Trusted science for safe food

1st Sounding Board meeting

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Practical Arrangements implementing the Transparency Regulation

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Layout

1. The role of Practical Arrangements in the TR
2. Status of the work on the Practical Arrangements
3. Timeline

1 - INTRODUCTION

Deliverables of the Transparency Regulation

Implementing rules (EC)	e.g. • Standard Data Format • Commission Regulation (EC) No 844/2012
Practical arrangements (EFSA)	•Notifications under Article 32b(8) •Transparency under Art 38(1) •Confidentiality under Art. 39d(5) •PAD & Aarhus under Art. 41 •Consistency of MS confidentiality assessments for NAS •Pre-submission advice •Public consultations
Practical arrangements (EC)	• (optional) for fact finding missions • General plan on risk communication
Guidance (EFSA)	e.g. • Sectoral guidance documents (e.g. smoke flavourings)

Nature of practical arrangements

What is a Practical Arrangement?

- Implementing legal act
- Delegation of power to EFSA
- Binding nature
- Rights & obligations
- Non-compliance

2. Transparency & Confidentiality

2.1 Subject matter, scope and definitions

Subject matter:

- Proactive transparency – Article 38(1)
- Confidentiality decision making – Articles 39-39e

Scope of confidentiality process

- all confidentiality processes
  - Pesticides New Active Substances
  - MSs confidentiality decisions implementing GMOs Directive
  - Food additives when EFSA is not consulted
  - Novel foods when EFSA is not consulted

2.2 Proactive transparency

Submission of information, documents and other data

- EFSA to make available docs printable, searchable or downloaded electronically
- Standard Data Formats to binding on applicants
- Pending adoption of Standard Data Formats, applicants supplying any information supporting applications, are required to do so:
  - in the form of structured dossiers, and wherever possible using existing structured templates such as those developed by the OECD (OHTs) and the Global Harmonised Submission Transport Standard (GHSTS) as transmission protocol;
  - Where the nature of the information, documents or data is technically not compatible with OHT, semi structured data may be submitted.

2.3 Proactive transparency

Disclosure of docs data on which **no confidentiality decision-making** requests may be submitted

- Where: «on EFSA's website»
- proactively disclosed with no sanitisation e.g.
  - DoIs,
  - summaries of advice under Article 32c(1),
  - documents for the MB
  - …

Proactive disclosure of docs and data on which **confidentiality decision-making requests** may be submitted

- first in non-confidential version,
- later updated if confidentiality status is awarded by EFSA decision
  - Meeting minutes
  - EFSA's outputs
  - Scientific data, studies and other information part of, or supporting, applications
  - …

2.4 Confidentiality

Minimum evidence for successful confidentiality requests	Confirmatory application	Confirmatory decisions
• Information not publicly available • Potentially harm to a significant degree (5% or explanation) • Interest worth of legal protection • Document not older than 5 years or explanation • Scientific discussions out of scope	• By two calendar weeks from notification • Review of points of law only • Suspensive effect	• Timeline: 3 weeks from receipt • Judicial review

2.5 PAs on confidentiality decision making for pesticides new active substances

Scope
Harmonising decision making managed by Rapporteur Member States on confidentiality requests by applicants concerning applications for approval of a new active substance

2.6 PAs on confidentiality decision making for pesticides new active substances

Assessment of confidentiality requests

- Responsibility of Rapporteur Member State
- Substantive screening criteria as per the main PAs
- EFSA's consultation obligatory but not binding

Minimum standards

- Written decision
- Case by case decision
- Non-disclosure pending decision
- Reasoned decision
- Right to be heard
- Notification of the decision
- Confirmatory application optional
- Judicial review available
- Review of initial decision in case of safety concerns
- EFSA's advice delivered with regard to compliance with these PAs

3. Public Access to Documents & Aarhus

3.1 Scope

Implements interplay between PAD & Aarhus Regulations

- Focus on practical operational aspects
- Lean and clarify based on a decade of experience with the reactive transparency process
- Clear commitment of case law: Aarhus

3.2 Main features

- Managing complexity and volume (extensions, fair solutions, batches by priority, queuing)
- Consultations - No veto right for Member States
- Distinct nature of the reactive case law
- Guidance
- Reproduction & reuse of documents

