



79th Advisory Forum meeting
Virtual meeting, 03-04 March 2021

Implementation of Transparency Regulation – 1st phase

Guilhem de Seze

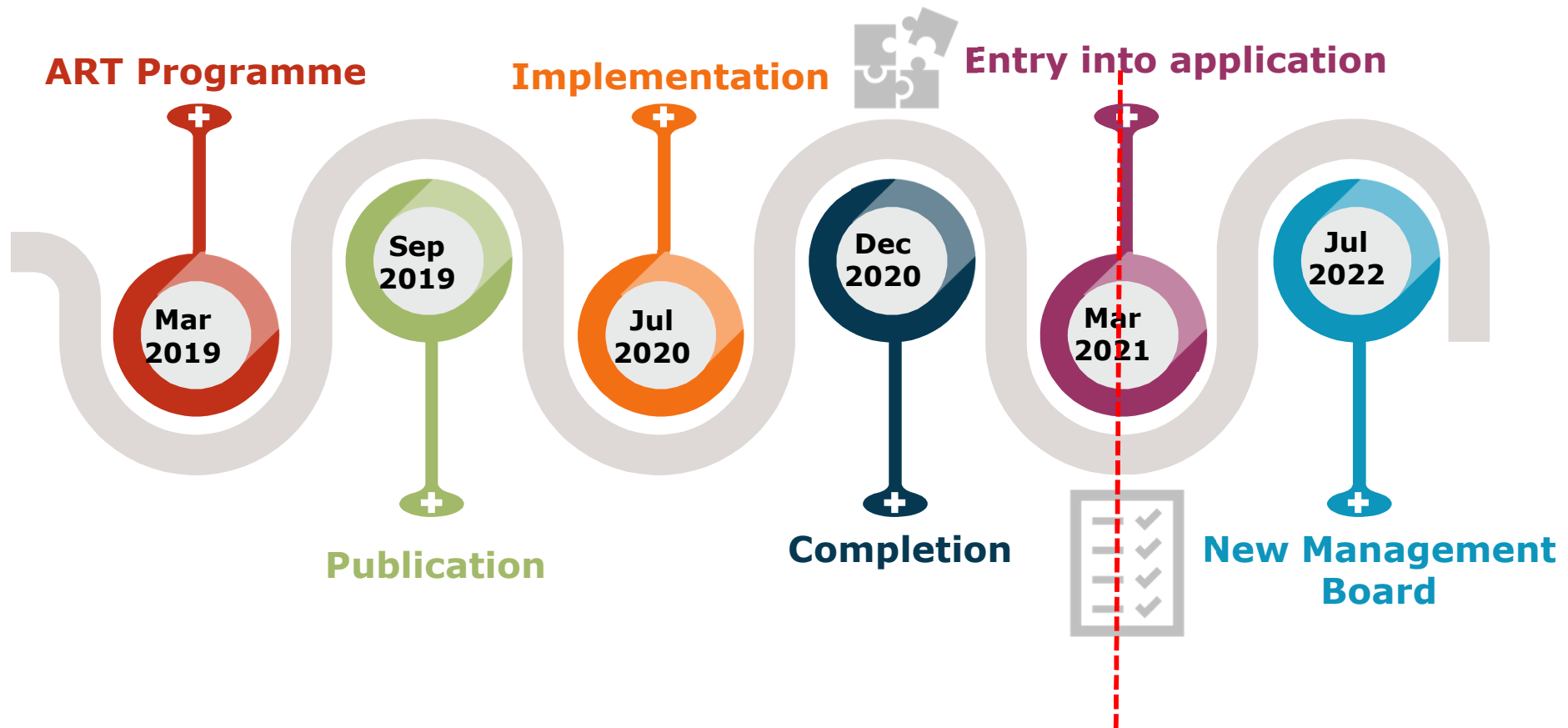
Head of REPRO Department

Trusted science for safe food



- 1. Readiness
 - 1.1. Documents
 - 1.2. Technology
 - 1.3. Training
 - 1.4. Hypercare
- 2. External Engagement
- 3. Look ahead

