Disclaimer

This document aims to assist users in complying with their obligations under the Biocides Regulation. However, users are reminded that the text of the Biocides Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

<table>
<thead>
<tr>
<th>Version</th>
<th>Changes</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version 1.0</td>
<td>First version.</td>
<td>October 2014</td>
</tr>
<tr>
<td>Version 1.1</td>
<td>Updated to reflect the changes in the BSM series.</td>
<td>December 2014</td>
</tr>
<tr>
<td>Version 1.2</td>
<td>Screenshots updated and a new chapter included 'Updating an SPC downloaded from R4BP 3’.</td>
<td>February 2015</td>
</tr>
<tr>
<td>Version 2.0</td>
<td>Updated to reflect the release of SPC 2.0. SPC 1.2 manual and addendum have been merged.</td>
<td>October 2016</td>
</tr>
<tr>
<td>Version 2.1</td>
<td>Chapter 1.3 added. ANNEX I table updated.</td>
<td>June 2017</td>
</tr>
<tr>
<td></td>
<td>Minor change in chapter 6.4.</td>
<td></td>
</tr>
<tr>
<td>Version 2.2</td>
<td>Updated to reflect the changes in the SPC Editor.</td>
<td>November 2017</td>
</tr>
<tr>
<td></td>
<td>Minor changes in chapters 3., 4. And 5.3. Chapter 6. Added.</td>
<td></td>
</tr>
<tr>
<td>Version 2.3</td>
<td>Updated to reflect the changes in the SPC Editor.</td>
<td>May 2018</td>
</tr>
<tr>
<td></td>
<td>Changes include the improvement of the comparison tool in chapter 7 and minor changes in chapter 8.</td>
<td></td>
</tr>
<tr>
<td>Version 2.4</td>
<td>Updated to reflect the changes in the SPC Editor.</td>
<td>October 2018</td>
</tr>
<tr>
<td></td>
<td>New word creator tool described in chapter 3. (See section 5. “Preview SPC” option).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>New chapters added:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5.7. Products (only for Product family SPC)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. Using the ‘Find’ functionality</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7.5. Apply for a same product from a single product SPC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7.6 Notify a new product in a family</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Minor changes in chapter 7.4 Apply for a same product from a Product family SPC.</td>
<td></td>
</tr>
<tr>
<td>Version 2.5</td>
<td>Updated to reflect the changes in the SPC Editor.</td>
<td>November 2019</td>
</tr>
<tr>
<td></td>
<td>New chapter added:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7. Use the ‘Commenting’ functionality.</td>
<td></td>
</tr>
</tbody>
</table>
Biocides submission manual: How to use the SPC Editor

**Reference:** ECHA-18-H-11-EN  
**ISBN:** 978-92-9020-562-3  
**Cat. Number:** ED-01-18-520-EN-N  
**DOI:** 10.2823/356332  
**Publ. date:** November 2019  
**Language:** EN

© European Chemicals Agency, 2019  
Cover page © European Chemicals Agency

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at: [http://echa.europa.eu/contact](http://echa.europa.eu/contact)

**European Chemicals Agency**

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland  
Visiting address: Annankatu 18, Helsinki, Finland
# Table of Contents

1. **Introduction** ................................................................. 9
   1.1 Objective ........................................................................ 9
   1.2 Biocides Submission Manuals ......................................... 9
   1.3 Additional assistance .................................................... 10

2. **Start using the SPC Editor** .............................................. 11

3. **Taskbar options** ............................................................... 12

4. **Create a new SPC** ............................................................ 15
   4.1 Product family .............................................................. 15
   4.2 Single product ............................................................ 16

5. **Sidebars** ........................................................................ 17
   5.1 Product information ...................................................... 17
   5.2 Administrative information ........................................... 20
   5.3 Meta SPC (only for Product family SPC) ......................... 22
   5.4 H & P statements ......................................................... 23
   5.5 Authorised uses ............................................................ 25
   5.6 Directions for use ........................................................... 28
   5.7 Other information .......................................................... 29
   5.8 Products (only for product family SPC) ........................... 30

