![ECHA - European Chemicals Agency]

Biocides IT training
Vienna - 4 December 2017

IUCLID 6

Creation and update of a Biocidal Product Authorisation dossier and use of the report generator

Background information

In the context of Article 20 of the BPR Regulation, the application for authorisation for biocidal products other than biocidal products eligible for the simplified authorisation procedure, shall contain:

- A dossier or letter of access for the biocidal product satisfying Annex II requirements for every single active substance
- A dossier or letter of access for the biocidal product satisfying Annex III requirements; and
- A summary of biocidal product characteristics (SPC).

The technical dossier satisfying requirements of Annex II and Annex III must be submitted in IUCLID format.

Scenario

You are an applicant who needs to fill in a IUCLID 6 application satisfying the requirements as specified in Article 20. The active substance to be included in the biocidal product is considered as approved for the relevant product type.

As an applicant, you will need to:

- **PART 1:** Launch IUCLID 6
- **PART 2:** Import a biocidal product dataset
- **PART 3:** Create a biocidal product authorisation dossier
- **PART 4:** Edit the product dataset and update the dossier
- **PART 5:** Generate report(s) based on IUCLID data

Please, complete the step-by-step instructions provided in the next pages.

The scientific information provided in the following exercise is not necessarily accurate but will help you to carry out some necessary steps to complete your biocidal products application. Due to the time constraints we cannot go through all mandatory sections during the exercise.

In orange tex boxes you will find additional information on IUCLID functionalities, that are not necessarily needed to perform the exercise but might help you in understanding IUCLID better.
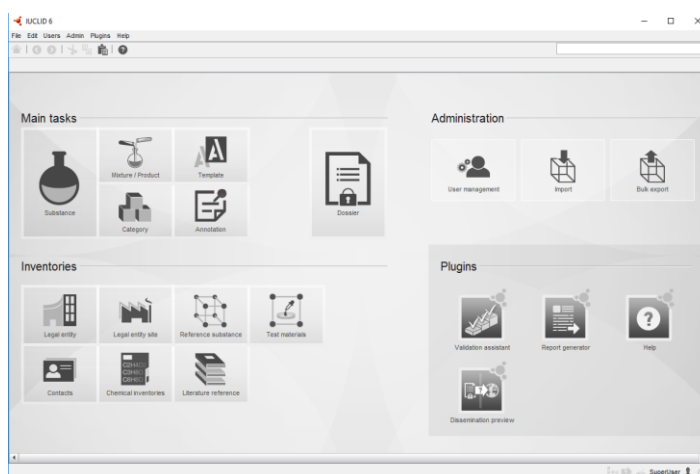
> Additional information on IUCLID

PART 1: Launch IUCLID 6

1. Open IUCLID 6 using the icon available on your Desktop[1]. Please note that the initial launch of IUCLID 6 might take more than one minute.

2. Once started, the IUCLID 6 home page will be displayed.

> The home page is shown by default when logging in to IUCLID database. You can always come back to this page by clicking on the house icon that is situated in the menu toolbar, or from the main menu by selecting Go / Home. The icons are grouped together in four areas, to indicate that each group has something in common. The panel for Dossier has been placed centrally and made bigger than the others, to reflect its central role in regulatory tasks.

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[1] If you do not have an icon on your desktop, please go to the folder in which you have installed IUCLID 6 and double click the file iuclid6.exe

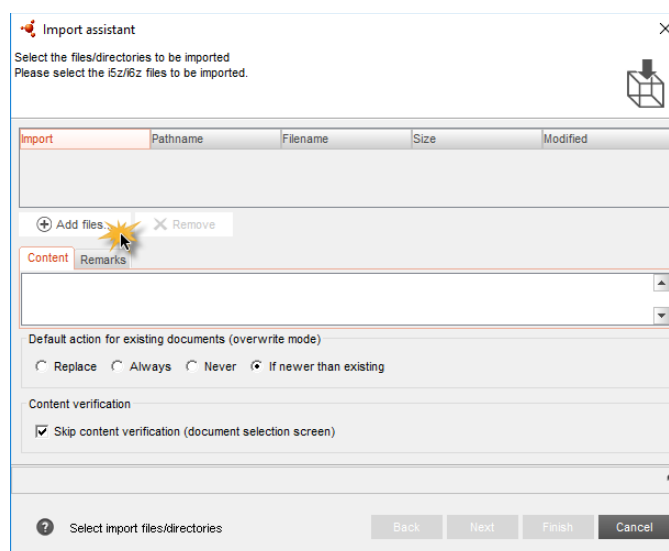## PART 2: Import a biocidal product dataset

