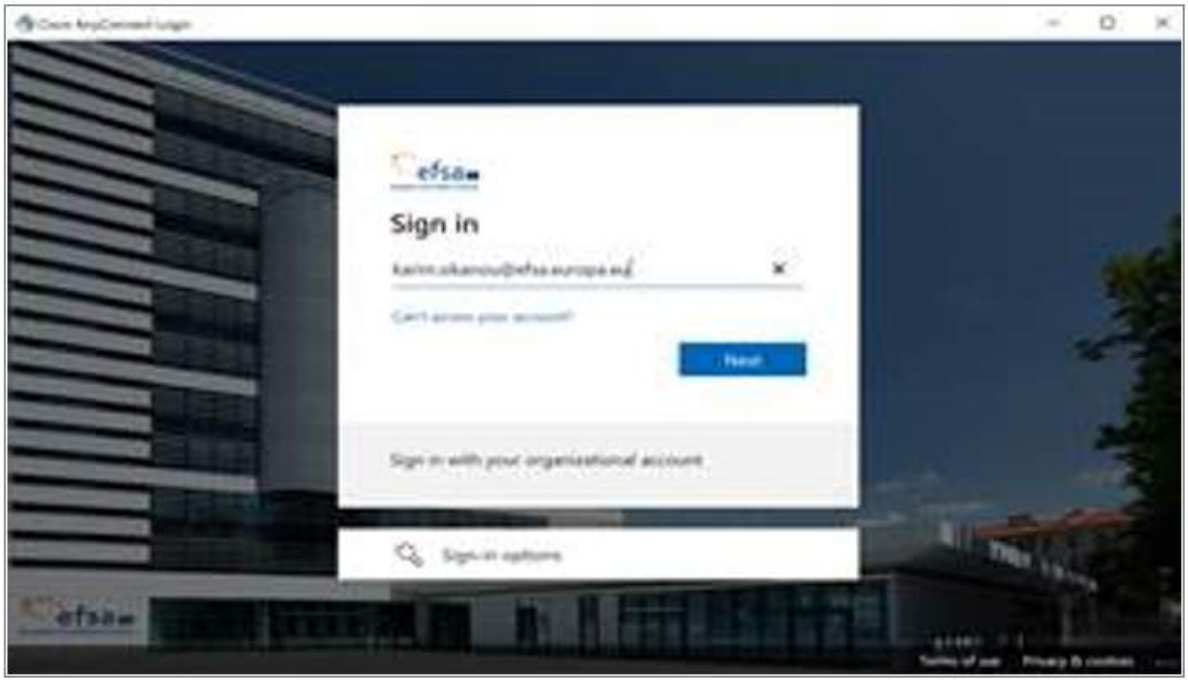


Open Duo/Cisco Any connect secure ... aplication

- Copy/Paste: sslvpn.efsa.europa.eu
- click Connect

Step 2

Log in with your EFSA email address



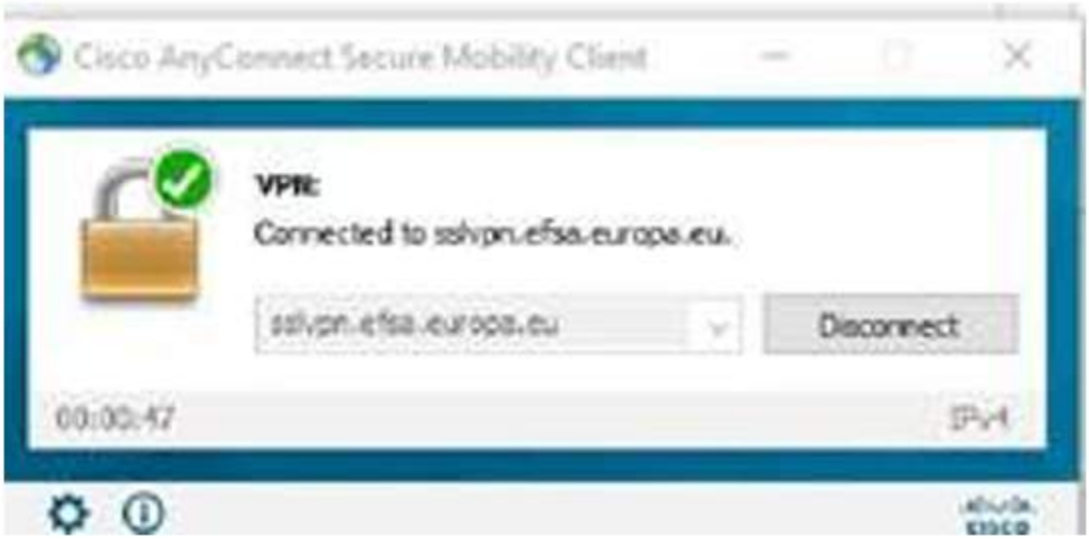
Click Next

Step 3

Enter Password and Sign in

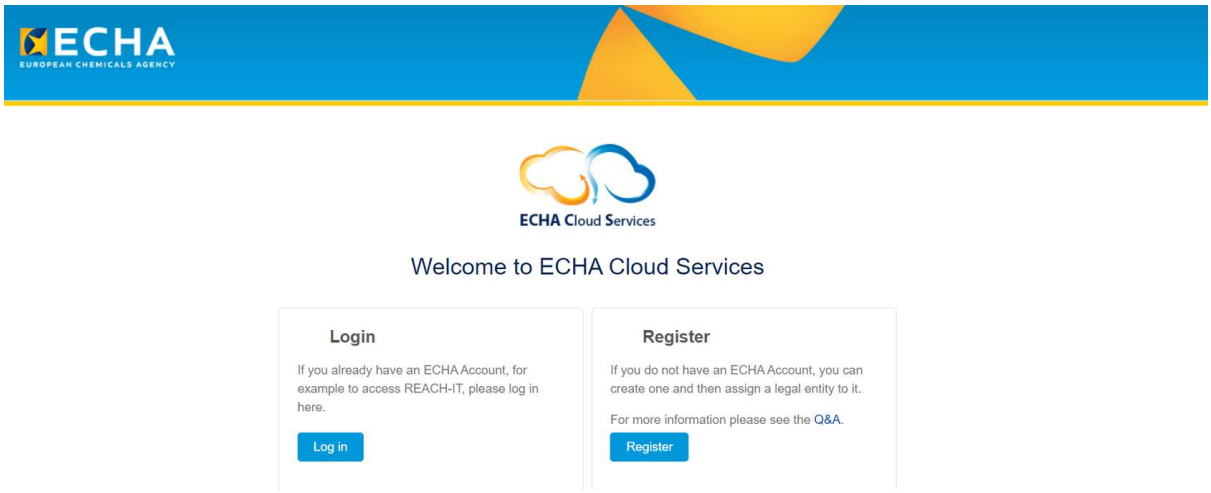
Step 4

You are connected



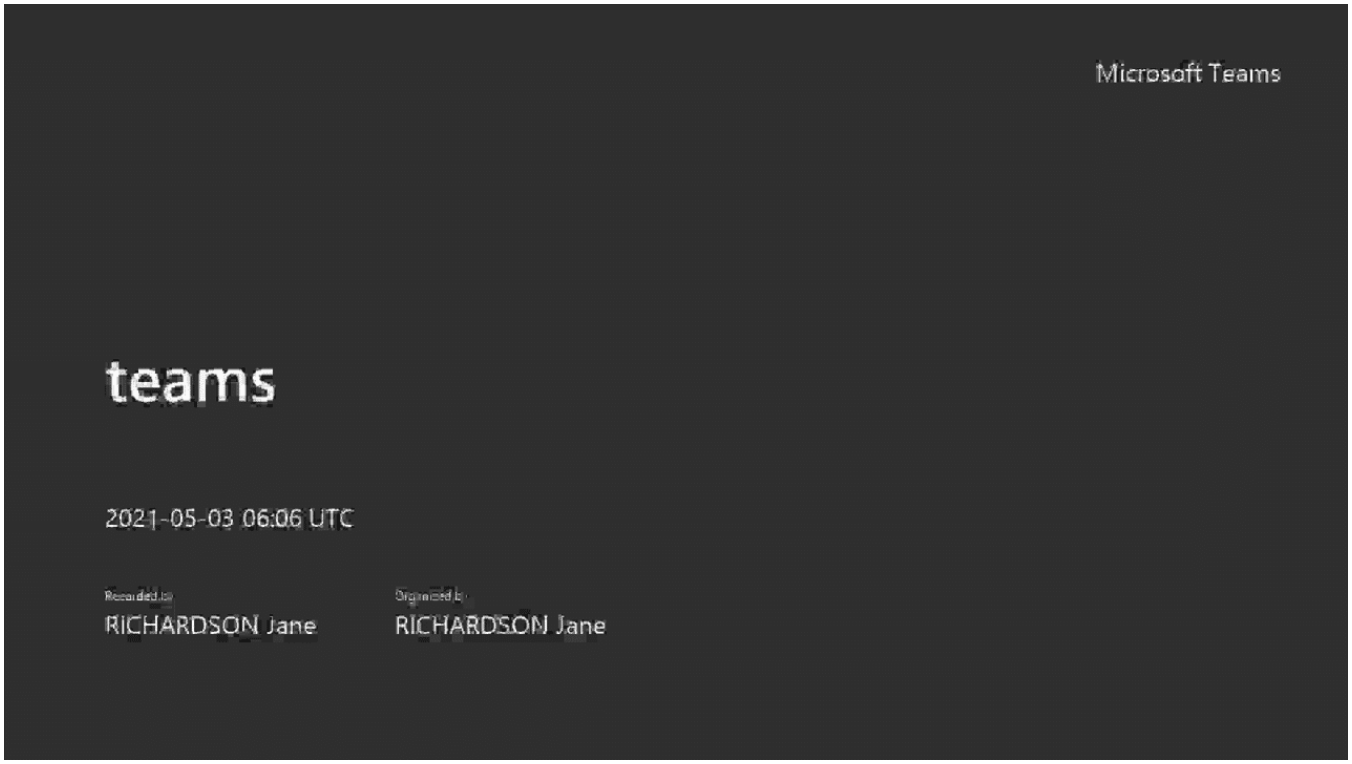
Step 5

Login to ECHA accounts



Copy link: https://ecs-efsa.echa.europa.eu/cloud/home.html

Login demo

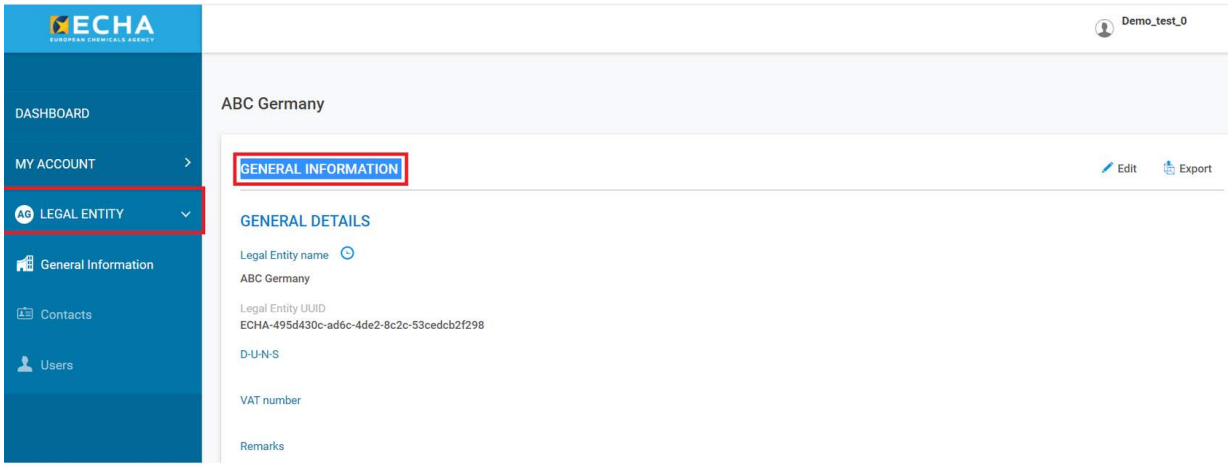


Legal Entity Management

Understanding the purpose of a Legal entity

- **A Legal entity is the organisation** for which the user is working. Applicants also have legal entities and the legal entity (owner, lead applicant) for a submission can be viewed in the dossier header.

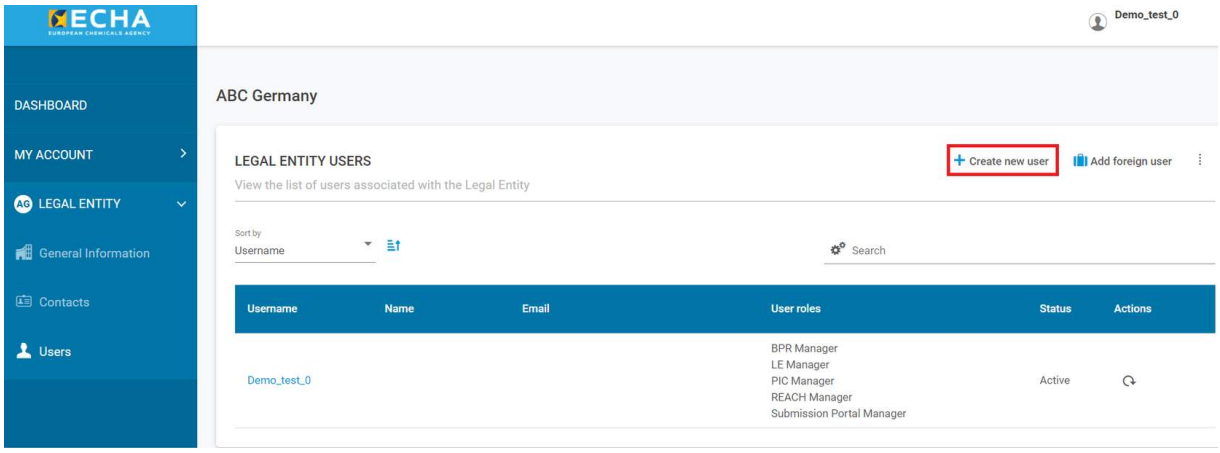
- Once the Legal entity has been created, it is important to maintain **accurate Legal entity information** and **keep them updated**. It is important **to remove users** when they **leave the organisation** or **move to a role** that does not require access to pesticide dossiers.



User Management

The cloud bar (on the top of the screen) contains a menu with several functionalities, including **MANAGE ACCOUNT**! This is where you can manage all information regarding your Legal entity account.

From here, you can **add new users, edit users' account details and assign specific roles** to them.
*Note: to add a user, the person must already have an **ECHA account**.*



Click the link below to access the guided tutorial.

[How to create users in a Legal Entity (company) as a Legal Entity Manager]

Types of users

EFSA will add the MS Office 365 software package users as foreign users to the EFSA legal entity. To do this, the following information is required:

- the Legal Entity UUID of the competent authority
- the username
- a signed confidentiality statement
- the role of the user

Two types of users are foreseen:

- **Viewer** - can view all submitted dossiers
- **Evaluator** - can also use the IUCLID tools such as validation assistant, compare, report generator and annotation.

Lesson 2 of 3

Key concepts of an IUCLID dossier

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Objectives

Throughout this module, you will get familiar with the following concepts:

1. Welcome to IUCLID Cloud Services
2. IUCLID format
3. Key concepts of an IUCLID dossier
4. Dossier header
5. Datasets
6. Document types
7. Endpoint study records
8. Endpoint study summaries
9. Crosswalks IUCLID 6.5 EU PPP Active substance application (product) to KCA&KCP

1

Welcome to IUCLID Cloud Services

What is IUCLID?

IUCLID (International Uniform Chemical Information Database) is the software used to record, store, maintain and exchange data on chemical substances' intrinsic and hazardous properties. It is a key software application for regulatory bodies and the chemical industry used to implement various regulatory programmes.

What is IUCLID used for?

IUCLID is built as a platform meant to provide regulatory authorities and industry with tools to manage information on chemicals, using a common format, facilitating the reuse and exchange of the data.

2

IUCLID format

- Commission Implementing Regulation (EU) 2021/428 of 10 March 2021 adopting standard data formats for the submission of applications for the approval or the amendment to the conditions of approval of active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council (Text with EEA relevance) http://data.europa.eu/eli/reg_impl/2021/428/oj
- Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012 (Text with EEA relevance) http://data.europa.eu/eli/reg_impl/2020/1740/oj
- Administrative guidance on the submission of dossiers and assessment reports for the peer-review of pesticide active substances and the maximum residue level (MRL) application procedure https://www.efsa.europa.eu/en/supporting/pub/en-6464
- Transparency Regulation
- All pesticide dossiers will be submitted in IUCLID format starting from March 27 2021. The relevant legislation, administrative guidance and practical arrangements can be accessed from the links below:

https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation

https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

Important!

