Biocides Submission Manual
How to use R4BP 3

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	
Version 1.0	First version	August 2013
Version 2.0	Updated manual to coincide with the release of R4BP 3.1. Main changes include enhanced submission message in the application wizard and authority request task items. In general, an improved layout and design including extra summary sheets and previous summary sheets updated. A glossary containing terms, definitions and identifiers applicable to the whole BSM series can now be found at the end of the manual.	April 2014
Version 2.1	Screenshots updated to reflect R4BP 3.1.2 release. Summary sheets removed and incorporated into the text.	June 2014
Version 3.0	Release of R4BP 3 version 3.2 changes include the following: - Change manual title in line with the BSM series - Removed reference to REACH-IT for accounts management which is now replaced by ECHA Accounts (section 2.3) - New features include delegation, nomination and transfer of assets (section 3.3.5), resubmission wizard (section 4.4.1) - Print/export feature of cases (section 3.3.2) - Restructuring of the application wizard (section 4.2)	December 2014
Version 3.1	Minor update to correct typos and to describe the process of asset transfer, section 3.3.5.5, more clearly.	February 2015
Version 4.0	Release of R4BP 3 version 3.3. Minor update which includes the following: - Information on Asset transfer updated in section 3.3.5.5, regarding parallel trade (PP) assets.	June 2015
Version 5.0	Release of R4BP 3 version 3.8. The entire manual has been restructured and updated.	January 2017
Version 6.0	Release of R4BP 3 version 3.9. Changes include the following: - Minor changes in the Case and Asset search functionalities (section 5.2.1 and section 5.3.1) - Additional chapter regarding the grouped submission (section 6)	June 2017

	- Include a case in an existing grouped submission (section 6.2) - Submit a batch of administrative change(s) (section 7) - Description of steps to be performed in the application wizard (section 8.4, 8.5, 8.6, 8.7, 8.9, 8.11, 8.14) - Withdraw a case from R4BP (section 10) - Accept an asset transfer (section 11.4.2) - Initiate and accept a case transfer (section 11.5.1 and 11.5.3)	
Version 7.0	Release of R4BP 3 version 3.10. Changes include the following: - Update of all possible actions in R4BP (section 2.2.2.) - Changes in the Case search functionalities (section 5.2.2.1.) - Additional features in the Case details page (section 5.2.2.2.) - Changes in the Assets search functionalities (section 5.3.2.1.) - Additional features in the Asset details page (section 5.3.2.2.) - Create a grouped submission in R4BP, prior and after the creation of an NA asset (section 6.1.1. and 6.1.2.) - Submit a batch of notification for placing on the market (section 7.2.) - Description of steps to be performed in the application wizard in order to submit a batch of notification for placing on the market (section 8) - Update of progress status messages (section 9.3.3.) - Changes regarding the 'search for messages' and 'message lists' features (section 9.3.) - Redefinition of Active substance (section 12.5.)	November 2017
Version 8.0	Release of R4BP 3 version 3.11. Changes include the following: - Remember search/filter results (section 5.2.2.1. and section 5.3.2.1.) - Display PT(s) information on case and asset results (section 5.2.2.1. and section 5.3.2.1.) - Progress bar in the wizard (section 8.) - Remove an asset from the selection when initiating a batch of administrative changes (section 8.1.6.) - Select Document III-A option *section 8.1.14.) - Save an application before submitting (section 8.2.) - Messaging functionality (section 10.)	May 2018

Version 9.0	Release of R4BP 3.12. Changes include the following: - Screenshots updated to reflect the changes in the user interface - Print-to-word functionality added in sections 5.2.2.2. and 5.3.2.2. - Downloading a PDF file to see the list of participants in section 5.2.2.2.(only for AS-EVA, AS-NAS, RP-NOT and PA-CHG cases) - The message page (section 9.3.3.): printing a communication, unarchiving a message and replying to a communication - Using the Cc function (section 10)	October 2018
Version 10.0	Release of R4BP 3.15. Changes include following: - Screenshots updated to reflect improvement of the user interface - Archiving messages functionality implemented on legal entity level (section 9) - Enhanced ad-hoc messaging functionality (section 10)	June 2020
Version 10.1	Update of references to 'ECHA Accounts portal' and 'ECHA Accounts manual for Industry Users'	December 2020
Version 11	Release of R4BP 3.22. Changes include following: - Tab dedicated to the events implemented on legal entity level - Grouped mutual recognition in sequence (NA-MRS) allowed	February 2022
Version 12	Release of R4BP 3.23. Changes include following: - At least one contact person for a case must be defined - Multiple contact persons can be identified for a case. - Only those contacts which have been identified as contact persons in the case receive the case relevant communication via email.	September 2022
Version 13	Release of R4BP 3.26 Changes include following: SPC editor discontinued, instead SPCs should be prepared in IUCLID format with specific working context.	February 2024

If you have questions or comments in relation to this document, please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at:
http://echa.europa.eu/contact

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Table of Contents

Table of Figures

List of Tables

1. Introduction

1.1. Objective

This manual gives guidance on how to navigate through the IT system of the Register for Biocidal Products version 3 (R4BP 3). It describes the functionalities of R4BP 3, explains how to submit applications under the Biocidal Products Regulation (BPR)[1] and how the Authorities process your submitted cases.

1.2. Biocides Submission Manuals

This manual is part of the Biocides Submission Manual (BSM) series which is composed of technical guides, application instructions, and specific process manuals available on the ECHA website.

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 user accounts in R4BP 3 via ECHA Accounts and gives a detailed description of the various functionalities of the system.

Application instructions:

Application instruction manual gives guidance on how to submit applications concerning various process related to active substance approvals and biocidal product authorisations.

- **How to submit an application for an active substance**

- **How to submit an application for a national authorisation**

- **How to submit simplified authorisations**

- **How to submit union authorisations**

- **How to submit an application for technical equivalence**

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 dissemination, which describes how to make confidentiality claims in IUCLID and which dossier information can be claimed confidential.

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[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. What is R4BP 3?

R4BP 3 is an IT system established and maintained by ECHA. It provides functions, which enable industry and authorities to comply with the Biocidal Products Regulation (BPR, Regulation (EU) No 528/2012) requirements and exchange information between them.

R4BP 3 consists of two independent interfaces:

- R4BP 3 Industry dedicated to **industry users**;

- R4BP 3 Authority dedicated to **authority users** (ECHA, MSCAs and the Commission).

2.1. R4BP 3 Authority interface

The R4BP 3 authority interface supports the day-to-day work in the regulatory process whereby authority users can process the applications by completing task items (e.g. sending an invoice) and communicate securely with industry users.

2.2. R4BP 3 Industry interface

The R4BP 3 industry interface is dedicated to industry users, allowing the secure submission of applications and exchange of information with authority users.

2.2.1.   Actors in R4BP 3 Industry

There are three main industry actors in R4BP 3: the **case owner**, the **asset owner** and the **participant(s)** (in the context of the Review Programme).

2.2.1.1.   Case owner

The case owner is the legal entity who is submitting an application/notification and monitoring the progress of a case, providing any additional information requested by authorities, commenting on any draft evaluation reports or opinions, etc.

In most cases, the case owner is also the asset owner. However, note that the case owner may differ from the asset owner (e.g. the case owner is a consultant appointed by an asset owner).

2.2.1.2.   Asset owner

The asset owner is the legal entity that will be the "owner" of the asset when it will be created (e.g. the (prospective) authorisation holder). The asset owner may be the same as the case owner when no representative is appointed.

> When the case owner and asset owner are different legal entities, both entities will be able to view submitted information, monitor the progress of a case and view asset details.

2.2.1.3.   Participants

Company (ies) that have an interest in substances in the review programme.

2.2.2.   Possible actions in R4BP 3 Industry

Through the industry interface, industry users can:

- see and update their own data,

- submit applications and view the status of submitted applications and payments,

- withdraw their own applications,

- delegate their own cases and/or assets,

- transfer a case/an asset to another legal entity,

- nominate an asset,

- contact the MSCA, the Commission and/or the Agency regarding their application(s),

- download documents (e.g. invoices),

- complete tasks assigned by authority users,

- receive the final decision/outcome concerning an application.

The table below identifies the necessary/possible actions for the Industry actors:

Table 1: Case owner, asset owner and participants access rights

Access rights in R4BP 3	Case owner	Asset owner	Participants
Submit applications	Y	Y	
Withdraw applications (when applicable)	Y		
Receive messages in R4BP 3	Y	Y	
Send messages to MSCA, Agency and Commission	Y		
Receive and complete task* items	Y		
View case details	Y	Y	Y
View asset details	Y	Y	
Delegate an asset		Y	
Delegate a case	Y	Y	
Transfer an asset		Y	
Transfer a case	Y	Y	
Nominate an asset		Y	
E-mail notifications*	Y	Y	

*   The asset owner will receive an e-mail notification only for major events: case approved, not approved, terminated or withdrawn.

3. User registration and login page

In order to submit an application, all users are required to register to ECHA IT tools.

3.1. New User of ECHA IT tools

'ECHA Accounts portal' allows you to log into ECHA IT tools such as R4BP 3.

If you are not a user, the creation of an account will be required. For further assistance please refer to 'ECHA Accounts Manual for Industry Users'.

3.2. Registered user of ECHA IT tools

If you have other ECHA accounts to be managed (e.g. PIC etc.), you will be redirected to the ECHA Accounts landing page after logging into 'ECHA Accounts portal'. Select 'R4BP submission tool' to access the R4BP 3 home page.

Note: All information on the creation and management of accounts can be found in 'ECHA Accounts Manual for Industry Users' available on the ECHA website.

4. R4BP 3 homepage

Once you have successfully logged in, you will access the R4BP 3 homepage, which allows you to perform certain actions.

4.1.   General features

The R4BP 3 homepage displays the following features:

Figure 1: R4BP 3 homepage

1. **ECHA logo**: click on the ECHA logo to go back to the homepage when on any R4BP 3 page.

2. **Toolbar**: the toolbar is available on all R4BP 3 pages and contains five tabs. Each tab allows you to perform certain actions or view information related to submitted applications. See section 4.2. for additional information on the toolbar.

3. **Logout**: the logout button is available ( ) at the top-right corner of the screen. This feature is available on all R4BP 3 pages.

4. **Logged in user**: the logged in 'User ID' and the industry account name are displayed in the top left corner. A drop-down list is available and allows you to select the company on whose behalf you wish to work on. When selecting another company, the system will automatically filter and display the data according to the selected company (cases, assets, messages, tasks, etc.).

5. **R4BP News**: when relevant, it displays the latest news regarding R4BP 3.

6. **Tasks due to expire**: a list of tasks that are due to expire within the next ten days are displayed.

7. **Good to know**: a list of useful definitions and other useful information can be found on the yellow 'Good to know' box.

8. **My messages**: the ten latest messages are displayed. Red messages indicate that the message has not been read yet. Click on 'see all messages' to access the message box.

9. **Terms of service**: the terms of service can be read by clicking on the 'Terms of Service' hyperlink at the bottom right of the page.

4.2. R4BP 3 toolbar

Once you have familiarized yourself with the homepage, you can start using the toolbar to perform actions and view information related to your applications. The toolbar is available on all R4BP 3 pages and contains five tabs:

Figure 2: R4BP 3 toolbar

1. **TASKS**: a task is a working item related to a particular case number that is assigned to a specific case or asset owner's account. Click on the 'TASKS' tab to see all the tasks assigned to you. See section 9.4. for additional details on the tasks tab.

2. **MESSAGES**: during the application process, authority users will send messages to the case owner (or asset owner, depending on the case type), providing updates or requesting further information in the context of a case. As of November 2017, Industry users are allowed to send messages to the authorities too. The 'MESSAGES' tab enables you to keep track of your correspondence with the Authorities. For additional information on messages, see section 9.3. and section 10.

3. **CASES**: once you have submitted an application through R4BP 3, a corresponding case with a unique number (i.e. a case number, to identify it) will be created. A case encompasses all of the steps in the application process, which leads to the creation, or the update, of an asset (the regulatory decision). Click on the 'CASES' tab to consult the list of your existing case and monitor the progress of a submitted application. For additional information on cases, see section 5.2.

4. **ASSETS**: an asset is a regulatory decision on an application related to either an active substance (e.g. approval of an active substance, decision on technical equivalence, etc.) or a biocidal product (e.g. a national authorisation, a union authorisation, etc.). The asset owner will receive a unique asset number once the asset has been authorised. The asset owner may be the same as the case owner where no representative is appointed. Click on the 'ASSETS' tab to see your existing assets list. For additional information on assets, see section 5.3.

5. **EVENTS**: an event is a step whereby information is submitted that is needed in the handling / processing of an application. Examples include the submission of an application, the submission of additional information on the request of the authorities, fee payment, and the communication of a decision.

6. **NEW APPLICATION**: click on 'NEW APPLICATION' to display a list of application types. Click on any of these application types to launch the corresponding application 'wizard'. If you wish to start a new application, see section 5.

5. Individual applications in R4BP 3

This chapter gives a general overview on how applicants can launch the submission wizard in R4BP 3 and submit an individual application to the Authorities.

Depending on the application type, a case owner can submit an application either via the 'NEW APPLICATION' tab or via the 'Asset/Case details' page.

Details how to submit a specific application type and what steps to expect in the wizard are provided in the Biocides Submission Manuals application instructions available on the ECHA website.

5.1. Create a single application (not related to an existing asset/case)

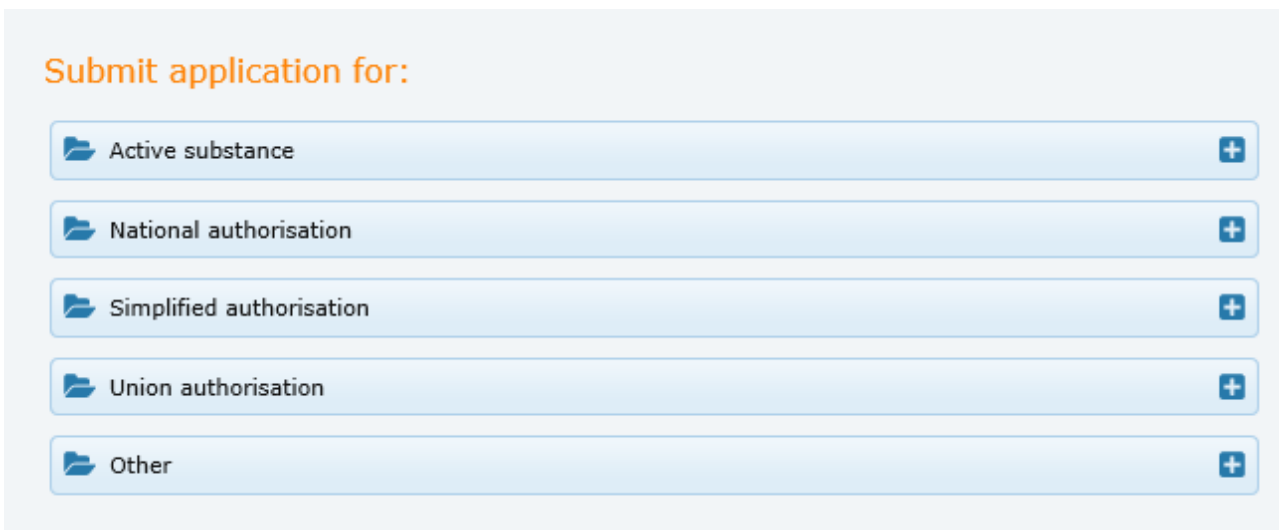To submit a new application (typically one that is **not related to an existing asset or case**) click on the 'NEW APPLICATION' tab on the R4BP 3 toolbar.

Figure 3: 'NEW APPLICATION' tab

Select the type of application you wish to submit.

Figure 4: 'NEW APPLICATION' page

The relevant application wizard (see section 8) will be launched to guide you through the application submission process.

5.2.   Create a new application (related to an existing case)

For submissions that are related to an 'in-progress' case and to which you have access (i.e. you own or have permission to use the appropriate case number), you may launch the application wizard through the 'NEW APPLICATION' tab or the relevant case.

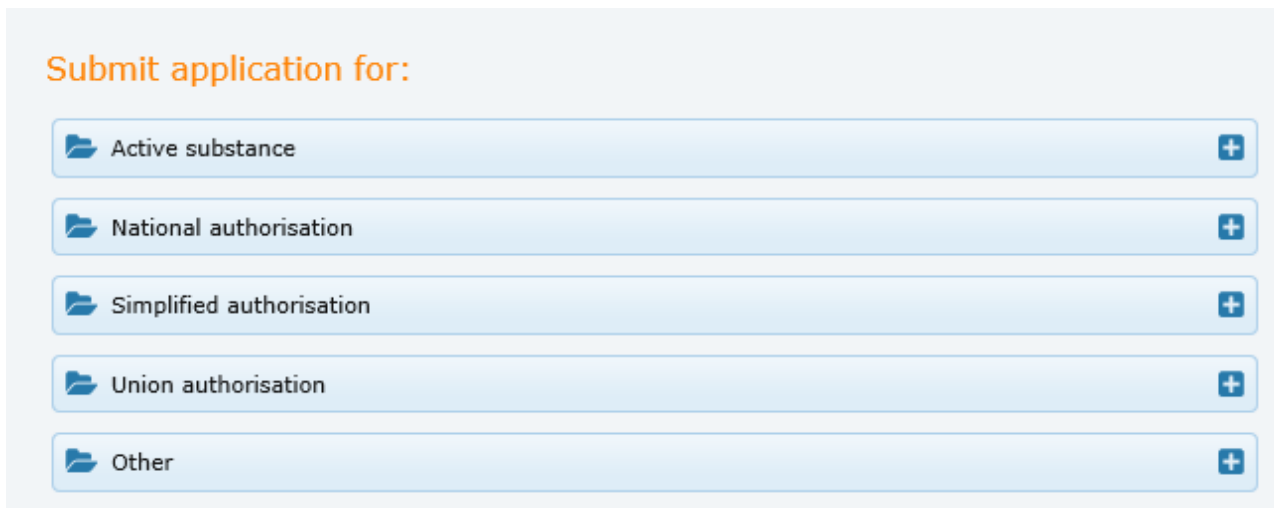### 5.2.1.   Create a new application from the 'NEW APPLICATION' tab

On the R4BP 3 toolbar, select 'NEW APPLICATION'.

Figure 5: 'NEW APPLICATION' tab

| TASKS | MESSAGES | CASES | ASSETS | EVENTS | NEW APPLICATION |

Choose the type of application you wish to submit. Note that you may select only one application each time.

