



Management Board
17 June 2020

Update on the Implementation of Transparency Regulation

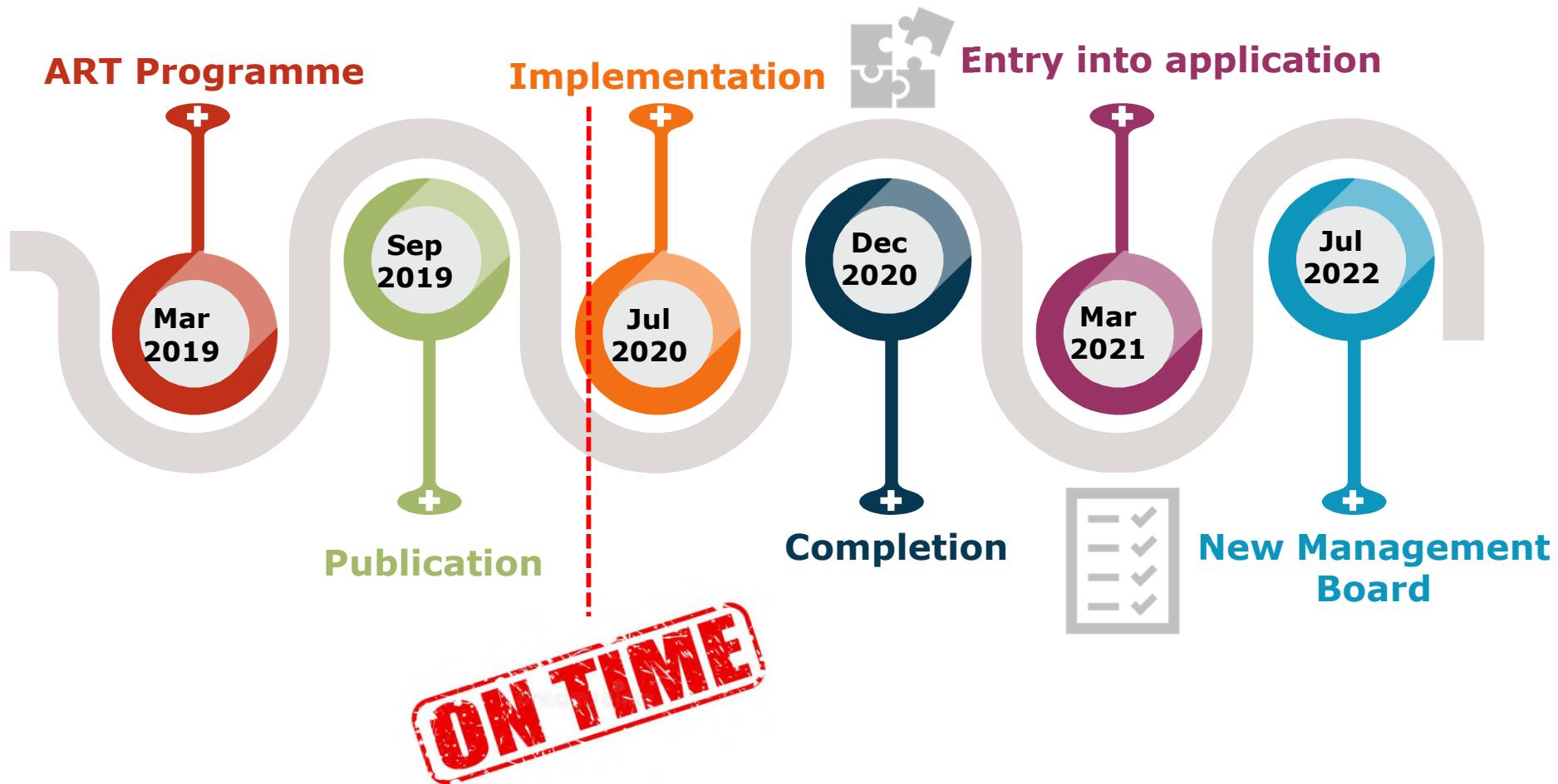
Claudia Paoletti

Programme Manager

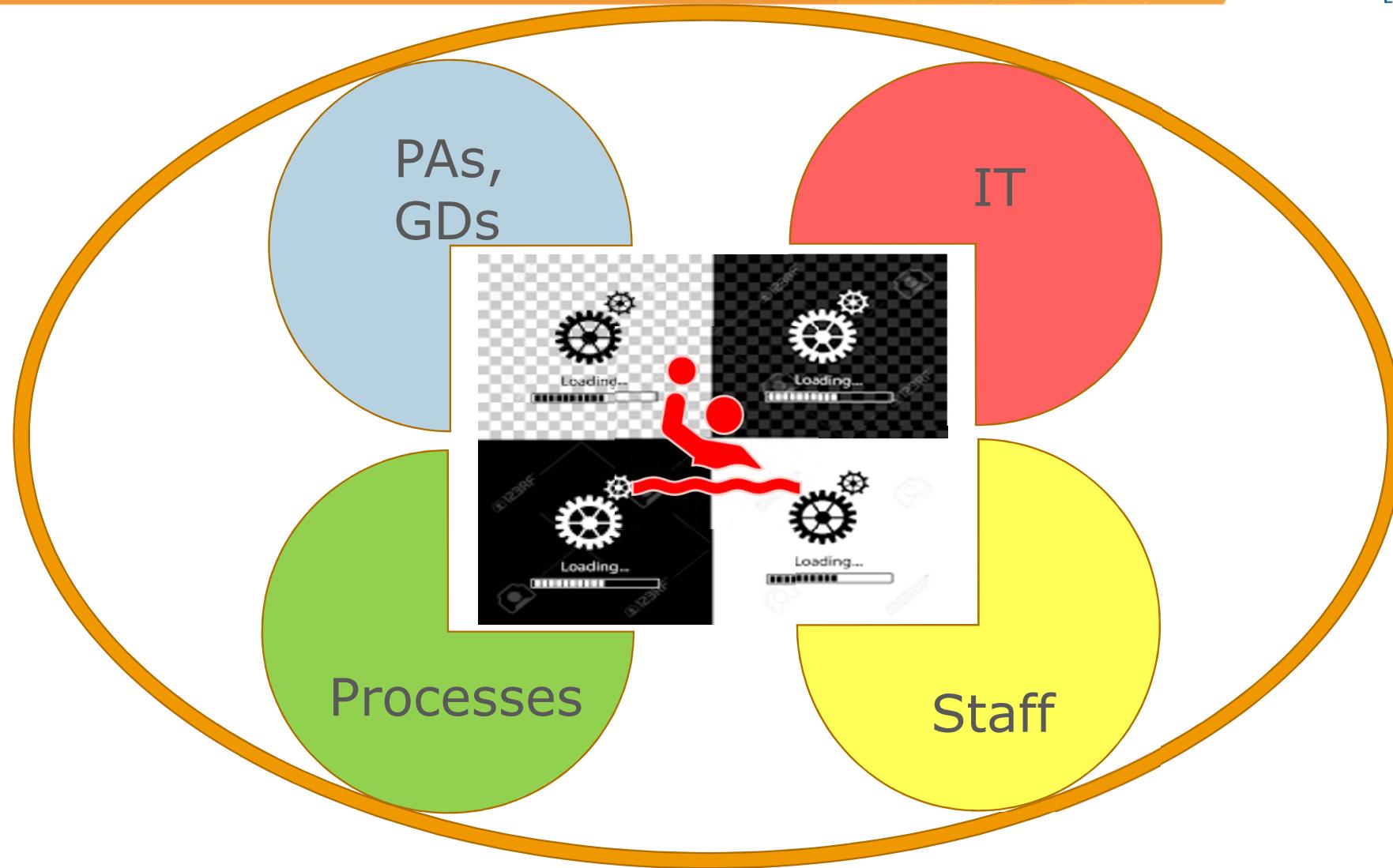
Trusted science for safe food



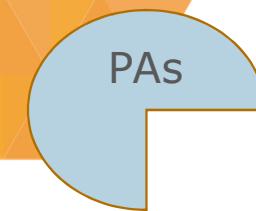
Progressing according to plan



Elements of ongoing work



Practical Arrangements



1. Transparency and Confidentiality Assessment

2. PPPs (Confidentiality Assessment by MS)

3. Pre-submission advice, NoS, Public Consultation

Under consultation with SANTE

➤ Under consultation with SANTE
➤ Consultation with MS in July

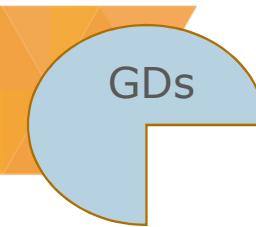
Under consultation with SANTE

Introduction, update to:

- ✓ Sounding Board (March, July, September)
- ✓ Advisory Group (June, September)

- ✓ Presentation to Stakeholders (November)

- ✓ Adoption and publication in December



➤ To be updated:

10 administrative GDs



16 scientific GDs

- All changes to GDs aligned with DG SANTE
- Work on GDs updating is ongoing, aligned with drafted Practical Arrangements
- To be shared with DG SANTE for comments

Finalization/Adoption:
Fall 2020

Processes (by end 2020)

Processes

New due to TR:

- Confidentiality assessment;
- Proactive dissemination;
- Verification studies;
- Pre-mandate activities:
 - Pre-submission advice
 - Advice for renewal
 - NoS database