- **Submissions must be in IUCLID format and submitted via the submission portal**
- **The IUCLID documents must be completed**
- **The attachments indicated in the manuals must be included**

Key concepts of an IUCLID dossier

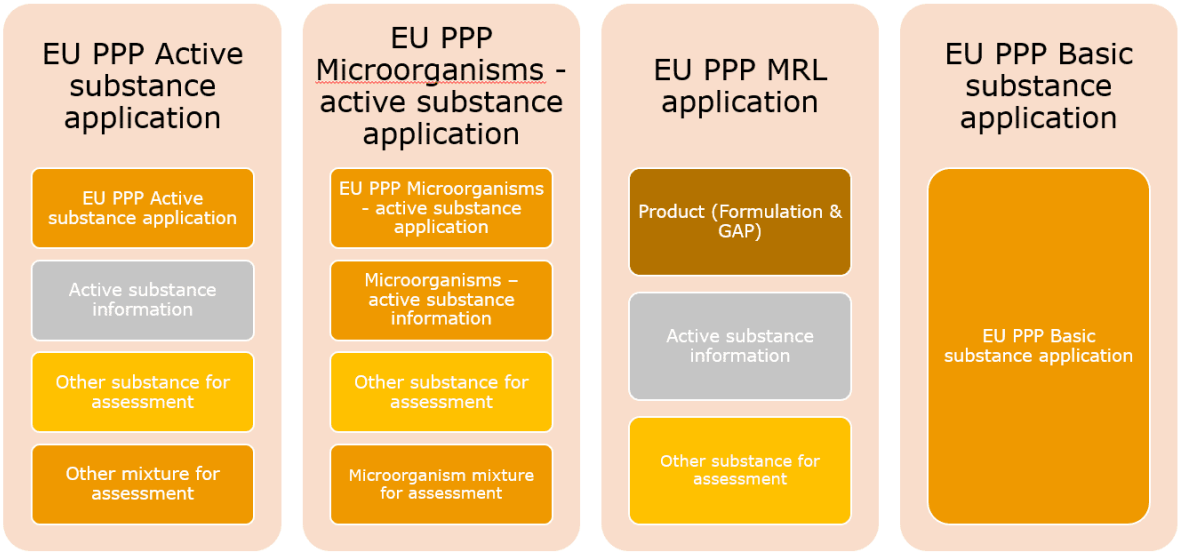
1. A **dossier** is the complete package of evidence for an active substance submitted for evaluation. It can contain administrative data, studies performed on the product, studies performed on the active substance, studies performed on metabolites or impurities, summaries and risk assessments.

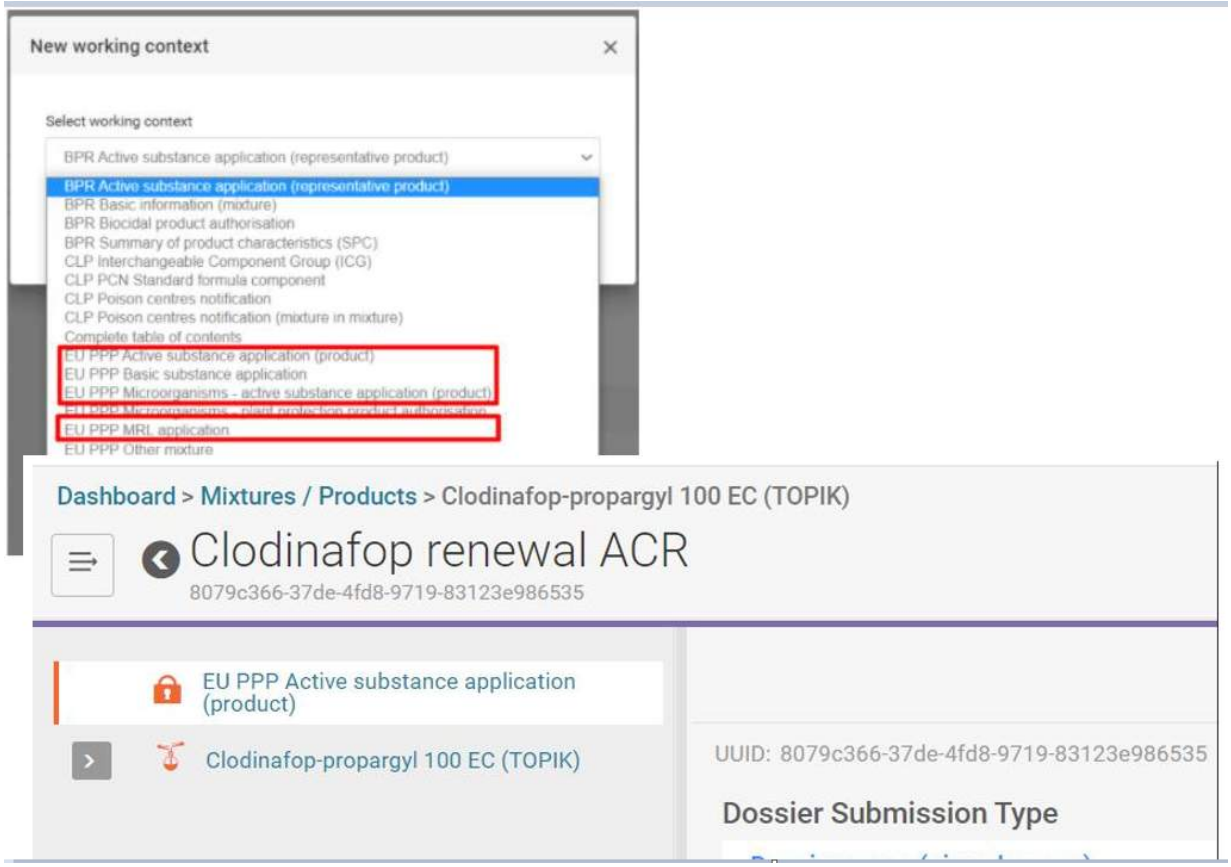
2. Each **data requirement** can be covered by one or more **IUCLID documents** plus attachments with supporting information, e.g. full study report or PRIMO excel template.

3. A dossier **cannot be edited,** but there are many tools available to support the assessment of dossiers in IUCLID.

Working context

The working context defines the format for regulatory dossier submission. The table of contents and the IUCLID documents, and the dossier header are all defined by the working context.





Selecting working context

The working context includes the Table of Contents and the IUCLID documents needed to meet the regulatory data requirements.

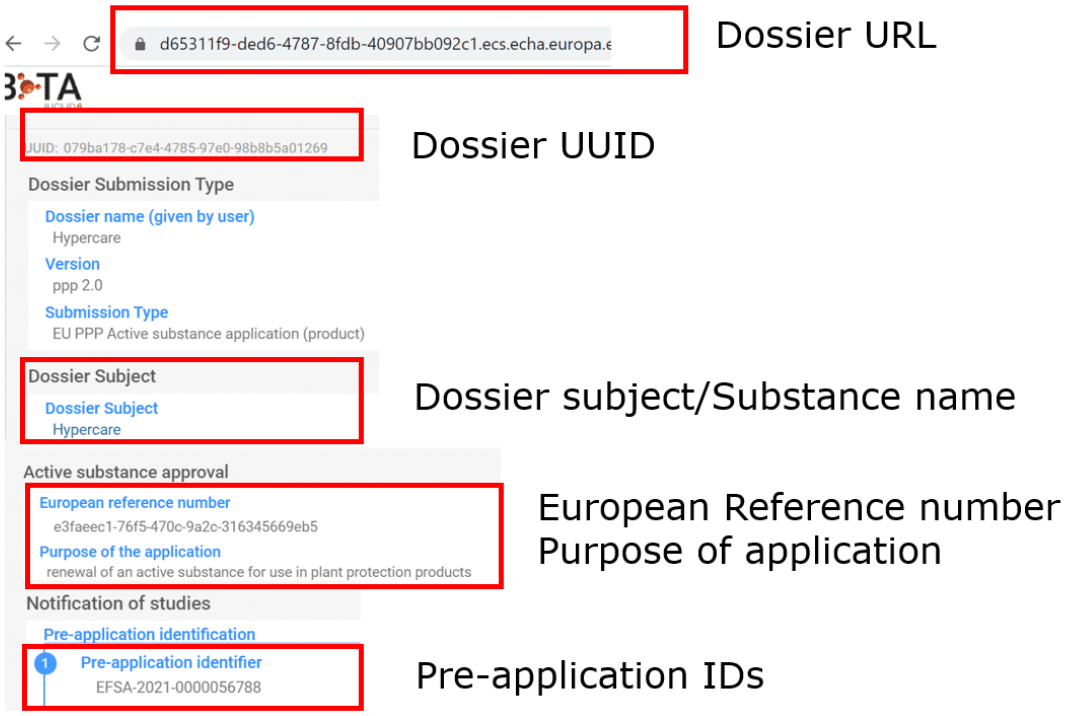
Dossier header

A **Dossier header** is a set of fields used to store administrative information relevant to data submission under a particular regulation.

The dossier header specifies the regulatory context and the purpose of the application.

The information from the dossier header should be used for communication about the status of the dossier/evaluation.

The following information from the dossier header must be included in the email notification to EFSA:



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"Pre-application ID" is shown only in case a study was pre-notified

What is a dataset?

A **dataset** is a **collection of documents** related to a particular chemical substance or grouping of chemical substances/micro-organism. It can be of the following types: Substance, Mixture/Product, Template.

A **dataset** is based on the regulatory data requirements and contains a Table of Contents so that the relevant documents can be found and viewed.

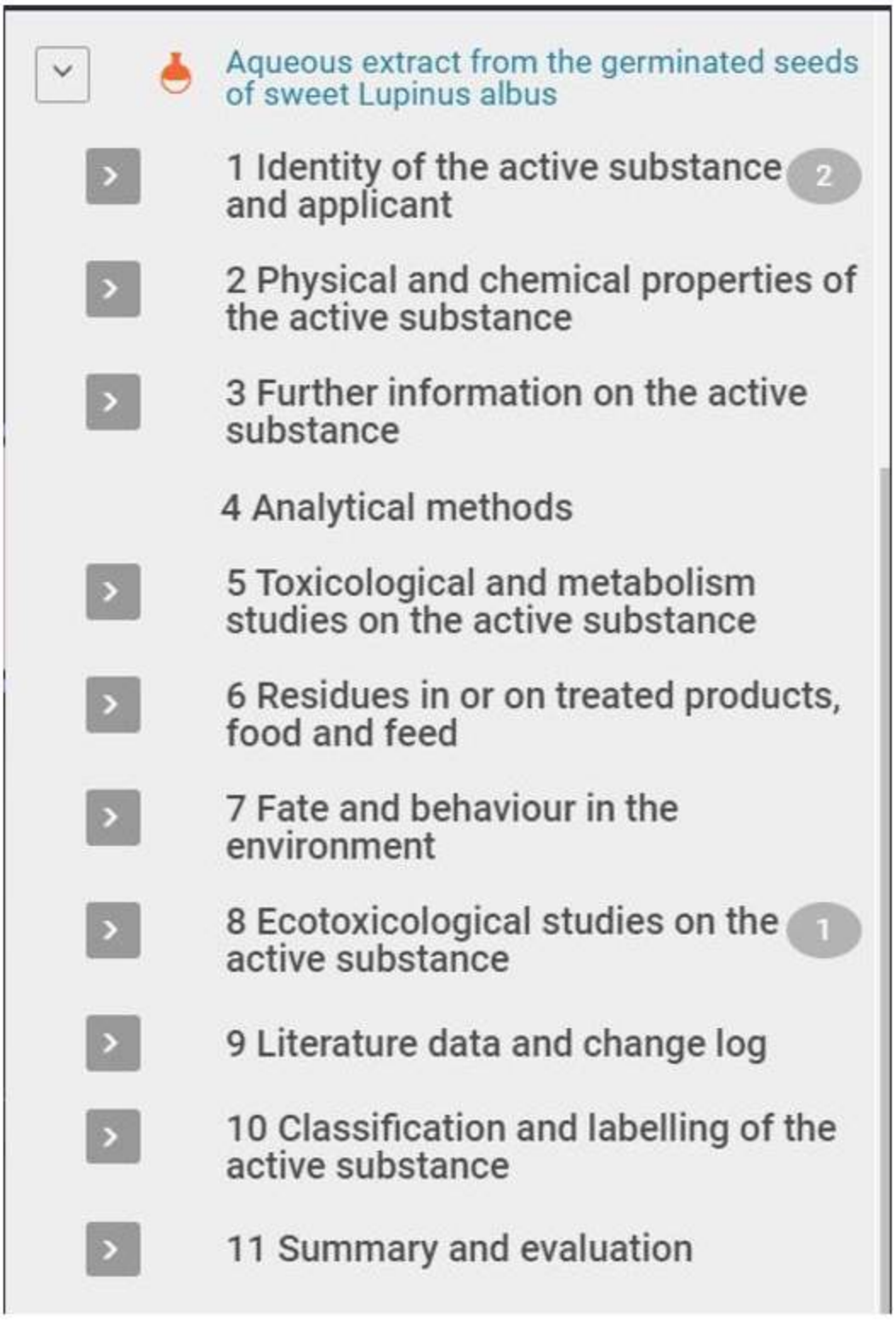
Mixture/Product dataset

A **mixture/product dataset** is a type of entity in IUCLID which stores information about the product or preparation. The table of content is defined by Regulation (EU) No 284/2013 of 1 March 2013, setting out the data requirements for plant protection products.

Either Part A or Part B depending on the working context. All studies performed using the product/preparation as the test material should be reported in this dataset.

A mixture/product can be **accessed** from the **Dashboard and the Main menu.**

Datasets



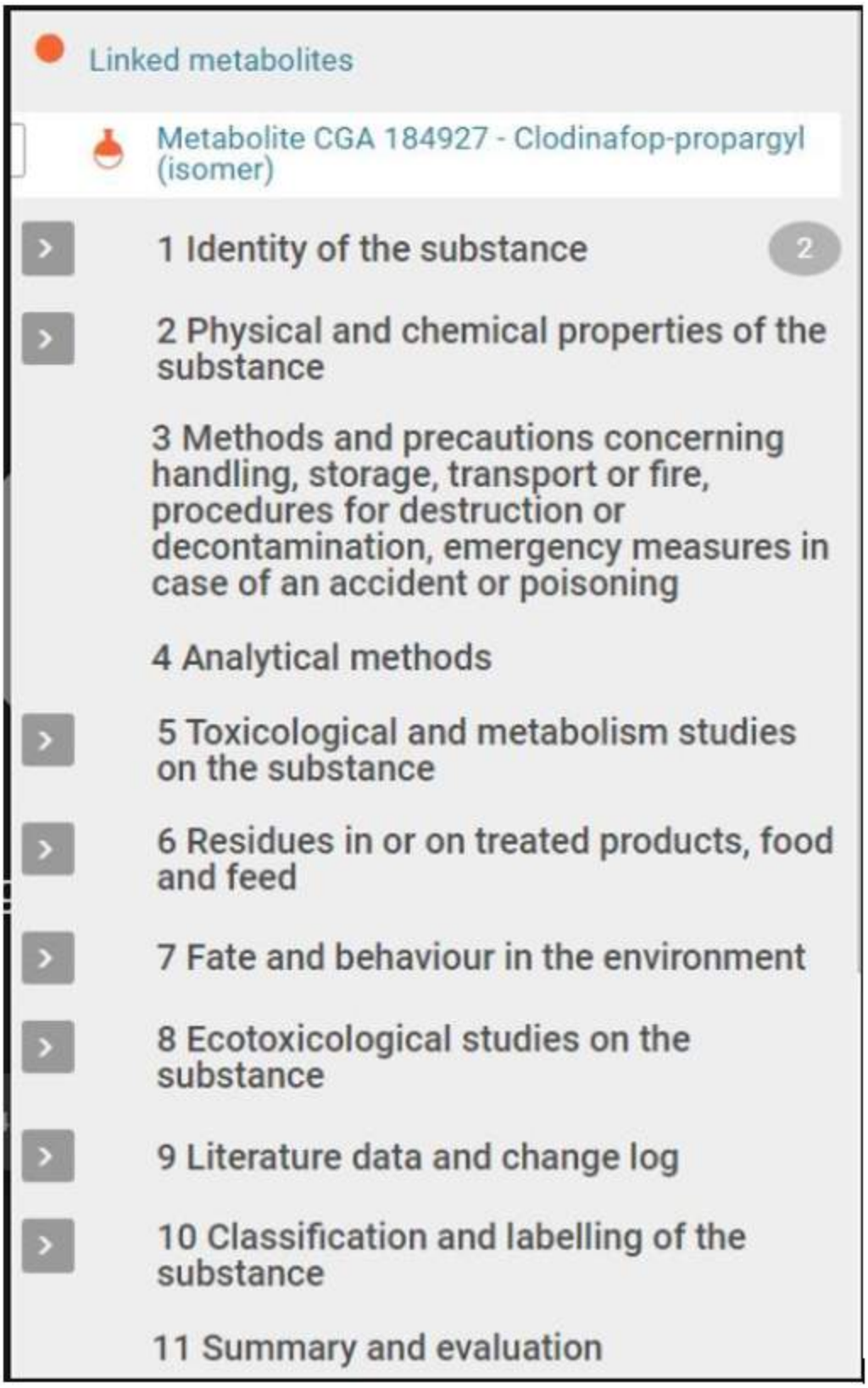
Active substance dataset

The active substance dataset is a type of entity in IUCLID which stores information about a chemical or micro-organism. The table of content is defined by **Regulation (EU) No 283/2013 of 1 March 2013,** setting out the data requirements for active substances.

Either Part A or Part B depending on the **working context**.

All studies performed using the active substance as the test material should be reported in this dataset.

