Presentation of Notification of Studies Database

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Summary

- Notification of studies database
- New applications – Article 32b
- Renewals – Article 32c1
Business operators, laboratories/testing facilities need to register before accessing the system and **initiate the notifications of studies**.

Laboratories/testing facilities need to register before accessing the system if they want **to perform co-notifications**.

Third parties acting on behalf of business operators, laboratories/testing facilities need to register before accessing the system and be delegated by their customers.
Pre-Application Identification

Preparing for new application

Notify Study 1
Notify Study 2
Notify Study 4
Notify Study 3
Notify Study 5
Notify Study N

Under development
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: the experimental starting date

Study planned completion date (M) - Date: the date on which the study report is expected to be signed

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

M: Mandatory  O: Optional  G: Group of elements
Study Scope - Article 32b

- **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.

- **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.

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

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

M: Mandatory O: Optional
Notifying a Study as Business Operator

Sarah

- Preparing for new application

New study notification

- YES: Request pre-application ID
- NO: Retrieve pre-application ID

Search

- Pre-application ID

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

Draft

- Fill-in mandatory fields & Notify

Notified

- Internal testing facility

- Alert Lab

END

Under development
Co-notifying a Study as Laboratory

Alert Lab

1st time to the Database
New study co-notification

YES: Register Lab

Click here

NO

Check notification

Co-notify

Co-Notified

END

John

NO co-notification

Under development
Notifying a Study as Laboratory

Create new study notification

John

Draft

Fill-in mandatory fields & Notify

Notified

Alert Business Operator

Under development
Co-notifying a Study as Business Operator

Alert BO

1st time to the Database
New study notification

?  

YES: Register BO

Click here

NO

Check notification

Co-notify

Co-Notified

END

Sarah

NO co-notification

Notified

END

Under development
Summary

- Notification of studies database
- New applications – Article 32b
- Renewals – Article 32c1
Pre-Application Identification for Renewal

Sarah is notifying for Potential Applicant A

Requests a Pre-Application-Id for Renewal

List of intended studies

Former application id

Pre-Application ID

Intended studies

Under development
**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

- **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. 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.

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

M: Mandatory  O: Optional

Under development
**Study design**

- **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.

M: Mandatory  O: Optional
Renewal Pre-Submission Advice Process

1. Submit List of Intended Studies for Renewal
2. Provide Advice
3. Generate Advice
4. Close Consultation
5. Publication for Public Consultation
Linking Intended Studies for renewal to the List

1. New/find list of Intended Studies
2. List of intended studies for renewal
3. Add Intended Studies to List
4. Intended studies
5. Complete List
6. Repeat steps until list is completed
7. Submit
8. Publication for Public Consultation

Under development
Business Operator Notifies Intended Study under 32b

1. Search intended Study
2. Complete information
3. Notify

Internal testing facility

Notified

Modify

Under development
Business Operator Notifies Intended Study under 32b

1. Search intended Study
2. Complete information
3. Notify
4. Co-notify
5. Modify
6. Notified

Under development
Technical group

**TG Notification of Studies Database**

- Composition: new members from laboratories/facilities
- Member States (x3), ECHA, EC (SANTE, JRC), industry stakeholders (x6), laboratories/facilities (4), other interested stakeholder groups (x3)

**Meetings**

- 2 core meetings ([February 2020](#), [October 2020](#))
- Regular virtual meetings to allow continuation of discussions
- Good progress and discussions; updated presentation to laboratories/facilities, process for new studies, for renewal studies, update process for multiple actors, basic information concept, testing database.
- January 2021 - next TG core meeting + trainings
Questions?