



# User Guide

## Pre-application ID

Last update: 5 December 2024

# Note for the users

This user guide has been updated on 5 December 2024 to take into account the latest system enhancements.

- The “Shared with” functionalities that allow organisations to share pre-application IDs among them, have been revised. In particular:
  - The name of this set of functionalities was changed from “Share with” to “Sharing options”.
  - The relationship type “Shared with”, which was granting read-only rights, has been renamed to “Read-only” accordingly.
  - A new section showing the history of sharing has been added to the pre-application ID page.

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)

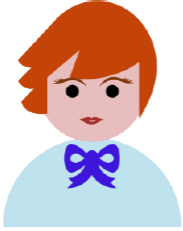
Third parties/consultants

(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**

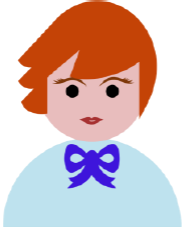
**Business operators:** these users create and manage their pre-application IDs in Connect.EFSA.



**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.

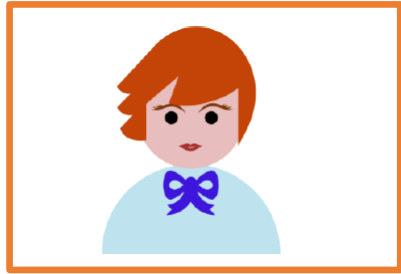
**Only these organisations can create pre-application IDs.**



**Third parties/  
Consultants**

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

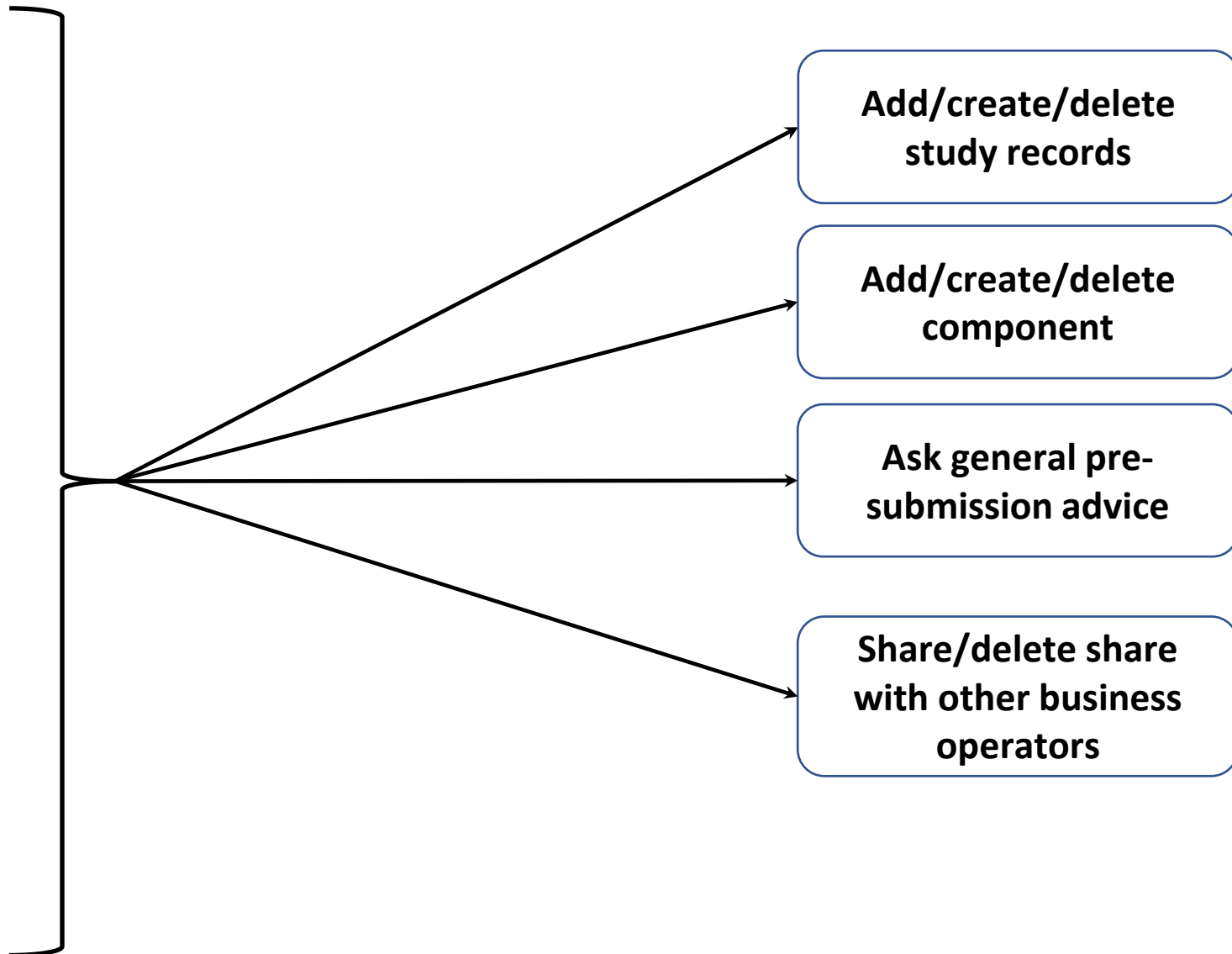
# 1.2 Pre-application ID activities



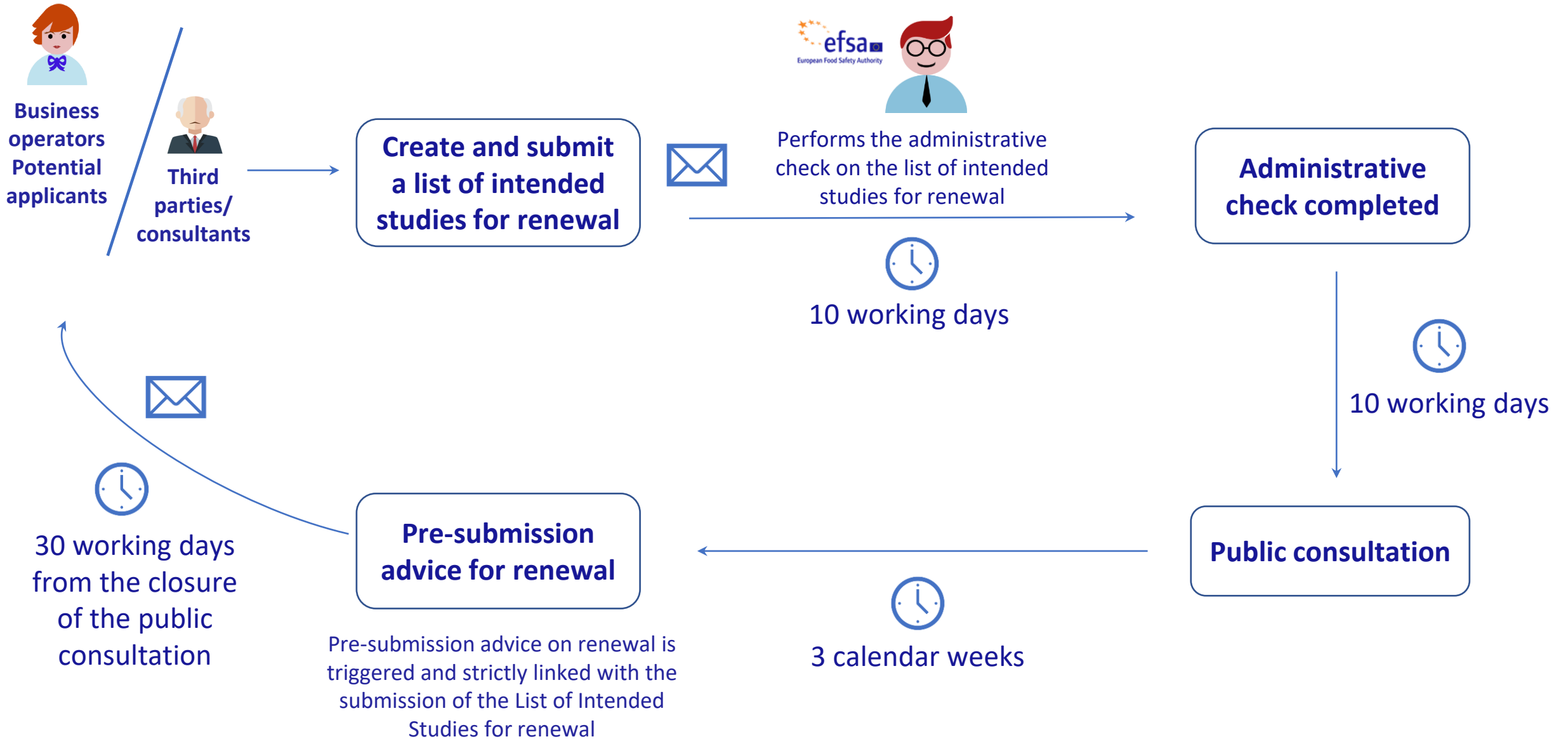
**Business operators**  
**Potential applicants**  
Create and manage  
pre-application IDs



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



# 1.3 List of intended studies for renewal: Process overview



# Accessing Connect.EFSA

#Connect.EFSA



## 2. Access the Connect.EFSA portal

**Business operators** and **their third parties/consultants** before starting to conduct pre-submission activities should [self-register an account](#) on behalf of their organisation by following the instructions available in the [Connect.EFSA registration user manual](#) and identifiable by a **pink banner** on the left-hand side of the slides.

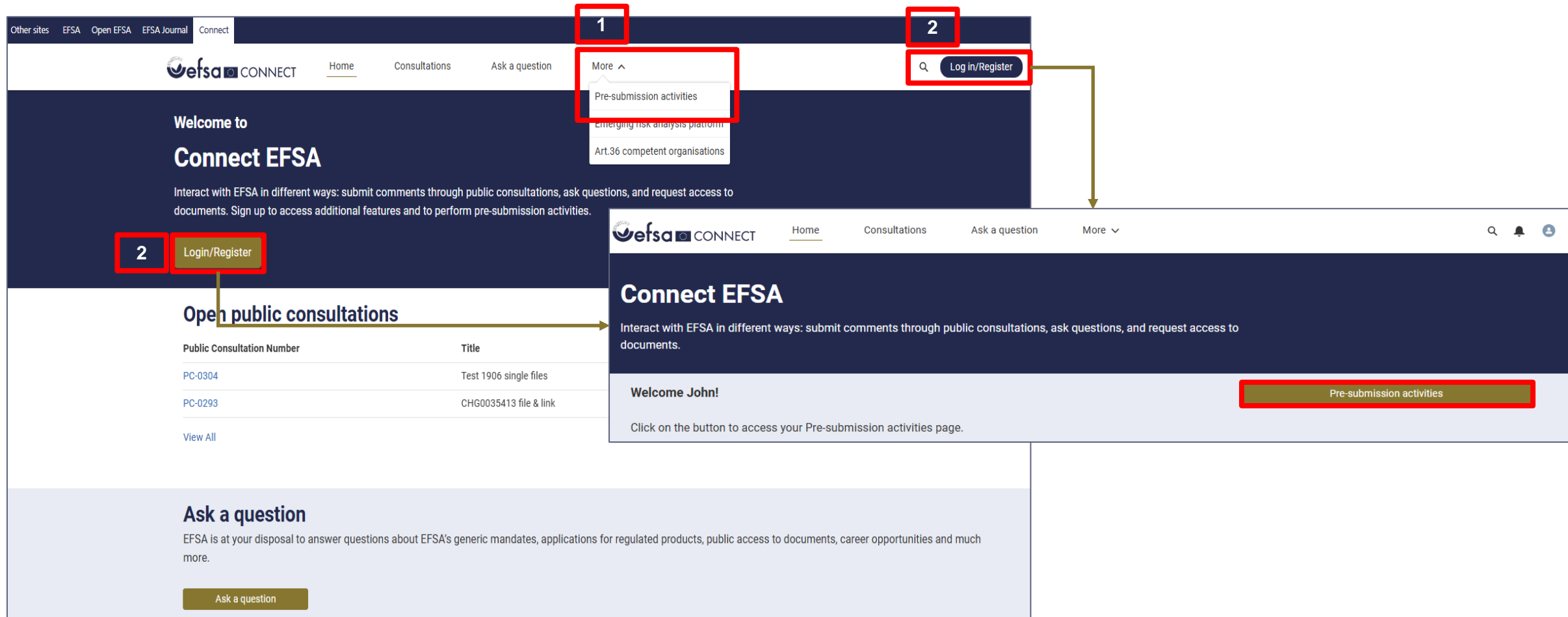
**Registered users from **business operator** and/or **third party/consultant**** organisations can access Connect.EFSA portal from their `trusted` devices via the following link: <https://connect.efsa.europa.eu/RM>



# 2.1 Accessing pre-submission activities

From the home page of Connect.EFSA users can access the **pre-submission activities page** in two ways:

1. before logging in, by clicking on 'More' and then selecting 'Pre-submission activities'
2. after logging in



## 2.2 The pre-submission activities main page

**efsa** CONNECT Home Consultations Ask a question More

# Pre-submission activities

New pre-application ID Reports

Quick buttons to create a new pre-application ID or access the report section.

This page contains **help texts** and **useful links** to guide the user across the available functionalities.

Welcome John,

In this section you can manage pre-application IDs and study notifications, access reports related to your pre-submission activities and have an overview of all your submitted applications.

### Pre-application IDs

Create pre-application IDs, request general pre-submission advice, create and submit study notifications, and create and submit a list of intended studies for renewal applications.

Access

### Notifications of studies database

Access the lists of study notifications created by your organisation or shared with you by other organisations.

Access

### Current applications

View your submitted applications once they have been received by EFSA and assigned to an EFSA's question number.

Access

### Frequently asked questions

Does EFSA suggest consultancy companies for preparing and submitting an application?

Where do I find the DAR (Draft Assessment Reports) application tool and related files?

I have submitted an application for evaluation by EFSA. How can I check the status of my application?

### Useful resources

[Connect EFSA registration manual](#)

[User guide on pre-application ID](#)

[User guide on notification of studies](#)

[EFSA's catalogue of services for applicants](#)



# Pre-application ID

#Connect.EFSA



# 3. Create a pre-application ID

efsa CONNECT Home Consultations Ask a question More ▾

## Pre-submission activities

New pre-application ID Reports

Welcome John,

In this section you can manage pre-application IDs and study notifications and have an overview of all your submitted applications.

**Pre-application IDs**  
Create pre-application IDs, request general pre-submission advice, create and submit study notifications, and create and submit a list of intended studies for renewal applications.

**Notifications of studies database**  
Access the lists of study notifications created by your organisation or shared with you by other organisations

**Current applications**  
View your submitted applications once they have been received by EFSA and assigned to an EFSA's question number.

Access Access Access

The user can **create a new pre-application ID** already from the main page of the pre-submission activities section by using **the quick button “New pre-application ID”**. **Alternatively**, the user navigates the pre-application IDs page and clicks on the “New pre-application ID” button.

