

**Biocides IT training
Helsinki – 25 October 2018**

R4BP 3.11 and SPC 2.3

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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

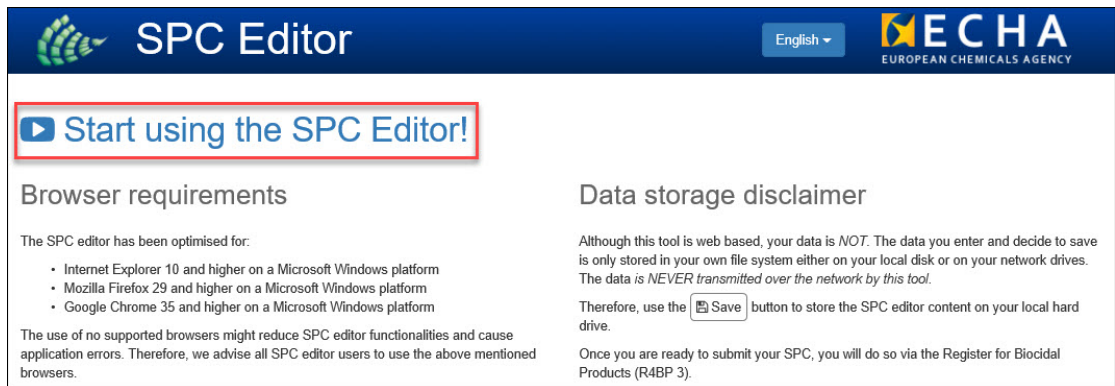
This manual lists the key points to keep in mind when running exercises 1 to 5, both in guided mode and in individual mode.

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.



SPC Editor English ECHA EUROPEAN CHEMICALS AGENCY

▶ Start using the SPC Editor!

Browser requirements


The SPC editor has been optimised for:

- Internet Explorer 10 and higher on a Microsoft Windows platform
- Mozilla Firefox 29 and higher on a Microsoft Windows platform
- Google Chrome 35 and higher on a Microsoft Windows platform

The use of no supported browsers might reduce SPC editor functionalities and cause application errors. Therefore, we advise all SPC editor users to use the above mentioned browsers.

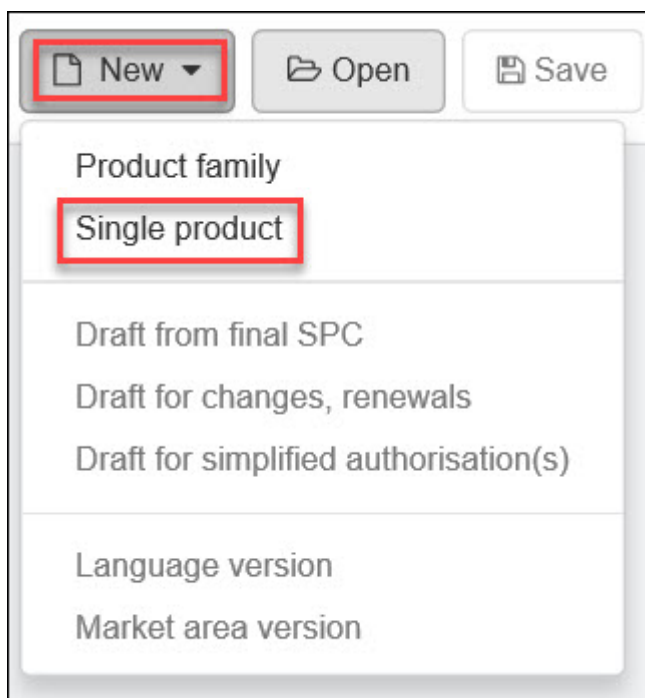
Data storage disclaimer

Although this tool is web based, your data is *NOT*. The data you enter and decide to save is only stored in your own file system either on your local disk or on your network drives. The data is *NEVER transmitted over the network by this tool*.

Therefore, use the  Save button to store the SPC editor content on your local hard drive.

Once you are ready to submit your SPC, you will do so via the Register for Biocidal Products (R4BP 3).

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



New Open Save

Product family

Single product

Draft from final SPC

Draft for changes, renewals

Draft for simplified authorisation(s)

Language version

Market area version

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).

New: Single product

| | |
|----------------|---------------|
| Product UUID | NEW |
| * Product name | Disinfect Now |
| * Market area | Italy |
| * Language | English |

OK Cancel

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'.

Disinfect Now

Product information

H & P statements

Authorised uses

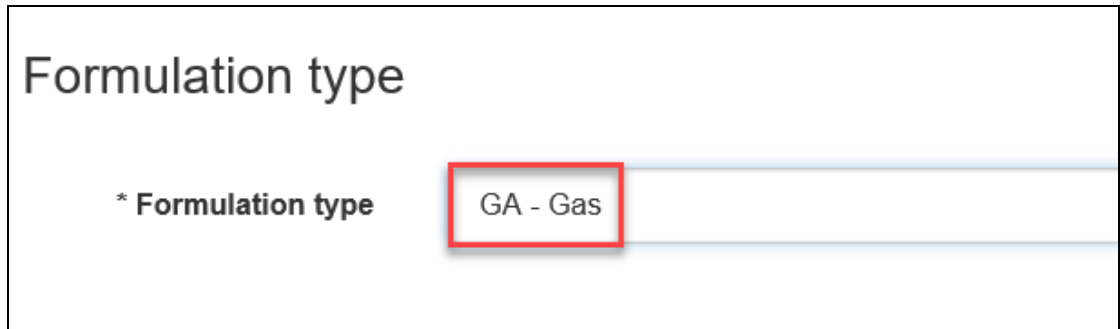
Use

Directions for use

Administrative information

Other information

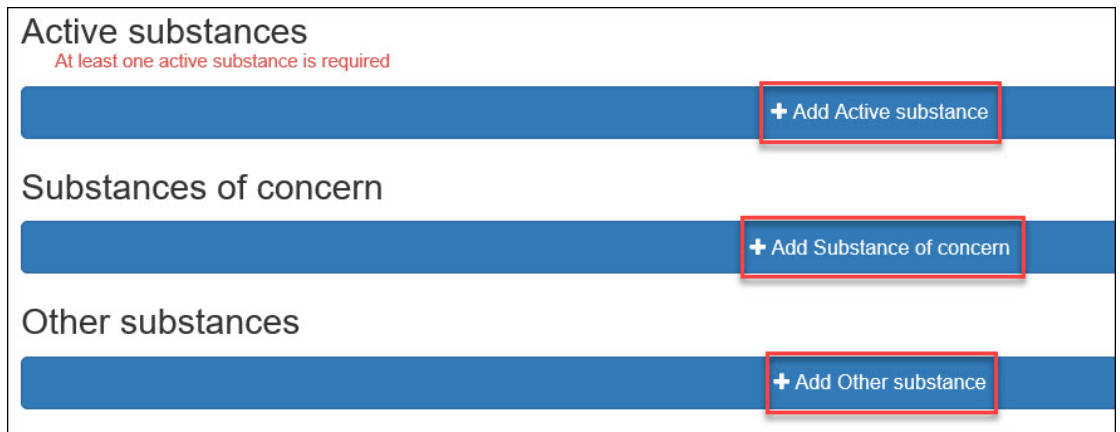
5. Select 'GA – Gas' as the formulation type.



