Biocides IT training
Helsinki – 25 October 2018

R4BP 3.11 and SPC 2.3

Table of contents

1. Introduction

The biocides IT training consists of five parts (exercises):

1. In the first part, the trainer will run a guided demonstration on how to prepare a summary of product characteristics (SPC) with SPC editor 2.3 for the process that will be used later for the application for national authorisation.

2. The participants will then be asked to individually prepare a second SPC, needed for the application for mutual recognition in sequence.

3. In the third part, the trainer will run a guided demonstration on how to make an application for the **approval of an in-situ generated active substance (AS-APP)** in Italy with R4BP 3.11.

4. Then, the trainer will run a guided demonstration on how to apply for a **national authorisation (NA-APP)** in Italy of a product containing the in-situ generated active substance.

5. Finally, participants are requested to individually perform an application for **mutual recognition in sequence (NA-MRS)** in Finland.

In every exercise, the tasks of the two different different roles (industry, Member State competent authority) will be described sequentially.

Objective of the training

The objective of this training is to improve the understanding of the participants on the regulatory processes to submit applications for authorisation of biocidal products and their evaluation as implemented in IT workflow, and to show the most important features of R4BP 3 and SPC editor.
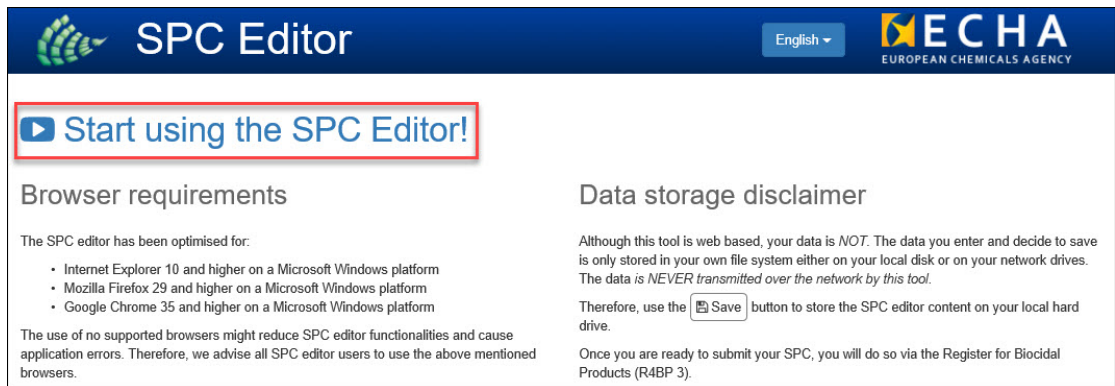
This manual

This manual lists the key points to keep in mind when running exercises 1 to 5, both in guided mode and in individual mode.

Method

Each participant to the training will have to run all the exercises. When guided, you may repeat what the trainer will perform on the screen, while individual exercises will have to be performed on your own. However, in this document you will find step-by-step instructions to reach the end of each exercise (guided or individual).

2. Exercise 1 (guided) – SPC for NA-APP

1. . Copy and paste the URL that you find in the document "Credentials" in Mozilla Firefox or Google Chrome (we recommend not to use Internet Explorer for this exercise) and then open SPC Editor version 2.3.

2. Create a single product SPC: click on 'New' and select 'Single product' from the list.

3. Fill in basic information of the new product:

   a. Enter the name of the product, 'Disinfect now';

   b. Select 'Italy' as the market area;

c. Select the language of the SPC files (for simplicity, we recommend English).

4. Fill in each field in the sidebar. **The objective is to fill in the required information so that the 'valid and complete information' icon (✓) appears next to each field of the sidebar.** You can start by clicking 'Product information'.
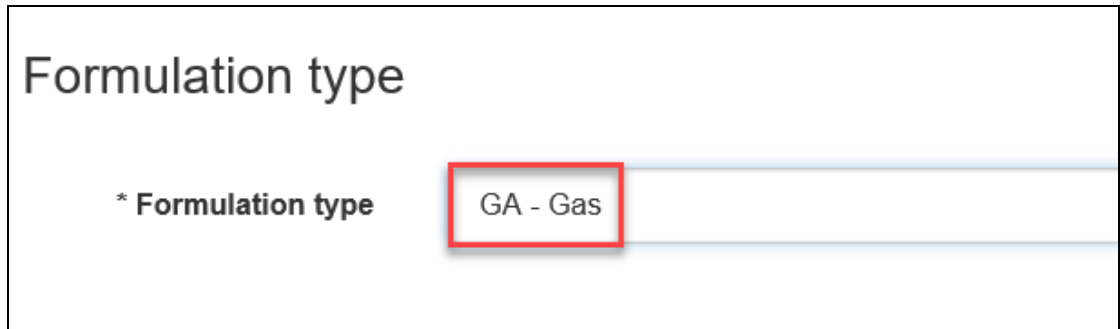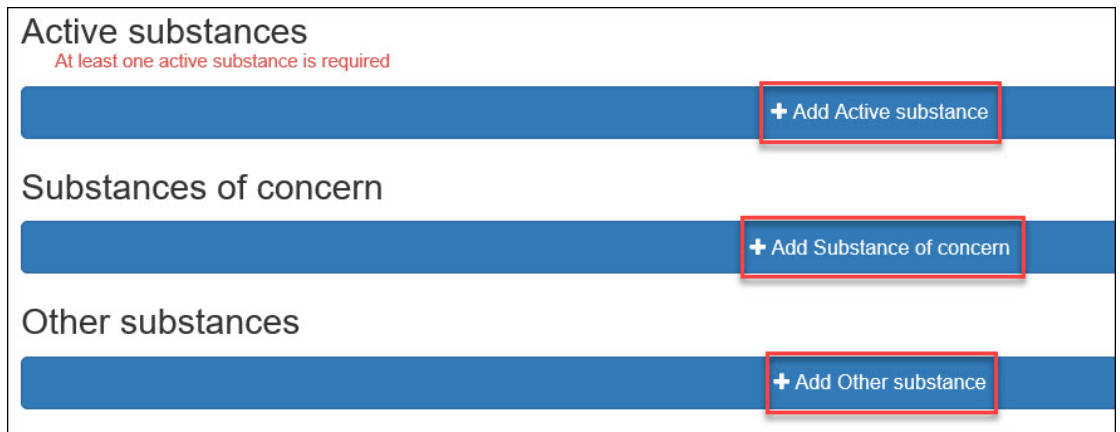
5. Select 'GA – Gas' as the formulation type.