# 3.1 Create a pre-application ID

**efsa** CONNECT Home Consultations Ask a question More ▾

## Pre-application ID

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

Pre-submission activities / Pre-application ID

From every page, users can identify where they are within the portal through this bar.

In this page you can see the details of your pre-application ID, its related records and 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 ID** Pre-submission advice Intended studies List of Intended Studies Components

My Pre-Application IDs ▾

2 items • Sorted by Request Name • Filtered by All pre-application ids - MyPreapplication

Search this list...

	Request... ↑ ▾	ID ▾	Food D... ▾	Applicatio... ▾	Authorisati... ▾	Contact N... ▾	Created D... ▾	
1	test bu2	EFSA-ID-2023-...	Feed Addi...	Application fo...	Feed Additives	Carl Washing...	23/08/2023 ...	▾
2	Test GPSA re...	EFSA-ID-2023-...	Novel Foo...	New Novel Fo...	Novel Food A...	Carl Washing...	31/03/2023 ...	▾

Use this dropdown menu to filter the results of a search.

# 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”.

- \* this sign means that the field is **mandatory**
- ⓘ this icon displays the **help text** for that field.

Pre-submission activities / Pre-application ID / New Pre-application ID

## New pre-application ID

\* = Required Information

\*Request Name

\*Business Operator

\*Food Domain ⓘ

--None--

Authorisation Type

--None--

Application Type

--None--

\*Subject Of The Application ⓘ

Note ⓘ

Save

# 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  
Paid Test 123

\* Business Operator  
Business & Business

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

\* Food Domain  
Administrative and Technical Support

Authorisation Type  
--None--

Application Type  
--None--

\* Subject Of The Application ⓘ  
subject

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 ⓘ

Save

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

## 3.1.1 Pre-application ID - Applications

**New Pre-Application ID**

\* Request Name

\* Business Operator

\* Food Domain ⓘ

\* Authorisation Type

\* Application Type

\* Subject Of The Application ⓘ

Note ⓘ

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 **Save** button to proceed.

## 3.1.1 Pre-application ID - Applications

The screenshot shows the 'Pre-Application ID' interface for a 'New application for JPQ'. The ID is 'EFSA-ID-2024-000949'. The interface includes a 'Details' tab (highlighted with a red box) and a 'History' tab. A red box labeled '1' highlights the top navigation bar with buttons for 'Edit', 'New Study', 'Add Studies', and a dropdown menu containing 'Ask GPSA', 'Share With', 'Delete', and 'Printable View'. A red box labeled '2' highlights the 'Subject Of The Application' section, which includes fields for 'Food Domain' (Novel Foods), 'Authorisation Type' (Novel Food Application), and 'Application Type' (New Novel Food). A red box labeled '3' highlights the 'Add Component' button. A red box labeled '4' highlights the 'Subject of the Application: Components (0)' and 'Study Notification (0)' sections. A text box on the left states: 'Under each tab the user can see different information regarding the pre-application ID.'

**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)

**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

Save

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

The screenshot displays the 'Pre-Application ID Renewal application for XYZ' interface. It features a top navigation bar with 'Details' and 'History' tabs. The main content area is divided into several sections: a header section with 'Request Name' and 'Business Operator', a 'Details' section with 'Subject Of The Application', 'Former Application ID', and 'Note', and a 'Food Domain' section with 'Feed Additives', 'Authorisation Type', and 'Application Type'. A 'Pre-Application Operations' panel is located on the right, containing a list of actions: 'New Study', 'New List', 'Add Studies', 'Share With', 'Ask GPSA', 'Delete', and 'Printable View'. Below this panel is an 'Add Component' button and a list of associated objects: 'Study Notification (0)', 'List of Intended Studies (0)', 'Pre-Submission Advice (0)', and 'Share With (0)'. Red boxes and numbers 1 through 4 highlight specific elements: 1 points to the 'Edit', 'New Study', and 'New List' buttons; 2 points to the 'Subject Of The Application' field; 3 points to the 'Add Component' button; and 4 points to the list of associated objects.

Pre-Application ID  
Renewal application for XYZ

ID  
EFSA-ID-2022-000646

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

**1**

Edit New Study New List

Add Studies

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
- 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

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)

**3**

Add Component

**4**

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

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.

New Study

**New Study**

To create a new study, fill out the mandatory fields (marked with a red asterisk). Please note that you are only creating a **draft version** of the study and will still be able to edit it later.

\* Study Title

Complete this field.

Study Title - English Name ⓘ

\* Business Operator ⓘ

Laboratory ⓘ

**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](#)

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

**Study Notification (4)**

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

**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 find a study record. It is possible to select one or more study records the user would like to add to the pre-application ID. **Only notified and co-notified studies** can be added to the pre-application ID. To continue click on **Next**.

Add Studies to Pre-Application ID

Search Studies...

**Selected Studies: 2**

EFSA-2023-00001617 x EFSA-2023-00001593 x

<input type="checkbox"/>	Study Number	Name	Status	Food Domain	Created Date
<input type="checkbox"/>	EFSA-2024-00001762	Study Title 98955191	Notified	Feed Additives	8-Feb-2024
<input checked="" type="checkbox"/>	EFSA-2023-00001617	Study Title 78372026	Notified	Feed Additives	20-Mar-2023
<input checked="" type="checkbox"/>	EFSA-2023-00001593	Study Title 24254589	Co-Notified	Animal Health	20-Mar-2023
<input type="checkbox"/>	EFSA-2023-00001597	Study Title 89219473	Co-Notified	Animal Health	20-Mar-2023

**Next**

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

**Study Notification (3)**

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

[View All](#)

Clarification added!

Add to

Selected Studies: 3

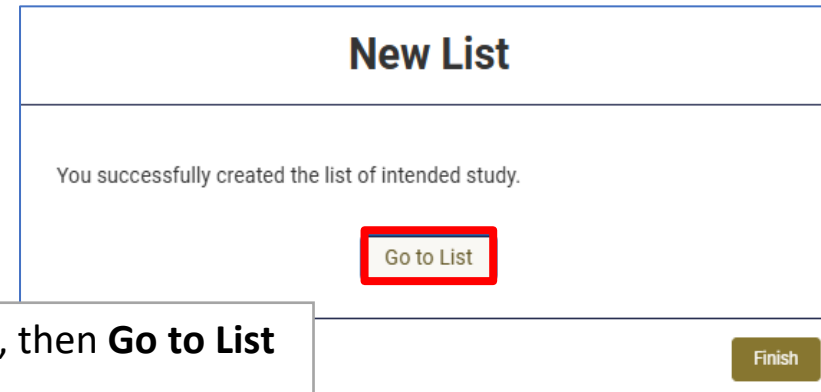
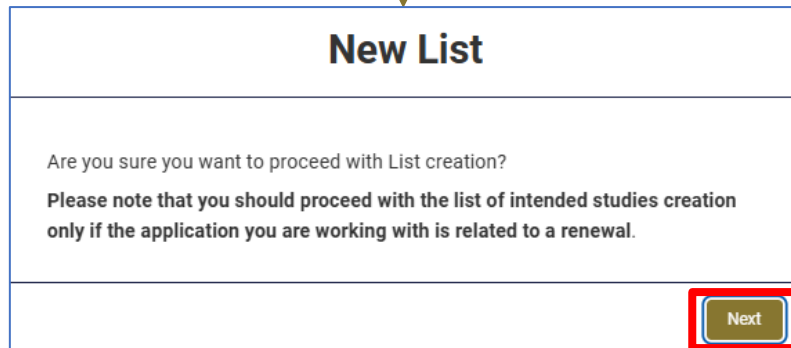
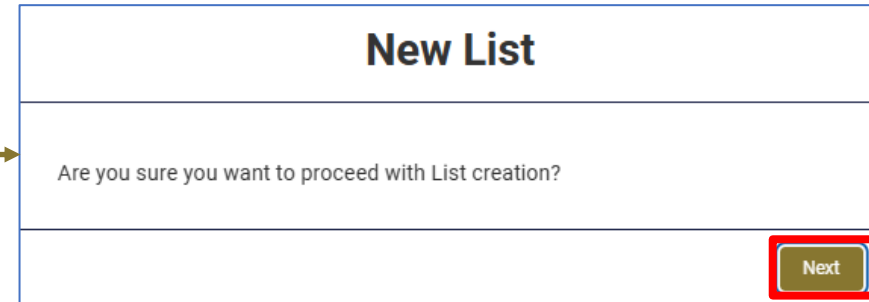
**Studies must be notified only once.** If a study notification has been already used in a pre-application ID, the function 'Add Study' allows to re-use a notified/co-notified study in another pre-application ID.

# 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

Pre-submission activities / Pre-application ID / List of intended studies detail page

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



List of Intended Studies  
LIST-06-2024-0523

New Intended Study Submit List Delete

**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)
- You may use the **Mass Conversion** button to select the intended studies to convert into notifiable draft studies

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

Business Operator  
[ABC Company](#)

Date Submitted

Pre-Application ID  
[Renewal of CPT](#)

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

List Details

Mass Conversion

A list of three items, each with an icon and a count in parentheses: 'Intended Studies (0)', 'Public Consultation (0)', and 'Pre-Submission Advice on Renewal (0)'. A red box highlights the first three items.

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

# 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](#).

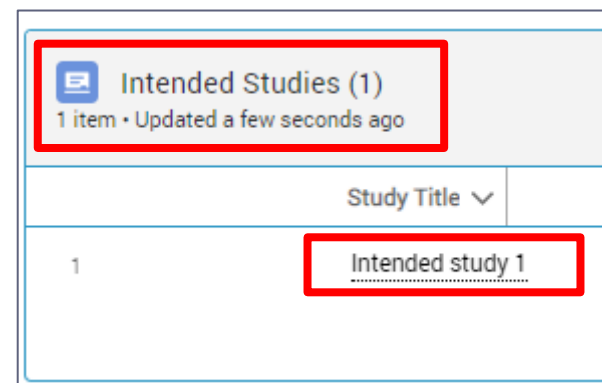


The New Intended Study form must be completed indicating all the mandatory information. Then the user clicks **Next**.

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

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

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

Intended Study ID: INTS-000125

Converted:

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

Study Title: QWERTY\_1

Study Title (English Name): QWERTY\_1

Study Scope: Acidity/Alkalinity And Ph Value

Study Objective: QWERTY\_1

Study Design: 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

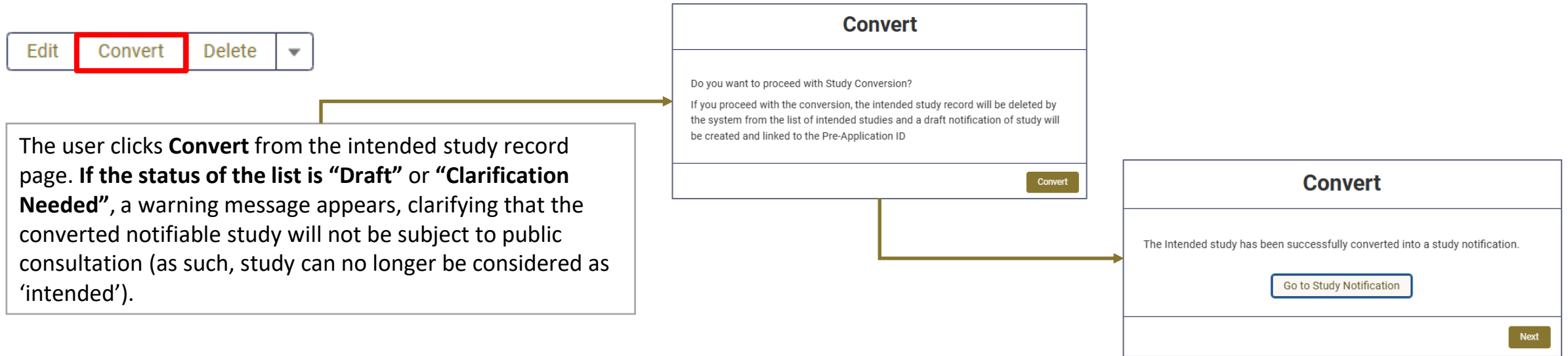
Other Information: [LIST-07-2022-0059](#)

**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 (L...	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	ID EFSA-ID-2023-000914
Business Operator ABC Company Spa	Contact Name

Details

Subject Of The Application Renewal application TJP	Food Domain Feed Additives
Former Application ID EFSA-Q-XXXXXXX	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)

**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"/> <span>▼</span>

[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 by using the function button **Submit List** and then **Next**.

**List of Intended Studies**  
LIST-06-2024-0523

New Intended Study **Submit List** Delete ▼

Business Operator: [ABC Company](#) Date Submitted: Pre-Application ID: [Renewal of CPT](#)

List Details

Mass Conversion

**Intended Studies (3)**  
3 items • Updated a few seconds ago

	Study Title	Study Type	Study Object...	Study Guideline	Test Item	Study Desig...	Study Detail...	Converted	
1	<a href="#">Intended study 2</a>	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	<a href="#">Intended study 3</a>	Active Substance Bioconcentration In Prey Of Birds And Ma...	Intended study 3	ISO 10707 Water quality - Evaluation in an aqueous medium ...	Subject of the application for XYZ	Intended study 3	Intended study 3	<input type="checkbox"/>	▼
3	<a href="#">Intended study 4</a>	Acute Contact Toxicity	Intended study 4	ISO 10253 (Water quality - Marine Algal Growth					

