26. June 2020

Practical Arrangements

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Trusted science for safe food

European Food Safety Authority

Engagement by law

Practical Arrangements to be adopted	MSs	EC	MB
Access to documents (Reg. 178/2002, Art. 41)			X
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

September 2019:
publication in OJEU

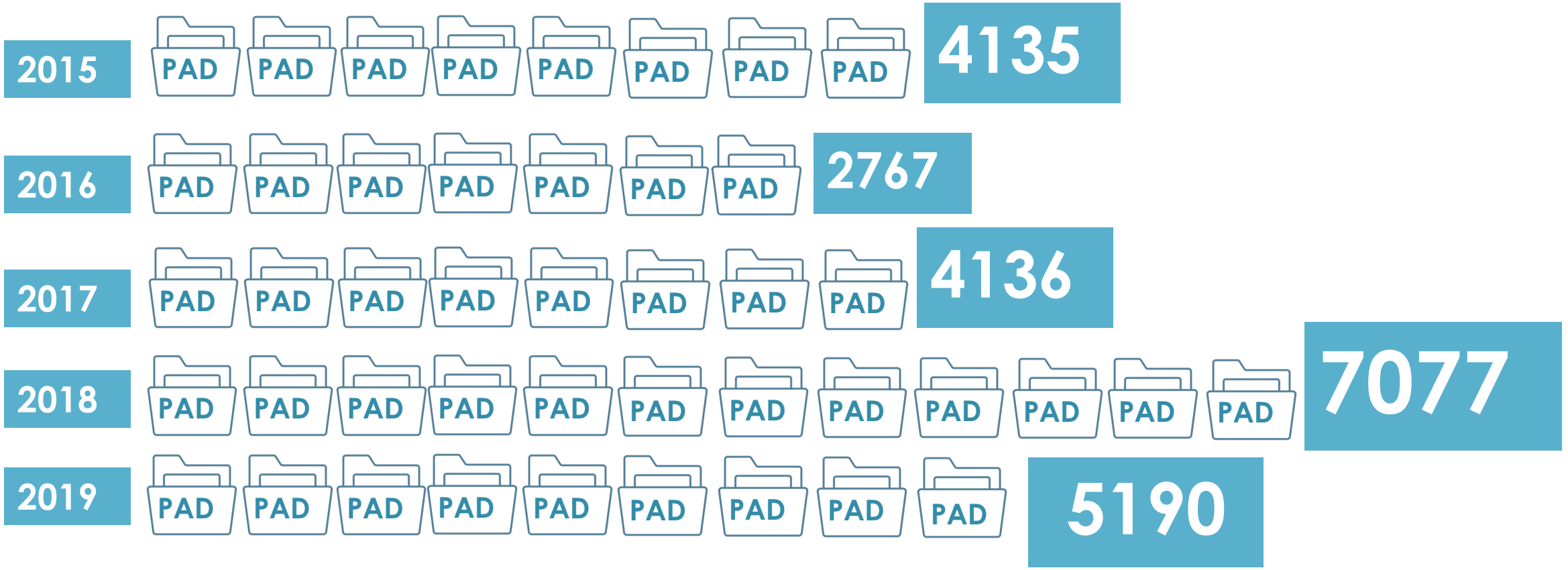
27 March 2020:
deadline for adoption
of PA on PAD & Aarhus

