



Notification of studies and pre-submission advice

Webinar

March 25th, 2021

Trusted science for safe food



Welcome and introduction

Who we are



Presenters of this session:

- Stefano Cappè (EFSA)
- Davide Gibin (EFSA)
- Remigio Marano (EFSA)
- Sorina Puiu (EFSA)

Video editing

- Zorka Varga (Contractor)

Presentation editing

- Eliana Pagnutti (Contractor)
- Edoardo Manfré (Contractor)

Goals



Inform about the **new tool - Connect.EFSA – and the processes** related to the pre-submission activities

Golden rules



You are connected through a one-way audio (listen only mode).

- Questions about technical aspects of NoS-DB and PSA, unanswered during previous webinar session on 16 February were used to define specific case-studies to present during this webinar. An additional “answering session” on the technical questions received during the previous webinar has been also included in this webinar
- Questions about Practical Arrangements (Pas) will not be answered in this webinar. EFSA will conclude the feedback cycle regarding the PAs with a Frequently Asked Questions document, aimed at providing replies to questions received during the engagement process.
- Additional questions on the webinar and other Transparency Regulation topics through EFSA official support service (servicedesk@efsa.europa.eu)



This session is recorded, the materials will be available on the EFSA website including the slides and the individual videos



Time



Topic



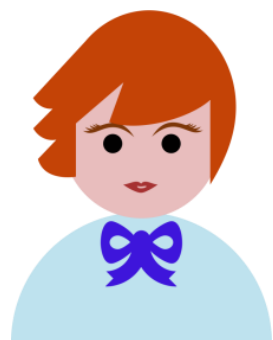
Speaker

14:30 – 14:40	Introduction and webinar outline	Stefano Cappè
14:40 – 15:00	Information to be notified in the NoS database	Davide Gibin
15:00 – 15:40	Case studies: notification of studies pre-submission advice list of intended studies for renewals renewal pre-submission advice	All
15:40 – 15:55	Follow-up on the first webinar held on 16 th February 2021	All
15:55 – 16:00	Closure of the webinar	All

Information to be notified in the NoS database

This presentation will
show the information
to be notified for
Article 32b and Article
32c1

Examples of the
different study
notification will be
provided



Sarah

Creates



New Pre-Application ID

*Request Name

*Food Domain

Authorisation Type

Application Type

*Subject Of The Application ⓘ

Note ⓘ

Confirm

Screen

New Pre-Application ID

1

* Request Name

* Food Domain

--None--

Authorisation Type

--None--

Application Type

--None--

* Subject Of The Application **i**

2

Note **i**

Confirm

Information

- 1** Complete the **required fields** labelled with a red asterisk (*)
- 2** Access the **information icon** next to each file for an overview of the elements to be selected/inserted

Name of the request:
to be used to search
among the pre-application
ID created

*Request Name

Area supported by
Pre-application ID e.g. (GMO,
FCM, Food improvement
agents, Nutrition, Novel Food,
Feed additives)

*Food Domain

Information about the
subject/product of
application. It can vary
according to the domain,
authorisation and application
type

*Subject Of The Application ⓘ



Complete all **required fields** labeled with a red asterisk

Dropdown menu based on the chosen food domain e.g. (Food additives authorisation, health claims, food enzyme, food allergen)

Authorisation Type

--None--

Dropdown menu based on the chosen food authorisation type e.g. Application for an authorisation of a new food enzyme

Application Type

--None--

These fields are **optional**: "Authorisation Type" and "Application Type"



For the pesticide area the user can **select** among three **different domains**:

- Pesticide MRL
- Pesticide Peer review (AIR)
- Pesticide Peer review (NAS)



No further authorisation/application types are **available**



For the pesticide domain: in the **subject of application** the indication about matrix should be provided when relevant e.g. *Modification of the existing maximum residue level for phenmedipham in strawberries*

Screen



Pre-Application ID
safety assessment of a recycling process
based on 4PET technology

[New Study](#)[Add Studies](#)[Ask PSA](#)

ID

EFSA-ID-2021-000366

[Details](#)[Components](#)[History](#)

Request Name

safety assessment of a recycling process based on
4PET technology

Business Operator

ABC Company

▼ Details

Subject Of The Application ⓘ

safety assessment of a recycling process based on
4PET technology

Other Components ⓘ

Note ⓘ

ID

EFSA-ID-2021-000366

Contact Name

Casey E. Lemieux

Food Domain

Food Contact Material

Authorisation Type

Recycling Processes

Application Type

Application for the authorisation of a new recycling
process



In case of a **Recycling process**, it is recommended to provide the technology information in the subject of application

Screen

Request Name
Feed additive Ferrous sulfate for chickens for fattening

Business Operator
ABC Company

Details

Subject Of The Application
Ferrous sulfate (Iron-SULF®) for chickens for fattening

Other Components

Note

ID
EFSA-ID-2021-000360

Contact Name
Casey E. Lemieux

Food Domain
Feed Additives

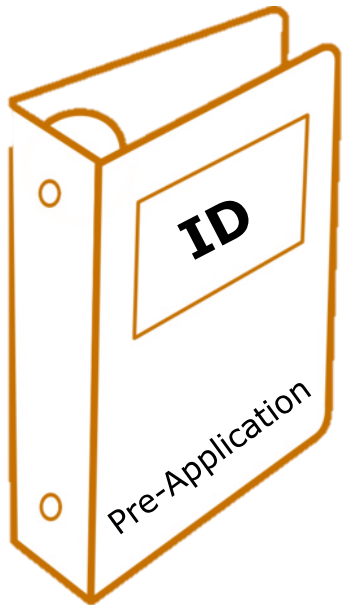
Authorisation Type
Feed Additives

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

Action



In case of **Feed additives**, it is recommended to provide the information about the target species in the subject of the application



- » Request name
- » Food Domain
- » Authorisation Type
- » Application Type
- » Subject of application



~~Notify Study ...~~

Notify Study 1

Notify Study 2

Notify Study 4

Notify Study 4

Notify Study ...



Food Domain
Authorisation Type
Application Type
Test item
...

All **mandatory fields** to complete a notification are described in the top right box of the page

Some fields offer the functionality to use drop-down lists



Study Status Tracker

This Study has been saved as a **draft**. When it is ready to be submitted, please click on the **Notify** button in the right-hand corner.

Please note that the following fields MUST contain a value before the Study can be notified:

- Study Title
- Study Starting Date
- Study Planned Completion Date

In Study Scope section:

- Study Type
- Food Domain
- Authorisation Type
- Application Type
- Study International Standard Certification
- Study Objective
- Study Test Item
- Components (where applicable)

Optional fields during the study notification are:

- ① **Study internal reference ID:** reference to internal laboratory number for the study
- ② **Component:** to be used for chemical substance, microorganism
- ③ **Other component:** to be used for other than chemical substance, microorganism

Drop-down list

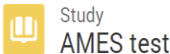
- ① Component
- ② Study type
- ③ International standard certification

Free text

- ① Test item
- ② Other components
- ③ Study internal reference ID
- ④ Study objective



Components



Study
AMES test

Notify

Share With

Withdraw Study

▼

EFSA Study Identification
EFSA-2021-00000512

Status
Notified

Details Components History

New Component



Test item: components (1)

Term Extended Name (Truncated)

Alpha-amylase



Drop-down list

Other components

Test Item

stack maize XYZ x KWZ



Other Components ⓘ

Protein ABC

Protein DEF

Protein GHK

Protein LMN



Food Domain

GMO



Authorisation Type


Food and Feed - Regulation (EC) No 1829/2003



Free text

Example of Study Notification

Food domain: Pesticide MRL

Study Type 

Metabolism

International Standard Certification 

GLP

Study Internal Reference ID 

Study Objective 

Investigated the metabolism of Clodinafop in wheat

Test Item

Clodinafop as active substance

Other Components 

Food Domain

Pesticides MRL

Authorisation Type

Application Type



Details

Components

History

New Component



Test item: components (1)

Term Extended Name (Truncated)

Clodinafop



Access the components section and insert the substance via the **"New component"** button

