ECHA
EUROPEAN CHEMICALS AGENCY

Biocides Submission Manual

How to submit an application for Simplified Authorisation

February 2024

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.

Version	Changes	Date
Version 1.0	First version	December 2014
Version 2.0	Release of R4BP version 3.3. Minor update which includes the following: Information on SN-NOT included in section 7.2.1. Information concerning changes on request updated in section 5.1 Information concerning the summary of product characteristics included in section 2.3.2	June 2015
Version 3.0	New paragraphs added under the chapter 4.1. Annex I and Annex II updated. References to IUCLID 5 removed and other minor updates included.	October 2016
Version 4.0	Release of R4BP version 3.9. The new following chapters added: 11. Administrative change of notification for placing on the market 12. Cancellation of notification for placing on the market The new sub-chapter added: 3.3 Submitting a batch of administrative change(s) applications Minor changes made for the following chapter: 7.1.1 Launching the SA-ADC/MIC/or MAC application wizard Updates in sub-chapters 6.1.2 and 7.1.2.	June 2017
Version 4.1	The following amendments made: New paragraphs added to chapter 10.2. Notification for placing on the market Amendments made in the chapter 12. Administrative change of notification for placing on the market	November 2017

Version	Changes	Date
Version 5	Release of R4BP 3.12. Minor updates which include the following: Screenshots updated References to the submission manuals updated to reflect the changes in their names New paragraph added to chapter 3.3 Chapter 3.4. added	November 2018
Version 6	Update to reflect transition from IUCLID 6.3 to IUCLID 6.4, and from the classic user interface to the web user interface. Annex I and II removed. Minor changes and updates.	January 2020
Version 7	Release of R4BP 3.26. Changes include following: SPC editor discontinued, instead SPC should be prepared in IUCLID format with specific working context.	February 2024

BSM: How to submit an application for Simplified Authorisation

Reference: ECHA-14-B-25-EN
ISBN: 978-92-9481-366-4
Cat. Number: ED-04-19-802-EN-N
DOI: 10.2823/29191
Publ.date: February 2024
Language: EN

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European Chemicals Agency

P.O. Box 400, FI-00121 Helsinki, Finland

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1. Introduction

1.1. Objective

This manual gives instructions on how to submit applications concerning national authorisations that assist the making available on the market and use of biocidal products, through the Register for Biocidal Products (R4BP 3) according to the Biocidal Products Regulation[1] (BPR) and specifically covers national authorisations – simplified procedure, and related applications.

1.2. Biocides Submission Manuals – application instructions

This manual is part of the Biocides Submission Manual (BSM) series concerning application instructions. It should be used with the following technical guides and process manuals:

Technical guides:

How to prepare a biocides dossier, which 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. Also, how to create a SPC in IUCLID format is described in that technical guide.

How to use R4BP 3, which describes how to create a valid legal entity in IUCLID, create user accounts in R4BP 3 through ECHA Accounts and gives a detailed description of the generic steps in an application wizard[2].

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.

A link to all of the Biocides Submission Manuals, including the technical guides, application instructions and related processes can be found from ECHA's website.

Additional assistance:

In addition to the Biocides Submission Manuals, you can find more information concerning the regulatory context of biocide applications and an overview of the evaluation process 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.

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

[2] The R4BP 3 application 'wizard' guides you through the various steps of an application form, prompting you to include necessary files such as a dossier and supporting documents.

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.

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

2. General submission information

This chapter gives a general overview of the different application types concerning the approval of active substances. Detailed submission information on each application type is provided in its own specific chapter. Summarised submission information (preparing, submitting, and monitoring an application) for each application can also be found from the ECHA Support pages. From here, you will also find links to video tutorials and webinars.

2.1. Application types and fees

Table 1 outlines the case abbreviations used for the application types in R4BP 3 presented in this manual.

You should always check with your Member State competent authority (MSCA) if an MSCA fee applies. For more information about MSCA fees, please contact the appropriate MSCA helpdesk. A comprehensive list of national helpdesks is available from ECHA's website.

Table 1: National authorisation (simplified procedure)

Case abbreviation	Application
SA-APP	National authorisation - simplified procedure
SA-BBS	Simplified authorisation of the same biocidal product (authorised)
SA-BBP	Simplified authorisation of the same biocidal product (pending)
SA-ADC	Simplified authorisation administrative change on request
SA-MIC	Simplified authorisation minor change on request
SA-MAC	Simplified authorisation major change on request
SA-TRS	Transfer of a simplified authorisation
SA-NPF	Notification of product in product family for simplified authorisation
SE-NOT	Notification of unexpected or adverse effect for simplified authorisation
SN-NOT	Notification for placing on the market
SN-ADC	Administrative change of notification for placing on the market

Case abbreviation	Application
SN-CCL	Cancellation of notification for placing on the market
IN-REB*	**Inquiry to share data (biocidal product)**
CC-APP*	**Request for a classification of a change to a product authorisation €**

***** Applications for an inquiry to share data for a biocidal product and the request for a classification of a change to a product authorisation are detailed in BSM Application instructions: How to submit an application for National Authorisation.

€ This application type is subject to an ECHA fee.

2.2. Application requirements

Depending on the application type, and your individual circumstances you may need to include a IUCLID dossier, an SPC, and/or other additional supporting documents. You can find specific instructions on what is required for your application and where to include it in the relevant sub-chapter of this manual.

For detailed information on how and what you can claim confidential under Article 67(3) of the BPR, please consult BSM 'Process of confidentiality requests for biocide applications'.

2.2.1. IUCLID dossier

A IUCLID dossier (.i6z format) may be required as part of your application. We recommend that you use the designated IUCLID fields wherever possible to store your data. When a dossier is required, you should upload it in R4BP 3 as prompted by the application wizard.

For full technical assistance on how to prepare a IUCLID dossier and enter data into the most important fields, please refer to the BSM 'Technical guide: How to prepare a biocides dossier'.

2.2.2. A summary of product characteristics (SPC)

You may need an SPC for your application and should submit it using the R4BP 3 wizard. The .i6z file format of the SPC is mandatory and you can create this with the IUCLID available from ECHA's website. We advise you to consult the relevant MSCA for further clarification on the language and the requirements for the SPC.

For technical assistance on how to prepare an SPC using IUCLID, please consult the BSM 'Technical guide: How to prepare a biocides dossier'.

IMPORTANT NOTE: On the date of the authorisation of a biocidal product, information on the product will be disseminated on ECHA's website, including information contained in the SPC.

2.2.3. Supporting documents

Under the BPR, you often need to submit supporting documents[3] as part of your application. Depending on the type of application you are submitting, the required supporting documents will need to be attached either in your IUCLID dossier or uploaded directly in the R4BP 3 application 'wizard'. You can find direct instructions on where to include individual supporting documents relevant to your application type in the applicable chapter of this manual.

Additional supporting documents: For many application types, ECHA or National Authority requires additional supporting documents to enable the correct handling and processing of your application. Consult the relevant chapter for your application for specific details or visit the Supporting documents page from ECHA's website for the full list.

[3] Including but not limited to, a draft risk assessment report, written confirmation from a proposed evaluating MSCA confirming their agreement to evaluate the application, letter of access, 'permission to refer' to data granted by ECHA under Article 63 of the BPR, or a decision on technical equivalence.

3. Submitting an application in R4BP 3

Make sure that you have fulfilled all of the application requirements in IUCLID and have all the necessary documents ready in your dossier or ready for uploading before you begin the submission process in R4BP 3.

When you launch an application in R4BP 3, the application wizard automatically prompts you in a step-wise fashion to upload the files such as a dossier, SPC and other supporting documents required for each application. Specific help texts and tool tips in R4BP 3 will further help you during the application procedure.

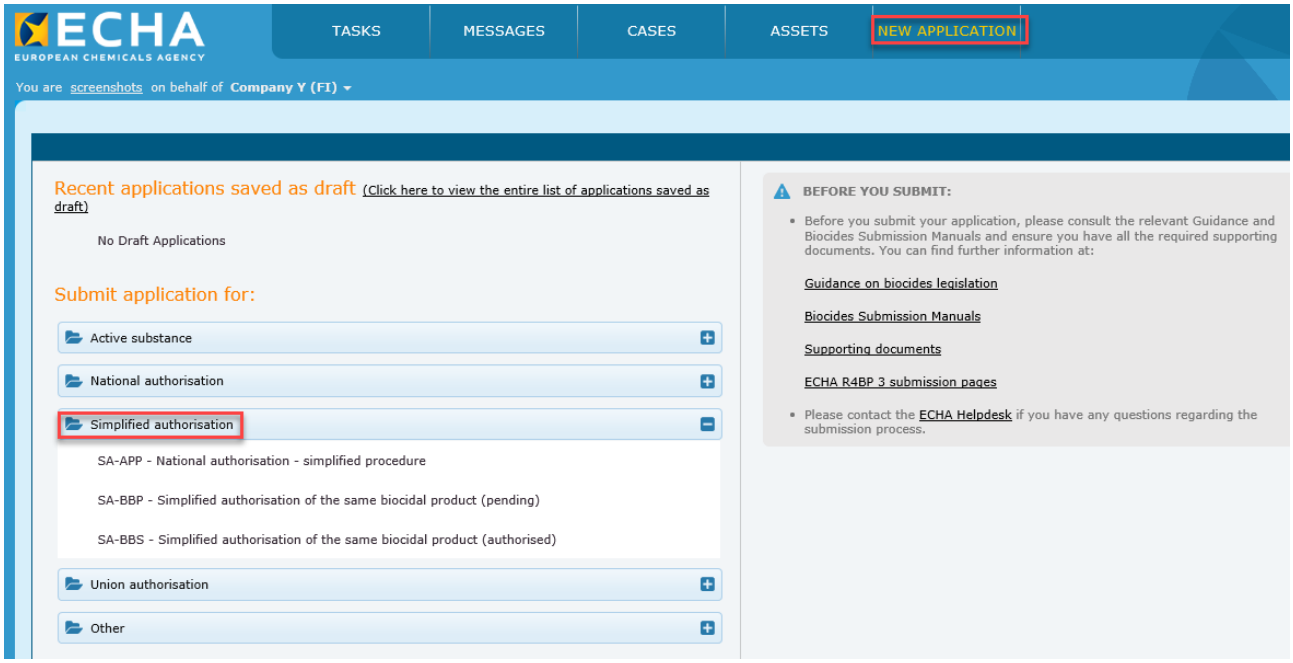
You can find additional guidance on using R4BP 3 in 'BSM Technical guide: How to use R4BP 3'.

Depending on the type of application you are submitting, you can launch the R4BP 3 application wizard in various ways:

3.1. Submitting a single application via the 'NEW APPLICATION' tab

You can launch the application wizard as a new application, click on the 'NEW APPLICATION' tab on the R4BP 3 taskbar and then click the folder 'Simplified authorisation' to see the full list of application types available. Then, select the relevant application for your purpose.

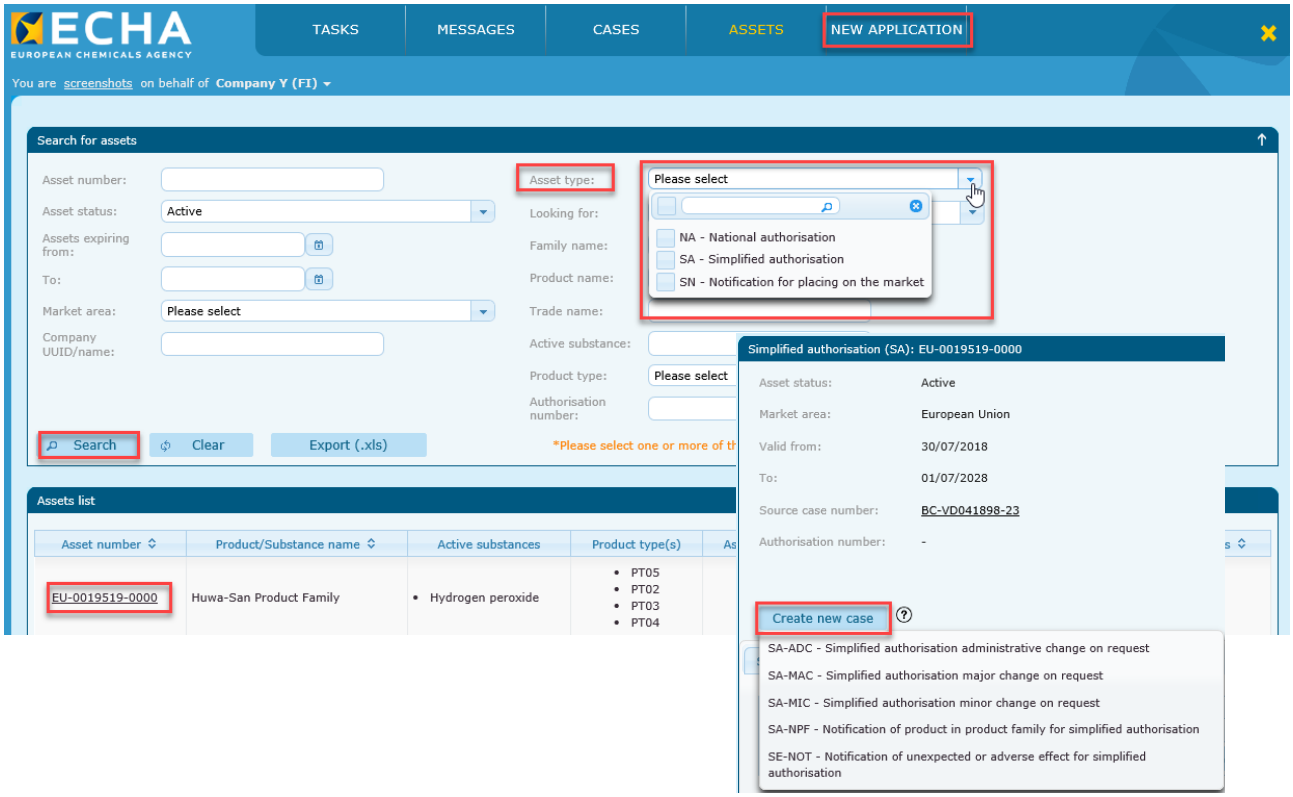
Figure 1: Launching the application wizard through a 'new application'



3.2. Submitting a single application via an 'existing asset'

You can launch the application wizard through an existing asset (Figure 2), click on the 'ASSETS' tab on the R4BP 3 taskbar. Then, search for the specific asset by filling in some search criterion (e.g. the asset type (SA – Simplified Authorisation), etc.). Clicking on the asset number hyperlink in the 'Assets list' will open a details page for that specific asset. On this page, click 'Create new case' and a list of application types available for that asset will appear. From this list, you can launch the wizard by selecting the relevant application for your purposes.

