

78th Advisory Forum meeting
Virtual meeting, 2-3 December 2020

Transparency Regulation: Update on Transparency in Risk Assessment

Guilhem de Seze
REPRO Head of Departement

Trusted science for safe food



Timeline

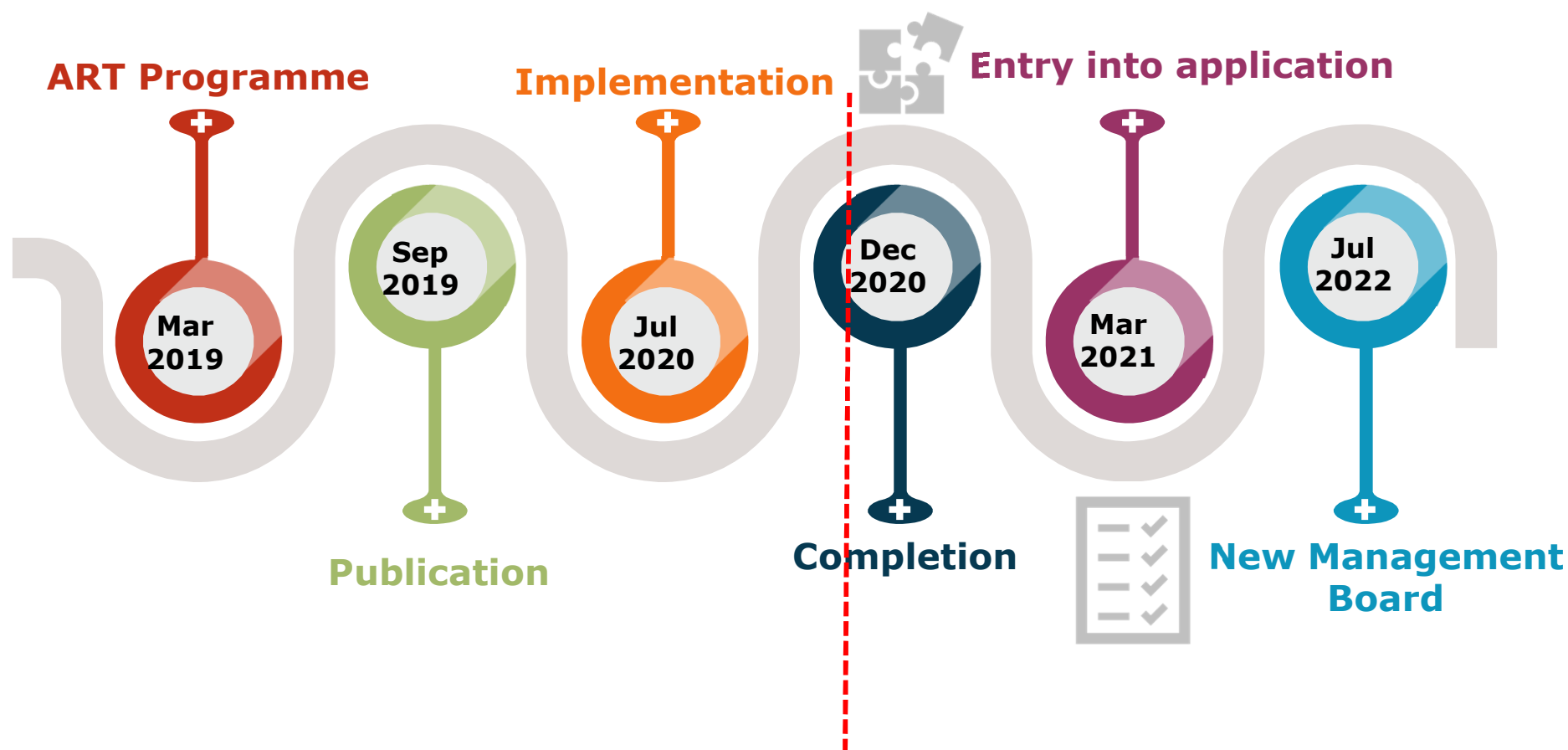
New, updated EFSA's documents

Technology

External engagement, communication, training

Conclusions

Progresses with respect to plan



New, updated EFSA's documents

To comply with the Transparency Regulation EFSA is developing and updating numerous documents:

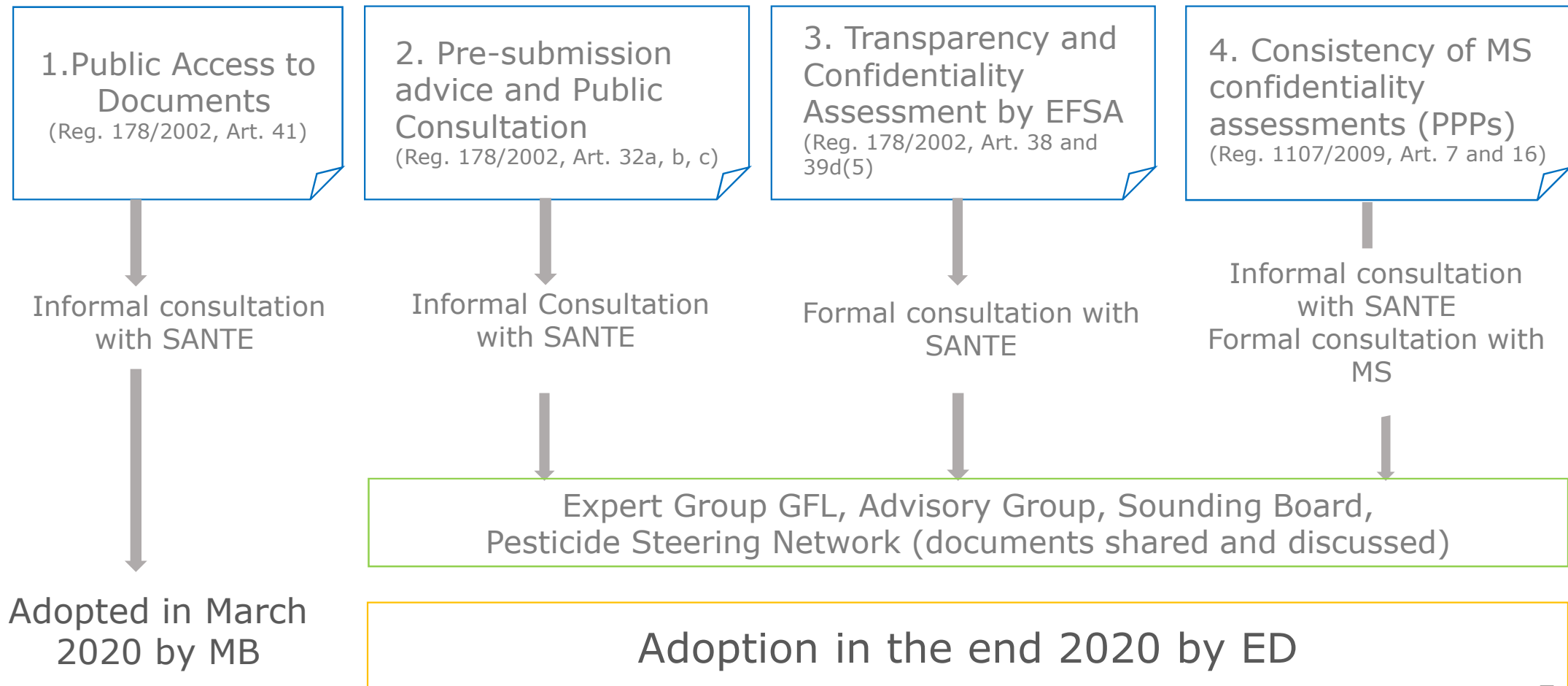
Practical
Arrangements

Guidance
Documents

Decisions of
Management
Board

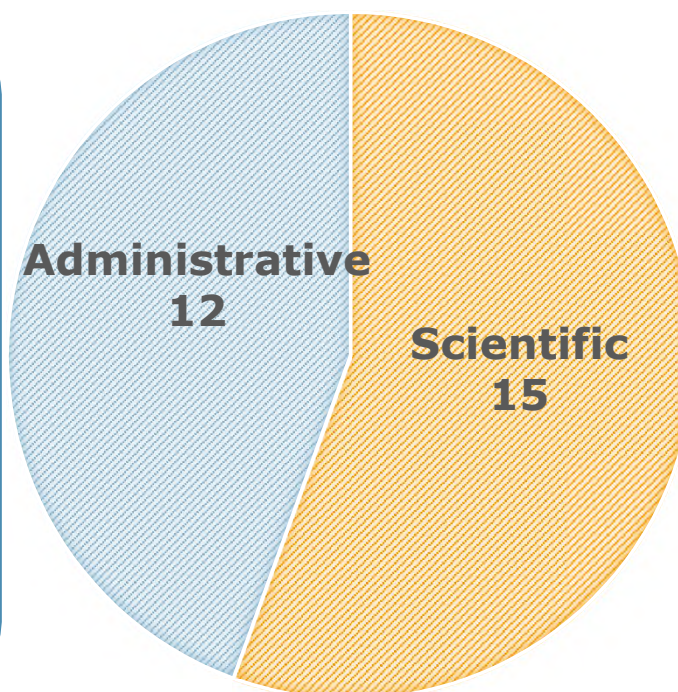
Quality
Management
Documents

Practical Arrangements



EFSA updated 27 Guidance documents

- EFSA's Catalogue of services during the lifecycle of applications
- General for regulated products
- Feed additives
- GMO renewal
- GMO authorisation
- Food contact materials (3 GDs)
- Food enzymes, additives and flavourings
- Smoke flavourings
- Pesticides and MRL
- Novel food



- Food enzymes
- Flavourings
- Food additives
- Novel food
- Nutrient sources
- Health claims (2 GDs)
- Allergenic foods
- Traditional foods from 3rd countries
- Infant formulae
- Foods for special medical purposes
- Decontamination of surface from foods of animal origin
- Food contact materials (3 GDs)