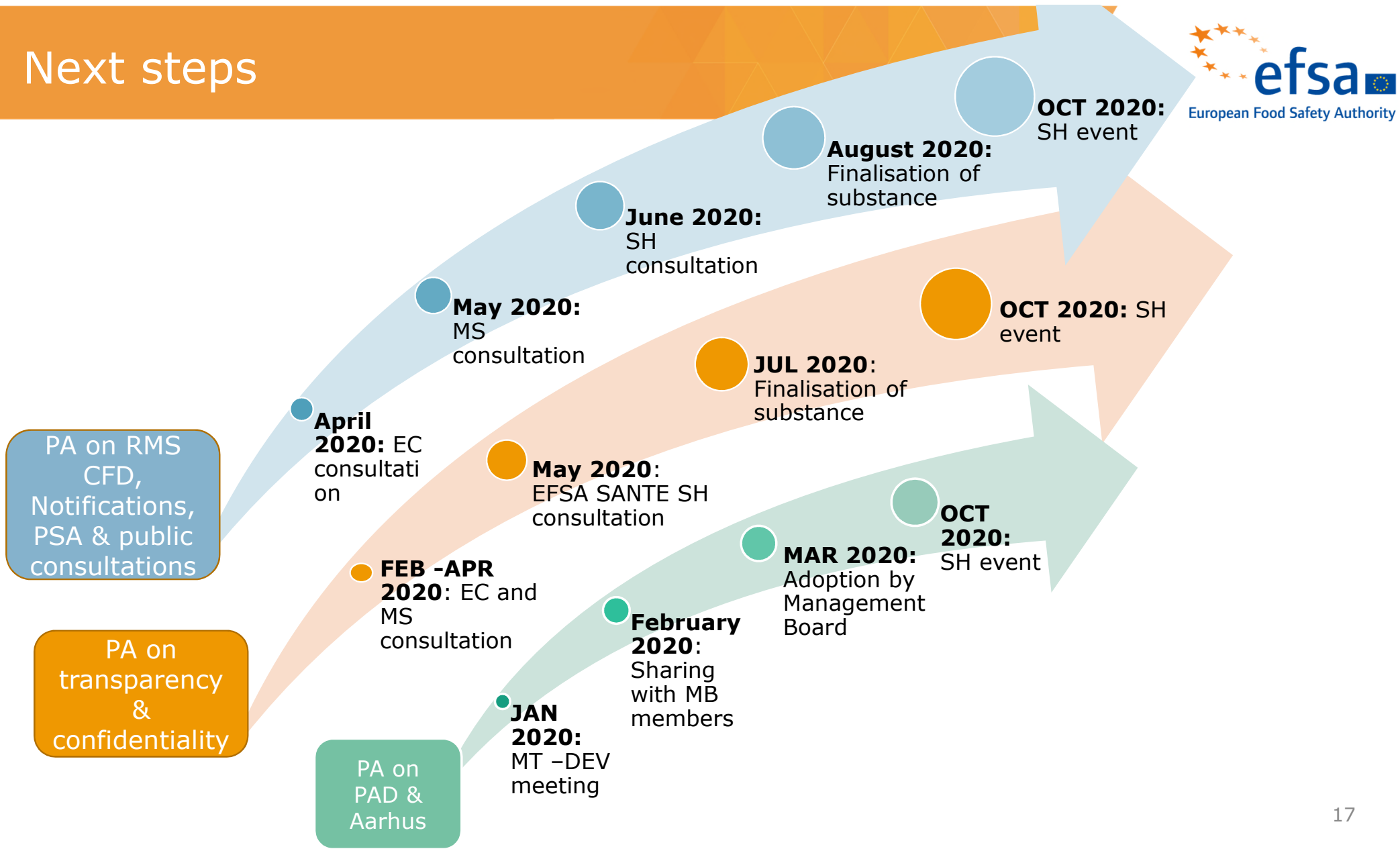
Next steps

4. Pre-submission advice

5. Notification of “studies”

6. Public consultation

Next steps


PA on RMS CFD, Notifications, PSA & public consultations
PA on transparency & confidentiality
PA on PAD & Aarhus
April 2020: EC consultation
May 2020: MS consultation
June 2020: SH consultation
August 2020: Finalisation of substance
OCT 2020: SH event
FEB -APR 2020: EC and MS consultation
May 2020: EFSA SANTE SH consultation
JUL 2020: Finalisation of substance
OCT 2020: SH event
JAN 2020: MT –DEV meeting
February 2020: Sharing with MB members
MAR 2020: Adoption by Management Board
OCT 2020: SH event