Figure 2: Launching the application wizard through an existing 'asset'

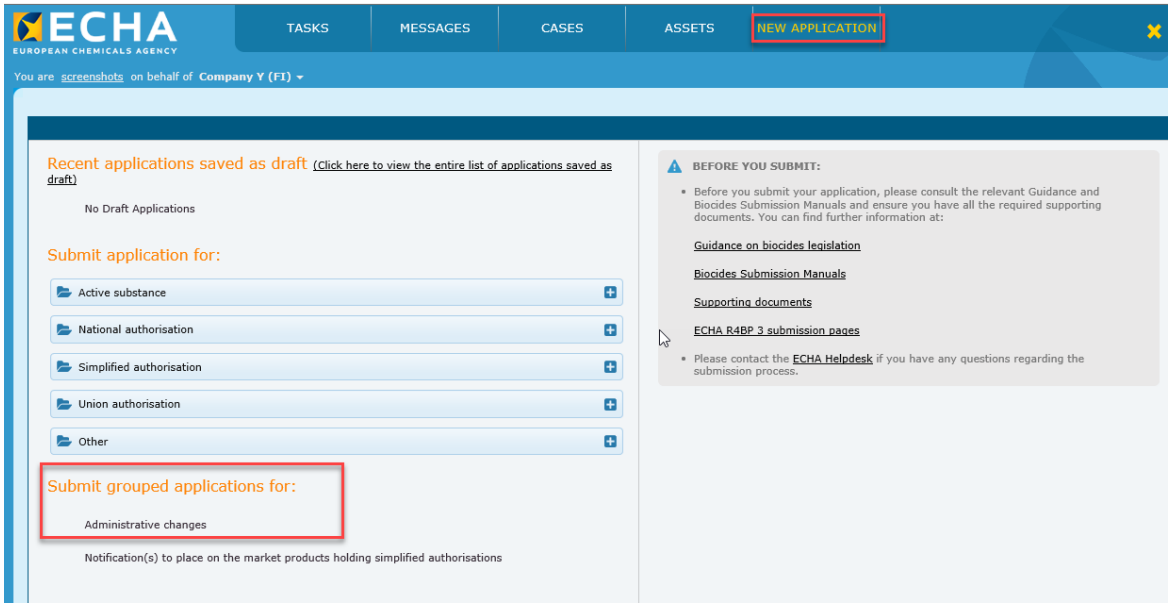


3.3. Submitting a batch of administrative change(s) applications (only for SA-ADC)

This step is facilitating the selection of the assets for which administrative change on request should be submitted in R4BP 3. Please note that each Administrative Change on Request submitted through this wizard will run independently from one another.

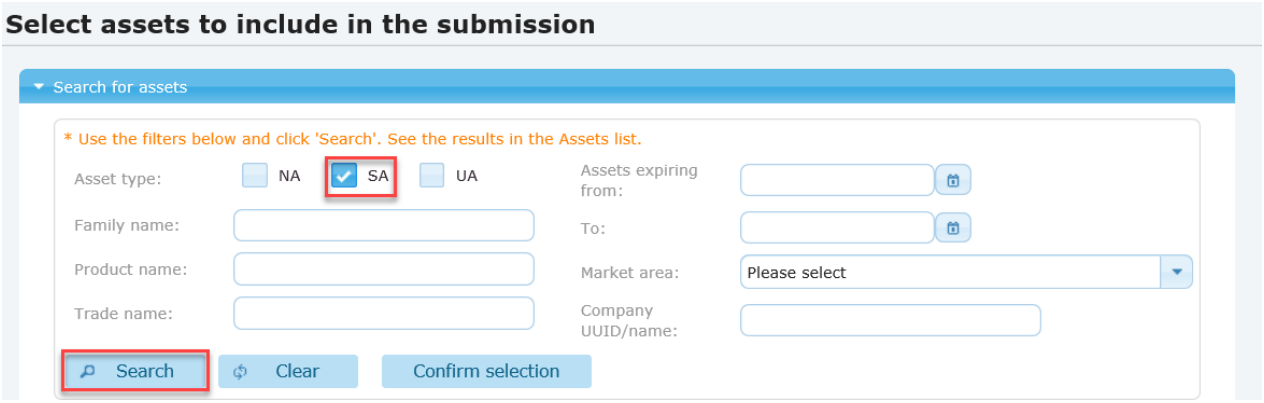
To submit several applications concerning administrative change(s) (i.e: SA-ADC), click on the 'NEW APPLICATION' tab on the R4BP 3 taskbar, and select 'Administrative changes' at the bottom of the page.

Figure 3: Submit a batch of administrative changes



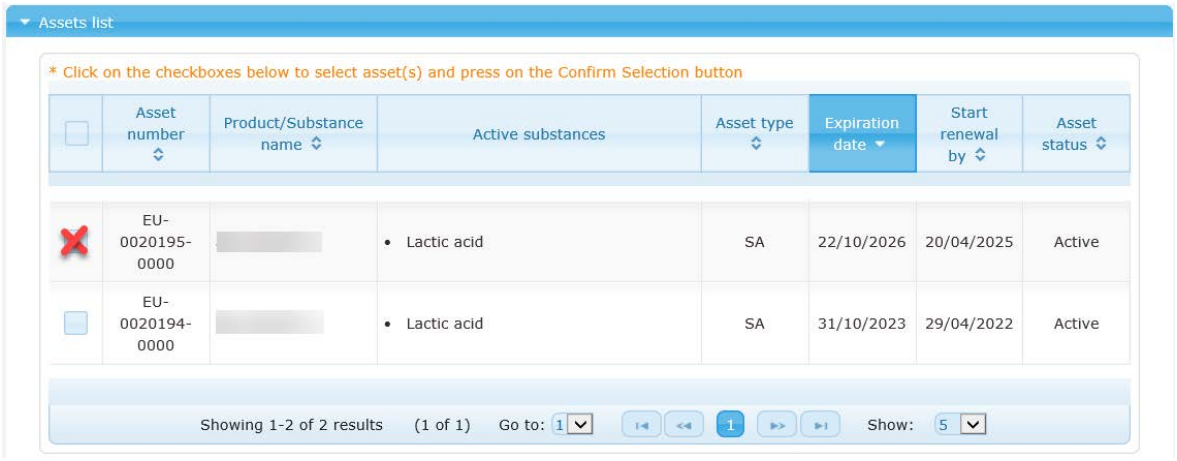
The submission wizard will prompt you to search for the relevant assets. Fill in some search criteria in the 'search for assets' section. When ready, click on 'search'.

Figure 4: select assets to include in the submission



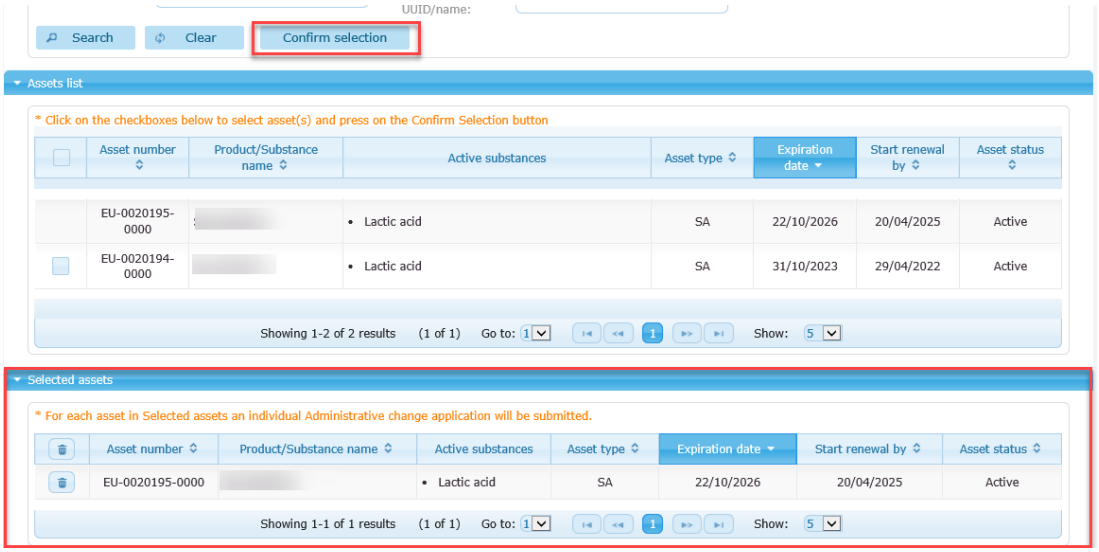
The 'Assets list' shows the list of all the assets that meet the conditions selected in the search criteria. Browse the page and select the asset(s) as needed.

Figure 5: The 'Asset list'



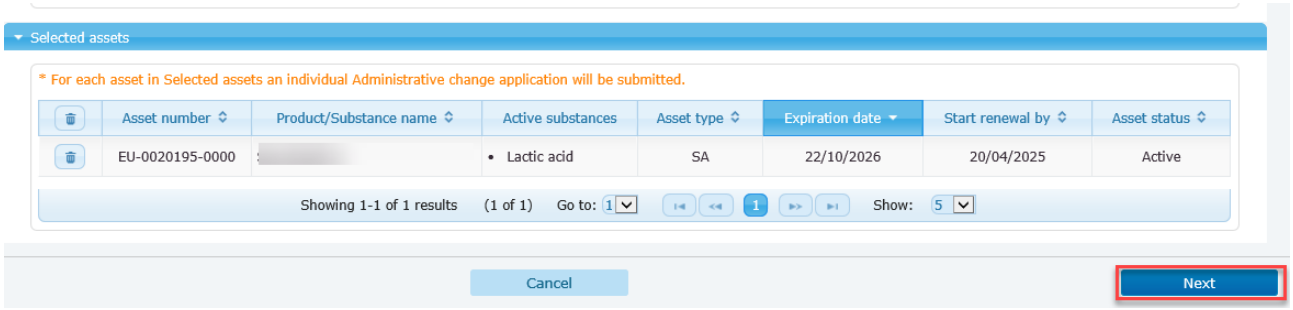
When you have found the relevant asset(s), press the 'confirm selection' button. The selected assets will be displayed in the relevant section.

Figure 6: The 'Selected assets' section



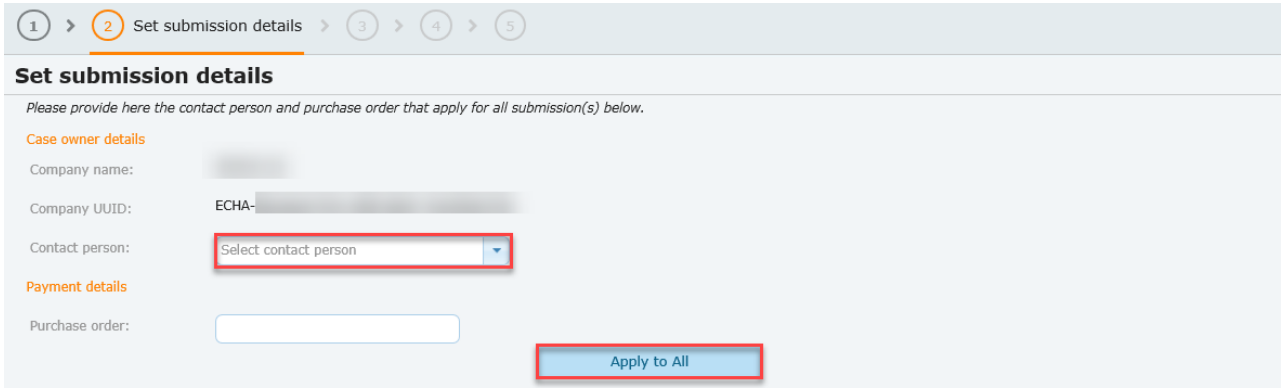
Click on ‘next’ to continue to step 2.