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)

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

The screenshot shows the 'Disinfect Now' product page in 'Italy English'. The sidebar on the left has 'Administrative information' selected. The main content area is titled 'Manufacturers of the product' and contains two input fields: '* Name of the manufacturer' and '* Address'.

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

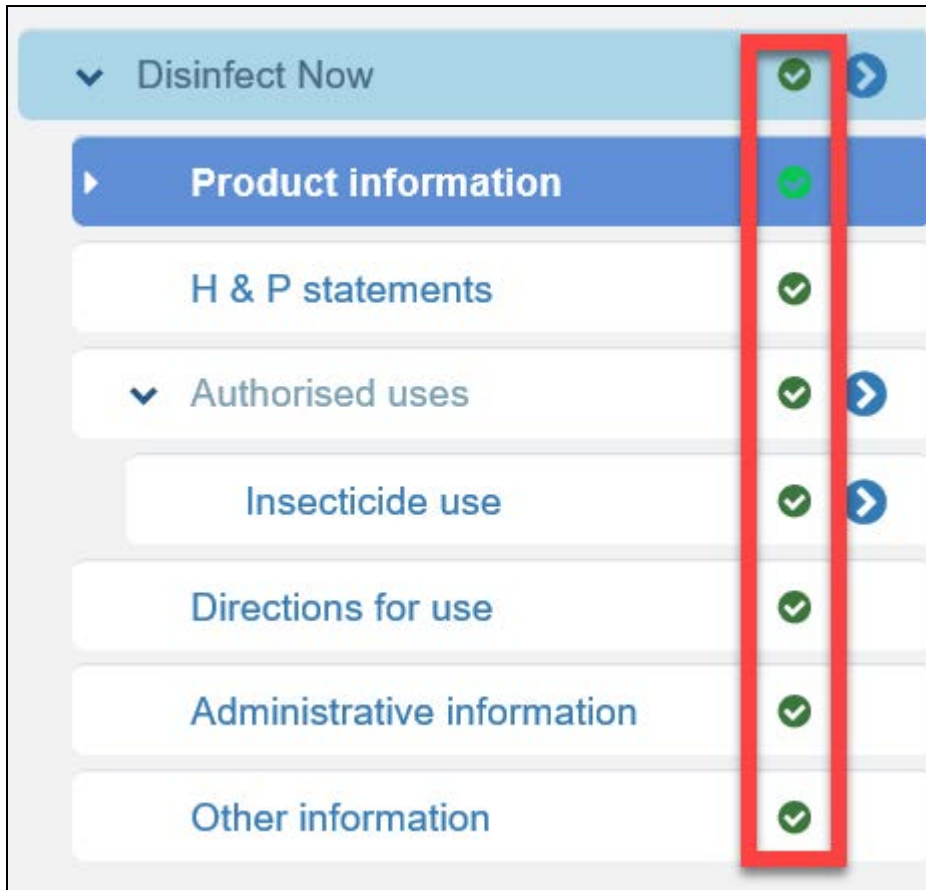
The screenshot shows the 'Disinfect Now' product page in 'Italy English'. The sidebar on the left has 'Disinfectant use' selected under 'Authorised uses'. The main content area shows the 'Disinfectant use' section with the following fields filled: '* Title for use' (Disinfectant use), 'Product type(s)' (PT05 - Drinking water (Disinfectants)), and '* Where relevant, an exact description of the authorised use' (TBD).

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

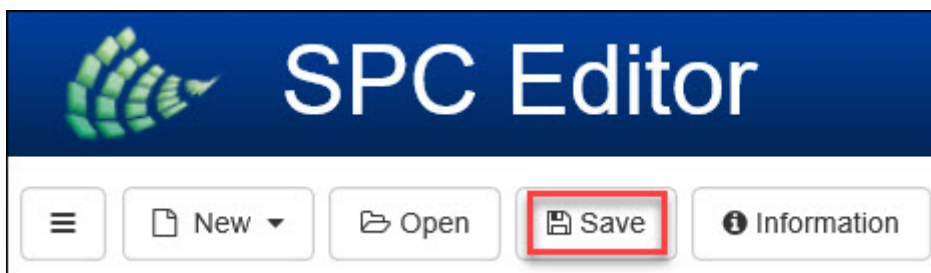
You can simply write "TBD" (to be decided) in the first field and then copy and paste this into all those where it is needed to obtain a 'valid and complete' checkmark for each field of the sidebar. Please note that the objective of this exercise is to understand how to produce a file that

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,

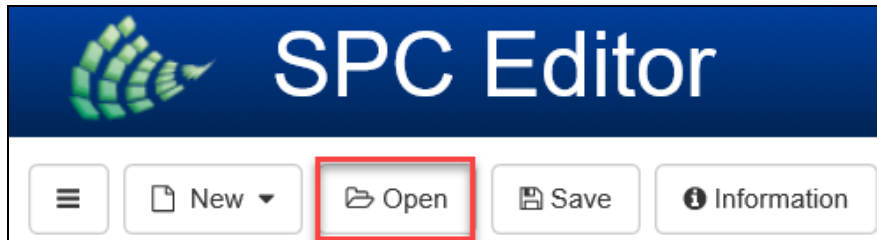


save the SPC on your PC.

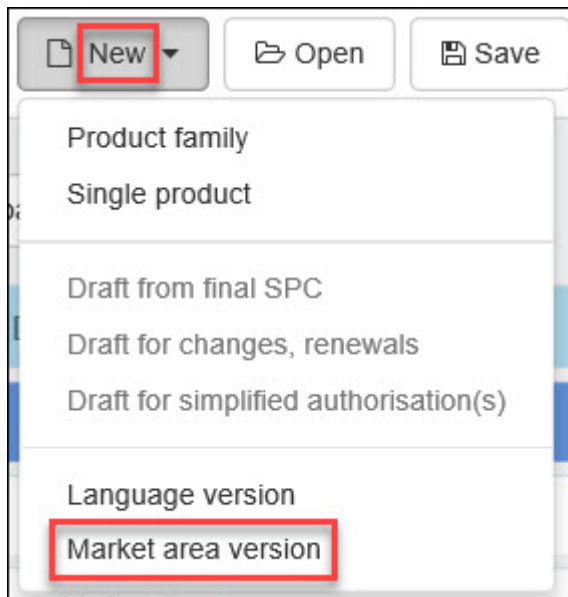


3. Exercise 2 (individual) - SPC for NA-MRS

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'.



