TG NoS meeting
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Information to be notified

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Trusted science for safe food

efsa
European Food Safety Authority

What We Talk and Don’t Talk About ….

In Scope

- Information to be notified

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

Transparency Regulation Article 32b(2)

- …**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.**

Transparency Regulation Article 32b(3)

- …laboratories ***and other testing facilities located in the Union*** shall also, without delay, notify the Authority of the ***title and the scope o***f 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.

Transparency Regulation Article 32b

An application or notification **shall not be considered valid** or **admissible** where it is supported by **studies that have not been previously notified** … (Article 32b(4))

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 … (Article 32b(5))

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 … (Article 32b(7))

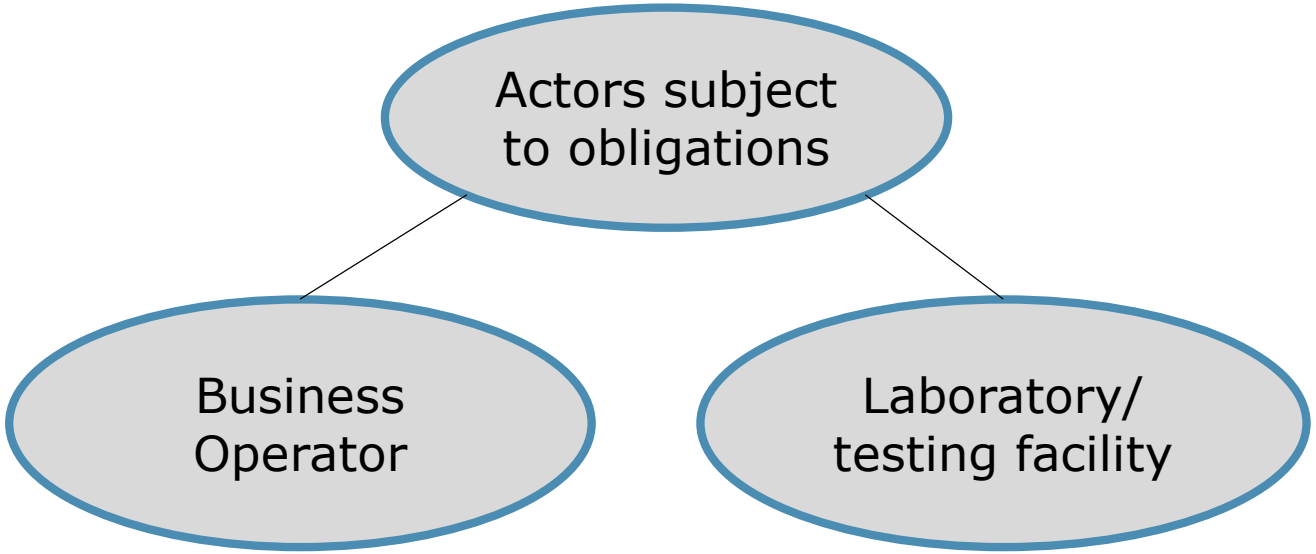
Transparency Regulation Article 32c(1)

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** …

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.

