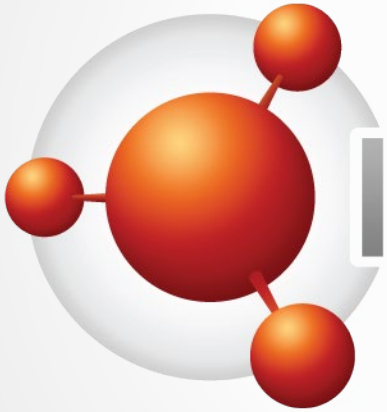


# IUCLID 6

ECHA
EUROPEAN CHEMICALS AGENCY

OECD

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

# IUCLID 6

## IUCLID 6.5 for Biocides users

*24th November 2020*

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

# IUCLID webinar

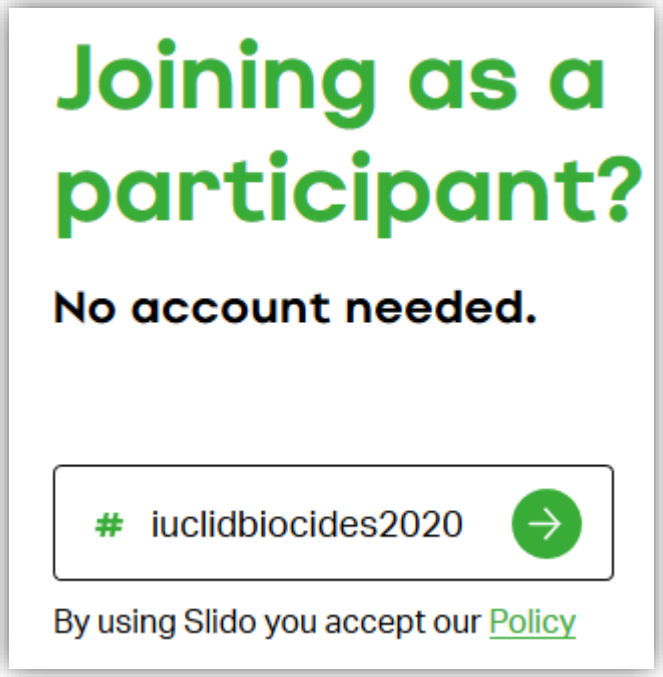
## Agenda for today

| What? | Who? | When? |
|---|---|---|
| Welcome and introduction | Dorota Burchard-Sosnowska | 12:30 (EEST) |
| Biocides submissions: biocidal product dataset, substance dataset, creation and navigation of a dossier in IUCLID 6.5 (web UI) | Dorota Burchard-Sosnowska | |
| Preparing a dossier for Technical Equivalence | Dorota Burchard-Sosnowska | |
| Format changes relevant to Biocides | Dorota Burchard-Sosnowska | |
| Annotations, attachments and print | Dorota Burchard-Sosnowska | |
| Report generator | Mark Roberts | |
| Plan for 2021 | Mark Roberts | |
| End of the webinar | | ~13:30 |

# Slido

## Question and answers session

- This time, the Q&A session is organised using Slido
- The Slido session will last until 14:30 pm (EET) on the webinar day
- You can decide to keep your questions anonymous
- We will answer your questions during the day




https://www.sli.do/

# WebEx instructions

## Recordings

After the meeting, we will publish on the IUCLID 6 website

- The recording of the webinar (+ presentation)
- Questions and answers (written document)

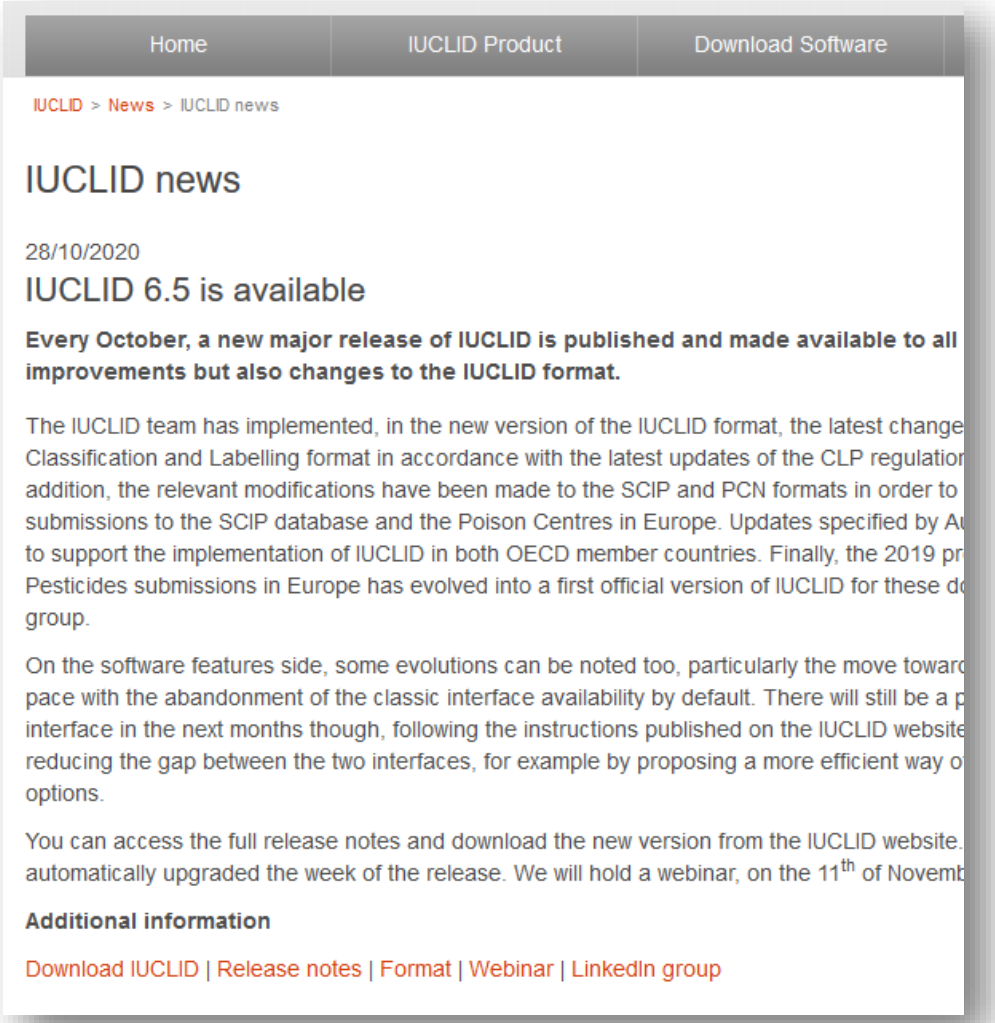
# IUCLID 6. 5 release

## Where to find information

- News alert published on the 28th of October to present the IUCLID 6.5 release
- A release webinar took place on Wednesday 11th of November

iuclid6.echa.europa.eu/webinars

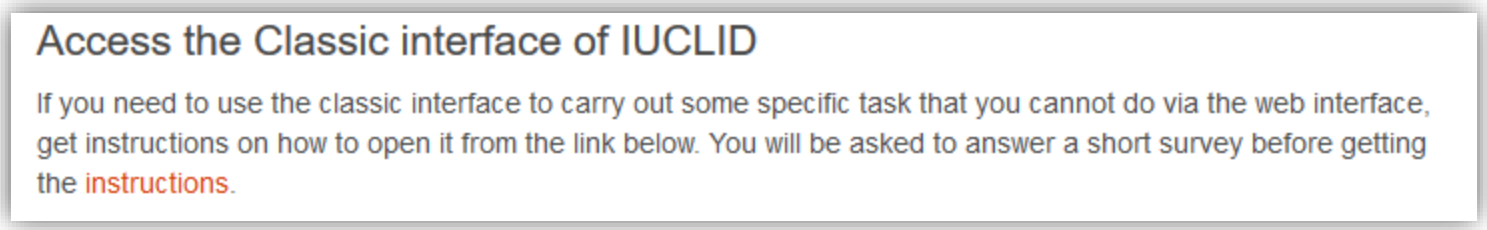
https://www.echa.europa.eu/-/iuclid-october-2020-release



# IUCLID 6. 5 release

## User interface

- Web user interface available by default
- Classic user interface available only for some advanced functionalities, e.g users and role managements

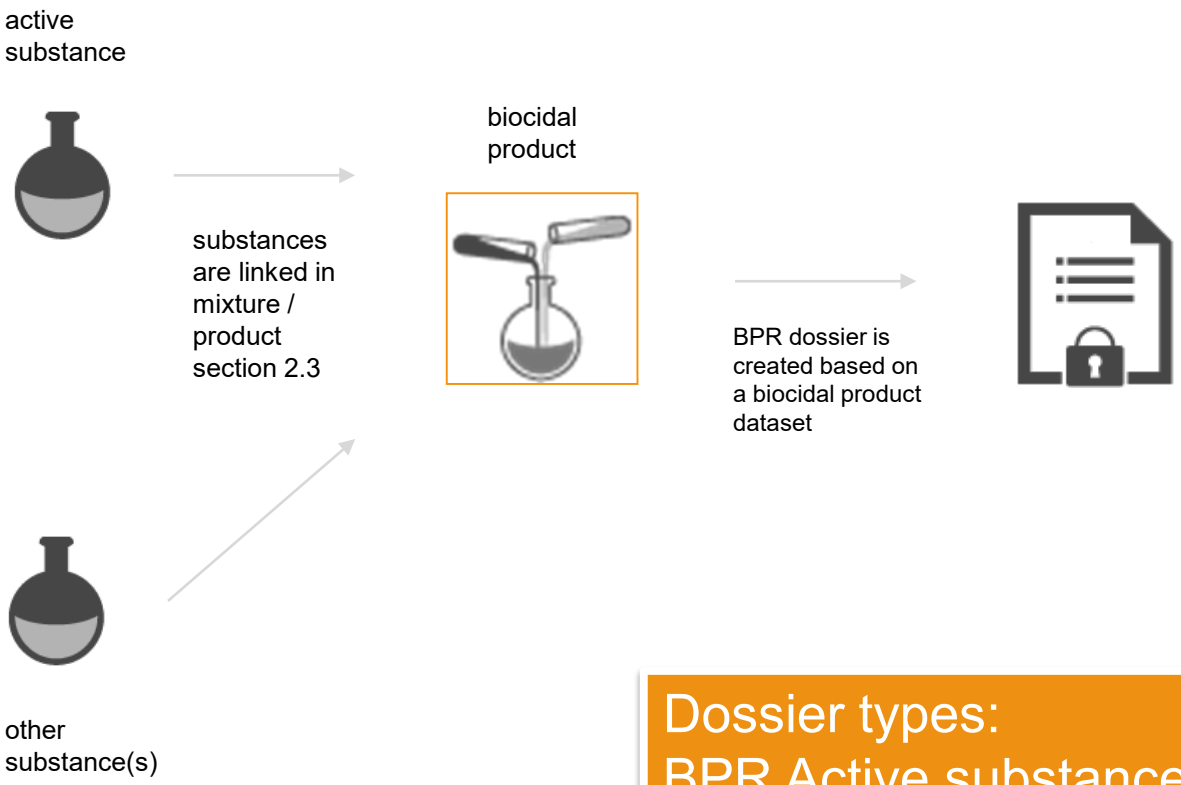



https://iuclid6.echa.europa.eu/fi/learn-to-use-the-new-interface

Biocides submissions:

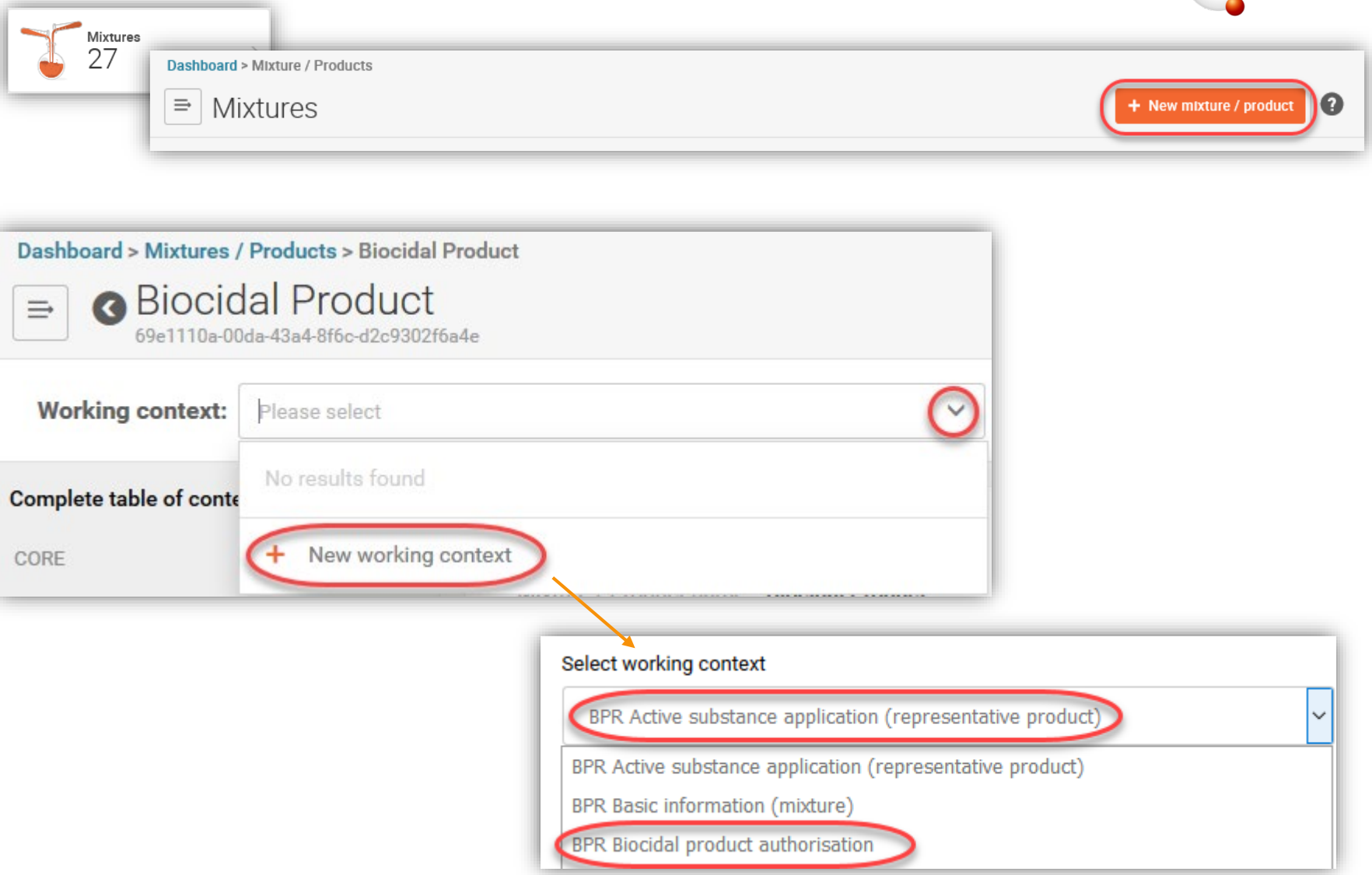
- mixture/product dataset
- substance dataset
- creation of a dossier
- navigation through a dossier

# Biocides submissions: BPR dossier structure

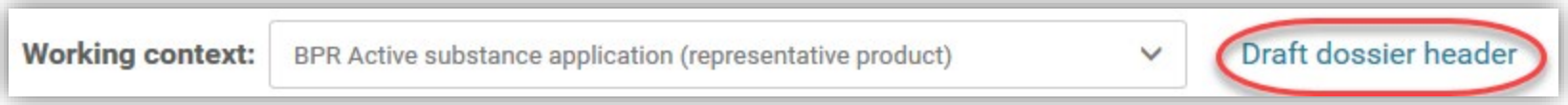


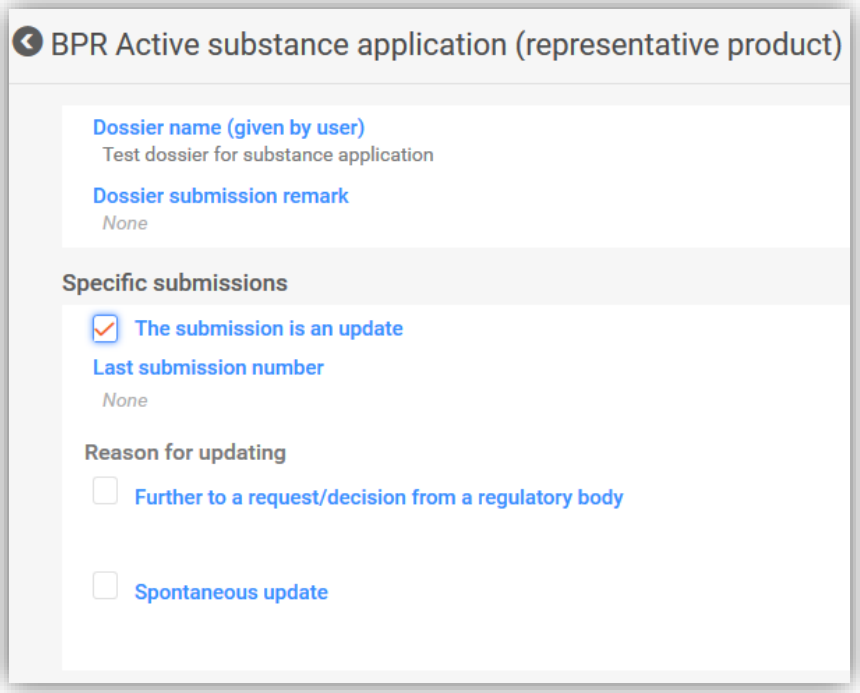

Dossier types:
BPR Active substance application (representative product)
BPR Biocidal product authorisation