Due to the time constraints the biocidal product dataset has been prepared in advance and sent to you by the organiser of the training session. You should have it saved on your computer. The file name is 'Biocidal product test dataset.i6z'.
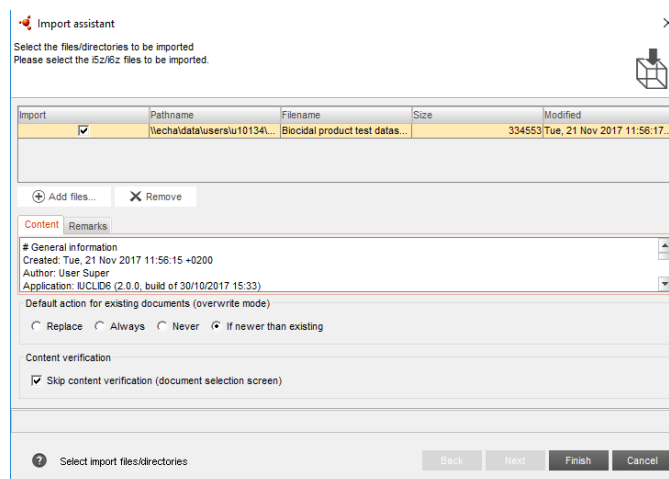
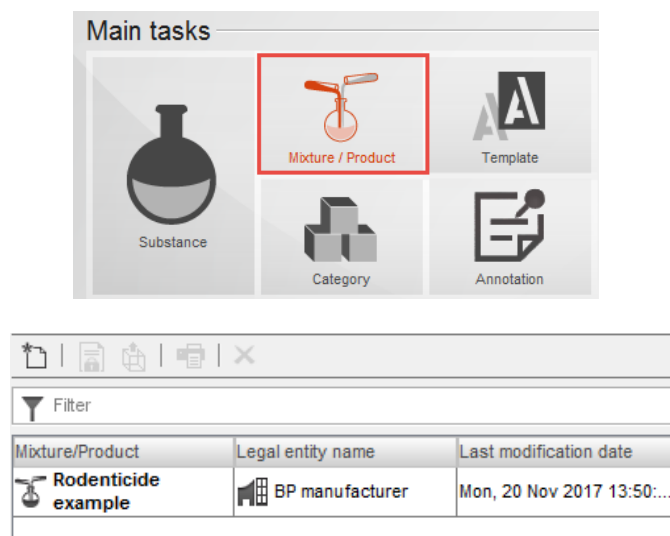**1.** Click the icon 'Import' on the IUCLID 6 homepage.
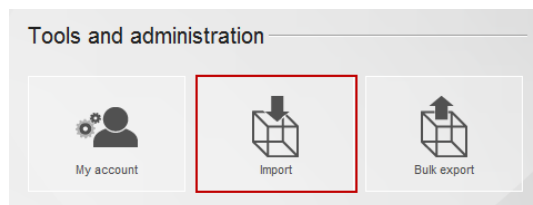
2. Click 'Add files' and select the file you downloaded, press 'Open'.

3. Press 'Finish'.

4. Click on the icon 'Mixture / product' and check that the biocidal product is there.

An important thing to know is that in IUCLID a distinction is made between the edition of the information, which is done in a substance or product dataset usually by the applicant, and the access to information that has been submitted by an applicant in a IUCLID dossier, and then viewed by the Competent Authority. The dataset is editable, a dossier is not.
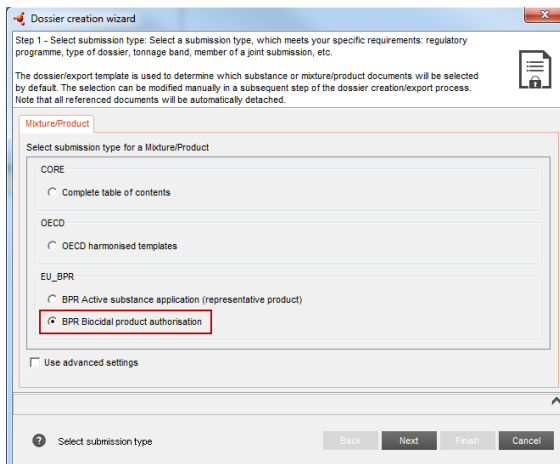
Under the icon Mixture/Product you access a dataset, so the editable data. Based on this dataset, you can create a dossier, which is a snapshot of the scientific and administrative information provided in a dataset, complemented with administrative information about the type of registration.

PART 3: Create a biocidal product authorisation dossier

1. In the Navigation panel right click on your biocidal product and select the option "Create Dossier"
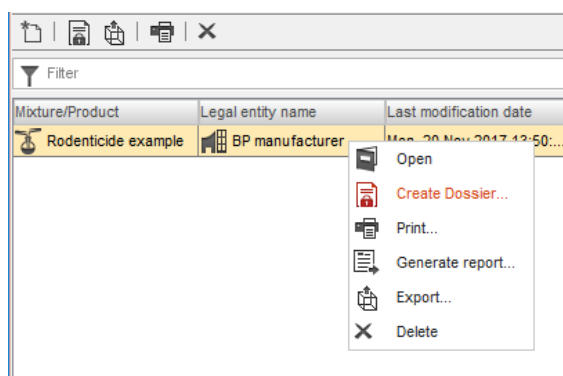
2. At the first step of the Dossier creation wizard select the submission appropriate for your biocidal product. In this case, it will be "BPR Biocidal product authorisation". Press Next.
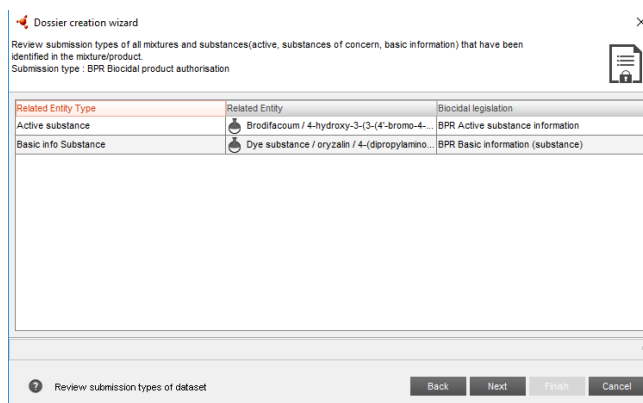
3. At the next step you will see components of the biocidal product, and you can check if all datasets have been prepared using the correct TOC (for example "BPR Active substance information' for an active substance). It should look like on the screen shot below. Press Next.

