Notification of studies and pre-submission advice

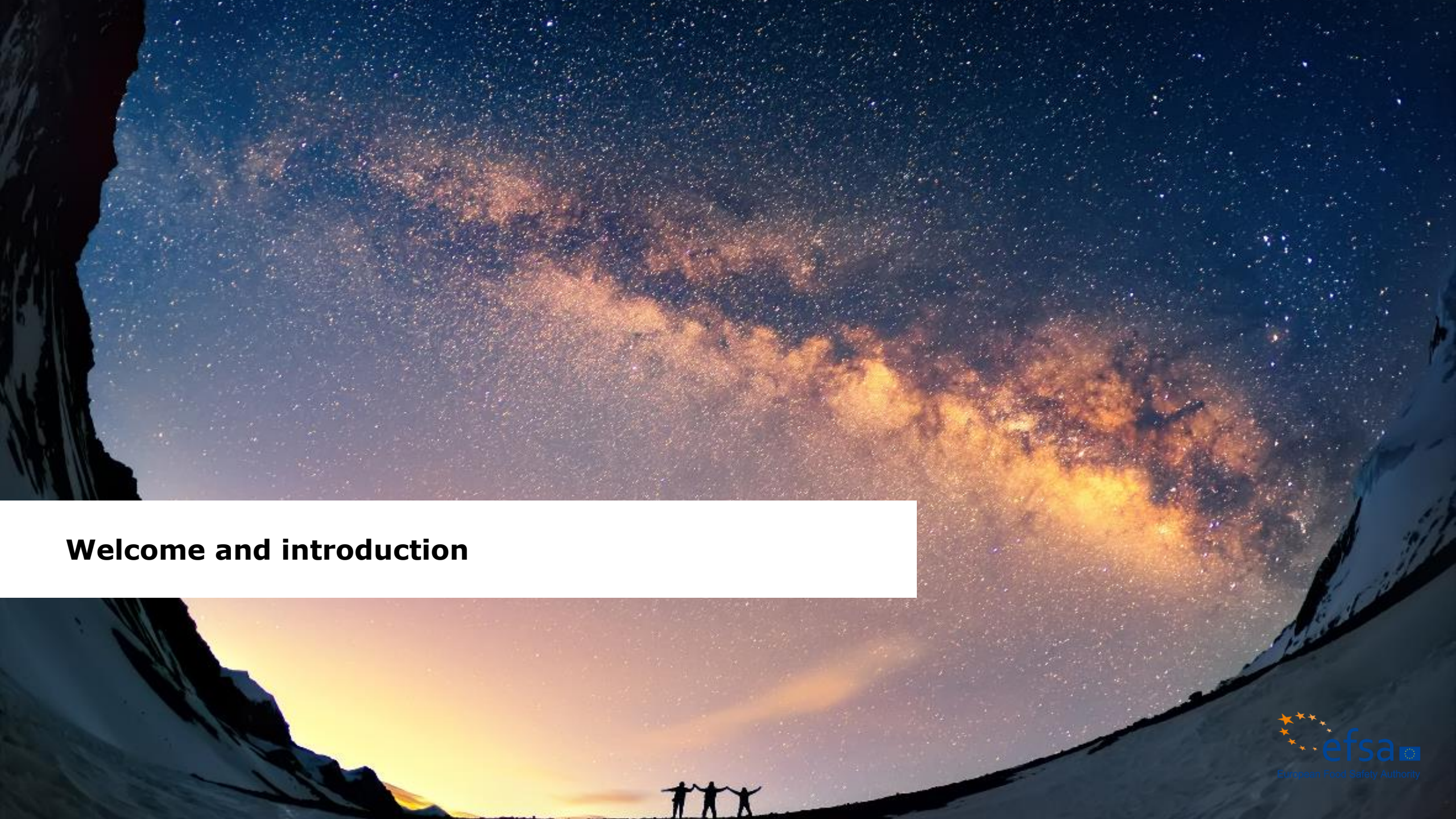
Webinar

16/02/2021

Trusted science for safe food

European Food Safety Authority

Welcome and introduction



Welcome and introduction

Who we are

Presenters of this session:

- Stefano Cappè (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). You may use the **chat box** for your questions:

- Questions shall be in English
- 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.
- Questions about technical aspects, NoS-DB and PSA, unanswered during this session, will be used to define specific case-studies to present during next webinar on **16 March**

This session is recorded, the materials will be available on the EFSA website

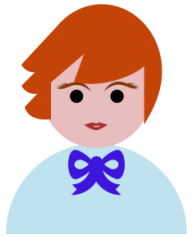
Agenda

Time	Topic	Speaker
09.30 – 09.35	Introduction and webinar outline	*Stefano*
09.35 – 09.45	Registration	*Sorina*
09.45 – 09.50	Pre-application identification	*Stefano*
09.50 – 10.05	Notification of studies	*Sorina*
10.05 – 10.15	General Pre-Submission Advice	*Remigio*
11.15 - 10.30	Notification of the list of intended studies and renewal Pre-Submission Advice	*Stefano*
10.30 - 11.00	Q&A session	*All*

Registration

efsa
European Food Safety Authority

The Actors



Sarah

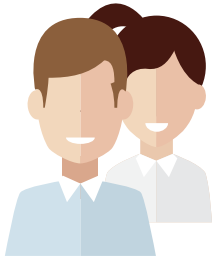
Business Operators
Potential Applicants

John

Laboratories
Testing facilities

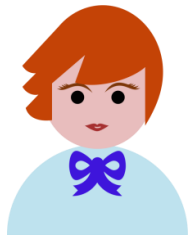
Martin

Third Parties



The public
(during PC or once studies are published)

Registration Process



Sarah

Business Operator
Potential Applicant

John

Laboratories
Testing facilities

Martin

Third Parties

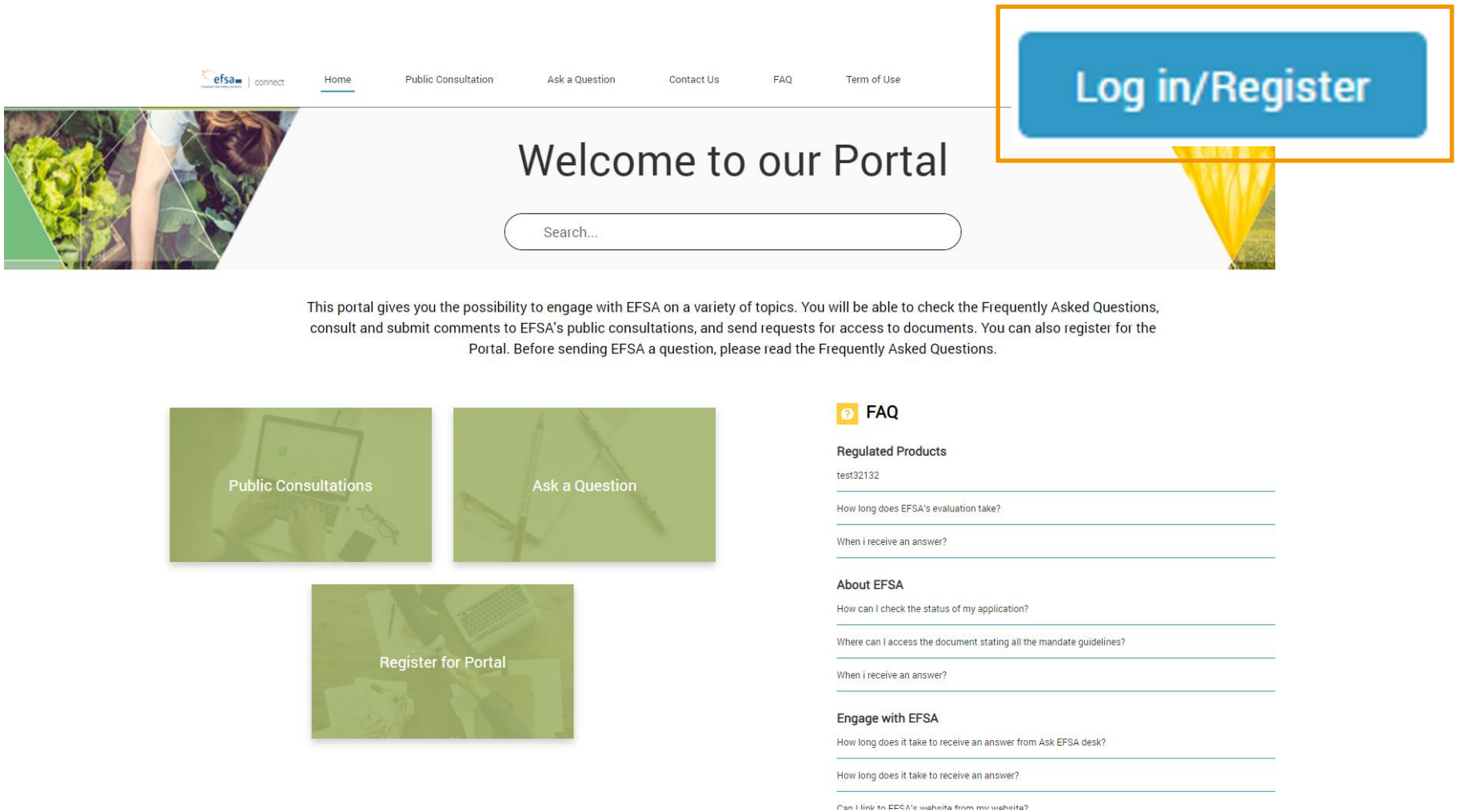
1. In order to initiate a pre-submission activity, a potential applicant or a laboratory or testing facility to which a study has been commissioned shall first register in the system …[1]