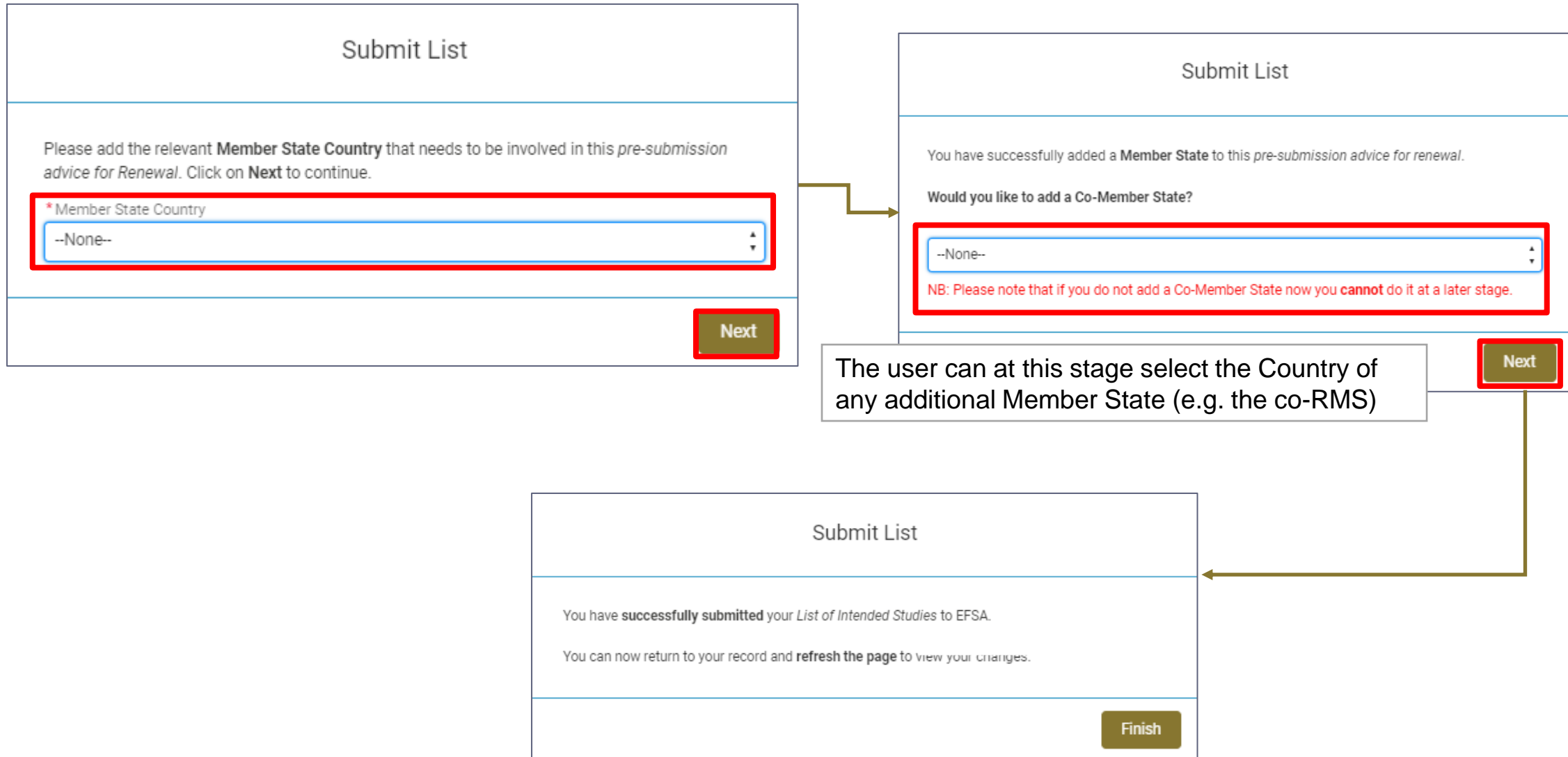
**Submit List**

To submit this record to EFSA, please click on **Next**.

**Next**

### 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.

Submit List

Please add the **Member State** that needs to be involved in this Pre-Application ID for Renewal. First, select the country to which the Member State belongs, then click on **Next**.

Member State Country

Italy

Proceed without adding Member State

Next

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.

Submit List

You have successfully added a **Member State** to this *pre-submission advice for renewal*.

Would you like to add a Co-Member State?

--None--

NB: Please note that if you do not add a Co-Member State now you **cannot** do it at a later stage.

Next

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

Submit List

You have **successfully submitted** your *List of Intended Studies* to EFSA.

You can now return to your record and **refresh the page** to view your changes.

Finish

## 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 with stages: Draft, Clarification Needed, Submitted (highlighted with a red box), Administrative Check Completed, Undergoing Public Consultation, In Progress, and Closed. Below the progress bar, there is a section for 'List of Intended Studies' with the ID LIST-07-2022-0049. A table lists the submission details:

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

Buttons for 'New Intended Study', 'Submit List', and 'Delete' are visible. A red box highlights a text area titled 'List Of Intended Studies for Renewal Operations' which contains the following text:

**List Of Intended Studies for Renewal Operations**

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 submitted list of intended studies. The 'Details' tab is highlighted with 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
Contact Name	
Pre-Application ID	PAID for the renewal of the user guide R8
EFSA Comment	
Note	
Closed Reason	
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
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 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 system shows details for a 'List of Intended Studies' with 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'. Action buttons include 'New Intended Study', 'Submit List', and 'Delete'. A red-bordered box on the right contains a message from EFSA regarding a clarification request and a list of actions: record responses in the 'Notes field', use the 'New Intended Study' button, edit all records and notify them, use the 'Submit' button to re-submit, use the 'Delete' button, and use the 'Mass Conversion' button to convert studies to draft status.

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

Buttons: New Intended Study, Submit List, Delete

**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.

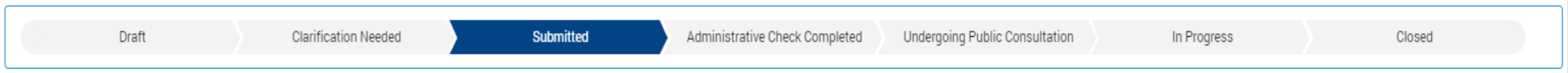
List of Intended Studies  
LIST-07-2022-0049

New Intended Study **Submit List** Delete ▾

Business Operator: [ABC Company](#)  
Date Submitted: 12/07/2022  
Pre-Application ID: [Renewal application for XYZ](#)

List	<b>Details</b>
List of Intended studies Name LIST-07-2022-0049	Contact Name .....
Business Operator <a href="#">ABC Company Spa</a>	Pre-Application ID <a href="#">Renewal application for XYZ</a>
▼ List of intended studies submission	
Date Submitted 12/07/2022	<b>EFSA Comment</b> Request from EFSA to amend the information
Status Clarification Needed	Note ⓘ
	Closed Reason

The status turns again into **Submitted**.



### 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 at the top with stages: Draft, Clarification Needed, Submitted, **Administrative Check Completed** (highlighted in a red box), 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 table with the following data:

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

Navigation buttons include 'New Intended Study', 'Submit List', and 'Delete'. A red-bordered box on the right contains the following text:

**List Of Intended Studies for Renewal Operations**

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 a red box. The interface details are identical to the previous screenshot. A red-bordered box on the right contains the following text:

**List Of Intended Studies for Renewal Operations**

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.

The screenshot shows a notification icon and the text 'Public Consultation (1)' highlighted in a red box. Below this, a table displays the public consultation details:

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. A dropdown menu contains 'New Intended Study', 'Submit List', and 'Delete'. A table lists the business operator as 'ABC Company Spa', the date submitted as '12/07/2022', and the pre-application ID as 'Renewal application for XYZ'. A red-bordered callout box titled 'List of Intended Studies for Renewal Operations' explains that renewal advice is being provided within 30 business days and that no further actions can be taken while the status is 'In Progress'.

Business Operator	Date Submitted	Pre-Application ID
<a href="#">ABC Company Spa</a>	12/07/2022	<a href="#">Renewal application for XYZ</a>



**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 process flow at the top with stages: Draft, Clarification Needed, Submitted, Administrative Check Completed, Undergoing Public Consultation, In Progress, and **Closed**. Below this, the 'List of Intended Studies' section displays the ID LIST-07-2022-0049 and buttons for 'New Intended Study', 'Submit List', and 'Delete'. A table lists the business operator as ABC Company Spa, the date submitted as 12/07/2022, and the pre-application ID as Renewal application for XYZ. A red box highlights the 'Closed' status in the flow, with an arrow pointing to a detailed text box on the right.

**List Of Intended Studies for Renewal Operations**

The process of the renewal pre-submission advice related to the submitted list of intended studies is closed.

To comply with provisions of Article 32b of the General Food Law Regulation you are requested to notify all the studies in this list that will support your future application for renewal, before their starting date.

- Use the **Convert** button to transform the intended study record in a notifiable draft study.
- 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' section. A 'List' tab is highlighted with a red box. A 'Mass Conversion' button is visible. Below, a table lists the advice with a 'Request Number' of 00001817 and a 'Subject' of 'PSA on Renewal for LIST-07-2022-0049'. Red boxes highlight the 'Pre-Submission Advice on Renewal (1)' header and the 'Request Number' cell. Arrows point from the text box above to these elements.

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


View All


# 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.

List Details

Mass Conversion

List Details

Intended Studies

<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.

Convert

## 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?

If you proceed with the mass conversion, for the selected intended study a draft notification will be created and linked to the Pre-Application ID.

Cancel

Convert

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

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)

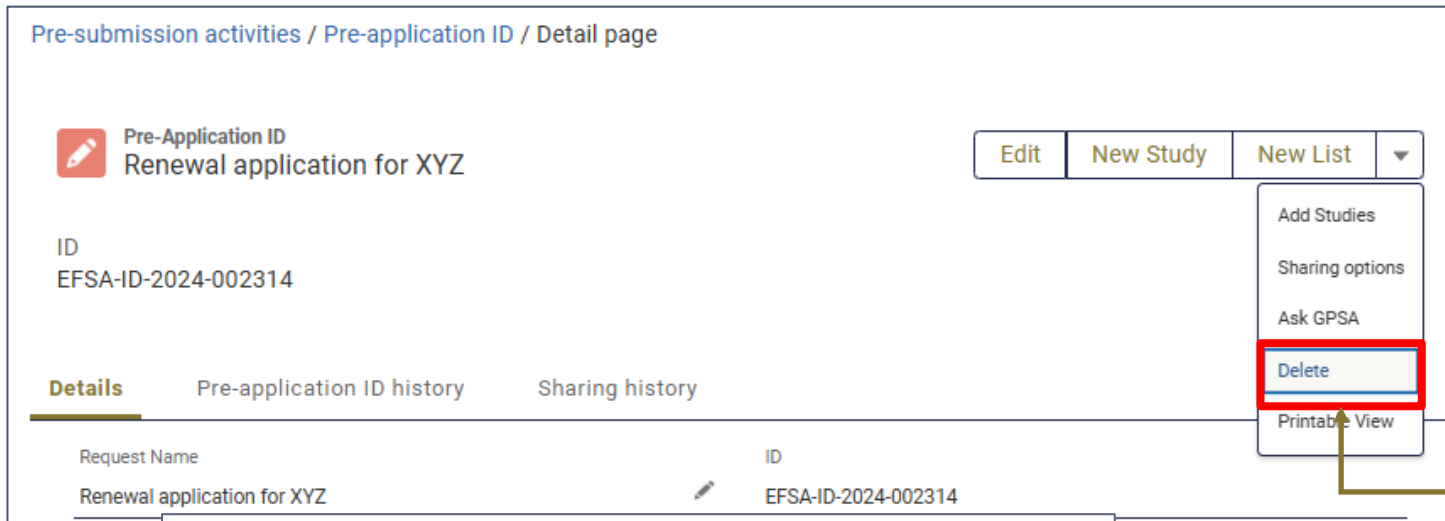
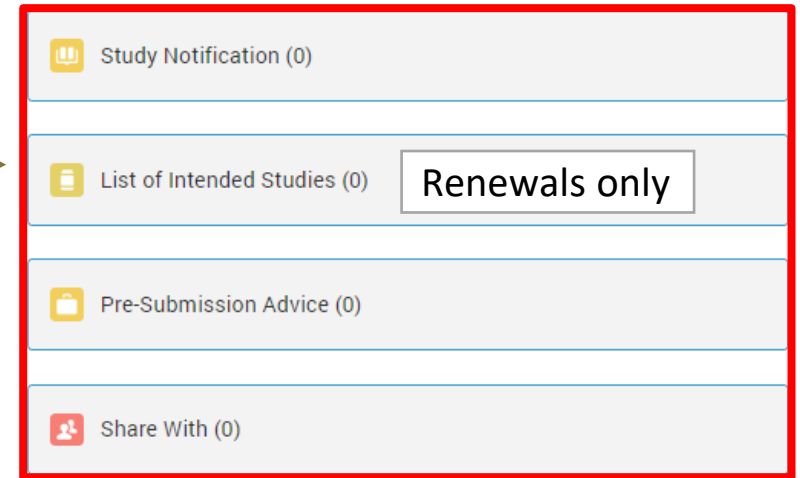
Study Title	EFSA Study Iden...	Status	Study Withdrawn
<a href="#">Intended study 1</a>	EFSA-2022-0000...	Draft	<input type="checkbox"/>
<a href="#">Intended study 2</a>	EFSA-2022-0000...	Draft	<input type="checkbox"/>
<a href="#">Intended study 3</a>	EFSA-2022-0000...	Draft	<input type="checkbox"/>

View All

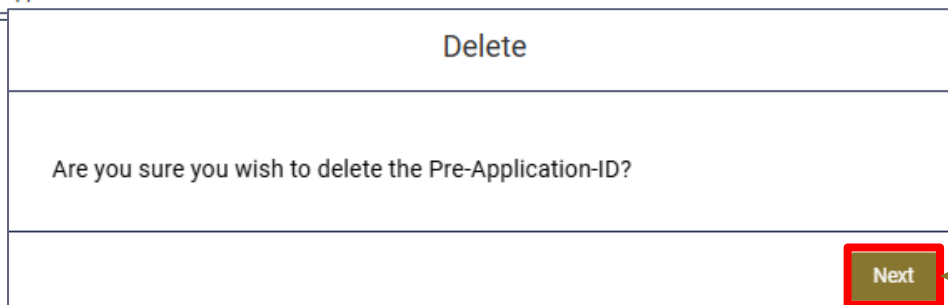
## 3.7 Delete a pre-application ID

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**.



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



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



### 3.7.1 Delete a pre-application ID and/or remove draft objects

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

Study Notification (1)

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

View All

Edit

Delete

Select **Delete** to remove a 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 (1) Renewals only

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

View All

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”**.

Pre-Submission Advice (1)

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

View All

Edit

Delete

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

# Components

#Connect.EFSA



## 3.8 Add a component

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

Add Component

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

### Add Component

Search for the *Component* you want to add to this record by using the search box below. Alternatively you can create a **new** Component by checking the box **Create New Component**.

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.

\* Component  
Search Components...

Create New Component

Next

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.

### Add Component

Search for the *Component* you want to add to this record by using the search box below. Alternatively you can create a **new** Component by checking the box **Create New Component**.

\* Component

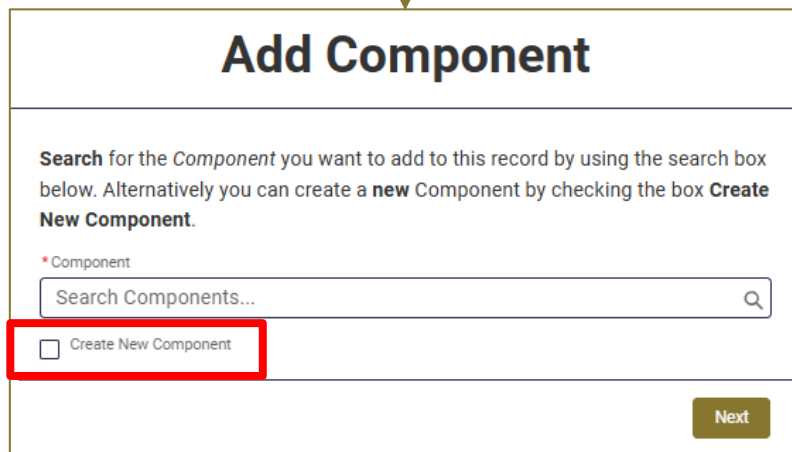
Wat

Show All Results for "Wat"

- Propolis (Water soluble extract)  
RF-00012023-PAR
- Water extract of Cistanche tubulosa stems  
RF-00012691-PAR
- fibre, water-insoluble  
RF-00000285-NTR
- fibre, water-soluble  
RF-00000286-NTR
- water (moisture)  
RF-00000433-NTR

## 3.8.1 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.



**Add Component**

Search for the *Component* you want to add to this record by using the search box below. Alternatively you can create a **new** Component by checking the box **Create New Component**.