All will be published before 27th March 2021

- 15 decisions of the Management Board to be updated
E.g. the MB Decision on the operations of EFSA's scientific Networks to be adopted during MB meeting in December 2020.
- Quality management documents to be updated or newly written



12
SOPs



98
WINs

Information Technology

SALESFORCE

- ✓ Notification of studies
- ✓ Pre-submission advice
- ✓ Public access to documents
- ✓ Public Consultation

FSCAP Dossier
eSubmission (except
pesticides)

IUCLID Pesticides PPP
& MRL eSubmission

APPIAN

- ✓ Risk
assessment
workflow
- ✓ Confidentiality
assessment

MICROSOFT AZURE

- ✓ Secure storage
and controlled
access
- ✓ Dissemination
- ✓ Proactive
disclosure

Construction
completed:
by September 2020

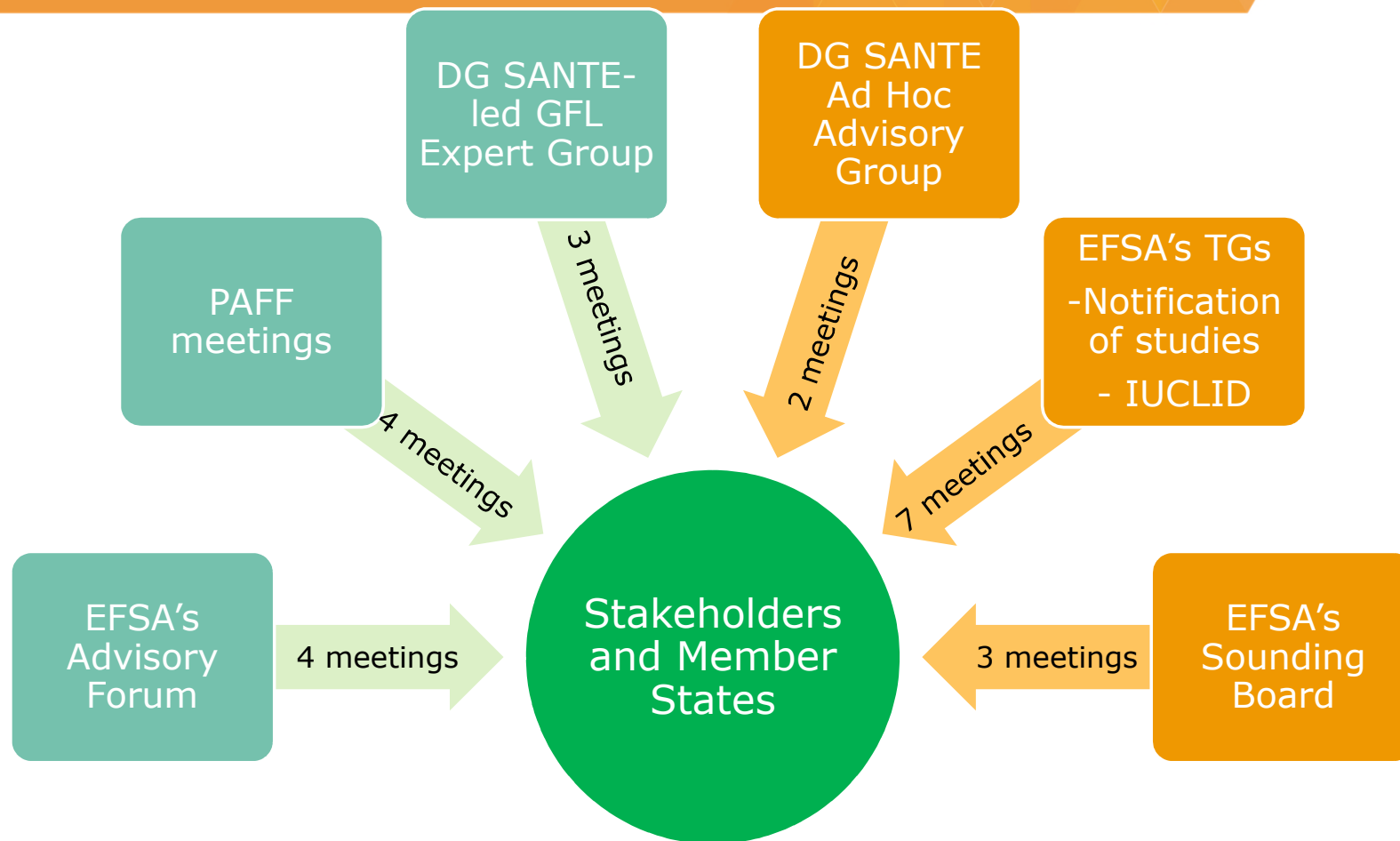
Validation
In Progress:
by December 2020