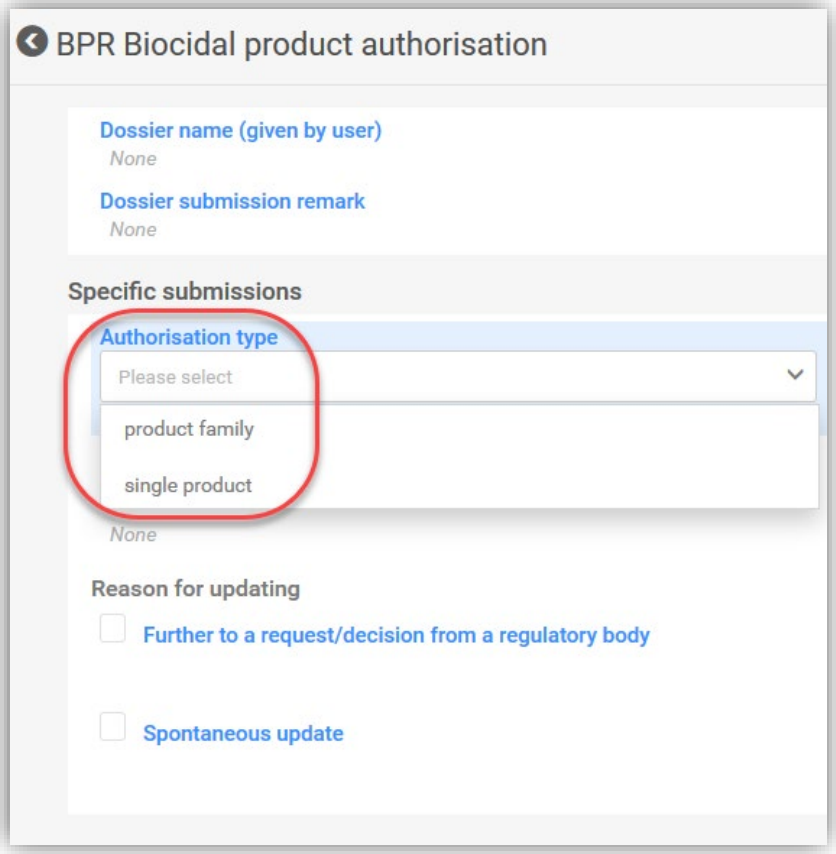
# Mixture/product dataset – starting point of a dossier



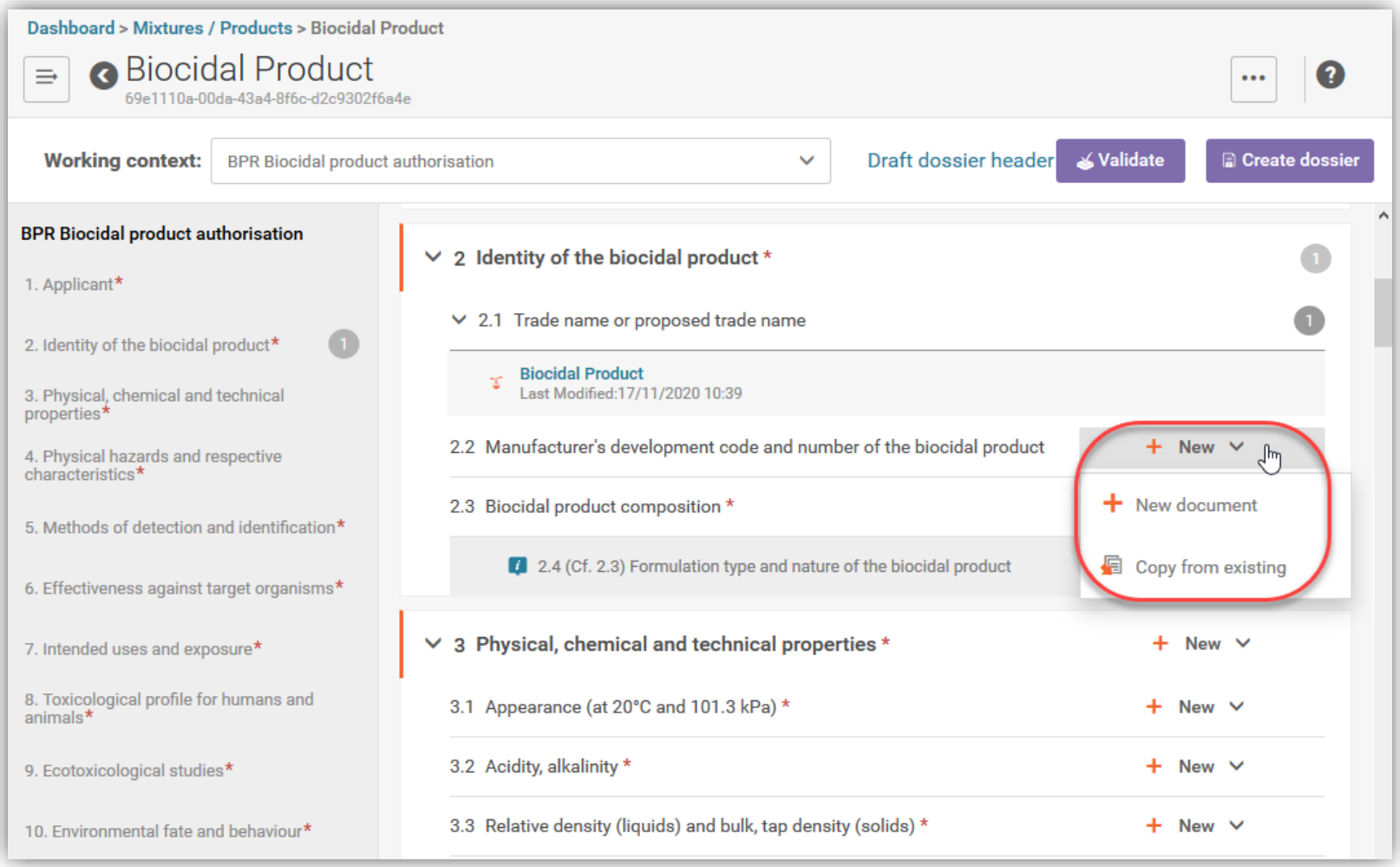
# Mixture/product dataset – starting point of a dossier



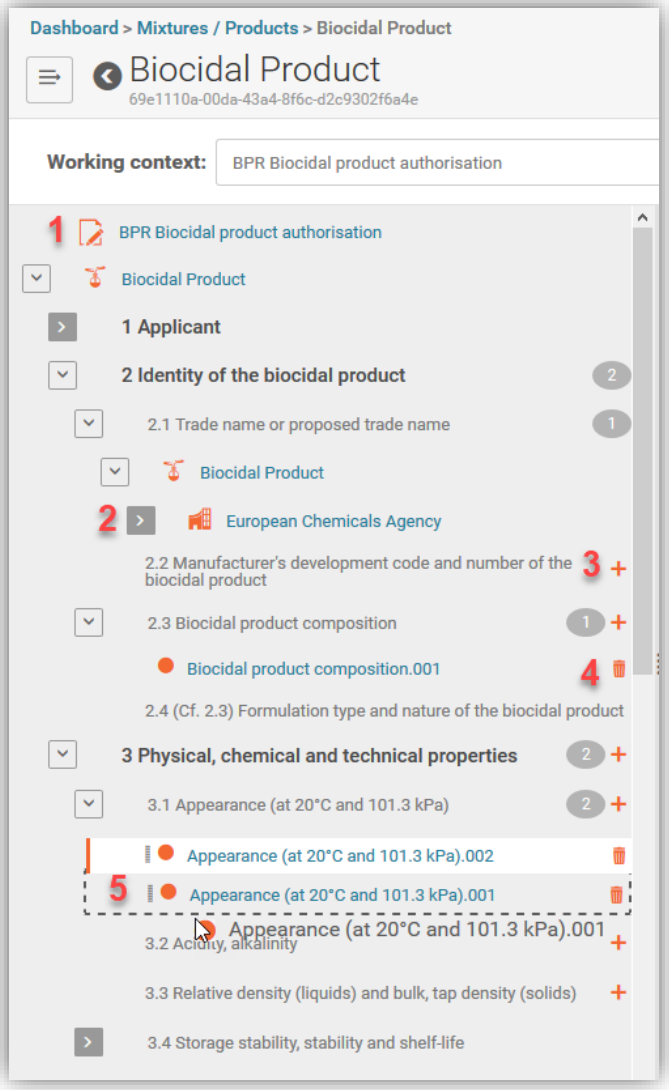



# Mixture/product dataset – starting point of a dossier



# Mixture/product dataset – starting point of a dossier

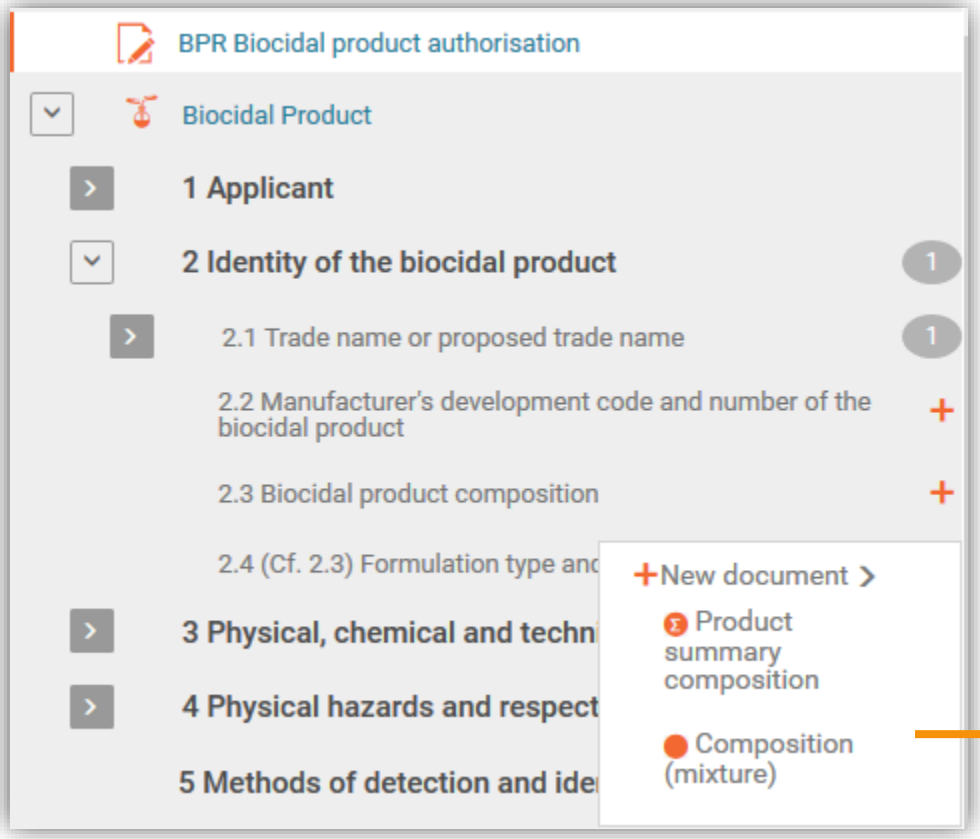


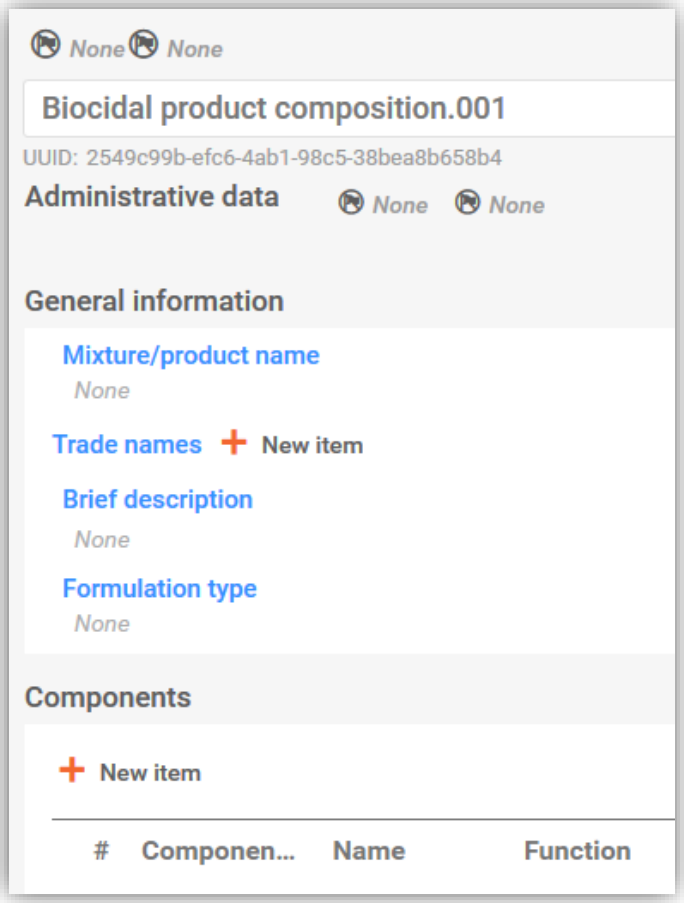

New table of contents allows:

1. access and edit a dossier header
2. see all outbound references of a section, for example legal entity, site, substance, reference substance
3. create new document (+)
4. delete a document (bin icon)
5. move a document up and down (drag and drop)
6. navigate easily throught the sections and its content

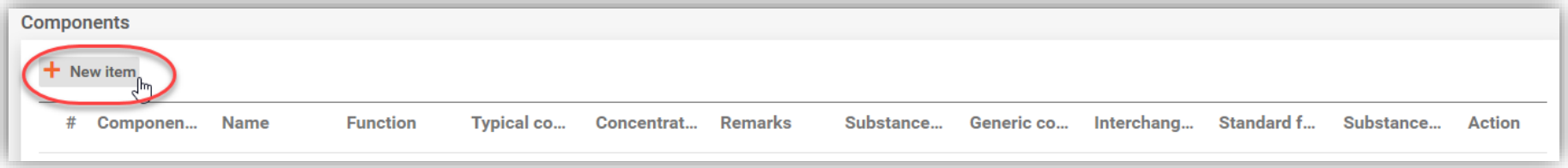
see also: IUCLID release webinar (11.11)

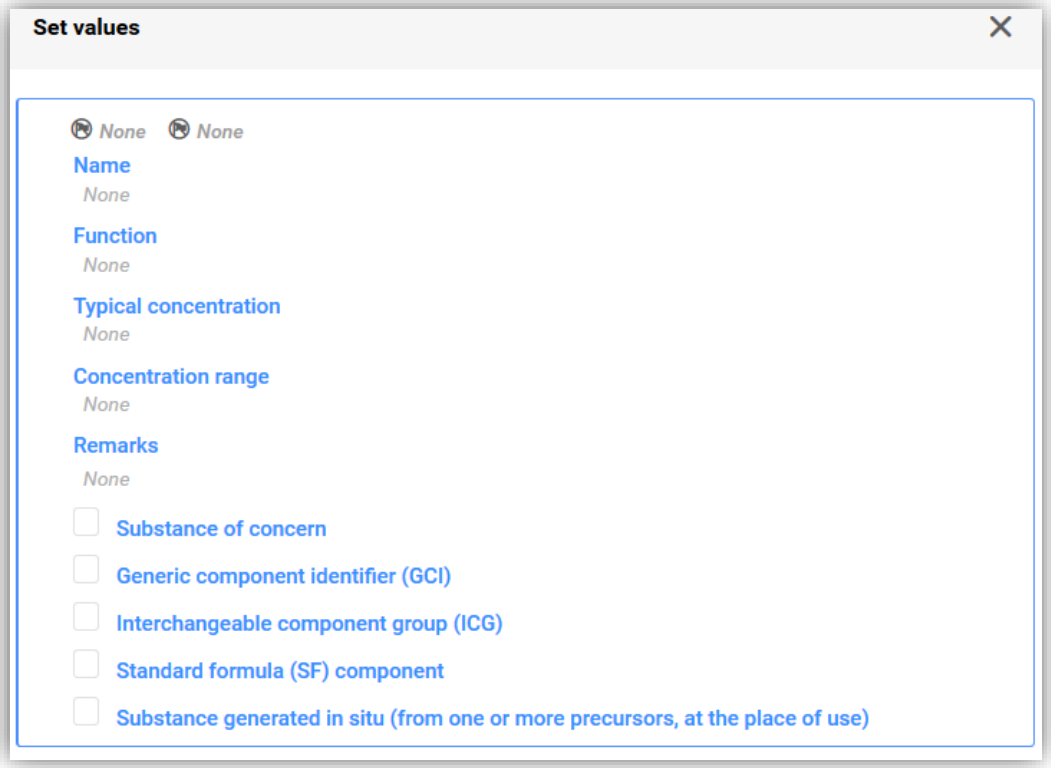
# Composition of a single biocidal product



