

	Standard Operating Procedure Handling and processing of external complaints
Public	

Scope	<p>This Standard Operating Procedure (SOP) lays down the procedure to be followed by EFSA regarding the handling and processing of complaints brought up against the Authority by external parties. Its aim is to ensure a consistent and uniform approach to the way these complaints are to be handled, processed and reported: that is promptly and in an effective and fair manner. This SOP lays down the workflow to be followed by EFSA from the reception of the complaint to the dispatch of a reply to the complainant within a given deadline. It does not apply to matters to be raised under other relevant EFSA procedures (requests for public access to documents, for confidential treatment of information, etc.).</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>
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Responsibilities	<p>The responsibilities for the implementation and execution of this procedure are identified under the title “Procedure”, herein below.</p> <ul style="list-style-type: none"> • Any EFSA Unit may receive an external complaint. • The processing of external complaints and the related legal assessment lies within the responsibility of the LA Unit. • All other Units/Departments considered by LA as supportive for the legal assessment and resolution of the complaint shall actively assist LA in this task. • The adoption of the final reply to the complainant lies with the ED. • The LA HoU is the owner of this SOP.
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Abbreviations and definitions

APDESK	Applications Desk Unit
BCC	Blind Carbon Copy
CC	Courtesy Copy
DMS	Document Management System
EC	European Commission
ED	Executive Director
EFSA	European Food Safety Authority
EO	European Ombudsman
EU	European Union

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EXREL	External Relations Unit
External Complaint	Expression of protest or dissatisfaction by one or more parties external to EFSA, in the present context against EFSA’s decisions, behaviours or omissions related to administrative practices, policies, strategies, scientific assessments, including the related scientific opinions and/or, in general, regulatory and implementing acts adopted either by the MB or the ED.
HoU	Head of Unit
LA	EFSA Legal and Assurance Services
MB	Management Board
Policies	Guiding principles EFSA uses to direct its actions in pursuit of its overall objectives.
SOPs	Standard Operating Procedures – Detailed, written instructions aiming at achieving uniformity in the performance and quality of a specific process followed to implement legal acts, strategies and decisions.
Sufficient information	Understood in the present context as including: <ul style="list-style-type: none"> • the identity of the complainant (employer/organization if relevant, contact information), • the reason for the complaint, • the result hoping to be achieved, and • any relevant supporting documentation or references to relevant documentation (link, product name, reference number, document, etc.).

Procedure

	Previous SOPs in the process: n/a
Step 1	1.0 Receipt and channeling of an external complaint
LA or any other EFSA Unit/Team.	<p>1.1 EFSA may receive complaints either by email through the “EFSA complaint mailbox” (complaints@efsa.europa.eu), through a letter or email addressed to any EFSA Unit/Team, or as part of a public consultation on draft versions of EFSA's scientific assessments and institutional initiatives.</p> <p>1.2 EFSA shall only process complaints submitted in writing: those addressed to EFSA orally (e.g. by phone call) shall not be acknowledged as such. However, the complainant shall be informed of the need to submit a written complaint.</p>

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	<p>1.3 The EFSA Team/Unit receiving the complaint channels it immediately to the “EFSA complaint mailbox” (complaints@efsa.europa.eu) and notifies the complainant of this transfer by indicating the name and telephone number of the HoU LA.</p> <p>1.4 In case of doubts regarding the nature of a correspondence received by an EFSA Unit/Team, that Unit/Team shall consult with LA to determine whether the correspondence should be considered as a complaint or not.</p> <p>1.5 Complaints must be handled with an appropriate level of confidentiality in accordance with the complainant’s request for confidentiality, if any. Information must only be released on a need-to-know basis in view of the preparation of the response to the complaint.</p>
Step 2	2.0 Acknowledgement of receipt
HoU LA; LA.	<p>2.1 The HoU LA allocates the complaint to a legal officer within LA.</p> <p>2.2 LA shall respond to complaints submitted by any natural or legal person, any association or other body, whether Member State citizen or not, whether with residence or registered office established in a Member State or not, as well as cases involving multiple complainants.</p> <p>2.3 LA shall only process complaints if:</p> <ul style="list-style-type: none"> i. submitted two years from the date on which the complainant was informed of or learnt about the facts on which the complaint is based. In case a complaint is not submitted on time, the complainant shall be informed of EFSA’s decision not to process it; and ii. concerning matters of legal relevance or instances of maladministration. <p>2.4 LA acknowledges receipt of the complaint in writing within two weeks from its receipt, without being obliged to acknowledge receipt of a complaint if a substantive reply can be sent to the complainant within two weeks or if the complaint lacks of sufficient information (e.g. contact information), is abusive, excessive in number, repetitive or of pointless character.</p> <p>2.5 Within the acknowledgement of receipt of the complaint, the complainant shall be informed of the name and contact details of the</p>