Food domain: Food improvement agents - Enzyme

Study Type 

Genetic toxicity in vitro

International Standard Certification 

GLP


Study Internal Reference ID 

Study Objective 

Study to test gene mutation

Test Item

Alpha-amylase from a genetically modified strain of
Bacillus licheniformis (strain NZYM-KE)

Other Components 

Food Domain

Food Improvement Agents

Authorisation Type

Food Enzymes Authorisation

Application Type

Application for the authorisation of a new food enzyme


Food domain: GMO – Food and Feed


Study Type 

Protein characterisation (e.g. enzymatic assay)

International Standard Certification 

GLP


Study Internal Reference ID 

Study Objective 

The purpose of this study was to characterize the LMN protein purified from stack maize grain of XYZ x KWZ and assess physicochemical and functional equivalence

Test Item

Stack maize XYZ x KWZ

Other Components 

Protein LMN

Food Domain

GMO

Authorisation Type

Food and Feed – Regulation (EC) No 1829/2003

Application Type

Application for authorisation of a new genetically modified food and/or feed

Food domain: food contact material – Recycling processes

Study Type ⓘ	Test Item
--None--	4PET technology
International Standard Certification ⓘ	Other Components ⓘ
GLP	
Study Internal Reference ID ⓘ	Food Domain
	Food Contact Material
Study Objective ⓘ	View all dependencies
Determination of decontamination efficiency of 4PET technology	* Authorisation Type
	Recycling Processes
	View all dependencies
	Application Type
	Application for the authorisation of a new recycling pro...
	View all dependencies



This type should contain the following information:

- The **Technology name**
- Information about the **migration type**:
 - Specific migration
 - Overall migration
 - Determination of reaction products
 - Residual content

Food allergens, health claims, infant formula

In these cases, we recommend to provide the following information in the study objective:

Study Objective



Sarah

Study description: the RCT is designed as an equivalence study

Intervention + dose: In a randomised controlled clinical trial performed in five countries (15 centres), healthy infants with a maximum age of 14 days were randomised, stratified by gender and centre and using a web-based randomisation system, to consume the formula manufactured from hydrolysed protein (protein 9.6 g/100 kJ (2.3 g/100 kcal); intervention group) or an intact cow's milk protein formula (protein 8.4 g/100 kJ (2.0 g/100 kcal); control group)

Food allergens, health claims, infant formula

In these cases, we recommend to provide the following information in the study objective:

Study Objective



Sarah

Control/placebo: intact cow's milk protein formula (protein 8.4 g/100 kJ (2.0 g/100 kcal)

Duration: exclusive formula feeding from a maximum age of 14 days up to the age of 4 months

Subjects characteristics: healthy term exclusively formula-fed infants with a maximum age of 14 days

Food allergens, health claims, infant formula

In these cases, we recommend to provide the following information in the study objective:

Study Objective



Sarah

Endpoints measured (at least the primary outcome): The primary outcome of the study was weight gain from age ≤ 14 days to day 119. Secondary outcomes were length, head circumference, anthropometric measures expressed as z-scores, frequency of adverse events and symptoms of digestive intolerance

Sample size: Power calculations were performed assuming xxx [derived from the expected difference between groups]. In order to reach 80% power, it was calculated that xxx infants per group were needed. Assuming a zz% drop-out rate, yyy infants per group were envisaged to be recruited. A total of aaaaaaa subjects (bbbbbbb/group) were randomised.


Food domain: Feed additives – Application for authorisation of a new feed additive (Article 4(1) of Regulation (EC) No 1831/2003)


Study Type 

Tolerance

International Standard Certification 

GLP


Study Internal Reference ID 

Study Objective 

Tolerance study in chickens for fattening

Test Item

Ferrous sulfate

Other Components 

Food Domain

Feed Additives

Authorisation Type

Feed Additives

Application Type

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

It is suggested to put the principal constituents as component



Sarah

Study title ⁱ

In vitro micronucleus assay

Test item ⁱ

Substance Grill Favour concentrate FL-no: 21.002

Components ⁱ

Octanoic acid, Decanoic acid, Heptanoic acid, 6-Heptenoic acid, (Z)-8-Heptadecene, Nonanoic acid, Hexanoic acid, 7-Octenoic acid, (E)-2-Decenal, 5-Hexenoic acid, Nonanal, (E)-2-Undecenal, 9-Decenoic acid, Pentanoic acid, 2-Octylfuran, 4-Pentenoic acid, Pentadecane, Heptadecane, 10-Undecenoic acid, Decan-2-one

For renewal the potential applicant should also prefill some information for the pre-application ID

New Pre-Application ID for Renewal

*Request Name

*Former Application ID ⓘ

*Subject Of The Application ⓘ

*Food Domain

Authorisation Type

Application Type

Note ⓘ



Link to the EFSA question number



Information needed for the intended study



Study Status Tracker

This Intended Study has been saved as a **draft intended study**. Intended studies must be submitted as a List of Intended Studies within the Pre-Application ID for renewal. You can transform an intended study in a draft study notification any time via the button “To Notify” (in the top right-hand side of the screen).

Please note that the following information elements MUST contain a value before the Intended Study for renewal can be submitted:

- Study Title

In Study Scope section:

- Study Type
- Food Domain
- Authorisation Type
- Application Type
- Study Objective
- Study Test Item
- Components (where applicable)

In the Study Design section:

- Study Guideline
- Study Design Description

Screen

For the intended study for renewal
the study design is mandatory

▼ Study Design (Mandatory only for Renewal Request)

Study Guideline ⓘ

Study Design Description ⓘ

Study Detailed Protocol ⓘ

1

2

3

Action

1

The user selects the study guideline from the picklist

2

In case the value "Other" or "Not applicable" is selected, it is mandatory to provide a detailed study design description

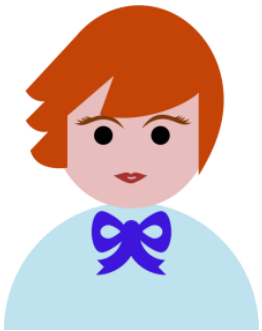
3

It is recommended to fill in the information related to the study protocol

Case studies

Case study

Notification of studies 1



Sarah
Business Operators
Potential Applicants



John
Laboratories
Testing facilities



Martin
Third Parties working on
behalf of Business Operators

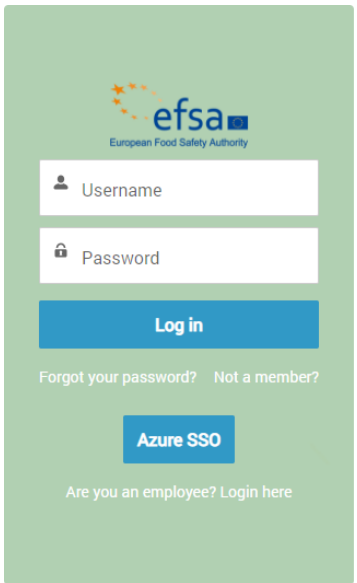
Case Study Scenario

Step1 - Third party registers in the system



Martin

Log in/Register



efsa
European Food Safety Authority

Username

Password

Log in

Forgot your password? Not a member?

Azure SSO

Are you an employee? Login here

Step2 - Business Operator delegates third party to work on its behalf



Sarah

Share With



Martin

Step3 - Third party notifies study on behalf of Business Operator



Martin



Notify




John

Step1 - Third Party Registers in the System



Contact Details

[Log in/Register](#)


European Food Safety Authority

Join the community to access services and information on EFSA activities.

Registration

Personal Information

* First Name
Martin

* Last Name
Martini

* Email
martin.martini@thirdparty.com

* Affiliation
Select

Consultant

Industry - Multinational

Industry - SME

NGO/Consumer Group

Private Citizen/Consumer

Public Authority

Science/Academia

Other

Account Details

Organisation

* Category
Select

* Subcategory
Select

Applicants

Notifiers acting on behalf of the Applicants

Stakeholders

General public

Media

EU-FORA

Website
www.gilesgilletconsulting.com

Street
Consulting Boulevard

City
Lisbon

Postal/Code
12345

* Country
Portugal

* Small/Medium Enterprise
No

SME Code

☒ I accept that EFSA will use my data to provide the service that I am registering for.

