

A stylized molecular structure logo consisting of a large central orange sphere with three smaller orange spheres attached to it by short red lines. The entire structure is set against a white, semi-transparent circular background.

# IUCLID 6





# IUCLID 6

IUCLID 6.5 for Biocides users

*24<sup>th</sup> November 2020*



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



## 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

## 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

**Joining as a participant?**

**No account needed.**

# iuclidbiocides2020



By using Slido you accept our [Policy](#)

<https://www.sli.do/>

## Recordings

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

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

### Documentation

- System requirements
- Videotutorials
- Training material
- **Webinars**
- Verification of downloads
- Learn to use the new interface

### Webinars

#### IUCLID April 2020 release (12<sup>th</sup> May 2020)

Watch our pre-recorded webinar where we present the scope of the April 2020 release. IUCLID is updated twice a year. The October release introduction is dedicated to improvements and bug fixes.



<https://iuclid6.echa.europa.eu/webinars>

# IUCLID 6.5 release



## Where to find information

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

[iuclid6.echa.europa.eu/webinars](https://iuclid6.echa.europa.eu/webinars)

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

A screenshot of the IUCLID website's news page. The page has a dark grey navigation bar with "Home", "IUCLID Product", and "Download Software" links. Below the navigation bar, the breadcrumb "IUCLID > News > IUCLID news" is visible. The main heading is "IUCLID news" with a date of "28/10/2020". The title of the news item is "IUCLID 6.5 is available". The text of the news item states: "Every October, a new major release of IUCLID is published and made available to all improvements but also changes to the IUCLID format." It then describes the changes implemented in the new version, including updates to the Classification and Labelling format and the SCIP and PCN formats. It also mentions the move towards a new interface and the webinar held on the 11<sup>th</sup> of November. At the bottom, there is an "Additional information" section with links for "Download IUCLID", "Release notes", "Format", "Webinar", and "LinkedIn group".

Home IUCLID Product Download Software

IUCLID > News > IUCLID news

## IUCLID news

28/10/2020

### IUCLID 6.5 is available

**Every October, a new major release of IUCLID is published and made available to all improvements but also changes to the IUCLID format.**

The IUCLID team has implemented, in the new version of the IUCLID format, the latest changes to the Classification and Labelling format in accordance with the latest updates of the CLP regulation. In addition, the relevant modifications have been made to the SCIP and PCN formats in order to support the implementation of IUCLID in both OECD member countries. Finally, the 2019 pesticide submissions to the SCIP database and the Poison Centres in Europe. Updates specified by Annex I to support the implementation of IUCLID in both OECD member countries. Finally, the 2019 pesticide submissions in Europe has evolved into a first official version of IUCLID for these data group.

On the software features side, some evolutions can be noted too, particularly the move towards a new interface with the abandonment of the classic interface availability by default. There will still be a classic interface in the next months though, following the instructions published on the IUCLID website to reduce the gap between the two interfaces, for example by proposing a more efficient way of data options.

You can access the full release notes and download the new version from the IUCLID website. The software was automatically upgraded the week of the release. We will hold a webinar, on the 11<sup>th</sup> of November.

#### Additional information

[Download IUCLID](#) | [Release notes](#) | [Format](#) | [Webinar](#) | [LinkedIn group](#)

## User interface

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

### Access the Classic interface of IUCLID

If you need to use the classic interface to carry out some specific task that you cannot do via the web interface, get instructions on how to open it from the link below. You will be asked to answer a short survey before getting the **instructions**.

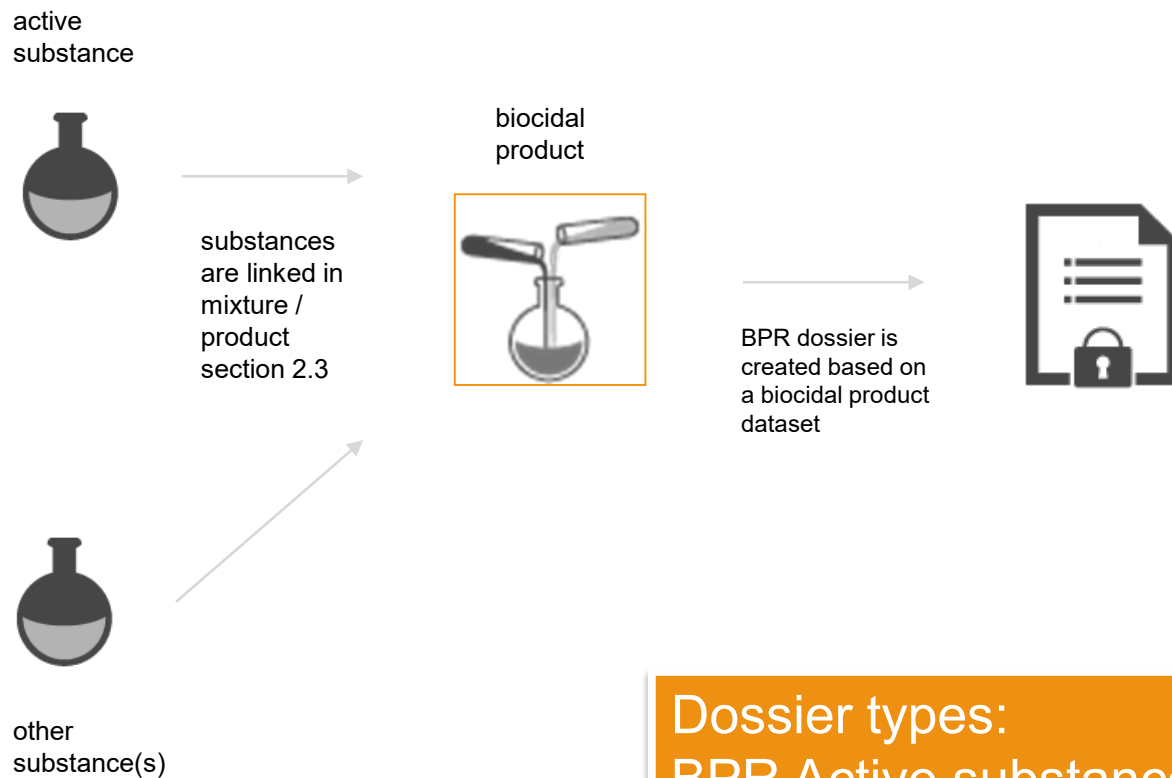
<https://iuclid6.echa.europa.eu/fi/learn-to-use-the-new-interface>

## Biocides submissions:

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







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

# Mixture/product dataset – starting point of a dossier



Mixtures 27

Dashboard > Mixture / Products

Mixtures

+ New mixture / product ?

Dashboard > Mixtures / Products > Biocidal Product

Biocidal Product  
69e1110a-00da-43a4-8f6c-d2c9302f6a4e

Working context: Please select

No results found

+ New working context

Select working context

- BPR Active substance application (representative product)
- BPR Active substance application (representative product)
- BPR Basic information (mixture)
- BPR Biocidal product authorisation

# Mixture/product dataset – starting point of a dossier



**Working context:** BPR Active substance application (representative product) ▼ **Draft dossier header**

← BPR Active substance application (representative product)

**Dossier name (given by user)**  
Test dossier for substance application

**Dossier submission remark**  
None

**Specific submissions**

The submission is an update

**Last submission number**  
None

**Reason for updating**

Further to a request/decision from a regulatory body

Spontaneous update

← BPR Biocidal product authorisation

**Dossier name (given by user)**  
None

**Dossier submission remark**  
None

**Specific submissions**

**Authorisation type**

Please select ▼

product family

single product

None

**Reason for updating**

Further to a request/decision from a regulatory body

Spontaneous update

# Mixture/product dataset – starting point of a dossier



Dashboard > Mixtures / Products > Biocidal Product

Biocidal Product  
69e1110a-00da-43a4-8f6c-d2c9302f6a4e

Working context: BPR Biocidal product authorisation

Draft dossier header [Validate](#) [Create dossier](#)

**BPR Biocidal product authorisation**

1. Applicant\*
2. Identity of the biocidal product\* **1**
3. Physical, chemical and technical properties\*
4. Physical hazards and respective characteristics\*
5. Methods of detection and identification\*
6. Effectiveness against target organisms\*
7. Intended uses and exposure\*
8. Toxicological profile for humans and animals\*
9. Ecotoxicological studies\*
10. Environmental fate and behaviour\*

**2 Identity of the biocidal product \*** **1**

2.1 Trade name or proposed trade name **1**

**Biocidal Product**  
Last Modified:17/11/2020 10:39

2.2 Manufacturer's development code and number of the biocidal product **+ New**

2.3 Biocidal product composition \*

**2.4 (Cf. 2.3) Formulation type and nature of the biocidal product**

**3 Physical, chemical and technical properties \***

3.1 Appearance (at 20°C and 101.3 kPa) \* **+ New**

3.2 Acidity, alkalinity \* **+ New**

3.3 Relative density (liquids) and bulk, tap density (solids) \* **+ New**

**+ New** **+ New document** **Copy from existing**

# 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 through the sections and its content

see also: IUCLID release webinar (11.11)

# Composition of a single biocidal product



BPR Biocidal product authorisation

- Biocidal Product
  - 1 Applicant
  - 2 Identity of the biocidal product 1
    - 2.1 Trade name or proposed trade name 1
    - 2.2 Manufacturer's development code and number of the biocidal product +
    - 2.3 Biocidal product composition +
    - 2.4 (Cf. 2.3) Formulation type and number of components +
  - 3 Physical, chemical and technical data
  - 4 Physical hazards and respect for the environment
  - 5 Methods of detection and identification

**+ New document >**

- Product summary composition
- Composition (mixture) →

**Biocidal product composition.001**  
UUID: 2549c99b-efc6-4ab1-98c5-38bea8b658b4

**Administrative data** None None

**General information**

Mixture/product name  
*None*

Trade names + New item

Brief description  
*None*

Formulation type  
*None*

**Components**

+ New item

#	Componen...	Name	Function
---	-------------	------	----------

# Assign components of a single biocidal product



Components

**+ New item**

#	Componen...	Name	Function	Typical co...	Concentrat...	Remarks	Substance...	Generic co...	Interchang...	Standard f...	Substance...	Action
---	-------------	------	----------	---------------	---------------	---------	--------------	---------------	---------------	---------------	--------------	--------

**Set values** [X]

None  None

**Name**  
None

**Function**  
None

**Typical concentration**  
None

**Concentration range**  
None

**Remarks**  
None

Substance of concern

Generic component identifier (GCI)

Interchangeable component group (ICG)

Standard formula (SF) component

Substance generated in situ (from one or more precursors, at the place of use)

# Assign components of a single biocidal product



**Set values**

None  
Name  
None

**Set values**

None None

Name

**+ Select**

Mixture / Product

Reference substance

Substance

**Select Substance** + Create ×

42 results found

[▶ Advanced search](#)

Hydrogen peroxide				17/11/2020 10:37
Inventory number	231-765-0	CAS number	7722-84-1	IUPAC name
Legal Entity	AS Company	UUID	IUC5-785b708c-a35b-4ff3-86bc-9668d72dd07	

test				17/11/2020 10:37
Inventory number		CAS number	IUPAC name	
Legal Entity	European Chemicals Agency	UUID	f63202ca-1a7c-4352-b615-779cef074e22	

different active				17/11/2020 10:37
Inventory number	231-791-2	CAS number	7732-18-5	IUPAC name
Legal Entity	DB_Company	UUID	b22ede6e-e9cf-4291-baba-491ee743ee1b	



# Create a substance directly in the mixture/product



Select Substance + Create

Hydr 0 results found

### Create new Substance

**Substance name\***  
None  
✗ Substance name field is mandatory.

**Public name**  
None

**Legal entity\*** None None  
None  
✗ Legal entity field is mandatory.

**Third party** None None  
None

**Other substance identifiers** + New item

#	Flags	Identifier	Identity	Country	Relation	Remarks	Action
---	-------	------------	----------	---------	----------	---------	--------

**Contact persons** + New item

**Identification of substance** None None

**Reference substance**  
None

**Type of substance**

**Type of substance**  
None

**Origin**  
None

**Role in the supply chain** None None

- Manufacturer
- Importer
- Only representative
- Downstream user

? Save

# Go to the substance dataset

Save



## Set values



 None  None

Name  

active substance for webinar

## Edit active substance for webinar

 Go to source 

 This IUCLID information is a re-usable data element. Note that any modification will impact all associated data. 