Figure 7: Proceed to the next step



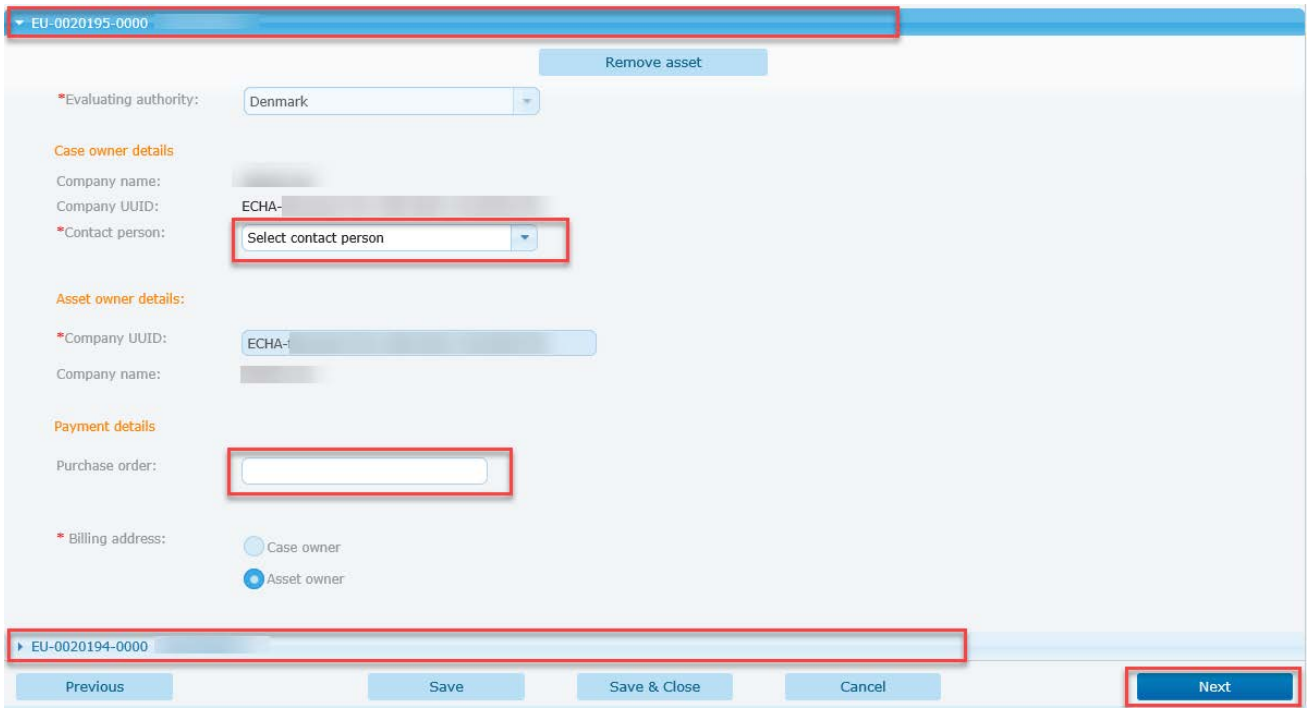
In step 2, you will be required to select the contact person from the drop down list and enter the purchase order. Press ‘Apply to all’ to set the indicated information into all the assets selected for this group.

Figure 8: Apply to all



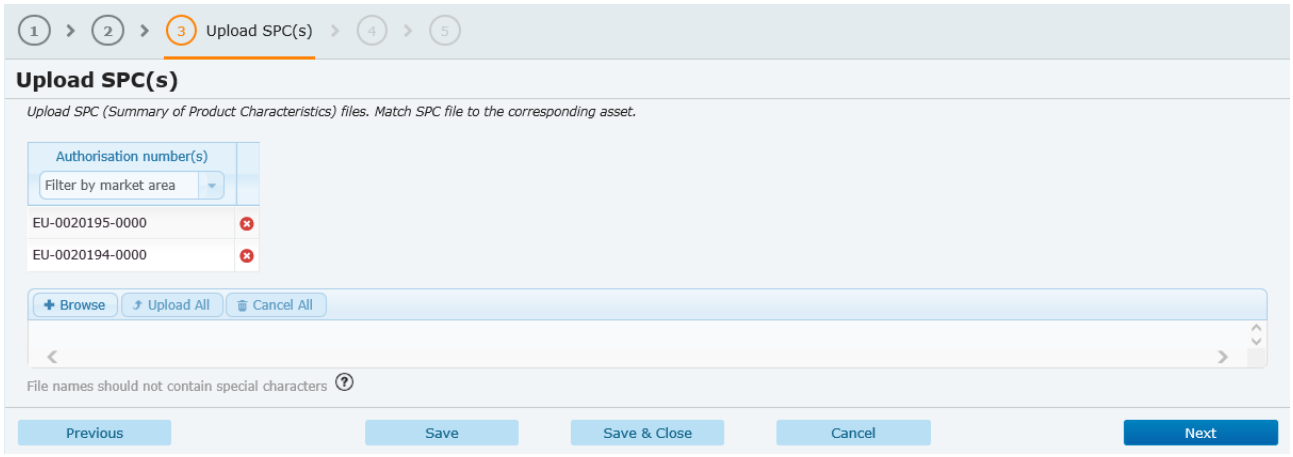
If the contact person and/or purchase order are different from one submission to another, expand the asset list and modify the relevant field(s). Press ‘Next’ when you are ready.

Figure 9: Select the contact person



In step 3, upload the relevant SPC files and match each SPC file to the corresponding asset. For applications for changes, the system is expecting SPC file(s) created from the original SPC.

Figure 10: Upload SPC(s)

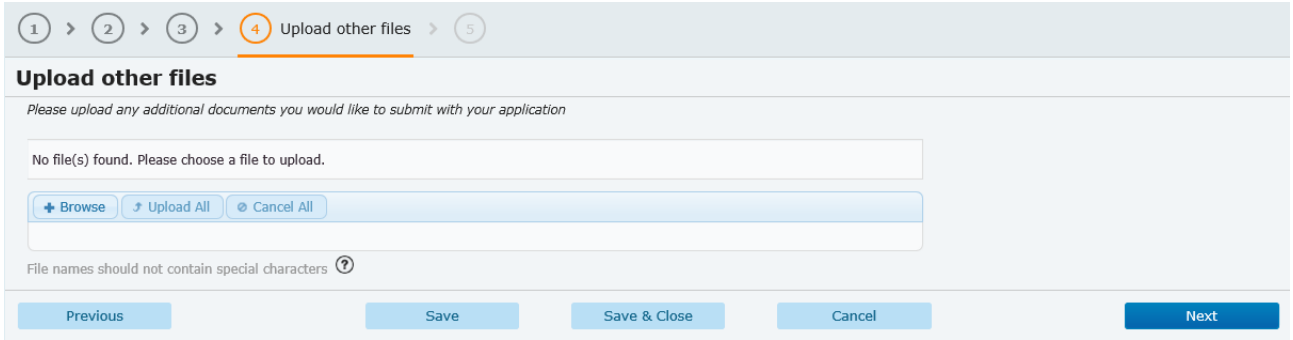


The SPC(s) can be found and downloaded from the assets details page.

Figure 11: SPC to be found and downloaded from the asset details page

In step 4, you can upload files to support your application.

Figure 12: Upload other files



Finally, you will be able to confirm your application.

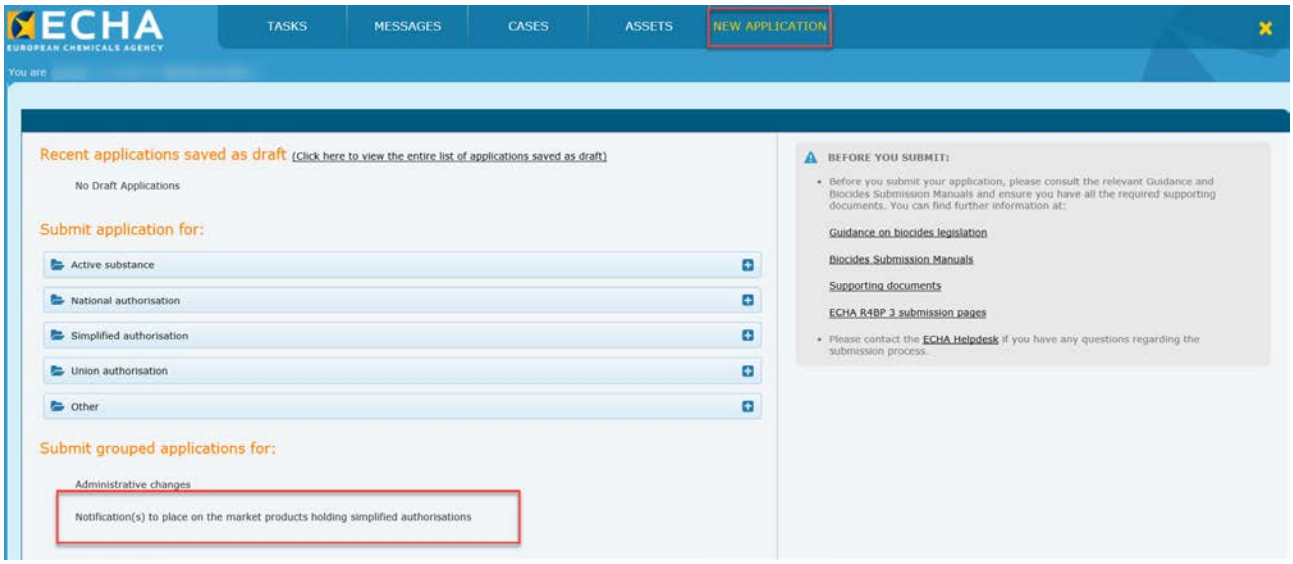
For additional information on SA-ADC submission (i.e. application requirements), see chapter 8.

3.4. Submitting a batch of notifications to place on the market products holding simplified authorisations

This step is facilitating the selection of the assets for which notification(s) to place on the market products holding simplified authorisation should be submitted in R4BP3. Please note that submitting a group of applications for notifications to place products on the market can be made per one **Market area** only and that each Notification submitted through this wizard will run independently from one another.

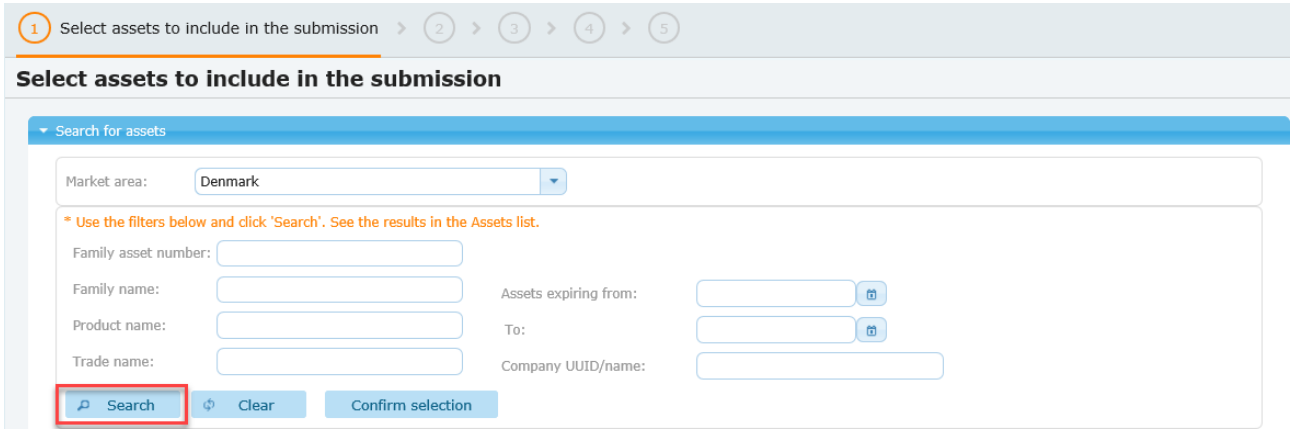
To submit several notifications to place on the market products holding simplified authorisations, click on the 'NEW APPLICATION' tab on the R4BP 3 taskbar, and select 'Notification(s) to place on the market products holding simplified authorisations'.

Figure 13: Notification(s) to place on the market products holding simplified authorisations'



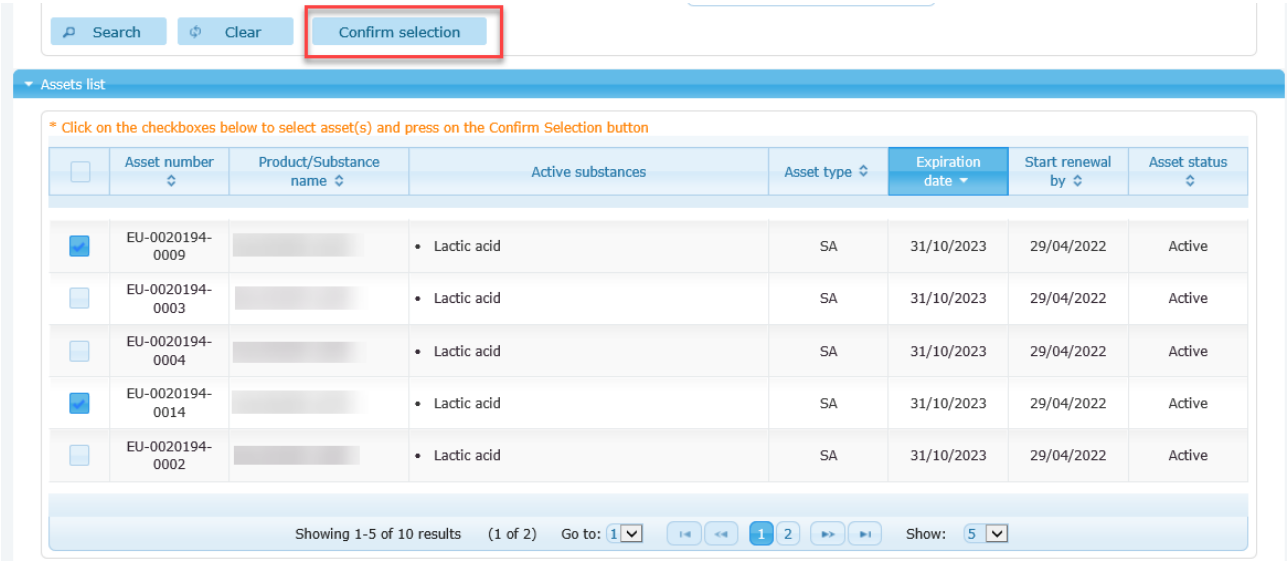
The submission wizard will prompt you to search for the relevant assets. Fill in some search criteria in the 'search for assets' section. When ready, click on 'search'.

