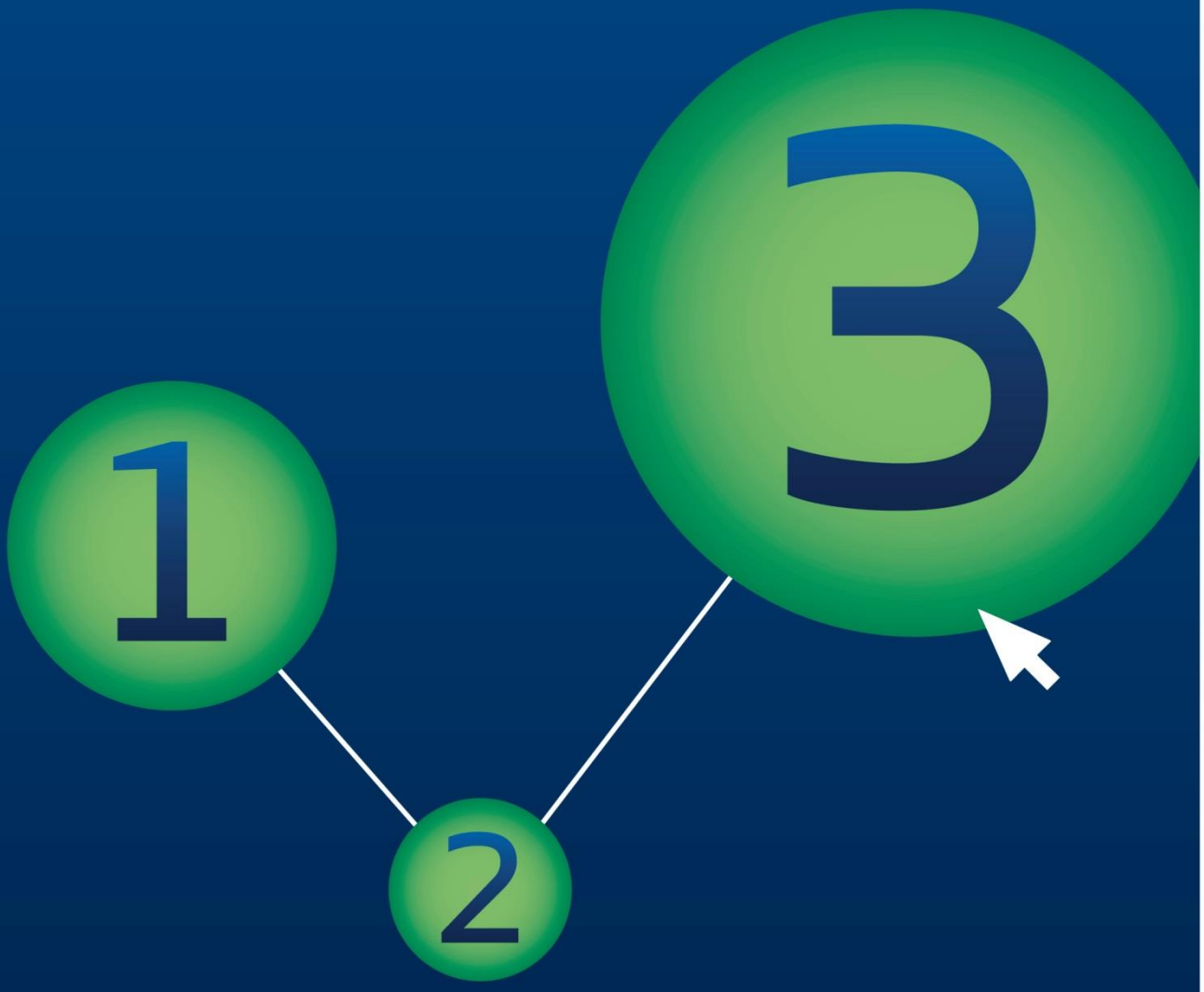
ECHA
EUROPEAN CHEMICALS AGENCY

MANUAL

Biocides Submission Manual

Technical guide: using the SPC Editor



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Version 2.2	Updated to reflect the changes in the SPC Editor. Minor changes in chapters 3., 4. And 5.3. Chapter 6. Added.	November 2017

Technical guide: using the SPC Editor

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Table of Contents

1. Introduction 6
1.1 Objective 6
1.2 Biocides Submission Manuals 6
1.3 Additional assistance 7
2. Start using the SPC Editor 8
3. Taskbar options 9
4. Creating a new SPC 12
4.1 Product family 12
4.2 Single product 13
5. Sidebars 14
5.1 Product information 14
5.2 Administrative information 17
5.3 Meta SPC (only for Product family SPC) 19
5.4 H & P statements 21
5.5 Authorised uses 23
6.6. Directions for use 25
5.6 Other information 26
5.7 Products (only for Product family SPC) 27
6. Amending an existing SPC 29
6.1 Creating a draft from final SPC 29
6.2 Creating a draft for changes, renewals 31
6.3 Draft for simplified authorisation(s) 32
7. Graphical user interface elements 33
ANNEX I 34
ANNEX II 36

Table of Figures

Figure 1: Choose the language 8
Figure 2: Starting page of the SPC Editor 8
Figure 3: Taskbar options 9
Figure 4: Import XML option for Product family SPC 11
Figure 5: Creating a new Product family SPC (step 1) 12
Figure 6: Creating a new Product family SPC (step 2) 12
Figure 7: Creating a new Single product SPC (step 1) 13
Figure 8: Creating a new Single product SPC (step 2) 13
Figure 9: Selecting Product information 14
Figure 10: Type(s) of formulation 14
Figure 11: Selecting Product information 14
Figure 12: Formulation type 14

Figure 13: Adding information on active substances, substances of concern, and other substances 15
Figure 14: Selecting the BAS number 15
Figure 15: Selecting the function 16
Figure 16: Selecting Administrative information 17
Figure 17: Selecting the product type 17
Figure 18: Selecting Administrative information 17
Figure 19: Defining the country and trade name 17
Figure 20: Import option 18
Figure 21: Export option 18
Figure 22: Selecting meta SPC 19
Figure 23: Selecting the product type(s) 19
Figure 24: Selecting the min and max content percentage 20
Figure 25: Selecting formulation type 20
Figure 26: Add meta SPC 20
Figure 27: Edit name 20
Figure 28: Selecting H & P statements 21
Figure 29: Selecting H & P statements 21
Figure 30: Creating a block for hazard or precautionary statement 22
Figure 31: Selecting the same H & P statement (step 1) 22
Figure 32: selecting the same H&P statement (step 2) 22
Figure 33: Selecting Use 23
Figure 34: Selecting Use 23
Figure 35: Adding a block for Target organism, application method and packaging 23
Figure 36: Creating a new block for authorised uses (step 1) 24
Figure 37: Creating a new block for authorised uses (step 2) 24
Figure 38: Selecting Directions for use 25
Figure 39: Selecting Directions for use 25
Figure 40: Selecting Other information 26
Figure 41: Selecting Other information 26
Figure 42: Free-text field under Other information 26
Figure 43: Selecting Product 27
Figure 44: Adding a trade name block (step 1) 27
Figure 45: Adding a trade name block (step 2) 27
Figure 46: Creating a duplicate tab 28
Figure 47: Add a Product 28
Figure 48: Applying for a same product 28
Figure 49: Open an existing SPC 29
Figure 50: Draft from final SPC 29
Figure 51: Market area version 30
Figure 52: Save the SPC file 30

Figure 53: Draft for changes, renewals to be uploaded in R4BP 31
Figure 54: Open an existing SPC 31
Figure 55: Draft for changes, renewals.....31
Figure 56: Save the SPC 31
Figure 57: Open an SPC.....32
Figure 58: Draft for simplified authorisation(s) 32
Figure 59: Save the SPC.....32

1. Introduction

1.1 Objective

A number of product applications subject to Biocidal Products Regulation (EU) 528/2012 require the inclusion of a Summary of Product Characteristics (SPC). To this end, ECHA has provided SPC Editor, a standalone tool to aid in the generation of an SPC.

This manual aims to describe the different functionalities in the SPC Editor.

1.2 Biocides Submission Manuals

This manual is part of the Biocides Submission Manual (BSM) series which is composed of technical guides, application instructions, and specific process manuals. All are available from the ECHA website.

Technical guides:

How to prepare a biocides dossier describes how to prepare a general IUCLID dossier, giving you details on the different functionalities in IUCLID, as well as explaining the different sections contained within a dossier.

Using R4BP 3, which describes how to create user accounts in R4BP 3 via ECHA Accounts and gives a detailed description of the various functionalities of the system.

Using the SPC Editor, which describes how to prepare a summary of the product characteristics (SPC) required for certain application types.

Application instructions:

Application instruction manual give guidance on how to submit applications concerning various process concerning active substance approvals and biocidal product authorisations.

- **Active substances**
- **National authorisations**
- **Simplified authorisations**
- **Union authorisations**
- **Technical equivalence and chemical similarity**

Process manuals:

Invoicing in R4BP 3, which describes the general information related to invoices and credit notes issued by ECHA following the submission of an application.

Confidentiality requests for biocide applications, which describes how to make confidentiality claims in IUCLID and which dossier information can be claimed confidential.

1.3 **Additional assistance**

In addition to the Biocides Submission Manuals, more information concerning the regulatory context of biocide applications and an overview of the evaluation process is available from:

Practical guides, which give a more detailed look at the procedures and obligations of certain processes under the BPR.

Guidance documents, which help to implement the BPR by describing good practice on how to fulfil the obligations.

Regulatory web pages, which offer a general introduction to some of the processes under the BPR.

Q&As on R4BP 3 (e.g. account management, invoicing, submissions) and the Biocidal Products Regulation (e.g. active substance suppliers, data sharing, treated articles).

The ECHA Helpdesk, which is available for specific and general advice on the BPR, particular submissions, as well as the IT tools IUCLID, R4BP 3, and the SPC Editor.

For all the latest news, subscribe to the weekly e-News and bimonthly Newsletter.

