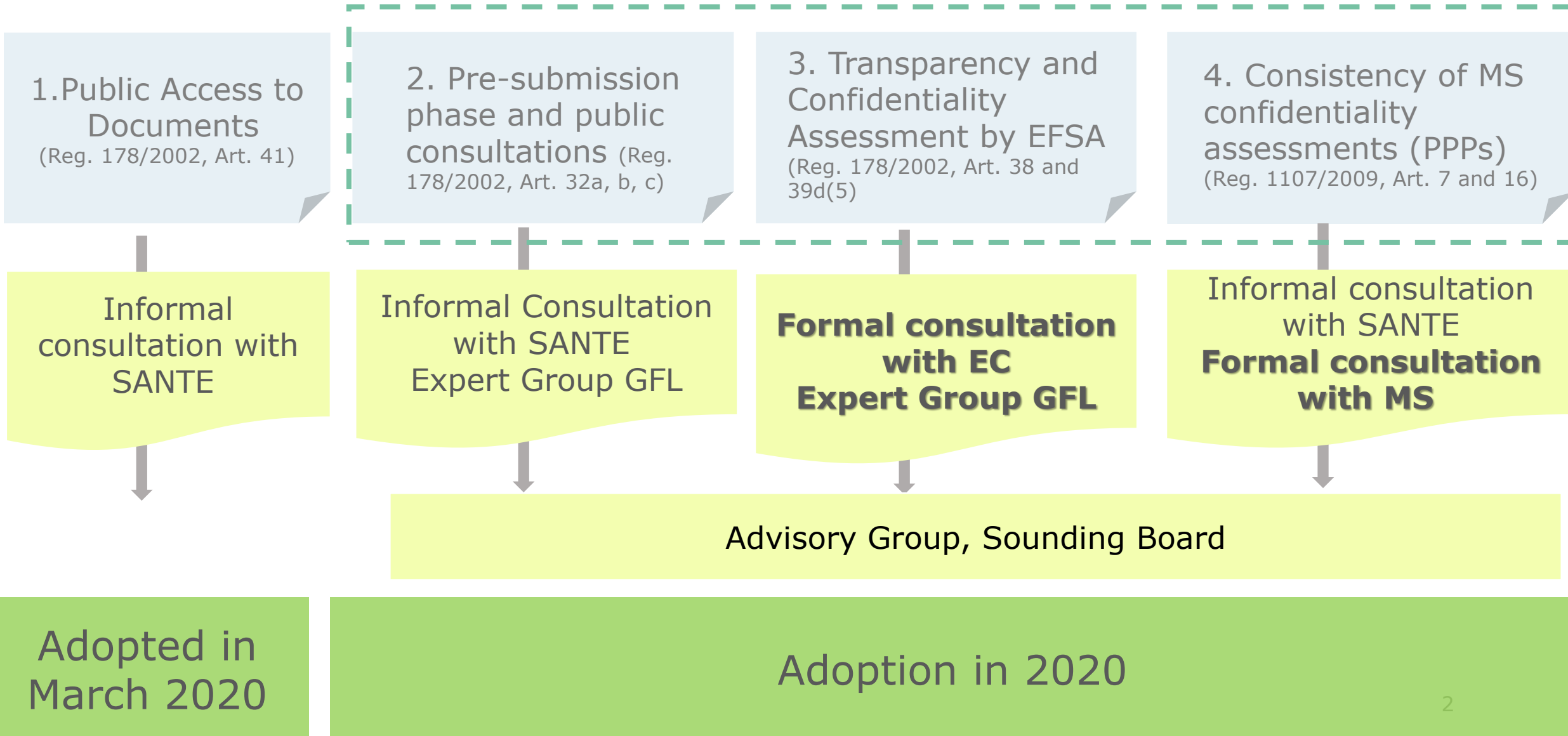


EFSA's Practical Arrangements

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**Second week
November**
Written
dissemination to MS
and stakeholders of
draft Practical
Arrangements

November
Experts Group GFL
+ Advisory group +
EFSA Sounding
Board to present
the Practical
Arrangements

December
Signing off by the
Executive Director

Practical Arrangements on Transparency and Confidentiality (Articles 38 and 39-39e of the TR)

- Extensive proactive disclosure requirements
- Confidentiality exception to transparency
- Burden of proof on applicant
- Individual assessment of, and decision on, confidentiality requests
- Reasoned decision by EFSA
- Non-disclosure pending decision
- Accessibility of documents, information and studies upon acceptance of “Terms of Reference”

Procedural requirements

Article 9 of the Practical Arrangements

- Applicants may submit confidentiality requests only via the IT tool(s)
- No fees
- Confidentiality requests
 - supported by verifiable justification
 - Identifying information whose confidentiality is claimed
- Applicants may not modify or complement confidentiality requests

Substantive screening criteria

Article 10 draft Practical Arrangements

- Closed positive List
- Potential harm to a significant degree
 - Information not publicly available
 - Interest acquired by legitimate mean
 - No negligible harm
 - Novelty
- Environmental information under Aarhus Regulation

Confidentiality Decision making process

Article 11 of the Practical Arrangements

- Admissibility of confidentiality request
- Possibility to seek clarifications
- Mandatory consultation with applicant
 - Applicant comments by 2 weeks
- EFSA adopts decision by 8 weeks
 - Implementation by 2 weeks from notification
- Dissemination by EFSA

Confirmatory application

- By two calendar weeks from notification of final decision
- No new confidentiality requests allowed
- Suspensive effect

Confirmatory decisions

- by 3 weeks from receipt of confirmatory application
- “segregation of duties”
- judicial review
- *Lex specialis vis-à-vis* “administrative review clauses”

Review of previously adopted decisions

Article 14 of the Practical Arrangements

- Foreseeable effects on human health, animal health or the environment identified in EFSA opinion
- Effects relate to items granted confidential status
- EFSA decision by 20 working days from adoption following same procedure in Article 11 of the PAs.
- EFSA decision on optional Confirmatory application by 10 working days from receipt following same procedure in Article 12 of the PAs.

Prior to the adoption of the confidentiality decision

- Compliance with initial confidentiality requests
- deletion of published information or data for six months after receipt of withdrawal notification

After the adoption of the confidentiality decision

- Implementation of, and compliance with, the confidentiality decision if adopted
- Deletion of published data after six months from receipt of withdrawal notification

- Annex & purpose
- Review of the Practical Arrangements

Practical Arrangements on Confidentiality (Articles 7 and 16 of Regulation (EC) No 1107/2009)

Article 7

New Active Substances

- Specific PAs ensuring consistency of RMS / EFSA confidentiality decisions

Article 16

Renewals

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

Confidentiality decision making for New Active Substances

Rapporteur Member State consults EFSA by 4 weeks from receipt

EFSA advice by 10 WDs from receipt

RMS draft decision to applicant by 1 week from EFSA's advice

RMS decision by 2 weeks from receipt of EFSA's advice

Implementation by 1 month from notification

Publication by EFSA

Confidentiality decision making for renewals

EFSA shares draft decision with applicant

Applicant comments by 2 weeks

EFSA adopts decision by 10 weeks

(Confirmatory application by 2 weeks from notification)

(Decision on confirmatory application by 3 weeks)

Implementation by 2 weeks from notification

Publication by EFSA

Assessment of confidentiality requests Shared Criteria

- Closed positive List
- Potential harm to a significant degree
 - Information not publicly available
 - Interest acquired by legitimate mean
 - No negligible harm
 - Novelty
- Environmental information under Aarhus Regulation