EFSA’s Practical Arrangements

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EFSA Legal & Assurance Services

- 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

- **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)
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

Withdrawal of previously adopted decisions
Article 15 of the Practical Arrangements
Annex & common provisions

- Annex & purpose
- Review of the Practical Arrangements
Practical Arrangements on Confidentiality (Articles 7 and 16 of Regulation (EC) No 1107/2009)
<table>
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PAs on confidentiality decision making for plant protection products - scope
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