2. Start using the SPC Editor

The SPC Editor can be accessed through the ECHA website at: https://r4bp.echa.europa.eu/spc/#/home.

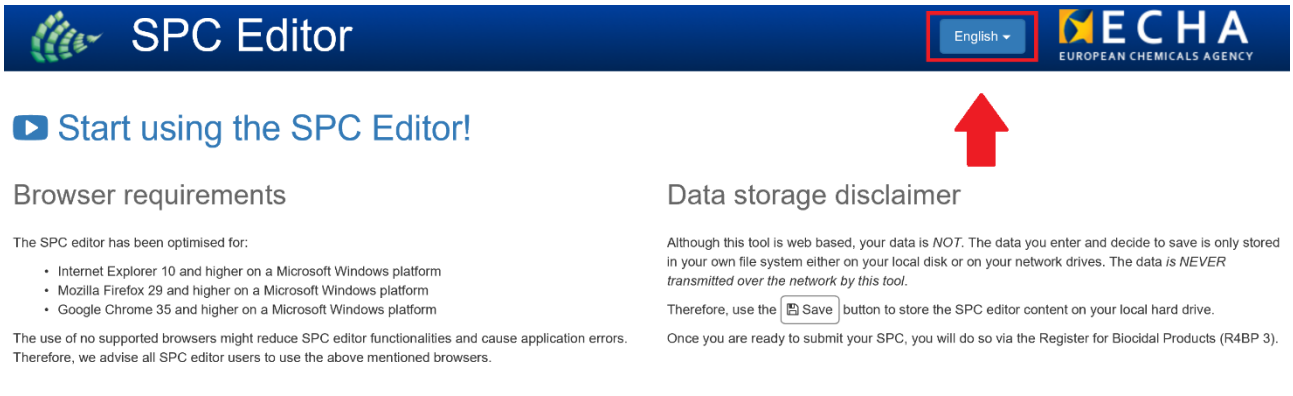
One of the following browsers will be required in order to run the SPC Editor:

- Chrome v.35 or above;
- Firefox v.29 or above;
- Internet Explorer 10 or above.

Some features may not be fully supported on older versions of these browsers or on browsers not listed above.

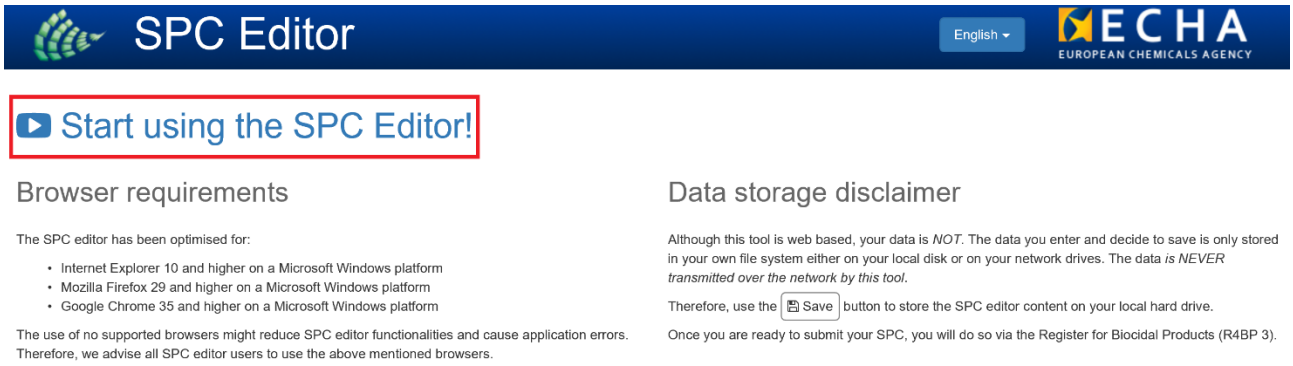
Choose the language to work in on the top right corner (Figure 1). The chosen language relates to the user interface and not to the document language.

Figure 1: Choose the language



To get started click on 'Start using the SPC Editor!' (Figure 2).

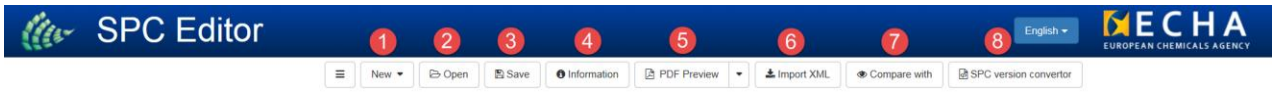
Figure 2: Starting page of the SPC Editor



3. Taskbar options

Once you have gained access to the SPC editor, you are presented with a taskbar. It currently displays eight options (Figure 3):

Figure 3: Taskbar options



1. "**New**" option: Create a new SPC for single product or for a product family.

   The *New* tab includes:

   - Product family; please see chapter 4.1 Product family.
   - Single product; please see chapter 4.2 Single product.
   - Draft from final SPC; this function is used every time you need to create a draft SPC file starting from a finalised SPC (e.g. to submit an NA-MRS you need to open the final SPC contained in the reference NA asset and create a draft SPC for another market area). Please see chapter 6.1. for additional details on this functionality.
   - Draft for changes, renewals; this function is used every time you need to create a draft SPC file starting from a finalised SPC. You are allowed to hold more than one authorisation in one market area for a specific product. Therefore, R4BP allows you to proceed with multiple changes (ADC, MIC, MAC, RNL) in authorisations under the same market. In this scenario, you must provide an XML of type 'Draft for changes, renewals". Please see chapter 6.2. for additional information.
   - Draft for simplified authorisation(s) this function is used very time you need to create a draft SPC file starting for a finalised SPC. You are allowed to notify for placing on the market one or more products (members of a family) in one wizard. In this scenario, you must provide an XML of type 'Draft for simplified authorisation(s)". Please see chapter 6.3. for additional information.
   - Language version; change the language of an existing SPC once uploaded in SPC Editor. Note that if your existing SPC contains free-text it will not be translated.
   - Market area version; change the market area of an existing SPC once uploaded in SPC Editor.

2. "**Open**" option: browse your local hard drive and locate the saved SPC. Only SPC files that respect the defined SPC XML schema will open correctly in the SPC Editor.

3. "**Save**" option: save the SPC XML file on your local hard drive. The name of the document is created automatically, incorporating the language and market area.

The data you enter and save in the SPC editor is stored in your own file system and is never transmitted over the network.

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

4. "**Information"** option: The 'Information' option contains three different tabs with general information concerning the product authorisation.

   The *Document information* tab includes:

   - The product and/or family UUID; a unique identifier created by the SPC Editor system to identify the product.
   - The product (or family) name UUID; defined by the user for the product.
   - Market area; the country in which the product is authorised or you are seeking authorisation in. This can be the European Union, for Union level authorisations.
   - Language; the language of the document content. This may differ from the language of the SPC Editor user interface.

   The *Authorisation details* tab (read-only) contains any available authorisation details. Information will be automatically entered into the SPC when the relevant authorising authority uploads the final SPC and completes the product authorisation in R4BP 3.

   The *File information* tab contains a proposed file name based on the name of the substance, as well as the market area and language you selected. The file name is linked to the name the SPC is saved under; the user can therefore alter this at any stage.

5. **"PDF Preview"** option: preview and print your SPC XML files:

   - "Preview current SPC": view the SPC file you are currently working on in PDF format or print it after saving it first on your local hard drive.

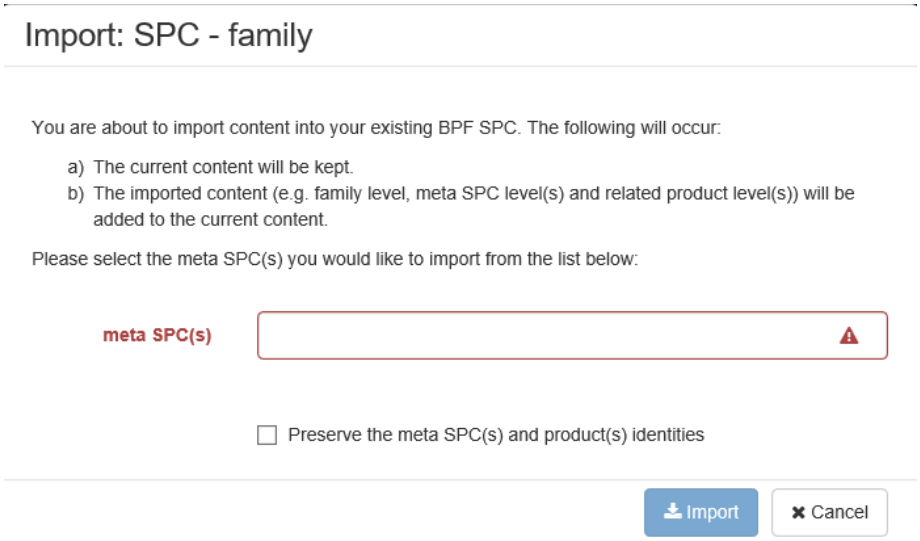
   - "Open & Preview": open previously saved SPC XML file to view in PDF format.

6. **"Import XML"** option: import previously saved SPC XML file. You can then modify (delete or add) the data from the original SPC file.

   - For Single product: this will import all the data from the previously saved SPC.

   - For Product family: select the meta SPC you wish to preserve. The tick-box "Preserve the meta SPC(S) and product(s) identities" saves only the identities (Figure 4).

Figure 4: Import XML option for Product family SPC



7. **"Compare with"** option: identify the differences between two SPCs. Once a second SPC file is opened from the prompted window, a system will colour codes will tell you if and where changes have been introduced in an SPC.

8. **"SPC version convertor"**: convert an SPC file created with the previous version of SPC Editor into the new format. Use the conversion feature before trying to open or import an SPC file in the old format.

Annex II describes how information has been migrated from submitted SPC or it will be migrated by using the "SPC version convertor". The Annex II also highlights which fields of the newly created SPC should be cross-checked and re-edited for consistency with the old SPC.

4. Creating a new SPC

Applicants who wish to submit a new application (typically one that is **not related to an existing asset or case**) in R4BP can use the SPC Editor to create a new SPC file.

