Standard Operation Procedures	SOP_013
Effective Date: 25/02/2026	**Public**

Risk Assessment of Pesticides

Special Requirements	This procedure is a controlled document maintained by Quality Management. It may not be deleted without comparable controls. Please note that this document becomes uncontrolled once printed. Make sure by always referring only to the Repository that you have the right version in use. Deviations from the provision of this document need to be recorded in the relevant tool. The procedure should be updated when there are changes in EFSA with respect to what is stated in the document (e.g. Relevant Standards, legislation, and documents, change in procedure, etc.). The person responsible for maintaining this procedure up to date is the Lead author with the support of the QM.

Process Responsibility	Process owners and/or Head of Units are accountable for this procedure being adhered to within their respective process or unit. All relevant staff is responsible for the correct implementation of the procedure. Responsibilities for performing specific steps are outlined in the document.

Scope and objectives

This Standard Operating Procedure (SOP) describes the **End2End** processes to perform the Peer-review[1] for the approval of new active substances **(NAS),** the amendment of approval conditions**,** or the renewal of approval of active substances **(Renewal dossier), basic substance applications**, and **the confirmatory information procedure (Art. 6(f)) of Regulation (EC) 1107/2009,** and the Assessment of Maximum Residues Levels **(MRLs)**

[1] The on-going technical developments and the implementation of requests for change on EFSA tools impact some of the steps and tasks described in this document. Such cases are duly reported. For further information, please see the **Annex I SOP 13 NC WA**

Art. 10 applications and for Art. 12 confirmatory data of Regulation (EC) 396/2005, spanning from Dossier Intake to Output Approval[2].

The End2End Pesticides macro-process is divided into four processes: Dossier Intake (**E03.01**), Risk Assessment (**E03.02**), Confidentiality Assessment (**E02.03**) and Scientific Output Publication (**E02.04**). Each macro-phase is composed by different activities all concurring to the production of a **Conclusion on Pesticides Peer-review/ Reasoned Opinion or Technical Report.**[3]

Relevant Standards, legislation and documents

1. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
2. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market
3. Commission Regulation (EU) 2024/1487 of 29 May 2024 defining data requirements for the approval of safeners and synergists and establishing a work programme for the gradual review of safeners and synergists on the market in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council
4. Commission Implement Regulation (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (Text with EEA relevance)
5. Commission Implementing Regulation (EU) No 844/2012 continues to apply to substances whose approval period ends before 27 March 2024 (as on 27 March 2021)
6. Commission Implementing Regulation (EU) No 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances[4]
7. Commission Working document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009
8. Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin
9. IMPRUL_108_PAs-confidentiality-Art-7-and-16-of-regulation-1107-2009
10. IMPRUL_109_PAs concerning transparency and confidentiality
11. SANCO Guidance document (2013) on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009
12. IMPRUL_111_PAs-pre-submission-phase-and-public-consultations
13. General framework mandate to undertake the evaluation of applications concerning "basic substances" submitted to the Commission under the provisions of Article 23 of Regulation (EC) No 1107/2009
14. Guidance Document on the MRL setting procedure
15. SOP_005_Managing meetings
16. Administrative Guidance on pesticides applications
17. SOP_009_S Approving Supporting Publications

[2] For applications submitted before the entry into force of the new Transparency Regulation, please refer to Annex I of the SOP listing the applicable and not applicable steps
[3] Please consult this Table for clarity on specific activities which do not fully follow the mainstream end2end processes (SOP 7, SOP 12, SOP 13) and the respective WINs (when available).
[4] In line with Article 2, this Regulation applies to the renewal of the approval of active substances whose approval period ends on or after 27 March 2024.

18. SOP_010__S_Scientific_Cooperation,_Grants_and_Procurements,_Planning,_Launch,_Evaluation,_Award and Implementation
19. SOP_014_S Publishing a scientific Output in the EFSA Journal and Supporting Publications
20. SOP_015_S Correction of a published scientific Output
21. SOP_020_M_Processing_of_confidentiality_claims_received_by_EFSA_in_the_context_of_its scientific operations prior to 27.03.2021
22. SOP_020_Confidentiality assessment, implementation and publication of documents
23. SOP_022_S Selection of studies performed in compliance with Good Laboratory Practice for audit purposes
24. WIN_SOP05_05_Peer Review Mtg organisation
25. WIN_SOP00_071 Processing of Public Consultations
26. WIN_SOP12_05_Processing of Targeted Consultations
27. WIN_SOP020_01_Practical_implementation_of_SOP_020__Processing_of_confidentiality claims
28. WIN_SOP23_01 Registration, approval and follow- up of non-conformities.
29. WIN_SOP_013_01__Post TR_Receipt to Validity_MRL applications
30. WIN_SOP_013_02__Post_TR_Receipt_to_Call_for_removal_AIR_dossiers_and_assessment report
31. WIN_SOP_013_03__Post TR_Receipt to Call for removal_NAS dossiers and assessment report
32. WIN_SOP013_05 Approval of basic substances
33. WIN_SOP013_06 Confirmatory information on active substances
34. WIN_SOP013_08 Approval of new active substances
35. WIN_SOP013_09 Renewal of the approval of active substances
36. WIN_SOP013_13_Processing MRL Art.10 applications
37. SOP_001_S Pre-submission activities
38. **Annex I_SOP 13_NC_WA**
39. **Annex II - Records**
40. **Annex III – Pre-TR applications, non-applicability to processes**

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PROCESS 1 - APPROVAL OF NEW ACTIVE SUBSTANCES (NAS) OR FOR AMENDMENT OF APPROVAL CONDITIONS	
Macro-phase 1	Dossier Intake
Step 1	**1.0 Receipt of Application dossier for approval or amendment of approval conditions and dissemination**
Applicant, FDP	**1.1** Applicant submits the application dossier for approval or amendment of approval conditions (including GLP, NoS related information and where relevant the MRL information), in IUCLID format through the central submission system, indicating the RMS to which they intend to submit the application. Applicant also indicates each pre-application ID associated with any pre-submission activities carried out in relation to the specific regulated product which is the subject of that application (see SOP Pre-submission and EFSA PAs on pre-submission and public consultations). **1.2** FDP forwards the automatic dossier notification to PREV FMB.
Step 2	**2.0 Withdrawal of application**
Applicant, FDP, RAL SMU	**2.1** An applicant can withdraw its application at any time. The request for withdrawal should be submitted via email to EC, the RMS and other Member States and EFSA. **2.2** For withdrawal procedure FDP is responsible for macrophase 1, RAL and SMU for the subsequent macrophases/steps. **2.3** Once the withdrawal is received by EFSA, all activities (e.g. confidentiality assessment, Dossier intake, RA) linked to the Dossier at stake are closed in Case Management Tool and the 00 merged timelines and Overview table are updated without delay, and this will be automatically reflected on the Open EFSA Portal. Information on the application made publicly available prior to the receipt of the withdrawal notice shall be set as confidential in Open EFSA portal and be no more visible as per SOP 020 Confidentiality assessment, implementation and publication of documents [5] **2.4** For information management purposes and auditing reasons, FDP/RAL stores for at least seven years one copy of the information, documents and correspondence in **dms**. The dossiers will be retained in Agency IUCLID (central submission system) while they will be

[5] For applications submitted before 27 March 2021 the information will remain visible and should not be deleted

	deleted from Public IUCLID and the relative links from Case Management Tool and Open EFSA.
Step 3	**3.0 Chartering**
SMU HoU, FDP, RAL	**3.1** An overarching process charter is in place for the assessment of Dossiers covered in this SOP. If an update is required, the SMU HoU (or his/her delegate), through the RAL planner, interacts with FDP to manage the requested changes. For further details on how the request for change is managed, please refer to the WIN_SOP51_01 Portfolio-Management of change requests.
Step 4	**4.0 Dossier admissibility by RMS**
FDP, RMS	**4.1** FDP extracts and filters the list of studies from the database of study notifications and uploads them in dms. **4.2** FDP notifies the RMS via email providing the link to access the extractions in **dms**. **4.3** RMS checks the matching of studies submitted in the dossier with the studies previously notified and verifies the compliance with notification of studies obligations, see SOP_001_S Pre- submission activities. **4.4** The RMS interrupts the admissibility check and informs the applicant. In case one of the conditions outlined in SOP_001_S Pre-submission activities is not met (without a valid justification) the application for approval is declared not admissible by the RMS. The RMS interrupts the admissibility check and informs the applicant. At this step, the applicant may re-submit through the EFSA Application Submission Portal in IUCLID format the application for approval or amendment of approval conditions, including an MRL information when relevant, by means of an updated dossier. The application may be re-submitted, provided that the applicant notifies the studies that were not previously notified; and/or the applicant submits all the studies which were previously notified or, even if withdrawn, the data delivered by the relevant laboratory or testing facility even without having the study completed. **4.5** In this case, the RMS informs the applicant that the assessment of the re-submitted application will commence in accordance with the conditions laid down in Article 32b(4) and (5) of the GFL Regulation. **4.6** The RMS checks that the information submitted is complete by performing the steps described in the Admissibility Checklist available in Appendix C to the Pesticides Administrative Guidance. If the checks pass, the RMS declares the admissibility of the application for approval or amendment of approval conditions, including an MRL information when relevant, and notifies FDP and SMU functional mailboxes, providing the relevant documents and identifiers required in the admissibility process. Upon declaration of admissibility the RMS uploads in **dms** the validation assistant report, NoS report and confidentiality report.

	4.7 Upon reception of the declaration of admissibility, FDP registers in Case Management Tool the admissibility and assigns the 'SPOC Collaborator'. FDP registers also the chemical substances and/or microorganisms subject of the mandate in Case Management tool. **4.8** Also, FDP records the admissibility in the relevant table, renames the folder in **dms** and stores relevant correspondence documents. Applicant should be correctly displayed in Case Management Tool and in Open.EFSA (if missing, FDP should follow-up). Upon declaration of admissibility by the RMS, FDP performs a light check in line with Procedure 7, Step 1.2 of SOP_020_Confidentiality assessment, implementation and publication of documents. If the light check passes, FDP publishes the non-confidential version of the application dossier (please see the document Publication of PPP dossiers post-admissibility.docx), making available on the Open EFSA, via the Case Management Tool, the relevant link to the Public instance of IUCLID. FDP also publishes the (sanitised) extract from the NoS database.
Step 5	**5.0 Confidentiality decision making process (incl. dissemination non-confidential dossier and summary (G)PSA)**
RMS, FDP, SMU, LA, RAL	**For NAS/amendment of approval conditions the RMS is responsible for the confidentiality decision making process as regards the dossier.** **5.1** Together with the application dossier for approval or amendment of approval conditions, including an MRL information when relevant, the applicant might submit confidentiality requests using the relevant IUCLID functionality. In line with EFSA's practical arrangements concerning confidentiality in accordance with Article 7(3) and 16 of Regulation (EC) No 1107/2009, RMS then assesses the confidentiality claims (for joint submission of NAS & MRL applications, LA will assess the confidentiality claims of the MRL application only) **5.2** Prior to finalising its confidentiality decision and in line with EFSA's practical arrangements, the RMS consults EFSA (LA) by sharing the draft confidentiality decision via the tool made available by EFSA. LA provides its comment within 10 working days. After taking into account LA's comments, RMS notifies the draft confidentiality decision to the Applicant and takes into account any observations from the Applicant before issuing the final confidentiality decision. **5.3** FDP publishes the final non-confidential version of the admissible dossier, making available on Open EFSA, via the Case Management Tool, the relevant link to the Public IUCLID and provides the link to SMU/RAL. **5.4** Once a confidentiality decision has been taken, FDP also proceeds with the publication of the list of NoS.
Step 6	**6.0 Public consultation on the non-confidential version of an admissible application**

	Extraction and publication of comments, dispatch to RMS for inclusion in DAR
RAL	**6.1** Following the confidentiality assessment and the dossier publication, FDP informs RAL that the non-confidential version of the dossier is published so RAL can trigger through Case Management Tool the creation of the PC in the Customer Portal. Also, RAL records the *start and end dates of PC* in the 00 merged timelines. For more information on the PC (e.g. duration), consult the relevant Practical Arrangements; for more information on RAL tasks consult WIN_SOP00_071 Processing of Public Consultations. Upon closure of the PC, comments become public on the Open EFSA portal automatically, while RAL extracts them from the Customer Portal in Excel format with the relevant attachments and dispatches everything to the RMS via **dms** for consideration in the preparation of the DAR. In duly justified cases, where there is a risk that the results of the public consultation performed in accordance with Art 32c(2) of Regulation 178/2002 cannot be given proper consideration because of the applicable time limits within which the Authority is required to deliver its scientific Output, those time limits may be extended for a maximum period of seven weeks.
Step 7	**7.0** **Receipt of draft DAR** ***Completeness Check of draft DAR and submission of updated draft DAR, if needed*** ***Dissemination to MSs and applicant (for sanit.)*** ***Confidentiality decision-making process***
RMS, FDP, Applicant, SMU, RAL	**For NAS, the RMS is responsible for the confidentiality decision making process on the dossier.** **7.1** If during consideration of the comments from the PC on the dossier, the RMS identifies the need for additional information, the applicant will be requested by RMS to update the dossier. **7.2** The RMS uploads in **dms** the draft DAR (including results of PCs as an annex to the draft DAR) together with the completeness check list (see Appendix A of Administrative Guidance on pesticides applications) at the latest 12 months (plus a max of 6-month extension in case the RMS requests additional information from the applicant during preparation of the draft DAR) after notification on admissibility of the application for approval or amendment for approval conditions (and MRL information if applicable) and notifies FDP via email. **7.3** FDP stores correspondence in **dms** and informs RAL and SMU (if needed). **7.4** Upon receiving the draft DAR, FDP updates the Case Management Tool and the relevant tables with the date of receipt of the draft DAR and performs the completeness check.