Formulation type

* **Formulation type** GA - Gas

6. Add the active substance and the four 'Other substances' in the appropriate fields (see figure below), reporting the concentrations indicated in Table 1.

Active substances
At least one active substance is required

+ Add Active substance

Substances of concern

+ Add Substance of concern

Other substances

+ Add Other substance

Table 1: Product composition
• Chlorine dioxide (active substance, 60% w/w) • Reaction by-product ABC (impurity, other substance, 40% w/w) • Sodium chlorite (precursor, other substance, 45% w/w) • Sodium bisulfate (precursor, other substance, 45% w/w) • Hydrochloric acid (precursor, other substance, 10% w/w)

7. Fill in the information on the manufacturer of the product in the 'Administrative information' page (even generic information is sufficient).

8. Add one use in the field 'Authorised uses' and call it 'Disinfectant use'. Select PT05 as product type. Fill in the remaining information.

9. Then continue to fill out the remaining fields: H & P statements, use, administrative information and other information.

You can simply write "**TBD**" (to be decided) in the first field and then copy and paste this into all those where it is needed to obtain a 'valid and complete' checkmark for each field of the sidebar. Please note that the objective of this exercise is to understand how to produce a file that

is ready (according to the IT checks) to be submitted for the application. More in-depth discussion on the scientific content of the information can be performed separately.

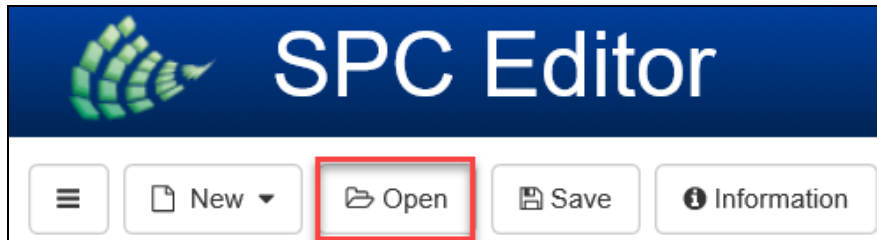10. Once you confirm that all fields are complete,
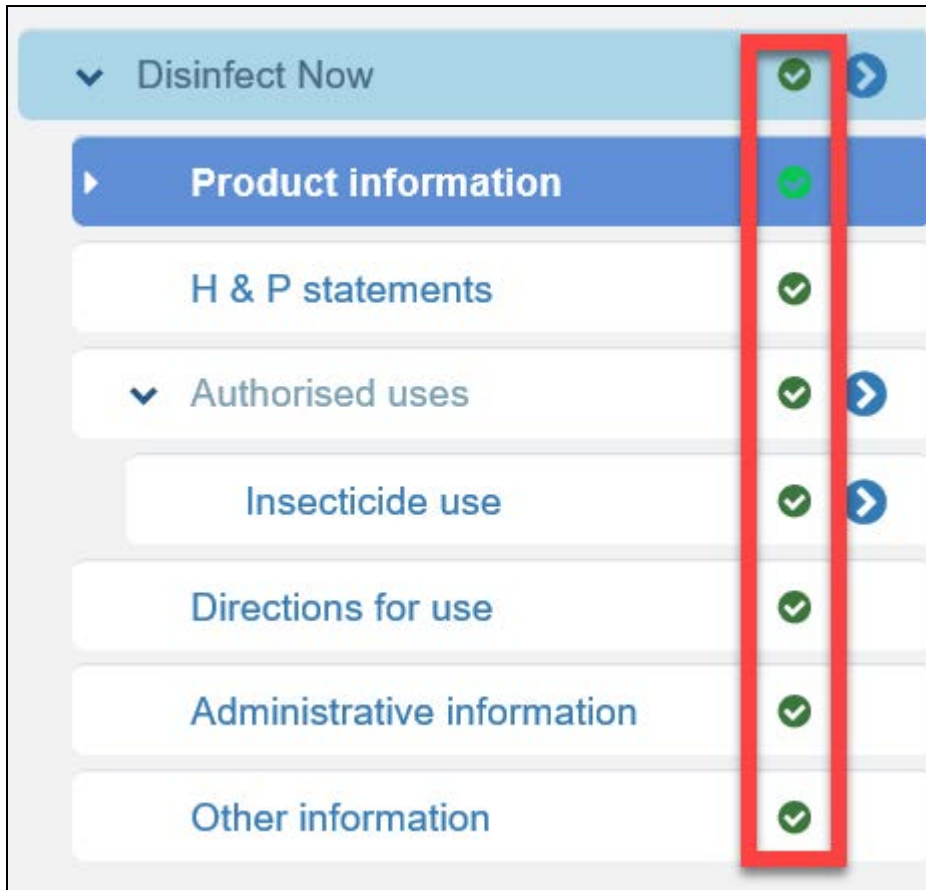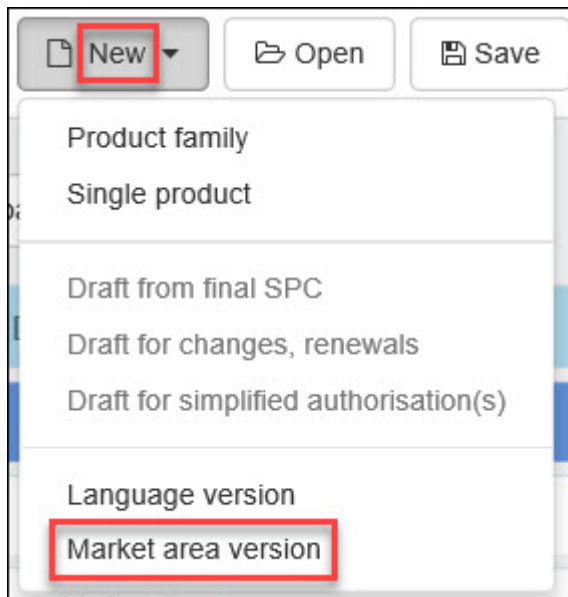

save the SPC on your PC.
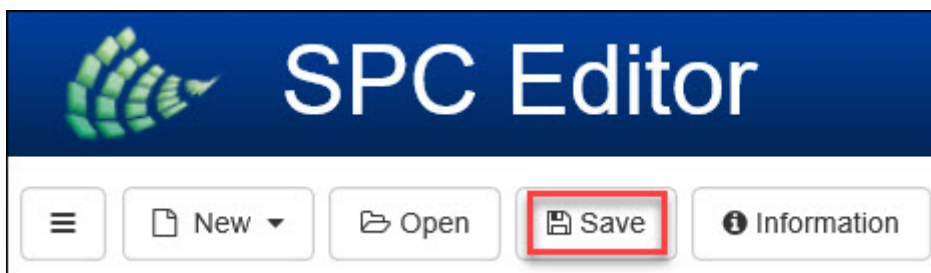
3. Exercise 2 (individual) - SPC for NA-MRS

1. Upload in the SPC Editor the SPC just saved and prepared for NA-APP by clicking 'Open' and selecting the file in the filing system.


