

# IUCLID 6

## Biocides Stakeholders' Day

27 September 2017

Dorota Burchard-Sosnowska  
IUCLID Team  
European Chemicals Agency



# Agenda

- Introduction
- IUCLID installation
  - IUCLID updater
- BPR dossiers
- Report generator
- Where to find further information
- **Hands-on training**

# Introduction



## Biocides IT tools



To manage your data and prepare dossiers

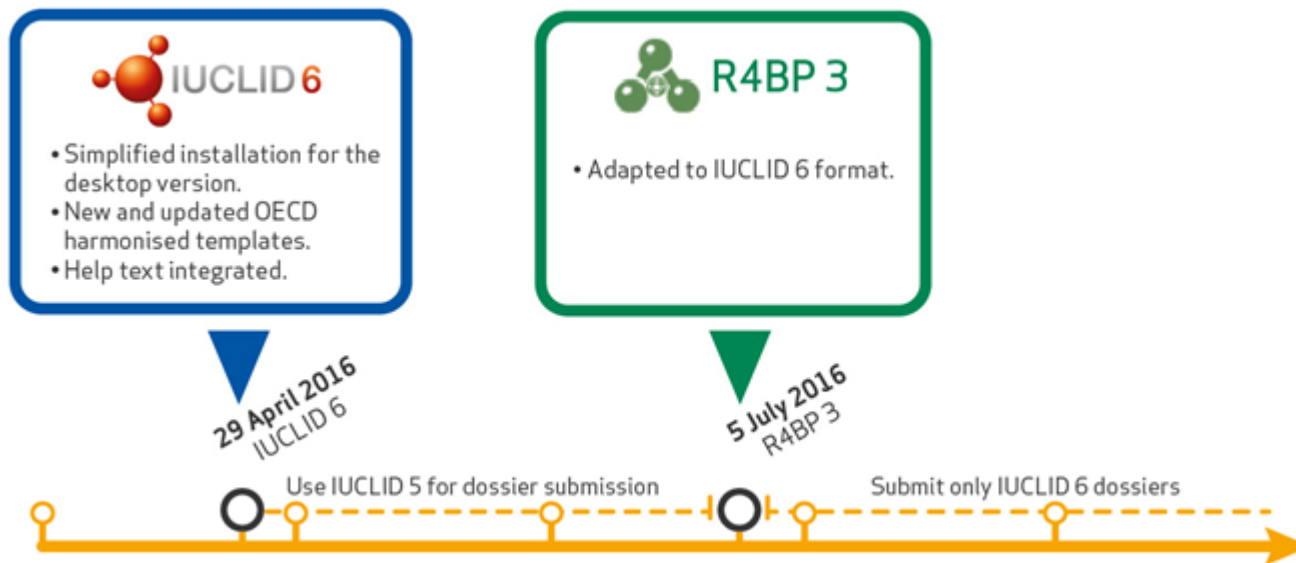


To create and edit your SPC



To submit and manage your dossiers

# IUCLID 6 and R4BP3





Sign In

Search the IUCLID 6 website

Home

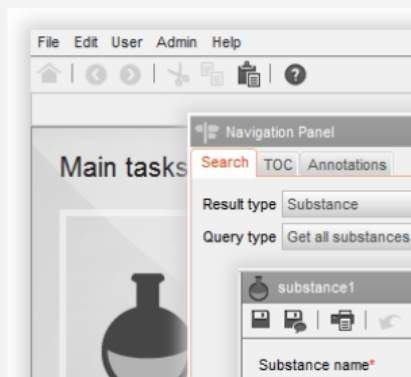
IUCLID Product

Download Software

Support

News

IUCLID > Home



Download

**IUCLID 6 plays a central role in the IT environments of all organisations that manage scientific data on chemicals in a regulatory context, for example under the OECD HPV, EU Biocides and EU REACH.**

- Industry stakeholders
- EU Member States
- The European Chemicals Agency (ECHA)
- And any other interested parties

01 August 2017

### Use of IUCLID under EU REACH - Cloud services launched

The cloud version of the chemical data management tool IUCLID is now available for smaller companies and their consultants preparing REACH registration dossiers.

28 April 2017

### IUCLID 6 version 1.3.0 is available

A new service release for IUCLID is available. It brings improvements and bug fixes, but also three new features: a PNEC calculator, re-use of the dossier header and the Report manager.

24 March 2017

### IUCLID 5 website closure

The IUCLID 5 website will be shut down permanently from 30th of March 2017 onwards. The relevant content has been transferred to the IUCLID 6 website. Before the closure, IUCLID 5 website users are invited to download any additional information they may need.

22 March 2017

### REACH study results are published

REACH study results is a collection of non-confidential substance data that was submitted to ECHA under the REACH regulation. It is now available for download free of charge from this website.

27 February 2017

### IUCLID 6 Desktop available for Mac

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

## News



[IUCLID](#) > [News](#)

### News

#### 01/08/2017 - Use of IUCLID under EU REACH - Cloud services launched

The cloud version of the chemical data management tool IUCLID is now available for smaller registration dossiers.

#### 28/04/2017 - IUCLID 6 version 1.3.0 is available

A new service release for IUCLID is available. It brings improvements and bug fixes, but also a dossier header and the Report manager.

#### 24/03/2017 - IUCLID 5 website closure

The IUCLID 5 website will be shut down permanently from 30th of March 2017 onwards. The website. Before the closure, IUCLID 5 website users are invited to download any additional

#### 22/03/2017 - REACH study results are published

REACH study results is a collection of non-confidential substance data that was submitted to the Agency. The data is available for download free of charge from this website.

#### 27/02/2017 - IUCLID 6 Desktop available for Mac OS X

#### 31/01/2017 - IUCLID 6 version 1.2.0 is available

A new service release for IUCLID is available. It brings improvements, bug fixes but also the new public API

## My account

Organization Name \*

ECHA

Organization Type

European Chemicals Agency



### Subscriptions

iuclid-news-general

iuclid-news-technical

# Planned releases

- Information on the planned IUCLID 6 releases can be found on the IUCLID 6 website
- <https://iuclid6.echa.europa.eu/project-iuclid-6#ServiceRelease>



IUCLID > IUCLID Product

## IUCLID Product

### IUCLID 6 maintenance and service releases

After the release of IUCLID 6 to the public, service and maintenance releases are prepared in order to fix re and new features requested by the users. In order to provide IUCLID users a predictable release plan, it w year, one (minor) release in Spring and one (major) release, including format changes, in Autumn.

