

TRANSFORMATION SERVICES

NOTE TO THE MANAGEMENT BOARD

Update on the implementation of the Transparency Regulation

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 and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC was published on the 6th of September 2019.

On 27 March 2021, the new requirements of the Transparency Regulation (TR) shall be in effect. Changes regarding Management Board, Scientific Committee and Scientific Panels will be applicable as of 1 July 2022.

EFSA is progressing according to the plan with slight delay, but the deadline of the Transparency regulation will be respected.

Documents to be drafted/updated in a view of the Transparency regulation: Practical arrangements, guidance documents, decisions of Management Board and quality management documents.

Practical Arrangements for Art. 32 referring to Pre-submission advice, Notification of Studies, Public Consultation have undergone informal consultation with SANTE. The document was shared with stakeholders (Sounding Board and DG SANTE Advisory group WG) and will be adopted by the end of 2020.

Practical Arrangements for Art. 38-39 referring to transparency and confidentiality have undergone formal consultation with SANTE. Then EFSA shared the documents with stakeholders (Sounding Board and DG SANTE Advisory group WG) and will adopt them by the end of 2020.

Practical Arrangements for Plant Protection Products (PPPs) Confidentiality assessment by Member States undergone informal consultation with SANTE. SANTE launched the formal consultation with Member States through PAFF meeting in November. Adoption will be by the end of 2020.

EFSA is updating 27 guidance documents (12 administrative and 15 scientific). Seven scientific guidance documents were already endorsed by EFSA's panels, the remaining 8 will be endorsed by the end of the year. The scientific part of scientific guidance documents remains untouched whereas the administrative part was either amended or removed. Administrative guidance documents will be adopted after adoption of the Practical Arrangements. Seven administrative GDs will be adopted by the end of January 2021. The administrative guidance document for peer review of pesticides active substances will require more time as the scope of the document was broadened upon SANTE request to include specific MRL provisions. Approval of the remaining 5 administrative guidance



documents for peer review of pesticides active substances, for smoke flavourings and 3 for food contact materials will be adopted early 2021 after formal consultation with Commission.

In total 15 Management Board decisions will be updated. The Decision concerning *the establishment and operation of European Networks of scientific organisations operating in the fields within the Authority's mission* to be adopted during this MB meeting.

External engagement, training and communication

EFSA and SANTE jointly defined principles for interaction with stakeholders and the engagement channels: Sounding Board, Technical Groups, Stakeholder event, dedicated space in EFSA website.

Three Sounding Board meetings have already taken place in March, July and November. Practical Arrangements were shared with stakeholders and discussed during 3rd Sounding Board and WG DG SANTE Advisory group meetings.

There are 2 Technical Groups: IUCLID (for pesticides) and Notification of Studies. Regular meetings are ongoing and progress well underway. The technical groups are involved in testing EFSA new tools.

EFSA jointly with DG SANTE is planning to organise a Stakeholder information event on the implementation of Transparency Regulation early 2021.

Upgraded EFSA website starts in February 2021. New portal Open.EFSA will begin in March. The portal will serve for accessing documents, such as dossiers and studies (non-confidential versions), meetings' agenda and minutes. The portal Open.EFSA will give the possibility to track the status of the application, from receipt to adoption.

External training will be provided during January - March 2021. Depending on the trainings' outcome and feedback, additional sessions might be organised after March. Training will cover Notification of studies, Pre-submission advice, EFSA's guidance documents update, new IT tools (FSCAP, IUCLID), account registration and others. An information session for external stakeholders (Introduction webinar) was held on November 19th. All trainings will be recorded and made available on the website ([link](#)). Every session will allow up to 10000 participants.

Risk communication

EFSA was mandated by the EC to support the EC's development & future implementation of the General Plan for Risk Communication by 2023. The Mandate consists of tasks to be delivered by end of March 2021:

- Scientific Output – Science of Risk Communication
- Communication Product Catalogue & Dissemination Best Practice
- Dissemination Best Practice Guidance
- Mapping of risk communication mechanisms

Additional tasks are: Social listening methodology, Pan-EU Web Platform - Food.eu, Customer Relationship Management tool.



Technology

In September 2020 EFSA completed construction and by December 2020 will complete validation of the technology. After that, the business simulation phase will start to be ready for March 2021.

EFSA will deliver: FSCAP integration and e-Submission format for regulated products; IUCLID Pesticides PPP & MRL e-Submission; Platform for Notification of studies; Pre-submission advice; Risk assessment workflow; Confidentiality assessment; Dissemination; Proactive disclosure; Secure storage and controlled access.

Further features beyond 2021: IUCLID workflow integration for confidentiality assessment of Pesticides dossiers, Additional IUCLID features for Pesticides, Sanitisation (document redaction) software, Confidentiality assessment for all EFSA data sets (beyond regulated products).

Change management

EFSA staff is being kept informed through internal communication channel and info sessions. Training for EFSA staff is ongoing until March 2021. A 'one-stop-shop' is introduced for all training material for internal and external peers to store documents, guides, videos and links.

Organisation "Interim year 2021"

To accommodate the new processes of the Transparency Regulation EFSA opted for a temporary solution, adding the necessary staff and tasks to relevant existing units. In total, over 3 years (2020-21-22) EFSA planned to recruit 106 employees.

Conclusions

The requirements of TR will be delivered on time. Joint efforts needed from EFSA, SANTE and stakeholders. EFSA staff commitment is excellent. Complexity is high. Strict prioritization is needed.