ECHA
EUROPEAN CHEMICALS AGENCY

Biocides Submission Manual

How to submit an application for National 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	August 2013
Version 2.0	Updated manual to coincide with the release of R4BP 3.1, in particular the inclusion of information concerning **renewal of a national authorisation**. Additional changes include an improved general layout and design, extra summary sheets included and previous summary sheets updated. A glossary section containing terms, definitions and identifiers applicable to the whole BSM series can now be found at the end of the manual.	April 2014
Version 2.1	Manual updated to reflect the changes in R4BP 3.1.2, namely, the removal of the 'access level' selection in the application wizard. New section 4.2 'Renewal of authorisations subject to mutual recognition' has been included resulting from the entry into force of Commission Delegating Regulation (EU) No 492/2014. Information concerning the process to apply for a provisional national authorisation has also been included in section 3.2 and provisional Union authorisation in section 8.2. All relevant screenshots updated.	June 2014
Version 3.0	Release of R4BP version 3.2 changes include the following: Change to the manual title and content to include all applications types concerning national authorisation - in line with the new BSM series. New application types covered include: Transfer of a national authorisation, and Merge of a product authorisation in a family. Wizard changes include: NA-APP allows a national authorisation at the same time as mutual recognition. Additional application types covered from previous manuals: National authorisation changes on request (previously BSM 4B) Notifications and permits (previously BSM 7)	December 2014
Version 3.1	Manual updated to reflect changes in section 4 resulting from an update to the supporting documents required for submitting a single NA-RNL and an NA-RNL with mutual recognition.	December 2014

Version	Changes	Date
Version 3.2	Information concerning the rodenticide renewals with the December 2014 deadline has been removed from Chapter 4 as it is no longer relevant. Improve the clarity of the description of the process of transferring assets in section 9.	February 2015
Version 4.0	Release of R4BP version 3.3. Minor update includes the following: Information concerning changes on request updated in section 7.1 Information concerning the summary of product characteristics included in section 2.3.2	June 2015
Version 5.0	Release of R4BP version 3.8. New following chapter added: 10. National authorisation cancellation on request New paragraphs added under the section 6.1. and 8.1.1. Annex I and Annex II updated. References to IUCLID 5 removed and other minor updates included.	October 2016
Version 6.0	Release of R4BP version 3.9. Following changes have been made: Grouped submission in section 3.4 Include a case in an existing grouped submission in section 3.5 Submission of a batch of administrative change(s) in section 3.6 Requesting an extension for a resubmission task in section 4.3 Withdrawing a case from R4BP in section 5 Updates in sections 6.1.2 and 9.1.2	June 2017
Version 7.0	Update to reflect transition from IUCLID 6.3 to IUCLID 6.4, and from the classic user interface to the web user interface. Annexes I and II removed. Minor changes and modifications.	October 2018
Version 8.0	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 9.0	Release of R4BP version 3.22. Following changes have been made: Grouped submission in section 3.4.2. Grouped mutual recognition in sequence (NA-MRS) allowed.	February 2022
Version 10.0	Release of R4BP 3.XX. Changes include following: SPC editor discontinued, instead SPCs should be prepared in IUCLID format with specific working context.	February 2024

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1. Introduction

1.1. Objective

This manual gives advice on how to submit applications concerning biocidal product 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). This manual covers national authorisation (NA) 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.

[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.

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 in ECHA Accounts, 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 national authorisation of biocidal products. 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 ECHA fees

Table 1 outlines the case abbreviations used for the application types in R4BP 3, and whether there is an associated ECHA fee (€).

ECHA informs the case owner of the fees payable and will reject the application if the fee is not paid **within 30 days**. For more general information regarding ECHA fees and invoicing, please consult the R4BP 3 Q&A on invoicing. Alternatively, for full details, please refer to Annexes II and III of the BPR Fee Regulation[3].

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 the national helpdesks is available from ECHA's website.

[3] 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.

Table 1: National authorisation (and related) application types

Case abbreviation	Application
NA-APP	National authorisation (including provisional) with the option of mutual recognition
NA-RNL	Renewal of national authorisation (including subject to mutual recognition)
NA-MRS	Mutual recognition in sequence €
NA-MRP	Mutual recognition in parallel €
NA-BBS	National authorisation of the same biocidal product (authorised)
NA-BBP	National authorisation of the same biocidal product (pending)
NA-ADC	National authorisation request for change (admin)
NA-MIC	National authorisation request for change (minor)
NA-MAC	National authorisation request for change (major)
NA-MRG	Merge of product authorisations in one product family
NA-TRS	Transfer of a national authorisation
NA-CCL	National authorisation cancellation on request
CC-APP	Request for classification of a change to a product authorisation €
IN-REB	Inquiry to share data for a biocidal product
ET-NOT	Notification of an experiment or test
NA-NPF	National authorisation notification of a product in a product family
NE-NOT	Notification of an unexpected or adverse effect – national authorisation
PP-APP	Parallel trade permit

2.2. Application requirements

Depending on the application type and your individual circumstances, you may need to include an IUCLID dossier, A Summary of the product characteristics (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 enter data into various sections of a IUCLID dataset and prepare a dossier, please refer to the BSM 'Technical guide: How to prepare a biocides dossier'.

2.2.2. 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 it with the IUCLID available on the ECHA website.

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

Where appropriate, we advise you to consult the relevant MSCA for further clarification on the language and other requirements for the SPC.

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

2.2.3. Supporting documents

Under the BPR, you often need to submit supporting documents[4] 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 ECHA supporting documents: For many application types, ECHA or National Authorities require 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.

[4] Including but not limited to, a draft SPC, 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 stepwise 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.

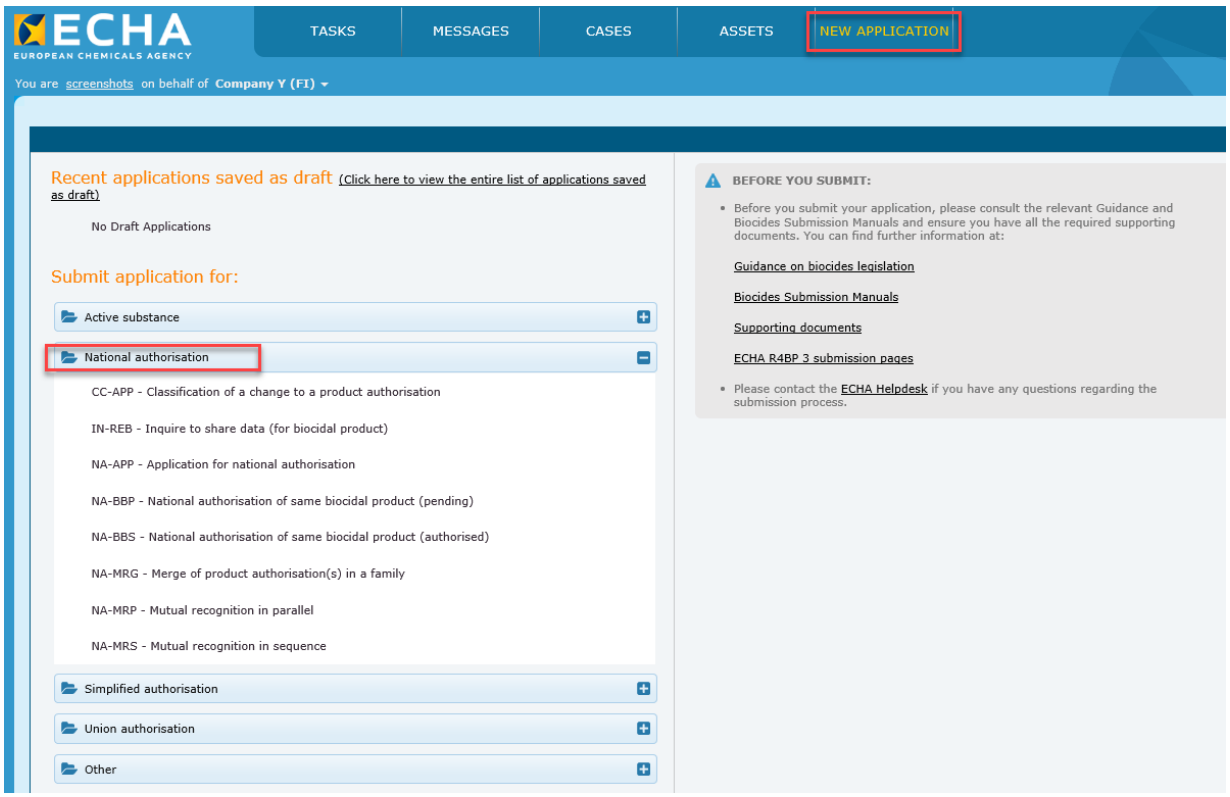
You can find additional guidance on working in R4BP 3 in 'BSM Technical guide: using R4BP 3'.

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

To launch the application wizard as a new application, click on the 'NEW APPLICATION' tab on the R4BP 3 taskbar and then click on the folder 'National authorisation' to see the full list of application types available (Figure 1). Then, select the relevant application type for your purpose.

Figure 1: Launching the application wizard via the 'new application' tab

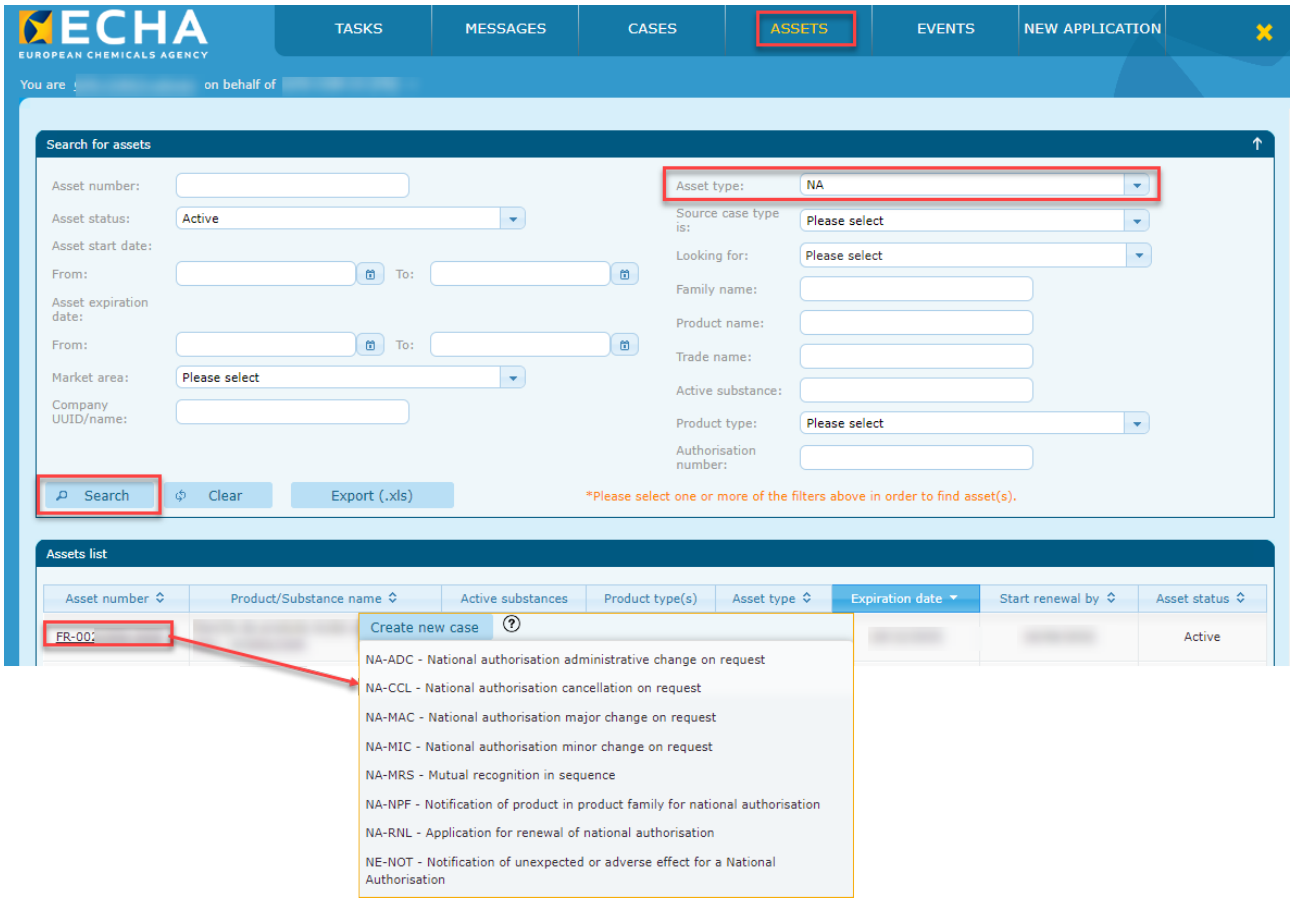


3.2. Submit a single application in the context of an existing 'asset'

To 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 NA asset by filling in some search criterion (e.g. the asset type (NA – National 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.

Does your migrated asset contain incorrect details? If your migrated asset (i.e. from R4BP 2 to R4BP 3) contains incorrect details (e.g. appears as a single product asset instead of a product family), you should consult the relevant Member State or ECHA Helpdesk to correct it. You are required to do this before launching any applications from that asset, including mutual recognition, requests for change, or a renewal of a product authorisation. Note that applications submitted from assets containing errors cannot be corrected.

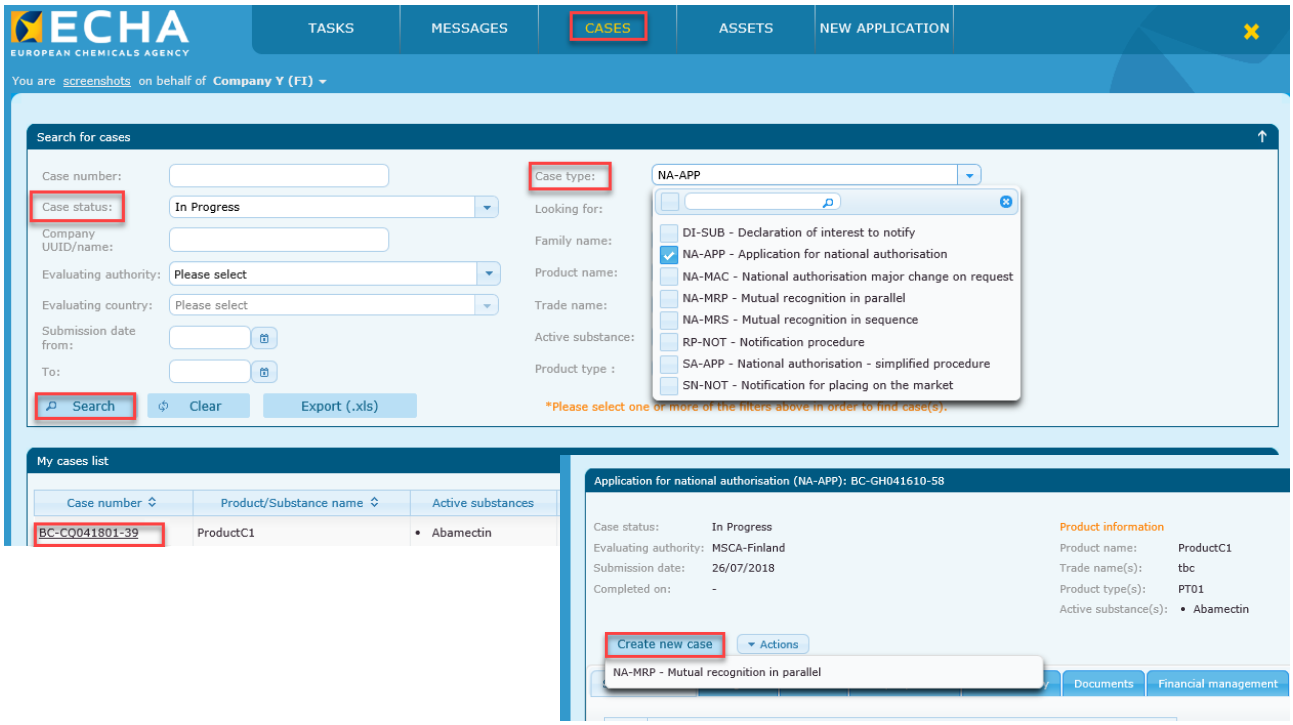
Figure 2: Launching the application wizard from the context of an existing 'asset'



3.3. Submit a single application in the context of an 'in progress' case

To launch the application wizard from an existing case, click on the 'CASES' tab in the R4BP 3 taskbar and search for the specific type of case by filling in some search criterion (e.g. the case type (NA-APP – Application for national authorisation). Click on the 'Case number' hyperlink in the 'My cases list' to open the details page for that specific case. On this page, click 'Create new case'. A list of application types allow to be started from that case will appear. From this list, you can launch the wizard by selecting the relevant application type for your purposes (Figure 3).