Progresses with respect to plan



Documents. Practical Arrangements

1. Public Access to Documents
(Reg. 178/2002, Art. 41)

Adopted in March 2020 by MB
Published on EFSA website

2. Pre-submission advice and Public
Consultation
(Reg. 178/2002, Art. 32a, b, c)

3. Transparency and Confidentiality
Assessment by EFSA
(Reg. 178/2002, Art. 38 and 39d(5))

Adopted in December 2020 by ED
Published on EFSA website

4. Consistency of MS confidentiality
assessments (PPPs)
(Reg. 1107/2009, Art. 7 and 16)

Answers to the Questions related to PAs received from the stakeholders are prepared by EFSA colleagues and will be published on the website by 27 March

EFSA completed the revision of 27 guidance documents (GDs):

✓ 12 administrative and 15 scientific GDs

- Concluding activities:

- Formal consultation of 4 administrative GDs (smoke flavourings and 3 food contact materials) with the College of Commissioners is finalized, comments addressed
- Pesticide GD was consulted with PAFF committee, comments under finalization

Publication of all GDs in EFSA Journal by 27th March

Technology building blocks and structure

Different portals will serve the public, authorities, stakeholders and the business operators:

CONNECT.EFSA (CRM/SALESFORCE)

- ✓ Account and Identity Management
- ✓ Notification of Study
- ✓ Pre-Submission Advice
- ✓ Public Consultation
- ✓ Ask EFSA
- ✓ Public Access Documents (PAD)
- ✓ Scientific Value and Mandate Negotiation Acceptance*

FSCAP:

- ✓ Dossier eSubmission (all sector area, except pesticides)

IUCLID:

- ✓ Pesticides PPP & MRL eSubmission

INTERNAL RA WORKFLOW (APPIAN):

- ✓ Risk assessment workflow
- ✓ Confidentiality assessment

MICROSOFT AZURE:

- ✓ Secure storage and controlled access
- ✓ Dissemination (Open.EFSA)
- ✓ Proactive disclosure

*- *under discussion with SANTE*

In all cases, security and confidentiality are key aspects of the new technology, and compared to today's systems a higher level of automation to ensure respect for deadlines and including auditability, dual factor authentication, monitoring and logging

- 54 organisations from 29 Countries have been identified as needing VPN access to Agency IUCLID
- 29 Organisations have accepted a solution and 23 have an implementation plan
- 8 are identifying the most suitable solution

How to move forward

- 1) Complete the [contact details survey](#) if you have not done so
- 2) Respond to EFSA IT consultants e-mail to define an implementation plan

Training activities targeted to external parties

A rich training programme developed to onboard EFSA Stakeholders and some specific sessions for Member States:

- ❑ 9 webinars planned by Q2 2021 (1st webinar in November (introduction on TR) was limited to 500 participants; 2nd webinar on 16th February had more than 1100 participants)
- ❑ 14 video-tutorials
- ❑ The recording of the webinars and the video-tutorials are progressively made available on the EFSA website ([link](#))

**Spread the word within your
Member State!**



What?

Hypercare is a **temporary** programme function. The main purpose of the Hyper care period is to give EFSA's internal and external Stakeholders a **smooth landing** by providing them crucial **end-user support**

When?



Who & how?

