



User Guide

Pre-application ID

Last update: 14 September 2023

Note for the users

This user guide has been updated on 14 September 2023 to take into account the latest system enhancements.

- When adding a new component to a pre-application ID, business operators and/or their consultants are prompted with a new and more visible button as well as an enhanced layout.
- Associated components are showed in the related list “Subject of the Application: Components” on the right-hand side of the pre-application ID page. For easier identification of listed components, additional fields (e.g. Name, Type of Term, Origin) have been added.
- The “Other components” field in the pre-application ID page has been discontinued. Previously recorded information has been moved to the “Note” field.
- A time-limited notification box on the Application page (for business operators and/or their consultants) or Studies page (for laboratories) has been be introduced. This allows to notify users about newly introduced functionalities.

Some editorial changes have been introduced to further clarify the existing content.



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Introduction

#Connect.EFSA



I - Scope of the pre-application ID

Pre-submission activities

- ✓ General pre-submission advice, Article 32a(1) of the GFL
- ✓ Notification of studies commissioned or carried out to support an application, Article 32b of the GFL
- ✓ Notification of intended studies for renewal application and renewal pre-submission advice, Article 32c(1) of the GFL



After registration and prior to initiating any pre-submission activity, a potential applicant must create a pre-application ID, which links all pre-submission activities undertaken by a potential applicant to support a future application related to a specific regulated product in a given regulated product area.

1. Actors of the Process

The process for managing the pre-application ID might involve up to **two types of actors**:

Business operators

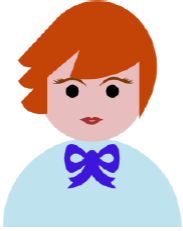
(orange)

Third parties/consultants

(blue)

For ease of reference through this guide, the two roles are visualised by the respective **colour stripe** on the left-hand side of slides.

1. Actors of the Process



Business operators
Potential applicants

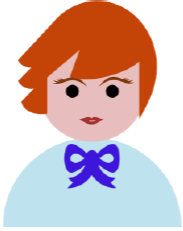
Business operators: these users create and manage their pre-application IDs in Connect.EFSA.



**Third parties/
Consultants**

Third parties/consultants: these users operate on behalf of business operators when authorised to represent one or more entities, shall also register-in (see the section on [Account Relationship](#)). They can create and manage pre-application IDs in Connect.EFSA.

1.1 Account qualification



**Business operators
Potential applicants**

This guide applies to users qualified as applicant, i.e. organisations such as business operators. They act as potential applicant conducting pre-submission activities linked to a future application for a regulated product in a specific regulated area.

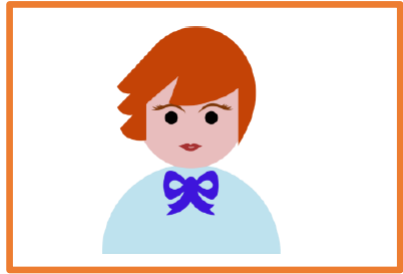
These organisations can create pre-application IDs.



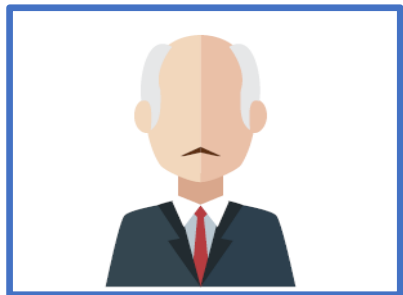
**Third parties/
Consultants**

The same qualification is assigned to consultants working on behalf of business operators.

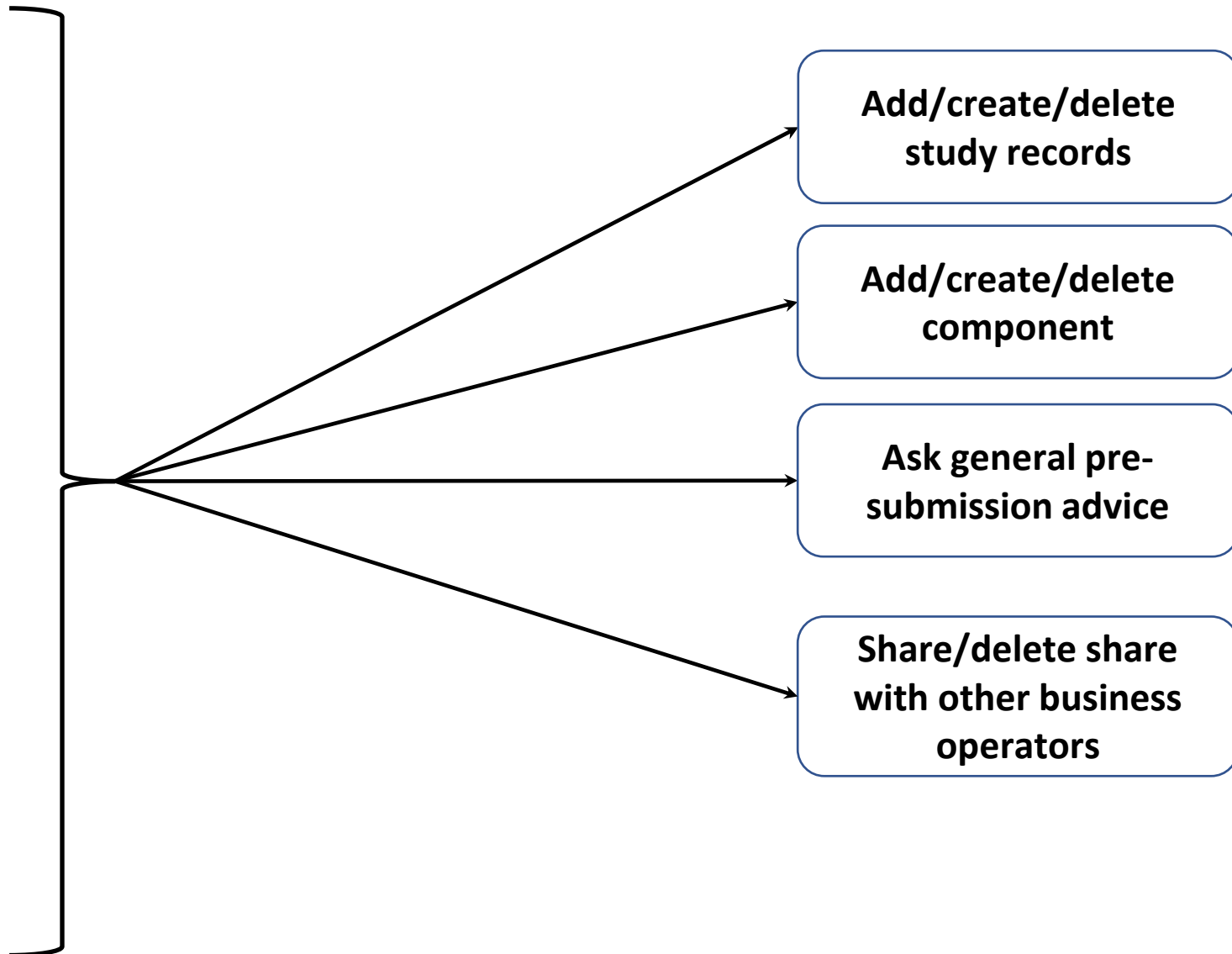
1.2 Pre-application ID activities



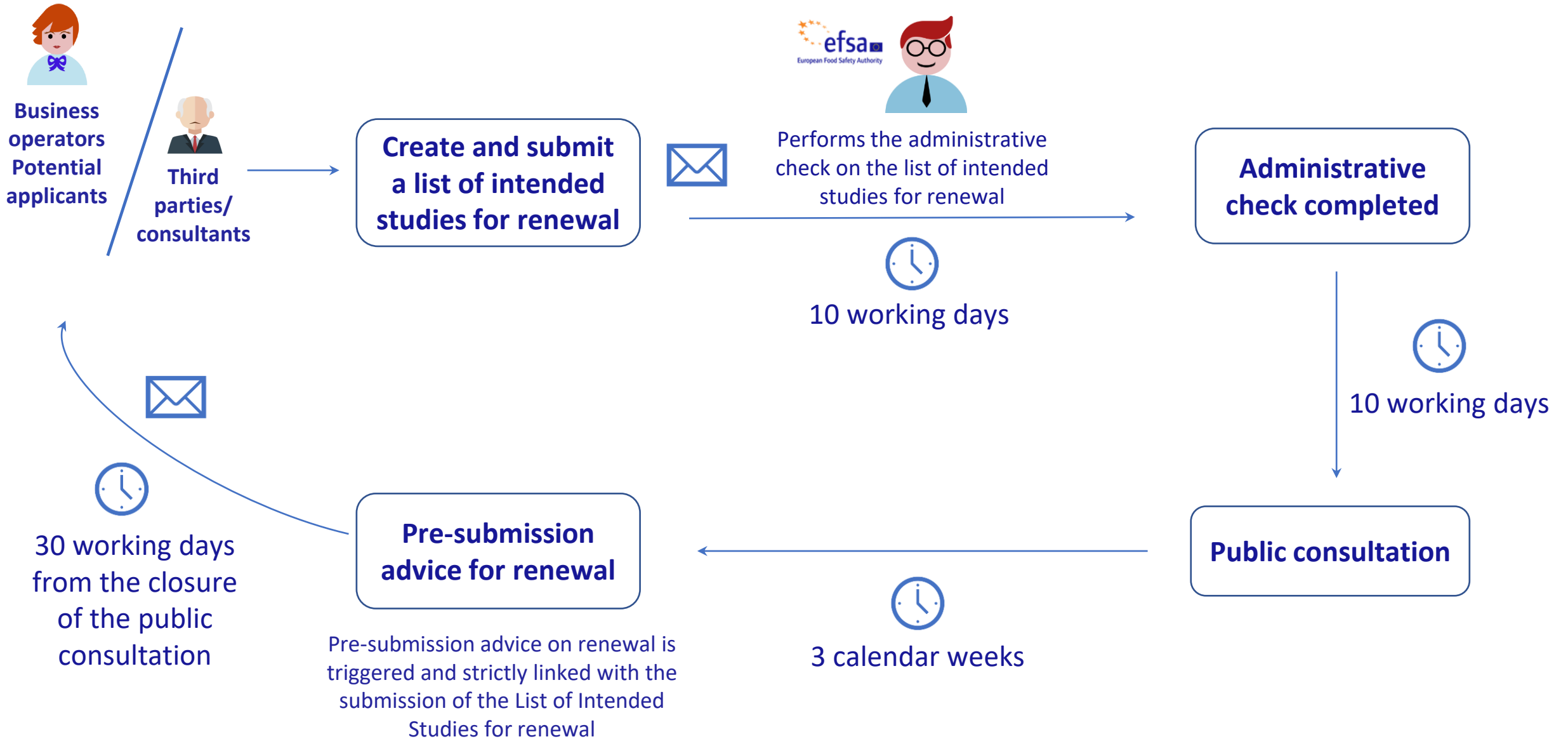
Business operators
Potential applicants
Create and manage
pre-application IDs



**Third parties/
Consultants**
Can be authorised to manage
pre-application IDs



1.3 List of intended studies for renewal: Process overview



Logging in

#Connect.EFSA



2. Log-in entry point

Users can access Connect.EFSA portal from their `trusted` devices

via the following link:

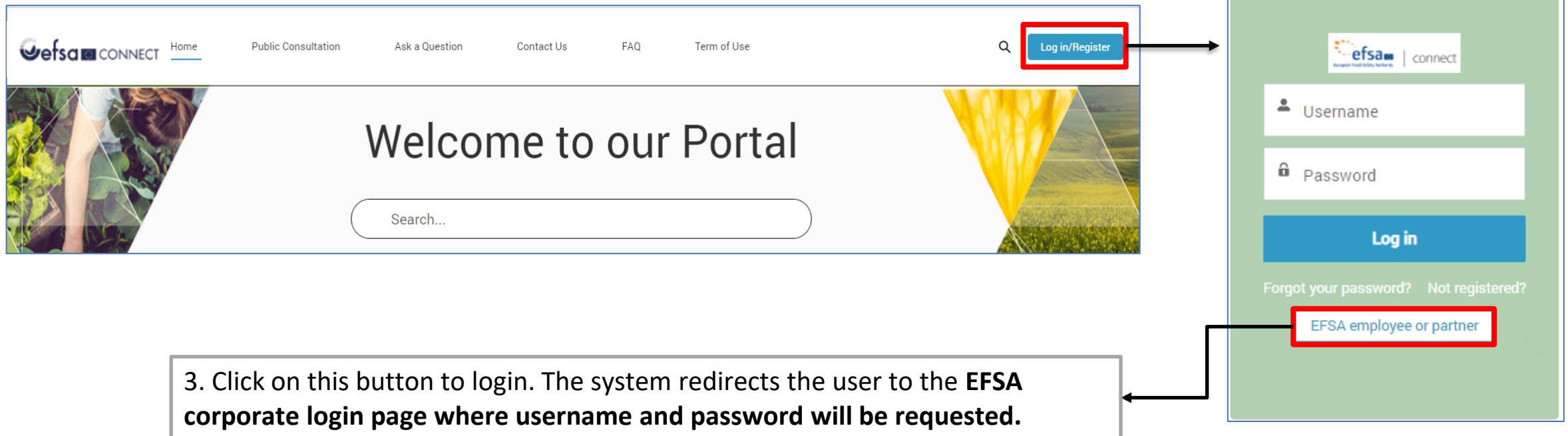
<https://connect.efsa.europa.eu/RM>



2.1 Users log in

To log into Connect.EFSA as Portal user:

1. Insert the following Url in the browser: <https://connect.efsa.europa.eu/RM>
2. Click on the Log in/Register button (right upper corner)



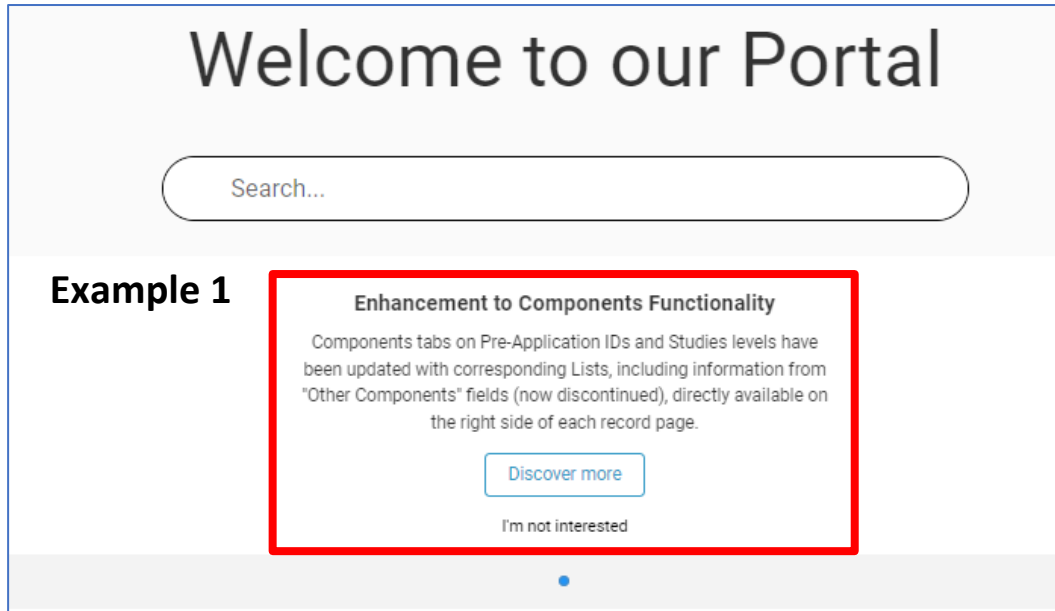
The image shows a screenshot of the EFSA Connect portal. The top navigation bar includes the EFSA logo, 'CONNECT', and links for 'Home', 'Public Consultation', 'Ask a Question', 'Contact Us', 'FAQ', and 'Term of Use'. A search icon and a 'Log in/Register' button (highlighted with a red box) are located in the top right corner. Below the navigation bar is a large banner with the text 'Welcome to our Portal' and a search input field. To the right of the banner is a login form with fields for 'Username' and 'Password', a 'Log in' button, and links for 'Forgot your password?' and 'Not registered?'. A red box highlights the 'EFSA employee or partner' link in the login form. An arrow points from the 'Log in/Register' button in the navigation bar to the login form, and another arrow points from the 'EFSA employee or partner' link to a text box below.

3. Click on this button to login. The system redirects the user to the **EFSA corporate login page where username and password will be requested.**

2.2 Time limited notification box

New!

Users find information about newly introduced functionalities in the time limited notification boxes, which according to the relevance of the information for the various users (applicants or laboratories) may be showed in different pages of the Connect.EFSA portal. For instance, the main Portal page (example 1) or in the Application section (example 2).



Example 1

Welcome to our Portal

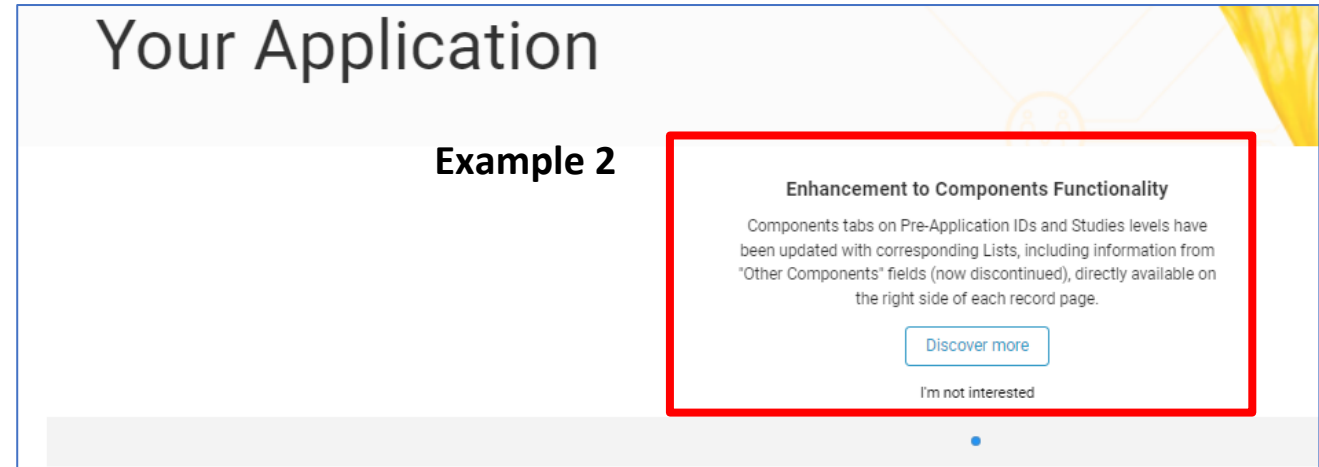
Search...

Enhancement to Components Functionality

Components tabs on Pre-Application IDs and Studies levels have been updated with corresponding Lists, including information from "Other Components" fields (now discontinued), directly available on the right side of each record page.

[Discover more](#)

[I'm not interested](#)



Example 2

Your Application

Enhancement to Components Functionality

Components tabs on Pre-Application IDs and Studies levels have been updated with corresponding Lists, including information from "Other Components" fields (now discontinued), directly available on the right side of each record page.

[Discover more](#)

[I'm not interested](#)

Pre-application ID

#Connect.EFSA



3. Connect.EFSA portal

efsa CONNECT Home Application Consultation Ask a Question My Details FAQ Contact Us

Welcome to our Portal

1 Search... Search Bar

2 Alerts Icon

3 User Information

1. Search bar
2. Alerts Icon
3. User Information

Access Application section from here

This portal gives you the possibility to engage with EFSA on a variety of topics. You will be able to check the Frequently Asked Questions, consult and submit comments to EFSA's public consultations, and send requests for access to documents. Before sending EFSA a question, please read the Frequently Asked Questions.

Applications Consultations Ask a Question My Details

FAQ Access FAQ

About EFSA

- [How do I subscribe to EFSA's newsletters?](#)
- [How can I find out which experts worked on a scientific opinion?](#)
- [Where can I find information on EU food safety legislation?](#)

Engage with EFSA

- [Where do I find the DAR \(Draft Assessment Reports\) application tool and related files?](#)
- [I did not receive an email confirming my registration to Connect EFSA. How can I complete my registration to the portal?](#)
- [I have a problem opening the database of health claims](#)

Didn't find what you were looking for?

3.1 Create a pre-application ID

The screenshot shows the 'Your Application' page on the EFSA CONNECT portal. The navigation bar includes 'Home', 'Application', 'Consultation', 'Ask a Question', 'My Details', 'FAQ', and 'Contact Us'. The main heading is 'Your Application'. A red box highlights a text area containing instructions on how to use the menu. Below this, there are three green buttons: 'Current Application', 'Pre-Application IDs', and 'Studies'. Arrows point from the 'Pre-Application IDs' and 'Studies' buttons to explanatory text boxes. The 'Pre-Application IDs' box explains that users can create a pre-application ID for new or renewal applications. The 'Studies' box explains that users can access the studies database and that studies must be created and notified from the related pre-application ID.

Using the menu below, you can access:

- **Current Application:** In this section you can find your applications once they have received the EFSA Question number
- **Pre-Application IDs:** A section where you can conduct pre-submission activities such as create a pre-application ID, create and submit a list of intended studies for renewal applications, create and notify studies, and request a general pre-submission advice regarding your future applications.
- **Studies database :** A section where you can create and notify studies in support of a future application

Information on Pre-Submission Activities

- [EFSA' s Practical Arrangements on pre-submission phase and public consultations](#)
- [Questions and Answers on the EFSA Practical Arrangements](#)
- [Connect.EFSA user guides](#)

In this box, instructions to help the user to conduct pre-submission activities are provided.