Figure 3: Launching the application wizard from the context of an 'in progress' case



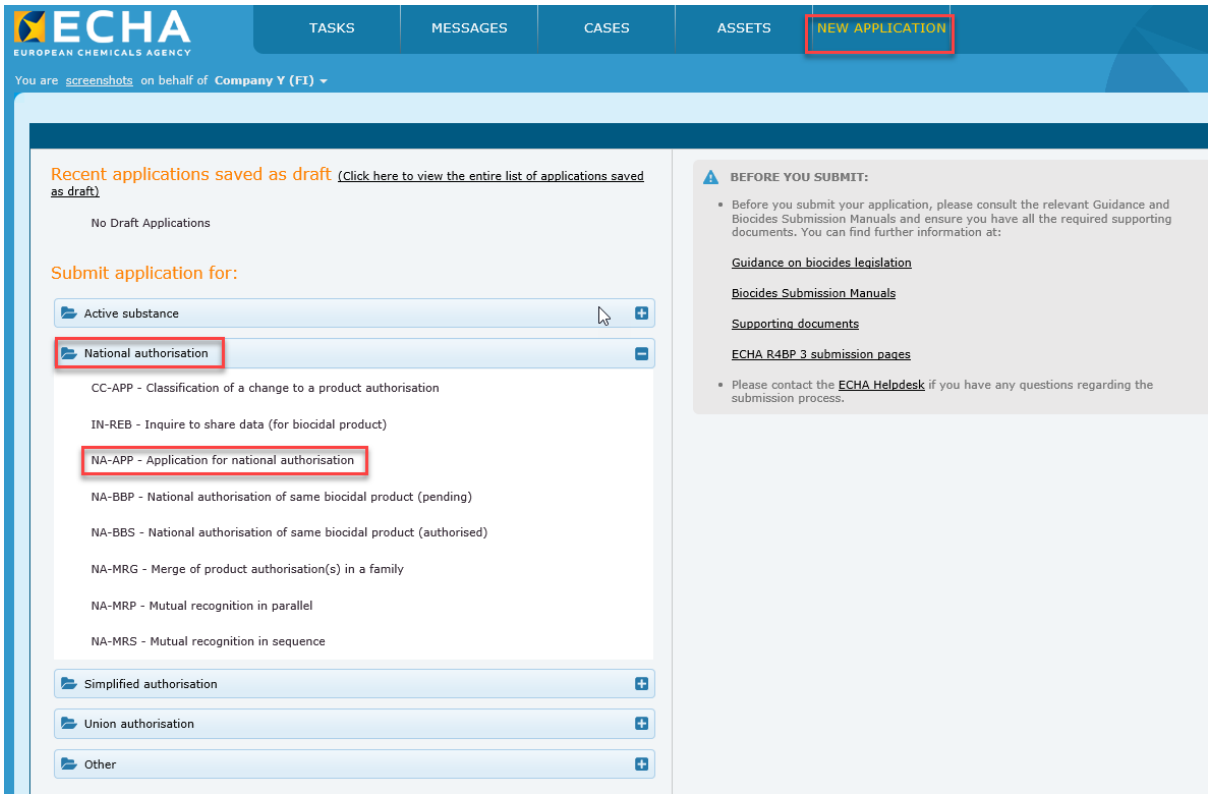
3.4. Submitting a grouped submission

3.4.1. Prior the creation of the NA asset

If you wish to apply for a national authorisation, you are allowed to seek mutual recognition in parallel (i.e. submit for NA-MRP).

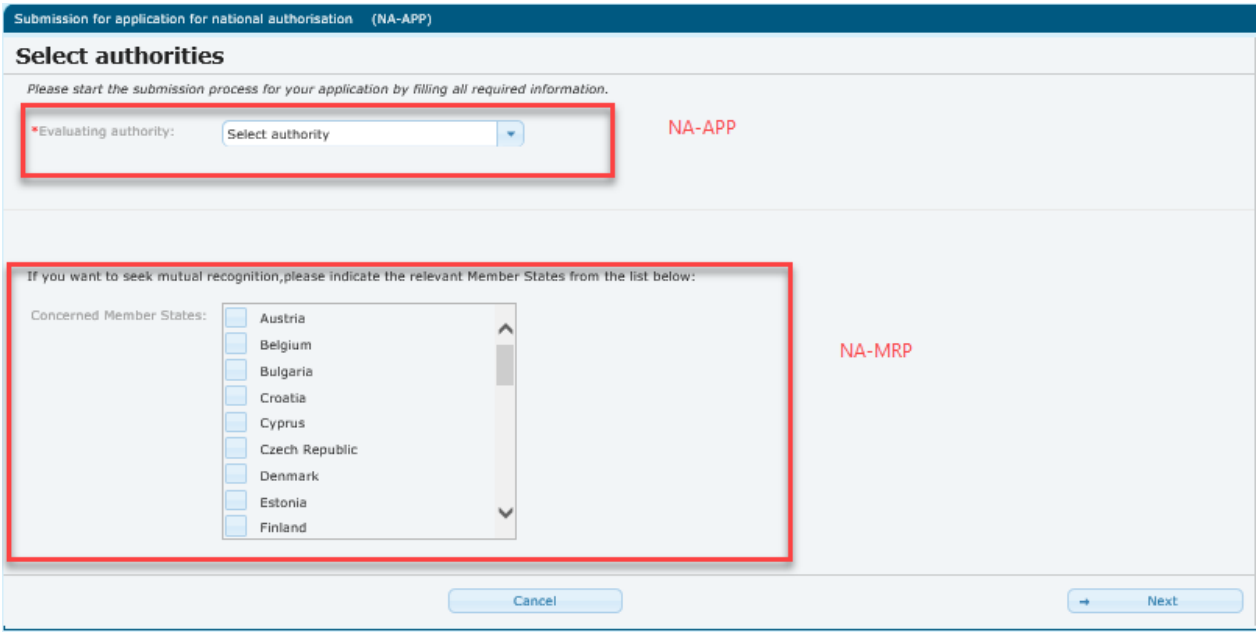
In this case, click on the 'NEW APPLICATION' tab and launch the NA-APP wizard (Figure 4).

Figure 4: Launch a NA-APP application



You will be required to select the evaluating authority for the National authorisation and pick up the relevant concerned member state(s) from the list (Figure 5: Choose the relevant member state(s)Figure 5).

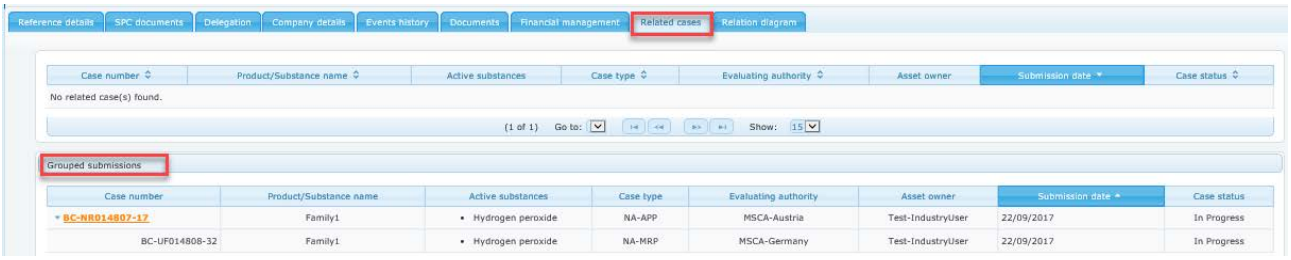
Figure 5: Choose the relevant member state(s)



The relevant application wizard will be launched to guide you through the application submission process. It will require you to select the authorities, set case owner details, set submission details, upload dossier, upload SPC, upload other files, and confirm your submission.

You can find the details of your grouped submission under the 'related cases' tab of the reference (NA-APP) or concerned (NA-MRP) cases (Figure 6).

Figure 6: Grouped submission under the 'related cases' tab



3.4.2. After the creation of the NA asset

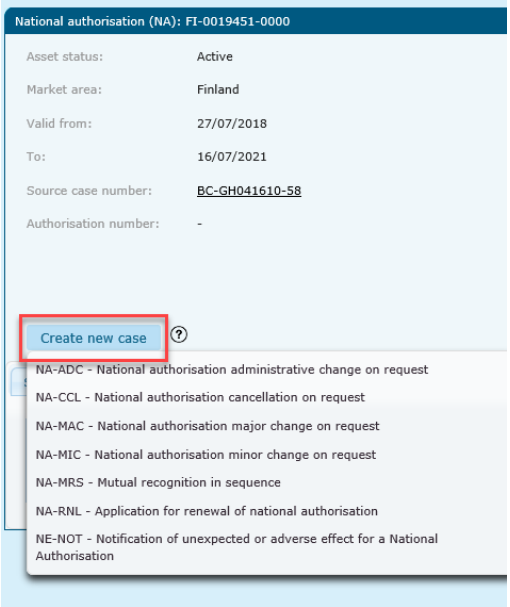
If your **NA reference** asset has been approved by the reference Member State:

A. You may apply for single or grouped **mutual recognition in sequence** (NA-MRS).

B. You are **seeking changes** (e.g: administrative, minor, or major changes) OR **a renewal**, you can submit a grouped submission by sending an application to every concerned Member states.

To submit a grouped submission, search for your reference asset number and click on 'Create new case' to launch the application wizard.
(Figure 7).

Figure 7: Submitting a grouped submission



3.5. Include a case in an existing grouped submission (for NA-ADC, NA-MIC, NA-MAC and NA-RNL)

R4BP 3 offers you the possibility to introduce a new case in an existing grouped submission.

Please note that the following considerations should be taken into account:

- You are the owner of the reference case;
- The reference case is related to either a National application for administrative change on request (**NA-ADC**), a National application for minor change on request (**NA-MIC**), major change on request or a renewal (**NA-RNL**);
- The reference case must be '**in progress**' or '**suspended**'.

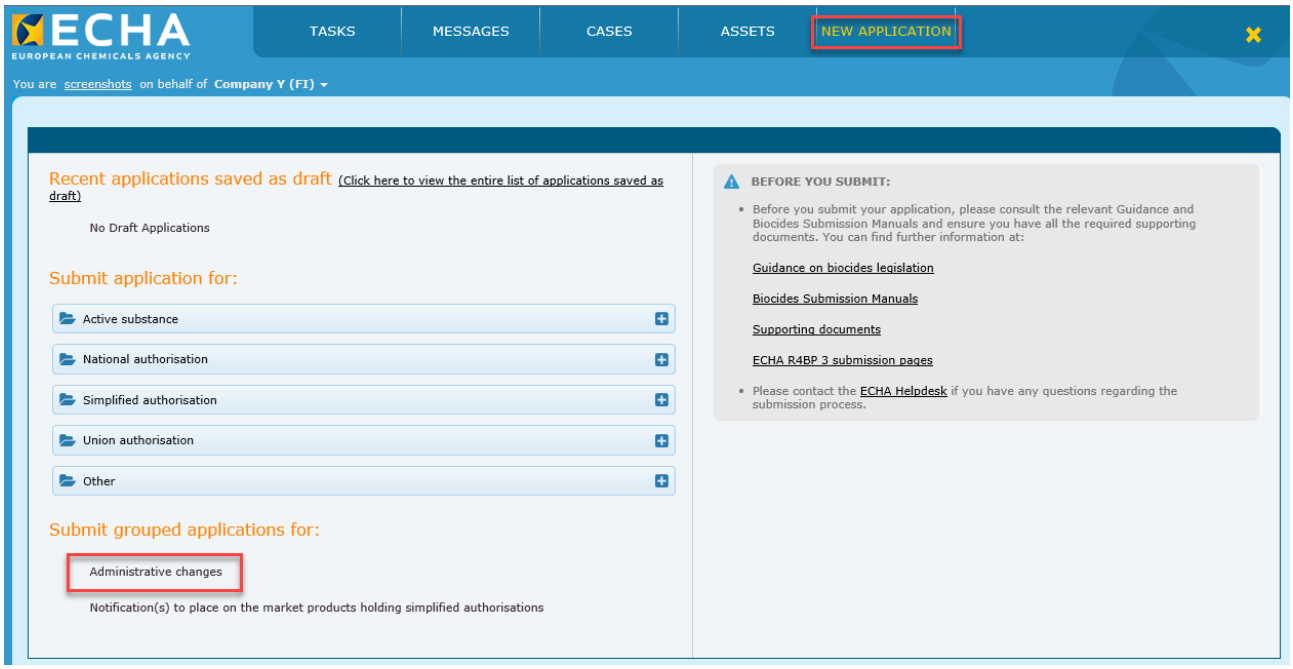
Click on 'Create new case' in the case details to launch the application wizard (Figure 8).

Figure 8: Include a case in an existing grouped submission

3.6. Submitting grouped applications for administrative change(s) (only for NA-ADC)

To submit several applications concerning administrative change(s) (i.e.: NA-ADC), click on the 'NEW APPLICATION' tab on the R4BP 3 toolbar, and select 'Apply for grouping administrative change(s)' at the bottom of the page (Figure 9).

Figure 9: Submit grouped applications for administrative changes



Note that each administrative change on request application will run independently from one another (e.g. you select two NA asset in the assets list. Two administrative change on request applications will be submitted. These administrative changes on request applications will be related to their corresponding assets but will be run independently from one another).

4. Post submission obligations

4.1. Verify your submission

After submitting your application, a message on the screen containing a submission number, i.e. the unique number identifying your case will appear. 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

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 up from the ECHA account application in order 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: using R4BP 3.

4.3. Resubmission tasks

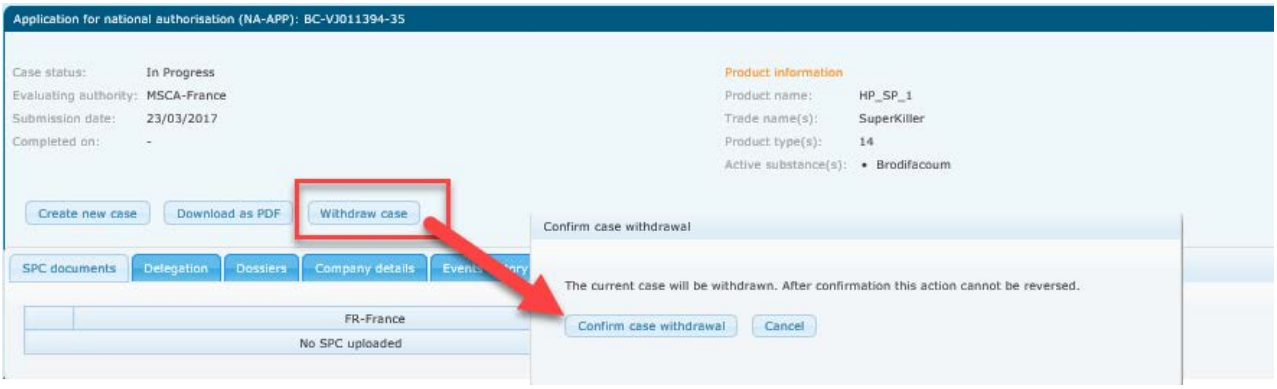
To make sure that an application can be processed correctly, a case owner may need to complete task items assigned by authority users (e.g. a 'Resubmit information' task). You are obliged to monitor your task items and complete them within the defined time. You can access the task items by selecting the 'TASKS' tab on the toolbar (Please refer to BSM Technical guide: using 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. If you need more time to complete a resubmission task, you are allowed to contact the relevant authority to request an extension.

5. Withdrawing a case from R4BP

If you do not want to proceed with one of your application, you can withdraw it via the Case details page. Click on 'withdraw case' and confirm the case withdrawal.

Figure 10: Withdraw case from R4BP

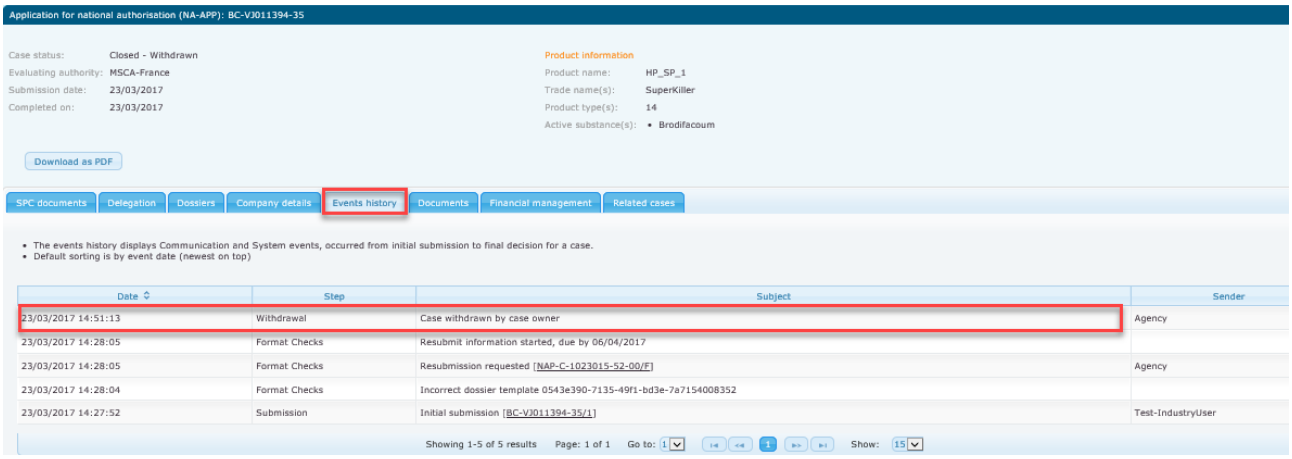


Note that this action is subject to some requirements:

- 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 11: Case withdrawal in the 'Events history'



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

Note that if you choose to withdraw a reference case while the concerned cases have not yet reached the Business rules step, the system will automatically set them as 'closed'. If the concerned cases have reached the Business rules check step, then the authority will have to withdraw all concerned cases.

Note that this action will also affect delegated cases to other companies.

6. National authorisation[5] with the option of mutual recognition (NA-APP)

An individual application for national authorisation can be submitted alone or with the option to apply to selected Member States for mutual recognition in parallel. These submissions are made through the NA-APP wizard in R4BP 3. The following sub-chapters guide you through each step of the application process.

You can make applications for mutual recognition in parallel of national authorisations simultaneously with the initial application for national authorisation in the NA-APP wizard. Requirements for the NA-MRP application are described in chapter 8.

The principles and processes behind national authorisation and provisional national authorisation are described in the Practical Guide 'chapter on national authorisation' available from ECHA's website.

For information requirements, please consult the Guidance on information requirements for biocides from ECHA's website.

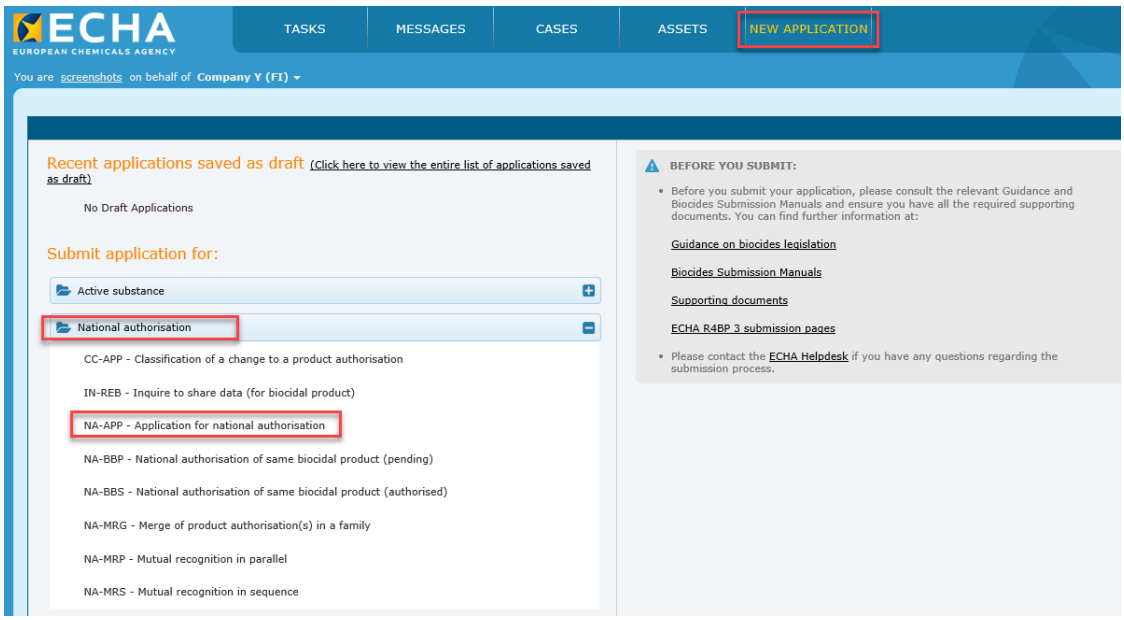
This sub-chapter describes the application requirements necessary for each step of the NA-APP application wizard in R4BP 3 for both national authorisation and provisional national authorisation applications.