	7.5 If the draft DAR is not considered complete, FDP requests an updated version from the RMS. Once it is considered complete, FDP informs the RMS and RAL about the completeness of the draft DAR. **7.6** Upon receipt of the complete initial DAR from the RMS, FDP shares the initial DAR with the applicant who has two (2) weeks to submit confidentiality requests along with a non- confidential, sanitised version as well as a confidential version thereof via Portalino informing EC/MS and EFSA by e-mail. **7.7** FDP informs the applicant that an updated dossier, reflecting the additional information that the RMS may have asked during the risk assessment, should be submitted in IUCLID format through the central submission system. **7.8** Upon receipt of confidentiality requests on the DAR, if any, LA carries out a confidentiality assessment in line with SOP 020 Confidentiality assessment, implementation and publication of documents. Upon indication from LA to RAL, RAL publishes the complete initial DAR on the OpenEFSA Portal upon opening of the PC and TC on the initial DAR. **7.9** Upon conclusion of the confidentiality decision-making and any follow-up activities related thereto, in accordance with SOP 020 Confidentiality assessment, implementation and publication of documents RAL makes available the final non-confidential version of the initial DAR on the OpenEFSA Portal without delay upon indication from LA to RAL. Should a confirmatory application be submitted by the Applicant in line with Article 39b(2) of Regulation (EC) 178/2002 or should an interim relief measure being granted by the General Court, the implementation shall be suspended. RAL saves it in dms and, upon confirmation from LA, communicates without delay the reasoned decision on the confidentiality requests to EC/MSs and/or the EU Reference Laboratory involved in the risk assessment process, as appropriate. To be noted that there might be cases where ECHA is launching a parallel consultation on the volume 1 CLH (Harmonised Classification and Labelling) of the DAR. In these cases, FDP shall timely inform LA of the parallel consultation and upon finalisation of the confidentiality assessment, RAL will provide ECHA with the sanitised DAR/RAR Vol 1 to launch a parallel consultation. **7.10** SMU agrees with FDP and RAL the planned date of consultation. If the DAR is of poor quality, EFSA may request the RMS to withdraw the DAR and resubmit it. In this case the Case Management Tool will need to be updated accordingly. **7.11** FDP/RAL see step 2 point 2.5 for keeping documents.
Step 8	**8.0** **Commenting period and dissemination** ***Consultation of the public, targeted stakeholders and EFSA on the DAR*** ***Comments collected and sent to RMS for the Reporting table preparation***

FDP, LA, RAL	**8.1** FDP publishes the updated dossier a few days before the planned PC and provides RAL the relevant dossier information. **8.2** RAL triggers through the Case Management Tool the creation of the public and targeted consultations on the DAR in the Customer Portal (please refer to WIN_SOP_00/71 Processing Public Consultations). **8.3** On the opening day of the public and targeted consultation, RAL informs the applicant and SMU on the launching of the consultation on the DAR requesting to provide their comments, while MSs, EC, EURL, ECHA are notified automatically via the tool. **8.4** RAL updates the Case Management tool by validating the DAR **8.5** Upon closure of the Public and Targeted Consultations, comments received through the public one become public on OPEN EFSA portal automatically while RAL ensures the dissemination of **all comments** (e.g. from public, applicant, MS, EC, EURL, ECHA and EFSA) to the RMS for the compilation of the Reporting Table with SMU in cc. EFSA internal comments and the applicant ones are collected outside the Customer Portal.
Macro-phase 2	Preliminary Activities Risk Assessment
Step 9	**9.0 Workforce mix definition**
SMU, RAL	**9.1** The Workforce Mix planning by the competent SMU may start at any time after Step 8.4 above. **9.2** The TEAM leader defines the high-level Workforce Mix Planning. (staff and externals). When assigning the Dossier to SOs, the SMU TL ensures the separation of tasks as requested by law checking that staff members involved in general pre-submission advice activities will not be involved in activities during the RA. **9.3** RAL define(s) in the Case Management Tool the **scientific Output type(s).**
Step 10	**10.0 Definition of outsourced tasks**
SMU	**10.1** In case of outsourcing, please refer to SOP_010_S Procurements and grants, Planning, Launch, Evaluation, Award and Implementation for more details**.**
Step 11	**11.0 Quality Standards (scientific check and follow-up to study audits)**
SMU, FDP, RAL	**11.1** For scientific check studies, please refer to SOP_022_S Selection of studies performed in compliance.. **11.2** Depending on the applications' life-cycle stage and the type of non-compliance identified, FDP will contact the officer in FDP in charge of the completeness check of the DAR/RAR and/or the respective SMU/RMS for ensuring the appropriate follow-up. The obligation for the Applicant to notify studies in the NoS database also applies to studies commissioned/carried out after the admissibility of the application and therefore during the RA for which Step 4 does not apply. However, in contrast to Step 4 (before admissibility), during

	the RA the Applicant does not have the obligations to submit the study notifications/justification in the application as, at this stage, the procedural consequences foreseen in Article 32b(4) and (5) of the General Food Law cannot be applied. Hence, during the RA the SMU does not have to assess the compliance with the obligations of study notifications. Notwithstanding the above, in accordance with Article 25 of the Practical arrangement on pre-submission phase and public consultations and Article 32b(6) of the Regulation 178/2002 , if during the risk assessment, following a more extensive verification of the data submitted by the applicant, the SMU detects that the studies previously notified (before the admissibility/validity of the application) are not included in the submitted application in full, the SMU, supported by RAL, requests the applicant to provide justifications regarding any missing data (under the normal stop-the-clock provision). The applicant is also informed that the time-limits within which EFSA is required to deliver its scientific Output shall be suspended, pending the provision of valid justifications by the applicant. The SMU assesses the justifications provided by the applicant, which will be declared valid by the SMU HoU if considered as such. The risk assessment process shall resume, and the applicant be informed accordingly. If during the assessment, the SMU considered the justifications not valid, the applicant shall be requested to submit the missing data. The applicant is also informed that the risk assessment process will remain suspended until six (6) months after the submission of any missing data relating to any supporting studies. For more information, please consult the EFSA's Practical Arrangements concerning pre-submission and public consultations and the SOP_001_S Pre-submission activities
Step 12	**12.0 Meetings**
SMU, RAL	**12.1** Meetings can occur any time during the RA process. They should be organised according to SOP_21_A Logistic services and are managed as described in SOP_005_Managing meetings and WIN_SOP05_05 Peer Review Mtg organisation. **12.2** Meetings other than Pesticide Peer review meetings might also be organised during the risk assessment process: e.g. internal meetings (e.g. preparatory meetings), meetings with applicants according to the EFSA Catalogue of Services (e.g. clarifications teleconference, applicants hearing). **Information related to these meetings is not subject to dissemination/publication.**
Macro-Phase 3	Peer Review

Step 13	**13.0 Reporting Table (RT) preparation**
SMU	**13.1** Upon receiving the compiled RT sent from the RMS to SMU and RAL, SMU responsible SO(s) reply to the comments.
Step 14	**14.0 First draft of the Conclusion**
SMU, RAL, Experts	**14.1** Upon receipt of the RT, SMU organises the kick-off teleconference with RMS (tollgate #1)[6], which aims at identifying open points (to be addressed by RMS), data requirements (to be addressed by the applicant as additional information) and expert's consultation points (to be addressed during the peer review meeting. **14.2** The SC informs RAL of an ADR. RAL ensures that all the sections of an ADR are uploaded in Case Management Tool and updates the monitoring table. RAL prepares the clock-stop letter and submits it to the SMU HoU for approval. Once approved, the ADR letter is sent by RAL to the applicant and RMS and uploaded in the **dms**. **14.3** RAL also registers the ADR and a "Clock Stop" event in the Case Management Tool. Relevant non-confidential ADR/clock-stop details (e.g. ADR/clock-stop date, ADR sections, expected date of ADR reply) are automatically made visible on the OpenEFSA Portal to comply with the 2019 Ombudsman recommendation[7]. **14.4** In case there is an Article 10 application included in the Peer-review process, if the data required for the Art 10 application during the clock-stop are not addressed, the Art 10 application would be separated from the peer review process and would go alone through the MRL process (see below MRL process). **14.5** Upon receiving the ADR, the Applicant might request a clarification teleconference as described in EFSA Catalogue of Services, the RMS is invited as well. **14.6** The applicant makes the requested additional information available to EFSA, RMS, all MSs and the EC, within 90 days, via IUCLID by means of an updated dossier**. Confidentiality requests presented by the applicant on the additional information concerning NAS are to be assessed by the RMS**. Prior to finalising its confidentiality decision and in line with EFSA's practical arrangements, the RMS consults EFSA (LA) by sharing the draft confidentiality decision via the tool made available by EFSA. LA provides its comment within 10 working days. After taking into account LA's comments, RMS notifies the draft confidentiality decision to the Applicant and takes into account any observations from the Applicant before issuing the final confidentiality decision. RMS uploads the final confidentiality decision in **dms** notifying LA/FDP/RAL. LA will perform a check on the RMS decision making sure it meets the criteria set out in the PAs. Following this check LA informs RAL and FDP of the finalisation of the RMS confidentiality assessment. RAL will then communicate the reasoned decision on the confidentiality requests to EC/MSs and/or the EU Reference Laboratory involved in the risk assessment process, as appropriate,

[6] Tollgates correspond to quality checks performed during the Risk Assessment. No dates (planned or passed) are associated to Tollgates. Three Tollgates are applicable for this process: Tollgate 1, 2 and 3.

[7] Please refer to case 176/2015/JF

	14.7 RAL updates the Case Management Tool by adding the reception date only and uploads the cover letter in the dms. **14.8** After evaluation of the additional information submitted by the applicant, RAL requests the RMS to submit a revised DAR and Evaluation Table (ET) within a period of 60 days by uploading in **dms.** **14.9** Upon receipt of the revised DAR, RAL restarts the clock in the Case Management Tool and updates 00 merged timelines accordingly. **14.10** The responsible SC, requests RAL, to launch a written procedure with MSs on the RMS's assessment of the additional information. If during step 15 it was decided to organise an expert consultation, responsible SC / RAL prepare the agenda and make it publicly available on the EFSA website. For more details on meeting organization, please see Step 12. **14.11** Once the meeting documents including the pre-filled meeting report(s) are available in the relevant meeting folders in **dms**, the RAL sends a reminder to MS Experts, asking them to provide preliminary comments. **14.12** Following the Expert Meeting, SMU SOs draft the meeting minutes. A high-level version of the report(s) shall be published on the EFSA website by RAL within 15 working days of the last day of the meeting and stored in **dms** as a record. The full version of the minutes shall be stored in **dms.** The RMS should complete the open points identified in the meeting, if any, i.e. so called 'homework' and provide within 2 weeks from the submission of the e-mail by SCs the revised assessment reports and evaluation tables accordingly. **14.13** If no Expert Meeting is needed, following the RMS evaluation of the additional information submitted by the applicant and completion of the written procedure on the RMS assessment of the additional information, SMU will proceed to draft the EFSA Conclusion. **14.14** Responsible and participant SOs draft the EFSA Conclusion and successively proceed with internal scientific review.
Step 15	**15.0 Finalization of the Conclusion**
SMU, RAL	**15.1** Once the draft Output passes the internal scientific review, SMU sends the draft for a written consultation first with the RMS (tollgate #2)[8] and subsequently, in a second step, with the other MSsIn case of disagreements with the RMS, an ad hoc expert teleconference may also be organized by SMU/RAL before launching the written consultation with the other MSs. **15.2** Upon receiving MSs' comments, responsible SO(s) and responsible SC amend the draft Conclusion and background documents as appropriate (tollgate #3)[9].
Step 16	**16.0 Approval of the Conclusion**

[8] Tollgates correspond to quality checks performed during the Risk Assessment. No dates (planned or passed) are associated to Tollgates. Three Tollgates are applicable for this process: Tollgate 1, 2 and 3.

[9] Tollgates correspond to quality checks performed during the Risk Assessment. No dates (planned or passed) are associated to Tollgates. Three Tollgates are applicable for this process: Tollgate 1, 2 and 3.

SMU, HoU, RAL	**16.1** Upon approval of the Output, RAL informs LA. If the approved EFSA Output identifies foreseeable effects on human health, animal health or the environment related to information that has been grante confidential status, Procedure 4 of the SOP 020 Confidentiality assessment, implementation and publication of documents shall apply *mutatis mutandis*.https://dms.efsa.europa.eu/otcs/cs.exe?func=ll&objaction=overview&objid=8363465 **16.2** SC notifies RAL that the final Output is ready for approval. RAL triggers the approval of the Output in the Case Management Tool by sending the workflow to the relevant HoU (or his/her delegate). **16.3** Upon approval of the Output by the HoU or his/her delegate, RAL (within 15 working days from approval) sends the approved Output to the EFSA Journal Team and initiate the pre-notification step with the applicant. RAL updates the Case Management tool and merged timelines. **16.4** Upon specific needs of the peer review, the finalized draft Output is sent to EJ by the RAL for the plagiarism check (please refer to SOP 014 S Publishing a scientific Output in the EFSA Journal and Supporting Publications).
Macro-Phase 4	Output Publication & Dissemination
Step 17	**17.0 Post-approval of approved scientific Output**
SMU, RAL, LA, FDP	**17.1** RAL notifies the applicant, EC, ECHA and all MSs of the approved Output. RAL also shares the final DAR and the peer review report with the applicant who, considering any relevant confidentiality decisions, has two (2) weeks to submit confidentiality requests, informing EC/MS and EFSA (LA SMU and RAL FMBs by e-mail. Please refer to SOP 020 Confidentiality assessment, implementation and publication of documents as regards further activities related to confidentiality assessment, implementation and publication to be carried out at the post-approval stage.
Step 18	**18.0 Editorial checks and corrections**
SMU/HoU, RAL	**18.1** If after the sending of the pre-notification, but prior to publication, EFSA SMU or MS identify a need for a significant change to the text approved by the ASSESS HoU EFSA puts the publication of the approved Output on hold, requests the HoU to withdraw the approval via written procedure and resubmits the scientific Output for revision and/or discussion, and if appropriate, additional approval to the ASSESS HoU.
Step 19	**19.0 Publication of Other Scientific Outputs (OSO)**
EJ, RAL	**19.1** Once the output (OSO) is approved upon indication from SMU and/or LA, RAL proceeds with the publication of the OSO and background documents in accordance with Procedure 8 and 10 of SOP 020 Confidentiality assessment, implementation and

	publication of documents and in line with the procedure described in SOP_014_S Publishing a scientific Output in the EFSA Journal. **19.2** Before the publication of the Scientific Output on the EFSA Journal, RAL ensures that the link to the Scientific Output published in EFSA journal is also captured in the Case Management Tool and update the Overview table **19.3** RAL notifies EC, ECHA, MSs and applicant of the published Output and updates the Case Management Tool and MRL progress table.
Step 20	**20.0 Correction and/or republication of a published scientific Output**
EJ	**20.1** See SOP_015_S Correction of a published scientific Output **20.2** The republication of the Output may be needed considering the finalisation of relevant confidentiality decisions (please refer to SOP_020 Confidentiality assessment, implementation and publication of documents).