2. Click on 'New' and select 'Market area version'.

3. From the options listed for the corresponding field, select 'Finland' as market area.

New: Market area version

Product UUID	813612cb-e11f-44b7-b539-5d206e92f231
* Product name	Disinfect Now
* Market area	Finland ▼
* Language	English ∨

OK Cancel

4. Once you have finished filling in the fields of the market area version, save the SPC on your PC.

SPC Editor

≡ ☐ New ▼ ▷ Open 🖫 Save ❶ Information
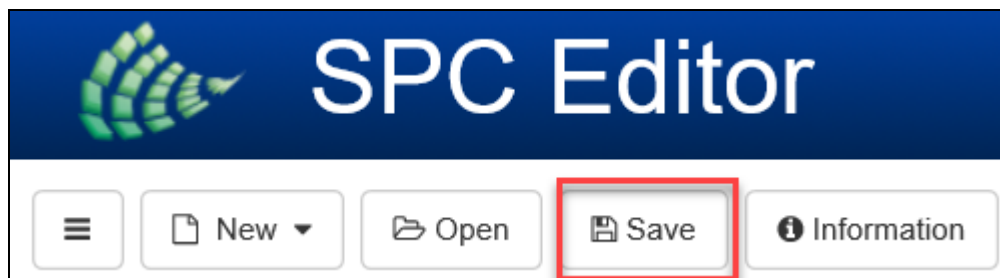
4. Exercise 3 (guided) – AS-APP

Introduction

The following flow chart serves as reference to indicate the various steps of an AS-APP process.
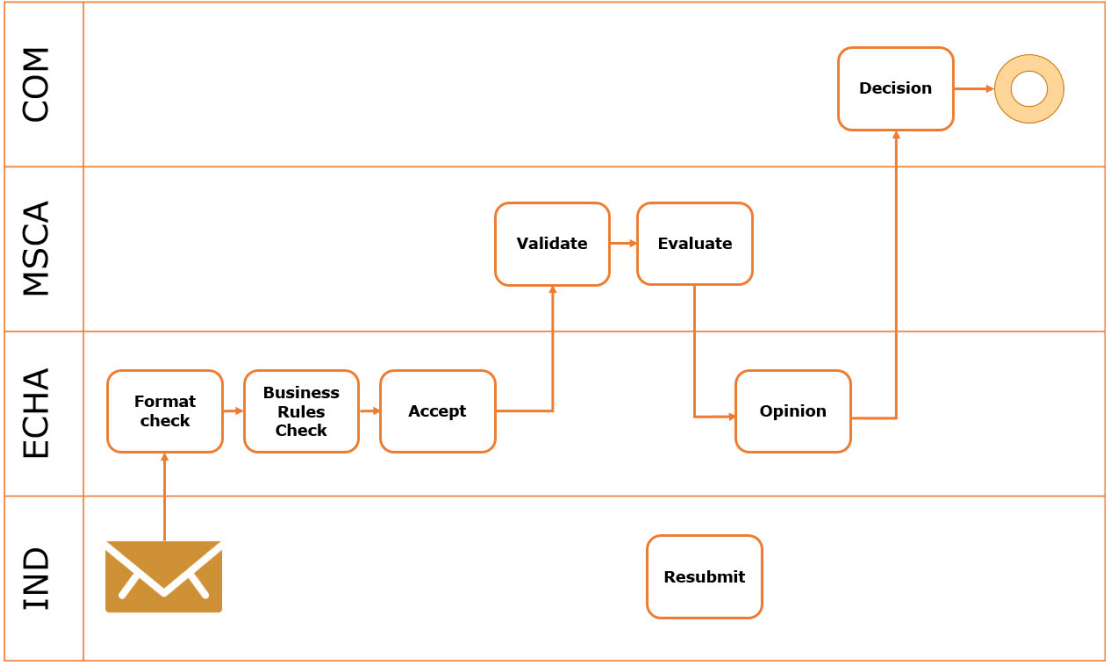
Application for approval of active substance (Italy)

> In order to proceed with the application, you should already have a IUCLID dossier (made available in advance for the exercise)

1. To access R4BP 3, copy and paste in your browser the URL of the industry testing environment that can be found in the "Credentials" file.

2. Enter the login credentials for the user of your company.

3. To start the wizard, click on 'New application' on the taskbar and select 'AS-APP – Application for approval of active substance' from the list of active substance processes.

4. Select a contact name from the drop-down list on the 'Set case owner details' page.

5. On the next screen (after clicking 'Next'), select 'Italy' as the evaluating authority.

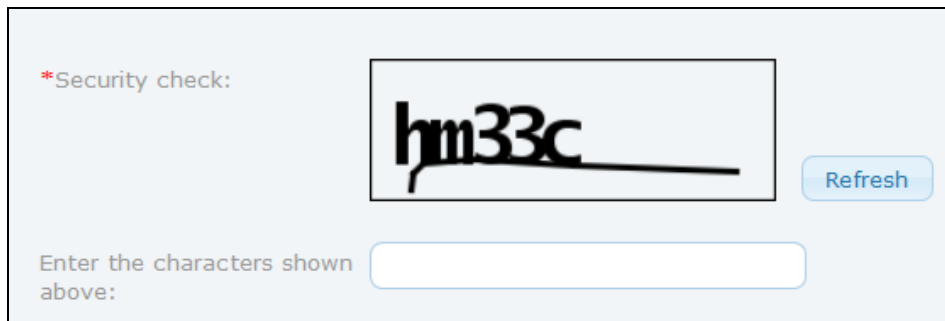6. At this stage it is not required to set a SME decision number. Go on to the next step.

7. Upload your IUCLID dossier, carrying out the following steps:

   a. Use the 'Browse' button to locate the file IUCLID provided and click 'Open';

   b. Click 'Upload' ;

   c. Select the language of the dossier (English).

