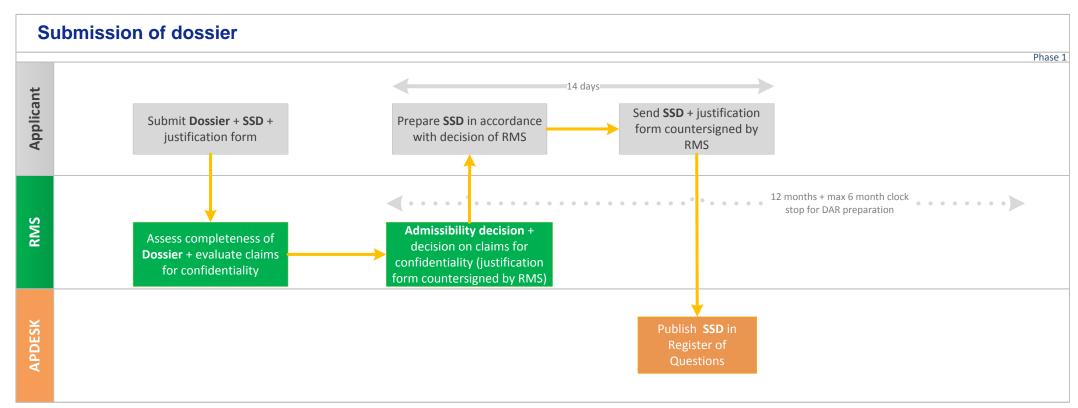


Applications helpdesk - New active substances + Amendment of approval conditions under Regulation EC 1107/2009



RMS: Rapporteur Member State EC: European Commission

APDESK: Applications Desk Unit (EFSA)

DAR: Draft Assessment Report SSD: Sanitised Summary Dossier



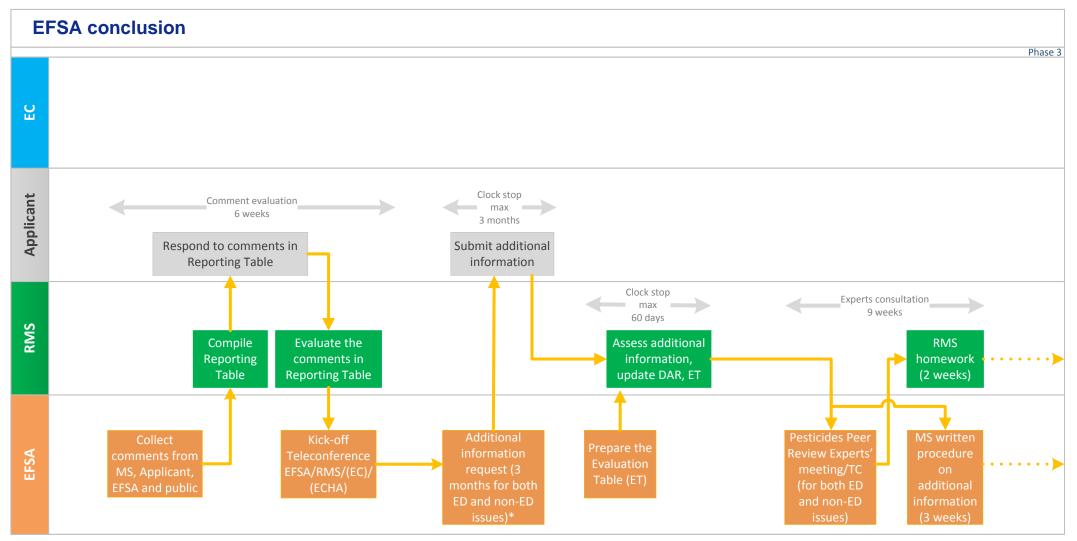
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DAR dispatch and call for comments Phase 2 14 days Applicant Submit sanitised DAR and justification form + Sanitise **DAR Updated Dossier** End of 12 months Submission of RMS from DAR* admissibility decision Make **DAR** 60 days for applicant, available for Take decision on **APDESK** Member States removal of check of DAR** and public to comment the DAR on the DAR

^{*}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.

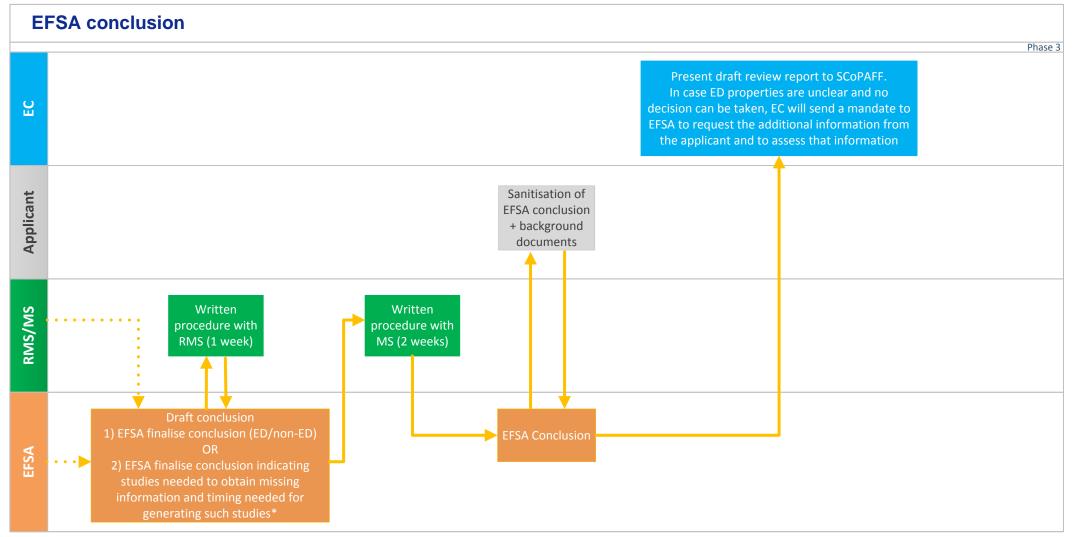
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^{*} In case the initial DAR was submitted before 10/11/2018 and does not contain updated ED assessment, the clock stop of 3 months is used for giving opportunity to applicant to update the ED assessment in line with the ECHA-EFSA Guidance.



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^{*}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.