IUCLID 6.4

Biocides Day

29th of October 2019

IUCLID 6 is developed by the European Chemicals Agency in association with the OECD

IUCLID 6 web user interface

Content of the presentation

- Transition to the web user interface
- BPR dossier structure
- BPR dossier creation
  - ✓ mixture / product dataset
  - ✓ substance dataset
  - ✓ dossier creation
- Navigation through the BPR dossier
- IUCLID 6.4 format changes relevant to biocides
- Report generator
- Comparison tool
- Plans of further improvements
- Where to find more information

Transition to the web user interface

Transition to the web user interface

October 2018
Major release (6.3)
Introduction of the web interface

April 2019
Service release (6.3.16)

October 2019
Major release (6.4)

April 2020
Service release (6.4.x)

October 2020
Major release (6.5)

The classic user interface remains available in the October 2019 release, however we recommend to use it only for the features not yet available in the web interface.

IUCLID 6 web user interface

Web user interface offers you the possibility to:

- Prepare the substances and mixtures/products datasets and create the BPR dossier
- Navigate through the BPR dossier (access dossier components, open attachments, read the fields) - **Chrome or Firefox should be used**
- Use most of the IUCLID functionalities (import, export, print, basic search)
- Compare dossiers
- Generate reports

We are aware of the need of some improvements, for example better print options for the BPR dossiers – we are working on that.

We kindly invite you to share your comments, remarks and requirements with us, so we could continuously improve IUCLID for you

IUCLID 6 web user interface

Using web user interface you can:

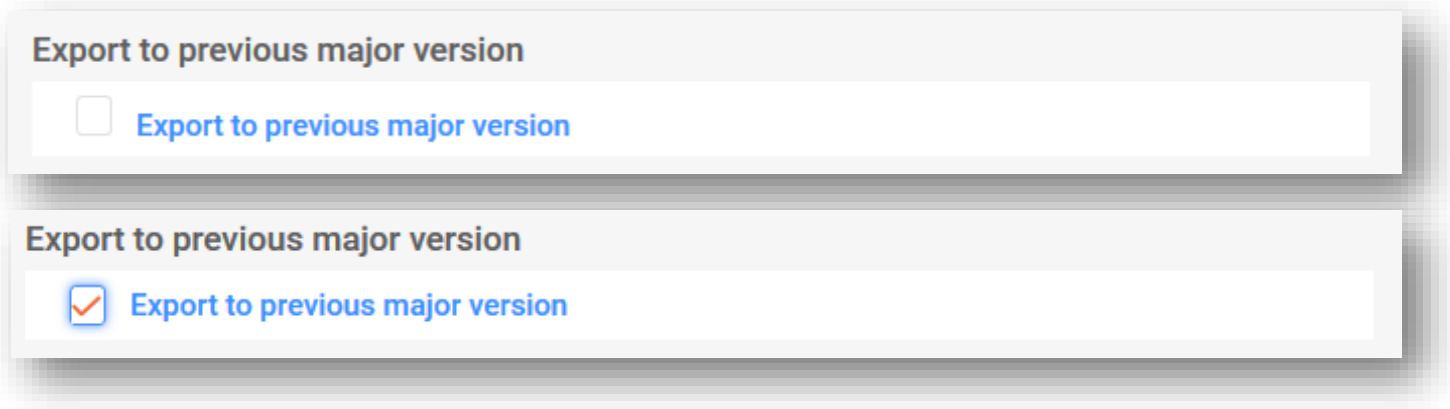
- work at the same time on different dossier components (product, substances) open in different tabs or windows
- search any text on the screen (Ctrl + F)
- bookmark an URL of each IUCLID document
- share the URL with other user within the same database
- zoom in / zoom out
- access your database through the browser

Compatibility between IUCLID versions

IUCLID 6.4

- You can import to IUCLID 6.4, your files from IUCLID 5.6, 6.1, 6.2 and 6.3

- I6z files exported from IUCLID 6.4 can be loaded in IUCLID 6.3 (all versions) if you use the '**Export to previous major version**' option in Export settings:



If you use older versions of IUCLID please visit IUCLID website for more information: https://iuclid6.echa.europa.eu/download

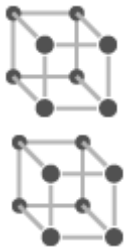
BPR dossier structure

Biocides submissions: BPR dossier structure

reference substances (constituents, impurities…)

active substance

biocidal product or representative biocidal product



substances are linked in mixture / product section 2.3

BPR dossier is created based on a biocidal product dataset or representative biocidal product dataset

other substance(s), if needed

The main component of a BPR dossier is always a mixture/product, even if it is a dossier for the Article 95 or the technical equivalence. All substance datasets are linked in the composition section of the (representative) biocidal product.

Biocides submissions: substance datasets

Substance datasets

BPR Active substance information

BPR Microorganisms

BPR Basic information (substance)

BPR Substance of concern

function: active substance

You do not need to prepare all substances datasets in advance. You can create a new substance directly in the section 2.3 of the product dataset!

Biocides submissions: mixture/product datasets

Mixture/product datasets

BPR Active substance application (representative product)

BPR Biocidal product authorisation

BPR Basic information (mixture)

relevant to dossier creation

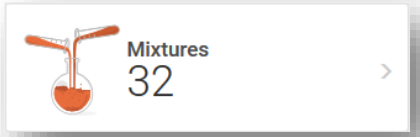
If the active substance is the main dossier component to be evaluated, for example for the Article 95 or the technical equivalence, use the dossier type:

BPR Active substance application (representative product)

BPR dossier creation

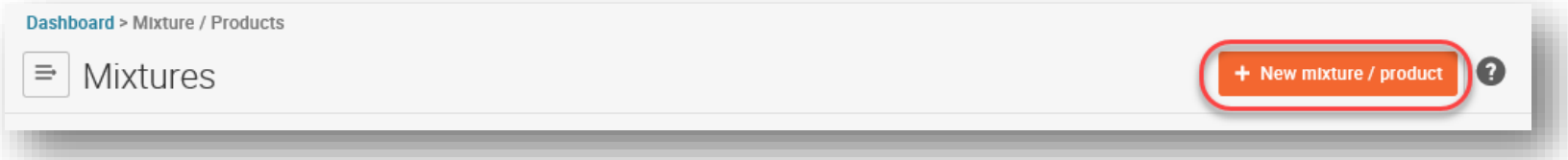
- mixture / product dataset
- substance dataset
- dossier creation

Mixture/product dataset – starting point of a dossier

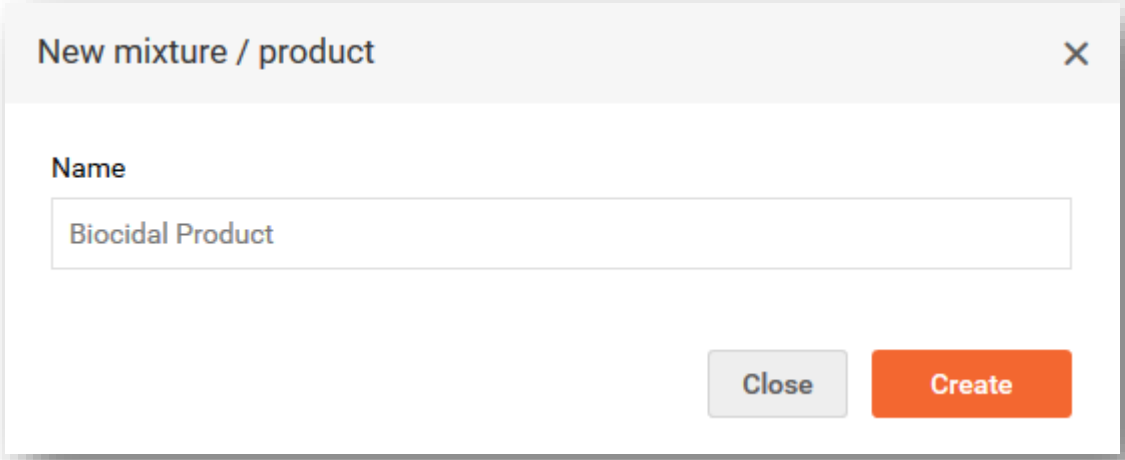


1. On the Dashboard click on 'Mixtures'

2. Click on '+ New mixture / product'

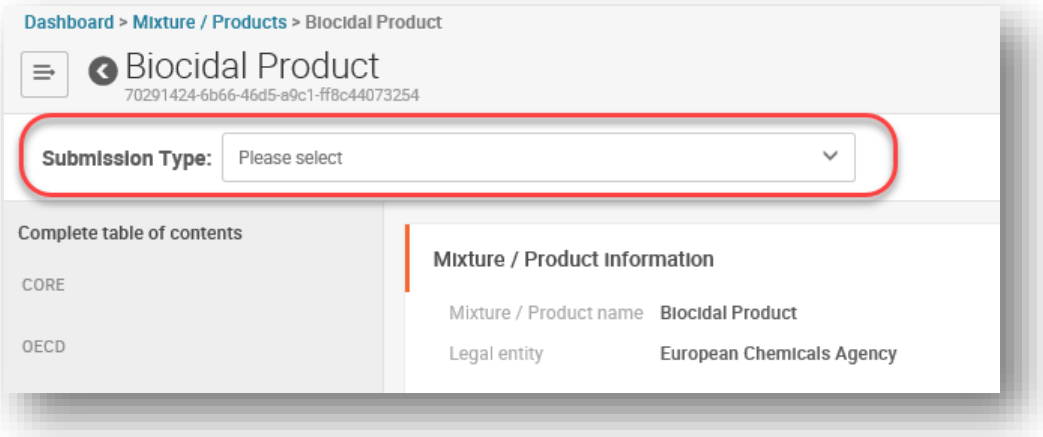


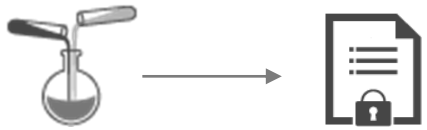
3. Insert mixture / product name (which is name of the (representative) biocidal product that you create)



Mixture/product dataset - TOC and dossier header

4. Select submission type of your product – one of two which are relevant for the dossier

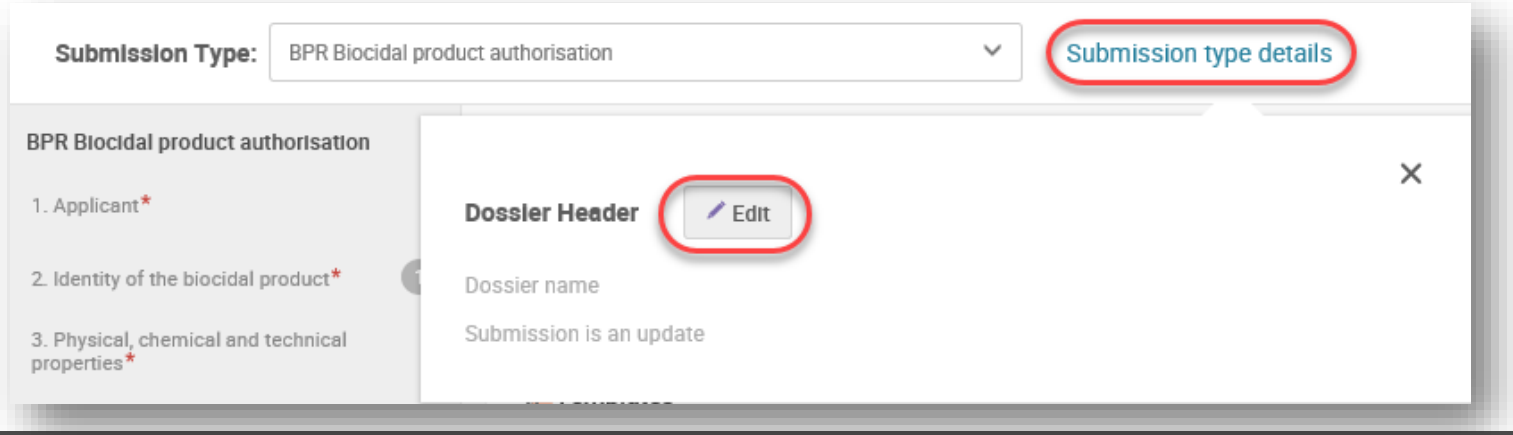




- BPR Active substance application (representative product)
- BPR Biocidal product authorisation

reminder

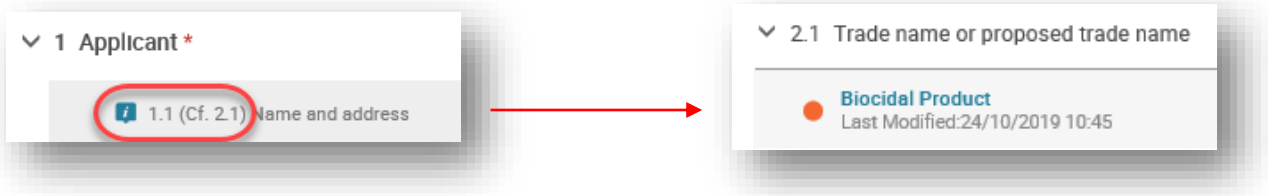
5. You can edit the dossier header (or do it at the dossier creation step)



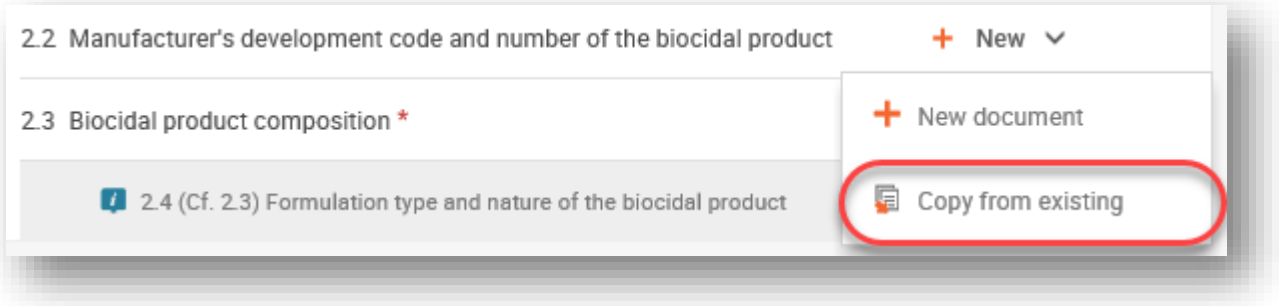
Filling the data for the biocidal product

