



ENGAGEMENT AND COOPERATION UNIT

2nd Sounding Board meeting – Report

20 July 2020

Introduction

The Sounding Board aims at providing stakeholders general information on the state of play of the Transparency Regulation (TR) implementation. EFSA's 2nd Sounding Board meeting took place virtually via the Microsoft Teams platform due to the Covid-19 restrictions on physical meetings and was chaired by the Head of Communication, Engagement and Cooperation Department (COMCO). Stakeholder, EFSA Advisory Forum, DG SANTE and EFSA representatives participated in the meeting, with the full list of participants available on EFSA's website¹.

Opening and welcome & Adoption of agenda

The objective of the 2nd Sounding Board was to inform Sounding Board members about the progress of the Transparency Regulation implementation since the 1st Sounding Board meeting on 23rd March. The agenda was based on the areas that Sounding Board members expressed an interest in and the four pillars of the Transparency Regulation. The Chair provided examples of how Sounding Board members' comments on stakeholder engagement, Technical groups and Practical Arrangements have been addressed: a calendar of engagement events had been published on the EFSA website to provide an overview of future meetings and is being regularly updated; an agenda item to inform about the ongoing work of the Technical groups and changes to their composition had been included in today's meeting; beyond providing replies to stakeholders' question on the subject matter where possible at the present meeting, documents on the Practical Arrangements will be shared with stakeholders in autumn. The agenda was adopted.

Engagement framework during Transparency Regulation (TR) implementation

Following a summary of the joint DG SANTE/EFSA engagement framework on stakeholder engagement during the TR implementation, an overview of the engagement events with Member States and stakeholders since March was provided. EFSA had organised two Advisory Forum meetings (1st April and 1st July) and Technical Group meetings (Technical Group on IUCLID for Pesticides, 21-22nd April; 17-18th June). DG SANTE highlighted the DG SANTE Advisory Group on the Food Chain and Animal and Plant Health Working Group meeting (5th June) with stakeholders that included an extended Q&A agenda item and the General Food Law Expert group meeting (26th June) with Member States. An outlook on the next engagement opportunities relating to the TR was given together with indicative meeting time frames, including as regards a 2nd meeting of the DG SANTE Advisory Group Working Group (October), and a 3rd Sounding Board meeting (October), as well as an information event on the overall

¹ <https://www.efsa.europa.eu/sites/default/files/event/2020/List-of-Participants-Sounding-Board-20-07-2020.pdf>

implementation of the TR (December). Sounding Board members will be informed of exact meeting dates.

An update was also provided on the progress of the two EFSA Technical Groups, on IUCLID for pesticides and Notification of Studies Database, as well as on changes in membership to reflect in particular the inclusion of laboratories.

Main session – Update on implementation of Transparency Regulation (TR)

Update on IT

DG SANTE gave a presentation on the future e-submission system for applications in all regulated product areas except for pesticides. The Common Food Authorisation System (FSCAP), formerly used for novel food applications and traditional food notifications, will be developed to integrate the new dossier structure and workflow for food domains impacted by the TR except for what concerns pesticides and MRLs, as well as to integrate the TR requirements on confidentiality and proactive disclosure. Information on the future submission of applications and division of roles between DG SANTE and EFSA as regards the confidentiality assessment was provided. Testing FSCAP is currently tentatively scheduled for the end of 2020.

EFSA provided an overview of the ongoing work to develop the future e-submission system for pesticides and MRLs, the International Uniform Chemical Information Database (IUCLID). Three proof of concept dossiers on new active substances, renewal of active substances and micro-organisms are available in IUCLID today, while the availability for e-submission of Maximum Residue Level (MRL) and basic substances dossiers is aimed for October 2020. EFSA informed participants that the table of contents (ToC) will remain the same, however the way in which data is submitted will change. A minimum viable product (MVP) will be available in March 2021, which will be refined over time.

User manuals will be provided for FSCAP and IUCLID and more information on training and testing will be made available in autumn to stakeholders and Member States.

Transparency & confidentiality and Quality & reliability of studies

EFSA also gave a presentation on the progress of the Practical Arrangements (PAs) focusing on the PAs on Confidentiality, Transparency, Notification of studies, Public consultation of third parties and Pre-submission advice. EFSA noted that while the formal feedback from DG SANTE on the PAs was scheduled to arrive shortly, the active informal exchange between DG SANTE and EFSA allowed EFSA to provide more detailed information to Sounding Board members at the present meeting. EFSA noted engagement on PAs was extensive; the Commission had been consulted on all PAs to ensure alignment with EFSA, information to and consultation of Member States was ensured through the DG SANTE General Food Law Expert group and Standing Committee on Plants, Animals, Food and Feed (PAFF Committee), while stakeholders were informed through the Sounding Board and Advisory Group Working Group and documents on the PAs will be shared.

EFSA and DG SANTE informed Sounding Board members about the ongoing update of EFSA Guidance documents and DG SANTE Implementing Acts, with the publication and formal adoption respectively foreseen for autumn 2020.

Governance and sustainability

EFSA gave a summary of the ongoing work on increased cooperation with Member States, which includes the increase in indemnity for and training of experts, as well the preparatory work on increasing capacity building in Member States through amplified grants and procurements. The focus of discussions takes place with EFSA's Advisory Forum, which is at the centre of the concept and strategy development in this context. Preparations also aimed at increasing harmonisation of risk assessment in Europe will continue together with Member States and DG SANTE in the future.

Risk communication

EFSA updated Sounding Board participants on the preparatory work regarding the General Plan for risk communication, and in particular on the delivery of the DG SANTE mandate on Technical assistance in the field of risk communication² being carried out by the EFSA Working Group on Social Research Methods and Advice³. A targeted consultation of experts followed by a public consultation on literature gaps beyond the selection of 250 papers analysed by the Working Group is scheduled to take place towards the end of 2020.

Discussion

EFSA and DG SANTE provided live replies to Sounding Board members' questions received via the Chat function. Written questions received prior to the meeting were addressed where possible, while questions not covered were noted for the next engagement opportunities. Questions from Sounding Board members mainly related to Practical Arrangements, IT training and Technical Groups. EFSA and DG SANTE informed participants about the intention to share the content of all Practical Arrangements in autumn, after which an even more detailed discussion will be possible; training on IT platforms will be provided once the current development of FSCAP and IUCLID has progressed; working procedures of the Technical Groups were clarified. The Industry and Food Business stakeholder category representative expressed their concern that applicants, particularly SMEs may not be ready to fulfil the new TR obligations by its entry into application due to the amount of new information industry will have to comply with. Specifically, in the context of notification of studies requirement, as envisaged in Article 32b, the Industry and Food Business stakeholder category representative requested DG SANTE to consider transitional periods and flexible approaches, underlining their general support for increased transparency. DG SANTE stated that no deviation from the date of entry into application of the TR was possible; in the context of the notification of studies transitional, periods have been included in Articles 32b(4), (5) and (6); the ongoing effort to make information available to applicants as early as possible will continue. EFSA underlined it will continue to take the responsibility to make TR requirements as clear as possible seriously.

Next steps

The Chair highlighted the upcoming engagement opportunities, with the 3rd Sounding Board foreseen to take place in autumn (October) and an information event on the overall implementation later this year (December). Today's meeting documentation will be sent to Sounding Board participants and published on EFSA's website in due course.

² <https://registerofquestions.efsa.europa.eu/roqFrontend/wicket/page?2>
[Mandate Number: M-2020-0059]

³ <http://www.efsa.europa.eu/en/communications/working-groups>