Under this section the current planning and scope for the future releases are made available for informatio 19<sup>th</sup> July 2017).

- Mid-November 2017 (version 2.0.0), including format changes
- Spring 2018, minor release
- Autumn 2018, major release, including format changes
- Other user requirements currently not prioritised
  - LDAP connectivity
  - Spell checker
  - Attachments versioning
  - Announcements for IUCLID system administrators
  - Link to email server (e.g. for resetting passwords)

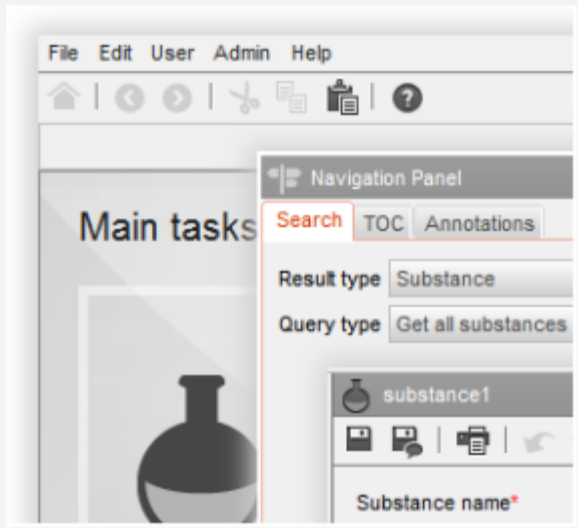



# IUCLID installation



# IUCLID 6 desktop version

- Installer contains all the elements needed to run IUCLID
- Installation in a few clicks
- Migration of your IUCLID 5 data
- Desktop version + one user  
= you don't need to log in





IUCLID 6 plays a central role in the IT environments of all organisations that manage scientific data on chemicals in a regulatory context, for example under the OECD HPV, EU Biocides and EU REACH.

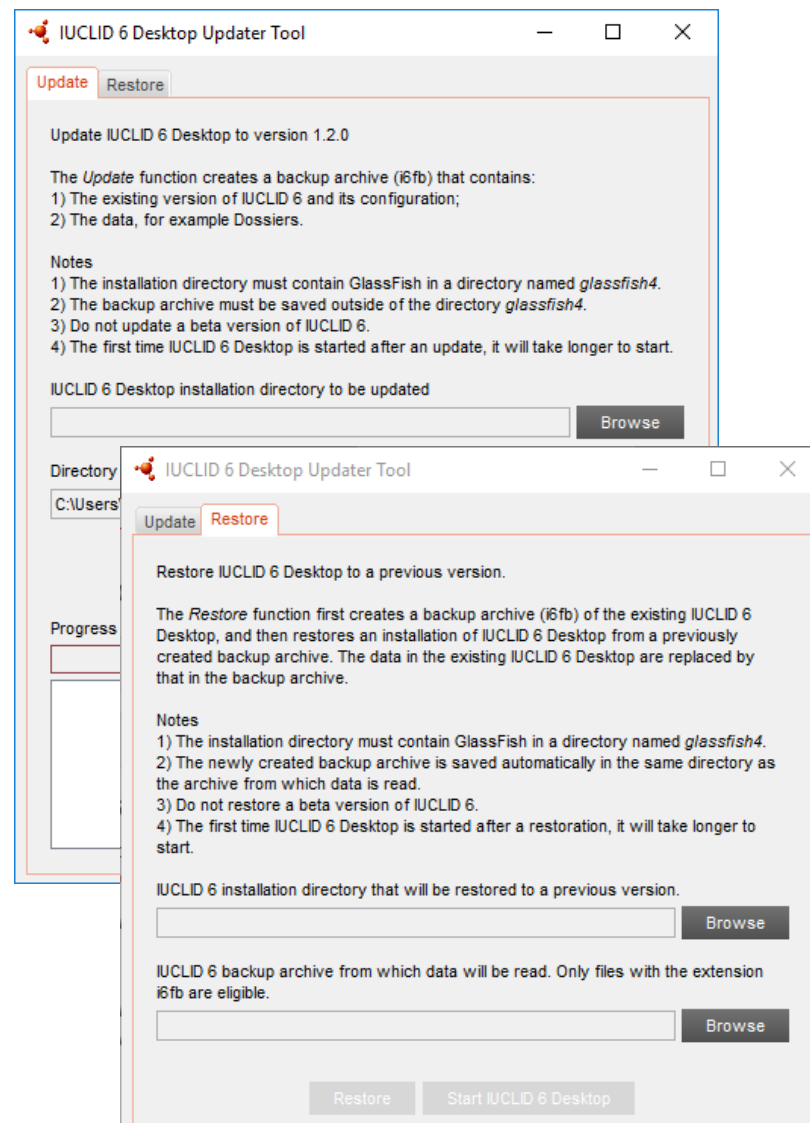
*Video tutorials available:*

<https://www.youtube.com/playlist?list=PLOGDACSD6qyDkdXwPua1Fjb5bJksY75k>

# IUCLID 6 updater

If you already have IUCLID 6 you can update to the latest available version

- *Update* function
- *Restore* function



Video tutorials available:

<https://www.youtube.com/playlist?list=PLOPGDACsD6qyDkdXwPua1Fjb5bJksY75k>

**BPR dossiers**



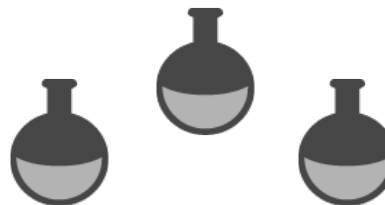
## Starting point for each submission type

**Representative  
biocidal product:**

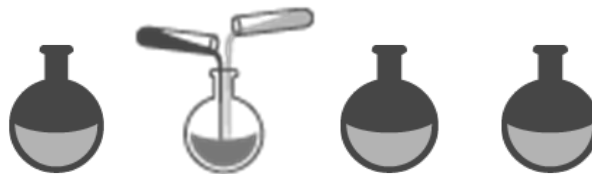


**one** active substance

**Biocidal product  
to be authorised:**



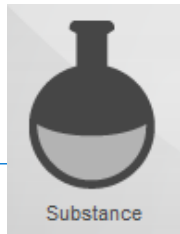
**one or more**  
active substances



other substances and mixtures


# Preparing a substance dataset (BP component)

- BPR Active substance information
- BPR Substance of concern
- BPR Basic information (substance)



