Submission of dossier

Phase 1

<table>
<thead>
<tr>
<th>Applicant</th>
<th>RMS</th>
<th>APDESK</th>
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<tbody>
<tr>
<td>Submit Dossier + SSD + justification form</td>
<td>Assess completeness of Dossier + evaluate claims for confidentiality</td>
<td>Admissibility decision + decision on claims for confidentiality (justification form countersigned by RMS)</td>
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<tr>
<td>Prepare SSD in accordance with decision of RMS</td>
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<td>Send SSD + justification form countersigned by RMS</td>
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<td>Admissibility decision + decision on claims for confidentiality (justification form countersigned by RMS)</td>
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<td>Publish SSD in Register of Questions</td>
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14 days

12 months + max 6 month clock stop for DAR preparation

RMS: Rapporteur Member State
EC: European Commission
APDESK: Applications Desk Unit (EFSA)

DAR: Draft Assessment Report
SSD: Sanitised Summary Dossier

EFSA, iStockphoto, Shutterstock
**DAR dispatch and call for comments**

- **Applicant**
  - Completeness check of DAR**
  - Sanitise DAR
  - Submit sanitised DAR and justification form + Updated Dossier

- **RMS**
  - End of 12 months from admissibility decision
  - Submission of DAR*

- **APDESK**
  - Make DAR available for removal of confidential information
  - Take decision on sanitisation of the DAR
  - Open commenting period DAR is published

*After 10/11/2018 DAR should include updated ED assessment in line with new criteria.

**EFSA verifies that the DAR includes the ED assessment in line with the ECHA-EFSA Guidance. If this is missing, EFSA will ask for completion before proceeding with the peer-review.
**Applications helpdesk – New active substances + Amendment of approval conditions under Regulation EC 1107/2009**

### EFSA conclusion

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<th>Phase 3</th>
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<tr>
<td><strong>RMS</strong></td>
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<td><strong>EFSA</strong></td>
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**EC**

- Compile Reporting Table
  - Respond to comments in Reporting Table
  - Submit additional information
  - Clock stop max 3 months

**Applicant**

- Collect comments from MS, Applicant, EFSA and public
  - Kick-off Teleconference EFSA/RMS/(EC)/(ECHA)

**RMS**

- Evaluate the comments in Reporting Table
- Assess additional information, update DAR, ET
- Clock stop max 60 days
  - RMS homework (2 weeks)

**EFSA**

- Additional information request (3 months for both ED and non-ED issues)*
  - Prepare the Evaluation Table (ET)
  - Clock stop max 3 months
  - Experts consultation 9 weeks

**Notes**

* In case the initial DAR was submitted before 10/11/2018 and does not contain updated ED assessment, the clock stop of 3 months is used for giving opportunity to applicant to update the ED assessment in line with the ECHA-EFSA Guidance.
Applications helpdesk – New active substances + Amendment of approval conditions under Regulation EC 1107/2009

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<td><strong>EFSA</strong></td>
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**EFSA conclusion**

Present draft review report to SCoPAFF.

In case ED properties are unclear and no decision can be taken, EC will send a mandate to EFSA to request the additional information from the applicant and to assess that information.

**Written procedure with RMS (1 week)**

**Written procedure with MS (2 weeks)**

Sanitisation of EFSA conclusion + background documents

Draft conclusion

1) EFSA finalise conclusion (ED/non-ED)
   OR

2) EFSA finalise conclusion indicating studies needed to obtain missing information and timing needed for generating such studies*

EFSA Conclusion

*Contrary to renewals, there is no possibility for a second clock stop, unless a mandate is sent by EC following up a Conclusion of EFSA which indicates that data are insufficient to conclude on ED properties.

SCoPAFF: Standing Committee on Plants, Animals, Food and Feed