☒ I accept that EFSA will use my data to select topics I might be interested in and invite me to events or send a newsletter about them.

☒ I accept that EFSA will use my data for statistical analysis.

Privacy Notice

[Submit](#)



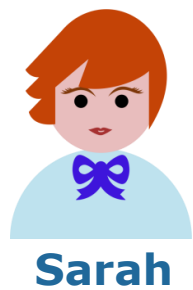
CHECK YOUR EMAIL

- Check the email account associated with your username for instruction on resetting your password.
- Remember to look in your spam folder, where automated messages sometimes filter.



Reset password email will be triggered upon EFSA validation of the registration request

Step2 – Business Operator Delegates Third Party to Work on its Behalf



Request
pre-application
ID



New Pre-Application ID

*Request Name
My new request for a pre-application ID

*Food Domain
Food Improvement Agents

*Authorization Type
Food Additives Authorization

*Application Type
Application for the authorisation of a new food additive

Subject Of The Application
New food additive to be released on the market

Note

Confirm



Pre-Application ID

Pre-Application ID
My new pre-application ID for training

ID
EFSA-ID-2021-000272

New Study Add Studies Ask PSA Pre-App

Share With



Share With

Please indicate whether you would like to share this record with a Business Operator or a Third Party.

* Category
Third Party

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

Third Party Organisation
Solution Consulting

Next



Step3a - Third Party Notifies Study on Behalf of Business Operator



Request
pre-application
ID



My Pre-Application ID ▼

38 items • Sorted by Created Date • Filtered by All pre-application ids - Record Type, UserContactID

Search this list...

	Request Name	ID	Contact Name	Created D...	
1	Training Remigio_18 Jan	EFSA-ID-2021-0002...	Remigio Marano Business Operat...	18/01/2021 12...	
2	My test for training	EFSA-ID-2021-0002...	Stefano Cappè Business Operator	18/01/2021 12...	
3	My new pre-application ID for training	EFSA-ID-2021-0002...	Sorina Puiu Business Operator	18/01/2021 12...	
4	PAID Training	EFSA-ID-2021-0002...	Werner Baumann	18/01/2021 9 25	

Open pre-
application ID
"folder" & create
new notification



Study
My new study on alluminium for traing

EFSA Study Identification
EFSA-2021-00000373

Status
Notified

Notify Share With Withdraw Study

Details Components History

Study Title
My new study on alluminium for traing

Study Title (English Name)

Study Starting Date
20/01/2021

Study Planned Completion Date
20/01/2022

Submitted to Internal Testing Facility

Business Operator
ABC company Spa

Owner
sorina.puiu.bo

Former Application ID



Internal testing
facility?

YES

NO

END

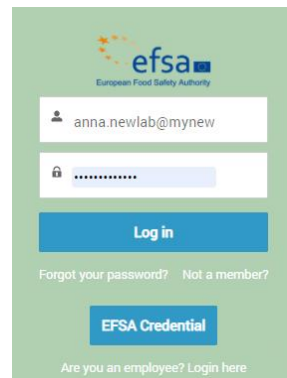
Alert
Email
to Lab

Step3b – Registered Laboratory Co-notifies the Notification (1/2)



**Alert
Lab**

Log in/Register



efsa
European Food Safety Authority

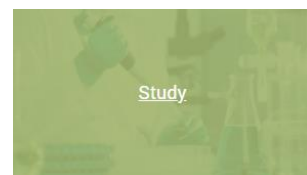
anna.newlab@mynew

Log in

Forgot your password? Not a member?

EFSA Credential

Are you an employee? Login here



In Draft Notified **To Co-Notify** Co-Notified Co-Notified by Me Additional Involvement Withdrawn

This list contains all studies that have been received from business operators and that are **awaiting your approval**. Use the search bar on the right to search for a study.

To Co-Notify

29 items • Sorted by Created Date • Filtered by All studies • Status, Study Withdrawn, Co-Notifier

Search this list...

	Study Title	Food Domain	Status	Created Date	
1	study YYY	Feed Additives	Notified	18/01/2021 9.44	



Study
study YYY

EFSA Study Identification
EFSA-2021-00000365

Status
Notified

Co-Notify

Co-Notify with Remarks

Share With



Details

Components

History

Study Title
study YYY


Study Title (English Name)
study YYY

Study Planned Completion Date
18/01/2021

Owner
mrossi

Laboratory
Pharma Spa

Step3b – Registered Laboratory Co-notifies the Notification (2/2)

 Study
study YYY

EFSA Study
EFSA-202

Details

Study Title
study YYY

Study Title
study YYY

Study Plann
20/01/2021

Co-Notify Co-Notify with Remarks Share With ▼

Co-Notify

Co-Notify with Remarks

Share With ▼

Co-Notify

Co-Notifier Comment ⓘ

Cancel Save

Co-Notify with Remarks

* Co-Notifier Comment ⓘ
Study Planned Completion Date is postponed 15 days, as agreed

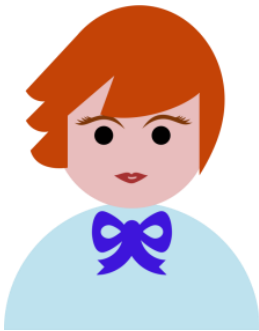
Cancel Save

Owner
mrossi

Laboratory ⓘ
Pharma Spa

Case study

Notification of studies 2



Sarah
Business Operators
Potential Applicants



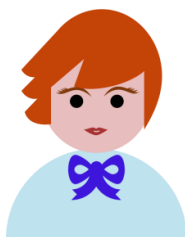
John
Laboratories
Testing facilities

Step1 - Laboratory notifies a study



John

Notify



Sarah

Step2 - Business Operator co-notifies the study and adds it to a Pre-Application ID



Sarah



Alert

Co-Notify

Co-Notify with Remarks



Co-Notified					
13 items • Sorted by Co-Notification Date • Filtered by All studies - Status, Study Withdrawn, UserAccountid					
Search this list...					
Study Title	Business Ope...	Labora...	Status	Co-Notifica..	
1 pelgar study test 1	ABC company Spa	Pharma Spa	Co-Notified	30/11/2020	
2 in vivo two indepe...	ABC company Spa	Pharma Spa	Co-Notified	21/10/2020	
3 3rd party notificati...	ABC company Spa	Pharma Spa	Co-Notified	19/10/2020	
4 Study title	ABC company Spa	Pharma Spa	Co-Notified	10/10/2020	

Step3 - Business Operator reuses a previously notified studies for another Pre-Application ID



Sarah

Add Studies



Pre-Application ID

Pre-Application ID
My new pre-application ID for training

New Study Add Studies Ask PSA

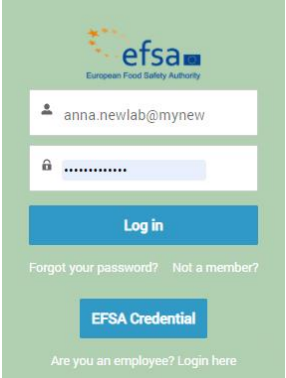
ID
EFSA-ID-2021-000272

Step1 - Laboratory Notifies the Study



John

Log in/Register



efsa
European Food Safety Authority

anna.newlab@mynew

Log in

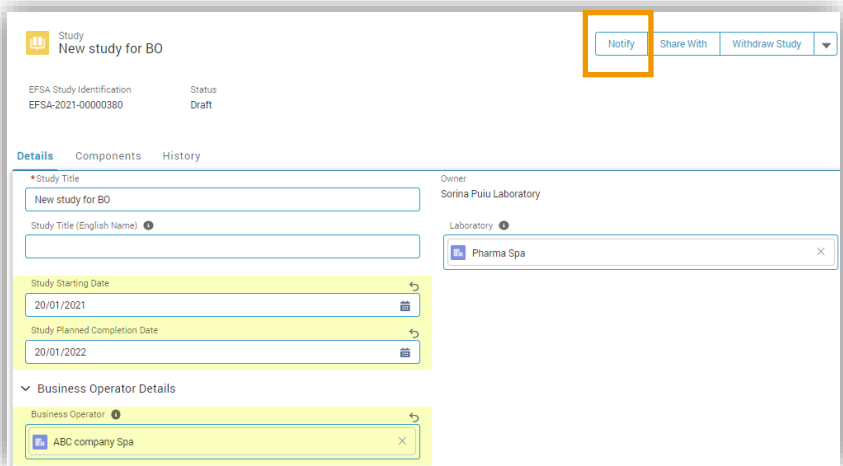
Forgot your password? Not a member?