4. At the next step give a name to your dossier, for example 'X Biocidal product dossier'. Press Finish.

5. Click "Yes" to access the created dossier
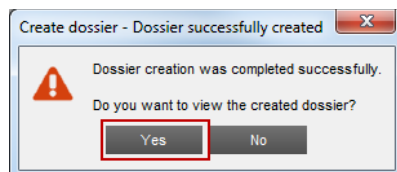
In the main panel a dossier header is displayed. It contains basic information about the dossier: name, version, dossier name given by user, main component of the dossier, legal entity (only if required by user during the dossier creation), creation date, information if the dossier is an update and remarks.

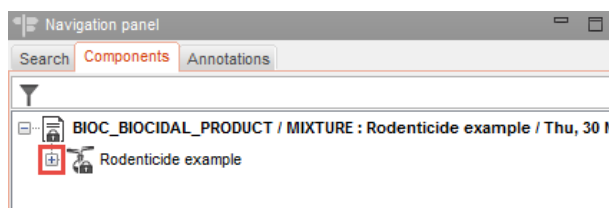When creating a dossier, the user can use advanced settings and decide to a bigger extent what information will be included in a dossier. It concerns for example legal entity, which by default is not included in a dossier.

To see all components of the biocidal product in the Navigation Panel, you need to press the plus sign next to main component of a dossier.
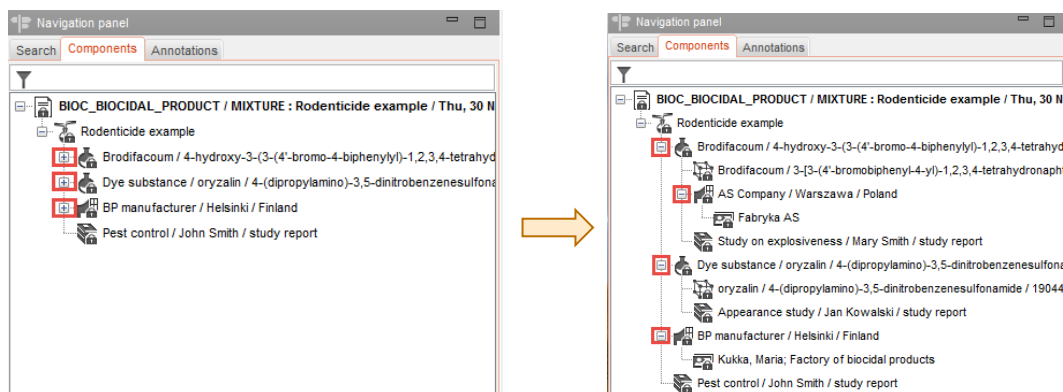
Then, you can open each element by double click on it.

When you are looking at the BPR dossier components in the navigation panel, you can see icons listed below. There is always indication that those elements are locked for the edition as they are part of a dossier (so the small padlock is added to each icon).

substance

legal entity

test materials

mixture/product

contact (and site for BPR dossiers)

reference substance

literature reference

In the Information Panel the UUID of the dossier is displayed. This is an unique identifier of each dossier.
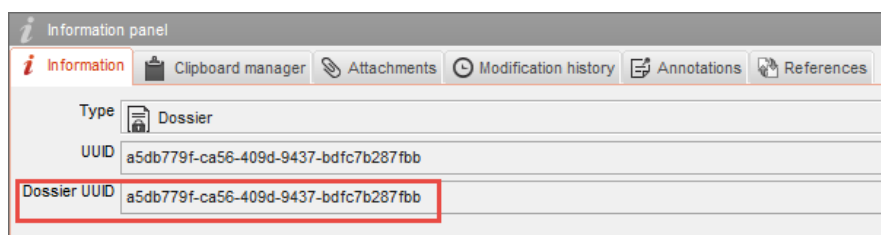
The quickest way for searching for a dossier is by pasting its UUID in the upper right corner of the main IUCLID page. (Search by UUID)

You can access you dossier also by by clicking the icon (to come back to the main page of IUCLID) and then clicking on the "Dossier" icon. There, you will have access to the 'Search'.

If you have several dossiers in your database, you can search for the needed one using different criteria, for example 'Mixture/Product name' or 'Mixture/Product other name'. Remember to always indicate 'Result type' as a 'Dossier' when you are looking for a dossier, and 'Mixture/Product' when you are looking for a dataset.

PART 4: Edit the product dataset and update the dossier

Imagine that you have forgotten to insert some information in your biocidal product dataset (so also in your biocidal product dossier). You need to open a dataset again, edit it, and create a dossier once more.