How to fill data

- Reference section informs you where to fill data, it is not a link, so you need to go to the section indicated in the brackets and fill the data there



- You can reuse previously created documents, no matter if they have been created under a substance or mixture / product dataset

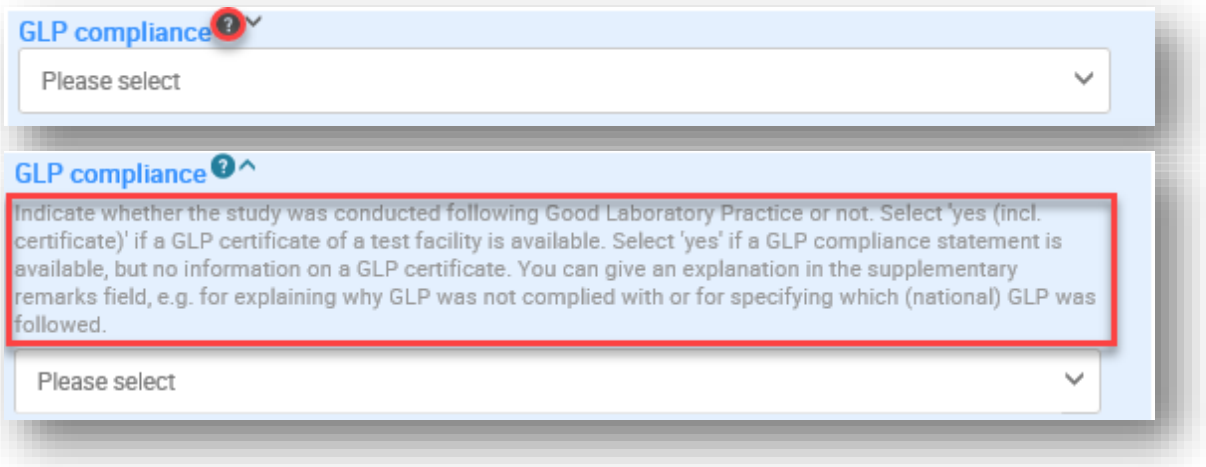


Once the submission type is selected, you can fill all relevant data. Use our tips to make it easier!

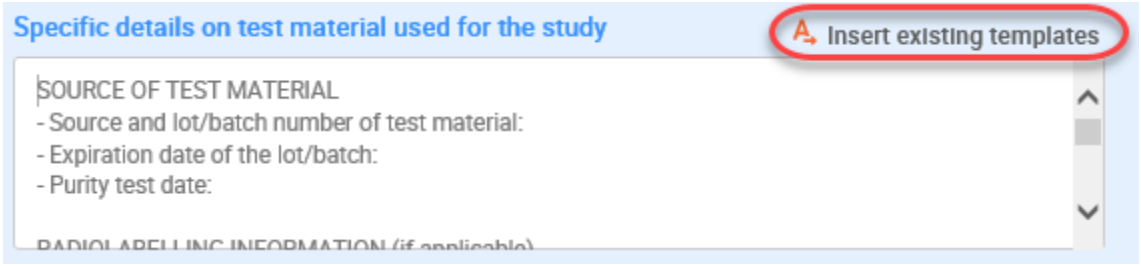
Filling the data for the biocidal product

How to fill data

- Use the help hidden under the question mark next to field

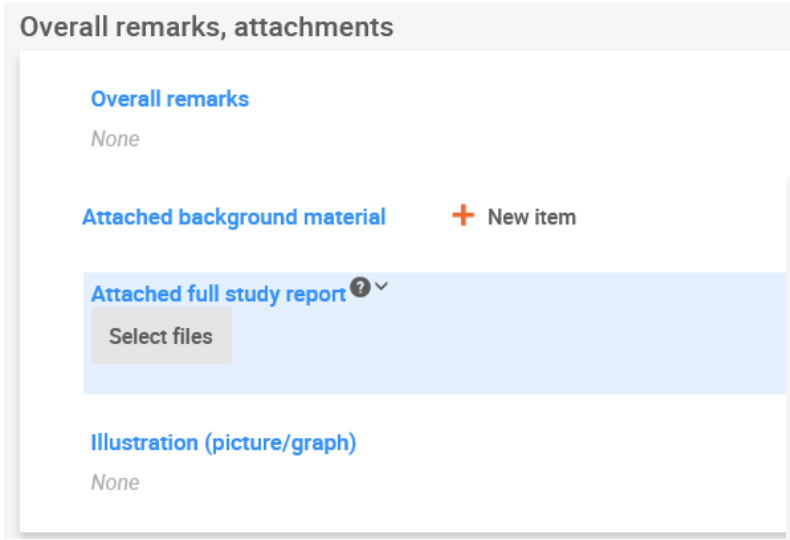


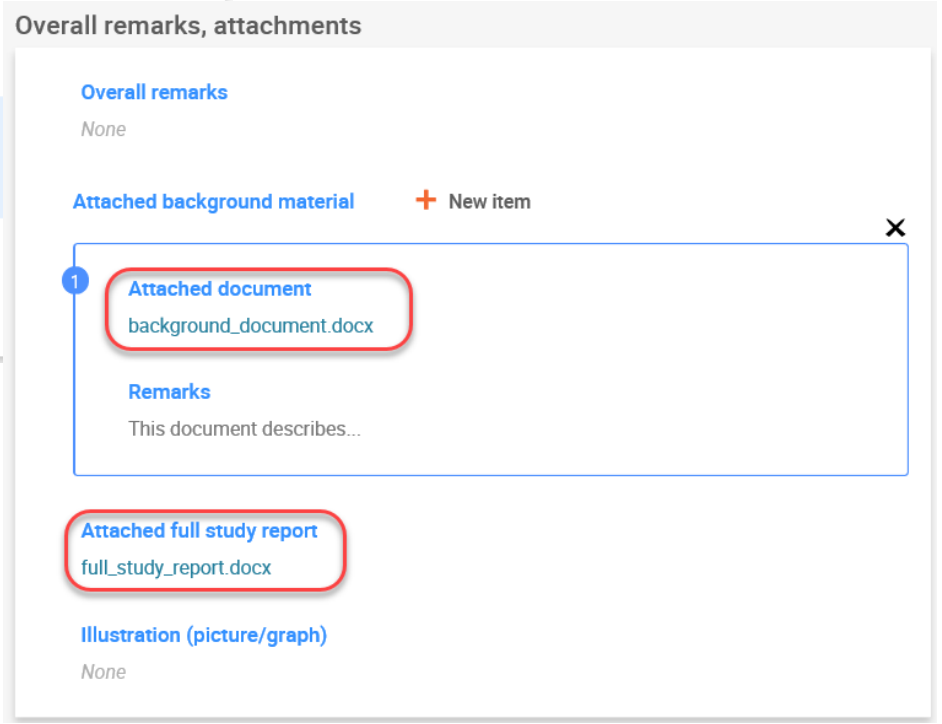
- Use the predefined text template



Attachments

…to the predefined fields

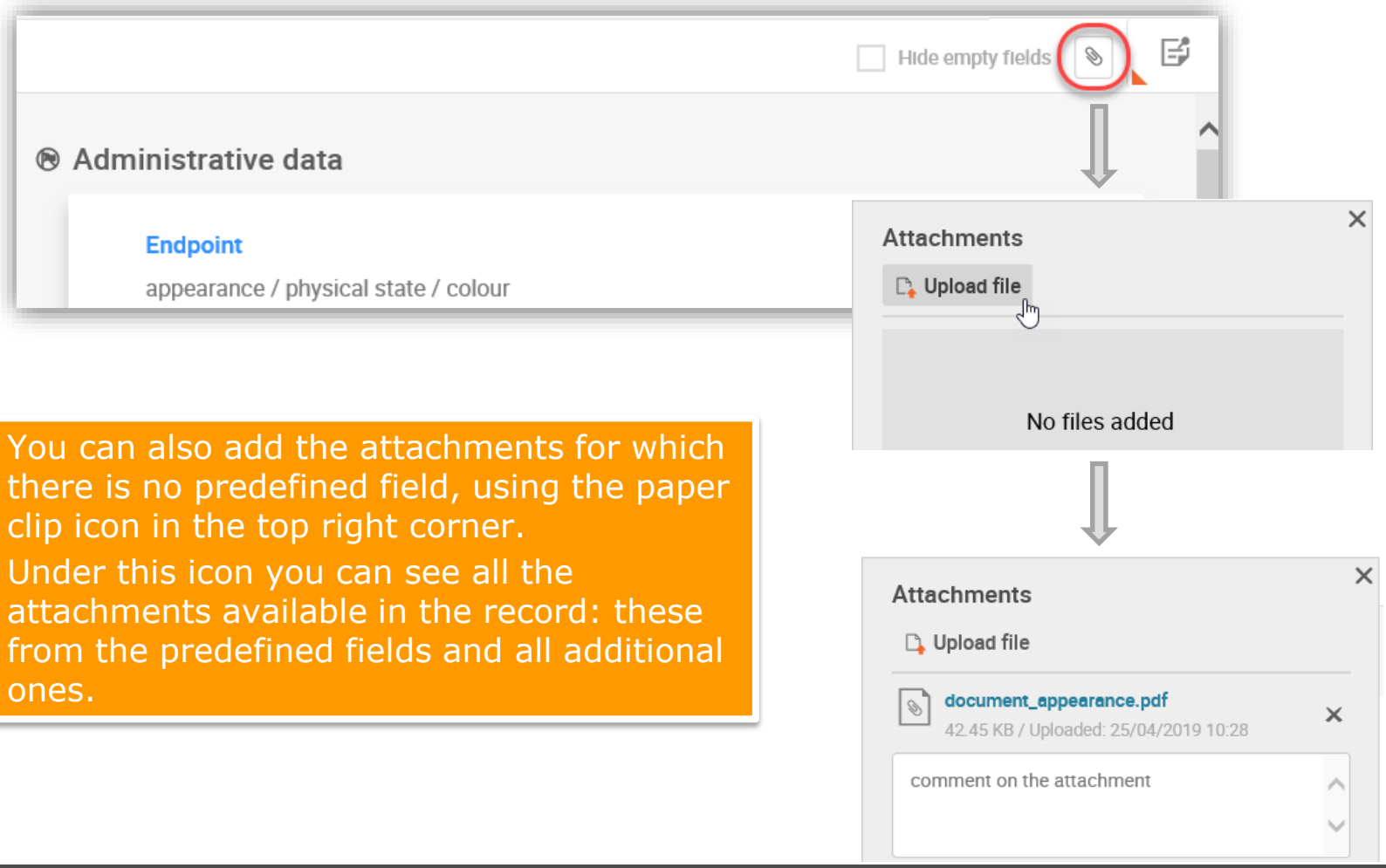




In the web user interface you can add the attachments in the predefined fields.

Attachments

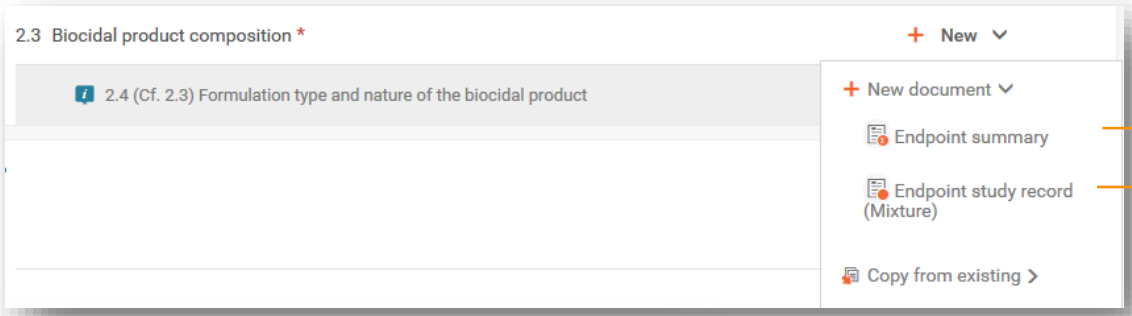
…to the whole endpoint /record



You can also add the attachments for which there is no predefined field, using the paper clip icon in the top right corner.

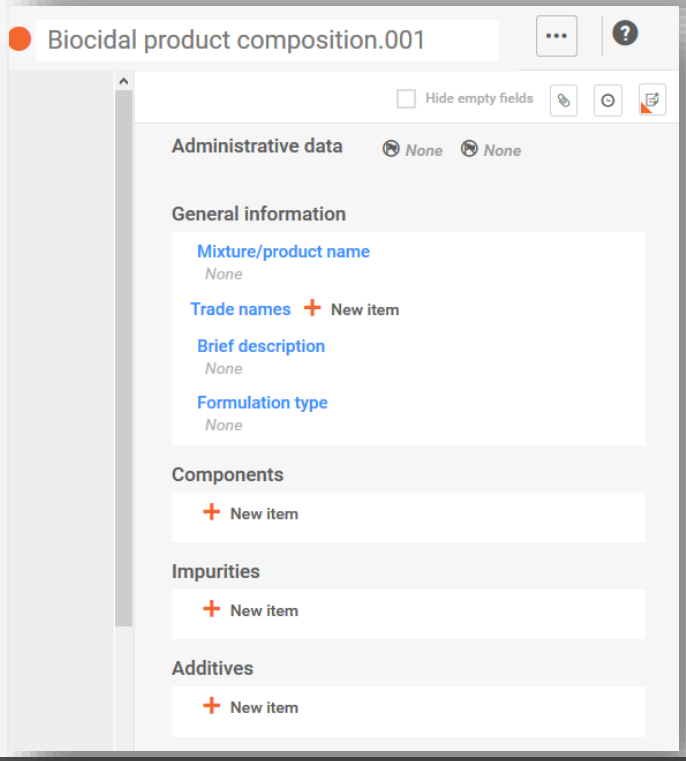
Under this icon you can see all the attachments available in the record: these from the predefined fields and all additional ones.

