efsa European Food Safety Authority	**Standard Operating Procedure** **Scientific risk assessment process and related documentation**
Public	

Scope	Description (and related documentation) of the scientific risk assessment (RA) process for EFSA's scientific outputs as defined in Definitions of EFSA Scientific Outputs and Supporting Publications.

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

Responsibilities	The Unit supporting the development of the Scientific Output, Other Scientific Output (OSO) or Supporting Publications executes and documents the key elements of the RA process.

Abbreviations and definitions

DMS	Document Management System
ED	Executive Director
OSO	Other Scientific Output
RA	Risk Assessment
SC	Scientific Committee
SO	Scientific Officer
SP	Scientific Panel
ToR	Terms of reference – included in the mandate
WG	Working Group of the Scientific Committee/Scientific Panel, of EFSA, or a Network

Procedure

	Previous SOPs in the process: SOP_001_S on Receiving a request
Step 1 Relevant Body	
	1.0 Planning phase of the risk assessment
	1.1 1When appropriate, the relevant body (EFSA Unit, SC/SP, WG) decides to conduct a RA in order to reply to a received mandate or to a self-mandate. The relevant body (EFSA Unit, SC/SP, WG) conducts and documents the pertinent clarifications/interpretations of the ToRs. A protocol / workplan should be developed beforehand so as to

	describe how the RA will be performed (in particular objectives, risk questions and sub-questions, selection of methodologies and tools to be used, resources, responsibilities, time management). 1.2 EFSA-adopted RA guidance(s) should be followed and indicated (e.g. Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. General Principles, Scientific Committee/Panel specific Guidance documents and Fostering Harmonised Risk Assessment Approaches in Member States). When dealing with RA to be developed under the frame of an application of a regulated product, relevant Regulations should be indicated and followed. 1.3 If EFSA-adopted guidances are NOT followed or only partially, justification for the use of alternative approaches and/or key studies must be appropriately documented in the output and/or in the SC/SP/WG minutes. 1.4. All relevant documentation is stored in DMS.
Step 2	**2.0 Development phase of the Risk Assessment**
	2.1 The relevant body (EFSA Unit, SC/SP, WG) describes the main decisions taken concerning the development of the Scientific RA Process and documents it accordingly (in the output and/or in the SC/SP/WG minutes). 2.2 Important aspects such as the implications of contradictory/ conflicting data, the identification of significant data gaps, opinions and diverging views from other expert bodies, limitations and uncertainties, and the decisions taken should be recorded including the possible implications of these aspects for the output/s. The relevant body (WG/SC/SP) need to ensure alignment with the ToRs. 2.3. All relevant documentation is stored in DMS.
Step 3	**3.0 Drafting the Scientific Output, Other Scientific Output or Supporting Publications**

	3.1 The relevant body (usually a WG of the SC/SP or an EFSA WG) explains in the output the RA approach taken in order to answer the ToRs. 3.2. If a protocol has been developed, deviations or additions to the protocol should be recorded. 3.3 The relevant body drafts the output and agrees on the final version of the draft output. 3.4. All relevant documentation is stored in DMS.
Step 4 Unit	**4.0 Checks on final draft Output, prior to submission for adoption/approval**
	4.1 The SO in charge of a mandate should check that the draft Output against the points listed below and report the outcome to the relevant Panel: □ adequately addresses the original/reviewed ToRs □ has conclusions that are coherent with the main content of the output/s □ adequately addresses assumptions, limitations and uncertainties □ has provisional/interim conclusions accompanied by clear recommendations or indications of further research or information that may be needed, together with a timeline for follow-up □ respects the boundaries between risk assessment and risk Management 4.2 All relevant documentation is stored in DMS.
Step 5	**5.0 Submission for Adoption/Approval of Output/s**
	5.1 The WG Chair sends the final version of the Output/s for review to the relevant body, usually the SC/SP, and then is submitted for adoption or approval.
	Following SOPs in the process: N/A