	Standard Operating Procedure Provision of Legal and Regulatory Advice (Promoting Legality and Regularity)
Public	


Scope	<p>This SOP covers the provision of legal and regulatory advice, delivered upon request by LA as the central reference point for legal and regulatory advice in EFSA. Hence, the legal and regulatory business support is a service offered to all EFSA's Departments for their operations in case of need. The legal and regulatory advice also serves the purpose of enabling EFSA's Management to take timely informed decisions in compliance with European Union Law and the principles of good governance.</p> <p>Unless SOPs for specific legal or regulatory issues are in place (see list below), this SOP applies to internal requests for legal or regulatory advice addressed to LA within the framework of EFSA's activities deriving from its Founding Regulation (EC) No 178/2002 and from its status as a regulatory Agency of the European Union.</p>
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Special Requirements	<p>This procedure is a controlled document maintained by Quality Management. It may not be deleted without comparable controls.</p> <p><i>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</i></p>
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Responsibilities	<p>The HoU LA is responsible for the processing of requests for legal and regulatory advice and the legal assessments provided by LA to EFSA.</p> <p>The responsibility for the dossier for which legal or regulatory advice has been sought is assigned to the requesting Department/Unit and not transferred to LA. Therefore, the requesting Department/Unit remains responsible for managerial decisions in the matter. Likewise, it is the requesting Department's/Unit's own authority to follow the legal/regulatory advice or to deviate from it.</p> <p>Within the timeframe when dealing with the dossier, the requesting Department/Unit shall ensure the timeliness of a legal or regulatory request submitted to LA</p>
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Abbreviations and definitions


Decision	Refers to an implementing act either from the MB, the ED or delegated staff, specifying a course of action(s) and laying down in a prescriptive manner detailed provisions for its operational implementation.
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ED	Executive Director
HoD	Head of Department
HoU	Head of Unit
Legal and Regulatory Advice	Legal advice consists in a sound legal opinion to an enquiry that demands a legal assessment. Based on legal expertise, regulatory advice refers to policy matters concerning EFSA's corporate framework as well as to operational matters in EFSA's remit that shall be regulated.
LA	EFSA Legal and Assurance Services
MB	Management Board
Policies	Define the guiding principles EFSA uses to direct its actions in pursuit of its overall objectives.
QM	EFSA Quality Management
SOPs	Standard Operating Procedures - prescribe the operational steps to be followed to implement the legal acts, strategies and decisions.

Procedure


	Previous SOPs in the process: N/A
Step 1	1.0 Launching a legal/regulatory request
Desk Officer	<p>1.1 The Departments/Units shall consult LA whenever they face a legal or regulatory issue that demands a legal assessment.</p> <p>1.2 The requester shall identify and describe as precisely as possible the legal/regulatory question(s) at hand.</p> <p>The requester shall deliver, together with that question(s),</p> <ul style="list-style-type: none"> -all relevant facts, including dates and deadlines, -documentation or references to EFSA's work or project concerned, which are necessary for LA to properly understand the context and the issues at stake in order to legally assess the issues raised. <p>Moreover, the requester shall:</p> <ul style="list-style-type: none"> - indicate the preferred solution (if so) and in this case, give

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	<p>reasons for the preferred outcome, answer or way forward, - be available for any further consultations (e.g. for clarification, need for additional information or documents related to the issues, discussion of options, use of margins, identification of legal risks).</p> <p>The requester sends the request for legal or regulatory advice to the centralised functional mailbox legal@efsa.europa.eu , managed by the HoU LA and the LA Secretariat. The Legal Officer who is the contact person for the Unit or Department concerned, according to assignment, shall be put in copy ('cc').</p>
Step 2	2.0 Processing the legal/regulatory request
HoU LA Legal Officer	<p>2.1 The HoU LA assigns the handling of the request to a Legal Officer. If the Legal Officer in copy of the request is the competent officer to deal with the question he/she processes the analysis of the case promptly informing the HoU and/or the LA Secretariat, unless the HoU LA assigns the case to another case handler. The Legal Officer assesses all the legal and regulatory aspects which are relevant for answering the request in the light of EFSA's legal and regulatory framework, procedural aspects, Union legislation and case law.</p> <p>2.2 As a general standard, legal/regulatory advice will be provided within 15 working days, as of the day after receipt. The Legal Officer who deals with the file shall keep the requester informed of the work progress. If the case is complex or if the legal assessment requires dedicated research or more time for some other reason, the Legal Officer promptly informs the requester until when the deadline is extended.</p> <p>2.3 Enquiries which are indicated as urgent shall be handled as soon as possible by LA, when possible within two working days from the receipt. Urgency shall be specifically justified by the requester. LA will prioritise requests with legal deadlines or particular urgency. By proper planning and other preventive measures, the requesting Departments/Units ensure to consult LA at an early stage, not too close to the deadlines.</p> <p>2.4 If needed for the legal opinion, LA requests contributions for further assessment by other Units/Departments within an appropriate timeframe, depending on the deadlines mentioned above</p>
Step 3	3.0 Legal/regulatory advice

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HoU LA Legal Officer	<p>3.1 The legal or regulatory advice, as the final output of the legal assessment by LA, shall meet the business needs and address the requester's need for clarification, by highlighting and assessing legal and reputational risks and, if deemed necessary, by outlining mitigating measures. In case the preferred solution cannot be chosen on legal grounds, LA shall outline alternatives.</p> <p>3.2 Upon approval of the HoU LA, the competent Legal Officer sends the final LA opinion by email to the requesting Department/Unit, by taking the centralised functional mailbox of LA in copy and, in important and sensitive cases, additionally the HoU LA. In case of urgent legal advice according to 2.3, the Legal Officer shall also take the Head of the requesting Unit/Department in copy. By way of derogation, the HoU LA can decide to dispatch the final LA opinion himself.</p>
Step 4	4.0 Implementing the legal/regulatory advice/Follow-up
HoU/Desk Officer	<p>4.1 The requesting Department/Unit is responsible for taking an informed decision for the specific dossier, based on the legal or regulatory advice. The Department/Unit is also responsible for all implementing measures. In case of need, LA helps with the legal/regulatory implementation, e.g. drafting support of legal or regulatory texts, and interpretation.</p> <p>4.2 LA shall be included in the signature workflow when the dossier is validated and submitted to Senior Management for decision. The requesting Department/Unit keeps LA informed of how the legal/regulatory advice is taken into account in the operational follow-up, by sending a copy of the final document to LA's functional mailbox or by summarising the final outcome in an email to LA's mailbox.</p>
	Following SOPs in the process: N/A

 <p>European Food Safety Authority</p>	<p>Standard Operating Procedure Provision of Legal and Regulatory Advice (Promoting Legality and Regularity)</p>
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Annex 1

WORKFLOW FOR LEGAL/REGULATORY REQUESTS