\* Component

Search Components...

Create New Component

Next

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 showed by passing over the **i** icons. Click **Next** to continue.



**Add Component**

Search for the *Component* you want to add to this record by using the search box below. Alternatively you can create a **new** Component by checking the box **Create New Component**.

Create New Component

▼ **Component Details**

\* Type of Term **i**

None

\* Name

Common Names

Other Names

CAS **i**

IUPAC **i**

InChI **i**

Additional Information

Next


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



## 3.8.2 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.

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

**Add Component**

 Subject of the Application: Components (2)

Name (short)	Type of Term	Origin	
<a href="#">Water</a>		ParamTerm	
<a href="#">RTY</a>	Chemical elements	Manual	

[View All](#)

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.

## 3.8.3 Note field and Other Components

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 New List ▾

ID  
EFSA-ID-2023-000899

**Details** Pre-application ID history Sharing history

Request Name  
TEST PAID INTEGRATION TESTS

Business Operator

**Note**  
Note...

Other components...

ID  
EFSA-ID-2023-000899

Contact Name  
Satya Nadella

Food Domain ⓘ  
Animal Welfare

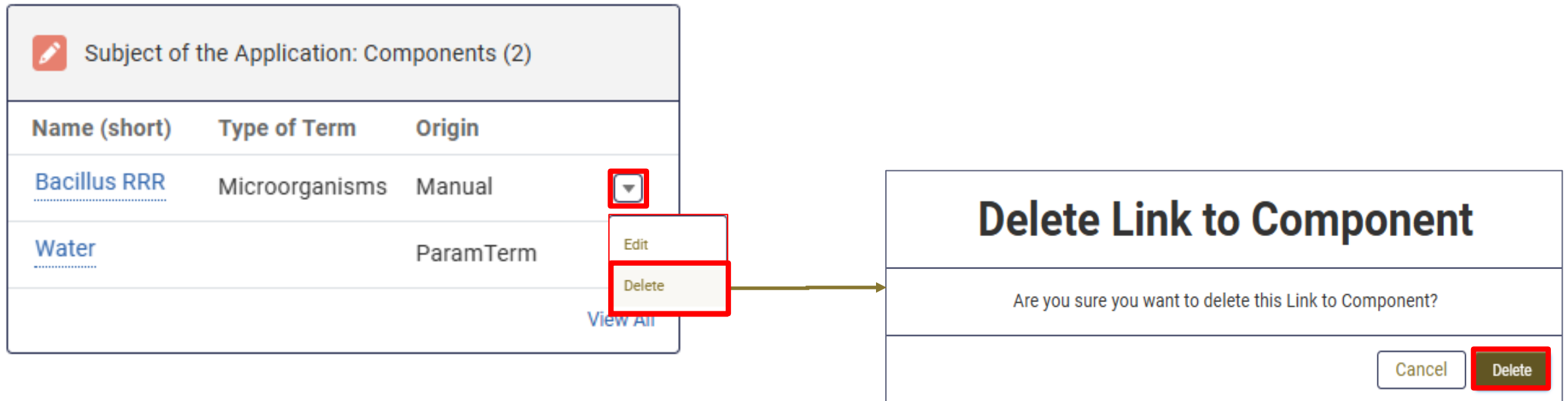
Authorisation Type

Application Type

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.

## 3.8.4 Delete link to components

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 contains "Bacillus RRR", "Microorganisms", and "Manual". The second row contains "Water", "ParamTerm", and "Manual". A dropdown menu is open for the "Bacillus RRR" row, showing "Edit" and "Delete" options. A red box highlights the "Delete" option, and an arrow points from it 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".

Name (short)	Type of Term	Origin
<a href="#">Bacillus RRR</a>	Microorganisms	Manual
<a href="#">Water</a>	ParamTerm	Manual

View All

### 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.

## 3.8.5 View Components


All Components created by the user are listed under the tab “**Components**” in the pre-application ID main page, and in the “My profile” page under “your organization information” section.

Pre-submission activities / Pre-application ID

In this page you can see the details of your pre-application ID, its related records and 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-
- 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 ID   Pre-submission advice   Intended studies   List of Intended Studies   **Components**

 My Components ▾

36 items • Sorted by Created Date • Filtered by All components - CreatedByMyAccount

	Name (short) ▾	Type of Term ▾	Common Names
1	test 12/09	Biogenic amines	
2	Bacillus RRR	Microorganisms	

### Your organisation information

 Account  
ABC Company

[+ Follow](#)   [New Contact](#)   [Manage Relationship](#)

English Name  
ABC Company

Parent Account  
[Luce Entertainment](#)

Related **My components**

**My Components** ▾

37 items • Sorted by Created Date • Filtered by All components - CreatedByMyAccount

	Name (s... ▾	Type of T... ▾	Common... ▾	Other Na... ▾	Create... ↓ ▾	
1	Lactobacillu...	Microorgani...			07/06/2024...	▾



## 3.8.6 Component details page

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.

Component **Bacillus RRR** Printable View Delete

Term Code      Term Status      Term Valid From  
Submitted

Information

Name <sup>1</sup>  
Bacillus RRR

Common Names

CAS <sup>1</sup>

EC Number <sup>1</sup>

Molecular Formula <sup>1</sup>

Zoo Label <sup>1</sup>

InChI <sup>1</sup>

Name (short)  
Bacillus RRR

Additional Information

Additional Information <sup>1</sup>

Type of Term <sup>1</sup>  
Microorganisms

Other Names

IUPAC <sup>1</sup>

Flavis Number <sup>1</sup>

Smiles Notation <sup>1</sup>

Level of Details <sup>1</sup>

Component History (1)

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

View All

PAIDs with this component (1)

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

View All

Studies with this component (1)

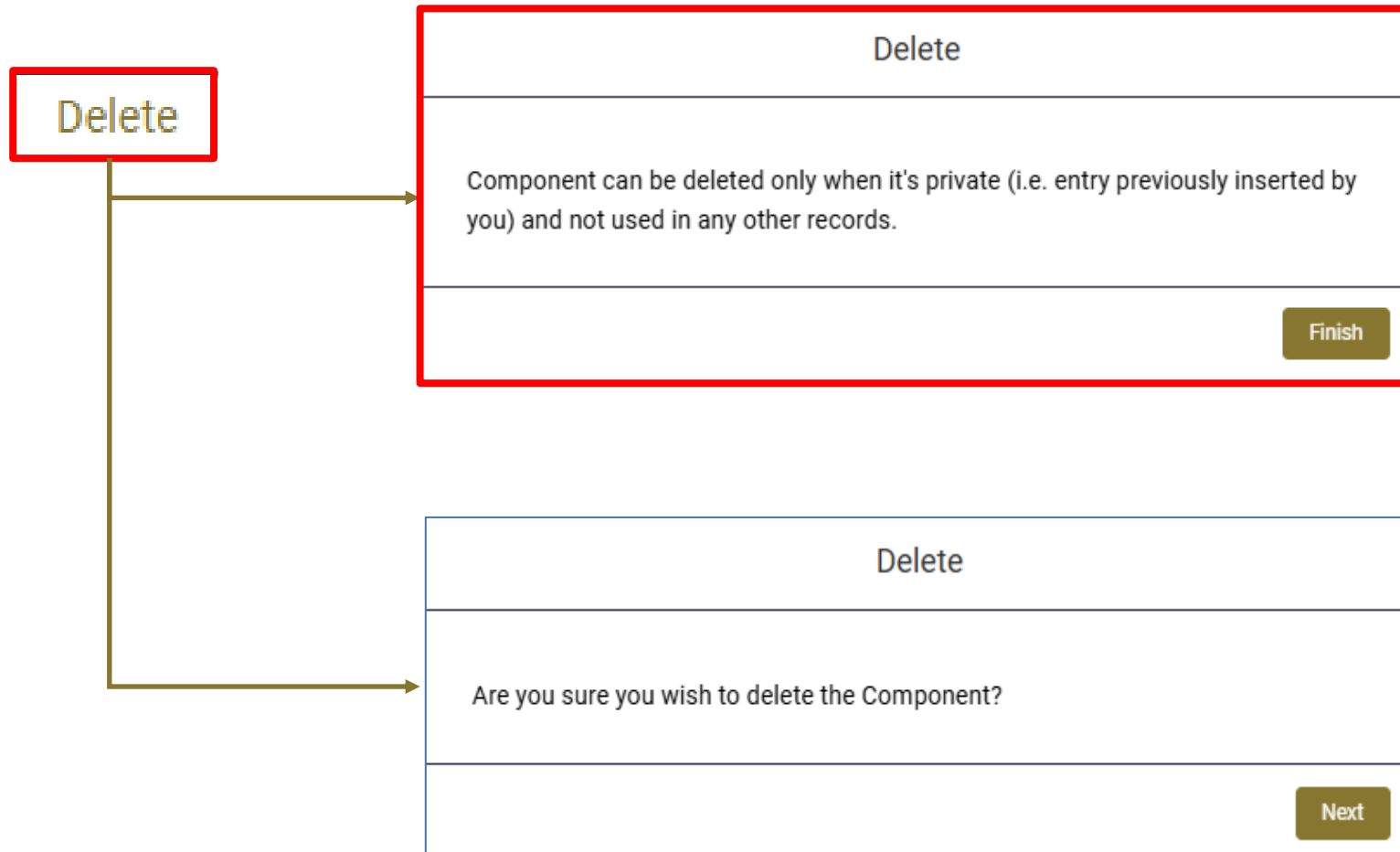
Study
Study RRR

View All

**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.

## 3.8.7 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.

# Account relationships and sharing options

#Connect.EFSA



# 3.9 Account relationship(s)

When a **business operator** wants to delegate a **third-party/consultant** to work on its behalf, a relationship “on behalf of” must be established at the account level from the **My profile** page under “**Your organization information**” section.

The screenshot shows the 'My profile' page. On the left is a navigation menu with 'My profile' highlighted. The main content area is titled 'Your organisation information' and shows account details for 'ABC Company', including its English name and parent account 'Luce Entertainment'. At the bottom right of this section are three buttons: '+ Follow', 'New Contact', and 'Manage Relationship'.

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.

The 'Related' tab is active, showing 'My components'. The first component is 'Contacts (6+)'. Below it is a table with the following structure:

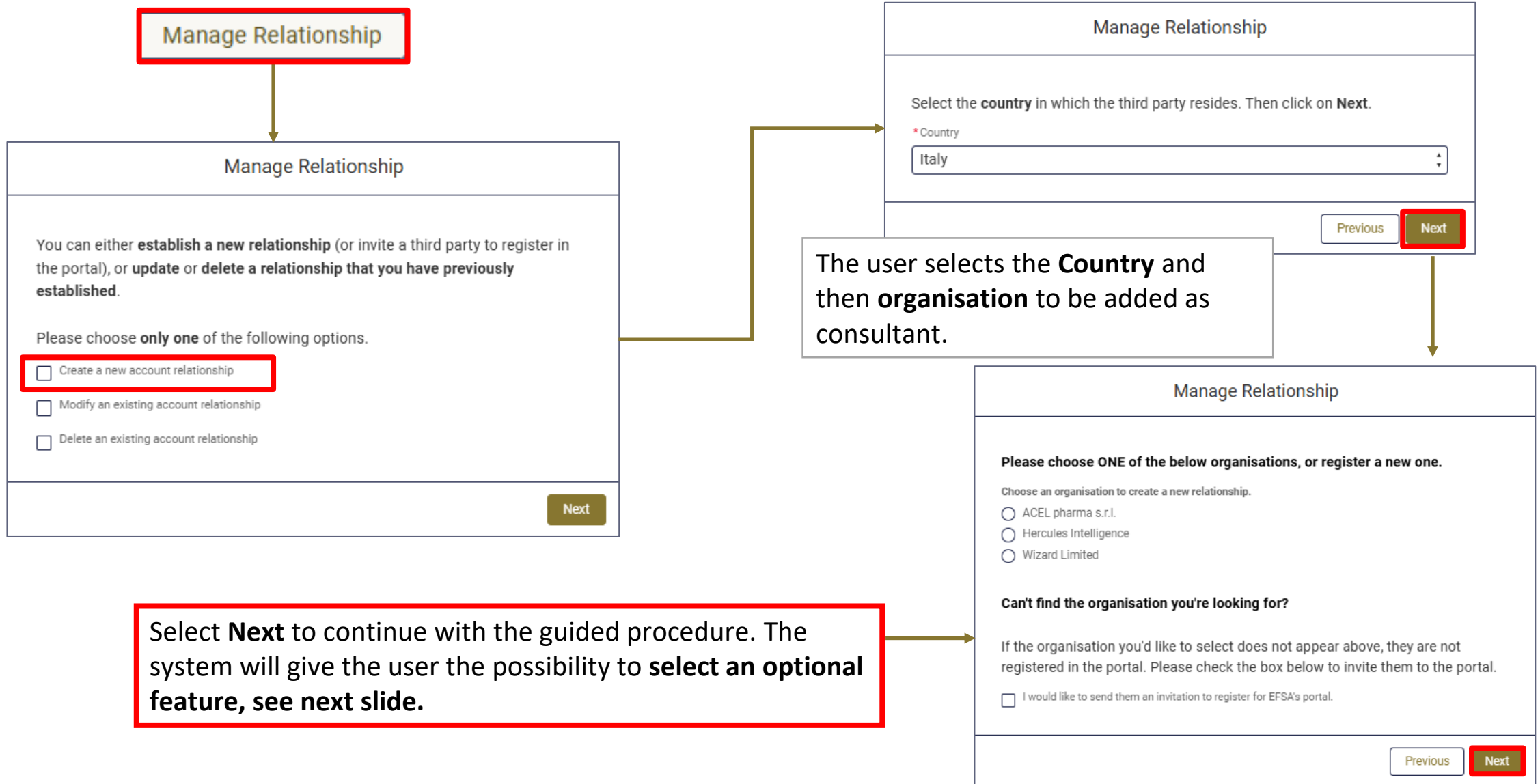
Contact Name	Email	Qualifications
--------------	-------	----------------

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

Two empty relationship lists are shown below the contacts section:

- Account Relationships: Account To (0)
- Account Relationships: Account From (0)

## 3.9.1 Create an account relationship



## 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 [Modify account relationship\(s\)](#) to know more details).

The image shows 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 three radio button options: "ACEL pharma s.r.l.", "Hercules Intelligence", and "Wizard Limited" (which is selected). Below this, it asks "Can't find the organisation you're looking for?" and provides a checkbox for "I would like to send them an invitation to register for EFSA's portal." At the bottom right, there are "Previous" and "Next" buttons. The "Next" button is highlighted with a red box.