8. No other files are needed to be uploaded at this stage. Go on to the last step step of the wizard.

9. As a final step, you can review all the information provided in the summary page 'Confirm application'. At the bottom of the page, there is a request to enter a graphical code in the appropriate field ('Security check').
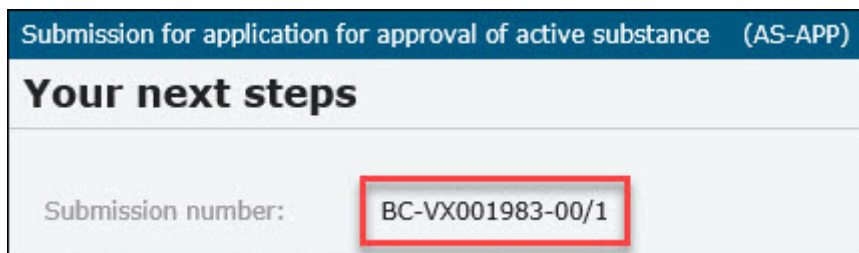

10. Once you have confirmed your submission, the screen will display the 'Submission number'. **Take note of the number in a separate file, as it is needed in subsequent phases**.


Processing of an application for the approval of an active substance as a competent authority (Italy)

Before proceeding with the evaluation of the application for authorisation by the competent authority, it is required that ECHA performs a check on the completeness of the dossier (format check and business rules check). In the context of this exercise, this task will be accomplished by the trainers, to focus the explanation on the details of the processes that directly affect authorities.

In this part of the exercise, **you are asked to take advantage of the opportunities of the test environment to try out the role of an evaluator**, by logging in to the system as if you were to make their assessments.

1. Access R4BP 3 as an Italian competent authority: copy and paste in your browser the URL that you will find in the document "Credentials" and enter your login details relating to the Italian competent authority.

2. Click on 'Tasks' in the taskbar and copy the previously saved case number in the 'Case number' field.
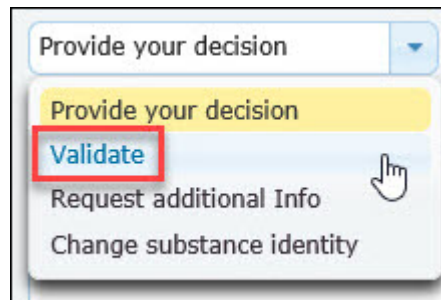
3. The 'Validate' task will appear in your list. Click on the hyperlink.
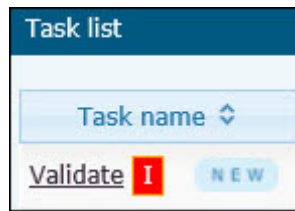
4. The task page will be opened. There you will see a series of icons – click on 'Start working'.
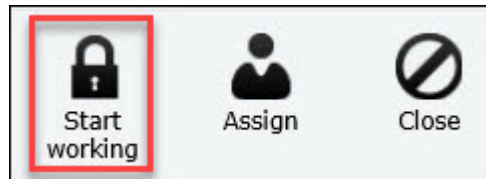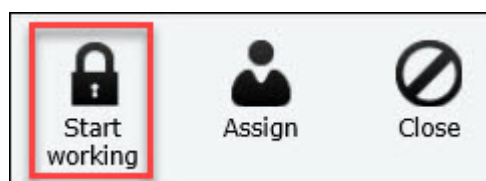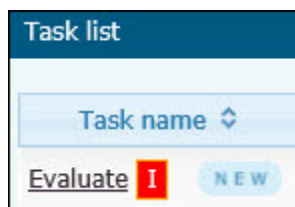

5. Proceed by selecting 'Validate' from the list of options and write a generic message in the 'Message' field.
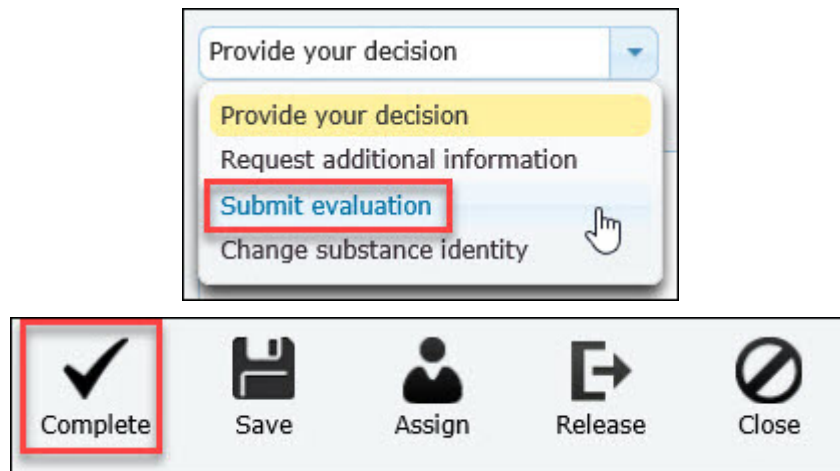

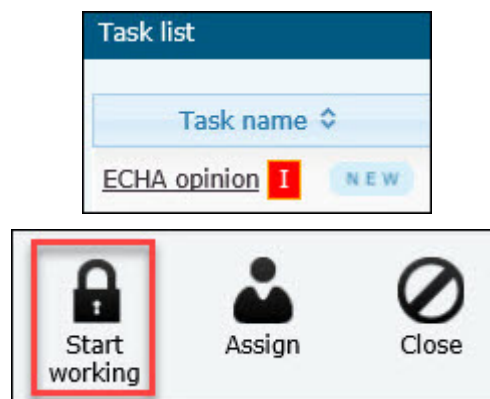
6. Click on 'Complete' to complete the task.

7. Click on 'Tasks' in the taskbar and enter the case number previously copied into the 'Case number' field. The task 'Evaluate' will appear in your list. Click on the hyperlink and 'Start working'.

8. Proceed by selecting 'Submit evaluation' from the list of options, write a generic message in the 'Message' field, and click on 'Complete'.