Current Application

Pre-Application IDs

From the Pre-Application IDs section, the user can create a pre-application ID supporting a new application or a renewal application.

Studies

From this section the user can access the notification of studies database. **It is reminded that studies must be preferentially created and notified from the related pre-application ID.**

3.1 Create a pre-application ID


Pre-Application ID

In this page you can see the details of your Pre-application ID, as well as its related records. You can perform the following actions:

- Create a **Pre-application ID** to link all your pre-submission activities in support of your future application
- Access and review all the **Pre-submission Advice**, i.e **requests for General Pre-Submission Advice** and **Pre-Submission Advice on Renewal**
- Access and review all **Intended Studies**
- Access and review all **Lists of Intended Studies** for renewal applications
- Access and review the **Components** Section

[Pre-Application IDs](#) [Pre-Submission Advice](#) [Intended Studies](#) [Lists of Intended Studies](#) [Components](#)

The list below contains all Pre-Application IDs that you have already created. Use the search bar on the right to search for a Pre-Application ID.

 My Pre-Application IDs ▾

50+ items • Sorted by Created Date • Filtered by All pre-application ids - MyPreapplication

	Request Name	ID	Food Dom...	Applicatio...	Authorisat...	Contact N...	Created ...
1	TR_test Edit button	EFSA-ID-2022...	GMO	Notification ...	Deliberate rel...		15/07/2022 1...
2	Paid 15/7	EFSA-ID-2022...	Pesticides Pe...				15/07/2022 1...

Use this dropdown menu to filter a search.

To create a new pre-application ID the user selects the **New Pre-Application ID** button.

[New Pre-Application ID](#)

In this box, the actions available to the user are described.

Here the user can perform a search according to values in the columns shown.

🔍 Search this list...

3.1 Create a pre-application ID

Step 1 – The user indicates the information required to create a new pre-application ID, such as the business operator name and the subject of the application.

The user can fill this field with:

- Its own organisation name (**business operators**)
- The name of the business operator for which the **third party/consultant** is creating the pre-application ID “On behalf of”.

The screenshot shows a web form titled "New Pre-Application ID". It contains several fields: "Request Name" (text input), "Business Operator" (text input with a search icon and "Search Accounts..." placeholder, highlighted with a red box), "Food Domain" (dropdown menu with "--None--" selected, containing an information icon), "Authorisation Type" (dropdown menu with "--None--" selected), "Application Type" (dropdown menu with "--None--" selected), and "Subject Of The Application" (text input, highlighted with a red box). Red asterisks are placed before the labels for "Request Name", "Business Operator", and "Subject Of The Application".

• * this sign means that the field is **mandatory**

• ⓘ this icon displays the **help text** for that field.

3.1 Create a pre-application ID

If a **business operator** or a **third party/consultant** tries to create a pre-application ID for another organisation, the system returns the following **error message**, unless a relationship between the two organisation has been previously established.

Review the errors on this page.

* Request Name

* Business Operator

It is not allowed to choose this Business Operator. Please review Organization Relationships and try again.

* Food Domain

Authorisation Type

Application Type

* Subject Of The Application ⓘ

Note ⓘ

Look at the [Account Relationship section](#) to understand how to establish a relationship “On behalf of” and enable an organisation to work on behalf of the user’s organisation.

3.1 Create a pre-application ID

Step 2 - With a given combination of **Food Domain** and **Application Type**, the user can create a pre-application ID to link all pre-submission activities supporting a new application or a renewal application.

New Pre-Application ID

*Request Name
New Application for XYZ

*Business Operator
ABC Company

*Food Domain ?
--None--

Authorisation Type
--None--

Application Type
--None--

*Subject Of The Application ?
Subject of the application for XYZ

Note ?

Confirm

Once all the required fields are filled in, the user selects the **Confirm** button to proceed.

3.1.1 Pre-application ID - Applications

New Pre-Application ID

* Request Name
New Application for of XYZ

* Business Operator
ABC Company Spa

* Food Domain ⓘ
Feed Additives

* Authorisation Type
Feed Additives

* Application Type
Application for authorisation of a new feed additive (Article 4(1) of Regulation (EC) No 1831/2003)

* Subject Of The Application ⓘ
Subject of the Application for XYZ

Note ⓘ

Confirm

In this case, the user creates a **pre-application ID** to link pre-submission activities **supporting an application**.

Once all the required fields are filled in, the user selects the **Confirm** button to proceed.

3.1.1 Pre-application ID - Applications

Pre-Application ID
New application for JPQ

ID
EFSA-ID-2023-000912

Under each **tab** the user can see different information regarding the pre-application ID.

1 Edit New Study Add Studies

Ask GPSA
Share With
Delete
Printable View

Pre-Application Operations

- Use the **New Study** button to create new Study records
- Use the **Add Studies** button to add notified and or co-notified studies
- Use **New List** button to create a List of Intended Studies for renewal (only for renewal applications)
- Add additional parties to this Pre-Application ID using the **Share With** button
- Use the **Add Component** button to add one or more components to this Pre-Application ID
- Request a General Pre-Submission Advice by using the **Ask GPSA** button
- Use the **Delete** button to delete your Pre-Application ID (certain conditions apply)

2 Food Domain
Novel Foods
Authorisation Type
Novel Food Authorisation
Application Type
New Novel Food

3 Add Component

4 Subject of the Application: Components (0)
Study Notification (0)
Share With (0)

New!

1 Use these buttons to [create a new draft study](#) or [add a notified study](#), [request a GPSA](#) or [delete](#) the pre-application ID.

2 Values in these fields can be modified only when there are no submitted objects associated to the pre-application ID.

3 Use the [Add Component](#) button to add/create one or more components and link them to the pre-application ID.

4 This section lists all the associated objects and the sharing relationships.

3.1.2 Pre-application ID - Renewal applications

New Pre-Application ID

*Request Name
Application for renewal of XYZ

*Business Operator
ABC Company Spa

*Food Domain
Feed Additives

*Authorisation Type
Feed Additives

*Application Type
Application for authorisation of a new use and/or modification and/or renewal of an already authorised feed additive (Articles 4(1), 13(3), 14 of Regul..

*Subject Of The Application
Subject of the Application for XYZ

Note

Confirm

Suggested video tutorial: [pre-application ID and list of intended studies.](#)

In this case, the user creates a **pre-application ID** to link pre-submission activities **supporting a renewal application.**

The system allows the creation and submission of a list of intended studies.

Once all the required fields are filled in, the user selects the **Confirm** button to proceed.

3.1.2 Pre-application ID - Renewal applications

Pre-Application ID
Renewal application for XYZ

ID
EFSA-ID-2022-000646

1

Under each **tab** the user can see different information regarding the pre-application ID.

2

3

4

Pre-Application Operations

- Use the **New Study** button to create new Study records
- Use the **Add Studies** button to add notified and or co-notified studies
- Use **New List** button to create a List of Intended Studies for renewal (only for renewal applications)
- Add additional parties to this Pre-Application ID using the **Share With** button
- Use the **Add Component** button to add one or more components to this Pre-Application ID
- Request a General Pre-Submission Advice by using the **Ask GPSA** button
- Use the **Delete** button to delete your Pre-Application ID (certain conditions apply)

New!

Add Component

Study Notification (0)

List of Intended Studies (0)

Pre-Submission Advice (0)

Share With (0)

1 Use these buttons to [create a new draft study](#) or [add a notified study](#), [request a GPSA](#), create and submit a [list of intended studies](#) or [delete](#) the pre-application ID.

2 Values in these fields can be modified only when there are not submitted objects associated to the pre-application ID.

3 Use the [Add Component](#) button to add/create one or more components and link them to the pre-application ID.

4 This section lists all the associated objects and the sharing relationships.

3.2 Create a new study

New Study

The user selects **New Study** and fill in the fields, then clicks **Next** to create a new draft study record and link it to this pre-application ID.

Study Notification

Please fill in the following information to create a new study.

In the Business Operator field insert your own organisation or, if you are working as third party, the organisation for which you want to create the study.

* Study Title

Study Title (English Name) ⓘ

* Business Operator ⓘ

Search Accounts...

Laboratory ⓘ

Search Accounts...

Next

New Study

A new Study has been created in Draft status. You can access by clicking on the button below.

Go to New Study

To return to your Pre-Application ID, simply click on **Next**.

Next

Study Notification (4)

Study Title	EFSA Study Iden...	Status	Study Withdrawn
Test Share wit...	EFSA-2022-0000...	Draft	<input type="checkbox"/>
Test Share wit...			<input type="checkbox"/>

The study created appears in the **Study Notification** section available in the page of the pre-application ID.

The user must indicate the business operator carrying out or commissioning the study. By default, it is the same user organisation as indicated in the pre-application ID. **When creating the notification** (and **only** at that stage), it is possible to edit the “Business Operator” field and indicate the actual business operator for that specific study notification. To do so, this entity should establish a relationship “on behalf of” with the third party/consultant (see [Create an account relationship](#)).

The user can also indicate the laboratory commissioned to conduct the study. This information can be revised also at a later stage.

3.3 Add a study to the pre-application ID

Add Studies

Click on **Add Studies** and use the search bar to search a study record. It is possible to select one or more study records the user would like to add to the pre-application ID. To continue click on **Next**.

Search Studies...
Q determi

Selected Studies: 2
EFSA-2020-00000208 X EFSA-2020-00000211 X

<input type="checkbox"/>	Study Number	Name	Food Domain	Created Date
<input type="checkbox"/>	EFSA-2020-00000192	Determination of the ferric citrate content add...	Feed Additives	21.10.2020
<input checked="" type="checkbox"/>	EFSA-2020-00000208	Determination of physico-chemical properties	Pesticides	28.10.2020
<input checked="" type="checkbox"/>	EFSA-2020-00000211	Determination of physico-chemical properties	Pesticides	29.10.2020
<input type="checkbox"/>	EFSA-2020-00000193	Determine the concentration of iron or nickel i...	Feed Additives	21.10.2020

Next

Only notified and co-notified studies can be added to the pre-application ID.

Added studies appear in the **Study Notification** section available in the page of the pre-application ID.

Add to

Selected Studies: 3

Close Submit

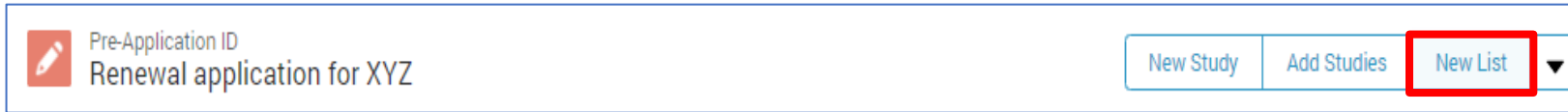
Study Notification (3)

Study Title	EFSA Study Iden...	Status	Study Withdrawn
TR_test2_Stud...	EFSA-2022-0000...	Notified	<input type="checkbox"/> <input type="checkbox"/>
Study 123	EFSA-2022-0000...	Notified	<input type="checkbox"/> <input type="checkbox"/>
Study to co-not...	EFSA-2022-0000...	Co-Notified	<input type="checkbox"/> <input type="checkbox"/>

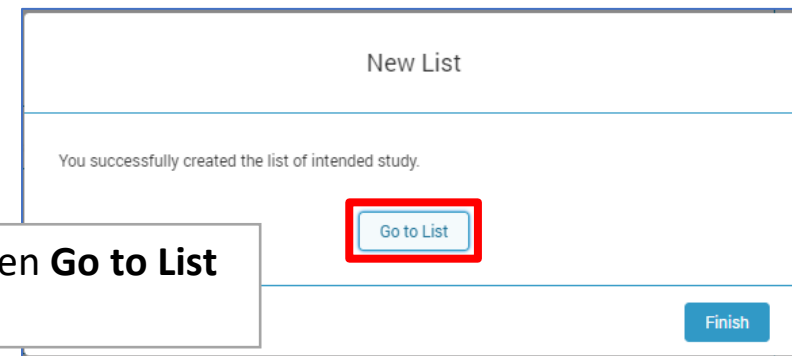
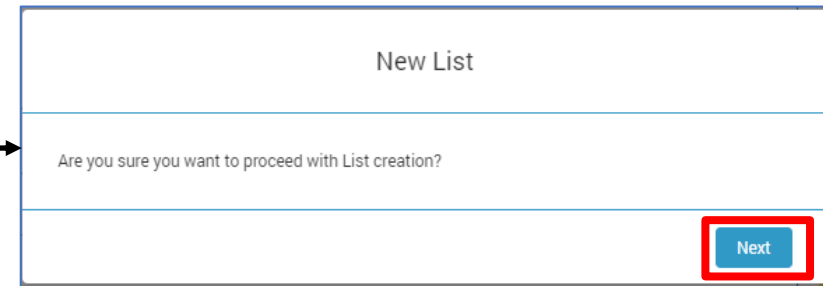
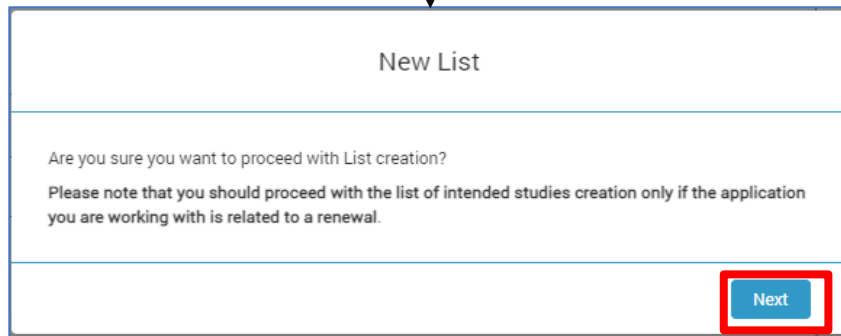
View All

3.4 Create a list of intended studies for renewal

From the page of a [pre-application ID supporting a renewal application](#) the user can create a new list of intended studies by clicking on **New List**.



If the selected Food Domain is Feed Additives the message below is shown (it is only a warning message that does not block the process). For all the other Food Domains, a simple alert appears.



In both cases click **Next**, then **Go to List** to proceed.

3.4 Create a list of intended studies for renewal

Upon creation, the status of the list of intended studies is set as **Draft**.

The screenshot shows the 'List of Intended Studies' interface. At the top, a progress bar indicates the status 'Draft' is selected. Below this, the user's business operator 'ABC Company Spa' and the pre-application ID 'LIST-07-2022-0049' are displayed. A toolbar contains buttons for 'New Intended Study', 'Submit List', and 'Delete'. A 'Mass Conversion' button is located below the toolbar. The main content area shows a list of intended studies, with a 'Public Consultation (0)' entry highlighted. A 'Details' tab is also visible.

List of Intended Studies for Renewal Operations

You have saved this record as a draft. You can perform the following actions:

- Use the **New Intended Study** button to create a new intended study. They will subsequently be displayed in the table "Intended Studies"
- When the List of Intended Studies for Renewal is complete, click on the **Submit List** button
- You can **edit all the records** of the intended studies present in your list or **notify** them. **Note:** notified studies will be excluded from the list of intended studies upon submission
- Use the **Delete** button to delete your list of intended studies (certain conditions apply)
- Use the **Mass Conversion** button to select the intended studies to be notified

Under each **tab** the user can see different information regarding the list of intended studies.

Here the user finds the objects associated to the list of intended studies.

In this box, the actions available to the user on the list of intended studies are described.

3.4.1 Create an intended study

Users can create **new intended studies** that will be part of the list according to the provisions of Article 32c(1) of the General Food Law and Article 12 of the [EFSA Practical Arrangements on pre-submission phase and public consultations](#).



New Intended Study

Please fill in the following information to create a new intended study

Study Title

* Study Title

Complete this field.

Study Title (English Name) ⓘ

Study Scope

Type the name of the Study Type and click 'Enter' or 'Search all result for ...' to see all results for your search. If you want to see all existing Study Types, type 'All' and click Enter.

* Study Objective

* Study Type

* Test Item

Study Desing

Type the name of the Study Guideline and click 'Enter' or 'Search all result for ...' to see all results for your search. If you want to see all existing Study Guidelines, type 'All' and click Enter.

Study Detailed Protocol

Study Guideline

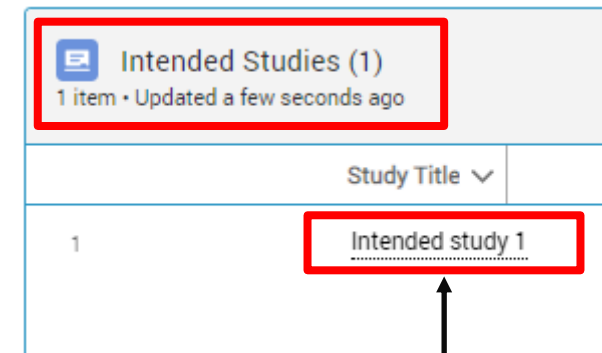
Next

The New Intended Study form must be completed indicating all the mandatory information. Then the user clicks **Next**.

If needed, it is possible to **edit** the information of the new intended study in a second moment before the submission of the list.

Suggested read: [Question and Answer on the EFSA Practical arrangements](#), section **Intended applications for renewal**.

Upon creation, the intended study is shown in the **Intended Studies section** of the list.



Click on the study title to access it.

3.4.1 Create an intended study

The form for the intended study allows to indicate a study title up to 300 characters long and to search more easily among values of Study Type and Study Guidelines and select the most relevant.

Please fill in the following information to create a new intended study

Study Title

* Study Title

Complete this field.

Study Title (English Name) ⓘ

Up to 300 characters long.

This field can be used to **search and select a specific Study Type or Guideline**. Click on the below message "Show All Results for..." to see the search results. **Type "All"** and press **Enter** to see the full list.

Study Scope

Type the name of the Study Type and click 'Enter' or 'Search all result for ...' to see all results for your search. If you want to see all existing Study Types, type 'All' and click Enter.

* Study Type

Q Show All Results for "Tox"

- Sediment toxicity
- Short-term toxicity to aquatic inverte...
- Short-term toxicity to fish
- Acute Toxicity. Skin Irritation/Corrosi...
- Acute Toxicity. Skin Sensitisation

all existing Study Guidelines, type 'All' and click Enter.

Study Type

Study Types

50+ Results • Sorted by [Relevance](#)

STUDY TYPE NAME

Toxins/Virulence factors

Toxicity to terrestrial plants

Study Desing

Type the name of the Study Guideline and click 'Enter' or 'Search all result for ...' to see all results for your search. If you want to see all existing Study Guidelines, type 'All' and click Enter.

Study Guideline

Q Show All Results for "OECD"

- OECD Guideline 492 (Reconstructed ...
- OECD Guideline 501 (Metabolism in ...
- OECD Guideline 502 (Metabolism in ...
- OECD Guideline 503 (Metabolism in ...
- OECD Guideline 504 (Residues in Rot...

Study Guideline

Study Guidelines

50+ Results • Sorted by [Relevance](#)

STUDY GUIDELINE NAME

OECD Guideline 301 E (Ready biodegradability. Modified OECD Screening Test)

OECD Guideline 417 (Toxicokinetics)

OECD Guideline 451 (Carcinogenicity Studies)

3.4.1 Create an intended study

In the intended study page, the user can revise the information provided and perform further actions on the intended study record.

Intended Study
QWERTY_1

[Edit](#) [Convert](#) [Delete](#) ▼

Intended Study ID INTS-000125	Converted <input type="checkbox"/>	List of Intended studies LIST-07-2022-0059
----------------------------------	---------------------------------------	---------------------------------------------------------------

▼ Study Title

Study Title
QWERTY_1

Study Title (English Name)
QWERTY_1

▼ Study Scope

Study Type Acidity/Alkalinity And Ph Value	Study Objective QWERTY_1
Test Item QWERTY	

▼ Study Design

Study Guideline ISO 10708 Water quality - Evaluation in an aqueous medium of the ultimate aerobic biodegradability of organic compounds - Determination of biochemical oxygen demand in a two-phase closed bottle test	Study Design Description QWERTY_1
Study Detailed Protocol QWERTY_1	

▼ Other Information

List of Intended studies
[LIST-07-2022-0059](#)

Intended studies can be **edited** or **deleted** only if the status of the list of intended studies is equal to “Draft” or “Clarification Needed”.

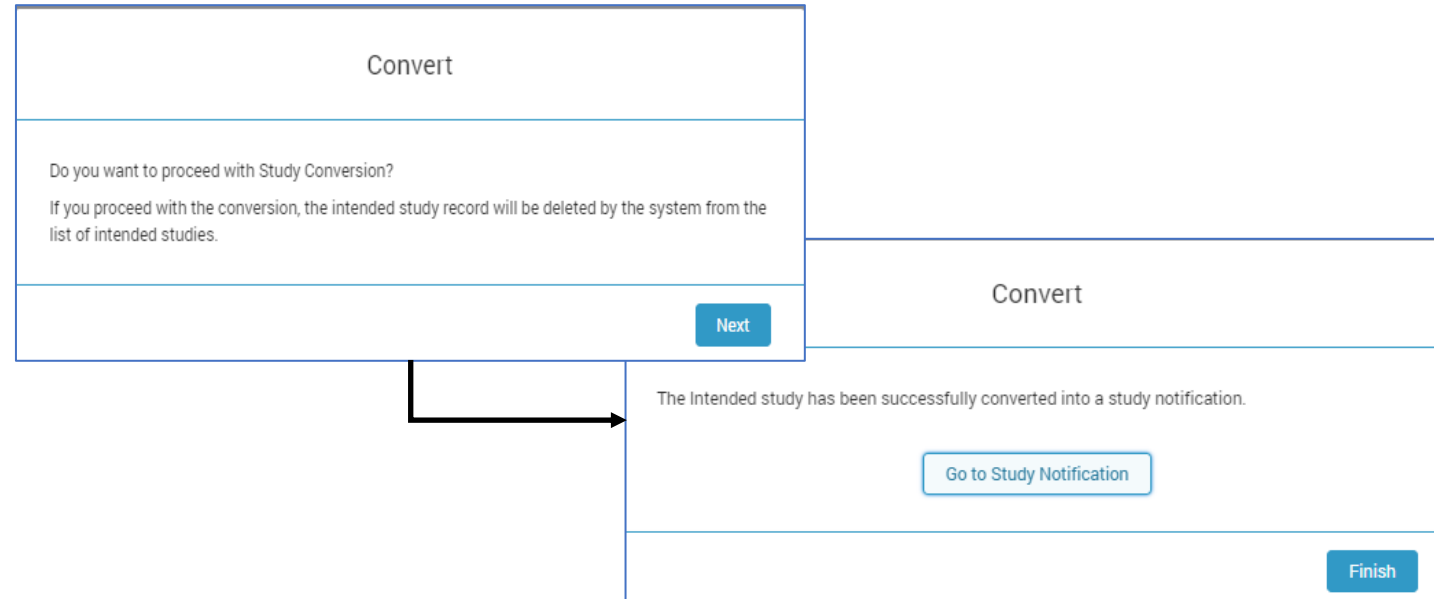
Intended studies can be **converted into notifiable draft studies (for notifications according to Article 32b of the General Food Law)** only if the status of the list of intended studies is “Draft”, “Clarification Needed” or “Closed”.