Assign components of the biocidal product



relevant to family, meta SPC

relevant to single product

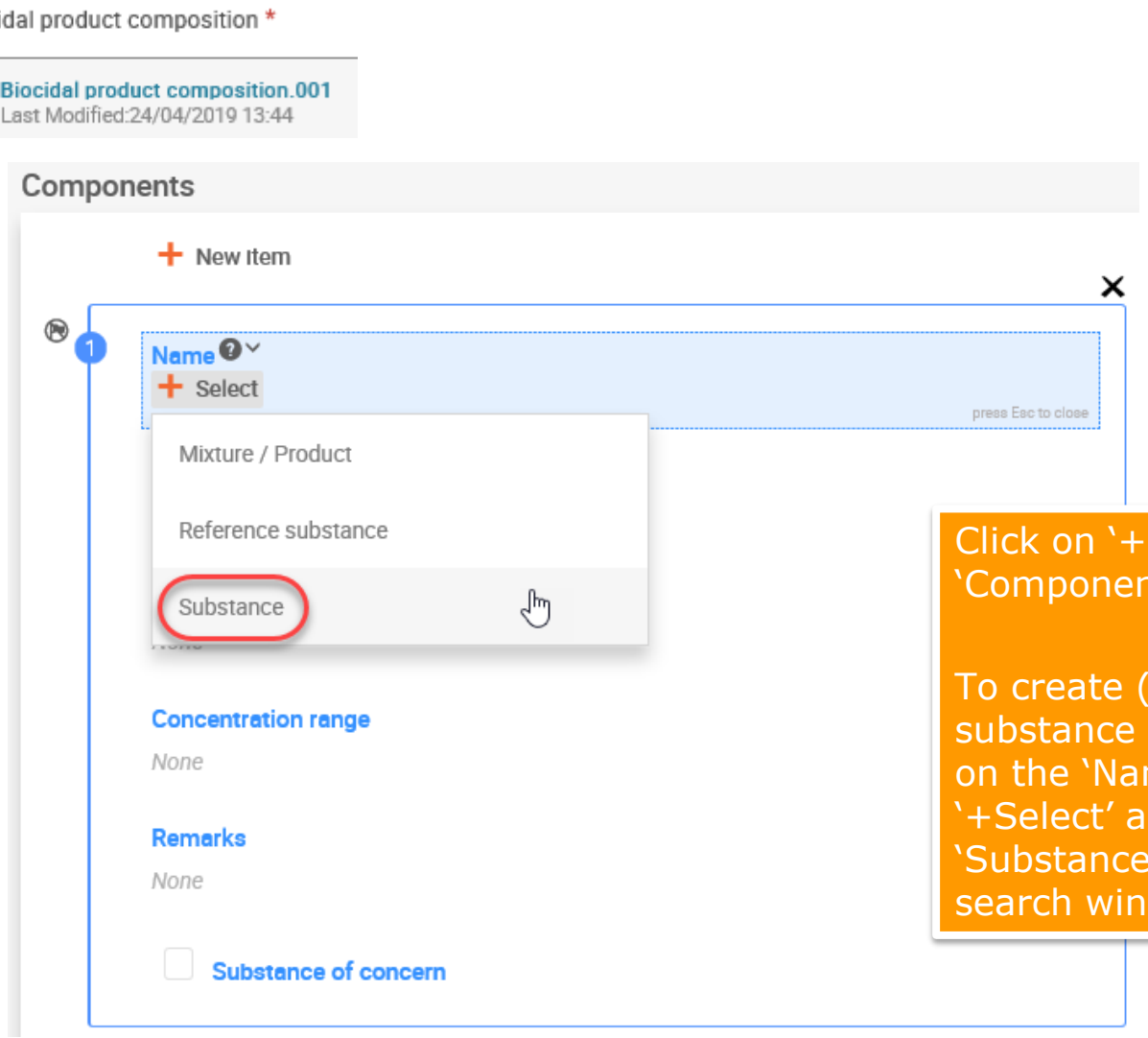


The crucial part of the correct BPR dossier is the composition section (2.3). In this section, you need to link all the components of the product, including the active substance.

You start by creating a new document in section 2.3.

Note: remember that 'Endpoint summary' is relevant only to family / meta SPC composition.

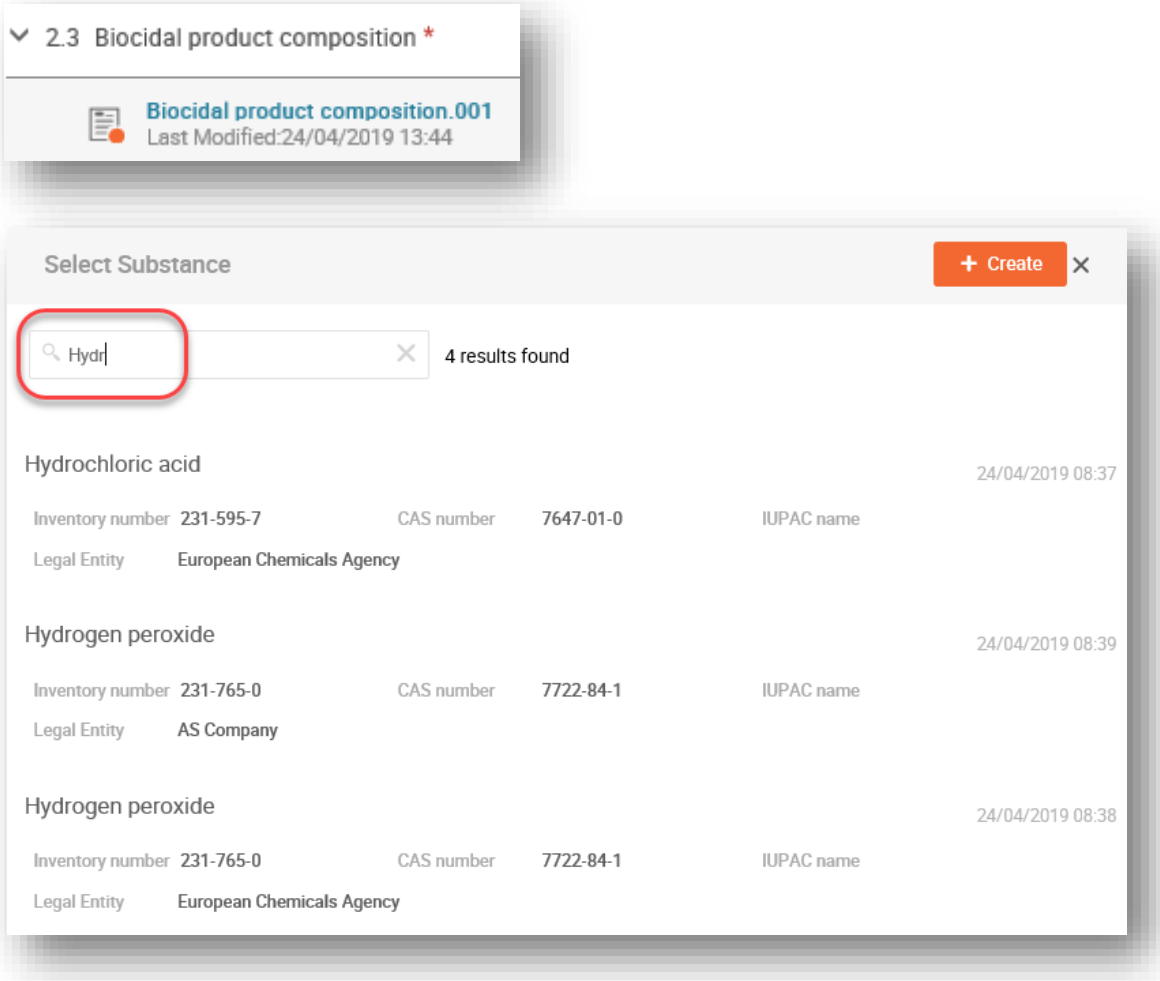
Select a substance component



Click on '+ New item' under 'Components.

To create (or link) the first substance component, click on the 'Name', then on '+Select' and finally on 'Substance' to open the search window.

Search for a substance component

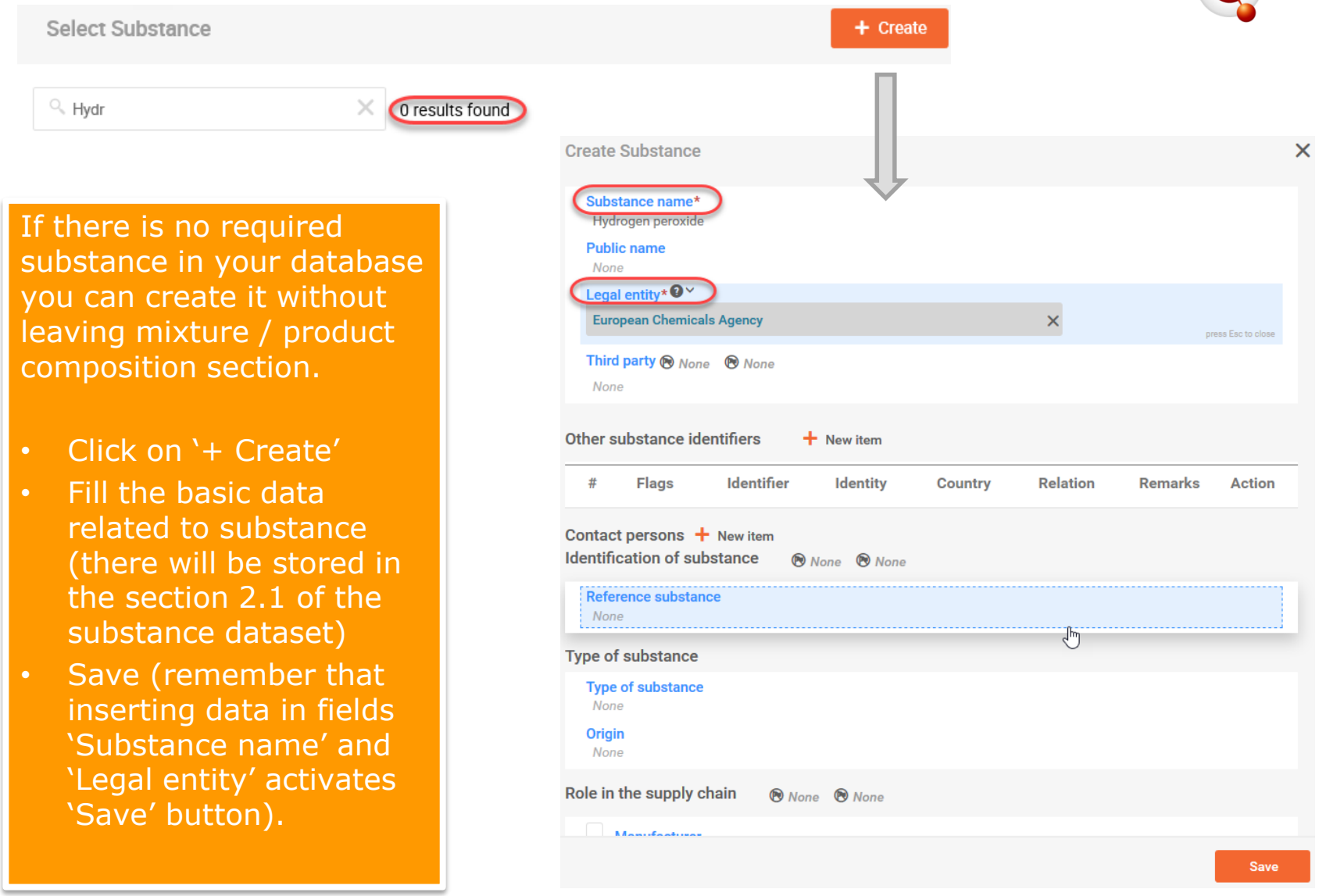


You can search a substance by:

- substance name
- EC number
- CAS number
- IUPAC name

Then it is enough to click on the selected substance to assign it.