**Right Screenshot:** This is the next step in the process. A large red-bordered box contains 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." It then lists two conditions: "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, it states: "By leaving the box unchecked you will establish only 'On behalf of ' relationship." At the bottom, there is a checkbox for "I want to enable this organisation to act as notifier and co-notifier." and "Previous" and "Next" buttons. The checkbox and the "Next" button are highlighted with red boxes.

Arrows indicate the flow from the "Next" button in the first screenshot to the checkbox in the second screenshot, and from the "Next" button in the second screenshot to the explanatory text box below.

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](#)

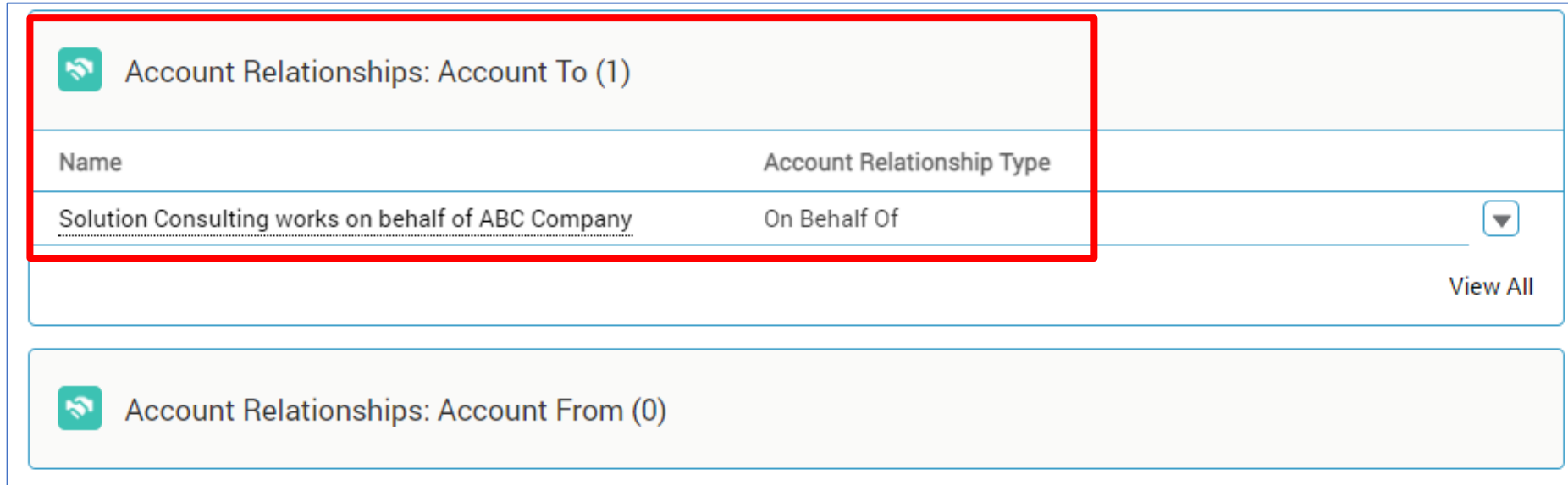
### How it works:

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.



The screenshot shows a user interface for managing account relationships. It features two main sections: 'Account Relationships: Account To (1)' and 'Account Relationships: Account From (0)'. The 'Account To' section is highlighted with a red border and contains a table with the following data:

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

Below the table, there is a 'View All' link and a dropdown arrow icon.

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**

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

John Smith

Email

you@example.com

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

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

**Manage Relationship**

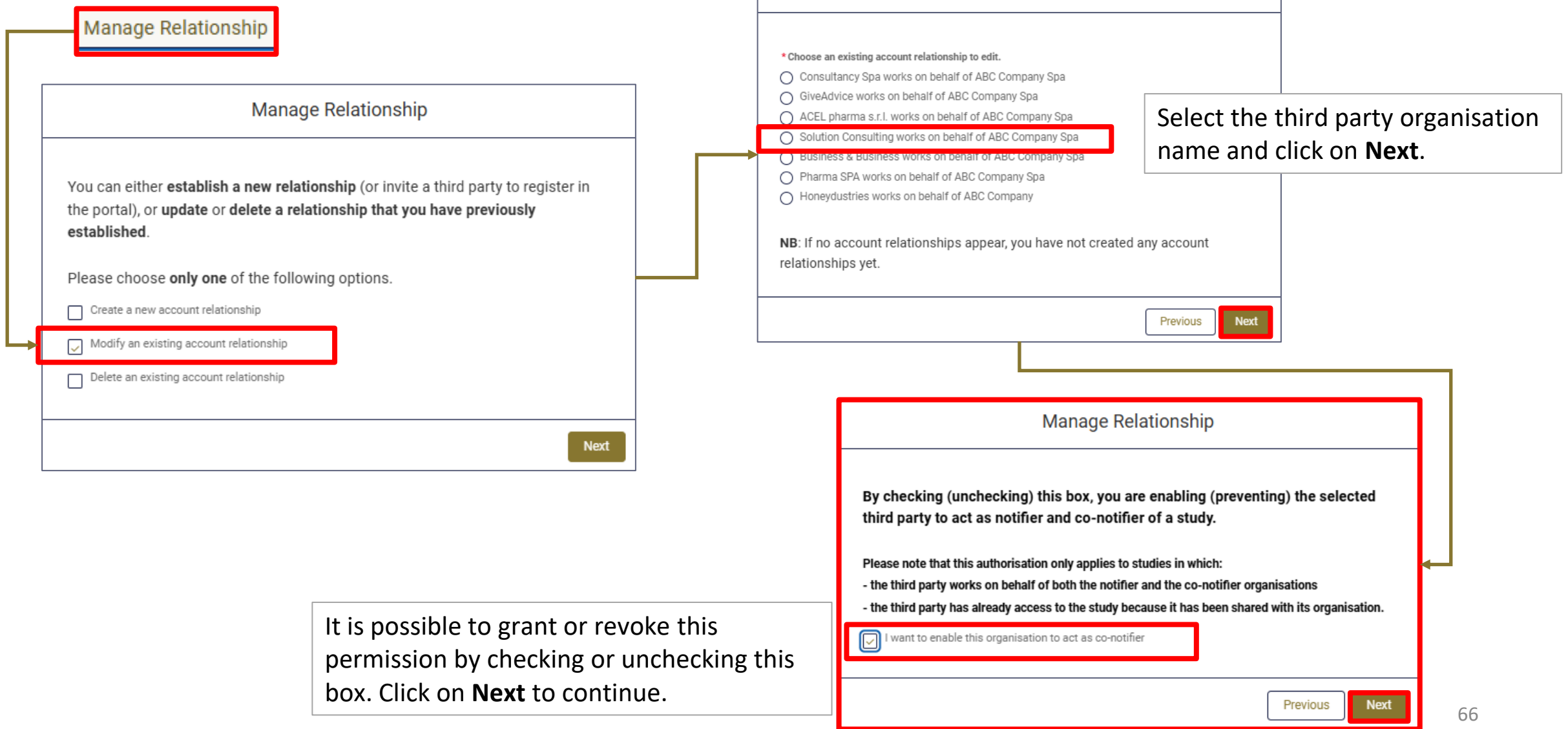
**Success!** You have sent the organisation an invitation to register for EFSA's portal.

**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](#)

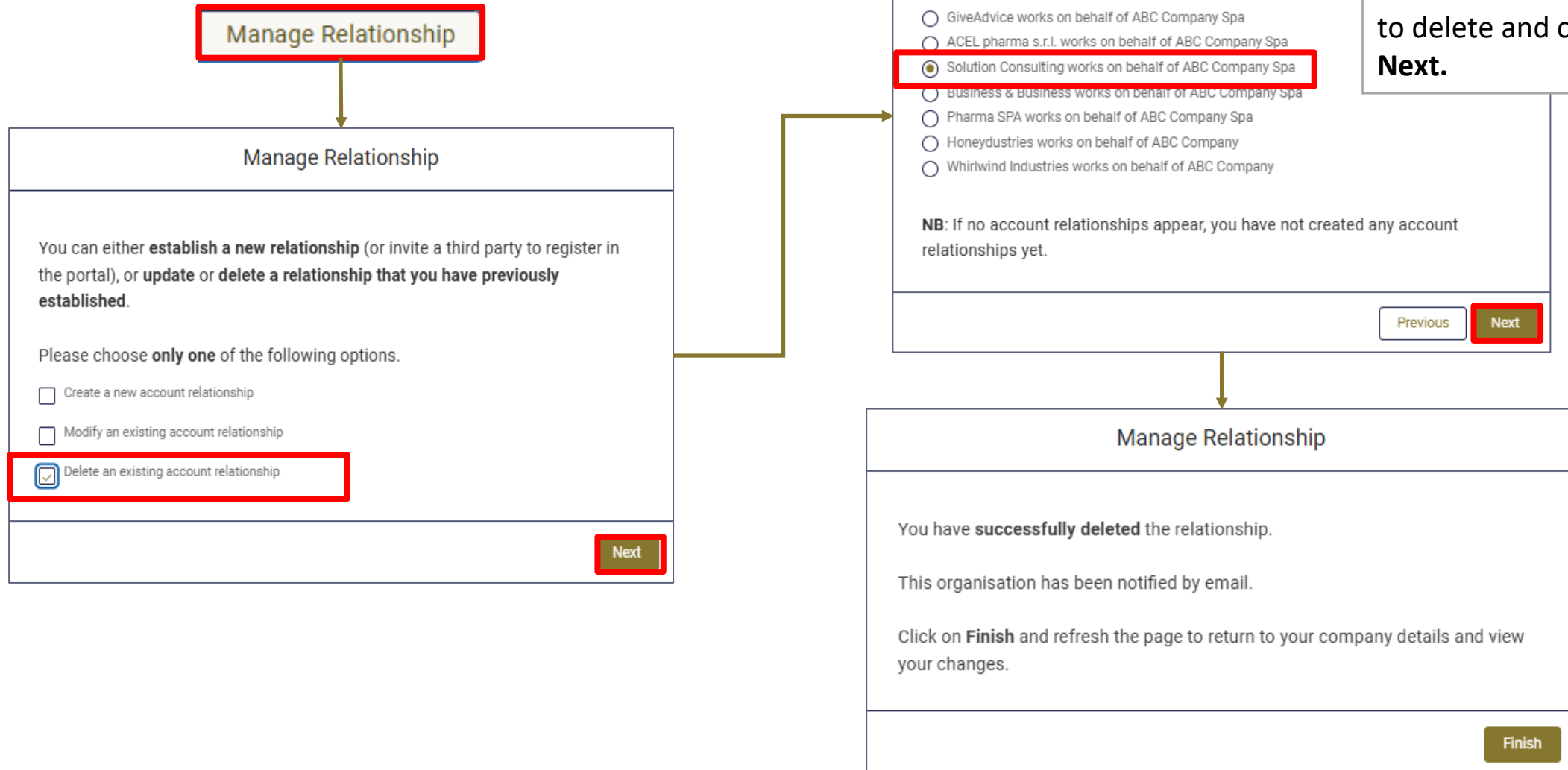
### 3.9.3 Modify an account relationship

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.



## 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 “**Sharing options**”.

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

- **“On behalf of” permissions:** the user allows **third parties/consultants** to **view/edit** only the pre-application ID or the pre-application ID along with some/all the study records already linked to it. An **account relationship “on behalf of”** with the chosen **third parties/consultants** is required in advance (see [Account Relationship](#)). This type of sharing can be revoked at any time.
- **“Read-only” permissions:** 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. “Read-only” permissions can be revoked if no submitted study notification(s), GPSA request(s) or list of intended studies are associated with the pre-application ID.

Pre-submission activities / Pre-application ID / Pre-application ID

Pre-Application ID  
Pre-application ID ABCD

ID  
EFSA-ID-2024-002313

Click here to see more function buttons.

Renamed!

“Sharing options” button.

Edit New Study Add Studies

Ask GPSA  
Sharing options  
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 **Sharing options** 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)

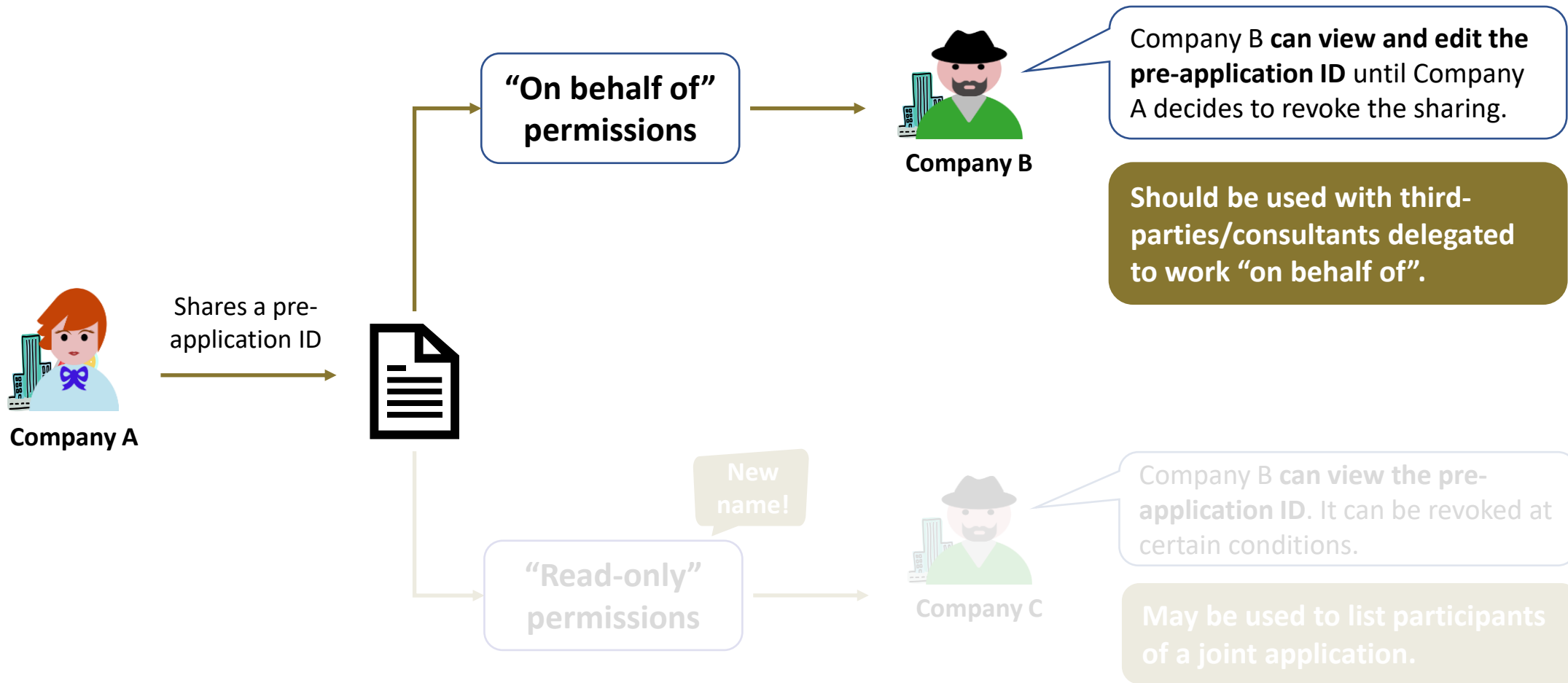
**Details** Pre-application ID history Sharing history

