Standard Operation Procedures	SOP 023
Effective Date: 12/10/2023	**Public**

Registration and approval of exceptions and non-conformities

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

The requirement to approve, register and follow-up the exceptions and non-conformities is an essential step in EFSA's Management System. Aside from its relevance across all ISO standards, it is outlined within the Internal Control Framework- Control Principle 12, on the deployment of control activities through corporate policies.

The overall purpose is to monitor the compliance, implementation and effectiveness of EFSA operations towards all applicable regulations, policies, procedures and management standards. This monitoring will in turn allow corrective and preventive actions where required. It is therefore important to have a complete overview of deviations in order to be able to provide a corporate remedy reply.

The scope and concept of the exception and non-conformity workflow (Exception Request Workflow) covers all rules and regulations that are applicable to EFSA and all policies, procedures and management standards in force. For EFSA, all documents in the Hierarchy of documents will constitute a mandatory requirement, except for WINs[1].The ex-ante approval and documentation of exceptions is not intended to transfer or otherwise avoid responsibility for any decisions taken or authorise or condone decisions taken or transactions performed in breach of applicable regulatory or contractual provisions.

[1] Some WINs due to their nature may be also deemed "mandatory", and in these cases a clear indication of this will be made on the document itself

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RELEVANT STANDARDS, LEGISLATION AND DOCUMENTS

- IMPRUL_060_Internal Control Framework of the European Food Safety Authority
- IMPRUL_064_EFSA Financial Regulation
- IMPRUL_076_Decision of the Management Board of EFSA concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups
- ISO 9001:2015 Quality Management
- ISO 45001: 2018 OH&S
- ISO 22301: 2019 Business Continuity Management
- ISO 14001: 2015 & EMAS Environmental Management
- WIN/SOP23/01 For the registration, approval and follow- up of non-conformities
- WIN_SOP023_02 MP04- Non conformità, Reclami, Azioni correttive

ABBREVIATIONS AND DEFINITION

AA	Assurance Adviser
Deviation	Deviations from processes or procedures mean replacing one or more steps of a process or procedure with other actions or no action. A deviation is defined as an event in which 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. If a deviation is provided for an existing process or procedure, it does not constitute an exception or non-conformity, but a derogation and does not fall under the scope of the exception reporting.

[2] Some WINs due to their nature may be also deemed "mandatory", and in these cases a clear indication of this will be made on the document itself

DMS	Document Management System
ED	Executive Director
ERW	Exceptions Register Workflow
Exceptions (ex-ante deviation)	To be defined as exception, the event needs to fulfil the following conditions: i. It constitutes either an overruling or a deviation from established processes and procedures; ii. It is not foreseen in already existing processes and procedures (derogations in the mission area for instance); iii. It is approved by the responsible person before action is taken (ex-ante)
EFSA Management Standards	ISO 9001:2015 Quality Management ISO 45001: 2018 OH&S ISO 22301: 2019 Business Continuity Management ISO 14001: 2015 & EMAS Environmental Management
GPS	Global Performance Services
HoD	Head of Department
HoU	Head of Unit
HSSE	Health, Safety, Security and Environment
IA	Internal Audit
ICC	Internal Control Coordinator
QM	Quality Management
LA	Legal Affairs Services
Non-Conformity/ Non-compliance (ex-post deviation)	A non-conformity needs to fulfil the following conditions: i. It constitutes either an overruling or a deviation from established processes and procedures. ii. It might constitute a breach of existing regulatory and/or contractual provisions. iii. It has been detected after action was taken (ex-post).
SOP	Standard Operating Procedure

PROCEDURE

	Previous SOPs in the process: n/a
Step 1 (Outside ERW tool)	1.0 Identifying an exception or non-conformity