Changed due to TR:

- Dossier validation (+ NoS, GLP)
- Public consultation

Leaned / harmonised:

- Risk assessment
- Scientific service support
- Scientific administrative support
- Shared Service Office (SSO)

Sourcing:

Partnership model/Sourcing framework: work in progress

Technology building blocks and structure

SALESFORCE 1,6 M Eur:

- ✓ Notification of studies
 - ✓ Pre-submission advice
 - ✓ Public access to documents
 - ✓ Public Consultation
- 49% Complete**

FSCAP – 0,8 M Eur:

- ✓ Dossier eSubmission (except pesticides)
- 33% Complete**

IUCLID - 1,3 M Eur:

- ✓ Pesticides PPP & MRL eSubmission
- 40% Complete**

APPIAN 1,3 M Eur:

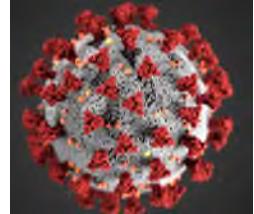
- ✓ Risk assessment workflow
 - ✓ Confidentiality assessment
- 23% Complete**

MICROSOFT AZURE 1,6 M Eur:

- ✓ Secure storage and controlled access
 - ✓ Dissemination
 - ✓ Proactive disclosure
- 18% Complete**

Percentages of completion refer to the percentage of user requirements that have been built. Completion of the build phase in September will be followed by user acceptance testing in Q3.

Interim solution for staff allocation



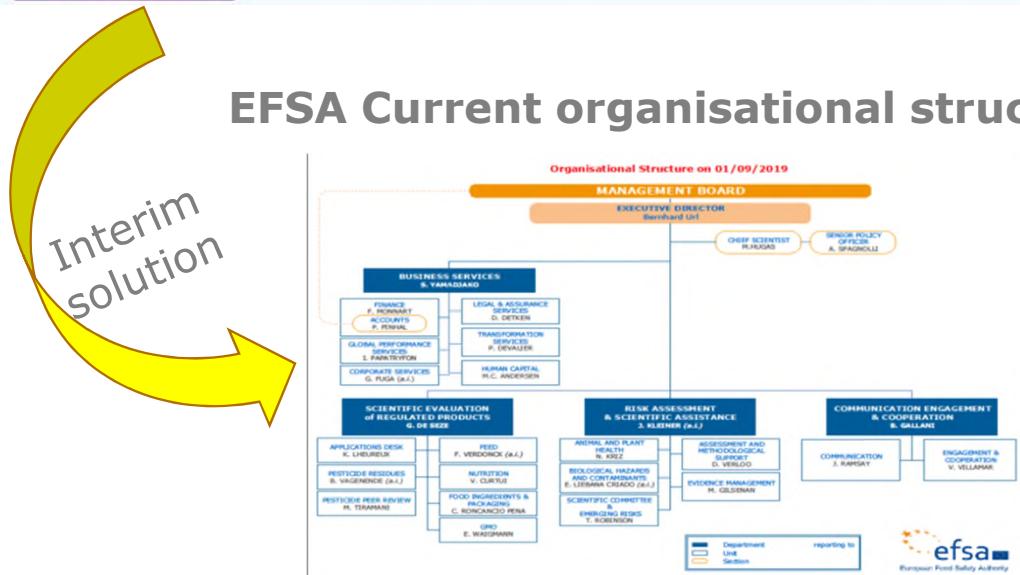
Organisational Design Project
postponed to the end 2021



End to End science to-be processes (including mandatory TR activities)



EFSA Current organisational structure



Challenges

Complexity of changes:

- ✓ new processes
- ✓ new tools

- ✓ Tight schedule
- ✓ COVID-19 emergency

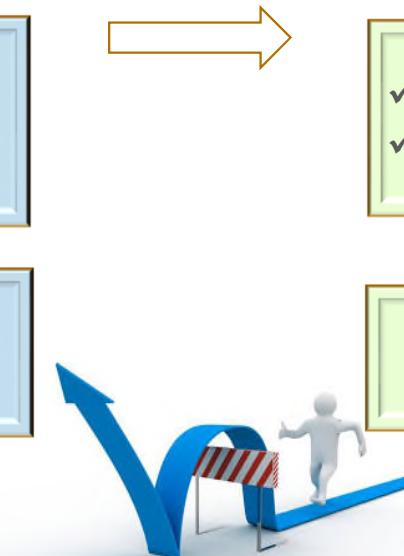
Alignment with MSs

Solutions

- ✓ Close monitoring of progresses and issues
- ✓ Training on new processes and tools

- ✓ Extensive consultancy
- ✓ Re-prioritisation

Structured cooperation



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