6. **Use the ‘Find’ functionality** .............................................. 32
   6.1 Product family SPC ......................................................... 32
      6.1.1 Find where? ............................................................. 32
      6.1.2 Find what? .............................................................. 33
      6.1.3 Replace with ............................................................ 34
   6.2 Single Product SPC ......................................................... 36
      6.2.1 Find what? .............................................................. 36
      6.2.2 Replace with ............................................................ 37

7. **Use the ‘Commenting’ functionality** ............................... 40
   7.1 Add a comment .............................................................. 41
   7.2 Edit comment ............................................................... 41
   7.3 Delete comment(s) ......................................................... 41
   7.4 Show/hide comments ..................................................... 42

8. **Create a new draft from an existing SPC** ....................... 44
   8.1 Draft from final SPC ....................................................... 44
   8.2 Draft for changes or renewals ....................................... 46
   8.3 Draft for simplified authorisation(s) ............................... 47
   8.4 Apply for a same product from a Product family SPC ....... 48
   8.5 Apply for a same product from a Single product SPC ..... 49
   8.6 Notify a new product in a family (only for Product family SPC) ................................................. 49

9. **Compare two SPC files** ................................................. 51
10. **Graphical user interface elements** ................................ 54
ANNEX I ........................................................................................................................................56
ANNEX II .....................................................................................................................................58
Table of Figures

Figure 1: Choose the language................................................................. 11
Figure 2: Starting page of the SPC Editor.................................................. 11
Figure 3: Taskbar options .................................................................... 12
Figure 4: Information on the SPC file....................................................... 13
Figure 5: Import XML option for Product family SPC............................... 14
Figure 6: Create a new Product family SPC (step 1)................................... 15
Figure 7: Create a new Product family SPC (step 2)................................. 15
Figure 8: Create a new Single product SPC (step 1)................................. 16
Figure 9: Create a new Single product SPC (step 2)................................. 16
Figure 10: The ‘Product information’ tab .................................................. 17
Figure 11: Choose the type(s) of formulation.......................................... 17
Figure 12: The ‘Product information’ tab .................................................. 17
Figure 13: Choose the formulation type.................................................. 17
Figure 14: Add information on active substances, substances of concern, and other substances .......................................................... 18
Figure 15: Select the BAS number.......................................................... 18
Figure 16: Select the function of a substance of concern........................... 19
Figure 17: The ‘Administrative information’ tab....................................... 20
Figure 18: Select the product type.......................................................... 20
Figure 19: The ‘Administrative information’ tab....................................... 20
Figure 20: Define the country and trade name........................................... 20
Figure 21: Import option....................................................................... 21
Figure 22: Export option....................................................................... 21
Figure 23: Select the ‘meta SPC’ sub tab.................................................. 22
Figure 24: Select the product type(s)....................................................... 22
Figure 25: Select the min and max content percentage............................. 23
Figure 26: Select the formulation type.................................................... 23
Figure 27: Add meta SPC..................................................................... 23
Figure 28: Edit name............................................................................. 23
Figure 29: Selecting the ‘H&P statements’ tab........................................... 24
Figure 30: Select the ‘H & P statements’ tab............................................ 24
Figure 31: Create a block for hazard or precautionary statement............. 25
Figure 32: Select the same H & P statement (step 1)............................... 25
Figure 33: Select the same H&P statement (step 1)................................. 25
Figure 34: Select the ‘Use’ sub tab........................................................... 26
Figure 35: Select the ‘Use’ sub tab........................................................... 26
Figure 36: Add a block for Target organism, application method and packaging................................................................. 26
Figure 37: Create a new block for authorised uses (step 1)....................... 27
Figure 38: Create a new block for authorised uses (step 2)....................... 27
Figure 39: Select the ‘Directions for use’ tab.......................................... 28
Figure 40: Select the ‘Directions for use’ tab.......................................... 28
Figure 41: Select the 'Other information' tab .................................................. 29
Figure 42: Select the 'Other information' tab .................................................. 29
Figure 43: Free-text field under Other information ........................................ 29
Figure 44: Select the 'Product' sub tab ............................................................ 30
Figure 45: Add a trade name block (step 1) ..................................................... 30
Figure 46: Add a trade name block (step 2) ..................................................... 30
Figure 47: Create a duplicate tab ................................................................. 31
Figure 48: Add a Product .............................................................................. 31
Figure 49: Open an SPC file to start using the 'Find' functionality .................... 32
Figure 50: The 'Find' panel for Product family SPC ........................................ 32
Figure 51: Select where to search for your keyword ........................................ 32
Figure 52: Find what you are looking for ...................................................... 33
Figure 53: Expand or collapse sections ......................................................... 34
Figure 54: Too many results found ............................................................... 34
Figure 55: Read-only mode .......................................................................... 34
Figure 56: Draft from final SPC .................................................................... 34
Figure 57: Replace a keyword ...................................................................... 35
Figure 58: Replace all ................................................................................... 35
Figure 59: Confirm your selection .................................................................. 35
Figure 60: Replace ....................................................................................... 36
Figure 61: The 'Find' panel for Single Product SPC ......................................... 36
Figure 62: Find your keyword ...................................................................... 37
Figure 63: Read-only mode .......................................................................... 37
Figure 64: Draft from final SPC .................................................................... 37
Figure 65: Replace a keyword ...................................................................... 38
Figure 66: Replace all ................................................................................... 38
Figure 67: Confirm your selection .................................................................. 38
Figure 68: Replace a keyword in a section .................................................... 39
Figure 69: Commenting icon ........................................................................ 40
Figure 70: Add a comment .......................................................................... 41
Figure 71: Edit comment .............................................................................. 41
Figure 72: Delete single comment .................................................................. 42
Figure 73: Delete comment .......................................................................... 42
Figure 74: Show/hide comments ................................................................... 43
Figure 75: Open an existing SPC .................................................................. 44
Figure 76: Draft from final SPC .................................................................... 44
Figure 77: Market area version ..................................................................... 45
Figure 78: Save the SPC file ......................................................................... 45
Figure 79: Draft for changes, renewals to be uploaded in R4BP 3 .................... 46
Figure 80: Open existing SPC ....................................................................... 46
Figure 81: Draft for changes, renewals .......................................................... 46
Figure 82: Save the SPC .............................................................................. 46
Figure 83: Open an SPC.................................................. 47
Figure 84: Draft for simplified authorisation(s).......................... 47
Figure 85: Save the SPC.................................................. 47
Figure 86: Open a Product family SPC file.............................. 48
Figure 87: Find the Product............................................. 48
Figure 88: Apply for a same product.................................... 48
Figure 89: Apply for a same product.................................... 48
Figure 90: Open a Single product SPC file............................. 49
Figure 91: Open an SPC.................................................. 49
Figure 92: Find the Product............................................. 49
Figure 93: Notify a new product in a family............................ 49
Figure 94: Create your notification..................................... 50
Figure 95: Compare two SPC files..................................... 51
Figure 96: SPC Comparison............................................. 51
Figure 97: Synchronous scrolling...................................... 52
Figure 98: Compare meta SPC or Product............................. 52
Figure 99: Content removed, added, modified or changed......... 53
Figure 100: Show products switch on-off button..................... 53
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 the 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.

