



20-21 October 2020  
NoS Technical Group Meeting

# Update on Notification of New Studies Process

**Sorina Puiu**  
Transformation Services Unit

Trusted science for safe food

# What We Talk About ....

## In Scope

- Business Operator notifies studies
- Business Operator modifies notification
- Laboratory/Testing facility notifies studies
- Laboratory/Testing facility modifies a notification

## Out of Scope

- Users Registration Process
- Creation of the list of intended studies for renewal and third parties consultation processes
- Validation/admissibility process of an application in relation to notifications of studies
- Publication process
- Application submission process

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** ...

<sup>1</sup>) 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)

4. An application or notification **shall not be considered valid or admissible** where it is supported by **studies that have not been previously notified ...**
5. An application or notification **shall not be considered valid or admissible, where studies that have previously been notified** in accordance with paragraph 2 or 3 **are not included in the application** or notification ...
6. The Authority shall make public the notified information **only** in cases **where it received a corresponding application** or notification and after the Authority has decided on the disclosure ...

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** ...
1. 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.
1. 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**

# Business Operator

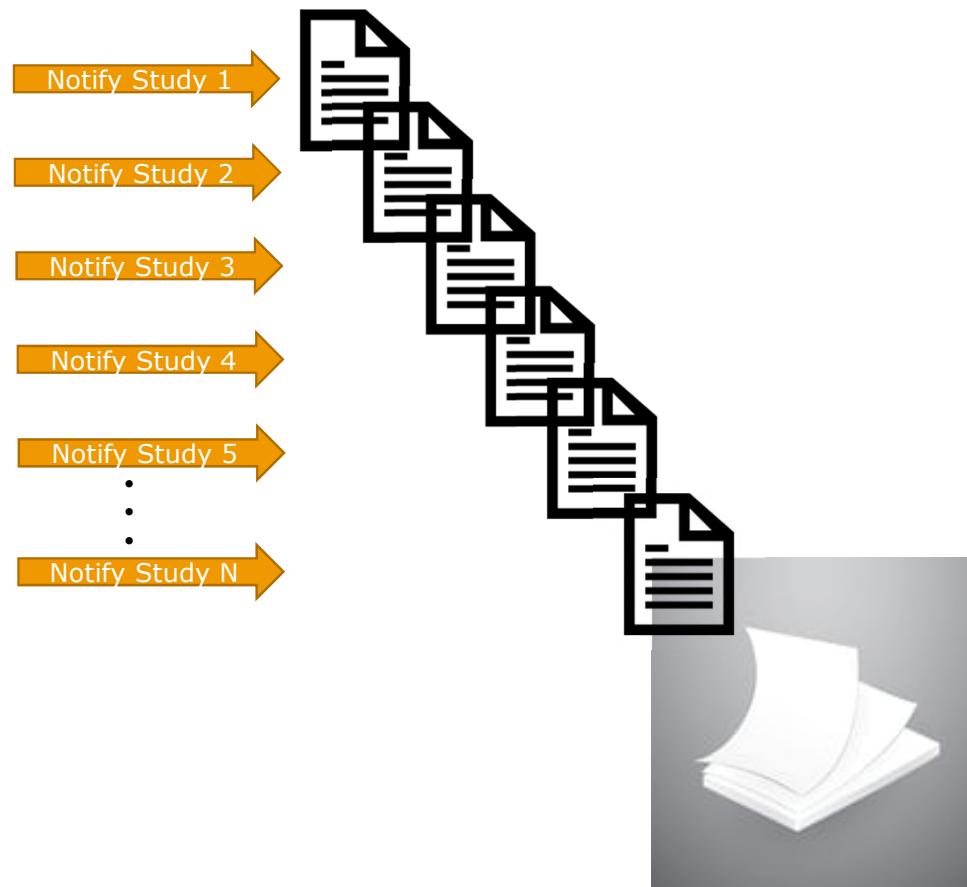


is notifying studies for a Business Operator

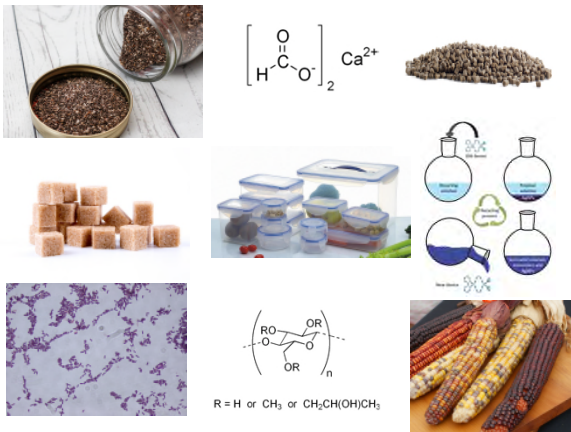
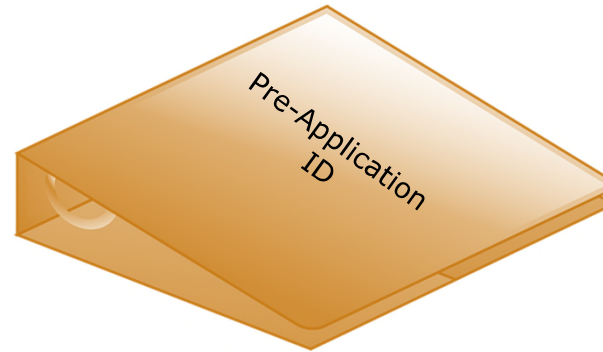
1<sup>st</sup> step before any interaction with the systems supporting the pre-application phase is the registration