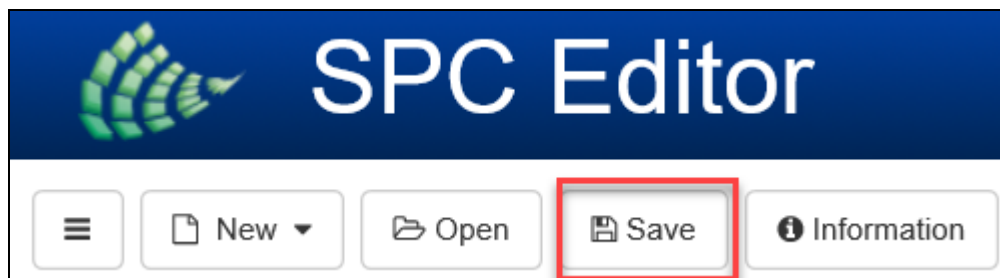
3. From the options listed for the corresponding field, select 'Finland' as market area.

New: Market area version

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

OK Cancel

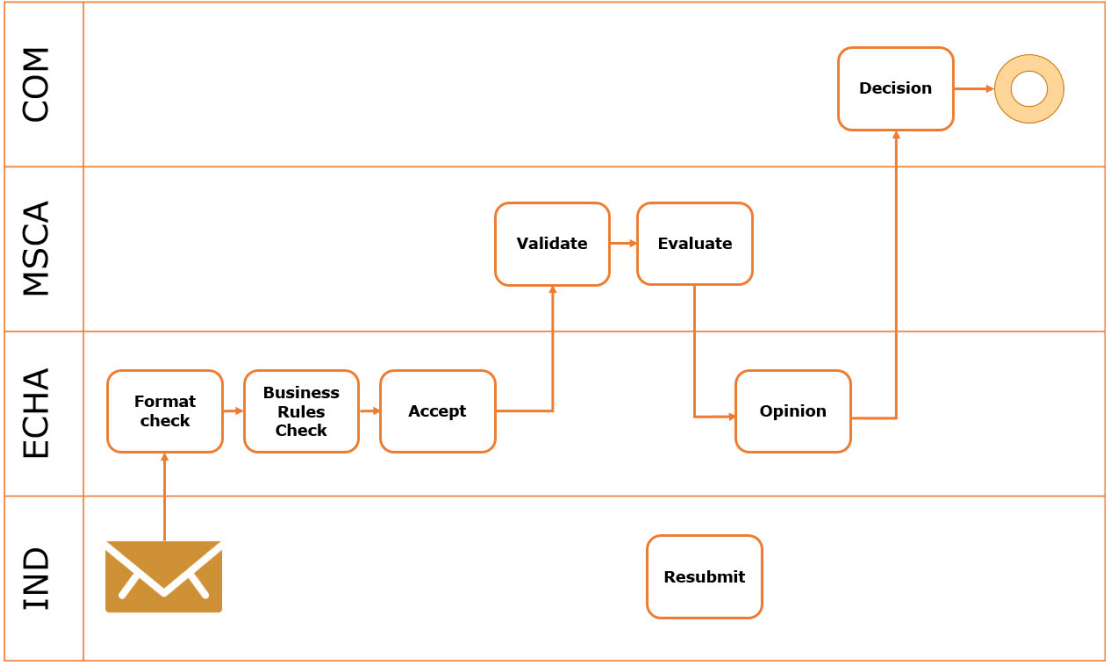
4. Once you have finished filling in the fields of the market area version, save the SPC on your PC.



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)

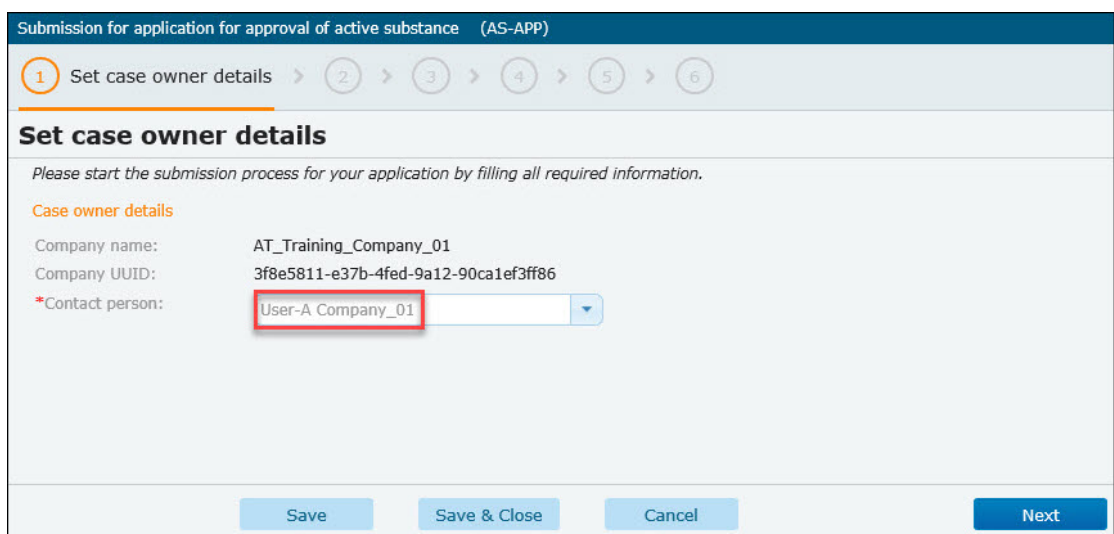
In order to proceed with the application, you should already have a IUCLID dossier (made available in advance for the exercise)

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.

- 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.



- 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.

The screenshot shows the 'Set submission details' screen in the AS-APP system. The title bar reads 'Submission for application for approval of active substance (AS-APP)'. A progress bar at the top indicates six steps, with step 2, 'Set submission details', highlighted in orange. Below the progress bar, the heading 'Set submission details' is displayed. A sub-heading reads 'Please fill in the submission details.' The main content area contains a dropdown menu for '*Evaluating authority:' with 'Italy' selected and highlighted by a red box. Below this, under the heading 'Payment details', there is a text input field for 'Purchase order:'. At the bottom of the screen, there are five buttons: 'Previous', 'Save', 'Save & Close', 'Cancel', and 'Next'.

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

The screenshot shows the 'Set SME decision number' screen in the AS-APP system. The title bar reads 'Submission for application for approval of active substance (AS-APP)'. A progress bar at the top indicates six steps, with step 3, 'Set SME decision number', highlighted in orange. Below the progress bar, the heading 'Set SME decision number' is displayed. A sub-heading reads 'Small and medium-sized enterprises established in the European Union can benefit from reduced fees under the BPR provided that certain conditions are met. If SME status has been recognised by ECHA, then include the SME asset number in this step, or go straight to 'next''. The main content area contains a text input field for 'SME asset number:'. At the bottom of the screen, there are five buttons: 'Previous', 'Save', 'Save & Close', 'Cancel', and 'Next', with the 'Next' button highlighted by a red box.