EFSA staff member	1.1 Any EFSA staff member can identify in the course of their work the need to deviate from any rule, regulation, policy procedure or any other mandatory requirement for the organisation (See Scope). 1.2 A deviation may arise via external sources (a. Complaints from interested parties, internal or external audits) or internally any EFSA staff member may identify or suspect through examination, internal verification, audit or control, a non-conformity to any rule, regulation, policy procedure or any other mandatory requirement for the organization. 1.3 As soon as the deviation is identified, the staff member needs to raise it without delay to the relevant line manager.
Step 2 (Outside of ERW tool)	2.0 Preliminary assessment of requirement to register exception
Relevant line manager, HoU, HoU Finance, HoD	2.1 The relevant line manager will need to decide if the identified issue qualifies as an exception as per criteria definition above. In case the line manager does not confirm the existence of an actual exception, the issue is closed and the procedure ends here. 2.2 In the case of a deviation the line manager will –based on advice of relevant stakeholders- assess the advisability of approving or not the ex-ante deviation. In case the exception is not approved the process stops here. 2.3 In case the deviation is approved the relevant line manager will then request the registration of the ex-ante deviation in the ERW within 15 working days. **Continue with step 4**
Step 3	3.0 Preliminary assessment of requirement to register non-conformity
Relevant line manager, HoU, HoD	3.1 The relevant line manager will need to decide if the identified issue qualifies as an exception as per criteria definition above. In case the line manager does not confirm the existence of an actual exception, the issue is closed and the procedure ends here. 3.2 Where the non-conformity represents a potential legal infringement the HoU will consult with LA before deciding on the appropriate corrective action(s) to be proposed. 3.3 If the non-conformity is confirmed, the line manager will then request the registration of the non-conformity in the ERW within 15 working days. **Continue with step 4**
Step 4 (ERW tool)	4.0 Registration in ERW
EFSA Staff member	4.1 When entering a deviation in the ERW, the following information must be included: i. The regulation, policy or procedure deviating from, or which would not be complied with, ii. The process where the deviation took place iii. The amount subject to the exception or non-conformity

	iv. The exceptional circumstances justifying the request v. The analysis of the root cause, assessment of the risks and corrective actions taken to mitigate them, vi. For non-conformities, the preventive actions, including owner and timeline, proposed to avoid reproduction of the non-conformity, vii. The reason for approving or rejecting the exception request will be substantiated in the overruling decision. (From ED decision) 4.2 The **exception** shall be introduced in the ERW tool and adequately documented. The accuracy and completeness of the provided information shall be validated by the respective Head of Unit. For **financial exceptions** having a financial impact or related to financial transactions, procurement & grants, expert compensation guide and mission guide, the workflow stops with the visa and approval to be provided: i. Up to an amount of EUR 2,500, by the Head of Finance; ii. Up to an amount of EUR 25,000, by the EMPOWER Head of Department; iii. or by the Executive Director. For **non-financial exceptions** related to Risk Assessment Production, Risk Assessment Services, Communication and Partnership, and Management Services, the workflow stops with the visa and approval to be provided: iv. by the Head of Department which the process or the procedure belongs to. 4.3 For **non-conformities/non-compliances** once the deviation is submitted in the workflow, the accuracy and completeness of the provided information shall be validated by the respective Head of Unit. The Head of Department assesses the information provided and approves the non-conformity. The registration process stops here. For HSSE For any extra information related to the follow up of non-conformities or any extra requirements that cannot be accommodated in the current tool, please see WIN_SOP023_02 MP04- Non conformità, Reclami, Azioni correttive
Step 5	5.0 Follow-up mitigating actions
Relevant EFSA staff member(s)	5.1 The relevant staff member(s) responsible for executing the corrective action(s) outlined when entering the deviation, will perform the actions within the predefined deadline. The line manager is responsible for ensuring that corrective actions are carried out in a timely manner. For HSSE For any extra information related to the follow up of non-conformities or any extra requirements that cannot be accommodated in the current tool, please see WIN_SOP023_02 MP04- Non conformità, Reclami, Azioni correttive

Step 6	6.0 Monitoring
GPS AA QM	6.1 Corporate level The GPS Unit is responsible for the monitoring of the exception workflow on an ongoing basis The AA with the QM function provides ad-hoc advice and unit level feedback on the approval process of all transactions and compliance with exception reporting procedures. The Exception Register is centrally analysed in GPS in order to identify potential systemic weaknesses, and to develop improvement actions together with Finance, HuCap, Competing Interest Management, and the respective EFSA Management Standards owners depending on the subject matter. 6.2 Ongoing monitoring at process level The responsible for each respective management standard regularly monitors the status of the deviation. - Once the actions are checked within the defined timeframe, and are deemed fit-for-purpose, the deviation can be closed. - If the actions are not deemed appropriate, or for some reason have not been performed within the agreed timeframe, the deviation will remain open.
Step 7	7.0 Reporting
	7.1 In the framework of the Internal Control Assessment, and the IMS review, the Accountability Council is provided with an overview of the Exception Register. 7.2 By analysing the outcome of the exception workflow based on the defined Internal Control monitoring criteria, the Accountability Council concludes on the materiality of deviations noted and effectiveness of the procedures in place. The Accountability Council can also decide whether the processes and procedures need adapting. 7.3 The corporate reporting on the outcome of the exception workflow is done on an annual basis in the IMS Report and the Annual Activity Report.
	Following SOPs in the process: n/a