1. Come back to the main page of IUCLID by clicking the icon

2. Click on the "Mixture / Product" icon

3. Open your product dataset called 'Rodenticide example' (double click or right click and option 'Open'), select tab TOC, click on the arrow on the right, and select the correct submission type: BPR Biocidal product authorisation
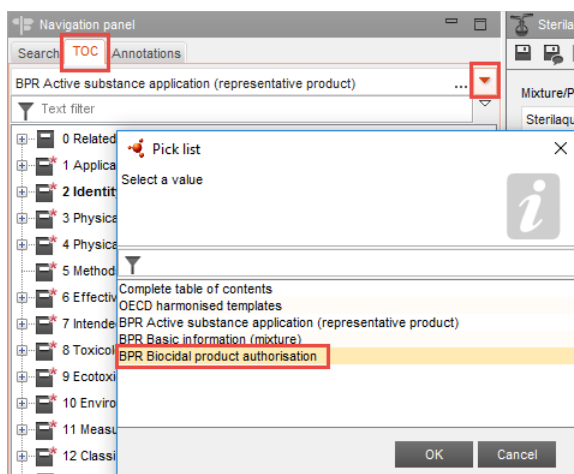
4. Go to section 2.3 'Biocidal Product composition'. You can see there one composition record. Double click on it to open it.
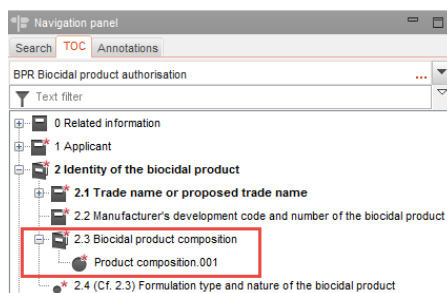
You can see that the composition record contains two components (you need to scroll down):

Brodifacoum - function: active substance, concentration: 5% (v/v)

Dye substance - function: dye, concentration 5 % (v/v)

You need to add one more component. In order to do that, you need to create a substance dataset and link it as a third component in the section 2.3 Biocidal product composition.

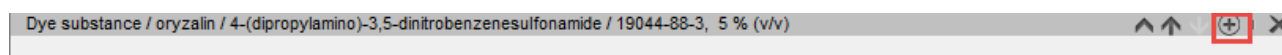**5.** Click 'File' from the top menu and select option 'New', then 'Substance'
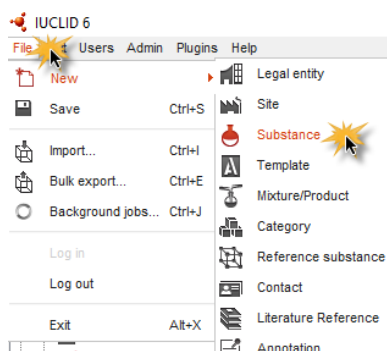
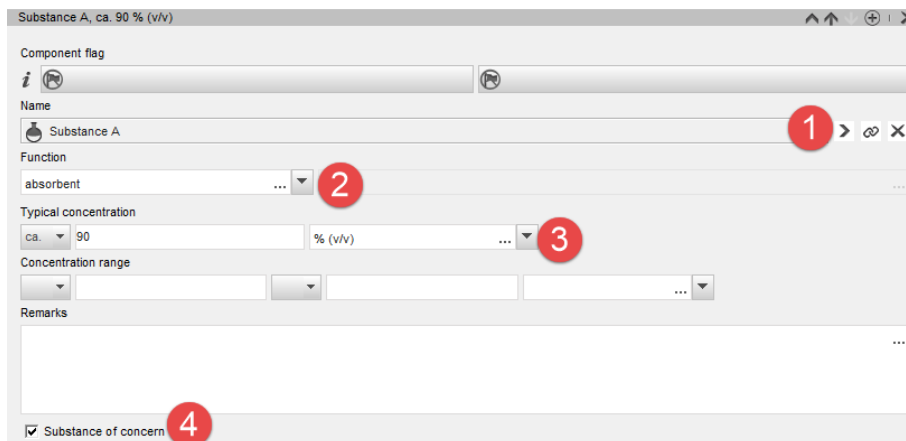**6.** Insert 'Substance name', for example 'Substance A' and save.

During this exercise we will not fill a dataset for the substance. If we would like to do that, we would need to go to the tab 'TOC' (marked in green below) to open the section tree for the substance and insert all data required by BPR.
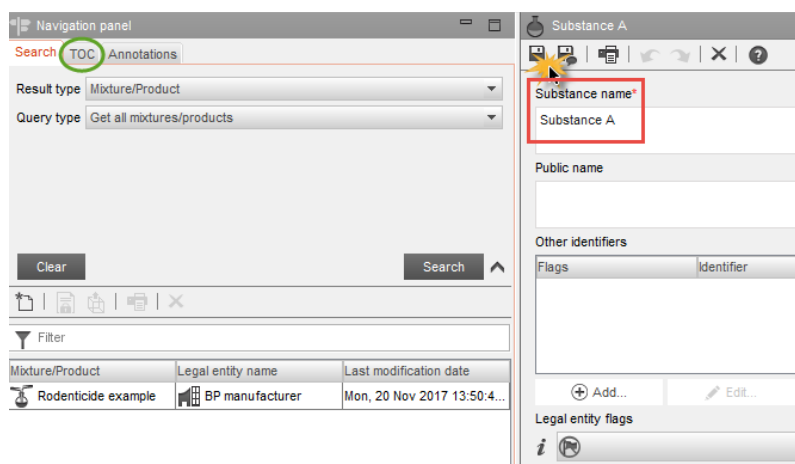
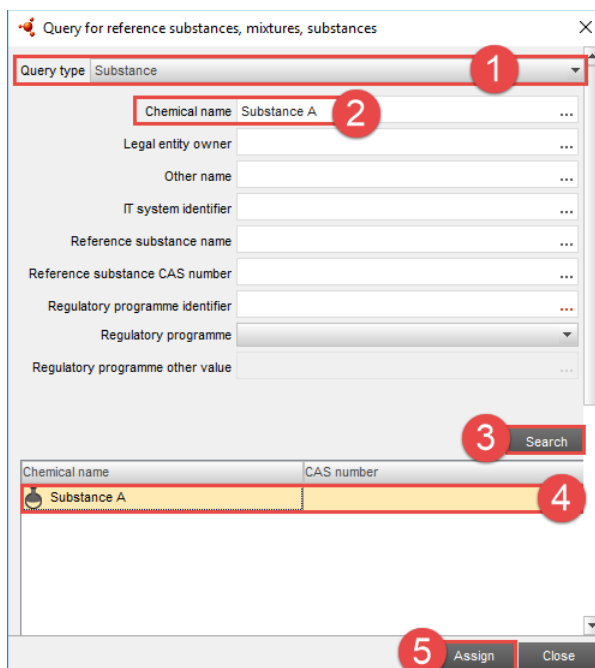**7.** Come back to the product dataset by double clicking it in the Navigation Panel.