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	officer handling his/her complaint and the deadline by when the complainant should expect a reply at the latest, that is in principle within two months, however depending on the complexity of the case (see 6.1).
Step 3	3.0 Evaluation of the external complaint
LA; any other EFSA Unit/Team concerned.	<p>3.1 LA analyses the external complaint by assessing the matter submitted for its consideration in the light of EFSA’s legal and regulatory framework, procedural aspects, Union legislation and case law.</p> <p>3.2 The designated legal officer shall determine the scope of the complaint, such as:</p> <ol style="list-style-type: none"> i. what specifically the complaint is about, ii. what the complainant wants to achieve by making the complaint, and iii. whether the complainant’s expectations appear to be reasonable and achievable. <p>3.3 LA consults the relevant EFSA Units/Teams concerned by the complaint on its substance and verifies the additional background documents if needed.</p>
Step 4	4.0 Request for clarification or additional information
LA	<p>4.1 In order to be able to investigate the concerns raised and make meaningful inquiries, LA may only evaluate complaints containing sufficient information - as defined in the above chapter “Abbreviations and definitions” -, including any relevant documentation.</p> <p>4.2 At any stage of the procedure, LA may request from the complainant further information, additional documentation or clarifications.</p> <p>4.3 If the complainant does not provide sufficient collaboration or information to enable further action, LA may decide not to pursue the complaint further and inform the complainant thereof. LA may also propose to take a decision or course of action based on the available information.</p> <p>4.4 In case the complainant’s expectations appear to exceed what</p>

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	<p>EFSA can reasonably provide or are not within the Authority’s power to provide, the complainant shall be advised of this as soon as possible in order to manage expectations about possible outcomes.</p> <p>4.5 If maintaining confidentiality as requested by the complainant means that the review of the complaint cannot be processed, EFSA shall inform the complainant accordingly.</p> <p>4.6 To the extent possible, LA will explore the possibility to reach an amicable solution to address the complaints.</p>
Step 5	5.0 Drafting of the EFSA Reply
ED; LA; any other EFSA Unit/Team	<p>5.1 At any stage of the procedure, LA may request contribution/feedback/advice for further assessment by other Units/Teams or by any person that may be directly affected by the complaint and sets an appropriate deadline for the reply. For sensitive cases, LA may also seek for advice on the position to be taken in EFSA’s reply.</p> <p>5.2 LA prepares its assessment based on the input received and the applicable procedures, legislation and case law.</p> <p>5.3 Upon completion of the assessment, LA prepares the draft reply and a draft note to the ED explaining its findings and EFSA’s proposed position as well as any lesson that may be learnt from the arguments or information shared by the complainant. The proposed course of action may:</p> <ul style="list-style-type: none"> • redress fully or partially the external complaint; and/or • reject fully or partially the complaint <p>5.4 LA shall indicate in its answer the means available to the complainant, if unsatisfied of EFSA’s reply: lodging a complaint with the EO in accordance with Article 228 of the Treaty of the Functioning of the European Union or challenging the legality of EFSA’s decision at the conditions set out in Article 263 TFEU.</p> <p>5.5 The ED endorses the draft reply with or without changes.</p> <p>5.6 LA informs the media relation mailbox (teammediarelations@efsa.europa.eu) of the upcoming reply in case of</p>

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	<p>sensitive complaints which may lead to media coverage. As far as possible and needed, the media relation team shall be kept updated during the drafting of the EFSA reply, in order to anticipate a potential reaction from the media.</p>
Step 6	6.0 Dispatching of the EFSA Reply
LA; any other EFSA Unit/Team	<p>6.1 Upon approval by the ED, LA dispatches the reply to the complainant within two months from the date of receipt of the complaint, unless a longer period is justified by the complexity of the matter (e.g. need for clarification or additional information). In that case, the complainant shall be informed thereof as soon as possible and a reply to the complaint shall be sent within the shortest time.</p> <p>6.2 LA puts the media relation mailbox (teammediarelations@efsa.europa.eu) in CC or BCC of the communication sharing the reply with the complainant.</p> <p>6.3 LA stores evidence of the dispatch and receipt of the reply in the unit DMS.</p> <p>6.4 If needed, EFSA shares the reply with any internal or external stakeholder, as far as compatible with the complainant request for confidential treatment, if any.</p> <p>6.5 If EFSA shares its reply with an external stakeholder, masking of personal data including signature is mandatory prior sharing.</p>
	Following SOPs in the process: n/a