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**

Basic concepts

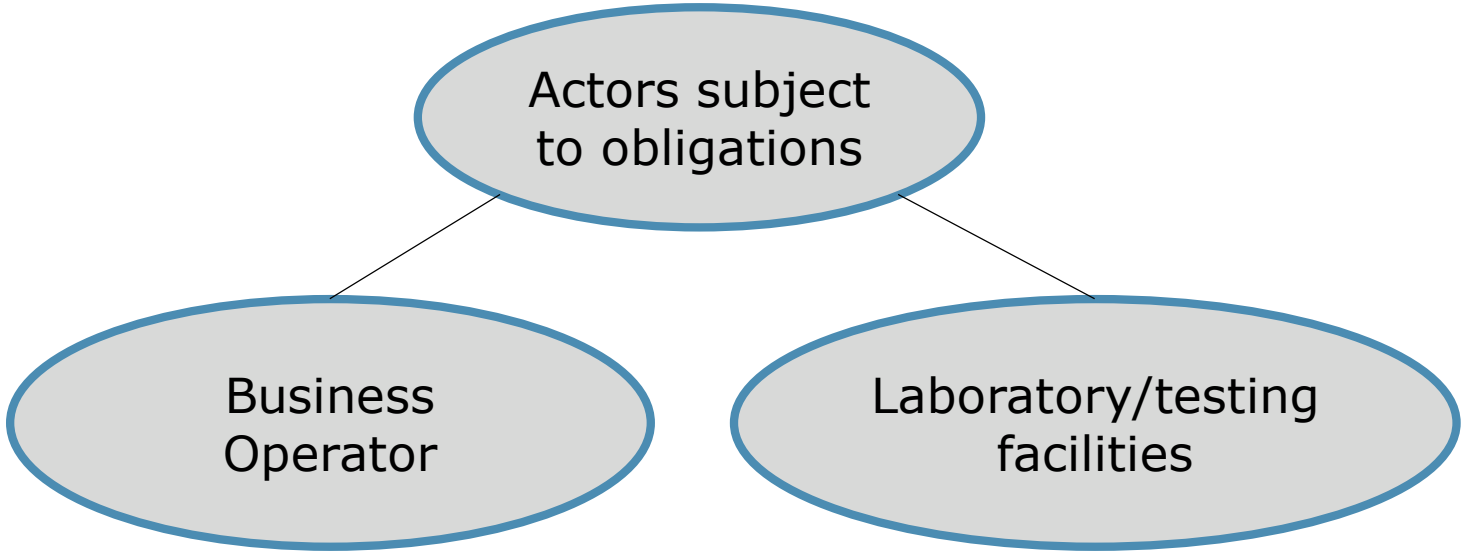


Study notification

Product/component e.g. (substance)

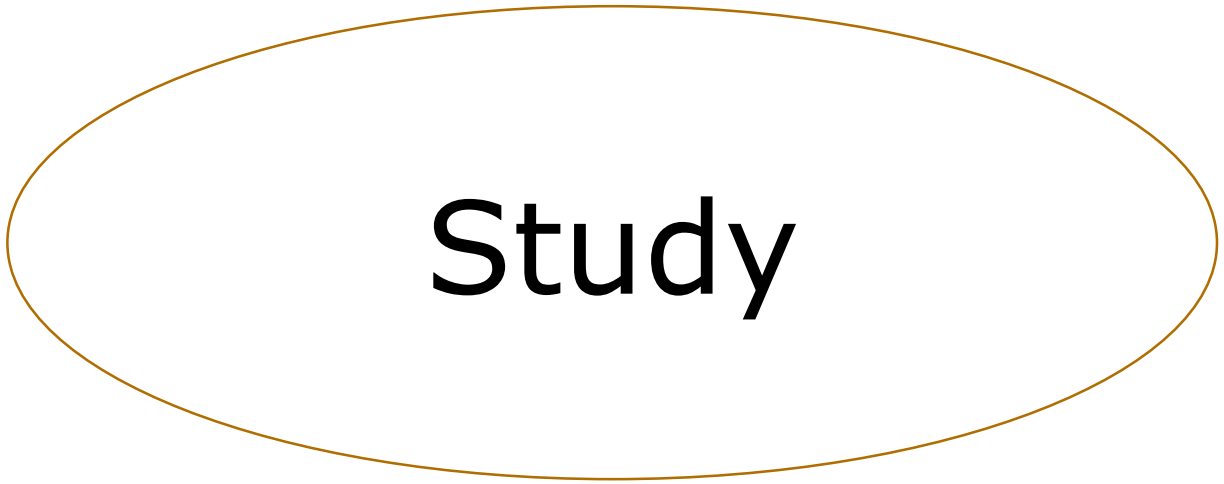
Business Operator /Laboratory or testing facility

- Actors subject to obligations: Business operator or laboratory/testing facility submitting the notification