PROCESS 2 - APPLICATION FOR RENEWAL (RENEWAL DOSSIER)	
Macro-phase 1	Dossier Intake
Step 1	**1.0 Receipt of Application for renewal consisting of a renewal dossier and dissemination**
Applicant(s), FDP	**1.0** Applicants submit the application for renewal in IUCLID format through the central submission system indicating the designated RMS. The application consisting of a renewal dossier, is submitted in line with the relevant legislation, i.e. no later than three years before the expiry of the approval pursuant to Article 15(1) of Regulation (EC) No 1107/2009. Applicant(s) shall also indicate each pre-application ID associated to any pre-submission activities carried out in relation to the specific regulated product which is the subject of that application (see SOP_001_S Pre-submission and EFSA PAs on pre-submission and public consultations). **1.1** FDP forwards the automatic dossier notification to PREV FMB.
Step 2	**2.0 Withdrawal of application**
Applicant, FDP, SMU, RAL	**2.1** An applicant can withdraw its application at any time. The request for withdrawal should be submitted via email to EC, RMS and other Member States and EFSA. **2.2** For the withdrawal procedure FDP is responsible for macrophase 1, RAL and SMU for the subsequent macrophases/steps. **2.3** Once the withdrawal is received by EFSA, all activities (e.g. confidentiality assessment, Dossier intake, RA) linked to the Dossier at stake are closed in Case Management Tool , 00_merged_timelines

	and Overview table without delay, and this will be automatically reflected on the Open EFSA Portal. Information from the application for renewal made publicly available prior to the receipt of the withdrawal notice shall be confidential in Open EFSA portal and no more visible as per SOP 020 Confidentiality assessment, implementation and publication of documents [10]. **2.4** FDP/RAL stores for at least seven years one copy of the information, documents and correspondence in the **dms** for auditing reasons. The dossiers will be retained in EFSA Agency IUCLID while they will be hidden in the IUCLID Public instance and the relative links from Case Management Tool and Open EFSA will be removed.
Step 3	**3.0 Chartering**
SMU HoU, FDP, RAL	**3.1** An overarching process charter is in place for the assessment of Dossiers covered in this SOP. If an update is required, the SMU HoU (or his/her delegate), through the RAL planner, interacts with FDP to manage the requested changes. For further details on how the request for change is managed, please refer to the WIN SOP51 01 Portfolio-Management of change requests.
Step 4	**4.0 Dossier admissibility by RMS**
FDP, RMS	**4.1** FDP extracts and filters the list of studies from the database of study notifications and uploads them in **dms**. **4.2** FDP notifies the RMS via email providing the link to access the extractions in **dms**. RMS checks the matching of studies submitted in the dossier with the studies previously notified and verifies the compliance with notification of studies obligations see SOP 001 S Pre- Submission Activities. **4.3** RMS checks the matching of studies submitted in the dossier with the studies previously notified and verifies the compliance with notification of studies obligations, see SOP 001 S Pre- Submission Activities. **4.4** In case the conditions outlined in SOP 001 S Pre- Submission Activities are not met (without a valid justification) the application for renewal is declared not admissible. The RMS shall interrupt the admissibility check and inform the applicant. **4.5** At this step, the applicant may re-submit through central submission system and in IUCLID format the application for renewal by means of an updated renewal dossier including an MRL information, when relevant. The application may be re-submitted, provided that the applicant notifies the studies that were not previously notified; and/or the applicant submits all the studies which were previously notified or, even if withdrawn, the data delivered by the relevant laboratory or testing facility even without having the study completed. **4.6** In this case, the RMS informs the applicant that the assessment of such re-submitted renewal dossier will commence in accordance with the conditions laid down in Article 32b(4) and

[10] For applications submitted before 27 March 2021 the information will remain visible and should not be deleted

	(5) of the GFL Regulation. provided that the new renewal dossier is resubmitted no later than three years before the expiry of the approval of the active substance (otherwise the resubmitted application for renewal shall be considered inadmissible). **4.7** The RMS checks that the information submitted is complete by performing the steps described in the Admissibility Checklist available in Appendix C to the Pesticides Administrative Guidance. If the checks pass, the RMS declares the admissibility of the renewal dossier, including an MRL information when relevant, and notifies FDP and SMU functional mailboxes. Upon declaration of admissibility the RMS uploads in **dms** the validation assistant report and the confidentiality report. **4.8** Upon reception of the declaration of admissibility, FDP registers in Case Management Tool the admissibility and assigns the 'SPOC Collaborator'. FDP registers also chemical substances and/or microorganisms. **4.9** Also, FDP records the admissibility in the relevant table, renames the folder in **dms** and stores relevant correspondence documents. Applicant should be correctly displayed in Case Management Tool and in Open.EFSA (if missing, FDP should follow-up). Upon declaration of admissibility by the RMS, FDP performs a light check in line with Procedure 8, Step 1.2 of SOP 020 Confidentiality assessment, implementation and publication of documents). If the light check passes, FDP publishes the non-confidential version of the application dossier (please see the document Publication of PPP dossiers post-admissibility.docx), making available on the Open EFSA, via the Case Management Tool, the relevant link to Public IUCLID. FDP also publishes the (sanitised) extract from the NoS database.
Step 5	**5.0 Confidentiality decision making process (incl. dissemination of non-confidential dossier and summary (G)PSA/ (R)PSA)**
FDP, SMU, LA, RAL	**For renewals, EFSA is responsible for the confidentiality decision making process.** **5.1** Together with the application dossier for renewal of approval, including an MRL information when relevant, the applicant might submit confidentiality requests using the relevant IUCLID functionality. After the dossier has been published FDP informs LA (confidentialityrequestassessment@efsa.europa.eu) in accordance with SOP 020 Confidentiality assessment, implementation and publication of documents. Confidentiality requests are processed in accordance with the PAs concerning transparency and confidentiality and SOP 020 Confidentiality assessment, implementation and publication of documents. **5.2** LA shares the confidentiality decision with SMU/RAL. Once the two weeks to submit a confirmatory application have expired and the applicant correctly implemented the decision, upon notification from LA to RAL of the completion of the implementation of the decision, RAL communicates the reasoned decision on the confidentiality requests to EC/MSs and/or the EU Reference Laboratory involved in the risk assessment process, as appropriate. LA provides FDP with

	the UUID of the version of the dossier to which the confidentiality decision refers. **5.3** FDP publishes the non-confidential version of the dossier post-confidentiality assessment. **5.4** Once a confidentiality decision has been taken, FDP also proceeds with the publication of the list of NoS.
Step 6	**6.0 Public consultationon the non-confidential version of an admissible application** ***Extraction and publication of comments, dispatch to RMS for inclusion in RAR***
SMU, RAL, LA	**6.1** Following the confidentiality assessment and the dossier publication, FDP informs RAL that the non-confidential version of the dossier is published so RAL can trigger through Case Management Tool the creation of the PC in the Customer Portal.RAL triggers through the Case Management Tool the creation of the PC in the Customer Portal, according to WIN SOP00/71 processing of public consultations. RAL also records the starting and ending dates of PC in the 00 merged timelines. Upon closure of the PC, comments become public on the OPEN EFSA portal automatically, while RAL extracts them from the Customer Portal in excel format with the relevant attachments and dispatches everything to the RMS via **dms** for consideration in the preparation of the RAR. In duly justified cases, where there is a risk that the results of the public consultation performed in accordance with Art 32c(2) of Regulation 178/2002 cannot be given proper consideration because of the applicable time limits within which the Authority is required to deliver its scientific Output, those time limits may be extended for a maximum period of seven weeks.
Step 7	**7.0 Receipt of draft RAR** ***Completeness Check of draft RAR and submission of updated draft RAR, if needed*** ***Dissemination to MSs and applicant (for sanit.)*** ***Confidentiality decision-making process***
RMS, FDP, Applicant, SMU, RAL	**7.1** If during consideration of the comments from the PC on the dossier, the RMS identifies the need for additional information, the applicant will be requested to update the dossier. **7.2** The RMS uploads in **dms** the draft RAR (including results of PCs as an annex to the draft RAR) together with the completeness check list (see Appendix A of Administrative Guidance on pesticides applications) at the latest 13-months after submission of the application for renewal and notifies FDP via email.

	7.3 FDP stores correspondence in **dms** and informs RAL and SMU (if needed). **7.4** Upon receiving the draft RAR, FDP updates Case Management Tool and the relevant tables with the date of receipt of the draft RAR and performs the completeness check. **7.5** If the draft RAR is not considered complete, FDP requests an updated version from the RMS. In this case the Case Management Tool will need to be updated accordingly. Once it is considered complete, FDP informs the RMS and RAL about the completeness of the draft RAR. **7.6** FDP makes available via **dms** the draft renewal assessment report to the applicant(s), MSs and EC at the latest three months after its receipt. FDP asks the applicant to submit confidentiality requests on the RAR, following SOP 020 Confidentiality assessment, implementation and publication of document **7.7** FDP informs the applicant that the updated dossier, reflecting the additional information that the RMS may have asked during the risk assessment, should be submitted in IUCLID format through the EFSA Application Submission Portal. **7.8** Upon receipt of confidentiality requests on the complete initial RAR, LA carries out a confidentiality assessment in line with SOP 020 Confidentiality assessment, implementation and publication of documents. Upon indication from LA to RAL, RAL publishes the complete initial RAR on the OpenEFSA Portal upon opening of the PC and TC on the initial RAR. **7.9** Upon conclusion of the confidentiality decision-making and any follow-up activities related thereto, in accordance with SOP 020 Confidentiality assessment, implementation and publication of documents RAL makes available the final non-confidential version of the initial RAR on the OpenEFSA Portal without delay on the launch day of the public and targeted consultation on the initial RAR, upon indication from LA to RAL, should a confirmatory application be submitted by the Applicant in line with Article 39b(2) of Regulation (EC) 178/2002 or should an interim relief measure being granted by the General Court, the implementation shall be suspended. **7.10** SMU agrees with FDP and RAL the planned date of consultation. If the RAR is of poor quality, EFSA may request the RMS to withdraw the RAR and resubmit it. In this case, the Case Management Tool will need to be updated accordingly. **7.11** FDP/RAL see step 2 point 2.5 for keeping documents**.**
Step 8	**8.0** **Commenting period and dissemination** ***Consultation of the public, targeted stakeholders and EFSA on the draft RAR*** ***Comments collected and sent to RMS for the Reporting table preparation.***

FDP, RAL, LA	**8.1**	FDP publishes the updated dossier a few days before the planned PC and provides RAL the relevant dossier information.
	8.2	RAL triggers through the Case Management Tool the creation of the public and targeted consultations on the RAR in the Customer Portal. (please refer to WIN_SOP00_071 Processing of Public Consultations).
	8.3	On the opening day of the public and targeted consultation, RAL informs the applicant and SMU on the launching of the consultation on the RAR requesting to provide their comments, while MSs, EC, EURL, ECHA are notified automatically via the tool.
	8.4	RAL updates the Case Management tool by validating the RAR. Upon closure of the Public and Targeted Consultations, comments received through the public consultation become public on the OPEN EFSA portal automatically, while RAL ensures the dissemination of **all comments** extracted from the Customer Portal (e.g. from public, applicant, MS, EC, EURL, ECHA and EFSA) to the RMS for the compilation of the Reporting Table with SMU in cc. EFSA internal comments and the applicant ones are collected outside the Customer Portal.
Macro-phase 2	Preliminary activities risk assessment	
Step 9	**9.0**	**Workforce Mix Definition**
SMU, FDP, RAL	**9.1**	The Workforce Mix planning by the competent SMU may start at any time after Step 8.4 above.
	9.2	The TEAM leader defines the high-level Workforce Mix Planning.
	9.3	When assigning the Dossier to SOs, the TL ensures the separation of tasks as requested by law checking that staff members involved in general or renewal pre-submission advice activities will not be involved in other activities during the RA.
	9.4	RAL defines in the Case Management Tool the **scientific Output type(s)**.
Step 10	**10.0**	**Definition of outsourced tasks**
SMU, RAL	**10.1**	Please refer to SOP 010 S Procurements and grants, Planning, Launch, Evaluation, Award and Implementation.
Step 11	**11.0**	**Quality Standards (scientific check and follow-up to study audits)**
SMU, FDP, RAL	**11.1**	For scientific check studies, please refer to SOP_022_S Selection of studies performed in compliance. Depending on the applications' life-cycle stage and the type of non-compliance identified, FDP will contact the officer in FDP in charge of the completeness check of the DAR/RAR and/or the respective SMU/RMS for ensuring the appropriate follow-up.
	11.2	The obligation for the Applicant to notify studies in the NoS database also applies to studies commissioned/carried out after the admissibility/validity of the application and therefore during the RA

		for which Step 4 does not apply (before admissibility), during the RA the Applicant does not have the obligations to submit the study notifications/justification in the application as, at this stage, the procedural consequences foreseen in Article 32b(4) and (5) of the General Food Law cannot be applied. Hence, during the RA the SMU does not have to assess the compliance with the obligations of study notifications. Notwithstanding the above, in accordance with Article 25 of the Practical arrangement on pre-submission phase and public consultations and Article 32b(6) of the Regulation 178/2002 , if during the risk assessment, following a more extensive verification of the data submitted by the applicant, the SMU detects that the studies previously notified (before the admissibility/validity of the application) are not included in the submitted application in full, the SMU, supported by RAL, shall request the applicant to provide justifications regarding any missing data (under the normal stop-the-clock provision). The applicant shall also be informed that the time-limits within which EFSA is required to deliver its scientific Output shall be suspended, pending the provision of valid justifications by the applicant. The SMU shall assess the justifications provided by the applicant, which will be declared valid by the SMU HoU if considered as such. The risk assessment process shall resume, and the applicant be informed accordingly. If during the assessment, the SMU considered the justifications not valid, the applicant shall be requested to submit the missing data. The applicant shall also be informed that the risk assessment process will remain suspended until six (6) months after the submission of any missing data relating to any supporting studies. For more information, please consult the EFSA's Practical Arrangements concerning pre-submission and public consultations and the SOP_001_S Pre-submission activities.
Step 12	**12.0**	**Meetings**
SMU, RAL	**12.1**	Meetings can occur any time during the RA process. They should be organised according to SOP_021_A Logistic services and are managed as described in SOP_05_Managing Scientific Meetings and WIN_SOP05_05 Peer Review Mtg organisation.
	12.2	Meetings other than Pesticide Peer review meetings might also be organised during the risk assessment process: e.g. internal meetings (e.g. preparatory meetings), meetings with applicants according to the EFSA Catalogue of Services (e.g. clarifications teleconference, applicants hearing). **Information related to these meetings is not subject to dissemination/publication.**
Macro-phase 3	Peer Review	

Step 13	**13.0 Reporting Table preparation**
SMU	**13.1** Upon receiving the compiled RT sent from the RMS to SMU and RAL in cc SMU responsible SO(s) reply to the comments.
Step 14	**14.0 First draft of the Conclusion**
SMU, RAL, Experts	**14.1** Upon receipt of the RT, SMU organises the kick-off teleconference with RMS (tollgate #1)[11], which aims at identifying open points (to be addressed by RMS), data requirements (to be addressed by the applicant as additional information) and expert's consultation points (to be addressed during the peer review meeting. **14.2** The SC informs RAL of an ADR. RAL ensures that all the sections of an ADR are uploaded in Case Management Tool and updates the 00 merged timelines. RAL prepares the clock stop letter and submits to the SMU HoU for approval. Once approved, the ADR letter is sent by RAL to the applicant and RMS and uploaded in the **dms**. **14.3** RAL registers the ADR and a "Clock Stop" event in the Case Management Tool and updates the 00 merged timelines accordingly. Relevant non-confidential ADR/clock-stop details (e.g. ADR/clock-stop date, ADR sections, expected date of ADR reply) are automatically made visible on the OpenEFSA Portal to comply with the 2019 Ombudsman recommendation[12]. **14.4** In case there is an Article 10 application included in the Peer-review process, if the data required for the Art 10 application during the clock-stop are not addressed, the Art 10 application would be separated from the peer review process and would go alone through the MRL process (see below MRL process). **14.5** Upon receiving the ADR, the Applicant might request a clarification teleconference as described in EFSA Catalogue of Services, the RMS is invited as well. **14.6** The applicant(s) make(s) the requested additional information available to EFSA, RMS, all MSs and the EC, within a period of 1 month, via IUCLID by means of an updated dossier. Confidentiality requests presented by the applicant on the additional information concerning RAR are to be assessed by LA in accordance with SOP 020 Confidentiality assessment, implementation and publication of documents. **14.7** RAL updates the Case Management Tool by adding the reception date only and uploads the cover letter in the **dms**. **14.8** After evaluation of the additional information submitted by the applicant(s), the RMS should submit a revised RAR and Evaluation Table (ET) within a period of 60 days by uploading in **dms.**

[11] Tollgates correspond to quality checks performed during the Risk Assessment. No dates (planned or passed) are associated to Tollgates. Three Tollgates are applicable for this process: Tollgate 1, 2 and 3.