2. Third parties authorised to represent one or more entities referred to in paragraph 1 shall also register in the Authority system supporting pre-submission activities …[1]

3. Registered entities shall ensure that all information provided is reported accurately and kept up-to-date.[1]

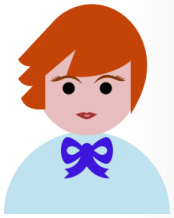
[1]) Practical arrangements on pre-submission phase and public consultations

Welcome to our Connect.EFSA Portal



https://connect.efsa.europa.eu/RM/s/

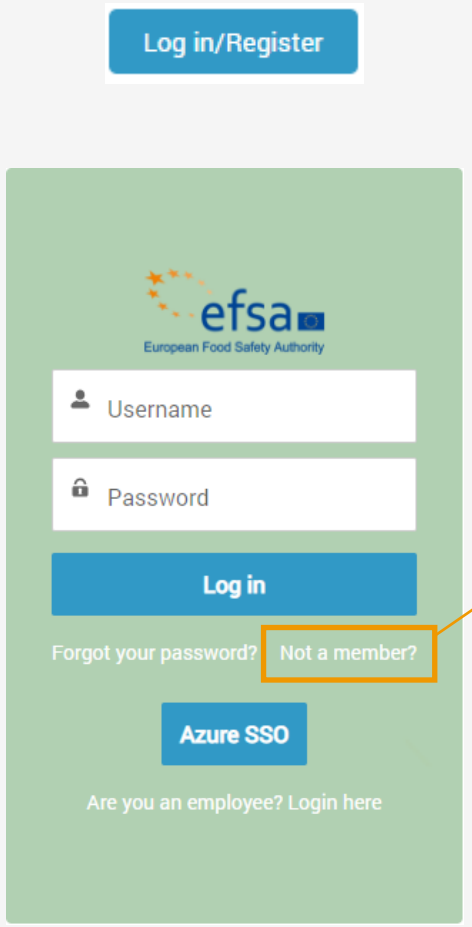
Registration Steps

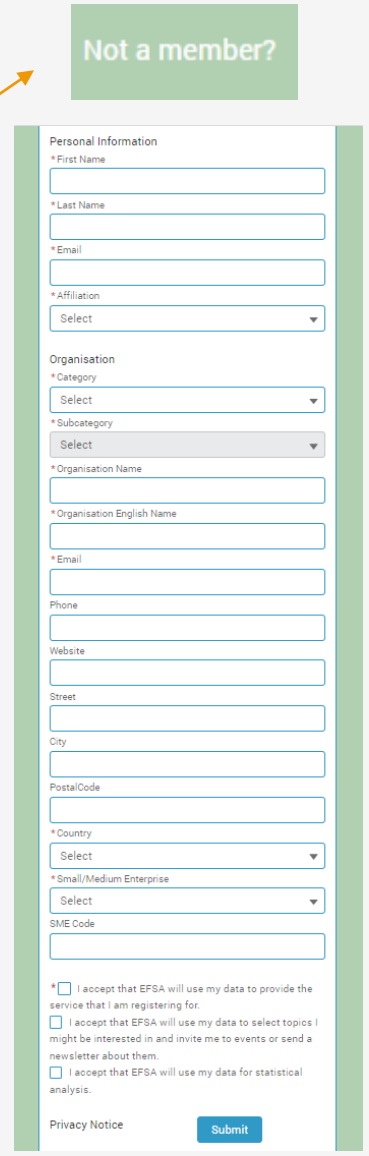


Sarah

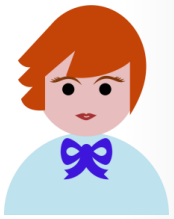
John

Martin



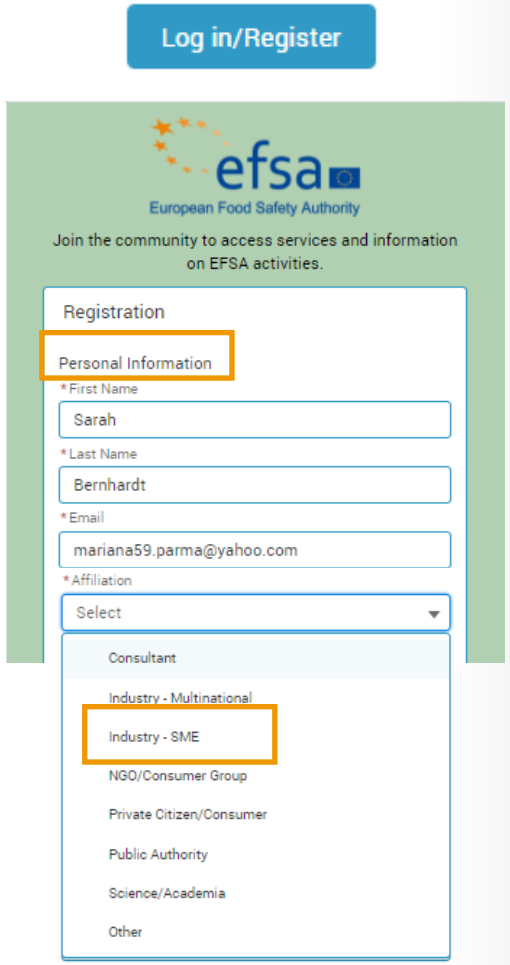


Registration Steps – Business Operator

