

AF

1st July 2020

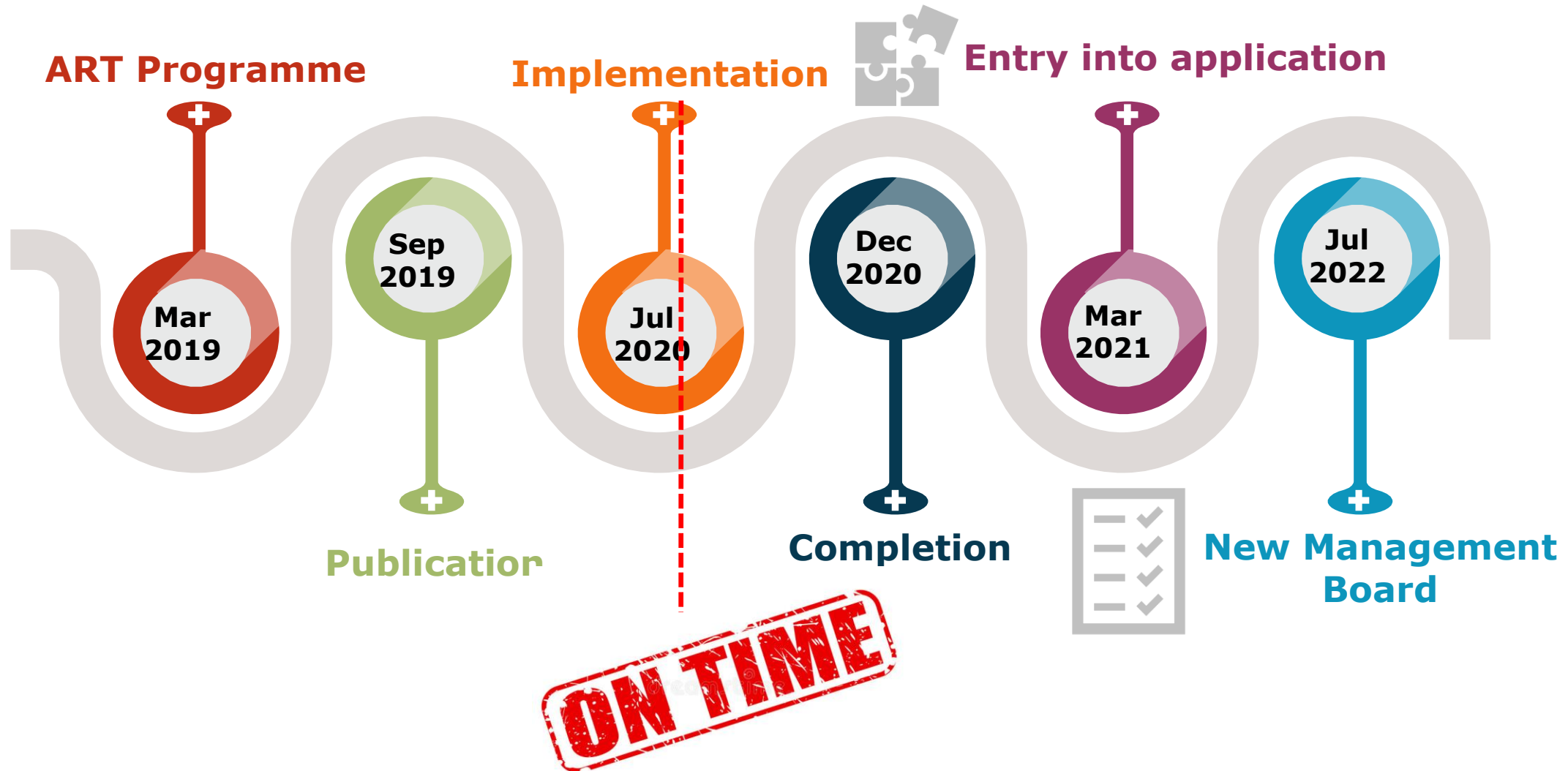
Update on the Implementation of Transparency Regulation