### Substance name\*


active substance for webinar

### Public name

None


### Legal entity\*

European Chemicals Agency | Helsinki | Finland | 10097

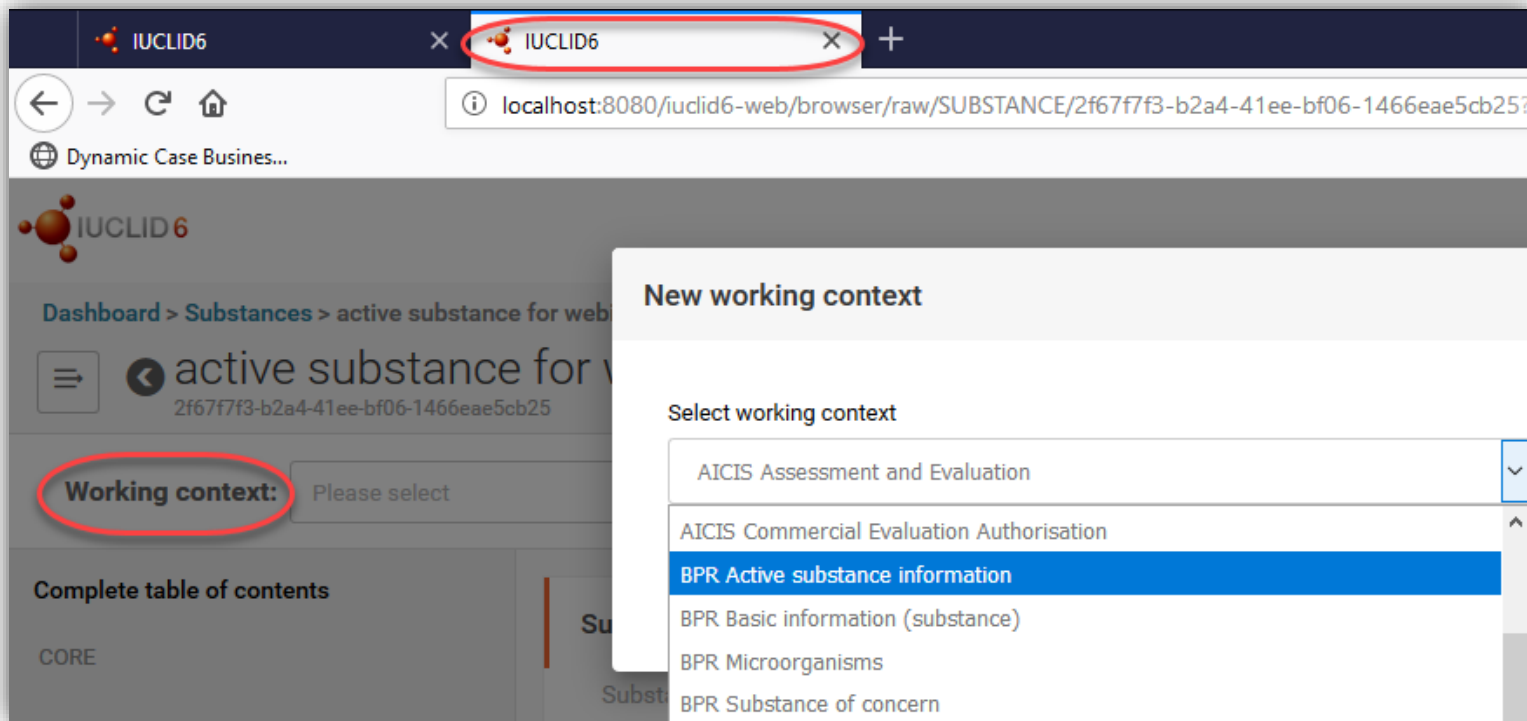
 None  None

### Third party

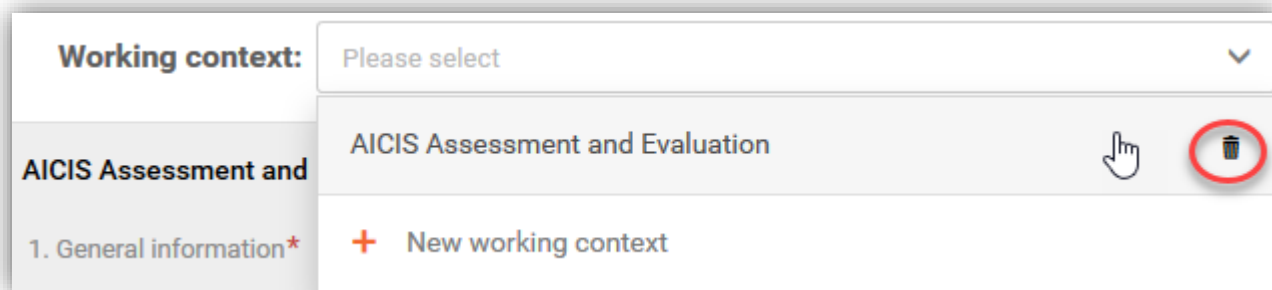
None

 None  None

# Edit substance dataset in a new tab

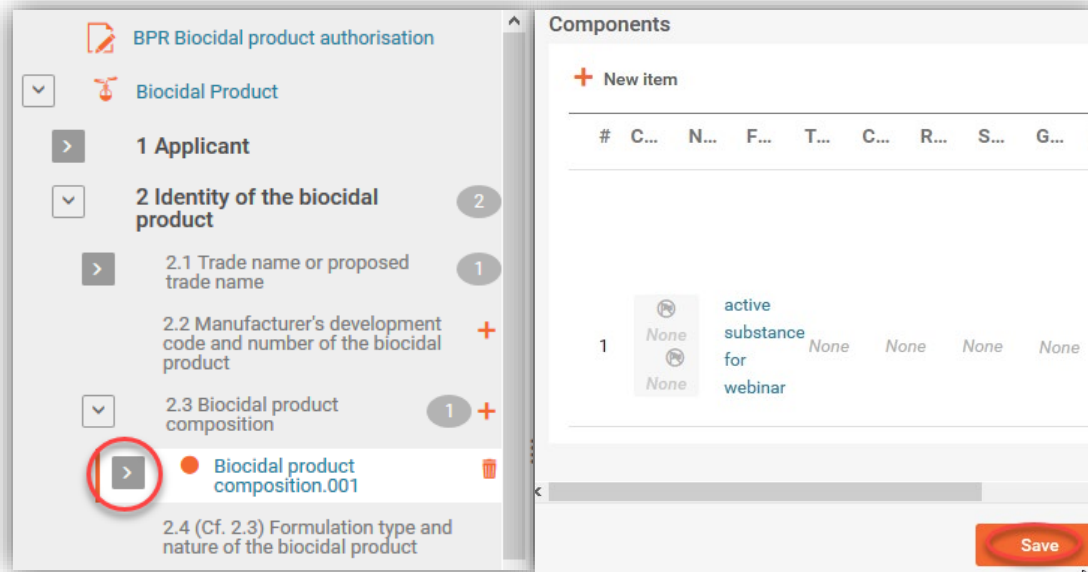


The screenshot shows a web browser with two tabs. The active tab is titled 'IUCLID6' and is circled in red. The address bar shows the URL: localhost:8080/iuclid6-web/browser/raw/SUBSTANCE/2f67f7f3-b2a4-41ee-bf06-1466eae5cb25? The page content includes a breadcrumb trail: Dashboard > Substances > active substance for web. Below this, there is a 'Working context:' label circled in red, followed by a dropdown menu with the text 'Please select'. A 'New working context' dialog box is open, showing a list of options: AICIS Assessment and Evaluation, AICIS Commercial Evaluation Authorisation, BPR Active substance information (highlighted in blue), BPR Basic information (substance), BPR Microorganisms, and BPR Substance of concern.



This close-up shows the 'Working context:' dropdown menu. The current selection is 'Please select'. Below the dropdown, the selected context 'AICIS Assessment and Evaluation' is displayed with a hand cursor icon and a trash can icon circled in red. At the bottom, there is a '+ New working context' button.

# Edit substance dataset in a product TOC

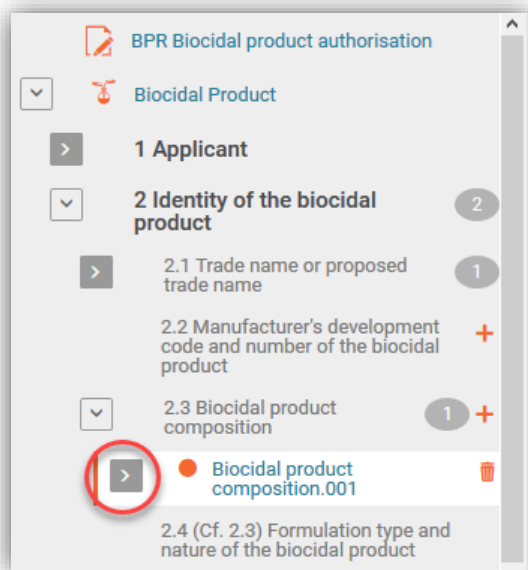


The screenshot shows the IUCLID 6 interface. On the left, a sidebar contains a tree view of the product TOC. The 'Biocidal product composition' section is selected, and its right arrow icon is circled in red. The main area displays the 'Components' table with one row containing the text 'active substance for webinar'. A 'Save' button is visible in the bottom right corner of the main area.