9. Now login as ECHA sat_rec_init. Click on 'Tasks' in the taskbar and copy the case number in the 'Case number' field. The task 'ECHA opinion' is now in your list. Click on the hyperlink and 'Start working'.
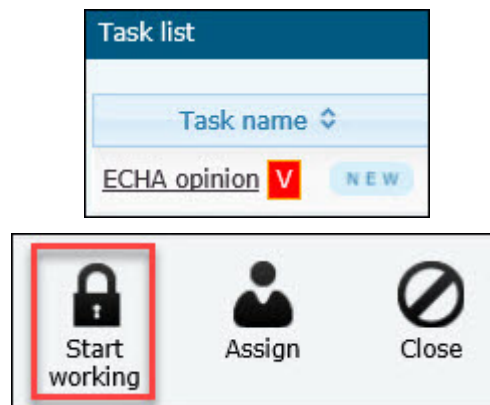

10. Proceed by selecting 'Submit opinion' from the list of options, write a generic message in the 'Message' field, and click on 'Complete'.
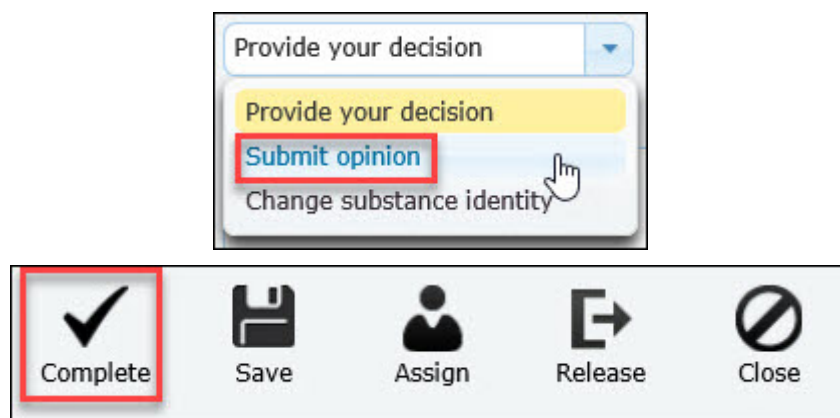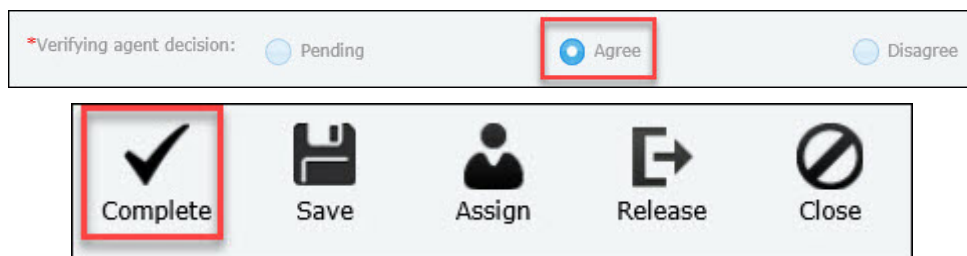

11. Login next as ECHA sat_rec_verif to verify the 'ECHA opinion' task. Click on 'Tasks' in the taskbar and copy the case number in the

'Case number' field. The task 'ECHA opinion' is now in your list. Click on the hyperlink and 'Start working'.

12. Proceed by selecting 'Agree' in the 'Verifying agent decision' step, and click on 'Complete'.

13. Finally login as the Commission. Click on 'Tasks' in the taskbar and copy the case number in the 'Case number' field. The task 'Commission decision' is now in your list. Click on the hyperlink and 'Start working'.
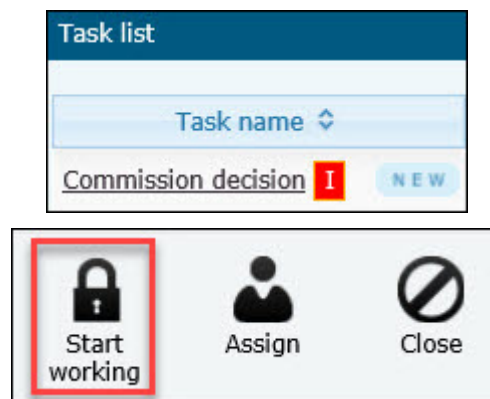
14. Proceed by selecting 'Approve' from the list of options, set the range of validity of the application (typically 10 years), and write a generic message in the 'Message' field. Use **Celex ID 32014R1062** where needed. Finally, click on 'Complete'.

15. Once you have completed the task, the active substance is approved. To verify the asset number, click on 'Cases' in the taskbar and enter the case number in the field provided. Search among closed-approved cases. The number of the asset will appear by clicking the hyperlink of the retrieved case. **Write the asset number down, as you will need it in the next steps.**

5. Exercise 4 (guided) – NA-APP

Introduction

The following flow chart serves as reference to indicate the various steps of a NA-APP process.
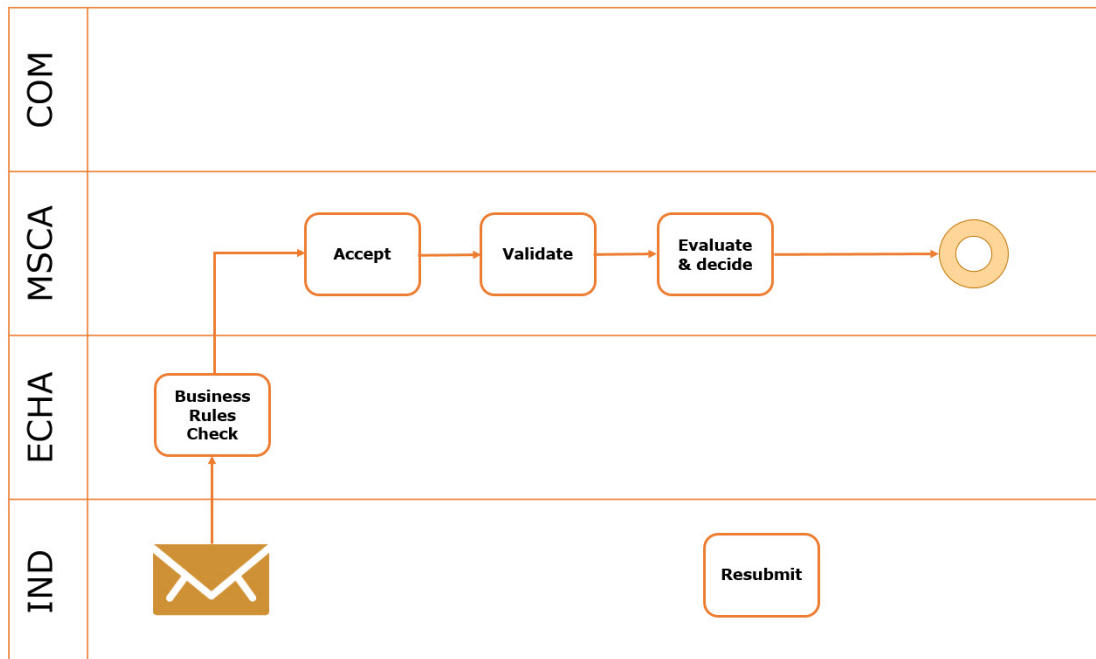
## Application for national authorisation (Italy)

In order to proceed with the application, you should already have a IUCLID dossier (made available in advance for the exercise) and a SPC file (created in Exercise 1)

1. To access R4BP 3, copy and paste in your browser the URL of the industry testing environment that can be found in the "Credentials" file.