[12] Please refer to case 176/2015/JF

	14.9 Upon receipt of the revised RAR, RAL restarts the clock in the Case Management tool and updates the 00_merged_timeline accordingly. **14.10** The responsible SC, supported by RAL, launches a written procedure with MS's on the RMS's assessment of the additional information. If during step 15 it was decided to organise an expert consultation, responsible SC/RAL prepare the agenda and makes it publicly available in the Open EFSA Portal. For more details on meeting organization, please see Step 12. **14.11** Once the meeting documents including the pre-filled meeting report(s) are available in the relevant meeting folders in **dms**, the RAL sends a reminder to MS Experts, asking them to provide preliminary comments. **14.12** Following the Expert Meeting, SMU SOs, supported by the RAL, draft the meeting minutes. A high-level version of the report(s) shall be published via EFSA website within 15 working days of the last day of the meeting and stored by the RAL in the **dms**. The full version of the minutes shall be stored in **dms**. The RMS should complete the open points identified in the meeting, if any, i.e. so called 'homework' and provide within 2 weeks the revised assessment reports and evaluation tables accordingly. **14.13** If no Expert Meeting is needed, following the RMS evaluation of the additional information submitted by the applicant(s) and completion of the written procedure on the RMS assessment of the additional information, SMU will proceed to draft the EFSA Conclusion. **14.14** Responsible and participant SOs draft the EFSA Conclusion and successively proceed with internal scientific review.
Step 15	**15.0 Finalization of the Conclusion**
SMU, RAL	**15.1** Once the draft Output passes the internal scientific review, SMU sends the draft for a written consultation first with the RMS (tollgate #2)[13] and subsequently, in a second step, with the other MSs. In case of disagreements with the RMS, an ad hoc expert teleconference may also be organized by SMU/RAL before launching the written consultation with the other MSs. **15.2** In addition, in case of renewals substances which have an expiry date on or after 27 March 2024, applicants are also granted a short timeframe of 2 weeks to submit comments / additional information at the end of this process on the draft Conclusion in relation to critical issues identified late in the process (in accordance with Art 13 of Reg (EU) 2020/1740). In this case, the information is further considered by SMU with the RMS and/or co-RMS and/or experts via ad hoc teleconference – as appropriate. Then, a second round of RMS/MSs' consultation before finalizing the Conclusion is also foreseen.

[13] Tollgates correspond to quality checks performed during the Risk Assessment. No dates (planned or passed) are associated to Tollgates. Three Tollgates are applicable for this process: Tollgate 1, 2 and 3.

	15.3 Upon receiving MSs' comments, responsible SO(s) and responsible SC amend the draft Conclusion and background documents as appropriate (tollgate #3)[14].
Step 16	**16.0 Approval of the Conclusion**
SMU, HoU, RAL	**16.1** Upon approval of the Output, RAL informs LA. If the approved EFSA Output identifies foreseeable effects on human health, animal health or the environment (Article 39c review of Regulation (EC) 178/2002) related to information that has been granted confidential status, SOP 020 Confidentiality assessment, implementation and publication of documents shall apply *mutatis mutandis*. If there are confidentiality requests on the additional information submitted with regard to the initial dossier, LA starts the confidentiality assessment in accordance with SOP 020 Confidentiality assessment, implementation and publication of documents applicable *mutatis mutandis* thereby taking account of all relevant confidentiality decisions, including the Article 39c review decision, if any. **16.2** SC notifies RAL that the final Output is ready for approval. RAL triggers the approval of the Output in the Case Management Tool by sending the workflow to the relevant HoU (or his/her delegates). Upon approval of the Output by the HoU or his/her delegate, RAL (within 15 working days from approval). Upon specific needs of the peer review, the finalized draft Output is sent to EJ for the plagiarism check if needed and copyediting (please refer to SOP 014 S Publishing a scientific Output in the EFSA Journal).
Macro-Phase 4	Output Publication & Dissemination
Step 17	**17.0 Post-approval of approved scientific Output**
SMU, RAL, LA, FDP	**17.1** RAL notifies the applicant, EC, ECHA and all MSs of the approved Output. RAL also shares the final RAR and the peer review report with the applicant. Considering any relevant confidentiality decisions the applicant has two weeks to submit confidentiality requests, informing EC/MS and EFSA (FDP, LA and SMU FMBs) by e-mail. Please refer to SOP 020 Confidentiality assessment, implementation and publication of documents as regards further activities related to confidentiality assessment, implementation and publication to be carried out at the post-approval stage.
Step 18	**18.0 Editorial checks and corrections**
SMU,HoU, RAL	**18.1** If after the sending of the pre-notification, but prior to publication, EFSA or MS identify a need for a significant change to the text approved by the ASSESS HoU, EFSA SMU / RAL put the publication of the approved Output on hold, requests the ASSESS HoU to withdraw the approval via written procedure and resubmits the

[14] Tollgates correspond to quality checks performed during the Risk Assessment. No dates (planned or passed) are associated to Tollgates. Three Tollgates are applicable for this process: Tollgate 1, 2 and 3.

	scientific Output for revision and/or discussion, and if appropriate, additional approval to the ASSESS HoU.
Step 19	**19.0 Publication of Other Scientific Outputs (OSO)**
EJ, RAL	**19.1** Once the output (OSO) is approved upon indication from SMU and/or LA,https://dms.efsa.europa.eu/otcs/cs.exe?func=ll&objaction=overview&objid=8363465 RAL proceeds with the publication of the OSO and background documents in accordance with SOP 020 Confidentiality assessment, implementation and publication of documents and in line with the procedure described in SOP_014_S Publishing a scientific Output in the EFSA Journal. RAL ensures that the link to the Scientific Output published in EFSA journal is also captured in the Case Management Tool. **19.2** RAL notifies EC, ECHA, MSs and applicant of the published Output and updates the Case Management Tool and MRL progress table.
Step 20	**20.0 Correction and/or republication of a published scientific Output**
EJ	**20.1** See SOP_015_S Correction of a published scientific Output. The republication of the Output may be needed considering the finalisation of relevant confidentiality decisions (please refer to SOP 020 Confidentiality assessment, implementation and publication of documents)

PROCESS 3 - ASSESSMENT OF MAXIMUM RESIDUES LEVELS (MRLS) ART. 10 APPLICATIONS AND ART. 12 CONFIRMATORY DATA FOLLOWING MRLS REVIEW	
Macro-Phase 1	Mandate[15] Intake
Step 1	**1.0 Receipt of Application Dossier and sharing with Authorities**
Applicant, FDP	**1.1** The applicant submits the application dossier in IUCLID format through the central submission system (including NoS ID, when relevant) indicating the EMS who will perform the assessment of the application. Applicant shall also indicate each pre-application ID associated to any pre-submission activities carried out in relation to the specific regulated product which is the subject of that application (see SOP 001 S Pre-submission and EFSA PAs on pre-submission

[15] Overarching mandate in place for routine applications such as Article 10 and Article 12 confirmatory data MRL applications.

	and public consultations). The application dossier is automatically made available to the European Commission, the Member States (including the one receiving the application), and to EFSA, through EFSA Agency IUCLID. **1.2** FDP forwards the automatic dossier notification (successful notifications) to PREV MRL FMB.
Step 2	**2.0 Withdrawal of application**
Applicant, FDP, RAL and SMU	**2.1** An applicant can withdraw its application at any time. The request for withdrawal should be submitted via email to EC, EMS, Member States and EFSA. **2.2** For withdrawal procedure FDP is responsible for macrophase 1, RAL and SMU for the subsequent macrophases/steps. **2.3** Once the withdrawal is received by EFSA, all activities (e.g. confidentiality assessment, Dossier intake, RA) linked to the Dossier at stake are closed in Case Management Tool and the 00_merged_timelines and Overview table without delay, and this will be automatically reflected on the Open EFSA Portal. **2.4** Information from the application made publicly available prior to the receipt of the withdrawal notice shall be set as confidential on Open EFSA portal and not visible anymore, as per SOP_020_Confidentiality assessment, implementation and publication of documents[16]. **2.5** FDP/RAL stores for at least seven years one copy of the information, documents and correspondence in **dms** for auditing reasons. The dossiers will be retained in the EFSA Agency IUCLID while they will be hidden from Public IUCLID and the relative links from Case Management Tool and Open EFSA will be removed. The MRL progress table is updated accordingly by FDP (macro-phase 1) or RAL (macro-phase 2 onwards).
Step 3	**3.0 Chartering**
SMU HoU, FDP, RAL	**3.1** An overarching process charter is in place for the assessment of Dossiers covered in this SOP. If an update is required, the SMU HoU (or his/her delegate), through the RAL planner, interacts with FDP to manage the requested changes. For further details on how the request for change is managed, please refer to the WIN_SOP51_01 Portfolio-Management of change requests.
Step 4	**4.0 Dossier admissibility by EMS**
FDP, EMS	**4.1** FDP extracts and filters the list of studies from the database of study notifications and upload them in **dms**. FDP notifies the EMS via email providing the link to access the extractions, with SMU in copy. EMS checks the matching of studies submitted in the application dossier

[16] For applications submitted before 27 March 2021 the information will remain visible and should not be deleted.

	with the studies previously notified and verifies the admissibility with notification of studies obligations, see SOP 001 Pre- Submission Activities. In case one of the conditions outlined in SOP_ 001_S_Pre-Submission Activities is not met (without a valid justification) the application dossier is declared not admissible. The EMS shall interrupt the admissibility check and inform the applicant. At this step, the applicant may re-submit through the central submission system and in IUCLID format the application dossier by means of an updated dossier. The application may be resubmitted, provided that the applicant notifies in the database the studies that were not previously notified; and/or the applicant submits all the studies which were previously notified in the database or, in case of unjustified withdrawal of a notification of a study, the data delivered by the relevant laboratory or testing facility even without having the study completed. In this case, the EMS informs the applicant that the assessment of such new submitted application will commence in accordance with the conditions laid down in Article 32b(4) and (5) of the GFL Regulation. **4.2** The EMS checks that the information submitted is complete, and after having performed a light check in line with Procedure 8, Step 1.1 of SOP 020 Confidentiality assessment, implementation and publication of documents, declares the admissibility of the application and notifies FDP and SMU FMB (providing the justifications that have been considered valid); and MSs and EC in a separate message. Upon declaration of admissibility EMS uploads in **dms** the validation assistant report and NoS report. **4.3** Upon receipt of the declaration of admissibility, FDP registers the admissibility in Case Management Tool and assign the 'SPOC collaborator'. FDP stores relevant correspondence documents in **dms**, Applicant should be correctly displayed in Case Management Tool and in Open.EFSA (if missing, FDP should follow-up). FDP adds when needed substances subject of the application in the Case Management Tool. The information on the substances subject of the application is published in the Open.EFSA portal and may be further updated during the assessment. **4.4** **Upon declaration of admissibility by the EMS,** and if the light check (performed in line with Procedure SOP 020 Confidentiality assessment, implementation and publication of documents) passes, FDP publishes the non-confidential version of the application dossier (please see the document Publication of PPP dossiers post-admissibility.docx), making available on the Open EFSA, via the Case Management Tool**,** the relevant link to Public IUCLID**.** FDP also publishes the (sanitised) extract from the NoS database.
Step 5	**5.0 Confidentiality decision making process incl. dissemination of non-confidential dossier and summary (G)PSA**
FDP, SMU, LA	**For MRL ART. 10 and Art. 12 confirmatory data, EFSA is responsible for the confidentiality decision making process.**