Pick list  
Select a value

Substance



▼

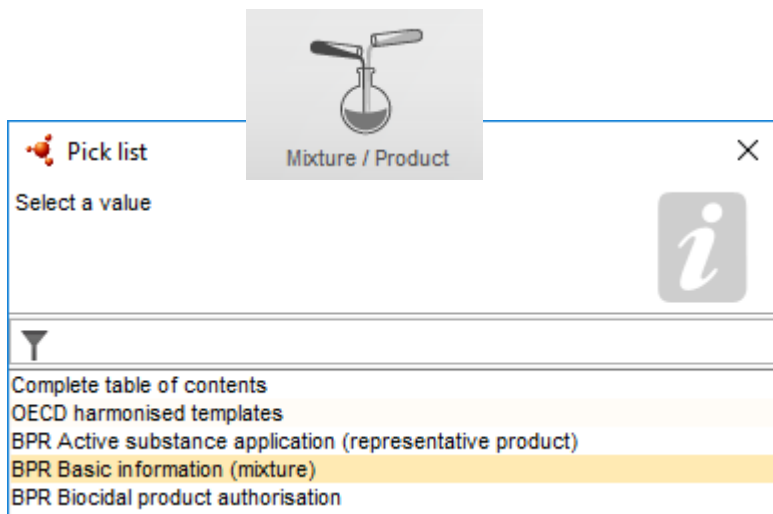
BPR Active substance information  
BPR Basic information (substance)  
BPR Substance of concern  
CLP alternative name request  
CLP notification  
CLP Regulation - CLH dossier  
REACH Annex XV - Restriction  
REACH Annex XV - SVHC  
REACH Application for authorisation

OK Cancel

- 2.9 Composition of the substance
  - Specification on purity of the active substance as manufactured
  - Composition of the substance of concern
  - Composition of the substance

# Preparing a mixture / product dataset (BP component)

- BPR Basic information (mixture)



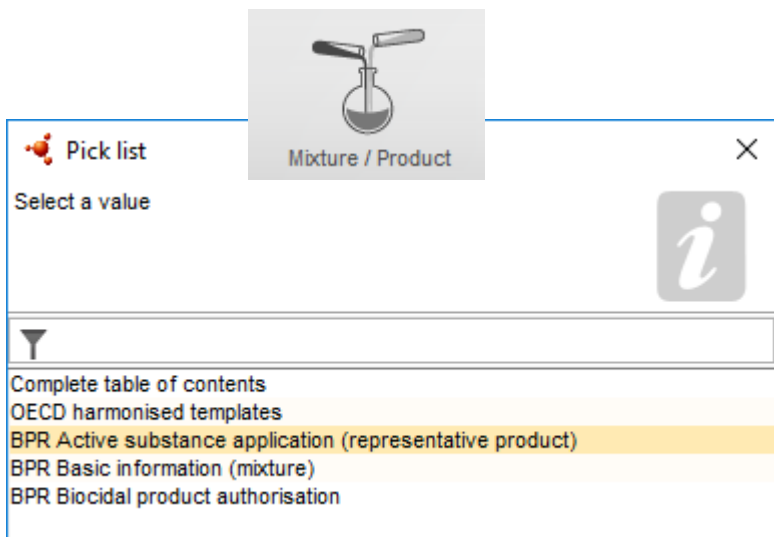
The screenshot shows a 'Pick list' dialog box with a close button (X) in the top right corner. The title bar reads 'Mixture / Product'. Below the title bar, there is a search field with the text 'Select a value' and an information icon (i). A dropdown arrow is visible on the left side of the search field. Below the search field, a list of options is displayed:

- Complete table of contents
- OECD harmonised templates
- BPR Active substance application (representative product)
- BPR Basic information (mixture)**
- BPR Biocidal product authorisation

- 2.3 Composition of the mixtures
  - Mixture composition

# Preparing a biocidal product dataset

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



- 2.3 Composition of the mixtures
  - Biocidal product composition
  - Representative biocidal product composition



# Dossier creation

Navigation panel

Search

Result type: Mixture/Product

Query type: Get all mixtures/products

Clear Search

Filter

Mixture/Product	Legal entity name	Last modification date
X Biocidal Product	BP manufacturer	2013-08-07T15:41:46.00...

- Open
- Create Dossier...
- Print...
- Generate report...
- Export...
- Delete

Dossier creation wizard

Select submission type: Select a submission type, which meets your specific requirements: regulatory programme, type of dossier, tonnage band, member of a joint submission, etc.

The dossier/export template is used to determine which substance or mixture/product documents will be selected by default. The selection can be modified manually in a subsequent step of the dossier creation/export process.

Note that all referenced documents will be automatically detached.

Mixture/Product

Select submission type for a Mixture/Product

CORE

Complete table of contents

OECD

OECD harmonised templates

EU\_BPR

BPR Active substance application (representative product)


BPR Biocidal product authorisation


Use advanced settings

Select submission type

Back Next Finish Cancel

# Dossier update

 Dossier creation wizard ✕

Administrative information: Enter additional information concerning your dossier  
Submission type : BPR Biocidal product authorisation 

Dossier name (given by user)

Dossier submission remark

**Specific submissions**

The submission is an update

Last submission number

**Reason for updating**

Further to a request/decision from a regulatory body

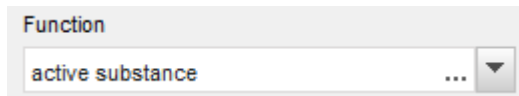
Spontaneous update

? Administrative information Back Next Finish Cancel

## Worth to remember (1)

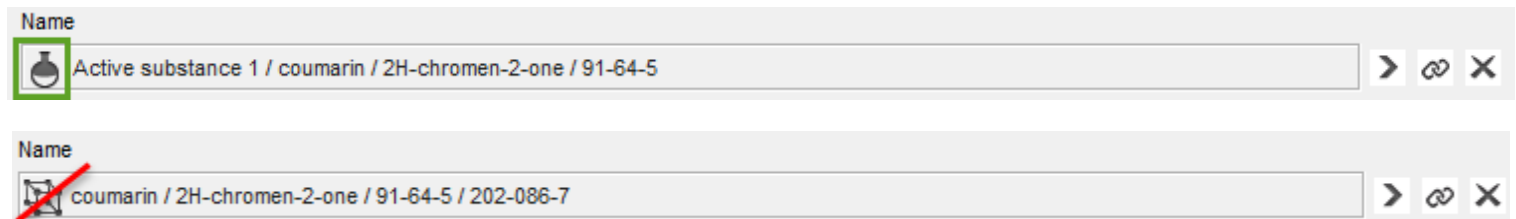
BPR Active substance application (representative product)

- Only one active substance allowed
- Function 'active substance' indicated



Function  
active substance ...