2. Enter the login credentials for the user of your company.

3. To start the wizard, click on 'New application' on the taskbar and select 'NA-APP – Application for national autorisation' from the list of types of applications.
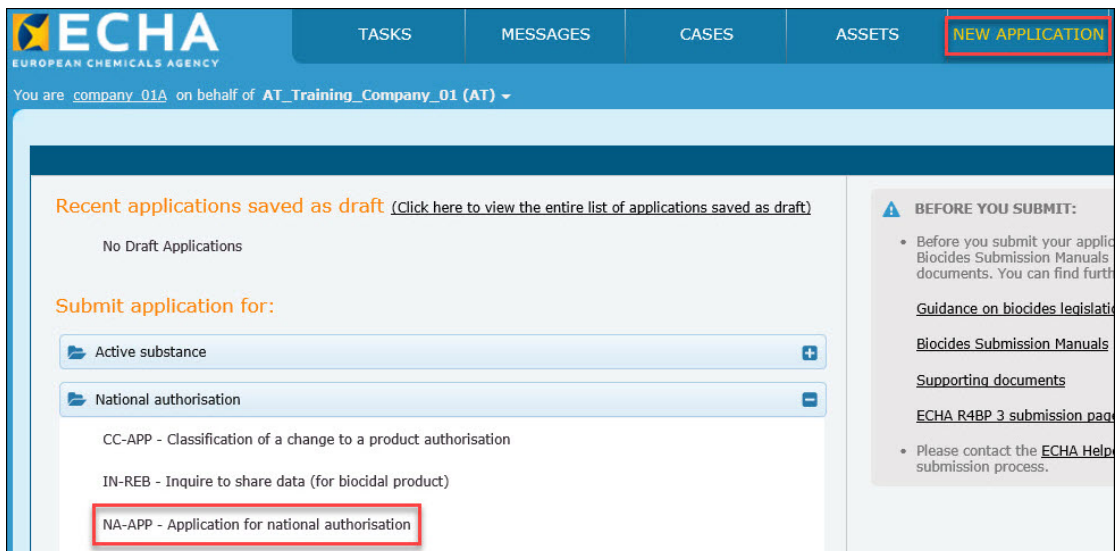
4. On the next screen (after clicking 'Next') select 'Italy' as the evaluating authority.
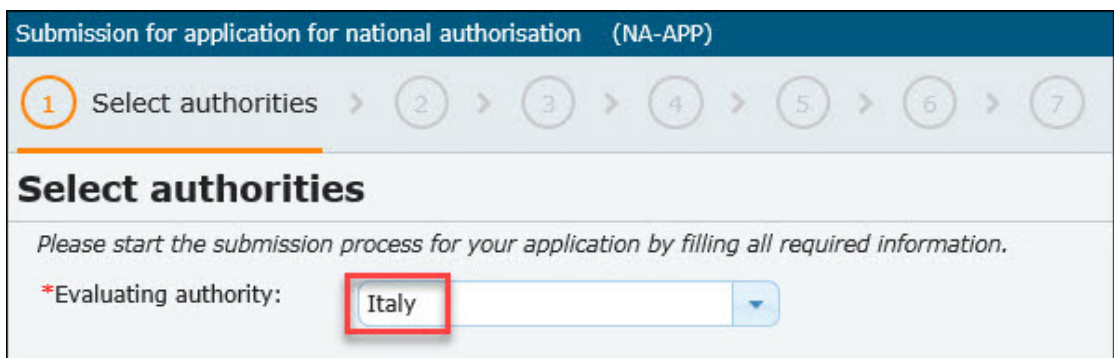
5. Select a contact name from the drop-down list on the 'Set case owner details' page.
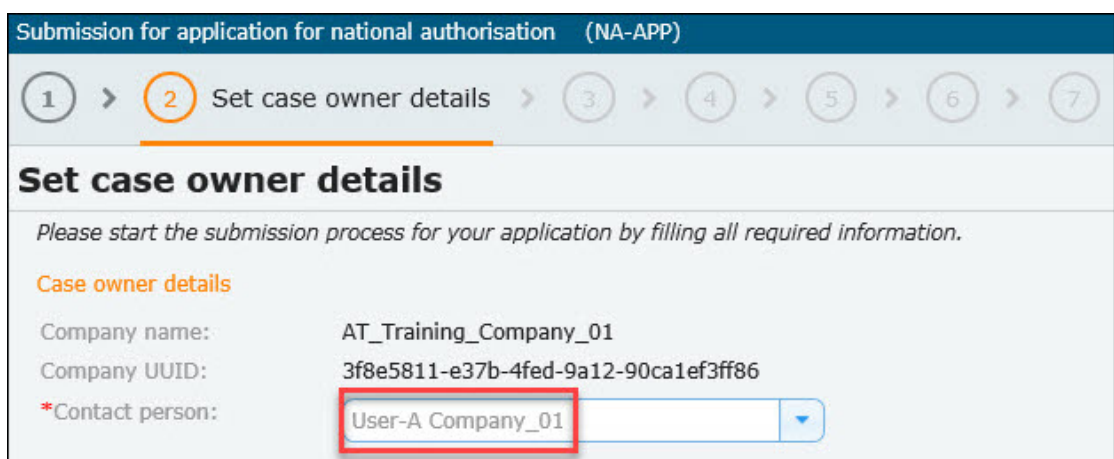
6. Set next the submission details:

   a. The evaluating authority, 'Italy', is selected by default;

   b. Check the 'Same as case owner' box under 'Asset owner details';

   c. Mark in the 'Billing address' field that the invoice will be paid by the asset owner.

7. Upload your IUCLID dossier, carrying out the following steps:

   d. Use the 'Browse' button to locate the file IUCLID provided and click 'Open';

   e. Click 'Upload' ;

   f. Select the language of the dossier (English).

8. Upload the SPC file that you created and saved on your PC in **exercise 1**, following the steps below:

   a. Use the 'Browse' button to locate the SPC file saved on your PC and click 'Open';

   b. Click 'Upload All'.