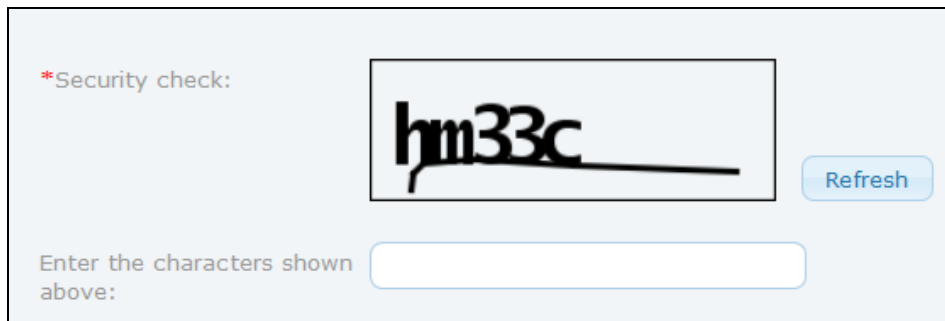
7. Upload your IUCLID dossier, carrying out the following steps:
 - a. Use the 'Browse' button to locate the file IUCLID provided and click 'Open';
 - b. Click 'Upload' ;
 - c. Select the language of the dossier (English).

The screenshot shows the 'Upload dossier' step of the 'Submission for application for approval of active substance (AS-APP)' wizard. The progress bar at the top indicates that step 4 is the current step. The main heading is 'Upload dossier'. Below the heading, there is a text instruction: 'Please upload below your file which contains your dossier (your file should have been created using IUCLID 6 and have an extension .i6z). Please make sure that you don't upload encrypted/password protected files.' Below this instruction is a text box containing the message 'No file(s) found. Please choose a file to upload.' Underneath the text box is a control bar with three buttons: '+ Browse', 'Upload', and 'Cancel'. Below the control bar is a file list area showing one file: 'IUCLID_dossier_active_substance_application.i6z' with a size of '76.9 K B'. To the right of the file name is a small 'x' icon. Below the file list is a note: 'File names should not contain special characters' with a question mark icon. At the bottom of the form are five buttons: 'Previous', 'Save', 'Save & Close', 'Cancel', and 'Next'.

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

The screenshot shows the 'Upload other files' step of the 'Submission for application for approval of active substance (AS-APP)' wizard. The progress bar at the top indicates that step 5 is the current step. The main heading is 'Upload other files'. Below the heading, there is a text instruction: 'Please upload any additional documents you would like to submit with your application'. Below this instruction is a text box containing the message 'No file(s) found. Please choose a file to upload.' Underneath the text box is a control bar with three buttons: '+ Browse', 'Upload All', and 'Cancel All'. Below the control bar is a note: 'File names should not contain special characters' with a question mark icon. At the bottom of the form are five buttons: 'Previous', 'Save', 'Save & Close', 'Cancel', and 'Next'. The 'Next' button is highlighted with a red border.

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').

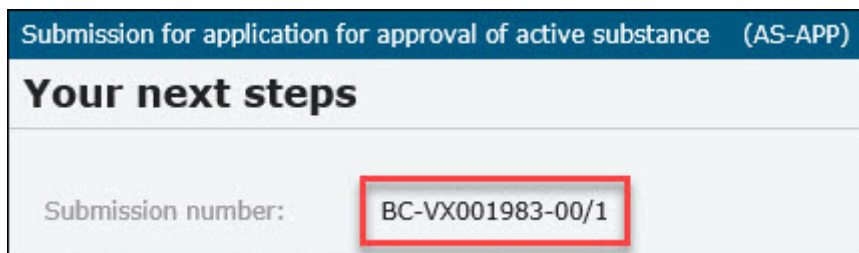


*Security check:

hm33c Refresh

Enter the characters shown above:

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.**



Submission for application for approval of active substance (AS-APP)

Your next steps

Submission number: BC-VX001983-00/1

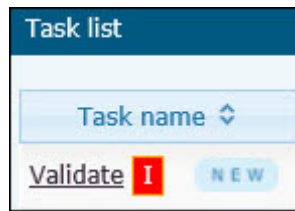
Processing of an application for the approval of an active substance as a competent authority (Italy)

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.

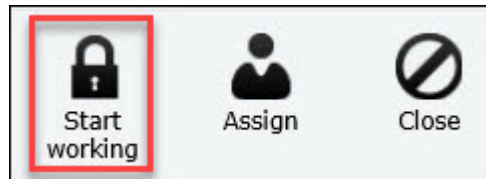
In this part of the exercise, **you are asked to take advantage of the opportunities of the test environment to try out the role of an evaluator**, by logging in to the system as if you were to make their assessments.

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.

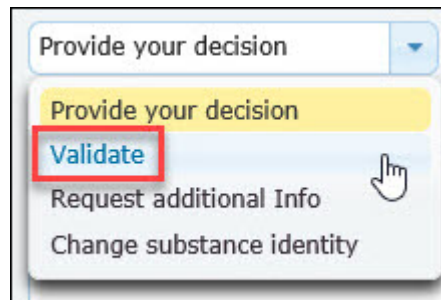
3. The 'Validate' task will appear in your list. Click on the hyperlink.



4. The task page will be opened. There you will see a series of icons – click on 'Start working'.



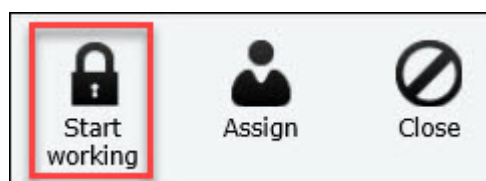
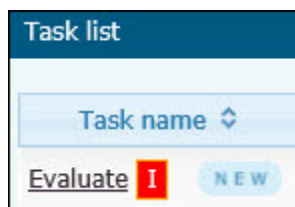
5. Proceed by selecting 'Validate' from the list of options and write a generic message in the 'Message' field.



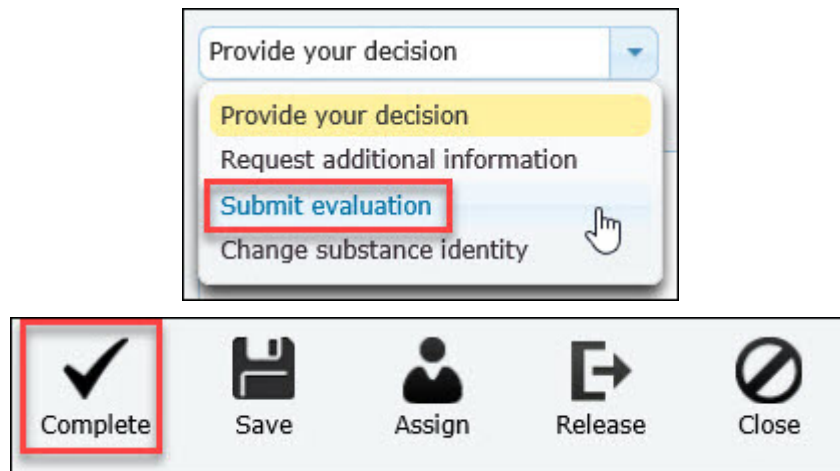
6. Click on 'Complete' to complete the task.



