

Update on the Implementation of Transparency Regulation

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Timeline



Practical Arrangements and Guidance documents



External engagement



Technology



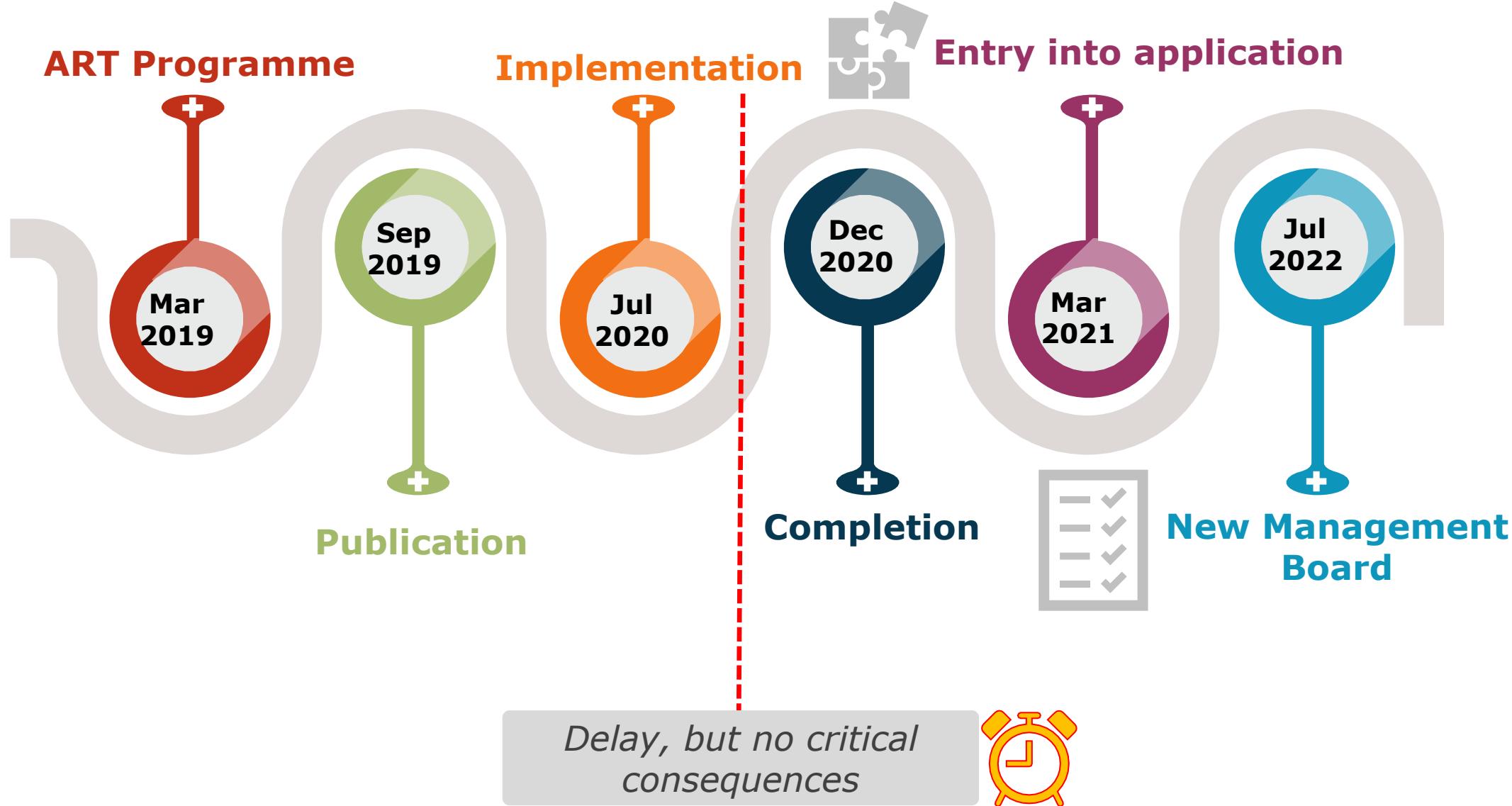
Change management



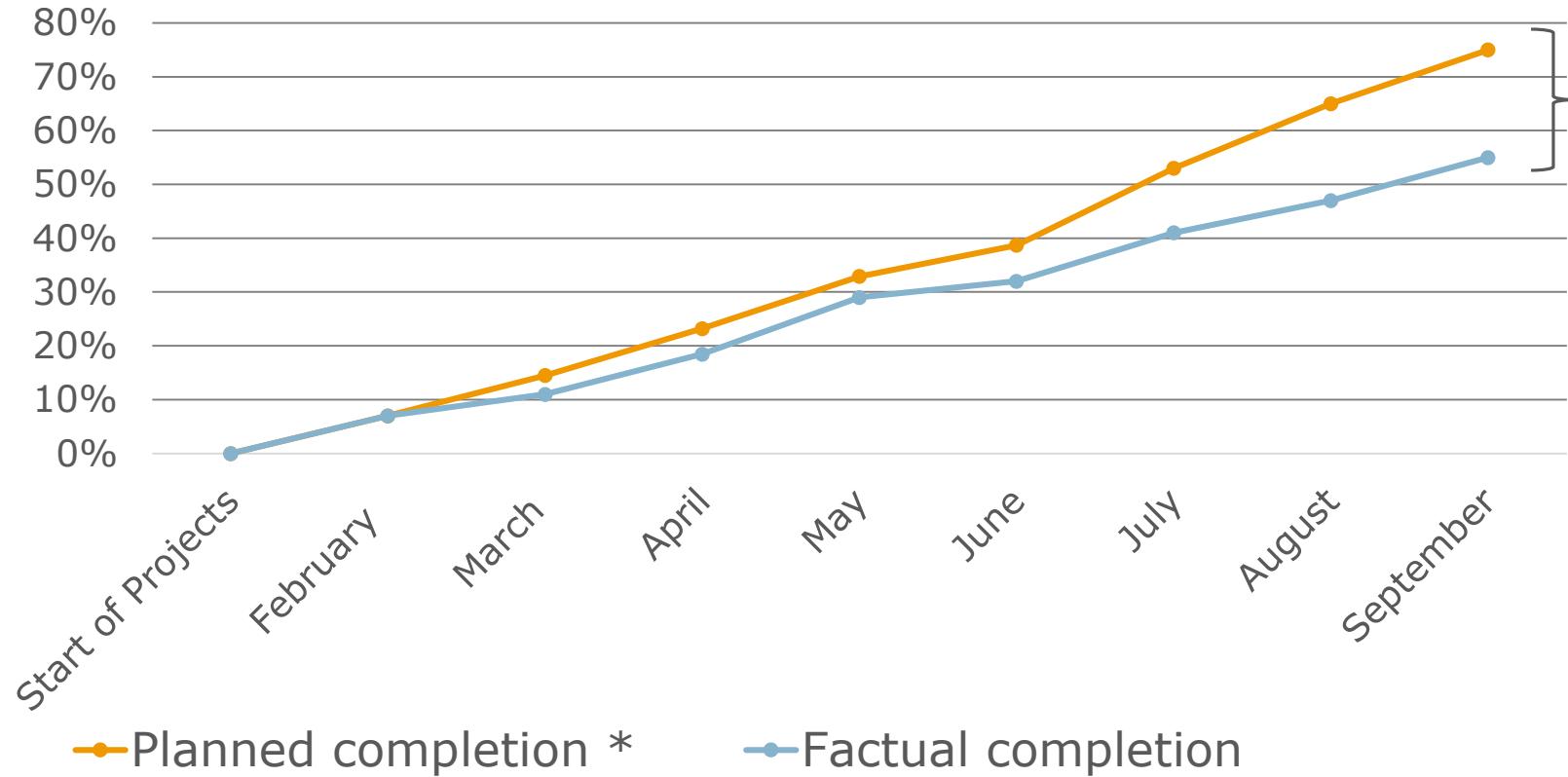
Organisation



Conclusions



Overall progress of the TR implementation



Δ: further details in following slides

Practical Arrangements

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

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

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

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

Informal consultation with SANTE

Informal Consultation with SANTE

Formal consultation with SANTE

Informal consultation with SANTE
Formal consultation with MS

Expert Group GFL, Pesticide Steering Network, Advisory Group, Advisory Forum, Sounding Board, GMO Regulatory Committee

Adopted in March 2020 by MB



Adoption in the end 2020 by ED
(due to additional round of consultation, + 3 months)

Guidance Documents

Guidance documents	Number of GDs	Endorsment/approval	Comments
Scientific GDs	7	Endorsed	Removed administrative part
	8	 End of November 2020 (2 months delay)	Updated administrative part
Administrative GDs	11	 End of December 2020 (3 months delay)	Under various consultation
	1	 Beginning of 2021 (5-6 months delay)	MRLs into pesticides GDs were included in September
Total	27	Publication in EJ in January 2021	