For full technical assistance on how to enter data into various sections of a IUCLID dataset and prepare a dossier and, please refer to the BSM 'Technical guide: How to prepare a biocides dossier'.

6.1. Launching the NA-APP application wizard

You can launch the application 'NA-APP -National authorisation' from the 'NEW APPLICATION' tab on the R4BP 3 taskbar.

Figure 12: Launching the application wizard for NA-APP



[5] Including provisional authorisation

6.2. Application requirements for NA-APP

This sub-chapter describes the application requirements necessary for each step of the NA-APP application wizard for both national authorisation and provisional national authorisation applications and how to apply for mutual recognition in parallel in the same time. You can find additional instructions and guidance in R4BP 3 at each step of the wizard to assist you with the application procedure.

Application requirements for NA-APP

Select authorities
Select the 'evaluating authority' that you are sending the application to for evaluation. If you are seeking mutual recognition, also select the relevant Member States.

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 dossier and select a language
The dossier must fulfil all of the information requirements laid out in Article 20(1)(a) of the BPR.

Where relevant: attach in section 13 'Summary and evaluation':

- a decision on technical equivalence (when the active substance is considered from a source different to the reference source).
- a letter of access
- 'permission to refer' to data granted by ECHA (Article 63 of the BPR)

Upload SPC (.i6z)

Create SPC in .i6z format in IUCLID. If multiple authorities are selected (step 1), upload the relevant market versions of the SPC. 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

If you are applying for a **national authorisation**, upload the supporting document 'Supporting document for national authorisation application'.

If you are applying for a **provisional national authorisation**, upload the ECHA supporting document 'Application for provisional authorisation'.

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').

All supporting information not available in the dossier must be included 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. Renewal of authorisation(s) including those subject to[6] or granted through[7] mutual recognition (NA-RNL)

You can apply for the renewal of a national authorisation for a single authorisation or for the renewal of those products mutually recognised in other Member States. In either case, you submit these through the NA-RNL wizard in R4BP 3.

For information requirements, please consult the Guidance on information requirements from ECHA's website.

The principles and processes behind the renewal of authorisations are described in the Practical Guide 'chapter on the renewal of national authorisation and authorisations subject to mutual recognition' available from ECHA's website.

Article 31 of the BPR sets out the procedure for the renewal of a national authorisation for a single authorisation.

The supplementary rules for the grouped renewal of authorisations subject to, or granted through mutual recognition procedures, are laid down in the Commission Delegated Regulation (EU) No 492/2014. The regulation applies both in the Member State that granted the first authorisation and in the subsequent Member States that granted an authorisation through mutual recognition, to authorisations with **the same terms and conditions** except where laid out in Article 1(3).

This sub-chapter describes the application requirements necessary for each step of the NA-RNL application wizard in R4BP 3 for the renewal of authorisations including those that were subject to or granted through mutual recognition.

If your application relates to a **frame formulation** which was established under the Biocidal Products Directive 98/8/EC[8] (BPD), then the relevant product authorisation must first be converted into a biocidal product family authorisation before you can apply for any other application. Refer to Chapter 11 'Merge of a product authorisation(s) in a family' for more details.

7.1. Launching the application wizard for NA-RNL

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

You can launch the NA-RNL application wizard from the relevant existing asset as previously described in section 3.2.

In the case of grouped submissions, i.e. where mutual recognition is concerned, you may wish to have a new reference Member State than the one who initially evaluated the application. In such cases, you should launch the application from the asset in the market of the Member State that will act as the new evaluating authority for the renewal.

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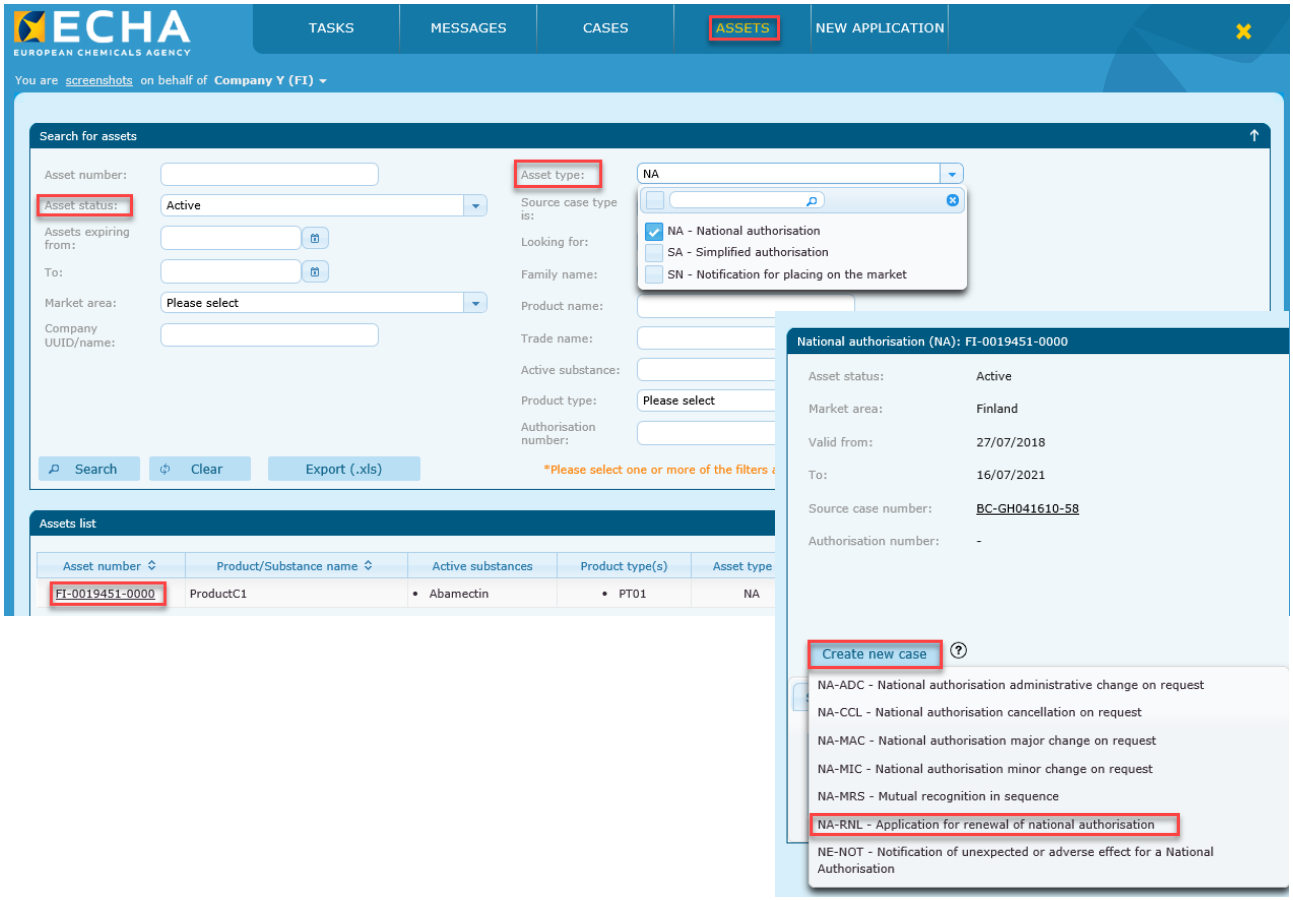
[6] Referring to the original national authorisation, which has been subject to mutual recognition in accordance with Article 4 of Directive 98/8/EC or with Articles 33 and 34 of Regulation (EU) No 528/2012.

[7] Referring to the subsequent national authorisation(s) granted through mutual recognition in accordance with Article 4 of Directive 98/8/EC or with Articles 33 and 34 of Regulation (EU) No 528/2012.

[8] 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.**

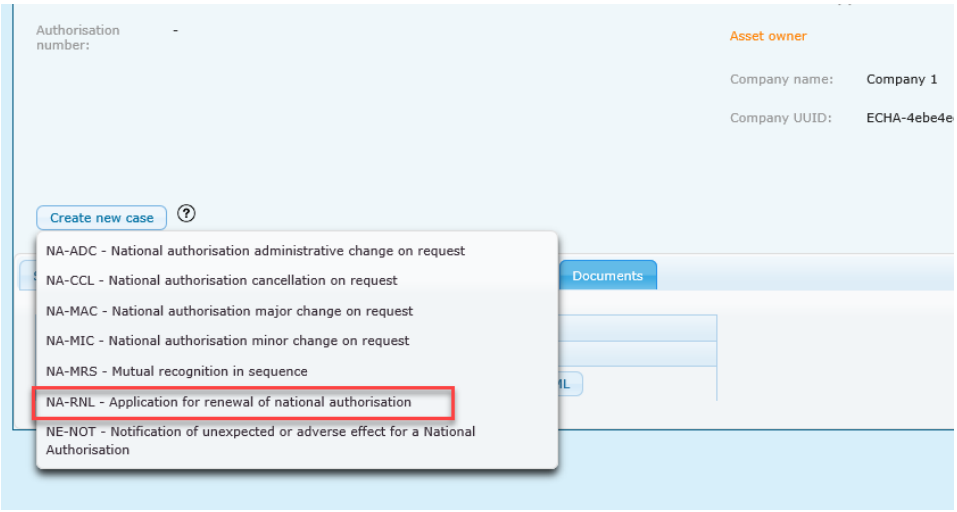
Figure 13: Launching the application wizard for NA-RNL



- **In the context of an 'in progress' case to include a case in an existing grouped submissions**

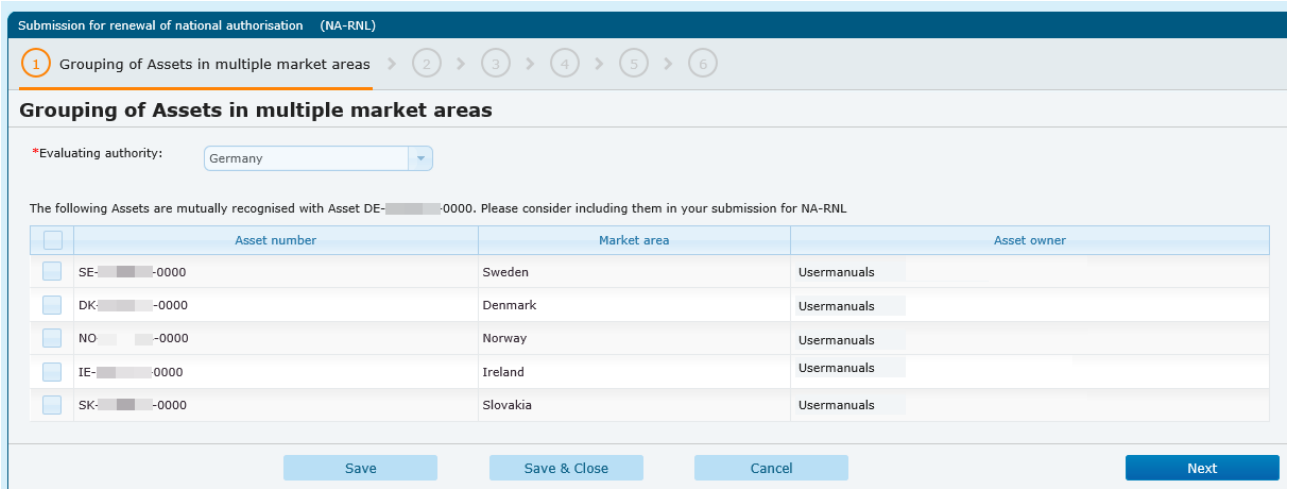
As described in section 3.5, you can launch the NA-RNL application wizard from the relevant reference case in order to introduce a new NA-RNL case into an existing group.

Figure 14: Launching the application wizard for NA-RNL



Once you have click on 'Create new case', you will then be able to select the assets to be included in the existing group submission, and launched the application wizard.

Figure 15: Assets to be included in the existing group submission



7.2. Application requirements for NA-RNL

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

You must include any **new data** that has been generated since the initial authorisation (or previous renewal) in the IUCLID file.

Where the renewal is sought for authorisations granted under the BPD, the **previously submitted data** may optionally be included in the IUCLID file.

Application requirements for NA-RNL

Grouping of assets in multiple market areas

If your reference asset has been mutually recognised in other Member States, you can select, where relevant, all the assets that you wish to renew at this step. If some assets are not visible for grouping, you will need to make separate applications to renew those assets. Please refer to the dedicated submission webpage for more details.

Case owner details

A contact person for the case must be specified.

Set submission details

Indicate the payment details i.e. purchase order number and billing address.

Upload dossier and select language

Submit your dossier with at minimum, the information on the product composition.

In all applications, attach an assessment of whether the conclusions of the initial (or previous) risk assessment of the product(s) remains valid in section 13 'Summary and evaluation'.

Where relevant attach in section 13:

- a letter of access
- a decision on technical equivalence
- 'permission to refer' to data granted by ECHA (Article 63 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.

Upload other files to support your application

Whenever relevant: written confirmation from the new 'reference Member State' agreeing to evaluate the application.

For the **renewal of a single national authorisation under Article 31 of BPR:** upload the supporting document for the 'Renewal of single national authorisation'.

For the **grouped renewal of several authorisations linked by mutual recognition under Article 2 of Regulation (EU) No 492/2014**: upload the ECHA supporting document for the 'Grouped renewal of several authorisations subject to mutual recognition'. Please note that with a renewal linked by mutual recognition you should list in the supporting document all the assets linked by mutual recognition in R4BP 3, e.g. where assets are not visible in R4BP 3.

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.

8. Mutual recognition of a national authorisation (NA-MRS, NA-MRP)

Applications for the mutual recognition of a national authorisation in another Member State can be made in **sequence** (where the reference product is authorised) or **in parallel** (where the reference product is pending authorisation).

You can make applications for mutual recognition in parallel of national authorisations either simultaneously with the initial application for national authorisation in the NA-APP wizard (described in Chapter 6) or from the application for national authorisation wizard as described in this chapter.

The principles and process for mutual recognition of a national authorisation are described in the Practical Guide 'chapter on renewal of national authorisation and authorisations subject to mutual recognition' available from ECHA's website.

This sub-chapter describes the application requirements necessary for each step of the application wizard in R4BP 3 for:

- **NA-MRS** - mutual recognition of a national authorisation in **sequence**
- **NA-MRP** - mutual recognition of a national authorisation in **parallel**.

For NA-MRS applications, where the application for authorisation was submitted under the BPD and on which a decision has not been made by 1 September 2013, please refer to Annex II B to the Note for Guidance CA-Sept13-Doc.5.1.g - Final available on the CIRCA website.

If your application relates to a **frame formulation,** which was established under the Biocidal Products Directive 98/8/EC, then the relevant product authorisation must first be converted into a biocidal product family authorisation before you can apply for any other application. Refer to Chapter 11 'Merge of a product authorisation(s) in a family' for more details.

8.1. Launching the NA-MRS and NA-MRP application wizards

There are three ways to launch both application wizards in R4BP 3, either through:

- A '**new application'**, useful if you do not have direct access to the relevant asset or case i.e. you are not the asset or case owner, or
- An '**existing asset**' (NA-MRS) or '**pending case**' (NA-MRP) (see section 3.3.), useful if you are the asset owner and have direct access to the relevant asset details, or
- Via the **NA-APP wizard** (NA-MRP)

Launching the wizard in these ways has been described in chapter 3. Note that whichever wizard is used, R4BP 3 will automatically link the application to the NA asset or case. As soon as the wizard is launched, the same steps are followed through the submission process.

8.2. Application requirements for NA-MRS and NA-MRP

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

If the prospective asset owner of the mutual recognition application is different from the initial asset owner of the 'NA' type asset or case owner of the 'NA-APP' case, an active delegation should exist otherwise the system will not let the user complete the application. Refer to BSM Technical guide: using R4BP 3 for more details.

Application requirements for NA-MRS and NA-MRP

Set reference details

This step occurs only when launching through a 'new application'. Enter a valid:

'**Reference case number**' for NA-MRP applications, or

'**Reference asset number**' for NA-MRS applications.

Case owner details

A contact person for the case must be specified.

Set submission details

The 'evaluating authority' and 'asset owner' details must be specified and the payment details relevant to the case indicated.

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.

The market area of the SPC must match the 'evaluating authority' indicated in the previous step.

Upload other files

Whenever relevant, a letter of access to the biocidal product and/or active substance dossier.

For **NA-MRS** applications, we advise you to consult the relevant MSCA for further clarification on the language requirements for the **translation of the national authorisation** granted by the reference Member State.

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. National authorisation of the same biocidal product (NA-BBS, NA-BBP)

An authorisation in any given Member State may be granted to a biocidal product or member family ('same product'), which is 'identical' to another biocidal product or member family, either authorised or pending authorisation, in that Member State.

The principles and process behind the authorisation of the same biocidal product (BP) is described in the Practical Guide 'chapter on same biocidal product' available from ECHA's website.

For the relevant implementing legislation, refer to the 'same BP Regulation'[9].

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

Already authorised (NA-BBS): When the 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 (**NA-BBP)**: When the national authorisation for the related reference product is currently being processed i.e. pending authorisation, and you are in possession of the case number[10].

If you need to seek National authorisation (NA) for the **family** of the same biocidal product, you may use relevant UA or NA family SPC and draft the **NA family SPC** file from it.

NA family SPC attached to NA-BBS/NA-BBP applications applies to the National authorisation of the **family** for the same biocidal product.

