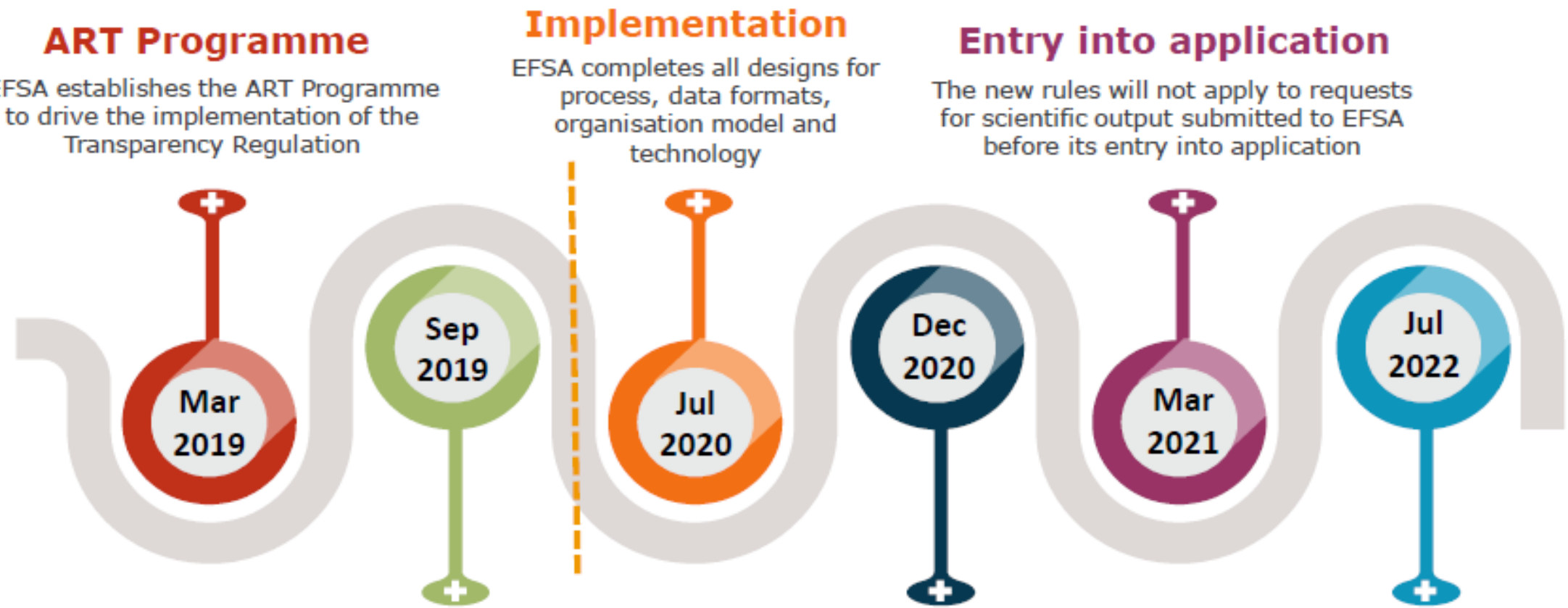
Regulatory challenges for implementation of General Food Law

ABIM 2020 Regulatory Seminar
20 October 2020

Dr. Martyn Griffiths
Senior Regulatory Scientific Affairs Manager, EMEA

Timing of Transparency Regulation

efsa
European Food Safety Authority



PA: Practical arrangements = Guidance/procedures

Summary of GFL Implementation

-Guidance documents
to be available by 4Q 2020 from EFSA
-no input of stakeholders but drafts should be circulated
-includes procedures for confidentiality, study notification, disclosure, MRL/IT submissions

-**Study notification**:
next WG meeting 20-21 October, major definitions still not clear on Study, test item etc
-ECPA & Europabio have sent questions in September
-database will go live on 27 March 2021
-All new studies started after this date will need to be entered in the new database

