Standard Operation Procedures	SOP_018
Effective Date: 27/07/2023	**Public**

Management of EFSA's Repository of governance and management documents

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. Deviations from the provision of this document need to be recorded in the Exception Request Workflow. The procedure should be updated when there are changes in EFSA with respect to what is stated in the document (e.g., Relevant Standards, legislation, and documents, change in procedure, etc.). The person responsible for maintaining this procedure up to date is the Lead author with the support of the QM.

Process Responsibility	Process owners are accountable this procedure being adhered to within their respective or unit. All relevant staff is responsible for the correct implementation of the procedure. Responsibilities for performing specific steps are outlined in the document.

SCOPE AND OBJECTIVES

This SOP covers the procedures to be followed regarding the management of EFSA's Hierarchy of Documents and the annual review of documents included in the Repository.
This SOP describes steps related to process **12.3 Quality Management**, and it applies to the development of documentation for all EPA processes
The **Hierarchy** of documents governing EFSA is a living list of normative documents (legal acts i.e., Policies, Implementing Rules, Processes/Procedures, Administrative Acts/Contractual Acts, WINs, Records, governance documents and management documents) that describe how EFSA operates. More detailed information is available in Annex 1, table 1. The **Repository** is the space in EFSA's Document Management System where most of these documents are stored (as shown in Annex 1).

RELEVANT STANDARDS, LEGISLATION AND DOCUMENTS

a) IMPRUL_060_Internal Control Framework of the European Food Safety Authority
b) ISO 9001:2015 Quality Management Systems
c) POL_003 EFSA's Quality Policy
d) POL_004 EFSA's Information Management Policy
e) POL_005 HSSE Management Policy
f) EFSA Process Architecture (EPA)
g) SOP 23 Control of Non-Conformities

ABBREVIATIONS AND DEFINITION

AA	Assurance Advisor
ADMACT	Administrative act refers to any decision or measure adopted by the authority in exercise of its official powers, formally and carrying the force of law, regarding legal relationships in respect of individually identified persons.
BAU	Business As Usual
CONACT	Contractual Act refers to a legally binding agreement that defines and governs the rights and duties between or among its parties or an Institutional agreement such as Memorandum of understanding (MoU)/Memorandum of cooperation (MoC)).
Corporate Documents Folder	Webpage on EFSA's intranet where all Documents included in the Repository of EFSA are posted (*http://www.efsa.europa.eu/en/aboutefsa/keydocs.htm*).
DMS	Document Management System
ED	Executive Director
EMPOWER	EFSA Management services Department
HoD	Head of Department
HoU	Head of Unit
IMPRUL (Implementing Rule)	Implementing rules (IRs) are binding in their entirety. They detail how to comply with the essential requirements of EU legislation or EFSA's policies, and regulate the subject matters included in its scope.
LA	EFSA Legal Affairs Services Unit
Lead Author	The person who has the most knowledge on the process/activity and thus is best place to draft the document. Usually, the process leader
Legal Framework	The Legal Framework contains all the legal acts by other institutions or governments defining the legal context within which the organisation must operate; (The documents on this level are not managed in the repository)
PII	Process Improvement Initiative
Policies	Policies define the guiding principles EFSA uses to direct its actions in pursuit of its overall objectives. Policies are proposed by the ED and approved by the Management Board (MB). This includes also the EFSA **Strategy document**, any document which sets out strategic and long-term goals for sectors of activities of EFSA.
POTI	Processes, Organisation, Technology, Information

Processes	Refers to a wide range of structured activities or tasks conducted by people or equipment to produce a specific service or product for a particular customer.
QCC	Quality Circle Correspondents
QM	EFSA Quality Management function
Records	Records are documents, irrespective of their format (including e-mails), that have been identified as records (as per EC Decision C(2020)4482, SEC 2020 800) because they must be maintained as evidence by EFSA in pursuance of legal obligations or in the transaction of business. For more information see EFSA Information Management Policy here (*The documents on this level are not managed in the repository*)
Repository	**The repository** will store documents that are designed to **assist** the organization in the **implementation** of its regulatory requirements, strategic goals and policies. They also **support staff** in **understanding** their processes and ensuring that these are **carried out correctly**, thus delivering a quality product/service in a consistent manner. The Repository can be accessed in the link below: 00. The repository of EFSA's governance documents (europa.eu)
RULOP (Rules of Procedure)	**Rules of procedure** are binding documents that tells us how a body/organ of EFSA works.
Scientific Guidances	Scientific assessment practices which guide and supports the experts in ensuring that EFSA's opinions and reports respect the highest scientific standards. They define the scientific rationale for evaluations and important scientific considerations such as data needs and formats, study design requirements and reporting standards.
SOPs	Standard Operating Procedures aim to achieve efficiency, quality output, and uniformity of performance, while reducing miscommunication and failure to comply with higher level regulations and documentation in the EFSA repository
Sounding Board	The sounding board ensures that the documents meet legal, internal control standards and ISO 9001:2015, as applicable. It is responsible for providing comments and advice in light of their role. Its composition can vary depending on the nature of the document to be discussed. The legal function will be consulted prior to the sounding board to ensure legal compliance, and feedback via written procedure is expected.
WIN	Working instruction - Detailed and written descriptions or/and workflows of how to perform and record tasks and activities which usually take place within one process /team or Unit. A WIN could also apply to several processes and Units from one or several EFSA Departments.
WD	Working Day