If you need to seek National authorisation (NA) for the same biocidal product for the **single product**, you may use relevant UA or NA family SPC or UA or NA single SPC and create the **NA single SPC file** from it.

NA single SPC attached to NA-BBS/NA-BBP applications applies to the National authorisation for the same **single biocidal product**.

The application for NA 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 national authorisation of the related reference product.

The application for NA authorisation of the same biocidal product derived for a UA reference product must be made to the MSCA of the chosen market. The conditions of authorisation for the 'same' biocidal product will be the same as for the national authorisation of the related reference product.

[9] 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

[10] The number relates to an individual application and is created after the submission of an application.

9.1. Launching the NA-BBS or NA-BBP application wizard

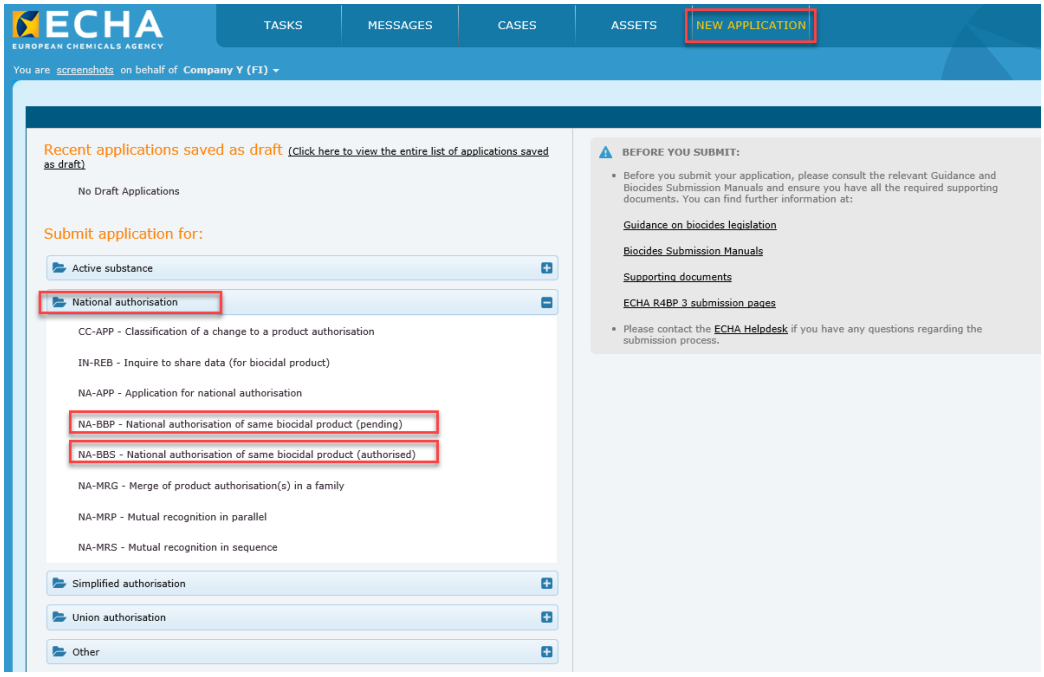
The R4BP 3 application wizard for both application types (authorised and pending) is launched through the 'NEW APPLICATION' tab on the R4BP 3 taskbar.

After selecting the right application type i.e. national authorisation of the same biocidal product **authorised** ('NA-BBS') or **pending** ('NA-BBP), enter the relevant 'reference number'; i.e. asset number for 'authorised' applications or the case number for 'pending' applications. It is important to note that when you are creating a UA-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 NA-APP application and want to apply for NA-BBP, you will need to contact the case owner of the application for authorisation of the related reference product to obtain the relevant 'reference case number(s)'.

If you are not the authorisation holder of the related reference product, you will only be able to launch an application from the 'New application' tab. Related 'reference numbers' (asset numbers) and other identifiers are publicly available on the ECHA website under '[Information on chemicals]'.

Figure 16: Launching the application wizard for NA of the same biocidal product



9.2. Application requirements for NA-BBS and NA-BBP

This sub-chapter describes the application requirements necessary for each step of the NA-BBS and NA-BBP application wizard. 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 authorisation of the same biocidal product application is different from the initial asset owner of the 'NA' type asset or case owner of the 'NA-APP' case, an active delegation should exist. Otherwise, the system will not let the user complete the application. Refer to [BSM Technical Guide: using R4BP 3] for more details.

Application requirements for NA-BBS & NA-BBP

Set reference details

Launching via a 'new application' requires a valid reference number.

An '**asset number**' for NA-BBS applications, or,

A '**case number**' for NA-BBP applications.

Case owner details

Contact person for the case must be specified.

Set submission details

Enter the details of the 'asset owner' and indicate the payment details relevant to the case.

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 ECHA supporting document 'Application for authorisation of the same biocidal product under Regulation (EU) No 414/2013'.

Where relevant upload:

- a letter of access
- a decision on technical equivalence
- 'permission to refer' to data granted by ECHA (Article 63 of the BPR).

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. National authorisation – administrative (NA-ADC), minor (NA-MIC), major (NA-MAC) changes

The following sub-chapters describe the application instructions concerning national authorisation changes on request. There are three classifications of change to a national authorisation of a biocidal product; administrative, minor and major changes and they are classified according to the level of assessment required (Figure 17).

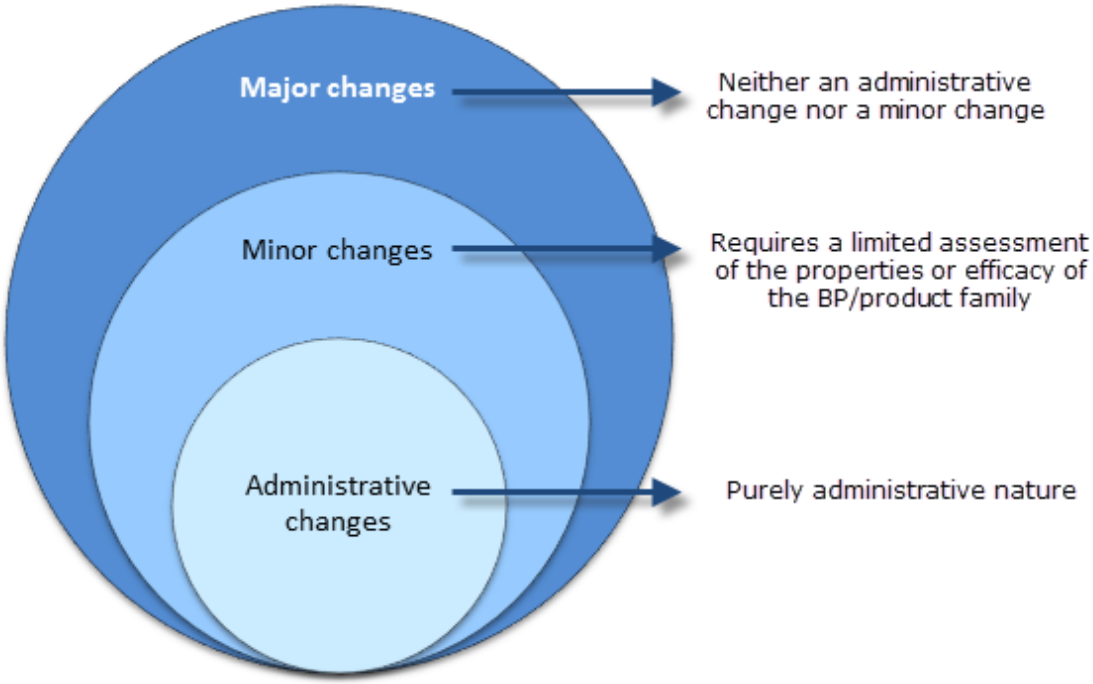
Please consult the 'Changes Regulation'[11] for a list of the different types of changes and the information requirements for these application types.

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

If 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 Chapter 14 for application instructions).

If your application relates to a frame formulation, which was established under the Biocidal Products Directive 98/8/EC, then the relevant product authorisation must first be converted into a biocidal product family authorisation before you can apply for any other application. Refer to Chapter 11 or more details.

Figure 17: Classification of changes to a national authorisation



[11] 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.

10.1. Application instructions

As a rule, a separate notification/application shall be submitted for each change. However, under certain conditions, the changes can be grouped.

You may wish to consult with the MSCA evaluating the application for information on more specific cases involving the grouping of changes. The evaluating MSCA will confirm if it is practically feasible to handle grouped changes in the same procedure.

If you are seeking changes in more than one Member State, you must submit identical applications to every concerned Member State simultaneously. You can do this in one application – see step 2 of the application wizard.

Each of the following sub-chapters describes the application requirements necessary for each step of the application wizard in R4BP 3 for the above mentioned application types. All applications are launched from the relevant asset in the 'Assets' tab. Please note that applications concerning requests for changes are not permitted by R4BP 3 if there is any of the following on-going cases:

- Merges of a product authorisation(s) in a family;
- Merge of a product authorisation(s) in a family while a notification of a product In a product family is on going (or vice versa);
- Asset transfer and administrative change is ongoing.

Special note concerning the supporting document for a change of an authorisation:

All assets where the change is sought shall be listed in the supporting document. Assets linked by mutual recognition should be visible in the 'grouping of assets' step in the application wizard if you are the asset owner or have rightful nomination, however. In addition, assets to which the change is applicable but which are not linked my mutual recognition are to be treated together by the same reference Member State. Refer to the submission webpage for more details.

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'.

10.2. Administrative changes to a national authorisation

The possibility to transfer 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 procedure '**transferring a national authorisation**' outlined in chapter 12.

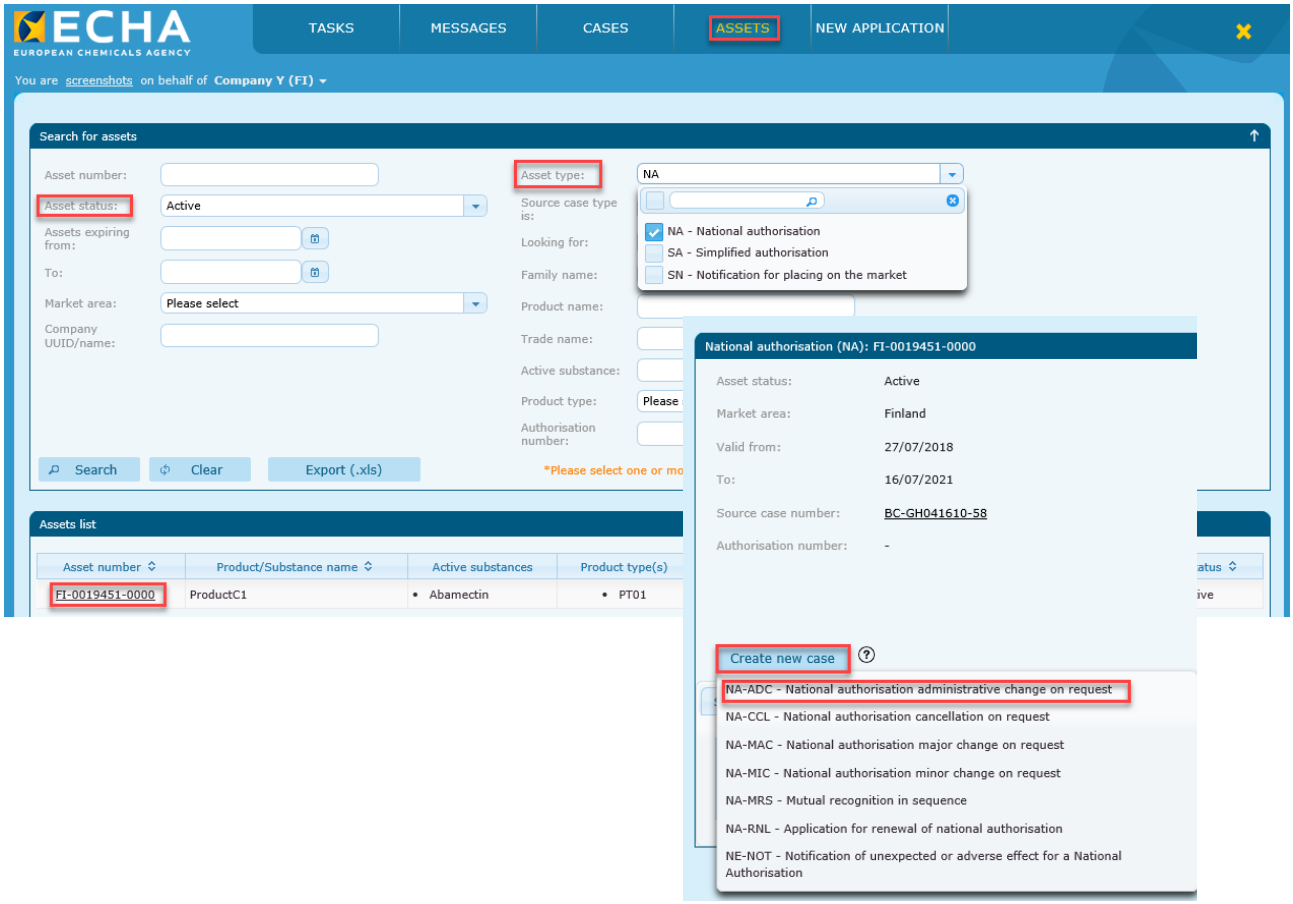
The possibility to transform a frame formulation into a product family is also listed as an administrative change in the Changes Regulation (Annex, title 1, section 1, item 6). However, this type of application must be made through the procedure '**Merge of a product authorisation(s) in a family**' outlined in Chapter 11.

10.2.1. Launching the NA-ADC application wizard

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

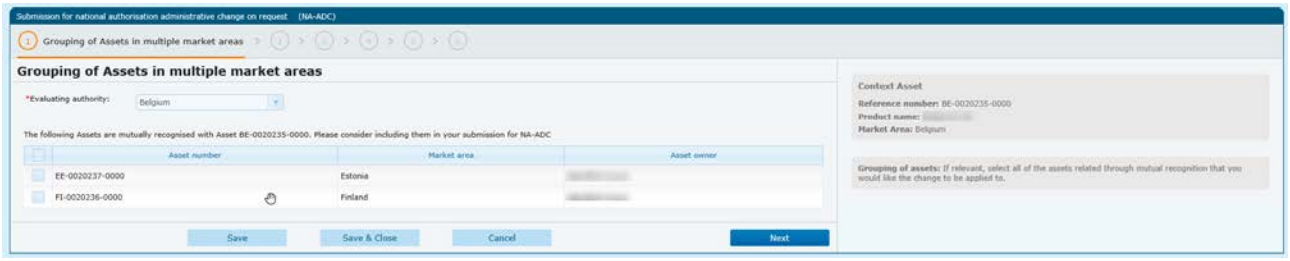
You can launch the NA-ADC application wizard from the relevant existing asset as previously described in section 3.2.
Please note that grouping of assets is possible via this option, for mutually recognised assets.

Figure 18: Launching the application wizard for NA-ADC



Once you have click on “Create new case”, you will then be able to select the assets (only, if there are mutually recognised assets identified) for which you want to initiate NA-ADC(s).

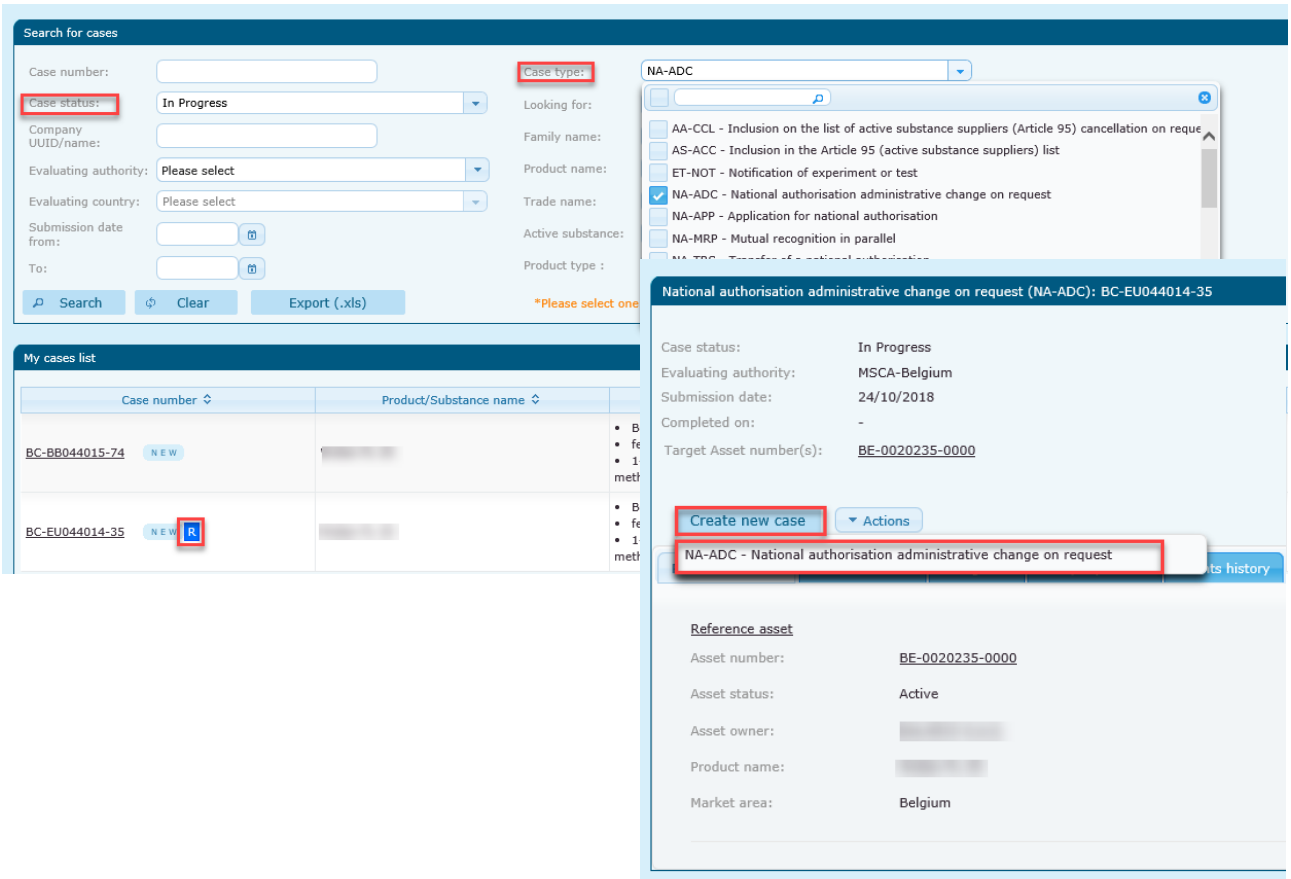
Figure 19: Grouping of assets in multiple market areas while initiating NA-ADC submission



- **In the context of an ‘in progress’ reference case to include a case in an existing group**

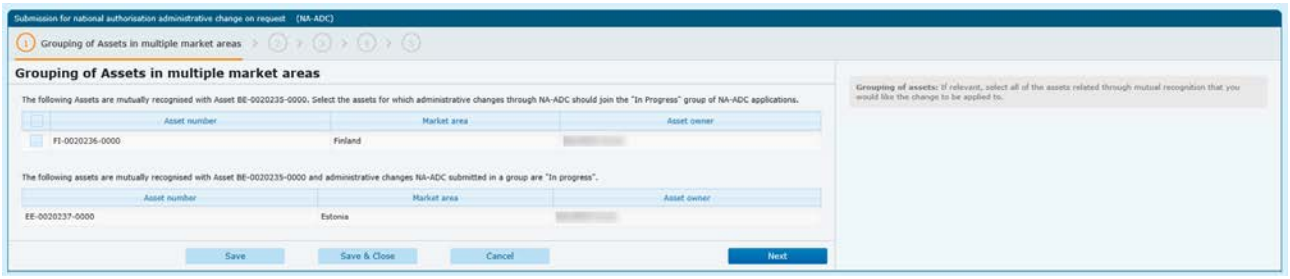
You can launch the NA-ADC application wizard from the relevant reference case of the group in order to introduce a new NA-ADC case in that existing group.