GFL: General food law

Summary of GFL Implementation

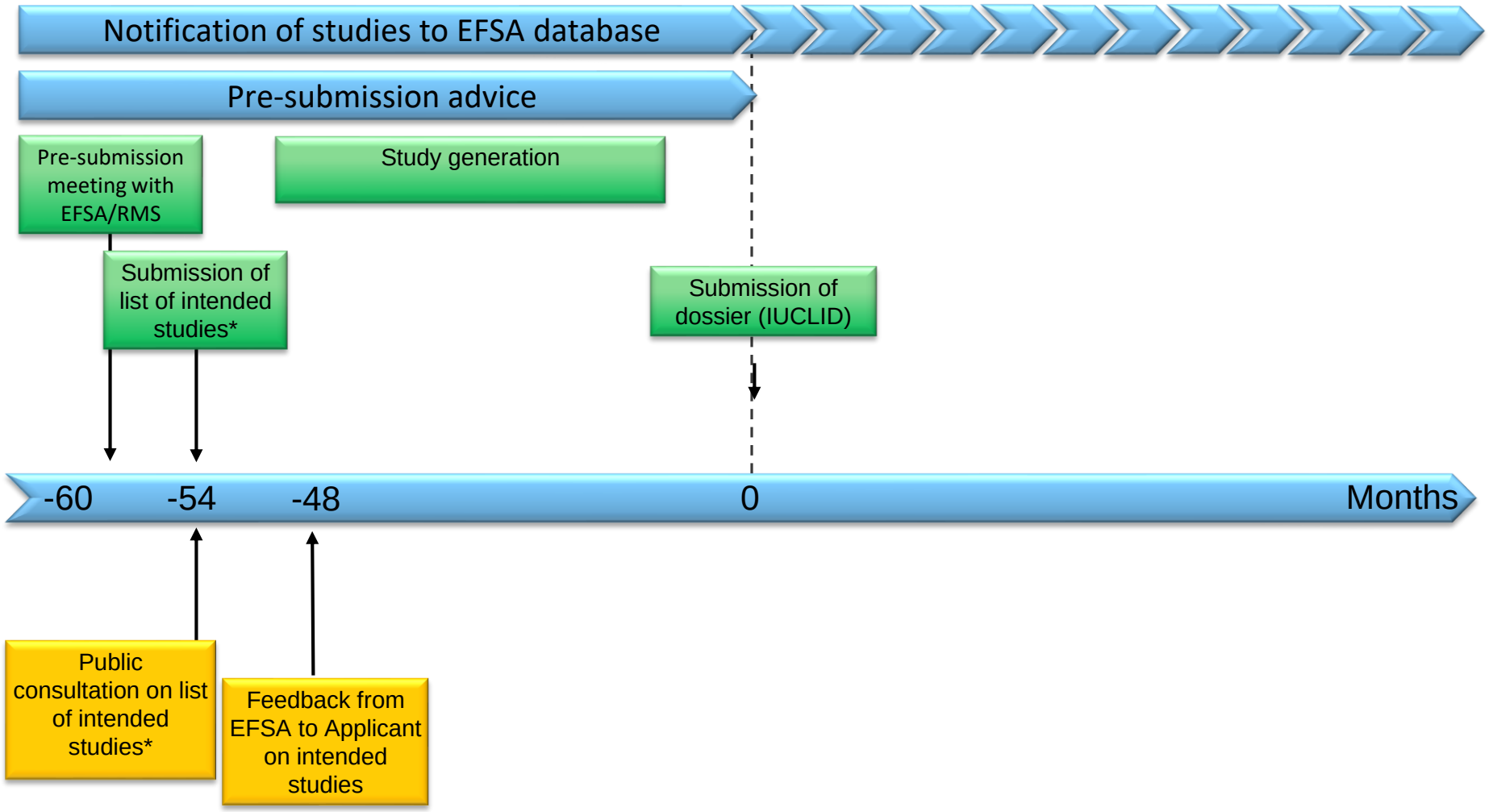
Dossier Format: IUCLID version 6.5
-applies to renewal submissions from July 2021
-applies to new substances, MRL/IT applications from 27 March 2021.
-For the active substance and representative formulation

-Release of the version of IUCLID for PPP: 28 Oct 2020
-EFSA training from January 2021

-**Hypercare process (Draft)** established by EFSA to accompany first submissions in July/August 2021
-Wil start from November 2020
-encompasses between 16-25 substances
-Biweekly calls between applicants/RMSs/EFSA
-designed to support future trainings, helpdesk, and implementation for later submissions

Timelines before submission for Renewal

-challenging for Candidates for Substitution



Draft new renewal regulation

Adobe Acrobat Document

- Aim is to vote in the SCOPAFF-legislation on 22-23 October
- Will be voted together with an implementing regulation, adapting expiry dates for some substances -objective to ensure 3 years from submission to expiry
- **Will apply to PPP substances submitted from July 2021 onwards**
- **Positive new element: Stop the Clock period of 2 weeks following draft EFSA conclusion**
- More detailed completeness check by EFSA/RMS
  -ensure all notified studies in application (dossier) unless valid justification eg if conducted before 03/21
- RAR shall include a recommendation with regard to renewal of approval including any necessary conditions & restrictions
- EFSA to consider Risk Mitigation Measures in its conclusions
- Dossier format: IUCLID for active substance and rep formulations

Draft new renewal regulation

- Will apply to PPP substances submitted from July 2021 onwards
  -implementation of all provisions of GFL in terms of dossier format, sanitisation, study notification
- Substances that expire **AFTER** 27 March 2024 will be in scope of the new regulation
- Substances that expire **BEFORE** 27 March 2024: Regulation 844/2012 continues to apply
- For 10 substances where the submission date is after 27 March 2021, but expiry before 27-03-2024 then Regulation 844/2012 will continue to Apply
  -Caddy dossier
  -sanitisation and disclosure of the summary dossier only
- In future all submissions of the dossier (application under GFL) will be made three years before expiry
  -no future AIR programs
  -obligation for SANTE to define the new RMS as amendment to regulation 686/2012