Dirk Detken

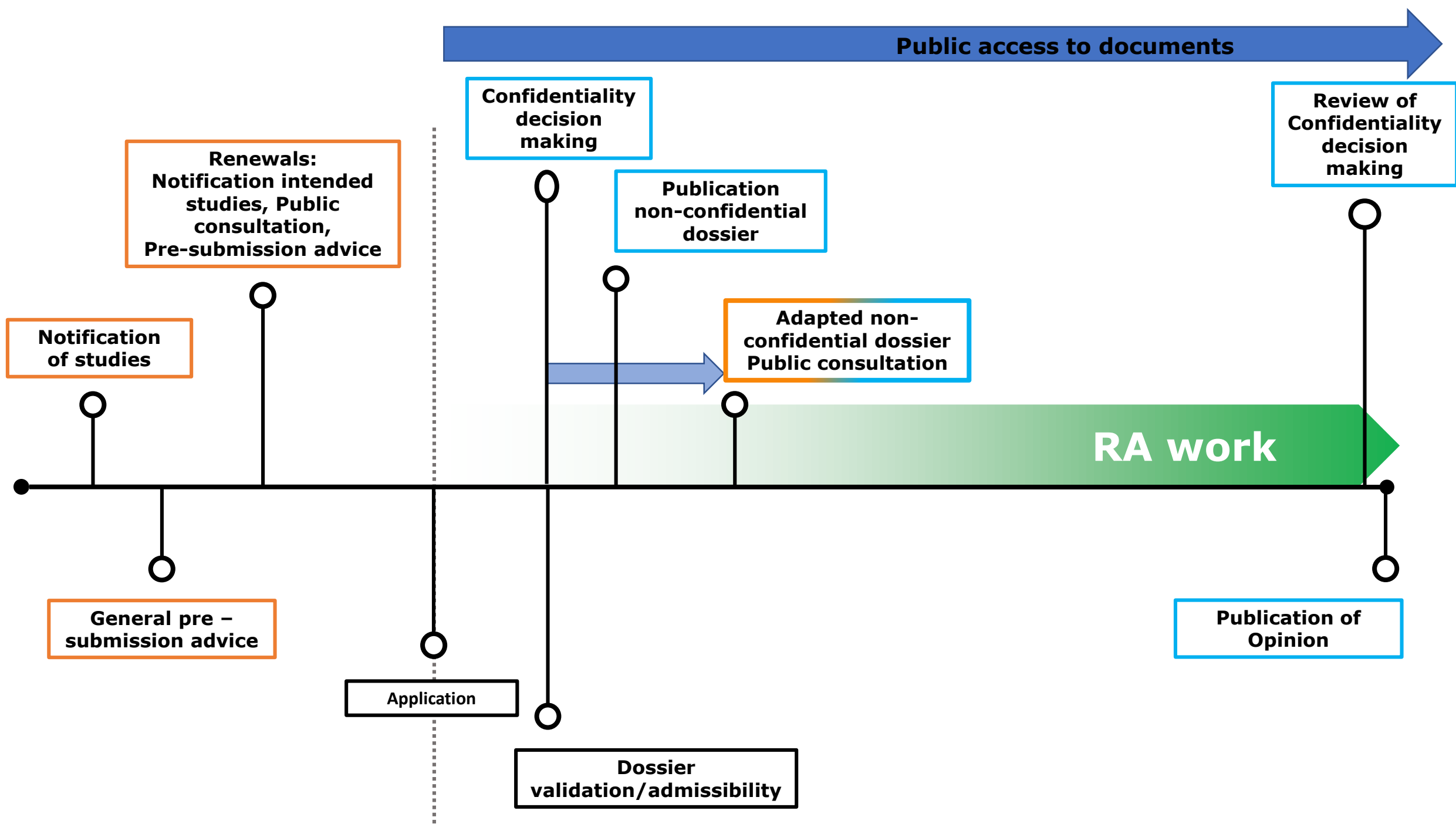
Head of Legal and Assurance

Trusted science for safe food

Progressing according to the plan



- Implementing legal act
- Delegation of power to EFSA
- Binding nature
- Rights & obligations
- PAs on 38, 39 & 41 regulate fundamental rights
- Non-compliance



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

Informal consultation with SANTE

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

Informal Consultation with SANTE Expert Group GFL

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

Formal consultation with EC
Expert Group GFL

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

Informal consultation with SANTE **Formal consultation with MS**

Advisory Group, Sounding Board, SH Event 2020

Adopted in March 2020

Adoption in 2020

Minimum evidence for successful confidentiality requests

- Scientific discussions out of scope
- Potentially **harm** to a **significant degree**
 - Information not publicly available
 - Interest worth of legal protection
 - Novelty
 - No negligible harm

New Active Substances

- Specific PAs harmonising
- confidentiality decision
- making by Rapporteur
- Member States

Renewals

- Applicability of PAs of
- Article 39d(5)

PAs on confidentiality decision making for New Active Substances

Assessment of confidentiality requests

- Responsibility of Rapporteur Member State
- Substantive screening criteria as per the PA's 38/39
- EFSA's consultation mandatory and not binding
- EFSA's advice delivered with regard to compliance with these PAs

Minimum standards

- Written decision
- Case by case decision
- Non-disclosure pending decision
- Reasoned decision
- Right to be heard
- Notification of the decision
- Judicial review available
- Review of initial decision in case of safety concerns



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