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

EFSA conclusion in finalisation step but not yet adopted by EFSA, or adopted but no voting on draft Regulation took place in SCoPAFF by the date of application of the new ED criteria* introduced by Regulation EU 2018/605

- Send a mandate to update ED assessment
- Prepare updated ED assessment (+draft proposal testing strategy)
- Open consultation on draft ED assessment with MS/applicant
- Collect comments and propose response

Based on the outcome of the assessment / ad hoc experts discussion:
1) EFSA proceeds with conclusion (non-ED)
   OR
2) EFSA sends clock stop (additional info needed)
   OR
3) EFSA sends letter giving applicant opportunity to submit additional information**/Art.4(7)/negligible exposure (ED)

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

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

Ad hoc experts discussion tox/ecotox

Finalise conclusion

Continue evaluation

*10 November 2018.
**To address the approval criteria set out in point 3.6.5 and 3.8.2 of Annex II to Regulation EC 1107/2009.

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