TG NoS meeting

19-20 February 2020

Notification of studies – Processes

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Transformation Services Unit

Trusted science for safe food

efsa

European Food Safety Authority

What We Talk and Don’t 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

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 … (Article 32b(1)

2. For the purposes of paragraph 1, **business operators shall**, without delay, **notify the Authority** … (Article 32b(2)

3. For the purposes of paragraph 1, **laboratories and other testing facilities** located in the Union **shall also**, without delay, **notify the Authority** … (Article 32b(3)

[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 and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC

Transparency Regulation Article 32b

4. 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)

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 … Article 32b(5)

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 … Article 32b(7)

Transparency Regulation Article 32c(1)

7. 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** …

8. 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.

9. 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

Sarah

is notifying studies for a Business Operator

Business Operator Notifies Studies

Sarah

Creates a study notification

Finalized

Submits

Submitted

Modify

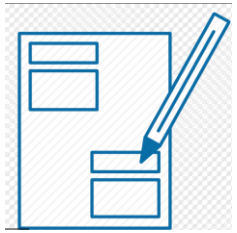
Under development

Business Operator Modifies Notifications

Sarah

Searches a study notification

Applies changes



Submits

Submitted

Under development

Laboratory/Testing facility

John

is notifying studies for the Laboratory/Testing facility

* Preliminary definition to be confirmed in Practical Arrangements

Under development

Laboratory/Testing Facility Notifies Studies

John

Creates a study notification

Finalized

Submits

Submitted

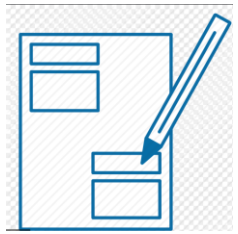
Modify

Laboratory/Testing Facility Modifies Notifications

John

Searches a study notification

Applies changes



Submits

Submitted

Looking for solutions

to avoid duplicated notifications of the same study

Business Operator & Lab Interaction When Notifying *

Sarah

Creates a study notification

Finalized

No confirmation within N days

Internal testing facility

Submits

Submitted

Modify

Alert

Co-notify

John

Under development

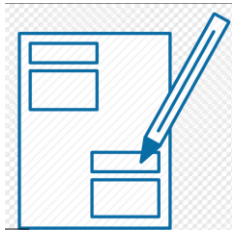
* Feasibility to be verified once solution platform is selected

Business Operator & Lab Interaction When Modifying *

Sarah

Searches a study notification

Applies changes



Submits

Submitted

Inform

John

Under development

* Feasibility to be verified once solution platform is selected

Lab & Business Operator Interaction When Notifying *

John

Creates a study notification

Finalized

No confirmation within N days

Submits

Submitted

Modify

Alert

Co-notify

Sarah

Under development

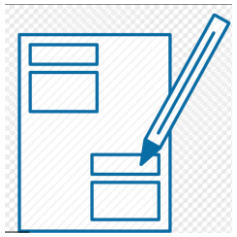
* Feasibility to be verified once solution platform is selected

Lab & Business Operator Interaction When Modifying *

John

Searches a study notification

Applies changes



Submits

Submitted

Inform

Sarah

Under development

* Feasibility to be verified once solution platform is selected

Q&A

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