Request Name	ID
Pre-application ID ABCD	EFSA-ID-2024-002313
Business Operator	Contact Name
<a href="#">Federico Business Operator</a>	<a href="#">Federico Applicant</a>

Details

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

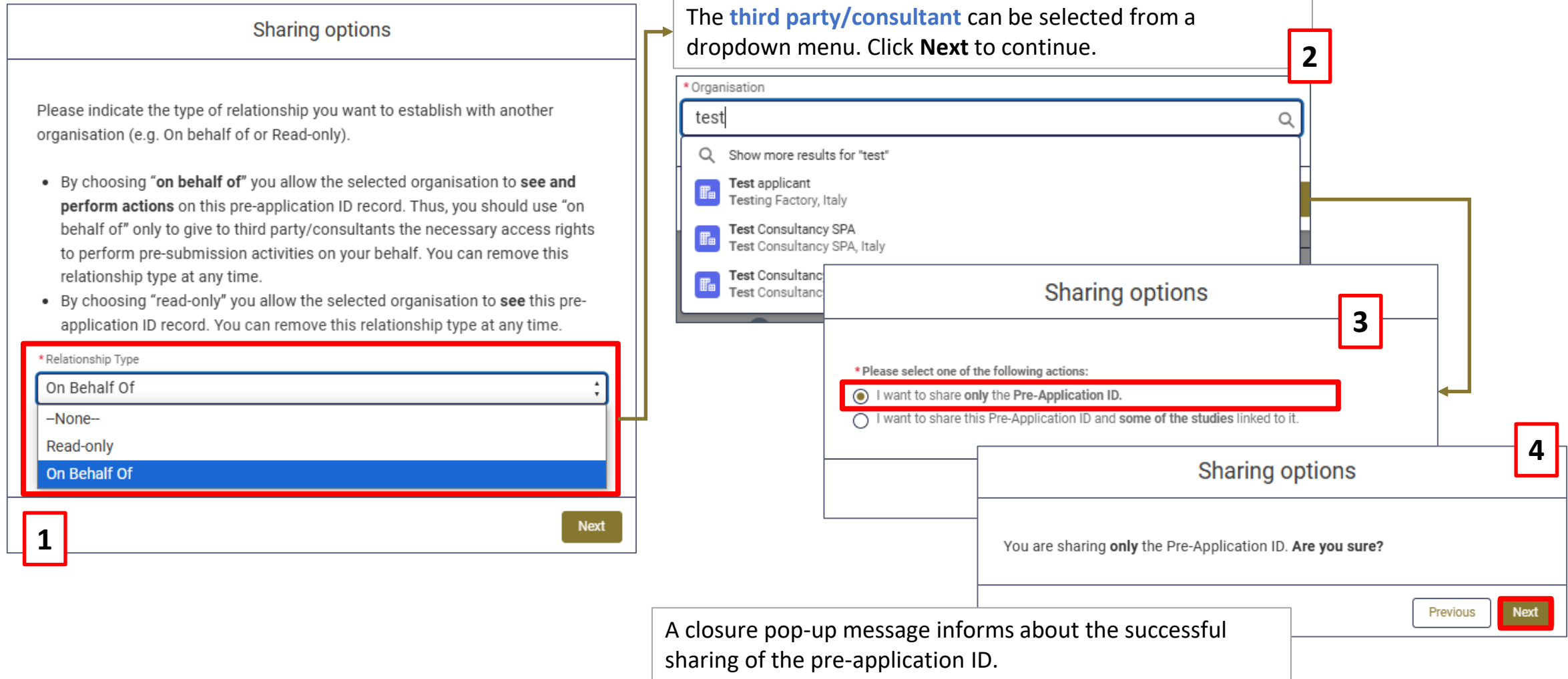
New!



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

Updated!

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".

**1**

Sharing options

\* 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**

Click **Next** to continue.

**2**

Sharing options

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 Identific... ▾	Study Title
<input type="checkbox"/> EFSA-2024-00029429	Study one
<input type="checkbox"/> EFSA-2024-00029416	Study two
<input type="checkbox"/> EFSA-2024-00029415	Study three

Previous **Next**

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

**3**

Sharing options

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: **2 studies**.

- EFSA-2024-00029429 - Wrong co-notifier study;
- EFSA-2024-00029416 - Study for testsdddd;

Previous **Next**

**4**

Sharing options

You have successfully shared this Pre-Application ID with another organisation. You can view your changes in the "Sharing options" and "Sharing history" related lists 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 "Sharing options" 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.

### 3.10.1c Share a pre-application ID “On behalf of” – error message

Updated!

Edit New Study Add Studies ▾

Ask GPSA

Sharing options

Delete

Printable View

Sharing options

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

- By choosing “on behalf of” you allow the selected organisation to **see and perform actions** on this pre-application ID record. Thus, you should use “on behalf of” only to give to third party/consultants the necessary access rights to perform pre-submission activities on your behalf. You can remove this relationship type at any time.
- By choosing “read-only” you allow the selected organisation to **see** this pre-application ID record. You can remove this relationship type at any time.

\* Relationship Type

On Behalf Of

–None–

Read-only

On Behalf Of

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”.

Sharing options

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 '**Read-only**' (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 profile** in the navigation menu, click the button **Manage Relationship** and follow the instruction

Finish



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

Updated!

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

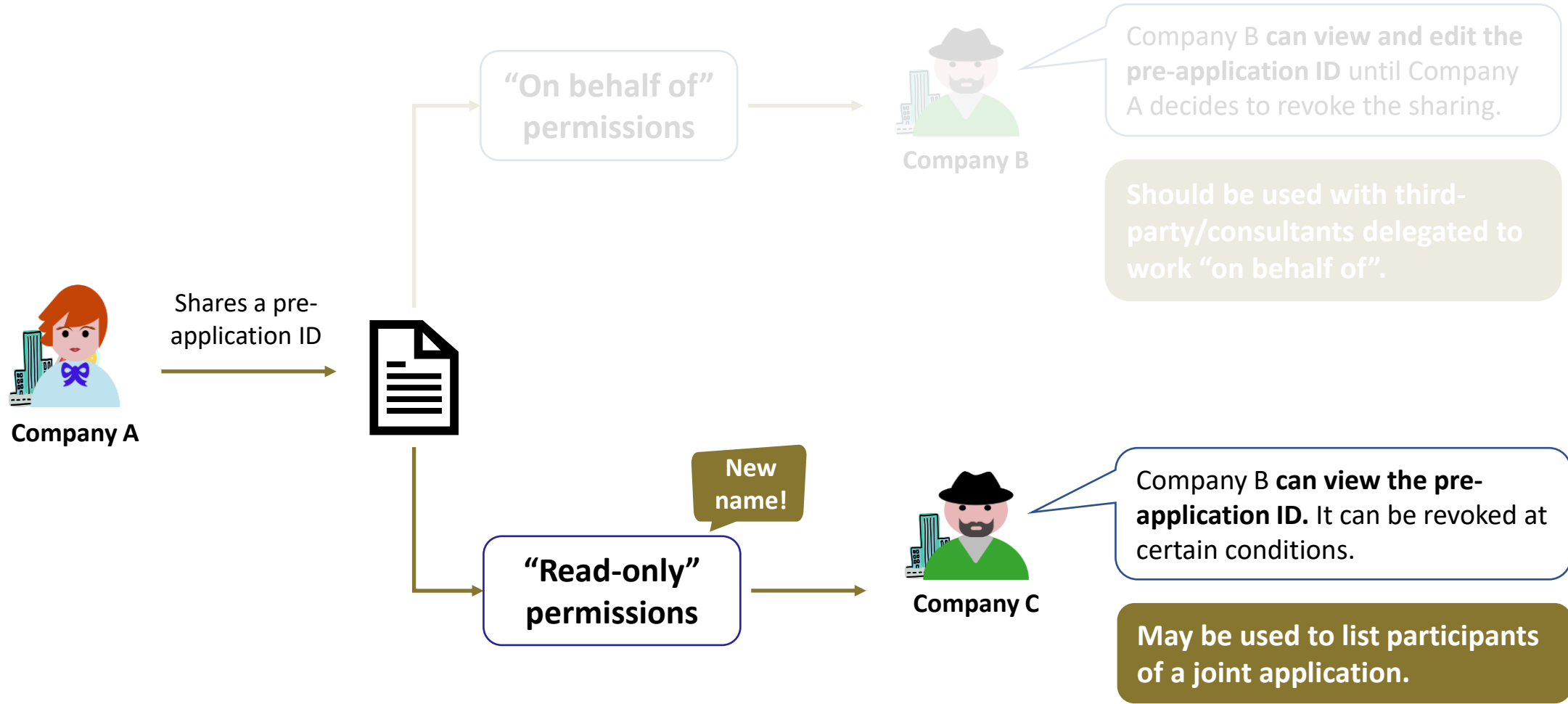
1. View and edit the pre-application ID information\*
2. Create new studies or add already existing studies to the pre-application ID
3. View and edit the studies that have been shared with the pre-application ID\*\*
4. Create, edit and submit a list of intended studies (for renewals only)
5. Manage 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 – “Read-only” - overview

New!



# 3.10.2a Share a pre-application ID “Read-only” - creation

Updated!

Edit New Study Add Studies

Ask GPSA  
Sharing options

**1** Sharing options

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

- By choosing “on behalf of” you allow the selected organisation to **see and perform actions** on this pre-application ID record. Thus, you should use “on behalf of” only to give to third party/consultants the necessary access rights to perform pre-submission activities on your behalf. You can remove this relationship type at any time.
- By choosing “read-only” you allow the selected organisation to **see** this pre-application ID record. You can remove this relationship type at any time.

\* Relationship Type

--None--

--None--

Read-only

The user chooses the relationship type “Read only” to enable another organisation to **only view** the pre-application ID information.

**2** \* Organisation

Test

Show more results for "Test"

Test applicant  
Testing Factory, Italy

The user searches and selects the organisation name to share the pre-application ID with and clicks **Next**.

**3** Sharing options

You have successfully shared this Pre-Application ID with another organisation. You can view your changes in the “Sharing options” and “Sharing history” related lists 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 organisation is added to the related list **Sharing options**, in the pre-application ID page.

## 3.10.2b Share a pre-application ID “Read-only” - summary

Updated!

Actions allowed to **business operator** or a **third party/consultant** for a pre-application ID shared granting “Read-only” permissions:

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.

# 3.10.3 Share a pre-application ID – Sharing history

Pre-Application ID  
Pre-application ID ABCD

Edit   New Study   Add Studies ▼

ID  
EFSA-ID-2024-002313

Details   Pre-application ID history   **Sharing history**

New name!   New!

The **Sharing history** section displays information about:

- The name of the **organisation** receiving the sharing.
- The **relationship type** (“on behalf of” or “read only”).
- The **status** of the sharing.
- The name of the user that made the **last modification**.

Details   Pre-application ID history   **Sharing history**

Sharing History (4)  
4 items • Sorted by Date • Updated a few seconds ago

	Date ↓	Organisation	Relations...	Status	Created Date	Last Modified...	
1	25/11/2024 17:...	Test applicant	Read-only	Created	25/11/2024 17:...	Federico Applic...	▼
2	25/11/2024 16:...	Tomas Consulta...	On behalf of	Revoked	25/11/2024 16:...	Federico Applic...	▼

## 3.10.4 Delete sharing permissions

Pre-Application ID  
Pre-application ID test sharing options

Edit New Study Add Studies

ID  
EFSA-ID-2024-002315

Details Pre-application ID history Sharing history

Request Name Pre-application ID test sharing options	ID EFSA-ID-2024-002315
Business Operator <a href="#">FRC Business Operator</a>	Contact Name <a href="#">FRC Applicant</a>

Details

Subject Of The Application Pre-application ID test sharing options	Food Domain Nutrition
Note	Authorisation Type Health Claims
	Application Type Application for the authorisation of a new health claim

Creation Details

Created Date	Created By <a href="#">Federico Applicant</a> , 06/12/2024 14.18
--------------	---

**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 **Sharing options** 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 (0)

Pre-Submission Advice (0)

Sharing Options (2)

Account Name	Relationship Type
<a href="#">TMS Consultancy</a>	Read-only
<a href="#">Test Consultancy SPA</a>	On Behalf Of

Edit  
Delete

**Sharing permission must be revoked to delete a pre-application ID.**

- “On behalf of” permissions can be always revoked.
- “Read-only” permissions can be revoked if no submitted study notification(s), GPSA request(s) or list of intended studies are associated with the pre-application ID.

The user clicks **Delete** to remove the sharing permission.

# General pre-submission advice

#Connect.EFSA



# 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-submission activities / Pre-application ID / Pre-application ID detail page

**Pre-Application ID**  
New application for FGH

ID  
EFSA-ID-2024-000951

**Details** History

Request Name	ID
New application for FGH	EFSA-ID-2024-000951
Business Operator	Contact Name
<a href="#">ABC Company</a>	<a href="#">Betty Cook</a>

Details

Subject Of The Application	Food Domain
New application for FGH	Novel Foods
Note	Authorisation Type

**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**

**Pre-Submission Advice (1)**

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

View All

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

Suggested tutorial: [How to request a GPSA in three simple steps](#)



# 3.11.1 Request a GPSA

Edit New Study Add Studies

Ask GPSA

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

Ask GPSA

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

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

Pre-Submission Advice (1)

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

View All

**Suggested read:** Q.10 and Q.11 of the [Questions and Answers on the EFSA Practical Arrangements](#)

# 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 user interface for a GPSA request. At the top, a horizontal progress bar shows four stages: **Draft** (highlighted in blue), Submitted, In Progress, and Closed. Below the progress bar, a toolbar contains three buttons: **Submit**, **View Meeting Timeslots**, and **Printable View**. To the left, the request title is "Request New application for FGH" with a status of "Draft" and a request number of "00002847". Below this, there are tabs for "Details" and "History". The "Details" section is expanded to show "Request Information" with fields for Request Number (00002847), Account Name (ABC Company), Fast-tracked GPSA (unchecked), and Contact Name (Betty Cook). On the right side, there is a "Pre-Submission Advice Guidance" box with text explaining the draft status and a "Submit" button. Below this are two summary boxes: "Open Activities (0)" and "Request Team (0)", with the latter including dropdowns for "Member State Organisat..." and "Member State Country".