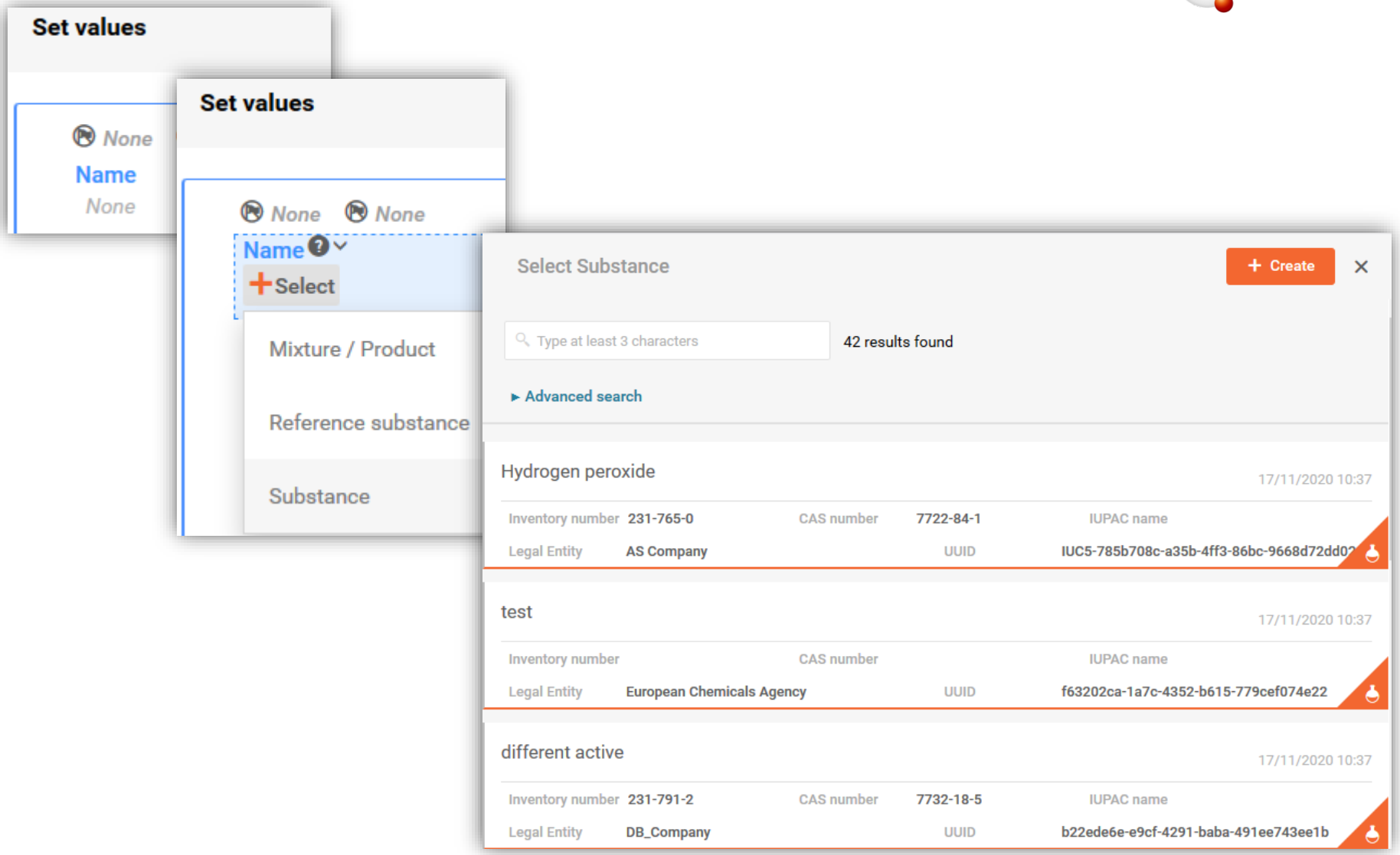



# Assign components of a single biocidal product

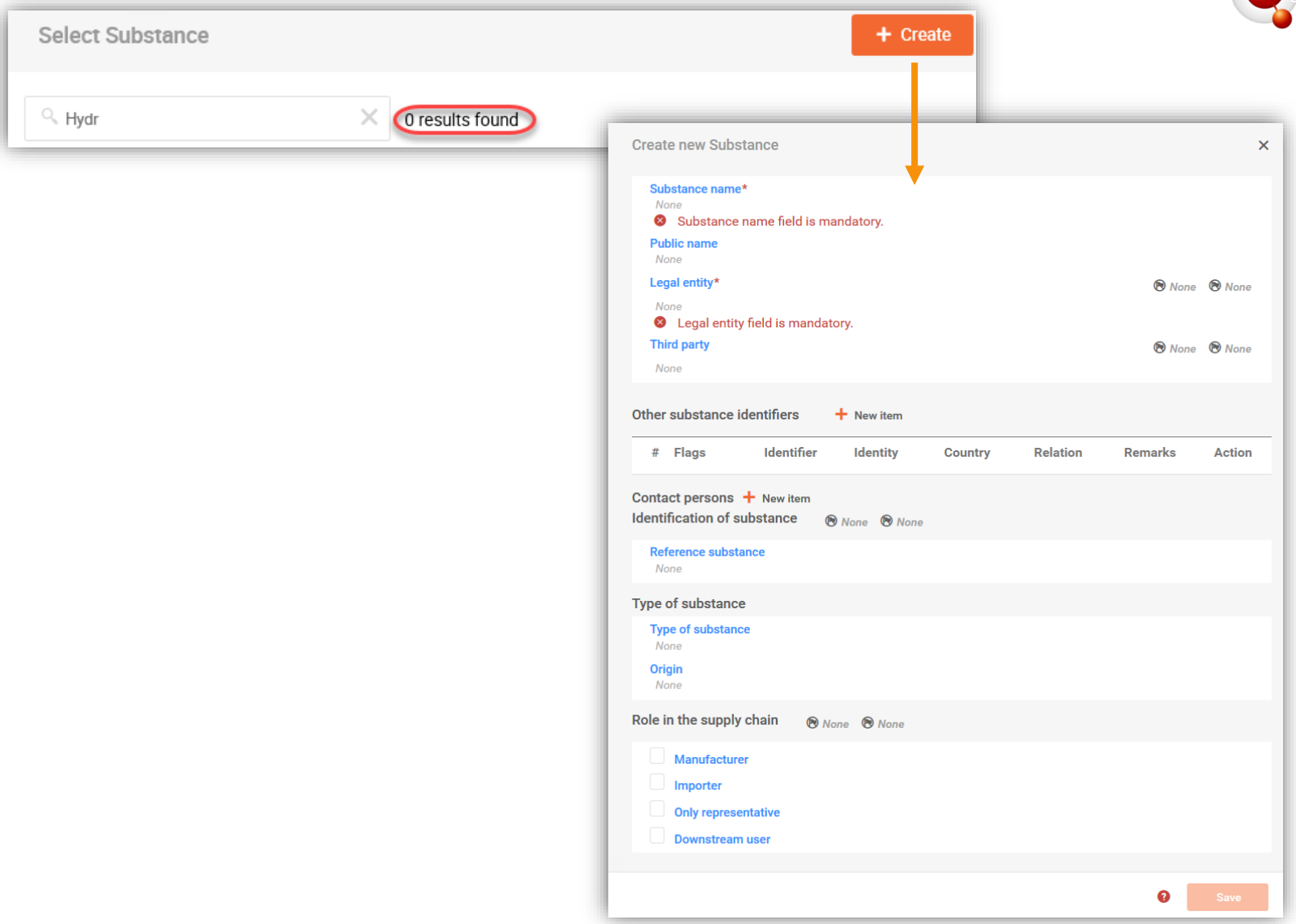


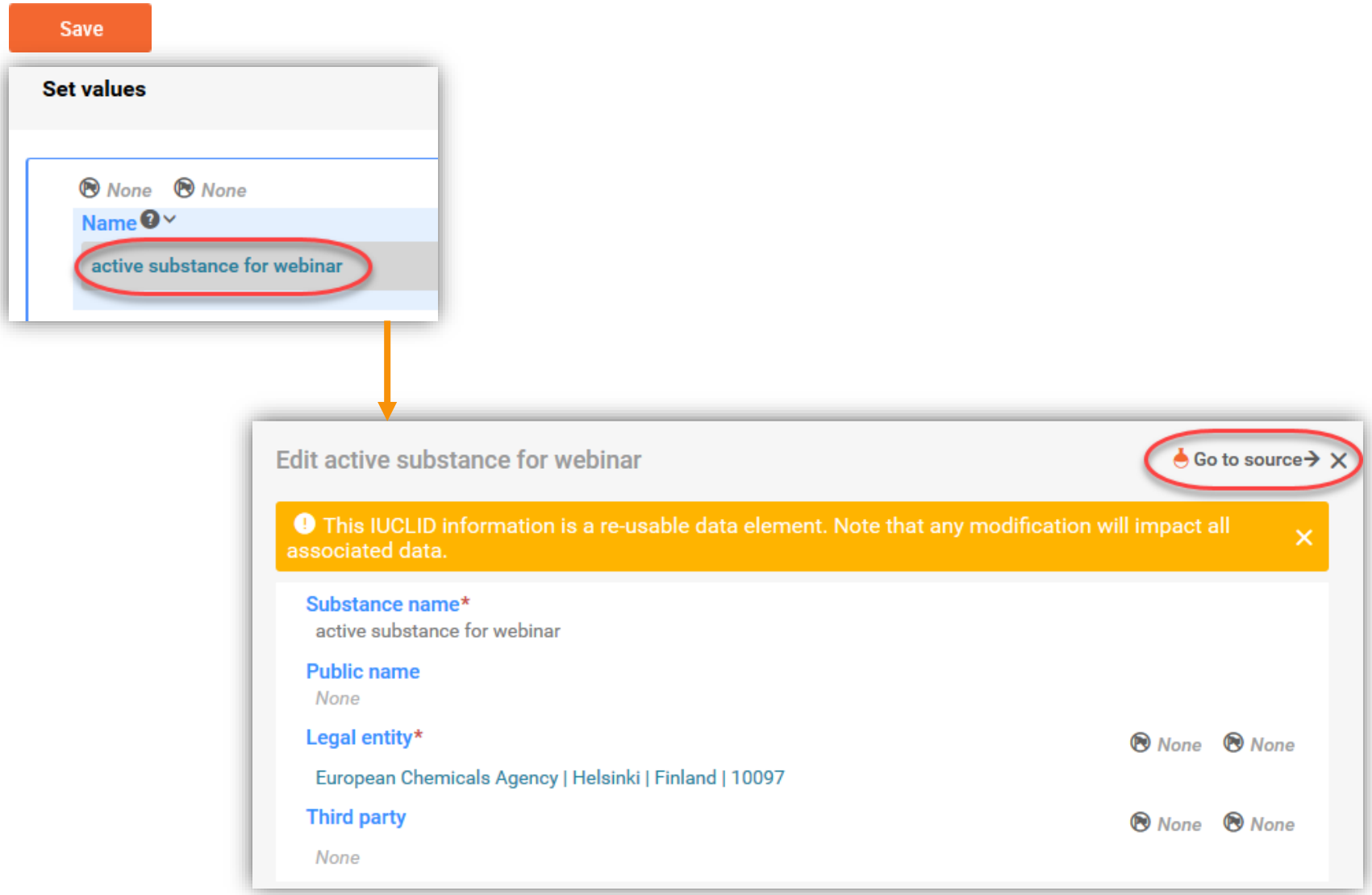
# Assign components of a single biocidal product



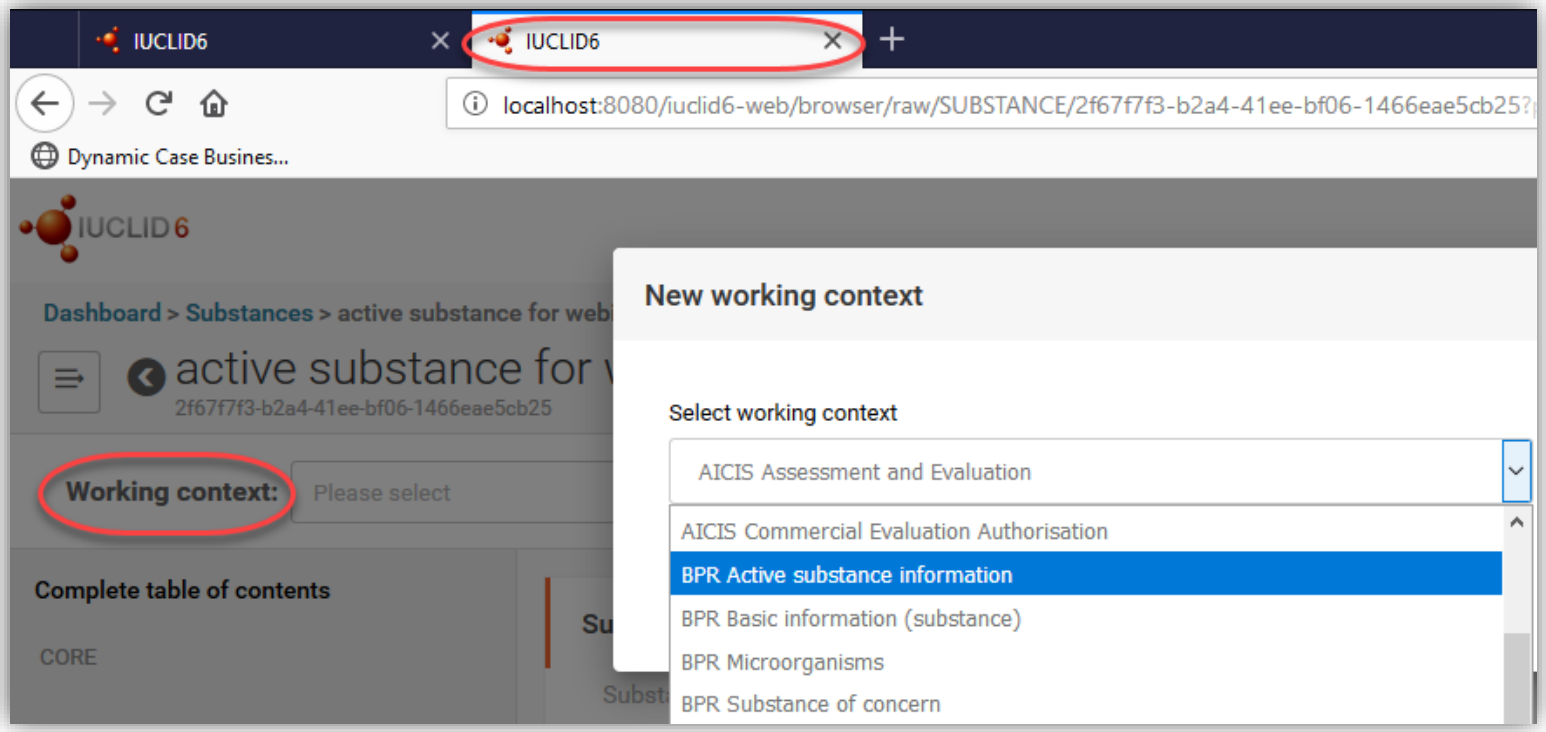
# Create a substance directly in the mixture/product

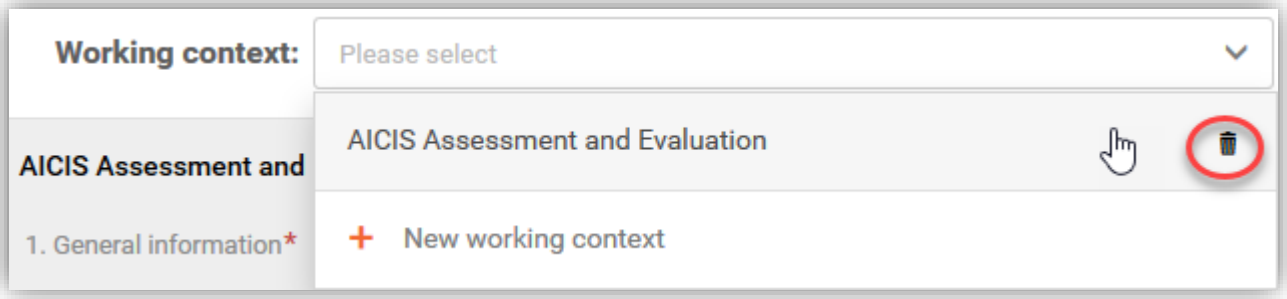


# Go to the substance dataset

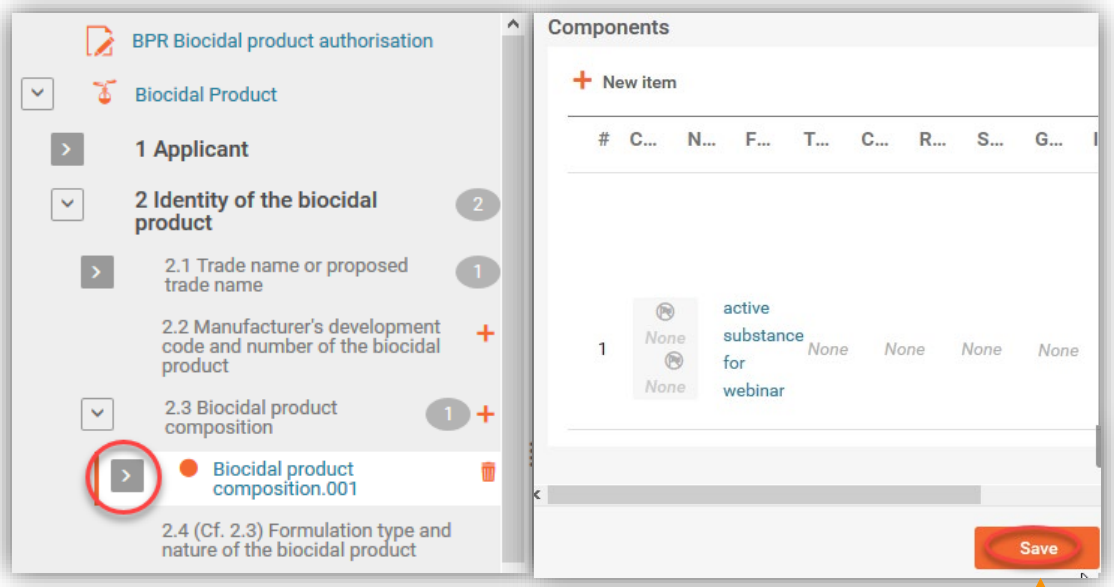


# Edit substance dataset in a new tab



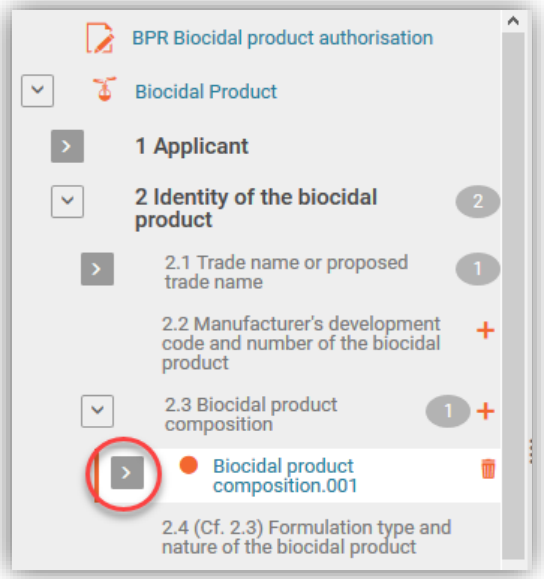



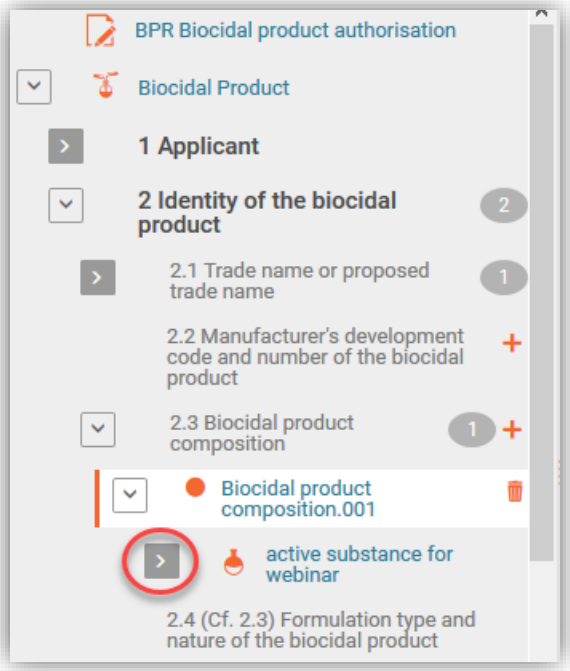
# Edit substance dataset in a product TOC