An active substance dataset can be accessed from the mixture composition document in the **mixture/product dataset.**

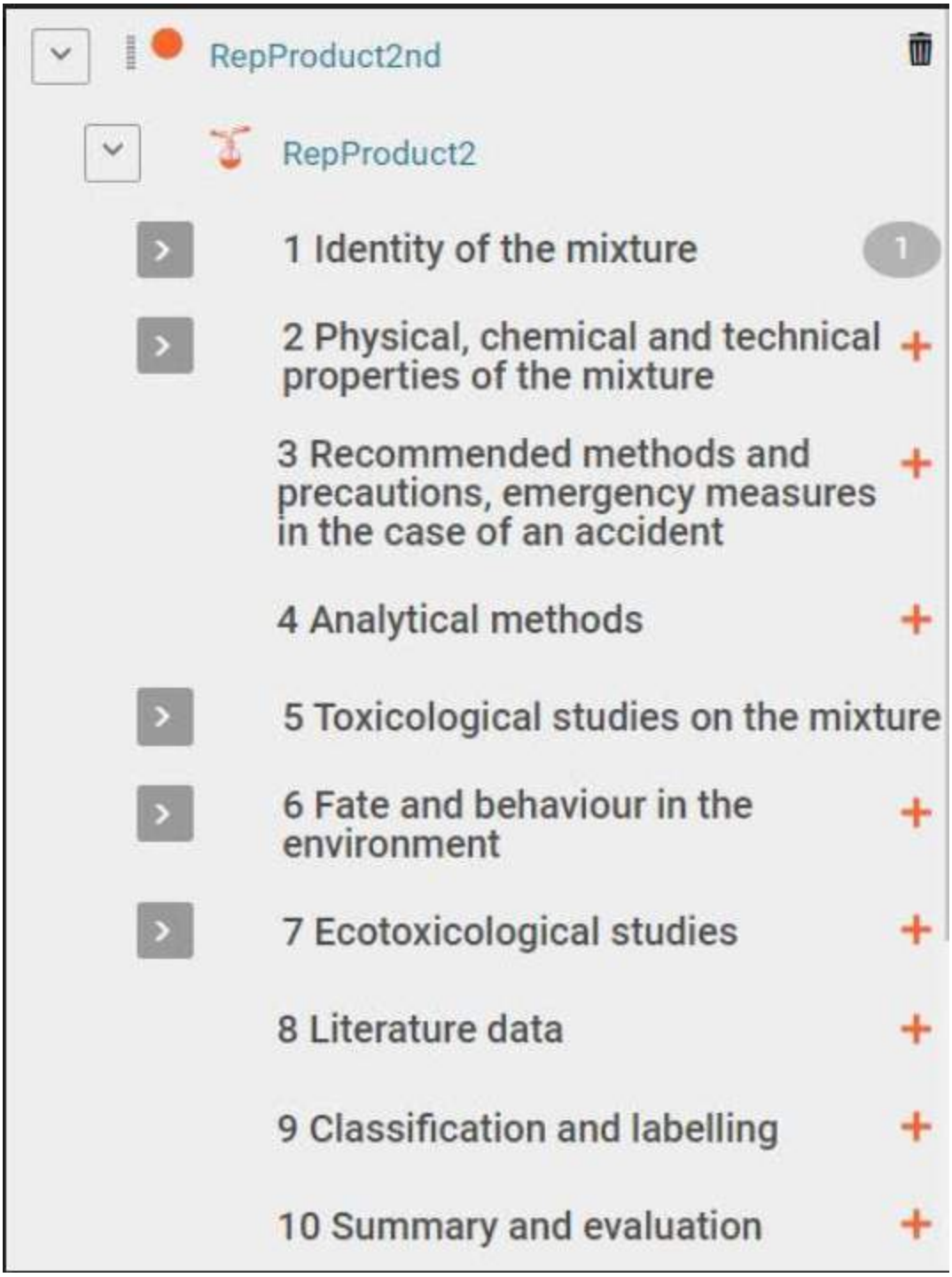


Other substance for assessment dataset

Other substance for the assessment dataset is a type of entity in IUCLID which stores information about metabolites, toxins, relevant impurities or other substances linked to chemical safety studies and included in the dossier.

The table of contents is a subset of the studies required for the active substance. All studies performed using the metabolite, impurity etc. as the test material should be reported in this dataset.

Other substance for the assessment dataset can be accessed from the mixture composition document in the mixture/product dataset or from the metabolites information document



Other mixture for assessment dataset

Other mixture for assessment dataset is a type of entity in IUCLID which stores information about other mixtures, e.g. an additional representative product.

The **table of contents** is a subset of the studies required for the mixture/product. All studies performed using the mixture, which is not the main/representative product as the test material, should be reported in this dataset.

An other mixture for assessment dataset can be accessed from the mixture composition document in the mixture product dataset.

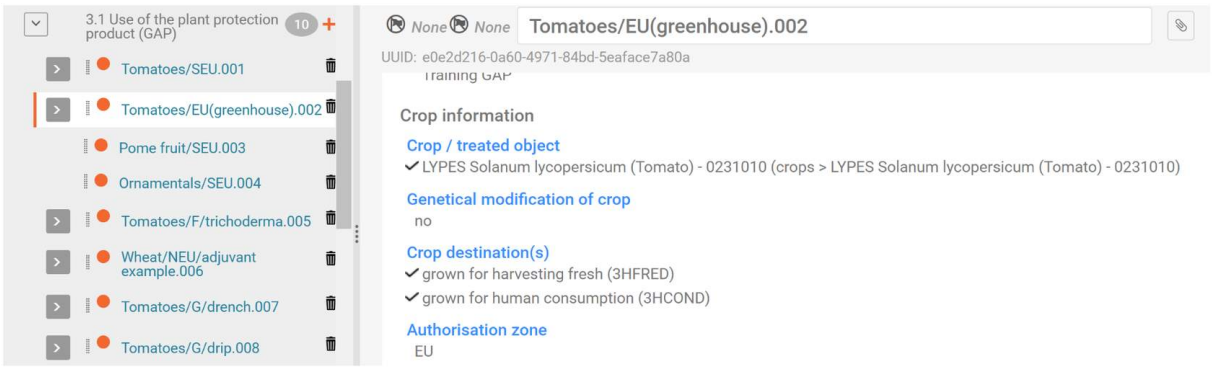
Document types

Fixed records

A **fixed record** is created in a section where there can be only one record.

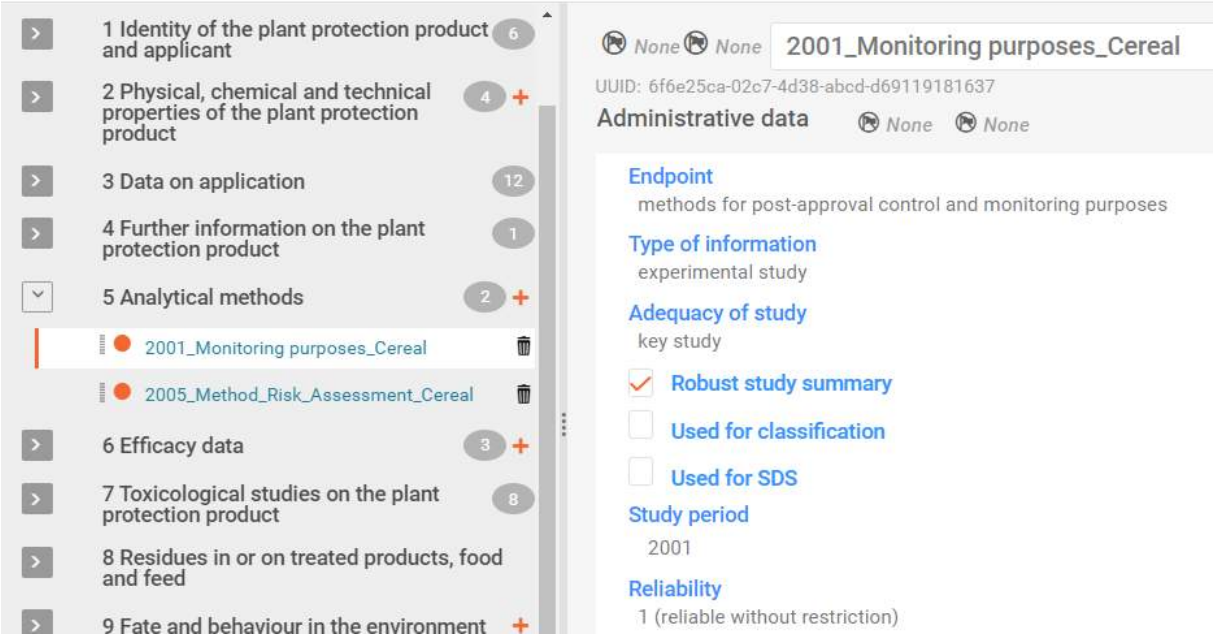
Flexible Records

A **flexible record** is created in a section where there can be more than one record.
Flexible records generally contain specific information for use in risk /hazard assessment which is not obtained from experimental studies. For example a product Use (Good Agricultural Practice), results of a Literature Search, Measures to be taken in case of accidents.



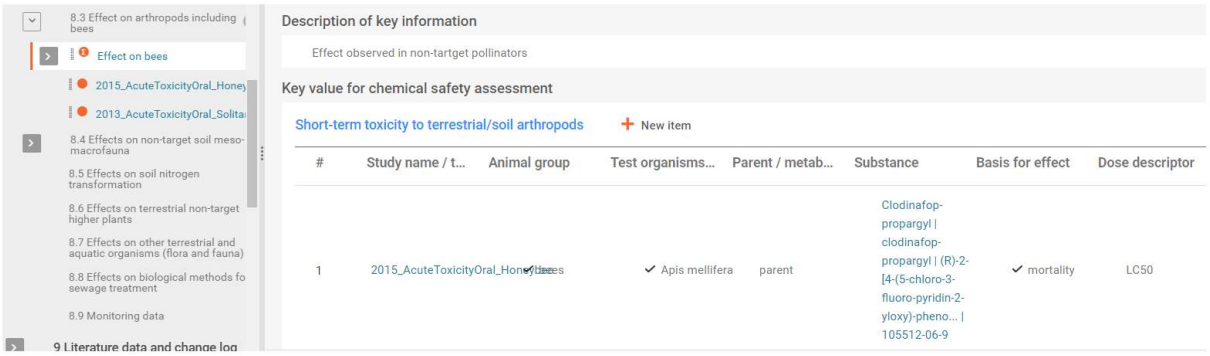
Endpoint Study Records

An **endpoint study record** provides a **template with predefined fields** in which data is entered to describe a study carried out within the subject area defined by the section's title.
All entries under the OECD (https://www.oecd.org/) harmonised templates are endpoint study records.



Endpoint Summaries

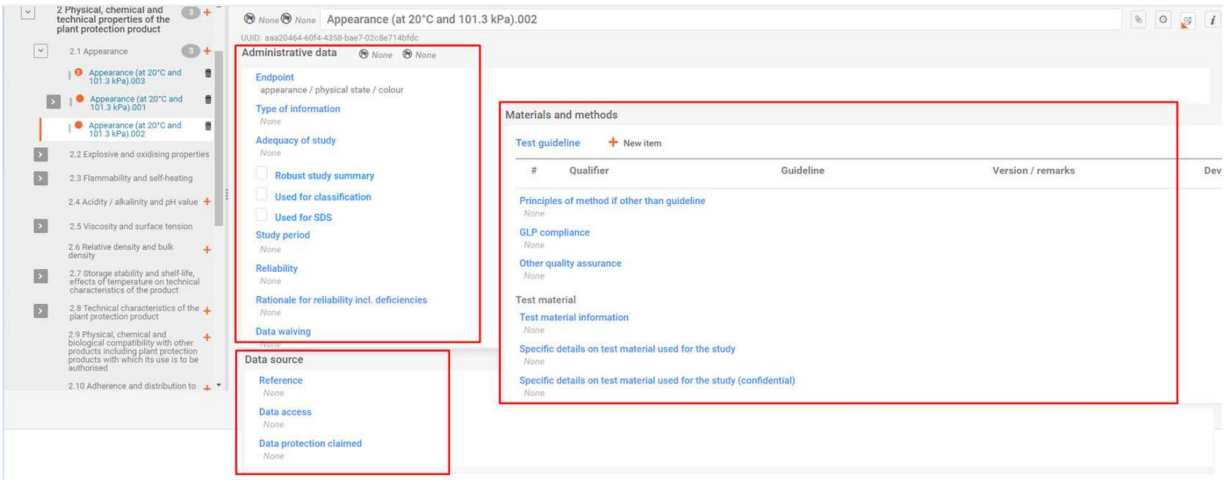
An **endpoint summary** presents the conclusion on the endpoint and key safety assessment values derived from the submitted endpoint study records.
An endpoint summary **contains links** to the endpoint study records in the field Link to relevant study records(s).



Endpoint study records

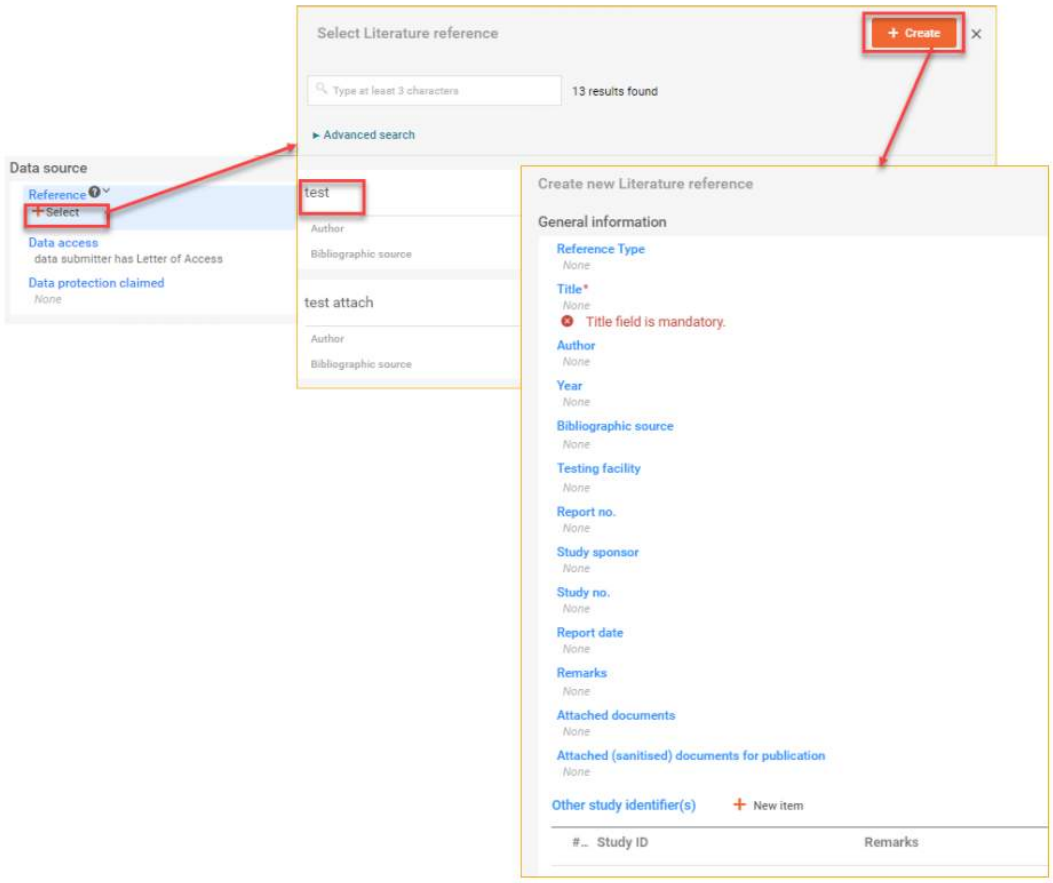
An endpoint study record provides a **template** with predefined fields where data is entered to describe a study carried out within the subject area defined by the section's title. All entries under the OECD harmonised templates are endpoint study records.

https://www.oecd.org/ehs/templates/



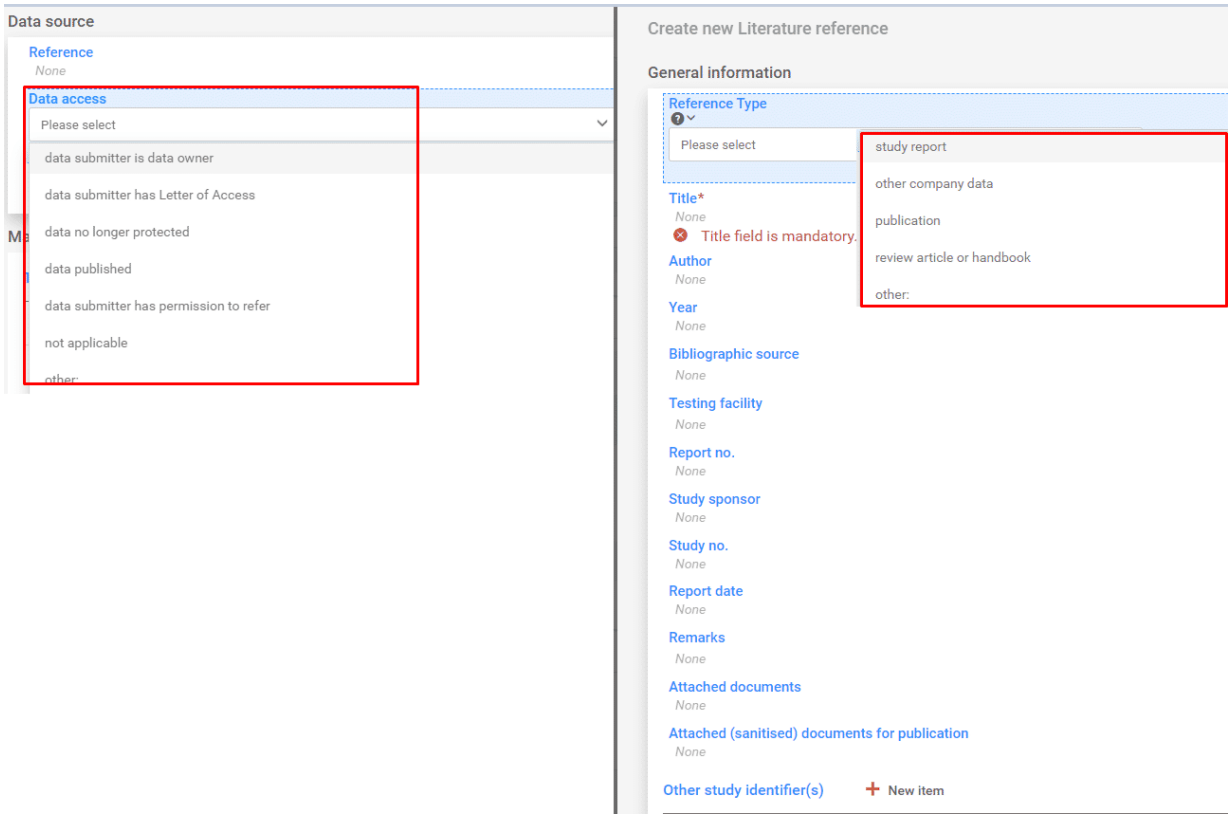
General information

Endpoint study records usually consist of the data entry blocks: '**Administrative data**', '**Data source**', '**Materials and methods**', '**Test material**'.