How to use 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.

How to use 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:

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

Process of 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. The chosen language relates to the user interface and not to the document language.

**Figure 1: Choose the language**

![Choose the language](image1.png)

**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).

To get started click on ‘Start using the SPC Editor!’.

**Figure 2: Starting page of the SPC Editor**

![Starting page of the SPC Editor](image2.png)
3. Taskbar options

Once you have gained access to the SPC editor, you are presented with a taskbar. It currently displays 10 options:

**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 8.1](#) 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 3 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 8.2](#) 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 8.3](#) 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. 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.

**Figure 4: Information on the SPC file**

<table>
<thead>
<tr>
<th>Document information</th>
<th>Authorization details</th>
<th>File information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product UUID</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family UUID</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product name</td>
<td>Product 1</td>
<td></td>
</tr>
<tr>
<td>Market area</td>
<td>European Union</td>
<td></td>
</tr>
<tr>
<td>Language</td>
<td>English</td>
<td></td>
</tr>
</tbody>
</table>

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. “Preview SPC” option: preview, open and print your SPC XML files:

- “Preview current SPC as PDF”: 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 in PDF”: open previously saved SPC XML file to view in PDF format.
• “Preview current SPC as Word”: view the SPC file you are currently working on in Word format or edit it after saving it first on your local hard drive.