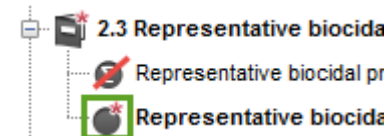
- Substance linked (not a reference substance)



Name  
Active substance 1 / coumarin / 2H-chromen-2-one / 91-64-5

Name  
~~coumarin / 2H-chromen-2-one / 91-64-5 / 202-086-7~~

- Only record allowed



## Worth to remember (2)

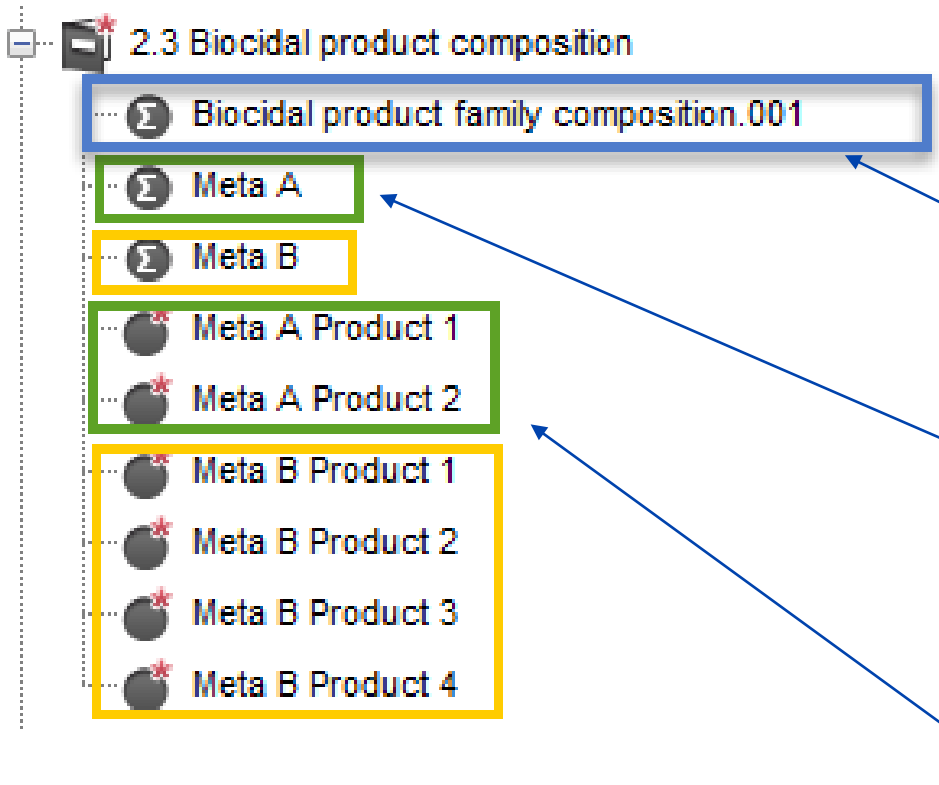
2.3 Biocidal product composition

- Biocidal product family composition.001
  - Meta A
    - Meta A Product 1
    - Meta A Product 2
  - Meta B
    - Meta B Product 1
    - Meta B Product 2
    - Meta B Product 3
    - Meta B Product 4

•Biocidal product family  
Concentration %  
>= 0.5 <= 1.5

•Meta  
Concentration %  
>= 0.8 <= 1.0

•Biocidal product (family member)  
Typical concentration  
ca. 1.0 % (w/w)



- Intended uses specified in section 7.1
- Classification & Labelling specified in section 12.1, 12.2
- Packaging specified in section 12.3


linked to a single product

# Worth to remember (3)

## Risk assessment report

- 13 Summary and evaluation
- Summary and evaluation


**Administrative data** ^



**Reports and administrative information / Reports and administrative information** ^

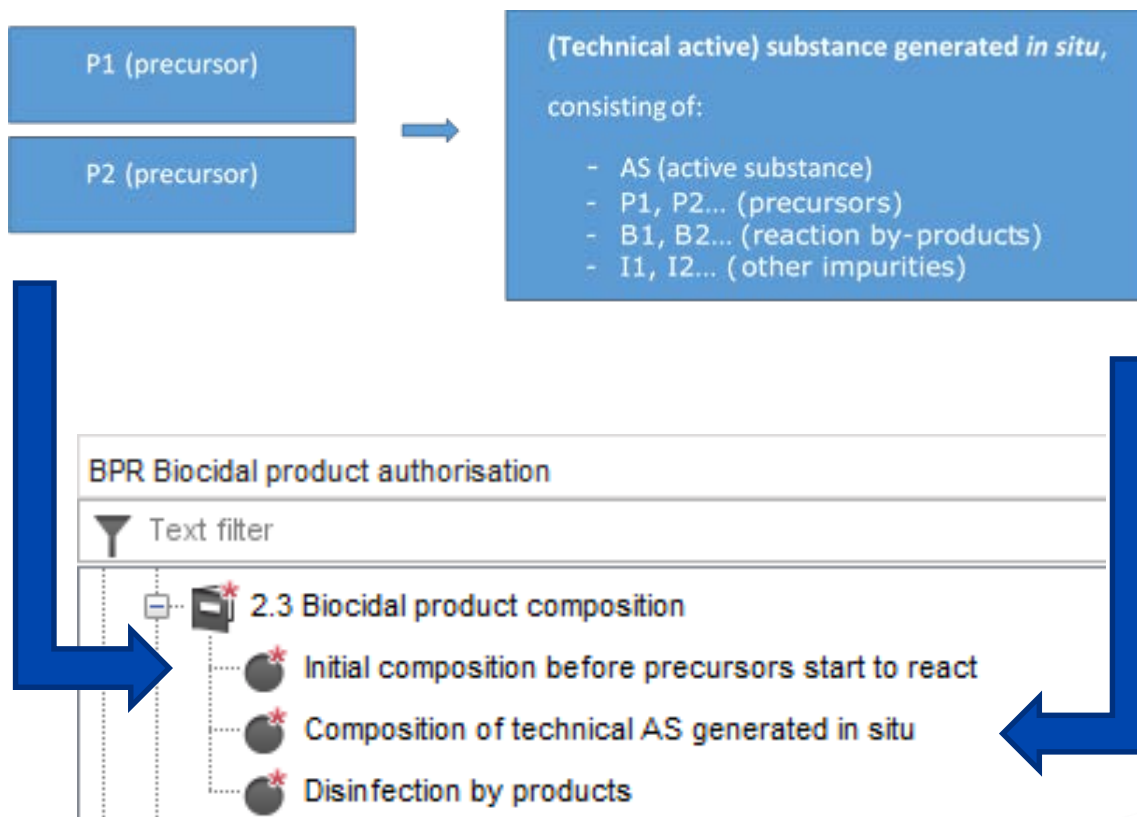
**Summary and evaluation** ^

Type of report	Attached document	Remarks
draft risk assessment	Draft_Risk_Assessment.doc / 21.5 KB / application/msword	