A new SPC can be created for:

- **A Product family:** A biocidal product family with composition defined as ranges.
- **A Single product:** An individual biocidal product with a specifically defined composition.

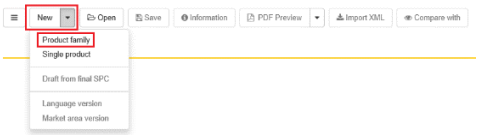
The key difference between product family SPC and single product SPC is that the first one presents a structure in three levels, family level, metaSPC level and Product level designed in a way that common set of information across products do not need to be repeated.

If you need to create an SPC file starting from a finalised SPC (e.g. you decide to apply for NA-MRS in R4BP, your SPC should be based on the SPC created for the initial case i.e. NA-APP), go to section 7.

4.1 Product family

To create an SPC for a product family, click on "new" and choose "Product family" from the drop-down list (Figure 5).

Figure 5: Creating a new Product family SPC (step 1)



A new window will appear and prompt you to enter the family name, the market area and the language of your SPC (Figure 6).

Figure 6: Creating a new Product family SPC (step 2)

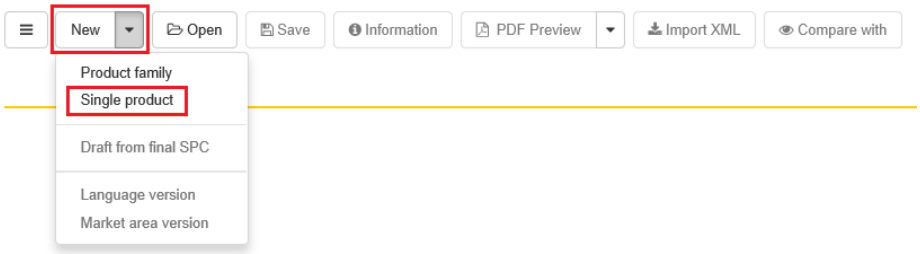
- **Family name**: Identify your family name (family name is only a technical name and does not refer to the trade name(s) of each single product).
- **Market area**: Choose the market area from the drop-down list (European Union market includes all EU, EEA and EFTA countries).
- **Language**: Choose the language for the SPC file.

Once you have filled in the required information, continue to step '5. Sidebars'.

4.2 Single product

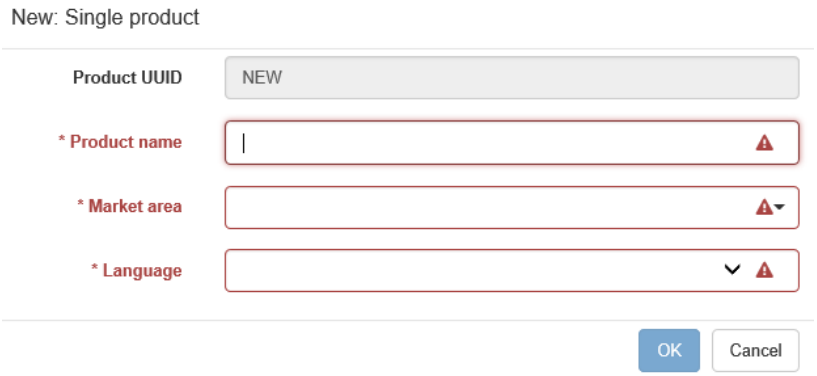
To create an SPC for a Single product click on "new" and select "Single product" from the drop-down list (Figure 7).

Figure 7: Creating a new Single product SPC (step 1)



A pop-up window will prompt you to fill in the product name, the market area and the language of your SPC (Figure 8).

Figure 8: Creating a new Single product SPC (step 2)



- **Product name**: Identify your product name.
- **Market area**: Choose the market area from the drop-down list (European Union market includes all EU, EEA and EFTA countries).
- **Language**: Choose the language for the SPC file.

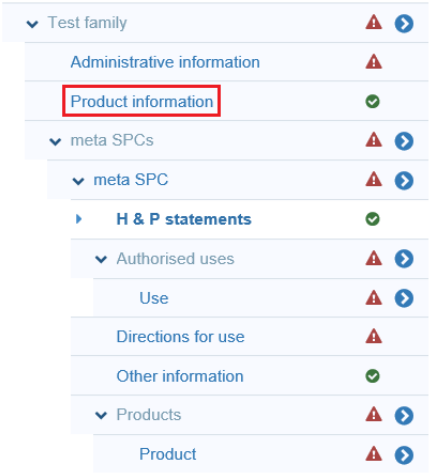
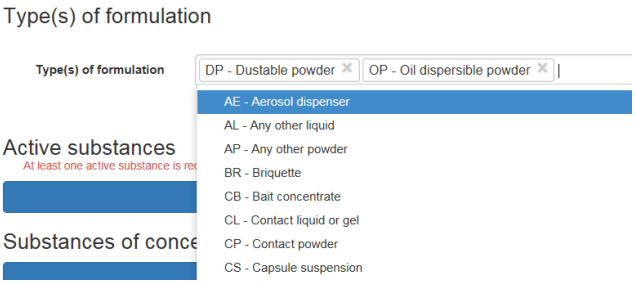
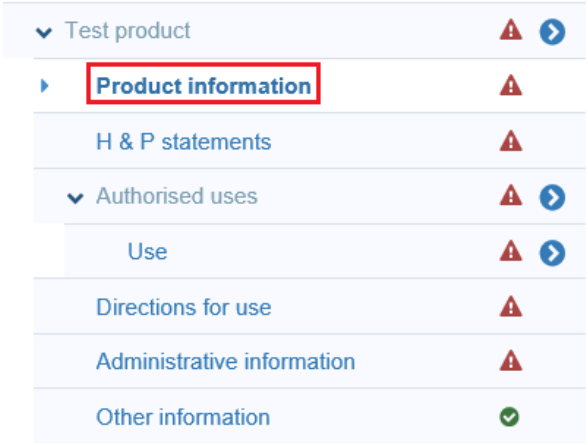
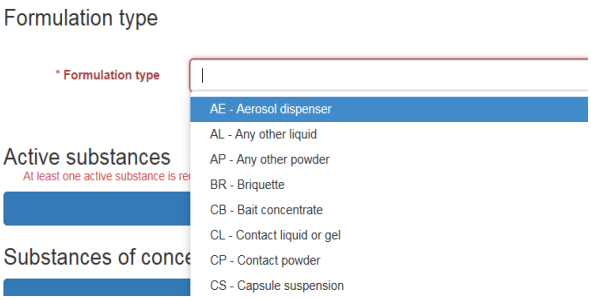
After you have filled in the required data, continue to chapter '6. Sidebars' to complete your SPC document.

5. Sidebars

In order to create a consistent SPC, you are required to provide different type of data. This data can vary significantly from Product family SPC to Single product SPC. Depending on your type of SPC, you will need to present the following information:

5.1 Product information

The 'Product information' tab includes information on the substance components of the product.

Product family SPC	Single product SPC
- In the sidebar menu, click on 'Product information' (Figure 9). **Figure 9: Selecting Product information**  - Choose one or several type(s) of formulation from the drop-down list (Figure 10). **Figure 10: Type(s) of formulation**  	- In the sidebar menu, click on 'Product information' (Figure 11). **Figure 11: Selecting Product information**  - Choose only one formulation type from the drop-down list (Figure 12). **Figure 12: Formulation type** 

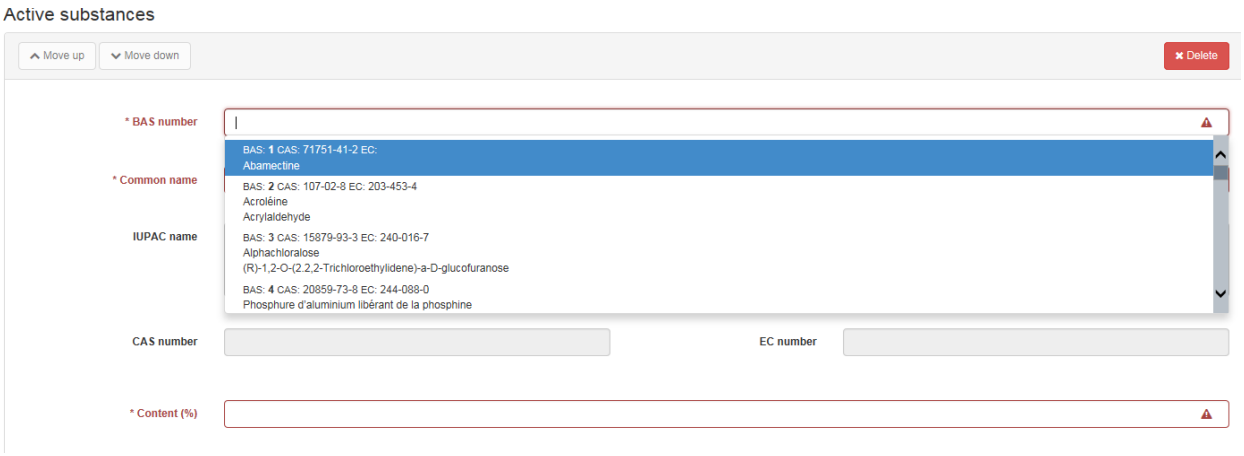
Common features (1/2)

- Click on '+Add…' to enter details regarding any any 'Active substances', 'Substances of concern' and 'Other substances'. Note **that at least one active substance is required** (Figure 13).

Figure 13: Adding information on active substances, substances of concern, and other substances

- To make your active substance identifiable, you are required to provide the 'BAS number', the 'Common name' (automatically pre-filled if you select the BAS number from the drop-down list) and the 'content range (%)' (for product family SPC) or 'content (%)' (for single product SPC) (Figure 14).