3.4.2 Convert single intended studies

Single intended studies that are going to be commissioned can be converted into notifiable draft studies (for notifications according to Article 32b of the [General Food Law](#)) **only** when the status of the list is **“Draft”**, **“Clarification Needed”** or **“Closed”**.



The user clicks **Convert** from the intended study record page. **If the status of the list is “Draft” or “Clarification Needed”**, a warning message appears, clarifying that the converted notifiable study will not be subject to public consultation (as such, study can no longer be considered as ‘intended’).



If the user decides to **convert an intended study when the status of the list is “Closed”** the original copy of the intended study will remain in the Intended Studies section of the list as record history and **marked as converted**.

	Study Title	Study Type	Study Objective	Study Guideline	Test Item	Study Design Descr...	Study Detailed Prot...	Converted	
1	test uat 6	Acute Toxicity To Bees	test uat 6	ISO 10253 (Water qual...	test uat 6	test uat 6	test uat 6	<input checked="" type="checkbox"/>	▼
2	test uat 5	Pre-Clinical Data: In Vit...	test uat 5	OECD Guideline 433 dr...	test uat 5	test uat 5	test uat 5	<input type="checkbox"/>	▼
3	test uat 4	Repeated dose toxicity...	test uat 4	OECD Guideline 438 (I...	test uat 4	test uat 4	test uat 4	<input checked="" type="checkbox"/>	▼
4	test uat 7	Acute toxicity, other ro...	test uat 7	Other	test uat 7	test uat 7	test uat 7	<input checked="" type="checkbox"/>	▼

3.4.2 Convert single intended studies

Following the conversion, an **intended study** is transformed into a **draft notifiable study** (for notifications according to Article 32b of the General Food Law). The **draft study record** is moved into the “Study Notification” section of the related pre-application ID. The user can access the draft study and edit it before the notification.

Pre-Application ID
Renewal application TJP

Edit New Study New List ▼

ID
EFSA-ID-2023-000914

Details History

Request Name
Renewal application TJP

Business Operator
ABC Company Spa

▼ Details

Subject Of The Application ⓘ
Renewal application TJP

Former Application ID ⓘ
EFSA-Q-XXXXXXX

Note ⓘ

ID
EFSA-ID-2023-000914

Contact Name

Food Domain ⓘ
Feed Additives

Authorisation Type
Feed Additives

Application Type
Application for authorisation of a new use and/or modification and/or renewal of an already authorised feed additive (Articles 4(1), 13(3), 14 of Regulation (EC) No 1831/2003 respectively)

Pre-Application Operations

- Use the **New Study** button to create new Study records
- Use the **Add Studies** button to add notified and or co-notified studies
- Use **New List** button to create a List of Intended Studies for renewal (only for renewal applications)
- Add additional parties to this Pre-Application ID using the **Share With** button
- Use the **Add Component** button to add one or more components to this Pre-Application ID
- Request a General Pre-Submission Advice by using the **Ask GPSA** button
- Use the **Delete** button to delete your Pre-Application ID (certain conditions apply)

Add Component

Subject of the Application: Components (0)

Study Notification (1)

Study Title (S...	EFSA Study Ide...	Status	Study Withdrawn	
Study TJP	EFSA-2023-000...	Draft	<input type="checkbox"/>	▼

[View All](#)

List of Intended Studies (1)

List of Intended studies Name	Status
LIST-09-2023-0513	Draft

3.4.3 Submit a list of intended studies

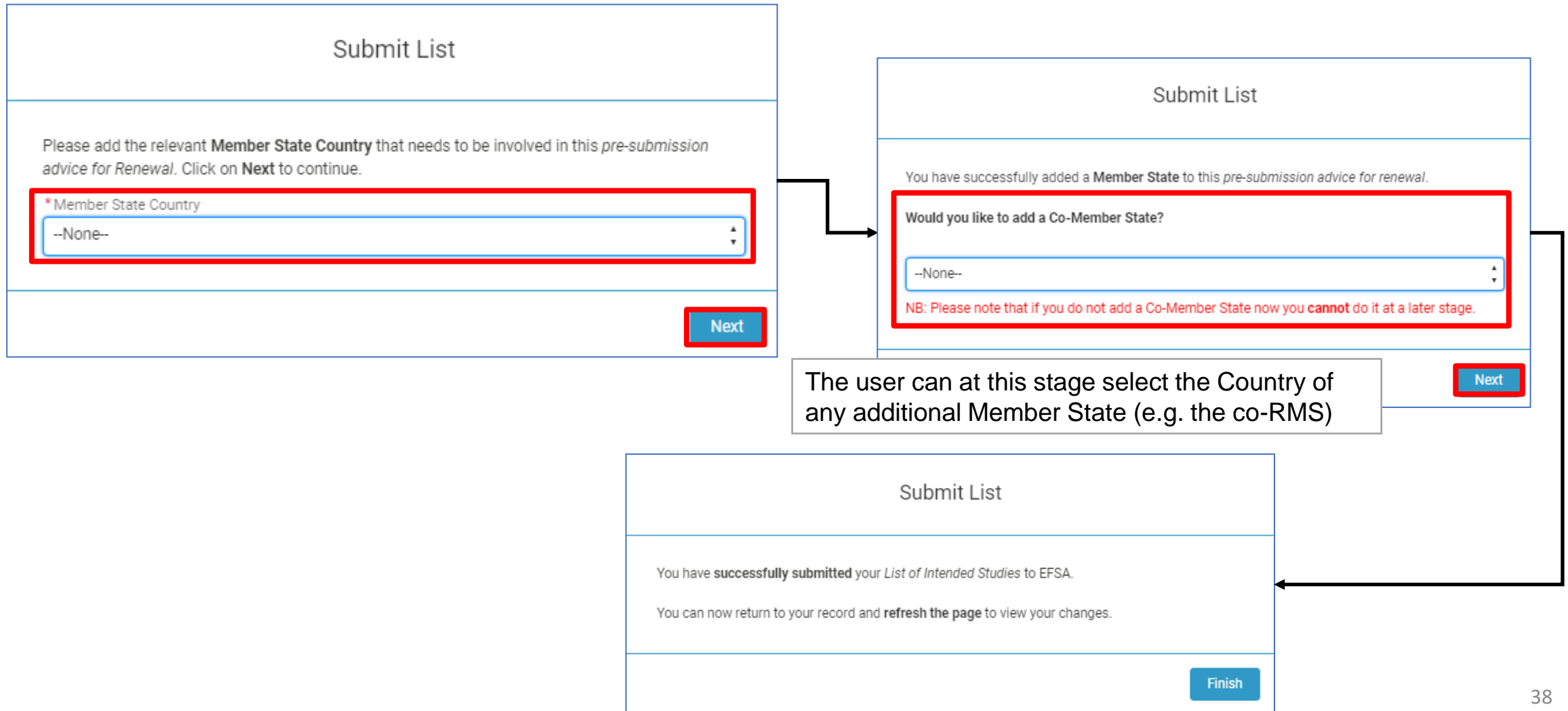
When the list of intended studies is ready, the user can submit it to EFSA by using the function button **Submit List** and then **Next**.

The screenshot displays the EFSA interface for managing intended studies. At the top, a header bar shows the application ID 'LIST-07-2022-0049' and a 'Business Operator' 'ABC Company Spa'. A 'Pre-Application ID' is 'Renewal application for XYZ'. A toolbar contains buttons for 'New Intended Study', 'Submit List' (highlighted in red), and 'Delete'. Below this is a 'List' tab with a 'Mass Conversion' button. A table titled 'Intended Studies (3)' lists three studies. A modal dialog box is open over the table, titled 'Submit List', with the text 'To submit this record to EFSA, please click on Next.' and a 'Next' button (highlighted in red). Arrows indicate the flow from the 'Submit List' button to the modal dialog.

Study Title	Study Type	Study Object...	Study Guideline	Test Item	Study Desig...	Study Detail...	Converted
1 Intended study 2	Acute Contact Toxicity	Intended study 2	ISO 10707 Water quality - Evaluation in an aqueous medium ...	Subject of the application for XYZ	Intended study 2	Intended study 2	<input type="checkbox"/>
2 Intended study 3	Active Substance Bioconcentration In Prey Of Birds And Ma...	Intended stud				y 3	<input type="checkbox"/>
3 Intended study 4	Acute Contact Toxicity	Intended stud				y 4	<input type="checkbox"/>

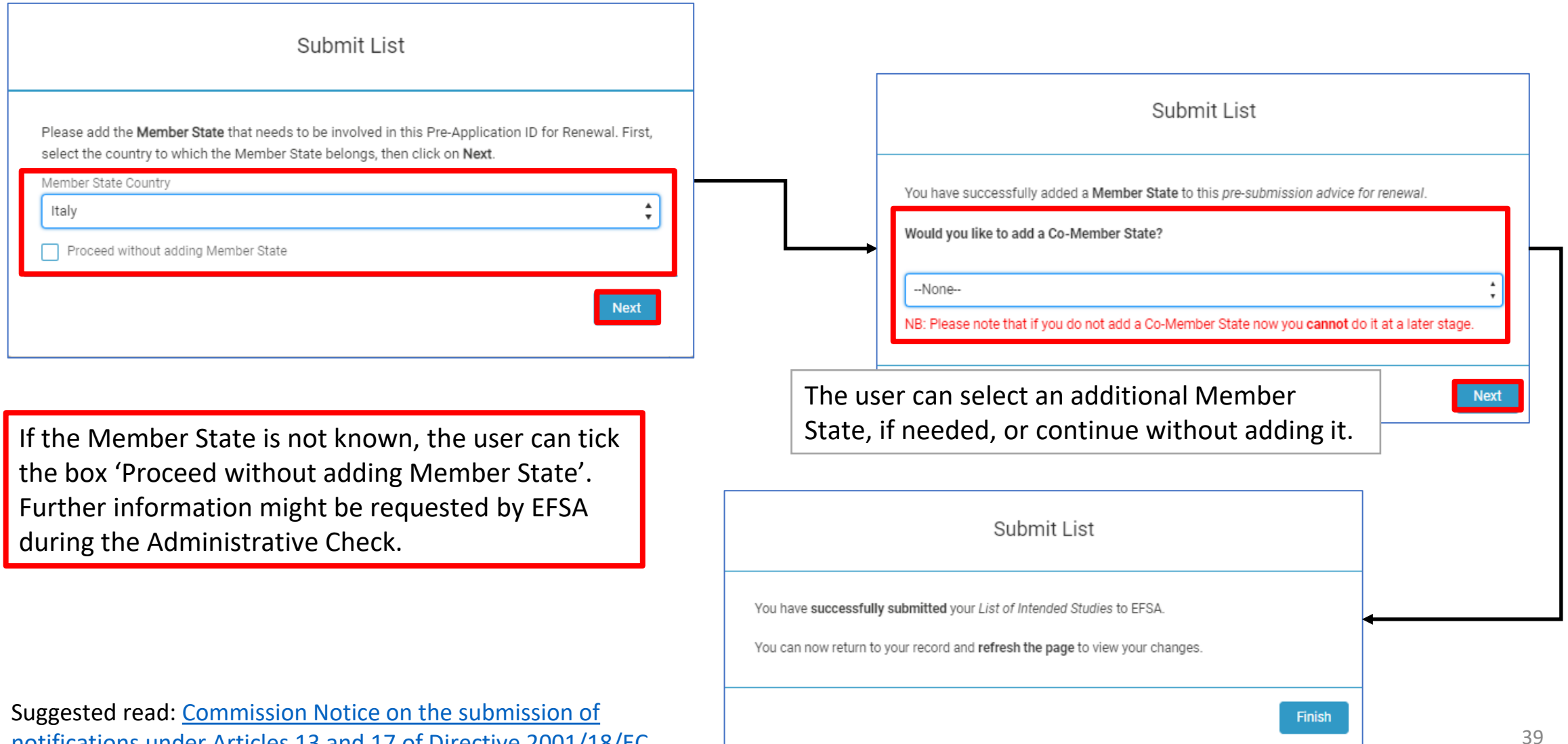
3.4.3.1 Submit a list of intended studies - Pesticides

When the pre-application ID for the renewal is related to the Food Domain **Pesticides (AIR)**, the user **must** select the **Member State Country** corresponding to the relevant Competent Authority in the rapporteur Member State/Co-rapporteur Member State for that renewal application.



3.4.3.2 Submit a list of intended studies - GMO Directive 2001/18/EC

When the pre-application ID for the renewal is related to **GMO Directive 2001/18/EC**, the user is asked to select the **Member State Country** corresponding to the relevant Competent Authority in the Member State for that renewal notification.



If the Member State is not known, the user can tick the box 'Proceed without adding Member State'. Further information might be requested by EFSA during the Administrative Check.

The user can select an additional Member State, if needed, or continue without adding it.

3.4.3 Submit a list of intended studies

Upon the submission of the list of intended studies its status turns into **Submitted**.

The screenshot shows a progress bar at the top with stages: Draft, Clarification Needed, Submitted (highlighted in a red box), Administrative Check Completed, Undergoing Public Consultation, In Progress, and Closed. Below the progress bar, the title 'List of Intended Studies' is followed by the ID 'LIST-07-2022-0049'. A toolbar contains buttons for 'New Intended Study', 'Submit List', and 'Delete'. A table below shows submission details:

Business Operator	Date Submitted	Pre-Application ID
ABC Company Spa	12/07/2022	Renewal application for XYZ

A red box highlights a text area on the right titled 'List Of Intended Studies for Renewal Operations'. It contains the following text:

You have successfully submitted the List of Intended Studies for Renewal to EFSA. You might be asked to provide clarifications. You will be alerted about any developments via email.

When the status is "Submitted" it is not possible to perform further actions on the List of Intended Studies, such as add further intended studies, notify the records present in the list or delete the entire list.

The screenshot shows the 'Details' tab for a specific study. The 'Details' tab is highlighted in a red box. The information is organized into two columns:

Field	Value
List of Intended studies Id	LIST-06-2023-0505
Business Operator	ABC Company Spa
List of intended studies submission	
Date Submitted	19/06/2023
Status	Submitted
Member State Information (Pesticides and GMO Directive 2001/18/EC only)	
Member State Country	Austria
Member State Organisation	Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH
Contact Name	
Pre-Application ID	PAID for the renewal of the user guide R8
EFSA Comment	
Note	
Closed Reason	
Co-Member State Country	Italy
Co-Member State Organisation	National Authority

Upon submission and after each step, the record information reported in the **Details tab** is automatically updated.

In the **Details tab** the user finds also the selected Member State(s) information, if required by the type of application for renewal.

3.4.4 List of intended studies - Clarification Needed

During the administrative check performed by EFSA, there might be the need for clarification on the information submitted with the list. EFSA will set the status of the list to **Clarification Needed**.

To reply to the clarification request, users can **edit** the pre-application ID and the list record. It is also possible to **add, delete or convert** intended studies into notifiable draft studies by using the specific buttons.

The screenshot displays a workflow progress bar at the top with stages: Draft, Clarification Needed (highlighted with a red box), Submitted, Administrative Check Completed, Undergoing Public Consultation, In Progress, and Closed. Below the progress bar, the main content area shows a 'List of Intended Studies' for 'LIST-07-2022-0049'. The business operator is 'ABC Company Spa', submitted on '12/07/2022', with a pre-application ID of 'Renewal application for XYZ'. Action buttons include 'New Intended Study', 'Submit List', and 'Delete'. A red box highlights a detailed message titled 'List of Intended Studies for Renewal Operations'. This message states that EFSA has reviewed the submitted list and requires clarifications. It lists several actions users can take: recording responses in the 'Notes field', using the 'New Intended Study' button, editing all records and notifying them (noting that notified studies are excluded), using the 'Submit' button to re-submit after amendments, using the 'Delete' button, and using the 'Mass Conversion' button to convert studies to notifiable draft status.

Business Operator: ABC Company Spa
Date Submitted: 12/07/2022
Pre-Application ID: Renewal application for XYZ

List of Intended Studies for Renewal Operations

EFSA has reviewed the submitted List of Intended Studies for Renewal. You have been asked to provide clarifications based on the feedback in the EFSA Comment field.

You can perform the following actions

- Record your clarification response in the **Notes field**
- Use the **New Intended Study button** to create a new intended study. They will subsequently be displayed in the section "List of Intended Studies for renewal"
- You can **edit all the records** of the intended studies present in your list or **notify** them. **Note:** notified studies will be excluded from the list of intended studies upon submission
- When you have provided all the amendments requested by EFSA you have to use the **Submit button** to re-submit the list
- Use the **Delete button** to delete your list of intended studies (certain conditions apply)
- You may use the **Mass Conversion** button to select the intended studies to convert into notifiable draft studies

3.4.4 List of intended studies - Clarification Needed

Under the **Details tab** of the list the user finds the section **EFSA comments** containing the request(s) of clarification. A reply can be submitted by the user using the **Note section**.

After the required amendments have been done and the list is ready, the user must **Submit** the **list** again.

List of Intended Studies
LIST-07-2022-0049

New Intended Study **Submit List** Delete

Business Operator: ABC Company Spa
Date Submitted: 12/07/2022
Pre-Application ID: Renewal application for XYZ

List **Details**

List of Intended studies Name: LIST-07-2022-0049
Business Operator: ABC Company Spa
Date Submitted: 12/07/2022
Status: Clarification Needed

Contact Name: _____
Pre-Application ID: Renewal application for XYZ

EFSA Comment: Request from EFSA to amend the information
Note ⓘ

Closed Reason: _____

The status turns again into **Submitted**.

Draft → Clarification Needed → **Submitted** → Administrative Check Completed → Undergoing Public Consultation → In Progress → Closed

3.4.5 List of intended studies – Administrative Check Completed and Public Consultation

When EFSA has completed the administrative check, the status turns into **Administrative Check Completed**.

The screenshot shows a progress bar with stages: Draft, Clarification Needed, Submitted, **Administrative Check Completed** (highlighted in red), Undergoing Public Consultation, In Progress, and Closed. Below the progress bar, the interface displays the title 'List of Intended Studies LIST-07-2022-0049' and a dropdown menu with options 'New Intended Study', 'Submit List', and 'Delete'. A table below shows application details:

Business Operator	Date Submitted	Pre-Application ID
ABC Company Spa	12/07/2022	Renewal application for XYZ

A red box highlights the 'List Of Intended Studies for Renewal Operations' section, which contains the following text:

EFSA completed the administrative check on the information submitted with your list of intended studies.

When the status is "Administrative check completed" it is not possible to perform further actions on the List of Intended Studies, such as add further intended studies, notify the records present in the list or delete the entire list.

The screenshot shows the progress bar with the status **Undergoing Public Consultation** highlighted in red. The interface details are identical to the previous screenshot. A red box highlights the 'List Of Intended Studies for Renewal Operations' section, which contains the following text:

A public consultation on the list of intended studies for renewal is ongoing.

Public Consultation End Date: 30 July 2022

When the status is "Undergoing Public Consultation" it is not possible to perform further actions on the List of Intended Studies, such as add further intended studies, notify the records present in the list or delete the entire list.

The day the public consultation is **planned** by EFSA, the status of the list turns into **Undergoing Public Consultation** and the user can access the public record of the public consultation from a dedicated section in the list page.

A red box highlights a notification icon with a bell and the text 'Public Consultation (1)'. An arrow points from this notification to a table below:

Public Consultation Number
PC-0172

A 'View All' link is located at the bottom right of the table.

3.4.6 List of intended studies – In Progress

After the end of the public consultation the status of the list turns into **In Progress**. This means that EFSA is considering the comments received during the public consultation and will provide the user with the renewal pre-submission advice in 30 working days.

The screenshot displays a progress bar at the top with stages: Draft, Clarification Needed, Submitted, Administrative Check Completed, Undergoing Public Consultation, **In Progress** (highlighted with a red box), and Closed. Below the progress bar, the system shows the 'List of Intended Studies' for ID LIST-07-2022-0049. The business operator is ABC Company Spa, the date submitted is 12/07/2022, and the pre-application ID is 'Renewal application for XYZ'. A dropdown menu contains 'New Intended Study', 'Submit List', and 'Delete'. A red box highlights a tooltip titled 'List of Intended Studies for Renewal Operations' which states: 'The renewal pre-submission advice related to the submitted list of intended studies is in progress. A written or verbal (meeting) advice will be provided to you within 30 business days. You will be alerted via email. When the status is "In Progress" it is not possible to perform further actions on the List of Intended Studies, such as add further intended studies, notify the records present in the list or delete the entire list.'