Business
Simulation:
by March 2021

Further features
beyond March 2021

- Sanitisation (document redaction) software
- Confidentiality assessment for all EFSA data sets (beyond regulated products)
- IUCLID workflow integration for confidentiality assessment of Pesticides dossiers
- Additional IUCLID features for Pesticides

External engagement throughout the process



In Q1 2021: Joint DG SANTE-EFSA info session with ENVI Committee
DG SANTE celebratory event with the participation of EFSA

Training activities targeted to external parties



When: January - March 2021

Depending on the trainings' outcome and feedback, additional sessions might be organised after March.

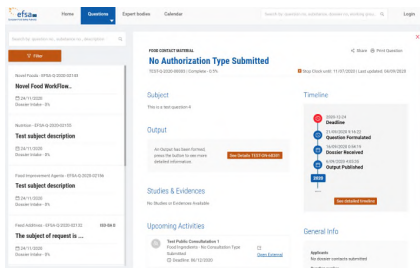
Information (Introduction webinar) session was on 19 November

What: Notification of studies, Pre-submission advice, EFSA's guidance documents update, new IT tools (FSCAP, IUCLID), account registration and others

How: Trainings will be recorded and made available in the training space on the website. Every session will allow up to 10000 participants

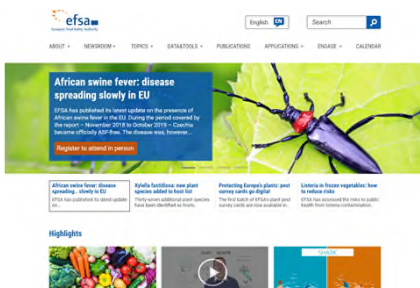
Promotion: EFSA's website section on TR dedicated to business operators, mailing list campaigns to: Advisory Forum, Focal Points, Art.36 organisations, applicants and stakeholders

Open.EFSA portal and Website



■ new Open.EFSA portal – March 2021 Risk assessment from receipt to adoption

- status of assessment
- dossier and studies (non-confidential versions)
- meetings agenda and minutes
- info on experts
- etc.



■ Website upgrade – February 2021

- Improved navigation and usability, focus on lay audience
- Increased speed, security and flexibility
- Visual revamp

Challenges and conclusions

Challenges



- ✦ Time, Workload, prioritisation
- ✦ Change management – for new processes, new IT tools
- ✦ Industry knowledge of e-Submission requirements to facilitate compliance
- ✦ Manage stakeholder expectations with regards to transparency

Conclusions

- ✦ EFSA will be ready to comply with TR requirements as of 27th March 2021
- ✦ Strict prioritization of tasks is a key
- ✦ Continued joint efforts needed from EFSA, DG SANTE, MSs and stakeholders

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