

27-28 January 2021
NoS Technical Group Meeting

Case Study4 Notification from a laboratory

Sorina Puiu
Transformation Services Unit

Trusted science for safe food

Case Study4

Step1 - Laboratory notifies a study



Laboratory/Testing facility

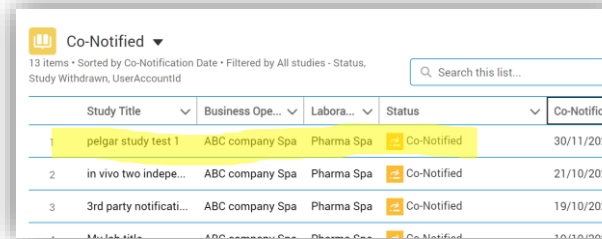


Business operator

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



Business operator

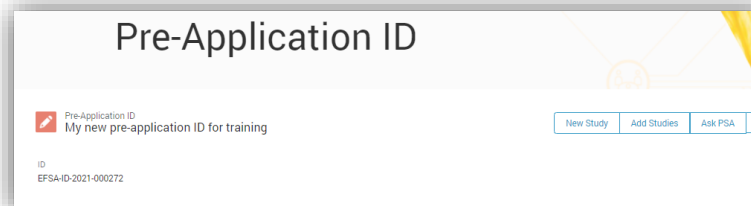
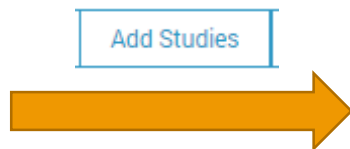


Study Title	Business Ope...	Labora...	Status	Co-Notifica..
pelgar study test 1	ABC company Spa	Pharma Spa	Co-Notified	30/11/2020
2 in vivo two indepe...	ABC company Spa	Pharma Spa	Co-Notified	21/10/2020
3rd party notificati...	ABC company Spa	Pharma Spa	Co-Notified	19/10/2020
4th party notificati...	ABC company Spa	Pharma Spa	Co-Notified	10/10/2020

Step3 – Business operator reuses a notified study for other Pre-Application activities



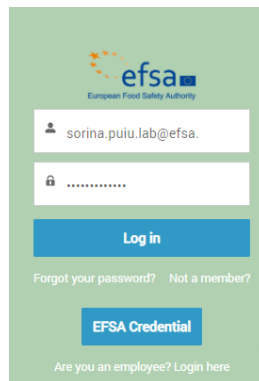
Business operator



Step1 - Laboratory Notifies the Study



Log in/Register



EFSA European Food Safety Authority

sorina.puiu.lab@efsa.

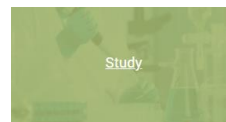
.....

Log in

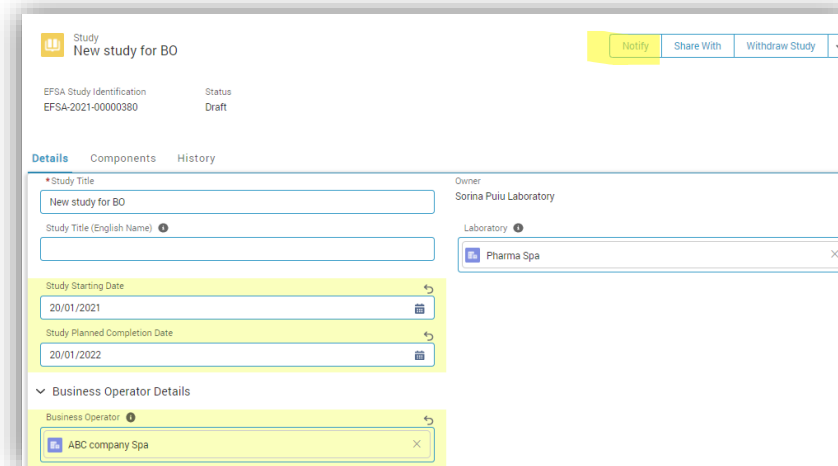
[Forgot your password?](#) [Not a member?](#)