27 March 2021:
application

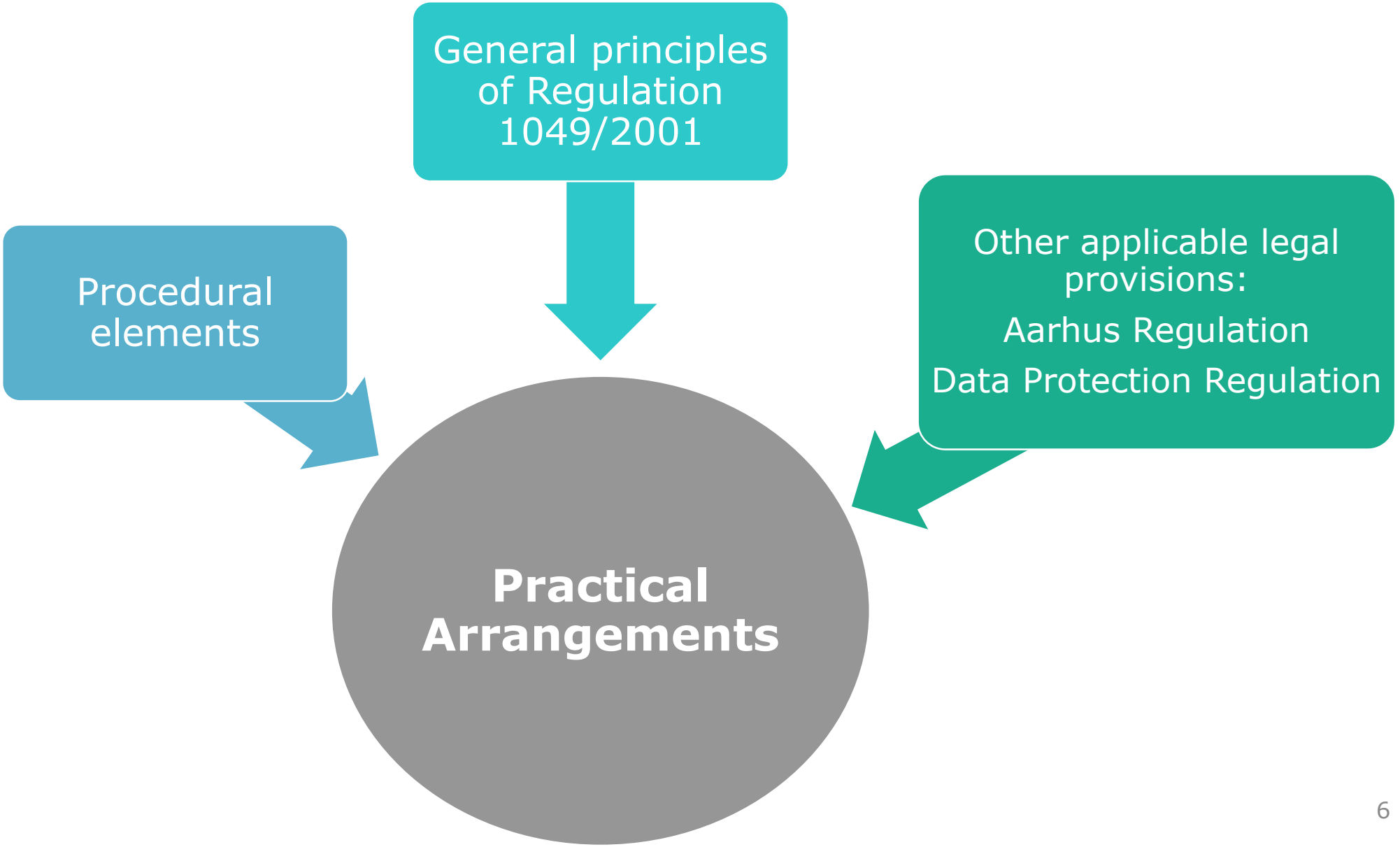
Practical arrangements on PAD & Aarhus

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

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Practical Arrangements on Transparency and Confidentiality