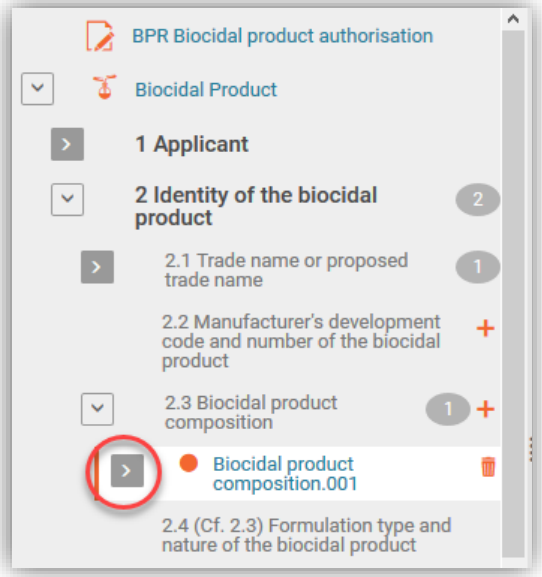

Note: If the arrow (marked here in red) does not appear, make sure that a document has been saved after addition of a new component

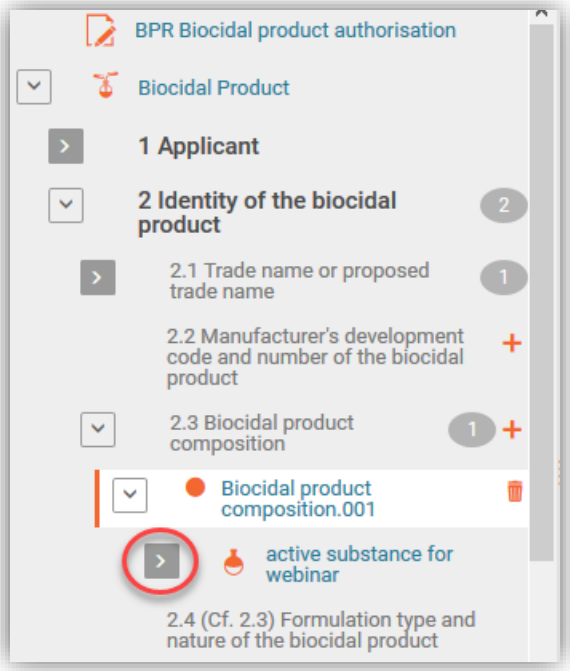
# Edit substance dataset in a product TOC

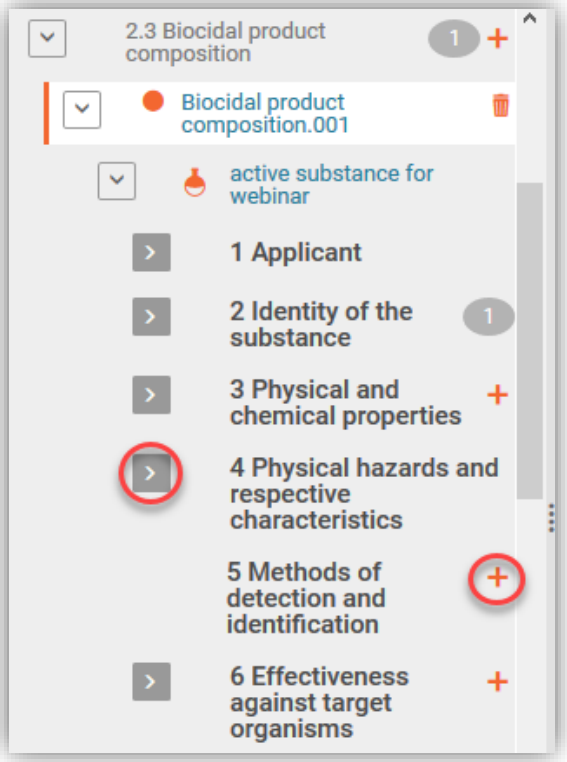


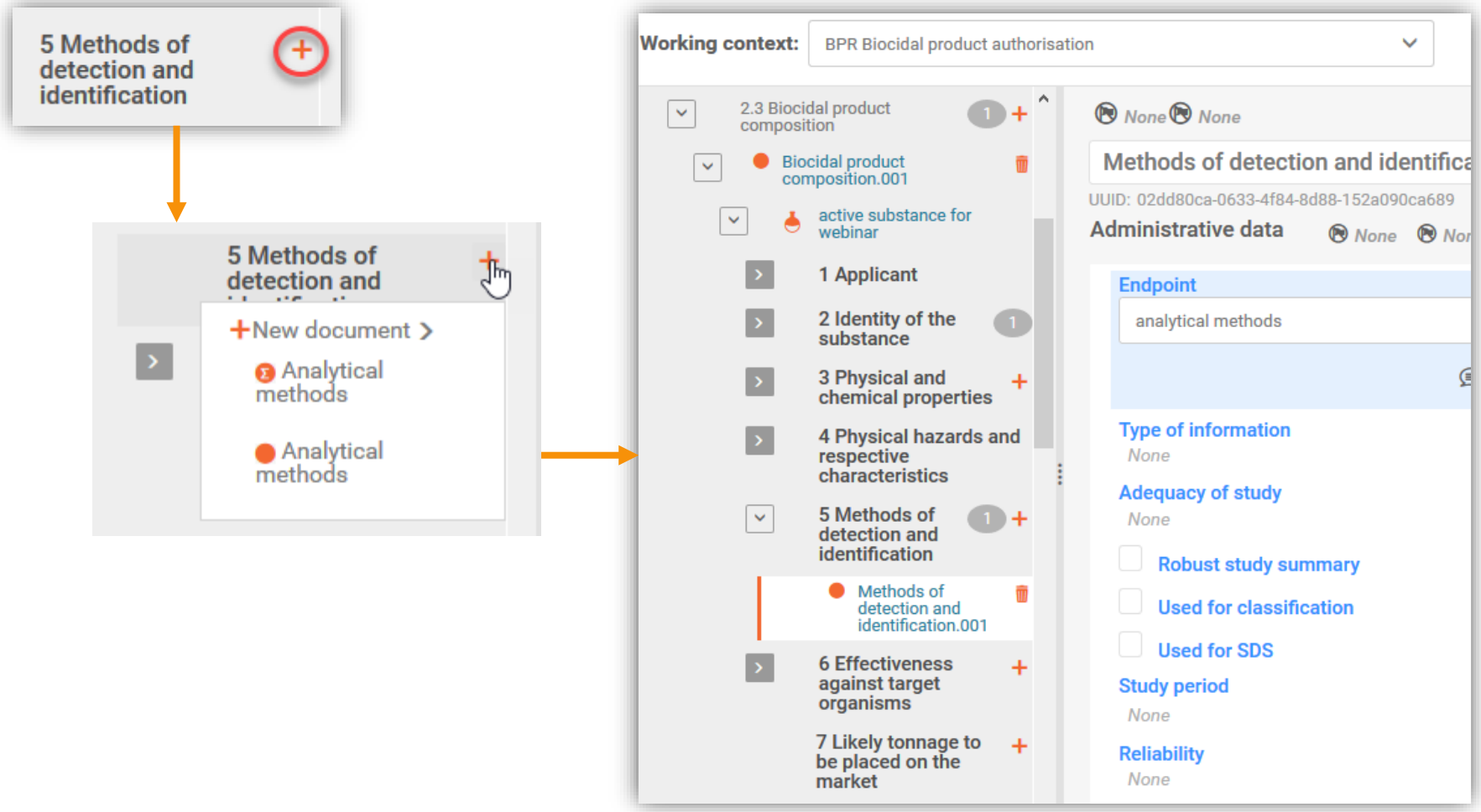
# Edit substance dataset in a product TOC



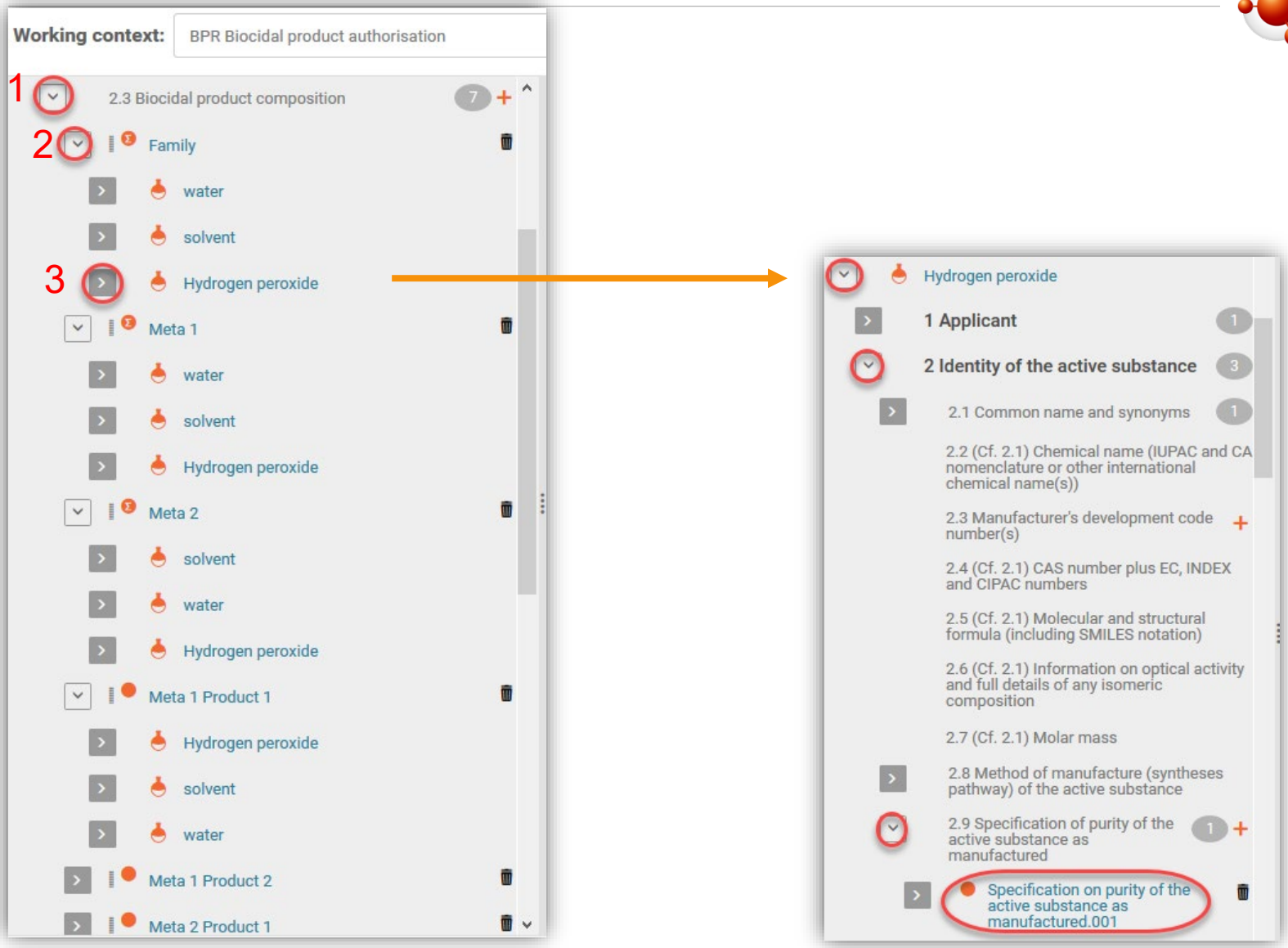



# Edit substance dataset from a product TOC



# Composition of a biocidal products family

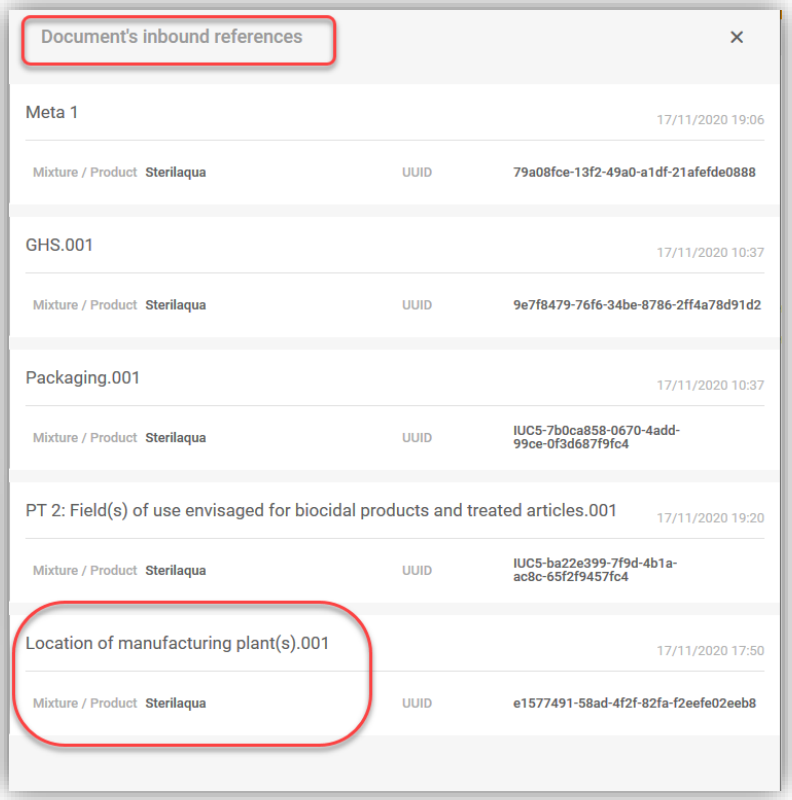


# Links between the documents: composition record

## Documents linked to the biocidal product composition record - inbound reference(s)

- Location of manufacturing plant(s) (section 1.3.1)
- Intended uses and exposure (section 7.1)
- GHS (section 12.1)
- Packaging (section 12.3)

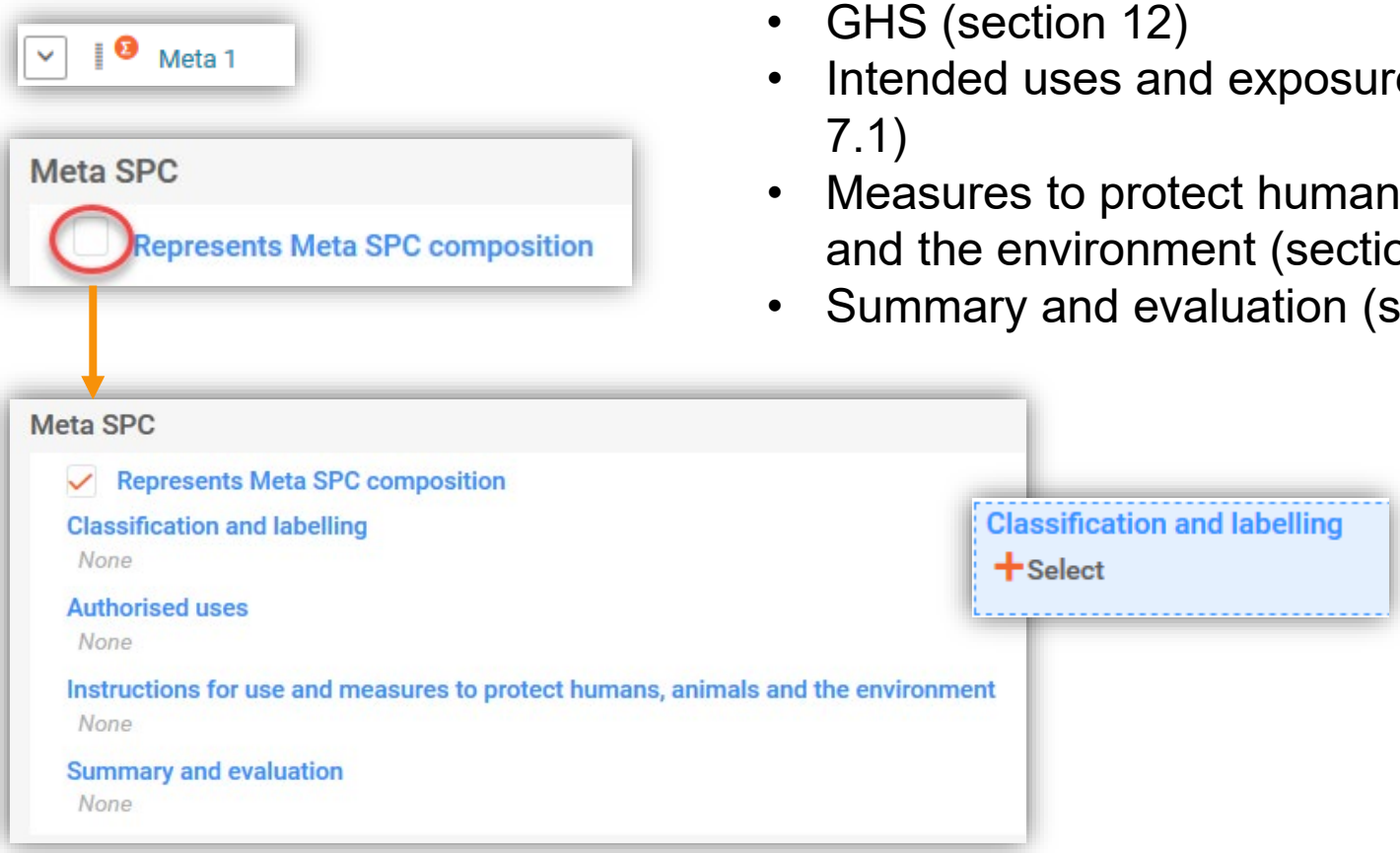

location of manufacturing plant(s)




composition

# Links between the documents: meta SPC

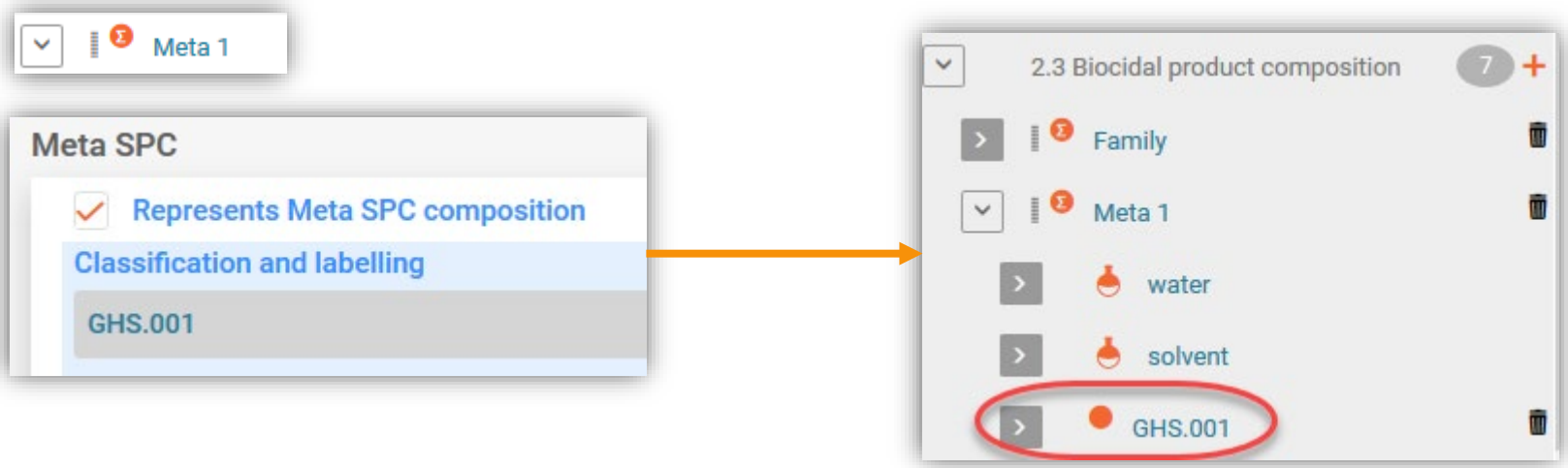
## Documents linked in the meta SPC (composition summary)