Figure 6: 'NEW APPLICATION' page

Submit application for:

- Active substance
- National authorisation
- Simplified authorisation
- Union authorisation
- Other

The relevant application wizard (see section 8) will be launched to guide you through the application submission process.

5.2.2.   Create a new application from the relevant case details page

On the R4BP 3 toolbar, select 'CASES'.

Figure 7: 'CASES' tab

| TASKS | MESSAGES | CASES | ASSETS | EVENTS | NEW APPLICATION |

5.2.2.1.   Search for a Case

A default search will cause all your 'In-Progress' cases to be displayed in the 'My cases list'. Select one or multiple search criteria to search for a specific case:

Figure 8: Search for a specific case

1. **Case number**: enter the unique number assigned to the case.

2. **Case status**: select the status of the case (e.g. 'In Progress', 'Closed – Approved', 'Closed – Rejected', 'Closed – Not Approved', 'Closed – Terminated', 'Closed – Withdrawn' or 'Suspended') from the drop-down list.

   If the case becomes 'Closed-Approved' a corresponding asset will be created.

3. **Company UUID/name**: enter the company UUID/name for the case owner or proposed asset owner. Note that in certain cases, the case owner and proposed asset owner are the same. However, this is not always the case, e.g. the case owner may be a representative appointed by the proposed asset owner.

4. **Evaluating authority**: select the authority body that is responsible for evaluating the case. The evaluating authority may be an MSCA or ECHA (e.g. assessment of technical equivalence).

5. **Evaluating country**: if 'MSCA' has been selected as the evaluating authority, you are allowed to choose the evaluating country from the pick list.

6. **Submission date**: select the starting and/or end date of a period in which cases where submitted.

7. **Case type**: the case type corresponds to an abbreviation of the process under evaluation. Select the relevant application type (e.g. NA– APP - national authorisation, etc.) from the picklist.

8. **Looking for**: select the type of submission you are looking for (family product or single product submission).

9. **Family name**: if you are looking for a family submission, type in the family name.

10. **Product name**: type in the assigned product name.

11. **Trade name**: enter the trade name.

12. **Active Substance**: enter the active substance name.

13. **Product type**: choose the relevant product type from the pick list.

14. **Search**: once you have entered all your search criteria, click on the corresponding button to display all relevant cases. All relevant case records will be displayed in 'My cases list' (see below).

15. **Clear**: click on 'clear' to set all search criteria to their default values.

16. **Export (.xls)**: You may wish to export your search results for future reference. Click on 'Export (.xls)' to open/save your results as a .xls file.
    You can generate different .xls files depending on your preferred search criteria.

17. **My cases list:** once you have entered your search criteria, all corresponding case records are displayed in 'My cases list'.

    In addition to your case numbers, you will be able to find (when relevant):
    - The Product/Substance name
    - The active substance(s)
    - Product type(s)
    - Case type
    - Evaluating authority
    - Submission date
    - Case status

    You may notice the following icons:

    R icons indicate reference cases. However, note that this functionality is available only for grouped submissions performed simultaneously and submitted after **16/06/2017**. Click on the case number hyperlink to display the details page.

    D icons indicate delegated cases. This icon appears next to a case number in the 'case list' only if you have delegated this case to another legal entity.

⚠ R4BP 3 will retain your selected search criteria. Press the [⟳ Clear] button or logout to remove the selected criteria.

5.2.2.2.   Case details page

Depending on the case type, the case details page may contain the following information and sub-tabs:

Figure 9: Case details

1. **Header displaying the case type**, the case type code abbreviation and the assigned case number.

2. **Basic information** concerning the case (e.g. the case status, evaluating authority, submission date, SME status, etc.).

3. **'Product information'** or '**Substance information'**: displays the information provided on the submitted SPC file(s) or another IUCLID dossier. Depending on your application type, it may include the product or family name(s), trade name(s), product type(s) and active substance(s).

4. **'Create new case'**: allows applications that are relevant to the specific case to be launched.

5. Click on **'Actions'** if you wish to perform the following activities:

    *   '**Download as PDF**': generate a PDF document containing detailed information for the case (e.g. case details, Product details, Active substance details, Name and address of the case owner, Name and address of the future asset owner, Name of the case owner contact information, as well as information regarding the uploaded dossier(s) and documents when applicable).

        For AS-EVA, AS-NAS, RP-NOT and PA-CHG cases, applicants can have an overview of the participants in the downloaded PDF file.

    *   **'Withdraw case'** (visible to the case/asset owner): withdraw your in-progress applications. Section 11 describes how to withdraw your case from the system.

    *   **Initiate a 'New communication'** (visible to the case/asset owner): contact the Agency, MSCA and/or Commission regarding your in-progress or closed case. See section 10 for additional details on the messaging functionality.
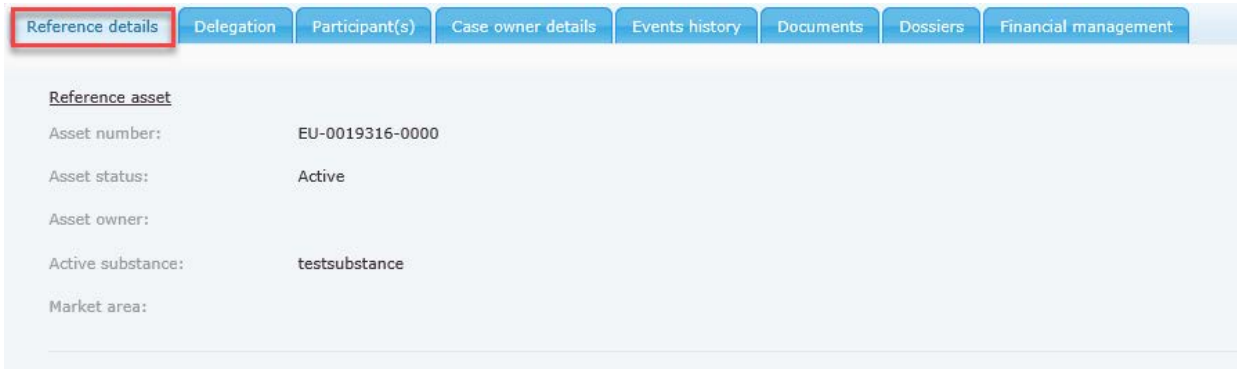
        ⚠️   Authorities are not bound to reply to your communication.

6. **Sub tabs** (*depending on the case type)*:

- **Reference details** sub-tab: displays information on the reference case and/or the reference asset. Click on the asset/case number hyperlink for more information on your reference application.

    Figure 10: 'reference details' sub-tab

- **Participant(s)** sub-tab: displays the list of participant(s) in a programme including the company name, the country, and the participant's role in the supply chain.

    Figure 11: 'Participant(s)' sub-tab
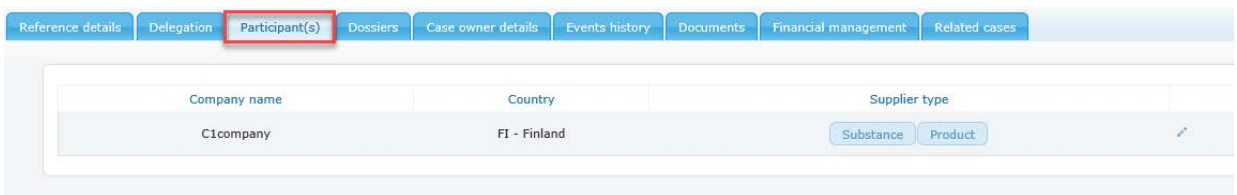
- **SPC documents** sub-tab: displays information on the uploaded SPC document(s) including the country of the evaluating authority and language(s) used in the SPC. The submitted SPC can be downloaded to PDF download to PDF , downloaded to WORD 'Download to WORD' download to WORD or downloaded in I6Z .   ↓ download in I6Z

    Figure 12: 'SPC documents' sub-tab
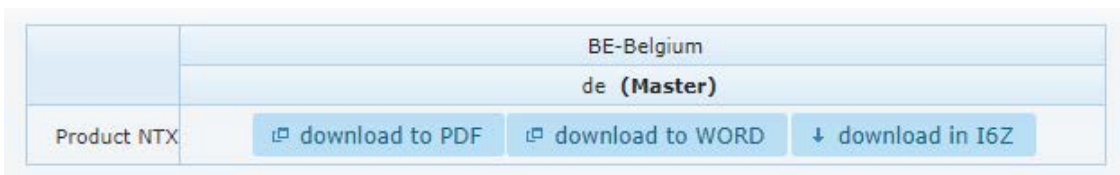
    If you have uploaded a product family SPC, click on the family name to see all the meta SPC and your product(s).

Figure 13: See the meta SPCs and relevant products
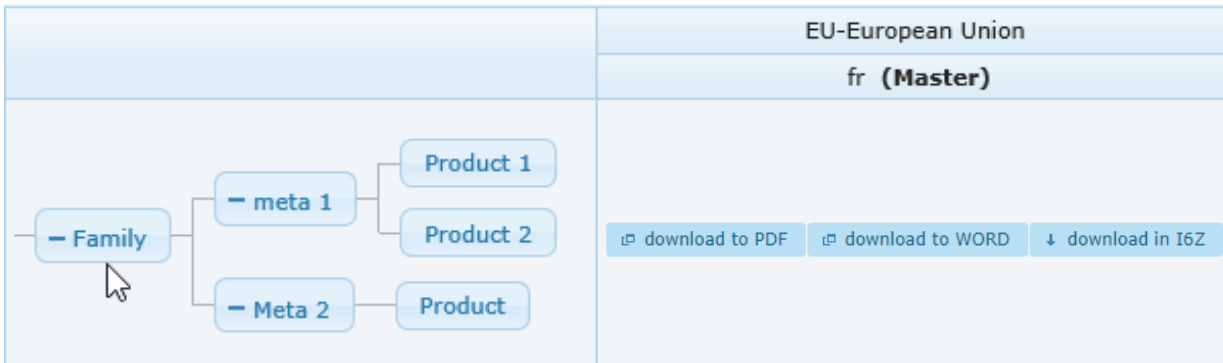
- **Dossiers** sub-tab: contains dossier details (e.g. submission number, file name, dossier UUID, etc.), the name of the entity which has submitted application and the date when the application has passed the pre-processing checks carried out by ECHA (i.e. the format check).

Figure 14: 'Dossier' sub-tab

- **Delegation** sub-tab: gives an overview of any related delegation, nomination and/or transfer requests. This includes the legal entity UUID number and the start and end date of the delegation, nomination and/or transfer. It also includes the possibility to initiate a delegation (→ Add delegation), a nomination (→ Add nomination) and/or a transfer of an asset (→ Add transfer) to another legal entity.

When adding a delegation, nomination, or transfer, you are requested to provide the legal entity UUID number and the start and end date of the delegation. For more information on delegation, nomination and transfer, please see chapter 12.

Figure 15: 'Delegation' sub-tab

- **Events history** sub-tab: outlining all of the outcomes, messages sent and actions completed in relation to this case. This is a very useful sub-tab to follow the application processing steps.

  Figure 16: 'Events history' sub tab

- **Financial management** sub-tab: allows you to view billing information, invoices and credit notes, along with the date they were sent and the status of payment.

  Figure 17: 'Financial management' sub tab

- **Documents sub-tab:** documents related to this case (e.g. supporting documents uploaded during the application process).

  It is possible to filter and sort documents displayed in the documents sub-tab using metadata fields.

  Note that the search by document name is case sensitive.

  Note that submitted dossiers and financial documents are found in their own sub-tabs.
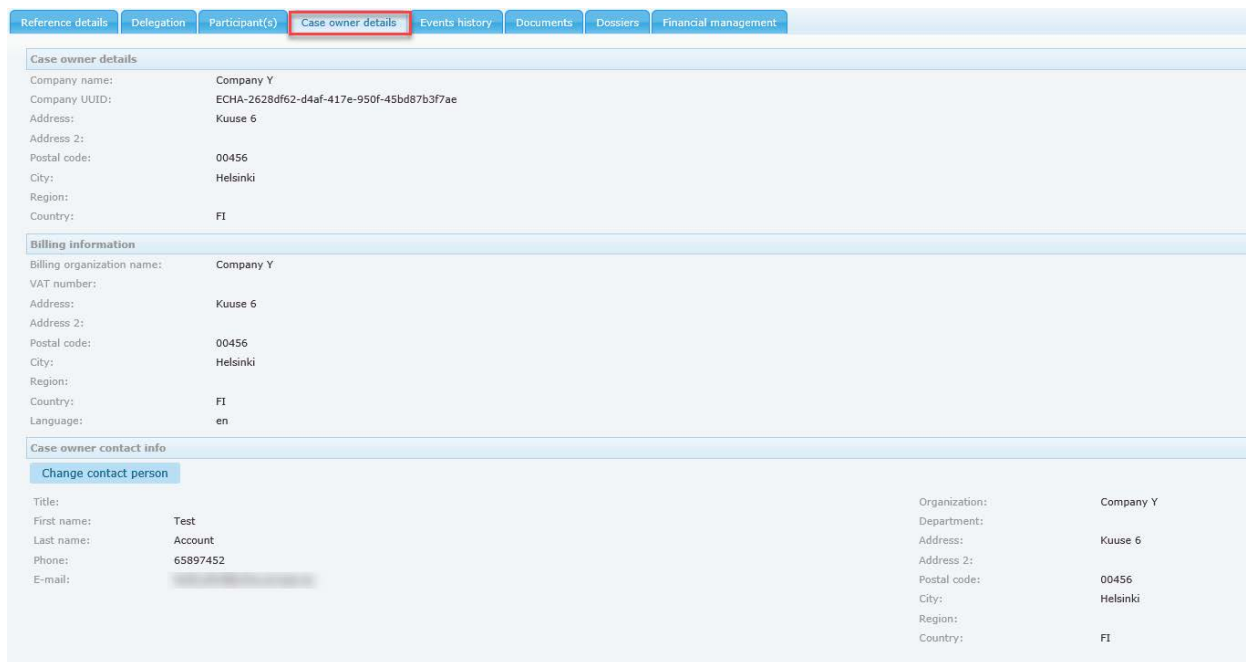
Figure 18: 'Documents' sub tab
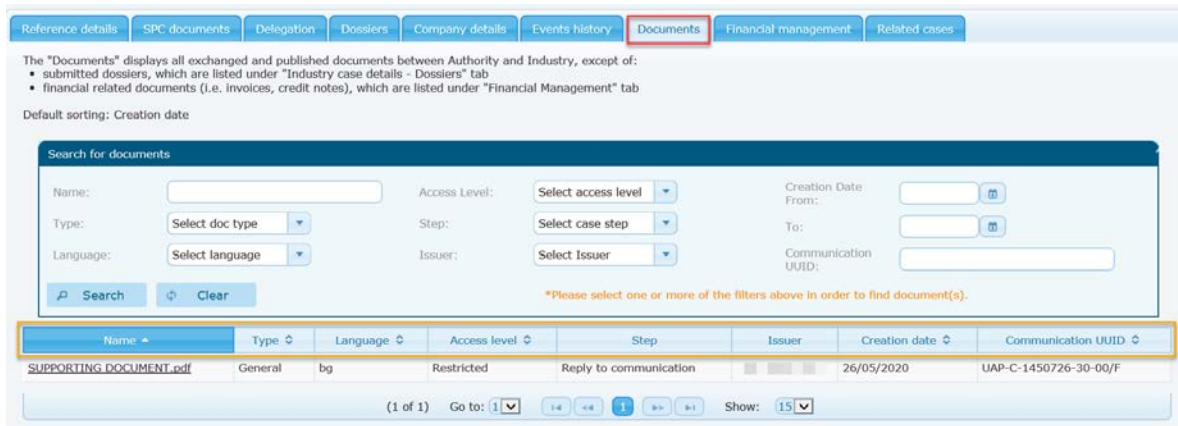
- **Company details** sub-tab: details of both the case owner and the asset owner, if different. Billing information can also be viewed here along with the designated contact person(s).

  Notice that you can also change the contact person(s) for the case from this tab.

Figure 19: 'Company details' sub-tab

- **Related cases** sub-tab: allows quick access to cases related to the case being viewed. For example, a 'Union authorisation of the same biocidal product (pending)' case can be viewed through the 'Union authorisation' case details page.

Figure 20: 'Related cases' sub-tab


For grouped submissions, the 'Grouped submissions' section allows you to identify the reference case (indicated in **bold**) and all the related case(s).
The related cases are hyperlinks, therefore you are required to click on the case number to access the submission details page.

⚠ **You can only access related cases that concern you, i.e. you are the case owner and/or asset owner of the related cases.**

- **Relation diagram** sub-tab: The diagram represents the relations between the current case and other cases and assets. It depict the whole history of submissions.

  ⚠ **Only the asset owner** will have the visibility of the diagram and only for cases that have access rights.

  ⚠ Only single and family asset numbers are presented in the diagram. Members are presented only if a back to back case (e.g. NA-MRS) has been started from a member level.

Figure 21: Case 'Relation diagram' sub tab
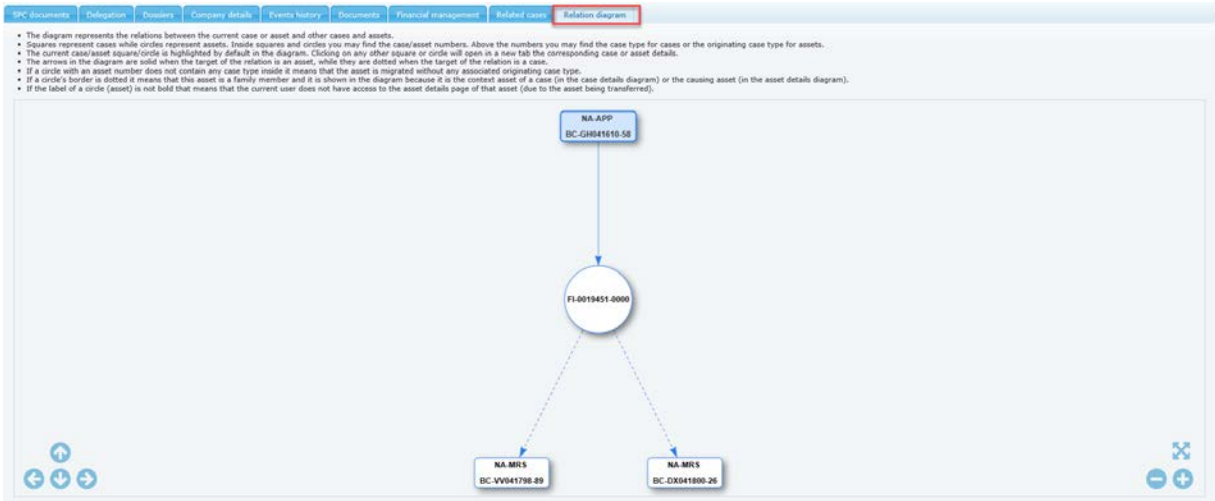
Use ⬆️🔄 to centre the diagram, and ➖➕ to zoom out/zoom in.