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

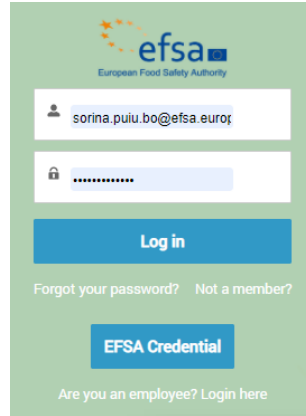
Buttons: Notify, Share With, Withdraw Study




Step2a – Business Operator Co-notifies the Study




Log in/Register

efsa
European Food Safety Authority

 sorina.puiu.bo@efsa.europa.eu





Log in

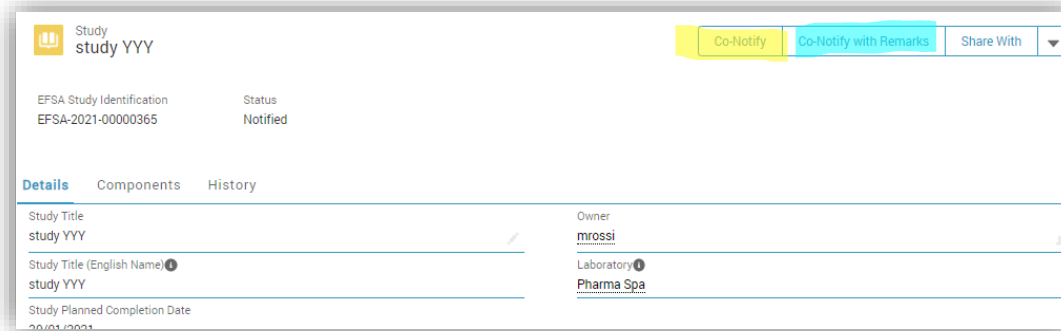
Forgot your password? Not a member?


EFSA Credential

Are you an employee? Login here



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						
<input type="text" value="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

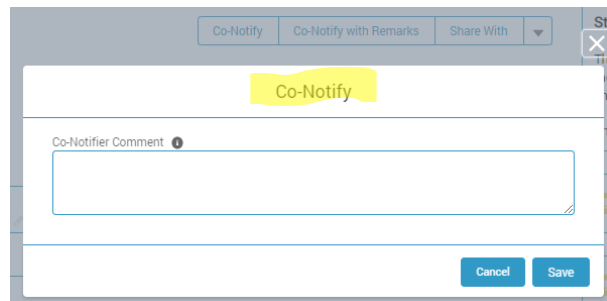
Study Title
study YYY

Study Title (English Name) ⓘ
study YYY

Study Planned Completion Date
20/01/2021

Owner
mrossi

Laboratory ⓘ
Pharma Spa

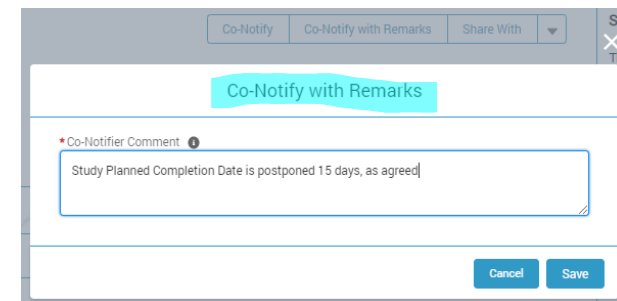


Co-Notify

Co-Notifier Comment ⓘ

Cancel **Save**

OR



Co-Notify with Remarks

Co-Notifier Comment ⓘ

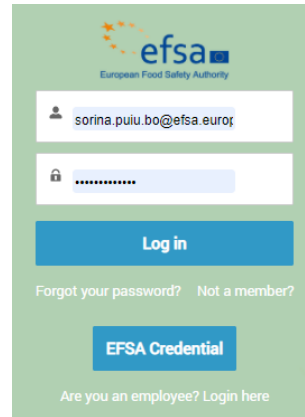
Study Planned Completion Date is postponed 15 days, as agreed