Figure 14: Selecting the BAS number

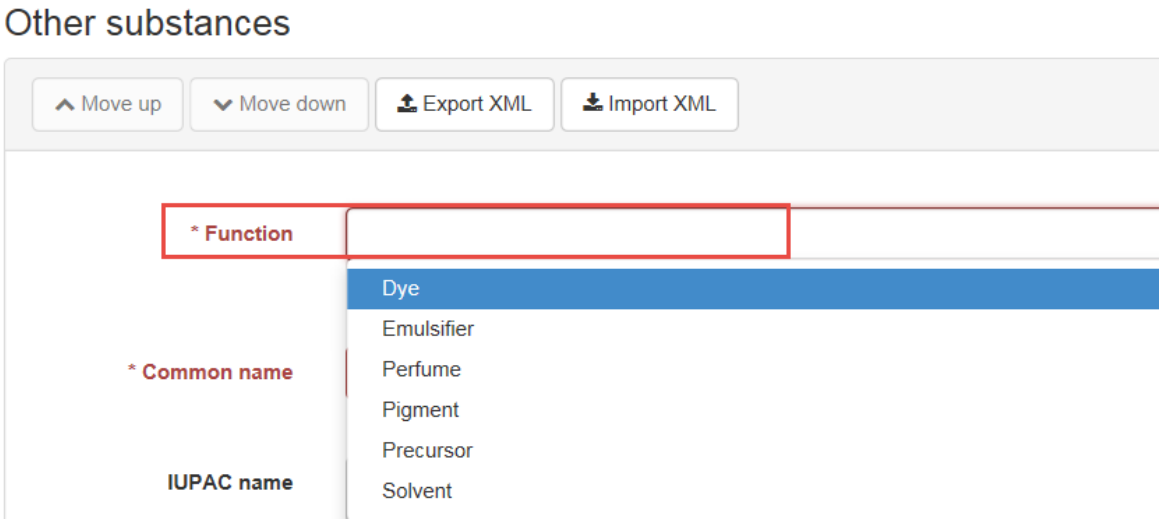


- If you have added a 'substance of concern' and/or 'other substance(s)', you will be required to fill in the 'Function' field. Select the function of the substance from the drop-down list, or add free text if the correct function is not listed (Figure 15).

- Fill in also the 'Common name' and the 'Content (%)' (for single product SPC) or the 'Content range (%) (for Product family SPC).

Common features (2/2)

Figure 15: Selecting the function



The Biocidal Active substance (BAS) number can be found in the list of approved active substances published on the ECHA website. If your active substance is not listed, contact the ECHA Helpdesk (select 'I am using R4BP 3 and I would like to clarify…' in the contact form).

If you do not know the BAS number, you can search for the substance by typing the common name, CAS number or EC number in the field 'BAS number'. If listed, the BAS number will be found automatically.

Selecting the correct BAS number from the drop-down list will automatically fill in other available data, e.g. common name, CAS number, etc.

Note that you must type in the Content (%); this will be a range if filling in an SPC for a product family.

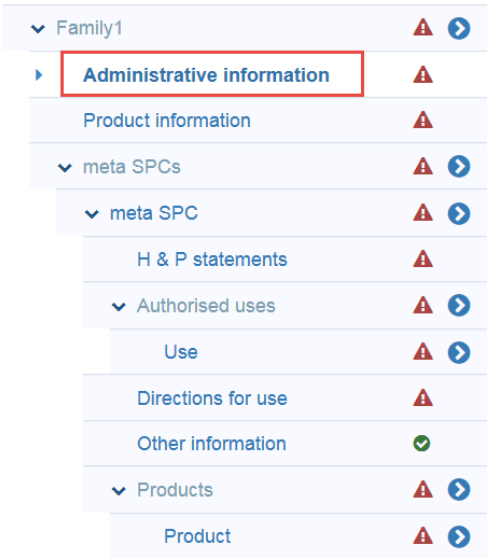
5.2 Administrative information

The 'Administrative information' tab includes administrative information on the manufacter(s) of the product/active substance.

Product family SPC

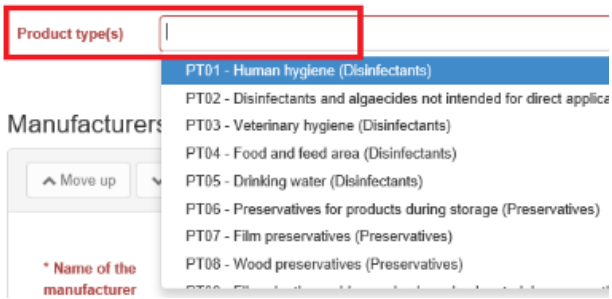
- Select 'Administrative information' in the sidebar menu (Figure 16).

Figure 16: Selecting Administrative information



- Select one or more product types from the drop-down menu (Figure 17).

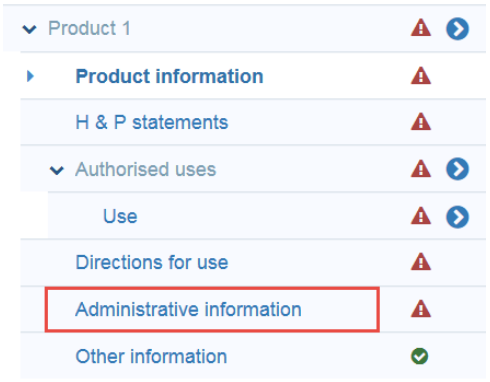
Figure 17: Selecting the product type



Single product SPC

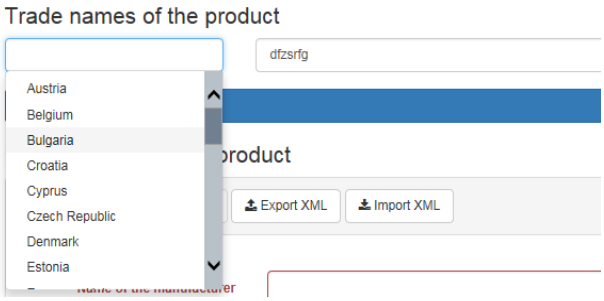
- Select 'Administrative information' in the sidebar menu (Figure 18).

Figure 18: Selecting Administrative information



- Choose the country from the drop-down menu and define the trade name of the product (Figure 19).

Figure 19: Defining the country and trade name



Common features

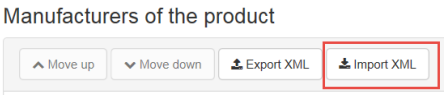
- Fill in the required fields concerning the 'manufacturer(s) of the product'.

- Fill in the required fields concerning the 'manufacturer(s) of the active substance'. Note that you will need to choose the active substance name from the drop-down list. It becomes activated once you have identified your active substance(s) in the relevant section in the 'Product information' tab.

You can choose to re-use and/or edit the administrative information from an existing SPC.

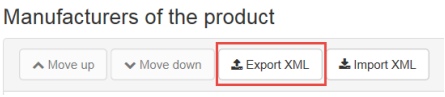
Click on import XML in each section to be able to browse your local IT environment and upload an SPC file (Figure 20).

Figure 20: Import option



Click on export XML in each section to be able to save your data in your local environment (Figure 21).

Figure 21: Export option



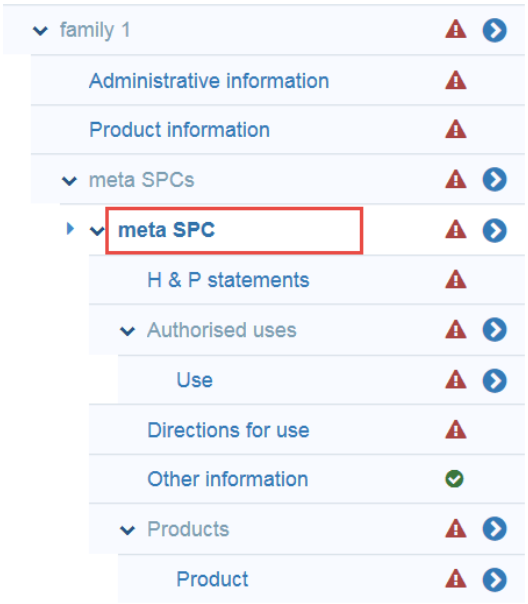
5.3 Meta SPC (only for Product family SPC)

The 'Meta SPC' tab includes information on your product(s). You can add one to many sub-tabs, depending on how big your family is and how many product types it contains.

Product family SPC (1/2)

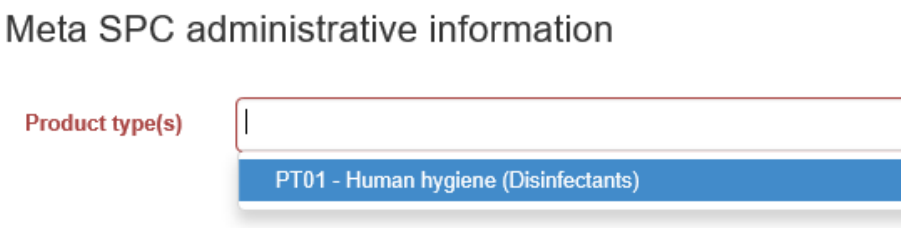
- Click on the sub tab 'meta SPC' in the sidebar menu (Figure 22).

Figure 22: Selecting meta SPC



- Fill in the 'Meta SPC administrative information' field: select the product type(s) from the drop-down list (Figure 23).

Figure 23: Selecting the product type(s)

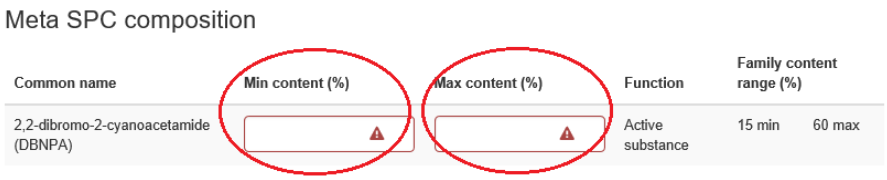


- Fill in the 'Meta SPC composition information': define the minimum and maximum content percentage of the active substance (Figure 24).

Note that at least one active substance must be defined in your SPC. To do so, please refer to chapter 6.1 Product information to know how to define an active substance. The rest of the information will be filled in automatically based on information inserted in other previously filled tabs.