- GHS (section 12)
- Intended uses and exposure (section 7.1)
- Measures to protect humans, animals and the environment (section 11)
- Summary and evaluation (section 13)

# Links between the documents: meta SPC

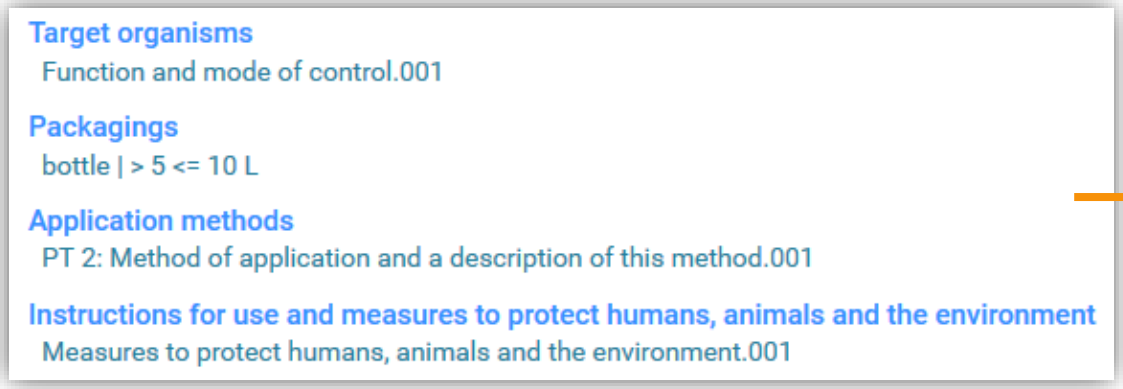
## Documents linked in the meta SPC (composition summary)

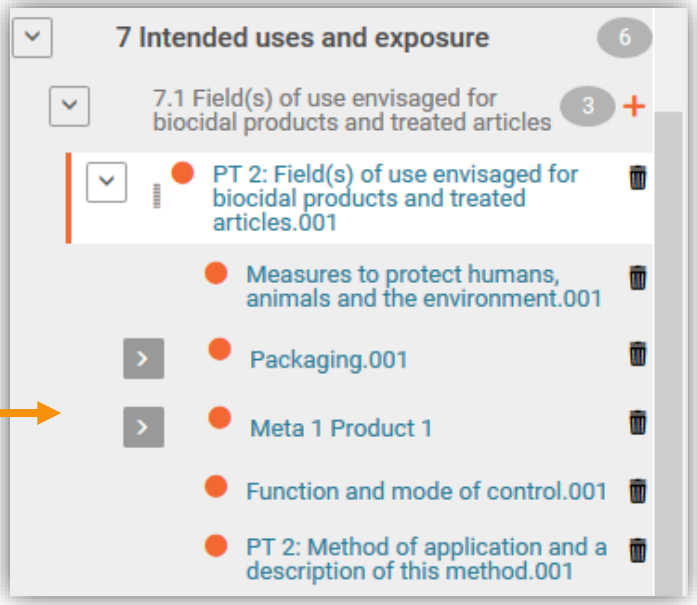


# Links between the documents: Intended uses

## Documents linked in the Intended uses and exposure (section 7.1):

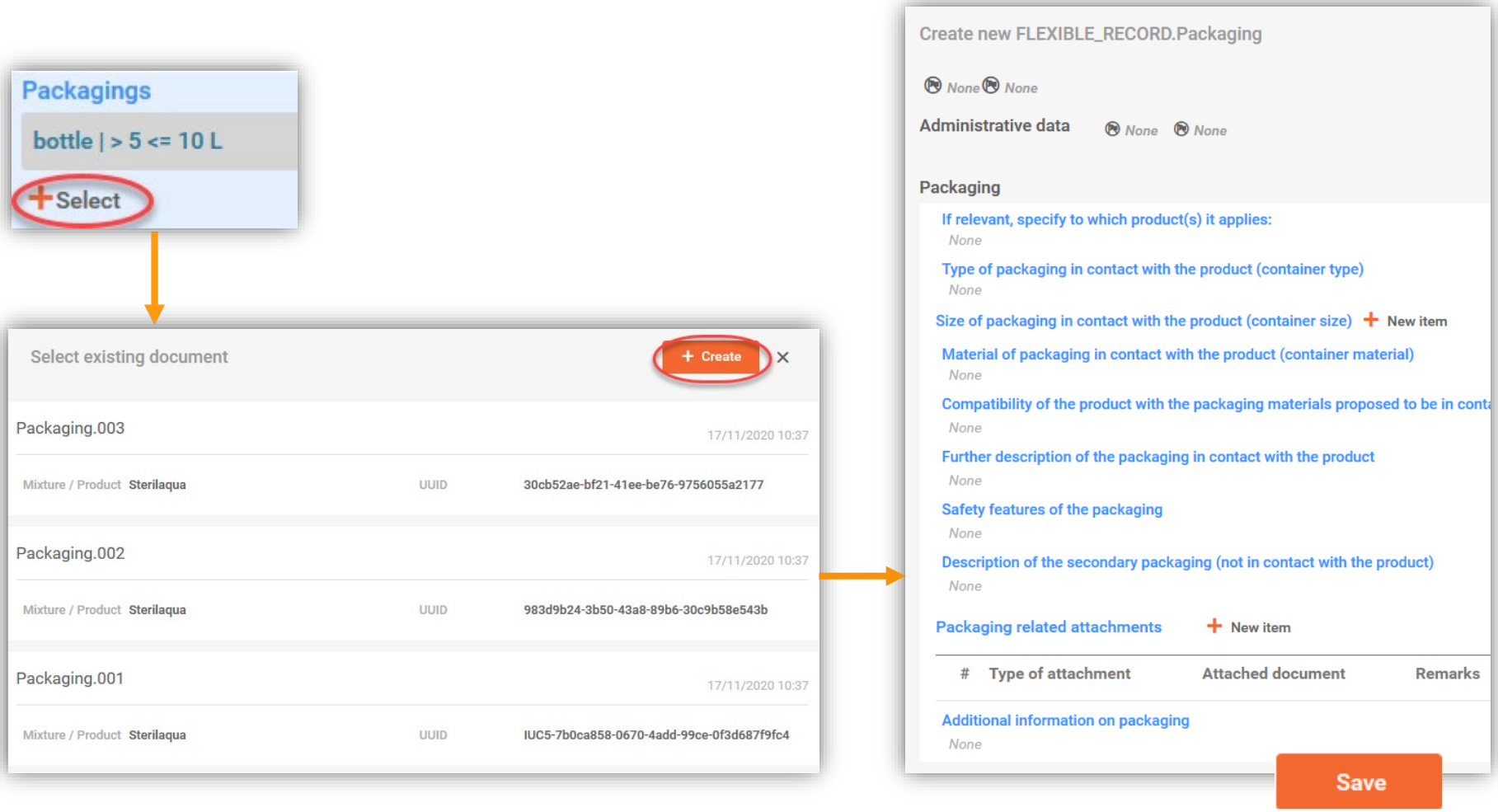
- Target organisms (section 6.1)
- Packagings (section 12.3)
- Application methods (section 7.6)
- Measures to protect humans, animals and the environment (section 11)



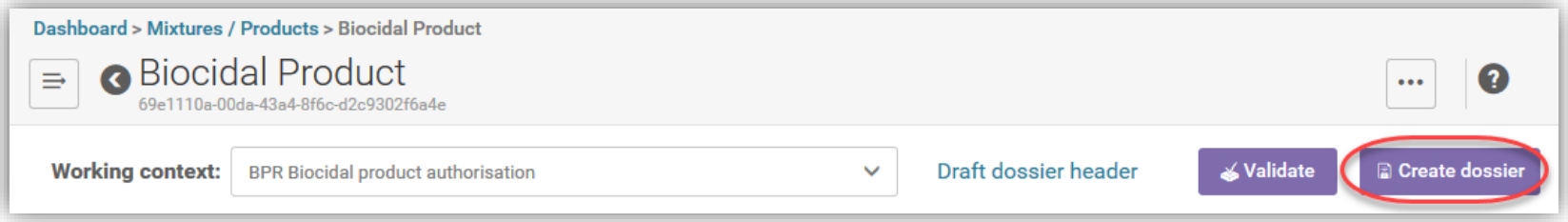



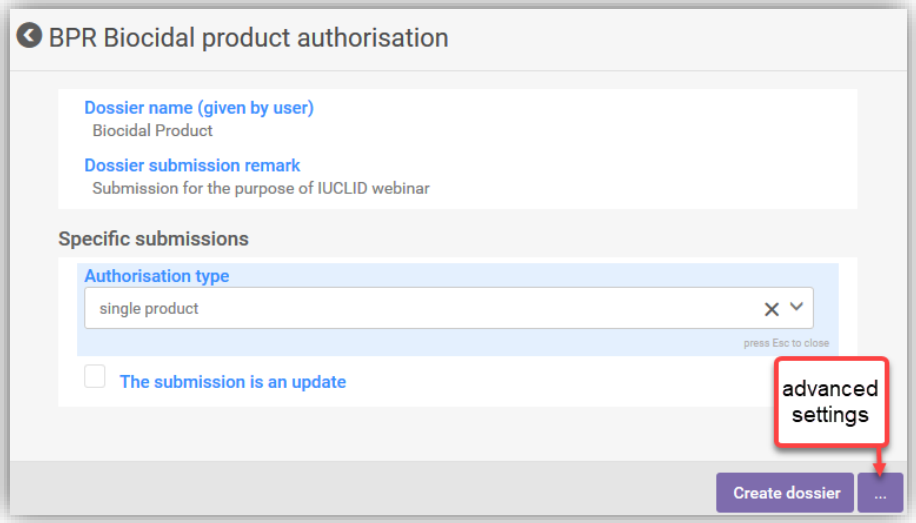
# Creation of the reference document

## …at the moment of linking (example of section 7.1)

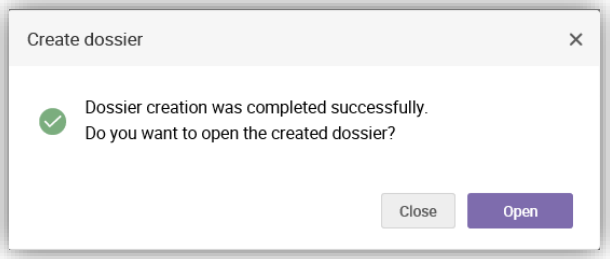


# Dossier creation



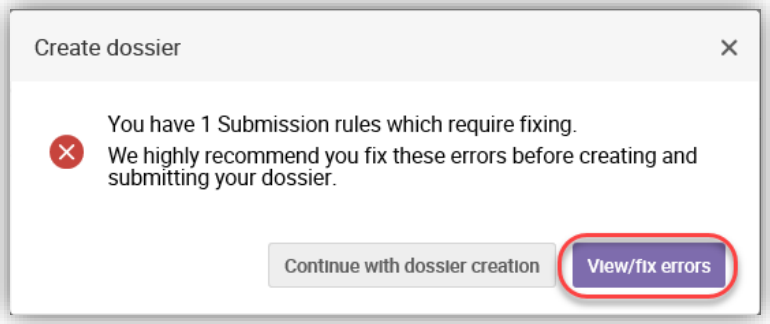



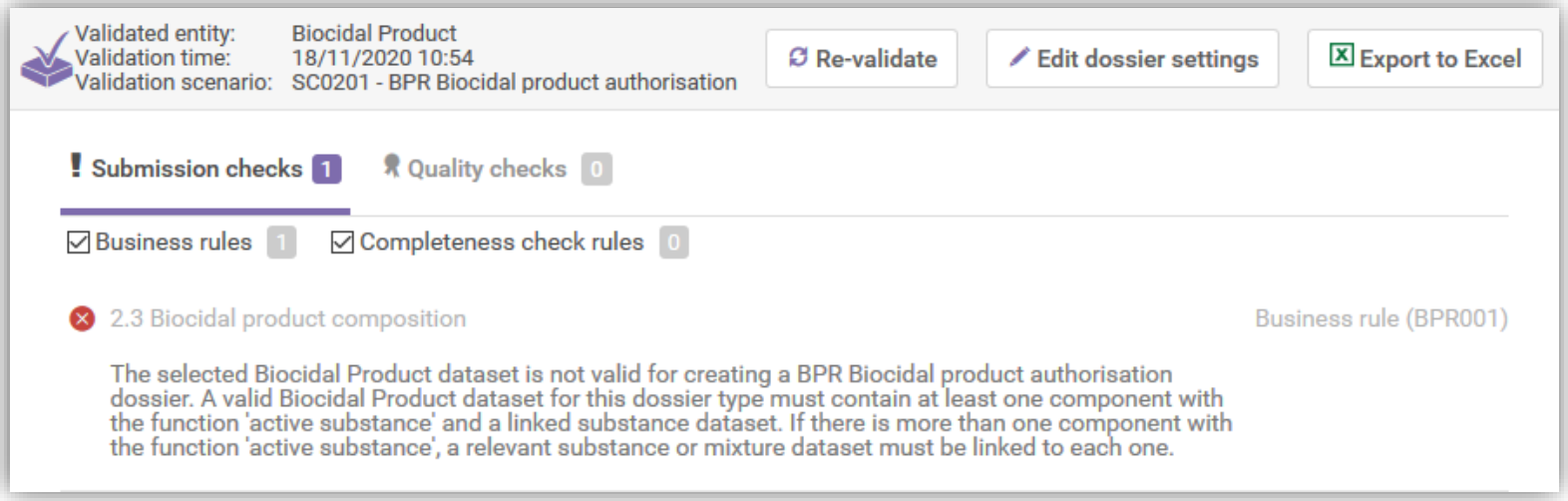

- Working context has to be indicated
- Dossier header information drafted earlier will be used
- Advanced setting available
- Existing validation rules (related to product composition) are checked automatically



# Dossier creation

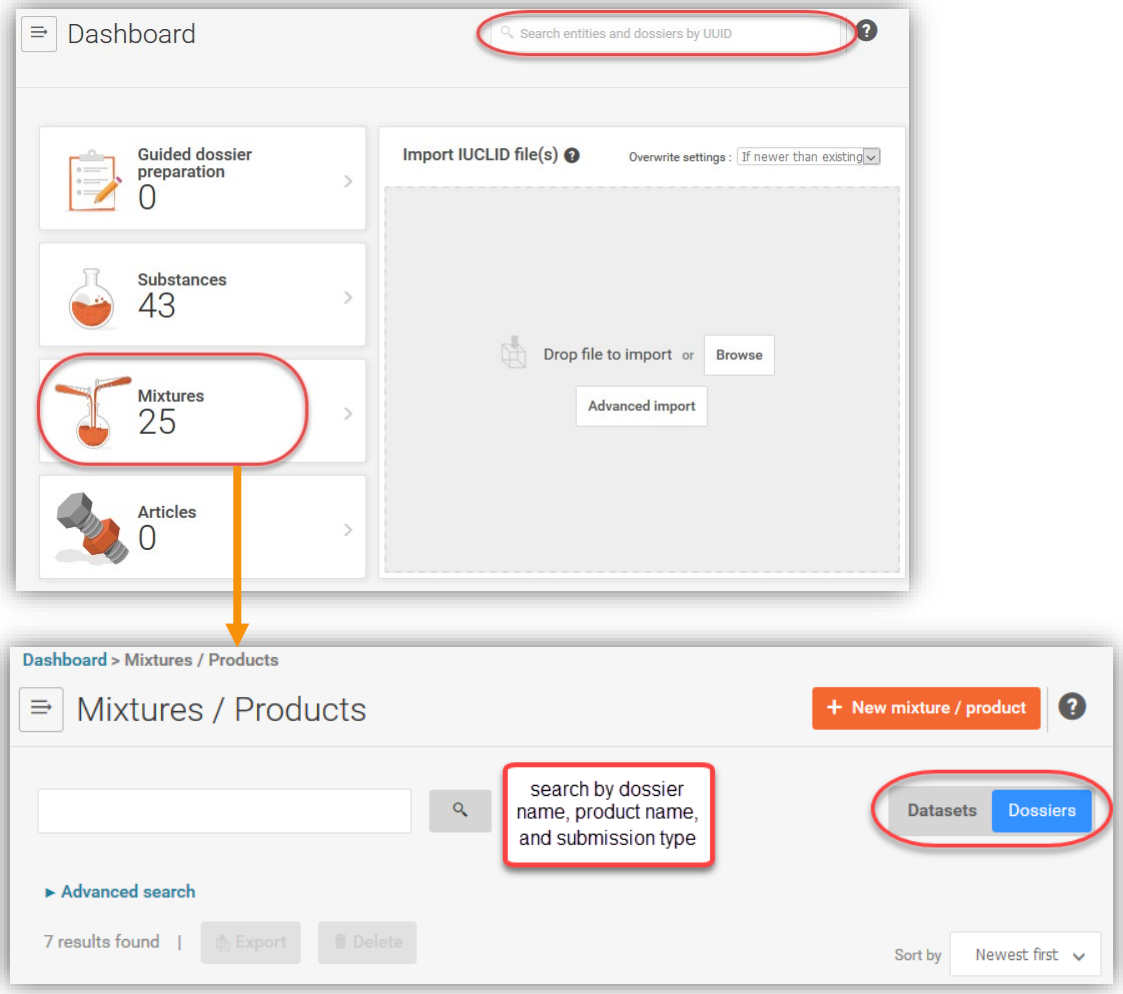
## Validation of data during dossier creation



