Approving EFSA Supporting Publications

SCOPE AND OBJECTIVES

This SOP covers the approval process of EFSA Supporting Publications (i.e. Technical Reports, External Scientific Reports and Event Reports).

This is a cross cutting SOP which supports the procedures of the following EPA level 2 science production processes: E02.02 Risk Assessment of Applications, E03.02 Peer-Review of Pesticides/Assessment of MRLs and E04.01 Risk Assessment of Generic Mandates

RELEVANT STANDARDS, LEGISLATION AND DOCUMENTS

- 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
- SOP_007_S RA of Generic Mandates
- SOP_012_S RA of Applications
- SOP_013_S RA of Pesticides
- SOP_010 Procurements and Grants, Planning, Launch, Evaluation, Award and Implementation
- SOP_014_S Publishing scientific outputs in the EFSA Journal and Supporting Publications
- WIN/SOP/014/10 Guidelines on assigning authorship
- WIN_SOP00_71_Processing of public consultations
- SOP_020_Confidentiality assessment, implementation and publication of documents
- EFSA Decision Making Framework 2.0

	Previous SOPs in the process: n/a
PRELIMINARY ACTIVITIES	
RAL & FDP	*To be able to publish a supporting publication, a question shall be created in the Case Management Tool.* *FDP creates a mandate and Question number, fills in the relevant fields, links the mandate and the question number in the Case Management Tool and uploads any supporting document in the Evidence Log during the intake phase.*

	RAL inserts indicative timing of tollgate #3 in the Case Management Tool in accordance with planned timelines for approval of the supporting publication.
PROCEDURE	
Step 1	**Tollgate #3 Draft Finalisation & Output Approval**
RAL, SMU SO & SMU HoU	1.1 During tollgate #3, the SMU responsible SO reviews the final report to ensure that it is of sufficient quality (Event report, Technical Report, External Scientific Report), that it meets expectations as defined in the specific contract to which it is linked (External Scientific Report) or the Terms of Reference to which it pertains (Technical Report). In the case of Technical Reports and External Scientific Reports, the responsible SO may consult, on a case-by-case basis, a checklist with guiding principles for the review (see Annex).
	1.2 In the case of External Scientific Reports, if shortcomings are identified, the responsible SO liaises with the contractor / beneficiary to address comments before the report is re-submitted to EFSA for acceptance.
	1.3 When the final report is accepted by the responsible SO, RAL enters the date of passing tollgate #3 and initiates the approval workflow in the Case Management Tool.
	1.4 The SMU HoU approves the output for publication in the Case Management Tool.
	1.5 Following approval, if applicable, the responsible SO sanitizes parts of the report deemed confidential as per SOP_020_Confidentiality assessment, implementation and publication of documents.
	1.6 Following approval (and sanitization, if applicable) RAL dispatches the public version of the final report to the EFSA Journal Team for publication (as EFSA Supporting Publications) in accordance with SOP_014_S_Publishing scientific outputs in the EFSA Journal and Supporting Publications.
	1.7 RAL uploads any supporting document, if applicable, in the Evidence Log.
	1.8 The responsible SO stores the final report in the DMS.

RECORDS

Reference	Title	Source or Link/Location
Step 1.4	Approval of the final report for publication	Case Management Tool (Appian)
Step 1.8	Final report	DMS of SMU

ANNEX

Guiding principles for review of Technical Reports and External Scientific Reports at Tollgate #3 prior to approval

	Aim of tollgate	Questions to be considered	Criteria to be analysed	RACI*
Tollgate #3	Decide if draft Supporting publication is ready for finalization	• Is there consistency between conclusions, summary, abstract and body text of the output? • Have different views identified during elaboration of the output, if applicable, been acknowledged? • Have all the comments received during a public consultation, if applicable, and reviewer(s), if applicable, been considered and addressed?	• Reporting quality of the draft scientific output – clarity and completeness • All TORs are answered • Cross-cutting issues addressed, if applicable • Methodological rigor according to protocol, if applicable • Implementation of transparency according to protocol, if applicable • Implementation of engagement according to protocol, if applicable	**R:** SMU SO **A:** SMU HoU **C:** Panel (if applicable) **I:** HoD for sensitive topics; HoUs for cross cutting topics

*R=Responsible, A=Accountable, C=Consulted, I=Informed