

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 requirement of the Transparency Regulation shall be in effect. Changes regarding Management Board, Scientific Committee and Scientific Panels will be applicable as of 1 July 2022.

Now EFSA is working on the implementation of the processes designed in 2019. The highest priority is given to the processes ensuring compliance to Transparency Regulation requirements and despite force major (COVID-19) EFSA will achieve the goal on time: Practical arrangements, Guidance Documents will be published, IT will be operational, human resources will be ensured and adequately trained.

Practical Arrangements

The Practical Arrangements on Public Access to Documents (PAD - Aarhus Regulation) has been adopted by the Management Board in March 2020, as required by law. All other Practical Arrangements, i.e. on Transparency, Confidentiality (by EFSA), pesticides (Confidentiality assessment by MS) and the one on Art. 32 of the Transparency Regulation (Pre-Submission Advice, Notification of Studies and Public consultation) are currently under consultation with SANTE.

Practical Arrangements on confidentiality assessment of pesticides will undergo formal consultation with the Member States (mandatory by law) in a dedicated meeting during the month of July. All Practical Arrangements will be presented/introduced during the Sounding Board meetings (March, July and September) and during SANTE Advisory Group Working Group scheduled on June 5th and in September (date to be defined). For November EFSA and SANTE are also organising a stakeholder event to present the final draft documents, before their adoption in December.

EFSA's Guidance Documents

EFSA will update in total 28 guidance document (12 administrative and 16 scientific). The approach for their update was discussed and agreed with DG SANTE during sectoral bilateral meetings. The necessary work is ongoing, taking into account also the Practical Arrangements as appropriate. Draft updated guidance documents will be shared with DG SANTE to ensure alignment with Implementing Acts issued by Commission. Guidance documents will be adopted by the end of 2020.

End-to-end processes

Following the Transparency Regulation requirements, EFSA is ready to implement new processes, such as: Confidentiality assessment, Proactive dissemination, Verification studies, Pre-mandate activities: Pre-submission advice, Advice for renewal, Notification of Studies database and other processes have extended, such as: dossier validation (Notification of Studies, Good Laboratory Practice), Public consultation.



Additionally to Transparency Regulation requirements, EFSA did a leaning exercise and will improve the following processes: Risk assessment, Scientific service support, Scientific administrative support, Shared Service Office.

Future partnership with MSs where some works for EFSA could be done by competent MS organisations is currently under discussion.

Technology building blocks and structure

EFSA's IT is built on five major building blocks: Salesforce, FSCAP, IUCLID, Appian, Microsoft Azure (explained below), each addressing an aspect of the Transparency Regulation. Progress continues and it is on average about a third of the way through construction of the software building blocks. A stabilisation and business simulation will be ongoing through the first quarter up until the deadline for the Transparency Regulation. The availability of each of these building blocks (for portions that do not require the legal mandate) will be introduced to applicants, Member States and the Commission, as early as January, and replacing EFSA existing IT such as Risk Assessment Workflow or Document Management System. This is to avoid one single massive go-live of all systems which will introduce resource constraints and difficulty in dealing with any problems, if they arise. EFSA plans to bring up the systems "live" approximately twice per month from January through March. There has been a remarkable collaboration and flexibility with SANTE's services. This is a great example of co-design and collaboration.

- **Salesforce** - Pre-Submission Advice, Notification of Studies, Public access to documents, Public Consultation.
- **FSCAP** – dossiers e-submission except pesticides
- **IUCLID** – dossier e-submission for pesticides PPP and MRLs.
- **Appian** – workflow automation for EFSA's risk assessment work
- **Microsoft Azure** – Secure storage and controlled access, Dissemination, proactive disclosure.

Organisational change

- In view of the COVID-19 crisis, given the need to de-prioritise certain activities (loss of productivity) and also taking into account the postponement of the new EFSA strategy, the reorganisation of EFSA (org. chart and process architecture – EFSA Process Architecture) was delayed until Jan 2022. Nevertheless, some changes are indispensable to integrate the capabilities and competencies needed to start implementing the mandatory Transparency Regulation measures entering into force on 27 March 2021. Work is ongoing to estimate the competences and Full Time Equivalents needed and to integrate them within the AS-IS organization. Concretely, this includes:
 - External recruitment and internal mobility of staff;
 - Define new or expanded Organisational Entities (Units, Teams);
 - Integrate new/revise existing processes within EFSA Process Architecture;
 - Update the governance/decision-making framework.

Conclusions

The complexity of new processes and tools will be explained to staff and newcomers via dedicated training and will be closely monitored. Higher budget for extensive consultancy and tasks reprioritisation will be needed in order to handle the tight schedule and the COVID-19 emergency. Alignment with the Member States is the base for a structured cooperation.