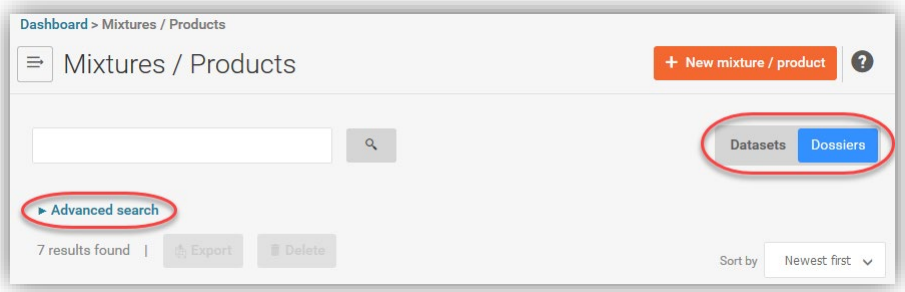
# Dossier search

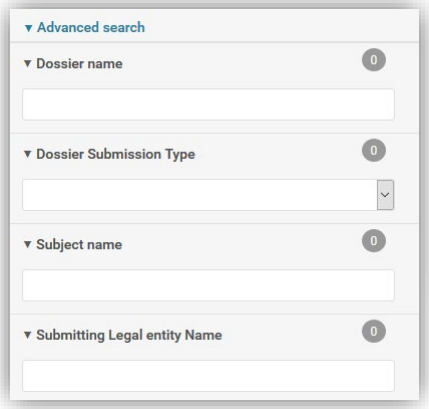
## Basic search for a dossier

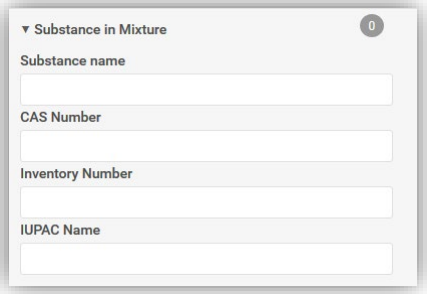


# Dossier search

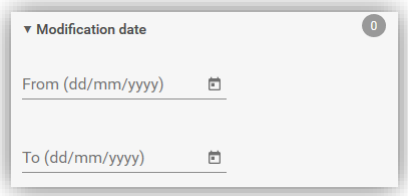
## Advanced search for a dossier

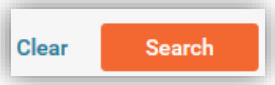


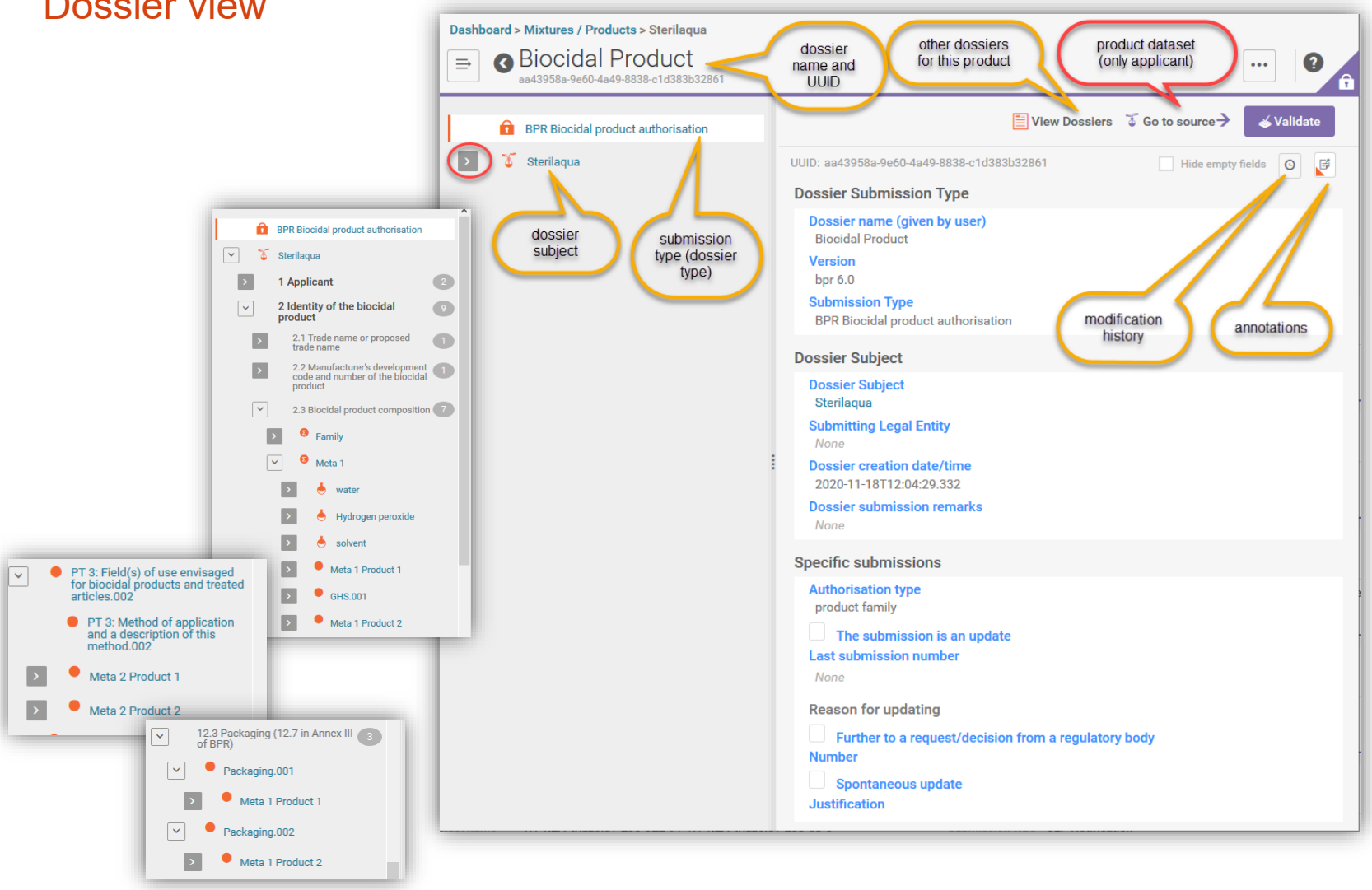




# Navigation through the BPR dossier

## Dossier view



# Preparing a dossier for Technical Equivalence

# Dossier for a Technical Equivalence

## Dossier made based on a substance dataset

active substance

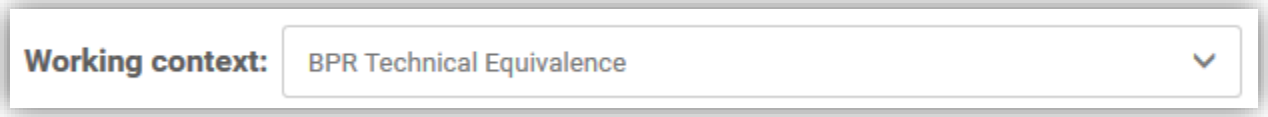


Technical Equivalence dossier is created based on an active substance dataset

**Dossier type:**
**BPR Technical Equivalence**

# Dossier for a Technical Equivalence

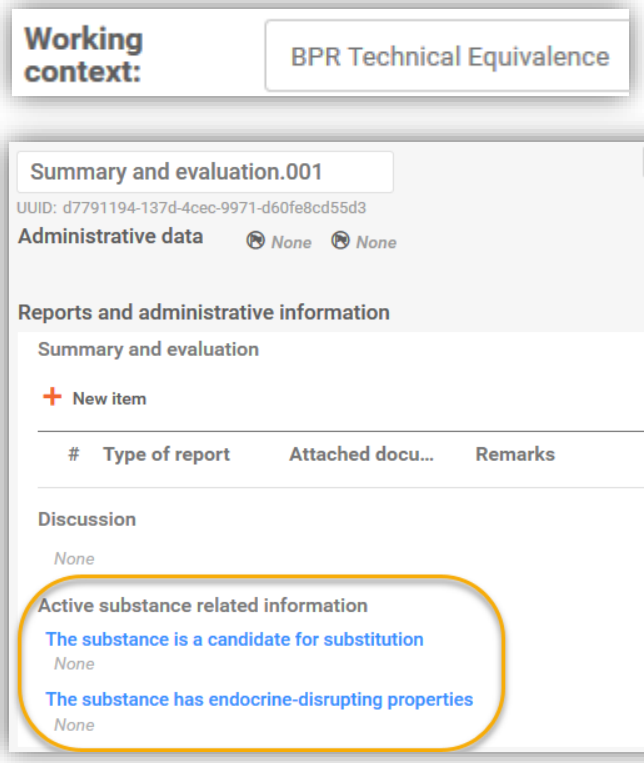
## Simplified table of contents

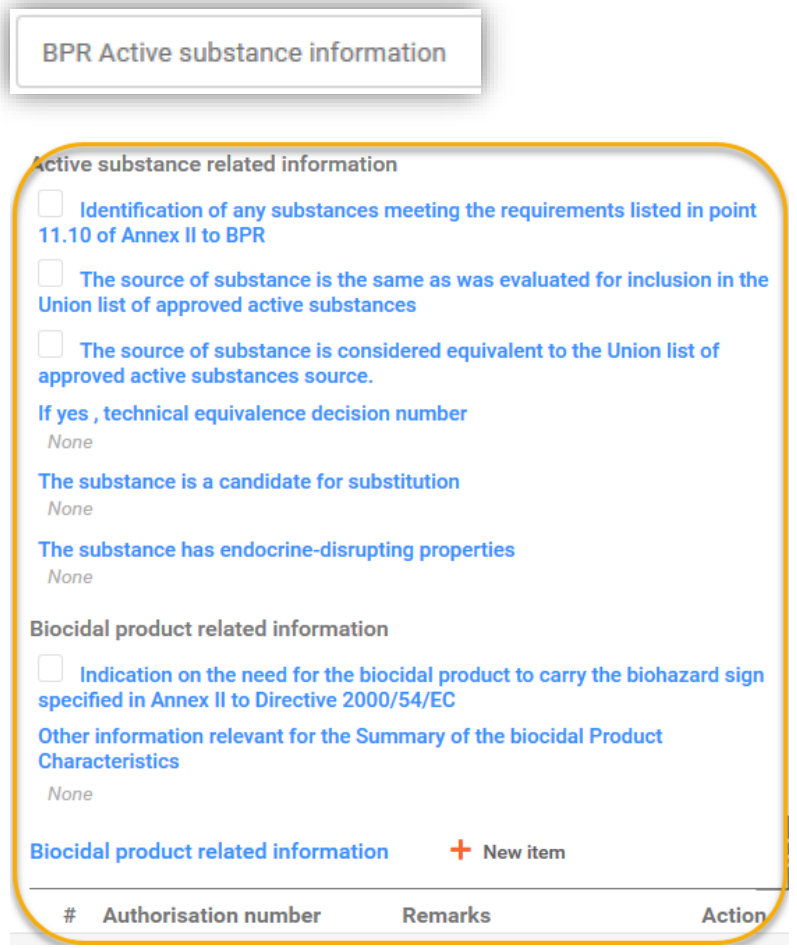



1. Applicant
2. Identity of the active substance
3. Absorption spectra (UV/VIS, IR, NMR) and a mass spectrum, molar extinction at relevant wavelengths (*document form the section 3.6 of BPR Active substance information*)
4. Methods of detection and identification
5. Product type(s) (*based on 7.1 of BPR Active substance information - custom definition applied*)
6. Toxicological profile for humans and animals
7. Ecotoxicological studies
8. Environmental fate and behaviour
9. Summary and evaluation (*based on section 13 of BPR Active substance information - custom definition applied*)

# Dossier for a Technical Equivalence

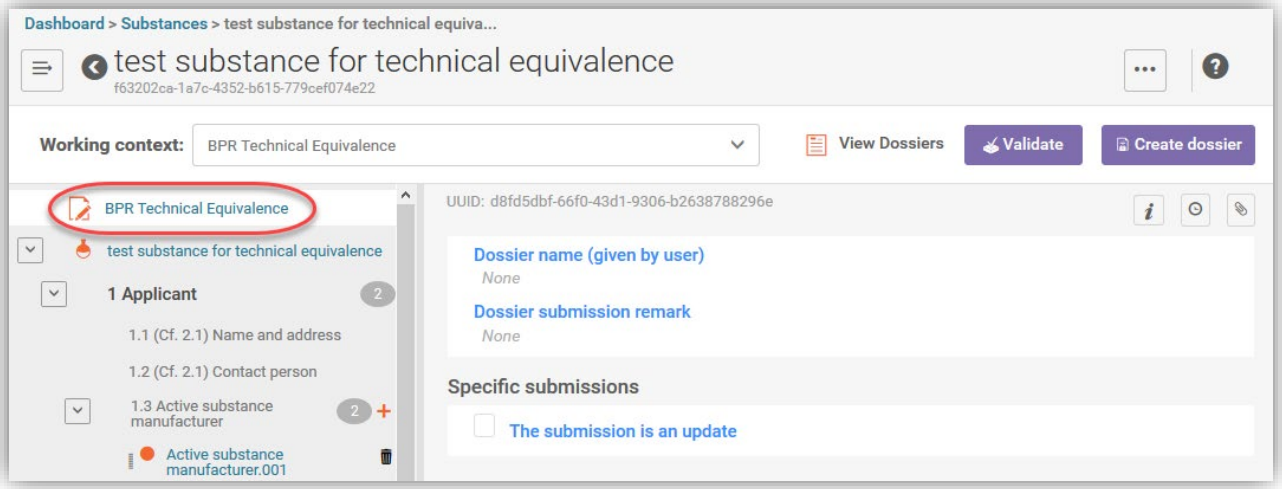
## Example of a customised document

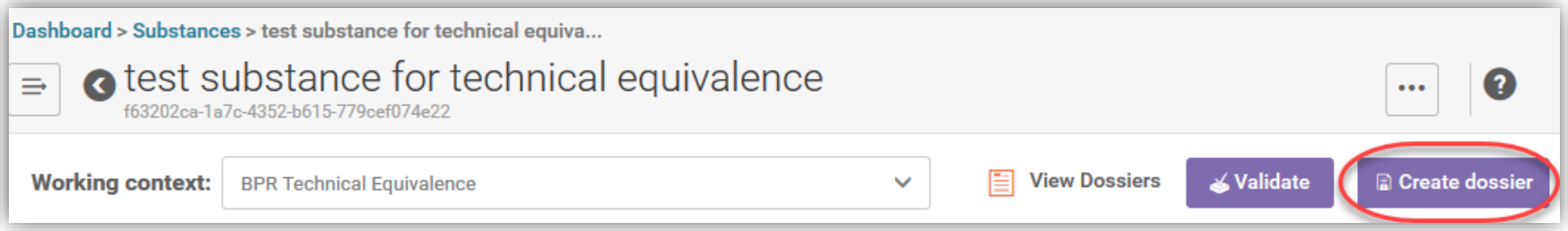


# Dossier for a Technical Equivalence

## Dossier header and dossier creation



# Dossier for a Technical Equivalence

## Practicalities on submission

1. There is no need to resubmit a dossier only because of the format change
2. If the dossier has to be resubmitted, the new dossier type has to be used, if not the file fails the file format check in R4BP 3
   - reuse your active substance dataset and change its working context to *BPR Technical Equivalence*
   - correct those parts of the dataset that have been requested in the resubmission task
   - create a dossier based on substance dataset
3. For initial submissions the new dossier type has to be used

More information:
Application instructions: How to submit an application for technical equivalence and chemical similarity