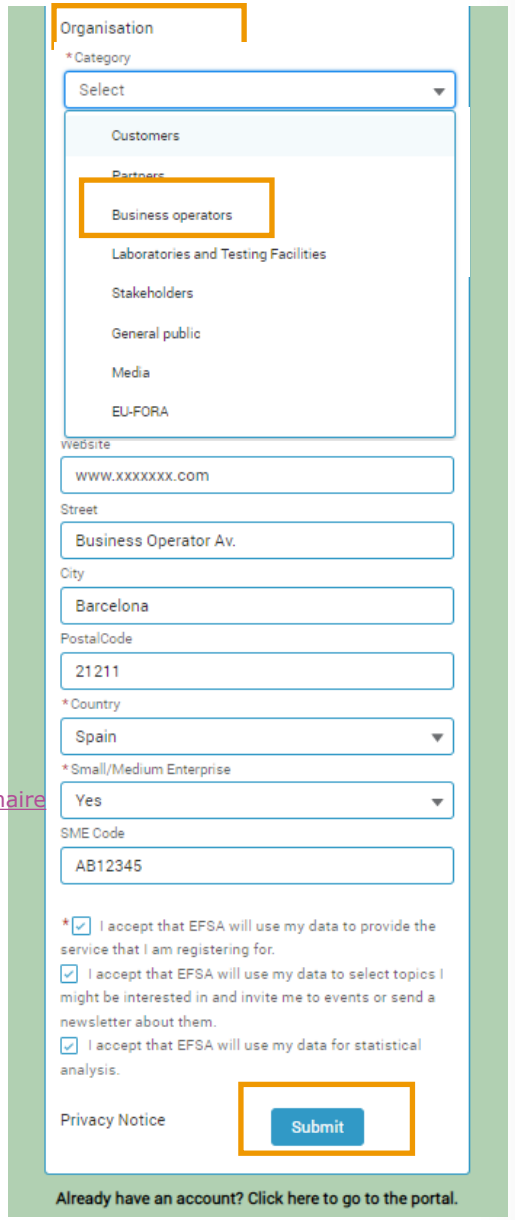


Sarah

Contact Details



Account Details



SME self-assessment questionnaire

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

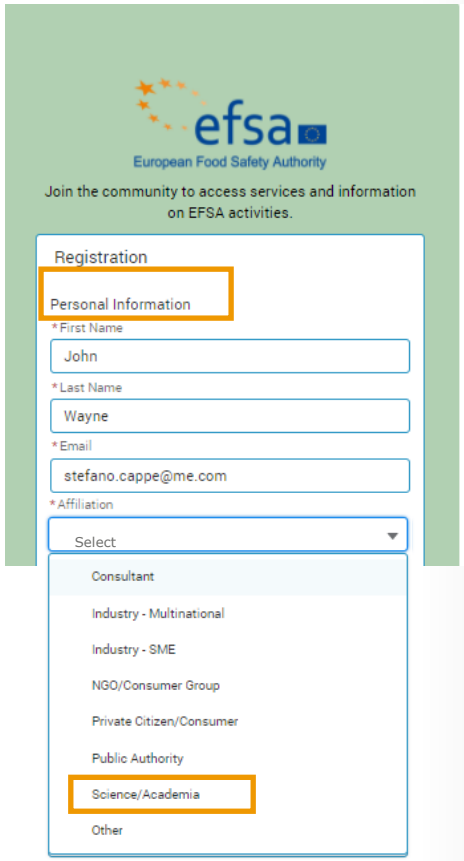
Video tutorial on registration of an account

Registration Steps – Laboratory/Testing Facility

John

Contact Details

Log in/Register



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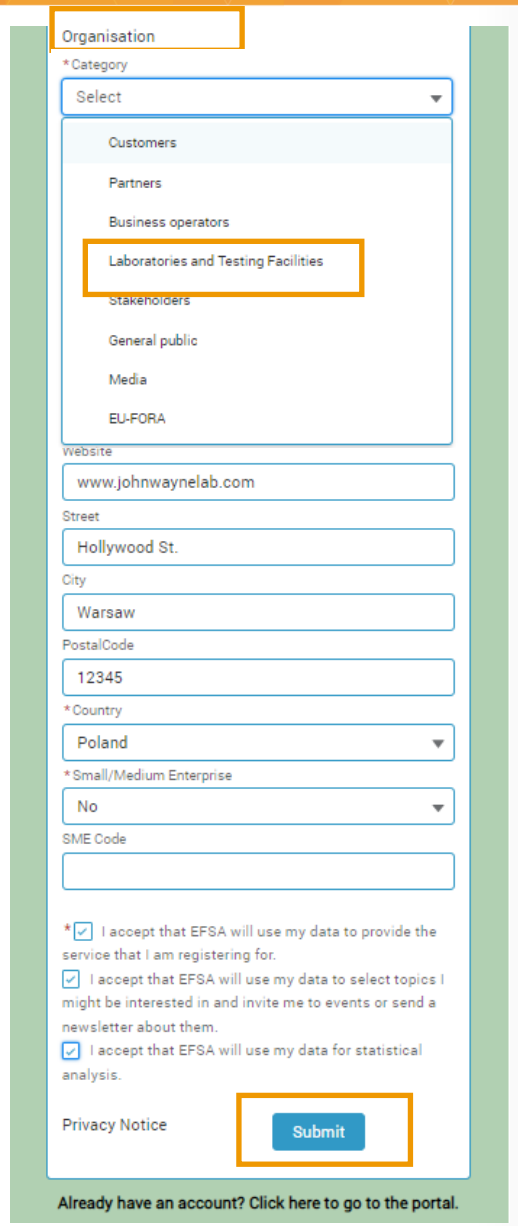

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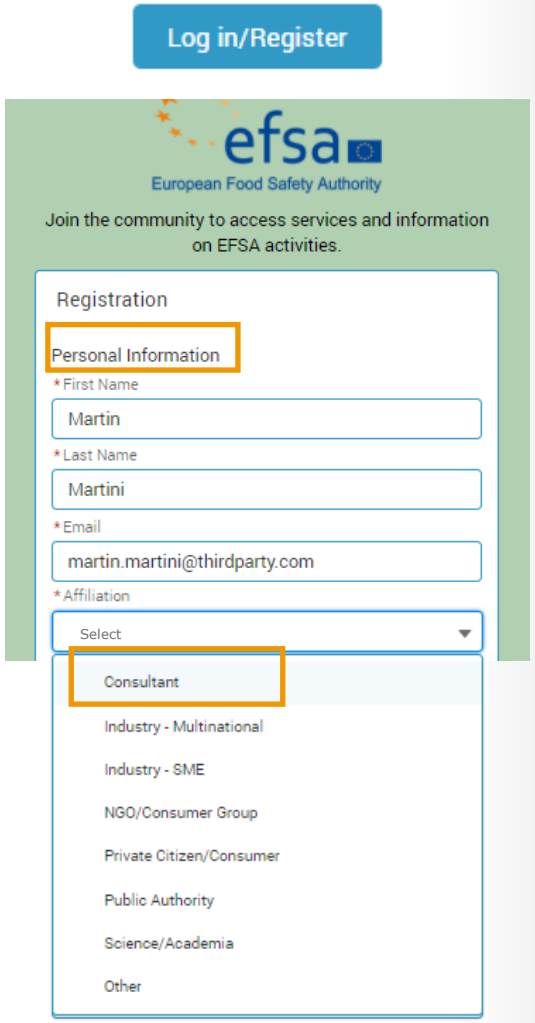
[Video tutorial on registration of an account]

Registration Steps – Third Party

Martin

Contact Details



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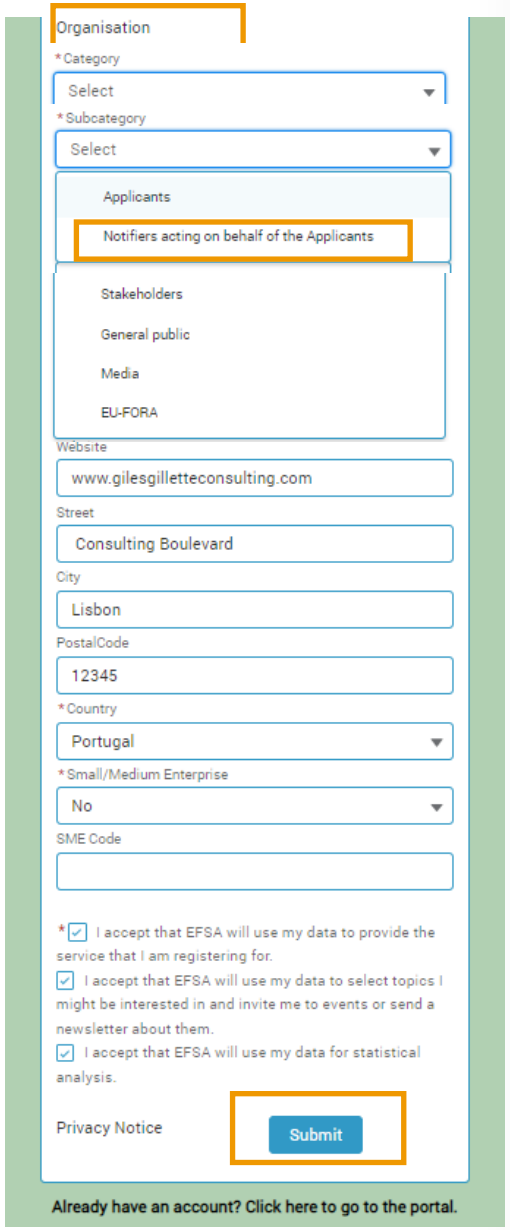

