

## 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 6<sup>th</sup> 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 with respect to the plan even though there is a delay. The delay will not create any critical consequences.

Overall work of implementation of TR is divided in to 4 parts: Practical arrangement and Guidance documents, Processes, IT and Organisational structure.

### **Practical Arrangements**

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

Practical Arrangements for Art. 38-39 referring to transparency and confidentiality have undergone formal consultation with SANTE. After internal alignment EFSA will send to SANTE a revised text by the end of September. Then EFSA will share 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 MS underwent informal consultation with SANTE. After internal alignment, EFSA will send to SANTE revised text by the end of September and SANTE will launch the formal consultation with Member States through PAFF meeting in November. Originally the formal consultation with MS was planned in July. Adoption will be by the end of 2020.

### **EFSA's Guidance Documents**

EFSA is updating in total 27 guidance documents (12 administrative and 15 scientific). Already endorsed by EFSA's Panels are 7 scientific guidance documents, the 8 remaining will be endorsed by the end of November. The scientific part within scientific guidance documents remains untouched



whereas the administrative part was corrected or removed. Majority of Administrative GDs will be adopted by the end of 2020 as it has a direct link with Practical Arrangements. The administrative guidance document for peer review of pesticides active substances will require more time as the scope of the document was broadened by SANTE request to include MRL specific provisions. The request was received in September 2020. Approval of administrative guidance document for peer review of pesticides active substances will be early 2021.

### **External engagement**

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

Two Sounding Board meetings already took place in March and July, during which stakeholder's questions were answered and commented.

Practical Arrangements will be shared with stakeholders and discussed during 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 of EFSA new tools.

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

EFSA has a dedicated space in its website where all information relevant to implementation of Transparency Regulation is shared.

### **Technology and automation**

The phase of implementation and completion means that by September EFSA completed construction and by December 2020 will be progressing validation of the technology. After that, business simulation phase will follow by 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

Training needs have been collected via ad-hoc interviews with ART project members. Training plan for all ART projects has been finalized. It will be implemented between October and March 2021. It will be implemented also through a 'one-stop-shop' for all training material for internal and external peers to store documents, guides, videos and links.

Internal Communication upgraded with internal and external resources, continuing to be centrally coordinated. Stepped up activities since July: Regular progress updates on Intranet; Big picture Intranet articles highlighting important milestones and providing context. All staff meeting with focus on TR planned for October.

## AS-IS Plus Organisation

To accommodate the new processes of the Transparency Regulation (Pre-submission advice, Notification of studies, Public consultations, Confidentiality assessment, Proactive disclosure of evidence, Verification studies) EFSA opted for temporary solution. The temporary solution of the organisational structure so called as-is plus. Meaning not changing the organisational structure but adding the necessary staff and tasks to relevant existing units. In total, for 3 years 2020-21-22 EFSA has planned to recruit 103 employees, by end of March 2021 almost 50 percent will be onboarded.

## Conclusions

Expectations for March 2021 are manageable. 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.