

Update on the implementation of the Transparency Regulation

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Trusted science for safe food

Main milestones in adoption process

October 2017 - Submission of ECI

January 2018 - Publication of
Commission Refit Evaluation of GFL

April 2018 - Adoption of Commission
proposal

February 2019 - Provisional agreement between
European Parliament and Council

April 2019 - European Parliament
approval of amended Commission
proposal

June 2019 – Council adoption of the
new Regulation

6 September 2019 – Publication of the new
Regulation in the Official Journal

6.9.2019

EN

Official Journal of the European Union

L 231/1

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(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

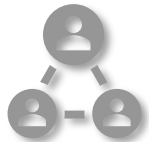
Governance

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



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

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



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



Scientific value

- 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



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



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

- **Sounding Board:**

- What: to inform on status of implementation in general
- Who: SH Bureau + up to 1 Rep per SH category, MS Reps, EC
- When: Launch in October – first meeting in Fall

- **Technical groups:**

- What: To inform SHs on specific technical area
- Who: Industry SHs and Pan Europe, MSs, EC, observers from all SH categories
- When:
 - “Technical group - IUCLID pilot” launched in September; 2 meetings foreseen: one in November 2019 and second in Q1 2020
 - Other technical groups as needed

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