This feature is available only for some case types. It can be found on the case details page of the following cases:

Table 2: 'Relation diagram' availability

NA	SA	UA
NA-APP	SA-APP	UA-APP
NA-MRP	SA-BBS	UA-BBS
NA-MRS	SA-BBP	UA-BBP
NA-BBS		
NA-BBP		

5.2.2.3.   'Create new case' option

When you have gained access to the case details, click on 'create new case' to launch the application wizard.

Figure 22: 'Create new case'
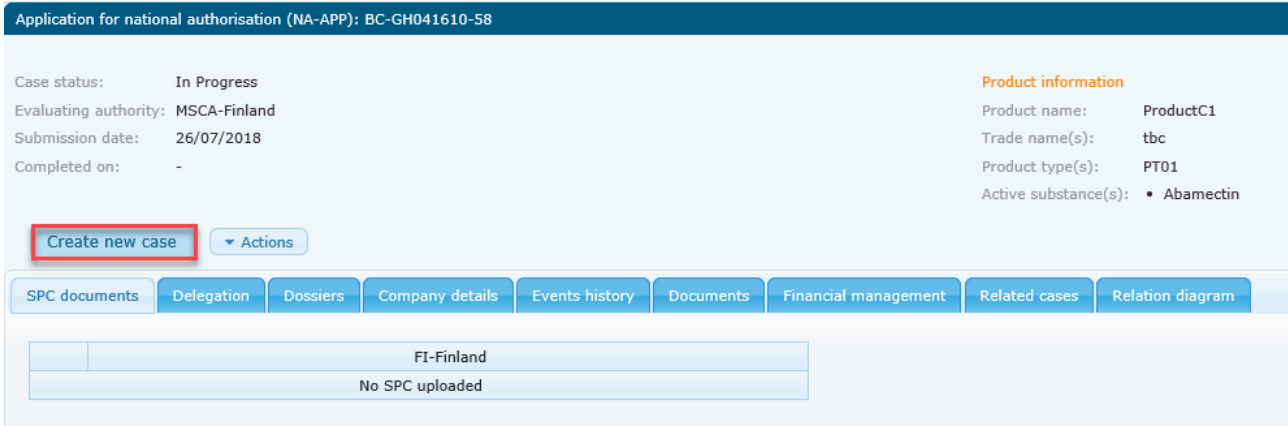
The created case (i.e. the application) is now linked to the case used to launch the application wizard.

The relevant application wizard (see section 8) will be launched to guide you through the application submission process.

5.3. Create a new application (related to an asset)

For applications that are related to an existing asset, and to which you have access (i.e. you own or have permission to use the appropriate asset number), you may launch the application wizard through the 'NEW APPLICATION' tab or the relevant existing asset page.

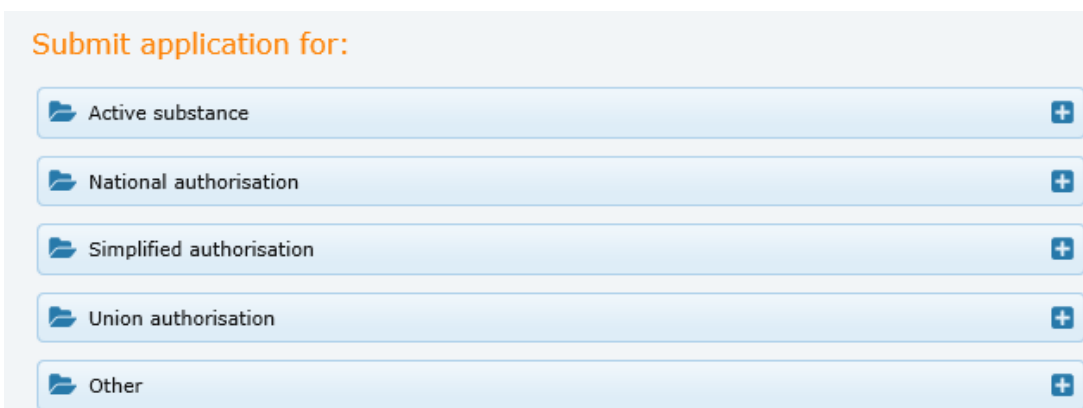### 5.3.1.   Create a new application from the 'NEW APPLICATION' tab

Click on the 'NEW APPLICATION' tab on the R4BP 3 toolbar.

Figure 23: 'New application' tab

You are then required to select the type of application you wish to submit.

Figure 24: New application page

The relevant application wizard will be launched to guide you through the application submission process. The relevant application wizard (see section 8) will be launched to guide you through the application submission process.

5.3.2. Create a new application from the relevant asset details page

In order to be able to search for the relevant asset, select the 'ASSETS' tab in the toolbar.

Figure 25: 'Assets' tab

| TASKS | MESSAGES | CASES | ASSETS | EVENTS | NEW APPLICATION |

5.3.2.1. Search for an asset

When you select the 'ASSETS' tab, a default search will cause all your assets that will expire in the next six months from the current day, to be displayed in the 'Assests list'.

If you are looking for a specific asset, fill in one or multiple search criteria in the 'Search for assets' table.

Figure 26: Searching for an asset

1. **Asset number**: enter the unique number assigned to the asset.

2. **Asset status**: select the status of the asset from the drop-down list containing all available asset statuses. They can be 'Active', 'Expired' (validity period has expired), 'Cancelled', or 'Revoked'.

3. **Asset start date from/to**: select the specific start date or time period within which start will occur

4. **Asset expiration date from/to**: select the specific expiration date or time period within which expiration will occur.

5. **Market area**: select the relevant option from the drop-down list containing all market areas.

6. **Company UUID/name**: enter the relevant company UUID or company name.

7. **Asset type**: select the application type for which a final decision has been taken from the drop-down list containing all available asset types. Please visit the ECHA website if you are looking for specific information on 'Biocidal active substances' from the 'Information on Chemicals' tab.

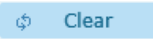8. **Looking for**: select if you are looking for a family product authorisation or a single product

authorisation.

9. **Family name**: if you are looking for a family authorisation, enter the family name.

10. **Product name**: enter the complete product name.

11. **Trade name**: enter the trade name.

12. **Active substance:** enter the active substance name.

13. **Product type**: select the product type from the drop-down list.

14. **Authorisation number:** type the authorisation number.

15. **Search:** once you have entered all your search criteria, click on the corresponding button to display all relevant assets.

16. **Clear**: click on 'clear' to set all search criteria to their default values.

17. **Export (.xls)**: You may wish to export your search results for future reference. Click on 'Export (.xls)' to open/save your results as a .xls file. You can generate different .xls files depending on your preferred search criteria.

18. **Assets list**: once you have entered your search criteria, all corresponding asset records are displayed in 'Asset list'. Click on the asset number <u>hyperlink</u> to access the asset's details page.

In the Assets list, you may find the following icons:

<kbd>D</kbd> icons indicate that your asset has been delegated to another legal entity.

<kbd>N</kbd> icons indicate that your asset has been nominated to another legal entity.

R4BP 3 will retain your selected search criteria. Press the <kbd>↺ Clear</kbd> button or logout to remove the selected criteria.

Note: If your asset is not visible in R4BP 3, please refer to the 'Migration' <u>Q&A</u> section on the ECHA website or contact the <u>ECHA helpdesk</u> for further advice on how to proceed with your application.

⚠️ AS and AN assets belong to the general public, therefore they are not visible in your asset list. You can consult the <u>list of approved active substances</u> on the ECHA website.

5.3.2.2.   Asset details page

Depending on the case type, the asset details page may contain the following information and sub-tabs:

Figure 27: Asset details page

1. **Header:** displaying the asset type, the asset type code abbreviation, and the assigned asset number.

2. **Basic information concerning the asset**: asset status, validity date, hyperlinked source case number (the case number that resulted in the creation of this asset) and other reference number (for instances where the evaluating MSCA has assigned one).

3. **'Product information'** or **'Substance information'**: displays the information provided on the submitted SPC file or IUCLID dossier. The information may include the product or family name, the product type(s), the active substance(s) name, the meta SPC identifier, and the Suffix of meta SPC.

4. **Asset owner details**: the name of the company as stated in the company registration, along with the legal entity UUID and the asset validity period.

5. '**Create new case**' option (Create new case) will be available for specific asset types and allows you, where relevant, to apply for other application types.

6. **Sub-tabs:**

• **SPC documents** sub-tab: displays information on the uploaded SPC document(s) including the country of the evaluating authority and the language(s) of the uploaded file(s). The submitted SPC file(s) can be viewed or downloaded and saved to your computer when clicking 'Download to PDF' download to PDF , 'Download to WORD' download to WORD or 'Download in I6Z' . ↓ download in I6Z

Figure 28: 'SPC document' sub-tab
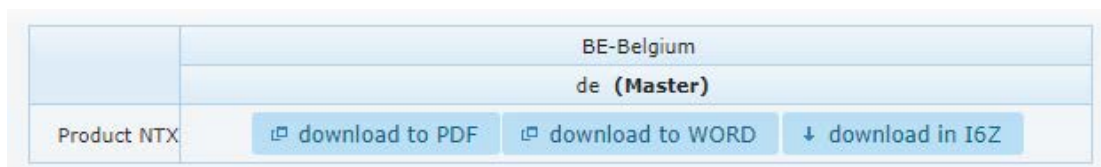
• **Delegation/Nomination** sub-tab: gives an overview of any related delegation, nomination and/or transfer requests. This includes the legal entity UUID number and the start and end date of the delegation, nomination and/or transfer. It also includes the button to click to initiate a delegation (→ Add delegation), a nomination (→ Add nomination) and/or a

transfer of an asset (→ Add transfer) to another legal entity. When adding a delegation, nomination, or transfer, you are requested to provide the legal entity UUID number and the start and end date of the delegation. For more information on delegation, nomination and transfer, please see chapter 12.

Figure 29: ' Delegation/nomination' sub-tab

- **Related assets** sub-tab: displays information regarding any relevant asset.

  The 'related assets' sub-tab also displays **caused asset** (cases submitted after the creation of the asset) and, for NA assets, **causing asset** (Mutual recognition in parallel and cases initiated prior the creation of the NA asset).

Figure 30: 'Related assets' sub-tab

- **Related cases** sub-tab: displays information regarding any related cases.

  This sub-tab allow a quick access to the case details. For example, a 'Mutual recognition in parallel' case can be viewed through the 'Application for national authorisation' case; connected cases can be viewed through each other. You can only access related cases that concern you, i.e. you are the case owner and/or asset owner of the related case.

  For **grouped submissions**, the 'Grouped submissions' sub-tab allows you to identify the reference case (indicated in **bold**) and the related case(s). The related cases are hyperlink, therefore you are required to click on the case number to access the submission details page.

  ⚠ **You can only access related cases that concern you, i.e. you are the case owner and/or asset owner of the related cases.**

Figure 31: 'Related cases' sub-tab
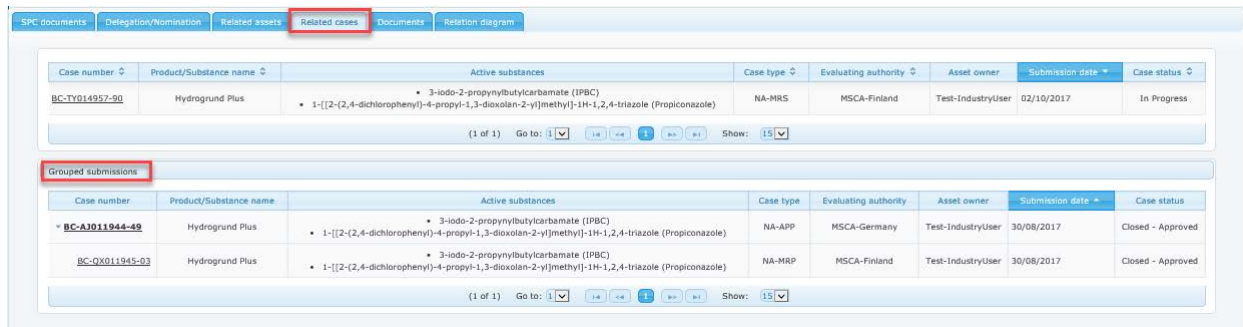
- **Documents** sub-tab: documents related to this case (e.g. supporting documents uploaded during the application process).

  For a family member asset, documents can be found at the parent asset's respective tab.

  Note that submitted dossiers and financial documents are found in their own sub-tabs.

Figure 32: 'Documents' sub-tab
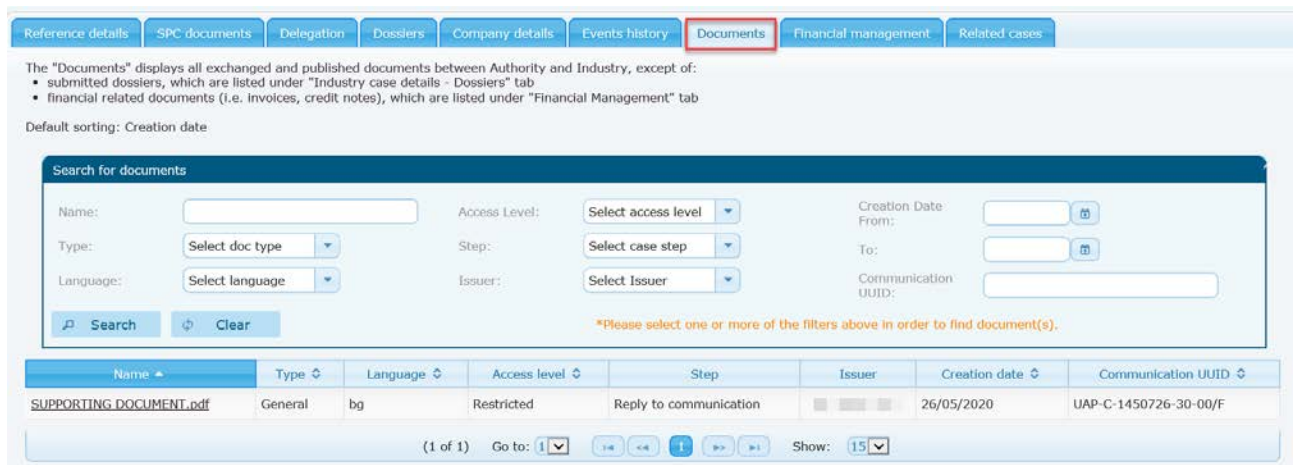
- **Family info** sub-tab: if applicable, displays information regarding the family of your asset.

  If your product asset is a **family asset**: all the members of the product family will be displayed in the family info sub-tab.

Figure 33: Family info sub tab (family asset)

  If your asset is a **family member asset**: the family asset will be displayed in the family info sub-tab.

Figure 34: Family info sub tab (family member asset)
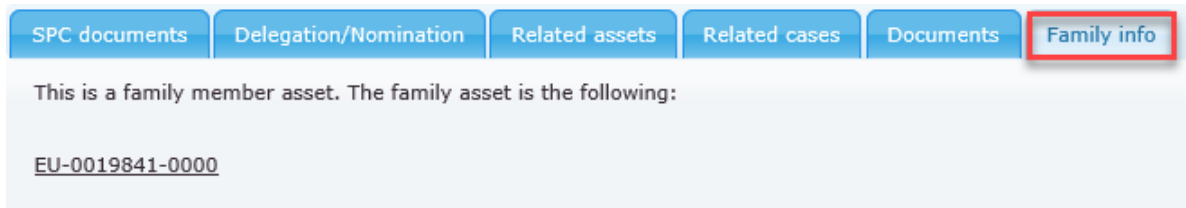
The family info sub-tab also displays the cancelled member(s) and/or family asset. The list of cancelled assets may also include converted assets
(e.g. NA-MRG).

Figure 35: Cancelled products
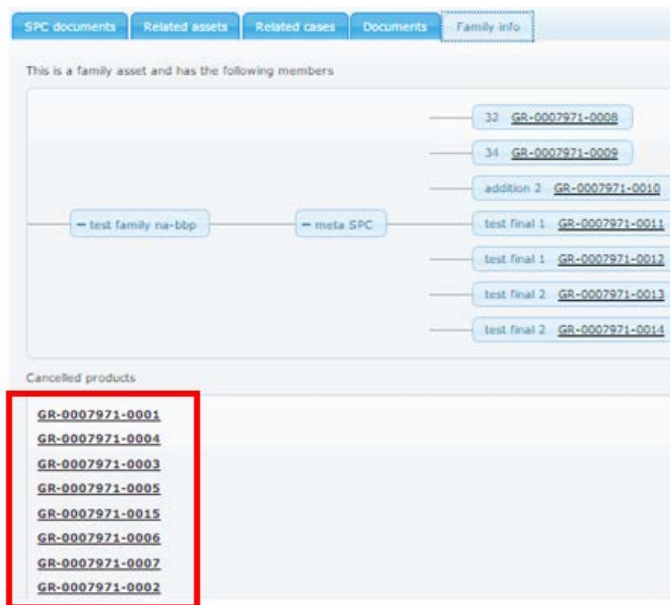
- **Relation diagram** sub tab: The diagram represents the relations between the current asset and other assets. It depict the whole history of submissions. Single and family asset numbers are presented in the diagram, excluding therefore all the members of a family. Only the asset owner will have the visibility of the diagram and only for assets that has access rights.