	5.1 After the dossier has been published FDP informs LA (confidentialityrequestassessment@efsa.europa.eu) in accordance with Procedure 8, Step 2.1 of SOP 020 Confidentiality assessment, implementation and publication of documents. Confidentiality requests are processed in accordance with the IMPRUL_109 PAs concerning transparency and confidentiality and SOP 020 Confidentiality assessment, implementation and publication of documents. **5.2** LA shares the confidentiality decision with SMU/RAL. Once the two-week deadline to submit a confirmatory application has expired and the applicant correctly implemented the decision, LA informs RAL about the completion of the implementation of the decision. LA provides FDP with the UUID of the final public version of the initial dossier. **5.3** FDP publishes the list of NoS once a confidentiality decision is adopted. **5.4** RAL communicates the reasoned decision on the confidentiality request to the Commission and the Member States' competent authorities and/or the EU Reference Laboratory involved in the risk assessment process, as appropriate. See SOP 020 Processing of confidentiality claims submitted by applicants
Step 6	**6.0 Public consultation on the non-confidential version of a validated application after confidentiality decision making** ***Extraction and publication of comments, dispatch to EMS for inclusion in ER***
RAL	**6.1** Following the confidentiality assessment and the application dossier publication, RAL triggers through the Case Management Tool and launches through the Customer Portal, a Public Consultation, according to WIN SOP00/71 processing of public consultations. **6.2** RAL also records the starting and ending dates of PC in the relevant MRL progress table. **6.3** Upon closure of the PC, comments become public on the Open EFSA Portal automatically, while RAL extracts them from the Customer Portal in Excel format with the relevant attachments and dispatches everything to the EMS for consideration in the preparation of the ER.
Step 7	**7.0 Receipt of Evaluation Report and EC Mandate and dissemination**
FDP, EC, EMS, RAL	**7.1** If during consideration of the comments from the PC, the EMS identifies the need for additional information, the applicant might be requested to update the dossier. **7.2** The EMS submits to FDP the ER by uploading it in **dms** (including results of PCs as an annex to the ER). **7.3** FDP performs a light check on the submitted ER and updates Case Management Tool and the relevant tables. In duly justified cases,

	where there is a risk that the results of the public consultation performed in accordance with the above paragraph cannot be given proper consideration, the applicable time limits within which the Authority is required to deliver its scientific Output may be extended for a maximum period of seven weeks, in order for SMU to proper consider the results of the PC during the assessment. **7.4** The **EC**, based on a **monthly collection** of available **ERs**, sends a **Mandate** asking EFSA to assess maximum residue levels requests and confirmatory data following MRL review. **7.5** For PREV/MRL applications, the legal deadline is 6-months for Art.12 confirmatory data applications and 3 months for Art.10 applications. For Art.10, only in exceptional cases where more detailed evaluations need to be carried out, the deadline may be extended to 6-months. Legal deadlines are calculated from the mandate receipt date. **7.6** Upon receipt of the mandate, FDP updates Case Management Tool and relevant tables, and notifies SMU and RAL, stores relevant documentation in **dms** and publishes the sanitised mandate on the Open EFSA Portal via Evidence log. **7.7** Following the scientific screening (step 13 below) performed by SMU, FDP validates the question in Case Management Tool and FDP HoU formally communicates the Acceptance of EC Request to EC, applicant, EMS, RAL and SMU. **7.8** RAL (in cc of acceptance of the mandate) proceeds validating the Preliminary Activities by adding the standard note in Case Management Tool. **7.9** FDP also stores relevant documents in **dms**, fills in all the relevant fields in Case Management Tool and publishes the sanitised version of the acceptance letter on the Open EFSA Portal via Evidence log.
Macro-Phase 2	Preliminary Activities Risk Assessment
Step 8	**8.0 Workforce Mix Definition**
SMU, FDP, RAL	**8.1** The Workforce Mix planning defined by the competent SMU, may start at any time after Step 12.0. **8.2** Upon receipt of the mandate, SMU Scientific Coordinator informs all Art. 10 SOs and TL. The question planner of the competent SMU (SC) and TL define the high-level Workforce Mix Planning by identifying and allocating tasks to responsible and participating Scientific Officers (SOs), Art.36 Organizations, other Tenderer(s)/Grant beneficiaries. **8.3** RAL define(s) in the Case Management Tool the scientific Output type(s) for all the documents that will be generated and published linked to a given Dossier. **8.4** When assigning the question to SOs, the SMU question planner checks in the Customer Portal for any involvement of SOs in general pre-

	submission advice as that would prevent them from involvement in other activities of the corresponding dossier. **8.5** The TL, on behalf of the HoU, decides whether the RA can be fully or partially outsourced to Art.36 Organization or other tenderers/ Grant beneficiaries (e.g. contractors, individual experts). Assignments can be modified/updated in Case Management Tool whenever needed.
Step 9	**9.0 Outsourced tasks**
SMU	**9.1** Please refer to SOP 010 S Procurements and grants, Planning, Launch, Evaluation, Award and Implementation.
Step 10	**10.0 Quality Standards (scientific check and follow-up to study audits)**
SMU, FDP	**10.1** Depending on the applications' life-cycle stage and the type of non-compliance identified, FDP will contact the Scientific Officer within FDP who is in charge of the light check of the ER and/or the respective SMU/ EMS for ensuring the appropriate follow-up. For further details, please refer to SOP 022 S Selection of studies performed in compliance with Good Laboratory Practice for audit purposes. **10.2** The obligation for the Applicant to notify studies in the NoS database also applies to studies commissioned/carried out after the admissibility/validity of the application and therefore during the RA for which Step 4 does not apply (before admissibility), during the RA the Applicant does not have the obligations to submit the study notifications/justification in the application as, at this stage, the procedural consequences foreseen in Article 32b(4) and (5) of the General Food Law cannot be applied. Hence, during the RA the SMU does not have to assess the compliance with the obligations of study notifications. Notwithstanding the above, in accordance with Article 25 of the Practical arrangement on pre-submission phase and public consultations and Article 32b(6) of the Regulation 178/2002, if during the risk assessment, following a more extensive verification of the data submitted by the applicant, the SMU detects that the studies previously notified (before the admissibility/validity of the application) are not included in the submitted application in full, the SMU, supported by FDP, shall request the applicant to provide justifications regarding any missing data (under the normal stop-the-clock provision). The applicant shall also be informed that the time-limits within which EFSA is required to deliver its scientific Output shall be suspended, pending the provision of valid justifications by the applicant. The SMU shall assess any justifications provided by the applicant, which will be declared valid by the SMU HoU if considered as such. The risk assessment process shall resume, and the applicant be

	informed accordingly. If during the assessment, the SMU considered the justifications not valid, the applicant shall be requested to submit the missing data. The applicant shall also be informed that the risk assessment process will remain suspended until six (6) months after the submission of any missing data relating to any supporting studies. For more information, please consult the EFSA's Practical Arrangements concerning pre-submission and public consultations and the SOP_001_S Pre-submission activities.
Step 11	**11.0 Meetings**
SMU, RAL	**11.1** Meetings can occur any time during the RA process. They should be organised according to SOP 05 Managing Scientific Meetings and WIN SOP05 05 Peer Review Mtg organisation. **11.2** Meetings other than Pesticide Peer review meetings might also be organised during the risk assessment process: e.g. internal meetings (e.g. preparatory meetings), meetings with applicants according to the EFSA Catalogue of Services (e.g. clarifications teleconference, applicants hearing). **Information related to these meetings is not subject to dissemination/publication.**
Macro-Phase 3	Assessment of MRLs
Step 12	**12.0 Screening of EC request**
SMU, EMS	**12.1** Upon receipt of the mandate, SMU Scientific Coordinator prepares regulatory background information and identifies the legal framework of the application. Responsible SOs then proceed with a scientific screening of the application. **12.2** If minor clarifications are needed, SOs directly liaise with the EMS. Upon clarification, if this requires an update of the ER, SOs update the progress table with the date of the request and the date of the reply by EMS.
Step 13	**13.0 Outcome of the screening and validation of EC request**
SMU	**13.1** Responsible SO, TL, other SOs and SC discuss in a team meeting the outcome of the screening (tollgate #1)[17]. **13.2** Based on the preliminary assessment and proposals of the responsible SO(s), the Art. 10 Team reaches an agreement on how to proceed with the application.

[17] Tollgates correspond to quality checks performed during the Risk Assessment. No dates (planned or passed) are associated to Tollgates. Three Tollgates are applicable for this process: Tollgate 1, 2 and 3.

	13.3 SMU SC performs the scientific acceptance of the EC request liaising with FDP[18].
Step 14	**14.0 MSC and/or Expert Meeting (optional)**
SMU, RAL MS Experts	**14.1** Responsible SO(s), SC and TL decide whether MS consultation (MSC) or Expert Meeting is needed to discuss outstanding issues. If MSC is needed SC proceeds as per internal procedures. If an Expert Meeting is needed, RAL records all the steps in Case Management Tool. For more details on meeting organisation, please refer to SOP_05_Managing Scientific Meetings. **14.2** RAL sends a reminder to MS Experts, asking them to provide preliminary comments. In case of MSC, the SMU is taking care of the reminder to MSs for comments. **14.3** The dissemination of meeting information (i.e. WG and Panel) should follow the PAs concerning transparency and Confidentiality WIN_SOP05_05 Peer Review Mtg organisation. **14.4** For each Pesticide Peer Review meeting, SO will systematically store the version of the draft Output before and after each meeting in the **dms**. **14.5** If the MS Consultation is on the draft RO this step could happen after step 17.
Step 15	**15.0 Sending Additional Data Request (ADR)**
RAL, SMU, SO, EMS	**15.1** If an ADR is needed, responsible SO drafts the requests, RAL prepares the clock-stop letter and submits it to the SMU HoU for approval. Once approved, the ADR letter is sent by RAL to the applicant and EMS and uploaded in **dms**. **15.2** RAL also registers the ADR and a "Clock Stop" event in the Case Management Tool and the MRL progress table. Relevant non-confidential ADR/clock-stop details (e.g. ADR/clock-stop date, ADR sections, expected date of ADR reply) are automatically made visible on the OpenEFSA Portal to comply with the 2019 Ombudsman recommendation[19]. **15.3** In case SMU detects that studies previously notified have not been submitted in full in accordance with Article 32b(6) of the Regulation 178/2002 and Article 25 of the Practical Arrangements on pre-submission phase and public consultations, SMU, supported by RAL, as needed, shall request the applicant to provide justifications regarding any missing data (risk assessment is put-on-hold). See point 10.2.

[18] In case of mandates with applications based only on Art.12 confirmatory data, for which a 6- months DL applies by default in accordance with SANTE/10235/2016, it is agreed that the mandate acceptance could take place even before the screening meeting.
[19] Please refer to case 176/2015/JF

	15.4 If the applicant retains that the request for additional information is unclear and considers the need of further explanations, a clarifications teleconference may be organised by SMU as described in the EFSA Catalogue of Services. The EMS is invited. The applicant re-submits through the EFSA Application Submission Portal and in IUCLID format the application dossier by means of an updated dossier. **Confidentiality decision making process on the additional information provided, is performed only after the Output approval, according to** SOP 020 Processing of confidentiality claims submitted by applicants**.** **15.5** The EMS provides an updated ER, uploads it in **dms** and notifies the SMU, FDP and RAL. **15.6** Responsible SO(s) check the completeness of the updated report. **15.7** The SO, in case the clock-stop is maintained, updates the clock-stop table with the responses to EMS/applicant and notifies SC/MRL inbox. **15.8** The SO, in case the clock is restarted[20], notifies SC/MRL inbox. **15.9** The Scientific Coordinator updates the progress table and the Case Management Tool indicating either that: (i) the clock cannot be restarted because the additional information request has not been fully addressed or (ii) the clock can be restarted because the additional information request has been fully addressed[21]
Step 16	**16.0 First Draft of the Reasoned Opinion (RO)**
SMU	**16.1** The SC prepares prefilled template for drafting the RO. **16.2** responsible SO(s) starts drafting the Reasoned Opinion. At the same time, any outsourced section(s) are drafted by the Article 36 Organization. **16.3** SO(s) liaises with EMS if additional clarifications are needed.
Step 17	**17.0 Scientific review**
SMU, RAL	**17.1** When the draft RO is generated, the responsible SOs initiate the scientific review with the allocated scientific reviewer within the team (tollgate #2))[22]. **17.2** If the scientific review is not satisfactory, responsible SOs then amend/ask participating SOs, experts and/or contractors to amend the relevant draft RO section(s) (the need for a MSC and/or Experts meeting might be considered).

[20] In case of clock stops for art.12 confirmatory data, the guidelines provisions are that after 2 months clock is anyhow restarted, even if data are not submitted. After 2 months, Scientific Coordinator checks with EMS availability of data, if data cannot be submitted soon the clock is restarted, and SO is informed to restart the assessment highlighting the deficiencies in the RO accordingly.
[21] In some cases, the EMS/applicant request that EFSA resumes the assessment, despite the data gaps. SANTE will be informed by SC that a RO based on incomplete data will be prepared which will be reflected in the RO.
22 Tollgates correspond to quality checks performed during the Risk Assessment. No dates (planned or passed) are associated to Tollgates. Three Tollgates are applicable for this process: Tollgate 1, 2 and 3.

Step 18	**18.0 Finalization of the Reasoned Opinion**
SMU	**18.1** Following **the scientific review** completion, responsible SO(s) and SC proceeds with the proof reading and finalization of the draft, in preparation for the approval of the RO (tollgate #3)[15]. **18.2** If any of the criteria is not met, responsible SC then amend/ask participating SOs, experts and/or contractors to amend the relevant draft RO and subsequently repeat the proofreading step.
Step 19	**19.0 Approval of the Reasoned Opinion[23]**
RAL, SMU, HoU	**19.1** SC notifies RAL that the final Output is ready for approval. RAL triggers the approval of the Output in the Case Management Tool by sending the workflow to the relevant HoU (or his/her delegate). **19.2** Upon approval of the Output, RAL updates the MRL progress table and informs LA. If the approved EFSA Output identifies foreseeable effects on human health, animal health or the environment (Article 39c review of Regulation (EC) 178/2002) related to information that has been granted confidential status, SOP 020 Confidentiality assessment, implementation and publication of documents shall apply *mutatis mutandis*. If there are confidentiality requests on the additional information submitted with regard to the initial dossier, LA starts the confidentiality assessment in accordance with SOP 020 Confidentiality assessment, implementation and publication of documents applicable *mutatis mutandis* thereby taking account of all relevant confidentiality decisions, if any. **19.3** Upon approval of the Output by the HoU or his/her delegate, RAL, within 15 working days from approval, sends the approved Output to the EFSA Journal and updates the Case Management tool and merged timelines, as described in SOP 014 Publishing a Scientific Output in the EFSA Journal and Supporting Publications.
Step 20	**21.1 Approval of supporting publications & supporting Evidence**
SMU, RAL	**20.1** Please refer to SOP 009 Approving Supporting Publications. **20.2** Additional documents generated during the risk assessment and defined as 'supporting evidence' (e.g. models, R code, raw data collected by EFSA, SAS export) may need approval. The supporting evidence are subject to confidentiality decision and so, where appropriate, subject to sanitisation.
Macro-Phase 4	Output Publication & Dissemination

[23] For an OSO, the SMU defines who will be involved in the review (if relevant), the endorsement (if relevant) and all the necessary approval steps. The approval of the final Output will be done by the HOU, who could decide to escalate it to the ED in case of sensitive topics. The timelines for each step should be specified in the charter (if applicable) or the planning.

Step 21	**14.0 Post-approval of approved (other) scientific Output**
RAL, SMU, FDP	**21.1** RAL notifies the applicant, EC and all MSs about the approved Output. **21.2** When notifying the applicant of the approved Output, RAL also shares the final ER, and any other relevant background document (i.e the Member states consultation report and/or experts meeting report (if any)) with the applicant. Considering any relevant confidentiality decisions, the applicant has one week to submit justified requests for removal of confidential information on the Output and MRL background documents informing EC/MS and EFSA (SMU and RAL FMBs) by e-mail. Please refer to P SOP 020 Confidentiality assessment, implementation and publication of documents for further activities related to confidentiality assessment, implementation and publication to be carried out at the post-approval stage.
Step 22	**22.0 Editorial checks and corrections**
RAL, SMU, HoU	**22.1** If after approval, but prior to publication, EFSA or MS identify a need for a significant change to the text approved by the HoU, SMU, supported by RAL, puts the publication of the approved Output on hold, requests the HoU to withdraw the approval via written procedure and resubmits the scientific Output for discussion, and if appropriate, additional approval to the ASSESS HoU. **22.2** The actions taken should be clearly communicated to EC, MSs and applicant and communication stored in the relevant folder in the **dms**. **22.3** RAL ensures that the link to the Scientific Output published in EFSA Journal is also captured in the Case Management Tool.
Step 23	**23.0 Publication of Other Scientific Outputs (OSO)**
EJ, RAL	**23.1** Once the OSO is approved, upon indication from SMU and/or LA, RAL proceeds with the publication of the OSO and background documents in accordance with SOP 020 Confidentiality assessment, implementation and publication of documents and in line with the procedure described in SOP_014_S Publishing a scientific Output in the EFSA Journal. **23.2** RAL notifies EC and EMS and applicant of the published Output and updates the Case Management Tool and MRL progress table.
Step 24	**24.0 Publication of supporting publications and supporting evidence (for all Output types)**
COM, RAL	**24.1** Once the supporting publication is approved, it is published by RAL in line with the procedure described in SOP 014 Publishing a scientific Output in the EFSA Journal and Supporting Publications.

