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

Submission of application

**Phase 1a**

**Applicant**
- Submit application + justification form

**RMS**
- Assess completeness of application + evaluate claims for confidentiality
- Decision of completeness of application + Decision on claims for confidentiality (justification form countersigned by RMS)

**APDESK**
- Prepare sanitised application in accordance with decision of RMS
- Send application, sanitised application + justification form countersigned by RMS
- Publish sanitised application in Register of Questions
**Applications helpdesk – Renewal of approval of active substances under Regulation EU 844/2012**

### Submission of supplementary dossier

<table>
<thead>
<tr>
<th>Applicant</th>
<th>RMS</th>
<th>APDESK</th>
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<tbody>
<tr>
<td>Submit SD + justification form</td>
<td>Assess completeness of SD + 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 SSSD in accordance with decision of RMS</td>
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<tr>
<td>Send Original dossier, SD, SSSD + justification form countersigned by RMS</td>
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<td>Publish SSSD in Register of Questions</td>
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**Phase 1b**

- Immediately after notification of admissibility
- 12 months for RAR submission

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SD: Supplementary Dossier
SSSD: Sanitised Supplementary Summary Dossier
RAR: Renewal Assessment Report
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RAR dispatch and call for comments

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<thead>
<tr>
<th>Applicant</th>
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<tr>
<td>End of 12 months of admissibility decision</td>
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<tr>
<td>Submission of RAR*</td>
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<tr>
<td>Completeness check of RAR**</td>
</tr>
<tr>
<td>Make RAR available for removal of confidential information</td>
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<tr>
<td>Take decision on sanitisation of the RAR and USSSD</td>
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<tr>
<td>Open commenting period RAR and USSSD are published</td>
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<thead>
<tr>
<th>RMS</th>
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<tbody>
<tr>
<td>14 days</td>
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<tr>
<td>Sanitise RAR</td>
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<tr>
<td>Submit sanitised RAR, USSSD and justification form + USD</td>
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<thead>
<tr>
<th>APDESK</th>
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<tbody>
<tr>
<td>After 10/11/2018 RAR should include updated ED assessment in line with new criteria.</td>
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<tr>
<td>**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.</td>
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USSSD: Updated Sanitised Supplementary Summary Dossier
USD: Updated Supplementary Dossier
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### EFSA conclusion

<table>
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<tr>
<th>Phase 3</th>
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- **EC**
  - Collect comments from MS, applicant, EFSA and public
  - Compile Reporting Table
  - Evaluate the comments in Reporting Table
  - Respond to comments in Reporting Table
  - Evaluate the comments. EC may inform EFSA if a conclusion is not necessary
- **Applicant**
  - Collect comments from MS, applicant, EFSA and public
  - Compile Reporting Table
  - Evaluate the comments in Reporting Table
- **RMS**
  - Collect comments from MS, applicant, EFSA and public
  - Evaluate the comments in Reporting Table
  - Submit additional information
  - Assess additional information, update RAR, ET
- **EFSA**
  - Collect comments from MS, applicant, EFSA and public
  - Kick-off teleconference EFSA/RMS/(EC)/ (ECHA)
  - Additional information request*
  - Prepare the Evaluation Table (ET)

**Clock stop**
- Max 1 month
- Max 60 days

**Comment evaluation**
- 6 weeks

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

**EFSA conclusion**

**Phase 3**

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**EC**

** Applicant**

- RMS homework (2 weeks) (deadline set on ad-hoc basis by EFSA in case ED clock stop needed)
- Experts consultation 9 weeks

**RMS**

- Pesticides Peer Review Experts’ meeting/teleconference - Available ED assessment discussed to agree on 2nd clock stop (where relevant)
- MS written procedure on additional information (3 weeks)

**EFSA**

- Data on ED sufficient?
- ED disruptor?

**YES**
- 2nd clock stop for updated ED

**NO**
- Submit further data on ED (and/or Art. 4(7)/negligible exposure assessment)
- Additional 3 months to follow-up ED criteria or submit Art. 4(7)/negligible exposure assessment

**YES**
- ED clock stop from 3 to 30 months

**NO**
- ED clock stop max 90 days

**REVISED RAR**

**Evaluate additional information in updated RAR**

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

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- **EC**
- **Applicant**
- **RMS**
- **EFSA**

**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**
  - **Ad hoc experts discussion tox/ecotox**
  - **Written procedure with RMS (1 week)**
  - **Written procedure with MS (2 weeks)**

- **YES**
  - **Draft conclusion**
  - **Collect comments from MS, applicant, EFSA and public**

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

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<td><strong>RMS</strong></td>
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<td><strong>EFSA</strong></td>
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### EFSA conclusion

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

### Decision on renewal or non-renewal of approval

- Sanitisation of EFSA conclusion + background documents

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*Phase 3*