'Data Source' block

To indicate literature reference under **'Reference',** click **'+ Select'** in the field. The '**Select Literature reference**' page is opened. Search for the relevant reference and then click on the title; this will add the reference to your data source.



'Data Source' information

As a minimum, the following fields are required:

• Provide ‘Reference Type’

• Provide ‘Title’

• Provide ‘Author’

• Provide the ‘Year’ or the ‘Report date’

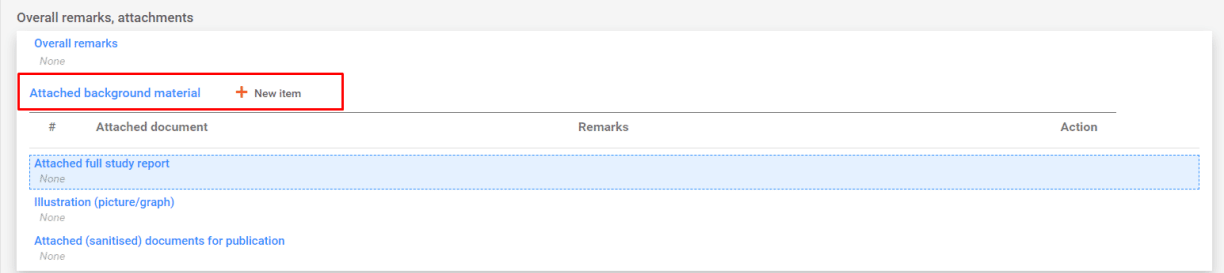
• If the data is from a literature source, fill in the field ‘**Bibliographic source**’

• If the data is from a testing laboratory, complete the field ‘**Testing facility**’. Provide the full address of the testing laboratory, including the city and country. In addition, provide either ‘Report no.’ or ‘Study no.’ and other relevant information.

• If the data is from a company, fill in the field '**Report no.**'. In addition, provide information in the fields '**Author**' and select in the field '**Reference Type**' value: other company data.

In the data source block, a selection must also be made from the drop-down menu '**Data access**'. If '**other**:' is selected, then the adjacent field must be filled in.

Note! The critical endpoints for each data requirement should be completed in these documents.

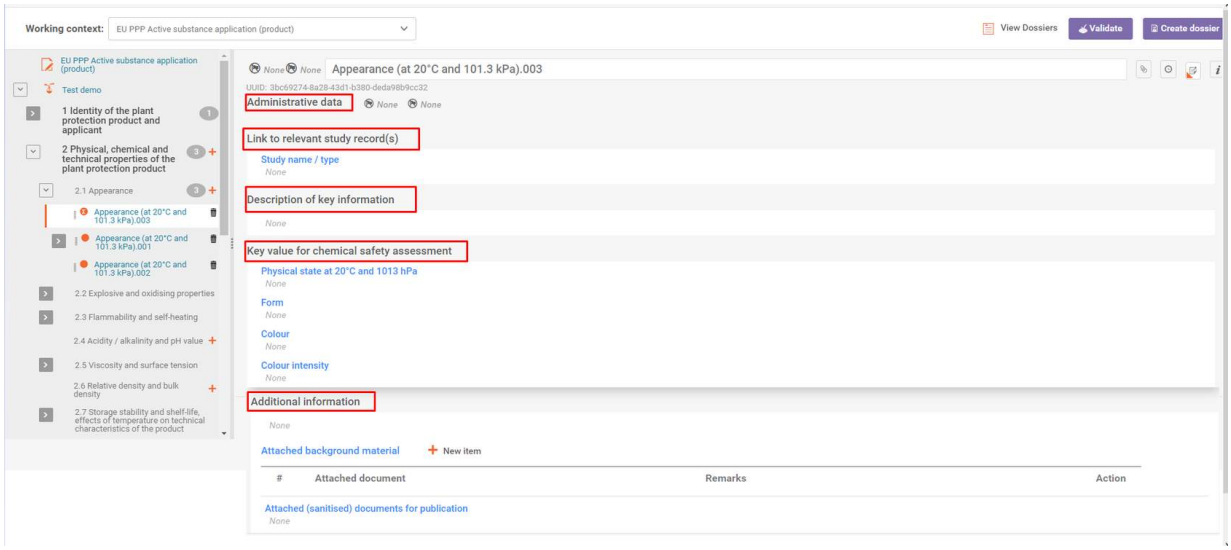


'Overall remarks, attachments' block

Supporting material such as result level data, models and calculations, excel tools and outputs from models should be available in the '**Attached background material**' sections

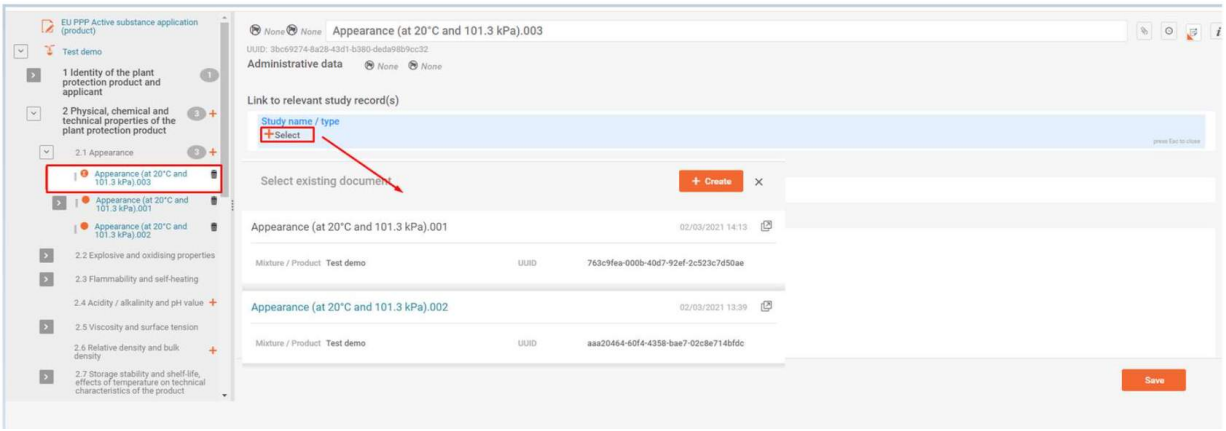
Endpoint study summaries

An endpoint study summary should summarise the evaluation made on all the data entered in the endpoint study records. An endpoint summary should **focus** on the most important **results and conclusions** and justify certain studies' use.



General information

Endpoint summaries usually consist of the data entry blocks: '**Administrative data**', '**Link to relevant study record(s)**', '**Description of key information**', '**Key value for chemical safety assessment**', and '**Additional information**'.



Complete the endpoint study summary

You can fill each field using the drop-down lists with pre-selected responses, add entries to the existing tables, or type text into the free text fields.

There is the possibility to link the summarised data to a specific endpoint study record. Achieve this by clicking the '**+ Select**' button and selecting the appropriate **endpoint study record** from the appearing page.

9

Crosswalks IUCLID 6.5 EU PPP Active substance application (product) to KCA&KCP

The Excel file provides detailed crosswalks from the E**U Table of Contents (SANCO/10181/2013)** for plant protection product (PPP) dossiers to IUCLID 6.5. It includes two spreadsheets, containing the mappings for active substance (as laid out in Commission Regulation (EU) No 283/2013) and representative product (Commission Regulation (EU) No 284/2013):

- **EU_PPP_ActiveSubstance**: mapping between the "KCA" ToC and IUCLID 6.5's working context "EU PPP Active substance information"
- **EU_PPP_Product**: mapping between the "KCP" ToC and IUCLID 6.5's working context "EU PPP Active substance application (product)"

Sequence	REVISED EU_NN	REVISED EU_NTitle	IUCLID section	Endpoint study record	Endpoint summary	Other IUCLID document	OHT	Additional context
CA001	*Document A*	*Statement of the context in which the dossier is submitted*	Dossier Header			DOSSIER		DOSSIER.EU_PPP_ACTIVE_SUBSTANCE_FOR_MIXTURES.ActiveSubstanceApproval.ApplicationPurpose
CA002	*Document B*	*Documentation relating to the joint submission of dossiers*	Dossier Header			DOSSIER		DOSSIER.EU_PPP_ACTIVE_SUBSTANCE_FOR_MIXTURES.ActiveSubstanceApproval.JointApplication
CA003	*Document C*	*Existing or proposed labels*	EU PPP Active substance application (product) 13. Summary and evaluation			FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP		FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.AttachedDocument; FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.TypeOfReport="Label"
CA004	*Document D*	*Uses*	EU PPP Active substance application (product) 3.1 Use of the plant protection product (GAP)			FLEXIBLE_RECORD.GAP		
CA005	*D 1*	*Intended uses supported in the EU for which data have been provided*	EU PPP Active substance application (product) 3.1 Use of the plant protection product (GAP)			FLEXIBLE_RECORD.GAP		
CA006	*D 2*	*List of currently authorized uses and extent of use*	EU PPP Active substance application (product) 3.1 Use of the plant protection product (GAP)			FLEXIBLE_RECORD.GAP		
CA007	*D 3*	*Intended uses supported in the EU for which data will be provided*	EU PPP Active substance application (product) 3.1 Use of the plant protection product (GAP)			FLEXIBLE_RECORD.GAP		

Crosswalks IUCLID 6.5 EU PPP Microorganisms - active substance application (product) to KMA&KMP

The Excel file provides detailed crosswalks from the EU Table of Contents (SANCO/10181/2013) for microbial plant protection product (PPP) dossiers to IUCLID 6.5. It includes two spreadsheets, containing the mappings for active substance (as laid out in Commission Regulation (EU) No 283/2013) and representative product (Commission Regulation (EU) No 284/2013):

- **EU_PPP_Micro_ActiveSubstance**: mapping between the "KMA" ToC and IUCLID 6.5's working context "EU PPP Microorganisms - active substance information"
- **EU_PPP_Micro_Product**: mapping between the "KMP" ToC and IUCLID 6.5's working context "EU PPP Microorganisms - active substance application (product)"

The spreadsheets map each section of the original EU ToC to:

- **IUCLID section**: name of the section in IUCLID where to input the corresponding data/information
- **Endpoint study record**: name of the document template used to report individual studies of the section (if exists). These usually correspond to OECD Harmonised Templates (OHT).
- **Endpoint summary:** name of the document template used to report the summary information of the studies presented in the section (if exists)
- **Other IUCLID document:** name of any other document template in IUCLID used to report information of the section (if exists)
- **OHT**: name/id of the OECD Harmonised Template used for the endpoint study record document (if exists)
- **Additional context**: fulI IUCLID paths indicating the section of the respective document where information needs to be provided and/or specific values to be indicated.

Level	Dossier File No	Description (Caddy <70 characters)	IUCLID section	Endpoint study record	Endpoint summary	Other IUCLID document	OHT	Additional context
1	Document A	*Statement of the context in which the dossier is submitted*	Dossier Header			DOSSIER		DOSSIER.EU_PPP_ACTIVE_SUBSTANCE_FOR_MIXTURES.ActiveSubstanceApproval.ApplicationPurpose
1	Document B	*Documentation relating to the joint submission of dossiers*	Dossier Header			DOSSIER		DOSSIER.EU_PPP_ACTIVE_SUBSTANCE_FOR_MIXTURES.ActiveSubstanceApproval.JointApplication
1	Document C	*Existing or proposed labels*	EU PPP Microorganisms - active substance application (product) 12 Summary and evaluation			FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP		FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.AttachedDocument; FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.TypeOfReport="Label"
1	Document D	*Uses*	EU PPP Microorganisms - active substance application (product) 3.1 Use of the plant protection product			FLEXIBLE_RECORD.GAP		
2	D 1	*Intended uses supported in the EU*	EU PPP Microorganisms - active substance application (product) 3.1 Use of the plant protection product			FLEXIBLE_RECORD.GAP		
2	D 2	*List of currently authorized uses and extent of use*	EU PPP Microorganisms - active substance application (product) 3.1 Use of the plant protection product (GAP)			FLEXIBLE_RECORD.GAP		
1	Document G	*Permission of each formulant in accordance with EU legislation*	EU PPP Microorganisms - active substance application (product) 12 Summary and evaluation			FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP		FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.AttachedDocument; FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.TypeOfReport="Documentation on formulants (General Information)"

Which are IUCLID entities?

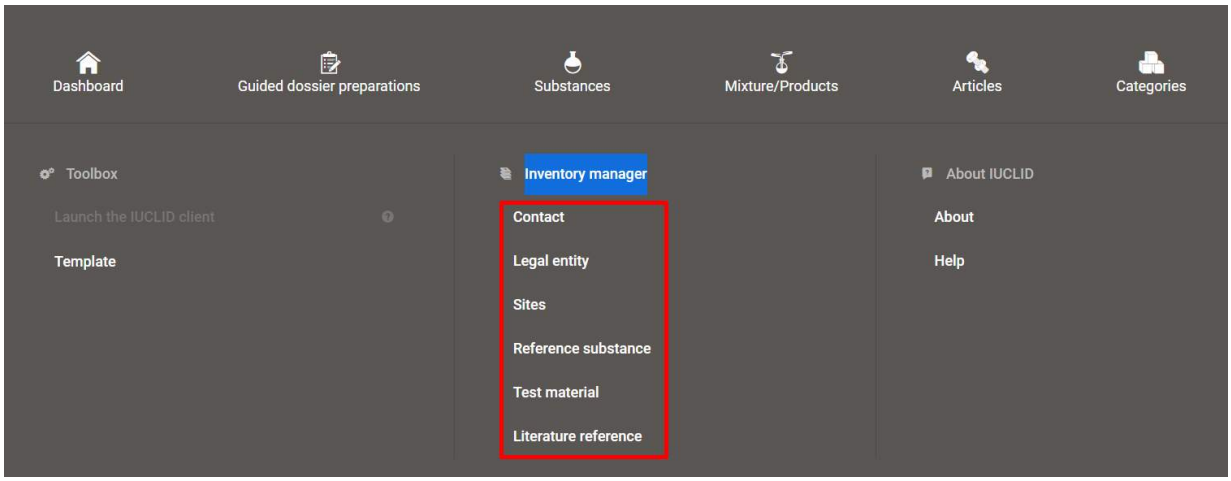
In IUCLID, an Entity is usually an inventory of information **linked to and reused** by any document.

Entities in IUCLID are software objects used to store data and have a particular purpose, depending on the type of entity.

Here is the list of reusable **IUCLID entities** that can be managed through the **Inventory Manager**:

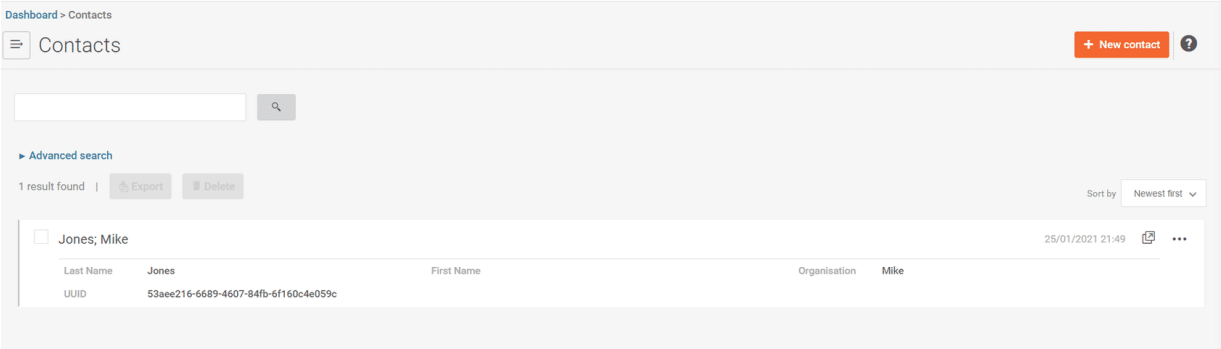
- Contact
- Legal entity
- Sites

- Referenced substance
- Test material
- Literature reference



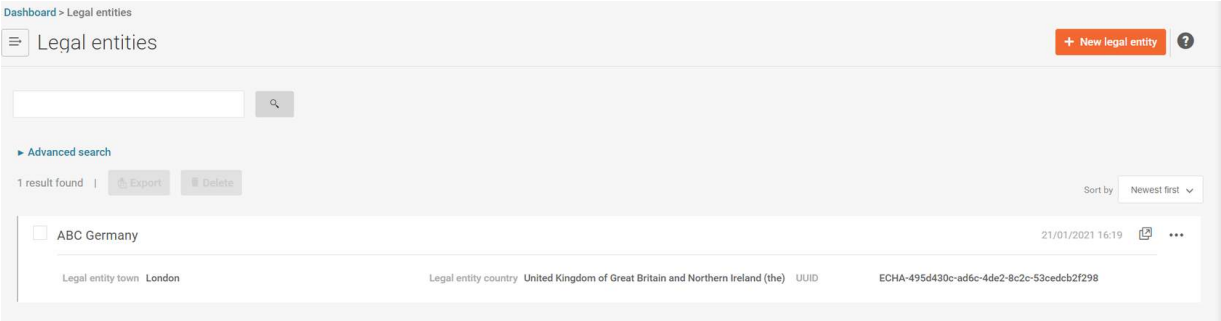
CONTACTS | LEGAL ENTITY | SITES | REFERENCE SUBSTANCE | TES

Contact is an entity that is used **to record the contact details of a particular person**. One can also use it to record something about a **person's role in a process**, such as the competent person responsible for a safety data sheet (SDS).
Using Contacts **removes the need to re-enter details** where a particular person is involved across multiple processes and Substances.
A Contact can be either **edited or created** from the place within a document or entity that links to it.



CONTACTS | LEGAL ENTITY | SITES | REFERENCE SUBSTANCE | TES

In IUCLID, a **Legal entity** is used **to store information about a party or person** involved in a chemical substance, mixture, or product life-cycle.
Can use a Legal entity to **identify the party** responsible for a certain activity, such as the manufacturing or importing of a substance.
The creation and editing of a Legal entity are done from the point where the Legal entity is referred to in a dataset.