+ Add  Edit... Delete

section 13

# *In situ* generated active substance



**NEW Annex 2 to BSM  
coming soon**

# *In situ* generated active substance

- 2.3 Biocidal product composition
  - Initial composition before precursors start to react
  - Composition of technical AS generated in situ**
  - Disinfection by products

**Components** ^

Peracetic acid / peracetic acid / 79-21-0, ca. 20.0 % (w/w)

Component flag

Name  
Peracetic acid / peracetic acid / 79-21-0

Function  
active substance ... Other

Typical concentration  
ca. 20.0 % (w/w) ...

Concentration range

Remarks  
Pure active substance of the in situ generated substance. The details of the process in the description of the composition in section 2.9 of the active substance dataset

**NEW Annex 2 to BSM  
coming soon**

# Filtering the content of a dossier















The screenshot shows the 'Navigation panel' of the ECHA dossier system. The panel is titled 'BPR Biocidal product authorisation'. It has four tabs: 'Search', 'Components', 'Annotations', and 'TOC'. The 'TOC' tab is currently selected. Below the tabs, there is a search input field with a magnifying glass icon and the text 'uses' entered. The search results are displayed as a tree structure:

- 7 Intended uses and exposure
  - 7.10 (Cf. 7.1) Exposure data in conformity with Annex VI to this Regulation
    - 7.10.1 (Cf. 7.1) Information on human exposure associated with production and formulation, proposed / expected
    - 7.10.2 (Cf. 13) Information on environmental exposure associated with production and formulation, proposed / expected



# Printing a dossier

Dossier Name	Subject Name	Creation date
 BIOC_BIOCIDAL_PRO / MIXTURE : X Biocida Product / 2016-09-14 / X Biocid Product	X Biocid	15:24:35.6...
 COMPLETE / SUBSTANCE : d / 2016-09-14	d	14:53:44.5...
 R_COMPLETE / SUBS 3,4-dihydroxyanthraq acid) / 1,2-dihydroxy 2016-06-08 / aggr_1	aggr_1	12:38:23.0...
 R_COMPLETE / SUBS 3,4-dihydroxyanthraq acid) / 1,2-dihydroxy 2016-06-08 / aggr_1	aggr_1	12:37:03.0...
 R_COMPLETE / SUBS 3,4-dihydroxyanthraq acid) / 1,2-dihydroxy 2016-06-08 / aggr_1	aggr_1	2016-09-14T12:35:47.0...

-  Open
-  Print...
-  Export...
-  Delete
-  Validate...
-  Dissemination preview...
-  Compare...




---

**Name:** BIOC\_BIOCIDAL\_PRODUCT / MIXTURE : X Biocidal Product Wed, 14 Sep 2016 15:24:35 +0300 / X Biocidal Product

---

**Legal entity owner:** DB\_Company

---

**Printing date:** 2016-09-15T08:45:49.707+03:00

## Table of Contents

X Biocidal Product .....	1
DB_Company .....	2
X Biocidal Product .....	2
2 Identity of the biocidal product .....	2
2.1 Trade name or proposed trade name .....	2
Trade name or proposed trade name .....	2
2.3 Biocidal product composition .....	3
Biocidal product composition.001 .....	3
4 Physical hazards and respective characteristics .....	4
4.1 Explosiveness .....	4
Explosiveness.001 .....	4
Explosiveness.001 .....	4
References .....	5
Active substance coumarin .....	5
Alizarin .....	5
triphenylene .....	6



BPR Biocidal product authorisation

Text filter

- 0 Related information
- 1 Applicant
- 2 Identity of the biocidal product
  - 2.1 Trade name or proposed trade name
  - 2.2 Manufacturer's development code and number of the biocidal product
  - 2.3 Biocidal product composition
    - Biocidal product composition.001
  - 2.4 (Cf. 2.3) Function and nature of the biocidal product
- 3 Physical, chemical and toxicological properties
- 4 Physical hazards and characteristics
- 5 Methods of detection and classification

Name: CORE / Composition / Biocidal product composition.001 / X Biocidal Product

Legal entity owner:

Printing date: 2016-09-15T08:48:10.510+03:00

## FLEXIBLE\_RECORD: Biocidal product composition.001

UUID: 28191910-c5ca-4a69-a0db-b0d563ea9c1e

Dossier UUID: 1ce4c29a-1c72-42bf-832d-6120e8bd79f9

Author: SuperUser

Date: 2016-09-14T15:24:35.708+03:00

Remarks:

### General information

Mixture/product name  
X Biocidal Product

Formulation type  
CB Bait concentrate

### Components

Name  
[Active substance coumarin / 2H-chromen-2-one / 91-64-5](#)