Note: when the status of the List is “Submitted”, “Administrative Check Completed”, “Undergoing Public Consultation” or “In Progress” it is not possible to perform further actions on the List. **However, it is always possible to create and notify studies or add already notified studies by using the function buttons (i.e. New Study, Add studies) in the related pre-application ID page.**

3.4.7 List of intended studies – Closed

When the renewal pre-submission advice is sent to the potential applicant, the status of the list turns into **Closed**.

The screenshot shows a progress bar at the top with stages: Draft, Clarification Needed, Submitted, Administrative Check Completed, Undergoing Public Consultation, In Progress, and **Closed**. Below the progress bar, the interface displays 'List of Intended Studies' with ID LIST-07-2022-0049. It includes buttons for 'New Intended Study', 'Submit List', and 'Delete'. A table below shows details for 'ABC Company Spa' with a submission date of 12/07/2022 and a pre-application ID of 'Renewal application for XYZ'. A red box highlights the 'Closed' status in the progress bar. Another red box highlights a text box titled 'List Of Intended Studies for Renewal Operations' which explains the renewal process and lists instructions: 'Use the **Convert** button to transform the intended study record in a notifiable draft study.' and 'You may use the **Mass Conversion** button to select the intended studies to convert into notifiable draft studies'.

When the renewal pre-submission advice process is concluded, the user can access the advice and its summary **by clicking on the request number in the Pre-Submission Advice on Renewal section.**

This screenshot shows the 'Pre-Submission Advice on Renewal (1)' section. It features a 'List' button and a 'Mass Conversion' button. Below these is a table with the following data:

Request Number	Subject
00001817	PSA on Renewal for LIST-07-2022-0049

A red box highlights the 'List' button and the 'Pre-Submission Advice on Renewal (1)' header. Another red box highlights the request number '00001817' in the table. A 'View All' link is located at the bottom right of the table.

3.5 Renewal pre-submission advice and summary of the advice

Request
PSA on Renewal for LIST-07-2022-0049

Printable View

Pre-Submission Advice Guidance
Your Pre-Submission Advice request is now **closed** and can no longer be modified.

Open Activities (0)

Request Team (0)

Member Name	Team Role Name
-------------	----------------

Status: Closed Request Number: 00001817

Details History

Request Information

Request Number	00001817	Account Name	ABC Company Spa
		Contact Name	

PSA Details

Subject	PSA on Renewal for LIST-07-2022-0049	Food Domain	Feed Additives
Old Application ID	0000001	Authorisation Type	Feed Additives
List of Intended Studies	LIST-07-2022-0049	Application Type	Application for authorisation of a new use and/or modification and/or renewal of an already authorised feed additive (Articles 4(1), 13(3), 14 of Regulation (EC) No 1831/2003 respectively)
		Test Item	Subject of the application for XYZ

PSA Submission Outcome

PSA Summary	Test written advice	Written Advice ⓘ	Test written advice
-------------	---------------------	------------------	---------------------

The advice and its summary can be found in the **PSA Submission Outcome** section.

3.6 Mass conversion of intended studies

Intended studies that are going to be commissioned can be converted into draft notifiable studies (for notifications according to Article 32b of the General Food Law) when the status of the list is “Draft”, “Clarification Needed” and “Closed”. Users can use the **Mass Conversion** button from the List tab to select which studies need to be converted. The same rules of the [conversion of single intended studies](#) apply.

The user clicks on **Mass Conversion** and a dedicated selection window appears.

<input type="checkbox"/>	Study Title	Study Type	Study Objective	Study Guideline	Test Item	Study Design Description	Study Detailed Protocol
<input type="checkbox"/>	Intended study 2	Acute Contact Toxicity	Intended study 2	ISO 10707 Water quality - Evaluation in an aqueous medium of the 'ultimate' aerobic biodegradability of organic compounds - Method by analysis of biochemical oxygen demand (closed bottle test)	Subject of the application for XYZ	Intended study 2	Intended study 2
<input type="checkbox"/>	Intended study 3	Active Substance Bioconcentration In Prey Of Birds And Mammals	Intended study 3	ISO 10707 Water quality - Evaluation in an aqueous medium of the 'ultimate' aerobic biodegradability of organic compounds - Method by analysis of biochemical oxygen demand (closed bottle test)	Subject of the application for XYZ	Intended study 3	Intended study 3
<input type="checkbox"/>	Intended study 4	Acute Contact Toxicity	Intended study 4	ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with Skeletonema costatum and Phaeodactylum tricornutum)	Subject of the application for XYZ	Intended study 4	Intended study 4

Select the intended studies by ticking the boxes and then click on **Convert** to continue.

3.6 Mass conversion of intended studies

Convert

Once the users clicks on Convert, a message appears.

List Details

Do you want to proceed with Study Conversion?

Click again on **Convert** to continue or **Cancel** to go back.

Cancel

Convert

Pre-Application ID
Renewal application for XYZ

Edit New Study New List

ID
EFSA-ID-2022-000646

Details History

Request Name
Renewal application for XYZ

ID
EFSA-ID-2022-000646

Business Operator
ABC Company Spa

Contact Name

Details

Subject Of The Application
Subject of the application for XYZ

Food Domain
Feed Additives

Former Application ID
0000001

Authorisation Type
Feed Additives

Note

Application Type
Application for authorisation of a new use and/or modification and/or renewal of an already authorised feed additive (Articles 4(1), 13(3), 14 of Regulation (EC) No 1831/2003 respectively)

Converted studies (in draft) can be found in the **Study Notification** section of the pre-application ID page. Click on **View All** for a complete view.

Study Notification (3)

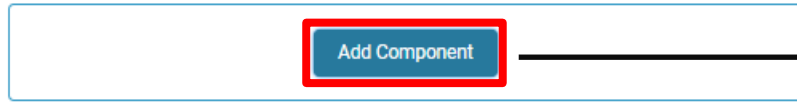
Study Title	EFSA Study Iden...	Status	Study Withdrawn
Intended study 1	EFSA-2022-0000...	Draft	<input type="checkbox"/>
Intended study 2	EFSA-2022-0000...	Draft	<input type="checkbox"/>
Intended study 3	EFSA-2022-0000...	Draft	<input type="checkbox"/>

View All

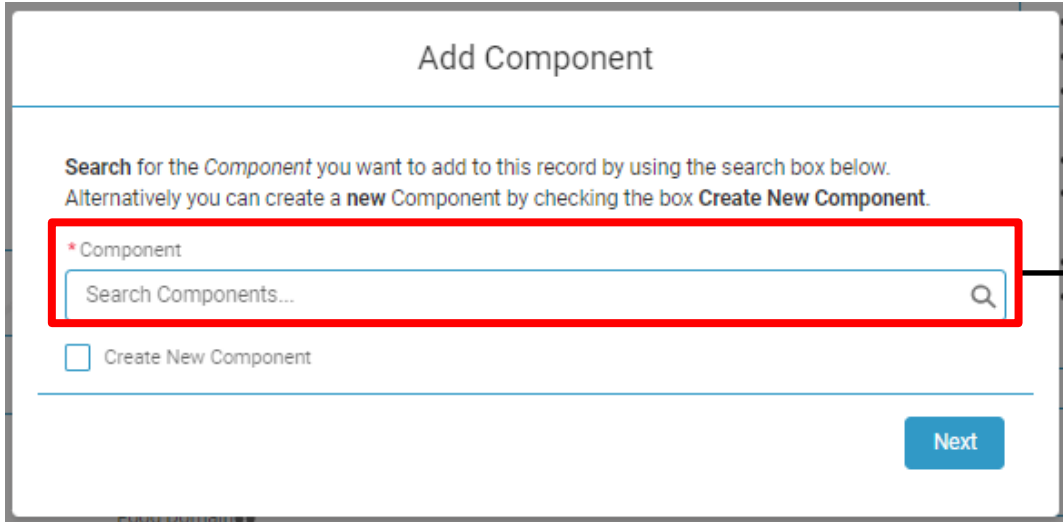
3.7 Add a component

New!

Component(s) can be added to a pre-application ID to give more information about the subject of the application.

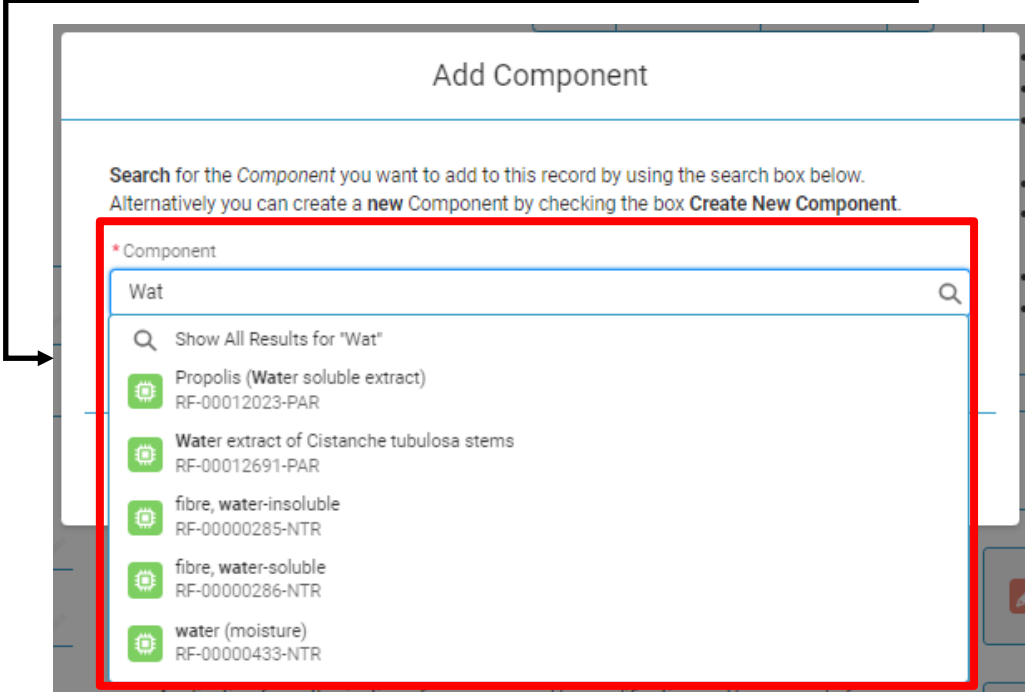


The user clicks on the “**Add Component**” button right-hand side of the pre-application ID page.



It is possible to **search for existing components in the EFSA catalogue (PARAM)**. The search includes also the components already created by the user. See “[View Component](#)” section for details.

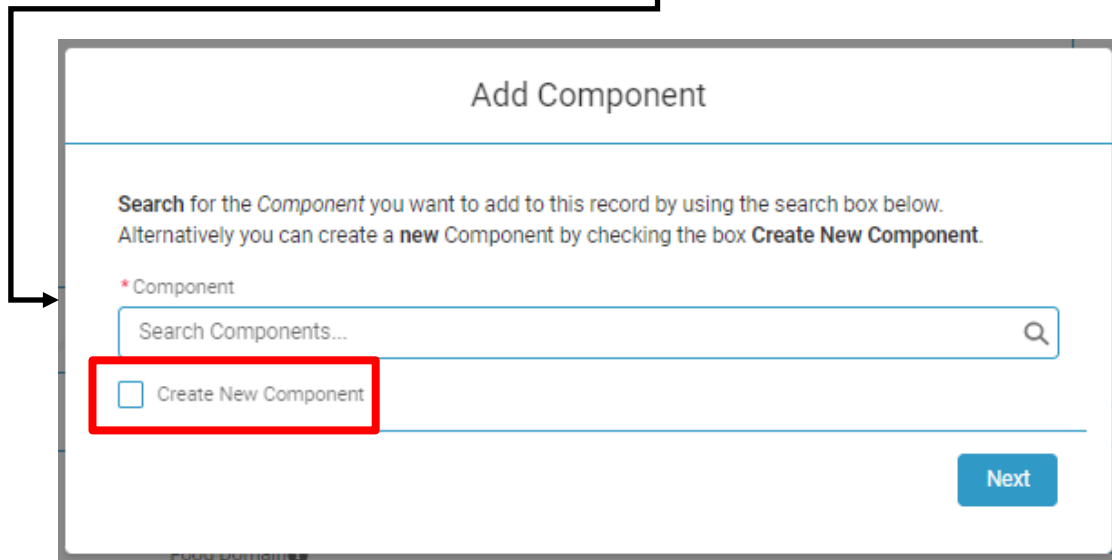
Type at least three letters of the component name to find all the related results. To expand the search results click on “Show All Results for ...”.



Select one of the results and click on **Next** to continue. The added component appears in the related list **Subject of the application: Components** in the pre-application ID page.

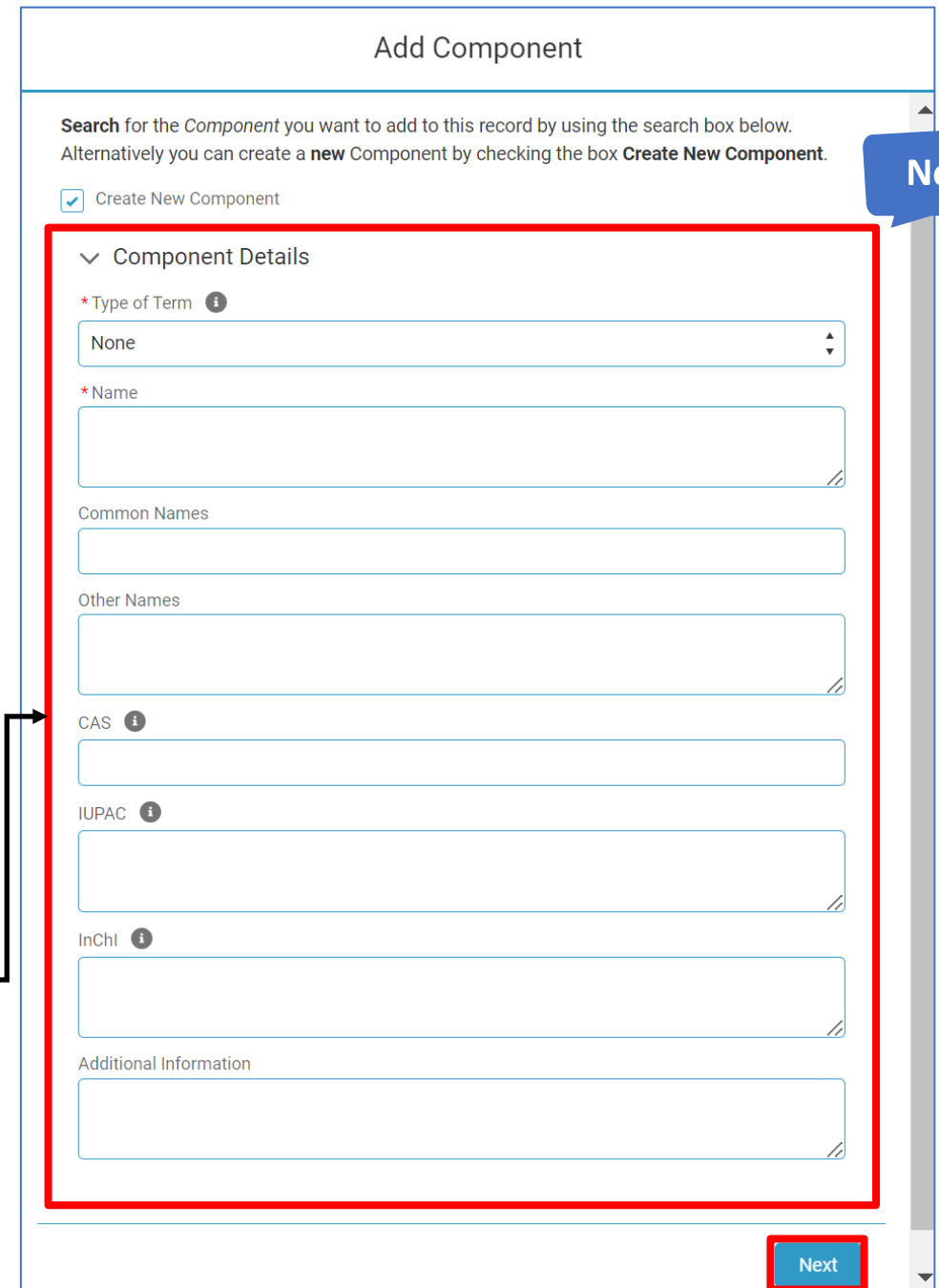
3.7.1 Create a new component

If a component is not retrievable using the search function, the user checks the box “Create New Component” in the “Add Component” pop-up window.



Fill in the “Component Details” form with the corresponding information. The fields “Type of Term” and “Name” are mandatory. More details on the information required by a certain field are shown by passing over the **i** icons. Click **Next** to continue.

The newly created component appears in the related list **Subject of the application: Components** in the pre-application ID page.



3.7.2 Related list “Subject of the Application: Components”

Users find the components associated to a pre-application ID in the related list “**Subject of the Application: Components**”. For easier identification of the listed components, additional fields (e.g. Name, Type of Term, Origin) are available.

Name (short)	Type of Term	Origin
Water	ParamTerm	▼
RTY	Chemical elements	▼

View All

Click on the name of the component to open the corresponding [details page](#).

Click on pointing down arrow to Edit or [Delete](#) the component from the list.

The related list shows a limited number of entries, users can click on “View All” to expand the related list box and view all the associated components.

3.7.3 Note field and Other Components

New!

The “Other Components” field was discontinued, the data previously contained, if any, is now available in the “Note” field. Users can modify such data or decide to [create a component](#) to be linked to the pre-application ID.

Pre-Application ID
TEST PAID INTEGRATION TESTS

Edit New Study Add Studies ▼

ID
EFSA-ID-2023-000899

Details History

Request Name TEST PAID INTEGRATION TESTS	ID EFSA-ID-2023-000899
Business Operator	Contact Name Satya Nadella
	Food Domain ⓘ Animal Welfare
	Authorisation Type
	Application Type

Note ⓘ
Note...

Other components...

This field can be used to indicate any additional information you may want to include in the pre-application ID. Previously recorded information from the “Other Components” field, which has been discontinued, is displayed here as well.

3.7.4 Delete link to components

Updated!

The user can **always** remove Components from the pre-application ID. By performing this action, the user will delete only the link between the pre-application ID and the Component, **not the Component itself**.

The screenshot shows a web interface with a table titled "Subject of the Application: Components (2)". The table has three columns: "Name (short)", "Type of Term", and "Origin". The first row is "Water" with "ParamTerm" as the origin. The second row is "RTY" with "Chemical elements" as the type and "Manual" as the origin. A dropdown menu is open for the "Water" row, showing "Edit" and "Delete" options. A red box highlights the "Delete" option. An arrow points from the "Delete" option to a confirmation dialog box titled "Delete Link to Component". The dialog box contains the text "Are you sure you want to delete this Link to Component?" and two buttons: "Cancel" and "Delete". The "Delete" button is highlighted with a red box.

Name (short)	Type of Term	Origin
Water		ParamTerm
RTY	Chemical elements	Manual

Delete Link to Component

Are you sure you want to delete this Link to Component?

Cancel Delete

As a result, **the Component is removed from the related list** "Subject of the Application: Components" on the pre-application ID page.

3.7.5 View Components

All Components created by the user are listed under the tab “**My Components**” in the Pre-Application ID, and in the “My Details” page.

Pre-Application ID

From this page, you can:

- Create a NEW Pre-Application ID clicking the button below. The Pre-Application ID is necessary to group pre-submission activities (notification of studies and pre-submission advice) to a future application
- Via the Pre-Application ID, you can create new notifications of studies, search for and associate notifications of studies that you previously created, and submit Pre-Submission Advice

Pre-Application ID Additional Involvement On Behalf Of **My Components**

My Components ▼

17 items • Sorted by Last Modified Date • Filtered by All param terms - CreatedByMyAccount

Search this list...

	Term Extended Na...	Term Exten...	Te...	Term...	CAS	Te...	Te...	Last Modif...	
1	component 14/1 14.32			Submitt...	44			14/01/2022 14...	▼
2	Component by Chiara			Submitt...	dd			12/01/2022 11...	▼

My Details

Account
ABC Company

English Name Billing Address
Milan
Italy

Details Related **My Components**

My Components ▼

17 items • Sorted by Last Modified Date • Filtered by All param terms - CreatedByMyAccount

Search this list...

	Term Extended Nam...	Term Exte...	Term...	Term St...	CAS	Term...	Term...	Last Modifie...	
1	component 14/1 14.32			Submitted	44			14/01/2022 14.33	▼
2	Component by Chiara			Submitted	dd			12/01/2022 11.57	▼

3.7.6 Component details page

Updated!

The detail page of the component appears as in the image below. Information on the component can be added/modified directly from this page only for components created by the user.

The screenshot shows the 'Component details page' for 'Bacillus RRR'. The page includes a header with 'Component Bacillus RRR', 'Printable View', and 'Delete' buttons. Below the header is a table with columns 'Term Code', 'Term Status', and 'Term Valid From'. The main content area is divided into two columns of input fields. The left column includes 'Name', 'Common Names', 'CAS', 'EC Number', 'Molecular Formula', 'Zoo Label', 'InChI', and 'Name (short)'. The right column includes 'Type of Term', 'Other Names', 'IUPAC', 'Flavis Number', 'Smiles Notation', and 'Level of Details'. Below these fields are sections for 'Additional Information' and 'Additional Information'. On the right side, there is a sidebar with three sections: 'Component History (1)', 'PAIDs with this component (1)', and 'Studies with this component (1)'. A red box highlights the sidebar, and an arrow points from the 'Level of Details' field to the 'Component History' section.

Date	Field	User	Original Value	New Value
12/09/202...	Created.	.		