• “Open & Preview in Word”: open previously saved SPC file to view in Word 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 of the meta SPC(s) and product(s) you are importing.

**Figure 5: Import XML option for Product family SPC**

Import: SPC - family

You are about to import content into your existing SPF SPC. The following will occur:

a) The current content will be kept.
b) The imported content (e.g. family level, meta SPC level(s) and related product level(s)) will be added to the current content.

Please select the meta SPC(s) you would like to import from the list below:

<table>
<thead>
<tr>
<th>meta SPC(s)</th>
<th>▲</th>
</tr>
</thead>
</table>

[ ] Preserve the meta SPC(s) and product(s) identities

7. “Compare SPC files” 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. See chapter 7 for additional details on the comparing functionality.

8. Choose the **language** of the SPC Editor.

9. “**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.

10. “**Find**” option: this functionality enables you to search and/or replace keywords in a draft SPC.

   For additional information, please see chapter 6.
4. Create a new SPC

Applicants who wish to submit a new application in R4BP 3 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 3, your SPC should be based on the SPC created for the initial case i.e. NA-APP), go to Chapter 8.

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 6: Create 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 7: Create a new Product family SPC (step 2)**

New: Product family

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family name</td>
<td></td>
</tr>
<tr>
<td>Market area</td>
<td></td>
</tr>
<tr>
<td>Language</td>
<td></td>
</tr>
</tbody>
</table>

OK  Cancel
**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 chapter ‘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 8: Create 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 9: Create 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 ‘5. 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.

<table>
<thead>
<tr>
<th>Product family SPC</th>
<th>Single product SPC</th>
</tr>
</thead>
<tbody>
<tr>
<td>- In the sidebar menu, click on ‘Product information’.</td>
<td>- In the sidebar menu, click on ‘Product information’.</td>
</tr>
<tr>
<td><strong>Figure 10: The ‘Product information’ tab</strong></td>
<td><strong>Figure 12: The ‘Product information’ tab</strong></td>
</tr>
<tr>
<td>![Sidebar menu with 'Product information' selected]</td>
<td>![Sidebar menu with 'Product information' selected]</td>
</tr>
<tr>
<td>- Choose one or several type(s) of formulation from the drop-down list.</td>
<td>- Choose only one formulation type from the drop-down list.</td>
</tr>
<tr>
<td><strong>Figure 11: Choose the type(s) of formulation</strong></td>
<td><strong>Figure 13: Choose the formulation type</strong></td>
</tr>
<tr>
<td>![Choice of formulation types]</td>
<td>![Choice of formulation types]</td>
</tr>
</tbody>
</table>

- Choose one or several type(s) of formulation from the drop-down list.
Common features (1/2)

- Click on ‘+Add…’ to enter details regarding any ‘Active substances’, ‘Substances of concern’ and ‘Other substances’. Note that at least one active substance is required.

Figure 14: Add 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).

⚠️ 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 https://echa.europa.eu/es/contact or alternatively 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.

Figure 15: Select the BAS number

- If you have added a ‘substance of concern’ and/or ‘other substance(s)’, you are not required to fill in the ‘Function’ field. However, the SPC Editor allows you to select a function from a drop-down list (Figure 16).

Fill in also the ‘Common name’ and the ‘Content (%)’ (for single product SPC) or the ‘Content range (%)’ (for Product family SPC).
Figure 16: Select the function of a substance of concern
5.2 Administrative information

The ‘Administrative information’ tab includes administrative information on the manufacturer(s) of the product/active substance.

### Product family SPC

- Select ‘Administrative information’ in the sidebar menu.

**Figure 17: The ‘Administrative information’ tab**

- Select one or more product types from the drop-down menu.

**Figure 18: Select the product type**

### Single product SPC

- Select ‘Administrative information’ in the sidebar menu.

**Figure 19: The ‘Administrative information’ tab**

- Choose the country from the drop-down menu and define the trade name of the product.

**Figure 20: Define 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 21: Import option**

  ![Import option](image)

  - Click on export XML in each section to be able to save your data in your local environment.

  **Figure 22: Export option**

  ![Export option](image)
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.

- Click on the sub tab ‘meta SPC’ in the sidebar menu.

**Figure 23: Selecte the ‘meta SPC’ sub tab**

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

**Figure 24: Select the product type(s)**

- Fill in the ‘Meta SPC composition information’: define the minimum and maximum content percentage of the active substance.