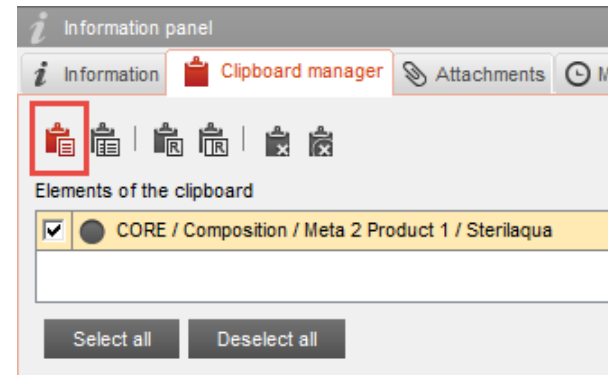
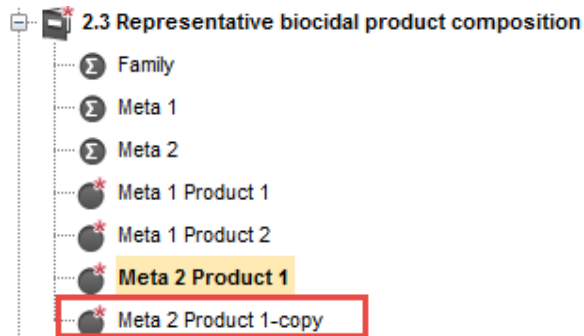
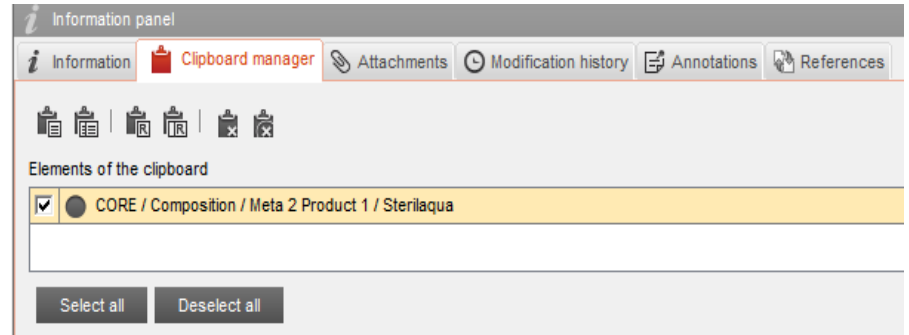
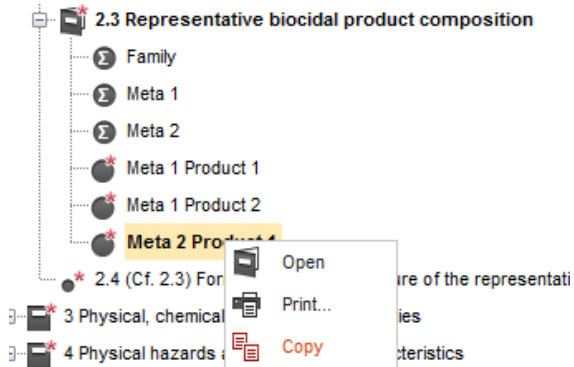
Function  
active substance

Typical concentration  
ca. 1.0 % (w/w)

Substance of concern  
false

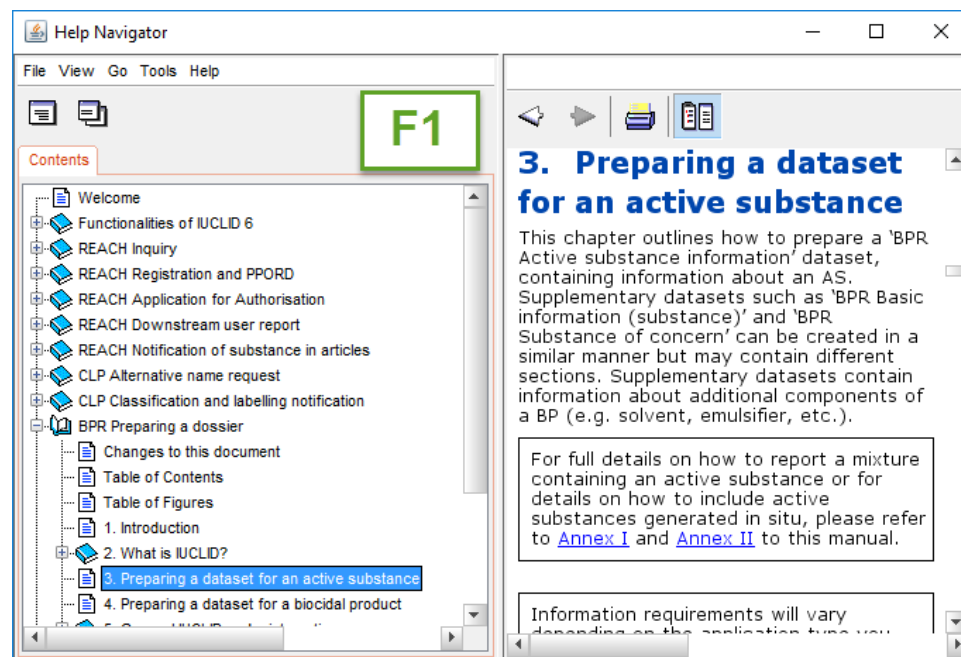
Name  
[trihenvlene / trihenvlene / 217-59-4](#)

# Copying a IUCLID document



# Embedded help system

- Help system integrated in IUCLID itself
- Dossier Submission Manuals included
- Including the Biocides Submission Manual: how to use IUCLID under BPR



# Report generator

Summary of product characteristics



## IUCLID Report generator - SPC

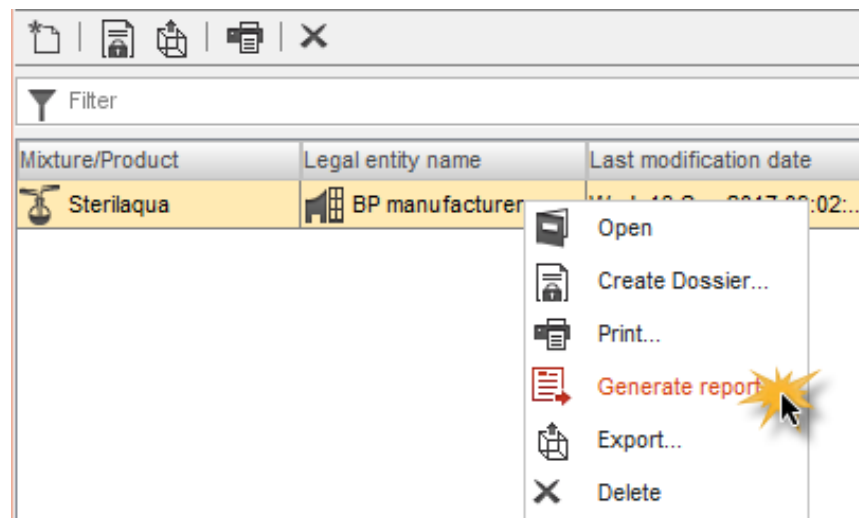
- Main purpose: extraction of the IUCLID data that are relevant for the Summary of Product Characteristics (SPC)
- Relevant for a single biocidal product
- Generates an XML file compatible with the SPC Editor

## IUCLID Report generator - SPC

- The generated file contains the following information:
  - Identity of the biocidal product
  - Product type, formulation type
  - Product composition
  - Authorized uses
  - Directions for use
  - Packaging
  - Measures to protect humans, animals and the environment
  - Classification and Labelling information
  - Some administrative information

