



Information on Commission's evaluation of EFSA's performance (2017-2024)

November 2024

DG SANTE, Unit E1

Background



EFSA conducted and published external evaluations in 2005, 2012 and in 2018



In 2012, the **Common approach towards decentralised agencies** =>the Council, Parliament and the Commission agreed to include provisions on **external evaluation by the Commission** in agency's founding act



Regulation (EU) No 2019/1381 ('the Transparency Regulation') amended Reg. (EC) No 178/2002 (GFL) to strengthen the transparency and sustainability of the EU risk assessment in the food chain (entry into application in March 2021) => **The Commission shall evaluate EFSA's performance (Art. 61(2) and (3) GFL) by 28 March 2026, and every five years thereafter**

EFSA's performance evaluation 2017-2024

Purpose and scope

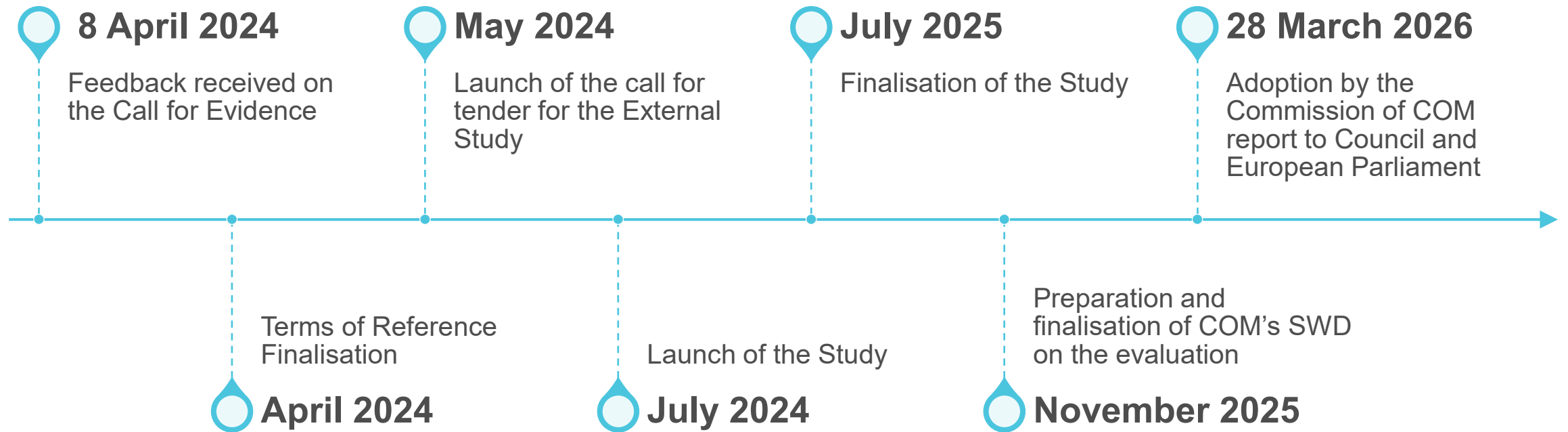
Evaluation period
2017 - 2024

**Before and after the
Transparency
Regulation**

Assess the
**effectiveness,
efficiency, relevance,
coherence, EU added
value of EFSA**

- Evaluation of EFSA's performance in relation to its **objectives, mandate, tasks, procedures and location**, in accordance with Better Regulation Guidelines (Art. 61(2) GFL)
- It should also cover:
 - the impact of “**Pre-submission advice**” by EFSA staff to applicants or notifiers (Art. 32a GFL) on the functioning of EFSA (Art. 61(2) GFL)
 - the possible **need to modify the mandate** of the EFSA, and the financial implications of any such modification (Art. 61(2) GFL)
 - whether the **organisational framework of EFSA** needs to be further updated with regard to decisions on requests for confidentiality and confirmatory applications, namely by setting up a specific Board of Appeal or by other appropriate means (Art. 61(3) GFL)