**Note** that at least one active substance must be defined in your SPC.
- Select one of the 'formulation type' indicated in the family level from the drop-down list.

**Figure 26: Select the formulation type**

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 27: Add meta SPC**

You can rename each sub tab according to your wishes.

**Figure 28: Edit name**

### 5.4 H & P statements

'H & P statements' tab includes the hazard and precautionary statements for the product.
### Product family SPC

- Click on ‘H&P statements’ in the sidebar menu.

**Figure 29: Selecting the ‘H&P statements’ tab**

<table>
<thead>
<tr>
<th>Administrative information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Information</td>
</tr>
<tr>
<td>meta SPCs</td>
</tr>
<tr>
<td>- meta SPC</td>
</tr>
<tr>
<td>- H &amp; P statements</td>
</tr>
<tr>
<td>- Authorised uses</td>
</tr>
<tr>
<td>- Use</td>
</tr>
<tr>
<td>- Directions for use</td>
</tr>
<tr>
<td>- Other information</td>
</tr>
<tr>
<td>- Products</td>
</tr>
<tr>
<td>- Product</td>
</tr>
</tbody>
</table>

### Single product SPC

- Click on ‘H&P statements’ in the sidebar menu.

**Figure 30: Select the ‘H & P statements’ tab**

<table>
<thead>
<tr>
<th>eez</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Product information</td>
</tr>
<tr>
<td>- H &amp; P statements</td>
</tr>
<tr>
<td>- Authorised uses</td>
</tr>
<tr>
<td>- Use</td>
</tr>
<tr>
<td>- Directions for use</td>
</tr>
<tr>
<td>- Administrative information</td>
</tr>
<tr>
<td>- Other information</td>
</tr>
</tbody>
</table>

### Common features

- Click on ‘+ Add…’ to create a block for ‘Hazard statements’ or ‘Precautionary statements’. 
5.5 Authorised uses

The ‘Authorised uses’ tab includes details about the use, target organism, application methods, and packaging.
How to use the SPC Editor

- Click on 'Use' below 'Authorised uses' in the sidebar menu.

**Figure 34: Select the 'Use' sub tab**

- Click on 'Use' below Authorised uses in the sidebar menu.

**Figure 35: Select the 'Use' sub tab**

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 36).

**Figure 36: Add 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 37, step 1) and type a title (Figure 38, step 2).

**Figure 37: Create a new block for authorised uses (step 1)**

**Figure 38: Create a new block for authorised uses (step 2)**
5.6 Directions for use

This tab includes information on general directions for use.

### Product family SPC

- Click on ‘Directions for use’.

**Figure 39: Select the ‘Directions for use’ tab**

#### Single product SPC

- Click on ‘Directions for use’.

**Figure 40: Select the ‘Directions for use’ tab**

### 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’.
5.7 Other information

Other information can be added to the SPC.

<table>
<thead>
<tr>
<th>Product Family SPC</th>
<th>Single Product SPC</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Click on ‘Other information’.</td>
<td>- Click on ‘Other information’.</td>
</tr>
<tr>
<td><strong>Figure 41: Select the ‘Other information’ tab</strong></td>
<td><strong>Figure 42: Select the ‘Other information’ tab</strong></td>
</tr>
</tbody>
</table>

**Common features**

- Enter any additional information into the free-text field under the ‘Other information’ tab.

**Figure 43: Free-text field under Other information**
5.8 Products (only for product family SPC)

Users can fill in information regarding their products but also create an SPC to apply for a same product or notify a new product in family (see chapters 8.4 and 8.5 and 8.6).

- Click on ‘Product’ in the sidebar menu.

**Figure 44: Select the ‘Product’ sub tab**

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

**Figure 45: Add a trade name block (step 1)**

**Figure 46: Add a trade name block (step 2)**

- Fill in also the ‘Content (%)’ field of each biocidal product and the required information regarding the manufacturer(s).
- After completing the required fields, you can create a ‘Duplicate’ tab.

**Figure 47: Create 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 48: Add a Product**

- If you wish to ‘Apply for a same product’ please see chapter 8.4 and 8.5.
- If you wish to ‘Notify a new product in a family’ please see chapter 8.6.
6. Use the ‘Find’ functionality

Users can find keywords and/or replace them in their draft SPCs.

