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.

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<th>Version</th>
<th>Changes</th>
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<tr>
<td>Version 1.0</td>
<td>First version</td>
<td>August 2013</td>
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<tr>
<td>Version 2.0</td>
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<td>Changes to Chapter 4 have been made for AS-ACC applications resulting from amendments to Article 95 of the BPR.</td>
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<tr>
<td>Version 2.2</td>
<td>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.</td>
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<tr>
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<td>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.</td>
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<tr>
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<td>New application wizards:</td>
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<td>Clarification of the evaluation due date for AS-ACC applications has been made in Chapter 6.</td>
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| 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).  
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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 |
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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 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.  
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13. Scientific data update of inclusion in Article 95 (active substance suppliers) list. | June 2020   |
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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 Regulation¹ (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.

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 wizard².

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

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.


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&A 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, and the SPC Editor.

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

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Table 1: Active substance applications

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<thead>
<tr>
<th>Case abbreviation</th>
<th>Application</th>
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<tr>
<td>AS-APP</td>
<td>Approval of an active substance €</td>
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<tr>
<td>AS-APP* (AS-CHG)</td>
<td>Amendment to the conditions of an approved active substance €</td>
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<tr>
<td>AS-UPD</td>
<td>Scientific data update of active substance</td>
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<tr>
<td>AS-RNL</td>
<td>Renewal of the approval of an active substance €</td>
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<tr>
<td>AN-APP</td>
<td>Inclusion of an AS in Annex I €</td>
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<tr>
<td>AN-UPD</td>
<td>Scientific data update of active substance in Annex I</td>
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<tr>
<td>AN-CHG</td>
<td>Amendment of active substance in Annex I €</td>
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<tr>
<td>AS-ACC</td>
<td>Inclusion on the list of active substance suppliers (Article 95) €</td>
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<td>AA-ADC</td>
<td>Inclusion on the list of active substance suppliers (Article 95) administrative change on request</td>
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<tr>
<td>AA-CCL</td>
<td>Submission for Inclusion on the list of active substance suppliers (Article 95) cancellation on request</td>
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<td>AA-TRS</td>
<td>Transfer of Article 95 asset (access to active substance dossier)</td>
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<td>AA-UPD</td>
<td>Scientific data update of inclusion in Article 95 (active substance suppliers) list</td>
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<td>IN-REA</td>
<td>Inquiry to share data for an active substance</td>
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<tr>
<td>DI-SUB</td>
<td>Declaration of interest to notify</td>
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<tr>
<td>RP-NOT</td>
<td>Review Programme notification €</td>
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<tr>
<td>AS-EVA</td>
<td>Active substance evaluation under Regulation (EU) No 1062/2014 (Participant) €</td>
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June 2020

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 publicly 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 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.

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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’.

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 1: Where to look for the submission number

![Figure 1: Where to look for the submission number](image)

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 2: 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 3: 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 4: 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 5: 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 (AS-APP)
- amendment to the conditions of an approval (AS-CHG)

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 application types.
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 IUCLID 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.

Also, the correct [ECHA supporting document](#) available from ECHA’s website, is required to be uploaded depending on 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.
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’.

Figure 7: Launching the application ‘wizard’ for AS-UPD

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 list of application types. You will be prompted to provide a reference ‘asset number’ for the active substance.

Figure 8: Launching the application ‘wizard’ for AS-RNL

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 fulfill 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)’.

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.
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.

In addition to this, the AN-APP wizard in R4BP 3 is also used to submit applications for the amendment to the relevant restrictions on such inclusions.

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’.

This sub-chapter describes the application requirements necessary for each step of the AN-APP application wizard in R4BP 3 for both the inclusion of an active substance and the amendment to the restrictions of an active substance to Annex I to the BPR.

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 list of application types.

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**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 or amended.

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.

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

If you are applying for an amendment to the restrictions of an active substance in Annex I, then: upload the ECHA 'Supporting document for the amendment of restrictions of an active substance in Annex I'.

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 included or 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'.

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 list of application types.

![Figure 10: Launching the application 'wizard' for AN-CHG](image)

9.2. Application requirements for AN-CHG

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

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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.

### 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.
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’.

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 list of application types.

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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.

**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 manufactures 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 list of application types (Figure 7).

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.
Figure 12: Launching the application 'wizard' for AS-ACC

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 is 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 complete substance dossier, then this should be uploaded at this step.

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 in order 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 13: 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 14: 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 15: 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. Inclusion on the list of active substance suppliers (Article 95) cancellation on request

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

14.1. 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 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 16: Launching the application ‘wizard’ for AA-CCL

14.2. 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.
**Application requirements for AA-CCL**

**Set case owner details**
A contact person for the case must be specified.

**Set submission details**

**Upload other files**
You are allowed to upload documents to support your application. However, files are not mandatory for this application type.

**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. 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.

15.1. 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 . 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 17: Launching the application ‘wizard for AA-TRS**

15.2. 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.
16. 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.

16.1. 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 list of application types.

**Figure 18: Launching the application ‘wizard’ for IN-REA**

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16.2. 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.

**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.
17. 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.

17.1. 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 list of application types.

Figure 19: Launching the application 'wizard' for DI-SUB

17.2. 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.
18. Notification procedure

Review Programme notifications shall 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'.

18.1. 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 (Figure 20). You will be prompted to provide a reference ‘asset number’ for either a valid declaration of interest to notify or for a valid active substance/product type combination.

Figure 20: Launching the application ‘wizard’ for RP-NOT

18.2. 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
Select by clicking either on the active substance/product type combination or the successful declaration of interest tab.

Depending on your selection provide either the active substance name and product type or the reference asset number of the published declaration of interest.

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 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 for renewal.
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.
19. **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](https://echa.europa.eu/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'](https://echa.europa.eu/bsm-technical-guide-how-to-prepare-biocides-dossier).

### 19.1. 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 (Figure 21). You will be prompted to provide a reference ‘asset number’ for the active substance.
19.2. 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.
20. 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.

20.1. 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 22: Search for your RP asset

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

*Please select one or more of the filters above in order to find asset(s).*
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.

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](#).

### 20.2. 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.
From the details page launch your application by clicking 'Create new case' for 'PA-CHG – Change of participants'.

**Figure 26: Create a PA-CHG from an RP asset**

20.3. **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 27: Launching the application 'wizard' for PA-CHG via AS-EVA case type - first step**
20.4. 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.