	Standard Operating Procedure Receiving a request
Public	


Scope	<p>To enable the reception of an external request and the review and assignment of an external, internal or self-task request, and the encoding and updating of all appropriate information in the Risk Assessment Workflow (RAW) tool at EFSA.</p> <p>This SOP also covers responding to urgent advice requests.</p>
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Special Requirements	This procedure is a controlled document maintained by Quality Management. It may not be deleted without comparable controls.
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Responsibilities	<p>1.0 Allocation of the external request (HoD office – PCO)</p> <p>2.0 Review and assignment of external, internal or self-task requests (relevant Unit, PCO, relevant HoD, 4D)</p> <p>3.0 Acceptance of request in RAW and initiation of the scientific work - relevant Department(s), relevant Unit(s).</p>
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Abbreviations and definitions


APDESK	Applications Desk Unit centralising receipts of all applications for regulated products within EFSA
Application	An application is hereby defined by the mandate (from EC or MSs) and the technical dossier (set of data prepared by the applicant).
Completeness check	Administrative and preliminary scientific verification of the technical dossier, as appropriate
DMS	Document Management System
ED	Executive Director
EFSA	European Food Safety Authority
External request	A request that EFSA receives from i) the European Commission, a Member State National Competent Authority or the European Parliament to provide a scientific opinion or statement ii) the European Commission to provide scientific or technical assistance.

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4D	Heads of Department Meeting (RASA, REPRO, COMCO and BUS Departments)
HoD	Head of Department
HoU	Head of Unit
Internal request	A request triggered by an EFSA Unit to carry out scientific work or other non-scientific developmental activities that are not included in the established business as usual EFSA processes.
Mandate	A request for scientific advice or scientific and technical assistance, either as an external, internal or self-task request, which has been accepted by the EFSA ED.
Mandate mailbox	A functional mailbox, to manage and coordinate all mandates received, except those related to applications on regulated products.
MT	Management Team
PCO	Project Coordination Office - responsible for supporting the analysis of the impact of the incoming request on the EFSA work programme, identify which require Management attention and escalate to the proper EFSA governance body depending on the case recommending acceptance, rejection or postponement
RAW	Risk Assessment Workflow database.
	Electronic application covering the workflow from receiving a request to publishing the scientific output.
Self-task request	A request by the Chair of one of EFSA's Scientific Panels to EFSA to issue a scientific opinion within its sphere of competence'
ToR	Terms of Reference
WIN	Working instruction

Procedure


	Previous SOPs in the process: N/A
Step 1 Responsible: HoD Office, PCO, relevant Unit	1.0 Receiving, allocating, reviewing <u>external</u> requests other than application 1.1. External requests to initiate scientific work arrive to the mandate mailbox (mandate@efsa.europa.eu). NOTE: In case the request is in relation to an urgent food-related advice, the EFSA Procedures for responding to urgent advice need to be applied. 1.2. The Post Office initiates a Correspondence workflow forwarding the mandate to the e-group CorrWorkflow_Mandates composed by

