Implementation schedule

Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances

Does not necessarily represent the views of the Commission
**Introduction**

On 22 March 2019, the Standing Committee on Plants, Animals, Food and Feed (Section – pesticides legislation) endorsed the “Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances” prepared by the European Food Safety Authority (EFSA).

The following additional guidance documents and templates were also updated in line with the above mentioned guidance and agreed by the PAFF Committee on 22 March. The date from which the amended version is applicable is indicated in each guidance document.

<table>
<thead>
<tr>
<th>Guidance Document</th>
<th>Reference</th>
<th>Version noted</th>
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<tbody>
<tr>
<td>Guidance Document on the renewal of approval of active substances to be assessed in compliance with Regulation (EU) No 844/2012 (the Renewal Regulation)</td>
<td>SANCO/2012/11251</td>
<td>Rev. 5</td>
</tr>
<tr>
<td>Guidance document on preparing lists of test and study reports according to Article 60 of Regulation (EC) No 1107/2009</td>
<td>SANCO/12580/2012</td>
<td>Rev. 4</td>
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<tr>
<td>Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 Including a revised document N-3</td>
<td>SANCO/10181/2013</td>
<td>Rev. 4</td>
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<tr>
<td>Combined Template to be used for Assessment Reports according to Regulation (EC) No 1107/2009 and Proposals for Harmonised Classification and Labelling according to Regulation (EC) No 1272/2008 Agreed by Member States' Competent Authorities in the SCoPAFF: Phytopharmaceutical legislation section. (Volume 1, Volume 2 and Volume 3).</td>
<td>SANCO/12592/2012</td>
<td>Rev. 2</td>
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**Implementation**

The Committee agreed that the EFSA Guidance should apply as follows:

- For (supplementary) dossiers submitted to Member States and EFSA on or after 1 October 2019;

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For Assessment Reports (DAR/RAR) submitted to EFSA by Member States after 1 October 2020.

The updated guidance documents will apply as indicated in the version history of each document.

However, in order to ensure an efficient peer review, applicants and Member States are encouraged to use the EFSA guidance or at least parts of it, immediately.

Concerning the checklists for Assessment Reports as included in the EFSA Guidance Document:

- The short-term Completeness Checklist for Assessment Reports (Appendix B1 of the Administrative guidance) is directly applicable and should be submitted together with DARs/RARs sent to EFSA after 1 April 2019. This 'short-term' list should be used until the 'long-term' or 'full' checklist will be implemented.

- The full Completeness Checklist for Assessment Reports (Appendix B2 of the Administrative guidance) should be used by RMS and submitted together with all DARs/RARs submitted to EFSA after 1 October 2020.

EFSA may consider whether the DAR/RAR is considered incomplete and needs amendments as it will be indicated in the Remarks column of the Completeness checklist. In case issues are identified related to the correct format and/or overall quality of the DAR/RAR/LoEP, or missing documents related to the presence of MRL application form, Art 4(7), negligible exposure assessment or presentation of ED assessment, the RMS should submit the documents in the correct format and/or complete missing documents before the public consultation on the DAR/RAR will be launched.