

	Standard Operating Procedure Approving Other Scientific Outputs
Public	

Scope	Process followed for approving Other Scientific Outputs. The OSO can be either endorsed or peer-reviewed, or both these procedures may be used. The relevant unit decides, in consultation with the relevant HoD, which procedure to apply for each OSO depending on the nature of the OSO. The endorsement may be carried out either before or after the peer-review. The endorsement and peer-review can also be launched at the same time.
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Special Requirements	This procedure is a controlled document maintained by Quality Management. It may not be deleted without comparable controls.
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Responsibilities	<ul style="list-style-type: none"> • EFSA Unit(s) for drafting the OSO • The EFSA Executive Director or the Relevant HoD for approving the OSO
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Abbreviations and definitions

Approving	The approval of OSOs is done by the Executive Director of EFSA or by the relevant Head of Department when delegated the task
COMMS	Communications Department
DMS	Document Management System
HoD	Head of Department
HoU	Head of Unit
Endorsing	In some instances, an OSO can be endorsed, i.e. supported, by e.g. Scientific Committee/Scientific Panel, a Network or a Working group.
Other Scientific Outputs (OSOs)	<p>The Other Scientific Outputs of EFSA are, as a general rule, prepared by an EFSA working group and/or by EFSA scientific staff. Their content and publication are approved by the Executive Director of EFSA or by a Head of Department when delegated. An OSO can be a Statement of EFSA, a Guidance of EFSA, a Conclusion on Pesticides Peer Review, a Reasoned Opinion, or a Scientific Report of EFSA.</p> <p>Definitions of EFSA Scientific Outputs and Supporting Publications</p>
SC	Scientific Committee
SP	Scientific Panel
WG	Working Group

Procedure

	Previous SOP in the process: SOP 001 S on Receiving a request SOP 006 S on Establishing, updating and closing a scientific WG SOP 007 S Documenting the Risk Assessment Process
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Step 1	1.0 Endorsing OSOs
Unit	<p>1.1 In case the endorsement of the OSO is applied, the relevant Unit places the draft OSO on the appropriate meeting agenda of the endorsing body (SC, SP, WG or a network) and, if relevant, on an exchange platform together with a notification on the endorsement.</p> <p>1.2 If appropriate and relevant, the Unit emails the draft OSO to the endorsing body at least 5 working days prior to the meeting.</p> <p>1.3 If the endorsement of an OSO does not require organizing a meeting, the endorsement is made via written procedure. For the written procedure, the draft OSO is distributed to the members of the endorsing body either by e-mail including the DMS link, or only by placing it on the exchange platform and at the same time informing the relevant members of this.</p> <p>1.4 At the meeting of the endorsing body, or via written procedure, the draft OSO is either:</p> <ul style="list-style-type: none"> - finalised and endorsed: proceed to step 2.0 (Scientific Peer Review) or to step 3.0 (Finalising an OSO). - not fully-finalised and not endorsed: the OSO is discussed and revised at a further meeting(s) or via written procedure. <p>1.5 Note is taken of who was involved in the endorsement and who has endorsed the output by recording this in the minutes of the meeting.</p> <p>1.6 Upon endorsement of the OSO, the relevant Unit stores it on the DMS together with the relevant documents of the endorsing process.</p>
Step 2	2.0 Scientific Peer Reviewing of OSOs
Unit	<p>2.1 The Unit sends the OSO to the previously defined expert(s) for peer reviewing. The peer-reviewers are appointed by the relevant Unit and the reasons for the selection are documented. The Unit stores the documents on the selection process on the DMS. For Conclusions on Pesticides and Reasoned Opinions (art.12) the experts are appointed by the Member States.</p> <p>2.2 The comments from peer reviewers are collected and stored on the DMS and linked to the OSO along with the Unit's proposal to address the comments. If the HoU decides that the result of the peer review requires significant changes, the OSO returns to step 1.1. Once the OSO has been appropriately updated in the light of the peer review comments it passes to the next step in the process (step 3).</p>
Step 3	3.0 Approval of OSO
Relevant HoD Unit	<p>3.1 The Unit prepares an email to the relevant HoD, including the link to the supporting documents and to the outcome of the endorsement and/or peer-review processes, for approval by the relevant HoD (Annex 1). In some cases such as Outputs related to Urgent Requests, or at the discretion of the HoD, the Executive Director approves the OSO.</p>



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3.2 Upon approval of the OSO by the HoD (or by the Executive Director), the Unit sends the approved OSO to COMMS for publication, after pre-notification and/or blackening of confidential information from the publicly available version of the OSO, as per SOP020 or relevant Commission decision on confidentiality claims of the relevant legal or natural person, as applicable. In the absence of the latter, EFSA shall comply with the confidentiality claims as submitted by the applicant.

Following SOP in the process:
[SOP_014_S Publishing a scientific output in the EFSA Journal](#)