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

To implement the Transparency Regulation EFSA has established a number of projects at the beginning of 2019, in close cooperation with DG SANTE.

Status of the implementation of Transparency Regulation in EFSA

The definition and mapping of the new EFSA's processes to implement the Transparency Regulation is being finalised by the end of 2019/February 2020, to proceed with implementation during 2020.

The actions and steps for the implementation of the Transparency Regulation are progressing in agreement with DG SANTE. EFSA and DG SANTE developed a joint baseline document listing the legally binding specific measures under the responsibility of DG SANTE and EFSA, respectively. Regular meetings of senior managers and technical groups of DG SANTE and EFSA are ongoing. The last meeting on the Transparency Regulation between DG SANTE and EFSA was held on 9 December 2019.

Along 2019, EFSA has designed new scientific processes to be implemented in 2020: internal scientists were supported by external consultants and senior managers have revised the newly developed TO-BE processes. Each process is accompanied by sub-processes.

The requirements of the Transparency Regulation will impact applicants and laboratories carrying out studies for the purposes of EU authorisations in the food chain, Member States, DG SANTE and citizens as following:

Applicants/Laboratories

- There will be the possibility to get general pre-submission advise from EFSA. All pre-submission advices will be made publicly available once a corresponding application is considered valid/admissible. In the case of renewals, applicants will also be getting tailor-made pre-submission advice including on study design.
- In the case of renewals only, applicants will have to notify EFSA of any intended studies.
- Applicants will have to notify EFSA of commissioned studies in all EU authorisation procedures relating to the food chain. The same obligation is also imposed on all EU laboratories which are commissioned to carry out studies for EU authorisation purposes located in the EU or in 3rd countries where relevant international agreements exist.
- All scientific studies/information supporting an EU application procedure will be made public proactively and automatically, early in the risk assessment process, with the exception of duly justified confidential information.

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- Applicants may claim confidential treatment for parts of the information contained in their applications on the basis of a closed list of confidential items and upon verifiable justification; EFSA will be – in principle - assessing confidentiality claims.
- Fact finding missions performed by DG SANTE in Laboratories (2021-2025)
- EFSA engaging with applicants to define suitable dossier structure for e-Submission.

Member States

- EFSA engaging with MSs to define suitable dossier structure for e-Submission.
- Will continue to perform confidentiality assessments in the area of PPP (new active substances) and in the context of the GMO Directive.
- When perform validation/admissibility checks, verifying the match between submitted and notified commissioned studies (in close collaboration with EFSA).
- Will be represented in the new Management Board, preparatory work will start in 2020 and will be finalised in 2022.
- Will have new tasks defined in the Focal Points agreement that will provide additional budget.
- Will be more involved in the production of scientific opinions. EFSA is planning to outsource some scientific tasks to organisations under Art. 36.
- Will actively support the pooling of scientific experts in support of EFSA's Scientific Committee, Panels and Working Groups.

Commission

- Will be assessing confidentiality claims only in two specific cases under the Novel Foods Regulation (traditional foods) and in the context of the common authorisation procedure for food additives/enzymes/flavourings (where no EFSA opinion is required).
- When perform validation/admissibility checks, verifying the match between submitted and notified commissioned studies (in close collaboration with EFSA).
- Will adopt a General plan on risk communication with input from EFSA and the Member States.
- Fact finding missions performed by DG SANTE in Laboratories (2021-2025)

Citizens

- Additional public consultations will be organised during several phases of risk assessment.
- Transparency: Practical arrangements on transparency and confidentiality are drafted and will be submitted for comments to DG SANTE with a view to be approved in 2020. This document provides details on the standards and procedure applicable to the obligation of proactive publication of information and the procedural and substantive requirements underlying the submission and assessment of confidentiality requests.
- All scientific data studies/information supporting any request for an EFSA scientific output an EU application procedure will be made proactively public on EFSA's website, except for duly justified confidential information. (Non-confidential documents, data related to applications and risk assessment process will be published on EFSA's website).

Main challenges

- Scope and complexity (integration) of the IT developments needed in a very short timeframe.
    - Change management: Commission, Member States and applicants.