



Version 3 - 30/04/2020

EFSA Technical Group on Notification of Studies Database

Terms of Reference (ToR)

1. Background

According to Article 32b of 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 ("Transparency Regulation"), EFSA "shall establish and manage a database of studies commissioned or carried out by business operators to support an application or notification [...]".

EFSA has developed its requirements to implement the database pursuant to Article 32b of the Transparency Regulation, including the collection of business requirements, the formalisation of the use-cases, the modelling of the relevant data and the related data flows according to legal provision. EFSA foresees the participation of all relevant actors to test usability of the proposal. In this context, EFSA established a dedicated forum for technical exchanges, for information and gathering input from participants on a specific technical area. The technical exchanges on the establishment of a database of notification of studies will take place through the EFSA Technical group on Notification of Studies Database.

2. Objectives

The main objective of the EFSA Technical group on Notification of Studies Database is to engage with all relevant actors in order to test the usability of the proposed requirements, data model and workflows.

The detailed objectives of the EFSA Technical group on Notification of Studies Database are as follows:

- To test the suitability and usability of the requirements,
- To refine estimates for the capacity of the database (e.g. number of studies),
- To provide feedback from users' experience on the technical requirements of the database,
- To suggest adjustment in terms of simplification, harmonisation, clarifications of requirements and workflows,
- To describe a test scenario for the future database,
- To provide input for training material for users.

3. Terms of Reference

Members of the EFSA Technical group on Notifications of Studies Database are expected to:

- Test and provide written feedback on usability and practicality of the proposed requirements and workflows
- Contribute to refine estimates on the capacity of the database (number of studies that the database may receive per year, type of intended applications)
- Describe test scenario for the future database
- Test the database and eventually provide suggestions for its adjustment before production
- Attend meetings (face-to face meetings, teleconferences)
- Report back experience of the test and make recommendations for next steps
- Provide input to the preparation of training material and webinar for applicants and laboratories.

4. Composition of the Technical group

The composition of the EFSA Technical group on Notifications of Studies Database has been established as follow:

- In January 2020, a call for expression of interest was sent to all Member States, to all EFSA registered stakeholders, to ECHA, to EMA, to the European Commission (DG JRC, DG SANTE). All expressions of interest received from the Member States were accepted. All expressions of interest received from stakeholders were reviewed. Six expressions of interest from the stakeholder category "Business and food industry" were selected based on their representativeness of the sector (e.g. the various areas of the Regulated products), the size of sector represented, type of stakeholders (e.g. multinational, small and medium companies, consultants). All expressions of interest received from other categories of stakeholders were accepted.
- In February 2020, a call for expression of interest was sent to several associations registered in the European Commission stakeholders list, representing the facilities and laboratories in Europe. No expression of interest was received.
- In March 2020, EFSA and the European Commission/Joint Research Centre launched a call for expression of interest to all members of the European Union Network of Laboratories for the Validation of Alternative Methods (EU-NETVAL) network. Three EU-NETVAL facilities were selected for their experience in performing studies for applications for regulated products. In addition, EFSA received the expression of interest of a representative of an independent Contract Research Organisations (CROs) Task Force representing several facilities in several sectors within Europe. EFSA accepted this expression of interest as it complements the experience and input of the individual EU-NETVAL facilities and will provide EFSA with a more complete overview.
- Today, the EFSA Technical group on Notification of Studies Database is composed of representatives from EFSA, ECHA, EC (JRC, DG SANTE), 3 Member States, 6 Industry representatives (registered stakeholders, category: Business and food industry), 4 laboratories/facilities, 3 other interested stakeholder groups (registered stakeholders, category: Consumers, Environmental/Health NGOs and Advocacy groups, Associations of Practitioners).

5. Timelines

The EFSA Technical group on Notification of Studies Database will be active between January 2020 to June 2022 with an EFSA milestone set September 2020 to report back experience and make recommendations for the next steps. Each meeting (tele-meeting, physical meeting) of the EFSA Technical group will be announced publicly and the following

documents will be made available on the EFSA webpage: agenda, participants list, presentations and a summary of the main issues discussed.

Technical group planning:

- Mid-January 2020: creation of the EFSA Technical group on Notification of Studies Database (finalised)
- **Mid-February 2020**: face-to-face meeting, EFSA, Parma **MILESTONE 1** (finalised)
- February 2020 to July 2020: teleconferences ad-hoc specific topics
- **September 2020**: teleconference meeting to present the system and start testing **MILESTONE 2**
- October 2020 to December 2020: teleconferences ad-hoc specific topics
- **January 2021**: face-to-face meeting to review final version of the database and present training materials
- **March 2021**: launch of the EFSA database of study notification – **MILESTONE 3**
- March 2021 – June 2022: implement, collect feedback for improvement, identify new requirements to be implemented, revise training materials.