**Pre-Submission Advice Guidance**  
Your Pre-Submission Advice request has been saved as a **draft**. When you are ready to submit it to EFSA, please click on the **Submit** button.

This section shows additional information on the GPSA request.

# 3.11.1 Request a GPSA

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

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).

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.

Submit View Meeting Timeslots Printable View ▾

Delete

Delete

Are you sure you wish to delete the Pre-Submission Advice request?

Next

The user is redirected to the pre-application ID page.

Delete

Pre-Submission Advice can be deleted only when its Status is Draft.

Finish

# 3.11.3 Submission of a request for GPSA

When the information required by the GPSA form are complete the user clicks **Submit** and follows the procedure.

The image shows a two-step process for submitting a GPSA request. The first step shows a 'Draft' status with a 'Submit' button highlighted in red. The second step shows the 'Submitted' status with a 'Next' button highlighted in red. A callout box states: 'The status of the GPSA changes to Submitted'.

**Step 1: Draft Status**

Request: New application for FGH  
Status: Draft  
Request Number: 00002869

**PSA Details (highlighted in red):**

Request Number: 00002869	Account Name: <a href="#">ABC Company</a>
Fast-tracked GPSA: <input type="checkbox"/>	Contact Name: <a href="#">Betty Cook</a>
Subject: New application for FGH	Food Domain: Novel Foods
List of Questions: 1	Authorisation Type: Novel Food Application
Question 1	
Question 2	
Question 3	
Question n	
Background Information on the Subject: 1	Application Type: New Novel Food
Lorem ipsum dolor sit amet, consectetur adipiscing elit. Donec consectetur porttitor mi, non rhoncus risus blandit sed. Nunc accumsan nec lectus sit amet elementum. Aliquam consectetur lectus eget quam semper condimentum.	
Conditions of use/Intended uses	Test Item: New application for FGH
Lorem ipsum dolor sit amet, consectetur adipiscing elit. Donec consectetur porttitor mi, non rhoncus risus blandit sed. Nunc accumsan nec lectus sit amet elementum. Aliquam consectetur lectus eget quam semper condimentum.	

**Step 2: Submitted Status**

Submit  
To submit this *general pre-submission advice* to EFSA, please click on **Next**.

**Next**

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 of the GPSA changes to Submitted

**Final Submitted Status**

Status: Submitted  
Request Number: 00002869

## 3.11.4 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.

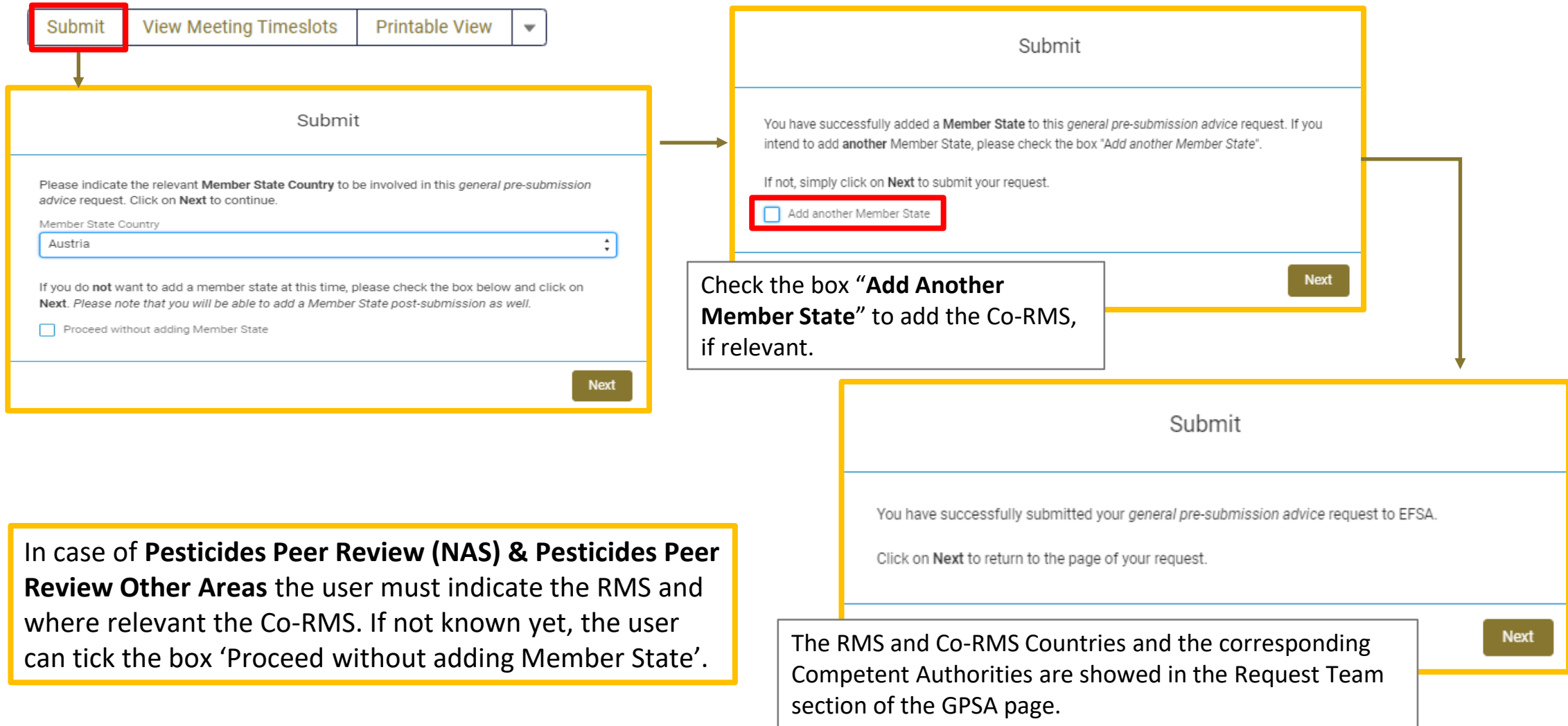
Member State Country  
Austria ▼

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

Next

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

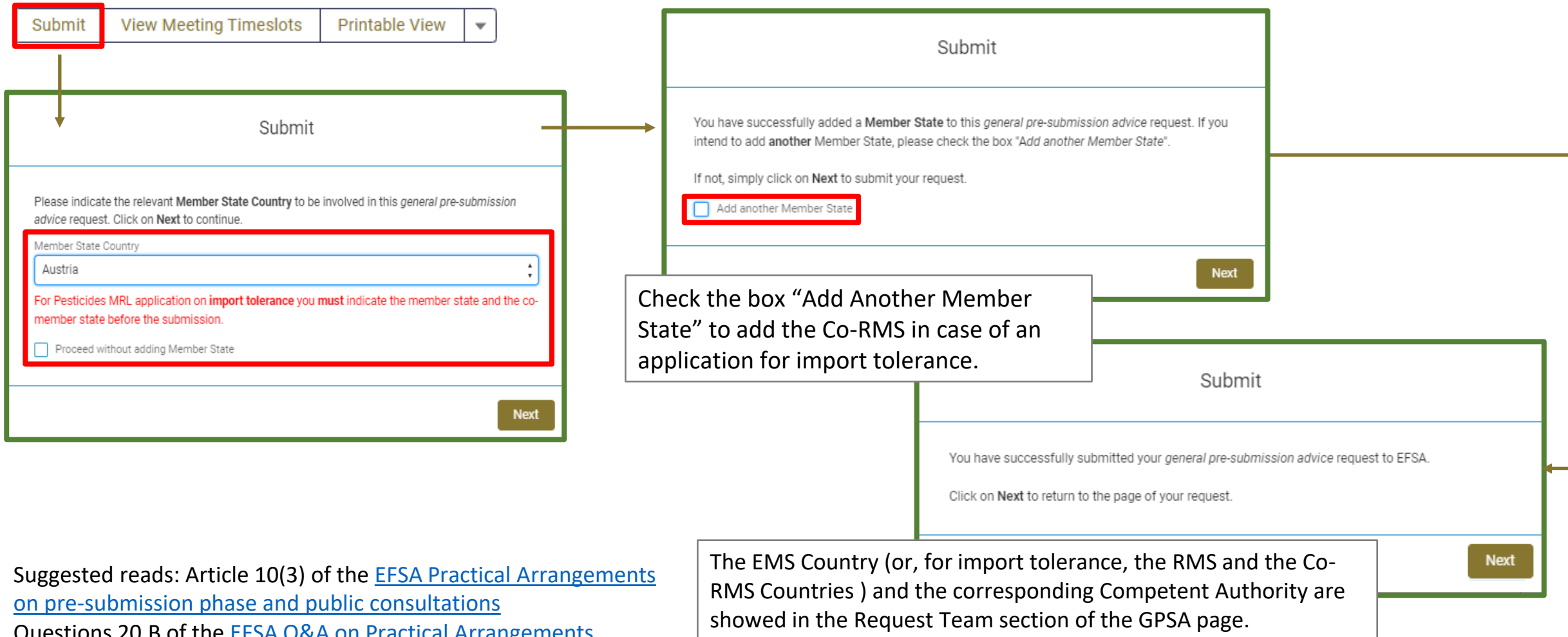
### 3.11.4.1 Submission of a request for GPSA – Pesticides Peer Review (NAS) & Other Areas



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'.

## 3.11.4.2 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](#).

The EMS Country (or, for import tolerance, the RMS and the Co-RMS Countries ) and the corresponding Competent Authority are showed in the Request Team section of the GPSA page.



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

**Submit** View Meeting Timeslots Printable View

**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

**Next**

**Submit**

You have successfully added a **Member State** to this *general pre-submission advice* request. If you intend to add **another** Member State, please check the box "Add another Member State".

If not, simply click on **Next** to submit your request.

Add another Member State

**Next**

Check the box "Add Another Member State" to add the Co-RMS.

**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  
Italy

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

**Previous** **Next**

**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**

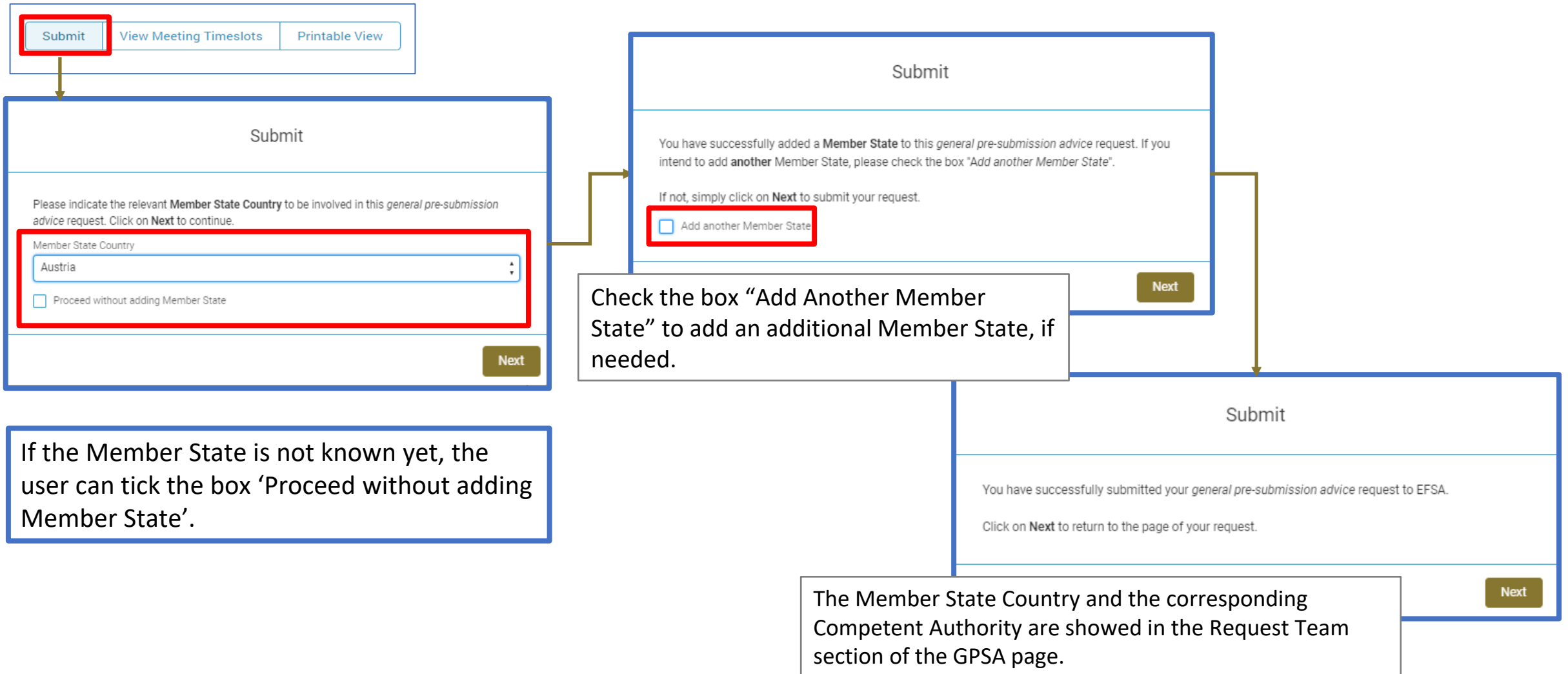
The RMS and Co-RMS Countries and the corresponding Competent Authorities are showed in the Request Team section of the GPSA page.

In case of Pesticides Peer Review (AIR), the information on **RMS and co-RMS is mandatory.**

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](#).

## 3.11.5 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.



# 3.11.6 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.



Request Subject 68225618

Submit View Meeting Timeslots Printable View

Status Submitted Request Number 00001501

### 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.

Open Activities (0)

Details History

### Request Information

Request Number	00001501	Account Name	<a href="#">ABC Company</a>
Fast-tracked GPSA	<input type="checkbox"/>	Contact Name	<a href="#">Scott Lopez</a>

Request Team (0)

Member State Organisat... Member State Country

# 3.11.7 Acceptance of a GPSA request by EFSA

Updated!

Following the EFSA’s acceptance the status of the GPSA turns to “In Progress”. If EFSA decides to provide the advice in a telemeeting, an email alert with the invitation to accept the proposed timeslot(s) is sent to **email address indicated for pre-submission activities** (more details in **Section 5.2 of the [registration user manual](#)**).

The screenshot displays the EFSA GPSA request management interface. At the top, a progress bar shows four stages: Draft, Submitted, In Progress (highlighted with a red box), and Closed. Below this, the request details for 'Request ABCD' are shown, with the status 'In Progress' and 'Request Number 00013045'. A callout box points to the 'View Meeting Timeslots' button, stating: 'The user clicks this button to see and accept the timeslot(s) proposed for the telemeeting.' To the right, a 'Pre-Submission Advice Guidance' box provides instructions: 'Your request is now being processed by EFSA and a meeting needs to be organized. Please click on **View Meeting Timeslots** to accept an available meeting timeslot or to propose an alternative.' Below the guidance, there is a section for 'Open Activities (1)' with a table listing one activity: 'PSA Me...' by 'FRC user' with a due date of '27/11/20...'. At the bottom right, a 'Request Team (0)' section is visible with dropdown menus for 'Member State Organisa...' and 'Member State Country'.