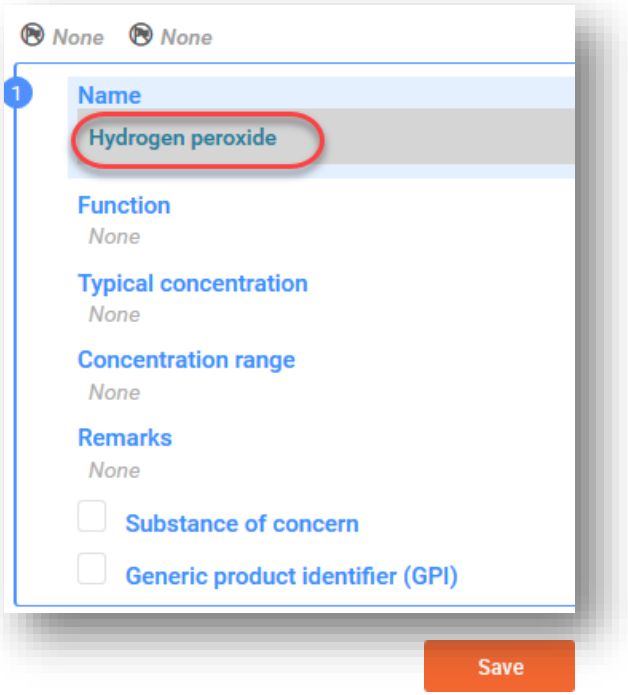
Create a substance component dataset

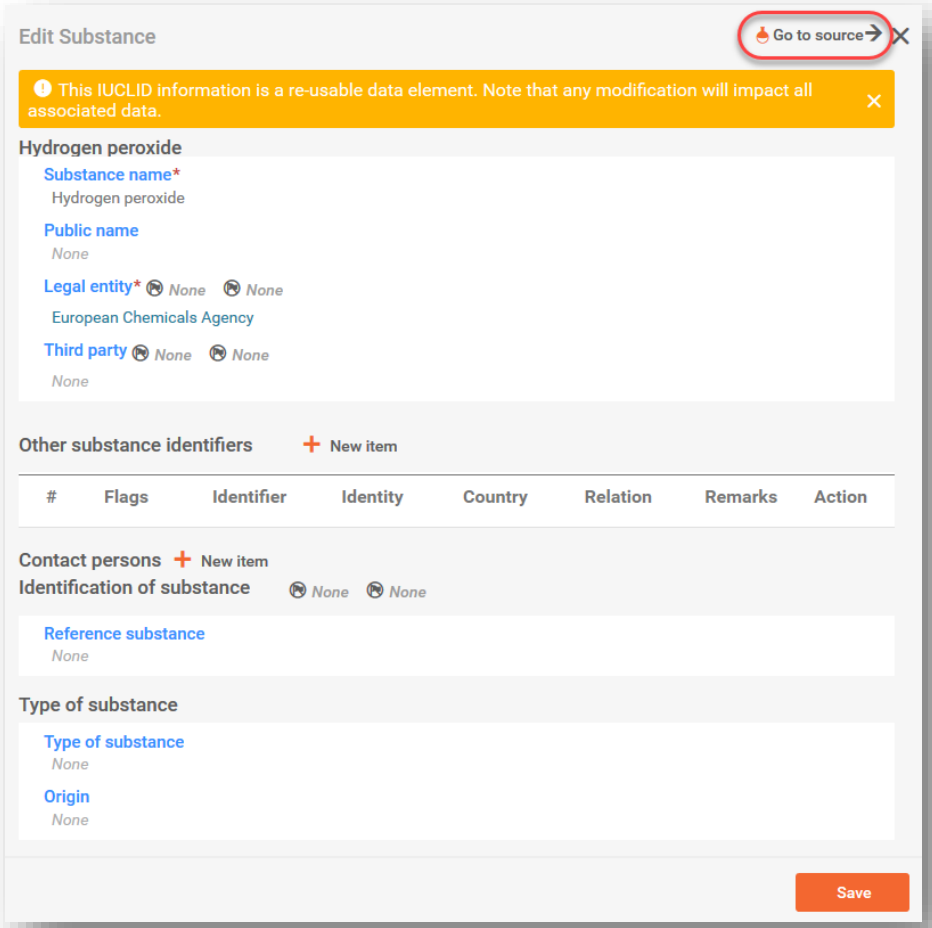


If there is no required substance in your database you can create it without leaving mixture / product composition section.

- Click on '+ Create'
- Fill the basic data related to substance (there will be stored in the section 2.1 of the substance dataset)
- Save (remember that inserting data in fields 'Substance name' and 'Legal entity' activates 'Save' button).

Open the substance component dataset

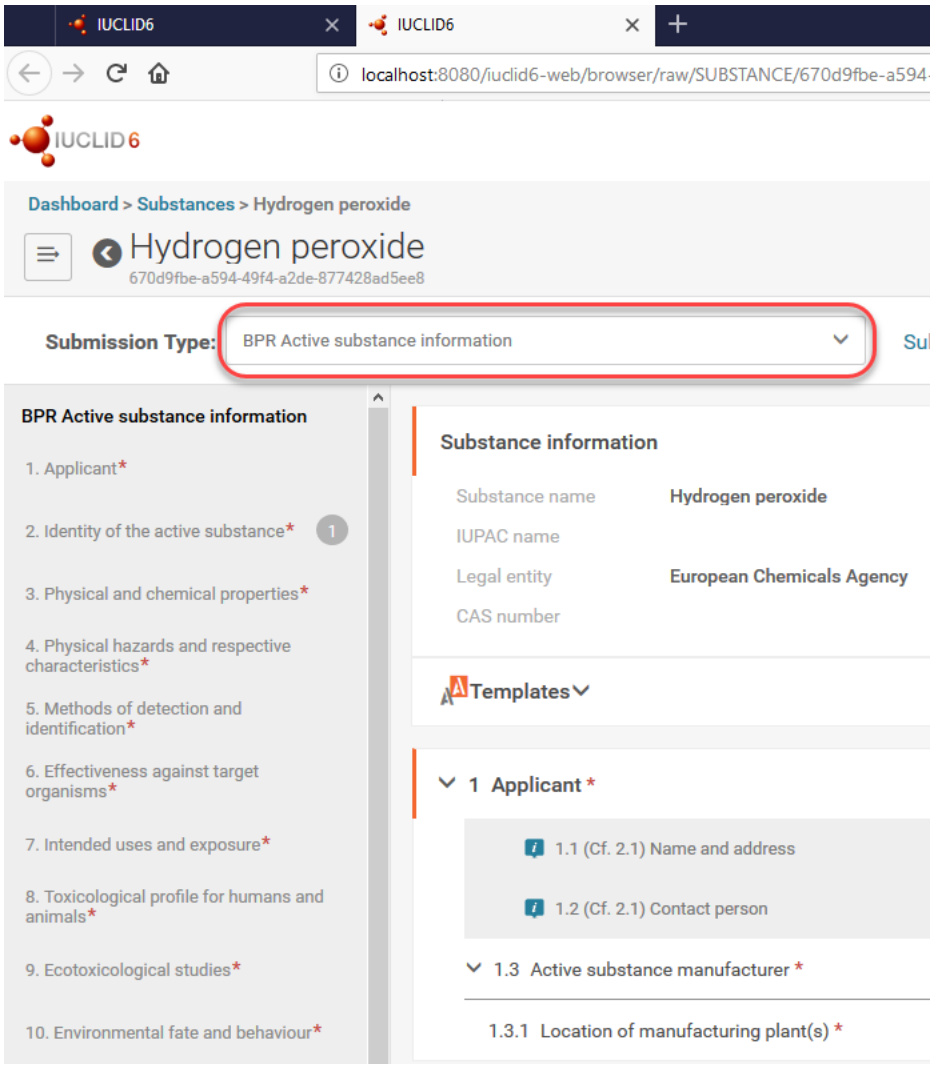




At any time, you can come back to the substance and edit it.

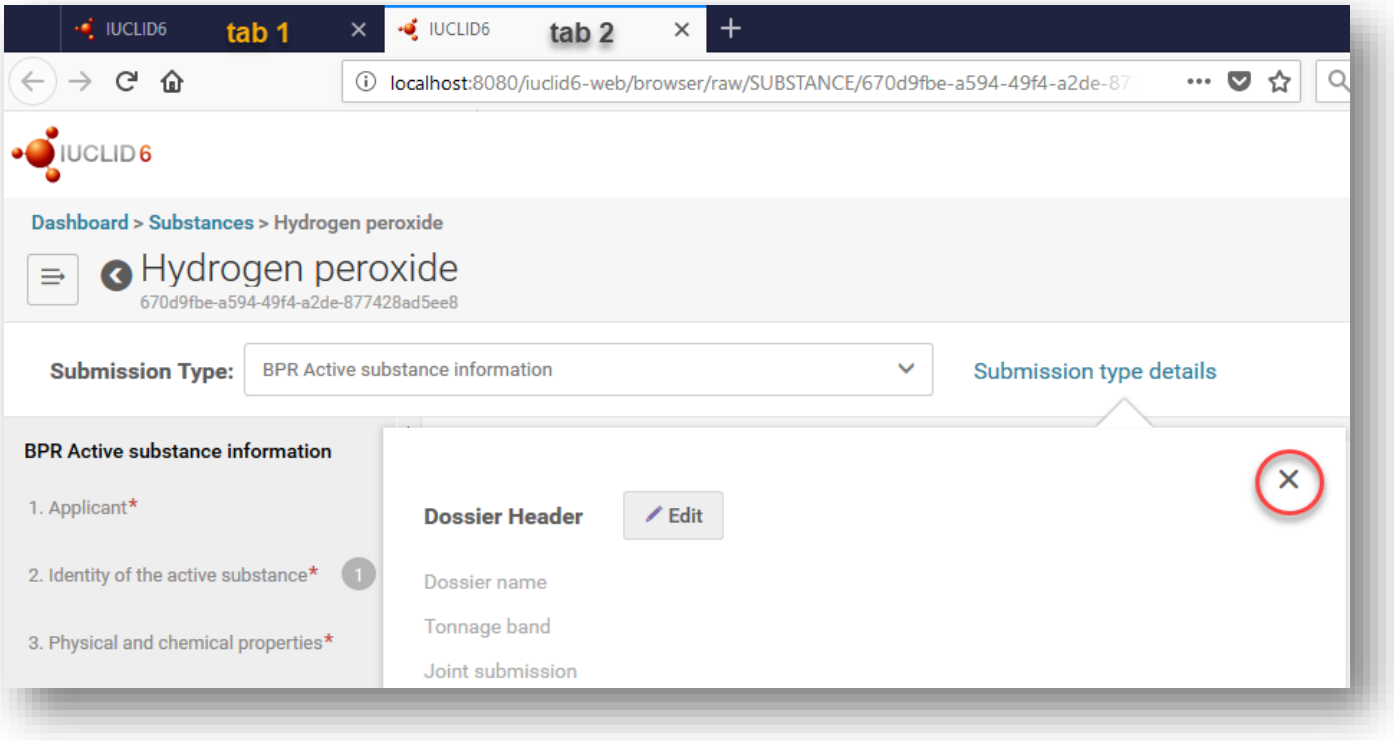
1. Click substance name which is a link
2. Click 'Go to source' button in the top right corner of the sliding window to open substance dataset in a new tab.

Edit substance dataset in a new tab



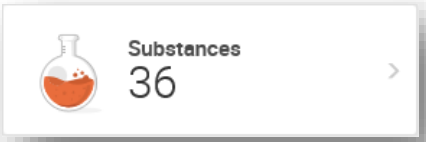
3. In the substance dataset which opened in the second tab, select correct submission type, so the correct table of contents can be displayed on the left

Select submission type

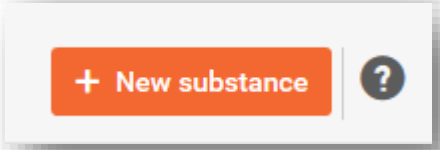


4. When the submission type is selected, the pop up window 'Dossier header' appears. You need to close it because the BPR dossier is created always based on mixture / product dataset, so you do not edit a dossier header for substance.
5. You can now work on both datasets: product (in the first tab) and substance (in the second tab).

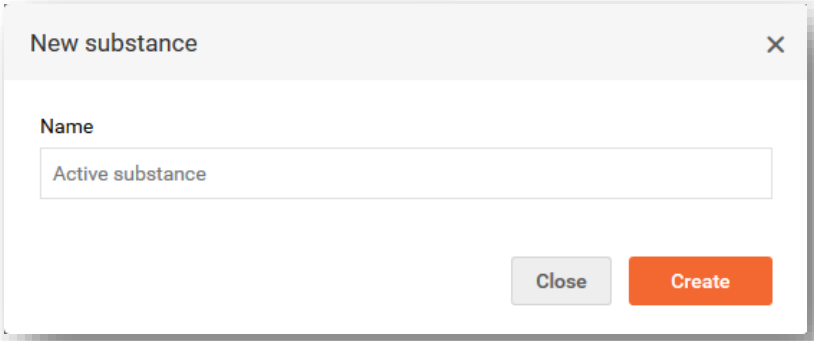
Alternative way of creating new substance



1. On the Dashboard click on 'Substances'



2. Click on '+ New substance'



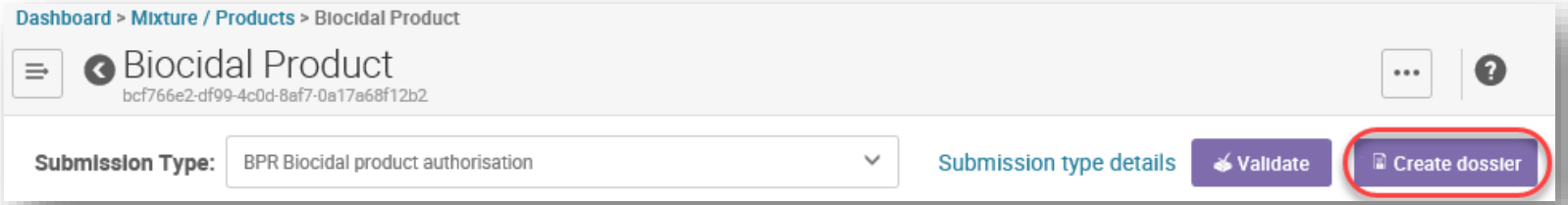
3. Insert substance name

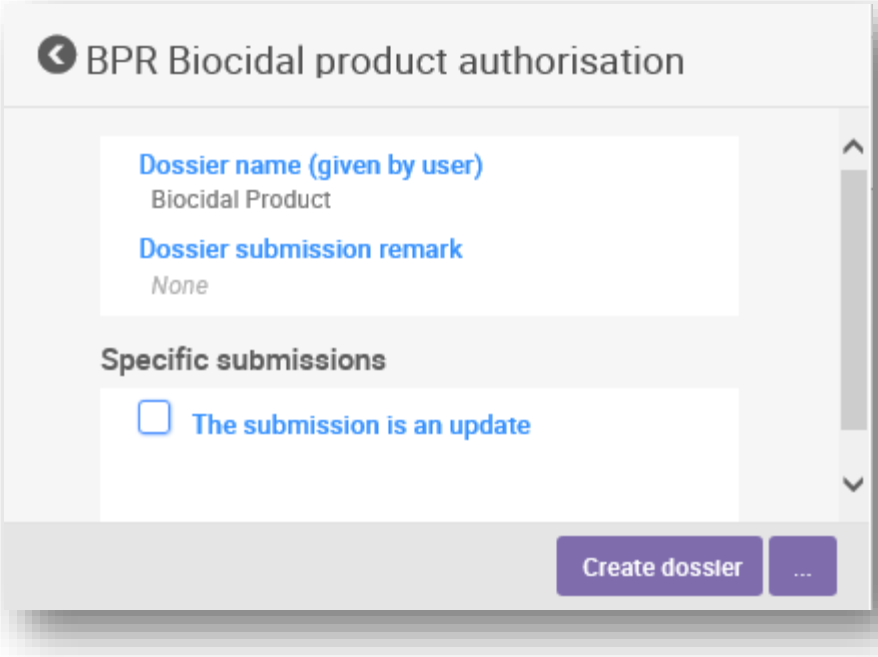
All following steps of editing substance remain the same, and once the substance dataset is saved, it can be linked in section 2.3 of the mixture / product composition.

