ECHA
EUROPEAN CHEMICALS AGENCY

Biocides Submission Manual

How to submit an application for an Active Substance

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. Main changes include an improved general layout and design, extra summary sheets added 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. New application types 'amendment of Annex I to the BPR' and 'renewal of AS' have been introduced (section 3.1)	April 2014
Version 2.1	Changes to Chapter 4 have been made for AS-ACC applications resulting from amendments to Article 95 of the BPR.	April 2014
Version 2.2	Manual updated to reflect the changes in R4BP 3.1.2, namely, the removal of the 'access level' selection in the application wizard and relevant screenshots.	June 2014
Version 2.3	Manual updated to clarify application requirements for AS-ACC applications. Specifically, dossier submission is optional when a letter of access to a complete dossier is available.	September 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 active substances - in line with the new BSM series. New application wizards: Renewal of an active substance Inclusion of an active substance in Annex I Clarification of the evaluation due date for AS-ACC applications has been made in Chapter 6.	December 2014
Version 3.1	Minor typos corrected and textual changes to improve clarity.	February 2015

Version	Changes	Date
Version 4.0	Release of R4BP version 3.3. Minor update includes the following: Reference to submissions for consortia included in section 6.1.	June 2015
Version 4.1	'Basic IUCLID requirements' table updated to include the substance dataset requirements for AS-APP and AS-RNL applications.	July 2015
Version 4.2	Following new chapters added: 8. Declaration of interest to notify 9. Review Programme notification 10. Active substance evaluation under Regulation (EU) No 1062/2014 (Participant) 11. Change participants by mutual agreement Annex I and Annex II updated. References to IUCLID 5 removed and minor updates included.	July 2016
Version 4.3	Updates in chapter 3.	August 2016
Version 4.4	Removing and modifying the sub-chapters of 3.1. The following chapter added: 4. Approval of an active substance in an additional product type.	October 2016
Version 4.5	New following chapter added: 7. Amendment of active substance in Annex I Other minor updates included.	June 2017

Version	Changes	Date
Version 4.6	The following chapter updated: 2.2 Application types and ECHA fees The following chapter modified to include instructions for the approval of an active substance in an additional product type: 3. Approval of AS and related applications. Following chapter removed: 4. Approval of an active substance in an additional product type. New following chapters added: 5. Scientific data update of active substance 8. Scientific data update of active substance in Annex I. New following sub-chapter added: 14.1.1 Launching the application wizard for PA-CHG via AS-EVA case type. Other minor updates included.	November 2017
Version 4.7	Manual updated to include important information on applications for active substance evaluation under Regulation (EU) No 1062/2014 (Participant) (AS-EVA) and applications for active substance approval (AS-APP). Additional information included in chapter 17.2. Any mention of AS-NPT has been removed. The following chapter titles have been updated to reflect the renaming of the wizards in R4BP 3: 4,7,10,13. New chapters added: 4. Withdrawing a case from R4BP 3 12. Inclusion on the list of active substance suppliers (Article 95) cancellation on request. 17. 1. Nomination of an RP asset for the purpose of making a PA-CHG.	October 2018
Version 4.8	Updates in chapter 11: Clarifications of the requirements for Article 95 applications based on a reference to a complete substance dossier for which all data protection periods have expired.	March 2019
Version 4.9	New chapter added: 13. Transfer of Article 95 asset (access to active substance dossier).	July 2019

Version	Changes	Date
Version 5.0	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. New chapter added: 12. Inclusion on the list of active substance suppliers (Article 95) administrative change on request.	February 2020
Version 5.1	Update of chapter 11.2 Application requirements for AS-ACC. New chapter added: 13. Scientific data update of inclusion in Article 95 (active substance suppliers) list.	June 2020
Version 5.2	New chapter added: 14. Scientific data renewal of inclusion in Article 95	March 2021
Version 5.3	Updated chapters 5.4.2., 7.2., 8.2., 20.2. in application requirement sections	December 2021
Version 5.4	Updated chapter 11.2 in application requirement section	July 2022
Version 5.5	Release of R4BP 3.26. Changes include following: SPC editor discontinued, instead SPCs should be prepared in IUCLID format with specific working context.	February 2024

BSM: How to submit an application for an active substance

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1. Introduction

1.1. Objective

This manual gives instructions on how to submit applications concerning the approval of active substances (AS) and related applications through the Register for Biocidal Products (R4BP 3) according to the Biocidal Products Regulation[1] (BPR).

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 an 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 on ECHA's website.

Additional assistance:

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

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

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

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

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

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

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2. General information

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

2.1. Application types and ECHA fees

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

Note that if the active substance manufacturer has been recognised as having small or medium-sized enterprise (SME) status, then there may be a reduced ECHA fee (unless the active substance is considered to be candidate for substitution) for the following applications:

- AS-APP (Approval of an active substance)
- AS-EVA (Active substance evaluation under Regulation (EU) No 1062/2014 (Participant))
- AS-RNL (Renewal of the approval of an active substance)
- AN-APP (Inclusion of an active substance in Annex I)

In the following scenarios, additional fees will apply to your application:

- If the active substance is candidate for substitution (does not apply to AN-APP);
- If a full evaluation was found to be necessary (only for AS-RNL).

Note that in above scenarios applications that benefitted of the reduced ECHA fee will have to pay the difference up to the standard fee.

For more information concerning SME fee reductions under the BPR and how to apply to have your SME status recognised, refer to the dedicated page on the ECHA website for full details.

ECHA informs the case owner of the fees payable for each application 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 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: Active substance applications

Case abbreviation	Application
AS-APP	Approval of an active substance **€**
AS-APP* *(AS-CHG)*	Amendment to the conditions of an approved active substance **€**
AS-UPD	Scientific data update of active substance
AS-RNL	Renewal of the approval of an active substance **€**
AN-APP	Inclusion of an AS in Annex I **€**
AN-UPD	Scientific data update of active substance in Annex I
AN-CHG	Amendment of active substance in Annex I **€**
AS-ACC	Inclusion on the list of active substance suppliers (Article 95) **€**
AA-ADC	Inclusion on the list of active substance suppliers (Article 95) administrative change on request
AA-CCL	Submission for Inclusion on the list of active substance suppliers (Article 95) cancellation on request
AA-TRS	Transfer of Article 95 asset (access to active substance dossier)
AA-UPD	Scientific data update of inclusion in Article 95 (active substance suppliers) list
AA-RNL	Scientific data renewal of inclusion in Article 95 (active substance suppliers) list
IN-REA	Inquiry to share data for an active substance
DI-SUB	Declaration of interest to notify
RP-NOT	Review Programme notification **€**

AS-EVA	Active substance evaluation under Regulation (EU) No 1062/2014 (Participant) **€**
PA-CHG	Change participants by mutual agreement

* These applications types are submitted through the same application 'wizard', i.e. AS-APP. *(Individual wizards for these application types will be made available in the future).*

2.2. Application requirements

Depending on the application type, and your individual circumstances, you may need to include a IUCLID dossier 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.

IMPORTANT NOTE: From the date on which an active substance is approved, certain information will be made publically available on ECHA's website under the 'Information on Chemicals' tab under Biocidal Active Substances.

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 may be required as part of your application. When a dossier is required, you should upload it in R4BP 3 as prompted by the application wizard.

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

2.2.2. 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'. The following file types are supported: doc/docx/pdf/xls/xlsx/ppt/txt; maximum file size is 3GB. 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 requires additional supporting documents to enable the correct handling and processing of your application. Consult the relevant chapter for your application for specific details or visit the Supporting documents page from ECHA's website for the full list.

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

3. Applying in R4BP 3

This chapter gives a general overview on how applicants can launch the submission wizard in R4BP 3 and follow up on their applications.

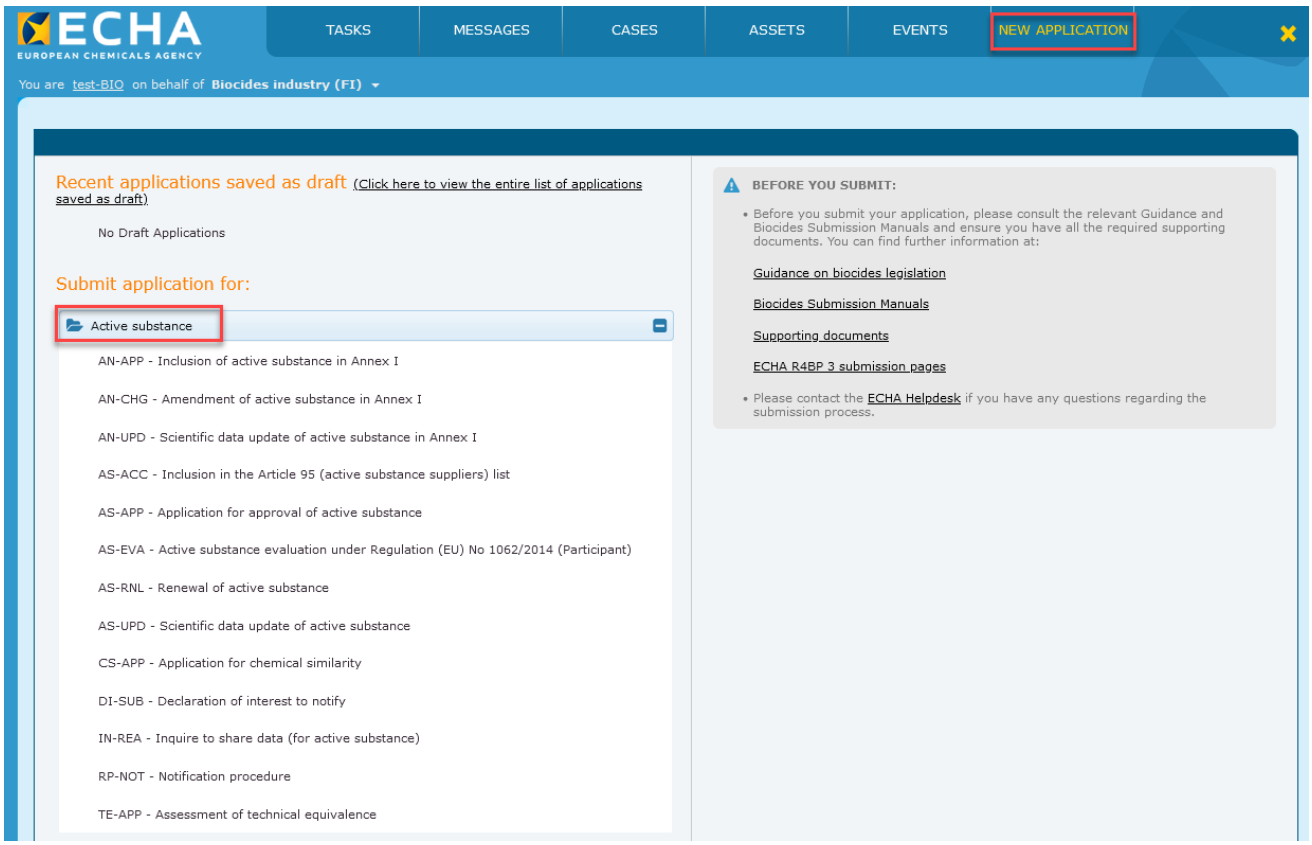
3.1. Submitting an application in R4BP 3

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

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

Technical guidance on using R4BP 3 can be found in 'BSM Technical guide: How to use R4BP 3'.