EFSA Credential

Are you an employee? Login here



New Study



Study
New study for BO

EFSA Study Identification
EFSA-2021-00000380

Status
Draft

Details Components History

*Study Title
New study for BO

Study Title (English Name)

Study Starting Date
20/01/2021

Study Planned Completion Date
20/01/2022

Business Operator Details

Business Operator
ABC company Spa

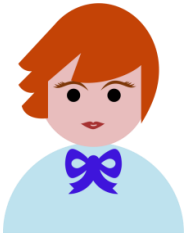
Owner
Sorina Puiu Laboratory

Laboratory
Pharma Spa

Notify Share With Withdraw Study




Alert

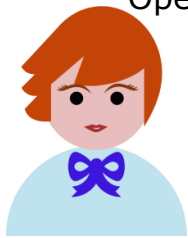


Sarah

Step2a – Business Operator Co-notifies the Study (1/2)




Alert
Business Operator



Sarah

[Log in/Register](#)



European Food Safety Authority

[Log in](#)

[Forgot your password?](#) [Not a member?](#)


[EFSA Credential](#)

[Are you an employee? Login here](#)





[In Draft](#) [Notified](#) **[To Co-Notify](#)** [Co-Notified](#) [Co-Notified by Me](#) [Additional Involvement](#) [Withdrawn](#)

This list contains all studies that have been received from business operators and that are **awaiting your approval**. Use the search bar on the right to search for a study.

 **To Co-Notify** ▼

29 items • Sorted by Created Date • Filtered by All studies • Status, Study Withdrawn, Co-Notifier

	Study Title	Food Domain	Status	Created Date	
1	study YYY	Feed Additives	 Notified	18/01/2021 9.44	▼

 Study
study YYY

EFSA Study Identification
EFSA-2021-00000365

Status
Notified

[Details](#) [Components](#) [History](#)

Study Title
study YYY

Study Title (English Name)
study YYY


Study Planned Completion Date
18/01/2021

Owner
mrossi

Laboratory
Pharma Spa

[Co-Notify](#) [Co-Notify with Remarks](#) [Share With](#) ▼

Step2a – Business Operator Co-notifies the Study (2/2)

 Study
study YYY

Co-Notify Co-Notify with Remarks Share With ▼

Co-Notify

Co-Notify with Remarks

Share With ▼

EFSA Study
EFSA-202

Details

Study Title
study YYY

Study Title
study YYY

Study Plann
20/01/2021

Co-Notify

Co-Notifier Comment ⓘ

Cancel

Save

Owner
mrossi

Laboratory ⓘ
Pharma Spa

Co-Notify with Remarks

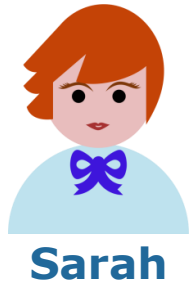
* Co-Notifier Comment ⓘ

Study Planned Completion Date is postponed 15 days, as agreed

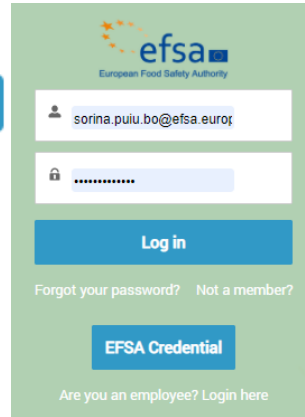
Cancel

Save

Step2b – Business Operator Adds Study Notified by Lab to Pre-Application ID



Log in/Register



EFSA European Food Safety Authority

sorina.puiu.bo@efsa.europa.eu

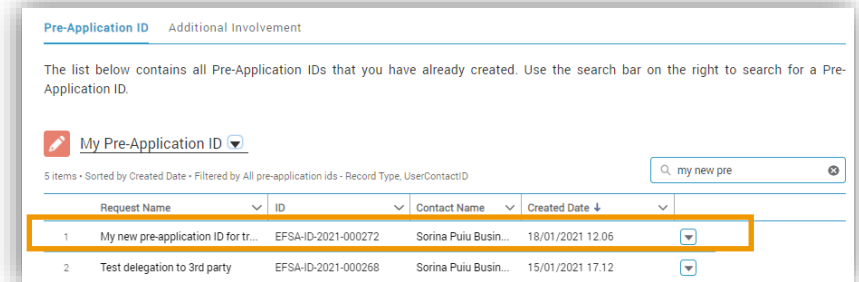
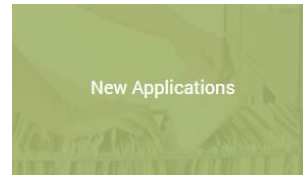
.....

Log in

Forgot your password? Not a member?

EFSA Credential

Are you an employee? Login here



Pre-Application ID Additional Involvement

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

My Pre-Application ID

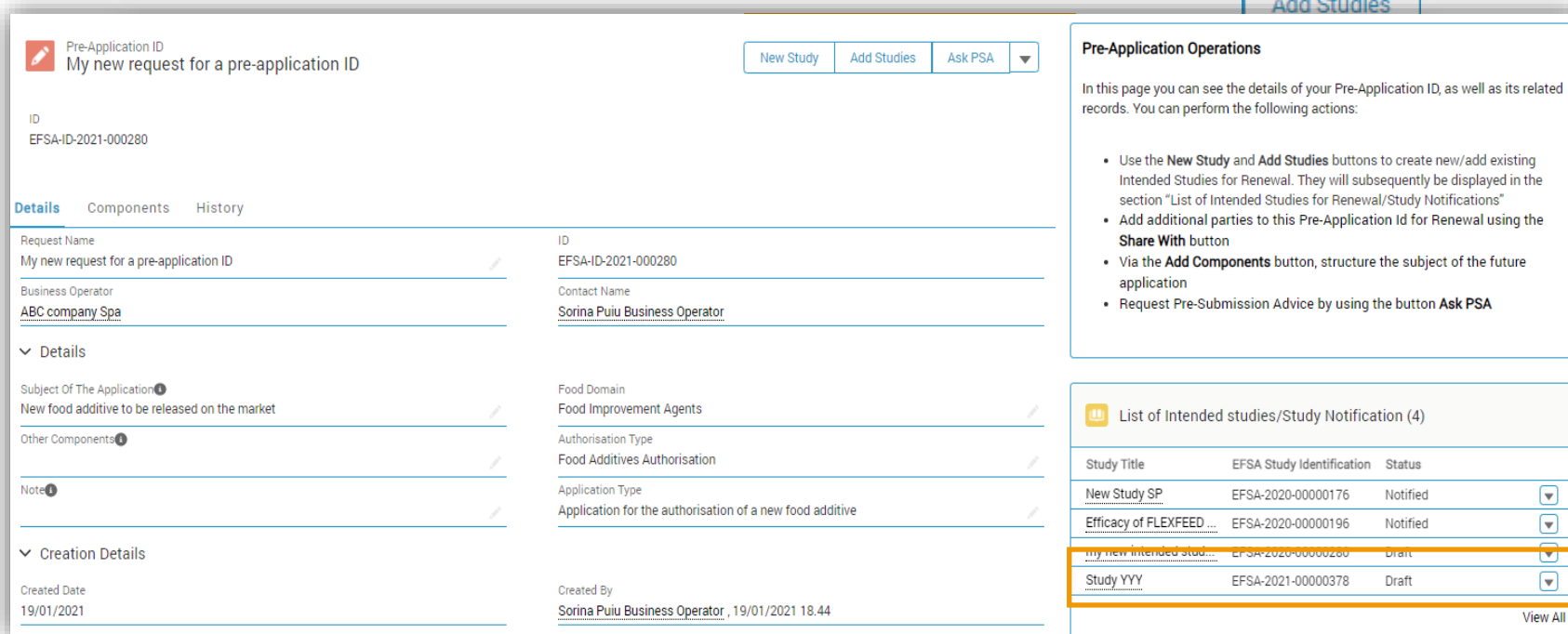
5 items • Sorted by Created Date • Filtered by All pre-application ids - Record Type, UserContactID

my new pre

	Request Name	ID	Contact Name	Created Date	
1	My new pre-application ID for tr...	EFSA-ID-2021-000272	Sorina Puiu Busin...	18/01/2021 12:06	
2	Test delegation to 3rd party	EFSA-ID-2021-000268	Sorina Puiu Busin...	15/01/2021 17:12	