Figure 20: Launching the application wizard from a reference case



Once you have click on “Create new case”, you will then be able to select the assets to be included in the existing group submission.

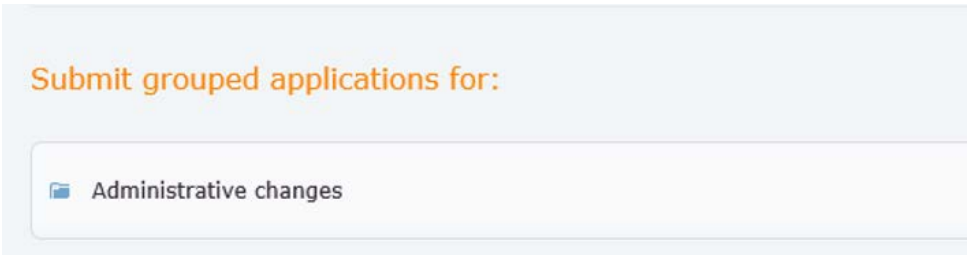
Figure 21: Grouping of assets in multiple market areas while initiating a case into ongoing grouped NA-ADC submission



- **Submitting a batch of NA-ADC applications**

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

Figure 22: Submitting grouped applications for administrative changes



The relevant application wizard will be launched to guide you through the application submission process.

10.2.2. Application requirements for NA-ADC

This sub-chapter describes the application requirements necessary for each step of the NA-ADC 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 NA-ADC

Grouping of assets in multiple market areas

If your reference asset has been mutually recognised in other Member States, and the changes are sought in more than one market area, you can submit an application to every concerned Member State, where relevant, by making a selection in the corresponding tick boxes.

Special cases: Not all assets affected by the change may be visible for grouping in this step. Refer to the special note concerning the ECHA supporting document for all applications affected by the change (section 10.2.) as separate applications for these assets will need to be made.

Case owner details

A contact person for the case must be specified.

Set submission details

Indicate the payment details relevant to the case.

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

Upload SPC (.i6z)

Upload updated draft SPC(s) reflecting the changes sought for every concerned Member State. 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

In all applications: upload the supporting document for the 'Notification for an administrative change of a national authorisation'. All assets where the change is sought shall be listed in the supporting document (see Section 10.1).

Where relevant:

- ECHA opinion regarding the classification of the pursued change;
- a decision on technical equivalence issued by ECHA;
- any other files you wish to support you application at this step.

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.

10.3. Minor changes to a national authorisation

Is a dossier required? If the original submission for the national authorisation was supported by a IUCLID file, an updated file should **always be submitted**. Where a change is sought for authorisations granted under the BPD, the submission of a IUCLID file is **optional**. However, given the nature of the information needed to specify and justify the change request, a IUCLID file would normally be **expected**. Consult the Evaluating Authority when needed.

10.3.1. Launching the application wizard for NA-MIC

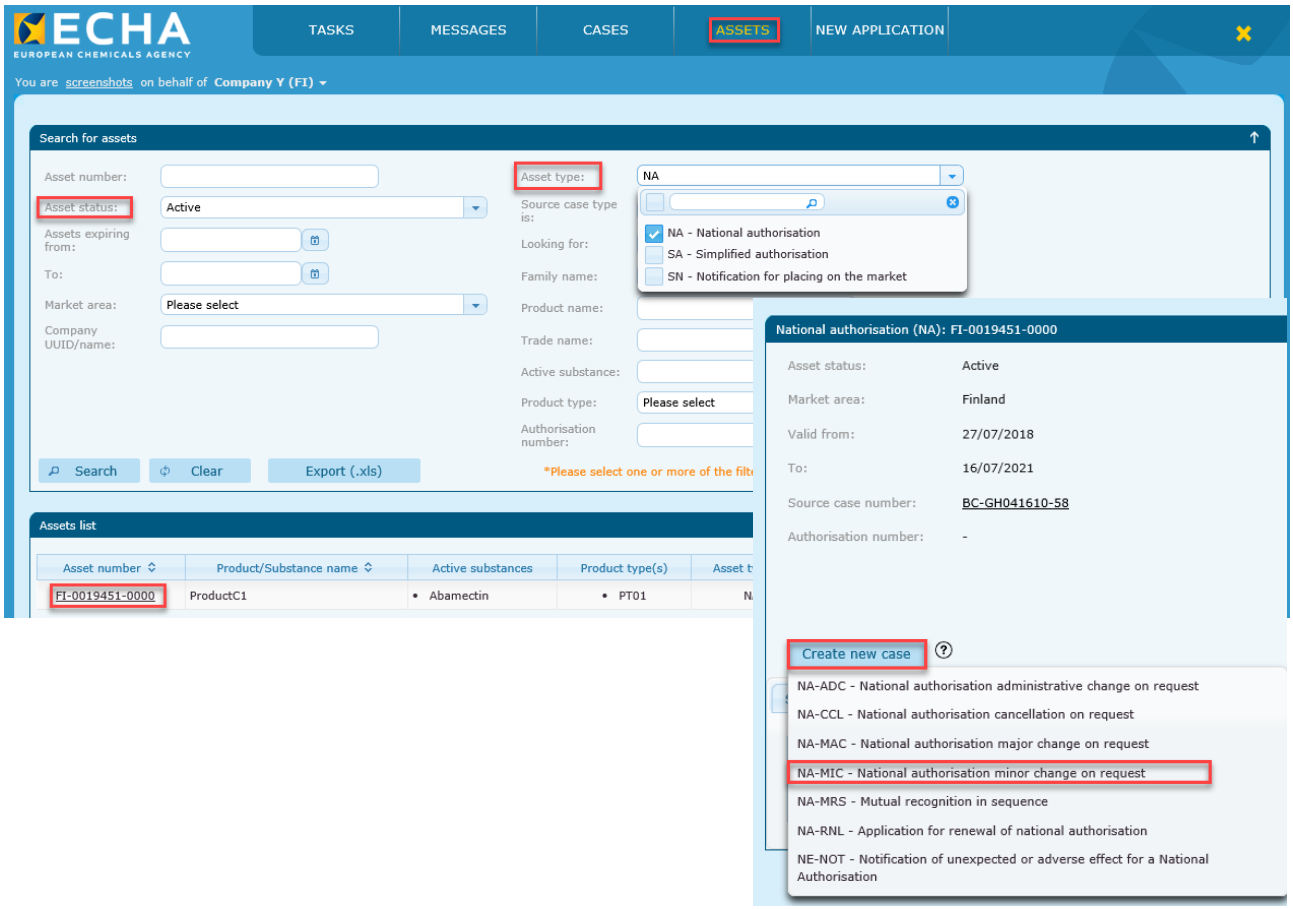
- **In the context of an existing asset**

You can launch the NA-MIC application wizard from the relevant existing asset (Figure 23) as previously described in section 3.2.

Where the changes are not sought in the Member State that evaluated the initial application for the authorisation of the biocidal product, a new reference Member State is required, i.e. the request for change should be launched from the asset derived from the Member State that has agreed and will act as the new evaluating authority.

If your asset is not visible in R4BP 3, please contact your national helpdesk or refer to the 'Migration' Q&A section on ECHA's website. If you are still unsure on how to proceed with your application, please contact the ECHA Helpdesk using the contact form.

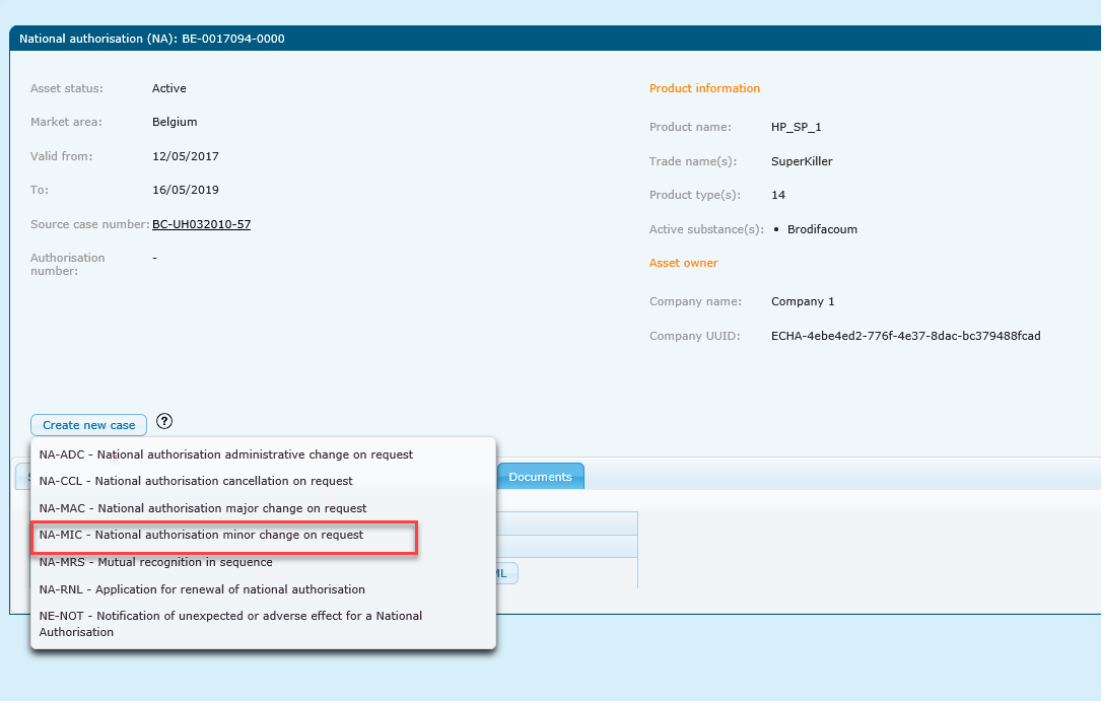
Figure 23: Launching the application wizard for NA-MIC



- **In the context of an 'in progress' case to include a case in an existing group**

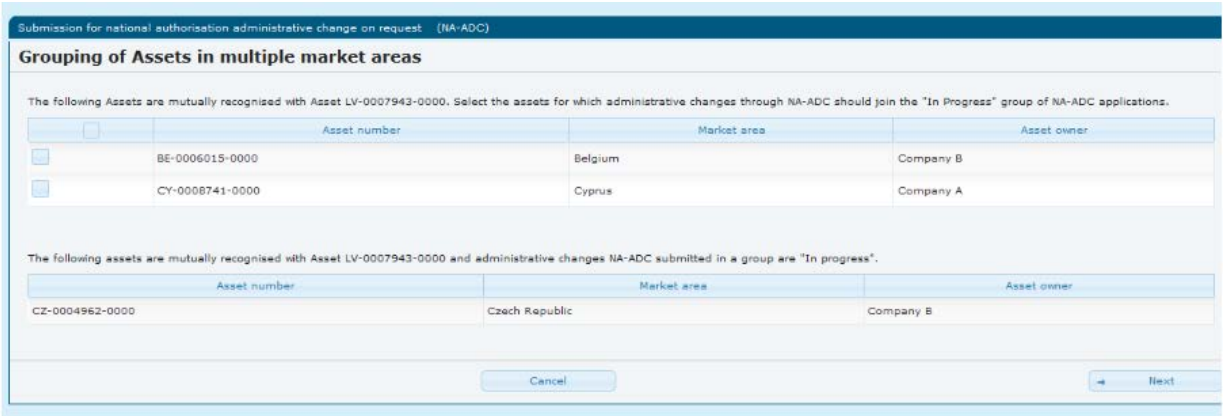
You can launch the NA-MIC application wizard from the relevant reference case in order to introduce a new NA-MIC case into an existing group (Figure 24).

Figure 24: Including a case in an existing group



Once you have click on "Create new case", you will then be able to select the assets to be included in the existing group submission, and launched the application wizard (Figure 25).

Figure 25: Selecting the asset(s) to be included in the existing group submission



10.3.2. Application requirements for NA-MIC

This sub-chapter describes the application requirements necessary for each step of the NA-MIC 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 NA-MIC

Grouping of assets in multiple market areas

If your reference asset has been mutually recognised in other Member States, and the changes are sought in more than one market area, you can submit an application to every concerned Member State, where relevant, by making a selection in the corresponding tick boxes.

Special cases: Not all assets affected by the change may be visible for grouping in this step. Refer to the special note concerning the ECHA supporting document for all applications affected by the change (section 7.1) as separate applications for these assets will need to be made.

Case owner details

A contact person for the case must be specified.

Set submission details

Indicate the payment details relevant for this case.

Upload dossier and select language

Where relevant, include in section 13 'Summary and evaluation' (*If not attached in the dossier, then must be uploaded in the 'upload other files' step of the wizard*).

- documents to demonstrate that the proposed changes would not adversely affect the conclusions previously reached, concerning the compliance with the conditions (Article 19 or 25 of the BPR).
- a decision on technical equivalence.
- the opinion issued by ECHA regarding the classification of the pursued change.

Upload SPC (.i6z)

Upload updated draft SPC(s) reflecting the changes sought for every concerned Member State. 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

If you did not upload a dossier, then include all your supporting documents, where relevant (see 'upload dossier' step) at this step.

In all applications: Upload the supporting document for the 'Application for a minor change of a national authorisation'. All assets where the change is sought shall be listed in the supporting document (see section 10.1).

Confirm application

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

10.4. Major changes to a national authorisation

Is a dossier required? If the original submission for the national authorisation was supported by a IUCLID file, an updated file should **always be submitted**. Where you are seeking a change for authorisations granted under the BPD, the submission of a IUCLID file is **optional**. However, given the nature of the information needed to specify and justify the change request, a IUCLID file would normally be **expected**. Consult the Evaluating Authority when needed.

10.4.1. Launching the application wizard for NA-MAC

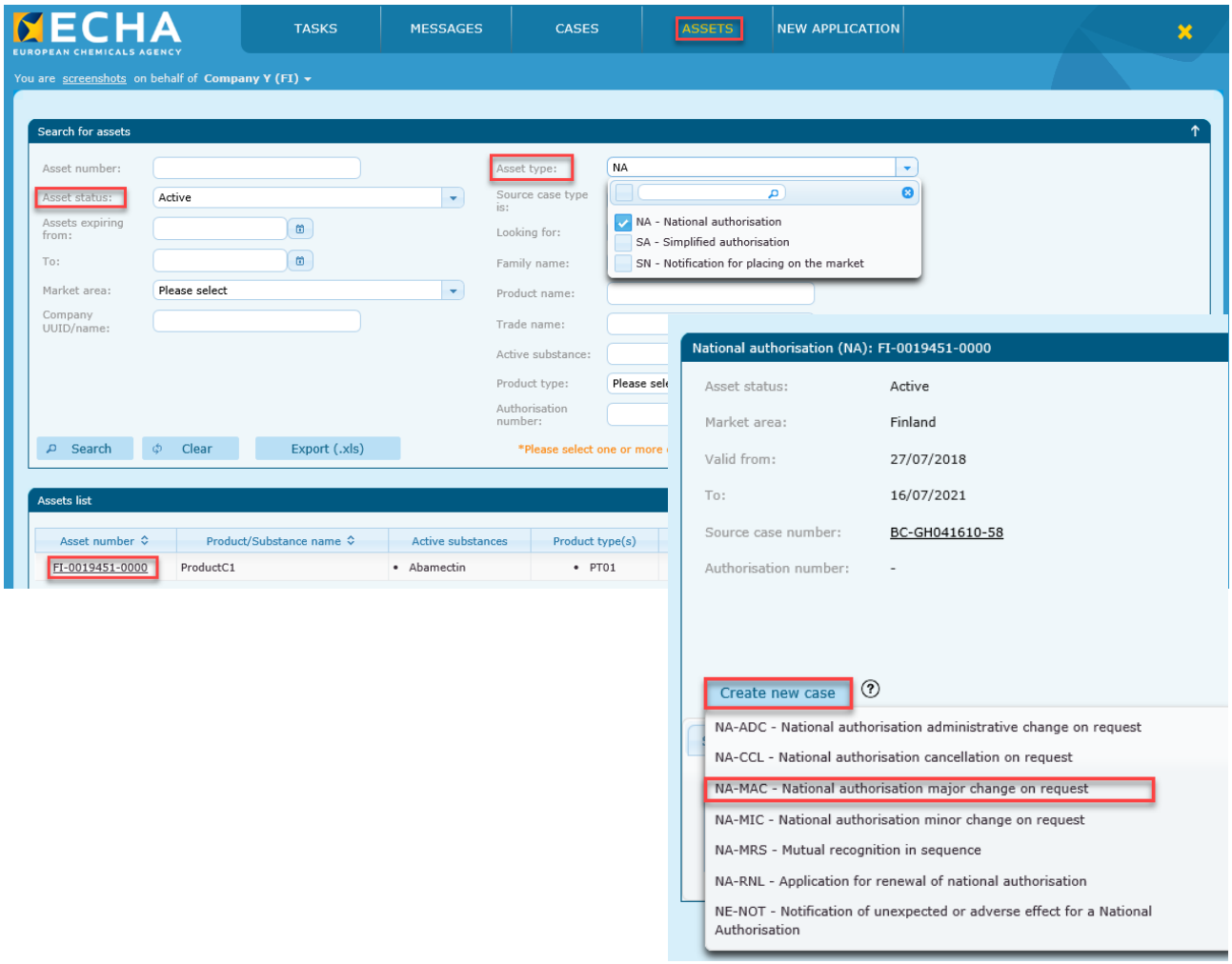
- **In the context of an existing asset**

You can launch the NA-MAC application wizard from the relevant existing NA asset (Figure 26) as previously described in section 3.2.