In order to start using this functionality, click on ‘Find’ (1) and open a product family or a single product SPC file (2).

Figure 49: Open an SPC file to start using the ‘Find’ functionality

6.1 Product family SPC

A ‘find’ panel will emerge from the left side of your screen and displays three different sections.

Figure 50: The ‘Find’ panel for Product family SPC

6.1.1 Find where?

- **Select section**: limit your search to meta SPC or Product family areas.

Figure 51: Select where to search for your keyword
• **Entire SPC file**: by default, the ‘entire SPC file’ option will be selected.

### 6.1.2 Find what?

In this section, enter a keyword and press ‘Find’. The total number of results as well as the location of the keyword will be displayed in the ‘results’ section.

**Figure 52: Find what you are looking for**

The results are categorized per SPC section. Note that you can expand or collapse these sections.
In case your keyword returns too many results, you will be required to refine your search criteria:

### Figure 54: Too many results found

6.1.3 Replace with

If you are viewing a final SPC in a read-only mode, the ‘Replace with’ function will be disabled.

### Figure 55: Read-only mode

Click on ‘Draft from final SPC’ in order to be able to edit your document.

### Figure 56: Draft from final SPC
Once you have typed in the text you are searching for, tick the ‘Replace with’ box. Enter the text to replace the keyword with and press ‘Find’.

**Figure 57: Replace a keyword**

If you need to replace the keyword in all the sections, press the ‘Replace all’ button.

**Figure 58: Replace all**

You will be required to confirm your selection.

**Figure 59: Confirm your selection**

If you need to replace the keyword in one section of the SPC, choose the relevant section and press ‘replace’.
6.2 Single Product SPC

A 'find' panel will emerge from the left side of your screen and displays two different sections.

6.2.1 Find what?

In 'Find what', insert a text and click on 'Find'. The total number of results as well as the location of the keyword will be displayed in the 'results' section.
Results are categorized per SPC section. You can expand or collapse these sections.

### 6.2.2 Replace with

If you are viewing a final SPC in Read-only mode, the ‘Replace with’ function will be disabled.

![Figure 63: Read-only mode](image)

Click on ‘Draft from final SPC’ in order to be able to edit your document.

![Figure 64: Draft from final SPC](image)

Once you have typed in the text you are searching for, tick the ‘Replace with’ box. Enter the text to replace the keyword with and press ‘Find’.
If you need to replace the keyword in all the sections, press the ‘Replace all’ button.

You will be required to confirm your selection.

If you need to replace the keyword in one section of the SPC, choose the relevant section and press ‘replace’.
Figure 68: Replace a keyword in a section

Find

Find what?
Difenacoum

Replace with
Brodexes

Find

Edit search

Results

Administrative information → Trade name

Directions for use → Instructions for use
Directions for use → Instructions for use

Replace all → Replace
7. Use the ‘Commenting’ functionality

Comments are meant to provide clarification of a specific SPC field between authorities and applicant during assessment of the SPC.

Commenting option is available only in the SPC editor, while the SPC is in status draft.

- Comments fields should not be used for delivering technical information describing a product.

- The comments are only visible, if the SPC is opened in the SPC editor.

- The SPC with comments can be exchanged with authorities only via new communication in R4BP 3.

  When uploading the SPC file in R4BP 3 during submission or re-submission, the SPC file must not have comments otherwise the upload of the SPC is failing.

Comments can be edited and deleted after being inserted. When comments are introduced, the commenting icon beside the field will indicate the number of comments inserted. If the number is not displayed, there are no comments.

Commenting icon(s) in the SPC menu in the left-hand side of the screen are visible only, if there is a comment inserted in the relevant section.

Figure 69: Commenting icon

![Commenting icon](image)

Meta SPC(s) can be re-arranged without losing the inserted comments. When sections of information are copied the comments are not copied together with the copied text.
7.1 Add a comment

Click on the commenting icon next to the relevant field: the comments panel opens and you are able to include your comment once the mandatory fields are filled in. You can see number of remaining characters while typing your comment below the comment field. You can respond to a comment by inserting a new one. One field can have more than one comment inserted.