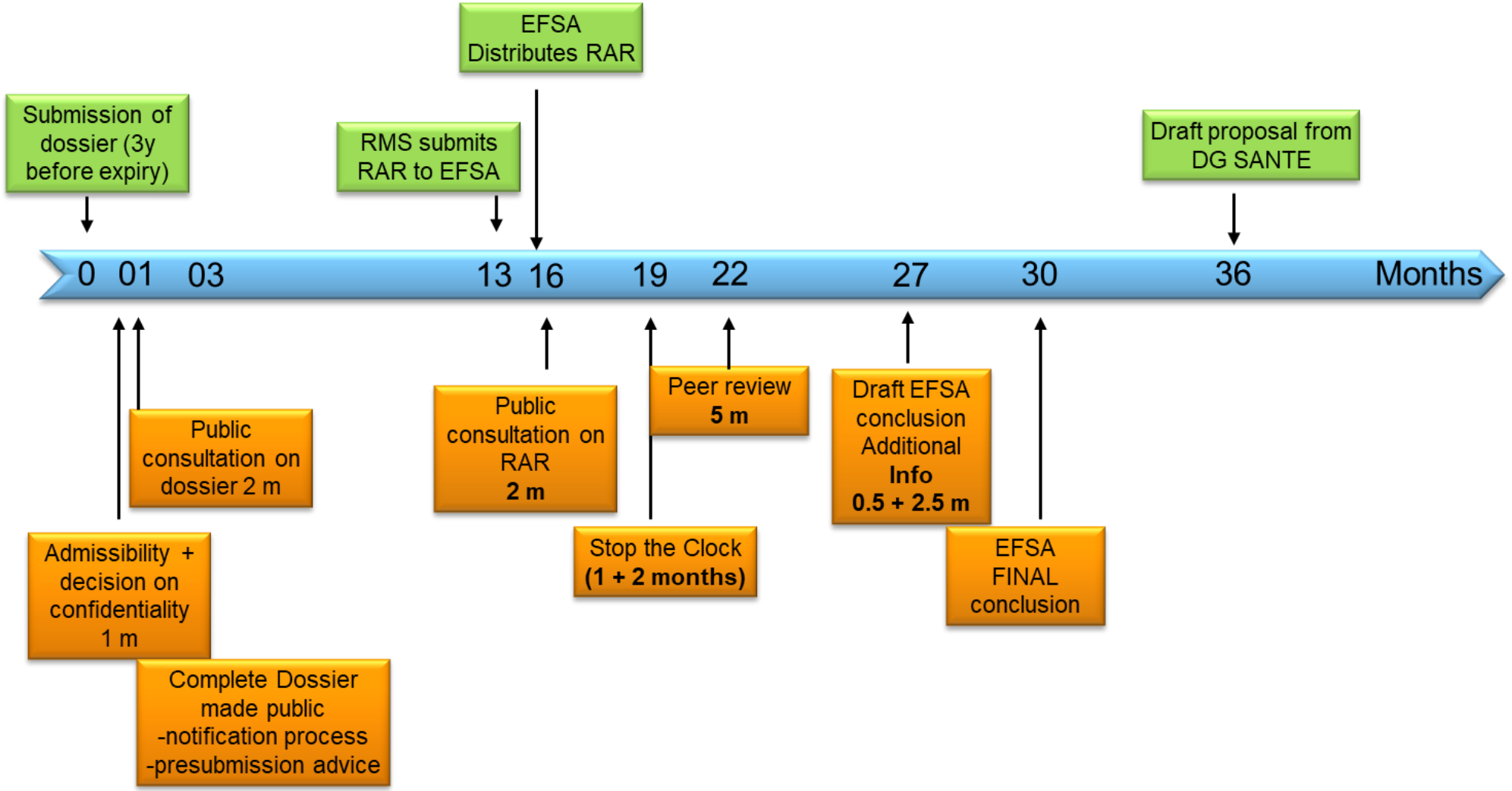
Submission dates and expiry dates

Document Microsoft Word

Document Microsoft Word

- **Substances to be submitted in 2021 (July to November)**
  -submission dates remain unchanged
  -expiry date for 37 substances will be extended by 3 months to ensure 3 years between submission and expiry (separate implementing regulation)
- **Other substances/AIR5 Program Group 2**
  -defined (potentially) expiry dates: No change to expiry dates
  -Submission dates will be brought forward 3 months to ensure a 3 year period between Submission and expiry
- All changes to submission dates/expiry dates will also be reflected on the DG SANTE website for AIR4 and AIR5 program documents

3 year renewal process: new draft renewal regulation
-Applies from submissions July 2021 onwards



Thank you

Questions ?