#	C...	N...	F...	T...	C...	R...	S...	G...	I
1	None	None	None	None	None	None	None	None	

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

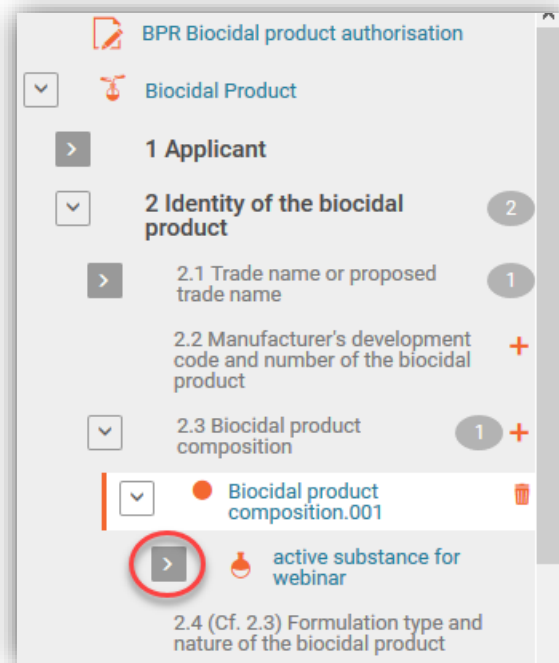
# Edit substance dataset in a product TOC



BPR Biocidal product authorisation

Biocidal Product

- 1 Applicant
- 2 Identity of the biocidal product (2)
  - 2.1 Trade name or proposed trade name (1)
  - 2.2 Manufacturer's development code and number of the biocidal product (+)
  - 2.3 Biocidal product composition (1) (+)
  - Biocidal product composition.001** (highlighted with a red circle)
  - 2.4 (Cf. 2.3) Formulation type and nature of the biocidal product

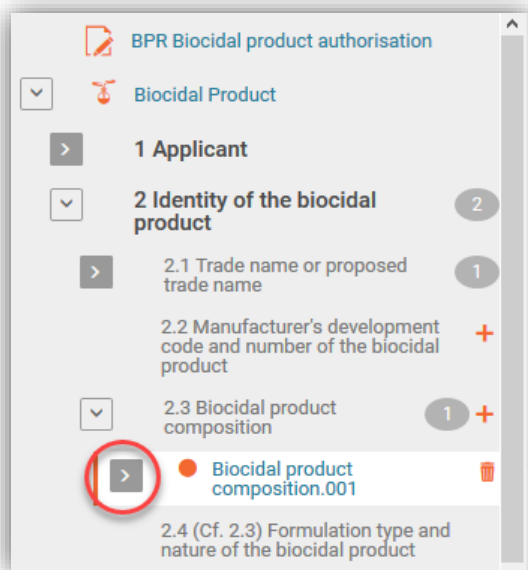


BPR Biocidal product authorisation

Biocidal Product

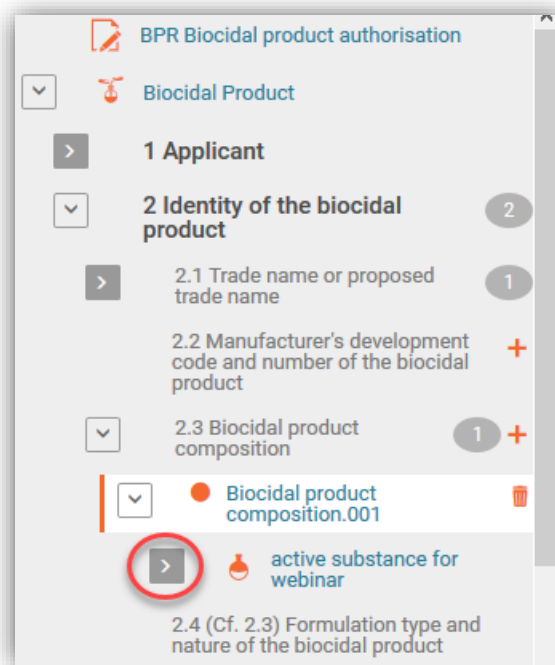
- 1 Applicant
- 2 Identity of the biocidal product (2)
  - 2.1 Trade name or proposed trade name (1)
  - 2.2 Manufacturer's development code and number of the biocidal product (+)
  - 2.3 Biocidal product composition (1) (+)
  - Biocidal product composition.001
  - active substance for webinar** (highlighted with a red circle)
  - 2.4 (Cf. 2.3) Formulation type and nature of the biocidal product

# Edit substance dataset in a product TOC



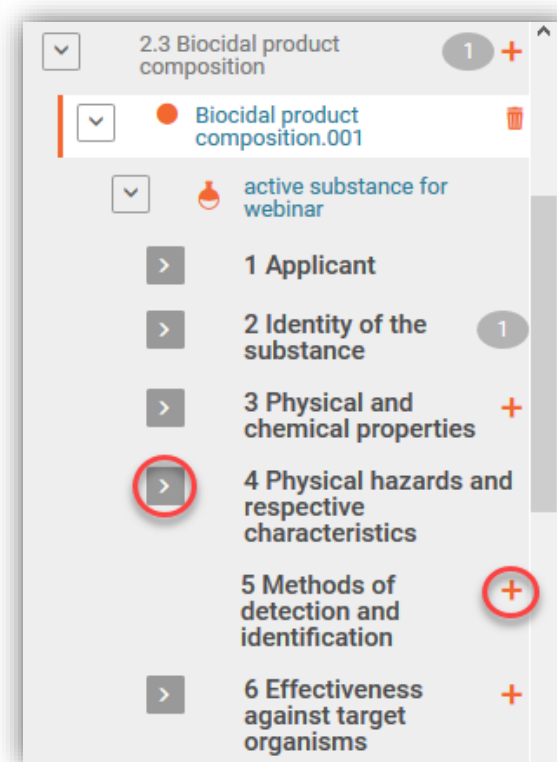
BPR Biocidal product authorisation

- Biocidal Product
  - 1 Applicant
  - 2 Identity of the biocidal product (2)
    - 2.1 Trade name or proposed trade name (1)
    - 2.2 Manufacturer's development code and number of the biocidal product (+)
    - 2.3 Biocidal product composition (1) (+)
    - Biocidal product composition.001** (1) (+)
    - 2.4 (Cf. 2.3) Formulation type and nature of the biocidal product



BPR Biocidal product authorisation

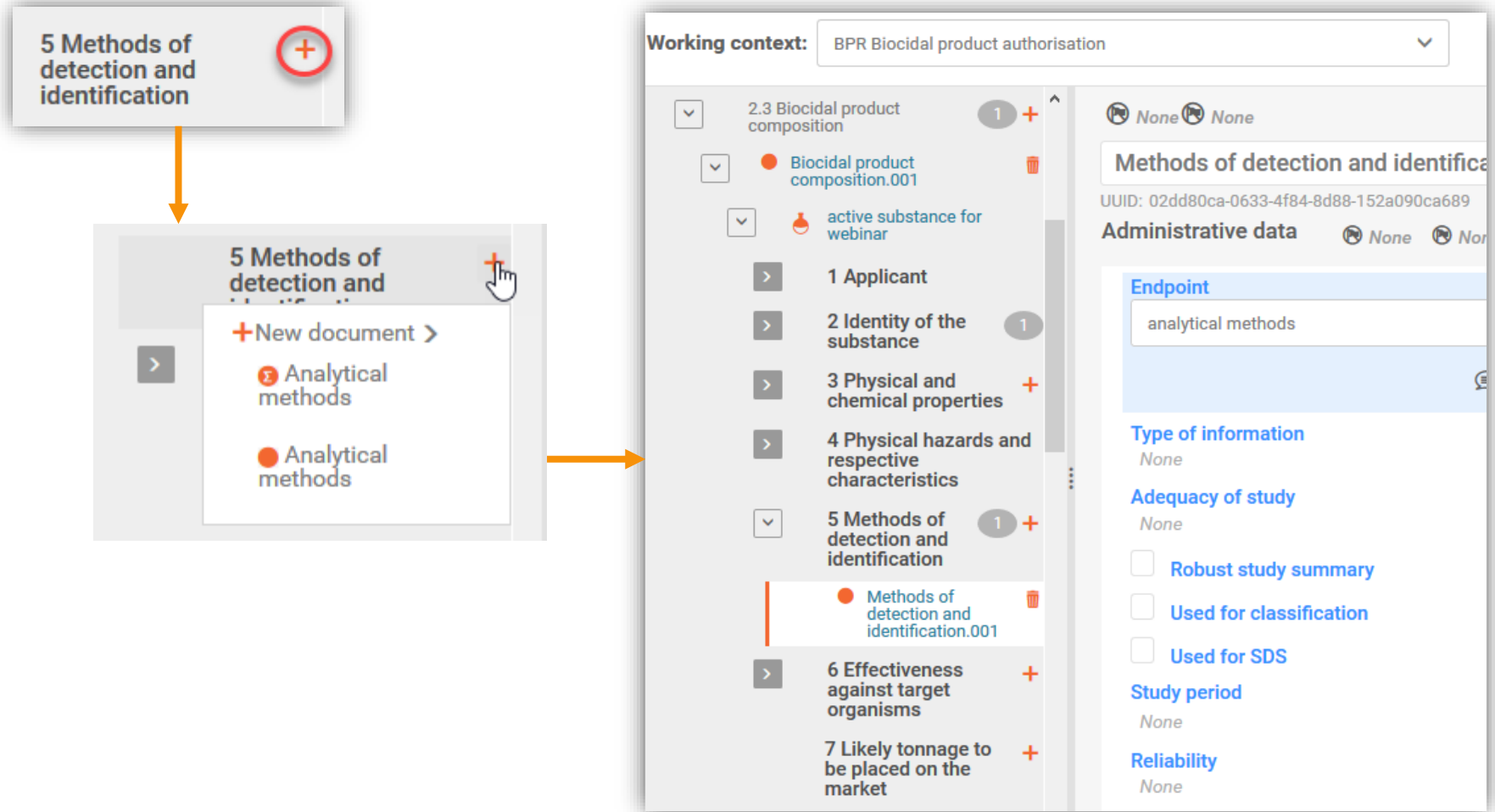
- Biocidal Product
  - 1 Applicant
  - 2 Identity of the biocidal product (2)
    - 2.1 Trade name or proposed trade name (1)
    - 2.2 Manufacturer's development code and number of the biocidal product (+)
    - 2.3 Biocidal product composition (1) (+)
    - active substance for webinar** (1) (+)
    - 2.4 (Cf. 2.3) Formulation type and nature of the biocidal product



2.3 Biocidal product composition (1) (+)

- Biocidal product composition.001** (1) (+)
- active substance for webinar
  - 1 Applicant
  - 2 Identity of the substance (1)
  - 3 Physical and chemical properties (+)
  - 4 Physical hazards and respective characteristics** (1) (+)
  - 5 Methods of detection and identification (+)
  - 6 Effectiveness against target organisms (+)

# Edit substance dataset from a product TOC



The image illustrates the workflow for editing a substance dataset from a product TOC in IUCLID 6.5. It is divided into three main visual components:

- Callout Box (Top Left):** A grey box with a red circle containing a plus sign, labeled "5 Methods of detection and identification". An orange arrow points from this box to the TOC view.
- TOC View (Middle Left):** A grey box representing the product TOC. It shows a list of sections, with "5 Methods of detection and identification" highlighted. A hand cursor is clicking on a plus sign next to this section. A dropdown menu is open, showing options: "+New document >", "Analytical methods" (with a red warning icon), and another "Analytical methods" (with a red circle icon). An orange arrow points from this view to the detailed view.
- Main Application Window (Right):** The IUCLID 6.5 interface. The "Working context" is "BPR Biocidal product authorisation". The TOC on the left lists sections 1 through 7. Section 5, "5 Methods of detection and identification", is selected and expanded. The right-hand pane shows the details for this section, including a "Methods of detection and identification" header, a UUID, and various data fields like "Endpoint" (analytical methods), "Type of information" (None), "Adequacy of study" (None), and "Reliability" (None). There are checkboxes for "Robust study summary", "Used for classification", and "Used for SDS".