Figure 70: Add a comment

7.2 Edit comment

Click on ‘Edit’ in the comments panel for editing your comment and save your changes.

Figure 71: Edit comment

7.3 Delete comment(s)

Click on ‘Delete’ in the comments panel for deleting a single comment and confirm your selection.
Click on the commenting icon on the top right-hand corner of the comment panel, select ‘Delete all’ for deleting all the comments across SPC and confirm your selection.

**Figure 73: Delete comment**

7.4 Show/hide comments

Click on the comment icon on the top right-hand corner of the comment panel and select either tick to show comments or un-tick to hide comments.

When the hide comments option is active the comment icons are not visible next to the fields but are still visible on the tree next to the relevant sections of the SPC for your convenience.
Figure 74: Show/hide comments
8. Create a new draft from 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.

8.1 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 3, 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 75: Open an existing SPC

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

Figure 76: 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’.
Finally, save the SPC on your local environment.

**Figure 78: Save the SPC file**

Your SPC is now ready for upload in R4BP 3.
8.2 Draft for changes or renewals

R4BP 3 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 3 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 79: Draft for changes, renewals to be uploaded in R4BP 3

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

Figure 80: Open existing SPC

Figure 81: Draft for changes, renewals

Save the SPC from the SPC Editor. It is now ready for upload in R4BP 3.

Figure 82: Save the SPC
8.3 Draft for simplified authorisation(s)

In R4BP 3, you are allowed to notify for placing one or more products (members of a family) in one wizard. In this scenario, you are required to upload an XML of type "Draft for simplified authorisation(s)".

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

**Figure 83: Open an SPC**

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

**Figure 84: Draft for simplified authorisation(s)**

Save the SPC from the SPC Editor and upload it in R4BP 3.

**Figure 85: Save the SPC**
8.4 Apply for a same product from a Product family SPC

If you need to apply for a same product, start by opening the relevant Product family SPC.

**Figure 86: Open a Product family SPC file**

In the sidebar, look for the required product(s).

**Figure 87: Find the Product**

Once you have found your product, click on the blue arrow to ‘Apply for a same product’.

**Figure 88: Apply for a same product**

A pop-up window will appear and display 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 89: Apply for a same product**
8.5 Apply for a same product from a Single product SPC

You can apply for a same product from a single product SPC. In this case, start by opening the relevant Single product SPC.

Figure 90: Open a Single product SPC file

You can edit the document, preview as PDF or Word, open in PDF or Word, use the find functionality, compare the SPC with another file and save it on your desktop.

8.6 Notify a new product in a family (only for Product family SPC)

If you need to notify a new product in a family, start by opening the relevant Product family SPC.

Figure 91: Open an SPC

In the sidebar, look for the required product(s).

Figure 92: Find the Product

Once you have found your product, click on the blue arrow to ‘Apply for a same product’.

Figure 93: Notify a new product in a family
You will be required to fill in the product name and the trade name of the product before being able to create your notification.

**Figure 94: Create your notification**

![SPC Editor interface](image)

- **Product name**
- **Trade names of the product**
- **Specific composition of each biocidal product**
  - Common name
  - Content (%)
  - Function
  - max. BPC content usage (%)
  - User unit
  - Active substance
  - 1.75
  - 1.75
- **Manufacturer(s) of the biocidal product**
  - Name of the manufacturer
  - Address
  - Contact person
9. Compare two SPC files

Users can use the SPC comparison feature to identify the differences between two SPC files. This feature supports the comparison between two SPC files of the same type making possible the comparison between:

- two single product SPC files;
- two product family SPC files;
- meta SPC & product levels of family SPC files.

In case an SPC file (single product or biocidal product family) has already been selected, the user should select for comparison a second SPC file of the same product category (single product or biocidal family product).

In case the user intends to compare a single product SPC file with a biocidal product family SPC file, a warning message will appear.

To start comparing your files, click on ‘compare SPC files’ and upload the original and revised SPC files.

**Figure 95: Compare two SPC files**

![Compare two SPC files](image)

**Figure 96: SPC Comparison**

You will be able to identify the changes between the two uploaded SPC files. Green color highlights new added content, orange color highlights modified content whereas red color indicates removed content.
The system also provides a higher level of granularity for the identified differences. Thus, within the modified text which is highlighted with orange color:

- The added text is displayed with a dashed underline.
- The removed text is displayed with a strikethrough.