CONTACTS | LEGAL ENTITY | SITES | REFERENCE SUBSTANCE | TES

An entity **site** is an entity used to associate a Legal or a Foreign entity, and therefore its associated entities, with a **physical location.**
This **can have important legal implications**, especially where the country is concerned.
A Legal entity site must have a name, a value in the field Site to indicate the physical location, and can be associated with a Legal entity.
The creation and editing of a Legal entity site are done from the point where the Legal entity site is referred to in a dataset.
One should report each manufacturing plant's name and report address in which the plant protection product and active substance are manufactured and reported in the Site entities.

CONTACTS | LEGAL ENTITY | SITES | REFERENCE SUBSTANCE | TES

A **Reference substance** is an entity used to **define a particular molecular structure** or **narrow range of molecular structures** that may re-use the definition.
A Reference substance **contains chemical identifiers and structural information**.

Chemicals: Identity of the active substance – ISO common name and synonyms, Chemical name following IUPAC and CA nomenclature, CAS Reg number EC number, molecular and structural formula, molar massMicroorganisms: Identity of the microorganism – Name, taxonomy, species description and strain characterisation.

Reference substances are efficient because some chemical substances frequently appear across multiple Substances and Mixture/products. Besides, Reference substances **can be shared and exchanged among instances and users** of IUCLID.

UUID: fe4e2639-841d-48ff-9ece-dd1cb4ceeb28

Reference substance name*
Impurity A

IUPAC name
2-(trichloromethylsulfanyl)isoindole-1,3-dione

Description
None

Inventory

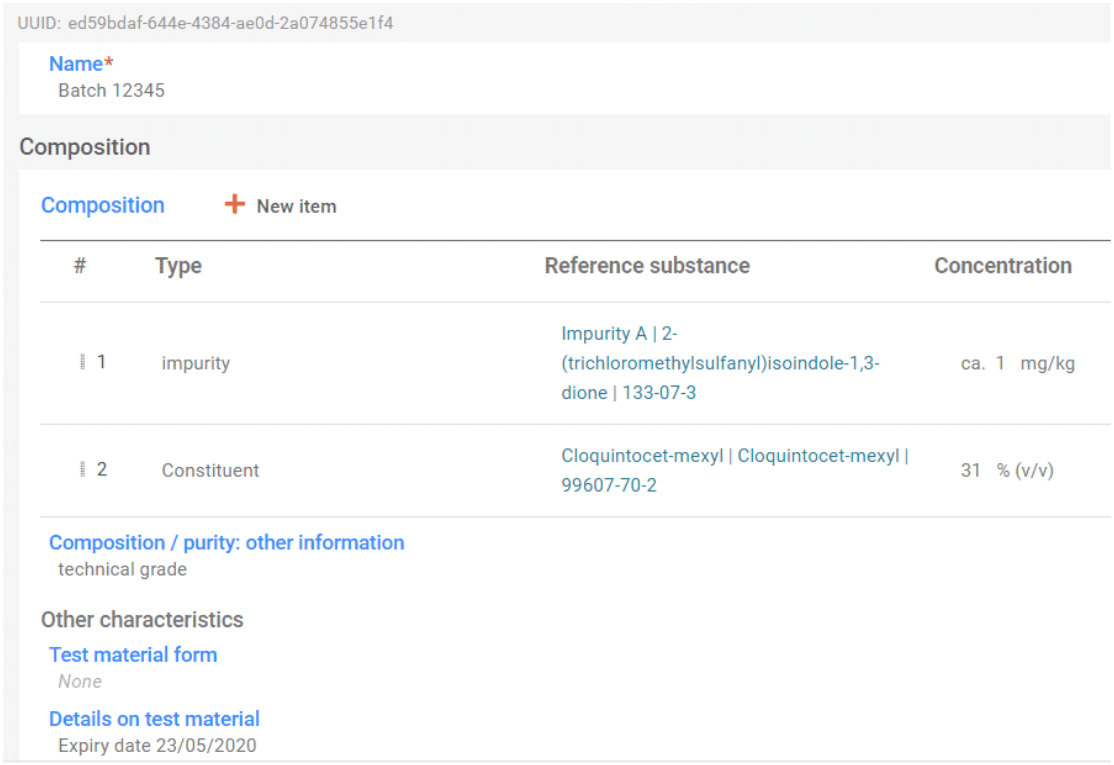
Inventory number
EC / 205-088-6 / N-(trichloromethylthio)phthalimide / 133-07-3 / C9H4Cl3NO2S

No inventory information available - Justification
None

CAS number
133-07-3

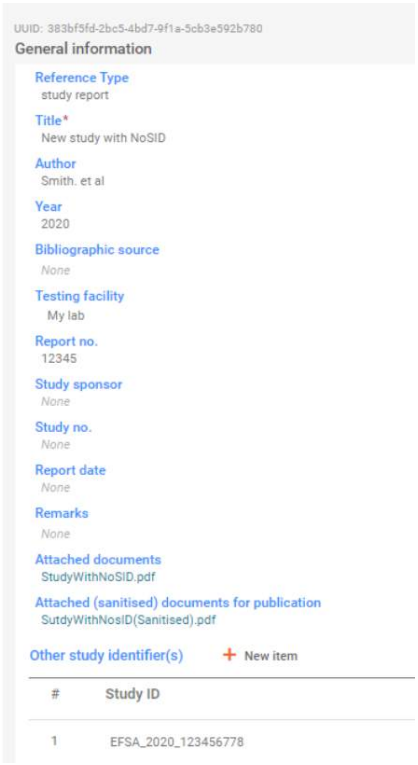
CAS name
None

Test materials is an entity used to **describe the material on which a physical test has been performed.**
A Test material entity can **describe the composition** of the batch used in a study, plus a **description of the physical form** and **some extra information** that may be considered confidential, such as information on impurities.
The **correct use of Test material** will provide the evaluator with an overview of which batches have been used in the studies submitted in the dossier.'

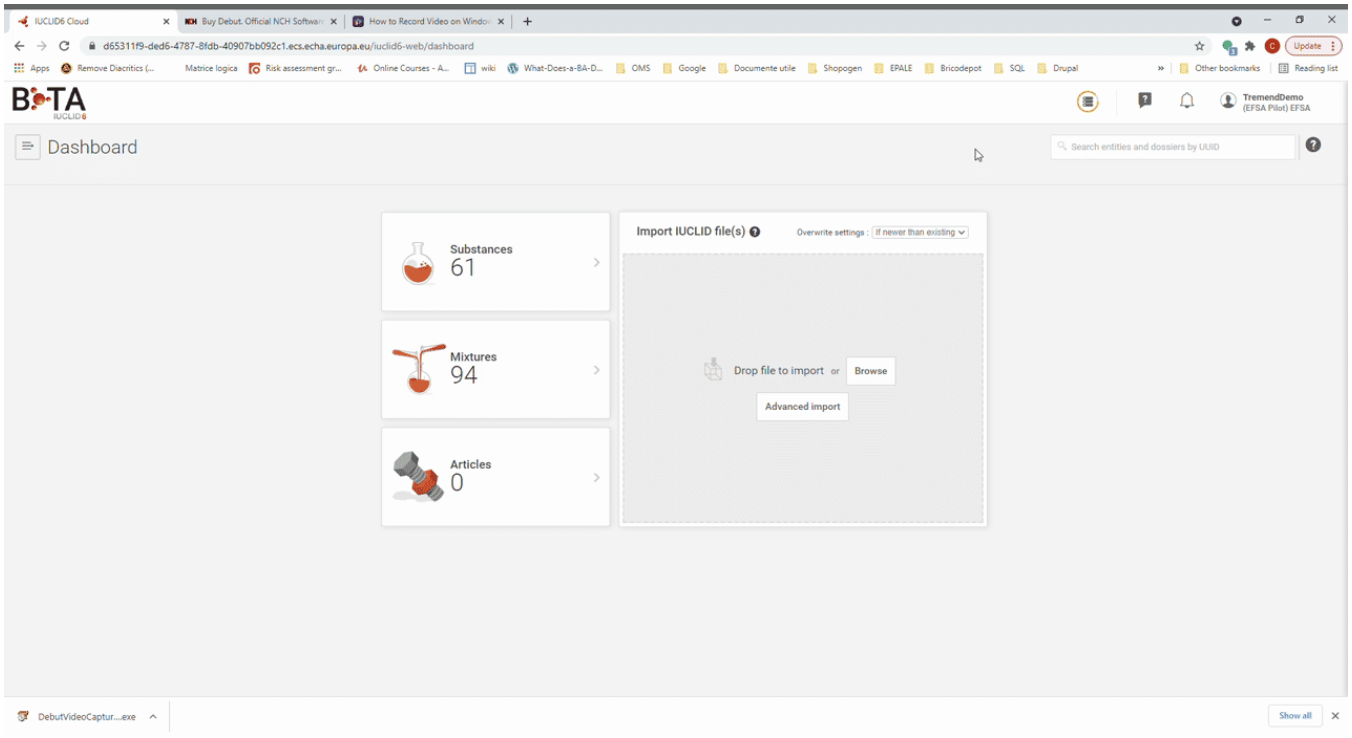


CONTACTS	LEGAL ENTITY	SITES	REFERENCE SUBSTANCE	TES

A **Literature reference** is an entity that contains the **bibliographic metadata** and the **full report** for each piece of evidence included in the dossier. If a study has been **notified** in the **Notification of Studies Database**, it will be available in the Literature Reference '**Study ID**' field. **Full study reports** and **published versions of the reports or citations** can be accessed from the **literature reference entities**.



Key concepts of an IUCLID dossier demo


IUCLID6 Cloud
Buy Debut. Official NCH Softwar
How to Record Video on Windo
d65311f9-ded6-4787-8fdb-40907bb092c1.ecs.echa.europa.eu/iuclid6-web/dashboard
Update
Apps
Remove Diacritics (...
Matrice logica
Risk assessment gr...
Online Courses - A...
wiki
What-Does-a-BA-D...
OMS
Google
Documente utile
Shopogen
EPALE
Bricodepot
SQL
Drupal
Other bookmarks
Reading list
BETA
IUCLID 6
TremendDemo
(EFSA Pilot) EFSA
Dashboard
Search entities and dossiers by UUID
Substances
61
Mixtures
94
Articles
0
Import IUCLID file(s)
Overwrite settings :
If newer than existing
Drop file to import
or
Browse
Advanced import
DebutVideoCaptur....exe
Show all

Lesson 3 of 3

Working in IUCLID

CP Carmen Pana

Objectives

Once completed this module, you will have a clear understanding of:

1. Dossier submitted
2. Searching for a dossier
3. Role and purpose of validation assistant
4. Annotation
5. Report generator
6. Comparison tool
7. Dossier admissible
8. Publication of the dossier
9. How to get more information and resolve issues

1

Dossier Submitted

When a valid dossier is received, you will receive this message in the designated mailbox.

Note! Copy the Dossier UUID received (highlighted below) to quickly find the related dossier in your IUCLID using the available search by UUID functionality.

Dear recipient

A new dossier has been submitted with the following outcome: Succeeded

Submission information

Submission type: EU PPP Basic substance application

Submission date and time: 16/03/2021 10:21

Submission number: RMH301884-16

Legal entity name: Dimitroula Chemicals QA

Legal entity UUID: ECHA-0bbfd310-cd75-41ca-ba15-8cb40fd86bd6

Dossier UUID: 2bafb2b4-fdf9-4ef4-9a87-382dcc4c38b3

Active substance name: Garlic extract

EU reference number: b36040fe-576f-4055-8b85-c1522a331621

Reason for submission:

Recipients:

The dossier has been uploaded to the EFSA instance.

Click here to access the EFSA instance and view the submitted dossier.

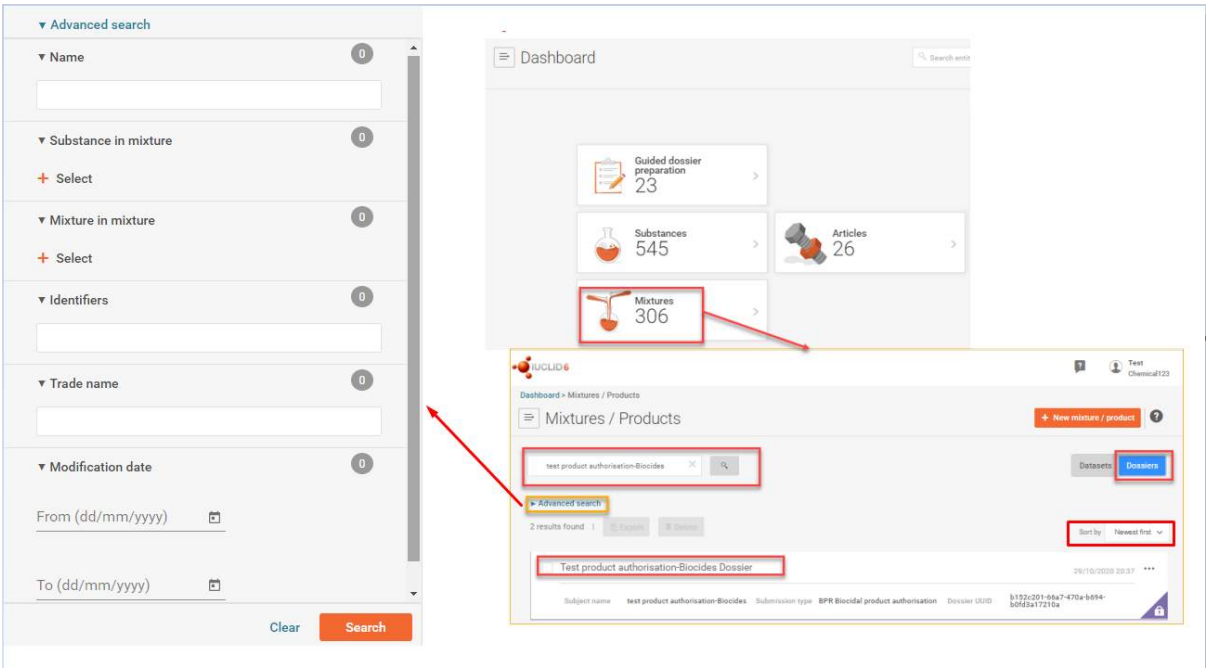
This message was sent by ECHA Submission portal on behalf of EFSA. Please do not reply to this email.

For any reply or clarification, please contact EFSA.

2

Searching for a dossier

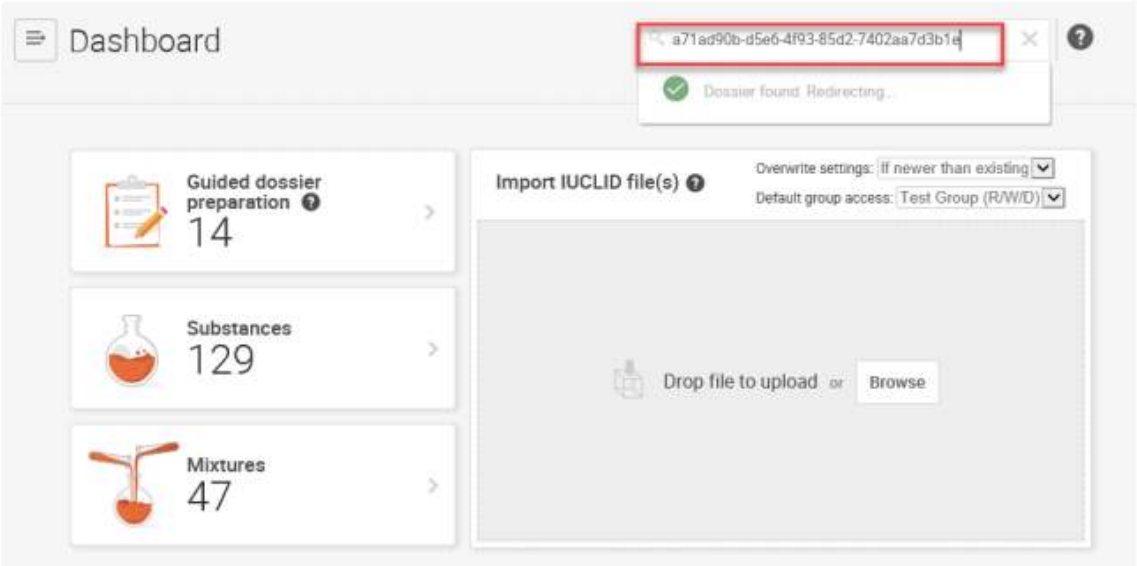
Searching for a dossier with the dossier name



To search a dossier, go to the IUCLID and click on the '**Mixtures**'. This will open the mixtures/products page, click '**Dossiers**', and a list of your dossiers will be displayed. Type in the name of your dossier, either partly or full name and relevant dossier(s) will be listed. When you have located the relevant dossier, click on the dossier title to open the '**Dossier information**' page.

