20-21 October 2020

NoS Technical Group Meeting

Database: Requirements for notified studies

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Evidence Management Unit

Trusted science for safe food

efsa

European Food Safety Authority

What We Talk About ….

In Scope

- Information for a notification of a commissioned or carried out study (Article 32b)
- Information for the creation of the list of intended studies for renewal (Article 32c1)

Out of Scope

- Users Registration Process
- Consultation process for renewal
- Validation/admissibility process of an application in relation to notifications of studies
- Publication process
- Application submission process

Summary

- ✓ Legal background
- Information entities 32b
- Information entities 32c1

Legal background: Article 32b

- …**business operators** shall, without delay, notify the Authority of the **title** and the **scope** of any study commissioned or carried out by them to support an application or a notification, as well as the **laboratory or testing facility** carrying out that study, and its **starting** and **planned completion dates**. (Article 32b(2))

Legal background: Article 32b

- …**laboratories and other testing facilities** located in the Union shall also, without delay, notify the Authority of the **title** and the **scope** of any study commissioned by business operators and carried out by such laboratories or other testing facilities to support an application or a notification, its **starting and planned completion dates**, as well as the **name of the business operator** who commissioned such a study. (Article 32b(3))

Legal background: Article 32c

- 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** …
- 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.**

Summary

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- Legal background
- ✓ Information entities 32b
- Information entities 32c1

Study Notification - Article 32b

- 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**

Sarah

Business Operator

John

Laboratory/testing facility

Study Notification - Article 32b

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

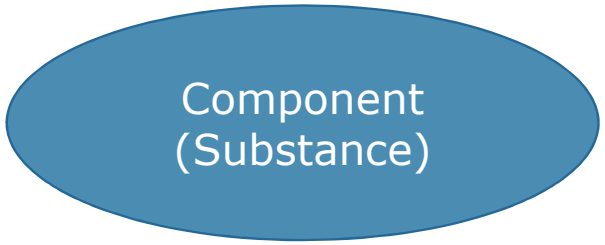
Study Scope - Article 32b

- **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

M: Mandatory
O: Optional

Under development

Test item/Component (Substance) - Article 32b



- Substance:

Choose from list (M)

OR specify manually

- Substance Name (M)
- CAS number (O)
- EC number (O)
- IUPAC name (O)
- Molecular formula (O)
- InChI (O)
- SMILES (O)
- FLAVIS number (O)
- IUBMB number (O)
- Synonym (O)
- Common name (O)

M: Mandatory
O: Optional

Under development

Test item/Component (Microorganism) - Article 32b

- Microorganism:

Choose from list (M)

OR specify manually

- Microorganism Name (M)
- Taxon (O)
- Subspecies (O)
- Strain name (O)
- Deposition number (O)
- Other names (O)

M: Mandatory
O: Optional

Under development

Study Notification: Component - Article 32b

- GMO Name (M)
- GMO Unique identifier (M)

OR

- Protein name (M)

M: Mandatory
O: Optional

Summary

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- Legal background
- Information entities 32b
- Information entities 32c1

Intended Studies for Renewal - Article 32c1

- Potential Applicants need to register before accessing the system and notifying intended studies for renewal

Sarah

Potential applicant

Intended Studies for Renewal - Article 32c1

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

M: Mandatory
O: Optional
G: Group of elements

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

M: Mandatory
O: Optional

Under development

Intended Studies for Renewal - Article 32c1

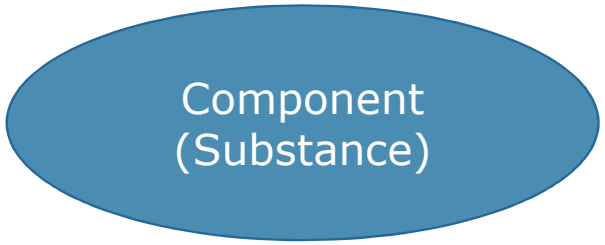
- **Study design**
  - **Study guideline (M) – Choose from list:** shall report the guideline or guidance document to be followed by the study

  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

Test item/Component (Substance) - Article 32c1



- Substance:

Choose from list (M)

OR specify manually

- Substance Name (M)
- CAS number (O)
- EC number (O)
- IUPAC name (O)
- Molecular formula (O)
- InChI (O)
- SMILES (O)
- FLAVIS number (O)
- IUBMB number (O)
- Synonym (O)
- Common name (O)

M: Mandatory
O: Optional

Test item/Component (Microorganism) - Article 32c1

- Microorganism:

Choose from list (M)

OR specify manually

- Microorganism Name (M)
- Taxon (O)
- Subspecies (O)
- Strain name (O)
- Deposition number (O)
- Other names (O)

M: Mandatory
O: Optional

Test item/Component (GMO) - Article 32c1

- GMO Name (M)
- GMO Unique identifier (M)

OR

- Protein name (M)

M: Mandatory
O: Optional

Under development

Questions?