efsa European Food Safety Authority	**Standard Operating Procedure** **Review and revision of cross-cutting and sectoral guidance documents**
Public	

Scope	This SOP describes the steps for regular review and revision of Scientific Committee, Scientific Panels and EFSA guidance documents (cross-cutting and sectoral).

Special Requirements	This procedure is a controlled document maintained by Quality Management. It may not be deleted without comparable controls.

Responsibilities	1 Units: Identify the timing for reviewing and possible revision of guidance documents and allocate an item on the agenda of the Scientific Committee and/or respective panels when applicable. 2 Scientific Committee/Panel/Unit: Perform review and revision of cross-cutting/sectoral guidance documents and record their use.

Abbreviations and definitions

Category of compliance for guidance documents	- Conditional compliance: requirement to follow the guidance document if the recommended approach is chosen - Unconditional compliance: must be followed.
Cross-cutting guidance document	Guidance document that is applicable to more than one panel or that is of horizontal nature.
DMS	Document Management System
EFSA	European Food Safety Authority
Guidance document	The term covers both cross-cutting and sectoral guidance documents. Guidance documents of the Scientific Committee/Panel/Units explain the principles behind EFSA's procedures and approaches to scientific assessments. Some Guidance documents specify the information and data which applicants must provide when submitting applications for evaluation.
Repository	EFSA Repository of Governance and Management Documents – the unique point of reference for legal acts, governance, management documents in force.
Review	The activity to indicate the screening of existing guidance documents in order to decide whether any revision is needed.
Revision	The activity to amend or update existing guidance documents.
Sectoral guidance	Guidance document specific to one panel or Unit.

document	
SC	Scientific Committee
SOP	Standard Operating Procedure
SP	Scientific Panel

Procedure

	Previous SOPs in the process: - SOP_012_S Adopting a scientific opinion, statement or guidance of the SC/SPs - SOP_014_S Publishing a scientific output in the EFSA Journal.
Step 1	**1.0 Review of guidance documents**
Units	1.1 At the beginning of the third year of the SC/SP mandate, or at any time a need is identified (e.g. an urgent scientific need/request or annual planning), the relevant EFSA Unit secretariat places the possible review of guidance documents belonging to their remit on the agenda of the SC/SP plenary meeting. Regarding guidance documents developed by EFSA Units, the relevant Units review these every 3 years or at any time a need is identified (e.g. an urgent scientific need/request or annual planning). 1.2 The SC/SP/Unit should base their review on the following criteria (list not exhaustive): a. which guidance documents were used; b. which guidance documents were not used and why not; c. any problems (see also 1.4 below) identified during the use of guidance documents. 1.3 The outcome of the review will result in one of the following decisions for each of the guidance documents: a. guidance document is to be kept (no further action needed); b. guidance document is to be archived as obsolete (Unit secretariat to send email to repository mailbox to inform repository manager of request to archive the guidance document); c. guidance document needs revision, an indication of the reasons for this decision and the possible impact of the revision.

	1.4 Possible reasons for the need to revise a guidance document are: a. New relevant, reliable and consistent scientific information/insight in hazard and/or exposure assessments has become available (e.g. concerning assumptions, exposure routes, identified group of sensitive individuals, methodologies); b. New regulation or new legal instruments have been published which have an impact on one or several EFSA scientific panels; c. A request from the Commission or a Member State for revision of guidance document(s) has been received; d. Mistakes or ambiguity have been identified that directly influence the outcome of the scientific assessment; e. The identification of different interpretations of the guidance by different Panels due to ambiguity in existing guidance documents; f. A need to reflect changes in target audience, application area, category of compliance (unconditional or conditional), or other. 1.5 The decision concerning the outcome of the review will be recorded in the SC/SP or Unit meeting minutes. In the case of cross-cutting guidance documents the Units need to consider the endorsement of these by the SC.
Step 2	**2.0 Revision of guidance documents**
SC/SP/Units	2.1 The SC/SP/Unit, based on the decision on which guidance documents need to be revised, follows the steps outlined in SOP_012_S. Adopting a scientific opinion, statement or guidance of the SC/SPs 2.2 In order to allow for suitable planning taking into consideration availability and expertise of resources needed for the revisions the SC/SP/Unit should carry out a prioritisation exercise leading to a suggested timing of the foreseen revisions. Possible prioritisation criteria are the following: a. The degree of impact of the proposed revision on the scientific assessments;

	b. Improving consistency in the way scientific assessment is carried out by the SC/Panels/Units; c. The obligation for EFSA/applicants to apply the guidance (when the guidance is categorised as "unconditional", revision is to be considered as high priority); d. For cross-cutting guidance documents prioritisation will need to take into consideration also the number of EFSA Panels for which the guidance is relevant. 2.3 The SC/SP/Units record the decision on the prioritisation in the relevant meeting minutes and save these in the DMS. For sectoral guidance documents this procedure ends here. For cross-cutting guidance documents go to step 3.
Step 3	**3.0 Communication on revised cross-cutting guidance documents**
SC/SP/Units	3.1 In case of revised cross-cutting guidance documents the relevant SC/SP/Units will place an item on the meeting agenda to discuss how to ensure efficient dissemination (e.g. training, presentation to EFSA staff and experts etc.). 3.2 The decision on any needs are recorded in the meeting minutes and followed up on by the panel secretariat.
	Following SOPs in the process: n/a