8. Select tab TOC, select the correct submission type: BPR Biocidal product authorisation (see screen shot in point 3) and open again section 2.3 Biocidal product composition.

9. Scroll down and click plus sign to create a third component.

Dye substance / oryzalin / 4-(dipropylamino)-3,5-dinitrobenzenesulfonamide / 19044-88-3, 5 % (v/v)

10. Link a substance dataset (1, see instruction below), select a function (2), indicate an exact concentration 90% (v/v) in a field 'Typical concentration' (3), as shown below. We assume that the third component is a substance of concern, so check in a relevant checkbox (4).
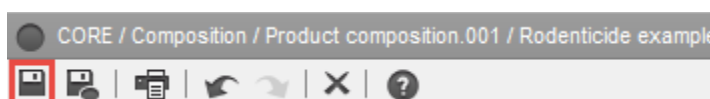

To link a substance dataset, click a chain next to 'Name' field to open a query window, and then select '**Substance**' (1), insert chemical name of the substance (2), press Search (3), select the substance (4) and press Assign (5).


Now your composition record is complete.

Save the changes every time when you leave the record after having modified data.

11. It is time for the next modification. Go to section 7 and using the plus signs next to sections 7.1 and 7.6, expand them. In section 7.1 you see three records containing information about uses. In section 7.6 there are directions for these uses. Each record in section 7.6 should be linked to one or more records in section 7.1.

Open the third record in section 7.6 (1) and link a reference use (2), which is 'Field(s) of use envisaged for biocidal products and treated articles.003' (3), and click 'Assign' (4). You might need to enlarge the pop up window to select a correct link.
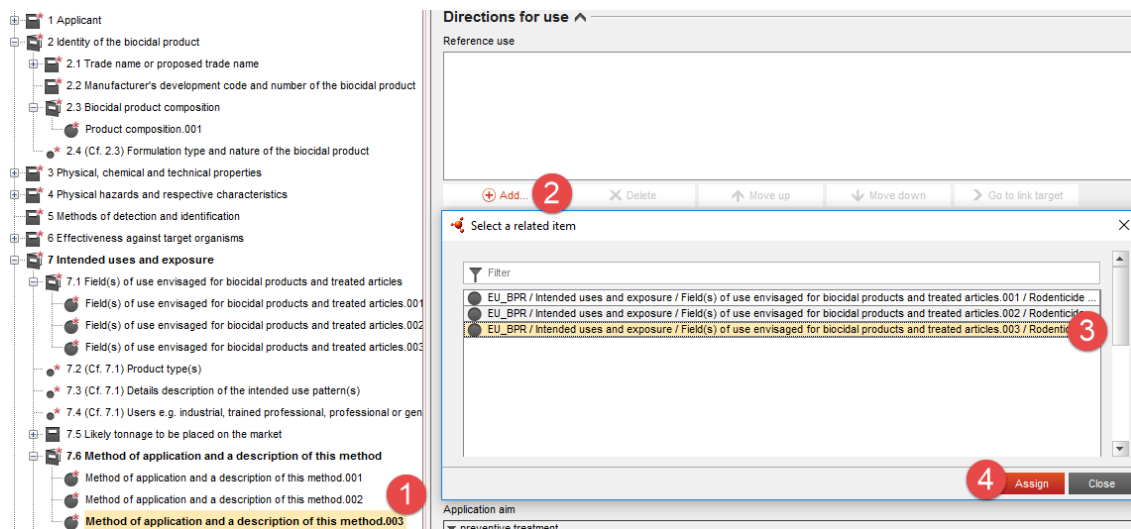
12. The last change is about creation of a new record in section 12.3 Packaging. Go to the section 12.3, right click and select option 'New record'.
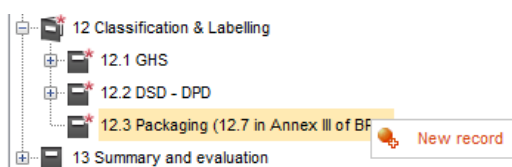

Now you can fill in all required information. You can invent your own information or use the one proposed below:

- Type of packaging: *sachet*
- Size: *>=15 <= 200 g*
- Material: plastic: *PCV, PP, PE*
- Compatibility: *compatible*
- Further description:
  Pre-baited stations: 15g (mice) and 100g (rats)
  Refill packs: 120g, 170g, 250g, 300g, 600g (the bait must be supplied in inner packs or units, each containing enough bait for one point)

  Pre-baited stations: 15g (mice) and 200g (rats)
  Refill packs: 2kg, 5kg and 20kg (the bait should be supplied in inner packs or units, each containing enough bait for one point)

- Safety features: *Covered bait stations (tamper resistant)*, w*rapped bait (sachets)*
- Description of the secondary packaging: *Bucket container – PP or PE*

Add the proposed label for your biocidal product. The file 'example_label_X_Biocidal_Product.png' has been sent to you by the organiser of the training.