Figure 1: Launch an active substance application



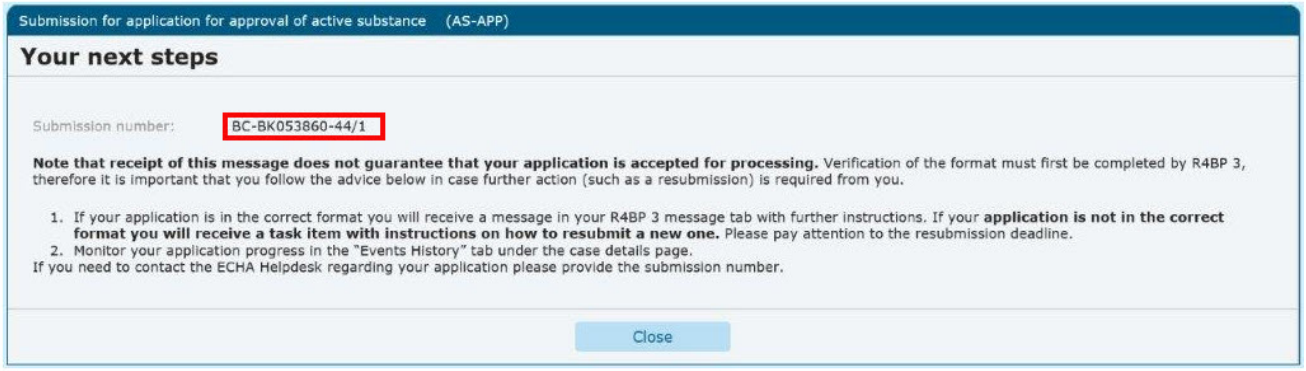
3.2. Post submission obligations

As a case owner and/or asset owner, you are required to monitor your case(s) and take the necessary actions.

3.2.1. Check your submission and note the submission number

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

Figure 2: Where to look for the submission number



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.

3.2.2. Monitor your case (as case owner role)

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. The chapter 5.2.2 of the BSM Technical guide: How to use R4BP 3 describes more specifically the case details page. In addition, email alerts can also be set to inform you of the case status – this is particularly helpful if you need to react to authority requests where a deadline has been set.

More detailed information on how to monitor your case can be found in 'BSM Technical guide: How to use R4BP 3'.

3.2.3. Resubmission tasks (as case owner role)

To ensure an application can be processed correctly, you, as a case owner may be required to complete task items assigned by authority users e.g.; 'Resubmit information' task.

You are obliged to monitor your task items and complete them **within the defined time period**. You can access the task items by selecting the 'TASKS' tab on the toolbar (Please refer to BSM Technical guide: How to use R4BP 3 for full details).

Note that only **one** reply to a 'request information' task is permitted in R4BP 3. Please ensure you include all the information requested in the task item.

4. Withdrawing a case from R4BP 3

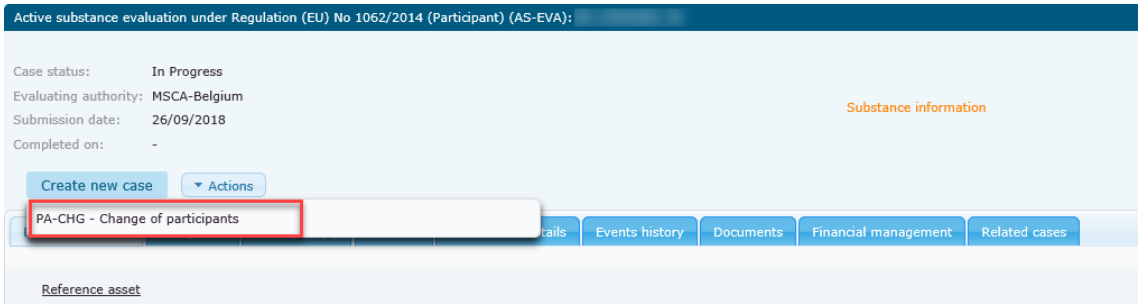
Applicants can withdraw their own cases from R4BP 3. Applicants who wish to withdraw an AS-EVA case must follow a specific procedure as described in 4.1. Withdrawing an AS-EVA.

4.1. Withdrawing an AS-EVA

You can withdraw your AS-EVA by submitting a PA-CHG.

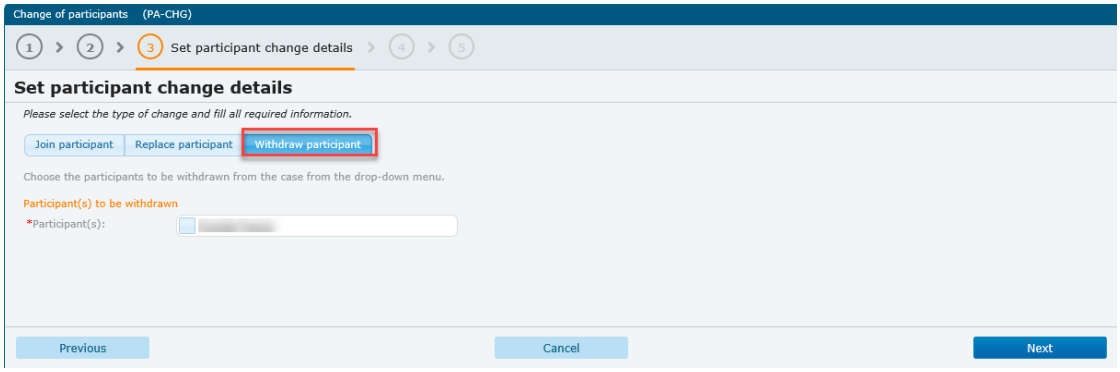
In this scenario, search for the relevant AS-EVA case and click on 'create new case' to launch the application wizard.

Figure 3: Submit a PA-CHG



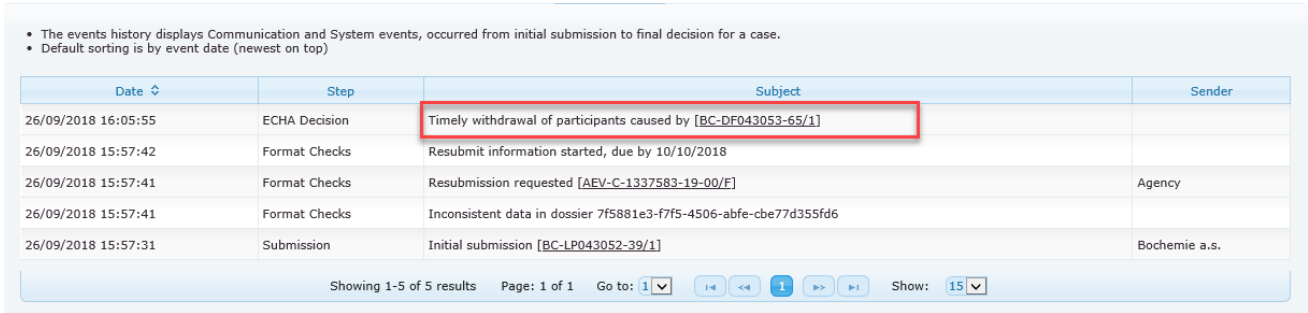
You will be required to set the participant change details (i.e. withdraw the participant(s)). Select the relevant tab ('withdraw participant') and tick the box(es) in order to remove all participant(s).

Figure 4: Withdraw participant



Once your PA-CHG has been approved by the European Chemicals Agency, the related AS-EVA will be withdrawn and any open task items will be closed. An appropriate event will be recorded in the events history.

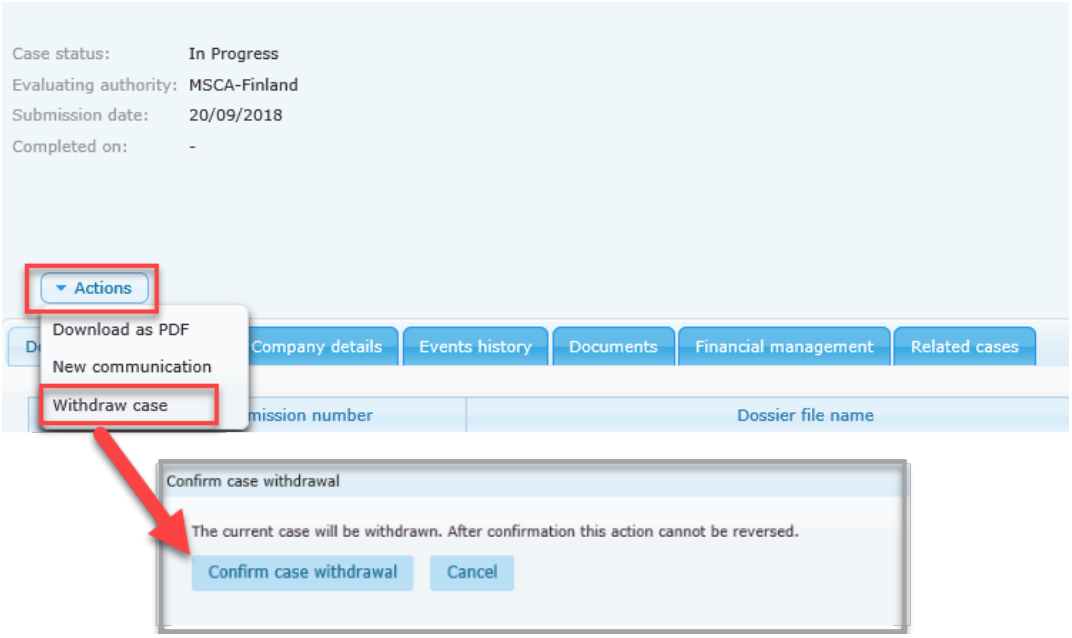
Figure 5: Case withdrawn- events history



4.2. Withdrawing any other AS related application

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

Figure 6: Withdrawing a case from R4BP 3



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.

5. Application for approval of an active substance and related applications

The principles and processes behind active substance approvals and related applications are described in the Practical Guide 'chapter on active substance approval' available from ECHA's website.

5.1. Application for approval of an active substance

If you wish to have an approval of an active substance in a specific product type, you need to submit an application for **approval of active substance** through the AS-APP application wizard in R4BP 3.