	24.2 Upon publication, RAL will trigger the publication, on the Open EFSA Portal, of the 'supporting evidence' that was inserted in the evidence log. The supporting evidence are subject to confidentiality decision and so, where appropriate, subject to sanitisation.
Step 25	**25.0 Correction of a published scientific Output**
EJ, SMU, RAL	**25.1** See SOP 015 Republication of a scientific Output or scientific publication. The republication of the Output may be needed considering the finalisation of relevant confidentiality decisions (please refer to SOP 020 Confidentiality assessment, implementation and publication of documents).

PROCESS 4 - ASSESSMENT OF BASIC SUBSTANCE APPLICATIONS SUBMITTED IN ACCORDANCE WITH ART 23 OF REGULATION 1107/2009[24]	
MACRO-PHASE 1	Dossier Intake
Step 1	**1.3 Receipt of Application Dossier and sharing with Authorities**
Applicant, FDP	**1.1** Applicant(s) submits the application dossier in IUCLID format through the central submission system (including NoS ID, when relevant). Applicant(s) shall also indicate each pre-application ID associated to any pre-submission activities carried out in relation to the specific regulated product which is the subject of that application (see SOP 001 Pre-submission and EFSA PAs on pre-submission and public consultations). The application dossier is automatically made available to the European Commission, the Member States and to EFSA, through the central submission system. **1.2** FDP forwards the automatic dossier notification (successful notifications) to PREV FMB.
Step 2	**2.0 Withdrawal of application**
Applicant, FDP, RAL and SMU	**2.1** An applicant can withdraw its application at any time. The request for withdrawal should be submitted via a letter or email to EC and EFSA. **2.2** For withdrawal procedure FDP is responsible for macrophase 1, RAL and SMU for the subsequent macrophases/steps. **2.3** Once the withdrawal is received by EFSA, all activities (e.g. confidentiality assessment, Dossier intake, RA) linked to the Dossier

[24] Revised general framework mandate to undertake the evaluation of applications concerning "basic substances" submitted to the Commission under the provisions of Article 23 of Regulation (EC) No 1107/2009, received in August 2021 (**Mandate M-2021-00071)**

	at stake are closed in Case Management Tool, the 00 merged timelines and Overview table without delay, and this will be automatically reflected on the Open EFSA Portal. Information from the application made publicly available prior to the receipt of the withdrawal notice shall be set as confidential in Open EFSA portal and no more visible as per "SOP 020 Confidentiality assessment, implementation and publication of documents"[25]. **2.4** FDP/RAL stores for at least seven years one copy of the information, documents and correspondence in **dms** for auditing reasons. The dossiers will be retained in the Agency instance of IUCLID (Central Submission System) while they will be deleted from Public IUCLID and the relative links from Case Management Tool and Open EFSA.
Step 3	**3.0 Chartering**
SMU HoU, FDP, RAL	**3.1** An overarching process charter is in place for the assessment of Dossiers covered in this SOP. If an update is required, the SMU HoU (or his/her delegate), through the RAL planner, interacts with FDP to manage the requested changes. For further details on how the request for change is managed, please refer to the WIN SOP51 01 Portfolio-Management of change requests.
Step 4	**4.0 Validity of the application by EC**
FDP, EC	**4.1** FDP extracts and filters the list of studies from the database of study notifications and upload them in **dms**. EC verifies the compliance with notification of studies obligations. FDP notifies the EC via email, providing the link to access the extractions in **dms**. **4.2** EC checks the matching of studies submitted in the application dossier with the studies previously notified and verifies the compliance with notification of studies obligations, see SOP 001 S Pre-Submission Activities and General framework mandate on basic substances (Mandate M-2021-00071). **4.3** In case of the conditions outline in SOP 001 S Pre-Submission Activities is not met (without a valid justification) the application dossier is declared not valid. The EC shall interrupt the validity check and inform the applicant. **4.4** At this step, the applicant may resubmit through the central submission system and in IUCLID format the basic substance application dossier by means of a new dossier. The application may be resubmitted, provided that the applicant notifies in the database the studies that were not previously notified; and/or the applicant submits all the studies which were previously notified in the database or, in case of unjustified withdrawal of a notification of a study, the data delivered by the relevant laboratory or testing facility even without having the study completed.

[25] For applications submitted before 27 March 2021 the information will remain visible and should not be deleted.

	4.5 In this case, the EC informs the applicant that the assessment of such new submitted application will commence in accordance with the conditions laid down in Article 32b(4) and (5) of the GFL Regulation. **4.6** The EC checks that the information submitted are complete, completes the validity check of the application and notifies FDP and SMU FMB. Upon completion of the validity check EC will inform the applicant and EFSA accordingly. **4.7** Upon reception of the declaration of validity, FDP registers in Case Management Tool the validity and assigns the 'SPOC Collaborator'. FDP registers the chemical substances, microorganism and / or botanical extract subject of the mandate in Appian. **4.8** Also, FDP records the validity of the application in the relevant tables, informs RAL and SMU FMB about the validation, and stores the relevant correspondence in **dms**. Applicant should be correctly displayed in the Case Management Tool and in Open EFSA (if missing, FDP should follow-up). **4.9** Upon validation by the EC, FDP performs a light check in line with SOP 020 Confidentiality assessment, implementation and publication of documents. If the light check passes, FDP publishes the non-confidential version of the application dossier (please see the document Publication of PPP dossiers post-admissibility.docx), making available on the Open EFSA, via the Case Management Tool, the relevant link to Public IUCLID. FDP also publishes the (sanitised) extract from the NoS database.
Step 5	**5.0 Confidentiality decision making process (incl. dissemination of the non-confidential dossier and summary GPSA)**
FDP, SMU, LA, RAL	**For Basic substance applications, EFSA is responsible for the confidentiality decision making process**. **5.1** After the confidentiality assessment has been finalised, LA provides FDP with the UUID of the dossier on which the confidentiality request assessment was performed. FDP publishes the non-confidential version of the application dossier post-confidentiality assessment, making available on the Open EFSA, and once available, via the Case Management Tool, the relevant link to the IUCLID Public instance and provides the link to SMU/RAL. **5.2** FDP proceeds with the publication of the list of NoS. In case of applications that do not contain notified studies (e.g. studies that have been commissioned/carried out before 27 March 2021), FDP proceeds with the publication of a document stating that there is no study to be published.
Step 6	**6.0 Public consultation on the non-confidential version of a validated application after confidentiality decision making, and possibility to propose additional uses.** **Extraction and publication of comments**

RAL	**6.1** Following the confidentiality assessment and the application dossier publication, RAL triggers through Case Management Tool the creation of the PC in the Customer Portal and launches the consultation with an opening period of 3 weeks to collect additional evidence, other relevant scientific data, studies and other information part of, or supporting, the submitted Dossier – as per Article 32c(2) of Regulation 178/2002. In accordance with the new general framework mandate (Mandate M-2021-00071), the public should also be given the possibility for the submission of information on possible additional uses of the basic substance in addition to the uses supported by the applicant. For more information on the PC (e.g. duration) consult the relevant Practical Arrangements and for more information on RAL tasks consult WIN_SOP00-071 Processing of public consultations. **6.2** Also, RAL records the starting and ending dates of PC in the 00_merged_timelines. **6.3** Upon closure of the PC, comments become public on the OPEN EFSA Portal automatically, while RAL extracts them from the Customer Portal in excel format with the relevant attachments. All is uploaded by RAL in the **dms** and informs PREV FMB about completion of the public consultation.
Step 7	**7.0 Targeted consultation with MSs on full application dossier and comments received during the public consultation**
SMU, RAL	**7.1** Following the closure of the public consultation on the application dossier, RAL triggers through Case Management Tool, the **2 months** Targeted Consultation with MSs on the confidential version of the application dossier and on the comments received during the public consultation (please refer to WIN_SOP012_05 Processing targeted consultations for details). **7.2** Upon the closing of the Targeted Consultation, RAL collates the comments from MSs and public into a consolidated reporting table (including any eventual additional data/documents submitted e.g. relating to supporting additional uses in an Annex to the reporting table) and saves the document in the **dms** and informs PREV FMB about completion of the Targeted Consultation.
MACRO-PHASE 2	Preliminary Activities Risk Assessment
Step 8	**8.0 Workforce Mix Definition**
SMU, FDP, RAL	**8.1** The Workforce Mix planning by the competent SMU may start at any time after Step 7.2 above. **8.2** The TEAM leader defines the high-level Workforce Mix Planning. **8.3** When assigning the Dossier to SOs, the SMU TL ensures the separation of tasks as requested by law checking that staff members involved in general pre-submission advice activities will not be involved in other activities during the risk assessment.

	8.4 RAL define(s) in the Case Management Tool the **scientific Output type(s).**
Step 9	**9.0 Outsourced tasks**
SMU	**9.1** Please refer to SOP 010 S Scientific Cooperation, Grants and Procurements, Planning, Launch, Evaluation, Award and Implementation.
Step 10	**10.0 Quality Standards (scientific check)**
SMU, FDP	**10.1** For scientific check studies, please refer to SOP 022 S Selection of studies performed in compliance. **10.2** Depending on the applications' life-cycle stage and the type of non-compliance identified, FDP will contact the EC in charge of the validity check of the application and/or the respective SMU for ensuring the appropriate follow-up.
Step 11	**11.0 Meetings**
SMU, RAL	**11.1** Meetings are unlikely to occur during the risk assessment process for basic substance applications. If any, they should be organised according to SOP_021_A Logistic services and are managed as described in SOP 05 Managing Scientific Meetings and WIN SOP05 05 Peer Review Mtg organisation. **11.2** Other meetings might also be organised during the risk assessment process: e.g. internal meetings (e.g. preparatory meetings), meetings with applicants according to the EFSA Catalogue of Services (e.g. clarifications teleconference) need to be recorded by RAL **Information related to these meetings is not subject to dissemination/publication.**
MACRO-PHASE 3	Risk Assessment by EFSA
Step 12	**12.0 EFSA commenting and consolidation of comments after public and targeted consultations**
SMU	**12.1** Upon the closure of the Targeted Consultation and availability of the consolidated reporting table, the responsible SOs proceed with a scientific check of the basic substance application within a 3-week period. EFSA internal comments are collected in **dms.**
Step 13	**13.0 Consultation of the applicant asking their input in the consolidated reporting table and for an updated application dossier**

RAL, FDP, SMU	**13.1** Following the closure of the EFSA commenting period, in collaboration with PREV SC, RAL prepares the letter for inviting applicants to provide their responses in the completed consolidated reporting table together with an application update **within a period of 60 days.** **13.2** RAL registers the request to the applicant in the Case Management Tool and updates the 00 merged timelines accordingly. Relevant non-confidential details (e.g. ADR date, ADR sections, expected date of ADR reply) are automatically made visible on the OpenEFSA Portal to comply with the 2019 Ombudsman recommendation[26]. **13.3** Upon receiving the EFSA letter, the applicant might request a clarification teleconference as described in EFSA Catalogue of Services. **13.4** The applicant provides their responses in the reporting table (column 4) within **60 days** via email to the SMU FMB and makes available through the EFSA Application Submission Portal in IUCLID format the application dossier by means of an updated dossier. **13.5** FDP shares the updated dossier and provides the link to SMU.(UUID link to the initial dossier available in **dms, new versions available in IUCLID in chronological order).** **13.6** Upon receipt of the applicant's responses in the reporting table, RAL updates the Case Management Tool by adding the reception date. RAL also uploads the cover letter and/or e-mail in the **dms** and updates the 00 merged timelines as well. **13.7** Confidentiality decision making process on the updated application dossier provided is performed by LA after the Output approval. **13.8** After the end of the applicant's 60-day consultation period, EC will send a specific individual mandate to EFSA to proceed with the finalisation of the reporting table and to deliver a Technical Report within 3 months of the receipt of the request. ***13.9*** Upon receipt of the mandate, FDP updates the Case Management Tool and notifies SMU and RAL, stores relevant documentation **in dms** and publishes the sanitised mandate on the Open EFSA Portal via Evidence log. **Legal deadline is calculated from the mandate receipt date**. **13.10** FDP HoU signs the validity letter, this triggers the validation of EC request (in Case Management Tool) and the formal communication of the Acceptance of EC Request to EC, RAL and SMU. **13.11** FDP then fills in the relevant fields in the Case Management Tool. **13.12** FDP also stores relevant documents in **dms** taking account of WIN_SOP020_01 Practical implementation of SOP_020 and publishes the sanitised version of the acceptance letter on the Open EFSA Portal via Evidence log.