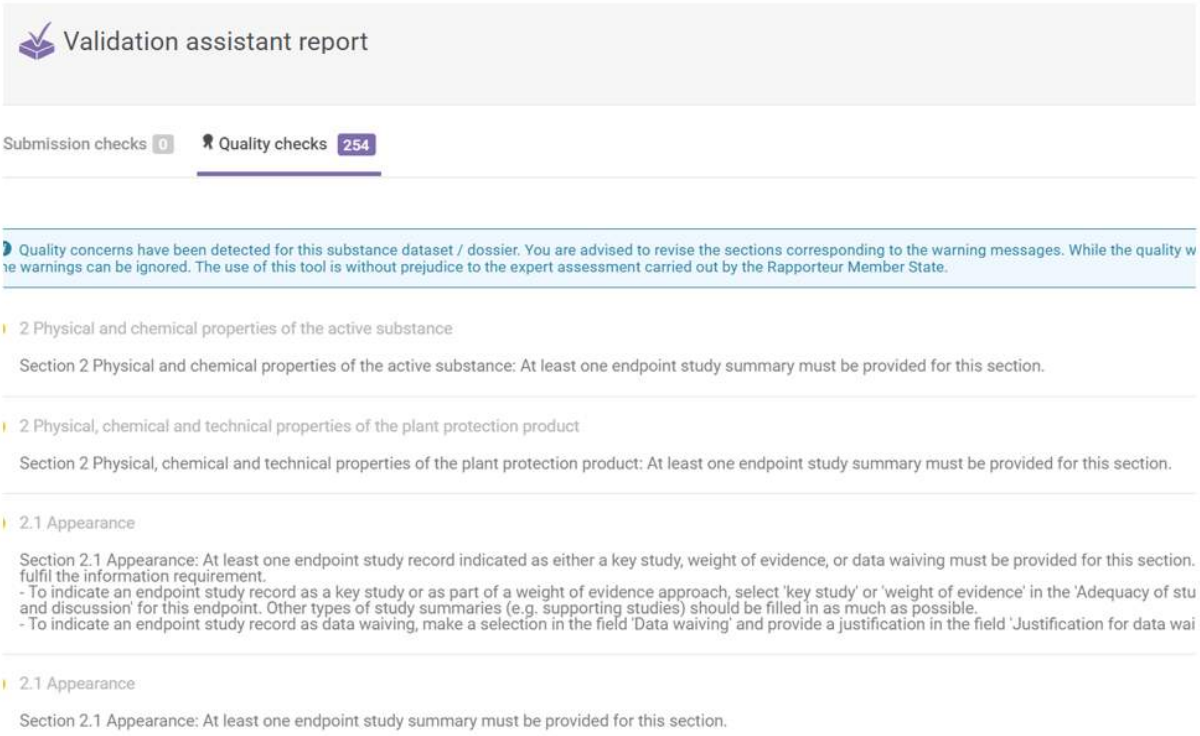
When viewing the list of dossiers in the Dashboard > Mixtures / Products, the **most recent dossier** will be **at the top** of the list by default. 'Sort by' can be used to record the dossiers.

Searching for a dossier with the dossier UUID



To search for a dossier with the unique dossier **UUID**, use the '**Search entities and dossiers by UUID**' field in the upper right corner of the IUCLID 6 dashboard. The dossier UUID can be obtained from the dossier header under the name of the dossier.

Role and purpose of validation assistant



Validation assistant applies Quality checks, Business rules and Completeness checks

- The report lists all the **errors** found in the substance or dossier.
- These checks **do not apply only to single documents** but also check values across **documents/datasets.**
- The report is also available as an **Excel** file.

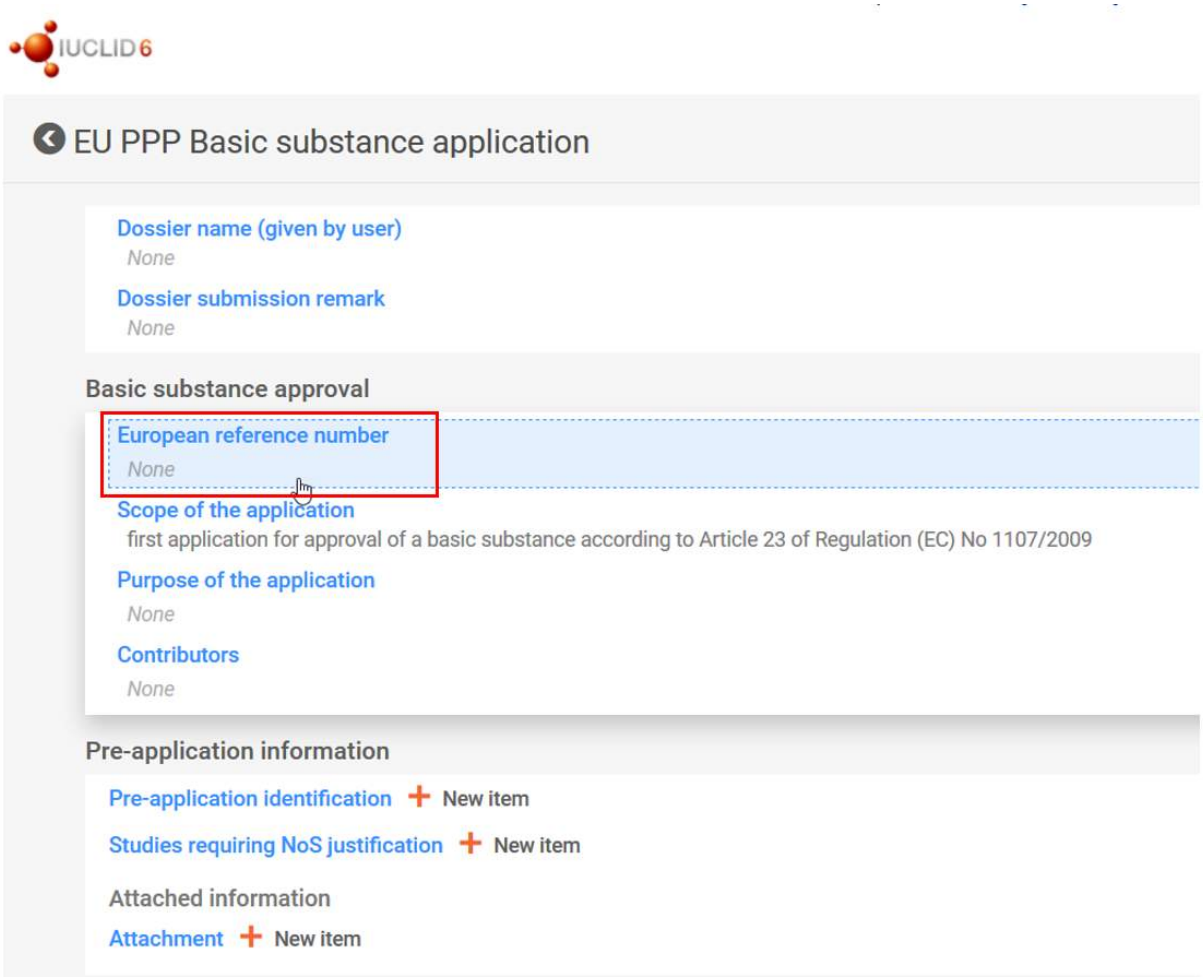
Validation rules levels

Two levels of validation checks:

Quality Rules

Quality Rules (QLT_PPP_xxx) from number 001 to 030. These rules are Warnings and not failures in order not to block submissions.

- **From 001 to 010** plus rule 027: rules performing checks within the endpoint study records (e.g. guidance, reliability, endpoint etc.)
- **From 011 to 020** plus rule 026: rules checking that minimum requirements per each type of working context are fulfilled (specific per Active Subst App, MO, MRL).
    - 2 rules for mixture dataset: the minimum amount of endpoint study records and endpoint study summaries are provided;
    - 2 rules for active substance: the minimum amount of endpoint study records and endpoint study summaries are provided;
    - Rule 026: rule checking that a GAP document table is provided.
- **From 021 to 030** (with the exception listed above): rules checking information within the mixture composition document and information related to the active substance (Substance IDentity rules).



Business Rules

Business Rules (BR_PPP_xxx) from number 033 to 036. These rules are **Failures** and must have been addressed by applicants, otherwise, the submission would have not been accepted in the Submission portal.

These rules are in place to ensure that the European reference number in format UUID is provided, otherwise, the dossier cannot be processed.

The results of the validation assistant can be **downloaded in Excel format**.

4

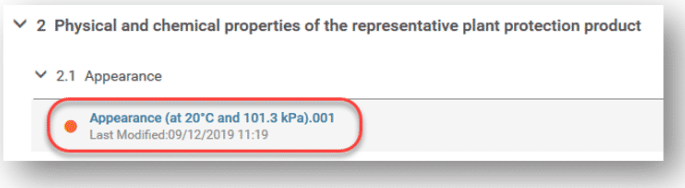
Annotation

Annotation is a type of IUCLID entity used as a container for information related to the evaluation of data in a particular regulatory context, for example, by a regulatory body. It allows the data **to be stored** in a structured manner, so **it is not just an attachment**.

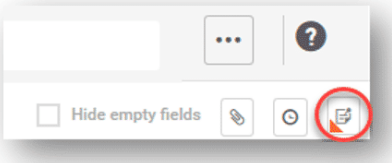
How to create an annotation on a study

Step 1

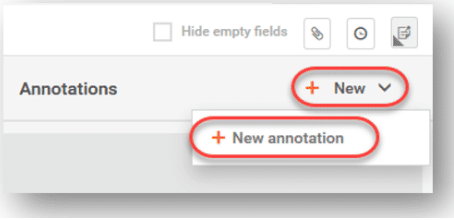
Select the document



1. Select the document, for example an endpoint study record which you want to annotate and open it



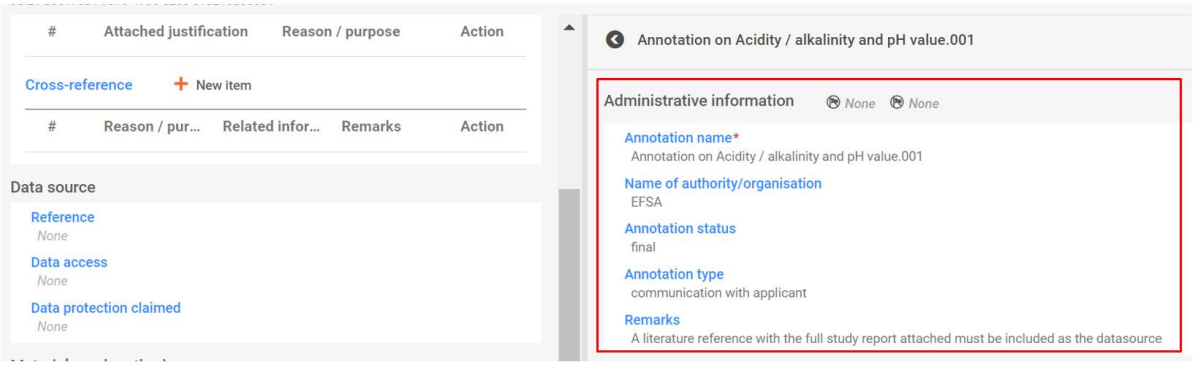
2. Click on the annotation icon on the right side of the bar



3. Click on '+New', and then on '+New annotation'

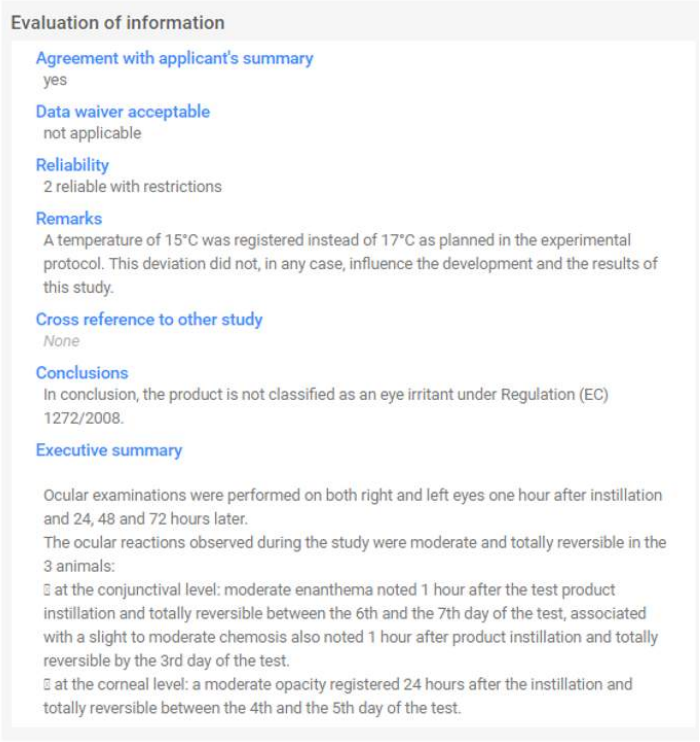
Step 2

Annotation - Administrative information



Enter a **name for the Annotation and the organisation** carrying out the work. The field **Annotation status** may be used to record whether the Annotation is still being worked on or whether it has been finalised. An evaluation may be uploaded as an attached file to the field Attached regulatory authorities' evaluation.

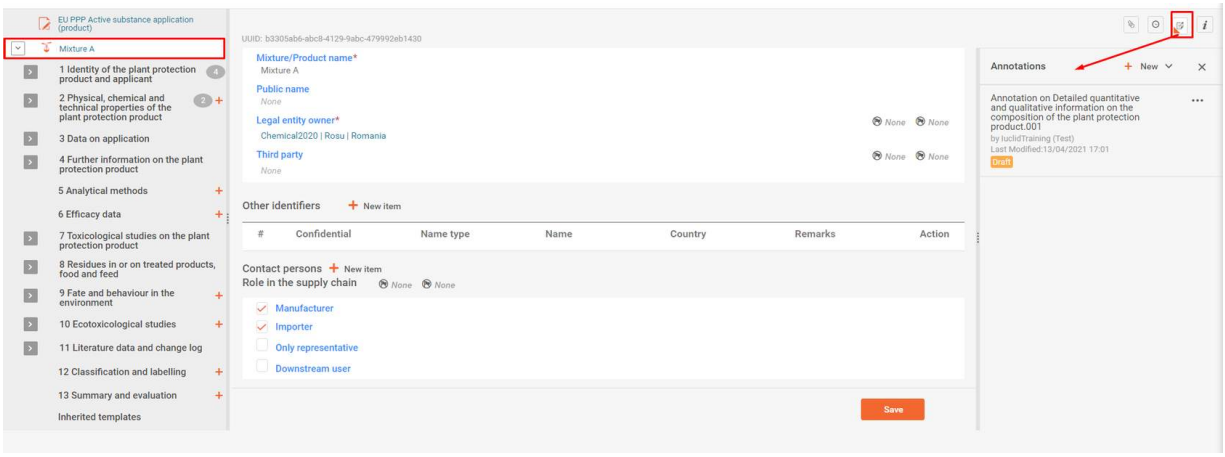
Annotation - Evaluation of information



Annotations can be used to record the conclusions of the evaluator

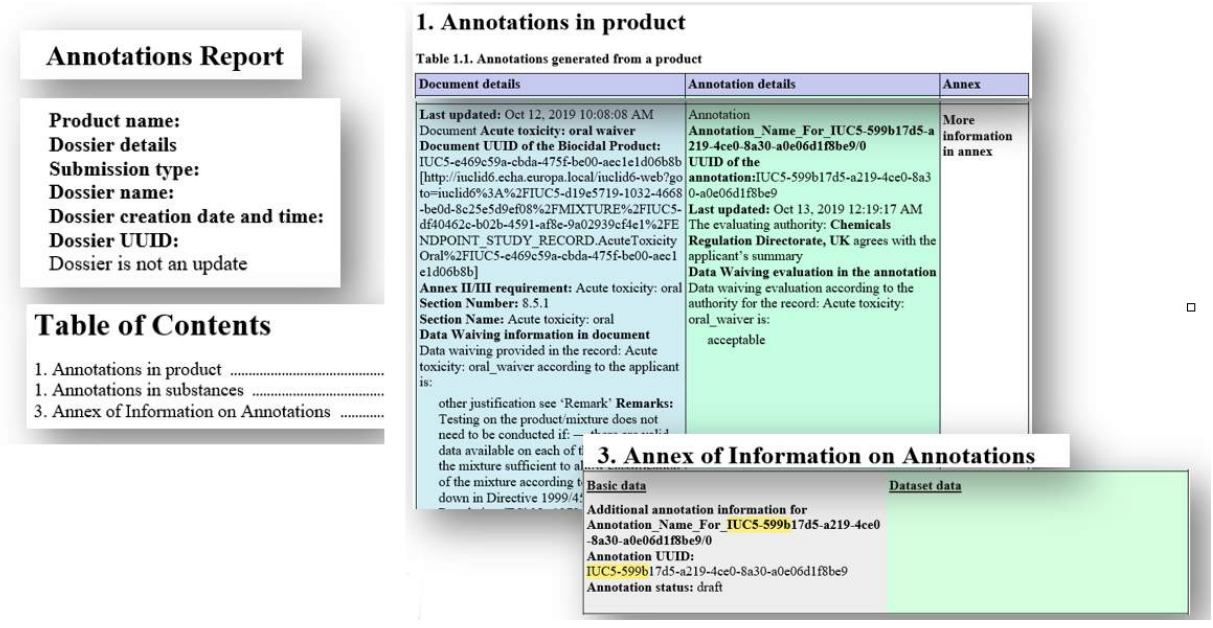
FIND THE ANNOTATION | ANNOTATIONS REPORT | ACTIONS ON ANNOTATIONS

- Annotation can be created on the raw data (**substance dataset, mixture/product dataset**) and a dossier. To open the annotation, you need **to open** the relevant document.
- In the main node of the navigation tree (the one with the name of the mixture) are displayed all the annotations. You can **open** each annotation from the list and **edit** it.