PROCEDURE 1 –ROLLING MANAGEMENT OF REPOSITORY OF DOCUMENTS	
This section outlines the lifecycle of documents in EFSA, i.e., procedures for identification for inclusion, drafting, reviewing, and approving of documents. Changes to documents can be triggered by several reasons e.g., change to a documentation / standard higher up in the repository (e.g., strategy, policy); changes to POTI elements stemming from a project, a PII or in BAU mode: new process or change to a process; changes to enabling technology/ tools, organizational changes)	
MANAGEMENT OF DOCUMENTS	
Step 1	1.0 Identifying a new document/required modification of a document
Lead author, QM, Sounding Board	1.1 The lead author consults the QM via the mailbox askgps@efsa.europa.eu, before starting the process of drafting a new document/updating an existing one. QM checks the repository to ensure that the new document or desired modification of existing document is in accordance with other existing documents, relevant standards and legislation and that there are no overlaps. 1.2 After performing the relevant checks, the QM informs the lead author on how to proceed. 1.3 In case of an existing document, the relevant lead author is consulted and the need for update is agreed upon with the support of QM. 1.4 QM will also perform a check to see if other documents will need to be updated based on this document.
Step 2	2.0 Drafting
Lead author	2.1 The lead author drafts the document in consultation with the appropriate stakeholders, using the relevant template (see Annex 2), ensuring the following: • all the sections of the template are filled in clearly indicating the process records, • filling in the document history box • making reference in the scope of the document to the corresponding EPA process code and name, • indicating in the relevant box (at the top of the document) if consultation with other Units/stakeholders is needed
Step 3	3.0 Reviewing
QM Lead author Sounding board	3.1 The draft document is shared with QM via askgps@efsa.europa.eu**.** If the lead author indicated the need of further consultation with other Units/ stakeholders the QM will distribute the document to those that need to be consulted, providing a deadline to receive feedback not more than 15 WD). 3.2 According to the nature of the document, the QM will decide if there would be further consultation with a Sounding Board (some documents e.g., all new SOPs, cross cutting WINs will always need Sounding Board consultation). The Sounding Board may be comprised of LA colleagues for review and regulatory advice, Assurance adviser and any other ad-hoc actors based on the nature of the document. In case of minor updates of an existing document, changes will be reflected in

	the History box. This will be managed centrally, and no re-signing or further consultation will be necessary. 3.3 Following consultation, the relevant lead author of the document shall address any points raised by either the QM or the Sounding Board. 3.4 Once all comments have been addressed the lead author shall share the final draft with the QM who would make any last checks to the document to ensure the compliance of the document submitted for approval and will assign the correct document reference number (For more details, see Annex 3).
Step 4	4.0 Approving
Approver, QM,	4.1 The final draft, after any remaining comments are addressed is to be sent by the lead author to the mailbox askgps@efsa.europa.eu. 4.2 The QM sends the document to the relevant actors for approval and signature according to the governance of the specific process. The QM will give indications of the level of approval of the document and advise/support the unit on the correct signature path 4.3 In case of rejection and/or suggestion of major changes to the document during approval, the lead author with the support of the QM will need to address the comments prior to approval.
Step 5	5.0 Inclusion and dissemination
QM	5.1 Once the document is signed, the QM will include the document in the Repository and update the Repository catalogue of governance documents, informing the lead author. 5.2 The QM communicates regularly during Quality Circle meetings any new document or change about existing document to the QC correspondents. Any documents that are no longer in force or superseded are maintained in the "No longer in force catalogue" available here. Depending on the nature and impact of the document further communication activities take place i.e., news on the portal, info sessions, trainings, etc. This is to be decided by the relevant lead author. 5.3 The QM maintains the various "catalogues" up-to-date to ensure that staff have access to the latest (i.e. active) versions of applicable documentation. The documents are stored in the Repository of EFSA's governance documents.

PROCEDURE 2 – ANNUAL REVIEW OF DOCUMENTS	
This section outlines the annual review of a document which is already included in the Repository	
Annual review	
Step 1	1.0 Identify the responsible actors for reviewing the documents
Lead Authors, QM	1.1 The QM will kick off the annual review exercise during the P2 of each year by identifying those documents that need to be revised, updated or archived. 1.2 The Lead authors/Process owner will receive an email asking to review the status of the identified documents. This feedback is to be received within 15 WD of receiving the email.

	1.3 If the Lead authors/ Process owner confirms a need to review and update the documents, a plan will be agreed with QM defining actors, deadlines etc. 1.4 If the Lead authors/ Process owner determines that no update is needed to the identified document, the reason behind this decision will be captured by the QM 1.5 The annual review exercise will finish once all the feedback from the Lead authors/Unit have been received and the follow up agreed. 1.6 The outcome of the exercise will be reported as part IMS cycle. 1.7 The drafting and update of the agreed identified documents will follow procedure 1.