Add Studies



Pre-Application ID

My new request for a pre-application ID

ID

EFSA-ID-2021-000280

Details Components History

Request Name	ID
My new request for a pre-application ID	EFSA-ID-2021-000280
Business Operator	Contact Name
ABC company Spa	Sorina Puiu Business Operator
Details	
Subject Of The Application	Food Domain
New food additive to be released on the market	Food Improvement Agents
Other Components	Authorisation Type
	Food Additives Authorisation
Note	Application Type
	Application for the authorisation of a new food additive
Creation Details	
Created Date	Created By
19/01/2021	Sorina Puiu Business Operator , 19/01/2021 18:44

New Study Add Studies Ask PSA

Pre-Application Operations

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

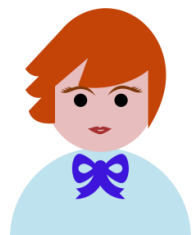
- Use the **New Study** and **Add Studies** buttons to create new/add existing Intended Studies for Renewal. They will subsequently be displayed in the section "List of Intended Studies for Renewal/Study Notifications"
- Add additional parties to this Pre-Application ID for Renewal using the **Share With** button
- Via the **Add Components** button, structure the subject of the future application
- Request Pre-Submission Advice by using the button **Ask PSA**

List of Intended studies/Study Notification (4)

Study Title	EFSA Study Identification	Status	
New Study SP	EFSA-2020-00000176	Notified	
Efficacy of FLEXFEED ...	EFSA-2020-00000196	Notified	
My new intended stud...	EFSA-2020-00000280	Draft	
Study YYY	EFSA-2021-00000378	Draft	

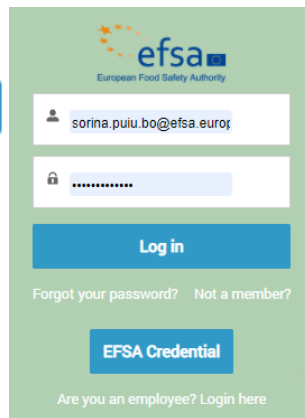
View All

Step3 – Business Operator Reuses Previously Notified Studies for Other Pre-Application ID (1/2)



Sarah

Log in/Register



EFSA European Food Safety Authority

sorina.puiu.bo@efsa.europa.eu

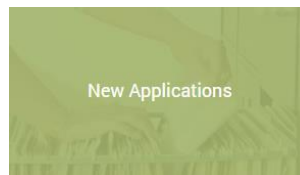
.....

Log in

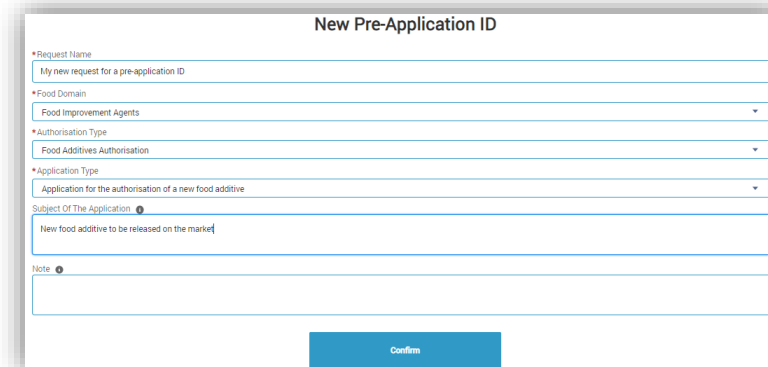
Forgot your password? Not a member?

EFSA Credential

Are you an employee? Login here



New Pre-Application ID



New Pre-Application ID

Request Name
My new request for a pre-application ID

Food Domain
Food Improvement Agents

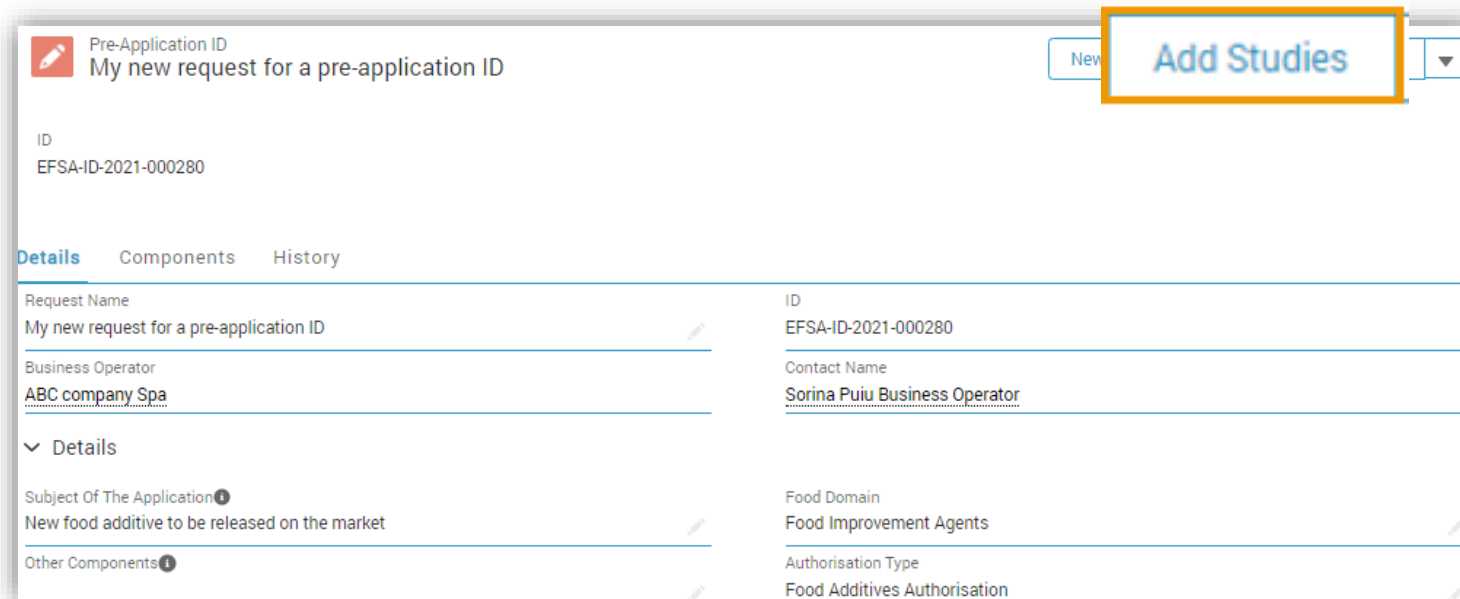
Authorisation Type
Food Additives Authorisation

Application Type
Application for the authorisation of a new food additive

Subject Of The Application
New food additive to be released on the market

Note

Confirm



Pre-Application ID
My new request for a pre-application ID

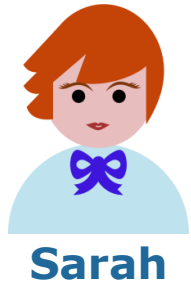
ID
EFSA-ID-2021-000280

Details Components History

Request Name My new request for a pre-application ID	ID EFSA-ID-2021-000280
Business Operator ABC company Spa	Contact Name Sorina Puiu Business Operator
Details	
Subject Of The Application New food additive to be released on the market	Food Domain Food Improvement Agents
Other Components	Authorisation Type Food Additives Authorisation

Add Studies

Step3 – Business Operator Reuses Previously Notified Studies for Other Pre-Application ID (2/2)



Add Studies

Add Studies to Pre-Application ID

Search Studies...