# Composition of a biocidal products family

Working context: BPR Biocidal product authorisation

1 2.3 Biocidal product composition 7 + ^

2 Family

- > water
- > solvent
- 3 > Hydrogen peroxide

Meta 1

- > water
- > solvent
- > Hydrogen peroxide

Meta 2

- > solvent
- > water
- > Hydrogen peroxide

Meta 1 Product 1

- > Hydrogen peroxide
- > solvent
- > water

Meta 1 Product 2

Meta 2 Product 1

> Hydrogen peroxide

1 Applicant 1

2 Identity of the active substance 3

- > 2.1 Common name and synonyms 1
- 2.2 (Cf. 2.1) Chemical name (IUPAC and CA nomenclature or other international chemical name(s))
- 2.3 Manufacturer's development code number(s) +
- 2.4 (Cf. 2.1) CAS number plus EC, INDEX and CIPAC numbers
- 2.5 (Cf. 2.1) Molecular and structural formula (including SMILES notation)
- 2.6 (Cf. 2.1) Information on optical activity and full details of any isomeric composition
- 2.7 (Cf. 2.1) Molar mass
- > 2.8 Method of manufacture (syntheses pathway) of the active substance
- > 2.9 Specification of purity of the active substance as manufactured 1 +

> **Specification on purity of the active substance as manufactured.001**

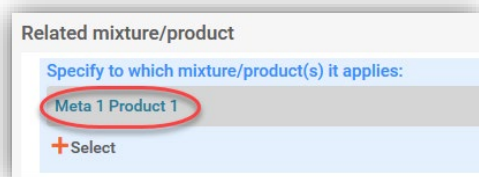


# Links between the documents: composition record

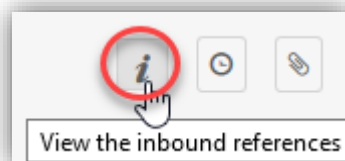


## Documents linked to the biocidal product composition record - inbound reference(s)

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



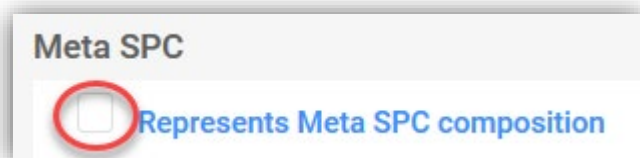
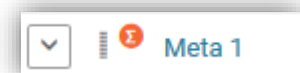
location of manufacturing plant(s)



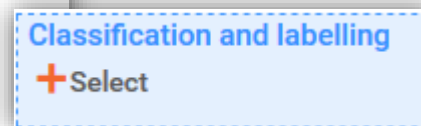
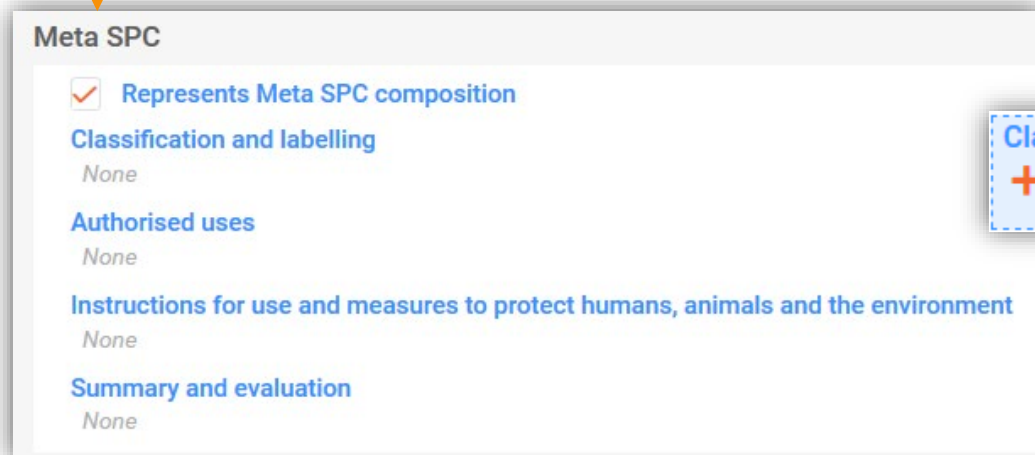
Document's inbound references			
Meta 1			17/11/2020 19:06
Mixture / Product	Sterilaqua	UUID	79a08fce-13f2-49a0-a1df-21afefde0888
GHS.001			17/11/2020 10:37
Mixture / Product	Sterilaqua	UUID	9e7f8479-76f6-34be-8786-2ff4a78d91d2
Packaging.001			17/11/2020 10:37
Mixture / Product	Sterilaqua	UUID	IUC5-7b0ca858-0670-4add-99ce-0f3d687f9fc4
PT 2: Field(s) of use envisaged for biocidal products and treated articles.001			17/11/2020 19:20
Mixture / Product	Sterilaqua	UUID	IUC5-ba22e399-7f9d-4b1a-ac8c-65f2f9457fc4
Location of manufacturing plant(s).001			17/11/2020 17:50
Mixture / Product	Sterilaqua	UUID	e1577491-58ad-4f2f-82fa-f2eef02eeb8

composition

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

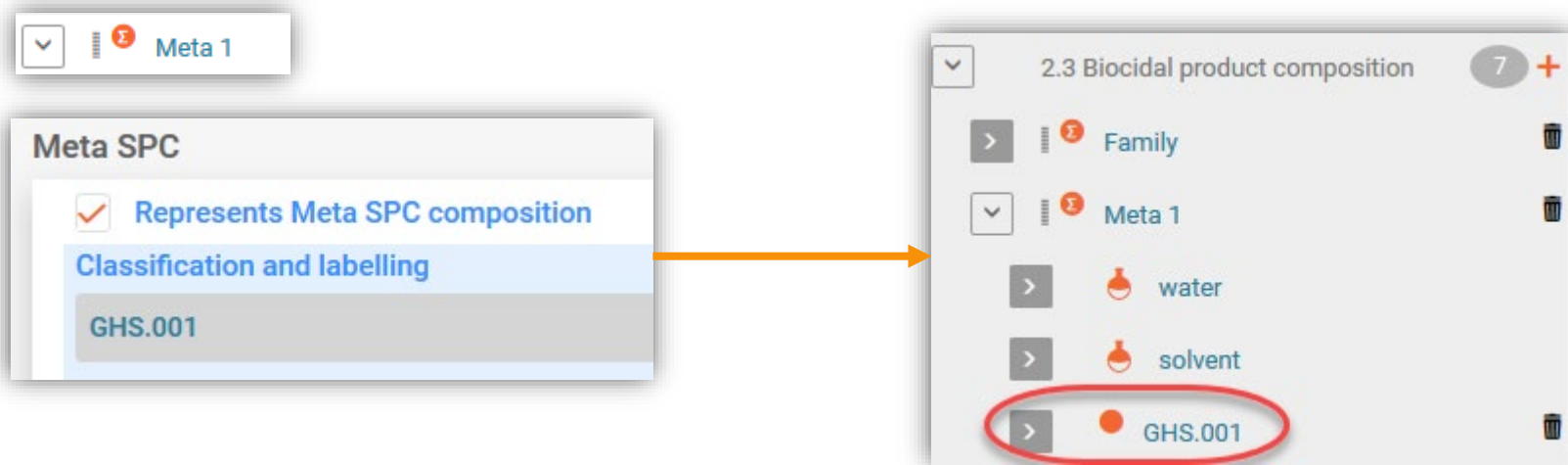


- GHS (section 12)
- Intended uses and exposure (section 7.1)
- Measures to protect humans, animals and the environment (section 11)
- Summary and evaluation (section 13)



# Links between the documents: meta SPC

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



## 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)

### Target organisms

Function and mode of control.001

### Packagings


bottle | > 5 <= 10 L

### Application methods

PT 2: Method of application and a description of this method.001

### Instructions for use and measures to protect humans, animals and the environment

Measures to protect humans, animals and the environment.001



7 Intended uses and exposure 6

7.1 Field(s) of use envisaged for biocidal products and treated articles 3 +

PT 2: Field(s) of use envisaged for biocidal products and treated articles.001

Measures to protect humans, animals and the environment.001

Packaging.001

Meta 1 Product 1

Function and mode of control.001

PT 2: Method of application and a description of this method.001

# Creation of the reference document



...at the moment of linking (example of section 7.1)

**Packagings**

bottle | > 5 <= 10 L

**+ Select**

Select existing document **+ Create** X

Packaging ID	Date
Packaging.003	17/11/2020 10:37
Mixture / Product Sterilaqua	UUID 30cb52ae-bf21-41ee-be76-9756055a2177
Packaging.002	17/11/2020 10:37
Mixture / Product Sterilaqua	UUID 983d9b24-3b50-43a8-89b6-30c9b58e543b
Packaging.001	17/11/2020 10:37
Mixture / Product Sterilaqua	UUID IUC5-7b0ca858-0670-4add-99ce-0f3d687f9fc4

Create new FLEXIBLE\_RECORD.Packaging

None  None

Administrative data  None  None

**Packaging**

If relevant, specify to which product(s) it applies:  
None

Type of packaging in contact with the product (container type)  
None

Size of packaging in contact with the product (container size) **+ New item**

Material of packaging in contact with the product (container material)  
None

Compatibility of the product with the packaging materials proposed to be in contact  
None

Further description of the packaging in contact with the product  
None

Safety features of the packaging  
None

Description of the secondary packaging (not in contact with the product)  
None

Packaging related attachments **+ New item**

#	Type of attachment	Attached document	Remarks
---	--------------------	-------------------	---------

Additional information on packaging  
None

**Save**

# Dossier creation

Dashboard > Mixtures / Products > Biocidal Product

Biocidal Product  
69e1110a-00da-43a4-8f6c-d2c9302f6a4e

Working context: BPR Biocidal product authorisation

Draft dossier header

Validate

Create dossier

BPR Biocidal product authorisation

Dossier name (given by user)  
Biocidal Product

Dossier submission remark  
Submission for the purpose of IUCLID webinar

Specific submissions

Authorisation type  
single product

The submission is an update

Create dossier

advanced settings

- 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

Create dossier

✓ Dossier creation was completed successfully.  
Do you want to open the created dossier?


Close Open

## Validation of data during dossier creation

Create dossier ✕

✕ You have 1 Submission rules which require fixing.  
We highly recommend you fix these errors before creating and submitting your dossier.

