EFSA Practical Arrangements

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Trusted science for safe food

European Food Safety Authority

EFSA practical arrangements

1.Public Access to Documents
(Reg. 178/2002, Art. 41)

2. Pre-submission phase and public consultations (Reg. 178/2002, Art. 32a, b, c)

3. Transparency and Confidentiality Assessment by EFSA
(Reg. 178/2002, Art. 38 and 39d(5)

4. Consistency of MS confidentiality assessments (PPPs)
(Reg. 1107/2009, Art. 7 and 16)

Informal consultation with SANTE

Informal Consultation with SANTE
Expert Group GFL

Formal consultation with EC
Expert Group GFL

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 all 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”

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 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.

Review of previously adopted decisions Article 15 of the Practical Arrangements

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)

PAs on confidentiality decision making for plant protection products - scope

Article 7 New Active Substances	Article 16 Renewals
Specific PAs ensuring consistency of RMS / EFSA confidentiality decisions	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

Confidentiality – Substantive screening criteria

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