1st Technical group meeting on Notification of Studies Database - Report

19-20 February 2020

Introduction

EFSA's 1st Technical group meeting on Notification of Studies Database took place in Parma, Italy and was chaired by Karine Lheureux (Head of Applications Desk Unit). Stakeholder, Member State, ECHA, DG SANTE and EFSA representatives participated in the meeting, with the full list of participants available on EFSA's website[1]. Facility/laboratory representatives have not been identified yet.

Introduction to Relationship Management Project

EFSA provided an overview of the ART programme, dedicated to the implementation of the Transparency Regulation. A presentation of one of the Programme's projects, the Relationship Management Project, was given, highlighting the scope and complexity of the project, the activities covered by the project and the expected timeline and milestones until March 2021. The Notification of Studies Database is one of the deliverables of this project and a specific work package of the project is dedicated to this subject.

Introduction to Notification of Studies Database

EFSA provided an overview of the activities planned to deliver the Notification of Studies Database, highlighting the legal requirements as defined by the Transparency Regulation. EFSA presented the distinction made by the legislators between the process for new applications and the process for applications for renewal for which a public consultation on the intended studies and study design is foreseen. EFSA presented an outline of the elements that fall within the scope of this Technical group, as . well as explained which elements would fall outside the scope of discussion.

Introduction to Legal entities and contact person registrations

EFSA provided a high-level overview of the activity dedicated to users and organisations identity management through the establishment of a customer relationship management (CRM) system.

Notification of studies processes and Q&A

EFSA presented the general processes designed to comply with the requirements of the Transparency Regulation for the notification of studies. The actions which

[1] https://www.efsa.europa.eu/sites/default/files/event/2020/notification-studies-1st/notification-1st-participants.pdf

business operators and laboratories/facilities will have to comply with were described, highlighting the chronological steps to be taken by the different actors and the proposed solutions to avoid duplication of notifications. Some clarifications on the processes were provided during the Q&A. The presentation was followed by a live exercise providing an opportunity for all participants, divided in three parallel breakout sessions, to review the workflows and to share their observations and feedback with the full audience. Feedback, questions and comments for clarification were collected and will be considered by the project team.

Information to be notified

EFSA presented in detail the set of information under development for the notification of each study to be notified according to the requirements of the Transparency Legislation (Article 32b and Article 32b(3)). EFSA expanded on the basic concepts of i) study title; ii) study starting date; iii) study/planned completion date; iv) business operators; v) laboratories/testing facilities; vi) study scope. The presentation was followed by a live exercise in which all participants had the opportunity to test the registration of a selected number of studies according to a set of pre-defined information. Comments and feedback were collected and will be considered by the project team.

Discussion

The first 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 this work with potential future users with experience in the field. The discussions held on the workflows/processes indicate that the implementation of the proposed process seems relatively clear, while questions were raised on the details required as regards the information to be notified. One of the concerns was how to avoid possible duplication of notifications between business operators and laboratories/facilities. Questions on the definition of studies to be notified were raised. Many other questions were raised by the participants during the Technical group meeting which were collected by EFSA participants and will be taken into consideration by the respective EFSA project teams. The participants highlighted the need to include laboratories/facilities in the Technical group.

Next steps

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