[Continue with dossier creation](#) [View/fix errors](#)

 Validated entity: Biocidal Product  
Validation time: 18/11/2020 10:54  
Validation scenario: SC0201 - BPR Biocidal product authorisation

[Re-validate](#) [Edit dossier settings](#) [Export to Excel](#)

**!** Submission checks **1** **?** Quality checks **0**

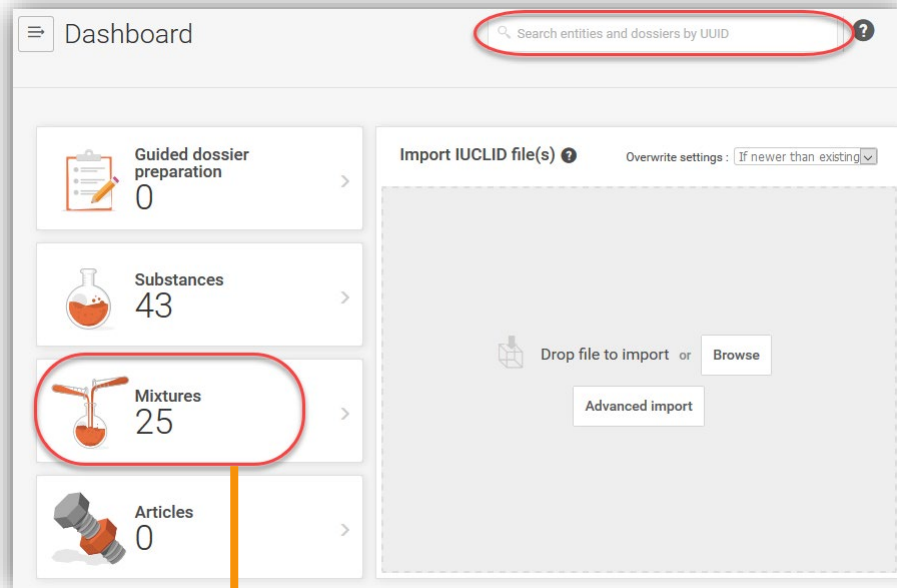
---

Business rules **1**  Completeness check rules **0**

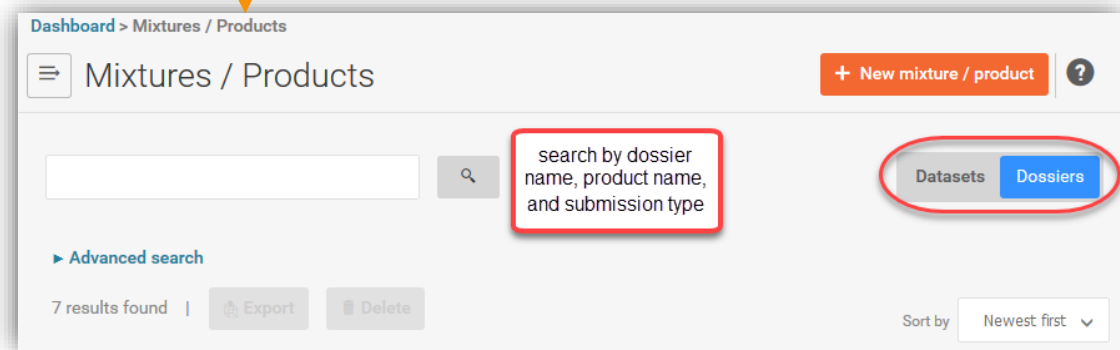
✕ 2.3 Biocidal product composition Business rule (BPR001)

The selected Biocidal Product dataset is not valid for creating a BPR Biocidal product authorisation dossier. A valid Biocidal Product dataset for this dossier type must contain at least one component with the function 'active substance' and a linked substance dataset. If there is more than one component with the function 'active substance', a relevant substance or mixture dataset must be linked to each one.

## Basic search for a dossier



The screenshot shows the IUCLID 6 Dashboard. At the top right, there is a search bar with the text "Search entities and dossiers by UUID" and a question mark icon. On the left side, there are four menu items: "Guided dossier preparation" with a count of 0, "Substances" with a count of 43, "Mixtures" with a count of 25, and "Articles" with a count of 0. The "Mixtures" item is highlighted with a red oval, and an orange arrow points from it to the second screenshot. To the right of the menu items is a section for "Import IUCLID file(s)" with an "Overwrite settings" dropdown set to "If newer than existing". Below this is a large dashed box for file upload, containing a "Drop file to import" instruction, a "Browse" button, and an "Advanced import" button.



The screenshot shows the "Mixtures / Products" page. At the top left, there is a breadcrumb "Dashboard > Mixtures / Products" and a menu icon. The page title is "Mixtures / Products". On the top right, there is a "+ New mixture / product" button and a question mark icon. Below the title is a search bar with a magnifying glass icon. A red box highlights the search bar with the text "search by dossier name, product name, and submission type". To the right of the search bar are two tabs: "Datasets" and "Dossiers", with "Dossiers" selected and highlighted by a red oval. Below the search bar is a link for "Advanced search". At the bottom left, it says "7 results found" and has "Export" and "Delete" buttons. At the bottom right, there is a "Sort by" dropdown menu set to "Newest first".



# Dossier search

## Advanced search for a dossier

Dashboard > Mixtures / Products

Mixtures / Products + New mixture / product ?

Datasets Dossiers

▶ Advanced search

7 results found |

Sort by

▼ Advanced search

▼ Dossier name 0

▼ Dossier Submission Type 0

▼ Subject name 0

▼ Submitting Legal entity Name 0

▼ Substance in Mixture 0

Substance name

CAS Number

Inventory Number

IUPAC Name

▼ Mixture in mixture name 0

▼ Identifiers 0

▼ Trade name 0

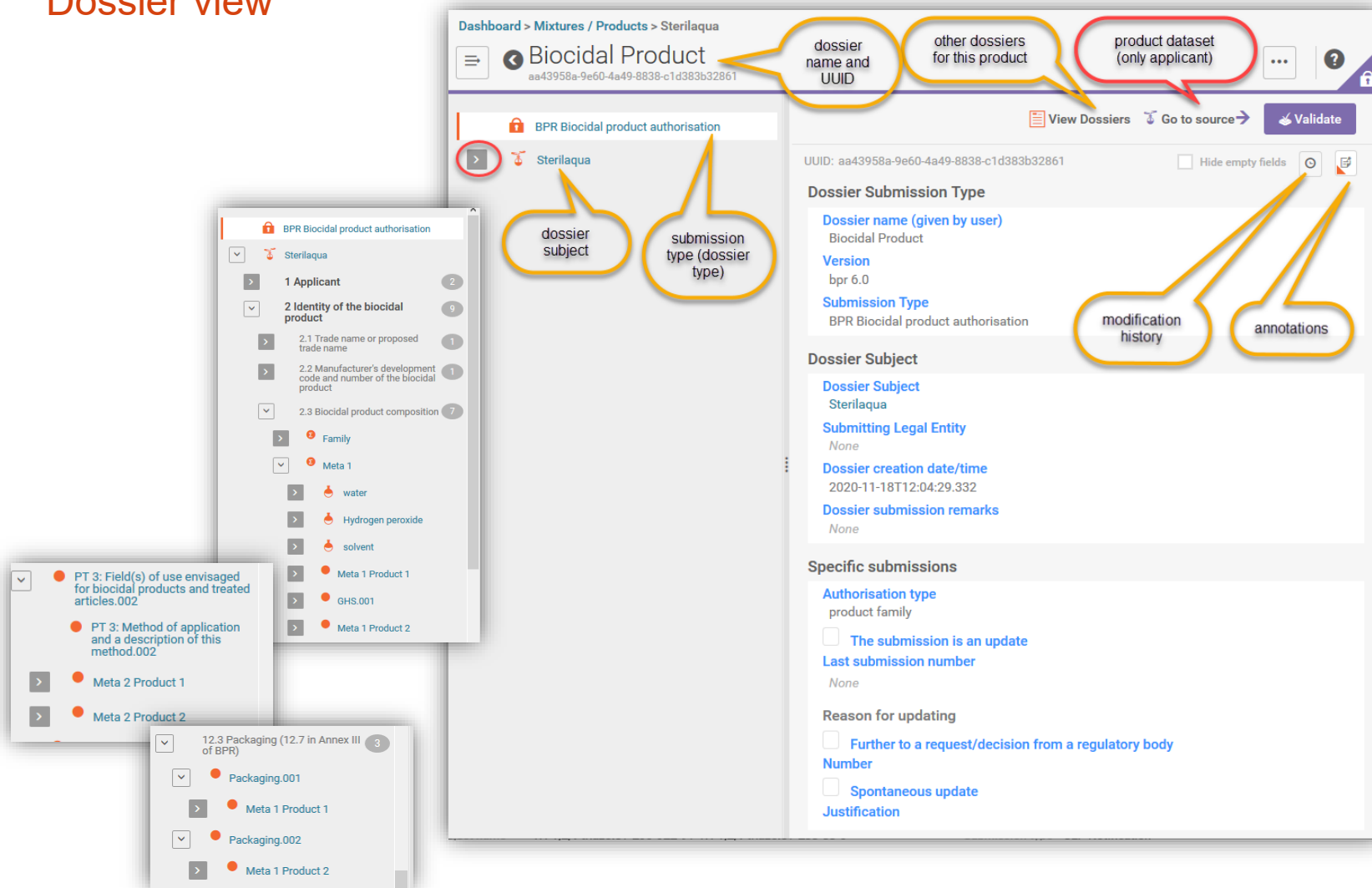
▼ Modification date 0

From (dd/mm/yyyy)

To (dd/mm/yyyy)

# Navigation through the BPR dossier

## Dossier view



The screenshot displays the IUCLID 6 interface for a BPR dossier. The main view shows the 'Biocidal Product' details for 'Sterilaqua' (UID: aa43958a-9e60-4a49-8838-c1d383b32861). Callouts highlight key elements: 'dossier name and UID', 'other dossiers for this product', 'product dataset (only applicant)', 'dossier subject', and 'submission type (dossier type)'. The right panel shows 'Dossier Submission Type' (Biocidal Product, Version bpr 6.0) and 'Dossier Subject' (Sterilaqua). The 'Specific submissions' section includes 'Authorisation type' (product family) and 'Reason for updating' (Further to a request/decision from a regulatory body, Spontaneous update). Callouts also point to 'modification history' and 'annotations' icons. Three expanded sections on the left show the 'BPR Biocidal product authorisation' tree, including '1 Applicant', '2 Identity of the biocidal product' (with sub-sections for Trade name, Development code, and Composition), and '12.3 Packaging (12.7 in Annex III of BPR)'.

# Preparing a dossier for 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

## Simplified table of contents

Working context: BPR Technical Equivalence

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

Working context:

BPR Technical Equivalence

BPR Active substance information

Summary and evaluation.001 i o l

UUID: d7791194-137d-4cec-9971-d60fe8cd55d3

Administrative data None None

Reports and administrative information

Summary and evaluation

+ New item

#	Type of report	Attached docu...	Remarks	Action
---	----------------	------------------	---------	--------

Discussion

None

Active substance related information

The substance is a candidate for substitution  
None

The substance has endocrine-disrupting properties  
None

Active substance related information

Identification of any substances meeting the requirements listed in point 11.10 of Annex II to BPR

The source of substance is the same as was evaluated for inclusion in the Union list of approved active substances

The source of substance is considered equivalent to the Union list of approved active substances source.