Q and A

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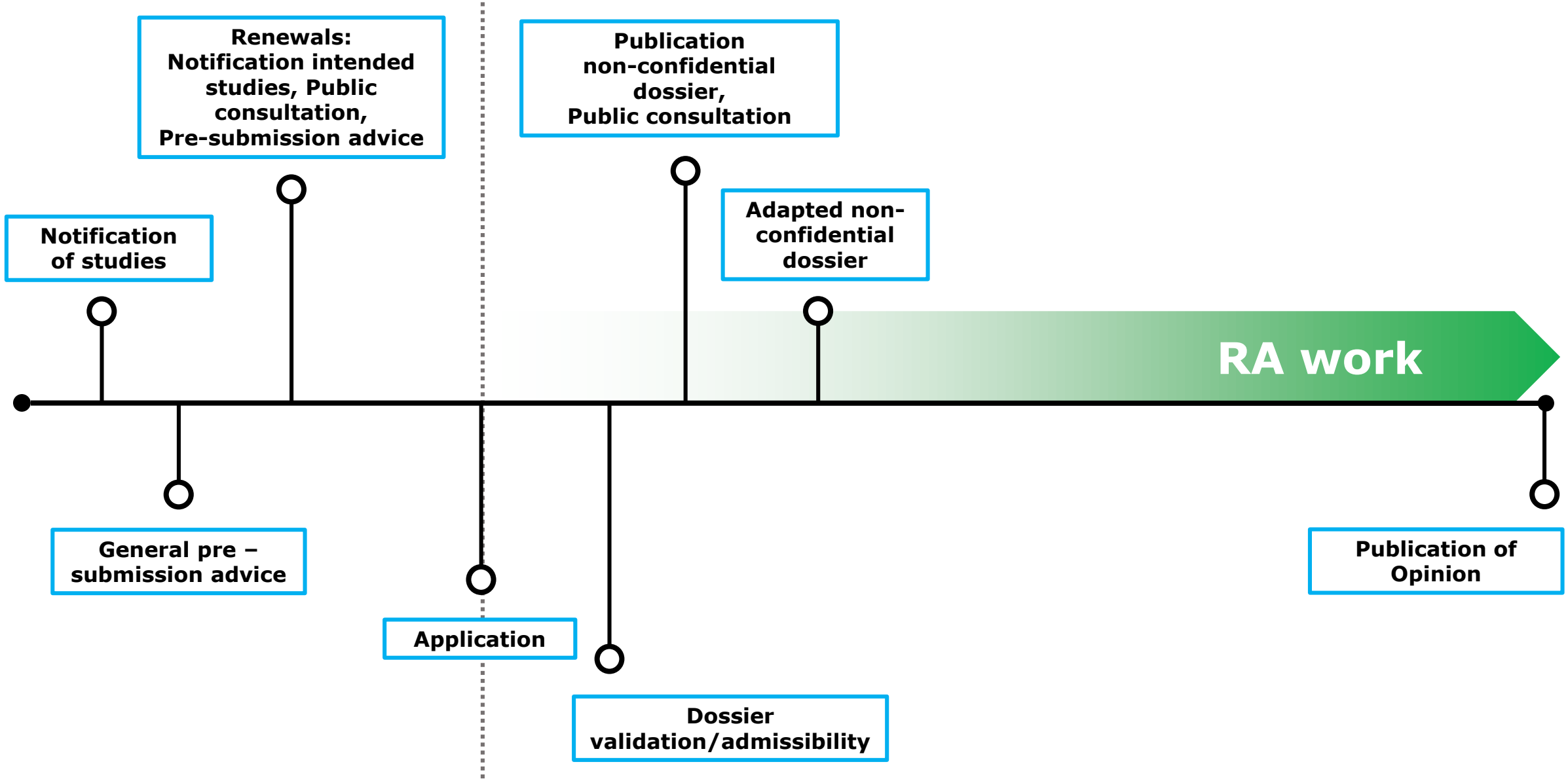
Practical Arrangements implementing Art. 32a, 32b and 32c of Transparency Regulation

Transparency and Quality of studies



General aspects

Definitions	Joint pre-submission activities	Link
• Study • Starting date of a study • Planned completion date of a study	• How to enable pre-submission activities to be carried out jointly by groups of business operators/potential applicants	• How to link pre-submission activities to the submission phase to ensure traceability and enforcement

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

Scope	✓Procedure	Specific
• = Art 32a(1) ➉rules applicable to, and the content required for, an application	• Requests • Modalities and timeline for the provision of GPSA by EFSA	• Pesticides: need to coordinate EFSA and intended/established RMS in the provision of GPSA

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

Intended studies	Public consultation	Renewal PSA
• Notification requirements • How to submit required intended studies information • Recommended timeline	• Procedure • Timeline • Analysis of comments	• 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	Obligations	Procedural consequences
• User Guide	• Only applicable to studies commissioned/carried out after 27/3/2021 • Notification requirements • How to submit study notifications • Timeline	• 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

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Practical Arrangements on confidentiality decision making for plant protection product

PAs on confidentiality decision making for plant protection products - Scope

New Active Substances	Renewals
• Specific PAs harmonising confidentiality decision making by Rapporteur Member States	• 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