[26] Please refer to case 176/2015/JF

Step 14	**14.0 First Draft of the Technical Report**
SMU	**14.1** The Scientific Coordinator prepares prefilled template for drafting the Technical Report. **14.2** After receipt of the mandate, based on the applicant's input in the reporting table and updated dossier, the responsible SO(s) proceed(s) to consider the responses from the applicant and to complete the Technical report including the finalised reporting table. Successively the SC may initiate a quality check on the Output.
Step 15	**15.0 Finalization of the Technical Report**
SMU	**15.1** Once the draft Technical Report is ready for circulation, SMU sends the draft Technical Report for written commenting to MSs. **15.2** Upon receiving MSs' comments, the responsible SO(s) and SC amend the draft Technical Report and background documents, if any, as appropriate. Subsequently, SC proceeds with the proofreading and finalization of the Technical Report (tollgate #3)[27] in preparation for the approval.
Step 16	**16.0 Approval of the Technical Report**
RAL, SMU, HoU	**16.1** SC notifies RAL that the final Output is ready for approval. RAL triggers the approval of the Output in the Case Management Tool by sending the workflow to the relevant HoU U . **16.2** Upon approval of the Output, RAL informs LA. If the approved EFSA Output identifies foreseeable effects on human health, animal health or the environment (Article 39c review of Regulation (EC) 178/2002) related to information that has been granted confidential status, SOP 020 Confidentiality assessment, implementation and publication of documents shall apply *mutatis mutandis*. If there are confidentiality requests on the additional information submitted with regard to the initial dossier, LA starts the confidentiality assessment in accordance with SOP 020 Confidentiality assessment, implementation and publication of documents applicable *mutatis mutandis* thereby taking account of all relevant confidentiality decisions. **16.3** Upon approval of the Output by the HoU, RAL initiates the pre-notification step and upon confirmation to publish the Technical Report on EFSA's website under Supporting Publications, RAL sends it (within 15 working days from approval) to the EFSA Journal Team

[27] Tollgates correspond to quality checks performed during the Risk Assessment. No dates (planned or passed) are associated to Tollgates. Only tollgate #3 is applicable to this process.

	for publication in accordance with SOP_014_S Publishing a Scientific Output in the EFSA Journal and Supporting Publications.
Step 17	**17.0 Approval of supporting publications & supporting Evidence**
SMU, RAL	**17.0** Please refer to SOP_009_S Approving Supporting Publications. **17.1** Additional documents generated during the risk assessment and defined as 'supporting evidence' (e.g. models, R code, raw data collected by EFSA, SAS export) may need approval. The supporting evidence are subject to confidentiality decision and so, where appropriate, subject to sanitisation by SMU/LA (please refer to step 18).
MACRO-PHASE 4	Output Publication & Dissemination
Step 18	**18.0 Post-approval of scientific Output**
RAL, SMU, LA, FDP	**18.1** RAL notifies the applicant, EC and all MSs of the approved Output. RAL also shares the background documents if any with the applicant who, considering any relevant confidentiality decisions, has **one (1) week** to submit justified requests informing EC/MS and EFSA (FDP, SMU and RAL FMBs) by e-mail. Please refer to WIN_SOP020_01 Practical implementation of SOP_020 as regards further activities related to confidentiality assessment, implementation and publication to be carried out at the post-approval stage.
Step 20	**19.0 Editorial checks and corrections**
RAL, SMU	**19.1** If after the sending of the pre-notification, but prior to publication, EFSA, EC, Applicant or MS identify a need for a significant change to the text approved by the HoU, SMU, supported by RAL, puts the publication of the approved Output on hold, requests the HoU to withdraw the approval via written procedure and resubmits the scientific Output for discussion, and if appropriate, additional approval to the HoU. **19.2** The actions taken should be clearly communicated to EC, MSs, Applicant and communication stored in the relevant folder in the **dms**. **19.3** Before the publication of the Scientific Output as EFSA Supporting Publication, RAL ensures that the link to the Scientific Output published on the Open EFSA Portal is also captured in the Case Management Tool.

Step 21	**20.0**	**Publication of EFSA Supporting Publications**
EJ, RAL	**20.1**	Once the Technical Report is approved, RAL proceeds with the publication of the Technical Report and background documents in line with the procedure described in SOP_014_S Publishing a scientific Output in the EFSA Journal and Supporting Publications.
	20.2	RAL notifies EC, MSs and applicant of the published Output and updates the Case Management Tool.
	20.3	Upon completion of the confidentiality assessment by LA, FDP publishes the non-confidential version of the updated application dossier taking into account WIN_SOP020_01 Practical implementation of SOP_020 and in line with Procedure 10 of SOP 020 Confidentiality assessment, implementation and publication of documents, making available on the Open EFSA, via the Case Management Tool the relevant link to Public IUCLID and provides the link to SMU/RAL.
Step 22	**21.0**	**Publication of supporting publications and supporting evidence (for all Output types)**
COM, RAL	**21.1**	Once the supporting publication is approved, it is published by RAL in line with the procedure described in SOP 014 S Publishing a scientific Output in the EFSA Journal and Supporting Publications.
	21.2	Upon approval, and following completion of sanitisation exercise, RAL will trigger the publication, on the Open EFSA Portal, of the sanitised 'supporting evidence' that was inserted in the evidence log. The supporting evidence are subject to confidentiality decision and so, where appropriate, subject to sanitisation. The competent SMU might also want to publish open data on Zenodo shall anyway include the link to Zenodo in the evidence log.
Step 23	**22.0**	**Correction and/or republication of a published scientific Output**
EJ, SMU, RAL	**22.1**	See SOP_015_S Correction of a published scientific Output. The republication of the Output may be needed considering the finalisation of relevant confidentiality decisions (please refer to WIN SOP020 01 Practical implementation of SOP 020.

PROCESS 5 - ASSESSMENT OF CONFIRMATORY INFORMATION FOLLOWING APPROVAL OF AN ACTIVE SUBSTANCE IN ACCORDANCE WITH ART 6(F) OF REGULATION 1107/2009 OR FOLLOWING A RENEWAL OF APPROVAL PROCEDURE

MACRO-PHASE 1	Dossier Intake	
Step 1	**1.0**	**Receipt of confirmatory information and dissemination**
Applicant, FDP	**1.1**	Applicant(s) submits the confirmatory information in IUCLID format through the central submission system (including NoS ID, when relevant). The obligation to use the IUCLID software for the submission of confirmatory information does not apply to substances conditionally approved under Implementing Regulation (EU) No 844/2012 regardless of when the decision on the renewal was taken (e.g. before or after 27 March 2021) or substance approved under Regulation 1107/2009 if the decision on their conditional approval was taken before 27 March 2021
	1.2	The confirmatory information is automatically made available to the European Commission, the Member States and EFSA, through the central submission system.
	1.3	FDP forwards the automatic dossier notification (successful notifications) to PREV FMB.
	1.4	FDP registers in Case Management Tool the confirmatory information submission, creates the Question number (for technical report) and internal/external folders in **dms** and registers the confirmatory information submission in the relevant table. FDP adds when needed substances/microorganisms subject of the application in the Case Management Tool. The information on the substances/microorganisms' subject of the application is published in the OpenEFSA portal and may be further updated during the assessment.
Step 2	**2.0**	**Withdrawal**
	2.1	Withdrawal of the application not applicable.
Step 3	**3.0**	**Chartering**
SMU HoU, FDP, RAL	**3.1**	An overarching process charter is in place for the assessment of Dossiers covered in this SOP. If an update is required, the SMU HoU (or his/her delegate), through the RAL planner, interacts with FDP to manage the requested changes. For further details on how the request for change is managed, please refer to the WIN_SOP51_01 Portfolio-Management of change requests..
Step 4	**4.0**	**Admissibility**

	4.1 No admissibility check at RMS level foreseen in the Regulation. The RMS carries out a light check with regard to the confirmatory information submitted via IUCLID.
Step 5	**5.0 Confidentiality decision making process (incl. dissemination non-confidential confirmatory information dossier)**
FDP, SMU, LA, RAL	**For confirmatory information procedure following an approval of a new active substance process,** the **RMS is responsible for the confidentiality decision making process on the confirmatory information dossier**. **For confirmatory information procedure following a renewal of the approval of an active substance process, EFSA is responsible for the confidentiality decision making process on the confirmatory information dossier:** **5.1** If the light check on personal data passes, FDP publishes in the IUCLID public instance the non-confidential version of the confirmatory **information** dossier (please see the document Publication of PPP dossiers post-admissibility.docx), making it available on the Open EFSA, and once available, via the Case Management Tool, the relevant link to the IUCLID Public instance. FDP also publishes the (sanitised) extract from the NoS database. **5.2** Together with the confirmatory information dossier, the applicant might submit confidentiality requests embedded in the IUCLID dossier. **For confirmatory information procedure following an approval process (EC Regulation 1107/2009, Article 6 f)**: go directly to step 6.2 **For confirmatory information procedure following a renewal of approval (EC Regulation 1107/2009, Article 6 f) procedure:** **5.3** Upon receipt of the final addendum to the RAR or final revised RAR from the RMS, FDP notifies LA FMB without delay providing the corresponding UUID of the confirmatory information. **5.4** LA shares the confidentiality decision with SMU/RAL. Once the two weeks' timeline to submit a confirmatory application has expired and the applicant correctly implemented the decision, upon notification from LA to RAL of the completion of the implementation of the decision, RAL communicates the reasoned decision on the confidentiality requests to EC/MSs and/or the EU Reference Laboratory involved in the risk assessment process, as appropriate. LA provides FDP with the UUID of the final public version of the initial dossier. informs SMU and RAL FMBs.. **5.5** FDP publishes the final non-confidential version of the confirmatory information application (please see the document Publication of PPP dossiers post-admissibility.docx). FDP also publishes the (sanitised) extract from the NoS database.

Step 6	***6.0***	***Receipt of the draft revised DAR/RAR or addendum to the DAR/RAR*** ***Dissemination to MSs and applicant (for sanit.)*** ***Confidentiality decision-making process***
RMS, FDP, LA, Applicant, SMU	**6.1**	The RMS uploads in CIRCABC the draft revised DAR/RAR or addendum to the DAR/RAR focusing only on the specific areas of assessment addressed by the confirmatory information at the latest **6-months** of the deadline for submission of the confirmatory information.
	6.2	FDP stores correspondence in **dms** and informs RAL and SMU.
	6.3	Upon receiving the draft revised DAR/RAR or addendum to the DAR/RAR, FDP updates Case Management Tool and relevant tables.
Step 7	**7.0**	**Commenting period** ***Consultation of the targeted stakeholders (MSs, applicants) and EFSA on the draft updated DAR/RAR*** or addendum to the DAR/RAR ***Comments collected by the RMS for the Reporting table preparation.***
RMS	**7.1**	The RMS launches **the 6-week** targeted consultation on the draft revised DAR/RAR or addendum to the DAR/RAR with targeted stakeholders (MSs, APPL) and EFSA.
	7.2	Upon the automated closing of the Targeted Consultation, the RMS is responsible for compiling all comments (i.e. from the applicant(s), MSs, and EFSA) in the Reporting Table (using the EFSA standard commenting table template). The RMS should insert its response to each comment. Once completed, the RMS sends the Reporting table to SMU and RAL. This process should be completed within 6 weeks from the end of the targeted consultation.
Macro-Phase 2	Preliminary Activities Risk Assessment	
Step 8	**8.0**	**Workforce Mix Definition**

SMU, RAL	**8.1**	The Workforce Mix planning by the competent SMU may start at any time after Step 7.2 above.
	8.2	The TEAM leader defines the high-level Workforce Mix Planning.
	8.3	When assigning the Dossier to SOs, the SMU TL ensures the separation of tasks as requested by law checking that the that staff members involved in general pre-submission advice will not be involved in activities during the RA.
	8.4	The RAL define(s) in the Case Management Tool **the scientific Output type(s)**.
Step 9	**9.0**	**Outsourced tasks**
SMU	**9.1**	Please refer to SOP_010_S Scientific Cooperation, Grants and Procurements, Planning, Launch, Evaluation, Award and Implementation.
Step 10	**10.0**	**Quality Standards (scientific check and follow-up to study audits)**
SMU, FDP	**10.1**	For scientific check studies, please refer to SOP_022_S Selection of studies performed in compliance
	10.2	Depending on the applications' life-cycle stage and the type of non-compliance identified, FDP will contact the respective SMU/RMS for ensuring the appropriate follow-up.
Macro-Phase 3	Risk Assessment By EFSA	
Step 11	**11.0**	**EFSA commenting and first Draft of the Technical Report**
SMU	**11.1**	The Scientific Coordinator prepares prefilled template for drafting the Technical Report.
	11.2	Upon receiving the compiled reporting table, the SMU responsible SOs proceed to consider the responses from the RMS and to finalise the reporting table on each specific point raised and based thereon, includes their scientific views in the format of a Technical Report. At the same time, any outsourced section(s) are drafted by the Article 36 Organization. Successively the SC may initiate a quality check on the Output.
Step 12	**12.0**	**Finalization, approval and dissemination of the Technical Report**

RAL, SMU, HoU	**12.1**	Following the finalization of the TR/updated conclusions, SC initiates tollgate #3[28] which aims to decide if the finalised TR is ready for HoU approval
	12.2	Upon approval of the TR (referring to confirmatory information set for renewal process) RAL informs LA. If the approved EFSA Output identifies foreseeable effects on human health, animal health or the environment related to information that has been granted confidential status, SOP_020_Confidentiality assessment, implementation and publication of documents shall apply *mutatis mutandis*.
	12.3	SC notifies RAL that the final Output is ready for approval. RAL triggers the approval of the Output in the Case Management Tool by sending the workflow to the relevant HoU (or his/her delegate).
	12.4	Upon approval of the Output by the HoU or his/her delegate. RAL (within 15 working days from approval) initiates the pre-notification step (see step 16.1) with the applicant and, once the the public version of the approved Output is agreed, it is sent to the EFSA Journal Team for publication , as described in SOP_014_S Publishing a Scientific Output in the EFSA Journal and Supporting Publications. RAL updates the Case Management tool and 00_merged_timelines
Step 13	**13.0**	**Approval of supporting publications & supporting Evidence (only in case of focussed peer review)**
SMU, RAL	**13.1**	Please refer to SOP_009_S Approving Supporting Publications. Additional documents generated during the risk assessment and defined as 'supporting evidence' (e.g. models, R code, raw data collected by EFSA, SAS export) may need approval. The supporting evidence are subject to confidentiality decision and so, where appropriate, subject to sanitisation by SMU/LA.
Macro-Phase 4	Output Publication & Dissemination	
Step 14	**14.0**	**Post-approval of approved scientific Output**
RAL, SMU, LA, FDP	**14.1**	RAL notifies the applicant, EC and all MSs of the approved Output. When notifying the applicant of the approved Output, RAL also shares the final revised DAR/RAR or final addendum to the DAR/RAR with the applicant who has **one (1) week (in case of TR), two (2) weeks (in case of Conclusion)** to submit confidentiality requests, informing EC/MS and EFSA (FDP_LA_SMU and RAL FMBs) by e-mail. Please refer to WIN_SOP020_01 Practical implementation of SOP_020 as regards further activities related to confidentiality assessment, implementation and publication to be carried out at the post-approval stage.

[28] Tollgates correspond to quality checks performed during the Risk Assessment. No dates (planned or passed) are associated to Tollgates. Only tollgate #3 is applicable to this process.