**Request ABCD**

Status: In Progress      Request Number: 00013045

Buttons: Submit, **View Meeting Timeslots**, Printable View

**Pre-Submission Advice Guidance**

Your request is now being processed by EFSA and a meeting needs to be organized. Please click on **View Meeting Timeslots** to accept an available meeting timeslot or to propose an alternative.

Subject	Name	Task	Due Date
PSA Me...	FRC user	<input type="checkbox"/>	27/11/20... <span>▼</span>

[View All](#)

**Request Team (0)**

Member State Organisa... ▼      Member State Country ▼

# 3.11.8 Receiving the reply to a GPSA request

Updated!

The user sees the record in Closed status.

The screenshot shows a navigation bar with four status options: Draft, Submitted, In Progress, and Closed. The 'Closed' option is highlighted with a red box. Below the navigation bar, the request details are displayed. The request is titled 'Request Subject 01895253' and has a status of 'Closed' with a request number of '00001541'. The subject is 'PSA on Protein XYZ'. There are buttons for 'View Meeting Timeslots', 'Add Member State', and 'Printable View'. A 'Pre-Submission Advice Guidance' box states: 'Your Pre-Submission Advice request is now closed and can no longer be modified.' There are also sections for 'Open Activities (0)' and 'Request Team (0)'. The 'Request Information' section shows the request number '00001541', account name 'ABC Company', and 'Fast-tracked GPSA'.

**If the advice is provided in written, the user finds the outcome under “Written Advice”.** No written version is made available by EFSA for an advice provided in a telemeeting.

A succinct summary or the advice, **not containing confidential information**, is always provided.

## 3.11.8 Limit number of GPSA requests

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

The screenshot shows a web interface with a navigation bar containing 'Edit', 'New Study', and 'Add Studies' buttons. A dropdown menu is open under 'Add Studies', with 'Ask GPSA' highlighted in a red box. A yellow arrow points from 'Ask GPSA' to a form titled 'Ask PSA'. The form contains a red error message: 'You cannot request more than 2 Pre-Submission Advice per Pre-Application ID.' and a 'Finish' button.

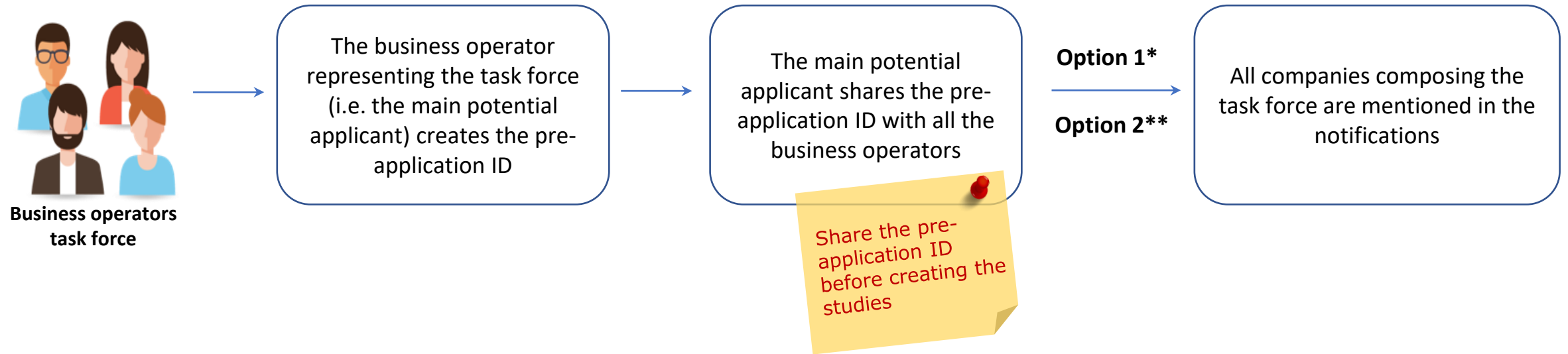
When the user tries to submit more than two GPSA requests for the same pre-application ID, the system returns an **error message**.

# **Joint pre-submission activities (task force)**



# 4 Task force scenario – no third party/consultant involved

Updated!



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 "Read-only" permissions: 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.

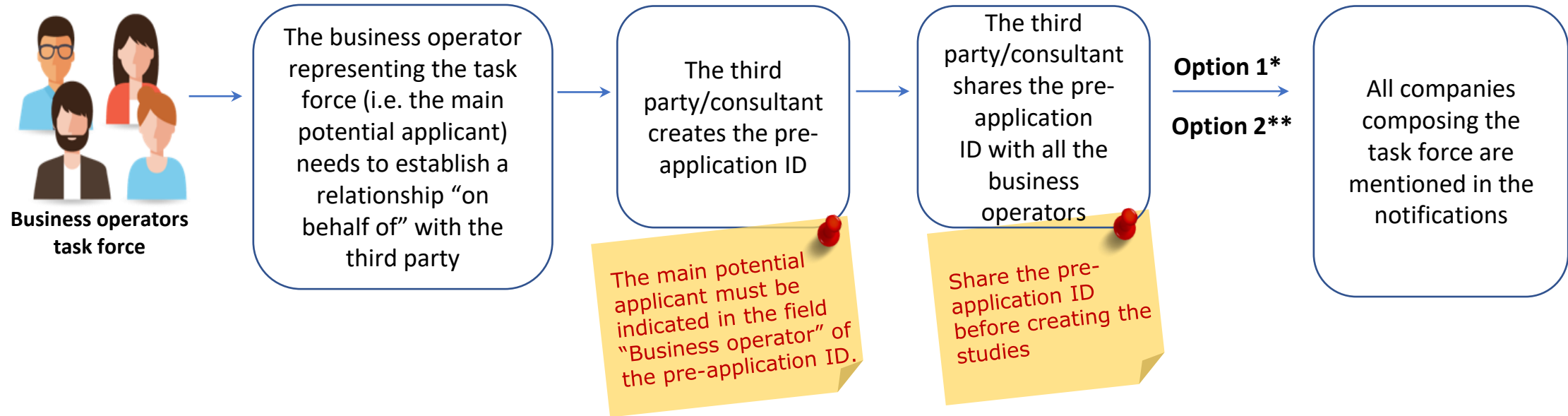
\*\*Option 2 – Pre-application ID shared with "On behalf of" permissions: **when creating the notification** (and **only** at that stage), the Business Operator may be changed to reflect the actual organisation in the task force commissioning the study/ies, as showed in [Section 3.2](#). To do so, the 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.



# 4.1 Task force scenario – with a third party/consultant involved

Updated!



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 “Read-only” permissions: 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 “On behalf of” permissions: **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.

## 4.2 Highlights of the task force scenario

Updated!

- 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 first establish an account relationship “on behalf of” with this organisation.
- The pre-application ID may be shared with “On behalf of” or “Read-only” permissions with the other companies composing the task force. The rules explained in Sections [3.10.1](#) and [3.10.2](#) apply.
- 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.

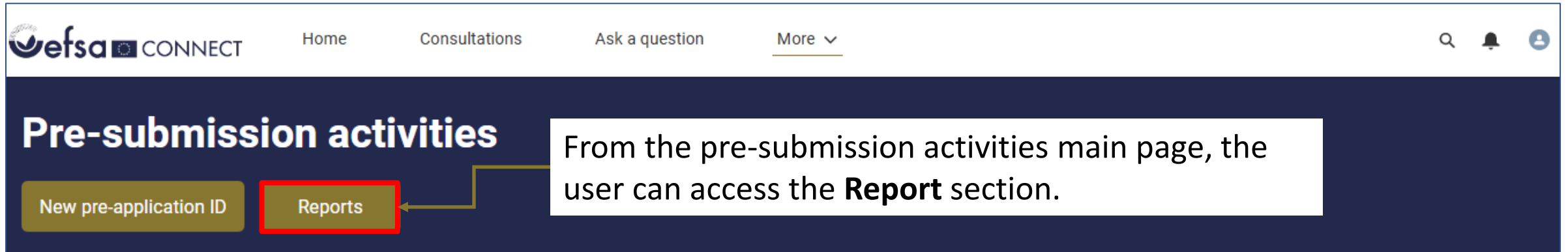


# Reporting features

#Connect.EFSA



## 5. Reporting features



The screenshot shows the EFSA CONNECT portal interface. At the top, there is a navigation bar with the EFSA logo and 'CONNECT' text, followed by links for 'Home', 'Consultations', 'Ask a question', and 'More'. On the right side of the navigation bar are icons for search, notifications, and user profile. Below the navigation bar, the main content area has a dark blue background with the heading 'Pre-submission activities'. Under this heading, there are two buttons: 'New pre-application ID' and 'Reports'. The 'Reports' button is highlighted with a red border. A white callout box with a black border is positioned to the right of the 'Reports' button, containing the text: 'From the pre-submission activities main page, the user can access the **Report** section.' A yellow line connects the callout box to the 'Reports' button.

### 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 form the REPORTS (All Reports) view, or from the FOLDERS (All Folders) view.

From every page, users can identify where they are within the portal through this bar.

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

Click on the report name to access it.

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

Home / Reports

Reports  
All Reports  
13 items

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	
Created by Me	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	
Shared with Me						
FAVORITES						
All Favorites						

## 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. A search bar is located in the top right corner. A red box highlights the folder name 'Records owned by my organisation' in the table, and a callout box with an arrow pointing to it contains 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	Study Types and Study Guidelines		12/10/2022, 14:18		1/2/2023, 20:18
All Reports					

FOLDERS

- All Folders
- Created by Me
- Shared with Me

FAVORITES

- All Favorites

Click on the folder name to access it.

## 5.3 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					

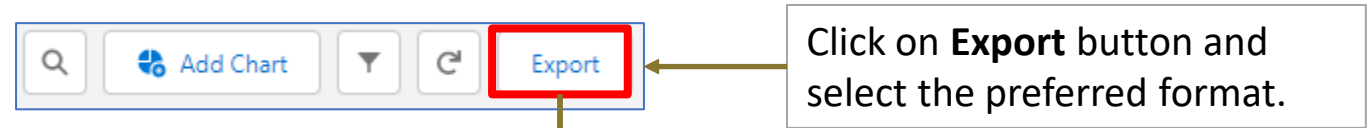
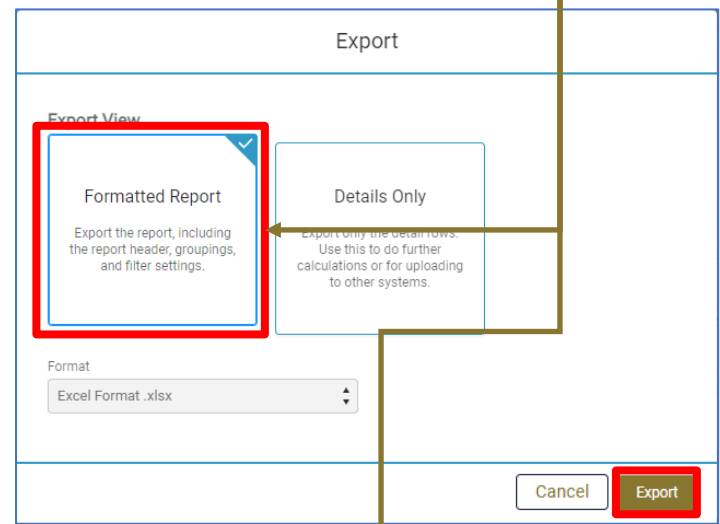
The toolbar contains the following buttons: Search, Add Chart, Filter, Refresh, and Export.

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

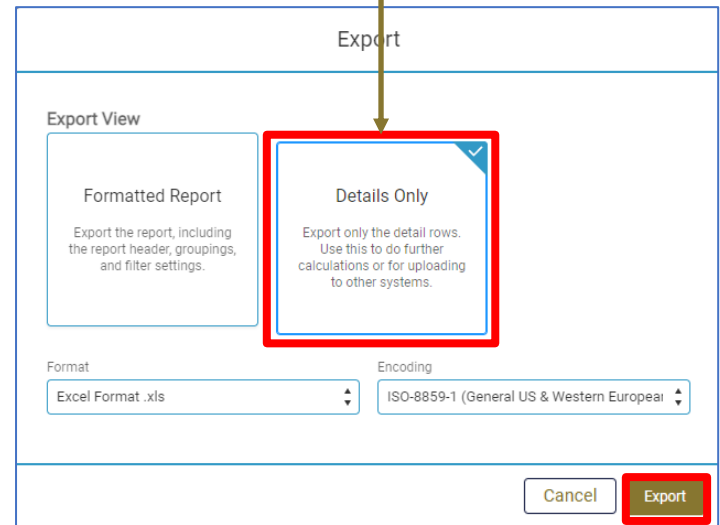
The user can:

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

# 5.4 Reporting features – Export a report

**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.



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

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	Filtered By		
4	Show: All pre-application ids		
5	Shared with other organisations equals False		
6	EFSA Study Identification ↑		
7	EFSA-2021-00000522		Study Title
8	Subtotal		Sum
9			Count
10			1
11	EFSA-2021-00000523		Test 2 - test lab
12	Subtotal		Sum
13			Count
14			1
15	EFSA-2021-00000543		test relationship
16	Subtotal		Sum
17			Count
18			1
19	EFSA-2021-00000545		test internal testing facility

	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



## 5.5 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.

The image shows two screenshots from a software interface. The left screenshot shows a 'Filters' panel with a dropdown menu open, highlighting 'All pre-application ids'. A red box highlights the 'Filters' icon in the top navigation bar. A callout box with an arrow pointing to the icon contains the text: 'Click on the Filters icon and select the filter to apply.' The right screenshot shows an 'Edit Filter' dialog box. The 'Show Me' dropdown is set to 'All pre-application ids', and a list of filter options is shown below it, with 'All pre-application ids' selected and checked. A red box highlights this list. To the right of the dialog is a 'Filters' sidebar with a red box highlighting the 'Show Me All pre-application ids' filter.

Some filters will allow to restrict the view to records on the basis of their **creation date**, while others allow to view only the records **shared with the user's organisation**.

The image shows two screenshots. The left screenshot shows a 'Filters' panel with three filters: 'Show Me All pre-application ids', 'Created Date All Time', and 'Shared with other organisations equals True'. Red boxes highlight the first two filters. A callout box with an arrow pointing to the 'Shared with other organisations' filter contains the text: 'Some filters will allow to restrict the view to records on the basis of their creation date, while others allow to view only the records shared with the user's organisation.' The right screenshot shows a 'Filter by Shared with other organisations' dialog box. The 'Shared with other organisations' dropdown is set to 'True', and a list of filter options is shown below it, with 'True' selected and checked. A red box highlights this dialog.





# 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>