# Format changes most relevant for Biocides users

# Format changes

## Format changes most relevant to biocides

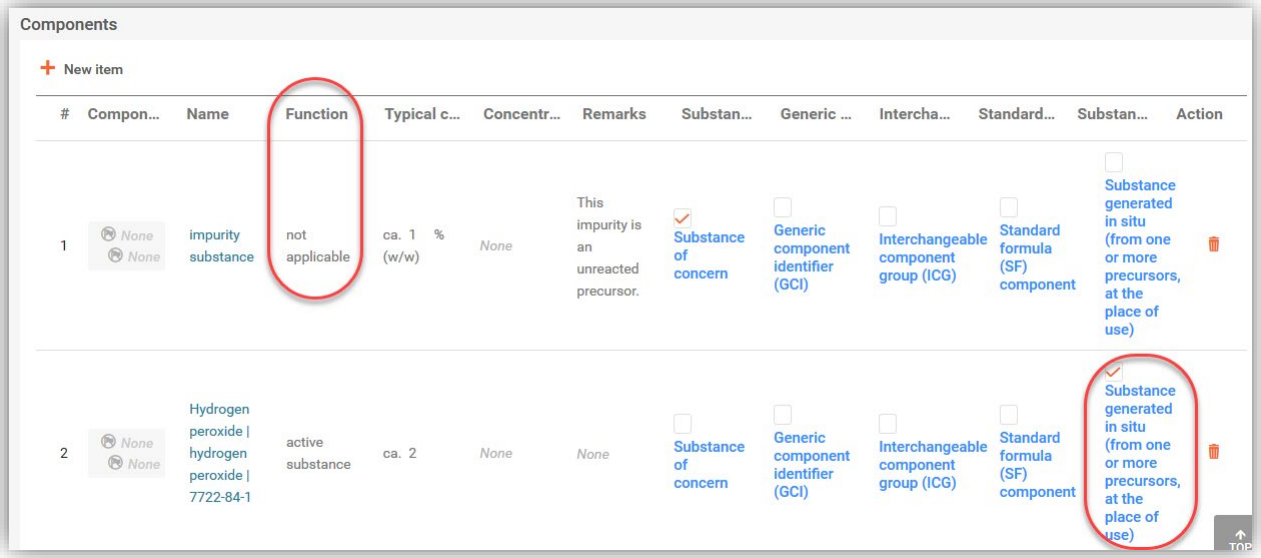
- Links between documents slightly modified to ensure compatibility between IUCLID and SPC Editor
- Several OHTs updated, for example 50-2, 88, 89
- Guidelines added in several documents, including those for microorganisms
- Reference section *8.13.1 (Cf. 8.13.6) Phototoxicity* replaced by the section containing a newly created document (OHT 66-3 In vitro phototoxicity) and a summary

To learn more about format changes in IUCLID latest version, please see:
- IUCLID release webinar (11.11)
- https://iuclid6.echa.europa.eu/fi/format

# Format changes

## Format changes most relevant to biocides (mixture composition)

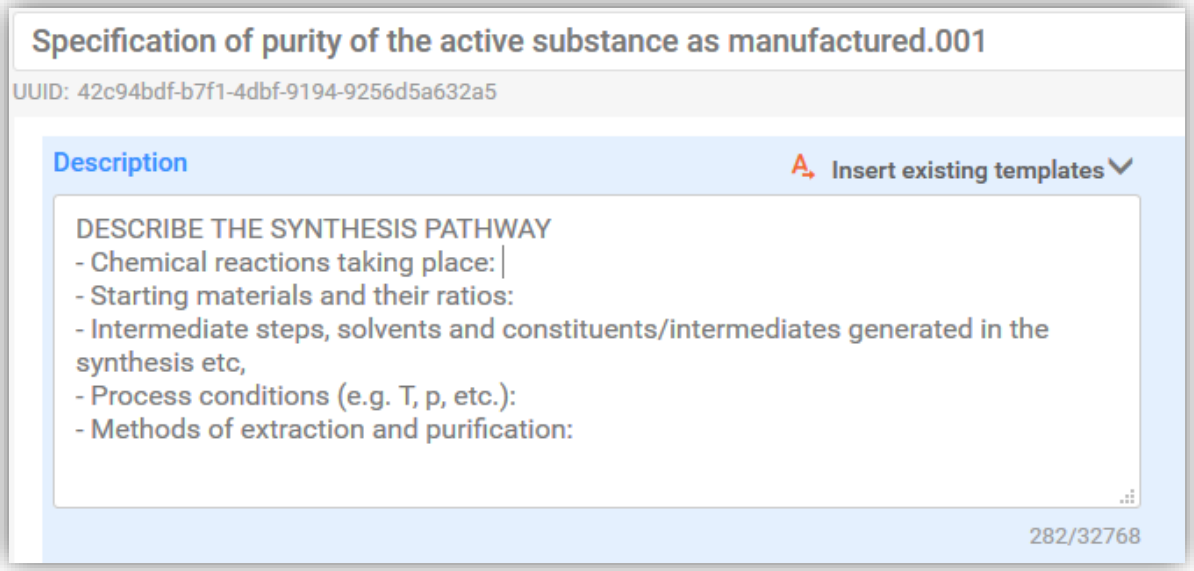
- Blocks *Impurities* and *Additives* removed from a mixture composition and migrated to *Components*
- *Function* picklist updated with phrases: *precursor* and *not applicable*
- Check box in the *Components* reflecting that an active substance has been generated *in situ*



# Format changes

## Format changes most relevant to biocides (substance composition)

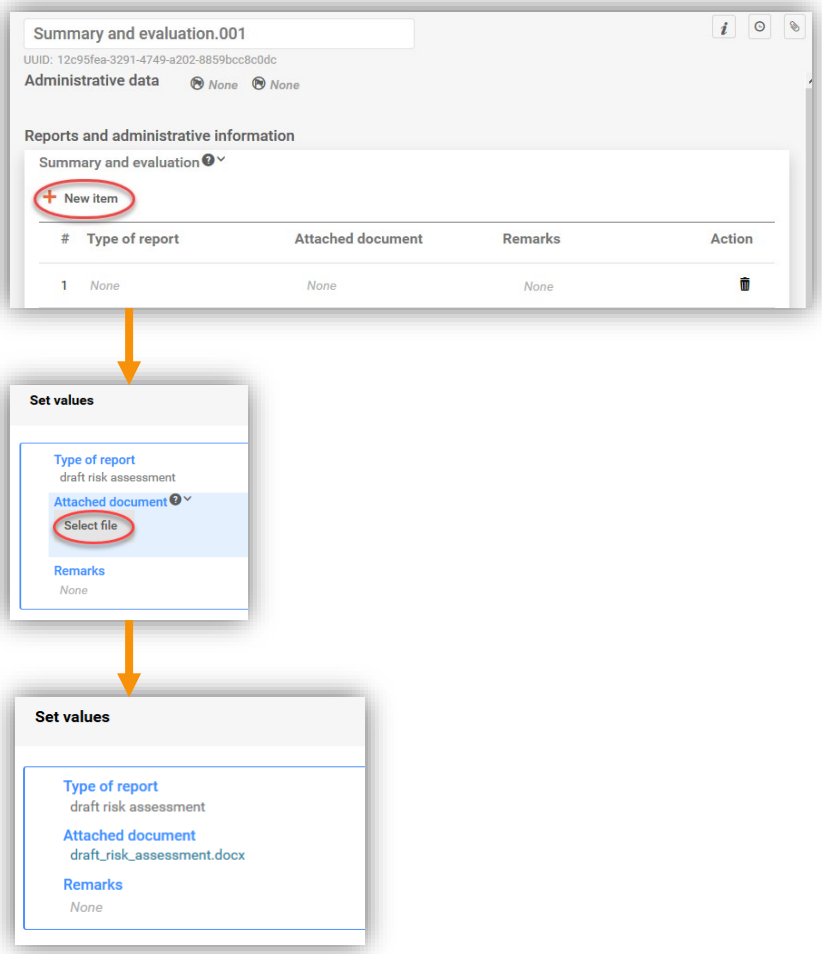
- New text template added in the field *Description*: Option 5: Method of manufacture (biocides)



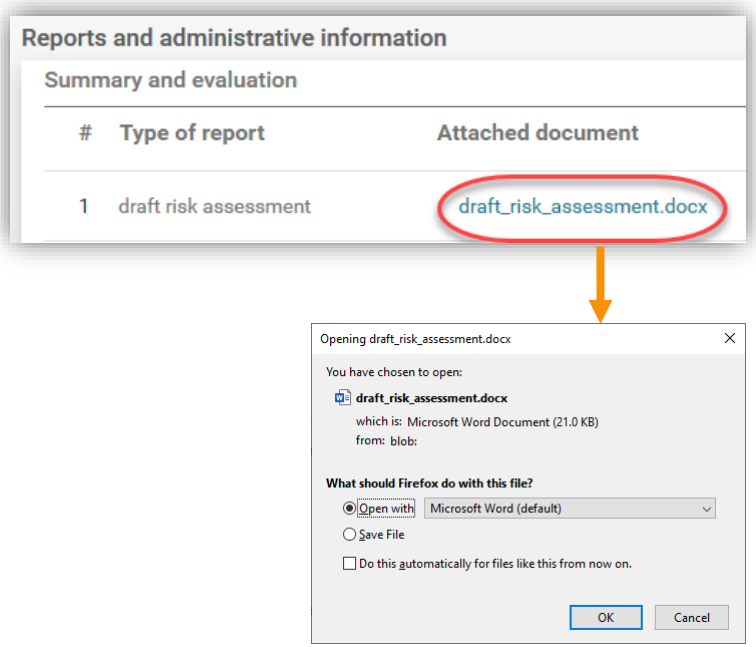
# Annotations, attachments and print

# Attachments to the predefined fields

## Dataset

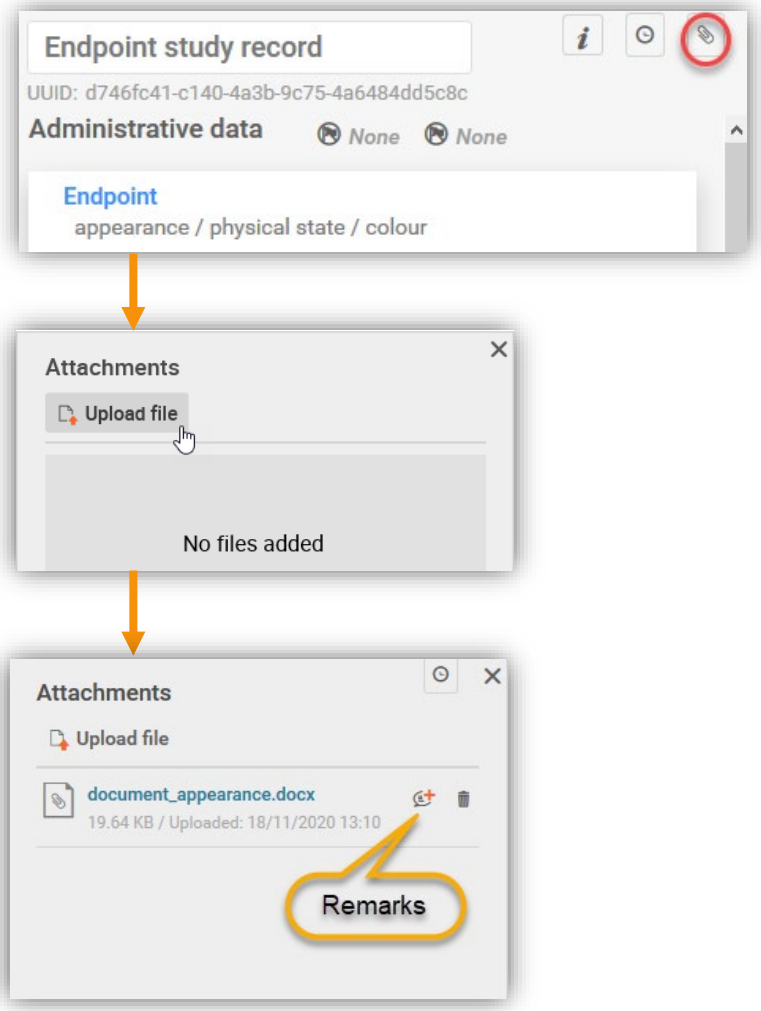



## Dossier

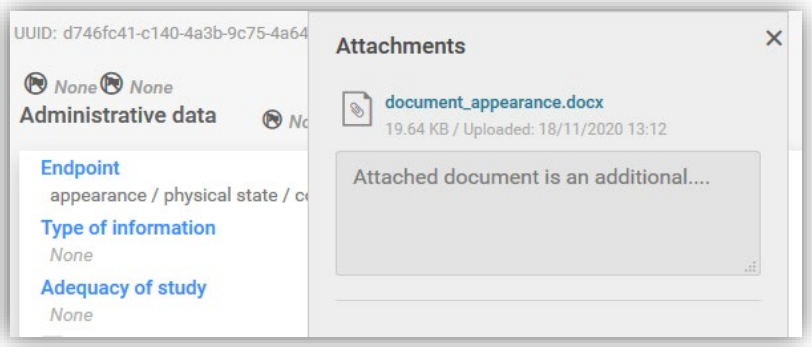


# Attachments to the whole record / endpoint

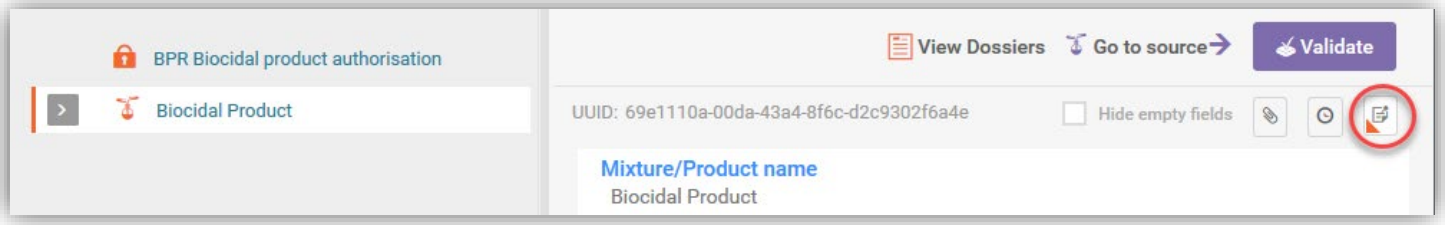
## Dataset



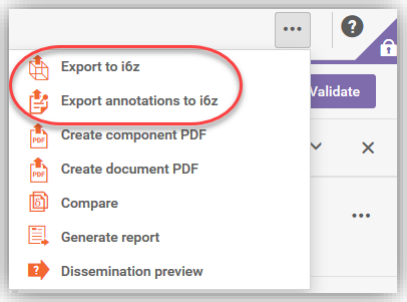

## Dossier



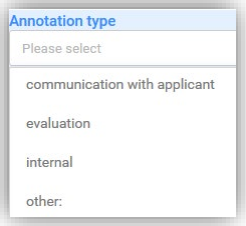
# Annotations (Competent Authorities)




- Competent Authorities can create annotations on the whole dossier and on the specific documents; an annotation relevant to a whole dossier will be displayed in the section 2.1
- Competent Authorities can export annotations:
  - ✓ as a zip file containing annotations – to be later imported to a database containg an original dossier
  - ✓ together with the whole dossier – to be imported to a database which does not contain an original dossier




- There is a new field added to an annotation: Annotation Type

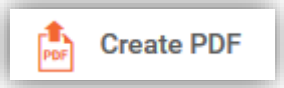


# Annotations (applicant)

- Annotations received from the Competent Authority can be imported to the original dossier
- Orphan annotations are not displayed – technically, an annotation can be imported, but if there is no original dossier, will not be displayed
- The whole dossier can be imported together with the annotations, if the original dossier is not in the database
- All the annotations imported to a dossier are displayed in the relevant documents (sections)
- Currently, annotations are not available for datasets - we will reintroduce this feature as soon as possible and no later than the April 2021 release

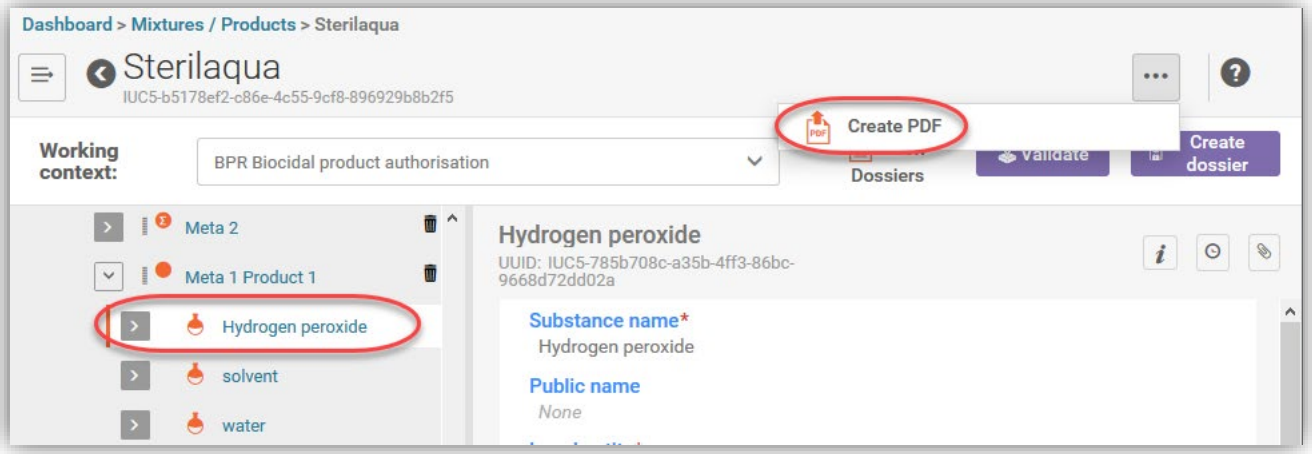
# Print

## Print of a dataset




is expected to print the main document with all its section documents (for example a mixture dataset; an active substance will be listed as a reference)

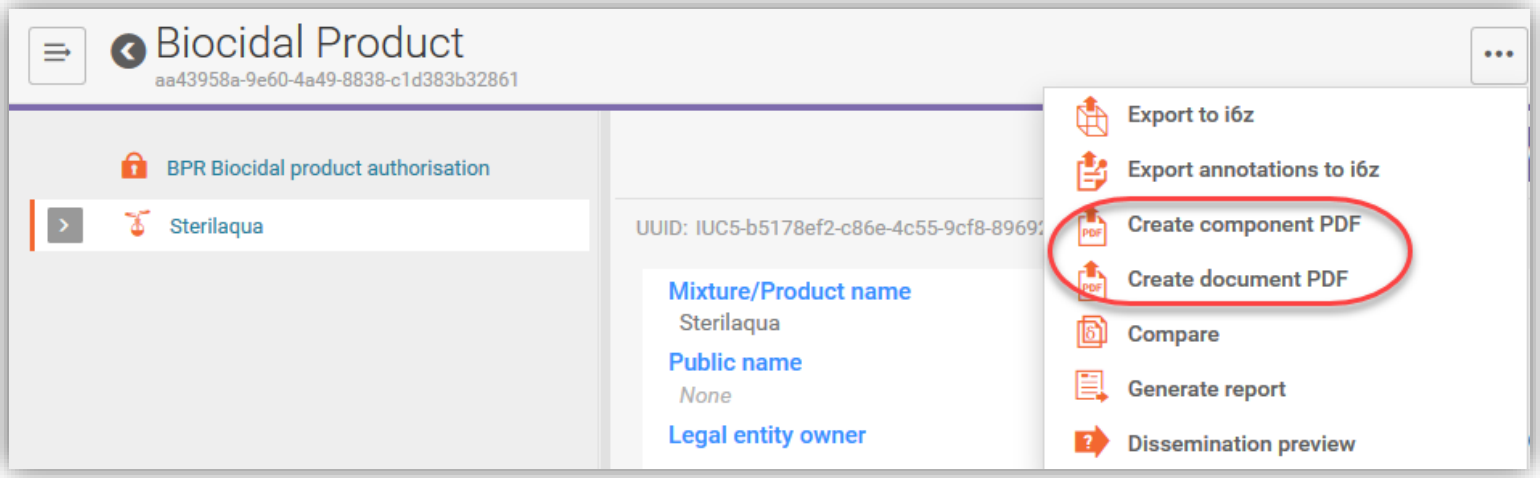
to print an active substance you need to access and active substance in the table of contents, and select *Create PDF* once more