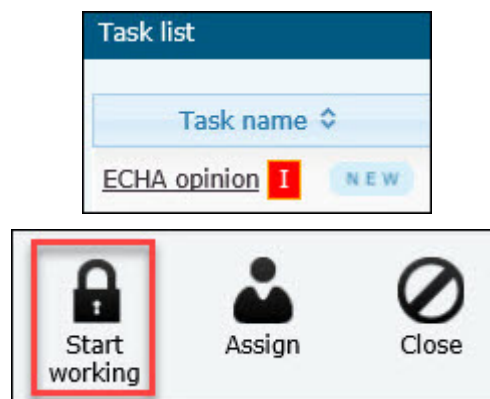
7. Click on 'Tasks' in the taskbar and enter the case number previously copied into the 'Case number' field. The task 'Evaluate' will appear in your list. Click on the hyperlink and 'Start working'.



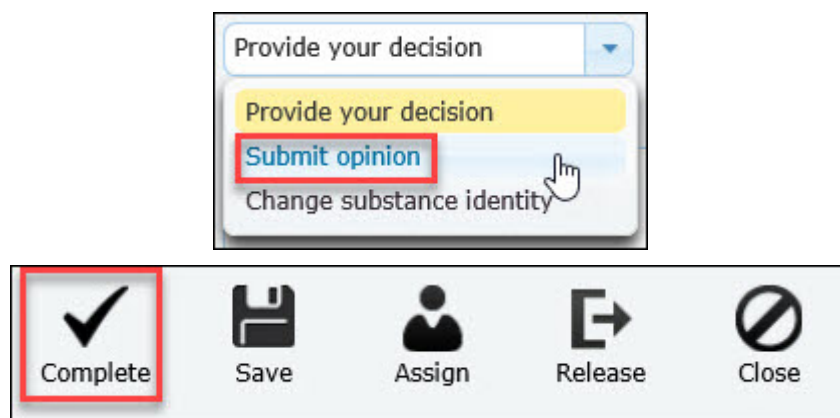
8. Proceed by selecting 'Submit evaluation' from the list of options, write a generic message in the 'Message' field, and click on 'Complete'.



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'.

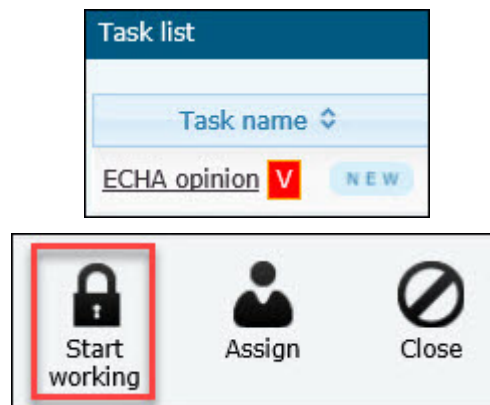


10. Proceed by selecting 'Submit opinion' from the list of options, write a generic message in the 'Message' field, and click on 'Complete'.

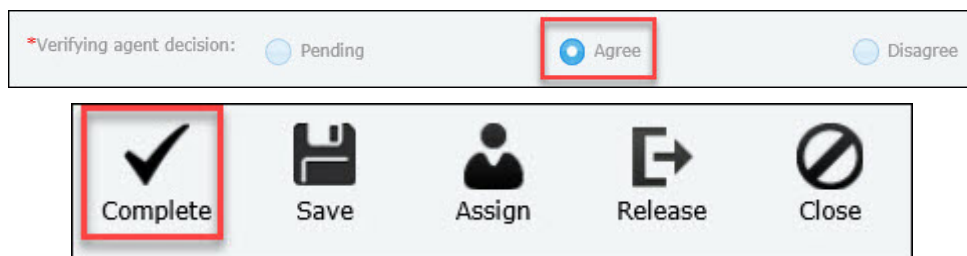


11. Login next as [ECHA sat_rec_verif](#) to verify the 'ECHA opinion' task. Click on 'Tasks' in the taskbar and copy the case number in the

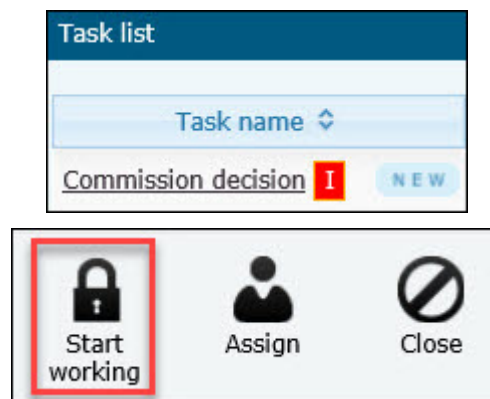
'Case number' field. The task 'ECHA opinion' is now in your list. Click on the hyperlink and 'Start working'.



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'.

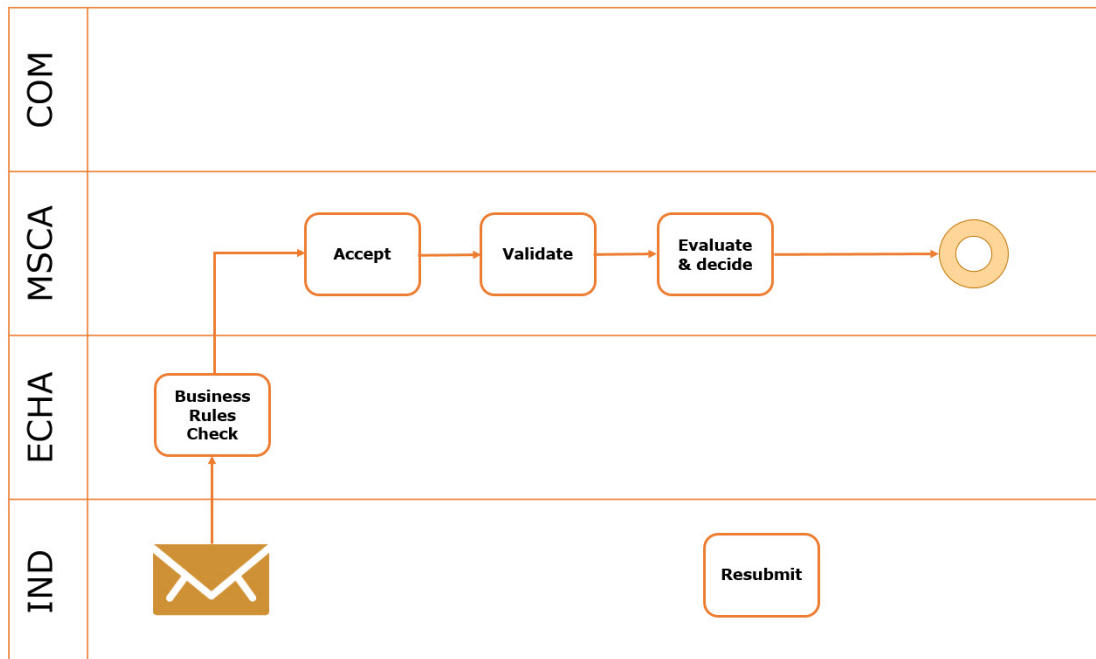


15. Once you have completed the task, the active substance is approved. To verify the asset number, click on 'Cases' in the taskbar and enter the case number in the field provided. Search among closed-approved cases. The number of the asset will appear by clicking the hyperlink of the retrieved case.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