Step 15	**15.0**	**Editorial checks and corrections**
RAL, SMU	**15.1**	If after the sending of the pre-notification, but prior to publication, EFSA, EC, Applicant or MS identify a need for a significant change to the text approved by the HoU, SMU, supported by RAL, puts the publication of the approved Output on hold, requests the HoU to withdraw the approval via written procedure and resubmits the scientific Output for discussion, and if appropriate, additional approval to the HoU.
	15.2	The actions taken should be clearly communicated to EC, MSs, Applicant and communication stored in the relevant folder in the **dms**.
	15.3	Before the publication of the Scientific Output as EFSA Supporting Publication, RAL ensures that the link to the Scientific Output published on the Open EFSA Portal is also captured in the Case Management Tool and updates the Overview table.
Step 16	**16.0**	**Publication of EFSA Supporting Publications**
EJ, RAL	**16.1**	Once the Technical Report is approved and upon indication from SMU and/or LA, RAL proceeds with the publication of the Technical Report and background documents in accordance with WIN_SOP020_01 Practical implementation of SOP_020 ; SOP_020_Confidentiality assessment, implementation and publication of documents and in line with the procedure described in SOP_014_S Publishing a scientific Output in the EFSA Journal and Supporting Publications.
	16.2	RAL notifies EC, MSs and applicant of the published Output and updates the Case Management Tool and updates the Overview table
	16.3	Upon completion of the confidentiality assessment, FDP publishes the non-confidential version of the updated dossier, taking into account WIN_SOP020_01 Practical implementation of SOP_020 and in line with Procedure 10 of SOP_020_Confidentiality assessment, implementation and publication of documents, making available on the Open EFSA, via the Case Management Tool , the relevant link to Public IUCLID and provide s the link to SMU/RAL.
Step 17	**17.0**	**Publication of supporting publications and supporting evidence (for all Output types)**
COM, RAL	**17.1**	Once the supporting publication is approved it is published by RAL in line with the procedure described in SOP_014_S Publishing a scientific Output in the EFSA Journal and Supporting Publications.
	17.2	Upon approval, t RAL will trigger the publication, on the Open EFSA Portal, of the sanitised 'supporting evidence' that was inserted in the evidence log. The supporting evidence are subject to confidentiality decision and so, where appropriate, subject to

		sanitisation. The competent SMU might also want to publish open data on Zenodo shall anyway include the link to Zenodo in the evidence log.
Step 18	**18.0**	**Correction and/or republication of a published scientific Output**
EJ, SMU, RAL	**18.1**	See SOP_015_S Correction of a published scientific Output. The republication of the Output may be needed considering the finalisation of relevant confidentiality decisions (please refer to WIN_SOP020_01 Practical implementation of SOP_020)

ANNEX I

- **Annex I _ SOP 13_NC_WA**

Records

Reference	Title	Location
Process 1 NAS		
2.4	Withdrawal correspondence	**dms**
4.1	Data extraction	**dms**
4.7	Validation assistant report	**dms**
4.8	Admissibility documentation	**dms**
7.2 & 7.3	Draft AR + relevant correspondence	**dms**
7.6	Accepted DAR	**dms**
7.8	Sanitised DAR	**dms and Open EFSA**
13.1	RT	**dms**
14.1	Kick-off meeting with RMS (tollgate #1)	**dms**
14.2	ADR letter + sanitised version	**dms**

14.8	Revised DAR + Evaluation Table	**dms**
14.9	Applicant's cover letter + sanitised version	**dms**
14.11	Pre-filled Meeting reports	**dms**
14.13	Draft Output	**dms**
15.1	Written consultation with RMS (tollgate #2)	**dms**
15.2	Final draft Output (tollgate #3)	**dms**
16.3	Approved OSO	**dms**
19.2	Correspondence + Published Output	**dms**
21.2	Correction and/or republication Output	**dms**
Process 2 AIR		
2.4	Withdrawn correspondence	**dms**
4.1	Data extraction	**dms**
4.7	Admissibility documentation	**dms**
7.2 & 7.3	Draft RAR + relevant correspondence	**dms**
7.5	Accepted AR	**dms**
7.6	Sanitised RAR	**dms**
13.1	RT	**dms**
14.1	Kick-off meeting with RMS (tollgate #1)	**dms**
14.2	DR letter + sanitised version	**dms**
14.7	Applicant's cover letter + sanitised version	**dms and OpenEFSA (for pre-TR applications only)**

14.8	Revised RAR + Evaluation table	**dms**
14.11	Pre-filled Meeting reports	**dms**
14.14	Draft Output	**dms**
15.1	Written consultation with RMS (tollgate #2)	**dms**
15.3	Final draft Output (tollgate #3)	**dms**
16.2	Approved OSO	**dms**
17.1	Correspondence + Published Output	**dms**
20.1	Correction and/or republication Output	**dms**
Process 3 MRL		
2.5	Withdrawn correspondence	**dms**
4.1	Data extraction	**dms**
4.2	Admissibility documentation	**dms**
5.2	Confidentiality decision	**dms**
7.2	Evaluation report and related docs	**dms**
7.6	Mandate + sanitised version	**dms and OpenEFSA**
7.7 and 7.9 (and 13.1-13.3)	Acceptance letter + sanitised version (tollgate#1 passed)	**dms and OpenEFSA**
15.1	AdR letter + sanitised version	**Dms and OpenEFSA**
15.5	Updated Evaluation report + sanitized version	**dms and OpenEFSA**

15.4	Applicant's cover letter sanitised version (only for pre-transparency applications)	**dms and OpenEFSA**
16.1	Draft Output	**dms**
17.1 -17-2	Draft output (reviewed) (tollgate #2)	**dms**
18.1	Final draft Output (tollgate#3 passed)	**dms**
19.3	Approved Output	**dms**
23.1	Background documents + sanitized versions	**Dms and OpenEFSA**
23.2	Correspondence + Published Output	**dms**
25.0	Corrected and republished Output	**dms**
Process 4 BASIC SUBSTANCES		
2.4	Withdrawn dossier and correspondence	**dms**
4.1	Data extraction	**dms**
4.7 & 4.8	Validity of the application	**dms**
6.3	Public comments	**dms**
7.2	Reporting Tables	**dms**
12.1	EFSA Internal comments	**dms**
13.2	Request letter + sanitised version and relevant correspondence	**dms**
13.5	UUID link to dossier	**dms**
13.6	Applicant's cover letter and/or email + sanitised version and	**dms**

	relevant correspondence	
13.9	Mandate + sanitised version	**dms**
13.12	Acceptance letter + sanitised version	**dms**
14.1, 15.1 and 15.2	Draft Output and finalization (tollgate #3)	**dms**
16.1	Final draft Output	**dms**
16.2	Approved Output	**dms**
19.2	Correspondence + Published Output	**dms**
19.3 and 20.01	Output + background documents	**Dms and Open EFSA**
22.0	Revision of Technical Reports	**dms**
Process 5 CONFIRMATORY INFORMATION		
1.1	Dossier	**IUCLID**
6.1 & 6.2	Draft RAR and relevant correspondence	**dms**
11.1 and 12.1	Commenting draft TR and finalization Technical Report (tollgate#3)	**dms**
12.3	Approved Output	**Dms**
16.1	Confidential version of the Output on Peer Review Report	**dms**
16.2	Correspondence published output	**dms**
18.0	Correction and/or republication Output	**dms**

ANNEX II – PRE-TR APPLICATIONS, NON-APPLICABILITY TO PROCESSES

Process 1 (NAS), and Process 2 (AIR)		
Step 1	Receipt of Application dossier	IUCLID steps not applicable. Submission of the dossier not done via IUCLID but via CD or e-submission
Step 2	Withdrawal of application	Deletion of application plus SOP 20, dossier and information from Open EFSA not applicable. IUCLID not applicable.
Step 3	Chartering	Applicable
Step 4	Dossier admissibility	• NoS/IUCLID tasks not applicable • Re-submission of dossier done via CD or e-submission
Step 5	Confidentiality decision making process	• Confidentiality assessment performed by RMS, LA not involved • NoS publication not applicable • Publication of sanitised dossier applicable but not with IUCLID link (FDP)
Step 6	Public consultation of non-confidential of admissible application	Not applicable
Step 7	Receipt of DAR/RAR	• CC and launching of PC applicable (FDP) • Confidentiality assessment performed by FDP, LA not involved
Step 8	Commenting period and dissemination	Comments will be published later together with Conclusion
Step 9	Workforce mix definition	Applicable, expect recording in internal report
Step 10	Definition of outsourced tasks	Applicable
Step 11	Quality Standards	Applicable, excluding reference to Pas
Step 12	Meetings	Applicable
Step 13	Peer Review	Applicable
Step 14	First draft conclusion	Applicable, except for IUCLID reference. AdR submitted via e-mail. Upload of ADR cover letter in OpenEFSA
Step 15	Finalization of the Conclusion	Applicable
Step 16	Approval Conclusion	SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents.
Step 17	Post-approval of approved scientific Output	Confidentiality assessment and IUCLID steps not applicable,

		SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents.
Step 18	Editorial checks and corrections	SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents.
Step 19	Publication of other scientific Outputs	SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents. IUCLID not applicable.
Step 20	Publication of supporting publications and supporting evidence	Applicable to AIR
Step 21	Correction and/or republication of a published scientific Output	SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents. IUCLID not applicable.

Process 3 (MRL)		
Step 1	Receipt of Application dossier	• IUCLID steps not applicable. • Submission of the dossier not done via IUCLID but via CD or e-submission.
Step 2	Withdrawal of application	Deletion of application, dossier and information from Open EFSA not applicable.
Step 3	Chartering	Steps applicable
Step 4	Dossier admissibility	• NoS/IUCLID tasks not applicable. • Re-submission of dossier done via CD or e-submission. • Pre-TR applications registration in APPIAN is done upon receipt of EC monthly mandate (named as EC Request) see step 7.3 (see annex SOP_013 on non-applicable steps to pre-TR applications)
Step 5	Confidentiality decision making process	• Confidentiality assessment not applicable • NoS publication not applicable • Publication of sanitised dossier not applicable
Step 6	Public consultation of non-confidential of admissible applicaiton	Not applicable

Step 7	Receipt of ER and mandate	• IUCLID tasks not applicable • No light check of the ER by FDP
Step 8	Workforce mix definition	• Applicable but recorded in Progress table (including TGs) • GPSA step not applicable
Step 9	Outsourced tasks	Applicable but recorded in Progress table
Step 10	Quality Standards	Applicable, except from step 10.3
Step 11	Meetings	Applicable
Step 12	Screening of EC request	Applicable
Step 13	Outcome of the screening and validation of EC request	Applicable
Step 14	MSC and/or Expert meeting (optional)	Applicable, except for reference to Pas
Step 15	Sending of Additional Data Request	Applicable, except for IUCLID/NoS and confidentiality assessment reference. AdR submitted via e-mail or CD
Step 16	First Draft of Reasoned Opinion	Applicable
Step 17	Scientific review	Applicable but recorded in progress table
Step 18	Finalization of the Reasoned Opinion	Applicable
Step 19	Approval of the Reasoned Opinion	Applicable, except Art. 39c review step. For pre-TR applications a sanitisation exercise on Output and background documents is undertaken by SMU (with the support of RAL) and the applicant directly.
Step 20	Approval of supporting publications & supporting Evidence	Applicable
Step 21	Post-approval of approved scientific Output	Confidentiality assessment and IUCLID steps not applicable, for pre-TR applications a sanitisation exercise on Output and background documents is undertaken by SMU (with the support of RAL) and the applicant directly.
Step 22	Editorial checks and corrections	Applicable
Step 23	Publication of Other Scientific Output	Applicable
Step 24	Publication of supporting publications and supporting evidence	Applicable
Step 25	Correction of a published Output	Applicable, except for Art. 39c review related step.

Process 4 (BS)		
Step 1	Receipt of Application dossier	IUCLID steps not applicable. Submission of the application not done via IUCLID but via CD or e-submission. Creation of Question number applicable also to pre-TR applications
Step 2	Withdrawal of application	Deletion of application, dossier and information from Open EFSA not applicable. IUCLID not applicable.
Step 3	Chartering	Applicable
Step 4	Validity of the application	• NoS/IUCLID tasks not applicable • Re-submission of dossier done via CD or e-submission
Step 5	Confidentiality decision making process	• Confidentiality assessment performed by LA not applicable. • NoS publication not applicable • Publication of sanitised dossier NOT applicable.
Step 6	Public consultation of non-confidential dossier	Not applicable
Step 7	Targeted consultation on full application dossier	Applicable
Step 8	Workforce mix definition	Applicable except recording in internal report. Only tollgate 3 applicable.
Step 9	Outsourced tasks	Applicable
Step 10	Quality Standards	Applicable, excluding from Fact-Finding missions as it is only relevant for post-TR applications. GLP studies are rarely submitted for basic substances.
Step 11	Meetings	Applicable, though never happened.
Step 12	EFSA Risk Assessment EFSA commenting and consolidation of comments after public and targeted consultations	Applicable, except that there is no public consultation in pre-TR process
Step 13	Consultation of the applicant asking their input in the consolidated reporting table and for an updated application dossier	Applicable, except for IUCLID /NoS reference. Requests submitted via e-mail/CD (also no cover letter provided for publication in Open EFSA portal)
Step 14	First Draft of the Technical Report	Applicable
Step 15	Finalization of the Technical Report	Applicable, except MS consultation.
Step 16	Approval of Technical Report	SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents, including the updated dossier.

Step 17	Approval of supporting publications & supporting Evidence	SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents, including the updated dossier.
Step 18	Post-approval of scientific Output	Confidentiality assessment steps by LA/IUCLID not applicable. SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents, including the updated dossier.
Step 19	Editorial checks and corrections	Applicable
Step 20	Publication of EFSA Supporting Publications	Applicable, except for IUCLID reference
Step 21	Publication of supporting publications and supporting evidence (for all Output types)	SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents, including the updated dossier.
Step 22	Correction of a published scientific Output	SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents. IUCLID not applicable.

Process 5 (Confirmatory information)		
Step 1	Receipt of confirmatory information and dissemination	IUCLID steps not applicable. Submission of the dossier not done via IUCLID but via CD or e-submission
Step 2	Withdrawal of application	N/A
Step 3	Chartering	Applicable
Step 4	Admissibility	N/A
Step 5	Confidentiality decision making process	• Confidentiality assessment performed by RMS, LA not involved

		• NoS publication not applicable • Publication of sanitised dossier NOT applicable
Step 6	Receipt of draft revised DAR/RAR	Applicable
Step 7	Commenting period	Applicable
Step 8	Workforce mix definition	Applicable except recording in internal report
Step 9	Outsourced tasks	Applicable
Step 10	Quality Standard (Scientific check and follow up to study audits)	Applicable except from Fact-Finding missions as it is only relevant for post-TR applications
Step 11	EFSA commenting first Draft of the Technical Report	Applicable
Step 12	Finalization, approval and dissemination of the Technical Report	SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents.
Step 13	Approval of supporting publications & supporting Evidence (only in case of focused peer review)	Applicable
Step 14	Post-approval of approved scientific Output	Confidentiality assessment and IUCLID steps not applicable SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents.
Step 15	Editorial checks and corrections	Applicable
Step 16	Publication of EFSA Supporting Publications	Applicable
Step 17	Publication of supporting publications and supporting evidence (for all Output types)	SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents.

Step 18	Correction and/or republication of a published scientific Output	SMU assesses the confidentiality requests submitted by the applicant on the Output and background documents.