Practical Arrangements

Dirk Detken
Head of the Legal & Assurance Services
### Practical Arrangements to be adopted

<table>
<thead>
<tr>
<th>Activity</th>
<th>MSs</th>
<th>EC</th>
<th>MB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to documents (Reg. 178/2002, Art. 41)</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Transparency and confidentiality (Reg. 178/2002, Art. 38 and 39)</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Consistency of MS confidentiality assessments (Reg. 1107/2009, Art. 7 and 16)</td>
<td></td>
<td></td>
<td>X</td>
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<tr>
<td>Consultation of third parties (Reg. 178/2002, Art. 32c)</td>
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<tr>
<td>Notification of studies (Reg. 178/2002, Art. 32b)</td>
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<tr>
<td>Pre-submission advice (Reg. 178/2002, Art. 32a)</td>
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</tbody>
</table>
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

Regulation (EU) 2019/1381
PA on access to documents

2015: 4135
2016: 2767
2017: 4136
2018: 7077
2019: 5190
Practical Arrangements

General principles of Regulation 1049/2001

Other applicable legal provisions:
Aarhus Regulation
Data Protection Regulation

Procedural elements
Future impact of access to documents?

Proactive

Reactive
Implementation phase

Automation of the PAD process

Guidance for the public
Practical Arrangements on Transparency and Confidentiality

Q and A
Practical Arrangements implementing Art. 32a, 32b and 32c of Transparency Regulation
Transparency and Quality of studies

Renewals:
Notification intended studies, Public consultation, Pre-submission advice

Publication
non-confidential dossier, Public consultation

Adapted non-confidential dossier

Notification of studies

General pre-submission advice

Application

Dossier validation/admissibility

Publication of Opinion
<table>
<thead>
<tr>
<th>Definitions</th>
<th>Joint pre-submission activities</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Study</td>
<td>• How to enable pre-submission activities to be carried out jointly by groups of business operators/potential applicants</td>
<td>• How to link pre-submission activities to the submission phase to ensure traceability and enforcement</td>
</tr>
<tr>
<td>• Starting date of a study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Planned completion date of a study</td>
<td></td>
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</tr>
</tbody>
</table>
### 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))

<table>
<thead>
<tr>
<th><strong>Intended studies</strong></th>
<th><strong>Public consultation</strong></th>
<th><strong>Renewal PSA</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Notification requirements</td>
<td>• Procedure</td>
<td>• Scope = 32c(1) \rightarrow content of the intended renewal application + design of intended studies</td>
</tr>
<tr>
<td>• How to submit required intended studies information</td>
<td>• Timeline</td>
<td>• Modalities and timeline for the provision of RPSA by EFSA</td>
</tr>
<tr>
<td>• Recommended timeline</td>
<td>• Analysis of comments</td>
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</tr>
</tbody>
</table>

- **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) \rightarrow 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)

<table>
<thead>
<tr>
<th>Database</th>
<th>Obligations</th>
<th>Procedural consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>• User Guide</td>
<td>• Only applicable to studies commissioned/carried out after 27/3/2021</td>
<td>• Requirements for application submission</td>
</tr>
<tr>
<td></td>
<td>• Notification requirements</td>
<td>• Procedure for assessing compliance and justifications</td>
</tr>
<tr>
<td></td>
<td>• How to submit study notifications</td>
<td>• Publication of valid justifications in the event of legitimate procedural deviations</td>
</tr>
<tr>
<td></td>
<td>• Timeline</td>
<td></td>
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</table>
6. Public consultation (Art. 32c(2))

PC on submitted applications

- Procedure
- Timeline
- Analysis of comments
Practical Arrangements on confidentiality decision making for plant protection product
## PAs on confidentiality decision making for plant protection products - Scope

<table>
<thead>
<tr>
<th>New Active Substances</th>
<th>Renewals</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Specific PAs harmonising confidentiality decision making by Rapporteur Member States</td>
<td>• Applicability of PAs on Article 39d(5)</td>
</tr>
</tbody>
</table>
### 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