

Management Board
18 December 2019

Update on the Implementation of the Transparency Regulation

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Programme Manager

Trusted science for safe food

Timing of Transparency Regulation

We are here

ART Programme

EFSA establishes the ART Programme to drive the implementation of the Transparency Regulation

Mar
2019

Sep
2019

Publication

The Union publishes the Transparency Regulation

Implementation

EFSA completes all designs for process, data formats, organisation model and technology

Jul
2020

Dec
2020

Completion

New policies, processes, guidelines, information technology are fully operational

Entry into application

The new rules will not apply to requests for scientific output submitted to EFSA before its entry into application

Mar
2021

Jul
2022

Management Board

As of 1 July 2022:

- New Management Board;
- New selection process procedure of experts

From design to implementation

2019

Design phase



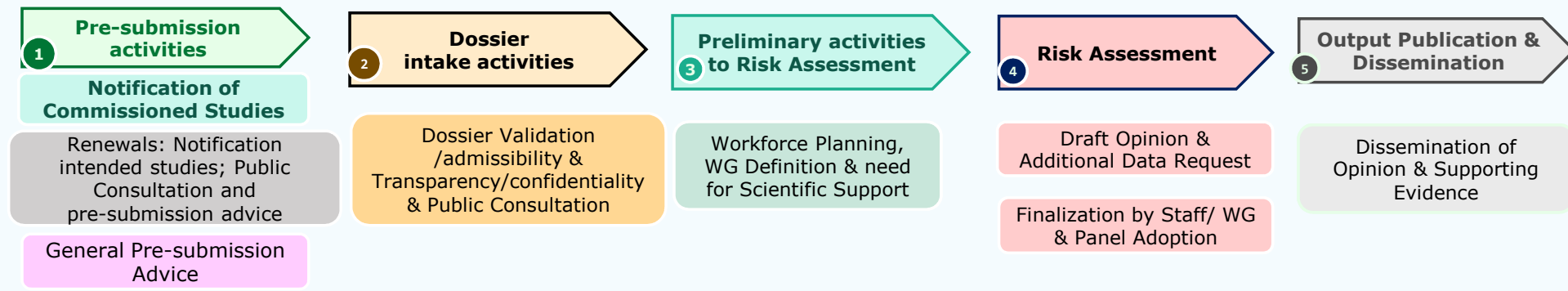
2020

Implementation phase

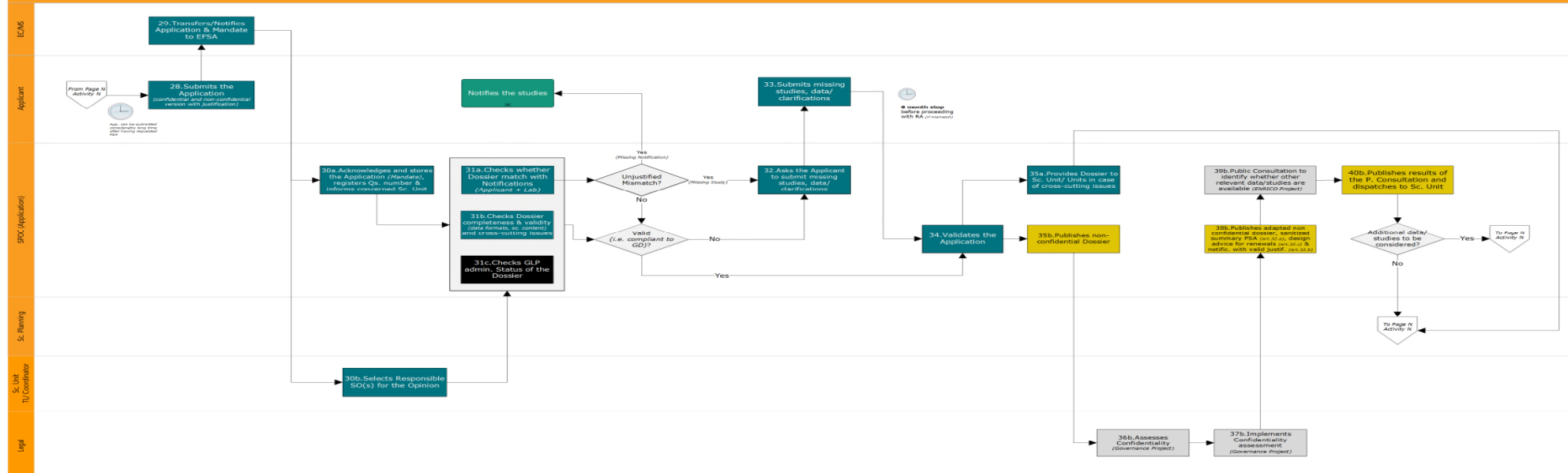


Example of scientific processes design

Scientific Risk Assessment of Applications



TO-BE RA Process: Dossier Ingestion/Management Activities



What does the Transparency Regulation mean?

for
applicants/
laboratories



for Member
States



for
Commission



for
Citizens



What does the Transparency Regulation mean for applicants / laboratories?



General Pre-submission advice to applicants

Process design is finalized
Implementation is beginning

Practical arrangements in 2020

Notification of commissioned studies, applicants/laboratories inform EFSA
(Renewals: intended studies)

Technical documents drafted

Practical arrangements in 2020,
Technological solutions in March 2021

Transparency/Confidentiality – applicant's claims (mainly) evaluated by EFSA

Practical arrangements drafted

Consultation and approval by 2021

Engaging with EFSA: Dossier structure for e-submission

Processes are mapped

Implementation with DG SANTE FSCAP
in 2020

Fact finding missions performed by DG SANTE in Laboratories (2021-2025)

What does the Transparency Regulation mean for Member States (1/3)



For MSs forwarding applications to EFSA:

a. Engaging with EFSA on Dossier structure for e-submission

Process under development

Implementation (2020)

b. Confidentiality assessment in case of PPP (new active substances), GMO directive