Indicative timeline for the Evaluation



Effectiveness (examples of assessment areas)

- **EFSA's ability to deliver robust, clear, actionable and timely advice**
 - Scientific robustness of EFSA scientific outputs (availability of experts ensuring scientific excellence, comprehensiveness of sources, data availability etc.)
 - Clarity, and 'conclusiveness' of scientific outputs
 - Timeliness (considering industry / market consequences, especially for SME)
 - Usefulness for risk managers (authorisations, policy development etc.)
 - Impact of EFSA on harmonisation of risk assessment methodologies
- **Compliance with fundamental principles (Transparency, Independence, Confidentiality, Cooperation)**
 - Openness, transparency, access to document and confidentiality - before and after TR
 - Effectiveness and sustainability of the independence policy, and impact on expertise
 - Enhanced cooperation/partnership with MS risk assessment bodies, opportunities and challenges
 - Increased outsourcing to Art 36 organisations, procurement > opportunities and challenges
- **Risk communication and overall engagement efforts throughout the risk analysis process**
 - Performance of EFSA's communication activities, shared responsibility with COM, coordination
 - Stakeholder engagement and use of tools (public consultation, pre-submission advice)

Efficiency (examples of assessment areas)

- **Evolution of human and financial resources available to EFSA**
 - Sufficiency in the face of changing tasks and workload (consequence of TR)
 - Efficiency in the use of resources to meet demands and needs, especially regarding outsourcing of risk assessments, and use of Panels
- **Changes to EFSA's governance (e.g. EFSA MB) and organisational structure**
 - Impact on performance and efficiency in delivery because of these changes (EFSA MB, KPIs, org. structure, provision of IT services...)
 - Efficiency in adoption and adaptation to these changes
- **Efficiency of operational processes, in particular:**
 - Timeliness of the Risk Assessment process (number of open questions (backlog), avg. time to adoption) – and reasons for delays
 - Use of IT and new data sources
- **Impact of the implementation of Transparency Regulation on EFSA's organisational and operational efficiency**

Relevance

- **Overall relevance of EFSA's mandate as set out in its founding regulation and sectoral legal acts?**
- **Assessment of EFSA's relevance objectives and mandate in light of stakeholders' needs, namely:**
 - EU / national risk managers (for risk management decision – e.g. authorisation, and/or policy development)
 - EU / national risk assessors
 - EU / national risk communicators
 - other stakeholder groups (businesses including SMEs, civil society and consumers, academia, professionals and the general public)
- **Evolving and future needs and challenges:**
 - Relevance of cooperation efforts to develop a harmonised risk assessment culture
 - Relevance of projects undertaken by EFSA and their added value for EFSA's work (in terms of data gaps/needs etc)
 - Assessment of scientific, digital and political challenges and opportunities >>> growing science complexity (e.g. toxicology), larger quantity of data, AI technologies, enlargement process, etc.

Coherence and EU Added Value (examples of assessment areas)

➤ Coherence

- Development of synergies and strengthened coordination with EU and MS bodies:
 - ENVI agencies >>> on policy frameworks (e.g., One Health approach, EU Chemicals Strategy and One Substance-One Assessment package, etc.), methodologies, IT, organisation (HR), etc.
 - the Commission, the Parliament and MS bodies (incl. on risk communication)
- Assessment of EFSA's internal coherence:
 - Internal coherence of risk assessment outputs/risk communication outputs
 - Coherence in the use of harmonised methodology across Panels
 - Coherence in the use of Scientific horizontal'/sectoral guidances by Panels

➤ EU Added Value

- EFSA's added value in comparison to what could have been achieved at national level without EFSA
- Contribution of EFSA work to the competitiveness of EU businesses globally
- Added value of EFSA international cooperation
- Support to the pre-accession process through capacity building