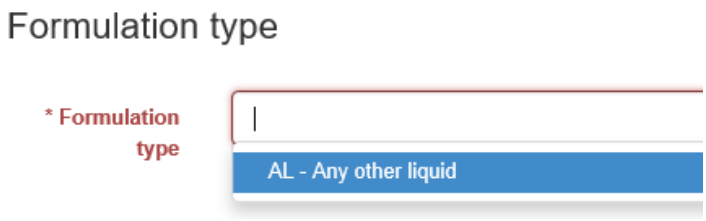
Product family SPC (2/2)

Figure 24: Selecting the min and max content percentage



- Select one of the 'formulation type' indicated in the family level from the drop-down list (Figure 25).

Figure 25: Selecting formulation type

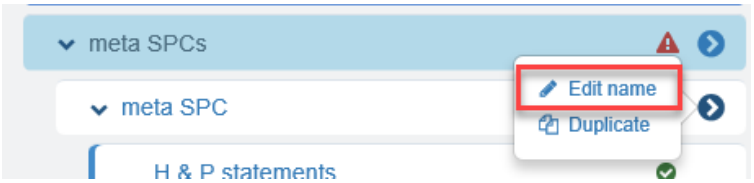


Note : you can add as many meta SPC sub tabs as needed (e.g. there are two different products in your family. The first one called "Product A" is a type 1 (PT1) and 2 (PT2) , and the second product, called Product B, is a type 3 (PT3) and 8 (PT8). You will need to add four 'meta SPC' sub tabs to indicate all the product types of your products.

Figure 26: Add meta SPC

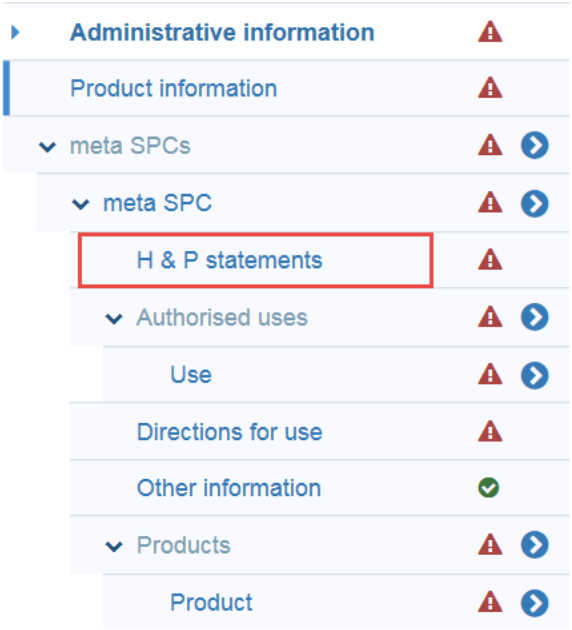
You can rename each sub tab according to your wishes (Figure 27).

Figure 27: Edit name



5.4 H & P statements

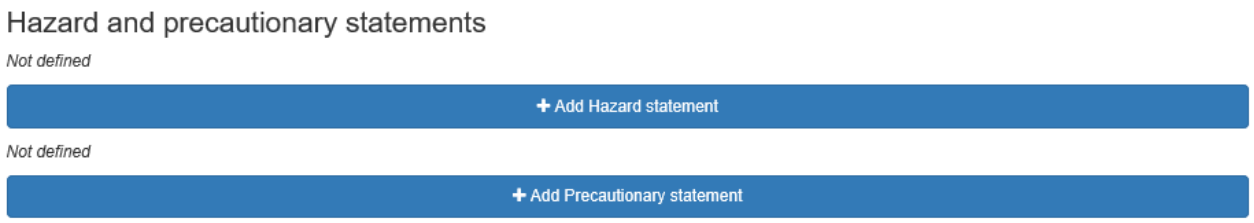
'H & P statements' tab includes the hazard and precautionary statements for the product.

Product family SPC	Single product SPC
- Click on 'H&P statements' in the sidebar menu (Figure 28). **Figure 28: Selecting H & P statements**  	- Click on 'H&P statements' in the sidebar menu (Figure 29). **Figure 29: Selecting H & P statements**

Common features

- Click on '+ Add…' to create a block for 'Hazard statements' or 'Precautionary statements' (Figure 30).

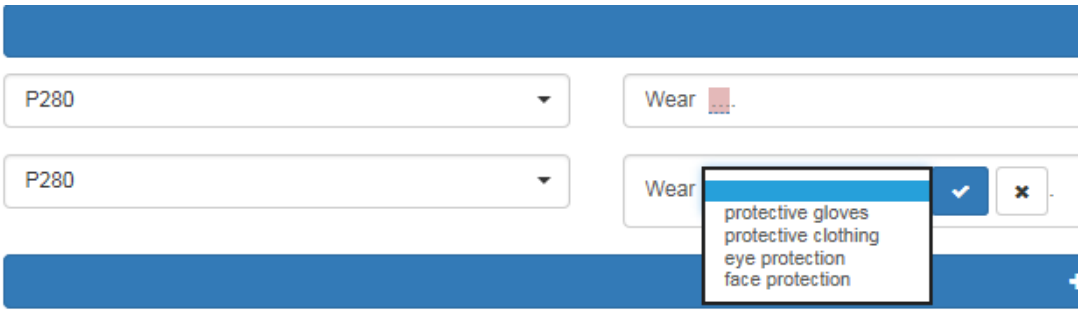
Figure 30: Creating a block for hazard or precautionary statement



- For some precautionary statement, it is possible to select the same statement several times. Some of the statements require additional input after their selection. A selection may require you to fill in a blank denoted by three dots (…) (Figure 31, step 1) by typing the correct words, or making a selection from a list of options (Figure 32, step 2).

Figure 31: Selecting the same H & P statement (step 1)

Figure 32: selecting the same H&P statement (step 1)



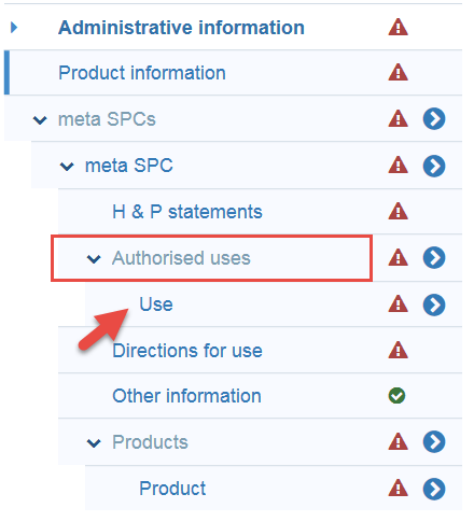
5.5 Authorised uses

The 'Authorised uses' tab includes details about the use, target organism, application methods, and packaging.

Product family SPC

- Click on 'Use' below 'Authorised uses' in the sidebar menu (Figure 33).

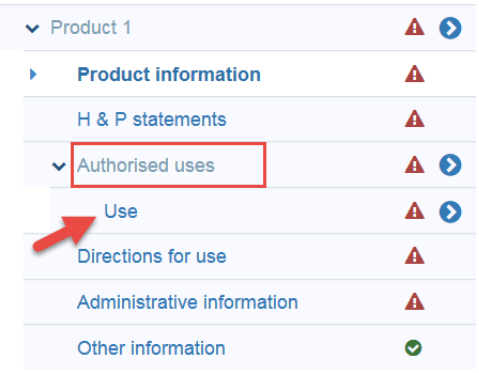
Figure 33: Selecting Use



Single product SPC

- Click on 'Use' below Authorised uses in the sidebar menu (Figure 34).

Figure 34: Selecting Use

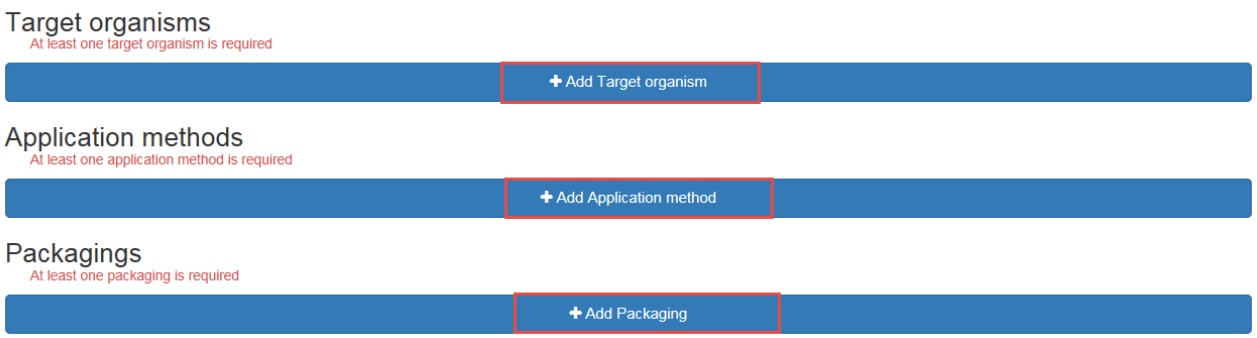


Common features (1/2)

- You can type text into the free-text fields e.g. 'Title for use', make selections from the drop-down lists ( ) e.g. 'Product type', or select the appropriate tick boxes e.g. 'Field of use'.

- Click on '+Add …' to mention details on target organisms (Note that target organisms are not translated but that a free text can be used to enter names in every official language), application methods, and packaging and fill in the required fields (Figure 35).

Figure 35: Adding a block for Target organism, application method and packaging



Common features (2/2)

- If needed, click on the blue arrow next to 'Authorised uses' to create a new use block (Figure 36, step 1) and type a title (Figure 37, step 2).