You can access any substance through the mixture / product composition to edit it further.

Dossier creation – editing dossier header

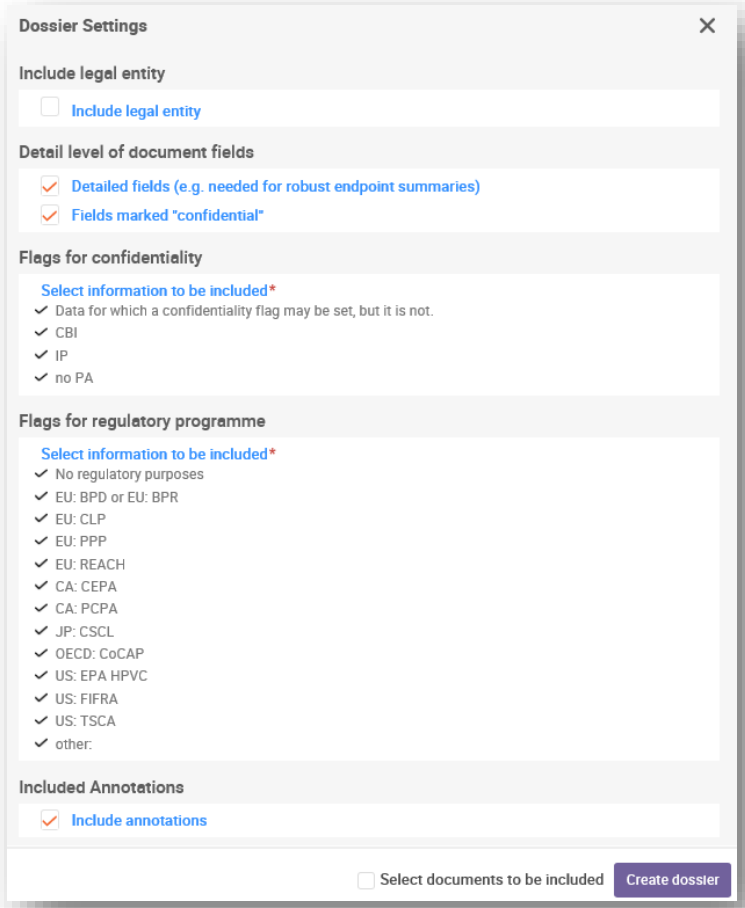
Once the biocidal product dataset is ready, there is time to create a dossier. The 'Create dossier' button is active only if the submission type is selected.

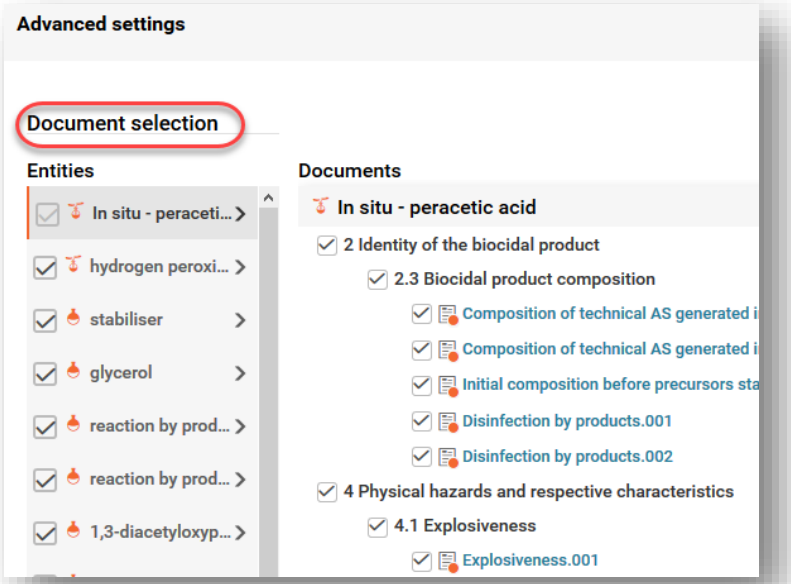




You edit Dossier header information; if there were any data inserted earlier, they will be displayed as well, and you can modify them.

Dossier creation – advanced settings

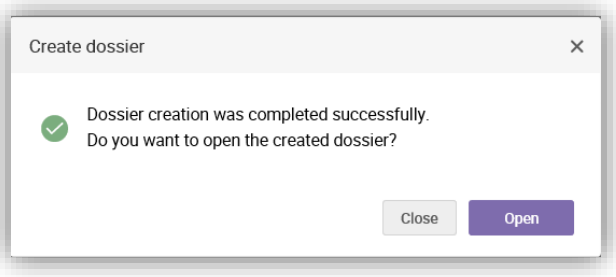




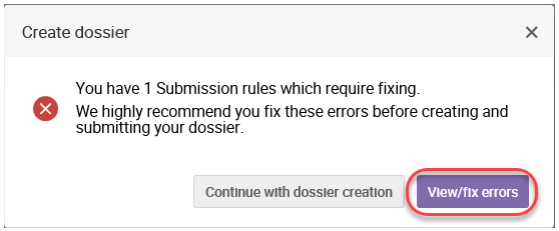
Under the '…' icon you approach the dossier settings, where you can decide for example whether the legal entity, or fields marked as confidential should be included. You can also select documents (records) to be included/excluded.

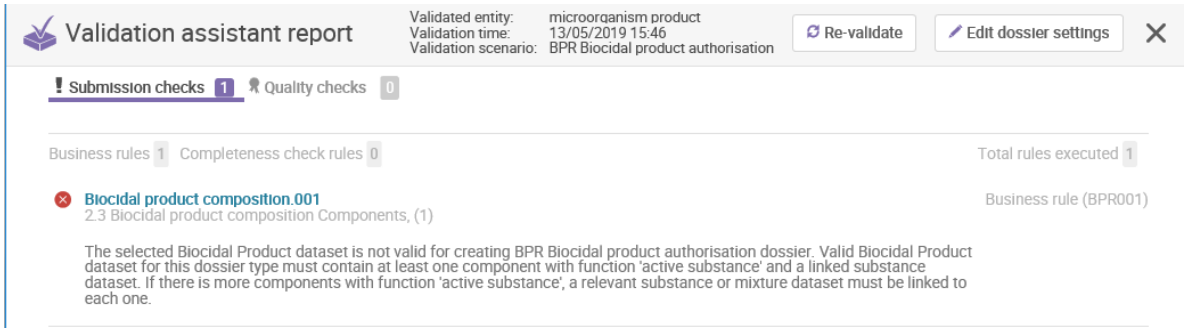
Dossier creation – validation

During the dossier creation existing validation rules are checked automatically, and if there is no failure, the message appears saying that the dossier has been created successfully.



If there is a failure, you are informed about what is the failure reason. It is recommended to fix the problem before the dossier is created, even if the continuation with dossier creation is possible.

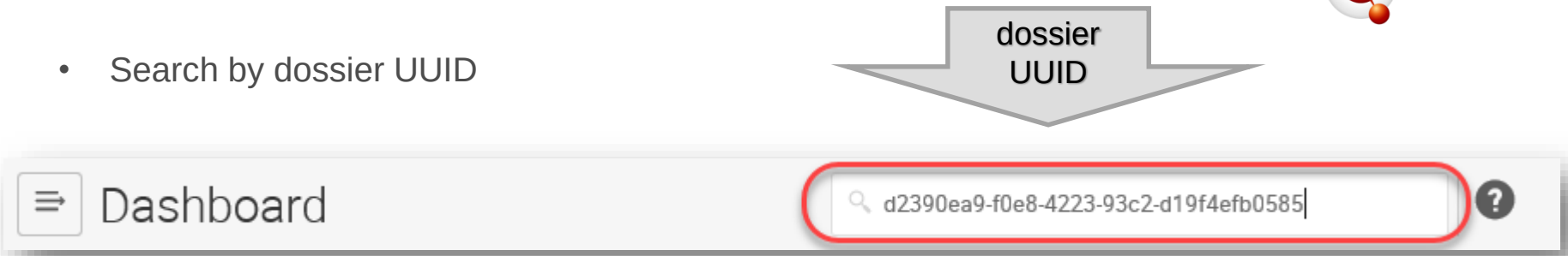




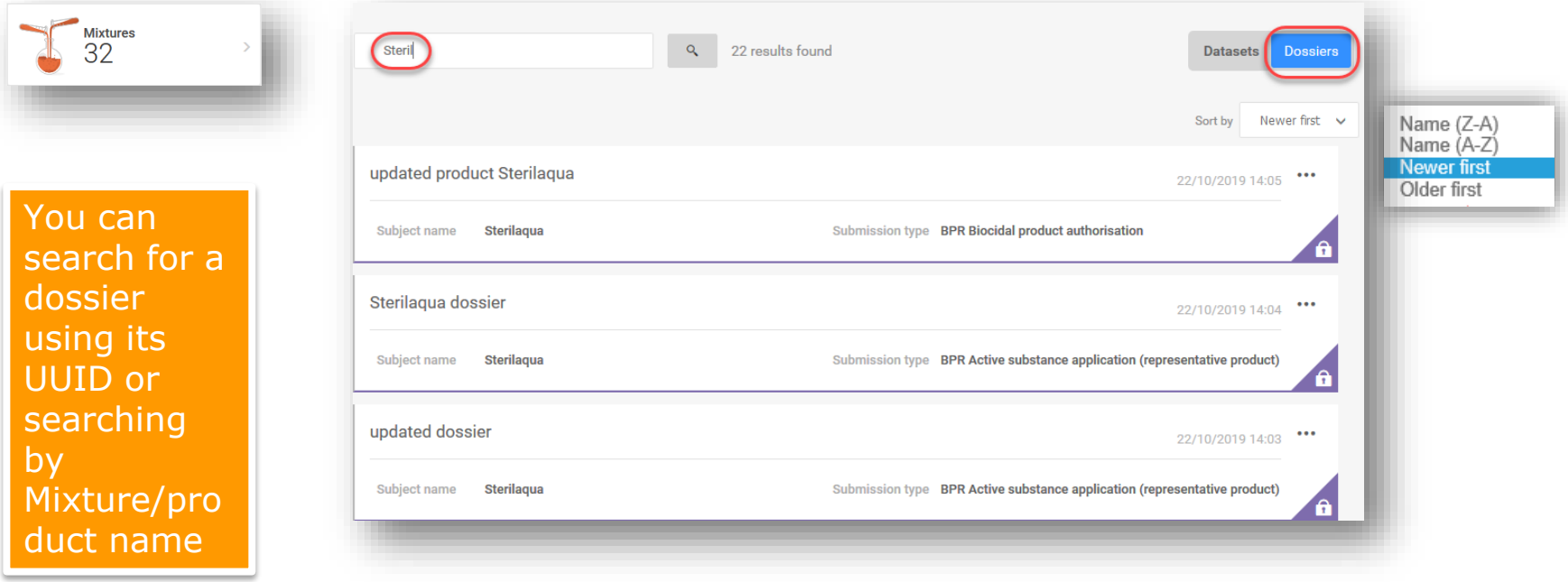
Navigation through the BPR dossier

Search for a dossier

- Search by dossier UUID



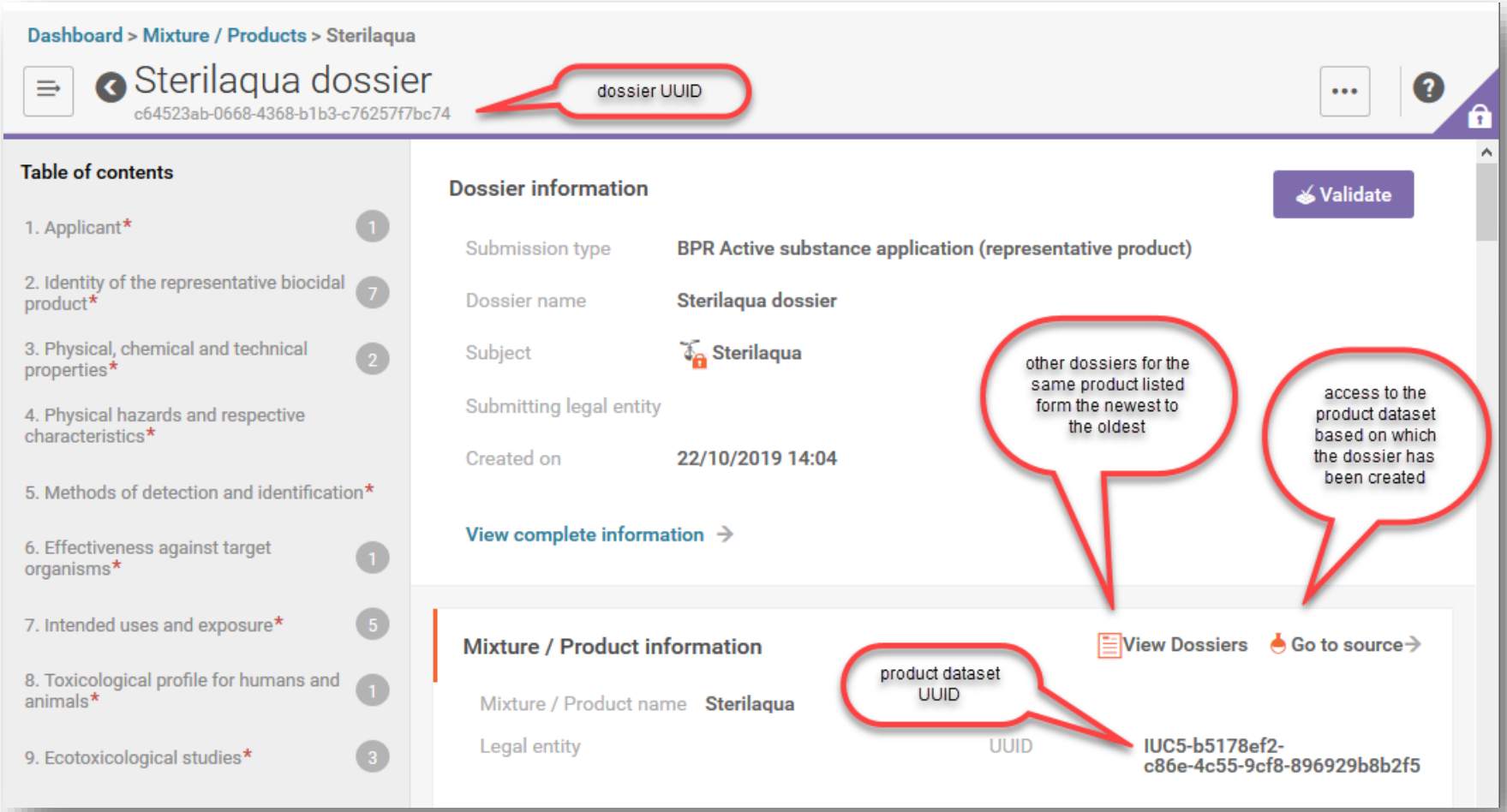
- Search by mixture/product name (Mixtures widget)