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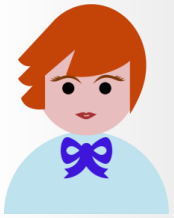
[Video tutorial on registration of an account]

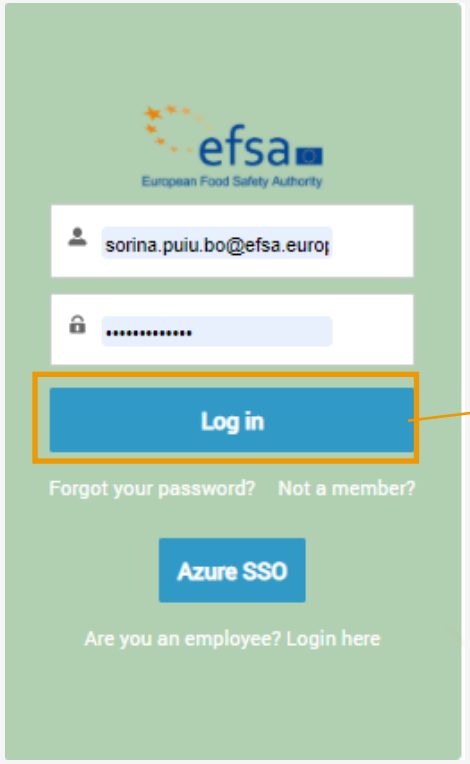
Adding Contacts to an Account



Sarah

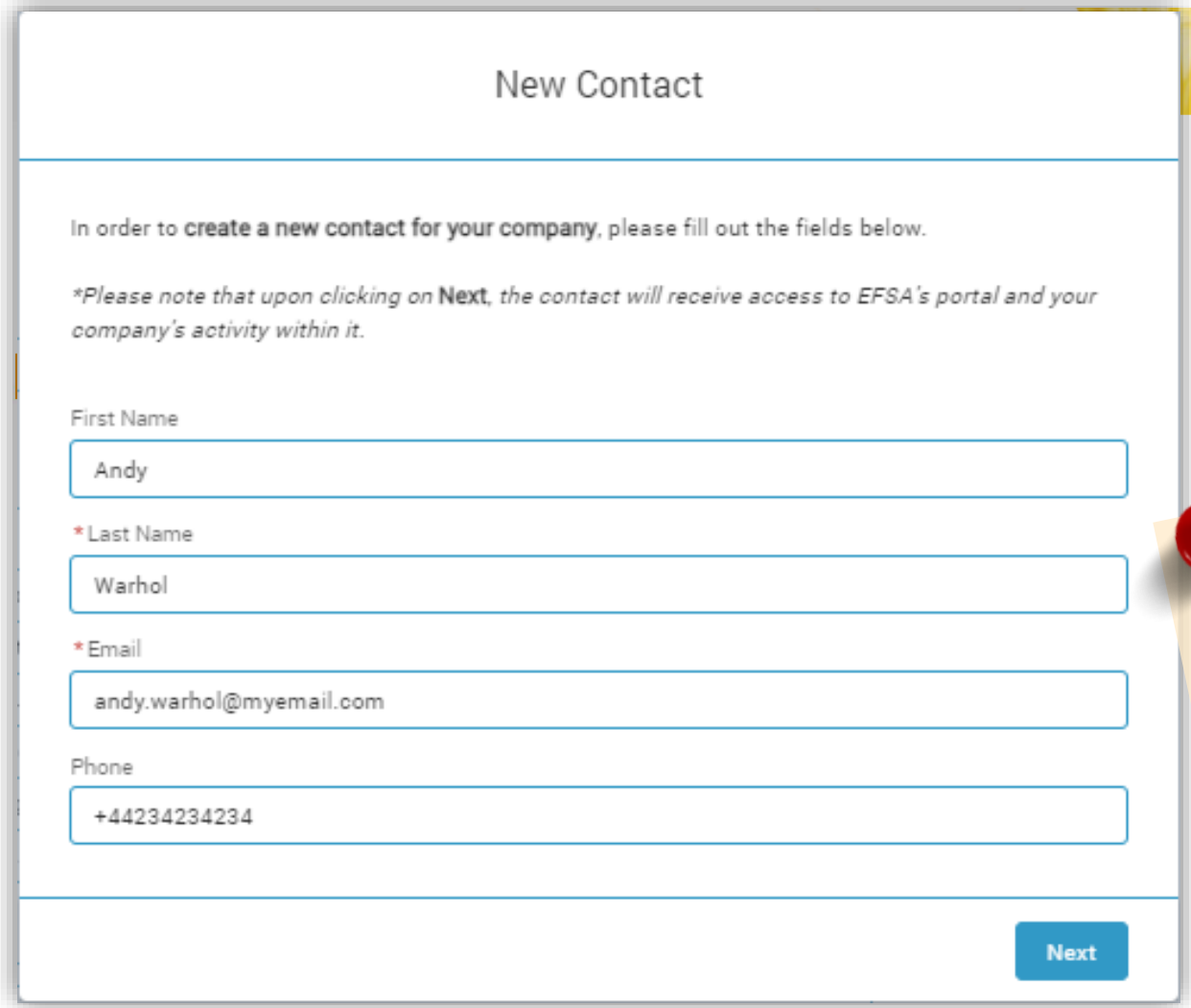
John

Martin



Video tutorial on registration of an account

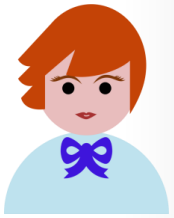
Adding Contacts to an Account



The new contact will receive a Reset password email triggered upon EFSA validation of the registration request

[Video tutorial on registration of an account]

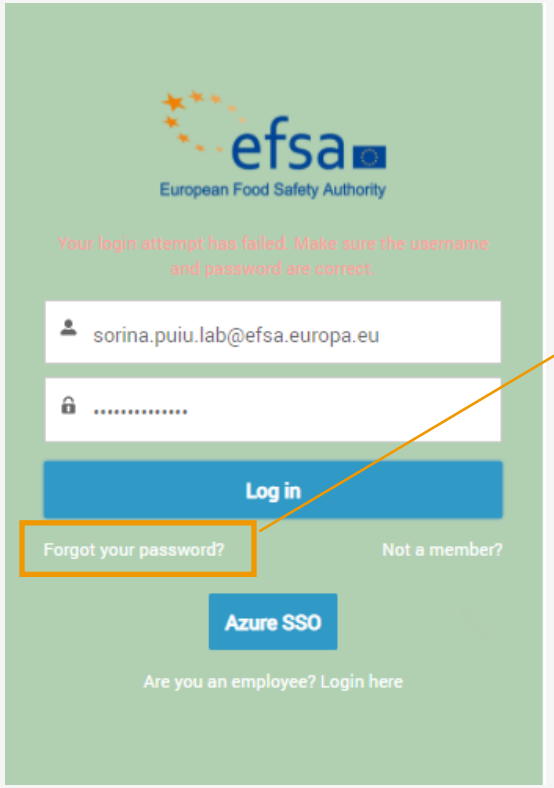
Reset Your Password

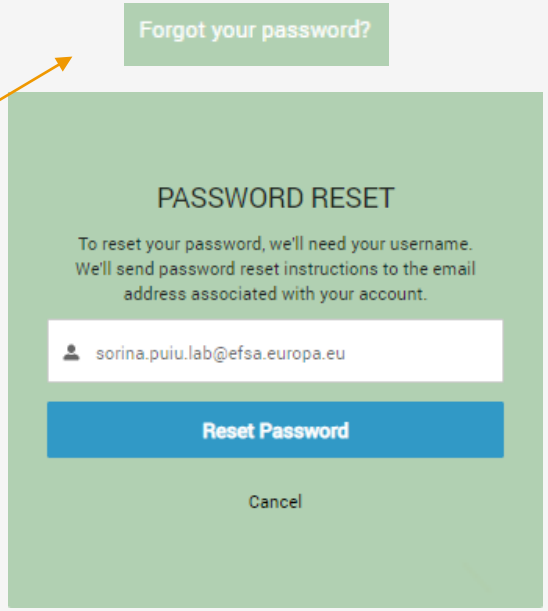


Sarah

John

Martin





NOW CHECK YOUR EMAIL

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Video tutorial on registration of an account