## Print of a dossier

*Create document PDF* - is expected to print only the single document content and references (the document currently displayed)

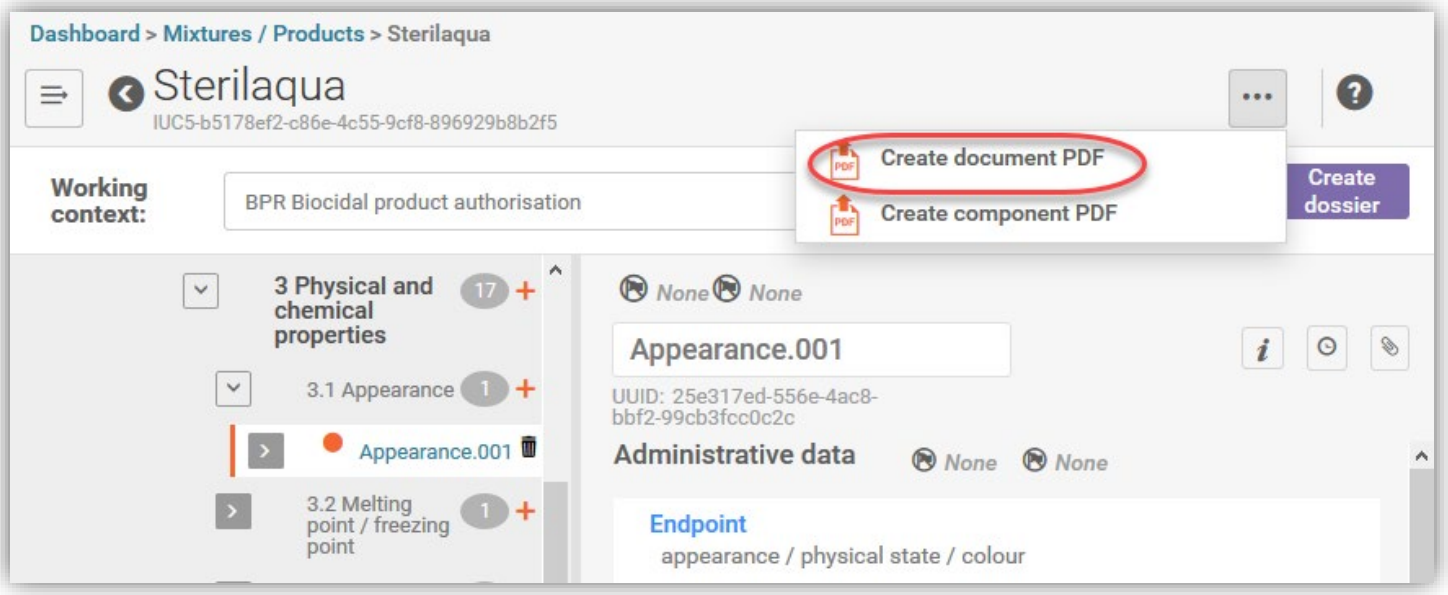
*Create component PDF* - is expected to print the main entity to which this document belongs, in this case a product dataset and documents (an active substance will be listed as a reference)



# Print

## Print of a document

*Create document PDF* - is expected to print only the single document content (and its references)



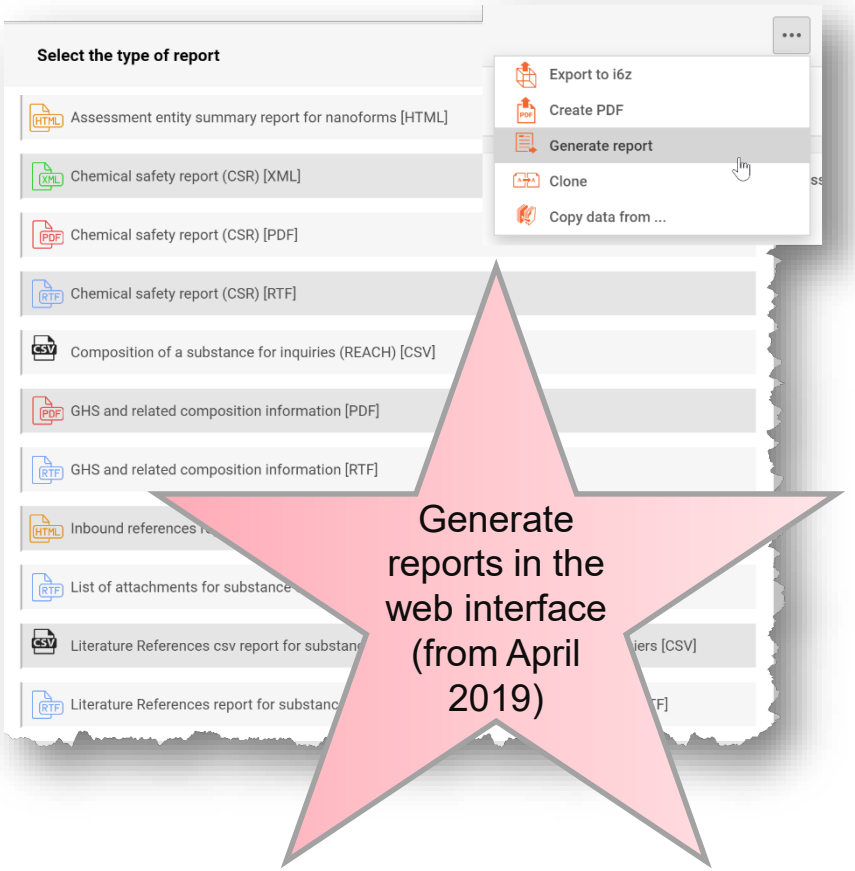
# Report Generator

# Report Generator

The IUCLID user community who use IUCLID to manage Biocides' data are heavy users of the IUCLID Report Generator.

- The Report Generator comes with a number of in-built reports to help users view IUCLID data in another format, such as CSV, RTF (Word), or PDF

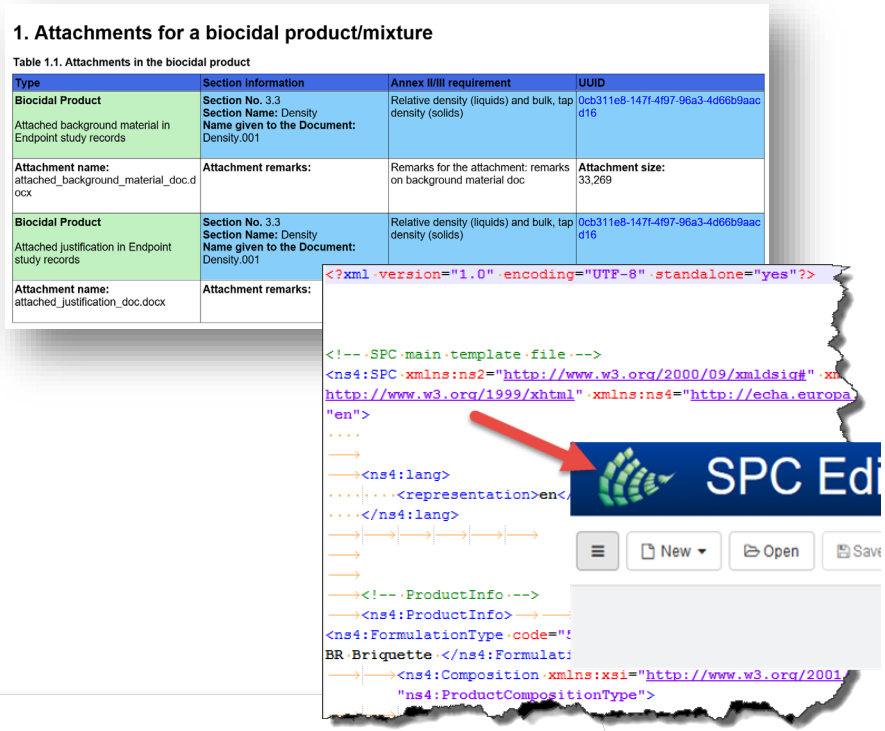
- These reports typically help users to:
  - Quality check the content and existence of specific data, such as attached literature references
  - Support the creation of larger assessment reports, such as the Product Authorisation Report under BPR
  - To provide an overview of the data about to be submitted
  - As an archive of what data has been submitted (used in conjunction with the Print PDF function)



# Reports for Biocides' users

Typically, the most frequent reports used are:

- Summary of Product Characteristics (SPC)
  - XML
- Confidentiality Report (BPR Article 66)
  - RTF/PDF/CSV
- Literature References report
  - RTF/PDF
  - An expanded CSV version of this report is also available
- Attachments report
  - CSV/RTF
- Annotations report
  - RTF/PDF



**1. Attachments for a biocidal product/mixture**

Table 1.1. Attachments in the biocidal product

| Type | Section information | Annex II/III requirement | UUID |
|---|---|---|---|
| **Biocidal Product**<br>Attached background material in Endpoint study records | **Section No.** 3.3<br>**Section Name:** Density<br>**Name given to the Document:** Density.001 | Relative density (liquids) and bulk, tap density (solids) | 0cb311e8-147f-4f97-96a3-4d66b9aacd16 |
| **Attachment name:** attached_background_material_doc.docx | **Attachment remarks:** | Remarks for the attachment: remarks on background material doc | **Attachment size:** 33,269 |
| **Biocidal Product**<br>Attached justification in Endpoint study records | **Section No.** 3.3<br>**Section Name:** Density<br>**Name given to the Document:** Density.001 | Relative density (liquids) and bulk, tap density (solids) | 0cb311e8-147f-4f97-96a3-4d66b9aacd16 |
| **Attachment name:** attached_justification_doc.docx | **Attachment remarks:** | | |



**1. Literature References**

Table 1.1. Literature References generated from a Mixture/Product (including Literature References in any linked Substance)

| Author(s) | Year and Report date | Annex II/III requirements and IUCLID section | IUCLID document name | Title and Report number | Type of publication | Source (where different from company) and Study sponsor | GLP | Data Protection Claimed (Yes/No) |
|---|---|---|---|---|---|---|---|---|
| Author: Ohlson, Klas | Year: 2006 | **Annex II/III requirement:** No Annex II requirement<br>**IUCLID Section No.** OECD numbering (2) | IUCLID Document name: Melting point / freezing point.001 | Title: Study for melting point<br>Report no. 213-324 | Type of publication: study report | Source: Journal of biocidal science<br>Company Owner: Sponsor | | No |

# Building your own reports

IUCLID reports can be created and customised by any user. If you wish to customise your own report, the IUCLID Report Manager permits you to upload your report for generation from a dataset or dossier – see the Report Generator **webpage**

To enhance the accessibility of customising your own reports, a new modular approach to creating reports has been started.

The 'Modular Approach to reporting' section of the Report Generator webpage provides:

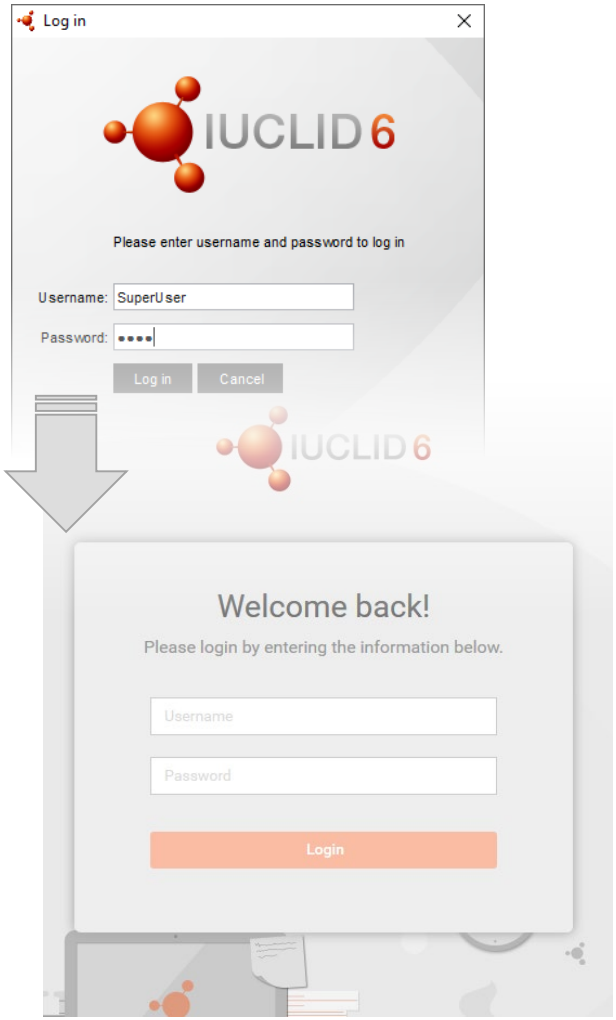
- A short video on how the modular approach works
- The modules which are available to re-use
- An elaboration of all the modules and what data can be extracted with them by comparing the modules to the REACH Chemical Safety Report
- An example Report Template which re-uses the modules

# Plans for 2021

# Plans 2021 (web interface)

## Web interface for advanced chemical management

- The web interface is now comparable to the classic interface with regards the features each interface shares
- The classic interface will remain available for the leftover advanced features until **April 2021**
- Remaining classic interface features to be implemented in the web interface in 2021 are:
  - Full User and Role management
  - Report and Inventory manager
  - Data editing features (ordering repeatable block items, bulk deletion of documents, improved cross-reference search, indication of existing annotations/attachments)
- New features coming in 2021:
  - Transfer annotations between dossiers (*this replaces the 'show all versions' of annotations in the classic interface*)
  - Simplified Classification and Labelling document for all submission types

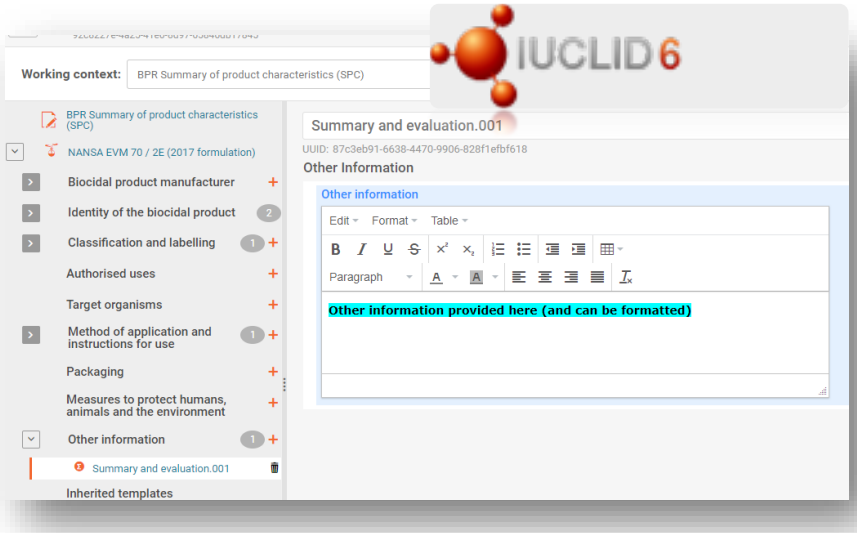


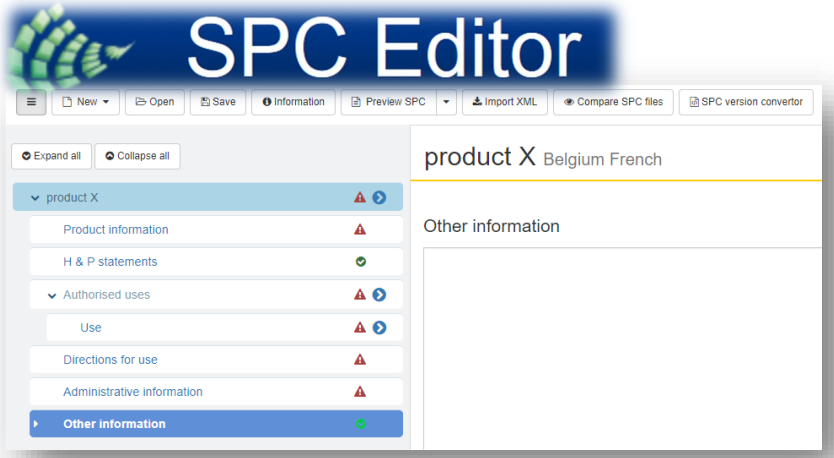
# Plans 2021 (Summary of Product Characteristics)

In IUCLID 6.5, the new SPC working context took advantage of the customisation possibilities in IUCLID. The SPC working context contains a Table of Contents and IUCLID Documents reflecting the SPC Editor table of contents and forms

In 2021 we will maintain the compatibility between the SPC Editor and IUCLID, with regards:

- Permitting the import of an SPC XML file into IUCLID
- Ensuring the IUCLID SPC working context and custom views continue and develop to reflect the SPC Editor forms



# Plans 2021 (Validation assistant)

In 2021 we may expand the set of validation rules for certain Biocidal working contexts'

**Benefits of validation rules**

Validation rules will support registrants to comply with the information requirements of the BPR regulation


**Re-use of existing rules**

Existing validation rules used for substances can be re-used, and can be applied for example, to the BPR Technical Equivalence working context (which is substance-based)


**Reviewing the use of validation rules**

Currently, the addition of more validation rules to the BPR working contexts' is under review, and if progress is made, ECHA will provide information on the rules and the working context(s) they apply to in due course


*Thank you for your participation*

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