Where the changes are not sought in the Member State which evaluated the initial application for the authorisation of the biocidal product, a new reference Member State is required, i.e. the request for change should be launched from the asset derived from the Member State that will act as the new evaluating authority.

If your asset is not visible in R4BP 3, please contact your national helpdesk or refer to the 'Migration' Q&A section on ECHA's website. If you are still unsure on how to proceed with your application, please contact the ECHA Helpdesk using the contact form.

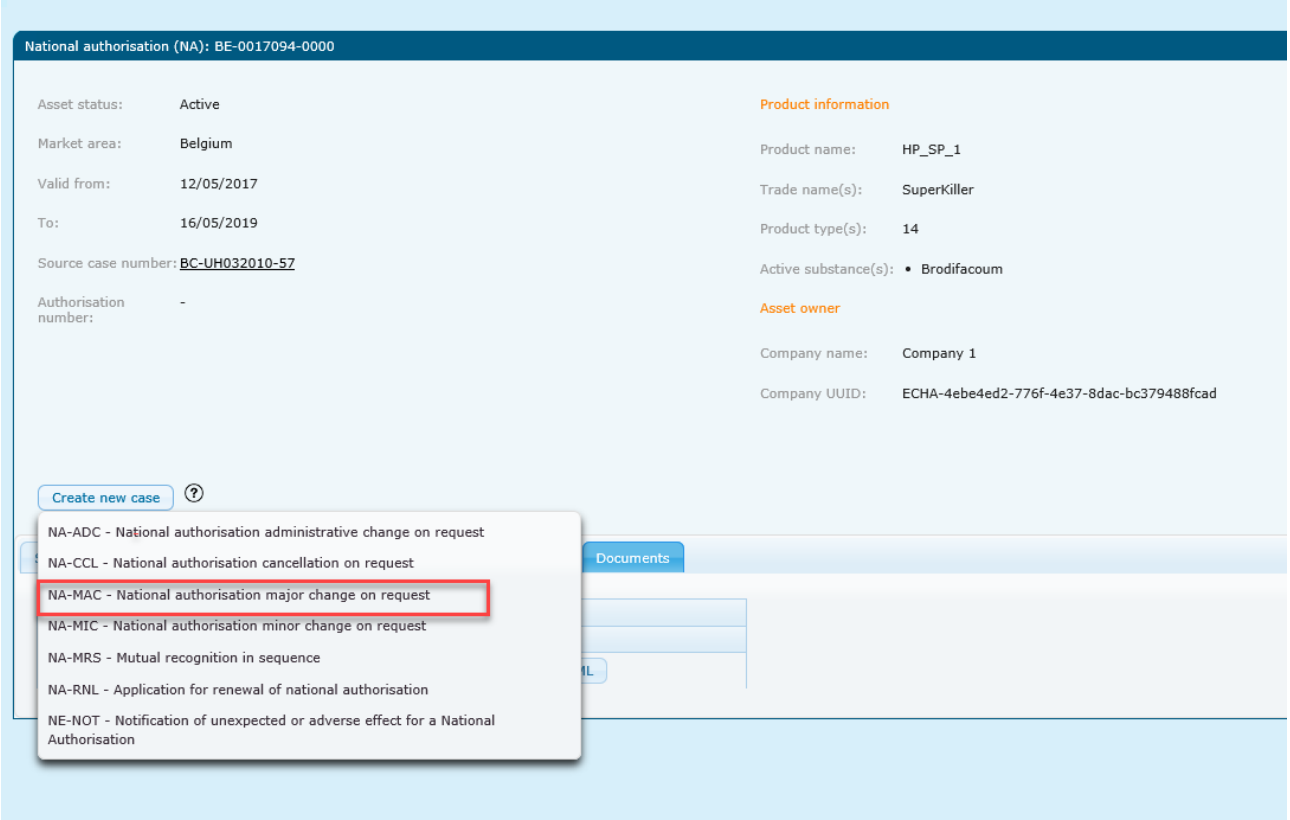
Figure 26: Launching the application wizard for NA-MAC



- **In the context of an 'in progress' case to include a case in an existing group**

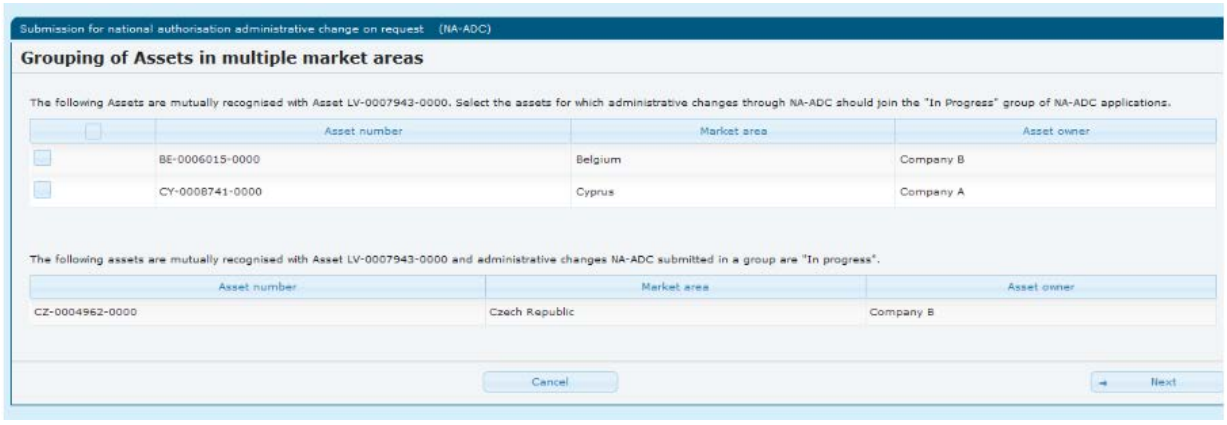
You can launch the NA-MAC application wizard from the relevant reference case in order to introduce a new NA-MAC case into an existing group (Figure 27).

Figure 27: Including a case in an existing group



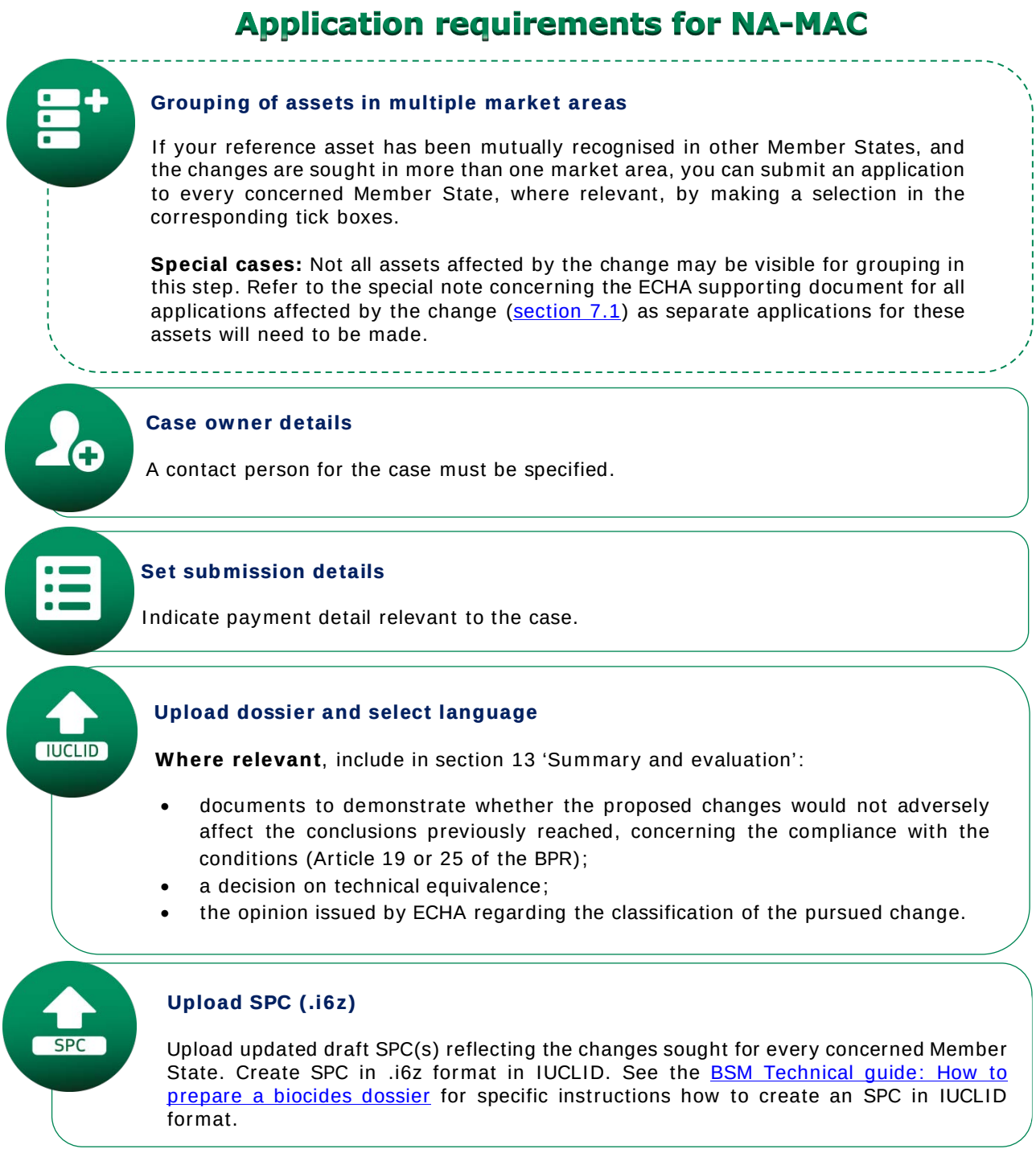
Once you have click on 'Create new case', you will then be able to select the assets to be included in the existing group submission, and launched the application wizard (Figure 28).

Figure 28: Selecting the asset(s) to be included in the submission



10.4.2. Application requirements for NA-MAC

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



Upload other files

If you did not upload a dossier, then include all your supporting documents, where relevant (see 'upload dossier' step) here. In addition, **In all cases:** Upload the supporting document for the 'Application for a major change of a national authorisation'. All assets where the change is sought shall be listed in the supporting document (see section 10.1).

Where relevant: written confirmation from the 'new reference Member State' agreeing to evaluate the application.

Confirm application

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

11. Merge of product authorisation(s) in a family (NA-MRG)

The transition between the BPD and the BPR requires **frame formulations** to be transformed into product families. Frame formulations have been migrated from R4BP 2 to R4BP 3 as 'single product' authorisation(s). To transform these single product authorisation(s) into a 'product family' in the system, you need to make an application in R4BP 3 to merge the authorisation(s) into a family using the migrated national authorisation asset(s).

Authorisation as a biocidal product family of a number of authorised products falling within a **frame formulation** is listed as an administrative change in the Changes Regulation[12] (Annex, title 1, section 1, item 6). However, this type of application must be made through the NA-MRG application wizard outlined in this chapter.

The principles and processes behind administrative changes are detailed in the Practical guide 'chapter on changes of biocidal products' on ECHA's website

In addition, an application for NA-MRG also needs to be made if you applied for product authorisation and the establishment of a frame formulation under the BPD but the decision was taken after 1 September 2013 and therefore formally granted for a product family. Such authorisations were also migrated from R4BP 2 to R4BP 3 as 'single product' authorisation(s) and, therefore, require a transformation into a product family.

If you applied for a product authorisation and the establishment of a frame formulation under the BPD and as a result an authorisation was **granted after 1 September 2013** for a product family, it is recommended that you contact the relevant MSCA prior to submitting your application for NA-MRG. See the CA Notes for Guidance on "Handling the transfer from frame formulations to biocidal product families" (CA-Sept13-Doc.6.2.c).

After a frame formulation has been successfully transformed into a product family through the NA-MRG application, the new product family asset will be visible in R4BP 3. If your NA-MRG application was launched from one single product asset, your product family will only contain one member asset. To have all the other members recognised in the product family asset, you will need to make a **notification of a product in a product family** (NA-NPF) application as detailed in chapter 16.2.

11.1. Launching the NA-MRG application wizard

You can launch the application 'NA-MRG –Merge of a product authorisation(s) in a family' from the 'NEW APPLICATION' tab on the R4BP 3 toolbar and add the relevant reference asset number (Figure 29). After you can select additional market areas by selecting the needed National authorisation assets (Figure 30).

[12] 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 29: Launching the application 'wizard' for NA-MRG – step 1

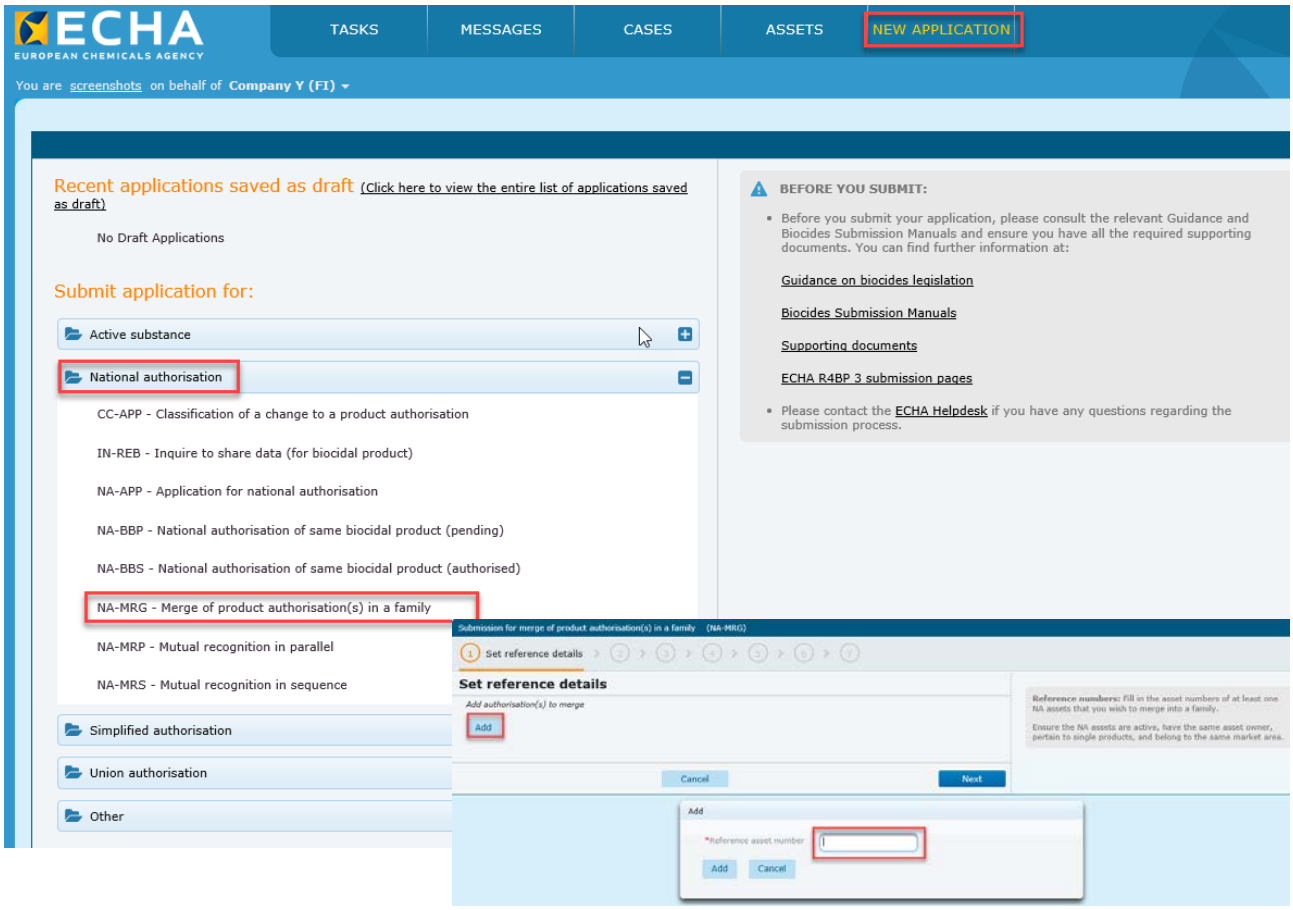
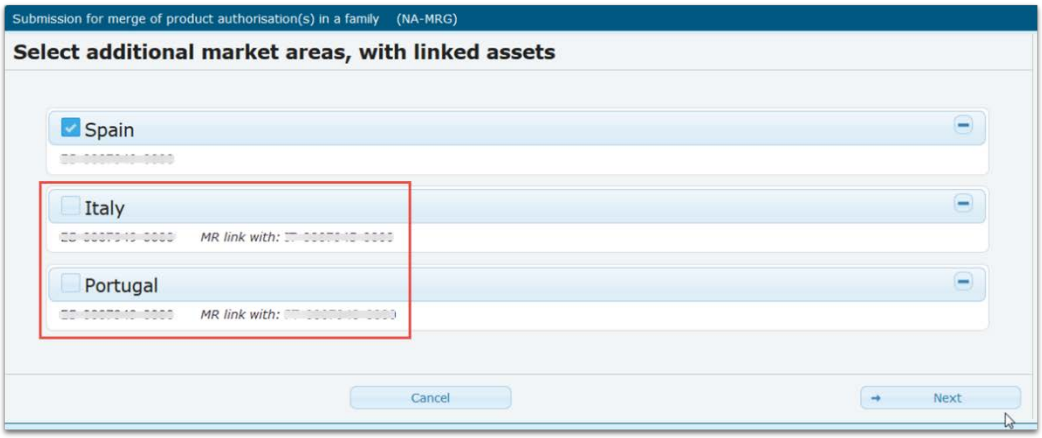


Figure 30: Launching the application 'wizard' for NA-MRG – step 2



11.2. Application requirements for each NA-MRG wizard step

This sub-chapter describes the application requirements necessary for each step of the NA-MRG 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 NA-MRG

Set reference details

A valid reference number is required to launch this application. Please provide at least one reference asset number referring to a single product that you wish to merge into a family.