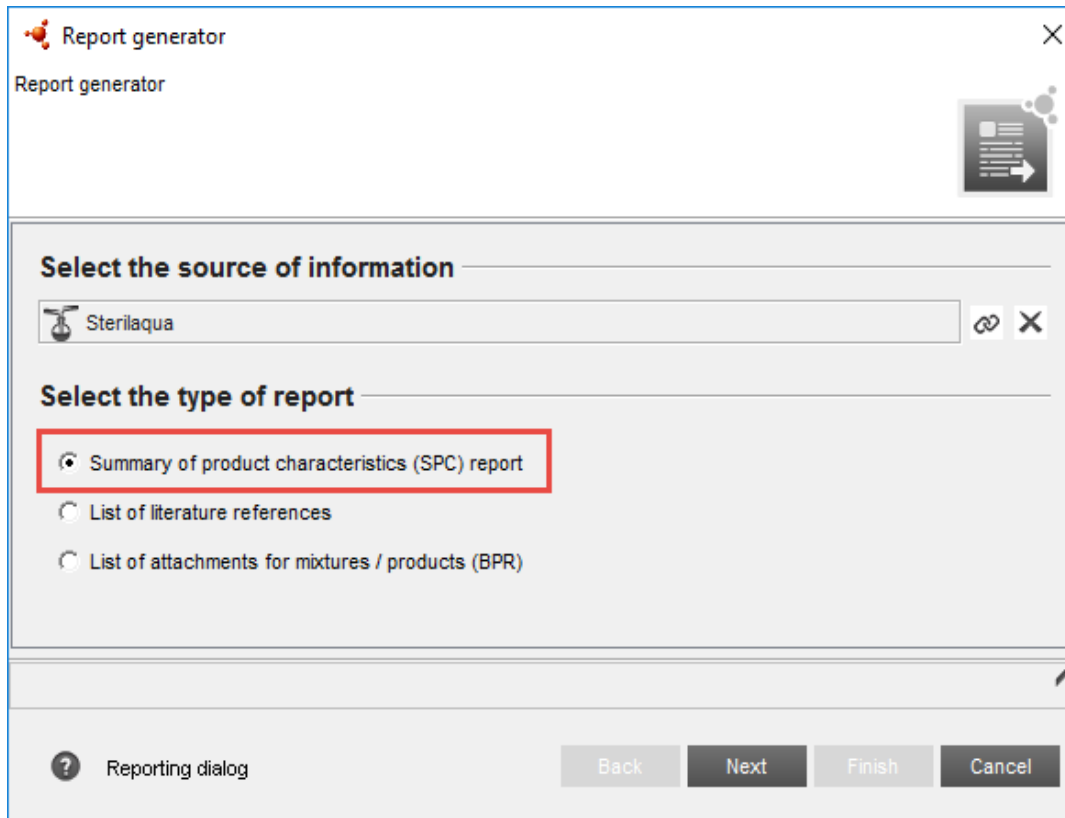
## How to generate a report

- Select a **biocidal product dataset** or **dossier** in the Navigation Panel and click 'Generate report...'





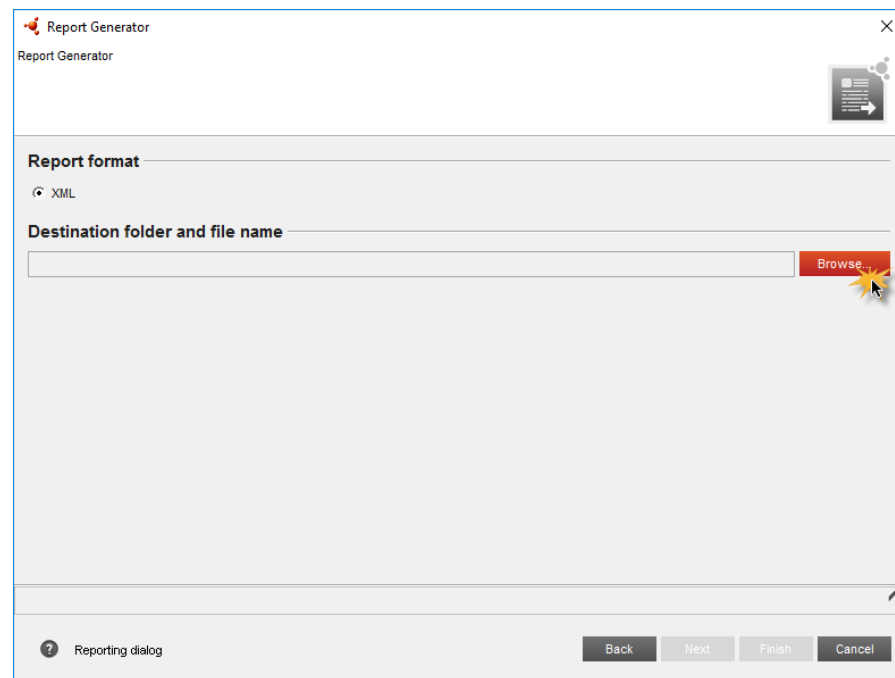
# How to generate a report



The screenshot shows a software dialog box titled "Report generator". At the top left, there is a small icon of a person and the text "Report generator". Below this, the text "Report generator" is repeated. On the right side, there is a close button (X) and a help icon (a document with a question mark). The main area of the dialog is divided into two sections. The first section is titled "Select the source of information" and contains a text input field with the value "Sterilaqua". To the right of the input field are two icons: a link icon and a close icon (X). The second section is titled "Select the type of report" and contains three radio button options. The first option, "Summary of product characteristics (SPC) report", is selected and highlighted with a red rectangular box. The other two options are "List of literature references" and "List of attachments for mixtures / products (BPR)". At the bottom of the dialog, there is a footer area containing a help icon (question mark) and the text "Reporting dialog". To the right of this are four buttons: "Back", "Next", "Finish", and "Cancel".

