

# Impact of the Transparency Regulation

**Gisèle Gizzi**

Relationship Management Project manager

Trusted science for safe food

## What does the Transparency Regulation change?

for  
applicants/  
laboratories

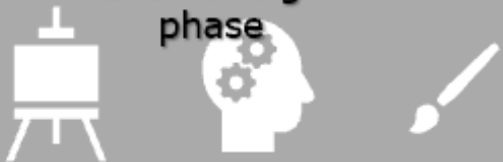
for  
Member  
States

for  
Commission

for  
citizens

## How EFSA's implementing

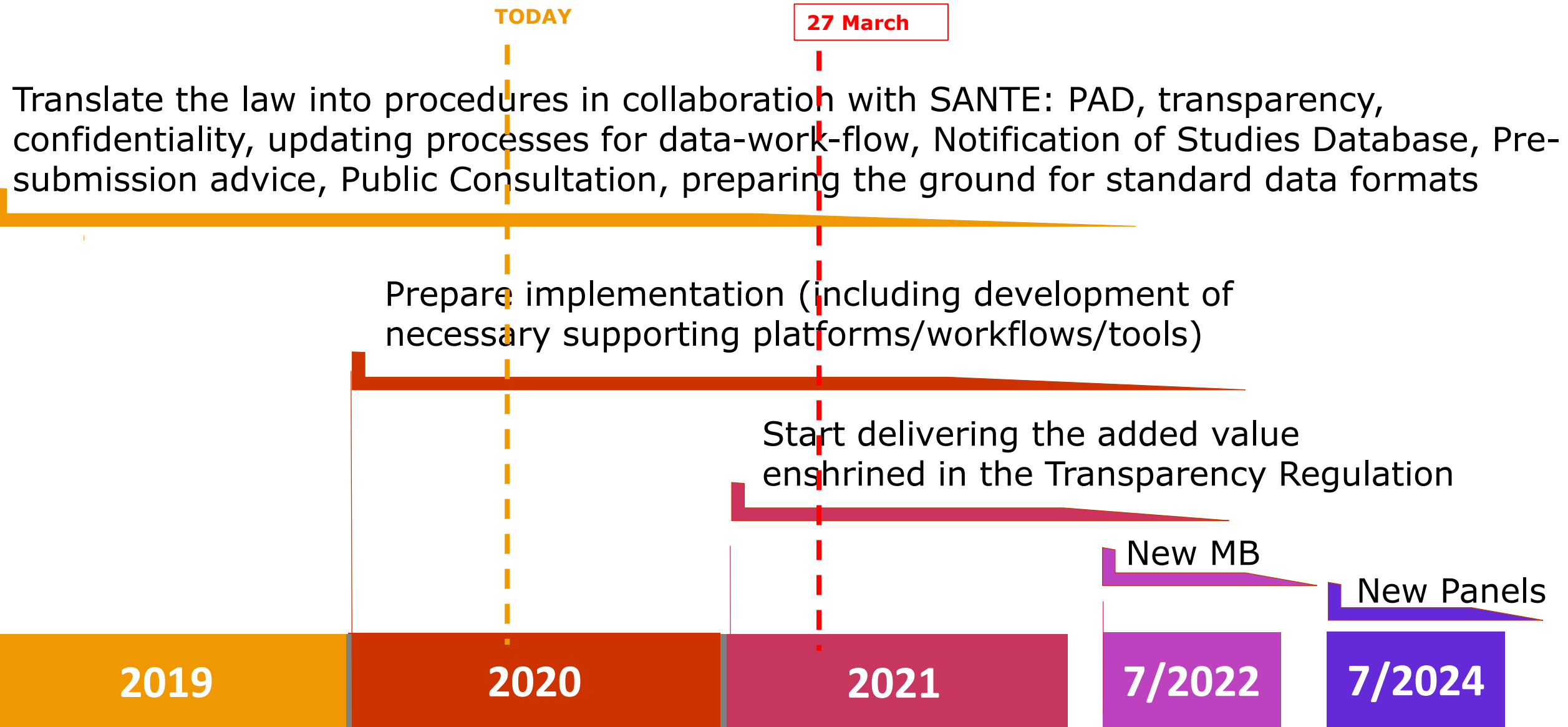
2019 Design  
phase



2020 Implementation  
phase



# HIGH LEVEL TIMELINES



# Priorities in a nutshell

Transparency &  
Confidentiality



Scientific value



Engagement & Risk  
Communication



Governance





## Transparency & Confidentiality

- Practical arrangements on Public Access to Documents (Aarhus) -> adopted by MB in March, published;
- Practical arrangements implementing the Transparency and Confidentiality requirements -> draft delivered by EFSA, now in consultation with EC
- Art. 32 Practical arrangements: setting up and managing the database of notification of commissioned studies; setting up and managing the pre-submission advice service; public consultations -> draft delivered by EFSA, now in consultation with EC



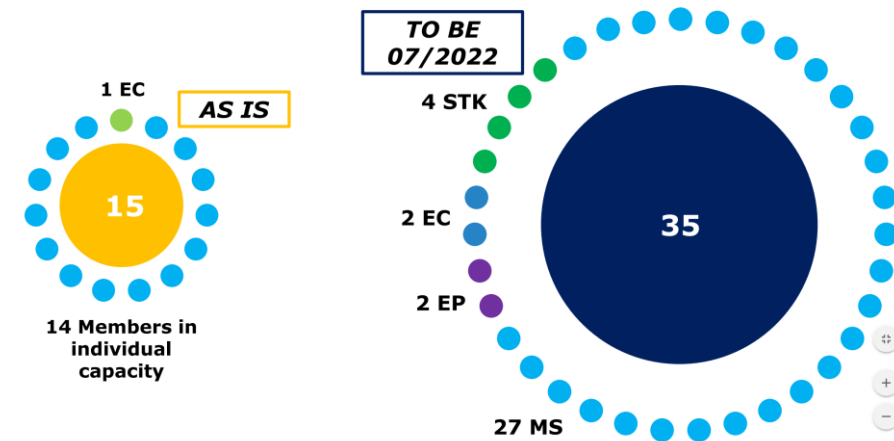
## Scientific value

- Review and update of 12 administrative & 17 scientific guidance documents in alignment with SANTE through sectoral meetings: work on going, expected adoption by fall 2020
- Preparing for the IT infrastructure to implement TR provisions, expected delivery by 12/2020, training until 03/2021:
  - Customer Relation Management : Notification of Studies Database; Pre-submission advice; Public access to documents; Public Consultation;
  - Dossier eSubmission (FSCAP, IUCLID);
  - End-to-End RA workflow, confidentiality assessment
  - Secure storage and controlled access; dissemination; proactive disclosure



## Governance

- Support DG SANTE in relation to the establishment of the new Management Board (7/2022)
- Getting equipped to delegate preparatory scientific work to the Authority's staff
- Defining new expert engagement models
- New expert compensation scheme, addressing preparatory work and indexations gap



## Compensation Scheme

Total Indemnity Increase **900 €**



Full Day Attendance Increase:

385 € → 450 €



Preparation Indemnity Increase:

0 € → 450 €



## Engagement & Risk Communication

- Joint Steering Committee for Coordinated Risk Communication, established in December 2019 with EC and 3 MSs
- EC mandate for the provision of technical assistance in the field of risk communication, received and accepted on 25 of March
- The EFSA's expert Working Group on Social Research Methods and Advice has kicked off work to respond to the mandate through a scientific report on risk communication
- Benchmark, identification and agreement on future social media monitoring requirements, reached (pilot in Q3 2020)
- TO-BE Processes linked to Public Consultation designed. Solution for technical management, identified
- Explore suitable models to allow comp. organisations to support EFSA