The principles and processes behind active substance approvals and related applications are described in the Practical Guide 'chapter on active substance approval' available from ECHA's website.

If your active substance / product type combination was accepted to be examined in the Review Programme (i.e. you have a valid RP asset), you are required to submit an AS-EVA instead.

5.2. Approval of an active substance in additional product types

If you wish to apply for the approval of an active substance in a different product type to the ones for which it is already approved, you are required to use the AS-APP wizard.

5.3. Amendment to the conditions of an approval

If an AS has been included in the Union list of approved active substances, certain conditions may have been imposed in the approval decision. Any person wishing to amend those conditions must make an application to amend the conditions of an approval.

For more information concerning the data requirements and submission process, please contact the ECHA Helpdesk.

5.4. Application instructions for the AS-APP wizard

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

- the approval of an active substance
- amendment to the conditions of an approval

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'.

5.4.1. Launching the application wizard

Launch the AS-APP application wizard by clicking the 'NEW APPLICATION' tab on the R4BP 3 toolbar. Then, select 'AS-APP – Application for approval of active substances' from the list of active substance application types (Figure 1).

5.4.2. Application requirements for AS-APP

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

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.

Set SME decision number

If you have previously been recognised with SME status, include the SME asset number.

Upload dossier and select language

For applications concerning the approval of an AS and the approval in an additional product type, the dossier must fulfil all of the information requirements laid out in Article 6 of the BPR.

Additionally, the dossier for the approval in an additional product type must fulfil all of the information requirements laid out in Annex II and III (for at least a representative product in the new PT and including PT specific additional data provided in guidance Vol. IV part A, Chapter V) of the BPR. You are required to include the following attachments:
- A letter of access to original AS dataset in section 13;
- All relevant studies related to the new Product Type;

In all applications, the following document should be provided:

- A draft risk assessment report attached in section 13 'Summary and Evaluation'.

Whenever relevant, attach in section 13 'Summary and Evaluation' of the IUCLIDD dossier:

- Justification(s) concerning exclusion criteria (BPR, Article 5);
- A Letter of access;
- A 'Permission to refer' to data granted by ECHA (BPR, Article 63).

Upload other files to support your application

In all applications, applicants are required to upload written confirmation from the competent evaluating MSCA confirming their agreement to evaluate the application.

Upload the ECHA supporting document – 'Supporting document for applications for approval of new active substances (AS-APP)/renewal of approval of active substances (AS-RNL)/ Annex I inclusion (AN-APP)'

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.

6. Scientific data update of active substance

If you wish to make an application for the Scientific data update of active substance, the active substance/Product Type combination needs to have the status Approved

The principles and processes behind active substance approvals and related applications are described in the Practical Guide 'chapter on active substance approval' available from ECHA's website.

This sub-chapter describes the application requirements necessary for each step of the AS-UPD application wizard in R4BP 3 for the scientific data update of active substance.

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'.

6.1. Launching the application wizard

Launch the AS-UPD application wizard by clicking the 'NEW APPLICATION' tab on the R4BP 3 toolbar. Then, select 'AS-UPD – Scientific data update of active substance' from the active substance application types (Figure 1).

6.2. Application requirements for AS-UPD

This sub-chapter describes the application requirements necessary for each step of the AS-UPD 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 AS-UPD

Set reference details

Define the relevant AS reference asset number to this case.

Set case owner details

A contact person for the case must be specified.

Set submission details

Select 'Evaluating authority' from the drop-down list and indicate the payment details i.e. purchase order number, if relevant to the case.

Upload IUCLID dossier and select language

For applications concerning the scientific data update of active substance, the dossier must fulfil all of the information requirements laid out in Article 6 of the BPR.

Whenever relevant, please include in section 13 'Summary and evaluation':

- 'permission to refer' to data granted by ECHA under Article 63 of the BPR,
- letter of access

Upload other files

Upload any other files at this step to support your application if they have not been included in section 13 of your IUCLID dossier.

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 an active substance

If you wish to have an approval of an active substance renewed for one product type, then an application for its renewal 550 days before the expiry date of the active substance approval must be made using the AS-RNL application wizard in R4BP 3.

The principles and processes behind the renewal of an active substance are described in the Practical Guide 'chapter on renewal of an approval of active substance' available from ECHA's website.

Chapter II and III of the BPR addresses the procedure of renewal including the conditions which have to be met for a renewal to be granted.

This sub-chapter describes the application requirements necessary for each step of the AS-RNL application wizard in R4BP 3 for the renewal of an active substance.

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'.

7.1. Launching the application wizard

Launch the AS-RNL application wizard by clicking the 'NEW APPLICATION' tab on the R4BP 3 toolbar. Then, select 'AS-RNL – Renewal of an active substance' from the active substance application types (Figure 1). You will be prompted to provide a reference 'asset number' for the active substance.

7.2. Application requirements for AS-RNL

This sub-chapter describes the application requirements necessary for each step of the AS-RNL 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 AS-RNL

Set reference details

Define the relevant AS reference asset number to this case.

Set case owner details

A contact person for the case must be specified.

Set submission details

Specify the 'Evaluating authority' and payment details relevant to this case.

Set SME decision number

If you have previously been recognised with SME status, include the SME asset number.

Upload IUCLID dossier

The dossier must fulfil all of the information requirements laid out in Article 6 of the BPR. In section 13 'Summary and evaluation', attach:

In all applications: an assessment whether the conclusions of the initial or previous assessment of the active substance are still valid.

Whenever relevant:

- A letter of access
- A 'permission to refer' to data granted by ECHA (BPR, Article 63)
- Justification(s) concerning exclusion criteria (BPR, Article 5).
- Any other supporting documentation if not already included in R4BP 3.

Upload other files

In all applications: written confirmation from the competent authority agreeing to evaluate the application for renewal.

Upload the ECHA supporting document – 'Supporting document for applications for approval of new active substances (AS-APP)/renewal of approval of active substances (AS-RNL)/ Annex I inclusion (AN-APP)'.

8. Inclusion of active substance in Annex I

Annex I of the BPR lists active substances with a more favourable environmental, human and animal health profile. If you wish to have an active substance **included in Annex I**, then an application through the AN-APP application wizard in R4BP 3 must be made.

The principles and processes behind the inclusion (or amendment of the restriction) of an active substance in Annex I are described in the Practical Guide ‘chapter on approval of active substances’ available on ECHA’s website.

For the relevant implementing legislation, please consult the ‘Amendment of Annex I Regulation[5].

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

Applicants seeking to include an active substance in **category 7** of Annex I should contact the ECHA Helpdesk.

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’.

8.1. Launching the application wizard

Launch the AN-APP application wizard by clicking the ‘NEW APPLICATION’ tab on the R4BP 3 toolbar. Then, select ‘AN-APP – Inclusion of active substance in Annex I’ from the active substance application types (Figure 1).

8.2. Application requirements for AN-APP

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

Annex I inclusion selection

Select the category of Annex I in which you intend the active substance to be included.

Set case owner details

A contact person for the case must be specified.

[5] C[illegible]on [illegible] r the **amendment of Annex I** to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

Set submission details

Select 'Evaluating authority' from the drop-down list and indicate the payment details i.e. purchase order number, if relevant to the case.

Set SME decision number

If you have previously been recognised with SME status, include the SME asset number.

Upload IUCLID dossier and select language

The data requirements are dependent on the category of Annex I to the BPR. For details on the full data requirements, please refer to the Amendment of Annex I Regulation.

Whenever relevant, please include in section 13 'Summary and evaluation':

- A 'permission to refer' to data granted by ECHA under Article 63 of the BPR,
- A letter of access

Upload other files

- Written confirmation from the competent authority agreeing to evaluate the application.
- 'Supporting document for applications for approval of new active substances (AS-APP)/renewal of approval of active substances (AS-RNL)/ Annex I inclusion (AN-APP)'
- A justification that substance complies with the category description, and a justification that Substance does not give rise to concern.
- Upload any other files at this step to support your application if they have not been included in section 13 of your IUCLID dossier.

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. Amendment of active substance in Annex I

If you wish to make an application for the Amendment of active substance in Annex I, a reference asset for the inclusion of an active substance is required. When creating the reference asset of AN-APP, you are required to select the category of Annex I in which you intend the active substance to be amended. The information related to the selection of category is extracted directly from the reference asset case.

The principles and processes behind the amendment of active substance in Annex I are described in the Practical Guide 'chapter on approval of active substances' available from ECHA's website.

For the relevant implementing legislation, please consult the 'Annex I amendment Regulation[6].

This sub-chapter describes the application requirements necessary for each step of the AN-CHG application wizard in R4BP 3 for the amendment of active substance in Annex I.

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'.

9.1. Launching the application wizard

Launch the AN-CHG application wizard by clicking the 'NEW APPLICATION' tab on the R4BP 3 toolbar. Then, select 'AN-CHG – Amendment of active substance in Annex I' from the active substance application types (Figure 1).

9.2. Application requirements for AN-CHG

This sub-chapter describes the application requirements necessary for each step of the AN-CHG 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 AN-CHG

Set reference details

Define the relevant AN reference asset number to this case.

Set case owner details

A contact person for the case must be specified.

[6] Commission Implementing Regulation (EU) No 88/2014 of 31 January 2014 specifying a procedure for the **Annex I amendment** to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

Set submission details

Select 'Evaluating authority' from the drop-down list and indicate the payment details i.e. purchase order number, if relevant to the case.

Upload IUCLID dossier and select language

The data requirements are dependent on the category of Annex I to the BPR. For details on the full data requirements, please refer to the Annex I amendment Regulation.

Whenever relevant, please include in section 13 'Summary and evaluation':

- A 'permission to refer' to data granted by ECHA under Article 63 of the BPR,
- A letter of access

Upload other files

- written confirmation from the competent authority agreeing to evaluate the application.
- 'Supporting document for applications for approval of new active substances (AS-APP)/renewal of approval of active substances (AS-RNL)/ Annex I inclusion (AN-APP)'
- a justification that substance complies with the category description, and
- a justification that Substance does not give rise to concern.
- Upload any other files at this step to support your application if they have not been included in section 13 of your IUCLID dossier.

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. Scientific data update of active substance in Annex I

If you wish to make an application for the Scientific data update of active substance in Annex I, a reference asset for the inclusion of an active substance is required.

The principles and processes behind the amendment of active substance in Annex I are described in the Practical Guide 'chapter on approval of active substances' available from ECHA's website.

For the relevant implementing legislation, please consult the 'Annex I amendment Regulation[7].

This sub-chapter describes the application requirements necessary for each step of the AN-UPD application wizard in R4BP 3 for the scientific data update of active substance in Annex I.

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'.

10.1. Launching the application wizard

Launch the AN-UPD application wizard by clicking the 'NEW APPLICATION' tab on the R4BP 3 toolbar. Then, select 'AN-UPD – Scientific data update of active substance in Annex I' from the active substance application types (Figure 1).

10.2. Application requirements for AN-UPD

This sub-chapter describes the application requirements necessary for each step of the AN-UPD 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 AN-UPD

Set reference details

Define the relevant AN reference asset number to this case.

Set case owner details

A contact person for the case must be specified.

[7] Commission Implementing Regulation (EU) No 88/2014 of 31 January 2014 specifying a procedure for the **Annex I amendment** to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

Set submission details

Select 'Evaluating authority' from the drop-down list and indicate the payment details i.e. purchase order number, if relevant to the case.

Upload IUCLID dossier and select language

The data requirements are dependent on the category of Annex I to the BPR. For details on the full data requirements, please refer to the Annex I amendment Regulation.

Whenever relevant, please include in section 13 'Summary and evaluation':

- A 'permission to refer' to data granted by ECHA under Article 63 of the BPR,
- A letter of access

Upload other files

Upload any other files at this step to support your application if they have not been included in section 13 of your IUCLID dossier.

Confirm application

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

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

11. Inclusion in the Article 95 (active substance suppliers) list

Any person established within the Union who manufacturers or imports an active substance (the 'substance supplier'), may apply to be included in the Article 95 list.

In addition, any person who manufactures or makes available on the EU market a BP which consists of, contains or generates that active substance (the 'product supplier'), may apply to be included in the Article 95 list, in particular where the manufacturer or importer of that active substance is not listed.

Submissions must be made individually and fees are charged per submission (the BPR does not provide for joint submissions under Article 95). However, entities may also wish to co-operate to make a complete substance dossier, for example in a consortium can follow the guidelines in the Guidance on active substance suppliers (Article 95 list).

An application for inclusion in the Article 95 list can be made in relation to existing active substances, either approved or pending approval, or new active substances that have been approved.

ECHA has provided a guidance document on its website to assist you in fulfilling the information requirements - Guidance on active substance suppliers (Article 95 list).

The principles and processes behind inclusion in the 'Article 95 List' are described in the Practical Guide 'chapter on Article 95: List of active substances and suppliers' available from ECHA's website.

ECHA will publish and regularly update the Article 95 list under List of active substances and suppliers.

Is a dossier required? If your application is based solely on a letter of access to a complete substance dossier or if your application is based on a reference to a complete substance dossier for which all data protection periods have expired, a IUCLID dossier is not required. However, in all other instances (e.g. based on letters of access together with complimentary information or a complete substance dossier) a IUCLID dossier is required.

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'.

11.1. Launching the application wizard

Launch the AS-ACC application wizard by clicking the 'NEW APPLICATION' tab on the R4BP 3 toolbar. Then, select 'AS-ACC - Inclusion in the Article 95 (active substance suppliers) list' from the active substance application types (Figure 1).

The application wizard requires you select an active substance from a drop-down list. If you cannot find the relevant active substance in the list, please contact the ECHA Helpdesk via the contact form.

11.2. Application requirements for AS-ACC

This sub-chapter describes the application requirements necessary for each step of the AS-ACC 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 AS-ACC

Set case owner details

Contact person for the case must be specified.

Set submission details

Insert the UUID of the asset owner (the EU entity to be included in the Article 95 list as supplier or as the EU representative of a non-EU entity).

Identify your 'Active Substance' and product type(s) from the drop-down list (only if IUCLID dossier is not applicable for your submission type).

If applicable, insert a Non-EU entity UUID and select a contact person (identified in the Non-EU entity UUID in ECHA accounts).

Specify the Supplier role of the asset owner.

Indicate the payment details relevant to the case.

Upload IUCLID dossier

If you are submitting a dossier as part of your application, i.e. complete or mixed type dossier then:
Whenever relevant, please include in section 13 'Summary and evaluation':

- 'permission to refer' to data granted by ECHA under Article 63 of the BPR,
- letter of access* (containing information about which product types the application is for)

**Note if the application if based solely on a letter of access, then upload it in 'Upload other files' step of the R4BP 3 wizard.*

Supporting information details

To ensure ECHA can issue the correct fee, you need to indicate the type of submission you wish to apply for at this step. If you are unsure of the types of submission under Article 95, please refer to the Guidance on active substance suppliers.

Upload other files

If your submission type is based on a **letter of access** to a co3906523588mplete substance dossier, then this should be uploaded at this step.

If your submission type is referring to a dossier for which all data protection periods have expired, upload the ECHA supporting document – 'Supporting document for applications for Article 95 inclusion (AS-ACC) with reference to a dossier for which all data protection periods have expired'

Upload any other files at this step to support your application if they have not been included in section 13 of a IUCLID dossier.

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.

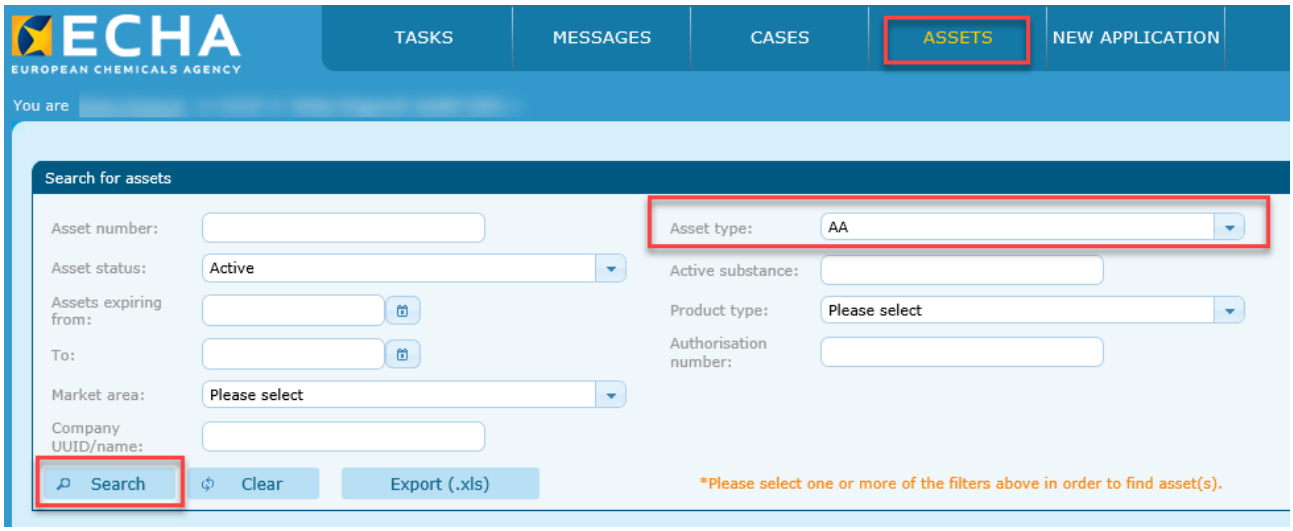
12. Inclusion on the list of active substance suppliers (Article 95) administrative change on request

The owner of an AA (Access to active substance dossier) asset can request an administrative change of the AA asset to update the supplier role or the non-EU entity of the asset.

12.1. Launching the application wizard

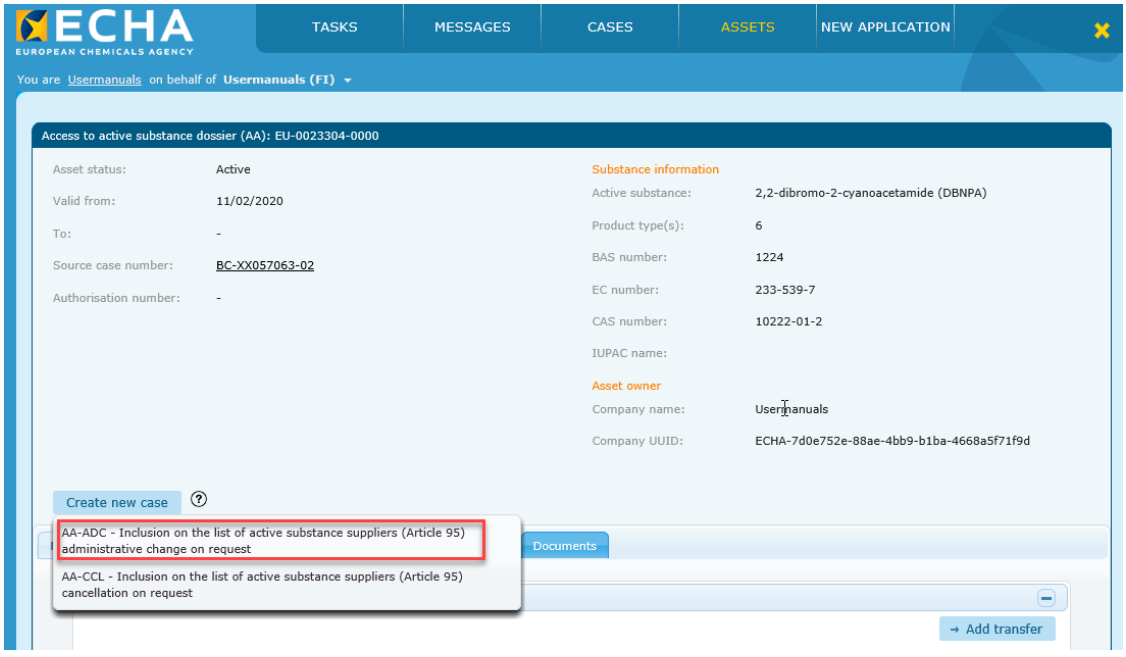
Click on the 'ASSETS' tab and search for the relevant AA asset.

Figure 7: Search for your AA asset



When you have gained access to the asset details page, click on 'create new case' and select 'AA-ADC –Inclusion on the list of active substance suppliers (Article 95) administrative change on request'.

Figure 8: Launching the application 'wizard' for AA-ADC



12.2. Application requirements for AA-ADC

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

Set case owner details

A contact person for the case must be specified.

Set submission details

If applicable, insert a Non-EU entity UUID and select a contact person (identified in the Non-EU entity UUID in ECHA accounts).

Specify the Supplier role of the asset owner.

Upload other files

Upload the ECHA supporting document 'Supporting document for applications for administrative change of Article 95 asset and any other documentation that supports your 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.

13. Scientific data update of inclusion in Article 95 (active substance suppliers) list

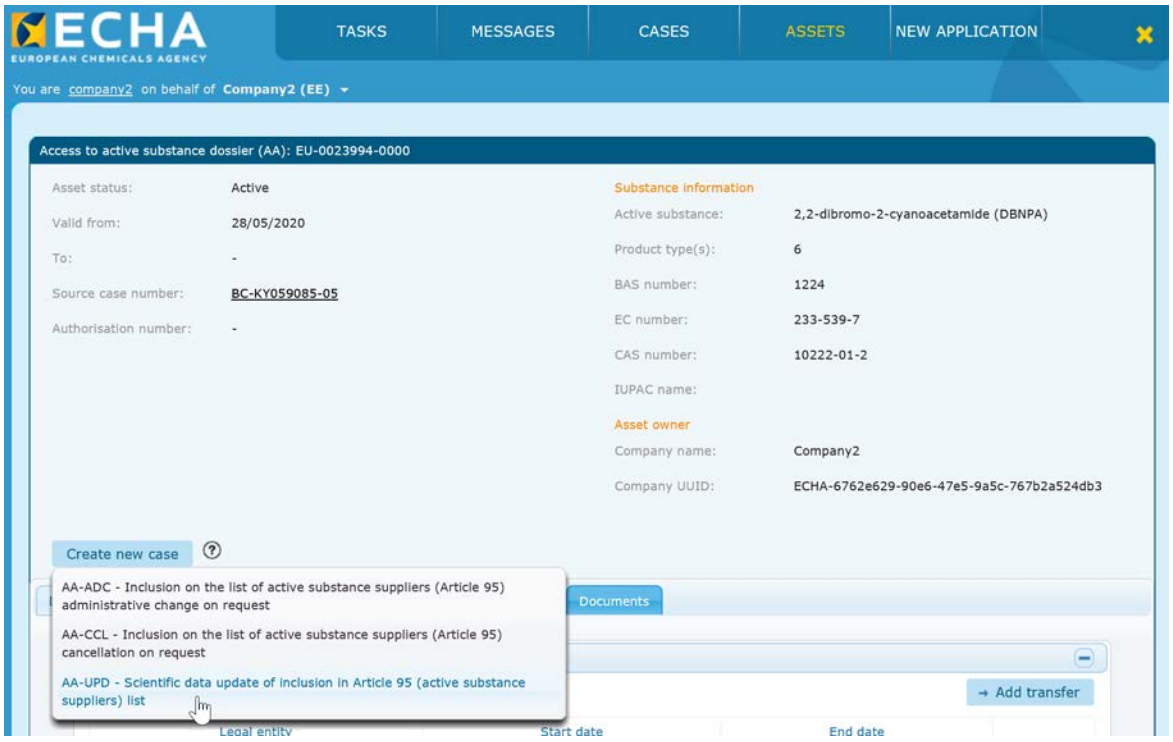
The owner of an AA (Access to active substance dossier) asset can request a scientific data update (provided with IUCLID dossier) of the AA asset.

13.1. Launching the application wizard

Click on the 'ASSETS' tab and search for the relevant AA asset (Figure 13).

When you have gained access to the asset details page, click on 'create new case' and select 'AA-UPD – Scientific data update of inclusion in Article 95 (active substance suppliers) list'.

Figure 9: Launching the application 'wizard' for AA-UPD



13.2. Application requirements for AA-UPD

This sub-chapter describes the application requirements necessary for each step of the AA-UPD 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 AA-UPD

Set case owner details

A contact person for the case must be specified.

Upload IUCLID dossier and select language

Whenever relevant, please include in section 13 'Summary and evaluation':

- A 'permission to refer' to data granted by ECHA under Article 63 of the BPR,
- A letter of access

Upload other files

Upload any other documentation that supports your 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.

14. Renewal of inclusion in Article 95 (active substance suppliers) list

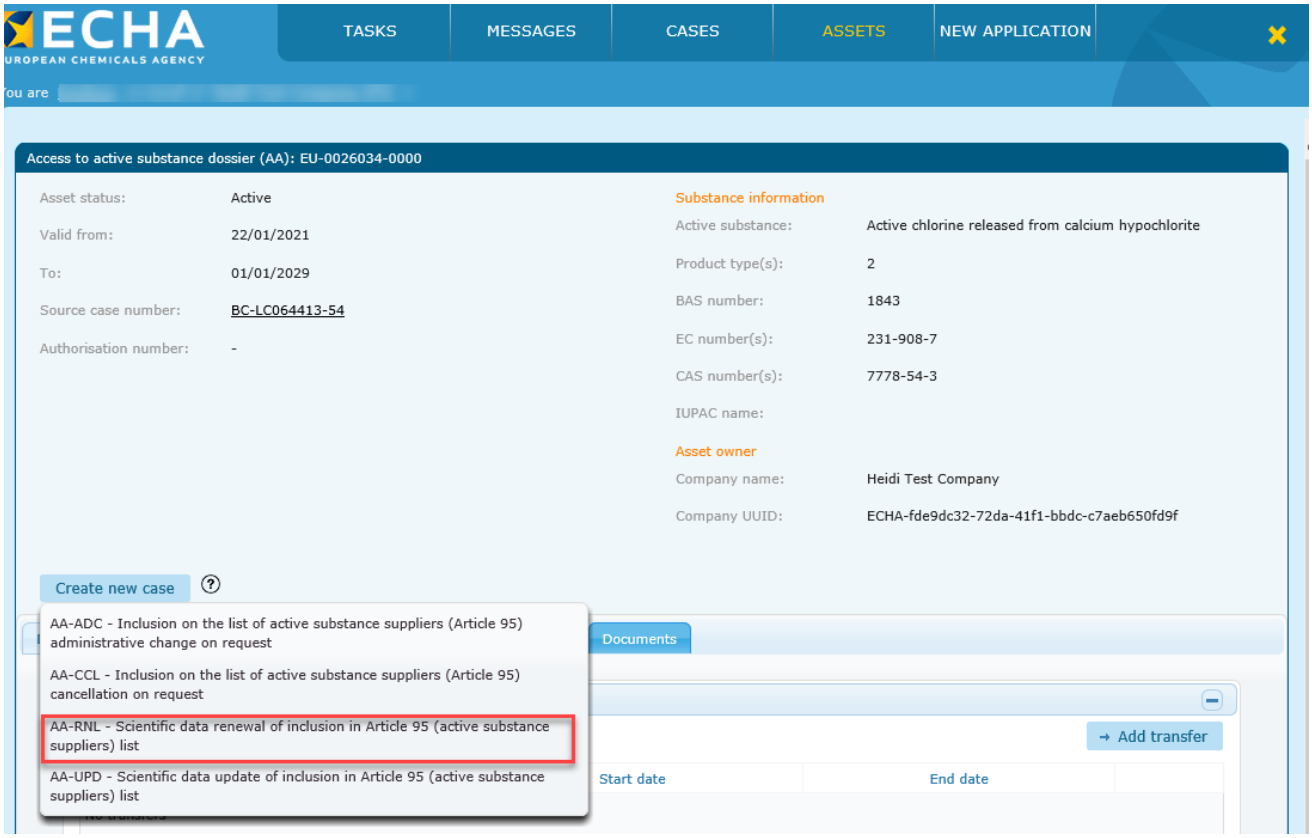
AA (Art. 95) asset owners can submit relevant data as identified during the renewal of an active substance approval through this application type.

14.1. Launching the application wizard

Click on the 'ASSETS' tab and search for the relevant AA asset (Figure 7)

When you have gained access to the asset details page, click on 'Create new case' and select 'AA-RNL –Scientific data renewal of inclusion in Article 95 (active substance suppliers) list'.

Figure 10: Launching the application 'wizard' for AA-RNL



14.2. Application requirements for AA-RNL

This sub-chapter describes the application requirements necessary for each step of the AA-RNL 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 AA-RNL

Set case owner details

A contact person for the case must be specified.

Upload IUCLID dossier and select language

If the application is based on a letter of access to all the relevant renewal data, proceed to the next step without uploading a IUCLID file.

The submission of (alternative) data in a IUCLID dossier for the purposes of Article 95(7) BPR is normally prohibited (see for further details section 4.2 of the CA document "CA-Sept20-Doc.7.1.b - Relevant Renewal Data under Article 95_FINAL").

If you are submitting a dossier as part of your application, add in section 13 'Summary and evaluation', as appropriate:

- Letters of access and any other documentation that supports your application.

Upload other files

If the application is based on a letter of access to all the relevant renewal data, upload the letter of access.

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. Inclusion on the list of active substance suppliers (Article 95) cancellation on request

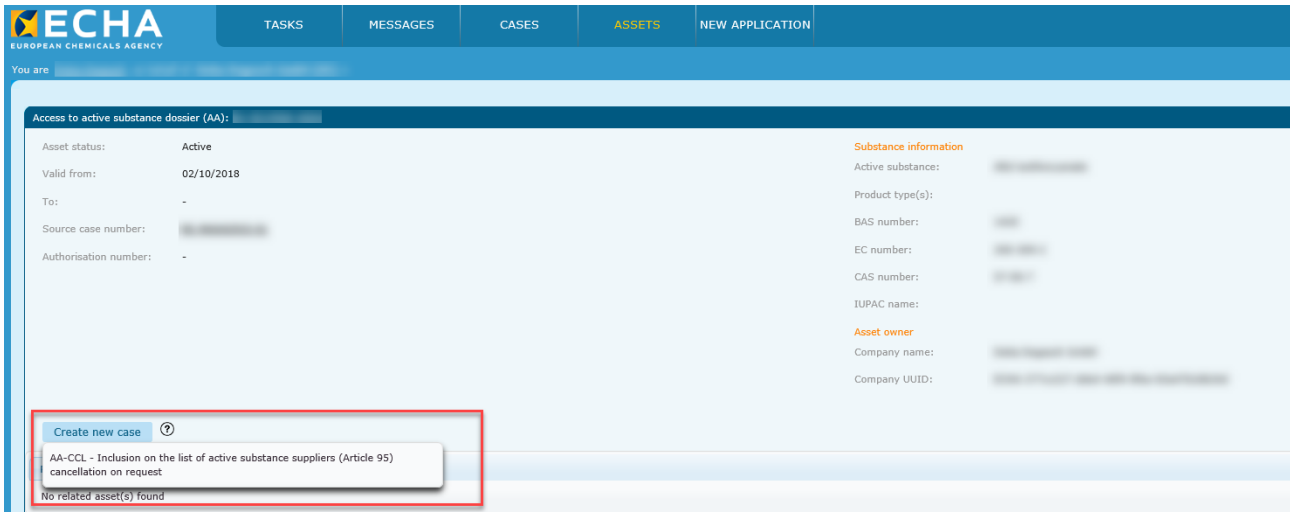
The owner of an AA asset can request the irrevocable cancellation of an entry in Article 95 list.

15.1. Launching the application wizard

Click on the 'ASSETS' tab and search for the relevant AA asset (Figure 7).

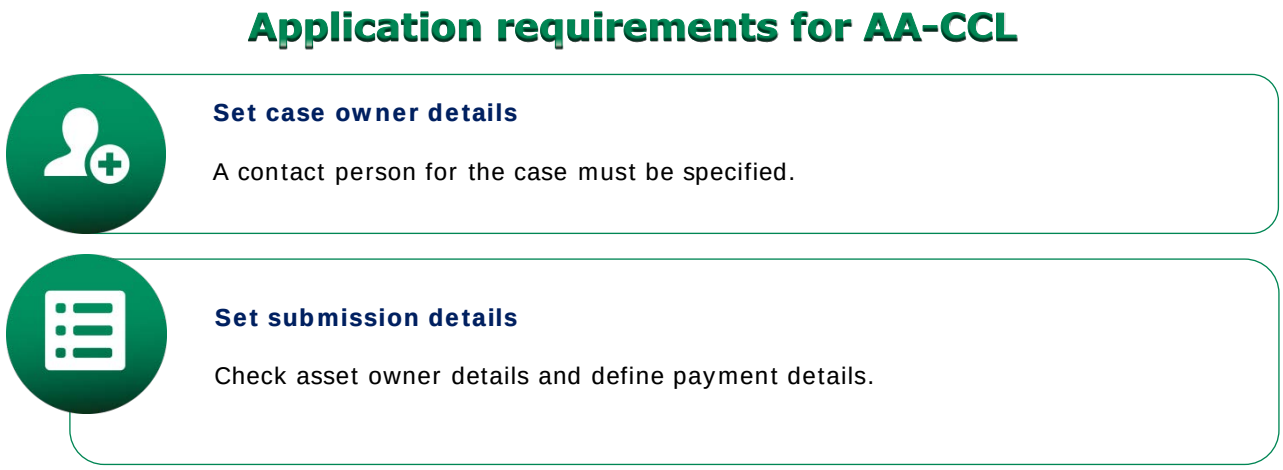
When you have gained access to the case details page, click on 'create new case' and select 'AA-CCL –Inclusion on the list of active substance suppliers (Article 95) cancellation on request'.

Figure 11: Launching the application 'wizard' for AA-CCL



15.2. Application requirements for AA-CCL

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



Upload other files
A confirmation by the Art. 95 supplier and, where applicable the non-EU entity, that they irrevocably want to cancel the asset in question.

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. Transfer of Article 95 asset (access to active substance dossier)

Applications for Transfer of an Article 95 asset (access to active substance dossier) AA-TRS are used to transfer the ownership of the 'AA' asset from one entity (asset owner) to another entity within the same group of companies. The change of ownership of the 'AA' asset will be reflected on the Article 95 list.

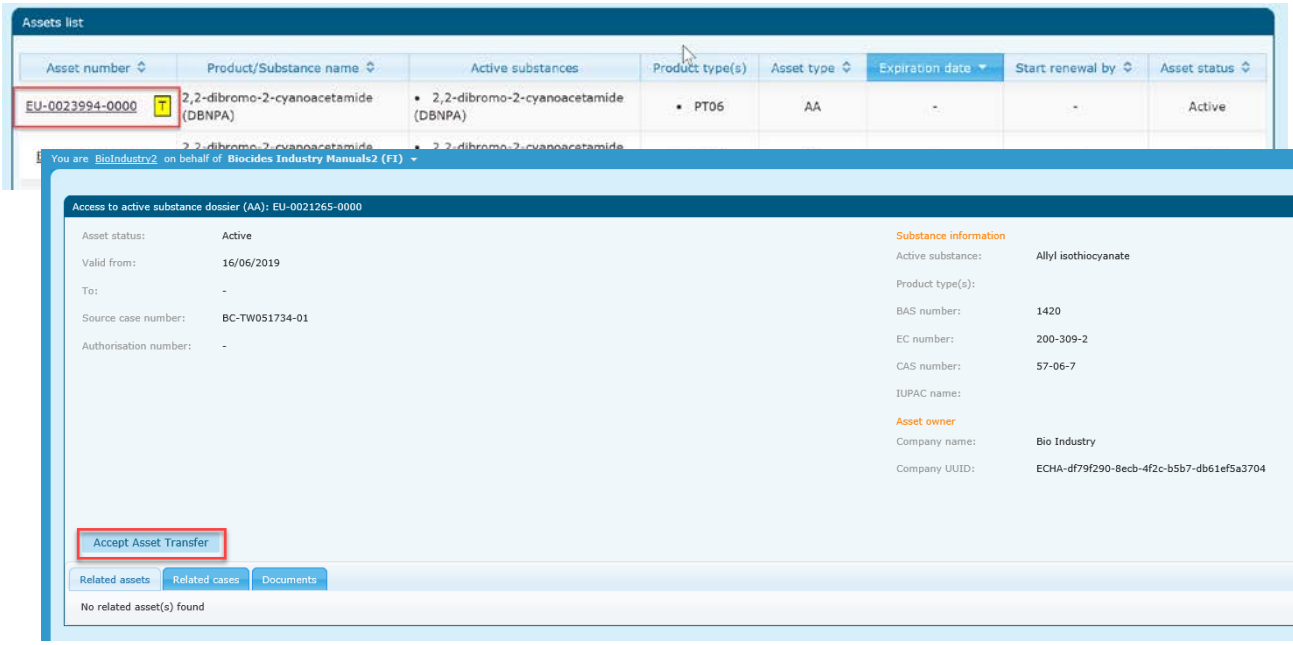
16.1. Launching the AA-TRS application wizard

As a first step, the owner of the 'AA' type asset must initiate the transfer process in R4BP 3. The procedure of initiating an asset transfer is described in the BSM Technical guide: using R4BP 3.

Once the initial asset owner has initiated the asset transfer, the asset will be visible in the 'Asset list' of the intended new asset owner, who can then 'accept' the transfer and launch the wizard steps for the AA-TRS application in R4BP 3:

To find and accept the 'AA' asset for which the transfer was initiated, you (the prospective new asset owner) should click on the 'ASSETS' tab on the R4BP 3 toolbar. If not immediately visible in the 'Assets list', search for the specific asset by the asset type 'AA-Access to active dossier'. 'AA' assets available for transfer are labelled with a T. To accept the 'AA' asset, click on the asset number hyperlink to open a details page for the asset. Clicking on 'Accept Asset Transfer' will launch the AA-TRS wizard.

Figure 12: Launching the application 'wizard for AA-TRS



16.2. Application requirements for AA-TRS

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

Set case owner details

A contact person for the case must be specified.

Set submission details

Asset owner details are prefilled.

Upload other files

Upload the ECHA supporting document - 'Supporting document for applications for transfer of Article 95 assets' and any other documentation that supports your application (for details, please see the supporting document template).

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.

17. Inquire to share data (for active substance)

Any person intending to gather data through animal testing or tests on vertebrates shall 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' on the ECHA website.

According to Article 62 of the BPR, an inquiry to share data is **obligatory** before performing any tests or studies involving vertebrates and is the basis and pre-condition for starting a dispute procedure under Article 63.

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

When submitting an inquiry to share data for an AS, please keep in mind that you can only inquire about tests or studies that have been submitted under the BPR or the Biocidal Products Directive[8].

17.1. Launching the IN-REA application wizard

Launch the IN-REA application wizard by clicking the 'NEW APPLICATION' tab on the R4BP 3 toolbar. Then, select 'IN–REA - Inquire to share data (for active substance)' from the active substance application types (Figure 1).

17.2. Application requirements for IN-REA

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

Only one active substance is permissible per application. If you wish to inquire about more than one, please submit separate applications for each.

The application wizard requires you select an active substance from a drop-down list. If you cannot find the relevant active substance in the list, please contact the ECHA Helpdesk via the contact form.

[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.

Application requirements for IN-REA

Set case owner details

A contact person for the case must be specified.

Set submission details

Enter the details of the 'asset owner' and identify your 'Active Substance' from the drop-down list.

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.

18. Declaration of interest to notify

Any person with an interest to notify an active substance/ product type combination which is eligible for inclusion in the Review Programme will submit a declaration of interest to notify.

This sub-chapter describes the application requirements necessary for each step of the DI-SUB application wizard in R4BP 3 for the declaration of interest to notify.

18.1. Launching the application wizard

Launch the DI-SUB application wizard by clicking the 'NEW APPLICATION' tab on the R4BP 3 toolbar. Then, select 'DI-SUB – Declaration of interest to notify' from the active substance application types (Figure 1).

18.2. Application requirements for DI-SUB

This sub-chapter describes the application requirements necessary for each step of the DI-SUB 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 DI-SUB

Set case owner details

A contact person for the case must be specified.

Enter active substance details

Specify the active substance name, product type(s) and identifiers relevant to this case.

Upload other files

Upload any other supporting documentation related to the 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.

19. Notification procedure

Review Programme notifications can be submitted to the Agency through R4BP 3 according to the following conditions:

• within 12 months from the date of publication of the open invitation to take over the role of participant.

• within 6 months from the date of publication of declaration of interest to notify an active substance/ product type.

This sub-chapter describes the application requirements necessary for each step of the RP-NOT application wizard in R4BP 3 for the Review Programme notification.

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'.

19.1. Launching the application wizard

Launch the RP-NOT application wizard by clicking the 'NEW APPLICATION' tab on the R4BP 3 toolbar. Then, select 'RP-NOT – Notification procedure' from the list of application types' from the active substance application types (Figure 1).

You will be prompted to set the reference details. There are two options available:

— providing an active substance/product type combination which has been published for notification on the ECHA website at: https://echa.europa.eu/regulations/biocidal-products-regulation/upcoming-deadlines (Figure 13)

— providing the reference 'DI asset number' for an active substance/product type combination for which a successful declaration of interest had been submitted. The 'DI asset number' can be found on the afore-mentioned webpage in the field "More information" of the respective entry (Figure 14).

Figure 13: Set reference details by providing active substance / product type combination

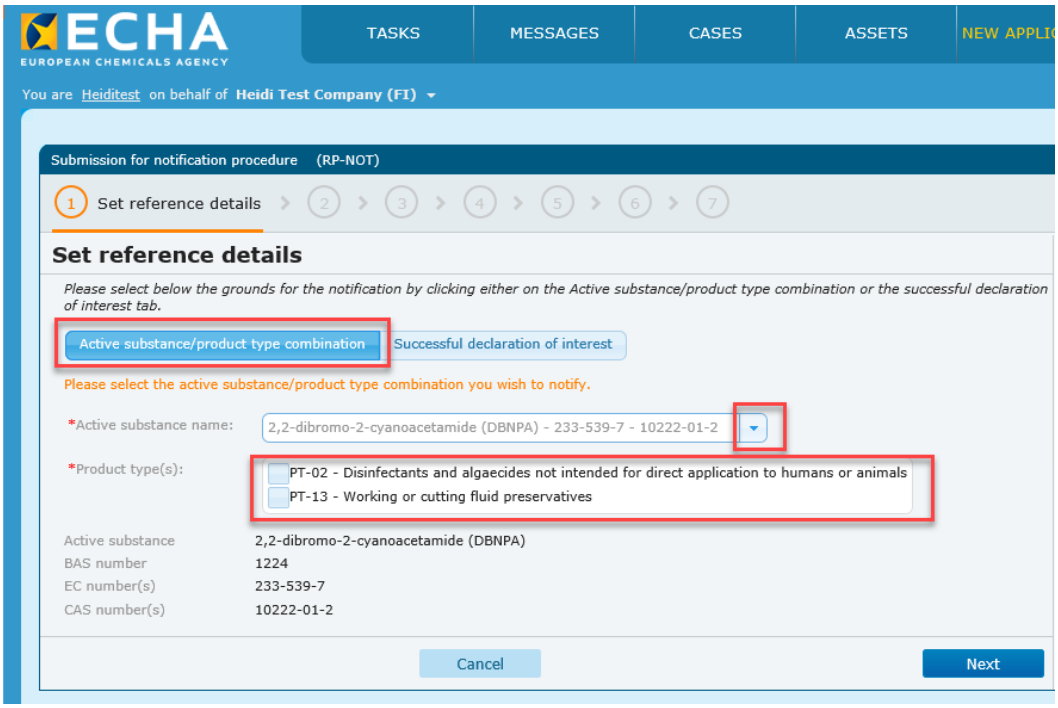
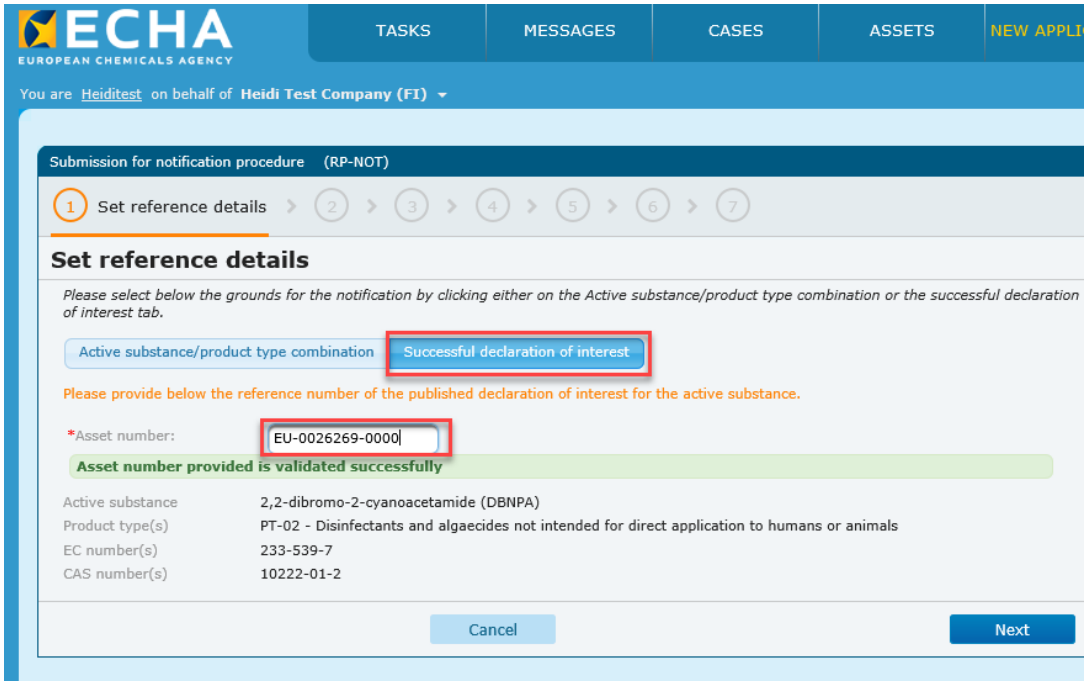


Figure 14: Set the reference details by providing valid successful declaration of interest asset number (DI asset type)



19.2. Application requirements for RP-NOT

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

Set reference details
Choose the appropriate reference detail (see section 19.1.)

Set case owner and participant(s) details

Specify the contact person and define the participant(s) details for the case. Define if the case owner is also a participant.

Set submission details

Indicate the payment details relevant to the case.

Upload IUCLID dossier

The dossier must fulfil the information requirements laid out in Annex I of the Review Programme Regulation.

Upload other files
In all applications, applicants are required to upload written confirmation from the competent evaluating MSCA confirming their agreement to evaluate the application.

Upload any other supporting documentation related to the application, if not already included in the IUCLID dossier.

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.

20. Active substance evaluation under Regulation (EU) No 1062/2014 (Participant)

The application of active substance evaluation under Regulation (EU) No 1062/2014 (Participant) shall be submitted to the Agency through R4BP 3 within 24 months from the date the active substance / product type has been notified.

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

In some specific cases, you may be asked to update the substance name of an active substance based on the outcome of redefinition. In this situation, a new IUCLID file with updated information needs to be uploaded in R4BP 3.

The updated IUCLID file will undergo a Substance Identity Check to confirm that the updated information is correct.

If confirmed as correct, a new BAS number will be associated to the updated substance and the existing case will be updated. The task will return to the Authority that triggered the redefinition and the previous substance name will be added to the list of those that are notified for inclusion in the Review Programme (if not already present) with an expiration date after which a "No Longer supported" process is triggered.

If incorrect, a "Request additional info" task will be triggered by the Authority to ask you to resubmit a IUCLID file.

This sub-chapter describes the application requirements necessary for each step of the AS-EVA application wizard in R4BP 3 for the active substance evaluation under Regulation (EU) No 1062/2014 (Participant).

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'.

20.1. Launching the application wizard via the 'NEW APPLICATION' tab

Launch the AS-EVA application wizard by clicking the 'NEW APPLICATION' tab on the R4BP 3 toolbar. Then, select 'AS-EVA – Active substance evaluation under Regulation (EU) No 1062/2014 (Participant)' from the list of application types' from the active substance application types (Figure 1). You will be prompted to provide a reference 'asset number' for the active substance.

20.2. Application requirements for AS-EVA

This sub-chapter describes the application requirements necessary for each step of the AS-EVA 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 AS-EVA

Set reference details

Define the relevant RP reference asset number to this case.

Set case owner and participant(s) details

Specify the contact person and define if the case owner is also a participant.
Define the participant(s) details and specify the supplier's role.

Set submission details

Specify the 'Evaluating authority' and payment details relevant to this case.

Set SME decision number

If you have previously been recognised with SME status, include the SME asset number.

Upload IUCLID dossier

The dossier must fulfil all of the information requirements laid out in Article 6 of the BPR.

Upload other files

In all applications: written confirmation from the competent authority agreeing to evaluate the application.

Upload any other supporting documentation related to the application, if not already included in the IUCLID dossier.

Whenever relevant:

- letter of access
- 'permission to refer' to data granted by ECHA (BPR, Article 63)
- Justification(s) concerning exclusion criteria (BPR, Article 5).
- Any other supporting documentation if not already included 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.

21. Change participants by mutual agreement

Any person with an interest to notify the taking over or sharing the role of participant can request the case owner of the AS-EVA case to initiate a PA-CHG case type. The case owner will be allowed to apply for withdrawing a specific participant(s) from a specific case or for joining or replacing a prospective participant(s) for an active substance/ product type case in R4BP 3.

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

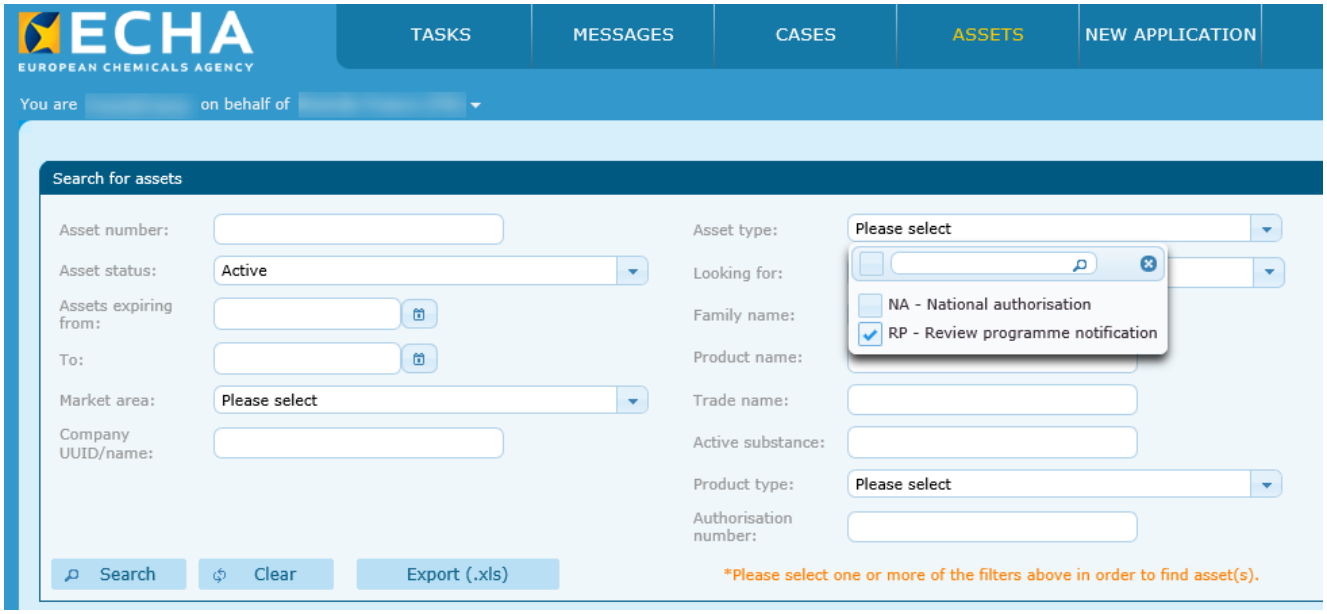
This sub-chapter describes the application requirements necessary for each step of the PA-CHG application wizard in R4BP 3 for the change participant by mutual agreement.

21.1. Nomination of RP asset for the purpose of making a PA-CHG

In order to initiate a PA-CHG, the asset owner of the Review Programme asset needs to make a nomination in the RP asset page.

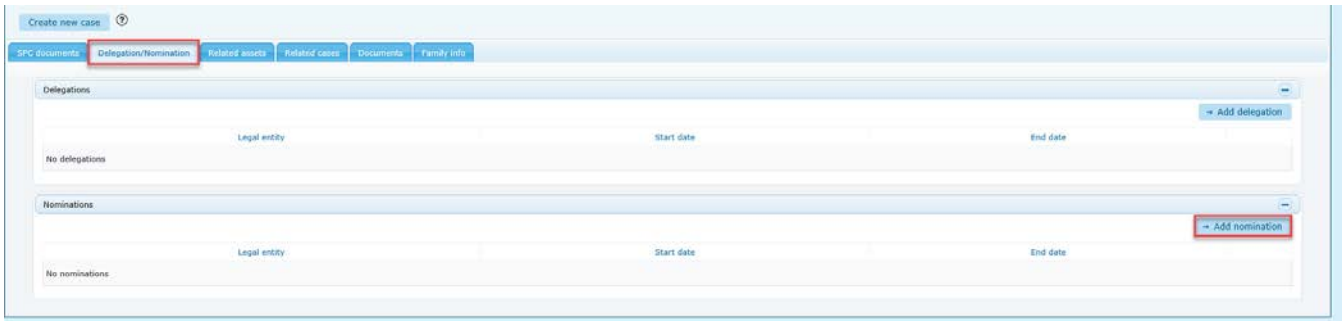
Click on the 'ASSETS' tab on the R4BP 3 toolbar and search for the relevant asset number by filling in some search criterion, e.g. the asset type. Clicking on the asset number hyperlink in the 'Assets list' will open a details page for that specific asset.

Figure 15: Search for your RP asset



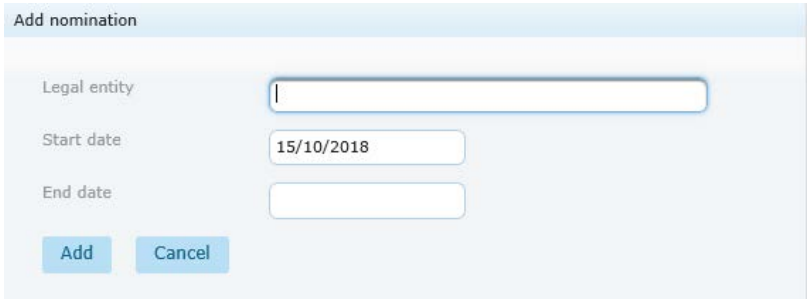
Once you have gained access to the case details page, click on the ‘Delegation/Nomination’ tab.

Figure 16: Make a Nomination



You will be required to fill in the legal entity UUID, a start date and an end date. Note that you are required to nominate yourself if you want to start a PA-CHG.

Figure 17: Nominate a company



Once the PA-CHG application has been approved, the company indicated in the nomination will be allowed to initiate a PA-CHG application and add new participants.

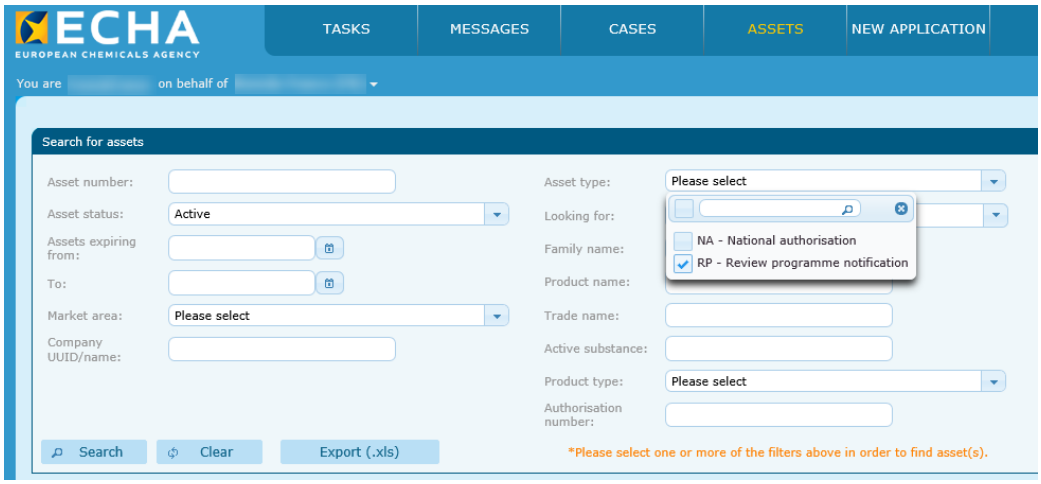
Nomination of an asset is explained in details in the BSM Technical guide: How to use R4BP 3.

21.2. Launching the application wizard for PA-CHG via RP asset

After nominating a legal entity in the RP asset page, you will be allowed to initiate a PA-CHG.

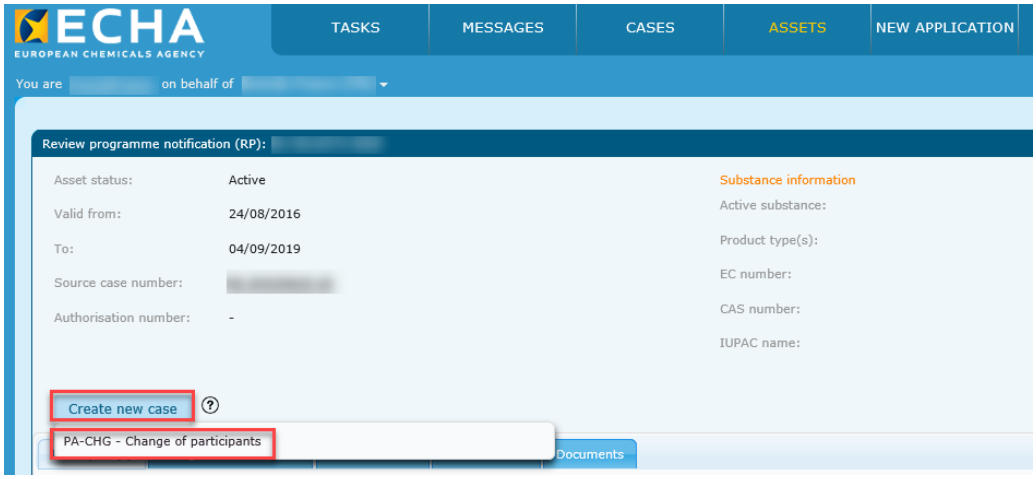
Launch the PA-CHG application wizard by clicking first the ‘ASSETS’ tab on the R4BP 3 toolbar and search for the relevant RP asset.

Figure 18: Search for your RP asset



From the details page launch your application by clicking ‘Create new case' for ‘PA-CHG – Change of participants’.

Figure 19: Create a PA-CHG from an RP asset



21.3. Launching the application wizard for PA-CHG via AS-EVA case type

Launch the PA-CHG application wizard by clicking first the 'CASES' tab on the R4BP 3 toolbar. From the 'CASES' tab, search with 'AS-EVA – Active substance evaluation under Regulation (EU) No 1062/2014 (Participant)' as case type. After making the search click on the relevant case number. From the details page launch your application by clicking 'Create new case' for 'PA-CHG – Change of participants'.

Figure 20: Launching the application 'wizard' for PA-CHG via AS-EVA case type - first step

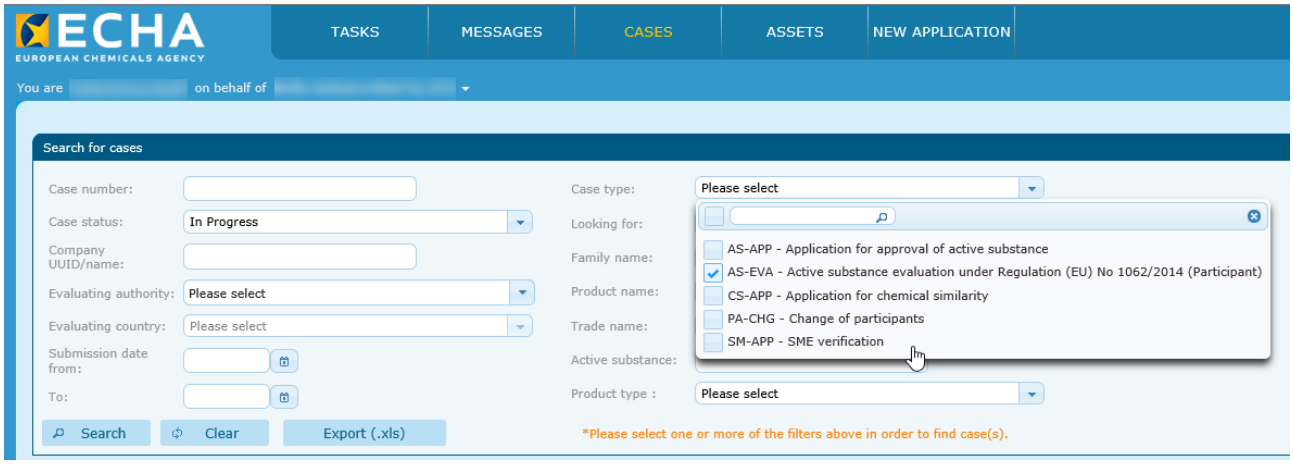
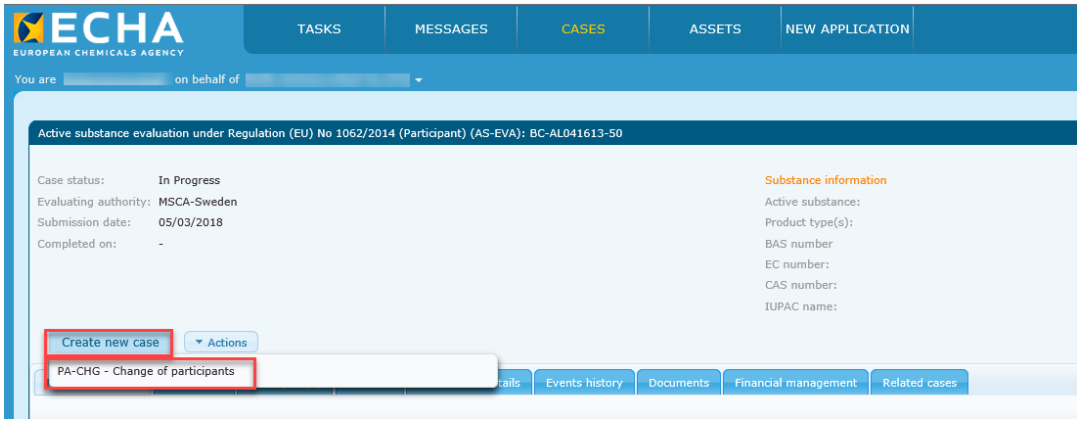


Figure 21: Launching the application 'wizard' for PA-CHG via AS-EVA case type – second step



21.4. Application requirements for PA-CHG

This sub-chapter describes the application requirements necessary for each step of the PA-CHG 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 PA-CHG

Set case owner details

A contact person for the case must be specified.

Set participant change details

Select the type of change from the following: Join participant/ Replace participant/ Withdraw participant.

When ‘Join participant’ is selected: provide the company UUID of the new participant;

When ‘Replace participant’ is selected: tick the box of the participant to be removed and provide the UUID of the participant to be added in the corresponding field;

When ‘Withdraw participant’ is selected: tick the box of the participant to be withdrawn.

Upload other files

Upload any other supporting documentation related to the application, if not already included in the IUCLID dossier.

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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