Figure 14: Search for the relevant assets



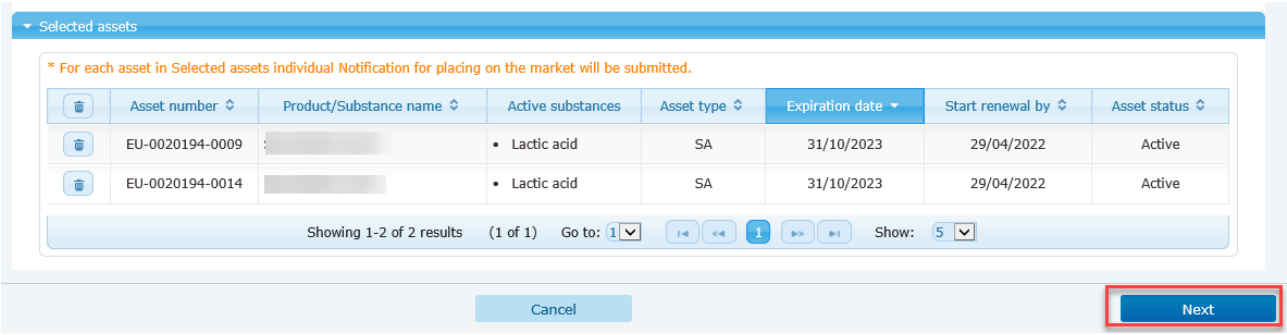
The 'Assets list' shows the list of all the assets that meet the conditions selected in the search criteria. Browse the page and select the asset(s) as needed.

Figure 15: Confirm your assets selection



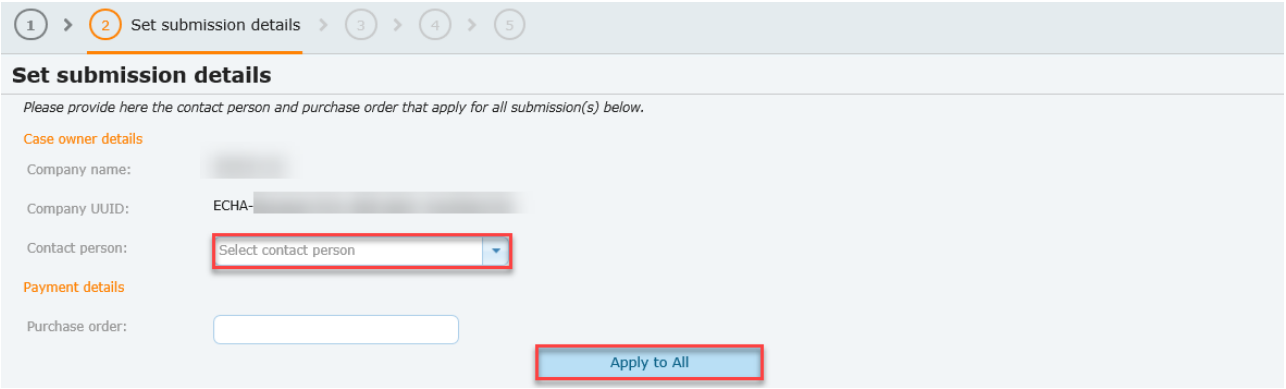
When you have found the relevant asset(s), press the 'confirm selection' button. The selected assets will be displayed in the relevant section. Click on 'next' to continue to step 2.

Figure 16: Proceed to the next step



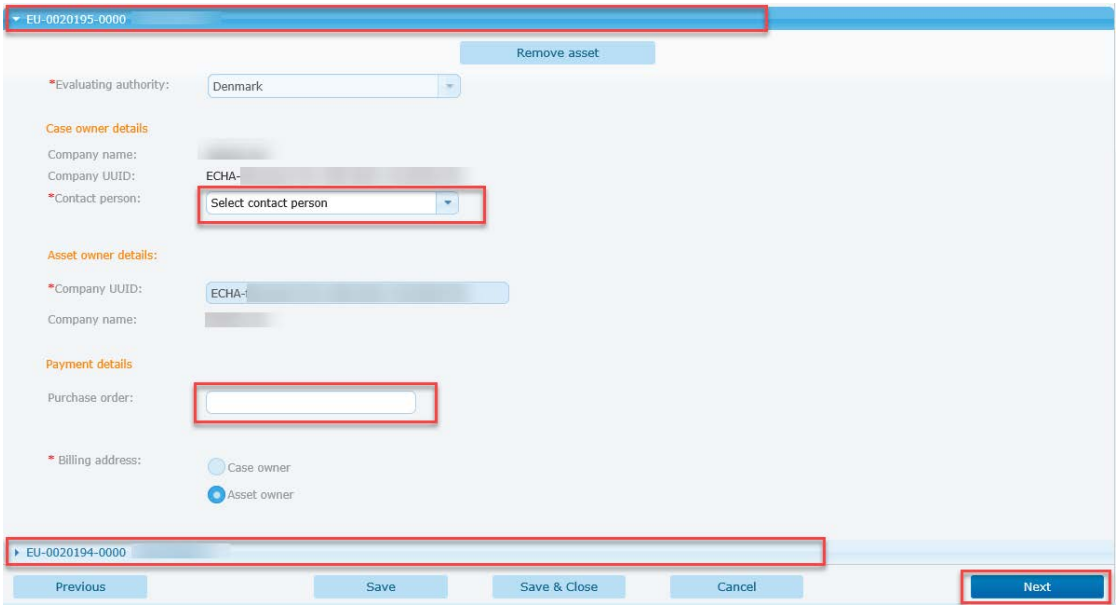
In step 2, you will be required to select the contact person from the drop-down list and enter the purchase order. Press 'Apply to all' to set the indicated information into all the assets selected for this group.

Figure 17: Select the contact person



If the contact person and/or purchase order are different from one submission to another, expand the asset list and modify the relevant field(s). Press 'Next' when you are ready.

Figure 18: Select the contact person / purchase order for each asset

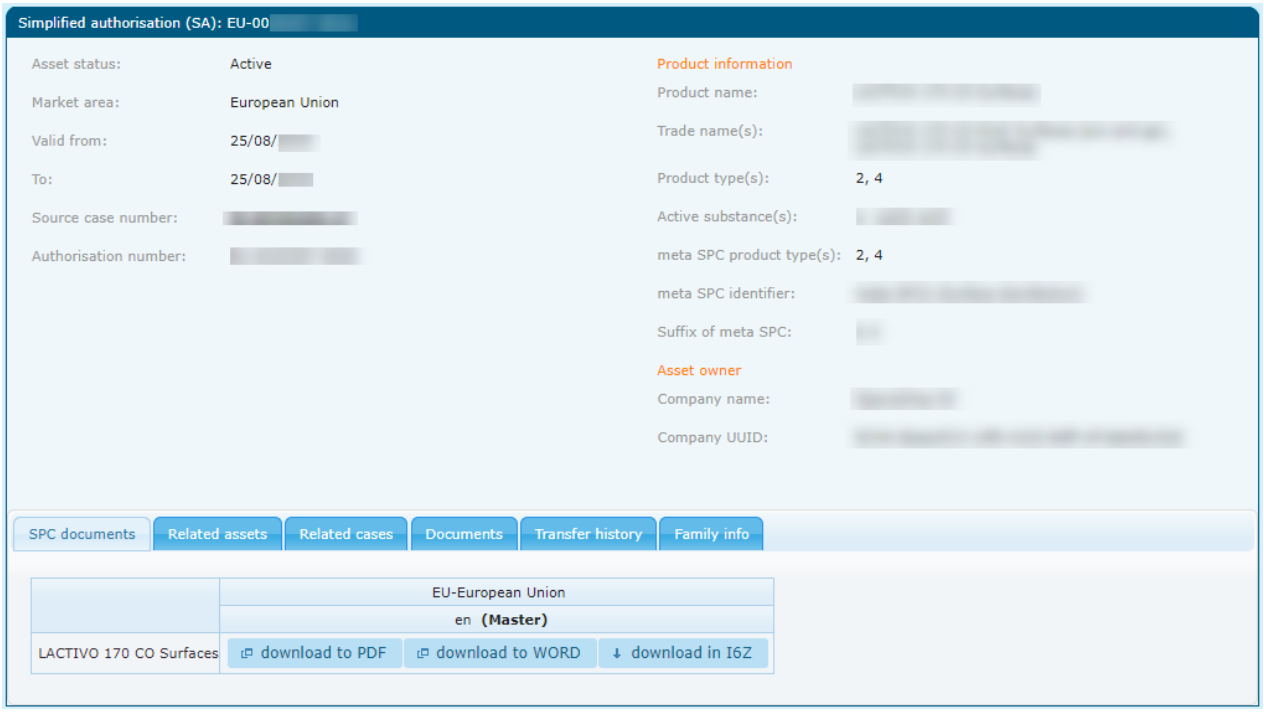


In step 3, upload the required SPC files. For applications on simplified authorisation the system is expecting SPC file(s) created from the initial SPC..

Figure 19: Upload SPC(s)

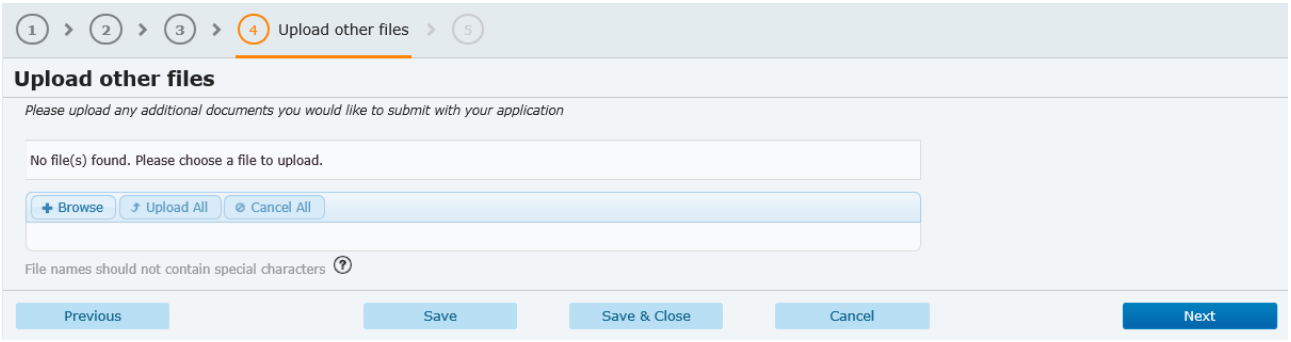
The SPC(s) can be found and downloaded from the assets details page.

Figure 20: Download SPC file



In step 4, you can upload files to support your application.

Figure 21: Upload other files



Finally, you will be able to confirm your application.

For additional information on SN-NOT applications, please see chapter 10.

4. Post submission obligations

4.1. Verify your submission

After submitting your application, an on-screen message will be visible to you containing a submission number, i.e. the unique number identifying your case. Read and pay attention to this on-screen message as it may contain instructions outlining further actions that you may need to do.

If you do not receive a post-submission message, your application has not been submitted correctly and you will have to start the application process again.

4.2. Monitor your case (case owner)

It is the case owner's responsibility to monitor individual cases on a regular basis. Through the 'Case details' sub tab, you can manage and view the progress of any of your submitted applications. In addition, email alerts can also be set to inform you of the case status – this is particularly helpful if you need to react to authority requests where a deadline has been set.

You can find more detailed information on how to monitor your case in: 'BSM Technical guide: How to use R4BP 3'.