Pre Application Identification

Background for today's session

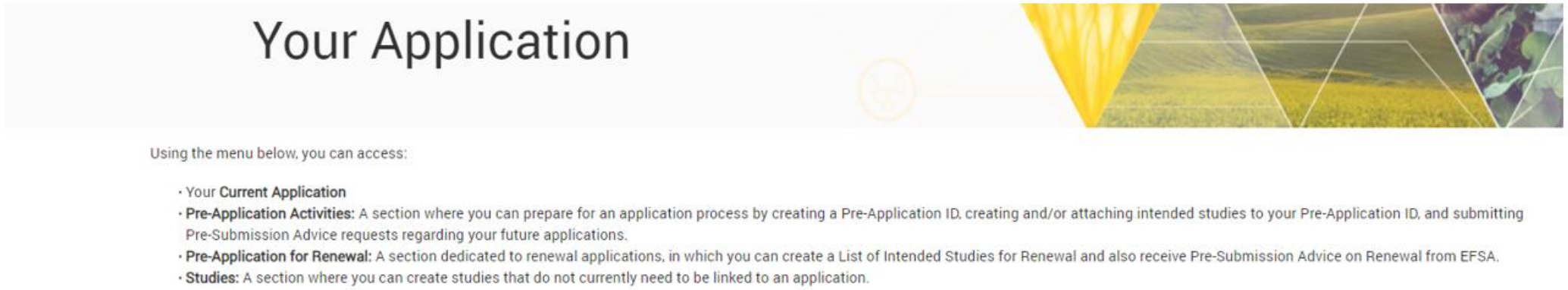
1. Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain (Transparency Regulation)

2. General pre-submission advice
   - Article 32a

3. Notification of studies for applications
   - Article 32b

4. Notification of intended studies for renewal application, public consultation and renewal pre-submission advice
   - Article 32c(1)

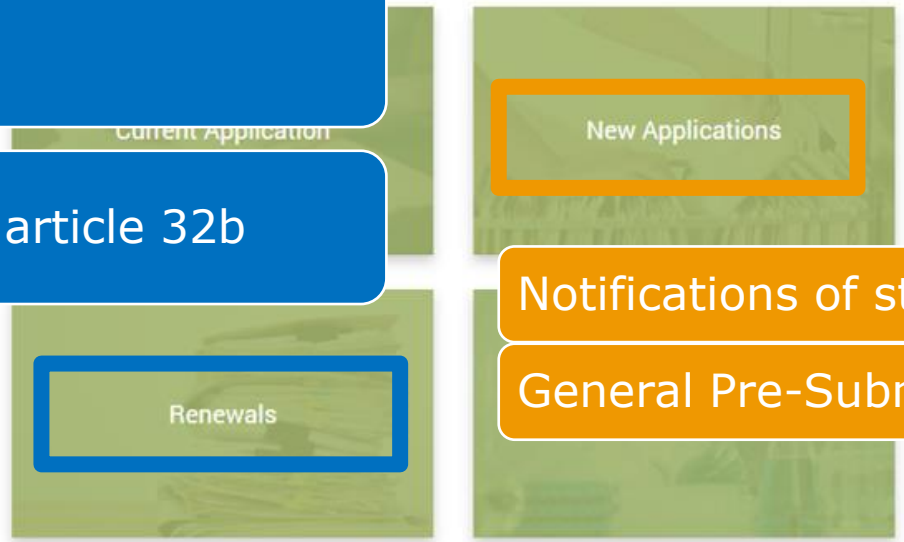
Your application sections



List of intended studies for renewal according to article 32c(1), PC and renewal PSA

General Pre-Submission Advice

Notifications of studies according to article 32b



Notifications of studies according to article 32b

General Pre-Submission Advice

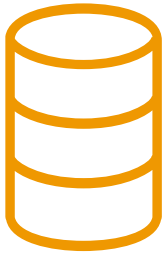
General Pre-Submission Advice

General Pre-Submission Advice

Sarah

The potential applicant gets the pre-application-ID

The potential applicant can ask pre-submission advice anytime



Pre-Submission Advice tool

General Pre-Submission Advice

EFSA provides advice

Step 3
Validation of application

EFSA publishes summary of Pre-Submission advice after application is declared valid/admissable

Notification of Studies for New Applications

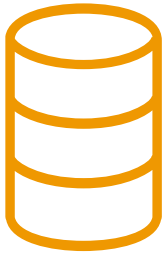
Step 1
Pre-submission phase

Sarah

John

The **Business Operator** gets the Pre-Application-ID

Both actors
Notify Studies (Article 32b)



Database of Study Notifications

Step 2
Submission of application

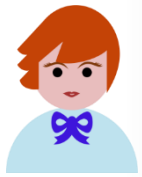
EFSA performs the validation of the application

Step 3
Validation of application

EFSA publishes study notifications with related studies after confidentiality decision making process

Notification of Studies for Renewal Application

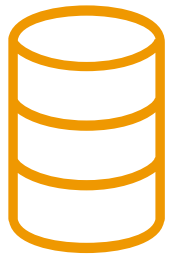
Step 1
Application renewal



Sarah

The potential applicant gets the Pre-Application-ID for renewal

The potential applicant submits the list of Intended studies and study design (Article 32c1)



Database of Study Notifications

Step 2
Public consultation and R-PSA

EFSA provides advice

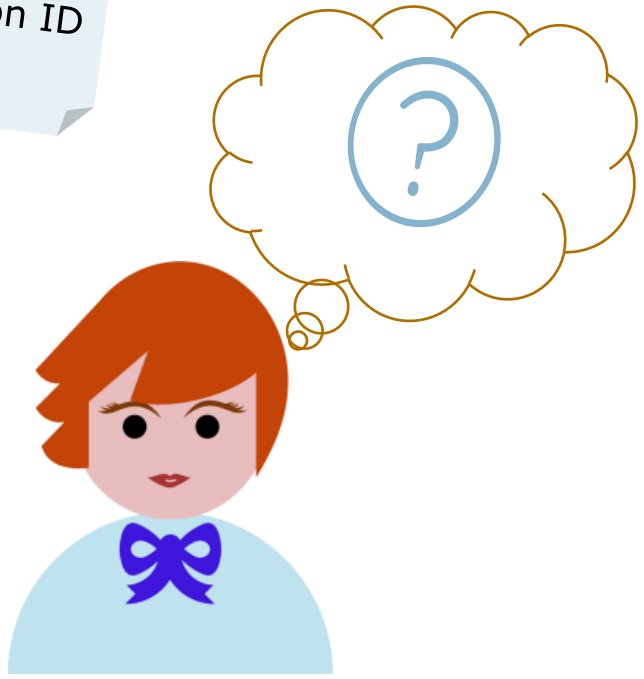
Step 3
Notify studies

Sarah

The potential applicant notifies Studies (Article 32b)

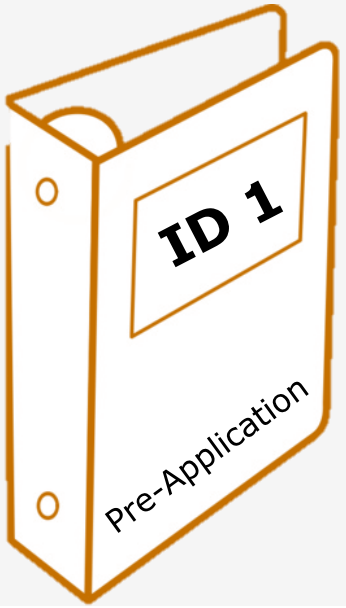
Pre-Application Identification

The pre-application ID is like a "folder"

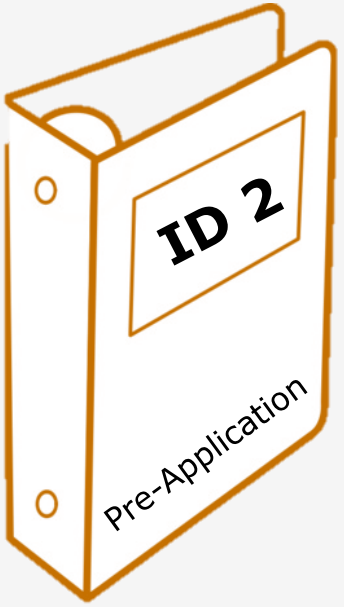


Sarah

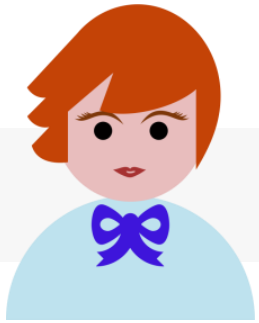
- *Notify Study 1*
- *Notify Study 2*
- *Notify Study 4*