# How to generate a report

- Select a destination folder to store your report as an XML file



# How to generate a report

- Import the XML file in the SPC Editor as a starting point for creating your SPC for a single product



SPC\_report.xml



SPC Editor

```
<?xml version="1.0" encoding="UTF-8" standalone="true"?>
<!-- SPC main template file -->
- <ns4:SPC xml:lang="en" xmlns:ns4="http://echa.europa.eu/s
xmlns:ns2="http://www.w3.org/2000/09/xmlsig#">
<!-- Macros -->
<!-- Functions -->
- <ns4:lang>
  <representation>en</representation>
</ns4:lang>
- <ns4:AdminInfo>
```

Rodenticide example Finland English

Formulation type

\* Formulation type

Active substances

Move up Move down

\* BAS number

\* Common name

IUPAC name

CAS number

# IUCLID Report generator

## More report templates

- List of confidentiality claims in BPR dossiers
- List of literature references included in a dossier
- List of attachments

*More information:*

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

# IUCLID Report Generator

1. You can download the report templates from ECHA's IUCLID website

Report templates

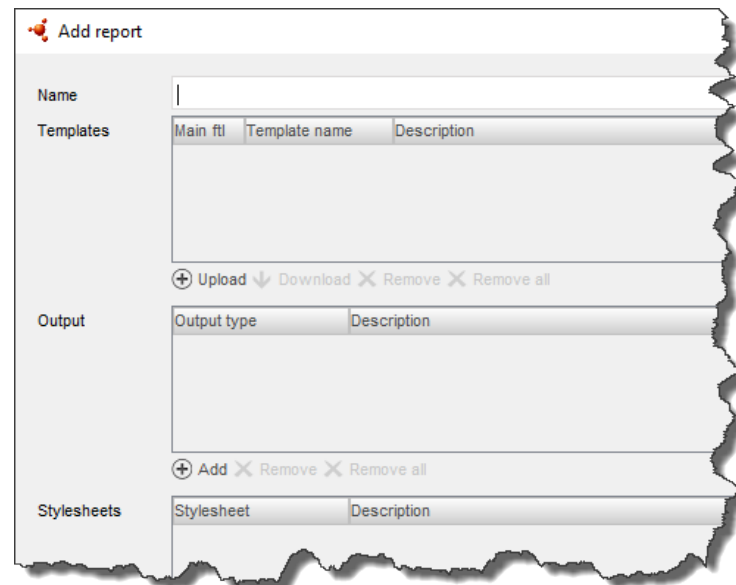
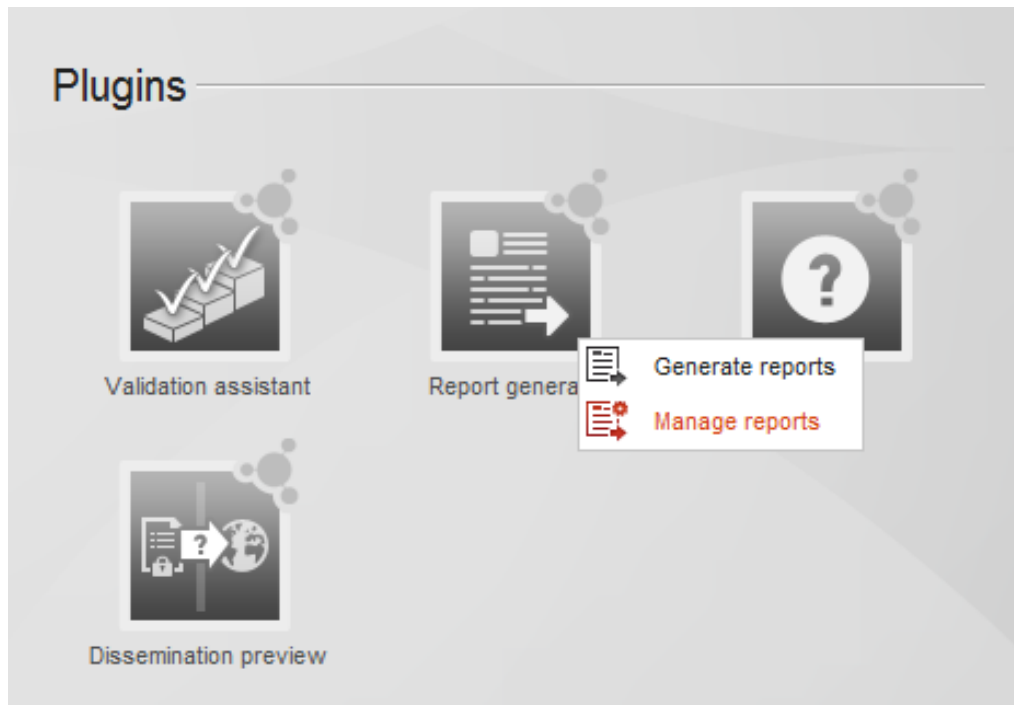
## Available report templates

Report template	Status
<a href="#">REACH Chemical Safety Report (CSR)</a> - 2 May 2017	Included in IUCLID 6
<a href="#">BPR Summary of Product Characteristics (SPC)</a> - 27 October 2016	Included in IUCLID 6
<a href="#">List of confidentiality claims in a BPR dossier</a> - 2 May 2017	Under testing
<a href="#">List of literature references</a> - 27 July 2017	Under testing
<a href="#">List of attachments for substances</a> - 8 August 2017	Under testing
<a href="#">List of attachments for mixtures / products (BPR)</a> - 8 August 2017	Under testing
<a href="#">List of annotations</a>	Under development

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

# IUCLID Report Generator

2. You can add and manage the report templates in IUCLID, and then generate different reports based on a dataset or a dossier



# IUCLID Report generator

## Create your own reports

### Creating your own report templates

IT developers, or users with a certain level of IT skills, can create their own report templates in order to generate reports based on IUCLID data, using the IUCLID 6 Report Generator.

Basic instructions are made available together with a few examples:

- **DocBook** report template example (.ftl)
- **XML** report template example (.ftl)
- Test IUCLID 6 **dataset** (.i6z)

### Sharing your report templates

If you wish to share the templates you have customised and potentially have these published on the IUCLID 6 website, please contact ECHA through the **IUCLID functional mailbox**.

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

**Where to find further information**





# IUCLID manuals and webinars

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

IUCLID > Support

## Support



### Documentation

Find anything you want to improve or enhance your knowledge in many issues related to IUCLID 6.

[Read more](#)

<https://www.echa.europa.eu/web/guest/support>



> [Publications](#)



> [Helpdesks](#)



> [Q&As Support](#)  
> [Webinars](#)

# Thank you!

Contact:

[dorota.burchard-sosnowska@echa.europa.eu](mailto:dorota.burchard-sosnowska@echa.europa.eu)

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# Hands on training

IUCLID 6 for biocides



## Scenario

- PART 1: Launch IUCLID 6
- PART 2: Create a biocidal product authorisation dossier
- PART 3: Edit the product dataset
  - How to create and rename a IUCLID document
  - How to update a dossier
  - How to copy a IUCLID document (optional exercise)*
- PART 4: Generate an SPC XML file
  - How to generate a list of literature references (optional exercise)*
  - How to generate a list of attachments (optional exercise)*