Selected Studies: 3

EFS-2020-00000176 X EFS-2020-00000196 X EFS-2020-00000280 X

Study Number	Name	Food Domain	Created Date
<input type="checkbox"/> EFS-2020-00000203	sequencing of event A in AxBxC stack	GMO	26-Oct-2020
<input type="checkbox"/> EFS-2020-00000201	Heat stability of Protein XYZ	GMO	26-Oct-2020
<input type="checkbox"/> EFS-2020-00000170	New Study1	Biological Hazards	12-Oct-2020
<input checked="" type="checkbox"/> EFS-2020-00000176	New Study SP	Feed Additives	19-Oct-2020
<input checked="" type="checkbox"/> EFS-2020-00000196	Efficacy of FLEXFEED 20000g in fattening pigs	Feed Additives	21-Oct-2020
<input checked="" type="checkbox"/> EFS-2020-00000280	my new intended studies	Feed Additives	30-Nov-2020
<input type="checkbox"/> EFS-2020-00000177	Title New Attempt to notify	Feed Additives	19-Oct-2020
<input type="checkbox"/> EFS-2020-00000192	Determination of the ferric citrate content added to premixtures ...	Feed Additives	21-Oct-2020
<input type="checkbox"/> EFS-2020-00000286	My title parallel art32b - art32c1	Biological Hazards	2-Dec-2020
<input type="checkbox"/> EFS-2020-00000175	Preparation of...	Biological Hazards	10-Oct-2020

Next

List of Intended studies/Study Notification (3)

Study Title	EFSA Study Identification	Status	
New Study SP	EFSA-2020-00000176	Notified	▼
Efficacy of FLEXFEED ...	EFSA-2020-00000196	Notified	▼
my new intended stud...	EFSA-2020-00000280	Draft	▼

View All

Pre-Application ID(s) (3)

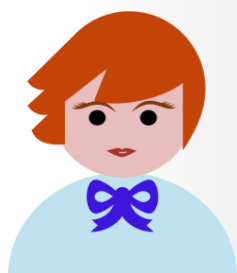
Request Name	Record Type	Basket of Studies: Crea...	
Request Name SP	Pre Submission ID	19/10/2020 14.49	▼
Pre-Application ID Na...	Pre Submission ID	11/01/2021 14.48	▼
My new request for a ...	Pre Submission ID	19/01/2021 18.50	▼

View All

Case study

Parallel notification Article 32c(1) and Article 32b

Case study



Sarah

Sarah has to start an application for renewal for the feed additive Y. She is preparing the list of intended studies for renewal in April 2021. She has a study S1 in the list of intended studies that she would like to commission and notify immediately.

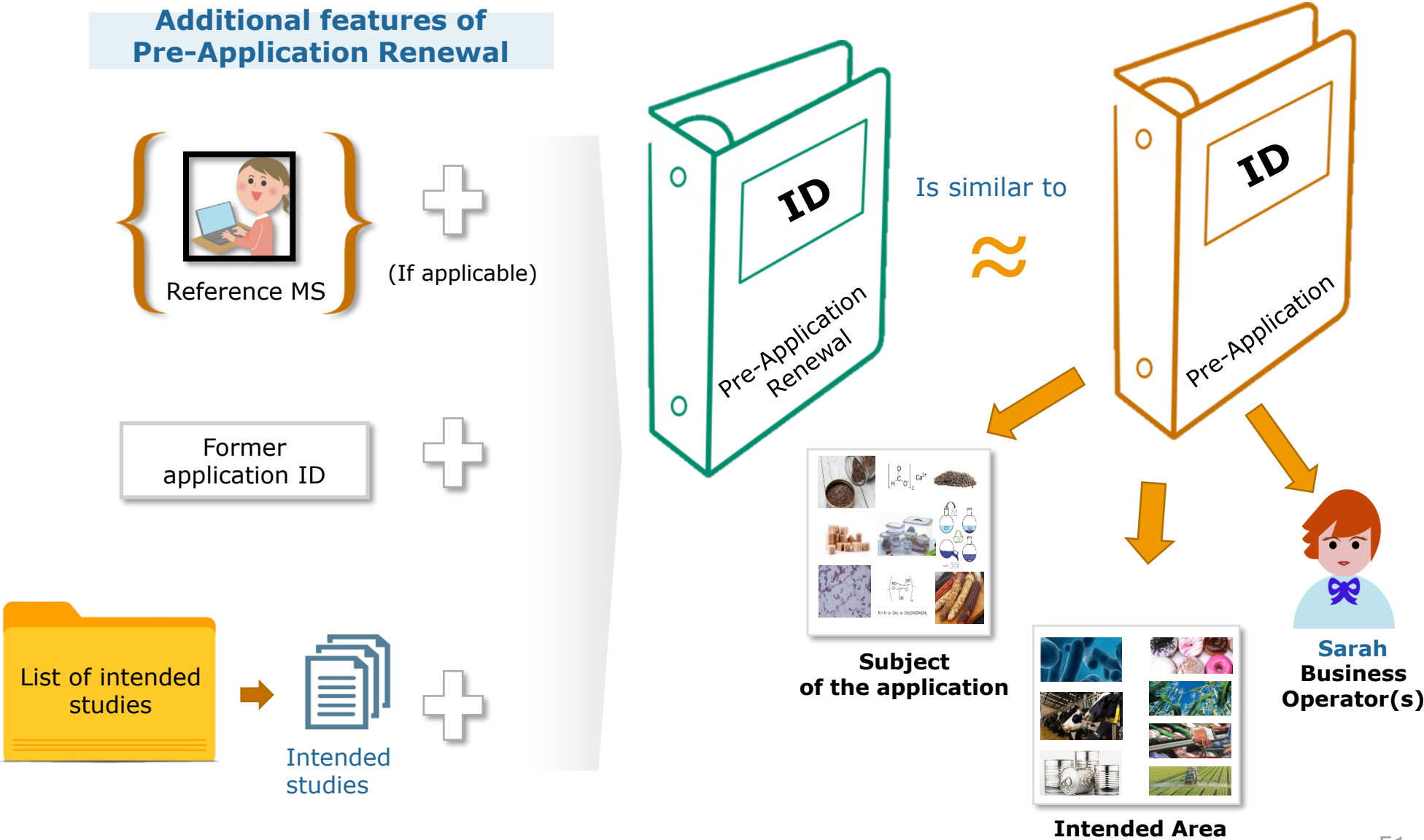
She is worried that she may not have time to include the data in the application and submit the latter by the expected deadline, if she waits for the process of Renewal Pre-submission Advice to be concluded.