Figure 36: Asset 'Relation diagram' sub-tab
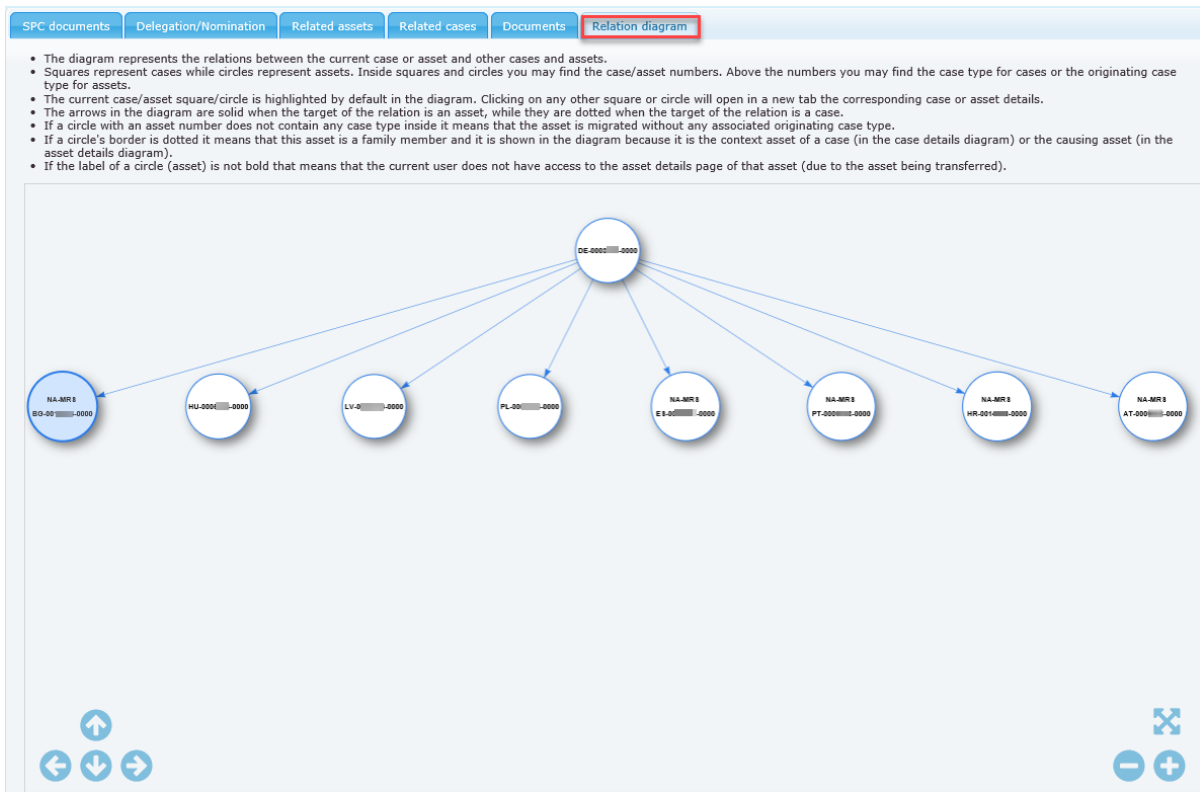
5.3.2.3. 'Create a new case' option

Click on 'Create new case' to launch the relevant application wizard.

Figure 37: 'Create a new case' option

The relevant application wizard (see section 8) will be launched to guide you through the application submission process.

The new case (i.e. the application) will be linked to the asset/case you used to launch the application wizard.

6. Grouped submissions in R4BP 3 (for National authorisations)

This chapter gives a general overview of how to submit grouped applications to the Authorities and launch the application wizard in R4BP 3. It is used for National authorisation and more precisely **to seek mutual recognition or a renewal/modification (MIC, MAC, ADC).** This functionality is **available for some specific cases.** To identify all relevant cases, please refer to the Application instructions guide.

6.1.   Create a grouped submission in R4BP 3

Grouped submission can be made **prior or after the creation of the NA asset.**

6.1.1. Prior the creation of the NA asset

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

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

Figure 38: 'NEW APPLICATION'

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

Figure 39: Select authorities

The relevant application wizard (see section 8) will be launched to guide you through the application submission process.

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

Figure 40: Grouped submissions under the 'related cases' tab

6.1.2.   After the creation of the NA asset

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

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

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

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

Figure 41: Submitting a grouped submission

The relevant application wizard (see section 8) will be launched to guide you through the application submission process.

You will find details of your submission under the 'related cases' tab of the asset.

Figure 42: Related cases

6.2. Include case(s) in a grouped submission (only for NA-ADC/MIC/MAC/RNL)

Registrants who have an NA asset can submit applications to request changes (MAC, MIC, ADC) or renewal (RNL). Those applications can be submitted in group. The applicant can introduce a new case in this existing grouped submission.

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

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

Click on 'Create new case' in the case details to launch the application wizard.

Figure 43: create new case

The relevant application wizard (see section 8) will be launched to guide you through the application submission process.

Once the submission is complete, the system will create a case for every selected asset in the wizard based on the context case type.

All new cases will be visible under the 'Grouped submission table' under the case details of every case, which is part of this submission.
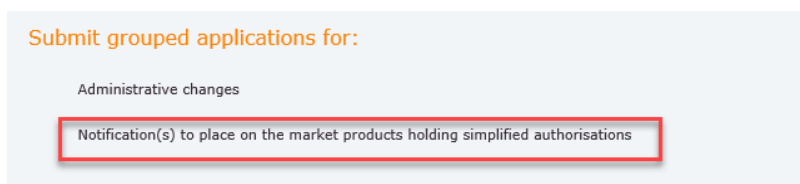
7.   Batch of applications

You can submit a batch of applications for administrative changes and/or notifications to place on the market products holding simplified authorisations. **These applications will run independently from one another.**

7.1. Submit a batch of administrative changes

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

Figure 44: Submitting a batch of administrative changes
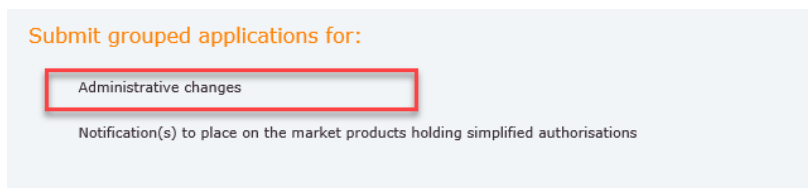
Submit grouped applications for:

Administrative changes

Notification(s) to place on the market products holding simplified authorisations

The relevant application wizard (see section 8) will be launched to guide you through the application submission process.

⚠ These applications will run independently from one another. Therefore, if you select two SA assets and a NA asset in the assets list, you will submit three different administrative change on request applications. These applications will be related to their corresponding assets.

7.2. Submit a batch of notification for placing on the market

To notify one or more products (members of a family) **to only one market area** in one wizard, click on the 'NEW APPLICATION' tab on the R4BP 3 toolbar, and select "**Notification(s) to place on the market products holding simplified authorisations**" at the bottom of the page.

**Figure 45: Notification(s) to place on the market products holding simplified authorisations**

Submit grouped applications for:

Administrative changes

Notification(s) to place on the market products holding simplified authorisations

The relevant application wizard (see section 8) will be launched to guide you through the application submission process.

⚠ Each notification for placing on the market will run independently from one another. Each SN-NOT case will pertain to a specific product (member of a family) and will have, as reference, the member SA asset number.
The result of each SN-NOT will be single product SN asset, without any relation with any other SN created. Therefore, after completion of the wizard, multiple SN-NOT cases will be created (depending on the amount of the SPCs uploaded in the wizard).

8.   R4BP 3 application wizard

When you launch an application wizard in R4BP 3, you will be guided through all the various steps until you reach the confirmation screen to 'submit' your application. Refer to the progress bar to see how far you are along the process.

Figure 46: Progress bar in the submission wizard
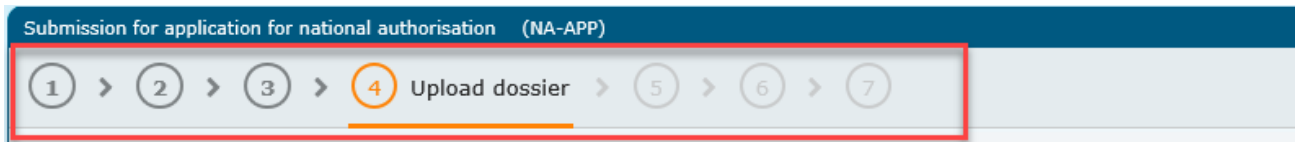
The steps and requirements at each step will vary depending on the application type you are applying for. For details on the wizard steps of a particular application, please see the relevant 'Biocides Submission Manual: application instructions' available on the ECHA website.

Excepted applications for PA-CHG , users have the option to 'Save' and 'Save and close' a submission wizard before the final submission. Please refer to section 8.2. for additional information on how to save an pending application.

8.1.   Wizard steps

Depending on your application, the main steps are:

8.1.1.   Set reference details / set the context asset

a) General feature

The reference number relates to the related reference asset or case. It is only applicable to some applications, when one application is based on another (e.g. a renewal of a biocidal product or active substance).

The reference will be known to you or you may have to request it from the holder. In some cases, the reference numbers may be available from the ECHA website 'Information on chemicals'.

When needed, fill in the reference number in the related field:

Figure 47: set reference details

b) Exceptions

- For all submissions concerning **notification procedures**, you can either:

- Click on 'Active substance/product type combination' and select the active substance name and product type from the drop-down lists;

Figure 48: set reference details for active substance/product type combination

- Fill in the related asset number if your submission refers to an existing declaration of interest

Figure 49: set reference details for successful declaration of interest

- For **submissions for parallel trade**, provide the assets for the member state of origin and member state of introduction.

Figure 50: Set reference details for submission for parallel trade

8.1.2.   Select authorities

Select from the drop-down list, the member state which is going to evaluate your application.

If mutual recognition in parallel (NA-MRP) or mutual recognition in sequence (NA-MRS) is sought, indicate the relevant concerned member state(s) as well.

Figure 51: select the evaluating authority

8.1.3.   Annex I inclusion selection

This step, relevant for AN-APP applications, allows you to select the category of Annex I. Tick only one category for the Inclusion of active substance in Annex I.

Figure 52: select the category for the inclusion of active substance in Annex I

8.1.4.   Set participant(s) details

In this step, you are required to provide details on the participant(s).

Participants can be:

- The case owner **and/or**,
- Any other company

For each participant, you will need to specify a supplier role. The participant can be supplier of the active substance, supplier of the final biocidal product or both.

Figure 53: set participants details

8.1.5.   Set participant change details

When you are required to select the type of change, you can either:

- **Add a participant to your submission**. In this case, click on 'join participant' and type in the participant UUID;

- **Remove a participant and choose a new participant**. In this case, click on 'replace participant' and choose the participants to be removed and/or added;

- **Choose the participants to be withdrawn**. In this case, click on 'withdraw participant' and choose the participant(s) to be withdrawn from the drop-down menu.

Figure 54: set participant change details

8.1.5. Grouping of asset in multiple market areas

Users who have assets related through mutual recognition and who wish to proceed with a submission for an administrative, a minor or major change can choose to include one or some of these assets in their application.

The screen will display two tables:

- The first table shows the concerned cases of the context case. A check box is provided to each asset to enable the user to select at least one of the asset. The user must select at least one asset number from the table.

- The second table displays the assets that are already included in the grouping submission. Note that there is no check box to select those assets.

Figure 55: Include asset in your grouped submission

8.1.6.   Select assets to include in the submission

a) To submit a batch of administrative change(s)

In this step, you are required to select the authorisations that are eligible for the submission. You first need to search for specific assets. Define at least one search criteria in the 'Search for assets' fields and click on 'Search'.

Figure 56: search for the asset(s) to be included in the submission

Based on your search criteria, you will be required to select the relevant asset(s) in the 'Assets list' and to 'Confirm selection' in the search for assets section.

Figure 57: Confirm selection

The selected assets will appear at the bottom of the page, in 'selected assets'.

Figure 58: verify the selected asset(s)

Note: for each selected assets, an individual administrative change application will be submitted.

b) Notification(s) for placing on the market

Define the market area and fill in additional field if necessary. Click on 'Search'.

Figure 59: Search for assets

Based on your search criteria, you will be required to select the relevant asset(s) in the 'Assets list' and to 'Confirm selection'.

Figure 60: Confirm selection

Click on 'next' to move to the next step.

Figure 61: select assets

8.1.7.   Set submission details

a) Individual cases

The basic aspects of the submission are covered in this step and may include identifying the asset owner, specifying the payment details, and selection of the evaluating authority, for example. If you are unsure of the terms, please consult the 'wizard tips' box during the application procedure.

Figure 62: set submission details

b) Grouped submissions

The evaluating and concerned authorities sections are already automatically filled in. However, you can update the company UUID for each case and provide a billing address and purchase order for each submission.

Figure 63: set submission details for grouped submissions

c) **Submission of a batch of administrative changes and notification(s) for placing on the market**

You are required to define a contact person(s) for all your submissions. Click on 'Apply to all' if the contact person and the purchase order apply for all submissions. Click on each asset number to expand the list and provide a different contact person(s)/purchase order.

Figure 64: set submission details for grouped submissions of administrative changes

Note: the evaluating authority is a read only field.

In case you want to remove an asset, click on the relevant button:

Figure 65: remove an asset from the selection

8.1.8.   Select additional market areas

For NA-MRG, you can select, where relevant, all the assets that you wish to merge at this step. If some assets are not visible for grouping, you will need to make separate applications to renew those assets. Please refer to the dedicated submission webpage for more details.

Figure 66: select additional market areas

8.1.9.   Set case owner details

The case owner details will be automatically filled in as those of the logged in user. However, a contact person(s) must be specified.

If you wish to modify your user information details or contact list of the legal entity, please click on either your username or company name. For further instructions refer to the ECHA Accounts manual available on the ECHA website.

Figure 67: set case owner details

8.1.10.   Enter the active substance details

This step, relevant for submission for declaration of interest to notify, allows you to fill in the active substance name and to choose the product type for the prospective approval.

If applicable, you are also required to enter the EC and CAS number.

Figure 68: enter active substance details

8.1.11.   SME reduction

In this step, you may fill in a SME decision number. A fee reduction for some application types may exist for small or medium sized enterprises (SME) provided certain conditions are met.

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 SME fees under the BPR on the ECHA website for full details.

Figure 69: Set SME decision number

8.1.12.   Upload dossier

If a dossier is required, you need to 'Browse' your local environment to be able to upload it into the system.

Note that all dossiers should have been created using IUCLID 6 (.i6z). For full technical assistance on how to prepare a IUCLID dossier and enter data into the fields that are of prime importance, please refer to the BSM 'How to prepare a biocides dossier'.

Note that R4BP 3 will warn you if you try to submit a dossier that fail to pass technical checks.

Figure 70: upload a dossier

8.1.13. Upload SPC

Where relevant, a summary of product characteristics may be required for an application. It is mandatory for the SPC to be in .I6Z format to be handled by R4BP 3.

For technical assistance on how to prepare create an SPC in IUCLID, you may consult the BSM 'Technical guide: How to prepare a biocides dossier'.

a) Individual submissions

Click on 'upload' to be able to upload your SPC file. The market area defined in the SPC must match the selected competent authority of the concerned Member State.

If you are submitting an application related to a biocidal product authorisation that has already been granted, the type of SPC (e.g. single product, product family or product family member) must be the same as the one submitted for the related asset;

Figure 71: Upload SPC

You are allowed to upload SPC files in any languages accepted by the respective competent authority of the concerned Member State. If you upload multiple SPC files with different languages, you will be required to **select a master language**. To select a master language, tick the box.

Figure 72: Select master language
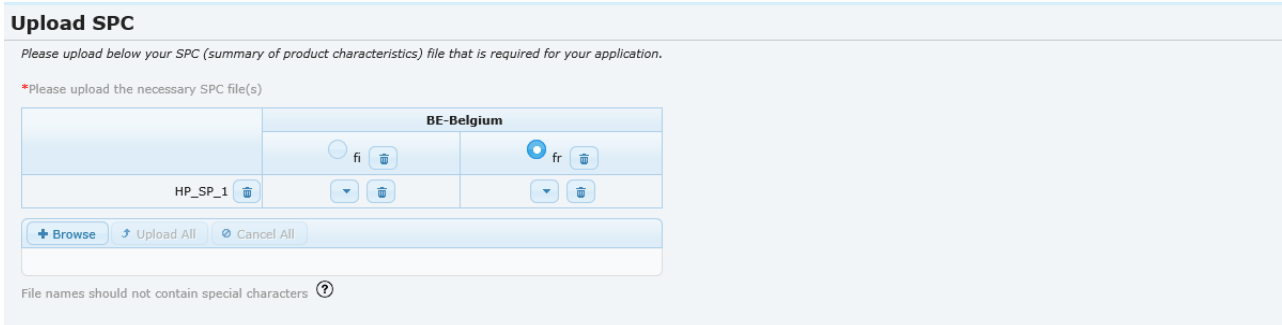
b) Grouped submissions

The market area is defined in the SPC and must match the selected competent authority of the referenced and concerned Member State(s). 'Browse' your local environment and 'upload all' relevant files. Alternatively, you can filter by market area and upload the SPCs one by one.

Figure 73: Upload SPC
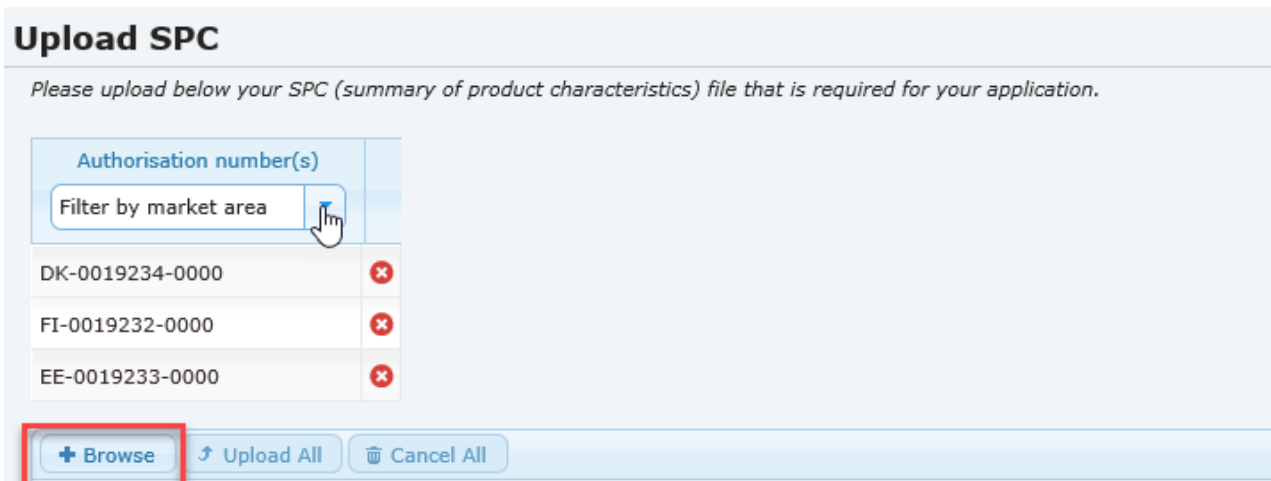
Figure 74: Upload SPC
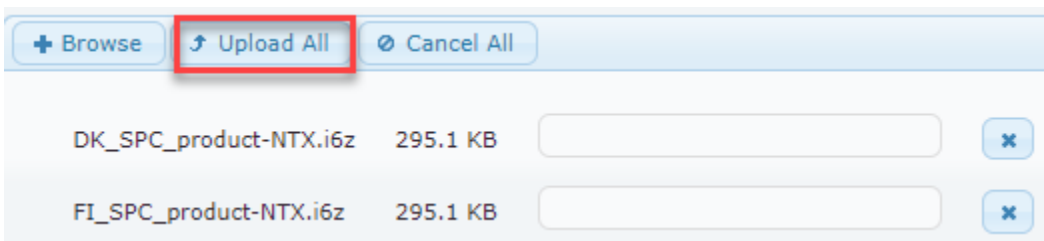
You are allowed to upload SPC files in any languages accepted by the respective competent authority of the concerned Member State. If you upload multiple SPC files with different languages, you will be required to **select a master language**. To select a master language, tick the relevant box.