Cancel **Save**

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



Log in/Register



efsa
European Food Safety Authority

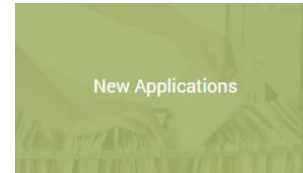
sorina.puiu.bo@efsa.europa.eu

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, User/ContactID

	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



Add Studies to Pre-Application ID

Search Studies...

Selected Studies: 1

EFSA-2021-00000378 X

Study Number	Name	Food Domain	Created Date
<input type="checkbox"/> EFSA-2020-00000119	Study 1 UAT	Feed Additives	25-Sep-2020
<input type="checkbox"/> EFSA-2020-00000112	bo nos FINAL	Feed Additives	24-Sep-2020
<input type="checkbox"/> EFSA-2020-00000105	validation 6	Novel Foods	24-Sep-2020
<input type="checkbox"/> EFSA-2020-00000100	study validation check		24-Sep-2020
<input type="checkbox"/> EFSA-2020-00000078	Study for training NoS	Food Contact Material	22-Sep-2020
<input checked="" type="checkbox"/> EFSA-2021-00000378	Study YYY	Feed Additives	18-Jan-2021
<input type="checkbox"/> EFSA-2021-00000376	Study 2	Pesticides	18-Jan-2021
<input type="checkbox"/> EFSA-2021-00000355	77	Feed Additives	17-Jan-2021
<input type="checkbox"/> EFSA-2021-00000347	Study test	Biological Hazards - Animal by-products	14-Jan-2021

Next



Pre-Application ID

My new request for a pre-application ID

New Study Add Studies Ask PSA

ID: EFSA-ID-2021-000280

Details Components History

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

Business Operator: ABC company Spa

Subject of the Application: New food additive to be released on the market

Other Components:

Notes:

Creation Details

Created Date: 19/01/2021

Food Domain: Food Improvement Agents

Authorisation Type: Food Additives Authorisation

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

Created By: Sorina Puiu Business Operator, 19/01/2021 18.44

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)

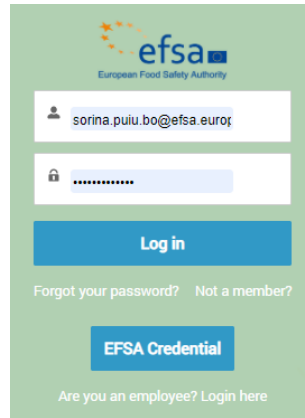
Study Title	EFSA Study Identification	Status
New Study SP	EFSA-2020-00000176	Notified
Efficacy of FLEXFEED ...	EFSA-2020-00000196	Notified
my new intended stud...	EFSA-2020-00000280	Draft
Study YYY	EFSA-2021-00000378	Draft

View All

Step3 – Business Operator Reuses Notified Studies for Other Pre-submission Activities



Log in/Register



efsa
European Food Safety Authority

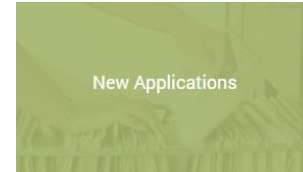
sorina.puiu.bo@efsa.europa.eu

Log in

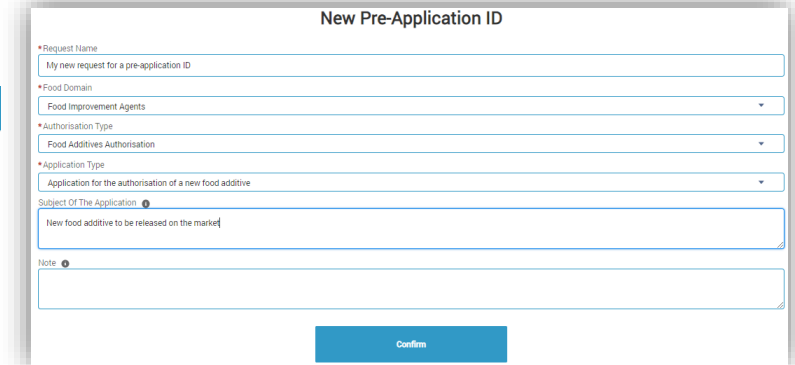
Forgot your password? Not a member?