Pre-Application Identification for Renewal



Sarah

Requests
Pre-Application-ID
for Renewal

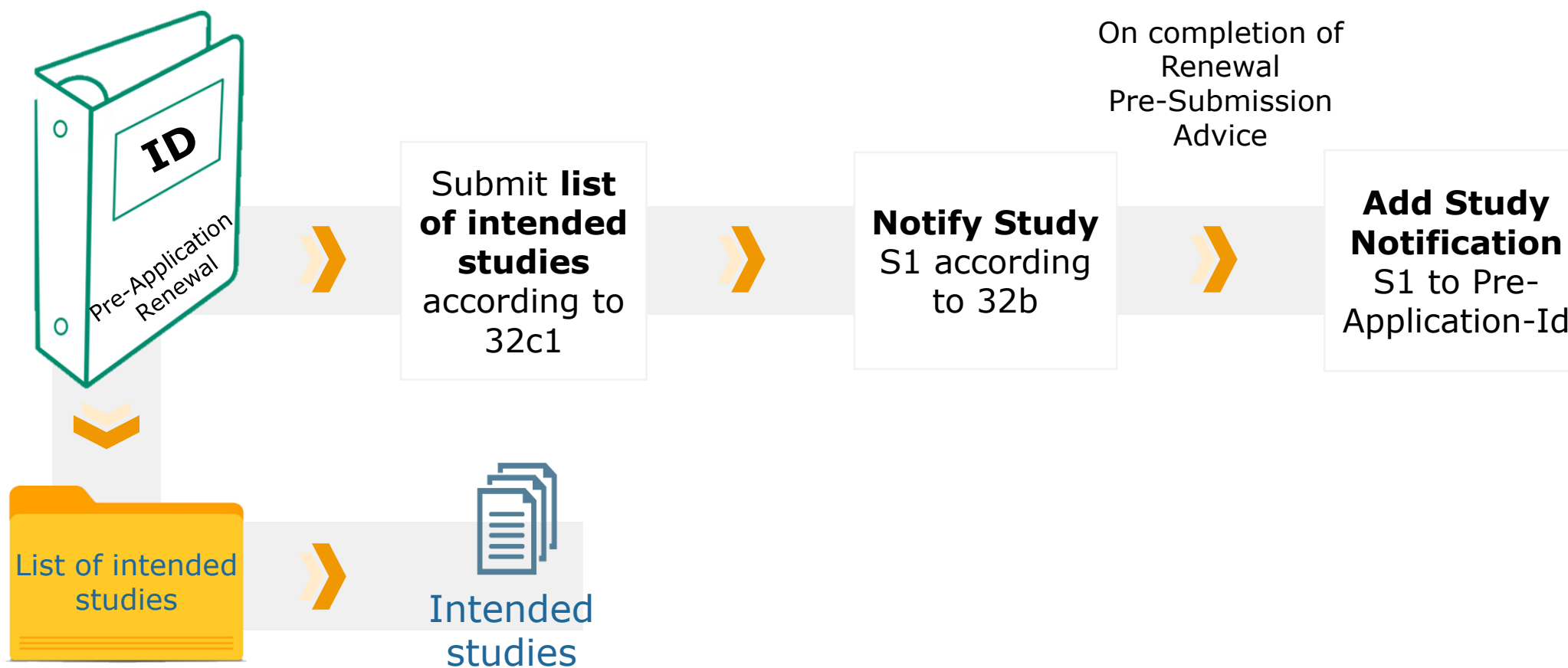



Pre-Application Identification for Renewal



Pre-Application Identification for Renewal

This situation occurs only in the first months of operation of the Transparency Regulation.
A possible NoS-DB work-around is proposed for this initial phase.





Pre-Appli

You can create a **NEW Pre-Applica**

ion ID for Renewal is necessary fo

obtain the renewal. Following you

n then continue your application p

at this stage only the **Study Nam**

nd the study can remain in the "Dr

renewal Additional Involvement

s all Pre-Application IDs for Ren

r Renewal. To view your Pre-Subm

pplication ID for Renewal ▼

Created Date • Filtered by All pre-application i

Name
renewal 10/03/2021
10/03/2021 @1700

New Pre-Application ID for Renewal

*Request Name

Renewal of smoke flavouring Z

*Former Application ID ⓘ

EFSA-2014-004

Subject Of The Application ⓘ

Substances S

*Food Domain

Food Improvement Agents ▼

*Authorisation Type

Smoke Flavourings Authorisation ▼


*Application Type

Renewal of an already authorised smoke flavouring ▼

Note ⓘ

Renewal performed according to new EFSA guidance document

Confirm



Renewal

Pre-Application ID for renewal



Pre-Application ID
Renewal of smoke flavouring Z

New Study

Add Studies

Ask PSA

New Component

Share With

Printable View

Pre-Application ID for Renewal Operations

oved this record as a **draft**. You can
following actions:

Use **New Study** and **Add Studies** buttons to
new/add existing Intended Studies for
al. They will subsequently **be displayed** in

the section "List of Intended Studies for
Renewal/Study Notifications"

- When the List of Intended Studies for Renewal is complete, click on the **Submit List of Intended Studies** button
- Add additional parties to this Pre-Application Id for Renewal using the **Share With** button
- Via the **Add Components** button, structure the

Status
Draft

Date Submitted

Details

Components

History

Request Name

Renewal of smoke flavouring Z

Business Operator

ABC company Spa

Details

Subject Of The Application

ID

EFSA-ID-2021-000269

Contact Name

Stefano Cappè Business Operator

Food Domain

Pre-Application ID for renewal



Pre-Application ID
Renewal of smoke

Status
Draft

Date Submitted

In 'Pre-Application ID for Renewal', before submitting the **New Study** intended studies for renewal, the action 'new study' means 'new intended study for renewal'

New Study

Pre-Application ID for Renewal Operations

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

Details Components History

Request Name
Renewal of smoke flavouring Z

Business Operator
ABC company Spa

▼ Details

Subject Of The Application

ID
EFSA-ID-2021-000269

Contact Name
Stefano Cappè Business Operator

Food Domain

- Use the **New Study** and **Add Studies** buttons to create new/add existing Intended Studies for Renewal. They will subsequently **be displayed** in the section "List of Intended Studies for Renewal/Study Notifications"
- When the List of Intended Studies for Renewal is complete, click on the **Submit List of Intended Studies** button
- Add additional parties to this Pre-Application Id for Renewal using the **Share With** button
- Via the **Add Components** button, structure the

Fill in **relevant information** for intended studies

Once all intended studies are completed, submit the **list of intended studies for renewal**



Study Status Tracker

This Intended Study has been saved as a **draft intended study**. Intended studies must be submitted as a List of Intended Studies within the Pre-Application ID for renewal. You can transform an intended study in a draft study notification any time via the button "To Notify" (in the top right-hand side of the screen).

Please note that the following information elements MUST contain a value before the Intended Study for renewal can be submitted:

- Study Title


In Study Scope section:

- Study Type
- Food Domain
- Authorisation Type
- Application Type
- Study Objective
- Study Test Item
- Components (where applicable)

In the Study Design section:

- Study Guideline
- Study Design Description

Pre-application-ID for Renewal: fill in the urgent study notification

 Study
Study on smoke flavouring 1

Notify

Share With

Withdraw Study

▼

EFSA Study Identification

EFSA-2021-00000353

Status

Draft

Details

Components

History

Study Title

Study on smoke flavouring 1

Study Title (English Name)

Study Starting Date

01/02/2021

Study Planned Completion Date

31/03/2021


Submitted to Internal Testing Facility

☐

Business Operator

ABC company Spa

Owner

 Stefano Cappè Business Operator

Former Application ID

> Laboratory Details

✓ Study Scope

Study Status Tracker

This Study has been saved as a **draft**. When it is ready to be submitted, please click on the **Notify** button in the right-hand corner.

Please note that the following fields MUST contain a value before the Study can be notified:

- Study Title
- Study Starting Date
- Study Planned Completion Date

In Study Scope section:

- Study Type
- Food Domain
- Authorisation Type
- Application Type
- Study International Standard Certification
- Study Objective
- Study Test Item
- Components (where applicable)

Fill in at least the mandatory information for study notification, and notify

Pre-application-ID for Renewal: Renewal pre-submission advice received

Pre

Add Studies to List of Intended Studies


Search Studies...
🔍 smoke ✕ ↺

Selected Studies: 1
📄 EFSA-2021-00000353 ✕

<input checked="" type="checkbox"/>	Study Number	Name	Food Domain	Created Date
<input checked="" type="checkbox"/>	EFSA-2021-00000353	Study on smoke flavouring 1	Food Improvement Agents	17-Jan-2021

The notified study is now under pre-application-ID for renewal

Next



ons

Advice on

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or

cation ID

Case Study

Pre-submission advice

Pesticides Peer Review
(NAS)

Pesticides Peer Review (AIS)

Pesticides MRL

Action



Submit

Selection of the intended/designated RMS or intended EMS

Screen

Submit

Action

1

Select the member state by using the **drop-down menu**

2

Press on "**Next**" button

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

* Member State Country

Czech Republic

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

Previous

Next

2



Complete all **required fields** labeled with a red asterisk

Submitting to the relevant member state

Screen

Submit

Please select the relevant member state contact below. Then click on **Next**.