Drafting of practical arrangements started

Consultation and approval (2021)

c. Validation/admissibility, verifying the match between submitted and notified studies

Access to system under design

Implementation March (2021)

What does the Transparency Regulation mean for Member States (2/3)



Member of EFSA's Management Board

Work will start in 2020

Finalisation in 2022

New tasks for Focal Points

Increased budget and amended FP Agreements

Implementation of new FP tasks in 2020

Contribute to the production of scientific opinions (outsourcing)

Possibilities and opportunities defined

Piloting in 2020

What does the Transparency Regulation mean for Member States (3/3)



Active role in pooling the best experts for EFSA's scientific committee, panels and working groups

Process under development

Expected outcome in 2022

Perform dossier acceptance/RA in EC-EFSA software tools (centralisation of dossier management needed to allow e-submission)

Technologies under development according to defined needs

Testing in 2020

What does the Transparency Regulation mean for the Commission



Assessment of confidentiality claims under the Novel Foods Regulation (traditional foods) and in the context of the common authorisation procedure for food additives/enzymes/flavourings

When perform validation/admissibility checks, verifying the match between submitted and notified commissioned studies [in close collaboration with EFSA]

Adoption of 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)

What does TR mean for citizens



Public Consultation - EFSA will consult the public during the risk assessment

The process is defined

Approval of Practical arrangements in 2021 March

Access to documents / Aarhus Regulation

Practical arrangements drafted and shared with DG SANTE. Mechanism is under development

Approval of Practical arrangements by end of March 2020

Transparency & confidentiality

Practical arrangements drafted

Approval of Practical arrangements in 2020

The General Plan on Risk Communication

Steering Group established

EFSA to provide input to DG SANTE

Main challenges



- Scope and complexity (integration) of the IT developments needed in a very short timeframe
- Change management with all actors, especially external: DG SANTE MSs and applicants

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