Figure 36: Creating a new block for authorised uses (step 1)

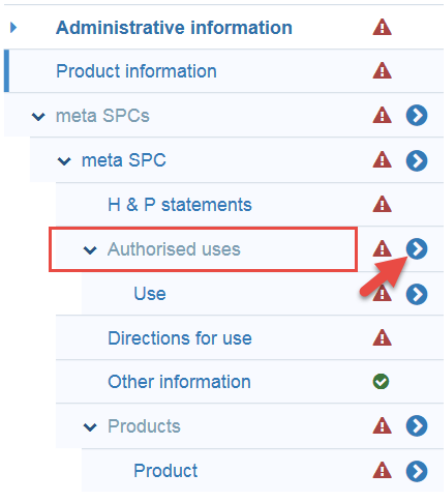


Figure 37: Creating a new block for authorised uses (step 2)

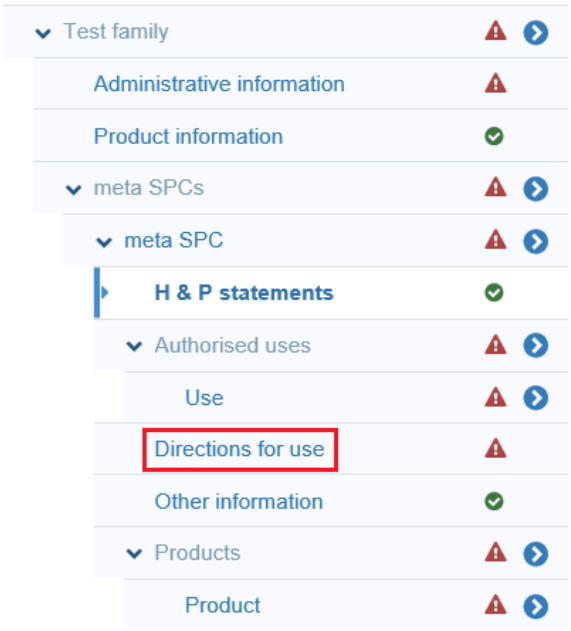
6.6. Directions for use

This tab includes information on general directions for use.

Product family SPC

- Click on 'Directions for use' (Figure 38).

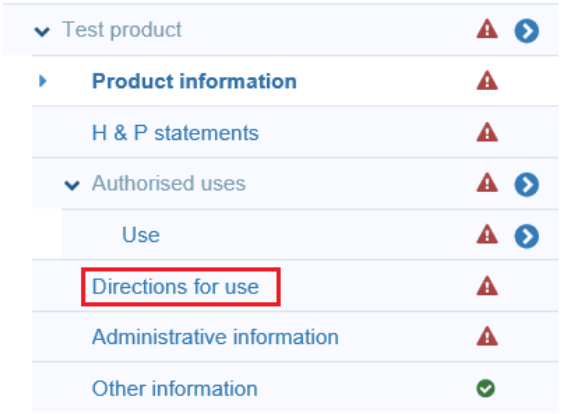
Figure 38: Selecting Directions for use



Single product SPC

- Click on 'Directions for use' (Figure 39).

Figure 39: Selecting Directions for use



Common features

- Type text into the free-text fields e.g. 'Instruction for use', 'risk mitigation measures', 'Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment', 'Instructions for safe disposal of the product and its packaging', 'Conditions of storage and shelf-life of the product under normal conditions of storage'.

5.6 Other information

Other information can be added to the SPC.

Product Family SPC	Single Product SPC
- Click on 'Other information' (Figure 40).	- Click on 'Other information' (Figure 41).

Figure 40: Selecting Other information

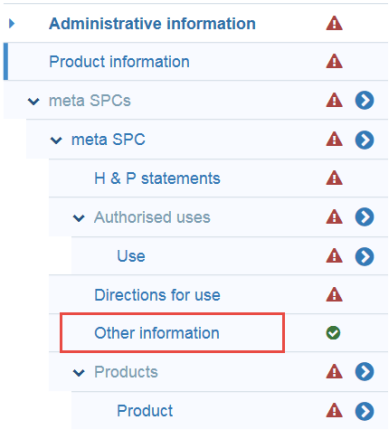
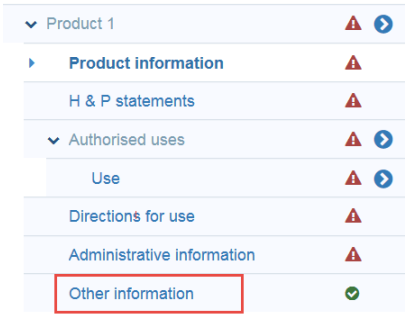


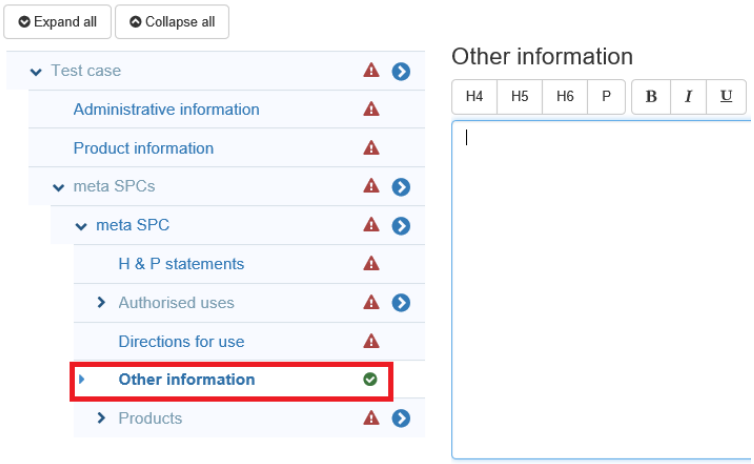
Figure 41: Selecting Other information



Common features

- Enter any additional information into the free-text field under the 'Other information' tab (Figure 42).

Figure 42: Free-text field under Other information



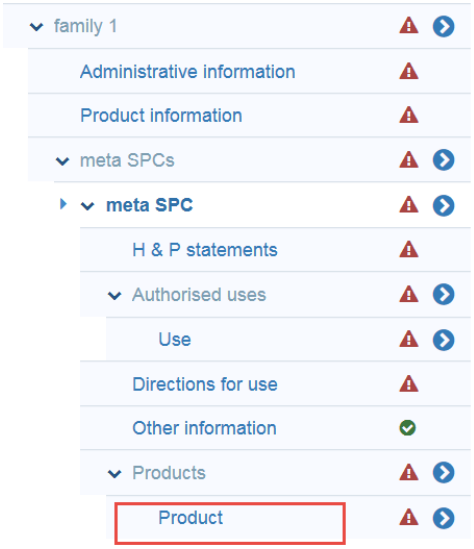
5.7 Products (only for Product family SPC)

Users are required to add additional information regarding their products.

Product family SPC (1/1)

- Click 'Product' in the sidebar menu (Figure 43).

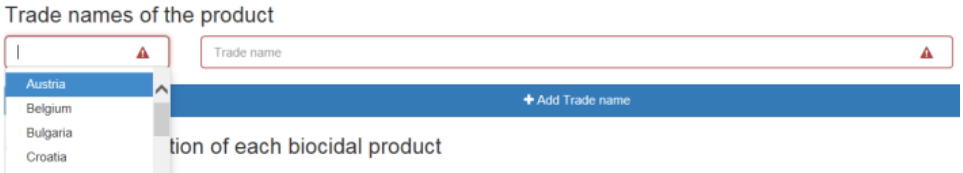
Figure 43: Selecting Product



- Click '+Add…' to add a trade name. Start by selecting the market area from the drop-down list and then type in the 'Trade name' of the product (Figure 44, step 1 and Figure 45, step 2).

Figure 44: Adding a trade name block (step 1)

Figure 45: Adding a trade name block (step 2)



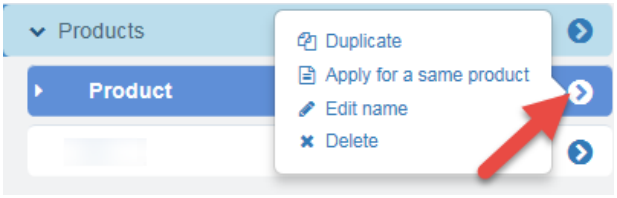
- Fill in also the 'Content (%)' field of each biocidal product and the required information regarding the manufacturer(s).

Product family SPC (1/2)

In case a product has more than one trade name, all trade names should be provided in this section.

- After completing the required fields, you can create a 'Duplicate' tab (Figure 46).

Figure 46: Creating a duplicate tab

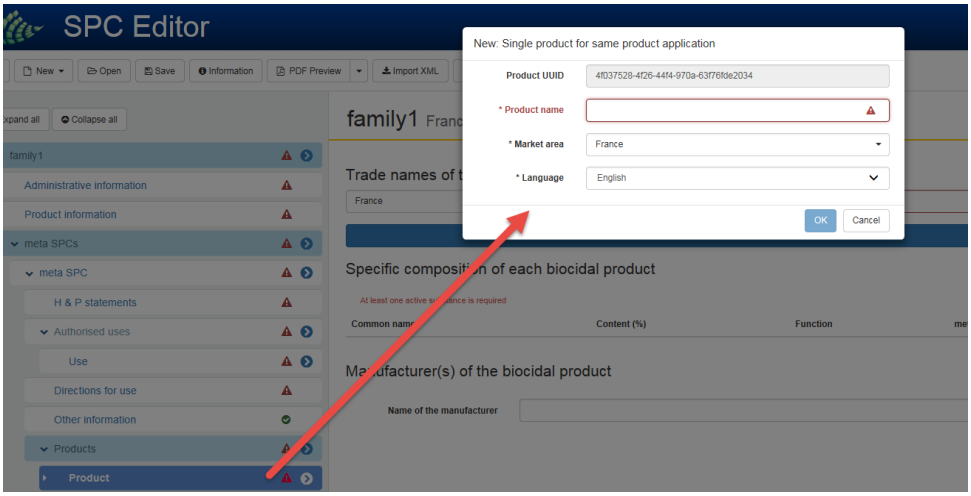


Note: you can add as many products sub-tab as needed (e.g. your family consists of two products: Product A and Product B. You will add two 'Products' sub tab: one for Product A and the other for Product B).

Figure 47: Add a Product

- If you wish to 'Apply for a same product', a pop-up window will appear and diplay your 'Product UUID' (a product unique identifier automatically generated by SPC Editor). You can enter the 'Product name', and modify the 'market area', and 'language' as you wish (Figure 48).