- *Notify Study 3*
- *Notify Study 5*
- *Notify Study N*



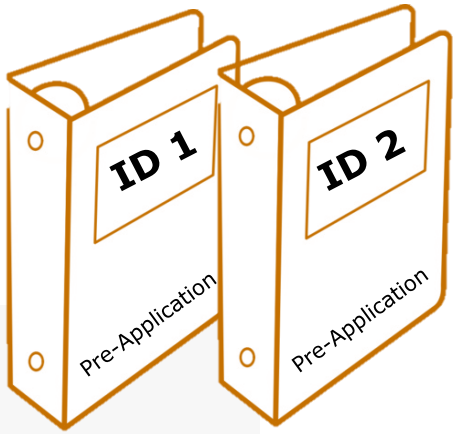
Pre-Application-IDs help in dossier validation



Sarah

Submits
the dossier

Reports
Pre-Application IDs



Finds
relevant
notifications

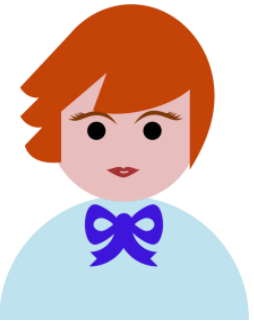
NoS-DB

Intended Applications and Pre-Application-Ids

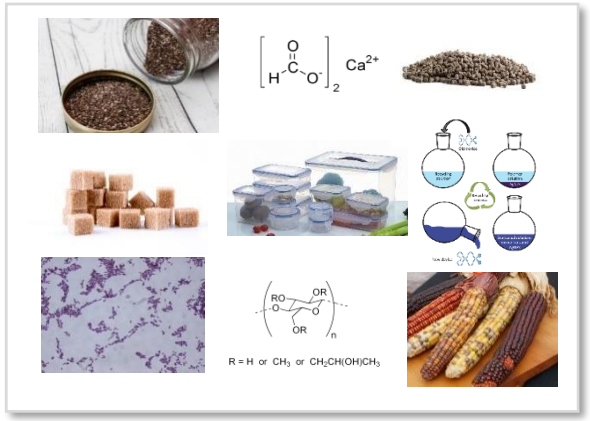
New
(and modifications)
applications

Renewal

Pre-Application Identification



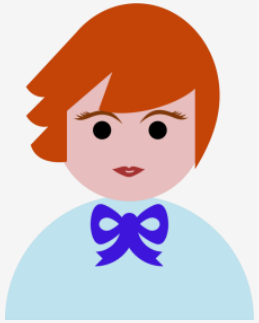
Sarah
Business Operator(s)



Subject of the application

Intended Area

Pre-Application Identification for Renewal



Sarah

Requests
Pre-Application-ID
for Renewal

Additional features of Pre-Application Renewal

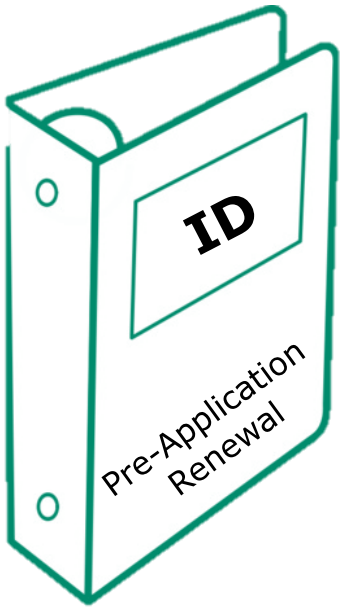
Reference MS

(If applicable)

Former application ID

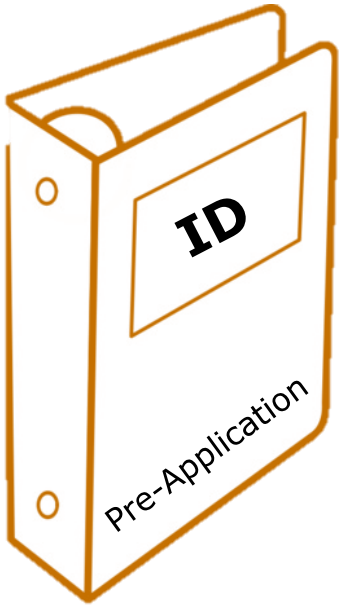
List of intended studies

Intended studies



Is similar to

≈



Practical Arrangements

Remember from the practical arrangements that..

- Prior to initiating any pre-submission activity, potential applicants shall request the Authority to provide a pre-application identification ('ID')

- The pre-application ID 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.

Link to the Practical Arrangements

Notification of Studies (NoS)

efsa
European Food Safety Authority

Notification of studies

Transparency Regulation[1] Article **32b**

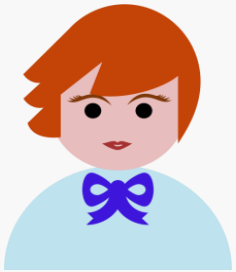
1 The Authority shall establish and manage **a database** of **studies commissioned or carried out** by business operators to support an application …

2 For the purposes of paragraph 1, **business operators shall**, without delay, **notify the Authority** …

3 For the purposes of paragraph 1, **laboratories and other testing facilities** located in the Union **shall also**, without delay, **notify the Authority** …

1) Regulation (EC) No 178/2002 as last amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain (aka General Food Law)

Business Operator



Sarah

is notifying studies for a **Business Operator**

Notifying a Study as Business Operator

Sarah

The Business Operator is preparing for notifying

New future application?

YES

Request pre-application ID

NO

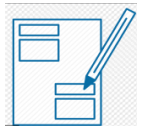
Retrieve pre-application ID

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

Draft

Fill-in mandatory fields & **Notify**

Notified



Study performed by internal facility?

YES

END

NO

Alert Email to Lab

Laboratory/Testing facility

John

is notifying studies for the **Laboratory/Testing facility**

Laboratory/Testing facility co-notifies Study

Alert
Lab

John

New
Study
co-notification

Not a member?