FIND THE ANNOTATION | ANNOTATIONS REPORT | ACTIONS ON ANNOTATIONS

- Feature available currently for biocides dossiers will be implemented for pesticides as well
- Annotations report can be generated from the dataset (raw data) and the dossier
- PDF / RTF



Annotations Report

Product name:
Dossier details
Submission type:
Dossier name:
Dossier creation date and time:
Dossier UUID:
Dossier is not an update

Table of Contents

1. Annotations in product .....
1. Annotations in substances .....
3. Annex of Information on Annotations .....

1. Annotations in product

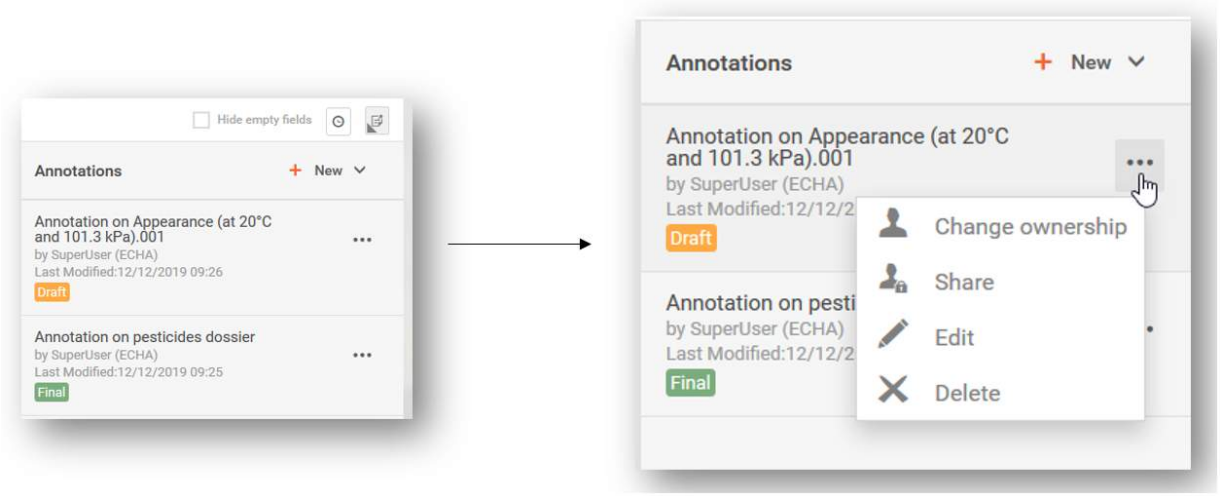
Table 1.1. Annotations generated from a product

Document details	Annotation details	Annex
Last updated: Oct 12, 2019 10:08:08 AM Document **Acute toxicity: oral waiver** **Document UUID of the Biocidal Product:** IUC5-e469c59a-cbda-475f-be00-aec1e1d06b8b [http://iuclid6.echa.europa.local/iuclid6-web?goto=iuclid6%3A%2FIUC5-d19e5719-1032-4668-be0d-8c25e5d9ef08%2FMIXTURE%2FIUC5-df40462c-b02b-4591-af8e-9a02939cf4e1%2FENDPOINT_STUDY_RECORD.AcuteToxicityOral%2FIUC5-e469c59a-cbda-475f-be00-aec1e1d06b8b] **Annex II/III requirement:** Acute toxicity: oral **Section Number:** 8.5.1 **Section Name:** Acute toxicity: oral **Data Waiving information in document** Data waiving provided in the record: Acute toxicity: oral_waiver according to the applicant is: other justification see 'Remark' **Remarks:** Testing on the product/mixture does not need to be conducted if: — data available on each of t the mixture sufficient to al of the mixture according t down in Directive 1999/45	Annotation **Annotation_Name_For_IUC5-599b17d5-a219-4ce0-8a30-a0e06d1f8be9/0** **UUID of the annotation:**IUC5-599b17d5-a219-4ce0-8a30-a0e06d1f8be9 **Last updated:** Oct 13, 2019 12:19:17 AM The evaluating authority: **Chemicals Regulation Directorate, UK** agrees with the applicant's summary **Data Waiving evaluation in the annotation** Data waiving evaluation according to the authority for the record: Acute toxicity: oral_waiver is: acceptable	**More information in annex**

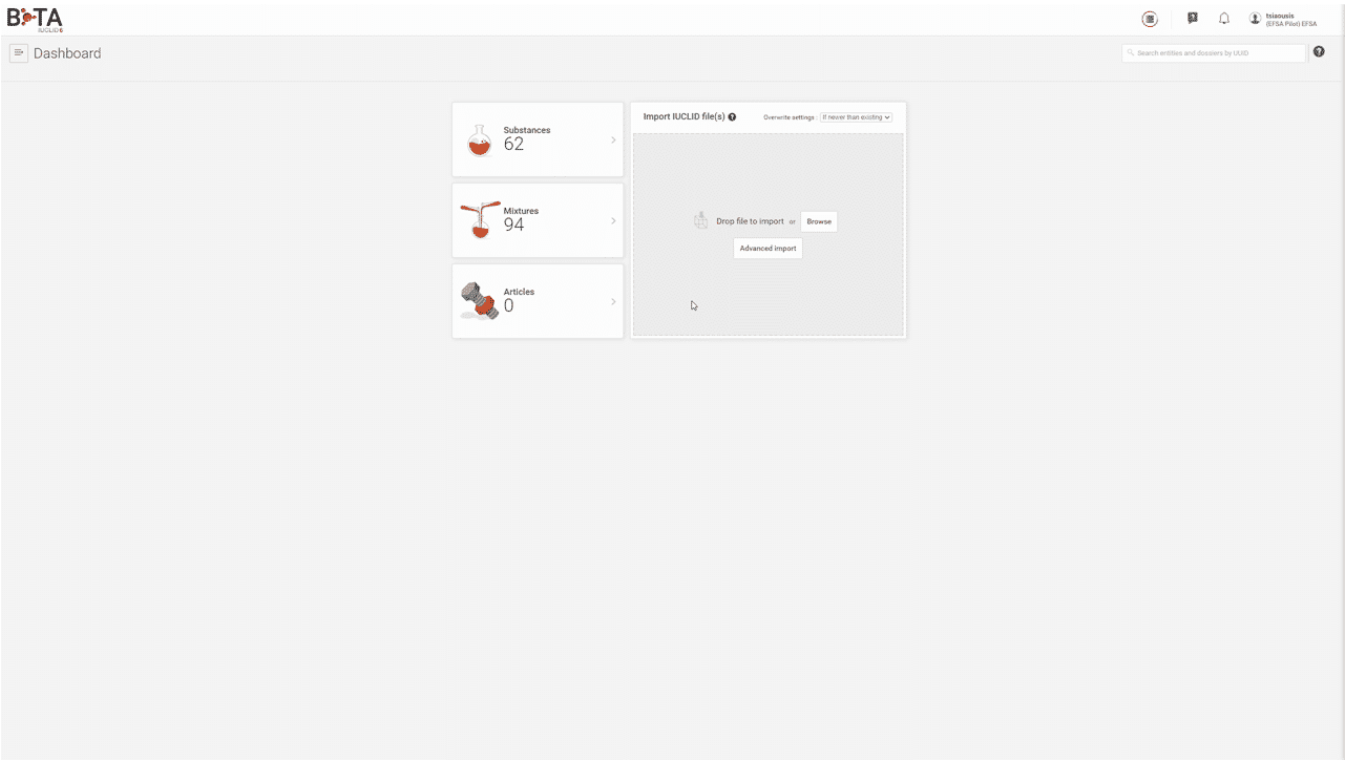
3. Annex of Information on Annotations

Basic data	Dataset data
Additional annotation information for Annotation_Name_For_IUC5-599b17d5-a219-4ce0-8a30-a0e06d1f8be9/0 **Annotation UUID:** IUC5-599b17d5-a219-4ce0-8a30-a0e06d1f8be9 **Annotation status:** draft	

- If you click on an icon with three dots next to an annotation have access to the following options (depend on the IUCLID database you are logged in and your rights):
  - **Change ownership** - to give the ownership of the annotation to the other user
  - **Share** - to share an annotation with other group of users, for example, your Country group
  - **Edit** – to update an annotation
  - **Delete** – to delete an annotation



How to search a dossier, validation assistant, and annotations demo



5

Report generator

The report generator extracts IUCLID data in a structured and standalone format such as: RTF/PDF/CSV/XML/HTML.

It is based on templates (.ftl) and stylesheets (.xsl) and follows a **modular approach** that allows re-usability across reports.

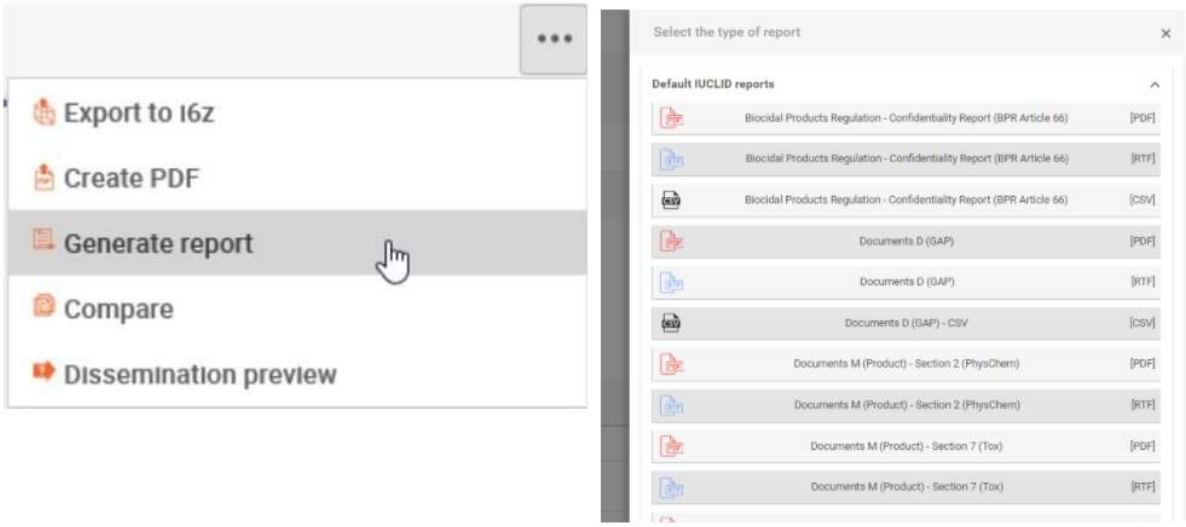
Available reports are progressively added to the list and updated to the latest format.

Detailed information can be found at https://iuclid6.echa.europa.eu/reports

1. How to access the Report generator

From a dataset or a dossier, select the option **'Generate report'** under the '...' icon, and look for a specific report in the list.

The report will generate in the format specified by the symbol on the left side, e.g. PDF, RTF, CSV.



2. Available reports for pesticides

Several reports are already available for pesticides and will be expanded in the subsequent releases of IUCLID. These appear under the **"Default IUCLID reports"** section and include:

- **NoS Extraction Request** (PDF, RTF or CSV): to be run from a mixture dossier; this report contains a summary of all the studies included in the application together with their **Notification of Studies** (NoS) IDs or justification for not providing them. Information on GLP and testing facility is also included. Using the information in the report, you can check against the extraction from the **Notification of Studies** database that EFSA will provide to RMS/EMS.

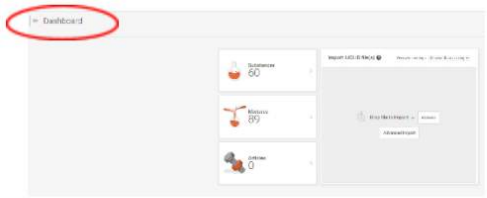
- **Documents D (GAP)** (PDF, RTF, CSV): to be run from a mixture dataset or dossier, this report contains a summary in table format of the intended (Document D1) and authorised (Document D2) uses for each product composition of the plant protection product.
- **Documents M:** to be run from a mixture dossier, Documents M reports summarise the different sections of the pesticides dossier for the active substance and the mixture separately. Two sections are currently available in IUCLID (4 reports):
    - Physical and chemical/biological properties:
        - **Documents M (Active substance) – Section 2 (PhysChem), and**
        - **Documents M (Product) – Section 2 (PhysChem)**
    - Toxicological studies:
        - **Documents M (Active substance) – Section 5 (Tox), and**
        - **Documents M (Product) – Section 7 (Tox)**

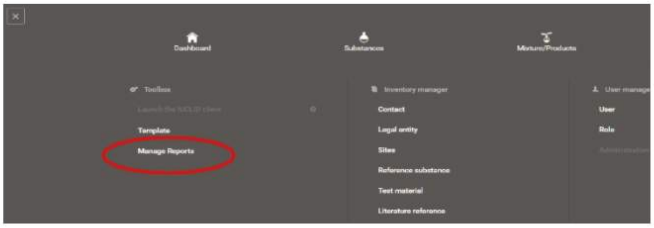
In subsequent releases of IUCLID, these reports will be expanded to include the remaining sections, e.g. Ecotox, Residues, FATE, etc.

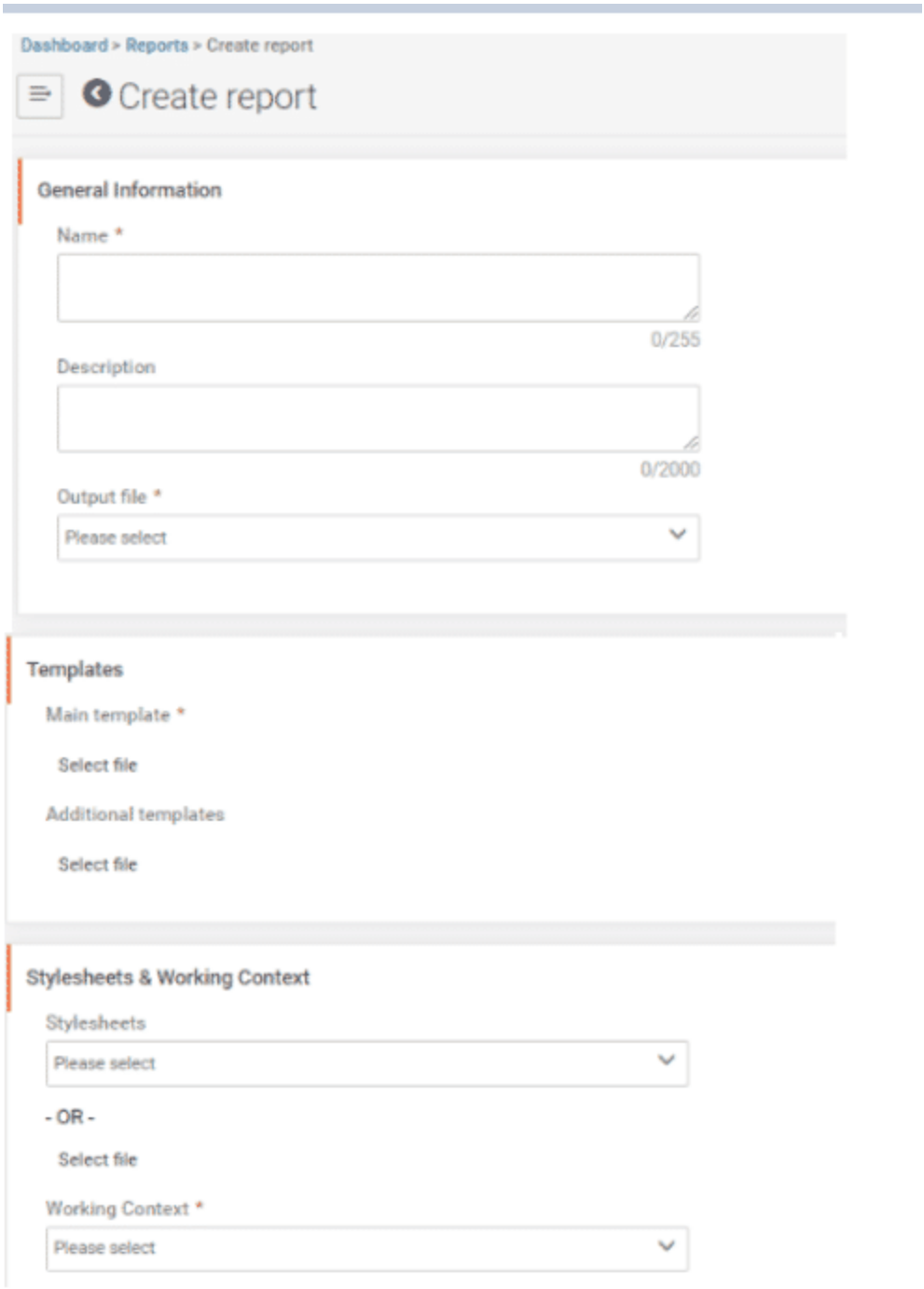
3. Upload your own report templates.

IUCLID allows you to upload your own report templates manually.

To do so, from the main dashboard page, click on the burger button on the top left and select “Manage Reports”.


Dashboard
Substances
60
Mixtures
89
Articles
0

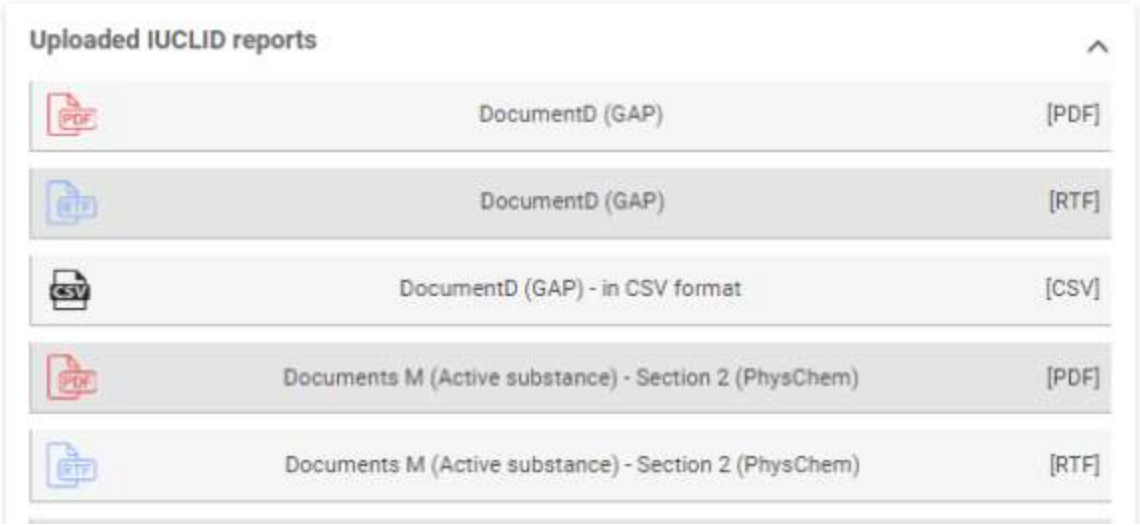

Dashboard
Substances
Mixtures/Products
Toolbox
Template
Manage Reports
Inventory manager
Contact
Legal entity
Sites
Reference substance
Test material
Literature reference
User
Role



In the new Reports page, click on “Create new” and fill in the required sections:

- **Name**: enter the name of the report to be displayed in IUCLID.
- **Output file**: select the output format (PDF, RTF…) for the report in alignment with the uploaded templates.

