



Quality Policy

Trusted science for safe food

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EFSA's Quality Policy

Scope of EFSA's Quality management system

The European Food Safety Authority (EFSA) contributes to the safety of the food chain from farm to fork, protecting human life and health, taking account of animal health and welfare, plant health and the environment as mandated in Regulation 178/2002. It does so by delivering independent and transparent scientific advice to policy makers, through cooperation with EFSA's partners, and in an open dialogue with society.

In order to deliver upon its mission with quality every day, EFSA has built an integrated Quality management system, based on international norms and implemented by a continuous commitment of its management community.

EFSA's integrated Quality management system ensures delivery of products and services that meet the needs and expectations of customers and stakeholders. Wide ranging engagement with risk managers, the scientific community, applicants, and citizens organisations via an ongoing transparent dialogue help understand and respond to the customer and stakeholders needs.

To ensure meeting customer requirements and enhancing customer satisfaction, the Authority has put in place an ISO 9001:2015 Quality management system, built on the seven ISO quality principles of Customer focus, Leadership, Engagement of People, Process Approach, Improvement, Evidence based decision making and Relationship management. The scope of the Quality management system covers all of EFSA's operations:

"The development and provision of independent scientific advice, information and risk communication in the areas of food, feed and emerging risks¹ according to the European Parliament and Council Regulation No178/2002 and its supporting functions" (excerpt from ISO 9001:2015 certificate)

¹ This covers all of EFSA's mission

1. Policy aim

The Quality Policy is the document from which EFSA's Quality management system is derived. It provides the basis for establishing and reviewing EFSA's quality objectives. The policy is built on EFSA's core values and it guides staff, external experts and other parties involved in the production and communication of EFSA's scientific advice. The Policy is designed to cover EFSA's core, enabling and management processes as defined in the EFSA Process Architecture.

The Policy also describes the essential ingredients of EFSA's scientific products and services (methods, expertise and data). The management of these is essential to assure product quality and continual improvement of EFSA's processes.

2. EFSA's Regulatory science environment

EFSA produces scientific advice for regulatory purposes. Different to hypothesis driven academic research, our scientific work provides answers to specific questions to support decision making by risk managers. Our work is done within a legislative framework and a timeframe set by risk managers.

Scientific advice for regulatory purposes comprises processes of scientific assessment and communication. Generally, it starts with problem formulation and defining an assessment approach, followed by collection, appraisal, synthesis and integration of evidence.

The main product is published scientific advice in the form of scientific outputs, that replies to the original question. The process ends with communication of both the approach and the results of the assessment.

EFSA's customers are the entities listed in the founding regulation that can mandate the Authority to produce advice: the European Commission, the European Parliament, the EU Member States and EFSA itself.

3. Customers' needs and expectations

As set out in ISO 9001:2015, the concept of quality is intrinsically linked to meeting the needs of an organization's 'customers' and ensuring continual improvement, while reflecting the organisation's core values in its processes.

3.1. Scientific advice

EFSA shall ensure meeting the expectations of its customers when requesting scientific advice, with the fulfilment of the following interdependent elements:

- Fitness for purpose: to adhere to and provide a comprehensive answer to the terms of reference, allowing for a full understanding of the uncertainties, assumptions and weight of evidence, and providing a clear basis for regulatory action
- Timeliness: to deliver within the agreed deadline
- Clarity, coherence and consistency: to be clear, comprehensible, and consistent throughout the scientific advice, facilitating risk management,
- To deliver the mutually agreed '**scientific value**'



“Scientific value” is defined in this context as the extent to which the following interdependent value components are fulfilled beyond standard minimum requirements during the assessment and process², captured in the final product:

- Impartiality (minimising risk of bias and maximising objectivity)
- Methodological rigour (minimising errors and maximising representativeness)
- Transparency (accessibility of inputs, intermediaries and outputs)
- Engagement (engagement of stakeholders and open dialogue)

Agreement about the scope of the question and the demanded extent of scientific value must be achieved between the customer and the Authority. These factors are also the main drivers for time and resources needed to deliver the work.

3.2. Communication of advice

EFSA shall ensure meeting the expectations of its customers for risk communication with the fulfilment of the following interdependent components:

- Fitness for purpose: to communicate in a way which faithfully reflects the scientific output, and to provide information which is tailored specifically to the intended audience(s) to ensure clarity, comprehensibility and meaning
- Timeliness: to deliver communication without undue delay
- To deliver the mutually agreed **“communication value”**

“Communication value” is defined in this context as the extent to which the following interdependent value components are fulfilled beyond standard minimum requirements and captured in the final product:

- Coherence (consistency of the messages throughout the risk analysis process)
- Reach (coverage of target audiences)
- Methodological rigour (communication planning, monitoring, research and evaluation)

The level of communication value is set by EFSA considering the needs of customers and society and the availability of resources.

3.3. Management and enabling services

EFSA shall ensure that its management and enabling processes provide services and products that meet the expectations of both external (e.g., EU Institutions) and internal (e.g., EFSA staff, experts, Member States) customers, with the overarching aim to assure the achievement of EFSA’s core processes described above, i.e., the provision and communication of scientific advice.

² Applicable to the “ingredients” of EFSA’s assessment process i.e. methods, expertise, and data:

- ‘Methods’ refer to any practice applied in a step of the process (e.g. a model, search strategy, expert knowledge elicitation method, a reporting standard, a public consultation)
- ‘Expertise’ concerns the competencies in a particular field that are required to complete a given task. In EFSA, competencies may derive from the Authority staff, together with all its partners with whom it cooperates, i.e. its independent experts (e.g. from panels or working groups), the Member States if they are actively participating in the scientific assessment, its contractors when outsourced projects are involved; ad hoc expertise via engagement practices.
- ‘Data’ is the information contained in a set of qualitative and quantitative variables, which are used as evidence for knowledge production, dissemination, and scientific decision-making.

4. Implementation of the Quality Policy through EFSA's Quality management system

EFSA's Quality management system provides the framework to assure and continually improve quality across all EFSA processes. The Quality management system helps the implementation of our activities via relevant documentation, such as its process architecture, policies, procedures and working instructions.

5. Responsibilities and Accountabilities

EFSA's Senior Management³ is accountable for establishing the Quality Policy and Quality objectives in line with EFSA's Founding Regulation and the organisation's Strategy document.

The EFSA Executive Director ensures the effectiveness of the Quality management system and the integration of its requirements into the business processes. This is done by applying a risk-based approach, i.e., identifying the processes and their criticalities and calibrating the effort according to the related risk. Furthermore, the Senior Management ensures that the processes needed for the Quality management system are in place. It also communicates the importance of conforming to the Quality management system requirements and supports the delivery of results.

EFSA staff and external experts including Member State representatives are responsible for adhering to the relevant policies and procedures.

EFSA Quality Management function maintains the Quality management system, drives the continual improvement process, verified through feedback, and provides advice to all staff on quality-related issues.

6. Entry into force and review

This policy will come into effect as of the date of its adoption by EFSA's Executive Director. It shall repeal and replace the previous version of the Quality Policy of 13th July 2016.

The Quality management system will be reviewed by EFSA's Senior Management at least once a year to ensure its continuing suitability, adequacy, effectiveness, and alignment with the EFSA Founding Regulation and Strategy. This Policy will be updated as needed to reflect any substantial change to EFSA's Quality management system.

³ EFSA Senior Management is composed of the Executive Director and the Heads of Department and refers to the "Top Management" as described in the ISO 9001:2018 standard.

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