You can search for a dossier using its UUID or searching by Mixture/product name

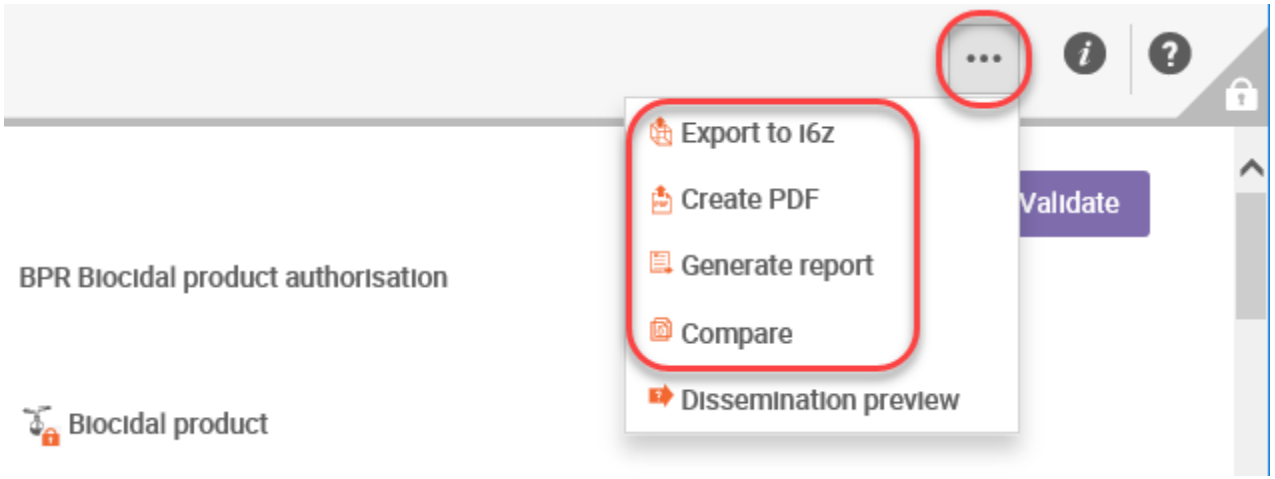
Navigation through the BPR dossier

When you open the dossier…

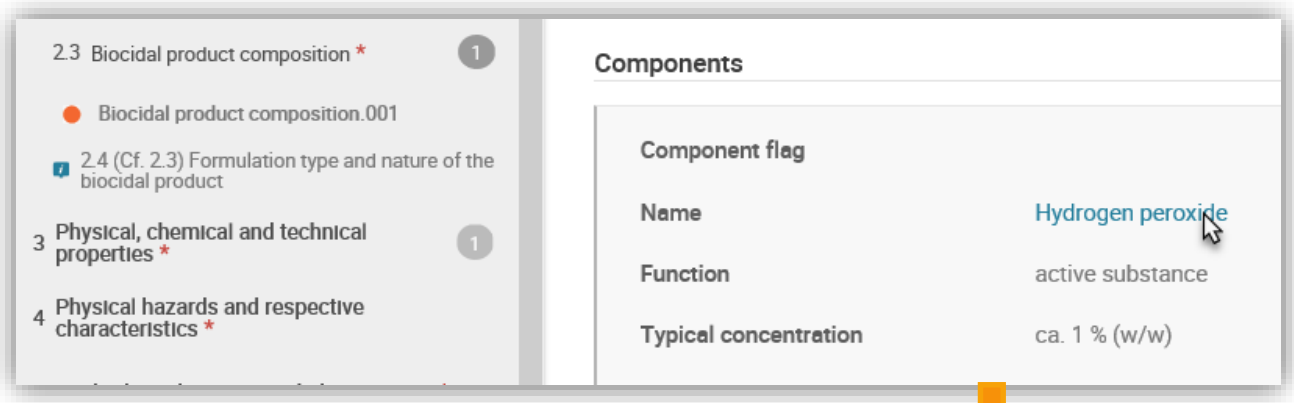


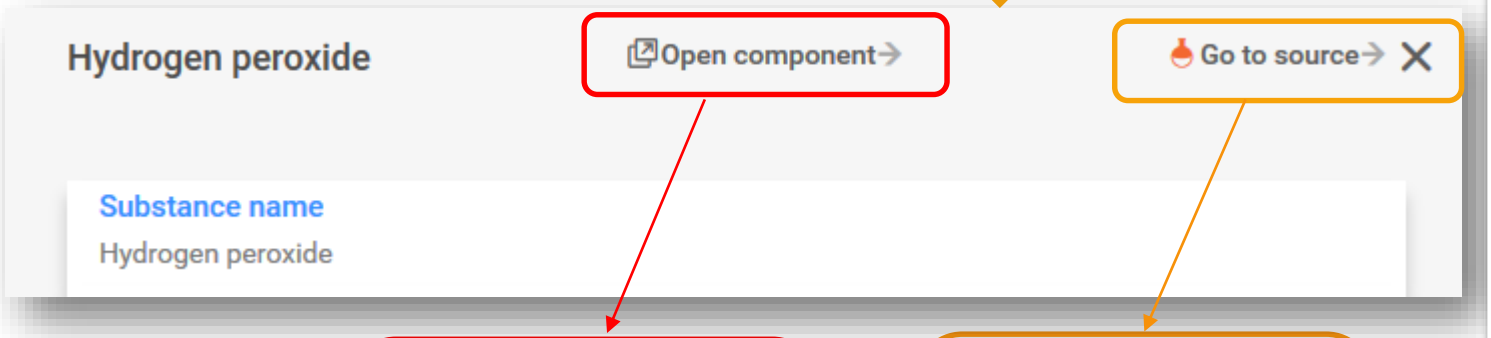
Actions on the BPR dossier

- Validate
- Export
- Print to pdf
- Generate report
- Compare two dossiers



Access to the dossier component





the substance dataset opens in a view mode

the substance dataset opens, can be edited and used in other mixture/product

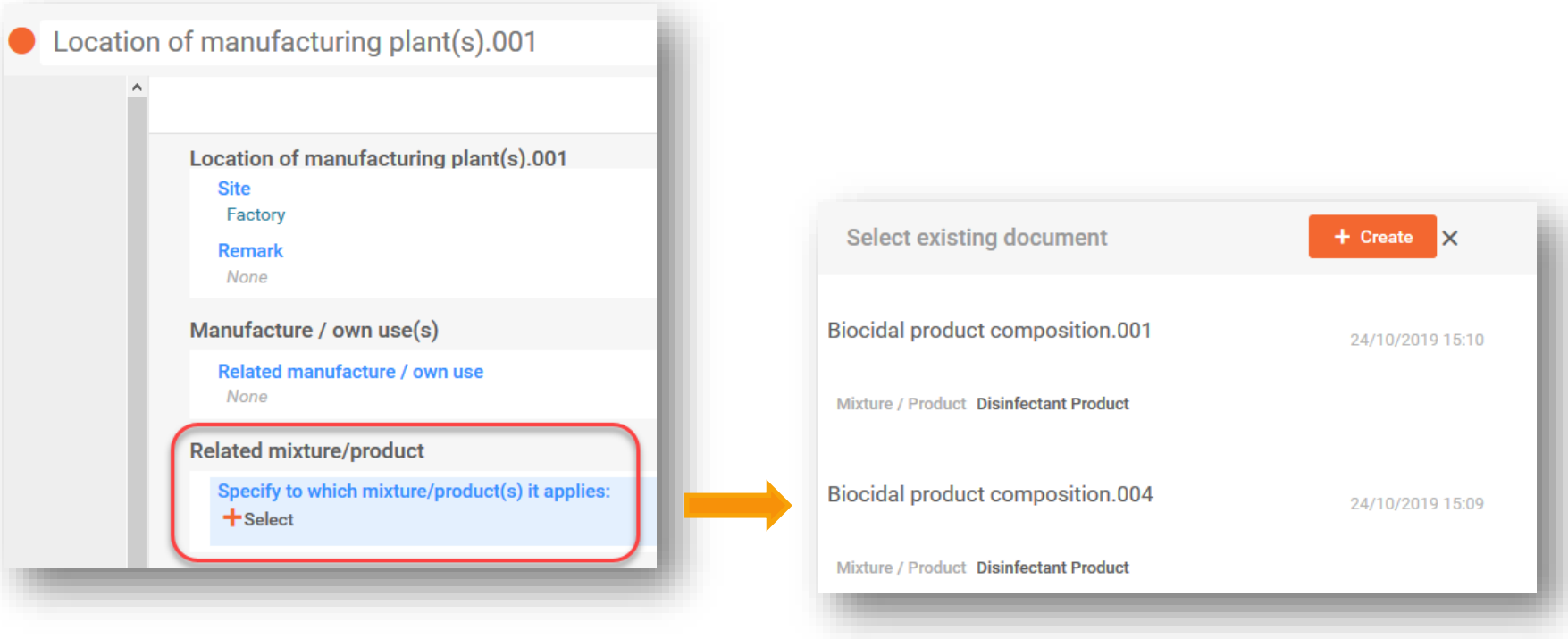
From the biocidal product composition section, inside of a dossier, you can open the substance dataset as a dossier component, or, you can open this substance dataset, edit it, and use it again.

IUCLID 6.4 format changes relevant to biocides

IUCLID 6.4 format changes (biocides)

Section 1.3.1 Location on manufacturing plant(s):

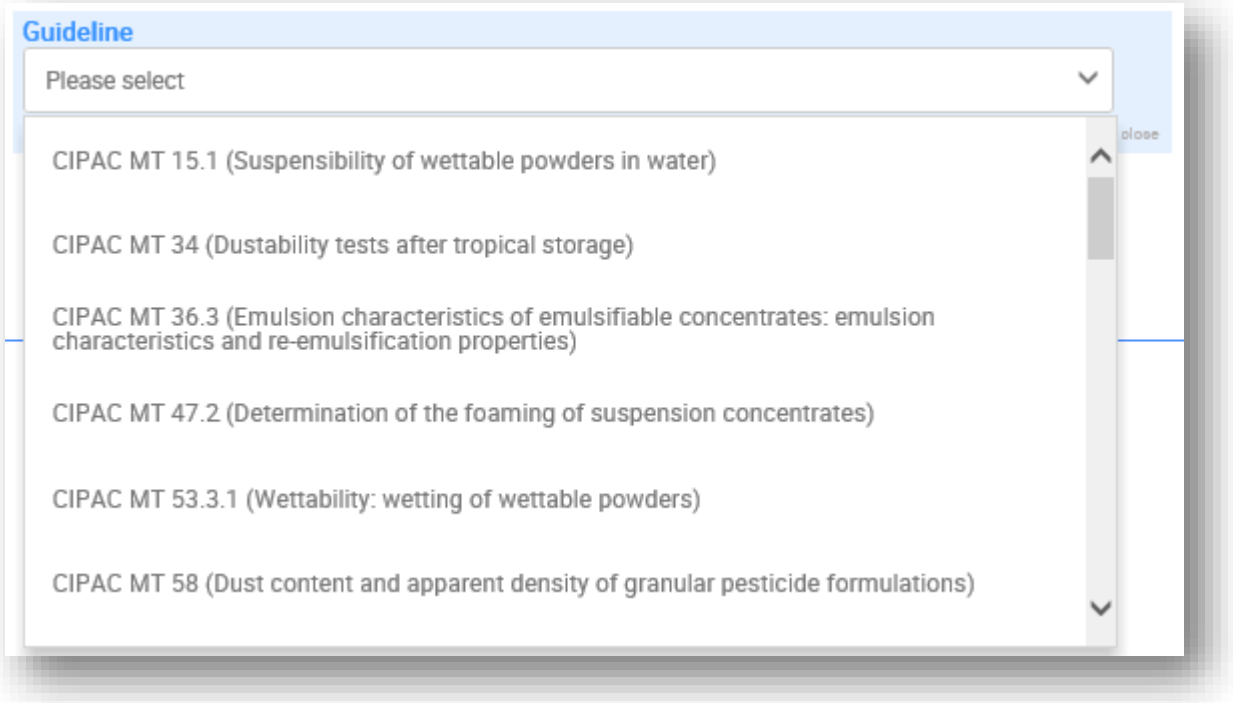
- Manufacturing plant is linked to the product (product composition) within the biocidal product family



IUCLID 6.4 format changes (biocides)