4.3. Resubmission tasks

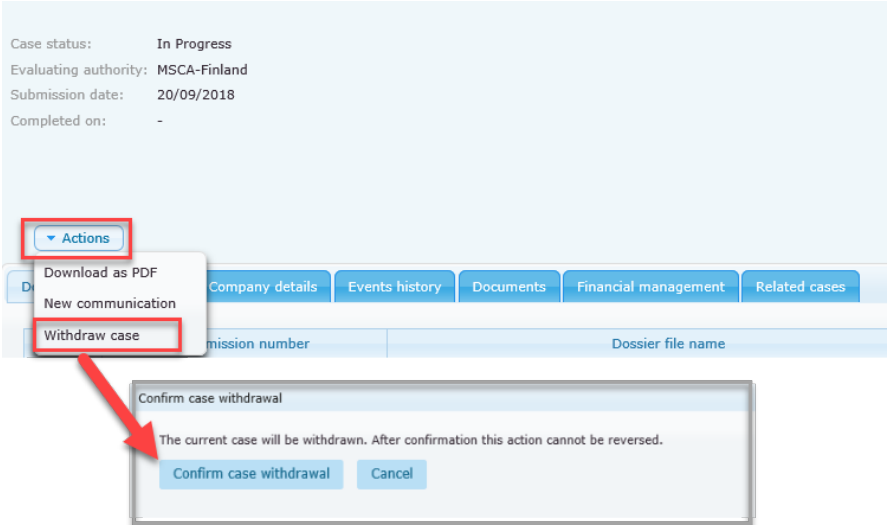
To make sure that an application can be processed correctly, a case owner may need to complete task items assigned by authority users e.g. a 'Resubmit information' task). You are obliged to monitor your task items and complete them within the defined time. You can access the task items by selecting the 'TASKS' tab on the taskbar (Please refer to BSM Technical guide: How to use R4BP 3 for full details).

Only one reply to a 'request information' task is permitted in R4BP 3. Please make sure that you include all the information requested in the task item. Note that your resubmission deadline can be extended. Please contact the relevant authorities.

5. Withdrawing a case from R4BP

You can withdraw your cases via the Case details page. Click on 'withdraw case' and confirm the case withdrawal.

Figure 22: withdraw a case from R4BP

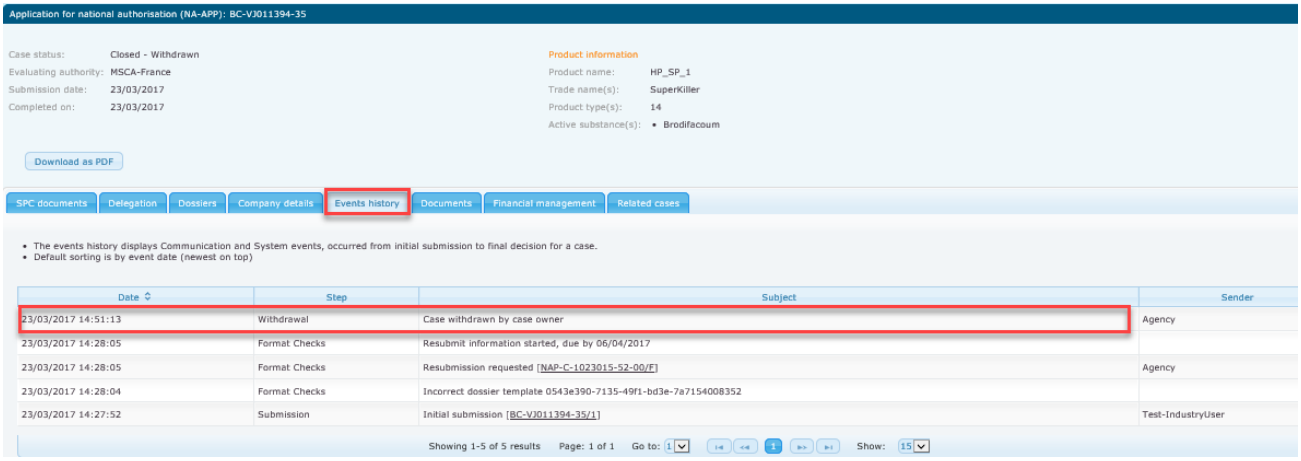


Note that this action is subject to some requirements:

- The case withdrawal can only be performed by the **case owner**;
- The case should be '**In progress**' or '**Suspended**'.

There will be no approval process for the case withdrawal. Once the withdrawal is triggered the case will receive the status 'Closed - Withdrawn'.

Figure 23: Case withdrawal in the 'Events history'



Once you have withdrawn your case, any open task items will be closed immediately, any pending transfers will be cancelled and an appropriate event will be recorded.

6. National authorisation - simplified procedure

The simplified authorisation (SA) procedure aims to encourage the use of biocidal products with a more favourable environmental, human and animal health profile. To apply for the simplified authorisation procedure, your biocidal product must be eligible according to Article 25 of the BPR.

Where a simplified authorisation is granted, the BP may be made available on the market in other Member States without the need for mutual recognition, under certain conditions by submitting an application called a 'Notification for placing on the market', refer to Notification for placing on the market of this manual.

The principles and processes behind Simplified national authorisation are described in the Practical Guide 'chapter on simplified authorisation' available from ECHA's website.
To assist you in fulfilling the information requirements, ECHA has provided guidance documents on its website - Guidance on information requirements.

An **inquiry to share data is obligatory** before performing any tests or studies involving vertebrates. Applications for an inquiry to share data for a biocidal product are detailed in BSM Application instructions: How to submit an application for National Authorisations.

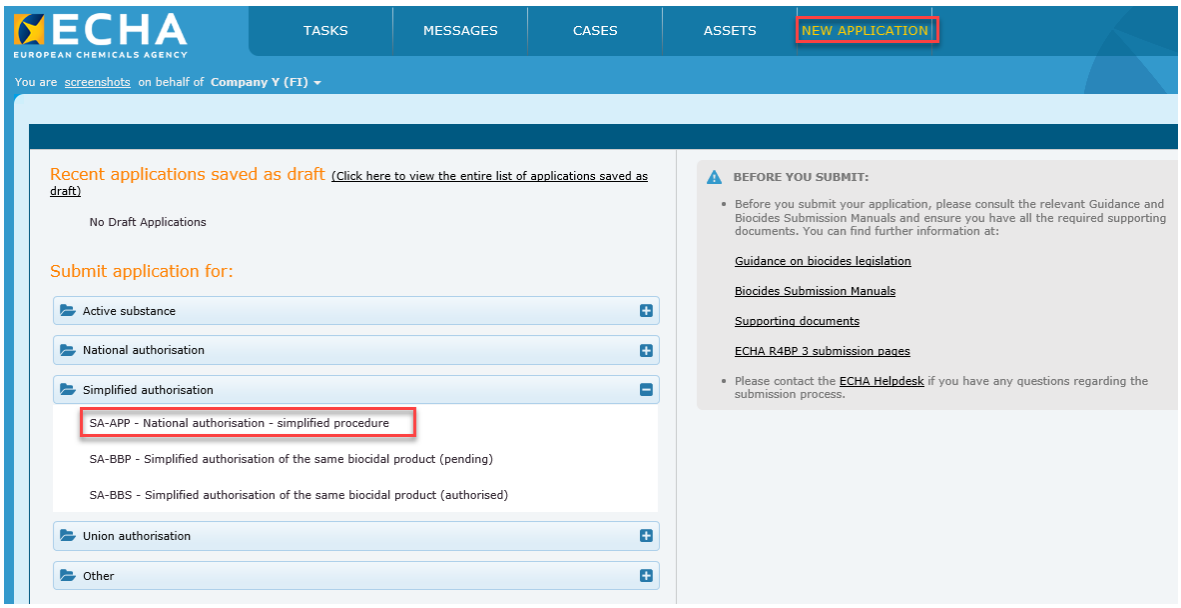
6.1. Launching the SA-APP wizard

This sub-chapter describes the application requirements necessary for each step of the R4BP 3 wizard for applications for national authorisation – simplified procedure.

For full technical assistance on how to prepare a IUCLID dossier and enter data into the most important fields, please refer to BSM Technical guide: How to prepare a biocides dossier.

Launch the application 'SA-APP - National authorisation – simplified procedure' from the 'NEW APPLICATION' tab on the R4BP 3 taskbar as previously described.

Figure 24: Launching the application 'wizard' for SA-APP



6.2. Application requirements for SA-APP

This sub-chapter describes the application requirements necessary for each step of the SA-APP application wizard. Additional instructions and guidance are available in R4BP 3 at each wizard step to help you with the application procedure.

Application requirements for SA-APP

Case owner details

Contact person for the case must be specified.

Set submission details

'Evaluating authority', must be specified.
Enter the details of the 'asset owner' and indicate the payment details.

Upload IUCLID dossier

The dossier must fulfil all of the information requirements laid out in Article 20(1)(b) of the BPR.

In all applications: section 13 'Summary and evaluation' must include written confirmation from the proposed evaluating MSCA confirming their agreement to evaluate the application, uploaded in the R4BP 3 application wizard

Where relevant: letter of access, 'permission to refer' to data granted by ECHA under Article 63 of the BPR must also be included in section 13.

Upload SPC (.i6z)

Create SPC in .i6z format in IUCLID. See the BSM Technical guide: How to prepare a biocides dossier for specific instructions how to create an SPC in IUCLID format.

You are advised to consult the relevant MSCA for further clarification on the language and the requirements for the SPC.

Upload other files

In case of a biocidal product family, the supporting document describing the structure of the family and its meta-SPCs ('Template overview of the biocidal product family').

Please upload any other files you wish to support you application at this step.

Confirm application

If the data in the confirmation screen is correct, enter the CAPTCHA and **submit** your application.

If any information is incorrect, you can update the specific fields by clicking the 'Previous' button to return to the application form.

7. Simplified authorisation of the same biocidal product

An authorisation in any given Member state may be granted to a biocidal product or product family ('same product'), which is 'identical' to another product or product family, either authorised or pending authorisation, in that Member state. Note that the conditions of authorisation for the 'same' biocidal product will be the same as for the authorisation of the related reference product.

The principles and processes behind the simplified authorisation of the same biocidal product are described in the Practical Guide 'chapter on simplified authorisation' available from ECHA's website.

For the relevant implementing legislation, please refer to the 'same BP Regulation'[4].

7.1. Application instructions for the SA-BBS and SA-BBP wizard

This sub-chapter describes the application requirements necessary for each step of the R4BP 3 wizard for individual applications for the simplified authorisation of the same biocidal product where the related reference product is:

Already authorised (SA-BBS): When the simplified national authorisation for the related reference product has been **authorised** and you are in possession of, or have access to, the related asset number, OR

Pending authorisation (SA-BBP): When the simplified national authorisation for the related reference product is currently being processed i.e. pending authorisation, and you are in possession of the case number.

If you need to seek Simplified Authorisation (SA) for the **family** of the same biocidal product, you may use relevant SA family SPC to create your own **SA family SPC**.

SA family SPC attached to SA-BBS/SA-BBP applications applies to the Simplified Authorisation of the **family** for the same biocidal product.

If you need to seek Simplified Authorisation (SA) for the same biocidal product for the **single product**, you may use relevant SA family SPC or SA single SPC to create (using the specific editor menu function) your own **SA single SPC**.

SA single SPC attached to SA-BBS/SA-BBP applications applies to the Simplified Authorisation based on the same reference **biocidal product**.

Note that the application for the simplified authorisation of the same biocidal product must be made to the same MSCA who authorised the reference biocidal product. The conditions of authorisation for the 'same' biocidal product will be the same as for the SA of the related reference product.

[4] Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a **procedure for the authorisation of same biocidal products** in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

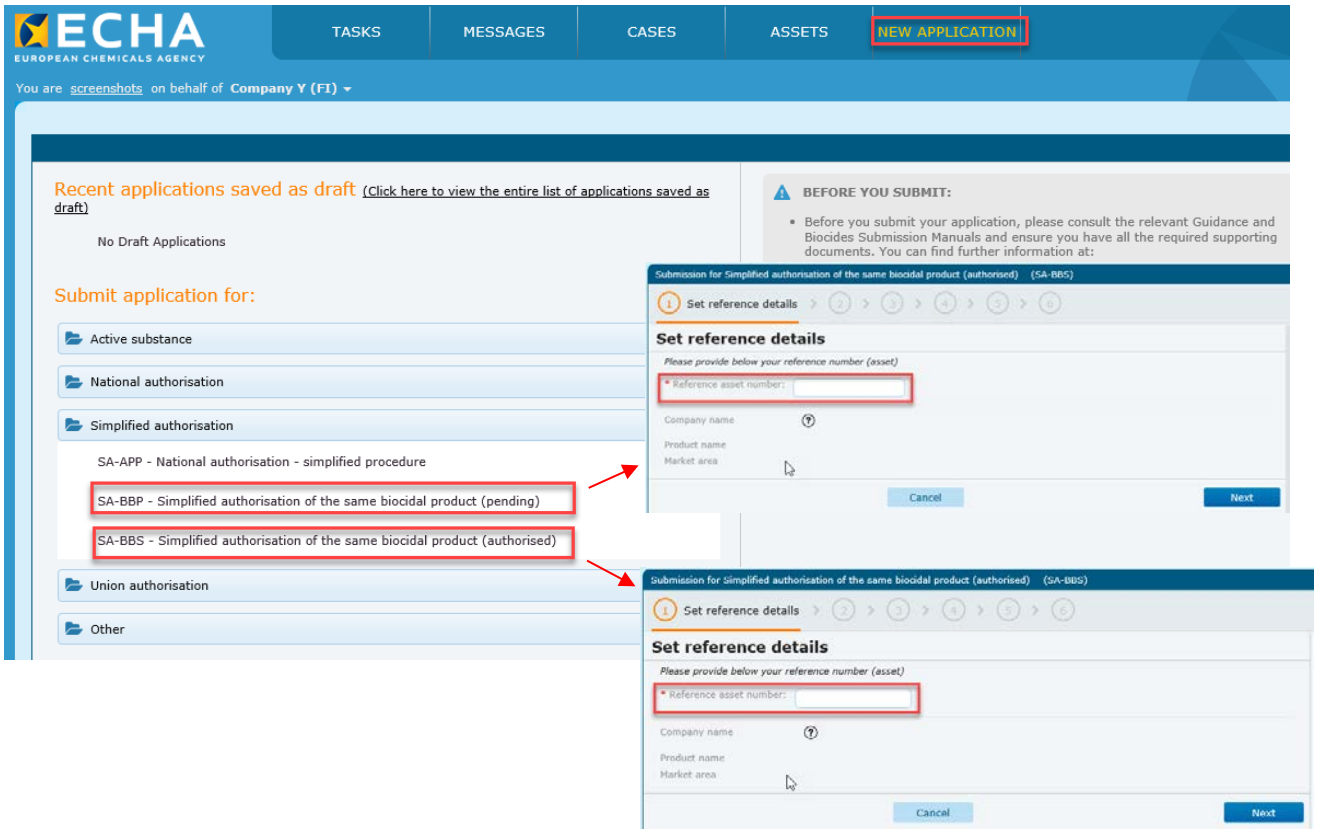
7.2. Launching the SA-BBS or SA-BBP application wizard

The R4BP 3 application wizard for both application types (authorised and pending) is launched through the 'NEW APPLICATION' tab on the R4BP 3 taskbar, however you need a valid reference number, i.e. **asset number** for 'authorised' applications or the **case number** for 'pending' applications to proceed (Figure 25). It is important to note that when you are creating an SA-BBS single product starting from a family, it is mandatory to insert the asset of the member of the family as reference asset in the submission wizard.