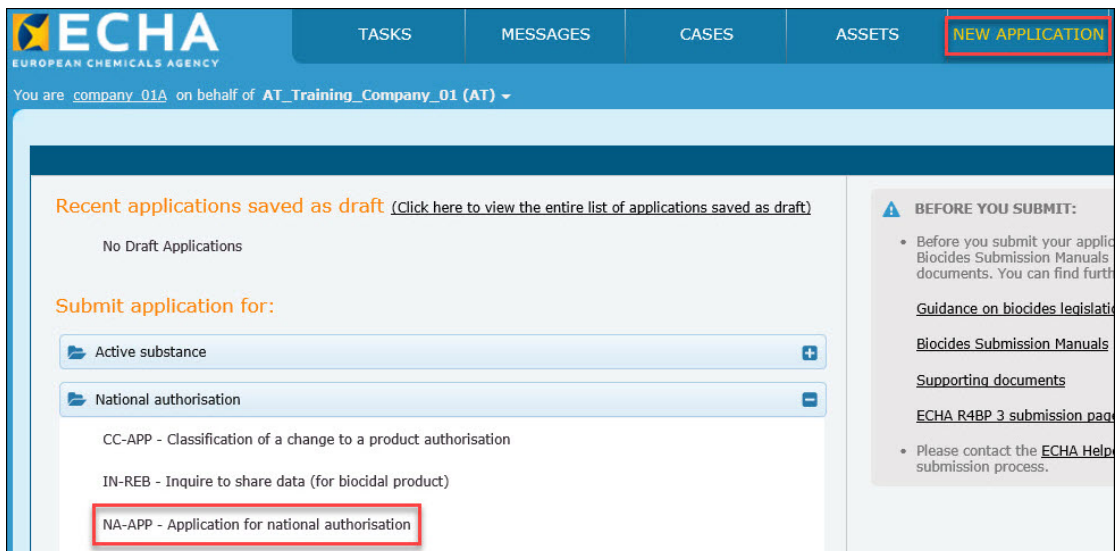


Application for national authorisation (Italy)

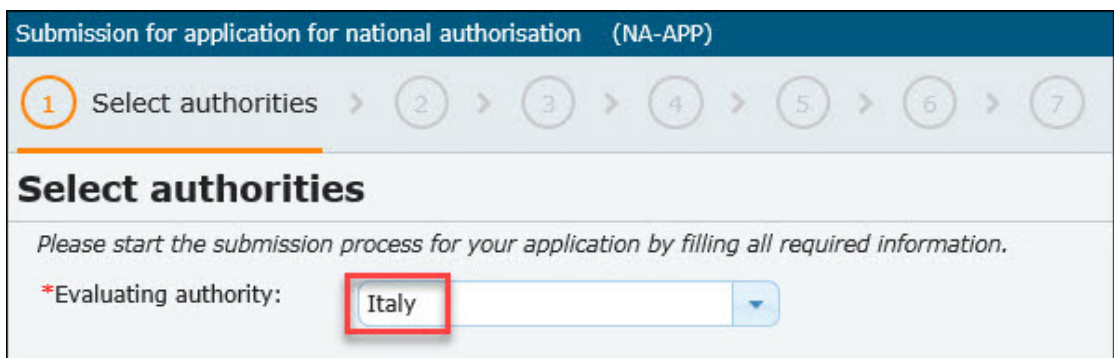
In order to proceed with the application, you should already have a IUCLID dossier (made available in advance for the exercise) and a SPC file (created in Exercise 1)

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.

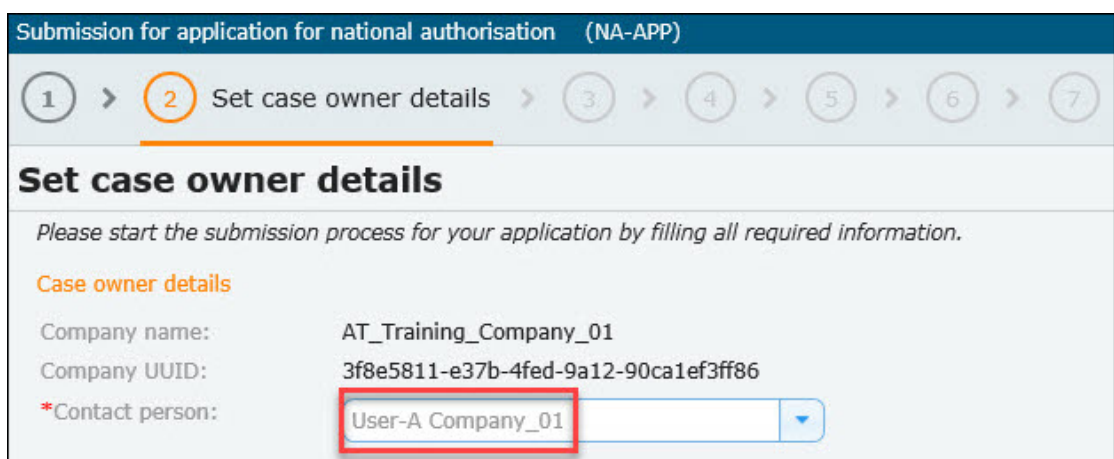
- To start the wizard, click on 'New application' on the taskbar and select 'NA-APP – Application for national autorisation' from the list of types of applications.



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



- 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.

Submission for application for national authorisation (NA-APP)

1 > 2 > 3 Set submission details > 4 > 5 > 6 > 7

Set submission details

Please fill in the submission details.

*Evaluating authority: Italy

Asset owner details: Same as case owner

*Company UUID: 3f8e5811-e37b-4fed-9a12-90ca1ef3ff86

Company name: AT_Training_Company_01

Payment details

Purchase order:

* Billing address: Case owner 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).

Submission for application for national authorisation (NA-APP)

1 > 2 > 3 > **4** Upload dossier > 5 > 6 > 7

Upload dossier

Please upload below your file which contains your dossier (your file should have been created using IUCLID 6 and have an extension .i6z). Please make sure that you don't upload encrypted/password protected files.