Study notification

- Studies commissioned or carried out to support applications for which Union law foresees EFSA to provide a scientific output



Study notification

Study Title

Business Operators

Laboratories/testing facilities

Study starting date

Study scope

Study planned completion date

Information element definition

- **Study Title** reports the title of the study as it will be submitted in the application submission.
- **Study Starting Date** is the experimental starting date. More precisely, it is the date on which the first study specific data are expected to be collected.
- **Study Planned Completion Date** is the expected date of the last collection of data from the study
- **Business Operators** is a repeatable section containing the information to identify the organisations that commissioned or carried out the study.
- **Laboratories** is a repeatable section containing the information to identify the laboratory or testing facility performing the study commissioned by the business operator

Information element definition: **Scope**

- **Scope intended area** contains the intended area of application (e.g. Novel foods, Feed Additives, Food additives, etc…) that the study is originally meant to support.
- **Scope intended application id*** contains the identifier of the intended application for which the study was commissioned/carried out.
- **Scope study type** contains the type of the study.
- **Scope study quality** contains the standard certification of the study (GLP, GMP, ISO, …)
- **Scope study flag renewal** contains a "Yes" /"No" value for identifying studies meant to support a renewal of an application.
- **Scope ethical committee approval** contains a "Yes"/"No" value reporting the acquisition by Business Operator of the authorisation of the ethical committee in case of studies on human or animals.

*This element is still under discussion.

Information element definition: **Scope**

- **Scope former application id*** contains the identifier of the application to be renewed, if applicable (if Scope Study Flag Renewal is Yes")
- **Scope study objective** contains the narrative where the objective can be extensively described
- **Scope study guideline** reports the guideline followed by the study (e.g. OECD, EPA, EFSA guideline, GCP).
- **Scope study design description*** contains the description of the design of study including the hypothesis. To be filled in when the study does not follow any study guideline. The field is mandatory if Scope Study Flag Renewal is set to "Yes"

*Only applicable for application renewal

Under development

Information element definition: **Scope**

- **Scope actor's study id** is an identifier of the study as provided by the actor (business operator or lab/testing facility) as in its systems. It is useful for the actor to search a specific notification by the identifier known in the organisation or to identify duplicated notification.
- **Scope product name** is a section containing the identification of the product. Depending on the type of product, the notifier may be requested to fill in information on the product components and sub-components (e.g. for chemical productions substances and metabolites)

Insights

- **Scope intended area:** contains the intended area of application e.g.:
  - Feed Additives
  - Flavouring substances
  - Food additives
  - Food contact materials
  - Food enzymes
  - Nutrition
  - GMO
  - Pesticide

Insights

- **Scope study type** contains the type of the study.

Study type were derived from sectorial guidance/regulation

Study type list to be notified
Study type
Acute toxicity: dermal
Acute toxicity: inhalation
Acute toxicity: oral
Acute toxicity: other routes
Skin irritation/corrosion
Eye irritation
Skin sensitisation
Respiratory sensitisation
Repeated dose toxicity: dermal
Repeated dose toxicity: inhalation
Repeated dose toxicity: oral (28d)
Repeated dose toxicity: other routes
Repeated dose toxicity: oral (90d whole food and feed)
Performance study on broiler
Performance study on catfish
Performance study on cattle
Performance study on other animals
Degradation and accumulation
Phototransformation
Phototransformation: in air
Degradation in manure
Bioaccumulation
Bioaccumulation: aquatic/sediment
Bioaccumulation: terrestrial
Adsorption/desorption

Under development

Automatic information

- **EFSA Study Id** is the identifier of the study created by the Database when the notification is submitted. This identifier shall be used by the applicant in the application submission in the study inventory
- **Notification creation date** is the date when the notification was created in the Database
- **Notification last update date** is the last date when the notification was modified in the Database
- **Notification submission date** is the date when the notification was submitted in the Database
- **Notification status** displays the status of the notification in the Database (e.g. draft, submitted)
- **Actor subject to obligation** contains the name of the organisation notifying the study

Under development

Simulation Time