Figure 75: Select master language

Upload SPC

Please upload below your SPC (summary of product characteristics) file that is required for your application.

*Please upload the necessary SPC file(s)

	FI-Finland		DK-Denmark	EE-Estonia
	en 🗑	fi 🗑	en 🗑	en 🗑
ProductC1 🗑	▾ 🗑	▾ 🗑	▾ 🗑	▾ 🗑

+ Browse   ⤓ Upload All   ⊘ Cancel All

File names should not contain special characters ⑦

⚠️ The system will display a warning message if you try to submit an NA-APP, NA-MRP or NA-MRS case while an 'in progress' or 'suspended' application with the same product or family UUID in the same market area is running in the system.

c) Submission of a batch of administrative changes(s) and notification(s) for placing on the market

Click on 'Browse SPC(s)' to be able to upload any SPC files corresponding to the assets for which administrative change(s) (if you are submitting a batch of ADC) or notifications for placing on the market (if you are submitting a batch of SN-NOT) will be submitted.

Figure 76: Upload SPC(s)

Upload SPC(s)

Upload SPC (Summary of Product Characteristics) files. Match SPC file to the corresponding asset.

Authorisation number(s)	
Filter by market area ▾	
EU-0010702-0001	❌
EU-0010702-0002	❌

+ Browse   ⤓ Upload All   🗑 Cancel All

8.1.14. Upload other files

a) Individual submission

All files that support the application and were not uploaded in the dossier should be included at this step. For many application types, ECHA requires additional supporting documentation to enable the correct handling and processing of your application. You can visit the '<u>Supporting documents</u>' page from ECHA's website for the full list.

Once you have uploaded your documents, select the relevant type. It can be a general document, an agreement or a document III-A related to the dissemination process.

Figure 77: Select the document type

b) Submission of a batch of administrative changes and simplified authorisation

Each uploaded document must be assigned to an asset. To assign the document click on 'Assign to submission(s) and select the doc type, and the language from the drop-down lists.

Figure 78: submission of a batch of administrative changes

8.1.15. Confirmation of submission

Following the submission of your application, an on-screen message will be visible containing instructions you are required to follow to ensure your application will be accepted for processing, for example, in cases where a resubmission may be required. Additionally information related to your submission will be displayed. A submission number is automatically assigned to your case and consists of a case number with additional digits. The last digit indicate the number of submissions that the case has undergone, i.e. the '/1' indicates that this is the first submission. If you do not receive this post-submission message, your application has not been submitted correctly and you will have to start the application process again.

You can monitor the progress of your case by searching for the specific case and messages related to the case by using the case number, so ensure you take note of this number.

8.2.   Save an application in the submission wizard

Excepted for applications of PA-CHG type, **users are allowed to save their application before submitting it to the Authorities**.

Figure 79. Save an application
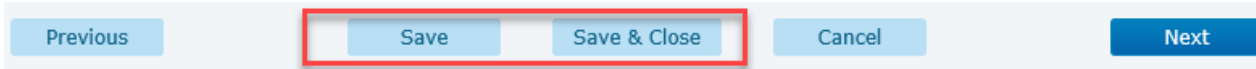
Depending on your application type, this feature will be visible:

- In the 'Grouping of Assets in multiple market areas' step for grouping applications NA-ADC/MIC/MAC/RNL;
- For a standalone NA-APP case as well as for a NA-APP with concerned NA-MRP cases (grouping submission), the user can save the application in the "Select authorities" step;
- For NA-BBP and NA-BBS cases that include a context step (reference case/asset to be provided), the users will be offer the possibility to save their draft in the "Set submission details" step;
- For a NA-MRG case, it is available in the "Set market areas" step;
- For all other cases that do not include a reference step and are considered standalone, this feature will be visible in the "Set case owner details" step.

If you want to edit your drafts (resume or delete them), click on the 'NEW APPLICATION' tab and visit the 'Edit applications saved as drafts' section. Click on 'view all applications' to get access to all your saved drafts.

Figure 80: Edit your drafts
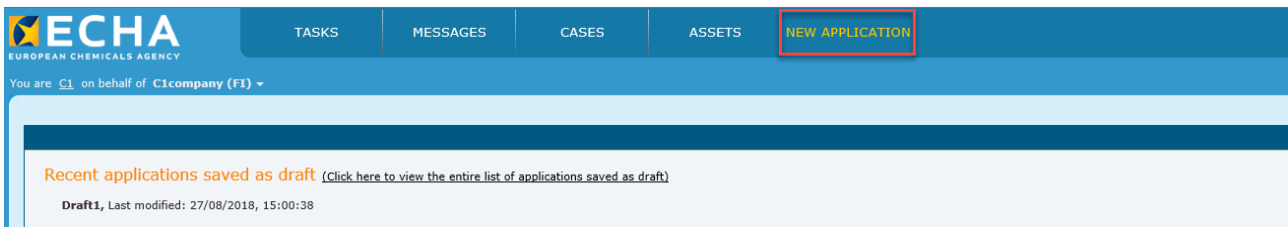
You can **edit your draft** (double click on the application name) or **delete** it (click on the trash icon).

Figure 81: Draft or delete your draft(s)
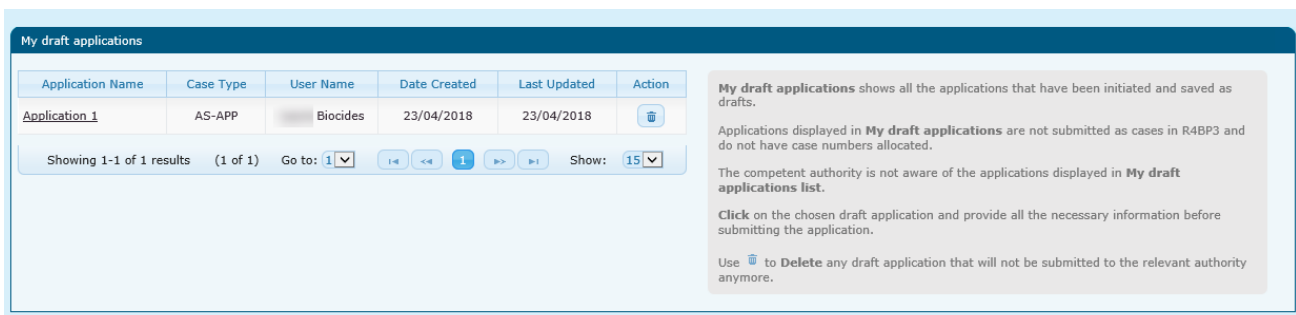
9.   Monitor your submission

It is the case owner's responsibility to **monitor the status of a submission** and **receive/react to requests** from the Authorities, therefore correct and updated contact person(s) must be also defined in your legal entity contacts list and in the relevant case in R4BP3.

In addition, the case owner contact person(s) defined in the case will receive e-mail notifications when there is important information to consider or actions to be taken, and status of a case has changed. These may include receiving **invoices**, **requests for resubmission** and **additional information, reminders,** or information about the **case** e.g., **moving in the workflow** to a next step. This will lead to the efficient processing of the application.

9.1. Identify your submission status through the 'CASES' tab

After selecting the 'Cases' tab, you can use the following options to monitor the status of your submission:

- **The 'Case status' in my cases list**

- **The Case details page**

- **The 'Events history' sub tab**

- **The 'Reference details' sub tab**

9.1.1.   'Case status' in my cases list

Select the 'CASES' tab in the toolbar and search for your case. The corresponding case records and their statuses are displayed in 'My cases list'.

- **In progress:** your submission is being processed. You may be required to resubmit your dossier and/or provide additional information.

- **Closed- Approved:** your submission has been accepted by the European Chemicals Agency (ECHA). No further action is required.

- **Closed- Rejected:** If the payment has not been received by ECHA by the due date, you will get the following message: '*Case rejected by ECHA*'. This mean that your payment has **not** been received in due time and your application has **not** been accepted for processing and it will **not** be forwarded to the relevant Authority.

- **Closed- Not approved:** your submission has not been approved by the authority due to the quality of the provided data.

- **Closed- Terminated:** The European Chemicals Agency (ECHA) has terminated your case; consequently your application will not be processed further. You may submit a new application which will receive a new case number. The new application will have no link to the application that was terminated.

- **Closed — Withdrawn:** The case has been withdrawn by the case owner or by ECHA per the case owner's request; consequently the application will not be processed further. You may submit a new application which will receive a new case number. The new application will have no link to the application that has been withdrawn.

- **Suspended:** your case has been suspended by ECHA.

Figure 82: Case status in 'case list'

9.1.2.   Case details page

Alternatively, you can find the case status in the case details page.

Figure 83: Case status in the case details page

9.1.3.   'Events history' sub tab

Search for your case and once you have gained access to your case, click on the 'Events history' sub-tab in the case details page. It will provide you with a list of all the actions the case has gone through to date
(e.g. format check passed, invoice sent, etc.).

Other useful information, such as all submitted documents or financial related documents, can be viewed in under the sub-tabs, e.g. 'Documents' or 'Financial management' tab.

Figure 84: Events history sub tab

9.1.4.   'Reference details' sub tab

If your application is based on another, you may wish to identify the status of the reference case. In this case, select the 'Reference case' sub-tab in the case details page.

Figure 85: Reference details sub-tab

9.2. Identify your submission status through the 'ASSETS' tab

After selecting the 'Assets' tab, you can use the following options to monitor the status of your submission:

- **The 'Asset status' in the assets list**

- **The Asset details page**

9.2.1.   'Asset status' in the assets list

Select the 'ASSETS' tab in the toolbar and search for your asset. The corresponding asset records and their statuses are displayed in 'Assets list'.

- **Active:** your asset is active. Depending on your asset, you can perform some specific type of action such as initiating a new case, initiating a delegation, a nomination or a transfer.

- **Expired:** the validity of your asset has expired. You are not allowed to perform any action (e.g. initiating a new case from this asset).

- **Cancelled:** your asset has been cancelled. You can still view your asset details but cannot perform any action anymore. Note that if you have initiated a new case from this asset while it was still valid, the decision making authority **will not approve the pending case.**

- **Revoked:** your asset has been revoked by the Authority. Consequently, you are not allowed to perform any kind of action on your asset.

- **Inactive:** if the validity date of the asset has not been reached yet.

Figure 86: Asset status in 'asset list'

9.2.2.   Asset details page

Search for your case and access the case details page to find the **asset status**.

Figure 87: Asset details page

9.3.   Identify latest events concerning your submissions through the 'EVENTS' tab

Select the 'Events' tab in the toolbar. Default events list shows all the events that have occurred (after the date when the feature was implemented – February 2022) and are listed in descending order (latest first). If you want to search for a specific event, in the 'Search for events' table, fill in some search criteria.

You may export the events list for your further analysis or monitoring purposes to excel file by clicking 'Export (.xls)'.

9.3.1. Monitor your submission step in the events list

Submission step, from the event was triggered, can be found in the 'Events list' in 'Step' column. In the 'Subject' column, the nature of the event is described.

Figure 88: 'EVENTS' tab

9.4.   Identify your submission status through the 'MESSAGES' tab

Messages showing the progress of each case will be sent to the case owner's R4BP 3 message list, accessed via the 'MESSAGES' tab, after each processing step. During the processing of an application, authority users will send messages to the case owner, providing information concerning the status of the case or requesting additional information.

9.4.1.   Search for a message

On the toolbar, click on 'MESSAGES'.

Figure 89: 'MESSAGES' tab

When you select the 'MESSAGES' tab, a default search will cause all the messages you received in the last year to be displayed in the 'Message list'. If you want to search for a specific message, in the 'Search for messages' table, fill in some search criteria.

Figure 90: 'Search for messages'

1. '**Sent/Received**': Search for sent **or** received messages. Note that only one selection can be provided at a time.

2. **Sender:** Use the drop-down list to select the sender(s) of any received messages.
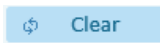
   ⚠️ If the sender 'Industry' has been selected, an additional field called 'Company UUID/name' will appear and allow you to search for a specific Industry UUID or Industry name.

   Figure 91: Enter the Company UUID/name

3. **Status:** Filter by read or unread received messages.

4. **Archived:** Archived messages are removed from the Inbox list. Tick the box to search for sent or received archived messages. Note that archiving sets a tag to all users of the legal entity. Other users in the same legal entity would also see the communication tagged as archived.

5. **Case number:** Type the Case number from the context of which a message was received or sent.

6. **Message topic:** Use the predefined drop-down list of topics to search for a specific message.

7. **Case type:** Select one or many case types from the drop-down list.

8. **Message subject:** Type in a message subject to search for specific sent or received messages.

9. **Active substance:** Enter the active substance name that is linked to a specific case from the context of which a message was received or sent.

10. **Message number:** enter the unique communication number assigned to the message. Any message sent by authority users will be assigned with a unique number to identify the message, i.e. a `Communication number´ or a `Decision number´.

11. **Product- Family name:** Search for a specific product or family name.

12. **Date received from/to**: Filter by specific dates.

13. **Trade name:** Enter a specific trade name.

14. **Product type:** Select a product type from the drop-down list.

⚠ R4BP 3 will retain your selected search criteria. Press the [↺ Clear] button or logout to remove the selected criteria.

9.4.2.   Message list

When you have entered the search criteria, click on 'Search' so that the corresponding messages are displayed in the 'Message list'.

Figure 92: 'Message list'

🖾 icons indicate that the message has been read.

🖾 icons indicate that the message has been left unopened.

The [🖿 Archive] button allows you to archive any message. Tick the box next to the relevant message and press 'Archive'. Notice that all archived messages will disappear from the general inbox.

If you want to '**unarchived**' a message, tick the 'Archived' box in the searching panel and press the 'Search' button.

Figure 93: Search for an archived message

You will be able to unarchive the message from the message page. See section 9.3.3. for additional information.

9.4.3.   The message page

Once you have click on the 'Topic: Subject' hyperlink, you can access the message page. From the message page, you can perform certain actions.

9.4.3.1.   Print communication

If you need to save the message on your local desktop, click on 'Print communication'.

Figure 94: Print communication

9.4.3.2.   Unarchive a message

An 'unarchived' button will offer you the possibility to unarchive the message and move it back to the general inbox.

Figure 95: Unarchive a message

9.4.3.3.   Reply/Reply all

If you are required to reply to a communication, you will have the possibility to reply from the message page. Click on 'Reply all' or 'Reply' (if you need to address your communication to some parties only) to start a new adhoc communication.

Figure 96: Reply/ Reply all
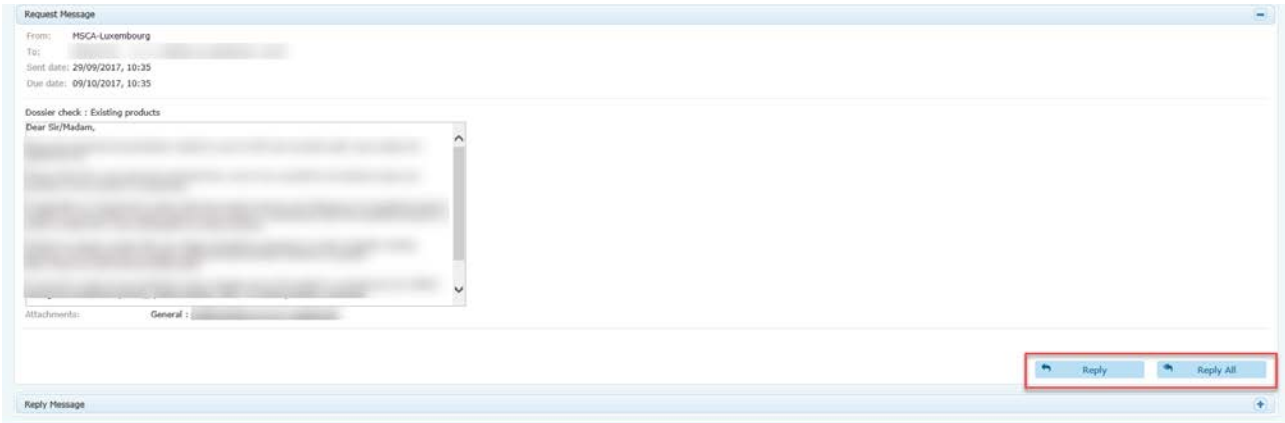
Once you have replied to the communication, your message will be visible in the 'Reply Message' section.

Figure 97: The Reply message section

If you need additional information on the messaging functionality, please see section 10. Messaging the Authorities.

⚠ Note: The Reply/Reply All buttons are visible for the very last message of the thread.

9.4.4.   Progress status messages

You can identify the progress of your submission via the 'topic: subject' tab. It indicates whether your application has been accepted or not and if you need to resubmit your application.

9.4.4.1.   Applications accepted by ECHA

Format check message: If your application (case) passes the initial processing steps (e.g. file format and business rule confirmation), a 'Format check' message will be sent to your message list.

Figure 98: Format checks messages
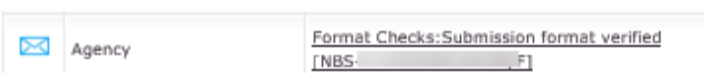
Submission 'accepted' message: If the ECHA invoice (where relevant) has been paid by the due date, a 'Submission' message will be sent to your message list. Clicking the hyperlinked subject under the 'Topic: Subject' column will open the Communication Details window which diplays the communication number, or decision number if it is a final decision, the case type abbreviation code and number, the Product/Substance name (where applicable) and the message(s) sent or exchanged by the appropriate users.