No file(s) found. Please choose a file to upload.

| | | | |
|--|---------|----------------------|----------------------------------|
| IUCLID_dossier_product_authorisation.i6z | 76.8 KB | <input type="text"/> | <input type="button" value="x"/> |
|--|---------|----------------------|----------------------------------|

File names should not contain special characters ?

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.

The screenshot shows a web interface for a submission. At the top, a blue header reads 'Submission for application for national authorisation (NA-APP)'. Below it is a breadcrumb trail with steps 1 through 7. Step 6, 'Upload other files', is highlighted with an orange circle. The main heading is 'Upload other files'. Below this is a sub-heading: 'Please upload any additional documents you would like to submit with your application'. There are two rows of controls. The first row has a dropdown menu with 'General' selected (highlighted with a red box), a 'Select language' dropdown, and a file name 'SUPPORTING DOCUMENT.pdf' with a trash icon. The second row has three buttons: '+ Browse' (highlighted with a red box), 'Upload All' (highlighted with a red box), and 'Cancel All'.

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').

The screenshot shows a 'Security check' section. It features a red asterisk and the text '*Security check:'. To the right is a box containing the 'eygee' logo. Below the logo is a 'Refresh' button. Underneath, the text 'Enter the characters shown above:' is followed by an empty input field.

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.**

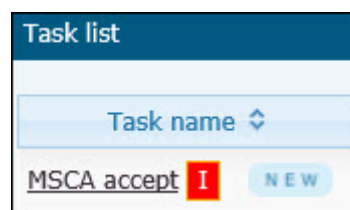
The screenshot shows a section titled 'Your next steps' under the same header as the previous screenshot. It contains two rows of information. The first row is 'Submission number:' followed by the value 'BC-WK002003-50/1', which is highlighted with a red box. The second row is 'Evaluating country:' followed by the value 'MSCA-Italy'.

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

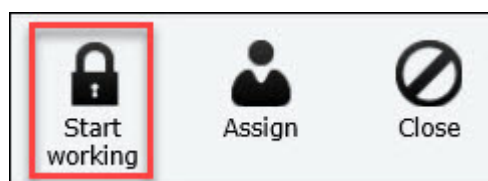
Before proceeding with the evaluation of the application for authorisation by the competent authority, it is required that ECHA performs a check on the completeness of the dossier (business rules check). In the context of this exercise, this task will be accomplished by the trainers, to focus the explanation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

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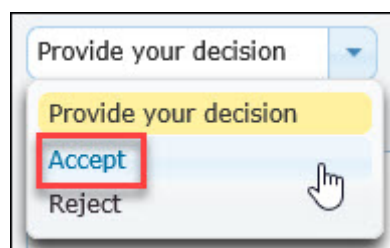
12. Access R4BP 3 as the Italian competent authority: copy and paste in your browser the URL that you will find in the document "Credentials" and enter your login details relating to Italian competent authority.
13. Click on 'Tasks' in the taskbar and copy the previously saved case number in the 'Case 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'.

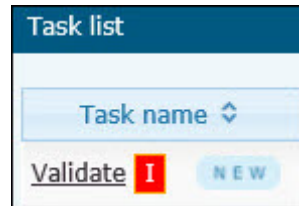


16. Proceed by clicking 'Accept' among the list of options, write a generic message in the 'message' field, and click on 'Complete'.

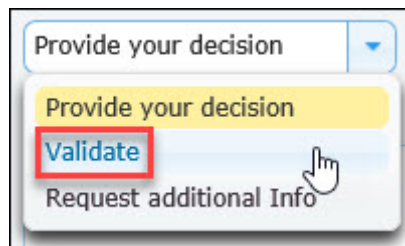




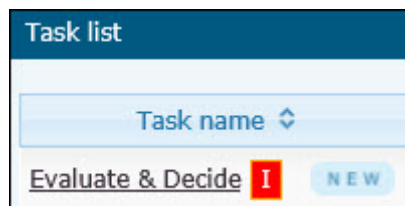
17. Click on 'Tasks' in the taskbar and enter the case number previously copied into the 'Case number' field.
18. The task 'Validate' will appear in your list. Click on the hyperlink and 'Start working'.



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

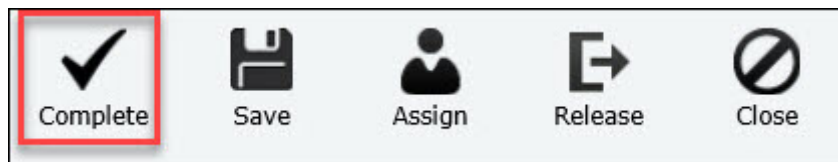
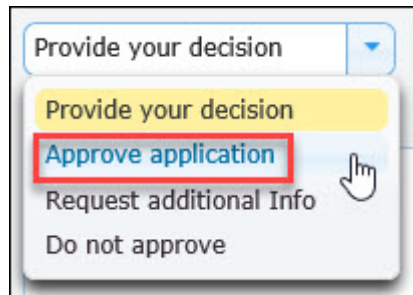


20. Click on 'Tasks' in the taskbar and enter the case number previously copied into the 'Case number' field.
21. The task 'Evaluate and decide' will appear in your list. Click on the hyperlink and 'Start working'.





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'.