# Notifying Studies



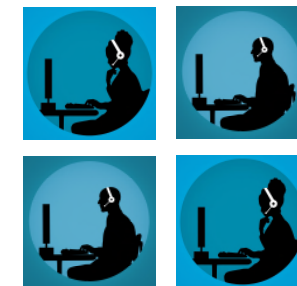
# Pre-Application Identification



**Subject of the application**



**Intended Area**



**Business Operator(s)**



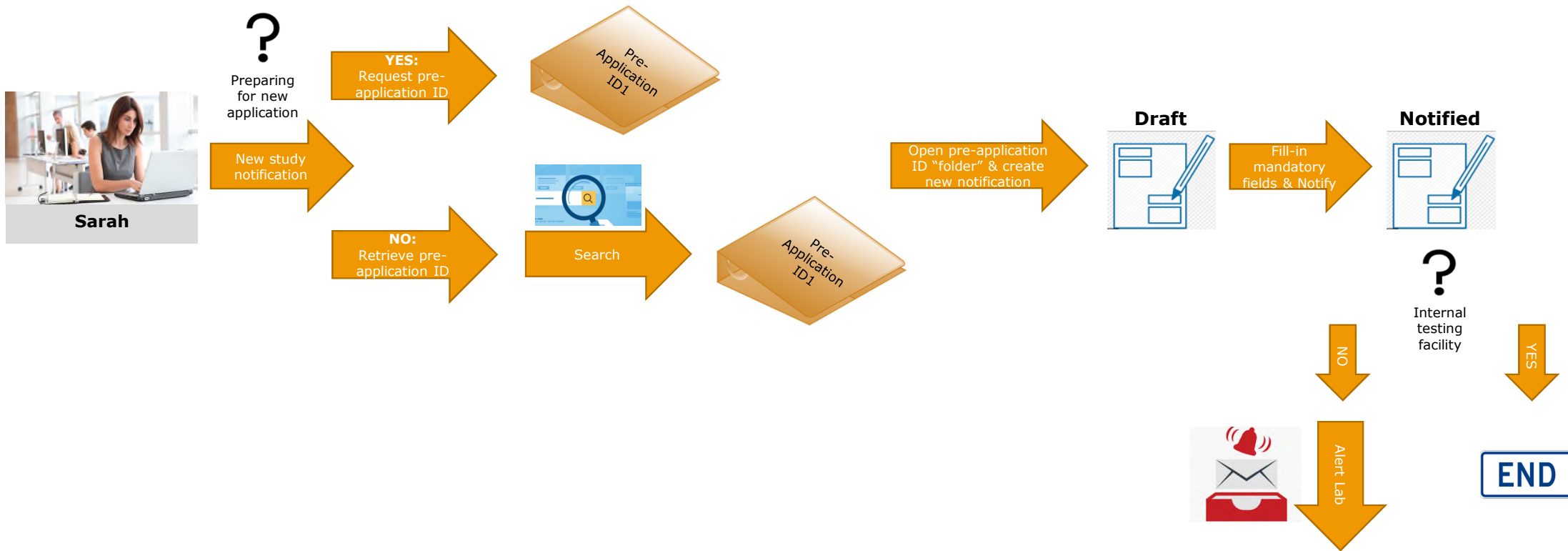
# Pre-application Identification



Preparing for new application



# Notifying a Study as Business Operator



# Co-notifying a Study as Laboratory



# Business Operator Modifies Notifications



Search a notification

Notified/  
Co-notified



Apply changes

Notified/  
Co-notified



Automatic save  
history

Study History (3+)

Date: 12/10/2020 19.44  
Field: International Standard Certification



Alert



# Laboratory/Testing facility

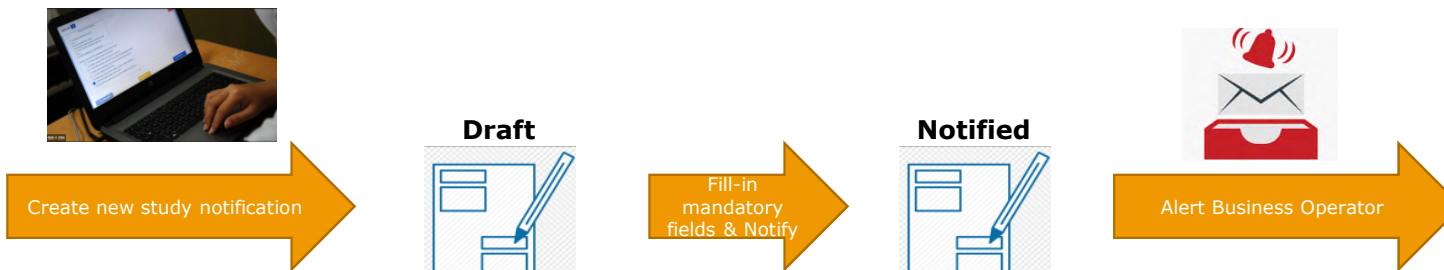


is notifying studies for the Laboratory/Testing facility

1<sup>st</sup> step before any interaction with the systems supporting the pre-application phase is the registration



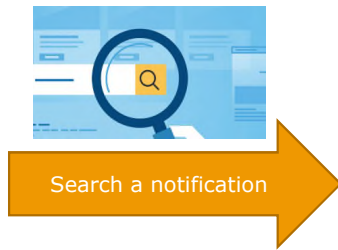
# Notifying a Study as Laboratory



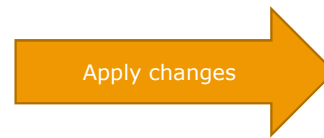
# Co-notifying a Study as Business Operator



# Laboratory Modifies Notifications



**Notified/  
Co-notified**



**Notified/  
Co-notified**



Study History (3+)	
Date:	12/10/2020 19.44
Field:	International Standard Certification