Section 3.5 Technical characteristics of the biocidal product

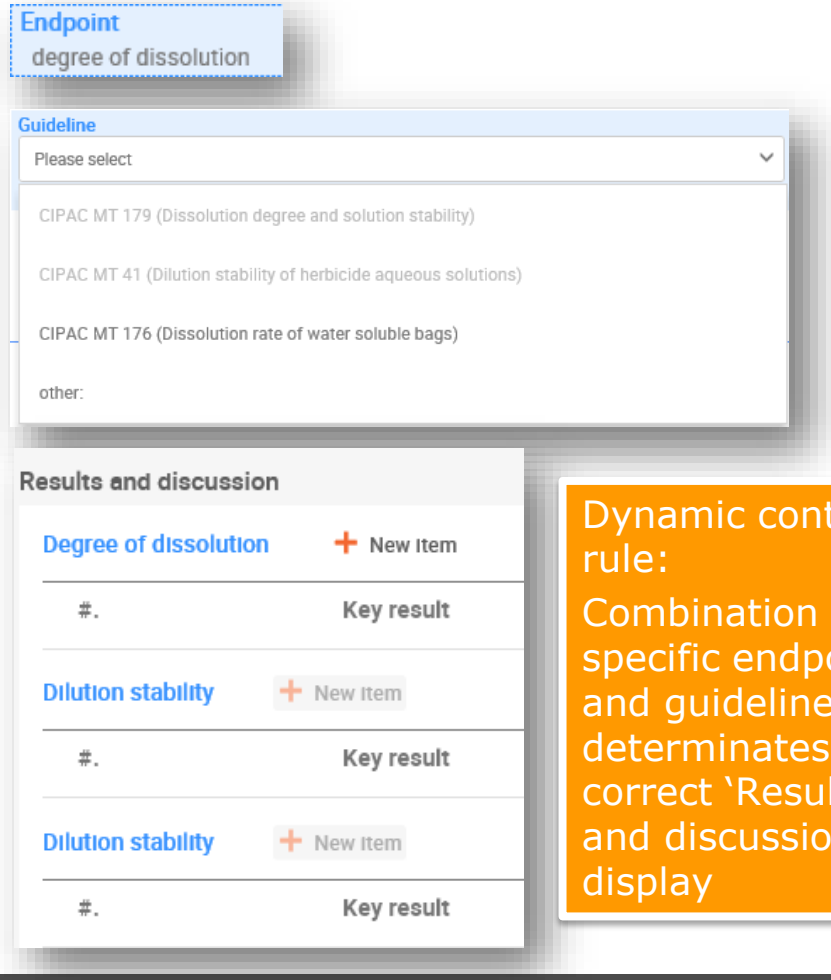
- Field ‘Type of method’ which contained only phrase ‘other:’ replaced by the list of the relevant methods in the ‘Guideline’ picklist



IUCLID 6.4 format changes (biocides)

Section 3.7 Degree of dissolution and dilution stability

- New document for mixture/product
- Methods covered:
  - ✓ CIPAC MT 176 Dissolution rate of water soluble bags
  - ✓ CIPAC MT 41 Dilution stability of herbicide aqueous solutions
  - ✓ CIPAC MT 179 Dilution stability and solution stability
- Dynamic content – specific 'Result and discussion' fields provided for each method

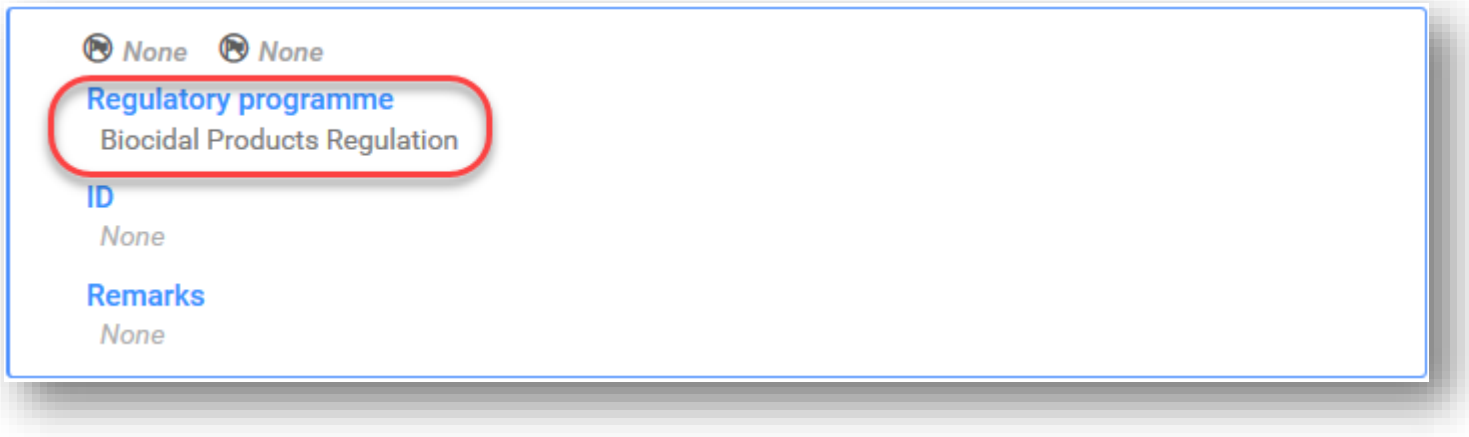


IUCLID 6.4 format changes (biocides)

Section 2.2 Manufacturer's development code and number of the biocidal product

Section 2.3 Manufacturer's development code number(s)

- This section became optional in all submission types
- Biocidal Products Regulation has been added to the ‘Regulatory programme’ picklist



IUCLID 6.4 format changes (biocides)

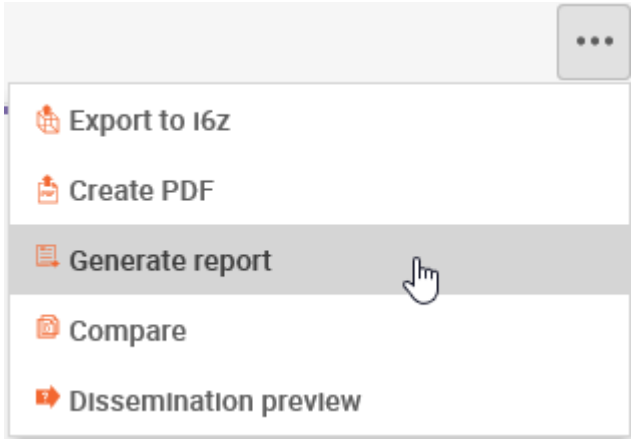
Updated OHT templates used by different legislations including BPR

- Dispersion stability of nanomaterials OHT #401
- Toxicity to microorganisms OHT #47
- Acute toxicity: inhalation OHT #61
- Acute toxicity: dermal OHT #62
- Repeated dose toxicity: inhalation OHT #68
- Genetic toxicity in vivo OHT #71
- Metabolism of residues in crops and rotational crops OHT #85-3
- Nature of residues in processed commodities OHT #85-8
- Repeated dose toxicity – oral OHT #67
- Toxicity to reproduction OHT #73
- Monitoring data OHT #38
- Residues in crops (field trials) and in rotational crops (limited field studies) OHT #85-5
- Effectiveness against target organisms and intended uses - general information OHT #88
- Efficacy data OHT #89
- Short-term toxicity to fish OHT #41
- Biodegradation in water screening tests OHT #28

Report generator

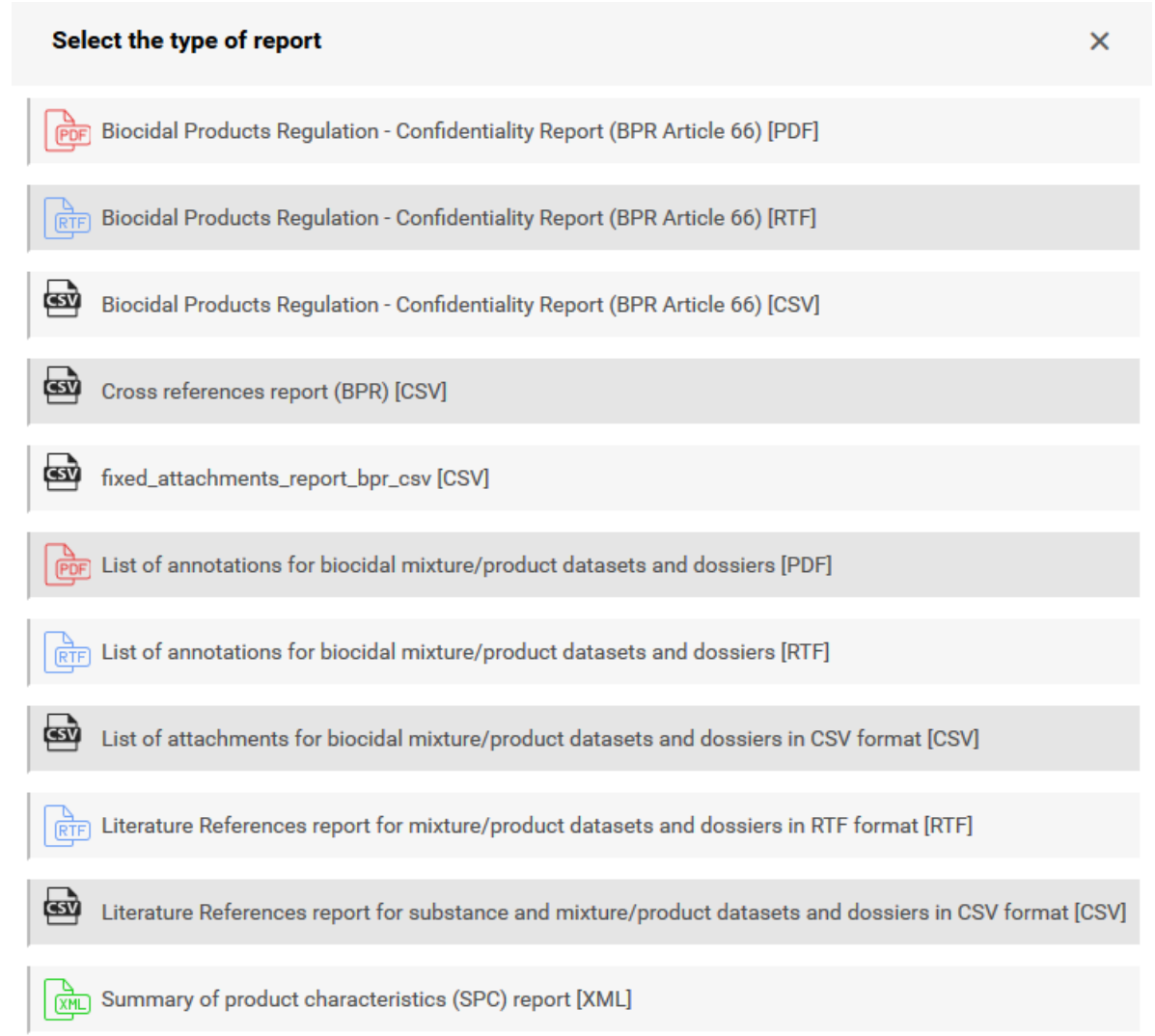
Report generator

What is the Report generator



- The report generator extracts IUCLID data in a structured and standalone format such as: RTF/PDF/CSV/XML/HTML
- IUCLID contains a number of reports made and added for Biocides users since IUCLID 6.1 (more on these later)
- IUCLID allows you to manually upload your own report templates. More info on the IUCLID website: https://iuclid6.echa.europa.eu/reports

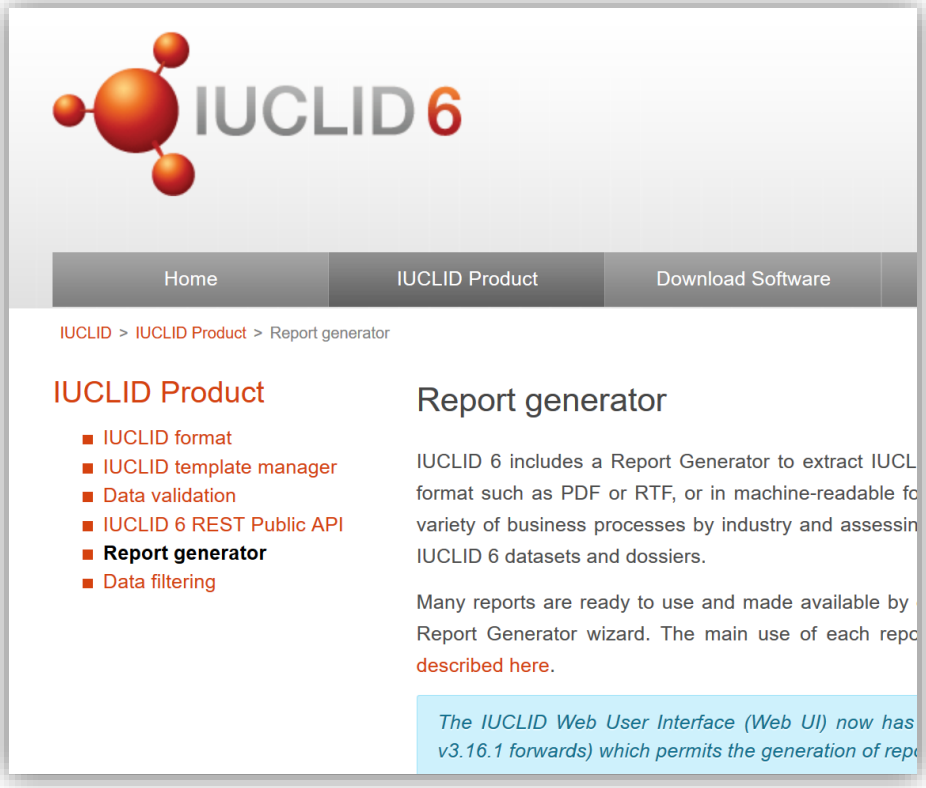
Report generator



Reports are progressively added to the list, and updated to the latest format.