Figure 99: Invoicing messages

After receiving these messages your application is considered **'accepted'** by ECHA and will be forwarded to the appropriate evaluating Authority.

The **relevant Authority** will relay the final decision/outcome of the case (e.g. granting a BP authorisation or approving an AS) to the case owner through R4BP 3 in due course, in accordance with the BPR.

Figure 100: Case approved

9.4.4.2.   Applications rejected by ECHA

If your application (case) does not meet all of the requirements laid out in the BPR, your application will be rejected. There are a number of reasons for a case to be rejected, for example an invoice not paid by the due date, files not provided in the correct format or data missing.

Format checks message: If your application (case) does not pass the initial processing steps (e.g. file format and business rule confirmation), a 'Format check' message will be sent to your message list. Open the message to identify the problem in your submission.

Figure 101: File format checks failure

Case 'not approved'/ Case 'rejected': If your application is not approved or has been rejected, you will receive a message informing you of the processing step your application was stopped. The message will inform the case owner of why the case was not approved and how to proceed. This may involve submitting a new application.

Figure 102: Message for not approved applications

9.4.4.3.   Resubmission messages

Notification of requested resubmission/information are available via the 'MESSAGES' tab.

Figure 103: Message for resubmission
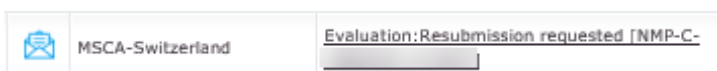
Open the message to read the content and click on the hyperlink to trigger the resubmission

wizard. To ensure an application can be processed correctly, you may be required to complete task items assigned by authority users. For additional details on resubmission tasks please see section 9.4.

Figure 104: Resubmit information

Communication Details

Communication number:	UAP-C-1330570-32-00/F
UA-APP:	BC-VV042368-99
Product/Substance name:	Family

🖺 Print Communication

Request Message

From: Agency

To: C1company   read by C1 on 24/08/2018, 17:29

Sent date: 24/08/2018, 10:44

Due date: 07/09/2018, 23:59

Format Checks : Incorrect dossier template 59a1c651-3025-4565-b6af-8f80e0a5a3d0

> You submitted a dossier that is not a biocidal product dossier. You are requested to create and resubmit a new dossier, using the dossier template 'BPR Biocidal product application'. Biocides Submission Manual "How to prepare a biocides dossier" describes in details the different functionalities in IUCLID: https://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals.
> If you have a specific concern about this issue, you can contact the ECHA Helpdesk using the contact form at https://echa.europa.eu/contact.
> Dossier UUID: 59a1c651-3025-4565-b6af-8f80e0a5a3d0

Related Tasks : Resubmit information

9.5.   Resubmission: authority requested task item

Resubmission tasks are available under the 'TASKS' tab. They are initiated by the authority in order to require additional information.

Figure 105: 'TASKS' tab

TASKS	MESSAGES	CASES	ASSETS	EVENTS	NEW APPLICATION

Depending on the application type, there are two possible task items you may be required to complete; '**Resubmit information**' task or '**Reply to communication**' task.

🔶
ℹ️ **Task items are assigned with a deadline for completion**; not completing a task item may lead to your application being rejected. The task will expire and you will not be able to complete it. Therefore, it is advised to regularly check your task items in R4BP 3.

Figure 106: Expired task

Note that the resubmission deadline can be extended per your request; it is therefore recommended that you contact the relevant evaluating authority to ask for an extension.

9.5.1.   Searching for a task

You can search for '**Resubmit information**' or '**Reply to communication**' tasks via the 'TASKS' tab. A default search will cause 'All open tasks' to be displayed in the 'Tasks list'.

If you want to search for a specific task, in the 'Search for tasks' field, fill in some search criteria:

Figure 107: Searching for a task

1. **Task status**: filter by whether the task is:

    • Completed' - the task has either been concluded or the task has expired and is no longer available for completion;

    • 'Overdue';

    • 'Claimed by me';

    • 'All open tasks' – tasks that are yet to be claimed and completed.

2. **Task name**: a 'Resubmit information' task will require you to upload a new dossier.

    A 'Reply to communication' task may require you to provide a reply or attach additional documents.
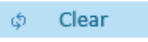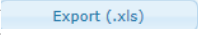
3. **Dates**: tasks can be searched by the 'Due date', the 'Creation date' when the authority user created the task, the 'Case submission date' when you submitted the application related to the task and by the 'Completion date' for completed tasks.

     Note that the task item must be completed by the due date or it will expire.

4. **Task number**: enter the unique number assigned to the task.

5. **Evaluating Authority type**: select from either MSCA or Agency

6. **Evaluating country**: only active when the criteria "Evaluating authority type" has been selected.

7. **Case number**: enter the unique number assigned to the case.

8. **Case type**: select the application type submitted (e.g. UA-APP - Union authorisation, NA-APP - national authorisation, etc.), from the drop-down list containing all available case types.

9. **Product name**: for application types related to biocidal products, enter the complete product name.

10. **Active substance**: for application types related to active substances, enter the common name.

11. **Search:** click on search once you have filled in some criteria

12. **Clear:** R4BP 3 will retain your selected search criteria. Press the [⟳ Clear] button or logout to remove the selected criteria.

13. **Export (.xls):** You may wish to export your search results for future reference. Clicking the 'Export (.xls)' button (Export (.xls)) will open a .xls file with the specific search results you have preselected.

    You can generate different .xls files depending on your preferred search criteria and by sorting the search results under 'Tasks list' by `Task name, 'Case number', 'Product/Substance name', 'Case type', 'Submission date', `Due date´ or 'Task status'.

9.5.2.   Tasks list

When you have entered the search criteria, click on the 'Search' button and the corresponding tasks are displayed in the 'Task list'.

The 'Tasks list' can be sorted by clicking on any of the parameters presented at the top of the list such as.

Figure 108: Task list

Tasks list								
Task name ⇕	Case number ⇕	Product/Substance name ⇕	Active substances	Case type ⇕	Evaluating authority	Submission date ⇕	Due date ▾	Task status ⇕
Resubmit information ⛔	BC-VV042368-99	Family	• Acrolein • Basic Copper carbonate • Abamectin	UA-APP	MSCA-Estonia	24/08/2018	07/09/2018	CLAIMED
		Showing 1-1 of 1 results (1 of 1) Go to: 1 ⌄ ⏮ ◄◄ **1** ►► ⏭ Show: 15 ⌄						

1. **Task name**: outlines the type of task (e.g. resubmit information). The task name is a <u>hyperlink</u> which, when clicked, opens the task item.

2. **Case number**: clicking on the case number <u>hyperlink</u> opens the corresponding 'Case details' page is displayed.

3. **Product/Substance name**: for application types related to biocidal products in which the product name was provided in the designated field of the submitted dossier.

4. **Active substances**: for application types related to active substances in which the common name was provided in the designated field of the submitted dossier.

5. **Case type**: sort tasks by the case type in alphabetical order.

6. **Evaluating authority**: outlines the Member State which is evaluating the application.

7. **Submission date of the application**: sort tasks by the submission date.

8. **Due date for task completion**: by default the task list is sorted according to the due date.

9. **Task status**: tasks can have the following statuses:

   - '**Unclaimed**': all open tasks created and not yet claimed in order to be completed by a specific user.

   - '**Claimed**': claimed by a specific user in order to complete the task actions.

     When opening an 'Unclaimed' task, the task is automatically assigned to you and its status is changed to 'Claimed'.

     'Claimed' tasks can be edited, completed and saved only by the claimant.

     If you close the claimed task without completing any of the task actions, its status is automatically changes back to 'Unclaimed'.

   - '**Completed**': when the claimant of a task performs the task actions and completes the task, its status changes to 'Completed'.

     The task is now considered closed; you can view the task details, but cannot perform any further actions.

   - '**Expired**': when a task has not been completed by the due date, its status automatically changes to 'Expired'.

     The task shall be labelled as 'Expired' and will no longer be editable. The task shall be recorded as not completed on the authority side.

     Note that this may lead to your application being rejected or initiate further evaluation to be carried out on your application.

⚠ When the due date for completion of a task is approaching, an exclamation mark 🛑 will appear next to the task name.

9.5.3.   'Resubmit information' task and the resubmission wizard

If any information needs to be resubmitted, a 'Resubmit information' task will be generated and **assigned to the case owner of the corresponding case**. There are a number of reasons for these tasks to be generated by the evaluating authority or by ECHA (e.g. failure of the file format check).

A detailed explanation of what is required can be viewed in the task item itself, in the 'Requested information' section.

To address the task, click on 'Start resubmission'. This will trigger the 'resubmission wizard' for the original application.

Figure 109: 'Resubmit information' task item

The resubmission wizard allow you to update the following information:
- **dossier**;
- **SPC**;
- **other files**.

Note that the previously submitted IUCLID and SPC files will be retained **unless a new file is uploaded.**

If you need to resubmit an **updated IUCLID dossier**, go to the IUCLID homepage and update the relevant dataset(s), then create a new dossier as outlined in the '<u>BSM Technical guide: How to prepare a biocides dossier'</u>.
If you need to submit an **updated SPC**, locate the latest available version of the SPC in .I6Z format from the relevant asset in R4BP 3, and download it to your computer. Make the necessary changes and create a new version for upload. Refer to the '<u>BSM Technical guide: How to prepare a biocides dossier</u>' for more details.

⚠️ For AS-ACC and TE-APP applications, any information provided under the 'supporting information details' cannot be resubmitted during the resubmission wizard steps.
The same applies for information under 'Category' for AN-APP applications and 'SME asset number' for UA-APP, AS-APP, AS-RNL, AN-APP application types.
Changes of this nature should be agreed with the concerned evaluating authority outside the system.

Click on ● Release if you do not want to proceed with the resubmission task. You will allow another user from your organisation to work on the resubmission.

9.5.4. 'Reply to communication' task

Alternatively, a 'Reply to communication' task may be generated if an authority user requires additional information to complete the processing of an application. In order to complete the

task, enter a message in the 'Reply note' field and/or uploading any requested files in the 'Task actions' section.

Figure 110: 'Reply to communication' task

In order to attach a file to this task, your local environment and click on 'Upload' or 'Upload All'.

When you have addressed the task actions and entered the security text, 'Submit' your reply to the communication task. If you have completed the task correctly, an on-screen 'Submit task confirmation' message will appear. Confirm your reply by clicking 'Continue'.

Figure 111: On-screen 'Submit task confirmation message'

10. Messaging the Authorities

R4BP 3 allows the case and asset owners to send messages to the following recipients:

- MSCA
- Concerned MSCAs (when applicable)
- Agency
- Commission

Search for your case, access the page details and click on 'Actions' to be able to initiate a 'New communication'.

Figure 112: Initiate a new communication
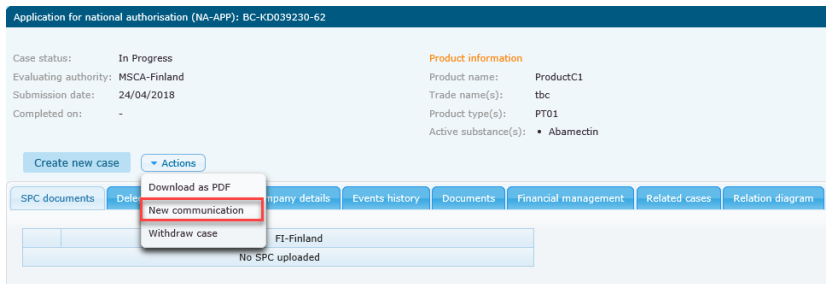
Figure 113: Fill in the recipient list, topic, subject and content fields

A pop-up page will prompt you to enter the following information:

- **The recipient:** choose the recipient(s) from the multiple selection drop-down list. The recipient can be the Agency, the Commission or one or many MSCA(s).

  If you need to send a message to a member state, choose 'MSCA' from the recipient list and select the country(ies) of your choice.

Figure 114: Choose an MSCA from the list (part 1)
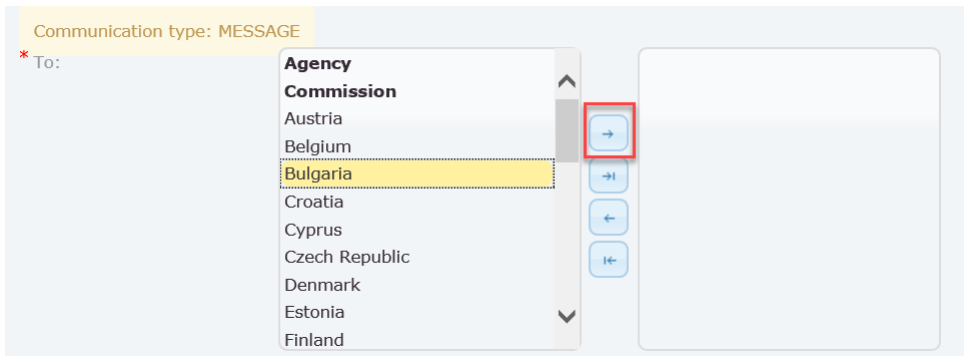
Figure 115: Choose an MSCA from the list (part 2)
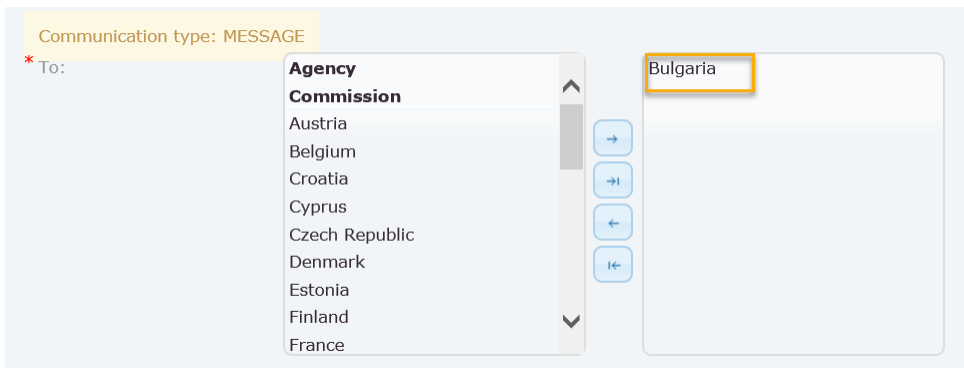
For grouping submissions (e.g. multiple MRP/ADC/MIC/MAC/RNL), click on 'Concerned MSCAs'. A pre-filled list will be available for you. You can also include any other MSCA.

Figure 116: Concerned MSCA
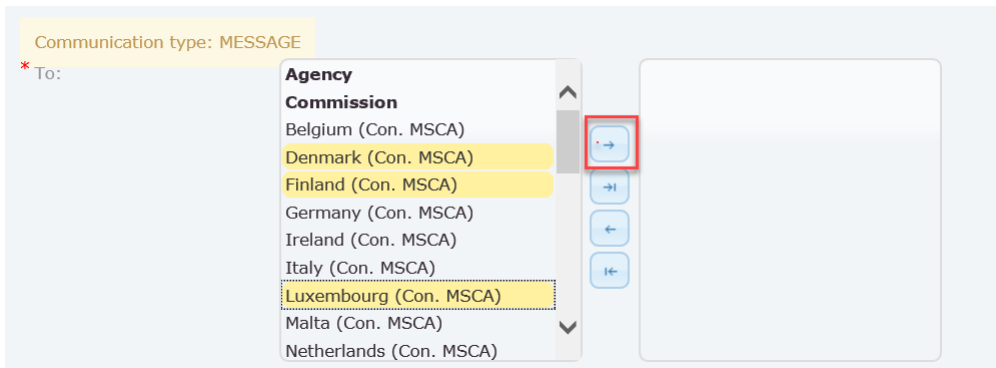
Figure 117: Remove a concerned MSCA from the recipient list
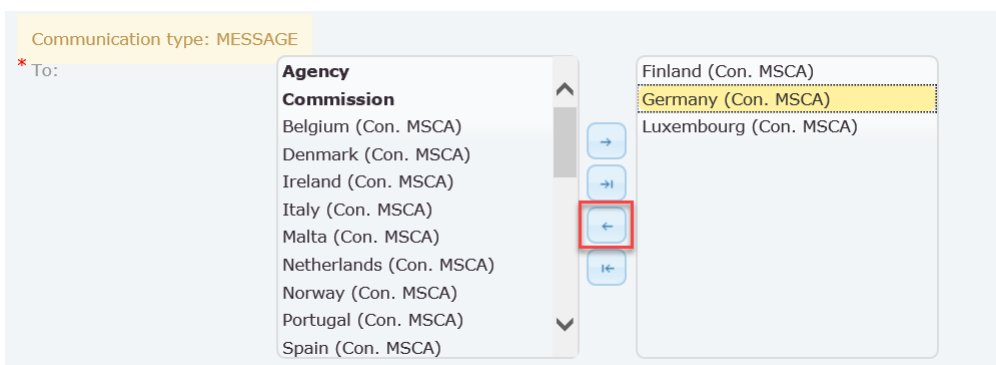
- **Cc:** choose the Cc member state(s)from the multiple selection drop-down list.

- **The topic:** choose the relevant topic from the drop-down list.

- **The subject:** define the subject of your message.

- **The content:** The following box displays a pre-defined message. However, you are able to modify or delete this text.

- **Upload one or more attachments** if necessary.

Click on 'Send' and confirm that you are going to send a new message.

Figure 118: send a message
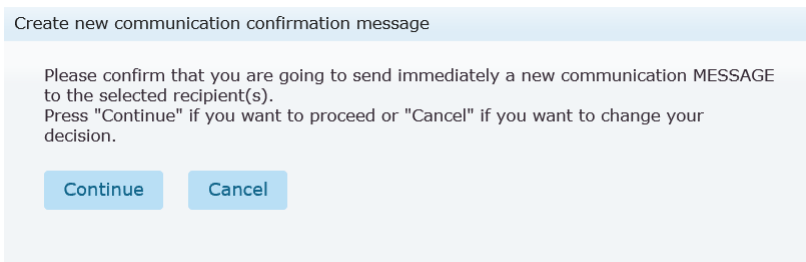
You will receive immediately a communication number. This number is particularly usefully if you want to retrieve your message from the 'Messages' tab.