If yes , technical equivalence decision number  
None

The substance is a candidate for substitution  
None

The substance has endocrine-disrupting properties  
None

Biocidal product related information

Indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC

Other information relevant for the Summary of the biocidal Product Characteristics  
None

Biocidal product related information + New item

#	Authorisation number	Remarks	Action
---	----------------------	---------	--------

# Dossier for a Technical Equivalence



## Dossier header and dossier creation

Dashboard > Substances > test substance for technical equiva...

test substance for technical equivalence  
f63202ca-1a7c-4352-b615-779cef074e22

Working context: BPR Technical Equivalence

View Dossiers Validate Create dossier

BPR Technical Equivalence

test substance for technical equivalence

1 Applicant 2

1.1 (Cf. 2.1) Name and address

1.2 (Cf. 2.1) Contact person

1.3 Active substance manufacturer 2 +

Active substance manufacturer.001

UUID: d8fd5dbf-66f0-43d1-9306-b2638788296e

Dossier name (given by user)  
None

Dossier submission remark  
None

Specific submissions

The submission is an update

Dashboard > Substances > test substance for technical equiva...

test substance for technical equivalence  
f63202ca-1a7c-4352-b615-779cef074e22

Working context: BPR Technical Equivalence

View Dossiers Validate Create dossier

## 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 most relevant to biocides

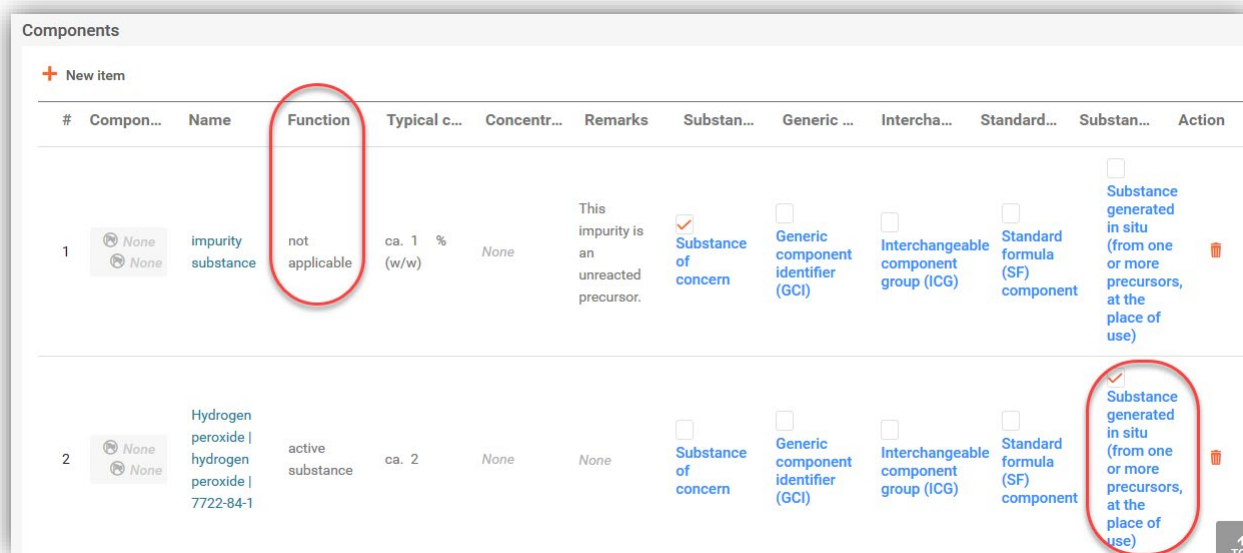
- Links between documents slightly modified to ensure compatibility between IUCLID and SPC Editor
- Several OHTs updated, for example 50-2, 88, 89
- Guidelines added in several documents, including those for microorganisms
- Reference section 8.13.1 (*Cf. 8.13.6 Phototoxicity*) replaced by the section 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 most relevant to biocides (mixture composition)

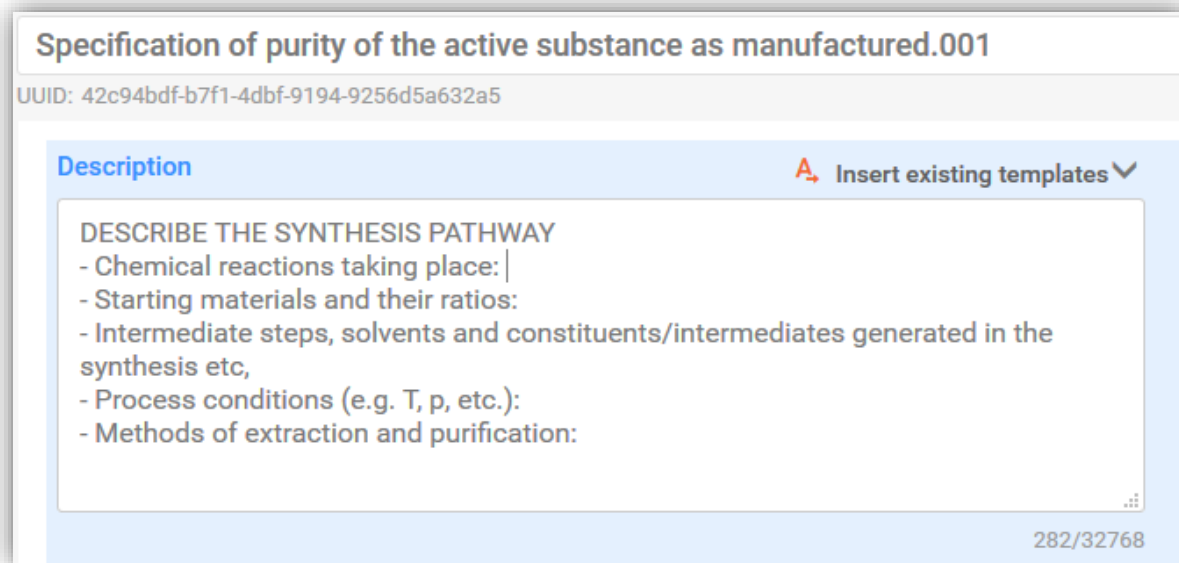
- Blocks *Impurities* and *Additives* removed from a mixture composition and migrated to *Components*
- *Function* picklist updated with phrases: *precursor* and *not applicable*
- Check box in the *Components* reflecting that an active substance has been generated *in situ*



#	Compon...	Name	Function	Typical c...	Concentr...	Remarks	Substan...	Generic ...	Intercha...	Standard...	Substan...	Action
1	<input type="radio"/> None <input type="radio"/> None	impurity substance	not applicable	ca. 1 % (w/w)	None	This impurity is an unreacted precursor.	<input checked="" type="checkbox"/> Substance of concern	<input type="checkbox"/> Generic component identifier (GCI)	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Standard formula (SF) component	<input type="checkbox"/> Substance generated in situ (from one or more precursors, at the place of use)	
2	<input type="radio"/> None <input type="radio"/> None	Hydrogen peroxide   hydrogen peroxide   7722-84-1	active substance	ca. 2	None	None	<input type="checkbox"/> Substance of concern	<input type="checkbox"/> Generic component identifier (GCI)	<input type="checkbox"/> Interchangeable component group (ICG)	<input type="checkbox"/> Standard formula (SF) component	<input checked="" type="checkbox"/> Substance generated in situ (from one or more precursors, at the place of use)	

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

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



Specification of purity of the active substance as manufactured.001

UUID: 42c94bdf-b7f1-4dbf-9194-9256d5a632a5

**Description** A. Insert existing templates ▾

DESCRIBE THE SYNTHESIS PATHWAY

- Chemical reactions taking place: |
- Starting materials and their ratios:
- Intermediate steps, solvents and constituents/intermediates generated in the synthesis etc,
- Process conditions (e.g. T, p, etc.):
- Methods of extraction and purification:

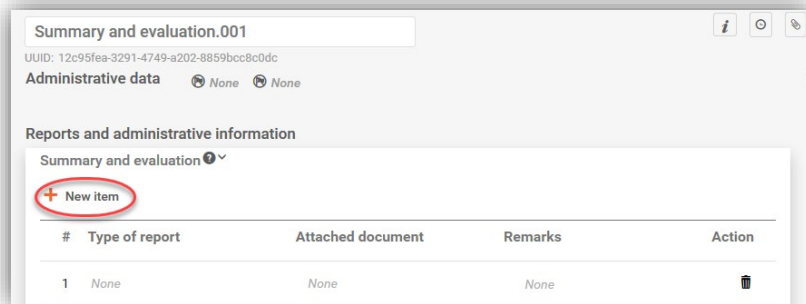
282/32768

# Annotations, attachments and print



# Attachments to the predefined fields

## Dataset

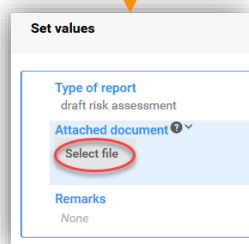


Summary and evaluation.001  
UUID: 12c95fea-3291-4749-a202-8859bcc8c0dc  
Administrative data None None

Reports and administrative information  
Summary and evaluation

**New item**

#	Type of report	Attached document	Remarks	Action
1	None	None	None	

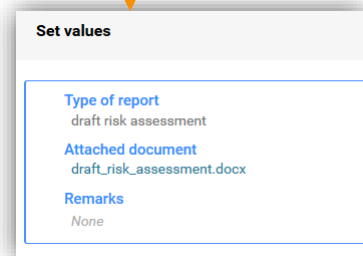


**Set values**

Type of report  
draft risk assessment

Attached document  
**Select file**

Remarks  
None



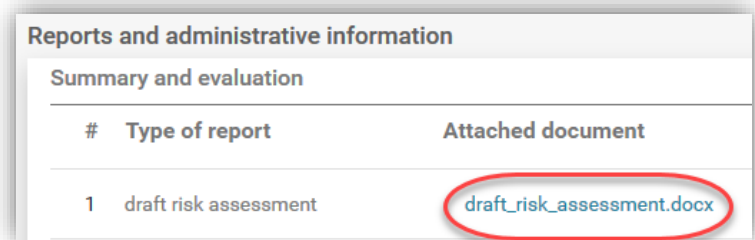
**Set values**

Type of report  
draft risk assessment

Attached document  
draft\_risk\_assessment.docx

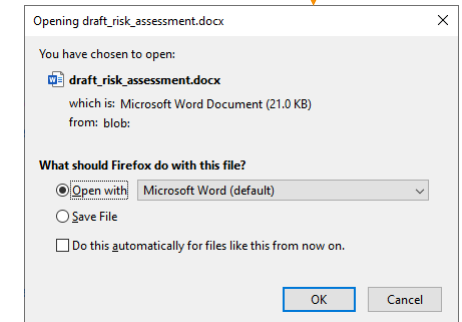
Remarks  
None

## Dossier



Reports and administrative information  
Summary and evaluation

#	Type of report	Attached document
1	draft risk assessment	<b>draft_risk_assessment.docx</b>



Opening draft\_risk\_assessment.docx

You have chosen to open:  
draft\_risk\_assessment.docx  
which is: Microsoft Word Document (21.0 KB)  
from: blob:

What should Firefox do with this file?

Open with Microsoft Word (default)

Save File

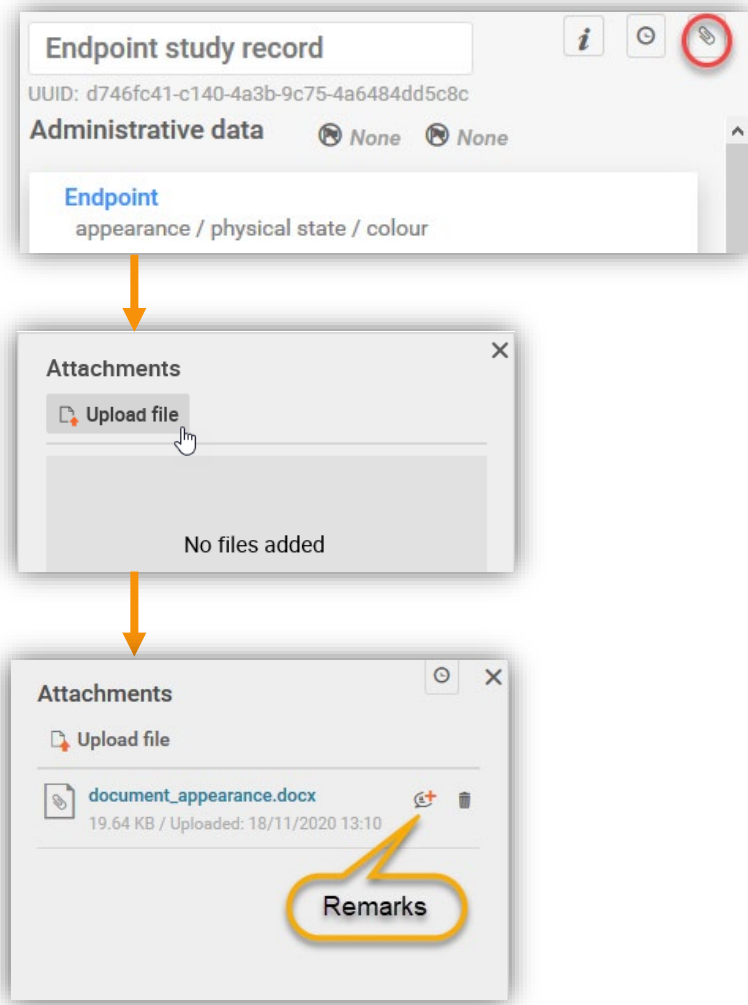
Do this automatically for files like this from now on.