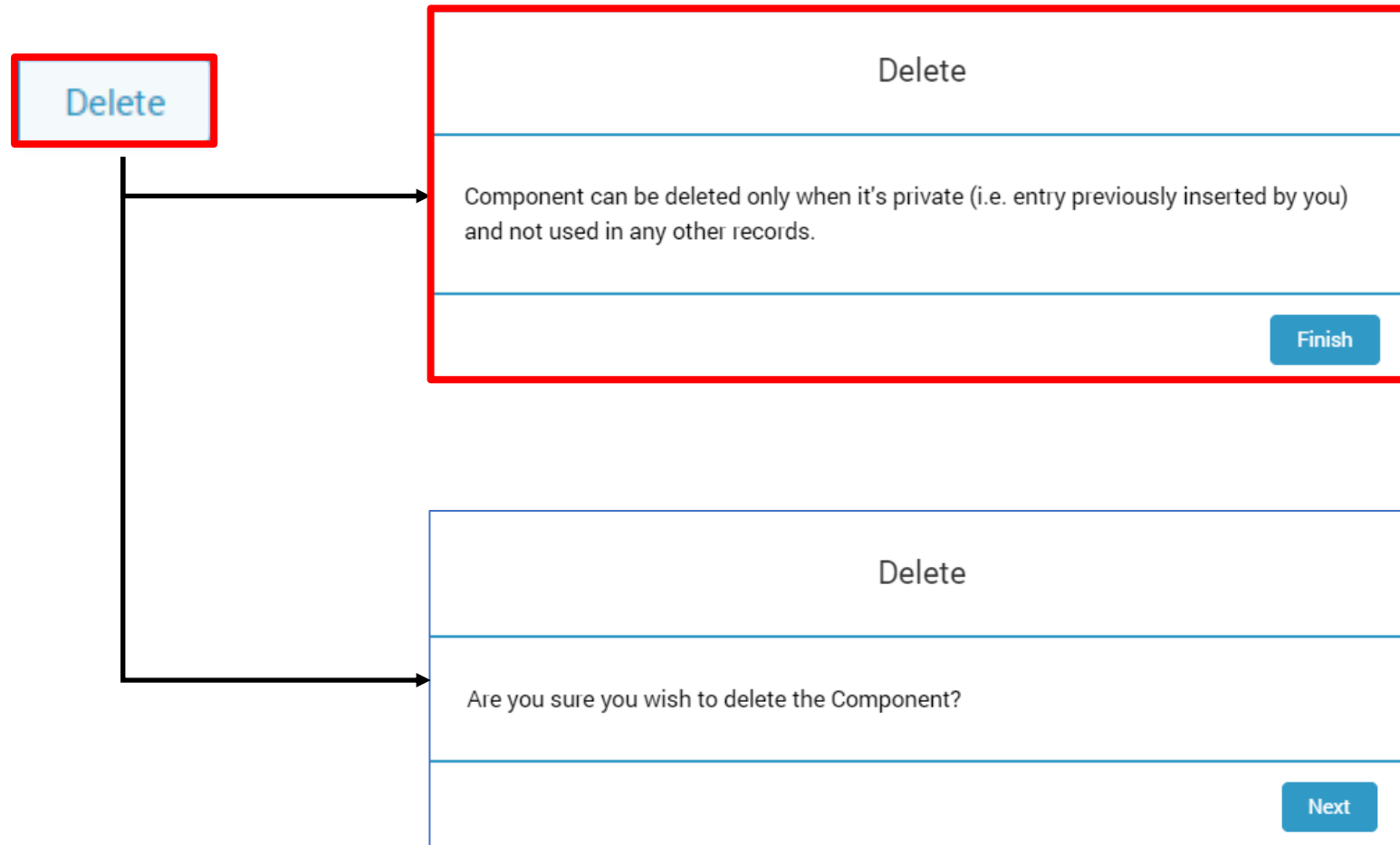
ID	Request Name
EFSA-ID-2023-000914	Renewal application TJP

Study
Study RRR

Related lists of the component page: inform the user about the history of the component record (e.g. creation, editing actions), and whether the component is associated to a pre-application ID or other study notifications.

3.7.7 Delete Components

From the detail page My Components the user can delete a component record by using the **Delete** function button.



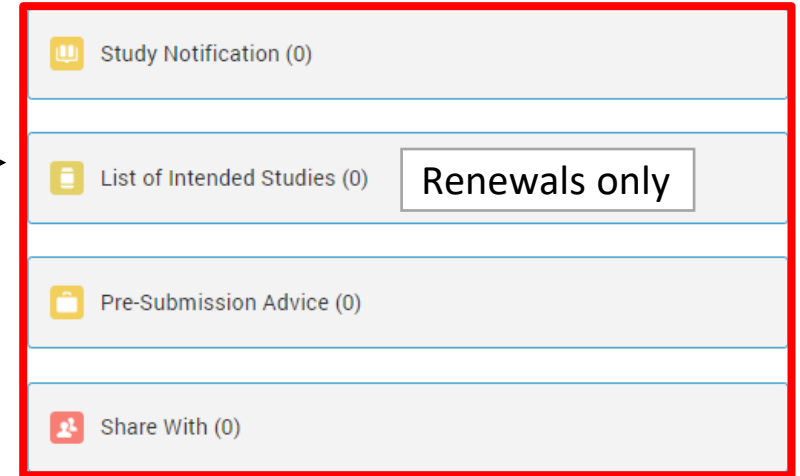
This **error message** appears if the component is used in any other record (i.e. Pre-Application IDs, Studies records).

To delete the component, the user must firstly [remove all the existing links](#) with the other records as explained in the previous slides.

3.8 Delete a pre-application ID

Users can delete a pre-application ID only when there are no records associated, such as notified studies, list of intended studies or general pre-submission advice.

If the above conditions are not fulfilled, the system will return an **error message**.



Pre-Application ID

Pre-Application ID
Test User Guide PAID

Status
Draft

Date Submitted

Delete New Study Add Studies ▼

In the pre-application ID page, click on the function button **Delete**.

Delete

Are you sure you wish to delete the Pre-Application-ID?

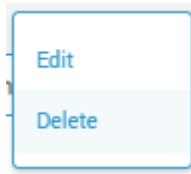
Next

Users must click on **Next** to confirm the deletion.

3.8.1 Delete a pre-application ID and/or remove relationships and draft objects

If a pre-application ID is associated with **draft objects**, such as **studies or general pre-submission advice** request(s), the user must first remove all the associations to be able to delete the pre-application ID record.

Study Title	EFSA Study Ident...	Status	Study Withdrawn
Draft study	EFSA-2022-0000...	Draft	<input type="checkbox"/>

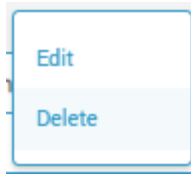


Select **Delete** to remove the draft study from the pre-application ID. This action will not delete the study itself.
Notified and co-notified studies cannot be removed.

List of Intended studies Name	Status
LIST-07-2022-0051	Draft

Click on the list name to open the list of intended studies page. **Only empty list of intended studies can be deleted.** Intended studies associated with the list can be deleted only when the status corresponds to “Draft” or “Clarification Needed”.

Request Number	Subject	Status	Date/Time Open...
00001815	Subject of the a...	Draft	12/07/2022 17.18



Select **Delete** to remove the draft general pre-submission advice. Submitted general pre-submission advice will prevent deletion of the pre-application ID.

Account Name	Relationship Type
Solution Consulting	Shared With
Business & Business	On Behalf Of



Select **Delete** to remove the relationship(s). If there are submitted records associated to the pre-application ID, “Shared with” relationship cannot be removed. “On behalf of” relationships can be always removed.

3.9 Account relationship(s)

When a **business operator** wants to commission a **third-party/consultant** to work on its behalf, a relationship “on behalf of” must be established at the account level in the page **My Details**.

The screenshot displays the 'My Details' page for 'ABC Company Spa'. At the top, there are three buttons: '+ Follow', 'New Contact', and 'Manage Relationship' (highlighted with a red box). Below these are fields for 'English Name' (Italy) and 'Billing Address' (Milano Milan Italy). A navigation bar at the bottom includes 'Details', 'Related' (highlighted with a red box), and 'My Components'. Under 'Related', there are two sections: 'Account Relationships: Account To (0)' and 'Account Relationships: Account From (0)'. A text box on the right explains that the 'Manage Relationship' button is used to create, modify, or delete relationships. Another text box at the bottom left states that the 'Related' tab shows existing relationships. A third text box at the bottom right defines 'Account To' as organizations working on behalf of the user and 'Account From' as organizations the user is working on behalf of.

My Details

Account
ABC Company Spa

+ Follow New Contact **Manage Relationship**

English Name: Italy Billing Address: Milano Milan Italy

Details **Related** My Components

Account Relationships: Account To (0)

Account Relationships: Account From (0)

User can click on the button **Manage Relationship** to **create, modify or delete** a relationship with an organisation that works on its behalf.

Under **Related** tab, the user can find the lists showing existing relationships.

Account To: list of organisations **working on behalf of the user.**
Account From: list of organisations the user is **working on behalf of.**

3.9.1 Create an account relationship

Manage Relationship

Manage Relationship

You can either **establish a new relationship** (or invite a third party to register in the portal), or **update or delete a relationship that you have previously established**.

Please choose **only one** of the following options.

- Create a new account relationship
- Modify an existing account relationship
- Delete an existing account relationship

Next

Manage Relationship

Select the **country** in which the third party resides. Then click on **Next**.

*Country

Italy

Previous **Next**

The user selects the **Country** and then **organisation** to be added as consultant.

Manage Relationship

Please choose **ONE** of the below organisations, or register a new one.

Choose an organisation to create a new relationship.

- DOI Test 1
- Solution Consulting
- Pharma Spaa
- Business & Business

Can't find the organisation you're looking for?

If the organisation you'd like to select does not appear above, they are not registered in the portal. Please check the box below to invite them to the portal.

I would like to send them an invitation to register for EFSA's portal.

Previous **Next**

Select **Next** to continue with the guided procedure. The system will give the user the possibility to **select an optional feature, see next slide**.

3.9.1 Create an account relationship

OPTIONAL FEATURE - During the creation of an account relationship, **business operators and laboratories can agree on enabling a selected third party/consultant to act as Notifier and Co-notifier**, at the same time, of one or more studies. It is possible to modify this choice at any time (see [Manage account relationship\(s\)](#) to know more details).

The image displays two sequential screenshots of a web form titled "Manage Relationship".

Left Screenshot: The form asks the user to "Please choose ONE of the below organisations, or register a new one." It lists several organizations with radio buttons: DOI Test 1, The Black Pearl, Bayer Fake 123, Solution Consulting (selected), Pharma Spaa, and Business & Business. Below this, there is a section "Can't find the organisation you're looking for?" with a checkbox "I would like to send them an invitation to register for EFSA's portal." At the bottom right, there are "Previous" and "Next" buttons, with the "Next" button highlighted in red.

Right Screenshot: This screenshot shows the next step in the process. A red box highlights the following text: "By checking the below box, you are enabling the selected third party to act as notifier and co-notifier of a study. Please note that this authorisation only applies to studies in which: - the third party works on behalf of both the notifier and the co-notifier organisations - the third party has already access to the study because it has been shared with its organisation." Below this, there is a section "By leaving the box unchecked you will establish only 'On behalf of ' relationship." and a note "This option can be updated at any time by selecting 'Manage Account relationships'". At the bottom, there is a checkbox "I want to enable this organisation to act as notifier and co-notifier." with a red box around it. At the bottom right, there are "Previous" and "Next" buttons, with the "Next" button highlighted in red.

Callout Box: A text box at the bottom center contains the instruction: "Check the box to enable the third party/consultant to perform this action or continue without checking the box. Click **Next** to complete the procedure."

Note: a practical example of how this feature works is given in the next slide.

3.9.1 Create an account relationship

Actors of the process:

- A business operator, e.g. "Business Operator"
- A laboratory, e.g. "Laboratory"
- A third party/consultant, e.g. "Consultant"

Scenario: "Business Operator" commissions a study to "Laboratory". **The two parties decide to delegate to "Consultant" part or the entire process of notification of studies.**

Manage Relationship

By checking the below box, you are enabling the selected third party to act as notifier and co-notifier of a study.

Please note that this authorisation only applies to studies in which:

- the third party works on behalf of both the notifier and the co-notifier organisations
- the third party has already access to the study because it has been shared with its organisation.

By leaving the box unchecked you will establish only "On behalf of" relationship.

This option can be updated at any time by selecting "Manage Account relationships"

I want to enable this organisation to act as notifier and co-notifier.

[Previous](#) [Next](#)

How it works:

1. "Business Operator" and "Laboratory" **create an account relationship with "Consultant"**, and both **enable this organisation to act as notifier and co-notifier.**
2. "Consultant" creates and notifies a new study record on behalf of "Business Operator".
3. "Consultant" co-notifies the study on behalf of "Laboratory".

The process works also if "Laboratory" starts the notification process.

3.9.2 Manage account relationship(s)

Created relationship will appear in the related list **Account Relationships: Account To** as shown below.

Name	Account Relationship Type
<u>Solution Consulting works on behalf of ABC Company</u>	On Behalf Of

View All

Once relationship has been established at the account level:

1. The business operator can **share single records** with its third party/consultant (to know more see [Share pre-application ID "On behalf of"](#))
2. The third party/consultant can create pre-application IDs and perform all associated actions for the business operator.

3.9.2 Manage account relationship(s)

If the organisation that the user wants to create a relationship with is not registered in the system, it is possible to send an invitation to register by following these steps.

Manage Relationship

Please choose ONE of the below organisations, or register a new one.
Choose an organisation to create a new relationship.

Can't find the organisation you're looking for?

If the organisation you'd like to select does not appear above, they are not registered in the portal.
Please check the box below to invite them to the portal.

I would like to send them an invitation to register for EFSA's portal.

Previous Next

Please note that the relationship with this organisation is not automatically created upon its registration. The user needs to create the relationship once the organisation is registered.

Manage Relationship

Fill in the information and click **Next**.

Please enter a name and an email address for the organisation you'd like to register in the portal.
They will subsequently receive an email notification with a registration link.

Fill in the fields

First Name
Mario Rossi

Email
mariorossi@test.com

Previous Next

Manage Relationship

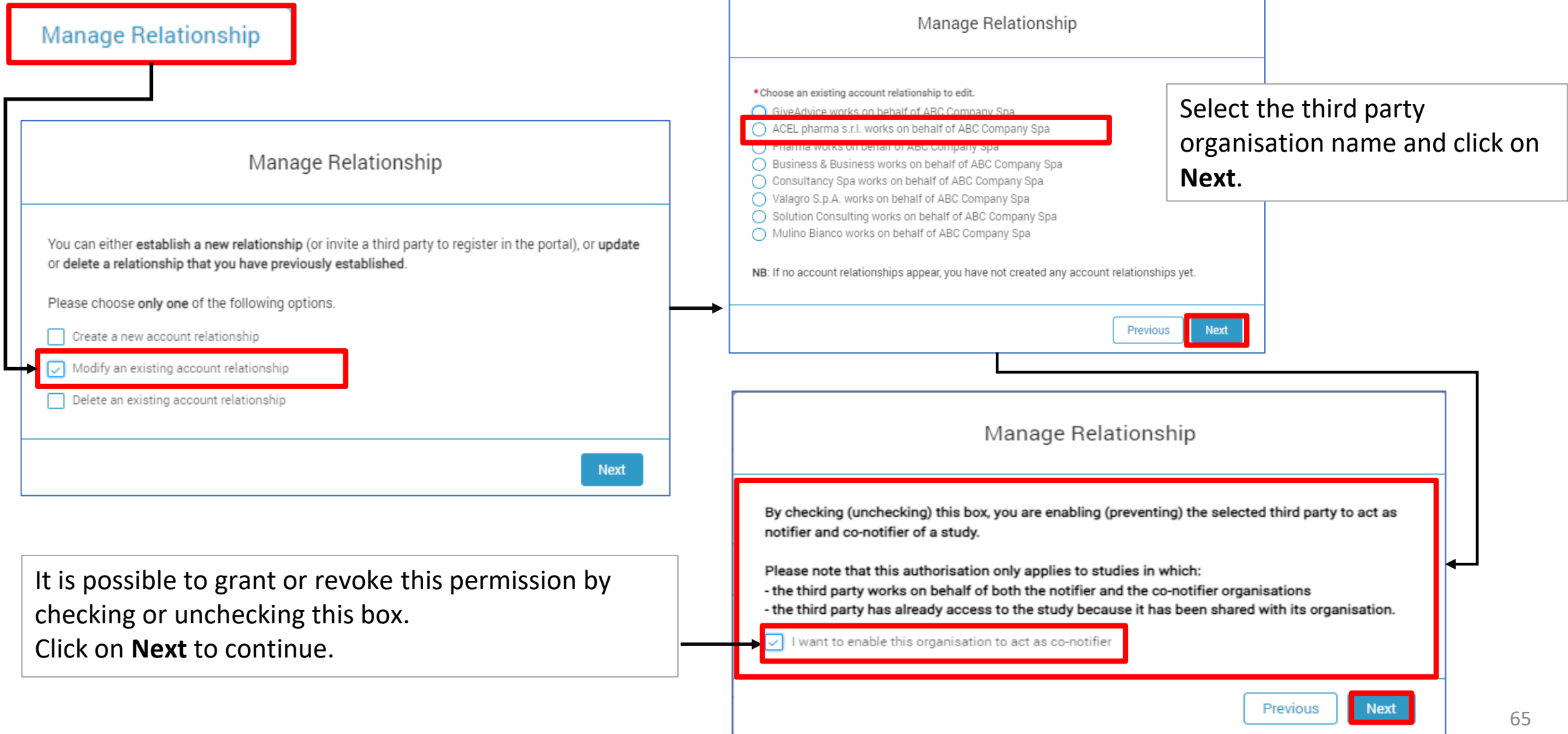
Success! You have sent the organisation an invitation to register for EFSA's portal.

IMPORTANT: Please note that the relationship to your organisation will NOT be automatically created when it has registered. Instead, you will need to manually add this relationship via the **Manage Relationship** button (the third party will be available in the list of organisations after they have registered).

Finish

3.9.3 Modify an account relationship

Business operators and Laboratories **can modify** the option that enables a selected third party/consultant to act as Notifier and Co-notifier at any time.



3.9.4 Delete an account relationship

To delete an existing relationship with an organisation, follow these steps.

Manage Relationship

Manage Relationship

You can either **establish a new relationship** (or invite a third party to register in the portal), or **update** or **delete a relationship** that you have previously established.

Please choose **only one** of the following options.

- Create a new account relationship
- Modify an existing account relationship
- Delete an existing account relationship

Next

Select the relationship to delete and click **Next**.

Manage Relationship

*Choose an existing account relationship to delete.

- Solution Consulting works on behalf of ABC Company

NB: If no account relationships appear, you have not created any account relationships yet.

Previous

Next

Manage Relationship

You have **successfully deleted** the relationship.

This organisation has been notified by email.

Click on **Finish** and refresh the page to return to your company details and view your changes.

Finish

3.10 Share a pre-application ID

Business operators or **third parties/consultants** can share pre-application ID(s) with other organisations using the button “Share With”.

The pre-application ID(s) can be shared in two different ways:

- Relationship type: **“On behalf of”**. With the sharing type “On behalf of” users can decide to share with **third parties/consultants** only the pre-application ID or the pre-application ID along with some/all the study records already linked to it. In order to be able to perform this type of sharing, the user must establish an **account relationship** with this organisation beforehand (see [Account Relationship](#)).
- Relationship type: **“Shared with”**. In this case the user involves another organisation in the pre-submission activities and provides **read-only access** to the shared pre-application ID. No previous actions are required to perform this sharing.

The screenshot displays the EFSA Pre-Application ID management interface. At the top, a callout box points to a dropdown menu with the text "Click here to see more function buttons". The dropdown menu is open, showing options: "Ask GPSA", "Share With", "Delete", and "Printable View". A red box highlights the "Share With" option, and a red arrow points to it with the text "“Share With” button".