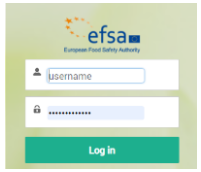
YES

Register

Register Here

NO

Login



Check
Notification

Co-Notify

Co-Notify
with remarks

END

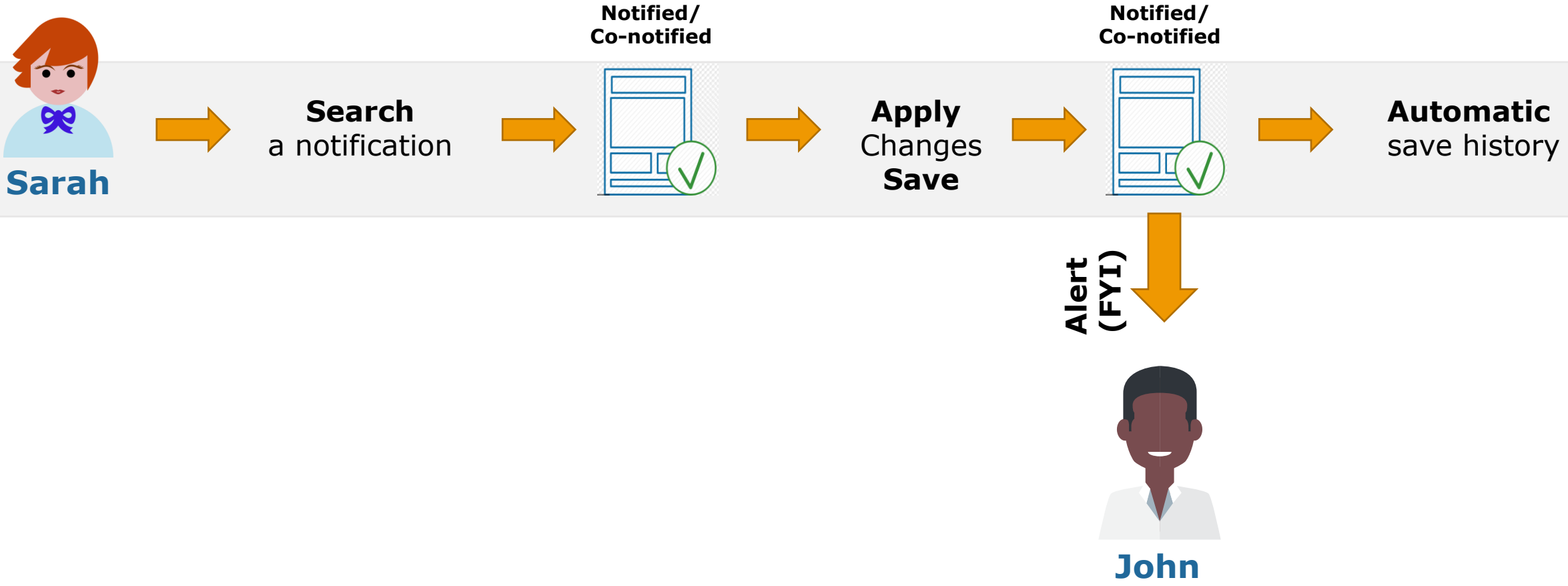
No
co-notification

30 days

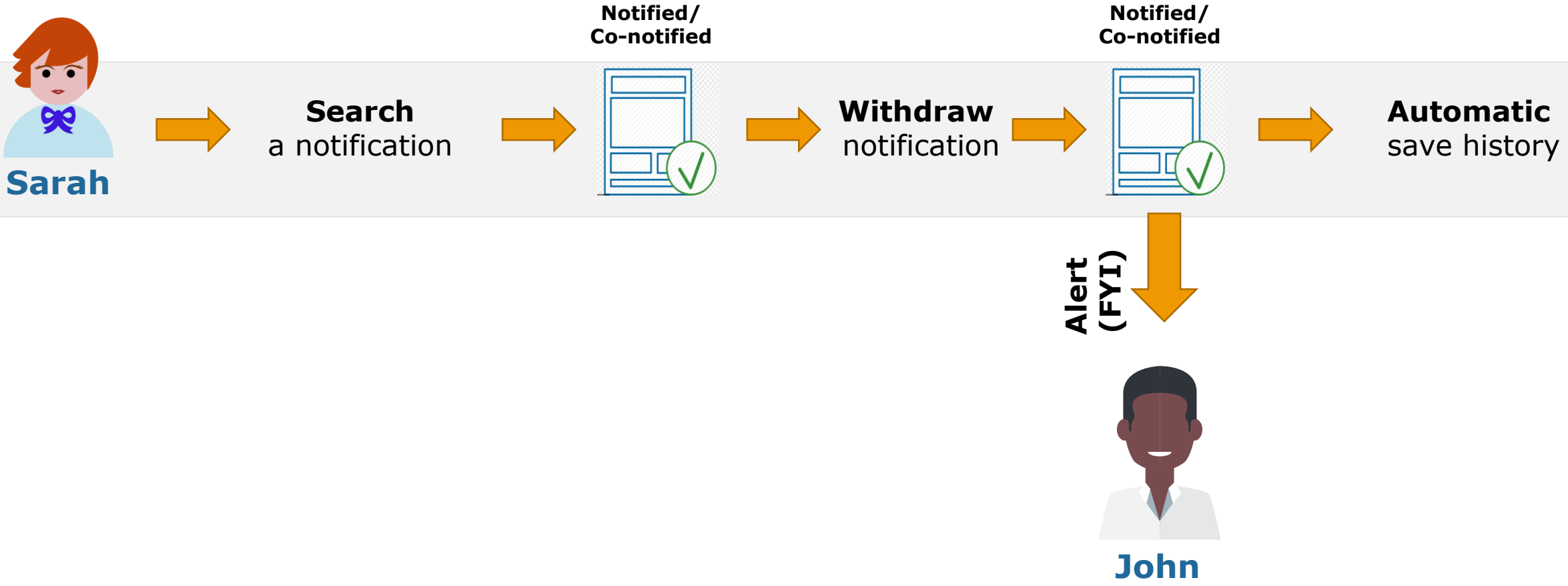
Notified

END

Business Operator Modifies Notifications



Business Operator Withdraws Notifications



Notifying a Study as Laboratory

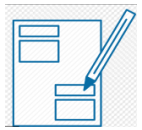
John

Create new study notification

Draft

Fill-in mandatory fields &
Notify

Notified



Alert
Business Operator

Business Operator co-notifies Study

Alert
BO

Sarah

New Study
co-notification

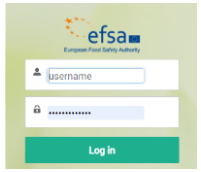
YES

Not a member?

Register

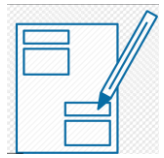
NO

Login

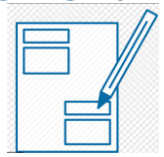


Check Notification

Co-Notify



Co-Notify with remarks



END

No
co-notification

30 days

Notified

END

Laboratory Modifies Notifications

John

Search
a notification

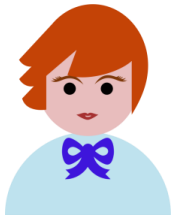
Notified/
Co-notified

Apply
Changes
Save

Notified/
Co-notified

Automatic
save history

Alert
(FYI)



Sarah

Laboratory Withdraws Notifications

John

Search
a notification

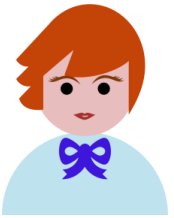
Notified/
Co-notified

Withdraw
notification

Notified/
Co-notified

Automatic
save history

Alert
(FYI)



Sarah

Information to be notified - Article 32b

Legend

- Mandatory
- Optional
- Group of elements

Study Title (M) – Free text: title of the study

Study Title (O) – Free text: (English name) title of the study in English language

Study Starting Date (M) – Date: starting date of the study

Study Planned Completion Date (M) – Date: planned completion date of the study

Study scope (G): Section composed of multiple elements. See next slide

Study Scope - Article 32b

Legend
- Mandatory
- Optional
- Group of elements

Study intended area (M) – Choose from list: shall report the regulated product area of the future application that the study is meant to support

Study type (M) – Choose from list: shall report the type of the study

Study international standard certification (M) – Choose from list: shall report the standard certification of the study (GLP, ISO, etc)

Study objective (M) – Free text: shall report the narrative describing the objective of the study

Study internal reference id (O) – Free text: shall report the identifier of the study as assigned by the business operator/laboratory or testing facility

Study Scope - Article 32b

Legend

- Mandatory
- Optional
- Group of elements

Test item (M) – Free text: shall report the identification of study test item. Depending on the type of test item, information on its **components** (for chemical productions substances and metabolites, microorganisms, GMOs) shall also be provided

Components (M) – if applicable: shall report the identification of substances, microorganisms, GMO Names: (GMO Unique identifier, Protein name). It is possible to select from pick lists or report free text.

General Pre-Submission Advice (G-PSA)

efsa
European Food Safety Authority

Background

Transparency regulation Article **32a**

1. **Applications meet the applicable specifications** in order to ensure the best quality scientific assessment

2. **Rules** applicable to, and the **content** required for, the application, prior to its submission. Should not address the design of the studies to be submitted

3. Small and medium sized enterprises **-SMEs-**

Regulation (EC) No 178/2002 as last amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain

General Pre-submission Advice - Business Operators

Sarah

Potential applicant may **request** general pre-submission advice at **any time**

Requests for general pre-submission advice

Submit to EFSA

HOW?

Link requests to the individual or joint pre-application ID

Fill in the general pre-submission advice form available on the EFSA's website

Submit questions

Up to 2 G-PSA per pre-app ID

General Pre-submission Advice form

Conditions of use/intended uses

Background information on the subject

List of questions

General Pre-submission Advice - EFSA

Receipt of the general pre-submission advice form

Step 1
Administrative Check

EFSA verifies that the related questions **fall within the scope**

Within **15 working days** from the receipt, EFSA informs the requester as to whether the request is **accepted or rejected**.

