**Applications helpdesk – Renewal of approval of active substances under Regulation EU 844/2012**

### Submission of application

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

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RMS: Rapporteur Member State  
EC: European Commission  
APDESK: Applications Desk Unit (EFSA)
Submission of supplementary dossier

**Applicant**
- Submit SD + justification form

**RMS**
- Assess completeness of SD + evaluate claims for confidentiality
- Admissibility decision + decision on claims for confidentiality (justification form countersigned by RMS)

**APDESK**
- Prepare SSSD in accordance with decision of RMS
- Publish SSSD in Register of Questions

**Phase 1b**
- Immediately after notification of admissibility
- Send Original dossier, SD, SSSD + justification form countersigned by RMS

**Dates**
- 12 months + 6 months clock stop for RAR submission

**Abbreviations**
- SD: Supplementary Dossier
- SSSD: Sanitised Supplementary Summary Dossier
- RAR: Renewal Assessment Report
- RMS: Risk Management System
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RAR dispatch and call for comments

Phase 2

Applicant

Sanitise RAR

Submit sanitised RAR, USSSD and justification form + USD

End of 12 months of admissibility decision

Submission of RAR*

RAR should include updated ED assessment in line with new criteria.

EFSA verifies that the RAR 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.

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

USSD: Updated Sanitised Supplementary Summary Dossier
USD: Updated Supplementary Dossier

End of 12 months of admissibility decision

Completeness check of RAR**

Make RAR available for removal of confidential information

Take decision on sanitisation of the RAR and USSD

Open commenting period

RAR and USSD are published

60 days for applicant, Member States and public to comment on the RAR

*EFSA verifies that the RAR 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.
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**EFSA conclusion**

- **EC**
  - Evaluate the comments. EC may inform EFSA if a conclusion is not necessary
  - STOP

- **Applicant**
  - Respond to comments in Reporting Table
  - Compile Reporting Table
  - Evaluate the comments in Reporting Table

- **RMS**
  - Submit additional information
  - Clock stop max 1 month

- **EFSA**
  - Collect comments from MS, applicant, EFSA and public
  - Kick-off teleconference EFSA/RMS/(EC)/(ECHA)
  - Preparation of Evaluation Table (ET)
  - Assess additional information, update RAR, ET
  - Additional information request*

*In case the initial RAR was submitted before 10/11/2018 and does not contain updated ED assessment, the clock stop of 1 month is used for giving opportunity to applicant to update the ED assessment in line with the ECHA-EFSA Guidance.
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#### EFSA conclusion

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**Phase 3**

1. **RMS homework (2 weeks)** (deadline set on ad-hoc basis by EFSA in case ED clock stop needed)

2. **Experts consultation** 9 weeks

3. **Pesticides Peer Review Experts’ meeting/teleconference - Available ED assessment discussed to agree on 2nd clock stop (where relevant)**

4. **MS written procedure on additional information (3 weeks)**

5. **Data on ED sufficient?**
   - YES
   - NO

6. **ED disruptor?**
   - YES
   - NO

7. **Submit further data on ED (and/or Art. 4(7)/negligible exposure assessment)**

8. **ED clock stop from 3 to 30 months**

9. **Additional 3 months to follow-up ED criteria or submit Art. 4(7)/negligible exposure assessment**

10. **Evaluate additional information in updated RAR**

11. **Revised RAR**

   - **Sanitisation of Revised RAR (Vol1, Vol3 CA B6, B9)**

   - **YES**
   - **NO**

**Criteria 3.6.5 and/or criteria 3.8.2 are met.**
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### EFSA conclusion

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<td><strong>EFSA</strong></td>
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- **Open commenting period on ED assessment with MS, applicant, EFSA and public**
- **Collect comments from MS, applicant, EFSA and public**
- **Compile ED comments and propose response**
- **Divergent comments on ED assessment?**
  - **NO**
    - **Written procedure with RMS (1 week)**
    - **Draft conclusion**
  - **YES**
    - **Ad hoc experts discussion tox/ecotox**
    - **Written procedure with MS (2 weeks)**

The image shows a flowchart illustrating the process of renewing the approval of active substances under Regulation EU 844/2012, with various stages highlighted in orange and green boxes.
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**EFSA conclusion**

- **EC**
  - Decision on renewal or non-renewal of approval

- **Applicant**
  - Sanitisation of EFSA conclusion + background documents

- **RMS**
  - Finalise conclusion

- **EFSA**
  - EFSA conclusion (within 5 months + clock stop after commenting on RAR, or within 120 days from receipt of revised RAR after ED clock stop)