



ENGAGEMENT AND COOPERATION UNIT

Sounding Board - Concluding Report

EFSA has engaged with stakeholders during the main implementation phase of Regulation (EU) 1381/2019, the 'Transparency Regulation' (TR), ahead of its entry into application, in accordance with an <u>engagement framework</u> jointly drafted by EFSA and DG SANTE. The framework specified the principles of engagement and the rules applied to meetings and to written input received from stakeholders.

EFSA established a Sounding Board and two Technical Groups (Technical Group on Notification of Studies Database, Technical Group on IUCLID for pesticides). These dedicated engagement channels are time limited and will conclude their activities in line with their Terms of Reference (ToR).

The objectives of the Sounding Board (SB) were to keep stakeholders informed about the state of play of the implementation of the TR in general during the main implementation phase leading up to the entry into application, to collect stakeholders' comments and to address questions where possible.

During the three SB meetings that took place in March, July, and November 2020, EFSA and DG SANTE updated SB members on the status of the TR implementation pertaining to all four pillars of the TR. SB meetings provided an opportunity for an open and productive discussion with stakeholders and Advisory Forum (AF) representatives in the spirit of transparency, independence, openness and inclusiveness, and were crucial in capturing stakeholders' feedback and opinions, as well as in providing relevant clarifications. In between and after meetings, EFSA regularly informed SB members, via email, on the latest developments in the context of the TR implementation including the publication of the Practical Arrangements and the TR training programme.

EFSA wishes to thank SB members for their availability, contribution and feedback during SB meetings, as well as through the written questions and comments sent to EFSA. This input has been crucial for EFSA in the implementation of the TR, as it allowed to address specific implementation aspects and to ensure that the new processes and tools are fit for purpose. For example, in response to the feedback received from stakeholders and Member States on the Draft Practical Arrangements (PAs) that EFSA shared in November 2020, EFSA considered all comments ahead of their finalisation and adoption in December 2020. A document addressing frequently asked questions on the PAs will be published on the EFSA website.

The cooperation with the members of the two Technical Groups allowed EFSA to receive specific feedback from relevant stakeholder and Member State representatives at technical level to find suitable solutions for the development of the Notification of Studies Database and use of the IUCLID e-submission system for pesticides. Feedback on the two tools included input on the requirements, on simplification and on clarifications of the workflows. During the testing phase we valued users' experience for the Notification of Studies Database, and feedback on the analysis and definition of changes to IUCLID for pesticides, the suitability of the IUCLID format for release in October 2020, as well as comments on the development of features to automate pesticides dossier processing.

An overview of the engagement activities that took place in the context of the TR implementation is available in the infographic "Transparency Regulation Implementation: Engagement throughout 2020".

Next steps

The SB will conclude its activities at the time of entry into application of the TR in line with its Terms of refence (ToR). The EFSA Technical Groups on IUCLID for pesticides and on Notification of Studies database will also conclude their activities in line with their Terms of reference (ToR): The Technical Group on Notification of Studies Database will conclude its activities by June 2022 and the Technical Group on IUCLID by June 2021.

EFSA's webpage on the TR and Stakeholder engagement will be kept updated with the latest information about the implementation of the TR governance and sustainability and risk communication pillars.

Following the conclusion of the main implementation phase leading up to the entry into application of the TR, EFSA will continue its stakeholder engagement on the TR through the fora foreseen by the Stakeholder Engagement Approach (SEA). Member States will continue to receive information about the TR implementation through the AF.

Annex I

Sounding Board: engaging with stakeholders during the implementation of the Transparency Regulation

Terms of Reference

1) Background

EFSA will interact with stakeholders during the Transparency Regulation through a separate engagement framework than the EFSA Stakeholder Engagement Approach (SEA). The Sounding Board will be one of the two main channels through which this engagement will take place.

2) Objective

The objective of the Sounding Board (SB) is to keep stakeholders informed about the state of play of implementation of the Transparency Regulation in general, to collect comments stakeholders may have and to address questions where possible. Equally, it will support the coordination of interactions between main interested parties, EFSA and the EC/DG SANTE.

3) Terms of Reference

Members of the SB are expected to attend SB meetings and to contribute to exchanging information by sharing information discussed during SB meeting with their stakeholder category, channelling questions from their category to EFSA and engaging in discussions with EFSA during Sounding Board meetings.

4) Composition

The Sounding Board is composed of the Stakeholder Bureau representatives (SHB) and one additional representative per stakeholder category – with the exception of the HORECA category which has decided that only the SHB member participates on its behalf -, 3 Member States representing the Advisory Forum (AF) and EC representatives from DG SANTE.

5) Launch of operations and establishment of Sounding Board

EFSA has informed its registered stakeholders of the launch of the Sounding Board in December 2019 and requested the Stakeholder Bureau to nominate up to one additional member per stakeholder category by 21st January 2020. The Stakeholder Bureau notified EFSA of the additional member. 3 Member States volunteered to represent the Advisory Forum (AF) and the European Commission will be represented by DG SANTE. With the confirmed membership the Sounding Board

has been established in February 2020. The Stakeholder representatives, AF representatives and DG SANTE have been informed of the establishment of the Sounding Board.

6) Frequency of meetings

A mix of virtual and face-to-face mechanisms will be in place. The SB will be kept informed about state of play of the implementation in a timely manner, in line with the timelines for the delivery of the tasks and the principles of engagement for the implementation of the new Regulation.

7) Reporting

The SB will operate under the principles of engagement, with a focus on transparency. Minutes or summaries from SB meetings will be made public on EFSA's website, as well as the agenda, participants list and presentations, where applicable.

8) Timelines

The Sounding Board will be operational during the main implementation phase of the Transparency Regulation until its entry into application on 27 March 2021.

The present document has been discussed and adopted at the $1^{\rm st}$ Sounding Board meeting on 23 March 2020.

Annex II

Sounding Board members

Advisory Forum representatives

First name	Last name	Organisation
Ana	Canals	Spanish Food Safety and Nutrition Agency
Ákos	Jóźwiak	National Food Chain Safety Office, Directorate for Food Safety Risk Assessment, Hungary
Per	Bergman	Swedish National Food Agency

Stakeholder representatives

First name	Last name	Category and Organisation
Camille	Perrin	Consumers, BEUC
Floriana	Cimmarusti	Consumers, SAFE
Martin	Dermine	NGOs and Advocacy Groups, Pesticide Action Network Europe
Apolline	Roger	NGOs and Advocacy Groups, Client Earth
Pekka	Personen	Farmers and Primary Producers, COPA-COGECA
Bruno	Menne	Farmers and Primary Producers, COPA-COGECA
Maud	Perrudin	Business and Food Industry, Association of the European Self-Medication Industry (AESGP)
Giuseppe Luca	Capodieci	Business and Food Industry, EU Association of Specialty Feed Ingredients and their Mixtures (FEFANA)
Els	Bedert	Distributors and HORECA, Euro Commerce
Ayla	Gülden Pekcan	Practitioners, European Federation of the Associations of Dietitians (EFAD)
Elinor	McCartney	Practitioners, Association of Veterinary Consultants (AVC)
José Julio	Ortega Calvo	Academia, Society of Environmental Toxicology and Chemistry Europe (SETAC)
Erik	Millstone	Academia, European Network of Scientists for Social and Environmental Responsibility (ENSSER)

European Commission representatives

First name	Last name	Organisation
Anastasia	Alvizou	DG SANTE, European Commission
Alexandra	Tuijtelaars	DG SANTE, European Commission