If you are not the case owner of the related SA-APP application and you are applying for **SA-BBP**, you will need to contact the case owner of the related reference product to obtain the relevant 'reference case number(s)'.

If you are not the asset owner of the related reference product will and you are applying for **SA-BBS**, you will only be able to launch an application from the 'New application' tab. Related 'reference numbers' (asset numbers) and other identifiers are publically available on the ECHA website under the '[Information on chemicals]' tab.

Figure 25: Launching the application wizard for SA of same biocidal product



7.3. Application requirements for simplified authorisation of the same biocidal product

This sub-chapter describes the application requirements necessary for each step of the SA-BBS/BBP application wizards in R4BP 3. Additional instructions and guidance are available in R4BP 3 at each wizard step to help you with the application procedure.

If the prospective asset owner of the simplified authorisation of the same biocidal product application is different from the initial asset owner of the 'SA' type asset or case owner of the 'SA-APP' case, an active delegation should exist otherwise the system will not let the user complete the application. Refer to BSM Technical Guide: How to use R4BP 3 for more details.

Context page

Enter a valid reference number, i.e. asset number for ‘authorised’ applications or the case number for ‘pending’ applications.

Application requirements for SA-BBS & SA-BBP

Case owner details

A contact person for the case must be specified.

Set submission details

Enter the details of the proposed ’asset owner’ and indicate the payment details.

Upload SPC (.i6z)

Create SPC in .i6z format in IUCLID. See the BSM Technical guide: How to prepare a biocides dossier for specific instructions how to create an SPC in IUCLID format.

Upload other files

In all applications: upload the supporting document ‘Application for authorisation of the same biocidal product under Regulation (EU) No 414/2013’.

Where relevant: upload any other files required to support you application:

SA-BBS: Permission to refer, a letter of access (only for category 6)

SA-BBP: A decision on technical equivalence, permission to refer, letter of access (only for category 6).

Confirm application

If the data in the confirmation screen is correct, enter the CAPTCHA and **submit** the application.

If any information is incorrect, you can update the specific fields by clicking the ‘Previous’ button to return to the application form.

8. Request for a change of a simplified authorisation

The following subchapters describe the application instructions concerning national authorisation – simplified procedure, changes on request. There are three classifications of change to an authorisation of a biocidal product; **administrative, minor and major changes** and they are classified according to the level of assessment required.

A non-exhaustive list of different administrative, minor and major changes is set out in the Annex to the Changes Regulation[5].

If you wish to transfer an authorisation to a new holder established in the European Economic Area (EEA) in accordance with the Changes Regulation, (Annex, title 1, section 1, item 3), please refer to chapter 6 of this manual 'Transfer of a simplified authorisation'.

8.1. Application instructions for a change of a simplified authorisation

This sub-chapter describes the application requirements necessary for each step of the R4BP 3 wizard for applications for changes to a national authorisation - simplified procedure.

Please note that applications concerning requests for changes are not permitted by R4BP 3 if there is an asset transfer on-going.

The principles and processes behind administrative, minor and major changes on request to an authorisation (simplified procedure) are described in the Practical Guide 'chapter on simplified authorisation' available from ECHA's website.

In case the asset owner is unable to determine the category to which their intended change belongs, they may request ECHA to issue an opinion on the **classification of the change** (see BSM Application instructions: How to submit an application for National Authorisations).

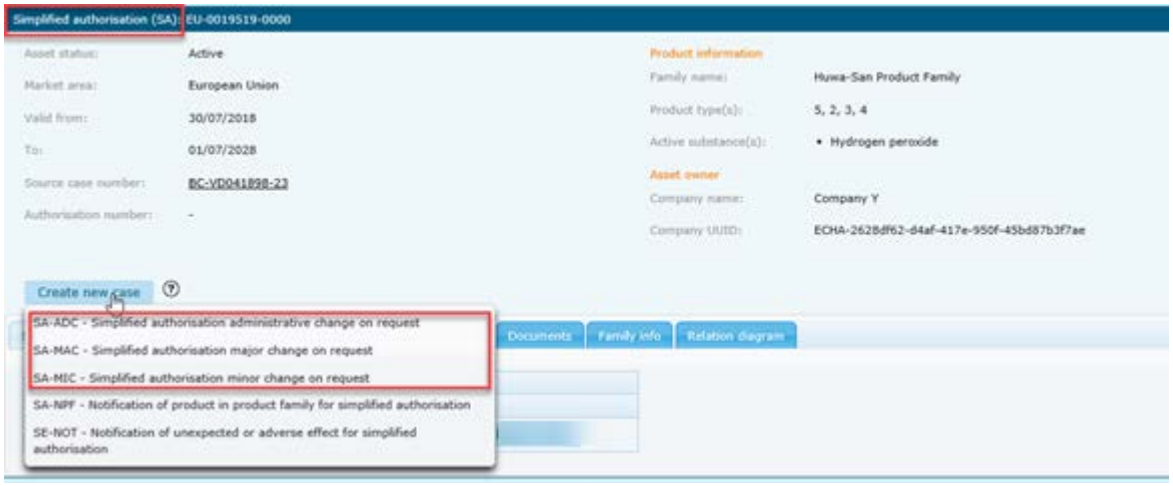
8.2. Launching the SA-ADC/MIC/or MAC application wizard

- **In the context of an existing asset**

To submit application in the context of an existing asset, click on the 'ASSETS' tab on the R4BP 3 taskbar. After opening relevant SA asset, select the relevant application type from the available 'create new case' list.

[5] Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.

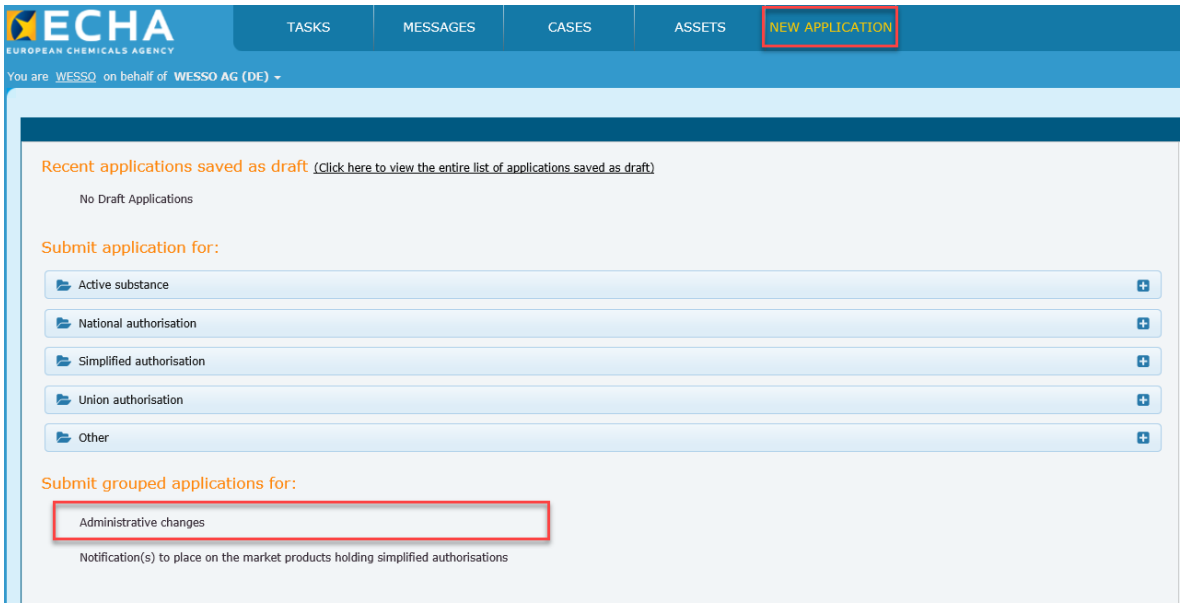
Figure 26: Launching the application wizard for SA-ADC/-MIC/or –MAC



- **From the 'NEW APPLICATION' tab to submit a batch of administrative changes applications**

To submit several applications concerning administrative change(s) SA-ADC, click on the 'NEW APPLICATION' tab on the R4BP 3 taskbar, and select 'Administrative changes' at the bottom of the page as described in section 3.3.

Figure 27: Submit a batch of administrative changes applications



8.3. Application requirements for SA-ADC/-MIC/ or -MAC

This sub-chapter describes the application requirements necessary for each step of the SA-ADC/-MIC/ or -MAC application wizard in R4BP 3. Additional instructions and guidance are available in R4BP 3 at each wizard step to help you with the application procedure.

Is a dossier required? A dossier is not required for applications in the SA-ADC wizard. For SA-MIC and SA-MAC applications, the inclusion of a dossier is optional. However, given the nature of the information needed to specify and justify the change request, a IUCLID file would normally be **expected**.

Case owner details

A contact person for the case must be specified.

Application requirements for SA-ADC/MIC or MAC

Set submission details

Indicate the payment details relevant to the case.

For applications submitted in bulk: define the contact details for every selected asset or define one common contact for all submission.

Upload IUCLID dossier

If a dossier is appropriate for your application, please include:

Where relevant: a decision on technical equivalence (category 6 only) in section 13 'Summary and evaluation'.

Any other documents to demonstrate that the proposed changes would not adversely affect the conclusions previously reached, concerning the compliance with the conditions set out in Article 25 of the BPR.

Upload SPC (.i6z)

Create SPC in .i6z format in IUCLID. See the BSM Technical guide: How to prepare a biocides dossier for specific instructions how to create an SPC in IUCLID format.

For applications submitted in bulk: bulk upload SPC(s) and assign the files to the relevant assets.

Upload other files

All documents, where not made available in a IUCLID dossier, that demonstrate that the proposed changes would not adversely affect the conclusions previously reached, concerning the compliance with the conditions set out in Article 25 of the BPR.

In all applications: the supporting document when applying for:

SA-ADC: 'Notification for an **administrative change** of a union/simplified authorisation'

SA-MIC: 'Application for a **minor change** of a simplified authorisation'

SA-MAC: 'Application for a **major change** of a simplified authorisation'

Where relevant: ECHA's opinion regarding the classification of a change.

For applications submitted in bulk: you are allowed to upload a batch of files. In this case, each uploaded document must be linked with an asset number from the list of selected assets.

Confirm application

If the data in the confirmation screen is correct, enter the CAPTCHA and **submit** your application. If any information is incorrect, you can update the specific fields by clicking the 'Previous' button to return to the application form.

9. Transfer of a simplified authorisation

Applications to allow an asset owner's Legal Entity to transfer a particular asset to a new Legal Entity established in the EEA can be made. For assets concerning simplified authorisation, the proposed new asset owner will need to 'accept the transfer' through R4BP 3 and submit an application through the wizard.

This process is a form of administrative change. The principles and processes behind the process of administrative changes are described in the Practical Guide 'chapter on changes of biocidal products' available from ECHA's website.

The possibility to transfer of an authorisation to a new holder is listed as an administrative change in the Changes Regulation (Annex, title 1, section 1, item 3). However, this type of application must be made through the application wizard SA-TRS outlined in this chapter.

An asset can only be owned by one legal entity at any given time, therefore, once it has been transferred, the previous owner (authorisation holder) forfeits all rights in relation to its ownership.

