European Food Safety Authority	**Standard Operating Procedure** Quality Management Review
Public	

Scope	The evidence based annual review by EFSA's Management Team of the performance of the organisation's quality management system, to ensure it is fit for purpose, adequate and effective. The annual Management Team Review completes the Plan/Do/Check/Act cycle.

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*

Responsibilities	• EFSA Management Team: perform the quality management review • QM: support the quality management review (prepare, facilitate, report and monitor follow-up)

Abbreviations and definitions

DMS	Document Management System
QM	Quality Management
MT	Management Team
Non-conformity (NC)	A non-conformity or non-compliance is the "non-fulfilment of a requirement" A non-conformity takes place when one (or several) of the following conditions are fulfilled; • It constitutes either an overruling or a deviation from mandatory processes and procedures; • It represents a gap in existing controls; • It might constitute a breach of existing regulatory and/or contractual provisions; In case of a non-conformity the finding has already happened – it is thus detected after (ex post) the related non-compliance has occurred. This is to be differentiated from an exception, which is approved by the responsible person before (ex-ante) the overruling or deviation has taken place.
Preventive Action (PA)	An ex ante action to eliminate the cause of a potential non-conformity or other undesirable potential situation before they have actually occurred. Preventive action is taken to prevent the occurrence of non-conformity.
QC	Quality Circle consisting of one Quality Correspondent per unit in EFSA, meets monthly and is coordinated by Quality Management
QMS	Quality Management System
SOP	Standard Operating Procedure
Internal Quality	EFSA has a team of Internal Quality Auditors which on an annual or

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Audits	biannual basis audit every Unit in the organisations against a particular Audit scope/goal.

Procedure

	Previous SOP in the process: n/a
Step 1 **QM, Quality circle**	**1.0 Preparation of the management review**
	1.1 During the last quarter of each year, QM prepares the annual management review of the quality management system by collecting the following inputs: • process performance and product/ service conformity; • follow-up actions from previous management reviews • recommendations for improvement; 1.2 Based on this input, QM prepares a draft report to support the management review. 1.3 The draft report is discussed with the Quality Circle as well as at the departments´ management team meetings
Step 2 **QM, Management Team**	**2.0 Quality Management Review**
	2.1 QM places the item Management Review on the MT agenda and submits the draft report and deadlines by end of Jan n+1 The Management Review takes place through a meeting of EFSA's MT facilitated by QM. During the meeting EFSA's QMS is reviewed based on the evidence collected (listed under 1.1) and the report provided. 2.2 QM presents previous year´s quality performance criteria together with - performance against the criteria - proposal for improvement 2.3 MT to confirm performance targets for following year and agree on improvement actions to close the gap. The outcome will feed into the Quality Manager´s Report as a building block of assurance.
Step 3 **QM, Management Team**	**3.0 Monitoring of actions implementation**
	3.1 QM monitors the implementation of the actions decided at the MT during the Quality Management Review. A record of the monitoring is kept. 3.2 On MT request the QM reports on progress of the implementation.

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