ANNEX 1

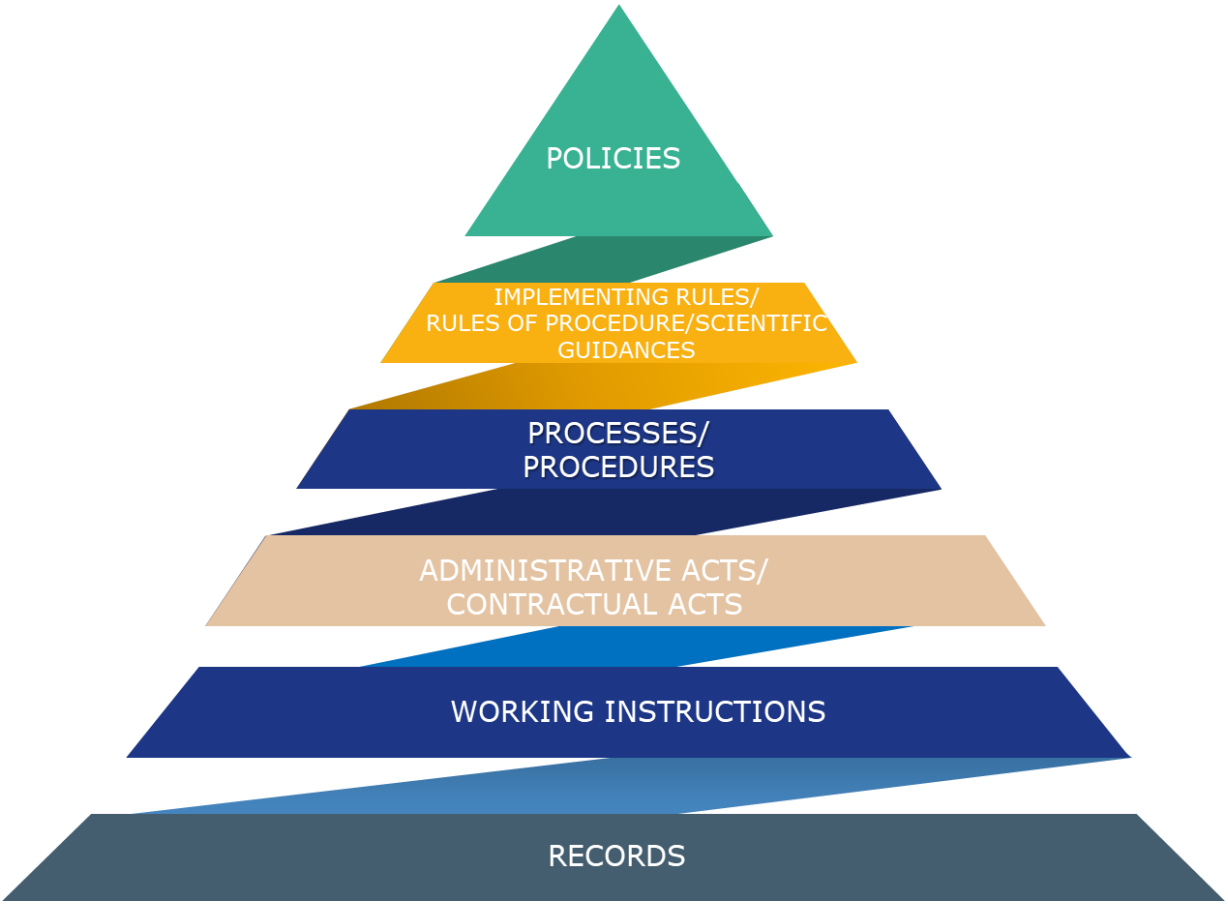

Table 1. Hierarchy of EFSA Documents

ANNEX 2

THE DOCUMENTS ARE LABELLED FOLLOWING THE CRITERIA BELOW:
Policies are named:
EFSA/ {UNIT NAME}/ POL_ {3 digit Identification number} _{YEAR}
Implementing Rules are named:
EFSA/ {UNIT NAME}/ IMPRUL_ {3 digit Identification number} _{YEAR}
Rules of Procedure are named:
EFSA/ {UNIT NAME}/ RULOP_ {3 digit Identification number} _{YEAR}
EPA Process Architecture is named:
EFSA/ {UNIT NAME}/ EPA _ {3 digit Identification number} _{YEAR}
SOPs are named:
SOP_ {3 digit Identification number}
Contractual Acts are named:
EFSA/ {UNIT NAME}/ CONACT_ {3 digit Identification number} _{YEAR}
Administrative Acts are named:
EFSA/ {UNIT NAME}/ ADMACT_ {3 digit Identification number} _{YEAR}
WINs are named:
WIN_ {2 digit SOP ID}/_{2 digit Identification number}