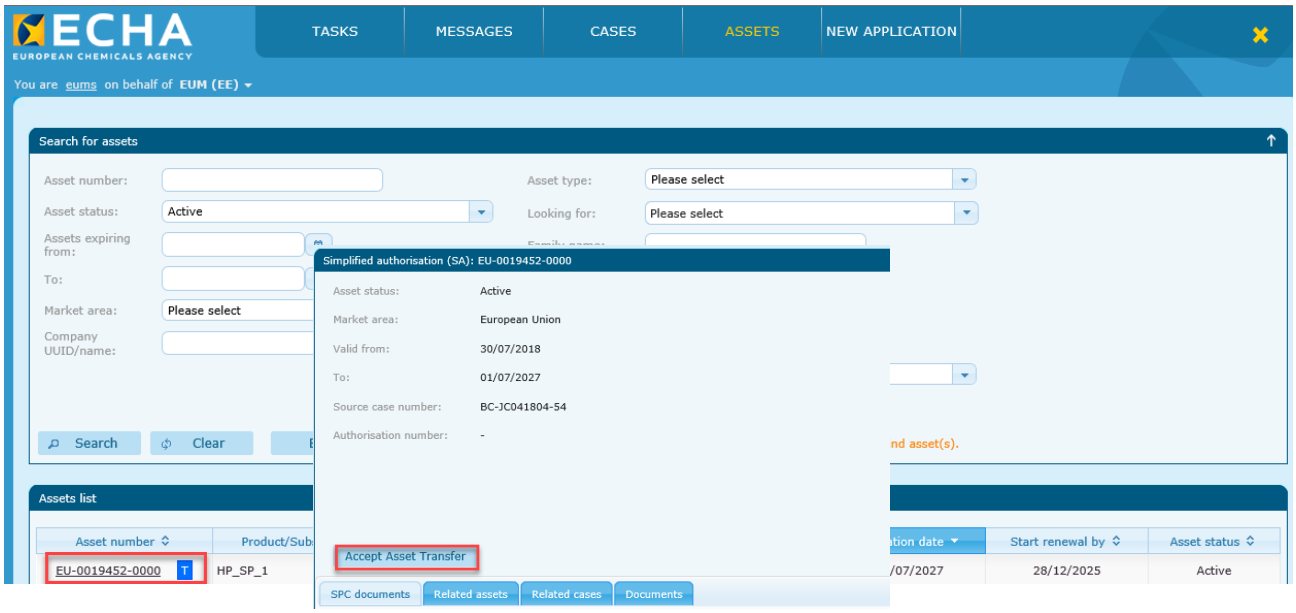
9.1. Application instructions for the SA-TRS wizard

An owner of an SA asset must first initiate a transferral in R4BP 3 before any application procedure can begin. This procedure is detailed in the BSM Technical guide: How to use R4BP 3. Once this has been carried out, the proposed new asset owner will be able to see the asset in the 'Asset list' labelled with a T and make an application to 'accept' the transferral.

9.2. Launching the SA-TRS application wizard

Click on the 'ASSETS' tab on the R4BP 3 taskbar as previously described. After opening relevant SA asset, Locate the specific asset labelled with a T in the in the 'Assets list'. Clicking on the asset number hyperlink will open a details page for that specific asset. Clicking on 'Accept Asset Transfer' will launch the SA-TRS wizard.

Figure 28: Launching the application wizard for SA-TRS



9.3. Application requirements

This sub-chapter describes the application requirements necessary for each step of the SA-TRS application wizard in R4BP 3. Additional instructions and guidance are available in R4BP 3 at each wizard step to help you with the application procedure.

Application requirements for SA-TRS

Case owner details

A contact person for the case must be specified.

Set submission details

Indicate payment details where relevant.

Upload SPC (.i6z)

Create SPC in .i6z format in IUCLID. See the BSM Technical guide: How to prepare a biocides dossier for specific instructions how to create an SPC in IUCLID format.

Upload other files

Please upload any other files you wish to support you application at this step.

Confirm application

If the data in the confirmation screen is correct, enter the CAPTCHA and **submit** your application.

If any information is incorrect, you can update the specific fields by clicking the 'Previous' button to return to the application form.

10. Notification for placing on the market

A biocidal product authorised according to the simplified procedure may be placed on the market in all Member States without the need to apply for mutual recognition. However, an authorisation holder must **notify each relevant Member State** no later than 30 days before placing the product on the market within the territory of that Member State. R4BP 3 allows the user to notify only a member in a specific market area.

Please refer to the 'CA Notes for Guidance'[6] regarding the placing on the market of a product not authorised according to Article 26 of the BPR but for which a biocidal product registration application was submitted and or granted according to the Biocidal Product Directive (BPD) [7].

The principles and processes behind notifications concerning simplified authorisations are detailed in the Practical Guide 'chapter on simplified authorisation' available from ECHA's website.

10.1. Launching the application wizard

- **Submitting an individual notification**

To submit application in the context of an existing asset, click on the 'ASSETS' tab on the R4BP 3 taskbar and search for specific type of asset as previously described in section 3.2.After opening relevant SA asset, select the relevant application type (SN-NOT) from the available 'create new case' list.

It is not allowed to initiate the notification from a 'Family' asset, but only from a 'Member' asset of the specific member at a time.

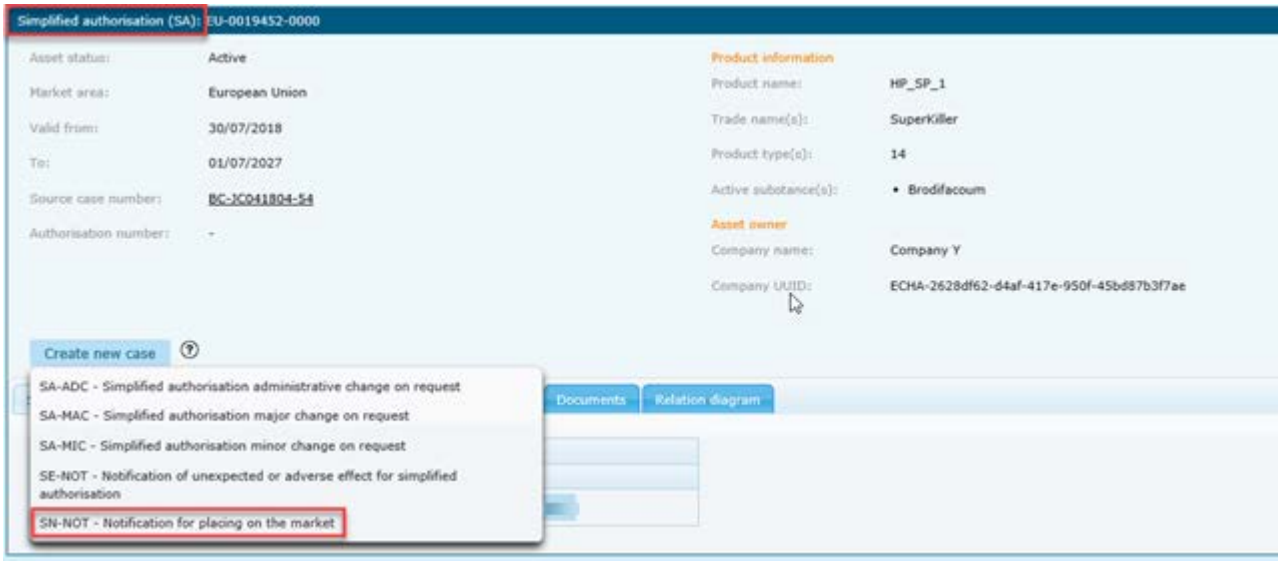
If your asset is not visible in R4BP 3 it may be because it is a registration of a low-risk biocidal product granted under the BPD. Such registrations are valid under Article 91 of the BPR until expiry but no notification can be made for placing the product on the market in another Member State. Refer to the CA notes for guidance[11] (Paragraphs (17) to (19)).

Please note that the SN-NOT application wizard cannot be initiated for assets that have an SA-TRS ongoing.

[6] "Handling of applications for product registration submitted under the Biocidal Products Directive for which the evaluation has not been completed by 1st September 2013

[7] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market

Figure 29: Launching an individual Notification for placing on the market



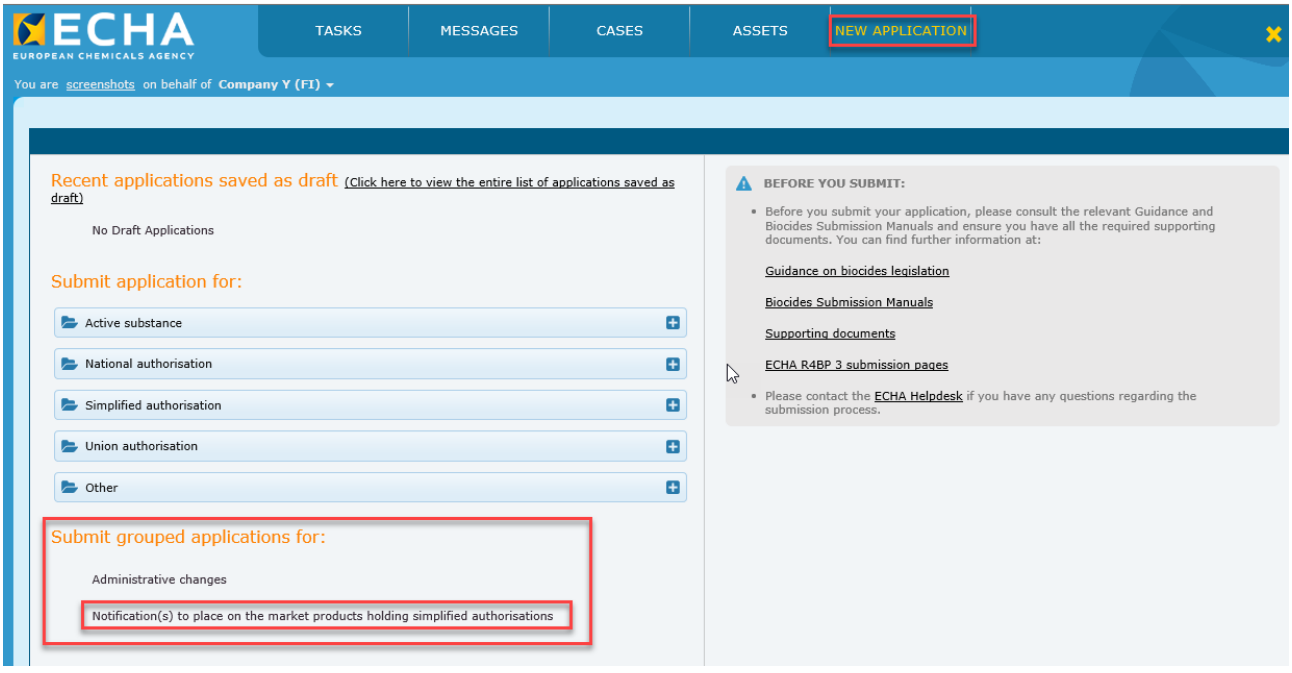
- **Submitting a batch of notifications**

Submitting a group of applications for notifications to place products on the market can be made per one Market area. Each Notification submitted through this wizard will run independently from one another.

To submit several notifications to place on the market products holding simplified authorisations, click on the 'NEW APPLICATION' tab on the R4BP 3 taskbar, and select 'Notification(s) to place on the market products holding simplified authorisations'. Note that each notification for placing on the market will run independently from one another. Each SN-NOT case will pertain to a specific product (member of a family) and will have, as reference, the member SA asset number.

For additional information, please see section 3.4.

Figure 30: Launching Notification(s) to place on the market products holding simplified authorisations



10.2. Notification requirements for SN-NOT

This sub-chapter describes the application requirements necessary for each step of the SN-NOT application wizard in R4BP 3. Additional instructions and guidance are available in R4BP 3 at each wizard step to assist you with the application procedure.

You may wish to consult the relevant MSCA helpdesk for clarification on which supporting documents are required.

Select assets to include in the submission

Search for the assets by selecting the market area and using the available filters. Once you have first selected the specific market area, the Assets list will display all the notifications that are eligible for that specific market area. Any SA assets which have already been notified in that area will not be displayed.

Select the assets to be included in the submission and click 'Confirm selection'.

Set case owner details

A contact person for the case must be specified.

Set submission details

Specify the 'Evaluating authority' – note that individual applications must be submitted to each concerned MSCA before placing the product on that market.

Upload SPC (.i6z)

Create SPC in .i6z format in IUCLID. See the BSM Technical guide: How to prepare a biocides dossier for specific instructions how to create an SPC in IUCLID format.

Upload other files

In all applications: check with the concerned MSCAs for the inclusion of a draft label for the biocidal product in one of the official languages of that Member State.

Please upload any other files you wish to support you application at this step.

Confirm application

If the data in the confirmation screen is correct, enter the CAPTCHA and **submit** your application. If any information is incorrect, you can update the specific fields by clicking the 'Previous' button to return to the application form.