Case owner details

A contact person for the case must be specified.

Set submission details

Indicate the evaluating and concerned (if applicable) authority and the payment details relevant to this case. Note that the evaluating authorities are as many as the different market areas selected to apply for MRG submissions.

Upload SPC (.i6z)

Please provide the family SPC file(s) for the new family and optionally, the updated single SPC file(s) of the single national authorisation asset(s) to be merged. Note that only family SPCs can be submitted for every market area that have been selected.

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.

12. Transferring a national authorisation (NA-TRS)

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

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

The possibility to transfer an authorisation to a new holder is listed as an administrative change in the Changes Regulation[13] (Annex, title 1, Section 1, item 3). However, this type of application must be made through the procedure outlined in this chapter.

An owner of an 'NA' type asset must first initiate a transfer process in R4BP 3 before any application procedure can begin. The procedure of initiating an asset transfer is detailed in the BSM Technical guide: using R4BP 3. Once the asset transfer has been initiated by the original asset owner, the asset will be visible in the 'Asset list' of the new or intended asset owner who can then choose to 'accept' the transfer and follow the wizard steps for the application in R4BP 3.

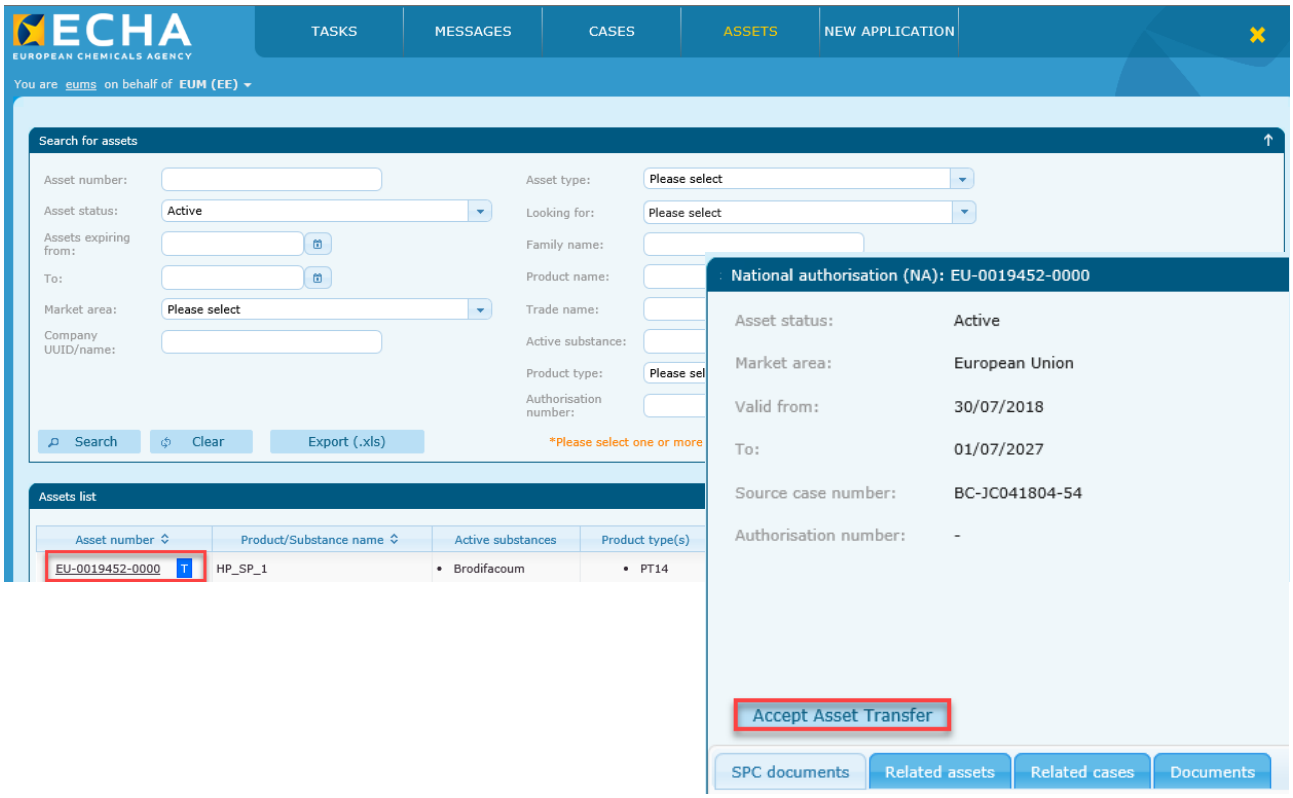
An asset can only be owned by one legal entity at any given time, therefore, once it has been transferred, the previous owner (authorisation holder) forfeits all rights in relation to its ownership.

12.1. Launching the NA-TRS application wizard

To launch the application wizard for a NA-TRS through an existing asset, you as the proposed new asset owner should click on the 'ASSETS' tab on the R4BP 3 toolbar. If not immediately visible in your 'Assets list', search for the specific asset by the relevant asset type 'NA – National authorisation'. Locate the specific asset labelled with T (for a 'transfer') and click on the asset number hyperlink to open a details page for that specific asset. Clicking on 'Accept Asset Transfer' will launch the NA-TRS wizard (Figure 31).

[13] 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 31: Launching the application 'wizard' for NA-TRS



12.2. Application requirements for each NA-TRS wizard step

This sub-chapter describes the application requirements necessary for each step of the NA-TRS 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 NA-TRS

Case owner details

A contact person for the case must be specified.

Set submission details

Indicate any payment details if relevant to the case.

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.

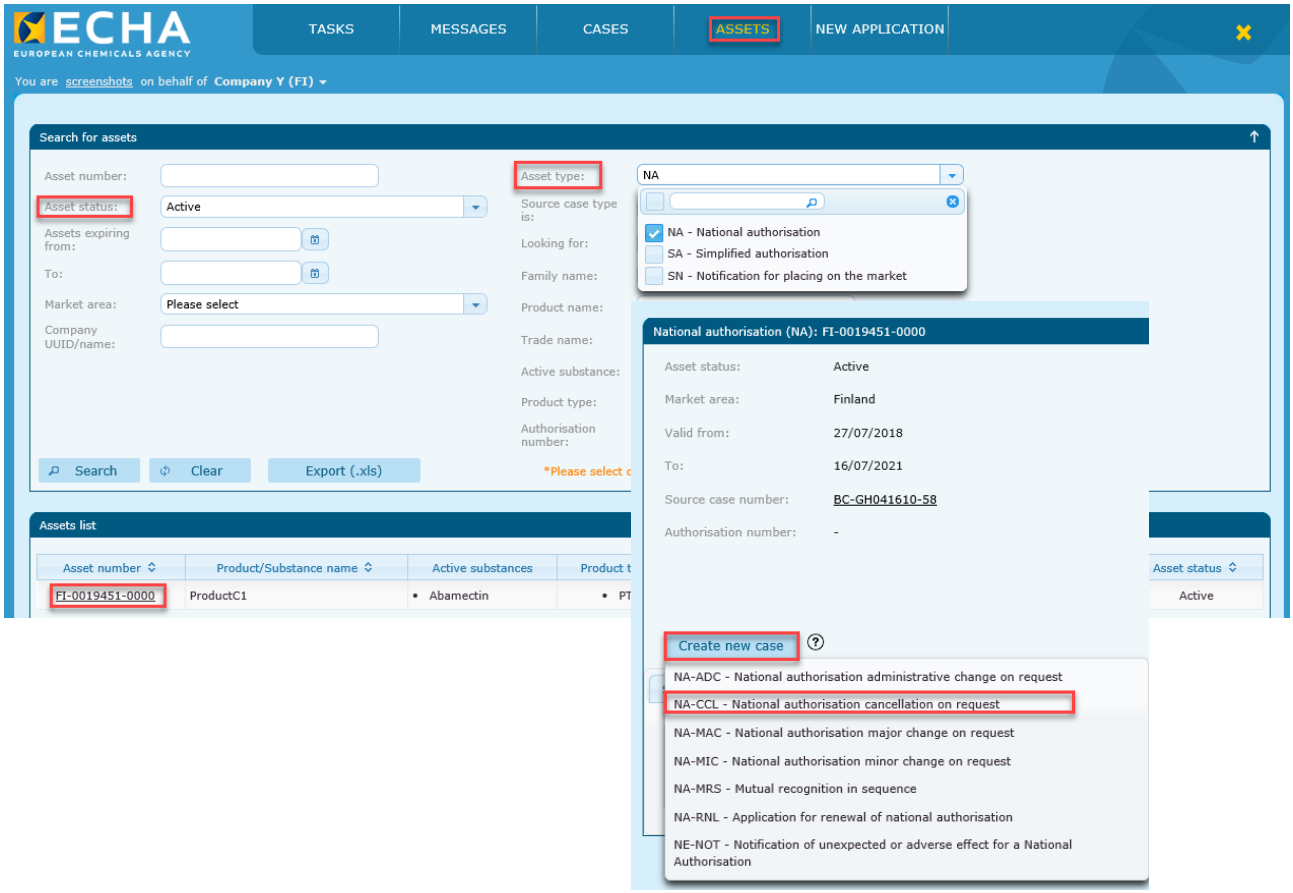
13. National authorisation cancellation on request (NA-CCL)

Any applicant can submit a National authorisation cancellation on request in order to cancel the National authorisation active asset. The application of National authorisation cancellation on request will be valid for Single and Family assets including Family member assets.

13.1. Launching the NA-CCL application wizard

Launch the NA-CCL application wizard by clicking first the 'ASSETS' tab on the R4BP 3 toolbar. Search for the specific asset number by filling in some search criterion, e.g. the asset type (Figure 32). 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 'NA-CCL – National authorisation cancellation on request' (Figure 32). It is important to note that when creating a member cancellation you have to start by selecting first the member asset.

Figure 32: Launching the application 'wizard' for NA-CCL



13.2. Application requirements for NA-CCL

This sub-chapter describes the application requirements necessary for each step of the NA-CCL 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 NA-CCL

Case owner details

A contact person for the case must be specified.

Set submission details

Indicate any payment details if relevant to the case.

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. Classification of a change to a product authorisation (CC-APP)

If a proposed change to a national authorisation is not listed in one of the Titles of the Annex to the Changes Regulation, the authorisation holder (asset owner) or an appointed representative may request an opinion from ECHA on the classification of the proposed changes, in accordance with the criteria laid down in the Annex to the Changes Regulation.

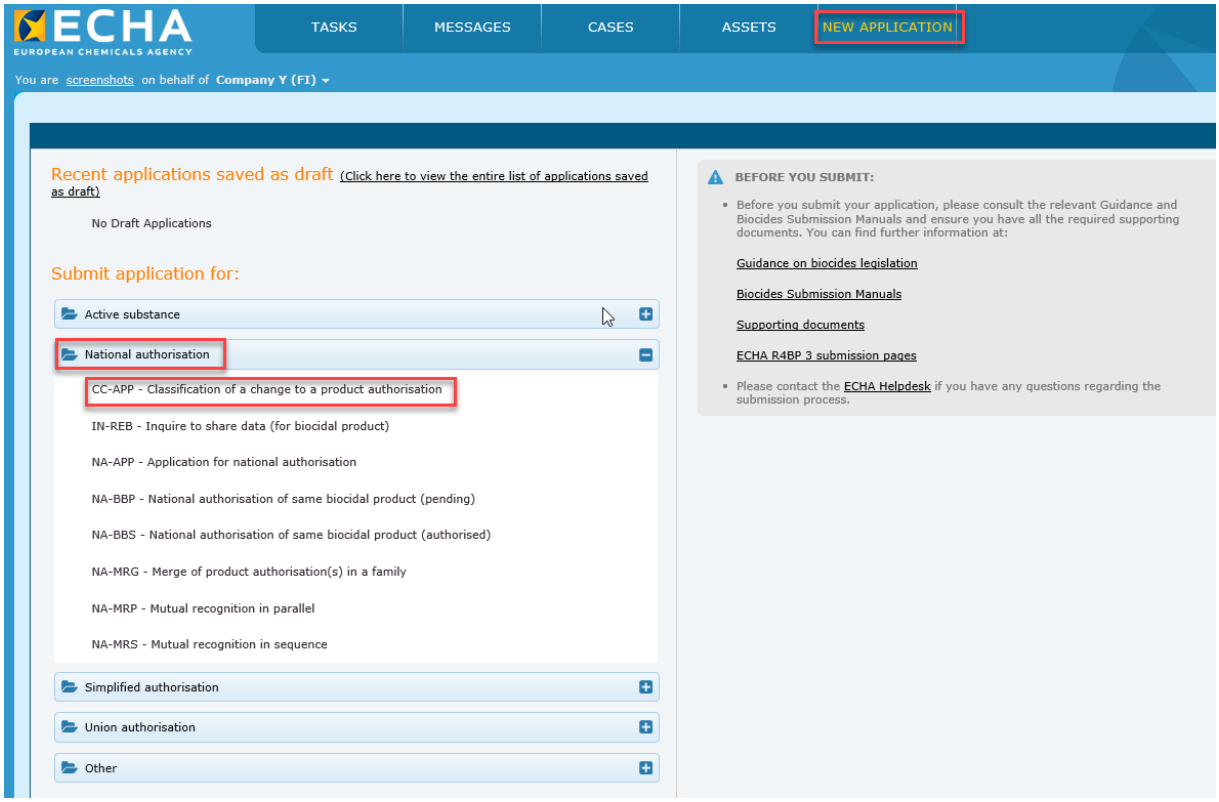
ECHA's opinion on the classification of the change sought will be published on ECHA's website.

The principles and processes behind the classification of a change to a product authorisation is described in the Practical Guide 'chapter on changes of biocidal products' available from ECHA's website.

14.1. Launching the CC-APP application wizard

You can launch the application 'CC-APP –classification of a change to a product authorisation' from the 'NEW APPLICATION' tab on the R4BP 3 (Figure 33).

Figure 33: Launching the application 'wizard' for CC-APP



14.2. Application requirements for CC-APP

This sub-chapter describes the application requirements necessary for each step of the CC-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 CC-APP

Case owner details

A contact person for the case must be specified.

Set submission details

Enter the details of the 'asset owner' and indicate the payment details relevant to the case.

Upload other files

In all applications: upload the ECHA 'Supporting document for the request to ECHA to provide an opinion on the classification of a change of a product'.

Where relevant, upload:

- an updated draft SPC (**word format**) reflecting the changes sought if it is considered that the information therein will support ECHA's assessment.
- any other document considered relevant by the applicant for ECHA's opinion.

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.

15. Inquiry to share data for a biocidal product (IN-REB)

Any person intending to gather data through animal testing or tests on vertebrates needs to submit a written request to ECHA to determine whether such tests or studies have already been submitted. Such requests can also be made for data not involving tests on vertebrates.

The principles and processes behind inquiring to share data is described in the Practical Guide 'chapter on data sharing' available from ECHA's website.

According to Article 62 of the BPR, an inquiry to share data is **obligatory** before performing any tests or studies involving vertebrates.

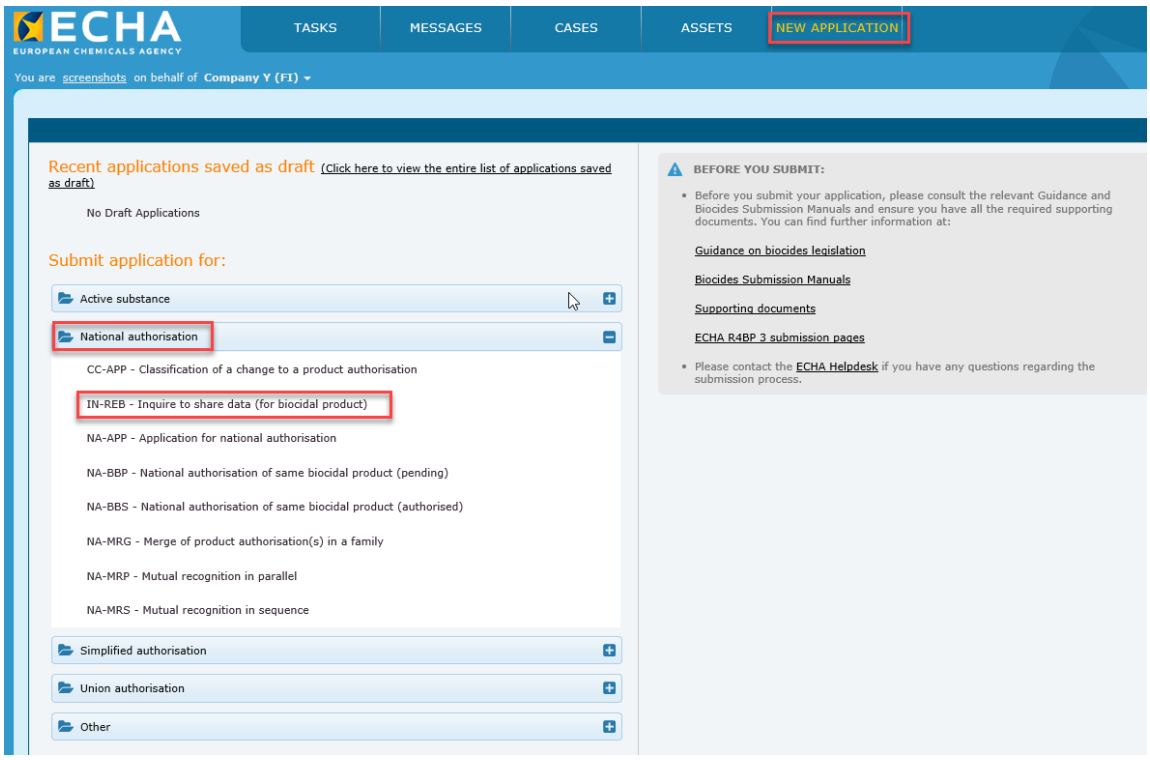
15.1. Launching the IN-REB application wizard

You can launch the application 'IN-REB – Inquiry to share data for a biocidal product' from the 'NEW APPLICATION' tab on the R4BP 3, then, enter the relevant 'reference number', i.e. the asset number of the product number you wish to inquire about (Figure 34).