When your two documents have been uploaded, you will notice that the synchronous scrolling option is enabled by default. You can disable or re-enable this option.

**Figure 97: Synchronous scrolling**

Users who have uploaded family product SPCs can compare their meta SPC or product(s). In order to have this kind of comparison, select the relevant levels (meta or product) (Figure 87, step 1 and 2) and click on the compare button (Figure 87, step 3). Note that the system will not allow you to compare a Meta level to a Product level.

**Figure 98: Compare meta SPC or Product**

The user should be able to see whether the specific level of the revised file has been modified, added, removed or not changed compared to the respective level of the original file.

The following functionalities are also available:

- reset the selection by clicking on the reset button
- use the auto complete drop down text fields in order to select a product / meta level simply by typing either its name or its UUID.
You have the option to view or hide product levels by using the 'Show products' switch on-off button.

⚠️ This feature is not available for SPC files generated in the old format.
10. 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 from the reference member product SPC

Notify a product – Creates a notification for a new member product (for NA-NPF, SA-NPF, UA-NPF case types) from the final authorised version of the family SPC

Add – 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 that 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 or to create a notification for a new
member product (for NA-NPF, SA-NPF and UA-NPF case types) from an authorised family.

Upload the original and revised SPC files

Perform a comparison of the selected meta/product levels of two BFP SPC files.

Reset the user’s selected levels from the two BFP SPC files

Enable the synchronous scrolling feature

Display or hide the product levels from the modal panel

Show or hide commenting icons next to fields

Delete all comments in SPC file

Indicates number of comments inserted for the field
**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.
<table>
<thead>
<tr>
<th>Type of SBP sought</th>
<th>Case type to use</th>
<th>R4BP 3 Reference asset/case to start from</th>
<th>Draft SPC needed</th>
<th>SPC Reference SPC to start from</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family UA</td>
<td>UA-BBP</td>
<td>UA-APP - case</td>
<td>UA family SPC</td>
<td>UA family SPC</td>
</tr>
<tr>
<td></td>
<td>UA-BBS</td>
<td>UA - asset</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single UA</td>
<td>UA-BBP</td>
<td>UA-APP - case</td>
<td>UA single SPC</td>
<td>UA family SPC</td>
</tr>
<tr>
<td></td>
<td>UA-BBS</td>
<td>UA – asset (member)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UA-BBP</td>
<td>UA-APP - case</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UA-BBS</td>
<td>UA - asset</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family NA</td>
<td>NA-BBP</td>
<td>UA-APP - case</td>
<td>NA family SPC</td>
<td>UA family SPC</td>
</tr>
<tr>
<td></td>
<td>NA-BBS</td>
<td>UA – asset</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single NA</td>
<td>NA-BBP</td>
<td>NA-APP - case</td>
<td>NA single SPC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NA-BBS</td>
<td>UA – asset (member)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NA-BBP</td>
<td>UA-APP - case</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NA-BBS</td>
<td>NA - asset</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family NA</td>
<td>NA-BBP</td>
<td>NA-APP - case</td>
<td>NA family SPC</td>
<td>NA family SPC</td>
</tr>
<tr>
<td></td>
<td>NA-BBS</td>
<td>NA - asset</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single NA</td>
<td>NA-BBP</td>
<td>NA-APP - case</td>
<td>NA single SPC</td>
<td>NA family SPC</td>
</tr>
<tr>
<td></td>
<td>NA-BBS</td>
<td>NA – asset (member)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NA-BBP</td>
<td>NA-APP - case</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NA-BBS</td>
<td>NA - asset</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family SA</td>
<td>SA-BBP</td>
<td>SA-APP - case</td>
<td>SA family SPC</td>
<td>SA family SPC</td>
</tr>
<tr>
<td></td>
<td>SA-BBS</td>
<td>SA - asset</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single SA</td>
<td>SA-BBP</td>
<td>SA-APP - case</td>
<td>SA single SPC</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SA-BBS</td>
<td>SA – asset (member)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SA-BBP</td>
<td>SA-APP - case</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SA-BBS</td>
<td>SA - asset</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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 NA-AAT and SA-AAT case types.

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.