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Trusted science for safe food

Nature of practical arrangements



- Implementing legal act
- Delegation of power to EFSA
- Binding nature
- Rights & obligations
- PAs on 38, 39 & 41 regulate fundamental rights
- Non-compliance

Engagement by law



Practical Arrangements to be adopted	MSs	EC
Access to documents (Reg. 178/2002, Art. 41)		
Transparency and confidentiality (Reg. 178/2002, Art. 38 and 39)		X
Consistency of MS confidentiality assessments (Reg. 1107/2009, Art. 7 and 16)	X	
Consultation of third parties (Reg. 178/2002, Art. 32c)		
Notification of studies (Reg. 178/2002, Art. 32b)		
Pre-submission advice (Reg. 178/2002, Art. 32a)		



Practical Arrangements on access to documents

PA on access to documents

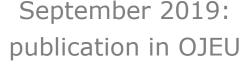


Regulation (EU) 2019/1381

27 March 2020:

deadline for adoption of PA on PAD & Aarhus

27 March 2021: application





Draft

EC consultation & consolidation

Management Board adoption

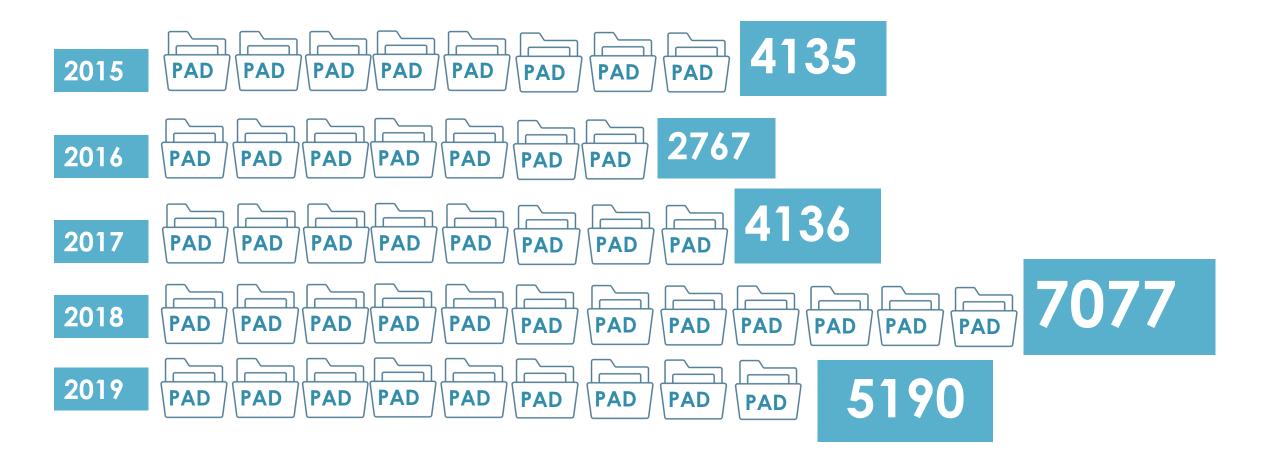
June - October 2019

November – December 2019

18-19 March 2020

PA on access to documents





Changes



General principles of Regulation 1049/2001

Procedural elements

Other applicable legal provisions:

Aarhus Regulation

Data Protection Regulation

Practical Arrangements

Future impact of access to documents?







Implementation phase



Automation of the PAD process

Guidance for the public



Practical Arrangements on Transparency and Confidentiality

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
- Except for:
 - Pesticides New Active Substances (MS)
 - GMOs Directive (MS)
 - Food additives when EFSA is not consulted (COM)
 - Novel foods when EFSA is not consulted (COM)

Proactive transparency



Submission of information, documents and other data

- EFSA to make available docs printable, searchable or downloaded electronically
- Standard Data Formats to be binding on applicants, where present
- Pending Standard Data Formats, applicants required to submit information:
 - 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 not compatible with OHT, semi structured data may be submitted.

Proactive transparency



Disclosure of docs data on which **no CFD** 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 CFD 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
 - ...

Confidentiality – PAs on 38(1) & 39d(5)



Procedural requirements for submission

- Applicants may submit confidentiality requests via the IT tool(s)
- Language of submission:
- •EN as EFSA working language
- •Response in same EU language if requested
 - No fees
 - Applicants may not modify or complement confidentiality requests

Confidentiality – PAs on 38(1) & 39d(5)



Confidentiality decision

- Case by case assessment of requests
- Non-disclosure of items claimed confidential pending assessment
- Timeline: 10 weeks from receipt

Minimum evidence for successful confidentiality requests

- Information not publicly available
- potentially harm to a significant degree
- Scientific discussions out of scope
- Interest worth of legal protection
- Novelty

Confidentiality – PAs on 38(1) & 39d(5)



Confirmatory application

- By two calendar weeks from notification
- Review of points of law only
- Suspensive effect