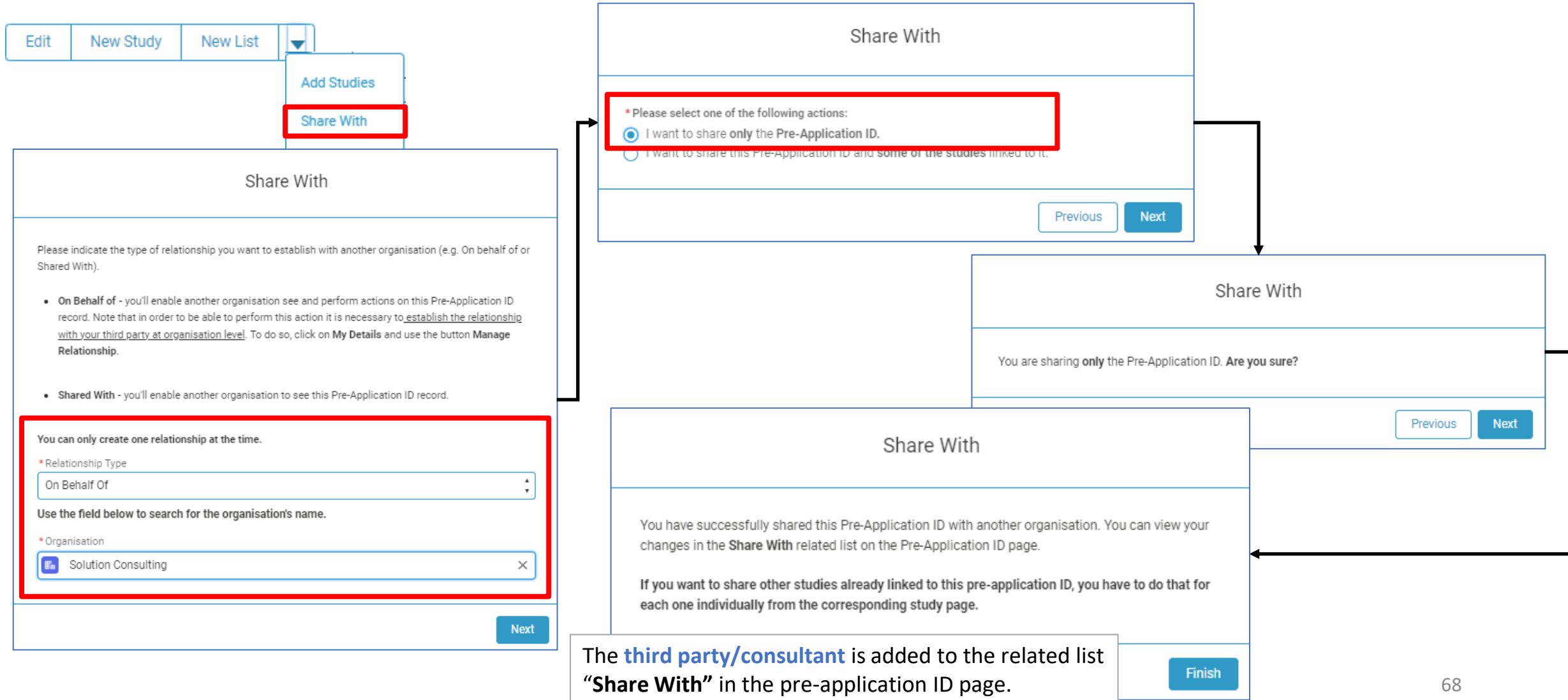
The main interface shows a "Pre-Application ID" card for "Shared pre-application ID" with ID "EFSA-ID-2023-000915". Below the card, there are tabs for "Details" and "History". The "Details" tab is active, showing a table with the following information:

Request Name	Shared pre-application ID	ID	EFSA-ID-2023-000915
Business Operator	ABC Company Spa	Contact Name	
Subject Of The Application	Shared pre-application ID	Food Domain	Novel Foods

On the right side, there is a "Pre-Application Operations" panel with instructions for various buttons: "New Study", "Add Studies", "New List", "Share With", and "Add Component". At the bottom right, there is an "Add Component" button.

3.10.1a Share a pre-application ID “On behalf of” – *without studies*

To share only the pre-application ID (without any of the linked studies), the user chooses the sharing type “On behalf of” and the name of the **third party/consultant**, then checks the box corresponding to “I want to share only the pre-application ID”.



3.10.1b Share a pre-application ID “On behalf of” – *with studies*

To share both **pre-application ID** and also some/all the **studies already linked to it**, the user chooses the sharing type “On behalf of” and the name of the **third party/consultant**, as showed in the previous slide, then checks the box corresponding to “**I want to share this pre-application ID and some of the studies linked to it**”.

Share With

* Please select one of the following actions:

I want to share only the Pre-Application ID.

I want to share this Pre-Application ID and some of the studies linked to it.

Previous Next

Share With

Find below the **studies** associated with this pre-application ID that have **not yet** been shared “on behalf of” with the selected organisation.

To select a study check the **box** next to it. When you have finished, click on “Next” to proceed.

You can select or deselect all studies by clicking on the checkbox near EFSA Study Identification

<input type="checkbox"/> EFSA Study Identification	Study Title	St
<input type="checkbox"/> EFSA-2023-00001682	TEST NEW STUDY	
<input type="checkbox"/> EFSA-2023-00001680	TEST DATA LOSS	
<input type="checkbox"/> EFSA-2023-00001669	TEST LINKED STUDY AMS BUG	

Previous Next

The system displays only the studies that have not been shared yet with the selected third party/consultant.

Share With

Please find below the list of studies you are going to share. To proceed click on **Next**.

Should you need to **revise** your choice and make change(s) to your selection click on “Previous” to go back to the selection window.

You selected: 3 studies.

- EFSA-2023-00001682 - TEST NEW STUDY;
- EFSA-2023-00001680 - TEST DATA LOSS;
- EFSA-2023-00001669 - TEST LINKED STUDY AMS BUG;

Previous Next

If any study was selected by mistake, click on **Previous** to edit the selection.

Share With

You have successfully shared this Pre-Application ID with another organisation. You can view your changes in the **Share With** related list on the Pre-Application ID page.

If you want to share other studies already linked to this pre-application ID, you have to do that for each one individually from the corresponding study page.

Finish

The **third party/consultant** is added to the related list “**Share With**” in the pre-application ID page.

Note: The user cannot repeat the sharing procedure by selecting the same **third party/consultant** to share additional studies.

3.10.1 Share a pre-application ID “On behalf of”

Share With

Share With

Please indicate the type of relationship you want to establish with another organisation (e.g. On behalf of or Shared With).

- **On Behalf of** - you'll enable another organisation see and perform actions on this Pre-Application ID record. Note that in order to be able to perform this action it is necessary to establish the relationship with your third party at organisation level. To do so, click on **My Details** and use the button **Manage Relationship**.
- **Shared With** - you'll enable another organisation to see this Pre-Application ID record.

You can only create one relationship at the time.

* Relationship Type
On Behalf Of

Use the field below to search for the organisation's name.

* Organisation
Solution Consulting

Next

If the account relationship with the **third party/consultant** has not been established beforehand, the system returns an **error message** when the user tries to share a record with the relationship type “On behalf of”.

Share With

You cannot do the sharing "on behalf of" with this organisation, because you did not establish a relationship with it.

Please, either select:

- relationship type '**Shared With**' (in this way the organisation selected will be able to only view, but not edit the record), or
- Enable a relationship with a third party. To do so click on **My Detail** in the navigation menu, click the button **Manage Relationship** and follow the instruction

Finish

3.10.1 Share a pre-application ID “On behalf of”

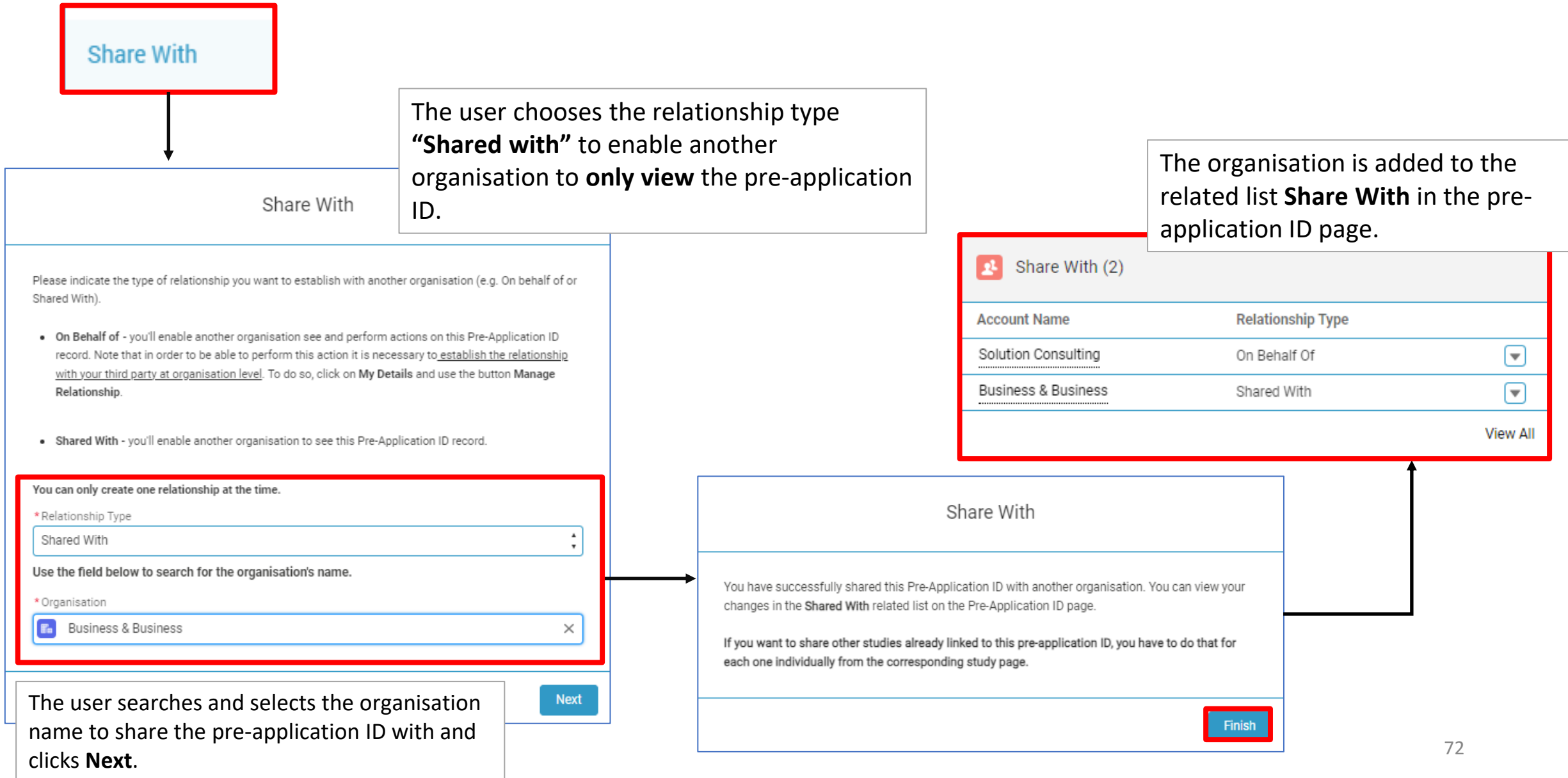
Actions allowed to **business operator** or a **third party/consultant** for a pre-application ID shared using the relationship type “**On behalf of**”:

1. View and edit the pre-application ID information*
2. Create new studies or add already existing studies to the pre-application ID
3. View and edit the studies that have been shared with the pre-application ID**
4. Create, edit and submit a list of intended studies (for renewals only)
5. Manage the intended studies associated to a list (for renewals only)
6. View and add components
7. Share the pre-application ID with other business operators

*if the pre-application ID contains already a list of intended studies, this will also be shared and editable by the consultant who will be able to submit it as well.

**studies previously created/added need to be shared following the procedure described in [Section 3.10.1b](#).

3.10.2 Share a pre-application ID “Shared with”



3.10.2 Share a pre-application ID “Shared with”

Actions allowed to **business operator** or a **third party/consultant** for a pre-application ID shared using the relationship type “**Shared with**”:

1. See the pre-application ID information
2. View the list of intended studies and all the information contained in its page (renewals only)
3. View components added to the pre-application ID
4. View **only** studies created/added after the record was shared*

*studies previously created/added need to be shared one by one.

3.11 General pre-submission advice (GPSA)

Users can request a general pre-submission advice from the pre-application ID by using the dedicated button **Ask GPSA**, at any moment prior the submission of the application. **This action is the same for new and renewal applications.**



Pre-Application ID

Click here to see more function buttons

Pre-Application ID

ID
EFSA-ID-2022-000646

Details History

Request Name ID

Business Operator Contact Name

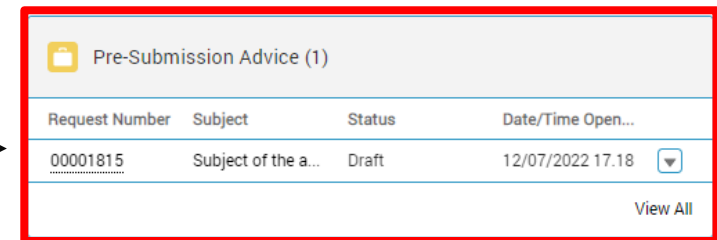
New Study Add Studies New List

Share With
Ask GPSA
Delete
Printable View

Pre-Application Operations

- Use the **New Study** button to create new study records
- Use the **Add Studies** button to add notified and or co-notified studies
- Use **New List** button to create a list of intended studies for renewal (only for renewal applications)
- Add additional parties to this pre-application ID using the **Share With** button
- Under the tab **Components** you can structure the subject of the future application by adding one or more components
- Request a general pre-submission advice by using the **Ask GPSA** button
- Use the **Delete** button to delete your pre-application ID (certain conditions apply)

The user can access the GPSA request(s) at any time from the dedicated section in the pre-application ID page.



Request Number	Subject	Status	Date/Time Open...
00001815	Subject of the a...	Draft	12/07/2022 17.18

View All

Suggested video tutorial: [request general pre-submission advice](#)

3.11.1 Request a GPSA

Ask GPSA

Fill in the information and click **Next** to create the GPSA request in draft status.

Ask PSA

Fill in the following fields to create a Pre-Submission Advice request.
You can later access the record to edit it and submit it to EFSA.

* Background Information on the Subject

|

* List of Questions

* Conditions of use/Intended uses

Next

The GPSA request will appear and be accessible from the related list **pre-submission advice** on the pre-application ID.

Pre-Submission Advice (1)

Request N...	Subject	Status	Date/Time O...
00001753	SUBJECT	Draft	15.01.2021 1...

View All

3.11.1 Request a GPSA

Use these function **buttons** to perform actions on the record.

The status bar shows the record progress.
When the status is **Draft** the user can still edit the record.

The screenshot displays the 'Pre-Submission Advice' interface. At the top, a status bar shows four stages: 'Draft' (highlighted in blue), 'Submitted', 'In Progress', and 'Closed'. Below the status bar, a red box highlights three action buttons: 'Submit', 'Printable View', and 'Delete'. To the right, a 'Pre-Submission Advice Guidance' box contains text about saving as a draft and clicking 'Submit'. Below that, another red box highlights two sections: 'Open Activities (0)' and 'Request Team (0)', which includes a table with columns for 'Member Name' and 'Team Role Name'. The main content area shows request details: Request 222, Status Draft, Request Number 00001630, Account Name ABC Company Spa, and Contact Name Mark Johnson. A navigation menu on the left includes 'Details', 'History', 'Request Information', 'PSA Details', and 'PSA Submission Outcome'.

This section shows additional information on the GPSA request.

3.11.1 Request a GPSA

The following fields are automatically copied from the pre-application ID information:

- Food Domain
- Authorisation Type
- Application Type
- Test Item

These fields cannot be edited.

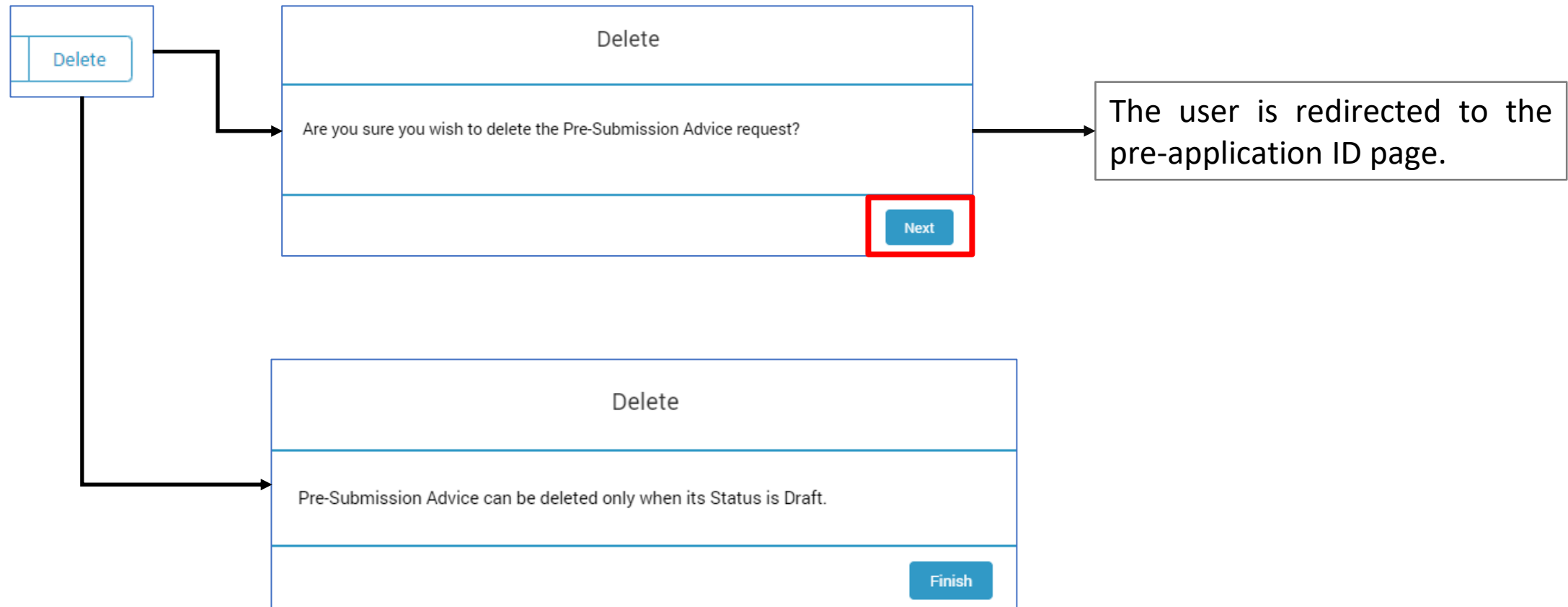
Under the **History** tab the user can see the changes made to the record on *Request History* and the past activities in *Activity History* (such as meetings).

Under the **Detail** tab the user can find the details of the record divided into sections.

Date	Field	User	Original Value	New Value
15.01.2021 15:45	Created.			

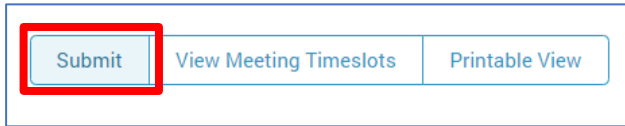
3.11.2 Deletion of a request for GPSA

It is possible to delete the GPSA request **only when its status is equal to Draft**, otherwise an **error message** will appear.



3.11.3 Submission of a request for GPSA – Pesticides

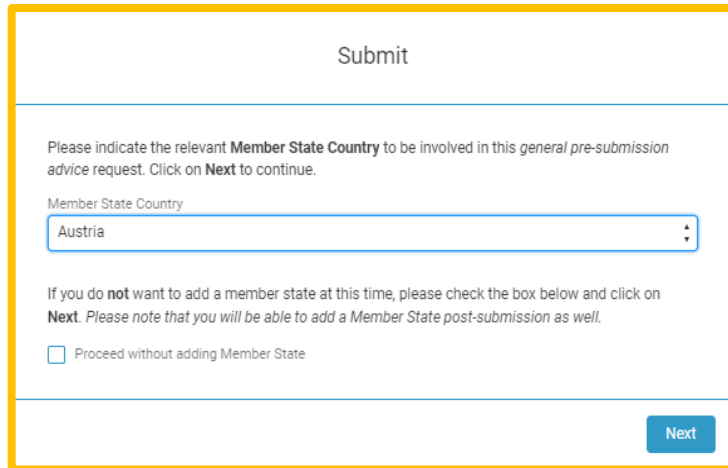
When submitting a GPSA requests linked to future applications with Food Domain: **Pesticides Peer Review (NAS), Pesticides MRL, Pesticides Peer Review (AIR) and Pesticides Peer Review - Other Areas**, the user is requested to indicate **the country** of the Rapporteur Member State (RMS) and the Co-Rapporteur Member State (Co-RMS).



Submit View Meeting Timeslots Printable View

Depending on the Food Domain, the system will display a different window for the selection of the Member State(s), to clarify when the selection of the RMS and co-RMS is mandatory.

Pesticides Peer Review (NAS) & Other Areas



Submit

Please indicate the relevant **Member State Country** to be involved in this *general pre-submission advice* request. Click on **Next** to continue.

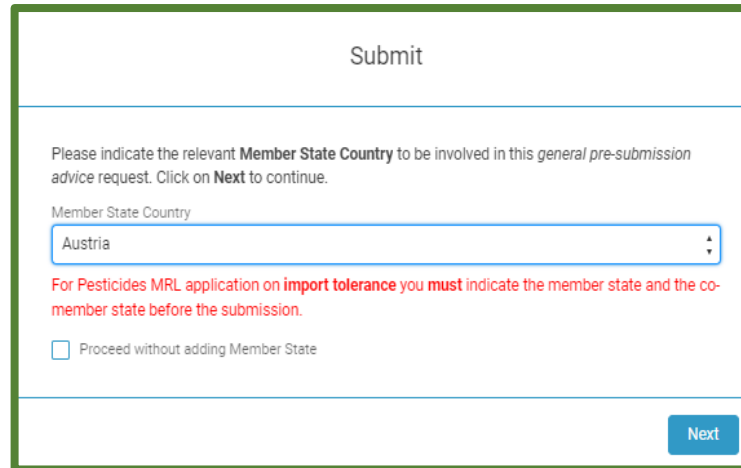
Member State Country
Austria

If you do **not** want to add a member state at this time, please check the box below and click on **Next**. Please note that you will be able to add a Member State post-submission as well.

Proceed without adding Member State

Next

Pesticides MRL



Submit

Please indicate the relevant **Member State Country** to be involved in this *general pre-submission advice* request. Click on **Next** to continue.

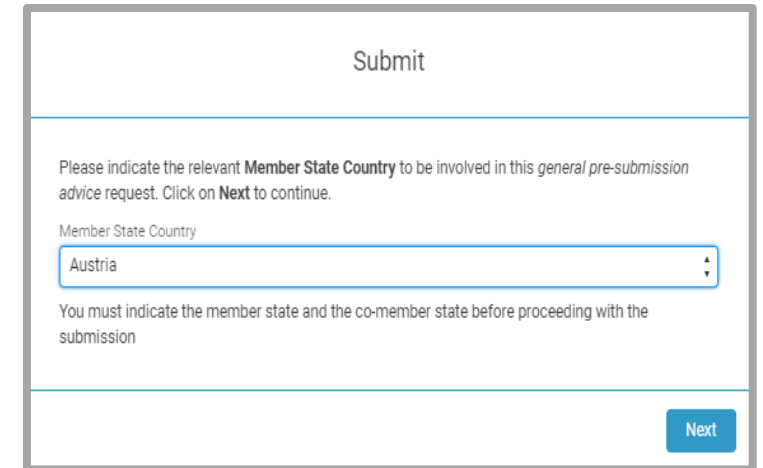
Member State Country
Austria

For Pesticides MRL application on import tolerance you must indicate the member state and the co-member state before the submission.