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

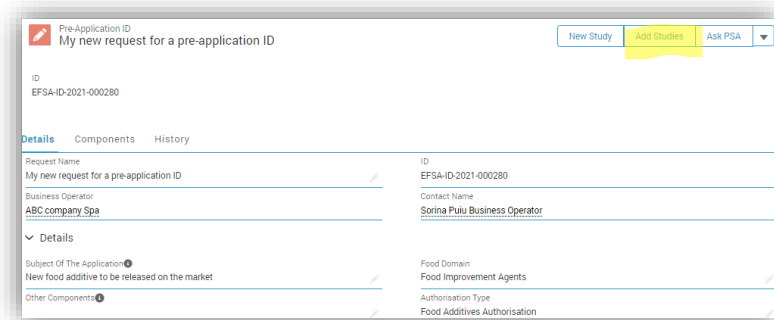
Authorisation Type
Food Additives Authorisation

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

Business Operator
ABC company Spa

Details

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

Other Components

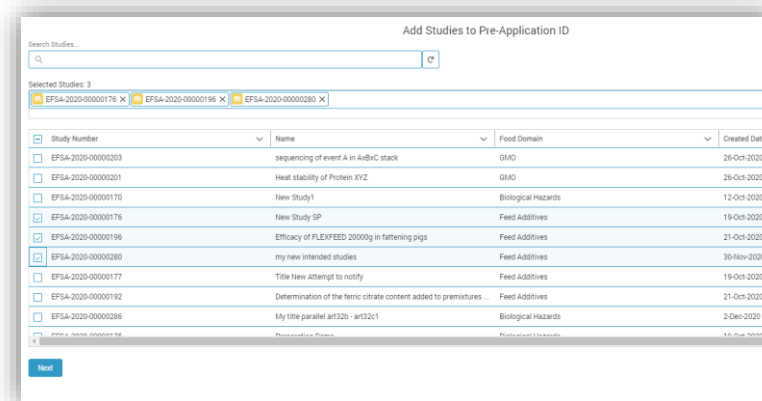
ID
EFSA-ID-2021-000280

Contact Name
Sorina Puiu Business Operator

Food Domain
Food Improvement Agents

Authorisation Type
Food Additives Authorisation

Add Studies



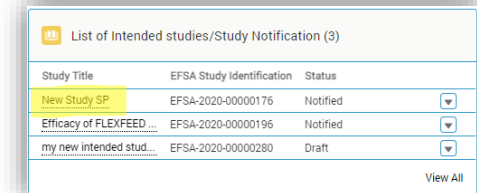
Add Studies to Pre-Application ID

Search Studies

Selected Studies: 3

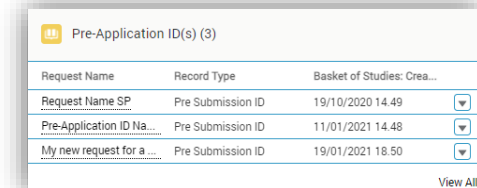
Study Number	Name	Food Domain	Created Date
<input checked="" type="checkbox"/> EFSA-2020-00000176 X	sequencing of event A in AxBxC stack	GMO	26-Oct-2020
<input type="checkbox"/> EFSA-2020-00000203	Heat stability of Protein XYZ	GMO	26-Oct-2020
<input type="checkbox"/> EFSA-2020-00000170	New Study1	Biological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

Next



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



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