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	<p>RASA/REPRO Dept. Offices and a PCO member from the GPS Unit.</p> <p>1.3. Members of the e-group forward the mandate with no delay to the relevant Unit e-group via the correspondence workflow.</p> <p>1.4. The designated person (or back-up) in the relevant Unit asks the relevant Department Office the creation of a mandate number(s) in RAW and, following the creation of the mandate, the Unit updates the RAW with relevant documents (see Register of Questions System Manual users for details).</p> <p>1.5. The Unit analyses the request and provides PCO, if necessary by creating a new charter in the Sciforma system (using a project/process/work package charter form), with information regarding the following:</p> <ul style="list-style-type: none"> - the request was planned/not planned; - issues on the ToR; - ability to implement the request or proposed amendments to the request; - additional information on the way the request will be implemented. <p>1.6. Once the Unit has provided PCO with the information, PCO reviews the information and:</p> <ul style="list-style-type: none"> - accepts and officially allocates the request to the relevant Unit(s), or - postpones acceptance and requests further information, or - recommends EFSA Management attention and escalates to the relevant Governance Body depending on the issue (relevant governance bodies could be a HoD, the 4D or the MT). <p>1.7. After the review of the requests, the PCO drafts and distributes the PCO meeting minutes to the PCO members for approval and publishes them on the EFSA Internal Portal.</p> <p>1.8. Following the recommendation by the PCO, the relevant Governance Body may in some cases review the requests and:</p> <ul style="list-style-type: none"> - approve the request with/without comments, - not accept the request. <p>1.9. The relevant Governance Body decisions are recorded in the PCO meeting minutes and made available on the EFSA Portal.</p> <p>1.10. In case of acceptance/non-acceptance of the request, the relevant Unit drafts the reply letter and forwards it for signature to the relevant Department in line with the Decision of the Executive Director concerning the delegation of decision rights with regard to correspondence and related signature rights in the regulated</p>
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	<p>products remit of the REPRO Department of the European Food Safety Authority (REPRO 2012/06/LA) or the Decision of the Executive Director concerning correspondence – signature level (14/02/2008) respecting the legal deadlines.</p> <p>1.11. The designated person (or back-up) in the relevant Department Office updates RAW with the relevant documents and asks the Unit to encode relevant information in RAW.</p> <p>1.12. The relevant Unit initiates the scientific work associated with the mandate within the Unit, or with the Scientific Panel/Scientific Committee, Working Group(s), Network or any other party, as relevant, and stores the relevant correspondence in the DMS.</p>
<p>Step 2 Responsible: PCO, relevant Unit</p>	<p>2.0 Receiving self-tasks or internal requests</p> <p>2.1 Self-task requests coming from Chair of the Scientific Panel/Scientific Committee arrive to the mandate mailbox (mandate@efsa.europa.eu).</p> <p>2.2 The Post Office initiate a Correspondence workflow forwarding the mandate to the e-group CorrWorkflow_Mandates composed by RASA/REPRO Dept. Offices and a PCO member from the GPS Unit.</p> <p>2.3 Members of the e-group forward the mandate with no delay to the relevant Unit e-group via the correspondence workflow.</p> <p>2.4 The unit analyses the Self task request and provides PCO, if necessary by creating a new charter in the Sciforma system (using the project charter form), with information regarding the following:</p> <ul style="list-style-type: none"> - the request was planned/not planned; - issues on the ToR; - ability to implement the request or proposed amendments to the request; - additional information on the way the request will be implemented. <p>2.5 Internal requests to initiate scientific work are directly submitted by Units to the PCO together with a project charter prepared by the Unit containing the following information:</p> <ul style="list-style-type: none"> - The request was planned/not planned; - Issues on the ToR;

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	<ul style="list-style-type: none"> - Ability to implement the request or proposed amendments to the request; - Additional information on the way the request will be implemented. <p>2.6 Steps 1.6 to 1.9 apply also to self-tasks and internal requests.</p> <p>2.7 For self-task mandates the Unit prepares a reply letter to the Chair of the Scientific Panel/Scientific Committee to be signed by the ED containing the acceptance/non-acceptance of the request. In case of non-acceptance of self-tasks or internal requests, this decision is recorded in the PCO meeting minutes and a letter prepared by the Unit to be signed by the ED informing the Chair of the Panel/Scientific Committee. For internal mandates the Unit is informed on acceptance/non-acceptance through the PCO register.</p> <p>2.8 Subsequently the designated person (or back-up) in the relevant Unit asks the relevant Department Office the creation of a mandate number(s) in RAW and, following the creation of the mandate, the Unit updates the RAW with relevant information.</p> <p>2.9 The relevant Unit initiates the scientific work associated with the mandate within the Unit or with the Scientific Panel/Scientific Committee, Working Group(s), Network or any other other party, as relevant, and stores the relevant correspondence in the DMS.</p>
<p>Step 3: Responsible: APDESK, relevant Unit</p>	<p>3.0 Receiving, allocating, reviewing requests related to applications on regulated products</p> <p>3.1 When the request is a mandate from the European Commission or the Member State to evaluate products within the scope of a sectoral food/feed law (Regulation), APDESK receives the mandate directly and performs the following actions: creates a mandate and question number(s) in RAW, uploads the mandate directly to RAW.</p> <p>3.2 APDESK as a rule sends a letter of acknowledgment of the receipt of the application. However, in some exceptional cases the acknowledgement is included in the acceptance letter (see 3.5) or no formal acknowledgment is required and the formal procedural tasks already set out in the vertical regulation are followed.</p> <p>3.3 The relevant Unit checks the information provided in the</p>

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	<p>request (e.g. ToR) for consistency and clarity.</p> <p>3.4 APDESK performs a completeness check of the data included in the technical dossier. In cases where APDESK, during completeness check, detects missing information (or, later during the scientific assessment phase, the relevant Unit requires additional information/ clarification), the appropriate letter is sent, in line with the Decision of the Executive Director concerning the delegation of decision rights with regard to correspondence and related signature rights in the regulated products remit of the REPRO Department of the European Food Safety Authority (REPRO 2012/06/LA) or the Decision of the Executive Director concerning correspondence – signature level (14/02/2008).</p> <p>3.5 In line with the same two ED Decisions mentioned in 3.4 here above, once the information is consistent and clarity is achieved on the technical dossier and the ToR, and where required by the applicable legal framework, APDESK or the relevant Unit sends a letter of acceptance.</p>
	<p>Following SOPs in the process:</p> <p>SOP_005_S on Managing meetings</p> <p>SOP_006_S on Establishing, updating and closing a scientific WG</p>