Figure 48: Applying for a same product



6. Amending an existing SPC

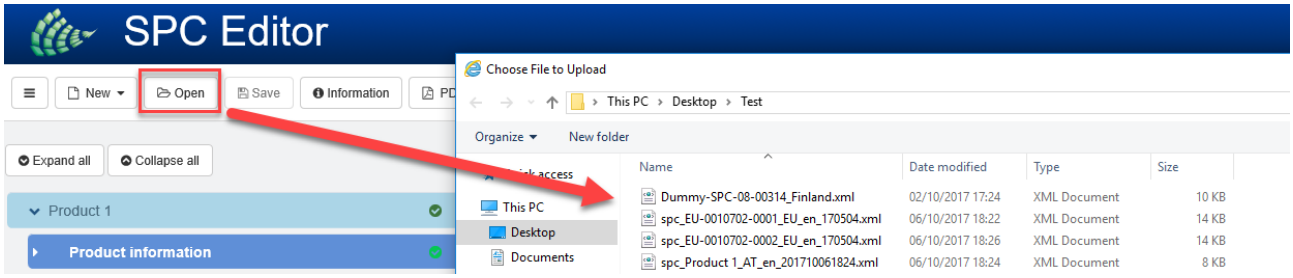
For applications that are related to an existing case or asset, registrants are required to create a draft SPC file starting from a finalised SPC.

6.1 Creating a draft from final SPC

This function needs to be used every time you have to create a draft SPC file starting from a finalised SPC (e.g. to submit an NA-MRS in R4BP, you need to open the final SPC contained in the reference NA asset and create a draft SPC for another market area).

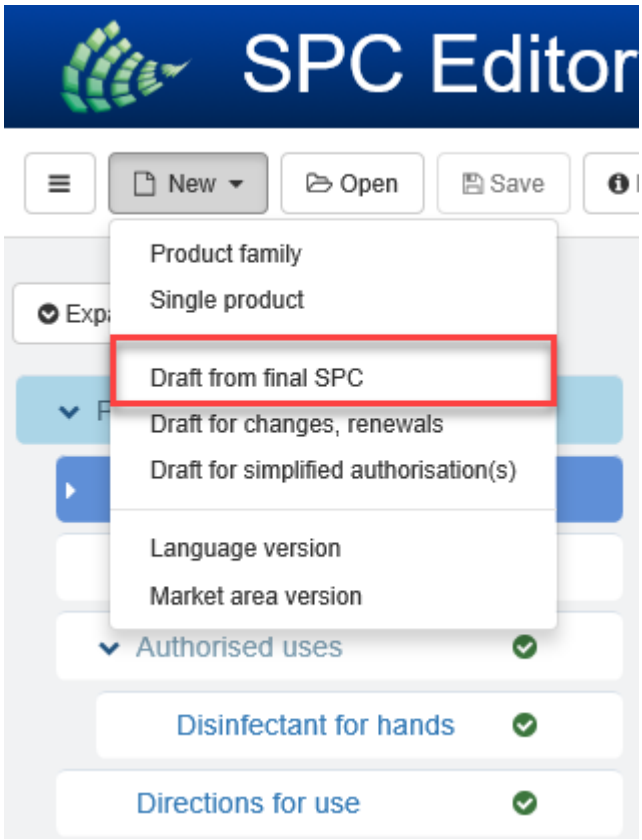
Click on 'Open' to browse your local environment and search for the relevant SPC (i.e the SPC created for the reference case/asset).

Figure 49: Open an existing SPC



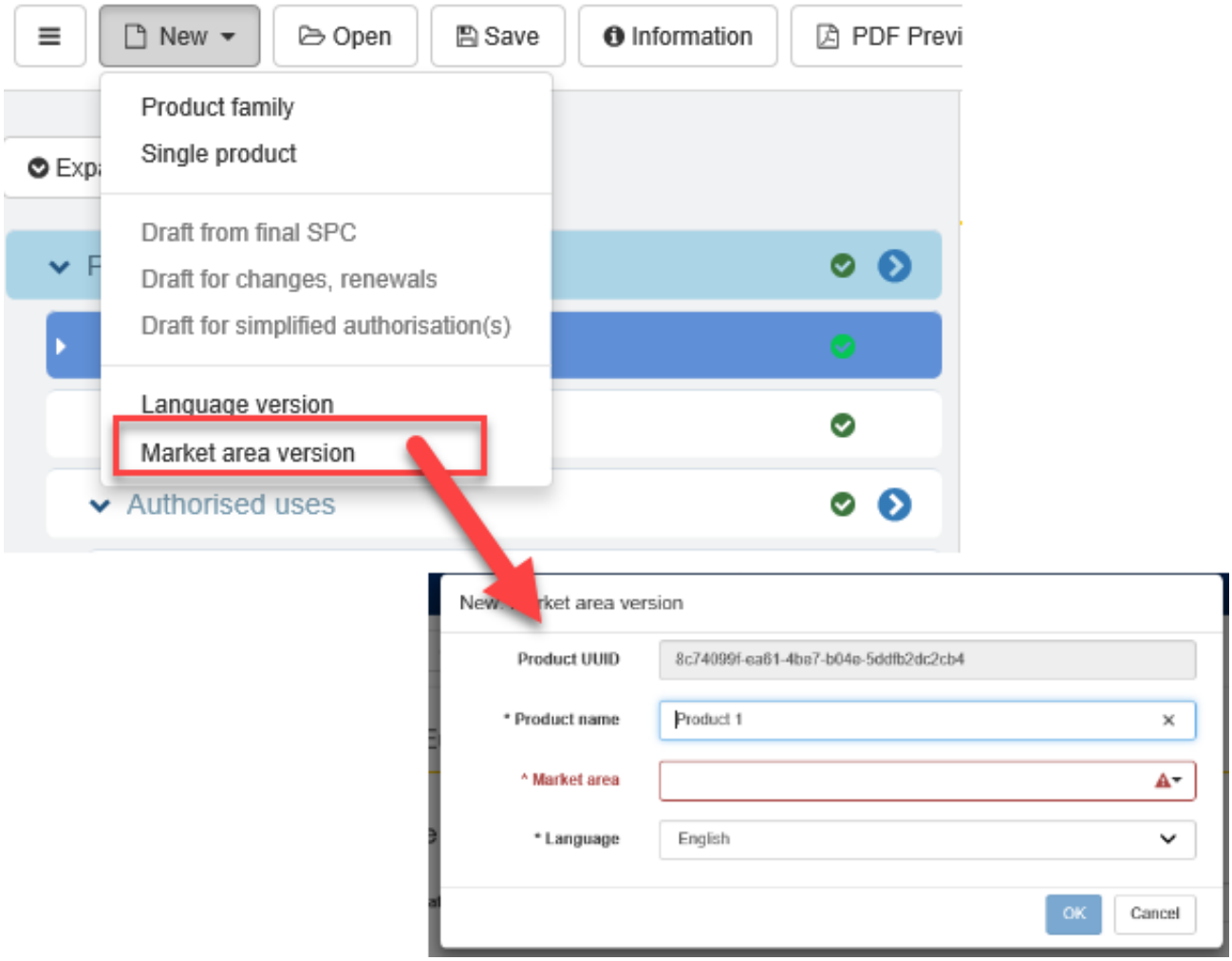
Once you have opened the relevant SPC, choose 'Draft from final SPC'.

Figure 50: Draft from final SPC



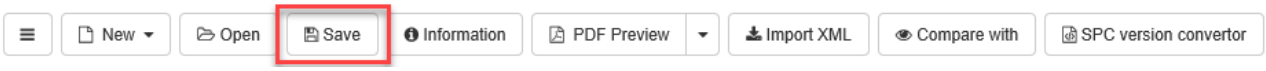
You can edit the SPC (modify the pre-filled fields) or modify the market area if you want to apply for mutual recognition. In this scenario, click on 'new' and choose to change the 'market area version'.

Figure 51: Market area version



Finally, save the SPC on your local environment.

Figure 52: Save the SPC file



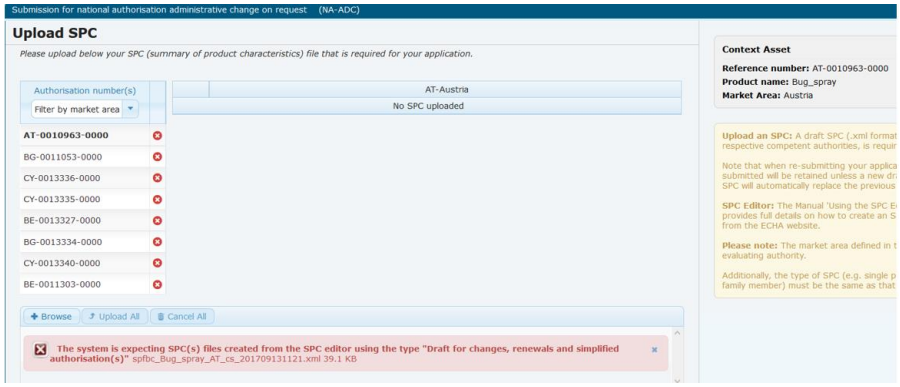
Your SPC is now ready for upload in R4BP.

6.2 Creating a draft for changes, renewals

You are allowed to hold **more than one authorisation** in **one market area** for a **specific product** (e.g. you own two National authorisations for the same product and for the same market area). Therefore, R4BP allows you to initiate changes (e.g. administrative changes (ADC), minor changes (MIC), major changes (MAC) or renewal (RNL)) in authorisations (i.e. assets) under the same market.

In this scenario, R4BP will require you to upload an XML of type 'Draft for changes, renewals" and with the same UUID than the initial SPC for the same market area.

Figure 53: Draft for changes, renewals to be uploaded in R4BP



In the SPC Editor, click on 'Open' to browse your local environment and search for the relevant SPC file(s) (Figure 53). Click on 'Draft for changes, renewals' (Figure 54).