Joint EFSA/DG SANTE engagement framework:

- EFSA engagement channels: Sounding Board and Technical Groups delivering on objective
 - **Sounding Board** meetings in March and July
 - ✓ Update on Practical Arrangements, e-submission, Implementing Acts, Guidances, risk communication, etc.
 - ✓ Interactive exchange, live EFSA/DG SANTE replies to stakeholder written/oral questions
 - ✓ Stakeholder feedback : engagement opportunities appreciated; request for more engagement/information on Practical Arrangements, IT tools/training

→ *Practical Arrangements will be shared with stakeholders and discussed at the next Sounding Board and DG SANTE Advisory group WG*

- Regular **Technical Group** meetings since November
 - ✓ 1)IUCLID for pesticides 2)Notification of studies
 - ✓ Tools-testing with stakeholders will start in autumn
- EFSA/DG SANTE stakeholder information event on TR implementation (early 2021 tbc)
- Dedicated EFSA webpage: Publication of all meeting documents and calendar, stakeholder questions and comments

SALESFORCE

- 1,6 M Eur:

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

FSCAP – 0,8 M Eur:

- ✓ Dossier eSubmission (except pesticides)

IUCLID – 1,3 M Eur:

- ✓ Pesticides PPP & MRL eSubmission

APPIAN

- 1,3 M Eur:

- ✓ Risk assessment workflow
- ✓ Confidentiality assessment

MICROSOFT AZURE

- 1,6 M Eur:

- ✓ 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

Will Deliver by March 2021

- ✓ FSCAP integration and eSubmission format for regulated products
- ✓ IUCLID Pesticides PPP & MRL eSubmission
- ✓ Notification of studies
- ✓ Pre-submission advice
- ✓ Risk assessment workflow
- ✓ Confidentiality assessment
- ✓ Dissemination
- ✓ Proactive disclosure
- ✓ Secure storage and controlled access

Further features requested:

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

Manual work until features are implemented

Training

- Training needs collected via ad-hoc internal interviews
- Training plan for all ART projects finalized.
Implementation during October – March 2021
- One-stop-shop for all training material for internal and external peers to store documents, guides, videos and links

Internal Communication

- Stepped up activities since July:
 - Regular progress updates on Intranet
 - Big picture Intranet articles highlighting important milestones and providing context
 - All staff meeting with focus on TR planned for October
- Internal Communication upgraded with internal and external resources, continuing to be centrally coordinated

Organisational structure becomes AS-IS **PLUS**:

New tasks are included within existing units:

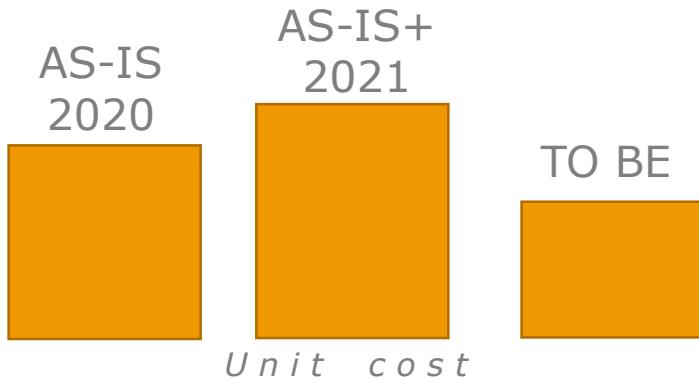
- ✓ **New tasks:** Pre-submission advice; Notification of studies; Public consultations; Confidentiality assessment; Proactive disclosure of evidence; Verification studies
- ✓ **New staff:** by 2021 March, 50 staff out of total 103 will be hired

Challenges over the Interim period (2021):

- Misalignment between the old organisation and the new processes (TR/ End to End)/related automation (e.g. Appian, Salesforce)
- Automation not fully deployed (e.g. IUCLID)
- Planned centralised services (SSO, Admin Centre, Scientific planning) not operational
- EFSA strategy 2020-2027 in the making



Inefficiencies & unrealized gains



Remedies:

- Flexible planning
- Interim staff/external contractors as buffer
- Keep Business As Usual (BAU) in strict check
- Reduce non-TR DEvelopment Projects (DEV)
- Nurture staff motivation

- ❖ Expectations for 03/2021 manageable
- ❖ The requirements of TR will be delivered on time
- ❖ Joint efforts needed from EFSA, SANTE and stakeholders
- ❖ EFSA staff commitment is excellent
- ❖ Complexity is high
- ❖ Strict prioritization needed