- **Templates**: upload your .ftl template files, i.e. one main template (mandatory) and other additional templates (optional). These are the files that define the structure and content of the report.
- **Stylesheets**: select an existing IUCLID stylesheet (default, landscape or portrait) or upload your own .xsl file. These are the files that define the layout style of the report.
- **Working context**: select the context for which the report should be generated, e.g. EU_PPP contexts for pesticides.



The new report appears in the Report Generator under the section **"Uploaded IUCLID reports".**

The latest report templates for pesticides can be downloaded from EFSA's publications in Zenodo Knowledge Junction **[NOTE: add a link to Zenodo when we have it]**

Comparison tool

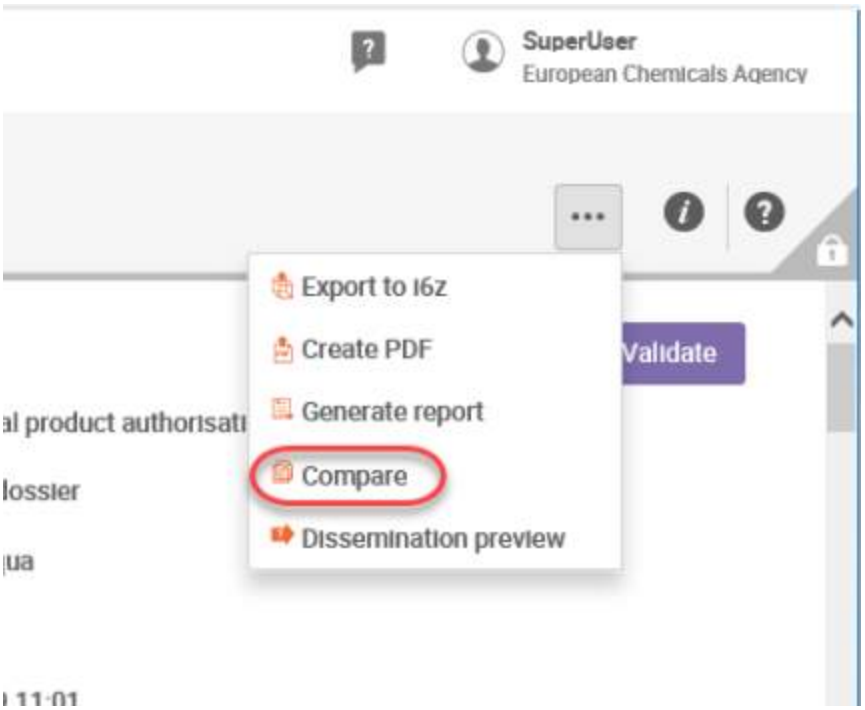
- compares two dossiers, and check for what is different or identical between:
    - all dossier entities (dossier header, mixtures, substances, legal entities, reference substances, contacts, literature references)
    - all section documents (records, endpoint study records, endpoint summaries)
    - fields
    - attachments

- provides a comparison report in the HTML format
    - all fields which are found to be different are listed
    - navigation between parts of the report is straightforward

Compare two dossiers

Step 1

Where to start

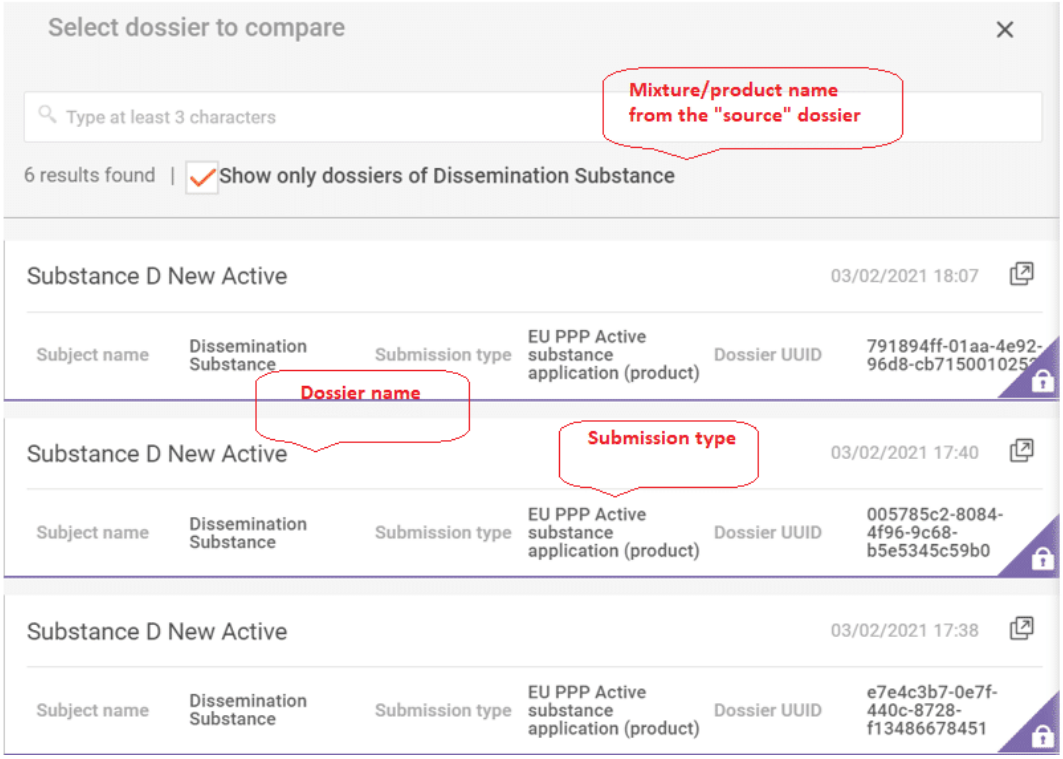


To begin with the tool, you must have at least two dossiers to compare in your database.

You need to open a dossier and select the option 'Compare' under '...' icon.

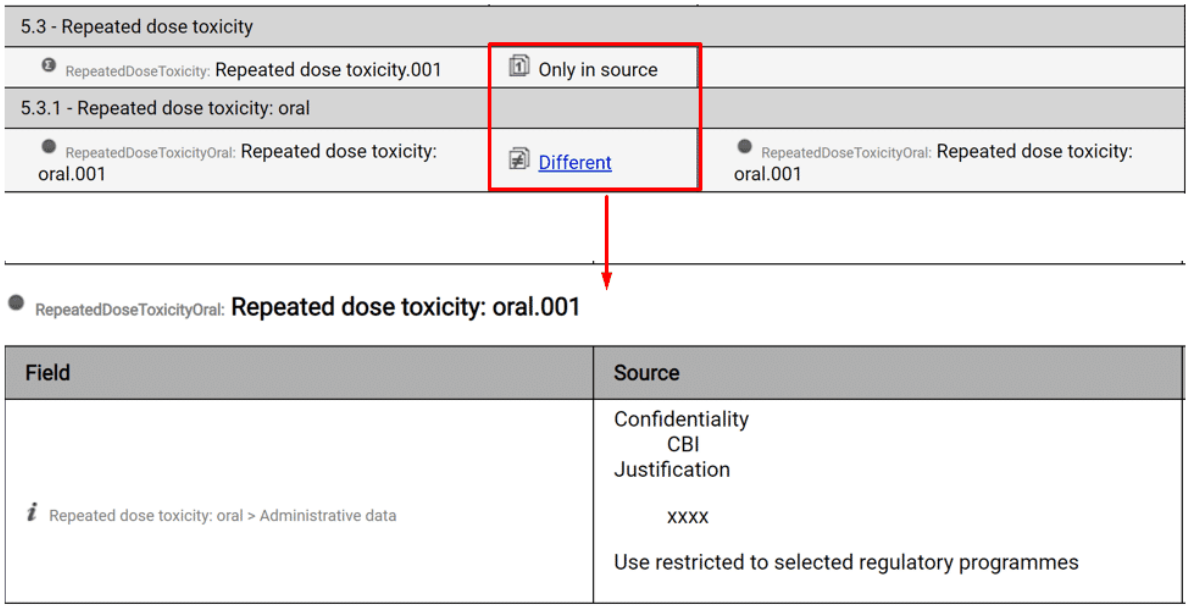
Step 2

Dossier to be compared



The side window will open, and you will be able to select a dossier for comparison. By default, you see only dossiers created based on the same product dataset.

Comparison report



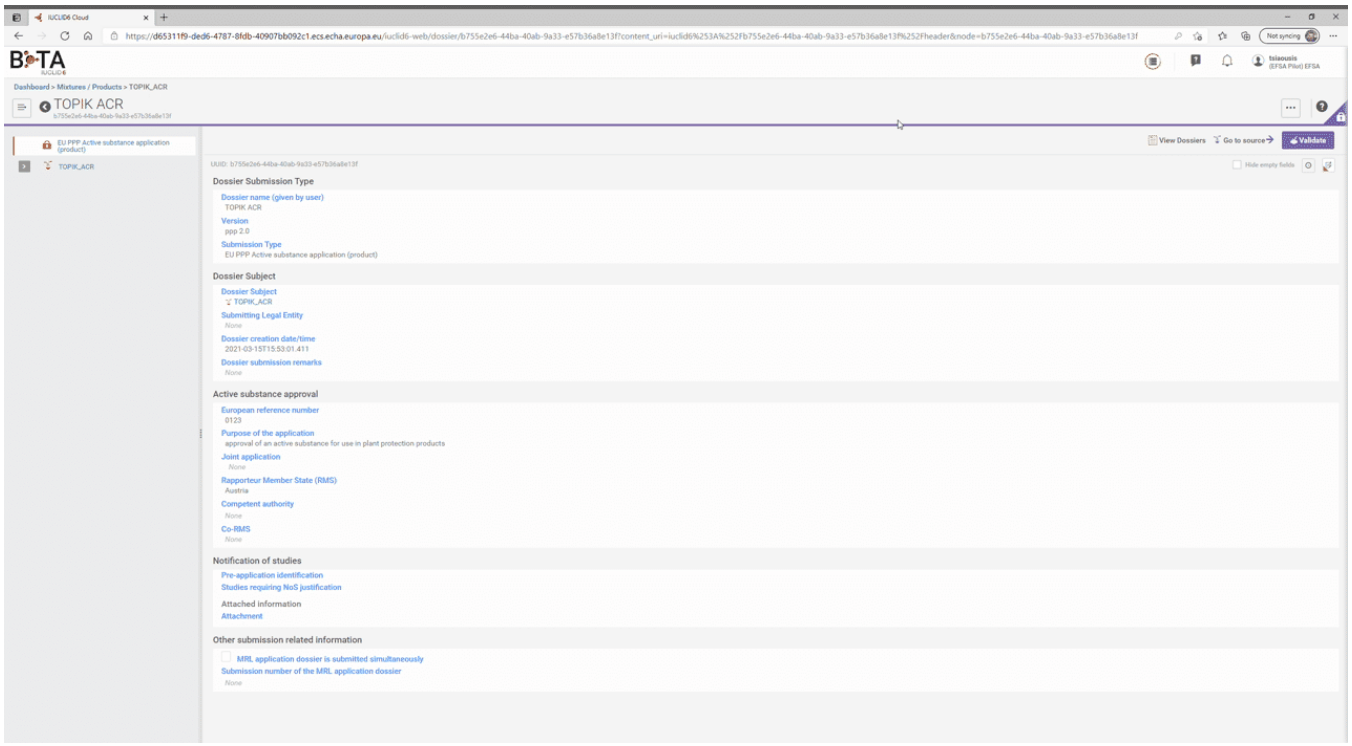
The detailed results of the comparison are displayed.

Firstly, the comparison at the dossier content level, so you can see which components of two dossiers are identical and different.

Mixtures, substances, legal entities, reference substances, contacts and literature references are analyzed.

If there are differences, the field level analysis is displayed, as shown in the example.

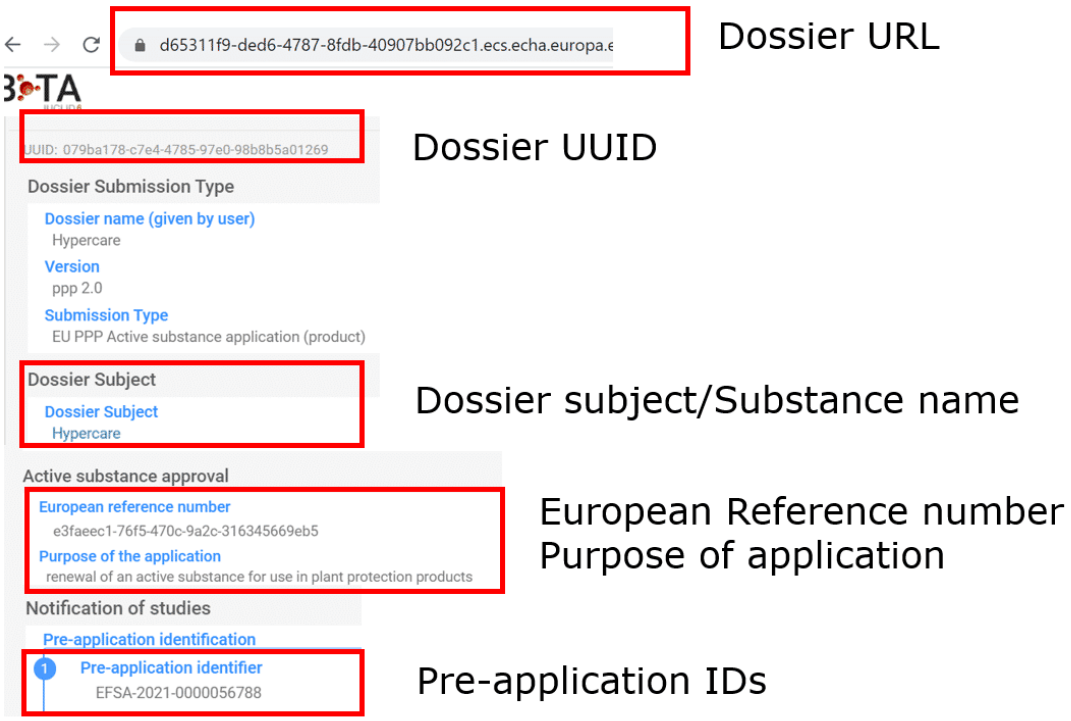
Reports and comparison tool demo



7

Dossier Admissible

The RMS/EMS must notify EFSA that the application is declared admissible. The following information from the dossier header must be included in the email notification to EFSA.

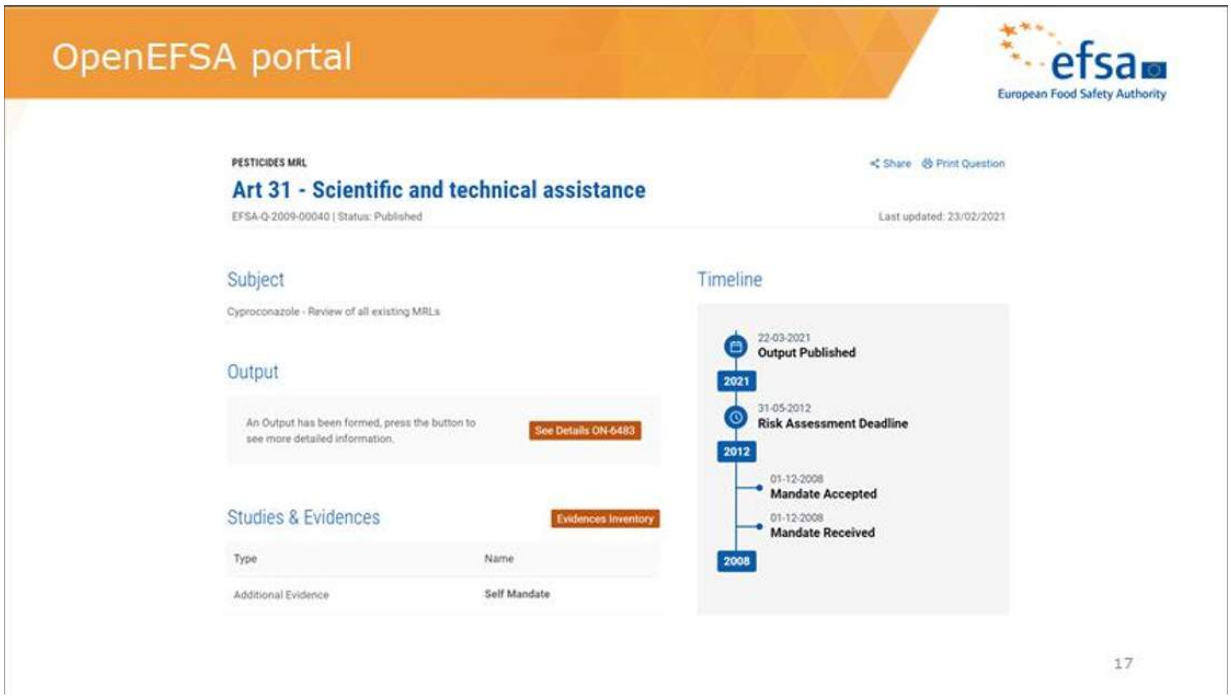


Publication of the dossier

EFSA APDESK will filter the dossier and publish the dossier in Public IUCLID, a standalone instance of IUCLID which does not require an ECHA account for access

The URL of the dossier is made available on the OpenEFSA portal

The public consultation on the dossier is performed by EFSA via SALESFORCE. The comments received are provided in an excel file to RMS/EMS



How to get more information and resolve issues

If you have any problems, send an e-mail to servicedesk@efsa.europa.eu

If you identify something that needs to be changed or improved, you can report this in the IUCLID backlog
https://docs.google.com/spreadsheets/d/1kFkttA6rXtR2K6LlaauHozq9BSfv6a5EgFDM1GgtmfQ/edit#gid=0