Consultation strategy - activities



Call for evidence



a **public consultation** of 12 weeks on the Commission's 'Have your say' website in the 3rd quarter of 2024 in all EU official languages



targeted consultation activities with EU and national risk managers as well as national risk assessment bodies



targeted consultation activities with stakeholders

Stakeholder consultation strategy (summary)

Main groups	Call for evidence	Public consultation	Targeted survey	Interviews	Focus group	Validation workshops
EFSA staff and governance bodies (MB, AF, management, staff)	✓	✓	✓	✓		
Risk Managers, Risk assessors and Institutional Cooperation Partners (EC, EP, MS, other EU and MS agencies, IOs)	✓	✓	✓	✓	✓	✓
EFSA scientific contributors (Panels, Committee, WGs, Art. 36 orgs, contractors, scientific networks)	✓	✓	✓	✓		✓
Other stakeholders (incl. consumers, NGOs, farmers, food industry, media, citizens...)	✓	✓	✓	✓	✓	✓

Interviews and surveys

Public Consultation (PC)

- Compliant with **Better Regulation Guidelines** (all EU languages, open for at least 12 weeks, etc.)
- Limited length and complexity
- To be launched in mid-December

Targeted survey (TS)

- Addressed at **all key stakeholders**
- **More comprehensive and technical** than the PC questionnaire, more open-ended questions
- **Modular design** to facilitate routing and 'self-customisation'
- **Potential respondents**; mostly identified with the support of EFSA
- To be launched by the end of November, open for 6 weeks (extendable)

Other tools

- **Call for Evidence** (analysis of responses already completed)
- Online **focus group** (20 participants)
- Two validation **workshops** (hybrid mode)

Interviews

- **70 in-depth interviews** (incl. exploratory interviews)
- To be conducted mostly after completion of targeted survey (except interviews related to case studies)

Category	Specific entities	No. of interviews
EFSA staff and governance bodies	MB Members - current and former AF Members EFSA Management	15-20
Risk Managers, Risk Assessors and Institutional Cooperation Partners	Commission ENVI Committee members PAFF Committee and expert groups National Focal Points EFSA 'sister' agencies (e.g. ECHA, EMA) National risk assessors International organisations	20-25
EFSA scientific contributors	Scientific Panel / Committee experts ART 36 organisation representatives Scientific networks coordinators	10-15
Other stakeholders	EFSA Stakeholder Forum/Bureau and Members of the Advisory Group on Sustainability of Food Systems	15-20
		Min. 70