Report generator

Description of all reports



Go to the Report generator webpage for a description of the main uses of the reports: https://iuclid6.echa.europa.eu/reports

Comparison tool

Comparison tool

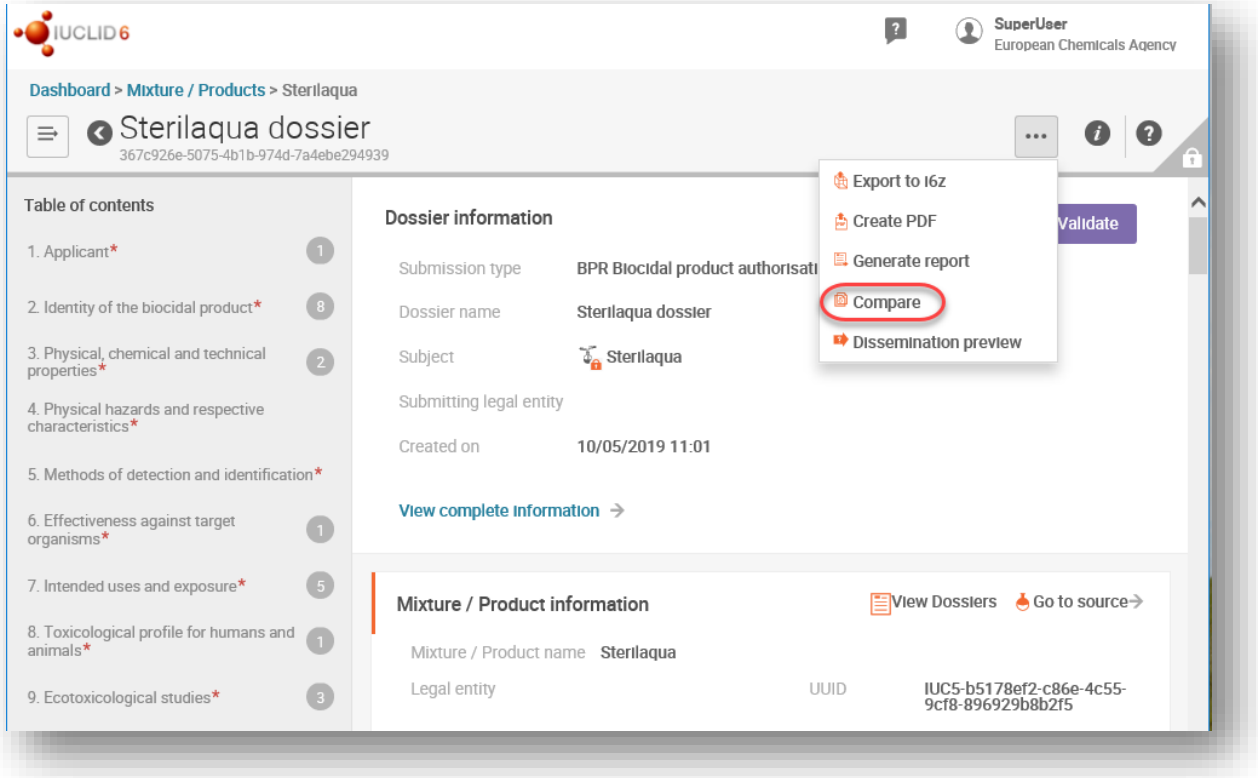
Purpose

- 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

Report is available only in the web user interface

Comparison tool

Where to start

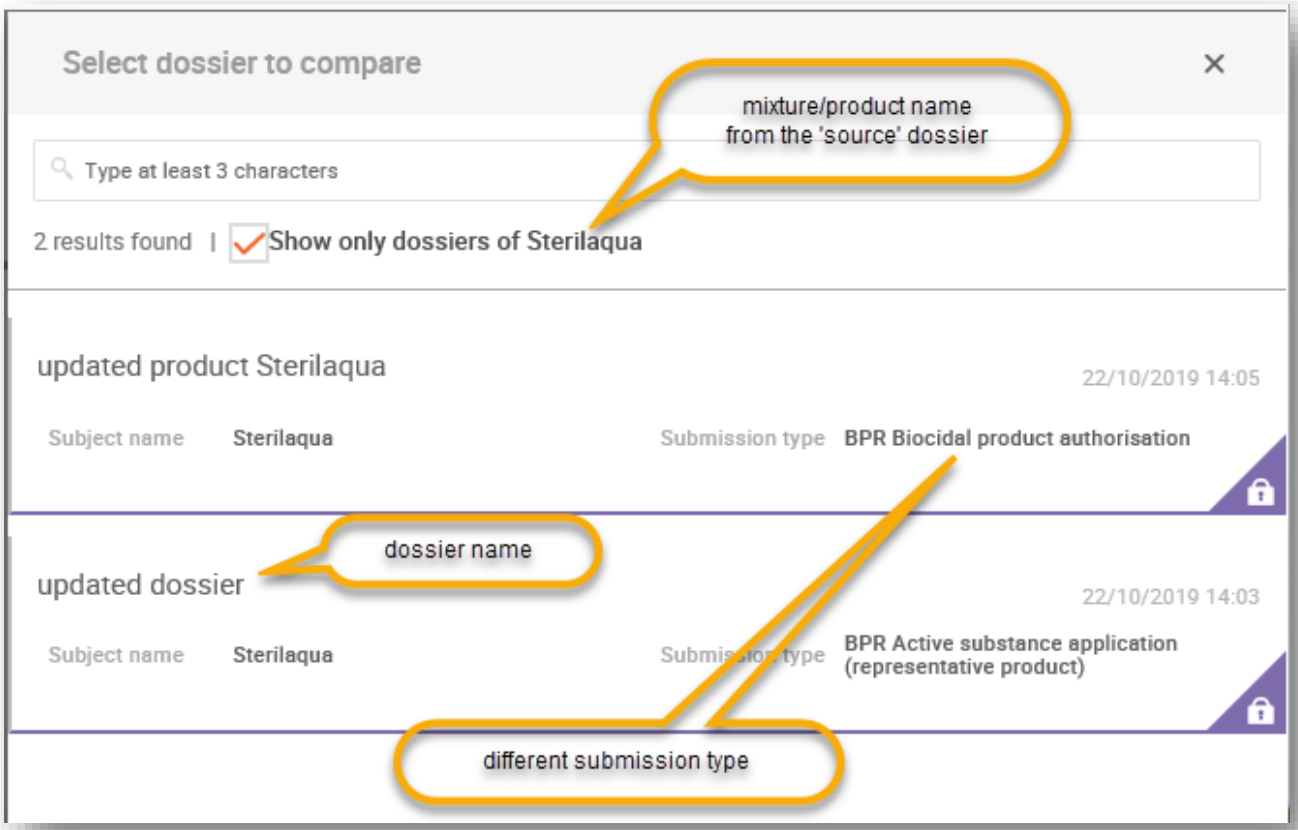


To begin with the tool, you must have at least two dossiers to compare in your database.

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

Comparison tool

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 tool

Comparison report – dossiers entities level

Dossier Comparison Report

Dossiers

Source	**Submission type:** BPR Biocidal product authorisation **Subject:** Sterilaqua **Creation date:** May 10, 2019 11:11:43 (+0300)
Target	**Submission type:** BPR Biocidal product authorisation **Subject:** Sterilaqua **Creation date:** May 10, 2019 11:01:52 (+0300)

Dossier contents

Source	Comparison	Target
Dossier headers		
BIOC_BIOCIDAL_PRODUCT / subject: Sterilaqua	Different	BIOC_BIOCIDAL_PRODUCT / sub Sterilaqua
Mixtures		
Sterilaqua	Identical	Sterilaqua
Substances		
Hydrogen peroxide hydrogen peroxide 7722-84-1	Different	Hydrogen peroxide hydrogen pe 84-1
water water oxidane 7732-18-5	Identical	water water oxidane 7732-18-5
Legal entities		
BP manufacturer Helsinki Finland	Identical	BP manufacturer Helsinki Finlan
AS Company Warszawa Poland	Identical	AS Company Warszawa Poland

Under 'Dossiers' you see the source and the target dossiers. Then, 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 which are different. Mixtures, substances, legal entities, reference substances, contacts, and literature references are analysed.

Comparison tool

Comparison report – section document level and field level

Section Document comparison

Sterilaqua

Source	Comparison	Target
Sterilaqua	Identical	Sterilaqua
1.3 - Biocidal product manufacturer		
Suppliers: BP manufacturer / Helsinki / Finland	Identical	Suppliers: BP manufacturer / Helsinki / Finland
2.3 - Biocidal product composition		
ProductSummaryComposition: Family	Identical	ProductSummaryComposition: Family
MixtureComposition: Meta 1 Product 1	Different	MixtureComposition: Meta 1 Product 1
ProductSummaryComposition: Meta 1	Identical	ProductSummaryComposition: Meta 1
MixtureComposition: Meta 1 Product 2	Identical	MixtureComposition: Meta 1 Product 2
ProductSummaryComposition: Meta 2	Identical	ProductSummaryComposition: Meta 2

MixtureComposition: Meta 1 Product 1

Field	Source	Target
Trade names Composition (mixture) > General information > Trade names	**Trade names** Country Trade name Produkt produkt	

Then, there are comparison results at the level of section documents. If there are differences here, the field level analysis is displayed, as you can see on the example.

Here, in the product composition the trade name of one of the products belonging to a family has been changed what is reflected on the field level.

Comparison tool

Comparison report – field level

- Melting: **Melting point / freezing point.001**

Field	Source	Target
Attached full study report *i* Melting point / freezing point > Overall remarks, attachments	• cebulice.jpg 63,476 image/jpeg	

- BoilingPoint: **Boiling point.001**

Field	Source	Target
Robust study summary *i* Boiling point > Administrative data	true	false

- Ph: **Acidity, alkalinity.001**

Field	Source	Target
Adequacy of study *i* pH > Administrative data	supporting study	key study

Further examples of the differences:

- attachment
- check box
- pick list phrase

Plans of further improvements

Coming improvements

We are working on:

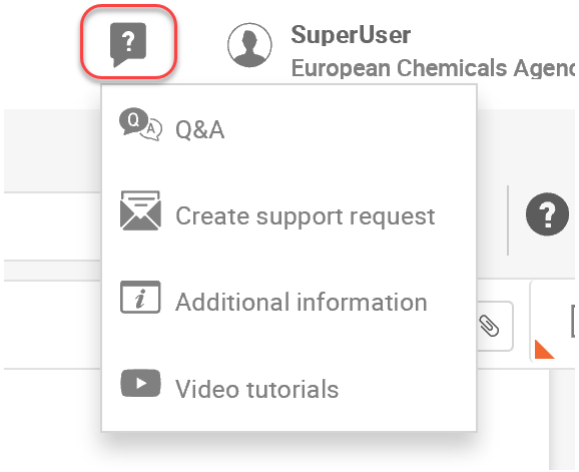
- Annotations
- Reference documents: enable multiple selection (for example selection of multiple products relevant for the meta SPC)
- Dataset cloning
- Bulk operation: copy, delete
- Navigation improvement
- Simplification of classification & labelling reporting
- New validation rules
- Improved printing of the dossier including the active substance data

Where to find more information

More information on the web user interface

Where to find more information:

- In IUCLID itself:
  - ✓ handy links to the IUCLID website: FAQ, news, video tutorials



- IUCLID website
  - ✓ Video tutorials
  - ✓ Training material
  - ✓ Webinars

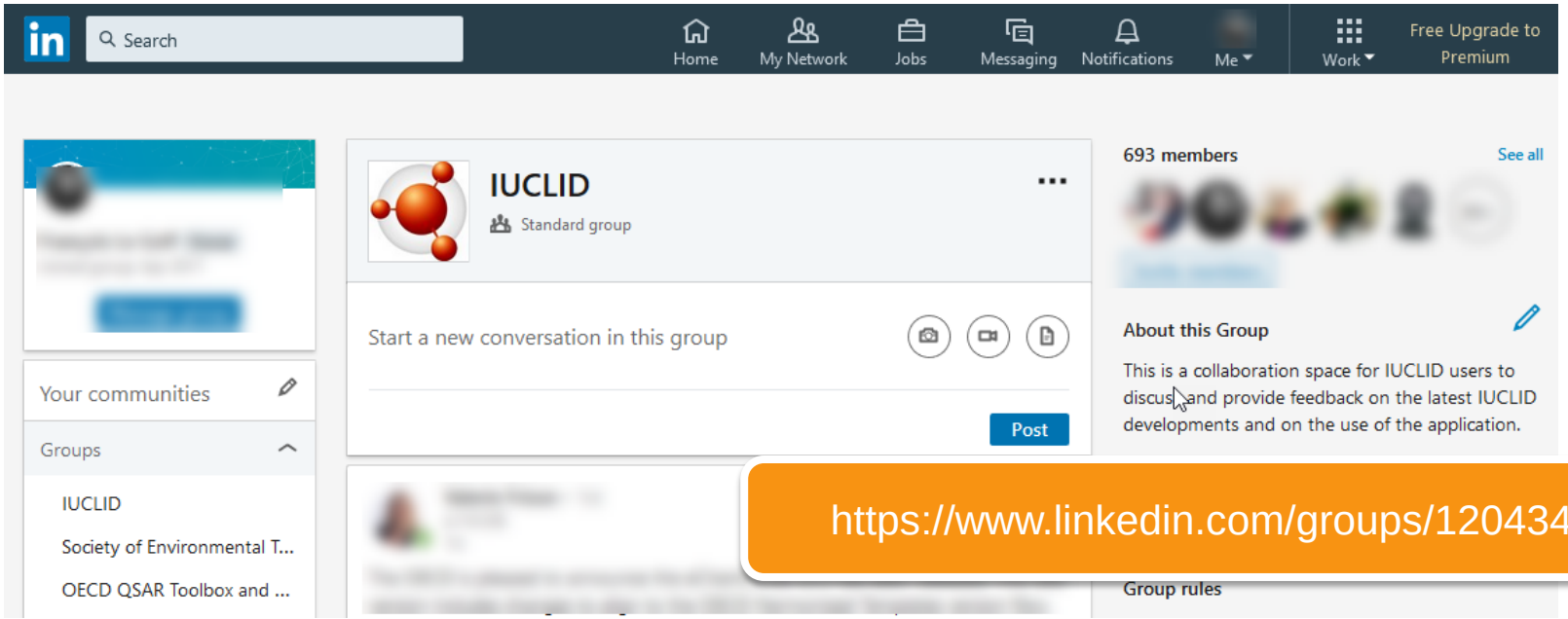
More information related to the release of IUCLID 6.4 is coming soon:

- on the IUCLID website: https://iuclid6.echa.europa.eu/news
- in the release webinar on 8th of November

More information on the web user interface

IUCLID LinkedIn group

IUCLID is the essential tool for any organisation or individual that needs to record, store, submit, and exchange data on chemical substances in the format of the OECD Harmonised Templates. Follow IUCLID on LinkedIn.



Thank you for your attention

echa.eu | iuclid6.echa.europa.eu | oecd.org/ehs/templates

ECHA EUROPEAN CHEMICALS AGENCY

OECD

IUCLID 6 is developed by the European Chemicals Agency in association with the OECD