Proceed without adding Member State

Next

Pesticides Peer Review (AIR)



Submit

Please indicate the relevant **Member State Country** to be involved in this *general pre-submission advice* request. Click on **Next** to continue.

Member State Country
Austria

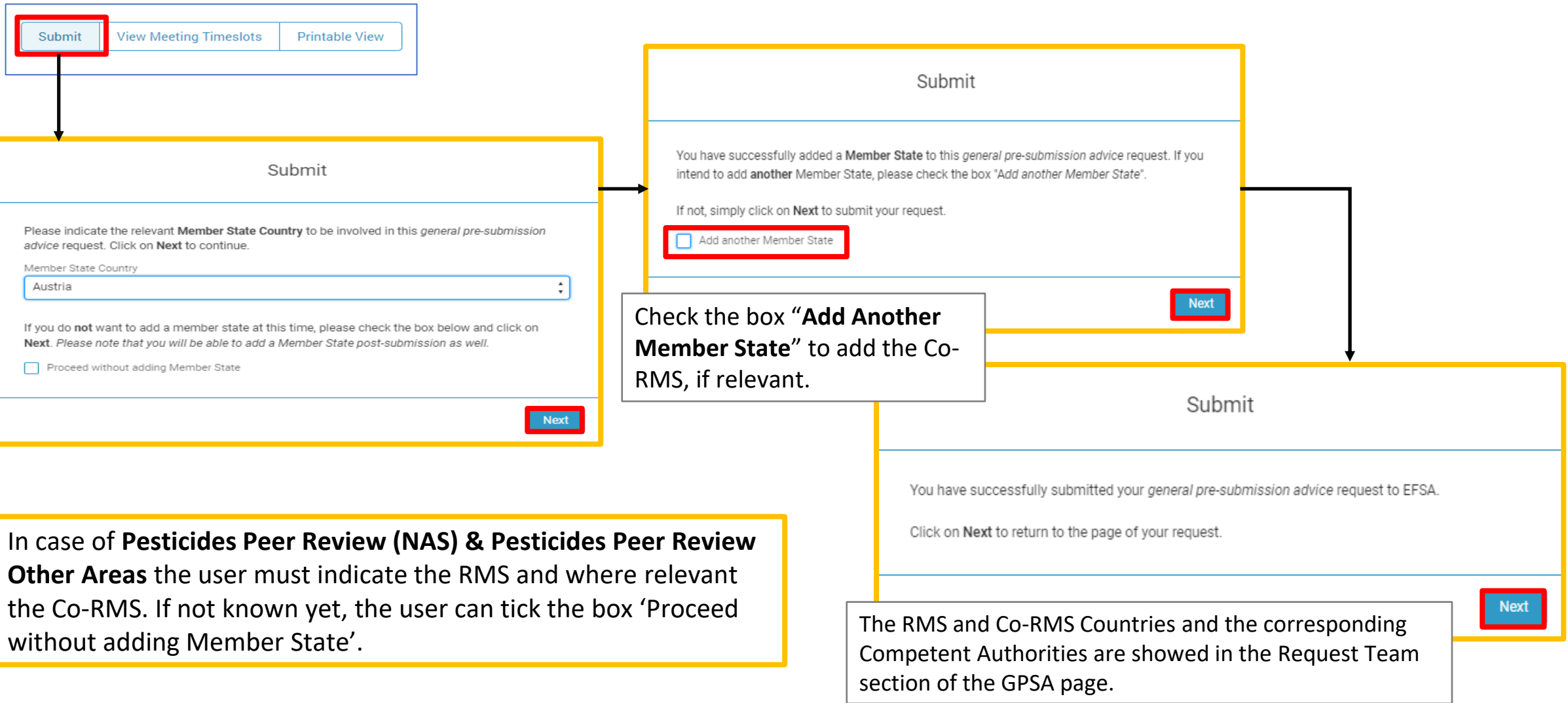
You must indicate the member state and the co-member state before proceeding with the submission

Proceed without adding Member State

Next

Note: more details on the submission workflow of a GPSA request for each Pesticides Food Domain are presented in the next slides.

3.11.3.1 Submission of a request for GPSA – Pesticides Peer Review (NAS) & Other Areas

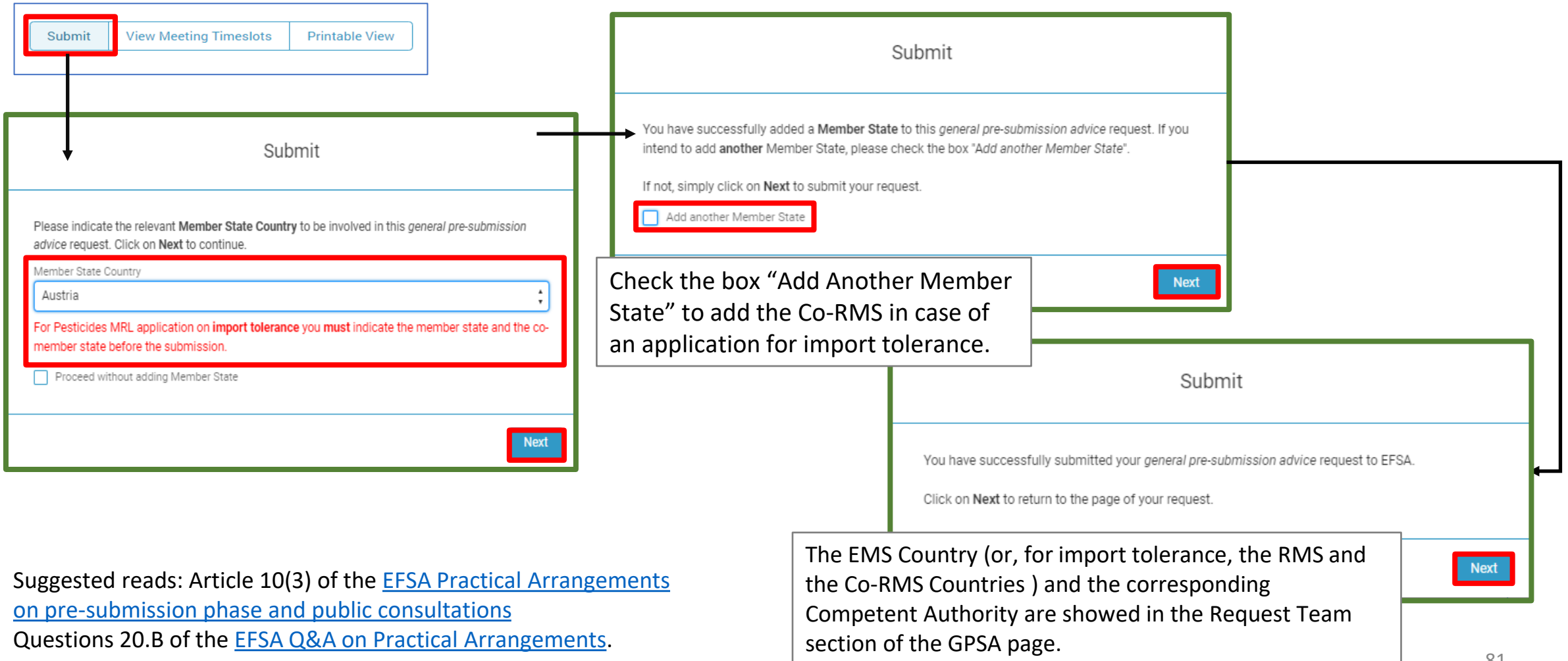


In case of **Pesticides Peer Review (NAS) & Pesticides Peer Review Other Areas** the user must indicate the RMS and where relevant the Co-RMS. If not known yet, the user can tick the box 'Proceed without adding Member State'.

The RMS and Co-RMS Countries and the corresponding Competent Authorities are showed in the Request Team section of the GPSA page.

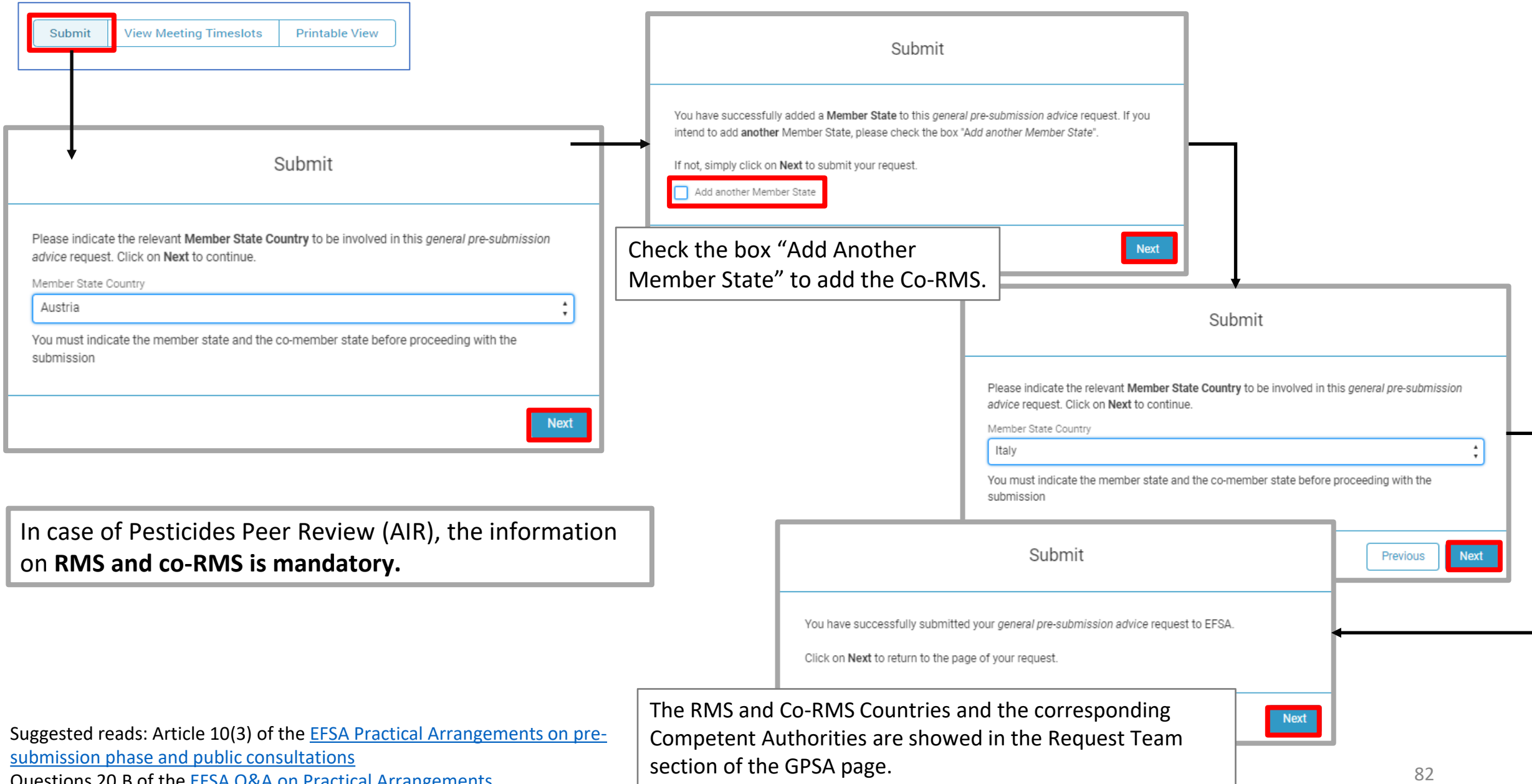
3.11.3.2 Submission of a request for GPSA – Pesticides MRL

In case of Pesticides MRL, the user must indicate the evaluating Member State (EMS). If not known yet, the user can tick the box 'Proceed without adding Member State'. For **Pesticide MRL applications on import tolerance**, the information on **RMS and Co-RMS is mandatory**, therefore the box must not be ticked.



Suggested reads: Article 10(3) of the [EFSA Practical Arrangements on pre-submission phase and public consultations](#)
Questions 20.B of the [EFSA Q&A on Practical Arrangements](#).

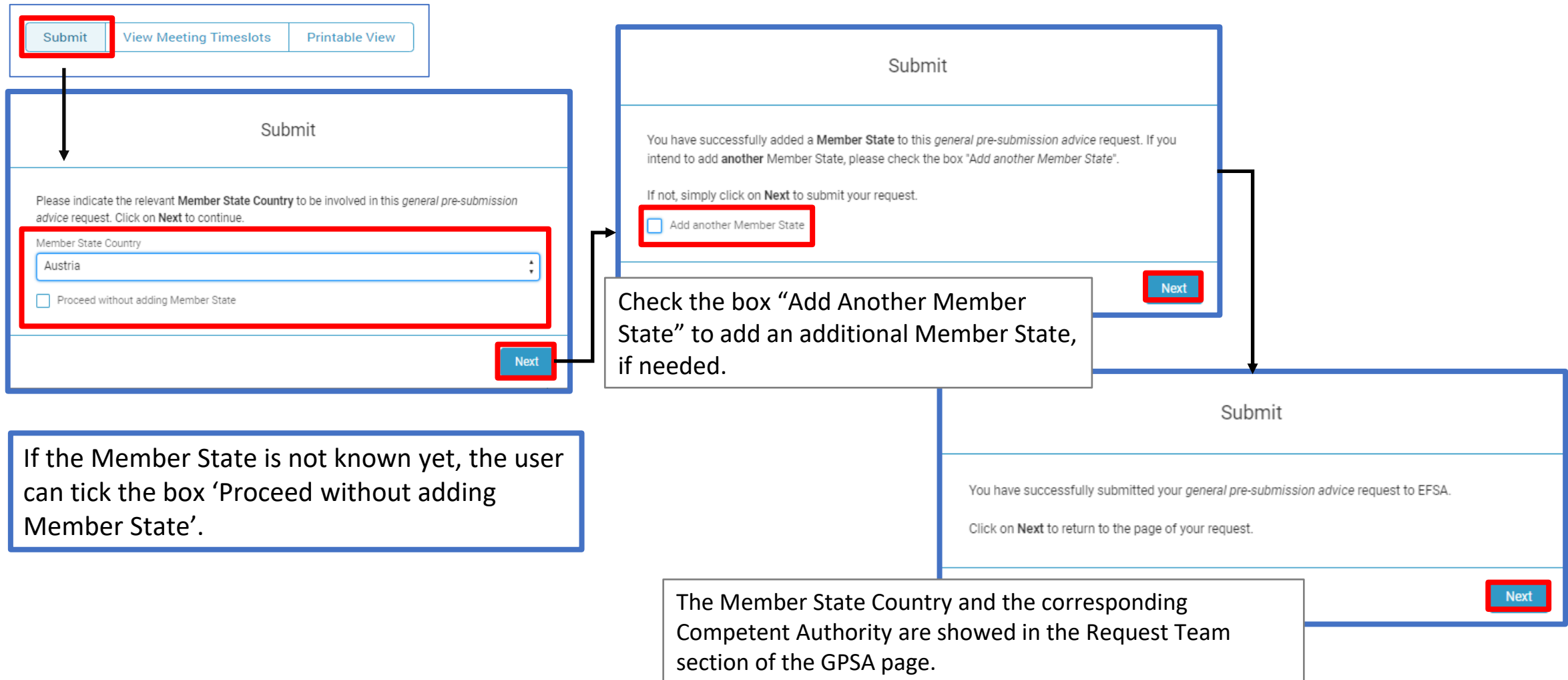
3.11.3.3 Submission of a request for GPSA – Pesticides Peer Review (AIR)



Suggested reads: Article 10(3) of the [EFSA Practical Arrangements on pre-submission phase and public consultations](#)
Questions 20.B of the [EFSA Q&A on Practical Arrangements](#).

3.11.4 Submission of a request for GPSA – GMO Directive

When submitting a GPSA requests linked to future notification under Articles 13 and 17 of Directive 2001/18/EC, the user is requested to indicate the **Country of the Member State** that will be notified.



3.11.5 Submitted request for GPSA – Pesticides and GMO Directive

Submit

You have successfully submitted your *general pre-submission advice* request to EFSA.

Click on **Next** to return to the page of your request.

Next

The Status turns into **Submitted** and the Member State contact is added to the **Request Team** related list.

The Member State contact will be alerted by email and will be able to see and read the GPSA request.

Pre-Submission Advice

Draft **Submitted** In Progress Closed

Request: UAT test pesticide AIR

Status: Submitted Request Number: 00001606

[Add Member State](#) [Printable View](#)

Pre-Submission Advice Guidance

Your request for Pre-Submission Advice has been successfully **submitted** to EFSA, and will be reviewed within 15 working days. You can no longer modify this request.

Click on **Add Member State** to notify a Member State of this Pre-Submission Advice request and give them access to the record. You can only perform this action before the request is Closed.

Open Activities (0)

Request Team (1)

Member Name	Team Role Name	Member State

3.11.6 Receiving a written GPSA

The user sees the record in Closed status and can read the written advice and the GPSA summary under the **PSA Submission Outcome** section.

Draft In Progress **Closed**

Request 00001334

View Meeting Timeslots Printable View

Pre-Submission Advice Guidance

Your Pre-Submission Advice request is now **closed** and can no longer be modified.

Request Team (0)

Open Activities (1)

Subject	Name	Task	Due Date
Business O...		<input type="checkbox"/>	21.01.2021

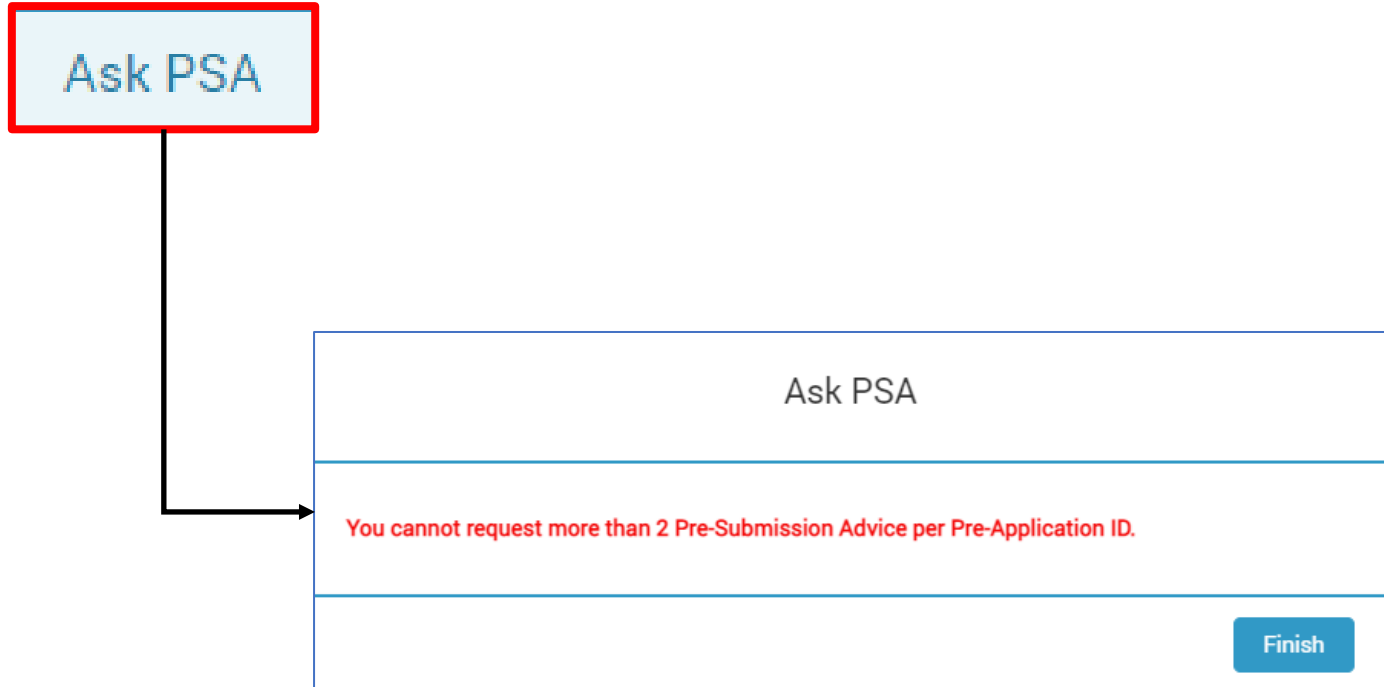
PSA Submission Outcome

PSA Summary
PSA summary information

Written Advice
written advice text

3.11.7 Limit number of GPSA requests

Each registered **business operator** or **third party/consultant** can submit **up to two GPSA requests** per pre-application ID.