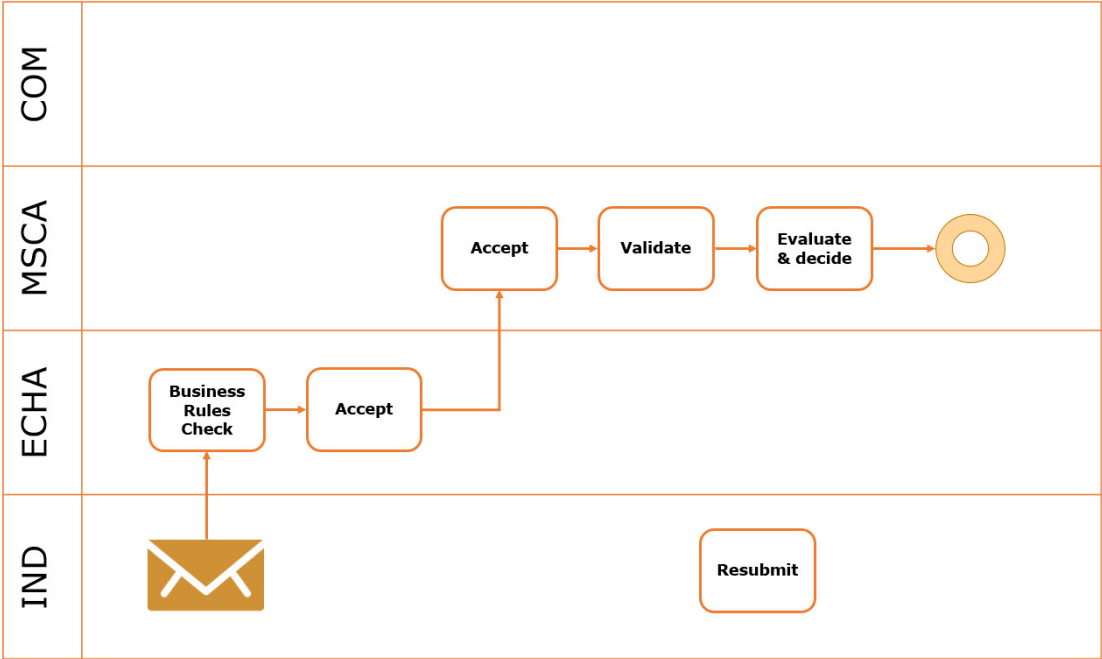


23. Once you have completed the task, the authorisation is issued. To verify the asset number, click on 'Asset' in the taskbar and enter and paste the case number in the field provided. The number of the asset will appear. **Write the asset number down, as you will need it in the next steps.**

6. Exercise 5 (individual) – NA-MRS

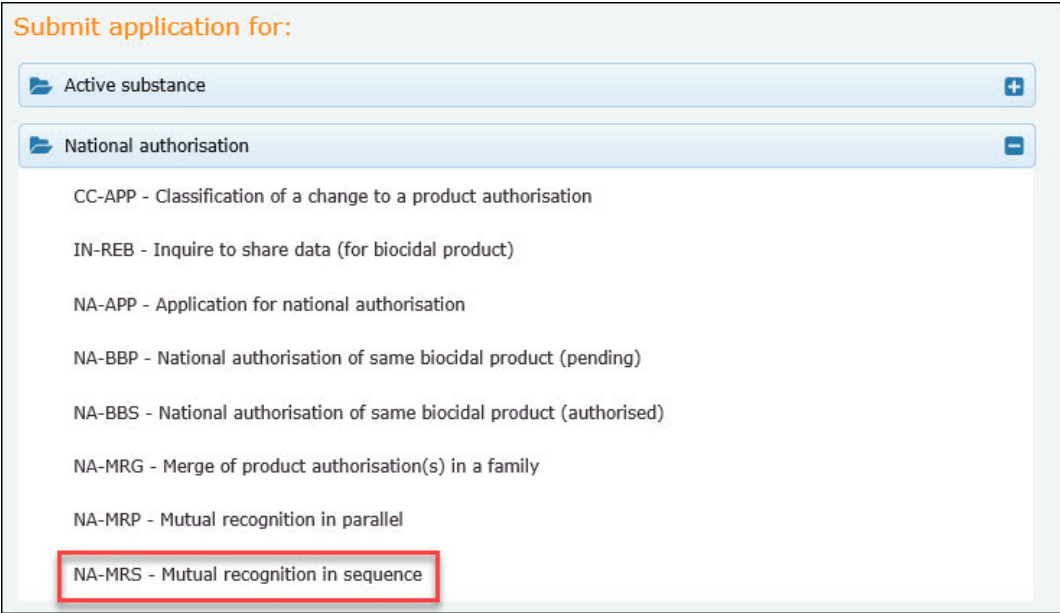
Introduction

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".

The screenshot shows a web interface for "Submission for mutual recognition in sequence (NA-MRS)". At the top, a progress bar indicates six steps, with step 1, "Set reference details", highlighted in orange. Below the progress bar, the title "Set reference details" is displayed. A message reads: "Please provide below the number of the reference asset". A red box highlights the input field for "Reference asset number" containing the text "IT-0001061-0000". Below this, a green banner states "Asset number provided is validated successfully". Further down, there are three rows of information: "Company name" (AT_Training_Company_01), "Product name" (Insecticide Product), and "Market area" (Italy). At the bottom, there are "Cancel" and "Next" buttons.

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

The screenshot shows a web interface for "Submission for mutual recognition in sequence (NA-MRS)". At the top, a progress bar indicates six steps, with step 2, "Set case owner details", highlighted in orange. Below the progress bar, the title "Set case owner details" is displayed. A message reads: "Please start the submission process for your application by filling all required information." Under the heading "Case owner details", there are three rows of information: "Company name" (AT_Training_Company_01), "Company UUID" (3f8e5811-e37b-4fed-9a12-90ca1ef3ff86), and "*Contact person" (User-A Company_01). The contact person field is a dropdown menu.

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.

Submission for mutual recognition in sequence (NA-MRS)

1 > 2 > 3 Set submission details > 4 > 5 > 6

Set submission details

Please fill in the submission details.

*Evaluating authority: Finland

Asset owner details: Same as case owner

*Company UUID: 3f8e5811-e37b-4fed-9a12-90ca1ef3ff86

Company name: AT_Training_Company_01

Payment details

Purchase order:

* Billing address: Case owner 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**.

Submission for mutual recognition in sequence (NA-MRS)

1 > 2 > 3 > 4 Upload SPC > 5 > 6

Upload SPC

Please upload below your SPC (summary of product characteristics) file that is required for your application.

*Please upload the necessary SPC file(s)

FI-Finland
No SPC uploaded

+ Browse Upload All Cancel All

spc_Insecticide Product_FI_en_2018080 91048.xml 4.2 K B

- 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.

The screenshot shows a web interface for 'Submission for mutual recognition in sequence (NA-MRS)'. At the top, a progress bar has six steps, with step 5, 'Upload other files', highlighted in orange. Below the progress bar, the heading 'Upload other files' is followed by the instruction: 'Please upload any additional documents you would like to submit with your application'. A message states 'No file(s) found. Please choose a file to upload.' Below this are three buttons: '+ Browse', 'Upload All', and 'Cancel All'. A note at the bottom of the upload area says 'File names should not contain special characters' with a question mark icon. At the bottom of the interface, there are five buttons: 'Previous', 'Save', 'Save & Close', 'Cancel', and 'Next'. The 'Next' button is highlighted with a red box.





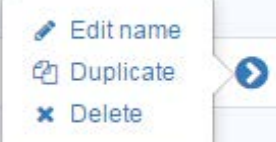
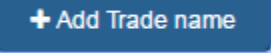




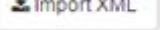

The screenshot shows the 'Your next steps' section of the application submission process. It displays the submission number 'BC-XN002023-41/1' and the evaluating country 'MSCA-Finland'. The submission number is highlighted with a red box.

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.

- 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.
- To perform the Accept, Validate and Evaluate tasks, carry out **steps 12 to 23 of exercise 4**.
- 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. |
|  | Adds a new SPC section (meta SPC, authorised use, product). |
|  | 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 – Adds a new field set. |
|  | Delete – Deletes the specific field set. |
|  | Move up – Moves the specific field set higher. |
|  | Move down – Moves the specific field set lower. |
|  | 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 – 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