R4BP 3 asset numbers and other identifiers are made publicly available on ECHA's website under the 'Information on chemicals' tab from the main toolbar.

If the relevant R4BP 3 asset number is not available, please refer to the 'Migration' Q&A section on ECHA's website or contact the National helpdesk for further advice on how to proceed with your application.

Figure 34: Launching the application 'wizard' for IN-REB



15.2. Application requirements for IN-REB

This sub-chapter describes the application requirements necessary for each step of the IN-REB 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 IN-REB

Context asset

Enter the reference asset number of the product you would like to inquire about.

Case owner details

A contact person for the case must be specified.

Set submission details

Enter the details of the 'asset owner'.

Upload other files

No files are necessary for this application.

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.

16. Notifications and permits

Each of the following sub-chapters describes the application instructions necessary for each step of the application wizard in R4BP 3 for the following application types:

- Notification of an experiment or test
- Notification of a product in a product family
- Notification of unexpected or adverse effects
- Parallel trade permit

Any person carrying out experiments or tests on either an **unauthorised biocidal product**, or, a **non-approved active substance** intended exclusively for use in a biocidal product, must maintain written records and compile a dossier that must be made available to the MSCA when appropriate.

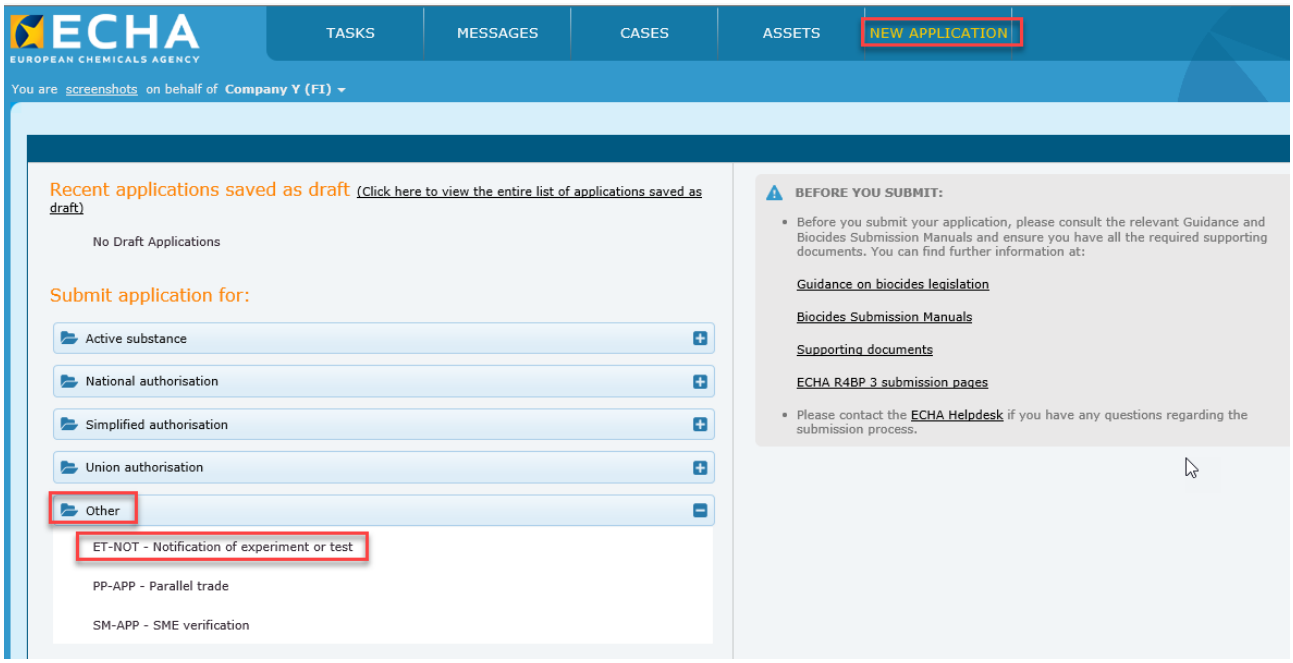
The principles and processes behind the notification concerning an experiment or test (to the MSCA) are available in the Practical Guide '[chapter on research and development]' on the ECHA website.

16.1. Notification of an experiment or test

16.1.1. Launching the ET-NOT application wizard

You can launch the application 'ET-NOT – Notification of experiment or test' from the 'NEW APPLICATION' tab on the R4BP 3 (Figure 35).

Figure 35: Launching the application wizard for ET-NOT



16.1.2. Application requirements for ET-NOT

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

All dossiers must contain two datasets (a 'Substance' dataset and a 'Mixture/Product' dataset) even if there is no relevant biocidal product. Before you start your application, please refer to the BSM 'Technical guide: How to prepare a biocides dossier'.

Application requirements for ET-NOT

Case owner details

A contact person for the case must be specified.

Set submission details

The 'evaluating authority', must be specified as well as the details of the company conducting test or experiment.

Upload dossier

The dossier must fulfil all of the information requirements laid out in Article 56 of the BPR.

- the identity of the biocidal product and/or active substance;
- labelling data;
- quantities supplied;
- all available data on possible effects on human or animal health, or impact on the environment.

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.

16.2. Notification of a product in a product family

Where a national authorisation for a biocidal product family has been granted, a notification can be made to place each biocidal product within that biocidal product family on the market of that market area.

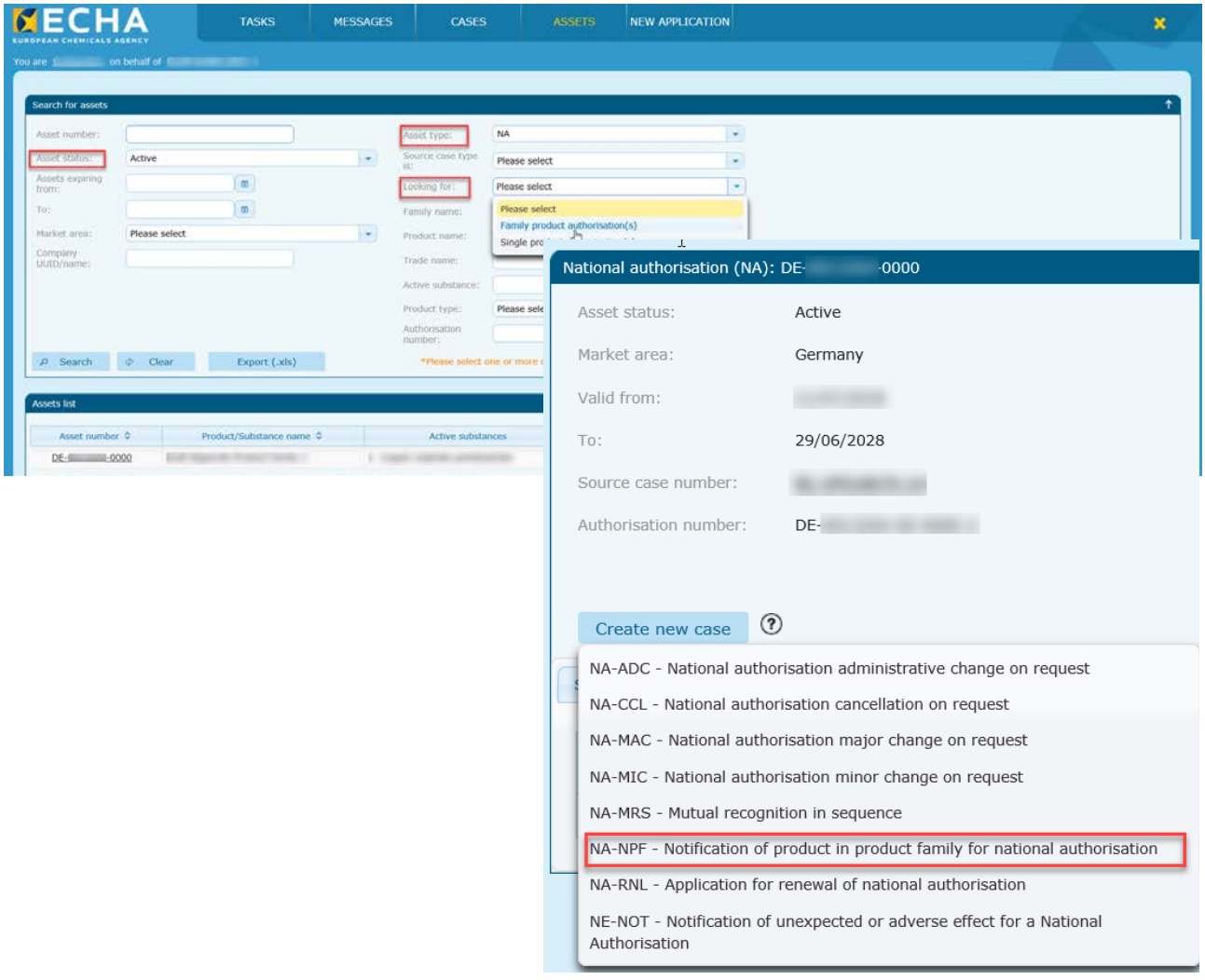
The principles and processes behind the notification of a product in a product family is described in the Practical Guide 'chapter on national authorisation' available from ECHA's website.

If your application relates to a **frame formulation** which was established under the Biocidal Products Directive 98/8/EC, then the relevant product authorisation must first be converted into a biocidal product family authorisation before you can apply for any other application. Refer to Chapter 11 'Merge of a product authorisation(s) in a family' for more details.

16.2.1. Launching the NA-NPF application wizard

Launch the 'NA-NPF Notification of product in product family' application wizard from the relevant existing NA (**family**) asset (Figure 36) as previously described in section 3.2.

Figure 36: Launching the application wizard for NA-NPF



Only the NA **family asset** (the product-family authorisation), and not a **member asset** (granted where a new product within the family is successfully notified), will allow you to launch the application wizard for NA-NPF. All member assets are connected to the family asset, which are detailed in the 'Family info' sub-tab on the details page of the individual asset.

16.2.2. Application requirements for NA-NPF

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

Viable NA type asset(s) must be 'Active' with no ongoing related applications, i.e. the system does not allow an NA-NPF application if there is another application being processed for the same asset at the same.

Application requirements for NA-NPF

Case owner details

Contact person for the case must be specified.

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. SPC must be created from the final authorised family SPC.

Only one draft SPC can be uploaded including both already authorised family members and new family member(s) to be assessed as part of your NA-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 ECHA ‘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.

16.3. Notification of unexpected or adverse effects

Applications to notify any new unexpected or adverse effects of your biocidal product (or the active substances within it) that may affect the authorisation, must be submitted through the NE-NOT application wizard in R4BP 3 without delay.

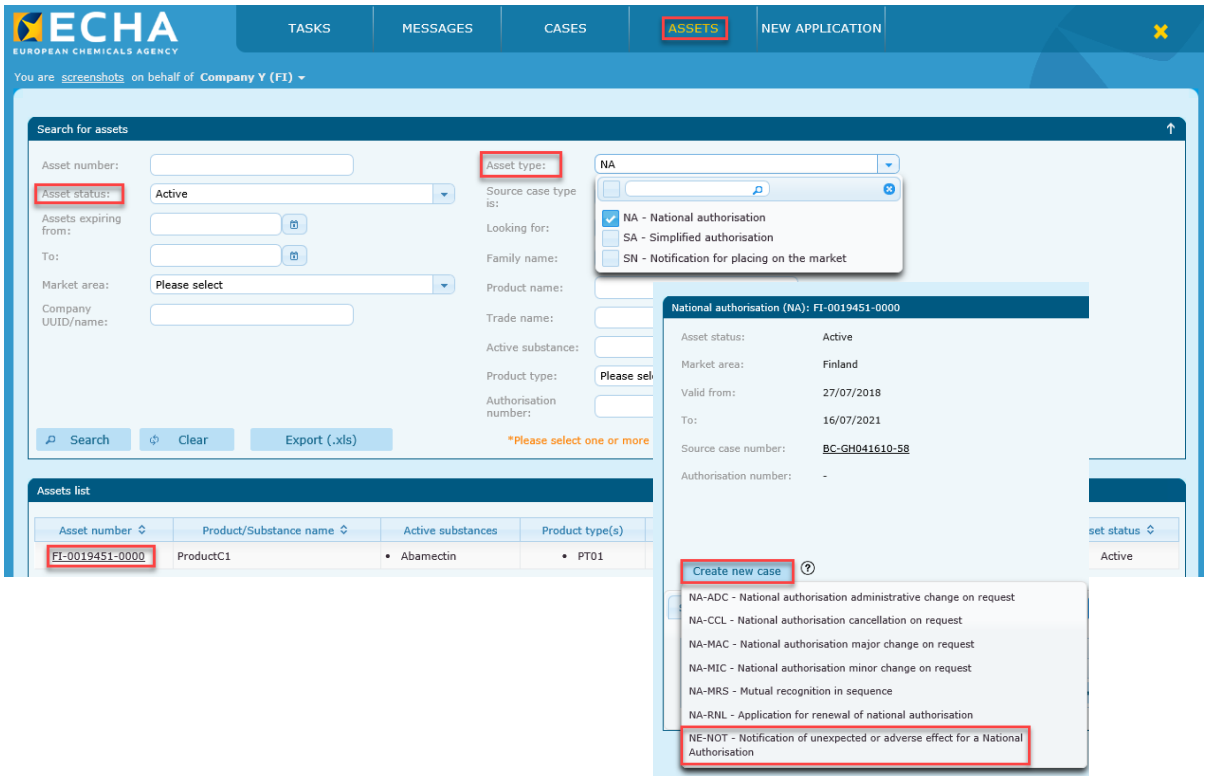
The principles and processes behind the notification of unexpected or adverse effects will are available in the Practical Guide 'chapter on national authorisation' on the ECHA website.

For full details, Article 47 of the BPR specifies the notification requirements that shall be submitted without due delay to the competent authority that granted the authorisation.

16.3.1. Launching the application wizard for NE-NOT

You can launch the 'NE-NOT Notification of unexpected or adverse effects' application wizard from the relevant existing NA asset (Figure 37) as previously described in section 3.2.

Figure 37: Launching the application wizard for NE-NOT



16.3.2. Application requirements for NE-NOT

This sub-chapter describes the application requirements necessary for each step of the NE-NOT 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 NE-NOT

Case owner details

A contact person for the case must be specified.

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 and/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.

16.4. Parallel trade permit

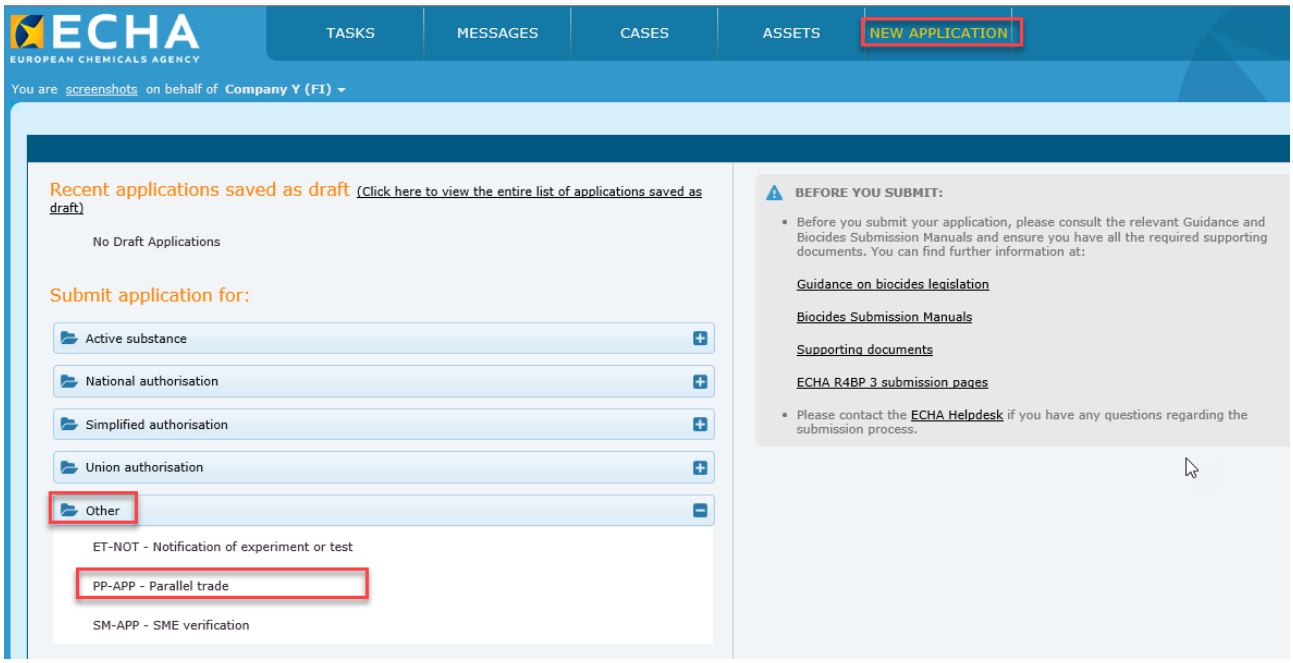
An application for a parallel trade permit can be made for a biocidal product that is authorised in the Member State of origin (MSO) and to be made available and used on the market of the Member State of introduction (MSI).

The principles and processes for obtaining a parallel trade permit are described in the Practical Guide 'chapter on national authorisation' available from ECHA's website.

16.4.1. Launching the application wizard for PP-APP

You can launch the application 'PP-APP –Parallel trade' from the 'NEW APPLICATION' tab on the R4BP 3 toolbar (Figure 38).

Figure 38: Launching the application wizard for PP-APP



16.4.2. Application requirements for PP-APP

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

You may wish to consult the MSCA helpdesk of the MSI to clarify the supporting documents they need **and** to check if it is necessary to submit a sample of the biocidal product directly to the MSI.

Application requirements for PP-APP

Set reference details

The asset numbers of the biocidal products in the

- Member State of origin, and
- Member State of introduction

are required to launch this application.

Case owner details

A contact person for the case must be specified.

Set submission details

Enter the details of the 'asset owner' and indicate the payment details relevant to the case.

Upload other files

Where necessary:

- Draft label for the biocidal product in the official language or languages of the Member State of introduction.
- The original label and instructions of use with which the biocidal product is distributed in the Member State of origin.

Please consult the MSCA helpdesk of the MSI to clarify the supporting documents they require **and** to check if it is necessary to submit a sample of the biocidal product.

Please upload any other relevant 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.

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