Member State Contact

- ☐ Casey E. Lemieux
- ☐ Cinthia Razo Marrero
- ☐ Michelangelo Cattaneo
- ☒ GPSA for peer-review
- ☐ Mario de Coninck
- ☐ Ties van de Lagemaat



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

Previous

Next



Action

- 1 In this case you have to select **"GPSA for peer-review"**
 - 2 Press on **"Next"** button
-  Find other contacts and select it in their respective cases:
- GPSA for peer-review
 - GPSA for MRL
 - RPSA for peer-review

Selection of the intended/designated co-RMS

Screen

Submit

You've successfully added a member state to this Pre-Submission advice. If you'd like to involve another at this time, please use check the box below. If not, simply click on **Next** to submit this record.

☒ Add Another Member State

1

Next

2

Action

1

Select "**Add Another Member State**" to add Co-RMS

2

Now press on "**Next**" button

Screen

Submit

Thank you! You have **successfully submitted** your request for Pre-Application Advice to EFSA. We'll be in touch shortly.

Click on **Next** to return to the Request page and view the changes you made.



Action

- 1 Click on **"Return to Request"** to start a new request for Pre-Application Advice
- or
- 2 Press on **"Next"** to return to the Request page

Case Study

Meeting organisation for pre-submission advice

1

Where possible, EFSA shall provide advice in **writing**

2

If EFSA considers that a discussion with the potential applicant(s) is required to clarify some of the aspects to be addressed in the advice, a **tele-conference or video-conference** shall be organised

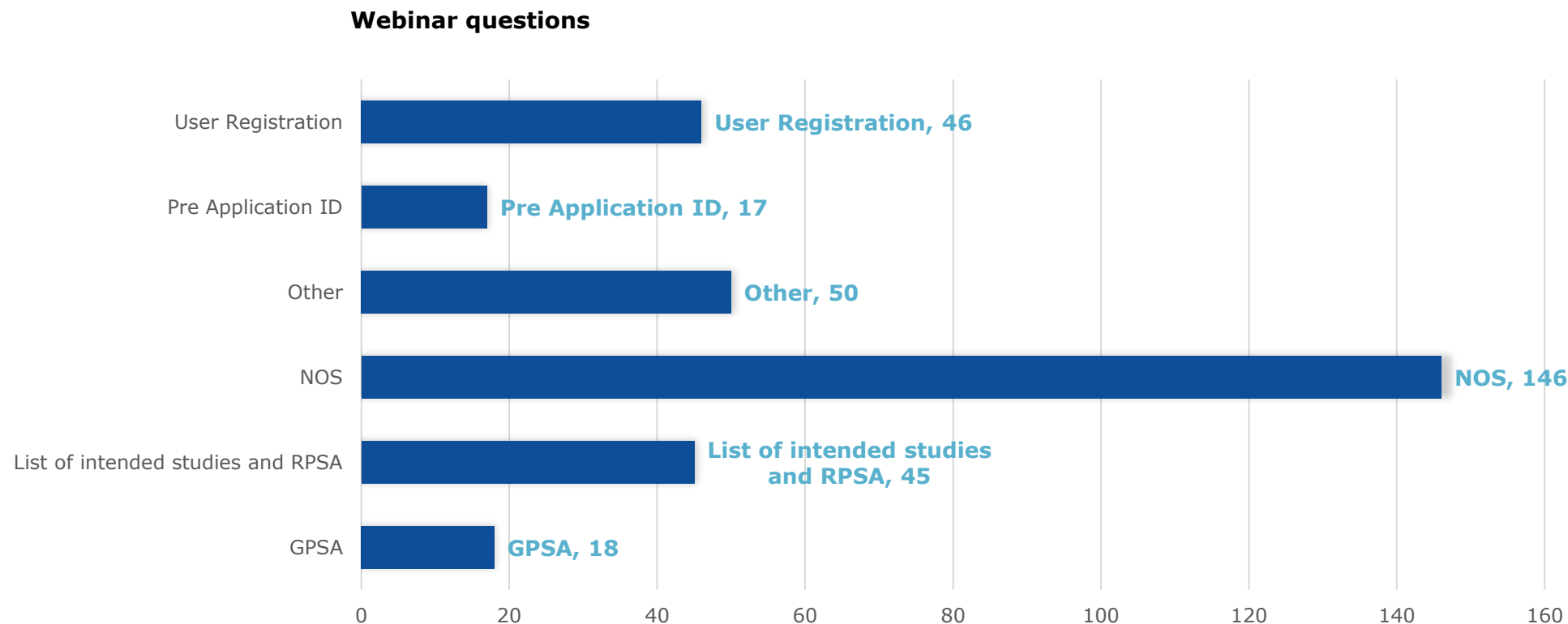
3

EFSA may organise physical meetings in exceptional cases, where the physical presence of the concerned individuals is deemed to be necessary for the discussion of the topic subject to the advice

Follow-up of the first webinar

February 16th, 2021

The majority of questions will be replied through the **FAQs document** on Practical Arrangements.
Remaining questions were used to prepare this webinar.



Total of
questions
322



Questions received on Pre-Application-ID

- What is the pre-application-ID?
- What are the confidentiality rules applied to pre-application-ID
- Notifications and pre-application-IDs
- ...

All questions related to the topics above will be answered through the FAQ document to be published by EFSA



How does the sharing of a pre-application-id with other business operators work?





Questions received on Notification of Studies

- Study notification obligation
- Provisional measures for 27 March
- Data protection and confidentiality
- Third country obligations
- Study definition
- Notification timing
- 6 Months suspension
- Notification and MSs
- Notifications and dossier validation

All questions related to the topics above will be answered through the FAQ document published by EFSA

“

Issue with selection of
some countries

”

“

Modification to studies
after notifications

”

“

Change of ownership

”

“

Bulk load and APIs

”



Questions received in pre-submission advice

- Scope (study design)
- Non-binding
- Summary

All questions related to the topics above will be answered through the FAQ document published by EFSA

Below a couple of questions identified

“

In case of Sarah, is it still possible to have **direct contact with RMS experts** to clarify technical questions linked to the dossier or studies or assessment?

”

“

Is there any additional cost for the G-PSA?

”

Below a couple of questions identified

“

Can you elaborate what "targeting the **SME**" for the general pre submission means in practice? There will be a different approach by EFSA depending on the size of company asking?

”

“

For the list of questions for PSA - **limited number of characters to be entered**? Pre-submission questions may be quite complex and require extensive information including tables or graphics in an extra document

”

Below a couple of questions identified



Does a **third party (consultant)** can request G-PSA on behalf of an applicant, without the applicant is registered?





Questions received in list of intended studies and renewal pre-submission advice

- When to submit the list of intended-studies
- What if the list of intended studies is not complete/needs to trigger new studies
- When a study needs to be notified art.32b
- How long is the process
- Information published during the public consultation

All questions related to the topics above will be answered through the FAQ document published by EFSA

Below a couple of questions identified



Renewal LoS: is the **available study data** taken into consideration by EFSA when providing advice on the new studies?



Renewal: what sort of **publicity** is made (and how) about the fact that a **consultation is open**?



Below a couple of questions identified among the FAQs

“

List of intended studies,
RPSA process and new
studies needed during
pre-application phase
not included in the list

”

“

List of intended studies:
what is published in
public consultation?

”

Conclusion

Relevant webinar

Confidentiality



27/03/2021

Video Introduction (All)

OpenEFSA Portal:
Features implementing the
Transparency Regulation

Dissemination



14/04/2021

Business Operators (Webinar)

Confidentiality for
Applicants/Business Operators



Registration



Video user guides



Connect.EFSA [link](#)



Application Toolkit [link](#)



Submit your questions to:

servicedesk@efsa.europa.eu



Technical Group on
Notification of Studies
database:
([link](#))



EFSA colleagues providing
scientific input



EFSA colleagues and
contractors working on the
implementation

Thank you for attending our webinar!



The recording of today's webinar will be available on the EFSA website in a few days

Please take few minutes to fill out the evaluation form that you will receive shortly in your inbox. Your feedback is essential to improve our future events



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@methods_efsa