Figure 54: Open an existing SPC

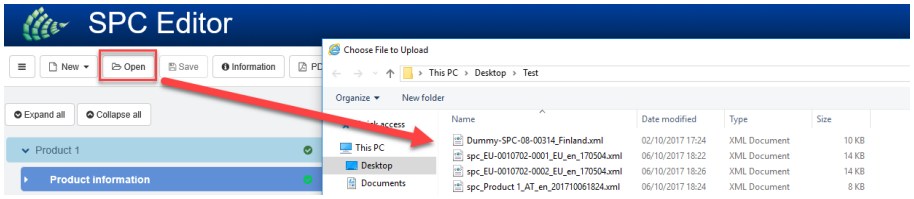
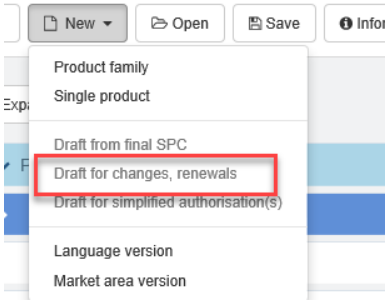
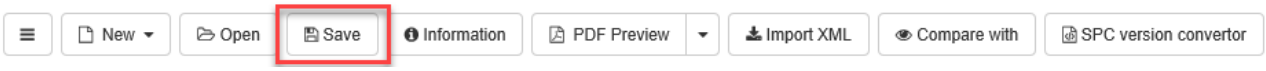


Figure 55: Draft for changes, renewals



Save the SPC from the SPC Editor (Figure 56). It is now ready for upload in R4BP.

Figure 56: Save the SPC

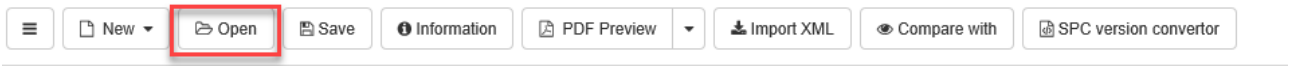


6.3 Draft for simplified authorisation(s)

In R4BP, you are allowed to notify for placing on the market one or more products (members of a family) in one wizard. In this scenario, you are require to upload an XML of type 'Draft for simplified authorisation(s)".

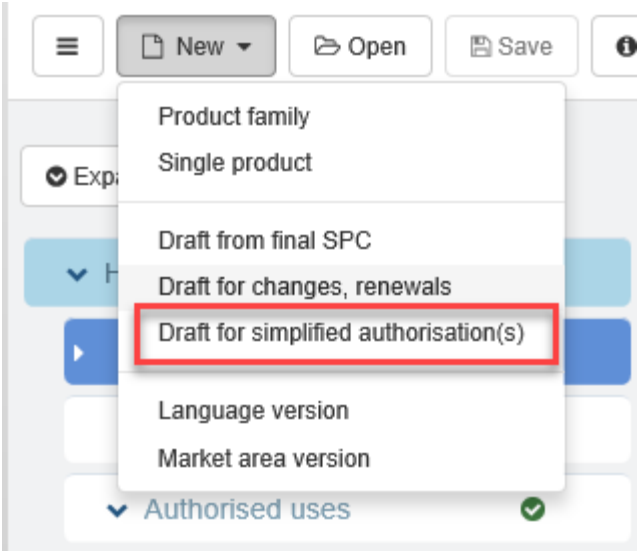
In the SPC Editor, open the SPC used for the reference asset.

Figure 57: Open an SPC



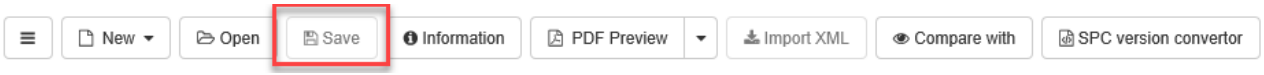
Click on 'New' and select 'Draft for simplified authorisation(s)" (Figure 58).

Figure 58: Draft for simplified authorisation(s)



Save the SPC from the SPC Editor and upload it in R4BP (Figure 59).

Figure 59: Save the SPC



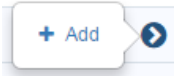
7. Graphical user interface elements

The graphical user interface elements used in SPC Editor are specified below.

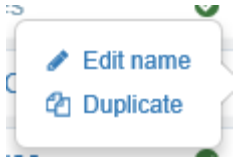
Indicates that a field is mandatory

Indicates that an SPC section or field is invalid

Indicates that an SPC section or field is complete and valid

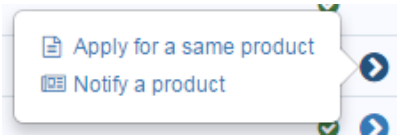


Add – Adds a new SPC section (meta SPC, authorised use, product)



Edit name – Edits the name of an SPC section (family, meta SPC, authorised use, product)

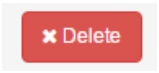
Duplicate – Creates a duplicate of an existing SPC section including all section data



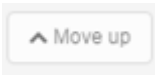
Apply for a same product – Creates a member product SPC based on the reference member product

Notify a product – Creates a notification for a member product (for the XX-NPF case type)

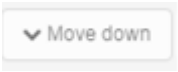
Add X – Adds a new field set



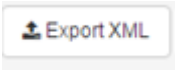
Delete – Deletes the specific field set



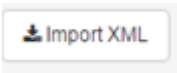
Move up – Moves the specific field set higher compared to the other similar field sets



Move down – Moves the specific field set lower compared to the other similar field sets



Export XML – Exports a specific field set to an XML file so than it can be imported in an active SPC in 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 eCA or COM in R4BP 3. It can be nevertheless used to create a draft SPC.

ANNEX I

Same biocidal product submission combinations

The below table indicates which reference SPC (to be downloaded from reference assets or cases) is needed to create a draft SPC which will eventually be uploaded in R4BP 3 when applying for SBP authorisations.

When creating a draft SPC, the reference SPC has to be first opened in the SPC Editor and then modified as needed. For example, for a single NA-BBP application (National authorisation of same biocidal product - pending), open in the SPC editor the reference NA-authorisation-case family SPC and select "apply for a same product" at product level in order to create a new draft. Alternatively if you have a Union authorisation you may open the reference UA-authorisation-case family SPC and select "apply for a same product" at product level in order to create a new draft SPC for a particular market area.

Please note that the SPC functionality "apply for a same product" is not present in single product SPC. Therefore in case you are applying for a BBS or BBP for a single product you will need to open the reference SPC in the editor, make sure that it is in a draft form and apply manually the envisaged administrative changes before uploading the newly created draft in the chosen single product R4BP 3 case type.

Please also note that the SPC functionality "apply for a same product" is not present at family level. Therefore in case you are applying for a BBS or BBP for a whole family or reduced family you will need to open the reference SPC in the editor, make sure that it is in a draft form and apply manually the envisaged administrative changes before uploading the newly created draft in the chosen family product R4BP 3 case type.

Type of SBP sought	R4BP 3		SPC	
	Case type to use	Reference asset/case to start from	Draft SPC needed	Reference SPC to start from
Family UA	UA-BBP	UA-APP - case	UA family SPC	UA family SPC
	UA-BBS	UA - asset		
Single UA	UA-BBP	UA-APP - case	UA single SPC	UA family SPC
	UA-BBS	UA – asset (member)		
	UA-BBP	UA-APP - case		UA single SPC
	UA-BBS	UA - asset		
Family NA	NA-BBP	NA-APP - case	NA family SPC	NA family SPC
	NA-BBS	NA – asset		
Single NA	NA-BBP	NA-APP - case	NA single SPC	NA family SPC
	NA-BBS	NA – asset (member)		
	NA-BBP	NA-APP - case		NA single SPC
	NA-BBS	NA - asset		
Family NA	NA-BBP	NA-APP - case	NA family SPC	NA family SPC
	NA-BBS	NA - asset		
Single NA	NA-BBP	NA-APP - case	NA single SPC	NA family SPC
	NA-BBS	NA – asset (member)		
	NA-BBP	NA-APP - case		NA single SPC
	NA-BBS	NA - asset		
Family SA	SA-BBP	SA-APP - case	SA family SPC	SA family SPC
	SA-BBS	SA - asset		
Single SA	SA-BBP	SA-APP - case	SA single SPC	SA family SPC
	SA-BBS	SA – asset (member)		
	SA-BBP	SA-APP- case		SA single SPC
	SA-BBS	SA - asset		

ANNEX II

SPC Migration to version 2.0

As a result of the adaptation to the new family structure, ECHA:

- migrated all existing family SPCs in R4BP 3 to the new family structure; and
- updated the SPC online editor to allow structured family applications.

ECHA carried out the automatic migration of existing SPCs for family applications in the cases/assets available in R4BP 3. The automatic migration process ensures that no data previously contained in SPCs is lost. However some adaptations may have to be applied to family SPC **anytime R4BP 3 requires their upload in a specific case type**. This may happen for:

1) on-going cases where applicants have followed the workaround solution proposed by ECHA in July 2015 and the new family structure has not been provided yet in structured format; or
2) when information available in the SPC had to be duplicated.

For point one if there are family cases without any member, the system will add one meta level and one 'empty' product in the converted family SPC. In this scenario you may be requested by the CA to add all the relevant information for the product in the third level of the SPC which appears empty after the migration.

If there are family assets without any member, the system will create one meta level and one new member asset in the converted family SPC. In this case, if you need to use the migrated asset to start a new case type, you will need to request the CA to add all the relevant information for the product in the third level of the SPC, which will appear empty after the migration, by amending the asset with an XX-AAT case type.

Point two implies that the CA may request you to update the new family SPC by removing any possible duplicates of information, which were necessary in order to avoid loss of data in the migration procedure. More in detail, please check the following fields at family level:

1) Manufacturers of the product
2) Manufacturers of the substance and at meta-SPC level
3) Authorised uses
4) General instructions for use

Please check also the content of the field "Other information" where the trade names that used to be in the old family SPC are migrated as free text.

Please consider that if there were cases or assets containing family SPC in language A and member SPCs in language B, the system will generate as many family SPCs as many different languages were present in the old SPC package (family and member SPCs). Choose only one of them before finalising any relevant task.

No changes will apply to SPCs for applications for single biocidal products.