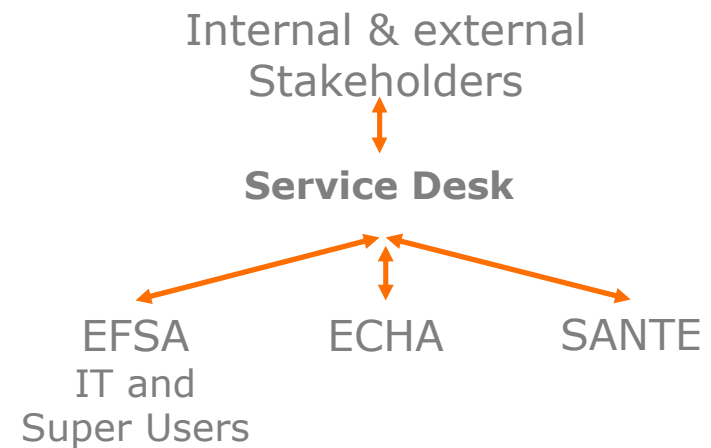
Internal Stakeholders



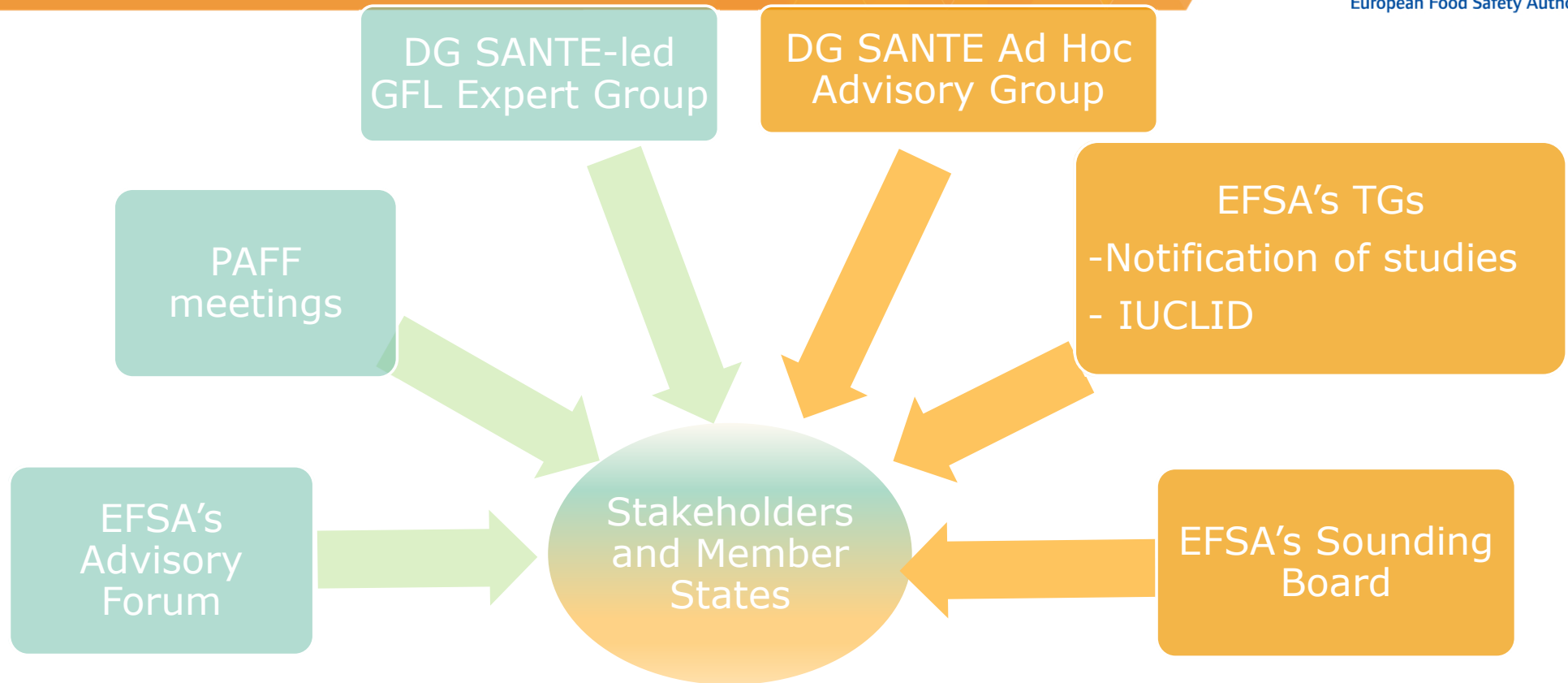
Purpose: answer all questions (not on PAs) received from **external** SH via the functional mailboxes (SH and TR), webinars and trainings

When: 1 Feb – 27 March 2021

Taskforce



External engagement



- ❑ Joint DG SANTE-EFSA info session with ENVI Committee is planned tentatively for April
- ❑ DG SANTE celebratory event with the participation of EFSA will be on 30th March

- Continuation of processes and IT improvements such as:
 - Redaction software to permit EFSA to sanitise the dossier
 - New separate portal for the confidentiality assessment of data sets submitted to EFSA due to non-regulated product mandates, EFSA calls for data and similar data sets
 - IUCLID workflow integration for confidentiality assessment of Pesticides dossiers
- Preparation for the new Management Board in 2022
- Preparation for new Scientific panels

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