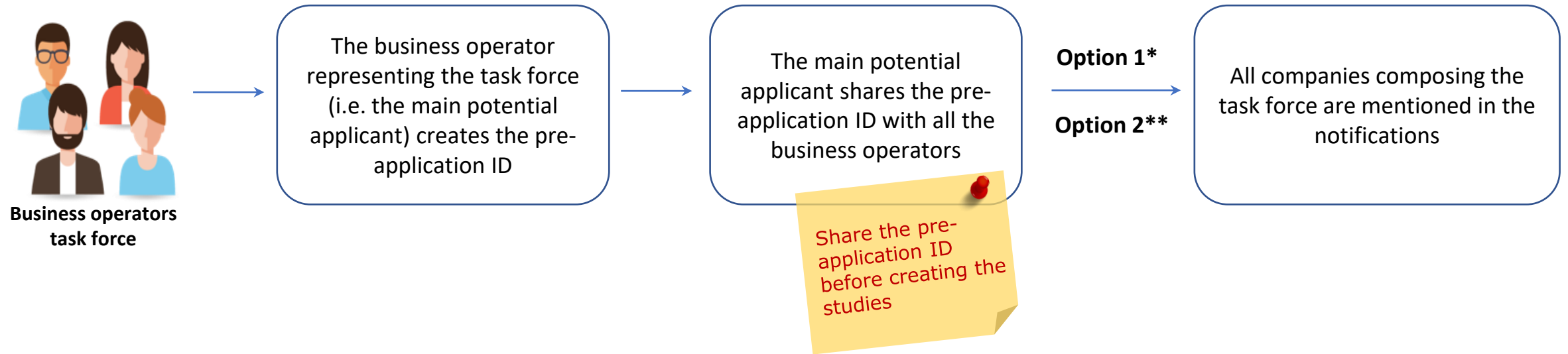


When the user tries to submit more than two GPSA requests for the same pre-application ID, the system returns an **error message**.

Task force scenario



4.1 Task force scenario – no third party/consultant involved



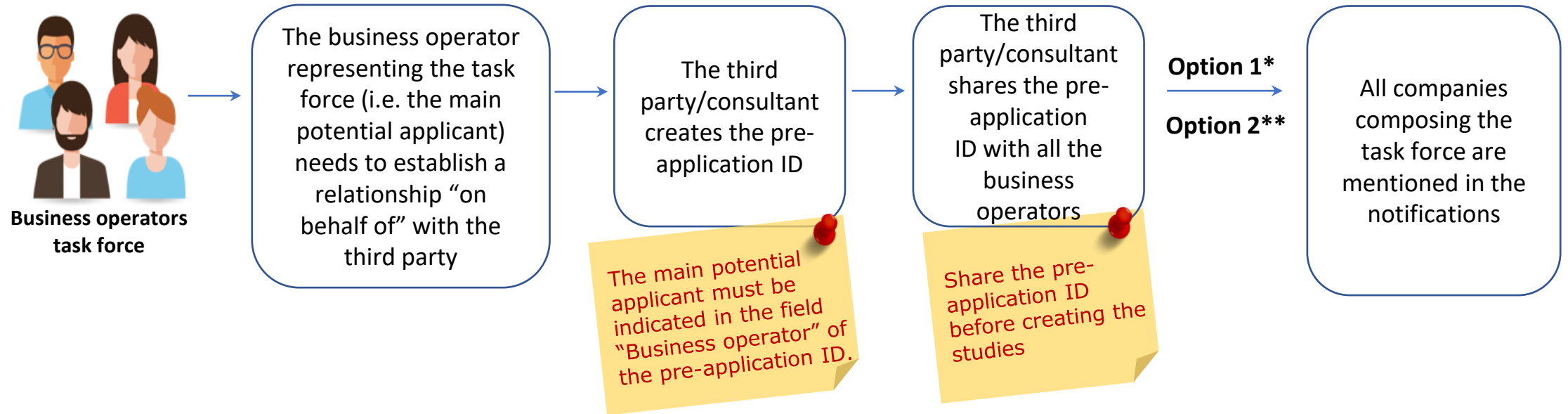
By default, the main potential applicant appears in the field ‘Business Operator’ of the pre-application ID and of all the studies linked therein.

*Option 1 - Pre-application ID shared with relationship type “Share With”: the companies composing the taskforce, other than the main potential applicant, can only view the studies created and notified that are linked to the pre-application ID.

Option 2 – Pre-application ID shared with relationship type “On behalf of”: **when creating the notification (and **only** at that stage), the Business Operator may be changed to reflect the actual organisation in the task force commissioning the study/ies, as showed in [Section 3.2](#). To do so, the main potential applicant should establish an additional relationship “on behalf of” with such organisation(s).

Both options are adequate to describe a task force scenario. Potential applicants can choose according to their needs.

4.2 Task force scenario – with a third party/consultant involved



By default, the main potential applicant appears in the field ‘Business Operator’ of the pre-application ID and of all the studies linked therein.

*Option 1 - Pre-application ID shared with relationship type “Share With”: the companies composing the taskforce, other than the main potential applicant, can only view the studies created and notified that are linked to the pre-application ID.

Option 2 – Pre-application ID shared with relationship type “On behalf of”: **when creating the notification (and **only** at that stage), the Business Operator field may be changed to reflect the actual organisation in the task force commissioning the study/ies, as showed in [Section 3.2](#). To do so, this entity should establish a relationship “on behalf of” with the third party/consultant.

Both options are adequate to describe a task force scenario. Potential applicants can choose according to their needs.

4.3 Highlights of the task force scenario

- The main potential applicant must be indicated in the field “Business operator” of the pre-application ID.
- If a third party/consultant is involved, the main potential applicant must establish firstly an account relationship “on behalf of” with this organisation.
- The pre-application ID may be shared with relationship type “share with” or “on behalf of” with the other companies composing the task force.
- It is possible to include, at a later stage, additional potential applicants under an already created pre-application ID by creating a relationship before sharing the pre-application ID with them.
- Should one of the joint potential applicants wish to seek general pre-submission advice separately or notify studies without sharing them with the other potential applicants of the task force (to avoid sharing confidential issues), they could request an additional individual pre-application ID. When the joint application will be submitted, all the pre-application IDs need to be reported.

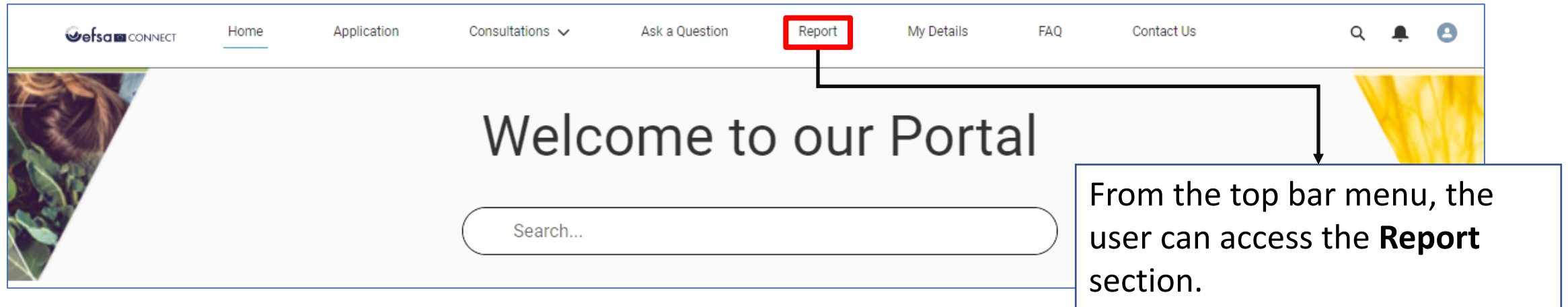


Reporting features

#Connect.EFSA



5. Reporting features



Important notes about reports:

- The user entering the Report section finds an overview of all the **Reports** available.
- Reports are collected in two main folders: “Records owned by my organisation”, “Records shared with my organisation”. Hence it is not possible to see records belonging to another organisation unless they have been shared. An additional folder “Study Types and Study Guidelines” contains the already available reports on study type and study guidelines.
- All reports and folders available on the portal are predefined by EFSA and in **read-only mode**. This means that changes done by the user will not be saved. When the page is refreshed, the system will restore the original version of the report. The user cannot create new folders.
- It is possible to (temporarily) apply some changes to the online reports. They can also be **exported in an editable Excel or CSV file**.



5.1 Reporting features – Overview

The user can access the reports from the REPORTS (All Reports) view, or from the FOLDERS (All Folders) view.

From this search bar it is possible to search for a specific report.

REPORTS	Report Name	Description	Folder	Created By	Created On	Subscribed
Recent	My components	This report shows the components created by your organisation	Records owned by my organisation		1/2/2023, 16:18	
Created by Me	My Components with Studies	This report shows the components linked with studies owned by your organisation	Records owned by my organisation		1/2/2023, 16:18	
Private Reports	My GPSA	This report shows the general pre-submission advice requests owned by your organisation	Records owned by my organisation		1/2/2023, 16:18	
All Reports	My list of intended studies	This report shows the pre-application IDs and the related list of intended studies created by your organisation	Records owned by my organisation		1/2/2023, 16:18	
FOLDERS	My PSA on Renewal	This report shows the list of intended studies and the related renewal pre-submission advice owned by your organisation.	Records owned by my organisation		1/2/2023, 16:18	
All Folders	My Studies	This report shows the studies and the linked pre-application IDs owned by your organisation	Records owned by my organisation		1/2/2023, 16:18	
Created by Me						
Shared with Me						
FAVORITES						
All Favorites						

Click on the report name to access it.

A short description of the content of the report is provided.

5.2 Reporting features - Folders

All the reports available to the user are saved in **three distinct folders**.

The screenshot displays a reporting interface with a sidebar on the left and a main content area. The sidebar is divided into three sections: 'REPORTS', 'FOLDERS', and 'FAVORITES'. The 'FOLDERS' section is highlighted with a red box and contains three items: 'All Folders', 'Created by Me', and 'Shared with Me'. The main content area shows a table of reports with columns for Name, Created By, Created On, Last Modified By, and Last Modified Date. The first row of the table is highlighted with a red box, and an arrow points from this row to a red box containing the text 'Click on the folder name to access it.'.

Reports
All Folders
3 items

Search all folders...

REPORTS	Name	Created By	Created On	Last Modified By	Last Modified Date
Recent	Records owned by my organisation		31/1/2023, 18:07		31/1/2023, 18:07
Created by Me	Records shared with my organisation		31/1/2023, 18:08		31/1/2023, 18:08
Private Reports					
All Reports	Study Types and Study Guidelines		12/10/2022, 14:18		1/2/2023, 20:18

FOLDERS

- All Folders
- Created by Me
- Shared with Me

FAVORITES

- All Favorites

Click on the folder name to access it.

5.4 Reporting features – Actions allowed on a report

The user can perform actions on the report using these buttons.

It is possible to:

- search for a specific value in the table
- add a chart
- apply filters
- refresh the values in table
- export the report in Excel or CSV formats

Report: Pre-Application IDs with Lists of Intended studies with Intended Studies
My list of intended studies
Report showing all Pre-Application IDs with associated List of Intended Studies and Studies owned by your own organisation

Total Records: 202 Total Converted: 18

<input type="checkbox"/> List of Intended studies Id ↑	Request Name	Study Title	Study Title (English Name)	Study Objective	Test Item	Study Type	Study Guideline	Study
<input type="checkbox"/> LIST-01-2023-0476 (1)	Test member state AIR	giga	↑ Sort Ascending	ff	Renewal	Sediment toxicity	OECD Guideline 105 (Water Solubility)	ff
<input type="checkbox"/> LIST-01-2023-0478 (1)	Test UAT 09.01.23 PLR 2	Study Test UAT 09.01.23 PLR 2	↓ Sort Descending	Study obj-Test UAT 09.01.23 PLR 2	Test UAT 09.01.23 PLR 2	Allergenicity		Study I
<input type="checkbox"/> LIST-06-2022-0001 (2)	Paid 9/6 12.13	Test Federico	Group Rows by This Field	Test Federico	Test Federico	Acidity/Alkalinity And Ph Value	ISO 10707 Water quality - Evaluation in an aqueous medium of the 'ultimate' aerobic biodegradability of organic compounds - Method by analysis of biochemical oxygen demand (closed bottle test)	Test Fe
	Paid 9/6 12.13	test gloria	Group Columns by This Field	asdasd	hhasdasd	Acute toxicity: inhalation	ISO 10156 (Gases and gas mixtures - Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets)	-
			Remove Column					

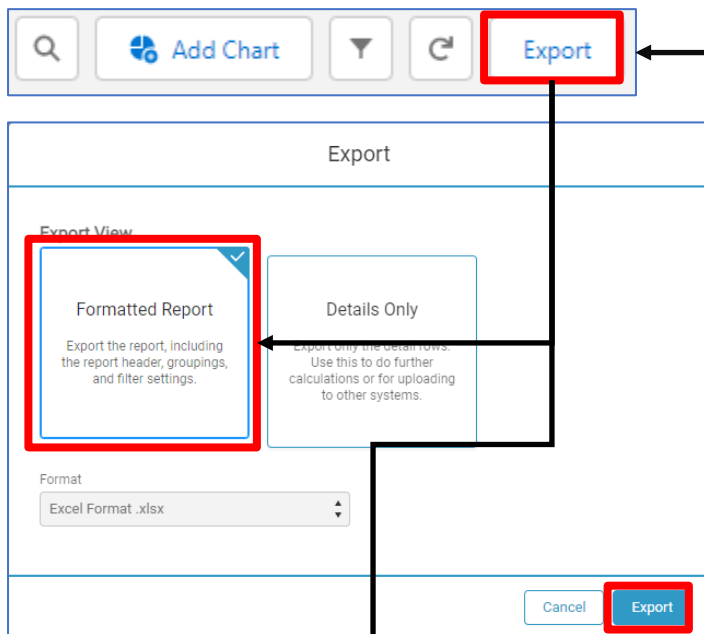
Toolbar buttons: Search, Add Chart, Filter, Refresh, Export

Click on one of the pointing down arrows to perform actions on the report table.

The user can:

- sort the values
- group/ungroup values
- remove columns

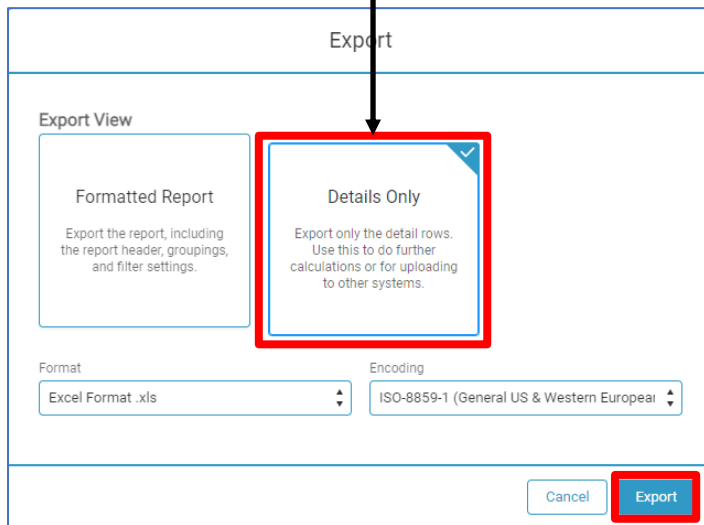
5.5 Reporting features – Export a report



Click on **Export** button and select the preferred format.

Formatted Report
Reports can be exported in a format similar to the online version, e.g., keeping the grouping and the other settings. This option exports the report as Excel file only.

A	B	C	D
1	My Studies with Pre-Application IDs		
2	As of 2023-01-06 17:10:54 Ora standard dell'Europa centrale/CET • Generated by User		
3			
4			
5			
6	Filtered By		
7	Show: All pre-application ids		
8	Shared with other organisations equals False		
9			
10	EFSA Study Identification ↑	Study Title	
11	EFSA-2021-00000522	Study - test notify to lab	
12	Subtotal	Sum	
13		Count	1
14	EFSA-2021-00000523	Test 2 - test lab	
15	Subtotal	Sum	
16		Count	1
17	EFSA-2021-00000543	test relationship	
18	Subtotal	Sum	
19		Count	1
20	EFSA-2021-00000545	test internal testing facility	

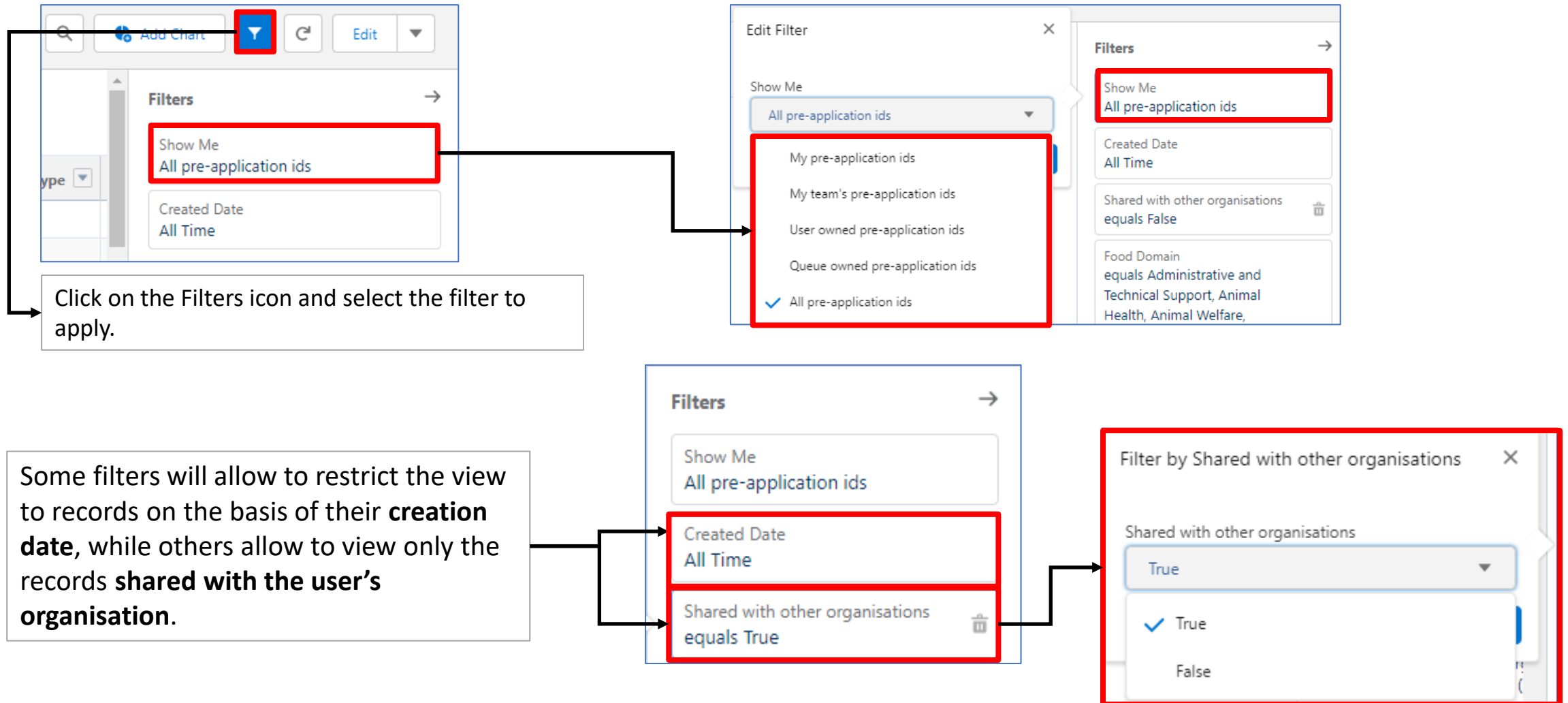


Details Only
Reports can be exported as Excel or CSV file showing only the detail rows.

	A
1	Study Title
2	Draft study
3	test
4	rr
5	test
6	new study test shared with
7	test on behalf solution consulting
8	Study as Solution consulting

5.6 Reporting features – Filters functionality

Depending on the type of data showed in the report, predefined filters are available. Once the user refreshes the page the default filtering rules set by EFSA will be restored.



5.7 Reporting features – All my Studies reports

Rapporto: Studies
All my Studies
This Report shows all your studies regardless of a link to one or several Pre-Application IDs.

Record totali: 13 Totale Submitted to Internal Testin...: 1

	EFSA Study Identification	Study: Study Title	Study Title	Study Title (English Name)	Status	Study Objective	Business Operator
1	EFSA-2022-00014929	Test_studyType_duplicates	Test_studyType_duplicates	-	Draft	test	FDP Team Advice B
2	EFSA-2022-00015871	Test study typeff	Test study typeff	Test study type	Draft	test	FDP Team Advice B
3	EFSA-2023-00016774	test2	test2	-	Draft	-	FDP Team Advice B
4	EFSA-2023-00017492	Study a	Study a	Study a	Draft	dd	FDP Team Advice B
5	EFSA-2023-00017493	Study b	Study b	Study b	Draft	-	FDP Team Advice B
6	EFSA-2023-00017494	Study cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStu	Study cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy cStudy c	Study c	Draft	-	FDP Team Advice B
7	EFSA-2023-00018347	Study XYZ	Study XYZ	-	Draft	-	FDP Team Advice B
8	EFSA-2023-00018348	Study ABC	Study ABC	-	Draft	-	FDP Team Advice B
9	EFSA-2023-00018349	Study CBD	Study CBD	-	Draft	-	FDP Team Advice B
10	EFSA-2023-00018350	Study FGI	Study FGI	-	Draft	-	FDP Team Advice B
11	EFSA-2023-00018351	Study EPO	Study EPO	-	Draft	-	FDP Team Advice B
12	EFSA-2022-00013462	This study is a test by FDP and IDATA to check the edit function after study not	This study is a test by FDP and IDATA to check the edit function after study notification	This study is a test by FDP and IDATA to check the edit function after study notification	Co-Notified	investigate acute tox	FDP Team Advice B

This report shows all the studies owned by the user organisation, regardless they are linked or not to a pre-application ID. The user finds:

1. The **EFSA Study IDs**.
2. The **Study Title information** comprehensive of “Study Title” with direct link to the study record page, “Study Title” (i.e. the full length version) and “Study Title (English Name)”.
3. Other available information includes: Status, Study Objective, Business Operator name and email, Laboratory name and email, etc.

Recommended documents and links

Applicants Toolkit

<https://www.efsa.europa.eu/en/applications/toolkit>

Transparency Regulation

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1381>

Practical Arrangements

<https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>

Q&A on Practical arrangements

<https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements>

