

NOTE TO THE MANAGEMENT BOARD

Update on the implementation of the Transparency Regulation

In 2 days (27 March) the new requirements of the Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain (TR) shall be in effect. EFSA is progressing according to the plan for the implementation of TR by 27th March and beyond.

EFSA developed and updated the documents which were planned, i.e. Practical arrangements, guidance documents and quality management documents.

Three Practical Arrangements were adopted in December 2020, the fourth was adopted earlier (March 2020). All Practical Arrangements are published on EFSA website. The answers to the questions received from stakeholders on the Practical Arrangement will be published on EFSA website in the next days.

EFSA updated 27 guidance documents (12 administrative and 15 scientific) and one additional scientific guidance document will be updated soon. All will be published in the EFSA Journal. Together with new processes and new tools, also EFSA's Process Architecture was revised leading to the update of many quality management documents.

The new processes to be implemented because of TR are the following: Pre-submission advice, advice for renewal, notification of studies, confidentiality assessment, proactive dissemination, verification studies. Additionally, in the context of TR requirements EFSA had to change several processes such as dossier validation, public consultation and overall risk assessment flow management.

The investment for IT development was very significant. The workflow of applications and generic mandates is going automatically through the integrated IT systems. An example of applications workflow: notification of studies, registration of business entity, pre-submission advice, public consultation starts in the portal Connect.EFSA. Then an application is submitted electronically via FSCAP (in case of PPPs – via IUCLID). The tool supporting the information flows of risk assessment and confidentiality assessment is Appian. Dissemination is ensured via the new portal Open.EFSA. The security of the data entering EFSA is compliant with highest standard. Yet, EFSA is facing some difficulties mainly linked to the uploading of master data in the new systems: cleansing of master data is complex and possibly we underestimated the amount of time needed.

To get TR requirements in place EFSA is strongly cooperating with DG SANTE, ECHA and Member States (MSs). EFSA and DG SANTE organize regular update meetings, brainstorming and together have developed e-submission tool FSCAP (for all food sectors except PPPs). The other e-submission tool, to be used for plant protection products is IUCLID, has been developed with the support of ECHA (European Chemical Agency). To prepare MSs to use IUCLID, EFSA is cooperating with the competent organisation of each MS. Intensive work is also on-going with MSs on the development of a partnership strategy to ensure EU risk assessment sustainability.

The engagement of stakeholders is important to familiarize interested parties with TR requirements, changes and new processes. The various meetings of Sounding Board, Technical Groups (on IUCLID



and Notification of studies) helped to reach a common understanding of the new TR requirements. Trainings in the form of video introductions, webinars, video tutorials (in total 21) are delivered and made available on the EFSA website.

The change management for EFSA staff and scientific panel members was organized through internal communication channel and *ad hoc* info sessions. Trainings are delivered, recorded and are available in a 'one-stop-shop' for EFSA staff as well as for scientific panel members.

To have smooth landing of changes a Hypercare strategy was introduced. Hypercare support is available since 25th January for EFSA staff and starting from 27th March it will be available also for external users.

EFSA will deliver Minimum Viable Product by the deadline. A second phase of work will ensure further improvement in the interest of the public, stakeholders and EFSA itself. EFSA will implement TR requirements beyond 27 March 2021 such as contribution to the general plan for risk communication, preparation for new Management Board, preparation for new Scientific Committee and Scientific Panels and sustainability of risk assessment.