Confirmatory decisions

- Timeline: 3 weeks from receipt
- judicial review

Review of adopted decisions

 If conclusions of scientific outputs relate to foreseeable effects on human health, animal health or the environment

PAs on confidentiality decision making for plant protection products - Scope



New Active Substances

Specific PAs
harmonising
confidentiality
decision making by
Rapporteur Member
States

Renewals

Applicability of PAs on Article 39d(5)

PAs on confidentiality decision making for New Active Substances



Assessment of confidentiality requests

- Responsibility of Rapporteur Member State
- Substantive screening criteria as per the main PAs
- EFSA's consultation mandatory and not binding
- EFSA's advice delivered with regard to compliance with these PAs

Minimum standards

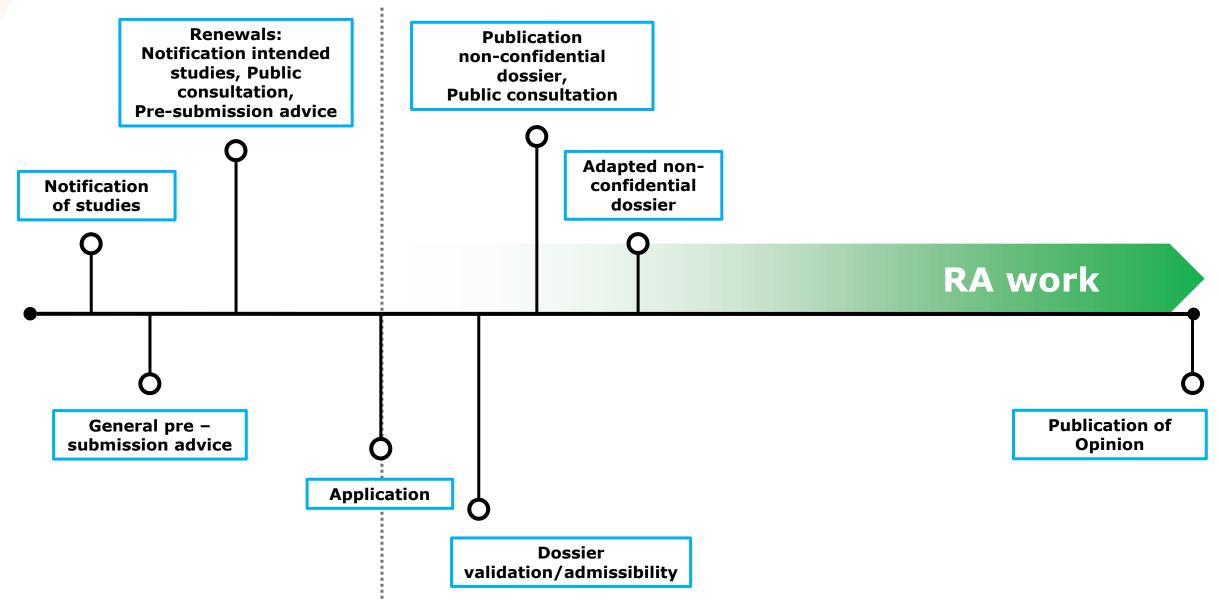
- Written decision
- Case by case decision
- Non-disclosure pending decision
- Reasoned decision
- Right to be heard
- Notification of the decision
- Judicial review available
- Review of initial decision in case of safety concerns



Practical Arrangements implementing Art. 32a, 32b and 32c of Transparency Regulation

Transparency and Quality of studies





General aspects



Definitions

- Study
- Starting date of a study
- Planned completion date of a study

Joint presubmission activities

 How to enable presubmission activities to be carried out jointly by groups of business operators/potential applicants

Link

 How to link presubmission activities to the submission phase to ensure traceability and enforcement

3. General pre-submission advice (Art. 32a)



Scope

 ■ Art 32a(1)
 ✓ rules applicable to, and the content required for, an application

Procedure

- Requests
- Modalities and timeline for the provision of GPSA by EFSA

Specific

 Pesticides: need to coordinate EFSA and intended/established RMS in the provision of GPSA

4. Intended renewals (Art. 32c(1))



Intended studies

- Notification requirements
- How to submit required intended studies information
- Recommended timeline

Public consultation

- Procedure
- Timeline
- Analysis of comments

Renewal PSA

- Scope = 32c(1) →
 content of the
 intended renewal
 application +
 design of intended
 studies
- Modalities and timeline for the provision of RPSA by EFSA

5. Notification of studies (Art. 32b)



Database

• User Guide

Obligations

- Only applicable to studies commissioned/carried out after 27/3/2021
- Notification requirements
- How to submit study notifications
- Timeline

Procedural consequences

- Requirements for application submission
- Procedure for assessing compliance and justifications
- Publication of valid justifications in the event of legitimate procedural deviations

6. Public consultation (Art. 32c(2))



PC on submitted applications

- Procedure
- Timeline
- Analysis of comments