

73rd Advisory Forum meeting Helsinki, Finland, 18-19.09.2019

Update on the implementation of the Transparency Regulation

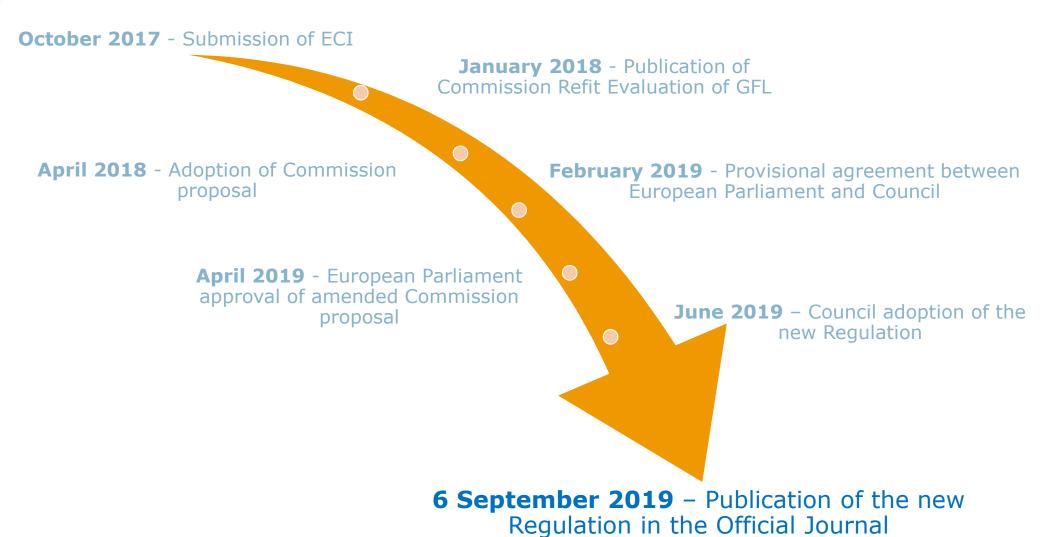
Guilhem de Seze REPRO Head of Department





Main milestones in adoption process





REGULATION (EU) 2019/1381



6.9.2019 EN Official Journal of the European Union L 231/1

I

(Legislative acts)

REGULATIONS

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Priorities in a nutshell



Transparency & Confidentiality



Scientific value



Engagement & Risk Communication



Governance



Working methodology to address Transparency Regulation priorities



Strengthened transparency (early proactive public disclosure), new processes for confidentiality assessment, and the new Management Board composition

Database of commissioned studies / updating work-flow for applications; efficient services to staff/ experts supporting the Transparency Regulation processes

Technology and Services

Providing capacity to address
Transparency Regulation
priorities and new processes
with additional staffing as
from 2020

Organisational Design



Governance







Science

New science processes - including adaptation/revision of related guidance documents - ensuring integration of Transparency Regulation requirements

Engagement and Risk Communication

Engagement and partnering with EFSA's stakeholders, in support of the science processes and contributing to a general plan for Risk Communication

Challenges



Translating the law into procedures delivering EFSA's new mandate

Managing time-frame and expectations

TRANSLATING LAW INTO PROCEDURES



DG SANTE and EFSA are working closely to meet the challenges

- Mapping of implementation actions legal bases, responsibility, expected timelines etc. (EC leading)
- Together with EC, shaping an engagement plan and calendar
- Discussions with MSs (e.g. ANSES, BfR in the context of recent institutional visits) and regular AF updates

EFSA preparatory work (1)





Transparency & Confidentiality

- Practical arrangements for implementing the transparency requirements
- Practical arrangements for setting up/managing the database of commissioned studies and the overall implementation of the notification obligation, including updating relevant workflows

EFSA preparatory work (2)





- Preparing for the review of scientific /administrative guidance's against new leg. requirements
- Preparing for the IT infrastructure to implement transparency provisions while collating requirements for data formats and relevant automation tools (short vs. long term needs and solutions)
- Enhancing engagement in scientific output production

EFSA preparatory work (3)





Governance

- Define new expert engagement models
- Support DG SANTE in relation to the establishment of the new Management Board
- Getting equipped to delegate preparatory scientific work to the Authority's staff
- Exploring solutions for accommodating the new staff (+106) and an enlarged MB

EFSA preparatory work (4)





Engagement & Risk Communication

- Explore suitable processes to allow competent organisations to support EFSA work
- Analyse future needs for public consultations and explore available technical solutions
- Review and benchmark available risk communication products, dissemination practices and societal listening mechanisms
- Define engagement principles and establish a Sounding Board and technical user groups to accompany implementation

HIGH LEVEL TIMELINES



TODAY

Translate the law into procedures in collaboration with SANTE: transparency, confidentiality updating processes for data-work-flow, database of commissioned studies, preparing the ground for standard data formats

Prepare implementation (including development of necessary supporting tools)

Start delivering the added value enshrined in the Transparency Regulation

2019

2020

2021... and beyond