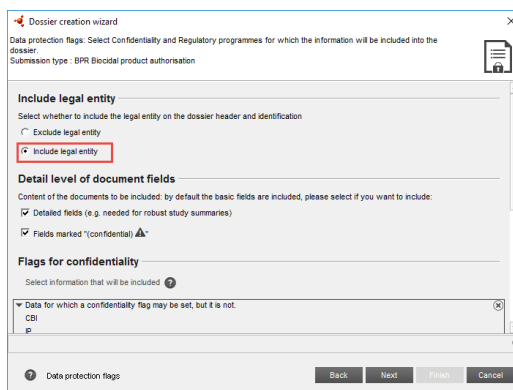To do it: click 'Add' (1), select 'Type of attachment' (2), link the attachment (3) and click 'OK' (4).
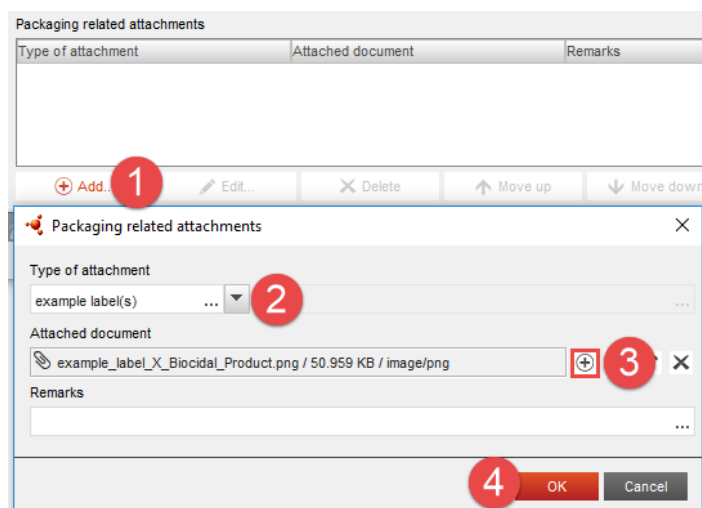
You can open your attachment by double clicking on the row containing the attachment and selecting the icon shown below.
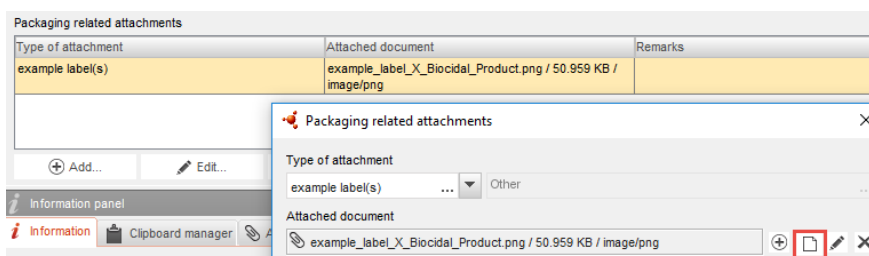

13. Create a new dossier (see PART 3 of the exercise). You might like to use advanced setting. In this case check in the box 'Use advanced settings' in Dossier creation wizard, and indicate (in one of the next steps), that you want to include legal entity in a dossier header. Give a different name to a new dossier, for example 'X Biocidal product dossier NEW'.
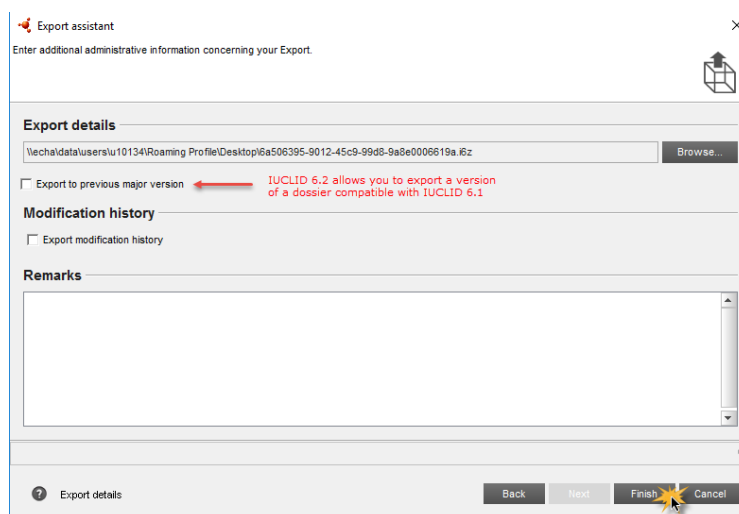
ECHA
EUROPEAN CHEMICALS AGENCY
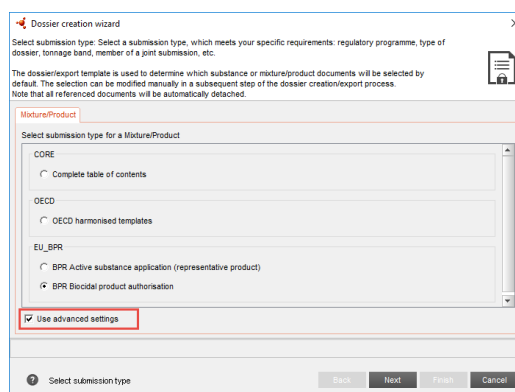
Additional exercise (optional) – **dossier export**:

1. Select the dossier from the list of dossiers in a Navigation panel and select an option 'Export', then press 'Next'
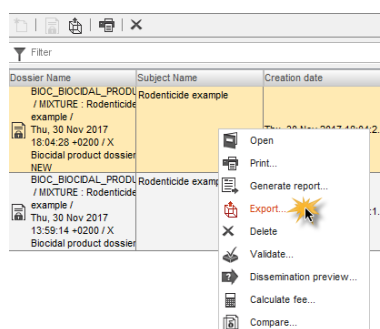
**2.** Indicate a location and a name for the exported dossier 'X_biocidal_product_dossier'. Press Finish.

The outcome will be .i6z file.

 6a506395-9012-45c9-99d8-9a8e0006619a.i6z

PART 5: Generate report(s) based on IUCLID data

Summary of product characteristics (SPC) report

1. Come back to the main page of IUCLID by clicking the icon

2. Click on the "Mixture / Product" icon.

3. Right click on your product dataset and select 'Generate report…'.
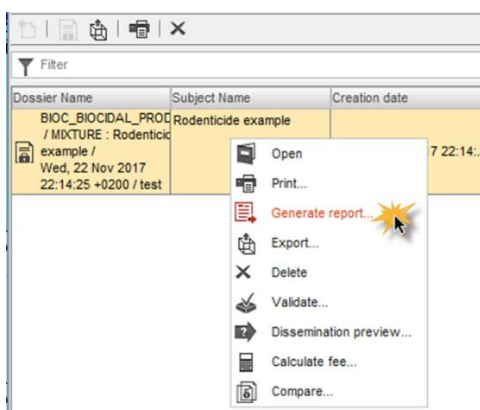
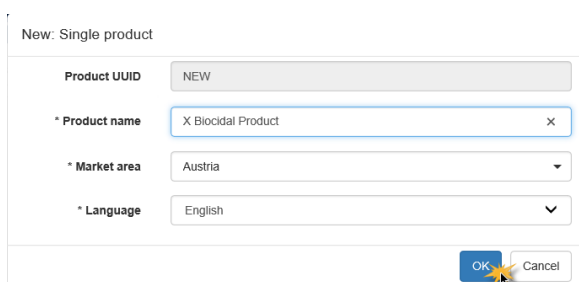**4.** Select 'Summary of product characteristics (SPC) report'. Press Next.
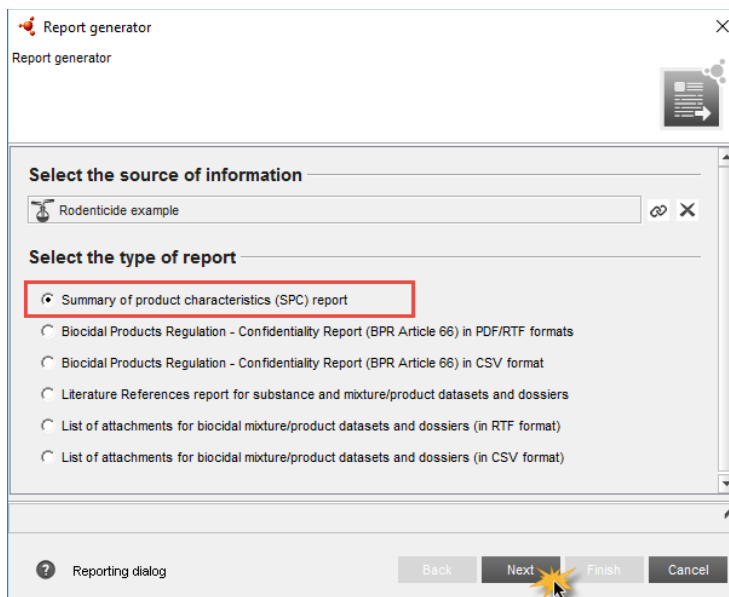
You can see here a shorter list of reports if you are using IUCLID 6.1 (1.3.0 released in spring 2017), because not all report templates have been available and included in the IUCLID package.

You can generate an SPC report based on a dataset and based on a dossier.

