EFSA practical arrangements

   - Informal consultation with SANTE

2. Pre-submission phase and public consultations (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 39d(5)
   - 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

Adopted in March 2020

Adoption in 2020
Next steps in 2020

**November**
- Experts Group GFL + Advisory group + EFSA Sounding Board to present all Practical Arrangements

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

**December**
- Signing off by the Executive Director
Practical Arrangements on Transparency and Confidentiality
(Articles 38 and 39-39e of the TR)
Practical Arrangements - Underlying principles

- 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”
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 applications procedure
Article 12 of the Practical Arrangements

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
Practical Arrangements on Confidentiality
(Articles 7 and 16 of Regulation (EC) No 1107/2009)
<table>
<thead>
<tr>
<th>Article 7</th>
<th>Article 16</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Active Substances</td>
<td>Renewals</td>
</tr>
<tr>
<td>Specific PAs ensuring consistency of RMS / EFSA confidentiality decisions</td>
<td>Applicability of PAs of Article 39d(5)</td>
</tr>
</tbody>
</table>
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