Figure 119: communication number
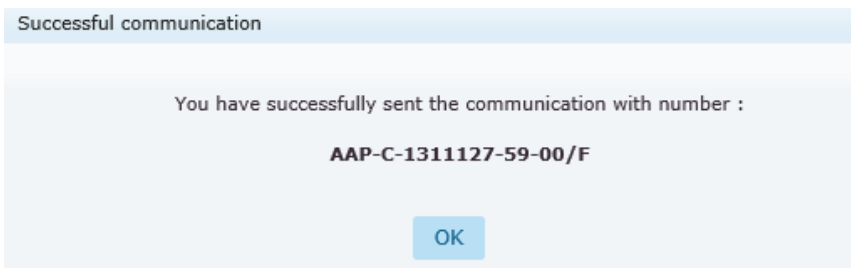
The system will update the 'Events history' with information regarding your communication. The 'Subject' column enables you to quickly identify the topic of your message and displays the relevant communication number.

Figure 120: New event logged in the events history tab
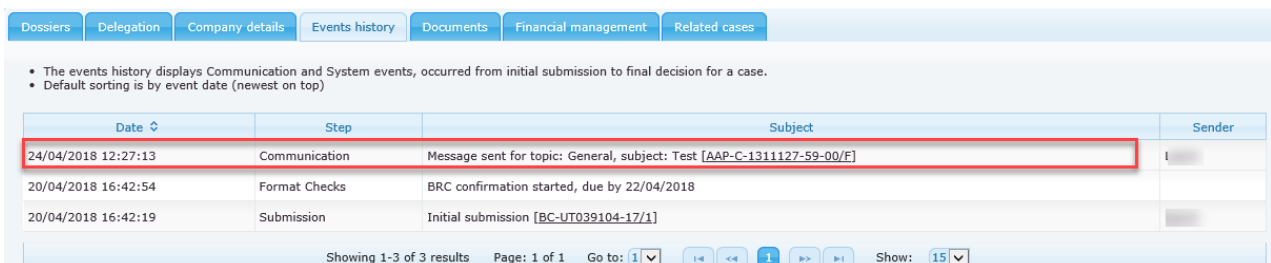
⚠ We kindly draw your attention on the fact that the Authorities are not bound to reply to your message(s).

11. Withdrawing a case from R4BP

You are allowed to withdraw any in-progress applications from R4BP 3. In this case, 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 121: withdraw a case from R4BP 3

This action is subject to the following requirements:

• Only the **case owner** can withdraw a case;
• The status of the case to be withdrawn should be 'In progress' or 'Suspended';
• The case is not of AS-EVA or PA-CHG types.

There will be no approval process for the case withdrawal. Once the withdrawal is triggered the case status will be set as 'Closed - Withdrawn'. Therefore, any open task items will be closed, any pending delegations or case transfers will be cancelled and an appropriate event will be recorded in the 'Events history' sub-tab.

Figure 122: Case withdrawal in the 'Events history'

⚠️ 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.

12. Exchanging data with other entities

R4BP 3 offers you the possibility to exchange information regarding your case(s) and asset(s) with other legal identities. You are allow to:

- Delegate a case or an asset
- Nominate an asset
- Transfer a case or an asset

12.1. Case delegation

Delegation of cases is used **when a legal entity wishes to provide the details of a specific case to another legal entity so that the second legal entity may launch certain application types using the delegated case's details** as a starting point.

The exchange of the case details (case number, etc.) must be agreed upon and exchanged outside R4BP 3, via e-mail for example. Once the case has been delegated and the legal entity has been provided with the case information, only then can the second legal entity initiate his own application using the delegated case as a starting point.

In order to initiate a delegation, the following considerations should be taken into account:

- the case status should be '**in progress**' ;

- Case delegations can be done **only for specific case types**. **Table 3** displays the case types for which a case can be delegated and the case types that can be created from the delegated case(s).

Table 3: Delegation case types

Case types for delegation	Case types initiated from delegated case
NA-APP	NA-MRP, NA-BBP
UA-APP	UA-BBP
SA-APP	SA-BBP
NA-MRP	NA-BBP
NA-MRS	NA-BBP

12.1.1.   Initiate a case delegation

To delegate a case in R4BP 3, search for your case. Once you have gained access to the required case, go to the 'Delegation' tab and click on 'Add delegation'.

Figure 123: Initiate a case delegation

You are requested to provide information regarding the delegation:

- the legal entity UUID number for which the case will be delegated to;
- Indicate a date when the delegation will become valid;
- An end date (empty by default) when the delegation is revoked from the delegated legal entity.

Figure 124: Delegation of a case

When a legal entity (or case owner) delegates a case, it will then be followed by an icon (D) in the case list, to differentiate it from the other cases. However, the icon will not appear to the legal entity to whom the case was delegated.

12.1.2. Modify a case delegation

A revocation of a case delegation can be made changing the 'End date' for the delegation. The D icon disappears if the delegating legal entity removes the delegation or if it expires.

Figure 125: Modify a case delegation

12.2. Asset delegation

Delegation of an asset is used **when a legal entity wishes to provide the details of a specific asset to another legal entity, in order that the second legal entity can create its own application for authorisation of the same biocidal product** using as starting point the delegated asset's details.

The exchange of the asset details must be agreed upon and exchanged outside R4BP 3, via e-mail for example. Once the asset has been delegated and the legal entity had been provided with the asset information, the second legal entity initiate his own application type using as starting point the delegated asset.

In order to initiate a delegation, the following considerations should be taken into account:

- the asset status should be 'Active';
- Asset delegations can be done only for specific asset types. **Table 4** displays the case types for which a case can be delegated and the case types that can be created from the delegated case(s).

Table 4: Delegation asset types

Asset types for delegation	Case types initiated from delegated asset
NA	NA-MRS, NA-BBS
UA	UA-BBS
SA	SA-BBS

12.2.1.   Initiate an asset delegation

To delegate an asset in R4BP 3, search for the specific asset. Once you have gained access to the required asset's detail page, go to the 'Delegation/Nomination' tab and click on the 'Add delegation' button.

Figure 126: Delegation of an asset

You are requested to provide information regarding the delegation:

- the legal entity UUID number for which the asset will be delegated to;
- A date when the delegation will become valid;
- An end date (empty by default), when the delegation is revoked from the delegated LE.

Figure 127: Delegation of an asset
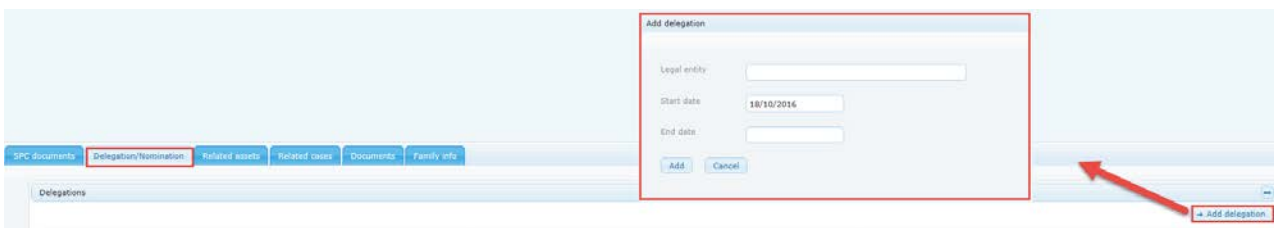
When a legal entity delegates an asset, it will then be followed by the ☐D☐ icon in the asset list, to differentiate it from the other assets.

12.2.2.   Modify an asset delegation

A revocation of an asset delegation can be made changing the 'End date' for the active delegation. The ☐D☐ icon disappears if the delegating legal entity removes the delegation or if it expires. Note that the second legal entity does not need to accept the delegation in R4BP 3.

Figure 128: Modify an asset delegation
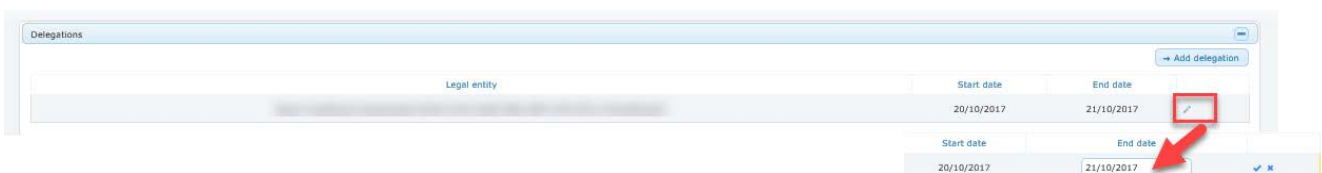
12.3. Nomination of an asset

Nomination of an asset is used **when a legal entity provides to another legal entity information regarding a specific asset in order that the second legal entity might initiate new cases on its behalf**. The nominated legal entity will have full access to the cases and/or assets initiated form the context of the nominated asset.

The exchange of the asset details must be agreed upon and exchanged outside R4BP 3, via e-mail for example. Once the asset has been nominated and the legal entity had been provided with the asset information only then can the second legal entity initiate his own application type using as starting point the nominated asset.

⚠ Nomination can only be done for specific asset types (NA, UA, SA and RP asset types). Asset nomination is only relevant to asset types which can be renewed and/or changed, meaning is not relevant for certain asset types such as TE, IN and CC.

Nomination of assets under Review Program is subject to some requirements:

- Only one nominee can exist under an RP asset;
- Participants can add/edit a nomination, therefore one of the participant can include itself as a nominee to start a PA-CHG application;
- Only the nominee can initiate a PA-CHG on a RP asset;
- If a PA-CHG case is in progress, the nomination of the RP asset cannot be revoked
- If there is no nominee, the PA-CHG button will not be activated.

12.3.1.   Initiate an asset nomination

To nominate an asset in R4BP 3, search for the specific asset. Once you have gained access to the asset's details page, go to the 'Delegation/Nomination' tab, and click on 'Add nomination'.

Figure 129: Initiate an asset nomination
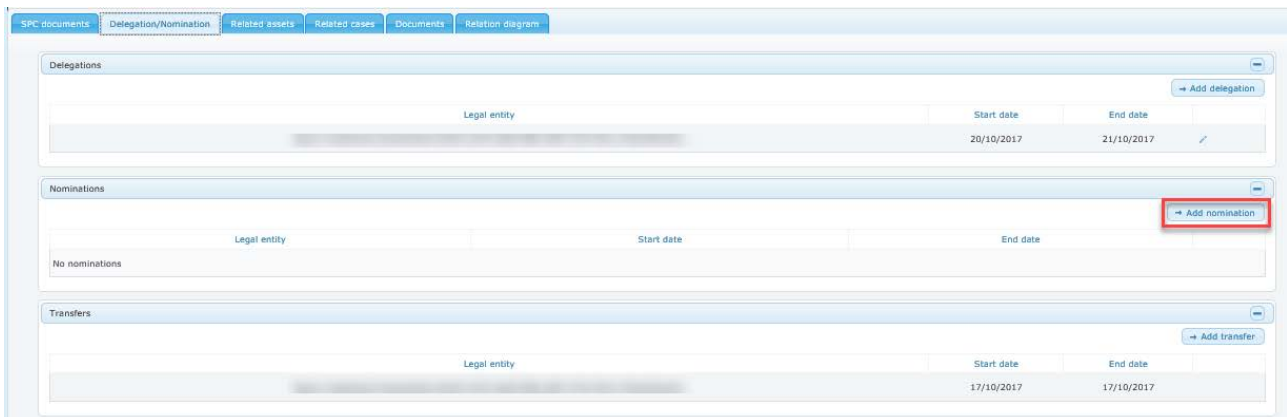
You are requested to provide information regarding the nomination:

- the legal entity UUID for which the asset will be nominated to;
- Indicate a date when the nomination will become valid,
- An end date (empty by default), i.e. the date when the nomination should expire.

Figure 130: Nomination of an asset

When a legal entity nominates an asset, the asset number will be followed by a [N] icon in the asset list, to differentiate it from the other assets. The nominee will see the nominated asset in his asset list. However, the icon will not appear to the legal entity to whom the asset was nominated.

12.3.2.   Modify an asset nomination

A revocation of an asset nomination can be made changing the 'End date' for the active nomination.

Figure 131: Modify an asset nomination

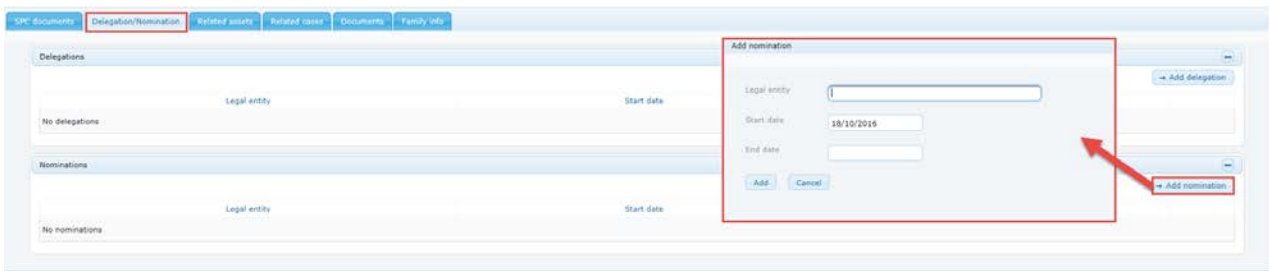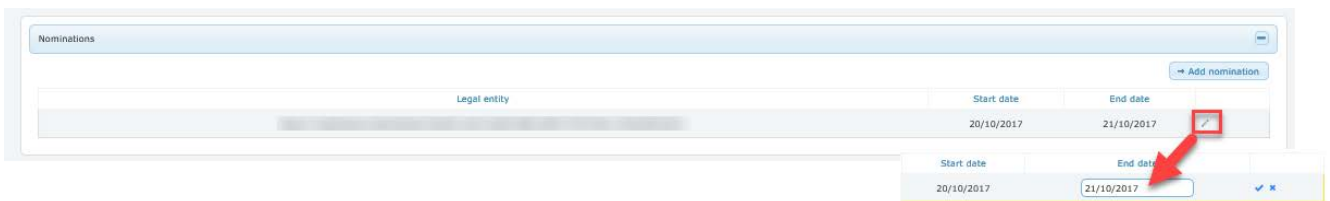The [N] icon disappears if the nominating legal entity removes the nomination or if it expires. Note that the second legal entity does not need to accept the nomination in R4BP 3.

12.4. Asset transfer

A product authorisation can be transferred from one legal entity to another by using the transfer of an asset function in R4BP 3. This means that **the full ownership of the asset will be transferred to the other legal entity**, the asset owner details are updated as well as all the associated rights and responsibilities.

Figure 132: Transfer of an asset in the asset list

⚠️ R4BP 3 does **no**t support the sending of explicit notifications (i.e. messages) when an asset has been transferred.

If you are the asset and case owner and want to **transfer both the case and authorisation** to another legal entity, you will need to perform two separate actions (a case transfer **and** an asset transfer.

12.4.1. Initiate a transfer

In order to initiate a transfer of an asset, the following considerations should be taken into account:

- the asset must be **active**;

- there is **no NA-MRG in progress** for the specific asset (only for NA asset);

- there has been **no other transfer** initiated for that asset;

- no case that affects the present asset or any other linked asset is initiated;

In that sense, an NA asset cannot be initiated for transfer in the following cases:

- if there is already an 'In Progress' NA-TRS case for this asset;

- if there is an 'In Progress' case that updates the specific NA asset (i.e. NA-ADC, NA-MIC, NA-MAC, NA-RNL, NA-MRG, NA-AAT, NA-CAT case types);

- if a family asset, and having a NA-NPF in progress;

- if a family asset, the member assets of the family asset have any cases 'In Progress' which update them (i.e. NA-ADC, NA-MIC, NA-MAC, NA-AAT, NA-CAT case types).

The same will apply for SA asset types. Additionally an SA asset cannot be transferred:

- if there is an 'In Progress' SN-NOT case having as context the specific SA asset;

- if there is an ongoing amendment or cancelation for the SN asset(s) of the SA asset;

- if there is an 'In Progress' SN-NOT case having as context any of the member SA assets;

if there is an ongoing amendment or cancelation for any SN assets of the member SA assets.

a) Asset owner transfer (when there is no same biocidal product or mutual recognition cases associated to the reference case)

Search for the relevant asset in R4BP 3. Once you have selected the specific asset, go to the 'Delegation/Nomination' tab and click on → Add transfer . You are requested to provide information regarding the transfer:

- the legal entity UUID to which the asset will be transferred to;
- A date when the transfer will become valid;
- An end date (empty by default), i.e. when the transfer should expire.

Figure 133: Transfer of an asset
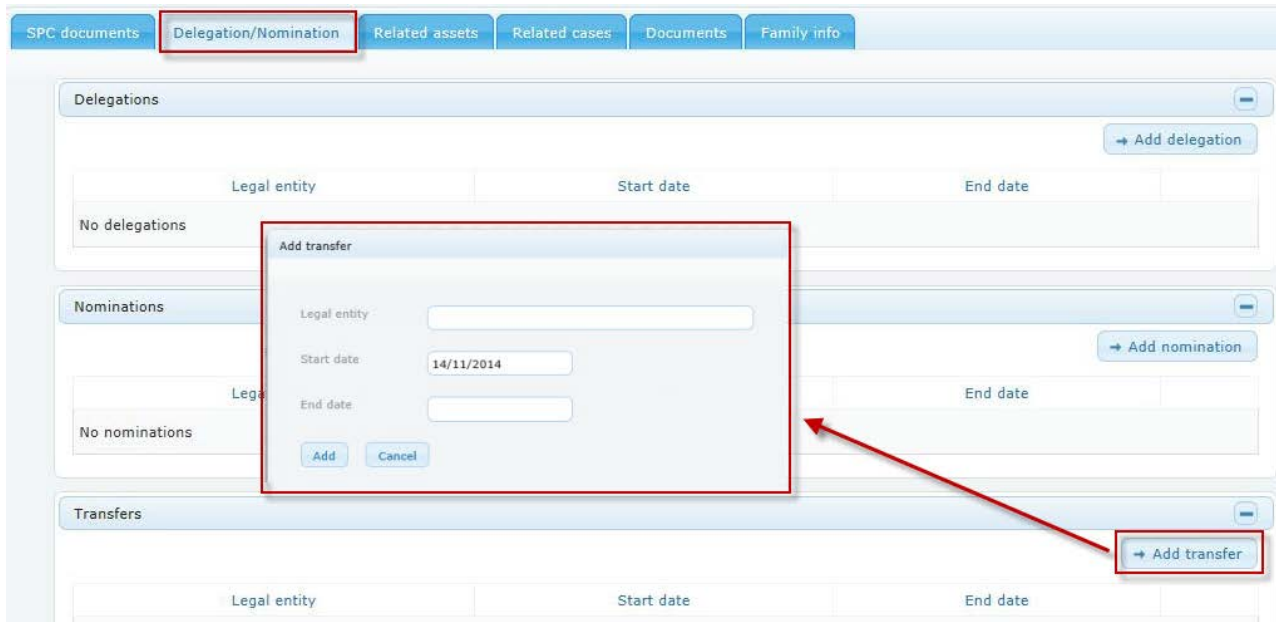
b) Asset owner transfer (in the context of same biocidal product or mutual recognition cases associated to the reference case)

Once you have click on 'add transfer', you will be able to check what cases are related to the reference case, and therefore are also going to be transferred. Any entered data concerning the asset owner transfer such as asset owner (UUID), start date and end date will be applicable for **all the related cases**.