Step 2
Written or meeting

Where possible, EFSA shall answer the questions in **writing**

A meeting might be organised by EFSA

Step 3
Provide the Advice

The written advice shall be provided within **15 working days** as of the date of the acceptance of the request;

The meeting shall be organised within **20 working days** as of the date of the acceptance of the request

Step 4
Summary of the PSA

EFSA draws up a **summary** providing an overview of the advice and sends it to the requester for information

Pre-submission Advice - Business Operators

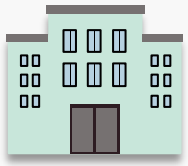
Sarah

Potential applicants may **request** general pre-submission advice at **any time**

Requests for general pre-submission advice

Submit to EFSA

Cooperation



Submit to the National Authority

EFSA shall provide the requester(s) with its advice **in close cooperation** with the following national competent authorities:

1. The Member State to which the application is going to be submitted, the **intended** rapporteur Member State and, where applicable, the **intended** co-rapporteur Member State

Plant protection products and maximum residue levels of pesticides ONLY

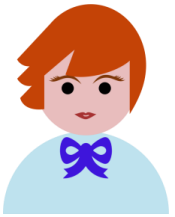
2. The **intended** evaluating Member State

3. The **designated** rapporteur Member State/co-rapporteur Member State.

Non-committal nature of G-PSA

Any subsequent **assessment of applications** by EFSA and the Member States

The **assessment of the** qualification of the specific regulated product under a given **regulated product area**

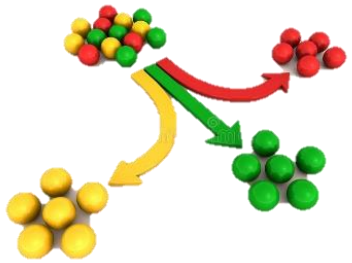


Sarah

The **potential applicant** shall not be bound by any general pre-submission advice

Submission of the application

EFSA **receives** the application



Segregation of task

Validity

Publication of the summary

List of Intended Studies for Renewal and Renewal Pre-Submission Advice

efsa
European Food Safety Authority

List of intended studies for renewal

Transparency Regulation Article **32c(1)**

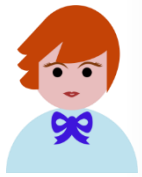
1. Where the relevant Union law provides that an approval or an authorisation may be renewed, the potential applicant shall **notify the Authority of the studies it intends to perform** for that purpose, including information on how the various studies are to be carried out.

2. Following such notification of studies, the **Authority shall launch a consultation of stakeholders** and the public on the intended studies for renewal, including on the proposed design of studies.

3. Taking into account the received comments which are relevant for the risk assessment of the intended renewal, **the Authority shall provide advice on the content** of the intended renewal application or notification, as well as on the **design of the studies**

Notification of Studies for Renewal Application

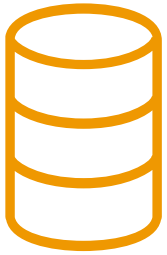
Step 1
Application renewal



Sarah

The potential applicant gets the Pre-Application-ID

The potential applicant submit the list intended studies and study design (Article 32c1)



Database of Study Notifications

Step 2
Public consultation and R-PSA

EFSA
Provides advice

Step 3
Notify studies

Sarah

The potential applicant notifies studies (Article 32b)

Intended Studies for Renewal - Article 32c1

Legend

- Mandatory
- Optional
- Group of element

Study Title (M) – Free text: title of the study

Study Title (O) – Free text: (English name) title of the study in English language

Former application id (M)– Free text: shall contain the identifier of the application to be renewed (e.g. former EFSA question number)

Study scope (G): Section composed of multiple elements. See next slide

Study Scope - Article 32c1

Legend
- Mandatory
- Optional
- Group of element

Study intended area (M) – Choose from list: shall report the regulated product area of the future application that the study is meant to support

Study type (M) – Choose from list: shall report the type of the study

Study objective (M) – Free text: shall report the narrative describing the objective of the study

Test item (M) – Free text: shall report the identification of study test item.

Components (O) – if applicable: Depending on the type of test item, information on the test item **components** (for chemical productions substances and metabolites, microorganisms, GMOs) shall also be provided

Design of study

Legend
- Mandatory
- Optional
- Group of elements

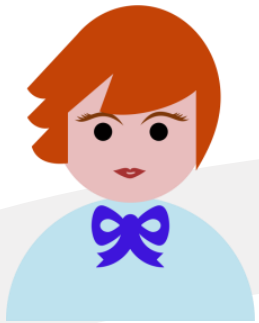
Study guideline (M) – Choose from list:
shall report the guideline or guidance document to be followed by the study

OR

Study design description (M) – Free text:
shall contain the description of the design of study including the hypothesis

Study detailed protocol (O) – Free text:
shall contain more detailed information and further elaborating methodology, statistical considerations, and organization of a study. The protocol usually gives the background and rationale for the study.

Building the list of intended studies for renewal



Sarah

New/**find** list of Intended Studies

List of intended studies for renewal

Add Intended Studies to List

Intended studies

Complete List

Repeat steps until list is completed

Submit

Public consultation on intended studies for renewal

National CA

Plant protection products ONLY

Receipt of the list of intended studies for renewal

Step 1
Administrative Check

EFSA launches the consultation of third parties on the **intended studies** for renewal

Including on the proposed **design** of the studies

Within 10 working days from the completion of the administrative check

Step 2
Public consultation

The consultation of third parties shall remain open for a period of **three weeks**

Step 3
Comments

All **comments received** by stakeholders and the public shall be made public by EFSA

Step 4
Summary of R-PSA

The **results** of the consultation of third parties shall be reported in the summary of the renewal pre-submission advice

Renewal Pre-Submission Advice

Comments received

Step 1
Written or meeting

Where possible, EFSA shall answer the questions in **writing**

A meeting might be organised by EFSA

Step 2
Provide the Advice

The written advice shall be provided within **30 working days** as of the closure of the PC;

The meeting shall be organised within **30 working days** as of the date of the closure of the PC

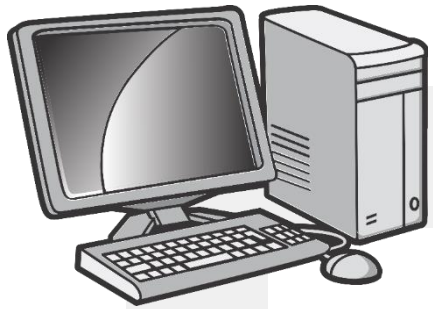
Step 3
Summary

EFSA draws up a **summary** proving an overview of the advice which includes how the **comments** were taken into account and sends it to the requester for information

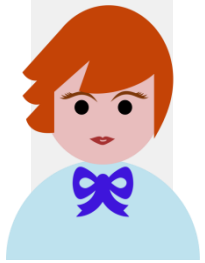
National CA

Plant protection products ONLY

Business Operator Notifies Study according to Article 32b



Search study and/or intended study



Sarah

Complete information

Notify

Modify

Alert

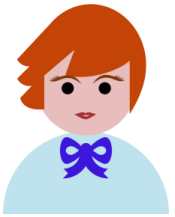
John

Co-notify

Non-committal nature of R-PSA

Any subsequent **assessment of applications** by EFSA and the Member States

The **assessment of the** qualification of the specific regulated product under a given **regulated product area**

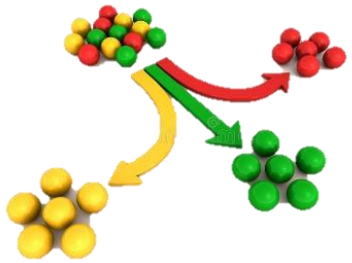


Sarah

The **potential applicant** shall not be bound by any renewal pre-submission advice

Submission of the application

EFSA **receives** the application



Segregation of task

Validity

Publication of the summary

G-PSA vs R-PSA

General pre-submission advice

- Upon request
- Rules/Content
- No proposed study design
- General
- SME

Renewal pre-submission advice

- Systematic and proactive
- Content
- Study design
- Specific and targeted
- Considers the public consultation

Non-committal

Acknowledgements

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