9. Upload the supporting document provided as course material, reporting a value for each of the fields prompted. We suggest to select 'General' for the type of document and 'English' as the language.

10. As a final step, you can review all the information provided in the summary page 'Confirm application'. At the bottom of the page, there is a request to enter a graphical code in the appropriate field ('Security check').

11. Once you have confirmed your submission, the screen will display the 'Submission number'. **Take note of the number in a separate file, as it is needed in subsequent phases**.

Processing of an application for national authorisation as a competent authority (Italy)

Before proceeding with the evaluation of the application for authorisation by the competent authority, it is required that ECHA performs a check on the completeness of the dossier (business rules check). In the context of this exercise, this task will be accomplished by the trainers, to focus the explanation on the details of the processes that directly affect authorities.

In this part of the exercise, **you are asked to take advantage of the opportunities of the test environment to try out the role of an evaluator**, by logging in to the system as if you were to make their assessments.

12. Access R4BP 3 as the Italian competent authority: copy and paste in your browser the URL that you will find in the document "Credentials" and enter your login details relating to Italian competent authority.

13. Click on 'Tasks' in the taskbar and copy the previously saved case number in the 'Case number' field.

14. The 'MSCA accept' task will appear in your list. Click on the hyperlink.
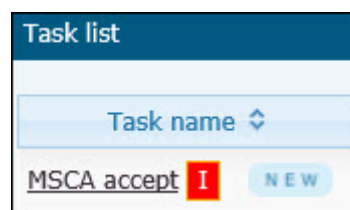
15. The task page will be opened. There you will see a series of icons – click on 'Start working'.
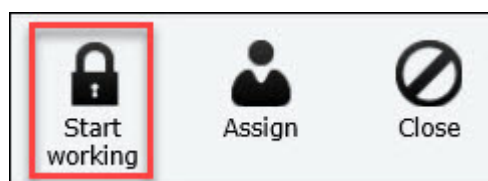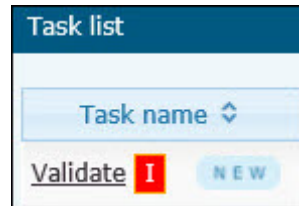

16. Proceed by clicking 'Accept' among the list of options, write a generic message in the 'message' field, and click on 'Complete'.
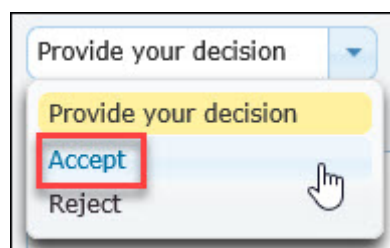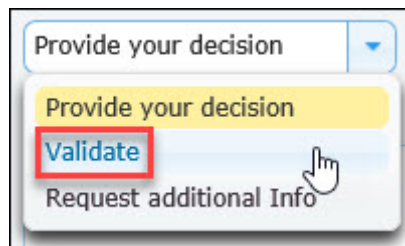
17. Click on 'Tasks' in the taskbar and enter the case number previously copied into the 'Case number' field.

18. The task 'Validate' will appear in your list. Click on the hyperlink and 'Start working'.

19. Proceed by selecting 'Validate' from the list of options, write a generic message in the 'Message' field, and click on 'Complete'.
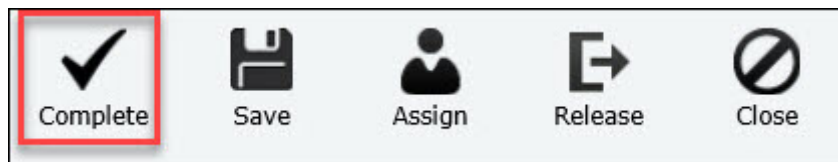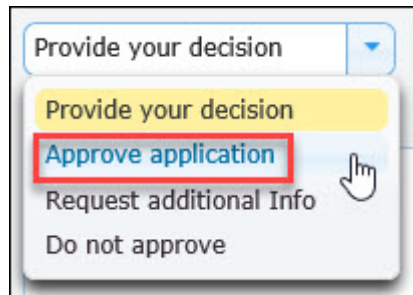

20. Click on 'Tasks' in the taskbar and enter the case number previously copied into the 'Case number' field.

21. The task 'Evaluate and decide' will appear in your list. Click on the hyperlink and 'Start working'.
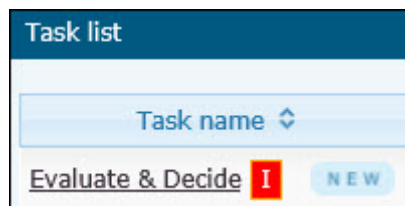
22. Proceed by selecting 'Approve application' from the list of options, set the range of validity of the application (typically 10 years), write a generic message in the 'Message' field, and click on 'Complete'.


23. Once you have completed the task, the authorisation is issued. To verify the asset number, click on 'Asset' in the taskbar and enter paste the case number in the field provided. The number of the asset will appear. **Write the asset number down, as you will need it in the next steps.**
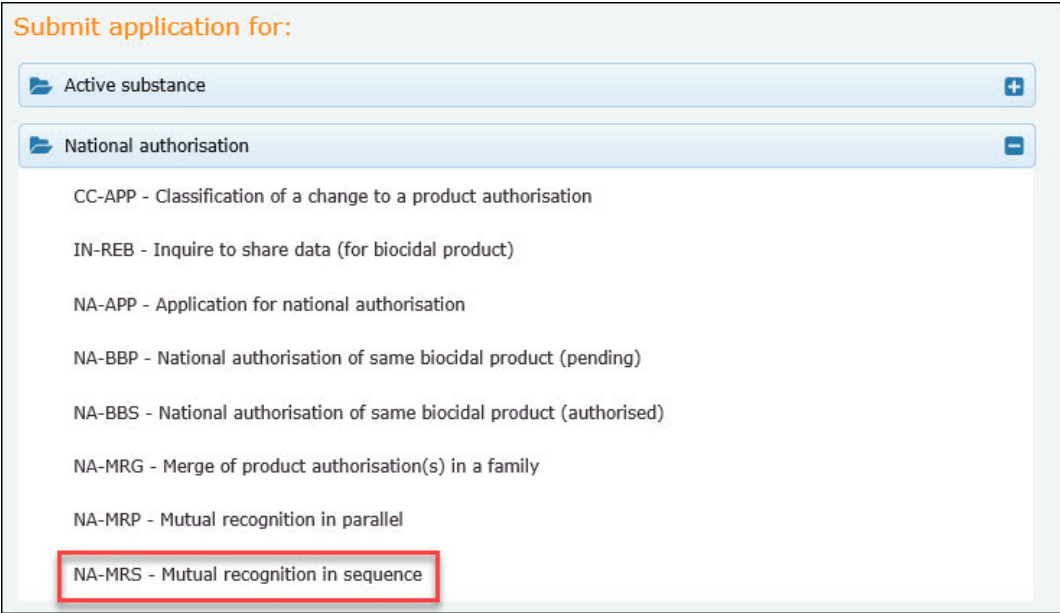
6. Exercise 5 (individual) – NA-MRS