OK Cancel

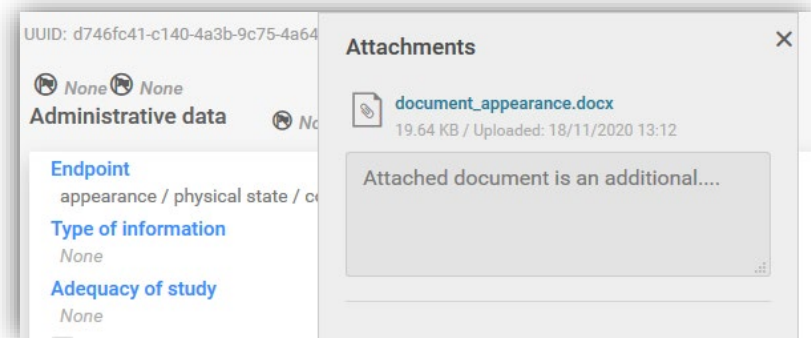
# Attachments to the whole record / endpoint



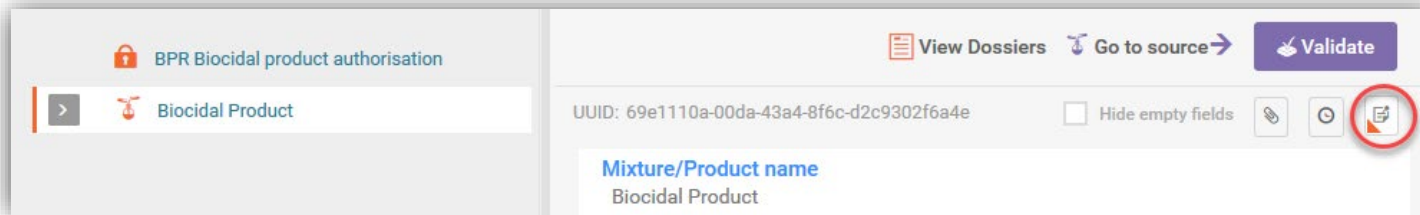
## Dataset



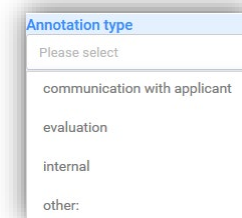
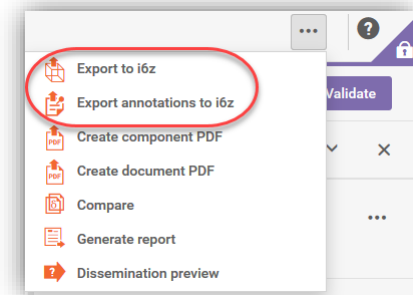
## Dossier



# Annotations (Competent Authorities)



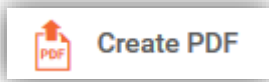
- Competent Authorities can create annotations on the whole dossier and on the specific documents; an annotation relevant to a whole dossier will be displayed in the section 2.1
- Competent Authorities can export annotations:
  - ✓ as a zip file containing annotations – to be later imported to a database containing 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





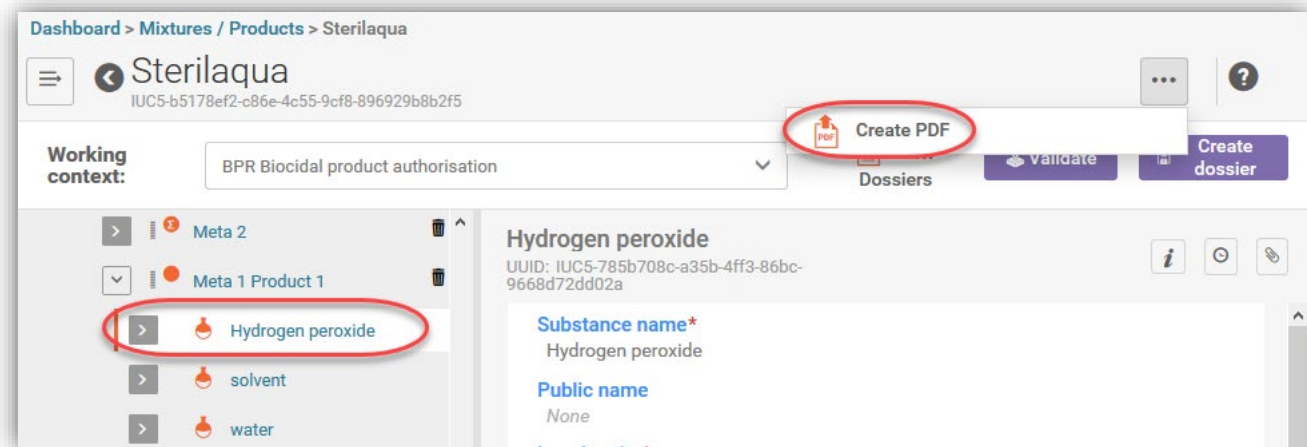
- Annotations received from the Competent Authority can be imported to the original dossier
- Orphan annotations are not displayed – technically, an annotation can be imported, but if there is no original dossier, will not be displayed
- The whole dossier can be imported together with the annotations, 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 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

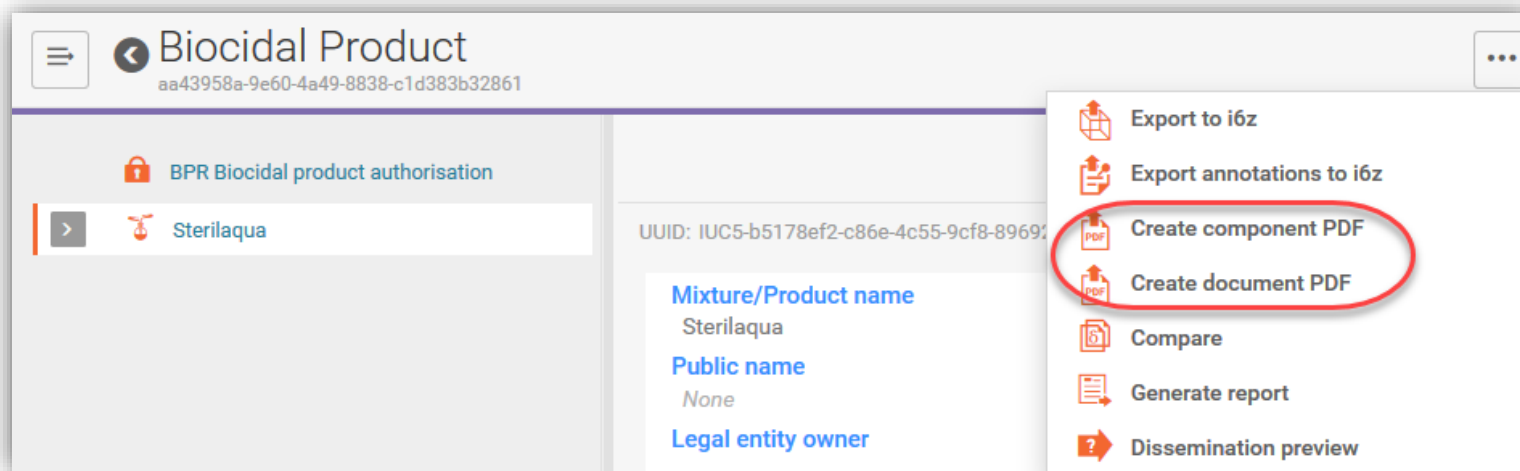


The screenshot shows the IUCLID 6.5 interface for the 'Sterilaqua' dataset. The breadcrumb trail is 'Dashboard > Mixtures / Products > Sterilaqua'. The main title is 'Sterilaqua' with the UUID 'IUC5-b5178ef2-c86e-4c55-9cf8-896929b8b2f5'. The 'Working context' is 'BPR Biocidal product authorisation'. A 'Create PDF' button is circled in red. Below the context, there is a table of contents with entries: 'Meta 2', 'Meta 1 Product 1', 'Hydrogen peroxide', 'solvent', and 'water'. The 'Hydrogen peroxide' entry is circled in red. The right panel shows details for 'Hydrogen peroxide' with UUID 'IUC5-785b708c-a35b-4ff3-86bc-9668d72dd02a'. The 'Substance name\*' is 'Hydrogen peroxide' and the 'Public name' is 'None'.

## Print of a dossier

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

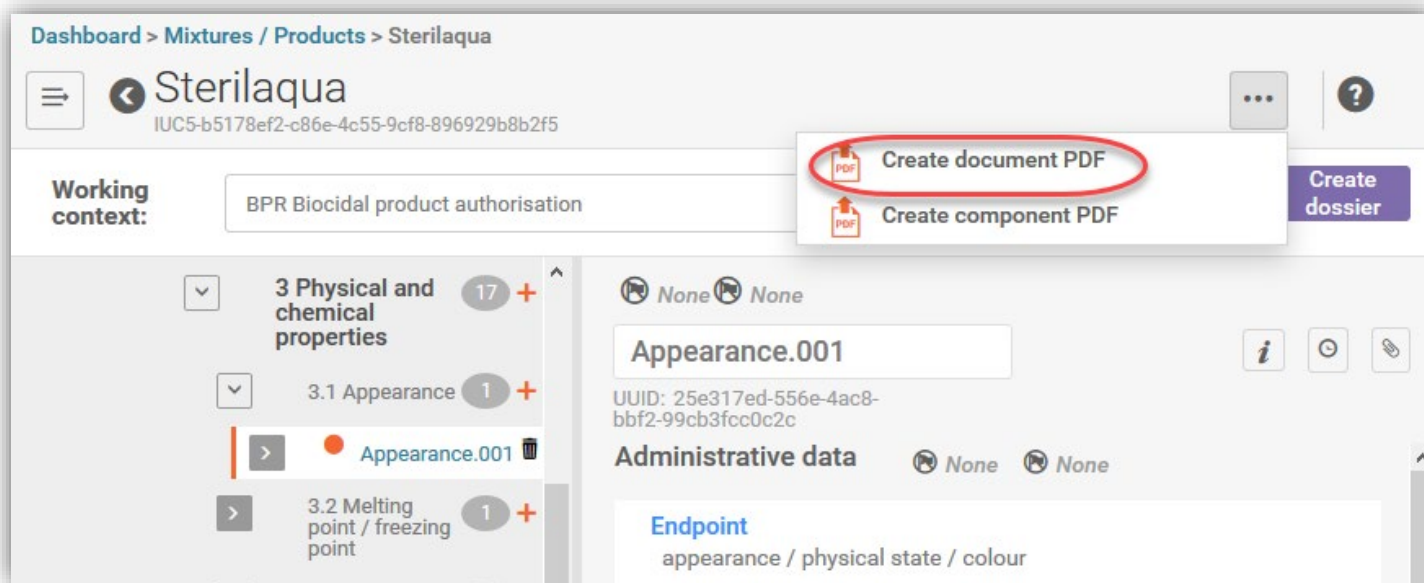
*Create component PDF* - is expected to print the main entity to which this document belongs, in this case a product dataset and documents (an active substance will be listed as a reference)



The screenshot displays the IUCLID 6 interface for a Biocidal Product dossier. The main header shows 'Biocidal Product' with a UUID: aa43958a-9e60-4a49-8838-c1d383b32861. The left sidebar contains a breadcrumb trail: 'BPR Biocidal product authorisation' > 'Sterilaqua'. The main content area shows the product details for 'Sterilaqua' with a UUID: IUC5-b5178ef2-c86e-4c55-9cf8-89692. A context menu is open over the product details, listing several actions: 'Export to i6z', 'Export annotations to i6z', 'Create component PDF', 'Create document PDF', 'Compare', 'Generate report', and 'Dissemination preview'. The 'Create component PDF' and 'Create document PDF' options are circled in red.