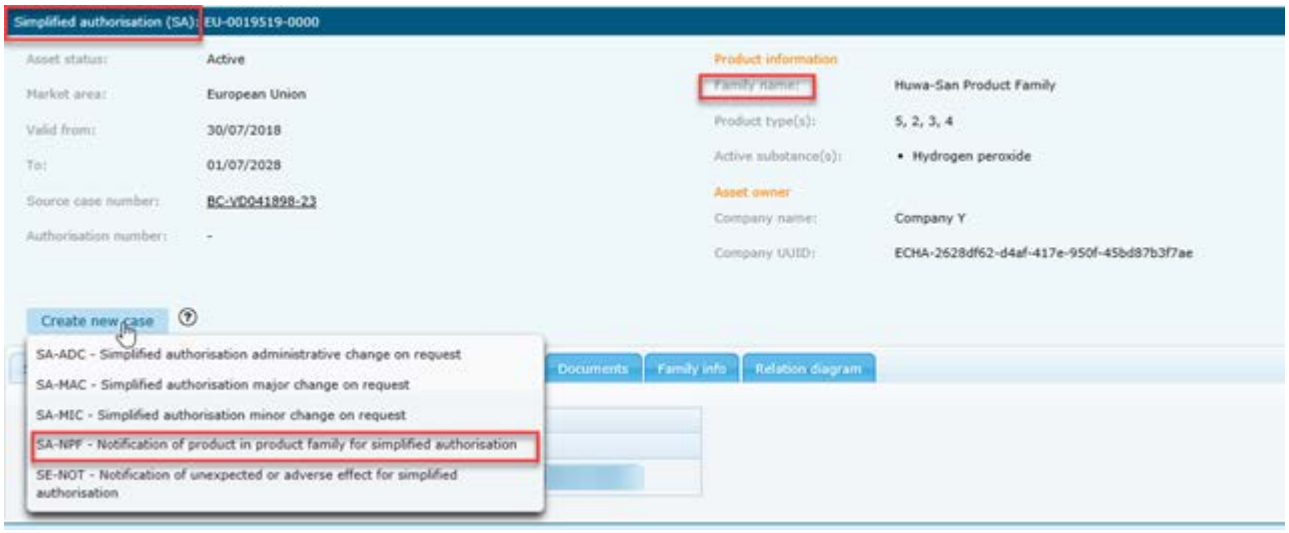
11. Notification of a product in a product family for simplified authorisation

An authorisation holder must notify each relevant MSCA, that has granted a simplified national authorisation for a biocidal product family, of each biocidal product within the biocidal product family at least 30 days before placing it on the market in that Member State. The notification of a biocidal product in a biocidal product family must be made through R4BP 3.

11.1. Launching the application wizard

To submit application in the context of an existing asset, click on the 'ASSETS' tab on the R4BP 3 taskbar and search for specific type of asset as previously described. After opening relevant SA family asset, select the relevant application type (SA-NPF) from the available 'create new case' list.

Figure 31: Launching an individual Notification of a product in product family



11.2. Notification requirements for SA-NPF

This sub-chapter describes the application requirements necessary for each step of the SA-NPF application wizard in R4BP 3. Additional instructions and guidance are available in R4BP 3 at each wizard step to help you with the application procedure.

Case owner details

A contact person for the case must be specified.

Application requirements for SA-NPF

Set submission details

The fields 'evaluating authority' and 'company UUID' are pre-set by default. Click next to proceed to the next step in the wizard.

Upload SPC (.i6z)

The application must contain an SPC, ensuring the requirements outlined in Article 17(6) of the BPR are included; such as the exact composition, the trade name and suffix to the authorisation number.
The SPC must be created form the final authorised version of the family SPC.

More than one draft SPC can be uploaded, meaning that you can notify more than one member of the product family in the same SA-NPF application.

Create SPC in .i6z format in IUCLID. See the BSM Technical guide: How to prepare a biocides dossier for specific instructions how to create an SPC in IUCLID format.

Upload other files

In all applications: upload the supporting document for 'Notification of a product in biocidal product family'.

Confirm application

If the data in the confirmation screen is correct, enter the CAPTCHA and **submit** your application.

If any information is incorrect, you can update the specific fields by clicking the 'Previous' button to return to the application form.

12. Notification of unexpected or adverse effects

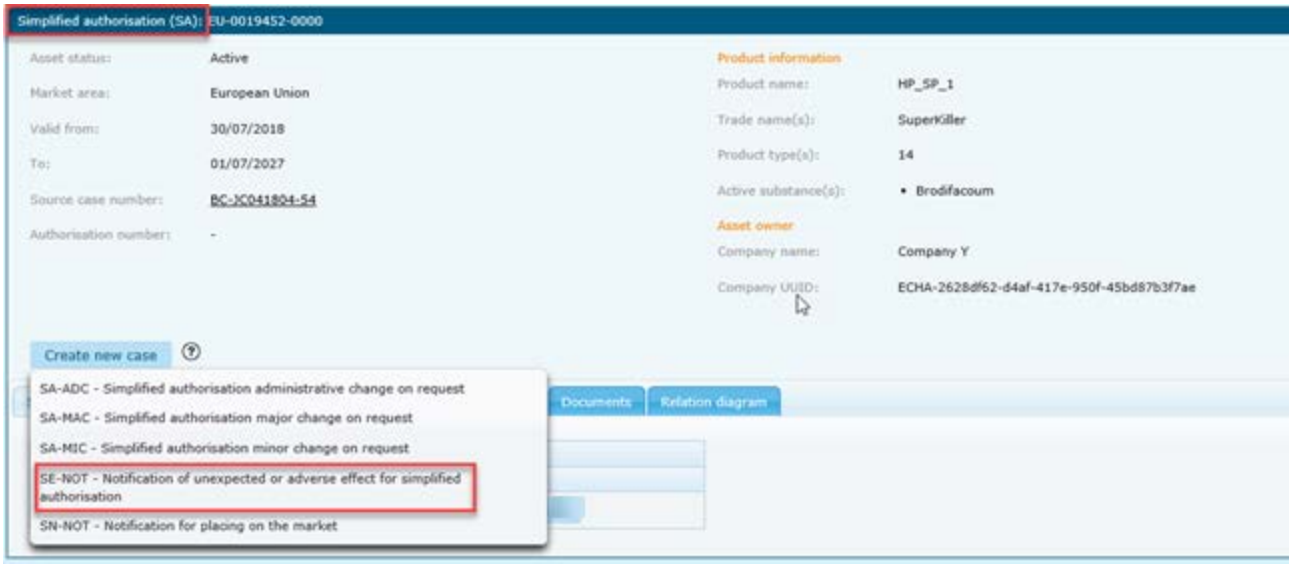
On becoming aware of new information about your biocidal product (or the active substances within it) that may affect the authorisation, a notification to the competent authority that granted the authorisation must be submitted without a delay.

Article 47 of the BPR details the notification requirements that shall be submitted without due delay to the competent Authority that granted the authorisation.

12.1. Launching the application wizard

To submit application in the context of an existing asset, click on the 'ASSETS' tab on the R4BP 3 taskbar and search for specific type of asset as previously described in section 3.2. After opening relevant SA asset, select the relevant application type (SE-NOT) from the available 'create new case' list.

Figure 32: Launching an individual Notification of unexpected or adverse effects



12.2. Notification requirements for SE-NOT

This sub-chapter describes the application requirements necessary for each step of the SE-NOT application wizard in R4BP 3. Additional instructions and guidance are available in R4BP 3 at each wizard step to help you with the application procedure.

Case owner details

A contact person for the case must be specified.

Application requirements for SE-NOT

Set submission details

The fields ‘evaluating authority’ and ‘company UUID’ are pre-set by default. Click next to proceed to the next step in the wizard.

Upload other files

Upload all relevant files detailing the new data or information on the unexpected or adverse effects on the authorised product (simplified procedure) or on the active substance(s) it contains.

Confirm application

If the data in the confirmation screen is correct, enter the CAPTCHA and **submit** your application.

If any information is incorrect, you can update the specific fields by clicking the ‘Previous’ button to return to the application form.

13. Administrative change of notification for placing on the market

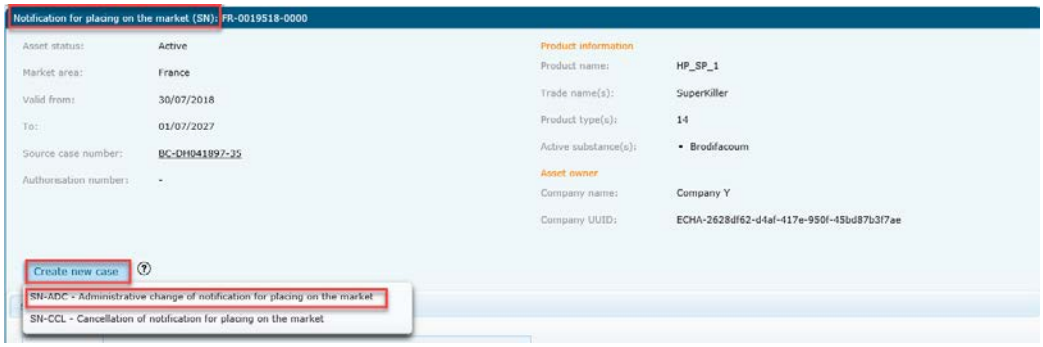
The administrative change of notification for placing on the market is used to allow an industry user to update a notified product with SN asset, consequently the relevant MSCA user will update the existing notification. The SN-ADC application is only for single products and family product excluding the members of a family.

This process is equivalent to an administrative change. The principles and processes behind the process of administrative changes are described in the Practical Guide 'chapter on changes of biocidal products' available from ECHA's website.

13.1. Launching the application wizard

To submit application in the context of an existing asset, click on the 'ASSETS' tab on the R4BP 3 taskbar and search for specific type of asset as previously described in section 3.2. After opening relevant SN asset, select the relevant application type (SN-ADC) from the available 'create new case' list.

Figure 33: Launching the application wizard for SN-ADC



13.2. Application requirements for SN-ADC

This sub-chapter describes the application requirements necessary for each step of the SN-ADC application wizard in R4BP 3. Additional instructions and guidance are available in R4BP 3 at each wizard step to help you with the application procedure.

Set case owner details

A contact person for the case must be specified.

Application requirements for SN-ADC

Set submission details

The payment details relevant to the case must be indicated. Evaluating authority and asset owner details cannot be edited.

Upload SPC (.i6z)

Create SPC in .i6z format in IUCLID. See the BSM Technical guide: How to prepare a biocides dossier for specific instructions how to create an SPC in IUCLID format.

Upload other files

Please upload any other files you wish to support you application at this step.

Confirm application

If the data in the confirmation screen is correct, enter the CAPTCHA and **submit** your application.

If any information is incorrect, you can update the specific fields by clicking the 'Previous' button to return to the application form.

14. Cancellation of notification for placing on the market

The cancellation of notification for placing on the market will be used to allow an industry user to cancel already notified product with SN asset. It can be used to cancel a single SN asset or all the family SN assets excluding a member of a family.

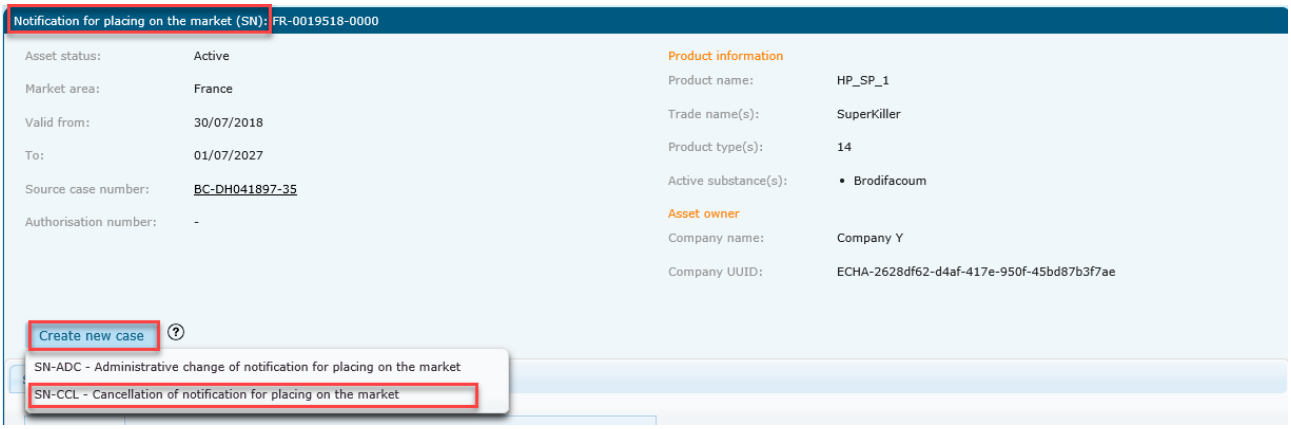
This process is a form of administrative change. The principles and processes behind the process of administrative changes are described in the Practical Guide 'chapter on changes of biocidal products' available from ECHA's website.

14.1. Launching the application wizard

This sub-chapter describes the application requirements necessary for each step of the SN-CCL application wizard in R4BP 3 for cancellation of notification for placing on the market.

To submit application in the context of an existing asset, click on the 'ASSETS' tab on the R4BP 3 taskbar and search for specific type of asset as previously described in section 3.2. After opening relevant SN asset, select the relevant application type (SN-CCL) from the available 'create new case' list.

Figure 34: Launching the application wizard for SN-CCL



14.2. Application requirements for SN-CCL

This sub-chapter describes the application requirements necessary for each step of the SN-CCL application wizard in R4BP 3. Additional instructions and guidance are available in R4BP 3 at each wizard step to help you with the application procedure.

Set case owner details

A contact person for the case must be specified.

Application requirements for SN-CCL

Set submission details

The payment details relevant to the case must be indicated. Evaluating authority and asset owner details cannot be edited.

Upload other files

Please upload any other files you wish to support you application at this step.

Confirm application

If the data in the confirmation screen is correct, enter the CAPTCHA and **submit** your application.

If any information is incorrect, you can update the specific fields by clicking the ‘Previous’ button to return to the application form.

EUROPEAN CHEMICALS AGENCY
P.O. BOX 400, FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU