ECHA
EUROPEAN CHEMICALS AGENCY

# Biocides Submission Manual

## How to submit an application for Union Authorisation

February 2024

**Disclaimer**

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

| Version | Changes | Date |
|---|---|---|
| Version 1.0 | First version | December 2014 |
| Version 2.0 | Release of R4BP version 3.3. Minor update which includes the following:<br><br>Information on Application for Union Authorisation updated in section 4.1.1 (UA-APP wizard)<br><br>Information concerning the summary of product characteristics and applications for biocidal product family included in section 2.3.2 | June 2015 |
| Version 3.0 | Release of R4BP version 3.8. New following chapters added:<br><br>6. Union authorisation major change on request<br>7. Notification of product in product family for Union authorisation<br>8. Union authorisation administrative change on request<br>9. Transfer of a Union authorisation<br>10. Union authorisation minor change on request<br>11. Union authorisation of the same biocidal product (authorised)<br><br>New sub-chapters added for chapter 3. New paragraphs added for 5.1 and 11.1 sub-chapters.<br><br>Annex I and Annex II updated.<br><br>References to IUCLID 5 removed and other minor updates included. | October 2016 |
| Version 3.1 | Release of R4BP version 3.9. New following chapters added:<br><br>3.1. Submit a single application in the context of an existing asset<br><br>3.2. Submit grouped applications for administrative changes<br><br>5. Withdrawing a case from the system<br><br>8. Notification of unexpected or adverse effect for Union authorisation<br><br>11.1.2. Information concerning the submission of a batch of administrative changes applications.<br><br>Updates in sections 6.3, 7.3, 8.3, 15.2. | June 2017 |
| Version 3.2 | Release of R4BP 3.11. Changes include:<br><br>Sub-chapters to describe all the application requirements | May 2018 |

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| | Information regarding the necessary documents updated in chapters 6.2.4, 7.2.4, 7.2.6, 8.2.5, 10,2.3 | |
| Version 3.3 | Release of R4BP 3.12.<br><br>Screenshots updated.<br><br>Manual reorganised. | October 2018 |
| Version 3.4 | Information regarding the necessary documents updated in chapters 7.2 and 8.2. | April 2019 |
| Version 3.5 | Update to reflect transition from IUCLID 6.3 to IUCLID 6.4, and from the classic user interface to the web user interface.<br><br>Annex I and II removed.<br><br>Minor changes and updates. | January 2020 |
| Version 3.6 | Corrections in Section 12.2. Application requirements for UA-NPF. | February2021 |
| Version 3.7 | Update of section 6.2 Applications requirements for UA-APP. | December 2021 |
| Version 3.8 | Update of section 5. Pre-submission application for Union authorisation (UP-APP) | February 2022 |
| Version 3.9 | Release of R4BP 3.23. New chapter added:<br>15. Cancellation of Union Authorisation upon request (UA-CCL)<br><br>New chapter added for:<br>16. Classification of a change to a product authorisation (CC-APP) | December 2022 |
| Version 3.10 | Release of R4BP 3.26. Changes include following:<br>SPC editor discontinued, instead SPCs should be prepared in IUCLID format with specific working context. | February 2024 |

**BSM: How to submit an application for Union Authorisation**

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http://echa.europa.eu/contact

**European Chemicals Agency**

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

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# 1. Introduction

## 1.1. Objective

This manual gives instructions on how to submit applications concerning Union authorisations (UA), 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 a SPC in IUCLID format is described in that technical guide.

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

### Process manuals:

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

**Process of confidentiality requests for biocide applications**, which describes how to make confidentiality claims in IUCLID and which dossier information can be claimed confidential.


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

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

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

## Additional assistance:

In addition to the Biocides Submission Manuals, 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 process under the BPR.


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

Regulatory web pages, which offer a general introduction to some of the processes under the BPR.

Q&As on R4BP 3 (e.g. account management, invoicing, submissions) and the Biocidal Products Regulation (e.g. active substance suppliers, data sharing, treated articles).


The ECHA Helpdesk, which is available for specific and general advice on the BPR, particular submissions, as well as the IT tools IUCLID, R4BP 3.

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

# 2. General submission information

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

## 2.1. Submitting an application in R4BP 3

Table 1 outlines the case abbreviations used for the application types in R4BP 3, and whether there is an associated ECHA fee (**€**). Note that when making an application for UA-APP (Union Authorisation), if the authorisation holder is established in the EU and has a recognised small and medium-sized enterprises (SME) status the applicant may be entitled to a reduced ECHA fee.

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


ECHA informs the case owner or asset owner of the fees payable and will reject the application if the fee is not paid **within 30 days**. In the case of annual fees for Union Authorisation(s), failure to pay in due time may result in the **cancellation of the Union Authorisation(s)**.
For more general information regarding ECHA fees and invoicing, please consult the R4BP 3 Q&A under R4BP 3 on invoicing and payments.
Alternatively, for full details, please refer to Annexes II and III of the BPR Fee Regulation[3].

**Table 1: Union authorisation (and related) application types**

| Case abbreviation | Application |
|---|---|
| UP-APP | Application for pre-submission |
| UA-APP | Union authorisation (including provisional) **€** |
| UA-BBP | Union authorisation of the same biocidal product (pending) **€** |
| UA-BBS | Union authorisation of the same biocidal product (authorised) **€** |
| UA-AFC | Collection of annual fee for Union Authorisations **€** |
| **IN-REB*** | **Inquiry to share data (biocidal product)** |
| UA-MAC | Union authorisation major change on request **€** |

[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.

| Case abbreviation | Application |
|---|---|
| UA-NPF | Notification of product in product family for Union authorisation |
| UE-NOT | Notification of unexpected or adverse effect for Union authorisation |
| UA-ADC | Union authorisation administrative change on request € |
| UA-TRS | Transfer of a Union authorisation € |
| UA-MIC | Union authorisation minor change on request € |
| CC-APP | Classification of a change to a product authorisation € |

*Applications for an inquiry to share data for a biocidal product are detailed in BSM Application instructions: How to submit an applicatuon for National Authorisations.

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

## 2.2. Application requirements

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


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

### 2.2.1. IUCLID dossier

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


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

### 2.2.2. A summary of product characteristics (SPC)

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


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

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

### 2.2.3. Supporting documents

Under the BPR, you often need to submit supporting documents[4] as part of your application. Depending on the type of application you are submitting, the required supporting documents will need to be attached either in your IUCLID dossier or uploaded directly in the R4BP 3 application 'wizard'. You can find direct instructions on where to include individual supporting documents relevant to your application type in the applicable chapter of this manual.

**Additional 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 SPC, draft risk assessment report, written confirmation from a proposed evaluating MSCA confirming their agreement to evaluate the application, letter of access, 'permission to refer' to data granted by ECHA under Article 63 of the BPR, or a decision on technical equivalence.

# 3. Applying 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.

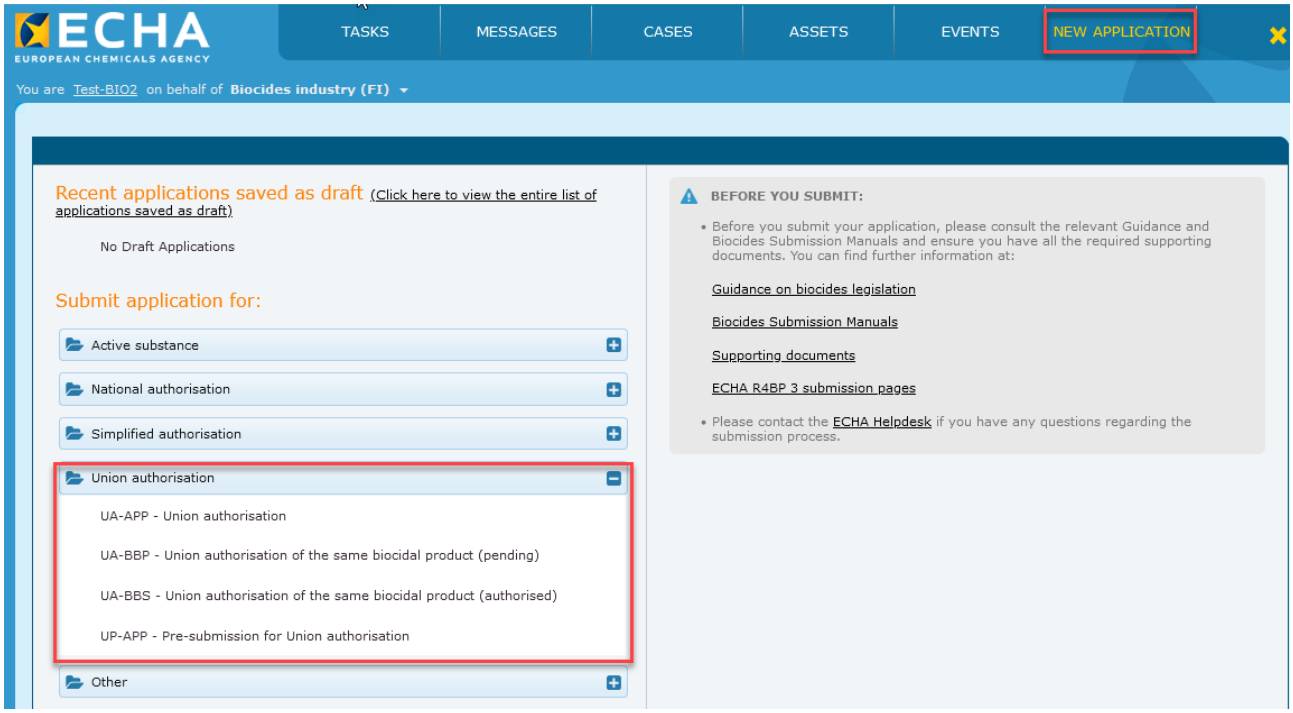
Technical guidance on using R4BP 3 can be found in BSM Technical guide: How to use R4BP 3.

## 3.1. Submitting an application in R4BP 3

### 3.1.1. Submit a single application via the 'NEW APPLICATION' tab

To launch the application wizard as a new application, click on the 'NEW APPLICATION' tab on the R4BP 3 taskbar to see the full list of application types available and select the application type you wish to apply for.

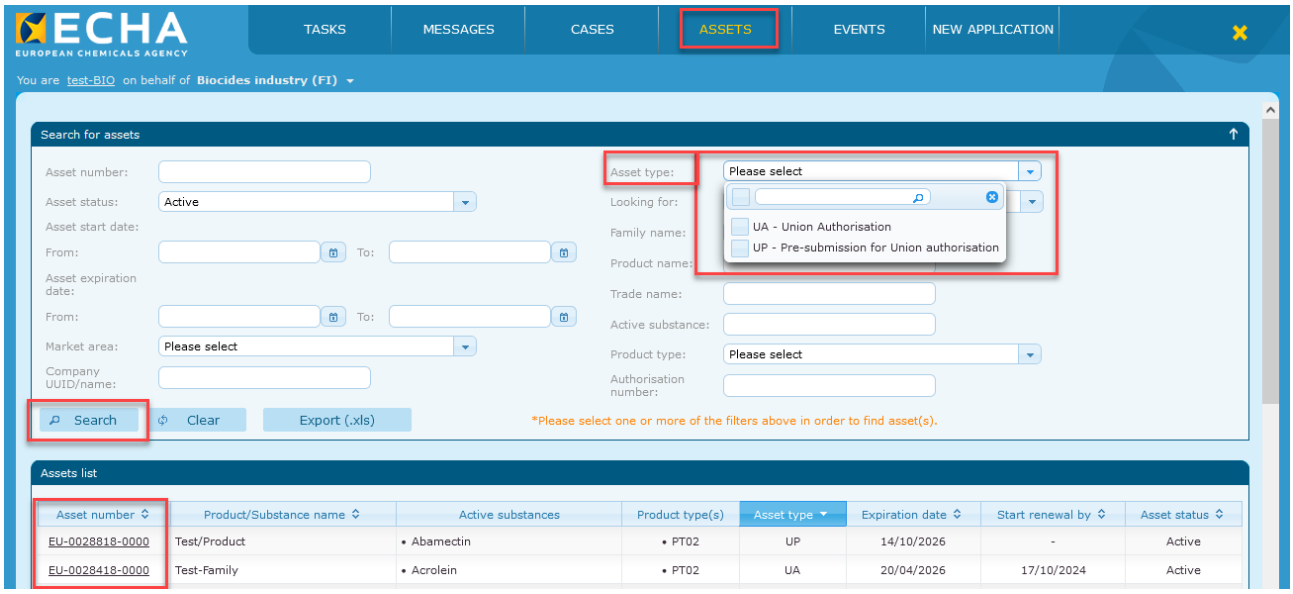
**Figure 1: Launching the application wizard via the 'NEW APPLICATION' tab**




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

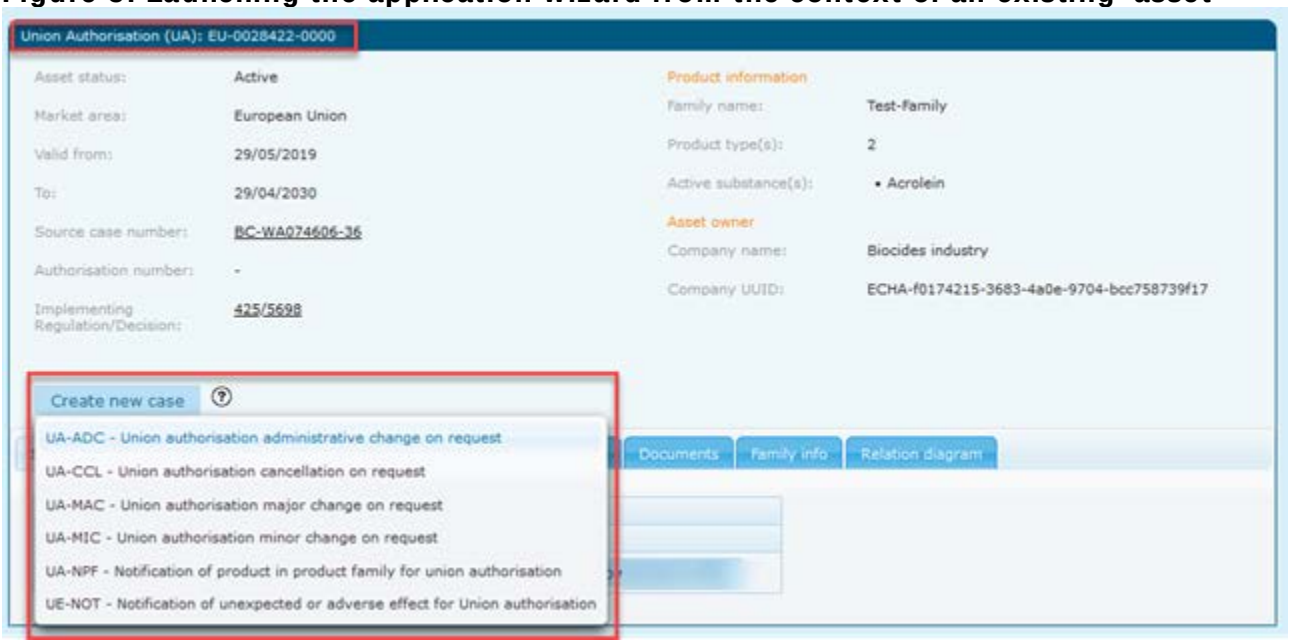
To launch the application wizard through an existing asset, click on the 'ASSETS' tab on the R4BP 3 taskbar.

**Figure 2: Submit an application in the context of an existing asset**




Search for the specific UA asset by filling in some search criterion (e.g. the asset type (UA – Union authorisation), etc.) (Figure 2). Clicking on the asset number hyperlink in the 'Assets list' will open a details page for that specific asset. On this page, click 'Create new case' and a list of application types available for that asset will appear. From this list, you can launch the wizard by selecting the relevant application for your purposes (Figure 3).

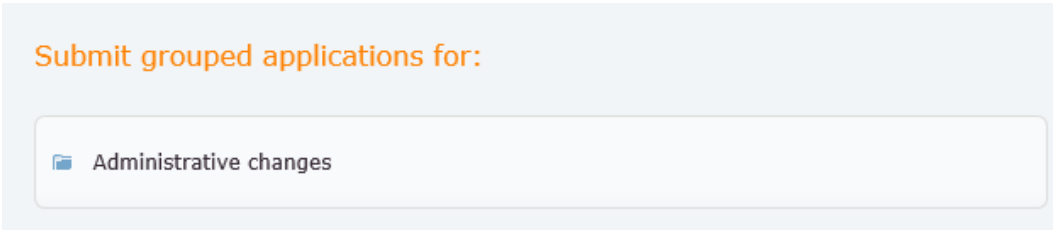
**Figure 3: Launching the application wizard from the context of an existing 'asset'**




### 3.1.3. Submit grouped applications for administrative change(s) (only for UA-ADC)

To submit several applications concerning administrative change(s) (i.e: UA-ADC), click on 'NEW APPLICATION' on the R4BP 3 toolbar, and select 'Administrative changes' to apply:

**Figure 4: Submit grouped applications for administrative changes**




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

## 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 you may need to do.

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

### 3.2.2. Monitor your case (case owner)

It is the case owner's responsibility to monitor individual cases on a regular basis. Through the 'Case details' sub tab, you can manage and view the progress of any of your submitted applications.

In addition, email alerts can also be set to inform you of the case status – this is particularly helpful if you need to react to authority requests where a deadline has been set.

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

### 3.2.3. Resubmission tasks

To make sure that an application can be processed correctly, a case owner may need to complete task items assigned by authority users (e.g. a 'Resubmit information' task). You are obliged to monitor your task items and complete them within the defined time.

You can access the task items by selecting the 'TASKS' tab on the toolbar (Please refer to BSM Technical guide: How to use R4BP 3 for full details).

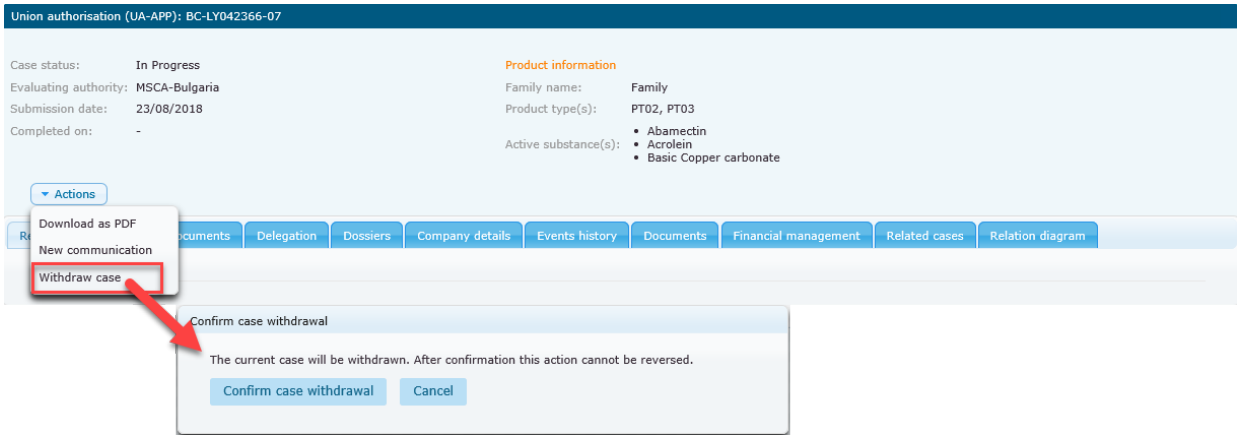
**Figure 5: Searching for a task**


Only **one** reply to a 'request information' task is permitted in R4BP 3. Please make sure that you include all the information requested in the task item. If you need more time to complete a resubmission task, you are allowed to contact the relevant authority to request an extension.

# 4. Withdrawing a case from R4BP 3

You are allowed to withdraw any in-progress applications from R4BP. Search for your case and access the case details page. Click on 'Actions' and from the drop-down list choose the related option 'withdraw case'.

**Figure 6: Withdrawing a case from R4BP 3**

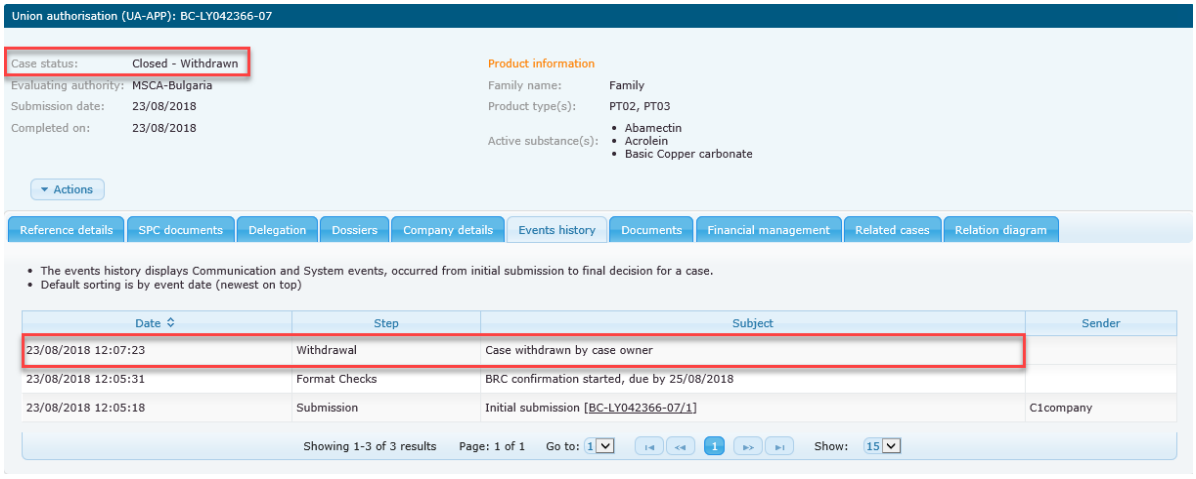



Note that this action is subject to some requirements:

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

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

**Figure 7: Case withdrawn in the event history tab**




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

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

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

# 5. Pre-submission application for Union authorisation (UP-APP)

As soon as possible and at the latest 6 months before the intended date of submission of a Union authorisation application, a prospective applicant should submit a  a pre-submission application for Union authorisation. The aim of this pre-submission is to confirm that the product falls within the scope of BPR, will have similar conditions of use across the Union, and that the appropriate product-type has been identified.

The principles and processes behind the pre-submission process for Union authorisation are described in the Practical Guide 'chapter on Union authorisation' available from ECHA's website.

## 5.1. Launching the UP-APP application wizard

Click on 'NEW APPLICATION' and submit your application for UP-APP (Figure 1).

Before making an application you will need to complete the following supporting documents :

- For all applications, the document 'pre-submission phase for Union authorisation'
- In case the application is for a **biocidal product family** (BPF), the 'overview of the biocidal product family' .

## 5.2. Application requirements for UP-APP

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

### Case owner details

A contact person for the case must be specified.

### Set submission details

Asset owner details must be specified.

### Upload SPC (.i6z)

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

### Upload other files

**In all applications, applicants are required to upload the following files:**
- A written confirmation from the evaluating MSCA stating their agreement to evaluate the application.
- The supporting document for the pre-submission phase compiled in all its sections ('Pre-submission phase for Union authorisation')

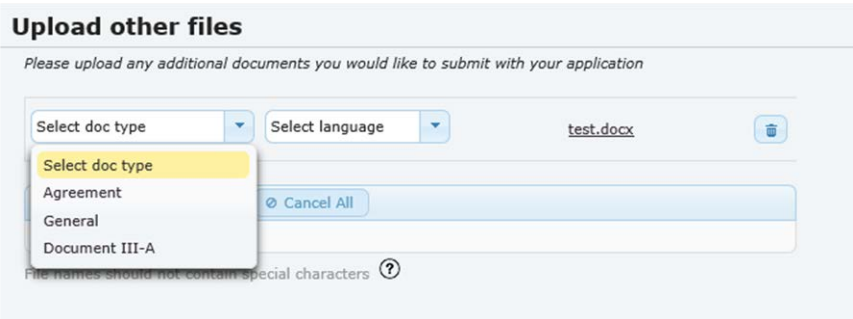
**In application for biocidal product family:**
- Upload the supporting document describing the structure of the family and its meta-SPCs 'Template overview of the biocidal product family'

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

**In application for provisional Union authorisation :** upload the supporting document 'Application for provisional authorisation'.

Please upload any other files you wish to support you application at this step.
Once you have uploaded your documents, select the relevant type.

**Figure 8: select the document 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.

# 6. Union authorisation and provisional Union authorisation (UA-APP)

An application for Union authorisation can be made by those wishing to have a biocidal product or product family to be made available and used in any Member State within the Union. A Union authorisation can only be granted for biocidal products with similar conditions of use in each Member State (Article 42 of the BPR).

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

**Provisional Union authorisation:** According to Article 55(2) of the BPR, an authorisation for a biocidal product containing a new active substance may, under certain conditions, be provisionally granted. An application for provisional authorisation may be submitted when the dossier for a new active substance approval has been evaluated and the evaluating Competent Authority has submitted a recommendation to ECHA for approval in its assessment report (CAR). Additionally, the CAR needs to pass the accordance check performed by ECHA.

The list of biocidal products with Union authorisation will be published on the ECHA website. The decision to grant, or refuse to grant, a Union authorisation is taken by the Commission and each decision will be published in the Official Journal of the European Union.

## 6.1. Launching the UA-APP application wizard

The applicant can launch the UA-APP wizard from an existing UP asset or from the 'NEW APPLICATION' tab.

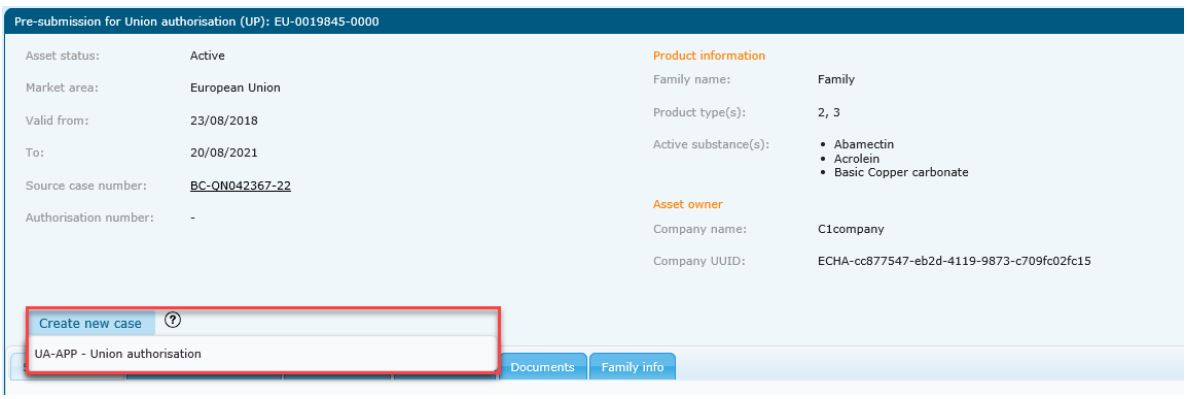
### 6.1.1. Launch the application wizard from an UP-APP asset

The UA-APP application wizard can be launched through an existing 'UP' asset granted to you after a successful pre-submission for Union authorisation.

Click on the 'ASSETS' tab on the R4BP 3 toolbar. Then, search for the specific UP asset by filling in some search criterion (e.g. the asset type (UP – Pre-submission for Union authorisation) (Figure 2).

Clicking on the asset number hyperlink in the 'Assets list' will open a details page for that specific asset. On this page, click 'Create new case' and a list of application types available for that asset will appear. From this list you can launch the wizard by selecting 'UA-APP - Union authorisation'.

**Figure 9: Launching the application 'wizard' for UA-APP from UP asset**



Please note that a pre-submission asset for Union authorisation is not mandatory, however it is highly recommended.
It is advised to apply for Union authorisation only after a successful pre-submission for Union authorisation, via the UA-APP application wizard.

### 6.1.2. Launching the UA-APP wizard from the 'NEW APPLICATION' tab

You can launch the UA-APP application wizard via the 'NEW APPLICATION' tab (Figure 1).

## 6.2. Application requirements for UA-APP

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


In addition to this sub-chapter, ECHA has provided guidance documents to assist you in fulfilling the information requirements for this process - Guidance on information requirements for biocides.

# Application requirements for UA-APP

### Case owner details

A contact person for the case must be specified.

### Set submission details

Evaluating authority and asset owner details must be specified. Specify the purchase order under the payment details. Billing address can be selected only if the case owner is different from the asset owner.

### Upload dossier

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

Therefore, all applicants are required to include in Section 13 of their dossier **a draft Product Assessment Report** and when relevant the following documents:

- A letter of access
- A decision on technical equivalence
- 'Permission to refer' to data granted by ECHA (BPR, Article 63).

### Upload SPC (.i6z)

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

### Upload other files

**In all applications, applicants are required to provide the following documents:**
- A written confirmation from the evaluating MSCA stating their agreement to evaluate the application;
- The outcome of the pre-submission consultation **OR**
- In the absence of pre-submission, a rationale, in the form of a self-assessment, to address the confirmation that the product would have similar conditions of use across the Union.
- The list of all existing and on-going product authorisations at national level, filling in the template 'List of existing new products for UA_NA_processes'.

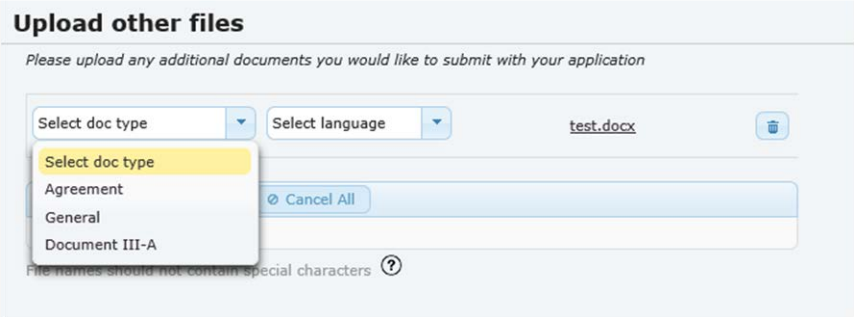
**In application for biocidal product family :**
- The supporting document describing the structure of the family and its meta-SPCs 'Template overview of the biocidal product family'.

**In application for single biocidal product :**
- In case of a single biocidal product claimed to be identical to the representative product for active substance approval, the supporting document 'Justification of the claim that the product is identical with (one of) the representative product(s)'.

**In application for** provisional Union authorisation:
- Upload the supporting document 'Application for provisional authorisation'.

Please upload any other files you wish to support you application at this step. Once you have upload the necessary document, you are required to select the relevant document type.

**Figure 10: Select thedocument 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.

## 6.3. Collection of annual fee for Union Authorisations (UA-AFC)

Annual fees are collected yearly for every biocidal product or biocidal product family authorised by the Union. Annual fees are due on the first and each subsequent anniversary of entry into force of the authorisation until its expiry. The fee relates to the preceding year.

Annual fees are collected with the case type “Collection of annual fee for Union Authorisation” in R4BP 3. The case is launched automatically before each subsequent anniversary of the relevant authorisation. Asset owner contact(s) of the respective authorisation will receive email notification(s) about the annual fee invoice available in financial management tab of the case in R4BP 3. The asset owner legal entity contact information has to be up to date to receive email notification(s).

The payment deadline for annual fees is 30 days and failure to pay in due time may result in the **cancellation of the Union Auhtorisation**.

# 7. Union authorisation of same biocidal product (UA-BBP)

Individual applications can be made for UA of same biocidal products or product families when the Union authorisation for the related reference product is currently being processed i.e. **pending authorisation**. In this case, the application 'UA-BBP - Union authorisation of same biocidal product (pending)' application should be submitted[5].

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

Commission Implementing Regulation (EU) No 414/2013 (the 'same BP Regulation') allows the authorisation, in a given Member State, of a BP or product family ('same product') which is identical to another BP or product family already authorised, or pending authorisation, in that Member State ('related reference product'). This is provided that the relevant biocidal products or product families are shown to be identical, and therefore one product evaluation is deemed sufficient.

## 7.1. Launching the UA-BBP application wizard

You can launch the application 'UA-BPP – Union authorisation for the same biocidal product (pending)' from the 'NEW APPLICATION' tab on the R4BP 3 toolbar and select UA-BBP –Union authorisation for the same biocidal product (pending) (Figure 1).

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

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

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

UA single SPC attached to UA-BBS/UA-BBP applications applies to the Union authorisation for the same **single biocidal product**.
The conditions of authorisation for the 'same' biocidal product will be the same as for the UA of the related reference product.

## 7.2. Application requirements for UA-BBP

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

The full information requirements are laid out in Article 2 of the Commission Implementing Regulation (EU) No 414/2013 (the 'same BP Regulation'[6]).

**Application requirements for UA-BBP**

[5] Applications for UA of same biocidal products or families will also be possible after the initial UA is granted, i.e. in sequence.

[6] 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

### Set reference details

The 'reference case number' will only be available to you if you are the same entity as the proposed authorisation holder/case owner for the related reference product.

If the applicant is a different company it will need to approach the company with the pending authorisation for the related reference product, to obtain the 'reference case number'. A valid delegation from the owner of the reference case is required in R4BP 3 when submitting the UA-BBP application.

### Case owner details

A contact person for the case must be specified.

### Set submission details

Specify the purchase order under the payment details. Case owner details cannot be specified because the invoice is sent to the asset owner.

### Upload SPC (.i6z)

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

### Upload other files

**In all applications:**
- Supporting document 'Application for authorisation of the same biocidal product under Regulation (EU) No 414/2013 [DOC]'
- The list of all existing and on-going product authorisations at national level, filling in the template 'List of existing new products for NA_UA processes'.

**Where relevant,** applicants are required to upload the following documents:

- decision on technical equivalence
- letter of access
- 'Permission to refer' to data granted by ECHA (BPR, Article 63).
- any other document relevant to your application

### Confirm application

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

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

## 7.3. Collection of annual fee for Union Authorisations (UA-AFC)

Annual fees are collected yearly for every biocidal product or biocidal product family authorised by the Union. Annual fees are due on the first and each subsequent anniversary of entry into force of the authorisation until its expiry. The fee relates to the preceding year.

Annual fees are collected with the case type “Collection of annual fee for Union Authorisation” in R4BP 3. Case is launched automatically before each subsequent anniversary of the relevant authorisation. Asset owner contact(s) of the respective authorisation will receive email notification(s) about the annual fee invoice available in financial management tab of the case in R4BP 3. Asset owner legal entity contact information has to be up to date to receive email notification(s).

The payment deadline for annual fees is 30 days and failure to pay in due time may result in the **cancellation of the Union Auhtorisation**.

# 8. Union authorisation of the same biocidal product (authorised) (UA-BBS)

An application for Union authorisation of the same authorized biocidal product, can be submitted by the authorization holder, when he wishes to make available to a market a similar biocidal product. The case type of UA-BBS can be submitted through active assets of Union authorisation. The UA-BBS case type will be valid for Single and Family assets including Family member assets.

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

## 8.1. Launching the UA-BBS application wizard

Launch the UA-BBS application wizard by clicking the 'NEW APPLICATION' tab on the R4BP 3 toolbar. Then, select 'UA-BBS – Union authorisation of the same biocidal product (authorised) from the list of application types (Figure 1). You will be prompted to provide a reference 'asset number'. It is important to note that when you are creating a UA-BBS single product starting from a family, it is mandatory to insert the asset of the member of the family as reference asset in the submission wizard.

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

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

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

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

UA single SPC attached to UA-BBS/UA-BBP applications applies to the Union authorisation for the same **single biocidal product**.
The conditions of authorisation for the 'same' biocidal product will be the same as for the UA of the related reference product.

## 8.2. Application requirements for UA-BBS

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

### Set reference details

The 'reference case number' will only be available to you if you are the same entity as the proposed authorisation holder/case owner for the related reference product.

Specify the Union authorisation asset number in the Reference asset number field.

### Case owner details

A contact person for the case must be specified.

### Set submission details

Specify the purchase order under the payment details. Case owner details cannot be specified because the invoice is sent to the asset owner.

### Upload SPC (.i6z)

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

### Upload other files

**In all applications:**
- Supporting document 'Application for authorisation of the same biocidal product under Regulation (EU) No 414/2013 [DOC]'
- The list of all existing and on-going product authorisations at national level, filling in the template 'List of existing new products for NA_UA processes'.

**Where relevant:** upload a
- decision on technical equivalence
- letter of access
- 'Permission to refer' to data granted by ECHA (BPR, Article 63).
- any other document relevant to 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.

## 8.3. Collection of annual fee for Union Authorisations (UA-AFC)

Annual fees are collected yearly for every biocidal product or biocidal product family authorised by the Union. Annual fees are due on the first and each subsequent anniversary of entry into force of the authorisation until its expiry. The fee relates to the preceding year.

Annual fees are collected with the case type “Collection of annual fee for Union Authorisation” in R4BP 3. Case is launched automatically before each subsequent anniversary of the relevant authorisation. Asset owner contact(s) of the respective authorisation will receive email notification(s) about the annual fee invoice available in financial management tab of the case in R4BP 3. Asset owner legal entity contact information has to be up to date to receive email notification(s).

The payment deadline for annual fees is 30 days and failure to pay in due time may result in the **cancellation of the Union Auhtorisation**.

# 9. Union authorisation major change on request (UA-MAC)

An application for Union authorisation major change on request can be made by any authorisation holder or the nominated case owner based on Union authorisation assets. Major changes refer to changes regarding biocidal product, micro-organism or active substance.

The principles and processes behind Union authorisation major change on request are described in the Practical Guide 'chapter on Changes of biocidal products' available on ECHA's website.

## 9.1. Launching the UA-MAC application wizard

Launch the UA-MAC application wizard by clicking first the 'ASSETS' tab on the R4BP 3 toolbar (Figure 2).

Search for the specific asset number by filling in some search criterion, e.g. the asset type. Click on the asset number hyperlink in the 'Assets list' to open a details page for that specific asset (Figure 3).

## 9.2. Application requirements for UA-MAC

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

### Case owner details

A contact person for the case must be specified.

### Set submission details

Specify the purchase order under the payment details. Case owner details cannot be specified because the invoice is sent to the asset owner.

### Upload dossier

The dossier must fulfil all of the information requirements laid out in Article 20 of the BPR. All applicants must include the following attachments in Section 13 of their IUCLID dossier:

- A letter of access
- A decision on technical equivalence
- A 'permission to refer' to data granted by ECHA (BPR, Article 63)
- An ECHA opinion on classification of changes

### Upload SPC (.i6z)

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

### Upload other files

Please upload any other files you wish to support your application at this step. Upload the supporting document for the 'Application of a major change of a union authorisation'.

### 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. Union authorisation minor change on request (UA-MIC)

An application for Union authorisation minor changes can be made by any authorisation holder based on Union authorisation assets. The case type of UA-MIC will be valid for Single and Family assets excluding Family member assets.

## 10.1. Launching the UA-MIC application wizard

Launch the UA-MIC application wizard by clicking first the ‘ASSETS’ tab on the R4BP 3 toolbar (Figure 2).

Search for the specific 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 3).

On this page, click ‘Create new case’ and a list of application types available for that asset will appear. From this list, you can launch the wizard by selecting ‘UA-MIC – Union authorisation minor change on request’ (Figure 3).

## 10.2. Application requirements for UA-MIC

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

# Application requirements for UA-MIC

### Case owner details

A contact person for the case must be specified.

### Set submission details

Specify the purchase order under the payment details. Case owner details cannot be specified because the invoice is sent to the asset owner.

### Upload dossier

The dossier must fulfil all of the information requirements laid out in Article 20 of the BPR. You are required to include the following attachments in Section 13:

- A letter of access
- A decision on technical equivalence
- A 'permission to refer' to data granted by ECHA (BPR, Article 63)
- An ECHA opinion on classification of changes

### Upload SPC (.i6z)

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

### Upload other files

Please upload any other files you wish to support you application at this step. Upload the supporting document for the 'Application of a minor change of a union authorisation'.

### 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. Union authorisation administrative change on request (UA-ADC)

An application for Union authorisation administrative change on request can be made by any authorisation holder based on Union authorisation assets. The case type of UA-ADC will be valid for Single and Family assets excluding Family member assets.

## 11.1. Launching the UA-ADC application wizard

### 11.1.1. For a single application

Launch the UA-ADC application wizard by clicking first the 'ASSETS' tab on the R4BP 3 toolbar (Figure 2).

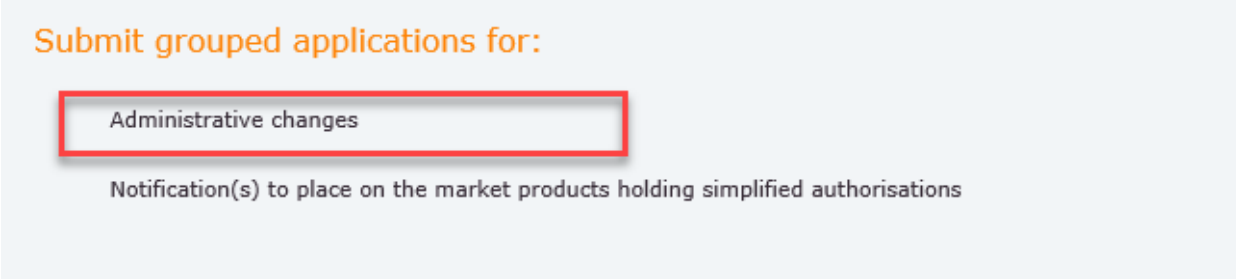
Search for the specific asset number by filling in some search criterion, e.g. the asset type. Clicking on the asset number hyperlink in the 'Assets list' will open a details page for that specific asset (Figure 3).

On this page, click 'Create new case' and a list of application types available for that asset will appear. From this list, you can launch the wizard by selecting 'UA-ADC – Union authorisation administrative change on request' (Figure 3).

### 11.1.2. For a batch of applications

To submit several applications concerning administrative change(s), click on the 'new application' tab on the R4BP 3 toolbar, and select "Apply for grouping administrative change(s)" at the bottom of the page.

**Figure 11: Submitting a batch of applications**




## 11.2. Application requirements for UA-ADC

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

### Case owner details

A contact person for the case must be specified.

### Set submission details

Specify the purchase order under the payment details. Case owner details cannot be specified because the invoice is sent to the asset owner.

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

### Upload SPC (.i6z)

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

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

### Upload other files

Please upload any other files you wish to support you application at this step. Upload the supporting document for the 'Application for an administrative change of a union/simplified authorisation'.

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

### Confirm application

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

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

# 12. Notification of product in product family for Union authorisation (UA-NPF)

Notification of product in product family for Union authorisation can be made by any authorisation holder based on Union authorisation assets.

## 12.1. Launching the UA-NPF application wizard

Launch the UA-NPF application wizard by clicking first the ‘ASSETS’ tab on the R4BP 3 toolbar (Figure 2).

Search for the specific family asset number by filling in some search criterion, e.g. the asset type. Clicking on the asset number hyperlink in the ‘Assets list’ in order to open a details page for that specific asset (Figure 3).

On this page, click ‘Create new case’ and a list of application types available for that asset will appear. From this list, you can launch the wizard by selecting ‘UA-NPF – Notification of product in product family for Union authorisation’ (Figure 3).

## 12.2. Application requirements for UA-NPF

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

### Case owner details

A contact person for the case must be specified.

### Set submission details

Specify the purchase order under the payment details. Case owner details cannot be specified because the invoice is sent to the asset owner.

### Upload SPC (.i6z)

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

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

Only one draft SPC can be uploaded including both already authorised family members and new family member(s) to be assessed as part of your UA-NPF application.
The relevant notification fee will be applied based on the number of additional products notified in the application (one notification fee per each notified additional product).

Please upload the draft SPC(s) in English and all other official languages of the Union.

### Upload other files

Upload the supporting document for 'Notification of a product in a biocidal product family' and any other files you wish to support you application at this step.

### Confirm application

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

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

# 13. Notification of unexpected or adverse effect for Union authorisation (UE-NOT)

The notification of unexpected or adverse effect for Union authorisation is made by the holder of a Union authorisation. The holder of a Union authorisation should without any delay notify the Commission or the Agency of any information that may affect the authorisation concerning the authorised biocidal product or the active substance it contains.

## 13.1. Launching the UE-NOT application wizard

Launch the UE-NOT application wizard by clicking first the ‘ASSETS’ tab on the R4BP 3 toolbar (Figure 2).

Search for the specific 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 3).

On this page, click ‘Create new case’ and a list of application types available for that asset will appear. From this list, you can launch the wizard by selecting
‘UE-NOT – Notification of unexpected or adverse effect for Union authorisation’ (Figure 3).

## 13.2. Application requirements for UE-NOT

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

### Case owner details

A contact person for the case must be specified.

### Set submission details

Specify the purchase order under the payment details. Case owner details cannot be specified because the invoice is sent to the asset owner.

### Upload other files

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

### Confirm application

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

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

# 14. Transfer of a Union authorisation (UA-TRS)

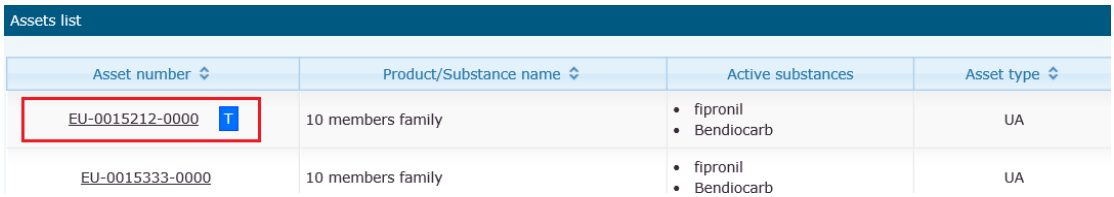
An application for Transfer of a Union authorisation can be submitted by an authorization holder of an active asset of Union authorisation, when he wishes to transfer this asset to another company. The case type of UA-TRS will be valid for Single and Family assets excluding Family member assets.

## 14.1. Launching the UA-TRS application wizard

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

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

**Figure 12: Launching the application 'wizard' for UA-TRS**




## 14.2. Application requirements for UA-TRS

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

### Case owner details

A contact person for the case must be specified.

### Set submission details

Specify the payment details.

### Upload SPC (.i6z)

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

### Upload other files

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

### Confirm application

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

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

# 15. Cancellation of Union Authorisation upon request (UA-CCL)

An application for 'Cancellation of a Union authorisation upon request' can be submitted by an authorisation holder of an active asset of Union authorisation, when they wish to cancel the relevant Union Authorisation (UA) asset. The case type UA-CCL will be valid for Single and Family assets, but not for Family member assets.

## 15.1. Launching the UA-CCL application wizard

Launch the UA-CCL application wizard by clicking first the 'ASSETS' tab on the R4BP 3 toolbar.

Search for the specific asset number by filling in some search criterion, e.g. the asset type. Click on the asset number hyperlink in the 'Assets list' to open a details page for that specific asset.

On this page, click 'Create new case' and a list of application types available for that asset will appear. From this list, you can launch the wizard by selecting 'UA-CCL – Union authorisation cancellation on request'

## 15.2. Application requirements for UA-CCL

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

### Case owner details

A contact person for the case must be specified.

### Set submission details

Specify the purchase order under the payment details. Case owner details cannot be specified because the invoice is sent to the asset owner.

### Upload other files

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

### Confirm application

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

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

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

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

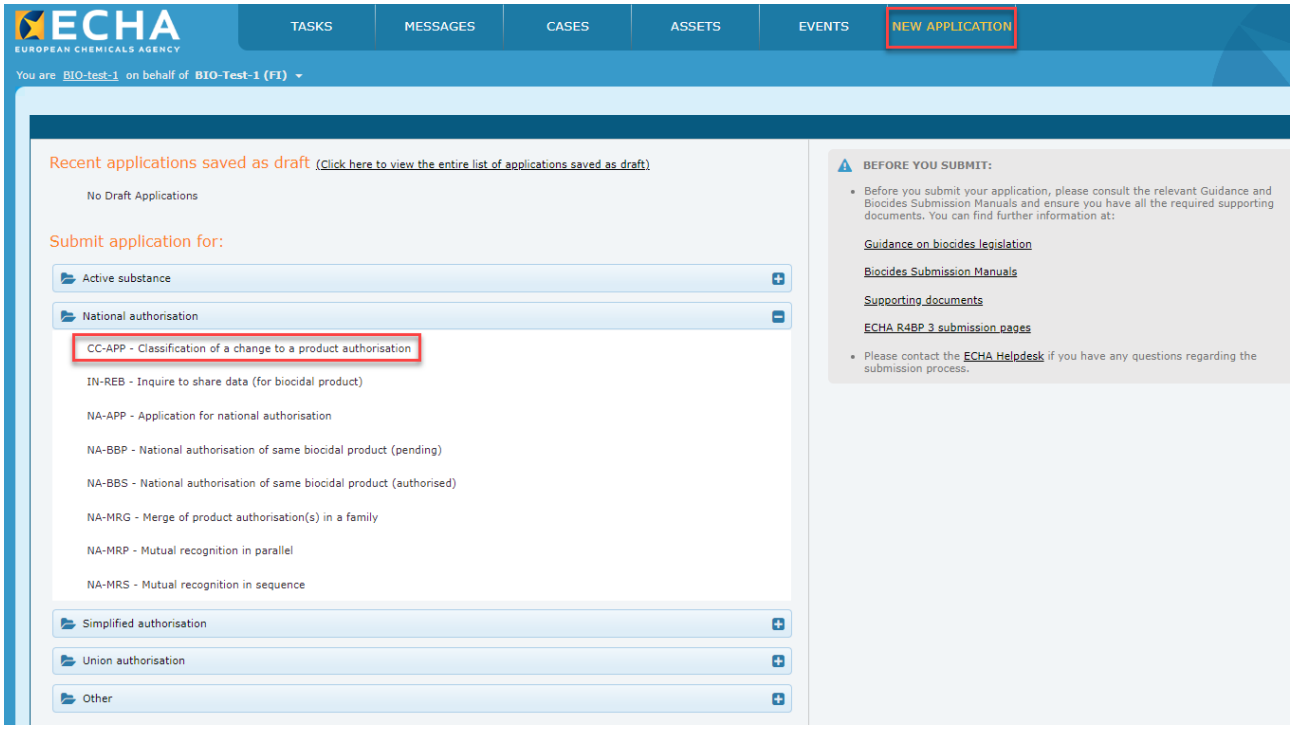
ECHA's opinion on the classification of the change sought will be published on ECHA's website.

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

## 16.1. Launching the CC-APP application wizard

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

**Figure 13: Launching the application 'wizard' for CC-APP**




## 16.2. Application requirements for CC-APP

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

# Application requirements for CC-APP

### Case owner details

A contact person for the case must be specified.

### Set submission details

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

### Upload other files

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

**Where relevant**, upload:

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

### Confirm application

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

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

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