Desk work and case study

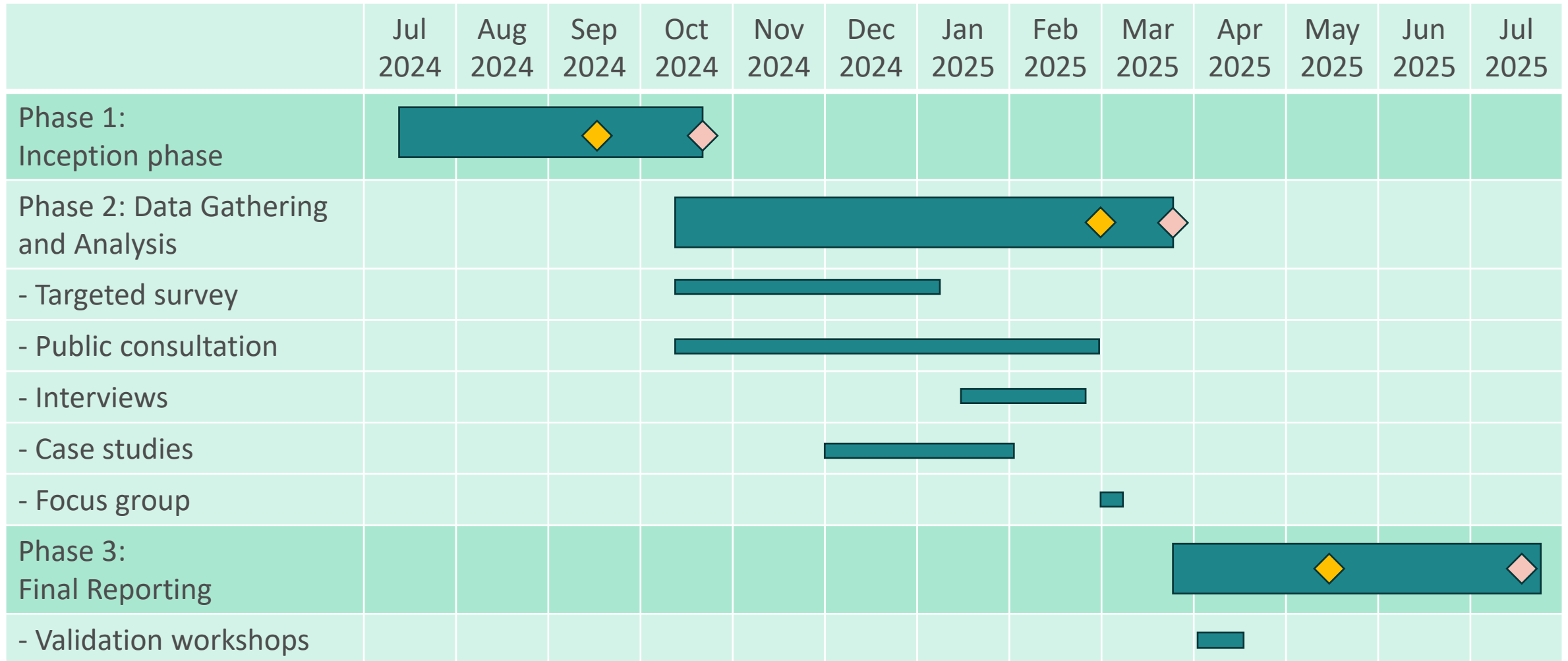
Desk work

Review of documents and literature	
Overall EU legal and policy framework	GFL, TR, sectoral legislation, EU strategic frameworks (e.g. Farm to Fork), other EU legislation (one-substance-one-assessment package etc.).
EFSA corporate documents	Strategies, programming documents, policies and implementing acts, operational documents (e.g. standard operating procedures), Annual Activity reports and other specific reports.
EFSA publications and resources	Selected scientific outputs (scientific opinions and other scientific outputs) and supporting publications; Databases, and dashboards; risk communication outputs; project/programmes etc.
Institutional reviews, evaluations and relevant Case Law	Previous evaluations / Fitness Check, Commission's opinions, EP budgetary discharge reports and EFSA's responses, Ombudsman cases, ECA reports, Internal Audit Service reports, etc.
Other sources	Academic publications, media coverage, stakeholder's publications (e.g. industry position papers, NGO investigations), etc.
Datasets	
Administrative and management data	EFSA programming documents, annual reports, financial documents, internal management data
Reputation and scientific excellence data	Bibliometrics, database access and use (e.g. EFSA Comprehensive European Food Consumption Database), relevant Eurobarometer surveys

Case studies

Case study	Topics
Risk to human health related to the presence of perfluoroalkyl substances (PFASs) in food (2020)	Contaminants in the food chain
Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (2019)	Risk assessment methodology
"Stop African swine fever" – communication campaign (2022)	Animal health
Endocrine Disruptors joint guidance of EFSA-ECHA regarding PPP/biocides (2018)	Pesticides
TBC	TBC

Work Plan for the external study – consultation



 Report – final version
  Report – draft version

EFSA evaluation - consultation activities

Input of national risk managers/risk assessors dealing with EFSA:

- Reply to the targeted survey questionnaire

The EC will share with you the link for the targeted survey questionnaire.

- Express interest for participating in an interview with the contractor,

For the interview, please send an email by 6 December to sante-consult-e1@ec.europa.eu, informing also in brief about your position and the area of work with EFSA.