5. Select 'Browse' and indicate a location and a name for the SPC XML file to be generated. Press Finish.
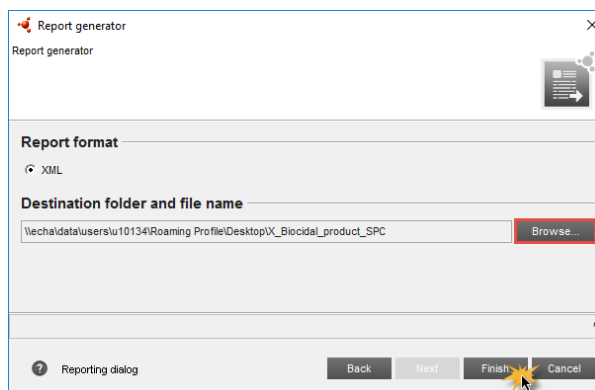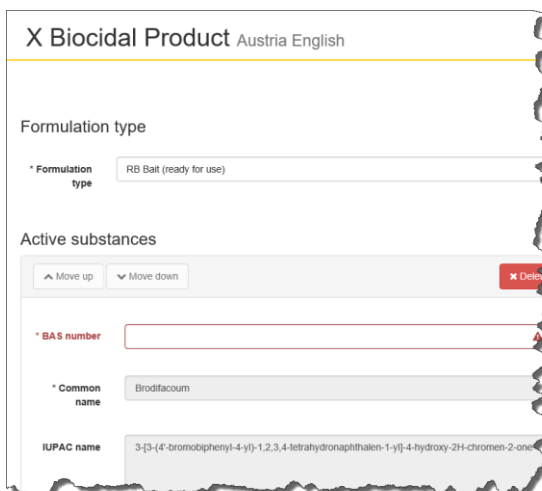
6. The XML file is generated and the relevant information is extracted from the IUCLID product dataset. The XML file opens in a browser.

7. Open the SPC Editor from the ECHA website: https://r4bp.echa.europa.eu/spc/#/home

8. Select 'Start using the SPC Editor'

9. In SPC Editor, create an SPC for a new single product
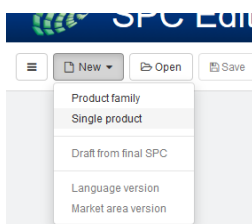
10. Click 'Import XML' and select the SPC XML file you exported from IUCLID. The data will be imported to the SPC Editor and the SPC can be updated from there.
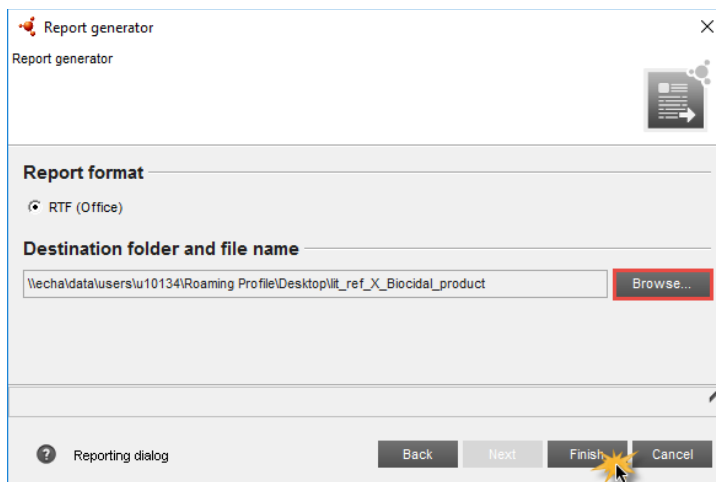
Literature reference report (additional exercise – available only for IUCLID 6.2)

1. Come back to the main page of IUCLID by clicking the icon

2. Click on the "Mixture / Product" icon.

3. Right-click your product dataset and select 'Generate report…'.

4. Select 'Literature References report for substance and mixture/product datasets and dossiers'. Press Next.

5. Select 'Browse' and indicate a location and a name for the list of literature references file to be generated. Press Finish.

6. The rtf file is generated and the relevant information is extracted from the IUCLID product dataset.

Literature References Report

Product name(s):
Rodenticide example

PT retrieved from each record in section 7.1;
in our example PT in all three records are the same

Product types(s):
EU BPR Product type 14: Rodenticides (Pest control)
EU BPR Product type 14: Rodenticides (Pest control)
EU BPR Product type 14: Rodenticides (Pest control)

Active substance name:
Brodifacoum

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

Type	Section information					Annex II/III requirement		UUID
Biocidal product	**Section No.** 3.1 **Section Name:** Appearance (at 20°C and 101.3 kPa) **Name given to the Document:** Appearance (at 20°C and 101.3 kPa).001					Appearance (at 20°C and 101.3 kPa)		6a459ff9-66d3-4c1f-b3ce-a3d4211dde26 *[http://localhost:8080/webstart/launch.jnlp?uuid=6a459ff9-66d3-4c1f-b3ce-a3d4211dde26&snapshot=0]*
Reference type: study report	Title: Pest control	Author: John Smith	Bibliographic source: Unknown Year: 2011	Testing laboratory: Testing Laboratory	Report no. 1/2011	Study sponsor: No company owner provided Company study number: 1	Report date: Jan 1, 2011	
Remarks: This is a no existing literature reference created for the training session in Vienna.								
Active Substance	**Section No.** 4.1 **Section Name:** Explosiveness **Name given to the Document:** Explosiveness.001					Explosives		50d6733f-1418-4489-ba2a-0924616cb9d5 *[http://localhost:8080/webstart/launch.jnlp?uuid=50d6733f-1418-4489-ba2a-0924616cb9d5&snapshot=0]*
Reference type: study report	Title: Study on explosiveness	Author: Mary Smith	Bibliographic source: unpublished Year: 2011	Testing laboratory: Testing Company	Report no. 1	Study sponsor: No company owner provided Company study number: 1	Report date: Jan 1, 2011	
Remarks: This study does not exist. It is a training literature reference.								
Other Substance	**Section No.** 3.1 **Section Name:** Appearance/physical					Appearance		IUC5-9e810dc4-2d3d-413e-b3a6-cd12498194c6

END OF THE TRAINING