Introduction

The following flow chart serves as reference to indicate the various steps of NA-MRS process.
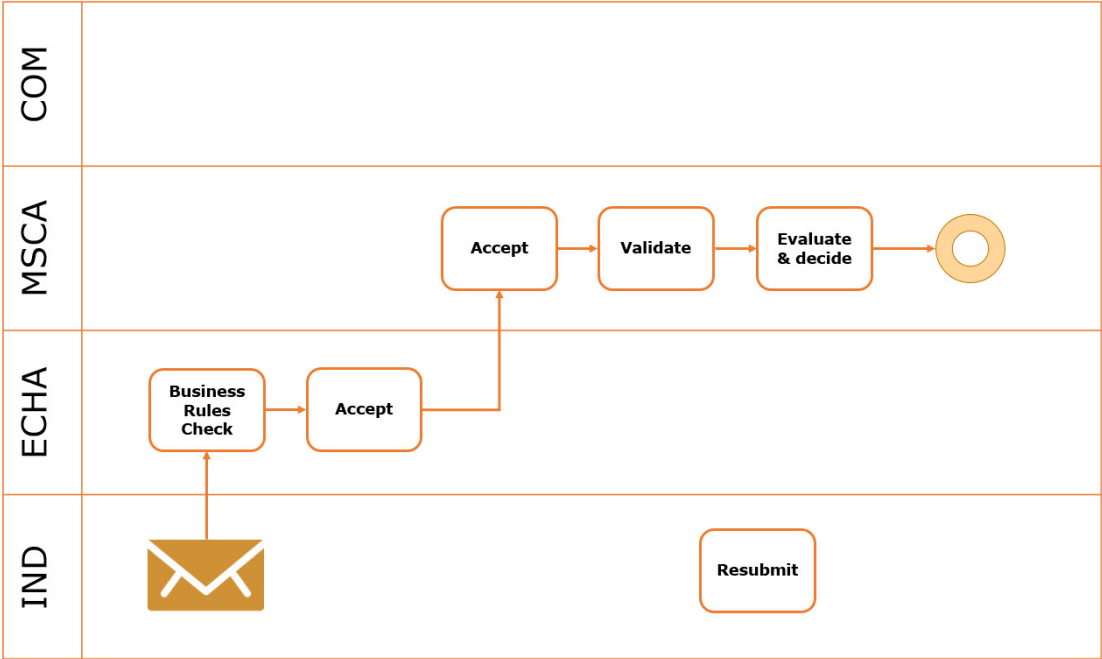
Application for mutual recognition in sequence (Finland)

1. To start the wizard, click on 'New Application' in the taskbar and select 'NA-MRS – Mutual recognition in sequence' from the list of types of applications.

2. R4BP 3 will ask you to insert a reference asset number: retrieve the asset number obtained in the National Authorisation in Italy, and enter it in the relevant field. Before proceeding, wait that the system message "Asset number provided is validated successfully".

3. In the 'Set case owner details' page insert the same information as indicated in **step 5 of exercise 4** (NA-APP).

4. In the 'Set submission details' page select 'Finland' as evaluating authority. Check the 'Same as case owner' box under 'Asset owner details' and mark in the 'Billing address' field that the invoice will be paid by the asset owner.

5. Upload the SPC valid in the market area 'Finland' you prepared in **exercise 2**. To do this, follow the steps described in **step 8 of exercise 4**.

6. To submit your application, follow **steps 9 to 11 of exercise 4** and, once you have finished, save the case number generated at the end of the process.

Processing of an application for mutual recognition in sequence as a competent authority (Finland)

Before proceeding with the evaluation of the application for authorisation by the competent authority, it is required that ECHA performs a check on the completeness of the dossier (business rules check). In the context of this exercise, this task will be accomplished by the trainers, to focus the explanation on the details of the processes that directly affect authorities.

7. Login R4BP 3 as a Finnish competent authority: you will find the user ID and password in the document "Credentials" distributed at the beginning of the course.

8. To perform the Accept, Validate and Evaluate tasks, carry out **steps 12 to 23 of exercise 4**.

9. Complete the case and take note of the case number.

Annex I – Graphical user interface elements

*	Indicates that a field is mandatory.
⚠	Indicates that an SPC section or field is invalid.
✓	Indicates that an SPC section or field is complete and valid.
+ Add ❯	Adds a new SPC section (meta SPC, authorised use, product).
✎ Edit name ❐ Duplicate ❯ ✖ Delete	Edit name – Edits the name of an SPC section (family, meta SPC, authorised use, product). Duplicate – Creates a duplicate of an existing SPC section, including all section data. Delete – Deletes an existing SPC section.
+ Add Trade name	Add Trade name – Adds a new field set.
✖ Delete	Delete – Deletes the specific field set.
∧ Move up	Move up – Moves the specific field set higher.
∨ Move down	Move down – Moves the specific field set lower.
⬆ Export XML	Export XML – Exports a specific field set to an XML file so than it can be imported in an active SPC into the SPC Editor.
⬇ Import XML	Import XML – Imports a field set that has been saved as an XML file into the current SPC.
🔒	Denotes that the current SPC is locked for editing since it is a final version authorised by an evaluating competent authority or the Commission (eCA or COM) in R4BP 3. The SPC can be nevertheless used to create a draft SPC.

Biocides Submission Manual (BSM) technical guides on ECHA's website

Manual: How to prepare a biocides dossier

https://echa.europa.eu/documents/10162/14938692/bpr_guide_preparing_dossier_en.pdf/f4187939-595d-40c2-9568-d1a0d3111b63

Technical guide: using R4BP 3

https://echa.europa.eu/documents/10162/14938692/bsm_02_using_r4bp3_en.pdf/48647153-4bdd-484b-ae2e-81457536be5b

Technical guide: using the SPC Editor

https://echa.europa.eu/documents/10162/14938692/bsm_using_spc_editor_en.pdf/4b3fe971-bfdd-450b-95f0-899d16518331