



2nd Technical group meeting on Notification of Studies Database - Report

20-21 October 2020

Introduction

EFSA's 2nd Technical group meeting on Notification of Studies Database took place virtually and was chaired by Karine Lheureux (Head of Applications Desk Unit). Stakeholder, facility/laboratory, Member State, DG SANTE and EFSA representatives participated in the meeting, with the full list of participants available on EFSA's website.¹

Where we are today: status of the progress of the technical group

EFSA provided an overview of the activities performed since the 1st Technical Group meeting until now, highlighting the three ad-hoc meetings that have taken place (28 April, 28 May, 25 June) and the topics discussed in each meeting.

Database: Requirements for notified studies

EFSA presented the list of information elements to be reported by business operators/laboratories/facilities fulfilling the obligations deriving from Article 32b and Article 32c1 of the Transparency Regulation.

The presentation was followed by questions to clarify the definition of certain information elements and their mandatory use in the notification of studies.

Notification of new studies

EFSA presented the general processes designed to comply with the requirements of the Transparency Regulation for the notification of studies for new applications (Article 32b of the Transparency Regulation). The actions foreseen for a business operator and for a laboratory/facility were described. The concept of pre-application identification was introduced to group a number of notifications to support the same future application. The presentation was followed by a Q&A session where clarifications on the processes were provided. During the Q&A session it was highlighted that the presented processes are applicable also to third parties working on behalf of business operators/facilities/laboratories. EFSA clarified that this aspect is already implemented, and it will be presented during the demo session the following day. Further questions were answered or collected for consideration by the project team.

Processes: Notification of intended studies for renewal

EFSA presented the general processes designed for a potential applicant to comply with the requirements of the Transparency Regulation for the notification of

¹ <https://www.efsa.europa.eu/sites/default/files/event/2020/notification-studies-2/Participants.pdf>

intended studies for application renewal according to Article 32c1 of the Transparency Regulation. The concept of pre-application identification for renewal (pre-application ID renewal) was also introduced to group a number of notifications intended to be commissioned for the renewal of an application. The presentation also included the steps required for the effective notification of studies according to Article 32b, after the public consultation on the list of intended studies for renewal and EFSA advice.

The presentation was followed by a Q&A session where clarifications on the processes were provided. Further questions were answered or collected for consideration by the project team.

Demo sessions

EFSA presented two demos of the Notification of Study Database, to notify a study for a new application and for the renewal of an application respectively, to collect feedback on its usability and accessibility. The demo, performed by EFSA, was dedicated to show the actual implementation of the processes introduced in the previous agenda items.

The demo was welcomed by stakeholders, who made positive remarks stating their views that the tool will facilitate the fulfilment of their obligations deriving from Article 32b and 32c1 of Transparency Regulation. During the Q&A session suggestions for improving the usability of the database were collected and will be considered by the project team for prioritisation and further improvements.

Database testing plan and collection of volunteers

EFSA introduced the testing session, to be held during the week of 26-30 October, asking for volunteers among the stakeholders. EFSA explained how the test will be organised and asked participants to prepare their own scenarios for the testing sessions.

Discussion

The second meeting of the Technical group on Notification of Studies Database aimed at presenting the work undertaken by EFSA to design the Notification of Studies Database and to discuss the development with potential future users with experience in the field, including discussions on the requirements for notified studies, workflows and users including third parties. Some questions were raised on the definition of studies, the scope of the notification of studies, the process of co-notification between business operator and laboratory/facility, access for third parties. Questions raised by the participants during the Technical group meeting collected by EFSA participants will be taken into consideration by the respective EFSA project teams. EFSA informed that, in addition to the dedicated demo sessions, trainings on the notification of studies database will be provided to all potential users, allowing them to be informed and aware of the way to notify studies in the EFSA database.

Next steps

The Chair summarised the discussion and informed the participants that meeting documentation will be published on EFSA's website. The next Technical group core meeting is scheduled to take place in January 2021 and monthly tele meetings will be planned to allow to progress with discussions on specific technical topics.