Once the delegation for asset owner transfer has been created, the delegation for asset owner transfer will be displayed under each relevant case (under Delegation tab).

Figure 134: Asset owner transfer applied to same biocidal product cases
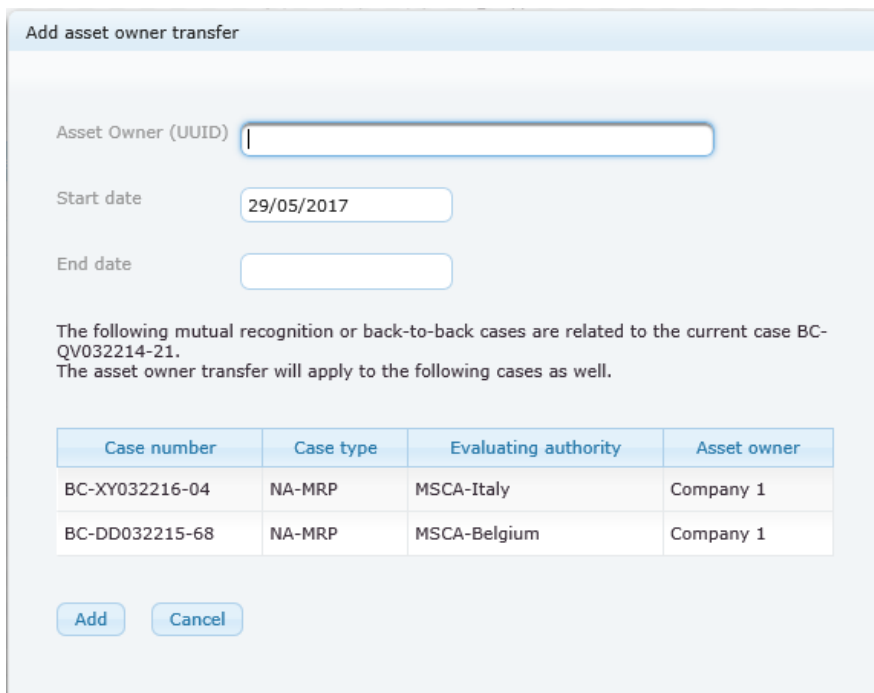
12.4.2.   Accepting an asset transfer

If an asset has been initiated for transfer to a second legal entity, **the second legal entity need to 'Accept asset transfer'**.

When a legal entity transfers an asset, the asset number will be followed by a [T] (in yellow) icon in the 'asset list' to differentiate it from the other assets. The icon will also be visible to the legal entity to whom the asset was transferred to. Once an asset has been successfully transferred, the initial asset owner will be able to view it in his asset list [T] (in green) but will have limited access to the asset details page.

a) Accepting an asset transfer (when there is no same biocidal product or mutual recognition cases associated to the reference case)

Search for your asset and select 'accept asset transfer' to approve the transfer.

Figure 135: Accept asset delegation for transfer

If the asset is an SA or NA asset, then either an SA-TRS or NA-TRS application wizard will be launched. Please refer to the Biocides Submission Manuals application instructions available on the ECHA website for more information on these specific application types.

Figure 136: NA-TRS wizard

For UA and PP asset transfer, clicking on the 'Accept asset transfer' will not trigger an

application wizard as the acceptance of the transfer will be effective immediately.

Once an asset has been successfully transferred, any delegations and nominations on cases or assets are cancelled, the SPC package of the asset is updated with the administrative data of the new legal entity, and any SN assets (i.e. notifications for placing on the market) linked to SA asset(s) are transferred to the new legal entity.

b) Accepting an asset transfer (in the context of a same biocidal product or mutual recognition cases associated to the reference case)

If you need to accept an asset transfer when many cases are related to this asset, note that **ONLY the reference case inherits the button to 'Accept the asset owner transfer'.** Once you have accepted the asset owner transfer from the reference case, any required change will apply to all related cases.
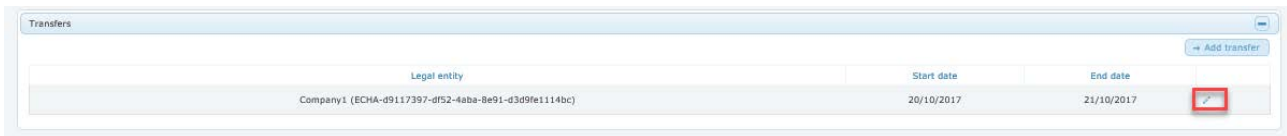
Figure 137: Accept asset transfer
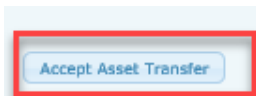
12.4.3. Modify a transfer

A revocation of an asset nomination can be made changing the 'End date' for the active nomination.

Figure 138: revocation of an asset nomination

The [T] (in yellow) icon disappears if the legal entity removes the pending transfer or if it expires.

12.5. Case transfer

A case can be transferred from one legal entity to another by using the relevant 'case transfer' function in R4BP 3. This means that **the full ownership of the case will be transferred to the other legal entity** and therefore the case owner details will be updated as well as all the associated rights and responsibilities.

Note that if you are the asset and case owner and want to transfer both the case and authorisation to another legal entity, you will need to perform two separate actions (a case transfer **and** an asset transfer).

12.5.1. Initiate a case transfer

In order to initiate a transfer of a case, the following considerations should be taken into account:

- the case status must be '**in progress**' or '**suspended**';
- You are the **case** or the **asset owner**
- there is **no PA-CHG 'In progress' for AS-EVA/AS-NAS cases**;
- there has **no other active transfer** for that case;
- depending on the case type, the transfer can be initiated by either the **case owner** or the **asset owner**;
- For same biocidal product cases you may initiate the case owner transfer for one or all

cases. If the asset owner is to be changed then **all grouped cases should be transferred together**. You will then need to transfer the asset owner. If only the case owner changes then each case can be transferred independently.

When you are ready to proceed, search for the relevant case in R4BP 3 and access the case details page. Click on the 'Delegation/Nomination' tab and choose to 'Add transfer'.

Figure 139: Case owner transfer

a) Case owner transfer for an individual case

You are then requested to provide information regarding the transfer:

- the legal entity UUID to which the case will be transferred to;
- A date when the transfer will become valid;
- An end date (empty by default), i.e. when the transfer should expire.

Figure 140: Transfer of a case

b) Case owner transfer in the context of a grouped submission

If a case owner transfer needs to be initiated for a case which is related to MRP and BBP cases, you will have the opportunity to select some or none of these cases.

Figure 141: Case owner transfer for same biocidal product applications

If you have selected one or many related cases, a delegation for case owner transfer will be automatically created with the same details (case owner LE, start date, end date).

Additionally, you are requested to provide information regarding the transfer:

- the legal entity UUID to which the case will be transferred to;
- A date when the transfer will become valid;
- An end date (empty by default), i.e. when the transfer should expire;

12.5.2. Modify a case transfer

You can edit the transfer at any stage of the submission. Click on the 'Delegation' tab in the case details page and modify the start date and/or the end date.

A revocation of a case transfer can be made changing the 'End date' for the transfer.

Figure 142: Modify a transfer of case

12.5.3. Accept a case transfer

Depending of the case type, **the case transfer can be approved by either the prospective case owner or the asset owner (prospective or current)**.

a) Accepting a transfer of an individual case

To accept the case transfer, search for your case and click on 'Action' to open the case transfer acceptance menu.

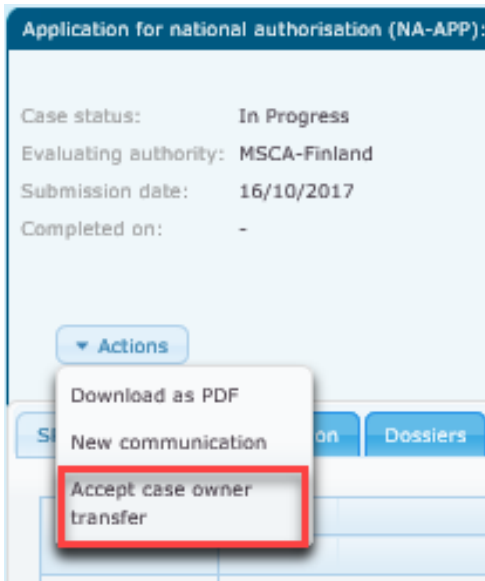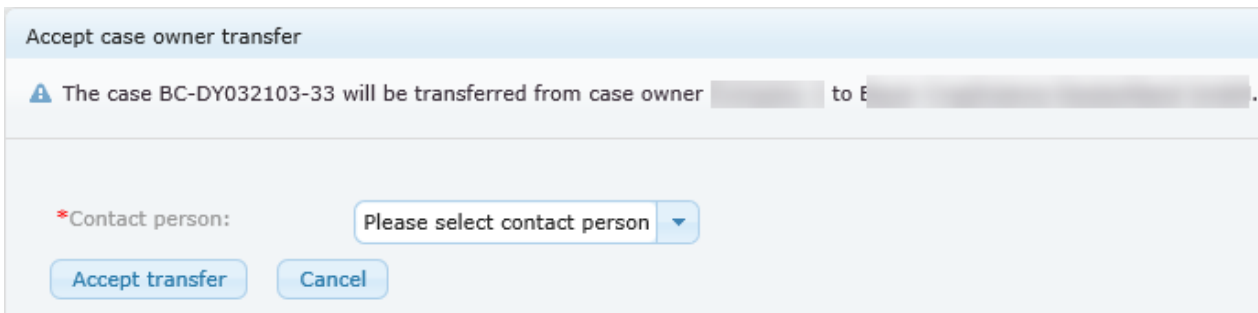**Figure 143: Accept asset delegation for transfer**

Figure 144: Accept case owner transfer

Once you have accepted the case transfer, an event will be lodged in the 'Events history' tab.

Figure 145: Events history

b) Accepting a transfer in the context of a grouped submission

If there are multiple cases being transferred, you will need to navigate to the case details for each individual case and repeat the 'accept case owner transfer' action for each of the transferred cases.

Figure 146: Accepting a case transfer for a case which has related cases
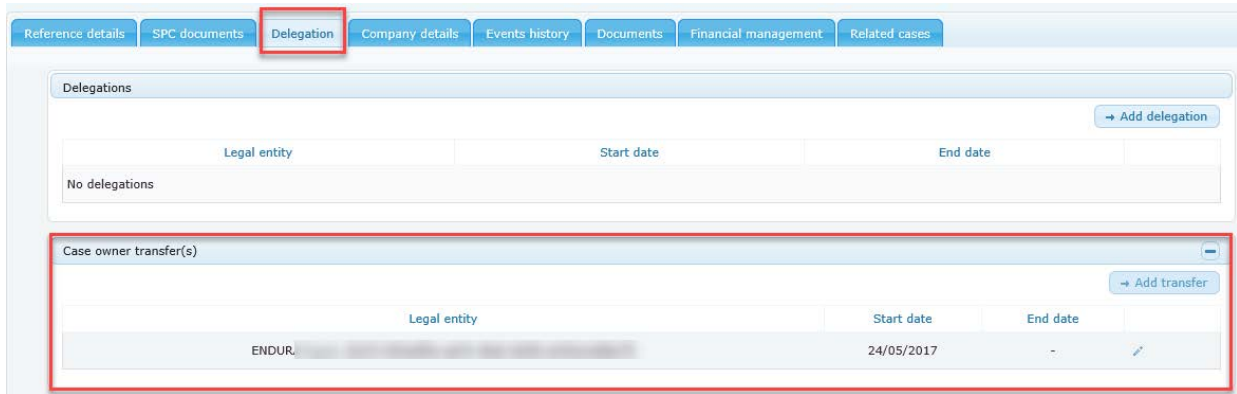
Once the transfer is completed, everything related to the case will be available for the new case owner.

13.   How ECHA handles your submission

Once an application has been submitted via R4BP 3, it subsequently goes through a series of processing steps.

13.1. File format check

This verification step ensures that the application and any attached files are virus free and in the correct format, i.e. those supported by R4BP 3. If an application contains unsupported file formats, the submission will be deemed invalid and a 'Resubmit information' task will be generated, allowing the case owner to resubmit the application with files in the correct formats.

13.2. Substance identity check

For any new active substance to be introduced in the database, ECHA will proceed with a substance evaluation (SID) check once the application has passed the file format check.

13.3. Business rules confirmation

If the virus scan and the substance identity checks have passed, an administrative check is carried out by ECHA. All valid applications received by ECHA undergo this administrative check, called 'business rules confirmation' (BRC). The business rules are a set of pre-requisites that must be fulfilled before ECHA can establish that the application can be handled properly and that the required regulatory processes can be carried out.

If all of the business rules have been met, the application will be allowed to progress to the next step and a 'Format check' message will be sent to the relevant case owner's message list. This message confirms that the application has been submitted and is awaiting further processing by ECHA. The application will then proceed to the next step, awaiting acceptance by ECHA.

If not all of the business rules have been met, the application will be stopped at this step and a message or a task item (depending on the application type) will be sent to the applicant informing them how to proceed. The message will contain information on what errors were found and how to correct the errors to pass this step. Depending on the application type, failure of the BRC step may lead to:

- a 'Resubmit information' task item being generated,
- a 'Reply to communication' task item being generated, and/or
- a message indicating how to submit a new application to pass this step.

13.4. Application acceptance

Once the application has passed the BRC step, ECHA will carry out an invoice assessment i.e. whether the application submitted will be subject to an ECHA invoice or not). If the application type does not require an ECHA invoice, the application will be 'accepted' by ECHA and forwarded to the appropriate evaluating authority - in most cases this will be the MSCA nominated by the applicant during the submission process, but it may also be ECHA, e.g. for an assessment of technical equivalence.

If an ECHA invoice is required, the fee amount will be calculated and an invoice generated addressed to the company indicated in the application. Regardless of the address, the invoice will be sent to the case owner's message list in R4BP 3. All invoices must be paid within the given deadline for an application to be accepted by ECHA.

If the invoice is paid, the application will then be 'accepted' by ECHA and forwarded to the evaluating authority (i.e. evaluating MSCA or internally within ECHA).

If an invoice is not paid by the given deadline the application is rejected at this stage. For more information concerning invoices, please see BSM: Process of Invoicing in R4BP 3.

13.5. Redefinition of Active substance (within the Review programme)

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

13.6. Invoice assessment

As the case owner, you will receive, when applicable, a message in your message list informing you that an invoice has been sent.

Click on the hyperlink of the message in order to open the 'Communication details' page.

Click on the hyperlink on this page to be redirected to the 'Financial management' tab of the corresponding case.

Figure 147: 'Communication details' page accessed through the 'Message list'
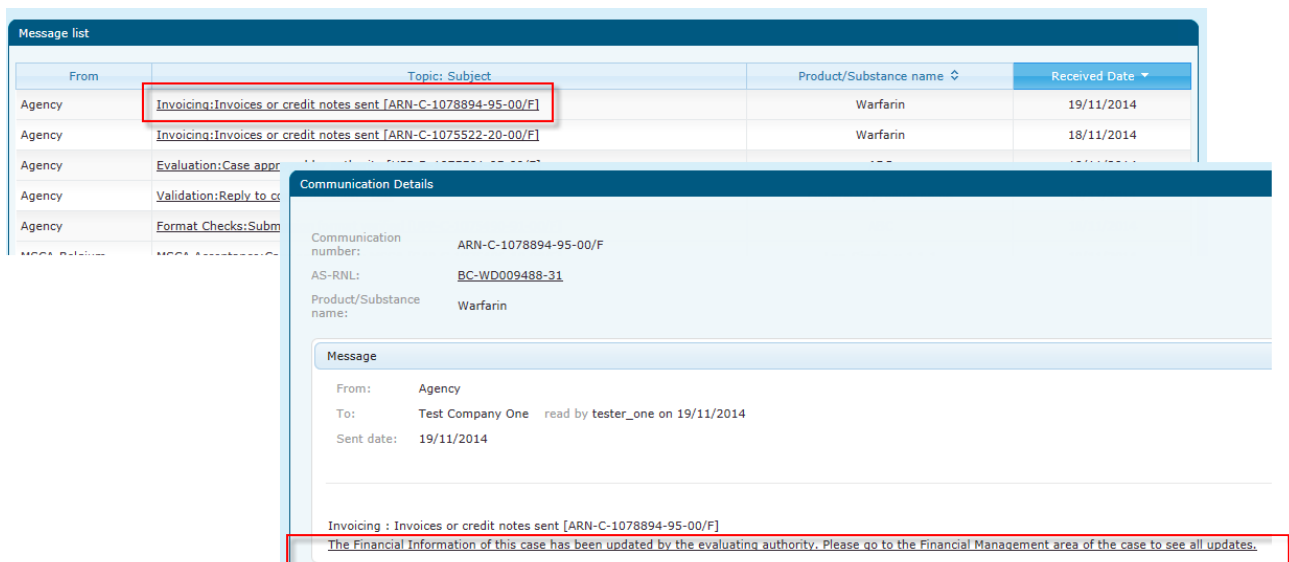
From the 'Financial management' tab, click on the relevant 'Invoice' <u>hyperlink</u> to download the invoice in PDF format.

Figure 148: Invoice downloaded from the 'Financial managements' tab

During the processing of an application, a second invoice or a reimbursement may be applicable. In these cases, ECHA will ensure that the correct fee is paid. This may lead to a subsequent invoice or the cancelation of an invoice with a credit note and reimbursement of the appropriate fee.

13.7. Confidentiality claim screening

ECHA screens all accepted biocidal related dossiers for confidentiality requests according to Article 67(3) and 67(4) of the BPR. However, the MSCA will perform the confidentiality assessment. For more information concerning the dissemination of data, please see <u>BSM: Process of confidentiality requests for biocide applications</u>.