## Print of a document

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



The screenshot shows the IUCLID 6 interface for a document titled 'Sterilaqua'. The breadcrumb trail is 'Dashboard > Mixtures / Products > Sterilaqua'. The document ID is 'IUC5-b5178ef2-c86e-4c55-9cf8-896929b8b2f5'. The working context is 'BPR Biocidal product authorisation'. A dropdown menu is open, showing two options: 'Create document PDF' (highlighted with a red circle) and 'Create component PDF'. The main content area shows a tree view on the left with '3 Physical and chemical properties' (17 items) and '3.1 Appearance' (1 item). The 'Appearance.001' item is selected, showing its details: 'Appearance.001', UUID: 25e317ed-556e-4ac8-bbf2-99cb3fcc0c2c, and 'Administrative data' (None). The 'Endpoint' is 'appearance / physical state / colour'.

# Report Generator

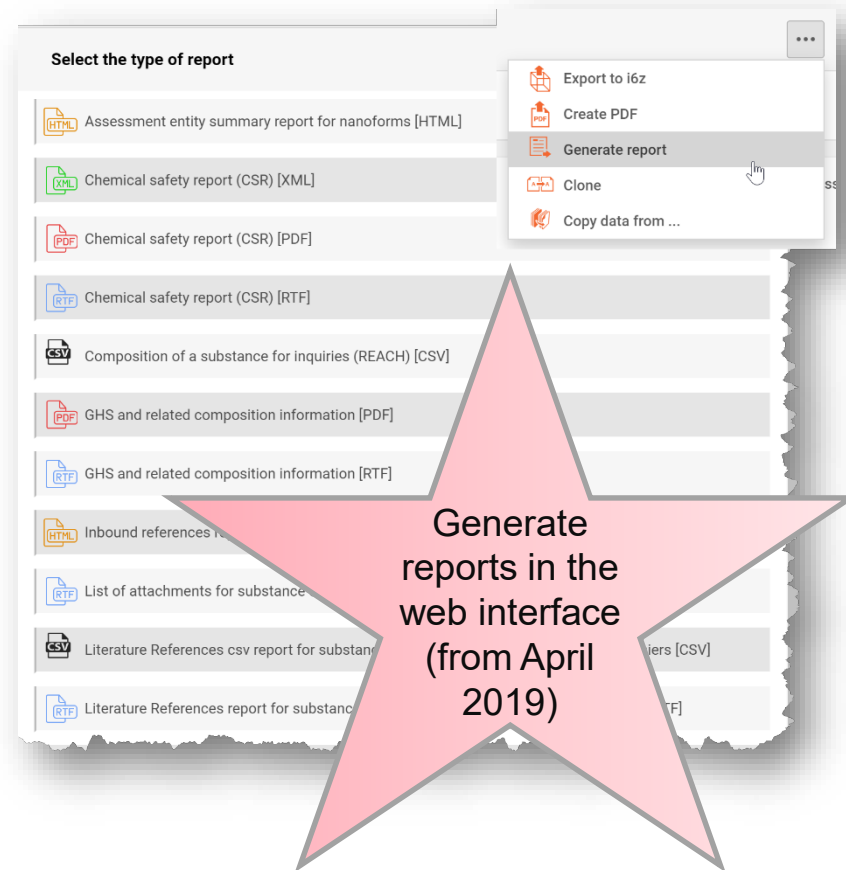


# Report Generator



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)



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	Section No. 3.3 Section Name: Density Name given to the Document: Density.001	Relative density (liquids) and bulk, tap density (solids)	0cb311e8-1471-4f97-96a3-4d66b9aacd16
Attachment name: attached_background_material_doc.docx	Attachment remarks:	Remarks for the attachment: remarks on background material doc	Attachment size: 33,269
Biocidal Product	Section No. 3.3 Section Name: Density Name given to the Document: Density.001	Relative density (liquids) and bulk, tap density (solids)	0cb311e8-1471-4f97-96a3-4d66b9aacd16
Attachment name: attached_justification_doc.docx	Attachment remarks:		



The screenshot shows XML code for an SPC template. A red arrow points from the code to a software interface titled "SPC Editor". The code includes namespace declarations and a representation element. The interface shows a menu with "New", "Open", and "Save" options.

## 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	<b>Annex II/III requirement:</b> No Annex II requirement  <b>IUCLID Section No.</b> OECD numbering (2)	IUCLID Document name: <a href="#">Melting point / freezing point.001</a>	Title: Study for melting point  Report no. 213-324	Type of publication: study report	Source: Journal of biocidal science  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

The screenshot shows the 'Creating your own reports' page in the IUCLID Report Manager. The main heading is 'Modular approach to reporting'. Below this, there is a section titled 'Modular approach to reporting' which contains text explaining that IUCLID 6.5 comes with a set of modules that can be re-used to generate reports. It mentions that these modules cover classification and labelling information, physical-chemical summaries, and composition. A video link is provided for more information. Below the text, there is a list of available modules: IUCLID format, Planned releases, Template manager (ITEM), Data validation, Report generator, Data filtering, and REST Public API. The page also includes a 'Table of Contents' section with two options: 'From a mixture' and 'From a substance'.

<https://iuclid6.echa.europa.eu/reports>



# Plans for 2021

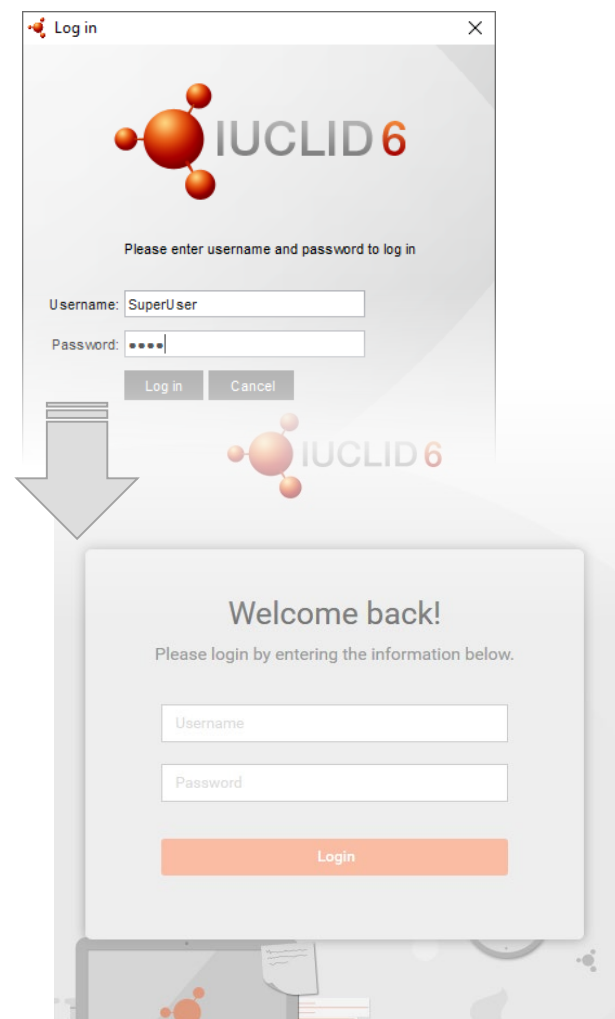


# Plans 2021 (web interface)



## 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



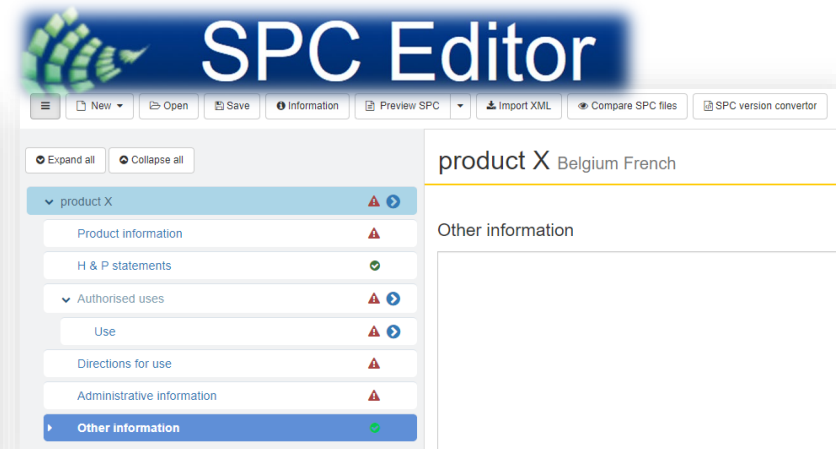
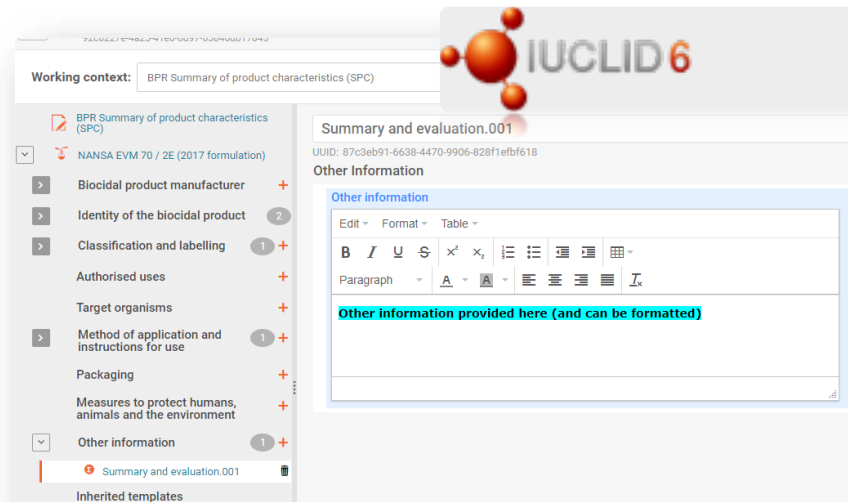
# Plans 2021 (Summary of Product Characteristics)



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



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

Benefits

## 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)

Re-use of existing rules

## 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

Use of Validation rules under review



*Thank you for your participation*

[echa.eu](http://echa.eu)

[iuclid6.echa.europa.eu](http://iuclid6.echa.europa.eu)

[oecd.org/ehs/templates](http://oecd.org/ehs/templates)



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